

# Quantifying the Holistic Costs of Controlled Substance Medication Waste



## Quantifying the Holistic Costs of Controlled Substance Medication Waste

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This activity is funded by **Fresenius Kabi**.

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## Learning Objectives

Following completion of this activity, participants will be able to:

1. Identify practices that impact the safe use of intravenous (IV) products in the inpatient setting.
2. Discuss interventions designed to detect and prevent diversion.
3. Recite quantifiable cost data accounting for workforce, waste, and disposal, associated with the waste process for intravenous push-controlled substance medications.



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# Quantifying the Holistic Costs of Controlled Substance Medication Waste

## Medication Administration

- Role of a variety of providers
- Nurses spend 26.9% of their time on the critical task of medication administration
  - “Most significant amount of time spent on obtaining and verifying medications”
- Approximately  $\frac{2}{3}$  of medication administration time related to drug delivery to the patient
- Other  $\frac{1}{3}$  spent preparing drugs for administration



Keohane, CA, Bane, AD, Featherstone, E, Hayes, J, Woolf, S, Hurley, A, et al. Quantifying Nursing Workflow in Medication Administration. *JONA*. 2008;38 (1), pp 19-26.  
Hendrich, A, Chow, M, Skierczynski, BA, Lu, Z, A 36-Hospital time and motion study: how do medical-surgical nurses spend their time? *The Permanente Journal*. 2008;12(3), pp 25-34.

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## IV Medication Use

- Essential component of care
- Clinically advantageous
- Many high-alert medications are administered IV
- Errors in use have potential for serious harm
- Clinician-prepared syringes are common
- ANA survey: 44% of nurses administer IV push medications more than 5 times each shift
- ISMP survey, 75% reported less than half of the time, IV push medications provided in pharmacy-prepared or commercially available ready-to-administer syringes



Medication Errors and Syringe Safety Are Top Concerns for Nurses According to New National Study [press release].  
<http://www.nursingworld.org/FunctionalMenuCategories/MediaResources/PressReleases/2007/SyringeSafetyStudy.aspx>. Silver Spring, MD: American Nurses Association; June 18, 2007.  
ISMP. Part I: Survey results show unsafe practices persist with IV push medications. *ISMP Medication Safety Alert!* 2018;23(22):1-5.

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## Not in My Organization...

- US Substance Abuse and Mental Health Services Administration and the America Nurses Association suggest that about 10% of health care workers are abusing drugs. Some believe this number to be underestimated. Ramifications of drug diversion in both inpatient and ambulatory healthcare settings are significant. Incidents have impacted patient and staff safety, increased costs, and resulted in infection outbreaks.
- 10%–15% of HCWs, including anesthesia professionals, will misuse drugs or alcohol at some time during their career. It has been suggested that substance use disorder is the most frequent disabling illness in HCWs. (*National State Boards of Nursing 2018; APSF, Feb 2019*)
- Easy to do, lack of formalized structure and oversight in organizations



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## Systems and Practices that Increase the Risk of Diversion in Clinical Locations

- System Failures
  - Storage vulnerabilities
    - Unnecessary Access
  - Documentation vulnerabilities
  - Lack of clearly defined organizational expectations; policy compliance
  - Environmental/Wasting limitations
- Behaviors
  - At risk behaviors
  - Unnecessary manipulation of controlled IV products



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## Practices (Manipulation) that Increases the Opportunity for Diversion with IV Medications

- Using part of a vial or ampule, or more than one vial or ampule for a single dose
- Selecting to use a vial, ampule or syringe that far exceeds the dose needed
- Selection and use of maximum dose for the patient
- Manipulations needed to prepare medications (e.g., vial-to-syringe, syringe-to-syringe transfer, withdrawing from a prefilled syringe)
- Dilution of some concentrated injectable drugs



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>

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## Unnecessary or Improper Dilution

- ISMP survey on dilution practices (adults) N =1,773

- 83% further dilute IV push medications

Single-dose vials and ampules	77% (14% always)
Multiple-dose vials	49% (11%)
Manufacturer's prefilled syringes	43% (10%)
Pharmacy-dispensed syringes	20% (5%)

- Common medications

Opioids	67% (27% always)
Antianxiety/antipsychotic	65% (24%)



ISMP. Part I: Survey results show unsafe practices persist with IV push medications. *ISMP Medication Safety Alert* 2018;23(22):1-5.

