System Dynamics Approach to Model Risk in Complex Healthcare Settings: Time Constraints, Production Pressures and Compliance with Safety Controls

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Abstract

Risk is an inherent part of healthcare, particularly in large referral centers, where some of the most complex cases are managed. While risk cannot be eliminated from the clinical activities, it is believed that some practices involving unnecessary risk can be mitigated without impacting overall performance. Our ability to identify these vulnerable practices, and develop durable preventative or mitigating strategies, however, is hampered by outdated models of risk and an inadequate approach to the analysis of risk. In an effort to

develop more realistic models of risk in complex healthcare settings, we applied a system dynamics framework to model how features of the environment (e.g., time pressures, resource shortages, etc.) and human attributes (e.g., risk tolerance, confidence in existing safety policies, etc.) combine to influence safety. The models have enabled us to study, through simulation, the complex interactions between production pressures, historical experience with adverse outcomes, inherent risk tolerance/propensity, confidence in and compliance with safety controls. We present here the modeling strategy and the results of a series of simulation experiments studying these phenomena.

Keywords: healthcare, risk, adverse events, production pressures, human decision-making

Introduction

Risk is an inherent part of healthcare, particularly in large referral centers, where some of the most complex cases are managed. While risk cannot be eliminated from the clinical activities, it is believed that some practices involving unnecessary risk can be mitigated without impacting overall performance. Our ability to identify these vulnerable practices, and develop durable preventative or mitigating strategies, however, is hampered by outdated models of risk and an inadequate approach to the analysis of risk. Current analytic approaches are based largely on the assumption that adverse events arise from a linear chain of failure events, or are due to a single component failure or human technical error. These analytic approaches do not adequately account for multiple indirect, non-linear, and feedback relationships, and do not explain system accidents, where a catastrophic outcome arises from the interaction among operating components, each functioning individually within a standard or acceptable performance range, or in the context of an appropriate objective. Current models of risk also do not adequately incorporate the organizational and social aspects of safety and safety culture, including the human decision-making that is required to manage multiple conflicting or competitive goals (e.g., safety and production pressures) and the high degrees of uncertainty associated with such decisions. These limitations in both our *models* and our *analytic approaches* make it very difficult for both designers and clinicians to develop durable strategies to manage and mitigate risk before adverse events occur.

In an effort to develop more realistic models of risk in complex healthcare settings, we are using a system dynamics framework to model how features of the environment (e.g., time pressures, resource shortages, etc.) and human attributes (e.g., risk tolerance, confidence in existing safety policies, etc.) combine to influence safety. For this initial phase of work, we focused on modeling risk associated with ambulatory/outpatient (vs. inpatient) surgical care. In particular, we studied the complex interactions between production pressures, historical experience with adverse outcomes, inherent risk tolerance/propensity, confidence in and compliance with safety controls. We also studied how these interactive factors drive the system above acceptable thresholds of safety. We present here the modeling strategy and the results of a series of simulation experiments studying these phenomena.

Background

For this modeling and analysis, we chose a specific clinical area – ambulatory/outpatient surgical care - for a number of reasons. Surgical care, in general, is a high-risk aspect of clinical medicine by virtue of the fact that the environment is technologically rich with significant human-machine interface issues, patient status is dynamically changing and outcomes depend

heavily on the success with which the humans recognize and respond appropriately to such change. However, surgical care is increasingly being delivered in an ambulatory/outpatient (vs. inpatient) setting, a phenomenon driven largely by cost-containment pressures and a desire to deliver this care more efficiently. Safety concerns associated with this newer model of care are numerous. Ambulatory surgical units can be less-fully equipped for contingencies, and often are 'remote' from inpatient crisis management teams. Pre-procedure patient preparation can be considerably less formal with this patient population, including little or no overt or pre-planned backup by specialists for management of complications. In contrast to impatient units, which are capable of processing patients continuously, 24-hours a day (round the clock), ambulatory units have fixed operational hours leading to 'sundown' issues: shut-down of these units at a specific time, increasing potential for premature patient discharge or rushed execution of procedures towards the end of the day. Even when patients are discharged using appropriate 'readiness' criteria, there can be heavy reliance on patient and family to manage post-procedure recovery and an increased need to coordinate care across several transitions: Home -> Ambulatory Procedural Unit → Recovery Unit → Home → Primary provider office. Perhaps the most important concern, however, is that operational decisions and policies governing staffing, resource allocation, information exchange, space allocation and prompt access to specialists, can favor case productivity goals over safety. This tension between productivity, efficiency and safety is particularly strong. High demand for services has generated tremendous throughput pressure. Because services can be delivered more economically in an outpatient/ambulatory setting, the envelope is being pushed to perform increasingly complex cases in this manner.

