NOTE

Controlled substance diversion in health systems: A failure modes and effects analysis for prevention

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Purpose. The purpose of this study was to demonstrate the utility of failure modes and effects analysis (FMEA) for systematically identifying potential sources of controlled substance diversion and developing solutions in an academic health system.

Methods. The FMEA was conducted by an 18-member cross-functional team from the department of pharmacy. The team developed scoring criteria specifically for controlled substance diversion, outlined the controlled substance processes from procurement to administration or disposal, and identified ways in which each step of the medication supply process might fail (failure modes) and result in diversion of controlled substances. Failure modes with a vulnerability score of 48 or 64 were considered highest risk and were immediately intervened on by the FMEA team.

Results. The FMEA outlined a total of 10 major steps and 30 substeps in the controlled substance supply process. From this, 103 potential failure modes were identified, with 24 modes (23%) receiving a vulnerability score of 48 or 64. Development of specific reports addressed 15 failure modes, while 9 involved pharmacy workflow alterations. Notable reports included controlled substance activity under temporary patients and discrepancy trends by user, medication, and patient care area. Notable workflow alterations included expanded use of cameras in high-risk areas and additional verification checks.

Conclusion. FMEA allowed for systematic identification of controlled substance diversion opportunities, prioritization by level of vulnerability, and the development of targeted strategies to reduce risk of diversion.

Keywords: analgesics, healthcare failure mode and effect analysis, medication systems, opioid, pharmaceutical services, prescription drug diversion

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In 2014, 52 people died each day on average as a result of prescription opioid overdose.[1] Further, the estimated total economic burden of opioid abuse for the United States was $78.5 billion in 2013.[2] Prescription drug abuse is an epidemic in the United States that has resulted in part from the widespread availability of controlled substances.[3] Controlled substances are also obtained through diversion, defined as removal of Drug Enforcement Administration–scheduled medications from within the lawful processes of a hospital or health system to an unlawful channel of distribution or use.[4]

Diversion in a health system is suspected to occur through burglary or employee theft, primarily in settings with loose safeguards or minimal oversight.[5-8] The extent of controlled substance diversion in health systems has not been empirically documented, and while preventive steps have been suggested, little guidance existed before October 2016.[5,9-14] Additionally, the literature does not thoroughly describe a process for identification and evaluation of high-risk opportunities for diversion.

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Without this knowledge, diversion in health systems has the potential to occur unnoticed over an extended period of time. Recent high-profile occurrences provide anecdotal evidence of this reality.[15,16] The consequences of a large-scale, high-profile controlled substance diversion may present a major problem for health systems and include financial penalties, unfavorable public perception of the health system's ability to provide care, and additional regulatory requirements to ensure that medications are used appropriately in the future.[5,14] Systematic identification of these high-risk controlled substance diversion opportunities offers the opportunity to minimize the occurrence of diversion and the resulting negative outcomes.

Historically, process improvement tools have been applied to health systems as a means of standardizing quality and ensuring necessary safeguards are in place.[17-19] In particular, failure modes and effects analysis (FMEA) is a tool that provides stepwise identification and vulnerability assessment of potential failures for a given process.[20] With regard to the controlled substance supply process, the FMEA approach is a potentially useful way for health systems to identify and prevent opportunities for diversion. This is particularly true given the large number of potential sources of diversion and recent recommendations to prevent them. Use of FMEA may help organizations to prioritize which potential sources of diversion and accompanying solutions are most immediately important.[11]

The two primary objectives of this study were to identify potential sources of controlled substance diversion in health systems and to propose viable strategies to reduce the probability of diversion in a health system by evaluating the controlled substance supply process with a FMEA. In accomplishing the primary objectives, our secondary objective was to provide an example of how pharmacy management and others might apply the FMEA approach to address controlled substance diversion in their own health systems.

KEY POINTS

- Systematic approaches are needed to identify potential sources of controlled substance diversion and develop solutions.
- Failure modes and effects analysis (FMEA) was tested as an approach to address that need and identified 103 steps where the medication supply process could result in diversion, resulting in the development of several reports and workflow alterations.
- FMEA allowed for systematic identification of controlled substance diversion opportunities, prioritization by level of vulnerability, and the development of targeted strategies to reduce risk of controlled substance diversion.

Methods

This quality improvement study was conducted at Lifespan, a large academic health system with 4 hospitals and a total of 1,242 inpatient beds. In fiscal year 2016, the largest hospital within the health system served approximately 37,000 inpatients, 10,000 inpatient surgical patients, and 154,000 emergency department patients.

