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Translation, Cultural Adaption, and Linguistic Validation of the Norwegian Wound-QoL Questionnaire

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Background and Purpose: A sound translation is complex but necessary to provide a valid patient-reported questionnaire. The aim of this study was therefore to translate, culturally adapt, and linguistically validate the 17-item Wound-Quality of Life (Wound-QoL) questionnaire from English to Norwegian. **Methods:** For translation and cultural adaption of the Wound-QoL, we followed the methods described by the ISPOR—The Professional Society for Health Economics and Outcomes Research (formerly, the International Society for Pharmacoeconomics and Outcome Research), Messaging Application Programming Interface Research Institute, and recommendations from literature reviews. **Results:** Differences in the language semantics and syntax caused challenges in the translation. The cognitive debriefing interviews revealed some irrelevant items related to personal preferences. **Conclusions:** This study provides a questionnaire that can improve the quality of clinical care and promote research and valuable knowledge to other researchers translating the Wound-QoL and similar questionnaires.
Keywords: Wound-QoL; translation; cultural adaption; linguistic validation

Hard-to-heal (HTH) or chronic wounds are wounds that fail to heal with standard treatment within an expected timeframe (Vowden, 2011). HTH wounds are often complications of other conditions (e.g., trauma, diabetes, arterial/venous insufficiency, cancer, and immobility). For some patients, complete healing is unrealistic despite optimum care. Consequently, HTH wounds often have a major impact on patients' health-related quality of life (HRQoL) causing distress due to pain, odor, drainage and bleeding, repeated infections, discomfort from dressing materials, restricted mobility, and sleep impairment (Chrisman, 2010; González de la Torre et al., 2017; Herberger et al., 2011; Kouris et al., 2016). Furthermore, living with a wound may affect HRQoL negatively due to physiological as well as psychosocial problems such as loss of self-esteem, loneliness, hopelessness, frustration, anxiety, and depression (Fagerdahl et al., 2014; World Health Organization, 2015). This type of distress may be associated with delayed wound healing (Gouin & Kiecolt-Glaser, 2012; Vileikyte, 2007). In addition, HTH wounds impose a substantial economic burden on society and individuals (Olsson et al., 2019).

There is a growing interest in HRQoL in patients with HTH wounds (González de la Torre et al., 2017; Gottrup et al., 2010), and the European Wound Management Association recommends the use of

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patient-reported outcomes both for clinical practice and research (Gottrup et al., 2010). HRQoL questionnaires assess patients' experience of how health affects their lives and are useful in various patient groups, health care settings, research, and clinical work (Gottrup et al., 2010; Price & Harding, 2004). While generic HRQoL questionnaires measure general health and well-being, disease-specific questionnaires assess the burden of particular health conditions (Augustin et al., 2017). Wound-specific HRQoL questionnaires are useful tools for promoting health and wound management, enabling clinicians to be aware of and understand patients' biopsychosocial challenges (Price & Harding, 2004; Reinboldt-Jockenhöfer et al., 2021). When healing is prolonged or unrealistic, assessing HRQoL can contribute to shared decision-making (Blome et al., 2014). Furthermore, wound-specific HRQoL questionnaires can be used to identify patients with a heavy symptom burden (Gottrup et al., 2010; Price & Harding, 2004) and to assess the treatment effects on important aspects of daily life (Patrick, 2002). While short HRQoL questionnaires are simple to use, comprehensive HRQoL questionnaires can be more beneficial in the management of complex health conditions. However, comprehensive questionnaires may be exhaustive for patients who are elderly and frail and thus lead to missing feedback and poor-quality data (Blome et al., 2014).

The Wound-Quality of Life (Wound-QoL) is a disease-specific HRQoL questionnaire for patients with HTH wounds. It was developed at the German Center for Health Service Research in Dermatology by Blome et al. (2014) and was derived from three wound-specific HRQoL questionnaires: the Freiburg Life Quality Assessment for Wounds (FLQA-w), the Cardiff Wound Impact Schedule, and the Würzburg Wound Score (Blome et al., 2014). The questionnaire has been translated and validated in several languages (Blome et al., 2014; Sommer et al., 2017).

The translation and psychometric validation of a patient-reported outcome measure (PROM) are two processes that are carried out sequentially (Epstein et al., 2015). Although there is no consensus on the guidelines for translation, linguistic validation, and cultural adaption of questionnaires (Epstein et al., 2015), the literature provides summarized recommendations, emphasizes methodological rigor, and strongly advises a multistep approach (Acquadro et al., 2008a; Epstein et al., 2015; Machado et al., 2018; Wild et al., 2005). ISPOR—The Professional Society for Health Economics and Outcomes Research (formerly, the International Society for Health Economics and Outcomes Research)—has outlined a Standard Linguistic Validation Process consisting of 10 steps, including preparation, forward translation, back translation, and cognitive debriefing interviews (CDIs; Wild et al., 2005). Manuals for PROMs provided by the Messaging Application Programming Interface (MAPI) Research Institute describe the same methodology (Acquadro et al., 2004). Reviews on cross-cultural adaption methods recommend adding a step including an expert committee (EC) review (Epstein et al., 2015; Machado et al., 2018) along with a conceptual translation method. A direct translation is advised against since this method often fails to account for variation, tone, culture, and semantics of the target language (Wild et al., 2005).

