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Human Reliability Analysis in Healthcare

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Final Technical Report

Human Reliability Analysis in Healthcare

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Prepared for
RIT-RGHS Alliance

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10. Supplementary Notes <p>This research was undertaken with support of \$20,000 seed funding award by the RIT-RGHS Alliance to Dr. Esa M. Rantanen (RIT) and Ms. Bernardette Murphy (RGH). This research is part of Mr. Joe Deeter's MS thesis in Applied Experimental and Engineering Psychology at RIT. We would like to thank Dr. Robert Mayo from RGH for his invaluable support in all phases of our work.</p>	
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Abstract

The problem of human error in healthcare is well documented. Other domains (such as transportation and energy) have used techniques and methods from the engineering disciplines to analyze and ultimately reduce instances of error. In New York State (NYS), the Department of Health (DOH) requires the use of one such method, Root Cause Analysis (RCA), in investigating and reporting the occurrence of and response to sentinel events by hospitals. Despite the use of the RCA technique in an attempt to identify and mitigate the root causes of error, the problem of human error contributing to sentinel events persists.

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Despite serious data limitations, our results reveal an apparent gap between RCA and CREAM analyses. We suggest that the gap highlights incomplete RCA that minimizes or does not appreciate the role that organizational factors play in contributing to the sentinel events. Due to data limitations, we cannot identify specific interventions to mitigate risk for sentinel events. However, we make several recommendations for improving the RCA process at Rochester General Hospital in an effort to improve the validity of the analyses data for further study.

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Introduction

Human error is a major problem in medicine, resulting in tens of thousands avoidable deaths and over a million excess injuries in a year in the U.S. alone (Institute of Medicine [IOM], 2000). The authors of the Institute of Medicine reports cited two large studies, one conducted in Colorado and Utah and the other in New York. These studies found that adverse events occurred in 2.9 and 3.7 percent of hospitalizations, respectively. In Colorado and Utah hospitals 6.6 percent and in New York hospitals 13.6 percent of adverse events led to death. In both studies, over half of these adverse events resulted from preventable medical errors. The report extrapolated from the New York numbers to estimate the nationwide number of deaths due to medical errors to be as high as 98,000, and estimated the total national costs (lost income, lost household production, disability and health care costs) of preventable medical errors resulting in injury to be between \$17 billion and \$29 billion, over half of which represent health care costs (IOM, 2000).

Human error is also a problem in many other domains, particularly in aviation and in process control. However, domains such as nuclear power generation, for example, have enjoyed decades of research and development of effective error analysis methods and error prevention protocols. Human reliability analysis (HRA) is an engineering discipline that has been an integral part of nuclear and other high-risk industries since 1970s; there also exist myriad well-documented HRA techniques that are applicable to health care systems for identification of sources of human error and prevention of adverse consequences of errors (Kirwan, 1998). A key to the success of all these efforts is abandonment of the traditional view of human error as a cause of adverse consequences (e.g., to patient safety). Instead, human error should be viewed as a consequent itself, and research efforts should be focused on identification and elimination of the antecedents of human error. This was the explicit focus of our research as well.

Publication of such seminal works as “To Err is Human” resulted in increased implementation of voluntary accident and incident reporting systems (IOM, 2000). In 2003, Rochester General Hospital (RGH) implemented a new web-based event reporting system, the Quantros Safety & Risk solution (Kumar & Carson-Martin, 2005). With this electronic incident reporting system, the number of events reported increased from 200 per month to about 450 per month in an 18-month period. Currently, events are reported at a rate of 600 to 620 per month, higher than the initial reporting rate, but showing a decreasing trend. A critical question is whether the decrease in reports reflects underreporting (cf. General Accounting Office, 1997) or a true reduction in incidents and mishaps. Alas, there is some evidence pointing to the former conclusion. The original reporting system at RGHS was Dr. Quality, which was purchased by Quantros in 2007. This change has led to some usability problems with the system’s interface, possibly resulting in decrease in its use.

A new HRA technique titled Cognitive Reliability and Error Analysis Method (CREAM) appears to be particularly well suited for health care applications. CREAM has been implemented in software that will allow subject matter experts (i.e., health care professionals) who may lack HRA training to conduct valid and reliable error analyses (Serwy & Rantanen, 2007). The purpose of this research was to evaluate these two very different approaches to event reporting and analysis, and to use both archival data and data collected during the project to examine the types and forms of human errors and their antecedents in health care in general and within RGHS in particular.

