The following protocol information is provided solely to describe how the authors conducted the research underlying the published report associated with the following article:

The Electronic Self Report Assessment for Cancer and Self-Care Support: Results of a Multi-Center Randomized Trial

Berry, et al

DOI: 10.1200/JCO.2013.48.6662

PROTOCOL **08-284**

Closed to New Accrual

Closure Effective Date: 06/22/11

No new subjects may be enrolled in the study as described above. Any questions regarding this closure should be directed to the study's Principal Investigator

DANA-FARBER CANCER INSTITUTE
DANA-FARBER / HARVARD CANCER CENTER

Office for Human Research Studies

Protocol Front Sheet

DFCI Protocol No.: 08-284

1. PROTOCOL TITLE AND VERSION

Title: Computerized Assessment for Patients with Cancer - ESRA-C II
Protocol Version No./ Date: 10/11-19-2010 **Sponsor Study Number:** 2RO1NR008726

2. DF/HCC STUDY CONTACT INFORMATION

Study Contact for Questions: Barbara Halpenny **Email:** barbara_halpenny@dfci.harvard.edu **Phone:** 617.582.7124

OVERALL AND SITE RESPONSIBLE INVESTIGATORS (List only those under DFCI IRB, *i.e.*, from institutions listed in Section 6 below)

Overall PI:	Donna L. Berry, PhD, RN	**Phone:**	617.632.1909	**Institution(s):**	DFCI
Site Responsible PI:		**Phone:**		**Institution(s):**	

Co-Investigators name (institution)**:** Ann Partridge, MD (DFCI), Lisa Kennedy Sheldon, PhD, RN (DFCI)

Additional Study Staff/Contacts name & institution (no more than one person per institution listed in section 6 below)**:**

3. DRUG / DEVICE INFORMATION N/A:

Drugs, Biologics, Devices (name & IND/IDE#):
IND/IDE held by: (Check if IND/IDE exempt: ☐)

Investigational Drug Brochure (IDB) Version No./ Date:
(Check if already on file with OHRS:☐)

4. PROTOCOL COORDINATION, FUNDING, PHASE, MODE, TYPE ETC.

Protocol Coordinated By:
DF/HCC Investigator

Cancer Related: Yes If yes:
Primary Disease Program:
[pull down]
or
Primary Discipline Based Program:
Cancer Nursing

Funding/Support (check all that apply)**:**
☐ Industry:
☒ Federal Organization: NINR
Grant #: 2R01NR008726
☐ Internal Funding:
☐ Non-Federal:
☐ Other:

Phase: Phase 3

Multi-Center (i.e., non-DF/HCC site participation)**:**
Yes

Protocol Type: Supportive Care
If Ancillary, provide parent protocol #:

Protocol Involves (check all that apply as listed in the protocol document, even if not part of the research but is mandated by the protocol document)**:**

☐ Chemotherapy	☐ Hormone Therapy	☒ Medical Record Review
☐ Immunotherapy	☐ Vaccine	☒ Questionnaires/Surveys/Interviews
☐ Surgery	☐ Data Repository	☐ Radiological Exams
☐ Bone Marrow/Stem Cell Transplant	☐ Exercise/Physical Therapy	☐ Required Biopsy Study
☐ Cell Based Therapy	☐ Genetic Studies	☐ Human Embryonic Stem Cell
☐ Gene Transfer (use of recombinant DNA)	☐ Human Material Banking	☒ Other: Audio-recordings
☐ Radiation Therapy	☐ Human Material Collection	

5. SUBJECT POPULATION (also applies to medical record review and specimen collection studies)

Total Study-Wide Enrollment Goal: 796 patients, 280 clinicians = 1076 total **Greater than 25% of the overall study accrual will be at DF/HCC:** ☒ Yes ☐ No

Total DF/HCC Estimated Enrollment Goal: 705 patients, 200 clinicians = 904 total **Adult Age Range:** 18+ **Pediatric Age Range:**

Will all subjects be recruited from pediatric clinics? ☐ Yes ☒ No

If enrolling both adults and pediatric subjects, anticipated percent of pediatric subjects:

6. INSTITUTIONAL PARTICIPANTS UNDER DFCI IRB

Dana-Farber/Harvard Cancer Center: (check all that apply)
☐ Beth Israel Deaconess Medical Center
☒ Brigham and Women's Hospital
☐ Children's Hospital Boston
☐ Dana-Farber Cancer Institute
☐ Dana-Farber Cancer Institute at Faulkner Hospital
☐ Dana-Farber Cancer Institute at Londonderry Hospital
☐ Dana-Farber Cancer Institute at Milford Hospital
☐ Dana-Farber Cancer Institute at South Shore
☐ Massachusetts General Hospital
☐ Massachusetts General Hospital/North Shore Cancer Center
☐ Massachusetts General Hospital Radiation Oncology at Emerson Hospital

DF/PCC Network Affiliates: (check all that apply)
☐ Cape Cod Healthcare (Hyannis, MA; Mashpee, MA)
☐ Lowell General Hospital (Lowell, MA)
☐ New Hampshire Oncology-Hematology-P.A. (Concord, NH; Hooksett, NH; Laconia, NH)
☐ Newton-Wellesley Hospital (Newton, MA)

7. DF/HCC INITIATED STUDIES ONLY - INSTITUTIONAL PARTICIPANTS UNDER OTHER IRB (N/A:)

DF/HCC Multi-Center Protocols: (list institution/location)
University of Washington/ Fred Hutchinson Cancer Res. Ctr. Seattle, WA

DF/PCC Network Affiliates: (list institution/location)

8. OTHER INVOLVED SITES NOT UNDER DFCI IRB (N/A:)

Protocol Number: 08-284

Approval Date: 10/17/08 (IRB meeting date when protocol/consent approved or conditionally approved)

Activation Date: 10/20/08 (Date when protocol open to patient entry)

Approval signatures are on file in the Office for Human Research Studies, tel. 617-632-3029.

Date Posted	Revised Sections	IRB Approval Date
03/02/09	Consent Form (Pt CF only), Front Sheet and Protocol (appendices C, G, K, L-new) replaced due to Amendment # 1	02/26/09
04/24/09	Consent Forms, Front Sheet and Protocol (appendices C, G, L) replaced due to Amendment # 2	04/23/09
06/29/09	Front sheet replaced due to Amendment #3	06/25/09
08/03/09	Front sheet replaced due to Amendment #4	08/03/09
08/04/09	Front Sheet and Protocol (appendix G) replaced due to Amendment # 5	08/03/09
09/08/09	Protocol, Patient Consent Form, Front Sheet and Appendix G replaced due to Amendment #6	09/01/09
09/29/09	Study renewal due to Continuing Review #1	09/23/09
11/25/09	Front sheet replaced due to Amendment #7	11/23/09
12/30/09	Front Sheet and Appendices C and G replaced due to Amendment #8	12/23/09
01/27/10	Clinician Consent Form replaced due to Amendment #9	01/21/10
04/30/10	Appendix M added; Protocol, Front Sheet and Appendices C and G replaced due to Amendment #11	04/05/10
07/28/10	Front sheet replaced due to Amendment #12	06/09/10
09/10/10	Protocol and Appendix G replaced due to Amendment #13	08/31/10
09/23/10	Study renewal due to Continuing Review #2	08/25/10
09/23/10	Consent Forms and Front Sheet replaced due to Amendment #14	09/16/10
01/21/11	Protocol, Consent Forms and Front Sheet replaced due to Amendment #15	01/14/11
03/23/11	Patient Consent Form and Front Sheet replaced due to Amendment #16	03/10/11
08/02/11	Permanent Closure to New Accrual: accrual goal met. (Effective 06/22/11; Amendment # 17)	08/01/11
08/05/11	Study renewal/ Consent Forms footer replaced due to Continuing Review #3	08/03/11

Computerized Assessment for Patients with Cancer (ESRA-C II)

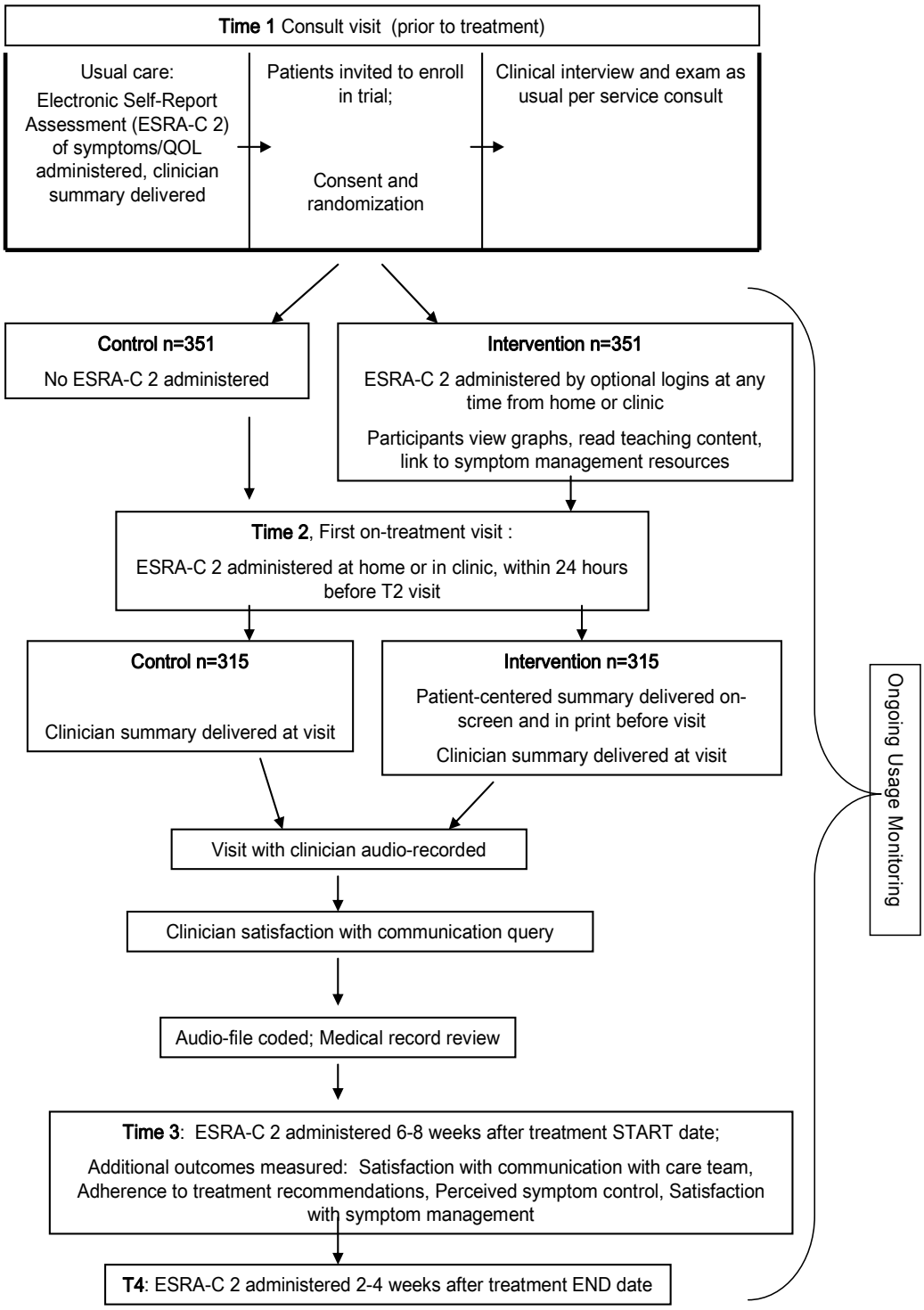
Protocol # 08-284

Participating Institutions

Dana-Farber Cancer Institute (Lead Site)
PI: Donna L Berry, PhD, RN, FAAN, AOCN

University of Washington / Seattle Cancer Care Alliance
PI: Seth Wolpin, PhD, RN, MPH

PROTOCOL SCHEMA



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1.0 INTRODUCTION

Patients with cancer arrive in the therapeutic setting with varying levels of symptomatology and other types of responses to the cancer diagnosis and experience. Once treatment begins, another profile of symptoms commences as toxicities and treatment-related complications develop. These symptoms, and the related psychological, social, family and work impact of cancer and its treatment, can be burdensome or overwhelming to many patients.[1,2]

Assessing and managing symptoms and quality of life (QOL) concerns is a major goal for both patients and oncology clinicians. Standardized assessments of symptoms and quality of life (SQI) have been developed and used widely in research studies to measure outcomes of treatments and interventions. They have also been used clinically, and have been found: to increase the depth and breadth of discussions of SQIs[3,4,5] and patient-reported emotional well-being[5,6] in audio-recorded clinic visits with cancer patients; to increase treatment of psychosocial issues and symptoms in patients in oncology[5] and general internal medicine clinics;[7,8] and to increase referral rates to other professionals for patients assessed with a QOL instrument in an emergency medicine setting.[9] Most clinical use of SQI assessments involves some summary report to clinicians, in numerical, textual or graphical format, of patient responses on the assessments, and aims thereby to enhance patient-provider communication.

With new information technologies, assessments can increasingly be conducted with computerized assessment, eliminating abstraction and data entry of paper forms, increasing accuracy of reports, and making summaries available to clinicians in real time. Additionally, the emerging fields of tele-health, and patient-centered management of health information, suggest avenues for enhancing patient-provider communication, and patient knowledge and control of SQI data, through the use of patient-centered Internet technology. An SQI assessment and management tool that is patient-centered may allow patients to perform self-assessments, learn about their SQIs, and be coached in communicating about them with their providers. An intervention that combines summaries delivered to patients with those delivered to clinicians may be a powerful tool in the management of cancer patients' symptom and quality of life concerns.

1.1 Overview

The goal of this study is to test, in a randomized trial, an online, patient-centered tool for self-assessment and management of symptoms and quality of life issues (SQIs). This tool, the Electronic Self-Report Assessment for Cancer (ESRA-C v 2), aims to improve patients' experience by enhancing communication between patients and their clinical care team as well as their home caregivers. ESRA-C 2 includes patient reports of SQIs using standardized assessments; a graphic summary of the patient's report delivered to the clinician; and, in the intervention arm, a graphic summary of the patient's report delivered to the patient along with educational instruction on self-care strategies and coaching on how to discuss their SQIs with their clinicians.

Patient participants in medical and radiation oncology will complete the ESRA-C 2 assessment twice as standard of care in study clinics, before beginning treatment (T1) and at the first clinic visit after treatment begins (T2). Summary reports will be delivered to clinicians in real-time for T1 and T2 clinic visits for all patients. Patient participants will additionally complete 2 follow-up assessments, 6-8 weeks after treatment begins (T3), and 2-4 weeks after treatment ends (T4). Completion of each assessment is estimated to take 15-20 minutes, plus an additional 10 minutes at T3 for outcomes questionnaires. Participants in the intervention arm can complete additional assessments as often as they like, and will receive customized feedback on self-care strategies, as well as coaching on discussing SQIs with their care team. The T2 clinic visit will be audio recorded; recordings, and medical records of the visit, will be coded for assessment, treatment and referrals regarding SQIs. Clinicians will respond to a short satisfaction-with-communication instrument after each visit. Patients will report at T3 on their satisfaction-with-communication with their care team, acceptance and adherence to clinical recommendations for SQI management, and self-care strategies. The study will be conducted in two primary sites, Dana-Farber Cancer Institute and Seattle Cancer Care Alliance, and is expected to enroll 795 patient and 280 clinician participants.

Funding for the study is from the National Institute of Nursing Research (NINR) through a competitive renewal of a research project grant. The ultimate goal of this line of research is to enhance patient-provider communication, clinical management of SQIs, patient experience and well-being during and after cancer treatment, and patient satisfaction with their treatment and experience.

1.2 Background and Rationale

Cancer symptoms and quality of life

Cancer symptoms not only are indications of the physiologic changes associated with disease and treatment toxicity, but also reflect linkages to patients' perceived reality, including social, psychological and cultural factors.[10] Pain and fatigue are the two pre-eminent, significant symptoms that are addressed in virtually every publication about cancer experiences and supportive care of persons with cancer. As reviewed by Cleeland,[11] the high incidence of cancer-related pain and fatigue, along with dyspnea, depression, and cognitive deficits, has been reported often over the last decade. The prevalence of elevated psychosocial distress among patients with cancer at diagnosis and recurrence is reported to be at least 30%,[12] with clinical depression also occurring in 25% of cases.[13] The National Institutes of Health convened a 2002 State-of-the-Science Conference on Symptom Management in Cancer: Pain, Depression, and Fatigue.[14] The conference panel consensus that the incidence of these symptoms was unacceptably high considering the interventions we have available. The panel recommended several areas of research, notably studies aimed at testing various screening and assessment methods. Clusters of symptoms are beginning to be evaluated and studied in the hope of providing enhanced symptom management for these concomitant experiences.[15]

The assessment of health-related quality of life (QOL) as a broad and comprehensive outcome of cancer and cancer treatment has become well established in health research and clinical trials in recent years. Consensus among researchers is that

the construct of QOL typically encompasses the dimensions of physical, psychological, and social functioning as well as symptomatology.[16,17,18,19,20] Although the definition of the term "quality of life" is elusive due to the subjective nature of its appraisal, the relationship between cancer symptoms and QOL is intuitive for most clinicians. Most research literature about cancer treatment and symptoms assumes that symptoms mediate between types of treatment and diminishing aspects of function. For example, Given et al.,[21] studied the relationship between symptoms and physical functioning in elderly patients with cancer, reporting a significant relationship between symptoms and function which was independent of treatment modality or cancer site. Recent research findings have documented the deleterious impact of symptom clusters on quality of life.[22]

With the incidence of individual and groups of cancer symptoms at such a high level across various diagnoses and stages and the apparent impact of such experiences on the dimensions of quality of life, the consequences of inadequate symptom management are complex and can be overwhelming to patients and their caregivers. For example: uncontrolled pain may shorten survival,[23] severe mucositis or radiation-associated skin changes can put patients at risk for additional complications,[24] and nausea, vomiting, diarrhea and anorexia can compromise not only nutritional status but ultimately can effect cognition, mobility and metabolism.[25,26] Early screening for psychosocial distress may enable clinicians to identify patients at higher risk and intervene to prevent development of crisis events. Depression, in particular, may increase disability, morbidity and mortality by compromising adherence with treatment, rehabilitation and risk factor modification.[27]

Making cancer symptoms and QOL issues visible and discussed in the clinic can promote partnership between clinicians and patients, validating the patients' experiences and enhancing communication and satisfaction.[28] Yet, recent trends in managed care to reduce physician time spent with each patient have rendered existing measures less feasible.[13] Rapid, predictive screening may help reduce unnecessary health care utilization costs and prolonged medical treatments, as well as enhance quality of life.[29] The challenge of efficient, systematic and meaningful assessment is important and timely in current clinical cancer settings.

Patient–Clinician Communication

Promoters

Various strategies to enhance communication between patients and clinicians have been studied. Three review papers published in 2005[30,31,32]concluded that most interventions in the oncology setting have focused on teaching and coaching the patient to ask pertinent questions designed to elicit the information most required by the patient to participate in a treatment decision. However, work in symptom management and QOL also have implications for improving patient-clinician communication.

European trials of computerized assessments reported by Taenzer[4] and Velikova[28] have found use of these assessments by patients and delivery of output to clinicians increased discussion of SQIs – as reported by patients or abstracted from medical records. Trials reported by Detmar,[5] Berry,[3] and Velikova[6] have introduced audio recordings of clinic visits as a way to measure communication more directly, and these studies have also found more counseling on SQIs occurs when patient-reported outcomes are provided in a summary to clinicians.

Barriers

Donovan and colleagues[33] conceptualized how patient behaviors are associated with optimal symptom management. For a survey study of symptom communication and management in 279 women with ovarian cancer, the authors based their work on the following beliefs: "Optimal symptom management…was dependent on patient efforts in 3 domains: communication with health care providers about symptoms, adherence to any treatments/strategies recommended by their health care provider, and use of self-directed strategies to cope with symptoms" (p. 405). The investigators found that symptom incidence was high, yet only 61% of the women recalled discussing the distressing symptom with a provider. Furthermore, when no recommendation for symptom management was given, women reported low perceived control of their symptoms. These results emphasize the importance of two-way communication about cancer symptoms and help form the foundation of the ESRA-C 2 intervention.

The manner in which clinicians respond to patient-initiated discussions of SQIs or computer-generated symptom may be poorly understood barriers. For instance, clinicians in the Cancer Pain Coaching study[34] were attentive to problems relevant to treatment side effects; however, the results also indicate a pattern of communication during the clinic visit that was typically clinician-oriented, including interruptions and many closed-ended questions. The nature of such communication may prevent the patient from sharing significant facts and experiences relevant to cancer pain and thus compromise the quality of symptom management. It is a clinical dilemma that clinicians are intent on helping their patients through the treatment but may attend only to the issues with which the clinician is most familiar. Additionally time constraints, institutional policy or reimbursement issues may preclude comprehensive symptom management. These factors were identified as possible contributors to inadequate symptom care by the NIH conference panel in 2002, and there is now empiric evidence to support the consensus. Assuring expedient clinician access to resources for symptom management and referrals is essential to any attempt to alleviate symptom distress.

