FINAL PROGRESS REPORT

TITLE PAGE

Project Title: Expansion, Implementation & Evaluation of Electronic Health Record-Integrated Patient-Reported Symptom Screening in a Comprehensive Cancer Center

Principal Investigator(s):

SOFIA F. GARCIA, PHD FRANK J. PENEDO, PHD

Co-Investigators (listed in alphabetical order)

Michael Bass, MS
David Cella, PhD
Sheetal Kircher, MD
Justin Dean Smith, PhD
Kimberly A. Webster, MA

Statisticians:

Katy Bedjeti, MS Michael Kallen, PhD* *Deceased

Organization: Northwestern University Feinberg School of Medicine, Department of Medical Social

Sciences, Chicago, IL, USA

Inclusive Dates of the Project: 08/01/2018 - 05/31/2023

Federal Project Officer: Christine Dymek, PhD

Acknowledgment of Agency Support: The Agency for Healthcare Research and Quality

Grant Number: 1R18HS026170-01

FAIN: R18HS026170

STRUCTURED ABSTRACT

Purpose: Cancer symptom monitoring programs address concerns that are undertreated, but they remain largely limited to trials versus healthcare applications. We previously piloted a patient-reported symptom and need assessment ('cPRO') within the electronic health record (EHR).

Scope: Evaluate cPRO across adult ambulatory cancer clinics in a large healthcare system via a type 2 hybrid effectiveness-implementation study.

Methods: Aim 1 was a mixed-method evaluation of implementation. Patients completed cPRO assessments (pain, fatigue, physical function, depression, anxiety & supportive care needs) before visits. Results were available in the EHR; severe symptoms/endorsed needs triggered clinician notifications. We used the Longitudinal Implementation Strategy Tracking System (LISTS). Aim 2 evaluated cPRO's impact on patient and system outcomes over 12 months via (a) a quality improvement study (n= 17,359) and (b) a human subjects substudy (n=1,108). Aim 2a evaluated EHR-documented healthcare usage and patient satisfaction. Aim 2b participants completed patient-reported healthcare utilization and quality, symptoms and health-related quality of life measures at baseline, 6 and 12 months. Aim 3 identified implementation facilitators and barriers via stakeholder feedback.

Results: cPRO was rolled out sequentially across three primary Northwestern Medicine regions. We disseminated pandemic-related outreach strategies; implementation changes due to healthcare system needs; and how cPRO guided implementation in a second healthcare system. The Aim 2a&b samples were predominantly White and female. Self-reported data for those pre- and post-cPRO implementation show no significant differences. Mixed methods data indicated that patients found cPRO easy and valuable but emphasized the importance of education and clinician engagement to motivate sustained completion.

Keywords: oncology, symptom monitoring, information technology, implementation, mental health

PURPOSE

We previously developed and piloted an electronic patient-reported symptom and need assessment ('cPRO' for cancer patient-reported outcomes) within the electronic health record (EHR).(1, 2) The current study sought to expand our cPRO assessment implementation to medical oncology patients at all regions of a healthcare system (Northwestern Medicine; serving >8,000 new oncology patients yearly) and to conduct a formal evaluation of the program's implementation and effectiveness outcomes using a modified stepped wedge trial with a type 2 hybrid effectiveness-implementation design. Our approach to the expansion, implementation, and evaluation of cPRO was informed by the Framework for Spread(3) and the Reach, Effectiveness, Adoption, Implementation, Maintenance (RE-AIM) framework.(4) Specific aims included:

- ➤ Aim 1: Evaluation of Expansion and Implementation: To use the Framework for Spread to guide the implementation process to expand cPRO to reach patients at all Northwestern Medicine-affiliated ambulatory cancer clinics and allow for both at-home and in-clinic symptom assessment prior to medical visits. A mixed methods evaluation of implementation success will adhere to RE-AIM and its extension to enhance health equity and sustainment.(5) The Consolidated Framework for Implementation Research (CFIR)(6) will be used to assess and characterize implementation determinants at multiple levels of the system.
- ➤ Aim 2: Evaluation of Effectiveness: To evaluate the effectiveness of system-wide cPRO implementation on outcomes at the system and patient levels over 12 months via a quality improvement study (planned minimum n=4,000 cases) and a human subjects sub-study (planned n=1,000 patients), respectively.
- ➤ Aim 3: Identification of Implementation Facilitators and Barriers: To identify implementation facilitators and barriers to system-wide expansion of cPRO via qualitative research, gathering feedback from clinicians, administrators, and patients participating in the symptom monitoring program expansion.

SCOPE

Advances in screening and early detection, and more successful treatment options, have led to an unprecedented number of people surviving cancer. There are currently almost 17 million cancer survivors in the U.S., and that number is expected to exceed 22 million by 2030.(7) Cancer is now characterized as a chronic, manageable condition requiring specific and targeted comprehensive efforts to address long-term challenges and late effects of treatment. Despite advances in early detection and treatment success that extends longevity, survival benefit is often offset by debilitating cancer- and treatment-related symptoms and psychosocial sequelae that compromise health-related quality of life (HRQoL).(8)

A growing body of literature has documented the needs of oncology patients, providing evidence that psychological and physical concerns are both prevalent and persistent.(9) About 32% of cancer patients have been shown to meet criteria for mental health conditions.(8, 10) In a meta-analysis of 70 studies with over 10,000 oncology patients in ambulatory settings, 16.3%, 10.3%, and 19.4% met DSM criteria for major depression, adjustment, and anxiety disorders, respectively; 38.2% met criteria for any psychological diagnosis.(11, 12) Physical symptoms such as fatigue, pain, and poor physical function are among the most common and debilitating reported in oncology settings.(13-15) Upon treatment completion, physical needs (e.g., pain and nutrition) are among the top unmet needs.(16) Other common concerns include practical needs (e.g., transportation, childcare).(17)

In recognition of these challenges, key leadership organizations have prioritized the need to address and embed symptom screening with a referral process in ambulatory cancer care.(18-20) This includes standards to better identify, monitor, and manage patients' health needs, including referral to supportive oncology care.(18, 21-24) However, work evaluating clinical management and intervention programs that address the unique needs of oncology patients remain limited and poorly integrated within most institutions.(25-28)

RELATED RESEARCH

Patient-reported symptom screening has been found to be feasible and efficacious in ambulatory oncology. In a randomized trial of 286 cancer patients, ongoing monitoring of HRQoL prior to clinical encounters, relative to no monitoring, was associated with better HRQoL over time and improved patient-physician communication.(29) Our team has documented high patient compliance (92%) in a technology-based monitoring system developed for lung cancer patients starting chemotherapy that assessed relevant PROs such as fatigue, dyspnea, cough, weight loss, anorexia, pain, insomnia, change in mental status, and psychological distress. (30) The majority (69%) of patients felt the questionnaire helped them focus on issues to be discussed with their physicians and, similarly, physicians indicated the reports from the monitoring system helped track and compare symptom burden over time. Recently, a web-based program that allowed patients to report symptoms to their clinicians was associated with improved HRQoL and longer survival within a randomized single-center trial.(31-33) Patients in the self-reporting arm (vs usual care) reported greater HRQoL at 6-months postbaseline and had a 5-year absolute survival benefit of 5 months. While promising, most of the work evaluating the efficacy of systematically capturing and addressing PROs via the EHR remains limited to controlled trials, with limited generalizability to health-system-wide application. (34) Generally, most previous studies evaluating the efficacy of symptom monitoring: (a) are limited in their scalability, generalizability, and implementation; (b) implemented measures limited in regard to sensitivity and specificity; (c) did not evaluate the impact of symptom monitoring on clinic workflows or system-level outcomes; or (d) did not evaluate or address implementation of the program as a standard of care.

