Canadian High-Alert Medication List

User Guide

2024 Edition

ISMP CANADA

CMIRPS SCDPIM

Canadian Medication Incident Reporting and Prevention System

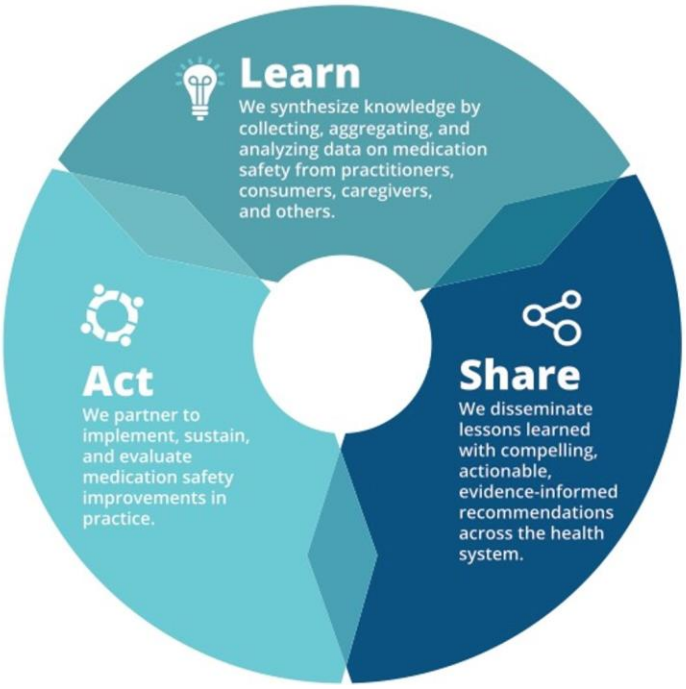
Système canadien de déclaration et de prévention des incidents médicamenteux

Canadian High-Alert Medication List

User Guide, 2024 Edition

The Institute for Safe Medication Practices Canada (ISMP Canada) is an independent national not-for-profit agency committed to the advancement of medication safety in all health care settings.

ISMP Canada's mandate includes collecting, reviewing, and analyzing medication incident and near-miss reports, identifying contributing factors and causes, and making recommendations for the prevention of harmful medication incidents.



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User Guide for the Canadian High-Alert Medication List

Contents

Introduction

High-alert medications are medications that bear a heightened risk of causing significant harm when they are used in error.[i] These medications are not necessarily more likely to be involved in an error or incident, but when such incidents occur, the consequences are often more severe relative to errors involving non–high-alert medications.

A high-alert medication list supports the identification of drugs requiring additional safeguards to reduce the risk of errors and patient harm. Given the range of health care sectors, the variety of care settings, the differing types of medications used, and the diversity of populations served, it is recommended that each individual organization adapt the list to reflect the local context.

The Canadian High-Alert Medication List is applicable to all health care settings.

It is recommended that individual organizations adapt the list to reflect their local context.

Section 1 – Establish and Implement a Local High-Alert Medication List

1.1 Using the Canadian High-Alert Medication List

The Canadian High-Alert Medication List is intended to assist care organizations in developing their own organization-specific high-alert medication list, based upon a review and/or risk assessment of medications in use, as well as the population(s) served. This Canadian list is not intended to be adopted in its entirety as an organization-specific list.

The development process for an organization-specific list will be informed by evidence available through local incident reporting, local safety committees, and staff feedback, as well as knowledge gained from medication safety organizations. Following this thoughtful process, it is possible that some of the medications on the Canadian High-Alert Medication List may not appear on an individual organization's list. Organizations may identify medications that warrant inclusion on their organization-specific high-alert list because of potential vulnerabilities recognized during their risk assessment. In this latter scenario, organizations are encouraged to share with ISMP Canada any medications or medication classes included on the organization-specific list that are not on the Canadian High-Alert Medication List, to inform future revisions and continuous improvement.

The 7 steps outlined in Figure 1 can be used to establish and implement an organization-specific high-alert medication list, as described in sections 1.2 and 1.3.

