

# Use of Tablet Personal Computers for Sensitive Patient-Reported Information

Alexandra Dupont, Jane Wheeler, MS, James E. Herndon II, PhD, April Coan, MPH, S. Yousuf Zafar, MD, Linda Hood, RN, MSN, Meenal Patwardhan, MD, Heather S. Shaw, MD, H. Kim Lysterly, MD, and Amy P. Abernethy, MD

Patient-reported survey data are becoming increasingly recognized as an important component of clinical research and patient care, but the sensitive nature of certain topics introduces challenges into the collection of patient-reported information. Most notably, sexuality-related questions introduce limitations into research due to their sensitivity and perceived invasiveness. In responding to surveys, participants may hesitate to ask for clarification if they do not understand a question; may be reluctant to proffer information that they consider highly personal and inherently private; may feel uncomfortable responding to personal questions in the presence of a spouse, caregiver, or clinician; and may experience discomfort in discussing sexuality-related questions with researchers and clinicians.<sup>1,2</sup> Unless the privacy of responses to sexuality-related questions can be ensured, patients may be unwilling to participate in research that solicits such intimate information; a self-selection factor in study populations may therefore compromise the validity and usefulness of research data.

Manuscript submitted February 19, 2009; accepted April 13, 2009

This study was funded through an Outcomes Research Service Agreement with Pfizer, Inc.; the primary purpose of this Agreement was to assess the feasibility, acceptability, and reliability of e/Tablets as a method for collecting patient-reported data in the academic oncology setting. Pfizer does not have access to individual data. SOS, Inc. served as vendor in this project; the vendor provided the hardware, which was not funded through the Pfizer agreement. Duke University Medical Center provided the wireless system and associated technical support. Dr. Abernethy has a consulting arrangement with SOS, Inc., which was reported to the Duke University Internal Review Board and Conflict of Interest Committee; there are no other conflicts to be disclosed.

Correspondence to: Amy P. Abernethy, MD, Duke University Medical Center, Box 3436, Durham, NC 27710; telephone: (919) 668-0647; fax: (919) 684-5325; e-mail: abern003@mc.duke.edu

J Support Oncol 2009;7:91-97

© 2009 Elsevier Inc. All rights reserved.

**Abstract** Notebook-style computers (e/Tablets) are increasingly replacing paper methods for collecting patient-reported information. Discrepancies in data between these methods have been found in oncology for sexuality-related questions. A study was performed to formulate hypotheses regarding causes for discrepant responses and to analyze whether electronic data collection adds value over paper-based methods when collecting data on sensitive topics. A total of 56 breast cancer patients visiting Duke Breast Clinic (North Carolina) participated by responding to 12 subscales of 5 survey instruments in electronic (e/Tablet) format and to a paper version of 1 of these surveys, at each visit. Twenty-one participants (38%) provided dissimilar responses on paper and electronic surveys to one item of the Functional Assessment of Cancer Therapy-General (FACT-G) Social Well-Being scale that asked patients to rate their satisfaction with their current sex life. Among these 21 patients were 8 patients who answered the question in the electronic environment, and 13 patients who answered both paper and electronic versions but with different responses. Eleven patients (29%) did not respond to the item on either e/Tablet or paper; 45 patients (80%) answered it on e/Tablet; and 37 patients (66%) responded on the paper version. The e/Tablet electronic system may provide a “safer” environment than paper questionnaires for cancer patients to answer private or highly personal questions on sensitive topics such as sexuality.

Previous studies requesting sensitive information have cited small sample sizes due to high participant refusal rates. For example, in a study of chronic pain and sexuality, Monga et al reported that only 40% of approached patients participated in the study, of which 12 (7%) were excluded from the final analysis because they did not respond to questions regarding sexual function.<sup>3,4</sup> Additional methodologic problems plaguing research concerning sexuality include limited capacity for external validation and questionable accuracy of responses, which could be biased, for instance, by participants' tendency to provide socially desirable responses.<sup>1,2,5</sup>

From the Department of Medicine, Division of Medical Oncology; Cancer Center Biostatistics; Duke Comprehensive Cancer Center; Department of Biostatistics and Bioinformatics; Duke Center for Clinical Health Policy Research; Department of Surgery, Duke University Medical Center, Durham, North Carolina

## Overcoming the Methodologic Obstacles

The advent of novel electronic data collection technologies has helped overcome the methodologic issues that have historically hindered clinical research requiring sensitive patient-reported data. Prior studies have found that patients may be more comfortable reporting sensitive information using electronic methods than traditional paper questionnaires.<sup>6–8</sup>

One technology designed to collect patient-reported data electronically is the e/Tablet, a programmed, wireless, notebook-and-pen style personal computer that gathers research-quality patient-reported data at the point of care. While in the waiting area, patients can complete surveys on the e/Tablet; the information furnished then travels wirelessly to a local or remote server. The e/Tablet can be used to collect and warehouse research data (eg, standardized and validated quality-of-life [QOL] or symptom surveys) and/or clinical data (eg, a review of systems). A real-time report can be generated within minutes for use in the subsequent clinical visit and/or for quality assurance in clinical research.

