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Complete List of Authors:	de Vries, Maaike; North York General Hospital, HumanEra, Research and Innovation; University of Toronto, Institute of Health Policy, Management and Evaluation Fan, Mark; North York General Hospital, HumanEra, Research and Innovation Tscheng, Dorothy; Institute for Safe Medication Practices - Canada Hamilton, Michael; Institute for Safe Medication Practices - Canada Trbovich, Patricia; North York General Hospital, HumanEra, Research and Innovation; University of Toronto, Institute of Health Policy, Management and Evaluation
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Study protocol for naturalistic observations and a Healthcare Failure Mode and Effect Analysis to identify vulnerabilities in the security and accounting of medications in Ontario hospitals

Author List: Maaike de Vries[1,2], Mark Fan[1], Dorothy Tscheng[3], Michael Hamilton[3], Patricia Trbovich[1,2]

Author Affiliations:

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

Corresponding Author:

Maaike deVries, MSc

Institute of Health Policy, Management and Evaluation

University of Toronto, Health Sciences Building

155 College Street, Suite 425

Toronto, ON Canada M5T 3M6

416-420-8678

maaike.devries@mail.utoronto.ca

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ABSTRACT

Introduction: An increasing number of opioids and other controlled substances are being stolen from healthcare facilities, diverting medications from their intended medical use to be used or sold illicitly. Many incidents of medication loss from Canadian hospitals are reported as unexplained losses. Together, this suggests not only that vulnerabilities for diversion exist within current medication use processes (MUPs), but that hospitals lack robust mechanisms to accurately track and account for discrepancies and loss in inventory. There is a paucity of primary research investigating vulnerabilities in the security and accounting of medications across hospital processes. The purpose of this study is to map hospital MUPs, systematically identify risks for diversion or unintentional loss, and proactively assess opportunities for improvements to medication accounting and security.

Methods and analysis: We will conduct human factors-informed naturalistic observations, followed by a Healthcare Failure Mode and Effect Analysis (HFMEA). We will observe hospital personnel in the intensive care unit, emergency department, operating room and inpatient pharmacy in two hospitals in Ontario, Canada. Observations will capture how participants complete tasks, as well as gather contextual information about the environment, technologies, and processes. A multidisciplinary team will complete an HFMEA to map process flow diagrams for the MUPs in the observed clinical units, identify and prioritize potential methods of medication loss (failure modes), and describe mechanisms or actions to prevent, detect, and trace medication loss.

Ethics and dissemination: We received province-wide research ethics via Clinical Trials Ontario Streamlined Research Review System, and site-specific approvals from each participating hospital. The results from this study will be presented at conferences and meetings,

as well as published in peer-reviewed journals. The findings will be shared with hospitals, professional, regulatory and accreditation organizations, patient safety and healthcare quality organizations, and equipment and drug manufacturers.

Keywords: Hospital medication use process, Diversion, Healthcare safety and quality, Human factors

ARTICLE SUMMARY

Strengths and limitations

1. Applying human factors methodologies embraces system complexity and allows diversion to be studied from a systems, as opposed to an individual blame, perspective.
2. Basing the analysis on data collected through observations enables the study to identify vulnerabilities in processes according to how they are actually performed instead of how they are perceived to occur (work as done versus work as imagined).
3. Conducting the study in multiple units in two hospitals enables corroboration of results between sites, as well as the comparison of workflows and failure modes across hospitals and as a function of clinical area.
4. Probability and severity scoring of failure modes (and other components of the hazard analysis) is subjective; however, our study design mitigates this with a multidisciplinary team and independent scoring.
5. There are widespread system-level and individual-level practice variations within a hospital, and point-in-time observations likely do not capture all possibilities, even as attempts to increase the number and time of observations are employed.

INTRODUCTION

The opioid crisis claims lives every day, with opioid misuse causing increasing rates of morbidity and mortality across Canada.[1–4] A worrisome parallel trend shows a growing number of opioids and other medications going missing or being stolen from Canadian healthcare facilities[5–10] and entering the illegal street market.[7,8] The theft of medications for personal substance use or trafficking is described as 'diversion', because drugs are transferred, or diverted, from legitimate medical to non-medical use.[11] Opioids are one of several classes of medications categorized as controlled substances, given their potential for misuse. Canadian hospitals have a responsibility for the safety and security of these medications. In contrast to the diversion prevention guidance in the United States that describes multiple safeguards that should be in place, including a broad multidisciplinary effort to assess diversion risks and implement mitigation strategies,[12–19] Canadian diversion prevention guidance for hospitals is outdated and does not comprehensively address elements covered in other jurisdictions.[20–25]

At present, Canadian hospitals lack robust processes and infrastructure to accurately track and resolve discrepancies in their controlled substance inventory. For example, Canadian hospitals detected and reported 1020 incidents of controlled substance loss and theft to Health Canada in 2016.[9] Over 80% of incidents were reported by hospitals as unexplained losses, meaning that at the time of reporting (i.e., within 10 days of discovery), the loss could not be attributed to any particular cause or action. Clearly, system-wide gaps in the traceability of medication transactions through technologies, processes, and environments can result in considerable losses of medications without recourse to audit or trace their whereabouts. As a result, many hospitals may not be aware of the deficiencies in their medication accounting and security processes. Further, the large proportion of unexplained losses suggest that current

estimates of medication thefts in Canadian hospitals, diversion or otherwise, underestimate the issue.

Impact of hospital medication diversion

The hospital setting is particularly vulnerable to diversion by healthcare workers because of the large quantity of stock, frequent use for treating patients, and the proximity with which many hospital personnel interact with medications. Ease of access and frequent interaction with controlled substances can be considered occupational hazards, increasing the risk of diversion and substance use disorder among healthcare workers.[26–28] The opportunity to divert medications can escalate drug seeking behaviour and lead to overdose and death.[19,29] The healthcare worker who diverts is at risk of infection from unsterile medications and needles.[30–32] There are also professional risks to the healthcare worker, including termination of employment, revocation of their license, civil malpractice claims, and criminal prosecution.[33–35]

Diversion has been shown to have negative effects beyond its impact on the person who is diverting medications, including on patients, healthcare facilities, and the larger community. Patients have been directly harmed by receiving inadequate analgesia or anesthesia when their medication is diverted,[36–38] been provided substandard care when their healthcare worker was impaired,[12,39] and even contracted viral or bacterial infections due to medications or syringes compromised in the diversion process.[30,31,40] Healthcare facilities and pharmacies bear the cost of diverted medications from their stock, as well as the cost of substandard care/services, follow-up activities to investigate the incident and address patient care, and reporting requirements to the authorities.[36,41,42] The larger community is impacted by the increase in

the supply of medications ending up on the street[7,8] and decreased public trust in healthcare professions, institutions, and workers.

Human factors approach to studying the medication use process and vulnerabilities for diversion

There is a lack of primary research describing how controlled substances are lost or stolen from hospitals. Diversion literature largely consists of expert commentary and institutional experience,[43–46] case reports,[47–49] and audit reports.[50–53] These build awareness of the issue and provide insights into potential mechanisms for diversion; however, none provide a systematic empirical investigation of the vulnerabilities compromising the security and accounting of medications across the entire hospital medication use process (MUP; e.g., procuring, storing, ordering, dispensing, preparing, administering, and wasting of medications). Consequently, it is unclear what organizational, technological, or educational interventions are needed and which specific vulnerabilities they should be optimized to address. In addition, literature discussing hospital medication abuse, security, and management are often written in response to an incident, such as an overdose.[31,54] Although it is important to investigate the effects of these incidents and update best practices in response, it is equally, if not more important, to proactively identify potential risks to prevent new and unexpected patterns of diversion.

To address this gap not only with respect to diversion but controlled substance stewardship in general, we propose a naturalistic observation study designed to map hospital MUPs and systematically identify vulnerabilities in these processes that increase the risk for diversion. Recognizing the sensitivity of the topic, we emphasize that our study seeks to understand

diversion from a systems perspective, empirically and objectively identifying process failures in the security and accounting of medications rather than characterizing, blaming, or otherwise criminalizing healthcare workers who may be diverting.

Human factors is the discipline concerned with understanding the interactions among humans and other elements of a system, such as processes and technology. As a result, it is uniquely equipped to consider the interplay of workload pressures, technology design, organizational culture, policies and procedures, and legislation on the security and accounting of medications within the hospital setting. Naturalistic observations are observations of participants in their own environment going about their day-to-day activities. From the time medications enter a hospital to their eventual use and/or disposal, handoffs occur between hospital staff, departments, dispensing technologies, and record keeping systems. A human factors approach to naturalistic observations will allow us to study vulnerabilities that emerge from these handoffs (e.g., departmental siloes), permitting the most comprehensive analysis possible. Specifically, we will conduct human factors-informed observations in four units in two hospitals, followed by a Healthcare Failure Mode and Effect Analysis.

