

Retrospective data collection and analytical techniques for patient safety studies[☆]

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Abstract

To enhance patient safety, data about actual clinical events must be collected and scrutinized. This paper has two purposes. First, it provides an overview of some of the methods available to collect and analyze *retrospective* data about medical errors, near misses, and other relevant patient safety events. Second, it introduces a methodological approach that focuses on non-routine events (NRE), defined as *all* events that deviate from optimal clinical care. In intermittent in-person surveys of anesthesia providers, 75 of 277 (27%) recently completed anesthetic cases contained a non-routine event (98 total NRE). Forty-six of the cases (17%) had patient impact while only 20 (7%) led to patient injury. In contrast, in the same hospitals over a two-year period, we collected event data on 135 cases identified with traditional quality improvement processes (event incidence of 0.7–2.7%). In these quality improvement cases, 120 (89%) had patient impact and 74 (55%) led to patient injury. Preliminary analyses not only illustrate some of the analytical methods applicable to safety data but also provide 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.

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1. Introduction

Unfortunately, much too often everyday clinical practice deviates undesirably from “best practice” or what is considered optimal clinical care. Patient safety has been defined as “freedom from accidental injury” [1]. In the last few years, patient safety has become a major public health issue and substantial resources have been dedicated to the problem. To reduce medical errors and enhance safety, rigorous methods must be applied to the study of everyday clinical care and the undesirable

events that occur. As has been described in detail elsewhere [1–3], because a lack of patient safety is a “systemic disease,” research must focus on care processes. Thus, traditional empirical research methods that use hard patient outcome variables (e.g., deaths) may be limited in scope or applicability when addressing many patient safety problems.

A variety of techniques are required to identify potential risk factors that can lead to patient injury and to then develop specific safety interventions to prevent them. For example, when evaluating the risks associated with the design of medical devices or difficulties with the use of software interfaces, techniques from human factors engineering (also called ergonomics) may be particularly useful [4,5]. Laboratory experiments involving biomechanical models and simulations can provide insight into the interaction between medical devices, the health care provider's who use them, and the clinical

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environment(s) in which they are used. Human engineering techniques have been used previously to design and develop safe medical devices, systems, and environments [4–6]. On the other hand, alternative approaches involving empirical or exploratory methods may be more fruitful when the risk factors are less clearly defined or understood, such as delineating the relative contribution to flawed processes of care of the myriad factors related to patient attributes and disease processes, clinician providers (e.g., psychological and demographical factors), and the clinical care environment (including deficient teamwork or communication). In this situation, rigorous evidence is required to design and implement successful patient safety interventions that will have application beyond a single event, process, or system. Such evidence can be obtained via either prospective or retrospective approaches. Retrospective data collection, the focus of this paper, is particularly useful when investigating factors contributing to a rare event, such as a medical error leading to patient injury, since data may be collected from various sources, and is less expensive than prospective collection.

This paper provides a succinct overview of some of the methods available to collect and analyze *retrospective* data about medical errors, near misses, and other relevant patient safety events. Second, it introduces the concept of the “non-routine event” (NRE) in medicine, a relatively new methodological approach that captures data from *all* events that deviate from optimal clinical care. Preliminary data from the retrospective collection of these “non-routine events” in anesthesiology are then presented and help to demonstrate several analytical methods.

2. Patient safety data collection methods

2.1. General approaches to collecting patient safety data

A wide variety of methods can be used to detect clinical events of relevance to those seeking to enhance patient safety. Patient safety data collection methods differ in the purpose of the effort, the type of data collected (both dependent and independent variables that are measured), how those data are detected and recorded, and how the data are managed and archived for later analysis. Clinical data may be collected for local quality assurance or patient safety improvement projects, for use by public or private regional, national, or even international entities for a variety of purposes, or for research. The goals of the patient safety initiative or project will affect the choice and focus of data collection methods.

At the highest level, there is a continuum from individual clinical cases about which one may have exhaustive detailed event information to databases that

contain only limited data about millions of cases. Obviously, the analysis techniques will differ—individual cases may be most amenable to human factors or industrial engineering techniques (e.g., cognitive task analysis interviews, failure-modes-and-effects analysis) whereas statistical or data mining techniques are more appropriate for extracting relevant information from large datasets. Similarly, how the results can be interpreted will also differ, depending on the type of risk factors associated with the adverse event. A detailed analysis of a *single* case will have a good chance of yielding an accurate understanding of the causes of that event and local intervention strategies to mitigate future similar events. Information gleaned from a single case can be used to recognize previously unappreciated risk factors and to design safety interventions to prevent injury. However, the results from the analysis of a single case (or relatively few cases) will only generalize well if the risk factor or sequence of events leading to injury is consistent in its manifestation across multiple care processes, environments, or institutions. Thus, a case involving complex multifactorial errors, in which both system problems and situational dynamics (e.g., a series of miscommunications among healthcare personnel, teamwork problems, errors in judgment, etc.) contributed to injury are unlikely to generalize well, possibly even to future events in the same care site. In contrast, conclusions from statistical analysis of large datasets can yield more generalized findings about risks to patient safety, but these findings may be of quite limited validity or applicability to specific local care settings.

With regard to the dependent measure of interest, data collection methods may seek to investigate medical errors, adverse events, “sentinel events [7],” near misses, or other deviations in process or outcome of care (Table 1). Near misses (or “near hits”) are events that could have led, if not detected and corrected in a timely manner, to patient injury. The study of near misses to ascertain the likelihood of adverse events is based on probabilistic risk assessment (i.e., if enough near misses occur, some will inevitably lead to adverse outcomes) [8]. The taxonomy of medical errors is complex and there is currently no universally accepted categorization strategy [3,9,10]. An emphasis during data collection on human error is fraught with methodological difficulties and may actually harm patient safety efforts within a healthcare organization [2,6,11].

