Title of Project:

Making Ambulatory Procedural Care Safer: STAMP-Based Risk Assessment and Redesign

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Structured Abstract

Structured Abstracts can have a maximum of 250 words.

Purpose:
Scope:
Methods:
Results:
Key Words:

Purpose/Objectives of Study

In recent years, we have seen a progressive movement of invasive procedural care from an inpatient to an ambulatory care model. There is already tremendous momentum behind this phenomenon, due, in part, to the potential to improve efficiency and reduce the cost of care as well as the innovative appeal of new technology that enables procedures to be performed in a 'minimally invasive' manner. However, the rapid and progressive conversion of procedural care to an ambulatory setting can occur without a clear understanding of the safety implications and without formal evaluation of the 'hidden' system-based risks associated with this practice model. Safety concerns associated with this model of care include, but certainly are not limited to:

- Heavy reliance on collaboration and data exchange between primary provider and proceduralist for pre-procedure planning, with inadequate communication infrastructure
- Difficulty reconciling variations in or accuracy of office-based and procedural unit-based patient data
- Less formal pre-procedure patient preparation and post-procedure monitoring
- Ad-hoc involvement by anesthesiologists
- Increasingly complex procedures, resulting in prolonged procedural times while trying to maintain an ambulatory care delivery model
- Little or no overt or pre-planned backup for management of complications or events, requiring urgent conversion to an open operation
- 'Sundown' issues: shutdown of these units at a specific time, increasing potential for premature patient discharge

- Physical locations less fully equipped for contingencies and often 'remote' from inpatient crisis management teams
- More resource and equipment intensive, with greater reliance on new technology and ancillary services (e.g., fluoroscopy)
- Higher-throughput pressures in these units and difficulty balancing elective and emergency demands on limited schedule resources
- Heavy reliance on patient and family to manage pre-procedure preparation and much of the post-procedure recovery
- The need to coordinate care across several different services and manage the patient across several transitions: Home → Ambulatory Procedural Unit → Recovery Unit →Home → Primary provider office

As practitioners and researchers in this environment, we know that the system is complex. There are important interactions and interdependencies between components *(staff, instrumentation, protocols, procedures, information, communication, and scheduling cycles)* that further influence provider performance and patient safety. Given this exposure, we are clearly overdue for a formal analysis of the systems-based risks associated with ambulatory procedural care. What hampers our progress, however, is a general lack of experience and knowledge regarding the most appropriate approach to prospectively assess risk in such a complex socio-technical environment. In other high-risk industries, such as nuclear power, chemical engineering, environmental protection, and telecommunications, experts have employed a number of powerful probabilistic modeling formalisms to help understand and manage systems-based risks associated with both standard and novel operating conditions. Our proposed work will focus on the use of a systems-theoretic strategy for assessing and managing risk in the ambulatory care setting. This strategy uses probabilistic techniques to manage uncertainties and quantify the risk of specific events and also incorporates systems dynamics and control theory. We hypothesized that this approach would be robust in terms of its ability to model interactions between system components (e.g., different providers and patients, policies, organizational processes, physical features of the care environment, technical components, etc.), human adaptation to new and emerging hazards, feedback loops, and recovery efforts on overall system risk. This is in contrast to the more conventional probabilistic modeling formalisms (PRA), including fault trees and event trees, which tend to model accidents in terms of linear chains of events and which can be too constraining for much of the healthcare domain. The purpose of this project was to conduct a comprehensive prospective risk analysis using probabilistic and system dynamics approaches, focusing on ambulatory procedural care delivered in a large urban setting, and will achieve the following specific aims:

[1] Identify the human, technical, structural, and organization components and processes (patients, family, referring providers, proceduralists, information resources, technology, prevailing safety culture teamwork, coordination, communication, schedules, and workload) that define the ambulatory procedural system of care

[2] Using a system dynamics formalism, qualitatively model relationships, interactions, and critical interdependencies between these system factors and components and determine how they combine to:
- influence performance
- compromise patient safety
- contribute to or increase the risk of adverse events and unexpected variations in clinical outcome

[3] Obtain quantitative estimates of risk, reliability, and recovery as a function of various system configurations (i.e., combinations of people, time constraints, acuity, information resources, and workload) using probabilistic techniques

[4] Using the models, simulate system responses using Monte Carlo techniques, assessing system performance (e.g., probability of recovery vs. progression to adverse event after system perturbation) as a function of:
- team processes
- synchronization of staffing schedules with unit acuity
- time of day, day of week, shift changes
- access to and utilization of information resources
- concurrent activities and competing demands for attention in the procedural or recovery units

[5] Use the simulation techniques to identify dominant contributors to risk and leading indicators of increasing system risk, predict (forecast) the effects of specific interventions

and risk reduction strategies, and establish priorities for system redesign
or organizational change to optimize 'safety'

[6] Identify other aspects of ambulatory or inpatient care to which the system dynamics and probabilistic risk analytic techniques are applicable for prospective risk assessment, and develop a process for use of the technique for routine safety assurances and improvement

Scope

Background and Context:

As we began our prospective risk assessment, our work was shaped by the following important premises:

1)   (Clinical) systems are composed of interacting human and technical components. The interactions are virtually continuous but usually achieve a state of dynamic equilibrium by feedback loops of information and control.

2)   Adverse events or states of heightened risk are the product of dysfunctional interactions between human and technical components of the healthcare environment – typically flawed/maladaptive feedback, adaptations to local resource constraints, or inadequate enforcement of control mechanisms.[1]

3)   Most adverse events result not from a unique set of proximal events but rather from a drift of the system to a state of increased risk over time as controls are relaxed due to conflicting goals and tradeoffs.

