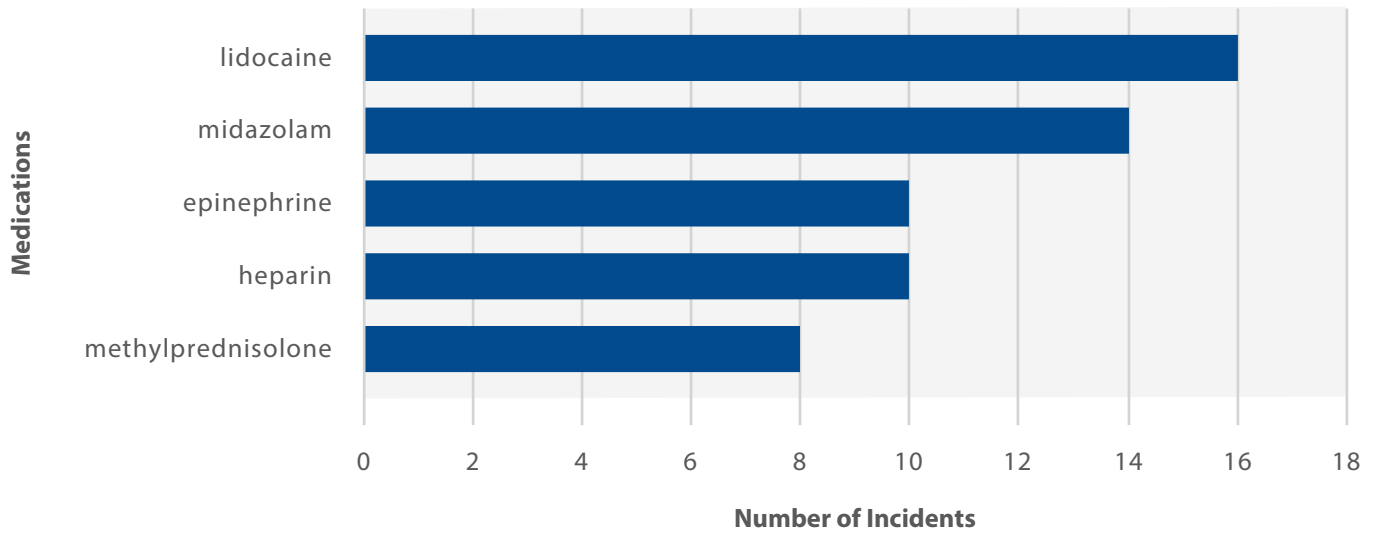


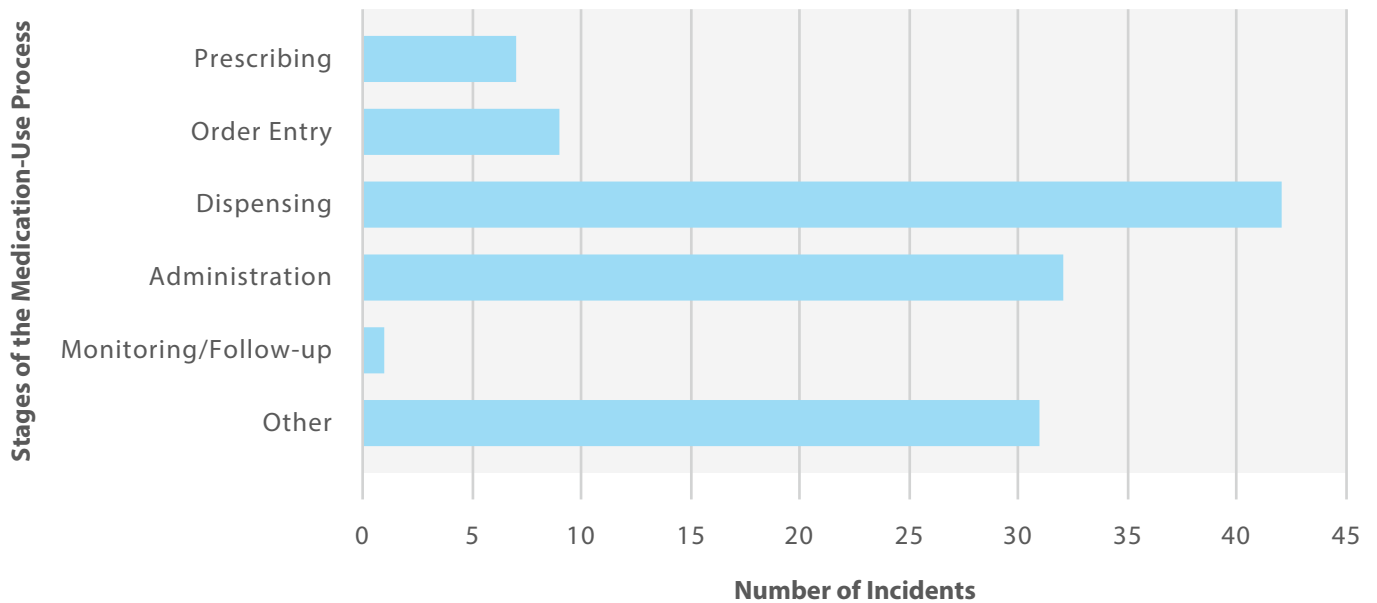


Figure 1 shows the top 5 medications most frequently cited in the analyzed dataset, and Figure 2 shows the stages of the medication-use process involved.

Concerns, near misses, or no harm were reported in 85% of incidents; harm to patients was reported in 15% of the incidents.



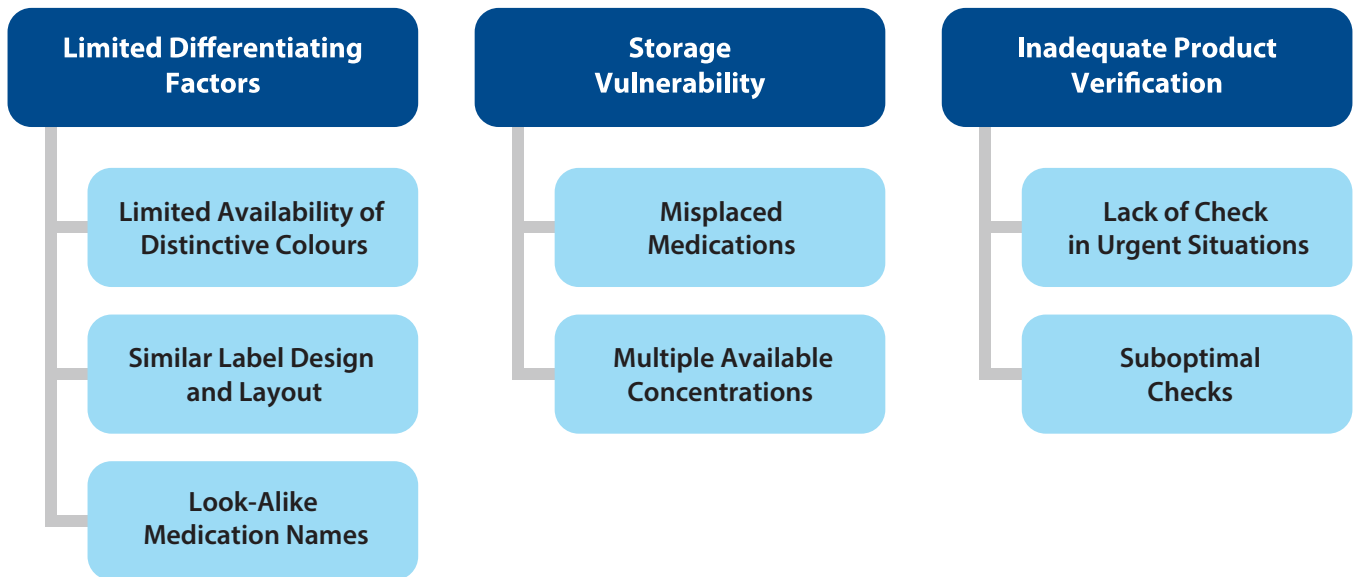
**Figure 1.** Top 5 medications involved in reported incidents (excludes insulins and opioids).



**Figure 2.** Stages of the medication-use process involved in reported incidents.

## QUALITATIVE ANALYSIS

Three main themes and associated subthemes were identified through the analysis (Figure 3).



**Figure 3.** Themes and subthemes identified in the analysis.

### ***Theme: Limited Differentiating Factors***

For medications provided in vials and ampoules, labelling, packaging and storage are important factors in the prevention of medication errors for the following general reasons:

- Vial and ampoule shapes and sizes are limited and not distinctive.
- Injectable solutions are often clear liquids, which are indistinguishable from one another.
- Space available on the label for printed information is limited, which may necessitate use of smaller font sizes, affecting readability.

The most frequently reported factors contributing to mix-ups were similar colours, similar label designs and layouts, and similar medication names.