PRELIMINARY WORK

To answer the need for comprehensive symptom assessment that leverages health information technology to reach patients in feasible ways, we developed and piloted an electronic PRO assessment specific to cancer ('cPRO' for cancer patient-reported outcomes) within Northwestern Medicine's primary electronic health record (EHR), Epic Systems medical record software (Epic, Verona, WI).

cPRO Development: The cPRO system was custom-designed to electronically administer validated PROs from the Patient-reported Outcomes Measurement Information System (PROMIS®)(35, 36) that assess key health outcomes in cancer patients (depression, anxiety, fatigue, pain interference, and physical function) across the trajectory of care and a checklist to identify practical and supportive care needs (e.g., financial and transportation concerns; nutritional support). PROMIS® measures can be administered as computer adaptive tests (CATs) or short forms, allowing for assessment efficiency and precision.(37) Assessment invitations are automated and launched 72 hours prior to scheduled medical oncology appointments (limited to once a month) and completed by patients via the EHR patient portal (Epic MyChart) prior to their visits.(1) Results are scored and immediately available in the EHR to inform clinical communications and decision making. Severe symptoms trigger notifications to clinicians (via the Epic inbox) who can then communicate with patients and make necessary referrals and care decisions in real time. Alerts are addressed by clinicians via MyChart, telephone or in-person contacts.

cPRO pilot studies: Two clinical quality improvement initiatives were conducted to assess the feasibility of implementing the cPRO system as a standard of oncology care at Northwestern Medicine. In the first, 636 women receiving gynecologic oncology outpatient care received invitations and completed at least one symptom and need assessment through their Epic MyChart portal.(2) In the second, 6825 adult oncology outpatients received invitations to complete an earlier version of the cPRO assessment through their Epic MyChart portal; 3526 (51%) completed at least one assessment.(1) Together, these pilot studies demonstrated a successful integration of PRO and need assessment administration, scoring and reporting within an EHR system, implemented within a specialized oncology clinic and then more broadly across medical oncology clinics at one geographic site. EHR integration enabled standardized routine assessment and real-time reporting of patient-reported symptoms and needs within ambulatory cancer care, towards the goal of improving care quality and efficiency.

METHODS

Study Design: This study used a cluster randomized stepped wedge trial with a type two hybrid effectiveness-implementation design to test the expansion of cPRO across oncology care clinic in a large healthcare system.

The first aim (**Aim 1**) focused on the expansion of the symptom monitoring program (cPRO) using health information technology (configuration and enhancement of technical workflows for the symptom assessment to allow for at-home and in-clinic assessment). Work focused on the execution of the plan for implementation spread across Northwestern Medicine's medical oncology clinics using the Framework for Spread, which provided key strategic considerations and goals for implementing a system-wide change that was evaluated using EHR and stakeholder survey data aligning with RE-AIM.

The second aim of the study centered on two evaluations of the effects of implementation: A quality improvement protocol (**Aim 2a**) to compare the impact of cPRO use on EHR-documented healthcare usage and patient satisfaction at the system level, using a stepped wedge design in which clusters of study sites were sequentially assigned to cross from serving as a control setting (pre-implementation) to implementing cPRO; and a human subjects sub-study (**Aim 2b**) with patients who completed the symptom screener and a battery of measures at baseline, 6, and 12 months to evaluate the impact of cPRO on patient-reported healthcare utilization, quality, symptoms, and HRQoL.

In **Aim 3**, mixed methods were used to identify facilitators and barriers to system-wide expansion and adoption of cPRO. We used qualitative methods (semi-structured focus groups and individual interviews) to identify themes pertaining to patient acceptability and quantitative methods (a structured survey of up to 86 items) to conduct a more systematic exploration of identified themes on a larger patient sample. Key stakeholders (clinicians, administrators) were invited to complete surveys designed to evaluate key measures of successful implementation (e.g., acceptability, appropriateness, and perceived sustainability of the intervention). We administered Research Electronic Data Capture (REDCap)(38, 39) platform-based surveys to clinicians and administrators who were involved in cPRO implementation at three timepoints (pre-implementation, during implementation, and post-Implementation). Surveys were administered across regions in a stepped-wedge design.

Data Sources/Collections: *Study Setting*: Research occurred at outpatient oncology settings across multiple hospitals that are part of a single healthcare system, Northwestern Medicine. Existing regional clusters (Central, North, and West) within Northwestern Medicine served as the clusters for the stepped wedge trial. The Central region includes a single, large, urban-based medical center; the North and West regions are each comprised of smaller hospitals (two and four, respectively) in suburban communities. All regions include specialty clinics for the diagnosis and management of cancer.

Study Population: For the implementation component of this study (Aim 1: cPRO administration within clinical care), the study population included any adult outpatient receiving, or clinician (physician, nurse, social worker, dietician) administering, cancer care at a participating medical oncology clinic, as well as clinic administrative staff. For the evaluation component of this study, inclusion criteria varied by aim and participant population. For Aims 2a and 2b and Aim 3, eligible patients had to have a confirmed cancer diagnosis and received oncology services within the past 12 months. Additional criteria for Aim 2b patient eligibility included recent completion of a cPRO assessment and authorization for access to the patients' disease and treatment information in the EHR. For Aim 3, participants had to have received at least four invitations to complete cPRO. Additional criterion regarding actual number of completed screeners defined focus group assignment. Patients who had one or more cPRO clinical alerts were assigned to participate in an individual interview. For Aim 3, healthcare clinicians and administrators had to work at a site participating in the cPRO implementation.

Sample Selection: For Aim 2a, Enterprise Data Warehouse (EDW) queries of the EHR system were performed on all cases with a completed symptom assessment within the year prior to the go-live date for implementation across each region. The rationale is to have sufficient data for comparison with

our implementation period for both the number of patients as well as across a calendar year to examine the presence of seasonal trends.

For **Aim 2b** and **Aim 3**, patients were recruited via e-mail invitation from among those receiving invitations to complete the cPRO assessment. For **Aim 3**, clinicians and administrators were recruited from the pool participating in the cPRO implementation, at the point of their in-person cPRO training and/or via e-mail invitation. Recruitment for both patients and healthcare system stakeholders happened across regions to ensure representation from each geographic site.

Interventions: In addition to the cPRO intervention, we aimed to measure the impact of a multicomponent implementation strategy. Implementation strategies are the methods and approaches used to support adoption and delivery of healthcare interventions in practice. (40) Our approach comprised a number of discrete strategies that target multiple levels of the delivery system, including oncologists, implementation leaders/operational managers, workflows and internal monitoring of use. These include developing stakeholder interrelationships, training and educating stakeholders, engaging consumers, using evaluative and iterative strategies, and changing infrastructure. While the majority of these discrete strategies were prospectively proposed, we carefully and comprehensively tracked strategy use over time using the Longitudinal Implementation Strategy Tracking System (LISTS).(41) LISTS involves a time-line follow back procedure, in which members of the research and implementation teams meet at least quarterly throughout the project period to report on all dimensions of the Proctor, Powell and McMillen(42) reporting standards for implementation strategies being used in the trial. This repeated evaluation of strategies allows for specifying when strategies are modified from their original planned usage (e.g., discontinued, changed) using dimensions from the Framework for Reporting Adaptations and Modifications to Evidence-based Implementation Strategies (FRAME-IS)(43) and when new strategies are added, either as planned or in response to emergent barriers or effects of other strategies in use. Reporting also specifies with which cluster of the study the strategy is used/modified.

Measures: Study Measures Related to Effectiveness and Implementation Outcomes: The cPRO assessment consists of PROMIS® measures(35, 36, 44) of 1) Depression (PROMIS Item Bank v1.0-Depression); 2) Anxiety (PROMIS Item Bank v1.0-Anxiety); 3) Fatigue (PROMIS Item Bank-Fatigue v1.0); 4) Pain Interference (PROMIS Item Bank v1.1-Pain Interference); and 5) Physical Function (PROMIS Item Bank v1.1-Physical Function), along with supportive care checklist items (covering psychosocial and nutritional needs). Cancer center patients are asked to complete a screener before each oncology visit (but no more than once a month). Data related to cPRO completion, scores, and alerts were utilized in all study aims, primarily to evaluate the effects of the symptom monitoring system on severity of patient-reported symptoms related to cancer and cancer treatment.

For Aim 2a, we obtained data collected independently from a hospital-based Press Ganey Patient Experience survey(45) and a Medallia customer experience questionnaire(46) to assess patient satisfaction with their care experience. Patients are provided the opportunity to complete the survey after a care experience (appointment or hospitalization). Patient-level healthcare utilization data (e.g., clinical notes, emergency room visits, and hospitalizations) were extracted from the EHR to help evaluate effectiveness of the intervention in terms of resource utilization.

For **Aim 2b**, participants completed questionnaires to assess intervention outcomes related to HRQoL, healthcare quality, symptom experience, financial toxicity, healthcare utilization (including healthcare utilization outside of the NM health system), shared decision-making, and health literacy (see Table 1 for Patient-reported Effectiveness Outcomes and Measures). Patients were asked to complete the battery assessment at baseline, 6, and 12 months via an electronic survey administered using the REDCap platform. REDCap is a secure and flexible web application that is available online and offline, supports longitudinal data collection, and allows for data exports to common data analysis packages.

