

This material is protected by U.S. copyright law. Unauthorized reproduction is prohibited.  
To purchase quantity reprints or request permission to reproduce multiple copies, please e-mail reprints@ons.org.

## Computerized Symptom and Quality-of-Life Assessment for Patients With Cancer Part I: Development and Pilot Testing

Donna L. Berry, PhD, RN, AOCN®, Lisa J. Trigg, MN, ARNP, William B. Lober, MD, Bryant T. Karras, MD, Mary L. Galligan, RN, BSN, Mary Austin-Seymour, MD, and Stephanie Martin, MSW, LICSW

**Purpose/Objectives:** To develop and test an innovative computerized symptom and quality-of-life (QOL) assessment for patients with cancer who are evaluated for and treated with radiation therapy.

**Design:** Descriptive, longitudinal prototype development and cross-sectional clinical data.

**Setting:** Department of radiation oncology in an urban, academic medical center.

**Sample:** 101 outpatients who were evaluated for radiation therapy, able to communicate in English (or through one of many interpreters available at the University of Washington), and competent to understand the study information and give informed consent. Six clinicians caring for the patients in the sample were enrolled.

**Methods:** Iterative prototype development was conducted using a standing focus group of clinicians. The software was developed based on survey markup language and implemented in a wireless, Web-based format. Patient participants completed the computerized assessment prior to consultation with the radiation physician. Graphical output pages with flagged areas of symptom distress or troublesome QOL issues were made available to consulting physicians and nurses.

**Main Research Variables:** Pain intensity, symptoms, QOL, and demographics.

**Instruments:** Computerized versions of a 0–10 Pain Intensity Numerical Scale (PINS), Symptom Distress Scale, and Short Form-8.

**Findings:** Focus group recommendations included clinician priorities of brevity, flexibility, and simplicity for both input interface and output and that the assessment output contain color graphic display. Patient participants included 45 women and 56 men with a mean age of 52.7 years (SD = 13.8). Fewer than half of the participants (40%) reported using a computer on a regular basis (weekly or daily). Completion time averaged 7.8 minutes (SD = 3.7). Moderate to high levels of distress were reported more often for fatigue, pain, and emotional issues than for other symptoms or concerns.

**Conclusions:** Computerized assessment of cancer symptoms and QOL is technically possible and feasible in an ambulatory cancer clinic. A wireless, Web-based system facilitates access to results and data entry and retrieval. The symptom and QOL profiles of these patients new to radiation therapy were comparable to other samples of outpatients with cancer.

**Implications for Nursing:** The ability to capture an easily interpreted illustration of a patient's symptom and QOL experience in less than 10 minutes is a potentially useful adjunct to traditional face-to-face interviewing. Ultimately, electronic patient-generated data could produce automated "red flags" directed to the most appropriate clinicians (e.g., nurse,

pain specialist, social worker, nutritionist) for further evaluation. Such system enhancement could greatly facilitate oncology nurses' coordination role in caring for complex patients with cancer.

### Key Points . . .

- ▶ Although cancer symptoms and quality-of-life issues are of the highest priority to oncology nurse clinicians, little time is available in most clinical settings for comprehensive screening and assessment of problematic areas.
- ▶ Advances in computer and Internet technologies have made electronic assessment a feasible and attractive method of gathering patient-reported information in busy clinical settings.
- ▶ Patient-generated symptom and quality-of-life assessment is feasible in an ambulatory setting with patients with various levels of education and prior computer use.

*Donna L. Berry, PhD, RN, AOCN®, is an associate professor in Biobehavioral Nursing and Health Systems in the School of Nursing, Lisa J. Trigg, MN, ARNP, is a predoctoral student in the School of Nursing and a National Library of Medicine postgraduate fellow in the Division of Biomedical and Health Informatics, William B. Lober, MD, is a research assistant professor in the Division of Biomedical and Health Informatics in the Department of Medical Education, and Bryant T. Karras, MD, is an assistant professor in the Department of Health Services in the School of Public Health and Community Medicine, all at the University of Washington in Seattle; Mary L. Galligan, RN, BSN, is a staff nurse in radiation oncology at the Seattle Cancer Care Alliance in Washington; Mary Austin-Seymour, MD, is a professor in radiation oncology at the University of Washington Medical Center in Seattle; and Stephanie Martin, MSW, LICSW, is an oncology social worker in radiation oncology at the University of Washington Medical Center. This study was supported by grants from the ONS Foundation (RE-07) and the Research Intramural Funding Program of the School of Nursing at the University of Washington. (Submitted May 2003. Accepted for publication March 25, 2004.)*

Digital Object Identifier: 10.1188/04.ONF.E75-E83

Cancer symptoms and quality-of-life (QOL) issues are of the highest priority to oncology nurse clinicians and researchers (King et al., 1997; Ropka et al., 2002). The workdays of oncology nurses are focused on symptom assessment, treatment, and patient teaching. Oncology nurses work in complex healthcare systems along with other professionals with whom the shared vision of excellent cancer care becomes reality. Nurses are the cancer care professionals who approach patients as individuals who experience cancer in all aspects of their lives: physiologic, emotional, sensory, and behavioral (Heitkemper, Levy, Jarrett, & Bond, 1995). However, clinicians are faced too often with shrinking resources, removing opportunities for lengthy interpersonal interactions with patients. Patients' symptom and QOL experiences, reported in a reliable and efficient way, must take their place as a component of the essential information on which complete clinical assessments, diagnoses, and treatment plans are based. This article is the first of two that report the results of an innovative approach to collecting patient-generated symptom and QOL information during clinical assessment. Part I reports findings related to the technical development of a computerized assessment program and the outcomes of symptom distress and QOL measures. Part II describes the acceptability and usability of the program.