Many types of patient safety data are gathered using “reporting systems,” structured processes for healthcare professionals to identify events that occur to them or their colleagues. These data typically are reported to and collated by hospitals or other healthcare entities. The primary goal of any reporting system should be to feedback information to clinicians that will guide changes in care processes, as well to administrators and legislators who are involved in making systemic changes

Table 1
Patient safety data gathering methods

How data are obtained?	Self-report, direct observation, survey instrument, interview, others report (including patient), chart review, automated quality assurance report
What types of data are collected?	Errors, adverse events, near misses, non-routine events
Method of entering data?	Traditional paper forms (structured or free text), internet (including e-mail), other computer devices (PDA), telephone
Purpose of data collection?	Mandatory (local facility/state/federal), voluntary for quality improvement, research, or clinical evaluation

to enhance patient safety and quality of care. The structure of the reporting system must address issues of confidentiality, immunity, and anonymity. Anonymous systems are limited by the inability to interview the reporter or otherwise obtain additional information about the event. Reporting systems that are not confidential, or do not at least provide immunity, will discourage reporting of events where the clinician is concerned about his/her culpability. These issues have been discussed in detail elsewhere [12].

Reporting systems can be voluntary or mandatory. There is concern with voluntary systems that there will be insufficient impetus to report all events and that, in fact, the most egregious events will be underreported. However, mandatory reporting systems, often created by state [13] and federal [14] agencies, are more likely to be associated with punitive consequences, and tend to discourage the accurate reporting of non-discoverable serious events and their details.

Voluntary methods of obtaining data of relevance to patient safety include clinician-activated event reporting systems, organizational patient safety data gathering systems (i.e., traditional event-based quality improvement systems), independent observational methods, and post-hoc mining of large clinical databases (Table 2). The Australian Incident Monitoring System is a classic example of a voluntary and anonymous clinician-activated reporting system [15]. Data about a wide variety

of events are collected using report forms available in specific clinical locations. The structured reporting sheet contains the parameters of interest to elicit details about an event's contributing factors and any corrective actions taken. This information is then entered into a central computerized national database. This type of reporting system can also be "automated" through the use of electronic forms [16].

In fact, patient safety data are increasingly collected via electronic means. Email, the internet, laptop computers, and personal digital assistants (PDA) have all facilitated data collection of clinical events, particularly for voluntary reporting systems. Electronic devices allow point-of-care incident reporting and on-demand support in a blame-free environment, for example, in the chemotherapy incident reporting and improvement system [17]. This type of software allows users to create logbooks that contain case information with event outcomes that can be filtered, aggregated, and stored in a secure database for later analysis.

Organizational patient safety data gathering systems include traditional quality improvement processes (e.g., point-of-care reporting of *specific* events being evaluated organization-wide), risk management and peer review processes (e.g., Patient Care Review Committees, the clinical Morbidity and Mortality (M&M) conference proceedings), routine care assessment surveys, medical chart reviews, and some clinical surveillance systems

Table 2
Voluntary methods of reporting

Type of system	Examples
Clinical event reporting systems	<ul style="list-style-type: none"> • Electronic monitoring databases—Anesthesia information management systems • Information technology—The chemotherapy incident reporting and improvement system (CIRIS) • Incident reporting technique—Australian incident monitoring study
Organizational patient safety data gathering systems	<ul style="list-style-type: none"> • Traditional quality improvement including morbidity and mortality reporting • Routine care assessment surveys—The clinical surveillance diary • Medical event-reporting system for transfusion medicine—MERS-TM
Independent observation by researchers or other experienced individuals	<ul style="list-style-type: none"> • Direct observation • Task analysis
Post-hoc data mining of large databases	<ul style="list-style-type: none"> • Closed claims databases • Pharmacological databases (e.g., VA RADARx, USP MedMARx) • Medicare databases • Electronic medical records from multiple facilities

(e.g., infection control). With proper structure and leadership, these systems can provide valuable data for patient safety improvement efforts. This is particularly true if the systems are non-punitive, have a focus that extends beyond adverse events (e.g., near misses), and utilize electronic processes for data collection and analysis. If they are well integrated into routine institutional care processes, such systems will provide constant surveillance and triggering, for example, daily procedure-induced reporting of adverse events. These advantages can help to overcome underreporting inherent in voluntary reporting systems.

Because medical chart reviews are so costly, alternatives have been sought. The clinical surveillance diary (SD) is part of the progress notes of the electronic medical record and includes a list of adverse events with medical actions taken, drugs administered, time-trend parameters, and hospital course [18]. This yields a physician-driven description of causative factors, and is easy to update. However, there has apparently been resistance by medical staff to reveal adverse events using this approach.

Organizational patient safety data gathering systems can also be developed and supported by professional societies and voluntary regulatory entities. A good example of a professional society or association-based system is the Medical Event Reporting System for Transfusion Medicine (MERS-TM) [19]. MERS-TM includes multiple components that facilitate event detection (any person who discovers an event can complete a discovery form), description and classification, investigation, analysis, interpretation, and evaluation.

Many large clinical databases, supported by institutions, national organizations, private parties, and government entities, can be used to extract information about patient safety. These range from federal databases, for example, containing cause of death information of all deceased Medicare beneficiaries [20] to smaller richer databases, for example, “closed claims” databases that contain detailed information about malpractice cases that have been settled or adjudicated [21,22]. The ASA Closed Claims database has thousands of case files that contain copies of medical records, deposition summaries, expert reviews, and outcome reports. These collected data are checked for completeness and consistency and then undergo further expert analysis. Limitations of closed claims data are that the selection of cases is not random, the initial data collection is done by insurance companies for liability purposes rather than patient safety, it takes an average of 5 years after an event occurs before the case enters the database, and reviewers’ assessments of causality are affected by knowledge of case outcome [21,22].

