FINAL REPORT SUMMARY

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Unexpected Clinical Events: Impact on Patient Safety

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ABSTRACT

Purpose: To improve patient safety, it is critical to understand how clinical systems actually work and why adverse events occur. We sought to demonstrate the value of studying Non-Routine Events (NRE) during actual anesthesia care. NRE are defined as any event that is perceived to deviate from ideal care for that specific patient in that specific clinical situation.

Scope: Using anesthesia as a model of a structured medical work environment, we collected prospective and retrospective data about NRE, developed a useful classification of these events, and began to relate them to clinical outcomes.

Methods: Direct observation and videotaping of NRE during actual patient care included task and workload analysis. A sophisticated data collection and analysis system was designed and constructed. NRE were also identified by systematic query of clinicians in the Recovery Room and by a traditional QA reporting system.

Results: We collected video data from 404 elective surgical cases representing a cross-section of anesthetic techniques, surgical procedures, and patient complexity; 34% of these cases contained at least one NRE, and 23% of the NRE cases had >1 NRE, with a total of 187 NRE. The patient was affected in 78% of NRE (36% of all cases), and patient injury occurred in 19% of NRE. Airway management NRE were the most frequent type of NRE. In a multivariate regression using 332 cases, provider experience and reported difficulty sleeping the previous night were significant predictors of NRE. The incidence, impact, and type of NRE were similar in a retrospective sample of 412 cases.

Keywords: Anesthesiology; Safety Management; Intraoperative Complications; Information Storage and Retrieval; Medical Audit; Medical Errors; Prevention & Control/Statistics & Numerical Data; Prospective Studies; Retrospective Studies; Risk Assessment.

Scope

Patient safety has become a major public concern. Human factors research in other high-risk fields has demonstrated how rigorous study of factors that affect job performance leads to improved outcome and reduced errors after evidence-based redesign of tasks or systems [1-3]. The PI and others have begun to apply these techniques to anesthesia patient safety research [4]. Anesthesiology has been a fertile environment for this kind of research because, more than other medical specialties, it has adopted a culture of patient safety and fostered efforts to study and reduce medical error. This is due in part to the fact that faulty systems or human fallibility during anesthesia care can rapidly produce serious patient injury.

Correction of latent failure modes in clinical systems is crucial to improving patient safety, yet it is unclear how to best identify these errors, especially those that are likely to cause patient harm. A popular method is to examine adverse events that have occurred and "trace back" to attempt to pinpoint a "root cause." This approach is limited, though, because adverse outcomes are relatively infrequent and retrospective analysis is contaminated by cognitive (especially hindsight) bias. This project utilizes an alternative approach that may have a higher likelihood of uncovering risks of **future** injury– the study of *non-routine events* (NRE). The NRE concept was borrowed from other industries, such as nuclear power and aviation, in which flaws within these complex systems can result in disaster if not identified and rectified. Here, safety efforts require the investigation of all deviations from standard processes and procedures. As has been found in these other industries, we suggest that NRE are early indicators of potential failure modes within clinical systems. Thus, NRE are measures of care *processes*, which may directly or indirectly affect outcome.

Purpose

In order to improve patient safety, it is critical to understand how clinical systems actually work, what factors make them work well (or not so well), and why adverse events occur. It is particularly important to elucidate the role clinicians play in medical system safety. Given the complexity of clinical processes and the large number of interdependent mediating variables, these types of questions may not be amenable to traditional empirical experimentation (e.g., randomized clinical trials). The state-of-the-art in patient safety efforts emphasize retrospective analysis of adverse events or "medical errors." However, this approach is limited in scope because such events are uncommon and usually unique. When adverse events do occur, it may be difficult retrospectively to accurately determine their etiology or identify optimal prevention strategies [13,14]. Instead, this project drew from established human factors techniques in the nuclear power, aviation, and process control industries. In these complex non-medical systems, it is highly undesirable to wait for a serious accident to happen before analyzing a system's safety attributes. Techniques were developed to extract detailed information about system performance and risks to safety from any deviation beyond expected or routine system function. This project applied this approach to medicine, using anesthesia and perioperative care as the initial test bed.

The NRE construct was used in this project as a mechanism for efficiently capturing dysfunctional clinical system attributes or potentially dangerous conditions. An NRE is defined as any event that is perceived by care providers or skilled observers to be unusual, out of the ordinary, or atypical. For expert clinicians, most everyday clinical activities are "routine," conducted seamlessly and with infrequent conscious deliberation [15]. NRE represent disruptions in these smooth expert processes. We purport that rigorous characterization of the factors

contributing to the occurrence of, and recovery from, NRE facilitates the understanding of what distinguishes safe from unsafe clinical practice.

NRE encompass a substantially larger class of events than adverse events, medical errors, or even "near misses." The greater frequency of NRE makes prospective data collection a more tenable strategy. Additionally, most NRE do not involve errors by the primary care provider, and few lead to patient injury. Thus, retrospective analyses of NRE are less likely to be affected by bias. Finally, study of NRE allows delineation of *process* as well as *outcome* of care. Modern management theories support the notion that understanding and improving process is critical to error reduction and enhanced quality [16,17]. Using anesthesia as a model of a structured medical work environment, the purpose of this project was to collect both prospective and retrospective data on non-routine events during the perioperative period.

