Title of Project:

Acute Care Learning Laboratory - Reducing Threats to Diagnostic Fidelity in Critical Illness

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1. **Structured Abstract**

Purpose: Diagnostic errors and delays (DEOD) are a significant cause of preventable deaths in the USA, but an effective strategy to reduce their rates has not yet been implemented. Previous research has identified contributing causes, but implementation efforts have focused solely on the healthcare team's role, neglecting the complexity of organizational and system processes within the clinical environment. This project aims to address this gap by combining systems engineering and mixed-methods research approaches to gain a holistic understanding of the various factors contributing to DEOD in acute care settings.

Scope: Our group worked with key stakeholders from ICU to identify threats to the diagnostic process and used this information to guide the design, development, implementation, and evaluation of interventions aimed at addressing system vulnerabilities in acute care settings.

Methods: Our group used mixed methods to determine of the key modifiable drivers of DEOD among acutely ill patients. Insights gained from both these approaches were used to guide the effective and informed design and development of novel sociotechnical solutions.

Results: The complex sociotechnical system within which individual clinicians operate includes systems, processes, and institutional factors that contribute to DEOD. A multi-pronged approach was proposed to develop interventions through “Control Tower/Acute Care Multi-Patient Platform (AMP)” that have the potential to reduce DEOD.

Key Words: diagnosis error, sociotechnical systems, mix methods, systems engineering.

1. **Purpose (Objectives of Study).**

The main goal of this project is to decrease the rate of diagnostic errors and delays in acutely ill patients by creating and utilizing an in situ acute hospital learning laboratory. The acute care learning laboratory involved key stakeholders in identifying threats to the diagnostic process and guided the problem analysis, design, development, implementation, and evaluation of interventions to reduce diagnostic errors.

- Aim 1: Develop and validate automated phenotypes of diagnostic error and delay that can be applied in near-real time to medical record data.
- Aim 2: Engage stakeholders in the mixed-methods and systems engineering approaches to identify factors contributing to diagnostic error and delay. Then, design and develop applicable system-based interventions.
- Aim 3: Evaluate the feasibility and preliminary effectiveness of learning laboratory interventions on the rate of diagnostic error and delay in patients with emerging critical illness.

2. **Scope** (Background, Context, Settings, Participants, Incidence, Prevalence).

Diagnostic error or delay (DEOD) is defined by the National Academy of Medicine as a "failure to establish an accurate and timely explanation of the patient's health problem or communicate that explanation to the patient and in the health record."[1] DEOD is a common problem in clinical practice and a leading cause of preventable harm and death in the United States, contributing to 40,000 to 80,000 deaths annually.[2-5] The risk of DEOD is higher in critically ill patients and those with a high risk of clinical deterioration.[6] DEOD in hospital settings is often under-recognized and under-reported due to the heterogeneity of approaches for DEOD definition and measurement.[7-10] Despite a considerable body of literature outlining contributing causes, an effective strategy to meaningfully reduce diagnostic error and delay rates has yet to be implemented. This, at least in part, has been due to ineffective implementation that has focused on the healthcare team's role and has failed to incorporate the complexity of the organizational and systems processes within the clinical environment.

3. **Methods** (Study Design, Data Sources/Collection, Interventions, Measures, Limitations).

Our project used a mixed-methods approach to systematically explore the organizational, clinician, and patient factors contributing to diagnostic error and delay among acutely ill patients within a health system. We conducted multiple studies to investigate various factors contributing to the DEOD in acute care settings and design and develop potential interventions:

- Study 1: Evaluated the reliability of real-time electronic health record (EHR) reviews using a search strategy for the identification of DE as a contributor to the rapid response team (RRT) activation.

