Title of Project: Failure to Rescue-Patient Safety Learning Lab (FTR-PSLL)

Principal Investigator and Team Members:
Dartmouth-Hitchcock: George Blike, MD, MHCDS, PI; Susan McGrath, PhD, CoI; Todd McKenzie, PhD; Irina Pearrard, PhD; Krystal McGovern, RN, MSN, MBA; Kathleen Stewart, MPH; Joshua Ramos, MD

University of Michigan: Amir Ghaferi, MD, CoI; Emily Wells, MPH

Additional Team Members/Consultants: Dennis McGrath, MA; Gay Landstrom, RN, PhD; Klaus Christoffersen, PhD

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Report Components:

I. Structured Abstract
II. Purpose (Objectives of Study).
III. Scope (Background, Context, Settings, Participants, Incidence, Prevalence).
IV. Methods (Study Design, Data Sources/Collection, Interventions, Measures, Limitations).
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I. Structured Abstract—(Five Elements: Maximum of 250 words.)

Purpose: To define, design, and field test ideal hospital rescue systems. We focused on early "upstream" recognition and management of non-preventable complications.
Scope: Studies in two acute tertiary hospitals sought to enhance understanding of 1) the technology factors behind ideal surveillance supporting early detection of complications across the continuum of inpatient care and 2) the human factors that support the ideal individual and team response in effectively managing these complications.
Methods: We used a mixed-methods approach to identify and understand gaps in current care systems and then rapidly integrate and translate new knowledge into an idealized system for rescue that would support more reliable "early" rescue. Interventions were developed iteratively using qualitative simulation and focus groups. A capability maturity framework was used to prioritize interventions for evaluation.
Results: Team identification and response and alignment of response improved by 40% and 35%, respectively, with role-specific pager assignments with tracking in the EMR, formal escalation criteria, and structured paging language. Patient recovery milestone guides were developed for two surgical conditions. Based on surveys and interviews, they have high acceptance and adoption. Technology that is designed to provide continuous surveillance of general care was deployed and reduced the time to collect data 30% and improved time monitored by 18%. Subsystems for continuous patient state surveillance were designed, and an implementation path was established. A retrospective study of this approach to surveillance, notification, and response reduced mortality from pharmacological respiratory arrest 19 fold.

Key Words: Systems analysis; failure-to-rescue; patient safety; ideal rescue care system; complication management; system design

II. Purpose (Objectives of Study):

The Failure to Rescue Patient Safety Learning Lab had three scientific cores: 1) Technology Factors Core; 2) Human Factors (Individual and Team) Core; and 3) Sociotechnical Integration Core. Each core had specific aims that matured over the course of the of the research due to the results of completing each step of the applied systems engineering methodology used. Ultimately the technology, human factors and sociotechnical integration work streams were integrated as the effort moved to the design and test phases of the work.

Objectives by phase of work across all three scientific cores:

1. Problem Analysis—The research team used a three-step approach that consisted of completing 1) macro analysis; 2) leverage point analysis; and 3) key deliverables, as shown in Figure 1.

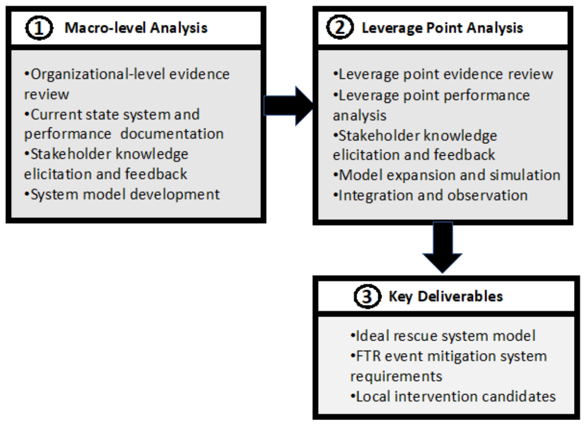


Figure 1. General Execution Approach. The approach includes (1) high-level (macro) analysis of FTR event contributors and mitigation interventions leading to (2) detailed analysis of key system leverage points. Deliverables (3) of the effort included a model of ideal patient rescue, system requirements, and local intervention candidates.

2. Design, Develop, and Test—The team used a hybrid Design Thinking/DMADV methodology to organize and prioritize the results of the problem analysis to then design and develop a subset of candidate solutions across the three core components of the current state system that was analyzed to be most likely to improve Ideal Rescue System performance (see Figure 2). Candidate solutions were "tested" with expert/stakeholder sessions and using a simulation model for their ability to answer four critical system-level questions associated with known key drivers of performance in a supervisory control system:
   - Does the intervention reduce information 'noise' and loss?
   - Does the intervention clarify and focus critical information in a timely way?
   - Does the intervention improve the shared mental models of the care team?
   - Does the intervention reduce response time of rescue teams?

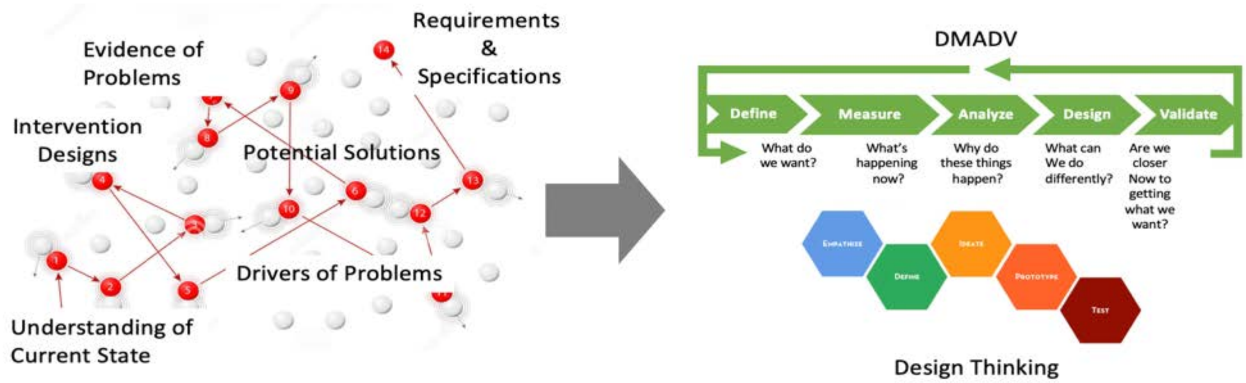


Figure 2: Problem analysis results were reviewed in design thinking sessions and then moved into a more formal design and develop process associated with six-sigma methods (i.e., DMADV).

3. Implementation and Evaluation—The team used a mixed-methods approach to implement/field test the best system and sub-system interventions that were designed to improve rescue and reduce Failure to Rescue Events—deaths from serious but treatable complications. In the final year of the study period, a set of implementation/field tests of the best interventions to improve the performance of the complex system delivering rescue care were conducted. These evaluations were generally conducted using a before and after cohort-controlled design and utilized a set of process and outcome measures that had been established in the previous year to baseline the overall and subsystem performance of rescue at the primary evaluation hospital of Dartmouth-Hitchcock Medical Center and the secondary testing site of University of Michigan Medical Center.

III. Scope (Background, Context, Settings, Participants, Incidence, Prevalence):

Background: Every year, at least 100,000 Americans die undergoing inpatient surgical procedures and another 100,000 patients die while hospitalized for a medical illness.[1–3] Wide variation in mortality rates across hospitals suggests substantial opportunities for improvement. Several decades of patient safety work have been focused on preventing complications in an effort to ultimately reduce mortality.[4] However, these efforts have not had a significant impact, and there is growing recognition that high-mortality and low-mortality hospitals are distinguished less by their complication rates than by how successfully they recognize and manage complications once they occur.[5] Thus, minimizing "failure to rescue" (i.e., death following a major complication) (FTR) is critical to reducing mortality in hospitalized patients.