Table 1: Patient-reported Effectiveness Outcomes and Measures (Aim 2b)

Outcome	Measure	Items	Measure Details	Assessment
Health-related quality of life: Effects of the symptom monitoring system on patient- reported quality of life related to cancer	Functional Assessment of Cancer Therapy – General – 7 Item Version (FACT-G7)(47)	7 items	The FACT-G-7 is a brief validated measure of patient-reported priority symptoms in cancer; The FACT-G7 has demonstrated internal consistency reliability, convergence, and known-groups validity and is highly correlated with the parent measure (FACT-G) total score(47)	Baseline, 6 and 12- months
Health care quality: Impact of the symptom monitoring system on patient experiences with their cancer care team	Select items from the Consumer Assessment of Healthcare Providers and Systems CAHPS® Cancer Care Survey(48, 49)	12 items (if endorsed up to 3 more)	CAHPS® is a survey system designed to capture patient experiences with their cancer care team; a rigorously developed, well-tested, reliable and valid survey of patient experiences with their cancer care.(49)	Baseline, 6 and 12- months
Health care utilization: Impact of the symptom monitoring system on health care services used by patients	Custom measure designed to assess healthcare utilization outside of the Northwestern system	3 items		Baseline, 6 and 12- months
Symptom burden: Effects of the symptom monitoring system on patient-reported adverse events related to cancer	Select items from the Patient- Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE™)(50)	6 items (if endorsed, up to 4 more)	PRO-CTCAE™ is a compendium of PRO items uniquely targeted to symptomatic treatment-related toxicity assessment in oncology care; Published data substantiates content and construct validity, reliability, and responsiveness.(51, 52)	Baseline, 6 and 12- months
Financial toxicity of cancer care	Summary item from FACIT Measure of Financial Toxicity (FACIT-COST)(53)	1 item	The last (overall summary) item of an 11-item questionnaire that measures personal financial burden of care.	Baseline, 6 and 12- months
Reading ability (component of health literacy)	Single Item Literacy Screener (SILS)(54)	1 item	A simple assessment of a person's ability to read and understand printed health material; The SILS 'performs moderately well at ruling out limited reading ability in adults.'(54)	Baseline
Shared decision-making	CollaboRATE survey(55)	3 items	A brief patient survey designed to assess the perceived extent of shared decision-making in a given clinical encounter; The measure has demonstrated discriminative and concurrent validity, interrater reliability and sensitivity to change.(55)	Baseline, 6 and 12- months

For Aim 3, carefully designed focus group and individual interview guides and self-administered surveys, informed by the Consolidated Framework for Implementation Research (CFIR) Interview Guide(6), were developed and used to facilitate data collection from clinicians, administrators, and patients. To assess the related barriers and facilitators to using cPRO, patients were invited to provide targeted feedback about their experience with cPRO (ease of navigation and completion, comprehension of purpose and goals, general experience with care team and communication related to the symptom and needs assessment) at one point in time. Most were invited to participate in a focus group; for privacy, consented patients who had one or more 'alerts' (e.g., for anxiety) were individually interviewed (which included prompts that could generate details about clinical services they received after alerts). A second set of participants completed an online survey based on themes that emerged from the qualitative feedback. Survey items addressed patient understanding of cPRO purpose and functionality, care team cPRO use and related clinical communications, exposure to cPRO educational materials, cPRO impact on health management self-efficacy and care, usability, and compliance.

For **Aim 3** surveys with clinicians and administrators, we assessed targeted implementation barriers and facilitators and implementation process domains from the Framework for Spread, including

salient constructs of implementation leadership support, implementation climate, and sustainability (see Table 2 for clinician- and administrator-reported Implementation Outcomes and Measures). Surveys were administered electronically at three time-points: baseline (pre-implementation) and then 3- and 7- months post-implementation.

Table 2: Clinician- and administrator-reported Implementation Outcomes and Measures (Aim 3)

Outcome Variable(s)	Measure	Items	Measure Details	Assessment
Organizational culture (Do	Organizational	Five items from	The OCRBS has good to excellent	Baseline (at the
clinicians, researchers, and staff	Change Recipients'	the	reported internal consistency reliability	point of regional
believe that implementing cPRO	Beliefs Scale	"Appropriateness"	(e.g., α = .8995 reported across several	intervention), and
is appropriate and beneficial for	(OCRBS)(56)	subscale	studies)(56) and includes item	3- and 7-month
the patients, the practice, and			indicators such as "the change we	post
themselves?)			implemented was correct for our organization."	implementation
Leadership support (Does staff	Implementation	Three items from	The ILS has excellent reported internal	Baseline (at the
feel supported by NM leadership	Leadership Scale	the "Supportive	consistency reliability (e.g., α = .95;	point of regional
to implement cPRO in their	(ILS) to assess the	Leadership"	Aarons, 2014) and includes item	intervention), and
practice? and	degree to which a	subscale	indicators such as "supports employee	3- and 7-month
Is the leadership proactive,	leader exhibits		efforts to use evidence-based practice."	post
supportive, knowledgeable, and	specific supportive			implementation
perseverant?	behaviors(57)			
Acceptability, appropriateness,	NoMAD	23 items	The NoMAD is anticipated to have	Baseline (at the
and feasibility	measure(58)		acceptable internal consistency	point of regional
(Do physicians, staff, and leaders			reliability (i.e., $\alpha \ge .70$)(59) and includes	intervention), and
find cPRO acceptable,			item indicators such as "I can see the	3- and 7-month
appropriate, and feasible for their			potential value of cPRO for my work."	post
practice?)				implementation
Training experience related to	CBH Post-Training	6 items	The Training Survey is anticipated to	Post-training and 3-
cPRO (Do physicians, staff, and	Survey(60)		have acceptable internal consistency	month post
leaders find cPRO training			reliability (i.e., $\alpha \ge .70$) and includes	implementation
experience effective)			item indicators such as ("the training	
			prepared me for my role in cPRO").	
Sustainability	Clinical	21 items	The CSAT includes items related to	7-months post-
	Sustainability		seven domains perceived by	implementation
	Assessment Tool		stakeholders to determine sustained	
	(CSAT)-Short		implementation. It has shown to be	
	Form(61, 62)		reliable, usable, and valid in a pilot	
			study (n=126).	

Limitations: This study evaluated implementation and impact of an electronic symptom monitoring program in one healthcare system, which may limit the generalizability of our findings to comparable high volume, well-resourced academic health systems. Similarly, study participants' demographics may limit generalizability to more diverse populations. The stepped wedge study design, while practical and highly acceptable to the healthcare system, limits the ability to mask conditions, as implementers and patients are aware of the change to screening, and a delayed intervention effect in any cluster could reduce power. The study faced unexpected barriers due to the COVID-19 pandemic. In addition to implementation and other timeline delays during that time, the pandemic resulted in the inability to launch in-clinic cPRO assessments (due to concerns about germs on tablets & kiosks) as well as more intensive implementation strategies (due to demands on overtaxed healthcare providers). As a result, we were not able to evaluate all planned implementation strategies. The study also has limitations (as well as advantages) characteristic of pragmatic trials that examine the relationships between interventions and outcomes in real-world healthcare system practice. Specifically, (1) some of the EHR data is less precise (e.g., including some variability in documentation across regions) than the patient-reported data collected per protocol and (2) we made iterative implementation changes (e.g.,

switching from PROMIS CATs to briefer PROMIS short forms) in response to healthcare system needs.

RESULTS

Principal Findings & Outcomes: Aim 1: Implementation strategies used: A total of 34 discrete implementation strategies were documented as having been used between January 2015 and May 2022. While the formal trial described here began September 1, 2018, the team decided to capture strategies used during preparation for the trial, which included pilot studies and strategies that made submission of the grant application possible (e.g., partnership formation with the healthcare system). These strategies were coded into the Expert Recommendations for Implementing Change (ERIC) categories(63) and all nine were represented. The category with the most strategies (n=13) were from "develop stakeholder interrelationships," followed by "use evaluative and iterative strategies" (n=8) and "train and educate stakeholders" (n=5). Only one strategy was used from each of "provide interactive assistance," "support clinicians," "utilize financial strategies," and "engage consumers." The remainder were from "change infrastructure" (n=2) and "adapt and tailor to context" (n=2). Most strategies (n=28) were prospective (i.e., planned to be used a priori as part of study protocol) and were used across all three regions of the healthcare system (n=29). Research staff (n=28) and/or quality improvement leaders (n=27) served as primary actors of the strategy (totals are not exclusive to one actor type).