To counter the increased complexity and risk a large number of safety controls have been introduced into this 'system' in an effort to safeguard patients. Examples include mandatory staffing ratios, pre-procedure 'time outs,' required engagement of specialists to assist with certain types of procedures and a large number of redundancy-based checklists and cross-referencing protocols. However, because these safety controls have the potential to add to the overall cost and slow or delay the process of care (thus undermining the dominant economic objective for this particular delivery model) they often are 'disengaged' or waived by physicians and nurses in the interest of maximizing the productivity and efficiency outcome objectives [1], [2], [3], [4], [5]. This type of violation may, in many cases, reflect a sound decision using a local judgment criterion given the time, resource constraints, throughput pressures and short-term incentives that shape behavior [6].

There are other reasons why safety controls are 'disengaged' or waived. Extensive research in non-healthcare domains has demonstrated that individual agent attributes, either operating alone or in combination, can strongly influence safety-related behavior. These attributes range from core risk tolerance/propensity (i.e., is the agent risk averse, or do they thrive on or seek high-risk situations?), perceived value or efficacy of a particular safety control, perceived accountability for negative outcomes, perceived control over exposure to the risk and perceived control over the negative outcome once risky behavior has been initiated [7], [8], [9], [10], [11], [12], [13], [14]. [15], [16].

We believe that this waiving phenomenon is a function of complex interactions between these variables - production pressures, historical experience with adverse outcomes, inherent risk tolerance/propensity, confidence in and compliance with safety controls. We also believe that the phenomenon is subject to strong feedback influences. Specifically, because the removal or waiving of the safety control does not guarantee that an adverse event will occur. In fact, in many instances, clinical care proceeds without incident. In a similar vein, full implementation of

the safety control also does not guarantee that an adverse event will not occur. This creates a strong reinforcing feedback influence, with both 'successful' waiving (i.e., disengaging or waiving the safety control without incurring an adverse event) and 'unsuccessful' implementation (i.e., implementing the safety control but still incurring an adverse event) both promoting future waiving.

Description of the Specific Clinical Problem Modeled

Through direct field observations, interviews with clinical experts working in this domain, and review of adverse event case histories, we identified several examples of this type of phenomenon in the ambulatory/outpatient procedural system of care. The most significant example related to the use of a specialist (Anesthesiologist) to assist with the case. The safety control can be described as follows:

> In situations where case complexity is perceived to be high, or where a patient co-morbidity is believed to put the patient at very high risk for a negative cardiac or respiratory outcome, a protocol (safety control) calls for the engagement of a specialist (Anesthesiologist) to assist the surgeon with management of the anesthetics and to conduct minute-to-minute physiological monitoring of the patient.
>
> In situations where case complexity is perceived to be low, or where there are no significant patient co-morbidities, the surgeon assumes responsibility for both the technical execution of the procedure, management of the anesthetics and minute-to-minute physiological monitoring of the patient.

Because there are no validated, objective measures of case complexity or 'need' for specialist involvement in the case, this decision making becomes a subjective assessment by the physicians 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 surgeon 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 was 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 our foundation, we then proceeded to model the interactions between these variables and evaluate how they drive the system above acceptable thresholds of safety. While

the following model describes the specific case of the Anesthesiology safety control, we feel that it is generalizable across other specific safety control issues in healthcare.

