

FRAMEWORK FOR IMPROVING THE SAFETY AND SECURITY OF CONTROLLED SUBSTANCES IN HOSPITAL HIGH RISK AREAS

*Recommendations of the Partnered Table to
Improve the Safety and Security of Controlled
Substances in Hospital High Risk Areas*

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This framework would not have been possible without the contribution of each Partner, and the College is grateful for their participation and commitment to the recommendations.

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TABLE OF CONTENTS

Preamble.....5

Introduction.....5

Purpose.....6

Definitions6

Guiding Principles6

Recommendations8

 A. Identifying Diversion.....8

 B. Shared Accountability and Responsibility.....9

 C. Culture of Safety9

 D. Collaboration.....9

 E. Transitions of Care.....9

 F. Knowledge Translation/Sharing Across the Health System 10

Measurement and Evaluation..... 10

Appendix A: Additional Resources 11

PREAMBLE

With Ontario in the midst of an opioid crisis, one area of concern is the safety and security of Controlled Substances in hospital high risk areas. Seeing an opportunity for stakeholder collaboration to address this issue, the Ontario College of Pharmacists established a Partnered Table composed of organizations that have made significant contributions to health care and medication management in Ontario. This Framework is the culmination of a commitment by the members of the Partnered Table to increase the safety and security of Controlled Substances in hospital high risk areas.

The Partnered Table objectives included establishing recommendations and committing to take action to enhance the security of Controlled Substances and minimize the risk of diversion in hospital settings (including both inpatient and outpatient care services), as well as informing, reviewing and endorsing action items developed on the advice and recommendations resulting from the Partnered Table. The recommendations are intended to focus on system level solutions and act as guidance for organizations as they strive to improve the safety and security of Controlled Substances in hospitals.

INTRODUCTION

Controlled Substances play a beneficial role for many patients in hospital settings. However, if not properly managed, Controlled Substances in hospitals can present a risk for diversion. This poses a risk for patients, health care professionals, and the public.

Drug diversion is the illegal distribution or abuse of prescription drugs, or their use for purposes not intended by the prescriber.¹ There are a number of ways in which drug diversion occurs, including theft from hospital inventories, defrauding patients, using medication samples, and misusing medications.² Understanding the mechanisms of diversion and putting safeguards in place to prevent them are vital to improve the safety and security of Controlled Substances.

Diversion affects patients, health care providers, hospitals and the public. When health care providers are impaired, patients receive substandard care and may not receive the pain relief they need.³ Patients and health care providers can be put at risk of exposure to life-threatening blood-borne infections due to exposure of contaminated needles.³ Whenever diversion occurs, the impact can be substantial. The abuse and misuse of Controlled Substances increases the risk of unintentional overdose and even death.⁴ Diversion poses a significant risk to the diverter themselves. If the diverter is a health care provider, they are at risk of losing their employment, their licence, and their reputation. Diversion can also result in consequences to the hospital itself such as loss of revenue from diverted drugs, potential for civil liability, and loss of reputation.

Health care providers, administrators and regulators are well positioned to help address the growing issue of Controlled Substances diversion. Identifying gaps in awareness, organizational policies, procedures and capacity that increase avenues for diversion and acting to bridge these gaps is vital to preventing diversion in hospitals. This Framework aims to utilize a multidisciplinary collaborative system-based approach, bringing together patients, regulators, health care providers, senior hospital leadership and other stakeholders in order to develop principles and recommendations.

1 Centers for Medicare & Medicaid Services. Retrieved from: <https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Provider-Education-Toolkits/Downloads/prescriberrole-drugdiversion-factsheet-082914.pdf>. Accessed on September 11, 2018.

2 Cummings, S. M., Merlo, L., & Cottler, L. Mechanisms of prescription drug diversion among impaired physicians. *J Addict Dis*. 2011. 30(3): 195-202. DOI: 10.1080/10550887.2011.581962. Accessed on August 13, 2018

3 Fan M, Tscheng D, Hamilton M, et. Al. Diversion of Controlled Drugs in Hospitals: A Scoping Review of Contributors and Safeguards. *J. Hosp. Med*. 2019. 14(7): 419-428.

4 Berge KH, Dillon KR, Sikkink KM, et al. Diversion of Drugs Within Health Care Facilities, a Multiple-Victim Crime: Patterns of Diversion, Scope, Consequences, Detection, and Prevention. *Mayo Clin Proc*. 2012 Jul; 87(7): 674-682.

PURPOSE

The purpose of this framework is to provide recommendations that enable healthcare system stakeholders to proactively identify and prevent the diversion of Controlled Substances in hospitals in order to promote patient and healthcare worker safety.

