Assessment of Need for a Fit-for-Purpose Patient-Reported Outcome (PRO) Measure for Diabetic Foot Ulcer (DFU)

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INTRODUCTION

A Core Outcome Set for assessing interventions for DFU was developed in 2024, and among the final 8 core outcomes for evaluation of effectiveness of a DFU intervention is health-related quality of life (QoL).[1]

Core Outcome Set for Studies Assessing Interventions for Diabetes-Related Foot Ulceration[1]	
1. Wound Healing	2. Time to Healing
3. New/Recurrent Ulceration	4. Infection
5. Above the Ankle Amputation	6. Below the Ankle Amputation
7. Health-Related Quality of Life	8. Mortality

PROs and assessments of QoL are known to be underutilized in DFU studies.[2,3] A systematic literature review conducted in **2022** found **no fully suitable PRO** for assessment of QoL in patients with diabetic foot ulcer.[4]

Category A: **PROs whose content validity had sufficient evidence, and at least a low quality of evidence for a sufficient internal consistency of its scores** *(recommended for use)*[4]	
None	
Category B: **PROs with high-quality evidence for an insufficient measurement property** *(unrecommended for use)*	
1. Diabetic Foot Ulcer Scale (DFS)	2. DFS-Short Form (DFS-SF)
Category C: **PROs categorized not in A or B** *(recommended for use until further evidence is provided)*	
1. American Orthopaedic Foot and Ankle Society Diabetic Foot Questionnaire (AOFAS-DFQ)	2. Cardiff Wound Impact Schedule/Scale (CWIS)
3. Health-Related Quality of Life Questionnaire in Diabetic Foot (HRQLQDFU)	4. Neuropathy- and Foot Ulcer-Specific Quality of Life (NeuroQOL)
5. Norfolk Quality of Life-Diabetic Neuropathy (Norfolk QoL-DN)	6. Quality of life instrument
7. Wound-Quality of Life (Wound-QoL)	8. Wound-QoL revised version

This study sought to **review newly generated evidence** since the cutoff date of that 2022 review to provide a recommendation on which PROs, if any, are fit-for-purpose for evidence generation of improvement in QoL for DFU interventions for patients in the United States (US).

METHODS

A **targeted literature review** was conducted using PubMed, ChatGPT, and Google to capture peer-reviewed journal articles as well as grey literature (e.g. publications from FDA) on evidence supporting **new or existing** English language **PROs** assessing QoL in **DFU patients** in the **US** published from February 1, 2022 to December 18, 2025.

RESULTS

New evidence on the **10 PROs** cited in the Romero-Collado et al. 2022 systematic review were **only in non-US patients**.[5-7]

Globally**, two new PROs** were developed, DiaFootQ and WOUND-Q.[8,9]

DiaFootQ did not include any US patients in its published studies and therefore was eliminated from consideration as being fit-for-purpose for evaluating improvement in QoL in response to DFU interventions in US patients.[8]

WOUND-Q was developed and validated with an international sample of patients, including US patients, of a variety of chronic wound types, including DFU.[10] Validation studies were recruited through an online sampling provider and DFU **diagnosis was not confirmed**.[11] Although WOUND-Q was qualified by the US Food and Drug Administration (FDA) as a **Medical Device Development Tool** (MDDT) in 2024, it was **not qualified for use in hypothesis testing**.[9] Additionally, WOUND-Q was developed and validated among patients with a chronic wound that had been **unhealed for at least 3 months**.[10,11] This makes it not applicable to most DFU studies, as even advanced wound therapies typically seek approval for indicated use **beginning at 4 weeks**. Finally, WOUND-Q studies were completed only in a **minority of US** patients (21.1%-26.4%), and only in a **minority of DFU** patients (8.8%-17.2%), without disaggregation by country or wound type to enable analysis of US DFU patients.[11] Overall, **limitations exist** for use of WOUND-Q in studies of interventions in DFU in the US.

