Pan-Canadian Diversion Risk Assessment Tool: Quick Reference Guide

This document may be periodically revised.
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Purpose

This “Quick Reference Guide” (QRG) is designed to support hospitals that have **completed** the Pan-Canadian Diversion Risk Assessment Tool. Completion of the tool will support hospitals to prioritize and rank the risks items requiring corrective action (decided by teams at each hospital based on feasibility, cost, alignment with other improvement projects).

This QRG provides strategies for implementing effective corrective actions and relevant literature to reduce the risk of diversion.

Who Created the Risk Assessment Tool and Quick Reference Guide?

The **Canadian Society of Hospital Pharmacists Ontario Branch** (CSHP OB) is the provincial chapter representing Ontario in a national voluntary organization of pharmacists committed to patient care through the advancement of safe, effective medication use in hospitals and other collaborative healthcare settings. CSHP OB volunteers met to review the risk assessment items or answered surveys to provide their feedback.

HumanEra is an applied human factors research team based at the Institute of Health Policy, Management and Evaluation (University of Toronto) and the Centre for Research and Innovation (North York General Hospital), and also is affiliated with the Centre for Global eHealth Innovation at UHN.

HumanEra's approach focuses on holistically capturing the *interactions* between people, technology, the environments in which they work, and the processes they facilitate. The team engages with the full spectrum of stakeholders (from front-line staff to patients, support workers, and organizational/policy decision-makers) by using methods such as clinical observations and in-situ and laboratory-based simulations. As a result, HumanEra: captures the complexity of day-to-day operations; designs interventions that are informed by and supported by those most affected; quantifies improvements in rigorous simulation; and maximizes the probability of intervention uptake, an ongoing challenge facing the health system today.

For more information, visit www.humanera.ca.

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 healthcare settings. ISMP Canada works collaboratively with the health care community, regulatory agencies and policy makers, provincial, national and international patient safety organizations, the pharmaceutical industry and the public to promote safe medication practices.

ISMP Canada's mandate includes collection, review and analysis of medication incident and near-miss reports, identifying contributing factors and causes and making recommendations for the prevention of harmful medication incidents. Information on safe medication practices for knowledge translation is published and disseminated.

Additional information about ISMP Canada, and its products and services, is available on the website: https://ismpcanada.ca/

Acknowledgement
The project team sincerely appreciates the efforts of members of the CSHP OB members who contributed to the project. The project team also acknowledges the efforts of all persons and organizations working to reduce diversion risks in hospitals, in particular those from whom we have drawn advice or guidance.

Disclaimer
This document has been prepared as part of a research project funded by the Canadian Institutes of Health Research and is provided as a service to others. We declare that a prior version of the risk assessment tool was built with funding provided as an educational grant by BD Canada Inc. (industry sponsor).

Not all evidence, knowledge, or advice may have been available or taken into account when preparing this document and not all possible practices informing hospital medication use processes may have been considered or presented. Any person seeking to apply or consult this document is expected to use independent judgement in the context of individual circumstances. The project team makes no representation or guarantee of any kind regarding the use or application of this document.

The project team is not a regulatory or standard setting body and as such recommendations must be evaluated in the context of professional standards, regulations and expectations.

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How the Risk Assessment and Quick Reference Guide is Organized

Risks Identified in the Literature

The safeguards recommended in the risk assessment tool and this QRG document are primarily informed by a scoping review of literature published in 2019. The scoping review included 312 articles and discussed the risk factors and safeguards for diversion at each stage of the medication use process (e.g., procurement, storage, preparation, prescribing, dispensing, administration, wasting, disposal).

Emerging from the literature were two main dynamics that enabled diversion:

1. **Failing to maintain the physical security of Controlled Substances:** Examples include:
    - Propping doors to secured areas open; failing to log out of automated dispensing cabinets so that they are functionally 'unlocked' for withdrawals.
    - Leaving Controlled Substances unsecured and unsupervised where they can easily be taken or tampered with.
2. **Falsification of clinical or inventory documentation:** Examples include:
    - Intentionally mis-documenting drug amounts ordered, administered, and wasted, or artificially increasing patients' pain scores.
    - Intentionally miscounting drug inventory, removing transaction records, forging signatures verifying counts.

Following the findings of the scoping review, we organized the Risk Assessment Tool and QRG into 9 Key Elements that address various phases of the medication use process, described below.

The Key Elements Work Together

The 9 Key Elements that describe safeguards across the medication use process are depicted in Figure 1.

Figure 1. Distribution of Key Elements that describe Diversion Safeguards across the Medication Use Process

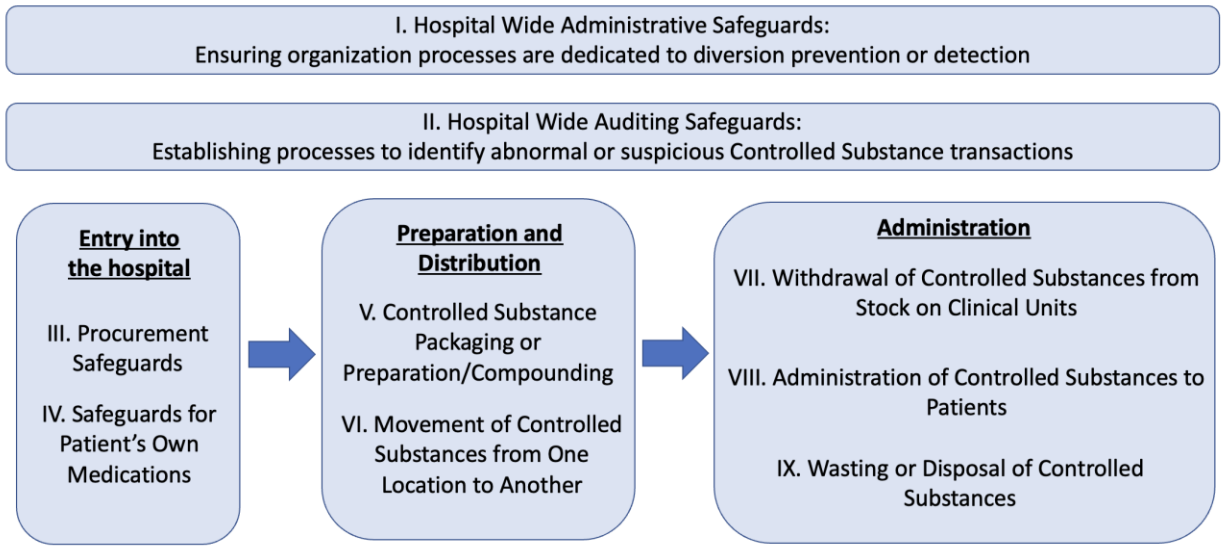

Figure 1 depicts Key Elements I and II as playing an important role in preventing or detecting diversion at any part of the lifecycle of Controlled Substances as they pass through the hospital. The remaining Key Elements address specific issues at each stage of the medication use process. For simplicity, we describe three main stages for Controlled Substances in the medication use process:

1. Controlled Substances enter the hospital through typical procurement processes (typically managed by inpatient pharmacy) or when patients bring their own medications.
2. Controlled Substances are then repackaged into smaller doses or amounts for distribution to patient care areas.
3. Controlled Substances are then used locally in specific patient care areas, where a high degree of teamwork and numerous transactions may result in many 'touch points' by a wide variety of clinical staff.

