DIABETIC Medicine

Research priorities to prevent and treat diabetic foot ulcers—A digital James Lind Alliance Priority Setting Partnership

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Abstract

Aim: To establish outcomes of a priority setting partnership between participants with diabetes mellitus and clinicians to identify the top 10 research priorities for preventing and treating diabetic foot ulcers (DFUs).

Methods: Due to the COVID-19 pandemic, the James Lind Alliance Priority Setting Partnership process was adapted into a digital format which involved a pilot survey to identify understandable uncertainties with high relevance for participants tested by calculating the content validity index; a main survey answered by 53 participants living with diabetes and 49 clinicians; and a final digital workshop to process and prioritise the final top 10 research priorities.

Results: The content validity index was satisfactory for 20 out of 25 uncertainties followed by minor changes and one additional uncertainty. After we processed the 26 uncertainties from the main survey and seven current guidelines, a list of 28 research uncertainties remained for review and discussion in the digital workshop. The final top 10 research priorities included the organisation of diabetes care; screening of diabetes, impaired blood circulation, neuropathy, and skin properties; vascular surgical treatment; importance of self-care; help from significant others; pressure relief; and prevention of infection.

Conclusion: The top 10 research priorities for preventing and treating DFUs represent consensus areas from persons living with diabetes and clinicians to guide future research. These research priorities can justify and inform strategic allocation of research funding. The digitalisation of James Lind Alliance methodology was feasible.

KEYWORDS
diabetic foot ulcer, digital platform, James Lind Alliance, prevention, priority setting partnership

1 | INTRODUCTION

Diabetic foot ulcer (DFU) is a common and often devastating complication of diabetes mellitus, resulting in a global burden for patients and the healthcare system.[1] The prevalence of DFUs is 4%–10%,[2] and the lifetime risk of developing a foot ulcer is estimated to be 25%.[3] For the individual, a DFU represents a major health problem due to the negative impact on quality of life, primarily from reduced physical and psychosocial functioning.[4] The risk of DFU recurrence, amputation, and mortality is increased in those who suffer from a first DFU.[5] In a national population-based study of people with diabetes with a five-year follow-up, 4.1% of people with no DFU at baseline developed new ulcers compared to 34.3% with a history of DFU prior to baseline.[6] The annual healthcare cost in Sweden is SEK 3.2 billion (EUR 31.4 million) based on 25,000 foot ulcers and 750 amputations annually.[7] Therefore, preventing DFUs is extremely important and recognised as a priority by the International Working Group on the Diabetic Foot (IWGDF).[1] However, a recent review concludes that more high-quality research is needed to better inform healthcare professionals about effective preventive treatment in diabetic foot disease.[8]

Recently, there has been a shift to involve participants, their family members, and the public in designing and conducting research to ensure they are person-centred.[9] By including person's unique perspective based on their experiences from disease, conditions, and situations, research questions that more effectively can be applied in person care are proposed.[10] The James Lind Alliance (JLA)[11] was established to support priority-setting partnerships—groups with members of partcipants, their significant others, and clinicians that together equally define uncertainties of a specific disease or condition. The process offers a systematic transparency approach that brings participants and clinicians closely together for joint discussions on research priorities. This approach ensures the voices of service users are heard.[9]

The JLA guidelines have previously been used to set research priorities to improve the health of people with type 1 diabetes[12] and with type 2 diabetes.[13] However, no previous literature has focused on research priorities specifically directed towards the prevention and treatment of DFUs. The present study was conducted during the COVID-19 pandemic, where it was unethical to have physical meetings, especially if vulnerable elderly persons with diabetes were involved. Therefore, the JLA concept had to be adapted into a digital format. The aim was to establish outcomes of a priority setting partnership to identify the top 10 research priorities to prevent and treat DFUs using a digital format of the JLA concept.

Novelty Statement

What is already known?

- DFU is a devastating complication with high demands on participants and healthcare.
- Preventing DFUs is a global top priority.

What has this study found?

- The JLA process can be digitalised.
- There are top 10 research priorities for preventing and treating DFUs.
- Most important were the organisation of diabetes care and the screening of diabetes, impaired blood circulation, neuropathy, and skin properties.

