

Establishing the national top 10 priority research questions to improve diabetes-related foot health and disease: a Delphi study of Australian stakeholders

Byron M Perrin ^{1,2}, Anita Raspovic,³ Cylie M Williams,⁴ Stephen M Twigg,^{2,5,6} Jonathan Golledge ^{2,7,8}, Emma J Hamilton,^{9,10} Anna Crawford,¹¹ Carol Hargreaves,¹² Jaap J van Netten ¹³, Nytasha Purcell,² Peter A Lazzarini ^{2,14,15}

To cite: Perrin BM, Raspovic A, Williams CM, *et al*. Establishing the national top 10 priority research questions to improve diabetes-related foot health and disease: a Delphi study of Australian stakeholders. *BMJ Open Diab Res Care* 2021;**9**:e002570. doi:10.1136/bmjdr-2021-002570

► Additional supplemental material is published online only. To view, please visit the journal online (<http://dx.doi.org/10.1136/bmjdr-2021-002570>).

Received 27 August 2021
Accepted 15 October 2021



© Author(s) (or their employer(s)) 2021. Re-use permitted under CC BY-NC. No commercial re-use. See rights and permissions. Published by BMJ.

For numbered affiliations see end of article.

Correspondence to

Dr Byron M Perrin;
b.perrin@latrobe.edu.au

ABSTRACT

Introduction Diabetes-related foot disease is a large cause of the global disease burden yet receives very little research funding to address this large burden. To help address this gap, it is recommended to first identify the consensus priority research questions of relevant stakeholders, yet this has not been performed for diabetes-related foot disease. The aim of this study was to determine the national top 10 priority research questions for diabetes-related foot health and disease from relevant Australian stakeholders.

Research design and methods A modified three-round Delphi online survey design was used to seek opinions from relevant Australian stakeholders including those with diabetes or diabetes-related foot disease or their carers (consumers), health professionals, researchers and industry. Participants were recruited via multiple public invitations and invited to propose three research questions of most importance to them (Round 1), prioritize their 10 most important questions from all proposed questions (Round 2), and then rank questions in order of importance (Round 3).

Results After Round 1, a total of 226 unique questions were proposed by 210 participants (including 121 health professionals and 72 consumers). Of those participants, 95 completed Round 2 and 69 completed Round 3. The top 10 priority research questions covered a range of topics, including health economics, peripheral neuropathy, education, infection, technology, exercise, and nutrition. Consumers prioritized peripheral neuropathy and prevention-related questions. Health professionals prioritized management-related questions including Australia's First Peoples foot health, health economics and infection questions.

Conclusions These priority research questions should guide future national research agendas, funding and projects to improve diabetes-related foot disease burdens in Australia and globally. Future research should focus on consumer priority research questions to improve the burden of diabetes-related foot disease on patients and nations. Further research should also investigate reasons for different priorities between consumers and health professionals.

INTRODUCTION

Diabetes-related foot disease (DFD) causes ~2% of the global disability burden

Significance of this study

What is already known about this subject?

► National priority research questions are needed to drive high-impact healthcare research, but, to our knowledge these have not been identified for diabetes-related foot disease anywhere.

What are the new findings?

- National priority research questions for diabetes-related foot disease stakeholders are identified for the first time.
- Consumers (patients and carers) prioritized peripheral neuropathy and prevention-related questions.
- Health professionals prioritized health economic and management-related questions.
- Australia's First Peoples health was the top priority question for health professionals.

How might these results change the focus of research or clinical practice?

► These national priority research questions should guide future national research agendas, funding and projects, and help ensure that patient priorities are the focus of future research to improve the burden of diabetes-related foot disease in Australia and globally.

and ~1%–2% of all healthcare costs,^{1–5} yet receives the equivalent of <0.01% of all healthcare research funding awarded.^{6 7} Furthermore, DFD causes ~60% of the global diabetes disability burden and ~33% of all diabetes healthcare costs,^{1–5} yet receives <0.2% of all diabetes research funding awarded.^{6 7} This large gap between the comparatively high disease burden caused by DFD and the comparatively low research funding it receives to address this burden,^{5–7} has seen DFD labeled the world's 'least known major health problem'.⁷

The development of a national research agenda is one method recommended to begin to close the gap for health conditions where research funding is not commensurate with the disease burden they create.^{7–10} However, to develop such a national research agenda, it is critical to first identify the national priority research questions that relevant stakeholders consider most important to address to improve the condition's burden.^{9–11} Such national priority research questions are also becoming more widely used by research granting bodies to ensure that research funding is targeted towards the most important research priorities.^{9 12}

While global DFD bodies have published priority areas for future research according to the gaps or uncertainties in the existing international literature,^{13–18} no studies to our knowledge have investigated the priority research questions that relevant stakeholders consider important for diabetes-related foot health and disease, such as patients/carers (consumers), health professionals, researchers and industry stakeholders. Thus, the aim of this study was to determine the national top 10 priority research questions to improve diabetes-related foot health and disease according to relevant stakeholders in Australia.

RESEARCH DESIGN AND METHODS

Design

The study was designed as a three-round modified Delphi online survey¹⁹ aligning with that used to determine the top 10 national research priorities in type 2 diabetes in the UK.^{9 20} The working group leading this research included Australian researchers, health professionals and consumers in the field of DFD ('the authors') appointed by the national peak body for DFD in Australia, Diabetes Feet Australia (DFA).

Participants

Eligible participants were residents of Australia who identified as being in any one or more of the following subgroups:

- ▶ Adults with lived experience of diabetes or DFD or their carers (consumers).
- ▶ Health professionals involved in the care of people with diabetes or DFD.
- ▶ Researchers or academics involved in diabetes or DFD research.
- ▶ Industry representatives such as government agencies involved with diabetes or DFD policy or a commercial organization involved with diabetes or DFD products.

Diabetes was defined as those having been diagnosed with type 1 or type 2 diabetes mellitus. The concept of diabetes-related foot health and disease was considered important in this study as it incorporates both foot disease, as defined as infection or ulceration of the foot of a person with diabetes mellitus usually accompanied by peripheral neuropathy and/or peripheral arterial disease,²¹ and foot health, as defined as maintaining

health and well-being while preventing foot disease in those with diabetes but without foot disease.

Eligible participants checked an online consent box at the start of the online survey to provide consent to participate in the study, receive ongoing communication as part of the research, and to acknowledge the three-round design of the study. Participants were free to withdraw at any time. The authors were excluded from participating in the surveys.

Recruitment

Eligible participants were recruited via multiple invitations and advertisements for the study over a 5-week period during Round 1 in August and September 2020. DFA led all recruitment, with the institutional, social and personal networks of DFA, the Australian Diabetes Society and the authors used. A series of infographics were produced to assist with promotion of the invitations. Emails were further sent using these infographics from DFA to existing DFA email subscribers and promoted weekly on the DFA website, Facebook, Instagram and Twitter social network platforms. Invitations were also sent by email to key peak diabetes, health professional and Aboriginal and Torres Strait Islander bodies to promote the study to members and social media followers. Snowballing and word-of-mouth promotion of the study were encouraged.

Procedure

All data were collected using the online survey platform Qualtrics software (Qualtrics, Provo, Utah, USA). All rounds were open for at least 4 weeks and participants were reminded weekly to respond. Data were linked at each round through participant-provided email, which was known to only one author (NP). Only participants who completed a previous round could participate in a subsequent round. Each participant who completed Round 1 was assigned a Round 1 unique identifier and then received a personalized survey link via the participant-provided email to complete Round 2. This process was repeated for participants who successfully completed Round 2. All unique identifier data were stored against the participant profile in the Qualtrics system to link the participant data across the three survey rounds. All personalized survey links could only be completed once. No enticements or compensation were provided. There was no communication between participants as a result of the data collection method and participants agreed as part of the consenting process for their responses to each round to be retained. Feedback to participants after Round 1 and Round 2 was provided within the online survey to provide a summary of the previous round's results. The procedure for each of the three rounds is outlined below and summarized in [figure 1](#).