Each hospital uses an electronic vault (Controlled Substance Management, Omnicell, Mountain View, CA), and, with limited exceptions, all controlled substances stored outside of the pharmacy department are maintained in electronically monitored automated dispensing cabinets. Lifespan has a total of 195 cabinets and 67 anesthesia stations. Controlled substances dispensed to patient care areas or for pharmacy compounding are removed from the pharmacy electronic vault by a designated pharmacist each shift. The hospital uses the electronic health record (Epic, Verona, WI) for medication prescribing, verification, dispensing, administration, and billing. Once a medication order is verified by a pharmacist, medications are removed from a unit-specific automated dispensing cabinet by a nurse or anesthesiologist in the operating room setting and administered. Any unusable remaining controlled substances will need to be rendered nonretrievable and witnessed by another licensed healthcare provider, with appropriate documentation. In the central pharmacy, a pharmacist will segregate the excess or expired controlled substances in a safe within a controlled substance vault. Later, these controlled substances will be reconciled at the time of transfer to a reverse distributor.

Though there are many adaptations of FMEA, it is generally defined as a technique to identify and minimize potential failures, problems, and errors in a given process or system.[20] Applied to the controlled substance supply process, a failure mode represents an opportunity for drug diversion, and implementation of FMEA will result in development of actions to limit the occurrence of diversion.

The FMEA was conducted by an 18-member cross-functional team from the Department of Pharmacy with in-depth knowledge of the controlled substance supply process. The team identified various ways in which each process step of the medication supply process might fail and result in diversion of controlled substances. The scope of the medication supply process included inpatient units, outpatient clinics, research areas, operating rooms, and emergency department patient care areas. Controlled substance processes were assessed from procurement to administration or disposal. Each failure mode was assigned a rating for severity and another for probability of occurrence. These ratings were then multiplied together to determine the hazard score

Table 1. Major Steps and Substeps Identified by FMEA[a]

Major Step	Substep
1: Controlled substance ordering	1A: CS pharmacist compares stock with recommended par levels to compile order
	1B: Purchasing technician/pharmacist electronically prepares order
	1C: Order is signed by PIC/PoA and placed
2: Order is received	2A: Technician/pharmacist receives cloaked order from wholesaler representative
	2B: Technician brings order to the pharmacy along designated path
3: Order is put away	3A: Totes opened and controls segregated
	3B: CS pharmacist compares 222 form/invoice with received products
	3C: Logged into controlled substance management system
	3D: Second pharmacist compares received from vendor report with 222 form/invoice
4: Medication is distributed to ADM	4A: Load request, stock-out request, or normal re-stock prompt ADM refill
	4B: CS pharmacist removes meds from safe and signs paperwork
	4C: Technician/pharmacist fill ADM
5: Pharmacy manages ADM inventory	5A: Technician/pharmacist removes using modify/ expire function from ADM
	5B: Med brought to CS pharmacist in pharmacy
	5C: CS pharmacist returns med to safe or wastes if expired
6: Pharmacy prepares order for non-stocked controls/non-ADM areas	6A: Order is sent to pharmacy outside of ADM
	6B: CS pharmacist fills request using DEA usage form
	6C: Pharmacist and licensed requester sign usage form
	6D: Licensed requester records patients/quantity
	6E: Completed usage form returned to pharmacy
7: User removes meds from ADM	7A: User enters Bio ID or password
	7B: Select patient's name
	7C: User removes meds under existing order or override
8: Medication is administered	8: RN scans medication, scans patient ID, then administers, and documents
9: Unused medication is returned or damaged	9A: Unused intact medication is returned to ADM and documented
	9B: Unusable medication is wasted with a witness and both document waste in ADM
10: Inventory confirmation	10A: Compounding (sterile and non-sterile)
	10B: Kits
	10C: Physical counts
	10D: Management of expired drugs

[a]The major steps were key components in the controlled substance supply process and were assigned a numerical value reflective of their chronological order. Each major step had several substeps that further detailed the flow of controlled substances through the health system. Substeps were assigned an alphanumeric value that may or may not have corresponded to their chronological order within the major step.
FMEA = failure modes and effects analysis, CS = controlled substance, PIC = pharmacist-in-charge, PoA = power of attorney, ADM = automated dispensing machine, DEA = Drug Enforcement Administration, Bio ID = Bio identification system, RN = registered nurse.