Healthcare Failure Mode and Effect Analysis for identifying vulnerabilities for diversion

Healthcare Failure Mode and Effect Analysis (HFMEA) involves mapping detailed process flow diagrams and then systematically identifying and prioritizing vulnerabilities via a structured decision-making algorithm.[55] HFMEA was developed by the Department of Veterans Affairs National Centre for Patient Safety (NCPS) in 2002.[56] It been successfully applied to several healthcare processes, including the ordering and administration of medications as well as the sterilization and use of surgical instruments.[57–61] HFMEA combines concepts and

components from the Failure Mode and Effect Analysis (FMEA), Hazard Analysis and Critical Control Point, and root cause analysis.[56] FMEA was originally used in aviation, manufacturing, and nuclear industries to evaluate risk of products, and has been used in healthcare to conduct proactive risk analyses on high-risk technologies and processes.[62,63]

The use of FMEA in healthcare has been criticized because of concerns with the manner in which a single risk priority number (RPN) is used to rank vulnerabilities.[64] The RPN in FMEA is calculated by multiplying scores from three ordinal scales: severity, probability and detectability. Multiplying these scores creates an RPN that is mathematically flawed, unstable (small changes in one score can lead to large changes in RPN), and masks important distinctions.[64–66]. For example, a failure mode with high detectability, high probability, but low severity could be prioritized the same as a failure mode with high detectability, low probability, but high severity. Given that failure modes with the highest RPN would be considered as hazards with the highest priority, efforts may be misdirected based on a misleading RPN score. HFMEA addresses these concerns by prioritizing vulnerabilities using a decision tree analysis that considers not only the severity and probability scores, but also whether there are control measures that prevent or detect these failures. The HFMEA decision tree analysis uses "yes" and "no" responses when assessing the criticality, presence of control measures, and detectability of the failure modes.[55] As a result, the prioritization in HFMEA is more robust than in FMEA.

The purpose of this study is to understand how medications are secured and accounted for throughout the MUP in two Ontario hospitals, generate data on where vulnerabilities exist for

diversion or unintentional losses, identify existing safeguards against these vulnerabilities, and proactively assess opportunities for improvements to medication accounting and security.

METHODS AND ANALYSIS

We will employ an observational study design comprised of two phases. In the first phase, we will conduct naturalistic observations to understand and contrast MUPs across units and hospitals. Although we are interested in identifying vulnerabilities in the MUP that could allow diversion to occur, we do not expect to observe incidents of diversion. Rather, the purpose of the observations is to map the MUPs. In the second phase, we will use HFMEA to proactively identify and evaluate failure modes in MUPs and identify opportunities for improvement to medication accounting and security. The study observations and analysis will take place from May 2018 to June 2019.

Clinical Observations

Setting

Naturalistic observations will be conducted in four units (intensive care unit, emergency department, operating room, and inpatient pharmacy) in two hospitals in Toronto, Ontario, Canada. We purposively selected the settings to meet three criteria: academic and community hospital sites, units with high use and access to controlled substances, and units with different types of automated dispensing cabinets.

Participants

We will use purposive sampling to recruit participants for the clinical observations. We will include front-line healthcare workers who have a role in or interaction with at least one

component of the MUP and who consent to being observed. This includes healthcare workers who directly interact with medications (e.g., dispensing and administering medications), as well as hospital personnel who are involved indirectly (e.g., encountering partial vials of medication while cleaning patient rooms). We estimate that a sample size of 20 participants is the minimum number of observations required to reach theoretical saturation, whereby additional sessions would not likely yield further insights. Therefore, the estimated number of participants is 160 (20 individuals per unit x 2 hospitals x 4 units). However, the number of healthcare workers recruited for observations is expected to differ somewhat between units because of differences in staffing complement, shift schedules, and number of tasks related to the MUP. For example, in the intensive care units, we expect to observe a minimum of 14 nurses, 2 pharmacists, 2 physicians, 1 respiratory therapist, and 1 environmental services staff, whereas in the inpatient pharmacies, we expect to observe 18 pharmacy technicians and 2 pharmacists.

Participants will be asked to sign consent forms before being observed. Participants will be given as much time as they require to review the consent form and have their questions answered by the research team prior to deciding if they wish to participate. The study team will highlight that participation is voluntary and can be stopped at any time for any reason and that clinical performance is not being assessed or evaluated.

Data Collection

One human factors specialist and one clinician will jointly observe within each hospital unit for approximately five times a week for four weeks. Observations will take place on all days of the week and include all hours of the day. Each observation session will last for two to eight hours, depending on the participants' availability, the shift duration, and the task(s) being

observed. Some tasks are frequent and repetitive so require less time to capture, whereas others occur infrequently or over the course of a longer time period so require longer observation periods. Observers will unobtrusively shadow participants as they carry out their daily activities. The purpose of the observations is to obtain a detailed understanding of participants' typical tasks and responsibilities, as well as the procedures and equipment related to the MUP. The observations will also characterize problematic issues that are observed (e.g., not logging out of the automated dispensing cabinet system) or that participants describe to the observer (e.g., unwillingness of peers to witness wasting). Observations will capture the MUP for all medications, but with a focus on controlled substances to identify safeguards and vulnerabilities specifically for these medications.

Observers will take free-form notes, collect artifacts of clinical practice (e.g., blank pre-printed forms), as well as take photographs of the environment, technology and supplies. The photographs will be used to recall or visualize process steps during the mapping process. Images will also be used to provide context when presenting and describing results. The free-form notes will capture step-by-step how participants complete tasks as well as contextual information, including the physical layout of the unit, the roles and shifts covered by staff, technologies used to document dispensing, and locations of medications on the unit. The observer will fully transcribe their free-form notes into Word© and upload them onto a secure SharePoint© site hosted at the research team's home organization.

Coding of observation data

Data collected during observations will be uploaded into MAXQDA© version 2018.1 data management and analysis software. One human factors specialist will code the observation

data using codes for hospital units (intensive care unit, emergency department, operating room, and inpatient pharmacy), tasks, and vulnerabilities or safeguards. A second research team member will review the codes, and any discrepancies will be resolved through discussion.

Healthcare Failure Mode and Effect Analysis

The HFMEA process includes five main steps.[56] We will first map the process flow diagrams for the management and use of medications in the observed clinical units. Next, we will identify potential methods of medication loss and evaluate their severity, risk and detectability, as well as identify potential areas where mitigation strategies can be implemented.

1. Define the topic

The first step is to define the HFMEA topic, including boundaries to limit its scope. Our HFMEA will examine the hospital MUP, including the procuring, storing, ordering, dispensing, preparing, administering and wasting of medications. We will limit the topic to specific units within the hospital (i.e., operating room, intensive care unit, inpatient pharmacy, and emergency department). Any hospital personnel role, technology, or object that directly or indirectly interacts with medications will be included. Processes that are external to the hospital unit or roles that are not affiliated with the hospital will be out of scope (e.g., administration of medications by paramedics, delivery of medications from distribution centre).

2. Assemble the team

The second step is to assemble a multidisciplinary team. Our team will be comprised of three human factors specialists, two pharmacists, one physician, two nurses, and two pharmacy

technicians. The members of the team will ensure there is expertise in conducting observations and proactive risk analysis, as well as knowledge and experience working in the different hospital settings and performing tasks covering the breadth of the MUP. For particular steps of the HFMEA, team members will vary as a function of the unit being analysed (e.g., pharmacists will brainstorm failure modes in the pharmacy).

3. Graphically describe the process

The third step is to develop process flow diagrams and number each task and subtask. Creating process flow diagrams is an important first step in identifying safety risks from different aspects of a work system (e.g., individual, technology, administration).[67] We will use the data collected during the naturalistic observations to graphically map the step-by-step MUPs from each clinical unit. Using direct observation of processes, as opposed to mapping processes according to how tasks are supposed to occur, will strengthen the validity of our results.[68] The maps will be created by retrieving data coded for specific units and tasks and translating the process steps into a visual flow diagram using draw.io©. The mapping process will be completed iteratively during the clinical observation period, so that gaps or steps requiring clarification can be gathered in the next observation session. If observers note differences in how participants perform the same process, this variation will be discussed by the HFMEA team and flagged in the flow diagrams, because variations may suggest vulnerabilities in process. The team will review the detailed process flow diagrams and one human factors specialist will transcribe each task (e.g., dispensing from automated dispensing cabinet) and subtask (e.g., logging into the automated dispensing cabinet, selecting the patient, selecting the desired medications) into Excel©.

4. Conduct a hazard analysis

The fourth step consists of four sub-steps: A) list and number all potential failure modes (ways a step within a subtask can fail to accomplish its intended purpose) and potential effects if a failure were to occur; B) score the severity and probability of potential failure modes; C) use a decision tree analysis to identify critical failure modes; D) list all causes of critical failure modes.

A) Two HFMEA team members will independently brainstorm failure modes and effects for each of the subtasks, and any discrepancies will be discussed. If a decision on whether or not to include a failure mode cannot be reached, a third member of the team will reconcile the discrepancy. Failure modes will be organized into a worksheet (Figure 1) to facilitate the recording of results from the next two sub-steps.

B) Two HFMEA team members will independently score failure modes based on their severity and probability, as described by the NCPS (Table 1).[55] A hazard score is calculated by multiplying the severity and probability scores. The intra-class correlation (ICC) will be calculated for a subset of hazard scores to assess inter-rater reliability. Definitions of scale scores will be discussed and refined until an accepted level of agreement is reached (ICC≥0.60). The severity and probability of the remaining failure modes will then be scored.