Previous research related to Failure-to-Rescue (FTR) has included single and multicenter studies of hospital[4] and patient[6] characteristics that contribute to FTR events using statistical methods and chart reviews. Interventions have included rescue systems comprising rapid response and code teams that are commonly employed to reduce FTR event frequency by providing prompt response upon recognition of patient deterioration.[7] Other tactics, such as algorithms to estimate patient state or risk of death[8,9] and continuous patient monitoring,[10,11] have also been integrated into rescue systems to support recognition of patient deterioration. Rescue system performance and its impact on FTR has been studied by looking at outcomes,[12] activation criteria,[13] and various aspects of response team utilization.[14] Despite the aforementioned research, performance analysis, and high adoption rates of well-known interventions, significant opportunity for improvement remains.[15,16]

The failure of conventional medical domain analysis methods to address FTR, even those that have proven effective for understanding disease states, is not surprising, given the varied nature of FTR events and the typically fragmented approaches taken to address them.

Unlike many other patient safety issues for which evidence-based prevention protocols have been developed, such as central line and catheter infections, the manifestation of FTR events can be highly convoluted, often involving a series of missed signals and misguided interventions that can cascade to produce a catastrophic outcome. Several of the studies cited earlier have called attention to the diversity of disciplines, skill levels, resources, and tools involved in preventing FTR events, highlighting the need to recognize FTR event mitigation as a system. Yet, there is little evidence of the application of systems analysis and design methods, such as system modeling, creation of systems requirements, or system-level design, which can provide additional insights and integrated intervention approaches.

Successful rescue hinges on early recognition and timely management of serious complications once they occur, particularly during the early period of clinical deterioration. Despite increased awareness of the importance of reducing FTR, gaps remain in understanding all the factors involved in effective rescue and which combination of factors is most important. For example, rescue may depend on technological factors (i.e., availability of information about patient status, and/or the availability and usability of tools and technology supporting timely diagnosis and treatment). Additionally, effective rescue may depend on a host of human and team factors (i.e., staffing levels and workload, primary and specialist team communication and coordination, and/or the safety culture of the clinical units.) Perhaps the complex adaptive interactions of the sociotechnical system as a whole may be the most important factor behind reliable rescue. There are also gaps in the translational sciences for how to best develop and implement innovation in complex systems, like that of hospital rescue. The design acceleration and rapid-prototyping/testing methods common to many industries noted for innovation are not common in healthcare. The Failure to Rescue Patient Safety Learning Lab (FTR-PSLL) addressed both gaps in understanding AND gaps in rapid translation impeding the realization of "Ideal Integrated Rescue Systems" within hospitals.

<u>Context (Problem and Rationale for Approach):</u>

It is widely acknowledged that healthcare systems are complex adaptive systems,[17,18] in which analysis of constituent subsystems cannot easily explain the behavior of the system as a whole. Yet, as McDaniel et al. discuss,[19] healthcare delivery systems also differ from other complex adaptive systems due to the incidence and relationship between many factors, including abundant non-determinate processes and behaviors, temporal and geographic variability, and lack of effective cost-benefit models. These properties complicate the many program management and resource investment decisions entrusted to healthcare system leaders.[20,21] Planning and management of hospital-wide programs can be especially difficult, as methods typically employed for strategic planning and prioritization vary widely across healthcare organizations, with most attention focused on national-level and patient bedside process planning versus institutional-level priorities.[22] Patient safety systems represent a key case in point, as they are commonly implemented across institutions and possess many of the factors that set healthcare systems apart from other complex adaptive systems.

The need for systems-focused practices to address healthcare management challenges has been acknowledged nationally,[23,24] and, as a consequence, some hospitals have turned to systems engineering analysis and design domains, such as systems thinking,[25,26] systems engineering,[27,28] continuous improvement,[29,30] and cognitive systems engineering.[31] These domains support investment decision making, facilitate more deliberate prioritization, and improve performance of healthcare delivery systems.[32,33] Systems engineering approaches are human-centered design disciplines and combine qualitative and quantitative analysis, objective and subjective considerations, and theoretical and empirical approaches to improvement. The engineering toolkit contains methods and instruments that allow complex systems to be described, analyzed, understood, and optimized.

Systems approaches use a set of structured execution steps. These include identifying goals, documenting current system performance, comparing the current state to the desired state, implementing improvements/designs, and measuring performance of the new system. The benefits of standardizing such methodologies within organizations, including healthcare, have been demonstrated,[34] although integrated systems engineering functions within healthcare management are not commonplace. There is also evidence that institutions with more mature capabilities[35] can derive added benefit from drawing upon a variety of tools to improve understanding and decision making, particularly in highly complex adaptive systems, such as healthcare delivery.[36]

Settings: Rescue systems in a tertiary hospital (Dartmouth Hitchcock Medical Center, DHMC) intended to reduce Failure-to-Rescue events. DHMC is a 400-bed tertiary medical center with a complexity of patients placing it in the top 5% of all tertiary medical centers. The baseline rescue care systems included a three-tier response system (Life Safety Consultations, Rapid Response Team, and STAT Airway/Code Blue). These tiers are triggered via surveillance and monitoring systems based upon the phase of care for medical and surgical patient populations. The general care setting has a pulse oximetry-based surveillance monitoring system that is used by all patients for the duration of their hospitalization unless there are contraindications or patient refuses after informed consent. Less than 25% of patients are not monitored with this surveillance system.

Participants, Incidence, Prevalence: To best characterize the nature of serious but treatable complications and the rescue systems activated to respond, baseline data was collected from the prior 4-year interval (as shown in Table 1). The locations and acuity of bed type along with patient days of care provided and rescue event types for the entire hospitalized population suggest the incidence of cardiac arrest necessitating a code blue response is 7.7 per 10,000 patient days of care delivered. The incidence of rapid response activation is 12.4 per 10,000 patient days of care delivered.

Table 1. Institutional-level Baseline Data for General and FTR Specific Metrics. Data were gathered from a 4-year period and analyzed using descriptive statistics.

Tertiary care hospital				
Patient population	Total adult patient count			67,142
	LOS, Days (mean+/-stdev)			5.6+/-8.1
Capacity	Care type	Bed count	Occupancy %	Patient days by unit type
	Surgical General care	83	87%	102,992
	Medicine General care	105	88%	222,943
	Progressive care	40(45)	85%	36,859
	Critical care	74	80%	49,291
	Total patient days			418,620
Patient Safety	Rescue Events	Life safety consult		3082
		HERT		520
		Code Blue		322
		Stat airway		79
	Mortality, Percent			2.73%
	AHRQ Safety indicator PSI4: Death among surgical inpatients with serious treatable complications*	Jul'11-Sep'13:		121 / 715
		Oct'13-Jun'15:		91 / 559
		Stratum A: DVT or PE		6
		Stratum B: Pneumonia		31
		Stratum C: Sepsis		12
		Stratum D: Shock or Cardiac Arrest		33
		Stratum E: GI Hemorrhage or Acute Ulcer		8
		Not classified		1

* AHRQ PSI4 definition/inclusion change took place in Oct 2013. Data is presented as count of PSI4 deaths (numerator) over the total number of cases considered (denominator).

IV. Methods (Study Design, Data Sources/Collection, Interventions, Measures, Limitations): A mixed -methods approach was used for this investigation. As shown in Table 2, it included an evidence review; documentation of policies and procedures regarding rescue systems; and process mapping of the detection, notification, and response to a serious but treatable complication. Multiple stakeholder workshops were conducted using a "design-thinking" facilitator and widespread culture of safety survey was used along with semi-structured interviews. In addition, all institutional performance data, equipment inventories, and patient safety data were analyzed to understand baseline performance and the impact of interventions to improve the rescue system performance.

