# A prospective study of patient safety in the operating room

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***Background.*** *To better understand the operating room as a system and to identify system features that influence patient safety, we performed an analysis of operating room patient care using a prospective observational technique.*
***Methods.*** *A multidisciplinary team comprised of human factors experts and surgeons conducted prospective observations of 10 complex general surgery cases in an academic hospital. Minute-to-minute observations were recorded in the field, and later coded and analyzed. A qualitative analysis first identified major system features that influenced team performance and patient safety. A quantitative analysis of factors related to these systems features followed. In addition, safety-compromising events were identified and analyzed for contributing and compensatory factors.*
***Results.*** *Problems in communication and information flow, and workload and competing tasks were found to have measurable negative impact on team performance and patient safety in all 10 cases. In particular, the counting protocol was found to significantly compromise case progression and patient safety. We identified 11 events that potentially compromised patient safety, allowing us to identify recurring factors that contributed to or mitigated the overall effect on the patient's outcome.*
***Conclusions.*** *This study demonstrates the role of prospective observational methods in exposing critical system features that influence patient safety and that can be the targets for patient safety initiatives. Communication breakdown and information loss, as well as increased workload and competing tasks, pose the greatest threats to patient safety in the operating room. (Surgery 2006;139:159-73.)*

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Traditional patient safety research and investigation have been largely outcome-driven and retrospective in design. Institutional investigations such as root cause analyses rely on postevent reconstruction of adverse events. Similarly, research efforts such as the Harvard Malpractice Study are retrospective and identify cases on the basis of outcome.[1-3] Such retrospective analyses attempt to recreate events through a review of hospital records and interviews with involved staff when possible, but often without first-hand knowledge of the events. This approach is reflected in the poor inter-rater reliabilities reported with these studies (κ, 0.2-0.6).[4] Much of the "noise" is likely due to a lack of necessary information about the processes of care that resulted in the outcome or the context in which a specific event occurred. Given that retrospective data collection may be incomplete, we thought a prospective study of the actual events, processes, and procedures that occur can lead to a better understanding of factors that influence patient safety before an adverse event occurs.

The operating room (OR) is one of the most complex work environments in health care. Complexity is manifest in the patient and treatment protocol, as well as the high level of technology and coordination required to effectively manage rapidly changing conditions. Several studies analyzed complex health care settings, such as the intensive care unit, OR, and emergency room, as systems and how interactions between components influence performance and patient safety; several of the studies utilized observational or video

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techniques.[5-20] A recent review article by Vincent et al[21] illustrates the need for further prospective systems analyses to identify features and processes of care that can be used to improve patient safety and quality of care. This study uses direct field observation in an exploratory study of the OR, with the goal of identifying recurring system features that can be the basis for future controlled studies or quality improvement initiatives.

To achieve this goal, we adopted techniques that had been used previously in systems analysis and human factors engineering to investigate other complex work environments.[22-26] *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. Human factors engineering is the study and (re)design of environments and processes to ensure safer, more effective, and more efficient use by humans. 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.[5,13,23,27-30] The goal was to obtain a detailed description of the system and its interacting components to identify features that influence safety.

## METHODS

A discussion of the methodology can be found in more detail in a separate publication.[31]

**Case selection and subject consent.** Patients were recruited from 6 general surgeons at a major academic institution. To maximize the opportunity to observe system vulnerabilities, we targeted colorectal cases involving pelvic dissections and hepatobiliary cases for the study. These cases have long operative times, a high degree of technical complexity, complex intraoperative decision making, high resource requirements, and frequent hand offs. A “hand off” is defined as the complete transfer of responsibility and caregiving activities from one provider to another in which the initial provider physically leaves the scene. Cases were identified by review of the OR schedules of 6 general surgeons; 10 successive cases meeting these criteria were enrolled.

**Subject consent.** Once a candidate case was identified, the patient was approached during the preadmission period and offered the option of participation. Written informed consent was obtained from all participating patient subjects. Staff subjects (surgery, anesthesiology, and nursing) were informed of the study in a series of open forums and consent for participation was obtained by using a confidential opt-out method before initiation of the study. The study was approved by the institutional review board of the study institution.

**Observers.** The credibility of an observational study depends on the expertise and experience of the observers. The surgical domain poses a particular challenge as surgeons are highly trained professionals and a human factors expert cannot possibly understand enough about the domain to make accurate and appropriately detailed observations. At the same time, surgeons understand the domain but lack the necessary formal training in human factors and systems performance. For this reason, we chose to utilize a multidisciplinary team comprised of 1 human factors expert and 1 surgeon to observe each case. The surgeons functioned as the domain experts. One surgeon had completed 3 years of general residency and was currently a research fellow in surgery. The other observer was a fully trained general surgeon with additional experience in human factors. The human factors experts included a cognitive psychologist with extensive experience in other high-risk work environments including nuclear reactor control rooms and transportation domains, as well as a human factors engineer with over 30 years of experience in high-risk work environments, most notably the aviation industry. Each observer took notes independently during the surgery, and the notes were then synthesized into a single protocol to reflect both domains of expertise.

**Observations.** The observers met the patient and the surgical team in the preoperative holding area (preop area) on the day of surgery. During this initial preoperative phase, 1 observer remained in the preop area performing detailed observations and documentation of the preoperative preparation, communication, and planning activities before the transportation of the patient to the OR. Simultaneously, the second observer was in the OR observing case preparation by the anesthesia team and the nursing team. Once the patient entered the OR, both observers performed continuous, independent observations of the events through each successive phase of the case. Minute-to-minute observations were recorded freehand into each individual observer’s field notes. Recorded observations included such occurrences as entrance and exits of individuals, operative events, key communications, additions of instruments to the surgical field, and counts of instruments, as well as hand offs between personnel that occurred (e.g., for lunch breaks, at the end of shifts). No attempt at interpretation or

