THE FIRST STEP

towards ending avoidable amputations within a generation

Diabetes Feet Australia

Australian Diabetes-Related Foot Disease Strategy

2018-2022

CONTENTS

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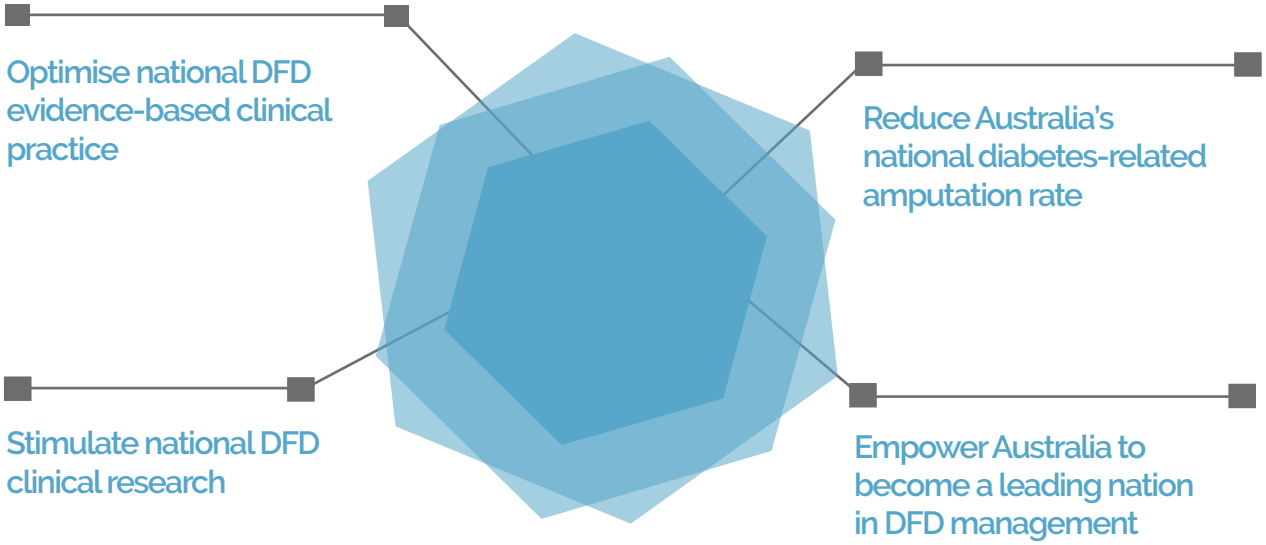
Diabetes Feet Australia

Diabetes Feet Australia

Diabetes Feet Australia (DFA) was established in 2015 with the goal of ending avoidable amputations within a generation in Australia. As a key initiative of the Wound Management Innovation CRC, DFA engaged the expertise of multiple partner organisations across Australia to create a national diabetes-related foot disease (DFD) body for Australia. On the 1st July 2018, Diabetes Feet Australia joined the Australian Diabetes Society's stable of national diabetes clinical and research programs. In 2020, DFA updated its name from Diabetic Foot Australia to become Diabetes Feet Australia.

Our Primary Objectives



DFA is led by a multi-disciplinary steering committee, chaired by Dr. Pete Lazzarini. The committee comprises a broad range of expert members from clinical practice, research and industry, with backgrounds in endocrinology, vascular surgery, podiatry, nursing, epidemiology, clinical research, biomechanical and biochemical research. Members also bring a wealth of experience having participated in international, national and state DFD groups, including the International Working Group on the Diabetic Foot and the former Australian Diabetic Foot Network (Australian Diabetes Society). For further information on the members of the DFA national steering committee go to: https://www.diabeticfootaustralia.org/

One of DFA's key activities to achieve its goal and objectives is the establishment of a national strategy to guide Australia's efforts toward reducing the burden of DFD in this country. This Australian DFD strategy 2018-2022: The first step towards ending avoidable amputations within a generation is the first strategy on Australia's pathway to reaching our goal of ending avoidable amputations within a generation (i.e. in 2040).

EXECUTIVE SUMMARY

On any day in Australia, the national burden of diabetes-related foot disease (DFD) is significant:

300,000 people are at-risk of developing DFD

50,000 people are living with DFD

12,500 people are living with a diabetes-related amputation

1,000 people are in hospital because of DFD

12 people will undergo a diabetes-related amputation

4 people will die because of DFD

4,000,000 will be spent managing DFD

To reduce this large national burden, the following three priorities should be addressed for people with, or at-risk of, DFD:

A	B	C
ACCESS TO AFFORDABLE AND EFFECTIVE CARE	PROVISION OF SAFE QUALITY CARE	RESEARCH AND DEVELOPMENT TO IMPROVE PATIENT OUTCOMES

EXECUTIVE SUMMARY

A ACCESS TO CARE

1 All people with diabetes should have access to annual DFD screening and understand their risk of developing diabetes-related foot disease

2 All people at-risk of diabetes-related foot disease should have access to preventative evidence-based healthcare from appropriately trained health professionals

3 All people with diabetes-related foot disease should have access to evidence-based healthcare from specialised interdisciplinary foot disease services

B SAFE QUALITY CARE

4 All health professionals and specialised interdisciplinary foot disease services caring for people with, or at-risk of, diabetes-related foot disease should demonstrate they meet minimum Australian evidence-based standards

5 All health service regions should report their diabetes-related foot disease outcomes annually to monitor progress towards ending avoidable amputations

6 Australian national diabetes-related foot disease guidelines should continually reflect the most up-to-date robust evidence to guide standards for healthcare provision and outcome reporting

C RESEARCH AND DEVELOPMENT

7 An "Australian Research Agenda for Diabetes-Related Foot Disease" should be developed and endorsed to guide national research priorities

8 An "Australian Diabetes-Related Foot Disease Clinical Trials Network" should be established to provide national research support and leadership

9 Investments in research and development for diabetes-related foot disease should be proportionate to the national health burden caused by the disease

Ending avoidable amputations in a generation

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

INTRODUCTION

The National Problem

Diabetes-related foot disease (DFD) is globally-recognised as the leading cause of diabetes-related hospitalisations and amputation (1-3), and has mortality rates that are comparable to many cancers (1,4,5). It poses a major burden on an individual's quality of life, significant risks to their morbidity and mortality, and increases their healthcare costs (1-3,5-7). DFD is defined as ulceration, infection, ischaemia or neuro-arthropathy of the foot in people with diabetes (7-9). People at-risk of DFD are defined as those with diabetes who have developed peripheral neuropathy, peripheral arterial disease or have a history of previous foot disease (8,10).

Each year in Australia DFD causes an estimated 27,600 public hospital admissions, 4,400 lower extremity amputations, 1,700 deaths, and it costs the Australian health system $1.6billion (6,7,11-13). Table 1 displays this burden per day for the nation and per 100,000 Australian residents. Australian cities with populations of approximately 100,000, such as Toowoomba (Queensland), Bendigo (Victoria) or Launceston (Tasmania), could expect this daily burden of DFD. Other cities and regions can apply these estimates to their population to calculate their daily burden.