DEFINITIONS

The Partnered Table used the following working definitions during its deliberations:

Controlled Substance: *Any drug or substance found in the Schedules to the Controlled Drugs and Substances Act.*⁵

High Risk Areas: *Areas within a hospital which require ease of access and high volume of Controlled Substances. Many different individuals frequent these areas and require efficient access to Controlled Substances. High risk areas can vary depending on the organization and may include operating rooms, interventional suites, ambulatory care clinics, critical care, and the emergency department, where enacting or enforcing appropriate protocols can be more challenging due to environmental factors such as time constraints, staffing levels, and unpredictable patient volumes.*

Drug Diversion: *The illegal distribution or abuse of prescription drugs, or their use for purposes not intended by the prescriber.*⁶

GUIDING PRINCIPLES

The guiding principles are statements that provide the overarching context for a collaborative system-based approach to increase the safety and security of Controlled Substances in hospital high risk areas:

- **PERSON CENTRED:** The safety of patients/caregivers and health care providers is central to all organizational policies and procedures regarding diversion.
- **CONTROLLING ACCESS APPROPRIATELY:** The organization has controls in place in high risk areas that allow efficient access of Controlled Substances without compromising safety and security. In organizations where a decision has been made to modify controls, the organization documents the risk mitigation steps taken and receives approval from the executive and senior leadership of the hospital, or appropriate decision-making table.
- **REDUCING STIGMA AND ENABLING A CULTURE OF SAFETY:**⁷ The organization embeds a “just” workplace culture for all staff including:
 - Ensuring that all individuals feel enabled and supported to discuss and report on suspected/confirmed diversion incidents.
 - Providing education to all staff to minimize any stigma against individuals with substance use disorder.⁸
- **SHARED ACCOUNTABILITY:** There is shared responsibility and accountability for the reduction of diversion in the organization and a delineation of this accountability at every level.

5 Controlled Drugs and Substances Act. S.C. 1996, c. 19 (Current to August 8, 2019). Available from: <https://laws-lois.justice.gc.ca/eng/acts/c-38.8/>. Accessed Oct 18, 2019.

6 Centers for Medicare & Medicaid Services. Retrieved from: <https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Provider-Education-Toolkits/Downloads/prescriberrole-drugdiversion-factsheet-082914.pdf>. Accessed on September 11, 2018.

7 A culture of safety is defined as the underlying beliefs and values of an organization as they relate to safety as a priority. ISMP Canada, HSO, CPSI; 2019. <https://www.ismp-canada.org/definitions.htm>. Accessed on Nov 11, 2019.

8 The term “substance use disorder” may be used interchangeably with the term “addiction”. In general, these terms refer to the use of substances despite harmful consequences for the individual. For more information, see the Centre for Addiction and Mental Health’s reference page – <https://www.camh.ca/en/health-info/mental-illness-and-addiction-index/addiction>

- **BEING PROACTIVE:** The organization has a comprehensive diversion prevention strategy in place which enables the proactive identification and prevention of diversion incidents.
- **ADDRESSING DIVERSION:** All suspected and confirmed diversion incidents in the organization are investigated and addressed in a standardized, timely, and appropriate manner. Namely this is done by:
 - o Ensuring a fair and consistent approach is taken when addressing a diversion incident.
 - o Ensuring individuals suffering from substance use disorder are provided with the support and resources needed.
 - o Ensuring individuals are held appropriately accountable for their actions.
 - o Ensuring incidents are reported to the appropriate channels (i.e. law enforcement, regulatory Colleges) and disclosed to patients/caregivers/families as appropriate.
- **CONTINUOUS EVALUATION AND QUALITY IMPROVEMENT:** The organization has a process in place to continuously evaluate and improve policies and procedures around diversion. The organization is also transparent in the handling of diversion incidents in order to share learnings as appropriate within the organization and across organizations.
- **LEVERAGING ENABLERS:** The organization leverages enablers to address the safety and security of Controlled Substances, such as:
 - o Health Canada
 - o Accreditation Canada
 - o Accountability of Regulatory Bodies
 - o Patient safety and medication safety initiatives
 - o Enterprise Risk Management
 - o Quality Improvement Plans (QIPs)
 - o Ontario Health Quality Standards

RECOMMENDATIONS

A. Identifying Diversion

There is an opportunity to improve the availability of standardized, reliable data with regards to Controlled Substances diversion. Data collection methods in many cases are still manual and subject to user variability. High quality, standardized data is vital in improving the safety and security of Controlled Substances and can help with the identification of diversion trends. Narcotic count data, for example, can help identify discrepancies in narcotic inventory and flag potentially inappropriate medication management. There are significant challenges with the availability of good quality, standard, interpretable data. For instance, experts have identified gaps in the number of hospitals reporting loss and theft data.⁹ Outdated or non-adhered to policies, procedures and processes may contribute to cases of diversion. This poses a significant diversion risk, as hospitals may continue to have multiple and continuous unexplained losses and thefts that remain unnoticed.

