

ISMP Canada Safety Bulletin

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Ambulatory Infusion Pumps: Analysis of Errors and Recommendations for Safe Use

The use of ambulatory infusion pumps to deliver medications parenterally has become increasingly common not only in hospitals but also in long-term care facilities and in patients' homes.¹ Such devices make it feasible to administer infusion therapies outside of acute care settings. ISMP Canada received a number of incident reports describing severe harm or death involving ambulatory infusion pumps, which prompted a multi-incident analysis to highlight opportunities for improvement.

METHODOLOGY

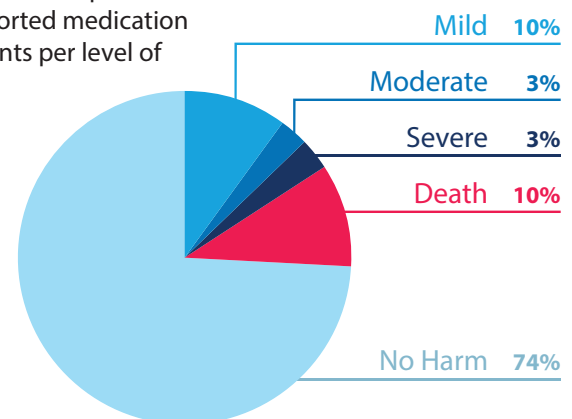
Medication incidents associated with ambulatory infusion pumps were extracted from reports submitted to 3 ISMP Canada reporting databases (Individual Practitioner Reporting, National Incident Data Repository for Community Pharmacies, and Consumer Reporting) and the Canadian Institute for Health Information's (CIHI) National System for Incident Reporting (NSIR) database* over the 5-year period from May 2016 to May 2021. Key terms used to search the databases included "ambulatory pump", "cassette", "portable", and "reservoir". Incidents were excluded if the pump involved was: a large-volume device; a burette, elastomeric, or syringe pump; or a pump dedicated only to providing patient-controlled analgesia (PCA), insulin, or enteral feeds. The analysis was conducted according to the

methodology outlined in the Canadian Incident Analysis Framework.²

QUANTITATIVE FINDINGS

Of the 279 incidents identified and screened using the exclusion criteria, a total of 39 incidents (32 from ISMP Canada databases and 7 from the NSIR database) were included in the final analysis.[†] About 95% of the cases involved an opioid, with HYDROMORPHONE accounting for over 85% of these incidents. Figure 1 shows the breakdown of the reported outcomes. More than one-quarter of the reports described harm to the patient, including death in about 10% of cases.

FIGURE 1. Proportion of reported medication incidents per level of harm.



* The databases are components of the Canadian Medication Incident Reporting and Prevention System (CMIRPS). More information about the databases is available from: <http://www.cmirps-scdpim.ca/?p=12>. NSIR data was provided by CIHI; however, the analyses, conclusion, opinions, and statements expressed herein are those of ISMP Canada.

[†] It is recognized that it is not possible to infer or project the probability of incidents on the basis of voluntary reporting systems.

QUALITATIVE ANALYSIS

The analysis revealed 4 main themes, further divided into subthemes (Table 1).

Table 1. Main Themes and Subthemes

Initiation of Infusion <ul style="list-style-type: none">• Pump Programming• Pump, Reservoir, and Tubing Preparation/Assembly
Preparation of Medication Reservoir <ul style="list-style-type: none">• Product Selection• Compounding and Labelling
Change in Medication Order <ul style="list-style-type: none">• Change in Medication Dose• Change in Infusion Rate• Change in Medication Concentration
Issues Related to Device <ul style="list-style-type: none">• Software Limitations• Maintenance Deficiencies

THEME: Initiation of Infusion

About 30% of the reported incidents occurred during initiation of an infusion. The errors most commonly cited were related to incorrect pump programming or incorrect preparation/assembly of the pump, medication reservoir (e.g., cassette, minibag), and/or tubing. Equipment assembly errors included tubing being connected to the wrong port and improper attachment of a medication reservoir to the pump. Knowledge deficit was one of the most frequently reported contributing factors within this theme.

