

**Patient Safety in Complex Medical Settings:
A Prospective Study in the Operating Room**

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ABSTRACT

Background: *There have been few formal investigations of how complex patient care environments (e.g., intensive care units, operating rooms, emergency rooms, etc.) function as a system, influencing provider performance and patient safety. To better understand the relationship between system complexity and patient safety, we performed an analysis of operating room patient care using a prospective field observational technique.* **Methods:** *A multi-disciplinary research team comprised of human factors experts and surgeons prospectively analyzed 10 complex general surgery cases in a major academic hospital. Minute to minute observations were recorded in the field and later coded and analyzed. Performance and safety were analyzed as a function of system components (staff, instrumentation, protocols, procedures, information, communication and scheduling cycles) and how they functioned as a coordinated unit. Safety compromising events were identified and analyzed for contributing and compensatory factors.* **Results:** *Three major recurring safety-influencing themes were identified: (1) communication and information flow; (2) resource availability and scheduling; (3) coordination of workload, concurrent tasks and staff transitions (handoffs). On average, more than one event per case was identified that significantly compromised patient*

safety. The prospective observational technique exposed several recurring factors that contributed to or compensated for the overall effect on the patient's outcome.

Conclusions: *This study demonstrates the value of prospective field observations in exposing hidden properties of a system that influence the abilities of providers to deliver optimal care. Despite the potential for significant patient injury, there was wide variability in the extent to which unexpected challenges impacted patient outcome. Exogenous controls, such as scheduling structures, policies and protocols (e.g., the counting protocol, scheduled shift changes and inventory control strategies), were frequently inadequate and sometimes had a paradoxically negative impact on system performance and safety even if their original intent was to address a specific performance or safety issue. In contrast, adaptive control strategies derived internally from the core team members, were more effective in returning the system to safety. While this study was conducted in a surgical setting, the methods described and some of the findings are translatable to other complex patient care environments.*

INTRODUCTION

Patient care settings such as intensive care units, operating rooms, and emergency rooms are extraordinarily complex. Complexity is manifest not only in the patient and treatment protocol, but also in the high level of automation and instrumentation, large volume of information, and interdisciplinary coordination required. There have been few formal investigations of how these care settings function as systems and how interactions between components (*staff, instrumentation, protocols, procedures, information, communication and scheduling cycles*) influence provider performance and patient safety.

In an effort to understand how system complexity affects patient safety, we performed a prospective observational field study of patient care in the operating rooms of an academic medical center. Our goal was to obtain a detailed description of the system and its interacting components to identify features that contribute to system complexity and influence safety. Specifically, we wanted to understand what system features contribute to adverse events and what features prevent or compensate for the effects of adverse events. This study reflects techniques used in systems analysis¹ and human factors engineering² to study complex and dynamic process environments. While this is an unconventional approach to clinical research, similar studies in industrial, aviation and other high-risk domains have led to major system redesigns and improvements in safety and performance. The study was conducted in an operating room (OR) setting, but the methods described and some of the findings are translatable to other complex patient care environments.

METHODS

Case Selection

To maximize the opportunity to observe system vulnerabilities, we chose colorectal cases involving pelvic dissections and hepatobiliary cases since these cases were likely to have long operative times, a high degree of technical complexity, intra-operative decision-making, high resource requirements, and frequent hand-offs. We performed a bi-monthly

¹ Systems Analysis is defined by the Federal Standard 1037C, *Glossary of Telecommunication Terms* (1996) as the study of the organization, interactions and interdependencies of people, information, resources, equipment and procedures as they work toward a common goal.

² Human Factors Engineering is the study and (re)-design of environments and processes to ensure safer, more effective, more efficient use by humans.

review of OR schedules of six staff general surgeons and enrolled 10 successive cases meeting these criteria during the study period.

Subject Consent

IRB approval was obtained at the study institution. Written informed consent was obtained pre-operatively from all participating patient subjects. Staff subjects (nursing, anesthesia, surgery) were informed of the study in open forums; consent for participation was obtained using an opt-out method.