Table 1. Probability and severity scoring

Score / Scale	1	2	3	4
Probability	Remote Unlikely to occur; may happen sometime in 5 to 30 years	Uncommon Possible to occur; may happen sometime in 2 to 5 years	Occasional Probably will occur; may happen several times in 1 to 2 years	Frequent Likely to occur immediately or within a short period; may happen several times a year
Severity *Patient outcome*	Minor Event No injury nor increased length of stay nor increased level of care	Moderate Event Increased length of stay or increased level of care for 1 or 2 patients	Major Event Permanent lessening of bodily functioning, disfigurement, surgical intervention required, increased length of stay for 3 or more patients	Catastrophic Event Death or major permanent loss of function or suicide
Staff outcome	First aid treatment only with no lost time or restricted duty injuries or illness	Medical expenses, lost time or restricted duty injuries or illness for 1 or 2 staff	Hospitalization of 1 or 2 staff, or 3 or more staff experiencing lost time or restricted duty injuries or illnesses	One death or hospitalization of 3 or more staff
Equipment or facility	Damages less than $10,000 without adverse patient outcome	Damages more than $10,000 but less than $100,000	Damages equal to or more than $100,000 but less than $250,000	Damages equal to or more than $250,000

Adapted from "The Basics of Healthcare Failure Mode & Effect Analysis" by the Department of Veterans Affairs National Center for Patient Safety (2014). Available from: https://www.patientsafety.va.gov/professionals/onthejob/hfmea.asp

C) The HFMEA team will use a decision tree to prioritize the failure modes (Figure 2). Failure modes with sufficient hazard scores or that are single point weaknesses (i.e., failure in this step will invariably result in an adverse event) are considered in the next step of the decision tree. If an effective control measure exists (e.g., storing medications in a locked drawer to prevent an individual from opening the drawer and removing medications from it) or the failure mode is so obvious and apparent that a control measure is not warranted, then the failure mode does not proceed through the next steps of the HFMEA. All remaining failure modes are labelled as critical and considered in sub-step D.

D) The HFMEA team will brainstorm the potential causes of the critical failure modes and record these in the worksheet. Completing the hazard analysis will produce a list of critical failure modes and their causes.

5. Develop action and outcome measures

The fifth step is to determine which failure mode causes can be eliminated or controlled and describe what actions could be used to accomplish this. This step also includes developing measures that can be used to test and analyse the success of a redesigned process. We will use the list of critical failure modes from the hazard analysis to describe each step in the MUP that increases the hospital's potential risk for medication loss, including those related to both the security and accounting of medications. We will consider the causes listed for the failure modes and describe mechanisms or actions that can be implemented to prevent, detect, and trace incidents of medication loss. Finally, we will suggest measures that could be used to assess successful implementation of these mechanisms and process improvements.

It is expected that the HFMEA will lead to an understanding of the current workflows and failure modes affecting the MUP in one community and one academic hospital. Results of this analysis will allow for a comparison of workflows and failure modes between hospitals and as a function of clinical area (e.g., emergency department versus operating room). Using a human factors approach, which considers interactions between all system elements (e.g., front-line healthcare workers, administrators, policies and regulations, technology), we anticipate that we will identify practices related to standards/guidelines, technologies and training.

Patient and public involvement

Hospital personnel have supported this work by facilitating opportunities for observations and analysis of different aspects of the MUP in units that have high controlled substance use and access. Healthcare providers and hospital staff will also be engaged during the HFMEA and will inform the dissemination strategy. Patients and public were not involved in the design of this study.

ETHICS AND DISSEMINATION

Ethics

This study has received province-wide Research Ethics Board (REB) approval via Clinical Trials Ontario Streamlined Research Review System, as well as site-specific approvals from each participating hospital under this framework.

Consent for observations is obtained for the healthcare worker who is being observed. When photographs are taken, no patients or healthcare workers will be photographed, and all person identifiers will be eliminated (e.g., patient name/ID will be covered). Hospitals that choose to participate will remain anonymous and will be described using general terms (e.g., a community hospital) in publications and presentations.

All signed consent forms, observation free-form notes, artifacts and photographs, and database records will be kept secure and confidential. Observational data will be associated with a participant number to reduce the risk of participant identification. All data reported outside of the study team will be in aggregate form, without reference to any specific participant.

The observers are only responsible for collecting data as part of the study and will not perform clinical duties (e.g., helping with tasks). However, in the unlikely event that observers

suspect an error is about to be made that could compromise patient safety, observers will intervene by asking the participant for clarification, as indicated in the REB.

Dissemination

The audience for our research includes front-line hospital staff and administrators, as well as professional, regulatory and accreditation organizations, patient safety and healthcare quality organizations, and equipment and drug manufacturers. The findings from our study will be used by organizations to inform recommendations, guidance and standards.

The results will be shared with hospitals in Ontario and across Canada through collaboration with the Institute for Safe Medication Practices Canada. Findings from this study will be presented at conferences and meetings, as well as in manuscripts submitted for publication. This study will be among the first to proactively capture empirical evidence of how current controls for MUPs in Ontario hospitals may be improved to protect against medication losses.

LIMITATIONS

It is challenging for observations to capture how participants actually conduct tasks, because participants may alter their behaviour due to the presence of the research team on the unit (i.e., the Hawthorne Effect[69]). We will mitigate this effect by reassuring participants that results will not be used to evaluate individual performance but will only be used to describe an overall process. To minimize disruption and further normalize our presence, we will be as unobtrusive as possible and conduct several hours of observations at multiple sites with multiple participants.

The validity of the results is strengthened by accurate note-taking by the observers. However, it is possible that some subtasks or contextual features of the environment will be missed. To limit the extent of missing information, observers will receive an orientation to each unit before beginning observations, will ask clarifying questions while observing, and will fully transcribe field notes. Two observers will capture MUPs in each unit, enabling corroboration and identification of tasks requiring further observation. Consistent team members will observe, transcribe and analyze the data.

The subjective nature of identifying potential failure modes and scoring the probability and severity of their effects may compromise the reliability of the results. But, by using data collected through observations to conduct the HFMEA, the subjectivity of the hazard analysis is lessened by basing the work on observed behaviours as opposed to perceived actions based on accepted practices. To further limit threats to reliability, brainstorming failure modes, scoring probability and severity, and completing the decision tree will be conducted independently by two consistent members on the HFMEA team, with a third member reconciling differences when required. There is no defined hazard score threshold to indicate when a failure mode should be considered for further analysis. Instead, the decision will be made by the HFMEA team based on several factors, including the number of failure modes and distribution of hazard scores. However, regardless of the hazard score threshold, all failure modes will be assessed for single point weaknesses and progress through the decision tree (Figure 2).

REQUIRED STATEMENTS

Author Contributions: PT, MF, MD, DT, and MH were involved in the conceptualization of the study. MD was responsible for drafting the protocol manuscript. PT, MF, DT, and MH reviewed and revised the manuscript for intellectual content. All authors reviewed and approved the final version of the manuscript.

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Competing Interests Statement: MF and PT have received honoraria from BD Canada Inc. for presenting at BD sponsored events.

LEGEND OF TABLES AND FIGURES

Table 1. Probability and severity scoring

Figure 1. Healthcare Failure Mode and Effect worksheet. CS, Controlled substances; ED, Emergency department; OR, Operating room; ICU, Intensive care unit; Pharm, Inpatient pharmacy

Figure 2. Decision tree analysis. Adapted from "The Basics of Healthcare Failure Mode & Effect Analysis" by the Department of Veterans Affairs National Center for Patient Safety (2014). Available from: https://www.patientsafety.va.gov/professionals/onthejob/hfmea.asp

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HFMEA Step 3					HFMEA Step 4							HFMEA Step 5	
Medication Use Process					Failure Mode and Effect			Setting	Scoring		Decision Tree	Action	
#	Task	Sub-task	Related to CS only? (Y/N)	Role involved in the task	Potential Failure Mode	Potential Effect(s)	Potential Cause(s)	Occurs in ED, OR, ICU and/or Pharm	Probability (1-4)	Severity (1-4)	Proceed or Stop?	Eliminate, Control or Accept	Action
1													
1.1													
1.2													
…													
…													

