Wasted Efforts: Engaging Key Stakeholders to Optimize Health System Drug Disposal and Prevent Diversion

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View faculty bios at ashpadvantage.com/preventdiversion

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The following persons in control of this activity's content have relevant financial relationships:

John Hertig: Fresenius Kabi, grant recipient
Ryan Haumschild: Viatris, advisory committee

All other persons in control of content do not have any relevant financial relationships with an ineligible company.

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Learning Objectives

- Identify practices that support the safe use of intravenous (IV) products in the inpatient setting, including the operating room and procedural areas.
- Describe the role of each member of the interprofessional team as it relates to cost-effective controlled substance management.
- Apply strategies to communicate with stakeholders how healthcare disciplines (e.g., nurses, physicians) might view waste-reduction and diversion prevention initiatives.
- Identify opportunities to facilitate aligning controlled substance product availability and clinical practice.

Practices That Support the Safe Use of Intravenous Products in the Inpatient Setting

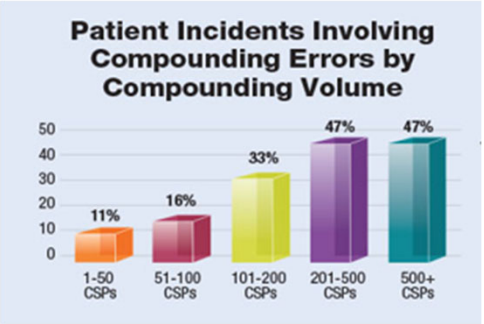
John B. Hertig, Pharm.D., M.S., CPPS, FASHP

Examples of IV Drug Delivery Systems

Delivery System	Examples
Manufacturer ready-to-use	Medications from the original manufacturer
Outsourced ready-to-use	Outsourced medications from companies registered with FDA as 503b "registered outsourcing facilities"
Point-of-care activated	Small volume parenteral bag with drug vial adapter (e.x. Mini-bag Plus, ADD-Vantage™ products)
Pharmacy compounded	Compounding medications in the pharmacy department
Non-pharmacy compounded at point-of-care	Compounding medications on nursing units
Ready-to-administer	Ready-to-use prefilled syringes (Simplist® prefilled syringes, CARPUJECT ™ Syringe System)

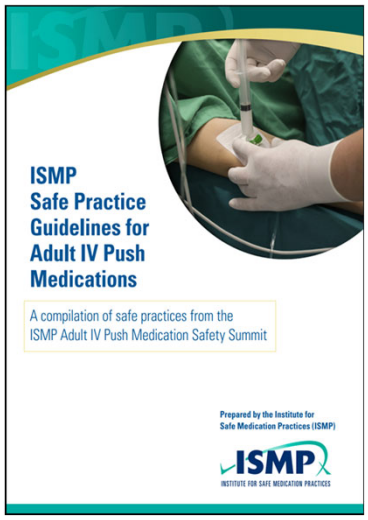
Sterile Compounding Errors and Harm

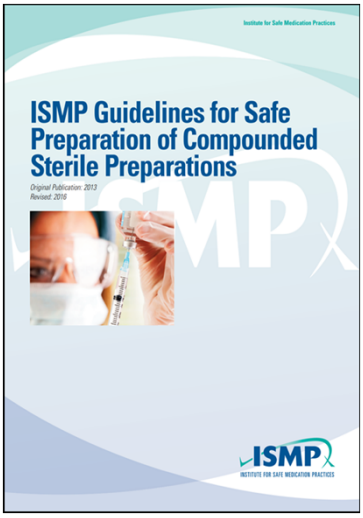
- Significant patient harm related to sterile compounding continues to occur in the United States and globally
- Data submitted to the Institute for Safe Medication Practices (ISMP) National Medication Errors Reporting Program (MERP) have repeatedly shown that manual inspection of IV admixture ingredients is inadequate for preventing preparation and dispensing errors



CSPs: Compounded Sterile Preparations

10th Annual National Survey State of Pharmacy Compounding 2017. *Pharmacy Purchasing & Products.* 2017; s4-52. https://www.pppmag.com/digitalmag/Main.php?MagNo=185&PageNo=1#page/1.





ISMP Safe Practice Guidelines for Adult IV Push Medications. 2015. https://www.ismp.org/sites/default/files/attachments/2017-11/ISMP97-Guidelines-071415-3.%20FINAL.pdf.

ISMP Guidelines for Safe Preparation of Compounded Sterile Preparations. 2016. https://www.ismp.org/sites/default/files/attachments/2017-11/Guidelines%20for%20Safe%20Preparation%20of%20Compounded%20Sterile%20Preperations_%20revised%202016.pdf.

ISMP Surveys on IV Push Medication Practices

2010
- **Survey: Impact of the economic crisis/shortages on medication safety**
  - Increase in nurses preparing or manipulating parenteral medications on the clinical unit

2012
- **Survey: Practices when using CARPUJECT prefilled medication syringes**
  - Withdrawing medication from prefilled syringe cartridges

2014
- **Survey: IV push practices**
  - Unnecessary dilution of dispensed ready-to-administer medications
  - Inappropriate use of prefilled saline flush syringes for dilution

2018
- **Survey: IV push practices**
  - Follow up to understand current practices associated with IV push medications
  - Determine if ongoing drug shortages and teaching strategies around this critical skill have impacted current practices

Survey shows recession has weakened patient safety net. *ISMP Medication Safety Alert!* 2010;15(1):1-4. https://www.ismp.org/resources/survey-shows-recession-has-weakened-patient-safety-net.

Some IV medications are diluted unnecessarily in patient care areas, creating undue risk. *ISMP Medication Safety Alert!* 2012;17(16):1-3. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5521294/.

Part I: Survey results show unsafe practices persist with IV push medications. *ISMP Medication Safety Alert!* 2018; 23(22):1-5. https://www.ismp.org/resources/part-i-survey-results-show-unsafe-practices-persist-iv-push-medications#:~:text=Overall%2C%2084%25%20of%20participants%20reported,diluted%20certain%20IV%20push%20medications.