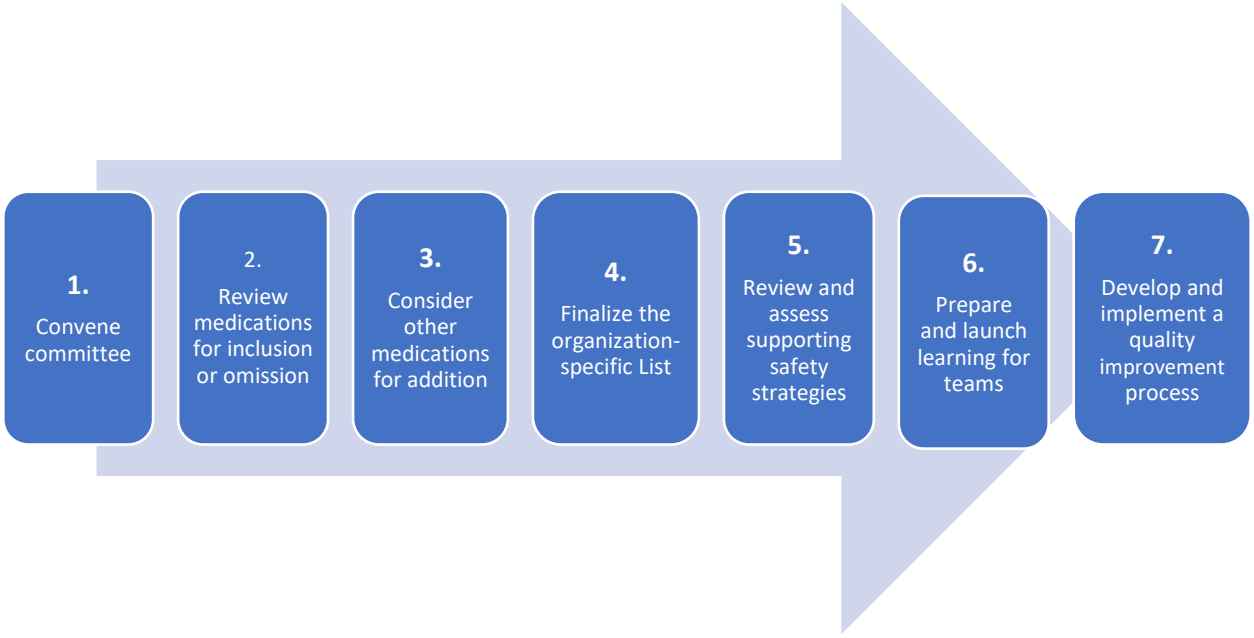

FIGURE 1. High-level process for use of the Canadian High-Alert Medication List.

1.2 Establishing an Organization-Specific High-Alert Medication List

Step 1: Convene a multidisciplinary/interprofessional committee that includes patient and care-provider representation to develop an organization-specific high-alert medication list.

- Assign dedicated personnel and resources to create the initial organization-specific list and provide ongoing resources for monitoring and sustaining safety practices.

- Ensure representation from (but not limited to) the following groups: physicians and other prescribers; nurses; pharmacists; other clinicians who may use high-alert medications; clinical managers; patient and patient representatives; leadership personnel; and quality, risk management, and/or safety practitioners.
- Select as chair of the committee someone who is familiar with medications and patient safety and who has decision-making authority to lead development of the organization-specific high-alert medication list.
- At each meeting of the committee, consider presenting a patient story or incident report related to a high-alert medication to help frame the discussion as critical to patient care.

Step 2: Review and assess each medication class, each medication used in specific circumstances, and each specific medication on the Canadian High-Alert Medication List for inclusion on the organization-specific list.

- Review each drug and class of medications on ISMP Canada's Canadian High-Alert Medication List and determine whether the drug or class is in use, or could potentially be used, in your organization or facility. A medication that is not used or that is out of the scope of practice for your organization may be omitted from the organization-specific list. The following paragraphs describe examples of such considerations:
    - A community pharmacy does not store or dispense oxytocin. Therefore, oxytocin could be omitted from the pharmacy's high-alert medication list.
    - Although a long-term care home does not administer cancer chemotherapy, the local committee believes there may be scenarios in which certain antineoplastic agents might be used within the organization. Therefore, the committee decides to maintain cancer chemotherapy and antineoplastic medications on the organization-specific high-alert medication list.
- Ensure that any omission from the organization-specific list has broad agreement among committee members and ensure that the rationale for omission is documented.

Step 3: Consider other medications of concern for addition to the organization-specific list, according to local data.