Another barrier for patients as they try to articulate their symptom experiences, rarely addressed in the professional literature is that of general versus specific assessments, a particular concern in the area of pain assessment. Because of certifying agency regulations (e.g., the Joint Commission), pain intensity is routinely assessed, very much like a vital sign. Pain is a dynamic, developmental process, not a single event or simple quantifiable product. The results of reviews on pain assessment in adults[35,36]support the recommendation that measures of pain intensity, the use of rescue treatments, pain quality, and the temporal components of pain should be considered when assessing pain outcomes. There is evidence from clinical trials of pain assessment methods that reliance on pain intensity alone results in over-sedation.[37] The available evidence indicates that measures of pain frequency have shown criterion-related validity through their association with pain intensity and interference composite scores, type of treatment received, and pain affect (the level of distress). These preliminary findings indicate that pain frequency is both related to, but also might be distinct from, measures of pain intensity. A number of pain assessment instruments are available, but in spite of the well-publicized recommendations, pain is typically assessed by single-item ratings of pain intensity. In clinical practice, not only the length, but also difficulties with reconciling scores from different scales contribute to the preference for single item scales

that only measure one of the important dimensions. ESRA-C 2 will incorporate a more comprehensive assessment of pain, and will evaluate the usefulness of this addition with regard to whether this approach enables a specific and customized assessment for our patients who have pain.

Customized education and coaching

In research addressing factors relevant to prostate cancer treatment decision making, the PI and colleagues have discovered the influence of personal factors, those which help the patient place the treatment decision in the context of his own life experience.[38] Only through customized education can clinicians guide and help a patient navigate the overwhelming amount of information for a given diagnosis.[39] Current interventions in symptom management education and coaching are typically either generic (e.g., books, handouts) or customized, involving one-to-one personnel resource utilization (e.g., the PRO-SELF Program)[40] limiting feasibility in many cost-conscious settings. The capabilities of computerized self assessment programs can enable auto-generated, customized education and coaching for patient-specific needs, as demonstrated with the PI's Personal Patient Profile-Prostate (P4) intervention.[41] The same software framework that supports the P4 intervention will be used in ESRA-C 2, which allows delivery of tailored education and coaching when patients report moderate or severe distress from SQIs.

Health care system issues

Health care consumers have experiences, opinions, knowledge and objective data about their health that are not systematically incorporated into their care. Human biology and behavior are complex under normal health states. These complexities are intensified in the context of health risks or adverse health conditions. Modern assessment and monitoring of an individual's health status, and delivery of cutting-edge interventions, require orchestration of not only patients and direct care providers, but also an entire community of technology experts, innovators and service providers. However, our current health system is characterized by limited face-to-face patient-clinician contacts that occur at times and locations that can be inconvenient for the patient. The system fails to provide the adequate opportunities for the integration of clinical data with patients' subjective and objective information, which are required to provide care that is "safe, effective, patient-centered, timely, efficient, and equitable" (p. 25).[42]

Changes in payment for and organization of care have resulted in a changing work environment for many clinicians. Many health care services, including much of the care provided to cancer patients, have shifted from inpatient to ambulatory settings. A move from traditional fee-for-service payment systems to managed care has created incentives for health care organizations to provide care using fewer resources.[43,44] One common result of these changes has been an increase in the numbers of ambulatory patients evaluated within a given time period. Patient surveys have reported that clinicians spent less time talking with patients and offered less explanation of care in a managed care setting than in settings primarily reimbursed through traditional fee-for-service payment structures.[45] At the same time, effective clinician-patient communication is increasingly emphasized as an important aspect of quality cancer care, as reflected in

standards for clinical care and clinical outcomes promoted by government[46] and accreditation bodies[47] and by oncology professionals.[48]

The future of health care delivery in the United States is moving well beyond the boundaries of the centralized, hospital based system. The deployment of assessment and intervention techniques must be distributed in all locations and available outside of normal clinic hours. Assessing and incorporating patient preferences and values, engaging the patient in the diagnostic processes and therapeutic interventions, and extending the interaction to the place and time favored by the patient are necessary to bring meaning to the term "patient-centered." Technological approaches to distributing patient assessments and interventions can offer the patient an opportunity to participate more fully in the clinical process by allowing information gathering and follow-up to occur a convenient location, at a convenient time, and without the clock ticking away the minutes of an office visit. Designing, implementing, and evaluating these approaches can only be addressed by sustained interdisciplinary collaboration, and by a new approach to extending health care to include asynchronous, distributed assessments and interventions. With these possibilities, routine symptom screening and monitoring can become a clinical reality.

Electronic assessment technology

Advances in computer and Internet technologies have made electronic health assessment a feasible and attractive method of gathering patient-reported information in clinical settings. The Internet, in particular, offers a dynamic, tailored and flexible mode of interaction with the user that is unavailable with paper materials. The benefits of moving from oral interview and/or paper questionnaire completion to electronic assessment have been described and studied over the last 3 decades and more recently in oncology settings.[28,6,4, 49,50,51,52,53,54,55] In these published studies, the majority of the participants reported a preference for electronic questionnaires when given experience with both paper and computerized versions of the same questionnaire. There is resounding acceptability for computerized versions of a variety of questionnaires from both patients and clinicians.[4,49,52,55,56] The majority report no significant or meaningful difference in responses between modes of administration, or difference between modes of administration.

Usability and acceptability

Usability may be defined as *"the degree to which people (users) can perform a set of required tasks."*[57] Most people have encountered usability difficulties in their everyday lives such trying to set the clock on the video player, ordering something online, and at self check-outs at libraries and grocery stores. Each of these tasks requires an interaction between a human and a computer interface. If the interface is well designed the application may be quickly embraced by the end user; however poor design can not only turn away potential users, but lead to measurement error and non-diffusion among target user groups. There is a well-established body of research in usability and structured software design methods,[58] but it has not been systematically applied to the development of patient-centered software. Too often, websites are created quickly, based on usability skills of professionals. The Department of Health and Human Services has posted guidance on web design for health consumer use,[59] but the adoption of these guidelines is largely unknown. Development of ESRA-C 2 has proceeded following this guiding

framework, through an iterative participatory design process involving extensive input and usability testing by cancer patients, caregivers and web usability experts.

Information portal

The ESRA-C has been successfully tested as a stand-alone intervention delivered in a clinical setting. While its content is "patient-centered," its delivery to date has been "clinician-centered," i.e., delivery of report summaries to clinicians, yet the Institute of Medicine report *Crossing the Quality Chasm* identifies patient-centered care as one of its fundamental tenets.[60] In the years since that report was released, the movement towards patient-centered health records has gathered momentum. While patients have always tried to organize information about their health care, frequently the only health information to which they had easy access was prescription receipts, insurance bills, appointment slips, and other secondary information that found its way to personal files or shoeboxes. Within the past 5 years, there have been a large number of personal health records introduced. While the goals of some of these systems are to provide a vehicle for targeted advertising, or connect a patient to a particular health care system, many systems share the explicit aim of providing a patient-centered location for storing electronic health information. The diverse business models and many entrants into this field suggest that the single "best" way to provide patient-centered health record systems, if there is one, is not clear.

The ESRA-C co-investigator Lober's Clinical Informatics Research Group (CIRG) at the University of Washington has developed several versions of a patient-centered, patient- controlled information system that have been implemented in diverse settings: to demonstrate patient-controlled sharing of information with a prototype regional health information network,[61] as well as to explore the barriers to use of personal health records in an elderly and disabled population.[62] One goal of the enhanced ESRA-C 2 is to develop it as a patient-controlled health record, and to explore its use for patient-directed data entry and sharing of information.

Summary

The comprehensive assessment of both cancer symptoms and quality of life issues (SQIs) are vital components of clinical care. Accurate assessment and clinical interpretation of SQIs allow timely and effective intervention that might potentially ameliorate morbidity and mortality. Electronic, patient-generated information and data has been shown to be feasible and acceptable in all previous work, and patients have demonstrated the ability to complete such assessments. Clinicians may be prevented from addressing important SQIs for a variety of reasons including lack of time to engage in an extended assessment and lack of knowledge about appropriate interventions, and patients may hesitate to bring forth a concern that the clinician appears not to prioritize. This study evaluates a unique clinical application of a computerized patient assessment of cancer SQIs, targeting a customized, patient-centered intervention to coach the patient regarding communicating their priority SQIs. Additionally, an exploration of a patient-controlled portal that can become a personal health record of the cancer treatment experience is warranted. The ultimate goal is to streamline meaningful assessment and enhance patient-clinician communication and consequential care in clinical oncology settings.

In the study described and previous work, the PI and co-investigators, in conjunction with CIRG, have developed the open-source Distributed Health Assessment and Intervention Research (DHAIR) software framework. DHAIR was used to develop and implement the Electronic Self-Report Assessment – Cancer (ESRA-C v. 1), used successfully by over 700 adult ambulatory patients in a comprehensive cancer center in 2005-2007. This study demonstrated that routine screening of adult ambulatory cancer patients with a variety of disease types is feasible in a large cancer center, and effective in identifying and prompting increased communication of some SQIs.[3]

With NINR funding through a competitive renewal, the PI and CIRG are completing a development cycle that expands the ESRA-C software from an assessment tool providing reports to clinicians only, to a tool that delivers feedback to patients in addition. ESRA-C 2 will be a patient-centered assessment tool, allowing access online from anywhere a patient stays, and delivering customized self-care strategies and coaching on the need to discuss SQIs with health care providers. ESRA-C 2 has been in development with input from patient focus groups, and individual patient and expert usability testing, since February, 2008 at the University of Washington / Fred Hutchinson Cancer Research Center (protocol 6574). Final development is expected to be completed by November, 2008, and the new software will be tested in this trial.

Previous study: Computerized Assessment for Patients with Cancer (aka Electronic Self Report Assessment-Cancer (**ESRA-C**). 2004-2007. D Berry, W Lober, B Karras, M Austin-Seymour, JR Fann, N Bush, S Wolpin.

Aims: 1) Compare the clinical impact of ESRA-C output to usual care in stem cell transplant, medical oncology and radiation oncology services; 2) compare process variables relating to the feasibility of using usual care forms and ESRA-C; and, 3) establish the clinical significance of quality of life measures for each of our target disease-treatment combinations in all patients who complete two assessments using ESRA-C.

Studies and Results: In this randomized clinical trial, 2 patients/clinician/month were enrolled at the Seattle Cancer Care Alliance, the clinical setting of a large comprehensive cancer center. Each participant completed the ESRA-C pre-treatment and approximately 6 weeks later on a portable touch screen computer. The questionnaires of ESRA-C included symptom distress, a pain intensity scale, a depression screening scale, quality of life, acceptability and a response shift assessment. At the second assessment point, the patient was randomized to the intervention arm (graphic results delivered to the clinical team) or the usual care control group. Audio-recordings were made for all participants of the clinic visit immediately following randomization. Coding of the recordings and chart review were conducted to measure the frequency of symptom and quality of life components discussed and documented during and after the visit.

Clinician enrollment was 262 of 295 approached (89%); 796 of 1104 (67%) patient participants enrolled, with an attrition rate of 11% throughout the study, mostly due to patients leaving the clinic and continuing their care elsewhere. Medical Oncology represented the largest recruitment group (48%), followed by HSCT (28%) and Radiation Oncology (24%). The racial diversity in the sample matched that of the SCCA patient population, i.e., 9% minority enrollment.

Regarding feasibility of routine symptom and quality of life screening, the primary finding was that patients were generally able to utilize ESRA-C quickly and without difficulty in a real-world clinical setting and that they were quite satisfied with the ESRA-C platform.[63] The mean time to complete was 15.33 minutes (SD=6.26 minutes). Significant differences were found in several acceptability areas with respect to demographics and quality of life measures, such as age and gender, but overall acceptability was high.

Successful use of the PHQ-9 as a screening instrument for depression has also been described in the same initial sample,[64] with prevalence estimates comparable to other methods of assessment. Using this screening method, 21 (6.1%) at T1 and 54 (15.8%) at T2 of the total sample were found to be in the moderate to severe range of depression. The average time to complete the PHQ-9 was about two minutes. Acceptability was high, with depressed patients finding the ESRA-C assessment slightly less acceptable.

Audio recordings of 590 clinic visits were coded by research coders blinded to group assignment, using a standardized coding manual; 15% of these recordings were repeat-coded for reliability with a cumulative kappa=.71 (percent-agreement=93.2%). Two analyses to date have used these data. An analysis of impact on sexual activities and interest[65] showed that 242 of 590 (41%) of patients reported "Quite a lot" (4) or "Very much so" (5) on a 5-point scale in response to the item "My cancer has affected or has had impact on my sexual activities and interest," the SQI reported at threshold most frequently of all SQI assessed. For these 242 patients, however, only 37 clinic visits (15%) included discussion impact on sexual activities and interest. 73% of these discussions occurred in the intervention group, in which clinicians received summary reports, and it was *only* in the intervention group that impact on sexual activities and interest was discussed with patients whose diagnoses were not genitourinary (13 of the 37, or 35%, versus 0 in the control group). These findings indicate that routine screening can improve communication of even a very sensitive issue that is yet highly incident in oncology patients.

For the study main analysis,[3] a binary variable was computed for whether each SQI reported by each patient at a threshold (problem) level, was discussed in the clinic visit, and a method of Generalized Estimating Equations (GEE) was used to model factors predicting discussion. 590 participants (295 each, control/intervention) were assessed by 76 clinicians. The null hypothesis that study arm had no effect was rejected, p=.024. Logistic regression models were fit for each SQI. Across all services, topics significantly more likely to be discussed when the ESRA-C summary was provided were: impact of cancer on sexual activities and interest (OR=2.90; CI=1.37-6.16) and perception of change in emotional function (OR=1.73; CI=1.08-2.77). In radiation oncology, the odds of discussing appetite were significantly higher (OR=2.51; CI 1.23-5.13), while patient concerns about physical appearance were discussed less often (OR=.15; CI=.03-.68) in transplant when ESRA-C was available. The ESRA-C is the first clinical self-report assessment to be tested in a randomized trial in the U.S. with directly measured communication outcomes. In the clinical intervention group, electronic screening and graphical reporting of cancer symptoms and QOL concerns via the ESRA-C summary had a significant, positive effect on communication about patients' experiences.

2.0 OBJECTIVES

The primary objective of this protocol is to compare the impact of ESRA-C 2 summaries delivered to patients *and* clinicians, to ESRA-C 2 summaries delivered solely to clinical providers, in medical and radiation oncology services by evaluating the following outcomes:

a. Frequencies of symptom/QOL issues (SQIs) initiated by patient or caregivers in the first post-treatment start date clinic visit.
b. Duration of conversation regarding patient/caregiver-initiated SQIs audio-recorded in the first post-treatment start date clinic visit.
c. Acceptance of and adherence to clinician-recommended therapies for SQIs at 6 weeks after treatment start date.
d. Frequencies of self-care strategies implemented for SQIs at 6 weeks after treatment start date.
e. Symptom distress scores at 6 weeks after treatment start and 2-4 weeks after treatment end date.

Hypotheses: We expect the use of patient-centered ESRA-C 2 summaries to enhance patient-clinician communication about SQIs by:

- Increasing the number of times a patient or caregiver initiates a verbal report of SQIs, lengthening the time that patients or caregivers talk with clinicians about SQIs;
- Increasing the acceptance of, and adherence to, any therapy recommended for SQIs;
- Increasing implementation of self-care for SQIs, and;
- Lowering symptom distress.

A secondary objective of this protocol is to assess the feasibility of delivering a patient oriented, patient-controlled ESRA-C directly to patients outside clinical settings. This will be done through *implementation and ongoing usage analysis*, while addressing computer access issues, authentication, and granting permissions to family/caregivers. In order to gain an understanding of usage patterns, a database and server logs will record each time a web page is accessed by a user, to continuously monitor location of access, frequency of use, and usage patterns of specific ESRA-C 2 components and information sharing behaviors.

3.0 RESEARCH SUBJECT SELECTION

There are two research subject populations for this study: clinicians and patients.

Eligible clinician participants will:

1) Be nurses, physicians, or physician assistants;
2) Perform consults/exams in clinics that have implemented routine use of the ESRA-C 2 screening tool as a standard of care (study clinics):

a. Transplant clinic at Seattle Cancer Care Alliance;
b. Radiation Oncology clinic at University of Washington Medical Center
c. Genitourinary Oncology clinic at Dana-Farber Cancer Institute;
d. Gastrointestinal Oncology clinic at Dana-Farber Cancer Institute;
e. Head and Neck Oncology clinic at Dana-Farber Cancer Institute;
f. Radiation Oncology department clinics at Dana-Farber Cancer Institute and Brigham and Women's Hospital
g. Sarcoma clinic at Dana-Farber Cancer Institute;
h. Breast Oncology clinic at Dana-Farber Cancer Institute
i. Gynecologic Oncology clinic at Dana-Farber Cancer Institute
j. Cutaneous Oncology clinic at Dana-Farber Cancer Institute
k. Medical Oncology clinic at Seattle Cancer Care Alliance
l. Lymphoma clinic at Dana-Farber Cancer Institute.

Eligible patient participants will:

1) Be 18 years or older;
2) Have a diagnosis of malignant disease;
3) Plan to start treatment in a study clinic with a consented clinician;
   3a. and with a new oral therapy (3a. final < 30 patients enrolled only)
4) Speak and read English at a 6th grade or higher level.

4.0 RESEARCH SUBJECT ENTRY

Screening/Recruitment Procedures

This study will recruit two groups of participants.

Clinicians: Clinician participants will be nurses, physicians, and physician assistants in the study clinics. A research team member will present information on the study in service staff meetings, explaining the study procedures applicable to clinician participants. Clinicians will be given the opportunity to ask questions about their participation. Written consent forms will be distributed together with opt-out cards (Appendix B) and campus return envelopes, if clinicians would prefer not to be contacted again about the study. Clinicians may sign the consent form at the time of this presentation, and will be given a copy of the written consent form to keep. They may return the opt-out card via campus mail within the next week declining participation in the study. If they do neither, the CRC will phone them to make an appointment to discuss the study; all questions will be answered and written informed consent will be obtained in that appointment.

Patients: When patients using the ESRA-C 2 assessment as standard care in study clinics finish their T1 assessment, an onscreen text (Appendix C) will inform the patient that a member of research team will contact the patient on the day of their appointment, or by phone in the next week, to discuss the study.

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(1) In medical and radiation oncology clinics: A CRC on-call, following the Patient Recruitment Script (Appendix M) will approach and greet the patient, explain the study with the aid of a visual study schema (Appendix L), and provide a written consent form describing study procedures in detail, and written HIPAA authorization form. Patients will have the opportunity to ask questions, and may choose to sign the consent/HIPAA forms at that time or within the next week. If they do not sign the consent/HIPAA forms at that time, the CRC will obtain contact information to follow-up the next day and arrange a future consent appointment, and will inform the patient of the one-week timeframe to decide about study participation. (2) In the transplant clinic: A CRC will ask the patient if a consent appointment may be scheduled on the next day the patient is in clinic. At that visit, the CRC will greet the patient, explain the study with the aid of a visual study schema (Appendix L), and provide a written consent form describing study procedures in detail, and written HIPAA authorization form. Patients will have the opportunity to ask questions, and may choose to sign the consent/HIPAA forms at that time or within the next week. If they do not sign the consent/HIPAA forms at that time, the CRC will obtain contact information to follow-up with the patient, informing the patient of the one-week timeframe to decide about study participation.

Patients who enroll will provide contact information, including preference for contact by phone or email. Participants will then choose whether to complete future ESRA-C 2 assessments in/near clinic, or from a remote site via the Internet. They will choose a user ID and password, and will then be randomized to control or intervention arms.

Control arm participants will be told that the CRC will contact them in advance of their T2 visit to schedule completion of the ESRA-C 2, either from a remote site or in/near clinic no more than 24 hours before the T2 visit. Participants will be given the URL and instructions to access ESRA-C 2 (Appendix D), and these will also be provided in subsequent contacts. They will also be given information on how to request help in using the program remotely, for example, how to request that their password be reset.

Intervention arm participants will be given a URL and instructions to access ESRA-C 2 remotely, and/or directions to the nearest patient resource or education room that provides computer and Internet access for patients. If they prefer, intervention arm participants may schedule appointments with the CRC to use study computers. Participants will be given brief verbal and written orientation to the patient component of ESRA-C 2, including how to report their experiences, view their reports, access teaching tips, and share their reports with family and caregivers. They will also be given information on how to request help in using the program remotely, for example, how to request that their password be reset. (Appendix E)

Patient participants in both arms will be given CRC contact information and copies of consent and HIPAA authorization forms (if separate from consent forms).

Other participants: In the case that other participants (e.g., the patient participant's family members) are present in the exam room during the T2 audio recording, no identifiable information about these participants will be gathered by the study team, and

recording the visit presents minimal risk to them. It is not practical to obtain consent in advance from these participants since even the patient participant may not know in advance who will be present the day of the recorded clinic visit. If other participants are present in the recorded exam, the CRC will, if possible, provide them with a written summary of the study purpose and procedures, including use of the recordings (see Appendix F).

5.0 STUDY DESIGN AND METHODS

5.1 Design/Study Type

This is a randomized, controlled trial of the effectiveness of the ESRA-C 2 intervention. Participants in the control arm of the study will complete the ESRA-C symptom and quality of life assessment, with summary delivered to clinicians, as standard care. Participants in the intervention will additionally view reports for patients – which they can elect to share online with caregivers, family and friends – and will receive tailored teaching on problematic symptoms and quality of life issues, as well as coaching on how to discuss these issues with the clinical team. Both arms will complete follow-up (T3 and T4) ESRA-C assessments, and questionnaires measuring key additional outcomes: satisfaction with communication with care team; perception their symptom can be controlled; acceptance of, and adherence to, clinical recommendations; and implementation of self-care strategies.

5.2 Selection of instruments

Wording of items for all instruments for patient participants are provided in Appendix G and for clinician participants in Appendix H.