Barriers and implementation outcomes targeted by strategies: Implemented strategies targeted barriers across all five CFIR domains. Most strategies were used to overcome barriers in the inner setting (n=26, 37%), followed by intervention characteristics (n=17, 25%), individuals (n=14, 20%), process (n=9, 12%), and outer setting (n=4, 6%). Strategies could target multiple determinants. Strategies were used primarily to increase adoption (n=23, 68%), followed by reach (n=5, 15%), acceptability (n=4, 12%), and feasibility (n=2, 6%) related to cPRO implementation. Regarding secondary outcomes, most strategies targeted feasibility (n=19, 58%), followed by acceptability (n=18, 55%) and fidelity (n=9, 27%). Costs (n=1, 6%) was the least targeted secondary outcome. A single primary outcome was selected, and multiple secondary outcomes could be selected. Results from this initiative were published in 2022 (Smith JD, Merle JL, Webster KA, Cahue S, Penedo FJ, Garcia SF. Tracking dynamic changes in implementation strategies over time within a hybrid type 2 trial of an electronic patient-reported oncology symptom and needs monitoring program. Front Health Serv. 2022 Nov 1;2:983217. Doi: 10.3389/frhs.2022.983217. PMID: 36925901; PMCID: PMC10012686).

We also disseminated alternative outreach strategies employed during the COVID-19 pandemic; these relied on intensive telephone outreach to promote remote cPRO completion and have informed current use of community health worker outreach to patients to facilitate cPRO completion. Results from this initiative were published in 2021.(70) Further, we shared our cPRO build, protocol, and strategies to guide implementation of a similar system in a second healthcare system (University of Miami, where MPI Dr. Penedo moved). We disseminated favorable findings on the implementation and feasibility of that c-PRO-informed system, "My Wellness Check," which assesses (in English & Spanish) physical and psychologic symptoms and needs of ambulatory oncology patients before appointments to triage them to supportive services when elevated symptoms, barriers to care, and nutritional needs were identified. Results from this initiative were published in 2022 (Penedo, F. J., Medina, H. N., Moreno, P. I., Sookdeo, V., Natori, A., Boland, C., Schlumbrecht, M. P., Calfa, C., MacIntyre, J., Crane, T. E., & Garcia, S. F. (2022). Implementation and feasibility of an electronic health record-integrated patient-reported outcomes symptom and needs monitoring pilot in ambulatory oncology. JCO Oncology Practice, 18, e1100-e1113).

Aim 2a: EHR data for aim 2a were obtained exclusively from the Northwestern Medicine Electronic Data Warehouse (EDW). Creation of the data set involved careful consideration to capture meaningful information both for clinicians and study analytical purposes while also being feasible within the NM EDW/EPIC ecosystem. A multidisciplinary team including clinicians, programmers, and study staff met regularly to define variables and revise as necessary. Data obtained from the EDW included demographics, cPRO (PROMIS, needs questionnaire), diagnosis and treatment variables, patient

satisfaction, and health system encounter data. The data team reviewed all health system encounter data and identified encounters that fell into the categories ER, inpatient, and outpatient. These encounters were summarized as number of events occurring in the 6 months preceding a cPRO completion. Once data were received from the EDW they were thoroughly reviewed and cleaned by study data analysts. This careful review was key in identifying irregularities in the data described below.

Study data were subject to shifts in health system data collection protocols that were outside the scope of the project. Addressing these issues and harmonizing data across different modalities took considerable time. The data team has assembled extensive documentation of the system changes over the study period and the approaches chosen to arrive at a common analysis data set. One such change was the patient satisfaction measure used across the health system which changed from Press Ganey to Medallia in November 2019. The multi-item patient satisfaction surveys contain one overlapping item, albeit scored on different scales. The Press Ganey item reads "Likelihood of your recommending...." with response options from 1 to 5. The Medalia item reads "How likely are you to recommend..." with response options 0 to 10. The study team opted to rescale the Medallia item from 0-10 to 1-5, an approach used by others at NM. In this approach, patients endorsing 0-2 on Medalia are recoded as 1, 3-4 as 2, 5-6 as 3, 8-7 as 4, and 9-10 as 5.

The largest issue identified involved scoring and administration changes to PROMIS measures in cPRO. All measures were subject to a change in administration from CAT to two item form in September 2021. T-scores generated from CAT and 2 item forms are comparable, though scores from the 2 item forms inherently exhibit less variation and have higher standard error due to fewer items being administered. This is a consideration in analysis, but not unexpected. Extensive review of data by the study team prior to analysis uncovered a few additional concerns and considerations when analyzing PROMIS cPRO data. These issues have been documented and the team has suggested approaches to remedy most identified issues. These additional issues include errors in the EPIC generated Physical Function and Anxiety two item form scores, item switch from PFB7 to PFB13 in the Physical Function two item form, and error in the response options for PFB13 in the two-item form. In addition to documenting these issues, the study team has drafted updated standard operating procedures to ensure that future updates to PROs in EPIC have multidisciplinary "sign-off" before implementation. The team has also communicated its findings widely among researchers using cPRO so that our findings may be utilized by other teams.

Final analysis data include information on 17,359 patients across the three health system regions between September 2019 and March 2022. The sample is predominantly White (83%), non-Hispanic/Latino (91%), and female (67%), and median sample age is 63 (Q1=53, Q3=71). As detailed above, extensive cleaning and quality work have been completed for the Aim2a sample. Remaining analysis work includes running generalized linear mixed models (GLMM) on the prepared data sets to test for change in health care utilization and patient satisfaction before and after cPRO implementation. Faculty and staff have been reassigned this work and plan to complete the modeling in the fourth quarter of 2023 with a manuscript work to follow—this was a change due to a loss in our team. Special note: We are very sad to report that the study's lead statistician, Dr. Michael Kallen, died last month after an illness-related health leave earlier this year. Dr. Kallen developed the project's statistical analysis plan, oversaw all analyses, and was working on Aim 2a&b analyses as well as final analysis of the implementation data. Progress on these analyses was delayed due to Dr. Kallen's health leave but he was determined to complete them—right up until he needed to take leave from work. Sadly, he did not recover and died. Dr. Kallen's death was a major loss not just to our study, but to our department, and to all who knew him. Supported by department leadership, our team has identified analysts and statisticians who can pick up from where he left off and complete the R18 analyses. We are committed to completing analyses and disseminating results in the future. Ben Schalet, PhD is now working with Katy Bedjeti, MS and other investigators to complete analyses. Then we plan to submit two additional manuscripts for publication: 1) "Trajectories of co-occurring patient-reported symptoms among cancer patients across the care continuum" (Target journal: Cancer) and 2) "Implementation of a system-wide

cancer symptom monitoring assessment in a large multi-region academic healthcare system: implications for health service usage and patient satisfaction" (Target journal: JCO Oncology Practice).

Aim 2b: The 2b sample (n=1,108) consists of those who were consented to complete additional follow-up via REDCap questionnaire following cPRO completion. Study data include FACT-G7, PROCTCAE, CAHPS, healthcare utilization outside NM, and sociodemographic questions collected via REDCap for study patients consented between July 2019 and December 2020. REDCap data were collected shortly following cPRO completion (n=1,106; n=2 do not have REDCap baseline data) and again at 6 (n=846) and 12 months (n=834). Baseline REDCap survey was captured for those pre (53%) and post cPRO implementation (47%). Participants are predominantly non-Hispanic White (88%) and female (67%). Both pre and post implementation groups consist predominantly of individuals who either have no symptoms or their symptoms do not require rest during the day (ECOG status 0 and 1, 78%). HRQoL (FACT-G7) scores were not significantly different in pre- and post-implementation groups (n=20, q1=16, q3=24 pre and post, p=0.40). Healthcare quality (CAHPS) scores did not vary significantly across pre- and post-implementation groups (overall pre mean=9.17, sd=1.24; post mean=9.12, sd=1.25). Shared decision-making (CollaboRATE) scores indicated that 52% of participants endorsed the highest levels of shared decision making ("top box" score) in both pre- and post-implementation groups (pre n=295 of 572, post n=266 of 515, p>0.9). Pre- to post-implementation tests were also conducted on PRO-CTCAE items assessing gastrointestinal disturbance and insomnia. These tests did not suggest a difference in symptom burden between pre- and post-implementation groups.

Dr. Kallen started work on latent class analysis for the Aim2b data before his passing. He had identified potential classes for change trajectories in HRQoL (FACT-G) and was working to describe the characteristics of each class. We plan to bring on an analyst/psychometrician/statistician with extensive experience analyzing PRO data and conducting latent class analysis to complete the modeling work started by Dr. Kallen. Work on Aim2b latent class models is expected to resume in Q3-Q4 of 2023.

Aim 3: Patient-facing mixed methods sample: The final analytic sample size was 180 (n=37 qualitative interviews and n=143 survey participants). Participants were equally represented across the three regional cancer centers sites. Participants' mean age was 62.9 years (range 33-90) and mean age of diagnosis was 57.6 years (range 26-85). The majority were female, White, non-Hispanic, and married; represented various solid tumor types and hematologic malignancies; and were relatively equally distributed by treatment status (see Table 3). Our sample reported a high level of education, computer literacy, and patient portal usage. Over three-fourths of participants indicated they were "Very Comfortable" using computers or touchscreen devices and used the patient portal frequently.

