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ORIGINAL REPORT

Patient Online Self-Reporting of Toxicity Symptoms During Chemotherapy

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ABSTRACT

Purpose
Tracking symptoms related to treatment toxicity is standard practice in routine care and during clinical trials. Currently, clinicians collect symptom information via complex and often inefficient mechanisms, but there is growing interest in collecting outcome information directly from patients.

Patients and Methods
The National Cancer Institute Common Terminology Criteria for Adverse Events schema for seven common symptoms was adapted into a Web-based patient-reporting system, accessible from desktop computers in outpatient clinics and from home computers. Eighty patients with gynecologic malignancies beginning standard chemotherapy regimens were enrolled between April and September 2004. During an 8-week observation period, participants were encouraged to log in and report symptoms at each follow-up visit, or alternatively, to access the system from home.

Results
All patients completed an initial log in. At each subsequent appointment, most enrollees (80% to 85%) reported symptoms using the online system, with a mean of three follow-up visits per patient during the observation period (range, one to six). Sixty of 80 patients (75%) logged in at least once from home. Use was significantly associated with prior Internet experience. Forty-two severe toxicities (grade 3 to 4) entered from home prompted seven clinician interventions. Most patients (96%) found the system useful and would recommend it to others.

Conclusion
Patients are capable of reporting symptoms experienced during chemotherapy using a Web-based interface. Assessment in the clinical trial setting and comparison of direct patient- versus clinician-based approaches for reporting symptoms and their severity are warranted.

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INTRODUCTION

Monitoring of symptoms during chemotherapy is a cornerstone of medical oncology practice. As patients experience adverse effects, their needs for therapy modifications, supportive care, and education often change. Traditionally, patients have been viewed as being incapable of directly reporting their symptoms, and a model has evolved in which patient experiences are elicited, filtered, and reported by health care professionals.[1] The National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) is the widely recognized gold standard in the United States for assessing symptom severity,[2] but most patients are unaware of this system, much less its details.

Direct collection of patient-reported outcomes (PROs) represents an alternative paradigm. Tracking PROs may provide

benefits over clinician-reported outcomes by fostering patient-clinician communication, providing information about additional symptoms beyond those typically reported by staff, and increasing efficiency and accuracy by eliminating the need for research study personnel to abstract symptoms from the medical record posthoc.[3-6] The relationship between PROs and clinician assessments has not been characterized fully, although there is some evidence to suggest discordance.[7-10]

Staff reporting of symptoms is mandated in NCI-sponsored trials, and is a prerequisite to US Food and Drug Administration approval. However, the current system of symptom collection can be cumbersome, with information transferred verbally from patient to clinician, then interpreted by the clinician, recorded in the medical chart, abstracted from the chart by a research study assistant, then entered manually into a database (Fig 1). At each step, the criteria used to evaluate symptoms may be inconsistent, data entry errors can occur, and information may be lost.[11]

Although symptoms are typically ascertained using this elaborate filtering system, patient self-reports have become the standard for quality-of-life (QoL) evaluations conducted in clinical trials.[12-16] Notably, QoL data were previously collected predominantly via staff-administered surveys, but after a period of questionnaire development and validation, patient self-reporting became the standard approach. Although not currently the case for symptom data, to a limited extent direct elicitation of patient symptoms (such as pain) has been shown as feasible in clinical practice[17] and in the research context.[18-22] The success of these efforts, in conjunction with the availability of new technologies for collecting patient data in real time,[23-25] support the extension of the model of PRO collection to include symptoms.

However, it is unknown whether patients can be engaged to regularly report symptoms during chemotherapy, or whether practitioners will consider this information to be a reliable basis for management decisions or regulatory reporting. Various media are available for the collection of PROs, including traditional paper-based approaches,[3,18] or electronic methods such as desktop/touch-screen computers,[7,17,23] handheld devices,[25] and automated telephone systems.[24] In contrast to paper-based methods, electronically collected information is immediately accessible, easily stored and transmitted, and does not require research personnel to enter information into a database by hand. Web interfaces in particular are widely accessible using equipment that is often already available in physician offices and patient homes,[26] and can be used to channel data gathered from patients at disparate locations into a common central database.

