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CMIRPS Canadian Medication Incident Reporting and Prevention System
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Acetaminophen-Related Harm: A Call for Improved Product Packaging

Although safe in recommended doses, acetaminophen is a leading cause of acute liver failure due to intentional and unintentional overdoses.[1] In the past decade, Health Canada has implemented several initiatives to improve the safe use of acetaminophen, including limiting the dose per unit (e.g., tablet or capsule) in prescription combination products and updating **product labelling** requirements.[2,3] The impact of these labelling requirements was the subject of a recent review; the authors found that modifications to product labels did not reduce the rate of acetaminophen-related harm soon after implementation.[4] Longer-term studies on the impact of product labelling and additional measures to optimize safe use of acetaminophen are needed.[5] This bulletin shares information about initiatives underway in other countries and includes recommendations for improvements to **product packaging** (i.e., restricted pack sizes, child-resistant closures).

DISCUSSION

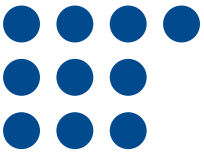
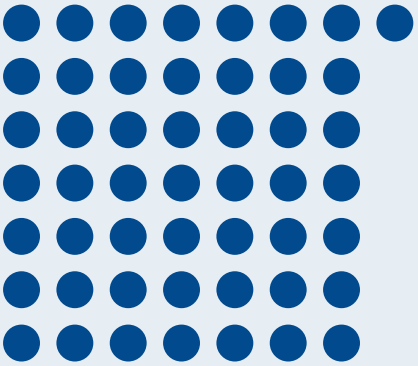
There are approximately 4500 hospitalizations due to acetaminophen overdose each year, 16% (n=700) of which were reported as accidental or unintentional overdoses.[1] Multiple factors contribute to acetaminophen-related harm.[5] Factors can include the ease of access to potentially large amounts of the medication, whether it be a result of the availability of large quantities, a lack of child-resistant closures, or inadequate storage.[5]

Restricted Pack Sizes

The content of acetaminophen in many Canadian packages for adults far exceeds the typical single-ingestion doses involved in acute acetaminophen toxicity.[6] The quantity of acetaminophen available in packages are limited in some other countries to reduce risk of harm (Table 1).

Additional Topics in this Issue:

TABLE 1. Pack sizes of acetaminophen products for adults in select countries.
(Note: units represent tablets or capsules; ● represents 10 units).

Country (year restrictions effective)	**Restrictions on pack sizes and retail settings**	**Comparative pack sizes of acetaminophen products sold in pharmacies**
United Kingdom (1998)[7,8]	• Up to 16 units per package sold in non-pharmacy settings • Up to 32 units per package sold in pharmacies	
Denmark (2013)[9]	• Up to 10 units per package sold in non-pharmacy settings • Up to 20 units per package sold in pharmacies	
Australia (2025)[10]	• Up to 16 units per package sold in supermarkets • Up to 50 units per package sold in pharmacies, without supervision of a pharmacist • Up to 100 units per package sold in pharmacies, under the supervision of a pharmacist	
Canada (2003)[11]	• No pack size or retail setting restriction for *immediate-release* acetaminophen Examples (immediate-release): ◦ 65 g (200 units/bottle × 325 mg/unit) ◦ 500 g (2 bottles × 500 units/bottle × 500 mg/unit) • Up to 50 units per package (or up to 650 mg per unit) of sustained-release formulations, sold in non-pharmacy settings	

Note: Canadian products for infants and children have limited quantities of acetaminophen to reduce the risk of harm with accidental overdose.[3]

Many European countries—including the United Kingdom, Denmark, and Sweden—have implemented pack size restrictions for over-the-counter sales of acetaminophen.[12] Imposing restrictions on pack sizes has been shown to reduce the incidence of acetaminophen-related fatalities in the UK. Since 1998, the United Kingdom has enforced limits on acetaminophen packaging (Table 1).[7,8] Recent data from England and Wales have shown a reduction in the number of deaths from acetaminophen toxicity, from 548 deaths in 1997 to 227 deaths in 2021.[13]

As of February 1, 2025, Australia will implement similar restrictions on package sizes (Table 1) with the aim of mitigating the harm caused by intentional acetaminophen overdoses. Limiting access to large amounts of acetaminophen may help to minimize potential harms associated with this medication.[10]

Child-Resistant Closures

Oral liquid acetaminophen products for infants, packaged with a child-resistant cap, may come with a separate dropper cap to help caregivers measure doses. Common caregiver practice is to replace the original cap with the dropper cap; however, not all of the dropper caps are child-resistant. The use of a product without a child-resistant dropper cap increases the risk of a child accessing the medication, which can lead to inadvertent poisoning.