Table 2. Analysis Methods Employed. Methods used in several commonly used systems engineering methods were selected to achieve stated goals of the initiative**.**

Method/Approach	Description of Analysis
Evidence review	A library of over 1200 documents including peer-reviewed articles, conference proceedings, and other literature related to FTR contributors and mitigation approaches was created via standard keyword searches. Documents were segmented into subcategories, reviewed, and summarized.
Policies, procedures and structure documentation	Policies, procedures, and documentation of structures (e.g., committees, rescue teams) within the hospital that were directly and indirectly related to FTR events and specific key leverage points were gathered and reviewed.
Process mapping	Field observations and expert interviews were used to map the range of pathways encountered by patients with conditions requiring hospitalization. These data were used to collectively characterize the assets comprising FTR event-related patient care and rescue at the study hospital.
Stakeholder knowledge elicitation and feedback	<u>Stakeholder workshops</u>: Annual multidisciplinary stakeholder workshops, led by a facilitator, were conducted to increase understanding of FTR events and mitigation approaches, elicit knowledge from experts, gather feedback regarding analysis findings, and generate improvement and redesign ideas. <u>Surveys:</u> A standardized culture and engagement surveys were sent to a clinical staff in various disciplines, roles, and work locations. Results were compiled, stratified, and compared to other organizations. <u>Interviews:</u> Semi-structured interviews of clinical staff were conducted to explore positive and negative influences of patient care and rescue in concepts of high reliability organizations. Responses were analyzed and examined to identify areas of opportunity for improvement or redesign.
Institutional performance data	Data related to mortality, failure-to-rescue events, rescue activities and complications associated with failure to rescue events were gathered and analyzed. Various statistical methods were applied to understand frequency, trends, and associations between events and various parameters, including time, location, and patient demographics.
Equipment inventories and patient safety data	Data related to equipment features, utilization, overall performance, and safety events were reviewed to identify patterns of performance failures and opportunities for improvement.
Modeling and simulation	A control model approach was used to develop a hospital-wide model of the patient care and rescue system. Stock and flow modeling and simulation were also used to identify and illustrate the impact of drivers of failure within the system.

Process mapping included phases of care when appropriate (e.g., surgical patients preoperatively, intraoperatives and postoperatively) and used a "swim-lane" format to characterize key activities by role and the interdependencies with other roles, as shown in Figure 3 below.

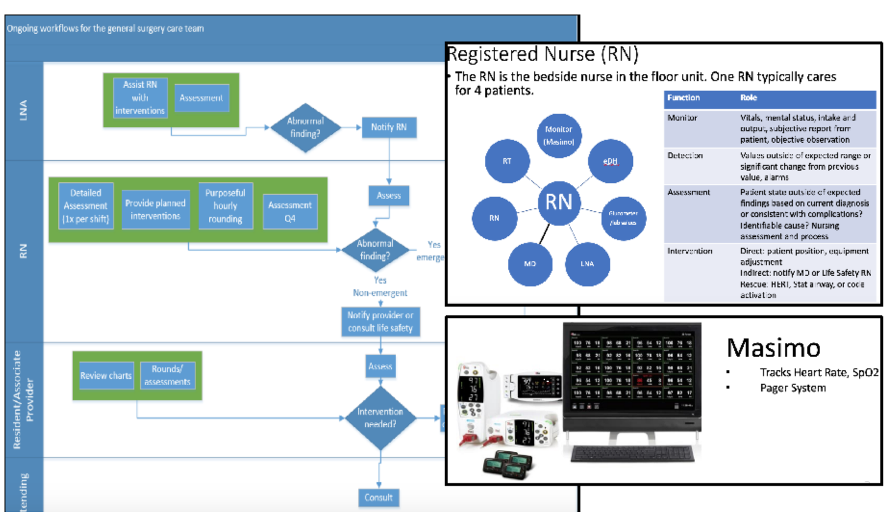


Figure 3. Process and Resource Mapping. A partial process flow diagram associated with specific roles of the surgical care team in managing patient events that deviate from the expected conditions.

The results of the problem analysis (macro analysis characterizing the rescue system and leverage point analysis to identifying opportunities to improve rescue care) was to recognize that the greatest opportunity (and risk of failure) is in the general care setting, where staffing is one RN to many patients, and in settings where junior house officers with limited experience are "covering" patients and responding to concerns. Furthermore, in aggregate, the analysis supported characterizing acute inpatient surveillance and response to problem states as an extended control model (ECOM, as described by Hollnagel in Figure 4). The rescue care process maps were used to inform the depiction of an ECOM for inpatient episodes of care and the activities of the care team in navigating the patient through an episode of illness and recovery. The model that was derived from ECOM and then used to represent patient rescue care is also shown in Figure 4.

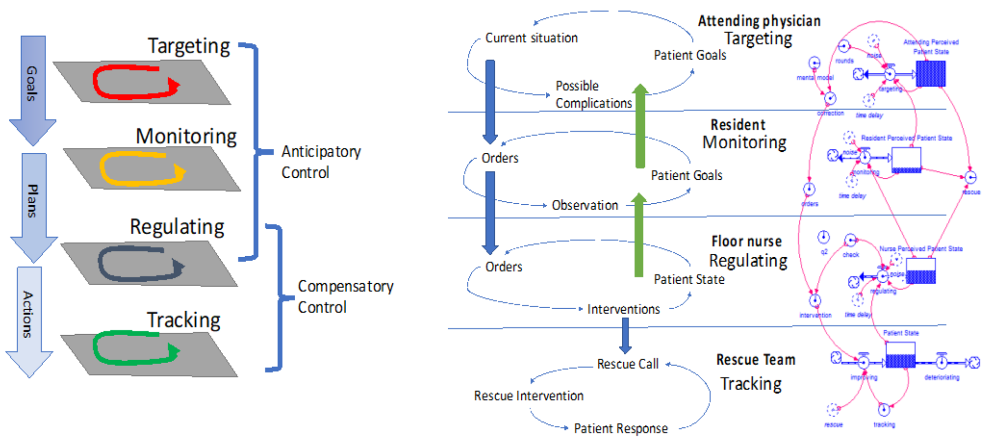


Figure 4. Depiction of the Hollnagel Extended Control Model (ECOM) and Stock and Flow Models Adapted to Patient Care and Rescue. The model on the left shows the relationship between types of control and activities. Adapted from Leonard and Frankel 2010. The image on the right shows layers of control for inpatient rescue care using an ECOM model rescue care. Mapping of elements of the ECOM model to a dynamic stock and flow model also is shown.

Results of the stakeholder causal analysis are shown in Figure 5, and the driver diagram is shown in Figure 6. The descriptive "Rescue Care Control Model" that has been developed allowed for a semi-structured method for prioritizing causes, drivers, and identifying design criteria, system requirements, and capabilities that are needed for ideal rescue care system performance.