Table 1: Estimated burden of diabetes-related foot disease in Australia each day

CHARACTERISTIC	AUSTRALIA [a]	PER 100,000 [b]
Populations		
People with diagnosed diabetes [c]	1,250,000	5,000
People at-risk of DFD [d]	300,000	1,000
People living with DFD [e]	50,000	200
Morbidity		
People with a previous diabetes-related amputation [f]	12,500	50
People in public hospital because of DFD [g]	1,000	4
People undergoing a diabetes-related amputation [h]	12	1 every 20 days
Morality		
People dying DFD [i]	4	1 every 60 days
Costs		
Estimated cost to public hospitals from DFD [j]	$1 million	$4,000
Estimated cost to all health systems from DFD [k]	$4.3 million	$18,000

DFD = Diabetes-related foot disease; a Estimated burden for the 24,450,000 resident population of Australia in 2017 (14); b Estimated burden for every 100,000 resident population of Australia in 2017 (i.e. 100,000 / 24,450,000); c Number of Australians with diagnosed diabetes in 2017 (15); d Prevalence of those at-risk of DFD (~24%) (16-19) x number of Australians with diagnosed diabetes in 2017 (15); e Prevalence of those with DFD (~4%: 3% ulcer (with or without infection (17,19-21)) + 1% critical ischaemia (revascularisation) (17)) x number of Australians with diagnosed diabetes in 2017 (15); f Prevalence of those with a previous diabetes-related amputation (~1%) (22,23) x number of Australians with diagnosed diabetes in 2017; g Prevalence of inpatients in hospital each day for the primary admitting reason of DFD (~2%) (6,7) x available overnight public hospital beds in Australia in 2013-14 (49,153) (24); h Numbers of diabetes-related lower limb amputation hospital admissions in 2012-13 (4,402) (13) / 365 days in a year; i Number of deaths with DFD recorded as a cause of death in 2005 (1,700) (12,25) / 365 days in a year; j Estimated direct costs incurred by DFD to the Australian Public Hospital System in 2015 ($348million) (11,26) / 365 days in a year; k Estimated direct cost incurred by DFD to the Australian Health System in 2015 ($1.57billion) (11,27) / 365 days in a year.

Unfortunately, this burden appears to be growing. Data from 1998 to 2011, a time-period where many countries reported a reduction in avoidable diabetes-related amputations, demonstrated a 30% increase in these amputations in Australia (28-30).).

The National Savings

In contrast, over the last decade, the states of Queensland and Western Australia have reported significant reductions in the order of 40% for DFD hospitalisation rates (31) and 30-72% for diabetes-related amputation rates (22,31,32). 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 (22,31,32)(16)(16). Additionally, a recent national health economic study has demonstrated that up to $2.7 billion can be saved over five years (~$10,000 per patient), when nationally-recommended, evidence-based, interdisciplinary care is implemented across Australia for people with, or at-risk of, DFD (27). These cost-savings are in addition to an improvement in the quality of life for persons living with DFD, and include the initial further investments needed to implement evidence-based treatment (27).

Table 2 displays the estimated savings to the burden per day if all people with DFD in Australia had access to nationally-recommended, evidence-based care. These forecasts suggest that we can save $1.5million dollars per day in costs from improved healthcare outcomes in Australia (or $6000 per day for each region of 100,000 Australians). A nationwide strategy is urgently needed to effectively combat and improve health service delivery for DFD, and reach the savings described in Table 2.

Table 2: Forecasted savings to the estimated burden of diabetes-related foot disease in Australia each day after systematic implementation of evidence-based care

CHARACTERISTIC	AUSTRALIA [a]	PER 100,000 [b]
Morbidity savings		
People now NOT in public hospital because of DFD [c]	400	1.5
People now NOT undergoing a diabetes-related amputation [d]	5.5	1 every 45 days
Morality savings		
People now NOT dying from DFD [e]	2	1 every 115 days
Cost savings		
Estimated cost SAVINGS to public hospitals from DFD [f]	$350,000	$1,400
Estimated cost SAVINGS to all health systems from DFD [g]	$1.5million	$6,000

DFD = Diabetes-related foot disease; a Estimated savings for the 24,450,000 resident population of Australia in 2017 (14); b Estimated burden for every 100,000 resident population of Australia in 2017 (i.e. 100,000 / 24,450,000); c People in public hospital because of DFD in Table 1 x percentage reduction demonstrated in people in public hospital because of DFD after systematic implementation of evidence-based care (~40%) (31); d People undergoing a diabetes-related amputation in Table 1 x percentage reduction demonstrated in people undergoing diabetes-related amputations after systematic implementation of evidence-based care (~45%) (22,31,32); e People dying from DFD in Table 1 x percentage reduction demonstrated in people dying from DFD after systematic implementation of evidence-based care (~45%) (5,33); f Estimated costs to public hospitals from DFD in Table 1 x percentage reduction demonstrated in estimated costs to public hospitals from DFD after systematic implementation of evidence-based care (~35%) (27); g Estimated costs to all health systems from DFD in Table 1 x percentage reduction demonstrated in estimated costs to all health systems from DFD after systematic implementation of evidence-based care (~35%)(27).

INTRODUCTION

The National Strategy

In this document, we describe the Australian diabetes-related foot disease strategy 2018-2022. This strategy identifies nine key goals and related areas for action and measures of progress that, if implemented, should put Australia firmly on a pathway towards ending avoidable amputations within a generation. Enacting this strategy aims to ensure that all people with DFD have access to and receive safe quality evidence-based care when and where they need it, and that they can be assured that future investments in research and development will continue to strive to improve their care delivery and health outcomes over time.

The development of this strategy was led by the DFA steering committee and its scientific director. They explored similar international strategies (e.g. (18,34)), and aligned the current strategy with best international evidence-based practices in DFD policies, as well as the Australian National Diabetes Strategy 2016-2020 (35). The committee approved the completed draft of this strategy, which was then sent for public consultation in May 2017.

During public consultation, feedback was received by three other national peak bodies, two state peak bodies, two tertiary interdisciplinary foot disease services and 52 individuals. Overall, feedback was positive: 61% strongly agreed and 32% agreed with the individual draft goals, areas for actions and measures of progress, while 6% were neutral and 1% disagreed. The committee has incorporated the respondents' feedback into this final document. For further feedback outcomes, a response to the suggestions and the resulting changes, please see the "Response to aggregated feedback" document, published at https://www.diabetesfeetaustralia.org/.

DFA appreciates the enthusiastic and constructive feedback received from all respondents, and encourages them and the wider Australian DFD community to now use this document to implement the plans that will bring us closer to ending avoidable amputations in Australia in a generation (i.e. by 2040).

Future of this National Strategy

DFA envisages periodically reviewing this Australian diabetes-related foot disease strategy 2018-2022 to ensure it continues to meet (inter)national best practice standards. DFA recommends formally reviewing the impact of this strategy and creating the next 5-year national strategy in 2021. DFA will endeavor to keep the Australian DFD community informed on any future progress and developments.

Please check our website (https://www.diabetesfeetaustralia.org/) for updates. For any further information please email: nationaloffice@diabetesfeetaustralia.org.

A ACCESS TO CARE

1 All people with diabetes should have access to annual DFD screening and understand their risk of developing diabetes-related foot disease

To implement any new system targeting a disease, people with the disease and those with risk factors for developing the disease firstly need to be systematically identified. This is essential in the case of DFD: the main risk factor for developing DFD is peripheral neuropathy, which causes a loss of sensation in the feet and does not result in physical symptoms of impending disease development (1,2,8,10). National and international guidelines recommend all people with diabetes need to receive an annual evidence-based DFD screening by an appropriately trained health professional, to identify if they are at-risk of developing DFD, or already have DFD and are unaware (8,10).