The Veterans Administration’s RADARx [23], the Center for Disease Control’s (CDC) VAERS, and United States Pharmacopeia’s (USP) MedMARx are ex-

amples of large nationwide voluntary event reporting systems. Practitioners can enter event data on hardcopy forms, with computerized software, or via the internet. MedMARx is an anonymous confidential internet-based adverse drug event reporting system. Subscribing hospitals can access all of their own data and also obtain standardized reports that show their results compared to nationwide benchmarks. Similar systems are available for cardiopulmonary resuscitation, cardiac surgical outcomes, and other quality and safety outcome metrics.

2.2. Direct observation and interviews

Medical errors and events can be detected during direct observation of clinical care. Much can be learned about safety from traditional observational studies that use ethnographic and related qualitative techniques [24,25]. More quantitative human factors approaches also generate useful data but trade-off reduced analysis effort for the less-filtered richness of qualitative data. 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 clinicians actually do under real-life conditions [26]. Gilbreth [27] was the first to apply work measurement principles, developed by Taylor, to medicine. Gilbreth’s time-and-motion study showed that surgeons spent excessive time looking for the correct instruments as they selected them from a tray. These findings led to the current practice of the surgeon requesting instruments from a nurse, who places the instrument in the surgeon’s hand. More recently, similar techniques have been used to study clinical workflow, for example, in ICUs [28,29], emergency departments [30], pharmacies [31], and of anesthesiologists [32], radiologists [33], and nurses [28].

Data about clinical events can be obtained using a variety of formal interview techniques. In addition to details about the nature and course of events, these techniques may elicit information about the mental state and decision-making processes of the clinicians involved. While direct observation will provide insights into what clinicians *do* during actual (or simulated) patient care, in the absence of special human factors techniques (e.g., think aloud protocols, situation awareness probes, workload assessment), it will provide only limited understanding of *why* they are doing what they do. Thus, cognitive task analysis (CTA) techniques can be used to elucidate the essential cognitive processes that drive overt behavior [34]. CTA encompasses both methods to ascertain the knowledge and cognitive skills required to perform a complex task, and methods for structuring and presenting this information in a usable format [34,35]. The Critical Decision Method (CDM) [36] is a CTA technique that may be particularly well

sued to study events that occur in clinical environments, particularly those that involve stress, risk, and uncertainty (e.g., critical care unit, operating room, emergency department) [37].

2.3. Non-routine events

Although individual clinicians have often been blamed for lapses in patient safety, research has shown that the root causes of most adverse events are systemic factors such as dysfunctional organizational structure, inadequate training, faulty communication, or poorly designed medical device user interfaces [1,5,38]. Such system factors (also referred to as “latent errors”) represent failure conditions that may lie dormant in complex systems until activated by the rare coincidence of multiple triggering events [10]. In complex, tightly coupled systems that contain multiple, dynamic, interdependent processes (e.g., surgical care), minor events in certain combinations are most likely to activate these latent errors, causing an accident [39]. Scrutiny of even minor, unexpected events, may unveil underlying latent errors that could otherwise remain hidden until an accident occurred.

Many popular methods for studying patient safety, especially root cause and sentinel event analysis, may have only limited value at preventing future adverse events. Techniques that rely on identifying the causes of specific events that have already produced patient injury may be problematic for several reasons. First, preventable serious adverse events are relatively uncommon. Second, each adverse event is unique, invariably caused by multiple factors presenting in a complex highly interdependent way. It is extremely difficult and time-consuming to ascertain retrospectively the true root causes of a single adverse event. Having invested precious patient safety or QI resources to elucidate the putative “causes” of an event, it can be quite difficult to determine each cause’s relative contribution to event occurrence, much less whether strategies to mitigate any specific cause will prevent future events. In fact, targeted interventions based on retrospective analysis of a single event can inadvertently create new latent errors that ultimately precipitate unanticipated adverse outcomes. Thus, there is a need to investigate alternative data collection strategies that can yield generalizable data about care processes to identify potential causes of future preventable adverse events.

One such alternative approach may be to study what we call “non-routine events” (NRE). A NRE is defined as *any* event that is perceived by clinicians or skilled observers to deviate from ideal care for that specific patient in that specific clinical situation. Thus, NRE include but are not the same as “near misses.” Whereas near misses are events that seem to be, at the time, directly linked to possible patient injury, NRE do not

necessarily have a *clearly identifiable* injury path. However, *all* NRE can yield important information about unknown or underappreciated system flaws that, under other (future) circumstances, could produce unsafe conditions. The concept of the non-routine event (NRE) in medicine was inspired by efforts in other high-risk fields to achieve safety by identifying and analyzing in depth all deviations beyond expected or routine system function. Preliminary data suggested that anesthesia NRE occur in about 25% of all surgical cases in an academic medical center [37]. Similarly, Boelle et al. [40] reported a 24% incidence of “undesirable anesthetic events” in a more circumscribed quality improvement project. We hypothesized that a broader scope of patient safety data collection could yield more events thereby permitting a broad range of analytical methods to uncover evidence of dysfunctional clinical system attributes or potentially dangerous conditions missed by traditional data collection methods.

2.4. Preliminary evaluation of the non-routine event concept in anesthesiology

In a pilot project to evaluate the potential value of studying NRE, trained research assistants collected data on randomly selected days in the Post-Anesthesia Care Units (PACU) at the University of California San Diego Medical Center and the Veterans Affairs San Diego Medical Center. With Human Subjects Committee approval, a researcher briefly interviewed anesthesia providers after they had transferred their patients’ care to the PACU nurse or, if there was insufficient time, during the quiescent maintenance phase of the next case. A standardized data collection form (Appendix A) was used to ascertain whether a NRE occurred in the just-completed case and to obtain initial information about the event’s nature and possible etiology. This NRE identification technique rarely took more than 5 min to complete.