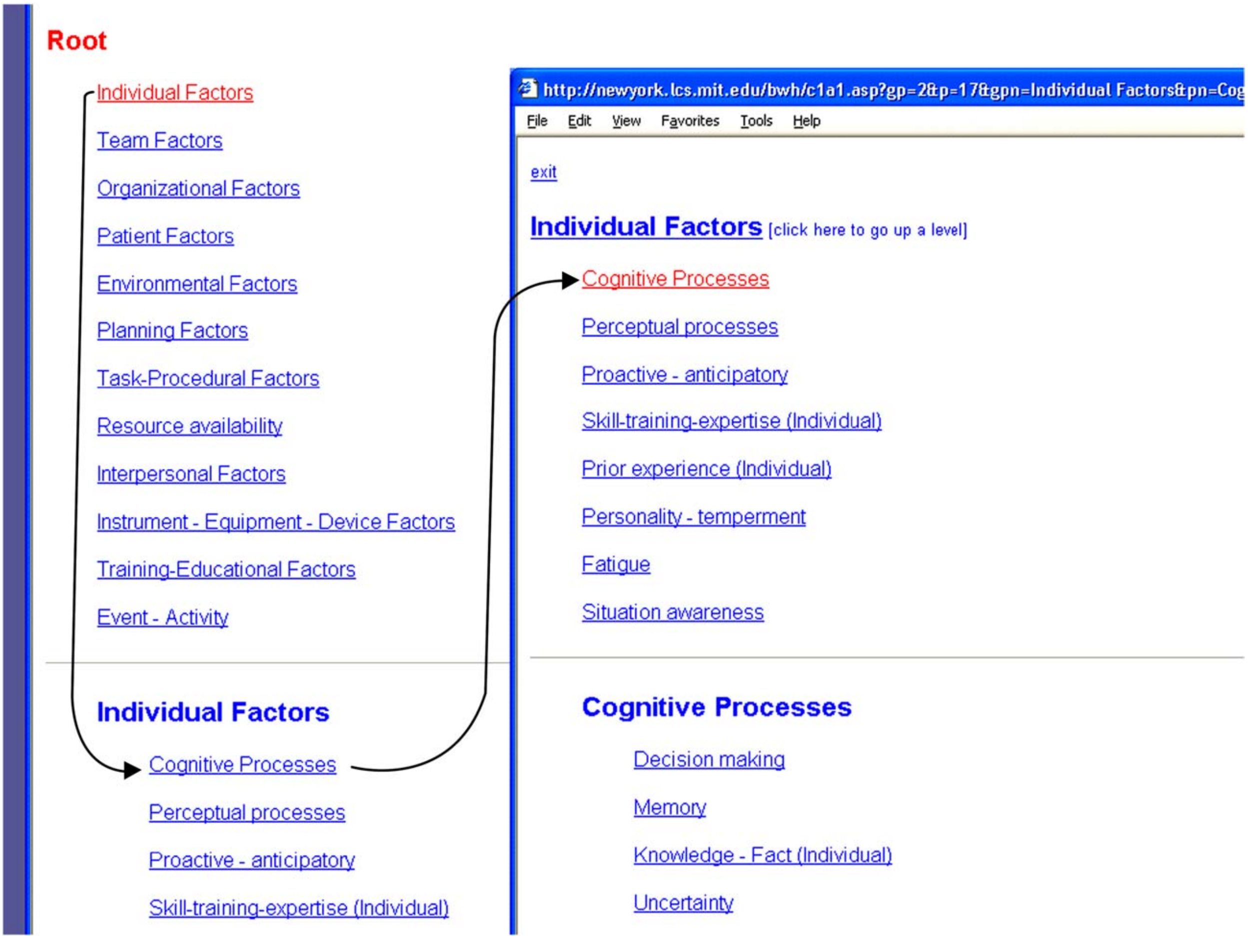


**Fig 1.** Example of the hierarchic coding scheme used in the study. The Root node indicates the top of the hierarchy. Two screen shots from the Web-enabled display of the scheme demonstrate the drill down to successively more granular details of Individual Factors → Cognitive Processes → Decision making, etc. Observers could choose to classify/code at one of several levels of granularity for detail. Because the coding scheme was hierarchical, data coded at the most detailed level would automatically be included in the same category of data coded at the more general level. For example, if one observation was coded as involving a Decision Making process, the data management system would automatically classify this observation as involving a Cognitive Process and, by direct inheritance, an Individual Factor.

analysis was made at this time. The goal was to document activities of the OR staff as comprehensively and objectively as possible for later case reconstruction.

**Coding scheme.** A hierarchic coding scheme was developed to code human factors and system factors associated with each observation. The coding scheme was developed from 10 major categories: (1) Individual staff factors; (2) interpersonal factors (1:1); (3) team factors; (4) organizational factors; (5) patient factors; (6) task-procedural factors; (7) environmental factors; (8) instrument/equipment factors; (9) training factors; and (10) resource availability. Each of these categories was further broken down into subcategories. The hierarchic nature of this coding scheme allowed us to document and code in a standardized manner each event as narrowly and detailed as possible, while maintaining the ability to search and analyze on a broad, categorical level. The observers worked together over a period of several weeks to iteratively refine the coding scheme and gain consensus on interpretation and application of each code during the design phase of the study. While formal inter-rater reliability analysis was not conducted, the authors feel that because of these preliminary consensus-building activities, the coding and classification process was consistent. Figure 1 illustrates an example of the hierarchic nature of this coding scheme for individual staff factors.

