Pan-Canadian Diversion Risk Assessment Tool

User Guide

Welcome to the ***Pan-Canadian Diversion Risk Assessment Tool***. This tool was developed in collaboration with:

- The Canadian Society of Hospital Pharmacists (Ontario Branch) (CSHP OB)
- HumanEra (a research team at the University of Toronto and North York General Hospital), and
- The Institute for Safe Medication Practices Canada (ISMP Canada).

Introduction and Background

- Controlled Substances: any drug or substance found in the Schedules of the Controlled Drugs and Standards Act, which includes narcotics and controlled & targeted substances.
    - Your hospital may consider additional medications or therapeutics as Controlled Substances.
- Drug diversion: the illegal distribution or abuse of prescription drugs, or their use for purposes not intended by the prescriber.

This risk assessment tool is designed to help your hospital identify diversion vulnerabilities in the medication use process (MUP) related to Controlled Substances. Each risk assessment item is not intended to be conclusive on its own but is used alongside other sources of information to identify areas of concern.

Previous literature has described a number of risk points in hospital medication management systems and has suggested safeguards. Risk points include handling tasks associated with selection & procurement, storage, prescribing & transcribing, preparing & dispensing, transferring, administering, and disposal processes of Controlled Substances.

Scope of the tool

The tool is **not** intended to be a comprehensive breakdown of all possible risks, in every possible scenario. **The development team is not a standard-setting organization and the assessment items in this document are not intended to represent a minimum standard of practice.**

Within scope: Clinical areas in the hospital, such as the emergency department, critical care, inpatient pharmacy, etc.

Out of scope: Clinical areas requiring procedural sedation and/or anesthesia (e.g., endoscopy suites, labour and delivery, operating suites). These clinical areas have a significantly different workflow and distinct risk profiles from areas that separate prescribing and administration roles (e.g., critical care). Future risk assessment tools will be developed for the OR and Ambulatory Surgery areas.

The evidence that the tool is based on

The tool presents a curated list of risk assessment items to help identify where vulnerabilities to diversion may exist in your hospital. The risk assessment items were drawn from:

- published literature, extracted and interpreted by the development team,
- in-depth feedback from a panel of Hospital Pharmacists drawn from CSHP OB, and
- feedback from a survey to all CSHP OB members.

Some risk items have more support in the literature than others. We expect risk assessment items will be updated in the future, as research develops.

Sections

Expanded Instructions

Expanded Instructions

Navigating and Understanding the Risk Assessment Tool

1. **Ideally one individual in the institution will be in charge of filling out the tool and retaining the login information.** Sharing the login information can result in multiple users completing the same page and causing conflicts or 'overwriting' existing answers provided by someone else.

2. **From the Navigation Box on the left side, select "Assessments" and the most recent dated assessment.**

3. **The tool is divided into Key Elements and Core Characteristics**.

    - **Key Elements** are high level attributes of an organization.
        - They are referred to by roman numeral tabs across the top of the instrument. (e.g., Tab "I" describes Hospital-wide Safeguards).

    - Each Key Element has subsections named **Core Characteristics** (e.g., *Maximize security of stored Controlled Substances* is a core characteristic of Tab "I")
        - Each Core Characteristic has one or more risk assessment items that make up the characteristic (e.g., electronic systems (e.g., medication carts, ADCs, pharmacy vault) time-out (i.e., automatically log out) when left idle.)

- **Navigate to the next section using the roman numerals in the tabs, or the "next section" link at the bottom of each section**
- **The full list is below:**
    - Key Element I: Hospital Wide Administrative Safeguards (13 items)
        - Core Characteristic: Screen and orient hospital staff working with Controlled Substances (4 items)
        - Core Characteristic: Develop organizational infrastructure to investigate, monitor, and report on Controlled Substance Discrepancies (5 items)
        - Core Characteristic: Maximize security of stored Controlled Substances (4 items)
    - Key Element II: Hospital Wide Auditing Safeguards (15 items)
        - Core Characteristic: Quality assurance processes are used to assess Controlled Substance transactions and adherence to procedure on a quarterly basis (6 items)
        - Core Characteristic: Ensure a detailed and accurate audit trail for Controlled Substance Access (3 items)
        - Core Characteristic: Regularly count and assess Controlled Substance inventory for product integrity (6 items)

- Key Element III: Procurement Safeguards
  - Core Characteristic: Procurement decisions are based on usage data and kept independent form receiving personnel (5 items)
- Key Element IV: Safeguards for Patient's Own Medications
  - Core Characteristic: Secure patients' own medications (4 items)
- Key Element V: Controlled Substance Packaging or Preparation/Compounding
  - Core Characteristic: Secure Controlled Substances throughout the repackaging or preparation/compounding process (4 items)
- Key Element VI: Movement of Controlled Substances from One Location to Another
  - Core Characteristic: Account for Controlled Substances when transferring between clinical units/departments (2 items)
- Key Element VII: Withdrawal of Controlled Substances from Stock on Clinical Units
  - Core Characteristic: Reduce unnecessary supply of Controlled Substances on clinical units (3 items)
  - Core Characteristic: Configure ADCs to maximize security and traceability of Controlled Substances transactions (items only for hospitals with ADCs) (6 items)
- Key Element VIII: Administration of Controlled Substances to Patients
  - Core Characteristic: Secure Controlled substances once withdrawn (2 items)
  - Core Characteristic: Employ measures to maximize accuracy of Controlled Substance patient administration records (2 items)
- Key Element IX: Wasting or Disposal of Controlled Substances
  - Core Characteristic: Deter diversion from Controlled Substance waste (5 items)