- Study 2: Conducted systematic review and meta-analysis study to evaluate the impact of health information technology (HIT) for early detection of patient deterioration on patient mortality and length of stay (LOS) in acute care hospital settings.
- Study 3: Explored clinicians' perceptions using survey methodology about the occurrence of and factors associated with diagnostic errors in patients evaluated during a rapid response team (RRT) activation or unplanned admission to the intensive care unit (ICU).
- Study 4: Conducted qualitative research using focus group to explore the perspectives of key clinician stakeholders from diverse hospitals and acute care settings about different contributors to DEOD, including the emergency room, hospital floor, and intensive care unit.
- Study 5: Conducted a follow up survey during phase 2 of the sequential mixed-methods investigation. The goal of the survey was to get feedback about the frequency with which those contributors occurred in various acute care settings and potential approaches to address them.
- Study 6: Using and analyzing temporal data of medical ICU patients of Mayo Clinic in Rochester, MN, between February 2016 to March 2018, we developed a quantitative model to investigate the association between the operational conditions and the quantity of medication orders as a measurable indicator of the multidisciplinary care team's cognitive capacity.
- Study 7: Developed a hybrid simulation model (ICU Digital Twin) to characterize major critical care delivery processes as discrete time events, feature patients, clinicians, and other artifacts as autonomous agents. We integrated them in the same simulation environment to capture their interactions under a variety of ICU production conditions.
- Study 8: Redesigning how direct care nurses visualize and interact with patient information during handoff is one opportunity to improve EHR use. A web-based survey was deployed to better understand the information and visualization needs at patient handoff to inform redesign.
- Study 9: Conducted a semi-structured interview of ICU clinicians who had experience with a novel acute care multi-patient viewer (Control Tower/AMP). The goal was to understand the information and process needs that support patient prioritization by clinicians caring for multiple patients in intensive care unit (ICU) and to inform the refinement of an acute care multi-patient viewer.
- Study 10: Conducted a pilot study in lab environment that investigated whether an AMP could reduce time to clinical decision and action by clinicians caring for populations of acutely ill patients compared to a widely used commercial Electronic Medical Record (EMR). The study scenario included assessment of entire ICU and four individual patients using the two electronic environments (Control Tower/AMP or EMR). Twenty subjects (10 pairs of clinicians) participated in the study. The time for assessment of the entire ICU and clinician task load (measured by NASA-TLX) were used as performance measures.

4. **Results** (Principal Findings, Outcomes, Discussion, Conclusions, Significance, Implications).

- Study 1: EHR manual review is of limited value in the real-time identification of DEOD in hospitalized patients. Alternative approaches are needed for research and quality improvement efforts in this field.[11] Our team also studied the time to diagnosis certainty for saddle pulmonary embolism in hospitalized patients.[12]
- Study 2: HIT for early detection of patient deterioration in acute care settings was not significantly associated with improved mortality or LOS in the meta-analyses of randomized controlled trials. In the meta-analyses of pre-post studies, HIT was associated with improved hospital mortality and LOS; however, these results should be interpreted with caution. The differences in patient outcomes between the findings of the RCTs and pre-post studies may be secondary to confounding caused by unmeasured improvements in practice and workflow over time.[13]

- Study 3: The survey results showed that 20% of patients were considered to have experienced a diagnostic error or delay as a primary contributor to the deterioration event. A similar number (20%) could have benefited from earlier engagement of a specialist in diagnostic evaluation and treatment planning.[14]

- Study 4: Multidisciplinary clinicians identified diverse but consistent contributors to DEOD. Stakeholders reported that organizational (infrastructure, workload, tools, processes), interactional (communication, coordination, roles, power), individual clinician (bias, experience, ego), and individual patient (health literacy, medical complexity, acuity of illness) factors interact in complex ways to impeded diagnostic performance. These contributors are considered to act synergistically on all aspects of accurate and timely diagnoses, including the information gathering, interpretation and synthesis, decision making, and communication. We also identified sociocultural phenomenon, such as clinician hierarchy and ego, as well as institutional culture as influences on DEOD.[15]

- Study 5: Physicians perceived cognitive factors to contribute to DEOD more frequently compared to those in other roles. Commonly proposed solutions included technological solutions, organization-level fixes, ensuring that staff know and are encouraged to work to the full scope of their role, and cultivating a culture of collaboration and respect. Multiple factors contribute to DEOD with similar frequency across acute care areas, suggesting the need for a multi-pronged approach that can be applied across acute care areas.[16]

- Study 6: ICU operational conditions may contribute to cognitive overload and negatively impact on clinical decision making. Our model suggests that ICU operational factors, such as admission rates and patient severity of illness, may impact the critical care team's cognitive function and result in changes in the production of medication orders. The results of this analysis highlighted the importance of increasing situational awareness of the care team to detect and react to changing circumstances in the ICU that may contribute to cognitive overload.[17]

