FINAL REPORT

Title: Cancer Patient Safety Learning Laboratory (CaPSLL): Preventing Clinical Deterioration in Outpatients

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STRUCTURED ABSTRACT

Purpose. A common cause of preventable harm is the failure to detect and appropriately respond to clinical deterioration. Timely intervention is needed, particularly in medically complex patients, to mitigate the effects of adverse events, disease progression, and medical error.

Scope. This was a multi-year, single-site study to design, develop, implement, and evaluate a prototype surveillance-and-response system to improve the detection and response to clinical deterioration in patients receiving cancer ambulatory care.

Methods. A human-centered design approach was used to design and evaluate the prototype of a surveillance-and-risk prediction system. The system included passive surveillance involving wearable sensors; active surveillance involving patient, caregiver, and clinician event reporting; a predictive model; and a risk communication system to notify clinicians.

Results. Using patient-reported outcome measures (PROMs) and clinical data from the electronic health record (EHR), the prototype system reliably predicted patients' 7-day risk of experiencing unplanned treatment events. Smartphone geolocation data could not be sufficiently evaluated for risk prediction due to missing data resulting from technical issues, privacy concerns, and decreased activity outside the home due to the COVID-19 pandemic. Patient risk scores and information on contributing factors were effectively communicated to clinicians using prototypes of a risk dashboard and patient risk profiles designed to be integrated into the EHR.

Conclusions. We demonstrated the feasibility and efficacy of a surveillance-and-risk prediction system for detecting and reporting clinical deterioration in cancer outpatients. Future research is needed to fully implement and evaluate system adoption and effectiveness across ambulatory care centers and cancer types.

Key Words: Cancer, outpatient, clinical deterioration, prediction, modeling, response

PURPOSE

A common cause of preventable harm is the failure to detect and appropriately respond to clinical deterioration.[1 2] Timely intervention is needed, particularly in medically complex (e.g., cancer) patients, to mitigate the effects of adverse events, disease progression, and medical error. This challenging problem requires effective clinical surveillance, early recognition, timely notification of the appropriate clinician, and effective intervention. In the hospital setting, "failure to rescue" (FTR) is a recognized safety failure.[1 3 4] To address FTR, hospitals have introduced new tools and processes (e.g., continuous monitoring,[5] early warning systems,[6] 'Rapid Response' teams[2]). Yet, death in bed remains common.[7 8]

Although inpatients may more likely experience clinical deterioration, outpatient deterioration remains a challenging problem, as clinicians are not immediately available to intervene. Ambulatory patients recovering from an acute event (e.g., surgery, illness), or those undergoing potentially hazardous treatments (e.g., chemotherapy), are at high risk for deterioration.[9] When early signs of deterioration are missed, it may lead to need for more acute care, readmission,[9] and often-preventable harm. Unfortunately, few outpatient systems reliably detect and prevent harm from unexpected clinical deterioration. An effective system must include both afferent (i.e., sensitive and specific detection) and efferent (rapid and reliable response) capabilities.[10] Currently, outpatient surveillance relies largely on a patient's or a caregiver's ability to recognize a problem and to communicate the situation effectively to a clinician. Patients and their families are perhaps the most effective detection system, and patient engagement in patient safety is an emerging priority, especially in cancer care.[11-14] Yet, reliable systems to harness this potential do not exist. Efferent systems require appropriate response and escalation of care to prevent further deterioration and correct the situation. Unfortunately, delayed clinical recognition and response are common.[15]

The Vanderbilt-Ingram Cancer Center, in collaboration with human factors and systems engineering faculty in the Center for Research and Innovation in Systems Safety (CRISS), as well as faculty in our Schools of Engineering and Management, created the Cancer Patient Safety Learning Laboratory (CaPSLL). We partnered with surgeons, oncologists, nurses, staff, and adult patients with head or neck, lung, and upper gastrointestinal cancer undergoing or recovering from outpatient treatment and their lay caregivers with the goal of more reliably detecting and effectively responding to unexpected clinical deterioration. We employed a systems engineering oriented user-centered design (UCD) process[16 17] to analyze, design, develop, implement, and evaluate innovative tools and processes to address this complex patient safety problem. The project was based on three Specific Aims:

Aim 1. *To create and refine software tools and a predictive model for a surveillance-and-response system to prevent harm from unexpected all-cause clinical deterioration in outpatients receiving cancer treatment*. We combined passive surveillance, in which patients wore wrist sensors (e.g., Fitbit) that provided near-continuous activity, heart rate, and geolocation data, and active surveillance with mobile app-based patient/caregiver reporting of non-routine events (NREs)[18-20] and validated patient-reported outcome measures (PROMs).[13 21-23] These data were used to create a personalized predictive model of deterioration, using ensemble machine learning methods to predict the possible occurrence of unplanned treatment events (UTEs; e.g., readmissions, ED visits, cancer therapy changes). We also explored how to implement a mobile app to notify clinicians to enable a timelier response to clinical deterioration.

Aim 2. *To create and refine processes and training that engage patients and their caregivers as active and reliable participants in detecting and reporting potential clinical deterioration*. We applied high-reliability organizational (HRO) principles and theories to develop processes and training for the relevant "team" – the cancer patients, their caregivers, and the clinicians who need to respond to signals from the surveillance system. Inculcating these teams with safety-focused HRO concepts and tools, we measured the resulting 'safety organizing behaviors' through sequential surveys of all team members.

This project was one of the first to study the application of HRO principles to patients and lay caregivers.

Aim 3. *To implement in the operational environment and formally evaluate the integrated detection and response tools and processe*s. We hypothesized (**H1**) that implementation of the fully integrated system will decrease the likelihood and severity of UTEs. Furthermore, with the incorporation of a patient/family focused HRO framework, we hypothesized that this system will increase NRE reporting (**H2**) and decrease clinician response time (**H3**).

The resulting tools, methods, and predictive model will be scalable to other cancer types and will be generalizable to other institutions and to other high-risk outpatient populations (e.g., heart failure).