Some packages of acetaminophen tablets marketed "for arthritis" may not have a child-resistant closure, to make it easier for patients with arthritis to open the container. Such products also make it easier for a child to open the container.

FIGURE 1.
Example of an infant acetaminophen product with a child-resistant dropper cap. *Not all infant products have this safety feature.*

Safe Storage and Disposal

Safe storage and disposal[14] of any unneeded medication, including acetaminophen, requires continuous patient awareness and efforts. Acetaminophen, like other medications, should be securely stored, out of sight, out of reach, and locked away from children, visitors, and pets. Parachute Canada has created a resource with suggestions for a proactive approach to safe storage: https://parachute.ca/wp-content/uploads/2020/04/CheckForPoisons-Parent-and-Caregiver-Tips-to-Prevent-Child-Poisoning-UA.pdf.

RECOMMENDATIONS

Health Care Practitioners

- Only carry and recommend infant's and children's acetaminophen products that have full child-resistant packaging (e.g., original cap AND dropper cap).
- Counsel patients/caregivers about the appropriate dose, recommended maximum daily dose,[15] and directions for safe use of acetaminophen, including the following:
  - acetaminophen content in other self-care products (e.g., cough and cold products)
  - potential interactions (including with alcohol)[1,16]
  - secure storage instructions (especially for products without child-resistant closures)
  - disposal of expired or unneeded products by returning them to the pharmacy
  - added risk when purchasing large quantities of acetaminophen
- If poisoning is suspected, contact the local poison centre through 1-844-POISON-X.[17]
- Consider patient-specific factors and therapeutic appropriateness before recommending analgesic medication. With increasing awareness of the potential for harm related to acetaminophen therapy, one might consider an alternative analgesic, including nonsteroidal anti-inflammatory drugs (NSAIDs) or opioids; however, these medications carry their own risks and may not be appropriate for use by certain patients.
  - NSAIDs may increase the risk of gastrointestinal, renal, and cardiovascular adverse events.
  - The adverse effects of opioids include sedation and constipation, and use of these drugs is associated with the risk of addiction and overdose.[5]

Health Canada, the National Association of Pharmacy Regulatory Authorities, and Manufacturers

- Review current evidence regarding the safest package size and format to reduce the risk for acetaminophen overdose.
- Ensure closures (e.g., original cap AND dropper caps) for all acetaminophen products intended for infants and children are child-resistant.
- Provide additional education and awareness about the safe use and potential harms of acetaminophen.