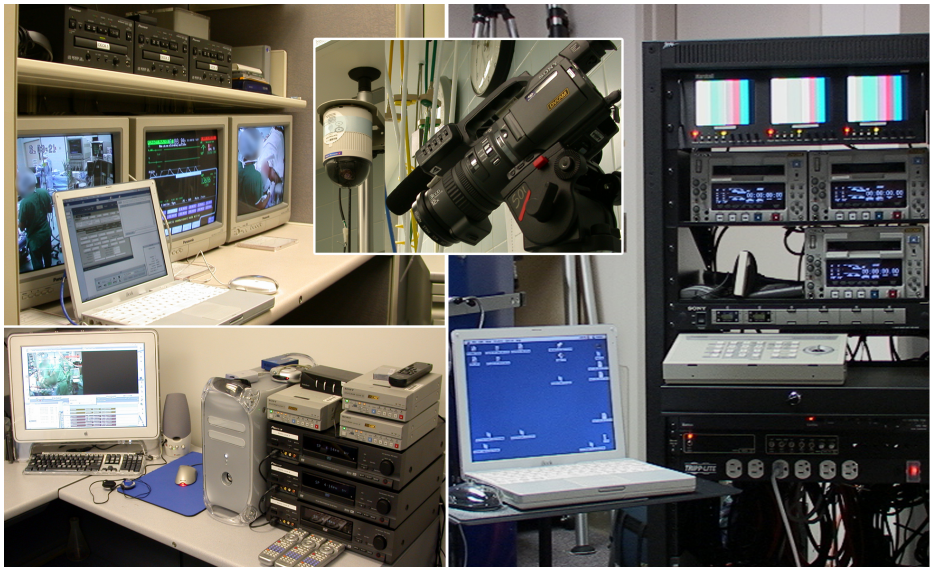
In this project, we used anesthesia as a model of a structured medical work environment, collected both prospective and retrospective data on NRE, developed a useful classification of these events, and began to relate NRE to clinical outcomes. The objectives of this project were to 1) demonstrate the utility of studying NRE as a strategy to enhance perioperative patient safety; 2) develop and validate prospective and retrospective techniques for identifying and analyzing NRE; 3) build a large database of perioperative NRE; and 4) elucidate the factors that differentiate NRE that lead to adverse outcomes from those that are handled successfully.

Design and Methods

The cornerstone of our research is structured observation and videotaping during actual patient care. NRE can be detected in real time so that a virtually complete record of the clinical events that precede and follow the NRE are captured on video and in computer data records for subsequent review and analysis. Much like the flight data recorder in an aircraft records audible and systems data during a flight, our Operating Room Audio-Video System (ORAVS; see **Figure 1**) creates an objective and detailed record of intraoperative anesthesia care. Although this method is resource intensive, it captures the fine-grain complexity of factors that affect patient safety. Because all data are obtained ***before*** patient outcome is known, the process is prospective and avoids hindsight bias.

The development of the Operating Room Audio-Video System (ORAVS) proved to be a major engineering endeavor that required consideration of complex issues of multiple device compatibility, communication protocols, power distribution, cabling, size, weight, and mobility. Establishing the infrastructure to allow videotaping of patient care was similarly challenging.

Figure 1. The Operating Room AV Data Collection System (ORAVS) and the Video Archiving, Editing, and Review Stations.

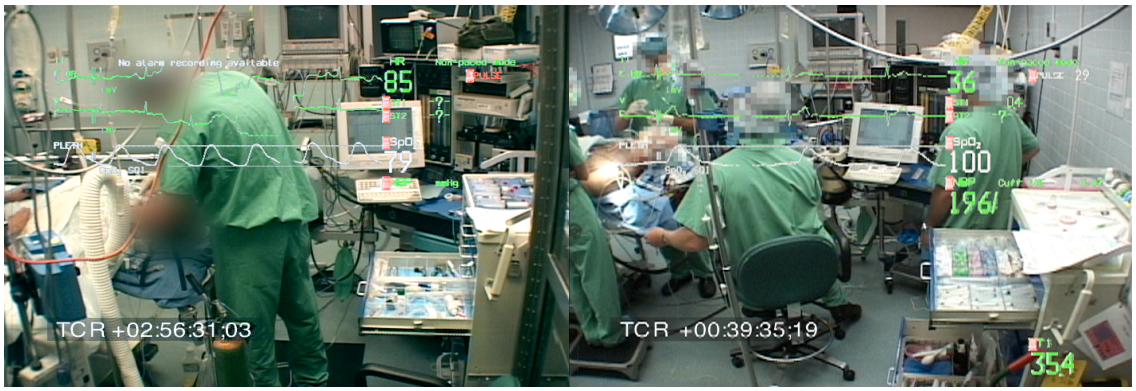


This composite figure shows (on the right) the components of our audio-video data collection system, including video monitors, recorders, wireless microphones, data-logging computer and two video cameras (inset) positioned in the operating room, one behind the anesthesia machine and one directed down from behind the anesthesia cart. A trained assistant controls the camera views and audio levels while concurrently recording task and event data on a laptop computer. The bottom image on the left shows the video archiving station, where video data streams are transferred directly to three DVD. The computer to the left in this bottom left image runs non-linear video editing software to, for example, de-identify faces and voices. The video review station is depicted in the upper left image. Here, custom review and annotation software, running on a laptop computer, controls three DVD players to permit frame-synchronous playback of the three video data streams, and time-stamped event annotation.

ORAVS allows concurrent collection of two separate high-quality digital video data streams, four audio channels, and patient vital signs data [18]. As a supplement to the video record, the observer continuously records all of the subject's activities [9,12]. All data streams are synchronized and archived for offline review and analysis [18] (see **Figure 1**). An example of NRE captured during patient care with this system can be seen in **Figure 2**.

Immediately after each case, a researcher briefly interviews the involved providers using a standardized interview form to identify NRE from the clinicians' response to nine open-ended questions. This Comprehensive Open-ended Non-routine Event Survey (CONES) was developed to elicit NRE at the end of prospective studies but can be used stand-alone for active event surveillance. Relevant data are abstracted from medical records.

Figure 2. Still photos of videotaped anesthesia cases containing NRE.



This composite figure shows two single images ("frame grabs") from videos containing NRE in the existing database of anesthesia cases. The image on the left shows a desaturation (low oxygen) event after extubation. The right image shows hypertension and bradycardia due to inadvertent intravascular injection of epinephrine by the surgical resident on the far left. A nurse anesthetist is seated, and a medical student is on the left.