Background

More than 1.6 million new cases of cancer occur annually in the United States.[24 25] Cancer often requires multi-modal therapy coordinated by multiple providers.[26 27] The U.S. National Academy of Medicine declared a *crisis in quality cancer care*, calling it, among other things, insufficiently patient centered, with limited patient engagement.[24 25] Cancer surgery, chemotherapy, and radiotherapy are all associated with significant treatment toxicity; more than 50% of elderly cancer patients receiving chemotherapy have at least one severe toxicity.[28] Furthermore, cancer care provides multiple opportunities for medical errors and associated harm.[29-34,35,36] Oncology patients, especially those who are elderly, have multiple comorbidities, or are medically underserved and/or of low socioeconomic status, are at particular risk of unexpected clinical deterioration from treatment toxicities or preventable harm.[37 38]

Cancer is increasingly being treated in ambulatory settings, where clinicians are not immediately available to intervene. Outpatients recovering from an acute event (e.g., surgery), experiencing illness post-discharge, or undergoing chemo- or radiotherapy are at high risk for clinical deterioration. Early signs of deterioration can be missed, leading to the need for more acute care (e.g., admission[9]) and preventable harm. Prior research found that, for cancer patients at academic cancer centers, 2 to 19% of admissions are preventable, and 31% for oncology patients in community hospitals[6,7,39]; unplanned hospitalization for outpatient chemo- or radiotherapy ranges from 14 to 37%.[9]

Preventing harm from unexpected clinical deterioration requires the ability to detect deterioration (i.e., sensitive detection) and swiftly respond to it. Numerous systems have been developed for inpatients including combining continuous monitoring technology[5 40] and early warning systems,[6 41 42] yet, there has been limited work using these technologies and systems to support outpatient cancer care[43-45,2 46] Some research has aimed to detect deterioration with more frequent clinic visits, phone calls,[30,31] and even ambulatory RRTs.[47,48] However, these approaches still typically rely on patient and/or caregiver recognition of early signs of deterioration and appropriately communicating it to activate a response.

In this study, we leveraged various technologies (e.g., smartphones, FitBit) to support proactive identification of clinical deterioration in outpatient cancer care. These approaches are emerging, but there remains limited evidence regarding their feasibility for continuous activity monitoring of ambulatory cancer patients[9 49-51] and their relationship with patient-reported outcome measures (PROMs).[52] Based on evidence from highly reliable care and palliative settings,[43-47] we applied a holistic approach to develop and implement a predictive system to detect and respond to clinical deterioration. This work was grounded in systems engineering approaches to patient safety, integrating the concepts of non-routine events (NREs) – defined as any deviation from optimal care[53 54] – and unplanned treatment events (UTEs) to better understand safety in outpatient cancer care. We detail the results of an iterative design and development process to create and validate a surveillance-and-risk prediction system intended to improve the detection and response to clinical deterioration in cancer outpatients.

METHODS

Study design

To develop a holistic and integrated approach to managing clinical deterioration in cancer outpatients, we used a human-centered design (HCD) process.[16 17] Our goals were to 1) gain a thorough understanding of the issues, opportunities, and challenges associated with the reliable detection of, and response to, unexpected deterioration across all stakeholders; 2) design and prototype a surveillance-and-risk prediction system; and (3) to evaluate the prototype by engaging clinicians in a realistic vignette-based usability and validation study. Multiple cycles of the HCD processes were completed to develop our system of patient-based data capture, an artificial intelligence (AI) based predictive model of 7-day risk for experiencing an unplanned treatment event, and an active risk communication system (RCS).

Setting and participants

The study occurred in the outpatient cancer clinics within a National Cancer Institute (NCI)-designated Comprehensive Cancer Care Center at an academic medical center in the Southeastern United States. Inclusion criteria for patient participants were adults (age > 18) with a diagnosis of any stage of head or neck, lung, esophageal, or pancreatic cancer who were receiving curative surgery chemotherapy and/or radiotherapy, who were able to provide informed consent, and who were willing to participate for at least 3 months. Family caregivers, who supported the care of eligible cancer patients, as well as physicians and staff involved in treating these patients were also eligible to participate in this study (e.g., reporting unplanned treatment events).

Conduct of Study

Potential participants were identified by a trained research assistant (RA) through direct weekly EHR surveillance and interactions with clinical co-investigators in the oncology clinics to identify and discuss prospective study candidates.[55] Once candidate participants were identified, the RA coordinated with the attending oncologists to attend their next scheduled clinic appointment to introduce the study opportunity via a short (10-15 minute) face-to-face recruitment presentation. Patients who requested or seemed to need more time to consider participating in this study were invited to take printed educational materials home with them to review. In such cases, the RA followed up with each patient approximately 1 week after initial contact to see if they had made a participation decision.

Once a patient enrolled in the study, the RA attended participants' weekly clinic visits, scheduled treatments, or before infusion appointments to administer the previously validated Patient Comprehensive OpeN-Ended Survey (PCONES) to elucidate NREs that the patient had experienced since their previous clinic visit.[56] The typically weekly surveys were administered in discrete locations within the areas listed above to maximize privacy.

After obtaining written informed consent, patients and their family caregivers were provided with a 30- to 45-minute, comprehensive "Set-Up Meeting," prior to the start of study activities, on the use and management of the passive surveillance technologies for health and activity monitoring and on active reporting of symptoms, health status and care events (e.g., via weekly surveys). Because many of the participants' treatment modalities involved 60- to 120+-minute chemotherapy sessions, this meeting typically took place during a patient's infusion appointment. During this meeting, the RA guided the patient through the onboarding forms (e.g., Demographics, Geolocation form if applicable, etc.) and provided training and instructions for using the wearable activity monitor (i.e., Fitbit) and the MyCap app on the patient's smartphone. The patient then received their activity monitor and Bluetooth-enabled weight scale, with instructions on how to use these devices and recommended guidelines for optimal data collection (e.g., using and charging the devices daily, instructions on filling out PROMs each week using MyCap app, etc.).