**Data coding and annotation.** Field notes were annotated, classified, and entered into a relational

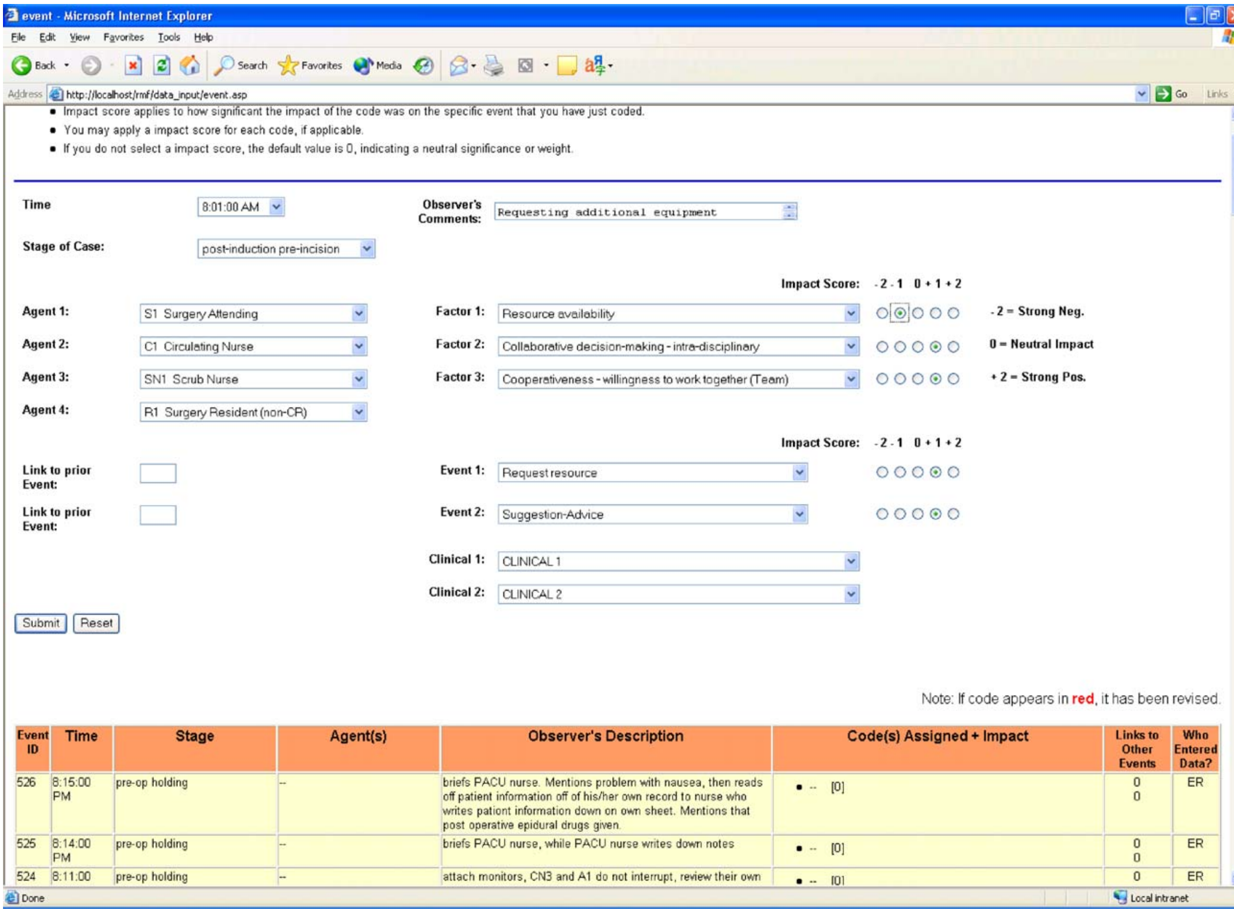


**Fig 2.** The Web-based interface demonstrating the data input field (*middle portion of screen*) and evolving protocol trace (*bottom portion of screen*).

database with the use of a custom-designed software application. The application featured a front-end Web interface for transcription of field notes with list-based fields to annotate time, case phase, and agents (staff) associated with each specific field observation (Fig 2). The observers for each case transcribed field notes into the data management system and applied factor codes to the observation as outlined above. A 5-point "impact score," ranging from [−2] to [+2], was assigned to each coded observation to reflect whether the factor had a positive, negative or neutral effect on case progress and/or outcome. As an example, the observers might assign the code *Decision-making under time pressure* to classify a specific observation and assign an impact score of [−1] to the coded observation, indicating a mildly negative effect on the safety or quality of care in the case. If the observation was deemed by the observers to be causally linked to an earlier event, a "linked-to" data field enabled recording of this relationship. Once entered in the database, the data can be searched on any term, factor, personnel, time, or stage of procedure.

The 2 observers worked collaboratively to generate a single consensus protocol. This task was accomplished by having one observer transcribe the field notes into the data management system, then assign factor codes and impact scores. The second observer then reviewed the data entries and made amendments and corrections on the basis of their field notes. This revised protocol was then reviewed by the first observer. Any differences that arose were discussed and resolved by consensus.

**Analysis.** On completion of the observations of all 10 cases, we performed 2 separate analyses. One analysis focused on safety-influencing system features. Each case was analyzed individually to identify system features that influenced case progression and patient safety. We computed the frequency with which these safety-influencing system features occurred across cases. Their impact on case progression and safety was assessed in terms of delays,

**Table I.** Safety-compromising events and contributing and compensatory factors

| | *Contributing factors** | | | | | | | | | | | | *Compensatory factors*† | | | | | *Event detection*‡ | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| *Event* | *A* | *B* | *C* | *D* | *E* | *F* | *G* | *H* | *I* | *J* | *K* | *L* | *M* | *N* | *O* | *P* | *Q* | *ND* | *Self* | *Other* |
| Wound dehiscence | ♦ | | | | | | | | ♦ | | | | | | | | | | | ✓ |
| Intraoperative tissue injury requiring surgical revision #1 | ♦ | | | | | | | | ♦ | ♦ | | | | | | | | | ✓ | |
| Intraoperative tissue injury requiring surgical revision #2 | ♦ | | | | | | | | ♦ | ♦ | | | | | | | | | ✓ | |
| Medication administration error #1 | | | | ♦ | | ♦ | ♦ | | | | | ♦ | | | | | | ✓ | | |
| Medication administration error #2 | | | | ♦ | | | ♦ | ♦ | | | | | ⊕ | | | | | | ✓ | |
| Adverse drug reaction | ♦ | | ♦ | | | | | ♦ | | | | | | | ⊕ | ⊕ | ⊕ | | ✓ | |
| Wound contamination #1 | | | ♦ | ♦ | ♦ | | | | | | | | | | | | | ✓ | | |
| Wound contamination #2 | | | ♦ | ♦ | ♦ | | | | | | | | | ⊕ | | | | | ✓ | |
| Hypothermia | | | | | | | | | | | ♦ | ♦ | | | ⊕ | ⊕ | ⊕ | | | ✓ |
| Inadequate preoperative preparation | | ♦ | | | | | | | | | | | ⊕ | ⊕ | | | | | ✓ | |
| Near-injury to inexperienced assistant | | | | | ♦ | | | | | | | | ⊕ | | | | | | ✓ | |

**Contributing Factors, A,* Patient factors; *B,* Communication breakdown/information loss; *C,* Hand off; *D,* Multiple competing tasks; *E,* Inexperience; *F,* Interruptions; *G,* Loss of situation awareness; *H,* High workload/high-intensity phase; *I,* Long operative time; *J,* Fatigue; *K,* Conflicting team goals; *L,* Status asymmetry between team members.