NRE Database Entry, Classification, and Review. We have created and populated a FileMaker Pro™ database that now contains hundreds of prospective and retrospective cases. An NRE case database file consists of all study variables, including patient characteristics (e.g., demographics), anesthesia (e.g., technique), surgical (e.g., type, duration), provider (mood, sleep habits), intraoperative (times, tasks, workload), NRE, and outcome variables (see Appendix 1-6 for database screen shots). The data are derived from medical records, video, real-time case data (generally automatically entered into the database), and expert post-case review.

Each case studied is given a random generated case number to ensure anonymity. All participant and patient identifiers are stripped. The database and associated data management processes comply with all institutional, state, and federal laws and standards to ensure subject and patient confidentiality and privacy as well as data security.

Two trained clinical domain experts reviewed each NRE-containing case and, using standardized rating systems, scored NRE type and severity, patient impact (e.g., tachycardia, oxygen desaturation), and putative contributory factors. The experts first reviewed deidentified medical records and either checked (i.e., factual data entered by the technician) or, as necessary, entered all demographic pre-NRE patient, provider, anesthesia, and surgical variables into the database. Then, they viewed the video while creating an annotation file of their impressions of the event as it transpires; this includes both time-stamped statements linked to the video and text summaries of the event. Finally, they coded the NRE for the presence of both binary (e.g., injury, impact, near miss, adverse drug event), and categorical elements. Patient impact events (PIE) and contributory factors were identified and coded. PIE were later segregated for analysis into true patient impacts (e.g., hypotension), events (e.g., equipment unavailable), consequences (e.g., case cancellation), and reasons (e.g., patient not NPO before surgery).

A rigorous taxonomy of event type and impact, informed by taxonomic research of anesthesia events [20], has been developed and refined. The flexibility of the database's design facilitates future enhancements or the addition of new variables. A comprehensive data dictionary specifies for each data element, the type of variable (e.g., categorical, numeric), units, range, and missing data code. All case data elements were systematically checked for consistency, completeness, and plausibility. If questions arose during data coding, the affected

clinical provider(s) was asked for clarification and possibly was asked to review the case summary and video.

Database Management. Database security is maintained using a multi-layered approach to both limit access and the ability to alter data. There are strong protections restricting access to the Vanderbilt network. Local installation of proprietary software is required to detect our server on the network. Each user has a unique username and password that allows specific access and editing privileges. Browsing level access is used except when data entry/editing is explicitly intended. Though multiple users can simultaneously view data, only a single authorized user can edit a given record at any time. All data entries were double-checked. When appropriate, automated range limit checking ensured that entered data lies within predefined acceptable ranges. Data integrity was insured through weekly audits and random spot checks that use automatically generated reports and manual exports to check for missing values and conflicting data. Database backups were conducted automatically on a daily, weekly, and monthly bases.

Video and Database Review. Each NRE case record was reviewed by trained clinician investigators. At the video review station (Figure 3), custom software allows reviewers to access a case's database information, near instantaneously go to any specific time in the case, and input annotative text comments into a time-labeled synchronized computer file. The expert reviewer abstracts those additional data elements requiring clinical judgment, such as patient pre-existing disease and codes event attributes. To reduce bias, reviewers had no a priori knowledge of the case's clinical course or the nature of the NRE and, especially, were blinded to the extent possible to ultimate patient outcome. Following established procedures [19], we confirmed on an ongoing basis that satisfactory levels of agreement and consistency (reliability estimates > 0.80) exist between reviewers' judgments. If there was drift, we recalibrated the reviewers. Additionally, the PI independently reviewed selected cases to ensure that there are no inherent coding biases. If analyses uncovered inconsistent use of criteria or unacceptable disagreement between the reviewers, a conference would be held, mediated by the PI. Although it proved unnecessary during the data review process in this project, remediation of reviewers may occur, if deemed necessary, until acceptable reliability is attained.

Results

The data deriving from this project so far strongly support the utility of the NRE construct and demonstrate that NRE can be studied prospectively. Studies have shown that NRE 1) occur frequently and are of diverse type; 2) are commonly associated with patient impact; and 3) are associated with multiple contributory factors, many of which may be amenable to intervention.

We were able to address most of the original aims of the project, but, in retrospect, we underestimated the technical difficulties in developing a production system for capturing and encoding high volumes of video data. Because no commercial software met our needs, we had to develop custom applications. We designed and implemented a complex database, selected and adapted methods for video and audio obscuration of subject/patient identity, and created a system to review and analyze multiple audio and video tracks. We successfully addressed issues of clinician and patient acceptance, consent, privacy, and confidentiality.

Frequency and Type of Prospective NRE. We collected video and human factors data from 404 elective surgical cases representing a cross-section of general anesthetic techniques, surgical procedures, and patient complexity. An example of NRE captured during patient care with this system was made available at http://simcenter.ucsd.edu/demovideos.

The demographics of our study population are shown in **Table 1**, and a representative sample of events are described in **Table 2**.

