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Human reliability analysis in healthcare: Application of the cognitive reliability and error analysis method (CREAM) in a hospital setting

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HUMAN RELIABILITY ANALYSIS IN HEALTHCARE: APPLICATION OF THE COGNITIVE RELIABILITY AND ERROR ANALYSIS METHOD (CREAM) IN A HOSPITAL SETTING

A Thesis

By

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Abstract

Patient safety is a concern within the healthcare domain as it is estimated that tens of thousands of people die annually from preventable medical errors. For over ten years, traditional Human Reliability Analysis (HRA) techniques (e.g., Root Cause Analysis and Failure Mode and Effect Analysis) have been used in hospitals nationwide in an attempt to explain why these errors occur and what can be done to prevent them. Still, patient safety has not improved significantly.

Traditional HRA techniques are limited as analysis tools. They do not consider the context in which workers operate. They are also not based on a valid psychological model that could explain human cognitive function. The Cognitive Reliability and Error Analysis Method (CREAM) is an HRA technique that allows analysts to examine worker actions through the context of performance-shaping factors. The CREAM also employs a cognitive model to explain cognitive failures.

This research used the CREAM to re-analyze events containing identifiable error modes that were previously analyzed by hospital team members using the RCA technique. The results of the re-analyses using the CREAM were compared with the previous analyses from RCA events. Additionally, several RCA events were observed and detailed written narratives of the observations were used to perform further independent analyses by three independent analysts in an effort to calculate inter-rater agreement. The results exposed a gap within categories of causal factors between the two techniques. The CREAM identified organizational factors as contributing to error in the events whereas those factors were either minimized or ignored in the RCA. The results also failed to demonstrate any significant inter-rater agreement among independent analysts performing the CREAM analyses. Due to serious data limitations, detailed analyses using the CREAM were not possible.

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Introduction

Human Error in Healthcare

Premise 1: *Human erroneous actions are a recognized problem in healthcare*. It is a well-documented fact in both academic and popular sources that healthcare delivery in the United States is subject to preventable medical errors (Carayon & Wood, 2009). It is sometimes hard to remember that behind every statistic is the story of a person who was injured as a result of a human erroneous action (or inaction). For example, Josie King, an 18-month old child, died as a result of severe dehydration and an inappropriate administration of narcotics while being treated for burns at Johns Hopkins hospital (Ayd, 2004). Another example (from a mass media source) was the heparin overdose of infants (including actor Dennis Quaids' twins and 17 infants in a neonatal intensive care unit in Texas) (CNN, 2008).

In the late 1990's, the Institute of Medicine (IOM) released results of studies about quality within the healthcare system (1999). They estimated that anywhere from 44,000 to 98,000 people (like Josie) die in hospitals each year due to preventable medical errors (IOM, 1999). The IOM defined a medical error as a "failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim" (IOM, 1999, p. 28).

At the same time these reports were published, Congress passed and President Clinton signed the Healthcare Research and Quality Act of 1999 which designated the U. S. Department of Health & Human Services Agency for Healthcare Research and Quality (AHRQ) as being the lead agency responsible for research efforts to reduce medical error (Clancy, 2009). As a result, medical errors and patient safety became the focus of much study across a variety of disciplines.

Instances of medical error have been given different labels. For example, the state Department of Health in New York State defines an "occurrence" as an "unintended adverse and undesirable development in an individual patient's condition occurring in a hospital" (Tuttle, Panzer, & Baird, 2002, p. 350). An occurrence is also a serious “adverse event” defined as “those which have a significant or lasting impact on patients, such as unexpected death or permanent impairment” (New York State Department of Health, n.d., p. 10). The Joint Commission (an independent, non-profit organization that provides accreditation and certification for many hospitals in the United States) uses the term “sentinel event” to define similar types of events (Joint Commission, 2009).

Types of adverse events have been categorized as diagnostic (e.g. failure to act on results of lab tests), treatment (e.g. performing the incorrect procedure), preventive (e.g. lack of follow-up), and other (e.g. equipment failure) (Leape, Lawthers, Brennan, & Johnson, 1993). Historically, efforts to explain and “recover” from these types of adverse events focused on “blame and train” in an effort to identify fault (Caldwell, 2008). However, especially after the IOM report, health care started to view adverse events as failures of the patient safety system. Longo, Hewett, Ge, and Schubert (2005) provided a definition for patient safety systems as “the various policies, procedures, technologies, services, and numerous interactions among them necessary for the proper functioning of hospital care. If implemented, these systems influence hospital environment, behavior, and actions; reduce the probability of error; and improve the probability of safety” (p. 2859). The IOM views errors as a result of imperfect systems that lead to mistakes (1999). Further, the IOM included viewing safety as a system property in its “Ten Rules for Redesign” of the health system. They advocated for an increased focus on systems that help to prevent errors in an effort to keep patients safe. (IOM, 2001).

Effect of Popular HRA Techniques

Premise 2: Despite the use of traditional HRA techniques to identify possible causes of error, the problem is not improving.

New York State. Even before the IOM reports in the late 1990's focused national attention to the problem of preventable medical errors, New York State was aware of and trying to measure adverse events through mandatory reporting requirements. New York State began requiring hospitals to report adverse events as early as 1985 and introduced an electronic statewide database in 1998 (Tuttle et al., 2002). The New York Patient Occurrence Reporting and Tracking System (NYPORTS) is the product of over 24 years of trying to track adverse events in healthcare. Reporting efforts in New York State began with Hospital Incident Reporting System (HIRS), evolved to Patient Event Tracking System (PETS), and is currently in operation as NYPORTS (New York State Department of Health, n.d.).

In a report ranging from 2005 to 2007, "serious occurrences" accounted for an average of 9% of all NYPORTS reports. When a hospital becomes aware of a serious occurrence, the New York State Department of Health (NYS DOH) requires a Root Cause Analysis (RCA) be performed by the hospital and submitted to the agency via NYPORTS. The RCA examines the various possible causes of failure that were precursors to the adverse event. Submitted with the RCA is a plan of action, which must be approved by the department, to mitigate the risk of similar events in the future (New York State Department of Health, n.d.).

