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Human Reliability Analysis – Cardiac Hospital Case Study with New Applicability

Joel M. Haight, Ph.D., P.E.
Branch Chief – Human Factors
U.S. Dept. of Health and Human Services
Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

Abstract

Cardiac care requires 24-hour monitoring of the condition of each cardiac patient's condition. This is achieved through evaluation and feedback of the patients' many critical physiological parameters. Increasingly, this monitoring is being accomplished through wireless technology. Technicians, located at remote monitoring stations, continuously monitor the many critical readings necessary to assess a cardiac patient's status. When an alarm comes in to the central monitoring station, technicians contact the nurses on the cardiac floor as necessary, and a nurse assesses and then addresses the patient's needs or potential cardiac condition. The case that motivated this study involved a patient whose cardiac condition was not addressed adequately by the hospital monitoring system.

The analysis described in this paper included a complete ergonomic assessment, a task analysis, a workload and task engagement assessment, an evaluation of training, an analysis of equipment reliability, and a fault tree analysis to bring together a reliability analysis of the entire system. The results of the analysis showed that there was a probability of 1.63 x 10^{-2} that the system would fail again, meaning that another patient could experience an unaddressed cardiac condition. With so many interdependent system components, it is difficult to reduce this likelihood. However, through many physical, process, and task-based changes made by the hospital administration, as well as diligent oversight and regular performance data analysis, in the five years since the

initial study, the hospital has not experienced another sentinel event to which the system failed to respond.

This type of monitoring system and the required responses described herein can be compared to the development of upset conditions in a chemical or minerals processing plant. In both cases, there is a critical system that must operate properly in order to ensure well-being and safety.

Introduction

A system and human reliability analysis of a cardiac hospital's central monitoring unit was completed in 2005. It is presented here more than five years later not only to show evidence that the interventions implemented after the analysis performed as intended, but also to encourage the use of this approach in industries involving humans and complex control systems. The purpose of the described ergonomic analysis, human reliability analysis, human-machine interface analysis, and machine reliability analysis was to provide information to assist hospital management representatives in their effort to reduce the likelihood of monitoring equipment failures and/or monitoring technician errors. However, in this case, the expectation is also that, through the presentation of the hospital's case, others will see benefit and applicability of these analytical techniques in their own industries.

When an unanticipated incident occurs in the health care industry with an adverse outcome (called a sentinel event), an appropriate systems analysis is completed. This study was completed after a case in which a patient's cardiac condition was not addressed adequately by the hospital monitoring system. The primary intention for the outcome of this study was to provide recommendations which, if followed, would allow hospital management representatives to make physical, procedural, and environmental changes to their cardiac monitoring system and its operation to help improve system performance, to minimize the probability of human error, and to ultimately better protect their patients. With this goal in mind, as part of this analysis, the author included failure or error scenarios that could potentially compromise patient care or attention. The scope of this analysis is the hospital's central monitoring process—i.e., its operation, hardware, technicians, environmental setting, and overall performance. The scope of the paper also includes suggestions for other applications for the analytical techniques. While a root cause analysis (RCA) was undertaken by the hospital as a response to the described case, the RCA is outside the scope of this paper.

The objective of this analysis was to identify each potential contribution to the creation of human error-likely situations, quantify each, and identify each potential performance shaping factor associated with the operation of the monitoring system. Once these contributions to error-likely situations and performance shaping factors were identified and understood, it then was important to develop and suggest improvements that would reduce error potential, to enhance the human contribution to system reliability, and to maximize the input of human judgment, experience, and decision-making capabilities.

Cardiac care requires constant monitoring of patient condition through evaluation and feedback of many of the patients' vital signs and other physiological measures. Increasingly, this monitoring is being done in hospitals using wireless technology and remote stations where technicians continuously monitor the many available readings 24 hours per day. The expectation is that when one of the measured parameters exceeds or undershoots its acceptable range, thus indicating the development of a potentially life threatening condition, an alarm comes in to the central monitoring station. The technicians assess and interpret the alarm and contact the nurses on the cardiac floor as necessary. The nurse addresses the patient's needs or potential cardiac condition.