Table 1. Demographic attributes of videotaped cases

Case Attributes	**No NRE Cases** (n=265)	**NRE Cases** (n=139)	**Sig.**
Patient age	59.0 ± 13.2 (23-86)	59.7 ± 11.3 (30-84)	NS
Patient gender (% male)	92.1%	92.1%	NS
Patient ASA Status (1/2/3/4 in %)	4.9 / 44.9 / 40.0 / 9.4	4.3 / 43.2 / 41.7 / 10.8	NS
% Performed by CRNA	41.9% (111)	35.3% (49)	NS
% By resident or fellow (CA1/CA2/CA3/fellow)	58.1% (12.8/24.2/20.7/0.4)	64.7% (18.7/30.2/15.8/0.0)	NS
Type of surgery: General / Urology / OB/GYN / Vascular	18.5% / 15.1% / 1.5% / 7.2%	11.5% / 20.9% / 2.2% / 11.5%	
Cardiothoracic / Neurosurg. / ENT	10.9% / 8.7% / 12.8%	10.1% / 10.8% / 11.5%	NS (Pearson)
Orthopedics / Plastics / Other	17.0% / 5.3% / 2.6%	12.9%/ 7.2% / 1.4%	

Thirty-five (141/404) percent of cases contained at least one NRE. More than one NRE occurred in 23% (32/139) of the NRE-containing cases, to yield a total of 187 NRE; 5% occurred preoperatively, 34% of NRE occurred during induction, 45% were during maintenance, 13% were during emergence, and 3% occurred postoperatively. The patient was affected in 78% (145/187) of NRE (36% of all cases), and patient injury occurred in 19% (36/187) of NRE (8.9% of all cases). Airway management NRE were the most frequent type of anesthesiology NRE and were associated with an increased risk of adverse patient outcome. NRE was strongly associated with injury (X^2=67.55, P<0.001). Moreover, clinician subjects rated 39% of NRE as having at least a 50% chance of *serious* injury if the event had not been detected and managed properly.

Table 2. Representative Sample of NRE from Cases in the Database

	# NRE	Brief Description of NRE
*	1	Desaturation to 74% after patient extubated. Required Narcan.
	1	After induction, discovered that surgical attending was on vacation. Case cancelled.
	1	Clinician providing break gave opiate to a spontaneously breathing patient who then hypoventilated and desaturated. Required controlled ventilation until drug effect gone.
	4	Hypotension with induction. Inadvertently treated with epinephrine instead of ephedrine (syringe swap). Muscle rigidity due to inadvertent bolus of opiate from poorly flowing IV. Drug concentration was double what was intended. Surgery almost done on the wrong side.
	2	MI during induction of anesthesia. Pulmonary edema ensued. During treatment, RN distracted clinicians by insisting on doing a "time out." Case cancelled and pt sent to ICU.
	1	A-line tubing caught on OR table and was disconnected from the transducer during patient movement to gurney at the end of the case.
*	1	Accidental patient extubation by surgeon during rigid oral endoscopy. Table turned away 90°. Patient difficult to ventilate. Anesthesia attending called to help reintubate.
*	1	Esophageal intubation by junior resident. Distracted by research study. Reintubated.
*	1	Bloody nose due to failure to use nasal vasoconstrictor during awake fiberoptic nasal intubation. Resident sprayed with patient's blood upon successful intubation.

* Airway management NRE

Airway Management. Adverse outcomes associated with airway management are the single largest cause of injury in anesthesia closed claims cases [22]. Substantial risks are involved with both intubation (insertion of the endotracheal tube (ETT)) and extubation (ETT removal). Failure to secure the airway (e.g., intubation), ETT malposition or obstruction, accidental extubation, and other airway problems are a major cause of death and brain damage in anesthesiology and during emergency situations [23-25]. The decision to extubate a patient is complex, involving multiple factors [26]. Delayed and failed extubation are associated with prolonged mechanical ventilation and increased morbidity [27]. Airway management problems also occur in the ICU [28], in the emergency room [29], and during cardiopulmonary resuscitations [30].

In the current database, there are 43 cases that contain airway management NRE (48 airway NRE total), representing 10.6% of all cases. Seven cases led to patient injury. Six of these were multiple NRE cases – in three, the airway NRE followed other NRE; in the other three, the airway NRE occurred first. Sixty-five percent of airway NRE contained mutable factors related to provider training, skill and knowledge, or judgment. These data suggest that changes in patient's surgical position, inadequate preoperative preparation, and failures of clinician-clinician communication are associated with airway NRE lead to patient injury.

Multivariate statistical analyses. In an interim analysis conducted a year ago, the relationship between antecedent variables and NRE occurrence was evaluated with multiple logistic regression using two patient (age, ASA status) and two provider (level of experience, difficulty sleeping the preceding night) putative variables. For the 332 cases with complete data at that time, only provider experience (Z=2.08, odds ratio of 1.62 (1.03-2.56)) and difficulty sleeping the preceding night (Z=2.03, odds ratio of 2.00 (1.03-3.90)) were significant.

Retrospective NRE Data. To demonstrate that our prospective sample was representative of all NRE, and to assess further NRE epidemiology, we studied 412 cases from anesthesia providers in the Recovery Room (RR) using a survey instrument; 32% (133/412) of cases contained at least one NRE. More than one NRE occurred in 12% (16/133) of the NRE-containing cases, to yield a total of 156 NRE. The similar NRE incidence in prospective and retrospective cases provides support for the validity of the NRE construct. The patient was impacted in 56% (88/156) of RR NRE, with 17% (26/156) producing injury. In contrast, over the same time period, the VA San Diego Healthcare System's (VASDHS) QI system identified events of interest in merely 3.6% of cases (175/4,800), and the academic anesthesia department M&M conference proceedings reported noteworthy events in only 1.0% (168/17,500) of cases. A paper summarizing these results has been submitted to *Anesthesiology*.

Evaluation of the Role of Clinical Workload in Anesthesia Care. We examined measures of workload during different phases of anesthesia care and during teaching (when the primary provider is teaching a medical student or new resident) and non-teaching cases [31]. In 24 cases, workload was measured using physiological (clinician heart rate (HR)), psychological (clinician self-rating and observer rating using the same scale), and procedural (response latency to an alarm light and workload density) techniques. Clinician workload was greater during induction and emergence than maintenance. However, workload during teaching was significantly greater than in the non-teaching cases. Response to the alarm light was significantly prolonged during the teaching compared with non-teaching cases. Thus, intraoperative teaching appears to increase anesthesiologist instructors' workload and may reduce their situation awareness.