- Identify medications not included in ISMP Canada's Canadian High-Alert Medication List that may warrant inclusion on the organization-specific list.
- Review organizational information and data such as safety reports, incident analysis reports, pharmacy utilization data, previous high-alert medication lists, risk management reports, policies and procedures pertaining to high-alert medications, complaint reports, patient and caregiver feedback, front-line practitioner feedback, results of accreditation surveys, and any other information that may assist the committee in developing the organization-specific list.

- Highlight those medications or classes that appear to be disproportionately associated with harm, given what is known about the organization's practice environment and patterns, as well as what is known about the physiologic effects of the medication. The following paragraphs describe examples of such considerations:
    - A hospital has had several harmful medication incidents involving aminoglycoside antibiotics and therefore decides to include aminoglycoside antibiotics on its high-alert medication list.
    - After reviewing its own incident data, a long-term care organization discovers numerous errors related to misdosing of digoxin that caused harm to residents; therefore, the committee decides to include this medication on its high-alert medication list.
    - Because of several serious product selection errors and reports of concern among pharmacy staff, an acute care facility adds medications with both conventional and liposomal forms (e.g., amphotericin B) to the facility's high-alert medication list.
- Consider external materials (e.g., advice from professional regulators) that provide evidence or convey shared knowledge regarding additional high-alert medications.
- Ensure that any addition to the organization-specific list has broad agreement among committee members and ensure that the rationale for inclusion is documented.

Step 4: Finalize the organization-specific list.

- Finalize the organization-specific list by taking into account the context of the practice environment, making the list as simple as possible to understand, implement, and consult. The following paragraphs describe ways in which the organization-specific list can be customized for ease of use:
    - A long-term care home recognizes that local staff members are generally unfamiliar with cancer chemotherapy agents. Therefore, the home decides to designate all cancer chemotherapy agents as high-alert medications, rather than designating select subclasses in this way.
    - A community clinic incorporates into the organization-specific list both the generic and trade names of high-alert medications used in the facility to ensure that practitioners can more easily identify these medications.
    - A long-term care home creates a simplified version of the organization-specific high-alert medication list by omitting medication classes that are not in use within the home (such as anesthetic agents and neuromuscular blockers) and creating visually engaging posters for use in medication storage areas.
    - An acute care facility determines that codeine and acetaminophen combination products do not pose a risk of severe harm if used in error within their organization and

therefore designates codeine as an exception to the opioid class on its organization-specific high-alert medication list.

1.3 Implementing the Organization-Specific List and Associated Safeguards

Step 5: Ensure that safety mechanisms and enhanced safety processes are in place for each medication on the organization-specific high-alert medication list.

- Confirm and evaluate the safety strategies associated with the high-alert medications on the organization-specific list.
    - Use existing policies, procedures, practice audits, and feedback from staff to substantiate the use of overlapping safety strategies that target multiple points in the medication-use process. Ensure that the interventions are as high as possible within the hierarchy of effectiveness [ii] (Figure 2). Where gaps in processes are identified, create an action plan to implement enhanced safety mechanisms and update policies and procedures accordingly.
    - For more detail, see Section 2 – Safety Strategies.

Step 6: Prepare and launch learning for teams.

- Raise awareness of the organization-specific high-alert medication list and associated safety strategies through learning delivered to all teams.
- Repeat learning at regular intervals to reinforce the safety strategies, and update the list and the strategies as appropriate to reflect changes in practice over time.

Step 7. Develop and implement a quality improvement process for the organization-specific high-alert medication list.

- Integrate quality improvement into existing organizational processes to ensure the ongoing effectiveness of the organization-specific list and system safeguards.
- Report to senior leadership the outcomes of the quality improvement processes, including evaluation of the effectiveness of enhanced safety strategies.
- Provide a mechanism for staff to share information about the organization-specific high-alert medication list.
- Continuously monitor incident data and practitioner feedback to identify opportunities and take action to improve the organization-specific list, as well as associated safety strategies.
- Periodically review the organization-specific list to identify any medications that may warrant inclusion or removal to reflect changes in practices or formularies over time.

- Share with ISMP Canada any additional medications, classes, or situations included on the organization-specific list to inform updates to the Canadian High-Alert Medication List.