Wound-specific HRQoL questionnaires can be utilized to provide valuable information for research and clinical care. However, a validated HRQoL assessment tool for patients with HTH wounds is not available in Norwegian. A thorough method of translation with cultural adaption and linguistic validation is a critical first step to validate and confirm the reliability of any translated tool. It begins with a rigorous translation procedure. Therefore, the aims of this study were twofold: (a) to translate the 17-item Wound-QoL from English to Norwegian using a sound forward–backward translation method and (b) to linguistically validate the Wound-QoL in Norwegian patients with HTH wounds.

METHOD

Design

This study is based on international recommendations for the translation and linguistic validation of PROMs (Acquadro et al., 2004, 2008a, b; Epstein et al., 2015; Machado et al., 2018; Wild et al., 2005). The study takes an explorative approach summarizing results from steps in the translation process and CDIs.

The Wound-QoL Questionnaire

The Wound-QoL is a multidimensional short self-report questionnaire. The 17 items are each scored from 0 (not at all) to 4 (very much). A global score is computed by averaging all items (Hamburg-Eppendorf, 2023). Three subscale scores (i.e., body, psyche, and everyday life) can also be calculated and are supported by factor analysis (Exploratory Factor Analysis) with oblique and orthogonal rotation (Blome et al., 2014). Lower scores indicate poorer HRQoL (Sommer et al., 2017). The psychometric properties of the original German Wound-QoL were tested in a validation study with 227 patients with HTH wounds of various etiologies (Blome et al., 2014). The questionnaire had strong internal consistency and good convergent validity with moderate to strong correlations with standards (FLQA-w and EQ-5D; Augustin et al., 2017). The questionnaire showed high responsiveness ($P \leq .001$; Augustin et al., 2017) and excellent test–retest reliability (0.79–0.86; Sommer et al., 2017).

The Translation Method

The English Wound-QoL questionnaire was translated into Norwegian in accordance with the ISPOR-The Professional Society for Health Economics and Outcomes Research report for translation and cultural adaption (Wild et al., 2005), the Standard Linguistic Validation Process by MAPI Research Institute (Acquadro et al., 2004), and recommendations in review articles by Acquadro, Epstein, and Machado (Acquadro et al., 2008a; Epstein et al., 2015; Machado et al., 2018). The translation and linguistic validation method consisted of 10 sequential steps. The translation was organized by the first author (MMS) and carried out by 19 contributors: the developers of the original questionnaire, three forward translators, nine experts (EC; see Table 1, Step 3), one back translator, and eight patients with HTH wounds undergoing CDIs. The EC was composed of recommendations in literature (Epstein et al., 2015). The process, challenges, arguments, agreements, explanations, and choices were documented in reports for each step of the translation and are listed in Table 1.

The Cognitive Debriefing Interviews

Informants were strategically recruited from a wound outpatient clinic at a hospital in Mid-Norway. The informants had HTH wounds (i.e., traumatic, arterial, venous, diabetic, and pressure) and Norwegian as their first language. There were three women and five men between 51 and 84 years of age. Their education varied between primary and post-graduate levels.

The informants independently completed the Norwegian Wound-QoL version 2 prior to the interview. Fully structured interviews using an interview guide (Table 2) were carried out to obtain patients' understanding of the instructions and items of the Wound-QoL. During the interviews, feedback and comments were handwritten in a structured form with help text based on the CDI guide. Patients were recruited and interviewed until saturation of information was obtained (n = 8). Information from the interviews was analyzed subsequently.

Analyses

Initially, face validity (Polit & Beck, 2021) of Wound-QoL was assessed, and apparent challenges in the questionnaire were identified and discussed among two authors (M.M.S. and T.M.L.) and the developers. Then, for all steps of the translation, results were (a) summarized by the first author, (b) discussed among relevant contributors, and (c) documented by the first author for the final report.

For the information obtained in the CDIs, the first author identified and thematically categorized challenges and then discussed the challenges and potential changes with the coauthors and the Wound-QoL developers.

RESULTS

Step 1—Preparation and Concept Clarification

The face validity of the Wound-QoL was satisfactory. The questionnaire covered apparent problems for patients with HTH wounds. While most items initially seemed uncomplicated to translate, certain words and terms were discussed and clarified with the developers to ensure the equivalence of concepts in the original and translated questionnaire (Table 3).

Step 2—Forward Translation

The three separate forward translations of the Wound-QoL were nearly identical. The discrepancies involved the questionnaire title and the use of synonyms. The forward translators did not agree in terms of translating or keeping the original title. Also, a number of synonyms were suggested: Chronic/long-lasting/HTH; moderately/to some degree/quite a lot; very much/a lot; hurt/painful; bad/nasty; discharge/secretion; burden/strain/load; sad/depressed; worried/afraid; bumping/knocking/hitting; problems/difficulties; moving about/be in motion/moving around; day-to-day/daily/everyday; limited/prevented/made it difficult; and social interaction/to be with other people/activities with others.

