EFFECTIVENESS OF MEDICAL INCIDENT DATABASES AS TOOLS FOR ADVERSE EVENT ANALYSIS

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INTRODUCTION

With the publication of the Institute of Medicine's *To Err Is Human* report in 1999, there has been a push to improve patient safety practices[1]. Towards this goal, the report strongly recommended the implementation of incident reporting systems[1]. High-risk industries such as aviation have been using incident reporting systems since the 1950's to collect error and near miss reports to identify, evaluate, and understand the types and trends of incidents[2]. Analysis of the collected reports then aims to guide recommendations for system and safety improvements. The medical community lagged in its timeline to adopt widespread incident reporting, but in the past two decades the role of incident reporting in healthcare has grown substantially[3]. Currently, incident reporting systems are integrated into many hospital risk management departments in countries such as Canada, the United States, Australia and the United Kingdom.

Top priority in healthcare safety literature on incident reporting systems has been given to improving incident reporting rates from healthcare practitioners and the barriers therein. The promotion of an open and fair non-punitive reporting environment rather than a culture of blame has been discussed at length as a vital necessity to promote reporting without fear of punishment[2]. While encouraging reporting and obtaining reports is important, limited attention in the literature has been paid to the use of incident reports for trending analysis once stored within reporting systems[4]. This is a key aspect of reporting systems as it allows for the monitoring of trends and patterns in patient safety issues. This aspect of reporting systems also enables learning from common events and devising strategies to mitigate future occurrences. In general, incident data is simply accumulated in healthcare and not effectively used[5]. The information presented in incident reports has the potential to be used to assess the range of incidents associated with healthcare practices.

For this study, incidents linked with the practice of delivering multiple intravenous (IV) infusions were examined. Medication related events have been found to contribute to 23.6% of all reported adverse events in Canada and medications given by IV lines are very common in hospitals[6-7]. Multiple IV infusions refer to the administration of several IV medications to a single patient simultaneously, in quick succession, or as a secondary infusion. Multiple IV infusion setups can involve complex operational sequences, increasing in complexity with the number of medications given, and often are given to high-risk, critical care patients. Also, the use of infusion pump technology to assist in the delivery of IV medication adds technological complexity to the setup. This makes it easy for errors to occur, either as the result of cognitive or technological factors. Studies have found that clinicians made a variety of errors that prevented them from successfully completing simulated secondary infusion tasks[8-9]. Incidents associated with multiple IV infusion errors have resulted in serious patient harm[10-11].

The aim of this study is to explore two databases and assess how the nature of the database affects the type of information and incidents presented within the reports. The databases' usefulness at capturing information, such as cause, location, and patient impact, was investigated to assess their effectiveness as an incident analysis tool for healthcare. To this end, multiple IV infusion incidents were used as the focus for this study.

METHODS

The FDA's Manufacturer and User Facility Device Experience (MAUDE) database and ISMP Canada's Medication Incident Database were searched for reports related to multiple IV infusion incidents. The MAUDE database can be accessed by the general public and collects reports of events in which a medical device may have been involved in an incident[12]. Mandatory reporting is required by device manufacturers and users for incidents in which medical devices may have malfunctioned or caused serious injury or death. The ISMP Canada database is a voluntary system that collects reports from hospitals and individual practitioners of incidents and near miss events which involve some form of medication error, including equipment and procedural issues. The ISMP Canada database is only accessible by ISMP Canada, who regularly publish safety bulletins updating the general public on their findings.

The databases were filtered using a large Boolean search term consisting of keywords related to multiple infusions, IV therapy, and IV equipment. Due to the large size of the MAUDE database, only incident reports from one year (2008) were extracted, whereas the entire ISMP Canada database was searched (May 2000 to April 2010).

Researchers from ISMP Canada and the Centre for Global eHealth Innovation developed a common coding scheme to apply to the search results. A two pass approach was used in coding the reports returned from the keyword search. The first pass coded the reports' applicability as a multiple IV infusion incident, location, and patient impact, and the second pass was used to categorize the error type of the applicable reports.

