Introduction

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. In complex high-risk systems it is highly undesirable to wait for a serious accident to happen before analyzing a system’s safety attributes. Thus, non-medical domains such as nuclear power and aviation have employed human factors techniques to extract detailed information about system performance and risks to safety. We have adapted this approach to medicine, using anesthesia as the initial test bed.

The Anesthesia Work Domain

Anesthesiologists, like surgeons and emergency room physicians, work in a complex, rapidly changing, time-constrained and stressful work environ-
The anesthesia domain is in many ways similar to aircraft cockpits, air traffic control rooms, and combat information centers where effective performance demands expert knowledge, appropriate problem-solving strategies, and fine motor skills. The safe administration of anesthesia requires vigilance (e.g., detection of changes in patient condition), time-sharing among multiple tasks, and the ability to rapidly make decisions and take actions. The anesthesiologist views his/her task as managing a single highly interactive system composed of the patient, clinical equipment, surgeons, other operating room (OR) personnel, and the broader OR environment. Primary goals include protecting the patient from harm and facilitating surgery. Intraoperative anesthesia care is divided into induction, maintenance (when surgery occurs), and emergence.

Non-routine Events

We recently proposed a new construct, “non-routine events” (NRE), as a mechanism to more efficiently capture dysfunctional clinical system attributes or potentially dangerous conditions. 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. NRE represent disruptions in these smooth expert processes. NRE encompass a substantially larger class of events than adverse events, medical errors, or even “near misses.” Thus, the NRE concept is appreciably broader than that used in prior studies to assess clinical performance and medical error, for example, in realistic patient simulators. In fact, most NRE do not involve errors by the care provider, and few lead to patient injury. Therefore, 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 enhanced quality.

Workload and Vigilance

Increased workload may be associated with an increased incidence of adverse events. Workload is affected by cognitive, psychological, and physical factors. A major factor in the effect of additional tasks on performance appears to be what perceptual or cognitive resources are required for each new task and whether those resources are already taxed. Workload measures can be divided into psychological, procedural (i.e., task related), and physiological. Subjective workload has been successfully measured during anesthesia by trained observers and by the clinicians themselves. For example, in one study, novice anesthesia residents reported higher subjective workload than did experts for equivalent task loads. Procedural techniques use alterations in primary and/or secondary task performance as an indirect measure of workload. Simple secondary task probes have been used in the OR to demonstrate increased anesthesiologist workload during induction and emergence, and during emergency surgery. We have developed a novel, near continuous, workload measure, workload density, that is based upon the clinical tasks actually being performed.

Vigilance is a subset of situational awareness and depends on alertness, attention, and diagnostic skills. Vigilance can be adversely affected by many factors including experience, attitude and motivation, task complexity, workload, and faulty equipment or system design. Anesthesiologists’ vigilance to alarm cues and to changes in clinical variables have been studied in both the laboratory and the OR. We showed that novices were slower than experts to detect the illumination of an alarm light placed adjacent to the monitors. Response rate was further impaired during high workload.

Task Analysis and Workload Assessment

Different analysis techniques may elucidate different attributes of domain performance and provider skills and knowledge. Workload assessment and situational awareness probes provide information about how task performance affects personal resources and capabilities. Task analysis methods involve the structured decomposition of work activities and/or decisions and the classification of these activities as a series of tasks, processes, or classes. Behavioral task analysis can define what tasks people actually do under real-life conditions. These techniques have been used to study clinical workflow in the OR, ICU, ER, pharmacy, and of ward nurses and radiologists. We have further refined these techniques, developing a computer-facilitated method to study the effects of performance-shaping factors on anesthesia task characteristics.
complex task,\textsuperscript{13,15} and methods for structuring and presenting this information in a usable format.\textsuperscript{13,16} Knowledge structures obtained with CTA correlate highly with problem solving and other measures of skilled performance.\textsuperscript{17}

Recent Findings

A variety of human factors techniques have been modified and refined to reliably and accurately record clinical behavior and workload, and to assess contextual factors that may impinge on clinical performance or contribute to non-routine events in anesthesia practice. We previously reported on the adverse impact of clinical experience,\textsuperscript{8} the introduction of complex new technologies,\textsuperscript{7} and the effects of fatigue on anesthesia provider performance in both actual and in realistically simulated\textsuperscript{18} cases. The results of more recent work are described below. For this research, we developed custom software that enables real-time data collection and efficient off-line data processing and analysis.