Round 1

After each participant provided informed consent, they self-selected the subgroup with which they most

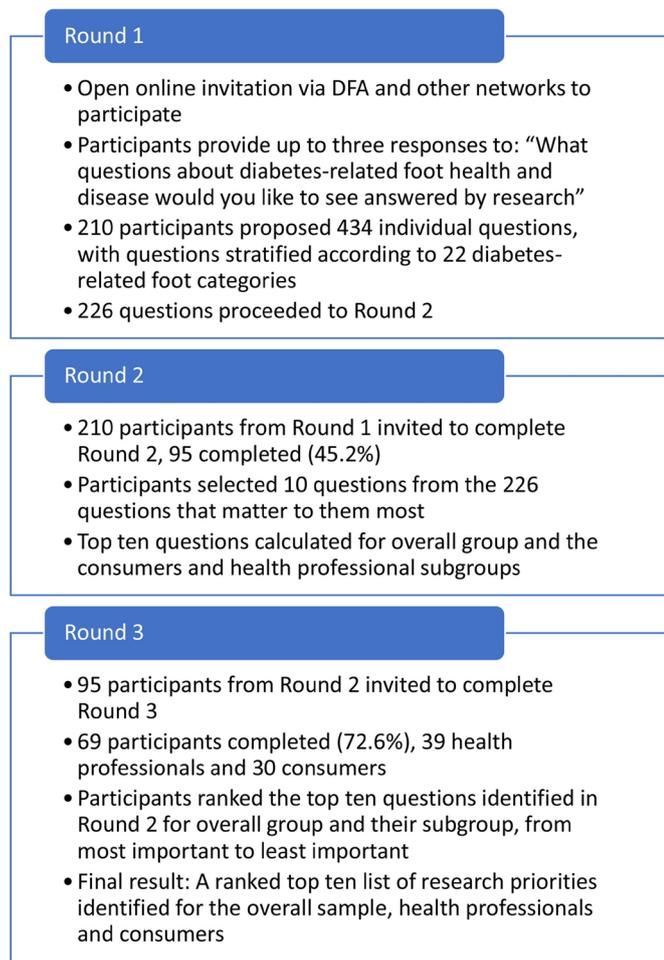


Figure 1 Participant flow and question development over the three rounds. DFA, Diabetes Feet Australia.

identified. Participants were asked to identify their gender, age grouping, state, territory, postcode and if they identified as an Aboriginal and/or Torres Strait Islander person. Based on the subgroup selected, additional information was collected using survey software logic. This meant that only the questions relevant to the selected subgroup were displayed to the particular participant, for example, health professionals were asked to provide their profession, state and working sector (public/private). All participants were asked the same core survey item questions. Participants then progressed through to the main survey item question, ‘What questions about diabetes-related foot health and disease would you most like to see answered by research?’⁹ Participants were required to provide at least one question in response to this item and had the option of providing up to a total of three questions.

Round 2

To develop Round 2 items, two authors (BMP and AR) used inductive and deductive thematic analyses to initially independently categorize all question responses from Round 1 into DFD subcategories. Categories were aligned with those contained in international guidelines^{13–18}

and it was left open for the two authors to inductively create other relevant DFD categories if they felt necessary. Any disagreements in categorization were reviewed and resolved by discussion between the two researchers to reach consensus. This involved each author providing a rationale for their choice and reaching a mutual agreement about which category was more fitting. Where there was a deadlock, a third reviewer was available to decide; however, this was not required. Responses were excluded if the question did not have an element of diabetes-related foot health or DFD in the question, was unable to be formulated as a question, or was a response asking for personal health advice.

All remaining questions were split among four pairs of authors to consider further exclusions, duplication of responses, and question editing if required. The editing principles used by the author pairs included: minimal disruption to the intent of response question, editing only to improve clarity of the original intent, use of culturally sensitive or person-centered language, and to ensure the end result was in the form of a question. Author pairs independently edited one-half of the questions in their shared list and then reviewed the alternate half. Any disagreements in suggested edits to responses or exclusion were resolved as described above. The consumer representative reviewed all final edited questions to check for readability and accessibility for consumers before finalization for Round 2. The final list of unique edited questions from Round 1 was grouped according to their DFD category and presented to participants in Round 2 in random order to minimize selection bias. Participants were informed that initially they could select as many questions as they thought important from the entire list provided, before being asked at the conclusion of Round 2 to select a maximum of 10 questions they considered to be most important from the initial selections they identified.

Round 3

The Round 3 top 10 research questions were determined by identifying the 10 questions most frequently selected by all participants and by participant subgroups after Round 2. Participants were then asked to rank the top 10 questions in order from most to least important. The questions were categorized independently by two authors (BMP and PAL) according to the UK Clinical Research Collaboration Health Research Classification System (UKCRC HRCS).²² This system classifies types of research activity according to the following codes: underpinning research; etiology; prevention of diseases and conditions; detection, screening and diagnosis; development of treatments and therapeutic interventions; evaluation of treatments and therapeutic interventions, management of diseases and conditions; and health and social care services research.²² Any disagreements were resolved as described above.

Statistical analyses

Round 1 responses were sorted within DFD categories using Microsoft Excel 2018 (Microsoft, Redmond, Washington). The frequency with which questions were prioritized (Round 2) and the scoring for final top 10 ranking (Round 3) were analyzed using SPSS V.26. The questions selected most frequently in Round 2 were included in Round 3 items, for the total sample of participants and for the subgroups of health professionals and consumers. If there was a tie for the 10th most frequent question, then all tied questions were also included. In Round 3, the final top 10 research questions identified by the total sample and the health professional and consumer subgroups were determined by inverse point scoring (eg, rank 1=10 points) for each participant response. The final results were based on the highest summed points for each question and were then ranked from 1 (highest rank) to 10 (lowest rank) for each group. X^2 analysis was undertaken to compare differences in the proportion of responses for participant characteristics from Round 1 to Round 3 with statistical significance defined as $p < 0.05$.

RESULTS

Two hundred and ten participants completed Round 1, including 121 health professionals, 72 consumers (including two carers), 9 researchers and 8 industry representatives. Of those completing Round 1, 95 (45.2%) also completed Round 2, and of those 69 (72.6%) completed Round 3. Table 1 shows participant characteristics were similar across all rounds ($p > 0.05$), except a higher proportion of females and those with lived experience of DFD completed Round 3 (both, $p < 0.05$). Figure 1 summarizes participant involvement in the three rounds with 69 (32.9% of 210) participants completing all three rounds.

Of the 69 participants completing all three rounds, 36 (52.2%) were health professionals, 29 (42%) consumers, 2 (2.9%) researchers, 1 (1.4%) carer and 1 (1.4%) industry representative. Only one participant identified as an Aboriginal or Torres Strait Islander person. Due to a low number of responses in some categories, the carer responses were consolidated with consumers, and the researchers and industry representative participants were consolidated with the health professional subgroup.

In Round 1, participants provided 434 research question responses. Of those, 208 were excluded due to 121 being duplicates and 87 not meeting the predefined criteria for a question (ie, contain an element of diabetes-related foot health or disease, be able to be formulated into a question and/or not a request for personal health advice). Thus, 226 unique questions were included after Round 1. These questions were allocated to 22 DFD subcategories (online supplemental table 1) with most questions in 'health services' (15.9%) or 'psychosocial or behavioural' (11.5%) subcategories (online supplemental table 2).

Table 1 Summary of participant characteristics (n (%))

Characteristics	Round 1	Round 2	Round 3
Total sample	210	95	69
Age (years)			
<30	9 (4.3)	4 (4.3)	3 (4.3)
30–39	44 (21.0)	22 (23.2)	14 (20.3)
40–49	36 (17.1)	14 (14.7)	9 (13.0)
50–59	58 (27.6)	28 (29.5)	20 (29.0)
60–69	36 (17.1)	18 (18.9)	15 (21.7)
>69	27 (12.9)	9 (9.5)	8 (11.6)
Female	122 (58.1)	62 (65.3)	47 (68.1)¶
Aboriginal or Torres Strait Islander person	2 (1.0)	1 (1.1)	1 (1.4)
Subgroups			
Live with, or at risk of, diabetes-related foot disease (consumer)	70 (33.3)	34 (35.8)	29 (42.0)
Carer for someone with diabetes	2 (1.0)	1 (1.1)	1 (1.4)
Health professional	121 (57.6)	52 (54.7)	36 (52.2)
Researcher/academic	9 (4.3)	5 (5.3)	2 (2.9)
Industry representative	8 (3.8)	3 (3.2)	1 (1.4)
Health professional subgroup	121	60	36
Professional discipline			
Podiatrist	62 (51.2)	31 (51.7)	20 (55.6)
Medical practitioner*	29 (24.0)	14 (23.3)	6 (16.7)
Nurse	6 (5.0)	3 (5.0)	3 (8.3)
Diabetes educator	8 (6.6)	2 (3.3)	1 (2.8)
Pedorthist	5 (4.1)	3 (5.0)	1 (2.8)
Dietitian	4 (3.3)	2 (3.3)	1 (2.8)
Other†	7 (5.8)	4 (6.7)	4 (11.1)
Healthcare sector			
Public	90 (74.4)	40 (66.7)	28 (77.8)
Private	25 (20.7)	11 (18.3)	8 (22.2)
Other‡	6 (5.0)	1 (1.7)	0 (0)
State/territory of health professional			
Victoria	29 (24.0)	13 (21.7)	5 (13.9)
New South Wales	24 (19.8)	13 (21.7)	10 (27.8)
South Australia	6 (5.0)	2 (3.3)	2 (5.6)
Queensland	28 (23.1)	12 (20.0)	8 (22.2)
Northern Territory	1 (0.8)	1 (1.7)	1 (2.8)
Australian Capital Territory	1 (0.8)	1 (1.7)	1 (2.8)
Western Australia	28 (23.1)	15 (25.0)	7 (19.4)
Tasmania	4 (3.3)	3 (5.0)	2 (5.6)
Consumer subgroup	n=72	n=35	n=30
Lived experience with diabetes			
Live with, or at risk of, diabetes-related foot disease	70 (97.2)	34 (97.1)	29 (96.7)