Parallel Research Efforts. In addition to the study of non-routine events in anesthesia, under the umbrella of our AHRQ-funded patient safety research program (including the Developing Center grant), we conducted additional investigations that assessed the impact of putative safety variables on measures of clinical performance. The results of some of these studies follow.

Task Analysis of the Drug and Fluid Administration Process. In this study, intravenous administration tasks were examined to identify opportunities for improved design. While observing anesthesia providers' activities during 35 cases (~90 h) in 66 task categories, task analysis and workload data were collected, focusing on drug/fluid administration tasks. Drug/fluid tasks consumed almost 50% and 75%, respectively, of the set-up time for noncardiac and cardiac cases. In eight cardiac anesthetics, drug/fluid tasks comprised 27±6% (mean±SD) of all prebypass clinical activities. During 20 noncardiac cases and 15 cardiac cases, drug/fluid tasks comprised 8% of induction and 7% of maintenance. Drug preparation far outweighed drug administration tasks. Inefficient or error-prone tasks were observed during drug/fluid preparation (e.g., supply acquisition, waste disposal, syringe labeling), administration (infusion device failure, leaking stopcock), and organization (workspace organization and navigation, untangling of intravenous lines). This study demonstrated the value of task analysis in understanding process deficiencies and identifying specific targets for intervention to improve both technology and clinical processes. This paper was published in *Anesthesiology* [32].

The Impact of Electronic Recordkeeping Systems on Nurse Workload and Task Distribution. In collaboration with Dr. David Wong and his colleagues at the VA Long Beach, we conducted a study to determine the percentage of time intensive care unit (ICU) nurses spend on documentation and other nursing activities before and after installation of a third-generation ICU electronic medical recordkeeping (EMR) and decision support system. Task analysis was conducted while observing 10 ICU nurses before and after installation of the ICU information system. The installation of a third-generation ICU information system decreased the percentage of time ICU nurses spent on documentation by over 30%. Almost half the time saved on documentation was spent on patient assessment, a direct patient care task. A manuscript detailing the results of this important study was published in *Critical Care Medicine* [33]. This work was important not only for the specific results but also because it demonstrated convincingly that we could apply successfully our tools to a domain (ICU) and specialty (nurses) beyond anesthesiologists in the operating room.

Assessing Clinical Expertise using Psychological Scaling Techniques. In collaboration with Nancy Cooke, Professor of Psychology at Arizona State University, we conducted a study to determine whether Pathfinder, a psychological scaling technique, applied to judgments of conceptual pairwise relatedness is a valid method for assessing the knowledge assumed to underlie expertise in anesthesiology. Participants included nine attending anesthesiologists, seven first-year anesthesiology residents, and eight second-year anesthesiology residents. Pathfinder was applied to participants' pair-wise relatedness judgments of the clinical concepts in the context of the scenario. Experts' data were aggregated to form an expert referent structure. Student anesthesiologists were assessed based on comparison of their structures to this referent. These comparisons yielded a knowledge score that was highly correlated with residents' exam grades. This finding

supports our hypothesis that Pathfinder is a valid knowledge assessment method and, as a complement to current evaluation methods, can be applied to assess a student's deep understanding of anesthesiology concepts. This work has been published as a proceedings paper [34] and a full manuscript is currently in preparation.

Intraoperative Reading and Non-Routine Events. Using data we had collected in the prospective NRE project, we are concurrently conducting a study to assess the impact of intraoperative reading on clinical performance. Particularly during routine clinical cases, anesthesia providers may read materials that are directly related (e.g., preoperative and anesthesia records) or unrelated to patient care. Clinicians may read because they have little to do or become bored during routine anesthesia care. Some feel intraoperative reading lowers the quality of anesthesia care because, when the anesthesia providers read, they have the appearance of being less attentive to the surgical procedure and their monitors. Therefore, intraoperative reading may have medicolegal implications. However, others have argued that reading may keep the anesthesia provider intellectually occupied, averting boredom that could otherwise decrease vigilance. The lack of outcome data on the effects of reading in the OR has protracted this debate. To study this issue, behavioral task analysis and workload assessment were used to measure the effects of reading on vigilance, workload, and task distribution. In addition, anesthesia providers were interviewed in the PACU using a standardized questionnaire at the end of 50 clinical cases regarding their intraoperative reading practices and the occurrence of unexpected clinical events (NRE). Although three different measures of clinical workload were all significantly lower during reading periods, intraoperative reading did *not* significantly affect the response time to the random illumination of an alarm light (i.e., no apparent difference in vigilance). In this study, much of the intraoperative reading involved clinical materials, some of which might have been relevant to current case management. These preliminary data suggest that selective reading (based on clinical judgment) may have limited effects on anesthetic vigilance and therefore may not *a priori* put patients' safety at risk. This work has been published as an abstract in *Anesthesia and Analgesia* and the associated poster presentation won an award for "Best Paper" at the 2003 International Anesthesia Research Society annual meeting. We are currently examining data about the relationship between intraoperative reading and the frequency, nature, and causative factors of clinical events as well as the effects of type of reading materials.

Examination of the Role of Clinical Training. We are interested in how anesthesia residents' clinical performance evolves throughout the course of their residency training as they gain clinical expertise. In a study initiated with the support of the National Patient Safety Foundation (NPSF) and continued with AHRQ support, we are comparing the anesthesia care (as measured by clinical task patterns, task efficiency, workload and vigilance) provided by residents at different levels of training with that of Board-Certified Anesthesiologists. Over a multi-year period, we collected a total of 221 cases for a between-subjects analysis. We are also undertaking a within-subjects analysis (three similar cases conducted by the same anesthesia resident performed at least 6 months apart). An experienced research assistant reviewed, in a blinded manner, case triads from eight residents. Unfortunately, this individual is no longer working for us, so we now must train a new data collector to analyze the remaining six case triads. Thus far, data suggest that more experienced anesthesia providers perform tasks more efficiently, spend

less time on secondary tasks, are more vigilant, and have a lower workload than less experienced residents.

