Consultation draft of the:

National plan to end avoidable amputations within a generation

Diabetic Foot Australia

May 2017



Version Tracking

Version	Who	Comment	
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Diabetic Foot Australia

Diabetic Foot Australia (DFA) was established in 2015 with goal of ending avoidable amputations within a generation in Australia. DFA is a key initiative of the Wound Management Innovation CRC and has engaged the expertise of multiple Partner Organisations across Australia to create a national diabetic foot ulcer (DFU) body for Australia. DFA's primary objectives are to:

- optimise national DFU evidence-based clinical practice,
- stimulate national DFU clinical research,
- reduce Australia's national diabetes amputation rate, and,
- empower Australia to become a leading nation in DFU management

DFA is led by a national multi-disciplinary steering committee, co-chaired by A/Professor Paul Wraight and Dr Pete Lazzarini. The committee is comprised of a broad range of DFU expert members from clinical practice, research and industry, with backgrounds in endocrinology, vascular surgery, podiatry, nursing, epidemiology, clinical research and biochemical research. Members also bring a wealth of experience having participated in international, national and state diabetic foot groups, including the *International Working Group on the Diabetic Foot* and the former national Australian Diabetes Society DFU group the *Australian Diabetic Foot Network*. For further information on DFA please go to: <u>https://www.diabeticfootaustralia.org/</u>

One of DFA's key projects to achieve its goal and objectives was the establishment of an agreed Australian diabetic foot community plan to guide Australia's national efforts toward reducing the burden of diabetic foot disease in this country. This *Consultation draft of the National plan to end avoidable amputations within a generation* is the first step to realising such an agreed national plan.



Executive summary

Introduction

On any given day in Australia, the burden of diabetic foot disease is large, and includes:

- 300,000 people at risk of developing diabetic foot disease
- 50,000 people suffering with diabetic foot disease
- 12,000 people with a previous diabetic foot disease-related amputation
- 1,000 people in hospital because of diabetic foot disease
- 12 people undergo a diabetic foot disease-related amputation
- 4 people die from diabetic foot disease
- \$2 million will be spent managing diabetic foot disease (half in hospital, half in primary care)

To reduce this large burden, all people with, or at risk of, diabetic foot disease should have the following three priorities addressed:

- A. Access to care when they need it
- B. Care that is safe and of quality
- C. Research and development that improves care in the future

A. Access to care

- 1. All people with, or at risk of, diabetic foot disease should have access to all recommended evidence-based treatments via reimbursement in the Medical Benefit Schedule (MBS) or Pharmaceutical Benefit Scheme (PBS)
- 2. All people with diabetic foot disease should have access to specialised interdisciplinary foot clinics, either face-to-face or via telemedicine

B. Safe quality care

- 3. The National Health and Medical Research Council (NHMRC) guideline on diabetic foot disease needs to reflect up-to-date scientific evidence regarding management and prevention of diabetic foot disease
- 4. All specialised interdisciplinary foot clinics should meet criteria for evidence-based treatment



5. National and regional outcomes of diabetic foot disease should be published annually

C. Research and development

- 6. An endorsed "National Research Agenda for Diabetic Foot Disease" needs to be developed
- 7. An "Australian Diabetic Foot Disease Clinical Trials Network" should be formalised and stimulated
- 8. Investments in diabetic foot disease research and development should be proportionate to the burden of the disease

Ending avoidable amputations in a generation

Australian research has already demonstrated that investments in these three areas will save up to 70% of the diabetic foot disease hospitalisations and amputations, and \$2.7billion to the Australian taxpayer over 5-years. This national plan describes how this can be done nationally, to achieve the goal of "ending avoidable amputations in a generation".



Introduction

Diabetic foot disease is a debilitating complication of diabetes that includes infection, ulceration or destruction of tissues in the foot associated with peripheral neuropathy and peripheral ischemia (1). Diabetic foot disease poses a major burden on an individual and society, with reduction in quality of life, and significant morbidity, mortality and costs (2-7).

On any given day in Australia, the burden of diabetic foot disease is large (8-13), and includes:

- 300,000 people at risk of developing diabetic foot disease
- 50,000 people suffering with diabetic foot disease
- 12,000 people with a previous diabetic foot disease-related amputation
- 1,000 people in hospital because of diabetic foot disease
- 12 people undergo a diabetic foot disease-related amputation
- 4 people die from diabetic foot disease
- \$2 million will be spent managing diabetic foot disease (half in hospital, half in primary care)

Unfortunately, between 1998 and 2011, a time-period where many developed countries reported a reduction in avoidable diabetic foot disease-related amputations, Australia reported a 30% increase in these amputations (10,14,15). However, during this period, regions in Queensland and Western Australia reported reductions in diabetic foot disease-related amputations and hospitalisations of up to 70%. These reductions occurred following the implementation of extensive coordinated clinical improvement programs, incentivising evidence-based treatment in primary, secondary and tertiary care, and monitoring clinical process indicators and outcomes with large regional datasets (16-18).