Unfortunately, the current proportion of Australians with diabetes receiving an annual DFD screening to identify DFD is unknown. The most recent population-based Australian data available is now over 15 years old, and reported that only 50% of all Australians with diabetes received an annual DFD screening (36). This rate is significantly below the 94% reported by other nations (18). A strategy used by other nations to improve national DFD screening rates is facilitating measurement of their occurrence via primary health care data systems (18). This is not available in Australia, but could be achieved with some minor changes to items within the Medicare Benefits Schedule (MBS).

In order to adequately provide the evidence-based DFD screening recommended in the National Health and Medical Research Council (NHMRC) DFD guideline for the 1.25 million Australians with diagnosed diabetes (15), we estimate the equivalent of 260fte health professionals are required in Australia, or 1fte per 100,000 Australian residents (see Table 3 for these workforce estimates). Currently, these screenings are being reimbursed under a range of other MBS items. We suggest creating a new MBS Item specifically for DFD screening, to systematically identify those people at-risk of, or with, DFD as early as possible. People can then be referred to appropriate services as their level of risk increases (see goal 2 and 3 for these appropriate services). This will not only improve future DFD care, but it will also enable more robust monitoring of DFD screening rates across the country. We suggest that this newly created MBS item should be used by appropriately trained health professionals. Any increased investment in funds needed with the introduction of a new item should be modest, as in essence it involves a cost shift from a range of other MBS items currently used to a defined MBS item for this purpose.

We recommend the criteria to receive reimbursement for such a new DFD screening MBS item should include performing the aforementioned DFD screening assessment, plus educating the patient on their identified level of DFD risk and referring the patient to appropriate evidence-based services when needed. This requires patients and primary care clinicians to be educated on the need to undertake this process and of the appropriate evidence-based services available to them.

We propose development of new DFD screening and referral tools, to help primary care clinicians fulfil the criteria for this new DFD screening item. There are several existing tools available that could be adopted for this purpose, such as from the previous NHMRC DFD guideline, the Indigenous diabetic foot program's "Diabetes Foot Assessment of Risk Test" form, and the "Queensland High Risk Foot Form" (10,37,38). Any endorsed tool should be made readily available on mainstream government health registries such as www.healthdirect.gov.au.

A ACCESS TO CARE

POTENTIAL AREAS FOR ACTION

- Establish a specific MBS Item number for DFD screening in line with Australian evidence-based guideline recommendations
- Develop nationally-agreed evidence-based DFD screening and referral tools for people with diabetes and their primary care clinicians
- Implement public awareness campaigns to encourage people with diabetes and primary care clinicians to initiate annual DFD screening

POTENTIAL MEASURES OF PROGRESS

- Proportion of people with diabetes receiving DFD screening per diagnosed diabetes population
- Proportion of people with diabetes at-risk of developing, or with, DFD receiving referrals to appropriate evidence-based care

one

Table 3: Estimated full-time equivalent health professional and interdisciplinary foot disease services required to ensure access to systematic evidence-based care for people with, or at-risk of, diabetes-related foot disease across Australia each year

CHARACTERISTIC	AUSTRALIA [a]	PER 100,000 [b]
Level 1 care: Screening for all people with diabetes		
People with diagnosed diabetes [c]	1,250,000	5,000
Number of health professional consultations required to perform screening [d]	1,250,000	5,000
Number of fte health professionals required to perform screening [e]	260	1
Level 2 care: Prevention for all people at-risk of DFD		
People at-risk of DFD [f]	300,000	1,000
Number of health professional consultations required to perform prevention [g]	1,200,000	4,000
Number of fte health professionals required to perform prevention [h]	250	1
Level 3a care: Care for all people with DFD in ambulatory settings		
People living with DFD [i]	50,000	200
Number of IFDS consultations required to perform ambulatory care [j]	2,600,000	10,600
Number of fte IFDS required to perform ambulatory care [k]	540	2
Level 3i care: Care for all people with DFD in inpatient hospital settings		
People in public hospital because of DFD [l]	1,000	4
Number of IFDS consultations required to perform inpatient care [m]	365,000	1,500
Number of IFDS required to perform inpatient care [n]	50	0.2

DFD = diabetes-related foot disease; fte = full-time equivalent; IFDS = interdisciplinary foot disease services. a Estimated population needing care and workforce required to adequately care for that population in the 24,450,000 resident population of Australia in 2017 (14); b Estimated population needing care and workforce required to adequately care for that population for every 100,000 resident population of Australia in 2017 (i.e. 100,000 / 24,450,000); c Number of Australians with diagnosed diabetes in 2017 (15); d Number of people with diabetes x number of consultations required to adequately perform DFD screening per year for each person (one screening consultation per year is required (10)); e Number of consultations required to adequately perform DFD screening per year / 4,800 x DFD screening consultations able to be performed by one full time equivalent (fte) health professional performing a DFD screening role only (20 x DFD screening consultations per day (assumed one screening takes 20 minutes) x 240 available working days per year); f Prevalence of those at-risk of DFD (~24%) (16-19) x number of Australians with diagnosed diabetes in 2017 (15); g Number of people at-risk of DFD x average number of consultations required to adequately perform DFD prevention per year for each person (average of 4 consultations per year assumed as numbers of consultations required range from 2 per year for those with one risk factor to 12 per year for those with previous DFD (10)); h Number of consultations required to adequately perform DFD prevention per year / 4,800 x DFD prevention consultations able to be performed by one fte health professional performing a DFD prevention role only (20 x DFD prevention consultations per day (assumed one prevention consultation takes 20 minutes) x 240 available working days per year); i Prevalence of those with DFD (~4%: 3% ulcer (with or without infection (17,19-21)) + 1% critical ischemia (revascularisation) (17)) x number of Australians with diagnosed diabetes in 2017 (15); j Number of people with DFD x number of IFDS consultations required to adequately perform DFD care per year for each person (average of 52 IFDS consultations assumed as a person with DFD requires weekly care (10,39)); k Number of IFDS consultations required to adequately perform DFD care per year / 4,800 x IFDS care consultations able to be performed by one fte IFDS (involving 2+ health professionals) performing a DFD care role only (20 x DFD care consultations per day (assumed one care consultation takes 20 minutes) x 240 available working days per year); l Prevalence of inpatients in hospital each day for the primary admitting reason of DFD (~2%) (6,7) x available overnight public hospital beds in Australia in 2013-14 (49,153) (24); m Number of people in hospital each day with DFD x number of IFDS consultations required to adequately perform DFD care per year for each person (average of 365 IFDS consultations assumed as an inpatient with DFD requires daily review (40)); n Number of IFDS consultations required to adequately perform DFD care per year / 7,300 x IFDS care consultations able to be performed by one fte IFDS (involving 2+ health professionals) performing a DFD care role only (20 x DFD care consultations per day (assumed one care consultation takes 20 minutes) x 365 available working days per year).

A ACCESS TO CARE

2 All people at-risk of diabetes-related foot disease should have access to preventative evidence-based healthcare from appropriately trained health professionals

People at-risk of developing DFD need increased vigilance and evidence-based care to prevent the development of DFD (8,10). Evidence-based care involves more regular foot clinical examinations, treatment of pre-ulcerative lesions (such as corns, callus and blisters), footwear and insoles to reduce high plantar pressure underneath the foot and self-care education (8,10). Many components of this care are not reimbursed via the MBS or Pharmaceutical Benefits Scheme (PBS), even though these components are nationally-recommended and evidence-based (10,12,39,41).