What are the implications of the study?

- The top 10 research priorities match the desires from persons with diabetes and clinicians.
- The research priorities can guide future research and inform strategic allocation of research funding.

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2 | METHODS

2.1 | Setting up the partnership

A priority-setting partnership was established according to the JLA process between the Diabetes Association in southern Sweden, Malmö University, Lund University, and Skåne University Hospital. The steering committee comprised 10 individuals: two members with diabetes (one woman and one man) from the Diabetes Association in southern Sweden, four researchers in Biomedical Science (with molecular-level knowledge needed to explain different aspects of diabetes, skin xerosis and effect of topical treatment), and four clinicians (one vascular nurse specialist, two diabetes nurse specialists, and one vascular surgeon) affiliated to Malmö and Lund Universities. The first physical meeting took place 2nd March 2020, where the aim and the JLA work process were presented. After the first meeting, the steering committee met in digital conferences approximately once a month and communicated by email on a regular basis.

2.2 | Pilot survey

A pilot questionnaire with 25 uncertainties, seven additional demographic questions, and the possibility to suggest other important uncertainties was developed by the steering committee based on previous literature and their own experiences as persons living with diabetes, as clinicians, and as researchers. Together with information about the importance of person involvement and encouragement to help prioritise research areas linked to prevention and healing of DFUs, the questionnaire was administered to selected members with diabetes from the Diabetes Association in southern Sweden. They were further asked to evaluate the relevance (face validity) and to understand all aspects of the uncertainties (content validity). Content validity was evaluated on a four-point Likert scale rated from 1 (absolutely disagree) to 4 (absolutely agree). A content validity index was calculated both according to item (I-CVI) and for the scale (S-CVI). The I-CVI was based on the respondent's positive responses, and the item rating score (3 or 4 on the Likert scale) showed the proportion of agreement for the item relevance. The S-CVI average was calculated by dividing the number of items with a positive response by the number of items. The recommended content validity index for the item level is I-CVI > 0.78, and for the scale is S-CVI > 0.9.[14]

2.3 | Guidelines on prevention and management of diabetic foot ulcers

The six most updated clinical guidelines from the IWGDF focusing on the prevention and management of DFUs were identified and reviewed.[1,15–19] All the stated research uncertainties or research recommendations were gathered and discussed by the steering committee.

2.4 | Gathering uncertainties

The revised questionnaire consisted of seven demographic questions and 26 uncertainties around diabetes, prevention, and healing of DFUs, with a five-point Likert scale rated from 1 (not important at all) to 5 (very important). There was a possibility to add further uncertainties at the end of the questionnaire. The questionnaire was distributed in paper or online in May 2020 to members with diabetes of three diabetes associations in Sweden and approximately 125 clinicians (physicians, nurses, biomedical scientists, and other professionals involved in the care of persons with DFU). The Artologik web software Survey&Report licenced by Malmö University was used for the online distribution of the questionnaire. All data

Setting up the partnership
4 researchers, 4 clinicians, 2 members from the Diabetes Association

Gathering uncertainties
Pilot survey (Content validity index)
25 uncertainties
14 members from the Diabetes Association
7 Guidelines on prevention and management of diabetic foot ulcers

Interim priority setting
Main survey, 26 uncertainties
52 persons with diabetes mellitus
49 clinicians

Processing the research uncertainties
Review of research uncertainties from the survey and clinical guidelines
Steering committee agreed on a list of 28 uncertainties

Final priority setting
Digital workshop
8 persons with diabetes mellitus
3 researchers
5 clinicians

Top 10 research priorities identified

FIGURE 1 Overview of the priority-setting process for the top 10 research priorities for preventing and treating diabetic foot ulcers.

was anonymised, analysed descriptively, and exported to SPSS version 25 (IBM SPSS Inc.)

2.5 | Processing the research uncertainties

All collected research uncertainties from the survey were processed and reviewed by the steering committee (Figure 1). Unclear or out-of-scope uncertainties and

duplicates were removed at this stage. Similar uncertainties were merged to form indicative summary uncertainties ready to be included in the workshop process.