Additionally, a recent health economic study has demonstrated that up to \$2.7 billion can be saved (~\$10,000 per patient) over five years when nationally-recommended, evidence-based, interdisciplinary, care is implemented across Australia (19). These cost-savings are in addition to increases in quality of life for persons suffering from diabetic foot disease, and take into account the initial extra costs needed to implement evidence-based treatment (19). With the existing large burden of diabetic foot disease in Australia, and the demonstrated significant reductions to this burden and costs in Australian regions that have improved care, it is clear that a nationwide approach is urgently needed to tackle this silent epidemic.

In this document, we describe the *National plan to end avoidable amputations in a generation*. This plan identifies eight key goals and related areas for action and measures of progress. Enacting this plan aims to ensure that all people with diabetic foot disease have access to evidence-based care when they need it, that they receive publicly-recognised safe and quality care, and how investment in research and development will ensure continuing improvement in their care over time. This plan has been designed to align with the Australian National Diabetes Strategy 2016-2020 (20).



We hope that all stakeholders involved in the prevention and management of diabetic foot disease embrace the benefits of a national plan, have their say on the key goals and other aspects of the plan they consider should be included and then work together to bring our Australian national plan to fruition. Together we believe we can end avoidable amputations in Australia in a generation.

Feedback on this consultation document

DFA very much welcomes feedback from the Australian diabetic foot community on any aspect on this consultation draft of the *National plan to end avoidable amputations within a generation*.

The consultation process for this document will remain open until COB 3rd July 2017. Please return any feedback to <u>nationaloffice@diabeticfootaustralia.org</u>.

As the aim of this document is to be a best practice national plan that has the best chance to deliver demonstrably better outcome for our patients with, or at risk of, diabetic foot disease. We kindly ask that any feedback is based on evidence of demonstrable success within Australia or in other nations. Therefore, we prefer that any feedback to this plan be referenced to appropriate evidence-based literature supporting the feedback for ease of consideration.

The DFA steering committee will review all feedback from the consultation process and modify the final *National plan to end avoidable amputations within a generation* document accordingly.

DFA aims to launch the final official National plan to end avoidable amputations within a generation at the Diabetic Foot Australia Conference on the Gold Coast on 3rd September 2017: <u>https://events.diabeticfootaustralia.org/</u>

In addition, DFA will notify the Australian Diabetic Foot Community of the plan on the DFA:

- Web site: <u>https://www.diabeticfootaustralia.org/</u>
- Facebook site: <u>https://www.facebook.com/DiabeticFootAustralia</u> &
- Twitter site: <u>https://twitter.com/diabeticfootaus</u>

We now encourage the Australian diabetic foot community to have your say!



A.Access to care

Goal 1: All people with, or at risk of, diabetic foot disease should have access to all recommended evidence-based treatments via reimbursement in the Medical Benefits Schedule (MBS) or Pharmaceutical Benefits Scheme (PBS)

Currently, different components of accepted evidence-based diabetic foot treatment are not reimbursed in the Medical Benefits Schedule (MBS) or Pharmaceutical Benefits Scheme (PBS) (21,22). This concerns, for example, offloading devices, footwear and wound dressings for people with diabetic foot disease. This lack of funding translates to lack of use of these evidence-based treatments, and subsequently increased healing times and long-term costs. Additionally, allied health consultations (including podiatry) are capped at five visits per year, forcing podiatry treatments for people with, or at risk of, diabetic foot disease to compete with other allied health care. Even without such competition, five visits does not go close to aligning with most of the NHMRC guideline, where people at-risk of diabetic foot disease are recommended to receive between 2 and 12 podiatry visits per year, depending on their level of risk. More importantly, people with active diabetic foot disease require weekly to fortnightly podiatric care (as part of an interdisciplinary diabetic foot team) until healing occurs (22). These treatments are not allocated funding within the MBS or PBS.

This lack of reimbursement within the MBS or PBS is striking, given that these treatments are accepted as major recommendations in the NHMRC diabetic foot disease guideline (22). The NHMRC guideline is a government-approved document that requires MBS and PBS reimbursements to ensure that all aspects of the guideline can be implemented in clinical practice, as has occurred in all other aspects of diabetes care (22). To improve access to evidence-based care for all people with diabetic foot disease, this needs to change: all recommended evidence-based treatments should be reimbursed within the MBS or PBS.

To balance against uncontrolled reimbursement claims and to ensure quality, a system change may be considered to only reimburse specialised interdisciplinary foot clinics for more advanced diabetic foot disease treatments (see goal 2 for a description of these clinics and the criteria they need to meet). Such a system is already in place in Germany and Belgium, where it has led to clinics consciously choosing to either treat people with diabetic foot disease in accordance with the highest standard, or referring them to other clinics (23). Additionally, this reimbursement could be tied to clinical outcomes within these clinics.

Recent health economic research has shown that up to \$2.7 billion may be saved over five years in Australia when evidence-based care can be delivered to all people with diabetic foot disease (19). These savings also account for the increased short-term investment needed to establish evidence-based care across Australia. All stakeholders should work towards a situation where all evidence-



based care for people with diabetic foot disease is reimbursed, with reimbursement aligning with NHMRC guidelines.