Continued

Table 1 Continued

Characteristics	Round 1	Round 2	Round 3
Carer for someone with diabetes	2 (2.8)	1 (2.9)	1 (3.3)
Level of diabetes-related foot disease			
Diabetes	44 (61.1)	18 (51.4)	13 (43.3)
Diabetes-related foot problems	26 (36.1)	16 (45.7)	16 (53.3)**
Missing (carer)	2 (2.8)	1 (2.9)	1 (3.3)
State/territory of consumer			
Victoria	34 (47.2)	15 (42.9)	13 (43.3)
New South Wales	10 (13.9)	5 (14.3)	4 (13.3)
South Australia	0 (0)	0 (0)	0 (0)
Queensland	10 (13.9)	5 (14.3)	4 (13.3)
Northern Territory	0 (0)	0 (0)	0 (0)
Australian Capital Territory	1 (1.3)	1 (2.9)	1 (0.3)
Western Australia	15 (20.8)	8 (22.9)	7 (23.0)
Tasmania	0 (0)	0 (0)	0 (0)
Missing	2 (2.8)	1 (2.9)	1 (0.3)
Geographical classification§			
Metropolitan	47 (65.3)	22 (62.9)	19 (63.3)
Regional	8 (11.1)	4 (11.4)	3 (10.0)
Rural	15 (20.8)	8 (22.9)	7 (23.3)
Remote	0 (0)	0 (0)	0 (0)
Missing	2 (2.8)	1 (2.9)	1 (3.3)

*Medical practitioners: Round 1 included endocrinologist (10), infectious disease specialist (7), undisclosed doctor, registrar or medical consultant (5), physician (2), vascular surgeon (2), orthopedic surgeon (1), rehabilitation physician (1), general practitioners (1); Round 3 included endocrinologist (3), infectious disease specialist (2), medical consultant (1).

†Other health professional: Round 1 included one each of exercise physiologist, health practitioner, health service manager, medical microbiologist, occupational therapist, orthotist/prosthetist and pharmacist; Round 3 included one each of health practitioner, health service manager, occupational therapist and orthotist/prosthetist.

‡Other health sector: public/private split.

§Location of consumers described according to Modified Monash Model.⁵⁰

¶P<0.05.

**P<0.01.

Tables 2–4 display the top 10 priority research questions ranked by the total sample, consumer and health professional subgroups, respectively. Table 2 shows the top 10 priority research questions of the total sample covered a diverse range of DFD topics, including health economics, peripheral neuropathy, education, infection, technology, exercise, and nutrition. Tables 3 and 4 show the consumer and health professional subgroups had descriptive differences in the prioritized research questions, with no questions shared by both consumers and health professionals in their respective top 10 lists. The consumer subgroup most frequently prioritized questions related to peripheral neuropathy, assessment/diagnosis and exercise subcategories; and within UKCRC HRCS subcategories of etiology, detection, screening and diagnosis, and evaluation of new treatments. However, health professionals prioritized questions related to Aboriginal and Torres Strait Islander health outcomes,

health economics and infection subcategories; and within UKCRC HRCS subcategories of management of diseases and health and social services.

CONCLUSIONS

To our knowledge, this is the first study to identify the priority research questions that a wide range of relevant DFD stakeholders consider important. The final national top 10 priority research questions from the Australian DFD stakeholders in this study covered a wide range of DFD and health research categories, which may be explained by differences in the priorities of consumers and health professionals. In terms of health research categories, consumers seemed to prioritize prevention-related category questions (ie, detection, screening and diagnosis, and evaluation of new treatment), whereas health professionals prioritized management-related category questions (ie, existing management of diseases, and health services research). This trend was further evident in specific DFD categories where consumers prioritized prevention-related DFD category topics (ie, neuropathy, assessment/diagnosis and exercise questions) and health professional management-related topics (ie, health economics and infection questions).

The overall top-ranked question from the total sample potentially reflects the uncertainty that stakeholders have about the health and economic benefits of multidisciplinary DFD services. Multidisciplinary DFD services have long been shown to significantly improve health outcomes^{23–25} and implementation of best practice DFD treatments has been shown to be cost-effective in managing DFD.^{26–28} However, global research has also shown that multidisciplinary DFD services are heterogeneous in composition and function,^{29–30} and implementation of best practice treatments is infrequent in real-world practice.^{31–32} Thus, perhaps it is no surprise that Australian DFD stakeholders are most interested in testing and identifying the health and economic outcomes of existing services. However, according to our findings, this is more of a priority for health professionals than consumers.

While it was expected that the subgroups of consumers and health professionals may show contrasting priorities, the degree of difference was somewhat surprising. Consumer questions focused on prevention-related topics such as etiology, detection, screening and diagnosis of DFD, with specific research on the detection and treatment of peripheral neuropathy (and neuropathic pain) prioritized. This is similar to findings by Diabetes UK, where the cause, prevention and treatment of peripheral neuropathy were prioritized by stakeholders involved with type 2 diabetes, especially consumers.⁹ These findings are perhaps understandable, as peripheral neuropathy is a major risk factor for DFD, has significant impacts on quality of life,³³ there are few effective treatments for neuropathic pain compared with other diabetes complications,³⁴ and there is a cognitive and emotional impact of being at

Table 2 Final 'top-10' research questions for the whole sample after Round 3 (n=69) comparing the rank in consumer or health professional subgroups

Overall sample rank	Consumer rank	Health professional rank	Research question	DFD category	UKCRC HRCS category	Final score
1		2	What are the health and cost benefits of providing government-funded, multidisciplinary high-risk foot services for optimal management of people with diabetes-related foot disease compared with usual care?	Economics	Health and social care services research	452
2	4		What are the most effective treatment options for pain associated with diabetes-related peripheral neuropathy?	Peripheral neuropathy	Management of diseases and conditions	431
3		4	What are the most effective educational programs to improve self-care practices to prevent foot disease in people with diabetes?	Education	Management of diseases and conditions	430
4		3	What are the long-term outcomes (wound recurrence, osteomyelitis recurrence) of osteomyelitis in people with diabetes, when treated conservatively/medically rather than surgically?	Infection	Management of diseases and conditions	413
5	1		Can established peripheral neuropathy be reversed, and if so how?	Peripheral neuropathy	Etiology	410
6		5	Is there a cost benefit of implementing a program to prevent diabetes-related foot ulcers in high-risk populations compared with the cost of treating diabetes-related foot ulcers?	Economics	Health and social care services research	381
7			What smart technology can be integrated into the care of people with diabetes-related foot ulcers that will help improve healing time?	Technology	Evaluation of treatments and therapeutic interventions	332
8	8		Is exercise beneficial in reducing the risk of diabetes-related foot complication?	Exercise	Evaluation of treatments and therapeutic interventions	327
9			What is the effectiveness of diet supplementation with micronutrients such as vitamins, protein, minerals and amino acids in improving healing rates in people with diabetes-related foot disease or ulcers?	Nutrition	Evaluation of treatments and therapeutic interventions	322
10			Is exercise safe for people with diabetes-related foot complications?	Exercise	Evaluation of treatments and therapeutic interventions	297

DFD, diabetes-related foot disease; UKCRC HRCS, UK Clinical Research Collaboration Health Research Classification System.

high risk for DFD.³⁵ Furthermore, consumers prioritized exercise-related questions. The safety, efficacy and effectiveness of exercise in relation to DFD have historically been a controversial topic, with recent data suggesting that prescribed exercise may in fact be safe in this population and may have benefits on preventing and treating peripheral neuropathy in addition to general health benefits.^{36 37} There is, however, no evidence from large randomized controlled trials that exercise prevents DFD or improves outcomes in people with DFD.^{18 38} Regardless, these priority exercise-related questions indicate that consumers would like more definitive answers on the benefit and risks of exercise on their DFD outcomes.