Methods

To optimally describe the behavior of the system components, we adopted a hybrid strategy involving:

- A discrete event component to represent the 'processing' 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 and production pressures on actions

We used AnyLogic 6 (XJ Technologies Company), a Java-based modeling and simulation software package. Data for quantitative modeling were derived from the administrative and clinical databases at the Beth Israel Deaconess Medical Center. The data set included process durations for surgical procedures, emergency case interruptions to the elective scheduled, delays in scheduled cases due to emergency issues, transition times between pre-procedure, procedure and recovery phases, delay times and reasons for delays in initiating emergency interventions for the procedural unit as a function of day of week and hour of day, length of stay in recovery units as a function of time of day or proximity to shift change. We used Stat:Fit software (Geer Mountain Software Corporation) to fit process durations from our clinical data set to standard distributions. This curve fitting algorithm uses a Kolmogorov-Smirnov Goodness of Fit Test. The parameterized distributions were then used as inputs to the simulation model. While the data were derived from data repositories at a single institution, we believe that the medical center's operational features are representative of other large tertiary healthcare referral centers in the US.

Model Description

Dynamics Underlying Risk-Related Behavior

Figure 1 depicts the major variables influencing the waiving phenomenon in the clinical system studied. There are 2 major loop structures. The first, a reinforcing loop, qualitatively describes how increasing risk tolerance or propensity increases the probability of waiving the Anesthesiology safety control, and how this behavior is reinforced each time an adverse event is avoided. The second loop, a balancing loop, 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 while 'unsuccessful' waiving – i.e., waiving with a subsequent adverse event – increases time pressure. The functional forms of these variables are discussed below.

'Processing' and 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 consisting of a single room with batch arrival of the entire days' patient load and serial processing of patients serially (see Figure 2). In the actual system,

the unit has 4 procedural rooms, and up to 4 patients can be processed in parallel. As noted above, we used data from the administrative and clinical databases at a large academic medical center to