Supplementary video-based training was also used as needed, especially during surges of the COVID-19 pandemic.

Outcomes Measurement: Unexpected Clinical Deterioration

An NRE is defined as *any event that deviates from expected or optimal care for a specific patient in a specific situation*. For our patients, an NRE was generally a care situation that deviated substantively from the care they expected or desired to receive. A UTE was defined as a major unanticipated change in care requirements including unplanned emergency department (ED) visits, hospital admissions, or major change in treatment plan.

Most NREs were reported by patients (and occasionally by their primary lay caregiver), although clinicians could also report NREs. The primary outcome for the study was the incidence of unplanned treatment events (UTEs). UTEs could be reported by patients using the MyCap app and/or directly to clinicians during clinic visits. UTEs were also identified through weekly queries of the EHR. Subject matter experts (i.e., clinical co-investigators) regularly reviewed the reported NREs for confirmation subsequently identified the occurrence of UTEs.

PART 1: Developing a passive and active surveillance system

Passive surveillance

For our passive surveillance system, patient participants used a low-cost activity monitor (i.e., Fitbit Charge 2), a smartphone either owned by or provided to the patient, and the hospital's EHR. The activity monitor was used to collect the following moment-to-moment health and activity data: calories, sedentary minutes, active minutes, sleep, steps walked, resting heart rate, average heart rate, minimum heart rate, and maximum heart rate. Based on clinician feedback gathered during the interviews, we added a Bluetooth-enabled smart scale, which collected and transmitted at-home patient weight to the activity monitor, to improve the regular capture of more accurate patient weights. With patient approval, we collected geolocation data from their phone's Google Maps app for up to 10 patient-selected "healthy" (e.g., church, gym, sibling's house, grocery) and "healthcare" locations (e.g., pharmacy, hospital, emergency department) to measure activity outside the home. We developed and used a computer algorithm that applied pre-specified temporal and spatial rules to the global positioning system (GPS) data to determine if patient trips outside the home qualified as visits to patient-designated locations or healthcare locations.

Finally, the EHR provided a set of clinician pre-specified clinical variables as potential biomarkers for clinical deterioration. We used a modified Delphi methodology with eight oncologist co-investigators who reviewed and prioritized a comprehensive list of 33 objective clinical EHR-based variables using the criteria that the variable was likely to be a reliable predictor of incipient clinical deterioration. This process was conducted asynchronously via iterative email questionnaires. The final set of five clinical predictor variables were patient weight (whether measured at clinic visits and or via the Bluetooth scale at home) and four laboratory values: serum albumin level, total protein level, total bilirubin, and hemoglobin. The data streams produced by each of these passive sensors served as independent inputs to our predictive models of 7-day risk for UTE.

Active surveillance

We used the MyCap™ smartphone app[57] to collect patient and family caregiver provided patient-reported outcome measures (PROMs) on their mobile devices especially when they were outside the clinical setting. These data were sent from MyCap directly to the REDCap database. We trained and encouraged patients and family caregivers to use MyCap to report NREs *anytime* they experienced them

and to fill out PROMs on a weekly basis. NREs were reported using the PCONES via MyCap and/or in person or by phone with a trained RA, as preferred by the patient.

PROMs included completion of a weekly National Comprehensive Cancer Network (NCCN) distress thermometer,[58] NCCN symptoms list, a Global Health Score,[59] and selected items from the Consumer Assessment of Healthcare Providers and Systems (CAHPS). The included questions addressed patient experiences of problems related to social determinants of health (e.g., transportation, childcare, housing), family (e.g., children, partner, family health), emotional state (e.g., depression, fears, nervousness), and the quality of the patient's interactions with their care team (e.g., communication and listening). The PROMs were a distinct input into the predictive model of UTE risk.

Results – Part 1: Passive and Active Surveillance

Patient recruitment and accrual

Seventy-one eligible patients were contacted based on our EHR-based pre-screening process and clinician recommendations. Fifty patients enrolled in the study (**Figure 1**), representing a 70% yield of those we approached. Of these 50 consenting patients, five withdrew during the study but allowed data to be kept, four patients died, and 41 completed the study in full (between 6 weeks minimum and 6 months maximum). Patient demographics are shown in **Table 1**.

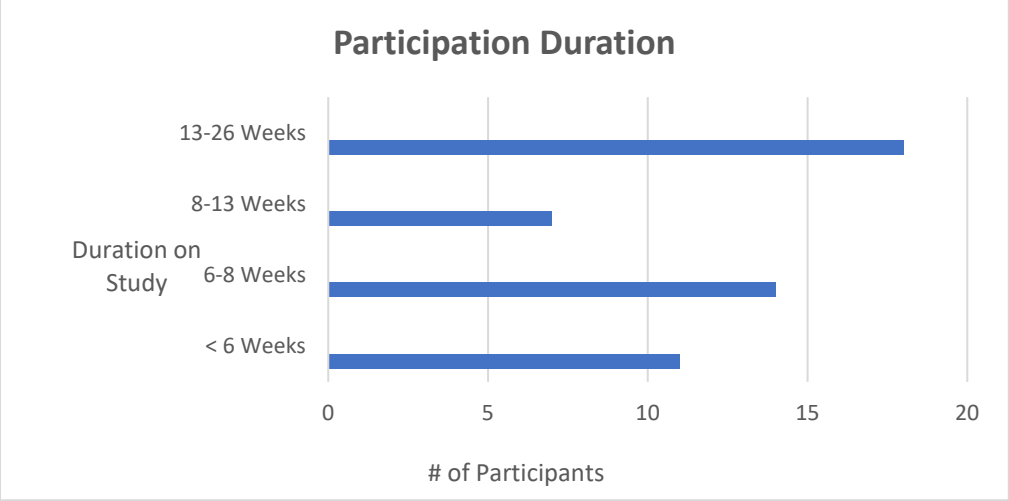

Figure 1. Distribution of Enrollment Duration

TABLE 1. Demographics of Enrolled Patients (N = 50)

