Proactive risk assessment of vulnerabilities for diversion of controlled substances in two Ontario hospital pharmacies

M de Vries[1,2], M Fan[2], D Tscheng[3], M Hamilton[3], P Trbovich[1,2]

1. Institute of Health Policy, Management and Evaluation, University of Toronto; 2. HumanEra, North York General Hospital;
3. Institute for Safe Medication Practices Canada

Background

- Diversion refers to the transfer of medications from legitimate medical use to unlawful use, which may include personal use or trafficking

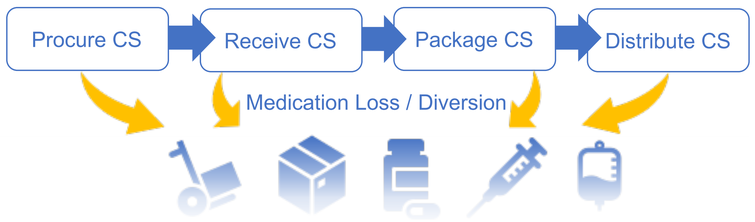

Figure 1: Controlled substance (CS) losses or diversion can occur at every stage of the hospital medication-use process

- Diversion can result in harm to those who divert, patient harm, legal and public relations issues for hospitals and an increased supply of controlled substances in the community
- Hospitals have high rates of "unexplained loss" suggesting that hospitals are unable or ill-equipped to investigate and analyze controlled substance loss
- Understanding vulnerabilities in inpatient pharmacy processes is required to better align interventions against diversion risks and improve management of controlled substances in hospitals

Objectives

1. Identify vulnerabilities for diversion in the medication-use processes of two inpatient pharmacies
2. Characterize the types of vulnerabilities identified

Methods

- We conducted a multimethod study comprised of clinical observations and a Healthcare Failure Mode and Effect Analysis (HFMEA) (Figure 1). A province-wide REB approval was granted for the study through Clinical Trials Ontario (REB #1354)

Clinical observations

- Purpose: To obtain a detailed understanding of participants' typical tasks and responsibilities, as well as the procedures and equipment related to each medication-use process
- Two full-service hospitals in Toronto, Ontario
- Sampling to recruit pharmacy staff with roles in at least one components of the medication-use process
- Observers shadowed participants as they carried out their daily activities, taking notes, collecting artifacts, and taking photographs of the environment, technology and supplies

Healthcare Failure Mode and Effect Analysis

- Purpose: To identify Critical Failure Modes in the MUPs (i.e., a failure mode which introduces a process failure by itself or is a failure mode which is not easily prevented or detected by the system)
- Used the HFMEA approach (Figure 2)
- The HFMEA team was comprised of pharmacists and human factors specialists
- Looked for similarities and differences in Critical Failure Modes within and between the sites

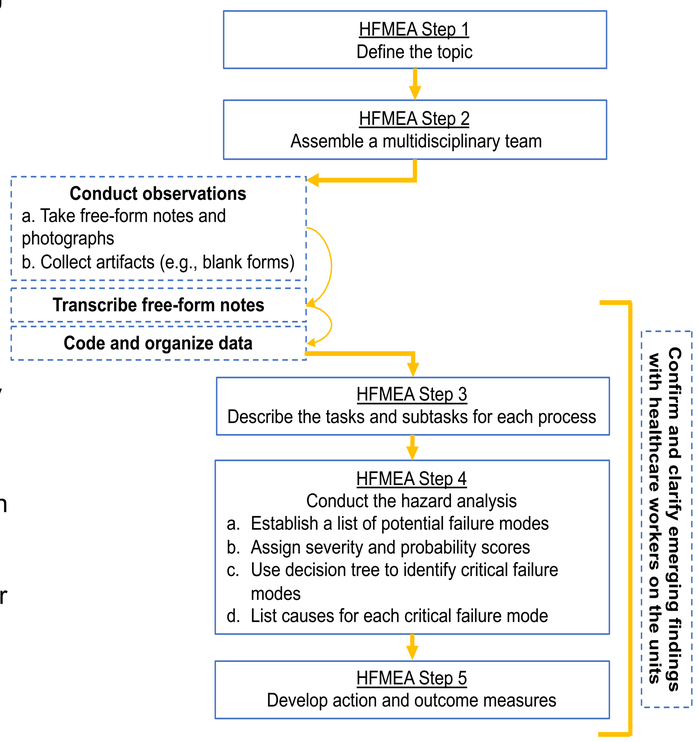

Figure 2: Description of the study design showing the integration of the clinical observations and Healthcare Failure Mode and Effect Analysis

Results

Table 1: Observation settings in two inpatient hospital pharmacy sites

		Site 1	Site 2
Setting	**Size of hospital**	400 beds	400 beds
	Type of hospital	Community academic	Academic
	Pharmacy hours of operation	Weekdays: 08:00 – 20:00 Weekends: 08:00 – 17:00	Weekdays: 07:30 – 21:00 Weekends: 07:30 – 17:00
	CS vault and ADC	Omnicell vault Omnicell ADCs	Pyxis C2Safe Pyxis ADCs
Observations	**Roles (number of participants)**	Pharmacy technician (16) Pharmacist (3)	Pharmacy technician (20) Pharmacist (1) Clerk (1)
	Number of observation hours	46 hrs	53 hrs