Guiding Principles

Each Key Element has sub-themes, known as Core Characteristics, which are groupings of risk assessment items related to a specific topic. All of the risk assessment items aim to address the two issues of **physical security** and accurate **documentation** of Controlled Substances. In practice, these are inter-related issues, because documentation can be compromised when the physical security of the Controlled Substances are not safeguarded (e.g., physical tampering may not show up in documentation).

Therefore, all of the risk assessment items aim to support one or more of the following principles, which should be considered at every stage of your hospital's medication use process:

1. **Maximizing Physical Security:** Controlled Substances should be secured (e.g., locked cabinets or compartments) at all times until needed.

2. **Minimize Access to Unsecured Controlled Substance:** The lowest appropriate quantity/dose of Controlled Substances are removed from locked cabinets or medication rooms, handled by as few people as possible, kept away from unmonitored non-clinical areas (e.g., staff lockers, washrooms, backpacks, purses), and used and disposed of in the shortest possible time.
3. **Data accuracy and completeness:** Records of Controlled Substance transactions should reliably capture as many relevant attributes as possible (e.g., correct staff, intended patient, time of transaction), reflect the correct quantities of Controlled Substances involved (e.g., counting quantities inside opaque boxes, verifying tamper seals are intact), and be verified by a second source if possible (e.g., independent witness for wasting, blind counts from automated dispensing cabinet vault).
4. **Data consistency:** Controlled Substance practices should be as standardized as possible so that clear 'baseline' patterns of use can be established so that abnormalities in documentation are more evident. If there is no 'standard' pattern of Controlled Substance use (for example, prescribers use highly variable doses for the same patient population or if nurses inconsistently document waste), the resulting audit trails will be difficult to interpret and abnormalities associated with diversion will not be detectable.
5. **Data monitoring:** Controlled Substance documentation should be regularly audited and reviewed for abnormal patterns (e.g., unexplained increases in usage, investigating clinical units with high rates of unresolved discrepancies in transactions, specific staff with usage patterns divergent from their peers).

How to Read this Document

After selecting which Key Element, Core Characteristic, or risk assessment items require further attention (based on the scores provided by the Risk Assessment Tool), please go to the relevant page in this document.

The QRG provides broad commentary for each Core Characteristic in three ways:

1. Rationale: Why is this practice recommended?
2. Implementation Considerations: What are some considerations when implementing these items?
3. Resources: What are the references that support having the item in the RA tool and which resources can inform efforts to address the item?

Recommended Reading

At the end of this document, we share a list of key resources that are **highly recommended** for readers who wish to understand Controlled Substance diversion prevention and detection further. These key resources inform a large part of the recommendations made in the QRG, and are therefore not repeated throughout.

Recognize that the literature is ever-evolving, and knowledge and practices change frequently. Much of the literature herein may be informed by non-Canadian jurisdictions, where regulations, laws, and practices may not be reflective of the standards and obligations in the Canadian practice milieu. Before assessing and implementing strategies, up to date local legislation and requirements related to Controlled Substances should reviewed.

Key Element I – Hospital Wide Administrative Safeguards

This Key Element contains 3 Core Characteristics:

1. I.1 – Screen and orient hospital staff working with Controlled Substances (Items 1 to 4)
2. I.2 – Develop organizational infrastructure to investigate, monitor, and report on Controlled Substance discrepancies (Items 5 to 9)
3. I.3 - Maximize security of stored Controlled Substances (Items 10 to 13)

These safeguards encourage staff to follow a standardized practice pertaining to the security and documentation of Controlled Substances, which in turns supports an easy to interpret audit trail for monitoring and investigation.

Core Characteristic I.1: Screen and Orient Hospital Staff Working with Controlled Substances

This Core Characteristic is made up of 4 risk assessment items:

- Item 1: Police background checks are conducted on all health care workers upon hire.
- Item 2: Orientation to Controlled Substance policies and procedures is completed before access to Controlled Substances is permitted.
- Item 3: Orientation for all individuals who access Controlled Substances describes standard operating procedures for Controlled Substance handling and documentation.
- Item 4: Education on diversion and substance use disorder is provided to all individuals who access Controlled Substances, on an annual basis. It includes the following topics:
    - Define and destigmatize diversion and substance use disorder
    - Describe what concerning activity might look like, and why and how to anonymously report it
    - Review support and treatment options available to staff

<u>Rationale</u>

- The objective of this Core Characteristic is to establish **consistent** medication handling and documentation processes for staff that interact with controlled substances. This allows for abnormal patterns of Controlled Substance use to be spotted more quickly.
- Education is essential to motivating staff to adhere to Controlled Substance practices, while also reducing stigma and addressing barriers to reporting suspected diversion. A culture of transparent discussion, trust in the organization's confidential investigative practices, and

assurance of rehabilitative support for affected staff will improve diversion detection and reporting.

Implementation Considerations

Police Background Checks

- It may be beneficial to periodically repeat police background checks on high-risk staff (e.g., pharmacy staff in charge of procurement), rather than only upon hire.

Orientation to Controlled Substance Policies and Procedures

- Consider how to orient staff in roles that may have tangential access to Controlled Substances. For example, environmental services staff may encounter unsupervised medications when cleaning rooms of patients who have been discharged, or have contact with medication waste bins.
- Orientation may be more compelling if updated with recent news stories of diversion from your city or region, or even cases that have occurred at the hospital. Ensure orientation is updated to match new processes (e.g., new technology may have affected Controlled Substance handling).

Education on Diversion and Substance Use Disorder

- Explaining how the hospital will respond to individuals with substance use disorder can reduce stigma and improve the likelihood that staff will report suspicious behaviour because they know their colleague will receive help (conversely, punitive approaches may discourage reporting – further research is required to determine what approach is optimal). Regardless, hospitals should establish the response that will be taken by human resources and occupational health and safety, and also identify what must be reported to regulatory professional colleges, law enforcement, and other entities. This can then be summarized in staff education sessions.
- Staff should be informed that diversion investigations will be handled confidentially and as a result, they will not necessarily be privy to the findings of an investigation. Silence from the investigation team should not be mistaken as a sign that no investigation was conducted. This knowledge may help prevent staff from feeling as if their concerns have not been heard, but rather that discretion and confidentiality are of the utmost importance to the organization until actionable evidence has been collected.
- Managers may require separate education around what to do if they suspect a worker is impaired, how to manage a worker in recovery, and what their responsibilities are should they become aware of or suspect diversion.