An RCA is mandated for specific occurrence codes listed in the NYPORTS Clinical Definitions Manual including "unexpected adverse occurrence in circumstances other than those related to the natural course of illness, disease, or proper treatment (e.g., delay in treatment, diagnoses or an omission of care) in accordance with generally accepted medical standards" (p. 13). Examples of occurrences requiring an RCA (NYS DOH) include wrong patient, wrong site surgical procedure, incorrect procedure of treatment, unexpected death, malfunction of equipment, and certain types of medication error.

The 2005 – 2007 NYPORTS report from the NYS DOH admits that compliance (especially regional variation) is a problem impacting their ability to validate "completeness of reporting" and produce occurrence rates. As a way to estimate rates, they used data from the Statewide Planning and Research Cooperative System (SPARCS). According to the report, "SPARCS currently collects patient level detail on patient characteristics, diagnoses and treatments, services, and charges for every hospital discharge, ambulatory surgery patient and emergency department admission in New York State" (p. 9). SPARCS was previously used as a way to identify underreporting of a specific NYPORTS occurrence code (Tuttle et al., 2002). SPARCS is based on "billing discharge requirements with complete data on discharge disposition" (Tuttle, 2002, p. 351). According to the report, the Finger Lakes region reported the highest rates of occurrences per 100,000 inpatient discharges by year (2005-2007). Due to the previously noted regional variation in reporting compliance (with New York City hospitals with the lowest reporting rates), it is assumed that hospitals in the Finger Lakes region are reporting more occurrences due to compliance rather than as a result of decreased quality of care.

Joint Commission. As previously discussed, the Joint Commission is an independent, non-profit organization that provides accreditation and certification to many hospitals nationwide. Hospitals in New York State are not only required to conduct an RCA to be submitted to the NYS DOH for serious occurrences, but are encouraged to notify the Joint Commission of sentinel events. As part of the accreditation and certification process, the Joint Commission also requires hospitals to perform an RCA to investigate those events (Rex, Turnbell, Allen, Voorde, & Luther, 2000). The RCA is retrospective in nature and requires an event to investigate. The Joint Commission (but not the NYS DOH) requires each hospital to also conduct an annual prospective risk assessment on a high-risk process. Although a specific methodology is not prescribed, the Failure Mode and Effect Analysis (FMEA) is recommended (Marx & Slonim, 2003) and widely used.

Agency for Healthcare Research and Quality. Serious adverse events occur in 4% - 12% of hospital admissions (Rex et al., 2000). Despite the attention given to the matter, in a 2008 report the AHRQ concluded that although healthcare quality in the United States is improving at a slow pace, patient safety is not. (AHRQ, 2009). The director of the AHRQ summarized the reports' conclusion bluntly by saying "patient safety has actually been getting worse instead of better" (Clancy, 2009).

Limitations of Traditional HRA Techniques

Premise 3: *Traditional HRA techniques have critical limitations*. Human Reliability Analysis (HRA) has been defined as "the application of relevant information about human characteristics and behavior to the design of objects, facilities, and environments that people use" (Lyons, Woloshynowyeh, & Vincent, 2004, p. 224). Lyons et al. (2004) went on to state that the goal of HRA is ultimately to improve reliability and safety. The AHRQ as part of its quality goals has advocated for the inclusion of human factors and systems engineering principles in order to address the problems of adverse events within healthcare (Caldwell, 2008).

Although organizations like the Joint Commission require the use of HRA techniques (e.g. RCA and FMEA), in the 2005 – 2007 NYPORTS Report, the NYS DOH, while acknowledging some progress, stated "much remains to be done in identifying the causes of medical errors and developing practical solutions to reduce the risk of recurrence" (NYS DOH, n.d., p. 5). Longo et al. (2005) examined the status of hospital patient safety systems and found that quality systems improvements were slow and a variance existed between "best" and "actual".

It has been noted that healthcare is highly complex and has a high tolerance for uncertainty when compared to other "high-hazard" industries (Lyons et al., 2004). Factors that impact reliability in healthcare include increasing complexity of care, rapidly changing healthcare environment, and increased use of new technology (IOM, 2001). As Wachter (2004) illustrated, "A critically ill patient might be seen by half-dozen different physician-specialists and scores of nurses, respiratory therapists, pharmacists, social workers, clergy, and others, and receive hundreds of medications and tests" (para. 6). In fact, Donchin et al. (1995) found that on average, a patient being cared for in an intensive care unit faces 1.7 errors per day.

Caldwell (2008) reported that the "systems engineering model of information and resource flows, common to many engineering practitioners, was difficult to communicate to practitioners in other domains" (p. S191). Some systems engineering techniques (e.g. RCA) use a linear progression to discuss events in a retrospective analysis instead of discussing events as a result of dynamic processes interacting with one another. Caldwell (2008) described the difference in a metaphor comparing a "pinball" vs. a "pachinko" perspective. In pinball, the ball travels the path revealed by a sequence of decisions. When a causal factor is found, the pinball drops into the hole. In pachinko, several balls are in play at one time. They travel down the board and the outcome is reached by combining the results of all of the balls. It is clear that systems engineering has a wide variety of techniques to offer healthcare in its goal of identifying causes of medical error and mitigating those factors (Kirwan, 1998; Lyons et al, 2004; Lyons, 2009). It is also clear that despite years of mandatory application of traditional approaches (e.g. RCA and FMEA), hospitals can benefit from the application of alternative techniques to supplement existing efforts as well as how to improve the effectiveness of traditional approaches.

Hollnagel (1998) categorized HRA techniques as "first-generation" and "second-generation". He pointed out that many HRA techniques focus on a cause and a consequence in an event (or potential event) being scrutinized. He grouped these techniques into four categories: (1) one cause, one consequence (e.g. Root Cause Analysis), (2) one cause, many consequences (e.g. Failure Mode and Effect Analysis), (3) many causes, one consequence (e.g. Fault Tree Analysis), and (4) many causes, many consequences.

Although Hollnagel (1998) offered six points of criticism of first-generation HRA techniques, two points illustrated the chief difference between first-generation and second-generation techniques: (1) "less-than-adequate psychological realism" and (2) "less-than-adequate treatment of some important performance shaping factors (PSF's)" (p. 9). Hollnagel (1998) stated that "an action always takes place in a context, and the context is partly the outcome of preceding human activities" (p. 32). Basically, descriptions of events in terms of success or failure of actions (e.g. event-tree representations) are an oversimplification of human performance results.