Table 3. Participating Patient Characteristics for Aim 3

1 0	Wave 1	Wave 2
	(n=37)	(n=143) n (%)
cPRO User Group		
Never User	3 (8.1%)	
Central	1 (2.7%)	
West	1 (2.7%)	
North	1 (2.7%)	
Regular User	16 (43.2%)	
Central	6 (16.2%)	
West	5 (13.5%)	
North	5 (13.5%)	
User Generating Clinical Alert(s)	18 (48.6%)	
Central	6 (16.2%)	
West	6 (16.2%)	

	Wave 1	Wave 2	
	(n=37)	(n=143)	
NIkl.	C (4.C 20()	n (%)	
North	6 (16.2%)	1.42 (1.00%)	
Cross-Cohort		143 (100%)	
Healthcare System Region Central	12 /25 10/\	40 (24 20/)	
West	13 (35.1%)	49 (34.3%)	
North	12 (32.4%)	46 (32.2%)	
	12 (32.4%)	48 (33.6%)	
Gender Identity Female	28 (75.7%)	88 (61.5%)	
Male	9 (24.3%)	53 (37.1%)	
Not listed/missing	0.0%	2 (1.4%)	
Age at recruitment - Mean (Range)	59.56 (33 – 86)	63.72 (36 – 90)	
Age at diagnosis – Mean (Range)	56.77 (26 – 83)	57.87 (26 – 85)	
Ethnicity	30.77 (20 - 63)	37.87 (20 - 83)	
Non-Hispanic	34 (91.9%)	136 (95.8%)	
Hispanic	2 (5.4%)	2 (1.4%)	
Declined	2 (3.4%) 1 (2.7%)	4 (2.8%)	
Race (check all that apply)	1 (2.770)	4 (2.070)	
White	35 (94.6%)	139 (97.2%)	
Black or African American	0 (0.0%)	0 (0.0%)	
Asian	2 (5.4%)	0 (0.0%)	
Native Hawaiian or Other Pacific Islander	1 (2.7%)	0 (0.0%)	
More than one race	1 (2.7%)	3 (2.1%)	
Other	0 (0.0%)	5 (3.5%)	
Marital Status	0 (0.070)	3 (3.370)	
Single/Never married	6 (16.2%)	6 (4.2%)	
Married	25 (67.6%)	109 (76.2%)	
In a committed relationship	0 (0.0%)	4 (2.8%)	
Separated	0 (0.0%)	1 (0.7%)	
Divorced	5 (13.5%)	11 (7.7%)	
Widowed	1 (2.7%)	10 (7.0%)	
Missing	0.0%	2 (1.4%)	
Highest Education		_ (=::,:,	
Less than high school grad.	0 (0.0%)	1 (0.7%)	
Some high school	0 (0.0%)	2 (1.4%)	
High school graduate	2 (5.4%)	9 (6.3%)	
Some college/technical degree/Associates	8 (21.6%)	28 (19.6%)	
degree	12 (32.4%)	39 (27.3%)	
College degree	15 (40.5%)	63 (44.1%)	
Advanced degree (MA, MS, MBA, PhD., MD, JD)	0 (0.0%)	1 (0.7%)	
Missing	, ,	, ,	
Employment Status			
Full-time employed	10 (27.0%)	57 (39.9%)	
Part-time employed	3 (8.1%)	10 (7.0%)	
Homemaker	3 (8.1%)	2 (1.4%)	
Unemployed	0 (0.0%)	2 (1.4%)	
On leave of absence	1 (2.7%)	2 (1.4%)	

	Wave 1	Wave 2	
	(n=37)	(n=143)	
		n (%)	
On disability	3 (8.1%)	6 (4.2%)	
Retired	15 (40.5%)	63 (44.1%)	
Prefer not to answer	2 (5.4%)	1 (0.7%)	
Frequency of MyChart (NM Patient Portal) Use			
Never	0 (0.0%)	0 (0.0%)	
Rarely	1 (2.7%)	2 (1.4%)	
Sometimes	7 (18.9%)	25 (17.5%)	
Often	29 (78.4%)	114 (79.7%)	
I don't have a MyChart account	0 (0%)	0 (0.0%)	
Missing	0 (0.0%)	2 (1.4%)	
Comfort with Computer/Touch screen device			
Not at all comfortable	0 (0/0%)	0 (0.0%)	
A little comfortable	1 (2.7%)	0 (0.0%)	
Somewhat comfortable	7 (18.9%)	11 (7.7%)	
Very comfortable	29 (78.4%)	130 (90.9%)	
I have never used a computer or touchscreen	0 (0.0%)	0 (0.0%)	
device			
Missing	0 (0.0%)	2 (1.4%)	
Frequency of Using Computer/Touchscreen device			
Never	0 (0.0%)	0 (0.0%	
Monthly	0 (0.0%)	0 (0.0%)	
Weekly	0 (0.0%)	5 (3.5%)	
Daily	37 (100.0%)	137 (95.8%)	
Missing	0 (0.0%)	1 (0.7%)	
Type of cancer			
Breast	15 (40.5%)	44 (30.8%)	
Bladder	0 (0.0%)	1 (0.7%)	
Cervical	0 (0.0%)	3 (2.1%)	
Colorectal	2 (5.4%)	10 (7.0%)	
Head/neck	0 (0.0%)	3 (2.1%)	
Leukemia	0 (0.0%)	15 (10.5%)	
Liver	1 (2.7%)	0 (0.0%)	
Lung	1 (2.7%)	6 (4.2%)	
Lymphoma	4 (10.8%)	18 (12.6%)	
Multiple Myeloma	2 (5.4%)	10 (7.0%)	
Neuroendocrine	1 (2.7%)	1 (0.7%)	
Ovarian	4 (10.8%)	6 (4.2%)	
Pancreatic	0 (0.0%)	2 (1.4%)	
Prostate	1 (2.7%)	12 (8.4%)	
Other	6 (16.2%)	12 (8.4%)	

	Wave 1	<i>Wave 2</i> (n=143)	
	(n=37)		
		n (%)	
Household Income			
Up to \$29,999	2 (5.4%)	4 2.8%)	
\$30,000 to \$59,999	3 (8.1%)	15 (10.5%)	
\$60,000 to \$100,000	13 (35.1%)	29 (20.3%)	
Greater than \$100,000	13 (35.1%)	77 (53.8%)	
Unsure	0 (0.0%)	1 (0.7%)	
Prefer not to Answer	5 (13.5%)	17 (11.9%%)	
Missing	1 (2.7%)	0 (0.0%)	
Stage of cancer			
Stage I	4 (10.8%)	11 (7.7%)	
Stage II	8 (21.6%)	8 (5.6%)	
Stage III	4 (10.8%)	11 (7.7%)	
Stage IV	7 (18.9%)	21 (14.7%)	
In remission or cured	9 (24.3%)	51 (35.7%)	
Other	2 (5.4%)	13 (9.1%)	
Unknown	3 (8.1%)	27 (18.9%)	
Missing	0 (0.0%)	1 (0.7%)	
Currently receiving cancer treatment			
Yes	15 (40.5%)	78 (54.5%)	
No	22 (59.5%)	65 (45.5%)	

Qualitative interviews with patients: Although we recruited and collected data separately from distinct cPRO user groups, formative review of preliminary findings indicated responses across regions and user groups were highly uniform. Therefore, we report cPRO user group data in a consolidated manner. No new themes emerged after analyzing data from 37 participants, indicating that we had reached saturation.(64) Overall, implementation determinants identified by participants broadly relate to the principal domains of perceived value, usability and relevance, education and communication, and care team engagement, each of which appears to be a key facilitator when present and a barrier when absent. Patients saw cPRO's unique value in its ability to monitor symptoms, facilitate reflection, boost self-efficacy, improve appointment efficiency, and strengthen sense of care quality. In terms of usability and relevance, patients found cPRO easy to access, navigate and complete and felt items were relevant while desiring additional flexibility when responding. Patients had not seen educational materials (brochures and posters) and wanted more communication from their care team about cPRO's purpose and functionality and emphasized the importance of their care team acknowledging their results and referring to completed cPRO rather than asking the same questions again during the visit.

Patient-facing survey: Results from this survey with a larger sample helped us understand the degree to which identified facilitators and barriers were endorsed or experienced by patients. Broadly, results suggest high (82-99%) endorsement of usability and relevance (items are relevant and easy to comprehend; the system is navigable), moderate (30-47%) endorsement of perceived value (cPRO improves communication at appointments and sense of self-efficacy; useful as a monitoring tool), low to moderate (7-57%) endorsement of education and communication (saw educational materials; care team communicated about cPRO; understood purpose of cPRO) and low (16%) endorsement of care team engagement (care team acknowledged/discussed cPRO results). Results from this initiative have been drafted and the manuscript is currently under review (Lyleroehr MJ, Webster KA, Perry LM, Patten EA Cantoral J, Smith JD, Cella D, Penedo FJ, Garcia SF. A mixed methods evaluation of patient perspectives on the implementation of an electronic health record-integrated patient-reported symptom and needs

monitoring program in cancer care. Submitted to the Journal of Patient-Reported Outcomes, July 2023).

