Validation of the Patient Care Monitor (Version 2.0): A Review of System Assessment Instrument for Cancer Patients

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Abstract

Context. The Patient Care Monitor (PCM) is a review of systems survey delivered by means of an electronic patient-reported outcomes (ePRO) data capture system that uses wireless tablet computers. Although the PCM 1.0 is validated, the updated PCM 2.0 has not been validated nor tested in the academic setting.

Objectives. To validate and test the PCM 2.0 in three cancer populations.

Methods. Two hundred seventy-five individuals participated in three clinical trials enrolling breast (n = 65), gastrointestinal (n = 113), and lung (n = 97) cancer patients. Internal consistency was evaluated using Cronbach’s alpha coefficients calculated for six PCM subscales (general physical symptoms, treatment side effects, distress, despair, impaired performance, and impaired ambulation) and a Quality-of-Life Index. Construct validity was evaluated through Pearson’s correlation between PCM subscales and subscales of the Functional Assessment of Cancer Therapy—General (FACT-G), the M.D. Anderson Symptom Inventory (MDASI), and the Functional Assessment of Chronic Illness

Conflict of interest was reported to the Duke University Health System Internal Review Board and Duke Conflict of Interest Committee. All of this work and result reporting were completed before the consulting agreement between Dr. Abernethy and SOS, Inc., was developed. The lung cancer protocol was conducted after Dr. Abernethy’s contract with SOS, Inc., was terminated. Dr. Abernethy provided nominal consulting to Pfizer, Inc., and received nominal honoraria from Pfizer, Inc., during the study periods.

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Therapy—Fatigue (FACIT-F). The participants had the following characteristics:

mean age was 58 years (standard deviation: 11), 52% were females, 79% were
whites, 17% were blacks, 62% had no college degree, and 78% had metastatic or
recurrent disease.

**Results.** Raw and normalized scores for PCM 2.0 subscales were internally
consistent across study cohorts. PCM 2.0 subscales correlated significantly
($P < 0.05$) with the corresponding subscales on FACT-G, MDASI, and FACIT-F,
with the exception of FACT-G social well-being, particularly for the lung cancer
population. These correlations demonstrated construct validity. PCM 2.0 results
followed expected patterns by cancer etiology. Prior reports demonstrate patient
satisfaction with PCM 2.0.

**Conclusion.** Within three unique academic oncology populations, PCM 2.0 is
a valid ePRO instrument for assessing symptoms with seven patient-centered
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**Key Words**

Patient-reported outcomes, electronic surveys, survey validation, cancer symptoms

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**Introduction**

Patient-reported outcomes (PROs) have increasingly gained acceptance as important
measures of physical symptoms and subjective constructs, such as quality of life (QOL).1–4
PROs are relevant for both patient-centered research and day-to-day clinical practice.5
Outside observers, such as clinicians, might underestimate the importance of symptoms and
symptom-related problems.6,7 Particularly in oncology, recognition is growing that traditional medical outcomes (i.e., survival, disease-free progression) do not fully capture the patient’s experience of health, and that a comprehensive picture of the patient’s health status must include the patient report. A recent analysis of data from 39 studies, which collected both baseline PROs and survival data, found that, in 36 of 39 studies, at least one PRO was a statistically significant predictor of mortality.8

Studies in diverse populations have found that technology-based methods of PRO data
collection in both research and clinical contexts are well received by patients, if not preferred over paper-based instruments.9–14 The comparability of PRO data collected by paper and by computer has been confirmed by meta-analysis.15 Regular, repeated electronic PRO (ePRO) collection and feedback to physicians have been shown to facilitate physician-patient communication and to exert a positive impact on QOL and emotional functioning.16

The use of wireless tablet computers programmed with PRO survey instruments is a well-developed technology for capturing patient-reported data. Surveys appear in a seamless fashion, with one question per screen.17 Patients can use computers in the clinic waiting area or chemotherapy treatment room to complete assessments. ePRO information travels securely over wireless channels into a central
database, warehousing longitudinal data locally and/or across multiple sites. ePRO data can also be collected online by means of a secure Internet connection.18,19 ePRO data collection systems can use a variety of technology platforms other than tablet computers. However, the portability and opportunity for bidirectional information flow in the clinic waiting room makes the tablet computer (“e/Tablet”) a preferred contemporary technology in many instances.