Patient demographics: Estimated time to complete 1 minute (T1 only).

European Organization for Research and Treatment of Cancer (EORTC QLQ-30 v.3): [17,66] The QLQ C-30 is a 30 item core or generic QOL tool for use with cancer patients. The QLQ-C30 indexes six multi-item scales of functioning: Physical Functioning, Role Functioning, Emotional Functioning, Cognitive Functioning, Social Functioning, and Global Health Status/QOL. It further measures nine multi-item scales or single items of symptomatology/problems: Fatigue, Nausea and Vomiting, Pain, Dyspnea, Constipation, Diarrhea, Sleep Disturbance, Appetite Loss, and Financial Impact. Items are scaled on a Yes or No basis or on 4 point Likert-type scales where 1=not at all, 2= a little bit, 3=quite a bit, and 4=very much. Global Physical Condition and Global QOL are assessed by two 7-point Likert scales. All multi-item scales and single item measures are transformed to standardized 0-100 scales, with higher scores representing better functioning or lower levels of symptomatology. The QLQ-C30 has been extensively tested and has shown good reliability and validity in many countries; the EORTC QLQ group and NCI of Canada reported Cronbach's alphas from .78 to .91 on the version 2, as tested in 1,181 cancer patients (696 in Canada, 485 in the

Netherlands).[66] In the first ESRA-C trial, participants completed the QLQ-C30 on a touchscreen computer over 1,300 times in an average time of 8 minutes.

EORTC QLQ-CIPN20:[126] The QLQ-CIPN20 is a 20 item questionnaire developed to elicit patients' experience of symptoms and functional limitations related to chemotherapy-induced peripheral neuropathy (PN). It is complementary to the EORTC QLQ-C30. The current version of the CIPN20 includes three scales assessing sensory (9 items), motor (8 items) and autonomic (3 items) symptoms and functioning. Based on the pre-testing sample, the internal consistency reliability (Cronbach's alphas) were 0.82, 0.73 and 0.76 for the sensory, motor and autonomic scales, respectively. The format of the questionnaire is the same as the QLQ-C30, meaning that patients can evaluate on a 4 point Likert-type scale to what extent they have experienced neuropathic sensations during the past week. The CIPN20 was developed using a detailed standard process by the EORTC QL Group. For the intended population of ESRA-C 2, the QLQ-CIPN20 is the most appropriate of several instruments reviewed for inclusion.[67] Estimated time to complete the QLQ-CIPN20 is 4 minutes.

Symptom Distress Scale (SDS):[68] The SDS is a13-item, cancer specific symptom assessment developed and tested by oncology nurse researchers over the last two decades. A review of the literature and patient interviews were used to generate items for the SDS.[69] Internal consistency and test-retest reliability were established for the SDS.[70] Content, construct, and criterion validity were supported for the SDS. McCorkle and Benoliel[69] used a known group method to establish construct validity for the SDS. Scores range from 13-65 on the SDS with a higher score indicating higher symptom distress. While item cut scores have not been empirically established, McCorkle[67] recommends intervention for a score indicating moderate distress (25) and severe distress (33). The SDS has been used in over 50 clinical cancer studies including multi-site international trials.[69] The PI has a 12 year history administering and analyzing the SDS. In the first ESRA-C trial, patients completed the SDS over 1,300 times in an average of 3 minutes.

Sexuality activity and interest / Fever and chills: The PI has added these two item for the last 5 years embedded in the symptom distress items and formatted similarly, with a 5 point categorical response format. In the first ESRA-C trial, there were minimal (<4%) missing on the sexual activities and interest item. Notably, the majority (56%) of our participants have identified moderate to great impact of the diagnosis and/or treatment on sexual activities and interests at approximately 5 weeks after start of new cancer therapy. Time to completion of these two items is included in the estimate for SDS above.

Patient Health Questionnaire-Nine Symptom Checklist (PHQ-9, depression module):[71] The PHQ-9 is the 9-item depression module from the Patient Health Questionnaire, the self-administered version of the interview-based PRIME-MD (Primary Care Evaluation of Mental Disorders). Like the PRIME-MD, the PHQ-9 measures depressive symptoms using diagnostic criteria from the Diagnostic and Statistical Manual for Mental Disorders (DSM-IV). It is useful as both a case-finding and a depression severity instrument. Major depression is diagnosed if 5 or more of the 9 depressive symptom criteria have been present at least "more than half the days" in the past 2 weeks,

and 1 of the symptoms is depressed mood or anhedonia. Other depression is diagnosed if 2, 3, or 4 symptoms have been present at least "more than half the days" in the past 2 weeks, and at least 1 of the symptoms is depressed mood or anhedonia. The item on suicidal ideation counts if present at all, regardless of duration. The PHQ-9 can also be used as a depression severity measure, ranging from 0 to 27, since each of the 9 items is scored from 0 (not at all) to 3 (nearly every day). A PHQ-9 score of $\geq$ 10 has a sensitivity of 88% and a specificity of 88% for major depression. Scores of 5, 10, 15, and 20 represent valid and easy-to-remember thresholds demarcating the lower limits of mild, moderate, moderately severe, and severe depression. The PHQ-9 has been validated in ambulatory medical settings, including primary care and obstetrics-gynecology clinics, and shows excellent internal and test-retest reliability and criterion and construct validity.[71,72] While the PHQ-9 compares favorably to other case-finding instruments for depression in medical settings, it has the advantage of brevity and a simple response format that is sensitive to change.[73] The PHQ-9 takes about 2 minutes for patients to complete.

Skin changes: Many of the newer targeted therapies for cancer have resulted in skin changes and side effects that previously were rare. No patient-reported assessments have been validated to date for these side effects. Investigators have utilized clinician-reported assessment grading with unsatisfactory results.[74] The ESRA-C 2 incorporates a new measure of skin changes developed by Ryan building on her and her colleagues' study of post-treatment skin reactions,[75] and will test the performance of this new measure. The items are estimated to take less than 1 minute to complete.

Pain assessment: Pain frequency and intensity are measured by the SDS (above), and ESRA-2 includes a 1-item Pain Intensity Numerical Scale of 0-10. Responses of moderately frequent or severe pain will prompt presentation of a 4-item scale measuring pain interference with activities. The pain interference items are a subset selected from the pain item banks developed by the Patient-Reported Outcomes Measurement Information System (PROMIS).[76] PROMIS-developed items have been administered to over 11,000 research participants and analyzed using item-response theory. Completion of these items is estimated to take less than 1 minute.

Religious Struggle Screening Protocol: Religious/spiritual concerns for patients are assessed with a 3-item screening protocol developed by Fitchett et al.[85] To date, the protocol has been evaluated for feasibility of administration verbally by patient care staff and medical residents in non-oncology settings. Adapting the measure for self-administration by computer in ESRA-C, and for an ambulatory oncology population, presents a new test case. Completion of the instrument is estimated to take less than 1 minute.

Priority SQI ranking and Open-ended question: After completing the instruments above, ESRA-C 2 will present patients with a screen listing all SQIs (in random order) that they endorsed as moderately to severely problematic, and will ask them to rank their two priority concerns. Patients will also be given the opportunity to answer an open-

ended question about anything else they would like to tell their care team, or questions they would like to ask. Completion of these items is estimated to require 1 to 3 minutes.

Acceptability scale: All patient participants will be presented at T2 with six acceptability items at the conclusion of the symptom and QOL questionnaires of ESRA-C 2. Responses range from 1-5, with1 indicating a low level of agreement and acceptability of the computerized SQI assessment and 5 indicating a high level. Adapted with permission from Carlson's work,[53] the Acceptability E-scale has been found to have high consistency and reliability.[77] Over 600 patients in the first ESRA-C trial completed the scale with minimal missingness in under 1 minute.

Audio-file coding tool: Using the same architecture as the ESRA-C software, the PI has developed a computerized audio-file coding schema used successfully in the first ESRA-C trial. The 30 SQIs assessed in the patient self-report were coded for their discussion during the recorded T2 clinical visit. Coders noted who initiated discussion of each SQI (patient, clinician, or family member), whether any treatment (pharmacological, non-pharmacological, or both) is offered, whether any referral is made and to whom, and whether any reference is made to the ESRA-C printed report to clinicians (when the report was discussed, coders were effectively unblinded to the patient's group assignment). The coding tool will be enhanced to measure all outcomes in the ESRA-C 2 trial.

Medical record audit tool: Using the same architecture as the ESRA-C software, the PI has developed a computerized medical record audit form. Auditors examine the patient's electronic and paper medical records for any clinician notation of 30 SQIs assessed in the patient self-report on the same day as the T2 clinical visit, and code the following: which member of the clinical care team made the notation in the medical record, whether any treatment (pharmacological, non-pharmacological, or both) was offered, which clinician recommended the treatment, whether any referral was made and to whom, plus any additional comments. Auditors confirm the patient's diagnosis and whether disease is primary or recurrent. Auditors also note whether the medical record contains a copy of the ESRA-C printed report to clinicians (when present, these reports effectively unblind the auditor to the patient's group assignment). The coding tool will be enhanced to complement the ESRA-C 2 trial.

Patient satisfaction with communication: The investigators have adapted, with permission, a patient satisfaction questionnaire, developed and tested for use in ambulatory care[78],[79] and utilized by Taenzer and colleagues in a trial of computerized QOL screening in an ambulatory cancer care setting.[4] Participants will be queried at T3 on their overall satisfaction with communication with their care team during their treatment; the 11-item questionnaire, with a 5-point Likert scale of response options from Strongly disagree (1) to Strongly agree (5), measures patient satisfaction in 3 communication sub-domains: Providing information, Rapport, and Patient needs. Completion of the questionnaire is estimated to require 1 minute.

Self-Management of SQIs (Adherence to treatment recommendations, Self-care activities, Perceived symptom control, Satisfaction with symptom management): Participants will be queried at T3 about the 2 priority SQIs they ranked highest at T2, using items developed and tested by Donovan in ovarian cancer symptom surveys.[33,80] They will be asked about adherence to clinical recommendation for treating the 2 priority symptoms with a single item measuring non-adherence, partial, or complete adherence to clinical recommendations. Additional self-care activities will be solicited with an open-ended question. Participants will be queried for the extent they feel their 2 priority symptoms are controllable, using 3 items from the cure/control subscale of the Symptom Representation Questionnaire (SRQ). The three items are rated from 1 to 5 with higher scores reflecting greater perceived control. In Donovan's analysis of psychometric properties of the SRQ (n=713 ovarian cancer patients),[79] Cronbach's alpha coefficients for this subscale ranged from .76 to .86 depending on symptom groupings. A single item measuring satisfaction with management of each of the 2 priority SQIs is based on a question from the American Pain Society's Patient Outcome Questionnaire.[81] Completion of these items is estimated to require 2 to 4 minutes.

Intervention Evaluation: Participants in the intervention arm only will be queried at T4 to inquire as to their use, experience and satisfaction with the various components of the intervention. An 11-item questionnaire is administered, with the first 4 questions using a 5-point Likert scale of response options from Not useful at all (1) to Very Useful (5), measures the patient's perceived usefulness of the 4 intervention features (Journal, View My Reports, Teaching Tips, and Share My Reports). The next 7 questions combine multiple choices, Likert Scale, and open text responses to inquire more specifically about the patient's evaluation of the intervention.

Clinician demographics: Completion of the form is expected to take less than 1 minute.

Clinician satisfaction with communication: The investigators have developed a 2-item assessment of clinician satisfaction with patient-clinician communication in the T2 visit. The reality of clinicians' schedules when seeing 15 to 20 clinic patients on a given day precludes lengthy same day assessment; however, this assessment cannot be meaningfully conducted by recall. Given the need to minimize response burden, this brief instrument is estimated to require no more than 20 seconds from the clinician.

Total time to completion and time on-study (estimated):
The T1, T2 and T4 assessments are estimated to require in total 20 to 25 minutes per patient participant; the T3 requires 5 minutes more due to the additional outcomes measured. This is a total of 85 to 105 minutes for the whole study for participants in both arms. Participants in the intervention arm will have the option of completing additional assessments, or components of the assessments, at their discretion throughout the study. In addition, intervention arm participants will read additional education and coaching at the end of the T2 assessment (described below; estimated to require an additional 5 to 15 minutes, depending on the number of SQIs they report at threshold), and may spend as much or as little time as they like besides this viewing their graphs, and reading additional teaching content. Furthermore, intervention arm patients will also be asked a

series of 11 additional questions at T4 evaluating their experiences with the intervention; this will add an additional 3-4 minutes to their T4 symptom report.

The total length of time patient participants will be on-study will vary depending on their treatment, and on the T1 and T2 administration schedule adopted as standard of care in their clinic. For example, the transplant clinic at Seattle Cancer Care Alliance has adopted a schedule of T1 on the first clinic visit day after nurse teach, and T2 on the first clinic visit day post-discharge from hospital. The expected range of time on-study is from 8 to 10 weeks for patients receiving chemotherapy or radiation treatment, and from 10 to 20 weeks for patients receiving HSCT.

Clinicians will participate in the study for up to the whole period, 18 months. During this time, depending on the number of study patient participants they see, they may complete an estimated 18 to 180 satisfaction with communication queries (requiring a total of 6 to 60 minutes). Adding the demographic form, total clinician participant time is estimated to be 7 to 61 minutes.

5.3 Description of Intervention

Usual Care

Two components of the ESRA-C 2 application are usual care: the patient Electronic Self-Report Assessment of SQIs, and the Clinician Printout.

Patient Electronic Self-Report Assessment: This is an online patient self-assessment completed on a touch screen computer. Patients report their symptoms and quality of life issues according to the following instruments described above: EORTC QLQ-C30 v. 3, EORTC QLQ-CIPN20, Symptom Distress Scale, PHQ-9, Pain Intensity Numeric Scale, Pain Impact Scale – Short Version from PROMIS, Skin Changes Numerical Index, ranking of two priority SQIs, open-ended question. This report will be completed as usual care in/near the clinic or from home no more than 24 hours before clinical visits at T1 (before treatment) and T2 (on treatment); at T3 (on treatment) and T4 (post-treatment), the assessments will be completed only as study procedures.

The usual care self-report assessment was developed at the University of Washington through extensive and iterative pilot usability testing and was shown to be feasible and highly acceptable to patients in the first ESRA-C randomized clinical trial. Items that are new in ESRAC-2 – the EORTC QLQ-CIPN 20, PROMIS Pain Interference – SF, Skin Changes, and SQI priority ranking – were added to ESRA-C 2 in response to provider requests from the HSCT clinic at Seattle Cancer Care Alliance and Radiation Oncology clinic at University of Washington Medical Center.

Clinician Printout: A two-page graphic summary of the patient's report (Appendix I) is printed on paper and attached to the patient chart before the clinic visit. Providers will be oriented to reading the printout through a presentation in their service meetings.
The usual care clinician printout was developed by the ESRA-C investigators based on input from clinicians at the Seattle Cancer Care Alliance. It was used by 262 clinicians in three service lines in the ESRA-C 1 randomized trial, with minimal prior orientation given to reading the printout. In the first year of the ESRA-C 2 study, as the original ESRA-C intervention has been implemented as usual care, new items have been added to the printout and feedback has been sought from providers on layout and clarity of content. The study design team has conducted feedback sessions in clinical service meetings in the HSCT clinic at Seattle Cancer Care Alliance and incorporated these in the revised printout.

Intervention: Patient-centered ESRA-C 2

In addition to the two components of the application above that are usual care, the patient-centered ESRA-C 2 application adds the following intervention:

Intervention, Pt 1 of 3: Teaching Tips (Appendix J)

Short Teaching Tips will be delivered automatically onscreen at T2 to patient participants in the intervention arm for any SQI for which they score at/above threshold, indicating a problem. A complete list of Teaching Tips is also available for browsing, if the patient would like to read about issues they may experience later.

Content of the Teaching Tips has been developed and reviewed by the investigative team. They deliver 3 key messages **tailored to participants**: (1) why and how often this SQI typically occurs in patients like you; (2) it can be dealt with; and (3) how to talk to your clinical team about the SQI.

First, in explaining how often this SQI occurs "in patients like you," the ESRA-C 2 software will look up the patient's clinical service and whether s/he has begun treatment, and will supply a percentage of the 600-800 patients enrolled in the original ESRA-C trial who reported experiencing that SQI as a problem – in the same service, and before (T1) or during treatment (T2).

Second, in telling patients "What can I do about this" SQI, the ESRA-C 2 software will link patients first to local resources, i.e., those provided to patients in their clinics at Seattle Cancer Care Alliance/University of Washington Medical Center or Dana-Farber Cancer Institute. The Teaching Tips will then present links to symptom management and quality of life teaching materials online at the National Cancer Institute's (NCI) cancer.gov, American Society of Clinical Oncology's (ASCO) cancer.net, Oncology Nursing Society's (ONS) cancersymptoms.org, and other professionally developed sites. In addition to providing resources for management of specific SQIs, the message that the SQIs can be dealt with is expected to reassure patients that their SQIs may be controllable.

Third, patients are coached in how to talk to their care team about their SQIs. Each sample message offers fill-in-the-blank options patients can use to describe the timing, degree, quality, context, co-occurrence and impact of their SQIs. The coaching messages are designed to reinforce for patients that the care team does care about their symptoms and quality of life, not just their disease and treatment. They also prepare patients to give a detailed and more clinically useful description of their SQIs.

Intervention, Pt 2 of 3: View My Reports (Graphs)

The second component of the patient-centered ESRA-C 2 intervention is the online display of graphic reports of the patient's symptom and quality of life assessment. These graphs allow patients to see their reports in a visually simple format and track their own SQIs over time. Patients using the intervention can click to access a page listing thumbnail graphs of each SQI they have reported. These line graphs use a shaded area to indicate reports at or above the designated problem threshold for each SQI. Patients can then click the thumbnail to see a larger version of the chart.

The large chart contains a shaded threshold area, and shows on the X-axis dates of patient reports for each data point. The default view is a line graph, but patients can select instead to view a bar graph, or tabular report of numerical values, to accommodate preferences for viewing data in different formats. Patients can also customize the date range displayed, for example, expanding to their entire course of treatment, or limiting their graph to the past two weeks. For SQIs measured on the same scale (e.g., each Symptom Distress Scale item), patients can check or uncheck a box to include or exclude each symptom in a single graph, allowing them to interpret the co-occurrence of multiple SQI. All of these controls are interactive on the web page, and the patient can change them as many times as they want, and can discard or save their settings for their next login session.

The graphs for each SQI also show the Teaching Tip for whichever issue the patient clicked to reach the graph. For example, the patient can view on one page their reported Pain Intensity Numeric Scale (PINS) graph and information about why pain occurs, how it can be dealt with, and how to tell their clinical team about it.

Intervention, Pt 3 of 3: Share My Reports

The third component of the ESRA-C 2 patient-centered intervention is a feature allowing the patient to send email invitations to family, friends and other caregivers to view their SQI reports and read teaching tips about each issue. In this feature, patients can specify which reports they wish to share; for example, they could choose to share Pain Intensity and Fatigue, but not Impact on Sexual Activities and Interests or Depression. The intent of this feature is to enhance communication of the patient's SQIs, and deliver teaching information to caregivers as well as the patient.

Security features of Share My Reports: No information in the patient's SQI reports will be sent via email. No information about the patient's diagnosis or treatment will be sent via email. The email invitation will be brief and generic, providing the invited caregiver a link to the website where they will have to create their own login (user ID and password) to access the application; this authentication step shares the same security features as the entire application (Appendix K). Then, before viewing any information in the patient's reports, invitees will have to enter a "secret word" conveyed by the patient to the invitee. This can be given in person or by phone, but ensures that an additional layer of security protects the patient's reports. The patient can change this secret word at any time to limit access to their reports. The patient can also elect to stop sharing any or all reports with any or all invitees.

Development of the Intervention:

The patient-centered ESRA-C 2 intervention has been developed through a 10-month, iterative, participatory design process led by Dr. Seth Wolpin of the University of Washington School of Nursing and the Clinical Informatics Research Group (CIRG). 6 patients and 3 family caregivers were recruited from the HSCT clinic at Seattle Cancer Care Alliance for two focus groups held in April and May 2008. In addition, 3 patient

and 2 expert individual usability sessions have been conducted in the University of Washington's Distributed Health Assessment and Intervention Research (DHAIR) usability lab. In these sessions, patients and caregivers critiqued prototypes of the intervention and gave detailed input as to sequencing of content, visual display (e.g., use of color, titling and bullet points, arrangement of graphs and text on web pages), terminology (e.g., "Report My Experiences" for initiation of patient self-assessment, "Teaching Tips" for educational content on SQIs), navigational elements (e.g., use of expandable text selections), and addition of new components (e.g., a Journal feature for patients to annotate their reports and graphs or narrate their experiences).

Iterative prototypes were then tested in usability sessions, with test subjects being asked to complete certain tasks in the application, for example, changing which symptoms are displayed on a graph, navigating to the sharing feature, or finding the Settings page to change their password. Usability testers' task completion was monitored by a researcher, and subject eye movements around the screen were tracked by a webcam integrated with usability research software. Results of these usability tests were used to further refine the interface.