## Literature Review

A patient's symptom experience typically is considered a component of QOL in the cancer context (Cella, Chang, Lai, & Webster, 2002). The relationship between cancer symptoms and QOL is intuitive for cancer clinicians. Not only are cancer symptoms indications of physiologic changes associated with disease and treatment toxicity, but they also reflect linkages to patients' perceived reality, including social, psychological, and cultural factors (Faithfull, 1995). Pain and fatigue are the two preeminent, significant symptoms that are addressed in virtually every publication about cancer experiences and supportive care of people with cancer. As reviewed by Cleeland (2000), the high incidence of cancer-related pain and fatigue has been studied and reported often, along with dyspnea, depression, and cognitive deficits. The prevalence of elevated psychosocial distress among patients with cancer at diagnosis and recurrence is reported to be about 30% (Zabora et al., 1997), with clinical depression occurring in about 25% (Pirl & Roth, 1999). Given, Given, Azzouz, Stommel, and Kozachik (2000) noted that most research literature about cancer treatment and symptoms assumes that symptoms mediate between types of treatment and diminishing aspects of function. The investigators combined two symptom assessment scales, the Memorial Symptom Assessment Scale (Portenoy, Thaler, Kornblith, Lepore, Friedlander-Klar, Coyle, et al., 1994) and the Symptom Distress Scale (SDS) (McCorkle, 1987), to measure cancer symptoms over one year in 907 patients newly diagnosed with cancer who were aged 65 and older and reported the most common symptoms as fatigue, pain, dry mouth, trouble sleeping, and weakness. Not only did patients with cancer report frequent symptom experiences, the severity and associated distress were rated highly as well, particularly for pain and fatigue.

With the incidence of cancer symptoms and groups of symptoms at such a high level across various diagnoses and stages

and the apparent impact of such experiences on the dimensions of QOL, the consequences of inadequate symptom management are complex and can be overwhelming to patients and their caregivers. For example, uncontrolled pain may shorten survival (Page & Ben-Eliyahu, 1998), severe mucositis or radiation-associated skin changes can put patients at risk for additional complications (Wujcik, 1999), and nausea, vomiting, diarrhea, and anorexia not only can compromise nutritional status but also can affect cognition, mobility, and metabolism (Wickham, 1999). Early screening for psychosocial distress may enable healthcare providers to identify patients at higher risk and initiate interventions to prevent development of crisis events. Depression may increase disability, morbidity, and mortality by compromising adherence with treatment, rehabilitation, and risk-factor modification. DiMatteo, Lepper, and Croghan (2000) showed that depression was associated with a threefold decrease in adherence to medical regimens. Yet recent trends in managed care to reduce time spent with each patient have rendered existing screening measures less feasible (Pirl & Roth, 1999). Making cancer symptoms and QOL issues visible and discussed in the clinic can promote partnership between clinicians and patients, validating the patients' experiences and enhancing communication and satisfaction (Velikova, Brown, Smith, & Selby, 2002). Rapid, predictive screening may help to reduce healthcare costs and prolonged medical treatments, as well as enhance QOL and increase patient satisfaction (Andersen, 1992). The challenge of efficient, systematic, and meaningful assessment is very important and timely in current clinical cancer settings.

Because of developments in the science of cancer screening, detection, and treatment, plus collaborative involvement of various professionals and consumers, assessment of QOL and symptoms now is an established, integral component of cancer clinical trials. Systematic assessment occurs less frequently outside of the research setting (Ganz, 1995; Levine & Ganz, 2002). Many instruments have been developed for use in research and may not be adapted easily to clinical patient care settings. The clinical interpretation of the meaning of QOL scores has not been publicized or taught during clinical training of professionals. Although major comprehensive cancer centers have developed and reported routine clinical use of multisymptom assessment tools (Cleeland, 2000; Portenoy, Thaler, Kornblith, Lepore, Friedlander-Klar, Kiyasu, et al., 1994), the routine clinical use of QOL questionnaires (which include symptom scales) has been reported on a limited basis, typically not in the United States (Detmar, Muller, Schornagel, Wever, & Aaronson, 2002; Levine & Ganz; Taenzer et al., 2000; Velikova et al., 2002; Wright et al., 2003).

Portable electronic technology has been developed and tested for patient self-reporting of symptom and QOL data using validated survey instruments delivered on notebook computers (Trigg, Berry, Karras, Austin-Seymour, & Lober, 2003). Not only do these devices eliminate the usual steps of abstracting patient interview data or computerizing marked responses, but the interface also permits customized, confidential, and private assistance in completely answering queries. Patients with diabetes, ulcerative colitis, mental illness, and cancer have participated successfully in the evaluation of computerized clinical assessment strategies. Although the reports are few, the results are positive, data integrity is enhanced by computerized assessment, patients with cancer are able to complete assessment (Trigg et al.), and they report a

preference for a computerized version (Mullen, Berry, & Zierler, 2004). The time has come for nurses and their colleagues in oncology settings to deploy electronic systems to streamline and prioritize delivery of care to individual patients and to build electronic databases with clinical outcome data.

The benefits of moving from oral interview or paper questionnaire to electronic assessment have been described and studied since the 1970s and more recently in oncology settings (Allenby, Matthews, Beresford, & McLachlan, 2002; Carlson, Speca, Hagen, & Taenzer, 2001; Taenzer et al., 2000; Velikova et al., 2002; Wilkie et al., 2003; Wright et al., 2003).

Four groups of investigators have evaluated formal acceptability of computerized screening (Allenby et al., 2002; Carlson et al., 2001; Mullen et al., 2004; Wilkie et al., 2003), and the University of Washington (Mullen et al.) and Carlson et al. in Canada have reported on utility. The research group at the University of Washington reported preliminary feasibility of a Web-based assessment in their current program of research as evidenced by high enrollment and completion rates in a diverse sample of adults with cancer (Trigg et al., 2003).

The radiation therapy setting for the current study provided the type of ambulatory cancer care service that will lead the future of multidisciplinary oncology care. Nurses, physicians, social workers, and nutritionists are focused on coordinated cancer care that demands efficient communication of all types of clinical information. The purpose of this pilot study was to develop and test a computerized symptom and QOL assessment for patients with cancer who are evaluated for and treated with radiation therapy.

## Methods

### Design

This descriptive, multimethod study established the necessary infrastructure, procedures, and database to pilot test a computerized QOL and symptom assessment in an outpatient clinical cancer setting. The study began in June 2001 and continued through September 2002. Approval from the Human Subjects Division at the University of Washington was in place at all times during data collection and analysis.

### Setting

The study was conducted in the department of radiation oncology at the University of Washington Medical Center in Seattle, where a full complement of certified specialists, trainees, and support staff actively provide state-of-the-science care to patients with cancer. Traditionally, all new patients receiving radiation receive a mailed, paper information and health history form with instructions to complete the form and turn it in at their clinic visit. The health history component of the one-time form includes several symptom queries in a review of systems framework. For patients receiving radiation therapy, opportunity for ongoing verbal pain assessment occurs at least during each weekly doctor visit and at times more frequently through additional nursing assessments. Progress notes are available for written documentation.

