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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., chemotherapy), are at high risk for deterioration. Deterioration in outpatients is more difficult to detect and there is less ready access to clinical services.
- If early signs of deterioration are missed, leading to the need for more acute care, readmission and often preventable harm.



Study Aims

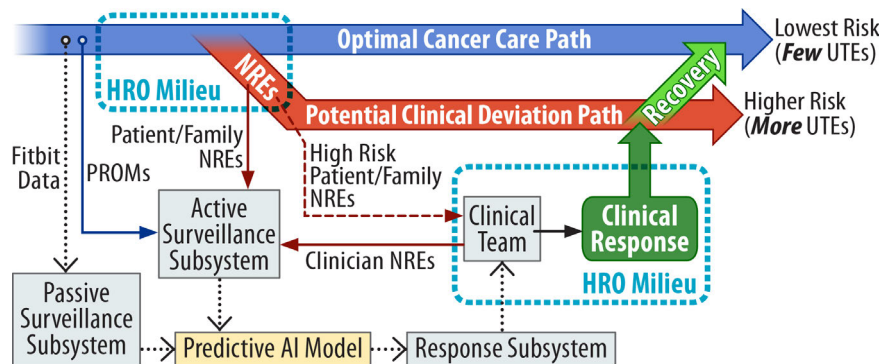


- Aim 1:** To create and refine software tools and a predictive model for a surveillance-and-response system to prevent harm from unexpected clinical deterioration in outpatients receiving cancer treatment.
- Aim 2:** To create and refine processes and training to engage patients and their caregivers as active and reliable participants in detecting and reporting potential clinical deterioration. We will apply high reliability organizational (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 **Lung Cancer** or **Head and Neck Cancer**.

Conceptual Model: Surveillance-and-Response System



Surveillance System:

- Passive Surveillance** – Patients will wear Fitbit sensors that provide near-continuous activity and heart rate, and will carry smartphones that record geolocation data.
- Active Surveillance** – Patients and their caregivers will use a mobile app to report non-routine events (NRE) and validated patient-reported outcome measures (PROM).

Response System:

- Predictive Model** – Personalized model of clinical deterioration, using ensemble machine learning methods to predict likelihood of near-term unplanned treatment events (UTE).
- Clinical Response** – Refine an EHR-linked mobile app for communicating and escalating abnormal laboratory values to clinical teams.

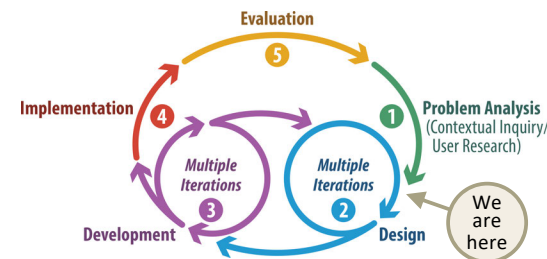
High Reliability Organization (HRO) Framework: HRO team training (i.e., Collective Mindfulness) will be provided to clinicians, patients, and caregiver engage and empower collective participation in the detection and response system.

Mapping Collective Mindfulness in Outpatient Micro-teams

CM Principle	Meaning	Clinical Team Behaviors	Patient/Caregiver Behaviors
Preoccupation with failure	Practicing with a chronic, proactive wariness of the unexpected	<ul style="list-style-type: none"> • Foster just culture for speaking up • Daily huddles and rounding • Event reporting 	Patients and family to report what happened or almost happened to them (i.e., NREs)
Sensitivity to operations	Ongoing interaction about expertise and current operations	<ul style="list-style-type: none"> • Closed loop communication • Information exchange • Shared situation awareness 	Patients and families participate in gap analysis between actual vs. theoretical system performance
Reluctance to simplify	Taking deliberate steps to question assumptions and create a more complete and nuanced picture of operations	<ul style="list-style-type: none"> • Adaptable/flexible strategies for reallocating resources and using compensatory behaviors • Planning before and during each episode of care 	Patients and families describe how well what was done to them achieves what matters most to them
Commitment to resilience	Developing and refining capabilities to quickly detect, contain and learn from errors and events	<ul style="list-style-type: none"> • Back-up (support) behavior • Performance monitoring • Shared mental models 	When things go wrong, patients and families try to understand what happened, why, and what can be done to prevent it from happening again
Deference to expertise	Ensuring that decision-making authority migrates to those with the most expertise	<ul style="list-style-type: none"> • Assertiveness • Collective orientation • Expertise 	The patient and family are accepted and respected as knowing more about their own care experiences than anyone else in the room

Methods

We will employ 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.



Study Timeline and Goals

Baseline Study (Years 1-2) [60 patients, 6 weeks each]

- Baseline patient-reported NREs and UTE data
- Initial data for creation of predictive model

Validation Study (Year 3) [60 patients, 8 weeks each]

- Pilot test in a live environment all of the surveillance tools and associated processes.
- Validate and refine the predictive model.
- Collect additional baseline data on NREs and UTEs.
- Test and refine the HRO-based training of both patients/caregivers and their interfacing clinicians.

Evaluation Study (Year 4) [60 patients, 90 days each]

- Conduct comprehensive clinical evaluation of the fully integrated tools and processes, including passive and active surveillance, predictive model, HRO-trained outpatient micro-care teams, and escalating response to test system performance.

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