Quantros Safety & Risk Management (SRM) Application

The Quantros event reporting system allows team members at RGH to use any computer in the organization to enter any event (actual or potential) that will affect the clinical outcome of a patient or poses a potential patient safety issue. The same event reporting system is also used to report employee events such as needle sticks, falls, sprains and strains, etc. The events entered are reviewed each morning by the Performance Improvement Coordinators and the event follow up is assigned at that time. Feedback is provided via e-mails to the unit manager or designee to notify them of the follow-up and date of

completion. Events concerning inpatients are reviewed and action plans developed by the appropriate Nurse Manager; employee events are reviewed and acted upon by the Employee Health Department.

A performance improvement report is generated for all inpatient units that contain the unit specific harm events that were entered into Quantros. Monthly and quarterly reports are generated and reported to senior leadership, specific committees and the board of directors. These reports are downloaded put into excel spreadsheets, analyzed, and sent out in a PowerPoint packet with appropriate graphs and suggestions for improvement.

The use of the Quantros event reporting system has been implemented at RGH and some affiliates, including a smaller acute hospital (150 beds) and a skilled nursing facility. The event reporting system contains information on patient falls, medication errors, mislabeled blood specimens, returns to the OR, pressure ulcer formation, failed devices, misdiagnosis, wrong patient events, disruptive behavior by professional staff, missing patient property, unexpected deaths, readmissions to the organization, all events are classified as actual or potential. The units/departments within the organization use these reports to identify opportunities for improvement organization wide as well as unit specific.

Quantros SRM is a web-based application that allows healthcare organizations to capture self-reported data on actual or perceived patient safety events. Quantros SRM is a customizable application. Users enter information into Quantros through a series of web forms through the application. The form content is dynamic and changes based on the event type being reported. Data fields required for completion of the submission form are determined by the organization pre-implementation as part of the application-specific parameters. Event reports can be submitted anonymously. Data submitted into Quantros SRM can be aggregated with pre-defined application reports available to stakeholders within the organization.

After an event is submitted in Quantros, notification occurs to certain administrative users within the organization (which may include the manager responsible for the unit on which the event was reported to have occurred). This notification is a signal to organization stakeholders that an occurrence can be viewed within the Quantros SRM application. Following the notification, a stakeholder (designated as the Event Manager) assigns a classification to the event. The Event Manager assigns the occurrence to a specific stakeholder (e.g., department manager) for investigation. Results from the investigation are entered into the application. The reports are considered "closed" when the event has been investigated and reviewed.

Although Quantros has been widely implemented and used for a relatively long time, it has some problems that erode its usefulness in revealing and analysis of errors within the healthcare system. For example, it is believed that actual events are underreported by staff members. Anecdotal reasons for underreporting include (1) length of time required to complete an event submission, (2) perception of creation of "work" for supervisors (e.g., investigations, additional administrative tasks related to reporting, etc.), and (3) perception that other staff members will submit the event. It is difficult, however, to procure reliable statistics to further research these issues.

Our experiences with Quantros also revealed that the data within this system lacked specificity and completeness, making it inadequate to meet the goals of our research. Consequently, other sources for data were explored.

New York Patient Occurrence Reporting & Tracking System (NYPORTS)

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 the NYPORTS web database. The hospital enters data from a RCA using the NYPORTS Framework for Root Cause Analysis and Action Plan in Response to a Sentinel Event form. A 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” (NYS DOH, 2005, p. 13). Examples of occurrences requiring an RCA include:

- Serious occurrence (voluntary)
- Wrong patient/wrong site surgical procedure
- Incorrect (invasive) procedure or treatment
- Unintentionally retained foreign body
- Unexpected death
- Cardiac and/or respiratory arrest requiring ACLS intervention
- Loss of limb or organ
- Impairment of limb, organ, or body function
- Fire or internal disaster
- Equipment malfunction

Due to the inadequacy of the data provided by the Quantros SRM application, we used the NYPORTS database to select cases for inclusion in this study.

Cognitive Reliability and Error Analysis Method

Human reliability analysis (HRA) refers to techniques that seek to model human error in the context of complex systems in similar terms as probabilistic risk assessment (PRA), which in turn refers to systematic and comprehensive methodology to evaluate risks associated with complex engineered systems (Kolaczowski et al., 2005). Serious criticism has, however, been leveled against many current HRA techniques: Human performance is typically too complex to be represented by models used for component and system reliability, that is, human actions and performance cannot be decomposed in a mechanical fashion. These shortcomings are shared by many different HRA techniques that Hollnagel (1998) has labeled collectively as “first-generation HRA”. Hollnagel (1998) also proposed an alternative approach to HRA, a “second-generation” technique, which explicitly and specifically considers the context of human performance and impact of contextual factors on human reliability. This technique is called Cognitive Reliability and Error Analysis Method (CREAM; Hollnagel, 1998). CREAM is meant to be both a predictive and retrospective analysis tool, that is, fully bidirectional, applying the same principles for either direction of analysis. The logic of this approach is that the same theory that goes into predicting an event must be consistent with explaining a past event. CREAM represents a departure from hierarchical classification for human error causes, which often fail to produce consistent hierarchies of human performance due to insufficient knowledge about the causes of human error, and which tend to be sequential (Hollnagel, 1998).