Observational Process and Coding

The observational methodology is described in detail in a separate publication (Roth, et al., 2003). A multidisciplinary team (consisting of one human factors expert and one observing surgeon) performed minute-to-minute recordings by hand of all events, activities interactions between system components, and information utilization from the inpatient pre-operative phase through intra-operative and post-anesthesia phases of the case, recording start and end time for discrete events or sustained processes. Raw data were entered into a relational database directly from consensus field notes of the two observers. A score (-2 = negative, +2 = positive, 0 = neutral) gauged the impact of each event on the expected course of care. Each observation was classified using a hierarchical coding scheme describing system and human factors concepts (developed specifically for this study) enabling analysis at both a detailed event-level and broad categorical level.

Analysis

On completion of all 10 cases, we performed: [1] qualitative analyses to identify themes or patterns across the entire set of cases; [2] quantitative analyses to evaluate system performance as a function of clock time, process time, case intensity and concurrent activities in the operating room, gross numbers, frequency and duration (aggregate duration and percentage of total case time) of activities, events, processes and delays; [3] causal modeling and event reconstruction using the prospectively sampled data. Table 1 summarizes the model and terminology that we developed to describe adverse events, contributing factors and compensatory factors.

INSERT TABLE 1 HERE

RESULTS

Case Overview

Ten cases were observed: nine were completed and observations are included for the pre-operative, intra-operative and post-operative phases; one was terminated during the pre-operative phase, restricting observations to this phase. Table 2 summarizes case characteristics.

INSERT TABLE 2 HERE

Emerging Patterns

Qualitatively, three themes emerged as major contributors to performance and complexity:

- Communication and information flow;
- Resource availability and scheduling;
- Coordination of workload and concurrent tasks.

Communication/Information Flow: Performance and safety relied heavily on how well information flowed through the system and between providers. Disturbances included inaccurate transmission or receipt of information, and restricted access to, utilization or interpretation of information. Figure 1 lists the range of information and sites of utilization, along with important feedback loops observed in the 10 study cases. The numbers in parentheses indicate documented instances of information loss or degradation. Items highlighted in red indicate cases where care was delayed or modified as a result. As shown there was wide variation in the type and format of the information that was degraded or lost, and the phase at which this occurred, suggesting a generalized system vulnerability to information loss. More often than not, information loss led to delays, over-utilization of staff and resources, and crucial oversights in patient preparation.

We identified transition phases – e.g., pre-operative to intra-operative phase, intra-operative to post-operative, and hand-offs³ or scheduled shift changes - as points where information loss was particularly prevalent. Twenty-two percent of all observed instances of information loss occurred during a ‘handoff.’ Given the vulnerability of these transitions, it is important to note the frequency with which they occurred. Excluding the post-anesthesia care unit (PACU) handoffs from analysis, in this series of cases, a hand-off occurred approximately every 60 minutes during the intra-operative phase of the case (range = 38 min. to 84 min.). The majority of handoffs occurred between nursing staff (n = 25) or between anesthesia staff (n = 16), but 4 surgeon handoffs were observed also. Information loss during hand-offs was primarily a

³ We define a ‘handoff’ as the complete transfer of responsibility and care-giving activities from one provider to another where the initial provider subsequently physically leaves the scene.

consequence of intra-disciplinary communication breakdown (in both verbal and written formats), but significant failures in cross-disciplinary communication were observed as well. We documented extensive intra-operative miscommunication (inadequate discussion of the clinical context, diagnostic intent, and relevance of results to ongoing decision-making and case progression) between the surgeon and the pathologist. This lack of shared understanding led to substantial delays; a mean of 43 minutes (range of 17 – 103 minutes), equivalent to 17.3% (range: 8.2-29.4%) of the incision time was spent waiting for diagnostic information necessary for case progression. In two of ten cases, the surgeon physically left the operating room to confer with the pathologist and resolve the issue. Whereas this action successfully resolved the uncertainty, it resulted in a significant disruption in progression of the case.