2.6 | Final priority setting digital workshop

People living with diabetes who were not previously involved in the priority-setting process were identified through an open call to members of local diabetes associations in Sweden and in different diabetes-related Facebook groups. Written invitations with information about the aim of the workshop emphasising the involvement in formulating future research questions regarding the diabetic foot and DFUs were sent out to members of these groups with assistance from the collaborators in the Diabetes Association. Additional information about the COVID-19 pandemic-adjusted digital format was given. Before the workshop, all persons who agreed to take part received an agenda and a list of the identified uncertainties, including clear instructions to rank them prior to and discuss them during the workshop.

The workshop was conducted through the digital platform Zoom in February 2021 and lasted for 3h. It was chaired by one of the steering committee members with previous experience from the JLA process. A nominal group technique was used where the uncertainties were discussed and ranked by the group to build consensus on the final top 10 priorities.[20] After a first introduction, the participants were split into two smaller groups in breakout rooms. One facilitator in each group led the discussions and took notes. During this phase, each participant contributed with their views on the uncertainties they felt most and least strongly about. After that, they started to discuss and rank the uncertainties together. In the next step, each group's rankings were presented and discussed in the reunited group, and the 15 most important uncertainties were disclosed. In the final step, the participants decided to continue working in the whole group as this was manageable. The chair shared the screen with the 15 uncertainties listed in a PowerPoint presentation slide. A consensus approach was used when the participants were focused on agreeing on a top 10 list of priorities. They were able to visually follow the mutual rankings of each uncertainty on the screen as the uncertainties switched places throughout the ranking process.

2.7 | Ethics statement

The JLA methodology has public and patient involvement in research. The persons who took part in the survey and digital workshop were not research participants. Those who had the experience of living with diabetes were taking part as experts together with clinicians on equal basis to define uncertainties about the prevention and treatment of DFUs. This project does not fall under the scope of the Swedish Ethical Review Act, and according to the Ethics Review Authority decision aid, no need for ethical approval was identified.

3 | RESULTS

The timeline and process described above and the outcomes of the priority setting partnership according to the JLA methodology are summarised in Figure 1.

3.1 | Gathering uncertainties

Fourteen members, 3 men and 11 women, from the local diabetes association in southern Sweden answered the pilot questionnaire. Seven participants were in the age group 70–79 years, and four were ≥80 years. Half of the participants had type 1 diabetes, and the other half had type 2 diabetes. Two participants chose not to evaluate the content validity. The overall S-CVI was 0.81, meaning that the respondents answered positively on 81% of the uncertainties. On the item level, the I-CVI was above the recommended 0.78 for 18 uncertainties and just below (0.75) for 3 of the 25 uncertainties (Table 1). Of the uncertainties with low I-CVI (poor understanding of the concept), endovascular treatment was removed, leaving vascular surgical treatment as a general term for all vascular treatments. Further, the uncertainties about skin sensitivity and the importance of the skin were merged and rephrased. Based on suggestions from the participants, two uncertainties about the importance of nerve function were added. One uncertainty concerning the treatment of DFUs with stem cells expressed in clinical practice guidelines was added.

3.2 | Interim priority setting

A total of 53 persons (26 men and 27 women) with experience of living with diabetes responded to the revised questionnaire. The participants' ages were 30–39 years ($n = 2$), 40–49 years ($n = 12$), 50–59 years ($n = 14$), 60–69 years ($n = 12$), 70–79 years ($n = 11$), and ≥80 years ($n = 2$). Of the participants, 34 had type 1 diabetes, 17 had type 2 diabetes, one reported another type of diabetes, and one reported not having diabetes. Five of the participants had previous experiences of DFU, and two had undergone vascular surgical treatment and amputation.