The telemetry system used at this particular hospital gathers signals that indicate the condition of cardiac patients monitored, then transmits the signals to the central monitoring unit. The parameters monitored include the patients' heart rate, respiration rate, pulse oxygen level, mean arteriole blood pressure, central venous pressure, premature ventricular contraction, and continuous real time blood pressure. Additional parameters are monitored as needed. The signals are monitored and tracked 24 hours per day at four computer stations by four monitoring technicians each working 8-hour shifts. The monitoring system is programmed to recognize acceptable ranges for each biometric parameter monitored, and upon occurrence of an out-of-range reading from any of the patients, the system alarms at the central monitoring station. Depending upon the criticality and magnitude of the out-of-range parameter, the alarm light will be either “yellow,” indicating the development of a critical condition, or “red,” indicating the development of a potentially life threatening condition. Each is recognized by its own distinctive tone and the yellow or red light activating on the applicable screen. In general, the technician acknowledges the alarm and responds by notifying the patient’s nurse of the problem. Alarms could be deactivated for a number of reasons; due to a heavy workload, it could be bothersome and thus it is deactivated or a distracting environment could cause the audible and visual alarm to be missed.

When an unhealthful cardiac condition develops and a patient becomes at risk, the condition, in most cases, has to be addressed by the appropriate medical professionals as soon as possible. Therefore, this patient care system requires several things: that, when a cardiac condition develops, the sensing equipment on the patient functions; that the transmission equipment from the patient to the monitoring station functions; that the monitoring equipment itself functions; and that the alarms function properly. Further requirements of the system are that the technicians hear, recognize, and properly interpret the alarm or out-of-range reading/condition; that the technicians contact the appropriate nurse on the floor; and that the communications equipment functions properly. The nurse must then respond to the information appropriately by either properly addressing the condition in a timely manner or by contacting the correct medical professional to handle the condition that developed. If the condition is not properly addressed as soon as possible, a patient can be at a greater risk of dying.

This monitoring system is similar to many process industry control systems where a process is monitored and controlled by a computer, with the feedback and process information transmitted to a computer screen that is continuously monitored by an operator or technician. This operator or technician monitors the process for out-of-control-limit or out-of-acceptable-range readings and alarm states. If an alarm comes in, outside operators or technicians are contacted to suggest adjustments to the process to bring it back under control or into its designed operating range. This type of monitoring system and the required responses can be compared to the development of upset conditions in a chemical or minerals processing plant. In both cases, there is a critical system that must operate properly in order to ensure the well-being of the cardiac patients (in the case of the hospital) or continued safe operation (in the case of a plant). As this comparison demonstrates, any complex system integrating computers, other hardware, and computer software output with humans, human interpretations, and human decision-making can benefit from this type and level of analysis.

Methodology

The human reliability analysis was conducted beginning with a visit to the hospital in November 2005. The composite of analyses was performed through visual inspection of the facilities and through interviews with the technicians, supervisory staff, and engineering representatives. It also included an analysis of representative samples of the monitoring system output (a 10% sample of the previous six months' daily data) to help determine and quantify the information processing requirements and workload of the technicians.

During December 2005, the evaluation included a detailed comparative ergonomic analysis followed by a fault tree analysis in January 2006 assessing the likelihood of an adverse cardiac event going unaddressed due to system error or failure. During the study, the monitoring facilities, process, and operations were evaluated and compared to recognized good ergonomic and cognitive engineering practices in the following areas: monitoring station arrangement, computer screen layout and information density, control device layout, room lighting, distraction level, and quantification of the monitoring duty load (Haight, 2007).

A second phase of this study included an analysis of the probability of errors associated with monitoring the cardiac-related condition of 150-200 patients per day. Potential errors were identified by the technicians themselves and these were validated and confirmed via documentation from an earlier Failure Modes and Effects Analysis (FMEA) done by the hospital staff. Human error in this case was defined as any action that resulted in a failure to respond to a patient's needs or to respond inappropriately to a patient's needs. Human error was further characterized by the ability of technicians to detect and respond to upset conditions.