Resources

- Examples of Canadian Guidance describing reporting requirements (seek appropriate equivalents in your province or territory):

    - Office of Controlled Substances. Guidance on reporting loss or theft of controlled substances and precursors: Overview. https://www.canada.ca/en/health-canada/services/publications/healthy-living/loss-theft-controlled-substances-precursors.html
    - Ontario College of Pharmacists. Code of Ethics. https://www.ocpinfo.com/wp-content/uploads/documents/CodeofEthics_final.pdf (See items 4.10 and 4.11).
    - College of Nurses of Ontario. Practice Standard: Ethics. https://www.cno.org/globalassets/docs/prac/41034_ethics.pdf (See behavioural directives on page 10 and 11).
    - College of Physicians and Surgeons of Ontario. Mandatory and Permissive Reporting. https://www.cpso.on.ca/Physicians/Policies-Guidance/Policies/Mandatory-and-Permissive-Reporting (See line item 21 and 86).
- Missouri Bureau of Narcotics & Dangerous Drugs. Drug diversion in hospitals-A guide to preventing and investigating diversion issues. https://health.mo.gov/safety/bndd/doc/drugdiversion.doc
- North Carolina Healthcare Association. (2018). Diversion Awareness Education Framework. https://www.ncha.org/wp-content/uploads/2018/06/Diversion-Awareness-Education-Framework.pdf
- Martin ES, Dzierba SH, Jones DM. Preventing Large-Scale Controlled Substance Diversion from within the Pharmacy. Hospital Pharmacy. 2013;48(5):406-412. https://doi.org/10.1310/hpj4805-406
- Berge, K. H., Dillon, K. R., Sikkink, K. M., Taylor, T. K., & Lanier, W. L. (2012, July). Diversion of drugs within health care facilities, a multiple-victim crime: patterns of diversion, scope, consequences, detection, and prevention. In *Mayo Clinic Proceedings* (Vol. 87, No. 7, pp. 674-682). Elsevier. https://doi.org/10.1016/j.mayocp.2012.03.013

Core Characteristic I.2: Develop organizational infrastructure to investigate, monitor, and report Controlled Substance discrepancies

This Core Characteristic is made up of 5 risk assessment items:

- Item 5: One or more interprofessional committees are assigned responsibility for the regular review of Controlled Substance quality assurance findings, interpretation of findings, etc.
- Item 6: An interprofessional diversion response team has been identified with clear expectations for each team member that responds quickly to potential incidents of diversion
- Item 7: Appropriate metrics that assess Controlled Substance diversion risk are reported quarterly to each clinical unit and to the executive level of the organization
- Item 8: An anonymous reporting mechanism, such as a phone hotline, is employed to allow staff to alert the appropriate interdisciplinary committee about diversion concerns
- Item 9: Reports (anonymous or otherwise) from the reporting mechanism(s) are reviewed by the diversion response team within 48 hours to maximize quality of investigative data, and detect possible diversion before it is repeated

Rationale

- The central idea behind this Core Characteristic is that monitoring, investigating and responding to diversion will not reliably occur unless the hospital creates dedicated committees and/or diversion response teams accountable for these tasks.
- Multiple professions should be included in these committees because Controlled Substance management is not solely a pharmacy responsibility. A diverse membership will account for practice variations between clinical units and professional roles.
- Committees should abide by set policies and procedures. This ensures standardized and consistent data collection and analysis of diversion metrics, supports consistency and confidentiality in diversion investigations, and formalizes accountability for diversion prevention and detection as an organizational priority.
- A dedicated diversion response team and anonymous hotline for tips from staff about suspicious behavior will facilitate rapid responses to investigate and stop individuals who are diverting as soon as possible, to prevent patient harm, staff harm, drug trafficking, and public relations challenges.

Implementation Considerations

It may be useful to implement two groups: 1) an interprofessional steering committee and 2) a diversion response team. Other arrangements may be more suitable in your institution.

Steering Committee

- The steering committee should be responsible for:

    - Defining monitoring and surveillance measures, including thresholds of variance that require action and reporting frequency (See Key Element II for ideas);
    - Regular interprofessional committee meetings (at least quarterly) should include discussions on trends or concerns identified in analyses based on relevant data sources (e.g., narcotic count reports, Health Canada loss and theft reports, tracer results, ADC data, override & discrepancy reports and routine or random audits). Use of these sources also contributes to improving the availability and quality of these data sources. (Clément et al., 2019);
    - Reporting key performance metrics to senior leadership on a regular basis;
    - Ensuring specific staff are resourced to conduct reviews of collected data and reporting back to the committee on a regular basis;
    - Creating or revising organizational policies to support diversion mitigation (e.g., wastage policies should enforce accountability and verification where possible, inpatient pharmacy compounding processes should account for risks);
    - Providing leadership, direction and guidance on the overall diversion prevention efforts for the organization (e.g., updating orientation materials, advocating for relevant features when new equipment is being procured that may affect Controlled Substance tracking or security, providing ongoing education to key hospital stakeholders so that diversion prevention and detection is understood to be an organizational priority).
- Interprofessional membership on diversion committees/teams is important. While membership may vary between institutions, examples and benefits of various roles include:
    - Pharmacy expertise can assess whether inventory levels have departed historical trends, per drug and per clinical unit in the hospital.
    - Medical and nursing expertise can comment on whether variability in ordering, administration or wastage between staff is within reasonable ranges for the practices observed in different units in the hospital.
    - Security and Information Technology personnel may be able to determine which staff have accessed which areas, at what times (e.g., ID access badge records, security footage)
    - Infection prevention and control may consult on outbreaks of bloodborne pathogens. This is because tampering of Controlled Substance stock on a specific clinical unit, or substitution of syringes used for patient care, can result in multiple patients becoming infected with the same pathogen.
    - Patient Safety, Risk Management, Compliance and Legal teams may be familiar with best practices for incident investigation, relevant legislation and defensible responses from an organizational perspective.
    - Occupational Health and Safety and Human Resources may be able to provide guidance and rehabilitation options for staff with substance use disorder.
    - Corporate Communications may be useful to framing messaging to internal staff and external stakeholders when needed.

- Other stakeholders may be useful based on each institution's experience and staffing.

Diversion Response Team

- The diversion response team is usually a smaller group tasked with immediately responding to potential diversion (discussed in risk assessment items 6 and 9). Key factors to consider:
    - The investigation process should be standardized to avoid bias (e.g., all individuals, regardless of role, seniority, gender, race, experience will be investigated in a fair manner).
    - Note, investigations may damage staff reputations, even if exonerated later, if not conducted discreetly; mitigating these issues should be considered in advance as much as possible.
    - Notifications or updates on diversion investigations to stakeholders should be tiered and based on the stage and findings of the investigation

Policies and Procedures to Consider

- The diversion response team should develop processes and define strategies for:
    - Responding quickly and within 48 hours
    - Collecting, securing and reviewing evidence
    - Confidentially investigating and interviewing staff who may be diverting
    - Recording the actions taken and outcomes from the response
    - Reporting to Health Canada, law enforcement, professional colleges, hospital leadership, etc.
- Procedures developed for diversion investigations may benefit from legal counsel review prior to investigating suspected diversion

<u>Resources</u>

- These safeguards are well supported in the Guidance Documents suggested in the Recommended Reading section at the end of this document.

Core Characteristic I.3: Maximize security of stored Controlled Substances

This Core Characteristic is made up of 4 risk assessment items:

- Item 10: Personal effects (e.g., backpacks, purses, bags and jackets) are prohibited from Controlled Substance (CS) areas (e.g., pharmacy vault, medication rooms on clinical units)
- Item 11: Access privileges are disabled or removed within 24 hours for staff who have been terminated or on leave
- Item 12: Controlled Substances are secured in a double-locked location (e.g., narcotic drawer in medication room). Access is limited to authorized personnel. Physical CS keys are treated as if they are CS themselves
- Item 13: Electronic systems (e.g., medication carts, ADCs, pharmacy vault) time-out (i.e., automatically log out) when left idle

Rationale

- This Core Characteristic emphasizes that Controlled Substance storage sites (e.g., medication rooms, ADCs, vaults) must protect the physical security of the medications.
- Secure storage sites also serve as the basis for synchronizing inventory against documentation because they are (typically) regularly counted and verified for integrity.
- Controlled Substance storage sites can also be configured so that access is tightly regulated and therefore auditable (e.g., as a static location, cameras can be used alongside access protocols that track time of access and identity of staff making transactions).