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## Unnecessary or Improper Dilution

- Volume of diluent and method to determine the volume of diluent is variable
  - Most had personal formulas
    - 1 mL per minute of time needed to slowly administer drug
    - Different if peripheral or central line
  - No respondents described a dilution process that would result in a specific concentration
  - 43% reported policies or guidelines on dilution
- 81% use flush syringes for drug dilution
  - 56% reported this practice half of the time
  - 19% reported always
- Most often, the syringe is not relabeled or labeled



ISMP. Some IV medications are diluted unnecessarily in patient care areas, creating undue risk. *ISMP Medication Safety Alert!* 2014;19(2):1-5.

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## Misuse of Vials, Syringes, and Needles

- Survey on Carpuject™ prefilled syringes (N=540)
  - Looking at issue of overfill and whether nurses were aware
  - Many nurses not concerned about overfill because they withdrew doses from the cartridges using a syringe
  - Using cartridges as single-/multiple-dose vials



ISMP. ISMP survey reveals user issues with Carpuject prefilled syringes. *Nurse Advise-ERR*. 2012;17(16):1-3.

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## Infusion Management Risk for Diversion


- Controlled IV medication or infusions removed from secure stock in significant advance of need of need
- Controlled substance infusions hanging on IV poles outside of lock boxes/secure pumps
- Controlled substances tubing with y-site allowing for easy diversion
- Controlled substance infusions that are discontinued, remain available at the bedside, and are not immediately discarded
- Compounding controlled substances outside of the pharmacy
  - Lack of 24-hour pharmacy
  - Epidurals by anesthesia providers



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November 5, 2020 ■ Volume 25 Issue 22



## Acute Care ISMP Medication Safety Alert!®


Educating the Healthcare Community About Safe Medication Practices

### ISMP survey provides insights into preparation and admixture practices **OUTSIDE** the pharmacy



In our August 2020 ISMP *Nurse AdviseERR* newsletter ([www.ismp.org/node/19769](http://www.ismp.org/node/19769)), we invited practitioners who prepare and/or admix sterile, injectable medications and/or infusions **OUTSIDE** the pharmacy to participate in a survey. The purpose of the survey was to learn about the frequency of preparing and admixing medications and/or infusions outside the pharmacy; the extent of implementing safe preparation and admixture practices; the training associated with medication preparation and admixture; the occurrence of preparation and admixture errors; and the perceived safety challenges associated with medication and/or infusion preparation and admixture. A description of the survey findings follows.

#### **SAFETY** briefs



**Warning regarding strength listed on oxytocin vials.** Several oxytocin 10-fold dosing errors occurred at a hospital recently, due in part to a pharmacy technician's misunderstanding of the product strength listed on the vial label. The technician meant to compound oxytocin 30 units in 500 mL of normal saline. However, she accidentally used three 10 mL vials (10 units per mL) instead of three 1 mL vials (10 units per mL). This resulted in a final concentration of 300 units per 500 mL instead of 30 units per

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## Survey Respondent Profile

- 444 practitioners
  - 77% Nurses
    - Including advanced practice nurses
  - 8% Anesthesia providers
    - CRNAs
    - Anesthesiologists
  - 15% decentralized pharmacists and technicians, physicians, and supervisors
- 81% acute care or specialty hospital
  - 5% ambulatory surgery center
  - 3% ambulatory infusion center
  - 3% physician practice setting or clinic
  - 1% LTC



<https://www.ismp.org/acute-care/medication-safety-alert-november-5-2020>

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## Frequency of Preparing/Admixing Sterile, Injectable Medications/Infusions Outside the Pharmacy

Sterile Injectable Medications and Infusions	Frequency (% of Responses)			
	Never/Rarely	Sometimes	Often	Always
IV push medications	17	25	34	24
IV intermittent infusions	28	19	31	22
IM injection medications	38	23	20	19
IV continuous infusions/titrations	52	20	14	14
Epidural/neuraxial injections/infusions	88	5	5	2

Key:

**Never/Rarely**=0 to 10% of the time; **Sometimes**= 11 to 50% of the time; **Often**= 51 to 95% of the time; **Always**= more than 95% of the time



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## Important Survey Findings

- 81% reported preparing parenteral drugs in less-than-ideal conditions
- 35% respondents reported they are required to have an independent double check of certain drugs is required outside of the pharmacy
  - 30% high-alert medications
  - 44% limited drugs (e.g., vasoactive medications, insulin, oxytocin)
  - No information as to the timing of this check
- Intravenous push medications: Mostly medications transferred from vials to syringes (e.g., **opioids**, antiemetics, antibiotics, proton pump inhibitors)