We developed a Web-based system that allows patients to enter and track their own symptoms based on the CTCAE, and which generates longitudinal reports that can be available to staff. By measuring patient and staff use of this system, two distinct but interrelated issues may be addressed: the feasibility of patient symptom self-reporting, and the usefulness of the Internet as a medium for PRO collection. Although prior QoL research suggests similar levels of patient compliance using touch-screen computers versus paper for self-reporting,[27] specific patient characteristics may be identified that serve as barriers to this method

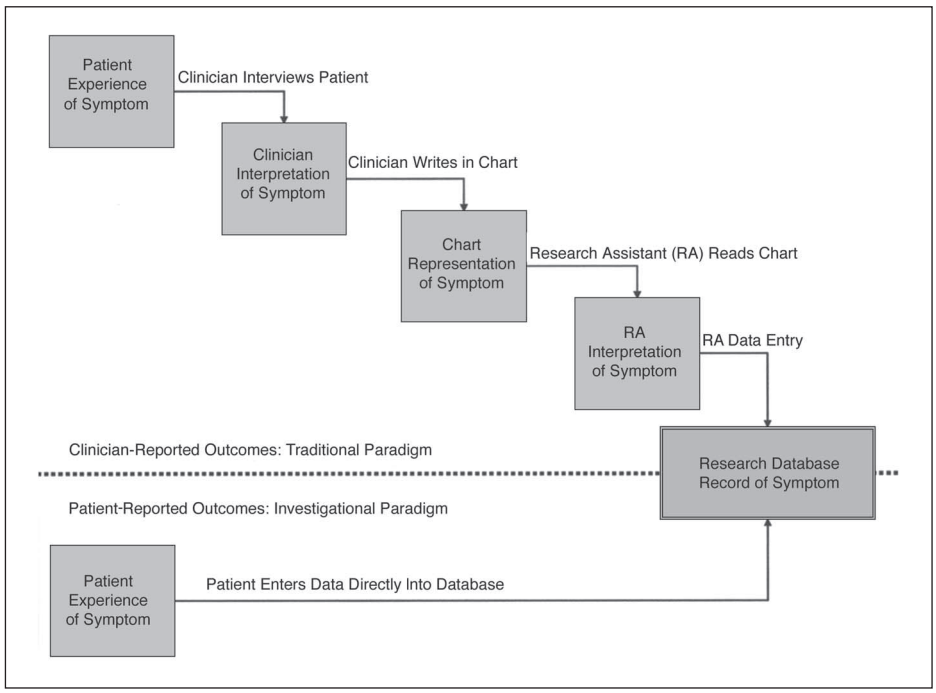

Fig 1. Potential reduction of link loss and data entry errors with direct collection of patient-reported symptoms.

of data collection. If this approach is found to be feasible, future investigations may be merited to establish the most efficient medium for patient symptom self-reporting, and the approach may be generalized to populations without computer avidity.

PATIENTS AND METHODS

Adaptation of NCI Toxicity Criteria for Patients

To collect symptom information directly from patients using schema that most closely approximate those used by clinicians for research reporting and clinical management, we adapted specific items from the CTCAE version 3.0 for patient use (Fig 2). CTCAE items are graded on an ordinal scale from 1 to 5, with each consecutive number corresponding to respective NCI-designated descriptors: mild, moderate, severe, disabling/life-threatening, death. Seven symptoms common in gynecologic malignancies were chosen based on a literature review and consultation with the gynecologic oncology service. The patient language adaptation included grade 4 toxicities when the specific symptom's source description was "disabling," but not when the source description was "life-threatening." Grade 5 toxicity (death) was not included in the patient version. A preliminary paper version of these items was administered to 30 patients to refine language and ensure comprehension.

We also adapted the single-item Eastern Cooperative Oncology Group (ECOG) performance status assessment, which is commonly used in clinical trials to establish patient eligibility.[28] The EuroQoL EQ-5D, a QoL instrument designed for patient self-reporting, was included to situate the characteristics of our study cohort in context with other populations.[29,30] The EQ-5D was chosen for its brevity (five items plus a visual analog scale) and increasing use in cancer clinical trials. A free-text diary field was included to allow patients to report additional concerns or feedback.

Technology Platform Development

We aimed to develop a technology platform that would be easy to understand, readily accessible, inexpensive to implement, secure, and capable of storing data in a quickly retrievable form. We chose a Web-based system so that patients would be able to enter their own data using desktop computers in waiting areas or via any outside Web-enabled computer. Such equipment is already widely available in patient homes and in oncologists' offices.