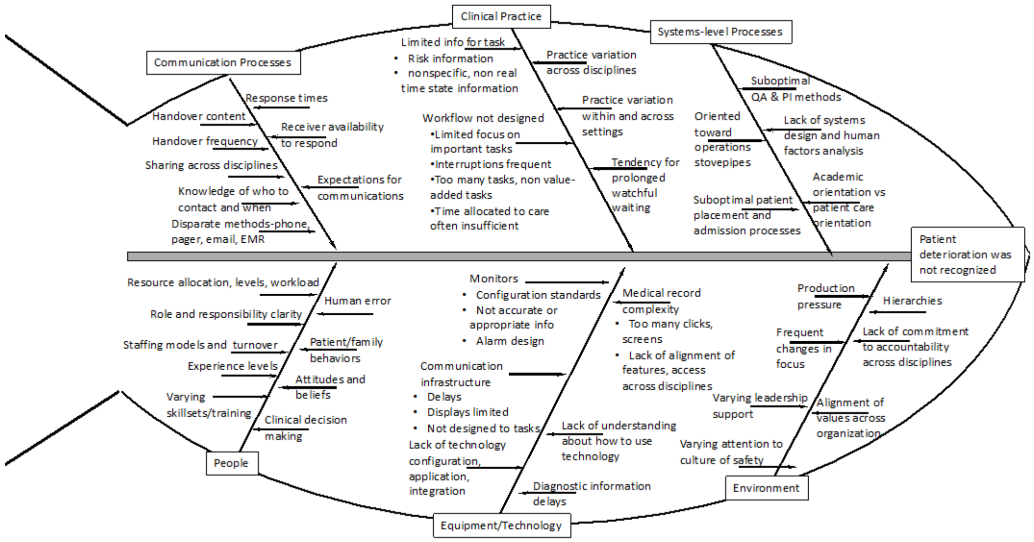


Figure 5. Integrated Fishbone Diagram. Root causes focused on early recognition of patient deterioration in the inpatient setting were gathered from macro-level and leverage point analysie and integrated into a single diagram.

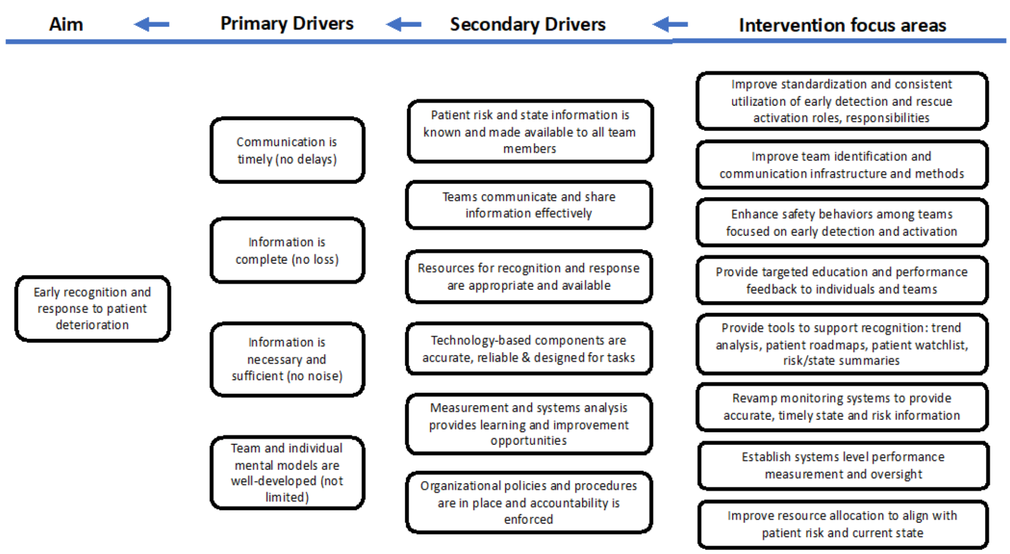


Figure 6. Driver diagram. The diagram illustrates the relationship between primary and secondary drivers and intervention focus areas.

Capability maturity models are a practical framework for implementing a set of those core functions that the system needs to possess to deliver optimal outcomes that can start basic and then mature over time with more advanced features (see Table 3 for example of interventions structured as capabilities).

Table 3. Example of FTR event mitigation system interventions and capability levels.

Intervention	Function	Objectives	Tactics
Trend Analysis	*Capability Level 1*	Increase detection of deterioration via analysis of trend information at the bedside	• Integrate trend analysis into vital signs assessment and handovers at the bedside in 3/4W

	Capability Level 2	Share trend information across teams to increase situational awareness	• Develop mobile application to allow distributed team members to view trends remotely (pilot single service) • Apply device integration to allow trends to be recorded in the EMR
	Capability Level 3	Alert care team based on trend events	• Develop and deploy algorithms to analyze trend patterns and enable notifications • Integrate trend analysis into broader patient assessment score
Mortality and Complication Risk	*Capability Level 1*	Provide pre-op mortality and complication risk data to care team	• Develop standard for application of online NSQIP tool in surgical population (pilot in single service) • Enable NSQIP score/report to be shared with care team in EMR
	Capability Level 2	Expand accessibility and application of mortality and complication risk tool	• Provide interface to online NSQIP tool within EMR • Populate fields from EMR whenever possible • Integrate risk calculations into broader patient assessment score
	Capability Level 3	Expand mortality and complication risk tools to medicine patients	• Implement risk tools similar to NSQIP for medicine patients

Preliminary intervention design and prototype testing was performed using a dynamic model of patient deterioration detection by a distributed clinical team (see Figure 7). This simulation allows aspects of the system to be explored with clinical teams. The systems engineering led team identified key design issues and would explore alternatives and use the dynamic simulation model when appropriate to estimate impact of an intervention relative to the current state rescue system in place.

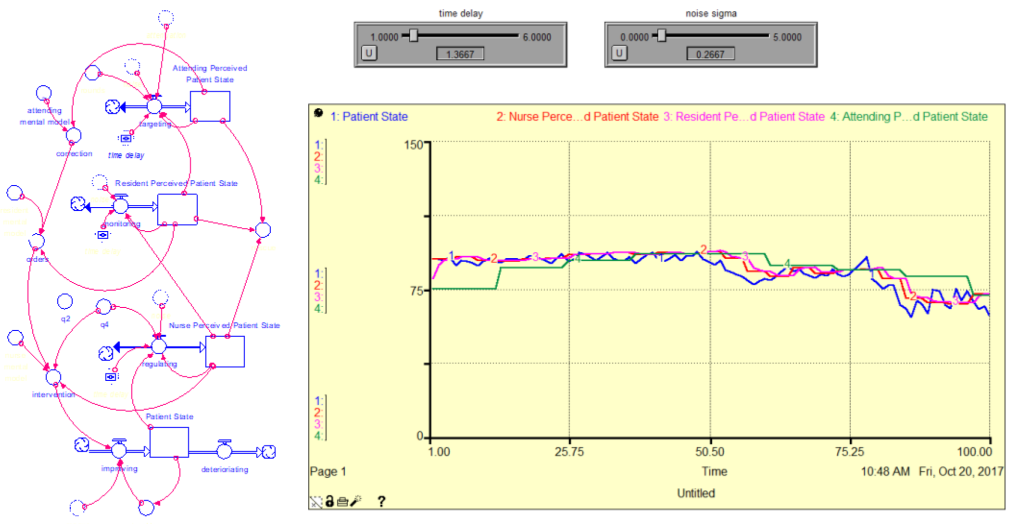


Figure 7. Simulation of Patient Deterioration. The simulation using a stock and flow model of patient deterioration incorporated varying model parameters that effect signal transmission between layers of the control system. Lines in the graph represent convergence or divergence of actual patient state from perceived patient state.

Ideal Rescue Care System and Subsystems: An overall system design with key subsystems has been developed to allow core capabilities to be established and then matured over time as shown below in Figure 8.