Implementation Considerations

- Controlled Substance storage locations may vary considerably throughout the hospital; ensure that each clinical unit's unique characteristics and access protocols are accounted for.
- Ensure policies and staffing are designed so that access privileges to Controlled Substance areas are regularly updated to account for changes in staff roster (e.g., transfers, termination) or assignment.
- Many electronic systems typically require staff to "log-in" so that transactions can be tied to specific individuals (e.g., an electronic signature). When staff fail to log-out, documentation is compromised and this may complicate diversion investigations. Diversion response teams should be sure to take this limitation into account.

Resources

- These safeguards are well supported in the Guidance Documents suggested in the Recommended Reading section at the end of this document.

Key Element II – Hospital-Wide Auditing Safeguards

This Key Element is comprised of 3 Core Characteristics, each of which will be discussed below.

1. II.1 - Quality assurance processes are used to assess Controlled Substance transactions and adherence to procedure, on a quarterly basis (Items 14 to 19)
2. II.2 - Ensure a detailed and accurate audit trail for Controlled Substance access (Items 20 to 22)
3. II.3 - Regularly count and assess Controlled Substance inventory for product integrity (Items 23 to 28)

The practices suggested in these Core Characteristics work together to form a consistent and well-documented medication process that will support the detection of diversion and facilitate a thorough investigation and resolution of anomalies when reported.

Core Characteristic II.1 Quality assurance processes are used to assess Controlled Substance transactions and adherence to procedure, on a quarterly basis

This Core Characteristic is made up of 6 risk assessment items:

- Item 14: Random in-person audits of clinical units to assess adherence to Controlled Substance standard operating procedures are conducted at least quarterly
- Item 15: Quality assurance processes are conducted at least quarterly on prescribing records
- Item 16: Quality assurance processes are conducted at least quarterly on records of retrieval from unit stock (e.g., narcotic drawer or ADC)
- Item 17: Quality assurance processes of administration records are conducted at least quarterly
- Item 18: Quality assurance processes of records of Controlled Substance waste are conducted at least quarterly
- Item 19: Quality assurance processes are conducted quarterly at a minimum to reconcile Controlled Substance records spanning multiple record-keeping systems

Rationale

- Regular auditing is essential to identify abnormalities in Controlled Substance use.
- Some types of diversion are only detectable when discrepancies *between* documentation systems are audited (e.g., does the amount prescribed, retrieved from unit stock, administered and wasted reconcile? Are the quantities/dosages similar to the general patterns of use for the clinical unit?)
- Auditing pathways, once established, can be re-used in a targeted fashion to support diversion investigations.

Implementation Considerations

Designing the Audit Process

- The interprofessional committee(s) described in Core Characteristic I.2 should be responsible for designing QA procedures, including identifying what metrics should be included in the audits, the schedule, who should conduct and participate in the audits, and how the results from the audits should be compiled, reviewed, stored and communicated
- Be aware that the auditors themselves can aid in diversion efforts (e.g., suspicious reports may be downplayed to protect staff on the unit and there have been reports of managers not flagging issues to obscure their own involvement diverting medications). Consider rotating auditors or occasional peer review of process.
- Random, unannounced in-person audits of Controlled Substance practices should be used to support adherence to standard operating procedures and accurate documentation of transactions.
- When resources are limited, consider focusing first on higher risk areas (e.g., pharmacy and procedural areas)

Interpreting and Using Audit Findings

- Audit procedures should be undertaken and reviewed in collaboration with managers and staff on each clinical unit to ensure contextual factors are considered in their interpretation and to embed a sense of shared accountability.
- Each audit suggested in this Core Characteristic is not intended to be conclusive on its own, but is used alongside other sources of information to identify areas of concern.
- Findings from audit activities should initiate and inform improvement processes and not be seen as a punitive exercise, helping to ensure staff remain invested in the process and receptive to change.
- Identify unusual or outliers in prescribing trends or patterns (e.g., quantities or frequencies of orders, order amounts or atypical concentrations, use of verbal orders) to support further diversion prevention and detection efforts. For example, flexible dose orders (e.g., as-needed doses, a dosing range) allow access to more drug than what may be needed which can facilitate diversion. Audit data can contribute to discussions of whether this practice should continue to be supported. All variances should signal opportunities for improvement.
- Controlled Substance transactions between staff should only be compared with peers with similar responsibilities. Hours worked and numbers of patients cared for should also be taken into consideration when making comparisons on Controlled Substance use (e.g., full-time versus casual staff may have vastly different usage rates unless normalized to an hourly rate). The audit should also review findings beyond medication counts and volume, including time of day, and personnel patterns (e.g., the same two staff who consistently witness each other's waste documentation where the general pattern in the unit is to have variability in who witnesses waste).

Resources

- Institute for Safe Medication Practices. Partially filled vials and syringes in sharps containers are a key source of drugs for diversion. Medication safety alerts. https://www.ismp.org/resources/partially-filled-vials-and-syringes-sharps-containers-are-key-source-drugs-diversion
- New, K. (2017). Diversion risk rounds: a reality check on your drug-handling policies. https://www.dropbox.com/s/qh7v14hq7c3u7p3/Diversion%20Risk%20Rounds%20A%20Reality%20Check%20on%20Your%20Drug%20Handling%20Policies.pdf?dl=0

Core Characteristic II.2 Ensure a detailed and accurate audit trail for Controlled Substance access

This Core Characteristic is made up of 3 risk assessment items:

- Item 20: Authentication systems that unlock access to physical CS inventory generate access logs traceable to an individual (e.g., ID badge scan rather than a shared password)
- Item 21: Cameras are installed in all areas where Controlled Substances are stored and accessed (e.g., narcotic vault, medication rooms), locations where Controlled Substance access is not traceable to an individual (e.g., common keycode know to multiple staff), and service areas undergoing an active diversion investigation (if appropriate)
- Item 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 are rendered unusable

Rationale

- Audits of Controlled Substance documentation are only as useful as they are accurate, precise, and complete.
- Authentication systems that track which staff accessed specific Controlled Substances, at what time, for what purpose, will provide a rich audit trail to support diversion investigations.

Implementation considerations

- Authentication systems that support the desired quality of documentation are often electronic and may be costly.
- Accessing transaction data may be hindered by how ownership of the data is divided. For example, prescribed orders, pharmacy verification of the order, automated dispensing cabinet records, and patient charts may all exist in separate systems and collect variable information which makes linking records difficult.
- Consideration should be given to who is granted blanket access to transaction data and identification of staff involved with respect to staff confidentiality.

Resources

- See Recommended Reading at the end of this document.

Core Characteristic II.3 Regularly count and assess Controlled Substance inventory for product integrity

This Core Characteristic is made up of 6 risk assessment items:

- Item 23: Controlled Substance inventory in each patient care area is counted at each shift handover
- Item 24: Inventory in the pharmacy Controlled Substance vault is counted at least monthly
- Item 25: Independent Controlled Substance inventory counts are conducted by two authorized health care staff and documented
- Item 26: The integrity of product packaging is verified (e.g., Controlled Substances are verified to be in unbroken and sealed packages) during inventory counts
- Item 27: Discrepancies are addressed upon discovery, no later than end of shift. Procedures for discrepancy resolution include:
    - All staff remain in the clinical area until discrepancies are resolved or until dismissed by a clinical manager
    - Discrepancies that cannot be resolved are jointly reviewed by clinical manager (or staff member in charge) and pharmacy manager within 24 hours
- Item 28: A perpetual inventory is maintained for pharmacies with Controlled Substance vaults, and a blind count process is used in clinical areas with ADCs when adding or removing Controlled Substances

Rationale

- Counts are designed to give an accurate assessment of what physical product is on hand. If a count is inaccurate, it obscures when diversion has occurred, because all subsequent documentation of transactions will have inherited an error.
- The integrity of product packaging should be verified (e.g., unbroken and sealed packages) during inventory counts as a means to identify when substitution or tampering has occurred.
- Therefore, counts are an essential and irreplaceable check that act as the foundational source of truth when determining how and when discrepancies were generated.