The analysis included an evaluation of the layout and condition of four monitoring stations and discussions with monitoring unit supervisors and four on-duty monitoring technicians. Particular attention was paid to monitoring activities, time demands, distractions, and responses to alarms (Haight and Caringi, 2007). Critical error concerns were highlighted and categorized from general industry task-based error rates. This process was carried out by categorizing each human response into groups matching general population categories. These categories of errors were then assigned a probability of failure based on several general industry sources (CCPS, 1994; Stephenson, 1991; Swain, and Guttman, 1983; Blanchard, 2001; Petersen, 1996). These error rates are based on the Basic Error Rate concept of errors per 1,000,000 performances (Salvendy, 2006). These general industry error rates were then weighted and adjusted to account for the hospital's operating philosophies and system condition. With input from the monitoring technicians, the analyst then subjectively or semi-quantitatively weighted each probability per hospital practice, experience, and expectations (to increase or decrease the general population rates as appropriate).

Weighting factors were derived through a survey of all technicians whereby they were asked to respond to a series of questions characterizing their perception of the importance of each performance variable that could potentially impact their error performance. Variables such as amount of experience, level of training, quality of procedures, perception of work load demand, etc., were considered, with technicians assigning a value from 0.1 to 10 to each performance variable (Wincek and Haight, 2007). These survey results were averaged across all technicians and the resulting weighting factor was applied to each error probability taken from the general industry databases. This new error rate was then considered to determine the error likelihood for each defined alarm or system response. Finally, these error probabilities were used in a fault tree analysis to determine the overall probability of an adverse cardiac event occurring without it being treated (Clemens and Simmons, 1998). The weighted results provided more confidence among the technicians and hospital management that the probabilities used in the fault tree analysis more accurately represented the hospital's own probability of error rather than that of a large general industry group. Table 1 lists weighted probabilities for each error type.

Table 1: Fault Tree Basic Events and Error/Failure Reliability

Error #	Event/Error description	Database error description match or assumptions	Database error likelihood base rate	Weighted error probabilities
1	Patient suffers adverse cardiac event.	Patients experience 30-50 alarms per day, but all are not life threatening.	1.0	0.1
2	Telemetry monitor alarm setting does not affect alarm setting.	Instrumentation and control system alarm failure—alarm failure.	3.0×10^{-5}	3.0×10^{-5}
3	Monitoring system alarm fails mechanically or electronically.	Transmitter failure.	3.0×10^{-6}	3.0×10^{-6}
4	Monitoring system fails to detect out-of-range patient condition.	Programmable Logic Controller failure.	3.0×10^{-5}	3.0×10^{-5}
5	Technician is overloaded and fails to see or notice alarm.	Error of omission—10 plus activities.	1×10^{-3}	5.276×10^{-3}

Table 1: Continued

Error #	Event/Error description	Database error description match or assumptions	Database error likelihood base rate	Weighted error probabilities
6	Technician is distracted and fails to see or notice alarm.	Error of omission—10 plus activities.	1×10^{-3}	5.276×10^{-3}
7	Alarm turned off by nursing staff and not communicated to monitoring technician.	General error of commission.	3.0×10^{-3}	1.58×10^{-2}
8	Monitoring technician and nurse interpretive differences not effectively communicated.	Two person team—checking each other—miscommunication.	1×10^{-5}	5.267×10^{-5}
9	Technician or nurse sets alarm parameter range too wide to correctly represent the safe condition of a particular patient.	Technician sees out-of-calibration instrument as "in tolerance."	1×10^{-2}	5.267×10^{-2}
10	Patient becomes disconnected and technician fails to notify nurse.	General error of omission for items imbedded in a procedure.	3×10^{-3}	1.58×10^{-2}
11	Technician fails to recognize or understand signal.	Read signal—read or interpret incorrectly	5×10^{-3}	2.64×10^{-2}
12	Technician reads signal or alarm incorrectly	Read signal—read or interpret incorrectly.	5×10^{-3}	2.64×10^{-2}
13	Technician reads signal and interprets correctly but responds incorrectly	Error of commission—selecting wrong control.	3×10^{-3}	1.58×10^{-2}

The fault tree was built using an understanding of the individual contributions as well as the integration details of all machine and human components associated with monitoring the condition of the cardiac patients over time. Standard fault tree methodology (Clemens and Simmons, 1998; Clemens, 2002) was used to construct the tree. The analysis was completed using the above weighted probabilities, and the failure pathways were reduced using standard Boolean reduction techniques. The results were presented to hospital management to ascertain the tolerability of the error likelihood. Conclusions drawn and recommendations made were based on the position of the hospital administration and whether they were able to tolerate the probability of failure of the monitoring system to prevent the development of a critical cardiac condition going undetected and leading to the loss of a patient.