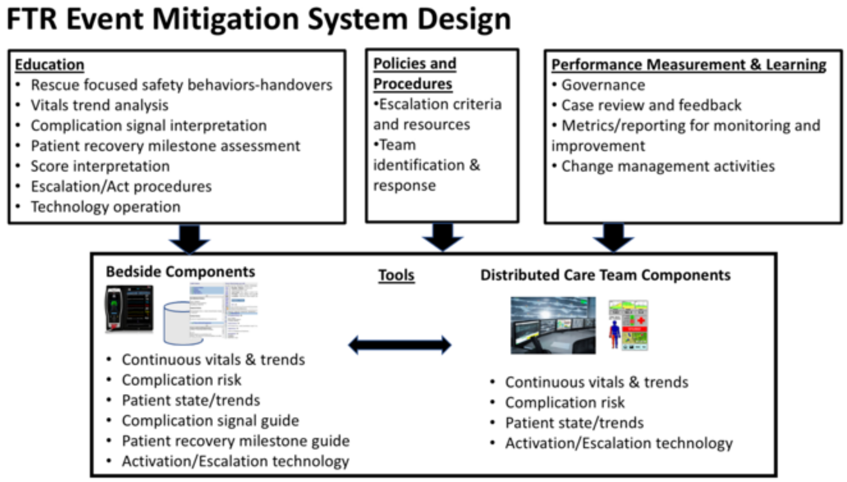


Figure 8. Information systems infrastructure concept. The figure depicts core information systems components and illustrates data types and flow. Application concepts for system and patient-level applications are shown with primary workflows identified for each platform.

From this system design, key interventions were prioritized for *in situ* validation:

1. *Team identification & response*-Frontline nurse needs to be able to notify the covering physician and attending physician of concerning patient conditions that may represent a serious but treatable complication needing early intervention. This information was unreliable.
2. *Escalation criteria and assessment resources*-Alerting communication by the nurse to resident, nurse to attending, and resident to others needs to be clear as to the urgency level (i.e., time to respond) and expectation regarding need for phone vs. bedside assessment.
3. *Patient recovery milestone guides (by condition)*-Detection and diagnosis failure are reduced when all members of the clinical team have shared mental models regarding the expected patient state during the episode of care that allow deviations to be recognized, mitigated, and diagnosed.
4. *Continuous vital & trends*-The biosensors, electronic record, and clinical assessments need to be continuous, comfortable, and convenient to be used reliably and need data to become available for any surveillance system based upon that data.
5. *Complication risk prediction*-Though many risk prediction algorithms were reviewed and considered for optimal deployment to support bedside and remote diagnostic decision making, we identified the need for surveillance monitoring of patient state across the continuum of an episode of care. Significant patient state changes signal a complication can be missed by clinicians that are multitasking, distracted, or impacted by cognitive tunnel vision and bias. Risk prediction tied to a narrow context have limited value. The set of algorithms for prediction of complications needs to be optimized for use across different care settings and designed to redirect attention of the clinical team. The sampling rates need to be such that events occurring over seconds and causing harm in minutes can be detected and rescue initiated before harm occurs.
6. *Metrics/reporting for monitoring and feedback*-Rescue care system performance cannot be optimized or assessed without a set of outcome metrics. Aggregate and complication-specific mortality rates using administrative data all.
7. *Case review and feedback*- Building highly reliable safety systems requires iterative learning loops. This allows for "maturing" the core capabilities over time.

V. Results (Principal Findings, Outcomes, Discussion, Conclusions, Significance, Implications):

<u>Principal Findings, Outcomes</u>

1. *Team identification & response:* Two interventions were fielded, one to establish the attending who is responsible for the patient at any given time and the second to establish the responding physician for any issues of concern by the bedside nurse needing further assessment. The interventions were deployed in initial pilot studies with a plan to spread to all inpatient units and clinical teams. Data were based on field observation of time to complete tasks. The intervention was to establish a policy, procedure, and EMR implementation of positional pagers that allowed for a consistent location in the chart to see who is responsible and who is responding at all times. The key metrics were speed and accuracy of identifying and reaching the person of interest relative to baseline system. Observational data was collected before and after implementation of the new system. The speed of task performance improved 40%.
2. *Escalation criteria and assessment resources*: Structured communication standards were developed and deployed to clarify the expected response turnaround time and type of response (phone vs. bedside). The intervention established a policy, procedures, and job aids and deployed to a pilot unit with field observation of response time after page and accuracy of expected response before and after the intervention (see image).
The accuracy of agreement regarding the time frame of response by members of the team improved 35%.

Communication Standards (i.e., Paging Etiquette)

Urgency Level	When to Use	Response Standard	Anticipated Response Time	Page Example
FYI	When discussion is not needed **RNs are required to notify providers of all critical lab values within 30 minutes, as well as vital signs that fall outside of the "Vital signs – Notify MD" parameters	No call back	If action needed: • By time specified in page • Within 12 hours/shift	*FYI 143 Smith, HR 140 ambulating, asymptomatic* *FYI 150 Doe, back from OR, diet order by 1830* *FYI 133A Smith, family here til 1400 for update*
Call Me	When discussion is needed	Call back	< 20 minutes	*Call me 131 Doe, firing Sepsis* *Call me 140 Doe, BP >180 post hydralazine* *Call me 131 Doe, hemoglobin 5.8*
Urgent	When patient is unstable, in need of prompt intervention	Call back or In person	< 10 minutes	*Urgent 140 Doe, BP 70/30 Life safety here*
Emergent	When patient is unstable, requiring HERT, STAT airway, Code Blue	Call back or In person	Immediate/ASAP	*Emergent 156 Smith, HERT Call*

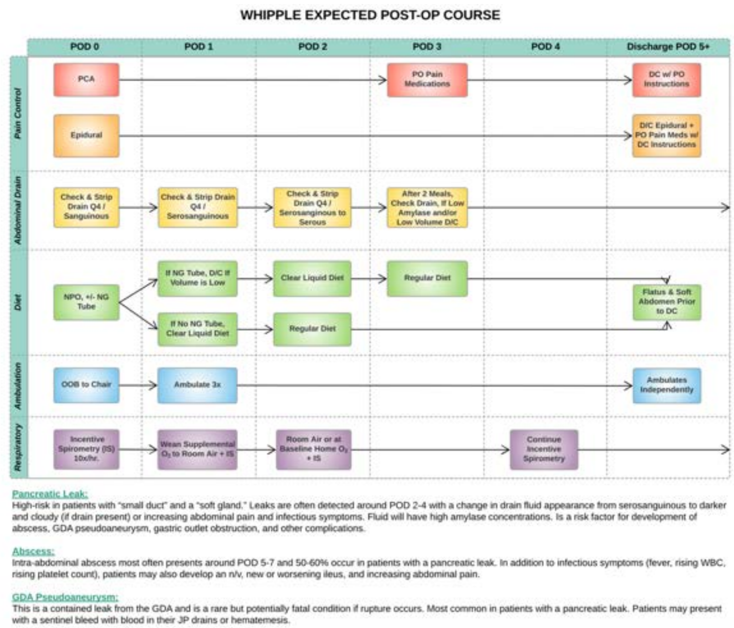
For those sending a page:

- **Text paging is the preferred paging method and allows providers to prioritize their care**
  - Please do not phone page unless absolutely necessary (i.e. computer failure)
- Keep text pages short! Less than 80 characters
- Use the patient name as listed in eDH (i.e. "Unknown 27" for patient Unknown in eDH, even if you know their identity)
- If possible, notify others in the vicinity that you have paged to that telephone
  - If you see a telephone flipped upside-down, someone is expecting a callback to that number. Find another phone to use if possible.