On the basis of these specifications, we developed Symptom Tracking and Reporting (STAR), a Web-based platform for collecting PROs. The essential features of STAR are a homepage at which users log in, online question items, a secure database, and an interface for generating longitudinal reports of previously entered data. Special attention was paid to the security and privacy of patient information. The system's architecture included two separate firewalls to create a so-called demilitarized zone in which the external Web server was located. This configuration was approved by the Memorial Sloan-Kettering Cancer Center (MSKCC) security/privacy officers and the Institutional Review Board.

Patients

Patients were eligible if they were receiving treatment at MSKCC, diagnosed with a gynecologic malignancy, were starting a new standard chemotherapy regimen, were not enrolled in a clinical treatment trial, were able to read and understand English, and had an ECOG performance status score less than 3. Potentially eligible patients were identified on the morning of each clinic weekday by reviewing medical records for all women with scheduled visits to the gynecologic oncology outpatient clinic, and confirming with physicians that identified patients were indeed starting a new chemotherapy regimen. Subsequently, consecutive patients identified in this manner were approached at visits to consider enrollment. All participants signed an informed consent and research authorization. Patients remained enrolled until the completion of the study or death.

Study Intervention

Training. All participants underwent a 10-minute teaching session using waiting-area computers, including a baseline index log-in session. A wallet-sized instruction card, a unique password, and technical support contact information were provided. Enrollees were informed that STAR was available via any Internet-connected computer inside or outside MSKCC. Patients were told that during the study they would be verbally encouraged to log in at each follow-up clinic visit, but that it was not mandatory for participants to log in, and no reminders would be given to log in from home.

Log-in procedures. Two computer kiosks were made available in the clinic waiting area for STAR access. At each follow-up clinic visit, enrollees were reminded when they checked in that they had the option to log in. No specific assistance was provided.

Reports. At clinic appointments, STAR reports were printed and added to materials that are routinely reviewed by clinicians before patient encounters. It was left to clinician discretion whether to incorporate discussion of STAR reports into visits.

Response to Severe Toxicity Reporting

A concern when designing this system was the possibility that patients might self-report severe toxicities from home computers between appointments and that these reports would not be reviewed by a clinician until the next visit. To address this, participating clinicians and the Institutional Review Board agreed that any time a toxicity grade of 3 or 4 was reported, a pop-up message would appear on the patient's screen stating that a potentially serious symptom had been reported and that medical evaluation should be considered. In addition, an automated e-mail alert would be transmitted to the study team, which forwarded these reports to the appropriate clinician. These cautions were approved by the MSKCC legal department to address concerns related to provider liability.

Outcomes Measured

We evaluated the impact of this intervention to directly ascertain patient-reported symptoms in three ways.

Patterns of STAR use. Data from STAR's manifest of the number of times patients logged in and the electronic medical record were used to tabulate the proportion of patients logging in to STAR at clinic visits, the rate of patients continuing to log in at follow-up appointments, patterns of STAR access between visits, and STAR use from clinic versus outside locations. Relationships between STAR participation (total number of times patients logged in) and specific baseline patient characteristics (age, cancer type, ECOG score, education level, prior Internet experience, home computer) were assessed using simple linear regression.

Patient impressions. A paper exit questionnaire was administered to patients between 4 and 6 weeks of participation. Items were adapted from validated measures used in prior studies of patient satisfaction with an ordinal scale for responses (Table 2).[31]