We have previously demonstrated that (1) e/Tablets are a feasible and acceptable method for collecting data directly from breast cancer patients in an academic cancer clinic; and (2) e/Tablets can reliably collect research survey data with quality comparable to that of data collected by traditional paper versions of the same instruments.<sup>9</sup> Benefits of the e/Tablet system include patient satisfaction with the system, ease of administration, convenient storage of longitudinal data, decrease in paperwork for researchers, fewer skipped data, less opportunity for ambiguous markings, and creation of a longitudinal patient-reported data repository that can be analyzed on both individual and aggregate levels.

## Context of Sexuality-Focused Analysis

This article explores the differences found between paper and electronic responses to the sexual satisfaction question included in the Functional Assessment of Cancer Therapy–General (FACT–G) when patients answered FACT–G questions in both formats. The current sexuality-focused analysis represents one component of a larger study, in which we examined whether data collected by e/Tablet are comparable in quality and consistency to data collected by traditional paper questionnaires for 12 subscales of 5 validated survey instruments frequently used in symptom and QOL research.<sup>9</sup> Congruent results were found between the paper and electronic versions of the M. D. Anderson Symptom Inventory (MDASI),<sup>10</sup> Functional Assessment of Chronic Illness Therapy–Fatigue (FACIT–Fatigue) scale,<sup>11</sup> Functional Assessment of Cancer Therapy–Breast (FACT–B) scale,<sup>12</sup> and three of four FACT–G subscales.<sup>13</sup> However, responses on the FACT–G Social Well-Being and all Self-Efficacy subscales<sup>14</sup> were disparate when completed by the two methods.

The purpose of this analysis was to explore potential reasons for the discrepancy found between sexual satisfaction data collected in paper format and by e/Tablet. Closer inspection of participants' responses to individual items on the FACT–G So-

cial Well-Being subscale showed that the lack of concordance between paper and electronic responses was primarily due to a significant variance in responses (including lack of a response) on the sexual satisfaction item, one of seven items comprising this subscale. Hence, this analysis explores how the responses are different and investigates the pattern of responses.

Specific aims of the current analysis were (1) to describe the difference between FACT–G Social Well-Being responses when data were collected sequentially from cancer patients using paper and electronic versions of this survey, with a focus on the sexual satisfaction question, which accounted for the discrepant results; (2) to determine whether the electronic method of data collection offers any added value over paper-based methods, especially when collecting data of a personal and/or sensitive nature; and (3) to formulate testable hypotheses regarding potential causes of the paper versus electronic discrepancy in survey responses to the sexual satisfaction question.

## Methods

The study was a secondary analysis of a nonrandomized, single-arm, pilot study conducted in the Duke Breast Cancer Clinic at Duke University Medical Center (DUMC), Durham, North Carolina. The protocol and all procedures were approved by the DUMC Institutional Review Board (IRB).

## INSTRUMENT

Originally developed in 1987, the FACT–G (now in version 4) is a 27-item survey of general QOL questions divided into 4 subscales: Physical Well-Being, Social/Family Well-Being, Emotional Well-Being, and Functional Well-Being. The FACT–G is considered a well-validated and reliable research instrument developed for patients with all types of cancer. Development and validation of the scale took place in five phases.<sup>13</sup> The questions were created through semistructured interviews with patients and health care providers.<sup>15</sup> Studies have validated it in rural populations, older adults, cross-cultural groups, and those with disease other than cancer.<sup>16,17</sup>

Sexual satisfaction is measured by one item on the FACT–G Social Well-Being subscale; this item reads, "I am satisfied with my sex life." Patients score the extent to which they have agreed with this statement over the past 7 days, using a five-point Likert scale with the options: not at all, a little bit, somewhat, quite a bit, and very much.