Understanding the Post-Anesthesia Extubation Decision. We are completing a study to elicit expert anesthesiologists' knowledge and decision-making processes regarding a specific clinical decision; whether or not to extubate a patient at the end of a general anesthetic. A Cognitive Task Analysis (CTA) technique, the Critical Decision Method, was used during 1- to 2-hour structured interviews of nine expert anesthesiologists to elicit the knowledge that they rely upon to make this decision. The transcribed interviews were decomposed and coded independently by two clinical experts into concepts and their inter-relationships. A third expert is currently coding the transcripts. For each case, a consensus conference rectifies disagreements between the two expert reviewers. A comprehensive taxonomy of concepts is being developed iteratively. This is a *very* time-consuming analytical process. Predefined rules are applied to eliminate redundancies and discern essential relationships. On the first analytical pass, more than 1000 unique concept-concept pairs were used to construct a composite expert concept map from the primary analysis (see attached poster presented last year). One finding to date is that the extubation decision depends largely on three key factors: 1) the patient's current respiratory status; 2) the expected ability to manage the patient's airway *if* extubation fails; and 3) the patient impact *if* extubation fails (e.g., greater risk of patient injury due to pre-existing disease). Psychosocial factors (e.g., surgeon preference, etc.) played a significant role, but economic implications were not expressed. Upon completion of this project, these data will generate a detailed expert model of this specific clinical decision as well as a coherent, more general, taxonomy of anesthesia knowledge applicable to the analysis of NRE and other clinical decisions.

Discussion and Implications

We have made important gains that clearly demonstrate the value of the overall approach. Because no commercial software met our needs, we had to develop our own cross-platform applications. We designed and implemented a complex database, selected and adapted methods for video and audio obscuration of subject/patient identity, and created a system to review and analyze multiple audio and video tracks. The many technical and logistical problems we have solved are integral to *any* type of real-time videotaping and analysis of patient care encounters. These "lessons learned" now allow us to be an invaluable resource to others. As a first step toward disseminating this knowledge, we published a summary of our experience in *Quality and Safety in Healthcare* [18].

We addressed all the objectives of the original 3-year project. We have developed techniques to identify and analyze NRE, built a large archive of anesthesia NRE, elucidated the role in the occurrence of NRE of specific pre-event factors (e.g., clinician inexperience), and demonstrated a statistical association between NRE and patient injury. We made great strides in developing the tools and methods to study events during actual patient care and in describing the epidemiology of anesthesia events. The collection and analysis of over 700 NRE have shown that these events are 1) frequent (occurring in >30% of cases); 2) heterogeneous; and 3) usually associated with patient impact.

The NRE construct offers a number of advantages for patient safety research. First, because there will be many more NRE than serious adverse events, the use of NRE as a study variable

provides substantially more power to detect differences in causative factors or the effects of interventions. Second, because NRE are not pre-defined (i.e., the clinician can report *anything* that deviates from ideal care), new or unanticipated types of events and failure modes can be more readily detected. Third, NRE can be identified prospectively as care is being delivered, either by provider report or observation, thereby reducing the impact of bias due to knowledge of outcome. Finally, because most NRE will usually not be associated with any obvious error or injury, reporting may be enhanced and investigation biases may be reduced.

Prospective study of NRE reduces many of the biases inherent in safety research but does not eliminate them. There may be under-reporting. What is considered "routine" or "non-routine" is subjective and may differ among providers. Some NRE may go undetected. Analysis of NRE will *not* provide direct empirical evidence that any particular clinical process caused patient injury or that a specific intervention will improve safety. Consistent patterns of flawed processes will emerge from these analyses, but accident evolution can be sufficiently complex to preclude definitive conclusions, particularly using statistical approaches. In-depth analysis of events, for example, using cognitive engineering may be a useful adjuvant.

This research extends the basic science of safety, allowed refinement of important research methods, and furthers our understanding of specific patient safety issues. Future work must evaluate whether NRE occurrence and severity are valid and reliable process variables for studying the causes of preventable patient injury. Thereafter, we expect this work to lead to testing of key hypotheses in prospective studies, during either actual or simulated patient care.

It will be relatively easy to generalize this approach, including our methods and tools, from anesthesia to other acute care domains (e.g., surgery, labor and delivery suites, intensive care units, emergency rooms), during medical procedures, or in clinical emergency situations. In fact, we have already demonstrated the validity of behavioral task analysis to study how the introduction of new technology affects critical care nurses' clinical task distribution. Also, a recently funded grant will employ cognitive engineering, task analysis, and workload assessment to discern factors that contribute to medication errors in general medical and pediatric hospital practice. Even if this approach were restricted to high-acuity domains, it would still be a significant contribution because flawed care in these environments represents a significant proportion of the medical errors that lead to patient injury.

The goal of all safety efforts should be to reduce the chances of *future* injuries through the redesign of systems to enable better detection of, and recovery from, events that could cause patient injury. Future research must determine if NRE occurrence is associated with a higher incidence of patient injury. If this proves true, then NRE may be a preferred end point for the prospective evaluation of safety interventions because of their high prevalence.

