



Questionnaire on quality of life with chronic wounds

# User Manual

Date: September 2022

## 1. Description and use

The Wound-QoL measures the disease-specific, health-related quality of life (HRQoL) of patients with chronic wounds. It can be used in clinical and observational studies as well as in daily practice.

Two versions are available:

- Wound-QoL-17: original version with 17 items (formerly referred to as “Wound-QoL” only)
- Wound-QoL-14: short version with 14 items

All items assess impairments within the preceding seven days. Generally, we recommend using the Wound-QoL-14 due to its better psychometric properties (von Stülpnagel et al. 2021).

## 2. Development

The **Wound-QoL-17** was developed on the basis of three validated instruments assessing HRQoL in chronic wounds: the Freiburg Life Quality Assessment for wounds (FLQA-w, Augustin et al. 2010), the Cardiff Wound Impact Schedule (CWIS, Price et al. 2004), and the Würzburg Wound Score (WWS, Spech 2003; Engelhardt et al. 2014).

These three questionnaires were filled in by 165 leg ulcer patients in a prospective study under routine care. For implementation in the Wound-QoL those of all 92 items were selected that showed the best psychometric properties and that were not redundant in content. Item and instruction wording of the Wound-QoL-17 were harmonized and improved by an expert panel. Wound-QoL subscales were determined with factor analysis.

The development and initial validation of the Wound-QoL-17 has been published in Blome et al. 2014. Further psychometric evaluations have been published in Augustin et al. 2014; Deufert et al. 2016; Augustin et al. 2017; Sommer et al. 2017. For publications on international Wound-QoL-17 versions, please see below (3. Languages).

The **Wound-QoL-14** is a shortened version of the Wound-QoL-17. It has been developed based on an Item Response Theory-based analysis of a multi-national data base (von Stülpnagel et al. 2021). The Wound-QoL-14 showed even better psychometric performance than the original version and demonstrated cross-cultural validity. The Wound-QoL-14 differs from the Wound-QoL-17 only in that items number 10, 12, and 17 are not included in the latter; everything else remained unchanged.

### 3. Languages

Translations of the original, German version of the Wound-QoL have been performed as follows:

1. independent translations by 2 native speakers
2. independent back-translations by 2 native speakers
3. tabulation of all translations (sentence by sentence) with listing of all differences between translations and differences between back translations and original
4. translators' and methodologists'/authors' conference (sentence by sentence) to find a consensus on the final translation
5. proof reading of the final questionnaire by a native speaker.

To date, linguistically validated translations of the Wound-QoL have been performed for:

- Arabic (Israel)
- Catalan (Catalonia)
- Chinese: Standard Chinese (China): Liu et al. 2022
- Chinese: Traditional Chinese (Taiwan)
- Croatian (Croatia)
- Czech (Czechia): Procházková & Pokorná 2017 (publication on translation)
- Danish (Denmark): Knudsen et al. 2021
- Dutch (Netherlands): Amesz et al. 2020
- English (Canada)
- English (UK)
- English (US): Sommer et al. 2020
- Finnish (Finland)
- French (France)
- French (Switzerland)
- German (Germany and Austria) [original version]: Blome et al. 2014
- German (Switzerland)
- Georgian (Georgia)
- Hebrew (Israel): Gamus et al. 2018
- Hungarian (Hungary)
- Italian (Italy)
- Latvian (Latvia)
- Lithaunian (Lithuania)
- Persian (Iran)
- Polish (Poland)
- Portuguese (Portugal)
- Portuguese (Brasil): Vogt et al. 2020
- Russian (Russia)
- Slovak (Slovakia)
- Slovenian (Slovenia)
- Spanish (Spain): Conde Montero et al. 2021
- Spanish (Central America)

- Swedish (Sweden): Fagerdahl & Bergström G 2018
- Tamil (India)
- Turkish (Turkey)
- Ukrainian (Ukraine)

#### 4. Instructions

The Wound-QoL is filled in by the patients themselves. The questionnaire is self-explanatory; yet, patients can be supported if they are not able to fill it in by themselves. In this case, the support has to be documented.