5.4 Data Collection

Data	***Pre-T1***	**T1**	**T2**	**T3**	**T4**
Clinician demographics	X				
Patient demographics		X			
ESRA-C 2 SQI assessment		X	X	X	X
Acceptability			X		
Audio recording (pt-provider communication)			X		
Medical record audit (communication, clinical recommendations			X		
Clinician satisfaction with communication			X		
Adherence to recommendations				X	
Self-care strategies				X	
Symptom control (perceived)				X	
Patient satisfaction with communication				X	
Satisfaction with symptom management				X	
Application usage monitoring: frequency, duration, location of access		X	X	X	X
Intervention Evaluation					X

5.5 Description of Study Process

5.51 Instrument Administration

Clinician participants:
Clinician participants will be asked for an email address when they consent. They will be emailed a link to a secure, online demographic questionnaire. If the clinician does not

respond to complete the questionnaire within two weeks, up to two additional reminders will be made by email, then followed up with a paper version of the questionnaire by campus mail.

Clinician satisfaction with communication queries will be self-administered on paper within 2 hours (most often within 10 minutes) of visit end. The CRC will give the paper questionnaire on a clipboard to the clinician at the conclusion of a study patient's visit. In the P4 study,[82] a similar post-visit questionnaire is administered to clinicians; some clinicians prefer to dictate their responses to the CRC, and this mode of administration is also acceptable. In the P4 study, completion of these post-visit clinician questionnaires is over 80%.

Patient participants:
For patient participants, all instruments will be self-administered by computer via the Internet. Patients will complete the T1 assessment in/near clinic as usual care on a touch-screen computer. Clinic staff will initiate the assessment and provide brief instructions for use. The application's user interface was developed for ease of use by those with little previous computer experience and does not require use of a mouse or keyboard. The T1 assessment is designed to screen for SQI concerns in a real-world clinical setting, so it will be administered according to guidelines developed by each clinic and in a usual clinical setting.

The T2 assessment is likewise a standard of care, and must be completed within 24 hours before the T2 clinic visit; as usual care, this would be in clinic on the day of, and usually immediately before, the appointment. Participants in the study will be given the option of completing the assessment remotely via the Internet within the 24-hour timeframe. They will be contacted by phone or email (according to their preference) by the CRC up to 3 days before the T2 is due to remind them of the option to complete the assessment remotely. The ESRA-C 2 application will also display the date and time the T2 is due; upon login, patients will see this date with the request for completing T2. At the end of the T2 assessment, intervention arm patients will be delivered teaching tips for any SQIs they report as moderately or severely problematic, and will have the option of viewing and printing more information. For this reason, intervention arm patients who will complete T2 in clinic will be asked by the CRC to come in an additional 15 minutes earlier if their T2 is scheduled immediately before the clinic visit.

T3 and T4 assessments are not usual care, and will be self-administered on study computers or remotely. Participants will be contacted by the CRC up to 3 days before the start of the 2-week window for T3 and T4 to arrange for completing the assessments. The ESRA-C 2 application will also display the date range for them; upon login, patients will see these dates with the request for completing T3 and T4.

Given the clinical setting and patient population, it is expected that a small percentage of patients (estimated to be <2% in the ESRA-C 1 trial), due to fatigue, emotional functioning, or other physical or symptom distress, may request assistance from family/friend caregivers in completing the assessment. Clinic staff and CRCs will

explain that if assistance is required, caregivers should read questions and response options to the patient, and the patient should answer the questions, rather than caregivers answering or suggesting answers themselves. Providing that patients meet other eligibility criteria, requesting assistance will not be an exclusion criterion. Clinic staff and CRCs will also tell patients that it is important to their care team that they answer all questions in the assessment, but if a question makes them feel uncomfortable, they are allowed to skip it. With these instructions, missing data in the ESRA-C 1 trial was minimal, not more than 4% on any one item and less than 1% on most.

5.52 Intervention Administration

Clinician printouts will be delivered by clinic staff as usual care. The exact means may differ according the procedures arranged in each clinic. In the ESRA-C 1 trial, CRCs clipped the printouts to the front of a patient's chart just before the clinic visit; this is also the procedure now conducted by medical assistants in the transplant clinic at Seattle Cancer Care Alliance.

The ESRA-C 2 patient intervention will be self-administered at any times from randomization until the end of the study. Intervention arm patients will be given access to the website via the Internet, at any time and from any location they choose.

Compensation

Neither clinicians nor patients will be compensated for participation in the study.

5.6 Adverse Reactions and Their Management

5.61 Reporting Adverse or Unanticipated Events

The Institutional Review Boards of Dana-Farber/Harvard Cancer Consortium (DF/HCC) and Fred Hutchinson Cancer Research Center/University of Washington Cancer Consortium will review and approve this protocol to ensure the protection of human subjects prior to implementation.

Serious adverse events are not expected, but any major or minor protocol violations or deviations will be reported per institutional review guidelines. Standard procedures for multi-center studies with DF/HCC as the coordinating center will be followed for order and timing of reporting unanticipated events (Appendix A).

5.62 Anticipated Reactions

Risk of participation for patients and clinicians is minimal, and no adverse reactions are anticipated from participation in this study. While the risks of participation are minimal for this sociobehavioral intervention, patient participants may experience distress as a result of completing questionnaires or viewing their reports. Consent forms will state that

if they experience distress as a result of participating in the study, they should contact their providers.

Both patient and clinician participants, in case they anticipate or experience discomfort with the audio recording of clinic visits, will be instructed how to pause or stop the recording. Recorders are placed in exam rooms with laminated instruction cards that show how to use the recorder.

5.63 Reaction Management

Any patient participants who express or appear to experience distress as a result of using the intervention, or of answering study questionnaires, will be referred to their primary provider in the clinic for further assessment if needed.

6.0 STATISTICAL ANALYSIS

Participant demographic data for both arms of the study will be summarized with descriptive statistics and examined for group differences as a precursor to the main analyses.

Sample Size and Statistical Power:
The sample is sized based on the primary objective, comparing the impact of ESRA-C 2 summaries delivered to both patients and clinicians, to those delivered to clinicians alone. In a 2002 publication, a group of Dutch researchers[5] reported an effect size of .38 regarding the ability of a computerized cancer QOL assessment and output to increase the number of QOL issues addressed in a clinical interview. The measure is analogous to the primary objective of this study. Using the previously published effect size and a significance level of .05 for a two-tailed test, a power estimate of .90 can be achieved with a sample size of 315 patient participants in each arm. Given the attrition rate of 11% in the ESRA-C 1 study, the target sample for enrollment in this study is 702.

Length of Time Required to Accrue Adequate Number of Subjects:
Based on the successful completion of the ESRA-C 1 trial at Seattle Cancer Care Alliance/ University of Washington Medical Center in 2005-2007, it is anticipated that an adequate number of subjects, i.e., 702, can be accrued in the two primary study sites in 18 months.

Stratification Factors and Intervention Allocation Plan:
Patient participants will be allocated to the study arms based on a stratified randomization plan. The single stratification factor is participants' means of access to the Internet, as a proxy for previous experience with, and ease of using, the Internet. Emerging research about online health communication has shown there are frequently differences in exposure to, and apprehension of, health materials presented online between those who have more and less prior experience with, and access to, the Internet.[83,84] For this reason, patient participants will be randomized within one of two groups, based on where and how they will access the ESRA-C 2 application: home (independent) or clinic (assisted) users. After consenting to the study, participants will be asked whether they will complete subsequent assessments primarily from a home computer or in clinic, and will be designated as home (independent) or clinic (assisted) users. Within these two groups, participants will be randomized in blocks of 4 to the control or intervention arms. The randomization algorithm will be performed by the study management database tied to the ESRA-C 2 application, so that the allocation can be presented to the CRC as soon as it occurs.

Unevaluable/Ineligible Patients:
It is not anticipated that there will be unevaluable/ineligible patients for this study.

Analysis Plan:

The analysis will compare study arms on the continuous variables of number of patient/caregiver initiations of verbal report of SQI and minutes in clinic visit discussing SQIs, some continuous and some ordinal variables for symptom distress, and ordinal variables of adherence to treatment recommendations and self-care strategies. With these multiple comparisons, the strategy will be first to conduct an omnibus test of the outcome measures. If this test is not significant, the conclusion will be that there is no evidence the intervention is effective. On the other hand, if the omnibus test is significant, further tests will be done to determine which outcome measures are most affected by the intervention and the mediating influence of system and client characteristics.

The omnibus test will use repeated measures MANCOVA where the outcomes measures are the outcomes variables. The model includes study arm as an across-subject factor, time as a within-subject factor, and the available baseline values of the outcome measures as covariates. Clinician effect will be controlled by including clinician as a random effect in the model. The main effect for study arm will test whether there is a significant intervention effect. Significance levels will be set at $p<.05$.

Handling of Missing Data in the Analysis:

For the MANCOVA, data may be imputed for comparison purposes (i.e., reported versus imputed datasets), and if there are not notable differences between the datasets, only complete data would be used for the MANCOVA. Data would be imputed according to the last report, in the case of repeated SQI measures. Use of constructed variables summarizing SQI distress or SQI management may be calculated for this purpose. For further tests of individual outcomes measures, only cases with complete data would be used.

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DFCI IRB Protocol #: 08-284

APPENDIX A

Dana-Farber/Harvard Cancer Center
Multi-Center Data and Safety Monitoring Plan

Table of Contents

1.0 INTRODUCTION

The Dana-Farber/Harvard Cancer Center Multi-Center Data and Safety Monitoring Plan (DF/HCC DSMP) outlines the procedures for a DF/HCC Multi-Center research protocol.

1.1 Purpose

To establish standards that will ensure that a Dana-Farber/Harvard Cancer Center (DF/HCC) Multi-center protocol will comply with Federal regulations (21 CFR Part 11); Good Clinical Practice (GCP) Guidelines; and Health Insurance Portability and Accountability Act (HIPAA) requirements in accordance with the CTEP Multi-center Guidelines.

1.2 Multi-Center Data and Safety Monitoring Plan Components

The Multi-Center Data and Safety Monitoring Plan includes the following components:

DF/HCC Multi-center Protocol: One or more outside institutions collaborating with Dana-Farber/Harvard Cancer Center on a research protocol where DF/HCC is the Lead Institution. *Dana-Farber/Partners Cancer Care (DF/PCC) Network Clinical Trial Affiliates are not viewed as outside sites in this definition.*

Lead Institution: One of the Dana-Farber/Harvard Cancer Center sites (DFCI) will be the Lead Institution and will be responsible for the coordination, development, submission, and approval of a protocol as well as its subsequent amendments per the DFCI IRB and applicable regulatory guidelines (CTEP, FDA, OBA etc.).

DF/HCC Contract Principal Investigator: Investigator located at the Lead Institution who will be charged with the responsibility of the administration of the DF/HCC Project. This most often will be the Protocol Chair, but occasionally this may be the overall grant or contract holder, as applicable.

Protocol Chair: The Protocol Chair is the Principal Investigator for the DF/HCC protocol submitted as the Lead Institution. For applicable protocols, the Protocol Chair will be the single liaison with any regulatory agencies (ie.CTEP Protocol and Information Office (PIO), FDA, OBA etc.).

Participating Institution: A participating institution is an institution that desires to collaborate with DF/HCC and commits to accruing participants to a DF/HCC protocol. The participating institution acknowledges the Protocol Chair as having the ultimate authority and responsibility for the overall conduct of the study.

Coordinating Center: The Lead Institution is the Coordinating Center for the DF/HCC Multi-

center Protocol. The Coordinating Center will provide the administrative support to the Protocol Chair in order that he/she may fulfill the responsibilities outlined in the DSMP and as specified in applicable regulatory guidelines (i.e. CTEP Multi-Center Guidelines).

2.0 GENERAL ROLES AND RESPONSIBILITIES

The Protocol Chair (DF/HCC Principal Investigator), Coordinating Center (Lead Institution), and the Participating Institutions will all agree to the general responsibilities as follows (specific procedures for these general responsibilities are detailed in the DSMP):

2.1 Protocol Chair (DF/HCC Principal Investigator)

The Protocol Chair, Donna Berry, PhD, RN, will accept responsibility for all aspects of the Multi-Center Data and Safety Monitoring Plan to:

- Oversee the coordination, development, submission, and approval of the protocol as well as subsequent amendments.
- Submit the Multi-Center Data and Safety Monitoring Plan as an inclusion to the protocol.
- Assure all participating institutions are using the correct version of the protocol.
- Monitor progress and overall conduct of the study at all participating institutions.
- Ensure all DFCI IRB and DF/HCC reporting requirements are met.
- Review data and maintain timely submission of data for study analysis.
- Identify participating institutions and obtain accrual commitments. The Protocol Chair will also submit a protocol attachment labeled as "Participating Investigators" to the DFCI IRB and if applicable CTEP, FDA or OBA that provides the names and contact information for all participating institutions that perform the function of recruiting, enrolling, and treating participants for the protocol. The Coordinating Center (Lead Institution or designee) must be designated on the title page. Revisions to the list will be submitted to the DFCI IRB as an administrative protocol amendment to reflect changes in staff and assignment of responsibility as they occur.

2.2 Coordinating Center (Lead Institution)

The Coordinating Center is the DF/HCC Lead Institution's study team or designee (i.e Medical Monitor, Clinical Research Organization). The DF/HCC Lead Institution will ensure that all participating sites within the Multi-Center Protocol demonstrate their intent and capability of complying with Federal Regulations, GCPs and Health Insurance Portability and Accountability Act (HIPAA) requirements. To assist the Protocol Chair in meeting his/her responsibilities as required by the DSMP, the DF/HCC Lead Institution's study team will assume the following general responsibilities:

- Assist in protocol review.
- Maintain copies of Institutional Review Board (IRB) approvals from all participating institutions.
- Maintain updated roster of participants.

- Verify eligibility.
- Verify completion of outcome measures.
- Collect data on protocol specific CRFs.
- Prepare all submitted data for review by the Protocol Chair.
- Monitor and audit Participating Institutions either by on-site inspection of selected participant records and/or with submitted source documents and research records submitted to the Lead Institution.

2.3 Participating Institution

The Participating Institution(s) will be identified on the title page for each protocol. In addition, each participating institution will provide to the Lead Institution a list of the key personnel assigned to the role for oversight of data management at their site. All sites must have office space, office equipment, and internet access that meet HIPAA standards.
The general responsibilities for each participating institution are as follows:

- Commit to accrual to the Lead Institution's (DF/HCC) protocol.
- Submit protocol and/or amendments to their local IRB.
- Update Coordinating Center (Lead Institution or designee) with research staff changes on a timely basis.
- Submit source documents, research records, and CRFs per protocol specific submission guidelines to the Coordinating Center (Lead Institution or designee).
- Submit deviations and violations to the Coordinating Center (Lead).

3.0 DF/HCC QUALITY ASSURANCE OFFICE FOR CLINICAL TRIALS
NOT APPLICABLE: THIS STUDY WILL NOT USE QACT SERVICES

4.0 PROTOCOL DEVELOPMENT

4.1 Activation of a Protocol

The Protocol Chair is responsible for the coordination, development, and approval of the protocol as well as its subsequent amendments, and reporting violations and deviations per DFCI IRB guidelines.

To meet these requirements, the Protocol Chair will be responsible for the following minimum

standards:

- Inclusion of the DF/HCC Multi-Center Data and Safety Monitoring Plan in the protocol as an appendix.
- Identify participating institutions and obtain accrual commitments. The Protocol Chair will also submit a protocol attachment labeled as "Participating Investigators" to the DFCI IRB that provides the names and contact information for all participating institutions that perform the function of recruiting, enrolling, and treating participants for the protocol. The Coordinating Center (Lead Institution) must be designated on the title page.
- Commit to the provision that the protocol will not be rewritten or modified by anyone other than the Protocol Chair.
- Ensure that there is only one version of the Protocol and that all Participating Institutions use the correct version.
- Oversee the development of data collection forms (case report forms) that are of common format for use at all the Participating Institutions.

4.2 Coordinating Center Support Function

The DF/HCC Lead Institution's study staff will provide administrative and clerical support to the Protocol Chair for the development and distribution of the protocol.

The tasks to be performed by the DF/HCC Lead Institution's study staff include:

- Review of the protocol and consent to check for logistics, spelling, and consistency. Provide the Protocol Chair a list of queries related to any inconsistencies.
- Provide necessary administrative sections, including paragraphs related to registration logistics, data management schedules, and multi-center guidelines.
- Maintenance of contact list of all participating institutions in the DF/HCC Multi-center Protocol and the distribution of updates to the sites as needed.
- Derivation of the study calendar, if applicable.
- Assistance in preparation and maintenance of case report forms.
- Maintain and document communication with all participating institutions.

5.0 PROTOCOL MANAGEMENT

The Coordinating Center (Lead Institution) is responsible for assuring that each Participating Institution in the DF/HCC Multi-center Protocol has the appropriate assurance on file with the Office of Human Research Protection (OHRP). Additionally, the Lead Institution must maintain

copies of all IRB approvals, for each participating institution.

5.1 Protocol Distribution

The Coordinating Center (Lead Institution) will distribute the final approved protocol and any subsequent amended protocols to all Participating Institutions.

5.2 Protocol Revisions and Closures

The participating institutions will receive phone, fax, mail or e-mail notification of protocol revisions from the Lead Institution. It is the individual participating institution's responsibility to notify its IRB of these revisions.

Non life-threatening revisions: Participating institutions will receive written notification of protocol revisions regarding non life-threatening events from the Lead Institution. Non-life-threatening protocol revisions should be implemented within 90 days from receipt of the notification.

Protocol Closures and Temporary Holds: Participating institutions will receive fax, e-mail, or phone notification of protocol closures and temporary holds, with follow-up by mail from the Lead Institution. Closures and holds will be effective immediately. In addition, the Lead Institution will update the Participating institutions on an ongoing basis about protocol accrual data so that they will be aware of imminent protocol closures.

5.3 Informed Consent Requirements

For this minimal risk trial, the Protocol Chair must approve non-physician members of the study team to obtain consent and sign the consent form.

5.4 IRB Documentation

The following must be on file with the DF/HCC Lead Institution prior to participant registration:

- Approval Letter of the institution's IRB **(**An Expedited IRB first approval is NOT acceptable)
- IRB approval for all amendments

It is the individual institution's responsibility to notify its IRB of protocol revisions. Participating institutions will have 90 days from receipt to provide the DH/HCC Lead Institution their IRB approval for Major Amendments* to a protocol.

*** DF/HCC defines a Major Amendment** as: A substantive change in the study which may increase or decrease the risk to study participants. Major revisions require full IRB approval. The following criteria are examples of revisions to a protocol that are considered to be major amendments:

- Change of eligibility (inclusion/exclusion) criteria
- Change in design of protocol
- Change in statistical section
- Change in sample size/accrual (e.g., doubling the sample size)
- Change in informed consent
- Change of estimated dropout rate
- Change of treatment or intervention
- Change of device
- Change in primary objective evaluation process

5.5 IRB Re-Approval

Annual IRB re-approval from the Participating institution is required in order to register participants onto a protocol. There is no grace period for annual re-approvals.

Protocol registrations will not be completed if a re-approval letter is not received by the DF/HCC Lead Institution from the Participating Institutions on or before the anniversary of the previous approval date.

5.6 Participant Confidentiality and Authorization Statement

The Health Insurance Portability and Accountability Act of 1996 contains, as one of its six major components, the requirement to create privacy standards for health care information that is used or disclosed in the course of treatment, payment or health care operations. The original Privacy Rule, as it has come to be known, was published in December 2000. The Final Rule was published on August 14, 2002, which has modified the privacy rule in significant ways vis-à-vis research.

In order for covered entities to use or disclose protected health information during the course of a DF/HCC Multi-Center Protocol the study participant must sign an Authorization. This Authorization may or may not be separate from the Informed Consent. The DF/HCC Multi-

Center Protocol, with the approval from the DFCI IRB, will provide an Informed Consent template, which covered entities (DF/HCC Multi-Center Protocol participating institutions) must use.

The DF/HCC Multi-Center Protocol will use all efforts to limit its use of protected health information in its trials. However, because of the nature of these trials, certain protected health information must be collected per National Cancer Institute requirements. These are the primary reasons why DF/HCC has chosen to use Authorizations, signed by the participant in the trial, rather than limited data sets with data use agreements.

5.7 Participant Registration

To register a participant, the following documents should be completed by the DF/HCC Multi-Center Protocol participating site and noted in the online study database:

- Signed informed consent form
- HIPAA authorization form (if separate from the informed consent document)
- Other appropriate forms (e.g., Eligibility Screening Worksheet, Registration form)

Electronic confirmation of eligibility and study registration will be provided and the study ID number assigned by the study database.

5.8 DF/HCC Multi-center Protocol Case Number
NOT APPLICABLE: THIS STUDY WILL NOT USE QACT SERVICES

5.9 DF/HCC Multi-center Protocol Registration Policy

5.9.1 Initiation of Therapy: **NOT APPLICABLE: THIS IS NOT A THERAPEUTIC STUDY**

5.9.2 Eligibility Exceptions: There will be no exceptions to the eligibility requirements for a protocol without DFCI IRB approval.

5.9.3 Verification of Registration and Arm Designation: Registration confirmation and arm designation will be provided immediately via the online study database for participants registered to DF/HCC Multi-Center.

5.9.4 Confidentiality: All documents, investigative reports, or information relating to the participant are strictly confidential. Any participant specific reports submitted to the Lead Institution will have the assigned study ID number printed on the form.

5.10 Schedule of Data Submission

This study will not use QACT for data management. The data submission schedule is outlined in the protocol, sections 5.4: Data Collection and 5.5: Description of Study Process, and will be monitored online by the protocol chair using the study database.

6.0 REQUISITIONING INVESTIGATIONAL DRUG
NOT APPLICABLE: THIS STUDY DOES NOT USE AN INVESTIGATIONAL DRUG

7.0 SAFETY ASSESSMENTS AND TOXICITY MONITORING

Adverse or unanticipated events will be monitored and reported as outlined in the protocol, section 5.6: Adverse Reactions and Their Management.