- Study 7: EHR data from a medical ICU of Mayo Clinic Rochester, MN, were used to calibrate model parameters for validation. Upon iterative refinement and validation, the digital twin model has the potential to be integrated with the hospital information system to simulate real-life events as a full-fledged digital twin of the system. It can be used as an in silico testbed to investigate the real-time allocation of ICU resources, such as medical equipment, flexible staffing, workflow change, and support decisions of patient admission, discharge, and transfer, for healthcare delivery innovation.[18]

- Study 8: The ICU nurse survey identified the information and visualization needs of direct care ICU care. Hemodynamics, mechanical circulatory support, laboratory results, and continuous IV medications were indicated as “big picture” items highly necessary to include in future EHR interfaces. Participants indicated that organizing this information by system and visualizing by schedules would improve the usability of the EHR. The study findings could serve as a baseline toward redesigning an EHR interface.[19]

- Study 9: This qualitative study explored ICU clinician perspectives about their information and process needs to enable the prioritization of care among ICU patients and gathered insights on organization of data within the AMP. Five main themes emerged: patient prioritization strategies, task organization strategies, information helpful for situational awareness, unrecognized critical events, and suggestions for AMP organization and content. Timely recognition of changes in patient physiology and labs and avoiding omissions and errors in patient management were perceived opportunities for improvement in preventing catastrophic events in the ICU. The results of this study can be used for informing digital strategies facilitating the prioritization of care among populations of critically ill patients.[20]

- Study 10: When compared to the standard EMR, AMP significantly reduced time to clinical task completion and clinician task load. Additional research is needed to assess the clinicians’ performance while using AMP in the “live” ICU setting.[21]

In partnership with institutional IT and with support from clinical practice, the team has developed a unique clinical informatics platform, Acute Care Multi-Patient Platform (Control Tower/AMP), that enables HIT innovations to be developed with stakeholder input and implemented within the hospital. The resulting applications are built and supported locally using agile methodologies and user centered design principles. The Control Tower/AMP was used to predict the need for palliative care intervention and has successfully been integrated it into the workflow of the palliative and primary care teams. The effectiveness of the palliative care intervention has been evaluated in a pragmatic clinical trial.[22]

Conclusions, Significance, Implications.

This project highlights the complex sociotechnical system within which individual clinicians operate and the contributions of systems, processes, and institutional factors to DEOD. Physicians perceived cognitive factors to contribute to DEOD more frequently compared to those in other roles. Multiple factors contribute to DEOD with similar frequency across acute care areas, suggesting the need for a multi-pronged approach that can be applied across acute care areas. The commonly proposed solutions included technological solutions, organization-level fixes, ensuring that staff know and are encouraged to work to the full scope of their role, and cultivating a culture of collaboration and respect.

The team has successfully used Control Tower/AMP infrastructure to engage multidisciplinary stakeholders across the hospital in the co-development, evaluation, and implementation of health-IT applications within their practice. Connecting our Acute Care *Learning Lab* to the work system through the AMP platform and processes is an important innovation and is expected to lead to the introduction of artifacts that accelerate our understanding of the complex contributors and influencers of diagnostic processes and outcomes. We plan to apply additional funding to test the AMP as diagnostic performance interventions in clinical practice, facilitate preliminary effectiveness studies, and capture lessons learned from resultant work system reorganization.

List of Publications and Products

1. Soleimani J, Pinevich Y, Barwise AK, Huang C, Dong Y, Herasevich V, Gajic O, Pickering BW. Feasibility and Reliability Testing of Manual Electronic Health Record Reviews as a Tool for Timely Identification of Diagnostic Error in Patients at Risk. Appl Clin Inform. 2020;11(3):474-82. Epub 20200715. doi: 10.1055/s-0040-1713750. PubMed PMID: 32668480; PMCID: PMC7363482.

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8. Zhong X, Babaie Sarijaloo F, Prakash A, Park J, Huang C, Barwise A, Herasevich V, Gajic O, Pickering B, Dong Y. A multidisciplinary approach to the development of digital twin models of critical care delivery in intensive care units. International Journal of Production Research. 2022;60(13):4197-213. doi: 10.1080/00207543.2021.2022235. . PMC Journal - In Process

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