The Patient Care Monitor (PCM, formerly Cancer Care Monitor) is a review of systems survey instrument comprising 80 items (86 for women). Developed by Fortner et al., it is delivered by means of ePRO systems commonly used in U.S. community oncology clinics. The PCM 1.0 survey has been validated for collection of symptom data in this setting;20,21 the updated 2.0 version incorporates minor modifications reflective of evolving
cancer treatments and toxicities. After the patient completes the PCM, a summary report reflecting the patient’s symptoms, psychological distress, QOL, and current activities over the prior four visits is generated at the point of care for medical review. The report is color coded, enabling the oncologist to quickly identify trends of worsening or improving problems and symptom severity.

The purpose of this study was to validate the PCM 2.0 in the academic oncology setting and to provide summary comparisons of the PCM with other PRO instruments commonly used for clinical research. The Food and Drug Administration draft guidance on PRO endpoints addresses the issue of validation of new instruments and, in the case of new electronic instruments, advises validation testing to ensure that a computerized measure is equivalent to its paper-based counterpart. In the case of the PCM, validation against a paper-based version was not possible, as the survey was originally developed for electronic delivery (PCM 1.0). Instead, this study sought to validate the PCM 2.0 by evaluating its internal consistency and by analyzing the correlation of PCM subscale results with similar subscales of other well-validated research instruments that are available in both paper and electronic versions.

Methods
Design
Validation of the PCM 2.0 constituted a sub-study of an overarching suite of trials conducted in three distinct cancer populations—breast, lung, and gastrointestinal (GI) cancer. A common denominator across trials was the use of an e/Tablet-based ePRO data collection system to administer a battery of standard assessment instruments. Each population was enrolled in a separate research protocol to ensure the assessment of the population independent of the other two cohorts.

The main objectives of the breast and GI cancer studies were to 1) test the logistical feasibility of electronic data collection using e/Tablets; 2) evaluate the equivalence of PRO data collected by paper and electronic methods; and 3) determine patient satisfaction with e/Tablets. The lung cancer protocol had similar objectives but also sought to understand the natural history of anorexia-cachexia syndrome in advanced lung cancer. Anorexia-cachexia syndrome is a complex experience, and patient-reported data are central to its assessment; in the lung cancer study, we sought to demonstrate how the ePRO monitoring method could be expanded as needed to provide in-depth information about a specific patient-centered concern.

The protocol for each of the three studies described a nonrandomized, single-arm pilot trial conducted in five academic (Duke; University of North Carolina—Chapel Hill [UNC]) or community cancer center settings. The protocol and all procedures were approved by the Duke Institutional Review Board (IRB) and UNC IRB, as appropriate. Participants were enrolled: March to September 19, 2006 (breast); February to October 2007 (GI); and December 2007 to June 2008 (lung). Practicing oncologists referred patients for screening, consent, and enrollment. Studies followed common standardized procedures, and surveys were delivered on successive clinic visits, according to the respective protocols (Table 1). This article reports the summarized results of the three PCM validation studies, with data presented separately for each population and also in aggregate for the total population.

Participants and Setting
Patients eligible for the breast cancer study were English-speaking, consenting adults with a pathologic diagnosis of breast cancer (any stage) and expecting at least four further visits (including prechemotherapy checks) to the Duke Breast Cancer Clinic over six months. Of 73 patients screened, 66 eligible patients enrolled (90% acceptance rate), and 65 completed at least one PCM assessment.

Patients eligible for the GI cancer study were English-speaking, consenting adults with a pathologic diagnosis of GI malignancy (any stage), receiving care in the Duke or UNC GI Oncology Clinics, and expecting at least four further visits (including prechemotherapy checks) to the clinic over six months. Of 121 patients screened, 115 eligible patients enrolled (90% acceptance rate), and 113 completed at least one PCM assessment.

