MDDT Summary of Evidence and Basis of Qualification For WOUND-Q

Background

MDDT Name: WOUND-Q

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Tool Description

The MDDT-qualified WOUND-Q scales are a set of seven Patient-Reported Outcome Measures (PROMs) that can be used to measure outcomes important to people with nonhealing chronic wounds (lasting three months or longer) in any anatomic location. The qualified scales are written in English and measure domains of wound characteristics and health-related quality of life. Each of these qualified 7 scales is described as below:

Wound Characteristics

1. Assessment – 11 item scale that measures how concerned someone is by their wound (e.g., pain, size, depth, holes, smell, drainage).
2. Drainage – 8 item scale that measures how bothered someone is by drainage from their wound.
3. Smell – 8 item scale that measures how bothered someone is by odor from their wound.

Health-Related Quality of Life (H-R QoL)

4. Life impact – 8 item scale that measures how much someone's wound has affected their quality of life.
5. Psychological – 10 item scale that measures how often someone's wound has affected their psychological function.
6. Sleep – 5 item scale that measures how often someone's wound has affected their sleep.
7. Social – 5 item scale that measures the impact of someone's wound on their social life.

Summed scores on each scale are transformed into scores that range from 0 to 100 using the respective scoring table for each scale. Higher scores indicate a better outcome for each scale.

Qualified Context of Use

Adult participants (22 years of age and older) in clinical studies or trials can complete paper or electronic versions of the qualified scales to self-report on different aspects of their wound characteristics and/or health-related quality of life affected by a nonhealing wound in any anatomic location. Medical device companies and sponsor-investigators may use the qualified scales separately as exploratory endpoints or secondary endpoints for descriptive reporting in feasibility, pivotal, and post-approval studies to generate hypotheses or uncover findings for future studies. The scales may also be used to characterize the study population at baseline and to characterize changes from baseline descriptively when that is relevant to the study evaluation, however the scales do not assess if there is a clinically meaningful change from baseline. The qualified WOUND-Q scales in this MDDT do not assess for safety or adverse events. This MDDT pertains only to the WOUND-Q English version. Language versions other than English for the WOUND-Q scales are not within the scope under the qualified Context of Use. Any changes to the qualified scales (e.g., revisions on the questionnaires such as modifying response options or questions themselves), the use of the scales (e.g., combining separate scales as an endpoint, using a subset of the questions from an individual scale, using different scoring rules), and the use of the scales for hypothesis testing are not within the scope under the qualified Context of Use.

Summary of Evidence to Support Qualification

The WOUND-Q scales were developed using a mixed methods multi-phased approach [1]. The WOUND-Q developers submitted published literature, qualitative research and testing, and quantitative testing to support the qualification of the MDDT for the qualified context of use.

Concept elicitation interviews were conducted with 60 patients with nonhealing chronic wounds recruited from wound care clinics in Canada, USA, Denmark and The Netherlands. Analysis led to development of a conceptual framework that covered four top-level domains: wound characteristics; H-R QoL; experience of care, and treatment [2]. A set of separate scales was developed from the coded material using words and phrases of patients. Cognitive debriefing interviews were conducted with patients to assess whether the scales were comprehensible, comprehensive, and relevant. An international sample of clinical experts also provided input on the scales. The field test study was used to recruit a sample of 881 international patients with a broad range of nonhealing wounds who provided 1020 assessments. Psychometric analysis of the data provided evidence of reliability and validity for the WOUND-Q scales for the international sample [4]. A further validation study was conducted using an international online sample of 421 people with 11 types of chronic wounds from 22 countries [5]. Psychometric analysis provided further evidence of reliability and validity of the WOUND-Q scales for the international sample. A test-retest reproducibility study was performed seven days after the online survey on a subset of respondents, providing evidence of the reproducibility of WOUND-Q scores [5]. The online sample was invited to complete the WOUND-Q four months after the initial assessment. A total of 320 completed the follow-up survey. Pre-defined hypotheses were tested and 75% of these were not rejected, providing evidence for responsiveness for the international sample [6]. Additionally, the WOUND-Q

developers submitted validity evidence for the US patients with nonhealing chronic wounds using the data from the field test.

The scientific evidence provided in the qualification package and the additional data from the US sample demonstrated general evidence of content validity, reliability, and construct validity through the development and testing of this tool for it to be used in the qualified context of use.

Discussion of the Evidence Strength to Support Qualification

The seven WOUND-Q scales have sufficient supportive evidence for use as a secondary endpoint or exploratory endpoint in clinical studies/trials as specified in the qualified context of use. The WOUND-Q developers submitted multiple documents and sources of evidence alongside peer-reviewed publications that outlined the steps taken to develop and validate the WOUND-Q scales seeking MDDT qualification. The qualitative evidence provides support for scale content validity. The quantitative evidence shows general support for the refinement of the scales and their validation across the international sample and the US sample. The updated study in 2022 provided further evidence of reliability and validity as well as responsiveness based on the internationally recruited participants online.