#### 5. Data entry

For statistical analyses, the data are entered into a spread sheet (e.g. Excel) or statistics software (e.g. SPSS). The spread sheet matrix must be structured as follows: Each row corresponds with one patient and each column corresponds with one variable (=item).

#### 6. Data analysis

If more than one box is ticked within an item or if a patient has ticked between two checkboxes, the item is treated as missing.

Answers to each item are coded with numbers (0='not at all' to 4='very much').

##### Wound-QoL-17:

A Wound-QoL-17 **global score** on overall disease-specific quality of life is computed by averaging all items. A global score can only be computed if at least 75% of the items have been answered (i.e., at least 13 in 17 items are valid).

In addition, **subscales** of the Wound-QoL can be calculated representing different dimensions of disease-specific quality of life by averaging the respective items. A subscale can only be computed if no more than 1 item of the subscale is missing. The items are assigned to subscales as follows:

1. Subscale '**Body**': Items #1 to #5
2. Subscale '**Psyche**': Items #6 to #10
3. Subscale '**Everyday life**': Items #11 to #16

Item #17 does not belong to either of the subscales.

##### Wound-QoL-14:

A Wound-QoL-14 **global score** on overall disease-specific quality of life is computed by averaging all items. A global score can only be computed if at least 75% of the items have been answered (i.e., at least 11 in 14 items are valid).

In addition, **subscales** of the Wound-QoL-14 can be calculated representing different dimensions of disease-specific quality of life by averaging the respective items. A subscale can only be computed if no more than 1 item of the subscale is missing. The items are assigned to subscales as follows:

1. Subscale '**Body**': Items #1 (pain), #2 (odor), #3 (discharge), #4 (sleep)
2. Subscale '**Psyche**': Items #6 (unhappy), #7 (frustrated), #8 (worried), #9 (fear of worsening)
3. Subscale '**Everyday life**': Items #10 (moving about), #11 (everyday activities), #12 (leisure activities), #13 (activities with others), #14 (depending on help)

Item 5 does not belong to either of the three dimensions and is thus used as a stand-alone item.

## 7. Psychometric properties of Wound-QoL-14 and Wound-QoL-17

The **Wound-QoL-17** has been tested for internal consistency, convergent validity regarding four generic HRQoL measures such as the EQ-5D, and responsiveness in a so-called virtual validation using the longitudinal study data on the three questionnaires FLQA-w, CWIS and WWS (Blome et al. 2014). A further validation has been conducted in a cross-sectional study (Augustin et al. 2014).

In a prospective validation study (Augustin et al. 2017), patients completed the **Wound-QoL-17** and two other QoL questionnaires (European Quality of Life-5 Dimensions, EQ-5D, and Freiburg Life Quality Assessment for wounds, FLQA-wk) at baseline and at two more time points (4 and 8 weeks). Wound status was assessed with an anchor question. 227 patients (48.5% women) participated in the study. Mean age was 66.9 years (range 17–96, median 69.5). Indications were venous leg ulcers (40.1%), pyoderma gangraenosum (14.1%), diabetic or ischemic foot ulcers (5.3%), pressure ulcers (2.6%), and other etiologies (30.0%). The Wound-QoL-17 showed good internal consistency, with high Cronbach's alpha in all the subscales and in the global scale on all time points ( $>0.8$ ). Convergent validity was indicated by moderate-to-high correlations with the EQ-5D (range 0.5–0.7,  $p<0.001$ ) and FLQA-wk global score ( $r>0.8$ ,  $p<0.001$ ) at every time point. Responsiveness was high, too.