Instead of the hierarchical and sequential approach, CREAM uses a recursive approach. Several tables interlink into each other through a set of rules for analysis, and each step offers several possibilities for proceeding. The context in which the erroneous action occurs helps simplify the analysis by helping indicate the more likely paths. This is an important consideration, for human actions never occur in a void but always within the context of the situation. CREAM organizes interactions between the human and the environment using the Human-Technology-Organization (HTO) triad. The conditions that shape context are called Common Performance Conditions (CPCs), and resemble the traditional performance shaping factors (PSFs) of other methods, such as the Technique of Human Error Rate Prediction (THERP; cf. Swain & Guttman, 1980).

The CREAM technique, too, suffers from various shortcomings that limit its applicability in real-world, operational settings (e.g., in health care). The method is quite tedious and time-consuming when done by hand because more than 15 tables need to be searched at each step and because of the rapid growth of branching points in the analysis. Consequently, there are few published human reliability

analyses or accident investigations that have used CREAM, or evaluations of the method using well-documented case studies; rather, CREAM appears in the HRA literature merely on a conceptual level (e.g., Kirwan, 1998).

CREAM Navigator

Because of the aforementioned drawbacks of CREAM as well as its unique and very strong advantages, Serwy and Rantanen (2007) created a computer program that bypassed much of the tediousness of CREAM analysis and made the technique more user-friendly and usable. Javascript, coupled with HTML, offered a rapid prototyping solution for user interface design. Making the software exclusively web-based and cross-platform compatible allows for easy dissemination of the method without a need to install additional software. The simplicity of the CREAM software readily allows even novices to analyze events in much detail. However, in past evaluations of the CREAM method and the Navigator software it was clearly demonstrated that domain expertise must be the foundation for any useful analysis of complex systems. Therefore, further development of both the CREAM method and its software implementations must consider expert operators as the primary users, that is, people who have the necessarily intimate understanding of the systems they interact with but who lack expertise and need much guidance and support in the HRA process.

Clear procedures for quantitative CREAM analysis are lacking at this time, with Hollnagel (1998) and Fujita and Hollnagel (2004) offering different alternatives for quantification of human error probabilities. After all, it is here where the computational prowess of computers can be put to best use. The CREAM Navigator will hopefully provide for a useful testbed for research, development, and testing of quantitative methods within the CREAM technique.

Purpose of the Research

This project sought to create a systematic method for tracking and analyzing medical errors, which will lay the foundation for further research on identification of their antecedents, development of practical interventions, and validation of the effectiveness of the interventions. We began with existing and available incident reporting systems, Quantros, RCA, and a novel one, CREAM, and compared them to find ways to improve error analysis methods specifically for health care application and RGHS operations.

Method

This research employed a descriptive design to analyze occurrences of sentinel events reported in the hospital (RGH) over the course of approximately six years. The occurrences were re-analyzed using the CREAM. Additionally, several RCA meetings were observed in situ to evaluate the effectiveness of the process.

Materials

Because the Quantros reports provided insufficient information for our purposes, our main source for data was archived RCA reports from the past several years (2004-2011). These reports were made available to us by RGH in hard copy format. They were reviewed on the RGH premises.

Root Cause Analyses (RCA). Occurrences were analyzed using data submitted by the hospital to the New York State Department of Health according to the NYPORTS Framework for RCA and Action Plan in Response to a sentinel event. NYPORTS is a secure database with access given only to authorized hospital employees. These RCA reports served as the primary source of data for this study. Secondary sources of data were observations of root cause analyses events conducted at the hospital.

CREAM Navigator. CREAM Navigator software was used to facilitate the retrospective analysis 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.

Design

Metadata analysis and systematic observation were used as methods for obtaining descriptive data. Results included qualitative data from the examination of retrospective analyses of occurrences using the CREAM. Descriptive statistics (e.g., frequency, mean, standard deviation) were used in further analyses of the metadata.

Procedure

Root Cause Analysis. RCA data were obtained through direct observation of RCA events and a review of historical RCA documents submitted to the NYPORTS database. The hospital supplied a list of reported sentinel event occurrences (by date) contained in the NYPORTS database. Cases were selected corresponding to the NYPORTS codes that required the organization to perform a RCA. The hospital printed the *Framework for Root Cause Analysis and Action Plan in Response to a Sentinel Event* report for each case selected. Each report was reviewed and data from them entered into the CREAM Navigator for further analysis.