Toxicity/Grade	Original Clinician Language	Patient Language Adaptation
Pain		
1 (mild)	Mild pain not interfering with function	I am having mild pain that does not interfere with my normal functioning
2 (moderate)	Moderate pain; pain or analgesics interfering with function, but not interfering with ADL	I am having moderate pain, and my pain or my use of pain medications interferes with my normal functioning, but I am still able to carry out my normal daily activities
3 (severe)	Severe pain; pain or analgesics severely interfering with ADL	I am having severe pain, and my pain or my use of pain medications severely interferes with my normal daily activities
4 (disabling)	Disabling	My pain is disabling me
Fatigue		
1 (mild)	Mild fatigue over baseline	I am having mild fatigue compared with my usual baseline
2 (moderate)	Moderate or causing difficulty performing some ADL	I am having moderate fatigue compared with my usual baseline, or fatigue causing moderate difficulty performing my normal daily activities
3 (severe)	Severe fatigue interfering with ADL	I am having severe fatigue that interferes with my normal daily activities
4 (disabling)	Disabling	My fatigue is disabling me
Nausea		
1 (mild)	Loss of appetite without alteration in eating habits	I have lost my appetite due to nausea, but I am able to eat
2 (moderate)	Oral intake decreased without significant weight loss, dehydration or malnutrition; IV fluids indicated $<$ 24 hours	The amount I eat or drink is decreased due to nausea, but I have not lost weight or become dehydrated or malnourished; I have not needed IV fluids for greater than 24 hours
3 (severe)	Inadequate oral caloric or fluid intake; IV fluids, tube feedings, or TPN indicated $\geq$ 24 hours	I am not eating or drinking adequately and I have required IV fluids, tube feedings, or intravenous nutrition (TPN) for 24 hours or longer
4 (disabling)	Life-threatening consequences	Not included in patient scale
Vomiting		
1 (mild)	1 episode in 24 hours	I have had vomiting, but I have not vomited more than once in a 24-hour period
2 (moderate)	2-5 episodes in 24 hours; IV fluids indicated $<$ 24 hours	I have had vomiting between 2 and 5 times in a 24-hour period, or I have needed IV fluids for less than 24 hours due to vomiting
3 (severe)	$\geq$ 6 episodes in 24 hours; IV fluids, or TPN indicated $\geq$ 24 hours	I have had vomiting 6 or more times over a 24-hour period, or I have needed IV fluids/nutrition for 24 hours or longer due to vomiting
4 (disabling)	Life-threatening; disabling	My vomiting is disabling me
Diarrhea (not including ostomy patients)		
1 (mild)	Increase of $<$ 4 stools per day over baseline	I am having 1-3 bowel movements more than usual each day
2 (moderate)	Increase of 4-6 stools per day over baseline; IV fluids indicated $<$ 24 hours; not interfering with ADL	I am having 4-6 bowel movements more than usual each day, but I have not needed IV fluids for greater than 24 hours, and diarrhea is not interfering with my normal daily activities
3 (severe)	Increase of $\geq$ 7 stools per day over baseline; incontinence; IV fluids $\geq$ 24 hours; hospitalization	I am having greater than 6 bowel movements more than usual each day, or I have needed IV fluids for greater than 24 hours and diarrhea is interfering with my normal daily activities
4 (disabling)	Life-threatening consequences (eg, hemodynamic collapse)	Not included in patient scale
Constipation		
1 (mild)	Occasional or intermittent symptoms; occasional use of stool softners, laxatives, dietary modification, or enema	I am having occasional or intermittent constipation, or I am occasionally using stool softners, laxatives, enemas, or dietary changes to help move my bowels
2 (moderate)	Persistent symptoms with regular use of laxatives or enemas indicated	I am having persistent (ongoing) constipation, and cannot have bowel movements without the regular use of laxatives or enemas
3 (severe)	Symptoms interfering with ADL; obstipation with manual evacuation indicated	Constipation is interfering with my normal daily activities, or I have required manual disimpaction
4 (disabling)	Life-threatening consequences (eg, obstruction, toxic megacolon)	Not included in patient scale

(continued on following page)

Fig 2. Patient language adaptation of National Cancer Institute Common Terminology Criteria for Adverse Events (version 3.0) and Eastern Cooperative Oncology Group performance status. ADL, activities of daily living; IV, intravenous; TPN, total parenteral nutrition.

Toxicity/Grade	Original Clinician Language	Patient Language Adaptation
Appetite/eating (anorexia)		
1 (mild)	Loss of appetite without alteration in eating habits	I have lost my appetite but have not changed my eating habits
2 (moderate)	Oral intake altered without significant weight loss or malnutrition	I am eating less but have not lost a lot of weight or become malnourished
3 (severe)	Associated with significant weight loss or malnutrition (eg, inadequate caloric and/or fluid intake); IV fluids, tube feedings, or TPN indicated	I am losing a lot of weight or I am malnourished, and I am taking in very little food or fluids (or I have needed to get IV fluids, tube feedings, or IV nutrition)
4 (disabling)	Life-threatening consequences	Not included in patient scale
ECOG performance status		
0	Fully active, able to carry out all predisease performance without restriction	I am fully active and able to carry out activities the same as before my cancer diagnosis, without any restrictions
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, eg, light house work, office work	I have difficulty with physically strenuous activity but I am able to walk and carry out work that is light or based in one location; such as light house-work or office-work
2	Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours	I can walk and take care of myself, but I am not able to carry out work activities; I am up and about more than half the hours that I am awake
3	Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours	I am capable only of limited self-care and spend more than half the hours that I am awake in bed or in a chair
4	Completely disabled. Cannot carry on any selfcare; totally confined to bed or chair	I am completely disabled, cannot carry on any self-care, and am totally confined to a bed or chair