Potential areas for action

- Reimburse offloading devices for all people with diabetic foot disease in line with the NHMRC guideline
- Reimburse dressings for all people with diabetic foot disease in line with the NHMRC guideline
- Reimburse evidence-based allied health and nursing for diabetic foot disease based on need and in line with the NHMRC recommendations; separate these consultations from other standard MBS (allied health) treatment
- Only reimburse advanced treatment for diabetic foot disease when provided within specialised interdisciplinary foot clinics
- Tie reimbursement of diabetic foot disease care to clinical outcomes

Potential measures of progress

- Number of NHMRC recommendations on diabetic foot disease that are reimbursed via MBS or PBS items
- Number of reimbursements or incentive agreements for publicly-recognised specialised interdisciplinary foot clinics
- Monitoring of diabetic foot disease care costs in primary care (i.e. MBS and PBS reimbursements) and tertiary care (i.e. hospitalisation and amputation costs) via ongoing cost-effectiveness analyses to report on return of investments



Goal 2: All people with diabetic foot disease should have access to specialised interdisciplinary foot clinics, either face-to-face or via telemedicine

Treatment of diabetic foot disease should take place in specialised interdisciplinary foot clinics. It is widely recognized in international and national evidence-based guidelines that no single healthcare professional discipline can manage all aspects of diabetic foot disease. Evidence consistently demonstrates that in order to improve clinical and financial outcomes, diabetic foot care needs to be provided through interdisciplinary foot clinics (1,19,24). To end avoidable amputations in a generation, it is imperative that people in Australia with diabetic foot disease have access to these clinics.

For this to be possible, the number of specialised interdisciplinary foot clinics in Australia needs to grow significantly. Using available Australian and international diabetic foot epidemiology data we conservatively estimate that for every 100,000 Australians there are approximately 200 people at any given time suffering with diabetic foot disease (12). This caseload of 200 people could be served by one full-time specialised interdisciplinary foot clinic if the clinic can consult approximately 40 patients per day, which means there needs to be at a minimum 1 full-time specialised interdisciplinary foot clinic (25). Therefore, to adequately service all 24 million Australians, at least 240 clinics are required Australia-wide.

There is currently no hard data available on the availability of specialised interdisciplinary foot clinics in Australia, as these clinics are not publicly recognized (see further Goal 4). However, we estimate from canvassing our networks there would be no more than 50 interdisciplinary clinics across Australia, and almost all are located within state-funded facilities (hospitals or community health centres). Thus, we estimate Australia has less than 25% of the specialised interdisciplinary foot clinics it needs to adequately service all the Australians with diabetic foot disease; this needs to grow significantly and soon.

Access to interdisciplinary foot clinics is complicated for people living in rural and remote areas. Telemedicine should be facilitated and reimbursed between general healthcare professionals in these areas and specialised interdisciplinary foot clinics. Such a telehealth system for diabetic foot disease management has already been shown to significantly reduce diabetic foot disease-related amputations in Western Australia (26). The NHMRC recommends diabetic foot disease telehealth, and this recommendation could easily be incorporated into the existing MBS telehealth item and expanded to include expertise provided by the interdisciplinary foot clinic coordinator (who may be a podiatrist or nurse, rather than specifically a medical specialist as required under the current MBS 'general telehealth').

To increase the number of specialised interdisciplinary foot clinics in Australia, there is a need for more healthcare professionals who are trained to deliver the specialised care to people with diabetic foot disease in both state-funded public facilities and Medicare-reimbursed private facilities (for



example large GP clinics). For this, diabetic foot disease specific training modules for healthcare providers need to be developed. These modules should, on the one hand, focus on healthcare professionals that make up a secondary or tertiary interdisciplinary diabetic foot care team (medical, surgical, nursing and allied health), to increase knowledge, skills and awareness of the evidence-based care of people with diabetic foot disease and evidence-based interdisciplinary care principles. Following their training, these individuals could be encouraged to set up new teams, to increase the capacity of highly-skilled healthcare professionals that are needed to meet the treatment-demand of people with diabetic foot disease in Australia. Additionally, such training modules should also aim to involve healthcare providers in primary care, such as general practitioners, primary care nurses, allied health practitioners and indigenous health workers. When these primary care professionals are appropriately trained, they can implement screening and prevention strategies for diabetic foot disease, and they may refer people with diabetic foot disease earlier to the specialised interdisciplinary foot clinics. Such early referral has been found to be critical to improve diabetic foot disease outcomes (27). Training modules should be offered both online and offline, and should involve formal examination of learning goals and outcomes.