In contrast, health professionals prioritized research questions relating more to health services research and management of DFD. The top-ranked question for health professionals focused on improving outcomes for Aboriginal and Torres Strait Islander peoples, particularly those living in remote communities. This high prioritization by health professionals is important as the burden of DFD for Aboriginal and Torres Strait Islander people in Australia is disproportionately high compared with non-Indigenous Australians and potentially recognizes the dearth of DFD research in this important population.³⁹ Research into educational programs to improve preventative self-care practices, including offloading

Table 3 Final 'top-10' research questions for consumers after Round 3 (n=30), compared with rank from overall sample

Consumer rank	Overall sample rank	Research question	DFD category	UKCRC HRCS category	Total score
1	5	Can established peripheral neuropathy be reversed, and if so how?	Peripheral neuropathy	Etiology	186
2		What are some of the early signs a person with diabetes must be aware of that they are developing diabetes-related foot problems?	Assessment/diagnosis	Detection, screening and diagnosis	183
3		What is the best way for a person with diabetes to cope with peripheral neuropathy to prevent possible amputation?	Management	Evaluation of treatments and therapeutic interventions	183
4	2	What are the most effective treatment options for pain associated with diabetes-related peripheral neuropathy?	Peripheral neuropathy	Management of diseases and conditions	173
5		What are the most effective treatments for circulatory disease involving the foot in diabetes?	Peripheral arterial disease	Management of diseases and conditions	172
6		What is the most effective way to detect diabetes-related peripheral neuropathy?	Peripheral neuropathy	Detection, screening and diagnosis	152
7		What are the symptoms of diabetes-related foot complications?	Assessment/diagnosis	Detection, screening and diagnosis	142
8	8	Is exercise beneficial in reducing the risk of diabetes-related foot complication?	Exercise	Evaluation of treatments and therapeutic interventions	124
9		Are people with diabetes aware of how peripheral neuropathy affects their feet and how to check for it?	Education	Detection, screening and diagnosis	123
10		Is exercise beneficial in improving symptoms of painful peripheral neuropathy?	Exercise	Evaluation of treatments and therapeutic interventions	114

DFD, diabetes-related foot disease; UKCRC HRCS, UK Clinical Research Collaboration Health Research Classification System.

adherence, was also prioritized by health professionals. This may reflect the challenges people with DFD have with self-care and how important it is for health professionals to understand the psychological and behavioral mechanisms of feasible and effective self-care behavior in this population.³⁵ There were also management-related priority questions that aimed to address the uncertainties around resolving infection, which included research into the comparative effectiveness of medical versus surgical treatment of osteomyelitis and length of antibiotic duration.¹⁵ This has also been an area of much debate for some time and more definitive data are required to assist health professionals with their clinical decision-making to resolve infection.⁴⁰ Lower ranked in the health professionals' top 10 priorities was the use of standardized clinical pathways to improve consistency of care. While clinical pathways have been shown to improve care and reduce DFD-related hospitalizations in certain populations in Australia,^{41 42} current national guidelines on which they are based are now over 10 years old.⁴³ While new Australian national DFD guidelines have been launched in late 2021,⁴⁴ more research is required to identify the most effective ways to implement best practice into clinical practice.

Most previous studies investigating priority research questions in other health conditions have also used a

similar consensus building technique to this study, but with differing procedures and population focus.^{9 10 45-49} Yet, unlike our study most previous similar studies have recruited health professionals only,^{10 46 48 49} with fewer including consumers with a lived experience of the condition concerned.^{9 45 47} An important previous study from the James Lind Alliance and Diabetes UK using a priority setting partnership approach with strong consumer input identified the top 10 research priority questions for people with type 2 diabetes and also found differences between health professionals and consumers.⁹ In this Diabetes UK study, the only top diabetes research question that was related to DFD focused on the prevention and treatment of peripheral neuropathy and was given much higher priority by consumers living with diabetes than by health professionals.⁹ Prevention has also been a focus of research priority question development for general foot health, with prevention of ulceration and other diabetes-related foot problems highlighted in two of the top 10 research questions identified.⁴⁵ It is clear from our collective findings that it is important to include consumers in DFD research priority setting, as consumer research priorities cannot be simply assumed by researchers and are likely to emphasize the importance of prevention, an underfunded and under-researched area of DFD.¹⁸

Table 4 Final 'top-10' research questions for health professionals after Round 3 (n=39*), compared with rank from overall sample

Health professional rank	Overall sample rank	Research question	DFD category	UKCRC HRCS category	Total score
1		How can we improve outcomes of diabetes-related foot complications for Aboriginal and Torres Strait Islander people, particularly those living in remote communities?	Aboriginal and Torres Strait Islander health	Management of diseases and conditions	214
2	1	What are the health and cost benefits of providing government-funded, multidisciplinary high-risk foot services for optimal management of people with diabetes-related foot disease compared with usual care?	Economics	Health and social care services research	212
3	4	What are the long-term outcomes (wound recurrence, osteomyelitis recurrence) of osteomyelitis in people with diabetes, when treated conservatively/medically rather than surgically?	Infection	Management of diseases and conditions	188
4	3	What are the most effective educational programs to improve self-care practices to prevent foot disease in people with diabetes?	Education	Management of diseases and conditions	185
5	6	Is there a cost benefit of implementing a program to prevent diabetes-related foot ulcers in high-risk populations compared with the cost of treating diabetes-related foot ulcers?	Economics	Health and social care services research	177
6		What are the most effective treatment approaches to help people with diabetes adhere to using their recommended offloading devices?	Offloading	Management of diseases and conditions	167
7		How can state and federal governments be engaged to better fund the community care of people with, or at risk of, diabetes-related foot disease?	Health services	Health and social care services research	167
8		Do standardized clinical pathways improve the consistency of care for people with diabetes-related foot disease?	Translational research	Management of diseases and conditions	158
9		What is the best duration for antibiotics in the management of osteomyelitis?	Infection	Management of diseases and conditions	125
10		What are the amputation rates in different local government areas in Australia?	Epidemiology	Health and social care services research	116

*Group consolidated 36 health professionals, 2 researchers/academics and 1 industry. DFD, diabetes-related foot disease; UKCRC HRCS, UK Clinical Research Collaboration Health Research Classification System.

The strengths of this study included the wide range of stakeholders who participated, with a particularly strong consumer and health professional voice. The Delphi design used also aligned with previous frameworks^{9, 10} and was an efficient and transparent process to determine the priorities from such a diverse sample of participants. There was a drop in participation retention rate in Round 2; however, overall participation rates were generally consistent with previous studies from other disciplines and conditions^{46–49} and the characteristics of participants in each round were very similar. Participation rates may though have been affected by the large number of questions that participants were asked to select from in Round 2, the impact of the coronavirus pandemic, and

rounds occurring over the Australian traditional holiday period of December/January. Finally, there was very limited participation from Aboriginal and Torres Strait Islander people and thus the priority research questions identified in this study cannot be considered reflective of the importance to Aboriginal and Torres Strait Islander peoples. It is strongly recommended that future similar studies investigate the priority research questions of Aboriginal and Torres Strait Islander peoples using a more personal approach such as culturally appropriate, qualitative, focus group study designs.

The findings from this study should guide future national research agendas that pursue answers to these important priority research questions and in turn

contribute to the reduction of the comparatively large disease burden caused by DFD on patients and nations. In the short term though, these findings should help facilitate diabetes-focused research granting bodies to establish criteria to target researchers and research funding towards these national priority research questions as has happened for diabetes research.⁹ In the longer term, these findings should assist diabetes peak bodies in lobbying government for targeted research funding which can help to bridge the current funding gap between the high DFD burden and low DFD research funding to address this burden. Lastly, in addition to future research investigating the perspectives of Aboriginal and Torres Strait Islander peoples, it is recommended that future studies from other nations investigate to determine if the priority research question findings of this Australian study are generalizable globally to other nations.

In conclusion, the findings from this study have identified national stakeholder-agreed priority research questions for DFD for the first time. The research questions identified potentially reflect the diversity in priorities across health professionals and consumers. Importantly, though, they also emphasize the need to prioritize research into typically under-researched areas of DFD, such as the prevention, diagnosis and treatment of peripheral neuropathy, and improving Aboriginal and Torres Strait Islander people DFD outcomes. Furthermore, they confirm the more established research need for more DFD research into effectiveness of health service delivery models and therapeutic interventions for diabetes-related foot infection.

Author affiliations

- ¹La Trobe Rural Health School, La Trobe University, Bendigo, Victoria, Australia
- ²Diabetes Feet Australia, Sydney, New South Wales, Australia
- ³Discipline of Podiatry, La Trobe University, Melbourne, Victoria, Australia
- ⁴School of Primary and Allied Health Care, Monash University, Frankston, Victoria, Australia
- ⁵Faculty of Medicine and Health, The University of Sydney, Camperdown, New South Wales, Australia
- ⁶Department of Endocrinology, Royal Prince Alfred Hospital, Camperdown, New South Wales, Australia
- ⁷Queensland Research Centre for Peripheral Vascular Disease, James Cook University, Townsville, Queensland, Australia
- ⁸Department of Vascular and Endovascular Surgery, Townsville University Hospital, Townsville, Queensland, Australia
- ⁹Department of Endocrinology, Fiona Stanley Hospital, Perth, Western Australia, Australia
- ¹⁰Medical School, University of Western Australia, Perth, Western Australia, Australia
- ¹¹Diabetes Centre, High Risk Foot Service, Royal Prince Alfred Hospital, Camperdown, New South Wales, Australia
- ¹²Consumer representative, Melbourne, Victoria, Australia
- ¹³Rehabilitation Medicine, Amsterdam UMC, Amsterdam, Netherlands
- ¹⁴School of Public Health and Social Work, Queensland University of Technology, Brisbane, Queensland, Australia
- ¹⁵Allied Health Research Collaborative, The Prince Charles Hospital, Brisbane, Queensland, Australia

Acknowledgements This study was a collaborative project between Diabetes Feet Australia (a division of the Australian Diabetes Society) and La Trobe University. Diabetes Feet Australia provided in-kind secretarial support and oversight.

Contributors BMP and PAL conceived the study. BMP, AR, CMW and PAL designed the study, with all authors reviewing, contributing and approving the design. All authors contributed to the data screening, question categorization and question editing. BMP undertook the analysis, with all authors reviewing and contributing. BMP drafted the manuscript and all authors critically reviewed the manuscript and approved the final version for submission. BMP is responsible for the overall content of the manuscript as the guarantor.