Historically, the Social Well-Being subscale of the FACT–G has been the least valid of all of the FACT–G subscales, with a published Cronbach's alpha of 0.69.<sup>12</sup> The Emotional Well-Being subscale is only slightly more internally consistent, with published studies reporting Cronbach's alpha ranging from 0.69–0.74.<sup>13,18</sup> By contrast, the Physical Well-Being and Functional Well-Being subscales have Cronbach's alphas of  $\geq 0.80$ .<sup>12,13</sup> Because of their recognized unreliability, the FACT–G Social and Emotional Well-Being subscales are not typically included in clinical trials of therapeutic cancer interventions. Instead, many studies employ the FACT Trial Outcome Index (TOI), a summation of the FACT–G Physical and Functional Well-Being subscales plus the FACT disease-specific subscale.<sup>19</sup>

## SUBJECTS

Eligible participants were (1) adults with a pathologic diagnosis of breast cancer; (2) expecting to have at least four further visits to the Duke Breast Cancer Clinic over the next 6 months; (3) able to speak and read English; and (4) able to provide informed consent. Seventy-three consecutive patients referred to the study by their treating oncology provider were screened, and 66 patients consented to participate in this study. Data were collected from 64 patients (1 patient died and 1 withdrew before study initiation). This analysis focuses on the 56 patients who provided electronic and paper data at the same assessment using the FACT-G Social Well-Being subscale (Table 1).

The study was intended to assess the difference between subscale scores derived from data collected via paper and those same scores derived from data collected via e/Tablet. A sample size of 60 was chosen, affording 85% power to detect a half standard deviation of the mean difference when a two-tailed paired *T*-test was conducted at the 0.007 level of significance. A Bonferroni correction was used to adjust for multiple testing.

## THE E/TABLET SYSTEM

The PACE™ system (Patient Assessment, Care & Education) developed by Supportive Oncology Services, Inc. (Memphis, TN) was used in conjunction with Motion Computing tablet personal computers. The standard PACE system was modified to electronically deliver multiple concatenated surveys in addition to the Patient Care Monitor, the standard review of systems survey available on PACE.<sup>20,21</sup> Approval was obtained from the author of each survey. An ANSI-compliant database, maintained on a server behind the Duke firewall, used Microsoft SQL Server (version 08.00.0760, Seattle, WA) to warehouse the Duke e/Tablet data.

## PROCEDURES

Attending physicians or mid-level providers suggested the study to patients during regularly scheduled clinic visits. The study's research nurse obtained informed consent. At each of four study visits, participants completed electronic versions of the FACT-G, FACT-B, MDASI, FACIT-Fatigue, and the National Comprehensive Cancer Network (NCCN) Distress Thermometer and Self-Efficacy assessment surveys. Before completing the series of questionnaires on the e/Tablet, the patient completed a paper version of the FACT-G, FACIT-Fatigue, MDASI, or Self-Efficacy survey. Participants only completed one paper survey at each visit to reduce patient burden; the survey given at each visit was randomized. During the first visit only, participants completed an electronically administered demographics survey. While patients were completing the demographics questionnaire, research staff sat with them to make sure they were able to accurately use the e/Tablet.

Instructions for each survey were identical on the electronic and paper versions. One notable difference between the two instruments, however, is that patients see and respond to questions one at a time on the e/Tablet. Each item is presented on the screen independently, and the next item appears immediately

**Table 1**  
Patient Characteristics

CHARACTERISTIC	FREQUENCY OR MEAN (SD)	PERCENTAGE OR RANGE
Total number of patients	56	
Age, years	54 (13)	31–84
Race/ethnicity		
White/Caucasian	43	77%
Black/African-American	11	20%
Chinese	1	2%
Not stated or missing	1	2%
Education		
Some high school/ high school diploma	8	14%
Some college/associate or technical degree	20	36%
Bachelor's degree	14	25%
Some graduate school/ graduate degree	14	25%
Marital status		
Married or permanent partner	37	66%
Divorced or separated	11	20%
Widowed	5	9%
Single	2	4%
Not stated or missing	1	2%
Metastatic breast cancer	30	54%
Receiving infusional chemotherapy	52	93%

SD = standard deviation

diately after a participant selects an answer choice. Obviously, with the paper versions, all questions are presented together.

Participants completed the surveys in the clinic waiting room before their appointments. Patients were told during informed consent and at each visit that the e/Tablet data would help facilitate communication about symptoms and QOL concerns with their provider through a printed summary report of responses as well as provide valuable research data around the feasibility of using e/Tablet computers in a clinical setting. At each visit, staff reminded the patient of how to use the e/Tablet computer and answered any specific questions. To protect the patient's privacy, the research staff did not wait with the patient while she completed the questionnaires.