Step 3—EC Evaluation

The EC advised keeping the title acronym "Wound-QoL" because this is a trademark of the questionnaire. The developers also supported keeping the title identical across different language versions. The EC further suggested removing several personal pronouns and courtesy phrases ("please"). Also, using the same phrases (i.e., "trouble" and "difficult") indicating different context-specific meanings in items 11, 12, and 13 should be avoided to promote understanding and prevent problems in performing and interpreting confirmatory factor analyses (i.e., correlated error terms; Table 4). The in-depth discussions in the EC did not lead to any disagreements.

Steps 4 and 5—Back Translation and Reconciliation

The back translation differed from the English and the Norwegian version 1 of the Wound-QoL, mainly in terms of synonyms. "Burden" was back-translated to "strain" (item 5), "unhappy" to "dejected" (item 6), and

TABLE 1. Translation Method

TRANSLATION STEPS	CONTRIBUTORS	PREMISES	TRANSLATION PROCESS
Step 1: Preparation and concept clarification	• First author (M.M.S.) • Coauthor (T.M.L.) • Developers of the original questionnaire		First author and coauthor assessed the face validity of the Wound-QoL to identify challenging concepts/items. Concepts and items were discussed and clarified with the developers of the original questionnaire.
Step 2: Forward translation	• Three forward translators (M.M.S., T.M.L., and L.L.)	The forward translators should • Have Norwegian as their first language • Be fluent in English	The three forward translators each translated the English version of the Wound-QoL into three separate Norwegian translations.
Step 3: Evaluation by EC	• One layperson with experience in having HTH wounds • One clinician working with HTH wounds • One expert on the concept/ methodology "health-related quality of life" • One researcher experienced in questionnaire validation • One researcher experienced in HTH wounds • One developer of the original questionnaire • Three forward translators	The evaluation should emphasize the conceptual and cultural understanding of the text and questionnaire items (not a literary approach).	The three forward-translated versions of the Wound-QoL were discussed in a digital meeting in the EC. The EC members prepared by examining the original questionnaire, the report from step 1, and the three forward translations. Step 3 resulted in the Norwegian Wound-QoL version 1. The EC discussed each item until agreement and reconciled the three forward translations into one Norwegian version.
Step 4: Back translation	• Professional translator	The translator had to have • Expertise in healthcare texts. • No prior knowledge of the Wound-QoL questionnaire.The translation should be direct, rather than conceptual.	The professional translator translated the Norwegian Wound-QoL version 1 back to English.
Step 5: Review of the back translation	• First author • One of the forward translators		The first author reviewed the back translation in collaboration with the forward translators, the professional back translator, and the developers

(*Continued*)

TABLE 1. Translation Method (*Continued*)

TRANSLATION STEPS	CONTRIBUTORS	PREMISES	TRANSLATION PROCESS
	• Back translator • Developers of the original questionnaire		of the original questionnaire. These reviewers agreed on a Norwegian Wound-QoL version 2 for harmonization and cognitive debriefing.
Step 6: Harmonization			This step was not performed since no other Norwegian version of the questionnaire was available for comparison.
Step 7: CDIs	• First author	The CDIs should include • Using an interview guide with structured questions • Data collection until saturation of information is obtained (e.g., 5–8 informants)	The informants completed the Norwegian Wound-QoL version 2 independently. The first author interviewed eight patients with HTH wounds on the premises of a hospital in Mid-Norway.
Step 8: Review of cognitive debriefing—results and finalization	• First author • Forward translators • Developers of the original questionnaire		Written notes from the CDIs were analyzed. Suggestions and changes were discussed and agreed upon by the first author, the three forward translators, and the developers of the original questionnaire. This resulted in the Norwegian Wound-QoL version 3.
Step 9: Proofreading	• One of the forward translators (T.M.L.) • Researcher (L.E.L.)	The proofreaders should be experienced in patient-reported outcomes.	The third version of the Norwegian Wound-QoL was proofread by one of the forward translators and a researcher experienced in patient-reported outcome questionnaires to detect and correct errors in language, spelling, grammar, and layout. This step resulted in the Norwegian Wound-QoL version 4.
Step 10: Final report	• First author		A report was written describing the process, challenges, arguments, agreements, explanations, and choices at each step of the translation process.

Note. CDI = cognitive debriefing interview; EC = expert committee; HTH = hard-to-heal; Wound-QoL = wound quality of life.

TABLE 2. The Cognitive Debriefing Interview Guide

QUESTIONNAIRE SECTIONS AND FEATURES	QUESTIONS
Instructions	How did you find the instructions for this questionnaire (clarifying, incomplete, precise, easy/difficult to understand, confusing, etc.)?
Layout	What do you think about the questionnaire format and layout (neat, easy to get an overview, messy, difficult to understand, confusing, etc.)?
Relevance	Is the questionnaire relevant to your diagnosis and situation?
Appropriateness	Did any of the items in the questionnaire seem strange, inappropriate, or provocative?
Items 1–17	Was it easy or difficult to understand the item (what was possibly difficult)? Can you explain in your own words what the item means? Would you prefer to phrase the item differently (how)? Is the item relevant for your diagnosis and situation?

"trouble" to "difficult" (item 13). The back translation satisfactorily covered the content and meaning of the original items. Clarifying questions were returned to the professional translator, and the rephrasing covered the content and concept in the original Wound-QoL (Table 5).