Clinician-facing implementation survey sample: We distributed implementation surveys to our clinician cPRO users in the Central, North, and West regions. The purpose of these surveys was to assess provider attitudes regarding the implementation and adoption of cPRO-Monitor. Unfortunately, final analyses of these data were not completed due to Dr. Kallen's health leave and death this year. We have now assigned these analyses to a data analyst in Northwestern's Department of Medical Social Sciences.

Discussion: Aim 1: Results indicated that 34 discrete implementation strategies were used, and at least one strategy was included from each of the nine strategy categories from the ERIC taxonomy. Since partnerships are crucial for implementation(65, 66), it was unsurprising that the category with the most strategies was "develop stakeholder interrelationships" (n = 12), and "evaluative and iterative strategies" was second (n = 7). Given the scope and complexity of this strategic implementation effort to effect system-wide change, the need for multilevel strategies to cut across ERIC categories seems reasonable and necessary.

Concerning the implementation strategy protocol, it was not surprising to see that most of the strategies used (28 of 34) were planned and relatively few modifications occurred to the strategies themselves once in use, which included no unplanned discontinuations, only six unplanned strategy introductions, and six unplanned modifications to a strategy's specification. The nature of the healthcare system and the experience of the study team are likely important determinants to consider when interpreting these results. This study occurred within the ambulatory oncology clinics of a large, academic medical center. As such, implementation was centralized, supported by established practice change processes, and championed by the Quality team of the health system to ensure greater uptake and uniformity across regions and clinics. This gave investigators considerable control over the protocol. Concerning the study team, there was a high degree of prior knowledge and experience related to PRO implementation in this specific healthcare system. Relatedly, this study represented an attempt to improve and expand on the implementation of an already-in-use innovation (i.e., PROs), allowing for the specification of planned, targeted, strategic initiatives informed by prior data on identified barriers and effective facilitators. As such, there was a high degree of confidence in the protocol as designed. We believe these contextual factors contributed to fewer modifications.

Rolling out cPRO during the COVID-19 pandemic brought unique and unexpected challenges to which we responded by adopting flexible implementation strategies. While maintaining all study data collection at Northwestern, Dr. Penedo's move to University of Miami allowed us to leverage our cPRO build, protocol, and strategies to guide implementation of a similar program (My Wellness Check) in a second healthcare system that serves both English- and Spanish- speaking patients. To our knowledge, this was the first EHR-integrated symptom and needs screening system implemented in routine oncology care for Spanish-speaking Hispanics/Latinos. Our experiences implementing cPRO (in Northwestern Medicine) and My Wellness Check (in University of Miami Health System) informed our review article in the Lancet Oncology on eHealth in the delivery of patient-centered cancer care.(34)

Aim 2: We will refrain from a final discussion of this aim because all analyses are not completed due to Dr. Kallen's death. However, initial cPRO adoption metrics indicate that the "soft-touch" implementation strategies employed (i.e., no clinician directives & incentives) may not be sufficient to achieve desired levels of use (>=75% of eligible patients). Likewise, initial pre- versus post-cPRO implementation analyses do not evidence significant changes in patient-reported health-related quality of life (based on our smaller Aim2b data set). However, we are still analyzing pre- and post-implementation health service usage and patient satisfaction in larger Aim 2a EHR-based data set. Further, completing the latent class analyses Dr. Kallen began will elucidate different symptom trajectories for different patient subgroups. This is particularly important given the considerable heterogeneity of the study sample (patients with numerous cancer types, stages, treatment histories—across the care continuum).

Aim 3: Patient-facing mixed methods Sample: Collectively, data from the qualitative interviews and survey provided insight on patient attitudes and experiences that can inform actionable changes to cPRO implementation. Results centered on four principal domains that appear to enhance or detract from patient uptake and adherence and point to implementation strategy enhancements needed to improve reach, adoption, sustainability, and effectiveness. Findings aligned with what we had learned anecdotally from clinicians, administrators, and patients during cPRO implementation, but there were some unexpected results. First, patients found value in cPRO, including that it improved communication with their care team, despite low care team engagement. Likewise, a significant number of patients (42%) indicated ("Somewhat" to "Very much") that cPRO enhanced their sense of self-efficacy, a desirable patient-centered benefit, pointing to how symptom monitoring programs like cPRO can activate patients.(67) Specifically, patients described how cPRO facilitated thoughtful reflection on their symptoms and needs and better prepared them to communicate concerns in medical visits. This finding maps onto one of the basic principles of patient-clinician communication: "the right information," (i.e., patients sharing relevant symptoms and experiences).(68) Finally, it is noteworthy that a quarter to over half (27.7%-56.7%) of survey respondents said they were "Never" or "Rarely" asked, within routine care, about some of the most common physical and, especially, psychological symptoms reported in oncology settings, This finding highlights the general need for symptom monitoring, and the specific need for mental health surveillance in cancer care. (69) When the data analyst taking over for Dr. Kallen completes analysis of the clinician-facing implementation survey data, we will evaluate how it relates to the other stakeholder input we have summarized.

Conclusions: We will refrain from stating final study conclusions because all analyses are not completed due to Dr. Kallen's death. However, we have assigned his uncompleted work to other analysts and are committed to disseminating results of those remaining (**Aim 2**) study components.

Significance: This was the first study to implement healthcare system-wide symptom and need assessment and referral across Northwestern Medicine cancer clinics. Since then, various subsequent studies conducted in Northwestern Medicine cancer clinics have benefitted from this study's EHR build; established network of physician champions and operational leads; implementation strategies; implementation tracking systems; and mixed methods protocols. These have included federally funded studies of EHR-integrated symptom management, depression management and health promotion. Most recently, Dr. Garcia (as MPI) was awarded a national Cancer Institute-funded center grant (P50CA271353) that includes a pragmatic trial of an EHR-integrated system to identify cancer survivors in need of health promotion (weigh management, increased physical activity & smoking cessation) and subsequently deliver services via telehealth. Further, we have leveraged cPRO protocols and tools to establish a similar, but bilingual, program in another healthcare system (University of Miami, under Dr. Penedo's leadership).

Implications: Although final study results are pending due to delays subsequent to Dr. Kallen's leave and death, we have established reproducible tool, models and strategies to implement EHR-integrated symptom and needs assessment and referral for ambulatory oncology patients. We have disseminated a catalogue of implementation strategies employed throughout the study and stakeholder input gathered using mixed methods.

LIST OF PUBLICATIONS and PRODUCTS

Published Manuscripts:

1. Penedo FJ, Oswald LB, Kronenfeld JP, Garcia SF, Cella D, Yanez B. The increasing value of eHealth in the delivery of patient-centred cancer care. Lancet Oncol. 2020 May;21(5):e240-e251. Doi: 10.1016/S1470-2045(20)30021-8. PMID: 32359500; PMCID: PMC7643123.

- Davis K, Wilbur K, Metzger S, Garcia SF, Cahue S, Webster K, Lylerohr M, Himelhoch HL, Bilimoria K, Cella D. Symptom and needs assessment screening in oncology patients: Alternate outreach methods during COVID-19. J Psychosoc Oncol. 2021;39(3):452-460. Doi: 10.1080/07347332.2021.1890663. Epub 2021 Apr 1. PMID: 33792515.(70)
- 3. Garcia SF, Smith JD, Kallen M, Webster KA, Lyleroehr M, Kircher S, Bass M, Cella D, Penedo FJ. Protocol for a type 2 hybrid effectiveness-implementation study expanding, implementing and evaluating electronic health record-integrated patient-reported symptom monitoring in a multisite cancer centre. BMJ Open. 2022 May 3;12(5):e059563. Doi: 10.1136/bmjopen-2021-059563. PMID: 35504641; PMCID: PMC9066503.
- 4. Penedo FJ, Medina HN, Moreno PI, Sookdeo V, Natori A, Boland C, Schlumbrecht MP, Calfa C, MacIntyre J, Crane TE, Garcia SF. Implementation and Feasibility of an Electronic Health Record-Integrated Patient-Reported Outcomes Symptom and Needs Monitoring Pilot in Ambulatory Oncology. JCO Oncol Pract. 2022 Jul;18(7):e1100-e1113. Doi: 10.1200/OP.21.00706. Epub 2022 Mar 15. PMID: 35290096; PMCID: PMC9287298.
- 5. Smith JD, Merle JL, Webster KA, Cahue S, Penedo FJ, Garcia SF. Tracking dynamic changes in implementation strategies over time within a hybrid type 2 trial of an electronic patient-reported oncology symptom and needs monitoring program. Front Health Serv. 2022 Nov 1;2:983217. Doi: 10.3389/frhs.2022.983217. PMID: 36925901; PMCID: PMC10012686.