Resource availability and scheduling: We defined resources as consumable supplies, equipment, personnel, drugs and blood products, information and intensive care unit or post-anesthesia care unit bed space. All of the study cases were resource intensive, involving combinations of incisions (abdominal and perineal) or approaches (laparoscopic and open), and requiring multiple pieces of specialized equipment and instrumentation. Resource availability was measured indirectly by how frequently the circulating nurse exited the room to procure equipment or other resources during the intraoperative phase of the case. Despite the similarity in the cases, there was wide variation in the frequency of these exits; the range was 10-59 times per case (3.5-12 times per hour of incision time), and retrieval activity had significant impact on case performance. In the absence of the circulating nurse and/or a specific instrument, the surgeon, scrub nurse and anesthesiologist in some instances modified their performance

of specific procedures and in other instances delayed or halted case progress while awaiting return of the nurse or resource. The frequency of resource retrieval may have been less a reflection of inventory control or case type than of the quality of information available to the nursing staff. From a resource management standpoint, well-coordinated cases were characterized by cross-disciplinary communication throughout the pre-operative and intra-operative phase of the case (e.g., via announcements of upcoming procedural variations or special equipment requirements) enabled nurses to anticipate requirements and coordinate resource acquisition with predictably low workload periods.

Coordination of workload and concurrent tasks: We analyzed 3 distinct aspects of workload: (1) the extent to which providers performed multiple tasks concurrently; (2) the extent to which concurrent tasks competed for attention; and (3) the extent to which concurrent tasks were synchronized with technically demanding phases of the case. These surgical cases had predictable variations in workload based on anatomic, physiologic and procedural constraints and the relative risks associated with patient-centered tasks.

Anesthesiologists faced considerable workload during induction, intubation and extubation. Surgeon workload (along both manual and cognitive dimensions) was most demanding during deep pelvic dissections, major vascular mobilizations and hepatic resections. Nursing staff experienced high workload during the preparatory phase, and the transition phase from a laparoscopic to an open surgical approach. Throughout each phase of a specific case, providers performed an identifiable set of primary tasks (generally patient-centered activities such as intubation, medication administration, procedure-based actions, etc.), as well as many auxiliary tasks (e.g., answering telephone, discussing case management on outside patients, counting instruments, etc.). By

recording all activities, we were able to document at least 12 instances where auxiliary tasks impaired a provider's ability to perform necessary primary tasks, significantly delayed case progression, or occurred during a high-risk phase of the case.

Chief among the nurses' auxiliary tasks was the protocol-based manual 'count' of all instruments and resources used, a protocol intended to reduce the risk of a retained foreign body. On quantitative analysis, nurses devoted 3.9 – 28.8% of total procedural time to counting activities. Because the counting process often interrupted or delayed primary patient care activities, it often had a paradoxically negative impact on performance and patient safety. On average, inconsistencies or inaccuracies in the counts requiring a repetition of the protocol or prolonged search, or delays and modifications in procedural tasks because nursing support was occupied with counting occurred 3 times per case (range: 0-8).

Handoffs and scheduled shift changes also increased workload, creating distractions from primary patient care activities and leading to unnecessary repetition of processes or procedures. Nursing handoffs often involved an interim 'count,' and a review of operating instructions for all specialized equipment that will be used. These handoff activities were often performed concurrently with ongoing procedure-based activities and occasionally delayed case progression. Since safe handoffs, regardless of provider role, required a comprehensive exchange of information about prior case events, current status and plans, it was not surprising that handoffs were temporally linked to many of the instances of information loss described above.

A more significant finding was that auxiliary workload was poorly synchronized with predictably high workload or high risk phases of the procedure. Figure 2 maps

events occurring during one of the nine complete cases we observed, although seven of the cases had similar profiles. The figure illustrates the large number of counting activities, hand-off activities and entrances and exits (competing demands for attention) that occurred during high-risk phases of the operation, and the comparatively few that occurred during a low-intensity pre-incision delay in the case. The impact of poor coordination and concurrent tasks on system performance and safety was measurable along several dimensions. We documented substantial delays and minor modifications in the activities of surgeons and anesthesiologists. Importantly, five safety compromising events were temporally related to the performance of multiple concurrent tasks.