8.0 PROTOCOL VIOLATIONS AND DEVIATIONS

Neither the FDA nor the ICH GCP guidelines define the terms "protocol violation" or "protocol deviation." All DF/HCC Protocol Chairs must adhere to those policies set by the DFCI IRB, the definitions for protocol violation and deviation as described by the DFCI IRB will be applied for reporting purposes for all institutions participating in the DF/HCC Multi-center Protocol.

8.1 Definitions

Protocol Deviation: Any departure from the defined procedures set forth in the IRB-approved protocol.

Protocol Violation: Any protocol deviation that was not prospectively approved by the IRB prior to its initiation or implementation.

8.2 Reporting Procedures

The Protocol Chair: is responsible for ensuring that clear documentation is available to describe all protocol deviations and violations. The Protocol Chair will also be responsible for ensuring that all protocol violations/deviations are promptly reported per DFCI IRB guidelines.

Participating Institutions: Protocol deviations require prospective approval from DFCI IRB. The Participating institution must submit the deviation request to the Protocol Chair and Lead Institution, who will submit the deviation request to the DFCI IRB. Upon DFCI IRB approval the deviation should be submitted to the participating site's own IRB, per its policy. Protocol violations occurring at a participating institution will be submitted to that site's own IRB. A copy of the participating institution's IRB report and determination will be forwarded to the DF/HCC Lead Institution by mail, facsimile, or via e-mail within 10 business days after the original submission.

Coordinating Center: Upon receipt of the violation/deviation report from the participating institution, the DF/HCC Lead Institution will submit the report to the Protocol Chair for review. Subsequently, the participating institution's IRB violation/deviation report will be submitted to the DFCI IRB for review per DFCI IRB reporting guidelines.

9.0 QUALITY ASSURANCE

1) The quality assurance process for a clinical trial research study requires verification of protocol compliance and data accuracy. As the Coordinating Center, the DF/HCC Lead provides quality assurance oversight for the DF/HCC Multi-center Protocol.

9.1 Ongoing Monitoring of Protocol Compliance

All data submitted to the DF/HCC Lead Institution will be monitored for timeliness of submission, completeness, and adherence to protocol requirements. Monitoring will begin at the time of participant registration and will continue during protocol performance and completion. The Lead Institution will perform the ongoing protocol compliance monitoring with the support of the participating institution's Coordinators, the Principal Investigators, and the Protocol Chair.

9.2 Evaluation of Participating Institution Performance

9.2.1 Eligibility Checklist: Eligibility will be monitored by the Protocol Chair.

9.2.5 Accrual of Eligible Participants: Annual accrual rates for eligible participants enrolled onto therapeutic clinical trials is calculated for each institution. Institutions are expected to maintain the minimum annual average accrual as defined by the protocol grant or contract.

9.2.6 Quality Improvement Report: Site performance will be monitored by the Protocol Chair and reported to the IRB and study sponsor on a yearly basis.

Yearly quality improvement reports will summarize proficiency from January 1 – December 31 and will be sent to the NCI in January.

The DF/HCC Lead Institution will distribute Quality Improvement Reports (QI) to each institution on a semi-annual basis to help the affiliate monitor data management and detect changes over time. This data can be used to detect trends in protocol adherence and present opportunities for improvement. The semi-annual reporting period will be:

January 1 - June 31
July 1 - December 31

9.3 On-Site Auditing

9.3.1 DF/HCC Sponsored Trials

NOT APPLICABLE

9.3.2 Participating Institution

It is the participating institution's responsibility to notify the DF/HCC Lead Institution of all scheduled audit dates (internal or NCI) and re-audit dates (if applicable), which involve

the DF/HCC Multi-Center Protocol. All institutions will forward a copy of final audit and/or re-audit reports and corrective action plans (if applicable) to the DF/HCC Lead Institution within 12 weeks after the audit date.

9.3.3 Coordinating Center (Lead Institution)

The Protocol Chair will review all DF/HCC Multi-Center Protocol Final Audit reports and corrective action plans if applicable. The Lead Institution or designee must forward these reports to the DF/HCC QACT per DF/HCC policy for review by the DF/HCC Audit Subcommittee. Based upon the audit assessments the DF/HCC Audit Subcommittee could accept or conditionally accept the audit rating and final report. Conditional approval could require the Protocol Chair to implement recommendations or require further follow-up. For unacceptable audits, the Audit Subcommittee would forward the final audit report and corrective action plan to the Clinical Investigations Policy and Oversight Committee and the DFCI IRB as applicable.

9.4 Sub-Standard Performance

The Protocol Chair and DFCI IRB are charged with considering the totality of an institution's performance in considering institutional participation in the DF/HCC Multi-Center Protocol.

9.4.1 Corrective Actions: Institutions that fail to meet the performance goals of accrual, submission of timely accurate data, and adherence to protocol requirements will be recommended for a six- month probation period. Such institutions must respond with a corrective action plan and must demonstrate during the probation period that deficiencies have been corrected, as evidenced by the improved performance measures. Institutions that fail to demonstrate significant improvement will be considered by the Protocol Chair for revocation of participation.

Appendix B
Clinician Recruitment: Opt out card for clinicians to decline participation in the study

Electronic Self Report Assessment (ESRA-C) II Study

_____ Check here if you do **not** wish to participate in the study.

Name: _____ Date: _____

Please return this form in the attached campus mail envelope.

Thank you for taking the time to consider participating in this study.

Appendix C
Patient Recruitment: Onscreen thank you message

When patients using the ESRA-C 2 assessment as standard care in study clinics finish their T1 assessment, the following text will appear on one screen.

”Thank You” Screen:

“Thank you! The report you have just finished is a way all patients in this clinic report their symptoms and quality of life concerns. Your answers will now be given to your care team.”

“Also, your care team is participating in a study to find out if using this program over the course of treatment will help patients take better care of their symptoms and quality of life concerns and tell their care team about these issues. You may be eligible to participate in this study, too. A research coordinator will contact you at your next appointment or by phone in the next week, to discuss the study and answer any questions you may have. You can then decide if you would like to join the study. Participation in the research study is voluntary.”

Appendix D
Information for Control Group Participants

Electronic Self-Report Assessment (ESRA-C 2) Research Study

The study coordinator will remind me when it is time to login for your Timepoint 2, 3 and 4 questionnaires. We will ask you to complete the Timepoint 2 questionnaire within 24 hours before a selected visit with your care team, and the study coordinator may contact you up to 3 days in advance to remind you.

Study coordinator: [NAME OF CRC]
[PHONE NUMBER OF CRC]
[EMAIL ADDRESS OF CRC]

For Timepoint 2, 3 and 4 questionnaires, you will use your login ID _____, and the password you chose, to login here:

[URL OF ESRA-C 2 APPLICATION]

If you forget your password, you can have it reset, or request any other assistance, by contacting:

ESRA-C Help Desk: [TOLL-FREE HELP DESK PHONE #]
[HELP DESK EMAIL ADDRESS]

As a reminder, email is not a secure means of communication. We recommend you do not include any personal health information in an email message.

Appendix E
Information for Intervention Group Participants

Electronic Self-Report Assessment (ESRA-C 2) Research Study

The study coordinator will remind me when it is time to login for your Timepoint 2, 3 and 4 questionnaires. We will ask you to complete the Timepoint 2 questionnaire within 24 hours before a selected visit with your care team, and the study coordinator may contact you up to 3 days in advance to remind you.

Study coordinator: [NAME OF CRC]
[PHONE NUMBER OF CRC]
[EMAIL ADDRESS OF CRC]

For Timepoint 2, 3 and 4 questionnaires, you will use your login ID _____, and the password you chose, to login here:

[URL OF ESRA-C 2 APPLICATION]

If you forget your password, you can have it reset, or request any other assistance, by contacting:

ESRA-C Help Desk: [TOLL-FREE HELP DESK PHONE #]
[HELP DESK EMAIL ADDRESS]

As a reminder, email is not a secure means of communication. We recommend you do not include any personal health information in an email message.

You may login any time you want to and use these tabs in ESRA-C 2 to:

Report My Experiences: Enter your answers to questionnaires about symptoms and quality of life issues. You can also add journal entries to report in your own words.

View My Reports: See color graphs that show your experiences over time.

Teaching Tips: Learn how and why symptoms and quality of life issues occur, what you can do about them, and how to talk to your care team about these problems.

Settings: Share your reports with family members and other caregivers. You can also change your password.

Appendix F
Study Information Disclosure to Other Participants
(i.e., Family/Friend Caregivers) in Recorded Clinic Visits

If family members or friends accompany patient participants to their T2 clinic visits, anything they say during the visit will be audio recorded. Though these incidental participants are not identified to the research team and written consent will not be obtained from them to be recorded, the CRC will, if possible, provide them a half-sheet of paper with the text below:

"Today you may be accompanying a family member or friend, who is participating in a research study, to an exam in their oncology clinic. Your family member or friend, and the doctors and nurses they will meet, have consented to be audio recorded in this meeting as a part of the study. The study is to learn about helping patients cope with their cancer experiences.

"Before these recordings are used as data for the study, members of the research team will erase any identifying information, such as the names of people in the room, or a phone number, that may be mentioned in the discussion. No individuals who are recorded will be identified in any reports written based on this study.

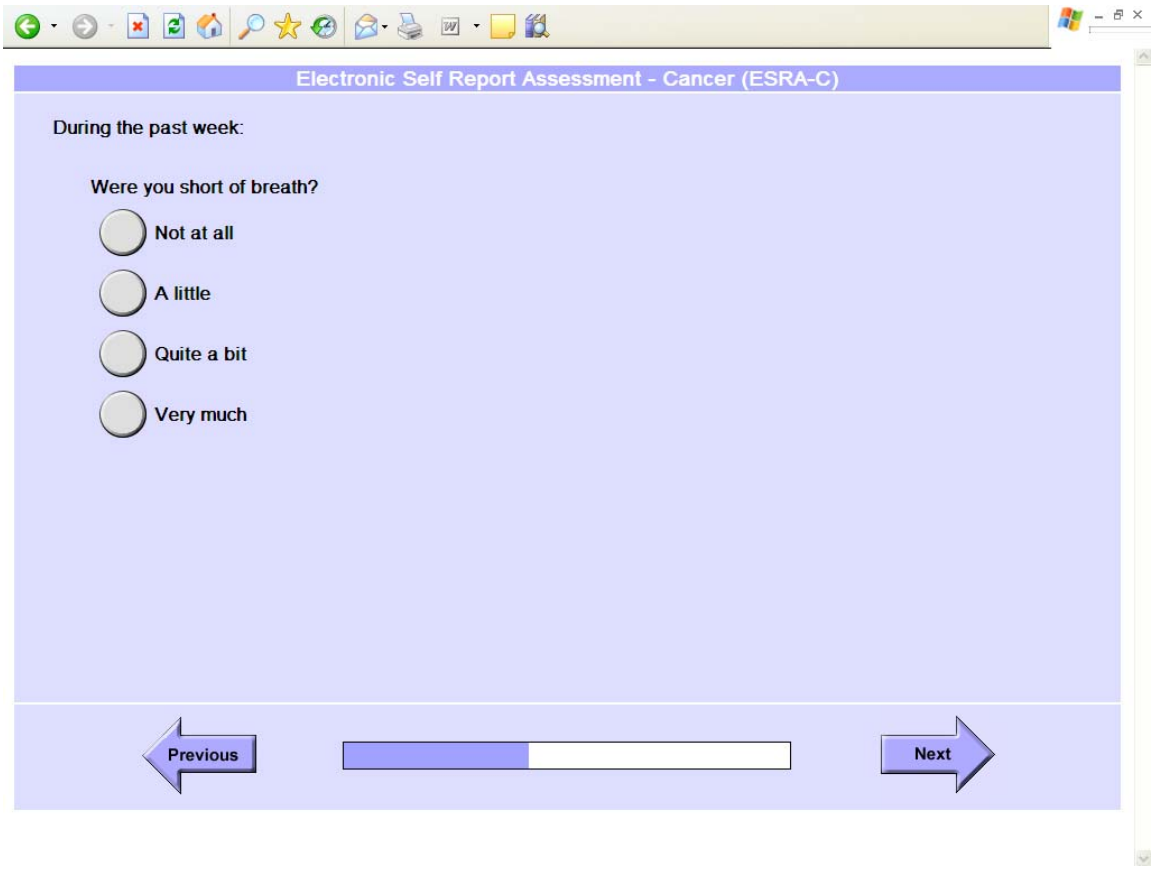
"If you have any questions about the recording or the study, please ask the research coordinator who gave you this notice."

Appendix G
Instruments Administered to Patient Participants

	Instrument	**T1**	**T2**	**T3**	**T4**
1	Demographic Questionnaire	x			
2	Symptom Distress Scale	x	x	x	x
3	Quality of Life Core Questionnaire (EORTC QLQ-c30 v3)	x	x	x	x
4	Chemotherapy-Induced Peripheral Neuropathy Questionnaire (EORTC QLQ-CIPN20)	x	x	x	x
5	Patient Health Questionnaire (PHQ-9)	x	x	x	x
6	Pain Intensity Numeric Scale (PINS)	x	x	x	x
7	PROMIS Pain Impact Scale – Short form	x	x	x	x
8	Skin Problems Questionnaire	x	x	x	x
9	Religion Questionnaire (Religious Struggle Screening Protocol)	x	x	x	x
10	Acceptability Questionnaire		x		
11	Self-Management of SQIs Questionnaire			x	
12	Patient Satisfaction with Communication Questionnaire			x	
13	Oral Chemotherapy Adherence			x	
14	Priority SQI Ranking	x	x	x	x
15	Open-Ended Item	x	x	x	X
16	Intervention Evaluation				x

Appendix G
Instruments Administered to Patient Participants

Screenshot of sample question self-administered by patient participant online in ESRA-C 2 application:



Appendix G
Instruments Administered to Patient Participants

1) DEMOGRAPHIC QUESTIONNAIRE

- What gender are you?
  - Male
  - Female

- Age group
  Under 20
  - 20-29
  - 30-39
  - 40-49
  - 50-59
  - 60 or above

- Are you Spanish/Hispanic/Latino?
  - Yes
  - No

- What is your race? (Select one or more)
  - White/Caucasian
  - Asian
  - Native Hawaiian or Other Pacific Islander
  - Black or African-American
  - American Indian/Native Alaskan

- What is your work status? (Select all that apply)
  - Working full-time
  - Working part-time
  - Working at home
  - Working, but on medical leave
  - Not working
  - Retired
  - Student

- Please select your highest level of education:
  - 8^{th} grade or less
  - $9\text{-}12^{th}$ grade
  - 2-year college
  - 4-year college
  - Graduate degree

Appendix G
Instruments Administered to Patient Participants

- Select the best answer for your current situation:
  - Single
  - Married/Partner
  - Separated
  - Divorced
  - Widowed

- I have used a computer at home (email, word-processing, spreadsheets, browsing the Internet, games):
  - Never
  - Rarely
  - Sometimes
  - Often
  - Very often

- I have used a computer at work:
  - Never
  - Rarely
  - Sometimes
  - Often
  - Very often

2) SYMPTOM DISTRESS SCALE (SDS)

Think about what each statement says, then choose the one statement that most closely indicates how you have been feeling during the past week including today.

During the past week including today …

- Nausea (Sick to Your Stomach) Frequency

  I seldom if ever have nausea
  I have nausea once in a while
  I have nausea fairly often
  I have nausea half the time at least
  I have nausea almost continually

- Nausea (Sick to Your Stomach) Intensity
  (If you had no nausea during the past week, please choose the first answer.)

  When I do have nausea, it is very mild
  When I do have nausea, it is mildly distressing
  When I have nausea, I feel pretty sick
  When I have nausea, I usually feel very sick
  When I have nausea, I am as sick as I could possibly be

- Appetite

  I have my normal appetite and enjoy good food
  My appetite is usually, but not always, pretty good
  I don't really enjoy my food
  I have to force myself to eat my food
  I cannot stand the thought of food

- Insomnia (Trouble Sleeping)

  I sleep as well as I always have
  I occasionally have trouble getting to sleep and staying asleep
  I frequently have trouble getting to sleep
  I have difficulty getting to sleep and staying asleep almost every night.
  It is almost impossible for me to get a decent night's sleep

Appendix G
Instruments Administered to Patient Participants

- Pain Frequency

  I almost never have pain
  I have pain once in a while
  I have pain several times a week
  I am usually in some degree of pain
  I am in some degree of pain almost constantly

- Pain Intensity
  (If you had no pain during the past week, please choose the first answer.)

  When I have pain, it is very mild
  When I do have pain, it is mildly distressing
  When I do have pain, it is fairly intense
  The pain I have is very intense
  The pain I have is almost unbearable

- Fatigue

  I seldom feel tired or fatigued
  There are periods when I am rather tired or fatigued
  There are periods when I am quite tired and fatigued
  I am usually very tired and fatigued
  Most of the time, I feel exhausted

- Bowel Pattern (Problems with Frequency or Pain During Bowel Movements)

  I have my normal bowel pattern
  My bowel pattern occasionally causes me some discomfort or distress
  My present bowel pattern occasionally causes me considerable discomfort or distress
  I am usually in considerable discomfort or distress because of my present bowel pattern
  I am in almost constant discomfort or distress because of my bowel pattern

- Concentration

  I have my normal ability to concentrate
  I occasionally have trouble concentrating
  I occasionally have considerably trouble concentrating
  I usually have considerable difficulty concentrating
  I just cannot seem to concentrate at all

Appendix G
Instruments Administered to Patient Participants

- Appearance

  My appearance has basically not changed
  Occasionally I am concerned about the worsening of my physical appearance
  I am often concerned that my appearance is worsening
  Most of the time I am concerned that my physical appearance is worsening
  The worsening of my physical appearance is a constant, preoccupying concern

- My cancer has affected or has had impact on my sexual activities and interests

  Not at all
  Somewhat
  Moderately so
  Quite a lot
  Very much so

- Breathing

  I usually breathe normally
  I occasionally have trouble breathing
  I often have trouble breathing
  I can hardly ever breathe as easily as I want
  I almost always have severe trouble with my breathing

- Outlook

  I am not fearful or worried
  I am a little worried about things
  I am quite worried, but unafraid
  I am worried and a little frightened about things
  I am worried and scared about things

- Cough

  I seldom cough
  I have an occasional cough
  I often cough
  I often cough and occasionally have severe coughing
  I often have persistent and severe coughing spells

- Fever/Chills

  I did not have fever and chills during the past week
  I had fever and chills once in a while
  I had fever and chills fairly often
  I had fever and chills half the time at least
  I had fever and chills almost continually

3) QUALITY OF LIFE CORE QUESTIONNAIRE - EORTC QLQ-C30 v3

Response Options (all but last 2 items):

Not at All
A Little
Quite a Bit
Very Much

- Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?
- Do you have any trouble taking a long walk?
- Do you have any trouble taking a short walk outside of the house?
- Do you need to stay in bed or a chair during the day?
- Do you need help with eating, dressing, washing yourself or using the toilet?

During the past week:

- Were you limited in doing either your work or other daily activities?
- Were you limited in pursuing your hobbies or other leisure time activities?
- Were you short of breath?
- Have you had pain?
- Did you need to rest?
- Have you had trouble sleeping?
- Have you felt weak?
- Have you lacked appetite?
- Have you felt nauseated?
- Have you vomited?
- Have you been constipated?
- Have you had diarrhea?
- Were you tired?
- Did pain interfere with your daily activities?
- Have you had difficulty in concentrating on things, like reading a newspaper or watching television?
- Did you feel tense?
- Did you worry?
- Did you feel irritable?
- Did you feel depressed?
- Have you had difficulty remembering things?
- Has your physical condition or medical treatment interfered with your family life?
- Has your physical condition or medical treatment interfered with your social activities?
- Has your physical condition or medical treatment caused you financial difficulties?
- How would you rate your overall health during the past week?

  Very Poor *Excellent*
  1 2 3 4 5 6 7
- How would you rate your overall quality of life during the past week?

  Very Poor *Excellent*
  1 2 3 4 5 6 7

4) CHEMOTHERAPY-INDUCED PERIPHERAL NEUROPATHY QUESTIONNAIRE - EORTC QLQ-CIPN20

Response Options:

Not at All
A Little
Quite a Bit
Very Much

During the past week:

- Did you have tingling fingers or hands?
- Did you have tingling toes or feet?
- Did you have numbness in your fingers or hands?
- Did you have numbness in your toes or feet?
- Did you have shooting or burning pain in your fingers or hands?
- Did you have shooting or burning pain in your toes or feet?
- Did you have cramp in your hands?
- Did you have cramp in your feet?
- Did you have problems standing or walking because of difficulty feeling the ground under your feet?
- Did you have difficulty distinguishing between hot and cold water?
- Did you have a problem holding a pen, which made writing difficult?
- Did you have difficulty manipulating small objects with your fingers (for example, fastening small buttons)?
- Did you have difficulty opening a jar or bottle because of weakness in your hands?
- Did you have difficulty walking because your feet dropped downwards?
- Did you have difficulty climbing stairs or getting up out of a chair because of weakness in your legs?
- Were you dizzy when standing up from a sitting or lying position?
- Did you have blurred vision?
- Did you have difficulty hearing?

Please answer the following question only if you drive a car

- Did you have difficulty using the pedals?

Please answer the following question only if you are a man

- Did you have difficulty getting or maintaining an erection?