TABLE 1 The content validity index of the pilot survey of 25 uncertainties for preventing and treating diabetic foot ulcers

Uncertainty	I-CVI (items rated 3 or 4) $n = 12$
1. Identifying causes of diabetes	0.92
2. Preventing onset of diabetes	1.0
3. Screening to detect diabetes	0.85
4. Self-care to prevent DFU	0.92
5. The importance of significant others in preventing DFU	0.61
6. Heredity and DFU	0.85
7. Preventing DFU with the help of relief (different types of shoes, insoles, or similar)	0.85
8. Patient education and information about DFU	0.85
9. DFU and the impact on quality of life	0.85
10. DFU and the impact on sex life	0.46
11. Preventing DFU with the help of cream or ointment	0.77
12. Grading of the skin's sensitivity to prevent DFU	0.58
13. The importance of the skin for the development of DFU	0.77
14. The importance of lifestyle (e.g., smoking, diet, alcohol, and physical activity) for onset of DFU	0.77
15. The importance of blood circulation for the development of DFU	0.92
16. Screening to detect impaired blood circulation in the foot	0.85
17. Methods for detecting DFU	0.77
18. Factors affecting the healing of DFU	0.85
19. Vascular surgical treatment of DFU	0.77
20. Endovascular treatment of DFU	0.31
21. Pharmacological treatment of DFU	0.84
22. Wound care for DFU	0.92
23. Treating infection in DFU	0.92
24. Amputation due to DFU	0.69
25. Improved care of people with DFU	1.0

Abbreviation: DFU, diabetic foot ulcer.

Overall, 49 clinicians (26 men and 23 women) responded to the questionnaire. The caregivers were aged 50–59 years ($n = 24$), 30–39 years ($n = 10$), 40–49 years ($n = 8$), 60–69 years ($n = 6$), and 70–79 years ($n = 1$). Their professional backgrounds were physician ($n = 31$), registered nurse ($n = 7$), biomedical scientist ($n = 2$), and other ($n = 9$).

Persons with diabetes ranked 'Preventing onset of diabetes' as highest, and clinicians ranked this as the second most important uncertainty. Clinicians ranked 'Factors affecting healing of diabetic foot ulcers' as highest, whereas persons with diabetes ranked it in eighth place. The top 10 most important uncertainties among both persons with diabetes and clinicians are shown in Table 2.

From the respondents' suggestions, the following additional uncertainties were gathered: 'The significance of impaired renal function when having DFU', 'Patient participation and collaboration with patient associations', and 'Effects of unstable blood sugar on DFU'. The uncertainty concerning 'DFU and the impact on sex life' was removed,

and the uncertainty 'Improved care of people with DFU' was rephrased into a broader concept: 'Organisation of diabetes care'.

3.3 | Final priority setting

Twelve persons had registered an interest to take part in the final digital workshop. One person withdrew participation, two persons did not turn up, and one had technical problems and could not connect to the workshop, leaving eight persons with diabetes (6 men and 2 women, aged > 60 years) taking part in the workshop. In addition, three researchers in Biomedical Science and five clinicians (three registered nurses, one vascular surgeon and one podiatrist) participated. The identified 28 research uncertainties were discussed and ranked during the workshop. After the first ranking in small groups and discussions in the whole group, the participants reached a consensus on the top 10 research

TABLE 2 Top 10 research uncertainties for preventing and treating diabetic foot ulcer from the main survey

Uncertainty	Rank	Percentage of ranking as very important[a]	Participants
Preventing onset of diabetes	1	90.5	Persons with diabetes $n = 53$
Identifying causes to diabetes	2	84.9	
Screening to detect impaired blood circulation	3	81.1	
The importance of nerve function for onset and healing of DFU	4	79.2	
The importance of blood circulation for the development of DFU	4	79.2	
Screening to detect neuropathy in the foot	4	79.2	
Treating infection in DFU	4	79.2	
Improved care of people with DFU	5	77.3	
Screening to detect diabetes	6	71.7	
Self-care to prevent DFU	6	71.7	
Methods for detecting and classifying DFU	6	71.7	
Factors affecting healing of DFU	6	71.7	
Factors affecting healing of DFU	1	81.6	Clinicians $n = 49$
Preventing onset of DM	2	75.5	
Vascular surgical treatment of DFU	2	75.5	
The importance of blood circulation for the development of DFU	3	71.4	
Treating infection in DFU	4	65.3	
Identifying causes to diabetes	5	63.2	
Pharmacological treatment of DFU	5	63.2	
Local wound treatment for DFU	5	63.2	
Improved care of people with DFU	6	61.2	
Screening to detect impaired blood circulation	6	62.2	

Abbreviation: DFU, diabetic foot ulcer.