Data on the RCA process were collected through observing RCA events at the hospital. Descriptive observations were recorded to (1) compare case elements discussed in the event to data elements reported in the final NYPORTS report submission and (2) analyze the effectiveness of the RCA process to make recommendations for improvement to the hospital team.

Retrospective CREAM analysis. Cases reviewed from the NYPORTS database and observed *in situ* were also analyzed using the CREAM. Some cases had to be excluded from CREAM analysis because (1) the original hospital RCA team reported that the standard of care had been met with no opportunity for improvement or (2) observable error mode could be determined.

Results

The Sample

A total of 87 cases were reviewed from RCAs reported to the NYS DOH through the NYPORTS database. These cases represented adverse events in the hospital for a period of approximately 6 years (2004-2011). Of the 87 cases reviewed, 58 were re-analyzed using the CREAM; 29 cases were excluded due to a lack of identifiable error mode. In most of the latter cases, the RCA team concluded that the appropriate standards of care were met with no opportunities for improvement, and hence there was no error to be analyzed in CREAM. Table 1 depicts the number of cases reviewed by year; 2004 and 2011 are partial years.

Table 1

Number of Cases Analyzed by Year.

Year	N (RCA)	N (CREAM)
2004	4	2
2005	11	8
2006	14	10
2007	6	6
2008	14	8
2009	17	12
2010	16	8
2011	5	4
Total	87	58

Root Cause Analyses (RCA)

Archived RCA reports of sentinel events reports covered a period of approximately 7 years (from early 2004 through early 2011). These events were reported to the NYS DOH using the NYPORTS. Table 2 presents the number of events by type. Note that the majority of cases analyzed by both RCA and CREAM were unexpected death (915) and unintentionally retained foreign body (913).

The NYPORTS framework for compiling data on RCA activities is separated into 6 main categories of *Aspect for Analysis*, (1) policy or process, (2) human resource factors and issues, (3) environment of care/equipment/supplies, (4) information management and communication issues, (5) leadership (corporate culture), and (6) other. When an RCA investigation of an event is conducted in the hospital, causes leading to the occurrence are identified within these 6 categories. Table 3 lists the numbers of *Aspects for Analysis* reported by the hospital in the archived RCAs reviewed. Policy or process dominated both analyses, followed by information management and communication issues.

Table 2

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

NYPORTS Code	Code Description	RCA		CREAM	
		N	%	N	%
901	Serious occurrence (voluntary reporting)	4	4.60	4	6.90
911	Wrong Patient, Wrong Site Surgical Procedure	2	2.30	2	3.45
912	Incorrect Invasive Procedure or Treatment	4	4.60	4	6.90
913	Unintentionally Retained Foreign Body	16	18.39	15	25.86
915	Unexpected Death	48	55.17	26	44.83
916	Cardiac and/or Respiratory Arrest Requiring ACLS Intervention	7	8.05	4	6.90
917	Loss of Limb or Organ	0	0	0	0
918	Impairment of Limb, Organ, or Body Function	3	3.45	1	1.72
935	Fire or Internal Disaster	1	1.15	0	0
938	Equipment Malfunction	2	2.30	2	3.45
Total		87	100.00	58	100.00

Table 3

Number of Cases Analyzed by RCA and CREAM by Aspects for Analysis.

Aspect for Analysis	RCA		CREAM	
	N	%	N	%
Policy or Process	126	45.65	120	45.80
Human Resource Factors & Issues	38	13.77	36	13.74
Environment of Care/Equipment/Supplies	21	7.61	19	7.25
Information Management & Communication Issues	87	31.52	83	31.68
Leadership (Corporate Culture)	1	0.36	1	0.38
Other	3	1.09	3	1.15
Total	87	100.00	58	100.00

Cognitive Reliability & Error Analysis Method (CREAM)

Common Performance Conditions (CPCs). CPCs were rated for each case. The nine CPCs are (1) adequacy of organization, (2) working conditions, (3) adequacy of man-machine interface (MMI)/operational support, (4) availability of procedures/plans, (5) number of simultaneous goals, (6) available time, (7) time of day, (8) adequacy of training/experience, and (9) crew collaboration quality.

Table 4

Ratings of the Common Performance Conditions (CPC) of CREAM 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 MMI/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

Impact of CPCs on reliability. According to CREAM, individual CPCs can have one of three impacts on reliability: (1) reliability improved, (2) reliability not significant, or (3) reliability reduced. When the CPCs are rated, CREAM presents a frequency of CPCs according to impact. The sum of these impacts is used to calculate the Operator Control Mode. Two CPCs do not have the ability to improve reliability, while all 9 CPCs can either reduce reliability or have an effect that is not significant. Table 5 presents the number of cases where reliability was influenced by the CPCs and Table 6 the resulting operator control modes in the cases analyzed.

Table 5

Number of Common Performance Conditions That Improved, Reduced, or Had No Effect on Reliability.