A Behavioral Task Analysis Focused on Anesthetists' Drug and Fluid Administration Tasks

Intravenous drug and fluid administration plays a critical role in anesthesia care yet the techniques used are dated and appear time consuming. After IRB approval and written informed consent, an observer sat in the OR and, using a portable computer and custom software, categorized in real-time clinicians' activities into 68 tasks (n = 20 routine and n = 8 cardiac cases). Inefficient/unsuccessful actions and user errors were specifically noted. Drug/fluid tasks, such as obtaining and filling syringes, consumed ~45\% of the initial set-up time at the start of a typical workday. Drug/fluid tasks comprised 20±6\% of induction, 15±8\% of maintenance, and 12±7\% of emergence during routine cases. During cardiac cases, drug/fluid tasks approached 30\% of the total clinical activities. Observed events that could be categorized as NRE (or could initiate a NRE) included, for example: Difficulties finding anesthesia supplies; Providers bumping into or tripping over IV poles or lines; Malfunctioning infusion pumps; and Blood leaking from IV's (e.g., tubing disconnection or stopcock turned the wrong direction). The results of this study suggest that many anesthesia drug/fluid tasks are inefficient, do not directly contribute to patient well being, and may promote medical error. A number of alternative strategies were identified to improve the safety and efficiency of intraoperative IV drug and fluid therapy. Additionally, these results demonstrate the ability of trained observers to detect abnormal, error-inducing, and inefficient events during real-time structured clinical observation.

Evaluation of Different Clinical Workload Measures

Because workload is a multidimensional construct, different measures of clinical workload may reveal different aspects of clinical care. We sought to assess anesthesiologists’ workload during actual patient care with several concurrent psychological, physiological, and procedural measures. Sixteen similar elective cases were studied. Prior to the start of each case, the anesthesia provider was attached to a 5-lead, two-channel Holter monitor. Behavioral task analysis and workload assessment was conducted as described previously.\textsuperscript{7-8} At 1- and 5-min intervals throughout each case, workload density was calculated by multiplying the duration of each task actually performed in that interval by that task’s workload factor score (determined from an earlier survey). Dedicated software calculated heart rate (HR) and HR variability every minute during each case. Case data were segregated into induction (I), maintenance (M), and emergence (E). To facilitate aggregation of data from cases of differing duration, defined time points were identified within each case segment based upon the time of intubation and extubation. HR and workload density were analyzed with one-way repeated ANOVA. Subjective workload was analyzed with Mann-Whitney U tests. Pairwise or Spearman Rank correlations were conducted between the measures.

Observer reported workload was greater during I and E (12±1 and 12±2) than during M (8±1, p < 0.001). Provider-reported workload was similarly greater during I and E (12±1 and 11±2) than during M (8±1, p<0.001). Observer and provider-reported workload values correlated highly (R = 0.68; p<0.005). 5 min mean and maximum HR were highest during I (87±9 and 108±11 bpm), falling significantly thereafter to a nadir in M (77±9 and 92±12; p < 0.05). Heart rate increased slightly during E. There was a weak correlation between psychological and physiological workload (highest R = 0.52). Workload density varied significantly during each case.

Both psychological (subjective ratings) and physiological workload data confirm that anesthesia workload is highest during induction and emergence. In contrast to previous work, workload density did not
show the same trend, perhaps due to high levels of teaching (a high workload task) during the maintenance phase of many of the cases studied. The weak correlation between the different measures of workload supports the initial hypothesis.

Cognitive Task Analysis Effectively Elicits Knowledge about Clinical Decision Making

Cognitive Task Analysis (CTA) interviews were conducted with 8 expert anesthesiologists to elicit their knowledge and decision processes regarding a specific clinical decision; whether or not to extubate (i.e., remove the breathing tube) a patient at the end of a general anesthetic. The first structured interview began by asking the clinician to describe a specific notable or difficult clinical decision. After the details of this case were delineated, the primary factors that influenced the decision were elicited. These initial factors were explored with structured cognitive probes (e.g., “Why/How did that factor affect your decision?”). Thereafter, secondary or contributory factors were similarly probed. Hypotheticals were used to broaden the scope of inquiry beyond the specific base case. The interview was recorded, transcribed, and decomposed sentence-by-sentence. Each sentence was then analyzed for concepts and their relationships (links) to other concepts. The concepts and links were graphically ordered using Inspiration® software. The concept maps thus illustrated both the content and structure of expert knowledge as it pertained to the extubation decision. In a follow-up interview, the clinician was asked to correct, comment, and elaborate on their map. The 8 concept maps were then combined into a single map. Predefined rules were applied to eliminate redundancies and discern essential relationships.

