Vanderbilt's Cancer Patient Safety Learning Laboratory
Preventing Clinical Deterioration in Outpatients

VANDERBILT UNIVERSITY MEDICAL CENTER

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CRISS CENTER FOR RESEARCH AND INNOVATION IN SYSTEMS SAFETY

Matt Weinger, MD, MS; Dan France, PHD, MPH; Jason Slagle, PhD; Shilo Anders, PhD, Lane Stiles, PhD; Terrell Smith, MSN, RN; Laurie Novak, PhD; Carrie Reale, MSN, RN; Sankaran Mahadevan, PhD; Tim Vogus, PhD; Xiaoge Zhang, PhD; Lisa Kachnic, MD; Sarah Rohde, MD; Erin Gillaspie, MD; Zachary Kohutek, MD; Christina Bailey, MD; Christoph U Lehmann, MD; Robert Freundlich, MD; Kim Unertl, PhD; Brandi Calderon, MBA; Emma Schremp, BS; Akhil Choudhary, BS; Timothy Newman, BS; Russ Beebe, BA; Ralph Conwill, BSEE; Barbara Yudiskas, BSN, ARNP; *Students:* Bishop Rhodes; Hannah Slater; Ashley Batugo

Introduction

- **A common cause of preventable harm is the failure to detect and appropriately respond to clinical deterioration.**
- This challenging problem requires effective clinical surveillance, early recognition, timely notification of the appropriate clinician, and effective intervention.
- Ambulatory patients recovering from an acute event (e.g., surgery, illness), or those undergoing potentially hazardous treatments (e.g., chemo-therapy), are at high risk for deterioration. In outpatients, deterioration is more difficult to detect and intervention is more challenging.
- Missing early signs of deterioration can lead to the need for more acute care, readmission and even preventable harm.

Study Aims

Aim 1: To develop software tools and a predictive model for a surveillance-and-response system to prevent harm from unexpected clinical deterioration in outpatients receiving cancer treatment.

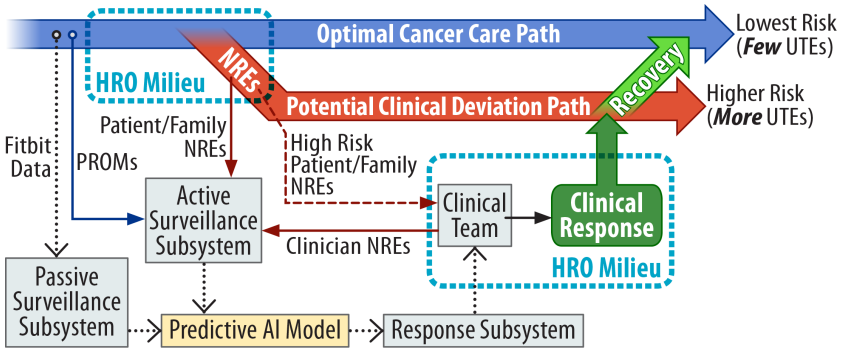
CaPSLL Cancer Patient Safety Learning Laboratory

Aim 2: To develop processes to engage patients and their caregivers as active participants in reliably detecting and reporting clinical deterioration. We will apply high reliability organization (HRO) principles and theories to develop processes and training for clinical micro-teams that include the patient/caregivers.

Aim 3: To implement in the operational environment and formally evaluate the integrated detection and response tools and processes.

Eligible Patients: Adult outpatients with ***Head and Neck, Lung*** or ***Pancreatic Cancer.***

Conceptual Model: Surveillance-and-Response System



AI: Artificial Intelligence	HRO: High Reliablity Organization	NRE: Non-Routine Event	PROM: Patient Self-Reported Outcome Measure	UTE: Unplanned Treatment Event

Methods

We are in the second year of a multi-year project. The patient data from our first study (planned enrollment of 60 patients, each studied for ≥8 weeks) will be used to create the AI model. A second study's data (2020-1) will be used to validate the AI model while a third study (2021-2) will evaluate the fully integrated system (including the response arm).

Active Surveillance: We developed and pilot-tested user-friendly mobile apps to collect patient-reported NREs and PROMs as well as a REDCap database for patient demographic and other study variables. We also developed processes to ensure that patients enter the required weekly data.

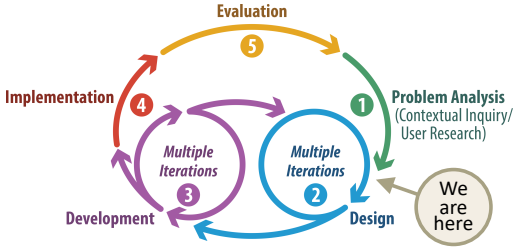
Passive Surveillance: We developed processes to capture, via a Fitbit Charge wrist activity monitor, real-time patient data including heart rate, steps, and sleep parameters. We are using the Google Maps app to capture geolocation data. All of these data are downloaded on a weekly basis.

Response Arm: We have begun to consider how best to deliver the results of the predictive AI model to responsible clinicians. This involves not only determining what to say (e.g., "Mr. Jones has a 83% probability of an unplanned treatment event in the coming week. Do you want to text him?") but to whom to send this and the technical capabilities and logistics to do so.

Patient Engagement: A critical determinant of success will be to engage patients and family members enrolled in the study. We have developed several methods to elicit patient input and enhance engagement.

Methods

We are employing a ***systems engineering-oriented user-centered design (UCD) process*** to analyze, design, develop, implement, and evaluate innovative tools and processes to address this complex patient safety problem.



Results

As of December 26, 2019, we have enrolled in the first study 13 head-and-neck cancer patients receiving outpatient chemo- or radiation therapy. We have successfully captured Fitbit data from all patients, and 35 patient/family reported NREs have been reported from 10 patients (range 1-5/patient). There have been 5 potential UTEs in 4 different patients. Enrollment in the first study continues.

Conclusions

In this complex study, we have **created innovative methods and tools to capture rich data from cancer outpatients that can be used as inputs to predictive AI models.**

Acknowledgements

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AHRQ Agency for Healthcare Research and Quality