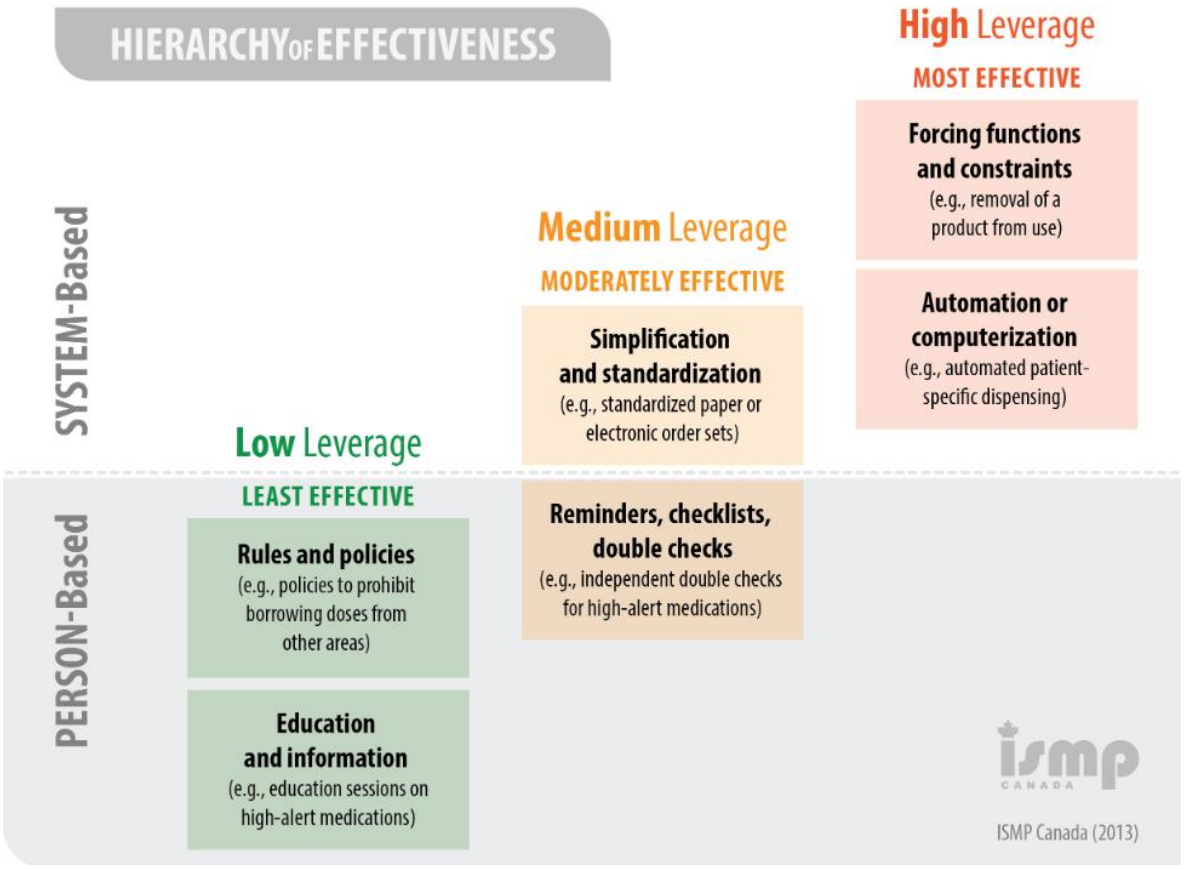

FIGURE 2. Hierarchy of effectiveness (ismpcanada.ca/resource/hierarchy-of-effectiveness/)

Section 2 – Safety Strategies

2.1 Background

Establishing an organization-specific high-alert medication list provides the opportunity for designing targeted safety interventions that will enhance safe and reliable medication-use processes.[iii,iv]

Ensure that multiple, layered safety strategies are used and that they reflect the most effective interventions set out in the hierarchy of effectiveness for safety interventions.

Safety interventions use organizational resources and can add to the physical and cognitive burden on practitioners; therefore, they are best deployed at points in the medication-use process where they will have the most benefit. For example, independent double checks can be useful, but a requirement for too many independent double checks may introduce "checking fatigue". Rather, such double checks should be implemented at the most impactful point(s) in the medication-use process and should be supplemented by other effective strategies.[v]

Strategies suggested in this user guide should be considered in the context of local resources, local processes and procedures, local human resource capacity, and continuous evaluation.