Abbreviations: NCI, National Cancer Institute; ECOG, Eastern Cooperative Oncology Group.

Fig 2. (continued)

Clinician feedback. Qualitative impressions and feedback were gathered from participating staff after the study via an anonymous survey and at a team debriefing session.

RESULTS

Enrollment

Eighty-five consecutive patients were approached and invited to participate between April and September 2004. Three were ineligible because they were not starting new chemotherapy regimens, and two were ineligible because of poor performance status (ECOG values of 3). The remaining 80 gave consent and were trained. No approached patients refused enrollment.

Patients

Baseline characteristics are listed in Table 1. Most enrollees were between the ages of 40 and 69. All were women with gynecologic malignancies, with predominantly good performance status (ECOG $<$ 3). Most (76%) reported regular or occasional Internet use, although almost one fourth noted rare or no online experience. The majority held a college or graduate degree, although 19% were not educated beyond high school.

STAR Use in Clinic

During the 8-week observation period, the number of times patients logged in was tracked and correlated with appointments. The proportion of patients logging in on visit days is shown in Figure 3. All participants successfully logged in at the initial training. Seven did not have a follow-up visit during the observation period. Of those who did have a follow-up visit, most (85%) logged in at the first follow-up visit, and log-in rates remained high even at the fourth and fifth visits. Because we did not prevent patients from using STAR after the 8-week observation period, we were also able to measure the log-in rates at clinic visits beyond that period during this 24-week study. We found that rates remained high even up to an eighth follow-up visit, with five of six enrollees continuing to log in (83%).

Table 3 shows the proportion of follow-up clinic visits at which patients logged in to STAR during the observation period. Most individuals used STAR at the majority of their appointments (using either waiting-area computers or home computers the day before). Notably, more than half (65%) logged in before receiving any verbal encouragement to do so.

Home Versus Clinic-Based Use

Table 4 shows the number of clinic visits and total number of times patients logged in to STAR during the observation period. Of the 80 patients, 25% used STAR only from MSKCC waiting area computers, whereas the remainder logged in using both MSKCC and outside computers. There was no difference in the mean number of clinic visits

Table 1. Patient Characteristics

Characteristic	No. of Patients (N = 80)	%
Age, years		
Mean	57	
Median	57	
18-39	5	< 1
40-49	18	23
50-59	22	28
60-69	21	26
> 70	14	18
Sex		
Female	80	100
Cancer type		
Ovarian	46	58
Endometrial	11	14
Other*	23	29
ECOG baseline score		
0	30	38
1	39	49
2	11	14
Computer at home		
Yes	72	90
Internet use frequency		
Regular	40	50
Occasional	21	26
Rare/never	19	24
Highest education level		
Professional/graduate degree	26	33
College degree	27	34
Some college	12	15
High school or less	15	19

Abbreviation: ECOG, Eastern Cooperative Oncology Group performance status criteria.
*Other cancer diagnoses included primary peritoneal (n = 5), cervical (n = 4), fallopian tube (n = 4), uterine leiomyosarcoma (n = 3), mixed müllerian tumor (n = 2), vaginal (n = 2), gestational trophoblastic disease (n = 1), immature teratoma (n = 1), and dysgerminoma (n = 1).

between these two groups (three during the 8-week observation period). However, those with outside access logged in to STAR significantly more frequently than those with MSKCC-only use, with a mean of nine versus three STAR sessions, respectively. Most patients with home computers (83%) logged in to STAR from home during the study without reminders.

Patterns of Use

Most individuals were able to complete and submit the STAR questionnaire in less than 5 minutes (Table 4). The majority of participants (90%) viewed their own STAR reports during the study. The optional free-text diary was also used by most patients (86%), with a mean of six diary entries and 19 participants entering diary information more than 10 times.