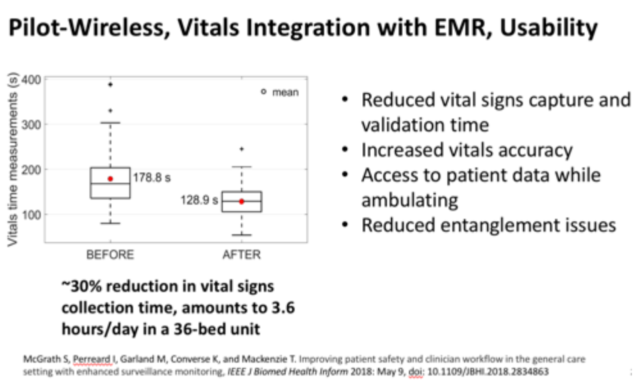
For those responding to a page:

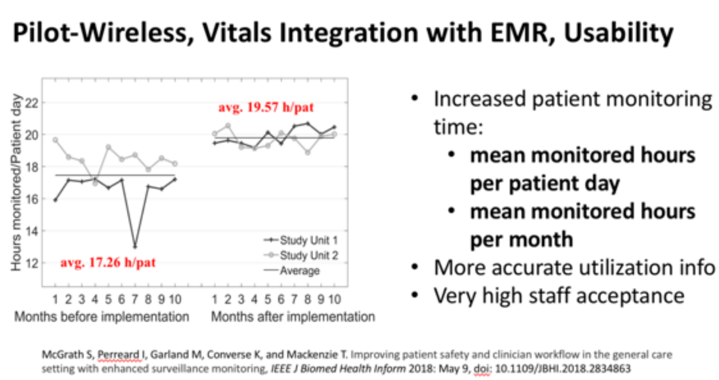
- Please ask for the person that sent the page and state the patient's last name when calling back
- If orders are to be written for a patient, two approved patient specific identifiers must be verified (i.e. DOB, MRN, Name)

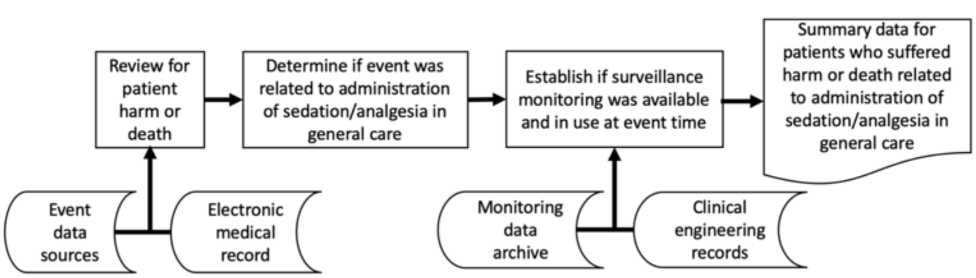
3. *Problem state recognition by the clinical team*: Two surgical procedures (renal transplantation and pancreatectomy) were analyzed with expert surgeons and senior nurses to identify an "Expected Postoperative Course" or EPOC (see graphic, below). These guidelines were taught to perioperative surgical teams and bedside nursing teams. Pilot data collected included before and after survey data as to acceptance and utility. In addition, semi-structured interviews were conducted.



4. *Continuous vitals and trends:*
Deploying an enhanced surveillance monitoring system-A monitoring platform that allowed continuous pulse oximetry using a wireless device attached to the upper arm and a bedside unit that allowed for vitals integrated into the electronic medical record were implemented in a pilot unit with a before and an after cohort in a controlled study design. Usability was improved compared to baseline in terms of both speed and accuracy. Staff time to collect vitals was reduced 30%, and accuracy increased. Patients tolerated the continuous wireless monitor well, with overall utilization increasing total time monitored by 13.4%. See graphics, below.







Inpatient Respiratory Arrest Associated With Sedative and Analgesic Medications: Impact of Continuous Monitoring on Patient Mortality and Severe Morbidity.

Continuous pulse oximetry has been used at the study institution for over 10 years. There are 35 million hospital admissions per annum in the United States; 50% receive opioids, and 1% of those individuals can suffer some form of respiratory depression (i.e., an estimated 180,000 patients having events that warrant rescue). Opioid overdose in the inpatient setting, if detected early and treated rapidly, should not be fatal. The method used to analyze deaths due to failure to rescue from sedative/analgesic-associated respiratory depression is show the figure on the previous page. The analysis found one death due to sedative/analgesic medication administration when surveillance monitoring was available (0.9/100,000 discharges). There were three deaths related to sedative/analgesic medication administration in units without surveillance monitoring available (19.7/100,000 discharges). These deaths all occurred during the 29-month period during which surveillance monitoring was being implemented throughout the institution. No patients experienced permanent harm due to sedative/ analgesic medication administration during the review period. The reduced death rate when surveillance monitoring was available (0.0009%) versus not available (0.02%) was significantly different (P = 0.03). This 10-year retrospective analysis found that continuous pulse oximetry monitoring was associated with a 19-fold reduction in sedative/analgesic-associated mortality.

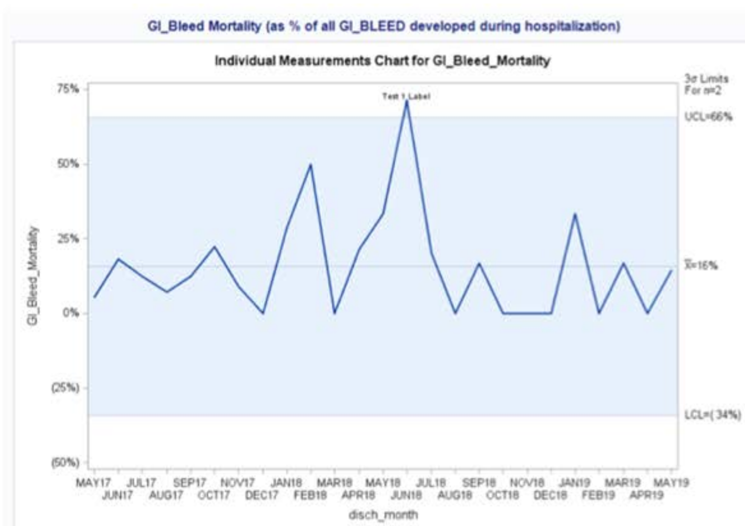
5. *Complication risk prediction:* A comprehensive review of complication risk prediction algorithms was conducted (partial review shown in Table 4 below).

Table 4. Summary of algorithm-based patient assessment tools. Examples are given for several phases of care. The ease of implementation was calculated based on three criteria: input availability; computation flexibility; and calculation transparency and automation opportunity.

Clinical Setting	**Algorithm Name**	**Clinical focus**	**Output**	**Frequency and common time of calculation**	**Types of input parameters and number [#]**	**Responses to output**	**Algorithm model**	**Model derivation cohort**	**Performance measurement**	**Ease of Implementation**
Pre-op	American College of Surgeons (ACS) National Surgical Quality Improvement Program (**NSQIP**) Surgical Risk Calculator	Pre-operative risk assessment score	Risk 30 day mortality Risk of complications	1 time, before surgery is scheduled	Labs Vital signs Comorbidities Clinical opinion	Surgery proceeds or not	Logistic regression	>700 member hospitals, >1 million total surgical patients	- Concordance-statistic - Performance adjusted to population periodically	Moderate
	Portsmouth Physiological and Operative Severity Score for the Enumeration of Mortality and Morbidity (**P-POSSUM**)	Pre-operative risk assessment score	Risk 30 day mortality	1 time, before surgery is scheduled	Labs Vital signs Surgical factors	Surgical and postsurgical planning	Logistic regression	Multiple hospitals, 10000 surgical patients	- Concordance-statistic	Easy
	American Society of Anesthesiologists (**ASA**) Physical Status Classification System	Pre-operative patient assessment score	Classification of pre-operative health, anesthesia risks	1 time, before surgery is scheduled	Comprehensive patient assessment and type of surgery	Anesthesia and surgical planning	Expert opinion	ASA committee	- Classification system; not a risk score	Difficult
PACU	Post Anesthesia Recovery (**PAR**), or **Aldrete score**	Post-operative assessment score	Measurement of recovery after anesthesia	At arrival to PACU, and every 15 minutes, until discharge criteria met	Clinical assessment, vital signs, O_2 saturation	Discharge from PACU to general care	Expert opinion	2 hospitals, 352 patients	- Qualitative comparison with other scores	Difficult
ICU	Acute Physiology and Chronic Health Evaluation (**APACHE 3**)	Illness severity score	Severity of illness score; can be converted to risk of mortality	1 time, after 24h from admission to ICU; recalculated if patient readmitted	Labs Vital signs Mental status Comorbidities	Management and treatment of ICU patients	Logistic regression	40 US hospitals, 17,440 adult medical and surgical ICU admissions [Apache 3]	- ROC	Moderate
	Simplified Acute Physiology Score (**SAPS 3**)	Illness severity score	Risk of mortality	Daily in the ICU	Labs Vital signs +age Admission type Clinical history LOS	Management and treatment of ICU patients	Multivariate analysis, logistic regression	Multiple hospitals, multinational cohort study, 16,784 patients	- AUROC	Moderate