Kirwan (1998) examined thirty-eight HRA techniques and categorized them into five categories: (1) taxonomic approaches, (2) psychology-based tools, (3) cognitive modeling (e.g. the CREAM), (4) cognitive simulations, and (5) reliability-oriented techniques (e.g. FMEA) (p. 160-164). Kirwan (1998) evaluated each of the HRA techniques according to preset criteria (e.g. likelihood of consistent results, validity base on theoretical models, etc.). Kirwan (1998) concluded "there is no single technique available at present which could be optimal on all the qualitative criteria" (p. 174). At the time, the CREAM was evaluated as "still being developed" in the criteria relating to availability (Kirwan, 1998, p. 171).

Root Cause Analysis. Root cause analysis (RCA) is a general term applied to a variety of methods which attempt to find a "root cause" for a particular event being analyzed. By definition, it is a retrospective analysis of a historical event. Root cause analysis has been used within the engineering domain to examine the causes of events reported to the Institute of Nuclear Power Operations (INPO) in the 1980's (Reason, 1990).

As a result of regulatory requirements relating to the mandatory reporting and investigation of adverse events (e.g. NYS DOH and Joint Commission), RCA has become a widely-used technique within healthcare. In an RCA, a team is selected to perform the analysis. Normally, an experienced facilitator leads the event with a scribe who records the activities of the team via the construction of an Ishikawa diagram. The facilitator ensures that the team stays focused on system properties instead of focusing on assigning blame to incident actors. The Ishikawa diagram is developed through either a process of asking "Why?" until no logical answer could be provided (Rex et al., 2000) or considering the event from actor perspectives (6 P's) (Weiss & Jayaram, 2009). The goal is to understand the various underlying "root" causes for actions leading to the incident. This allows for the development of specific action plans to mitigate the network of factors which gave rise to the incident.

Failure Mode and Effect Analysis. Failure Mode and Effect Analysis (FMEA) is a prospective analysis technique used to identify the effects of failures associated with individual failures for a system (Marx & Slonim, 2003). The FMEA provides users with information to rate risk in an effort to prioritize efforts to reduce the risk or redesign the system so the effect of a failure is reduced.

Traditional HRA techniques (like the RCA and the FMEA) are limited because they do not examine the influence of contextual factors which shape human reliability such as performance-shaping factors and cognitive functions as explained by a valid theoretical model. This may explain why, despite their use in healthcare, human erroneous actions leading to patient safety concerns are still a problem.

Cognitive Reliability and Error Analysis Method (CREAM)

Premise 4: *The Cognitive Reliability and Error Analysis Method (CREAM), not previously applied as an analysis tool within healthcare, addresses limitations of traditional HRA techniques.* Since the stated goal of HRA is to improve reliability and safety, the ultimate goal is to be able to predict human/system failures and be able to mitigate the factors contributing to those errors. In the absence of the ability to predict with accuracy, the ability to offer quantitative measurements (e.g. probabilities) to prioritize risks is beneficial. Within the healthcare domain, a second-generation technique might provide additional insight to achieve these goals when the application of first-generation techniques is still not providing the desired results.

The CREAM is a bi-directional HRA method created by Hollnagel (1998). It allows for the retrospective analysis of a historical event, but also a prospective analysis of a high-risk system or process. Unlike traditional HRA approaches which focus on the result binary actions, the CREAM attempts to examine the environmental context in which humans operate and evaluate actions within the framework of a psychological model (Kirwan, 1998). The CREAM integrates tools from other models (e.g. event-tree analysis) within its framework.

Hollnagel (1998) used a distinction between competence and control in the CREAM. Competence refers to what a person can do, while control refers to how competence is applied. Hollnagel (1998) categorized “control modes” as “scrambled, opportunistic, tactical, and strategic” (p.155-156). These control modes roughly correlate to the Skills-Rules-Knowledge (SRK) framework of Rasmussen (1983). Hollnagel categorized “competence” as “observation, interpretation, planning, and execution” (p. 155). They are combined to form the Contextual Control Model (COCOM) which is used as the cognitive model upon which the CREAM was constructed. In COCOM, there are no "predefined cause and effects", but rather human performance is seen as "an outcome of the controlled use of competence adapted to the requirements of the situation" (Hollnagel, 1998, p. 154).

Within the CREAM, Hollnagel distinguished between actions (phenotype) and possible causes (genotype). The possible causes were realized through the observation of system effects. He further separated genotypes into distal and proximal categories (indirect and direct, respectively). The CREAM categorizes genotypes according to the Man, Technology, and Organization (MTO) triad. The MTO triad represents individual factors (M), technological factors (T), and organizational factors (O) (Hollnagel, 1998).

The CREAM treats the relationship of phenotype and genotype as a network of links rather than as being linear or hierarchical in structure. The network is expressed in terms of consequent-antecedent links (Hollnagel, 1998). As previously stated, those links are not pre-defined. Instead, Hollnagel (1998) relied on a series of tables illustrating possible general and specific antecedents (causes) and general and specific consequents (effects). Analysis is completed from directing links between classification groups.

Since there is no obvious single "end" in a network structure, the CREAM employs a "stop-rule". If a consequent has no general antecedents (either through having a specific antecedent or not having any antecedents to consider), the analysis stops.

Qualitative Retrospective Event Analysis Using the CREAM. A retrospective analysis of an event using the CREAM begins with an analysis of the context in which a historical event occurred. Hollnagel (1998) used "Common Performance Conditions (CPCs)" to capture contextual elements. The CPC rating is used to classify control mode. The nine CPCs used by the CREAM are: (1) Adequacy of organization, (2) Working conditions, (3) Adequacy of MMI and operational support, (4) Availability of procedures/plans, (5) Number of simultaneous goals, (6) Available time, (7) Time of day, (8) Adequacy of training and experience, and (9) Crew collaboration quality. The next step in a retrospective analysis using the CREAM is to consider possible error modes (Hollnagel, 1998). Error modes consist of the following eight categories: (1) Timing, (2) Duration, (3) Force, (4) Distance/magnitude, (5) Speed, (6) Direction, (7) Wrong object, (8) Sequence.