Examples of this are the specific insoles and footwear required to reduce high plantar pressures causing DFD (42,43). Also, increases in the number of clinical consultations required to regularly examine and treat pre-ulcerative lesions are often not reimbursed (12). People at-risk of DFD, depending on their level of risk, need between 2-12 clinical consultations per year as part of an evidence-based foot disease protection program, in line with NHMRC recommendations (10). Such consultations are often provided by podiatrists, although other appropriately trained clinicians can provide them as well (10). However, such podiatry consultations are capped within the maximum number of five allied health consultations permitted per year for people with chronic conditions in the MBS (12). This results in pre-ulcerative care treatments for people at-risk of DFD having to compete with other allied health care requirements (12).

This lack of reimbursement within the MBS and PBS is striking, given that these treatments are accepted as major recommendations in the government approved NHMRC DFD guideline (10,12). Furthermore, MBS and PBS reimbursements are provided for all other NHMRC diabetes-related guideline recommendations to ensure Australia-wide implementation of diabetes-related care, except for these specific DFD recommendations (10,12). Failure to reimburse these DFD recommendations translates to lack of access and use of these evidence-based treatments by people at-risk of DFD, and inevitably development or recurrence of DFD. All evidence-based treatments recommended by NHMRC DFD guidelines require reimbursement within MBS, PBS or similar national public-funded schemes (such as the National Diabetes Services Scheme) to improve access to evidence-based care for all people at-risk of DFD and prevent avoidable DFD (12). In order to adequately provide the evidence-based prevention recommended in the NHMRC DFD guideline for the 300,000 Australians at-risk of DFD, we estimate the equivalent of 260fte health professionals are required in Australia, or 1fte per 100,000 Australians (Table 3).

With the majority of appropriately trained clinicians practicing in the private sector (for example 80% of registered podiatrists practice privately (44)), reimbursements from MBS, PBS or other similar schemes is important in the care of people at-risk of developing DFD. To ensure increased access to quality care and prevent uncontrolled reimbursement claims, we recommend that only people with confirmed risk factors for developing DFD be eligible for reimbursement (see criteria for new MBS item for DFD screening in Goal 1). Furthermore, we recommended that only health professionals who can demonstrate to be appropriately trained in DFD prevention are reimbursed for any new MBS items in this area (see further Goal 4). Similar DFD reimbursement systems are in place in Germany and Belgium, where it has led to clinicians consciously choosing to either treat people at-risk of DFD in accordance with the highest standard, or referring to clinicians that do (34). Additionally, further reimbursements could be tied to demonstrated improved DFD clinical performance and outcomes achieved (see further Goal 5).

A ACCESS TO CARE

POTENTIAL AREAS FOR ACTION

- Establish MBS, PBS or similar publicly-funded scheme item numbers to reimburse preventative DFD consultations for all people at-risk of DFD in line with Australian evidence-based guideline recommendations

- Establish MBS, PBS or similar publicly-funded scheme item numbers to reimburse insoles and footwear for all people at-risk of DFD in line with Australian evidence-based guideline recommendations

POTENTIAL MEASURES OF PROGRESS

- Proportion of people at-risk of developing DFD receiving DFD prevention consultations

- Proportion of people at-risk of developing DFD receiving DFD insoles and footwear

two

A ACCESS TO CARE

3 All people with diabetes-related foot disease should have access to evidence-based healthcare from specialised interdisciplinary foot disease services

It is widely recognised in international and national evidence-based guidelines that no single healthcare discipline has the breadth of clinical skills to manage all aspects of care for people with DFD (8,10,39,40,45-48). People with DFD need access to regular evidence-based care that requires clinical skills in the assessment and management of metabolic, vascular, neurological, orthopaedic, biomechanical, ulcer and infection aspects of DFD (8,10,39,40,45-48). For this, care should be provided by a range of clinicians with these different skills working together in specialised interdisciplinary foot disease services (IFDS) (8,10,39,40,45-48). Evidence consistently demonstrates that when IFDS are implemented they significantly improve clinical and financial outcomes (8,10,27). If we are to progress toward ending avoidable amputations in a generation, it is vital that all Australians with DFD have access to evidence-based healthcare from IFDS (8,10,39,40,45-47).

Currently no hard data are available on the numbers of IFDS available in Australia, as a nationally-agreed definition for ambulatory or inpatient IFDS has yet to be developed and IFDS are not publicly recognized (see Goal 4). However, it is estimated from canvassing networks in the Australian diabetic foot community there would be at most of 50 IFDS across Australia, albeit of unknown make-up and quality and with almost all located within state-funded ambulatory facilities (hospitals or community health centres). In contrast, in order to adequately provide the evidence-based care recommended in the NHMRC DFD guideline for the 50,000 Australians with DFD, we estimate the equivalent of 540 ambulatory IFDS are required across Australia, or 2 ambulatory IFDS per 100,000 Australians (Table 3). These ambulatory IFDS could be located in hospital outpatient departments, community health centres or general practice clinics, as long as the interdisciplinary team and facilities are available at that location. In addition, we estimate the equivalent of 50 inpatient IFDS are required in Australia, or 0.2 inpatient IFDS per 100,000 Australians, to adequately care for the 1,000 Australian inpatients in hospital each night with complex DFD (Table 3). Thus, we suggest Australia has less than 10% of the IFDS it needs to adequately provide evidence-based services to all the Australians with DFD. This needs to improve significantly and quickly.

A rapid increase in IFDS will require substantial initial investment from state and federal governments. However, as outlined in Table 2, even after accounting for this initial substantial investment to ensure access to evidence-based care for all Australians who need it, savings in the order of $1.5 million per day (or $6,000 per 100,000 Australian residents per day) can be achieved. Based on these cost savings, in conjunction with significant improvements in patient outcomes, we suggest it is a 'no brainer' for governments to facilitate the establishment of IFDS. This could be done through innovative incentives for public or conjoint public/private health services to establish IFDS to cover staff, facilities and consumables.

Once established, we suggest IFDS could be funded based on agreements to improve DFD outcomes in their region (see Goal 5). Similar to prevention (see Goal 2), there is striking lack of reimbursement via MBS or PBS for many nationally-recommended evidence-based care components necessary to treat people with DFD (10,12). For example, the significant increases in clinical consultations required to adequately treat DFD on a weekly basis, provision of weekly wound dressings and necessary offloading devices are not reimbursed (8,10,39,42,48). In addition, there is no MBS incentive to facilitate the establishment of IFDS in the private sector. Without reimbursement for nationally-recognised evidence-based care (12), it is unlikely that any IFDS will be established in the private sector and thus people with DFD will nearly always need to seek care in the public health sector.

A ACCESS TO CARE

Access to IFDS is often more difficult for people living in rural and remote areas. Telehealth should be facilitated and reimbursed between clinicians in these areas and IFDS in regional hubs. Telehealth for DFD management has been shown to significantly reduce diabetes-related amputations in Western Australia (49). The NHMRC DFD guideline also recommends DFD telehealth (10). This recommendation could easily be incorporated into the existing MBS telehealth item numbers. To increase the number of ambulatory, inpatient and telehealth services provided by IFDS in Australia, there is also a need to train more clinicians to support an IFDS to deliver the required specialised care in both state-funded public facilities (for example hospital or community health care facilities) and Medicare-reimbursed private facilities (for example large GP clinics) (see Goal 4).