### Sample

Full-time clinicians (eight total) in radiation oncology were invited to participate in the prototype development evaluation of the computerized assessment output. A convenience

sample of 107 outpatients who were newly evaluated for radiation therapy, able to communicate in English (or through one of many interpreters available at the medical center), and competent to understand the study information and give informed consent were invited to participate. Exclusion criteria included those who were being evaluated for total body irradiation, gamma knife stereotactic radiosurgery, or combined modality radiation and neurosurgery.

### Instruments

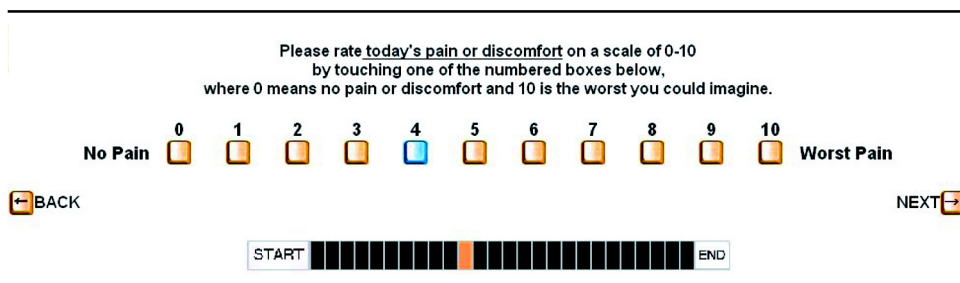
The **Short Form-8 (SF-8)** is a short-form, multipurpose health survey developed by Ware (2000) based on extensive previous work with the SF-36 and SF-12 (Quality Metrics, Inc., 2004). The subscales and component summary scales of the SF-8 have been evaluated in population-based studies. The survey contains one item for each of eight subscales: physical function, role physical, bodily pain, general health, mental health, role emotional, social function, and vitality. Each item allows a response on a five- or six-point categorical scale. The paper versions of the SF scales have been used often in the cancer research setting. Yet the SF-8 does not cover all issues considered relevant and important in oncology patient care. Among the content not included in the SF-8 and relevant to the oncology patient care setting and sample are sexuality, sleep adequacy, cognitive functioning, and appetite.

The **SDS** is a 13-item, cancer-specific symptom assessment developed and tested by oncology nurse researchers for two decades (McCorkle, Cooley, & Shea, 2000). A literature review and patient interviews were used to generate items for the SDS. McCorkle and Young (1978) used a known group method to establish construct validity for the SDS. Scores range from 13–65, with a higher score indicating higher symptom distress. Although cut scores have not been established empirically, McCorkle et al. recommended intervention for a score indicating moderate distress (25) or severe distress (33). The SDS has been used in more than 50 clinical cancer studies, including multisite, international trials (McCorkle & Quint-Benoliel, 1983). A substantial body of literature now supports the reliability and validity of the SDS (McCorkle et al.). Results of studies have underscored the usefulness of the SDS in examining the relationship between symptom distress and QOL. The clinical utility of the SDS in improving patient outcomes also has been documented in a number of studies. In fact, the SDS has been recommended as an instrument to screen patients who may be in need of closer follow-up (Degner & Sloan, 1995; Peruselli et al., 1992).

Three additional items were included to complement these instruments: an 11-point (0–10) pain-intensity numerical scale (McGuire, 1984) (see Figure 1) and two 5-point response items related to fever and chills and the impact of cancer on sexual interest and function.

### Procedures

**Software development and application:** The investigative team used a standing focus group of clinicians to determine program modifications needed to improve the specifications for display. The rapid application development (Beynon-Davies & Holmes, 1998) and refinement based on feedback were intended to ensure that the clinicians would find the graphical output useful. The focus group met in the second and fourth months of the project. Examples of the output were



**Figure 1. Eleven-Point Pain-Intensity Numerical Scale**

presented, and participants gave suggestions for improvement. Focus group discussions were recorded on audiotape.

The software is a Web application built with open-source technology and uses a forms-based Web protocol to communicate between a central server and a laptop browser. (See inset for explanations of technical terms.) The software was developed iteratively by a programming staff, using the open-source text-editing tool GNU Emacs (GNU Project, 2004) and the Web development environment Allaire Homesite™ (Macromedia Inc., San Francisco, CA). The application is implemented as a completely server-side application, using a MySQL™ database management system (MySQL-AB, 2003). The software was written in the PHP: hypertext preprocessor language and runs on the Linux-Apache-MySQL-Perl-PHP (LAMP) platform (Dougherty, 2001) with standard personal computer (PC) server hardware. The LAMP platform is attractive for this purpose because it is supported widely and

available freely in the open-source domain.

The software infrastructure supports secure queries for identified and deidentified data, with independent authorization and auditing structures for clinical reporting and research use. It effectively produces a functionally deidentified research copy of the database while maintaining the simpler design and maintenance of a single database. The software

runs on a secure, centrally located server that can be accessed by any Internet-enabled computer with the proper authorization codes. The application is implemented as a Web-based application accessed over a wireless network. The clinical site has been equipped with wireless connectivity for this project only, with a LinkSys™ (Linksys Broadband and Wireless Networking, a division of Cisco Systems, Irvine, CA) WAP11 access point using the 802.11b protocol and a Lucent Gold/Orinoco™ wireless card (Lucent Technologies, Bell Labs Innovations, Murray Hills, NJ). To ensure data security, access to the Web application requires 128-bit SSL encryption (Cam & Trigg, 2002). Further network security is achieved by restriction of use of the wireless network to authenticated users, from specific PCs to specific servers. This network security combined with the mandatory end-to-end encryption addresses the inherent insecurities of wireless networking while supporting the mobility required for this project.

## Explanation of Technical Terms

**Open source:** A philosophy and practice of software development and distribution characterized by the free distribution of software source code and redistribution rights for modified code or derived works. This approach enables volunteer developers or end users to further develop and customize the software by building on existing code. Contrast this to proprietary code, which is not made publicly available to end users or software developers in the community. It has been compared to the scientific method, where results and methods are shared freely with the scientific community (Dibona, Ockman, & Stone, 1999; Howe, 2004b).

