Medications Most Frequently Reported in Harm Incidents over the Past 5 Years (2015–2020)

The Institute for Safe Medication Practices Canada (ISMP Canada) has a vision of **Zero Preventable Harm from Medications**. To help attain this goal, the organization is one of five national partners in the Canadian Medication Incident Reporting and Prevention System (CMIRPS – see Figure 1).

Key activities within the CMIRPS program include the capture and analysis of medication incidents (including harmful events, no-harm events, near misses, and circumstances that could lead to harmful incidents), as well as dissemination of learning to inform and support actions to improve medication safety.

**FIGURE 1.** An Overview of the Canadian Medication Incident Reporting and Prevention System*

*Databases are administered by ISMP Canada and the Canadian Institute for Health Information (CIHI)
the safety of medications for Canadians. This bulletin shares findings from analyses of incidents reported to the CMIRPS reporting components over a recent 5-year period.

**METHODOLOGY**

Reports of medication incidents resulting in harm (“harm incidents”) were retrieved from the 4 CMIRPS databases: ISMP Canada’s Individual Practitioner Reporting, Consumer Reporting, and National Incident Data Repository for Community Pharmacies and CIHI’s National System for Incident Reporting (NSIR). Data were extracted for the 5-year period from January 27, 2015 to January 26, 2020.

The incident reports were reviewed to exclude duplicates and those in which the medication could not be identified. The remaining reports were then sorted by medication, such that all reports for a given generic medication, including various brand names, were grouped together. The most frequently cited medications involved in harm incidents were identified and then categorized by health care setting (hospital, long-term care, community pharmacy, and home and community care) and degree of harm (i.e., mild, moderate, severe, death).

**QUANTITATIVE FINDINGS**

A total of 7531 harm incidents were included in the analysis: 5234 and 2297 from NSIR and ISMP Canada databases, respectively. A key finding is that nearly 86% of all harm incidents were reported as mild in severity, as seen in Figure 2. Reports from hospitals form the majority of the incidents, followed by those from community pharmacy (Figure 3).

Figure 4 highlights the top 3 medications cited in reports of harm incidents in each health care setting. Two medications appear in the top 3 in multiple settings—hydromorphone in all except community pharmacy and insulin in the 2 institutional care settings. Notably, each of these 2 medications was cited twice as often as any other medication in harm incidents from all health care settings combined (Table 1A).

The data from all health care settings for the 5-year period were compiled to identify the medications most frequently cited in reports of harm incidents with outcomes of any degree of severity (Table 1A) and those reported to have resulted in severe harm or death (Table 1B).

**FIGURE 2.**
Degree of harm reported in harm incidents over a 5-year period from Jan 27, 2015 to Jan 26, 2020

**FIGURE 3.**
Reported care setting where harm incidents occurred over a 5-year period from Jan 27, 2015 to Jan 26, 2020

Reports by **DEGREE OF HARM**

- **Severe**: 2.1%
- **Moderate**: 11.2%
- **Mild**: 85.5%

Reports by **CARE SETTING**

- **Hospital**: 65.9%
- **Community Pharmacy**: 26.5%
- **Long-Term Care**: 6.7%
- **Home and Community Care**: 0.8%
- **Other**: 0.1%

**REFERENCE**

Available from: https://www.ismp.org/recommendations/high-alert-medications-community-ambulatory-list
$\text{FIGURE 4. Medications most frequently cited in reports of harm incidents, by health care setting, over a 5-year period Jan 27, 2015 to Jan 26, 2020}$

$\text{TABLES 1A AND 1B. Medications* most frequently reported in harm incidents with outcomes of any degree of severity, across all health care settings1 (Table 1A, left) and medications most frequently reported in severe harm or death incidents, across all health care settings2 (Table 1B, right), over a 5-year period Jan 27, 2015 to Jan 26, 2020}$

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Number of Incidents</th>
<th>% of Harm Reports</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin</td>
<td>459</td>
<td>6.1%</td>
</tr>
<tr>
<td>HYDROmorphine</td>
<td>447</td>
<td>5.9%</td>
</tr>
<tr>
<td>Morphine</td>
<td>211</td>
<td>2.8%</td>
</tr>
<tr>
<td>Acetaminophen*</td>
<td>199</td>
<td>2.6%</td>
</tr>
<tr>
<td>Methadone</td>
<td>198</td>
<td>2.6%</td>
</tr>
<tr>
<td>Fentanyl</td>
<td>172</td>
<td>2.3%</td>
</tr>
<tr>
<td>Heparin</td>
<td>167</td>
<td>2.2%</td>
</tr>
<tr>
<td>Furosemide</td>
<td>156</td>
<td>2.1%</td>
</tr>
<tr>
<td>Metoprolol</td>
<td>152</td>
<td>2%</td>
</tr>
<tr>
<td>Warfarin</td>
<td>137</td>
<td>1.8%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Number of Incidents</th>
<th>% of Severe Harm or Death Reports</th>
</tr>
</thead>
<tbody>
<tr>
<td>HYDROmorphine</td>
<td>27</td>
<td>11.1%</td>
</tr>
<tr>
<td>Morphine</td>
<td>16</td>
<td>6.6%</td>
</tr>
<tr>
<td>Methotrexate</td>
<td>13</td>
<td>5.3%</td>
</tr>
<tr>
<td>Methadone</td>
<td>11</td>
<td>4.5%</td>
</tr>
<tr>
<td>Lorazepam</td>
<td>7</td>
<td>2.9%</td>
</tr>
</tbody>
</table>

*Any incident involving a combination product was counted toward the total for each of the active medicinal ingredients (e.g., an incident involving Percocet was counted with the totals for both oxycodone and acetaminophen).