Variable (ordered by frequency)	**Value**
Age	
Mean years, Standard deviation, (Range)	57 ± 9 (35-78)
Sex (%)	
Male	74%
Female	26%

Ethnicity (%)	
White or Caucasian	86%
Black or African American	8%
American Indian or Alaska Native	6%
Religious Affiliation (%)	
Protestant	56%
Other	26%
Catholic	10%
N/A	8%
Education (%)	
High School/GED	24%
Some College Education	20%
Associate's/Trade School	18%
BS/BA	16%
Advanced college degree (%)	12%
N/A	8%
No Diploma	2%
Household Income (% in $1,000)	
25 - 50	22%
More than 150	18%
75 - 100	18%
100 - 150	14%
50 - 75	12%
N/A	12%
Less than 25	4%
Cancer Type (%)	
Head and Neck	66%
Gastrointestinal	18%
Pancreatic	10%
Lung	6%
Treatment Type (%)	
Chemotherapy	96%
Radiation	68%
Surgery	12%
Immunotherapy	6%

Passive Surveillance

Data included EHR laboratory data and activity monitor data for all 50 patients during their enrollment. Over half of enrolled participants had missing activity monitor data due to challenges associated compliance (e.g., device removal, failure to routinely charge or synchronize them, etc.). Even with reminders from the RAs and treating clinicians, these patterns persisted. Moreover, even when the activity monitors were used appropriately by patients, there were unexpected occurrences drop-outs of heart rate and sleep data.

Seventy-four percent of patients used their smart scales routinely, whereas only 40% allowed access to their geolocation data. The EHR was effective in picking up signals of clinical deterioration. Patients demonstrated comfort and confidence actively reporting PROMS (90% data capture), including symptoms, events, and CAHPS survey items.

Active Surveillance

Patients submitted 347 self-reports using the MyCap app, including 305 PROMs (see **Table 2**), detailing various problems that they experienced each week. Additionally, 229 NREs were reported through weekly PCONES, either by patient self-reports using MyCap at home or by RA-facilitated administration of the PCONES during clinic visits.

With regard to EHR data, 78% of our patients exhibited low hemoglobin, and 10% had low albumin.

Table 2. Summary of PROMs (305 in total; N = 50 patients)

Measure	Value
Overall Health (mean, standard deviation, 0-100 scale, low-high)	72±17.6 (0-100)
Distress Thermometer (mean, standard deviation, 0-10 scale, low-high)	3.6±2.8 (0-10)
Care Experience in last week (mean, standard deviation, 0-10 scale, low-high)	9.4±1.2 (0-10)
Physical problems	
Fatigue	42%
Constipation	27%
Pain	26%
Eating	25%
Mouth sores	25%
Breathing	14%
Nose dry/Congested	12%
Tingling in hands/feet	11%
Appearance	10%
Sleep	10%
Nausea	9%
Feeling Swollen	9%
Diarrhea	8%
Memory/Concentration	8%
Skin dry/itchy	7%
Indigestion	6%
Changes in Urination	5%
Getting around	4%
Bathing/Dressing	2%
Sexual	2%
Emotional problems	
Worry	38%

Nervousness	19%
Fear	14%
Depression	13%
Sadness	10%
Loss of interest in usual activities	6%
Practical problems	
Treatment decisions	16%
Dealing with insurance/financial issues	10%
Work/School	5%
Housing	3%
Transportation	3%
Child care	2%
Family problems	
Family health issues	10%
Dealing with children	5%
Dealing with partner	3%

Of the 229 reported NREs, 88% (N=203) occurred at home, and over half (57%, N=131) were related to symptoms of disease. Conversely, 43% of reported NREs were related to side effects of treatment or direct treatment effects. They were multifactorial, with complex etiology. Only slightly more than half of all NREs were reported to clinicians or staff (often with encouragement from the RA). Common symptoms reported via PCONES include Pain (89 incidents reported), Difficulty swallowing (34 incidents), Nausea (23 incidents), and Fatigue (20 incidents). Symptoms were classified into 48 different categories, and each symptom was reviewed by a clinical co-investigator to determine if it was treatment related. **Table 3** provides examples of patient-reported NREs.

Table 3. Sample of patient reported NREs

Equipment or technology related
Patient was having his feeding tube adjusted and the care team involved forgot to clamp the tube, resulting in a leakage. Patient's advice about clamping the tube was not heeded by care team involved.
Consequences of treatment
*Patient experienced severe nausea and cramping with chemotherapy. Began to question faith and had very dark thoughts, to the point of considering suicide. Patient waited out the nausea and pain and prayed to deal with his suicidal thoughts. Said he had sent a message to his doctors via [*Confidential Patient Health Portal*]. As a result, patient was waiting to see his doctors to discuss stopping chemotherapy treatments.*
Patient factors
Patient had increasing soreness and pain over the course of a weekend but forgot they had pain medicine that they could take. Even though this event occurred over the weekend, they did not alert their clinician about their uncontrolled pain until the following Tuesday.
Patient takes ropinirole for restless legs but forgot to take this medication before chemotherapy.
Patient had an adverse response to chemotherapy involving involuntary spasms while sitting.

Smart scales were not included in the original surveillance architecture; after they were added based on clinicians' recommendations, patients reliably used them to capture weight during their enrollment. Sixty-eight percent of our enrolled patients lost weight during their enrollment period.

Additionally, 18 incidents of weight loss were related to a reported NRE. Geolocation data was not reliably captured due to frequent changes in the security protocols of Google and Google Maps, reduced patient activity outside the home during the COVID-19 pandemic, and patients' general reluctance to share geolocation data even with the research study's privacy protections in place and explained.