4)   Systems can function in unsafe states for significant periods of time. Simply because the system has not realized a catastrophic adverse event does not mean that it is 'safe.' Persistence in these boundary states is not desirable, as there is little absorptive capacity for minor perturbations.

By modeling the core clinical processes – the component interactions required for these processes, feedback, and control mechanisms that influenced performance of each component (human, technical, and organizational), our goal was to gain insight into risks, vulnerabilities, or potential adverse event causal sequences before the events actually occurred. Simulation would then enable us to measure how risk changes (i.e., increases or decreases) over time as controls are strengthened or weakened (e.g., due to tradeoffs), as new controls are introduced, as components (typically the human components) adapt and adjust the quality of feedback, etc. Simulation would also enable us to 'see' how much the system has drifted into a higher-risk state as a function of various human and technical features.

Setting, Participants, Scope of Problem/Project: BIDMC GI Endoscopy Unit – Ambulatory Procedural Population

The Beth Israel Deaconess Medical Center is known for its clinical expertise in providing high-level ambulatory procedural care to an underserved urban population. Up to 30% of the patients receiving care in the interventional procedural areas at the BIDMC are uninsured. Although this does not represent a specifically defined priority population in the US healthcare

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[1] It is important to note that control mechanisms include not just direct intervention but also indirect influence through policies, shared values, perceptions, tolerance, and other aspects of organizational culture.

system, the delivery of safe and effective care to this subpopulation can be uniquely challenging. Racial distribution was 65.7% White, 11.9% Black, 14.4% Asian/Pacific Islander, 0.3% American Indian, and 7.8% other race. Six percent of patients reported their ethnicity as Hispanic. Other relevant characteristics of the ambulatory patient population at the Beth Israel Deaconess Medical Center include a substantial number of patients for whom English is not a primary language. The ambulatory procedural units also serve a large population of Russian- and Cape-Verdean Creole-speaking patients, creating unique safety issues around information sharing, patient education, and other aspects of patient-provider communication. In FY'07, the GI Endoscopy Unit, which served as our specific focus of risk analysis and modeling (prior to generalizing across other ambulatory procedural care areas), performed 22,156 procedures, of which 1800 involved complex interventions, such as ERCP, sphincterotomy, and endoscopic ultrasound/biopsy for staging of pancreaticobiliary tumors. Although the rate of serious adverse events was low within this particular unit, we knew from historical experience at the BIDMC that the high demand for complex interventional procedures performed in the ambulatory setting created specific safety challenges and that the unit might be functioning near the margins of safety. First, many of the patients for whom interventional procedures are planned have already been identified as high-surgical-risk patients, with the goals of nonsurgical intervention being either to palliate or to rule out a specific diagnostic indication for more definitive surgical care. Second, procedures can have ill-defined endpoints, making it difficult to predict total procedural duration, workload, and other resource demands. Third, there can be unpredictable and sudden demand from distant referral sources that must be interposed with an existing elective case load. Fourth, like other non-OR procedural units, the GI endoscopy unit functions semi-autonomously with respect to scheduling and planning/procurement of shared ancillary resources, such as radiology technical support, laboratory support, and anesthesia services. This means that, on any given day, there can be simultaneously high scheduled demand for shared services and resources from multiple procedural areas within the medical center, creating the potential for significant delays or pressures to expedite or abbreviate services in order to meet institution-wide demand. Finally, this and other non-OR procedural areas do not have a mandatory pre-anesthesia screening process, and anesthesiology staff do not conduct an audit of the next-day's non-OR procedural schedule as part of their staffing routine. Although we understood the high-level safety concerns, we had never conducted a formal risk assessment to identify how these features of the system interacted to influence performance. Nor did we understand what were the dominant contributors to the risk.

Methods

The work evolved in three phases: qualitative modeling phase, quantitative modeling phase, and simulation phase. Before discussing the results of our risk modeling and simulation efforts, we will review the data sources that we used to conduct this work, as these will continue to serve as an important source of data for the implementation and evaluation phase of work described in this proposal. In engineering domains, information used to support a risk assessment or systems-dynamic modeling is derived from a combination of empirical data, expert knowledge, expert opinion, physical laws, and human factors and engineering principles. We used a similar approach for this ambulatory care risk assessment, using information from the following combination of sources:

- Expert opinion from the procedural care staff (MD, RN, technician) and patients at the

> Beth Israel Deaconess Medical Center
>   ▪   Case summaries from Joint Commission-mandated root cause analysis reports, institutional morbidity and mortality case presentations, and clinical registries from the interventional procedural areas
>   ▪   Administrative database of the Beth Israel Deaconess Medical Center