*See Figure 3 for the breakdown of reports by care settings; the top 2 settings from which reports originated were hospital (65.9%) and community pharmacy (26.5%).
DISCUSSION

All 5 of the medications most frequently reported in severe harm or death incidents across all care settings over the past 5 years are defined as high-alert medications. For example, methotrexate for non-oncologic indications is considered to be a high-alert medication in the community and ambulatory setting. Contributing factors associated with severe harm related to methotrexate were dosage errors where doses prescribed for weekly administration were taken daily, unrecognized drug interactions, and inappropriately high doses prescribed for patients who were experiencing renal failure. Patients, families, and health care providers may not appreciate the increased risks associated with this medication, nor be aware of the best practices recommended to prevent associated harm and death.

Although awareness of high-alert medications and the need for related safeguards has increased over time, findings from the analyses in this bulletin serve as an opportune reminder that these and other medications continue to cause patient harm. There are known effective strategies for reducing the risk for error and harm for high-alert agents. Safety strategies and risk reduction measures, including optimization of technology, process improvement, patient/caregiver/health care provider education, and enhanced patient monitoring systems must be implemented.

The analyses highlight findings that merit further investigation:

- Hydromorphone was among the top 3 drugs reported in harm incidents in 3 out of the 4 health care settings. Insulin was also frequently reported in harm incidents across multiple health care settings.
- In the community pharmacy setting, methadone was associated with the highest number of harm incidents. Insufficient patient identification processes, the need for individualized dosing regimens, and complex preparation steps were all contributing factors identified.
- Two medications reported as causing harm (acetaminophen and furosemide in Table 1A) are not identified high-alert drugs. Some reports that included acetaminophen involved a combination product containing this drug and an opioid (e.g., codeine, oxycodone).

- The appearance of levothyroxine in the list of medications involved in harm incidents may be influenced by the frequency of prescribing and dispensing this drug. Nonetheless, its presence in harm reports merits investigation into the root causes and contributing factors leading to patient harm.

LIMITATIONS

The reports submitted likely represent only a subset of the actual medication errors that are occurring. It is not possible to infer or project the probability of incidents on the basis of voluntary reporting systems.

CONCLUSION

Consumers, practitioners, health care organizations, and regulators can use the findings presented in this bulletin to inform the development of strategies for improving medication safety. One such strategy is the use of Medication Safety Self-Assessment tools focusing on “never events”; a resource is currently available for long-term care and another for hospitals and ambulatory care centres, while a third is in development for community pharmacy. These self-assessments support identification of practice and system vulnerabilities in each of the care settings and suggest safety strategies to prevent and mitigate harm.

The value of reporting medication errors to CMIRPS for national analyses and shared learning is increasingly being recognized across health care settings. The findings from these analyses provide important insights into medications most frequently reported in association with preventable harm and death in Canada.
The Institute for Safe Medication Practices Canada (CMIRPS – see Figure 1). The organization is one of five national partners in the Canadian Medication Incident Reporting and Prevention System. To help attain this goal, harmful incidents, as well as dissemination of misses, and circumstances that could lead to the capture and analysis of medication incidents identified and then categorized by health care setting. Medications involved in harm incidents were sorted by medication, such that all reports for a given were then identified. The remaining reports were then The incident reports were reviewed to exclude from January 27, 2015 to January 26, 2020.

Two medications appear in the top 3 in multiple settings—hydromorphone and insulin. Notably, each of these 2 medications was cited twice as often as any other medication in harm incidents from all health care settings combined. Methotrexate is known as a high-alert medication in the community and home and community care) and degree of harm (hospital, long-term care, community pharmacy, and home). A total of 7531 harm incidents were included in the analysis: 5234 and 2297 from NSIR and ISMP databases: ISMP Canada's Individual Practitioner Reports of medication incidents resulting in harm.

### METHODOLOGY

A recent 5-year period.

