Improving intravenous (IV) medication safety at the point of care: Retrospective analysis of pooled data using an innovative IV Harm Assessment Index

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Of all the medication errors, intravenous (IV) infusion errors, which involve high-risk medications delivered directly into a patient’s bloodstream, have the greatest potential for patient harm. IV medications have been associated with up to 54% of potential adverse drug events (ADEs) and 56% of medication errors. A nurse would never give 100 pills to a patient intended to receive only one; however, he or she can inadvertently misprogram a general-purpose infusion device and deliver such a massive overdose.

As detailed below, the Alaris® System with Guardrails® Suite MX safety software incorporates institution-established dosing limits and other parameters, which provide additional verification at the point of care to help prevent IV medication errors. The Guardrails Continuous Quality Improvement (CQI) standard software records the “near misses” (programming errors) averted by the smart system. Clinicians can use this new tool to assess current practices and identify ways to improve IV medication administration safety. Most importantly, the new infusion technology provides tools to prevent harm, which can now be part of the research focus on infusion therapy.

This article describes the development of an innovative IV Harm Assessment Index to evaluate pooled data on averted IV medication errors gathered from seven hospitals using the Alaris System with Guardrails Suite MX software. This index was then applied to determine the averted IV harm that resulted from the implementation of the Alaris System smart technology.

Error vs. harm

The National Coordinating Council for Medication Error and Prevention (NCC MERP) approved the following working definition of medication error:

“... any preventable event that may cause or lead to inappropriate medication use or patient harm, while the medication is in the control of the healthcare professional, patient, or consumer.”

The NCC MERP definition of harm is:

“...death or temporary or permanent impairment of body function/structure requiring intervention. Intervention may include monitoring the patient’s condition, change in therapy, or active medical or surgical treatment.”

Most medication errors do not lead to harm. In order for harm to occur, two primary conditions must be met: 1) the error must reach the patient (i.e., there must be a “point of harm”) and 2) the error must be of sufficient severity to result in physical injury or damage to the patient.

The “sharp end”: where errors become harm. In any complex system, such as a large healthcare system or an intensive care unit, multiple defenses are built into the system to prevent error. Complex system failure occurs when multiple faults align (shown by the arrow, Figure 1) in a chain of events in which the faults grow and evolve, building

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up to produce an accident. The point of the arrow—the point at which accumulated errors result in harm—can be thought of as the “sharp end” of the system. Preventing critical errors at the “point of harm” turns them into “near misses” in which no harm is done.

In healthcare, the “sharp end” of the system is at the point of care. This is where the risk of harm to the patient is greatest and error-prevention efforts can have the greatest impact on reducing harm.

**Error severity.** Not all “arrows” pose the same risk, i.e., medication errors do not all have the same potential to cause harm (Figure 2). The most severe medication errors are generally associated with intravenous, not oral, therapy.

Thus, to achieve the greatest impact in preventing patient harm, it makes sense to focus on IV medications at the point of care and, in particular, on the critical IV medication errors that are most likely to cause patient harm.

**Patient care settings.** A recent study of a 500-bed hospital showed that IV medication devices are used in every patient care area of the hospital (Figure 3).

**High-risk IV medications.** Analysis of the pooled data collected in the Guardrails CQI database from seven hospitals, adjusted to show the results for a 350-bed hospital for three months, revealed that nine medications were associated with the greatest number of averted errors (Figure 4).

Since the frequency of IV medication errors does not necessarily directly correlate to patient harm, a new IV Harm Assessment Index was needed to evaluate the severity and potential harm of these averted errors.
Harm assessment

Earlier harm assessment methods categorize actual errors that have reached a patient. Two such methods provided key concepts for the development of a new IV Harm Assessment Index to evaluate the harm that has been avoided, thus has not reached a patient.

Harm severity. The NCC MERP developed the index shown in Figure 5. This categorizes errors ranging from minimal harm potential (little to no clinical patient effect) to severe harm potential (life-threatening). This index is used to categorize errors that have actually occurred and where the patient’s condition is known.