First Consensus Development Conference - 1999

- Evaluated the relative safety of (non-electronic) drug delivery systems available at that time
- Decision-analysis method ranked 6 systems
  - Safety, cost, simplicity-of-use, and training required
- Highest scored: **manufacturer-prepared**, point-of-care activated, and pharmacy-based admixture systems
- The requirement for a combination of systems was discussed
  - Lack of availability of highly-rated systems

Schneider PJ. *Hosp Pharm*. 1999; 34(9):1044-56.

Second Consensus Development Conference – 2008

- Ranked 5 systems, noting few major developments in availability of systems
  - Applicability, ease-of-use, regulatory compliance, cost, safety, and resources required
- **Manufacturer-prepared** ranked highest again
- Panel noted the complexity of IV medication delivery had increased
  - No single system meets all needs and situations

Sanborn MD, Moody ML, Harder KA et al. *Am J Health Syst Pharm*. 2009; 66: 185-92.

IV Drug Delivery Since 2008…

- Regulatory and standards changes
  - Continued revisions to USP chapters <797> and <800>
  - Updates to National Patient Safety Goals
  - Passage of the 2013 Drug Quality and Security Act
  - Standardize for Safety
- Development and expansion of technology
  - IV workflow, interoperability, and automation
  - Robotics
- Clinical challenges
  - Drug shortages
  - Pricing and access
  - Pandemic-related (e.g., staffing)

Rodriguez R. *Hosp Pharm*. 2018; 53:408-14.

Comparing Practices Over Time

Table 2. Results from Preconference Survey Statements Specific to the 2018 Conference

Statement	No. (%) Who Agree in 2018 (*n* = 31)
My hospital has experienced a disruption of supply from manufacturers or outsourced (503B) compounding entities.	30 (97)
My hospital has a proactive system in place to identify and mitigate diversion of i.v. products.	11 (35)
My hospital uses an automated i.v. workflow management system to i[illegible]e safety and efficiency of the medication use process.	11 (35)
My institution consistently uses electronic health record operability to interfa[illegible] tween the i.v. pump and the electronic health record.	6 (19)
The majority of US hospitals have a complete understanding of the various facto[illegible] that contribute to the cost-effectiveness of delivering safe i.v. admixtures to pati[illegible] (i.e., product and staffing waste).	0 (0)

Gabay M, Hertig JB, Degnan D, Burger M, Yaniv A, Mclaughlin M, Lynn Moody M. *Am J Health Syst Pharm*. 2020; 77:215-20. https://pubmed.ncbi.nlm.nih.gov/31811297/.

Key Survey Observations

- Respondents suggest that IV admixture use is safer than 5 years ago.
  - 90% agree, improving from 76% in 2008
- 45% agree that outsourcing IV admixtures is cost-effective (59% in 2008)
  - No respondents (0%) had a complete understanding of factors that contribute to cost-effectiveness.
- 97% of respondents experienced a supply disruption.
  - 81% experienced a patient safety event related to a disruption
- Approximately 35% of respondents have a proactive diversion system to identify and mitigate risk.

Gabay M, Hertig JB, Degnan D, Burger M, Yaniv A, Mclaughlin M, Lynn Moody M. *Am J Health Syst Pharm.* 2020; 77:215-20. https://pubmed.ncbi.nlm.nih.gov/31811297/.

Drug Diversion

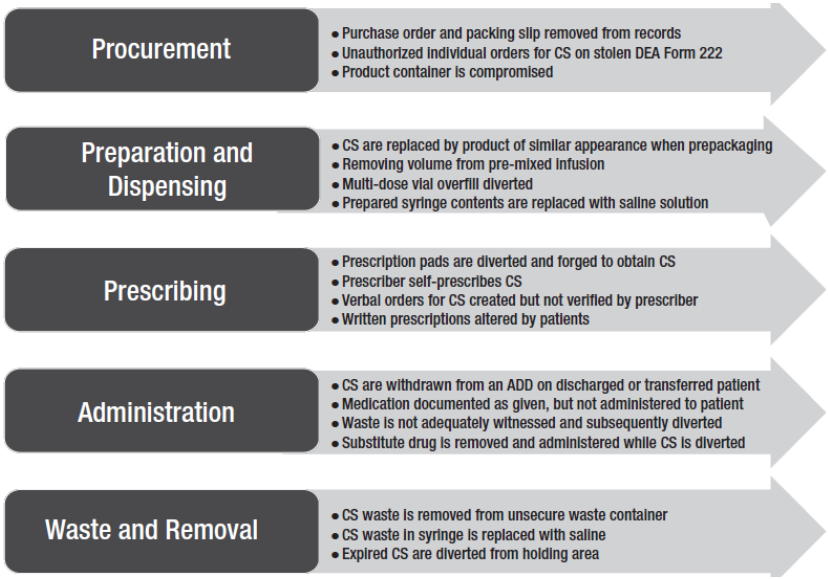
- Occupational hazard for healthcare workers (e.g., anesthesia, nursing, pharmacy)
  - High-risk setting/stress, easy access, self-medicating, parenteral skills, curiosity/familiarity/knowledge
- Risk: legal, financial, and reputational
- Impact -"multi-victim"
  - Provider, patient, staff, institution
- Focus: prevention and detection

Seek and You Shall Find

"If you haven't caught anyone, you may not be looking hard enough."