Data Sources Used

Expert Opinion: Expert opinion was used for qualitative and quantitative phases, for the purposes of both model refinement and validation. The research team worked one on one with additional domain experts at the Beth Israel Deaconess Medical Center in order to define core clinical processes, the management of patients as they transition through the physical and function phases of care, the resources required to achieve these transitions, and the major factors that influenced performance at key nodes in the process. The data derived from these interviews were then used initially to develop the qualitative stock-flow models, causal influence diagrams, and human behavioral variables and values that will be used to generate the master system model (more details provided below). Individuals from primary nursing, nurse management, risk management, and physician and organizational leadership as well as from specific areas of clinical expertise (including gastroenterology, anesthesiology, surgery, and respiratory therapy) were recruited to participate in individual sessions with the study team. Through an iterative process, the experts reviewed, refined, and validated the evolving qualitative models, focusing on the relevance and completeness of the human, technical, structural, and organization components and processes that have been incorporated into the models. Experts were asked to define key variables that they perceived influenced the 'processing' of patients and task performance and to assess whether the feedback influences were balancing or reinforcing. The domain experts also assisted with modeling the outcome implications of delays. In some cases, there was a need to assign an importance weight; this was elicited from the experts and by using a modified Delphi technique. The final role of the experts was to provide estimates of specific event probabilities and the magnitude of various feedback influences on process steps. We used an Analytic Hierarchy Process as the initial elicitation method of expert opinion to determine the a priori distribution of key events or influence variables, with Bayesian treatment of the probability distributions, as this technique has had wide use by risk analysts modeling engineering system safety.

Case Summary Reviews: In conjunction with ongoing quality activities at the Beth Israel Deaconess Medical Center, the research team used case review data from the Patient Safety Reporting System, the Adverse Event Management System, and root cause analysis reports to develop a broad range of causal sequences that might be used in the qualitative modeling phase of this work. The root cause analyses performed at this institution are more comprehensive than the Joint Commission's format (per Joint Commission on the Accreditation of Healthcare Organizations, 2001) and provide a rich classification of system and human factors thought to have contributed to the initiation or propagation of the event. Recognizing that reported events do not accurately reflect prevalence or frequency of actual events (an example of an under-reported event is prolonged hypoventilation during procedural sedation), we did not use the data for quantitative modeling of probabilities but instead used them as a source for the qualitative modeling of theoretical contributors to event initiation and propagation.

Administrative Databases at the Beth Israel Deaconess Medical Center: Clinical process, outcome, and resource utilization data derived from the administrative and clinical databases at

the Beth Israel Deaconess Medical Center were used primarily for the quantitative modeling phase. The team used five different SQL servers that support 62 linked relational databases storing contemporary and historical clinical data (FY'98-FY'08) and disease registries for all major clinical areas as well as the more recently implemented computerized order entry data. Data were accessed using the Microsoft Management Console toolkit and SQL Server Enterprise Manager Software using a series of SQL queries and stored procedures that had been developed for routine institutional quality audits. Categories of data that were extracted included, but were not limited to, patient and provider scheduling data for procedural and inpatient units; acuity levels and patient volume in the target unit population as well as concurrent levels in other units of the hospital; total resource utilization at the unit and case levels; nursing scheduling cycles; drug utilization (both standard and emergency pharmaceutical agents); laboratory results matched to the pre-, intra-, and post-procedural phases of care in procedural areas; and subprocess time stamps for procedural areas. The process data in these sources were remarkably detailed and enabled us to model durations of key phases of care, such as pre- procedure preparation, sedation phase, prep/drape phase, post-procedure recovery phase, admission and discharge times, room turnover times, emergency case interruptions to the elective scheduled, and delays in scheduled cases due to emergency issues.

Modeling and Simulation Software Used: We used the AnyLogic modeling and simulation software tool to conduct all of the analytic and simulation modeling tasks. This is an object-oriented application that codes in Java and is built on the Eclipse open source platform. Because of its object-oriented foundation, this tool supports the development of hierarchical levels of component objects. Modeling also is scalable, with collections of objects and components that can be packaged and re-used, enabling us to create a customized library of objects. We felt that this feature would be of considerable value as we began to generalize the work to other aspects of healthcare. The application also features an intuitive graphical interface for qualitative modeling: editing dependencies modeling flow, representing shadow variables and polarities. Modeling formalisms to optimally describe the behavior of the system components, we adopted a hybrid strategy involving:

- A discrete event component to represent the 'processing' of a patient in the system of care and global state changes of the patient as a function of time and of the specific decisions/ actions of physicians
- A system dynamics component to represent the interactive influences (including feedback) of human decision variables, production pressures, and system constraints on actions and events

We used feedback control loops to represent the relationship between two or more model variables. Figure 1a depicts a generic example of feedback/control loop formalism. Relationships are either positive (+, reinforcing; i.e., an increase in the strength or magnitude of one variable causes an increase in the strength or magnitude of the second variable and influencing changes in the same direction) or are negative (-, balancing; i.e., an increase in the strength or magnitude of one variable causes an increase in the strength or magnitude of the second variable). Figure 1b depicts a specific example of one of the feedback/control loops that was actually modeled. In this specific example, high degrees of accuracy with which a proceduralist books the anticipated scope or duration of the case leads to high degrees of reliability in the master case schedule for the day, which, in turn, reduces the need to rearrange the schedule ad hoc to manage impending staffing or other resource constraints. Note that it is a specific behavioral attribute of the provider (either accurately or inaccurately representing the scope or duration of the case) that interacts with normative scheduling and staffing functions. For each variable (either a system component or a specific attribute of a component) in our evolving model, we systematically identified the family of other variables with which it

interacted, assigned the appropriate polarity, and modeled it using this formalism.
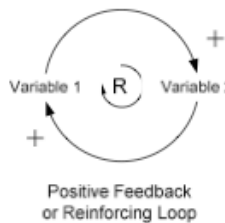

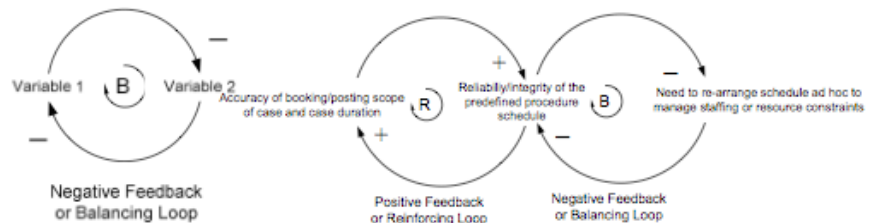**Figure 1a:** Generic feedback/control loop formalism   **Figure 1b:** Specific feedback/control loop modeled.