Apart from training healthcare professionals, people with DFD can also be better empowered regarding the care they should expect to receive. If people are more aware of the evidence-based care that they should be receiving, they should start to demand it from their healthcare providers and governments when it isn't available locally. Similar initiatives have focused primarily on public awareness for the need for DFD screening to identify the risk of developing DFD (e.g. Diabetic Foot Australia's patient passport, the Australian Diabetes Society's general practitioner diabetes-related foot training, or Diabetes UK's campaign "Putting Feet First"). No published data is available on the success of these campaigns, but anecdotally they have led to more people demanding foot screens from their general practitioners. There is a surprisingly limited amount of patient-centred information available to inform people with, or at-risk of, DFD on the evidence-based care they should expect to be provided. The Australian NHMRC guideline should be translated into more patient-friendly and understandable information for patients. These resources should then be disseminated as widely as possible via social media, patient organisations and government. In that way, the information will reach the people who need it most, who may then demand such evidence-based care from their healthcare providers and governments.

POTENTIAL AREAS FOR ACTION

- Establish innovative incentives and funding model agreements to significantly increase the number of interdisciplinary foot disease services (IFDS) in the public and private sector
- Establish an MBS, PBS or similar publicly-funded scheme item number to reimburse offloading devices for all people with DFD in line with Australian evidence-based guideline recommendations
- Establish an MBS, PBS or similar publicly-funded scheme item number to reimburse wound dressings for all people with DFD in line with Australian evidence-based guideline recommendations
- Consider tying ongoing reimbursement of IFDS for DFD care to improvements in regional clinical processes and outcomes
- Implement public awareness campaigns and patient-friendly tools to encourage people with DFD to seek early access to evidence-based care in their community

POTENTIAL MEASURES OF PROGRESS

- Number and proportion of IFDS available across Australia and in each health service region
- Proportion of people with DFD treated in IFDS
- Proportion of people with DFD receiving offloading devices
- Proportion of people with DFD receiving wound dressings
- Proportion of people with DFD receiving telehealth consultations with IFDS
- Perform cost-effectiveness analyses of increased DFD ambulatory clinical care costs compared with decreased hospital DFD outcome costs (i.e. hospitalisation and amputation costs) to report on return of investments

three

B

SAFE QUALITY CARE

4 All health professionals and specialised interdisciplinary foot disease services caring for people with, or at-risk of, diabetes-related foot disease should demonstrate they meet minimum Australian evidence-based standards

To improve transparency of the provision of safe quality care, all stakeholders should be able to identify those health professionals and IFDS that deliver evidence-based care as recommended by the Australian DFD guidelines. Available directories that could be used for such public identification are, for example, the Australian Government's www.healthdirect.gov.au and local Primary Health Network websites. By publicly recognising and listing appropriately trained health professionals and accredited IFDS, people with, or at-risk of, DFD can gain easier access to this information and the care they need. We therefore recommend that all health professionals treating people with DFD and all IFDS demonstrate they meet minimum evidence-based standards for the care they provide. Health professionals should be credentialed following demonstration of appropriate training. IFDS should be accredited following demonstration of dedicated health professionals' time and their clinical pathways and data capturing.

Certification and Credentialing

For health professionals to be appropriately trained, specific training modules need to be developed and endorsed. These modules should target the care required for the three levels of care outlined in Goals 1-3: i) DFD screening for all people with diabetes, ii) prevention for those identified to be at-risk of developing DFD, and iii) interdisciplinary care for those with DFD. Associated competency standards should be developed, endorsed and implemented. This could then lead towards a formal pathway of certification for DFD screening (level i), and credentialing for health professionals treating people with, or at-risk of, DFD (levels ii and iii).

Certification and credentialing, plus competency standards and associated training, should be developed in consultation with all healthcare disciplines involved in the care of people with, or at-risk of, DFD. This will create a common language between disciplines and will provide insight into the competencies needed for treating these patients. Such a competency framework is currently being developed by the Australasian Podiatry Council. This framework could be modified to capture generic competencies that are applicable to all healthcare professionals managing DFD, as has occurred in the United Kingdom (50,51), or modified to each individual healthcare professional discipline. Either way, this will require considerable input and engagement from all disciplines' professional associations.

For DFD screening (level i), training modules should be made freely available with the aim to educate health professionals. The Australian Diabetes Society, Queensland Health and the Indigenous Diabetic Foot Program already provide training modules that could be adopted for this purpose (37,52)). Once healthcare professionals are appropriately trained to deliver such screening, they can implement screening, identification and referral strategies for those with, or at-risk of, DFD. This should enable people with DFD earlier access to treatment by appropriately trained health professionals when they need it. Such early referral has been found critical to improve DFD outcomes (53). For prevention and care (levels ii and iii), training modules should also be made available with the aim to upskill relevant and interested health professionals wanting to deliver care to people with, or at-risk of, DFD. The Wound Healing Institute Australia, Queensland Health and the Indigenous Diabetic Foot Program already provide training modules that could be adopted for this purpose (37,52,54).

B SAFE QUALITY CARE

Accreditation

For nationwide accreditation of IFDS, the way has been led by three European countries (Belgium, Germany and Scotland) (18,34). 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 standards for IFDS, before developing more mature national accreditation standards. Once they generated a "critical mass" of IFDS demonstrating that they met the basic standards, they were able to forge alliances with stakeholders to integrate auditing and recognition of IFDS sustainably within their healthcare systems. The crucial stakeholders were patient organisations in Belgium and government enforced legislation in Germany (34). In Australia, the crucial stakeholders will need to be determined as the accreditation process matures, like it did in these countries.

Any Australian accreditation system should emulate two basic standards that formed the foundation of more mature international accreditation (18,34). These are that an IFDS should demonstrate they have:

i. Medical, nursing and allied health clinicians with dedicated time and access to essential evidence-based treatment modalities who work together in a facility-recognised IFDS
ii. Evidence-based care pathways that align with Australian guideline recommendations for people with DFD, as demonstrated by the regular capture of evidence-based care data recommended in the "Australian
Diabetic Foot Ulcer Minimum Dataset (55)"

The first is based on general directions on the clinical disciplines for an IFDS as described in the NHMRC and other DFD guidelines (8,10,40). These indicate that disciplines of medicine (either medical or surgical disciplines, preferably both), allied health (preferably including podiatrists) and nursing (preferably including wound care nurses and diabetes educators) should be included (8,10,40). For the second, the IFDS should follow evidence-based pathways of care that align with Australian DFD guideline recommendations (10), should capture data that demonstrates this, such as recommended by the Australian Diabetic Foot Ulcer Minimum Dataset (55), and submit their aggregated data for national audit and research purposes. This can then be combined with data from all accredited IFDS, to provide a benchmark with which health service regions can compare themselves, both on clinical and process of care outcomes.

A fully operating accreditation system may take years of negotiation with various stakeholders (government, health insurance companies, professional organisations, patient organisations, etc.). The National Association of Diabetes Centres in collaboration with DFA and multiple other DFD organisations is currently drafting an Australian accreditation standards framework for IFDS. As aforementioned, Australia has proportionally very few IFDS; however, this may be a blessing in disguise in initiating the IFDS accreditation standards. When the few existing IFDS support this framework it will quickly generate momentum to bring an IFDS accreditation system to fruition.

Once the above basic standards are in place, further standards could be developed, as well as continuous auditing processes. In Germany, recognized IFDS visit each other at least six monthly for peer-auditing (34). This generates unique learning opportunities, strengthens networks, and avoids the need for a separate arbitrary external auditing body. In Germany, auditing IFDS need to be separated by a minimum of 50 kilometres. Australia should consider excluding IFDS from auditing another IFDS if they are in the same health service region.