Implementation Considerations

- Counts can be time consuming, especially when there is careful verification that the integrity of Controlled Substance packaging remains intact (i.e., seeking to detect tampering). Support staff on an ongoing basis to ensure that count quality does not degrade over time.
- Tamper-evident packaging, if available, may speed count processes and increase detection of abnormalities in the integrity of the packaging.
- Some institutions choose not to require counts of Controlled Substances that do not have any transactions since the last count (this is only determinable if an electronic narcotic vault or similar

technology is being used). This may reduce burden on nursing staff, but at the potential cost of delayed detection of discrepancies.

- When discrepancies are detected, aim for immediate resolution whenever possible, ideally before end of shift. Unresolved discrepancies may be a useful metric to monitor.

Resources

- See Recommended Reading at the end of this document.

Key Element III – Procurement Safeguards

This Key Element contains 5 risk assessment items grouped into a single Core Characteristic:

1. III.1 – Procurement decisions are based on usage data and kept independent from receiving personnel (Items 29 to 33)

Procurement of all Controlled Substances in the hospital is often controlled through a single department, such as inpatient pharmacy. Since this leads to bulk quantities of Controlled Substances moving through a few hands, the potential for entire boxes of Controlled Substances being pilfered, or small quantities being diverted unnoticed, is a risk.

Core Characteristic III.1 Procurement decisions are based on usage data and kept independent from receiving personnel

This Core Characteristic is made up of 5 risk assessment items:

- Item 29: Persons authorized to order the Controlled Substances are different from those receiving the Controlled Substances
- Item 30: A manager or delegate approves Controlled Substance invoices and purchase orders if orders deviate from re-ordering threshold levels
- Item 31: The quantity of Controlled Substances purchased is regularly assessed against historical values for expected and appropriate usage and replenishment amounts
- Item 32: The ability to modify Controlled Substance reordering thresholds is restricted to authorized personnel and the history of the thresholds is documented and reviewed to identify trends
- Item 33: The number of available concentrations, package sizes and dosage formats is limited for each Controlled Substance

<u>Rationale</u>

- Bulk orders of CS are a high-risk point of diversion because of the sheer volume of medication available for diversion at one time. Since these medications are often delivered in boxes, large quantities can be vulnerable at each transaction.

- The amounts diverted at this stage might be easily missed, or blamed on the manufacturer, and therefore careful procedures related to counts, documentation, double checks, and monitoring of overall ordering throughput is important to detect diversion.
- Limiting the number of available concentrations, package sizes, and dosage formats, facilitates the identification of outliers and expedites inventory counts.

Implementation Considerations

- Line of sight by a second pharmacy team member, particularly when shipments arrive and when boxes and their contents are counted may be helpful. Some pharmacies choose to use cameras to record the receiving area to ensure the arrival of packages are recorded and reviewable.
- Rotating receiving staff may help reduce diversion by a single staff member or even a team, as access to relevant documentation or Controlled Substances will be dynamic.
- Consider using multiple forms of documentation and quantity reconciliation. For example, reconcile billing records and costs against quantities received to ensure that they match. This helps circumvent documentation tampering by pharmacy staff obscuring diversion.

Resources

- See Recommended Reading at the end of this document.

Key Element IV – Safeguards for Patient's Own Medications

This Key Element contains 4 risk assessment items grouped into a single Core Characteristic:

1. IV.1 – Secure patient's own medications (Items 34 to 37)

Hospitals may address patient's bringing their own medications in a variety of ways. For hospitals that refuse to accept a patient's own medications, this section may not be applicable.

Core Characteristic IV.1 – Secure patients' own medications

This Core Characteristic is made up of 4 risk assessment items:

- Item 34: A policy exists and is followed that is consistent with hospital practices for Controlled Substance is used for managing patients' own supply of Controlled Substances
- Item 35: The patients' own supply of Controlled Substances is verified and counted by two different health care professionals
- Item 36: The patients' own supply of Controlled Substances is kept secure to the same degree as hospital supplied Controlled Substances
- Item 37: A policy exists and is followed to address Controlled Substances not picked up by the patient after discharge, or if patient is deceased

<u>Rationale</u>

- Patient's bringing their own medications to the hospital is a less common method of Controlled Substance entry into the hospital; policies and procedures may not have been developed at all hospitals.
- If staff are less familiar with this process, documenting, storing, counting, and disposing of patient's own medications may be vulnerable to diversion and harder to detect.
- By introducing safeguards similar to those of hospital Controlled Substances, the documentation and security of these medications can be maintained.

<u>Implementation Considerations</u>

- Practices for securely managing patient's own Controlled Substances should be addressed in staff orientation.

- Patients' own medications may be accidentally excluded during documentation audits or count procedures. For this reason, ensure that these edge scenarios are accounted for in hospital policy and staff training.
- Consider whether patient's own medications should be stored in the same location as the unit stock, and whether staff are allowed to administer the patient's own medications during their care.

Resources

- See Recommended Reading at the end of this document.

Key Element V – Controlled Substance Packaging or Preparation/Compounding

This Key Element contains 4 risk assessment items grouped into a single Core Characteristic:

1. V.1 – Secure Controlled Substances throughout the repackaging or preparation/compounding process (Items 38 to 41)

After Controlled Substances have been received by the inpatient pharmacy, some may require further repackaging into unit doses or compounded into dosage formats or sizes specific to clinical needs. Given that these repackaging or compounding processes involve large quantities of Controlled Substances being handled more directly than in earlier procurement process checks, they may be at risk of diversion and require safeguards.

Core Characteristic V.1 Secure Controlled Substances throughout the repackaging or preparation/compounding process

This Core Characteristic is made up of 4 risk assessment items:

- Item 38: The entire contents of a bulk container is used before opening a second container when repackaging tablets and capsules
- Item 39: Overfill amounts in the repackaging or compounding process are identified, documented, and used immediately or wasted accordingly
- Item 40: Intravenous medication preparation is witnessed in real-time, starting prior to withdrawal from the vial until injection is complete. The process is co-signed.
- Item 41: Bulk Controlled Substance is repackaged by pharmacy such that the repackaged contents cannot be opened without obvious destruction of the seal (i.e., tamper seal)

<u>Rationale</u>

- At this stage of the medication use process, staff may be handling large quantities of Controlled Substances at one time. This is an opportunity to divert and possibly obscure by falsifying documentation (e.g., accidentally ‘miscounting’ doses, substituting similar looking tablets).

- Similar issues of diversion exist with compounding of injectable Controlled Substances, as diversion may occur from undocumented overfill, substitution, and/or poorly monitored wastage procedures.
- Given the high number of transactions and the duration of the repackaging/compounding process, real-time verification of the process is costly, which can be taken advantage of by those seeking to divert.