We used Stat:Fit software (Geer Mountain Software Corporation) to fit process data derived from our sources to standard distributions. This curve-fitting algorithm uses a Kolmogorov-Smirnov goodness-of-fit test. The parameterized distributions were then used as quantitative models for Monte Carlo sampling during simulation. An example is given in Figure 2, in which clinical data were fitted to both a gamma and a log-normal distribution.
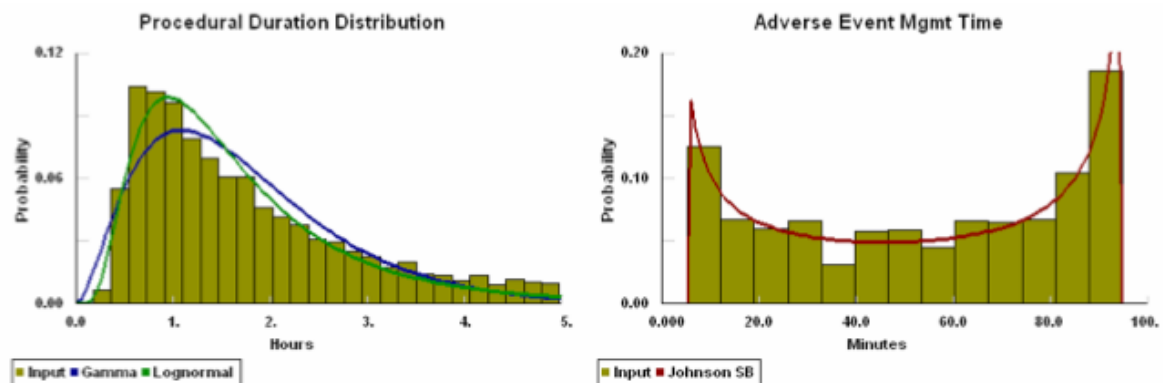

Figure 2: LEFT - Curve fitting of clinical data to establish gamma and lognormal distributions as appropriate quantitative model for procedural duration. RIGHT - Use of the Johnson SB distribution to estimate additional procedural time required to manage adverse event.

In cases when the data were insufficient, probability distributions were selected and parameterized by the domain experts. As an example, we did not have sufficient data from administrative, clinical, or published literature sources to estimate the additional procedural time required to manage a range of adverse events that might occur during interventional procedures. Using expert opinion to describe the shape and scale parameters, we were able to establish a Johnson SB distribution as an appropriate quantitative model for Monte Carlo sampling (see Figure 2 – RIGHT).

Results

Model Description and Analytical Results

We initially modeled three specific and dominant clinical processes because they a) were felt by the clinical experts to strongly influence overall safety and productivity in the unit and b) were generalizable across other ambulatory and procedural care units. The processes were:
- Screening to assess need for anesthesiology consultation and use of anesthesiology consultation for moderate sedation when screening criteria are met

- Assessing readiness for discharge to home (vs. admission to inpatient unit)
- Managing the elective vs. urgent/emergent case load (including 'takebacks' – patients initially managed as an elective case but with a complication requiring urgent return/re-evaluation in the procedural room)

This comprehensive model has over 250 variables associated with it. Based on our initial work with domain experts, a request was made to focus most closely on the first process, assessment of the need for anesthesiology consultation and actual utilization of anesthesiology consultation for moderate sedation when screening criteria are met. The initial modeling suggested that this represented an acute vulnerability, justifying submodel refinement. The details of the anesthesiology safety/risk issue can be described as follows:

> In situations when case complexity of the case is perceived to be high, in which a patient comorbidity is believed to put the patient at very high risk for a negative cardiac or respiratory outcome, or when the probability of crossover from moderate to deep sedation is high, a protocol (safety control) calls for the engagement of a specialist (anesthesiologist) to assist the GI proceduralist with management of the anesthetics and conduct minute-to-minute physiological monitoring of the patient.

> In situations when case complexity is perceived to be low, when there are no significant patient comorbidities, or when the probability of crossover from moderate to deep sedation is low, the GI proceduralist assumes responsibility for the technical execution of the procedure, including both the management of the anesthetics and the minute-to-minute physiological monitoring of the patient.

Because there currently are no validated, objective measures of case complexity or 'need' for specialist involvement in the case, this becomes a subjective assessment by the GI proceduralist involved in the case. Further, the anesthesiologist specialist is a limited resource; when this service is used, there can be delays in case start times while awaiting release of this resource from another case. As a result, use of the anesthesiology specialist is frequently waived. Even when the GI proceduralist waives the use of an anesthesiologist, clinical care can proceed without incident. This reinforces the behavior, promoting future waiving even when use of the specialty services is indicated. Similarly, because of the uncertainties in clinical care, use of the anesthesiology specialist also does not guarantee that an adverse event will not occur. This erodes confidence in the value or efficacy of the service and promotes future waiving. The historical adverse event reviews and interview data also confirmed that the willingness or tendency to disengage or waive the use of the anesthesiologist is influenced by:

- Inherent risk tolerance among the clinicians
- Perceptions about the risks associated with a specific case
- Confidence in/perceived utility of the anesthesiology services
- Potential costs associated the use of the safety control (e.g., delays imposed, increased resource costs, longer procedural times, general erosion in productivity, etc.)