Apart from training healthcare professionals, people with diabetic foot disease can also be better empowered in regard to what evidence-based treatment they should be expecting to receive in specialised interdisciplinary foot clinics. If people are aware of the evidence-based treatment that they should be receiving, they should start to demand it from their healthcare providers, even when they are not aware of their nearest foot clinics. Various initiatives in this field are available, but these focus primarily on screening of foot risk (e.g. Diabetic Foot Australia's patient passport, the Australian Diabetes Society's general practitioner diabetic foot training, or Diabetes UK's campaign "Putting Feet First"). No published data is available on the success of these campaigns, but it is expected they have led to more people demanding foot checks from their general practitioners. There is a surprisingly limited amount of patient-centred information available to inform people with diabetic foot disease on evidence-based treatment when they present with a foot ulcer. The NHMRC guideline should be translated into more readily understandable, interactive and available information for patients. This should then be spread via patient organisations and government. In that way, the information will reach the people who most need it, and these people may then demand evidence-based treatment by their healthcare providers.

Potential areas for action

- Significantly incentivise and increase the number of specialised interdisciplinary foot clinics in Australia
- Develop diabetic foot disease specific training modules for healthcare providers who want to work with people with, or at-risk of, diabetic foot disease



• Increase awareness among people with diabetes to seek urgent treatment in specialised interdisciplinary foot clinics for diabetic foot disease

Potential measures of progress

- Number of specialised interdisciplinary foot clinics in each Primary Health Network and Hospital & Health Service in Australia
- Number of people with diabetic foot disease treated in specialised interdisciplinary foot clinics compared to those not treated in such clinics
- Number of telemedicine treatments within specialised interdisciplinary diabetic foot clinics



B.Safe quality care

Goal 3: The National Health and Medical Research Council (NHMRC) guideline on diabetic foot disease needs to reflect up-to-date scientific evidence regarding management and prevention of diabetic foot disease

Evidence-based guidelines are the cornerstone of medical treatment. For diabetic foot disease, the current NHMRC-endorsed Australian guideline was published in 2011, based on a 2009 literature search (22). In this guideline, it is stated that "This guideline should be fully reviewed within 5 years from date of release; however the guideline developers strongly recommend annual re-running of the literature searches to identify new evidence for consideration as to whether the recommendations or expert opinions should be revised." To the best of our knowledge, neither of these recommendations have been undertaken. As a result, the guideline that describes how people with diabetic foot disease should be treated in Australia is outdated, and in some topics not reflective of, or even contradictory to, contemporary scientific evidence. The NHMRC guideline should therefore be updated as soon as possible.

To re-initiate this process, it is recommended that a more efficient and effective methodology for writing the guideline should be undertaken. This is in contrast to the extensive methodology of the existing guideline that runs the risk of being outdated soon after completion, as occurred in 2011. A guideline writing methodology should be adopted, and processes should be put in place, that allow for continuous efficient updates. Alternatively, as a minimum, it should be clear who is responsible for initiating the interdisciplinary process of updating the guideline within 5 years of publication of the next guideline.

Furthermore, rather than re-inventing the wheel by undertaking further extensive systematic reviews of the literature and doing the entire process again, it is recommended that existing highquality systematic reviews should be used to inform new guidelines. It is possible to follow a strict and rigorous guideline development methodology without having to repeat all the systematic literature searches that were performed for the 2011 NHMRC guideline. Available high-quality diabetic foot disease documents that could be used immediately for any future updating of the NHMRC diabetic foot guideline, include the guidance documents published in 2016 by the International Working Group on the Diabetic Foot (IWGDF; (1,28-32)), the 2016 NICE (National Institute for Health and Care Excellence) guideline from the United Kingdom (24), the 2012 IDSA (Infectious Diseases Society America) guidelines (33), and multiple systematic reviews in the field of diabetic foot disease published over the last 3 years (e.g. (34-42)).

When such an approach is adopted, the fields of peripheral artery disease and infection (not included in the current NHMRC guideline) should also be included. This would create a more extensive guideline, reflecting the interdisciplinary fields involved in the treatment of diabetic foot



disease. Additionally, specific chapters on diabetic foot care for Aboriginals and Torres Strait Islanders, remote consultations, Charcot foot, amputation and rehabilitation should also be considered for inclusion.

Potential areas for action

- Urgently update the 2011 NHMRC guideline on diabetic foot disease
- Develop a "continuous update" methodology for the NHMRC guideline on diabetic foot disease using existing high-quality systematic reviews or other guidelines as the basis
- Extend any new NHMRC guideline on diabetic foot disease with chapters on peripheral artery disease and diabetic foot infection, and consider chapters on diabetic foot care for Aboriginals and Torres Strait Islanders, remote consultations, Charcot foot, amputation and rehabilitation

Potential measures of progress

- Time to launch of an updated NHMRC guideline on diabetic foot disease
- Availability of "continuous update" methodology for the NHMRC guideline on diabetic foot disease



Goal 4: All specialised interdisciplinary foot clinics should meet criteria for evidence-based treatment

To improve foot care, all stakeholders should be made aware of clinics that deliver evidence-based treatment that meets the highest standards as recommended by the NHMRC guidelines. As diabetic foot disease is complex, multifactorial and requires interdisciplinary treatment, it is not always easy to recognize specialised interdisciplinary foot clinics. Further, any clinic can call themselves a "Diabetic Foot Clinic", even when the care is not consistent with evidence-based standards. This can be improved by publicly recognizing specialised interdisciplinary foot clinics that meet specified criteria.

