Evaluating a Medical Error Taxonomy

Juliana Brixey MSN, MPH, RN[1,2], Todd R. Johnson, PhD[1], Jiajie Zhang, PhD[1]
[1]The University of Texas Health Science Center at Houston
School of Health Information Sciences, Houston TX
[2]The Methodist Hospital, Houston TX

ABSTRACT

Healthcare has been slow in using human factors principles to reduce medical errors. The Center for Devices and Radiological Health (CDRH) recognizes that a lack of attention to human factors during product development may lead to errors that have the potential for patient injury, or even death. In response to the need for reducing medication errors, the National Coordinating Council for Medication Errors Reporting and Prevention (NCC MERP) released the NCC MERP taxonomy that provides a standard language for reporting medication errors. This project maps the NCC MERP taxonomy of medication error to MedWatch medical errors involving infusion pumps. Of particular interest are human factors associated with medical device errors. The NCC MERP taxonomy of medication errors is limited in mapping information from MEDWATCH because of the focus on the medical device and the format of reporting.

INTRODUCTION

According to the Institute of Medicine, medical errors rank as the eighth leading cause of death in the United States.[1] Other high-risk industries such as aviation and nuclear power plants have reduced errors by applying human factors engineering – a discipline that designs software, devices, systems, and policies to increase worker efficiency and decrease human errors. This reduction was possible, in part, from the ability to collect, and share with outsiders, data on errors and incidents that occur within an organization. In contrast, healthcare has a history of shame and blame for errors. Due to a culture of secrecy and an indifference to safety, healthcare lags behind in reporting and reducing errors. Healthcare has been slow in using human factors principles to reduce medical errors. The U.S. Food and Drug Administration—Center for Devices and Radiological Health (CDRH) recognizes that a lack of attention to human factors during product development may lead to errors that have the potential for patient injury, or even death.[2] Therefore, it is critical to understand the underlying human factors mechanisms that cause medical errors. Equally important is understanding how a person's work environment contributes to and even induces those errors.

This research evaluates the utility of the NCC MERP taxonomy of medication errors for coding human and system factors from medical device error reports received by the FDA involving infusion pumps and attributed to user error. The primary research question was how well the NCC MERP could capture human and systems factors that contributed to user error. A secondary question was to characterize the kind of human and systems factors information available in the FDA's databases. Because the FDA data collection forms do not specifically ask for such information and because an awareness of the importance of such factors in healthcare appears low, we expected to find very little.

Central to the development of medical error reporting is a need for a controlled vocabulary and taxonomy. In response to reducing medication errors, the National Coordinating Council for Medication Errors Reporting and Prevention (NCC MERP) released a medication error taxonomy.[3] Released in 1999, this taxonomy provides a standard language and structure of medication error-related data for use in developing databases to analyze medication errors. The NCC MERP taxonomy is available for download from the World Wide Web. NCC MERP does not charge for use of the taxonomy. Due to the newness of the taxonomy, little research has been conducted to evaluate its usefulness.

The NCC MERP medication error taxonomy is organized into eight major categories:

1. patient information
2. medication error event
3. patient outcome
4. product information
5. personnel involved
6. type of medication error
7. causes
8. contributing factors

Each category has numerous attributes to be selected or completed about the error. In Category 1, patient demographic information is requested. Category 2 is concerned with the specifics of the medication error event. The description of the event is a free text entry field. Category 3 requests information about the patient's outcome. Information about the product that

was actually or potentially given is classified in Category 4. The personnel involved in the error are classified under Category 5. In this category, information about who made the initial error is identified as well as who perpetuated the error. In Category 6, the type of medication error is categorized by such occurrences as dose omission, improper dose, and wrong route of administration, wrong rate, and monitoring. Category 7 identifies communication, name confusion, labeling, and human factors that contributed to the error.Although human factors are known to contribute significantly to medical errors, the role has not been well studied in healthcare compared to other industries.[4] This has hindered both identification and understanding of human factors in medical errors. The FDA recognizes that individual performance is influenced by knowledge about a device, cognitive abilities, sensory capabilities, previous experience with devices, size and strength, and coordination. Environmental factors such as light, noise, distraction, motion, and workload have an effect on individual performance.[5] Category 8, the contributing factors, is important because it recognizes that the healthcare environment can contribute to errors. According to Leape et al[6]., a major breakthrough in the study of errors was the recognition that system factors influence the performance of an individual. Successful techniques of error avoidance require insight and awareness of potential error-causing system defects. Flawed system design has two outcomes: it causes user errors, and it makes them difficult to detect in time to prevent the error. Within healthcare, the usual response has been to focus on the error and not the systemic cause. It is proposed that correction of the system deficiencies will most likely result in a reduction of errors.