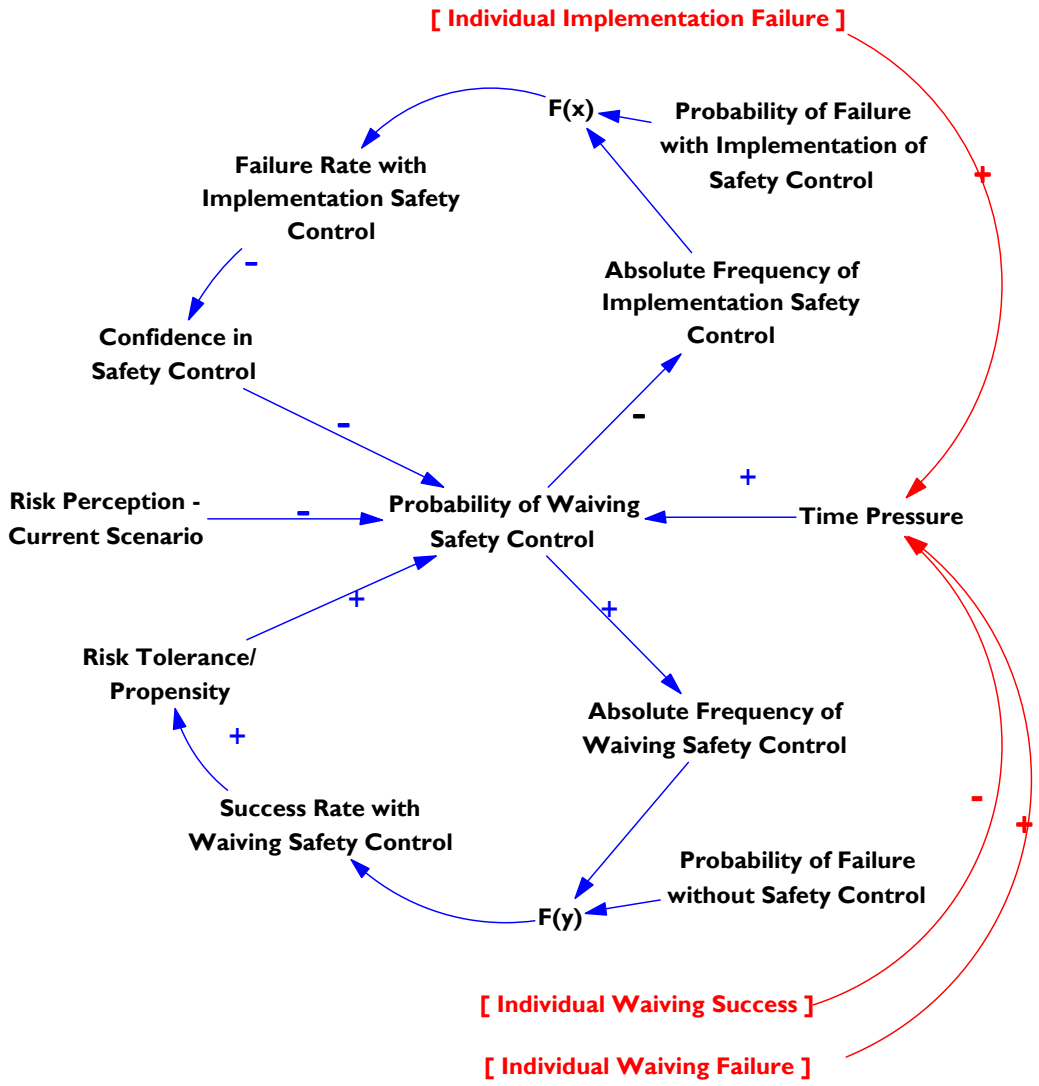


Figure 1: Factors influencing the waiving behavior of surgeons

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 lognormal distribution (min = 0.17 hr.; μ = 0.358 hr.; σ = 0.641 hr.) for overall procedural duration and a point estimate of number of cases processed per room per day (μ = 8). In contrast to impatient units, which are capable of, and processing patients continuously, 24-hours a day (round 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 of 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 2) 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 2) 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 2) and $Pr = 0.02$ following implementation of the safety control (see 'C' in Figure 2). The third key event is the occurrence (arrow 'D' in Figure 2) or non-occurrence (arrow 'E' in Figure 2) of an adverse event during the post-procedural recovery phase. The probability of type D event versus type E event is a function of the underlying health status/co-morbidity of the patient, the complexity and duration of the procedure and whether the use of Anesthesiology services was waived despite indications.

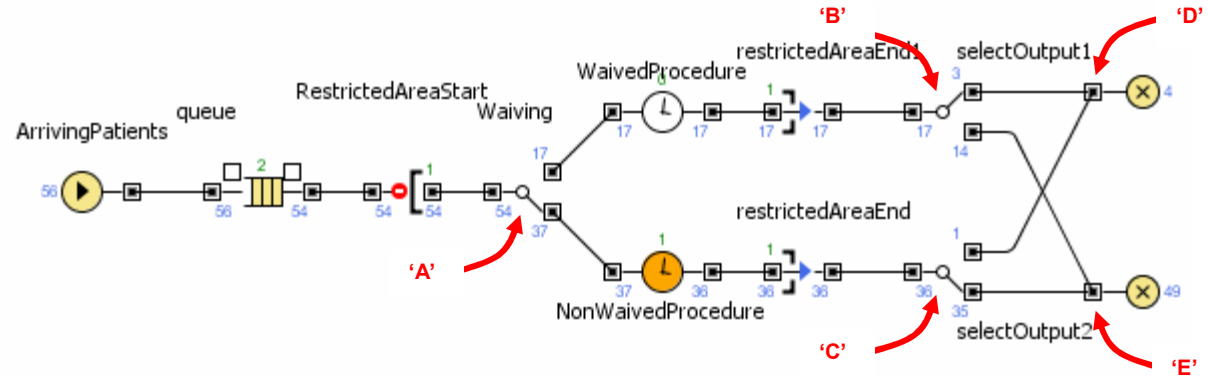


Figure 2: Simplified model of patient care and waiving behavior

Functional forms of Variables

Variables were created for the Risk Tolerance, Confidence in the Safety Control and the 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 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 surgeon 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 that was described by the domain experts. We established a baseline value for the Confidence in Safety Controls variable that

decreases incrementally each time that the control is used and is ineffective in preventing an adverse event. Confidence slowly returns to the 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 3).