Use by Patient Characteristic

In a simple linear regression model, prior Internet experience was found to be associated with a greater number of total (home or clinic) times patients logged in during the observation period ($P = .035$), as well as to a greater number of times patients logged in coincident with clinic visits ($P = .002$). Lower (better) baseline ECOG performance status was associated with a greater number of total times patients logged in ($P = .04$), but not with the number of coincident times patients logged in ($P = .29$). Patient characteristics found not to be associated with log-in frequency in univariate models were age, cancer type, and education level.

Severe Toxicity Alerts

During the study, 57 e-mail alerts were triggered by grade 3 or 4 symptoms, reported by 25 different patients. Fifteen of these alerts originated from waiting area computers on visit days, and these symptoms were addressed by clinicians during appointments. Notably, chemotherapy was withheld or dose was reduced in four patients based on STAR report data. Forty-two of the alerts originated from home computers between visits, in a total of 16 different patients. Of these, 15 alerts were grade 3 fatigue and were not reported to the clinical team in real time. The remaining

Table 2. Patient Impressions of STAR (n = 74)*

Impression	Strongly Agree (%)	Agree (%)	Disagree (%)	Strongly Disagree (%)
I found STAR easy to use	38	58	1	3
I found STAR to be useful	29	63	7	1
Questions were easy to understand	36	61	0	3
STAR made it easier for me to remember symptoms at my clinic visits	30	64	5	1
STAR improved discussions with my doctor/nurse	23	67	10	0
STAR improved my communication with my doctor/nurse	25	60	15	0
STAR made me feel more in control of my own care	13	64	23	0
STAR Improved the quality of my care	0	65	35	0
I would like to continue using STAR	26	70	4	0
I would recommend STAR to other patients	23	75	2	0

Abbreviation: STAR, Symptom Tracking and Reporting.
*Six questionnaires were not returned.

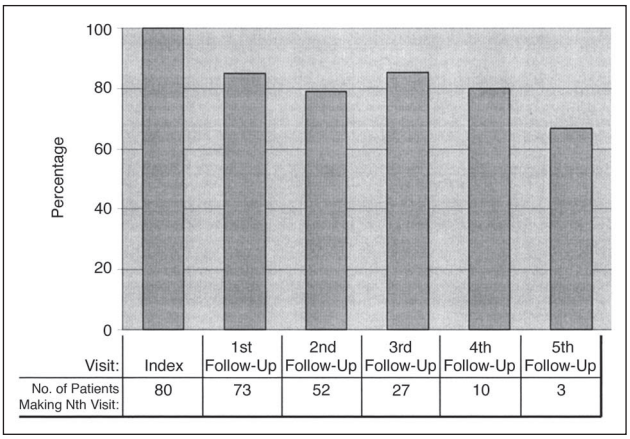

Fig 3. Proportion of patients using the Symptom Tracking and Reporting (STAR) system at a given clinic visit.

reports were communicated to the nurse on the primary team. These contacts resulted in seven telephone contacts with patients (one occurrence of grade 4 pain, one occurrence of grade 3 nausea, two occurrences of grade 3 diarrhea, two occurrences of grade 3 vomiting, one occurrence of grade 3 constipation), with three medication changes and arrangements made for three new clinic visits.

Patient Impressions

Exit questionnaires were retrieved from 74 of 80 patients (one death and five unreturned questionnaires). Results are shown in Table 2. Most patients found STAR easy to use and useful. The majority believed STAR improved discussion and communication with clinicians. Patients were divided about whether STAR improved quality of care. The vast majority wished to continue using the system and would recommend it to others.

Reasons for Using STAR

When asked for reasons that prevented them from using STAR more often, eight patients cited technical problems; four stated that when they felt well they did not perceive the value of reporting symptom information; three noted that on occasion they had felt too ill to log in; three believed that the system was not useful to them; two cited inconvenience on select occasions due to competing demands; and two noted that they had no clinic visits so could not access the site. No patient responded that the system was too difficult to use.

Table 3. Coordination of STAR Sessions With Follow-Up Clinic Visits

Proportion of Visits at Which Patients Logged in (%)	No. of Patients (n = 73)*	%
81-100	49	67
61-80	13	18
41-60	8	11
21-40	3	4
0-20	0	0

Abbreviation: STAR, Symptom Tracking and Reporting.
*Does not include seven patients who did not return for a clinic appointment after enrollment.