E.g., Stocking the automated dispensing cabinet

E.g., Confirm number of units in current stock, verify count with witness

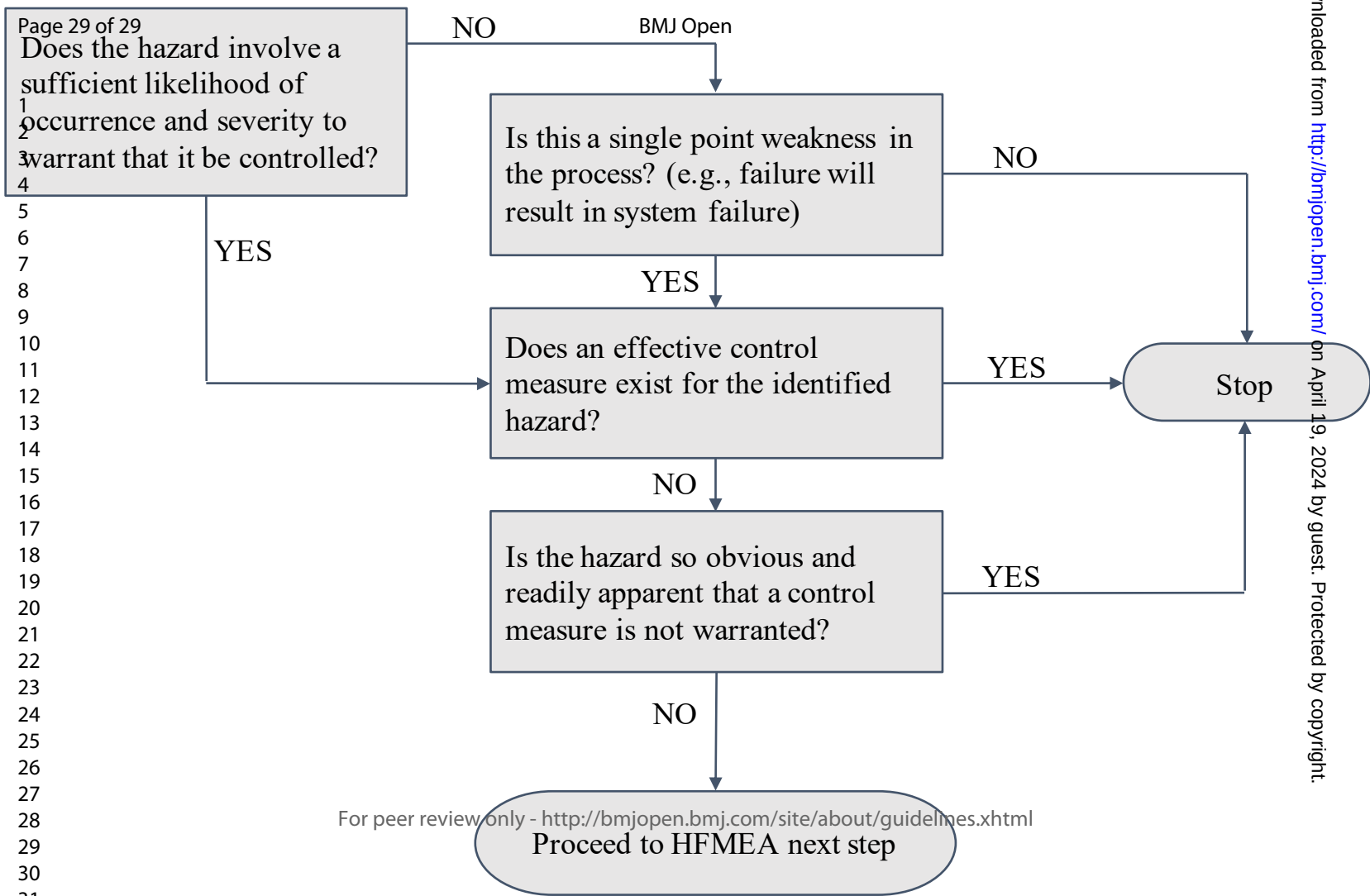
E.g., Pharmacy technician, nurse

E.g., Accept prepopulated count of stocked units without correctly counting the number of items

E.g., Discrepant count between documented number of stocked units and number

E.g., Confirmation bias, witness rushing technician to complete count

E.g., Program automated dispensing cabinet to require blind count of current stock



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Study protocol for clinical observations and a Healthcare Failure Mode and Effect Analysis to identify vulnerabilities in the security and accounting of medications in Ontario hospitals

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Study protocol for clinical observations and a Healthcare Failure Mode and Effect Analysis to identify vulnerabilities in the security and accounting of medications in Ontario hospitals

Author List: Maaike de Vries[1,2], Mark Fan[1], Dorothy Tscheng[3], Michael Hamilton[3], Patricia Trbovich[1,2]

Author Affiliations:

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

Corresponding Author:

Maaike deVries, MSc

Institute of Health Policy, Management and Evaluation

University of Toronto, Health Sciences Building

155 College Street, Suite 425

Toronto, ON Canada M5T 3M6

416-420-8678

maaike.devries@mail.utoronto.ca

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ABSTRACT

Introduction: An increasing number of opioids and other controlled substances are being stolen from healthcare facilities, diverting medications from their intended medical use to be used or sold illicitly. Many incidents of medication loss from Canadian hospitals are reported as unexplained losses. Together, this suggests not only that vulnerabilities for diversion exist within current medication use processes (MUPs), but that hospitals lack robust mechanisms to accurately track and account for discrepancies and loss in inventory. There is a paucity of primary research investigating vulnerabilities in the security and accounting of medications across hospital processes. The purpose of this study is to map hospital MUPs, systematically identify risks for diversion or unintentional loss, and proactively assess opportunities for improvements to medication accounting and security.

Methods and analysis: We will conduct human factors-informed clinical observations and a Healthcare Failure Mode and Effect Analysis (HFMEA). We will observe hospital personnel in the intensive care unit, emergency department, and inpatient pharmacy in two hospitals in Ontario, Canada. Observations will capture how participants complete tasks, as well as gather contextual information about the environment, technologies, and processes. A multidisciplinary team will complete an HFMEA to map process flow diagrams for the MUPs in the observed clinical units, identify and prioritize potential methods of medication loss (failure modes), and describe mechanisms or actions to prevent, detect, and trace medication loss.

Ethics and dissemination: We received province-wide research ethics via Clinical Trials Ontario Streamlined Research Review System, and site-specific approvals from each participating hospital. The results from this study will be presented at conferences and meetings, as well as published in peer-reviewed journals. The findings will be shared with hospitals,

professional, regulatory and accreditation organizations, patient safety and healthcare quality organizations, and equipment and drug manufacturers.

Keywords: Hospital medication use process, Diversion, Healthcare safety and quality, Human factors

STRENGTHS AND LIMITATIONS OF THIS STUDY

1. Applying human factors methodologies embraces system complexity and allows diversion to be studied from a systems, as opposed to an individual blame, perspective.
2. Basing the analysis on data collected through observations enables the study to identify vulnerabilities in processes according to how they are actually performed instead of how they are perceived to occur (work as done versus work as imagined).
3. Conducting the study in multiple units in two hospitals enables corroboration of results between sites, as well as the comparison of workflows and failure modes across hospitals and as a function of clinical area.
4. Probability and severity scoring of failure modes (and other components of the hazard analysis) is subjective; however, our study design mitigates this with a multidisciplinary team and independent scoring.
5. There are widespread system-level and individual-level practice variations within a hospital, and point-in-time observations likely do not capture all possibilities, even as attempts to increase the number and time of observations are employed.

INTRODUCTION

The opioid crisis claims lives every day, with opioid misuse causing increasing rates of morbidity and mortality across Canada.[1–4] A worrisome parallel trend suggests a growing number of opioids and other controlled substances (CS) going missing or being stolen from Canadian healthcare facilities[5–11] and entering the illegal street market.[7,8] The theft of medications for personal substance use or trafficking is described as 'diversion', as drugs are transferred, or diverted, from legitimate medical to non-medical use.[12] Weaknesses in the security and accounting of CS in hospitals enables medications to be lost or diverted.[13] It is increasingly recognized that Canadian hospitals lack robust processes and infrastructure to accurately track and resolve discrepancies in their CS inventory. For example, of the 1020 incidents of CS losses and thefts detected and reported by Canadian hospitals to Health Canada in 2016,[9] over 80% were reported as unexplained losses, meaning that at the time of reporting (i.e., within 10 days of discovery), the loss could not be attributed to any particular cause or action. What has not been explored are the vulnerabilities within the hospital medication use process (MUP; e.g., procurement, storage, preparation, prescription, dispensing, administration, reconciliation, waste, return, removal) that increase the potential for diversion to occur. With Canadian hospitals experiencing increasingly formal expectations that they will verify and enhance diversion safeguards to protect patients and healthcare workers[14,15], they require systematic knowledge about where vulnerabilities exist and advice and guidance on how to mitigate these risks.

Impact of hospital medication diversion

The hospital setting is vulnerable to diversion by healthcare workers because of the large quantity of stock and proximity with which many hospital personnel interact with medications. Ease of access and frequent interaction with CS can be considered occupational hazards, increasing the risk of diversion and substance use disorder among healthcare workers.[16–18] The opportunity to divert medications can escalate drug seeking behaviour and lead to overdose and death[13,19] or infection from unsterile medications and needles.[20–22] There are also professional risks, including suspension or termination of employment, revocation of license to practice, civil malpractice claims, and criminal prosecution.[23–25]

Diversion has been shown to have negative effects beyond its impact on the person who is diverting medications, including on patients, healthcare facilities, and the larger community. Patients have been directly harmed by receiving inadequate analgesia or anesthesia when their medication is diverted,[26–28] been provided substandard care when their healthcare worker was impaired,[29,30] and even contracted viral or bacterial infections due to medications or syringes compromised in the diversion process.[20,21,31] Hospitals bear the cost of diverted medications from their stock, follow-up patient care and investigations stemming from diversion, and reporting to authorities.[26,32,33] The larger community is impacted by the increase in the supply of medications ending up on the street[7,8] and decreased public trust in healthcare professions, institutions, and workers.