RECOMMENDATION A-1: That analysis from relevant data sources are incorporated into discussions at existing interdisciplinary meetings (such as the Pharmacy and Therapeutics Committee, Quality Committee, or any other internal or Board committees, as appropriate) or at dedicated diversion meetings in order to identify diversion themes and trends. These data sources may include, but are not limited to, narcotic count reports, Health Canada loss and theft reports, tracer results, Automated Dispensing Cabinet data, override & discrepancy reports and routine audits. Awareness at the point-of-care level should occur through opportunities such as informal unit discussions or team huddles.

RECOMMENDATION A-2: That policies, procedures (e.g. Standard Operating Procedures) and processes (e.g. Order Sets) are reviewed regularly to ensure safeguards are in place to optimize Controlled Substances safety.

B. Shared Accountability and Responsibility

Increasing awareness through education provided to the public, patients, health care providers, administrators and system representatives is vital to ensure a thorough understanding of the risks of unsafe and unsecure Controlled Substances in hospitals. Although an organization may have policies in place to ensure the safety and security of Controlled Substances, knowledge gaps often exist amongst organization staff around responsibilities and accountabilities associated with these policies. This may result in non-adherence to these safeguards, thereby increasing the risk of diversion. Recognizing that there are many competing priorities within the organization, senior leadership should establish the prevention and monitoring of diversion as a priority, reiterating for all staff the importance of ensuring the security of Controlled Substances for patient and staff safety.

RECOMMENDATION B-1: That orientation for all individuals who will have access to Controlled Substances include a discussion of policies, procedures and controls that the hospital has in place for these substances. Whenever possible, the goal should be for this orientation to be completed before access to Controlled Substances is permitted.

RECOMMENDATION B-2: That staff and health care providers with hospital privileges have access to continuous training and development that incorporates information on optimizing the safety and security of Controlled Substances.

RECOMMENDATION B-3: That hospitals ensure Controlled Substances diversion is considered in their organizational risk management strategies.

RECOMMENDATION B-4: That the Framework be shared with educational facilities, educational programs, and practitioners in training to ensure awareness before entry to practice.

⁹ Winter, J. It's 'just too easy' for doctors to steal. That's why opioids are vanishing by the fistful in B.C.'s Lower Mainland. *The Star*. <https://www.thestar.com/vancouver/2019/02/15/its-just-too-easy-for-doctors-to-steal-thats-why-opioids-are-vanishing-by-the-fistful-in-the-lower-mainland.html>. Published February 15, 2019. Accessed October 17, 2019.

C. Culture of Safety

It has been recognized that there is an opportunity to enhance education around the challenges related to substance use disorder and implement efforts to help reduce the stigma associated with it. Vulnerable staff may not feel that it is safe to come forward to share their health concern. There can be concern that accessing help will expose them to loss of licensure and stigma by their peers, and hence self-referral to treatment is atypical. Additionally, staff who may suspect that their colleague is diverting are fearful of consequences to their colleague, and therefore may not report. This can lead to an overall lack of a positive safety culture in hospital settings.

RECOMMENDATION C-1: That training modules incorporate training on safety culture and reducing stigma. Routine in-services through lunch-and-learn sessions focusing on safety culture and wellness programs can help create awareness throughout the organization. Planning of the training and education should be a collaborative effort among relevant departments from across the organization, including Occupational Health and Safety and Human Resources.

RECOMMENDATION C-2: That each organization establish methods for staff to report diversion anonymously. An example of such a method is through an anonymous reporting line where staff can be assured that information will be kept confidential and resources will be provided to support the employee.

RECOMMENDATION C-3: That each organization clearly communicate the process to support individuals who self refer, or are referred by a colleague, with a substance use disorder. This process should outline the supports and resources available to the individual. Substance use disorders can affect anyone, including those working within healthcare. It is important to consider this, and to encourage the individual's recovery. A non-punitive and supportive approach to minimize stigma would be beneficial to the individual's health.

D. Collaboration

Sharing feedback promotes collaboration between departments throughout an organization. Departments sometimes operate in a siloed manner and miss opportunities to share feedback and review controls in place in high risk areas, especially with health care providers who spend the most time in high risk areas. Reviewing measures and controls for high risks areas at inter-department meetings supports system level improvements for health care providers in alternate areas of the hospital.