**Server-side processing:** A Web programming technique in which the application software runs on the Web server rather than the Web browser on the end user, or “client” computer. This enables greater independence from different browsers, at the cost of some decrease in user interface function and responsiveness. It also reduces the burden on the client computer for processing all of the code necessary to display the Web content. Server-side processing contrasts with “client-side” processing, where much of the code is executed by the browser in the end user computer (Howe, 2004a).

**PHP: hypertext preprocessor language:** PHP was developed in 1994 by Rasmus Lerdorf to track visitors to his home page. PHP originally stood for “personal home page,” but as the capabilities of PHP increased, it came to mean PHP: hypertext preprocessor (Ulman, 2001). PHP is a widely used open-source, server-side scripting language used in Web development. PHP “scripts” execute on the server and can be interspersed with ordinary hypertext markup language (HTML) that normally is sent directly to the browser in the client computer. These “server-side” PHP processes can include the collection of data from a Web page, generation of dynamic page content, and sending and receiving cookies. PHP can be used in Web servers on all major operating systems (PHP Group, 2004).

**LAMP platform:** An acronym for Linux-Apache-MySQL-Perl-Python-PHP, which comprises the “open-source platform.” Linux is an operating

system, Apache is a Web server, MySQL is a database program, and Perl, Python, and PHP are server-side programming languages with their own parsers or machine-reader applications. They are well maintained by the volunteer open-source community and freely distributed. They frequently are used together in open-source development and distribution projects because they are reliable, robust, and economically attractive tools (Dougherty, 2001).

**Authentication, authorization, and auditing structures:** These are the basis of security between Internet applications and sometimes are referred to as AAA structures (Piskiel, 2000).

- Authentication asks, “Who are you, and how do we know you are who you claim to be?”
- Authorization determines, “What are you permitted to do?”
- Auditing services record, “What did you attempt to do with the software, and was it successful or not?”

**Wireless network:** A computer network connected through transmission of radio signals rather than wired connections. Most commonly, wireless networks use a standard called 802.11b, or related “a” or “g” standards, which replaces a wired Ethernet network (Howe, 2004c).

**128-bit SSL (secure socket layer) encryption:** A protocol used to encrypt messages sent through the Internet. It permits server and client computers to negotiate an encryption algorithm to be used between them and can be used by the computers to “authenticate” each other. It was designed by Netscape Communications Corporation to ensure privacy and reliability between communicating applications by preventing eavesdropping, tampering, or message forgery. It does so by supporting data encryption and server authentication and ensuring message integrity. 128-bit refers to the length of the session key generated: The longer the key, the more secure the encryption. SSL is built into all major browsers (Freier, Karlton, & Kocher, 1996; Netscape, 2003).

**Clinical implementation:** At their initial radiation oncology appointments, patients were invited to hear about the computerized assessment and, if agreeable, were given the laptop computer and consent screens to view. Consenting patients were asked to complete the computerized QOL and symptom assessment using the touch-screen computer in the reception and waiting area, where privacy is most available. In most cases, assessment was completed prior to visits with radiation oncology physicians. The program is intended to be user friendly and can be completed independently by patients; however, an assistant or student was assigned to help each patient with any questions about the equipment or use of the computerized questionnaire. The first screen of the program queries patients for permission to use the responses to the questions for two purposes: a clinical database and a research study. Patients were able to agree to one, both, or neither purpose. The assistant printed the graphic results of each completed assessment and placed one copy on the clinic chart for immediate use by the physician during that day's visit, gave one copy to the RN, and placed an archive copy in a notebook in the radiation treatment area, where patients' records are kept.

The application provides a Web-based graphic user interface for the patient and survey assistant to use and produces a paper report (see Figure 2) for the clinician to review prior to or during the visit with the patient. The patient-entered data automatically populate a MySQL database on the central server.

### Variables, Measures, and Analyses

Data collected during the clinical implementation of the program were organized as follows: (a) QOL was measured

by the SF-8 health survey scores and the single-item sexual activities and interest score; (b) symptoms were measured by the summative symptom distress score and the pain intensity number reported; (c) threshold scores were any score on the SF-8, the SDS, or the sexual activities and interest item at or above the third response for each item; (d) demographics were queried onscreen to include age, gender, education, and prior computer experience; (e) data completeness was defined as the percent of the items answered by the participant; and (f) time to complete was recorded automatically by the software program for each item. All numerical data were exported from the MySQL database into SPSS® 10.0 (SPSS Inc., Chicago, IL) for analysis. Descriptive frequencies and measures of central tendency were used to describe sample characteristics. Percent of answers beyond the clinical threshold values were calculated.

Standard scoring for the SF-8 and SDS were conducted. These scores plus the single items of sexual activities and interest and pain intensity were described in measures of central tendency.

## Results

### Prototype Development

Five radiation oncology clinicians met with the three investigators in July 2001 for the initial focus group. An additional clinician and another investigator joined the focus group in September 2001. Physicians, nurses, and a social worker participated in the iterative prototype development. The first recommendations addressed clinician priorities of brevity, flexibility, and simplicity for input interface and output. The

participants suggested that the assessment output contain color graphics, which normalized the threshold categorical item values at three or higher and displayed the results in two methods: a vertical rank order graph, so high distress could be seen at the "top," and a horizontal bar graph that showed levels above and below the threshold values for each item in order of each query. A final major suggestion included placing truncated language of the patient's selected response in the vertical graph.

Web-based versions of the SF-8 and SDS were developed with a forms-based Web protocol approach, using the LAMP platform as described. The instructions and wording of the original scale items were maintained.

All responses could be answered with a touch selection on a computer screen or with a keyboard touchpad. Participants could move forward and backward by touching arrows at the bottom of the screen. Skipping past items was allowed, but a