Gap in understanding vulnerabilities for diversion in hospital MUPs

System-wide gaps in the security and traceability of medication transactions through technologies, processes, and environments can result in considerable losses of medications

without recourse to audit or trace their whereabouts. As a result, many hospitals may not be aware of the deficiencies in their medication accounting and security processes. Further, the large proportion of unexplained losses suggest that current estimates of medication thefts in Canadian hospitals, diversion or otherwise, underestimate the issue. There is a lack of primary research describing how medications are lost or stolen from hospitals. Diversion literature largely consists of expert commentary and institutional experience,[34–37] case reports,[38–40] commentary on past incidents,[21,41] and audit reports.[42–45] These methods are retrospective and limited in their ability to identify or adequately characterize the system vulnerabilities that enable diversion. Although it is important to investigate the effects of these incidents and update best practices in response, it is equally, if not more important, to proactively identify potential risks to prevent new and unexpected patterns of diversion. To address this gap, we propose a study designed to map two hospitals' MUPs and systematically identify vulnerabilities in these processes that increase the risk for diversion. To our knowledge, this is the first study to prospectively and systematically investigate the vulnerabilities compromising the security and accounting of medications across the scope of hospital MUPs, as opposed to confined to a specific task or process, and to suggest mitigation strategies.

Objectives

The objectives of this study are to understand the security and accounting of medications throughout the MUPs in two Ontario hospitals, to identify vulnerabilities and existing safeguards, and to proactively identify opportunities for improvement.

Recognizing the sensitivity of the topic, we emphasize that our study seeks to understand diversion from a systems perspective, empirically and objectively identifying process failures in

the security and accounting of medications rather than characterizing, blaming, or otherwise criminalizing healthcare workers who may be diverting.

METHODS AND ANALYSIS

Overview

The study team is comprised of five health services researchers with backgrounds in medication safety, three (MD, MF and PT) with expertise in human factors, one with clinical experience as a hospital pharmacist (DT) and one as a practising physician (MH).

Our study is comprised of two integrated parts, as one (clinical observations) informs the other (risk analysis). Figure 1 describes the study design, showing the order of the steps from each part. We will conduct clinical observations to understand and contrast MUPs across units and hospitals. Although we are interested in identifying vulnerabilities in the MUP that could allow diversion to occur, we do not expect to observe incidents of diversion. Rather, the purpose of the observations is to map the MUPs. We will use Healthcare Failure Mode and Effect Analysis (HFMEA) to proactively identify and evaluate failure modes in MUPs and identify opportunities for improvement to medication accounting and security. The study observations and analysis will take place from May 2018 to October 2019.

Clinical observations

Setting

Clinical observations will be conducted in three units (intensive care unit, emergency department, and inpatient pharmacy) in two large (over 400 acute care beds) full-service hospitals in Toronto, Ontario, Canada. We purposively selected the settings to meet three criteria: one academic and one community hospital site, units with high use and access to CS,

and sites using different automated dispensing cabinet (ADC) platforms. Table 1 describes the units and lists the processes and personnel that we expect to observe at each. Several process tasks are expected to follow similar procedures/protocols given that both hospitals have central inpatient pharmacies that distribute unit-dosed medications to the floors, have ADCs on the clinical units, and operate within the same provincial health system. However, some process tasks are expected to differ between hospitals and clinical units because of differences in technologies (e.g., use of different ADCs) and protocols (e.g., requirement of a witness for wasting). For example, emergency departments often use paper documentation of medication orders and administration, whereas electronic systems are used to record these events in the intensive care units.

Table 1. Description of clinical observation sites and medication use processes

	Intensive Care Unit	Emergency Department	Inpatient Pharmacy
Setting	- Combined medical surgical and coronary care intensive care unit - Site 1: 20-25 beds - Site 2: 20-25 beds	- Acute, subacute, and ambulatory care - Site 1: over 100,000 emergency visits annually - Site 2: over 50,000 emergency visits annually	- Preparation, manufacturing, and dispensing of oral and intravenous medications - Site 1: Omnicell ADC and vault - Site 2: Pyxis ADC and vault
Processes	- Ordering/prescribing - Dispensing - Preparing - Administering - Wasting - Returning - Reconciling	- Ordering/prescribing - Dispensing - Preparing - Administering - Wasting - Returning - Reconciling	- Procuring - Delivering - Storing - Preparing - Distributing - Returning - Reconciling - Wasting - Disposing/removing
Personnel	- Physicians - Registered nurses - Nurse practitioners - Pharmacists - Respiratory therapists* - Environmental services staff - Porters/transportation staff	- Physicians - Registered nurses - Nurse practitioners - Pharmacists - Physician assistants - Environmental services staff - Porters/transportation staff - Security guards	- Pharmacy technicians - Pharmacists - Environmental services staff

*Respiratory therapy is a regulated profession in Canada requiring licensing from the Canadian Society for Respiratory Therapy or one of the provincial regulatory bodies.

Participants

We will use purposive sampling to recruit participants for the clinical observations. We will include front-line healthcare workers who have a role in or interaction with at least one component of the MUP and who consent to being observed. This includes healthcare workers who directly interact with medications (e.g., dispensing and administering medications), as well as hospital personnel who are involved indirectly (e.g., encountering partial vials of medication while cleaning patient rooms). We estimate that a sample size of 20 participants is the minimum number of observations required to reach theoretical saturation, whereby additional sessions would not likely yield further insights. Therefore, the estimated number of participants is 160 (20 individuals per unit x 2 hospitals x 4 units). However, the number of healthcare workers recruited for observations is expected to differ somewhat between units because of differences in staffing complement, shift schedules, and number of tasks related to the MUP. For example, in the intensive care units, we expect to observe a minimum of 14 nurses, 2 pharmacists, 2 physicians, 1 respiratory therapist, and 1 environmental services staff, whereas in the inpatient pharmacies, we expect to observe 18 pharmacy technicians and 2 pharmacists (see Table 1 for a description of MUPs and personnel that will be observed in each clinical unit at each site).

Participants will be asked by the study team to sign consent forms before being observed. Participants will be given as much time as they require to review the consent form and have their questions answered by the study team prior to deciding if they wish to participate. The study team will highlight that participation is voluntary and can be stopped at any time for any reason and that clinical performance is not being assessed or evaluated.

Data collection

Two members of the study team (one human factors specialist and one clinician) will jointly observe within each hospital unit for approximately five times a week for four weeks. Observations will take place on all days of the week and include all hours of the day. Each observation session will last for two to eight hours, depending on the participants' availability, the shift duration, and the task(s) being observed. Some tasks are frequent and repetitive so require less time to capture, whereas others occur infrequently or over the course of a longer time period so require longer observation periods. Observers will unobtrusively shadow participants as they carry out their daily activities. The purpose of the observations is to obtain a detailed understanding of participants' typical tasks and responsibilities, as well as the procedures and equipment related to the MUP. The observations will also characterize problematic issues that are observed (e.g., not logging out of the automated dispensing cabinet system) or that participants describe to the observer (e.g., unwillingness of peers to witness wasting). Observations will capture the MUP for all medications, but with a focus on CS to identify safeguards and vulnerabilities specifically for these medications.

Observers will take free-form notes, collect artifacts of clinical practice (e.g., blank pre-printed forms), as well as take photographs of the environment, technology and supplies. The photographs will be used to recall or visualize process steps during the mapping process. Images will also be used to provide context when presenting and describing results. The free-form notes will capture step-by-step how participants complete tasks as well as contextual information, including the physical layout of the unit, the roles and shifts covered by staff, technologies used to document dispensing, and locations of medications on the unit. The observer will fully

transcribe their free-form notes into Word© and upload them onto a secure SharePoint© site hosted at the study team's home organization. Emerging findings will be confirmed with healthcare workers in the units.

Coding of observation data

Data collected during observations will be uploaded into MAXQDA© version 2018.1 data management and analysis software. One human factors specialist will code the observation data using codes for hospital units (intensive care unit, emergency department, and inpatient pharmacy), tasks, and vulnerabilities or safeguards. A second study team member will review the codes, and any discrepancies will be resolved through discussion. Coding of the observational data in MAXQDA© will create a dataset that is structured so that the study team can search and filter data related to specific MUP tasks, roles, technologies, or environments. These are important inputs for conducting the HFMEA, providing not only information on how tasks were performed and by whom but also contextual information for conducting the hazard analysis described below.

Healthcare Failure Mode and Effect Analysis (HFMEA)

Overview of HFMEA

Healthcare Failure Mode and Effect Analysis (HFMEA) is a prospective risk analysis that involves mapping detailed process flow diagrams and then systematically identifying and prioritizing vulnerabilities via a structured decision-making algorithm.[46] HFMEA was developed by the Department of Veterans Affairs National Centre for Patient Safety (NCPS) in 2002.[47] It been successfully applied to several healthcare processes, including the ordering and

administration of medications as well as the sterilization and use of surgical instruments.[48–52] HFMEA combines concepts and components from the Failure Mode and Effect Analysis (FMEA), Hazard Analysis and Critical Control Point, and root cause analysis.[47] FMEA was originally used in aviation, manufacturing, and nuclear industries to evaluate risk of products, and has been used in healthcare to conduct proactive risk analyses on high-risk technologies and processes.[53,54]

The HFMEA approach was developed to address criticisms of using FMEA in healthcare, particularly with respect to the use of a single risk priority number (RPN) to rank vulnerabilities.[55] The RPN in FMEA is calculated by multiplying scores from three ordinal scales: severity, probability and detectability. Multiplying these scores creates an RPN that is mathematically flawed, unstable (small changes in one score can lead to large changes in RPN), and masks important distinctions.[55–57]. For example, a failure mode with high detectability, high probability, but low severity would be prioritized the same as a failure mode with high detectability, low probability, but high severity despite having different risk implications.[55] Given that failure modes with the highest RPN would be considered as hazards with the highest priority, efforts may be misdirected based on a misleading RPN score. HFMEA addresses these concerns by prioritizing vulnerabilities using a decision tree analysis. The decision tree analysis considers not only severity and probability scores, but also assesses the criticality of the failures (i.e., single point weaknesses) and whether there are controls in place to prevent or detect these failures. The use of "yes" and "no" responses in the HFMEA decision tree to assess the criticality, presence of control measures, and detectability of the failure modes[46] is less subjective and more easily agreed upon than assigning scores.[58]

The HFMEA process includes five main steps.[47] After the study team defines the topic that will be analyzed and assembles a multidisciplinary team, information from the clinical observations will be used to map process flow diagrams for the management and use of medications in the clinical units. Next, we will identify potential methods of medication loss and evaluate their severity, risk and detectability, as well as identify potential areas where mitigation strategies can be implemented. Unique to our study is that the HFMEA will be conducted for the same processes at two sites, enabling us to find similarities and differences in processes, failure modes, and controls.