Funding Podiatrists Registration Board of Victoria (novated to the Podiatry Education Trust) provided financial assistance with this project.

Competing interests None declared.

Patient consent for publication Not required.

Ethics approval The La Trobe University Human Research Ethics Committee (HEC20282) approved this research.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement All data relevant to the study are included in the article or uploaded as supplemental information.

Supplemental material This content has been supplied by the author(s). It has not been vetted by BMJ Publishing Group Limited (BMJ) and may not have been peer-reviewed. Any opinions or recommendations discussed are solely those of the author(s) and are not endorsed by BMJ. BMJ disclaims all liability and responsibility arising from any reliance placed on the content. Where the content includes any translated material, BMJ does not warrant the accuracy and reliability of the translations (including but not limited to local regulations, clinical guidelines, terminology, drug names and drug dosages), and is not responsible for any error and/or omissions arising from translation and adaptation or otherwise.

Open access This is an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: <http://creativecommons.org/licenses/by-nc/4.0/>.

ORCID iDs

- Byron M Perrin <http://orcid.org/0000-0003-4616-3510>
 Jonathan Golledge <http://orcid.org/0000-0002-5779-8848>
 Jaap J van Netten <http://orcid.org/0000-0002-6420-6046>
 Peter A Lazzarini <http://orcid.org/0000-0002-8235-7964>

REFERENCES

- 1 Lazzarini PA, Pacella RE, Armstrong DG, *et al*. Diabetes-related lower-extremity complications are a leading cause of the global burden of disability. *Diabet Med* 2018;35:1297–9.
- 2 Zhang Y, Lazzarini PA, McPhail SM, *et al*. Global disability burdens of diabetes-related lower-extremity complications in 1990 and 2016. *Diabetes Care* 2020;43:964–74.
- 3 Kerr M, Barron E, Chadwick P, *et al*. The cost of diabetic foot ulcers and amputations to the National health service in England. *Diabet Med* 2019;36:995–1002.
- 4 Lazzarini PA, Hurn SE, Kuys SS, *et al*. The silent overall burden of foot disease in a representative hospitalised population. *Int Wound J* 2017;14:716–28.
- 5 Jeffcoate WJ, Vileikyte L, Boyko EJ, *et al*. Current challenges and opportunities in the prevention and management of diabetic foot ulcers. *Diabetes Care* 2018;41:645–52.
- 6 Armstrong DG, Kanda VA, Lavery LA, *et al*. Mind the gap: disparity between research funding and costs of care for diabetic foot ulcers. *Diabetes Care* 2013;36:1815–7.
- 7 Lazzarini PA, van Netten JJ, Fitridge RA, *et al*. Pathway to ending avoidable diabetes-related amputations in Australia. *Med J Aust* 2018;209:288–90.
- 8 van Netten JJ, Lazzarini PA, Fitridge R, *et al*. *Australian diabetes-related foot disease strategy 2018–2022: the first step towards ending avoidable amputations within a generation*. Brisbane: Diabetic Foot Australia, Wound Management Innovations CRC, 2017. <https://www.diabetesfeetaustralia.org/wp-content/uploads/2020/12/Australian-diabetes-related-foot-disease-strategy-2018-2022-DFA2020.pdf>
- 9 Finer S, Robb P, Cowan K, *et al*. Setting the top 10 research priorities to improve the health of people with type 2 diabetes: a diabetes UK–James Lind alliance priority setting partnership. *Diabet Med* 2018;35:862–70.

- 10 Smith GE, Long J, Wallace T, *et al.* Identifying the research priorities of healthcare professionals in UK vascular surgery: modified Delphi approach. *BMJ Open* 2021;5. doi:10.1093/bjsoopen/zraa025. [Epub ahead of print: 05 03 2021].
- 11 Yoshida S. Approaches, tools and methods used for setting priorities in health research in the 21(st) century. *J Glob Health* 2016;6:010507–07.
- 12 Diabetes UK. Patient and public involvement (PPI) in your study: diabetes UK, 2021. Available: <https://www.diabetes.org.uk/research-for-researchers/apply-for-a-grant/help-with-involving-participants> [Accessed 17 May 2021].
- 13 Bus SA, Armstrong DG, Gooday C, *et al.* Guidelines on offloading foot ulcers in persons with diabetes (IWGDF 2019 update). *Diabetes Metab Res Rev* 2020;36(Suppl 1):e3274.
- 14 Hinchliffe RJ, Forsythe RO, Apelqvist J, *et al.* Guidelines on diagnosis, prognosis, and management of peripheral artery disease in patients with foot ulcers and diabetes (IWGDF 2019 update). *Diabetes Metab Res Rev* 2020;36(Suppl 1):e3276.
- 15 Lipsky BA, Senneville Éric, Abbas ZG, *et al.* Guidelines on the diagnosis and treatment of foot infection in persons with diabetes (IWGDF 2019 update). *Diabetes Metab Res Rev* 2020;36(Suppl 1):e3280.
- 16 Monteiro-Soares M, Russell D, Boyko EJ, *et al.* Guidelines on the classification of diabetic foot ulcers (IWGDF 2019). *Diabetes Metab Res Rev* 2020;36(Suppl 1):e3273.
- 17 Rayman G, Vas P, Dhatriya K, *et al.* Guidelines on use of interventions to enhance healing of chronic foot ulcers in diabetes (IWGDF 2019 update). *Diabetes Metab Res Rev* 2020;36(Suppl 1):e3283.
- 18 Bus SA, Lavery LA, Monteiro-Soares M, *et al.* Guidelines on the prevention of foot ulcers in persons with diabetes (IWGDF 2019 update). *Diabetes Metab Res Rev* 2020;36(Suppl 1):e3269.
- 19 Keeney S, McKenna H, Hasson F. *The Delphi technique in nursing and health research*. Chichester, UK: John Wiley & Sons, Incorporated, 2011.
- 20 Finer S, Robb P, Cowan K, *et al.* Top ten research priorities for type 2 diabetes: results from the diabetes UK-James Lind alliance priority setting partnership. *Lancet Diabetes Endocrinol* 2017;5:935–6.
- 21 van Netten JJ, Bus SA, Apelqvist J, *et al.* Definitions and criteria for diabetic foot disease. *Diabetes Metab Res Rev* 2020;36 Suppl 1:e3268.
- 22 UK Clinical Research Collaboration. UKCRC health research classification system, 2020. Available: <https://hrcsonline.net/research-activities/> [Accessed 3 Jun 2020].
- 23 Albright RH, Manohar NB, Murillo JF, *et al.* Effectiveness of multidisciplinary care teams in reducing major amputation rate in adults with diabetes: A systematic review & meta-analysis. *Diabetes Res Clin Pract* 2020;161:107996.
- 24 Blanchette V, Brousseau-Foley M, Cloutier L. Effect of contact with podiatry in a team approach context on diabetic foot ulcer and lower extremity amputation: systematic review and meta-analysis. *J Foot Ankle Res* 2020;13:15.
- 25 Meza-Torres B, Carinci F, Heiss C, *et al.* Health service organisation impact on lower extremity amputations in people with type 2 diabetes with foot ulcers: systematic review and meta-analysis. *Acta Diabetol* 2021;58:735–47.
- 26 Cheng Q, Lazzarini PA, Gibb M, *et al.* A cost-effectiveness analysis of optimal care for diabetic foot ulcers in Australia. *Int Wound J* 2017;14:616–28.
- 27 Ortegon MM, Redekop WK, Niessen LW. Cost-effectiveness of prevention and treatment of the diabetic foot: a Markov analysis. *Diabetes Care* 2004;27:901–7.
- 28 Ragnarson Tennvall G, Apelqvist J. Prevention of diabetes-related foot ulcers and amputations: a cost-utility analysis based on Markov model simulations. *Diabetologia* 2001;44:2077–87.
- 29 Vo UG, Gilfillan M, Hamilton EJ, *et al.* Availability and service provision of multidisciplinary diabetes foot units in Australia: a cross-sectional survey. *J Foot Ankle Res* 2021;14:27.
- 30 Musuuzia J, Sutherland BL, Kurter S, *et al.* A systematic review of multidisciplinary teams to reduce major amputations for patients with diabetic foot ulcers. *J Vasc Surg* 2020;71:1433–46.
- 31 Prompers L, Huijberts M, Apelqvist J, *et al.* Delivery of care to diabetic patients with foot ulcers in daily practice: results of the Eurodiale study, a prospective cohort study. *Diabet Med* 2008;25:700–7.
- 32 Zhang Y, Cramb S, McPhail SM, *et al.* Factors associated with healing of diabetes-related foot ulcers: observations from a large prospective real-world cohort. *Diabetes Care* 2021;44:e143–5.
- 33 Girach A, Julian TH, Varrassi G, *et al.* Quality of life in painful peripheral neuropathies: a systematic review. *Pain Res Manag* 2019;2019:1–9.
- 34 American Diabetes Association. 11. Microvascular Complications and Foot Care: *standards of medical care in diabetes-2021*. *Diabetes Care* 2021;44:S151–67.
- 35 Vileikyte L, Pouwer F, Gonzalez JS. Psychosocial research in the diabetic foot: are we making progress? *Diabetes Metab Res Rev* 2020;36(Suppl 1):e3257.
- 36 Kluding PM, Bareiss SK, Hastings M, *et al.* Physical training and activity in people with diabetic peripheral neuropathy: paradigm shift. *Phys Ther* 2017;97:31–43.
- 37 Zilliox LA, Russell JW. Physical activity and dietary interventions in diabetic neuropathy: a systematic review. *Clin Auton Res* 2019;29:443–55.
- 38 Lazzarini PA, Crews RT, van Netten JJ, *et al.* Measuring plantar tissue stress in people with diabetic peripheral neuropathy: a critical concept in diabetic foot management. *J Diabetes Sci Technol* 2019;13:869–80.
- 39 West M, Chuter V, Munteanu S, *et al.* Defining the gap: a systematic review of the difference in rates of diabetes-related foot complications in Aboriginal and Torres Strait Islander Australians and non-Indigenous Australians. *J Foot Ankle Res* 2017;10:48.
- 40 Commons RJ, Raby E, Athan E, *et al.* Managing diabetic foot infections: a survey of Australasian infectious diseases clinicians. *J Foot Ankle Res* 2018;11:13.
- 41 Lazzarini PA, O'Rourke SR, Russell AW, *et al.* Standardising practices improves clinical diabetic foot management: the Queensland diabetic foot innovation project, 2006–09. *Aust Health Rev* 2012;36:8–15.
- 42 Lazzarini PA, O'Rourke SR, Russell AW, *et al.* Reduced incidence of foot-related hospitalisation and amputation amongst persons with diabetes in Queensland, Australia. *PLoS One* 2015;10:e0130609.
- 43 Baker IDI Heart and Diabetes Institute, The George Institute for Global Health, Adelaide Health Technology Assessment. *National evidence-based guideline on prevention, identification and management of foot complications in diabetes (part of the guidelines on management of type 2 diabetes)*. Melbourne, Australia, 2011.
- 44 Lazzarini PA, Raspovic A, Prentice J, *et al.* *Guidelines development protocol and findings: part of the 2021 Australian evidence-based guidelines for diabetes-related foot disease*. Brisbane: Diabetes Feet Australia, Australian Diabetes Society, 2021. <https://www.diabetesfeetaustralia.org/new-guidelines/>
- 45 James Lind Alliance. Foot health top 10, 2019. Available: <https://www.jla.nihr.ac.uk/priority-setting-partnerships/foot-health/top-10-priorities.htm> [Accessed 09 Jul 2021].
- 46 Bäck-Pettersson S, Hermansson E, Sernert N, *et al.* Research priorities in nursing--a Delphi study among Swedish nurses. *J Clin Nurs* 2008;17:2221–31.
- 47 Hamlet C, Rumsey N, Williamson H, *et al.* Consensus research priorities for facial palsy: a Delphi survey of patients, carers, clinicians and researchers. *J Plast Reconstr Aesthet Surg* 2018;71:1777–84.
- 48 Tume LN, van den Hoogen A, Wielenga JM, *et al.* An electronic Delphi study to establish pediatric intensive care nursing research priorities in twenty European countries*. *Pediatr Crit Care Med* 2014;15:e206–13.
- 49 Ramelet AS, Gill F, ACCCN Paediatric Intensive Care Special Interest Group. A Delphi study on national PICU nursing research priorities in Australia and New Zealand. *Aust Crit Care* 2012;25:41–57.
- 50 Department of Health. Modified Monash model: Commonwealth government of Australia. Available: <https://www.health.gov.au/health-topics/health-workforce/health-workforce-classifications/modified-monash-model> [Accessed 15 Jun 2021].