## ANALYSIS

Analyses focused on scores of the FACT-G Social Well-Being subscale computed from data collected via paper and e/Tablet at the same visit, between March 19 and October 31, 2006. Paper forms were double-entered into a Microsoft Excel 2003 database (Seattle, WA), compared for discrepancies, and cleaned as warranted. Data from the e/Tables and paper databases were imported into SAS 9.1 (Cary, NC) datasets using an SAS-based data importation macro program. All analyses were conducted using SAS 9.1. FACT-G subscale scores were computed by summing the responses to domain-specific questions, where responses are on a scale of 0–4. As a result, the scale score ranges from 0 to 28, as responses are summed for a total score. When subscale components were missing and less than 20% of components were missing, available data were

prorated to compute the subscale score. Results were summarized using descriptive statistics. Cronbach's alpha scores were used to assess internal validity. Subscale scores were compared using paired student *T*-tests. A  $P < 0.05$  was considered evi-

dence of a significant difference. Kappa statistics were not incorporated into analyses, as such an approach did not allow simultaneous accounting for "near-perfect" agreement of ordinal responses as well as disagreements between responses and nonresponses.

**Table 2**

### Responses on the Individual Items of the FACT-G Social Well-Being Subscale

QUESTION	PAPER RESPONSES		ELECTRONIC RESPONSES	
	FREQUENCY	PERCENTAGE	FREQUENCY	PERCENTAGE
Number of patients	58		56	
<b>I feel close to my friends</b>				
Not at all	1	2%	3	5%
A little bit	2	4%	6	11%
Somewhat	8	14%	7	13%
Quite a bit	12	21%	15	27%
Very much	33	59%	25	45%
<b>I get emotional support from my family</b>				
Not at all	0	0%	0	0%
A little bit	1	2%	2	4%
Somewhat	6	11%	5	9%
Quite a bit	8	14%	9	16%
Very much	41	73%	40	71%
<b>I get support from my friends</b>				
Not at all	1	2%	1	2%
A little bit	2	4%	4	7%
Somewhat	3	5%	5	9%
Quite a bit	13	23%	14	25%
Very much	37	66%	32	57%
<b>My family has accepted my illness</b>				
Not at all	0	0%	0	0%
A little bit	1	2%	3	5%
Somewhat	8	14%	6	11%
Quite a bit	10	18%	14	25%
Very much	37	66%	33	59%
<b>I am satisfied with family communication about my illness</b>				
Not at all	1	2%	1	2%
A little bit	2	4%	3	5%
Somewhat	5	9%	7	13%
Quite a bit	12	21%	12	21%
Very much	36	64%	33	59%
<b>I feel close to my partner</b>				
Not at all	2	4%	1	2%
A little bit	2	4%	4	7%
Somewhat	5	9%	4	7%
Quite a bit	8	14%	8	14%
Very much	38	68%	39	70%
Missing	1	2%	0	0%
<b>I am satisfied with my sex life</b>				
Not at all	9	16%	8	14%
A little bit	7	13%	9	16%
Somewhat	5	9%	12	21%
Quite a bit	7	13%	4	7%
Very much	9	16%	12	21%
Missing	19	34%	11	20%

FACT-G = Functional Assessment of Cancer Therapy-General

## Results

### PARENT STUDY SCALES/SUBSCALES

Mean values of all subscales of paper and electronic versions of the MDASI, FACIT, and FACT-B surveys were similar to those expected for an outpatient breast cancer population.<sup>22</sup> Cronbach's alphas were acceptable and were the same or higher than those already published for all scales. These results have been previously reported, as has the high level of consistency between paper and electronic data on all subscales except as described here.<sup>9,23</sup>

### FACT-G Social Well-Being Subscale

Standardized Cronbach's alphas for the FACT-G Social Well-Being subscale were 0.86 for the paper questionnaire and 0.89 for the electronic method. Responses on the paper and electronic versions of the FACT-G Social Well-Being subscale were dissimilar. For the 56 patients who provided both paper and electronic data, the raw mean paper and electronic Social Well-Being subscale scores were 23.24 (standard deviation [SD], 5.25) and 22.27 (SD, 5.69), respectively. The mean difference (electronic-paper) was -0.97 (SD, 2.53), reflecting a statistically significant difference ( $P = 0.006$ ). A 95% confidence interval for the mean difference was -1.65 to -0.29. Scores using the electronic method were usually lower than paper scores; in other words, patients reported a poorer sense of social well-being using the electronic scale than they did using the paper questionnaire.