1. Define the topic

The first step is to define the HFMEA topic, including boundaries to limit its scope. Our HFMEA will examine the hospital MUP, including the procuring, storing, ordering, dispensing, preparing, administering and wasting of medications. The study team will limit the topic to specific units within the hospital (i.e., intensive care unit, inpatient pharmacy, and emergency department). Any hospital personnel role, technology, or object that directly or indirectly interacts with medications will be included. Processes that are external to the hospital unit or roles that are not affiliated with the hospital will be out of scope (e.g., administration of medications by paramedics, delivery of medications from distribution centre).

2. Assemble the team

The second step is to assemble a multidisciplinary team. The HFMEA team will be comprised of three human factors specialists, two pharmacists, one physician, two nurses, and two pharmacy technicians. The membership of the team ensures there is expertise in collecting and

analysing observational data and proactive risk analysis, as well as knowledge and experience working in the different hospital settings and performing tasks covering the breadth of the MUP. For particular steps of the HFMEA, team members will vary as a function of the unit being analysed (e.g., pharmacists will brainstorm failure modes in the pharmacy). The team will communicate over email as well as during in-person meetings. A minimum of five in-person meetings for each clinical unit will take place to cover the graphical description of the MUPs; identification and description of failure modes; assignment of severity and probability scores; decision tree analysis and identification of critical failure modes, causes, and controls; and actions and outcome measures. These meetings are embedded within the remaining steps described below.

3. Graphically describe the process

The third step is to develop process flow diagrams and number each task and subtask. Creating process flow diagrams is an important first step in identifying safety risks from different aspects of a work system (e.g., individual, technology, administration).[59] The HFMEA team will use the data collected during the clinical observations to graphically map the step-by-step MUPs from each clinical unit at each hospital site. Using direct observation of processes, as opposed to mapping processes according to how tasks are supposed to occur, will strengthen the validity of our results.[60] The maps will be created by retrieving data coded for specific units and tasks and translating the process steps into a visual process flow diagram using draw.io©. The mapping process will be completed collaboratively between observers and iteratively during the clinical observation period, so that gaps or steps requiring clarification can be gathered in the next observation session. If observers note differences in how participants perform the same

process, this variation will be discussed by the team and described in the process flow diagrams, because variations may suggest vulnerabilities in process. Figure 2 shows an example of the task and subtask figure that will be constructed from the process flow diagrams produced in this step of the HFMEA. The team will review the detailed process flow diagrams and one human factors specialist will transcribe each task (e.g., dispensing from automated dispensing cabinet) and subtask (e.g., logging into the automated dispensing cabinet, selecting the patient, selecting the desired medications) into Excel©.

4. Conduct a hazard analysis

The fourth step consists of four sub-steps: A) list and number all potential failure modes (ways a step within a subtask can fail to accomplish its intended purpose) and potential effects if a failure were to occur; B) score the severity and probability of potential failure modes; C) use a decision tree analysis to identify critical failure modes; D) list all causes of critical failure modes.

A) Two HFMEA team members will independently brainstorm failure modes and effects for each of the subtasks, and any discrepancies will be discussed. If a decision on whether or not to include a failure mode cannot be reached, a third member of the team will reconcile the discrepancy. Failure modes will be organized into a worksheet (Figure 3) to facilitate the recording of results.

B) Two HFMEA team members will independently score failure modes based on their severity and probability, as described by the NCPS (Table 2).[46] A hazard score is calculated by multiplying the severity and probability scores. The intra-class correlation (ICC) will be calculated for a subset of hazard scores to assess inter-rater reliability. Definitions of scale scores will be discussed and refined until an accepted

level of agreement is reached (ICC≥0.60). The severity and probability of the remaining failure modes will then be scored.

Table 2. Probability and severity scoring

Scale \ Score	1	2	3	4
Probability	Remote Unlikely to occur; may happen sometime in 5 to 30 years	Uncommon Possible to occur; may happen sometime in 2 to 5 years	Occasional Probably will occur; may happen several times in 1 to 2 years	Frequent Likely to occur immediately or within a short period; may happen several times a year
Severity *Patient outcome*	Minor Event No injury nor increased length of stay nor increased level of care	Moderate Event Increased length of stay or increased level of care for 1 or 2 patients	Major Event Permanent lessening of bodily functioning, disfigurement, surgical intervention required, increased length of stay for 3 or more patients	Catastrophic Event Death or major permanent loss of function or suicide
Staff outcome	First aid treatment only with no lost time or restricted duty injuries or illness	Medical expenses, lost time or restricted duty injuries or illness for 1 or 2 staff	Hospitalization of 1 or 2 staff, or 3 or more staff experiencing lost time or restricted duty injuries or illnesses	One death or hospitalization of 3 or more staff
Equipment or facility	Damages less than $10,000 without adverse patient outcome	Damages more than $10,000 but less than $100,000	Damages equal to or more than $100,000 but less than $250,000	Damages equal to or more than $250,000

Adapted from "The Basics of Healthcare Failure Mode & Effect Analysis" by the Department of Veterans Affairs National Center for Patient Safety (2014). Available from: https://www.patientsafety.va.gov/professionals/onthejob/hfmea.asp

C) The HFMEA team will use a decision tree to prioritize the failure modes (Figure 4). Failure modes with sufficient hazard scores or that are single point weaknesses (i.e., failure in this step will invariably result in an adverse event) are considered in the next step of the decision tree. If an effective control measure exists (e.g., storing medications in a locked drawer to prevent an individual from opening the drawer and removing medications from it) or the failure mode is so obvious and apparent that a

control measure is not warranted, then the failure mode does not proceed through the next steps of the HFMEA. All remaining failure modes are labelled as critical and considered in sub-step D. Figures 2 and 5 together provide an example of the anticipated outputs of the hazard analysis. Figure 2 shows which subtasks are associated with critical failure modes at each site using FM1, FM2, etc. as markers. When one site has a control in place to mitigate a critical failure mode identified in the other site, this is flagged with C1, C2, etc. Figure 5 provides a description of the corresponding critical failure mode and controls.

D) The HFMEA team will brainstorm the potential causes of the critical failure modes and record these in the worksheet. Completing the hazard analysis will produce a list of critical failure modes and their causes.

5. Develop action and outcome measures

The fifth step is to determine which failure mode causes can be eliminated or controlled and describe what actions could be used to accomplish this. This step also includes developing measures that can be used to test and analyse the success of a redesigned process. The HFMEA team will use the list of critical failure modes from the hazard analysis to describe each step in the MUP that increases the hospital's potential risk for medication loss, including those related to both the security and accounting of medications. The team will consider the causes listed for the failure modes and describe mechanisms or actions that can be implemented to prevent, detect, and trace incidents of medication loss. Finally, the team will suggest measures that could be used to assess successful implementation of these mechanisms and process improvements.

Patient and public involvement

Hospital personnel have supported this work by facilitating opportunities for observations and analysis of different aspects of the MUP in units that have high CS use and access. Healthcare providers and hospital staff will also be engaged during the HFMEA and will inform the dissemination strategy. Patients and public were not involved in the design of this study.

ETHICS AND DISSEMINATION

Ethics

This study has received province-wide Research Ethics Board (REB) approval via Clinical Trials Ontario Streamlined Research Review System, as well as site-specific approvals from each participating hospital under this framework.

Consent for observations is obtained for the healthcare worker who is being observed. When photographs are taken, no patients or healthcare workers will be photographed, and all person identifiers will be eliminated (e.g., patient name/ID will be covered). Hospitals that choose to participate will remain anonymous and will be described using general terms (e.g., a community hospital) in publications and presentations.

All signed consent forms, observation free-form notes, artifacts and photographs, and database records will be kept secure and confidential. Observational data will be associated with a participant number to reduce the risk of participant identification. All data reported outside of the study team will be in aggregate form, without reference to any specific participant.

The observers are only responsible for collecting data as part of the study and will not perform clinical duties (e.g., helping with tasks). However, in the unlikely event that observers

suspect an error is about to be made that could compromise patient safety, observers will intervene by asking the participant for clarification, as indicated in the REB.

Dissemination

The audience for our research includes front-line hospital staff and administrators, as well as professional, regulatory and accreditation organizations, patient safety and healthcare quality organizations, and equipment and drug manufacturers. The findings from our study will be used by organizations to inform recommendations, guidance and standards.