†*Compensatory Factors, M,* Intradisciplinary check/verification; *N,* Cross-disciplinary check/verification; *O,* Collaboration/compromise; *P,* Adaptation/innovation; *Q,* Leadership/authority.

‡*ND,* Event not detected or mitigated; *Other,* event detected by health care giver who was not present at or involved in the initial event, but involved in a subsequent part of the postoperative care; *Self,* event detected by party involved.

wasted resources, and increased risk to the patient or members of the OR team.

A second analysis focused on safety-compromising events. In this study, we define a "safety-compromising event" as an action or inaction that significantly increased the vulnerability of the system and had the potential to lead to an adverse event. In this context, safety-compromising events can range from events that have no consequence in the current case but that could have consequences under different circumstances (often referred to as "close-calls" or "near-misses") to events that produce a measurable negative change in patient status. In each case, the circumstances surrounding the event were examined to identify system factors that appeared to contribute to the event (ie, contributing factors) and system factors that appeared to mitigate the impact of the event on the patient or clinical outcome—preventing more serious consequences (ie, compensatory factors). Table I provides examples of contributing and compensatory factors. Safety-compromising events and the contributory and compensating factors were identified through consensus of the observation team.

**Feedback to participants.** At the completion of the study, another series of open forums was held with the surgical, anesthesia, and nursing departments. The methodology and results of the study, including a description of the safety-compromising events and the contributing and compensating factors, were reported to the participants, and their feedback was encouraged. Feedback from all specialties was favorable. The results were felt to accurately reflect the system under investigation by the study participants.

## RESULTS

**Case overview.** Of the 10 cases observed, 9 were completed; observations are included for the preoperative, intraoperative, and postoperative phases. Mean case duration was 4 hours 27 minutes (range, 2:02-9:33). One case was terminated by the surgeon during the preoperative phase, restricting observations to just this phase. Sixty-three hours of observation yielded over 4500 observations that were analyzed subsequently.

**Safety-influencing system features.** Qualitatively, 2 system features were identified that significantly influenced case progression and patient safety in every case: (1) communication and information flow, and (2) coordination of workload and competing auxiliary tasks.

**Communication/information flow.** Figure 3 depicts the flow of patient-related information through the perioperative period. For each phase of care, specific examples of information or data