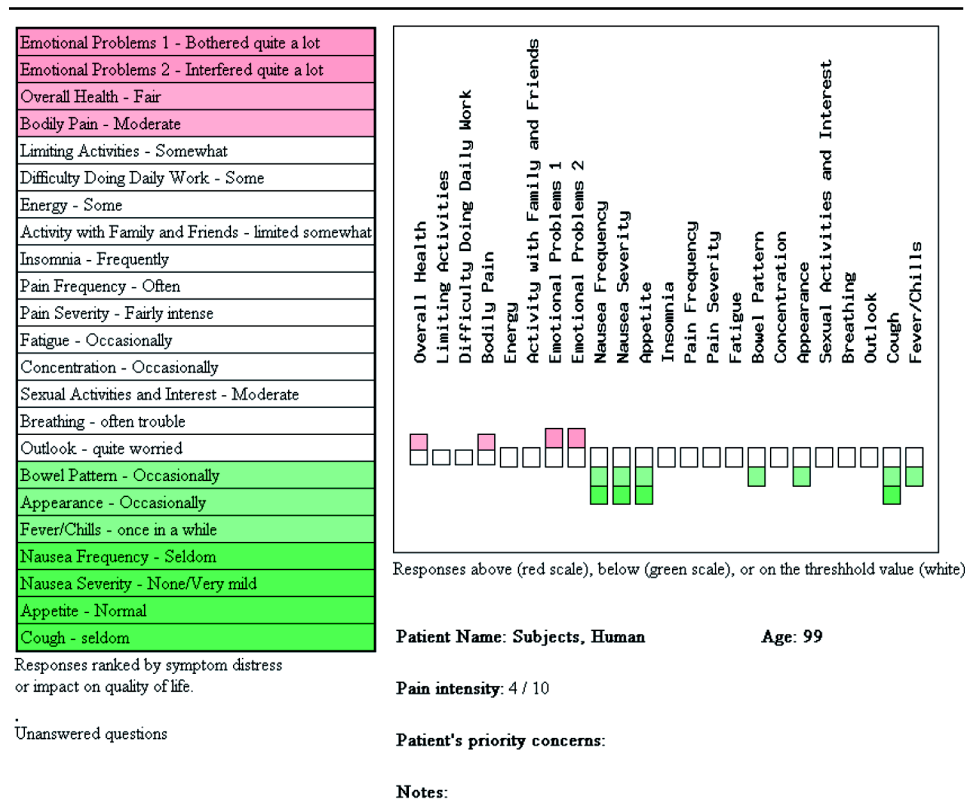


Figure 2. Graphic Results for Clinicians

query at the end of the program asked the respondent whether he or she would like to answer the missed questions. The laptop computer used is lightweight and has a privacy screen (no one else can see the screen from any angle except that of the individual participant).

The computerized QOL and symptom assessment also included demographic items on separate screens. Acceptability questions were added to the assessment to query the participant's opinions about using the electronic assessment (Mullen et al., 2004). Selected responses were stored automatically in a MySQL database file. A one-page color graphic output was generated to display the results of each patient's entries.

## Clinical Findings

Analysis of enrollment records revealed that a total of 121 patients in radiation oncology were approached for participation in the study. Of these, 119 were eligible for the study and 108 agreed to view the consent information onscreen. A detailed analysis of reasons for nonparticipation has been reported elsewhere (Trigg et al., 2003). All but one patient began answering the computerized assessment, with six choosing that their data be used only for clinical use. Therefore, the sample for the following results included 101 participants, 45 women and 56 men with a mean age of 52.7 years (SD = 13.8). Fewer than half of the participants (40%) reported using a computer weekly or daily. Although 9% chose not to report educational levels, 38% reported having an undergraduate or graduate degree, and the majority (53%) reported having received technical training, a high school education, or less.

During deployment of the Web-based assessment tool, the research team members met and resolved a variety of technical problems, including server, hardware, and wireless deployment issues. These occurred largely during system and infrastructure upgrades to improve wireless network security and correct the code for "bugs" that crept into the software as a result of vendor upgrades to components of the LAMP platform software. Another technical interruption of the survey occurred as a result of a misunderstanding of the range of the secure wireless system, when patients (along with the laptop) were seated in a part of the clinic where the wireless signal could not reach. Finally, the research team members found that implementation of such an application required that special attention be paid to how the application is integrated into general clinic workflow. For example, a number of patient assessments were interrupted when the residents, eager to stay ahead of their caseloads, called for patients early and, therefore, patients did not have time to complete their assessments prior to seeing clinicians.

Because of symptom distress, difficulties with the wireless connection, or interruptions by clinic staff, 19 participants were unable to fully complete the electronic assessment. Of the remaining 82 (81%) participants who finished, 70 completed the assessment without major interruption. The 12 participants who were interrupted by clinic staff or the appearance of the consulting physician paused the assessment and continued answering as soon as they could. For those without external interruptions, the total time required to answer the symptom and QOL components of the assessment averaged 7.8 minutes (SD = 3.7).

The SDS, SF-8, and pain intensity scores are summarized in Table 1. Internal consistency was calculated at  $\alpha = 0.83$  for

**Table 1. Symptom Distress, Quality of Life, and Pain Intensity Scores**

Instrument or Item	n	Possible Range	Actual Range	$\bar{x}$	SD
<b>SDS</b>	63	13–65	13–45	25.00	8.30
<b>Quality of life (SF-8)</b>					
Physical component	86	0–100	19.75–63.59	39.76	12.18
Mental component	87	0–100	18.13–64.24	43.72	10.97
<b>Pain intensity</b>	82	0–10	0–9	2.10	2.40

SDS—Symptom Distress Scale; SF-8—Short Form-8

the SDS and at 0.89 and 0.86, respectively, for the SF-8 physical component scale and mental component scale in this sample. Only those with complete data are included in the SDS scale scores. Those scores with missing items on the SF-8 were calculated using the missing data estimation technique employed by Quality Metrics, Inc. (2004). The responses to the single item on sexual activities and interest included 44% reporting minimal or no effect and 27% reporting moderate to great effect or impact of their diagnosis or disease. Seventy percent of the sample replied to this item. The number of participants who selected responses at or above the threshold scores (indicating a level of distress or problem important to address clinically) is listed for each item in Table 2.

## Discussion

Inclusion of end users in the software design process is a practice that has gained widespread acceptance in software design and engineering and might be considered by many as a fundamental requirement of the design process. Involving end users in various ways is an element of several software design approaches, including but not limited to participatory design and rapid application development (Beynon-Davies & Holmes, 1998), contextual inquiry (Spinuzzi, 2000), value-sensitive design (Friedman, Kahn, & Borning, 2003), and customer partnering (Hackos, Elser, & Hammer, 1997). These approaches represent a trend away from the "design expert" model in acknowledgement of the value of the insight and preferences of those who ultimately will use the end software product. Involving end users is thought to increase empowerment of the users (Spinuzzi) and result in software that more closely meets the needs of those who will use the system (Hackos et al.). The research team members found the clinicians eager to participate in focus groups whose purpose was to improve the clinician report design.