Supplementary Table 1: Round 1 questions identified after exclusion, consolidation and editing

Diabetes-related foot health and disease category	Question
Offloading	<p>What are the most effective treatment approaches to help people with diabetes adhere to using their recommended offloading devices?</p> <p>What are the main reasons that clinicians do not provide recommended evidence-based offloading interventions to people with or at risk of diabetes-related foot ulcers?</p> <p>What are the most effective treatment options for offloading the foot in people at risk of diabetes-related foot ulceration?</p> <p>What are patient experiences of offloading?</p> <p>What is the relationship between foot muscle volume and strength with diabetes-related foot disease?</p>
Peripheral Arterial Disease	<p>What are the most accurate methods to assess circulation to the feet in diabetes?</p> <p>What are the most effective approaches to preventing circulatory disease involving the foot in diabetes?</p> <p>What are the most effective treatments for circulatory disease involving the foot in diabetes?</p> <p>How common is circulatory disease involving the foot in diabetes?</p> <p>What are the best approaches to incorporate research findings into clinical practice in the area of circulation to the foot in diabetes?</p> <p>What is the incidence of monophasic doppler waveforms in people with diabetes accessing primary health care?</p>
Peripheral Neuropathy	<p>What are the most effective treatment options for pain associated with diabetes-related peripheral neuropathy?</p> <p>What are the most effective strategies to prevent diabetes-related peripheral neuropathy?</p> <p>What is the most effective way to detect diabetes-related peripheral neuropathy?</p> <p>What pharmacological therapies are effective for the prevention of diabetes-related peripheral neuropathy?</p> <p>Can established peripheral neuropathy be reversed, and if so how?</p> <p>What is the pathogenesis of diabetes related peripheral neuropathy?</p> <p>What are the most effective treatment options for diabetes-related peripheral neuropathy?</p> <p>Can cannabis oil be effective in reducing pain associated with diabetes-related peripheral neuropathy?</p> <p>What is the effectiveness of glyceryl trinitrate and/or film dressings in reducing symptoms of peripheral neuropathic pain in people with diabetes related foot disease?</p> <p>Do motion control orthoses reduce proprioception in people with diabetes-related foot disease?</p>

Infection	<p>What are the treatment protocols for treating infection in diabetes related foot disease?</p> <p>What are the key predictors of antibiotic failure in non destructive osteomyelitis identified on MRI?</p> <p>What topical antimicrobials/antiseptics yield the greatest outcomes for infection control and healing with or without standard antibiotic use?</p> <p>What topical antimicrobials are effective for treatment of chronic wounds?</p> <p>What are the long term outcomes (wound recurrence, osteomyelitis recurrence) of osteomyelitis in people with diabetes, when treated conservatively/medically rather than surgically?</p> <p>What are the best type/s of antibiotics for osteomyelitis?</p> <p>What is the best duration for antibiotics in the management of osteomyelitis?</p> <p>Are rates of diabetes-related foot infections improving in Australia?</p> <p>What is the optimal diagnostic algorithm for osteomyelitis including residual infection after surgery?</p> <p>What is the best way to manage osteomyelitis in people with diabetes?</p> <p>What type of infection in feet can lead to limb loss in people with diabetes?</p> <p>When is the best time to commence antibiotic treatment for infection in people with diabetes-related foot disease?</p> <p>What antibiotics should be used for infection in people with diabetes-related foot disease?</p> <p>What are the readmission rates as a result of infection after amputation?</p> <p>Is there a role for proximal debrided bone and tissue samples in guiding antimicrobial therapy decisions and re-debridement?</p> <p>What are the new methods of delivering antimicrobial therapies?</p>
Wound Healing Interventions	<p>What is the role of leukocyte and platelet-rich fibrin in chronic wound healing?</p> <p>What is the most effective and cost effective wound dressing for diabetes related foot wounds?</p> <p>How often should diabetes related foot wounds be debrided?</p> <p>What wound management is easier for people who have a diabetes related wound?</p>

Charcot neuropathic Osteoarthropathy	<p>What are the best ways to treat active Charcot neuropathic osteoarthropathy?</p> <p>Which clinical parameters predict better outcomes of reconstructive foot surgery in people with Charcot neuropathic osteoarthropathy?</p> <p>Is amputation or orthotic devices more effective in treating Charcot neuropathic osteoarthropathy in terms of quality of life and cost benefit?</p> <p>How can Charcot's neuroarthropathy be diagnosed earlier to prevent deformity?</p> <p>Why does Charcot neuropathic osteoarthropathy predominantly affect people with diabetes?</p> <p>What are the potentially modifiable risk factors for Charcot neuropathic osteoarthropathy?</p> <p>What causes Charcot neuropathic osteoarthropathy in people with diabetes?</p> <p>What are the most recent evidence-based guidelines around treating Charcot neuropathic osteoarthropathy, and are they effective?</p> <p>How long should Charcot neuropathic osteoarthropathy be treated?</p> <p>Is there a way to prevent Charcot neuropathic osteoarthropathy in a person with diabetes?</p> <p>In a person with diabetes, how can the level of misdiagnosis for Charcot neuropathic osteoarthropathy and delayed referral be reduced within the community?</p> <p>What factors can halt progressive joint deformity in Charcot neuropathic osteoarthropathy?</p> <p>Is there a role for pharmacological therapies in acute Charcot neuropathic osteoarthropathy, and is there a role for combining pharmacological and surgical approaches?</p>
Amputation	<p>How can the number of diabetes related lower limb amputations required by people living in regional and remote areas be reduced?</p> <p>How can a definitive decision regarding the requirement for amputation be made earlier?</p> <p>Does amputation or conservative treatment lead to better quality of life for diabetes-related foot disease?</p> <p>What is best practice care after a transmetatarsal amputation?</p> <p>Do some species of bacterial infections more commonly result in requirement for amputation in diabetes-related foot disease?</p> <p>How often does a transmetatarsal amputation ultimately end up in below knee amputation?</p> <p>How can phantom pain after amputation be prevented?</p> <p>How can ulcer development after amputation be prevented?</p> <p>How long should antibiotics be continued after toe amputations?</p> <p>What is the percentage of people with type 1 diabetes who require amputation of toes or feet during their lifetime?</p>

Psychosocial or
behavioural

What impact does diabetes-related foot disease have on the quality of life for someone living in a rural or remote area of Australia?