	Sequential Organ Failure Assessment (**SOFA**) Score	Illness severity score	Organ status, correlates with risk of mortality	As needed, may be automatically triggered	Labs Vital signs Mental status	Management and treatment of ICU patients	Expert opinion	European Society of Intensive Care Medicine	- AUROC	Moderate
General Care	Early Warning Scores (**NEWS/EWS/MEWS**)	Track and trigger score	Composite score indicative of current patient state	As needed, minimum once every 12h	Vitals Mental status	Nothing, closer monitoring, call for assistance	Multi-professional expert system	Multiple hospitals, 198,755 vital signs datasets obtained from 35,585 patient episodes	- ROC	Easy
	Systemic inflammatory response syndrome (**SIRS**)	Assessment of SIRS/ Sepsis	Diagnosis of SIRS or sepsis in patients with a suspected or proven infection	As needed, may be automatically triggered	Vitals WBC	Management and treatment of SIRS/sepsis	Expert panel	American College of Chest Physicians/Society of Critical Care Medicine Consensus Conference, 1991	- ROC	Easy
	Quick Sequential Organ Failure Assessment Score for Sepsis (**qSOFA**)	Illness severity score	Identification of high-risk patients with suspected infection	As needed, may be automatically triggered	Vitals, Mental state	Management and treatment of sepsis	Statistical methods	12 hospitals, 1.3 million electronic health record encounters	- ROC	Easy

6. *Metrics/reporting for monitoring and feedback:* To better understand failure to rescue from serious but treatable complications, a score card was created using existing AHRQ administrative data definitions for nine inpatient complications: GI bleed, pneumonia, respiratory failure, cardiac shock/MI, sepsis, kidney failure, stroke, and pulmonary embolism. Statistical Process Control Charts have been created for each complication showing the occurrence rate and the complication mortality rate for all inpatient admissions. All patients on the palliative care service were excluded. These data are available in a comparative data set using risk adjustment with an Observed-to-Expected (O/E) rate. This outcomes-based scorecard allows interventions to prevent complication AND allows early recognition and rapid treatment of nonpreventable instances of these complications.



1. Data source - Clarity (EMR)
2. Criteria
   a. Billed DX Codes Stratum: GI Bleed, (AHRQ)
   b. LOCATION_NAME = 'N MHMH'
   c. Billed DX Codes Type: ICD-10
   d. Hospital Discharge Time = last 25 Months
   e. Present on admission = No
3. Numerator - # of in-hospital deceased patients with complication developed during hospitalization
4. Denominator - # of patients with complication developed during hospitalization

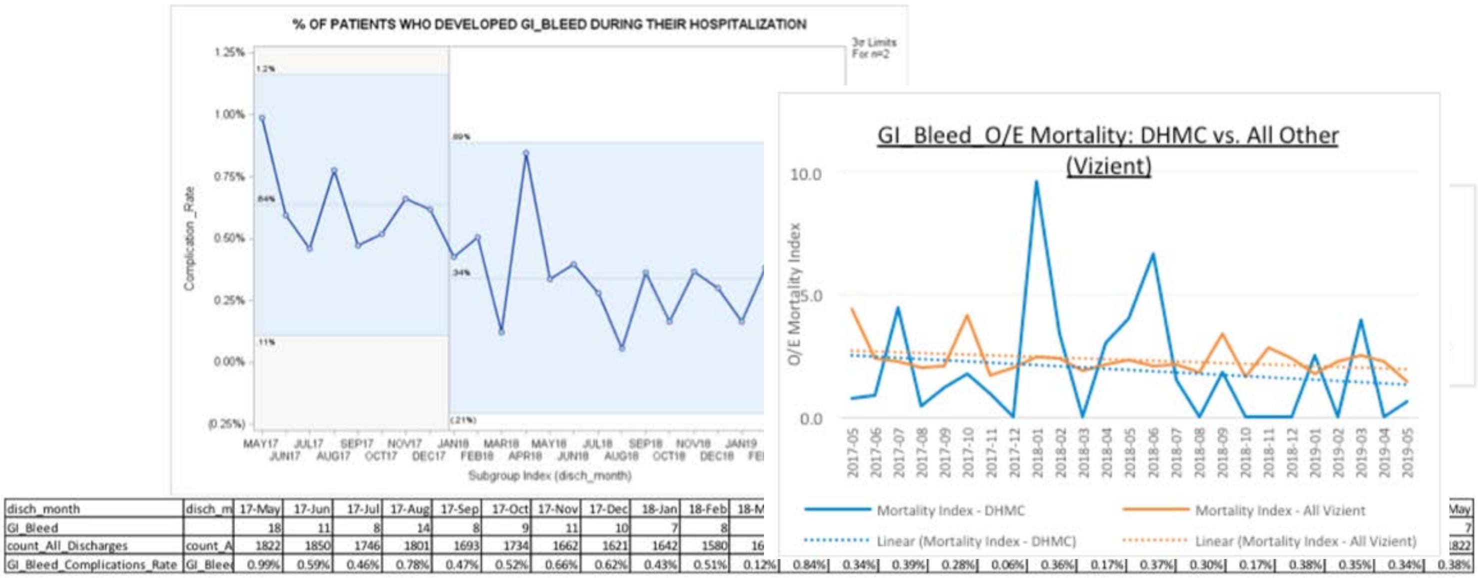
Complication Mortality Rate = # deceased patients with this complication / # of all patients with this complication

disch_month	17-May	17-Jun	17-Jul	17-Aug	17-Sep	17-Oct	17-Nov	17-Dec	18-Jan	18-Feb	18-Mar	18-Apr
GI_Bleed_Deceased	1	2	1	1	1	2	1	0	2	4	0	3
GI_Bleed_All	18	11	8	14	8	9	11	10	7	8	2	14
GI_Bleed_Mort_Rate	6.00%	18.00%	13.00%	7.00%	13.00%	22.00%	9.00%	0.00%	29.00%	50.00%	0.00%	21.00%

disch_month	18-May	18-Jun	18-Jul	18-Aug	18-Sep	18-Oct	18-Nov	18-Dec	19-Jan	19-Feb	19-Mar	19-Apr	19-May
GI_Bleed_Deceased	2	5	1	0	1	0	0	0	1	0	1	0	1
GI_Bleed_All	6	7	5	1	6	3	6	5	3	6	6	6	7
GI_Bleed_Mort_Rate	33.00%	71.00%	20.00%	0.00%	17.00%	0.00%	0.00%	0.00%	33.00%	0.00%	17.00%	0.00%	14.00%

A study was conducted in which PSI-4 cases were analyzed with chart review and application of NSQIP complication definitions; it found significant errors in the administrative data. In addition, aggregating multiple complications into a single metric undermined the ability to truly compare complication mortality rates between hospitals, because each complication has a different mortality rate, and the prevalence of complications varied between hospitals due to the care provided.