The diversity in this sample with regard to age, education, and computer use affirms not only the willingness to participate in such a pilot study, but also the ability of literate people with minimal education to use a simple, touch-screen computer interface. These findings are consistent with a study conducted in cancer clinics and wards in the United Kingdom by Wright et al. (2003); education levels were not predictive of using an automated QOL screening program on touch-screen computers, and younger age was associated with higher use levels. Most of the British sample also reported that they were not frequent computer users.

The average length of time required to answer the questions, 7.8 minutes, was in a reasonable and practical range.

**Table 2. Participants Responding at or Above Threshold Score for Each Item**

Item	n Who Responded	% at or Above Threshold	Rank <sup>a</sup>
<b>Short Form-8</b>			
General health	91	66	2
Physical activities limited by physical health (physical function)	92	32	7
Difficulty doing daily work because of physical health (role physical)	90	27	8
Bodily pain	91	37	6
Energy (vitality)	86	66	1
Limited social activities (social functioning)	85	54	3, 4 <sup>b</sup>
Emotional problems (mental health)	87	54	3, 4 <sup>b</sup>
Emotional problems limiting daily activities (role emotional)	86	38	5
<b>Symptom Distress Scale</b>			
Nausea frequency	80	11	12
Nausea severity	70	11	11
Appetite	78	24	7
Insomnia	78	30	4
Pain frequency	81	33	3
Pain severity	73	26	6
Fatigue	79	44	2
Bowel pattern	77	16	8
Concentration	79	29	5
Appearance	79	13	10
Breathing	77	8	13
Outlook	75	48	1
Cough	75	15	9

<sup>a</sup> 1 = most frequently at or above threshold

<sup>b</sup> Tie

Other reports of computerized screening in cancer settings have used somewhat longer instruments, yet completion times were not distinctly different (e.g., 8.6 minutes reported by Taenzer et al., 2000).

Technical difficulties are known to interrupt the performance of any mechanistic or electronic system, particularly during pilot testing. In this study, wireless connectivity issues were addressed easily once discovered. Because few authors have conducted such evaluations of computerized patient assessment and even fewer have reported the technical findings, the authors are challenged to place their findings in the context of others' work in health care. Wright et al. (2003) described problems with patients inadvertently powering down the PC. A recent report of the computerized PAINReportIT (Wilkie et al., 2003) alluded to technical difficulties, describing an unknown number of comments by users about touchscreen insensitivity and 15 system "crashes" occurring in 213 subject sessions on a PC-based system. The current study's results indicate less severe, quickly correctable technical issues using a wireless, Web-based system.

Most participants who did not complete the computerized assessment were interrupted by clinic staff to conduct routine care (e.g., vital signs) and accompany patients from one area of the clinic to another to wait for examining clinicians. Fu-

ture evaluations must include opportunity to complete the assessment and protection from unwarranted interruptions. Routine application of screening procedures for symptoms and QOL information will necessitate permanent change in the study site's check-in procedures that are founded on time-efficient patient flow patterns. This is the same conclusion reached by Wright et al. (2003); overall compliance with longitudinal, automated QOL screening in cancer services rose from an average of 43% to 72% when the procedure changed from a prospective cohort study without staff prompting to a regular clinic procedure facilitated by check-in staff.

The findings describe a sample of patients with cancer who were about to embark on major cancer therapy. Knowing and documenting baseline information about patients' symptom experiences are accepted universally as requisites to treatment planning and patient education (Yarbro, Frogge, & Goodman, 2003). Yet routine clinical screening of cancer symptoms and other QOL dimensions has not been adapted widely and has been evaluated and reported infrequently. One reason for this lack of clinical application is the unfamiliarity with the meaning of QOL and symptom scores on the part of practicing cancer specialists and oncology nurses (Soni & Cella, 2002). Indeed, the clinician participants in this study voiced no need for output in the clinic that reported numerical scores. The results of item responses in tabular and graphic form, highlighting moderate to high levels of distress in color, were requested. The clinicians in the standing focus group had agreed on a threshold score of three out of five on the SDS and corresponding levels on the SF-8. At this point for each item, the clinicians believed that either further assessment or intervention would be appropriate. Because almost half of the sample reported scores at or above the threshold for SDS items related to fatigue and outlook (worry and fear about the future) and about a third of the respondents identified threshold scores for pain frequency and insomnia, intervention certainly would have been appropriate. Hinds, Schum, and Srivastava (2002) explored the clinical use of SDS threshold item scores in comparison to total scale scores in a sample of 77 adolescents with cancer. Using the same threshold of the third response, they reported underestimation of symptom distress for most of the items when only the scale score was considered. The authors concluded that valuable clinical information is gained by an initial single-item approach to symptom assessment. In this study, the SDS mean score of 25 indicates a moderate level of symptom distress, comparable to four studies of newly diagnosed (within 100 days of diagnosis) patients with cancer with varying stages and diagnoses in which the mean SDS score ranged from 22.8–27.5 (McCorkle et al., 2000). An analysis of the relationship between item scores and total scores is pending.

The physical component score (PCS) and the mental component score (MCS) from the SF-8 indicated worse and somewhat more variable QOL in both physical and mental components than in the general population ( $\bar{X}$  PCS and MCS = 50, SD = 10). Specific comparisons of these scores to reported PCS and MCS scores in the cancer literature are less useful because of the nature of this pilot study with mixed diagnoses and stages of disease. Clearly, the findings describe a sample of patients with cancer who perceive themselves to be compromised in physical and emotional role or function.

Fatigue, pain, and emotional issues were placed in priority positions by the threshold rankings of symptom distress and

QOL items. Although pain frequency was the third most frequently cited symptom of moderate to high distress, pain intensity was reported as less distressful. This could indicate a variety of situations, from well-managed pain control to pain intensity levels associated with newer diagnoses. Completely consistent with recent literature (National Institutes of Health, 2002), this constellation of problems is faced by the majority of patients with cancer.

This developmental pilot study is limited by the very nature of its design. Single-institution findings cannot be generalized beyond the academic radiation oncology setting. Minimal study resources for data collection precluded chart reviews for additional demographic or clinical factors; therefore, differential analyses based on ethnicity or cancer diagnosis cannot be explored.