No. CPCs	Improved Reliability		Reduced Reliability		No Sig. Effect on Reliability	
	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

Table 6

Operator Control Mode

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

In the vast majority of cases we reanalyzed, the operator control mode was either opportunistic or scrambled (81.1%), posing a serious threat to the operation. Even more striking result is the nearly 20% of cases where the operator control mode was scrambled, indicating an almost total loss of control in the situation.

Error modes. The CREAM analysis of the 58 archived RCA cases identified 80 specific error modes. In CREAM, error modes belong to one of four types of errors: (1) action at wrong time, (2) action at wrong type, (3) action at wrong object, and (4) action in wrong place. Specific errors within the category of action at wrong time include timing and duration. Errors within the category of action at wrong type include force, distance/magnitude, speed, and direction. Wrong object is the error within the category of action at wrong object while sequence is the error within the category of action in wrong place. The numbers of each error mode is presented in Table 7. Within the 80 error modes identified the error modes of Timing and Sequence accounted for over 73.75% of the errors (with 31.25% and 42.50%, respectively).

Table 7

CREAM Error Modes in the Cases Analyzed

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

Antecedents. Antecedents in CREAM are grouped according to categories in the HTO triad (representing Human, Technology, and Organizational factors). As part of the CREAM analysis of the 58 archived RCA cases, a total of 536 antecedents (general direct and general indirect) were identified contributing to the 80 error modes. Table 8 reports the frequency of antecedents within each of the HTO categories.

Table 8

Number of Antecedents by Classification Group

Antecedent Classification Group	N	% Total
Human	150	27.98
Technology	105	19.58
Organization	281	52.42

Within the Human part of the triad, the antecedent genotypes are divided into categories of (1) observation, (2) interpretation, (3) planning, (4) temporary person-related functions, and (5) permanent person-related functions. Of the 150 antecedents, Table 9 shows the number of antecedents within each of these categories. Inadequate Plan ranked as the most frequent antecedent (67) followed by Faulty Diagnosis (17) and Observation Missed (17).

Table 9

Number of Antecedents in the Human Genotype Classification Group

Antecedent Category	Frequency ($n = 150$)	%
Observation	27	18.00
Observation missed	17	11.33
False observation	1	0.66
Wrong identification	9	6.00
Interpretation	19	12.66
Faulty diagnosis	17	11.33
Wrong reasoning	2	1.33
Decision error	0	0.00
Delayed interpretation	0	0.00
Incorrect prediction	0	0.00
Planning	67	44.66
Inadequate plan	67	44.66
Priority error	0	0.00
Temporary person-related functions	31	20.66
Memory failure	9	6.00
Fear	0	0.00
Distraction	12	8.00
Fatigue	1	0.66
Performance variability	4	2.66
Inattention	5	3.33
Physiological stress	0	0.00
Psychological stress	0	0.00
Permanent person-related functions	6	4.00
Functional impairment	0	0.00
Cognitive style	0	0.00
Cognitive bias	6	4.00

Within the Technology part of the triad, the antecedent genotypes are divided into categories of (1) components, (2) procedures, (3) temporary interface problems, and (4) permanent interface problems. Of the 105 antecedents (Table 10). Inadequate Procedure ranked as the most frequent antecedent (94) followed by Equipment Failure (6) and Access Limitations (2).

Table 10

Number of Antecedents in the Technology Genotype Classification Group

Antecedent Category	Frequency (<i>n</i> = 105)	% Total
Equipment failure	6	5.71
Equipment failure	6	5.71
Software failure	0	0.00
Procedures	94	89.52
Inadequate procedures	94	89.52
Temporary interface problems	3	2.86
Access limitations	2	1.90
Ambiguous information	0	0
Incomplete information	1	0.95
Permanent interface problems	2	1.90
Access problems	1	0.95
Mislabeling	1	0.95

Within the Organization part of the triad, the antecedent genotypes are divided into categories of (1) communication, (2) organization, (3) training, (4) ambient conditions, and (5) working conditions. Of the 281 antecedents, Design Failure ranked as the most frequent antecedent (64) followed by Inadequate Quality Control (53), and Communication Failure (45) (Table 11).