<table>
<thead>
<tr>
<th>Error category</th>
<th>Error and harm</th>
<th>Error category</th>
<th>Error and harm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category A</td>
<td>Error/no harm experienced by the patient</td>
<td>Category E</td>
<td>An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention.</td>
</tr>
<tr>
<td>Category B</td>
<td>An error occurred that reached the patient and required monitoring/intervention to confirm that it resulted in no harm to the patient.</td>
<td>Category F</td>
<td>An error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization.</td>
</tr>
<tr>
<td>Category C</td>
<td>An error occurred that may have contributed to or resulted in no harm to the patient.</td>
<td>Category G</td>
<td>An error occurred that may have contributed to or resulted in permanent patient harm.</td>
</tr>
<tr>
<td>Category D</td>
<td>Error/harm experienced by the patient</td>
<td>Category H</td>
<td>An error occurred that required intervention to sustain life.</td>
</tr>
</tbody>
</table>

- **Minimal harm potential** (No or minor clinical patient effect)
- **Moderate harm potential** (Significant clinical effect likely)
- **Severe harm potential** (Potentially life threatening)

The Guardrails CQI database does not include additional clinical patient information. Nonetheless, the NCC MERP three-tiered approach provides a useful schema for categorizing near misses’ potential for harm (e.g., using “potentially life-threatening” as the criterion for severe harm potential).

Dosing magnitude. Anderson et al. provided the concept of using dosing magnitude to define error severity. This study included both oral and IV medication errors and assessed actual errors in terms of their potential for harm based on times normal dose.

- **Potentially significant errors** were those that may have resulted in adverse effects or inadequate therapy. These included orders that specified a high dose of 1.4-4.0 times the normal dose of a medication with the potential for an adverse drug event; dose was inadequate to produce intended therapeutic effects.
- **Potentially serious errors** included those that might have resulted in serious toxic reactions or inadequate therapy for a serious illness (e.g., a high dose of medication 4-10 times the normal dose that potentially would have resulted in a serious toxic reaction).
- **Potentially fatal errors** included an order for a medication with a narrow therapeutic index that was >10 times the normal dose; a dose of a medication that would potentially result in pharmacologic effects or serum concentrations associated with fatal toxic reactions; a drug that had the potential to produce a life-threatening reaction in the patient and a dose of a life-saving drug that was too low for the patient.

The study included both oral and IV medication errors and assessed actual errors in terms of their potential for harm based on times normal dose. The data collected in the Guardrails CQI database on averted errors (“near misses”) report on intravenous errors in terms of dose causing the alert vs maximum limit. Thus, a modified harm assessment index needed to be developed to assess the severity of the IV medication errors (i.e., potential patient harm that had been averted by the Guardrails software).
Medication risk criteria. The risk associated with a particular drug was determined conservatively, using the three criteria listed below.

1. Potentially toxic nature of drug. Drugs were considered “high risk” if they had a narrow therapeutic index and were included on the USP’s MEDMARX list of high-risk medications.\textsuperscript{10}

2. Intensity of patient monitoring. For example, dopamine was considered a moderate-risk, not a high-risk drug, because patients receiving dopamine therapy are usually closely monitored, so a medication error would more likely be detected before harm ensued.

3. Clinical judgment. Drs. David Bates and Matthew Weinger, as well as physicians, pharmacists and nurses visiting the CareFusion Center for Safety and Clinical Excellence, were asked to provide feedback for the proposed severity rankings, based on clinical experience.

These concepts and criteria then were used to develop an innovative IV Harm Assessment Index that could be used to evaluate the averted harm that resulted from use of the Alaris System with Guardrails Suite MX software.

During a medication safety workshop held in Cape Cod, MA on July 9-10, 2003, the proposed IV Harm Index was reviewed and refined by distinguished thought leaders in the field of medication safety.

IV Harm Assessment Index

As noted above, in addition to helping to prevent IV medication errors, the Alaris System with Guardrails Suite MX software provides objective documentation of the types of errors averted. These previously unavailable data make it possible for the first time to document and assess IV errors that have been averted through the use of this new technology. The new IV Harm Assessment Index makes it possible to assess the averted harm resulting from the use of this new technology.

It is important to note that the IV Harm Assessment Index uses the criterion, “times the maximum dosing limit,” rather than the criterion used by Anderson et al, “times normal dose.”

“Maximum limits” refers to the upper dosing limits that have been included in the Guardrails Suite MX software in clinical practice. These maximum limits were established for each institution through painstaking, multidisciplinary processes involving a hospital’s pharmacists, physicians and nursing staff. Maximum limits define the highest dose that is considered to be safe and standard practice for that institution. Any dose that is programmed above that limit results in a Guardrails alert to the clinician, and the infusion cannot proceed until the alert is addressed. “Harm” was defined conservatively, i.e., only in terms of whether a serious error would be potentially life-threatening.

Categorizing risk. Using the above criteria and conservative estimates of the potential for harm, the drugs with the highest frequency of averted errors were categorized as moderate- or high-risk IV medications.