The literature contains a number of reports on user errors involving medical devices. In all cases, these reports indicate that more problems are caused by user error than device failure. For instance, one study showed that 82% of all preventable medical errors involving anesthesia devices was due to human error.[7] Other data suggests that patients may be 3 to 10 times more at risk due to user error than device failure.[8] One study of errors involving infusion pumps found that the most frequent cause of patient harm was user error and inadequate device education.[9] Bogner notes that human factors errors are more likely to occur in the use of technologically advanced devices such as programmable infusion pumps and that remedial efforts often focus on users when the real problems arise from faulty design. In addition, Bogner states that "devices that are not designed for ease of operation can be difficult to operate safely and effectively, leading to errors.[10]

To track medical device failures, the FDA maintains publicly searchable databases for medical devices. The Medical Device Reporting Program (MDR) database contains reports on medical devices which may have malfunctioned or caused death, or serious injury from 1984 – to 1996.[11] The Manufacturer and User Facility Device Experience Database (MAUDE) contains voluntary reports of adverse events involving medical devices since June, 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August, 1996.[12]

FDA receives the medical error reports via the MedWatch form from consumers and health professionals. Clinicians and lay people are encouraged to voluntarily report significant adverse events with medical products. Healthcare organizations are required to report suspected medical device related deaths to both the FDA and the manufacturers. All confidential information is removed from the report before posting.

METHODS

Using search terms "volumetric infusion pump" and "user error", the MAUDE was queried. The query returned 73 reports from April 1992 thru December 31, 2001. The reports were coded and entered into an Access® Database. Tables for the database were constructed based on the categories in the NCC MERP taxonomy with two exceptions. Two additional tables were designed for human factors and devices. This was done for ease of coding human factors and device errors. This did not result in any change to the original taxonomy. The Access® database was analyzed for coding of information given in the medical device error reports.

RESULTS

The query returned 73 reports for the terms volumetric infusion pump and user error. Two reports were determined to be duplicates and were discarded. The remaining 71 reports were analyzed. Data were coded from the 64 fields of the Medwatch form for reporting medical errors to MAUDE. In Category 1 for patient information, no patient information was reported. All patient identifiers are stripped before making the information public. Identifying names of healthcare organizations are not made available.

In Category 2 for medication event, only one report had the actual date of the error. The MedWatch report has the date that the manufacturer was notified and the date that the FDA received notification. Five reports included the time of the error. In 60 reports (82.2%), the hospital was identified as the type of healthcare facility. This information was found in the

free text section. Thirteen reports (17.8%) provided no information about the setting of the error. Three reports specified the area of the hospital that the error occurred such as the emergency room (ER) or an intensive care unit (ICU). All reports had a free text description of the error. The degree of detail varied from a few words to an in-depth description.

In Category 3 for patient outcome, sixty reports (82.2%) reported a patient outcome. In Category 4 for product information, the name of the medication involved with the infusion pump error was identified in twenty-eight records (38%). No additional product information was reported.

In Category 5 for personnel involved, nurses were identified as making the error in eight cases and patient/caregiver in one incident. Five recorded who perpetuated the error and nine logged who discovered the error. In fifty-eight records, the device operator was referred to as a health care professional. In three records, the device operator was named as other health care professional.

In Category 6 for the type of error, 64 reports were recorded. Fifty-four records documented that the infusion was delivered too fast. Another six records indicated that infusions were delivered too slowly. Four reports logged the wrong rate.

All reports selected for this project were attributed to user error due to human factors. However, the reports failed to state specific human factors that may have led to the error. In our analysis, 36 records were classified as performance deficits based on details of the electronic logs in the free text of the MedWatch report. The human factors issues leading to the remaining user errors could not be coded in the NCC MERP taxonomy, except as free text. All reports for this project involved infusion pumps. While the medical device error was attributed to user error, thirty-eight records reported a possible device malfunction; however, as indicated below only one pump was found to be malfunctioning. One record reported that systems factors contributed to the error by a lack of training.

In reading the free text description of the event, we noted the following:

- In one error more than one pump was involved
- In one error a multipurpose pump was involved
- Multi-channel pumps were involved in three errors
- Problems with pump tubing led to four errors
- Administration of a secondary medication was cited in four errors
- Problems with programming pumps were reported in eleven errors
- Free flow of fluids contributed to four errors
- Eighteen electronic logs downloaded from the infusion pump memory indicated problems with programming the pump
- Sixty-one reports indicated that the pump was either investigated, visually inspected, tested, or evaluated by the manufacturer, the hospital biomedical engineering department, or a third party for malfunction but could not confirm the malfunction and therefore attributed the problem to user error
- One investigation determined an actual malfunction of the infusion pump
- Two reports acknowledged pump design that could contribute to user error
- 26 reports recommended additional training, education, or reading the operating manual as an intervention to reduce or prevent error

DISCUSSION

This study demonstrates the difficulty in coding medical device errors with the NCCMERP taxonomy of medication errors. An error involving an infusion pump is both a device use error and a medication error involving the use of a device. This type of event requires a reporting form and taxonomy that will handle complex medical errors.