RECOMMENDATION D-1: That frequent cross collaboration across departments occur where diversion risk and mitigation strategies are discussed. This collaborative group should include not only executive members, but also point-of-care health care providers to ensure a process is in place to continuously evaluate and improve workflow design, and policies and procedures around Controlled Substance safety. The team should have designated roles and expectations. Some hospitals have benefited from the creation of a Drug Diversion Response Team, with wide membership from various departments. The introduction of this team has proven effective when addressing diversion.¹⁰

Professional Practice Leaders, medication safety officers and patient safety officers, in hospitals where those roles exist, can also act as diversion specialists, dedicating time to lead diversion prevention and management strategies.

E. Transitions of Care

Health care organizations are increasingly focused on improving transitions of care. When patients are admitted to hospital they may bring their medications from home, including Controlled Substances. This can present a risk of diversion if these medications are not managed appropriately.

RECOMMENDATION E-1: That hospitals have processes, policies and procedures in place to ensure that patient's own Controlled Substances are managed appropriately. If the patient's medication remains at the hospital after admission, it

10 Berge, K. H., Dillon, K. R., Sikkink, K. M., Taylor, T. K., & Lanier, W. L. 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. Retrieved from: <https://doi.org/10.1016/j.mayocp.2012.03.013>. Accessed on August 13, 2018.

11 Health Canada: Reporting of loss or theft of controlled substances, precursors and cannabis <https://www.canada.ca/en/health-canada/services/publications/healthy-living/loss-theft-controlled-substances-precursors.html>. Accessed Nov 11, 2019.

should be counted and reconciled regularly during the hospital stay, and upon discharge or death of the patient. Upon discharge, as per the [Ontario Health Quality Standard of Transitions from Hospital to Home](#), it is recommended that a dedicated clinician be named responsible for coordinating the patient's transitions from hospital to home, and this clinician should be involved in transition-related decisions.

F. Knowledge Translation/Sharing Across the Health System

There can be variation in the way individual diversion incidents are dealt with both within hospitals and across the health system. Encouraging consistency in addressing diversion will enable the opportunity to share best practices within the system.

RECOMMENDATION F-1: Reporting suspected and confirmed incidents of diversion as medication incidents, through the existing medication incident reporting system at the hospital, enables greater awareness of the frequency of diversion in the hospital setting. It is recommended that data collected through this method also be reported directly to Health Canada through the [Loss or Theft Report Form](#) when appropriate,¹¹ as well as to the [Canadian Medication Incident Reporting and Prevention System](#) to contribute to the sharing of best practices across the health system.

RECOMMENDATION F-2: That diversion be highlighted as a priority for all hospitals as part of their continuous quality improvement. Hospitals should conduct a gap analysis to identify processes, policies and procedures which need to be updated to minimize risk of harm. Diversion incident reporting could be included as a core indicator on Quality Improvement Plans for hospitals. The [Canadian Incident Analysis Framework](#) can be used to analyze incidents.

MEASUREMENT AND EVALUATION

This framework establishes recommendations outlining best practices for hospitals to incorporate to reduce the risk of diversion. Organizations should establish key performance indicators (KPIs) to evaluate their progress on improving the safety and security of Controlled Substances. Such indicators may include, but not be limited to, the number of Health Canada loss and theft reports, the number of confirmed diversions and the results of physical security and process audits on a regular basis to track the impact of their diversion prevention and mitigation strategies.

NEXT STEPS

The Ontario College of Pharmacists will continue working with the Partnered Table members in the coming months to identify opportunities to measure and evaluate the impact of the recommendations from the framework. The recommendations are meant to be evolving and will be regularly reviewed for quality improvement.

APPENDIX A: ADDITIONAL RESOURCES

[Canadian Guideline for Safe and Effective Use of Opioids for CNCP](#): McMaster University, National Pain Centre

[Controlled Drugs and Substances Act and Regulations](#): Health Canada

[Controlled Drugs and Substances in Hospitals and Healthcare Facilities: Guidelines on Secure Management and Diversion Prevention](#): Canadian Society of Hospital Pharmacists

[Drug Diversion Allegations Settlement](#): District of Massachusetts

[Guidelines on Preventing Diversion of Controlled Substances](#): American Society of Hospital Pharmacists

[Nurse Health Program](#): College of Nurses of Ontario

[Opioid Prescribing for Acute Pain](#); [Opioid Prescribing for Chronic Pain](#); [Opioid Use Disorder \(Opioid Addiction\)](#): Ontario Health Quality Standards

[Opioid Resource Hub](#): Centre for Addiction and Mental Health

[Road Map to Controlled Substance Diversion Prevention](#): Minnesota Hospital Association