What factors affect the wellbeing of clinicians providing diabetes-related foot health and disease care?

What is the influence of social determinants of health and other co morbidities on diabetes-related foot disease development, outcome and severity?

What is the role of a peer support group for people with type 1 diabetes and foot disease including those with ulceration or amputation?

What is the role of a clinical psychologist in mental health support of a person with diabetes-related foot disease as part of multidisciplinary care?

How can people with diabetes be encouraged to adhere to prescribed therapy to prevent and manage diabetes-related foot complications?

What is the impact of socioeconomic and psychosocial factors on the prevalence and incidence of diabetes-related foot ulceration and amputation?

What are the social and psychological implications for people with diabetes-related foot ulcers?

What is the best way to help people who have diabetes-related foot disease adhere to wearing appropriate footwear?

Why do some people with diabetes not look after their feet?

How do socio-economic factors impact access to offloading the diabetic foot outside of an appropriately funded high risk foot clinic?

Does providing a patient with an individualised foot first-aid box (and action plan) trigger active self care and improve foot health outcomes?

Why do people with diabetes who have access to care plans neglect to have regular foot assessments?

Does a personalised at-risk foot assessment help a person with diabetes to adhere to their foot care plan?

What lifestyle changes can a person with diabetes make to reduce the risk of developing diabetes-related foot disease?

What affect does diabetes-related foot disease have on the life of people?

How can we get a better understanding of factors that affect compliance in care for people who have diabetes-related foot disease?

What are the most effective evidence-based preventative actions people with diabetes can do to reduce their risk of developing diabetes-related foot disease?

What behavioural management strategies in people with diabetes who have foot disease are most effective in supporting compliance with treatment plans?

What is the role of psychological interventions to help people with diabetes to build their motivation, confidence and self-efficacy to proactively engage in their foot monitoring and foot care?

How can a person with diabetes form a routine for good foot health?

What are the psychological and social needs of people who have diabetes-related foot disease?

How can engagement in management plans such as offloading strategies be improved in a person who has diabetes-related foot disease?

What is the greatest concern of people who have diabetes-related foot disease?

What is the impact of regular, ongoing support from a diabetes-trained psychologist on healing of diabetes-related foot ulcers?

What is the impact on family members and carers of people who have diabetes-related foot disease?

Epidemiology	<p>How frequently do people with type 2 diabetes and elevated blood glucose under the age of 50 develop foot ulcers and does this age group regularly get foot checks?</p> <p>What percentage of people with diabetes aged 70 years and older are at risk of lower limb amputation in different states in Australia?</p> <p>Is there a difference in the rate of diabetes-related foot disease in men and women in Australia and if so why?</p> <p>What is the prevalence of diabetes-related foot disease in people with type 1 diabetes and blood glucose levels of >8% for one year?</p> <p>What percentage of people with diabetes develop foot disease, and how long do people have diabetes before they develop symptoms of foot disease?</p> <p>What percentage of people with poorly controlled diabetes do not develop foot disease?</p> <p>What is the prevalence of diabetes-related foot complications across Australia?</p> <p>What are the amputation rates in different local government areas in Australia?</p>
Education	<p>Are people with diabetes aware of how peripheral neuropathy affects their feet and how to check for it?</p> <p>What are the most effective educational programs to improve self-care practices to prevent foot disease in people with diabetes?</p> <p>What information do people want to know about their foot health when they are first diagnosed with diabetes-related foot disease?</p> <p>What information do podiatrists (and other health professionals) currently provide to people with diabetes-related foot disease about their prognosis?</p> <p>What is the most effective patient education method to increase adherence to prescribed offloading?</p> <p>What are the most effective education methods to improve knowledge about how foot complications develop in people with diabetes?</p> <p>Can the current evidence base be used to create written patient education dressing plans for people with foot ulcers to better manage their own dressings?</p> <p>What are the main reasons that people with diabetes do not receive foot health education?</p> <p>What percentage of people with different risk levels for developing diabetes-related foot disease access additional foot health education in addition to their regular podiatry appointments?</p> <p>What are the most effective education methods to help people with diabetes self-diagnose foot complications?</p> <p>Do people with diabetes understand what could happen to their feet if they don't control their diabetes?</p> <p>Does intensive, on-going foot-care education from early on after the diagnosis of diabetes impact positively on long-term foot health outcomes?</p> <p>What is the impact of a dedicated podiatrist performing foot care education sessions to people admitted to hospital with diabetes-related foot ulcers?</p> <p>What types of education on foot complications are currently provided to people with different risk levels for developing diabetes-related foot disease?</p> <p>What are the most effective education methods to prevent ulcer recurrence in people with a history of diabetes-related foot ulcers?</p> <p>Where do newly diagnosed persons with diabetes mostly access their foot health education (e.g health professionals, Diabetes Australia, social media, others)?</p> <p>Is the use of social media an appropriate method in which to provide foot health education for persons with diabetes?</p>

Health Services

What percentage of High Risk Foot Services are providing foot plantar pressure assessments to their patients?

What are the main barriers faced by rural and remote clinicians to providing diabetes-related foot disease services?

How can communication be improved between High Risk Foot Services and Podiatrists?

What are the main barriers to people with diabetes receiving foot care from a podiatrist?

What are the most efficient and effective service models to prevent diabetes-related foot disease in the community?

What are the most efficient and effective models to provide custom-made footwear to people who need them to prevent diabetes-related foot disease?

What is the best method to establish an interdisciplinary high risk foot clinic in regional areas?

Do people with or without diabetes-related foot ulcers value telehealth as a modality to manage their foot health?

Is there a disparity in the availability, quality and costs of care for people with diabetes-related foot ulcerations living in rural and regional areas compared with those in metropolitan areas of Australia?

How can foot ulcer prevention and treatment in remote primary care settings be enhanced to reduce the need to travel long distances for multidisciplinary care?

Do different state funding systems for footwear and orthotics lead to different access and outcomes for people at risk of developing diabetes-related foot ulcers?

Is diabetes-related foot disease treatment adequately funded in Australia?

Are diabetes-related foot units all funded in the same way?

How can diabetes-related foot services ensure that those people with the highest diabetes-related foot care needs are being provided with that care?

How can accessibility to vascular surgical teams be improved in rural and remote settings?

What are the main reasons why rural and remote areas have difficulty in retaining good foot health professionals including podiatrists?

To what extent are podiatrists and general practitioners capable in managing diabetes-related foot ulcers in rural and remote areas of Australia?

How can state and federal governments be engaged to better fund the community care of people with, or at risk of, diabetes-related foot disease?

Does improving access to Diabetes Educators for people with diabetes prevent foot disease?

Do people with diabetes attending private services have better foot-health outcomes than those attending public health services?

What impact does limited access to podiatrists and other health professionals in rural and remote areas have on people with, or at risk of, diabetes-related foot disease?

What level of access is available in public hospitals for surgical offloading procedures for people with, or at risk of, diabetes-related foot disease when indicated?

What are the main reasons that diabetes-related foot concerns are sometimes ignored by GPs?

What factors prevent people with diabetes visiting podiatrists or other foot specialists?

How good are General Practitioners at accurately diagnosing and referring diabetes-related foot problems?

What are the best ways for people with ongoing diabetes-related foot problems and concerns to seek the advice they need?

What are the best multi-disciplinary foot team approaches to improve access and quality of care for people with diabetes-related foot

disease in Australia and especially in regional and remote areas?

Would a register of podiatrists who are competent in managing diabetes-related foot disease improve outcomes for people with, or at risk, of diabetes-related foot disease?

What has been the level of access, and any barriers to access, to Podiatrists by High Risk Foot Clinics since the introduction of the National Association of Diabetes Centres Interdisciplinary Diabetes High Risk Foot Services (HRFS) Standards were launched 2 years ago?

How can telemedicine methods be most effectively delivered to people with diabetes-related foot complications?

Do inpatient podiatry services improve the outcomes of people in hospital with diabetes-related foot disease?

What is the level of availability and affordability of extra width and depth footwear in Australia?

What is the impact of early intervention by community health podiatry on reducing the rate of ulcerations, amputations and improving quality of life in people with diabetes?

