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Using a Structured, Computer-Administered Questionnaire for Evaluating Health-Related Quality of Life in Patients with Chronic Lower Extremity Wounds

Stephen L. Harlin, MD; Ryan D. Harlin, BA; Thomas I. Sherman; Courtney M. Rozsas; M. Shuja Shafqat; and William Meyers, MD

Abstract

Patients with chronic wounds of the lower extremity (CWLEs) often experience functional disability and emotional distress; incorporating health-related quality of life (HRQoL) measurements in clinical practice may improve understanding of chronic wound patients' healthcare needs. A computer-administered instrument that measures HRQoL variables in patients with CWLEs was developed to overcome common limitations to assessing HRQoL in this population. Face validity of the questionnaire variables assessing physical, social, emotional, and functional well-being was obtained and a computer application to display the structured questionnaire on an electronic kiosk with touch-screen interface was developed. All patient responses are stored in the clinic's electronic health record system. To evaluate use of this system in a wound care clinic, 66 consecutive patients were asked to complete the questionnaire; of those, 64 participated. Internal consistency of the instrument across responses was estimated by the Kuder-Richardson formula 20 as 0.79. None of the patients requested help completing the questionnaire or working with the touch-screen interface. Patients most frequently reported frustration (63%), trouble sleeping (48%), anxiety (42%), and impaired mobility (41%), confirming that CWLEs negatively affect patient quality of life. These findings suggest that additional validation and reliability studies, including research to evaluate the relationship between HRQoL, protocols of care, and wound outcomes, are warranted.

Key Words: healthcare quality, electronic records, evaluation, quality of life, wounds and injuries

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Potential Conflicts of Interest: none disclosed

The lived experience of chronic wounds evokes powerful emotional issues; more than 25% of patients report symptoms of depression or anxiety.^{1,2} In a large sociodemographic study³ of 120 patients with venous ulceration, 16% were out of work and 49% were disabled in terms of work tasks. Notwithstanding these circumstances, most clinical assessments of wound healing focus on healing rates and/or morbidity (eg, delayed epithelialization, limb loss, and/or infectious complications). Assessment of functional status and quality of life is fundamental to the care of patients with chronic wounds of the lower extremity (CWLEs) and should not be overlooked.

Health-related quality of life (HRQoL) evaluations examine the psychosocial stresses faced by patients with chronic conditions. HRQoL assessments offer important information throughout the wound care continuum because efforts to improve quality of life and relieve suffering are integral to all wound treatment regimens. The importance of quality of life measurement for patients with CWLEs is gaining recognition.⁴⁻⁶ However, as with other areas of healthcare, progress in this area has not been accompanied by widespread implementation and testing for several reasons. First, HRQoL has been shown to be a complex concept, widely understood to be a multidomain phe-

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Key Points

- The authors of this study describe the development and use of an electronic lower extremity wound quality of life (QoL) instrument.
- QoL questions, covering four domains, can be completed by the patient using a touch screen; responses are stored in the patient's electronic record.
- The results of this evaluation confirm that lower extremity wounds negatively affect patient QoL.
- Additional research using QoL instruments for patients with these wounds is needed.

nomenon with physical, psychological, and social components.⁷ Second, as described by Price and Harding and observed in the authors' experiences, many clinicians may be hesitant to regularly employ a generic measurement strategy of HRQoL because such approaches often fail to encompass significant aspects of the condition-specific health state of CWLEs and the clinicians themselves may be unaware of the few measures that have been developed specific to CWLEs, such as the Cardiff Wound Impact Schedule designed by Price and Harding.⁴ Lastly, the authors often have found in practice that comprehensive and systematic assessment of patients' psychosocial needs can substantially increase provider time, including carrying out the interview, making appropriate subspecialty referrals, and systematic monitoring as needed.