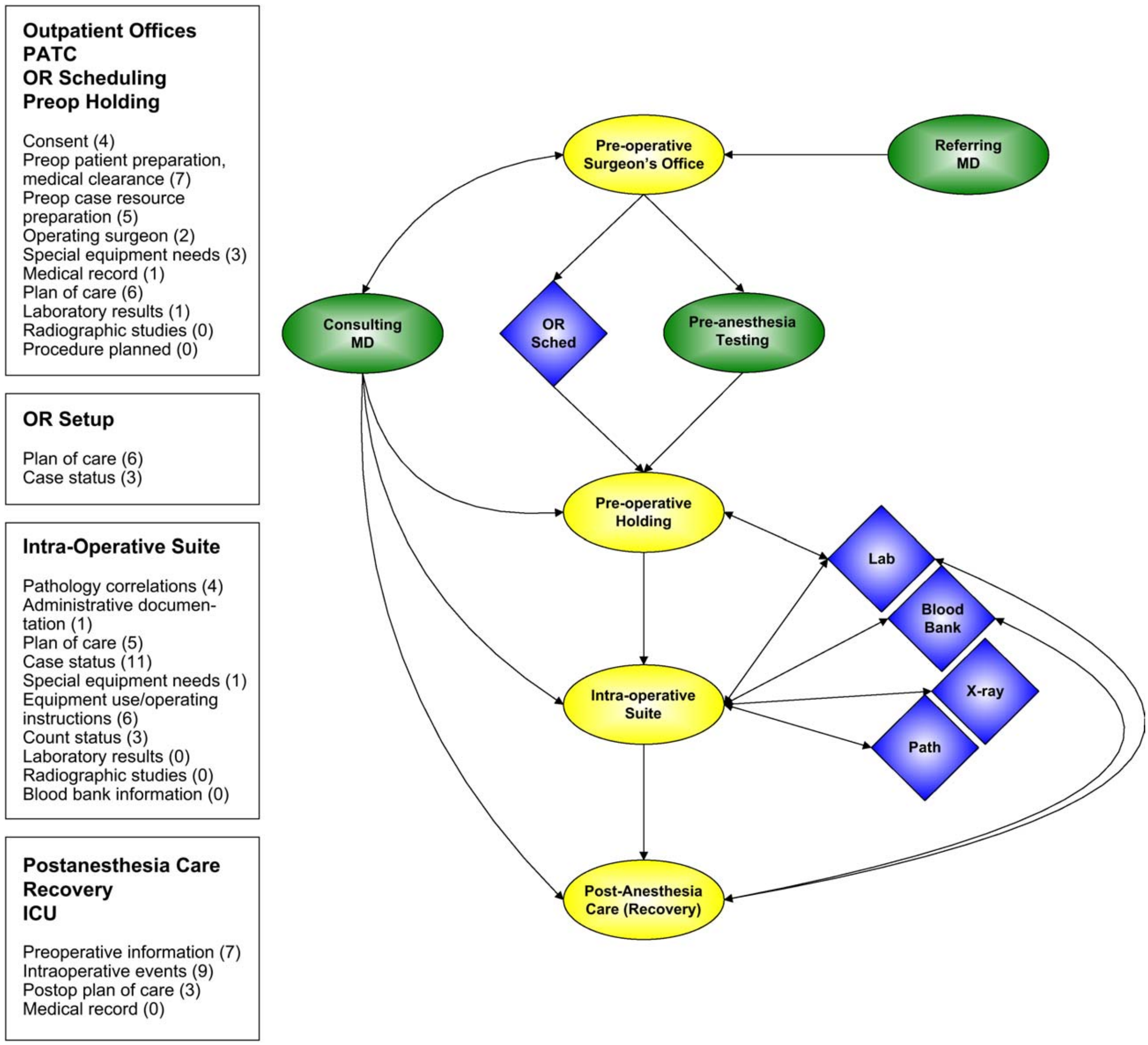


**Fig 3.** Phases of surgical care, information flow, and instances of information loss or degradation observed in study cases. *Elliptic symbols* reflect sites where the patient typically is present when case-specific information is accessed or used. *Lightly shaded ellipses* reflect sites where the operating surgeon typically is present during information use. *Blue diamond symbols* reflect sites where neither the patient nor the treating MD (surgeon, anesthesiologist, or nonpathology consulting MD) typically are present to validate or verify the case-specific information. *Arrows* reflect the directionality of information flow observed in theses cases, although the flow can be considerably more complex, in principle. Examples of specific types of information or data that were observed to be either used or requested by providers to deliver perioperative care in the study cases are listed on the left side of the diagram, along with the specific phase of care in which the information was used. Enclosed in parentheses is the number of times in which we observed that this specific piece of information or datum was unavailable (either lost, significantly degraded, or incorrect) when sought by the provider at the point of care. The observers only recorded events in which the information was sought by a provider, was not available, and influenced the progression of the case or the safety of the patient. *ICU,* Intensive Care Unit; *OR Sched,* operating room scheduling office; *PATC,* preadmission test center; *Path,* pathology; *postop,* postoperative; *preop,* preoperative.

required for safe patient care are listed along the left side of the diagram. "Information flow" refers to the successful transfer of this information from one provider to another, or across physical locations, for use in continued patient care. Information flow can be achieved through physical transactions (eg, transfer of a signed informed consent document or medical record from office to OR)

**Table II.** Quantitative analysis of communication/information flow and its influence on performance and safety (n = 10 cases)*

| **Instances of information loss or degradation** | | **Per-case range** |
|---|---|---|
| Aggregate number of instances across all cases | 88 | |
| Per-case mean | 9 | 3-18 |
| **Influence of information loss on performance or safety** | **Total instances across all cases** | **Per-case range** |
| Delay in case progression | 19 | 0-5 |
| Increased workload | 15 | 0-7 |
| Increased uncertainty in patient mgmt for other providers | 29 | 2-8 |
| Overuse of material resources | 6 | 0-3 |
| Increased exposure to injury (patient) | 6 | 0-3 |
| Cancellation of case | 1 | 0-1 |
| No influence detected | 12 | 0-8 |
| **Hand off of patient care across provider groups, phases or locations** | | **Per-case range** |
| Mean number of hand offs per case† | | |
| All provider groups | 4.8 | 2-13 |
| Nursing staff | 2.8 | 1-7 |
| Anesthesia staff | 1.8 | 0-6 |
| Surgeons | 0.4 | 0-4 |
| Frequency of hand offs‡ | 1 per 60 min of incision time | 1 per 38-84 min |
| **Communication with pathology** | | **Per-case range** |
| Mean time waiting for response from pathologist | 43 min | 17-103 min |
| Mean % of incision time spent waiting for response† | 17.3% | 8.2%-29.4% |

*Communication and case-specific information was monitored throughout the surgical processes of care and as patient care was transferred across different provider groups, locations, and phases of a surgical case.
†See definition of "hand off" in text. Hand-off data exclude the standard final hand off from intraoperative anesthesia staff to postanesthesia care team.
‡Incision time is defined as the period between incision and completion of fascial closure. Incision time was selected as the unit of measure because it represents the most vulnerable period of time for several specific surgical adverse events including tissue injury, wound infection, hypothermia, blood loss, and retained foreign body.

or verbal communication (eg, communication of patient status or plan of care by surgeon to the OR team, or explanation of diagnostic goals from surgeon to pathologist). In total, there were 88 distinct instances in which information was either lost or degraded (content substantially altered) in 10 cases, with an average of 9 instances per case (range, 3-18; Table II). Of these, 76 (86%) had significant consequences for case progression, which included 19 delays in case progression, 15 instances of increased workload, 29 instances of uncertainty for other team members, 6 instances of wasted resources; 6 instances of increased risk to the patient, and 1 last-minute cancellation of a case.

Transitions in care, including the movement of the patient from one phase of care to another (eg, the OR to the recovery room) and the hand off of patient care from one provider to another, were particularly vulnerable to information loss. Table II describes the observations relating to hand offs. There were an average of 5 hand offs per case or about 1 hand off every 60 minutes of incision time. Twenty-two percent of the observed instances of information loss were related temporally to a hand off.

With respect to specific types of information transfer, the communication and information exchange between the operating surgeon and the pathologist were particularly vulnerable to loss or degradation. Communication problems relating to inadequate discussion of clinical context, diagnostic intent, and relevance of diagnosis to ongoing decision making led to substantial delays in case progression (Table II). Pathology results were returned in an average of 43 minutes (range, 17-103 minutes), representing approximately 17% of the total incision time. The problematic transactions often began as an asynchronous communication between the surgeon and the pathologist through a third party (nurse or written document). In 2 cases, the surgeon appropriately physically left the OR to confer with the pathologist and resolve the issue. While this is one way to ensure accurate communication

**Table III.** Quantitative analysis of workload and auxiliary tasks and their influence on performance and safety in cases that progressed to the intra-operative phase (n = 9 cases)

| | | |
|---|---|---|
| **Circulating nurse exits for resource procurement or retrieval** | | **Per-case range** |
| Aggregate number of exits across all cases | 299 | |
| Per-case average number of exits | 33 | 14-66 |
| Mean frequency of exits* | 7.5 per hour of incision time† | 4-12 per hour |
| **Addition of instruments or materials to operative field after start of case** | | **Per-case range** |
| Aggregate no. of objects added across all cases‡ | 131 | |
| Per-case average no. of objects added | 14.6 | 6-33 |
| Mean frequency of addition to field | 1 per 27 min of incision time† | 1 per 7-72 min |
| **Counting activities** | | **Per-case range** |
| Mean time spent on counting¶ | 35 min | 16-73 min |
| Mean % of incision time spent on counting† | 14.5% | |
| **Influence of counting activities on performance or safety** | | **Per-case range** |
| Aggregate no. of performance issues during counting# | 28 | 0-8 |
| Errors or inconsistencies in the count | 17 | 0-5 |
| Increased workload for non-nursing providers | 11 | 0-5 |
| Interruption of case to perform X-ray after failure to resolve inconsistencies | 2 | 0-2 |
| Increased exposure to injury (patient) | 2 | 0-2 |

*Exits made by circulating nurse to procure equipment or other resources during the incision time.
†Incision time is defined as the period between incision and completion of fascial closure. Incision time was selected as the unit of measure because it represents the most vulnerable period of time for several specific surgical adverse events including tissue injury, wound infection, hypothermia, blood loss, and retained foreign body.
‡Objects required for progression of case that were added to the surgical field after start of case.
¶Cumulative time spent on discontinuous episodes of counting.
#Problems were defined as errors or inconsistencies in the counting process, disruptions or slowing of case progress attributable to counting activities, and increased workload for surgeons or anesthesia staff while the nurses were engaged in counting activities.

between the pathologist and the surgeon, it led to further disruption of case flow and prolonged the duration of the case.