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 one 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 apply it 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. The linear table functions used in the model are shown in Figure 4. Additional data collection and interviews with domain experts are underway to further refine these functions.

Figure 3: 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.

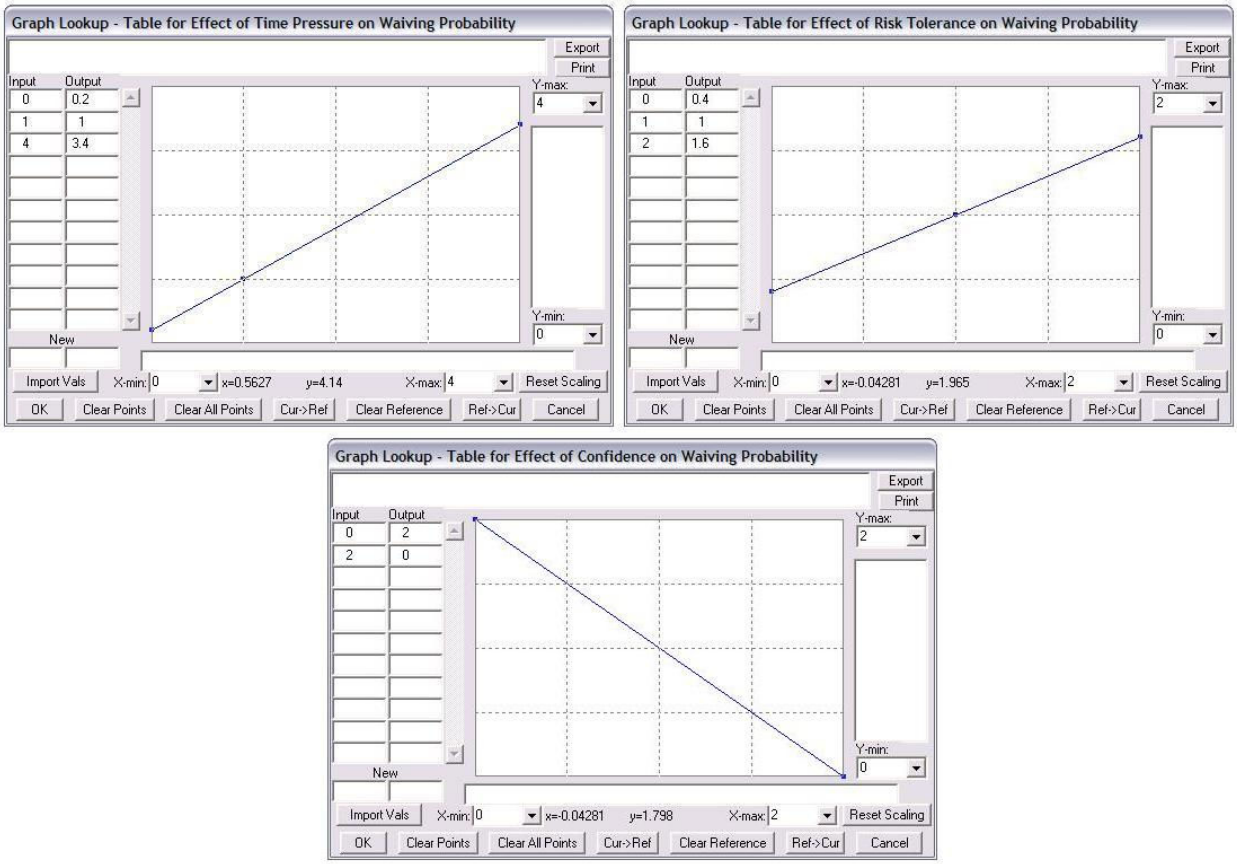


Figure 4: Table functions used to define variable influences

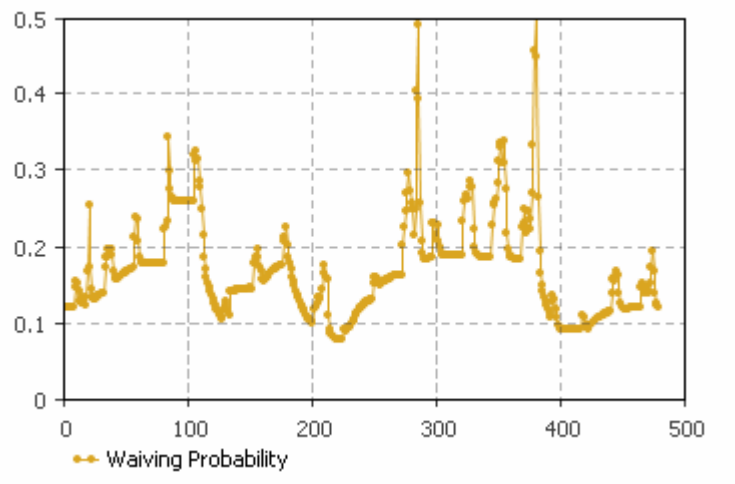
Experimental Results

We designed a series of experiments to study the complex interactions between production pressures, historical experience with adverse outcomes, inherent risk tolerance/propensity, confidence in and compliance with safety controls, and 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), 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 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 5a and 5b 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.



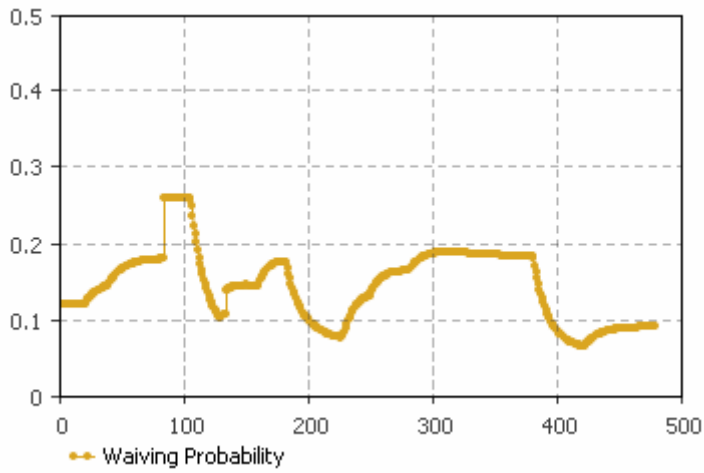


Figure 5a (upper) and 5b (lower) depicting the impact of daily time/production pressures on waiving probabilities.

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 the parameters described above, simulation experiments demonstrated 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 probability of exceedence to < 25% of the operational time for the unit, it is necessary to reduce patient volume from 8 to 5 patients. At this patient volume, time pressures are sufficiently relaxed to reduce the episodically high rates of waiving.

Discussion