After selecting possible error modes, each possibility must be analyzed. The analysis begins with the possible error mode representing a general consequent. That general consequent is linked to an associated antecedent (either specific or general). If the linked antecedent is a specific antecedent, the stop rule is enforced. If the antecedent is a general antecedent, that general antecedent becomes a (second) general consequent. This continues until the stop rule is employed. The CPCs help the analysis go from the realm of possible antecedents to probable antecedents (given the context described by the CPCs).

Quantitative prospective CREAM. The prospective analysis using the CREAM begins with a qualitative analysis (basic method) and leads to a quantitative analysis (extended method) (Hollnagel, 1998). The prospective analysis does not rely on a historical event for analysis (by definition). Instead, a scenario must be examined. Scenarios can be developed by utilizing other HRA techniques (e.g. FMEA or Hierarchical Task Analysis (HTA), etc.). Hollnagel (1998) suggested that a detailed task analysis is preferable to developing an additional fault tree.

As with the retrospective analysis, the context is described using CPC ratings. Instead of an error mode starting the analysis process, an initiating event is used. Links between general consequents and general antecedents among the classification groups provide the basis for identifying possible failures modes. Hollnagel used the term “forward path” to describe the link that a general antecedent has either to an error mode or a general consequent. If the general consequent is selected, that general observation links back to another antecedent. This is repeated until only an error mode is selected (Hollnagel, 1998).

In the extended method, Hollnagel (1998) provided failure probabilities in the term of "reliability interval" (p. 240). Each task within the scenario must be identified by a cognitive activity type (Hollnagel, 1998). Those activity types are then assigned one or more of the four COCOM functions. Hollnagel provided a list of "generic failure types" for each COCOM function with probability ranges for each type (p. 252). This provides a base reliability interval for possible cognitive function failures.

Hollnagel (1998) provided an adjustment for the influence of the CPCs on each of the COCOM functions. For each CPC rating, the sum of the weighting factors for all four COCOM functions is multiplied by the frequency of the failures to arrive at the adjusted reliability interval for possible cognitive function failures.

Purpose of the Research.

The purpose of this study was to apply the novel ("second-generation") Human Reliability Analysis (HRA) technique called the Cognitive Reliability and Error Analysis Method (CREAM) to instances of human error in a hospital setting. By applying the CREAM to human error within the medical domain and comparing it to the currently used Root Cause Analysis (RCA) technique, we examined the differences between the information provided by each analysis technique.

Thesis. Retrospective analyses using the CREAM applied to sentinel events in a hospital setting will yield different information than the RCA technique currently employed by the hospital and help to identify additional risks for and possible causes contributing to medical error.

Method

Participants

Participants in this study included hospital personnel facilitating RCAs following sentinel events and clinical personnel involved in the events. They were observed *in situ* in a group setting as they interacted during RCA events at a medium-sized hospital located in New York State. Participants were not interviewed individually or contacted outside of the RCA event.

Materials

CREAM Navigator. The CREAM Navigator software was used to facilitate the retrospective reanalysis of events. The CREAM Navigator (version 0.6) was obtained online at http://www.ews.uiuc.edu/~serwy/cream/. The software was developed and evaluated by Serwy and Rantanen (2007) and is available at no cost under the GNU General Public License.

Root Cause Analyses. RCA events were analyzed using data submitted by the hospital to the New York State Department of Health according to the NYPORTS Framework for Root Cause Analysis and Action Plan in Response to a Sentinel Event form. NYPORTS is a secure database with access given to authorized individuals. No data was retrieved directly from the NYPORTS database during this study. Data from the RCA events was analyzed on-site at the hospital to ensure the security and confidentiality of the data.

Design

This study employed metadata analysis and systematic observation as methods for obtaining data. Results included qualitative data from the examination of retrospective analysis of events using the CREAM. Descriptive statistics (e.g., frequency and mean) were used to compare the hospitals previous RCA data with a retrospective reanalysis of each event using the CREAM.

Procedure

Root Cause Analysis. RCA data was obtained through direct observation (passive observation) of RCA events *in situ* and a review of historical RCA documents (NYPORTS Framework for Root Cause Analysis and Action Plan in Response to a Sentinel Event as reported to the NYS DOH through the NYPORTS database). Altogether, 87 cases were reviewed and 58 cases were selected for retrospective re-analyses using the CREAM. There were 29 cases that were excluded from the CREAM analyses because an error mode could not be identified from the source documentation. In most of those cases, the original RCA team found that the clinical standard of care was met with no opportunities for improvement.

Retrospective CREAM Analysis. A retrospective analysis using the CREAM was performed for 58 of the RCA events reviewed using portions of the NYPORTS Framework for Root Cause Analysis and Action Plan in Response to a Sentinel Event form as a source document. The sections of the form that provided the data for the reanalysis using the CREAM were the "Detailed Narrative Description/Chronology of Event" and the "Executive Summary". The results of the CREAM analyses were compared to the results of the RCA. General comparisons were made between the CREAM antecedent categories and the section of the NYPORTS Framework for Root Cause Analysis and Action Plan in Response to a Sentinel Event form where hospital staff assigned root causes to causal factor categories called "Aspects for Analysis".

Additionally, notes were taken on five RCA events observed. These notes were used to create a detailed narrative of each RCA event. Three individuals (a professor with experience in Human Factors Engineering, a professor with experience in Industrial Systems Engineering, and a graduate student in Applied Experimental and Engineering Psychology) performed retrospective analyses using the narrative from the RCA events as source documentation. The results of the analyses using the CREAM were compared among the three raters in an attempt to measure inter-rater agreement.

Approximately one year after the initial analysis, five events that were previously re-analyzed with the CREAM using the archived RCA documents as a data source were once again re-analyzed with the CREAM using the narrative report created during the *in situ* RCA event observations. A comparison was made between the two CREAM analyses results of the same event with differing data sources (archived RCA report vs. narrative from observed RCA event).