Patient outcomes: Unplanned Treatment Events (UTEs)

Among the 50 enrolled patients, 16 patients (32%) experienced 30 UTEs (i.e., unplanned ER visit, hospitalization, or major change in care plan). Ten of these 16 patients experienced two UTEs, and one patient experienced three UTEs. Contributors to these UTEs included intractable nausea and/or vomiting (n=6 occurrences), malnourishment and/or weight loss (n=6 occurrences), infections (n=6 occurrences, 1 sepsis), hemoptysis (n=2 occurrences), unexpected complications with G-Tube (n=4 occurrences), chemotherapy reactions (anaphylaxis, angina; n=2 occurrences), and one occurrence each of difficulty breathing, mucositis, severe hypokalemia, and thrombosis. Nearly 2/3 of the UTEs (63%) required hospital admission.

PART 2: Building a Predictive Model

We developed and validated independent statistical models for each of the four components of our surveillance system – PROMS, EHR data, Fitbit data, and geolocation data – to predict the class probabilities that a patient would experience one or more UTEs within the following 7 days. Prior to model development, dimension reduction techniques, such as Pearson correlation analysis, were applied to the set of candidate predictor variables to eliminate redundant variables from each model. Ensemble learning techniques were applied to the model outputs to calculate a 7-day UTE risk score for each patient. Because UTEs are rare events, they were oversampled using the Synthetic Minority Oversampling Technique (SMOTE) to balance the dataset.[60] A random forest classification model was trained to predict 7-day UTE risk.

The accuracy of the prediction models were calculated using the mean of stratified five-fold cross-validation with 10 repeats. We used sensitivity, specificity, area under the receiver operating characteristic curve (AUC-ROC), and the F-measure to evaluate model performance.

Results – Part 2: Performance of UTE risk prediction model

Table 4 shows the performance of four independent 7-day UTE risk prediction models using (1) PROMs data, (2) clinical data from the EHR, (3) activity monitor data, and (4) geolocation data. The PROMs model and EHR model demonstrated moderate performance for the prototype. Models based on activity monitor data and geolocation demonstrated low sensitivity and therefore suboptimal performance.

Table 4. Performance Metrics of Independent Prediction Models

Model	Accuracy	Specificity	Sensitivity	F-measure	ROC AUC
PROMs	0.989	0.99	0.74	0.80	0.98
EHR	0.989	0.99	0.77	0.80	0.98
Activity Monitor	0.982	0.96	0	-	0.75
Geolocation	0.924	0.97	0.143	0.200	0.570

The suboptimal performance of the prediction models can be attributed at least in part to missing and unbalanced data. **Figure 2** illustrates the extent of missing data for some of the variables recorded by the activity monitor. Following data cleaning, about 42% of the collected data with all the features (heart rate, steps, sleep, etc.) relevant to the predictive model was considered in the construction of the predictive model. In the case of geolocation data, the 2-10 locations designated as "healthy" and "healthcare" by each participant did not adequately represent their outside activity, with 86% of the participants' movements categorized as "unknown." Similarly, participants did not consistently report PROMs through the MyCap app, resulting in 39% missing data during the enrollment period.

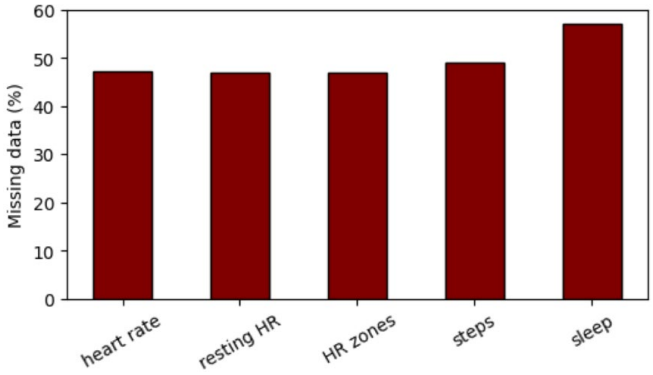

Figure 2. Missing heart rate and activity data

The distribution of classes in the classification dataset is highly imbalanced, with minority (UTE) and majority (non-UTE) classes having proportions ranging from 2% to 3% and 97% to 98%, respectively, across the various models. Despite employing the SMOTE technique to generate synthetic samples for the minority class, the data imbalance issue was not adequately resolved.

PART 3: Human-centered design of the risk communication system

Understanding the environment of use and user needs

We conducted 36 observations (over 80 hours and across 100 patient encounters) of clinicians, patients, and family caregivers in the cancer clinics to gain a thorough understanding of ambulatory cancer care and to develop preliminary design guidelines for the surveillance-and-risk prediction system. Observations focused on general clinic operations, including patient flow, information flow, and clinician workflow. We also observed clinic processes related to patient and family caregiver engagement, care team interactions, and clinician-technology interactions.

We supplemented observations with 17 interviews with oncology clinicians to understand the current processes by which clinical deterioration is detected, communicated, and managed. The clinician interviews focused on three themes: 1) structure and function of clinic teams; 2) improving teamwork between clinicians and patients and their caregivers; and 3) design of an optimal surveillance-and-risk prediction system. Participants included medical, surgical, and radiation oncologists, dentists, dieticians, pharmacists, nurse practitioners, and nurses working in the clinics caring for patients with head or neck, lung, esophageal, and pancreatic cancer.

To gain an understanding of patients' and caregivers' perspectives, we independently interviewed eight current and past cancer patients and their personal caregivers. Interviews of patient and family caregivers focused on four themes: 1) past episodes with cancer care; 2) people involved in care; 3) tracking of health; and 4) design of a surveillance system. Additionally, to represent the patient voice even more, our project team included a cancer survivor, a spouse of a former patient, and the director of the cancer center's patient and family advisory council as co-investigators; they were all engaged throughout development of the surveillance and risk system.