Using this as a foundation for the more detailed submodel analysis, we then proceeded to refine the master model to identify the specific interactions between variables and evaluate how they drive the system above acceptable thresholds of safety. In an iterative manner, we applied the same strategy used for the master model construction: identifying and modeling the clinical processes, core components, feedback and interactions, and hierarchical control structures that control the processes within this submodel. For the purposes of description and discussion, we will refer to the of the anesthesiology specialist as the anesthesiology safety control.

Dynamics Underlying Risk-Related Behavior

Figures 3 and 4 depict the major variables influencing the waiving phenomenon in the clinical system studied. There are two major loop structures. The first, depicted in Figure 3, qualitatively describes the system factors that influence the dynamics of the waiving phenomenon. The second, depicted in Figure 4, qualitatively describes the individual behavioral aspects that influence the dynamics. In Figure 4, there is a reinforcing loop, in which increasing risk tolerance or propensity increases the probability of waiving the anesthesiology safety control and explains how this behavior is reinforced each time an adverse event is avoided. There is a second loop, a balancing loop, that qualitatively describes how high confidence in the value or efficacy of the anesthesiology safety control decreases the probability of waiving (or, conversely, increases the probability of implementing) the control. However, high failure rates with implementation decrease confidence in the value and efficacy of the control, thus further increasing the probability of waiving. Time pressures can increase with each instance of an adverse event, particularly if it occurs in conjunction with implementation. 'Successful' waiving (i.e., waiving without incurring an adverse event) reduces time pressure, whereas 'unsuccessful' waiving (i.e., waiving with a subsequent adverse event) increases time pressure. The functional forms of these variables are discussed below.

Processing Global State Changes of the Patient and System

We used a discrete event model to represent the processing of patients and state changes to the patient in the surgical unit. We simplified our model by limiting the procedural care unit to a modified single-server queuing system with batch arrival of the entire days' patient load and serial processing of patients (see Figure 2). As noted above, we used data from the administrative and clinical databases at a large academic medical center to establish representative processing times and operational time intervals for the unit. Patients are generated by the model at the beginning of this operational time interval and accumulate in an infinite-capacity queue that represents the 'pre-op holding area' in the surgery unit. We used our clinical data to establish a log-normal distribution (min = 0.17 hr; $\propto$ = 0.358 hr; $\int$ = 0.641 hr) for overall procedural duration and a point estimate of number of cases processed per room per day ($\propto$ = 8). In contrast to impatient units, which are capable of processing patients continuously, 24 hours a day (around the clock), ambulatory units have fixed operational hours, typically 8-12 hours, depending on the specific organization. To reflect this schedule constraint, we established a 12-hour operational time interval for the model. Any patients remaining in the queue at the end of the 12-hour operational time interval remained unprocessed.

Key Event Nodes that Prescribe Change the System State

After batch arrival of all the patients for the day, each patient is processed individually. There are three key events that prescribe state changes for the patient/system. The first key event (see arrow 'A' in Figure 5) is a simulated decision by the physician to either 1) implement the safety control (i.e., use anesthesiology specialist services during the case) or 2) waive the safety control (i.e., perform the case without the use of anesthesiology specialist services). The logic defining the transition at this event node is described below. The second key event (see arrows 'B' and 'C' in Figure 5) is exposure of the patient to a hazard during the course of a procedure. Exposure leads to a transition to one of two outcomes: 1) adverse event/harm or 2) no adverse event/no harm. The transition is probabilistic, with different parameters depending on whether the safety control has been waived or implemented. We used clinical data from the most complex cases and established a point estimate (Pr = 0.2 following waiving [see arrow 'B' in Figure 1] and Pr = 0.02 following implementation of the safety control [see 'C' in Figure 5]). The third key event is represented by arrows 'D' and 'E' in Figure 5.
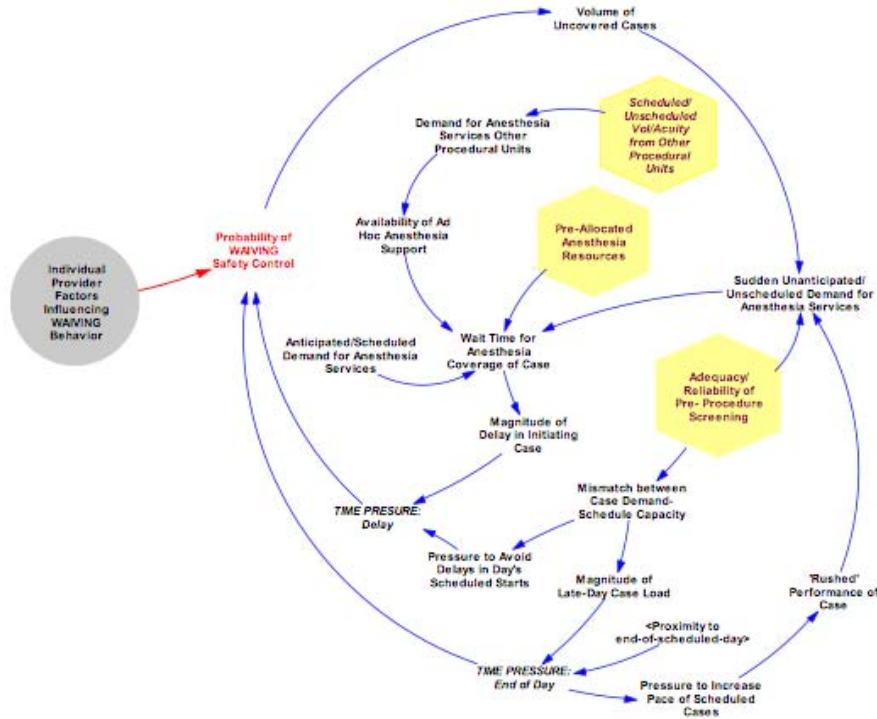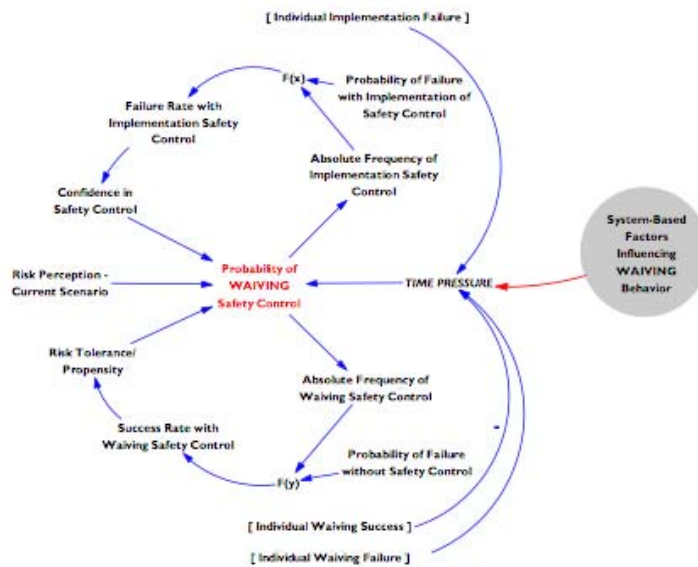
Figure 3: SYSTEM Factors influencing the waiving behavior of proceduralists