Safety Compromising and Adverse Events

We examined the extent to which system features contributed to adverse events, and how well surgical teams adapted to or compensated for challenges to safety. Based on conventional outcome-driven estimates, we did not expect to identify any intra-operative adverse events in this small series. Using our prospective and detailed sampling protocol, however, we identified 11 distinct events that significantly compromised patient safety or had the *potential* to cause injury (see Table 3). Of those, five resulted in measurable adverse change in patient status (*adverse events*).⁴ Through our detailed recording of state variables, we were able to reconstruct a model of the system at various intervals before, during and after a specific ‘benchmark’ event and evaluate specific state variables or precursor events in terms of their *potential* to cause injury, establishing a set of *contributing* and *compensatory factors* associated with the benchmark event. While direct causality cannot be asserted, factors associated with these 11 events are

⁴ Refer to terminology in Table 1 for definitions of adverse event and safety compromising event.

summarized in Table 3. Most events had multiple contributing and compensatory factors.

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INSERT TABLE 3 HERE

DISCUSSION

In this study, we took a systems view of the operating room, examining performance and safety not just in terms of individual components but also in terms of how they functioned as a coordinated unit. Our premise was that global performance, especially in terms of outcome, risk and safety, would be influenced to a great extent by local interactions and synchronization of system components (e.g., providers, patients, scheduling cycles, technologies, information and material resources, physical and temporal constraints). Because the operating room is a complex system, functioning within an even larger system (an academic tertiary care facility) performance and outcomes cannot be completely explained in terms of patient and surgeon factors, alone. The design and execution of this study sought to identify the range of system factors that may play a role in performance and safety. Despite the relatively small number of cases studied, our analysis was detailed and yielded important results. Across the study cases, we identified frequent deviations in the expected course of care that put patients and providers at risk. We think that the prevalence of safety compromising events identified can be explained by the sensitivity of the prospective observational technique in capturing process variations that may be undetectable through retrospective review. In fact, only 1 of the 11 events was subsequently reported using conventional chart review, a rate that is consistent with recent estimates of the proportion of adverse events reported through traditional means[ref].Our study suggested at least a partial explanation for this

discrepancy. Our protocol identified events that compromised safety but may have gone unnoticed by the providers involved because the outcome was favorable. When a harmful event was recognized and interventions successfully restored the patient to a ‘normal’ state, providers seemed to overlook the event, even when prompted during post-case interviews. This may reflect a special form of ‘outcome bias’ in clinical care.

Despite the potential for significant patient injury, there was wide variability in the extent to which such disturbances actually impacted patient outcome. In some cases, the events were self-correcting (possible patient factors). Under other circumstances, the same events might have had more serious consequences. In other cases, providers were able to adapt and/or compensate for unexpected challenges, often through coordinated information exchange and mutual awareness of intentions and plans.

In contrast to the relatively robust internal control strategies by the core team members, exogenous controls, such as scheduling structures, policies and protocols (e.g., the counting protocol, scheduled shift changes and inventory control strategies), were frequently inadequate and sometimes had a paradoxically negative impact on system performance and safety even if their original intent was to address a specific performance or safety issue.

These findings have a number of implications for the study of and response to performance and safety issues in complex medical settings. First, in such settings, safety should not be measured strictly in terms of outcome, since good outcomes may emerge from unsafe processes (that might result in bad outcomes in other situations). In some cases, exogenous controls can be overly constraining or even produce an unanticipated negative side effect with regard to safety. Prospective observations can expose hidden

vulnerabilities that influence outcome and may prove to be a valuable tool for studying clinical situations in which there is variability in outcome not otherwise explained by conventional variables. Formal observation of system performance can also be a useful and practical tool to evaluate the impact (both positive and negative) of new technologies, protocols or procedure on safety.