Preventing errors using safety strategies is always the goal, but detecting errors that do occur (making them visible) and facilitating recovery (or rescue) from errors are also important approaches to mitigating harm. Detecting errors allows for the process to be halted and potential recovery and correction to be undertaken. Detection of an error can occur at any point in the medication-use process, including after a medication has been administered. For example, a robust process for evaluating a patient's respiratory rate after intravenous injection of an opioid might detect an unexpected decrease in respiratory drive, making a potential error visible and allowing an error recovery response (in the form of naloxone) to be initiated.

2.2 Contributing Factors in Medication Errors

Understanding the factors that contribute to errors is an important step when developing and implementing safety interventions.[vi,vii] For example, if mathematical calculations are noted as a frequent source of vulnerability in medication preparation, then safety strategies should seek to simplify, reduce, or eliminate the need for calculations and may include use of a premixed product or implementation of an independent double check of calculations.

Review organizational incident reports and investigations, as well as the safety literature, to understand key contributors to errors. Table 1 outlines some examples of errors and related contributing factors.

Table 1. Examples of Types of Errors and Related Contributing Factors

Type of error	Selected contributing factors
Prescribing error	• Missing patient information such as allergy, patient weight, medication history, or organ function • Confusing presentation of drop-down selection options in electronic systems • Lack of clinical decision support
Order entry/transcription error	• Use of abbreviations or "do not use" designations, such as "U" for "units" or trailing zeroes • Poor handwriting • Lack of integrated electronic systems (and consequent reliance on human transcribing between systems)
Selection/dispensing/preparation error	• Cluttered and disorganized storage practices • Availability of multiple formulations or strengths of medications • Confusing or look-alike labelling • Look-alike and sound-alike medication names • Calculation/mathematical errors • Incorrect selection or amount of diluent • Use of atypical concentrations or formulations
Administration error	• Unlabelled syringes or containers • Unclear instructions for use • Lack of patient identification • Disabled or out-of-date error-reduction software in "smart" infusion pumps • Limited information or assistance at the point of care
Monitoring error	• Expected patient monitoring practices not included in order sets • Unrecognized need for antidote or reversal agent • Limited means of escalation of clinical concerns

2.3 Medication System Safeguards

Interventions or safety strategies should target identified contributing factors, should consider the hierarchy of effectiveness (Figure 2), and should be tailored to the organization's care settings, resources available, and populations served. Workload and cognitive burden must always be considered when implementing safety strategies.

Table 2 presents examples of safety strategies that can be considered in the design of system safeguards to help prevent, detect, or recover from errors with high-alert medications.[viii,ix,x,xi]

Table 2. Examples of System Safety Strategies

Strategy type	Safety strategy examples
Forcing functions and constraints ***Forcing functions*** are design elements that prevent something from occurring unless specified conditions have been met. ***Constraints*** are restrictions or barriers to use.	• Computerized prescriber order entry (CPOE) systems require completion of the allergy field before an order can be submitted. • Commercially manufactured premixed intravenous solutions and prefilled syringes are used whenever available, to avoid compounding by pharmacy and medication manipulation at the bedside. • High-alert medications are stored in single-product drawers in automated dispensing cabinets and are available only in single-use containers. • Error-reduction software in "smart" intravenous infusion pumps has hard dosing limits. • Neuromuscular blocking agents are available only in rapid-sequence intubation kits, operating rooms, postanesthetic care units, and/or critical care areas, and these medications are sequestered from other floor stock.
Automation and computerization ***Automation*** is the use of technology to minimize human input into a task. ***Computerization*** is the use of computer software to facilitate a process or provide guidance in safe completion of a task.	• CPOE systems are integrated with pharmacy management software, obviating the need for error-prone transcription. • Infusion pumps with "smart" technology are used in all patient care areas for administration of high-alert medications. • Automated compliance pack filling machines are used by community pharmacies. • Updates to drug libraries in "smart" infusion pumps are performed wirelessly, in real time, so that pumps reflect the most recent version of organizational protocols, order sets, and best practice.[xii] • Product verification strategies (e.g., bar coding) are applied at each step of the medication-use process, including stocking and restocking.[xiii] • Pharmacy computer systems default to a weekly rather than daily dosage regimen for subcutaneous, intramuscular, and oral methotrexate.[xiv] • Laboratory test results can be electronically accessed by members of the health care team who may require this information.[xv]