This recognition should be seen as a first step towards accreditation of clinics. Three European countries (Belgium, Germany and Scotland) have led the way in nationwide accreditation of specialised interdisciplinary foot clinics (23,43). The approaches in these three countries have similarities and differences, depending on the national system and available opportunities. The most important similarity between these countries is that they all started with basic criteria for clinics, before developing more mature national accreditation criteria. Once they generated a 'critical mass' of clinics providing evidence that they met the basic criteria, they were able to forge alliances with stakeholders to integrate auditing and recognition of services sustainably within their healthcare systems. The crucial stakeholders were patient organisations in Belgium, while it was government enforced legislation in Germany. For the Australian situation, the crucial stakeholders will need to be determined as the accreditation process matures, like it did in these other countries

A fully operating accreditation system will take years and much negotiation with various stakeholders (government, health insurance companies, professional organisations, patient organisations, etc.), but if existing specialized interdisciplinary foot clinics pledge their involvement early on, this should generate enough momentum to bring this to fruition. As mentioned before, Australia has proportionally very few specialised interdisciplinary foot clinics; however, this may be a blessing in disguise in initiating the public recognition of these clinics.

There are two basic criteria that form the basis of the more mature accreditation systems from other nations that can be implemented immediately in Australia. Those criteria are that specialized interdisciplinary foot clinics should demonstrate they have:

- i. Medical, nursing and allied health discipline personnel working in a dedicated interdisciplinary diabetic foot team with access to essential evidence-based treatment modalities
- ii. Regular capture of data that align with the standards stated by the nationally-endorsed "Australian Diabetic Foot Ulcer Minimum Dataset (44)"



No agreed specific definition of personnel required for a specialised interdisciplinary diabetic foot team is available, but general directions are available from the NHMRC and other guidelines, suggesting they should include medical (either medical or surgical disciplines, but preferably both), allied health (preferably including podiatrists) and nursing (preferably including wound care nurses and diabetes educators) disciplines (1,22,24). More stringent criteria describing a foot team and competency frameworks for all the different healthcare professional disciplines involved in diabetic foot care should be developed. This will create a common language between professions and will provide all healthcare professionals with insight into their competence in treating these patients. Currently, the Australasian Podiatry Council is developing such a competency framework for podiatrists managing people with diabetic foot disease. This framework could be modified to capture generic competencies that are applicable to all healthcare professionals managing diabetic foot disease, or modified to each individual healthcare professional discipline. These competencies could then be aligned and incorporated within the aforementioned training modules for healthcare professionals (described under Goal 2).

As part of being a recognized Diabetic Foot Clinic, healthcare professionals should capture data that aligns with the Australian Diabetic Foot Ulcer Minimum Dataset and provide aggregate data (44). This can then be combined with aggregate data from all recognized Diabetic Foot Clinics, to provide a benchmark with which clinics and healthcare professionals can compare themselves, both on clinical outcomes and process of care outcomes.

Once these two basic criteria are in place, further criteria should be developed, as well as continuous auditing processes. In Germany, recognized interdisciplinary foot clinics visit each other at least once every six months for peer-auditing. This generates unique learning opportunities, strengthens networks, and makes for a system that does not involve a separate arbitrary external auditing body. In line with the German system, where auditing clinics need to be separated by a minimum of 50 kilometres, it should be considered that clinics cannot be audited by other clinics in the same Primary Health Network or Hospital and Health Service region. Another longer-term strategy is to align reimbursement with accreditation (see Goal 1). In Germany and Belgium, only accredited clinics are eligible to receive reimbursement when they treat people with diabetic foot disease, which has been essential for the longevity of their systems of specialised interdisciplinary foot clinics (23).

Special attention is needed in Australia for rural and remote clinics. These may not be able to comply with all the criteria for an interdisciplinary foot team because of lack of availability of healthcare professionals. However, these clinics serve an important need in the treatment of diabetic foot disease in these areas. Separate criteria should be made for rural/remote foot clinics, and a program to stimulate telemedicine between these clinics and specialised interdisciplinary foot clinics meeting all criteria should be put in place.



Potential areas for action

- Create an online platform to publicly recognize specialised interdisciplinary foot clinics that meet the two basic criteria of having recommended dedicated personnel with access to essential evidence-based treatment modalities and data collection in place
- Create competency frameworks for all healthcare professionals involved in care for people with diabetic foot disease
- Aggregate data that aligns with the Australian Diabetic Foot Ulcer Minimum Dataset to benchmark clinics and healthcare professionals on diabetic foot disease treatment
- Stimulate telemedicine between specialised interdisciplinary foot clinics health professionals in rural/remote areas of Australia
- Forge alliances between the different stakeholders to work towards an accreditation system for specialised interdisciplinary foot clinics

Potential measures of progress

- Number of recognized specialised interdisciplinary foot clinics in Australia per population
- Number of healthcare professional disciplines involved in care for people with diabetic foot disease with competency frameworks
- Number of healthcare professionals competent in care for people with diabetic foot disease
- Number of patients with data captured according to the Australian Diabetic Foot Ulcer Minimum Dataset



Goal 5: National and regional outcomes of diabetic foot disease should be published annually

Information is needed to continuously inform people on processes and clinical outcomes in different parts of Australia. This information should be transparently published annually by region (for example each Hospital and Health Service or Primary Health Network), to monitor, learn and improve our national progress towards ending avoidable amputations in a generation.