CS, Controlled substance(s); ADC, automated dispensing cabinet

- We observed four stages of the medication-use process at both sites:
  1. *Procurement of controlled substances*
  2. *Receiving controlled substance deliveries to the pharmacy*
  3. *Unit-dose packaging of controlled substance oral solids*
  4. *Distribution of controlled substances to patient care areas*
- We identified 220 failure modes, with 34 deemed Critical Failure Modes

Table 2: Number of critical failure modes (CFMs) identified in each medication-use process task

Medication-Use Process Tasks	CFM Category			Total
	Handling	Data Entry	Verifying	
1. Procure CS for inpatient pharmacy	*0*	*4*	*2*	***6***
1.1 Determine which CS to procure	0	1	0	
1.2 Create purchase order	0	2	0	
1.3 Submit purchase order to vendor	0	1	1	
1.4 Reconcile invoiced items with purchase order	0	0	1	
2. Receive CS from vendor deliveries	*1*	*1*	*3*	***5***
2.1 Deliver boxes of CS to inpatient pharmacy	0	0	0	
2.2 Verify delivered items against packing slip and/or invoice	1	0	2	
2.3 Place items into CS vault	0	1	0	
2.4 Sign off on delivered items	0	0	1	
3. Package CS into unit doses (oral solids)	*5*	*2*	*1*	***8***
3.1 Retrieve CS from vault for unit dose packaging	1	1	0	
3.2 Program unit dose packaging machine	1	0	1	
3.3 Run unit dose packaging machine	1	0	0	
3.4 Check unit dose packaged items	1	0	0	
3.5 Return unit dose packaged items to CS vault	1	1	0	
4. Distribute CS to the ADCs on hospital units	*2*	*6*	*7*	***15***
4.1 Trigger delivery for interim orders, orders for scheduled medications, or restocking of supplies in ADCs on hospital floors	0	1	1	
4.2 Retrieve CS from inpatient pharmacy stock	1	2	3	
4.3 Deliver CS to hospital units	1	3	3	
Total	**8**	**13**	**13**	**34**

CS, Controlled substance(s); ADC, automated dispensing cabinet

- Three categories of failure modes emerged during analysis of the Critical Failure Modes
- Some Critical Failure Modes were found only at one site because the other site had a control in place that safeguards against the failure (e.g., use of locked carts and additional verification processes)

Table 3: Description of critical failure mode (CFM) categories

CFM Category	Description
1. Handling	• Tasks that involve CS moving from one place to another or being left in holding areas before the next task takes place • CFMs related to handling highlight vulnerabilities to theft, tampering or substitution • CFM results show that most of these occurred during the distribution of CS to patient care areas
2. Data Entry	• Tasks involve the entering of information or instructions into electronic systems or the recording of information manually into paper log books or electronic databases • CFMs related to data entry tasks highlight vulnerabilities to forgery, hiding discrepancies or accessing CS fraudulently • CFM results found a subset of data entry CFMs that highlight the risk of failing to log out of electronic systems, allowing CS ordering, dispensing or transaction verification to occur under another individual's username
3. Verifying	• Tasks involve verifying work conducted by a staff member using a second individual or a technology • CFMs related to verifying highlight vulnerabilities to the integrity of medication or accuracy of documentation • CFM results found two types of verification CFMs: omission of double checks or double checks that fail to detect inaccuracies

Discussion

- Our study contributes the first empirical observation of the medication-use processes of two different pharmacies and new evidence to the literature on the prevention and detection of hospital diversion
- In both sites, automated dispensing cabinets and controlled substance vaults were installed, which literature suggests are strong safeguards against diversion. Our results demonstrate that several Critical Failure Modes exist despite implementation of these safeguards.
- Diversion is a complex problem and requires a multifaceted approach to addressing it.

References

Study Protocol: M deVries, Fan M, Tscheng D, Hamilton M, Trbovich P. Clinical observations and a Healthcare Failure Mode and Effect Analysis to identify vulnerabilities in the security and accounting of medications in Ontario hospitals: a study protocol. *BMJ Open*. 2019;9(6):e027629. doi:10.1136/bmjopen-2018-027629

Scoping review on contributors and safeguards for diversion: Fan M, Tscheng D, Hamilton M, Hyland B, Reding R, Trbovich P. Diversion of Controlled Drugs in Hospitals: A Scoping Review of Contributors and Safeguards. *Journal of Hospital Medicine*. 2019;14(7):419-428. doi:10.12788/jhm.3228

ISMP CANADA

Institute of Health Policy, Management and Evaluation
UNIVERSITY OF TORONTO

NORTH YORK GENERAL
Making a World of Difference