The results will be shared with hospitals in Ontario and across Canada through collaboration with the Institute for Safe Medication Practices Canada. Findings from this study will be presented at conferences and meetings, as well as in manuscripts submitted for publication. This study will be among the first to proactively capture empirical evidence of how current controls for MUPs in Ontario hospitals may be improved to protect against medication losses.

LIMITATIONS

It is challenging for observations to capture how participants actually conduct tasks, because participants may alter their behaviour due to the presence of the study team on the unit (i.e., the Hawthorne Effect[61]). We will mitigate this effect by reassuring participants that results will not be used to evaluate individual performance but will only be used to describe an overall process. To minimize disruption and further normalize our presence, we will be as unobtrusive as possible and conduct several hours of observations at multiple sites with multiple participants.

The validity of the results is strengthened by accurate note-taking by the observers. However, it is possible that some subtasks or contextual features of the environment will be missed. To limit the extent of missing information, observers will receive an orientation to each unit before beginning observations, will ask clarifying questions while observing, and will fully transcribe field notes. Two observers will capture MUPs in each unit, enabling corroboration and identification of tasks requiring further observation. Consistent study team members will observe, transcribe and analyze the data.

The subjective nature of identifying potential failure modes and scoring the probability and severity of their effects may compromise the reliability of the results.[62] But, by using data collected through observations to conduct the HFMEA, the subjectivity of the hazard analysis is lessened by basing the work on observed behaviours as opposed to perceived actions based on accepted practices.[58,63,64] To further limit threats to reliability, brainstorming failure modes, scoring probability and severity, and completing the decision tree will be conducted independently by two consistent members on the HFMEA team, with a third member reconciling differences when required.

CONCLUSION

It is expected that the clinical observations and HFMEA will lead to an understanding of the current workflows and failure modes affecting the MUPs in one community and one academic hospital. Results of this analysis will allow for a comparison of workflows, failure modes, and controls between hospitals and as a function of clinical area (e.g., emergency department versus intensive care unit). Identification of critical failure modes and controls will demonstrate where vulnerabilities exist for diversion or unintentional loss and how they can be

mitigated, including those related to the physical security as well as the documentation and accounting of CS.

REQUIRED STATEMENTS

Author Contributions:

PT, MF, MD, DT, and MH were involved in the conceptualization of the study. MD was responsible for drafting the protocol manuscript. PT, MF, DT, and MH reviewed and revised the manuscript for intellectual content. All authors reviewed and approved the final version of the manuscript.

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Competing Interests Statement:

MD, MF, and PT have received honoraria from BD Canada Inc. for presenting at BD sponsored events.

LEGEND OF TABLES AND FIGURES

Table 1. Description of clinical observation sites and medication use processes

Table 2. Probability and severity scoring

Figure 1. Study design. Integration of clinical observations and Healthcare Failure Mode and Effect Analysis (HFMEA).

Figure 2. Example task and subtask figure for the distribution of medications from the inpatient pharmacy to the clinical unit. The first level of the figure is the pharmacy process, the second level is the flow diagram of tasks, and the third level is the numbered subtasks that occur within each task. Subtasks are described separately for the two hospital sites. FM1, FM2, etc. indicate the subtasks where critical failure modes were identified. C1, C2, etc. indicate the subtasks that act as controls at one site for critical failure modes identified at the other site. Numbering of critical failure modes and controls correspond to the descriptions in Figure 5. ADC, automated dispensing cabinet; CS, controlled substances

Figure 3. Example of Healthcare Failure Mode and Effect (HFMEA) worksheet. CS, Controlled substances; ED, Emergency department; ICU, Intensive care unit; Pharm, Inpatient pharmacy

Figure 4. Decision tree analysis. Used to conduct step 4C of the Healthcare Failure Mode and Effect Analysis. Adapted from "The Basics of Healthcare Failure Mode & Effect Analysis" by

the Department of Veterans Affairs National Center for Patient Safety (2014). Available from: https://www.patientsafety.va.gov/professionals/onthejob/hfmea.asp

Figure 5. Example results table of critical failure modes and controls for the distribution of medications from the inpatient pharmacy to the clinical unit. The table describes the critical failure modes and controls identified in step 4 of the Healthcare Failure Mode and Effect Analysis. Numbering of critical failure modes and controls correspond to the markers in Figure 2. "X" indicates the hospital sites where the critical failure mode was identified. "C" indicates the site where a control was identified for a critical failure mode at the other site. Numbers in square brackets correspond to the numbered subtasks in Figure 2. CS, controlled substance

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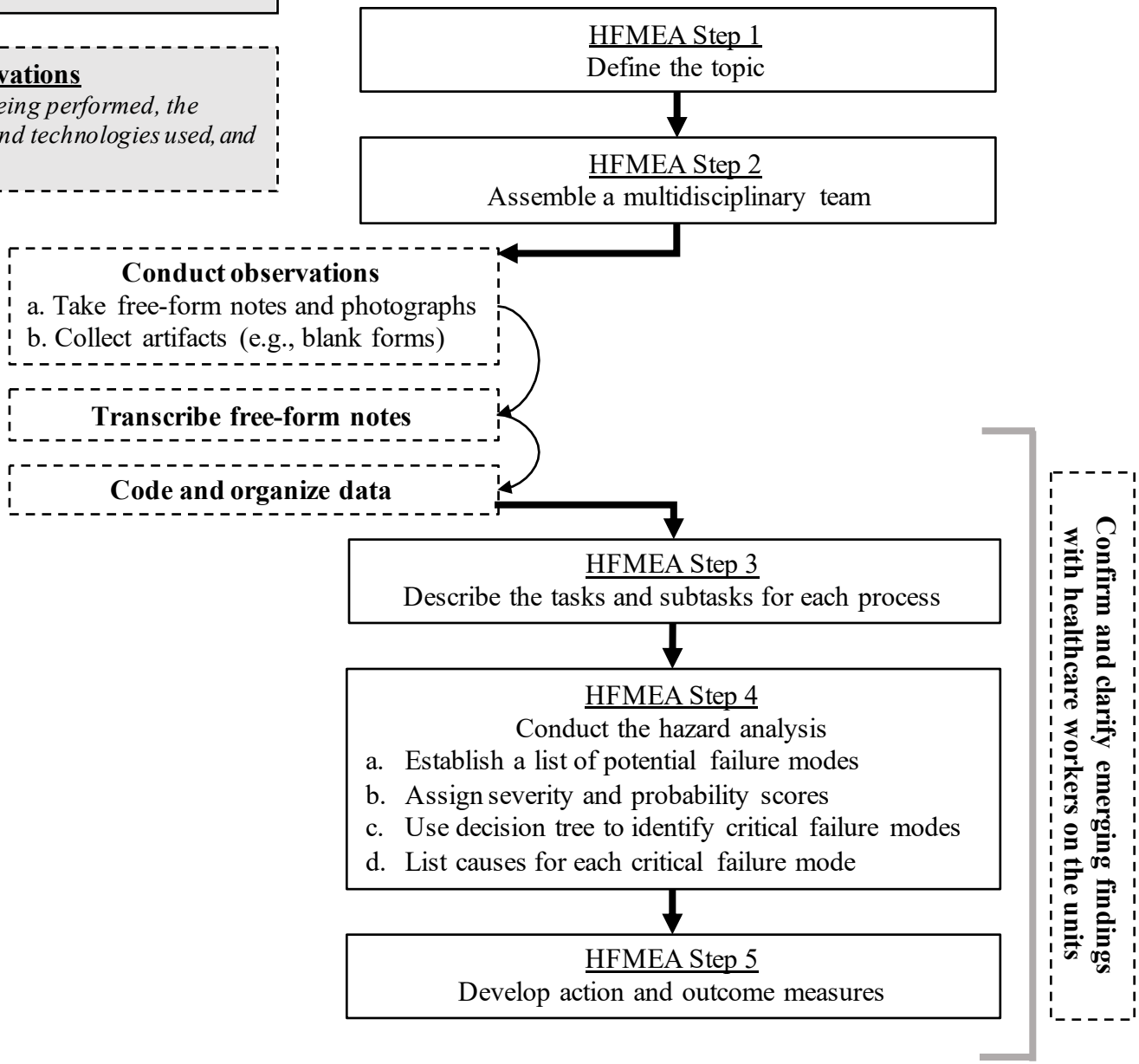
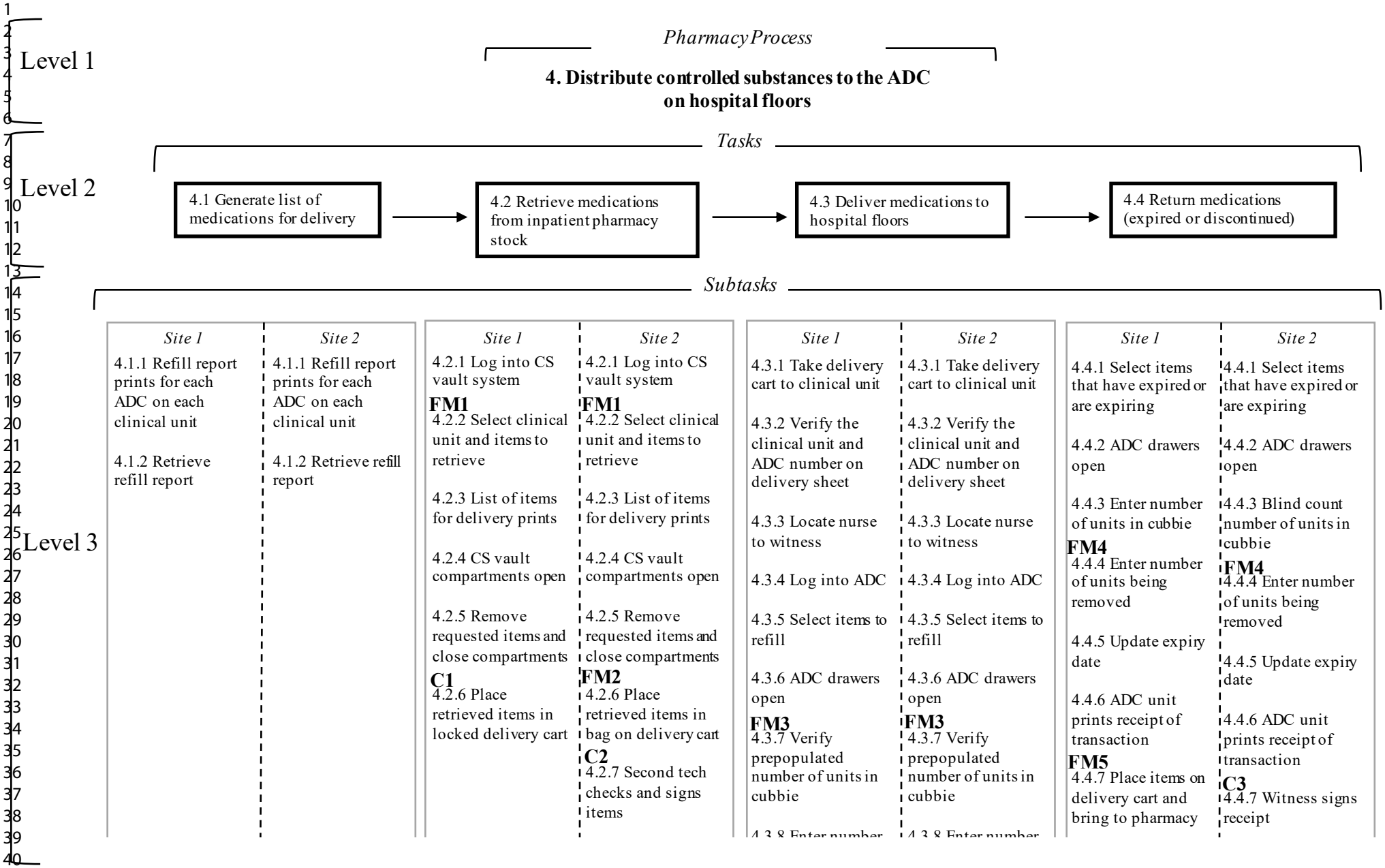
Steps for Healthcare Failure Mode and Effect Analysis