Patients eligible for the lung cancer study were English-speaking, consenting adults with a pathologic diagnosis of Stage IV non-small
### Table 1

**Summary of Procedures**

<table>
<thead>
<tr>
<th>Study Population</th>
<th>Primary Study Aims</th>
<th>Frequency of PCM Administration</th>
<th>Instruments Used</th>
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<tr>
<td>GI</td>
<td>1) Determine whether there is high agreement between data collected by means of e/Tablets and data collected by means of paper forms; 2) locally validate the PCM survey; 3) describe the problems and challenges encountered in the administration of patient-reported outcomes by means of e/Tablets and determine workable solutions; 4) determine the best surveys to administer by this manner; 5) create a reliable longitudinal system for ROS and other survey data collection for GI malignancy patients that can be used within the clinical encounter to improve practice efficiency, patient and clinician satisfaction, and quality improvement processes.</td>
<td>Minimum 4 times in 6 months Beginning time ≥5 using the e/Tablet data collection system; participants were asked if they wanted to continue participation. If they elected to continue: • They would still receive the complete electronic survey battery; • Their personal health data would still be collected as part of the e/Tablet pilot feasibility study; and • They would not fill out any further paper-based surveys.</td>
<td>• Demographics o Up to 14 questions depending on responses o Participant answers the first time using e/Tablet only • SOS Patient Care Monitor 2 o Up to 86 questions (80 for men; 86 for women) measured on 0–10 11-point scales o Only administered electronically • FACT-G plus disease-specific supplemental questions o FACT-G = 27 questions on 0–4 5-point scales o Electronic and paper-based versions (combined with the FACT supplemental questions) o Supplemental questions: ▪ FACT-C—colorectal cancer supplemental questions; 10 questions measured on 0–4 5-point scales (1 is a yes/no question) ▪ FACT-E—esophageal cancer supplemental questions; 17 questions measured on 0–4 5-point scales ▪ FACT-Hep—hepatobiliary cancer supplemental questions; 18 questions measured on 0–4 5-point scales ▪ FACT-Ga—gastric cancer supplemental questions; 19 questions measured on 0–4 5-point scales • MDASI: MD Anderson Symptom o 19 questions measured on 0–10 11-point scales o Electronic and paper-based versions • GOG Neurotoxicity Scale o 11 questions measured on 0–4 5-point scales o Electronic and paper-based versions • Self-Efficacy Scale o 16 questions measured on 10–100 10-point scales o Electronic and paper-based versions • NCCN Distress Scale o 34 questions—1 measured on 0–10 11-point scale and 33 yes/no questions o Only the electronic version used • Satisfaction with care o 21 questions o Only the electronic version used • Acceptance and satisfaction with the e/Tablet system o 11 questions o Only the electronic version used</td>
</tr>
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</table>
Breast

1) Assess e/Tablets as a feasible way of collecting patient-reported information in the Duke Breast Cancer Clinic; 2) provide insight into our ability to use the e/Tablet to collect survey data from common instruments used in clinical practice and trials here at Duke, such as the FACT QOL Scale; 3) understand practical challenges and solutions to use this technology in our environment; 4) serve as local validation study of the PCM survey instrument as compared with standard survey instruments (e.g., FACT).

Minimum 4 times in 6 months
Beginning time ≥5 using the e/Tablet data collection system; participants were asked if they wanted to continue participation. If they elected to continue:
- They would still receive the complete electronic survey battery;
- Their personal health data would still be collected as part of the e/Tablet pilot feasibility study; and
- They would not fill out any further paper-based surveys.

Lung

1) Better understand the lung cancer patient experience as it relates to CACS, from both the cross-sectional and longitudinal standpoints; 2) establish a specific definition of CACS for subsequent KLT studies and to determine the prevalence of CACS in NSCLC patients according to this definition; 3) assess the feasibility of a KLT Phase II trial among NSCLC patients at Duke; 4) program e/Tablets with assessment surveys relevant to CACS in lung cancer patients; and 5) document the validity of the electronic scales that will be used for a subsequent Phase II trial in patients with inoperable NSCLC.

Patients asked to complete 1 of 3 different survey instruments—FACT-L, FAACT, and FACIT-F—on paper at the initial time point. Patients provided basic information on dietary intake. If participants agreed, they completed the electronic battery during subsequent clinic visits for up to 6 months (maximum 4 clinic visits including baseline).