What is the impact of having a podiatrist available in Emergency Departments to manage people presenting with diabetes-related foot disease?

What are the main barriers to people with diabetes-related foot disease from accessing ongoing care from High Risk Foot Services?

What are the optimal time periods between podiatry appointments for people with diabetes?

Mortality	What is the life expectancy of a person following an initial diabetes-related amputation? What is the life expectancy of a person following an initial diagnosis of a diabetes-related foot ulcer?
Economics	What are the health and cost benefits of providing government funded, multidisciplinary high risk foot services for optimal management of people with diabetes-related foot disease compared with usual care? Is there a cost benefit of implementing a program to prevent diabetes-related foot ulcers in high risk populations compared to the cost of treating diabetes-related foot ulcers?
Technology	Are there new technologies with proven efficacy to prevent diabetes-related foot ulcers and amputation? What modern technologies can be utilised to improve foot education for people with diabetes and prevent diabetes-related foot ulceration? What smart technology can be integrated into the care of people with diabetes-related foot ulcers that will help improve healing time? What are the roles, feasibility, health and cost benefits of foot monitoring technologies in Australia for people with diabetes with, or at risk of, diabetes-related foot disease?
Assessment/diagnosis	Should temperature of feet be taken as part of a basic diabetes assessment? What are the barriers to performing the recommended foot assessments in people with diabetes? What are the best tests to predict developing diabetes-related foot ulcers in people with diabetes? What are some of the early signs a person with diabetes must be aware of that they are developing diabetes-related foot problems? How often should people with diabetes have their feet assessed by a health professional? Is it normal for people with diabetes to have hard, cracked skin on their heels? What are the symptoms of diabetes-related foot complications? Are there predictive tools that can be used to identify people with, or at risk of, diabetes-related foot disease who don't respond to treatments? How often does biopsy help in the management of diabetes-related foot ulcers? How can plantar shear stress be reliably measured?

Management	<p>How can more randomised controlled trials be undertaken to evaluate the effectiveness of interventions to manage diabetes-related foot ulceration?</p> <p>Does surgery, directed to specific location and ulcer phenotypes improve healing rates in patients with diabetes-related foot ulcers?</p> <p>Can informal carers play an active role in the management of diabetes-related foot ulcers?</p> <p>What is the best patient-centred management plan for people living with both diabetes-related foot ulceration and Charcot Neuroarthropathy?</p> <p>What is the best way to manage deteriorating diabetes-related foot ulceration?</p> <p>What are the typical treatment alternatives for diabetes-related foot complications?</p> <p>Is there more prevalence of arthritic joints in the feet among people with diabetes compared to those without diabetes?</p> <p>What are reliable physiological characteristics of a person with diabetes to assess for appropriateness for surgery for diabetes-related foot complications and to minimise risk of complications?</p> <p>What is the best way for a person with diabetes to cope with peripheral neuropathy to prevent possible amputation?</p> <p>What are the best methods to treat diabetes-related neuropathic ulcers?</p>
Prevention	<p>How can young people with type 2 diabetes prevent the onset of complications due to diabetes such as neuropathy and retinopathy?</p> <p>What is the best way to prevent foot re-ulceration in people with diabetes?</p> <p>What is the relationship between skin temperature and the formation of diabetes-related foot ulceration?</p> <p>How can the progress of diabetes-related foot disease be slowed?</p> <p>How can diabetes-related foot disease be prevented?</p> <p>How often should a person with diabetes see a podiatrist?</p> <p>What management is required for people with newly diagnosed diabetes to prevent diabetes-related foot complications?</p> <p>What are the preferred strategies to ensure good foot health and reduce diabetes-related foot disease?</p> <p>Does regular screening of foot health prevent diabetes-related foot disease?</p> <p>Should SGLT2 inhibitors medications be used in patients with active diabetes related foot ulceration?</p> <p>Why are there more resources allocated to treatment of diabetes-related foot disease than to community awareness?</p> <p>Does podiatry treatment reduce the risk of developing diabetes-related foot disease for people with diabetes?</p>
Blood Glucose Control	<p>Does achieving blood glucose levels at target reduce the risk of developing diabetes-related foot disease?</p> <p>Does achieving blood glucose levels at target reduce the risk of recurrence of diabetes-related foot ulceration?</p> <p>Does achieving blood glucose levels at target improve diabetes-related foot infection outcomes?</p> <p>Does achieving blood glucose levels at target improve healing of a diabetes-related foot ulcer?</p>

Exercise	<p>What is the relationship between blood glucose control and diabetes-related foot disease?</p> <p>Does the use of continuous glucose monitoring to achieve blood glucose levels at target reduce the risk of diabetes-related foot disease?</p> <p>Is maintaining regular exercise more challenging for people with diabetes and peripheral neuropathy compared to a healthy population?</p> <p>Is exercise beneficial in reducing the risk of diabetes-related foot complication?</p> <p>Is exercise beneficial in the treatment of diabetes-related foot complications such as ulceration?</p> <p>Is exercise beneficial in improving symptoms of painful peripheral neuropathy</p> <p>Is exercise safe for people with diabetes-related foot complications?</p> <p>Can loss of ankle proprioception be reversed with exercise?</p>
Aboriginal and Torres Strait Islander health	<p>For Aboriginal and Torres Strait Islander people, what are the barriers to seeking help early for acute diabetes-related foot complications?</p> <p>For Aboriginal and Torres Strait Islander people, what is the relationship between depression and diabetes-related foot disease?</p> <p>How can we improve outcomes of diabetes-related foot complications for Aboriginal and Torres Strait Islander people, particularly those living in remote communities?</p> <p>What is the level of diabetes-related foot disease of Aboriginal people compared to Torres Strait Islander people?</p> <p>How can foot health outcomes be improved for Aboriginal and Torres Strait Islander people with diabetes?</p> <p>How can access to high risk foot services for Aboriginal and Torres Strait Islander people in rural and remote locations be improved?</p> <p>How can we effectively provide culturally responsive foot care education for Aboriginal and Torres Strait Islander people with diabetes or at risk of diabetes?</p>
Nutrition	<p>How do current dietary guidelines impact on blood glucose control and development of diabetes-related foot disease?</p> <p>If remission of type 2 diabetes is achieved with a carbohydrate restricted diet, does remission of diabetes related foot disease also occur?</p> <p>What is the effectiveness of diet supplementation with micronutrients such as vitamins, protein, minerals and amino acids in improving healing rates in people with diabetes-related foot disease or ulcers?</p> <p>Is a poor diet a risk factor for diabetes-related foot disease?</p> <p>Does being overweight and/or obese increase the risk of diabetes related foot disease?</p> <p>What is the most appropriate diet for people with diabetes-related foot complications to improve health-related outcomes?</p> <p>Does dietary optimisation improve diabetes related foot health?</p> <p>Does structured education by a dietitian improve healing of diabetes-related foot ulcers?</p> <p>What is the effectiveness of diet supplementation with micronutrients such as vitamins and fish oil in improving progression of peripheral neuropathy?</p> <p>What nutrients are people with a diabetes-related foot ulcer most likely to be deficient in?</p> <p>What nutrients are required for healing of diabetes-related foot ulceration?</p> <p>Do people with Charcot osteo-neuroarthropathy require the same nutrients for healing than those with a diabetes-related foot ulceration?</p>

Translational Research	What factors influence adherence to recommended treatment options for diabetes related foot disease? How can diabetes-related foot health and disease clinical guidelines be implemented into daily clinical practice? Do standardised clinical pathways improve the consistency of care for people with diabetes-related foot disease? How can health professionals and health services translate evidence-based care into practice in a sustainable and cost effective way?
------------------------	--

Supplementary Table 2: Number of questions per DFD category after Rounds 1 and 3

Diabetes-related foot health and disease category	Number (%) of questions after Round 1	Number (%) of questions after Round 3		
	Overall sample	Overall Sample	Consumers	Health professionals
Health Services	36 (15.9)			1 (10)
Psychosocial or behavioural	26 (11.5)			
Education	17 (7.5)	1 (10)	1 (10)	1 (10)
Infection	16 (7.0)	1 (10)		2 (20)
Charcot Neuro-osteoarthropathy	13 (5.8)			
Prevention	12 (5.3)			
Nutrition	12 (5.3)	1 (10)		
Peripheral neuropathy	10 (4.4)	2 (20)	3 (30)	
Amputation	10 (4.4)			
Assessment/diagnosis	10 (4.4)		2 (20)	
Management	10 (4.4)		1 (10)	
Epidemiology	8 (3.5)			1 (10)
Aboriginal and Torres Strait Islander health	7 (3.1)			1 (10)
Peripheral arterial disease	6 (2.7)		1 (10)	
Blood Glucose Management	6 (2.7)			
Exercise	6 (2.7)	2 (20)	2 (20)	
Offloading	5 (2.2)			1 (10)
Wound Healing Interventions	4 (1.8)			
Technology	4 (1.8)	1 (10)		
Translational research	4 (1.8)			1 (10)
Mortality	2 (0.9)			
Economics	2 (0.9)	2 (20)		2 (20)

Note: Ordered according to number of responses after Round 1