We also collected data about anesthesia care events from our two hospitals’ traditional peer-review or quality improvement systems. We obtained retrospective case data from one hospital’s departmental QI process where, after every anesthetic, the provider is supposed to fill out a hardcopy form that indicates if one or more specific clinical events occurred during the case. The data from these forms, along with the relevant medical records and dictated event summaries were abstracted. We also collected data about cases presented at the other hospital’s mandatory departmental morbidity and mortality (M&M) conferences.

Each case identified was assigned a randomly generated unique code number to assure anonymity and the data were then entered into a custom password-protected database, written in FileMaker Pro and residing on a central server. To ensure confidentiality, all names

and identifiable information of the care providers and patients, as well as specific dates, were stripped from all data records. At least two clinicians then independently reviewed the case information in the database and the medical records for that case (e.g., anesthesia record, preoperative summary sheet, QI reports, etc.). The database also contained available information about the patient [e.g., age, gender, and American Society of Anesthesiologists (ASA) physical status score], the anesthesia provider (e.g., age, years of experience), the anesthetic technique (e.g., primary type of anesthesia), and surgical care (e.g., type of surgery performed). In many cases, because of the retrospective nature of the event reports, desired data elements were missing. Clinician reviewers scored whether the event caused patient impact (had an effect on the patient physiologically or psychologically), was a “near miss” [12], or actually caused patient injury, and, if the latter, the severity of injury (using a standard scale developed for the ASA Closed Claims Study [22]). Specific causes of patient impact or injury were coded with a standardized structured taxonomy in which each possible outcome has a unique code number.¹ Reviewers also scored whether any of 19 “contributory factors” appeared to play a role in the occurrence of the event. The clinicians then discussed and reviewed the cases together and reached a consensus on each item scored. Unresolved differences of opinion were resolved by a third domain expert.

3. Analytical methods

3.1. General analytical approach to patient safety data

The first step in extracting information from data obtained by various data collection methods is to understand the different sources of bias and variability inherent in these techniques (this is discussed in more detail below). Two main types of data are collected in these systems: fixed patient, provider, and system attributes (for instance, demographical patient data) and contributory (perhaps preventable) risk factors. The next step in understanding safety data is to inspect the data qualitatively or descriptively. This stage could involve summary statistics (such as means, medians, and standard deviations), descriptive graphs (histograms, scatter plots), and a thorough analysis of unusual or influential observations. Since the incidence of patient injury is hopefully quite low, these catastrophic or unusual cases, often considered statistical outliers, should

be examined in great depth to understand the mechanism or sequence of events leading to patient injury.

The general analytical approach to patient safety data will depend upon the goals of the project and the hypotheses under investigation. In a hypothesis-driven retrospective patient safety study, an appropriate *case-control framework* can be designed to study the relationship between an adverse patient outcome and exposure to possible contributory factors. For hypothesis-driven, case-control studies, it is necessary to have contributory factors data collected on both patients that have experienced an adverse outcome (cases) and patients who have not (controls). Data collected from Quality Improvement (QI) or other peer review processes (including M&M conference proceedings) are not suitable for these types of studies, given that these cases are pre-selected - they reflect adverse patient events, serious near misses, or otherwise have unusual or special clinical circumstances. However, since QI data specifically address the causative factors leading to patient injury, they can be used to develop various hypotheses regarding the mechanisms or paths of injury.

Events leading to patient injury are considered to be multi-factorial in nature [10], which makes it difficult to specify a priori the factors that should be studied. Another approach that can be taken with patient safety data is an *exploratory analysis*, in which the multivariate relationship between contributory factors is determined via *data mining* techniques such as cluster analyses, classification and regression trees, and mixture models.

3.2. Engineering analysis methods

A variety of engineering techniques can facilitate efforts to improve the safety and efficiency of clinical care. Methods from industrial engineering such as risk analysis and quality control have been employed productively for safety in a wide range of domains [8,41]. For example, Xerox reduced the percentage of defective parts by a factor of 30 through use of quality control. Human factors engineering techniques, including heuristic analysis, expert reviews, behavioral and cognitive task analysis, clinical simulation, think aloud protocols, situation awareness probing, and workload assessment, have been used in the design, evaluation, and modification of medical devices and clinical processes [4,42,43]. Cognitive work analyses, in which system functions are decomposed, abstracted, and prioritized, can help to understand events and processes, identify system requirements, ascertain proper allocation of people and equipment, or facilitate the design of information or decision support systems [4,44,45].

Quality control techniques can be applied to aggregated data or to individual events. The application to aggregate data is well described in the clinical quality control (often termed quality or performance

¹ This adverse event taxonomy was developed in collaboration with anesthesiologists at the Chang-Gung Memorial Hospital, Taoyuan, Taiwan, Republic of China. A copy is available upon request from the authors.

improvement) literature and, in recent years, has been extended to patient safety specific issues [46,47]. For individual clinical events, safety engineering and risk management methods like fault tree analysis (FTA) and failure modes, effects and criticality analysis (FMECA) identify the consequence of failures and the probability of such failures. By combining the severity of a failure with the probability of the underlying causes, it is possible to identify critical aspects of the system, and where safety interventions may have the greatest benefit. FTA is a top-down approach that uses domain and system analysis expertise to ascertain possible scenarios that can have system level consequences. For each negative system level outcome, the experts attempt to identify all possible scenarios that can lead to these negative outcomes. Alternatively, FMECA is a bottom-up approach that begins by analyzing the consequence of failures at the individual component level, and can potentially identify failure modes overlooked in a top-down approach. The two approaches are complementary and their use minimizes possible oversights in either approach. The validity of a safety engineering analysis depends on the generation of a model that accurately describes the relationship between individual failures and overall consequence at the system level, and on the availability of accurate data regarding the probability of individual failure events.