Appendix G
Instruments Administered to Patient Participants

5) PATIENT HEALTH QUESTIONNAIRE – NINE SYMPTOM CHECKLIST (PHQ-9)

Response options:

Not at all
Several days
More than half the days
Nearly every day

Over the last 2 weeks, how often have you been bothered by any of the following problems:

- Little interest or pleasure in doing things
- Feeling down, depressed, or hopeless
- Trouble falling or staying asleep, or sleeping too much
- Feeling tired or having little energy
- Poor appetite or overeating
- Feeling bad about yourself – or that you are a failure or have let yourself or your family down
- Trouble concentrating on things, such as reading the newspaper or watching television
- Moving or speaking so slowly that other people have noticed? Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual
- Thoughts that you would be better off dead or of hurting yourself in some way

6) PAIN INTENSITY NUMERIC SCALE (PINS)

- Please rate **today's pain or discomfort** on a scale of 0-10 by touching or clicking one of the numbered buttons below, where 0 means no pain or discomfort and 10 is the worst you could imagine.

0 1 2 3 4 5 6 7 8 9 10

7) PROMIS PAIN INTERFERENCE – SHORT FORM

- Administered only if PINS score > 5, or SDS Pain Frequency or Intensity > 3

In the past 7 days:

- How much did pain interfere with your ability to concentrate?
  - Not at all
  - A little bit
  - Somewhat
  - Quite a bit
  - Very much

- How much did pain interfere with your day to day activities?
  - Not at all
  - A little bit
  - Somewhat
  - Quite a bit
  - Very much

- How much did pain interfere with doing your tasks away from home (e.g., getting groceries, running errands)?
  - Not applicable (I have been told by my care team to avoid these activities)
  - Not at all
  - A little bit
  - Somewhat
  - Quite a bit
  - Very much

- How often did pain keep you from socializing with others?
  - Not applicable (I have been told by my care team to avoid these activities)
  - Not at all
  - A little bit
  - Somewhat
  - Quite a bit
  - Very much

8) SKIN PROBLEMS QUESTIONNAIRE

- How severe are your skin problems?

  Not Present
  Very Mild
  Mild
  Moderate
  Severe
  Very Severe

  [If "Not Present" endorsed, skip remaining items]

Please describe your skin problems using the following terms.
Touch or click the answer that best describes the feeling and appearance of your skin problems.

Response options:

Not Present
Very Mild
Mild
Moderate
Severe
Very Severe

- Itchy
- Throbbing-Aching
- Tender
- Hot-Burning
- Tight-Splitting
- Redness-Discoloration
- Flaking-Peeling
- Bumpy-Spotted

9) RELIGION/SPIRITUALITY QUESTIONNAIRE

- Is religion or spirituality important to you as you cope with your illness?
  Yes
  No

  [If Yes]:
  - How much strength/comfort do you get from your religion or spirituality now?
    All that I need
    Somewhat less than I need
    None at all

  [If No]:
  - Has there ever been a time when religion or spirituality was important to you?
    Yes
    No

  [If 'Yes' and 'All that I need'] or [If 'No' and 'No' to Has there ever…]: Ask next item:

- Would you like a visit from a chaplain?
  Yes
  No

Appendix G
Instruments Administered to Patient Participants

10) ACCEPTABILITY QUESTIONNAIRE

Thank you for your answers on how you are feeling. Now we would like to ask your thoughts on using this computer program (ESRA-C).

- How easy was this computer program (ESRA-C) for you to use?

Very Difficult				*Very Easy*
1	2	3	4	5

- How understandable were the questions?

Difficult to Understand				*Easy to Understand*
1	2	3	4	5

- How much did you enjoy using this computer program (ESRA-C)?

Not at All				*Very Much*
1	2	3	4	5

- How helpful to you was this computer program (ESRA-C) in describing your symptoms and quality of life?

Very Unhelpful				*Very Helpful*
1	2	3	4	5

- Was the amount of time it took to complete this computer program (ESRA-C) acceptable?

Very Unacceptable				*Very Acceptable*
1	2	3	4	5

- How would you rate your overall satisfaction with this computer program (ESRA-C)?

Very Dissatisfied				*Very Satisfied*
1	2	3	4	5

12) SELF-MANAGEMENT OF SQIs QUESTIONNAIRE
- Questionnaire uses two SQIs ranked highest in patient priority at Time 2

In your Timepoint 2 report on [DATE], you said [T2A] and [T2B] were the two things bothering you most. This may have changed for you, but we would like to ask you about your experience with [T2A] and [T2B] since Timepoint 2. These questions are not part of the report your health care providers will receive.

A. Adherence to Treatment Recommendations

- Since Timepoint 2, to what extent did you follow the recommendations that your health care providers have given you for managing [T2A]?

  I did not follow the recommendations that my health care providers have given me for managing this problem.
  I partly followed the recommendations that my health care providers have given me for managing this problem.
  I exactly followed the recommendations that my health care providers have given me for managing this problem.
  My health care providers have not given me recommendations for managing this problem.

- Since Timepoint 2, to what extent did you follow the recommendations that your health care providers have given you for managing [T2B]?

  I did not follow the recommendations that my health care providers have given me for managing this problem.
  I partly followed the recommendations that my health care providers have given me for managing this problem.
  I exactly followed the recommendations that my health care providers have given me for managing this problem.
  My health care providers have not given me recommendations for managing this problem.

B. Self-Care Activities

- Since Timepoint 2, did you do anything else on your own to manage [T2A]?
  Yes
  No
  [If No, skip next item]

- Please type in the box below anything else you did on your own to manage [T2A]. (Touch or click inside the box to begin typing)

- Since Timepoint 2, did you do anything else on your own to manage [T2B]?
  Yes
  No
  [If No, skip next item]

- Please type in the box below anything else you did on your own to manage [T2B]. (Touch or click inside the box to begin typing)

C. Perceived Control of SQIs

We are interested in your own personal views about how you now see your symptoms and quality of life.

Response options:

Strongly Disagree
Disagree
Neither Agree Nor Disagree
Agree
Strongly Agree

For the following questions, please respond with regard to [T2A]. Please indicate how much you agree or disagree with the following statements about [T2A].

- What I do can determine whether this problem gets better or worse
- There is a lot which I can do to control this problem
- Treatment will be effective in controlling this problem

For the following questions, please respond with regard to [T2B]. Please indicate how much you agree or disagree with the following statements about [T2B].

- What I do can determine whether this problem gets better or worse
- There is a lot which I can do to control this problem
- Treatment will be effective in controlling this problem

D. Satisfaction with Symptom Management

Finally, we would like to ask how satisfied you are with how the two things that were bothering you the most at Timepoint 2 (on [DATE]) have been managed since then.

How satisfied are you with how [T2A] has been managed since Timepoint 2 (on [DATE])?

Very Dissatisfied								Very Satisfied		
0	1	2	3	4	5	6	7	8	9	10

How satisfied are you with how [T2B] has been managed since Timepoint 2 (on [DATE])?

Very Dissatisfied								Very Satisfied		
0	1	2	3	4	5	6	7	8	9	10

Appendix G
Instruments Administered to Patient Participants

12) PATIENT SATISFACTION WITH COMMUNICATION QUESTIONNAIRE

Thinking back over your time in treatment and now, choose the answer for each statement that best describes how you feel about communication with your care team.

Response options:

Strongly Disagree
Disagree
Neither Agree Nor Disagree
Agree
Strongly Agree

- My care team gave me the information I needed.
- My care team helped me understand my condition.
- I feel that I can contact my care team if I need to.
- I could talk to my care team.
- I would recommend my care team to a friend.
- My care team were attentive to me.
- My care team were not in a rush.
- My care team were professional.
- My care team explained the reason for treatment.
- My needs were addressed.
- My care team used words I understood.

13) ORAL CHEMOTHERAPY ADHERENCE

Some chemotherapy or hormone medications are taken as pills or capsules. Please touch or click the button for any of the following medications that you take. [List oral chemotherapy/hormone medications (OCHM) administered at study sites]

[If none endorsed, skip remaining items]

You told us that you are taking oral chemotherapy or hormone pills or capsules for your cancer. In the past, people have identified several issues regarding their medication-taking behavior, and we are interested in your experiences. There are no right or wrong answers. Again, these questions are not part of the report your health care provider will receive. Please answer each question based on your personal experience with your cancer pills or capsules ([fills in name of OCHM]).

• Do you sometimes forget to take your [OCHM]?	No	Yes
• People sometimes miss taking their medications for reasons other than forgetting. Thinking over the past two weeks, were there any days when you did not take your [OCHM]?	No	Yes
• Have you ever cut back or stopped taking your [OCHM] without telling your doctor, because you felt worse when you took it?	No	Yes
• When you travel or leave home, do you sometimes forget to bring along your [OCHM]?	No	Yes
• Did you take your [OCHM] yesterday?	No	Yes
• When you feel like your cancer is under control, do you sometimes stop taking your medicine?	No	Yes
• Have you ever taken more than your regular dose of your [OCHM], other than when you are making up for a skipped dose?	No	Yes
• Taking medication everyday is a real inconvenience for some people. Do you ever feel hassled about sticking to your cancer treatment plan?	No	Yes

- How often do you have difficulty remembering to take your [OCM]?
  - Never/Rarely
  - Once in a while
  - Sometimes
  - Usually
  - All the time

Appendix G
Instruments Administered to Patient Participants

14) PRIORITY SQI RANKING

- Based on your answers, it seems the problems below may be bothering you today. Please touch or click the **TWO** problems that are bothering you most right now.

  [All symptoms and quality of life issues endorsed at a designated threshold in the assessment session will be listed in random order.]

15) OPEN-ENDED ITEM

- If there is anything else you would like to discuss, or any questions you have for your care team, please type them in the box below.
  (Touch or click inside the box to begin typing)

16) INTERVENTION EVALUATION
[Questions administered to intervention participants only.]

Thank you for participating in the ESRA-C research study. Before you finish, we have a few questions about your experience using the ESRA-C program.

Every patient in your clinic may report symptoms and quality of life issues using the ESRA-C question and answer program (Report My Experiences). Only members of your group in the research study could use some additional features of the program (Journal, View My Reports, Teaching Tips, Share My Reports). The following questions ask about these additional features.

Please rate the usefulness to you of each ESRA-C feature.

1. Journal feature

Not useful at all				Very useful	Did not visit or see
1	2	3	4	5	

[If Did not visit or see]

1a. Why didn't you use the Journal feature of ESRA-C? (Select one or more)

- I already keep a journal of my symptoms and cancer information
- I am not interested in keeping a journal
- I did not know there was a journal feature
- I did not know how to use the journal feature
- Other (please explain) _____

2. View My Reports feature

Not useful at all				Very useful	Did not visit or see
1	2	3	4	5	

[If Did not visit or see]

2a. Why didn't you use the View My Reports feature of ESRA-C? (Select one or more)

- I am not interested in viewing graphs of my symptoms over time
- I did not know there was a View My Reports feature
- I did not know how to use the feature or read the graphs
- Other (please explain) _____

3. Teaching Tips feature

Not useful at all				Very useful	Did not visit or see
1	2	3	4	5	

[If Did not visit or see]

3a. Why didn't you use the Teaching Tips feature of ESRA-C? (Select one or more)

- I prefer to learn about symptoms from my doctor/nurse
- I prefer other information booklets or websites to learn about my symptoms
- I did not know there was a Teaching Tips feature
- I did not know how to use the feature
- Other (please explain) _____

4. Share My Reports feature

Not useful at all				Very useful	Did not visit or see
1	2	3	4	5	

[If Did not visit or see]

4a. Why didn't you use the Share My Reports feature of ESRA-C? (Select one or more)

- I am not interested in sharing my reports
- I did not know there was a Share My Reports feature
- I did not know how to use the feature
- Other (please explain) _____

[If yes to any use question]

5. How frequently did you use any of the Journal, View My Reports, Teaching Tips, or Share My Reports features?

- Never
- One time only
- Monthly or more often
- Weekly or more often
- Daily

6. Did anyone else view the ESRA-C program with you?

- Yes
- No

[If Yes]

6a. Who viewed this program with you?

- Spouse or partner
- Other family member
- Friend

7. If a friend or family member were being treated for cancer, would you recommend this type of program to them?

- Definitely not
- Probably not
- Maybe / unsure
- Probably
- Definitely

8. How helpful were phone calls / email messages in reminding you to use the ESRA-C program?

Not helpful at all				Very helpful	Did not receive reminders
1	2	3	4	5	

9. How easy was it for you to access the ESRA-C website from home?

Not easy at all				Very easy	Did not try to access ESRA-C from home
1	2	3	4	5	

10. How responsive was the ESRA-C Help Desk when you had problems logging in or using the ESRA-C program?

Not responsive at all				Very responsive	Did not contact the Help Desk
1	2	3	4	5	

11. Please describe any part of the ESRA-C program you found especially useful, any part that was a problem to use, or any other comments you have about the program.
[open text]

Appendix H

Instruments Administered to Clinician Participants

1) Demographic questionnaire
   - Self-administered one time online by email invitation; if no response after two email reminders, sent for self-administration as paper questionnaire by traditional campus mail

2) Clinician satisfaction with patient-clinician communication questionnaire
   - Self-administered as paper questionnaire immediately following patient visit, each time a patient participant completes Time 2 visit

Appendix H
ESRA-C II: Clinician Demographic Questionnaire

Age Group:

(1) 20-29
(2) 30-39
(3) 40-49
(4) 50-59
(5) 60 and above

Gender: (1) Male (2) Female

Ethnicity: Are you Spanish/Hispanic/Latino?

(1) Yes (2) No

Race: *[Select one or more]*

(1) White/Caucasian
(2) Asian
(3) Native Hawaiian or other Pacific Islander
(4) Black/African-American
(5) American Indian/Native American

Specialty:

(1) Heme/Stem Cell Transplant
(2) Radiation Oncology
(3) Medical Oncology
(4) Surgical Oncology
(5) Other _____

Position Title:

(1) Attending MD
(2) Resident/Fellow
(3) ARNP or RN
(4) Physician Assistant
(5) Other _____

Appendix XX

Electronic Self-Report Assessment – Cancer (ESRA-C 2):
Clinician Satisfaction with Patient-Clinician Communication Questionnaire

How satisfied were you with communication between you and your patient today overall?

Not at all satisfied *Completely satisfied*

0 1 2 3 4 5 6 7 8 9 10

How satisfied were you with communication about symptoms and quality of life concerns?

Not at all satisfied *Completely satisfied*

0 1 2 3 4 5 6 7 8 9 10

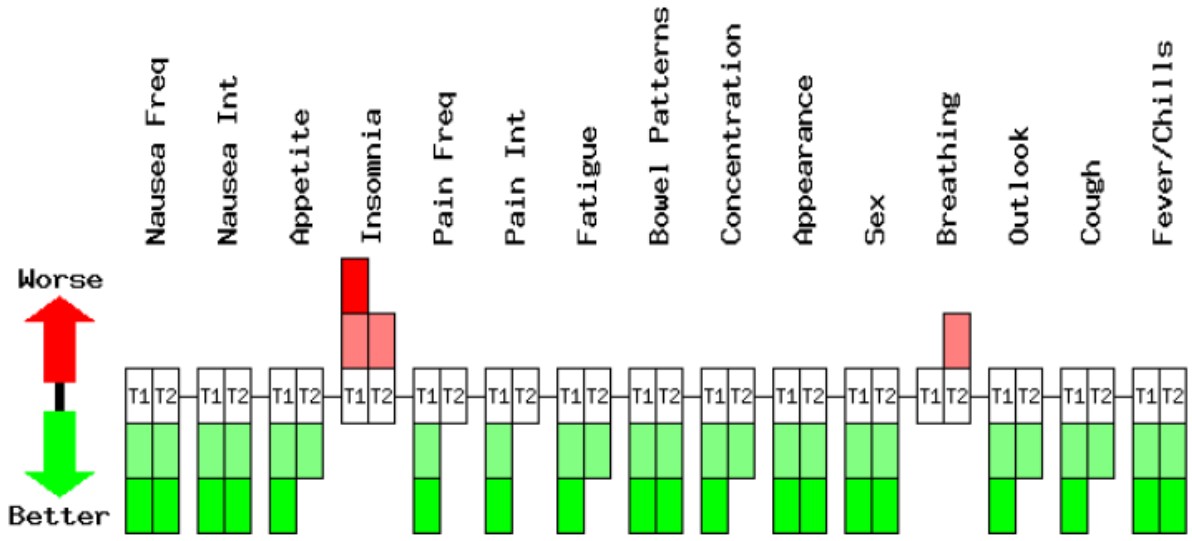
Appendix I
Sample ESRA-C 1 Clinician Printout

Electronic Self Report Assessment - Cancer

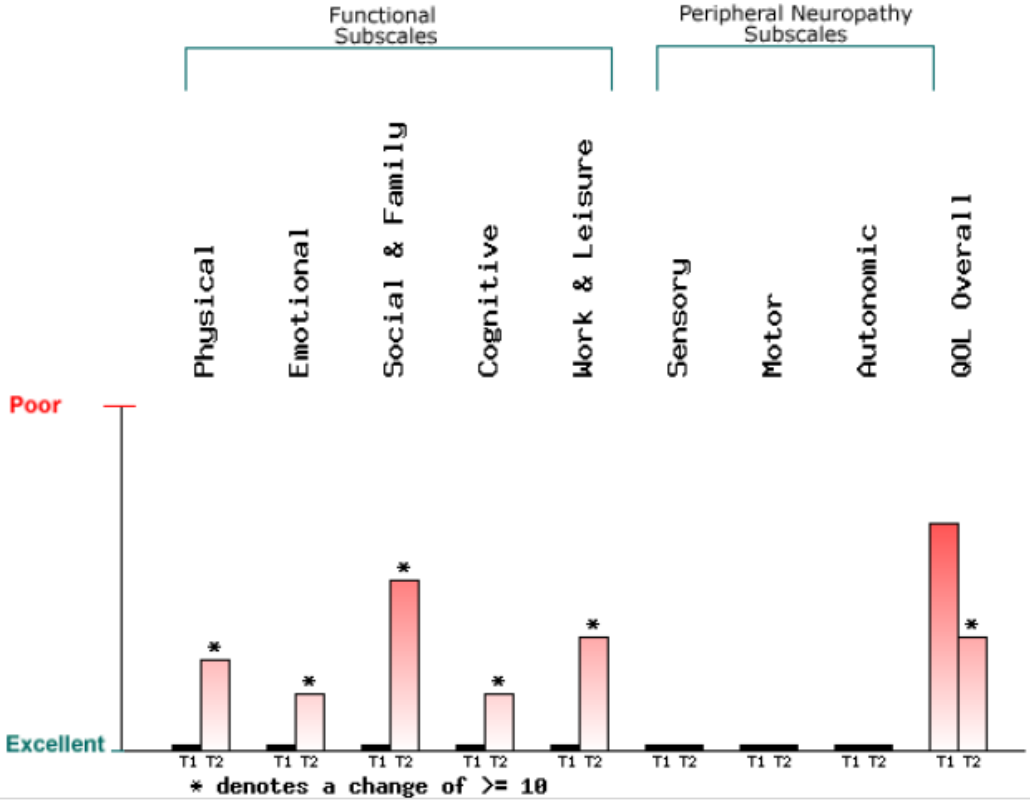
Name: Bunny, Bugs
U Number: 0

T1 Date: 08/27/2008
T2 Date: 08/27/2008

Symptom Distress Scale



Quality of Life (EORTC Scales)

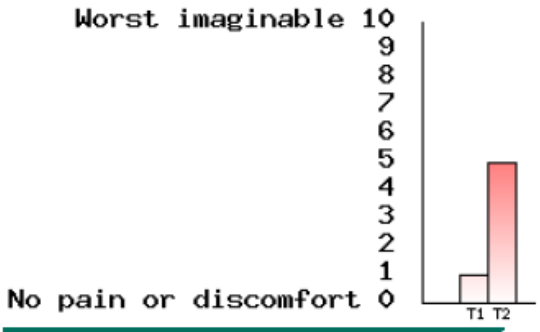


Electronic Self Report Assessment - Cancer

Name: Bunny, Bugs
U Number: 0

T1 Date: 08/27/2008
T2 Date: 08/27/2008

Pain or Discomfort

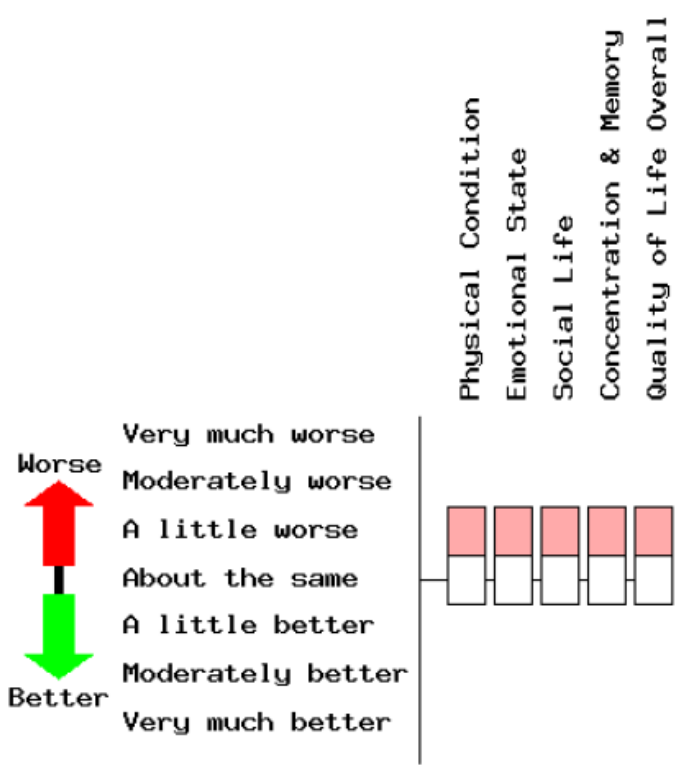


Additional Concerns (free text)

T1: Nothing, I feel pretty good. Only I don\'t sleep much, but that is normal for me. Sometimes I have to catch my breath.