[a]Percentage of highest-ranking items rated 5 on a five-point Likert-type scale.

TABLE 3 Final top 10 research uncertainties for preventing and treating diabetic foot ulcers

Rankings	Uncertainties
1	Organisation of diabetes care
2	Screening to detect diabetes
3	Screening to detect impaired blood circulation in the foot
4	Screening to detect neuropathy in the foot
5	Screening/grading skin's properties at risk for developing and
6	healing a DFU
7	Vascular surgical treatment of DFU
8	Self-care to prevent DFU
9	The importance of significant others in preventing DFU
10	Preventing DFU with the help of relief (shoes, insoles, or similar). Treating infection in DFU

Abbreviation: DFU, diabetic foot ulcer.

priorities (Table 3). All participants agreed that the uncertainty 'Preventing onset of diabetes' was too general for the specific topic of interest and thereby removed. 'The importance of nerve function for onset and healing of DFU' was merged with 'Screening to detect neuropathy in the foot'. The highest ranking was assigned to 'Organisation of diabetes care', and the participants concluded that this could ensure equal care for all persons with diabetes, independent of place of residence and socioeconomic conditions. Equal care included increased patient participation and collaboration with the Diabetes Associations. 'Screening to detect diabetes,

impaired blood circulation, neuropathy, and skin properties in the foot' to prevent DFUs was ranked as number two, three, four, and five, respectively.

4 | DISCUSSION

This priority-setting partnership was performed during the COVID-19 pandemic. To proceed in a safe and secure manner, we needed to adapt the JLA concept into a digital format. Despite shortcomings from not being able to meet face-to-face, the results show that it was possible to work according to the JLA process in a digital form as well. Persons with diabetes, researchers, and clinicians were actively involved in this process, and together they identified the top 10 research priorities for preventing and treating DFUs. This is an important contribution and complements the previous published research priorities for type 1 and type 2 diabetes.[12,13]

The organisation of diabetes care was ranked as the number one research priority for preventing and treating DFUs. The arguments for this were a need for a more equal diabetes care and the lack of evidence for how to organise cost-effective and high-quality care specifically directed to prevent DFUs. Recent systematic reviews conclude that specific healthcare arrangements, including care pathways, multidisciplinary teams, and combined interventions, reduce the amputation rate for persons with DFU.[21,22] However, the outcome of healthcare arrangements to prevent DFUs are not so well investigated. Moreover, recent research shows a strong association between a history of DFU and lower amputation-free survival rate.[6] Therefore, research with focus on the organisation of diabetes care to prevent DFUs is important to reduce mortality and the number of amputations in the future.

Setting up screening programs to detect diabetes was the number two research priority. Screening for type 2 diabetes has previously been evaluated, and The US Preventive Task Force has concluded that screening for prediabetes and type 2 diabetes in adults aged 35–70 years with overweight or obesity is recommended according to available evidence. Further, persons with prediabetes should be offered preventive interventions.[23] However, screening to identify persons at risk for type 1 diabetes is controversial since it typically targets children, and currently, there is no way to prevent the disease.[24] Even though screening for diabetes indirectly prevents the development of a DFU, until more effective preventive treatments exists, many people will continue to suffer from diabetes and, consequently, DFUs.

Screening for impaired blood circulation and neuropathy in the foot were ranked as the third and fourth priorities and stressed as vital in the prevention of DFUs and detection of the foot at risk. Further, screening or grading of the skin's properties at risk for developing and healing DFUs was number five. According to the IWGDF guidelines,[1] a person with diabetes with very low risk of foot ulceration should be examined annually for signs or symptoms of loss of protective sensation and peripheral arterial disease. However, there are no simple markers for early detection of diabetic neuropathy in routine clinical practise, and the tests tend to diagnose neuropathy when it is already established.[25] The Ankle Brachial Pressure Index is the gold standard test for peripheral arterial circulation, but for persons with diabetes, toe pressure is recommended with a 63% sensitivity and a 97% specificity in detecting haemodynamically significant peripheral arterial disease.[26] Further, there is some evidence that skin hydration in the feet of patients with diabetes is influenced by microcirculation and not by peripheral nerve function.[27] This suggests that further research regarding new non-invasive, easy-to-use diagnostic measurements to detect impaired blood circulation, neuropathy, and skin properties associated with diabetes that can be used in the primary health care is still needed.