Results

RCA Results

A total of 87 documents were reviewed from archived RCA events conducted at the hospital over a period of approximately 6 years. Of the 87 cases, 58 were re-analyzed using the CREAM. The number of cases re-analyzed using the CREAM was less than the total number of cases initially reviewed due to an inability to discern an error mode in 29 of the cases (Table 1).

Table 1

Number of Cases Analyzed by Year of Event Occurrence

Year	Number of Archived RCA Events Reviewed	Number of RCA Events Reanalyzed Using the CREAM
2004 (partial)	4	2
2005	11	8
2006	14	10
2007	6	6
2008	14	8
2009	17	12
2010	16	8
2011(partial)	5	4
Total	87	58

Despite the use of an RCA technique intended to reduce the risk factors associated with each event, the frequency of events per year did not seem to decrease (Table 1) and almost all of the event types experienced reoccurrence (Table 2). For example, there were 16 instances of unintentionally retained foreign objects during the almost six year period under review. In 16 instances, a foreign object was unintentionally left inside of a patient during a surgical procedure. The reoccurrence of these events suggests that not all causal factors have been identified in the RCA process. Admittedly, it may also suggest that the identified causal factors may not have been effectively mitigated. Or, it might be a combination of both.

Within the cases reviewed, the highest number of cases involved unexpected death and unintentionally retained foreign bodies (Table 2). The cases involving unexpected death had the highest number of cases in which an error mode could not be discerned from the available information present in the RCA report submitted by the hospital. Of the 48 instances of unexpected death reviewed, only 26 were re-analyzed using the CREAM.

Table 2

Number of Cases Analyzed by RCA and the CREAM by NYPORTS Code

		RCA		CREAM	
NYPORTS Code	Code Description	N	%	N	%
901	Serious occurrence (voluntary reporting)	4	4.6	4	6.9
911	Wrong Patient, Wrong Site Surgical Procedure	2	2.3	2	3.5
912	Incorrect Invasive Procedure or Treatment	4	4.6	4	6.9
913	Unintentionally Retained Foreign Body	16	18.4	15	25.9
915	Unexpected Death	48	55.2	26	44.8
916	Cardiac and/or Respiratory Arrest Requiring ACLS Intervention	7	8.1	4	6.9
917	Loss of Limb or Organ	0	0	0	0
918	Impairment of Limb, Organ, or Body Function	3	3.5	1	1.7
935	Fire or Internal Disaster	1	1.2	0	0
938	Equipment Malfunction	2	2.33	2	3.5
Total		87	100.0	58	100.0

Note. The cases are presented by NYPORTS code as a means to establish that the cases examined were classified within a defined set by the New York State Department of Health.

The NYS DOH identifies “Aspects for Analysis” which are categories of factors that each root cause must be assigned to when an RCA is conducted for an event. The NYS DOH does not limit organizations from assigning a root cause to more than one category. In both RCA cases reviewed and in cases re-analyzed using the CREAM, the hospital identified the category “Policy or Process” as being a root cause most frequently (Table 3). In fact, this category was identified as a root cause approximately 45% of the time. Root causes were assigned by the hospital to the category of “Information Management & Communication Issues” approximately 31% of the time. The hospital assigned a root cause to the category of "Leadership (Corporate Culture)" only one time in the period under review.

Table 3

Causal Factor Categories (Aspects for Analysis) by RCA and the CREAM

	RCA		CREAM	
Aspect for Analysis	N	%	N	%
Policy or Process	126	45.6	120	45.8
Human Resource Factors & Issues	38	13.8	36	13.7
Environment of Care/Equipment/Supplies	21	7.6	19	7.2
Information Management & Communication Issues	87	31.5	83	31.7
Leadership (Corporate Culture)	1	0.4	1	0.4
Other	3	1.1	3	1.2
Total	276	100.0	262	100.0

CREAM Results

The retrospective analysis of an event using the CREAM began by rating the nine Common Performance Conditions (CPCs) for each case. Each rating assignment is correlated to having an effect on performance reliability ranging from increasing reliability to not having a significant effect on reliability to decreasing reliability. For the 58 RCA events re-analyzed using the CREAM, Adequacy of Organization was rated as inefficient or deficient almost 90% of the time (Table 4). Also noteworthy was that Availability of Procedures/Plans was rated as Inappropriate almost 90% of the time in the cases. Available Time was rated as temporarily inadequate 50% of the time with Number of Simultaneous Goals rated as more than capacity in 36.2% of the events. Crew Collaboration Quality was rated as either inefficient or deficient in approximately 88% of the events.

Table 4

Ratings of the CREAM Common Performance Conditions (CPCs) by CPC Category

CPC	Rating	N	%
Adequacy of Organization	Efficient	6	10.3
	Inefficient	26	44.8
	Deficient	26	44.8
Working Conditions	Advantageous	2	3.4
	Compatible	40	69.0
	Incompatible	16	27.6
Adequacy of Man-Machine Interface/Operational Support	Supportive	1	1.7
	Tolerable	34	58.6
	Inappropriate	23	39.7
Availability of Procedures/Plans	Acceptable	6	10.3
	Inappropriate	52	89.7
Number of Simultaneous Goals	Fewer than capacity	4	6.9
	Matching current capacity	33	56.9
	More than capacity	21	36.2
Available Time	Adequate	28	48.3
	Temporarily inadequate	29	50.0
	Continuously inadequate	1	1.7
Time of Day	Day-time	40	69.0
	Night-time	18	31.0
Adequacy of Training/Experience	Adequate – high experience	11	19.0
	Adequate – limited experience	39	67.2
	Inadequate	8	13.8
Crew Collaboration Quality	Efficient	7	12.1
	Inefficient	32	55.2
	Deficient	19	32.8

The CPC ratings seemed to be a good predictor of reliability in the cases re-analyzed using the retrospective analysis of the CREAM (Table 5). Over 90% of the time, CPCs were rated in a way which reflected reduced reliability for 3 or more CPCs. On the contrary, approximately 98% of the time only 2 or less CPCs were rated in a way which reflected increased reliability.