## Conclusions

Driven by a clinical need to enhance patient assessment, this project and its findings reflect a future direction for oncology clinical care integrated with informatics-based systems. Computerized assessment of cancer symptoms and QOL is feasible in an ambulatory cancer clinic. The ability to capture

an easily interpreted illustration of a patient's symptom and QOL experience in less than 10 minutes is a potentially useful adjunct to traditional face-to-face interviewing. Ultimately, electronic patient-generated data could be used in event-monitoring systems (Tao, Wang, Shortliffe, & Lussier, 2002) to produce automated notifications or "red flags" directed to the most appropriate clinicians (e.g., nurse, pain specialist, social worker, nutritionist) for further evaluation and response. Such system enhancement could greatly facilitate oncology nurses' coordination role in caring for these complex patients with cancer. Automated entry to a database and clinician access to results from any Internet access point are added benefits. Success of future integration of patient-generated data into housewide electronic medical record systems will be founded on developmental efforts such as this study.

*The authors wish to acknowledge Terri Whitney, Mary Monahan, RN, MN, and the staff of the University of Washington Clinical Informatics Research Group for their excellent assistance throughout the project.*

**Author Contact:** Donna L. Berry, PhD, RN, AOCN<sup>®</sup>, can be reached at donnalb@u.washington.edu, with copy to editor at rose\_mary@earthlink.net.

## References

- Allenby, A., Matthews, J., Beresford, J., & McLachlan, S.A. (2002). The application of computer touch-screen technology in screening for psychosocial distress in an ambulatory oncology setting. *European Journal of Cancer Care, 11*, 245–253.
- Andersen, B.L. (1992). Psychological interventions for cancer patients to enhance the quality of life. *Journal of Consulting and Clinical Psychology, 60*, 552–568.
- Beynon-Davies, P., & Holmes, S. (1998). Integrating rapid application development and participatory design. *IEEE Proceedings Software, 145*, 105–112.
- Cam, K., & Trigg, L. (2002). *Cancer electronic quality of life project: Delivering wireless Web-based technology at the point of care*. Unpublished manuscript.
- Carlson, L.E., Specia, M., Hagen, N., & Taenzer, P. (2001). Computerized quality-of-life screening in a cancer pain clinic. *Journal of Palliative Care, 17*, 46–52.
- Cella, D., Chang, C.H., Lai, J.S., & Webster, K. (2002). Advances in quality of life measurements in oncology patients. *Seminars in Oncology, 29*(3, Suppl. 8), 60–68.
- Cleeland, C.S. (2000). Cancer-related symptoms. *Seminars in Radiation Oncology, 10*, 175–190.
- Degner, L.F., & Sloan, J.A. (1995). Symptom distress in newly diagnosed ambulatory cancer patients and as a predictor of survival in lung cancer. *Journal of Pain and Symptom Management, 10*, 423–431.
- Detmar, S.B., Muller, M.J., Schornagel, J.H., Wever, L.D., & Aaronson, N.K. (2002). Health-related quality-of-life assessments and patient-physician communication: A randomized controlled trial. *JAMA, 288*, 3027–3034.
- Dibona, C., Ockman, S., & Stone, M. (Eds.). (1999). Open sources: Voices from the open source revolution. Retrieved January 15, 2004, from <http://www.oreilly.com/catalog/opensources/index.html>
- DiMatteo, M.R., Lepper, H.S., & Croghan, T.W. (2000). Depression is a risk factor for noncompliance with medical treatment: Meta-analysis of the effects of anxiety and depression on patient adherence. *Archives of Internal Medicine, 160*, 2101–2107.
- Dougherty, D. (2001). LAMP: The open source Web platform. Retrieved May 20, 2002, from <http://www.onlamp.com/pub/a/onlamp/2001/01/25/lamp.html>
- Faithfull, S. (1995). 'Just grin and bear it and hope that it will go away': Coping with urinary symptoms from pelvic radiotherapy. *European Journal of Cancer Care, 4*, 158–165.
- Freier, A.O., Karlton, P., & Kocher, P.C. (1996). The SSL Protocol Version 3.0. Netscape Communications Corporation. Retrieved January 15, 2004, from <http://wp.netscape.com/eng/ssl3/draft302.txt>
- Friedman, B., Kahn, P.H., Jr., & Borning, A. (2003). Value sensitive design: Theory and methods. Retrieved February 1, 2004, from <http://www.ischool.washington.edu/vsd/vsd-theory-methods-draft-june2003.pdf>
- Ganz, P.A. (1995). Impact of quality of life outcomes on clinical practice. *Oncology, 9*(11, Suppl.), 61–65.
- Given, C.W., Given, B., Azzouz, F., Stommel, M., & Kozachik, S. (2000). Comparison of changes in physical functioning of elderly patients with new diagnoses of cancer. *Medical Care, 38*, 482–493.
- GNU Project. (2004). GNU Emacs. Retrieved July 27, 2004, from <http://www.gnu.org/software/emacs/emacs.html>
- Hackos, J., Elser, A., & Hammer, M. (1997). Customer partnering: A new approach to needs analysis. *IEEE Transactions on Professional Communication, 40*, 102–110.
- Heitkemper, M., Levy, R.L., Jarrett, M., & Bond, E.F. (1995). Interventions for irritable bowel syndrome: A nursing model. *Gastroenterology Nursing, 18*, 224–230.
- Hinds, P.S., Schum, L., & Srivastava, D.K. (2002). Is clinical relevance sometimes lost in summative scores? *Western Journal of Nursing Research, 24*, 345–353.
- Howe, D. (Ed.) (2004a). Client. Retrieved January 15, 2004, from <http://wombat.doc.ic.ac.uk/foldoc>
- Howe, D. (Ed.) (2004b). Open source. Retrieved January 15, 2004, from <http://wombat.doc.ic.ac.uk/foldoc>
- Howe, D. (Ed.) (2004c). Wireless. Retrieved January 15, 2004, from <http://wombat.doc.ic.ac.uk/foldoc>
- King, C.R., Haberman, M., Berry, D.L., Bush, N., Butler, L., Dow, K.H., et al. (1997). Quality of life and the cancer experience: The state-of-the-knowledge. *Oncology Nursing Forum, 24*, 27–41.
- Levine, M.N., & Ganz, P.A. (2002). Beyond the development of quality-of-life instruments: Where do we go from here? *Journal of Clinical Oncology, 20*, 2215–2216.
- McCorkle, R. (1987). The measurement of symptom distress. *Seminars in Oncology Nursing, 3*, 248–256.
- McCorkle, R., Cooley, M., & Shea, J. (2000). *A user's manual for the symptom distress scale*. Unpublished manuscript.
- McCorkle, R., & Quint-Benoliel, J. (1983). Symptom distress, current con-