Steps 7 and 8—CDIs and Review

The informants spent 3–7 minutes completing the Norwegian Wound-QoL version 2. They reported that it was easy to understand the instructions and items, and they were able to correctly explain (in their own words) the content and meaning of the items. They stated that the format and layout were neat and did not find any of the items to be strange, inappropriate, or provocative. Although the questionnaire was relevant to their diagnosis and situation, five informants reported difficulties with relating their answers to the past 7 days. Various items were irrelevant to some of the informant's situations. It was not necessary to clarify the meaning of their answers provided from the interview guide. Challenges and solutions are presented in Table 6.

Step 9—Proofreading

Two proofreaders assessed the Norwegian Wound-QoL version 3. Minor improvements were necessary due to missing spaces between words and missing circles for ticking off answers.

DISCUSSION

Translation Method

The present study describes a thorough process of translation, cultural adaption, and linguistical validation of the Wound-QoL questionnaire from English to Norwegian. To make the translation transparent to clinicians and academics, the translation work, challenges, arguments, and decisions made throughout the multistep procedure should be outlined in detail. A sound translation method ensures the validity and reliability of the questionnaire and provides a PROM that adequately covers the culture and language spoken in the target population (Wild et al., 2005, 2009). In fact, poorly translated PROMs threaten the validity of research data (Wild et al., 2005). Although there is a lack of consensus on one ideal translation method, a multistep approach is strongly recommended to ensure quality (Acquadro et al., 2008a; Epstein et al., 2015; Finnerty, 2020; Machado et al., 2018). The translation process should be transparent and verifiable; however, most validation studies merely describe and discuss this important work. The present study though shares information and knowledge about challenges and decisions in the translation process, which may be instructive and useful to other researchers translating the same and similar PROMs. Transparency of future studies will enable harmonization among future translations of the Wound-QoL (Beaton et al., 2000; Wild et al., 2005).

TABLE 3. Results From the Concept Clarification With the Developers of the Wound-QoL

QUESTIONNAIRE PART	ORIGINAL PHRASE	CONCEPTUAL CHALLENGES	CLARIFICATIONS AND DECISIONS
Introduction We aim to find out how your chronic wound(s) affect(s) your quality of life.	Chronic wound(s)	"Chronic" indicates that the condition is irreversible and the wound will not heal.	"Chronic" was replaced with "HTH."
Item 3 There was a disturbing discharge from the wound.	Disturbing discharge	It is unclear which aspects "disturbing" refers to: The affective state and feelings toward the discharge or that the discharge interferes with physical activity and function.	"Disturbing" refers to the affective state. Disturbing" can be replaced with "annoying" to highlight the intended meaning, namely, that the discharge makes the patient unhappy.
Item 6 The wound has made me unhappy.	Unhappy	The equivalent Norwegian word "ulykkelig" is an inadequate synonym when a health condition evokes a state of mind or feeling.	Unhappy can be replaced by synonyms such as "feel bad" or "depressed." We used to "feel bad."
Item 11 I have had trouble moving about because of the wound.	Moving about	It was unclear whether the phrase refers to the patient's general activity, the change in position (e.g., of an arm and foot), or moving from one place to another.	The phrase refers to the patients' activity when moving from one place to another.
Item 12 Climbing stairs has been difficult because of the wound.	Climbing the stairs	In Norwegian, climbing indicates moving upward the staircase, and it was unclear whether the direction (up or down) was of importance for patients with HTH wounds.	The phrase includes both walking up and down stairs.
Item 13 I have had trouble with day-to-day activities because of the wound.	Day-to-day	"Daily activities" are a more common phrase in Norwegian when referring to for instance getting dressed, eating breakfast, and doing household chores.	The phrase can be replaced by "everyday activities" or "daily activities." We decided on "daily activities."
Item 15 The wound has forced me to limit my activities with others.	Activities	It was unclear whether "physical activity" or "social activity" was of importance in this item.	The social setting and meeting other people were of importance.

Note. HTH = hard-to-heal.

TABLE 4. Expert Committee Evaluation and Advice for the Norwegian Wound-QoL Version 1

ORIGINAL PHRASE	FORWARD TRANSLATION PHRASE	ADVICE/ARGUMENTS	PHRASE USED IN THE NORWEGIAN WOUND-QoL v1
Chronic (instruction)	Kronisk	Avoid "chronic" due to the negative association of the term (perceived as if the wound will never heal).	Persistent (langvarig)
Please (instruction)	Vennligst	Remove "please" from the text because courtesy phrases are seldom used in the Norwegian language.	Tick one box per line (sett ett kryss for hvert spørsmål).
Your and mine (items 1, 2, and 8)	Din, ditt, dine, mine, and mitt	Remove several personal pronouns to improve fluency in the items.	"…how chronic wound(s) affect your life" ("…hvordan det langvarige såret eller sårene påvirker livskvaliteten din") "…the wound hurt" ("…har såret gjort vondt") "…the wound had a bad smell" ("…har såret luktet ubehagelig") "…worried about the wound" ("…har jeg vært bekymret for såret")
Hurt (item 1)	Smertefullt and vondt	Choose a pain term that does not imply a symptom of severe intensity. "Pain" is a strong expression in many Norwegian dialects and may lead some respondents to tick the box "not at all."	Hurt (vondt)
Bad (item 2)	Vondt, stygt	Avoid using adjectives that express stronger symptoms than the original questionnaire implies.	Unpleasant (plagsom)
Discharge (item 3)	Sekresjon	Avoid using clinical terms that can be difficult to understand among people who do not work in health care.	Oozing (væsking)
…my sleep (item 4)	…søvnen min	The type of sleep (e.g., naps and night sleep) was not specified in the original English item and should also be expressed in a general way in the Norwegian version.	My sleep (søvnen min)
Burden (item 5)	Byrde	Use a less old-fashioned expression in Norwegian. "Burden" is rarely used in	Strain (påkjenning)