**Coordination of workload and competing tasks.** Auxiliary tasks are defined as any task that is not directly patient-centered. Examples include answering telephones and returning pages, discussing case management for other patients, counting instruments, and retrieving resources. While auxiliary tasks are necessary to OR function, they constitute a source of workload that can compete for attention with primary, patient-centered tasks. There was wide variation in workload and distractions produced by auxiliary tasks across cases, despite similarities in case type. We documented 12 specific instances in which auxiliary tasks impaired a provider's ability to perform necessary primary tasks, delayed case progression, or distracted the provider during a high-risk phase of the case.

Chief among the nurses' auxiliary tasks was the manual "count" of all instruments and sponges. This counting protocol, intended to reduce the risk of a retained foreign body, is mandated by the Association of Operating Room Nurses (AORN) and enforced to varying degrees in most ORs across the country.[32,33] An average of 35 minutes per case was dedicated to the counting protocol, representing 14.5% of the incision time (Table III). Despite this large time commitment, there were 17 inconsistencies in the counts over the 9 observed cases and 11 instances in which counting activities disrupted the activities of other team members. Figure 4 provides an example of the effect of the counting protocol on case flow in one of the cases we observed. Before initiating the counting protocol, each request for an instrument or supply was promptly met; however, once the counting protocol was initiated, there were delays in meeting requests made by the surgeons. In fact, there were multiple instances in which the requests were repeated before being met. Even more concerning is the fact that 2 safety-compromising events occurred during the period when the nurses were attempting to reconcile an inconsistent count. It was the consensus of the observers that these safety-compromising events likely would not have occurred had the nurses' attention not been diverted by the competing count task. Competing demands also influenced team members' ability to perform the auxiliary tasks. In all cases, the process of

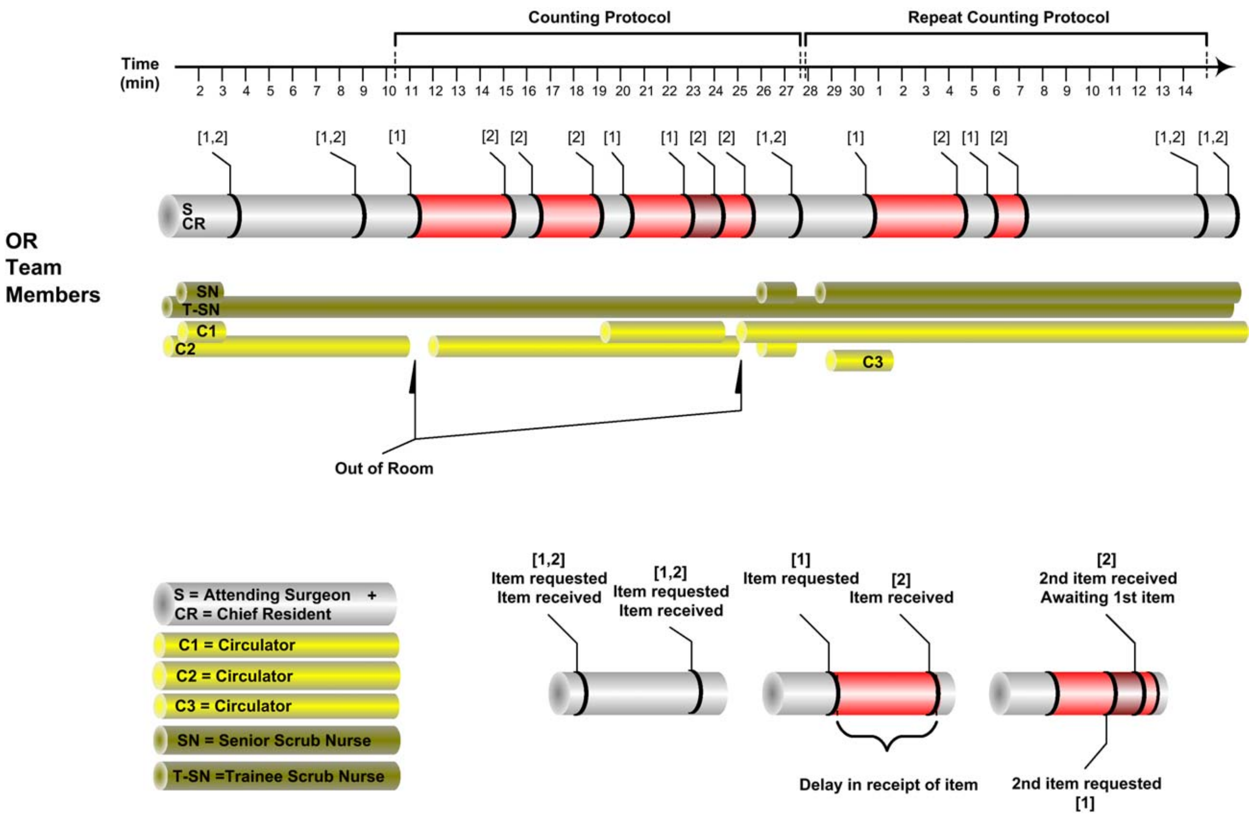


**Fig 4.** Influence of auxiliary tasks on surgical flow. The time course of the case is noted at the top. The *thick bar* represents the progress and activities of the attending surgeon (S) and surgical chief resident (CR) who is assisting him. Each *black line* on this surgeon's activity bar signifies a request for an instrument with [1] indicating the request, and [2] indicating the receipt of the instrument. The *thin bars* represent the progress and activities of scrub nurses (SN), the scrub nurse trainee (T-SN), and the circulating nurses (CN). During this time interval, the primary scrub and circulating team handed off the case to a second team to take a scheduled break. Before the counting procedure began, the surgeon and chief resident request and receive instruments promptly. After the counting protocol begins, there are significant delays, noted by the shading between black hash marks, before the requests are filled. In this case, counting activities also contributed to 2 near misses. Moreover, during the counting procedure, an inconsistency was encountered by the secondary team of nurses, and the count needed to be repeated when the primary team returned from break.

counting was interrupted by other case demands and/or hand offs. Not uncommonly, inconsistencies were detected in the numbers of instruments counted. In 2 of the 9 cases, the discrepancy between the initial and final counts could not be reconciled, the count was abandoned, and an X-ray was taken to rule out a retained foreign body.