A detailed review of responses to the individual questions in the Social Well-Being subscale was performed to identify the locus of the paper versus electronic response discrepancy (Table 2). The greatest discrepancy was found between paper and electronic responses to the single item asking patients to rate their satisfaction with their current sex life, by indicating their level of agreement with the statement, "I am satisfied with my sex life." Twenty-one participants (38%) recorded dissimilar responses on paper and electronic surveys when responding to the sexual satisfaction item. Dissimilar responses included both differently scored responses and missing responses on either paper or e/Tablet, since not answering the question provides insight into the pattern of providing responses. Notably, 45 women (80%) answered this question on the e/Tablet, whereas only 37 (66%) responded to it on the paper version. Only two questions, "I feel close to my partner" and "I am satisfied with my sex life," had missing data; missing data were more common on paper scales than on electronic ones.

Tables 3 and 4 show the percent of patients in "perfect" agreement (ie, responses on paper and electronic versions exactly the same) and "almost-perfect" agreement, defined as the individual's responses differing by no more than one category

(ie, from not at all to a little bit or from a little bit to somewhat), for each question of the FACT-G Social Well-Being subscale. Only 43% of patients provided identical responses to the sexual satisfaction question using the two methods; this percentage contrasts sharply with that of the other six items in the subscale. Four items on this subscale exhibited 100% “almost-perfect” agreement; in other words, all respondents recorded either exactly the same responses (“perfect” agreement) on electronic and paper surveys or answers that deviated by one category or less between the two versions. As with “perfect” agreement, the proportion of patients recording answers in “almost-perfect” agreement on paper and electronic surveys (59%) was dramatically lower on the sexual satisfaction item than on the other six items in the Social Well-Being subscale. A missing response on one version of the survey was considered a differing response, as we were interested in the change and pattern of response choice.

Figure 1 shows the correlation between paper and electronic scores to the sexual satisfaction question. Nineteen participants did not answer the sexual satisfaction item on the paper form, but 8 of 19 did not answer the question electronically.

## Discussion

FACT-G Social Well-Being subscale scores are significantly different using electronic versus paper data-collection methods in this population of breast cancer patients. The difference is driven by the significant variance in responses to the sexual satisfaction question. More patients answered this question when completing the questionnaire electronically. Patients varied their paper and electronic responses more on this item than on any of the other six items in the subscale. Of note, we considered not answering a question as a type of response and thus included missing responses in our analyses. Questions may have been actively skipped due to the sensitive nature of the item, and thus these responses are crucial to understanding response patterns. We were interested in numerical responses on both paper and electronic formats as well as patterns of providing a response (or actively deciding not to respond) on either format.

These findings are consistent with the existing literature, where studies have shown that electronic data-capture methods enhance collection of sensitive patient-reported QOL information. A study involving 311 asthma patients demonstrated that use of electronic questionnaires reduced the number of skipped questions, especially on surveys that included sensitive personal questions such as the mental health and emotional effects of asthma.<sup>24</sup> Des Jarlais and colleagues reported that patients were more likely to report sexual behaviors and other HIV risk behaviors using a computer-based reporting method than in face-to-face interviews.<sup>25</sup> In a study involving 280 women, computer-based audio interviews helped to remove social desirability bias from responses to questions about sensitive sexual behaviors.<sup>1</sup> The results presented in the current analysis add to this evidence base by (1) reinforcing previous findings; (2) demonstrating the value of electronic data collection for sensitive patient-reported health information in the

**Table 3**

### “Perfect” Agreement<sup>a</sup> on FACT-G Social Well-Being Questions

QUESTION	N	PERCENTAGE
My family has accepted my illness	56	86%
I feel close to my partner	56	84%
I am satisfied with family communication about my illness	56	84%
I get emotional support from my family	56	82%
I get support from my friends	56	73%
I feel close to my friends	56	66%
I am satisfied with my sex life	56	43%

FACT-G = Functional Assessment of Cancer Therapy-General

<sup>a</sup> Defined as exact same response

**Table 4**

### “Almost-Perfect” agreement<sup>a</sup> on FACT-G Social Well-Being Questions

QUESTION	N	PERCENTAGE
I get emotional support from my family	56	100%
I get support from my friends	56	100%
My family has accepted my illness	56	100%
I am satisfied with family communication about my illness	56	100%
I feel close to my partner	56	95%
I feel close to my friends	56	89%
I am satisfied with my sex life	56	59%