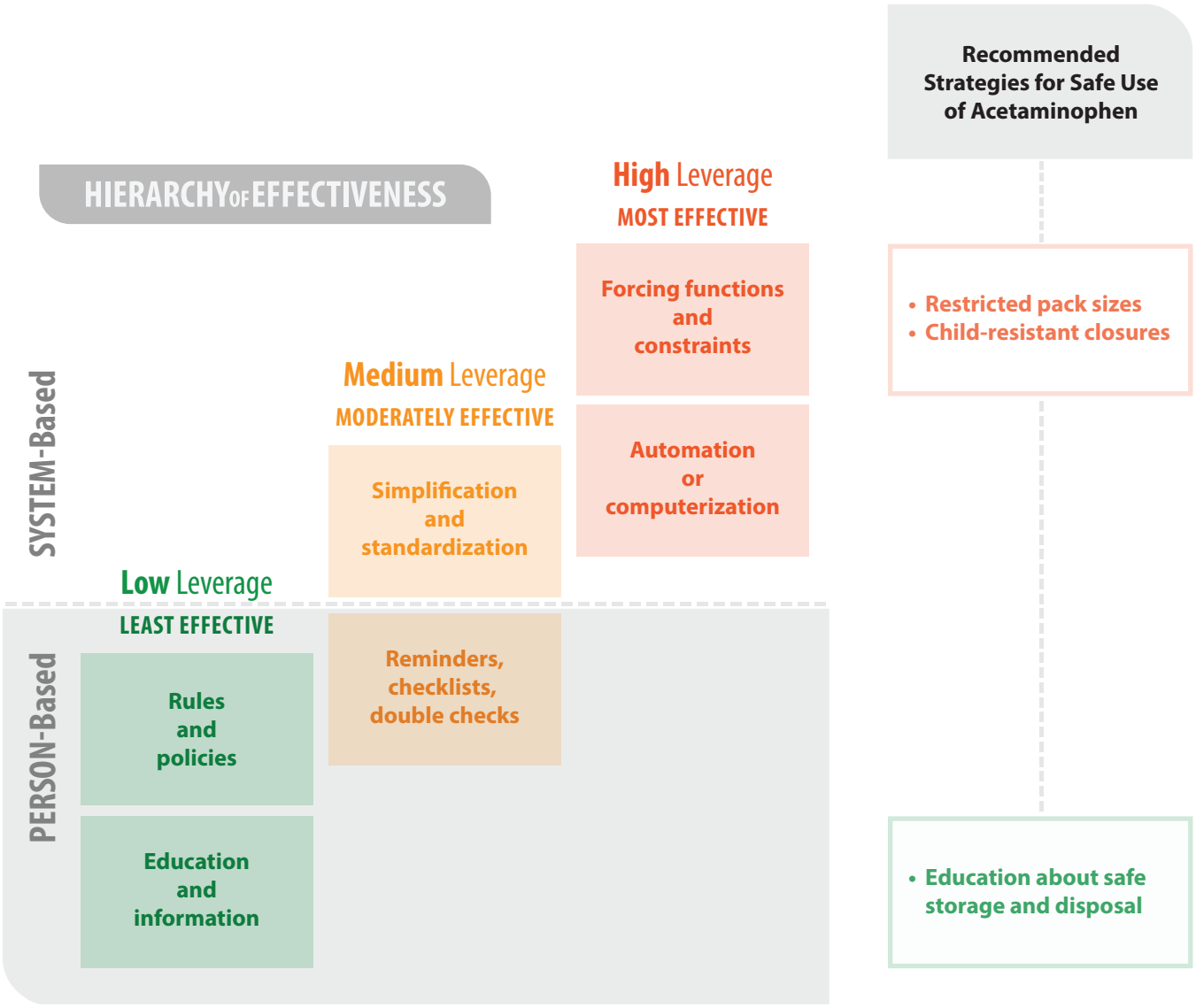


FIGURE 2. The key recommended strategies for safe use of acetaminophen are listed on the right alongside the Hierarchy of Effectiveness,[18] which helps to illustrate relative impact with system improvement.

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Lactulose for Hepatic Encephalopathy

Lactulose is commonly used to treat constipation. This medication is also first-line therapy for the treatment of hepatic encephalopathy, a neurologic complication of cirrhosis.[1,2] When prescribed to treat hepatic encephalopathy, lactulose is administered several times a day to induce 2 or 3 loose or soft bowel movements daily, which facilitates removal of excess ammonia.[1,2] Once the overt symptoms have resolved and the patient is receiving care in the community, lactulose therapy is continued to achieve the same bowel movement targets, so as to prevent recurrence of an acute episode.[2]

ISMP Canada has received several medication error reports describing omission of lactulose doses or substitution of another laxative for the prescribed lactulose, which led or could have led to serious harm. A common theme in these incidents was the mistaken perception that lactulose was prescribed to manage constipation.

> *Incident Example: To treat hepatic encephalopathy, lactulose was ordered to be given every 4 hours. Because the indication was not well understood, the lactulose was not given for 2 days, resulting in the patient becoming confused, a neurologic symptom of hepatic encephalopathy, and requiring additional care.*

To prevent these errors, the following recommendations are shared, including some that have already been implemented by incident reporters.

Organizations/Facilities

- For organizations with computerized prescriber order entry (CPOE) systems, develop a hepatic encephalopathy order set that includes appropriate dosing instructions. This allows for direct communication of the indication and instructions with pharmacy systems, electronic medication administration records, and discharge systems.

Health Care Providers

- When prescribing lactulose for hepatic encephalopathy, include the indication, desired outcome, and a note that lactulose should be given regularly, not as needed.
  - E.g., *For hepatic encephalopathy: Target 2-3 bowel movements per day*
- When providing lactulose for hepatic encephalopathy, share the following counselling points (verbally and/or in writing) with patients and/or their caregivers: indication for lactulose, therapeutic goals/parameters, and potential side effects.
  - Emphasize that lactulose should be given regularly to maintain the desired outcome (i.e., should not be taken on an as-needed basis).
  - Assist patients in coping with side effects such as nausea, bloating, and skin breakdown (e.g., encouraging the use of topical barrier creams).
- Before discharge, arrange for post-discharge follow-up with the patient and/or caregiver, as well as other members of the care team, to support intended lactulose use and to review the desired outcomes of treatment.[2]