Table 5

Number of CPCs that Improved, Reduced, or Had No Effect on Reliability

	Improved Reliability		Reduced Reliability		No Significant Effect on Reliability	
CPCs	N	%	N	%	N	%
0	26	44.8	0	0	0	0
1	23	39.7	2	3.4	0	0
2	8	13.8	3	5.2	3	5.2
3	1	1.7	16	27.6	19	32.8
4	0	0	12	20.7	17	29.3
5	0	0	14	24.1	11	19.0
6	0	0	9	15.5	5	8.6
7	0	0	2	3.4	2	3.4
8			0	0	1	1.7
9			0	0	0	0

After the CPCs are rated, an Operator Control Mode is calculated in the CREAM. The control mode expresses the context in which the operator was functioning during the event. Control modes are Strategic, Tactical, Opportunistic, and Scrambled (in order of reliability from improved to reduced). For example, Strategic Control Mode is associated with a high degree of operator control. Scrambled Control Mode is associated with an almost complete lack of control.

In the 58 events re-analyzed using the CREAM, the operators were found to be most likely working within the Opportunistic control mode (Table 6). The operators were functioning within the Scrambled control mode 19% of the time. In over 80% of the events, the results of the analyses using the retrospective CREAM suggest that operators had little control. None of the events was associated with an Operator Control Mode of Strategic (or a high level of control).

Table 6

Operator Control Mode

Operator Control Mode	N	%
Opportunistic	36	62.1
Tactical	11	19.0
Scrambled	11	19.0
Strategic	0	0.0

Following the rating of the nine CPCs and the determination of the operator control mode (as an expression of performance reliability within the specific context in which the event occurred), the analysis proceeds with the identification of an error mode. The 58 events were associated with 80 error modes (Table 7). The most frequent error mode was Action in Wrong Place which was closely followed by Action at Wrong Time. Together, these two error types accounted for 80% of all error modes identified.

Table 7

Error Modes in the Cases Reanalyzed with the CREAM

Error Mode Classification	N	% Total Errors
Action in Wrong Place	34	42.5
Action at Wrong Time	30	37.5
Action at Wrong Object	10	12.5
Action at Wrong Type	6	7.5

In the CREAM, error modes are associated with antecedent categories through a series of tables. Antecedents "give rise" to an error mode. Once an initial antecedent is selected, an antecedent is selected for that particular previous antecedent. The selection of antecedents according to the CREAM tables continues until no antecedent is found or the stop rule is employed. The result is a branching series of nodes leading toward each error mode.

Each antecedent category is classified as belonging to either the Man (Human), Technology, or Organization genotype classification group. For the events re-analyzed using the CREAM, the most frequent antecedent category belonged to the Organization classification group (Table 8). Over 50% of the antecedents within the 80 error modes were selected from within that category (as opposed to the Policy/Process category found in the hospitals RCA's).

Table 8

Number of Antecedents by Classification Group

Antecedent Classification Group	N	% Total
Organization	281	52.4
Man (Human)	150	28.0
Technology	105	19.6

For antecedents selected within the Man (Human) genotype group, the most frequent classification was planning (44.7%), temporary person-related functions (20.7%), and observation (18.0%) (Table 9). Inadequate plan was the antecedent most frequently selected within the Man (Human) genotype group.

Table 9

Number of Antecedents in the Man (Human) Genotype Classification Group

Antecedent Category	N	%
Observation	27	18.0
Observation missed	17	11.3
False Observation	1	0.7
Wrong identification	9	6.0
Interpretation	19	12.6
Faulty diagnosis	17	11.3
Wrong reasoning	2	1.3
Decision error	0	0.0
Delayed interpretation	0	0.0
Incorrect prediction	0	0.0
Planning	67	44.7
Inadequate plan	67	44.7
Priority error	0	0.0
Temporary person-related functions	31	20.7
Memory failure	9	6.0
Fear	0	0.0
Distraction	12	8.0
Fatigue	1	0.7
Performance variability	4	2.7
Inattention	5	3.3
Physiological stress	0	0.0
Psychological stress	0	0.0
Permanent person-related functions	6	4.0
Functional impairment	0	0.0
Cognitive style	0	0.0
Cognitive bias	6	4.0
Total	150	

For antecedents selected within the Technology genotype group, the most frequent classification was procedure. The most frequently selected antecedent was inadequate procedure (89.5%) (Table 10).

Table 10

Number of Antecedents in the Technology Classification Group

Antecedent Category	Frequency	%
Equipment failure	6	5.7
Equipment failure	6	5.7
Software fault	0	0.0
Procedures	94	89.5
Inadequate procedures	94	89.5
Temporary interface problems	3	2.9
Access limitations	2	1.9
Ambiguous information	0	0
Incomplete information	1	1.0
Permanent interface problems	2	1.9
Access problems	1	1.0
Mislabeling	1	1.0
Total	105	

The antecedents selected from the Organization genotype group belonged to the Organization category most frequently (56.6%) followed by the Communication category (17.8%) (Table 11). The antecedent most frequently selected within the Organization category was Design Failure (22.8%) followed by Inadequate Quality Control (18.9%). Incidentally, the antecedent Management Problems was selected 31 times (as opposed to the hospital identifying Leadership (Corporate Culture) as being a factor in the RCA's only once).

Table 11

Number of Antecedents in the Organization Classification Group

Antecedent Category	Frequency	%
Communication	50	17.8
Communication failure	45	16.0
Missing information	5	1.8
Organization	159	56.6
Maintenance failure	3	1.1
Inadequate quality control	53	18.9
Management problem	31	11.0
Design failure	64	22.8
Inadequate task allocation	5	1.8
Social pressure	3	1.1
Training	34	12.1
Insufficient skills	3	1.1
Insufficient knowledge	31	11.0
Ambient conditions	27	9.6
Temperature	0	0.0
Sound	1	0.4
Humidity	0	0.0
Illumination	0	0.0
Other	13	4.6
Adverse ambient conditions	13	4.6
Working conditions	11	3.9
Excessive demand	8	2.9
Inadequate workplace layout	1	0.4
Inadequate team support	1	0.4
Irregular working hours	1	0.4
Total	281	

Inter-rater Agreement in the CREAM Analyses

Three raters performed retrospective analyses of five events in which the actual RCA event was observed by a separate observer. The analyses of the five events were based on a detailed written narrative supplied to the raters by the observer. Qualitatively, the narrative contained more detailed information than was present in the hospital's archived RCA reports submitted to the NYS DOH through the NYPORTS event database.