- cerns and mood disturbance after diagnosis of life-threatening disease. *Social Science and Medicine*, 17, 431–438.
- McCorkle, R., & Young, K. (1978). Development of a symptom distress scale. *Cancer Nursing*, 1, 373–378.
- McGuire, D.B. (1984). The measurement of clinical pain. *Nursing Research*, 33, 152–156.
- Mullen, K.H., Berry, D.L., & Zierler, B.K. (2004). Computerized symptom and quality-of-life assessment for patients with cancer. Part II: Acceptability and usability. *Oncology Nursing Forum*, 31, 896.
- MySQL-AB. (2003). MySQL. Retrieved April 1, 2003, from <http://www.mysql.com>
- National Institutes of Health. (2002, October 26). *State-of-the-science conference on symptom management in cancer: Pain, depression, and fatigue*. Retrieved January 21, 2003, from <http://consensus.nih.gov/ta/022/cancerfinalstatement-10-26-.pdf>
- Netscape. (2003). Secure sockets layer. Retrieved January 15, 2004, from <http://wp.netscape.com/security/techbriefs/ssl.html?cp=sciln>
- Page, G.G., & Ben-Eliyahu, S. (1998). *Pain kills: Animal models and neuro-immunological links*. Seattle, WA: IASP Press.
- Peruselli, C., Camporesi, E., Colombo, A.M., Cucci, M., Sironi, P.G., Bellodi, M., et al. (1992). Nursing care planning for terminally ill cancer patients receiving home care. *Journal of Palliative Care*, 8(4), 4–7.
- PHP Group. (2004). What can PHP do? Retrieved January 15, 2004, from <http://us3.php.net>
- Pirl, W.F., & Roth, A.J. (1999). Diagnosis and treatment of depression in cancer patients. *Oncology*, 13, 1293–1302.
- Piskiel, H. (2000). Rules-driven authorization. Securities Industry Middleware Council, Inc. Retrieved January 15, 2004, from <http://www.simc-inc.org/archive9900/Feb00/neon/Default.htm>
- Portenoy, R.K., Thaler, H.T., Kornblith, A.B., Lepore, J.M., Friedlander-Klar, H., Coyle, N., et al. (1994). Symptom prevalence, characteristics and distress in a cancer population. *Quality of Life Research*, 3, 183–189.
- Portenoy, R.K., Thaler, H.T., Kornblith, A.B., Lepore, J.M., Friedlander-Klar, H., Kiyasu, E., et al. (1994). The Memorial Symptom Assessment Scale: An instrument for the evaluation of symptom prevalence, characteristics and distress. *European Journal of Cancer*, 9, 1326–1336.
- Quality Metrics, Inc. (2004). Comparisons among SF surveys. Retrieved August 10, 2004, from <http://www.qualitymetric.com/products/CompareSFSurveys.shtml>
- Ropka, M.E., Guterbock, T., Krebs, L., Murphy-Ende, K., Stetz, K., Summers, B., et al. (2002). Year 2000 Oncology Nursing Society Research Priorities Survey. *Oncology Nursing Forum*, 29, 481–491.
- Soni, M.K., & Cella, D. (2002). Quality of life and symptom measures in oncology: An overview. *American Journal of Managed Care*, 8(18, Suppl.), S560–S573.
- Spinuzzi, C. (2000, June). *Investigating the technology-work relationship: A critical comparison of three qualitative field methods*. Paper presented at the Proceedings of IEEE Professional Communication Society International Professional Communication Conference, Cambridge, MA.
- Taenzler, P., Bultz, B.D., Carlson, L.E., Specia, M., DeGagne, T., Olson, K., et al. (2000). Impact of computerized quality of life screening on physician behaviour and patient satisfaction in lung cancer outpatients. *Psychooncology*, 9, 203–213.
- Tao, Y., Wang, D., Shortliffe, E.H., & Lussier, Y.A. (2002). Extended attributes of event monitor systems for criteria-based notification modalities. *Proceedings of AMIA Symposium*, 762–766.
- Trigg, L., Berry, D., Karras, B., Austin-Seymour, M., & Lober, W. (2003). Feasibility of patient entered QOL assessment data in a radiation oncology clinic. In H. Marin, E. Marques, E. Hovenga, & W. Goosen (Eds.), *eHealth for all: Designing nursing agenda for the future* [CD-ROM]. San Palo, Brazil: NI 2003.
- Ulman, L. (2001). *PHP for the World Wide Web*. Berkeley, CA: Peachpit Press.
- Velikova, G., Brown, J.M., Smith, A.B., & Selby, P.J. (2002). Computer-based quality of life questionnaires may contribute to doctor-patient interactions in oncology. *British Journal of Cancer*, 86, 51–59.
- Ware, J. (2000). SF-8 health survey. Retrieved July 27, 2004, from <http://www.sf-36.org/tools/sf8.shtml>
- Wickham, R. (1999). Nausea and vomiting. In C.H. Yarbro, M.H. Frogge, & M. Goodman (Eds.), *Cancer symptom management* (pp. 228–263). Sudbury, MA: Jones and Bartlett.
- Wilkie, D.J., Judge, M.K., Berry, D.L., Dell, J., Zong, S., & Gillespie, R. (2003). Usability of a computerized PAINReportIt in the general public with pain and people with cancer pain. *Journal of Pain and Symptom Management*, 25(3), 213–224.
- Wright, E.P., Selby, P.J., Crawford, M., Gillibrand, A., Johnston, C., Perren, T.J., et al. (2003). Feasibility and compliance of automated measurement of quality of life in oncology practice. *Journal of Clinical Oncology*, 21, 374–382.
- Wujcik, D. (1999). Infection. In M.H. Frogge, C.H. Yarbro, & M. Goodman (Eds.), *Cancer symptom management* (3rd ed., pp. 307–327). Sudbury, MA: Jones and Bartlett.
- Yarbro, C.H., Frogge, M.H., & Goodman, M. (Eds.). (2003). *Cancer symptom management* (3rd ed.). Sudbury, MA: Jones and Bartlett.
- Zabora, J.R., Blanchard, C.G., Smith, E.D., Roberts, C.S., Glajchen, M., Sharp, J.W., et al. (1997). Prevalence of psychological distress among cancer patients across the disease continuum. *Journal of Psychosocial Oncology*, 15(2), 73–87.