3.3. Specific methods to analyze our retrospective anesthesia safety data

In our studies, the key variable of interest is the occurrence of a NRE. In the PACU surveys, cases (occurrence of NRE) could be distinguished from controls (no NRE). The case-selection bias with the PACU survey technique is minimal although data collection occurred only during regular daytime shifts so nighttime cases were excluded. In contrast, the other source of retrospective data (QI and M&M reports) presents a strong selection bias, since they primarily represent cases in which an adverse patient outcome either did or could have occurred (i.e., by definition, a NRE). After identifying the cohort, exposure to various potential contributory factors was examined. As a quality control measure, the data were initially examined with univariate techniques to identify unusual or influential observations, and case data from outliers were reexamined. Additionally, data from the two sources were analyzed separately to provide a rough indication of reporting bias.

A list of potential contributory factors was generated based on experience, a review of the patient safety literature, and analysis of pilot data. A different list may be generated for other clinical domains. The role of these putative contributory factors were then assessed by two domain experts in each NRE case in the data-

base. To facilitate statistical model building, individual dichotomous contributory factors were combined into ten dichotomous composite variables as described in the legend of Table 4. Note that if any individual contributory factor in a group was coded as being present, then the entire composite category was coded as being present.

3.4. Statistical methods

A variety of statistical methods can be applied to patient safety data depending on its structure and the goals of the analysis. In our study, the response variable of interest was the occurrence or non-occurrence of a NRE, a dichotomous variable. Thus, a two-stage analysis was performed. The first stage was “variable-directed” [48], in which a relationship between the dependent variable, NRE occurrence, and independent (or predictor) variables was established. The second stage was “individual-directed” [48], in which relationships between individual cases and independent variables were investigated. For the first stage, univariate tests were conducted to determine associations between patient and provider attributes and NRE occurrence. Here, we considered five predictor variables: three patient attributes (age, gender, ASA status), level of anesthesia provider experience, and type of anesthetic administered. At this stage, the 10 composite contributory factors were not included in the modeling, since data on these factors cannot be collected for non-NRE cases. Also, only data obtained from the PACU surveys were considered, since the QI data did not contain routine cases. Categorical variables were tested via the χ^2 procedure. The only continuous variable, age, was discretized and then the χ^2 procedure was used.

These univariate tests were used to build a larger multivariate logistic regression model, which was then used to investigate our first research question; “which risk factors are associated with, or predict, the occurrence of an NRE?” Here, a p value less than 0.3 from the univariate tests was used as the inclusion criterion to enter the logistic model. Factors in the multivariate logistic model with a p value less than 0.05 were considered statistically significant. Logistic regression is a type of regression used when the dependent variable is dichotomous, while the independent variables can take either a categorical or continuous form [49]. In logistic regression, the dependent variable undergoes a logit transformation, such that the regression is based on the natural log of the odds of the dependent variable occurring.

In the second stage of the analysis, groups of similar individual cases were identified to address our second research question; “Are there specific combinations of risk factors that produce certain types of NRE?” Data from the PACU surveys and QI reports were considered

separately. Cochran's Q test was used to test the hypothesis that the probability of each factor contributing to a NRE is not the same across all ten factors [50].

Finally, an exploratory hierarchical clustering approach [51] for dichotomous variables was applied to isolate combinations of the ten contributory factors that contribute to specific NRE. The objective of clustering is to partition a set of data into groups such that the observations in a single group are similar to one another, while observations in different groups are as different as possible. A "similarity" measure is the key to determining how the clusters are formed. Similarity or dissimilarity between observations is expressed in terms of a distance measure $d(x,y)$, where x and y are individual observations. The type of distance measure selected will depend on the type of data (i.e., categorical, ordinal, ratio, or continuous) under consideration. In our study, the observations were the individual NRE cases, and the clustering was based on the 10 composite contributory factors. The 10 composite factors were considered to be *asymmetric* binary variables, since the two states (i.e., did or did not contribute to the NRE) for each variable were not equally important. An appropriate distance measure for non-invariant similarity utilized as the clustering criteria was the Jaccard distance measure [51]. Hierarchical clustering via the centroid method was performed, in which similarity of the clusters was determined by comparing the average values for the clusters. A dissimilarity value was calculated for each of these centroid computations, and the two clusters with the lowest dissimilarity score (i.e., the two most similar clusters) were merged in that iteration of the clustering algorithm. Data from cases allocated to the resulting clusters were then examined to address the third research question; "Does the type of NRE (as defined by the pattern of contributory factors) predict the severity of NRE outcome?"

3.5. Preliminary results for retrospective anesthesiology NRE

Thus far, data have been collected from 72 different anesthesia residents, certified registered nurse anesthetists (CRNA), and board-certified anesthesiologists. Although the interview process presented some logistical challenges (e.g., busy clinical schedules, the need for divided or follow-up interviews, etc.), the subjects were quite cooperative and only rarely turned down a request for event information. 277 cases were collected in the early post-operative period (usually in the PACU immediately after the case of interest) using the retrospective survey instrument. Seventy-five cases had at least one NRE—an incidence of 27%. Some cases had more than one NRE with an overall total of 98 NRE (net incidence 35%). Forty-six of the PACU-collected cases (17%) had patient impact while 20 (7%) led to patient injury.

Concurrently, we collected clinical events identified through our hospitals' traditional QI reporting systems. The incidence of events detected through this process is relatively low—in 2002, one hospital's comprehensive QI process captured 86 notable events out of 3200 cases (2.7%) while the other hospital's departmental M&M conference proceedings reported on 82 notable events out of 11,500 anesthetic cases (0.7%). All of these events were considered NRE.