yielding values ranging between 1 as a minimum and 16 as a maximum, with a higher score reflecting a greater opportunity for diversion. Failure modes with a hazard score greater than or equal to 12 were also assigned a control value to determine the likelihood that a potential failure would be detected. From this, a vulnerability score was calculated by multiplying the hazard score and control value. Vulnerability scores ranged from 12 to 64, with 64 indicating the highest risk of failure. Failure modes with a vulnerability score of 48 or 64 were considered highest risk and the FMEA team immediately intervened. Assigning of values in an FMEA is an arbitrary process that is a limitation of the methodology and may vary between institutions.

Results

The team identified 10 major steps and 30 substeps (Table 1) in the controlled substance supply process. From this, 103 potential failure modes were identified, with 24 modes receiving a high vulnerability score of 48 or 64 (Table 2).

Development of specific reports addressed 15 failure modes, while 9 involved pharmacy workflow alterations. In some cases, one of the implemented measures simultaneously addressed multiple failure modes. Workflow actions included optimizing automated dispensing cabinet settings; installation of additional cameras in the pharmacy vault, nonsterile preparation area, and cleanroom; product imprint verification; reconciliation of expired medications with reverse distributor; installation of a limited-access safe for expired medications; and additional verification requirements.

Specific reports that emanated from the FMEA included a reconciliation report covering the previous 2 shifts; an extended reconciliation report for management; discrepancy trends by medication, user, and patient care areas; overall usage by drug, quantity, and user; drug movement to compare purchases against usage; controlled substance activity under temporary patients; reconciliation of medications given to reverse distributor; override transactions; user/witness team report; and waste transaction trends by user and witness. Pharmacy operations and management review reports on a daily, weekly, or monthly basis depending on the report type. Most reports were designed to generate automatically.

Discussion

The systematic and detailed analysis provided through the FMEA allowed for the development of targeted surveillance reports, such as controlled substance activity under temporary patients and discrepancy trends by medication, user, and patient care area. The former was previously unconsidered, and the latter was previously reviewed on a case-by-case basis rather than with the intention of identifying trends and outliers. Many of the workflow actions taken were integrated into the pharmacy department's daily operations. The most extensive modifications required were the expansion of location-specific cameras and the addition of a limited-access safe for expired controlled substances. Each of these actions were deemed necessary because, in the aforementioned locations, an individual would potentially have access to large amounts of controlled substances with insufficient barriers to diversion. It is worth noting that to enhance the cameras' value in detecting diversion, they must be used in conjunction with review of surveillance reports as part of an auditing process. The vulnerability assessment component of the FMEA allowed for stratification based on risk, as seen with the immediate action taken for 24 high-risk failure modes from the 103 identified. While solutions were eventually developed for all 103 potential failure modes, time and resources were targeted to address those modes at greatest risk.

Although the controlled substance supply process is conceptually similar between health systems, the results of an FMEA may vary between institutions.[10,21] Differences can result from institution-specific details of each process step that influence failure mode frequency and severity. The level of institutional safeguards already in place will ultimately determine the vulnerability score for each failure mode, resulting in a different distribution of high-risk failure modes. Additionally, different versions of the FMEA may use different grading values or criteria for severity, probability, and control.

Few authoritative guidelines on diversion prevention measures existed prior to October 2016, when ASHP published guidelines designed to help healthcare organizations devise and implement strategies to prevent the diversion of controlled substances.[11] In 2007, an article series described a formal process for investigating and addressing suspected diversion, along with preventive strategies.[9,12,13] Our study builds on the existing literature by demonstrating that FMEA is a tool that provides a stepwise approach to identifying institution-specific failure modes and preferentially implementing preventive measures through risk-based stratification.[22-26] Previously suggested preventive interventions, especially those with supporting evidence and data, can then be referenced and applied to address each health system–specific failure mode.[27]

Our study had 2 main limitations. First, limited baseline data on controlled substance diversion in our health system precluded estimating the impact of implementing FMEA-identified solutions. It is important to note, however, that controlled substance diversion is very challenging to measure. Outcomes such as medication overrides and usage per department or individual could potentially serve as proxies, but little validation work is available to support this approach. Second, the scope of the FMEA team in our study was limited to the pharmacy department and included no other departments from the hospital. While individuals with diverse and extensive knowledge of the controlled substance supply process were included, increased benefit may have been derived from involvement of physicians, nursing staff, and

