CATEGORIZING ADVERSE MEDICAL DEVICE AND MEDICATION EVENT FREQUENCY

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Much of the research interest in reducing adverse medical events emphasizes medical device interfaces and software design. Infusion pump programming has enjoyed particular research attention. This study categorized 1260 adverse medical event reports at three Midwestern hospitals. Although an important contributor, infusion pump programming contributes to fewer adverse events than the amount of literature implies. More common problems involve opening the intravenous infusion piggyback clamp and medication identification.

INTRODUCTION

Frequently, human factors practitioners focus on improving the interface design of a device in order to prevent adverse events. The adverse medical event prevention literature focuses primarily on medical device use and design, particularly infusion pump programming (Gagnon et al., 2004; Lamsdale et al., 2005; Rothschild, Keohane et al., 2005). However, a structured analysis of internal occurrence reports from Iowa Health – Des Moines, a three hospital, 1140 bed medical system, indicates infusion pump programming problems constitute only a small percentage of the human factors issues confronting the medical domain. This study suggests that to prevent adverse medical events, human factors research must be broadened in scope and consider the plethora of other challenges related to the safe, reliable and effective use of medication devices.

Occurrence Reports

Currently, all medical facilities use an internal occurrence reporting system to facilitate clinical quality improvement and to comply with federal law. Occurrence reports are generated in response to unexpected or undesirable clinical issues, ranging from medication errors to device malfunctions to holes in new latex gloves. In Iowa Health – Des Moines, the occurrence report system has been in place in all departments for over eight years. These reports generally record structured information regarding the people, devices, and medications involved in the event, the time of day, and the procedure being performed along with an unstructured narrative of the event. These reports are typically completed by a staff member who was either directly involved or was witness to the event. Often the reports, particularly the narrative fields, contain the minimum amount of information necessary to convey the general story to the reader. Rarely do the structured report fields describe the cause of the event. However, a structured analysis of the narratives may reveal the frequency of each error and shed light on the cause of the adverse event.

ANALYSIS METHOD

This project was undertaken in an effort to help Iowa Health – Des Moines identify human

factors-related risks to patient safety caused by medical devices, which, in recent years, have become the center of much scrutiny (FDA, 2003; Ginsburg, 2005; Gosbee, 2002; Keselman et al., 2003; Lin, 2001; Zhang, 2003). Specifically, the project focused on the identification of medication delivery device-related issues that might be mitigated by interface design or training.

Initial Analysis

The event report database was filtered for reports concerning medication or devices, which yielded 12,600 reports. The most recent 10% (1260) of these reports, dating back approximately 12 months, were then categorized according to the decision diagram in Figure 1. Most reports were flagged for further analysis to further categorize the occurrence or because more information was needed.

Categorization Process

An initial survey of a sample of reports was conducted which recorded the types of occurrence in a general sense (e.g. communication between units). Information gained from this survey was used to specifically categorize the medication or medical device data based on the specific device or procedure involved. Five general classes of occurrence types became apparent through the sub-categorization process. These classes were hardware and setup, pump software, medication or patient identification, medication dispensers, and communication (including documents). Each occurrence was placed into a particular type class, capturing the specific classification as well as outcome severity information which resulted in a structured, frequency-based categorization of the types of events.