– K. Harper

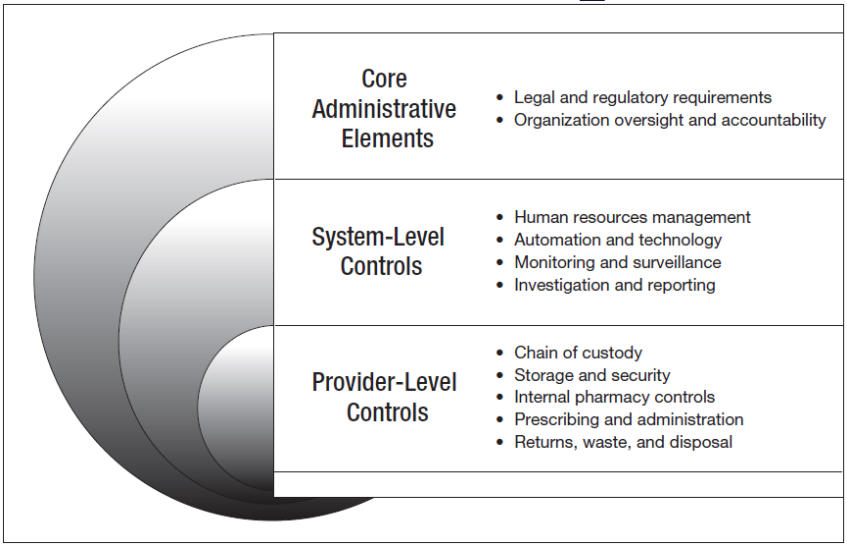
Diversion Risk Points



CS: controlled substances
ADD: automated dispensing device

ASHP guidelines on preventing diversion of controlled substances. *Am J Health-Syst Pharm*. 2017. https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/preventing-diversion-of-controlled-substances.ashx.

Diversion Prevention Program Elements



ASHP guidelines on preventing diversion of controlled substances. *Am J Health-Syst Pharm*. 2017. https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/preventing-diversion-of-controlled-substances.ashx.

Third Consensus Development Conference

- Participants/Process
- Statements:

(1) Healthcare institutions should promote a culture of IV drug delivery safety across all sites of care that is patient-centric and proactive

(2) Organizational leadership is accountable for ensuring the highest level of safety regarding IV drug delivery systems

(3) Manufacturer-prepared products are the safest IV drug delivery system, and manufacturer-prepared, ready-to-administer products are preferred for patient use whenever possible

(4) Compounding sterile preparations is a high-risk practice, and incorporating established standards, such as USP chapter <797>, is essential to ensure benefit while reducing risks to the patient

(5) All non-pharmacy compounding should be restricted to only immediate-use, urgent situations

Gabay M, Hertig JB, Degnan D, Burger M, Yaniv A, Mclaughlin M, Lynn Moody M. *Am J Health Syst Pharm*. 2020; 77:215-20. https://pubmed.ncbi.nlm.nih.gov/31811297/.

Third Consensus Development Conference

- Statements (continued)

6) Specialized education, training, certification, and competency with regard to compounding of sterile preparations should be required for pharmacists, pharmacy technicians, and other involved healthcare providers

(7) Automation and technology that have been validated to improve the safety of CSPs should be implemented

(8) The profession of pharmacy must take the lead in interdisciplinary efforts for the safety of IV drug delivery systems

(9) A legislative and regulatory framework that supports and encourages IV medication safety in all settings should be developed

(10) the organizational costs of inaction, or of pursuing the minimum action necessary with regard to the safety of IV drug delivery, far exceed an institutional financial investment in the safest systems for the patient and staff

- Better understanding of the "costs of inaction" and "holistic costs" is vital

Gabay M, Hertig JB, Degnan D, Burger M, Yaniv A, Mclaughlin M, Lynn Moody M. *Am J Health Syst Pharm.* 2020; 77:215-20. https://pubmed.ncbi.nlm.nih.gov/31811297/.

Contemporary Research

SPECIAL FEATURE

Third Consensus Development Conference on the Safety of Intravenous Drug Delivery Systems—2018

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Maureen Burger, M.S.N., RN, CPHQ, FACHE, Visante, Inc., St. Paul, MN.

Angela Yaniv, Pharm.D., Sterile Products, Cleveland Clinic, Cleveland, OH.

Maureen McLaughlin, M.S., RN, ACNS-BC, CPAN, CAPA, Division of Anesthesiology, Lahey Hospital and Medical Center, Acton, MA.

Mary Lynn Moody, B.S.Pharm., University of Illinois at Chicago College of Pharmacy, Chicago, IL.

Purpose. The Third Consensus Conference on the Safety of Intravenous Drug Delivery Systems was convened to evaluate the benefits and risks of available systems and assess ongoing threats to the safety of intravenous drug delivery.

Summary. The Third Consensus Conference on the Safety of Intravenous Drug Delivery Systems convened in Chicago, Illinois in November 2018. An expert panel of healthcare providers with experience in medication quality and safety, pharmacy and nursing operations, information technology, and/or sterile compounding led the conference. An experienced audience of approximately 30 healthcare leaders provided feedback to the panel via preconference survey and during the conference. Additionally, expert speakers presented on a range of issues, including the effects of drug shortages, the impact of standards and guidelines, and patient and administrator perspectives on the importance of intravenous drug delivery safety.

Conclusion. At the end of the conference, the expert panel concluded that manufacturer ready-to-use products remain the safest intravenous drug delivery system due to their many benefits and low overall risk profile. The panel identified various ongoing threats to the safety of intravenous drug delivery, with major concerns including the impact of drug shortages and lack of intravenous product standardization. Finally, the panel agreed upon a series of statements designed to advance the safety of intravenous drug delivery in healthcare institutions.