- Demographics
  - Participant answers the first time using e/Tablet only
- SOS PCM 2
  - Up to 86 questions measured on 0–10 11-point scales
  - Only administered electronically
- FACT-B
  - 37 questions measured on 0–4 5-point scales
  - Electronic and paper-based versions
- MDASI
  - 19 questions measured on 0–10 11-point scales
  - Electronic and paper-based versions
- FACT-F
  - 13 questions measured on 0–4 5-point scales
  - Electronic and paper-based versions
- Self-Efficacy Scale
  - 16 questions measured on 10–100 10-point scales
  - Electronic and paper-based versions
- Satisfaction with care—subset of the new ambulatory oncology Press Ganey questions
  - 21 questions
  - Only electronic version used
  - Collected every other visit as proof of concept
- Acceptance and satisfaction with the e/Tablet system
  - 8 questions
  - Only the electronic version used
  - Collected every other visit as proof of concept
- Demographics—6 items with up to 9 total questions depending on responses
- PCM—86 items for women; 79 items for men
  - FACT-L—36 items
  - FAACT—12 items
  - FACIT-F—13 items
  - Nutrition survey—15 items

NSCLC = non-small cell lung cancer; ROS = review of systems; NCCN = National Comprehensive Cancer Network; CACS = cancer anorexia cachexia syndrome; KLT = Kanglaite; FAACT = Functional Assessment of Anorexia/Cachexia Therapy.
cell lung cancer (of any histologic subtype), and receiving oncology care at the Duke Thoracic Oncology or Duke Health Raleigh Oncology Clinic. Of 136 patients screened, 99 eligible patients enrolled, and 97 completed at least one PCM assessment.

Procedures

The three studies followed a common set of procedures that accommodated adjustments to the specifics of each population as well as protocol modifications based on experience. A “patient flow protocol” for handing out the tablet computers, identifying appropriate survey instruments for each participant at each time point, collecting computers, and getting reports to clinicians, was prepared and approved by all clinic senior medical and nursing staff. A “clinical response thresholds protocol” was developed to standardize clinician response to urgent symptom scores (e.g., if the patient reports “chest pain” or suicidal ideation of any level on the PCM, then research staff alert the midlevel provider or attending physician verbally and document this alert in writing). These protocols were requested by clinic administrators and were important for achieving buy-in of physicians and administrators alike.

Four study visits were planned. At each visit, participants completed the planned survey instruments; the surveys to be completed, survey order, and timing of assessments were customized to each participant according to the respective protocol. Research staff launched the designated surveys on the e/Tablet, identifying survey order as needed. Participants completed a demographics survey electronically at the first visit only; all other electronic surveys and an eight-item e/Tablet satisfaction survey were presented in full at each study visit. Participants received $25 reimbursement per visit for their time.

Instruments

The following instruments were used, after obtaining permission from the instruments’ authors:

1. PCM 2.0 Review of Systems Survey.\textsuperscript{20} PCM 2.0 comprises 86 items for women and 80 items for men, rated on 11-point (0–10) scales. The PCM is administered only in electronic form and is the standard assessment programmed onto the e/Tablet-based ePRO data collection system. It has six subscales (general physical symptoms, treatment side effects, distress, despair, impaired performance, and impaired ambulation) and a Quality-of-Life (QOL) Index, which incorporate 54 of the total items. The PCM was completed by all three study populations.

2. Functional Assessment of Cancer Therapy—General (FACT-G).\textsuperscript{23} FACT-G comprises 27 items rated on 5-point (0–4) scales and was completed by all three study populations. There are four subscales (physical, emotional, functional, and social well-being). Disease-specific surveys supplemental to the FACT-G included the following: FACT-B\textsuperscript{24} (breast cancer supplement); FACT-C\textsuperscript{25} (colorectal cancer supplement); FACT-L\textsuperscript{26} (lung cancer supplement). The FACT/GOG-Ntx\textsuperscript{27} (Gynecologic Oncology Group, neurotoxicity supplement) was used in the GI cancer study.