When programming an infusion pump, the user must recognize the various ways that dosing units might be communicated (e.g., mg/h, mcg/h, mL/h). Several of the reported incidents described situations where the dosage was prescribed in milligrams per hour (e.g., 1 mg/h) but was programmed into the pump as millilitres per hour (e.g., 1 mL/h).

Incident Example

An ambulatory pump order for HYDROmorphine was written using units of milligrams per hour (mg/h), but the pump was incorrectly programmed using units of millilitres per hour (mL/h). The patient received 10 times the intended dose and died because of the overdose.

Recommendations

- Develop standardized order sets that include options consistent with products provided by pharmacy. Include critical programming parameters in order sets and medication labels, where possible, to help eliminate or minimize the need for calculations at the time of pump programming.
- Tailor the pump library to include the standardized medication concentrations presented in the order sets (e.g., HYDROmorphine 1 mg/mL). This will minimize the programming needed for each infusion.
- Use consistent terminology (and avoid potentially dangerous abbreviations)³ in the design of medication order sets, medication labels, and medication administration records.
- Conduct an independent double check before initiating the infusion of a high-alert medication.⁴
 - For practitioners working alone, options include having the pharmacy team provide the medication reservoir together with a pre-programmed pump, utilizing technology to virtually connect with colleagues for confirmation, and engaging patients and families, whenever appropriate.
- Provide regular training programs for staff to support them in maintaining up-to-date knowledge on the correct use and monitoring of infusion pumps.^{5,6} Such programs should include information about the most relevant safety

functions of the pumps in use, as well as potential challenges associated with the equipment.⁵

- Ensure ready access to the device manufacturer’s instruction and user guides as resources for pump setup and programming, as well as ongoing user training.⁶

THEME: Preparation of Medication Reservoir

Incidents reported to have occurred during the preparation of medication reservoirs are captured within this theme. These include errors related to product selection, compounding, and labelling. Several reports described administration of an incorrect dose of a medication resulting from a compounding or a labelling error.

Incident Example

A patient receiving HYDROmorphone via ambulatory pump was admitted to hospital because of inadequate pain control. Several days later, it was discovered that the concentration of the medication in the patient’s cassette was one-tenth of the prescribed amount.

Recommendations

- Develop and maintain standardized compounding protocols and worksheets for each compounded product. Include documentation of the ingredients, equipment, calculations, step-by-step compounding procedure, and sample labels in compliance with [NAPRA Standards](#).⁷
- Include a process for independent verification, either electronic (e.g., scan a barcode) or manual (e.g., visually check product name and unique identification number), of each ingredient before product preparation.

THEME: Change in Medication Order

This theme encompasses errors related to changes in medication orders that require modifications to pump settings and/or setup. One example is an order change that requires a new medication reservoir containing a different concentration; errors have occurred when the pump programming is not adjusted accordingly.

Incorrect unit selection, as described above (i.e., confusion related to “mg/h”, “mcg/h”, and “mL/h”), has also contributed to pump reprogramming incidents. Lack of independent double checks and inadequate monitoring (e.g., residual volume in the cassette) were contributing factors.

Incident Example

A new cassette containing a lower concentration of HYDROmorphone solution was connected to tubing that was being used to administer a solution that was 10 times more concentrated. The tubing was not replaced when the new cassette was connected. As a result, the patient received an additional amount of the higher concentration of HYDROmorphone.

Recommendations

- Ensure the following processes are in place for changes in the medication order:
 - Standardized format for communicating order changes to pharmacy and nursing.
 - Preparation, labelling, and delivery of a new medication reservoir, where feasible, to ensure that the new order is accurately reflected.
 - Direct communication with the practitioner who is administering the medication, to inform them about the change(s).
- Confirm all pump programming parameters **every** time a medication reservoir is changed, even if there has not been an order change. This step should include resetting the reservoir volume to enable checks of the residual volume throughout the infusion.
- Regularly assess the residual volume in the medication reservoir against the volume expected based on the medication order. A discrepancy in the expected volume can help identify potential problems before harm occurs.
- When appropriate, engage patients and their family members or caregivers in monitoring activities. In particular, provide information and examples that will help them to identify “red flags” indicating potential issues with the medication delivery.⁸ The increased use of virtual technologies can assist with communication between practitioners and patients or their caregivers.