Keywords: drug administration, drug compounding, drug safety, intravenous infusion, pharmacy administration

Am J Health-Syst Pharm. 2020; 77:215-221

Original Article

A Continuous Observation Workflow Time Study to Assess Intravenous Push Waste

John Hertig, Kaitlyn Jarrell, Prachi Arora, Jonell Nwabueze, Charlotte Moureaud, Daniel D. Degnan, and Tate Trujillo

Abstract

Background: There are significant costs associated with proper controlled substance disposal, management, and regulatory compliance. Given the high abuse potential of fentanyl, hydromorphone, and morphine it is imperative that (1) product waste is minimized, and (2) waste procedures are followed to ensure safe disposal. Research is needed to better understand the financial and workforce impacts of drug waste on inpatient hospital units. The primary objective of this study was to quantify the waste associated with administering fentanyl, hydromorphone, and morphine via the intravenous push route. Two categories of waste were evaluated: (1) the quantity (mg/µg) of drug disposed; and (2) workforce time associated with the waste disposal process. **Methods:** A workflow time study design, a sub-set of continuous direct observation time motion studies, was employed to achieve the research objectives. A data collection tool was developed to capture medication type, waste amount, activity time stamps, total time, and number of interruptions at two separate study sites. Descriptive statistics were conducted on all the data measures. The number of assessments, total values, and mean values were reported for each drug (fentanyl, hydromorphone, and morphine) separately as well as grouped data. **Results:** A total of 669 distinct waste observations meeting inclusion criteria were collected during a study period of 15 days. In total, 207 mg of hydromorphone and 17 962.50 µg of fentanyl were wasted during this study. Nursing staff time associated with the wasting process totaled 50 190 seconds (849.83 minutes or 14.16 hours). A combined waste (loss) of approximately $1605.39 was associated with controlled substance wasting. The cost per dose wasted in this study was found to be $2.40 for all medications. When a yearly extrapolation model was applied to the four study units, the total combined product and workforce waste cost was $35 425. **Conclusion:** There are financially significant costs associated with wasting both the product and the valuable time of a skilled workforce. Optimizing product size, taking special note to match product availability with common practice use, would reduce the associated financial burden on our health-systems nationwide.

Keywords

intravenous therapy, cost effectiveness, medication process, purchasing

Introduction

Background

Health-system policies and procedures for handling and disposing of controlled substances vary. Proper disposal is an essential best practice, as controlled substances including fentanyl, hydromorphone, and morphine are associated with particularly high abuse and diversion risk. The Drug Enforcement Administration (DEA) estimates that prescription drug diversion in the United States is a $25 billion-a-year industry.[1]

Current federal statute dictates the appropriate disposal of controlled substance medications must occur immediately with documentation, and be witnessed by two licensed healthcare professionals.[1] Depending on the patient care unit, the quantity, and variety of controlled substances administered can create an administrative and regulatory burden on healthcare professionals. Policies requiring thorough documentation, checks-and-balances, and possible audits necessitate an institutional investment of time and resources.

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Email: jhertig@butler.edu

Hertig JB, Jarrell K, Arora P, Nwabueze J, Moureaud C, Degnan D, Trujillo T. *Hosp Pharm.* 2020. https://journals.sagepub.com/doi/10.1177/0018578720931754.

Gabay M, Hertig JB, Degnan D, Burger M, Yaniv A, Mclaughlin M, Lynn Moody M. *Am J Health Syst Pharm.* 2020; 77:215-20. https://pubmed.ncbi.nlm.nih.gov/31811297/.

Waste Study Results

- 669 distinct waste observations met inclusion criteria
- Collected during 15 days across four units – 80 beds (two hospitals)
- In total, 207 mg of hydromorphone and 17,962.50 µg of fentanyl were wasted
- Nursing staff time associated with the wasting process totaled 50,990 seconds (849.83 minutes or 14.16 hours)

Table 2. Most Frequently Observed Waste Amounts for Fentanyl and Hydromorphone.

Drug	N	Waste amount	Percentage of total wastes (%)
Fentanyl (50 µg/mL) 2 mL vial	143	50 µg	49.83
Fentanyl (50 µg/mL) 2 mL vial	132	75 µg	45.99
Hydromorphone (1 mg/mL) 1 mL vial	239	0.5 mg	62.89
Hydromorphone (1 mg/mL) 1 mL vial	68	0.8 mg	17.89

Hertig JB, Jarrell K, Arora P, Nwabueze J, Moureaud C, Degnan D, Trujillo T. *Hosp Pharm.* 2020. https://journals.sagepub.com/doi/10.1177/0018578720931754.

Waste Study Results

- The average total cost per dose wasted was $2.40 for all medications
- When a yearly extrapolation model was applied, the total waste was $35,425
- 86 of the 669 PWs observed were interrupted
- Average time to chart PW was 2 hours, 4 minutes, 52 seconds
- 31 PWs documented more than 8 hours after removed to be administered

Table 3. Observed Total Cost of Waste.

Drug	N	Product waste (PW)	Workforce waste (WTW)	Total waste	Total waste per dose
Fentanyl (50 µg/mL) 2 mL vial	287	$226.33	$217.58	$443.91	$1.55
Hydromorphone (1 mg/mL) 1 mL vial	380	$886.89	$270.23	$1157.12	$3.05
Morphine (2 mg/mL) 1 mL vial	2	$2.66	$1.70	$4.36	$2.18
Total	669	$1115.88	$489.51	$1605.39	

Hertig JB, Jarrell K, Arora P, Nwabueze J, Moureaud C, Degnan D, Trujillo T. *Hosp Pharm.* 2020. https://journals.sagepub.com/doi/10.1177/0018578720931754.

Key Takeaways: Optimizing Care Delivery

- Survey respondents suggest that IV admixture use is safer today than 5 years ago but risks remain
  - Manufacturer-prepared, ready-to-administer products are preferred whenever possible
- Controlled substance waste is significant, especially in areas of high use (e.g., OR)
  - There are significant financial costs associated with wasting product AND workforce
- Delays in proper waste documentation put patients, nurses, and the organization at risk (e.g., "to-be" wasted medications may pose increased drug diversion risk)
- Better understanding of the total cost of delivering safe IV drug therapy is needed!