FACT-G = Functional Assessment of Cancer Therapy-General

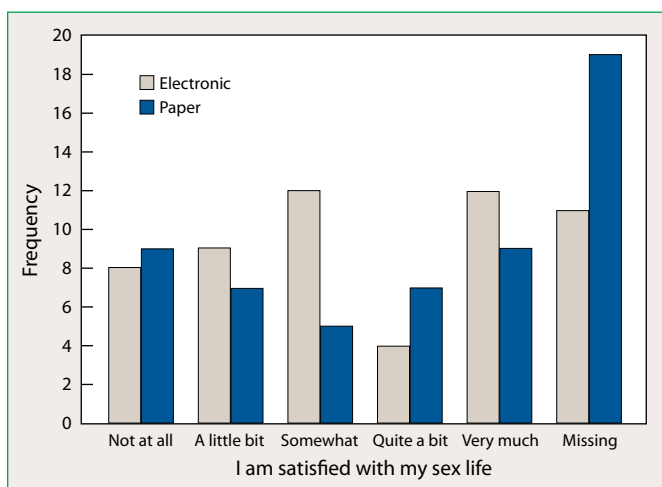
<sup>a</sup> Defined as difference of only one category of response, from paper to electronic, including nonresponse

cancer population; (3) showing the use of the e/Tablet system as an electronic data-capture mechanism for patient-reported data; and (4) proposing that electronic methods produce more accurate data than traditional paper-based methods.

The increased response rate when using the e/Tablet suggests that electronic methods may be more appropriate for assessing sensitive domains such as sexual function. Patients may have a higher level of comfort and/or greater confidence in the privacy of this method. The electronic environment may be perceived as “safer” than traditional methods for answering questions that seem intimate, private, or highly personal.

Each question on the e/Tablet appears on a screen by itself and disappears from the screen immediately after the patient responds. Caregivers, research nurses, or other nearby individuals are unlikely to view the patient’s responses in this brief time window. By contrast, a paper questionnaire contains an enduring hard-copy record of the patient’s response, which could conceivably be read by clinic personnel. Thus, the electronic environment may represent an improvement over paper-based surveys in that it provides patients a protected space for responding to sensitive questions, obviating the perceived need to give socially desirable responses and allowing the freedom to answer more truthfully.

The higher sexual satisfaction level reported by patients



**Figure 1** Correlation Between Paper and Electronic FACT-G Social Well-Being Scores on the Sexual Satisfaction Item

using paper-based questionnaires may reflect patients' perceptions of the relative privacy of paper versus electronic surveys. We hypothesize that patients may choose to provide socially desirable responses (ie, indicating greater satisfaction with their sex lives) on the paper survey because they believe that there is a greater chance that others will be able to see their responses. Two participants responded that they were "very much" satisfied on the e/Tablet but "not at all" satisfied on paper. These responses are contrary to our hypothesis and are outliers in the data. Misunderstanding the survey instructions for this item could explain these outliers. Other subscales did not have similar outliers. Aside from these two participants, the remainder expressed less sexual satisfaction while completing an electronic survey. Although still not perfect, the privacy of the e/Tablet may support a greater sense of anonymity and may allow patients comfort when answering the question honestly.

A similar trend in response rate to a sexuality-related question was noticed in one of our ongoing observational studies, seemingly associated with patients' perceptions of privacy—or lack thereof—of the survey environment. The study is testing the validity of a newly developed scale to measure cancer-related breathlessness; the FACT-G was included in the validation package of patient-reported instruments. In the course of this study, 10 of the 32 participating patients chose not to respond to the sexual satisfaction question on the FACT-G paper survey. Study coordinators noted that many participants commented on the item to their partner or caregiver in the examination room. This field experience indicates that protocols should be adjusted to ensure privacy, and electronic tools should be used when possible to elicit more accurate responses.

Other explanations that may account for the increased response rate in the electronic environment follow:

- Patients find electronic data-collection methods more credible. A technology-based mode of delivery may be more readily connected in patients' minds with research and scien-

tific purposes, and thus patients may feel that their responses are somehow more important.

- Patients' perceptions of who will be viewing and using the data may differ for paper and electronic methods. Unlike paper-based data, electronic data never physically appear to reside in the waiting room or preclinical areas, and thus patients may have greater confidence that electronically entered data will only be viewed by researchers and their physician, whose attention they value.

- The novelty of the e/Tablet, as compared with the familiarity of paper forms, may hold the patients' attention and therefore elicit more complete and thoughtful responses.

- Patients were told their providers would receive a report of their responses to questions completed on the e/Tablet; this knowledge might make patients more likely to respond—and to respond honestly—to electronic survey questions.