The uncertainty about endovascular treatment of DFU was removed from the priority uncertainty list since the persons with diabetes in the JLA process had vague perceptions of endovascular therapy and did not find this statement to be understandable and relevant, reflected by a very low I-CVI. However, multidisciplinary assessment and vascular evaluation have an undisputed place in the management of DFUs, and vascular surgery was ranked as number six. When chronic limb-threatening ischaemia and foot ulcer in persons with diabetes is present, revascularisation by surgical bypass or endovascular therapy should be attempted within 2 weeks from first evaluation by a specialist in order to have the same limb salvage rate as those without diabetes and foot ulcer.[28] The role of surgical bypass compared to endovascular therapy to prevent DFU in persons with diabetes who suffer from lower extremity arterial disease with rest pain is still unclear.[29]

Self-care and the importance of involving significant others in the prevention of DFUs were ranked as seven and eight, respectively. According to existing guidelines and systematic reviews, self-care is important for preventing DFUs.[1,7,18] Adherence to foot self-care may reduce the risk for developing a DFU; however, the quality of evidence is low.[8] One randomised controlled trial suggests that creams containing emollients reduce foot xerosis and fissures, precursors of DFU, in persons with diabetes.[30] Structural education about proper foot care directed to persons with diabetes and their significant others is important in the prevention of DFU.[1] The education should consider cultural aspects, health literacy, and personal

conditions. However, studies evaluating educational interventions are few, providing a low level of evidence.[27] This implies that experimental controlled studies focusing on what makes self-care management successful are needed. Moreover, research evaluating educational interventions to prevent DFUs involving both persons with diabetes and their significant others is warranted.

4.1 | Limitations

One limitation of this priority-setting partnership was perhaps the need to digitalise the whole process. According to the JLA guidebook, the workshop should be held in person, but the ability to take part via internet needs to be considered on a case-by-case basis.[11] However, improved meeting platforms have increased the possibilities for interaction and group discussions. In this study, the use of Zoom worked relatively well. In fact, the use of a PowerPoint slide displaying the ranking position of each research uncertainty on the screen was perceived as facilitating the ranking process in a transparent way. Four persons with diabetes cancelled their participation in the digital workshop, which might have decreased the influence of patient representativeness. However, persons with diabetes and researchers/clinicians were evenly balanced. Furthermore, few participants had their own experiences of DFU, which may have influenced the ranking process. Yet, most of the participants were active in the Swedish Diabetes Association, and had knowledge about current and important issues related to diabetes. The list of uncertainties was at the planning stage aimed mainly for primary prevention of DFU but during the partnership process a few issues about treatment uncertainties remained highly important. In a nation-wide study on people with type 1 and type 2 diabetes, 94.4% had no history of DFU at baseline,[6] justifying our focus on primary prevention, and not prevention of recurrence of DFU. The rankings of research uncertainties might have been different if this JLA priority setting partnership exclusively were about people with a history of DFU with, above all, increased risk of death.[31] More attention would probably have been paid to uncertainties to reduce modifiable cardiovascular risk factors such as smoking, diet, obesity and physical activity, and medical therapy. During the workshop, the participants suggested merging some of the initial uncertainties, which may have resulted in uncertainties that were too broad and non-specific.[11] Nevertheless, the current priority setting partnership process provided an actual list of research priorities to address in future research aimed at preventing and treating DFUs. However, the top 10 list of research priorities may to some extent reflect a Swedish context and, therefore, not entirely appropriate to other countries.

5 | CONCLUSION

The top 10 research priorities for preventing and treating DFUs represent consensus areas from persons living with diabetes and clinicians that can guide future research. These research priorities can justify and inform strategic allocation of research funding. Moreover, the digitalisation of James Lind Alliance methodology was feasible.

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