For two clinical outcomes, diabetic foot disease related hospitalisation and amputation, national hospital admission dataset systems are already in place to register these outcomes, which can facilitate quick availability of this data. However, it should be noted that amputation should not be used as a simplistic marker of quality of care or acute incidence of diabetic foot disease. An amputation is a surgical procedure (not a medical diagnosis of diabetic foot disease), registration of different amputation-types can be complex and additional specific population information is needed for accurate interpretation (45,46). This includes, for example differentiating between major and minor amputations, or correctly counting people rather than procedures. Diabetic foot disease hospitalisation has been found to be a more precise marker of acute incidence of diabetic foot disease, as it is a pseudo-diagnosis of medical severity and thus comparable to other diabetesrelated acute incidence markers (such as myocardial infarction or stroke hospitalisation). Hospitalisation is still relatively easily to measure within existing hospital admission datasets (7,9,16). Regardless, the current registration system for diabetic foot disease hospitalisation and amputation needs to be improved, agreed and formalised. Data should then be transparently published to track the progress in ending avoidable amputations within a generation. Agreements need to be made as to who will be responsible for these publications.

Additionally, more meaningful clinical outcomes (e.g. ulcer healing durations or ulcer-free survival days) and process of care outcomes (e.g. time to presentation to an interdisciplinary foot clinic; time to revascularization) should be adopted, as has occurred successfully in the UK. These additional measures can be captured using standards outlined in the Australian Diabetic Foot Ulcer Minimum Dataset. It is recommended that publicly recognized specialised interdisciplinary diabetic foot clinics should collect this data (see Goal 4). It will then be possible to aggregate the data and use this to provide clinically meaningful outcomes on the current state, and the improvements required, in the care of people with diabetic foot disease.

To optimally detect areas where the need for further improvement in services is needed, national, state-wide and regional differences in outcomes should be presented. With major differences within states, for example in metropolitan areas versus rural/remote areas, geographical regions need to be smaller than the state boundaries and comparable, following the example set by the UK (47).

To stimulate participating stakeholders (e.g. specialised clinics collecting data, government workers responsible for registration systems, researchers), a yearly forum should be convened to publish and



discuss these data. A similar forum occurs in Germany, where healthcare professionals from recognized specialised interdisciplinary foot clinics present the data from their clinic for the past 12 months, and discuss positive and negative outcomes and recommended quality improvements. If outcomes from government agencies are added, this will create a truly unique quality-improvement forum. This event is also an important external deadline that will help to guarantee that these outcomes are indeed collected and published each year. Finally, public presentation of results, including discussions, will stimulate learning, avoid duplication of potential mistakes, and will guarantee continuing improvements to end avoidable amputations in a generation. Participation in such forums is a binding criterion for foot clinics in Germany to be accredited, thus should also be considered in Australia to guarantee the viability and positivity of such a learning forum.

Potential areas for action

- Annually publish national and regional diabetic foot disease outcomes, including ulcer-free survival days, ulcer healing durations, hospitalization, and amputation
- Present national and regional diabetic foot disease data at yearly forums to discuss and learn from these outcomes

Potential measures of progress

- Yearly diabetic foot disease outcomes (national and regional) of:
 - Ulcer-free survival days
 - o Ulcer healing duration
 - o Diabetic foot disease related hospitalization
 - Diabetic foot disease related minor and major amputations
 - Time to access of specialised interdisciplinary foot clinics



C. Research and Development

Goal 6: An endorsed "National Research Agenda for Diabetic Foot Disease" needs to be developed

Experts within the field of diabetic foot disease are well aware of the most relevant gaps in the literature, but this is generally not known within funding agencies, government and industry. A widely endorsed and communicated national research agenda may overcome this and provide focus on Australian research that targets gaps in the literature, to deliver the 'biggest bang for the buck' for Australia. When such an agenda is published, researchers can easily refer to it to prove the importance and clinical relevance of their research question.

For a national research agenda to hold value, all relevant stakeholders should be involved during its creation. This includes healthcare professional organisations, researchers, universities, government, industry, funding institutions and patient groups. It is especially important to try to ensure that the common priorities of different stakeholders come together to work towards a common national goal; for example improving clinical outcomes for people with diabetic foot disease and ending avoidable amputations in a generation. However, differences in priorities are often seen between the priorities of industry and healthcare professionals / researchers. These differences are evidenced by the majority of registered randomized controlled trials concern dressings or devices to improve ulcer healing, whereas these topics are not rated as highest priorities in the NHMRC and IWGDF guidelines (1,22). Additionally, the RCTs on wound dressings and devices are often criticized with regard to a high risk of bias and poor study quality (42,48). To address current priority differences more effort should be undertaken by all stakeholders to make more efficient use of the limited resources available (e.g., finances, availability of potential participants for trials) by focusing on the common long-term outcome of ending avoidable amputations in a generation. All parties need to commit to research priorities that meet the common interest of all.