A potential limitation of the scales is that the validity of these scales for devices or patient populations that have not been studied is not known, especially if the effect of the proposed device or device-based procedure could reasonably be thought to differ from the demographic and clinical/self-reported sample used to develop and validate the qualified scales. Sponsors should engage with FDA to determine if the MDDT is being used within the qualified context of use to support their proposed regulatory questions of interest.

See Table 1 in the following publication for sample characteristics of the qualitative concept elicitation study (Phase 1) and of the field test (Phase 2):

Klassen AF, van Haren ELWG, van Alphen TC, Cano S, Cross KM, van Dishoeck A, Fan KL, Hoogbergen MM, Orgill D, Poulsen L, Sørensen JA, Squitieri L, Tsangaris E, Vasilic D, Pusic AL. International Study to Develop the WOUND-Q Patient-Reported Outcome Measure for all Types of Chronic Wounds. Int Wound J. 2021; 1-23. doi.org/10.1111/iwj.13549.

The quantitative evidence relied on to qualify this MDDT was US data (excluding outside of US data) from the field test.

Advantages and Limitations of using the MDDT

Assessment of Advantages of Using this MDDT:

- Developed for use across any type of nonhealing wound on any anatomic location.
- Developed using a modern psychometric approach (i.e., Rasch Measurement Theory) to provide interval level measurement.
- Developed with a modular design to permit researchers to choose a subset of scales, which minimizes respondent burden, maximizes targeting, and allows for more flexible trial/study design.

Assessment of Limitations of the WOUND-Q are as follows:

1) Does not measure all important outcomes in chronic wounds from the patient perspective.
2) At the time of qualification, it is relatively new so there are few published studies to date in the literature.
3) Developed in a population that may not reflect all patients with nonhealing wounds.
4) More evidence is needed to determine scores' reproducibility over time (including test-retest reliability) and responsiveness for US patients.
5) Larger US sample sizes are needed to evaluate bias between subgroups on items.
6) Information at baseline for WOUND-Q is also needed to understand the relevance of the respective scale before treatment so that change from baseline and post-intervention outcomes can be properly interpreted.

Conclusions

The submitted qualification materials, including published studies, support the validity and reliability of the qualified WOUND-Q within the specific context of use.

References

1. Klassen AF, Cross K, Gibbons C, Hoogbergen MM, Longmire N, Poulsen L, Squitieri L, Tsangaris E, van Alphen T, van Haren ELWG, Pusic AL. International mixed methods study protocol to develop a patient-reported outcome instrument for all types of chronic wounds: The WOUND-Q. BMJ Open. 2020 Mar 25;10(3):e032332. doi: 10.1136/bmjopen-2019-032332.
2. Tsangaris E, van Haren EL, Poulsen L, Squitieri L, Hoogbergen MM, Cross K, Sørensen JA, van Alphen TC, Pusic A, Klassen AF. Identifying health-related quality of life concepts to inform the development of the WOUND-Q. J Wound Care. 2024 Jan 2;33(1):28-38. doi: 10.12968/jowc.2024.33.1.28.
3. van Alphen T, Poulsen L, van Haren E, Lind Jacobsen A, Tsangaris E, Sørensen JA, Hoogbergen M, van der Hulst R, Pusic A, Klassen A. Danish and Dutch linguistic validation and cultural adaptation of the WOUND-Q, a PROM for chronic wounds. Eur J Plast Surg. 2019; 10:1-0. doi.org/10.1007/s00238-019-01529-7
4. Klassen AF, van Haren ELWG, van Alphen TC, Cano S, Cross KM, van Dishoeck A, Fan KL, Hoogbergen MM, Orgill D, Poulsen L, Sørensen JA, Squitieri L, Tsangaris E, Vasilic D, Pusic AL. International Study to Develop the WOUND-Q Patient-Reported Outcome Measure for all Types of Chronic Wounds. Int Wound J. 2021 Aug;18(4):487-509. doi: 10.1111/iwj.13549. Epub 2021 Mar 10.
5. Simonsen NV, Klassen AF, Rae C, Dalaei F, Cano S, Poulsen L, Pusic AL, Sørensen JA. Further psychometric validation and test-retest reproducibility of the WOUND-Q. Int Wound J. 2024 Jan;21(1):e14354. doi: 10.1111/iwj.14354. Epub 2023 Aug 15.
6. Gallo L, Rae C, Voineskos S, Simonsen NV, Pusic AL, Poulsen L, Sørensen JA, Klassen AF, Cano SJ. Further psychometric evaluation of the WOUND-Q: A responsiveness study. Wound Repair and Regeneration. Wound Repair Regen. 2024 Jul-Aug;32(4):451-463. doi: 10.1111/wrr.13179. Epub 2024 Apr 24.

7. van Alphen TC, Ter Brugge F, van Haren ELWG, Hoogbergen MM, Rakhorst H. SCI-QOL and WOUND-Q Have the Best Patient-reported Outcome Measure Design: A Systematic Literature Review of PROMs Used in Chronic Wounds. Plast Reconstr Surg Glob Open. 2023 Jan 10;11(1):e4723. doi: 10.1097/GOX.0000000000004723. eCollection 2023 Jan.

Contact Information for Access to Tool

More information about WOUND-Q is available at https://qportfolio.org/wound-q/
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