Figure 4: INDIVIDUAL PROVIDER Factors influencing the waiving behavior of proceduralists
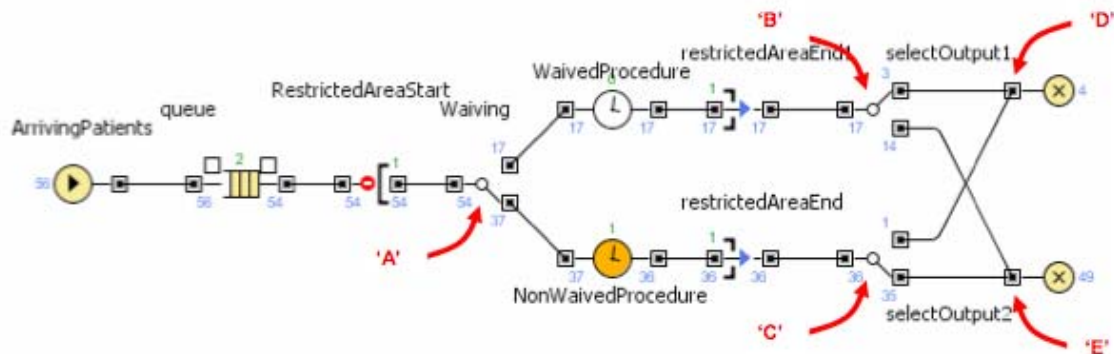
Figure 5: Simplified model of core patient care process and waiving behavior

Functional Forms of Variables

Variables were created for the Risk Tolerance, Confidence in the Safety Control, and Time Pressure parameters discussed above. The instantaneous value of the variable is defined based on parameters in the discrete-event model. Once these three variables are dynamically defined, they influence the Waiving Probability through specific table functions to be discussed later. We established a baseline value for the Risk Tolerance variable that increases incrementally to a maximum each time that the waiving results in a favorable outcome (waiving without incurring an adverse event). The variable resets to a minimum value of zero each time that the proceduralist incurs an adverse event. A continuous first-order delay (using a time delay of 12 hours) was implemented to account for the adjustment time in surgeon risk tolerance. This enabled us to model the quasi-oscillatory nature of risk tolerance around adverse events, as described by the domain experts. We established a baseline value for the Confidence in the Safety Control variable that decreases incrementally each time that the control is used and is ineffective in preventing an adverse event. Confidence slowly returns to baseline as positive experience with the use of safety controls accumulates over time. The return-to-baseline function was implemented as a continuous third-order delay, with a time constant of 100 hours (see Figure 6).
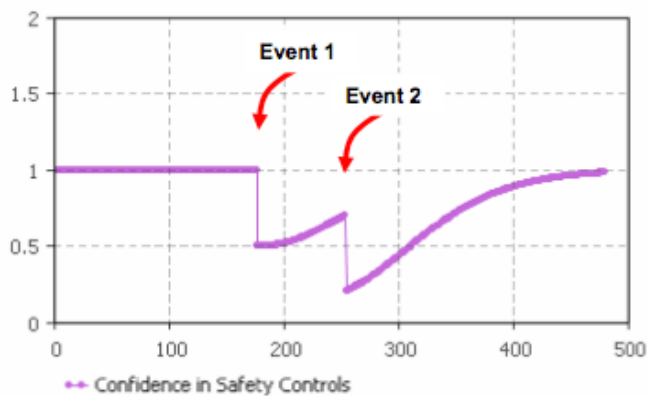
Figure 6: Loss of confidence in safety controls and return to baseline. The 'Event 1' arrow reflects the occurrence of an adverse event after implementation of the safety control, which results in an incremental decrease in confidence. With no further adverse events, the confidence slowly returns to baseline over a 30 d. timeline using a continuous 3rd order delay function. The 'Event 2' arrow reflects the occurrence of a second adverse event after implementation of the safety control before confidence returns to baseline.