Various options are available to create such an agenda. Firstly, an agenda can be incorporated as national priorities within the updated NHMRC guideline (see Goal 3). As part of creating the guideline, literature searches could be performed to identify gaps in the literature and thus knowledge. This would identify areas that need specific resource allocation to close existing gaps in our knowledge. As the NHMRC guideline is endorsed by a large number of professional bodies, endorsement of the guidelines will simultaneously result in endorsement of a directed research agenda. The disadvantage of this method is that it may take some years before the NHMRC guideline is completely updated and published, and it would be ideal to have a research agenda ready as soon as possible. An alternative method could be to draft an agenda, and send out for review and subsequent endorsement to relevant stakeholders (professional bodies, government, industry, patient groups). This could be done both robustly and pragmatically based on expert consensus opinion using a Delphi method.



Potential areas for action

• Create a "National Research Agenda for Diabetic Foot Disease" involving all stakeholders, using either the national guideline or a consensus Delphi methodology

Potential measures of progress

- Number of stakeholders' endorsements of a published "National Research Agenda for Diabetic Foot Disease"
- Number of successfully funded projects that align with the "National Research Agenda for Diabetic Foot Disease" in the years following
- Number of future national guideline recommendations that are based on new Australian research that aligned with the "National Research Agenda for Diabetic Foot Disease"





Goal 7: An "Australian Diabetic Foot Disease Clinical Trials Network" should be formalised and stimulated

Efforts should be undertaken to improve the quality and output of Australian research on diabetic foot disease. Although Australia is large enough to accommodate a variety of experts in different areas of diabetic foot disease research, it is too small for these experts to be competing with each other for limited research resources: participants and funding. An "Australian Diabetic Foot Disease Clinical Trials Network" needs to be set up, to attract Australian and international investigator-initiated and industry-initiated research.

Randomized controlled trials (RCT) are seen as the top-end of the research pyramid and form the basis for (inter)national guidelines. High-quality trials are limited in the majority of diabetic foot disease related research fields (48). Investing in RCTs will therefore result in global impact. To reach adequate power, nationwide collaboration is needed in order to recruit sufficient participants, as it is unlikely that single-centres in Australia will be able to recruit sufficient participants to deliver the high-quality output needed to have an impact on their own.

The limitation of RCTs in their applicability in daily clinical practice is gaining more attention, and well performed prospective real-life cohort studies are becoming increasingly attractive as additional sources of high-quality publications to inform guidelines and clinical decisions. Observational studies can be beneficial, provided they include data from major cohorts, and validate (rather than create) risk classifications and stratifications, or report on treatment outcomes. When product specific data is also included, these observational studies may generate real-world data from daily clinical practice providing industry with unique insights. Ways to share these insights with industry in a way that is beneficial for all should be explored. It is important that the study design of cohort studies minimises the risk of bias and that participants are recruited in relative short timeframes. Clinical practice changes over time and cohort studies reporting on treatment outcomes over long periods of time are at high risk of bias because of these changes. With the Australian Diabetic Foot Ulcer Minimum Dataset, baseline and service characteristics can be captured with adequate and validated detail. If relevant treatment details can be coupled to this dataset, Australia is in a good position to produce meaningful observational study outcomes.

When studies are completed, effort should be made to maximize the output. Rather than simply publishing one high-quality paper from an RCT, impact increases when multiple publications and presentations are the result. This is not a call to salami-slice the data, as each trial needs one primary high-quality paper. However, repetition of a study group and name is a great method to spread the message of the study outcomes and increase its impact. Clinicians and scientists need to hear the message of quality findings over and over again to enhance widespread acceptance and use of findings. Two great examples of this in international diabetic foot research are the Eurodiale study (e.g. (49,50)) and the DIAFOS trial (e.g. (51-53)). Both Eurodiale and DIAFOS have resulted in 2 PhD



theses, 11 publications and numerous conference presentations each. As a result, the findings of these studies are consistently being referred to and well-known. If the authors had chosen to publish just one or two publications and a few conference presentations, these studies would not have had the impact they have had now. Such output maximization, however, requires smart study design (to capture enough relevant data for secondary outcome analyses) and most of all dedication to the project once data collection has been completed.

Another opportunity a clinical trials network offers is to collect information on the scientific work undertaken by the participating sites, for example in terms of number of publications and number of participants recruited. This information can then be made available and communicated, to give attention to the endeavours of diabetic foot disease research in Australia; this is an essential component in obtaining more impactful studies. Only when industry, funding agencies, government and potential international collaborators are made aware of the quality and quantity of the research that is being done in Australia, will they be tempted to invest (further) in this. This may be especially important in attracting multi-centre research trials from Europe and the US, for whom the geographical distance to Australia is currently an important obstacle in initiating trials here.