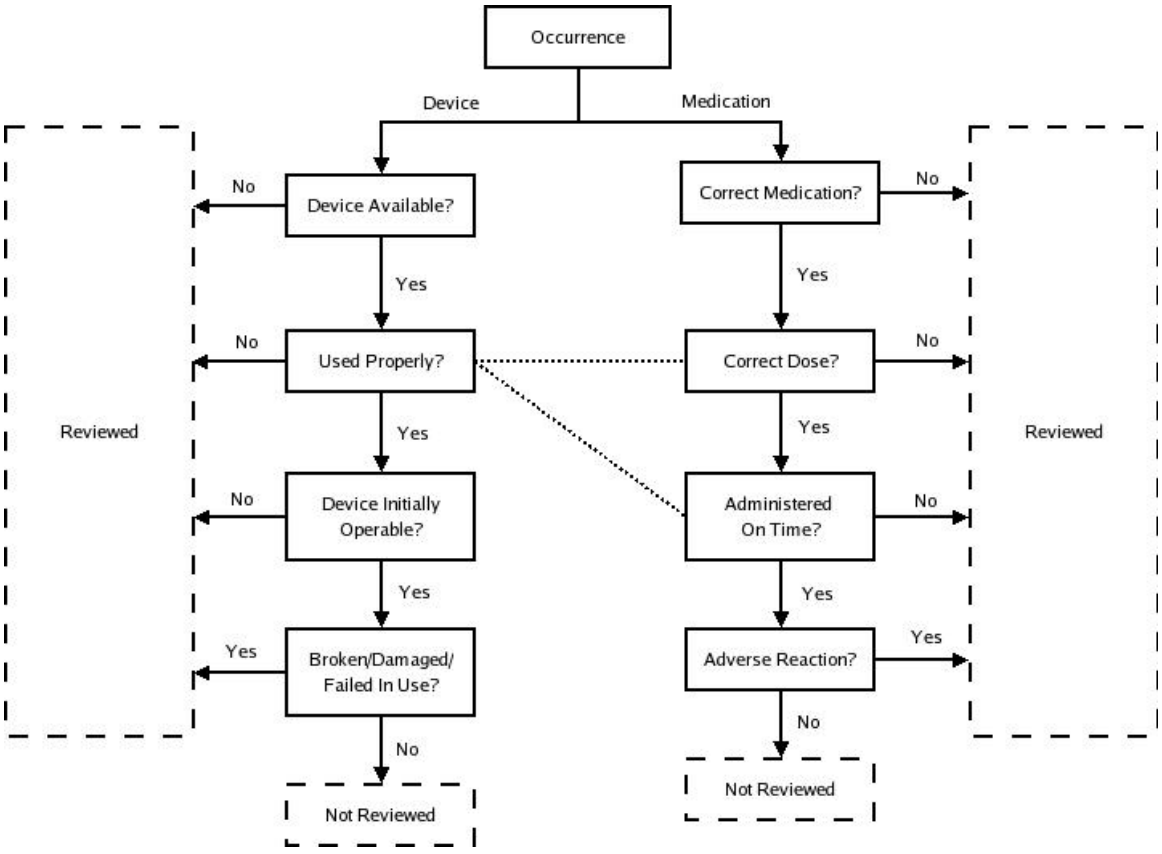

Figure 1: Decision flowchart for occurrence report narrative analysis. This flowchart was used to generally capture the occurrences which needed to be further investigated.

Occurrence Classes

Each report contained fields denoting whether the occurrence involved medications or devices, which facilitated the initial classification. The occurrence was then categorized further according to the particular occurrence details. The Hardware and Setup class contained errors in which the pump tubing was not loaded correctly, bags hung improperly, or the hardware was not applied properly to the patient. Each of these errors was captured within a separate subcategory. The Pump Software class contained errors such as the medication dose was programmed incorrectly, the user became confused when using the device, or unit conversion calculations were wrong. Identification of patients and identification of medication are two issues that are inherently related and so formed another class of errors. The cause of these errors could be attributed to font or label size, label or text color, or look-alike and sound-alike medication or patient names, or container similarity. Medication Dispensers is a broad class, capturing errors which occur during the interaction between the medication dispenser machines and the user, such as the machine not operating as the user anticipated, as well as errors that occur within pharmacy operations, generally regarding efficiency and double checking. The Communication class is also very broad, capturing errors relating to inter- and intra-department communications, legibility, duplicate forms, conflicting orders, and adherence to protocol.

Category Analysis

The total number of categorized occurrences was used to calculate the incidence frequency by occurrence type. Limiting the occurrences to those that could reliably be categorized reveals the potential benefit of focusing research efforts in those categories. Particular attention was given to medical devices in this study, but other categories were noted. The analysis of the occurrence reports also did not include severity ratings because most of the occurrence reports rated severity of injury as “unknown” or “no injury”. There were very few occasions in which any other rating option was selected and these few arose over all occurrence classes.

RESULTS

Of the 1260 reviewed reports, 183 reports (14.5%) contained an error in the occurrence that could be categorized, while an additional 163 reports (12.9% of reviewed reports) were too vague to make a definite categorization. The vague reports were excluded from the analysis. Additionally, there were 309 reports that fell solely into the communication category, which account for approximately 25% of all reports reviewed. The communication reports also were not included in the analysis.

The report frequency of each category and sub-category of occurrence types can be found in Table 1. The percentages are based on the 183 occurrence reports which were categorized as having definitive relevance. The three most frequent occurrences were: failure to open intravenous infusion “piggyback” medication bag clamp (23.1%), medication identification failure (13.7%), and pump (predominately intravenous pump) programming (11.5%). Following at 9.9% include IV hardware setup, medication dispenser issues, and pharmacy related issues.

DISCUSSION

Table 1 reveals that adverse medical events do not occur solely within one focus area, but range across many domains. It also suggests that many areas would benefit from further human factors research. The highest frequency single occurrence related to human factors in the Iowa Health – Des Moines system is the failure to open the intravenous infusion piggyback clamp (23.1%), which has not been well documented and researched within the existing literature. This challenge also indicates that researchers should extend their focus to the physical product design and design of associated periphery

products rather than limit their investigation to the interface design. This high frequency of IV hardware setup errors underscores the importance of the extended design.

Table 1: General category type frequencies followed by sub-category frequencies. The percentages are based on the total number of categorized occurrence reports.

Categories	Percentage of Categorized Occurrences
Hardware/Setup	**40.1%**
IV	9.9%
IV Clamps	23.1%
Epidural	1.7%
PCA	1.7%
Pulse Oximeter	0.6%
Mini Infuser	1.1%
Intralipid Pump	0.6%
Feeding Pump	1.1%
Ventilator	0.6%
Pump Software	**15.4%**
Programming	11.5%
Interaction	3.3%
Calculations	0.6%
Identification	**23.1%**
Medication	13.7%
Patient	9.3%
Med Dispensers	**21.4%**
Dispenser Related	9.9%
Pharmacy Related	9.9%
Calculations	1.7%

The second highest frequency of occurrence (13.7%) was medication identification failure. Human Factors researchers would perform a great service by developing medication labeling guidelines that reduces confusion leading to the administration of incorrect medicines and dosages.

The popular pump programming research topic was the third most frequent error (11.5%). Semi-automatic medication dispensers accounted for a surprising large share of the medical device events (9.9%), suggesting that significant benefits could be derived from further human factors research in this area as well.

Although not included in this analysis, the 309 reports that fell into the communications category suggests that communication between health care practitioners remains an important problem that may benefit from study by human factors practitioners.

This project suggests that the need for human factors research in the medical domain continues to be high. The study of event reports suggests that more research emphasis is needed in the areas of IV pump peripheral devices, medication labeling, medication delivery machines and hospital communication protocols. In order to curb adverse medical events, human factors research needs to be broadened to encompass all aspects of the medical domain. The results presented here suggest that nearly 40% of adverse event reports are related to factors that may be alleviated with better human factors designs. Focusing research efforts in these areas will improve health care safety and reliability, ultimately saving lives.

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