While this study was conducted in a surgical setting, the methods and findings are translatable to other complex patient care environments. In such settings it is essential to examine safety-influencing properties of a system over time to understand the sources of system vulnerabilities and develop effective strategies for managing complexity and improving patient safety.

ACKNOWLEDGEMENTS

This study was funded in part by the Risk Management Foundation, Harvard Medical Institutions. The authors owe tremendous thanks to Jack McCarthy at the Risk Management Foundation who supported this work; to Kathy Dwyer at the Risk Management Foundation who facilitated interactions between the institutions; to Janet Nally Barnes and Tejal Gandhi who provided insight relating to risk management issues; and to Margaret Doyle and other staff who granted access to the clinical setting in which we conducted the study.

Figures and Tables

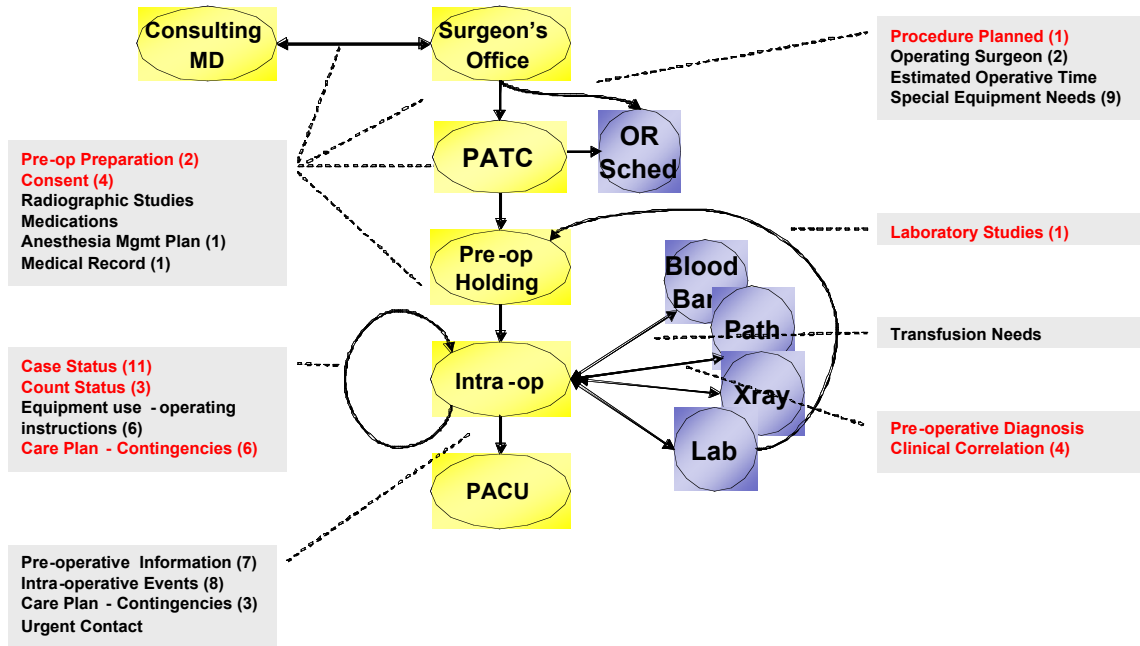


Figure 1: The flow of patient information and important communication feedback loops for safe surgical care observed in 10 study cases. Red lettering indicates that care was significantly delayed or modified as a result of information loss or degradation. The absolute counts of that particular type of loss or degradation are noted parenthetically. PACU = post anesthesia care unit; OR Sched = Operating room scheduling office; Path = Pathology department; X-ray = intra-operative radiology services.