The Time Pressure variable was represented as a function of the remaining time before the unit closes and the approximate time required for all the patients in the queue to receive appropriate care. The time required for each remaining patient was established by sampling randomly from the procedural duration distribution discussed above. A simple, continuous, first-order delay with a time delay of 1 hour was implemented to account for the perception of time pressure by service providers. A Waiving Probability function was defined to represent the combined influence of the Risk Tolerance, Confidence, and Time Pressure variables and to apply to the discrete-event model. Table functions are used to define the effect of Time Pressure, Risk Tolerance, and Confidence on Waiving Probability. Based on input from clinical experts, we set the Baseline Waiving Probability to 0.10. As a first approximation, and using all available data, the functions used to define the effects are chosen to be linear and to indicate the relative importance of each influence on waiving behavior.

Experimental Results
We designed a series of experiments to study the complex interactions between production pressures, historical experience with adverse outcomes, inherent risk tolerance/propensity, and confidence in and compliance with safety controls as well as how these interactive factors drive the system above acceptable thresholds of safety.
Experiment 1: Assessing the Impact of Time Pressure on Waiving Behavior:
Operating on the assumption that individual physician attributes (e.g., risk tolerance/propensity) are more difficult to manipulate in a real-world setting than system properties (e.g., time pressures induced by resource constraints) are, we conducted an experiment to assess the impact of time pressure on overall waiving behavior. We conducted a series of 100 simulation runs, each simulating 500 consecutive operating hours for the clinical unit. Using average daily patient load and procedural durations derived from historical data sources, and following the parameters described above, we generated data on waiving probabilities. We then eliminated the time pressure variable from the model and repeated the experiments, generating a data set representing waiving probabilities solely due to the human factors (risk tolerance/propensity and confidence in the safety controls). Figures 7a and 7b illustrate a typical comparative run with and without time pressures, using a fixed seed for the simulation runs to enable comparative analysis following manipulation of the time pressure variable. Statistical analysis of the two data sets demonstrated a significant ($p < 0.005$) reduction in waiving probability with removal of all time pressure using a Student's t test.

Experiment 2: Tracking Proportion of Time that Unit Operates Above Safety Thresholds
Traditionally, 'safety' in a healthcare domain has been measured in terms of outcomes rather than processes. This means that clinical units that experience infrequent adverse events are assumed to be safe, even when the process of care is, in fact, highly vulnerable. The objective behind this experiment was to measure the percentage of time that waiving probability exceeds baseline rates and how this rates change as a function of unit capacity and case volume. We conducted a series of 100 simulation runs, each simulating 500 consecutive operating hours for the clinical unit. Using average daily patient load and procedural durations derived from historical data sources, and following the parameters described above, simulation experiments demonstrated that waiving of safety controls exceeded baseline rates 62% (+/-18%) of the operational time. Detailed examination of traces reveal that, over longer operational intervals, exceedance is disproportionately related to core risk tolerance/propensity attributes and feedback reinforcement of this behavior, but daily production/time pressures produce episodic high waiving probabilities. We then systematically reduced the workload, repeating the experimental runs, and determined that, in order to reduce exceedances to < 25% of the operational time for the unit, it is necessary to reduce patient volume from eight to five patients. At this patient volume, time pressures are sufficiently relaxed to reduce the episodically high rates of waiving. Results of a representative simulation run are depicted in Figure 8.
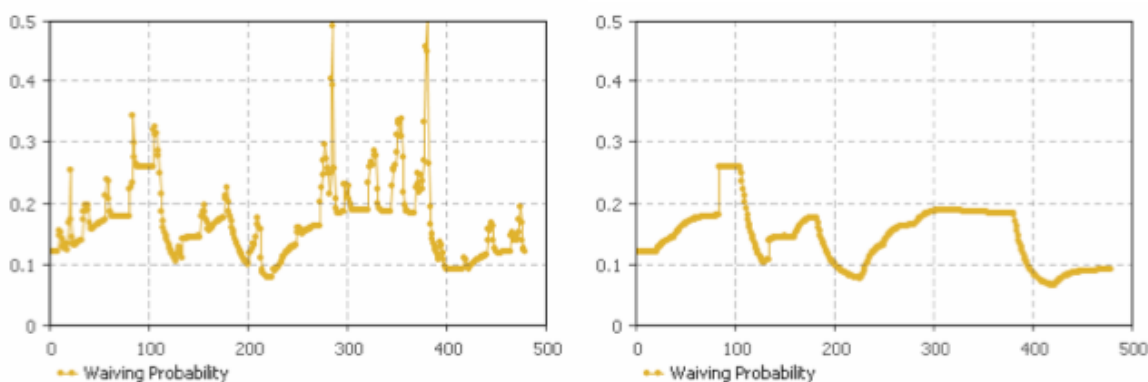