Table 11

Number of Antecedents in the Organization Genotype Classification Group

Antecedent Category	Frequency (n = 281)	%
Communication	50	17.79
Communication failure	45	16.01
Missing information	5	1.78
Organization	159	56.58
Maintenance failure	3	1.07
Inadequate quality control	53	18.86
Management problem	31	11.03
Design failure	64	22.78
Inadequate task allocation	5	1.78
Social pressure	3	1.07
Training	34	12.10
Insufficient skills	3	1.07
Insufficient knowledge	31	11.03
Ambient conditions	27	9.60
Temperature	0	0.00
Sound	1	0.36
Humidity	0	0.00
Illumination	0	0.00
Other	13	4.63
Adverse ambient conditions	13	4.63
Working conditions	11	3.91
Excessive demand	8	2.85
Inadequate workplace layout	1	0.36
Inadequate team support	1	0.36
Irregular working hours	1	0.36

Analyses of Cases by Event Type

We did separate CREAM analyses on the top two sentinel event types. Unexpected death (NYPORTS code 915) accounted for 26 cases (44.93%) and Unintentionally retained foreign body (NYPORTS code 913) for 15 cases (25.86%). All of the remaining event types contained less than 5 cases each.

Table 12

Number of Unexpected Deaths and Unintentionally Retained Foreign Bodies by Year in the Cases Reviewed.

Year	Unexpected Death (NYPORTS Code 915)		Unint. Retained Foreign Body (Code 913)	
	N	%	N	%
2004	1	3.84	1	6.66
2005	3	11.54	3	20.00
2006	7	26.92	2	13.33
2007	2	7.69	2	13.33
2008	1	3.84	2	13.33
2009	8	30.76	2	13.33
2010	3	11.54	0	0.00
2011	1	3.84	3	20.00

Table 13

RCA Aspects for Analysis by Unexpected Deaths and Unintentionally Retained Foreign Bodies

Year	Unexpected Death (Code 915)		Foreign Body (Code 913)	
	N	%	N	%
Policy or Process	56	43.41	26	52.00
Human Resource Factors & Issues	14	10.85	6	12.00
Environment of Care/Equipment/Supplies	12	9.30	4	8.00
Information Management & Communication Issues	46	35.66	14	28.00
Leadership (Corporate Culture)	1	0.78	0	0.00

Table 14

CREAM Error Modes by Unexpected Deaths and Unintentionally Retained Foreign Bodies

Error Mode Classification	Unexpected Death (Code 915)		Foreign Body (Code 913)	
	N	%	N	%
Action at Wrong Time	23	58.97	1	5.00
Action at Wrong Type	1	2.56	4	20.00
Action at Wrong Object	1	2.56	0	0.00
Action in Wrong Place	14	35.90	15	75.00

As part of the CREAM analysis of the 26 archived RCA cases coded as unexpected death, a total of 264 antecedents (general direct and general indirect) were identified contributing to the 39 error modes present (Table 15).

Table 15

CREAM Antecedent Classification Groups by Unexpected Deaths and Unintentionally Retained Foreign Bodies

Antecedent Classification Group	Unexpected Death (Code 915)		Foreign Body (Code 913)	
	N	%	N	%
Human	62	23.48	46	36.22
Technology	55	20.83	20	15.74
Organization	147	55.68	61	48.03

Within the 62 Human genotype antecedents, Inadequate Plan ranked as the most frequent antecedent (31) followed by Faulty Diagnosis (12) and Cognitive Bias (5) (Table 16).

Table 16

CREAM Antecedents in the Human Genotype Class by Unexpected Deaths and Unintentionally Retained Foreign Bodies

Antecedent Category	Unexpected Death (Code 915)		Foreign Body (Code 913)	
	Freq. (n = 62)	%	Freq. (n = 46)	%
Observation	6	9.68	12	26.08
Observation missed	4	6.45	10	21.74
False observation	0	0.00	0	0.00
Wrong observation	2	3.23	2	4.35
Interpretation	13	20.96	3	6.52
Faulty diagnosis	12	19.35	2	4.35
Wrong reasoning	1	1.61	1	2.17
Decision error	0	0.00	0	0.00
Delayed interpretation	0	0.00	0	0.00
Incorrect prediction	0	0.00	0	0.00
Planning	31	50.00	17	36.96
Inadequate plan	31	50.00	17	36.96
Priority error	0	0.00	0	0.00
Temporary person-related functions	7	11.29	14	30.44
Memory failure	3	4.84	2	4.35
Fear	0	0.00	0	0.00
Distraction	1	1.61	7	15.22
Fatigue	1	1.61	0	0.00
Performance variability	2	3.23	2	4.35
Inattention	0	0.00	3	6.52
Physiological stress	0	0.00	0	0.00
Psychological stress	0	0.00	0	0.00
Permanent person-related functions	5	8.06	0	0.00
Functional impairment	0	0.00	0	0.00
Cognitive style	0	0.00	0	0.00
Cognitive bias	5	8.06	0	0.00

Within the 55 Technology genotype antecedents, Inadequate Procedure ranked as the most frequent antecedent (94) followed by Equipment Failure (6) and Access Limitations (2) (Table 17).