We implemented a 100% inpatient review, excluding complications present on admission and patients admitted to the palliative care service. Nine complications were individually tracked monthly for incident and mortality rate. Comparative analysis with a national hospital cohort was performed annually to identify complications with a high FTR rate relative to other benchmark organizations.



7. *Case review and feedback:* Learning cultures are associated with safety culture. A learning system was recognized as important for sustaining highly reliable complex rescue care system performance. A pilot of an adapted Morbidity and Mortality Conference to review FTR cases was conducted at the University of Michigan site. The team conducted quantitative and qualitative surveys to assess the current state of M&M conferences. Purposeful selection of cases was used to identify opportunities for early recognition and timely treatment in response to post-op complications deemed serious but treatable. Guidelines were developed to structure the case review adapted from work by Pat Croskerry and "The Ottowa M&M Model." A facilitator used this case analysis checklist to guide the conference with interactive discussion and identification of opportunities for improvement. Surveys were conducted as to the acceptance and utility of the conference. The feedback was very positive, with the following as representative quotes: "I love these sessions, and having multidisciplinary interactions is even better." "Really helpful having representative from other departments at conference. We interface with so many different people; having their input is beneficial for learning and knowing how we can make things better." "[We reviewed] a tough case with clear issues with bias that would affect every person in a situation like that. It was very useful to hear about every decision point from the people involved, including the trauma team and radiology."

1. Were there any *patient factors* that increased this patient's risk for harm?	☑ Yes	☐ No
2. Were there any issues with communication with outside facilities?	☐ Yes	☑ No
3. Were there any *cognitive issues (see Appendix B)*?	☑ Yes	☐ No
4. Were there any contributing *skill-set errors (see Appendix C)*?	☑ Yes	☐ No
5. Were there any *task-based errors (see Appendix C)*?	☑ Yes	☐ No
6. Were there any issues of *personal impairment*?	☐ Yes	☑ No
7. Did *teamwork failure (see Appendix C)* contribute to the outcome?	☑ Yes	☐ No
8. Were there any *local environmental contributors*?	☑ Yes	☐ No
9. Were there any *hospital-wide contributors (see Appendix C)*?	☐ Yes	☑ No
10. Were there any *hospital administration contributors*?	☐ Yes	☑ No
11. If you answered yes to any of the above questions, describe what the issues were.		

Discussion, Conclusions, Significance, Implications:
Healthcare delivery in modern hospitals requires a combination of engineered components supporting diagnostic and therapeutic activity (e.g., MRIs, physiological monitors, and pharmaceuticals) used and interpreted by human operators (i.e., healthcare providers) to diagnose and manage the complex adaptive biological systems that are our patients. Such complex adaptive systems present particular design and management challenges to achieve highly reliable performance (Cassel & Saunders, 2014). This study employed quantitative and qualitative systems engineering analysis and design methods to the highly complex area of recognizing and then diagnosing and rapidly treating serious but treatable complications in hospitalized patients to mitigate FTR events. The strategy and tactics presented represent a robust yet practical approach analysis and design of a system with variability and complexity in many dimensions (e.g., roles, disciplines, care settings, patient populations, procedures, equipment). Methods were selected and applied from the various systems engineering approaches available, with examples of how each method was used to identify system requirements and changes to the existing FTR event mitigation system to meet those requirements.

Modeling the rescue care system as a set of parallel control loops focused on early recognition of patient deterioration and rapid intervention and enabled stakeholders and system designers to explore the inter-relationship and impact of key features of the control system delivering rescue care. The model influenced the technical aspects of design and helped to build stakeholder understanding of the broader system, encouraging discussion about strengths and weaknesses in the system and resulting in a rich set of stakeholder-generated design concepts and improvements. Extensive analysis of best practices and baseline performance were additional methods that aided in the generation of comprehensive systems-level requirements that can be extended to healthcare systems more generally. Although results from implementation of intervention are not presented here, the study organization has successfully applied these methods to other patient safety systems, with sustained results.

Several salient points emerged from the study. First, introduction of an engineering mindset into the medical sciences with a focus on engineering care delivery for optimal performance represents "convergence" research. The National Academy of Science in Medicine describes convergence research as applied to health as an approach to problem solving that integrates expertise from life sciences with physical, mathematical, and computational sciences as well as engineering to form comprehensive frameworks that merge areas of knowledge from multiple fields to address specific challenges (National Research Council, 2014). Convergence builds on fundamental progress made within individual disciplines and cuts across disciplinary boundaries in these fields. Convergent research is most closely linked to transdisciplinary research in its merging of distinct and diverse approaches into a unified whole to foster new paradigms or domains. Bridging gaps in understanding of the engineering discipline within the medical science community and quality improvement community in healthcare is difficult and yet critical.

A second salient lesson is the importance of a structured execution process and early establishment of a measurement strategy. The decision to use a variety of methods from engineering domains was challenging, especially when coordinating activities across a multidisciplinary team. Refining the measurement approach allowed movement from anecdote to analysis of actual system performance and yet recognize the practical limitations of being able to apply rigorous quantitative engineering methods. A third lesson was that tradeoffs and competing priorities must be explicitly managed when moving into the design phase of building an ideal rescue care system.

The final and most critical lesson concerns change management issues. Engineers and clinicians see the same system from very different perspectives. Insights from engineering concepts, such as control loops, sampling rates, managing signal and noise, and reducing delays in notification and response are essentially first principles for engineers, but they are not immediately obvious to clinicians.

In contrast, clinicians are trained in the development of best practice through hundreds or thousands of study samples. This gap in approaches to problem solving required significant change management activities within both the execution team and the operational stakeholders to achieve confidence in the system design. Providing basic education regarding feedback systems, control loops, and response times allowed the clinical team to understand the rationale and efficacy of proposed changes. Although this work is an example of the successful application of systems engineering methods to redesign a clinical system, significant issues remain. The inherent momentum of any complex system makes it resistant to change, and engineering methods can only succeed in small steps. Competing influences also have impact, such as financial constraints that create pressure for hospitals to achieve economies of scale by growing and doing more with less, and have unknown effects on system performance. However, the increasing complexity and need to achieve better and more reliable performance make the continuous application of system engineering principles described here essential for achieving the goals of high-quality patient treatment and recovery.

VI. List of Publications and Products (Bibliography of Published Works and Electronic Resources from Study—Use AHRQ Citation Style for Reference Lists):

<u>Book Chapters:</u>

1. McGrath, S. Perreard, I., Ramos, J., McGovern, K., MacKenzie, T., Blike, G., A Systems Approach to Design and Implementation of Patient Assessment Tools in the Inpatient Setting. In: Leonard H. Friedman, Jim Goes, Grant T. Savage (editors). <u>Advances in Health Care Management</u>; London: Emerald Publishing Limited; 2019, 227-254.
2. McGrath, S. Wells, E., McGovern, K., Perreard, I., Stewart, K., Blike, G., Failure to Rescue Event Mitigation: A Mixed-Methods Approach to Analysis of Complex Systems. A Systems Approach to Design and Implementation of Patient Assessment Tools in the Inpatient Setting. In: Leonard H. Friedman, Jim Goes, Grant T. Savage (editors). <u>Advances in Health Care Management</u>; London: Emerald Publishing Limited; 2019, 119-157.

<u>Journals:</u>

1. McGrath, S, Perreard, I, MacKenzie, T, et al. Patterns in continuous pulse oximetry data prior to pulseless electrical activity arrest in the general care setting. J Clin Monit Comput (2020). https://doi.org/10.1007/s10877-020-00509-8.
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