Interviews of clinicians and patients were approximately 1 hour in length, conducted using Zoom, audio recorded, anonymized, and transcribed by a professional transcription service. The transcribed interviews were uploaded into Dedoose.[61] Two qualitative researchers deductively coded each interview in a consensus-based process to detail the roles, activities, and tools/technologies involved in outpatient

cancer care and to identify barriers and facilitators to the five High-Reliability Organization (HRO) principles (see **Table 5**) – preoccupation with failure, reluctance to simplify, sensitivity to operations, commitment to resilience, and deference to expertise.[62]

Table 5. HRO coding structure

Category	Code	Definition
HRO principles [63 64]	Preoccupation with failure	Operating with a chronic wariness of the possibility of unexpected events that may jeopardize safety by engaging in proactive and preemptive analysis and discussion
	Reluctance to simplify interpretations	Taking deliberate steps to question assumptions and received wisdom to create a more complete and nuanced picture of ongoing operations
	Sensitivity to operations	Ongoing interaction and information sharing about the human and organizational factors that determine the safety of a system as a whole
	Commitment to resilience	Developing capabilities to detect, contain, and bounce back from errors that have already occurred but before they worsen and cause more serious harm
	Deference to expertise	Decision-making authority migrates to the person or people with the most expertise with the problem at hand, regardless of their rank
Barriers and facilitators to HRO	Barrier	A factor that hinders high-reliability cancer care
	Facilitator	A factor that supports or enhances high-reliability cancer care

Iterative design and evaluation

Following an HCD process,[65] we iteratively developed mock-ups of the risk communication system (RCS) that will be used to communicate patient predicted risk scores to their clinical team. Mock-ups were developed based on design guidelines developed from our clinical observations and interviews. For instance, during interviews with clinicians, we uncovered that patient weight changes (i.e., weight loss) are often a first warning sign that a patient is unwell at home. As a result, we gave patients Bluetooth scales to take home. We then incorporated a trend in patient weight over time into the RCS. The design guidelines indicated that the RCS prototype should include individual patient risk profiles and clinic dashboards to display the risk profile of all patients in a clinic panel to support clinic-wide surveillance and monitoring of UTE risk. An important design criterion was that the system needed to be integrated into the EHR and that it should include information on the patients and family caregivers (e.g., who they are, how to contact them). Once initial prototypes were developed, our multidisciplinary team of human factors engineers, user-interface design experts, clinicians, and informaticians conducted seven virtual design sessions using the MURAL platform[66] to refine the RCS prototype prior to formative usability testing with end users.

We conducted formative usability testing of the RCS with three medical oncologists, a thoracic surgeon, two nurse practitioners, and a nurse who regularly perform outpatient oncology care. To provide real-world context, we developed two realistic patient vignettes using anonymized actual patient data collected during our study to populate the RCS interface. In 1-hour Zoom sessions, we presented the two patient scenarios via the RCS mock-up to clinicians and asked for their feedback on the interface elements using a semi-structured interview guide. At the end of the session, clinicians completed the system usability scale (SUS)[67] in Qualtrics and answered additional open-ended interview questions on the overall safety, acceptability, and potential effectiveness of the RCS to support their workflow and patient care.

All sessions were audio recorded, transcribed, and uploaded into Dedoose for qualitative analysis. In Dedoose, we coded each transcript for aspects of the RCS that clinicians "liked," "disliked," and "would like to have" (things not present on the interface currently). We also coded all transcripts for the 3 C's of teamwork – communication, coordination, and cooperation.[68]

Results – Part 3: Usability of the risk communication system

Physicians and nurses (n=7) indicated very good usability of the RCS, with an average SUS score of 76 of 100 (median=80; range: 60-85).[67] A SUS score equal to or greater than 72 is considered "good" usability, whereas a score greater than 85 is considered "excellent."[69] Clinician participants liked that the high-level dashboard allowed them to quickly scan their patient panel and identify patients who needed care (e.g., phone call from a nurse, clinic visit for IV fluids). They also liked that the interface displayed the patient's next appointment. In the patient-specific mock-up (**Figure 3**), participants liked the information on patient weight changes over time, as this can be an important indicator of clinical deterioration.

Figure 3. Clinician-facing RCS individual patient mock-up

The tracker for patient symptoms (e.g., nausea and throat swelling) was also helpful to clinicians. Participants identified several areas for improvement in the RCS. For instance, participants recommended removing some information, such as the patient's cancer stage, risk score percent change, time on study, activity monitor data integrity, and last visit information from the high-level dashboard interface. Participants suggested the terms "unplanned treatment event (UTE)" and "non-routine event (NRE)" be removed, as this is jargon that clinicians did not understand; instead, we replaced this text with the phrase "patient event log."

From this analysis, we identified design modifications recommended across the diverse interviewee types and gathered insights on how the RCS may influence clinician teamwork. For instance, clinicians reported that they would need to communicate with other members of the care team (e.g., nurse, pharmacist) after reviewing a high patient risk score to coordinate next steps (e.g., a phone call to the patient). We discovered that the RCS needed to support and streamline the communication and coordination activities After these design modifications are made, we plan to test the revised mock-ups in a future real-world (i.e., clinic) RCS evaluation.

Barriers and Facilitators to HRO

In 25 interviews of clinicians and patients, we identified 218 excerpts as barriers and 167 excerpts as facilitators to resilience cancer care. **Table 6** depicts a comprehensive list of the barriers and facilitators within each HRO principle. The interview data were also used to create role networks depicting the individual and team activities as well as the communication and coordination involved in outpatient cancer care. The role networks and findings regarding the structures and processes supporting or impeding safety organizing behaviors are being used to develop design guidelines for a future surveillance-and-risk prediction system and supporting team processes for reliable detection and response.