Table 17

CREAM Antecedents in the Technology Class by Unexpected Deaths and Unintentionally Retained Foreign Bodies

Antecedent Category	Unexpected Death (Code 915)		Foreign Body (Code 913)	
	Freq. (n = 55)	%	Freq. (n = 20)	%
Equipment/Components	2	3.64	1	5.00
Equipment failure	2	3.64	1	5.00
Software fault	0	0.00	0	0.00
Procedures	49	89.09	19	95.00
Inadequate procedures	49	89.09	19	95.00
Temporary interface problems	3	5.46	0	0.00
Access limitations	2	3.64	0	0.00
Ambiguous information	0	0.00	0	0.00
Incomplete information	1	1.82	0	0.00
Permanent interface problems	1	1.82	0	0.00
Access problems	1	1.82	0	0.00
Mislabeling	0	0.00	0	0.00

Within the 147 organization genotype antecedents, Design Failure ranked as the most frequent antecedent (39) followed by Inadequate Quality Control (26), and Communication Failure (22) (Table 18).

Table 18

CREAM Antecedents in the Organization Class by Unexpected Deaths and Unintentionally Retained Foreign Bodies

Antecedent Category	Unexpected Death (Code 915)		Foreign Body (Code 913)	
	Freq. (n = 147)	%	Freq. (n = 61)	%
Communication	25	17.00	7	11.48
Communication failure	22	14.97	6	9.84
Missing information	3	2.04	1	1.64
Organization	89	60.54	32	52.46
Maintenance failure	1	0.68	1	1.64
Inadequate quality control	26	17.69	11	18.03
Management problem	19	12.93	8	13.11
Design failure	39	26.53	12	19.67
Inadequate task allocation	3	2.04	0	0.00
Social pressure	1	0.68	0	0.00
Training	19	12.92	8	13.12
Insufficient skills	0	0.00	2	3.28
Insufficient knowledge	19	12.93	6	9.84
Ambient conditions	8	5.44	13	21.31
Temperature	0	0.00	0	0.00
Sound	0	0.00	0	0.00
Humidity	0	0.00	0	0.00
Illumination	0	0.00	0	0.00
Other	4	2.72	7	11.48
Adverse ambient conditions	4	2.72	6	9.84
Working conditions	6	4.08	1	1.64
Excess demand	5	3.40	0	0.00
Inadequate workplace layout	1	0.68	0	0.00
Inadequate team support	0	0.00	0	0.00
Irregular working hours	0	0.00	1	1.64

Discussion

Data Limitations

There were substantial limitations in the data available for this research. The archived RCAs reviewed included several discrepancies, including checkboxes for Aspects for Analysis that sometimes did not agree with written statements in the report and some root cause statements and measures of effectiveness were incomplete or missing. We obviously had no knowledge of the original facts (e.g. interviews/witnesses/data) in the RCA process and had to rely solely on the written reports, despite—and including—the aforementioned corruption. We also encountered several incomplete RCAs (e.g. listing human error as a cause). The RCAs we observed revealed more details of the events for additional analysis. As observers, we could not ask questions or influence the process in any way, however, and these sessions tended to be more of an informal discussion rather than a structured activity, which limited the quality of data available for further analyses. Despite these limitations, our CREAM analyses revealed some very clear trends and pointed to specific antecedents that could guide design and implementation of interventions.

Common Performance Conditions (CPCs)

For each case, the context of the event in which the team members (operators) functioned was described in CREAM by rating Common Performance Conditions (CPCs). Each of the CPCs was rated based on the content of the archived RCA documents. In the event that specific information did not exist in the RCA document relating to the individual CPC, the rating that did not have an effect on reliability was selected. For example, if the CPC “Working Conditions” is rated as “Advantageous”, reliability will be improved. If the CPC “Working Conditions” is rated as “Compatible”, reliability is not significantly impacted. If the CPC “Working Conditions” is rated as “Incompatible”, reliability will be reduced. Therefore, in cases where no information was present in the RCA report with respect to working conditions, the CPC “Working Conditions” was rated as “Compatible”.

Most notable among the CPCs that signaled a reduction in performance reliability, “Adequacy of Organization” was rated as “inefficient” or “deficient” in 89.6% of cases. The CPC “Availability of Procedures/Plans” was rated as “Inappropriate” in 89.7% of cases and “Crew Collaboration Quality” “Inefficient” or “Deficient” in 88.0% of cases. Altogether 91.3% of cases had three or more CPCs that were rated as reducing reliability. Only a single case (1.7%) had three or more CPC’s that were rated as improving reliability.