Inter-rater reliability was established for each coding pass to statistically demonstrate uniformity between the coders so that the databases and reports could be divided amongst the members of each team. Prior to each coding pass a subset of trial MAUDE reports from years other than 2008 were coded independently by each rater and a Fleiss' Kappa test was used to assess reliability. A kappa value of 0.6 (a substantial level of agreement) was used as the minimum value acceptable to establish inter-rater reliability. If below this kappa value, the raters would discuss and resolve disagreements and modify the coding definitions to arrive at a uniform agreement on the coding categories. Trial reports were used until a minimum kappa of 0.6 was obtained and then 30 reports from the actual database of interest were coded to establish the inter-rater reliability. Two researchers from ISMP Canada and three from the Centre for Global eHealth Innovation reviewed and categorized the ISMP Canada database and MAUDE database respectively. The researchers involved had multi-disciplinary backgrounds which included nursing, pharmacy, human factors, and clinical engineering.

RESULTS

The initial keyword search of the databases revealed 3,486 reports in the MAUDE database and 1,320 in the ISMP Canada database. Of these reports only 211 (6%) from the MAUDE database and 424 (32%) from the ISMP Canada database were relevant to multiple IV infusions (see Figure 1). Another 12% from the MAUDE database and 51% from the ISMP Canada database were suspected to be linked to multiple IV infusion incidents based on the medications involved, but lacked sufficient

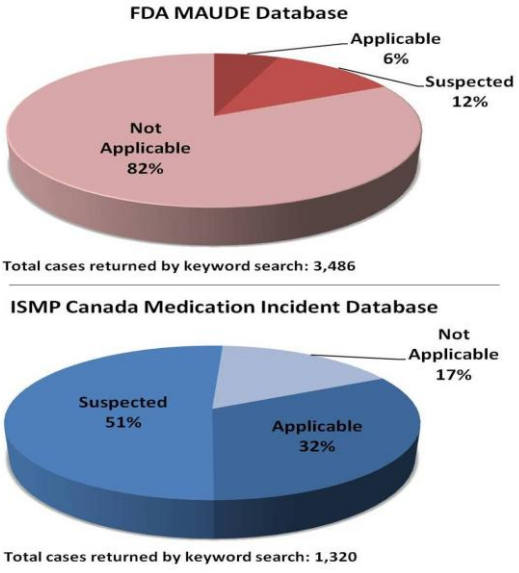

Figure 1: Keyword search results - applicability as a multiple IV infusion incident