3. Functional Assessment of Chronic Illness Therapy—Fatigue Scale (FACIT-F).\textsuperscript{28} FACIT-F comprises 13 items rated on 5-point (0–4) scales. FACIT-F was completed by the breast and lung cancer populations.

4. M.D. Anderson Symptom Inventory (MDASI).\textsuperscript{29} MDASI comprises 19 items rated on 11-point (0–10) scales. There are two subscales measuring symptom severity and interference with daily living. The MDASI was completed by the breast and GI cancer populations.

Electronic Patient-Reported Outcome Data Capture System

We modified the Patient Assessment Care and Education System (PACE\textsuperscript{TM} System), developed by Supportive Oncology Services, Inc. (Memphis, TN), to electronically deliver multiple surveys in addition to the PCM 2.0. An American National Standards Institute-compliant database built on Microsoft SQL Server (version 08.00.0760; Seattle, WA) warehoused ePRO data; the server was behind the institutional (Duke or UNC) firewall and was backed up every night. Data were extracted using SAS 9.1 (SAS Institute Inc., Cary, NC).
analysis. A more complete description of the e/Tablet-based ePRO data collection system is presented elsewhere.5

Statistical Analysis

Statistical analyses focused on two time points: the first and last assessments during which the patient completed the PCM. The number of PCM assessments completed by the patient in between these time points varied depending on how long the patient remained in the study. Any patient completing only one PCM was included only in the first assessment analysis. All analyses were conducted using SAS 9.1. A two-sided significance level of 0.05 was used.

PCM 2.0 data were scored using an algorithm provided by the developers of the PCM (Supportive Oncology Services). Four of the six subscales were identical in PCM versions 1.0 and 2.0. Additional items were added to the general physical symptoms (four items) and treatment side effects (five items) subscales in version 2.0, allowing for a more accurate assessment of symptoms. To score these subscales, the additional PCM 2.0 items were used to create composite symptom items for use in the subscales (e.g., rash, dry skin, and itching were combined to create a single skin item). These composite items were computed using predefined regression coefficients derived from PCM 1.0. The QOL index was calculated by dividing each of the six PCM 2.0 subscale scores by the number of items, summing the resulting quotients, and multiplying that sum by \( \frac{1}{2} \). For each of the subscale scores and the QOL index, normalized T-scores were determined from PCM 1.0 look-up tables provided by the instrument’s authors.

Internal consistency for each of the seven subscales of the PCM 2.0 was evaluated through computation of 1) standardized Cronbach’s alpha coefficients for the PCM subscales and 2) Pearson correlation coefficients among the PCM subscales. Cronbach’s alpha coefficients were computed excluding the NOMISS option in SAS PROC CORR to allow for missing values.

Construct (convergent) validity was evaluated through calculation of Pearson correlation coefficients for the relationship between the PCM 2.0 (by subscale) and the FACT-G (by subscale), FACIT-F, and MDASI (by subscale). Other surveys administered in the three studies (e.g., disease-specific FACT instruments) were not included in this analysis if they were specific to one study only.

Formal test-retest reliability of the PCM, with repeated assessments in close time proximity, had been previously established and, therefore, was not repeated in this study.20 Given the exceptional similarity between PCM 1.0 and 2.0, it was removed from protocols to reduce participant burden. We evaluated whether PCM characteristics were performing similarly on two time points in terms of their internal consistency and construct validity. Because these time points were distant in time, and hence patient concerns were likely to have changed, we did not assess within-subject reliability.

Results

Participants’ (n = 275) characteristics were as follows: 52% were females; mean age at study enrollment was 58 years (standard deviation, 11); 79% were whites, 17% were African Americans; 62% had less than a college degree; 74% were married or partnered; 78% had metastatic or recurrent disease. Demographics differed between the three study populations in a manner expected for these three diseases (Table 2).

Raw and normalized PCM 2.0 subscale scores were similar across the three populations (Table 3), with minor differences consistent with that which would be expected by cancer etiology (e.g., metastatic lung cancer patients have slightly poorer QOL T-scores [lower scores] and worse impairment of ambulation [higher scores]). Cronbach’s alpha coefficients for the PCM 2.0 subscales in these populations were nearly all acceptable (>0.70) for both PCM time points assessed, indicating good internal consistency that persisted over time (Table 3). These coefficients were similar to those published for PCM 1.0 from the community oncology validation study (references in Table 3).