In a study on the test–retest reliability of the **Wound-QoL-17** (Sommer et al. 2017), patients were asked to complete the Wound-QoL-17 twice within 3–7 days. Intraclass correlation coefficients (ICCs) ranged 0.79 and 0.86, which can be considered evidence of excellent reliability. Another indicator of very good reliability was high internal consistency of both global score (0.92) and subscale scores (body: 0.91; psyche: 0.88; everyday life: 0.90).

Additional validation studies have been conducted for language versions other than German (e.g., US English, Swedish); please see 3. *Languages* above.

In the development study of the **Wound-QoL-14** (von Stülpnagel et al. 2014), the instrument showed good internal consistency with Cronbach's alpha of 0.913 for the total score, and 0.709–0.907 for the three subscales. Furthermore, strict invariance was shown across sociodemographic and clinical variables.

In a longitudinal validation study on both the **Wound-QoL-14** and the **Wound-QoL-17** including multiple European countries (Janke et al., under publication), both versions showed good psychometric properties. Internal consistency was high in both Wound-QoL-17 (Cronbach's alpha: 0.820 to 0.933) and Wound-QoL-14 (0.779 to 0.925). Test-retest reliability was moderate to good (intraclass correlation coefficient: 0.618 to 0.808). For Wound-QoL-17 and Wound-QoL-14, convergent validity analyses showed largest effect sizes for global HRQoL ratings ( $r=0.765$ ;  $r=0.751$ ) and skin-related HRQoL (Dermatology Life Quality Index, DLQI:  $r=0.684$ ;  $r=0.682$ ). Regarding clinical data, effect sizes were largest for odour ( $r=-0.371$ ;  $r=-0.388$ ) and wound size ( $r=0.381$ ;  $r=0.383$ ).

## 8. Minimal important difference of the Wound-QoL

The minimal important difference (MID) in Wound-QoL-17 overall score was determined in a German sample of 227 patients with chronic wounds (Topp et al. 2021). Depending on the method, MID estimates ranged from 0.47 to 0.52. We suggest using an MID 0.50. This means that a decrease of the Wound-QoL-17 total score of 0.50 or more (i.e., HRQoL improvement) in a group of patients can be assumed to indicate patient-relevant change.

## 9. The Wound-Act Implementation Tool

In order to identify areas of need for action, a panel of wound specialists and patients developed a one-page implementation tool called Wound-Act. The Wound-Act is a decision aid for taking further action once quality of life problems at the level of single items are identified with the Wound-QoL. Within the Wound-Act, each Wound-QoL item answered with "quite a lot" or "very much" by the patient is regarded an important area of need for action. The Wound-Act is available in two versions: Wound-Act-14 (for use with the Wound-QoL-14) und Wound-Act-17 (for use with the Wound-QoL-17).

## 10. Contact and license information

PD Dr. Christine Blome, [c.blome@uke.de](mailto:c.blome@uke.de)

*Head of Research Group Patient-Reported Outcomes*

Licence holder: Prof. Dr. med. Matthias Augustin

German Center for Health Services Research in Dermatology (CVderm)

Director, Institute for Health Services Research in Dermatology and Nursing (IVDP)

University Medical Center Hamburg-Eppendorf

Martinistr. 52, 20246 Hamburg, Tel. \*49-40-7410-55428, Fax -55348

cvderm@derma.de, [www.cvderm.de](http://www.cvderm.de)

## 11. Literature

Amesz SF, Klein TM, Meulendijks AM, Nguyen TV, Blome C, Roodbol PF, van Montfrans C (2020). A translation and preliminary validation of the Dutch Wound-QoL questionnaire. *BMC Dermatol* 26;20(1):5

Augustin M, Baade K, Herberger K, Protz K, Goepel L, Wild T, Blome C. (2014). Use of the WoundQoL instrument in routine practice: feasibility, validity and development of an implementation tool. *Wound Medicine* 5:4-8

Augustin M, Conde Montero E, Zander N, Baade K, Herberger K, Debus S, Diener H, Neubert T, Blome C (2017). Validity and feasibility of the Wound-QoL questionnaire on health-related quality of life in chronic wounds. *Wound Repair Regen* 25(5):852-7