Implementation Considerations

- Implementing interventions in this stage of the medication use process is well-recognized to be challenging.
- Minimize the need to repackage or compound by purchasing pre-made product in typical clinically appropriate amounts, doses, and volumes, where possible.
- Given the high costs of staffing to verify counts and monitor for substitution, tightly controlled processes managed through technology may be an avenue to consider in the future (e.g., automated video recording to support auditing, barcoding, weight scales, tamper sealing technologies). The cost of these technologies may therefore require capital cost planning and require a multi-year plan.
- Notably, periodic auditing or assaying has been used successfully to monitor drug waste from the operating room at the Mayo Clinic and reduce diversion. Although only a small percentage of product is assayed, it has a disproportionately large effect on deterring diversion. This principle of small percentage audits triggering asymmetric deterrence of diversion may be useful to consider when brainstorming potential interventions.

Resources

- The discussion of assaying of waste is discussed in:
    - Berge KH, Dillon KR, Sikkink KM, Taylor TK, Lanier WL. Diversion of drugs within health care facilities, a multiple-victim crime: patterns of diversion, scope, consequences, detection, and prevention. Mayo Clin Proc. 2012;87(7):674-682. doi: 10.1016/j.mayocp.2012.03.013

Key Element VI – Movement of Controlled Substances from One Location to Another

This Key Element contains 2 risk assessment items grouped into a single Core Characteristic:

1. VI.1 – Account for Controlled Substances when transferring between clinical units/departments (Items 42 to 43)

These risk assessment items support verification that Controlled Substances have not been diverted or tampered with while being transferred and likely unsupervised, and also act as a deterrent.

Core Characteristic VI.1 – Account for Controlled Substances when transferring between clinical units/departments

This Core Characteristic is made up of 2 risk assessment items:

- Item 42: The quantity of Controlled Substance being sent to a service area is counted and signed into the record by any two authorized health care staff and the destination is indicated in the documentation
- Item 43: The quantity of Controlled Substance being received in a service area is counted and signed into the record by any two authorized health care staff and immediately secured in the service area's locked Controlled Substance storage and the inventory count is immediately updated

Movement of Controlled Substances throughout the hospital should be tracked. For example, reports should show that narcotic vault transaction reports of Controlled Substances retrieved for distribution to the clinical areas match ADC receipts of Controlled Substances being added to the inventory and/or paper inventory records.

<u>Rationale</u>

- Transferring Controlled Substances between clinical units is often performed by a single individual. This leaves a large quantity of Controlled Substances unmonitored and vulnerable to substitution or tampering.

- While solutions are not likely to prevent all possible forms of diversion during distribution and transportation, this Core Characteristic emphasizes minimum standards to verify the quantities at the point of departure and arrival, while also monitoring for the integrity of packaging to safe-guard against diversion.

Implementation Considerations

- Ideally, the cart used to transfer Controlled Substances will be lockable; all the contents will therefore be protected if the cart is accidentally left unattended.
- Some automated dispensing cabinets may have features that communicate with a central narcotic vault in the inpatient pharmacy (e.g., central vault records how much is withdrawn, unit ADC reports how much was deposited, discrepancies are flagged). This improves the security of the documentation because it is more difficult to falsify compared to a paper record that moves with the card.
- It is important that count checks verify the packaging of the Controlled Substance being transferred to guard against tampering or substitution of the contents.

Resources

- See Recommended Reading at the end of this document.

Key Element VII – Withdrawal of Controlled Substances from Stock on Clinical Units

This Key Element contains 9 risk assessment items grouped into 2 Core Characteristics:

1. VII.1 – Reduce unnecessary supply of Controlled Substances on clinical units (Items 44 to 46)
2. VII.2 – Configure ADCs to maximize security and traceability of Controlled Substances transactions (items only for hospitals with ADCs) (Items 47 to 52)

This Key Element highlights the importance of restricting excess Controlled Substance (e.g., minimizing supply), and carefully regulating (and logging) access to unit stock stored in automated dispensing cabinets (ADCs).

Core Characteristic VII.1 Reduce unnecessary supply of Controlled Substances on clinical units

This Core Characteristic is made up of 3 risk assessment items:

- Item 44: Quantities of Controlled Substances stocked on the clinical unit are limited to typical clinical needs and usage patterns
- Item 45: Controlled Substances for a patient are selected in the package size equivalent to, or the closest available to, the dose to be administered
- Item 46: Controlled Substances are withdrawn and prepared only once the patient need has been verified, and at the time of need, on a patient-by-patient basis

Rationale

- The goal of this Core Characteristic is to reduce the amount of Controlled Substance available to divert, primarily by reducing the amount wasted.
- Providing fewer options for dosage formats, and ensuring they are matched to typical doses provided to patients helps standardize prescribing, procurement, dispensing, administration and wasting. Consequently, it improves the quality of auditing as abnormalities from standard dosages and routes will be easier to detect.

Implementation Considerations

Potential Challenges

- Note that implementing this safeguard may also have potential costs. For example, by limiting the amount of Controlled Substances available in unit stock, delays in refills from the inpatient pharmacy may cause delays in patient care.
- Manufacturers may not offer desirable package sizes. Hospitals may need to partner with other hospitals to pressure manufacturers to create the necessary dosage formats and quantities.
- Changing the package sizes purchased may also impact purchasing costs; each hospital will need to assess costs and benefits.

Potential Risk of introducing these Safeguards

- By reducing the amount of Controlled Substance available to waste, individuals seeking to divert may turn to depriving patients of the prescribed dose. Therefore, hospitals must prioritize a strong auditing and investigation process to counter this.

Considerations for Implementing Safeguards

- An alternative option to purchasing different package sizes of medication may be to alter prescribing/ordering practices to better match existing inventory so that waste is minimized. Discussion with prescribers may be helpful, alongside education on the risks of diversion.
- The types and quantities of medications stocked in clinical areas should be determined by clinical managers, as well as input from the interprofessional diversion committee.

Clinical Practices Should Complement the Suggested Safeguards

- To guard against long delays between withdrawing, preparing, administering and wasting medications, hospital standard operating procedures should specify appropriate time windows for these tasks. Failure to do so allows individuals seeking to divert the flexibility to substitute, tamper or divert at an opportune moment.
- Clinicians may be tempted to save time by dispensing and preparing multiple patients' medications or multiple doses for the same patient; this counteracts the intentions of limiting the Controlled Substance available to divert. A one-patient-at-a-time approach to withdrawing and administering Controlled Substances is ideal, but must be balanced with clinical workflow.

Resources

- See Recommended Reading at the end of this document.

Core Characteristic VII.2 Configure ADCs to maximize security and traceability of Controlled Substance transactions

This Core Characteristic is made up of 6 risk assessment items:

- Item 47: Controlled Substances override options in ADCs are minimized (e.g., one-time injectables for emergencies only)
- Item 48: Critical override transactions are reviewed within 24 hours by the pharmacy to verify the transaction is associated with an appropriate order
- Item 49: Controlled Substances are stocked in individual locked compartments in the ADC
- Item 50: Automated dispensing cabinets interface with hospital information systems so that Controlled Substance transactions are linked with patient profiles. ADCs are set up for profile dispense.
- Item 51: Automated dispensing cabinets interface with hospital information systems so that Controlled Substance withdrawals are automatically documented as open transactions that require closure (e.g., signed-off upon administration, return, or waste)
- Item 52: Processes are in place to rapidly update patient profiles in automated dispensing cabinets

Rationale

- Automated dispensing cabinets (ADCs) are an important resource for automated tracking of Controlled Substance transactions, but must be configured appropriately to support diversion investigations and auditing.