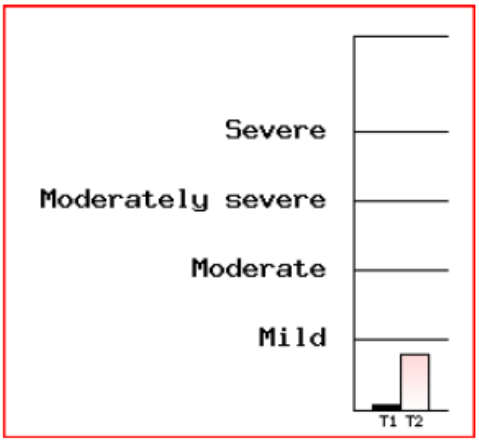
T2: I guess i feel tired, in the daytime which is not normal for me. And I\'m a little worried. What will be the outcome of my treatment, will it get the cancer.

Subjective Significance Scale



PHQ-9 Depression Inventory

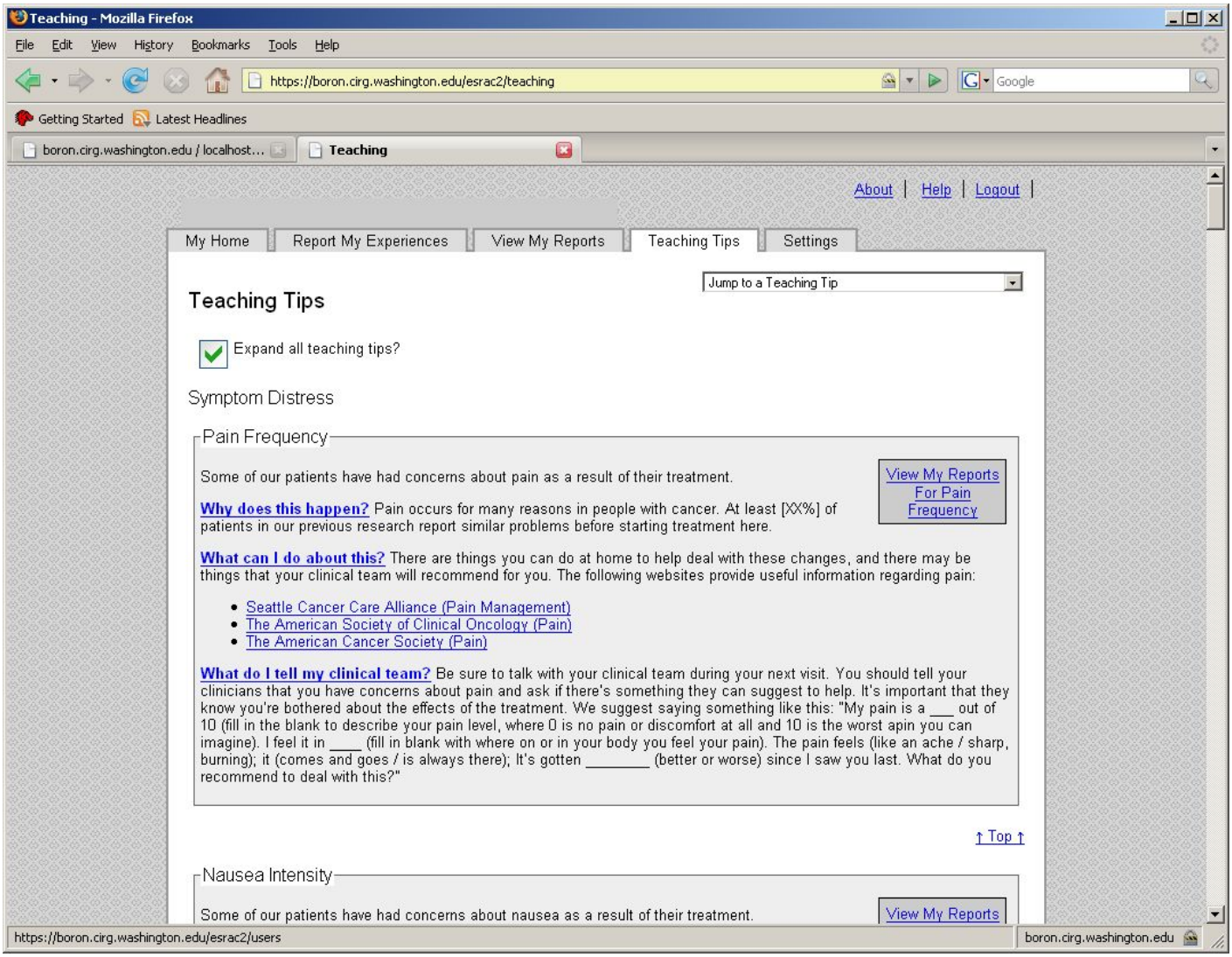
Alert! Depression questions triggered T1 and T2.



Appendix J

Information for Intervention Group Participants

Screenshot of Teaching Tips in ESRA-C 2 application



Appendix J

Information for Intervention Group Participants

Pain Frequency

Some of our patients have had concerns about pain as a result of their treatment.

Based on your answers in the survey, you seem to have experienced pain. If your pain intensity score is 5 or higher, call your team/clinic nurse right now.

Why does this happen? Pain occurs for many reasons in people with cancer. At least [XX%] of patients in our previous research report similar problems [before/after] starting treatment here.

What can I do about this? There are things you can do at home to help deal with these changes, and there may be things that your clinical team will recommend for you. The following websites provide useful information regarding pain:

- Seattle Cancer Care Alliance (Pain Management)
- The American Society of Clinical Oncology (Pain)
- The American Cancer Society (Pain)

What do I tell my clinical team? Be sure to talk with your clinical team during your next visit. You should tell your clinicians that you have concerns about pain and ask if there's something they can suggest to help. It's important that they know you're bothered about the effects of the treatment. We suggest saying something like this: "My pain is a ___ out of 10 (fill in the blank to describe your pain level, where 0 is no pain or discomfort at all and 10 is the worst pain you can imagine). I feel it in ____ (fill in blank with where on or in your body you feel your pain). The pain feels (like an ache / sharp, burning); it (comes and goes / is always there); It's gotten _____ (better or worse) since I saw you last. What do you recommend to deal with this?"

Nausea Intensity

Some of our patients have had concerns about nausea as a result of their treatment.

Based on your answers on the survey, you may have felt sick to your stomach.

Why does this happen? This happens sometimes due to the effect of cancer treatment or medications on both the brain and the lining of your stomach; about [XX%] of our patients like yourself have reported similar symptoms [before/after] starting treatment here.

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Information for Intervention Group Participants

What can I do about this? There are things you can do at home to help deal with this symptom and there may be things that your clinical team will recommend for you. The following websites provide useful information regarding nausea:

- Seattle Cancer Care Alliance (Nausea and Vomiting)
- Cancer.net from the American Society of Clinical Oncology (Nausea and Vomiting)
- The American Cancer Society website (Nausea and Vomiting)

What do I tell my clinical team? Be sure to talk with your clinical team about this the next time you see them in clinic. Ask if there's something they can suggest to help. It's important that they know you're having these kinds of problems. We suggest saying something like this: "I've been sick to my stomach. It started _____ (fill in the blank with when you first felt like this). It has gotten _____ (better or worse) since I saw you last. What do you recommend to deal with this?"

Fatigue

Some of our patients have had concerns about feeling tired as a result of their treatment.

Based on your answers in the survey, you may be fatigued or have a lack of energy. This often involves feeling tired or exhausted, even with enough rest and sleep. Fatigue may interfere with one's sense of well-being, daily activities, relationships with family and friends, and ability to adhere to medical treatment.

Why does this happen? Fatigue can result from many things, such as cancer treatment, medications, pain, anxiety, depression, or lack of exercise. While fatigue is common during cancer treatment, many patients report continuing problems with fatigue after completing treatment. At least [XX%] of patients in our previous research report similar problems [before/after] starting treatment here.

What can I do about this? Fatigue is often temporary while you receive treatment, but may persist for some time even after treatment. There are things you can do at home to help deal with these changes, and there may be things that your clinical team will recommend for you. The following websites provide useful information regarding fatigue:

- Seattle Cancer Care Alliance (Fatigue)
- Dana-Farber Cancer Institute: Fatigue management

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Information for Intervention Group Participants

- The National Cancer Institute (Fatigue)
- The American Cancer Society (Fatigue Treatment Guidelines)
- LiveStrong Lance Armstrong Foundation (Fatigue)
- The Oncology Nursing Society (Fatigue)
- The American Society of Clinical Oncology (Fatigue)

What do I tell my clinical team? Be sure to talk with your clinical team during your next visit. You should tell your clinicians that you have concerns about fatigue and ask if there's something they can suggest to help. It's important that they know you're bothered about the effects of the treatment. We suggest saying something like this: "My fatigue is a ___ out of 10 (fill in the blank to describe your fatigue level where 0 is no fatigue at all and 10 is the worst fatigue you can imagine). For example _____ (describe how the fatigue has affected you or interfered with your daily activities). It's gotten _____ (better or worse) since I saw you last. What do you recommend to deal with this?"

Appetite

Some of our patients have had concerns about changes in their appetite as a result of their treatment.

Based on your answers on the survey, it seems you may be experiencing loss of appetite.

Why does this happen? Sometimes this happens because cancer medications change the taste of your food, because you are worried, or because you are less active than normal as a result of your cancer or treatment. About [XX%] of patients in our previous research reported loss of appetite [before/after] starting treatment here.

What can I do about this? There are things you can do at home to help deal with this symptom, such as eating small meals throughout the day, and there may be things that your clinical team will recommend for you. The following websites provide useful information regarding appetite:

- The American Society of Clinical Oncology (Appetite Loss)
- Cancersymptoms.org from the Oncology Nursing Society (Anorexia)
- The American Cancer Society website (Appetite, Poor)

Appendix J

Information for Intervention Group Participants

What do I tell my clinical team? Be sure to talk with your clinical team about your appetite the next time you see them, and ask what they suggest to help. It's important that they know about your loss of appetite. We suggest saying something like this: "I don't want to eat ____ (fill in the blank: in the morning; before going out; when my mouth is sore; when I feel anxious and worried; anything at all). It started _____(fill in the blank with when you first felt like this). It has gotten _____ (better or worse) since I saw you last. What do you recommend to deal with this?"

Bowel Troubles

Some of our patients have had concerns about bowel problems as a result of their treatment.

Based on your answers in the survey, it seems you have had troubles with diarrhea or loose bowel movements, or have been uncomfortable due to constipation or not being able to have a bowel movement.

Why does this happen? This happens sometimes due to the effect of cancer treatment or medications on your bowels. Or, it can be a result of something else, such as diet or infection. At least [XX%] of patients in our previous research report similar problems [before/after] starting treatment here.

What can I do about this? There are things you can do at home to help deal with this symptom and there may be things that your clinical team will recommend for you. The following websites provide useful information regarding bowel troubles:

- The American Society of Clinical Oncology (Diarrhea)
- The American Society of Clinical Oncology (Constipation)

What do I tell my clinical team? Be sure to talk with your clinical team about this next time you are in the clinic. Ask what they suggest to help. It is important that they know you are having these kinds of problems. You might say: "I've had trouble with my bowels, consisting of (describe nature of the problem). It started _____(fill in the blank with when you first felt like this). It has gotten _____ (better or worse) since I saw you last. What do you recommend to deal with this?"

Appendix J

Information for Intervention Group Participants

Concentration

Some of our patients have had concerns about Concentration, Memory, and Cognitive Function as a result of their treatment.

Based on your answers on the survey, you may have some difficulty concentrating and staying focused on tasks.

Why does this happen? It may be the effect of cancer treatment or medications on the brain. At least [XX%] of our patients in previous research report similar problems [before/after] starting treatment here.

What can I do about this? There are things you can do at home to help deal with this symptom and there may be things that your clinical team will recommend for you. The following websites provide useful information regarding concentration and memory:

- Seattle Cancer Care Alliance (Memory and Concentration)
- Dana-Farber Cancer Institute (Cognitive Disorders and Delirium)
- The American Society of Clinical Oncology (Cognitive Problems)
- The American Cancer Society (Confusion)

What do I tell my clinical team? Be sure to talk with your clinical team about this the next time you see them in the clinic. We suggest saying something like this: "I've noticed that I cannot concentrate very long or stay focused on things I'm doing. It started _____(fill in the blank with when you first noticed the symptom). It has gotten _____ (better or worse) since I saw you last. What do you recommend to deal with this?"

Sleeping troubles

Some of our patients have had concerns about changes in sleeping patterns as a result of their treatment.

Based on your answers in the survey, you may have some concerns about your sleep. This may include trouble falling asleep or staying asleep, awakening too early, not feeling refreshed upon awakening, or poor sleep interfering with your daytime activities. Sleep disturbances can affect your mood and functioning during the day, and may be a sign of other medical or emotional issues.

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Information for Intervention Group Participants

Why does this happen? Insomnia can result from many things, such as pain, stress, worry, anxiety, depression, medications, or environmental factors such as an uncomfortable bed or too much noise or light. At least [XX%] of patients in our previous research report similar problems [before/after] starting treatment here.

What can I do about this? Insomnia is often temporary while you receive treatment. There are things you can do at home to help deal with these changes, and there may be things that your clinical team will recommend for you. The following websites provide useful information regarding insomnia:

- The National Cancer Institute (Sleep Disorders)
- LiveStrong Lance Armstrong Foundation (Body Image)
- The American Society of Clinical Oncology (Insomnia)

What do I tell my clinical team? Be sure to talk with your clinical team during your next visit. You should tell your clinicians that you have concerns about sleep and ask if there's something they can suggest to help. It's important that they know you're bothered about the effects of the treatment. We suggest saying something like this: "I've noticed that _____(fill in the blank to describe your sleep pattern). For example _____ (describe how the sleep problem has affected you or interfered with your daily activities). It has gotten _____ (better or worse) since I saw you last. What do you recommend to deal with this?"

Appendix J

Information for Intervention Group Participants

Appearance

Some of our patients have had concerns about changes in their physical appearance as a result of their treatment.

Based on your answers in the survey, you may have some concerns about changes in your physical appearance.

Why does this happen? Changes in appearance, such as losing hair, or gaining or losing weight, are quite common in patients undergoing cancer treatments. These kinds of changes are due to the effects of chemotherapy, radiation, surgery, and various cancer medications. At least [XX%] of our patients in our previous research have reported similar changes in their appearance [before/after] starting treatment here.

What can I do about this? Many of these changes in appearance are only temporary while you receive treatment. There are things you can do at home to help deal with these changes, and there may be things that your clinical team will recommend for you. The following websites provide useful information about cancer-related appearance changes:

- Seattle Cancer Care Alliance (Body Image Changes)
- LiveStrong Lance Armstrong Foundation website (Body Image)
- Cancer.gov from the National Cancer Institute (Hair Loss)
- Cancer.gov from the National Cancer Institute (Radiation Related Skin Changes)

What do I tell my clinical team? Be sure to talk with your clinical team during your next visit. You should tell your clinicians that you have concerns about your appearance and ask what they suggest to help. It is important that they know you are bothered by the effects of the treatment. You might say: "I've noticed that _____(fill in the blank to describe changes in your appearance that concern you). It's gotten _____ (better or worse) since I saw you last. What do you recommend to deal with this?"

Impact on Sexuality

Some of our patients have had concerns about changes in their sexual activities or interest.

Based on your answers in the survey, you may have some concerns about sexual activities or reduced sexual interest.

Appendix J

Information for Intervention Group Participants

Why does this happen? Treatments for cancer, such as chemotherapy, radiation or other medications can often have a physical effect on the body that makes sexual activity difficult or painful and which reduces a patient's interest in sex. The emotional stress of cancer treatment can also have an effect. Changes in sexual activity and interest are quite common in patients undergoing treatment for cancer. At least [XX%] of patients in our previous research report similar problems [before/after] starting treatment here.

What can I do about this? Many of these sexual difficulties are temporary. And there are things you can do at home to help deal with these problems. There may also be things that your clinical team will recommend for you. The following websites provide useful information regarding the impact of cancer and treatment on sexuality:

- The American Society of Clinical Oncology (Sexual Dysfunction)
- Cancer Supportive Care Programs (Changes in Sexuality and Sexual Problems)
- The National Cancer Institute (Sexual Changes)

What do I tell my clinical team? Be sure to talk with your clinical team during your next visit. You should tell your clinicians that you have concerns about difficulty with sex or reduced sexual interest. Ask if there's something they can suggest to help. It's important that they know you're bothered about these treatment effects. We suggest saying something like this: "I've noticed that having sex has become [painful, difficult etc] _____(fill in the blank to describe physical difficulty/ I'm concerned that I have less/no interest). It's gotten _____ (better or worse) since I saw you last. What do you recommend to deal with this?"

Cough

Some of our patients have had concerns about coughing as a result of their treatment.

Based on your answers in the survey, you may have been coughing.

Why does this happen? This happens sometimes due to the effect of cancer itself, treatments or other problems in your airway, such as an infection. At least [XX%] of patients in our previous research report similar problems [before/after] starting treatment here.

What can I do about this? There are things you can do at home to help deal with this symptom and there may be things that your clinical team will recommend for you. The following websites provide useful information about cancer-related coughing:

- The Cleveland Clinic (Cough and Chemotherapy)
- Women and Cancer Magazine (Cough)

What do I tell my clinical team? Be sure to talk with your clinical team about this the next time you see them in the clinic. Ask if there's something they can suggest to help. It's important that they know you're having these kinds of problems. We suggest saying something like this: "I've had a cough recently. It started _____(fill in the blank with when you first felt like this). It has gotten _____ (better or worse) since I saw you last. What do you recommend to deal with this?"

Fear and Worry

Some of our patients have had concerns about worry and fear as a result of their treatment.

Based on your answers in the survey, you may have some concerns about worry and fear. Cancer and its treatment often lead to fear and anxiety, such as about the future. These feelings often fluctuate over time, but can become overwhelming and lead to difficulty with sleep, relationships, work, home and social life, or other activities.

Why does this happen? Fear and worry are common during cancer treatment, but these feelings can become overwhelming at times. At least [XX%] of patients in our previous research report similar problems [before/after] starting treatment here.

What can I do about this? Fear, worry, and anxiety are often temporary while you receive treatment, although they can occur at any time. There are things you can do at home to help deal with these changes, and there may be things that your clinical team will recommend for you. The following websites provide useful information regarding fear, worry, and other emotional effects of cancer:

- The National Cancer Institute (Anxiety)
- The American Cancer Society (Anxiety and Fear)
- The American Cancer Society (Panic Attacks)
- LiveStrong Lance Armstrong Foundation (Emotional Effects of Cancer)
- The American Society of Clinical Oncology (Fear of Recurrence)

Appendix J

Information for Intervention Group Participants

What do I tell my clinical team? Be sure to talk with your clinical team during your next visit. You should tell your clinicians if you have anxiety and fear. Ask if there's something they can suggest to help. It's important that they know you're bothered about the effects of the treatment. We suggest saying something like this: "I've noticed that _____(fill in the blank to describe your fears and worries). For example _____ (describe what you're worried or fearful about and how your anxiety has affected you or interfered with your daily activities). It has gotten _____ (better or worse) since I saw you last. What do you recommend to deal with this?"

Breathing

Some of our patients have had concerns about changes in breathing as a result of their treatment.

Based on your answers on the survey, you seem to have some concerns about your breathing. Breathing trouble can be difficulty breathing, painful breathing or shortness of breath. The distress caused by this is different for each patient, from mild discomfort in one patient to severe discomfort in another.

Why does this happen? Breathing difficulty may be due to the tumor or the effects from treatment of your cancer or another health condition. At least [XX%] of patients in our previous research report similar problems [before/after] starting treatment here.

What can I do about this? Your breathing trouble can be managed through many different ways after identifying the condition that caused it by performing certain tests. Keep track of your breathing problem from day to day. The following websites provide useful information regarding breathing difficulty and its management:

- Dana-Farber Cancer Institute (Cardiopulmonary Syndrome Overview)
- The American Cancer Society (Shortness of Breath)
- The National Cancer Institute (Cardiopulmonary Syndrome Overview)

What do I tell my clinical team? Be sure to talk with your clinical team about your breathing trouble the next time you see them in the clinic. Be sure to tell them how it started (suddenly or gradually), and any patterns that you may have observed: is it there all the time or only at certain times, for example, with physical activity? We suggest starting the conversation with something like this: "I've been feeling _____ (describe breathing problem, such as being short of breath). It started _____ (fill blank with when you first noticed breathing difficulty). It's gotten ____ (better or worse) since I last saw you. What do you recommend to deal with this?"

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Information for Intervention Group Participants

Fever and Chills

Some of our patients have had concerns about fever and/or chills as a result of their treatment.

Based on your answers on the survey, you may have had a fever (increased temperature) and/or chills (shaking/rigors). If you have had chills OR your temperature is over 101 degrees Fahrenheit, call your team/clinic nurse right now.

Why does this happen? This happens sometimes due to the effect of cancer itself, treatments or other problems in your tissues such as infection or inflammation. At least [XX%] of patients in our previous research report similar problems [before/after] starting treatment here.