Improved patient experience

Prioritizing nursing time

Ensuring patient safety

Establishing a compliant practice

Multidisciplinary Approach to Waste Reduction and Prevention of Diversion

Bernadette Henrichs, Ph.D., CRNA, CCRN, CHSE, FAANA

Diversion in the Health System

- **Drug diversion can lead to:**
  - Serious patient safety issues
  - Harm to the diverter
  - Significant liability risk to the organization
- **Diversion driven by addiction:**
  - Puts patients at risk of harm (e.g., inadequate pain relief, infection), inaccurate documentation of care, impaired healthcare worker performance
  - Can lead to fraudulent billing and liability for damages
  - Can lead to decreased community confidence in the healthcare system

ASHP guidelines on preventing diversion of controlled substances. *Am J Health-Syst Pharm*. 2017. https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/preventing-diversion-of-controlled-substances.ashx.

Waste Reduction & Diversion Prevention Initiatives

- ***How do healthcare professionals view waste reduction and diversion prevention initiatives?***
  - Dependent on what is being asked of them and how time consuming it is
  - Dependent on whether they believe it will prevent or decrease diversion
    - Studies show that interventions decrease substance abuse
    - Healthcare workers, including anesthesia providers, have important roles in reducing patient exposure to opioids and providing education about appropriate use

Clark DJ et al. *Anesth Analg.* 2017; 125:1667-1674.
Surratt HL et al. *Pharmacoepidemiol Drug Saf*. 2014; 23:314-20. https://www.chpso.org/sites/main/files/file-attachments/controlled_substance_diversion.pdf.

Waste Reduction & Diversion Prevention Initiatives

- ***What is being asked of healthcare workers?***
  - Continuous prioritization and active management to guard against complacency
  - Awareness that prevention of diversion, detection if it occurs, and responding appropriately to the discovery of diversion are essential.

Three elements of organizational drug diversion programs. *The Joint Commission.* 2019. https://www.jointcommission.org/resources/news-and-multimedia/blogs/dateline-tjc/2019/06/three-elements-of-organizational-drug-diversion-programs/.

Diversion

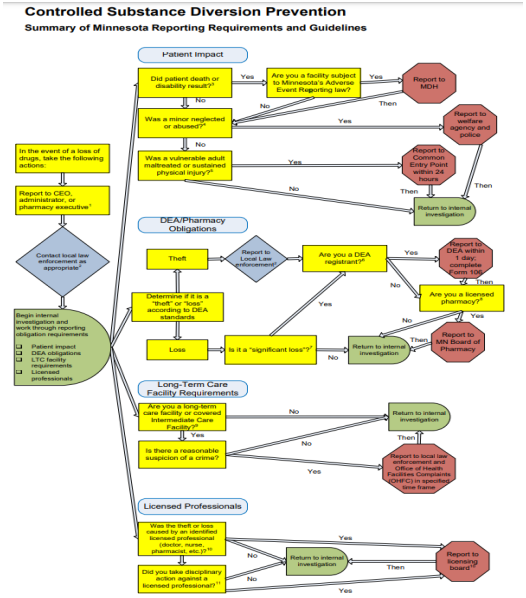
- **The DEA expects facilities to adhere to the best practices for patient safety and drug security**
  - Regulations and best practices are constantly changing
- **Most facilities have a core group of stakeholders addressing these issues**
  - Must recognize the importance of risks associated with diversion
  - Must acknowledge the importance of preventing and detecting diversion when it occurs

Best Practices and Guidelines

- ***Many states have toolkits and road maps to help them perform their own gap analyses***
  - Minnesota Hospital Association road map and toolkit
  - California Hospital Association road map
  - Missouri Bureau of Narcotics and Dangerous Drugs guide to preventing and investigating diversion issues in hospitals

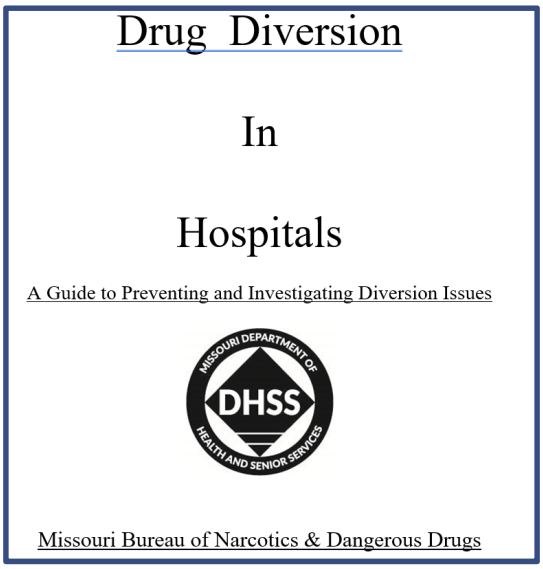
Drug diversion prevention. *Minnesota Hospital Assoc.* 2015. https://www.mnhospitals.org/quality-patient-safety/quality-patient-safety-improvement-topics/medication-safety/drug-diversion.
Reducing controlled substances diversion in hospitals. *CA Hosp Assoc Med Safety Collaborative Committee.* 2013. https://www.chpso.org/sites/main/files/file-attachments/controlled_substance_diversion.pdf.
MO DHSS. https://health.mo.gov/safety/bndd/publications.php (accessed 2021).

Example of Road Map



Drug diversion prevention. *Minnesota Hospital Assoc.* 2015. https://www.mnhospitals.org/Portals/0/Documents/patientsafety/Collaborations/DDWG_Flow_Chart_2014_07_01.pdf.

Missouri BNDD Guide



MO DHSS. https://health.mo.gov/safety/bndd/publications.php. (accessed 2021)

Healthcare Workers

- ***We must do our part in securing controlled substances at all times to prevent tampering and substitution***
  - *Automatic dispensing machines and liquid narcotics in syringes or infusion bags are the most common areas where drug diversion occurs.*
- ***Should not be easy for narcotics to be stolen***
  - *Easy access to medications is a major factor impacting the incidence of misuse of controlled substances by healthcare professionals.*

Giuffre M. Practical steps to address drug diversion and abuse during the pandemic. 2020. https://www.shrm.org/resourcesandtools/hr-topics/risk-management/pages/practical-steps-to-address-drug-diversion-and-abuse-during-the-pandemic.aspx.
Bell DM et al. *AANA J.* 1999: 67(2):133-40.