THEME: Issues Related to Device

Captured under this theme were reports describing infusions that were not delivered as expected, because of incorrect device configuration and/or improper maintenance. In some cases, the error was related to pump software limitations and in others, to the tubing or connectors, rather than to the device itself.

Incident Example

A change to both the continuous infusion rate and the breakthrough dose was ordered for a subcutaneous infusion of HYDRomorphone. The rate change was programmed correctly; however, the breakthrough dose adjustment was omitted because the pump software could not accommodate the new dose.

Recommendations

- Ensure that dose error reduction software is uploaded and activated in all ambulatory pumps.⁹
- Include nursing, pharmacy, and medical staff in all communications about the functionality of pump software (e.g., programming breakthrough doses), as well as alarm features and power requirements of the device (e.g., expected battery life and charging time).¹⁰ Ensure ready access to the device manufacturer's instruction and user guides to support regular training.⁶
- Test pumps following software upgrades.
- Remove the device from patient use if a device problem is suspected and tag it with a description of the problem experienced. The device should be inspected and/or repaired by a qualified technician, then tested before being released for use.
- Report device-related errors (including those attributed to infusion administration supplies, such as tubing and connectors) to organizational reporting systems (and the device manufacturer, as applicable) and to [Health Canada](#) to support analysis and necessary action.

CONCLUSION

High-alert medications, such as opioids and chemotherapy, are frequently administered using ambulatory infusion pumps and carry a heightened risk of causing significant harm or even death.^{11,12}

This multi-incident analysis highlights the types of errors reported with ambulatory infusion pumps and raises awareness of opportunities to improve their safe use. Key recommendations relate to pump programming or reprogramming (e.g., to improve system supports) and to medication orders and labels (i.e., to ensure availability of information needed at the point of care). Virtual technologies can provide new opportunities for improved care by assisting the care team with independent checks and enabling communication between practitioners and patients or their caregivers.

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ONE NEEDLE, ONE SYRINGE, ONLY ONE TIME

Recently, ISMP Canada’s consumer reporting program, [SafeMedicationuse.ca](https://www.safemedicationuse.ca), received a report from a distressed patient who was one of several individuals asked to get tested for HIV and hepatitis because of unsafe injection practices. These patients were told that a syringe that had been used to give them an injection had also been used to give injections to others; only the needle had been changed in between injections.



FIGURE 1. Poster from the *One & Only Campaign* of the US Centers for Disease Control and Prevention (reprinted with permission from the CDC).

Reuse of the same syringe (and/or needle) for different patients can increase the likelihood of transmitting HIV, hepatitis B virus, hepatitis C virus, and other blood-borne pathogens.¹

Recommendations

The following recommendations are based on the One & Only Campaign¹ (Figure 1), initiated by the US Centers for Disease Control and Prevention:

- *Practitioners:* Use one needle, one syringe, only one time.
- *Management:* Enhance injection training programs to include infection control principles and the rationale for safe injection practices.

Reference

1. One & Only Campaign [website]. Atlanta (GA): Centers for Disease Control and Prevention; 2019 Dec 3 [cited 2021 Sep 22]. Available from: <https://www.cdc.gov/injectionsafety/one-and-only.html>



Call for Shared Learning with Virtual Care Experiences

ISMP Canada, in partnership with Healthcare Excellence Canada, is working to advance safety in virtual care. We are exploring medication safety concerns, facilitators, and barriers. Help turn your experiences into system-based improvements by sharing your virtual care-related medication incidents with ISMP Canada at:

- Practitioners: www.ismp-canada.org/err_ipr.htm
- Patients: www.mederror.ca

Questions related to this initiative can be directed to info@ismpcanada.ca. Together we can continuously improve medication safety!



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.



The Healthcare Insurance Reciprocal of Canada (HIROC) provides support for the bulletin and is a member owned expert provider of professional and general liability coverage and risk management support.



The Institute for Safe Medication Practices Canada (ISMP Canada) is an independent national not-for-profit organization committed to the advancement of medication safety in all healthcare settings. ISMP Canada's mandate includes analyzing medication incidents, making recommendations for the prevention of harmful medication incidents, and facilitating quality improvement initiatives.

Report Medication Incidents

(Including near misses)

Online: www.ismp-canada.org/err_index.htm

Phone: 1-866-544-7672

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