Map process flow diagrams for the MUPs, identify vulnerabilities for diversion, and suggest areas where mitigation strategies can be implemented

Steps for Clinical Observations

Develop detailed descriptions of the MUPs being performed, the people/team performing the tasks, the tools and technologies used, and the environment where the MUPs take place





HFMEA Step 3					HFMEA Step 4							HFMEA Step 5	
Medication Use Process					Failure Mode and Effect			Setting	Scoring		Decision Tree	Action	
#	Task	Sub-task	Related to CS only? (Y/N)	Role involved in the task	Potential Failure Mode	Potential Effect(s)	Potential Cause(s)	Occurs in ED, ICU and/or Pharm	Probability (1-4)	Severity (1-4)	Proceed or Stop?	Eliminate, Control or Accept	Action
1.1.1													
1.1.2													
….													
….													

E.g., Stocking the automated dispensing cabinet

E.g., Confirm number of units in current stock, verify count with witness

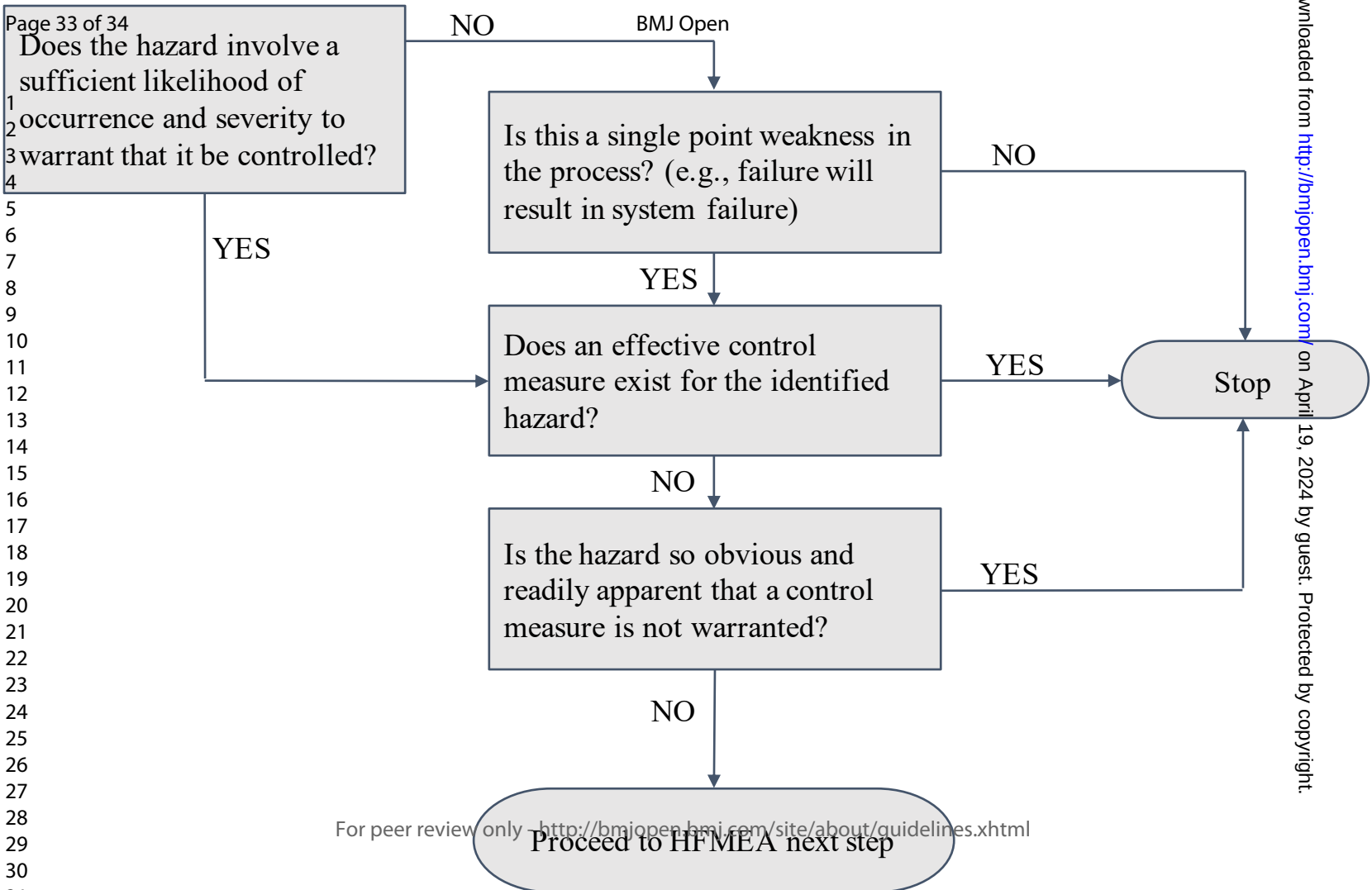
E.g., Pharmacy technician, nurse

E.g., Accept prepopulated count of stocked units without correctly counting the number of items

E.g., Discrepant count between documented number of stocked units and number

E.g., Confirmation bias, witness rushing technician to complete count

E.g., Program automated dispensing cabinet to require blind count of current stock



Pharmacy Process: 4. Distribute controlled substances to the ADC on hospital floors	Site 1 [subtask]	Site 2 [subtask]
FM1. Technician programs the CS vault to retrieve a greater number of unit doses than indicated based on minimum and maximum levels for each automated dispensing cabinet, creating an opportunity to gain access to a greater quantity of controlled substance	X [4.2.2]	X [4.2.2]
FM2. Items placed on delivery cart are left unlocked and observed, creating an opportunity to for theft or tampering ***C1.*** *Site 1 places the retrieved medications in a locked cart, which limits access to the medications once outside of the CS vault and acts as a control for this failure mode*	C [4.2.6]	X [4.2.6]
FM3. Number of units in cubbie are counted/verified incorrectly, creating an opportunity to introduce a discrepancy	X [4.3.7]	X [4.3.7]

Correction: *Clinical observations and a ealthcare ailure ode and ffect nalysis to identify vulnerabilities in the security and accounting of medications in Ontario hospitals: a study protocol*

de Vries M, Fan M, Tscheng D, *et al*. Clinical observations and a ealthcare ailure ode and ffect nalysis to identify vulnerabilities in the security and accounting of medications in Ontario hospitals: a study protocol. *BMJ Open* 2019;9:e027629. doi: 10.1136/bmjopen-2018-027629.

This article was previously published with an error in article title.
The correct title is **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**:e027629corr1. doi:10.1136/bmjopen-2018-027629corr1