- *Limited Availability of Distinctive Colours:* In this analysis, medication vial caps with the same colour were frequently reported as a cause for concern or were implicated in errors. Although colour differentiation can support identification of the intended product, the number of colours that can be accurately differentiated, or readily identified without errors, is limited to 12.<sup>9,10</sup> Recognizing that a hospital may typically carry 200 or more different injectable products in their inventory, use of distinct colours for product differentiation is not possible. Additionally, colour changes to a product in inventory (including intentional changes by the manufacturer and changes due to shortages) may inadvertently increase the risk of a look-alike error.
- *Similar Label Design and Layout:* Differences on product labels used to differentiate among various strengths of a medication from the same manufacturer may not be easily perceived. For products from different manufacturers, vial and

ampoule labels may share a similar visual style (e.g., type style, content layout).

- *Look-Alike Medication Names:* Reported incidents described the dispensing or administration of the incorrect product where medication names started with and/or ended with similar letters. Other contributing factors to these types of errors included staff fatigue and insufficient independent double checks.

*Incident Example: A mix-up between a vial of rocuronium and succinylcholine was reported. These vials have a standardized red cap and warning designed to prevent fatal errors that have occurred with neuromuscular blocking agents. Preventing mix-ups within this group of medications requires storage and practice safeguards.*

### **Theme: Storage Vulnerability**

Storage was one of the most frequently reported factors contributing to medications errors in the analyzed dataset, which is reflected in the following subthemes.

- *Misplaced Medications:* In some reports, look-alike medications (i.e., those with similar-sized vials/ampoules and labels) that were received at the same time were mistakenly stored together in the pharmacy. In other reports, medications were placed in the wrong area when returning medications to stock.
- *Multiple Available Concentrations:* Medications in vials and ampoules are commonly available in more than one concentration. Different concentrations of the same medication were stored together instead of being separated.

*Incident Example: A patient asked for pain medication during a shift change. A vial of midazolam was retrieved from a drawer instead of the intended hydromorphone. By the time the error was recognized, the cap had been removed in readiness for administration but was not given to the patient.*

### **Theme: Inadequate Product Verification**

Safeguards against selection errors (e.g., verification by pharmacy, dispensing by means of an automated dispensing unit [ADU], use of barcoding) may not be in place in all care areas. The analysis showed that independent double checks for product verification were sometimes overlooked or insufficient during medication dispensing and administration. Reporters also described situations in which staffing shortages meant that replacement nurses were less familiar with local processes for accessing medications and the need for double checks.

- *Lack of Check in Urgent Situations:* Health care requires efficiency without compromising accuracy and safety. Stress and poor individual performance were often reported as contributing factors in urgent situations that did not allow for an extra check.
- *Suboptimal Checks:* Human factors (e.g., confirmation bias) play a role in suboptimal checks. An independent double check process, including use of technology (e.g., barcoding), is important to support product selection, dose preparation, and medication administration.

*Incident Example: A vial of epinephrine was inadvertently retrieved from the supply cart instead of the intended vial of ondansetron. The selection error was not recognized, despite a double-check process involving another staff member. The patient experienced an adverse reaction to the epinephrine, which led to identification of the error.*

## KEY RECOMMENDATIONS

- Integrate a high-leverage product verification strategy (e.g., barcoding) for high-alert medications identified by the organization in each step of the medication-use process, including stocking and restocking.
- Provide medications in a ready-to-use format (e.g., premixed minibag) to reduce selection, preparation, and administration errors with medications in look-alike vials and ampoules.<sup>11</sup>
- Store vials on their sides, with labels facing up; use storage compartments to separate look-alike products.<sup>11</sup> Technology, such as automated dispensing units, can support safe storage.
- Add auxiliary warnings to storage containers, where appropriate (e.g., for neuromuscular blocking agents stored outside the operating room).<sup>12</sup>
- Communicate product changes to alert point-of-care providers.
- Consider error potential when making purchasing decisions.

## CONCLUSION

The Good Label and Package Practices Guide for Prescription Drugs<sup>2</sup> was developed to guide manufacturers in designing safer labels and packages. Many manufacturers have implemented safe practices outlined in the Guide and there have been improvements made to labels and packages. Continuous reporting and learning will inform updates to the Guide and also help identify strategies for quality improvement in medication management and the prevention of errors and associated harm.

This multi-incident analysis demonstrates and serves as a reminder that substitution errors with vials or ampoules containing high-alert medications continue to be reported. Given that there are limits to the variety of shapes, sizes, colours, designs, and layouts for labelling and packaging, it is important to incorporate system safeguards to reduce reliance on product appearance only.

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The Canadian Medication Incident Reporting and Prevention System (CMIRPS) is a collaborative pan-Canadian program of Health Canada, the Canadian Institute for Health Information (CIHI), the Institute for Safe Medication Practices Canada (ISMP Canada) and Healthcare Excellence Canada (HEC). The goal of CMIRPS is to reduce and prevent harmful medication incidents in Canada.



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