Of 135 QI events analyzed to date from both hospitals, 120 (89%) had patient impact and 74 (55%) led to patient injury. Thus, the NRE collected randomly with our survey instrument were less likely to have a patient impact ($p < 0.001$) and much less likely to lead to patient injury ($p < 0.001$) than the events reported through these traditional QI reporting systems. Note that none of the NRE cases in the PACU data were duplicated in either of the two QI data sets.

For all 233 NRE cases collected retrospectively (i.e., both PACU and QI), there was a patient impact in 166 NRE (71%) with 94 of these events (40%) producing patient injury. One hundred and eleven of the NRE (48%) could be classified as "near misses."

A preliminary analysis of *all* of these retrospective NRE cases suggested several putative contributory factors (Table 3). The patient's preexisting disease and/or an unexpected physiological response played a role in over two-thirds of all retrospective NRE. In slightly over a third of NRE, issues related to provider supervision, knowledge, experience, or judgment (SKEJ) may have contributed to the event. In fact, 66 out of 167 NRE involving anesthesia residents were coded as having at least one putative SKEJ factor (39%) whereas only 10 of 53 cases (19%) involving experienced CRNA did ($p < 0.01$).

Contributory factors included surgical requirements (e.g., need for lights out to view monitors during laparoscopy led to delayed detection of patient malpositioning), surgeon action or inaction (e.g., a respiratory gas sampling line was inadvertently clamped by the surgeons precluding effective respiratory monitoring),

Table 3
Categorization of putative contributory factors in retrospective anesthesia non-routine events^a

Patient disease/unexpected response	156	67.0%
Provider supervision, knowledge, experience, or judgment	76	32.6%
Surgical issues	61	26.2%
Logistical or system issues	44	18.9%
Preoperative preparation	40	17.2%
Equipment failure or usability	36	15.5%
Coordination/communication	34	14.6%
Patient positioning	21	9.0%
Other	14	6.0%
Environmental factors/support staff	5	2.2%

^aTotal cases = 233. Note that each NRE generally has more than one contributory factor.

and logistical or system issues (e.g., fluoroscopy was not available when needed so that the case duration was longer than expected). Inadequate preoperative patient preparation contributed to quite a few NRE—for example, failure to appreciate the magnitude of patients' pre-existing disease, to order necessary laboratory exams in a timely manner, or to discuss key aspects of intraoperative management with the surgeons before inducing anesthesia (which was also coded as a communication factor).

There was a significant number of NRE involving clinical equipment. Although, as in previous studies [52,53], there was a relatively low incidence of outright equipment failure, problems with equipment usability [5], reliability, and availability commonly played a role in NRE. This issue merits a more detailed investigation.

We also noted a higher than expected incidence of NRE related to patient positioning. Although positioning *injuries* are recognized as a serious cause of surgical patient morbidity, hypotheses for etiology and proposed prevention strategies have been previously primarily based on retrospective database analysis [54,55]. These NRE data appear to provide complementary information that can guide both local process improvements and potential prospective studies.

3.6. Results of statistical modeling

There were insufficient data in this preliminary analysis to include all of the patient-related factors in the statistical models. Data for two factors, provider experience and type of primary anesthetic, could be included. Experience was a four-level categorical variable that includes inexperienced (CA1, CA2) and intermediate (CA3) residents, experienced (i.e., board-certified or eligible) physician providers, and Certified Registered Nurse Anesthetists (CRNA) with at least 5 years of clinical experience. The five types of anesthetics were general, spinal, epidural, regional block, and local. χ^2 tests of association, performed between each factor and the occurrence of a NRE, did not attain statistical significance (anesthesia type: p value = 0.29; clinician experience: p value = 0.125).

A multivariate analysis was performed to evaluate the role of each of the ten composite contributory factors in NRE occurrence. A 10-dimensional contingency table was constructed separately for the PACU and QI retrospective data and a Cochran's Q test was performed. Preliminary findings for both types of data were statistically significant (PACU: p value = 0.0001, n = 98; QI: p value = 0.0001, n = 135), suggesting that the probability of each factor contributing to a NRE is not the same across all 10 variables. This is consistent with the expectation that patient safety events are multifactorial in origin and putative contributory factors will be different across a cohort of non-selected cases.

A cluster analysis was then conducted to discern differences between the contributory factors and highlight dependencies, if any, amongst these factors. The PACU and QI data produced different clustering configurations. The PACU data were partitioned into six clusters, in which each cluster consisted of primarily one dominating factor (Table 4A). Provider and patient factors were the most prevalent in this preliminary analysis. There were no clear dependencies between the contributory factors, except that approximately half of the cases in both the surgical- and system-related clusters also had teamwork problems. This is consistent with other data suggesting the importance of provider–provider communication in team-based patient care [38]. As seen in the table, there were no obvious relationships between cluster and patient outcome (percent of cases with patient impact or injury severity). However, with the collection of additional cases, we believe this approach could yield valuable insights into the choice of patient safety interventions likely to have the greatest impact on patient outcomes. Unlike the PACU data, the QI cases produced only one major cluster and several smaller clusters (Table 4B). This is perhaps not surprising since patients with a history of pre-existing disease or those who have an unexpected physiological responses are more likely to have an unusual or adverse event leading to their capture through traditional departmental peer-review processes.

Because NRE vary in terms of severity (e.g., from delayed case starts to patient death), the range of NRE can be considered a continuum in which it is then difficult to specify a priori the number of possibly overlapping clusters. Thus, traditional hierarchical clustering techniques may not yield an optimal solution under these circumstances.