What can I do about this? There are things you can do at home to help deal with this symptom and there may be things that your clinical team will recommend for you.

- The National Cancer Institute (Fever, Sweats, and Hot Flashes)
- The Cleveland Clinic (Fever)
- Washington Hospital Symptom Management (Frever, Chills, and Sweats)

What do I tell my clinical team? Be sure to talk with your clinical team the next time you see them in the clinic. Ask if there's something they can suggest to help. It's important that they know you're having these kinds of problems. We suggest saying something like this: "I've had a fever and chills. It started _____(fill in the blank with when you first felt like this). It was _____ degrees when it was its worst. What do you recommend to deal with this?"

Depression

Some of our patients have had concerns about depression as a result of their treatment.

Based on your answers in the survey, you may have some concerns about feeling down, depressed, or blue. This may include having little interest or pleasure in doing things or feeling hopeless. Along with these feelings, people often have trouble with sleep, appetite, energy, or concentration. These symptoms can lead to difficulty with relationships, work, home or social life, or other activities. If you are having thoughts of suicide, call your team/clinic nurse right now.

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Information for Intervention Group Participants

Why does this happen? Depression can result from the stress of cancer treatment, but may also result from certain medications or medical conditions. At least [XX%] of patients in our previous research report similar problems [before/after] starting treatment here.

What can I do about this? Depression is often temporary while you receive treatment, although it can occur at any time. There are things you can do at home to help deal with these changes, and there may be things that your clinical team will recommend for you. The following websites provide useful information regarding depression:

- Dana-Farber Cancer Institute (Depression)
- The National Cancer Institute (Depression)
- The American Cancer Society (Depression)
- LiveStrong Lance Armstrong Foundation (Emotional Effects of Cancer)
- The American Society of Clinical Oncology (Depression & Anxiety)
- The American Society of Clinical Oncology (Anxiety)

What do I tell my clinical team? Be sure to talk with your clinical team during your next visit. You should tell your clinicians that you have concerns about depression and ask if there's something they can suggest to help. It's important that they know you're bothered about the effects of the treatment. We suggest saying something like this: "I've noticed that _____(fill in the blank to describe your mood, such as feeling down, depressed, or hopeless). For example _____ (describe how your mood has affected you or interfered with your daily activities). It has gotten _____ (better or worse) since I saw you last. What do you recommend to deal with this?"

Pain Intensity

Some of our patients have had concerns pain as a result of their treatment.

Based on your answers in the survey, you seem to have experienced pain. If your pain intensity score is 5 or higher, call your team/clinic nurse right now.

Why does this happen? Pain occurs for many reasons in people with cancer. At least [XX%] of patients in our previous research report similar problems [before/after] starting treatment here.

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Information for Intervention Group Participants

What can I do about this? There are things you can do at home to help deal with these changes, and there may be things that your clinical team will recommend for you. The following websites provide useful information regarding fatigue:

- Seattle Cancer Care Alliance (Pain Management)
- The American Society of Clinical Oncology (Pain)
- The American Cancer Society (Pain)

What do I tell my clinical team? Be sure to talk with your clinical team during your next visit. You should tell your clinicians that you have concerns about pain and ask if there's something they can suggest to help. It's important that they know you're bothered about the effects of the treatment. We suggest saying something like this: "My pain is a ___ out of 10 (fill in the blank to describe your pain level, where 0 is no pain or discomfort at all and 10 is the worst pain you can imagine). I feel it in ____ (fill in blank with where on or in your body you feel your pain). The pain feels (like an ache / sharp, burning); it (comes and goes / is always there); It's gotten _____ (better or worse) since I saw you last. What do you recommend to deal with this?"

Skin Changes

Some of our patients have had concerns about changes in their skin as a result of their treatment.

Based on your answers in the survey, you may have experienced changes to your skin.

Why does this happen? Problems with skin, including changes in color, changes in feeling cold or hot, rashes, itching, burning or painful areas, may be due to the effect of cancer treatment or medications or the cancer itself.

What can I do about this? There are things you can do at home to help deal with these changes, and there may be things that your clinical team will recommend for you. The following websites provide useful information regarding skin changes:

- The Cleveland Clinic (Skin Reactions)
- The Cleveland Clinic (Itching)
- The National Cancer Institute (Skin Changes Related To Radiation Therapy)

What do I tell my clinical team? Be sure to talk with your clinical team during your next visit. You should tell your clinicians that you have concerns about your skin and ask what they suggest

to help. It is important that they know you are bothered by the effects of the treatment. You might say: "I've noticed that my skin _____(fill in the blank to describe what changes you have experienced). It's gotten _____ (better or worse) since I saw you last. What do you recommend to deal with this?"

Physical Function

Some of our patients have had concerns about their physical functioning as a result of their treatment.

Based on your answers in the survey, you may have some concerns about your physical functioning.

Why does this happen? Problems with physical functioning, including difficulty getting around your house, doing daily activities and getting out in your community, may be due to the effect of cancer treatment or medications or the cancer itself. At least [XX%] of our patients in our previous research have reported similar issues with physical functioning [before/after] starting treatment here.

What can I do about this? Your physical functioning may be decreased temporarily while you receive treatment. There are things you can do at home to help deal with these changes, and there may be things that your clinical team will recommend for you. Read more about what you can do:

- The American Society of Clinical Oncology (Physical Activity: Suggestions and Tips)

What do I tell my clinical team? Be sure to talk with your clinical team during your next visit. You should tell your clinicians that you have concerns about your physical functioning and ask what they suggest to help. It is important that they know you are bothered by the effects of the treatment. You might say: "I've noticed that _____(fill in the blank to describe what you have difficulty doing). It's gotten _____ (better or worse) since I saw you last. What do you recommend to deal with this?"

Appendix J

Information for Intervention Group Participants

Emotional Function

Some of our patients have had concerns about emotional functioning as a result of their treatment.

Based on your answers in the survey, you may have some concerns about your emotional state. While some emotional distress is normal, cancer and its treatment can sometimes lead to severe distress. For example, patients can feel nervous or tense, down or depressed, hopeless, demoralized, irritable or angry. Severe distress can lead to difficulty with sleep, relationships, work, home or social life, or other activities. If you are having thoughts of suicide, call your team/clinic nurse right now.

Why does this happen? Emotional distress can result from the stress of cancer treatment, but may also result from certain medications or medical conditions. At least [XX%] of patients in our previous research report similar problems [before/after] starting treatment here.

What can I do about this? Emotional distress is often temporary while you receive treatment, although it can occur at any time. There are things you can do at home to help deal with these changes, and there may be things that your clinical team will recommend for you. The following websites provide useful information regarding emotional changes related to cancer:

- Dana-Farber Cancer Institute (Anxiety Disorder)
- The National Cancer Institute (Normal Adjustment & Adjustment Disorders)
- The American Cancer Society (Coping)
- The American Cancer Society (Coping and Prevention)
- LiveStrong Lance Armstrong Foundation (Emotional Effects of Cancer)
- The American Society of Clinical Oncology (Depression & Anxiety)

What do I tell my clinical team? Be sure to talk with your clinical team during your next visit. You should tell your clinicians that you have concerns about how your disease and treatment seem to be affecting you emotionally. Ask if there's something they can suggest to help. It's important that they know you're bothered about the effects of the treatment. We suggest saying something like this: "I've noticed that _____(fill in the blank to describe your emotional distress). For example _____ (describe how your distress has affected you or interfered with your daily activities). It has gotten _____ (better or worse) since I saw you last. What do you recommend to deal with this?"

Appendix J

Information for Intervention Group Participants

Social and Family

Some of our patients have had concerns about changes in their family or social issues as a result of their treatment.

Based on your answers in the survey, you may have some concerns about your cancer and treatment interfering with your family or social life.

Why does this happen? Treatment for cancer can have a physical and emotional impact on patients' family and social life. Your relationship with family and friends can be disrupted and you and your family may face anxiety and upheaval. At least [XX%] of patients in previous research have reported these issues [before/after] starting treatment here.

What can I do about this? There are things you can do at home to help deal with these problems. There may also be things that your clinical team will recommend for you. The following websites provide useful information regarding social and family issues related to cancer:

- The American Society of Clinical Oncology (Caring for the Whole Patient)
- The American Society of Clinical Oncology (How an Oncology Social Worker Can Help)
- The National Cancer Institute (Life After Treatment)

What do I tell my clinical team? Be sure to talk with your clinical team during your next visit. You should tell your clinicians that you have concerns about how your disease and treatment seem to be interfering with your family and social life. Ask if there's something they can suggest to help. It's important that they know you're having these kinds of difficulties. We suggest saying something like this: "I'm concerned that my cancer and treatment is interfering with my _____(fill in the blank to describe problems with family/social life). For example _____ (describe problems that concern you, such as disrupted roles or relationships) It has gotten _____ (better or worse) since I saw you last. What do you recommend to deal with this?"

Work and Leisure

Some of our patients have had concerns about changes in their work or leisure activities as a result of their treatment.

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Information for Intervention Group Participants

Based on your answers on the survey, you may have some concerns about your cancer and treatment interfering with your work or leisure activities.

Why does this happen? Cancer and its treatment often disrupt patients' work and interfere with their leisure time and activities. For example, patients can find that they have difficulty working because of treatment side effects such as poor concentration and energy, or that their relationship with their workmates has changed. Physical and emotional effects of treatment can also make it hard to do the leisure activities you enjoy. At least [XX%] of patients in our previous research report similar problems [before/after] starting treatment here.

What can I do about this? There are things you can do to help deal with these problems. The following websites provide useful information regarding work and leisure issues related to cancer:

- The American Society of Clinical Oncology (Caring for the Whole Patient)
- The American Society of Clinical Oncology (How an Oncology Social Worker Can Help)

What do I tell my clinical team? Be sure to talk with your clinical team during today's or tomorrow's visit. You should tell your clinicians that you have concerns about how your disease and treatment seem to be interfering with your work and leisure time. Ask if there's something they can suggest to help. It's important that they know you're having these kinds of difficulties. We suggest saying something like this: "I'm concerned that my cancer and treatment is interfering with my _____(fill in the blank to describe problems with work and leisure). For example _____ (describe problems that concern you). It's gotten _____ (better or worse) since I saw you last. What do you recommend to deal with this?"

Cognitive and Memory

Some of our patients have had concerns about Concentration, Memory, and Cognitive Function as a result of their treatment.

Based on your answers on the survey, you may have some difficulty concentrating and staying focused on tasks.

Why does this happen? It may be the effect of cancer treatment or medications on the brain. At least [XX%] of our patients in previous research report similar problems [before/after] starting treatment here.

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Information for Intervention Group Participants

What can I do about this? There are things you can do at home to help deal with this symptom and there may be things that your clinical team will recommend for you. The following websites provide useful information regarding concentration and memory:

- Seattle Cancer Care Alliance (Memory and Concentration)
- Dana-Farber Cancer Institute (Cognitive Disorders and Delirium)
- The American Society of Clinical Oncology (Cognitive Problems)
- The American Cancer Society (Confusion)

What do I tell my clinical team? Be sure to talk with your clinical team about this the next time you see them in the clinic. We suggest saying something like this: "I've noticed that I cannot concentrate very long or stay focused on things I'm doing. It started _____(fill in the blank with when you first noticed the symptom). It has gotten _____ (better or worse) since I saw you last. What do you recommend to deal with this?"

Sensory

Some of our patients have had concerns about changes in nervous system function (neuropathy) as a result of their treatment.

Based on your answers in the survey, you may have had trouble with uncomfortable sensations in your legs, feet, hands or arms. The sensations can range from tingling to coldness to numbness. You may have had trouble doing things with your feet (for example, walking or driving). Or you may have experienced other symptoms such as blurred vision.

Why does this happen? This happens sometimes due to the effect of cancer medications or the cancer itself. At least [XX%] of patients in our previous research report similar problems [before/after] starting treatment here.

What can I do about this? There are things you can do at home to help deal with this symptom and there may be things that your clinical team will recommend for you. The following websites provide useful information regarding peripheral neuropathy:

- The Oncology Nursing Society (Peripheral Neuropathy)
- Lance Armstrong Foundation (Neuropathy)
- National Coalition for Cancer Survivorship (Neuropathy)

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Information for Intervention Group Participants

What do I tell my clinical team? Be sure to talk with your clinical team about this the next time you see them in the clinic. Ask if there's something they can suggest to help. It's important that they know you're having these kinds of problems. We suggest saying something like this: "I've had a [little; a lot] of tingling in my feet. It started _____(fill in the blank with when you first felt like this). It has gotten _____ (better or worse) since I saw you last. What do you recommend to deal with this?"

Motor

Some of our patients have had concerns about changes in nervous system function (neuropathy) as a result of their treatment.

Based on your answers in the survey, you may have had trouble with uncomfortable sensations in your legs, feet, hands or arms. The sensations can range from tingling to coldness to numbness. You may have had trouble doing things with your feet (for example, walking or driving). Or you may have experienced other symptoms such as blurred vision.

Why does this happen? This happens sometimes due to the effect of cancer medications or the cancer itself. At least [XX%] of patients in our previous research report similar problems [before/after] starting treatment here.

What can I do about this? There are things you can do at home to help deal with this symptom and there may be things that your clinical team will recommend for you. The following websites provide useful information regarding peripheral neuropathy:

- The Oncology Nursing Society (Peripheral Neuropathy)
- Lance Armstrong Foundation (Neuropathy)
- National Coalition for Cancer Survivorship (Neuropathy)

What do I tell my clinical team? Be sure to talk with your clinical team about this the next time you see them in the clinic. Ask if there's something they can suggest to help. It's important that they know you're having these kinds of problems. We suggest saying something like this: "I've had a [little; a lot] of tingling in my feet. It started _____(fill in the blank with when you first felt like this). It has gotten _____ (better or worse) since I saw you last. What do you recommend to deal with this?"

Appendix J

Information for Intervention Group Participants

Autonomic

Some of our patients have had concerns about changes in nervous system function (neuropathy) as a result of their treatment.

Based on your answers in the survey, you may have had trouble with uncomfortable sensations in your legs, feet, hands or arms. The sensations can range from tingling to coldness to numbness. You may have had trouble doing things with your feet (for example, walking or driving). Or you may have experienced other symptoms such as blurred vision.

Why does this happen? This happens sometimes due to the effect of cancer medications or the cancer itself. At least [XX%] of patients in our previous research report similar problems [before/after] starting treatment here.

What can I do about this? There are things you can do at home to help deal with this symptom and there may be things that your clinical team will recommend for you. The following websites provide useful information regarding peripheral neuropathy:

- The Oncology Nursing Society (Peripheral Neuropathy)
- Lance Armstrong Foundation (Neuropathy)
- National Coalition for Cancer Survivorship (Neuropathy)

What do I tell my clinical team? Be sure to talk with your clinical team about this the next time you see them in the clinic. Ask if there's something they can suggest to help. It's important that they know you're having these kinds of problems. We suggest saying something like this: "I've had a [little; a lot] of tingling in my feet. It started _____(fill in the blank with when you first felt like this). It has gotten _____ (better or worse) since I saw you last. What do you recommend to deal with this?"

Appendix K
Security Features of the DHAIR System

Co-investigator Lober and collaborators have developed an interactive software infrastructure for Distributed Health Assessment and Intervention Research (DHAIR). This has been used as a framework for developing web-based applications for both patients and providers. The software permits secure, database driven delivery of structured survey instruments over the public Internet to any computer equipped with a standard web browser. The key features of this software platform, as it pertains to system security, are outlined below.

Security Features

Authentication

- Robust framework-based or federated authentication techniques such as Lightweight

Directory Access Protocol (LDAP), PubCookie or Shibboleth.

Authorization

- Permissions are based on the assignment of users to groups such as patient, administrator, or researcher, and role-based access and auditing are implemented consistent with the federal regulations required by the Health Care Portability and Accountability Act (HIPAA).

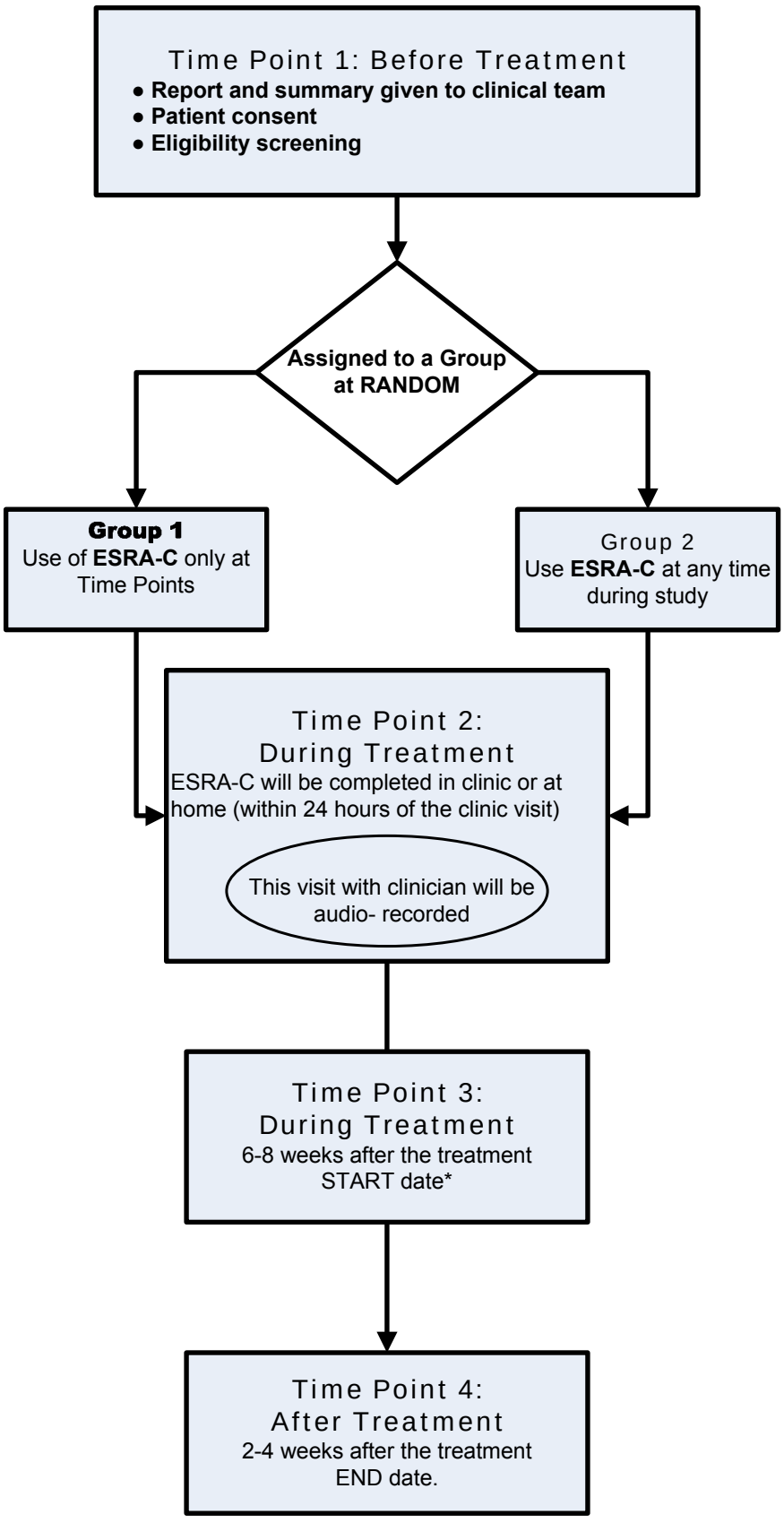
Encryption

- Data both to and from the users' PCs are encrypted using the same commercial-grade, 128-bit Secure Sockets Layer/Transport Layer Security ("SSL/TLS") standard used for e-commerce and banking transactions.

Location of data in hardware

- Our research group maintains a cluster of secure servers in the University of Washington's data center space at Sabey Intergate West; the servers house this and our other project applications containing identified patient data used for research, clinical practice and public health.

Electronic Self-Report Assessment for Patients with Cancer: Process Chart



*Depending on treatment

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Appendix M

Patient Recruitment Script

"Hello, Patient Name. My name is CRC's Name; I am a Clinical Research Coordinator at Name of organization (Dana-Farber Cancer Institute or Seattle Cancer Care Alliance). Thank you for completing the symptom and quality life report. Your report (has been) or (will be delivered) to your care team. I would like to tell you about a research study we are doing about this program and find out if you may be interested in participating. Would it be alright to tell you about the study?"

"Your clinical team is participating in a research study to find out if using this program (ESRA-C) over the course of treatment will help our patients talk with their team about any problems they experience and take better care of their symptoms and quality of life concerns at home."

"Participation is voluntary. During the study you will complete up to three additional reports similar to the one you completed. If you agree to participate, you will be randomized (like a coin flip) and placed in one of two groups. The study will compare outcomes for the two groups."

"In Group 1 each person uses this computer program up to three more times during and after treatment."

"In Group 2 each person uses this program up to three more times during and after treatment. In addition, each person can use the program any time to make reports, view graphs of reports, access information about how to deal with symptoms and quality of life concerns, and learn how to talk to their clinical care team about these issues. The program may help improve how a patient feels during and after treatment."

"Participation in the study also involves audio-recording of one future visit with your clinical care team. The study will be conducted in both Dana-Farber Cancer Institute, and Seattle Cancer Care Alliance. Approximately 702 patients will be recruited to participate in this study."

"Do you have any questions so far? Are you interested in participating in this study?" If "YES", the CRC will review the consent form and answer questions about the study before the patient signs consent.