Another auxiliary task relates to resource procurement activities, including (1) the addition of resources to the operative field after incision and (2) the need for the circulating nurse to exit the room to procure equipment or other resources (Table III). All study cases were resource intensive, involving combinations of incisions (eg, abdominal and perineal) or approaches (eg, laparoscopic and open), and requiring multiple pieces of specialized equipment. It is therefore not surprising that nurses frequently needed to add resources to the operative field after incision (14.6 times per case) and exit the room to retrieve additional resources (33 times per case). These activities impacted case progression. In the absence of the circulating nurse and/or a specific instrument, the surgeon, scrub nurse, and anesthesiologist either modified their technique or delayed case progress. Despite the similarity in the procedures performed, there was wide variation in the frequency with which the nurse exited the room to procure resources (Table III).

Auxiliary activities were synchronized poorly with predictably high workload or high-risk phases of the case. Figure 5 maps auxiliary tasks (exits, hand

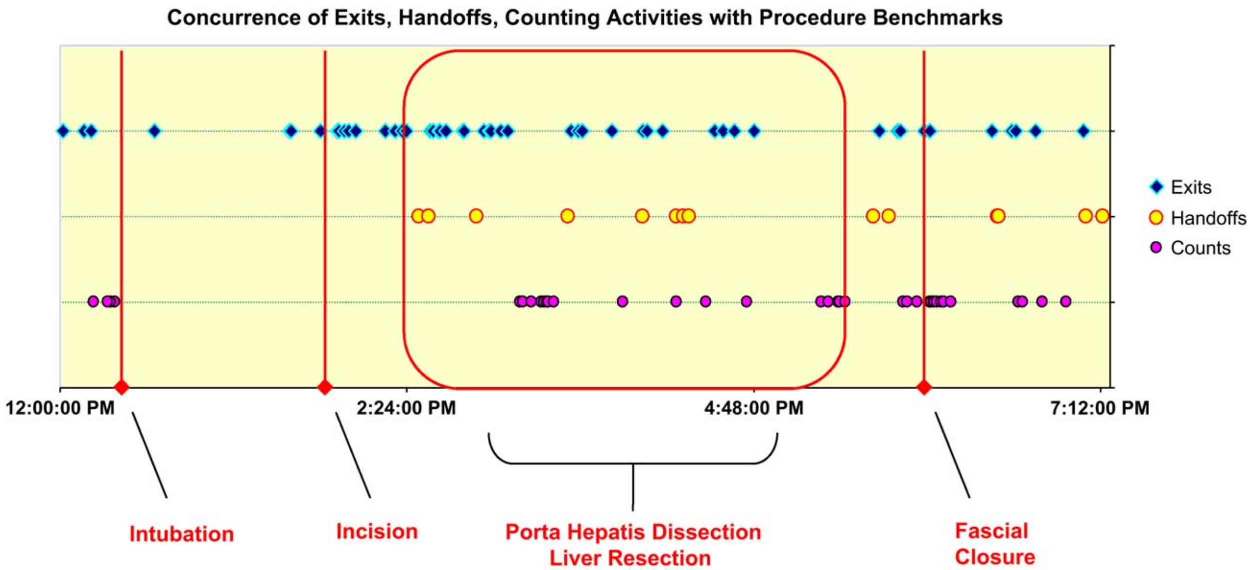


**Fig 5.** Correlation of competing tasks with predictable variation in workload. The timing of auxiliary tasks, including exits, hand offs, and counting activities, are graphed in relation to the various phases of the case. A disproportionate number of auxiliary tasks were performed during the most technically demanding phases of the case. A prolonged delay between intubation and incision was related to difficulty obtaining additional venous and arterial access for monitoring purposes. Despite this opportunity, relatively auxiliary tasks were performed during this delay.

offs, and counts) occurring during one of the cases we observed. Seven of the cases had similar profiles. A large number of auxiliary tasks were carried out during the high-intensity phase of the operation, and comparatively few occurred during a low-intensity preincision delay. While some of the poor synchronization is unavoidable because of emerging or unanticipated events, it was the consensus of the observers that many of these auxiliary tasks could be better coordinated with low-risk or low-demand phases of the case. Importantly, 5 safety-compromising events were related temporally to the performance of multiple competing tasks or periods of high workload. (Table I lists items with contributing factors D and H.)

**Safety-compromising events.** In the 10 cases, we observed 11 events that compromised patient safety or had the potential to cause patient injury, which we refer to as safety-compromising events. Five of the events resulted in a measurable adverse change in patient status. Most of these events were temporary changes in patient status, with recognition of the adverse change by one or more providers, leading to an intervention to correct the trajectory of the event.

Table III summarizes the 11 observed safety-compromising events and indicates the contributing and compensatory factors that were identified for each. The most commonly observed contributing factors included patient factors, hand offs, inexperience of staff members, high workload, and hierarchy among team members. Compensation was most frequently achieved through checks and verifications (both within and across disciplines), compromise, adaptation, and leadership that enabled emerging safety problems to be detected and corrected. Table I also indicates whether the events were detected by the OR team members involved. Four of the 11 events were not detected by the team in the OR; of these 4 events, 2 were never detected and therefore could not have been analyzed by traditional methodologies for studying adverse events, such as root cause analyses.

## DISCUSSION

In this study, we preformed a prospective observational field study of a specific health care microsystem: the OR. The goal was to identify specific system features that negatively influence provider performance and patient safety and that could be the basis for further controlled investigation and quality improvement initiatives. Across all cases, we identified frequent system-based factors that changed the expected course of care and often compromised patient safety. These factors related to communication and information flow, particularly as they related to hand offs in care, as well as multiple competing tasks and high workload.