4. Discussion

4.1. Limitations of retrospective methods of data collection

There are inherent biases that affect both the reporting and investigation of adverse events, which also significantly limits their value for improving patient safety. For a number of reasons, only a small proportion of adverse events are ever reported [12], resulting in a potentially biased sample from which to draw conclusions. In addition, retrospective analysis of adverse events or near misses is often contaminated by cognitive biases (especially hindsight and attribution bias) [11,56] and influenced by the context and the perspective of event participants and analysts [57]. Importantly, the results of adverse event analysis are strongly influenced by knowledge of their outcome [21,58]. Because of these limitations, the most important causes of future adverse

Table 4
Results of Preliminary Cluster Analysis

Cluster No.	Equip	Surg	SEKJ	System	Team	Envir	Preop	Patient	Pt position	Other	Total Size	No. with Pt. Impact	NRE Severity ^a
<i>(A) Clusters discerned for PACU case data (n = 98)</i>													
1	1	3	0	0	0	0	3	24	3	0	24	17 (70.8%)	1.06 (0.19–1.92)
2	15	0	0	5	0	1	0	0	2	1	15	1 (6.7%)	0.00
3	1	2	30	1	4	0	2	17	3	1	30	16 (53.3%)	0.69 (0.20–1.17)
4	3	12	0	0	6	3	4	1	3	0	12	3 (25.0%)	1.33 (0.03–2.64)
5	0	4	1	16	9	0	3	1	0	1	16	8 (50.0%)	1.00 (0.55–1.45)
6	0	0	0	0	0	0	0	0	0	1	1	1 (100%)	2.00
<i>(B) Clusters discerned for QI case data (n = 135)</i>													
1	11	30	37	20	12	1	27	113	4	9	115	102 (88.7%)	2.71 (2.18–3.23)
2	0	0	6	0	0	0	0	0	2	1	6	6 (100%)	1.50 (0.0–3.16)
3	2	0	0	0	0	0	0	0	0	0	2	0 (0.0%)	0
4	3	10	2	2	3	0	1	0	3	0	11	11 (100%)	1.18 (0.40–1.97)
5	0	0	0	0	0	0	0	0	1	0	1	1 (100%)	2.00

Abbreviations: Equip, equipment failure or usability issues; Surg, surgeon action/inaction or surgical requirements; SEKJ, anesthesia provider supervision, experience, knowledge, or judgment; System, system/logistical factors or inadequate support or other staff action/inaction; Team, interpersonal communication or teamwork; Envir, environmental factors (e.g., noise, crowding); Preop, preoperative preparation of the patient or the anesthesia workspace; Patient, patient pre-existing disease or unexpected response; Pt position, intraoperative patient positioning. NRE, non-routine event (see text for definition).

^a Only cases with patient impact received severity scores (see text for details). Severity was scored on a 10-point scale (0–9) according to the system developed for use in the ASA Closed Claims Project [22].

events may remain invisible to those striving to improve safety.

Data integrity and quality issues often arise in the collection of retrospective event data. For example, in our study, the PACU survey data obtained from anesthesia providers might not have been accurate or there may have been a “recall bias” in the reporting of events that occurred. A serious consequence of recall bias is that a NRE could be overlooked, and this would inadvertently lead to classifying a potential NRE case as a control case instead. Another problem with (especially anonymous) survey data is that once a sample is collected it is frequently impossible to go back and obtain missing or additional sources of data. For example, patient demographical details were not collected in early PACU surveys; this problem has since been rectified.

4.2. Potential advantages of studying non-routine events

Non-routine events offer a number of advantages for patient safety research. First, these events encompass a substantially larger class of events than adverse events, medical errors, or even “near misses.” Because of their frequency, NRE represent a potentially rich data source to be “mined” to generate hypotheses about key factors and processes related to safety. This facilitates data collection permitting for example, the cost-effective conduct of in-person surveys (which enhances voluntary reporting) and prospective studies. Second, although labeling a given event as “non-routine” will not be free from bias, there may be less opportunity for biases to affect reporting or investigation, as most NRE will not be associated with any obvious error or patient injury. Third, NRE can be identified prospectively, as care is being delivered, either by provider report or observation, reducing the impact of bias due to knowledge of outcome. Finally, analysis of NRE may also be particularly helpful in delineating processes that could result in inefficient or unsafe care. Our pilot data identified many process inefficiencies as NRE triggers, including lost or missing paperwork or medical records, delayed surgeons, unavailability of equipment or personnel, and failure to perform standard preoperative procedures or obtain data. For example, in one case, the NRE was the cancellation of surgery after the patient was already anesthetized because surgical house staff failed to confirm that the attending surgeon was available, a process failure with both safety and efficiency implications.

4.3. Limitations of non-routine event analysis

The collection and analysis of NRE will not provide experimental evidence that any particular clinical process caused patient injury or that a proposed intervention will reduce medical errors or improve safety. Rather, in-depth analysis of actual care processes and

their associated NRE will be most useful for generating hypotheses about factors influencing system safety—policies, processes, and actions that affect the occurrence, propagation, or prevention of patient injury [32]. In many clinical circumstances, this may be sufficient to guide reengineering and other process improvement efforts that will have a tangible effect on patient safety. However, proof that any given factor plays either a positive or negative role in safety will necessitate experimental methods including controlled simulation and/or clinical trials.

It should be noted that in our study the events were analyzed and coded from the perspective of anesthesia care providers. Therefore, some events, for example, those in which surgical and/or positioning issues were coded as being contributory factors, may be seen differently from the perspective of surgeons or other operating room personnel.