For rural and remote regions of Australia, flexibility for accreditation may need to be considered for IFDS-type services provided. These services may not be able to comply with IFDS standards because of lack of available credentialed health professionals and treatment modalities. IFDS under these constraints should be afforded opportunities to mitigate these factors operationally by facilitating links with IFDS in major regional hubs or tertiary services via the use of telehealth services.

B

SAFE QUALITY CARE

Reimbursement

A long-term strategy for health professional certification and credentialing and IFDS accreditation is to align these qualifications with reimbursement (Goals 1-3). In Germany and Belgium, for example, only accredited IFDS are eligible to receive public or private reimbursement when treating people with DFD, which has been essential for the longevity of IFDS (34). For Australia, screening, prevention and care reimbursement should be linked to the suggested new MBS, PBS or other government initiative items for DFD screening, prevention and care (see Goals 1-3).

POTENTIAL AREAS FOR ACTION

- Develop or adopt specific training modules for healthcare professionals working with people with, or at-risk of, DFD
- Forge alliances between stakeholders to work towards a competency framework for health professionals, and associated certification (for DFD screening) and credentialing (for DFD prevention and care)
- Establish standards and frameworks for accreditation of IFDS
- Establish a public register of credentialed health professionals and accredited IFDS
- Aggregate data that aligns with the Australian Diabetic Foot Ulcer Minimum Dataset to benchmark health service regions on DFD treatment
- Align DFD reimbursement strategies with certification, credentialing and accreditation

POTENTIAL MEASURES OF PROGRESS

- Nationally-endorsed competency frameworks for certification and credentialing of health professionals, and accreditation of IFDS are implemented
- Number of health professionals certified for DFD screening
- Number of health professionals credentialed for DFD treatment
- Number of accredited IFDS
- Number of patient datasets captured by health professionals and IFDS according to the Australian Diabetic Foot Ulcer Minimum Dataset

four

B SAFE QUALITY CARE

5 All health service regions should report their diabetes-related foot disease outcomes annually to monitor progress towards ending avoidable amputations

Information is needed to continuously inform stakeholders on the progress of key clinical process indicators and outcomes for the care of people with DFD across Australia. Data collected should be reported annually by health service regions (for example each Primary Health Network) to monitor, learn and continually improve care processes, and achieve the goal of ending avoidable amputations in a generation. Information should also be reported publicly, preferably on an annual basis. This requires the development and adoption of nationally-agreed standard definitions, data capture processes, expert analysis and interpretation of data collected.

Some processes already exist in Australia to undertake minimal reporting now. Most importantly, national hospital admission dataset systems are in place to capture and analyse the clinical outcomes of DFD hospitalisation and amputation. This can facilitate quick ongoing reporting of these outcomes by region. However, it should be noted that caution is required to interpret both outcomes. For example, amputation should not be used as a simplistic marker of quality of care or acute incidence of DFD. An amputation is a surgical procedure (not a medical diagnosis of DFD severity), interpretation of different amputation-types can be complex and additional specific general and diabetes-related population information is needed for accurate interpretation (56,57). Whereas DFD hospitalisation is rarely used, it has been found to be a more precise marker of acute incidence of DFD (1,6,7,19). Hospitalisation aligns with the definition of incidence severity for disease from global bodies and is therefore comparable to other acute incidence markers (such as myocardial infarction, stroke or chronic kidney disease as a result of diabetes) (19,58). Although episodes of diabetes-related hospitalisation and amputation are still relatively easily to measure within existing hospital admission datasets (3,6,31), different Australian government funded organisations use different definitions and associated hospital admission dataset system codes to report these outcomes with often different results (such as Australian Institute of Health and Welfare (25,59), Australian Commission on Safety and Quality in Health care (13), and Australian National Diabetes Audit (60)). Thus, DFD hospitalisation and amputation episodes and rates need to have their definitions and associated hospital dataset system codes standardised nationally, to enable consistent monitoring of these DFD outcomes.

Additionally, more meaningful ambulatory clinical outcomes (e.g. ulcer healing durations or ulcer-free survival days), clinical process of care indicators (e.g. time to presentation to an IFDS; time to revascularization) and patient-reported outcome measures (e.g. quality of life, satisfaction with IFDS) should be adopted, as has occurred successfully in the UK (53,61). These additional measures can be captured using national standards already defined in the Australian Diabetic Foot Ulcer Minimum Dataset Dictionary (55). It is recommended that publicly recognised IFDS should collect this minimum data (see Goal 4). It will then be possible to aggregate and use this data to provide clinically meaningful outcomes on the current state, and the improvements required, of the care of people with DFD. We recommend that items from the Australian Diabetic Foot Ulcer Minimum Dataset Dictionary are captured in a newly-established clinician-friendly national DFD Registry or incorporated into existing similar relevant registries such as the Australian National Diabetes Audit (60).

To optimally detect health services where the need for further improvement in services is needed, national, state-wide and health service region differences in outcomes should be presented. With major differences within regions, for example in metropolitan versus rural/remote areas or lower socioeconomic versus higher socioeconomic areas, regions need to be smaller than the state boundaries, following the example set by the UK (62). As DFD outcomes are influenced by socio-demographic characteristics, they have the potential to be unintentionally used as 'league tables' with such regional reporting.

B SAFE QUALITY CARE

We therefore recommend that reported rates are adjusted for socio-demographic characteristics of the different regions to enable more objective benchmarks and continuous quality improvement learnings across the nation. We also recommend that it is important to establish an expert advisory group of patients, clinicians and researchers with expertise in DFD clinical process indicators and outcomes. This group can more objectively interpret outcomes and provide context to such publicly available reports. Data should then be transparently published, benchmarked and monitored, with an assurance that all regions are objectively monitoring their progress towards ending avoidable amputations within a generation. Agreements need to be made as to who will be responsible for developing, analysing and interpreting these regular publications.

To stimulate participating key stakeholders (e.g. clinicians collecting data, government policymakers responsible for registration systems, researchers and patients), a yearly forum should be convened to publish and discuss these reports. A similar forum occurs in Germany, where healthcare professionals from recognized IFDS present their yearly clinical process indicator and outcome data, and discuss positive and negative outcomes and recommended quality improvements with key stakeholders (34). If input from patient advocate bodies and government policymakers are also utilised this will create a truly unique quality-improvement forum. This annual forum event is also an important external deadline that will help to guarantee that the data from IFDS is indeed collected and published each year.

Finally, public presentation of results, including discussions, will stimulate learning, avoid duplication of potential mistakes in other health service regions, and will guarantee continuing improvements toward ending avoidable amputations in a generation. Participation in such forums is a binding criterion for IFDS in Germany to be accredited (34). This should also be considered in Australia to guarantee the viability and positivity of such a learning forum. Further, the outcomes of these forums and ongoing consultation quality improvement activities stemming from these forums could be integrated into social media forums to directly engage with patients, clinicians and researchers on the nation's DFD care progress.