(*Continued*)

TABLE 4. Expert Committee Evaluation and Advice for the Norwegian Wound-QoL Version 1 (*Continued*)

ORIGINAL PHRASE	FORWARD TRANSLATION PHRASE	ADVICE/ARGUMENTS	PHRASE USED IN THE NORWEGIAN WOUND-QoL v1
		Norwegian and is a more negatively charged noun in the context of this particular item.	
Unhappy (item 6)	Deprimert (depressed)	Avoid using the diagnosis "depressed" and choose a more appropriate word for feeling unhappy. Depression is an ICD10 medical diagnosis and is not the issue in this item.	Feeling down (nedstem)
…afraid of the wound getting worse or of new wounds appearing (item 9)	…redd for at såret blir verre eller at nye sår oppstår	Use imperative instead of present tense to express in a more precise manner that the wound is getting worse or that new wounds appear. Use the Norwegian word for "concerned" instead of "afraid." In Norwegian, "afraid" implies a more defined fear of something, but one can be "concerned" without being anxious.	…concerned that the wound will get worse or new wounds will appear (…urolig for at såret skal bli verre, eller at jeg skal få nye sår)
Knocking (item 10)	Three different synonyms were discussed (komme borti, slå borti, and dunke borti).	The power of "knocking" was discussed to select the most suitable alternative.	Knocking (dunke borti)
Moving about (item 11)	Three synonyms were discussed (være i bevegelse, bevege meg rundt, and forflytte meg).	Use a phrase expressing that the patient moves from one place to another. This understanding of the item was also supported by the developers of the Wound-QoL in step 1 preparation.	Move from one place to another (bevege meg rundt)
Trouble (item 11)	Two synonyms were discussed (vanskeligheter and problemer).	Since the item implies a less serious condition than "problems," apply the Norwegian word for "difficulties."	Difficulties (vansker)
Day-to-day (item 13)	Three synonyms were discussed (dagligdagse, daglige, and hverdagslige).	Use the simplest and easy-to-understand alternative that describes the concept well.	Daily (daglige)
Forced (item 15)	Two synonyms were discussed (begrenset and tvunget).	The direct Norwegian translation of the word "forced" (tvunget) is negatively charged. The Norwegian word for "limited" is a more suitable term.	Limited (begrenset)

(*Continued*)

TABLE 4. Expert Committee Evaluation and Advice for the Norwegian Wound-QoL Version 1 (*Continued*)

ORIGINAL PHRASE	FORWARD TRANSLATION PHRASE	ADVICE/ARGUMENTS	PHRASE USED IN THE NORWEGIAN WOUND-QoL v1
Burden (item 17)	Two synonyms were discussed (byrde and påkjenning).	Consider a third alternative translation of "burden" that may better describe the concept and the situation that the item refers to.	Load (belastning)

TABLE 5. Results of the Back Translation

ORIGINAL WOUND-QoL TERMS AND PHRASES	FORWARD TRANSLATION NORWEGIAN WOUND-QoL v2	BACK TRANSLATION PHRASE	ARGUMENTS/DECISIONS	REPHRASE IN THE NORWEGIAN WOUND-QoL v3
With the following questions, we aim to find out… (introduction)	Med disse spørsmålene ønsker vi å finne ut…	This questionnaire is designed to…	"Designed" is a common way to phrase this type of request in English questionnaires. The back translator was asked to translate the introduction in a more direct rather than conceptual way. The rephrase covers the concept of the introduction well.	With these questions, we wish to find out…
Bad smell (item 2)	Luktet ubehagelig	Unpleasant smell	The translator was asked for options of "ubehagelig" (unpleasant). The rephrase is identical to the original questionnaire.	Bad smell
Burden (item 5)	Påkjenning	Strain	"Burden" was discussed in the EC in step 3, and it was agreed on a conceptual translation (see Table 2). Note that "burden" and "strain" are synonyms (Inc (2021).	Strain
Unhappy (item 6)	Nedstemt	Dejected	"Unhappy" was discussed in the concept clarification and the EC (steps 1 and 3), resulting in a conceptual translation to "feeling down" (nedstem) instead of "unhappy" (ulykkelig). Note that "unhappy" and "dejected" are synonyms (Inc, 2021).	Dejected
Trouble (item 13)	Vanskelig	Difficult	"Trouble" and "difficult" are synonyms (Inc, 2021).	Difficult
…my activities with others (item 15)	…min sosiale kontakt med andre	…my social contact with others	The original item emphasizes the social setting and meeting with other people (not the physical activities); therefore, the translator was asked to translate the item differently. The rephrase describes the concept of the item well.	My social interaction with others…
…dependent on help from others (item 16)	…avhengig av andre	…dependent on others	The word "help" was omitted in the back translation. The translator was asked how she would translate this item if she had to include the Norwegian word for "help" (hjelp). The rephrase covers the concept well.	…dependent on the assistance of others