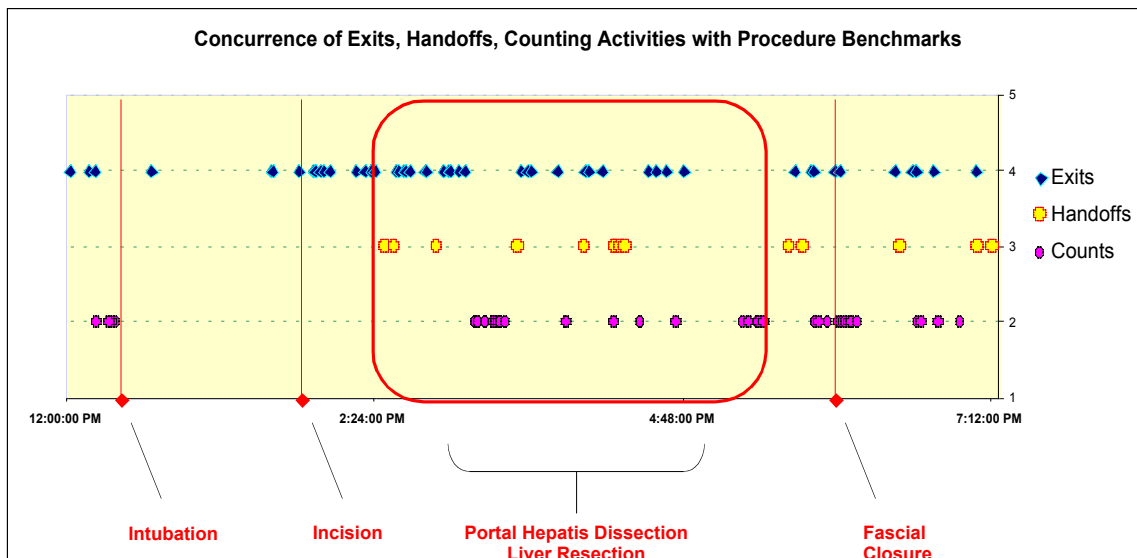


Figure 2: Concurrency of exits, handoffs and counting activities with technically demanding phases of case involving hepatic resection and implantation of hepatic

infusion pump. Prolonged delay between intubation and incision related to difficulty obtaining additional venous and arterial access for monitoring purposes.

Table 1: Terminology for Classifying Adverse Events

System Vulnerability	The exposure to or opportunity for adverse events.
Safety-Compromising Event	A variation in the expected course of care that has a negative effect on patient safety and puts the patient <i>at risk</i> for a measurable adverse change in patient status.
Adverse Event	A safety-compromising event that progresses to a measurable adverse change in patient status.
Contributing Factor	Conditions or properties that increase the vulnerability of the system, therefore increasing the chance of an adverse event.
Compensatory Factor	Conditions or properties that decrease the vulnerability of the system or reduce the severity of an adverse event.

Table 2: Case Summary

Case Types	5 colorectal (low anterior resections, abdomino-perineal resections) 5 hepatobiliary (liver resections, common bile duct resection, Whipple procedure)
Hours of Observation	63 hours
Annotated Events	4583
Room Assignment	General-surgery-specific: 3 Subspecialty-specific: 6
Case Start Time	First Start: 3 Later Start: 6 * * 4 cases scheduled as first start were subsequently delayed
Estimated Blood Loss	Mean: 750 cc Range: 200-1500 cc
Case Duration	Mean: 4:27 (hr:min) Range: 2:02-9:33 (hr:min)

Table 3: Safety Compromising Events or Adverse Events and Contributing and Compensatory Factors Prospectively Observed

Adverse or Safety Compromising Events
Tissue injury requiring surgical revision (3)
Medication administration error (2)
Adverse drug reaction (1)
Wound contamination (2)
Hypothermia (1)
Inadequate pre-operative preparation (1)
Near-injury to inexperienced surgical assistant (1)
Adverse or Safety Compromising Events

Contributing Factors
Hand-off
Multiple competing tasks
Inexperience
Interruptions
Loss of situation awareness
Late start
Long operative time
Fatigue
Status asymmetry
Communication breakdown-information loss
Patient factors

Compensatory Factors
Intra-disciplinary check/verification
Cross-disciplinary check/verification
Collaboration/compromise
Adaptation/innovation
Leadership/authority