Strategy type	Safety strategy examples
Standardization ***Standardization*** seeks to make processes more consistent both to reduce cognitive burden and to make potential errors more visible.	• Pharmacy-prepared standardized unit doses are used for high-alert medications that are not commercially available. • Drug concentrations, dosing, and infusion rates (e.g., units/min, units/h, mcg/min, mcg/kg/min) are standardized across the organization. • Evidence-informed standard order sets and care pathways that include expected patient monitoring practices are implemented.[xvi]
Simplification ***Simplification*** aims to reduce cognitive load and limit the need for practitioners to make decisions.	• Ready-to-use products are available to the practitioner. • Order sets and protocols are designed with the end-user in mind and include critical information for safe usage.[xvii]
Reminders, checks, and redundancies ***Reminders*** are repetitions of previously encountered information and can be useful as memory refreshers or references. ***Checks*** are methods of reviewing and evaluating work. ***Redundancies*** are additional components of a process,	• Posters or charts that serve as memory aids or quick references are displayed in work areas. • Independent double checks are judiciously incorporated into the medication-use process. • Checklists are used to introduce verification steps into a process. • Computer pop-up alerts are thoughtfully integrated to serve as reminders and checks. • Auxiliary warnings are added to products intended for use with a specific pump (e.g., "for Patient Controlled Analgesia Pump only").[xviii] • Master formula sheets and compounding worksheets accompany final products received from pharmacies outsourced to provide compounding services. This allows community pharmacy staff to perform their own independent double checks of the calculations and amounts/weights.[xix] • Patients and families are engaged in the plan of care and are aware of signs and symptoms of concern to bring to the attention of a health care provider.[xx] • Clinical advisories that appear during infusion pump programming help guide a check of the pump settings.

Strategy type	Safety strategy examples
implemented to catch errors or process failures.	• Vincristine (and other vinca alkaloids as applicable) is dispensed with a prominent warning label that reads "**For intravenous use only – fatal if given by other routes**".[xxi]
Rules and policies ***Rules and policies*** describe expected behaviours and the processes by which tasks are completed safely in the organization.	• A culture of safety[xxii] is nurtured to support reporting and learning[xxiii] and to offer protections to ensure that learning is shared. • Organizational policy prohibits borrowing medication doses from other care areas. • A process is developed to quickly support end-users when incorrect or missing drug library settings are identified and to remedy the concern.[xxiv] • Prescribers include the clinical indication for all medication and treatment orders, whether routine or "as needed", to support monitoring of drug therapy outcomes.[xxv] • Monitoring of patients receiving medications known to cause sedation (e.g., opioids, benzodiazepines) is carried out through an established process designed to detect unintended advancing sedation, in particular during medication initiation and after dosing changes.[xxvi] • A process is in place to verify patients' opioid tolerance before dispensing of high-dose or long-acting opioids (e.g., fentanyl patches).[xxvii]
Education and information ***Education and information*** are critical to instill knowledge and skills and to raise awareness among practitioners and patients.	• Clinical and prescribing resources (e.g., clinical pathways) are current and easily accessed by all staff in the organization. • Regular educational opportunities are offered to raise awareness of the organization-specific high-alert medication list and related safety strategies, as well as updates to the list and/or new interventions. • Product changes and potential implications are communicated to point-of-care providers.[xxviii]

2.4 Effective and Layered Safety Strategies

Given that most medication errors have multiple contributing factors, no single intervention will eliminate all potential harm. Strategies should directly address the factors known to be contributing to errors; in addition, they should be layered, should be active at different points in the medication-use process, and should seek to prevent, detect, and recover from error.[xxix,xxx] Safety mechanisms should aim to be as effective as possible according to the hierarchy of intervention effectiveness (Figure 2).[xxxi] Although lower-leverage approaches such as education, policies, and procedures are necessary for documentation and staff members' understanding, these should always be accompanied by more robust strategies.