The utility of patient self-administered health history questionnaires has been studied extensively.⁸⁻¹⁰ Several reviews analyzing¹¹⁻¹³ studies that explored the effectiveness of computer-administered surveys for obtaining patient health information have concluded that dialogue between patient and computer is an effective and well-accepted means of obtaining accurate and comprehensive medical histories. Compared to paper-and-pencil questionnaires and face-to-face interviews, patients have reported a preference for computer-administered surveys, especially when being assessed for psychological histories.^{14,15} However, a valid, reliable, computer-interpretable instrument for measuring HRQoL in patients with CWLEs does not exist.

The measurement instrument developed by the authors is an electronic, patient self-administered, internally consistent questionnaire that is displayed on a computer kiosk with touch-screen interface and integrated with the clinic's pre-existing electronic health record (EHR) system for storage. It also has the potential to track patients' responses each time they receive treatment. The purpose of this prospective descriptive study is to evaluate use of an electronic HRQoL evaluation system in clinical practice.

Methods

Instrument development.

Literature analysis. To identify the relevant literature, a comprehensive search of English-language articles published between January 1996 and December 2006 was performed of OVID Medline, CINAHL, EMBASE, the Cochrane Wounds Group database within the Cochrane Collaboration Library, the Agency for Healthcare Research and Quality (AHRQ) Clinical Practice Guidelines, and the National Guideline Clearinghouse™ database of evidence-based clinical practice guidelines. The search term combination captured the concepts *functional status*, *quality of life*, and *wound* using a wide range of indexing terms, free text words, and word variants. Bibliographies of key articles also were searched to supplement the literature searches and concise definitions of key terms were adopted (see Table 1).

Development of a preliminary set of items and domains. To identify a set of simple, uncorrelated, closed-ended questions that might measure HRQoL, questions extracted from the medical literature review¹⁶⁻¹⁹ were pooled along with a retrospective review of interviews contained in the clinic's EHR from 724 patient visits to the authors' ambulatory wound care center.^{18,19} From the item pool, content domains were ascertained representing four health attributes that assessed HRQoL: physical, social, emotional, and functional well-being. A set of four questions representing each domain for a total of 16 questions was defined (see Table 2). These questions were selected because they were frequently reported in the literature and similar questions are widely incorporated into existing validated health surveys such as the CWLE-specific Cardiff Wound Impact Schedule.⁴ A yes/no dichotomous response format was chosen for each attribute's representative question. A positive response to a question is scored as a value of 1 and a negative response as 0; therefore, the scores for each domain can range from 0 to 4. The questions were designed to facilitate a rapid, sensitive, accurate rating of a comprehensive range of relevant domains by naive raters with minimal burden on respondents.

Consensus process and content validity. The first stage of ensuring content validity involved formation of a cross-specialty panel composed of clinical and methodological experts from the fields of nutrition, interventional radiology, anesthesiology, pharmacology, podiatry, vascular surgery, general surgery, plastic surgery, and healthcare policy research to review the instrument and ensure content domains had been sampled adequately (see Table 3). Panel members were informed that the instrument was being designed to measure the physical, social, emotional, and functional aspects of patients' lived experience with nonhealing wounds. All panel members volunteered their time; no commercial support was provided. The panel also declared in writing their independence from any industry relevant to this topic according to standard reporting requirements.

Consensus was achieved in open forum with foremost consideration given to comments made by participants with

Table 1. Quality measurement and information technology terminology

Electronic health record (EHR) <small>Adapted from 18,19</small>	Longitudinal electronic record of patient health information. The EHR aids decision-making by providing real-time access to health information at the point of care. The EHR automates workflow and supports the collection of data for uses other than clinical care, such as billing, quality management, outcomes reporting, and public health disease surveillance and reporting
Electronic kiosk	Computer screen that employs custom software designed to permit simple, often unattended, data entry
Functional status	Individual's ability to perform normal daily activities required to meet basic needs, fulfill usual roles, and maintain health and well-being
Health-related quality of life (HRQoL)	Individual's overall satisfaction with physical capacity and mental and social well-being
Quality measures <small>Adapted from 38</small>	Degree to which healthcare services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge
Survey instrument	Series of questions scientifically designed to measure existing beliefs or aspects of behavior. Data collected can be used to estimate the prevalence of existing attitudes, check the validity of previous exploratory studies, or compare responses in subgroups of larger populations