Table 6. Barriers and Facilitators to HRO

HRO Principle	Barriers	Facilitators
Preoccupation with failure	• Role ambiguity • Coordination of care • Suboptimal management and availability of time • Communication	• Coordination of care • Formal engagement of patients and caregivers in the process of care • Formal safety protocols
Reluctance to simplify interpretations	• Organizational rigidity • Poor communication	• Team processes • Time management • Working through details • Using tools to embrace complexity
Sensitivity to operations	• Workload and staffing • Team cohesion and coordination • No existing surveillance system	• Accessibility to clinicians • Supporting technology (patient portal, telehealth, text messaging) • Shared workspace • Communication and huddles • Surveillance and monitoring of worrisome patients
Commitment to resilience	• Workload and work balancing • Lack of care management system • Limited family caregiver support • Sub-optimal systems	• Patient engagement and developing trust • Formal and information huddles • Multiple communication channels for patients and clinicians • Quick response to deterioration (incorporate this with above?) • Support of ancillary staff
Deference to expertise	• Accessibility of expertise • Making time for all patients	• Multidisciplinary care • Patients' expertise and advocacy • Family engagement

DISCUSSION

Our study detailed a holistic, human-centered design process of creating and testing a robust system to surveil, predict, and communicate near-term risk for clinical deterioration of ambulatory cancer patients. Although the technologies needed to build clinical surveillance systems for ambulatory care applications are commercially available and reasonably affordable, integrating these components to create a safe, reliable and usable system that is seamlessly integrated into clinical care systems remains technically and operationally challenging. Our prototype system demonstrated modest, but consequential and encouraging, performance. We were able to capture meaningful data from 50 patients

undergoing ambulatory cancer treatments over 3 to 6 months through passive capture of heart rate and activity data using a commercial activity monitor, geolocation data from smartphones, weight from an in-home Bluetooth-enabled scale, and EHR-derived clinical variables. Via a user-friendly smartphone app, we also actively captured a range of PROMs. These data were used to develop four independent predictive models of patients' risk of UTEs in the subsequent week. The EHR model and PROMs model both demonstrated moderate performance in predicting the 7-day risk of significant patient deterioration.

We also developed a system prototype to deliver synthesized risk information to both responsible clinicians and back to the patients and their caregivers. Design guidance for the delivery, escalation, and response to risk data was obtained through interviews conducted with clinicians working in the cancer clinics. This guidance recommended the integration of the following structural and process attributes: a dashboard to display UTE risk per clinic patient panel; individual risk profiles for each patient; daily surveillance and monitoring of patient risks scores by a charge nurse (or other frontline clinician); future integration of the RCS with the hospital EHR; charge nurse-triggered escalation of high/urgent risk to clinical fellows and faculty physicians; clinical response activation by faculty physician; and close-the-loop confirmation of clinical response and patient outcome by charge nurse. Future work will be needed to implement and evaluate this promising tool for communicating risk and guiding appropriate response.

Relevance to Existing Literature on Health Monitoring in Ambulatory Care

Our prototype system is among only a few apparently in development to improve the health monitoring of cancer outpatients specifically and in complex outpatients more generally. The MyPal platform, a multi-national digital intervention, is being developed and validated (n=9 patients) to improve palliative care in adult patients with hematologic malignancies.[70] That system includes an activity monitor (Fitbit), a mobile app for PROMs reporting, medication management, uploading images, and viewing health activity collected from the Fitbit. The system also includes a web application for the care team that includes an aggregated (i.e., clinic) dashboard, individual dashboard, a discussion tool focused on issues of nonadherence to treatment. Pavic et. al.[71] completed a feasibility study (n=30 patients) of a continuous monitoring system for cancer patients in palliative care. This system also includes an activity monitor and an app for PROMs reporting. Owusuaa et. al.[72] conducted a multi-center prognostic study (n=867 patients) of a system to predict 1-year mortality in patients in general oncology inpatients and outpatient clinics. This study evaluated three predictive models: the first with a "surprise question" to managing clinicians ("Would I be surprised if this patient died in the next year?"); the second with the surprise question along with selected patient clinical characteristics; and the third that also added patient laboratory values. The model with the surprise question, clinical characteristics, and laboratory values demonstrated better discriminative ability in predicting mortality than the independent models.

Outside of oncology, Li et al.[73] developed a prototype system (n=25 patients) to predict clinical deterioration on heart failure patients recently discharged from the hospital. Like our system, their system uses the Fitbit Charge activity monitors, cloud-based data management and processing, and machine learning to collect and analyze multimodal data from patients. A model based on sleep, step, and heart rate data significantly outperformed the standard clinical approach for predicting readmission. The system demonstrated effectiveness in predicting 30-day deterioration based on the first 10 days of data collection.

Though smaller in scale, our system is most similar in design and scope to the MyPal platform. Key differences, however, include the routine collection of weight and EHR data and, most importantly, the development and implementation of a predictive model that estimates individual risk for 7-day clinical deterioration. The aims of this small sample of development and validation studies, including Li's study in heart failure, is the same: improve care through improved patient engagement. However, it is noteworthy that all these published studies have struggled to recruit and retain patients.

This struggle underscores the opportunity for an HRO approach that engages patients and family caregivers early in both their care and in the design of systems intended to help them.

Lessons Learned and Remaining Challenges

The anticipated backbone of our passive surveillance system - heart rate, physical activity, and sleep data collected from wrist-worn activity monitors (i.e., Fitbit Charge 2) - as well as geolocation data collected from patients' smartphones were ineffective in predicting UTE risk scores, largely because of operational barriers leading to appreciable missing data. Specifically, the lengthy enrollment process required for patient education and device set-up, the added burden of daily device management (e.g., participant reliably wearing, charging, and syncing), and the complexity of data management (which was compounded by various and frequent software updates by Google and Fitbit, including changes to privacy and security settings) were all deterrents to patient adoption and use.