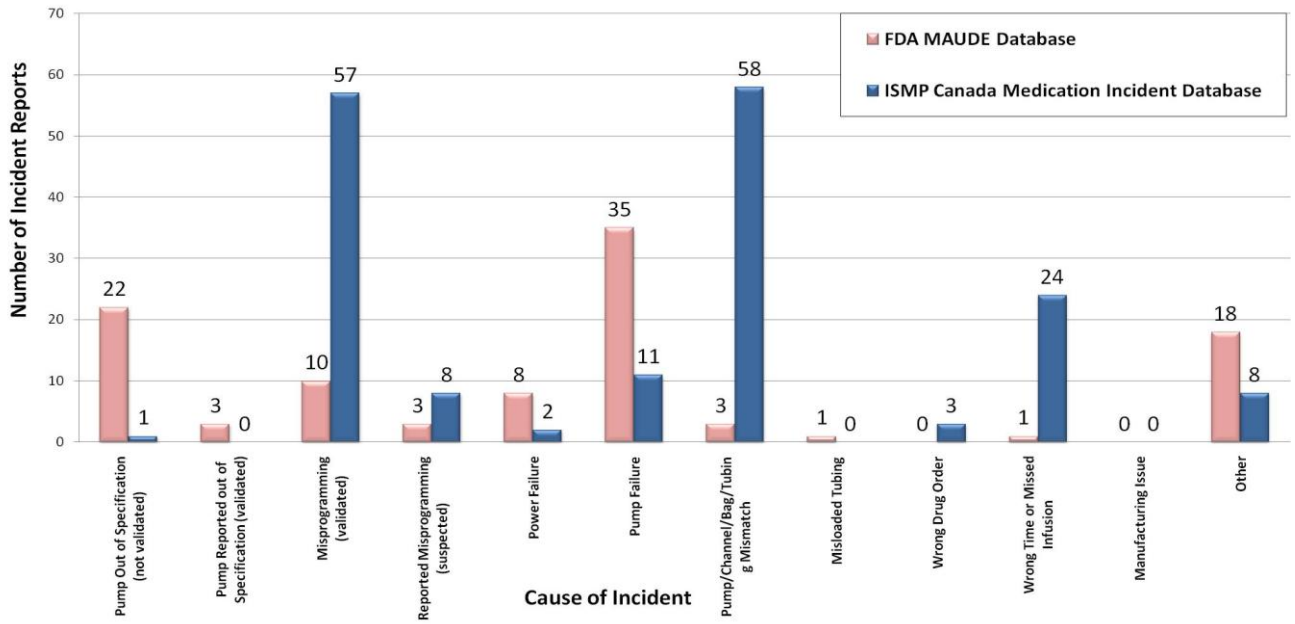

Figure 2: Distribution of the IV infusion pump related incident reports between the MAUDE and ISMP Canada database

information to be conclusive and were therefore not used in the analysis. The remaining reports were determined to not be multiple IV infusion incidents.

A majority of the applicable incidents from both databases occurred in a hospital environment (59% in the MAUDE database and 99% in the Medication Incident database). In the MAUDE database 41% of the incidents were associated with some form of harm to the patient, 3% with a patient's death, and 32% with no patient harm. In the ISMP Canada database harm was noted in 8%, death in 3%, and no harm in 73% of the applicable reports. The remaining reports in each database were associated with hazardous situations, near misses, or unknown patient impacts. A variety of incident causes were found between the two databases and were distributed across components of the IV setup, such as the IV bag, tubing, access site, and infusion pump. Figure 2 shows an example of incident causes found in the two databases, specifically those found to be associated with the infusion pump.

DISCUSSION

There was a distinct division seen between the two databases due to their different definitions of a reportable incident. While both captured incidents related to multiple IV infusions, they tended to capture different types, with neither alone providing a comprehensive list of multiple IV infusion errors. MAUDE incident reporting is more focused on the equipment involved in an incident, and often reported a perceived equipment failure. The ISMP Canada Database focused on reporting medication errors, including the user processes, so more errors were seen due to IV setup confusion or infusion pump misprogramming. Figure 2 highlights these differences by showing how reports from the two databases were distributed between incidents caused due to infusion pump issues. The MAUDE database reported substantially more issues with the pump being out of specification and failing than the ISMP Canada database. Meanwhile, the ISMP Canada database had many more incidents reported that were caused by misprogramming, mismatching the infusion setup, and mistakes administering medication.

Differences were also noted regarding the specificity of information provided between the two databases. The specificity of the information provided in the ISMP Canada database was better than the MAUDE database for analyzing specific trends. For example, in 40% of the MAUDE database reports there was

insufficient information provided to determine if the incident occurred at a hospital, much less a specific department in the hospital. In the ISMP Canada database a location was always identifiable, quite often with a specific hospital department mentioned.

The questions being asked and the scope of problems being assessed are important to consider when searching an incident database. The purpose of a database, its definition of a "reportable incident", and any legislature governing reporting to it influence what type of incidents can be found in it. A comprehensive overview of multiple infusion incidents was not found exclusively in either database; together they showed cognitive and technical issues that can arise from multiple IV infusion setups. Therefore, it is important to recognize that absence of data doesn't necessarily mean it does not exist, it may be out of the scope of that particular database. The nature of the incident reporting database highly influences the reports contained therein.

A publicly available comprehensive incident database covering all types of healthcare incidents, whether cognitive or equipment based, would provide a valuable tool for studying patient safety. However, the concern with this would be the large data set which could limit a user's ability to search for specific types of reports. As seen with the search of the MAUDE database, a large number of reports were found with the keyword search, but only 6% turned out to be applicable. An alternative would be to create highly specialized databases available to the public containing incidents pertaining to a specific scope of topic in healthcare, such as equipment failure or surgical errors. However, as in this case, multiple databases may need to be searched for a comprehensive picture and questions arise about how reports should be entered in the databases as some incidents have causal factors relevant to multiple databases.

CONCLUSION

In summary, incident databases are potentially useful tools to assess incidents related to specific healthcare practices. However, when undertaking a database search the user must be aware of the questions they are trying to answer and how the nature of the database affects the answers they find. Being aware of the nature of the database and its definition of a reportable incident will help guide the user to perform an effective analysis of healthcare incidents.

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