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## Survey Summation

- ISMP survey suggests that sterile compounding practices *outside of the pharmacy* are variable:
  - Risk errors
  - Risk breeches in infection control
  - **Heightened risk of diversion**



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## Key Risk Reduction Strategies to Decrease the Risk of IV Drug Manipulation

### High Leverage Strategy



- Provide IV push medications in ready-to-administer form
  - Minimize the need for manipulation outside of the pharmacy sterile compounding area

ISMP. *Safe Practice Guidelines for Adult IV Push Medications* (2015) <https://www.ismp.org/guidelines/iv-push>

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

*Third Consensus Development Conference on the Safety of Intravenous Drug Delivery Systems (2020) Gabay M, Hertig JB, Degnan D, Burger M, Yaniv A, McLaughlin M, Lynn Moody M. Am J Health Syst Pharm. 77:215-20. <https://pubmed.ncbi.nlm.nih.gov/31811297/>*

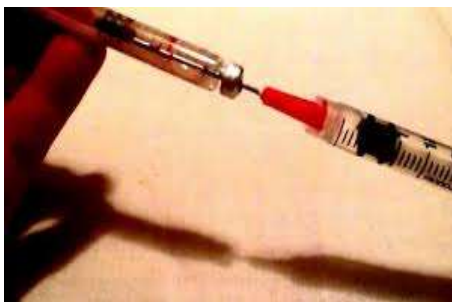


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## Key Risk Reduction Strategies to Decrease the Risk of IV Drug Manipulation

### Safe Practice Guidelines for Adult IV Push Medications



- Do NOT withdraw IV push medications from commercially-available, cartridge-type syringes into another syringe for administration
- Do NOT dilute or reconstitute IV push medications by drawing up the contents into a commercially available, prefilled flush syringe of 0.9% sodium chloride



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## Key Risk Reduction Strategies to Identify and Decrease the Risk of IV Infusion Manipulation

- Limit accessibility
  - In lock lidded compartments and not in matrix/tower storage
- Manual counts of ADCs; Immediate follow up for identified cabinet discrepancies
- Track controlled substances taken on override from ADC
- No process that allows for a single individual to waste or reconcile waste
- Remove controlled substance infusions from the room when discontinued
- Increase index of suspicion when drug volume changes in an unsecured IV
- Clearly defining expectations for controlled substance waste
- Reconciling documented waste from IV infusions



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## Drug Diversion in Healthcare