Implementation Considerations

- This Core Characteristic applies only to hospitals or areas of the hospital with ADCs.
- ADCs can produce a wealth of data, however this data is only as useful as the ability of the team to review it and understand its significance in the context of the care area.
- The configuration of the ADC should be periodically reviewed by the committees established in Core Characteristic I.2 to ensure they capture the information needed to investigate and mitigate diversion.
- Evidence that the ADCs are not being used as intended (e.g., medications are being withdrawn without a link to a patient) should trigger immediate follow-up to understand why this practice is occurring. Medication workflows, policies, the configuration of the ADC itself should be updated to address the practice. This will ensure that ADCs produce audit trails that are maximally useful for diversion investigations.

Resources

- Lichtner, V., Prgomet, M., Gates, P., & Franklin, B. D. (2021). Automatic dispensing cabinets and governance of controlled drugs: an exploratory study in an intensive care unit. *European Journal of Hospital Pharmacy*. http://dx.doi.org/10.1136/ejhpharm-2020-002552
- Zheng, W. Y., Lichtner, V., Van Dort, B. A., & Baysari, M. T. (2021). The impact of introducing automated dispensing cabinets, barcode medication administration, and closed-loop electronic medication management systems on work processes and safety of controlled medications in hospitals: A systematic review. *Research in Social and Administrative Pharmacy*, *17*(5), 832-841. https://doi.org/10.1016/j.sapharm.2020.08.001
- Hyland S, Koczmara C, Salsman B, Musing ELS, Greenall J. Optimizing the use of automated dispensing cabinets. *Can J Hosp Pharm.* 2007;60(5):332- 334. http://dx.doi.org/10.4212/cjhp.v60i5.205
- Forrey R, Siegel J. (2017). Four case studies on diversion prevention. https://www.ppp-mag.com/article/1469/March_2014/Four_Case_Studies_on_Diversion_Prevention

Key Element VIII – Administration of Controlled Substances to Patients

This Key Element contains 4 risk assessment items grouped into 2 Core Characteristics:

1. VIII.1 – Secure Controlled Substances once withdrawn (Items 53 to 54)
2. VIII.2 – Employ measures to maximize accuracy of Controlled Substance patient administration records (Items 55 to 56)

Administration of Controlled Substances is one of the most difficult aspects of the medication use process to monitor. The risk assessment items in this section are suggested to increase the barriers to diversion when Controlled Substances are unmonitored and support the accuracy of administration documentation.

Core Characteristic VIII.1 Secure Controlled Substances once withdrawn

This Core Characteristic is made up of 2 risk assessment items:

- Item 53: The interface of infusion pumps administering Controlled Substances is locked
- Item 54: Controlled Substances are never left unattended (e.g., syringes are not left out and left unsupervised)

<u>Rationale</u>

- Preventing unauthorized users from manipulating pump programming can reduce the risk of diversion
- When Controlled Substances have left secure storage, they become highly vulnerable to diversion. In addition, administration tends to be performed by a single staff member, which means diversion is difficult to prevent if it occurs during this stage.
- Limiting the window of time for administration may help narrow the window for individuals to divert or substitute Controlled Substances; this may be desirable in clinical areas where such a policy is feasible.

<u>Implementation considerations</u>

- Administration of Controlled Substances is one of the most difficult phases of the medication use process to monitor. Interventions for this phase of the medication use process are limited.

Infusion Pump Considerations

- Infusion pumps that have interfaces that can be locked so they cannot be reprogrammed except for authorized staff. This may be possible with a keycode, or a hidden button that patients or visitors may not be aware of. Explore whether this feature exists for the infusion pumps in your institution.
- Patient-Controlled Analgesia pumps typically have a locking mechanism to protect the syringe from tampering or theft; these are a valuable safety feature, but must be complemented with secure practices for key control. Anecdotally, there have been reports that some patients and visitors know how to purchase keys to PCA pumps online.
- The use of portless intravenous tubing may also help reduce the risk of withdrawal of Controlled Substance from the tubing itself.
- Amounts of Controlled Substance ordered, prepared, and administered should be reconciled at the end of each shift (New, 2014)

Surge and COVID-19 Considerations

- Note that during high demand or dynamic practice situations (e.g., surge capacity, patient transported for imaging and requiring pain control, increased donning/doffing due to airborne precautions), monitoring of unsecured Controlled Substances may be particularly challenging.

Potential Interventions

- Some hospitals have introduced lockboxes for temporary storage of Controlled Substances near the bedside after they have been withdrawn from unit stock; at present most institutions have no place for staff to secure Controlled Substances once removed from central unit storage. We are not aware of any literature on this intervention at this time.

Resources

- See case study 5 in *Uncovering Diversion: 6 Case Studies* linked in the Recommend Reading section at the end of this document.
- Ientile, G. (2020). Managing drug diversion amid pandemic: The covid-19 crisis poses unique challenges for managing controlled substances in hospitals. *Drug Topics*, 44-45.

Core Characteristic VIII.2 Employ measures to maximize accuracy of Controlled Substance patient administration records

This Core Characteristic is made up of 2 risk assessment items:

- Item 55: Independent double checks are required for administration of high-risk Controlled Substances to patients
- Item 56: Withdrawal, administration, and wastage of Controlled Substances are all done by the same individual

Rationale

- This Core Characteristic aims to reduce handoffs of Controlled Substance and documentation between multiple staff members. This closes loopholes for one individual to obscure their diversion activity by associating transactions to other staff or patients that they are not responsible for.

Implementation

- This safeguard may be challenging to implement due to the time commitment required by unit staff. Education regarding diversion risks may be helpful in motivating behavior change.
- If these safeguards cannot be implemented, efforts should maximize the quality of audit data, and the frequency of audit review (see Core Characteristic II.1 and II.2), so that suspicious administration patterns of Controlled Substances can be detected.

Resources

- See Recommended Reading at the end of this document.

Key Element IX – Wasting or Disposal of Controlled Substances

This Key Element contains 5 risk assessment items grouped into a single Core Characteristic:

1. IX.1 – Deter diversion from Controlled Substance waste (Items 57 to 61)

The wasting of Controlled Substances is a high-risk aspect of the medication use process because the patient's needs have been met and therefore missing waste may be harder to detect. Literature suggests it is a common source of diverted substances. Strong processes are needed to ensure that Controlled Substances are actually disposed of rather than diverted.

Core Characteristic IX.1 Deter diversion from Controlled Substance waste

This Core Characteristic is made up of 5 risk assessment items:

- Item 57: Witnessing of waste is performed with real time visual line of sight
- Item 58: Excess Controlled Substance is wasted immediately or as soon as possible after use
- Item 59: Controlled Substance waste is rendered irretrievable and unusable
- Item 60: Waste receptacles are secured (e.g., locked to the wall or other stationary equipment) so they cannot be easily removed. Waste receptacle keys or removal devices are kept secured, restricted to authorized personnel, and chain of custody is documented.
- Item 61: Expired Controlled Substance is destroyed on a weekly basis to mitigate accumulation of expired products

<u>Rationale</u>

- This Core Characteristic aims to minimize the amount of time Controlled Substance waste is vulnerable to diversion, deter diversion through witnessing procedures, and immediately render wastage unusable.