Pearson correlation coefficients among PCM subscales were similar across the three study populations; results are presented for the combined analysis only (Table 4). Patterns were consistent with the expected relationships between domains. Highest correlations
The lowest correlations were found between distress and impaired performance (0.33, 0.32) and distress and impaired ambulation (0.31, 0.38). All correlations were significant at the 0.05 level.

To assess construct validity and confirm that PCM domains are correlating with corresponding domains in the FACT-G, FACIT-F, and MDASI, Pearson correlation coefficients were calculated. With the exception of the FACT-G social well-being subscale in the lung cancer population, nearly all correlations with the PCM subscales were statistically significant (i.e., $P \leq 0.05$). High correlations (>0.5) were notable for subscale domains reflecting similar constructs (Table 5), including:

- PCM QOL subscale and the FACT-G physical well-being subscale (0.75 and 0.82 for first and last assessments, respectively, in the total population);
- PCM distress subscale and the FACT-G emotional well-being subscale (−0.73, −0.82);
- PCM general physical subscale and FACT-G physical well-being subscale (−0.70, −0.76);
- PCM despair subscale and the FACT-G emotional well-being subscale (−0.63, −0.77);
- PCM impaired performance and FACIT-F (−0.71, −0.71);
- PCM general physical subscale and FACIT-F (−0.63, −0.71);
- PCM QOL subscale and FACIT-F (0.72, 0.77);
- PCM QOL and MDASI severity (−0.65, −0.82) and interference (−0.78, −0.82) subscales.

### Discussion

This study establishes the validity—in three academic oncology populations—of a PRO-based review of systems data collection instrument, which is widely used in community oncology clinical practice, the PCM 2.0. Our patient sample was ethnically and socioeconomically diverse, because more than 20% were nonwhite and 62% had less than...
### Table 3

<table>
<thead>
<tr>
<th>Subscales</th>
<th>Breast Mean (SD)</th>
<th>Breast T-Score</th>
<th>Breast Alpha&lt;sup&gt;a&lt;/sup&gt;</th>
<th>GI Mean (SD)</th>
<th>GI T-Score</th>
<th>GI Alpha&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Lung Mean (SD)</th>
<th>Lung T-Score</th>
<th>Lung Alpha&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Total Mean (SD)</th>
<th>Total T-Score</th>
<th>Total Alpha&lt;sup&gt;a&lt;/sup&gt;</th>
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<tr>
<td>General physical symptoms</td>
<td>65 21.58 (14.60)</td>
<td>50.7 0.81</td>
<td>113 18.30 (11.67)</td>
<td>97 21.88 (15.84)</td>
<td>51.0 0.81</td>
<td>275 20.34 (13.25)</td>
<td>50.1 0.79</td>
<td>0.83</td>
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<tr>
<td>Treatment side effects</td>
<td>65 13.16 (10.63)</td>
<td>50.8 0.80</td>
<td>113 9.82 (7.31)</td>
<td>97 11.89 (8.86)</td>
<td>50.3 0.75</td>
<td>275 11.34 (8.81)</td>
<td>49.9 0.74</td>
<td>0.80</td>
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<td>Distress</td>
<td>65 6.05 (7.97)</td>
<td>49.8 0.92</td>
<td>112 5.68 (7.32)</td>
<td>97 6.38 (8.60)</td>
<td>49.9 0.93</td>
<td>274 6.01 (7.93)</td>
<td>49.7 0.91</td>
<td>0.87</td>
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<tr>
<td>Despair</td>
<td>65 4.46 (7.96)</td>
<td>50.1 0.87</td>
<td>113 5.46 (10.07)</td>
<td>97 6.98 (12.20)</td>
<td>51.8 0.94</td>
<td>275 5.76 (10.46)</td>
<td>51.1 0.92</td>
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<td>Impaired performance</td>
<td>61 9.57 (10.53)</td>
<td>45.0 0.91</td>
<td>109 10.75 (10.14)</td>
<td>90 13.81 (10.87)</td>
<td>47.9 0.88</td>
<td>260 11.53 (10.59)</td>
<td>46.2 0.89</td>
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<td>Impaired ambulation</td>
<td>65 2.74 (4.90)</td>
<td>52.5 0.77</td>
<td>112 2.65 (4.65)</td>
<td>96 4.16 (6.26)</td>
<td>55.0 0.84</td>
<td>273 3.20 (5.35)</td>
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<td>Quality of life</td>
<td>61 −8.95 (7.71)</td>
<td>52.1 0.94</td>
<td>107 −8.44 (6.89)</td>
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<tr>
<td>General physical symptoms</td>
<td>59 21.52 (13.63)</td>
<td>50.8 0.74</td>
<td>96 19.93 (13.18)</td>
<td>77 21.45 (14.28)</td>
<td>50.7 0.78</td>
<td>232 20.84 (13.63)</td>
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<tr>
<td>Treatment side effects</td>
<td>60 13.08 (9.68)</td>
<td>50.9 0.72</td>
<td>96 10.92 (8.23)</td>
<td>78 12.61 (8.78)</td>
<td>50.8 0.70</td>
<td>234 12.94 (8.82)</td>
<td>50.3 0.72</td>
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<td>Distress</td>
<td>59 6.71 (8.62)</td>
<td>50.6 0.94</td>
<td>96 5.53 (7.76)</td>
<td>77 5.94 (7.46)</td>
<td>49.3 0.89</td>
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<td>49.5 0.93</td>
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<td>51.1 0.91</td>
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<tr>
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<td>53 11.85 (11.46)</td>
<td>46.4 0.92</td>
<td>93 11.52 (10.63)</td>
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<td>48.7 0.92</td>
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<sup>a</sup>Standardized Cronbach’s alpha coefficients were computed excluding the NOMISS option in SAS PROC CORR to allow for missing values.