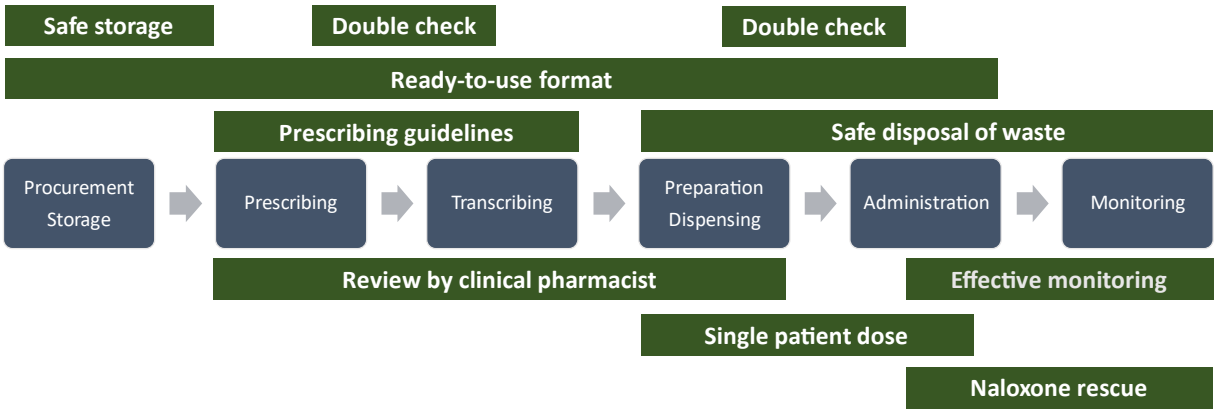

FIGURE 3: Example of multiple overlapping safety strategies in the medication-use process for opioid medications.

As illustrated in Figure 3, the safe use of opioids within an organization can be enhanced across the medication-use process by mitigating factors that might contribute to errors through multiple and overlapping strategies, such as the following:

- Ensuring the safe storage and disposal of opioids and opioid waste
- Adhering to prescribing guidelines
- Instituting a clinical review before administering the first dose
- Providing opioids for administration in single-dose, ready-to-use formats, especially when injectable opioids are prescribed

- Implementing strategic independent double checks
- Appropriately monitoring the patient for adverse effects and recognizing the need for rescue interventions

Similarly, the risk of harm from neuromuscular blocking agents can be mitigated through interventions such as the following:[xxxii]

- Packaging neuromuscular blockers in vials that contain additional warnings on the vial cap and ferrule.
- Sequestering these medications from other floor stock medications (including those stocked in automated dispensing cabinets) in pharmacy storage areas.
- Additionally securing these products in locked containers with lids and locked-and-lidded drawers in automated dispensing cabinets.
- Applying auxiliary labels that provide additional warnings before release to patient care areas.
- Limiting these medications to rapid-sequence intubation kits, operating rooms, postanesthetic care units, and/or critical care areas.
- Limiting permission to administer neuromuscular blockers to trained clinicians who have the knowledge and skill to ensure patient safety.

Conclusion

A high-alert medication list can assist organizations in providing safe and reliable care by identifying medications for which additional safeguards are required to reduce the risk of errors and patient harm. The Canadian High-Alert Medication List incorporates learning from various components of the Canadian Medication Incident Reporting and Prevention System (also known as CMIRPS), the academic and grey literature, international safety organizations, and the opinion of Canadian experts. This list is intended to assist care organizations in developing their own organization-specific high-alert medication list according to the local practice context and local factors of individual health care organizations. To reduce the risk of harm to patients, each organization should ensure that multiple, layered, and effective interventions are built into the management of medications on its organization-specific list. ISMP Canada welcomes shared learning and experiences from all health care settings and will periodically update the Canadian High-Alert Medication List and User Guide to reflect such input and other developments.

Resources

The following is a small selection of the numerous resources available:

- ISMP Canada Safety Bulletins
  https://ismpcanada.ca/safety-bulletins/

- ISMP Canada's Medication Safety Self-Assessments
  https://ismpcanada.ca/resource/mssa/

- ISMP (US) Medication Safety Alert! newsletters
  https://www.ismp.org/newsletters

- Medication safety in high-risk situations. WHO/UHC/SDS/2019.10. Geneva (CH): World Health Organization; 2019. Available from: https://iris.who.int/bitstream/handle/10665/325131/WHO-UHC-SDS-2019.10-eng.pdf?sequence=1

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Dall-E 2 image of "painting of high-alert medications"