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"Mild" or "Severe" Harm? Ensuring the Accuracy of Reported Incidents

Incident outcome (captured by level of harm) is a core component of the Minimal Information Model for Patient Safety Incident Reporting and Learning Systems developed by the World Health Organization.[1] The Canadian Medication Incident Reporting and Prevention System (CMIRPS) defines harm as "a temporary or permanent impairment in body functions or structures".[2] The levels of harm (Figure 1)[3] in ISMP Canada's Individual Practitioner Reporting program are shown to provide an example of definitions that incorporate the immediate consequences of an incident, as well as the patient's eventual outcome.[4] How we understand, interpret, and assign harm in medication incident reports is a key consideration in the decision to conduct a comprehensive, concise, or multi-incident analysis for shared learning.[5]

Accurately attributing harm when reporting an incident helps to ensure that each incident is given appropriate attention in the form of investigation, analysis, and response, which meaningfully contributes to shared learning and overall safety monitoring. Below are recommendations for providers of medication incident reporting platforms, as well as reporters of medication incidents, to support accurate harm attribution.

> *Incident Example: A patient inadvertently received hydromorphone intended for another patient, leading to an opioid overdose. The patient experienced respiratory arrest, with full resuscitative efforts and multiple doses of naloxone being required. The patient had to be intubated and thus needed several days of care in an intensive care unit. After extubation and transfer to a medical ward, the patient was discharged home with no perceptible deficit.*

In this incident example, the reporter shared that they considered "mild harm" and even "no harm" because the patient was discharged with no perceptible deficit. However, with consideration of the specific case details (especially the need for resuscitative efforts, naloxone, and intubation), it was recognized that "severe harm" was justifiable given that life-sustaining interventions were required. If the case was reported as having a lesser level of harm, a comprehensive analysis might be overlooked, and subsequent learning and quality improvement initiatives could be missed.

Mild Harm
An incident occurred that may have contributed to or resulted in temporary harm to the patient and required intervention

Moderate Harm
An incident occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization

Moderate-Severe Harm
An incident occurred that may have contributed to or resulted in permanent patient harm

Severe Harm
An incident occurred that required intervention necessary to sustain life

FIGURE 1. The levels of harm defined in ISMP Canada's Individual Practitioner Reporting program, in addition to the near miss, no harm, and death options not listed here. The levels of harm are adapted from the National Coordinating Council for Medication Error Reporting and Prevention (NCC-MERP) taxonomy of medication errors.[3]

Recommendations

- *Providers of medication incident reporting platforms:*
  - Consider the addition of an algorithm, readily accessible at the point of reporting, to guide the reporter in determining the most appropriate level of harm to report.[3,6]
  - Include in the incident description field a prompt for information about the immediate consequences of the incident, as well as the patient's eventual outcome (if known).
  - Periodically check for alignment with international safety organizations to identify leading practices and support collaborative efforts in analysis and shared learning.[7]
- *Health care providers and patients/families reporting medication incidents:*
  - Review all harm levels in reporting systems before selecting the level that would be most appropriate.
  - Include in the incident description field information about the immediate consequences of the incident, as well as the patient's eventual outcome (if known), to support analyses.

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Join the New Canadian Medication Safety Network!

The Canadian Medication Safety Network (CMSN) is a new, virtual community created for engaging patients, families, and health care providers in improving medication safety. Members will be invited to share their perspectives about medication safety issues with like-minded individuals and organizations. The creation of this network is part of ISMP Canada's commitment to developing purposeful partnerships to advance medication safety across the country.

By joining this complimentary network, you will become part of a pan-Canadian community dedicated to reducing preventable harm from medications. ISMP Canada will also invite members to join virtual consultations on specific medication safety topics. Through your involvement, you will be able to help in designing strategies and tools to meaningfully reduce preventable harm. In addition, you can sign up to receive complimentary issues of the ISMP Canada Safety Bulletin and the consumer oriented SafeMedicationUse.ca Newsletter. You will also have access to online educational modules and workshops at a discounted rate.

On **Wednesday, September 20, 2023**, we will launch the network with a webinar marking the World Health Organization's World Patient Safety Day 2023. The launch event will be an opportunity for providers and patients to come together to celebrate this year's theme of Engaging Patients for Patient Safety.

We look forward to collaborating with you! Membership in the Canadian Medication Safety Network is free to patients, consumers, and health care professionals alike.

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Canadian Medication Safety Network

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CMIRPS SCDPIM
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Système canadien de déclaration et de prévention des incidents médicamenteux

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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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.

ISMP CANADA

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.

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