greatest expertise on the matter under discussion. When opinions diverged, sources of disagreement were discussed. Throughout the process of collaboration, the group's aim was to understand the factors that caused disagreement and minimize potential biases. The panel's overarching goal was to answer four questions: 1) Are the content domains of the instrument salient to the HRQoL status of patients with CWLE? 2) Is the content of the questionnaire fairly estimated from the review of the medical literature? 3) Does the instrument have the potential to meaningfully discriminate between different levels of severity? 4) Would the instrument reasonably appear to be a valid way to monitor the HRQoL for patients with CWLEs if formally tested? Once the panel of experts achieved consensus on these issues, there was extensive discussion as to how the questionnaire could most effectively present these issues to the patient. The final questionnaire was a product of the panel's expertise and experience in the participants' respective fields.

Data collection instrument. Next, the paper-based structured questionnaire was converted to an interactive electronic document stored in the clinic's EHR (see Figure 1).²⁰ To administer the questionnaire, a computer application was developed to "call up" or execute the questionnaire, display it on an electronic kiosk with touch-screen interface (Cintiq, Wacom Technology Corporation, Vancouver, WA), monitor the respondent's progress, and store each patient's

choices in a relational database. The system provides the ability to de-identify protected health information (PHI) on electronic output while leaving the actual PHI data unmodified in the original record. Before deployment, the application was thoroughly tested by Ryan D. Harlin, information technology consultant for The Wound Clinic (Broomall, PA) for reliability in loading the interface and saving patient data, as well as for overall runtime stability.

The graphic user interface was programmed to be simple, efficient, and immediately comprehensible. When displayed on the touch screen, the digital questionnaire was completed by an easy "see-and-point" process. To ensure survey completeness, the user interface provided immediate feedback when an item was missed (see Figure 2). No time restrictions were imposed and patients were provided a private setting to complete the form.

System engineering respected Nielsen's²¹ principles for "usability" and sought to provide a satisfying human-computer interaction. The program that conducted the interview was built in Apple Computer's Xcode environment using the Cocoa Objective-C application development framework. The customized application was implemented as a three-tiered client/server architecture on the Mac OS X (Apple, Inc., Cupertino, CA) UNIX-based operating system.

Data collection, reliability testing, and scoring. Institutional Review Board approval was obtained from the Delaware County Memorial Hospital (Drexel Hill, PA) IRB



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Table 2. Assessment of functional status and quality of life in patients with chronic wounds of the lower extremity Adapted from 16-19

1 Physical well-being		
1. My wound interferes with my mobility.	YES	NO
2. My dressings cause me discomfort.	YES	NO
3. I am not sleeping well.	YES	NO
4. I am bothered by side effects of medication.	YES	NO
2 Social/family well-being		
1. I get emotional support from my family and/or friends.	YES	NO
2. My wound interferes with close relationships.	YES	NO
3. My role in the family has changed.	YES	NO
4. Wound odor and/or drainage hinder my social interactions.	YES	NO
3 Emotional well-being		
1. I feel anxious.	YES	NO
2. I feel frustrated.	YES	NO
3. I feel depressed.	YES	NO
4. My self-confidence is marred.	YES	NO
4 Functional well-being		
1. I am able to work.	YES	NO
2. I am able to perform daily tasks.	YES	NO
3. I am able to enjoy leisure activities.	YES	NO
4. Wound care expenses cause me financial strain.	YES	NO

for collection of clinical data. The study complied with HIPAA provisions for protecting confidentiality of patient data and the security of EHRs.²² Study participants were seen in a community-based, university-affiliated ambulatory wound care center. All patients who presented for a new-patient visit and care of a chronic wound of the lower extremity were eligible to participate. Sixty-six consecutively eligible patients were approached. The study was explained and 64 patients (97%) agreed to participate and provide informed consent. One patient refused to participate due to concerns about the demands of information technology and the other for unspecified reasons. All participants were asked to describe their current status

and instructed to ask the clinic staff for assistance if needed. All sixty-four participants completed the 16-item HRQoL structured questionnaire.