Submitted/Planned Manuscripts:

- 6. Lyleroehr MJ, Webster KA, Perry LM, Patten EA Cantoral J, Smith JD, Cella D, Penedo FJ, Garcia SF. A mixed methods evaluation of patient perspectives on the implementation of an electronic health record-integrated patient-reported symptom and needs monitoring program in cancer care. Submitted to the Journal of Patient-Reported Outcomes, July 2023.
- 7. Trajectories of co-occurring patient-reported symptoms among cancer patients across the care continuum; Target journal: Cancer; Psycho-oncology
- 8. Implementation of a system-wide cancer symptom monitoring assessment in a large multiregion academic healthcare system: implications for health service usage and patient satisfaction; Target journal: Cancer, JCO Oncology Practice

REFERENCES:

- 1. Garcia SF, Wortman K, Cella D, Wagner LI, Bass M, Kircher S, et al. Implementing electronic health record—integrated screening of patient-reported symptoms and supportive care needs in a comprehensive cancer center. Cancer. 2019;125(22):4059-68.
- 2. Wagner LI, Schink J, Bass M, Patel S, Diaz MV, Rothrock N, et al. Bringing PROMIS to practice: brief and precise symptom screening in ambulatory cancer care. Cancer. 2015;121(6):927-34.
- 3. Nolan K, Schall MW, Erb F, Nolan T. Using a framework for spread: the case of patient access in the Veterans Health Administration. The Joint Commission Journal on Quality and Patient Safety. 2005;31(6):339-47.
- 4. Glasgow RE, Harden SM, Gaglio B, Rabin B, Smith ML, Porter GC, et al. RE-AIM planning and evaluation framework: adapting to new science and practice with a 20-year review. Frontiers in Public Health. 2019;7:64.
- 5. Shelton RC, Chambers DA, Glasgow RE. An extension of RE-AIM to enhance sustainability: addressing dynamic context and promoting health equity over time. Frontiers in public health. 2020;8:134.
- 6. The Consolidated Framework for Implementation Research (CFIR) [Available from:
- 7. Miller KD, Nogueira L, Mariotto AB, Rowland JH, Yabroff KR, Alfano CM, et al. Cancer treatment and survivorship statistics, 2019. CA: a cancer journal for clinicians. 2019;69(5):363-85.
- 8. Caruso R, Nanni MG, Riba MB, Sabato S, Grassi L. The burden of psychosocial morbidity related to cancer: patient and family issues. International Review of Psychiatry. 2017;29(5):389-402.

- 9. Penedo FJ, Cella D. Responding to the quality imperative to embed mental health care into ambulatory oncology. Wiley Online Library; 2017.
- 10. Mehnert A, Brähler E, Faller H, Härter M, Keller M, Schulz H, et al. Four-week prevalence of mental disorders in patients with cancer across major tumor entities. Journal of Clinical Oncology. 2014;32(31):3540-6.
- 11. Kanani R, Davies EA, Hanchett N, Jack RH. The association of mood disorders with breast cancer survival: an investigation of linked cancer registration and hospital admission data for South East England. Psycho-Oncology. 2016;25(1):19-27.
- 12. Mitchell AJ, Chan M, Bhatti H, Halton M, Grassi L, Johansen C, et al. Prevalence of depression, anxiety, and adjustment disorder in oncological, haematological, and palliative-care settings: a meta-analysis of 94 interview-based studies. The lancet oncology. 2011;12(2):160-74.
- 13. Cella D, Peterman A, Passik S, Jacobsen P, Breitbart W. Progress toward guidelines for the management of fatigue. Oncology (Williston Park, NY). 1998;12(11A):369-77.
- 14. Deshields TL, Potter P, Olsen S, Liu J. The persistence of symptom burden: symptom experience and quality of life of cancer patients across one year. Supportive Care in Cancer. 2014;22(4):1089-96.
- 15. Pearman TP, Garcia SF, Penedo F, Yanez B, Wagner LI, Cella D, 3. Implementation of distress screening in an oncology setting. Journal of Community and Supportive Oncology. 2015;13(12):423-8.
- 16. Burg MA, Adorno G, Lopez ED, Loerzel V, Stein K, Wallace C, et al. Current unmet needs of cancer survivors: Analysis of open-ended responses to the A merican C ancer S ociety S tudy of C ancer S urvivors II. Cancer. 2015;121(4):623-30.
- 17. Wang T, Molassiotis A, Chung BPM, Tan J-Y. Unmet care needs of advanced cancer patients and their informal caregivers: a systematic review. BMC palliative care. 2018;17(1):1-29.
- 18. Cancer ACoSCo. Cancer Program Standards 2016: ensuring patient-centered care. 2016 [cited 2016. Available from: https://www.facs.org/quality-programs/cancer/coc/standards/2016.
- 19. Page AE, Adler NE. Cancer care for the whole patient: Meeting psychosocial health needs. 2008.
- 20. Riba MB, Donovan KA, Andersen B, Braun I, Breitbart WS, Brewer BW, et al. Distress Management, Version 3.2019, NCCN Clinical Practice Guidelines in Oncology. Journal of the National Comprehensive Cancer Network J Natl Compr Canc Netw. 2019;17(10):1229-49.
- 21. Swarm RA, Paice JA, Anghelescu DL, Are M, Bruce JY, Buga S, et al. Adult cancer pain, version 3.2019, NCCN clinical practice guidelines in oncology. Journal of the National Comprehensive Cancer Network. 2019;17(8):977-1007.
- 22. [Available from: https://www.nccn.org/guidelines/guidelines-detail?category=3&id=1424.
- 23. Holland JC, Andersen B, Breitbart WS, Buchmann LO, Compas B, Deshields TL, et al. Distress management. Journal of the National Comprehensive Cancer Network. 2013;11(2):190-209.
- 24. Jacobsen PB, Donovan KA, Trask PC, Fleishman SB, Zabora J, Baker F, et al. Screening for psychologic distress in ambulatory cancer patients: a multicenter evaluation of the distress thermometer. Cancer. 2005;103(7):1494-502.
- 25. Jensen RE, Snyder CF, Abernethy AP, Basch E, Potosky AL, Roberts AC, et al. Review of electronic patient-reported outcomes systems used in cancer clinical care. Journal of oncology practice. 2014;10(4):e215-e22.
- 26. Kotronoulas G, Kearney N, Maguire R, Harrow A, Di Domenico D, Croy S, et al. What is the value of the routine use of patient-reported outcome measures toward improvement of patient outcomes, processes of care, and health service outcomes in cancer care? A systematic review of controlled trials. Journal of clinical oncology. 2014;32(14):1480-510.
- 27. Valderas J, Kotzeva A, Espallargues M, Guyatt G, Ferrans C, Halyard M, et al. The impact of measuring patient-reported outcomes in clinical practice: a systematic review of the literature. Quality of life research. 2008;17(2):179-93.
- 28. Chen J, Ou L, Hollis SJ. A systematic review of the impact of routine collection of patient reported outcome measures on patients, providers and health organisations in an oncologic setting. BMC health services research. 2013;13(1):1-24.

