Questionnaire on quality of life with chronic wounds

User Manual

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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.

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

- Arabic (Israel)
- Catalan (Catalonia)
- Chinese: Standard Chinese (China)
- 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
- Finnsih (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
- 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 the Wound-QoL

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.

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.

10. Contact and license information

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11. Literature

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