The Kuder-Richardson formula 20 (KR20) was employed to test the internal consistency of the HRQoL instrument. The scoring procedure was straightforward and customary for discriminative HRQoL instruments.²³ Because individual items had been formulated to be relatively uncorrelated, scores for each item were equally weighted. The domain scores were summed and then combined into a single overall score.

Table 3. Panel of experts

**Multi-Specialty Consensus Group Members
Stephen L. Harlin, MD, Chair**

Joseph C. Goldschmidt, MD, PhD	Internal Medicine and Geriatrics
Bruce G. Greenfield, DPM	Podiatry
Veronica E. Hache, PT-WCC	Physical Therapy
Cynthia A. Hoffman, MSRD, CNSD	Clinical Nutrition (Wound Healing)
Leslie C. Ghisletta, MD	General Surgery
Julie Holtsberg, MHA	Health Care Policy
Seth A. Malin, MD	General Surgery
Lawrence J. Mayer, MD	General Surgery
Kelsey J. Rush, BS	Clinical Research on Wound Healing
Rajit R. Shah, MD	Interventional Radiology
Andrew T. Teplica, DPM	Podiatry
Joan C. Waller, MD	Infectious Diseases
Douglas A. Whitney, MD	Anesthesiology
Lauren A. Willard, PharmD	Wound Care Pharmaceuticals and Devices
Denise P. Young, BSN, RN, WCC	Nursing

Integrating Quality Measurement in Clinical Practice

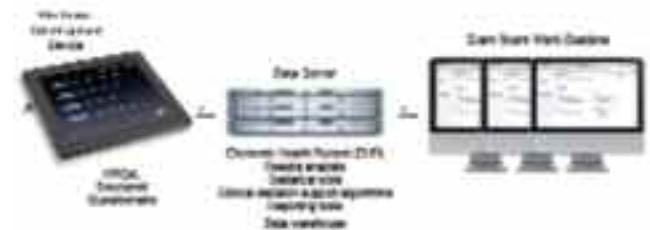


Figure 1. An advanced health record (EHR) system with patient quality measurement software. The system is capable of patient self-reporting through structured questionnaires, clinical results analysis, summary reporting of de-identified clinical data, and warehousing for clinical research.

Results

The mean total score for HRQoL (n = 64) was 12.2 (SD 3.3) (range 1 to 16). Mean scores for each domain were: Physical — 3.0 (SD 1.1), Social — 3.5 (SD 1.0), Emotional — 2.7 (SD 1.2), and Functional — 3.0 (SD 1.2) (see Table 4). When rank-ordered, almost two thirds of patients with CWLEs experienced general frustration, while nearly half reported anxiety and problems sleeping (see Table 5). Impaired mobility affected 41% and more than one third were unfit for work. Wound care services and/or dressing supplies burdened the budgets of approximately 20%. It is interesting to note that although a majority of patients reported frustration, trouble sleeping, anxiety, impaired mobility, and inability to work, only 8% of the participants described themselves as depressed. This finding is closely corroborated by the group's infrequent reporting of changes in self-confidence (8%) and frequent reporting of compassionate support from family and/or friends (92%).