<sup>b</sup>Published results are based on PCM 1.0 from Ref. 20.
a college degree. Validity was defined in research-based terms for this clinical tool. By design, this validation study used three separate protocols in three distinct cancer populations at two time points; data were evaluated separately by study population and in aggregate for the total population. In this way, the design constituted three validations of the PCM, in each of the three diseases in the academic setting, while enabling comparison of results in distinct populations to evaluate the stability of PCM subscales across populations and over time. PCM raw and normalized subscale scores were consistent across the three study populations. Comparability of results across populations suggests that this instrument may be generalizable to various cancer populations in academic oncology.

Cronbach’s alpha coefficients were nearly all greater than 0.70, demonstrating that internal consistency was similar to published values. Correlations calculated between PCM 2.0 subscales measuring similar domains (e.g., distress and despair) and subscales for corresponding domains in three other well-validated oncology assessment instruments provided evidence of construct validity. Highly correlated subscales (e.g., PCM QOL and FACT-G physical well-being, PCM QOL and FACIT-F, PCM Distress and FACT-G emotional well-being) were sensible, indicating that the PCM subscales do, indeed, measure the constructs that they purport to measure. Low correlation coefficients were found between subscales measuring constructs that would not be expected to be correlated with one another (e.g., social well-being and PCM subscales). Results held up across disease groups and time.

This validation study should be viewed within the larger context of the evolution of patient assessment in oncology. PROs are a relatively recent addition to assessment measures in academic oncology, and their recognition as valid endpoints is still building. Traditional data systems—clinical, administrative, and research—do not typically capture assessment information directly from patients. Moreover, routine patient assessment has not historically encompassed many of the items included in PRO surveys, such as various subjective symptoms, affective measures, and QOL. Correspondingly, attention to assessment instruments that can capture PROs in oncology is a relatively new phenomenon.