The utility of geolocation data for risk prediction modeling was especially limited by technical, operational, and situational factors. First, extracting geolocation data from the Google Maps app on the patients' smartphones required a manual multi-step process. Determining whether patients visited their pre-selected and approved locations necessitated developing custom computer algorithms. Also, one quarter of enrolled patients declined to allow us to capture geolocation data due to privacy concerns (i.e., potential for misuse of personal data). Perhaps most importantly, the study unexpectedly occurred during the COVID-19 pandemic, when cancer patients deliberately changed their behaviors and out-of-home activity patterns. Finally, extensive processing was required to clean the data and to format it appropriately for use in the predictive models. In summary, due to high levels of missingness in the patient activity monitor and geolocation data, we could not conclusively determine the effectiveness of variables derived from these sources in predicting clinical deterioration.

Despite these challenges, we were able to use machine learning-based predictive algorithms with PROMS,[74-81] NRE reporting, and clinical variables derived from the EHR[82 83] for deterioration surveillance in ambulatory cancer. Our interviews with oncologists reinforced the value of these efforts, given the consistent reluctance of patients to inform their clinicians when they are suffering or concerned about their health and well-being at home, often withholding experiences of pain, severe nausea, changes in self-treatment practices (e.g., stopped taking a medication), and/or other clinically relevant events until their next scheduled clinic visit, if at all. This undermines the well-being of patients and jeopardizes safe and effective care provision.

Although the RCS produced some encouraging results using PROMs and EHR data, it is important to note that patient-centered clinical surveillance systems require patient engagement and, more importantly, patient work. For cancer patients who already feel overburdened by their diagnosis, prognosis, and disease management activities, the effort and predictive benefits may not be sustainable. Future research is needed to improve patient acceptance and compliance with system components, especially the activity monitors and geolocation tracking. Recommended next steps include simplifying the patient onboarding process (i.e., education and training), reducing the burden of daily device management, and improving the inclusion of family caregivers as critical members of the care team. Encapsulating these recommended changes within a broader HRO design and management approach is recommended to realize a transformational, patient-centric model of ambulatory cancer care. The HRO analysis found numerous facilitators of high reliability already in place in the participating cancer clinics. However, the implementation and coordination of many of the identified HRO practices and procedures are not uniform across the various clinics and ancillary services cancer patients frequently navigate during the diagnostic and therapeutic stages of care. These gaps create variability and fragmentation across the care system, which ultimately undermines the ability to fully realize high reliability.

In the highest-performing organizations, HRO principles are manifested through behaviors and practices of individuals and teams and across all work. Carayon's Systems Engineering Initiative for Patient Safety (SEIPS) 3.0 model re-imagines patient care as a *journey* to describe "the spatiotemporal distributions of patients' interactions with multiple care settings over time."[84] The SEIPS 3.0 model can be used to reframe modern cancer care as a continuum in which HRO principles are weaved throughout the system intentionally and thoughtfully to achieve uniform, high-quality, patient-centered care at each step of the way. Moving away from the model of siloed clinical microsystems is the first step.

Despite expanding the scope of our study (i.e., adding GI and pancreatic cancer) and additional patient recruitment throughout a no-cost extension year, we were unable to formally evaluate the response arm CaPSLL's surveillance and response system. Specifically, we were unable to formally test Aim 3's original hypotheses primarily due to low accrual during the COVID-19 pandemic as well as, more generally, patients' reluctance to enroll in research immediately after receiving a cancer diagnosis (unanticipated during project design and initial roll-out). Even in enrolled patients, both COVID and the work of managing cancer had secondary effects on the usefulness of the FitBit and geolocation data, the data sources we had anticipated would produce the strongest signals of deterioration in our predictive model. As our results show, we had very high rates of missing data from these sources of passive surveillance. This is consistent with patient fatigue and distraction from managing cancer, reduced levels of activity outside the home during the pandemic, and the burden of managing the research devices as well. In consultation with our External Advisory Board (consisting of leading human factors and cancer researchers), we determined that it would be imprudent and potentially counterproductive to our project's core objectives to implement a suboptimal predictive model prematurely in the cancer clinics. Implementing an unreliable model could well undermine long-term trust and confidence of our oncology colleagues in the system. Instead, we invested our efforts in optimizing the surveillance arm, developing design guidelines based on HRO principles and context-specific findings. We are now well positioned, with additional funding, to fully implement and formally evaluate our integrated surveillance-and-response arm in a targeted cancer population (e.g., head and neck cancer).

Future work will need to focus on designing, developing, and pilot testing a parallel clinical response system that incorporates the predictive insights and makes use of the delivered data to realize a fully integrated surveillance-and-response system. Merging the RCS prototype and HCD approach documented here with implementation science is also a necessary next step for ensuring successful clinical uptake and achievement of the desired patient outcomes. An integrated systems approach must include a thorough evaluation of system performance in the contexts of clinical workflow, clinician and patient workload, patient-centered teamwork, bi-directional and closed-loop communications, and other safety-critical processes and attributes to facilitate adoption and decrease the likelihood of unintended consequences.

CONCLUSION

Our study provides initial evidence regarding designing and developing a system for surveilling the health and well-being of cancer outpatients and predicting risk of near-term clinical deterioration. The tools and technologies necessary to develop patient-centered surveillance-and-response systems are becoming more accessible and affordable, and their functionality is rapidly improving. There is work to be done to further engage patients and their family caregivers as members of the care team; to improve patient trust, acceptance, and compliance of wearables and smart apps; and to integrate at-home reporting of PROMS as a routine component of cancer care. Improving the onboarding and engagement of cancer patients and their family caregivers will go a long way in removing the barriers patients currently experience or perceive in contacting their providers during times of need.

Simplifying device management and automating data processing will support the seamless integration and implementation of commercial wearable technologies into modern ambulatory cancer care.

REFERENCES A list of references was not provided; please contact the P.I. for additional details.

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DISSEMINATION

As shown in the following list, CaPSSL has presented 18 scientific abstracts or posters at local and national conferences during the project period. Manuscripts are currently in preparation for submission to BMJ Quality and Safety ("Development and Validation of a Surveillance and Risk Prediction System for Clinical Deterioration in Ambulatory Cancer Care") and to Applied Ergonomics ("Achieving High Reliability Cancer Care

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