TABLE 6. Results From the Cognitive Debriefing Interviews and Review

QUESTIONNAIRE PART	INFORMANT COMMENTS AND SUGGESTED CHANGES	ARGUMENTS/DECISIONS	CHANGE IN THE WOUND-QoL v3
Heading above the items In the last 7 days…	Use the number "7" instead of the word "seven" in the text.	This suggestion was considered appropriate to make the timeframe stand out and attract attention. The developers of the Wound-QoL supported the suggestion and argument and accepted the change as it does not represent a major deviation from the original questionnaire.	Within the last 7 days… (I løpet av de siste 7 dager…).
Introduction With the following questions, we aim to find out how your chronic wound(s) affect(s) your life.	Add "during the last 7 days" to the questionnaire instruction as well as in the heading just above the questions.	This suggestion was in line with the former suggestion and would make the timeframe stand out. The developers of the Wound-QoL and translators rejected this suggestion since the timeframe is already made more visible with the digit "7" in the heading above the items.	None
Item 5 …The treatment of the wound has been a burden to me.	Use "unpleasant" instead of "strain."	This change was suggested by one informant and considered a personal preference. "Unpleasant" does not adequately cover the concept in the original item ("burden").	None
Item 6 …The wound has made me unhappy.	Use "frustrated" instead of "unhappy" or both.	Reported by only one informant and considered to be a personal preference. Adding "frustrated" would expand and change the concept ("unhappy") in the original item.	None
Item 2 …My wound had a bad smell.	The item was reported not relevant by one informant.	These reports of irrelevant items were considered personal preferences due to the informants' individual health and life situations, rather than irrelevant items for patients with HTH wounds in general.	None
Item 15 …The wound has forced me to limit my activities with others.	The item was reported not relevant by three informants.		
Item 17 …The wound has been a financial burden to me.	The item was reported not relevant by four informants.		
Items 5–15	The 10 items were reported not relevant by one informant.		
Items 5, 8, 9, 12, 17, and partly items 11–14	The item was reported not relevant by one informant.		
Layout	One of the participants suggested to remove the circles in the area	This change was rejected by the developers of the Wound-QoL to ensure consistency in the	None

(*Continued*)

TABLE 6. Results From the Cognitive Debriefing Interviews and Review (*Continued*)

QUESTIONNAIRE PART	INFORMANT COMMENTS AND SUGGESTED CHANGES	ARGUMENTS/DECISIONS	CHANGE IN THE WOUND-QoL v3
	of ticking off the answers.	layout across different language versions of the Wound-QoL.	

Note. HTH = hard to heal.

The First Norwegian HRQoL Questionnaire for Wounds

The Wound-QoL is the first Norwegian wound-specific HRQoL questionnaire for assessing patients' experiences of living with HTH wounds (Augustin et al., 2017). Measuring HRQoL is the cornerstone of evidence-based clinical wound treatment and research. Note that wound management services in Norway are fragmentary and experience-based, rather than holistic and evidence-based (Hofstad, 2019; Smith-Strøm & Thornes, 2008). Research on patients with HTH wounds in Norway is scarce, and wound treatment has a low status in the healthcare system (Hofstad, 2019). Therefore, a translated and validated international HRQoL instrument is crucial in order to gain evidence-based knowledge about this patient population. Patients with HTH wounds report that information from such questionnaires may contribute to an increase in clinicians' and researchers' knowledge, shift their focus toward the patient perspective, and help them understand the personal and societal consequences of living with HTH wounds (Deufert & Graml, 2017). Translated and validated language versions in different languages of HRQoL questionnaires can be used at local, national, and international levels to examine the current practice, promote health, facilitate shared decision-making, improve treatment quality, and enable comparison of health conditions across countries and cultures (Wahl & Rokne, 2004).

Involvement of Experts in the Translation Process

A major methodological strength of this study was the involvement of the developers of the Wound-QoL and experts on PROMs and wounds throughout the translation process. They clarified ambiguities and helped solving discrepancies, and their involvement was useful to ensure equivalent concepts and avoid major deviations between the original and Norwegian Wound-QoL questionnaire. For example, in item 11 (*I have had trouble moving about because of the wound*), it was crucial to clarify whether the phrase referred to the patient's general activity, the change of position of extremity, or moving from one place to another. Not involving the developers of the original questionnaire in the translation may have led to misinterpretation of items or concepts resulting in a PROM that does not measure what it is intended to measure (Wild et al., 2005).

Furthermore, the advice from the EC members was important to achieve a linguistically valid and culturally adapted translation of the Wound-QoL. For instance, the EC members recommended toning down the use of personal pronouns, courtesy phrases, and identical words with different meanings. Language and culture have a complex homologous relationship. The way people (i.e., health care personnel, patients, academics, and researchers) think about the world is unique in every culture. Individuals' understanding of the world is directly influenced by the language they use to talk about it (Kramsch, 1998). Hence, culture and language should be carefully considered when translating a questionnaire: the wording must be kept conceptually equivalent to the original text, as well as culturally adapted to the new language and context. In the present study, the competence of the EC members and the composition of the committee contributed to nuanced and in-depth discussions on semantics, as well as reaching a conceptual and cultural understanding of the items and concepts. Although there is no consensus on using experts in the guidelines for translation, linguistic validation, and cultural adaption, previous reviews suggest that an EC in translational work is valuable in making critical decisions, reaching a consensus, and consolidating translated questionnaires (Epstein et al., 2015; Machado et al., 2018). The experience from the present study signifies the importance of involving experts to ensure the intended meaning of the Wound-QoL across different language versions despite differences among the British, German, and Norwegian cultures (Epstein et al., 2015; Machado et al., 2018).