Figure 7a (Left) and 7b (Right) depicting the impact of daily time/production pressures on waiving probabilities.
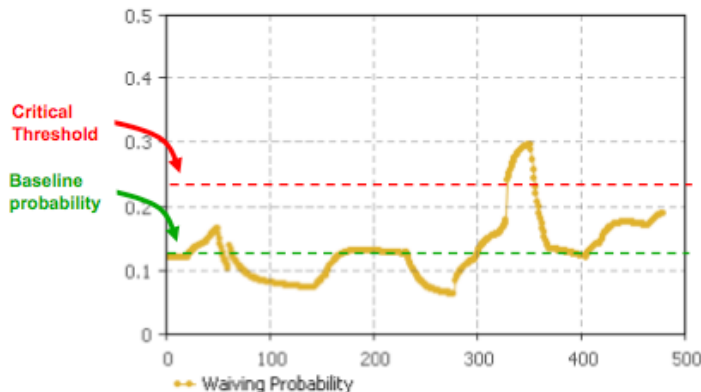
Figure 8: Sample simulation run depicting exceedance above a critical safety threshold.

Discussion of Results and Implications for Intervention In this preliminary work, we used a system dynamics framework to model the complex interactions between production pressures, historical experience with adverse outcomes, inherent risk tolerance/propensity, and confidence in and compliance with safety controls. The models developed have enabled us to study the dynamic changes in risk and develop some understanding of how often the human attributes and organizational pressures combine to push the system into an unacceptably hazardous state of operation. This represents a unique approach to modeling and analyzing risk in healthcare. As noted earlier, 'safety' and risk in a healthcare domain have been measured in terms of outcomes rather than processes. This means that clinical units that experience infrequent adverse events are assumed to be safe, even when the process of care is, in fact, highly vulnerable. Our experimental results indicated that specific interventions directed at reducing time pressures and delays could significantly shift the percentage of time that the unit functioned in a higher-risk state. In particular, in reviewing the models and simulation results, our domain experts felt that interventions designed to improve access to anesthesiology support and improvement in the reliability of the scheduling and booking would significantly reduce the magnitude of time pressures facing the system. These results now inform the series of interventions in the local environment.

Applying this Risk Modeling Technique to Other Areas of Healthcare

During the study period, we critically evaluated the use of this novel modeling formalism for risk assessment in other healthcare settings/scenarios. We determined that the strengths of this approach over conventional PRA rest in the ability to capture the dynamics of risk (i.e., how it changes over time, and how it changes in response to reinforcing or stabilizing feedback). In addition, the system dynamics component of this modeling strategy is particularly effective in assessing how organizational policies affect decision making by healthcare providers at the point of care and paradoxically may encourage providers to operate in a high-risk state with respect to patient care. The types of models explicitly depict how:

- multiple system goals are dependent upon each other,
- how the effects of delayed feedback in the system create instability, and
- how the instability renders system goals unattainable.

The types of models that this approach generates also enable measurement of the relative magnitude and effect of various policies and exploration of system structure changes for the achievement of system goals.

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As part of this project, we also applied the modeling formalism to assess the impact of investment in proactive safety interventions on overall systemic risk in a hospital and the unintended consequences of reduced reimbursement for management of hospital-acquired conditions and iatrogenic complications. This work was used as the basis for a doctoral thesis completed by Reza Kazemi-Tabriz, PhD (2011, in Reliability Engineering, University of Maryland), and supervised by Meghan M. Dierks, MD.

List of Publications and Products

Dissertations and Theses (partially supported by this project)

Kazemi-Tabriz, Reza. *A Hybrid Methodology for Modeling Risk of Adverse Events in Complex Healthcare Settings.* Doctoral Thesis in Reliability Engineering. Reliability Engineering Program, University of Maryland Department of Mechanical Engineering, June 2011.

Stringfellow, Margaret V. *Accident Analysis and Hazard Analysis for Human and Organizational Factors.* Doctoral Thesis in Aeronautics and Astronautics, Massachusetts Institute of Technology, June 2011.

Peer-Reviewed Publications and Abstracts:

Dierks M, Dulac N, and Leveson N. System dynamics approach to modeling risk in complex healthcare settings. IN: *Proceedings of the 26th International Conference of the System Dynamics Society.* System Dynamics Society and Wiley-Blackwell, 2008. ISBN 978-1-935056-01-0.

Dierks M and Stringfellow MV. Healthcare Industry Incentive Structures Pressure System Operators to Operate in a High-risk State. IN: *Proceedings of the 27th International Conference of the System Dynamics Society*. System Dynamics Society and Wiley-Blackwell, 2009. ISBN 978-1-935056-02-7.

Mosleh A, Kazemi R, and **Dierks M**. A hybrid technique to model dynamic aspects of risk in healthcare settings. IN: *Reliability, Risk, and Safety Theory and Applications.* Edited by C. Guedes Soares, Radim Briš, and Sebastián Martorell. CRC Press 2010. ISBN: 978-0-415-55509-8.

Kazemi R, **Dierks M**, Mosleh A. A Hybrid Technique to Model Dynamic Aspects of Risk in Healthcare Settings. IN: *Proceedings of the 2009 Annual Conference of European Safety and Reliability Association (ESREL)*. Prague, Czech Republic, September 2009.

Kazemi R, Mosleh A, **Dierks M**. On Modeling Risk of Adverse Events in Complex Healthcare Settings. IN: *Proceedings of International Probabilistic Safety Assessment and Management Conference.* Seattle, Washington, June 2010.

Kazemi R, Mosleh A, **Dierks, M.** Methodology to Manage Risk in Complex Healthcare settings. IN: *Proceedings of the Society for Risk Analysis.* Baltimore, Maryland, December 2009 (Best Paper award).