List of Publications and Products

Published Papers and Book Chapters

1. Weinger MB and Ancoli-Israel S: Sleep deprivation and clinical performance. *JAMA* 2002; 287(8): 955-957. *A review of the current literature on the effects of sleep deprivation and fatigue on clinical performance, which includes a summary of some of our preliminary data.*

2. Fraind DB, Slagle JS, Tubbesing V, Hughes S, Weinger MB: Reengineering intravenous drug and fluid administration processes in the operating room: Step one: Task analysis of existing processes. *Anesthesiology* 2002; 97: 139-147. *IV drug and fluid administration task and workload data are presented that demonstrates the substantial opportunity to improve quality and cost of care through the reengineering of perioperative IV drug and fluid administration processes.*

3. Weinger MB and Slagle J: Human factors research in anesthesia patient safety: Techniques to elucidate factors affecting clinical task performance and decision-making. *J Am Med Inform Assoc* 2002; 9(6 Suppl): S58-63. *This paper introduces a novel concept of "non-routine events" and discusses some pilot data obtained using task analysis and workload assessment during actual patient care as well as the use of cognitive task analysis to study clinical decision making.*

4. Weinger MB, Dunn EJ, Cohn F: Dying of gallstones. *Hastings Cent Rep* 2003; 33: 14-16. *This paper discusses the ethical, social, and policy issues raised by the multiple contributory factors in a case in which a patient is harmed while undergoing endoscopy.*

5. Howard SK, Gaba DM, Smith BE, Weinger MB, Herndon C, Keshavacharya S, and Rosekind MR: Simulation study of rested versus sleep-deprived anesthesiologists. *Anesthesiology* 2003; 98:1345-55. *A randomized controlled prospective study in a realistic simulation environment demonstrated clear effects of sleep deprivation on psychomotor performance, and on subjective, EEG and behavioral evidence of sleepiness. There were only minor effects on clinical performance.*

6. Weinger MB, Slagle J, Jain S, and Ordonez N: Retrospective data collection and analytical techniques for patient safety studies. *J Biomed Inform* 2003; 36:106-119. *A brief overview of some of the methods available to collect and analyze retrospective data about medical errors and near misses is presented and insight into the potential value of the non-routine event approach for the early detection of risks to patient safety before serious patient harm occurs is provided.*

7. Wong DH, Gallegos Y, Weinger MB, Clack S, Slagle J, and Anderson CT: Changes in intensive care unit nurse task activity after installation of a third-generation intensive care unit information system. *Crit Care Med* 2003; 31:2488-2494. *This important study using behavioral task analysis demonstrated that the implementation of a third-generation ICU information system decreased the percentage of time ICU nurses spent on documentation tasks by over 30% with almost half of the time saved redirected direct patient care tasks (e.g., patient assessment).*

8. Weinger MB: Anesthesia incidents and accidents. In: Bogner MS (ed): *Misadventures in Health Care: The Inside Stories*. Lawrence Erlbaum Associates, Mahwah, New Jersey, 2003, pp. 89-103. *This chapter, in a book for the educated public, provides a case-based discussion of critical patient safety issues in anesthesia.*

9. Weinger MB and Blike GT: Infant paralyzed for intubation before airway materials ready (case discussion). *AHRQ Web M&M* September 2003. *A case-based discussion describes how poor teamwork can lead to errors from deficiencies of interpersonal communication, coordination, and competence. A tutorial on improving clinical communication and teamwork includes videos of simulated re-enactments of the case with both poor (actual case) and good team behaviors demonstrated.*

10. Weinger MB, Gonzales DC, Slagle J, and Syeed M: Video capture of clinical care to enhance patient safety: The nuts and bolts. *Qual Saf Health Care* 2004; 13: 136-144. *Methods are described for the videotaping and analysis of clinical care using a high-quality portable multi-angle digital video system that enables simultaneous capture of vital signs and time code synchronization of all data streams captured on tape.*

11. Weinger MB, Reddy S, and Slagle J: Multiple measures of anesthesia workload during teaching and non-teaching cases. *Anesth. Analg.* 2004; 98(5): 1419-1425. *This study, which used several novel methods to measure anesthesia provider workload, demonstrated that intra-operative teaching increases the workload of the clinician instructor and may reduce vigilance during anesthesia care.*

12. Connor O, Cooke N, Weinger MB, and Slagle J: Using psychological scaling techniques to assess clinical expertise in anesthesiology. *Proceedings of the Human Factors and Ergonomics Society* 2004; 48: 1746-1750. *This study investigated the validity of the application of a psychological scaling technique (Pathfinder™) to clinicians' scores of context-dependent concept relatedness as a valid knowledge assessment tool to assess trainees' deep understanding of clinical concepts.*

13. Barach P and Weinger MB: Trauma team performance. Wilson, W. C., Grande, C. M., Hoyt, D. *TRAUMA: Resuscitation, Anesthesia, Surgery, and Critical Care*. Marcel Dekker: New York (in press). *This chapter provides a comprehensive overview of teamwork, communication, and leadership in acute care medicine, with an emphasis on methods to train and measure a team's quality of care in the trauma setting.*

14. Rasmussen MD, Jain S, Slagle J, Ordonez N, Kuykendall T, and Weinger MB: A Brief Survey Instrument Captures Significantly More Anesthetic Patient Safety Events Than Does Traditional Event Reporting. *Anesthesiology. (Submitted) This paper will be the first comprehensive summary of the results of our prospective non-routine event study and, in addition to methodological insights, will provide NRE demographics, etiological factors, and outcome.*

Planned Publications

1. Weinger MB, Slagle J, Cao C, Ou J, Vora S, Sheh B, Herndon OW, Thomas R, Mazzei W, and Kobus DA: Effects of fatigue on anesthesiologists' task patterns, mood, and workload. *This study identifies some of the benefits and limitations inherent in naturalistic research and provides evidence of changes in task patterns, mood, and workload that occur in anesthesia residents due to nighttime fatigue.* Anticipated date of manuscript completion: Winter 2006.

2. Weinger MB and Slagle J: Reading in the operating room: Impact on vigilance, workload, and task distribution. *After behavioral task analysis and workload assessment were conducted to measure the effects of reading on vigilance, workload, and task distribution, the results demonstrated that subjects read selectively during low workload periods and when they did read,*

their vigilance was not significantly impaired. Anticipated date of manuscript completion: Spring 2006.

3. Weinger MB, Slagle J, Rasmussen MD, Ordonez N, and Jain S: Analysis of videotaped anesthesia events. *This paper will be the first comprehensive summary of the results of our prospective non-routine event study and, in addition to methodological insights, will provide NRE demographics, etiological factors, and outcome.* Anticipated date of manuscript completion: Spring 2006.