The resulting comprehensive cognitive map illuminated the finding that the post-anesthesia extubation decision depends almost exclusively on four key fundamental factors: 1) the patient’s current ability to ventilate and oxygenate; 2) the expected ability to mask ventilate the patient if extubation fails; 3) the expected ability to reintubate the patient if extubation fails; and 4) the implications to the patient and providers if extubation fails (i.e., greater risk of patient injury due to pre-existing disease). Psychosocial issues (e.g., surgeon preferences, postoperative disposition, etc.) play a significant role in this clinical decision. Preliminary CTA interviews of less expert clinicians suggest that this approach will elucidate how the nature and quality of knowledge structure, decision processes, factor prioritization, and critical threshold values differ with level of clinical experience.

Near Real-time Detection of Non-routine Events in the Post-anesthesia Care Unit

Pilot data demonstrates the feasibility of obtaining initial reports of intraoperative NRE immediately after their occurrence. A trained assistant spent four 6-hr shifts in the post-anesthesia care unit (PACU) and briefly interviewed anesthesia providers after they signed their patients out to the PACU nurse. A standardized data collection form was used to ascertain whether an NRE occurred in the just-completed cases. This screening technique rarely took more than 5 min. Thirty-nine out of 129 cases had at least one NRE (see Table 1), an incidence per case of 30%. Seven cases had more than one NRE. A preliminary analysis of the first 51 cases identified a number of etiological factors: 1) equipment failure or usability problems (in 5 cases); 2) team coordination or communication (4 cases); 3) deficient drug therapy (3); 4) patient disease/clinical issues (3); 5) surgical issues

Table 1

Sample Non-routine Events (NRE) Elicited from Clinicians in the Post-Anesthesia Care Unit

<table>
<thead>
<tr>
<th>Procedure: Non-Routine Event(s)</th>
<th>Brief Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Knee arthroscopy: Surgeon took 3 times longer than expected and prolonged tourniquet time adversely affected the patient’s blood pressure.</td>
<td></td>
</tr>
<tr>
<td>2) Allograft neck/face burn: Unable to monitor ventilation during case because expired gas monitoring line inadvertently clamped in the surgical drapes.</td>
<td></td>
</tr>
<tr>
<td>3) Parotidectomy: Patient movement during surgery despite perceived adequate depth of anesthesia. No muscle relaxant administered at surgeon request.</td>
<td></td>
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<tr>
<td>4) Repair distal tibia fracture: a) Patient moved during laryngoscopy. Provider admitted he was unfamiliar with muscle relaxant used and waited insufficient time prior to laryngoscopy; b) Failure of anesthetic agent analyzer requiring its intraoperative replacement.</td>
<td></td>
</tr>
<tr>
<td>5) Laparoscopic cholecystectomy: Slow to detect obese patient slipping off OR bed because patient’s body was largely obscured by surgical drapes in a darkened room.</td>
<td></td>
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<tr>
<td>6) Repair mandible fracture: Patient was induced with general anesthesia and was difficult intubation but surgeons unavailable for &gt;1 hr. Previous 2-hr delay of case start led surgeons to leave hospital without notifying anyone.</td>
<td></td>
</tr>
<tr>
<td>7) Tonsillectomy: Unanticipated difficult pediatric airway and failed intubation—multiple attempts associated with substantial coughing and laryngospasm. Attending not immediately available.</td>
<td></td>
</tr>
</tbody>
</table>
Table 2