Implications From the CDI

The translation process included CDIs with persons with HTH wounds to explore the comprehensibility and cognitive equivalence of the Wound-QoL content. In these types of interviews, the informants' understanding of the instructions, each item, and the reply options are explored so that any inappropriate or confusing information and concepts can be corrected. CDIs may also reveal translation alternatives not suggested by the translators (Beaton et al., 2000; Wild et al., 2005). However, in the present study, most changes suggested by the CDI informants could not be accommodated. For example, five informants reported that it was difficult to remember and thus relate their responses to the past 7 days. To overcome this problem, one informant suggested to add "during the last 7 days" to the questionnaire's instruction. The developers of the Wound-QoL

believed this would not solve the problem since respondents often overlook instructions. A more comprehensive introductory text would probably reinforce this problem. The challenge of relating the answer to "the last 7 days" was not reported in previous Wound-QoL translation and validation studies (Amesz et al., 2020; Conde Montero et al., 2021; Fagerdahl & Bergström, 2018; Gamus et al., 2018; Knudsen et al., 2021; Santos et al., 2017). Although the instructions of the Wound-QoL are short and user-friendly, clinicians and researchers who distribute the questionnaires to patients may enhance the preciseness and quality of responses by pointing out the 7 days' timeframe.

While all items of the questionnaire were relevant to the patient group, several items were reported as irrelevant by individual CDI informants (i.e., 2, 5–15, and 17). Various aspects may explain this finding, such as personal preferences and resources, variations in wound severity, poor understanding of their condition, or place of treatment. For instance, items regarding financial expenses, symptoms, and function may be more relevant to patients treated in primary care. In fact, patients treated at wound outpatient clinics in Norway receive wound treatment at a low individual cost, having only to pay a deductible once they obtain their exemption card for public health service (Helfo, 2022). They receive treatment from specialized clinicians with expertise in how to prevent and manage wounds and bothersome symptoms. Specialized care provides control of the odor and drainage and comfortable bandages, which again promote mobility and physical and social activities. The wound care in outpatient clinics is affordable and of a high standard compared with wound management in primary care. In general practitioners' offices, wounds are often treated by nonexperts, and the patient must pay for bandages and equipment.

Interestingly, CDIs performed in the present and previous translations of the original 17-item Wound-QoL have not identified any completely irrelevant items of the questionnaires (Amesz et al., 2020; Conde Montero et al., 2021; Fagerdahl & Bergström, 2018; Gamus et al., 2018; Santos et al., 2017; Sommer et al., 2017). Nonetheless, some patients in the present study struggled with answering items 11 and 12 concerning mobility (e.g., everyday activities and climbing stairs) along with item 16 concerning dependency on others. An explanation may be that limited mobility can be due to other impairments than the wound, such as musculoskeletal pain problems, paraplegia, and amputations (Amesz et al., 2020; Conde Montero et al., 2021; Fagerdahl & Bergström, 2018; Gamus et al., 2018; Santos et al., 2017; Sommer et al., 2020). Notably, these items regarding mobility and dependency are suggested to be omitted from the revised Wound-QoL (von Stülpnagel et al., 2021). The revision was performed based on a validation study from the United States suggesting that the Wound-QoL would benefit from further adaptions (Sommer et al., 2020). Items 11, 12, and 16 did, in fact, show poor discrimination in the item response theory analysis and incomplete confirmation of the factor structure of the original German version (Sommer et al., 2020).

It is of uttermost importance to take the informants' perspectives, advice, and suggested improvements into account when translating PROMs. It is also necessary to make sure that changes made in a translated version do not alter the intended meaning or concepts of the original questionnaire. Different language versions must be consistent and comparable and ensure the comparison of data across countries. This would not be possible if major changes were implemented or single items were deleted in some language versions (Polit & Beck, 2021). Therefore, although some patients in the present study found particular items irrelevant or difficult to answer, none of the Wound-QoL items were irrelevant to most patients. Indeed, all the suggested alterations and irrelevant items revealed in the CDIs were carefully considered but not implemented in the final Norwegian version of the Wound-QoL. Further psychometric analyses for exploring the reliability and validity of the Norwegian Wound-QoL will follow this study.

Cultural Adaption

To culturally adapt the Wound-QoL into the Norwegian context, changes were made in semantics, syntax, wording, verbs, and nouns in the title, introduction, and items. The items were also adjusted to fit the response scale. In fact, these changes are similar to those in the translation and cultural adaption of the Brazilian Portuguese Wound-QoL (Santos et al., 2017). Note that alterations in translated versions of the Wound-QoL are scarcely described and explained, such as in the Hebrew translation (Gamus et al., 2018) and the pretest of the Dutch Wound-QoL (Amesz et al., 2020). Only the Brazilian (Santos et al., 2017) and Danish (Knudsen et al., 2021) Wound-QoL describe the results from the translation and cultural adaption process in detail. Although the translation method across studies seems to vary, these studies were conducted according to international standards for cross-cultural adaptions of outcome instruments and in collaboration with the developers of the original questionnaire.