What is unique about the PCM 2.0, and its distinct advantage, is its utility simultaneously as a clinical and research tool. The PCM 2.0 constitutes a full review of systems that can be used in patient management and clinical decision making. It also allows for calculation of seven subscales, including a global QOL score, which can be used to monitor

<table>
<thead>
<tr>
<th>PCM Subscales</th>
<th>General Physical Symptoms</th>
<th>Treatment Side Effects</th>
<th>Distress</th>
<th>Despair</th>
<th>Impaired Performance</th>
<th>Impaired Ambulation</th>
<th>Quality of Life</th>
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Values within brackets indicate n. Bold values highlight correlations ≥0.70. All correlations were significant at the 0.05 level.
<table>
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<tr>
<th>Assessment</th>
<th>FACT-G Physical (Total)</th>
<th>FACT-G Emotional (Total)</th>
<th>FACT-G Functional (Total)</th>
<th>FACT-G Social (Breast)</th>
<th>FACT-G Social (GI)</th>
<th>FACT-G Social (Lung)</th>
<th>FACT-G Social (Total)</th>
<th>FACIT-F (Total)</th>
<th>MDASI Severity (Total)</th>
<th>MDASI Interference (Total)</th>
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<tr>
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<td>-0.49 (268)</td>
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<td>-0.33 (268)</td>
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Values within brackets indicate n.

Bold values highlight correlations ≥0.50.

1Values within brackets indicate n. Bold values highlight correlations ≥0.50.
2All correlations were significant at the 0.05 level except for select correlations within study-specific populations that involved the FACT-G social subscale (indicated with an asterisk).
interventions within a research or clinical context. This one instrument thus gathers data that are otherwise collected using multiple assessment instruments targeting single constructs. The PCM strategy for collecting PROs may prove more efficient and may entail less patient burden than the standard research approach of using multiple surveys. By using the PCM in place of other research assessment surveys when appropriate, the process of data collection and symptom screening is streamlined. Identified concerns can be explored more fully by research instruments, such as the FACT, MDASI, or PROMIS short forms, as needed. Furthermore, by collecting and longitudinally storing a broad array of PROs at each time point, rather than limiting data collection to those elements required for the clinical trial or clinical concern at hand, the PCM may also support and facilitate future research, quality monitoring, and evidence-based implementation. The study’s results suggesting that the PCM is a valid research instrument in academic oncology pave the way for the introduction of the PCM in settings seeking to integrate clinical and research functions, efficiently collect and longitudinally store PROs, and minimize the burden that data collection can place on both patients and clinicians.

This study has certain limitations. Electronic versions of all included assessment instruments were used in this validation study. It was beyond the scope of this study to separately validate each of these instruments in its electronic format before using it for the current comparison purposes, although this was previously accomplished for all of the surveys used for the breast and GI portions of this study. The time frame of the studies did not permit the analysis of whether the PCM subscales were sensitive to changes in disease state or functional status. PCM 2.0 comprises 80 or more items, but only 54 are used in calculating subscales. There is the possibility that patient burden could be decreased by eliminating items; this must be carefully approached, because some items not incorporated into PCM subscales may have substantial clinical utility (e.g., fever, chills), and removing them from the PCM would be inconsistent with the intent of fulfilling both research and clinical aims.

This study represents an important building block within the process of constructing a model of a rapid learning cancer clinic that features electronic data capture and linkage. As defined by the Institute of Medicine, in a rapid learning health care system, data routinely collected in patient care feed into an ever-growing databank or a set of coordinated databases. The system “learns” by routinely analyzing captured information, iteratively generating evidence, and constantly translating new insights to tailor personalized care. Data collected at the individual patient level can be used to inform care for that person; contribute to evidence development and implementation projects at the clinic level; and support evidence synthesis, comparative effectiveness, and evidence implementation on the larger health system and societal levels. The first, completed step in this process entailed validation of ePRO instruments for data capture, comparing these electronic methods to traditional pen-and-paper surveys. The second step, presented here, involves subjecting a clinical ePRO tool, the PCM, to research validation in multiple cancer populations. Ongoing research is focusing on adapting the tools and the approach to ensure highest-quality, clinically relevant information that simultaneously meets clinical, research, and practice efficiency purposes. Clinical, administrative, and ePRO data sets and approaches will be linked in the rapid learning cancer clinic model.

Acknowledgments

The authors would like to thank all of the study participants who generously donated their time and personal information in an effort to improve the care of others. The authors also are deeply indebted to the clinical teams in the Duke Breast, Thoracic, and GI Cancer Clinics.

References