Preparation

4. **Establish an interdisciplinary team.** Completion of the tool by an interdisciplinary team will foster greater awareness and discussion of diversion vulnerabilities across the organization. The engagement of senior leadership in these discussions may facilitate the advancement of related initiatives.

    a. **We recommend:**

        i. Senior leadership representative
        ii. Patient or patient representative/advocate
        iii. Patient safety/quality improvement and/or risk management professional
        iv. Nursing director/manager
        v. Professional Practice leader
        vi. Pharmacy director/manager
        vii. Physician leader (e.g., chief of service)
        viii. Frontline staff (at least one of each of the following):
            1. Registered nurse
            2. Registered practical nurse

3. Pharmacist
4. Pharmacy technician
5. Physician

5. **Distribute the assessment document before the team meeting so that team members can review and consider the questions in advance. This can be accessed as a PDF from the Navigation Box on the left side.**

    - **Consider assigning an individual to record any discussion generated around each assessment item and the rationale behind the selected choice.** This information, meant for internal use only, can assist the team when reviewing scores for individual items or reassessing the Organization in the future.

Scoring the Risk Items

The assessment items refer to Controlled Substances prescribed, dispensed, and administered to patients. Clinical areas requiring procedural sedation and/or anesthesia (e.g., endoscopy suites, operating suites) and Emergency Situations are considered outside the scope of this tool.

6. **Discuss each assessment item amongst the interdisciplinary team and select the option that represents the level of implementation of the item in the organization.**

    Possible responses:

    The risk assessment tool consists of 61 assessment items divided into 9 Key Elements. Possible responses to each assessment item are described below and assigned a numerical score.

    N- Not Implemented/Never – Select "Not Implemented" for items that are not in use at this time. These items are designed to proactively inform safeguards if or when the practice applies in the future. Scored as 0

    R- Rarely – Select "Rarely" for items that are implemented and in practice less than 50% of the time. Scored as 1

    S- Sometimes – Select "Sometimes" for items that are implemented and in practice 50-75% of the time. Scored as 2

O- Often - Select "Often" for items that are implemented and in practice 75-90% of the time. Scored as 3

A- Always - Select "Always" for items that are implemented and in practice more than 90% of the time. For self-assessment items with multiple components, full implementation (score of A) is appropriate only if all components are present. Scored as 4

Scoring interpretation notes are provided for select assessment items

Category	Degree/level of implementation	Score
Not implemented or Never	Not in use (0%)	0
Rarely	<50%	1
Sometimes	50-75%	2
Often	75-90%	3
Always	>90%	4

The risk assessment tool will sum the scores across all risk assessment items for a total score (higher is better), as well as for each section of the tool, to highlight broad areas of the medication use process that require further attention.

Please note, the scoring standard is not evenly distributed across responses. High scores are disproportionately more difficult to achieve than mid-range scores. The scoring standard is designed this way in an attempt to reflect that having an assessment item in practice 50% of the time ("R = rarely") is only marginally better than not having implemented the safeguard at all ("N = never"). Diversion safeguards require a high degree of consistency and reliability to be effective.

Discretion in Scoring

The risk assessment items are designed for typical clinical scenarios, but your team may have questions about how to balance different situations. For example:

- Regular inpatient Controlled Substance administration protocols may differ from code blue practices,
- Documentation practices may differ between admitted and non-admitted patients in the emergency department,
- Outpatient prescribing may differ significantly from inpatient settings,
- Your hospital may already have a safeguard in place, but it is unclear how well it aligns with what is suggested in the risk assessment item.

While the risk assessment items are general enough to highlight potential diversion risks, your team will need to ascertain the degree to which your specific workflows are vulnerable and score appropriately.

The risk assessment tool aims to ensure that Controlled Substances remain physically protected, documentation of each transaction is accurate, and auditing procedures are in

place for both medications and practices, so that anomalies can be detected. You may choose to exclude some of your hospital's clinical areas to simplify your thought processes around scoring. However, be cognizant that **excluding elements of your practice when performing the assessment may artificially boost your perception of safety against diversion.**

Items not applicable to your facility

The "not applicable" option is not available for any risk assessment item. If the interdisciplinary team feels that an item is not applicable, scoring options include:

- Selecting A "Always" – select "A", if, in the opinion of the team, this item, despite being not applicable, truly does not represent a risk. For example, in item number 22 *(Controlled Substances dispensed to patients on temporary leave from the hospital (e.g., Pass medications) have quantity dispensed to patient and quantity on patient's return documented by two authorized health care staff and returned medications are rendered unusable),* if the facility does not allow patients to leave on temporary terms, then this scenario does not pose an actual risk, and a score of "A" is applicable.
- Select N "Never" - select "N" if, in the opinion of the team, this item, despite being not applicable, still does represent a risk.
- Select N "Never" – as this is a self assessment-instrument designed to highlight good practices and identify areas for improvement, selecting "N" serves to highlight a potential risk area that deserves further consideration or investigation.