Peer-Reviewed Abstracts

1. Weinger MB, and Slagle JM: Task and workload analysis of the clinical performance of anesthesia residents with different levels of experience. *Anesthesiology* 2001; 95: A1145. *These preliminary results, based on task and workload analysis of anesthesia residents' clinical performance during routine general anesthesia cases over the course of their training, support the hypothesis that, as clinicians gain experience, they can more efficiently accomplish critical clinical tasks and avoid distraction while maintaining low workload and "spare capacity" to respond to new task demands.*

2. Weinger MB, Slagle JM, Kim R, Hughes S, and Gonzales DC: A task analysis of anesthesia residents' initial clinical training. *Anesthesiology* 2001; 95: A1146. *During the first few weeks of anesthesia residency training, new trainees initially focus on manual task performance and neglect other tasks while the supervising anesthesiologist compensates by performing many of these essential cognitive tasks while simultaneously teaching. The data support a cognitive apprenticeship model of new specialist physician training.*

3. Weinger MB, Larson JW, Slagle JM, and Gonzales DC: Elicitation of expert knowledge about the post-anesthesia extubation decision. *Anesthesiology* 2001; 95: A1187. *This paper describes our initial efforts to use cognitive task analysis techniques to better understand how clinicians make complex medical decisions.*

4. Ou JC, Weinger MB, Vora S, Mazzei WJ, and Slagle JM: Further evaluation of the effects of nighttime work on mood, task patterns, and workload during anesthesia care. *Anesthesiology* 2001; 95: A1196. *This abstract provided preliminary results of the paper described in Planned Publication #1.*

5. Weinger MB, Reddy S, Slagle J: Clinical workload during teaching and non-teaching cases. *Anesth. Analg.* 2002; 94: S136. *This abstract provided preliminary results of the paper described in Publication #11.*

6. Wong DH, Gallegos Y, Weinger M, Clack S, Slagle J, Hughes S, Anderson CT: Changes in ICU nursing activities after installation of a computer-based ICU information system. *Anesth. Analg.* 2002; 95 (2S): A74, S133. *This abstract provided preliminary results of the paper described in Publication #7.*

7. Weinger MB, Barker E, and Slagle J: The effect of reading on the vigilance, clinical workload, and task distribution of anesthesia providers. *Anesth. Analg.* 2003; 96 (2S): A99. *This abstract provided preliminary results of the paper described in Planned Publication #2. It won a* ***"Best of Meeting" Award*** *for scientific presentation at the International Anesthesia Research Society 76th Congress, March 2003.*

8. Weinger MB, Gonzales DC, Slagle J, Syeed M: Videotaping of anesthesia non-routine events. *Anesth. Analg.* 2003; 97 (2S): A66, S20. *This abstract provided preliminary results of the paper described in Publication #10.*

9. Connor O, Cooke NJ, Slagle J, and Weinger MB: Pilot study of the measurement of context-dependent concept relatedness to assess anesthesiologist expertise. *Anesth. Analg.* 2004; 98 (5S): A7, 2004. *This abstract provided preliminary results of the paper described in Publication #12.*

10. Weinger MB, Slagle J, Ordonez N, and Jain N: Preliminary analysis of videotaped anesthesia events. *Anesth. Analg.* 2004; 98 (2S): S58. *This abstract provided preliminary results of the paper described in Planned Publications #2 and 3. It won a* ***"Best of Meeting" Award*** *for scientific presentation at the International Anesthesia Research Society 77th Congress, March 2004.*

11. Lui PW, Liu FC, Li HL, Tso AS, Tsang CH, Yu CC, Lin KT, and Weinger MB: A continuous quality improvement program reduced perioperative adverse outcomes in a large hospital in Taiwan. *Anesthesiology* 2004; 101: A1278.

Other Products

As we have discussed above, over the past 3 years, this project has involved a substantial effort to develop technology, methods, and processes to facilitate the collection and analysis of audio and video recordings of clinician-patient encounters as well as other fine-grain clinical data. These tools and procedures have already been published (Publications #6 and 10) and disseminated widely – presentations to five government/regulatory entity sponsored conferences, 11 different academic society meetings, and 14 university- or health system-sponsored meetings across 17 different states and three foreign countries.

Perhaps one of the most important products of any research laboratory is the training of students who can become future health services research investigators or healthcare industry leaders who appreciate the importance of health services research. Although no federal funds provided direct training stipends, AHRQ support of this research created an environment in which a large number of undergraduate, graduate, and post-graduate students (listed below along with current position) could be trained in patient safety and health services research methods.

Students Trained during Project Period and Current Status

Mark Rasmussen, MD	Completed post-doctoral fellowship with us, now on tour of duty with US Navy
David Gonzales, MD	Completed post-doctoral fellowship, now working in the medical device industry
Nelda Ordonez, MD	Completed post-doctoral fellowship, now in medical device industry
Jason Slagle	Completed PhD, now Assistant Professor of Anesthesiology at Vanderbilt Univ.
Steven Suydam, JD	Completed medical school, now in anesthesiology residency
Debbie Fraind	Completed medical school, now in pediatrics residency

Jennie Ou	Completed medical school, now in pediatrics residency
John Larson, MD	Completed medical school, now in anesthesiology residency
Andrew Linn	Completed medical school, now in anesthesiology residency
Olina Connor	Current doctoral student at Arizona State University
Eva Barker	In industry
Robin Kim	In medical school
Peter Jensen	In medical school
Swapna Reddy	In medical school
Jessica Buckley	In law school
Bryant Sheh	In medical school
Amanda Lamond	In medical school
Linda Zhou	In medical school
Doreen Nguyen	Still in undergraduate school
Noah Pores	Completed B.S. degree and applying to graduate school

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