Validity and internal consistency. Data collection using an electronic kiosk was well accepted by all study participants. None of the subjects requested help of the clinic's staff despite instruction to do so if needed and no one reported respondent fatigue. No malfunctions in computer hardware or the application created to execute the study occurred. Based on expert interpretation of the scientific evidence and group consensus, the survey questions appear to satisfy the content domains, support for content validity was favorable, and internal consistency was strong, as estimated by the index KR20 = 0.79. Furthermore, the staff at The Wound Clinic did not experience increased administrative burden with this device because the questionnaire was completed by the patients independently in the waiting area and the results stored in the practice's EHR.

Discussion

Physiologic measures such as wound-healing trajectories, quality of exudate, and transcutaneous oxygen measurements provide important information to wound care practitioners; patients' functional capacity and well being are also important. Clearly, measuring HRQoL is an important part of assessing the full burden of nonhealing wounds.

This study is the first report in which an instrument to measure HRQoL was developed and tested for internal consistency using a patient-interactive touch-screen device, integrated with the EHR.²⁶⁻³⁴ Historically, studies exploring the impact of CWLEs on quality of life have utilized questionnaires administered by trained interviewers^{25,27-32} or patients themselves using paper forms.^{24,26} The former method is resource-intensive but ensures compliance and decreases missing items. The latter method relies on the patient's literacy to understand the questions. The authors believe that none of this study's subjects had difficulty because no one requested assistance they knew was available. Still, the possibility exists that some patients may have had difficulty understanding the questions and failed to ask for help due to embarrassment or lack of interest. Furthermore, traditional self-administered paper-based questionnaires have been associated with numerous shortcomings, including illegible responses and risk of misplacement.³³⁻³⁷ A computer-administered structured questionnaire minimizes administrator burden, ensures compliance, decreases errors, eliminates missing items, collects uniform data for outcomes research, and provides an opportunity for clinical decision support.¹¹⁻¹³

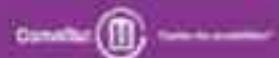


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Structured Questionnaire User Interface



Figure 2. A self-report survey displaying four of 16 questions designed to measure HRQoL. The structured questionnaire was computer-administered using an electronic kiosk with touch-screen interface. The data application ensures survey completeness by highlighting missed entries before allowing respondents to advance.

Table 4. Rank order distribution of scores (N = 64)

	Frequency (f)	%
Frustration	40	63
Trouble sleeping	31	48
Anxiety	27	42
Impaired mobility	26	41
Unable to work	23	36
Unable to enjoy leisure	16	25
Unable to perform daily tasks	13	20
Financial strain	12	19
Dressing comfort	11	17
Interference with relationships	10	16
Changes in role in the family	9	14
Wound odor	8	13
Depression	8	13
Marred self-confidence	8	13
Medication side effects	6	9
Inadequate support	5	8

Ranked responses by frequency of 64 patients with CWLEs of factors impacting their overall well-being. Frustration was most commonly reported and inadequate support was most infrequently reported.

Table 5. Domain scores for well-being

Physical well-being			
Score	Frequency (f)	%	Cumulative %
0	2	3	3
1	5	9	12
2	7	11	23
3	23	36	59
4	26	41	100
<i>Mean: 3 (SD 1.1)</i>			
<i>Median: 3</i>			
<i>Mode: 4</i>			

Social well-being			
Score	Frequency (f)	%	Cumulative %
0	1	2	2
1	2	3	5
2	4	6	11
3	14	22	33
4	43	67	100
<i>Mean: 3.5 (SD 1.0)</i>			
<i>Median: 4</i>			
<i>Mode: 4</i>			

Emotional well-being			
Score	Frequency (f)	%	Cumulative %
0	3	5	5
1	6	9	14
2	18	28	42
3	17	27	69
4	20	31	100
<i>Mean: 2.7 (SD 1.2)</i>			
<i>Median: 3</i>			
<i>Mode: 4</i>			

Functional well-being			
Score	Frequency (f)	%	Cumulative %
0	2	3	3
1	8	13	16
2	10	16	32
3	12	19	51
4	32	50	100
<i>Mean: 3 (SD 1.2)</i>			
<i>Median: 3.5</i>			
<i>Mode: 4</i>			

Frequency of scored responses of 64 patients with CWLEs for four different domains of well-being. Responses were measured on a scale of 0 to 4, positively related to well being. A score of 0 indicated no positive responses to a particular domain's questions; whereas, a score of 4 indicated four positive responses to a domain's questions — ie, 0 = no positive responses and 4 = four positive responses.