Comparison of a Routine vs. Non-routine Endotracheal Tube Insertion

<p>| Raw task data during routine intubation (D&amp;C) | Raw task data from case with NRE during intubation (D&amp;C)—failed intubation |</p>
<table>
<thead>
<tr>
<th>Clock Time</th>
<th>Time from 0</th>
<th>Length (sec)</th>
<th>Task performed</th>
<th>Clock Time</th>
<th>Time from 0</th>
<th>Length (sec)</th>
<th>Task performed</th>
</tr>
</thead>
<tbody>
<tr>
<td>7:29:29</td>
<td>5</td>
<td>Position patient</td>
<td>7:29:53</td>
<td>3</td>
<td>*Attending conversation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7:29:34</td>
<td>121</td>
<td>Laryngoscopy</td>
<td>7:29:56</td>
<td>8</td>
<td>Secure/ manip. airway</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7:29:42</td>
<td>129</td>
<td>Intubation</td>
<td>7:30:04</td>
<td>7</td>
<td>Bag ventilation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7:29:52</td>
<td>139</td>
<td>Secure/ manip. airway</td>
<td>9:44:00</td>
<td>174</td>
<td>Observe airway</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7:29:53</td>
<td>140</td>
<td>*Attending conversation</td>
<td>9:44:02</td>
<td>176</td>
<td>Laryngoscopy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7:29:56</td>
<td>143</td>
<td>Secure/ manip. airway</td>
<td>9:44:11</td>
<td>185</td>
<td>Intubation (esophageal)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7:30:04</td>
<td>151</td>
<td>Bag ventilation</td>
<td>9:44:27</td>
<td>201</td>
<td>Manip. airway (extubation)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7:29:53</td>
<td>140</td>
<td>*Attending conversation</td>
<td>9:44:34</td>
<td>208</td>
<td>Bag ventilation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7:29:56</td>
<td>143</td>
<td>Secure/ manip. airway</td>
<td>9:45:02</td>
<td>236</td>
<td>Laryngoscopy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7:30:04</td>
<td>151</td>
<td>Bag ventilation</td>
<td>9:45:11</td>
<td>245</td>
<td>Intubation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7:30:04</td>
<td>151</td>
<td>Bag ventilation</td>
<td>9:45:41</td>
<td>275</td>
<td>Bag ventilation</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Performed concurrently with preceding task—the total Secure Airway task time was 12 sec.

(2); 6) patient positioning (2); and 7) logistical or system issues (2). In 4 of 51 cases, human errors could be readily identified in retrospect (including one self-admitted dosing error). There was patient impact in 7 of the 15 NRE (47%) although no permanent injury. These pilot data show that providers will reliably report NRE immediately after case completion and the incidence of NRE is high.

Prospective Detection of a Non-routine Event; Effects on Workload Density

The potential value of prospective data collection is demonstrated by an OR case in which a NRE occurred during anesthetic induction. In this case, a first-year resident was inducing general anesthesia for a healthy young female undergoing a dilation and curettage (D&C). During laryngoscopy, the light of the laryngoscope failed and, with the resulting inadequate view, the resident inserted the endotracheal tube (ETT) into the esophagus. The resident fortunately realized his mistake, removed the ETT, and performed controlled ventilation via mask (“bag ventilation”). The expert who reviewed the videotape felt that the resident’s actions were disorganized (suggestive of increased workload). The resident then repeated laryngoscopy and inserted the ETT correctly into the trachea. Although the entire NRE lasted <2 min, and there were no adverse effects, a number of contributory factors were identified (i.e., equipment, experience, supervision, and communication). This case was compared with a routine induction performed by another junior resident that was otherwise virtually identical in terms of patient, surgical, and anesthesia characteristics. The initial airway management task sequences are compared in Table 2. Workload density during induction, calculated with custom software, is shown in Figure 1. This type of matched-case comparison, which can delineate specifically how NRE-containing cases differ from routine cases may be a valuable tool.

Summary and Conclusions

Studies conducted over the past decade in our laboratory and by others (e.g.,) demonstrate the potential value of applying human factors techniques to the study of patient safety. The present work extends this foundation and begins to explore the use of a non-routine event (NRE) construct that permits study underlying system processes without the negative connotations of “medical error”. The apparently high incidence (>20%) of NRE makes prospective data collection a tenable strategy. Based on these results, we suggest that in-depth analysis of NRE will aid in the
generation of specific causal hypotheses and identify changes in clinical processes to improve safety and efficiency. Information technologies are essential to such safety research.

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