Like other complex systems, the OR is information-intensive, with performance and safety relying heavily on how well information flows between phases, physical locations, and providers. We observed wide variation in the type and format of the information that was lost or degraded and the phase at which this occurred, suggesting a generalized vulnerability of the OR system to information loss. Information loss led to delays, overuse of staff and resources, uncertainty in clinical decision making and planning, and oversights in patient preparation. Hand offs of patient care across physical locations and provider groups required a comprehensive exchange of information about prior case events, current status, and plans, and were particularly prone to information loss. These results demonstrate that hand offs in the OR are subject to the same vulnerabilities as in other clinical settings.[15,34] Our results also support those of a previous observational field study in the perioperative setting that documented a 30% rate of communication failure in the OR with 36% of these breakdowns having a substantial impact on patient safety.[35]

Among the communication events that were observed in this study, those between the surgeon and the pathologist were particularly vulnerable. In this particular setting, although the pathologist is co-located with the surgeon in the larger perioperative suite, communication between these individuals is typically asynchronous and performed using secondary messengers such as nurses or technicians. For a subset of surgical cases, particularly surgical oncology cases, the information generated by the pathologist can play a key role in intraoperative strategy and decision making. It is in these types of cases that efforts might be focused to improve the quality, effectiveness, and timeliness of communication between the surgeon and the pathologist. Potential ways to improve the communication between the surgeon and the pathologist for complex cases include (1) a required, standardized face-to-face meeting between the pathologist and the surgeon before incision to discuss expectations, goals, timing and importance of consultation to intraoperative decision making (ie, including the pathologist in the "preflight" meeting); (2) intraoperative consultation by the pathologist to observe the surgical context and discuss the case with the surgeon; and (3) creation of a virtual presence for each team through real-time video linkage, with transmission of pathology images to the OR and intraoperative images to the pathologist.

Auxiliary tasks influenced performance and safety by increasing workload and placing competing demands on provider attention from primary patient-centered activities. As the complexity of the perioperative environment has increased (in part because of increased use of technology and throughput requirements), the demands for attention and skill, particularly on the part of the nursing and support staff, have increased. While system complexity cannot be eliminated, it can be controlled or managed to limit its impact on patient safety. For example, to the extent possible, performance of auxiliary tasks and occurrence of hand offs can be shifted so that they are better synchronized with periods in which patient-specific case demands are lower. Anesthesiologists face considerable workload during induction, intubation, and extubation.[38] Surgeon workload increases during deep pelvic dissections, major vascular mobilizations, and hepatic resections. Nurses face some of the highest workload during case setup and transitions from laparoscopic to open surgical approaches. Despite this underlying predictability, it was not uncommon to see auxiliary tasks unnecessarily superimposed on technically demanding phases of the case. One way we propose to improve safety in the OR focuses on increasing the use of low workload periods for the performance of auxiliary tasks to the extent possible, thereby off loading high workload periods to focus on primary, patient-centered activities.

Among all auxiliary tasks, the counting protocol appeared to impact primary, patient-centered care the most. When considered with other recent findings, our results raise questions about the overall reliability of the count protocol. Published data relating to the efficacy of the counting process in reducing the risk of a retained foreign body are inconclusive. Some studies suggest that the counting of instruments and other resources can decrease the risk of a retained foreign body.[39,40] However, a recent case-control study[41] on retained foreign bodies found that in 88% of the cases of retained foreign bodies, all instruments had been thought to be accounted for on the basis of a manual count. This percentage did not differ significantly from that for matched controls without a retained foreign body. While, in their conclusion, the authors still advocate adherence to the AORN counting protocol, their results place in question the effectiveness of the counting protocol in preventing retained foreign bodies. Our results raise further questions by revealing that the counting protocol imposes considerable demands on the attention of the nursing staff, detracting from their ability to perform other primary tasks. In our series, there were 2 specific safety-compromising events that occurred in the face of the intensive counting

prospective methodology, however, we identified 11 safety-compromising events that compromised patient safety or had the *potential* to cause injury (Table I). While the majority of these events would not be classified as "adverse events" by conventional definition, they offer much insight into patient safety. By examining prospectively collected data on system features before, during, and after a specific event, we were able to recreate the event, and identify contributing and compensatory conditions or factors in each case.

Another important finding is that system features that simply influenced case progression or produced delays in some cases actually can contribute to safety-compromising events in others. Communication breakdown or information loss, hand offs, multiple competing tasks, and high workload are cited anecdotally as "annoying but accepted features" of the perioperative environment. Through close observation, we were able to document the extent to which these same factors can compromise safety.

Direct field observation is a sensitive technique for capturing process variations that either may or may not progress to unfavorable outcomes, as is demonstrated in the prevalence of safety-compromising events detected during this study. Importantly, most of the process variations ultimately were recognized and corrected or reversed by providers, so they did not progress to an adverse outcome. The prospective approach enabled us to detect the vulnerabilities that would be otherwise undetectable through outcome-driven retrospective review or post-case reporting by providers, a phenomenon also noted by Donchin et al.[5] In our study, only 2 of the 11 events would have been detectable using conventional methodologies such as chart review, a rate that is consistent with previous studies.[2-4,62] Equally important is the sensitivity of the observational technique to identify strategies used by providers to compensate for system constraints or recover from evolving adverse events.

## CONCLUSION

This study describes 2 areas that can compromise patient safety and need to be the focus of future controlled studies and patient safety initiatives: (1) communication breakdown and information loss and (2) high workload and multiple competing tasks. In addition, we have illustrated the importance of direct field observation in the study of patient safety. Through such prospective studies, we can gain a deeper understanding of complex medical environments and the processes by which care is delivered.

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# *Editors' corner*

## Does the Patient Undergo a Surgery or an Operation?

What do surgeons really do? Do we practice the art of surgery or do we only perform surgeries (or operations)? We hope that we all like to think of ourselves as doctors—but doctors who can also operate. Much of our practice as surgeons in the art of surgery is nonoperative-preoperative, postoperative, and often, more importantly, the decision not to operate. Indeed, the term *surgery* should be saved for our respected overall practice, while *operation* defines only a part of what we do (in the operating room). Let's not denigrate our art by inappropriate use of the word *surgery* to describe one specific but limited aspect of our art. The patient is evaluated surgically, but undergoes an operation.

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