Reporting of medical errors without understanding the role of human factors in medical errors continues to perpetuate unsafe healthcare. From the perspective of cognitive science and human factors, medical errors occur in large part due to inadequate information processing in cognitive tasks.[9,13-15] However, the deficit in cognitive processing is often due to poor device design and environmental factors that induce people to make errors. In order to prevent or greatly reduce medical errors it is critical to understand the underlying cognitive mechanisms that cause medical errors and how a person's work environment (physical, social, cultural, & cognitive) contributes to and even induces those errors.

The MedWatch is highly structured for reporting medical device errors. This is important for identifying potentially unsafe medical devices in use. However, the form asks no information about human factors. The free text section and the electronic log from the infusion pumps provide limited information about possible contributing human factors. Completing the free text section to record user error requires that the reporter know and understand how human and systems factors contribute to medical

errors. Research indicates that the frequency and consequence of hazards resulting from medical device use attributed to user errors far surpass those resulting from device failures.[7] Furthermore, the FDA suggests that user error can be reduced by the systematic and careful design of the user interface, i.e., the hardware and software features that define the interaction between users and equipment. However, the results of our study demonstrate that the current MedWatch reporting form is inadequate in coding user error related to the user interface. As a result, these reports provide little feedback to help device manufactures make safety improvements to the user interfaces of their devices.

The NCC MERP taxonomy was designed for reporting a medication error. It lacks robustness and specificity for recording device errors associated with a medication error. One useful feature of the NCCMERP taxonomy in understanding medical errors is that it explicitly pays attention to the role of human factors and contributing systems factors. However, its human factors codes are far from sufficient to characterize the causes of user errors reported in the MedWatch database. As noted above only around half of the human factors causes could be coded in the NCC MERP taxonomy, and these had to be coded using the single code "performance deficit." Coding the causes of user errors as a performance deficit masks the underlying causes that led to the deficit, making it difficult to see how to prevent the problem from occurring again.

Analysis of the user errors from the MedWatch database reveals several problems relating to human and systems factors. The large number of reports in which pumps were suspected to be malfunctioning, but found to be functioning correctly, as well as the large number of programming errors, indicates that users often have difficulty understanding or using the devices. Instead of blaming these difficulties on the users, the manufacturers should investigate the source of these difficulties and redesign their devices to prevent them.

The fact that errors were attributed to the user in devices that were not found to be malfunctioning, along with the many reports that recommend additional training or reading the manual, reflects a poor understanding of how device design and the environment in which the device is used may contribute to user errors. Suggesting that users should receive more training or read the manual overlooks the fact that even well-trained individuals may make mistakes given poor device design or certain environmental factors (such as poor lighting or a high workload). Whenever a device error is attributed to the user, hospital staff and manufacturers should determine whether the device or environmental factors induced or contributed to the error. Sadly, many of the reports end the analysis once user error is determined and make no attempt to determine whether device design or systems factors may have contributed to the error. User training is certainly an important component to safe medical device use, but reducing the chances of user errors through careful device design and environmental changes is a better approach for improving safety while simultaneously decreasing training time.

CONCLUSION

We evaluated a taxonomy (NCC MERP), an error reporting system (MedWatch form), and the mapping between them.

The NCC MERP taxonomy is comprehensive and it is good for certain data collection and archiving purposes. However, it is not based on a systematicapproach, a theory of errors, or an approach that can categorize errors not only for archiving and statistics but also for generating interventions of error reduction. One good feature of NCC MERP is its explicit inclusion of human factors. However, its treatment and presentation of human factors are far from sufficient. In our opinion, human factors are one of the most fundamental causes of medical errors. A systematic treatment of human factors is essential for a useful taxonomy that has values for interventions.

The MedWatch error reporting system is mostly based on free text in an unstructured format. Medical error data collected in this way are rarely useful for the detection of patterns, discovery of underlying factors, and generation of solutions, because user entered free text do not contain the right types of information needed for interventions and is difficult to analyze in a systematic way. Medical error reporting systems should not be merely record keeping systems. They should be systems for the identification of problems and generation of solutions.