POTENTIAL AREAS FOR ACTION

- Establish nationally-agreed standard definitions and criteria for DFD outcomes, especially for diabetes-related hospitalisation and amputation rates

- Establish formal agreements on which national bodies are responsible for regularly developing, interpreting and publishing national DFD outcomes

- Annually publish standard national, state and health service region DFD clinical process of care indicators, clinical outcomes and patient-reported outcome measures, and present these at DFD forums

POTENTIAL MEASURES OF PROGRESS

- Clinical process of care indicators; such as time-to-access specialised IFDS, time-to-revascularisation, % patients receiving offloading devices, % patients with infection receiving antibiotics

- Patient-reported outcomes measures; such as quality of life, IFDS satisfaction

- Ambulatory clinical outcomes; such as ulcer-free survival days, ulcer healing duration

- Hospital clinical outcomes; such as DFD hospitalisation and minor and major amputations

five

B SAFE QUALITY CARE

6 Australian national diabetes-related foot disease guidelines should continually reflect the most up-to-date robust evidence to guide standards for healthcare provision and outcome reporting

Evidence-based guidelines are the cornerstone of medical treatment. The current NHMRC-endorsed Australian DFD guideline was published n 2011, based on a 2009 literature search (10). 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" (10). To the best of our knowledge, neither of these recommendations has been undertaken. As a result, the national guideline that describes how people with DFD should be treated in Australia is outdated, and in some topics not reflective of, or even contradictory to, contemporary scientific evidence. The NHMRC DFD 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 an extensive methodology 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 high-quality 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 DFD guideline (10). Relevant documents that could be immediately used for any future updates of the NHMRC DFD guideline include the IWGDF (International Working Group on the Diabetic Foot) guidance documents published in 2016 (8,42,45-48,63)), the 2016 NICE (National Institute for Health and Care Excellence) guideline from the United Kingdom (40), the 2012 IDSA (Infectious Diseases Society America) guidelines (64), and multiple systematic reviews in the field of DFD published over the last 3 years (e.g. (41,65-70)).

If this approach is adopted, the fields of peripheral artery disease, infection and neuroarthropathy (not included in the current NHMRC guideline) need to also be included. This would create a more extensive guideline, reflecting the interdisciplinary fields involved in the treatment of DFD. Additionally, specific chapters on inpatient DFD care, DFD care for Aboriginals and Torres Strait Islanders, remote consultations (including telehealth services), and rehabilitation for people with previous DFD and amputation should also be considered for inclusion.

B SAFE QUALITY CARE

POTENTIAL AREAS FOR ACTION

• Urgently update the 2011 NHMRC-endorsed Australian DFD guideline

• Develop a methodology to continuously update the Australian DFD guideline using existing high-quality systematic reviews or other guidelines as the basis

• Include within any new Australian DFD guideline chapters on peripheral artery disease, foot infection and neuroarthropathy, and consider chapters on inpatient care, care for Aboriginals and Torres Strait Islanders, remote consultations, and rehabilitation of people with previous DFD

POTENTIAL MEASURES OF PROGRESS

• Time to launch of an updated NHMRC-endorsed Australian DFD guideline

• Methodology for providing "continuous updates" of the Australian DFD guideline is implemented

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C RESEARCH AND DEVELOPMENT

7 An "Australian Research Agenda for Diabetes-Related Foot Disease" should be developed and endorsed to guide national research priorities

Experts within the field of DFD are well aware of the relevant gaps in the evidence for care provided (42,45-48), but this is generally not known within funding, government and industry agencies. A widely endorsed and well communicated national research agenda may overcome this deficit and provide focus on Australian research that targets the most pertinent gaps in the evidence, to deliver the "biggest bang for the buck" for Australia. This national research agenda for DFD should aim to align with the priority area for action to "develop a national research agenda" from the Australian National Diabetes Strategy 2016-2020 (35). When 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 be of value, all relevant stakeholders should be involved in its development. This includes healthcare professional organisations, researchers, universities, government, industry, funding institutions and patient groups. It is especially important all stakeholders mutually agree on the common priorities to be included on the research agenda to end avoidable amputations in a generation. Perceived or actual differences in research priorities between industry, healthcare professionals and researchers need to be resolved. For example, 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 (8,10). Additionally, the RCTs on wound dressings and devices are often criticized with regard to a high risk of bias and poor study quality (69,71). To address these differences, more effort is required by all stakeholders to make more efficient use of the limited research resources available (e.g., finances or availability of potential participants for trials) by focusing research priorities on achieving the common long-term national goal of ending avoidable amputations in a generation.

Various options are available to create a national research agenda. Firstly, an agenda could be incorporated as a national priority within the updated NHMRC DFD guideline (see Goal 6). Literature searches conducted to support revision of the national guideline could be used concomitantly to identify gaps in the literature and thus gaps in knowledge. This would identify areas that need specific resource allocation to close existing gaps. As the NHMRC DFD guideline is endorsed by a large number of professional bodies, endorsement of the guidelines may simultaneously result in endorsement of a directed national research agenda. The disadvantage of this method is the length of time before this guideline is updated, endorsed and published. It would be ideal to establish a national research agenda as soon as possible. An alternative method could be to draft an agenda, and send out for review and subsequent endorsement to relevant DFD stakeholders (professional bodies, government, industry, patient groups). This could be done both robustly and pragmatically based on expert consensus opinion using a Delphi method (Ref).

POTENTIAL AREAS FOR ACTION

- Consult with all relevant stakeholders to identify an "Australian Research Agenda for DFD" using either national guideline development processes or a consensus Delphi methodology
- Ensure this agenda aligns with the "National Diabetes Research Agenda"

POTENTIAL MEASURES OF PROGRESS

- Number of stakeholder endorsements of a published "Australian Research Agenda for DFD"
- Number and value of successfully funded projects that align with the research priorities in the "Australian Research Agenda for DFD"
- Number of future national guideline recommendations based on new Australian research that aligned with the "Australian Research Agenda for DFD"

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C RESEARCH AND DEVELOPMENT

8 An "Australian Diabetes-Related Foot Disease Clinical Trials Network" should be established to provide national research support and leadership

Efforts should be undertaken to improve the quality and output of Australian research on DFD. Geographically, Australia is large enough to accommodate a variety of experts in different areas of DFD research. However, the clinical and research pool is much too small for these experts to be competing with each other for limited research resources: participants and funding. An "Australian Diabetes-Related Foot Disease Clinical Trials Network" (CTN) needs to be established, to attract Australian and international investigator-initiated and industry-initiated research projects and funding. Such a network's objectives and activities should be based on the aforementioned "Australian Research Agenda for Diabetes-Related Foot Disease" priorities (see goal 7). The CTN could encourage and coordinate active involvement with all interested key stakeholder patient, clinician, researcher and industry groups.

CTN Studies

A primary area for the CTN is randomized controlled trials (RCT). These are seen as the top-end of the research pyramid, form the basis for (inter)national guidelines, and high-quality trials are limited in the field of DFD (71). Nationwide collaboration within the CTN is required to recruit sufficient participants, as it is unlikely that single-centres in Australia can deliver quality RCTs on their own. As such, a CTN investing in RCTs will potentially create the greatest and quickest global impact.

Next to RCTs, well-performed prospective observational cohort studies are becoming increasingly attractive as additional sources of high-quality publications to inform guidelines and clinical decisions (72). These 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. An Australian DFD CTN can relatively easily perform such studies. 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 relatively 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 accurately captured (55). If relevant treatment details can be coupled to this dataset via the CTN, Australia would be well positioned to produce meaningful observational study outcomes.