- Misunderstanding the paper survey instructions for the sexual satisfaction question may account for some missed data. On the paper version, patients were instructed to check a box if they wanted to skip the question. Three patients did not mark an answer or check the box, but instead wrote "N/A," meaning "not applicable," on the paper. We assume that these participants incorrectly believed the question did not apply to them since they were not sexually active. Because the e/Tablet does not allow respondents to write notes (eg, "N/A") but rather requires either a score or a skipped question, its format may have encouraged more participants to answer the question using the specified options.

Patients may have responded differently on paper versus electronic surveys because of the fundamental differences between each instrument. The presentation of each question on a screen by itself may promote greater reflection on the individual item, whereas location of a question within a list of questions on a paper page might lead the patient to speed along through the battery, spending less time and attention on each individual item. Additionally, patients may respond in a more stable way if they understand that e/Tablet data are retained in a database and will be used for research purposes in the future.

The results of this study prompt the question, which data (those collected by paper or those collected by e/Tablet) are more accurate? A limitation in the current analysis is that it does not definitively answer the question of discriminate accuracy between the two methods. The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) electronic Patient-Reported Outcomes Good Research Practices Task Force recently published recommendations on the process behind adapting paper-based patient-reported outcomes into electronic modes.<sup>26</sup> The report agrees that with only minor adaptations from paper to electronic mode, the psychometric properties of the survey tool will likely be unchanged. For more significant changes in the tool, the Task Force recommends formal determination of equivalence using measures such as cognitive debriefing and usability testing. Semistructured interviews with patients are critical next steps to determine which method yields more accurate results and help to characterize better the reasons for answering in one

format but not another. Our hypotheses are suitable for exploration in focus groups, where patients could provide insights in an open-ended format.

This study carries some intriguing implications for the conduct of research that examines or includes patient-reported data on sensitive health issues. The variations that we found between paper and electronic answers to the FACT-G sexual satisfaction question raise concerns about the validity of routinely collected scores on this measure and more generally on measures of sensitive health issues. When selecting survey instruments, determining mode of delivery, and analyzing validity of results, it is important to carefully consider the questions being asked and the setting in which they are asked. The electronic collection of patient-reported outcomes is becoming more accepted.

Researchers must also make the purposes for which data are being collected clear to the participant and explain who will have access to the data. Patients should guide us in the area of sexual health. We are currently enrolling patients in an ongoing study that addresses physical intimacy and sexual concerns in couples facing colorectal cancer.

When viewed in a broader context, this study provides an

opportunity to rethink the ways in which we collect personal information from patients and the design and conduct of research studies that involve requesting sensitive information directly from patients. Sexuality is a domain that most would consider private and intimate. However, privacy itself is a highly personal matter, and, for any given type of information, patients will have differing definitions of what private information is and to what extent it should be protected. A logical extension of the mandate for protected health information (PHI) is the inclusion of methods of collecting health information in the requirements placed on PHI. Ideally, the methods used to gather PHI should be as protected as the information itself. According to this study, patients may believe that electronic methods might offer an improvement over paper methods for protection of sensitive health information.

## Acknowledgment

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. We are also deeply indebted to the patients and clinical teams in the Duke Breast Cancer Clinic.