<u>Implementation</u>

- Controlled Substance waste is a common vulnerability to diversion because individuals who divert feel it does not affect patients. Additionally, wastage is often poorly monitored, documented and reconciled; witnessing of waste by colleagues is often lax or easy to feign if needed.

- Despite the limitations associated witnessing wasting accurately, wasting documentation is a critical input to the auditing processes recommended in Core Characteristic II.1. For example, auditing can detect when specific staff waste more or less than expected via peer comparison, or identify staff who co-sign each other's waste with an unusually high frequency.
- Consider the use of cameras in defined wasting areas for high-risk clinical units to supplement the data available for diversion investigations.
- Assaying a small proportion of waste (linking waste containers to specific staff) to confirm its content can have a disproportionately large effect in deterring diversion (see Mayo Clinic experience). This may not be feasible for all institutions, and the process of securely collecting the waste must be thought through to ensure it is not manipulated. It may be a useful intervention for hospitals eager to reduce diversion from the wasting phase of the medication use process.

Resources

- The discussion of assaying of waste is discussed in:
    - Berge KH, Dillon KR, Sikkink KM, Taylor TK, Lanier WL. Diversion of drugs within health care facilities, a multiple-victim crime: patterns of diversion, scope, consequences, detection, and prevention. Mayo Clin Proc. 2012;87(7):674-682. doi: 10.1016/j.mayocp.2012.03.013.
- Institute for Safe Medication Practices. Partially filled vials and syringes in sharps containers are a key source of drugs for diversion. Medication safety alerts. https://www.ismp.org/resources/partially-filled-vials-and-syringes-sharps-containers-are-key-source-drugs-diversion
- See Parts 1 and 2 of the series described in the Recommend Reading Section at the end of this document:
    - O'Neal B, Siegel J. Diversion in the pharmacy.
    - Siegel J, O'Neal B, Code N. Prevention of controlled substance diversion-Code N: multi-disciplinary approach to proactive drug diversion prevention.

Recommended Reading

Any individual seeking to address drug diversion within their institution would benefit from being familiar with the following guidance documents.

Canadian Guidance

- Canadian Society of Hospital Pharmacists. (2019). Controlled Drugs and Substances in Hospitals and Healthcare Facilities: Guidelines on Secure Management and Diversion Prevention. https://www.cshp.ca/Site/Resources/Official-Publications/Guidelines/Site/Content/Resources/guidelines.aspx
- Partnered Table to Improve the Safety and Security of Controlled Substances in Hospital High Risk Areas. (2019). Framework for improving the safety and security of controlled substances in hospital high risk areas. Ontario College of Pharmacists. https://www.ocpinfo.com/wp-content/uploads/2020/01/framework-for-improving-the-safety-and-security-of-controlled-substances-in-hospital-high-risk-areas.pdf

United States Guidance

- Minnesota Hospital Association. Roadmap to Controlled Substance Diversion Prevention. https://www.mnhospitals.org/Portals/0/Documents/ptsafety/diversion/controlled-substance-diversion-prevention-roadmap.pdf
- Brummond, P. W., Chen, D. F., Churchill, W. W., Clark, J. S., Dillon, K. R., Dumitru, D., ... & Smith, J. S. (2017). ASHP guidelines on preventing diversion of controlled substances. *American Journal of Health-System Pharmacy*, *74*(5), 325-348. https://doi.org/10.2146/ajhp160919
- California Hospital Association (2013). Reducing Controlled Substances Diversion in Hospitals. https://www.chpso.org/sites/main/files/file-attachments/controlled_substance_diversion.pdf?1368720872

Scoping Review of Diversion Risks and Safeguards

- Fan, M., Tscheng, D., Hamilton, M., Hyland, B., Reding, R. and Trbovich, P. (2019), Diversion of Controlled Drugs in Hospitals: A Scoping Review of Contributors and Safeguards. Journal of Hospital Medicine, 14: 419-428. https://doi.org/10.12788/jhm.3228

Case Studies and Risk Considerations

- New, K. (2014). Preventing, detecting, and investigating drug diversion in health care facilities. Journal of Nursing Regulation, 5(1), 18-25. https://doi.org/10.1016/S2155-8256(15)30095-8
- New, K. (2018). Uncovering Diversion: 6 case studies on Diversion. https://www.ppp-mag.com/article/2162

- Schaefer, M. K., & Perz, J. F. (2014, July). Outbreaks of infections associated with drug diversion by US health care personnel. In *Mayo Clinic Proceedings* (Vol. 89, No. 7, pp. 878-887). Elsevier. https://doi.org/10.1016/j.mayocp.2014.04.007
- Eichenwald. (2015). When drug addicts work in hospitals, no one is safe. Newsweek. http://www.newsweek.com/2015/06/26/traveler-one-junkies-harrowing-journey-across-america-344125.html
- [Highlights discrepancies of missing medication in documentation] Horvath, Catherine DNP, CRNA. Implementation of a new method to track propofol in an endoscopy unit. International Journal of Evidence-Based Healthcare: September 2017 - Volume 15 - Issue 3 - p 102-110 doi: 10.1097/XEB.0000000000000112. https://journals.lww.com/ijebh/Abstract/2017/09000/Implementation_of_a_new_method_to_track_propofol.4.aspx

"How to Start" At Your Hospital

- A 6-part series by O'neal, B., & Siegel, J. (2007). While these are older articles, they provide a helpful starting point for many readers:
    1. Diversion in the pharmacy: https://doi.org/10.1310/hpj4202-145
    2. Code N: multidisciplinary approach to proactive drug diversion prevention: https://doi.org/10.1310/hpj4203-244
    3. Diversion in the operating room: https://doi.org/10.1310/hpj4204-359
    4. The investigative process: https://doi.org/10.1310/hpj4205-466
    5. Prevention of controlled substance diversion-use of diversion detection software: https://doi.org/10.1310/hpj4206-564
    6. Code N: the intervention process: https://doi.org/10.1310/hpj4207-653

Hospitals Conducting Diversion Risk Assessments

Examples of other hospitals who are performing risk assessments:

- Videau, M., Atkinson, S., Thibault, M., Lebel, D., & Bussières, J. F. (2019). Compliance with recommended practices for management of controlled substances in a health care facility and corrective actions. *The Canadian Journal of Hospital Pharmacy*, *72*(3), 175. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6592654/
- Eason, B. E., Vest, T. A., Mieure, K. D., Neal, D., & Tryon, J. (2021). Evaluation and Enhancement of a Comprehensive Controlled Substances Management Process at an Academic Medical Center. *Journal of Pharmacy Practice*, 08971900211022286. https://doi.org/10.1177/08971900211022286
- Nolan, K., Zullo, A. R., Bosco, E., Marchese, C., & Berard-Collins, C. (2019). Controlled substance diversion in health systems: a failure modes and effects analysis for prevention. *American Journal of Health-System Pharmacy*, *76*(15), 1158-1164. https://doi.org/10.1093/ajhp/zxz116

- Derington, C. G., Lopez, B. R., Weber, R. J., & Tubbs, C. R. (2020). Comparison of 3 Surveillance Methods to Detect Potential Controlled Substance Diversion in an Academic Medical Center. *Hospital pharmacy*, *55*(5), 323-331. https://doi.org/10.1177/0018578719844170

Diversion Conferences and Support

Interested readers may also wish to pursue membership with the International Health Facility Diversion Association (www.ihfda.org), or the US-based National Association of Drug Diversion Investigators (www.naddi.org), which may provide continuing education and active mailing lists.