Inter-rater agreement for the determination of the context in which the operators were functioning (as represented by the Operator Control Mode) was calculated for the five events (Table 12). The three raters agreed on the control mode of the operator in only 1 of the 5 events (or 20% inter-rater agreement).

Table 12

Inter-Rater Agreement of Operator Control Mode in the CREAM Re-Analyses

	Raters A, B, & C		Raters A & B		Raters A & C		Raters B & C	
Event	Number	%	Number	%	Number	%	Number	%
1	0	0	0	0	0	0	2	100
2	2	66	0	0	0	0	2	100
3	3	100	2	100	2	100	2	100
4	2	66	0	0	2	100	0	0
5	0	0	0	0	0	0	0	0
Mean		59.6		20		40.0		60.0

An attempt was made to calculate inter-rater agreement for error-modes selected by the three raters for the five events. However, there was almost no agreement among the raters. Among the raters, 14 different error modes were suggested within the five events. There was agreement among the three raters for only a single error mode in a single event. As the beginning of the retrospective analysis using the CREAM is the selection of an error mode and there was virtually no agreement among the raters in that step, it was not practical to attempt to calculate the inter-rater agreement for specific antecedents which gave rise to the error modes. (Incidentally, in the case where all raters agreed on at least one error mode, each rater selected a different antecedent from that error mode.)

Comparison of the CREAM Analyses by Data Source

Approximately one year after the initial analyses, five events originally analyzed using the hospital's archived RCA documents were re-analyzed using the narrative report from the observed RCA event. The comparison of the CREAM analyses by data source was completed to determine if there was a difference in the data sources (each describing the same event). The results of the comparison of data sources for the five events are presented in Table 13. One additional error mode was identified during the CREAM analyses using the narrative reports from the observed RCA events. Additionally, there was an increase in the overall number of antecedents in the cases re-analyzed using the CREAM from the narrative report describing the observed RCA event. (There was no difference in the calculation of the Operator Control Mode.)

Table 13

Comparison of the CREAM Analyses

		Antecedents			
Data Source	Error Modes	Man	Technology	Organization	Total
Archived RCA documents	7	14	6	14	34
Observed RCA event	8	13	11	24	48

Discussion

Each hospital in New York State is required by the DOH to conduct an RCA to examine the causal factors of specific occurrences. Results of the internal RCA are submitted to the DOH via the NYPORTS database. To submit the RCA results, hospital team members complete a form called the Framework for Root Cause Analysis and Action Plan in Response to a Sentinel Event. As part of this form, each root cause is assigned causal factor categories called Aspects for Analysis. These causal factor categories when compared to the antecedent categories selected during the CREAM analyses confirmed the hypothesis that different information would exist between the two retrospective event analysis techniques.

The first result in this research suggests that the RCA technique may not be identifying all causative factors as part of the RCA process since most of the occurrences repeated during the approximate six-year period under review. (For example, there were 16 occurrences of unintentionally retained foreign bodies during surgical procedures within the timeframe reviewed.) As the goal of the RCA process is to reduce the chance that an event will occur again in the future, the analyses suggest that further study on the causes of repeat events is warranted.

Additionally, results suggest that there may be a gap in the hospital's RCA that minimizes the role that organizational and leadership factors play in these specific occurrences. The most frequent category of causal factors in the hospital's RCA was Policy or Process (45.8%). The most frequent category of antecedents in the CREAM analyses of the same events was Organization (52.4%). Additionally, the CREAM analyses found the antecedent Management Problem was selected 31 times as opposed to the RCA assigning the category Leadership (Corporate Culture) only once. These results further reinforce the confirmation of the hypothesis.

A third result in this research suggests that team members are working within sub-optimal control modes during the events. The CPCs Adequacy of Organization, Availability of Plans/Procedures, and Crew Collaboration Quality was rated having an effect of reduced human performance reliability in almost 90% of the events. Almost 20% of all events were associated with team members working in a chaotic work environment with a complete lack of control.

The result from an attempt to calculate inter-rater agreement in the analyses using the CREAM raises a question about the validity of the CREAM analyses. The question of inter-rater agreement in the CREAM should be explored further. The lack of inter-rater agreement suggests that the error modes and antecedent categories in the CREAM need better definition. Also, there was evidence that the CREAM Navigator interface design may have contributed to small errors in the CREAM analyses. In the retrospective CREAM analyses, each node should begin with an error mode. In the prospective CREAM analyses, each node should begin with the selection of antecedent categories from the MTO triad. Some of the analyses from the analysts performing inter-rater reliability included nodes beginning with an antecedent category. This suggests some degree of confusion performing the CREAM using the navigator software. When these errors were observed in the data analyses, the erroneous nodes in question were ignored.

The comparison of results from the CREAM analyses by data source seemed to reinforce the qualitative observation that there was a difference between the information discussed at the RCA event and the information recorded in the RCA form submitted by the hospital. The difference allowed the selection of more antecedents in the analyses based on observed RCA events vs. archived report of RCA events. There was an average of 6.0 antecedents per error mode selected in the analyses from the observed RCA events. There was an average of 4.9 antecedents per error mode selected in the analyses from the archived RCA reports. The re-analyses were completed approximately one year after the initial analyses to minimize the memory of the event specifics for the analyst.

Wu, Lipshutz, and Pronovost (2008) reported problems with the RCA approach to investigating incidents involving mistakes in medicine. They suggested that the RCA method is flawed and contended that there is no evidence of it being effective to reduce the occurrence of events. Wu et al. (2008) proposed that the RCA as applied to medical mistakes needs to be modified to be more effective. Spath and Minogue (2008) counter Wu, et al. (2008) by asserting that it is the "soil" and not the "seed" that is the problem. They proposed that "…hospitable organizational factors are the most important predictor of safety intervention effectiveness" (para 4.) Wu et al. (2008) cite several specific organizational factors as barriers to conducting an effective RCA. It seems there is a consensus that there are problems with the RCA method, but differing opinions as to whether the problem is in the tool, the implementation of the tool, or both. This research sought to explore differences in causal factors giving rise to error modes between the RCA method and the CREAM. The study suggests that both the tool and the implementation of the tool may be suboptimal. Logically, it follows that if organizational factors are a major category of contributing factors to errors in the practice of medicine (as the results suggest), then organizational factors would also effect the implementation of the tool used to analyze them.