Healthcare Workers

- ***Taking an active role is expected of us professionally***
  - Accurate documentation of narcotics administered and wasted
  - Auditing of patient chart: watching, checking, verifying
  - Investigation of "red flags" addressed by managers
  - Audit questions addressed promptly and taken seriously
  - *Audit, audit, audit*
    - The lifeblood of successful drug diversion programs
    - Vital for managers to monitor and surveil employees; address promptly
      - Ex: What was given based on the electronic health record and what was wasted does not equal the amount in the vial
      - *Question the person in detail*

Giuffre M. Practical steps to address drug diversion and abuse during the pandemic. 2020. https://www.shrm.org/resourcesandtools/hr-topics/risk-management/pages/practical-steps-to-address-drug-diversion-and-abuse-during-the-pandemic.aspx.

Elements of Audits

- *Includes everything in the life cycle of controlled substances*
  - ***Procurement of controlled substances, disbursement, and disposal***
    - *The ordering system, separation of duties between those who order and receive the order, signatures of witnesses receiving the orders, verification of licensed registrants involved, validation of procedures and documentation, quarterly review of purchases against inventory, and examination of compliance with purchasing in unit dose packages*
  - ***If done accurately, audits will highlight any noncompliance***
    - *Will identify opportunities to improve procedures with the involved managers*

Giuffre M. Practical steps to address drug diversion and abuse during the pandemic. 2020. https://www.shrm.org/resourcesandtools/hr-topics/risk-management/pages/practical-steps-to-address-drug-diversion-and-abuse-during-the-pandemic.aspx.

Elements of Audits-Best Practices

- Should be independent, 3rd-party audits
  - Another set of eyes
- Review of policies and procedures, controls, monitoring, enforcement and internal improvement processes
- Evaluation of human resources practices, employee drug abuse awareness programs, supervisor and employee training on drug diversion and employee discipline for diversion violations

Giuffre M. Practical steps to address drug diversion and abuse during the pandemic. 2020. https://www.shrm.org/resourcesandtools/hr-topics/risk-management/pages/practical-steps-to-address-drug-diversion-and-abuse-during-the-pandemic.aspx.

Waste Reduction and Diversion Prevention

- ***May be more laborious but important to do***
  - Pre-employment background check and random drug screening
  - Do not share pass codes
  - Cameras in high-risk areas
  - Cameras on computers used in the clinical area
  - Log out of automated dispensing system when not used; set system to automatically lock after a short, specified amount of time
    - *Trust no one*
    - *Although this is not convenient, it is important to do*

Waste Reduction and Diversion Prevention

- ***May be more laborious but important to do***
  - Remove smallest amount of narcotic needed for patient
  - Secure narcotics removed from automated dispensing device/cabinet
  - Avoid carrying patient narcotics in pocket; availability of safes in areas that do not have an automated dispensing system
  - Precisely document what was used and what was wasted
  - Verify waste with another person; be judicious
  - Fill out any necessary forms
  - Waste with pharmacy personnel if required

Statistics

- **Studies show that 10-15% of healthcare workers are at risk of substance abuse**
  - Pose great risk for diversion of drugs
- ***This means majority of us (85-90%) can serve as the first line of defense to protect the organization and its patients from risks of drug diversion***
  - Can be educated on what to look for, how to report

Giuffre M. Practical steps to address drug diversion and abuse during the pandemic. 2020. https://www.shrm.org/resourcesandtools/hr-topics/risk-management/pages/practical-steps-to-address-drug-diversion-and-abuse-during-the-pandemic.aspx.

Strategies to Communicate with Stakeholders

- ***How do we get our message to the stakeholders?***
  - **Include healthcare workers and leadership (the stakeholders) on drug diversion committees**
    - Input is vital for success
    - Be on the lookout for patients reporting increased pain despite documented pain medication administration
    - Watch for signs of diversion and assure that a person can be reported anonymously or confidentially

Strategies to Communicate with Stakeholders

- ***How do we get our message to the stakeholders?***
  - **Form a subcommittee responsible for communicating the information**
    - Can communicate with the stakeholders and leadership
  - **Work towards the goal of "preventing," "detecting," and "reporting" diversion**
    - Involve leadership of each department to help with the auditing, prevention, detection, and reporting
    - Stress the importance of educating healthcare workers on drug diversion
    - Encourage all healthcare workers to get involved
    - ***If you see something, say something; speak up!***

Important Facts

- Drug diversion violates the core value that "*The needs of the patient come first*" and places the abuser "*under the influence.*"
- Preventing diversion requires ongoing vigilance at every level.
- Having a dedicated drug diversion task force to follow up on discrepancies is vital.
- Key stakeholders must be involved with how faculty and staff are addressing prevention, detection, and reporting of drug diversion.

Berge KH et al. *Mayo Clin Proc.* 2012; 87(7): 674-82. https://pubmed.ncbi.nlm.nih.gov/22766087/.

Key Takeaways

- *Prevention of diversion, early detection if it occurs, and responding appropriately to the discovery of diversion are essential.*
- *An essential component of any diversion program is education!*

Wasted Efforts: Engaging Key Stakeholders and Developing the Implementation Plan

Ryan Haumschild, Pharm.D., M.S., M.B.A.

Developing the Controlled Substance Management Value Proposition

Controlled substance management requires recognition of safety, prevention, waste, and cost savings across the organization

Diversion is Costly to Organizations

University of Michigan Health System to pay record drug diversion settlement

Updated: Jan. 30, 2019, 1:10 a.m. | Published: Aug. 30, 2018, 5:28 p.m.