Internal consistency of the data was good. The results also suggest that QoL is affected by a CWLE, especially emotional well-being. This finding is similar to Jones et al,¹ who reported 52 out of 190 patients with venous leg ulcers

in their study were depressed, as well as to Goodridge et al's⁶ cross-sectional study of adult patients with diabetes and foot ulcers in which patients with nonhealing ulcers experience notable anxiety about their wounds.

Among the obstacles to implementing a measurement of HRQoL is a paucity of rigorous scientific evidence that clearly establishes its value in the clinical care of chronic wounds. Well-designed clinical trials that verify its usefulness and establish an explicit role for standardized HRQoL measurement in this area do not exist. Barring their absence, the development of high-quality decision support systems is beyond reach.

Unfortunately, ideological hurdles must be overcome. The current payment system fails to reward providers who measure results, adopt information systems, and demonstrate excellent approaches to care.⁴² In fairness, however, it should be noted that steps recently have been made toward ensuring quality of care on this end, such as denied reimbursements for the occurrences of “Never Events” that were devised by the National Quality Forum.⁴³ Yet by and large, industry-wide strategies to bring down costs by reducing provider payments and paring back services effectively subsidize high-volume services and dampen quality improvement efforts. Thus, even if future studies indicated that the formal assessment of the HRQoL data improves treatment, which could be determined by correlation with outcome measures such as healing time, incentives to integrate measures similar to the current endeavor may be negligible. Finally, the prospect of shared knowledge, collaborative processes, and a more egalitarian working environment may be inhibited by providers’ reluctance to relinquish authority and power.

Implications

The paucity of valid and reliable measurement tools for HRQoL in this patient population calls for methodological standards of instrument development along with computer-assisted cooperative work and sound clinical data analysis. This is an enormous undertaking and requires fundamental shifts in wound care delivery systems. Current programs are in their infancy.

Outcome measurement and reporting likely will play an important role in national initiatives aimed at integrating clinical goals with patients’ values. By providing a basis for developing easily employable HRQoL data collection devices, the study instrument is a step in this direction. More steps will be required for widespread integration into clinical practice, including: 1) determining the external validity of the questionnaire; 2) establishing the sensitivity, specificity, and reliability of the instrument; 3) correlating the outcome measures to changes in HRQoL status for improved patient monitoring and care; 4) determining patient-specific acceptable HRQoL threshold value; and 5) implementing high-quality treatment plans that produce positive changes in nonhealing wound patients’ HRQoL statuses. To truly deliver high standards of care for patients with complex wounds, the authors believe an expert information system and a mature workflow management

scheme are imperative. Wound care practitioners need to find their place across the broad rubric of national quality initiatives and define clear strategies to critically evaluate how wound treatments affect patient outcomes.

Conclusion

The instrument described herein demonstrates it is possible to assess the impact of CWLEs on patients’ QoL regarding physical, social, emotional, and functional well-being through an electronic questionnaire and integrate this information into an existing EHR system. This was achieved without increasing the healthcare professionals’ administrative burden, as reported by the staff of the clinic in which this instrument was developed. In an age where the benefits of EHR are becoming more readily touted and more commonly employed in practice, it will become increasingly important to find means to seamlessly integrate health information into these records. This instrument provides a basis for future development of devices that can routinely be used to assess HRQoL data from patients with CWLEs that could potentially help improve quality of care, continuously monitor the effectiveness of treatment, and help bring attention to the vast impact that CWLEs have on many facets of patient’s lives. ■

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