Results and Discussion

The results of this human reliability analysis indicate that, in this case, the probability that an adverse heart event would occur without being treated appropriately was relatively high—1.63×10^{-2} (or roughly 1.5 chances in 100). Through the analysis, it was determined that the most important contributors to this relatively high probability were the number of distractions in the monitoring area, the technician workload, and potential communication problems between monitoring technicians and nursing staff. Competency and training of the technicians was also identified as a significant contributor to the overall error probability. At the time of the analysis, it was conceivable that if the recommendations offered were implemented, the failure probability could be lowered by as much as one order of magnitude (to roughly 1 in 1000).

The human factors concerns with the monitoring system and its operation were identified during the analysis. Human factors such as room lighting, distractions, information processing load, station and screen layout, and training/qualification to task expectation match-up all contribute to the overall error rate of the system. Therefore, it was recommended that several improvements be considered. Recommendations included reducing the illumination intensity in the room from an estimated 80-100 foot-candles to 15-20 foot-candles; moving the unit to a room dedicated to the monitoring unit itself to eliminate copy machine, telephone, and general traffic distractions; creating a horseshoe arrangement for the four monitoring stations. The computer screen layout was recommended to be made consistent from station to station and with the control device layout. Computer screen content density reduction by ~20% to 40% (i.e., from

12 patients per screen to 8 patients per screen) was recommended, but not completely accomplished on a consistent basis (this remains a goal of the hospital). These considerations were implemented by the hospital over a two-year period and were made in an effort to improve the work environment with the expectation of improving system and human performance and reliability.

As of 2010 and after collecting performance data since 2006, the hospital reported no sentinel events that were addressed inappropriately, inadequately, and in an untimely manner. While it is difficult to measure the effect of any one or any combination of interventions in a safety context (because events that do not occur cannot be counted), ever-increasing time between events can be used as an anecdotal claim that the overall system changes had an effect. It is difficult to determine which intervention had the most effect or if any one intervention had any effect.

Conclusions

While further research could be done in this case to prove which and to what extent each intervention explains the reduction in events or the increase in time between events, it is not practical and may not be ethical to allow known adverse conditions that may put a patient at risk to exist or to continue for the sole purpose of holding a variable constant. For this reason, anecdotal evidence only, but with solid experience and a strong sense of reasonableness, will act as proof that the interventions accomplished their objectives.

In 2010, hospital staff stated that the results of these analyses and subsequent implementation of recommended system improvements continue to aid hospital management in making the decisions necessary to ensure that monitoring system performance continues at a level necessary to protect patients 24 hours a day.

Since one of the objectives of this paper was to suggest the use of these human reliability techniques to analyze performance in other similar industry applications, a listing of the techniques is important. They are listed here in order of accomplishment:

- Site assessment—visual evaluation of the work station layout and structure.
- Comparison of work station layout and structure to recognized good engineering and ergonomic standards and practices.
- Task analysis to identify and quantify distraction level, information processing load, lighting levels, and communication demands.
- Comparison of cognitive variable levels to recognized good cognitive engineering practices and standards.
- Identification and characterization of potential errors and system failures, mapped to a recognized general industry error probability database, followed by weighting of those error probabilities for use in a system and fault tree analysis based on human reliability. A better, but more difficult, approach is to collect site-specific error data from one's own operations to determine internal and more exacting error rates.
- Analysis and characterization of human and system reliability through fault tree analysis.
- Consideration by management of the tolerance for failure probability and subsequent implementation of system improvement recommendations to increase system reliability levels that management can accept.

It is important to note that the above approach can be used on any application in which human operators have to evaluate and interpret process feedback, make decisions based on that feedback, and then respond to that feedback to ensure successful operation. The analytical techniques used here are not constrained by industry type. Any human-machine interface-based system can be analyzed using the techniques described in this particular study. Future research at NIOSH is being developed for proposal to apply this human reliability analysis model to mining applications, such as in mineral and coal preparation plant control systems, as they become more automated and more complex over time.

Disclaimer

The findings and conclusions in this paper are those of the authors and do not necessarily represent the views of the National Institute for Occupational Safety and Health. Mention of company names or products does not constitute endorsement by the Centers for Disease Control and Prevention.

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