### RESULTS

The reports submitted likely represent only a subset of the actual medication errors that are occurring. It is increasingly being recognized across health care settings. The findings from these analyses provide important insights into medications most frequently reported in association with preventable harm and death.6

#### 1. Medical Errors and Medication Safety

- **Patient Safety**: Patient monitoring systems must be enhanced and patient/caregiver/health care provider education, and optimization of technology, process improvement, strategies and risk reduction measures, including the use of Medication Safety Self-Assessment tools. A resource is currently focusing on “never events”.
- **Patient Engagement**: Consumers, practitioners, health care organizations, and regulators can use the findings presented in this bulletin to inform the development of strategies for investigation:

- **Patient Safety**: Patient monitoring systems must be enhanced patient monitoring systems must be enhanced and patient/caregiver/health care provider education, and optimization of technology, process improvement, strategies and risk reduction measures, including the use of Medication Safety Self-Assessment tools. A resource is currently focusing on “never events”.
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#### REFERENCES

Oxytocin to Start or Advance Labour: 5 Questions to Ask

Invitation to Participate in Testing

A patient handout entitled Oxytocin to Start or Advance Labour: 5 Questions to Ask has been developed by a pan-Canadian advisory group of patients and family members, clinicians, and other experts. The handout provides information about using oxytocin to start and/or advance labour. It is designed as a quality improvement resource for health care providers to share with patients.

The handout is intended to be given to the patient after the doctor or midwife has talked with the patient about her potential need for this medication, as well as the associated benefits and risks.

You can download the handout here:

You are invited to participate in testing to determine whether this resource is helpful to providers and patients and whether any changes are needed. If you are interested in participating in the testing process, please contact Alice Watt: alice.watt@ismpcanada.ca

You can also provide general feedback, before January 31, 2021, through a confidential survey:
• Health care provider survey: https://www.surveymonkey.com/r/oxytocinsurvey1
• Patient survey: https://www.surveymonkey.com/r/oxytocin5Qsm

Oxytocin to Start or Advance Labour: 5 Questions to Ask

1. What is oxytocin?
   • Oxytocin is a hormone that is produced naturally during labour to make the uterus contract. It is commonly given during labour if the natural supply is not enough.
   • Oxytocin should only be used when the benefits of delivery outweigh the risks of continuing the pregnancy.

2. Why is it used and what are the benefits?

   2.1. To help start labour (induction), so:
   • Labour begins, where the uterus contracts in between 20-30 minutes.
   • Labour continues, the uterus contracts in between 5-10 minutes.

   Benefits may include:
   • A vaginal delivery not requiring a surgical delivery (C-section). (European Council, 2009)
   • Did you know? Out of 10 patients who received oxytocin for induction or augmentation gave birth vaginally.

3. What are the risks?

   3.1. What to watch for:
   • Fetal to baby heart rate changes may include:
     • Normal labour pains
     • Fetal bradycardia
     • Tachycardia
     • Changes in fetal heart rate
     • Changes in fetal heart rate and oxygen levels
     • Fetal bradycardia

   Family members may cause stress or be overwhelming. Here are ways to deal with:
   • It is important to have already discussed the risks and benefits of additional care use with your doctor or midwife before treatment is started.

   3.2. What to do if:
   • Oxytocin may include waiting for labour to start.
   • Changes, or using other medications, which each have their own benefits and risks – discuss with your doctor or midwife.

4. Proper Use: How is it given?
   • Oxytocin for induction or augmentation is given intravenously using a pump.
   • The medicine will start at a low dose and then will be increased gradually to get the right contraction pattern for you.
   • If the contractions are affecting the baby’s heart rate or if the benefits of delivery outweigh the risks of continuing the pregnancy, your health care provider may reduce or stop the oxytocin.

5. Monitor: What do I watch for?

   5.1. Your baby’s heart rate will be closely monitored using a fetal monitor.
   • Your health care provider will check on you often and watch over your labour closely.
   • Your contractions, blood pressure, and birth rate will be checked regularly.
   • You may need to have pain medicine to help you with the pain of labour. You will be provided with choices to manage your pain.
   • Let your nurse, midwife or doctor know right away if you have:
     • Sudden onset of severe abdominal pain
     • Heavy bleeding from your vagina
     • Increased labour pain
     • Fast/irregular heart rate or changes in blood pressure
     • Heavy bleeding or post-partum bleeding
     • Severe contractions that are too long or too frequent
     • Severe contractions that are too long or too frequent
     • Headache, nausea, vomiting
     • Jaundice, kidney failure, or other symptoms

   Risks to the baby may include:
   • Oxytocin may cause stress or be overwhelming. Here are ways to deal with:
     • It is important to have already discussed the risks and benefits of additional care use with your doctor or midwife before treatment is started.

   Risks to you may include:
   • Heart rate changes
   • shortage of oxygen
   • Jaundice
   • Jaundice

   To help start labour (induction), or
   • To help increase labour (augmentation), where the uterus contracts in between 20-30 minutes.
   • Labour continues, the uterus contracts in between 5-10 minutes.

   Benefits may include:
   • A vaginal delivery not requiring a surgical delivery (C-section).

   For more information about induction of labour visit:
   www.pregnancyinfo.ca/birth/labour/induction/

*Funding for this initiative was provided by the Canadian Medication Safety Coalition.
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 the Canadian Patient Safety Institute (CPSI). 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

ISMP Canada strives to ensure confidentiality and security of information received, and respects the wishes of the reporter as to the level of detail to be included in publications. Medication Safety bulletins contribute to Global Patient Safety Alerts.

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