University Hospital, part of the University of Michigan Health System. Katie McLean | The Ann Arbor News Katie McLean | MLive.com (Submitted photo)

Establishing a comprehensive diversion program requires investment in:

- Automation
- Artificial Intelligence
- Audit team
- Waste mitigation
- Changing practices

Slagter M. *M* Live. 2019. https://www.mlive.com/news/ann-arbor/2018/08/university_of_michigan_health_33.html (accessed 2021).

Quantifying Controlled Substance-Related Expenses

Leveraging published literature is important to identify all direct and indirect costs of managing controlled substance waste and adopting a validated approach

Original Article

A Continuous Observation Workflow Time Study to Assess Intravenous Push Waste

Hospital Pharmacy
1–8
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DOI: 10.1177/0018578720931754
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SAGE

John Hertig[1], Kaitlyn Jarrell[2], Prachi Arora[1], Jonell Nwabueze[1], Charlotte Moureaud[1], Daniel D. Degnan[1], and Tate Trujillo[2]

Abstract

Background: There are significant costs associated with proper controlled substance disposal, management, and regulatory compliance. Given the high abuse potential of fentanyl, hydromorphone, and morphine it is imperative that (1) product waste is minimized; and (2) waste procedures are followed to ensure safe disposal. Research is needed to better understand the financial and workforce impacts of drug waste on inpatient hospital units. The primary objective of this study was to quantify the waste associated with administering fentanyl, hydromorphone, and morphine via the intravenous push route. Two categories of waste were evaluated: (1) the quantity (mg/µg) of drug disposed, and (2) workforce time associated with the waste disposal process. **Methods:** A workflow time study design, a sub-set of continuous direct observation time motion studies, was employed to achieve the research objectives. A data collection tool was developed to capture medication type, waste amount, activity time stamps, total time, and number of interruptions at two separate study sites. Descriptive statistics were conducted on all the data measures. The number of assessments, total values, and mean values were reported for each drug (fentanyl, hydromorphone, and morphine) separately as well as grouped data. **Results:** A total of 669 distinct waste observations meeting inclusion criteria were collected during a study period of 15 days. In total, 207 mg of hydromorphone and 17 962.50 µg of fentanyl were wasted during this study. Nursing staff time associated with the wasting process totaled 50 990 seconds (849.83 minutes or 14.16 hours). A combined waste (loss) of approximately $ 960.39 was associated with controlled substance wasting. The cost per dose wasted in this study was found to be $2.40 for all medications. When a yearly extrapolation model was applied to the four study units, the total combined product and workforce waste cost was $33 453. **Conclusion:** There are financially significant costs associated with wasting both the product and the valuable time of a skilled workforce. Optimizing product size, taking special note to match product availability with common practice use, would reduce the associated financial burden on our health-systems nationwide.

Keywords
intravenous therapy, cost effectiveness, medication process, purchasing

Introduction

Background

Health-system policies and procedures for handling and disposing of controlled substances vary. Proper disposal is an essential best practice, as controlled substances including fentanyl, hydromorphone, and morphine are associated with particularly high abuse and diversion risk. The Drug Enforcement Administration (DEA) estimates that prescription drug diversion in the United States is a $25 billion-a-year industry.[1]

Current federal statute dictates the appropriate disposal of controlled substance medications must occur immediately with documentation, and be witnessed by two licensed healthcare professionals.[1] Depending on the patient care unit, the quantity, and variety of controlled substances administered can create an administrative and regulatory burden on healthcare professionals. Policies requiring thorough documentation, checks-and-balances, and possible audits necessitate an institutional investment of time and resources.

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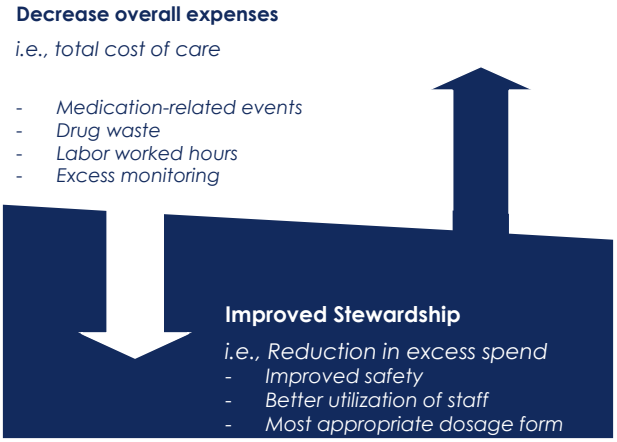
Hertig JB, Jarrell K, Arora P, Nwabueze J, Moureaud C, Degnan D, Trujillo T. *Hosp Pharm.* 2020. https://journals.sagepub.com/doi/10.1177/0018578720931754.

The goals of cost-effective controlled substance management

- Acquisition cost is important but **total cost of care** is more indicative of expenses
- Understand how appropriate management of waste, medication safety, disposal, and labor can decrease organizational liability and spending



Hertig JB, Jarrell K, Arora P, Nwabueze J, Moureaud C, Degnan D, Trujillo T. *Hosp Pharm.* 2020. https://journals.sagepub.com/doi/10.1177/0018578720931754.

Direct Costs Related to Controlled Substance Waste

- Each waste activity requires the labor of a nurse or other healthcare provider
- If dosage forms are not optimized, each unit of waste leads to additional expense

Available at: <https://www.istockphoto.com/search/2/image?phrase=two+nurses> [Accessed 2021].