Table 2. Highest-Risk Failure Modes[a]

MS	SS	Failure Mode	P	S	H	C	V	Action Taken
4	A	Pharmacist can add manual load request	4	4	16	4	64	Extended reconciliation report
4	A	Pharmacist can change requested quantity	4	4	16	4	64	Extended reconciliation report
4	B	Could remove CS that was not requested	4	4	16	4	64	Limit modify bin functions
4	B	Remove more CS than needed	4	4	16	4	64	Pharmacy discrepancy report
4	B	Resolved self-created discrepancy	4	4	16	4	64	Daily review of open/closed discrepancies
6	B	Fill without order or request	4	4	16	4	64	Usage form tracking report
6	C	Forge signature of requester	4	4	16	4	64	Usage form tracking report
7	B	Create a fabricated temporary patient	4	4	16	4	64	Temporary patient CII-V transaction report
7	B	Remove under generic name or generic trauma patient	4	4	16	4	64	Temporary patient CII-V transaction report
9	B	Witness did not directly observe waste	4	4	16	4	64	User/witness team report and waste transaction reports
10	A	Tampering with final product before returning to vault	4	4	16	4	64	Product imprint verification, camera surveillance
10	C	Tamper with or replace CS	4	4	16	4	64	Product imprint verification, camera surveillance
10	D	Potentially inaccurate inventory of expired meds in CSM	4	4	16	4	64	Depository safe with limited access
10	D	No reconciliation for offsite distributor	4	4	16	4	64	Reconciliation process implemented
4	C	Tamper with ADM cassette	4	4	16	3	48	Limit new hire exposure
5	C	Pharmacist does not return	4	4	16	3	48	Extended reconciliation report
5	C	Document CS as waste but does not waste	4	4	16	3	48	Waste transaction reports
5	C	Document CS as expired but not returned to vault	4	4	16	3	48	Drugs surrendered for disposal report, reconciliation process implemented
7	A	Manager could create false temporary access	4	4	16	3	48	Temporary user name created with controlled substance transactions report
10	A	Request more CS than needed	4	4	16	3	48	Additional verification checks
10	A	Tampering with product prior to compounding	4	4	16	3	48	Expansion of location-specific cameras
10	A	Tampering with product during compounding	4	4	16	3	48	Expansion of location-specific cameras
10	A	Tampering with waste	4	4	16	3	48	Expansion of location-specific cameras
10	C	Can fabricate a discrepancy	4	4	16	3	48	Pharmacy discrepancy report

[a]Failure modes with a vulnerability score of 48 or 64. These 24 failure modes received preferential consideration as they were the highest-risk opportunities for diversion. MS = major step, SS = substep, S = severity, P = probability, H = hazard, C = control, V = vulnerability, CS = controlled substances, CSM = controlled substance management, ADM = automated dispensing machine.

other individuals. Similarly, workflow strategies against diversion primarily addressed pharmacy department operations and did not comprehensively extend to other departments or services, though reports are routinely disseminated to them. Many healthcare providers use controlled substances in daily operations, so additional opportunities for diversion could have been identified by inclusion of other providers in the deliberation process.

In summary, FMEA is a quality improvement tool that can be easily implemented in health systems to help address controlled substance diversion from within the health system. Many of the high vulnerability failure modes identified would be applicable to other hospital systems. Some examples include inappropriate removal of more controlled substances than needed, witnesses not observing waste, tampering with controlled substances, and creation of fabricated temporary patients. Many of these can be prevented or identified using specific reports, such as controlled substance usage by temporary patients and employee-level and patient care area–level discrepancies, while others may require the use of cameras for closer monitoring. The FMEA proved to have greatest use in the creation of specific reports, allowing for existing data to be leveraged and provide comprehensive monitoring against diversion.

With the reasonable time requirement for implementation and highly actionable output of this quality improvement tool, health systems can greatly enhance efforts in combating controlled substance diversion by adopting the FMEA approach. While reducing diversion in the health system is beneficial from a legal standpoint, there is a much larger benefit to society when the consequences of prescription drug and other substance abuse are considered. Reducing hospital-based diversion keeps controlled substances within the confines of the law and helps combat the prescription drug epidemic plaguing the United States.

Conclusion

FMEA allowed for systematic identification of controlled substance diversion opportunities, prioritization by level of vulnerability, and the development of targeted strategies to reduce risk of diversion.

Disclosures

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