**“If you haven’t caught anyone, you may not be looking hard enough.”**

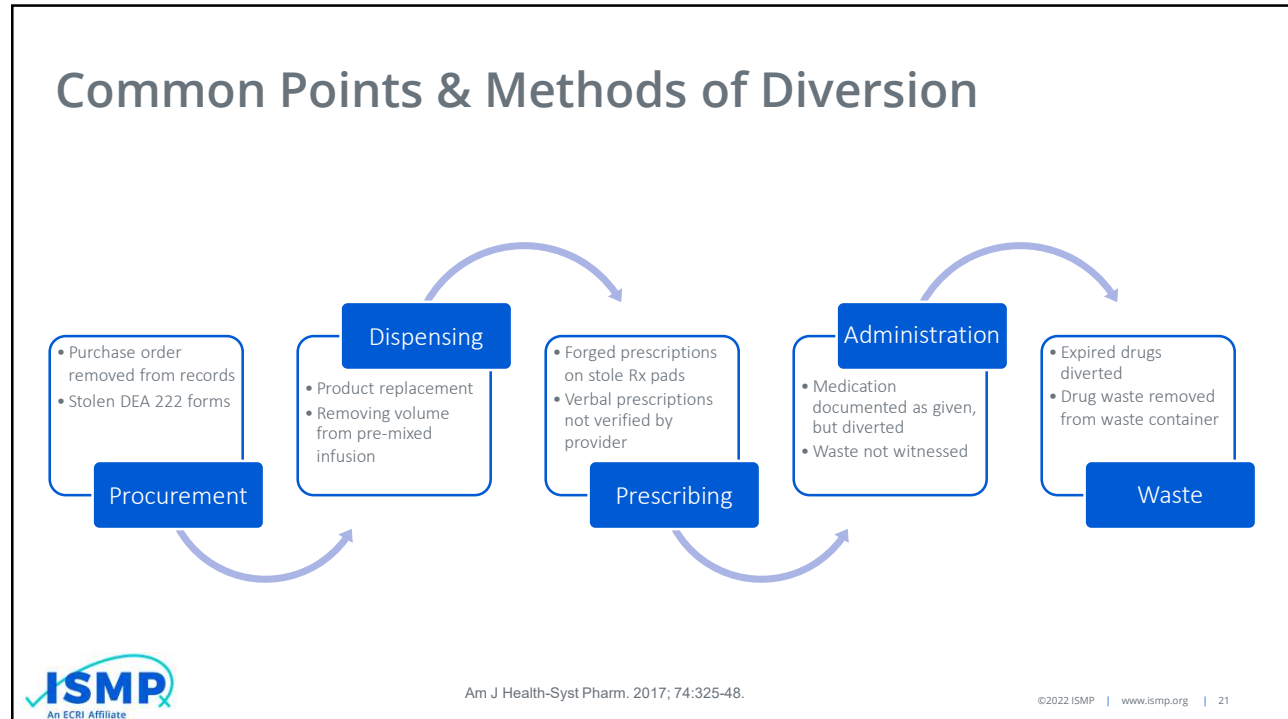
—K Harper



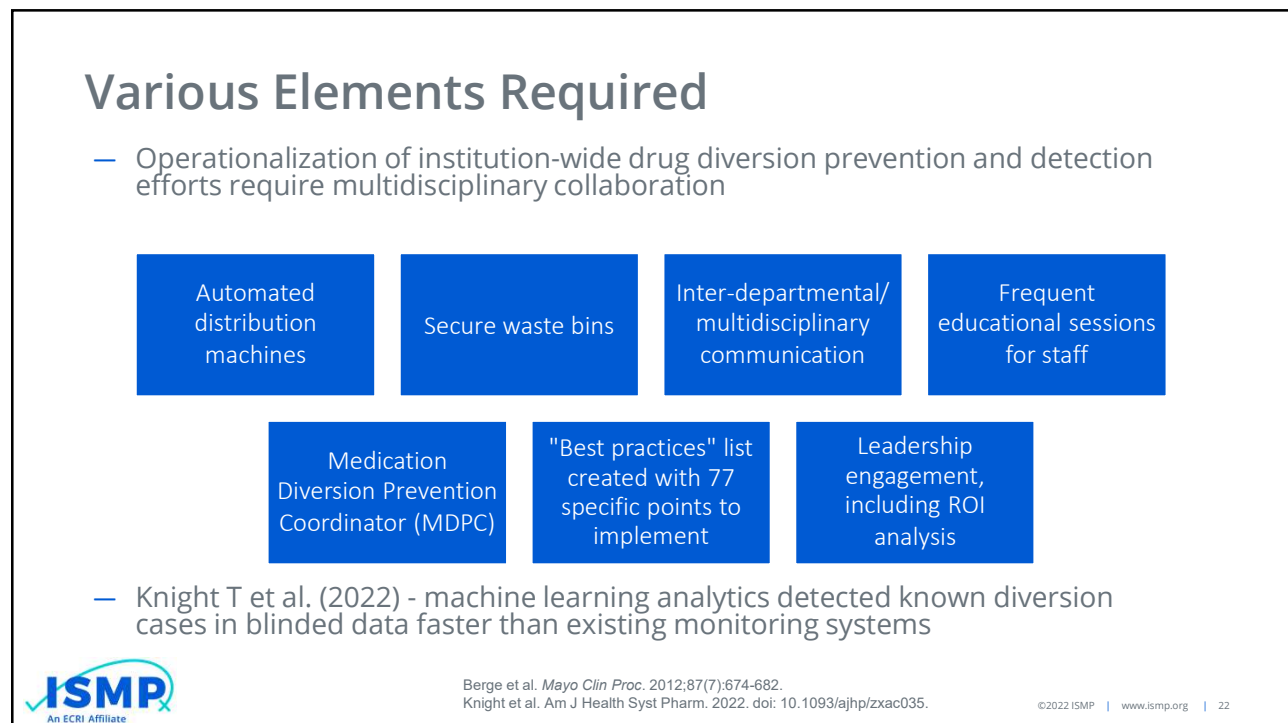
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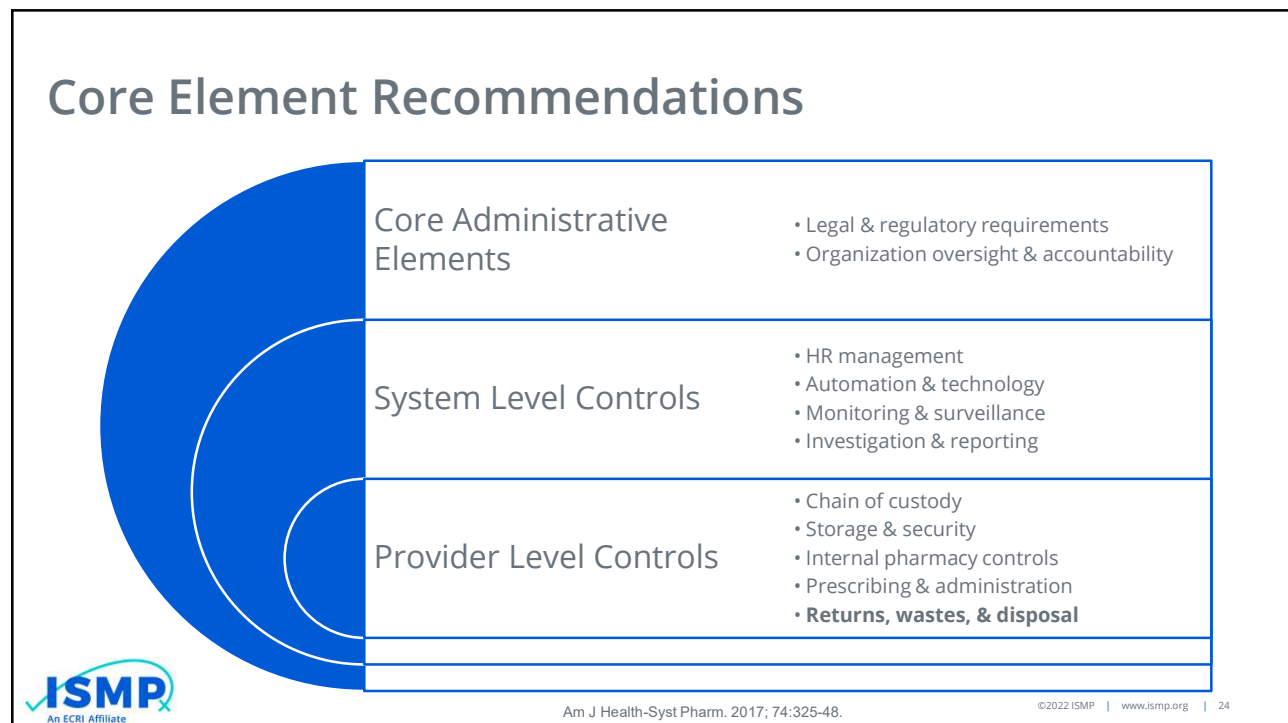