DISCUSSION

A validated PRO to measure change in QoL in response to therapeutic interventions and outcomes to such interventions for DFU is **necessary** in the US for both **regulatory and market access** purposes. **Existing PROs should be further studied** to validate their use in assessing improvement in QoL for US patients with any stage of DFU in response to any type of intervention, **or a new PRO should be developed** and validated to be fit-for-purpose for this use case. Studies to develop and validate any existing or new measures should be conducted with **US DFU patients**, or at least disaggregate the data of US DFU patients, and should strive for a **diverse sample** reflective of the US DFU population, especially of those typically underrepresented in research, including Black, Hispanic, and Native American individuals. Studies should also include a **variety of stages of DFU**, clinically **confirm diagnosis** of participants to increase accuracy of findings, and enroll patients being seen at a **variety of sites of care** to reflect the diversity of DFU treatment settings in the US, including the growth of mobile wound care. Finally, **patient usability** of the measure should be further studied and reported.

REFERENCES

1. Staniszewska A, Game F, Nixon J, et al. Development of a Core Outcome Set for Studies Assessing Interventions for Diabetes-Related Foot Ulceration. *Diabetes Care*. 2024;47(11):1958-1968. doi:10.2337/DC24-1112
2. Findings - Skin Substitutes for Treating Chronic Wounds - NCBI Bookshelf. Accessed December 18, 2025. https://www.ncbi.nlm.nih.gov/books/NBK554222/#ch4.s4
3. Vecin NM, Kirsner RS. Skin substitutes as treatment for chronic wounds: current and future directions. *Front Med (Lausanne)*. 2023;10:1154567. doi:10.3389/FMED.2023.1154567
4. Romero-Collado À, Hernández-Martínez-Esparza E, Zabaleta-del-Olmo E, Urpí-Fernández AM, Santesmases-Masana R. Patient-Reported Outcome Measures of Quality of Life in People Affected by Diabetic Foot: A Psychometric Systematic Review. *Value in Health*. 2022;25(9):1602-1618. doi:10.1016/j.jval.2022.04.1737
5. Ferreira G, Pedras S, Louro A, Carvalho A, Pereira MG. Portuguese validation of the foot health status Questionnaire in patients with diabetic foot disease. Disabil Rehabil. 2025;47(9):2426-2435. doi:10.1080/09638288.2024.2392038
6. Janke TM, Hester B, Jahn J, et al. Content validation of the Wound-QoL questionnaire measuring quality of life in chronic wounds – a qualitative study in patients with leg ulcers and diabetic foot ulcers. Journal of Patient-Reported Outcomes 2025 9:1. 2025;9(1):124-. doi:10.1186/S41687-025-00935-9
7. Ma L, Ma W, Lin S, Li Y, Ran X. Adaptation and Validation of the Diabetic Foot Ulcer Scale-Short Form Scale for Chinese Diabetic Foot Ulcers Individuals. Int J Environ Res Public Health. 2022;19(21). doi:10.3390/IJERPH192114568
8. Ruiz-Muñoz M, Fernández-Torres R, Formosa C, et al. Development and validation of a new questionnaire for the assessment of patients with diabetic foot disease: The Diabetic Foot Questionnaire (DiaFootQ). *Prim Care Diabetes*. 2024;18(5):525-532. doi:10.1016/J.PCD.2024.07.002
9. FDA. MDDT Summary of Evidence and Basis of Qualification For WOUND-Q. doi:10.1111/iwj.13549
10. Klassen AF, W G van Haren EL, van Alphen TC, et al. International study to develop the WOUND-Q patient-reported outcome measure for all types of chronic wounds. *Int Wound J*. 2021;18:487-509. doi:10.1111/iwj.13549
11. Simonsen NV, Klassen AF, Rae C, et al. Further psychometric validation and test-retest reproducibility of the WOUND-Q. Published online 2023. doi:10.1111/iwj.14354

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