C RESEARCH AND DEVELOPMENT

Study Output

When studies are completed, efforts should be made to maximize their outputs. Rather than simply publishing one high-quality paper from an RCT, impact increases when multiple publications and presentations occur. This is not a call to dilute the data, as each trial needs one primary high-quality paper. However, repetition of a study group name is a great method to spread study messages, outcomes and increase its impact. Clinicians and researchers need to hear the message of quality findings repeatedly to enhance widespread acceptance and use of findings. Two great examples of this in international DFD research are the Eurodiale study (e.g. (73,74)) and the DIAFOS trial (e.g. (75-77)). Both Eurodiale and DIAFOS have resulted in 2 PhD theses, 11 publications and numerous conference presentations. As a result, the findings of these studies are consistently being referred to and have led to further projects and funding. If the authors had chosen to publish just one or two publications plus a few conference presentations, these studies would have had substantially less impact. 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 CTN offers is to collect information on the research work undertaken by the participating sites, for example in terms of number of publications and participants recruited. This information can then be communicated, to gain improved attention to the endeavours of DFD research in Australia; 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 track record of research performed in Australia, will they be tempted to invest (further) in Australian DFD research. 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.

Next Generation Researchers

For Australian researchers, a CTN also provides unique opportunities to nurture the next generation of DFD 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. Ideally, when setting up trials, roles should be created for early career researchers to do the ‘footwork’ in these trials. 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. Furthermore, DFD researchers and universities considering DFD research should be encouraged to align PhD student’s topics with priorities outlined in the Australian Research Agenda for DFD and CTN activities once established.

Not all early career researchers will be able to participate in larger trials, for example when they are based at universities without DFD researchers or in universities and health services where DFD is not a priority. A mentoring system should be created for those researchers, preferably within the CTN. To further stimulate the next generation of DFD researchers, a “National DFD 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 international researchers and related forums and an allocated keynote presentation at the next national

Clinician Participation and Training

Clinicians should be encouraged to participate in the CTN as scientific research makes a direct contribution to the advancement of the clinical treatment of people with DFD. This is especially the case for multi-centre research or prospective single-centre research. Additionally, a stronger research culture is associated with significant benefits to patients, staff and the organisation (78-80). Recognized specialised IFDS should therefore be stimulated to participate in the CTN as part of their accreditation and credentialing processes, or it could even be made an obligatory criterion for recognition.

C RESEARCH AND DEVELOPMENT

Research on DFD has many intricacies that are specific to this field, and it requires training to understand and appreciate them all (71). Some clinicians, for example, may understand the disease process, but have limited training in research. Training modules should be developed, aiming to improve the knowledge and skills for novice and early career researchers in the field of DFD research. Module content may include: critical assessment of the history and salient DFD publications; designing research trials; data capture and analysis and minimum reporting standards (71).

Cooperation

Finally, this goal is a call to all Australian DFD researchers, clinicians and patients to maximize communication and cooperation around multi-centre trials, research and funding application plans, and to share 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, DFD is historically such a small part within healthcare, that cooperation rather than competition is the only strategy for long-term survival. Thus, maximising inter-agency collaboration and funding opportunities for DFD research is essential.

POTENTIAL AREAS FOR ACTION

- Establish an "Australian DFD CTN" based on the priorities of the Australian Research Agenda for DFD
- Initiate RCTs and observational studies within the CTN
- Communicate results from Australian DFD research to clinicians, the community, industry and funding bodies to maximise output, attract more research projects and funding and influence clinical practice
- Establish a "National DFD Early Career Researcher Award"
- Establish DFD research training modules for novice researchers
- Incorporate active involvement of credentialed clinicians and accredited IFDS in the CTN as a criterion for credentialing and accreditation

POTENTIAL MEASURES OF PROGRESS

- Number of researchers and PhD students undertaking DFD research with affiliations to the Australian DFD CTN and Australian institutions
- Number and amount of funding provided to DFD research studies and projects within the Australian DFD CTN and Australian institutions
- Number of accredited IFDS participating in the Australian DFD CTN
- Number of credentialed clinicians participating in the Australian DFD CTN
- Number of patients included in studies within the Australian DFD CTN
- Number of publications, theses and conference presentations resulting from the Australian DFD CTN and Australian institutions

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C

RESEARCH AND DEVELOPMENT

9

Investments in research and development for diabetes-related foot disease should be proportionate to the national health burden caused by the disease

An enormous gap exists between the clinical costs of managing DFD and funding for research and development for this disease (12,81). While up to 33% of all costs for diabetes-related complications is spent on DFD, the proportion of diabetes research funding spent on DFD research and development is <0.2% in both the UK and US (81). In Australia, DFD research funding comes under the "not classified" group within NHMRC research funding for diabetes. It is suggested any NHMRC funding for DFD has been much less than $1 million from 2011-2015, and likely to be far below 0.2% of total diabetes research funded in Australia (82). This is strikingly different to other diabetes-related complications that cause comparable national burdens of disease to DFD (12): diabetes-related 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 (82). From this, it can be seen that Australian funding for DFD research is disproportionally low compared to other diabetes-related complications. We suggest investments in funding for DFD research and development should be proportionate to the national burden of disease it causes, and this should be done within a very short time-frame.

To close this gap, from a government agency (e.g. NHMRC) or funding agency (e.g. Diabetes Australia Research Program) perspective, a first step is to develop, endorse, acknowledge and implement a consensus "Australian Research Agenda for Diabetes-Related Foot Disease" (Goal 7). This should then be matched, in the short-term, with additional funding for priority DFD research, to reduce current funding deficits. In the longer-term, we suggest equitable funding amongst different fields of diabetes research based on the proportion of the national disease burden it causes should be the goal. The activities to close this gap from a research and clinical perspective are described under Goal 8, including the necessary developments required to formalise and stimulate an Australian DFD CTN.

POTENTIAL AREAS FOR ACTION

- Explore additional funding opportunities nationally for DFD research with relevant government, professional, industry and research agencies to increase funding to equivalent levels already provided for other diabetes-related complications with similar burdens to DFD

- Initiate or assist in the development and implementation of national (diabetes) research funding schemes that allocate funding based on the proportion of the national disease burden caused by specific diabetes-related complications

POTENTIAL MEASURES OF PROGRESS

- Number, and funding, of nationally-funded DFD research projects

- Proportion of funds for DFD research projects from the total national diabetes research funding available

- Proportion of national clinical costs expended and proportion of national research funding expended to address the national burden for different aspects of diabetes and diabetes-related complications

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CONCLUSION

This "Australian diabetes-related foot disease strategy 2018-2022" is the first step towards ending avoidable generations within a generation. This strategy was written by Diabetes Feet Australia with input from various national and state peak bodies, interdisciplinary foot disease services and individual experts from the Australian DFD community. In this strategy, we describe three priorities to be addressed for people with, or at-risk of, DFD:

Nine goals are formulated within these priorities, each with their potential areas for action and measures to keep track of their progress. We look forward to the uptake of this strategy, and monitoring the positive steps the Australian DFD community will take on the pathway towards ending avoidable amputations in a generation.

APPENDIX ONE: VERSION TRACKING

VERSION	DRAFT AUTHOR(S)	COMMENT
1.0	DFA Scientific Director	1st draft of DFA Consultation Draft (v1.0; January 2017)
1.1	DFA Co-Chairs	2nd draft following DFA Co-Chairs review (v1.1; March 2017)
1.2	DFA Steering Committee	3rd draft following DFA Steering Committee review (v1.2; April 2017)
1.3	DFA	4th draft following DFA Steering Committee consensus meeting - DFA Endorsed Draft for Consultation (v1.3; May 2017)
1.4	DFA Co-Chairs and Scientific Director	5th draft following the DFA public consultation draft feedback round with changes made to reflect the feedback (v1.4; July 2017)
1.5	DFA Steering Committee	6th draft following DFA Steering Committee review of feedback incorporation (v1.5; August 2017)
1.6	DFA	Published version of the "Australian diabetes-related foot disease strategy 2018-2022"

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