- **The final tab is an evaluation section for you to provide feedback.**

  This section allows the tool developers to understand how users complete and use the tool, in order to improve future releases. The development team also welcomes any feedback via mssa@ismpcanada.ca.

Finalizing your assessment

7. Save and validate your answers

You will be prompted to save your assessment responses for each section before you proceed to the next section. You can edit any responses until the assessment is submitted. When all responses have been entered, you will be prompted to "Check Assessment for errors" and then to submit your results

Once submitted, the web-based survey tool will immediately download the information into a secure database maintained solely by ISMP Canada. No data is maintained on the internet survey form after it has been submitted. Individual results can be viewed or accessed only by the Organization submitting them.

8. **Print/view your completed assessment.**

   Once your results have been submitted you will be able to print a report summarizing your results.

Interpreting and Using your Score

How to Think About Your Risk Assessment Score

- **A higher score suggests that your practices are better positioned to prevent or detect diversion:** Although this is a risk assessment tool, we have worded the items so that a 'high' score means the hospital is doing well (i.e., the risk has been addressed).
- **The goal is to find vulnerabilities rather than score well:** Hospitals may be tempted to 'maximize' their scores, much like a student doing well on a test. However, the goal of the assessment is to identify where scores are low, so that hospitals know where risks exist (even if they do not have the resources to immediately address it). Rather than viewing low scores as failing, we hope hospitals use the tool to prioritize areas requiring further attention and discussion.
- **Hospitals are unlikely to achieve a perfect score:** Diversion is difficult to detect and prevent, therefore some of the risk assessment items describe practices that are aspirational. This is deliberate (see next bullet). Individual hospitals should not expect to score highly in all areas.
- **All of the presented strategies are achievable given sufficient resources** (e.g., financial, human, technological, etc.): We anticipate that certain risk assessment items will have universally low scores across hospitals, and this will serve as evidence that further research, funding and policy are needed to target these risks. We recognize hospitals must balance diversion risks against other objectives (e.g., staff workload), but the goal of this tool is to identify diversion risks.
- **A maximum score on an item or the entire tool does not necessarily suggest a hospital is well guarded against diversion:** This risk assessment tool itself does not capture all possible mechanisms of diversion nor does it address operating rooms or procedure rooms. The tool only provides a snapshot of current vulnerabilities – changes to practices and policies over time will alter the risk of diversion.
- **Risk assessment items are technology agnostic:** For example, a risk assessment item may ask if hospitals ensure there is a documented audit trail of who retrieved Controlled Substances and for which patient. This audit trail can be achieved with automated dispensing cabinets, but there may be other means of achieving a high score on the item.

9. **Compare your results to the aggregate.**

Once your results have been submitted you be able to compare your results to the aggregate response using the “Graph Results”. Navigate through the graphs using the roman numeral tabs above the graph. Hovering over each graph element will bring forth the appropriate assessment item. You can compare to the total aggregate or to demographically similar facilities, using the filters provided.

What to do next

Identify those elements of characteristic in which you score low, or lower than the aggregate. With the help of the team, identify the vulnerabilities that carry a high risk of enabling diversion and prioritize these for mitigation. To support your next steps in deciding how to address areas of high risk, please consult the Reference Guide from the left navigation panel. This document will provide recommended reading and considerations related to improving your hospital’s medication processes. Review the literature and guidance on good practices that may mitigate these vulnerabilities and consider implementing changes to reduce the risk of diversion.

Using aggregate data

Organizations can freely share their own results internally and externally to the organization as they deem appropriate; however, any comparisons to aggregate data can only be shared externally with written permission from ISMP Canada.
Email mssa@ismpcanada.ca for more information.

Data Use, Privacy, and Confidentiality

How Your Data Will Be Used

All hospitals participating in the use of the tool will have their responses captured in an aggregate, non-attributable, non-identifiable way in the ISMP Canada server. Aggregate data will be reviewed to identify systemic issues across all hospitals, and identify differences by hospital size, technologies used etc. Individual hospitals will be able to access aggregate results for comparative purposes only.

Data Privacy and Confidentiality

Data submitted via this online assessment tool is stored by ISMP Canada. ISMP Canada is committed to protecting the privacy, confidentiality, and security of any information for which it is responsible. All

activities related to this risk assessment tool data are conducted in compliance with ISMP Canada's privacy policy.

Individual hospitals are able to access aggregate results for comparative purposes. Individual respondents cannot be identified from the aggregate results. ISMP Canada has a minimum sample size of 3, such that any data field with less than 3 responses is redacted from the aggregate.

Aggregate data will be used by ISMP Canada for quality improvement, research, and education purposes, including sharing de-identified summaries with system partners.

Contact Information

For more information, please contact mssa@ismpcanada.ca or info@ismpcanada.ca.