Strengths and Limitations of the Study

A major strength of this study is that the step-by-step translation and cultural adaptation process were carried out with methodological rigor (Acquadro et al., 2004, 2008b; Epstein et al., 2015; Machado et al., 2018; Wild et al., 2005). The collaboration with the developers of the original questionnaire through all steps of the translation process ensured that the intended meaning and concepts in the introduction and each item were kept similar to the original Wound-QoL. Also, the involvement of the EC in step 3 increased the quality of

the Norwegian Wound-QoL. The review in this step provided a nuanced and in-depth discussion which led to a common language that was easy for the patients to understand. The CDIs with patients ensured that the questionnaire was appropriate and secured a high level of comprehensibility and cognitive equivalence. A limitation of this study is that the CDIs were conducted in one outpatient clinic and in ethnic Norwegians, which may result in less generalizable findings. Nevertheless, we expect that the understanding of the language and content in the Wound-QoL will not vary greatly between patients treated in specialist health service or in primary health care service. However, recruiting a more diverse patient group would perhaps have ensured a broader consideration of various patients' perspectives, languages, dialects, and cultures. Note also that, while the Norwegian version of Wound-QoL is thoroughly translated, linguistically validated, and culturally adapted, the questionnaire must undergo psychometric testing to establish its validity and reliability. The last limitation worth noting is that the present study translated the first 17-item Wound-QoL and not the modified and further developed Wound-QoL 2.0. The newer version, with better psychometric performance, was not available at the time of commencement of the present study.

Relevance to Nursing Practice, Education, or Research

In conclusion, the Norwegian 17-item Wound-QoL is a rigorously translated, linguistically validated, and culturally adapted questionnaire. The items were easy to understand and highly relevant to the diagnosis and situation of patients with HTH wounds. This study provides a translated questionnaire that can give nurses an increased understanding of HRQoL in the population of patients having HTH wounds, improve the quality of nursing care, and promote wound research. When used in clinical settings, the HRQoL assessment tool can enhance the patients' experience of shared decision-making in wound management. This study also provides a deeper understanding of the importance of a complex but necessary sound translation to ensure a valid patient-reported questionnaire that adequately covers the culture and language spoken in the target population. It can give valuable knowledge to other researchers who translate the Wound-QoL and similar questionnaires into other languages. The Norwegian Wound-QoL will be tested for reliability and validity in a longitudinal study of its psychometric properties.

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Author Note. This study was performed in line with the principles of the Declaration of Helsinki. Permission to translate the Wound-QoL into Norwegian was granted by the developers of Wound-QoL in 2019. The Regional Committee for Medical and Health Research Ethics (REK Midt; Date 18.12.2019/No 31816) and the Data Access Committee at Nord-Trøndelag Hospital Trust approved the study (Date 01.11.2019/No 2019_3394). A Data Protection Impact Assessment was filled out in accordance with guidelines of the Faculty of Medicine and Health Science at the Norwegian University of Technology and Science. This research was prepared under support by Nord-Trøndelag Health Trust and the Norwegian University of Science and Technology. No external funding was provided. The dataset generated and analyzed in the current study is publicly unavailable to ensure the anonymity of the CDI informants. M.S. and T.M.L. contributed in all parts of the study. M.S. collected the CDI data and analyzed and interpreted the data from each step of the translation process. All authors contributed in the planning of the study, the discussion of expert committee feedback, and writing the manuscript. All authors read and approved the final manuscript. The authors declare that they have no competing interests.

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SUPPLEMENTARY MATERIALS

Wound-QoL questionnaire on quality of life with chronic wounds

With the following questions, we aim to find out how your chronic wound(s) affect(s) your quality of life.

Please tick one box per line!

	In the <u>last seven days</u> …	**not at all**	**a little**	**moderately**	**quite a lot**	**very much**
1	…my wound hurt	O	O	O	O	O
2	…my wound had a bad smell	O	O	O	O	O
3	…there was a disturbing discharge from the wound	O	O	O	O	O
4	…the wound has affected my sleep	O	O	O	O	O
5	…the treatment of the wound has been a burden to me	O	O	O	O	O
6	…the wound has made me unhappy	O	O	O	O	O
7	…I have felt frustrated because the wound is taking so long to heal	O	O	O	O	O
8	…I have worried about my wound	O	O	O	O	O
9	…I have been afraid of the wound getting worse or of new wounds appearing	O	O	O	O	O
10	…I have been afraid of knocking the wound	O	O	O	O	O
11	…I have had trouble moving about because of the wound	O	O	O	O	O
12	…climbing stairs has been difficult because of the wound	O	O	O	O	O
13	…I have had trouble with day-to-day activities because of the wound	O	O	O	O	O
14	…the wound has limited my leisure activities	O	O	O	O	O
15	…the wound has forced me to limit my activities with others	O	O	O	O	O
16	…I have felt dependent on help from others because of the wound	O	O	O	O	O
17	…the wound has been a financial burden to me	O	O	O	O	O