Staff Feedback

In the clinician surveys and team debriefing meeting, the five participating medical oncologists and four nurses stated that they had reviewed enrollees' STAR reports before clinic appointments. All but one reported discussing issues raised in STAR reports with patients during visits. This one clinician had only three patient enrollees. Seven of nine clinicians believed that STAR reports were an accurate reflection of patients' clinical status, and noted basing clinical decisions on these data. Eight of nine clinicians believed that patients rated symptoms more severely than clinicians, and that patients reported a larger number of symptoms compared with staff. Nonetheless, eight believed that patient self-reporting would be a useful means to monitor toxicity symptoms during chemotherapy. Seven believed these data could potentially serve as a source of research-grade data during clinical trials, warranting additional evaluation.

Technical Assistance

Four patients sent e-mails requesting technical assistance with logging in, and three called the STAR helpline with questions. All issues were addressed and resolved by members of the MSKCC Information Services Department within 48 hours.

DISCUSSION

This study demonstrates a high level of enthusiasm in a pilot group of patients to regularly self-report symptoms during chemotherapy via the Internet. Most participants logged in at the majority of their follow-up clinic visits, with minimal reminders. Notably, patients had little difficulty using evaluation systems that are usually restricted to staff use, specifically NCI common toxicity symptoms and ECOG performance status.

The ability to collect these data directly from patients at appointments holds clear benefits in the routine care setting. Severe symptoms or functional difficulties can be flagged for clinician review, and the limited clinical time available can be focused on areas where problems have been reported. Self-identification of problems may circumvent the reporting bias of third parties.

Our results suggest potential benefits of real-time PRO collection between visits, when patients are in their home environments. Patients with home computers accessed STAR an average of three times between each appointment, without any reminders to do so. Collection of symptom data between visits may provide valuable insights about the

Table 4. Clinic Visits and STAR Use During the Observation Period

Variable	All Users (n = 80)	Home/Clinic Users (n = 60)	Clinic-Only Users (n = 20)
Clinic visits			
Mean No. of visits	3	3	3
Range of visits	1-6	1-6	1-5
Total No. of times patients logged in to STAR			
Mean	7	9	3
Median	5	8	2
Range	1-30	1-30	1-5
Duration of STAR sessions, minutes			
Mean duration	4.6	4.8	4.5
Median duration	4.8	4.9	4.8
Range	1-14	1-14	1-9
STAR feature use			
Patients who viewed own reports	72	55	17
%	90	92	90
Patients who used the diary	69	52	17
%	86	87	85

Abbreviation: STAR, Symptom Tracking and Reporting.

experience of chemotherapy patients. Patients may forget symptoms they have experienced by the time they attend their next appointment.[32] Real-time reporting may also provide early warnings about potentially concerning symptoms and improve clinician response times. In this study there were 42 grade 3 or 4 toxicities voluntarily reported by patients from home computers between visits. Recent attention has been given to the development of rapid reporting systems for early detection of toxicities in clinical trials,[33,34] and systems such as STAR may aid in such initiatives.

Collection of PROs using systems such as STAR may be of particular use in clinical trials.[12-14] During most NCI-sponsored treatment trials, a complex chain of toxicity reporting is employed in which symptoms are often elicited by physicians or nurses, noted in the medical chart, abstracted by research assistants/data managers, and entered into a database. Responses and measurement criteria may not be consistent between reporters or steps in this process, and there is a risk of losing or altering content at each step.[11] In contrast, patient self-reporting removes several intermediate steps, and may improve the capture and consistency of recorded outcomes. Provision of PROs may obviate the need for symptom gathering by data managers for many patients. The role of these data managers could then be redefined to focus on more detailed characterization of patient toxicities, or to evaluate those who are unable or unwilling to provide their own PROs.

The demonstrated feasibility of collecting patient-reported ECOG performance status is also notable. ECOG scores are often used to determine eligibility for trials or for off-trial chemotherapy. Our results suggest the feasibility of continuous ECOG assessment during chemotherapy, which may provide a superior account of the patient experience compared with current methods.