Operator Control Mode

The operator control mode attempts to characterize operator performance within a specific level of control. According to Hollnagel (1998), operator control modes are classified along a continuum (with operators moving between control modes) as (1) scrambled, (2) opportunistic, (3) tactical, and (4) strategic. Hollnagel equated effective control with the ability of an operator to plan within a given context. Operators in the scrambled control mode have low performance reliability and opportunistic control mode is associated with medium performance reliability. Tactical and strategic control modes relate to higher performance reliability. In the vast majority of cases we reanalyzed, the operator control mode was either opportunistic or scrambled (81.1%), posing a serious threat to operation. Even more striking is nearly 20% of cases where the operator control mode was scrambled, indicating an almost total loss of control in the situation.

Organizational Factors

Within CREAM, antecedents “give rise” to consequents. Therefore, retrospective analysis of an event begins by describing an error mode. Antecedents, which gave rise to the error mode, are selected in an

iterative process until a “stop-rule” is employed or no further antecedents can be identified. The stop-rule ends the analysis for a given node. For example, in a hypothetical error where an operator selected the wrong object for use, the error mode would be “Wrong Object”. The antecedent “Wrong identification” might be selected because the operator jumped to a conclusion and selected the wrong object. The antecedent “Inadequate Plan” might be selected as the antecedent which gave rise to the wrong identification which gave rise to the error mode of wrong object (and so on).

Antecedents were categorized in three classification groups: (1) Human, (2) Technology, and (3) Organization (the HTO triad). In the cases we reanalyzed, organizational factors accounted for the largest number of antecedents (52.4%). Within the Human classification group, antecedents related to planning accounted for 44.7% of cases. Antecedents relating to procedures were almost 90% of the Technology classification group.

Event Type-Specific Antecedents

Analyses on two specific types of events (unexpected death and unintentionally retained foreign body) were conducted as all other event types had fewer than five cases in the time period under review. Within the unintentionally retained foreign body cases, there is a slight increase in the number of antecedents classified in the Human group (36.2%) compared to the same classification group in the unexpected death cases (23.5%). In the Human classification group, more antecedents related to observation (26.1%) and temporary person-related functions (30.4%) were identified in the unintentionally retained foreign body cases (compared to 9.7% and 11.3%, respectively in unexpected death cases). Additionally, in the Organization classification group, the unintentionally retained foreign body cases saw a slight increase in the number of antecedents related to ambient conditions (21.3%) compared to unexpected death cases (5.4%).

Comparing RCA Aspect for Analysis to CREAM Results

Within the NYPORTS framework, the Aspects for Analysis are fairly broad and ill-defined. For analyses, it would be helpful to have more precision in the definition of each aspect listed in the Aspects for Analysis. Without such precision, it is questionable if inter-rater agreement exists in the completion of the NYPORTS RCA documents among various staff members. However, our results suggest that there might be a distinctive bias in the RCA event/process. For example, “Leadership (Corporate Culture)” was listed as an aspect for analysis in the RCA documents only once (0.4%) in all the cases we reanalyzed. However, the CREAM analyses found more than half (52.4%) of the antecedents associated with error modes in cases belonged to the organizational classification group. Further analyses should focus on exploring the specific organizational antecedents (factors) within the cases.

Interventions

The practical goal for the use of any error analysis method is to be able to identify or develop interventions which lead to mitigation of the factors contributing to reduced performance reliability and erroneous action. In the current study, the data limitations within the RCA process cast serious doubt on the ability of either the Root Cause or CREAM analyses to be able to offer insight into *specific* root causes or antecedents contributing to reduced performance and erroneous actions with validity. Our study offers insight into the role that the Operator Control Mode and CPC’s have on performance reliability. The results also suggest some degree of bias in past event analyses where organizational factors were not recognized as proximate or root causes during RCA events. We offer several recommendations for improving the RCA process as a means to increase the quality of the data in order to improve the RCA and CREAM analyses to ultimately arrive at specific and credible interventions that will improve performance reliability and reduce events.

Conclusion

The Cognitive Reliability and Error Analysis Method (CREAM) was used to re-analyze occurrences reported to the NYS DOH via the NYPORTS database. CREAM not only provided a structured way to describe the context in which the event occurred (through rating the CPCs), but also provided further causal insight into the cognitive functions (i.e., lack of available plans) which contributed to some of the error modes. The CREAM analyses provided different information than what was arrived at using the RCA method employed by the hospital.

Our aggregate CREAM analyses of the archived RCA's exposed a gap between the NYPORTS Aspects for Analysis and CREAM antecedents. This gap suggests that organizational and leadership factors/antecedents may not be adequately considered in the RCA process due to incomplete RCA analysis of proximate causes. We think that further analysis of sentinel events and other serious occurrences using CREAM should be continued. Further analyses should focus on inter-rater reliability/agreement and incorporating prospective analyses of high-risk process or repeat Sentinel or other serious events. Additional effort should also include identifying interventions that will help mitigate antecedents giving rise to event error modes.

Recommendations

Based on our research we offer several recommendations:

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.

B. 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).

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