Indirect Impacts of Medication Waste

- Increased documentation and witnessing of controlled substance waste
- Required pharmacy follow up on unreconciled administrations
- Lack of aseptic technique utilized at the bedside with immediate administration
- Risk of healthcare provider diversion and DEA fines

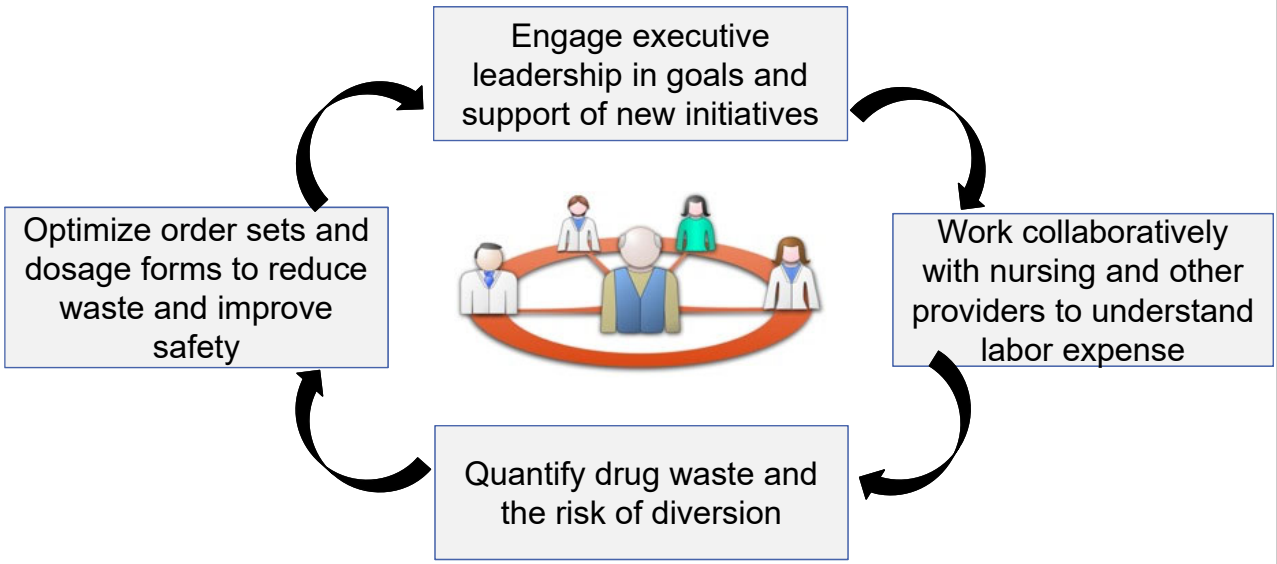
The Joint Commission. Medication Management Standard MM.08.01.01. 2019. Oakbrook Terrace, IL: Joint Commission Resources.

Pharmaceutical Waste Management

- As of August 21, 2020, the EPA has banned sewering of controlled substance medications under the federal Resource Conservation and Recovery Act (RCRA)
- The DEA additionally requires controlled substances to be "rendered irretrievable" if any waste exists after administration
- The antiquated method of "free" sewering of controlled substance waste down a sink is no longer acceptable
- Rx waste disposal systems add recurrent costs to a health care facility's budget that many forget to factor into the cost of drug waste

Brechtelsbauer E and Shah S. *Am J Health-Syst Pharm.* 2020; 77:574-82.
https://academic.oup.com/ajhp/article-abstract/77/7/574/5734863?redirectedFrom=fulltext.

Developing a comprehensive game plan



Quantify Facility-specific Financial Impact of Waste

- **Leverage reports from automated dispensing cabinets or electronic medical record to identify medications with highest waste**
- **Identify waste events to quantify labor expense associated with each occurrence**
- **Quantify total drug waste by drug in mL**
- **Extrapolate cost per mL of drug wasted to total waste and quantify total number of worked hours associated with waste events**

Quantifying Impact

Medication	Medication expense (AWP) per mL	Average mL wasted per dose	Total mL wasted annualized	Medication waste expense annualized	Workforce expense per waste	Total doses wasted	Workforce waste expense annualized	Disposal bin expense	Disposal bin capacity in mL	Disposal bin expense annualized	Total annual expense (USD)	Total waste expense per dose (USD)
Fentanyl (50 μg/mL)	$0.78	1	3,444	$2,686	$0.73	3,444	$2,514	$68	3785	$68	$2,969.57	$5,268

AWP: Average wholesale price

Hertig JB, Jarrell K, Arora P, Nwabueze J, Moureaud C, Degnan D, Trujillo T. *Hosp Pharm.* 2020. https://journals.sagepub.com/doi/10.1177/0018578720931754.

Consider the Total Cost of Care

- Consider acquisition cost, but more importantly the total waste that could be generated from a specific medication
- Aim to decrease waste events to better manage labor worked hours within nursing and pharmacy
- Evaluate the costs of diversion when reviewing medication use or adopting new practices

Key Takeaways to Optimize Controlled Substance Practices

- Create medication order sets where dose ordered matches medication product
  - This is especially important in procedural areas where controlled substance waste is generated in high volumes
- Consider purchasing ready-to-use dosage forms that reduce the need for manipulation at the bedside
- Utilize one product as identified by the National Drug Code (NDC) if possible to consolidate product use and familiarity

Creating a Cross Discipline Value Proposition

- Recognize that change must be initiated across disciplines for lasting impact
- Gaining provider and nursing buy in is key
  - Quantify cost-saving opportunities both inside and outside of the pharmacy department
  - Emphasize labor and financial stewardship opportunities that can be achieved within a controlled substance management program
- Organizations more than ever before are looking for initiatives that can improve standard work and lean principles

Putting it All Together

Changing an organization's approach to controlled substance use and management takes a team approach

How will you change your practice?

- Identify practices that support medication safety and eliminate risks for drug diversion.
- Discuss with key stakeholders interventions to minimize diversion of controlled substances.
- Engage key stakeholders in my health system to develop a drug diversion stewardship program.
- Collaborate with other healthcare providers and hospital staff to reduce the opportunity for controlled substance diversion.
- Develop a plan to ensure controlled substance medications are supplied in the smallest ready to use dosage forms as possible.
- Educate staff on identifying and preventing controlled substance diversion.

Take a moment to reflect on the changes you would make based on what you learned today.

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