The RCA process at the hospital studied in this research did not frequently utilize front-line staff with first-hand credible knowledge of the events as participants in the RCA. Instead, those staff members were interviewed and the contents of the interview were shared with RCA participants during the event. Without first-hand credible sources participating in the RCA, it was observed that the event was subject to speculation and hearsay. Additionally, RCA event participants included administrative and clinical leaders. Cosby and Croskerry (2004) report that medicine is practiced in a system that is highly hierarchical with a steep authority gradient. Therefore, it follows that honest and open dialogue about causal factors may be problematic. The RCA process also viewed each event as a separate instance. By looking at each event individually, analysts might not identify recurrent factors or learn from ineffective strategies to mitigate risk.

Limitations

Several significant limitations were encountered in this research. Due to time and resource availability constraints, it was not feasible to train hospital analysts in the CREAM to perform the CREAM analyses in parallel with RCA in an effort compare techniques. The CREAM was conducted utilizing information from the RCA. This had the potential to bias the results as one was somewhat dependent on the other. The source document containing event data (from the RCA) was obtained from the archived NYPORTS Framework for Root Cause Analysis and Action Plan in Response to a Sentinel Event form. This form is formatted in separate sections (a) Detailed Narrative Description/Chronology of Events, (b) Aspects for Analysis, (c) Root Cause Analysis Section, (d) Literature Search, and (e) Executive Summary. The potential bias was minimized through using the information contained in the Detailed Narrative Description/Chronology of Events and Executive Summary sections as a basis for the retrospective analysis using the CREAM.

Additionally, this study utilized the data from events in a single hospital. Approximately 60 additional hospitals were solicited to be participants in the study. None of those hospitals accepted the invitation to participate. As the implementation of the RCA process varies from hospital to hospital, utilizing data from more than one hospital might have introduced additional confounding factors to the research.

There were data limitations within the RCA source documents provided by the hospital. Qualitatively, when comparing observed RCA event details to their corresponding source documents, it was obvious that much information was filtered by the analysts in the process of preparing the RCA for submission to the New York State Department of Health. In an effort to avoid influencing the results of the RCA, observations of events *in situ* were passive. Participants in the event were not asked follow-up questions or interviewed. Additionally, inconsistencies were observed in the hospital's selection of Aspects for Analysis causal factor categories when contrasted with the written case summaries within the case source documents. These conflicts may come from a lack of definition for the Aspects for Analysis categories. These inconsistencies also suggest a problem with inter-rater agreement present within the RCA technique. This problem was not examined in this research.

The attempt to examine inter-rater reliability was limited by a small sample (5 cases) and raters with little experience or training in the CREAM. Although two of the three raters were trained in the CREAM together and completed one event retrospective analysis together as an attempt to calibrate classification decisions, it would have been more desirable to provide practice trial cases and additional training for all raters prior to our attempt to explore inter-rater agreement.

Conclusions and Future Research

Despite the limitations of the research, comparison of general causal factor categories was accomplished and presented some interesting results. We conclude that alternative methods (such as the CREAM) should be explored as alternatives or supplements to RCA methods. Additionally, efforts should be made to improve the organizational "soil" for the analyses of errors by (a) including all levels of staff in the analysis process, (b) reducing the authority gradient between participants, and (c) examining recurrent events in aggregate (as opposed to individual events).

Recommendations

The results of this research allow for several recommendations to be made to the hospital on ways to improve the RCA process in an effort to improve data validity. The recommendations may be organized in four main categories.

RCA process.

1. Perform the RCA with more structure and add elements such as "5-Why's" to force deeper exploration/discussion of proximate causes.

2. Whenever possible, conduct the RCA with the staff members who participated in/witnessed the event.

3. Work to minimize the authority gradient within the meeting.

4. Facilitation should ensure that each participant has an equal opportunity to participate (rather than the conversation being directed primarily by senior leaders).

5. Separate "fact" from "speculation" clearly within the RCA process and document as such.

6. Tie action steps to specific and measurable outcomes and include plan for continued follow-up.

7. Consider performing a CREAM analysis before the RCA to: (1) help structure interviews and fact-finding before the event and (2) ensure more complete data.

Further Analyses.

8. Consider aggregate RCA's for events that consistently occur over a period of time (repeat events) despite efforts to mitigate.

9. Instead of analyzing "failures", also analyze "good catches" and instances where the action was "optimal"; this will offer a more complete picture of sources of variance and risk.

10. For repeat types of events, perform a prospective analysis (e.g. CREAM or FMEA).

NYPORTS Form.

11. Consider creating more precise definitions for Aspects for Analysis to ensure consistency in completing the checklist.

12. Ensure the Aspects for Analysis checklist matches the narrated portion of the report.

13. Consider adding addendums to the NYPORTS case submission which document outcome of efforts to implement measures and results of follow-up.

Organizational.

14. Consider educating quality staff/leaders on the role of bias in decision-making.

15. Explore the role organizational and leadership factors play in events (e.g., identify and document organizational/cultural barriers).

16. Continue to analyze RCA events on an aggregate basis vs. an individual basis.

17. Research ways to improve validation of error rate (i.e. using other administrative/coding data to identify events).

Future Research

Further research might examine the source of the differences seen between the two retrospective event analysis techniques. One source might be that the CREAM provides a structured method for analysts to explore the relationships between event causal factors and error modes. The effectiveness of the RCA technique depends on frank, open, honest dialogue among RCA participants. Authority gradient and other organizational pressures may impede the discussion of causal factors among healthcare workers that may be politically sensitive in nature.

Further research might also explore the effectiveness of risk reduction strategies implemented to reduce the chance of event re-occurrence when RCA and the CREAM are used to supplement each other in retrospective event analysis. As the goal of any HRA technique in healthcare is to provide a thorough and credible analysis of the factors contributing to patient safety events, our research suggests that the CREAM used in conjunction with the RCA might provide healthcare workers with more insight into why the events occurred in an effort to reduce the risk of them happening again in the future.

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