- **Moderate-risk IV medications** (e.g., milrinone): For these drugs an overdose greater than 5 times the institution-established maximum limit was considered to have the potential to cause severe harm (potentially life-threatening).

- **High-risk IV medications** (e.g., heparin): For these drugs an overdose greater than 2.5 times the maximum institution-established limit was considered to have the potential to cause severe harm (potentially life-threatening).

Analysis of the data collected in the Guardrails CQI database (Figure 6) showed that three of the four IV medications associated with the greatest frequency of “near misses”—
heparin, midazolam and fentanyl—were high-risk medications with the potential for severe harm (i.e., are potentially life-threatening at doses greater than 2.5 times the maximum limit). The six other high-frequency medications were considered to be moderate-risk medications.

Figure 6. 3 of top 4 IV drugs are high-risk medications

Categorizing harm: In a similar fashion, criteria were also established for minimal, moderate and severe harm potential using dose times maximum limit as the criteria (Figure 7).

Analysis of averted IV medication errors using IV Harm Assessment Index

Methodology. A retrospective analysis evaluated pooled data gathered from seven hospitals obtained from the previously defined Guardrails CQI Reporter software, an application of the Guardrails Suite MX software.

- The seven hospitals included specialty, academic and community hospitals.
- Guardrails CQI data were received from seven hospitals and were imported into a relational database. All findings were reported in aggregate.
- The pooled data represented 39,000 patient days* and 2,149 “near misses.” For purposes of comparison, findings were adjusted to show the results for a 350-bed hospital for three months (approximately 36,000 patient days).
- Analysis distinguished between IV medications with severe and moderate harm potential using the newly developed IV Harm Assessment Index.

Results. The “near misses” were analyzed in terms of their potential for harm (e.g., for heparin) depending on whether the averted error was 1.0-1.5, 1.6-2.5 or >2.5 times the maximum limit; an error was categorized having minimal, moderate or severe harm potential, respectively (Figure 8).

Please note: Both moderate- and high-risk IV drugs may be associated with minimal, moderate or severe harm potential Guardrails alerts.

* Patient days were estimated based on infusion system days represented in the pooled data and the results of a CareFusion survey that demonstrated two of every three hospital patients are on an infusion device at any one point in time.
Next, the “near misses” associated with severe harm potential were analyzed in terms of the severity of the programmed overdose compared with the hospital’s maximum dosing limit for a given drug (Figure 9). A Chi-Square Test did not show a significant relationship between distribution of alerts and type of hospital (p = 0.127).

Overall, analysis of pooled data showed:

- 33 of 2,149 (1.5% [CI 1.06-2.15%]) “near misses” had the potential for moderate harm.
- 43 (2.0% [CI 1.45-2.69%]) “near misses” had the potential for severe harm.

Finally, the data were analyzed to show the incidence of moderate- and high-risk “near misses” per 1,000 patient days. Results showed:

- Harm potential:
  - 2.6 minimal harm potential for every 1,000 patient days.
  - 0.8 moderate harm potential for every 1,000 patient days.
  - 1.1 severe harm potential for every 1,000 patient days.

- For a 350-bed hospital, this means that the Guardrails Suite MX software averted an IV medication error that may have been life-threatening every 2.6 days.

- Also, the Guardrails Suite MX software averted another serious IV medication error with moderate harm potential every 3.6 days.

- The current Harm Assessment model does not address harm that may have resulted from significant under-doses.

Discussion

Data analysis using the IV Harm Assessment Index shows that all of the “frequent-error” IV medications were associated with “near misses” that could have caused severe harm, had they not been averted by the infusion medication safety system.

A particularly high number of “near misses” involved heparin. This widely used drug has the distinction of appearing on both the USP’s MEDMARX list, a national database for medication errors, and in CareFusion studies as being one of the medications most commonly associated with potential ADEs.

Although dopamine was associated with a greater number of near misses, midazolam and fentanyl were shown to have a greater potential to cause harm.

Since there was very little variation around the mean in the percentage of errors per patient days, and no relation between type of hospital and type of error, these data can be projected to other hospital populations.
Conclusion

Retrospective analysis of pooled data using an innovative IV Harm Assessment Index shows that the Alaris System with Guardrails Suite MX software helps avert frequently occurring IV medication errors that have the potential to cause severe harm, if not intercepted before reaching the patient. By helping to prevent these errors, this smart infusion technology can help to lower the risk of patient harm at every “sharp end” (i.e., at every point of care in the hospital).

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For more information, contact your CareFusion Alaris System Sales Consultant at 800.482.4822, in Canada 800.387.8309, Fax 858.488.7760 or visit our website at carefusion.com

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