- 29. Velikova G, Booth L, Smith AB, Brown PM, Lynch P, Brown JM, et al. Measuring quality of life in routine oncology practice improves communication and patient well-being: a randomized controlled trial. Journal of Clinical Oncology. 2004;22(4):714-24.
- 30. Davis K, Yount S, Del Ciello K, Whalen M, Khan S, Bass M, et al. An innovative symptom monitoring tool for people with advanced lung cancer: a pilot demonstration. J Support Oncol. 2007;5(8):381-7.
- 31. Basch E, Deal AM, Kris MG, Scher HI, Hudis CA, Sabbatini P, et al. Symptom monitoring with patient-reported outcomes during routine cancer treatment: a randomized controlled trial. Journal of Clinical Oncology. 2016;34(6):557.
- 32. Basch E, Deal AM, Dueck AC, Scher HI, Kris MG, Hudis C, et al. Overall survival results of a trial assessing patient-reported outcomes for symptom monitoring during routine cancer treatment. Jama. 2017;318(2):197-8.
- 33. Basch EM, Deal AM, Dueck AC, Bennett AV, Atkinson TM, Scher HI, et al. Overall survival results of a randomized trial assessing patient-reported outcomes for symptom monitoring during routine cancer treatment. Journal of Clinical Oncology. 2017;35(18_suppl):LBA2-LBA.
- Penedo FJ, Oswald LB, Kronenfeld JP, Garcia SF, Cella D, Yanez B. The increasing value of eHealth in the delivery of patient-centred cancer care. The Lancet Oncology. 2020;21(5):e240-e51.
- 35. Cella D, Riley W, Stone A, Rothrock N, Reeve B, Yount S, et al. The Patient-Reported Outcomes Measurement Information System (PROMIS) developed and tested its first wave of adult self-reported health outcome item banks: 2005–2008. Journal of clinical epidemiology. 2010;63(11):1179-94.
- 36. Jensen RE, Moinpour CM, Potosky AL, Lobo T, Hahn EA, Hays RD, et al. Responsiveness of 8 Patient-Reported Outcomes Measurement Information System (PROMIS) measures in a large, community-based cancer study cohort. Cancer. 2017;123(2):327-35.
- 37. Bass M, Morris S, Neapolitan R, editors. Utilizing multidimensional computer adaptive testing to mitigate burden with patient reported outcomes. AMIA Annual Symposium Proceedings; 2015: American Medical Informatics Association.
- 38. NUCATS is funded in part by a Clinical and Translational Science Award (CTSA) grant from the National Institutes of Health (NIH). UL1TR001422
- 39. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support. Journal of biomedical informatics. 2009;42(2):377-81.
- 40. Powell BJ, Waltz TJ, Chinman MJ, Damschroder LJ, Smith JL, Matthieu MM, et al. A refined compilation of implementation strategies: results from the Expert Recommendations for Implementing Change (ERIC) project. Implementation Science. 2015;10(1):1-14.
- 41. Smith J, Norton W, DiMartino L, Battestilli W, Rutten L, Mitchell S, et al., editors. A longitudinal implementation strategies tracking system: Development and initial acceptability. 13 th Annual Conference on the Science of Dissemination and Implementation: AcademyHealth.
- 42. Proctor EK, Powell BJ, McMillen JC. Implementation strategies: recommendations for specifying and reporting. Implementation Science. 2013;8(1):1-11.
- 43. Miller CJ, Barnett ML, Baumann AA, Gutner CA, Wiltsey-Stirman S. The FRAME-IS: a framework for documenting modifications to implementation strategies in healthcare. Implementation Science. 2021;16(1):1-12.
- 44. Healthmeasures.net [Available from: <u>www.healthmeasures.net</u>.
- 45. Presson AP, Zhang C, Abtahi AM, Kean J, Hung M, Tyser AR. Psychometric properties of the Press Ganey® outpatient medical practice survey. Health and quality of life outcomes. 2017;15(1):1-7.
- 46. Medallia [Available from: https://www.medallia.com/.
- 47. Cella DF, Tulsky DS, Gray G, Sarafian B, Linn E, Bonomi A, et al. The Functional Assessment of Cancer Therapy scale: development and validation of the general measure. J Clin Oncol. 1993;11(3):570-9.

- 48. Quality AfHRa. CAHPS Cancer Care Survey Rockville, MD. [updated Content last reviewed July 2020. Available from: https://www.ahrq.gov/cahps/surveys-guidance/cancer/index.html
- 49. Evensen CT, Yost KJ, Keller S, Arora NK, Frentzel E, Cowans T, et al. Development and testing of the CAHPS cancer care survey. Journal of oncology practice. 2019;15(11):e969-e78.
- 50. Basch E, Reeve BB, Mitchell SA, Clauser SB, Minasian LM, Dueck AC, et al. Development of the National Cancer Institute's patient-reported outcomes version of the common terminology criteria for adverse events (PRO-CTCAE). Journal of the National Cancer Institute. 2014;106(9):dju244.
- 51. Hay JL, Atkinson TM, Reeve BB, Mitchell SA, Mendoza TR, Willis G, et al. Cognitive interviewing of the US National Cancer Institute's patient-reported outcomes version of the common terminology criteria for adverse events (PRO-CTCAE). Quality of Life Research. 2014;23(1):257-69.
- 52. Dueck AC, Mendoza TR, Mitchell SA, Reeve BB, Castro KM, Denicoff A, et al. Validity and reliability of the patient-reported outcomes version of the common terminology criteria for adverse events (PRO-CTCAE). American Society of Clinical Oncology; 2012.
- 53. De Souza JA, Yap BJ, Hlubocky FJ, Wroblewski K, Ratain MJ, Cella D, et al. The development of a financial toxicity patient-reported outcome in cancer: the COST measure. Cancer. 2014;120(20):3245-53.
- 54. Morris NS, MacLean CD, Chew LD, Littenberg B. The Single Item Literacy Screener: evaluation of a brief instrument to identify limited reading ability. BMC family practice. 2006;7(1):1-7.
- 55. Barr PJ, Thompson R, Walsh T, Grande SW, Ozanne EM, Elwyn G. The psychometric properties of CollaboRATE: a fast and frugal patient-reported measure of the shared decision-making process. Journal of medical Internet research. 2014;16(1):e3085.
- Armenakis AA, Bernerth JB, Pitts JP, Walker HJ. Organizational change recipients' beliefs scale: Development of an assessment instrument. The Journal of applied behavioral science. 2007;43(4):481-505.
- 57. Aarons GA, Ehrhart MG, Farahnak LR. The implementation leadership scale (ILS): development of a brief measure of unit level implementation leadership. Implementation Science. 2014;9(1):1-10.
- 58. Rapley T, Girling M, Mair FS, Murray E, Treweek S, McColl E, et al. Improving the normalization of complex interventions: part 1-development of the NoMAD instrument for assessing implementation work based on normalization process theory (NPT). BMC medical research methodology. 2018;18(1):1-17.
- 59. Finch TL, Girling M, May CR, Mair FS, Murray E, Treweek S, et al. Improving the normalization of complex interventions: part 2-validation of the NoMAD instrument for assessing implementation work based on normalization process theory (NPT). BMC medical research methodology. 2018;18(1):1-13.
- 60. Smith JD, Fu E, Rado J, Rosenthal LJ, Carroll AJ, Atlas JA, et al. Collaborative care for depression management in primary care: A randomized roll-out trial using a type 2 hybrid effectiveness-implementation design. Contemporary clinical trials communications. 2021;23:100823.
- 61. Malone S, Mckay V, Prewitt K, Luke D, editors. Assessing clinical sustainability: A new, user-friendly tool for evaluating real-world practices. APHA's 2020 VIRTUAL Annual Meeting and Expo (Oct 24-28); 2020: American Public Health Association.
- 62. Malone S, Prewitt K, Hackett R, Lin JC, McKay V, Walsh-Bailey C, et al. The clinical sustainability assessment tool: measuring organizational capacity to promote sustainability in healthcare. Implementation science communications. 2021;2(1):1-12.
- 63. Waltz TJ, Powell BJ, Matthieu MM, Damschroder LJ, Chinman MJ, Smith JL, et al. Use of concept mapping to characterize relationships among implementation strategies and assess their feasibility and importance: results from the Expert Recommendations for Implementing Change (ERIC) study. Implementation Science. 2015;10:1-8.
- 64. Bowen GA. Naturalistic inquiry and the saturation concept: a research note. Qualitative research. 2008;8(1):137-52.
- 65. Brown CH, Kellam SG, Kaupert S, Muthén BO, Wang W, Muthén LK, et al. Partnerships for the design, conduct, and analysis of effectiveness, and implementation research: experiences of the

prevention science and methodology group. Administration and Policy in Mental Health and Mental Health Services Research. 2012;39:301-16.

- 66. Chambers DA, Azrin ST. Research and services partnerships: partnership: a fundamental component of dissemination and implementation research. Psychiatric Services. 2013;64(6):509-11.
- 67. Howell D, Rosberger Z, Mayer C, Faria R, Hamel M, Snider A, et al. Personalized symptom management: a quality improvement collaborative for implementation of patient reported outcomes (PROs) in 'real-world'oncology multisite practices. Journal of Patient-Reported Outcomes. 2020;4(1):1-13.
- 68. Paget L, Han P, Nedza S, Kurtz P, Racine E, Russell S, et al. Patient-clinician communication: Basic principles and expectations. NAM Perspectives. 2011.
- 69. McFarland DC, Holland JC. The management of psychological issues in oncology. Clin Adv Hematol Oncol. 2016;8:13-6.
- 70. Davis K, Wilbur K, Metzger S, Garcia SF, Cahue S, Webster K, et al. Symptom and needs assessment screening in oncology patients: Alternate outreach methods during COVID-19. Journal of Psychosocial Oncology. 2021;39(3):452-60.