To make the study of NRE a viable endeavor, several challenges must be met. Distinguishing non-routine from routine events is complicated by the fact that what is routine to one clinician may be exceptional to another. Even serious safety flaws might be considered “routine” by providers inured to their presence. Routine and non-routine must be carefully defined, either based on local practice and expectations, or using a sufficiently broad context to assure capture of a wide range of events and processes that could jeopardize patient safety. At the local level, multidisciplinary teams of practicing clinicians, quality improvement personnel, risk managers, and high-level administrators should participate in both study design and data analysis. Provider education about the non-routine event concept will be a critical element in the technique’s success. Additionally, even with these precautions, reliance on clinician event reporting may be less than fully successful for the reasons delineated earlier, unless *all* personnel involved in patient care (i.e., not just physicians, pharmacists, and nurses but medical technicians, orderlies, clerks, and janitors) have the opportunity to participate. Finally, prospective data collection by trained observers may be an important independent mechanism for event identification and verification of reporting incidence and accuracy. In the absence of prospective data collection, analysis of reported NRE could be influenced by some of the same biases affecting retrospective error or accident reporting systems. However, since most NRE do not involve patient injury and are often caused by factors unrelated to the competence or actions of the reporter, the risk of a biased account of these events appears less likely.

4.4. What about prospective data collection?

Prospective empirical studies of patient safety avoid many of the methodological pitfalls of retrospective

analyses but have their own limitations including cost and time constraints, the need for large numbers of subjects, and difficulty controlling, measuring, or accounting for the complex interdependent clinical and environmental factors likely to play a prominent role in patient safety [43]. Patient safety oriented prospective randomized controlled trials conducted in actual patient care settings have generally either examined a putative contributory factor (e.g., sleep deprivation/fatigue during on-call shifts [59]) or measured the impact of a potential intervention (e.g., reduced incidence of serious medication errors with the implementation of computerized physician order entry [60]). Preliminary results suggest that NRE can be collected prospectively through the videotaping of actual patient care. However, these resource-intensive studies of real-life clinician–patient encounters are dependent on knowing the cause of events, and are complicated by the base rate of medical events in the patient population of interest (which may be quite low, particularly for those producing serious adverse events) as well as the tremendous heterogeneity of patient and confounding factors. Human factors techniques can be applied prospectively, and may not suffer these same limitations. For example, events associated with the use of a medical device can be proactively reduced by the iterative evaluation in a laboratory of prototypes of the device’s user interface to discern potential sources of use error [4,5].

Simulation studies are a viable, but also resource-intensive, alternative to the study of actual patient care. A well-controlled reproducible simulated interaction between clinical care provider(s) and a patient (or another clinician) can be conducted using realistic patient or virtual reality simulators, or standardized patients. Realistic patient simulators are fully interactive physical simulations in which the patient mannequin responds to clinical interventions just as would a real patient [61,62]. Virtual reality simulators are computer-based multimedia devices that “immerse” the clinician in a clinically realistic computer-generated environment [63]. Standardized patients are professional actors trained to accurately and consistently provide a live, interactive simulation of an actual physician–patient encounter and who can be inserted into actual clinical practices to evaluate the quality or cost of care [64]. Such “standardized encounters” allow for the real-time study of many facets of medical care processes, and thus represent an important supplementary approach to understanding risks to patient safety or the potential efficacy of proposed safety interventions.

4.5. Extension of the NRE technique

It should be relatively straightforward to study NRE in acute care settings, including the operating room, labor and delivery suites, intensive care units, emergency

rooms, during medical procedures, and in emergency situations. Even if the technique was limited to these high-acuity domains, it would still be of significant value since a substantial proportion of all preventable adverse patient outcomes occur in these acute care domains [65]. How applicable the NRE approach will be to other, less acute (e.g., ambulatory) care settings remains to be determined.

Since the NRE technique represents a systematic approach to the study of complex processes, it could shed light on undesirable deviations or potential failures in various systems, components, or interactions that may have distributed, and sometimes unanticipated, effects on patient care. Finally, shifting the focus of patient safety initiatives to the collection and analysis of non-routine events (instead of only medical errors or adverse outcomes) within an institution may facilitate the desired inculcation of a safety culture.

This paper has provided a framework for, and outlined some of, the types of retrospective data collection and analysis methods that can be productively applied to patient safety research. In particular, the concept of the non-routine event has been introduced. Preliminary data suggest that NRE data can be successfully collected and analyzed, and that the resulting information can generate testable hypotheses about threats to, and opportunities for improving, the safety of clinical processes. Further research appears warranted to determine if identification of factors that contribute to the occurrence of, and recovery from, non-routine events will advance patient safety.

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Appendix A. Non-routine event probes²

Told to subject:

“We are beginning to study how unusual or non-routine occurrences might directly or indirectly affect anesthesia providers’ ability to detect, interpret, or treat

adverse events during anesthesia. Most of what we call “non-routine events” may seem trivial, but understanding what causes them and how they affect you will lead to a better appreciation of the essential attributes of safer anesthesia care. We would like to ask you some brief questions about the case you’ve just completed.”

1. Were there any deviations from ideal?
2. In what ways was the anesthetic less than optimal?
3. Did anything occur that was annoying?
4. Did anything occur that was distracting?
5. Did you make any unanticipated or unplanned actions or interventions?
6. Were any unusual requests or demands made on you?
7. Did anything occur that affected your workload?
8. Did anything occur that affected your vigilance?

Specific probes:

1. Did your tools and equipment perform as expected?
2. Was there anything distinctive about other peoples’ actions or interactions with you?
3. Did the patient do anything that was out-of-the-ordinary or notable?
4. Did the patient respond as expected to your treatment and interventions?

If YES to any of the above:

1. Please briefly describe the event.
2. What about the event made it stand-out?
3. What were your initial clues that something was atypical?
4. Why did it occur?
5. What were the precipitating factors?
6. How did you respond (if you did)?
7. What factors, issues, or other events influenced your response?
8. What was the result of your intervention?
9. Was there any temporary or permanent patient injury as a result of event?
10. What is your estimate of the percent likelihood that the event, if not managed correctly, could have led to patient injury?

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² Designed for use in anesthesiology.

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