Our pilot study raises questions that merit additional evaluation. It remains unclear if symptom PROs represent a source of data that could be regarded as sufficiently reliable for routine patient management, for decision-making in the clinical trial context, or by regulators considering drug approval. Although QoL and utility elicitation directly from patients has become well-accepted in clinical research, PROs are not routinely collected during clinical practice, and patient-reported symptoms are not widely regarded as a source of research-grade data. Additional research assessing the relationship between patient and clinician symptom reporting and models of complementarity is also needed (we could not compare the severity or completeness of patient reporting *v* clinician assessments because in the routine care setting, standardized clinician symptom reporting is not mandated or consistently documented). Integration of PRO collection into current paradigms could take various forms: as a source of additional information that enhances clinician assessments or as a replacement for information currently gathered by staff.

Aside from any potential value to clinicians or trialists, STAR clearly was appreciated by patients. The vast majority expressed a desire to continue using the system, and would recommend it to others. Preliminary evidence suggests that the process of self-reporting improves patient satisfaction.[3] The clinicians involved in our study believed that a primary benefit of STAR was the increased sense of empowerment in patients, and 77% of patients stated that STAR made them feel more in control of their own care.

This study demonstrates the potential advantages of using the Internet specifically as a platform for PRO collection. No specialized equipment was necessary in clinic areas, patients logged in from home using their own computers and Web-browsing software, minimal training was necessary, and technical difficulties were few and were quickly resolved. Therefore, regardless of whether patient symptom self-reporting is ultimately accepted as a source of clinically meaningful data, this study suggests the feasibility of the Web for collecting information directly from patients with cancer.

As the digital divide narrows, so grows our ability to communicate with patients over the Internet. Most US households now have Web access,[26] and electronic collection of data affords the opportunity to store large volumes of information and retrieve it for clinical care or research. Online PRO collection also provides an opportunity to integrate new strategies that reduce the number of necessary questionnaire items, such as computerized adaptive testing and item response theory.[35,36] As a growing number of personal digital assistants and mobile telephones become Web-enabled, the prospect grows for real-time Web-based reporting via these devices.

There are notable limitations of this study. All enrollees were women with gynecologic malignancies being cared for at an urban tertiary cancer center. These characteristics may not be generalizable to the overall cancer population. Patients were relatively well educated, with a high degree of computer ownership and Internet experience, although levels of Web access were comparable with levels reported for the US population overall.[26] All had good baseline performance status (ECOG < 3), a selection criterion shared by many chemotherapy trials. Better baseline ECOG score was associated with a greater total number of times patients logged in, suggesting that ill patients may be less inclined to self-report (although the number of times patients logged in concordant with clinic visits was not related to ECOG score). Because patients were reminded at appointment check-in that they could log in to STAR, adherence levels may have been increased (although home use was popular without any reminders). Only seven specific toxicity symptoms were included in the online questionnaire, rather than the wider span of categories generally included in a review of systems. The 24-week duration of this study and observation period of 8 weeks may not have been sufficient to detect attrition that may occur over longer periods of time.

This study does not compare the feasibility of computer- versus paper-based data collection. It is possible that compliance might have differed if another method were used to gather patient symptoms. Prior QoL research suggests similar levels of patient compliance using touch-screen computers versus paper surveys, including symptom items.[27] However, specific patients may be unable or unwilling to use computers, necessitating other approaches in these individuals. In our patient population, we found a significant association between prior Web use and total number of times patients logged in. Furthermore, when surveyed about barriers to using the system more frequently, eight patients cited technical difficulties and two noted inconvenience. These findings suggest that the Web interface itself presented barriers to data collection on some occasions. These barriers might be overcome with technical improvements or over time as computers become progressively familiar across patient populations. However, they may present persistent limitations of this approach, particularly in populations without computer avidity. This remains a question for future investigations.

In conclusion, our results support the feasibility of collecting patient-reported symptoms over the Internet during chemotherapy. Systems such as STAR may potentially increase the depth and accuracy of available clinical data, save administrative time, prompt early intervention that improves the patient experience, foster patient-clinician communication, improve patient safety, and enhance the consistency of data collection across sites. Currently, it is not standard practice in routine cancer care or treatment trials to gather symptoms directly from patients, or to use these data as a basis for clinical decisions, research conclusions, or drug approval. Future research should focus on comparing patient versus clinician reporting for the same symptom items, evaluating the impact of PROs on staff reporting patterns, and assessing the feasibility of gathering patient-reported symptoms during clinical trials.

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Authors' Disclosures of Potential Conflicts of Interest

The authors indicated no potential conflicts of interest.

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