For Australian researchers, a clinical trials network also provides unique opportunities to nurture the next generation of diabetic foot disease researchers. The best opportunity for early career researchers is to be made part of large, high-quality, studies. No university truly prepares researchers for the intricacies of performing large trials in real-world clinical practice; roles in such trials are "golden" experiences for early career researchers. When setting up trials, this should be considered. Roles should be created for early career researchers to do the 'footwork' in these trials, and whenever possible these roles should be filled by researchers with the potential to grow, rather than by research assistants or clinicians with no interest in pursuing further research undertakings.

Not all early career researchers will be able to participate in larger trials, for example when they are based at other universities or in other cities. Similarly, some early career researchers may find themselves at a university without diabetic foot disease specific specialists. A mentoring system should be created for those researchers, preferably within the clinical trials network.

To further stimulate the next generation, a "National Diabetic Foot Disease Early Career Researcher Award" should be created. This should be promoted and awarded at a national conference, and may provide the recipient with (for example) dedicated mentoring-support for two years, a small travel grant to visit an overseas conference and overseas experienced researcher (provided they present at the conference and have a plan to collaborate with the researcher), and an allocated keynote presentation at the next national conference to present their findings.

For clinicians, participation in scientific research is a direct contribution to the advancement of the evidence on treatment of people with diabetic foot disease. This is especially the case for multi-centre research or prospective single-centre research. Additionally, a stronger research culture is



associated with benefits to patients, staff and the organisation (54,55). Recognized specialised interdisciplinary foot clinics should therefore be stimulated to participate in the clinical trials network, or it could even be made an obligatory criterion for recognition.

Research on diabetic foot disease has many intricacies that are specific for this field, and it requires training to understand and appreciate them all (48). This holds especially for clinicians who understand the disease process, but may have limited training in research on diabetic foot disease. Training modules should be developed, aiming to improve the knowledge and skills for novice and early career researchers in the field of diabetic foot disease research. These modules may educate on critical assessment of diabetic foot disease publications, designing trials, and minimum reporting standards (48), but may also discuss the history of research in this field and the most important publications of note.

Finally, this recommendation is a call to all Australian diabetic foot disease researchers and clinicians to maximize cooperation in multi-centre trials, keep communicating amongst themselves on their research and funding application plans, and sharing the main stage while gifting each other the honours where appropriate. Research is a highly competitive world and, by its history and its nature, rather hierarchical. However, diabetic foot disease is such a small part within medicine, that cooperation rather than competition is the only strategy for long-term survival.

Potential areas for action

- Create an Australian diabetic foot disease clinical trials network
- Initiate RCTs and observational diabetic foot disease studies within this network, and maximize output
- Communicate diabetic foot disease results from Australian researchers to industry and funding bodies to attract more research
- Create a "National Diabetic Foot Disease Early Career Researcher Award"
- Create diabetic foot disease research training modules

Potential measures of progress

- Number of sites participating in the Australian diabetic foot disease clinical trials network
- Number of studies on diabetic foot disease within Australia
- Number of patients included in these diabetic foot disease studies within Australia
- Number of diabetic foot disease publications, theses and conference presentations resulting from these studies



Goal 8: Investments in funding for diabetic foot disease research and development should be proportionate to the burden of the disease

An enormous gap exists between the clinical costs of managing diabetic foot disease and funding for research and development for this disease (21,56). While up to 33% of all costs for diabetes-related complications is spent on diabetic foot disease, the diabetes research funding spent on diabetic foot disease research and development is <0.2% in both the UK and US (56). In Australia, diabetic foot research funding comes under the "not classified" group within NHMRC research funding for diabetes; our network suggests any NHMRC funding for diabetic foot disease has been much less than \$1 million over the last period, and likely considerably below 0.2% of total diabetes research funded in Australia (57). This is strikingly different to other diabetes-related complications that cause comparable burdens of disease (9,21); diabetic nephropathy and retinopathy received a reported \$37.1 and \$21.6 million respectively in national research funding from 2011-2015, or 10.3% and 6% of the total diabetes research budget respectively (57). From this it can be seen that funding for diabetic foot-disease research is disproportionally low compared to other diabetes complications in Australia. Investments in funding for diabetic foot disease research and development should be proportionate to the burden of disease it causes, within a very short time-frame.

To close this gap, from a government or funding agency perspective, a first step is to endorse, acknowledge and implement the "National Research Agenda for Diabetic Foot Disease" (Goal 6). This should then be matched, in the short-term, with additional funding for diabetic foot disease research, to make up for the years of under-representation of diabetic foot disease in funding. In the longer-term, equitable funding amongst different fields of diabetes research based on disease burden is the goal. The activities to close this gap from a researchers and clinicians perspective have already been described under Goal 7, including the necessary developments required to formalise and stimulate an Australian diabetic foot disease clinical trials network.

Potential areas for action

- Create additional national funding opportunities specifically aimed at diabetic foot disease in the short-term
- Create equitable funding amongst different fields of diabetes research based on disease burden

Potential measures of progress

• Number of nationally (NHMRC-funded) diabetic foot disease related research projects



- Proportion of dollars for diabetic foot disease related research projects out of total diabetes research funding available
- Ratio between percentage of clinical costs and percentage of research funding for different aspects of diabetes and diabetes-related complications





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