Blome C, Baade K, Sebastian Debus E, Price P and Augustin M (2014). The "Wound-QoL": A short questionnaire measuring quality of life in patients with chronic wounds based on three established disease-specific instruments. *Wound Repair Regen* 22:504–14

Conde Montero E, Sommer R, Augustin M, Blome C, Cabeza Martínez R, Horcajada Reales C, Alsina Gibert M, Ramón Sapena R, Peral Vázquez A, Montoro López J, Guisado Muñoz S, Pérez Jerónimo L, de la Cueva Dobao P, Kressel N, Mohr N. *Actas Dermosifiliogr*. Validation of the Spanish Wound-QoL Questionnaire. 2021 Jan;112(1):44-51

Deufert D, Graml R, Matteucci Gothe R (2016). Überprüfung der Test-Retest-Reliabilität des „Wound-QoL“ – Ein Instrument zur Erfassung der krankheitsspezifischen, gesundheitsbezogenen Lebensqualität von Menschen mit chronischen Wunden. *Pflegewissenschaft* 9-10:484-90

Fagerdahl AM, Bergström G (2018). Translation and Validation of a Wound-specific, Quality-of-life Instrument (The Wound-QoL) in a Swedish Population. *Ostomy Wound Management* 64(5):40-6

Gamus A, Kaufman H, Keren E, Brandin G, Peles D, Chodick G (2018). Validation of "Wound QoL" Hebrew version disease-specific questionnaire for patients with lower extremity ulcerations. *Int Wound J* 15(4):600-4

Knudsen JT, Johansen CW, Hansen AØ, Eshoj HR (2021). The Danish wound-quality of life (Wound-QoL) questionnaire: Translation and psychometric properties. *Wound Repair Regen* 29(6):973-84

Liu J, Li H, Zhang P, Bai R, Fu X, Guan H, Wen B, Ding Y, Qi X (2022). Translation and validation of 17-item Wound-QoL questionnaire in a Chinese population. *Int Wound J*. 2022 Jul 26. Online ahead of print

Procházková & Pokorná: Česká verze dotazníku Wound-QoL [Czech version of the questionnaire Wound-QoL], *Dermatol. praxi* 2017; 11(3): 126–130

Sommer R, Augustin M, Hampel-Kalthoff C and Blome C (2017). The Wound-QoL questionnaire on quality of life in chronic wounds is highly reliable. *Wound Repair Reg* 25:730–32

Sommer R, Hampel-Kalthoff C, Kalthoff B, Neht C, Scherfer E, Winkler M, Blome C (2018). Differences between Patient- and Proxy-reported HRQoL Using the Wound-QoL. *Wound Repair Regen* 26(3):293-6

Sommer R, von Stuelpnagel C, Fife C, Blasingame M, Sanders MJ, Thompson D, Augustin M, da Silva N, Blome C. Development and psychometric evaluation of the U.S. English Wound-QoL questionnaire to assess health-related quality of life in people with chronic wounds (2020). *Wound Repair Regen* Sep;28(5):609-16

Topp J, Blome C, Augustin M, Mohr N, Debus ES, Diener H, Sommer R (2021). Determining the minimal important difference for the Wound-QoL questionnaire. *Pat Pref Adherence* 1571-8

Vogt TN, Santos PND, Mantovani MF, Tomim DH, Guimarães PRB, Kalinke LP (2020). Psychometric properties of the Brazilian version of the Wound Quality of Life questionnaire. *Rev Rene* 21:e43855

von Stülpnagel CC, da Silva N, Augustin M, van Montfrans C, Fife C, Fagerdahl AM, Gamus A, Klein TM, Blome C, Sommer R (2021). Assessing the quality of life of people with chronic wounds by using the cross-culturally valid and revised Wound-QoL questionnaire. *Wound Repair Regen* 29(3):452-9