## References

PubMed ID in brackets

- Kissinger P, Rice J, Farley T, et al. Application of computer-assisted interviews to sexual behavior research. *Am J Epidemiol* 1999;149:950-954. [10342804]
- Perlis TE, Des Jarlais DC, Friedman SR, Arasteh K, Turner CF. Audio-computerized self-interviewing versus face-to-face interviewing for research data collection at drug abuse treatment programs. *Addiction* 2004;99:885-896. [15200584]
- Monga TN, Tan G, Ostermann HJ, Monga U, Grabois M. Sexuality and sexual adjustment of patients with chronic pain. *Disabil Rehabil* 1998;20:317-329. [9664190]
- Ambler N, Williams AC, Hill P, Gunary R, Cratchley G. Sexual difficulties of chronic pain patients. *Clin J Pain* 2001;17:138-145. [11444715]
- Arrington R, Cofrancesco J, Wu AW. Questionnaires to measure sexual quality of life. *Qual Life Res* 2004;13:1643-1658. [15651536]
- Wright DL, Aquilino WS, Supple AJ. A comparison of computer-assisted paper-and-pencil self-administered questionnaires in a survey on smoking, alcohol, and drug use. *Public Opin Q* 1998;62:331-353.
- Turner CF, Ku L, Rogers SM, Lindberg LD, Pleck JH, Sonenstein FL. Adolescent sexual behavior, drug use, and violence: increased reporting with computer survey technology. *Science* 1998;280:867-873. [9572724]
- Tourangeau R, Smith TW. Asking sensitive questions: the impact of data collection mode, question format, and question context. *Public Opin Q* 1996;60:275-304.
- Abernethy AP, Herndon J, Day J, et al. E-tablets to collect research-quality patient-reported data. *J Clin Oncol* 2007;25(18S):6609.
- Cleeland CS, Mendoza TR, Wang XS, et al. Assessing symptom distress in cancer patients: the M.D. Anderson Symptom Inventory. *Cancer* 2000;89:1634-1646. [11013380]
- Yellen SB, Cella DF, Webster K, Blendowski C, Kaplan E. Measuring fatigue and other anemia-related symptoms with the Functional Assessment of Cancer Therapy (FACT) measurement system. *J Pain Symptom Manage* 1997;13:63-74. [9095563]
- Brady MJ, Cella DF, Mo F, et al. Reliability and validity of the Functional Assessment of Cancer Therapy-Breast quality-of-life instrument. *J Clin Oncol* 1997;15:974-986. [9060536]
- Cella DF, Tulsky DS, Gray G, et al. The Functional Assessment of Cancer Therapy scale: development and validation of the general measure. *J Clin Oncol* 1993;11:570-579. [8445433]
- Lorig K, Chastain RL, Ung E, Shoor S, Holman HR. Development and evaluation of a scale to measure perceived self-efficacy in people with arthritis. *Arthritis Rheum* 1989;32:37-44. [2912463]
- Webster K, Cella D, Yost K. The Functional Assessment of Chronic Illness Therapy (FACIT) Measurement System: properties, applications, and interpretation. *Health Qual Life Outcomes* 2003;1:79. [14678568]
- Overcash J, Extermann M, Parr J, Perry J, Balducci L. Validity and reliability of the FACT-G scale for use in the older patient with cancer. *Am J Clin Oncol* 2001;24: 591-596.
- Winstead-Fry P, Shultz A. Psychometric analysis of the Functional Assessment of Cancer Therapy-General (FACT-G) scale in a rural sample. *Cancer* 1997;79:2446-2452. [9191537]
- Shelby-James TM, Abernethy AP, McAlindon A, Currow DC. Handheld computers for data entry: high tech has its problems too. *Trial* 2007;8:5. [17309807]
- Cella D, Eton DT, Fairclough DL, et al. What is a clinically meaningful change on the Functional Assessment of Cancer Therapy-Lung (FACT-L) Questionnaire? results from Eastern Cooperative Oncology Group (ECOG) Study 5592. *J Clin Epidemiol* 2002;55:285-295. [11864800]
- Fortner B, Baldwin S, Schwartzberg L, Houts AC. Validation of the Cancer Care Monitor items for physical symptoms and treatment side effects using expert oncology nurse evaluation. *J Pain Symptom Manage* 2006;31:207-214. [16563315]
- Fortner B, Okon T, Schwartzberg L, Tauer K, Houts AC. The Cancer Care Monitor: psychometric content evaluation and pilot testing of a computer administered system for symptom screening and quality of life in adult cancer patients. *J Pain Symptom Manage* 2003;26:1077-1092. [14654260]
- Downie FP, Mar Fan HG, Houédé-Tchen N, Yi Q, Tannock IF. Cognitive function, fatigue, and menopausal symptoms in breast cancer patients receiving adjuvant chemotherapy: evaluation with patient interview after formal assessment. *Psychooncology* 2006;15:921-930. [16477674]
- Abernethy AP, Herndon JE, Day JD, et al. Validation of electronically collected patient-reported outcomes: a comparison of data collected by e-tablets and paper based questionnaires. *Support Care Cancer*. In press.
- Caro JJ Sr, Caro J, Caro J, Wouters F, Juniper EF. Does electronic implementation of questionnaires used in asthma alter responses compared to paper implementation? *Qual Life Res* 2001;10:683-691. [11871589]
- Des Jarlais DC, Paone D, Milliken J, et al. Audio-computer interviewing to measure risk behaviour for HIV among injecting drug users: a quasi-randomised trial. *Lancet* 1999;353:1657-1661. [10335785]
- Coons SJ, Gwaltney CJ, Hays RD, et al. Recommendations on evidence needed to support measurement equivalence between electronic and paper-based patient-reported outcome (PRO) measures: ISPOR ePRO Good Research Practices Task Force Report. *Value in Health*. www3.interscience.wiley.com/journal/12151162/abstract. Accessed April 13, 2009. In press; Published online Nov 11, 2008; DOI: 10.1111/j.1524-4733.2008.00470.x.