In this work, our goal was to develop a more realistic model of healthcare risk, one that captured the complex interactions between production pressures, historical experience with adverse outcomes, inherent risk tolerance/propensity, 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 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. While we believe that the system dynamics modeling approach that we have introduced here begins to address many of the deficiencies of current or traditional models of healthcare risk. However, it does have some limitations. System dynamics modeling typically works only with aggregates, meaning that the individuals within a 'stock' (e.g., the patient 'stock' or the provider 'stock') are indistinguishable. This makes it difficult to explore the general problem of multiple agency, i.e., the behavior of individuals in the face of imperfect incentives. We overcame this limitation by restricting the current model to a single provider unit. We believe that an agent-based model (ABM) is a computational strategy that will enable us to more realistically capture the actions and interactions of multiple autonomous individuals in a clinical network, with a view to assessing their effects on the system as a whole. This extended strategy may be particularly effective in providing a systematic way to explore structure-agency Relationships that extend beyond the risk tolerance/propensity and confidence constructs described in the current work. In particular, we hope to extend the work to model the impact of cooperativeness, communication efficacy, trust, rule-consciousness, decisiveness, vigilance, deference to hierarchy, interest in maximizing profit, indifference to safety goals, etc. Patient-specific attributes, exclusive of standard co-morbidities, might include compliance, trust, communication efficacy (e.g., language proficiency), assertiveness could also be represented in the extended model. The specific effects of these combinations can be formally evaluated using the agent-based modeling and simulation.

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