The NCC MERP taxonomy of medication errors cannot be mapped to the structured entries of the MedWatch form and can only be partially mapped to the free text description with effortful hand coding of the contents in the free text. The free text gives an unstructured account of the medical error in the reporter's own words but presents problems in coding using a standard taxonomy. The NCC MERP taxonomy is limited in coding specific details of a

medical device error. In order to expand its utility, the NCC MERP taxonomy should be expanded for more detailed coding.

Partially in response to the problems with NCC MERP taxonomy and the MedWatch reporting system, we developed a preliminary cognitive taxonomy[16] of medical errors that may be developed (1) to categorize all types of errors along cognitive dimensions, (2) to associate each type of error with a specific underlying cognitive mechanism, (3) to explain why, and even predict when and where, a specific error will occur, and (4) to generate intervention strategies for each type of error. One important practical implication of this cognitive taxonomy is that it can provide systematic, principled methods for the design of medical error reporting systems that can capture information not just for record keeping and statistics but also for the identification of problems and generation of solutions. We are currently developing an online medical error reporting system that is based on the cognitive taxonomy we have been developing. In this system, questions and inquiries are generated to encode cognitively relevant information; the categorization of errors is along relevant cognitive dimensions; and it is designed to generate immediate recommendations on possible intervention strategies.

ACKNOWLEDGEMENTS

This study was supported by a training fellowship from the Keck Center for Computational and Structural Biology of the Gulf Coast Consortia (NLM Grant No. 5 T15 LM07093), and National Medical Technology Testbed (Grant No.DAMD17-97-27016).

REFERENCES

1. Kohn, LT, Corrigan, J M, Donaldson, MS. *To Err is Human*. Washington, D.C.: National Academy Press; 1999.
2. Sawyer, D, Aziz, K J, Backinger, CL, Beers, E T, Lowery, A, Sykes, SM, Thomas, S, Trautman, K.A. Do it by design: An introduction to human factors in medical devices, U.S. Department of Health and Human Services. Public Health Services, Food and Drug Administration, Center for Devices and Radiological Health; 1996. Available at: http://www.fda.gov/cdrh/humfac/doit.html. Accessed April 1, 2001.
3. NCC MERP. Taxonomy of Medication Errors. National Coordinating Council on Medication Error Reporting and Prevention. 1998. Available at: http://www.nccmerp.org/taxo0514.pdf Accessed April 1, 2001.
4. Leape, LL. Error in medicine. JAMA 1994 272(23):1851-1857.
5. Food and Drug Administration: Center for Device and Radiological Health. Medical device use-safety: Incorporating human factors engineering into risk management. 2000. Available at: http://www.fda.gov.cdrh.humfac/1497.html Accessed January 20, 2002.
6. Leape, LL, Bates, DW, Cullen, DJ, Cooper, J, Demonasco, HJ, Gallivan, T, Hallisay, R, Ives, J, Laird, N, Laffel, G, Nemeskal, R, Peterson, L A, Porter, K, Servi, D, Shea, BF, Small, SD, Sweitzer, BJ, Thompson, BT, Vliet, MV. Systems analysis of adverse drug events. JAMA 1995 274(1): 35-43.
7. Cooper, JB, Newbower, RS, Long, CD, McPeek, B. Preventable anesthesia mishaps: a study of human factors. Anesthesiology 1978 49(6):399-406.
8. Grant, L. Medical equipment. Devices and desires. Health Service Journal 1998 109(5603) :34-35.
9. McConnell, EA, Cattonar, M, Manning, J. (1996). Australian registered nurse medical device education: a comparison of simple vs. complex devices [published erratum in Journal of Advanced Nursing 1996 July; 24(1):221]. Journal of Advance Nursing 1996 23(2) : 322-328.
10. Bogner, MS. Human error in medicine. Hillsdale, NJ: Lawrence Erlbaum Associates, Inc: 1994.
11. Food and Drug Administration: Center for Devices and Radiological Health. MDR data files. 2001. Available at: http://www.fda.gov/cdrh/mdrfile.html Accessed April 15, 2001.
12. Food and Drug Administration: Center for Devices and Radiological Health. Manufacturer and User Facility Device Experience Database (MAUDE). 2001. Available at : http://www.fda.gov/cdrh/maude.html Accessed April 15, 2001.
13. Norman, DA. Categorization of action slips. Psychological Review 1981 88:1-15.
14. Reason, J. Human Error. Cambridge University Press; 1992.
15. Woods, DD, Johannesen, L, Cook, RI, Sarter, N. Behind Human Error: Cognitive Systems, Computers and Hindsight. Crew Systems Ergonomic Information and Analysis Center, WPAFB, Dayton, OH; 1994.
16. Zhang, J, Patel, VL, Johnson, TR, Shortliffe, EH. Toward a cognitive taxonomy of medical errors. (In press) AMIA2002.