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## The Medication Waste Problem

Pharmacy Technician OR Nurse Anesthesiologist Pharmacy Director Nursing Leader

Waste decreases staff productivity, increases overall labor expense and adversely impacts patient care

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An ECRI Affiliate

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## Medication Use in OR/Procedural Areas

- Medication errors that occur in the OR are especially problematic
  - Anesthesia provider is often the only person involved in the entire process (e.g. prescribing, formulating, dispensing, and administering), removing the protection of double checks that exist in other hospital areas
  - One Comprehensive expert review paper evaluated 138 recommendations
  - Highest ranked included: standardization of concentrations, written policies for medication safety, and the “use prefilled whenever possible.”
- One study collected data on 13,078 prepared drug syringes
  - Drug wastage varied from 7.8% (Urapidil, an alpha-1 antagonist antihypertensive) to 85.7% (epinephrine) of prepared syringes
  - Mean waste was 38% with an estimated yearly waste of 139,531 syringes
  - “The overall extent of drug wastage in ORs and ICUs is concerning”

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Anesthesia & Analgesia: May 2021 - Volume 132 - Issue 5 - p 1450-1456.doi: 10.1213/ANE.0000000000005457.  
British Journal of Anesthesia, 118 (1): 32–43 (2017).

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## Controlled Substance Waste

- Due to high abuse and diversion risks, laws and best practices dictate the appropriate disposal (waste) of controlled substance medications
  - Must occur immediately with documentation by two health professional witnesses
  - Compliance requires investments of time and resources
- Modelling published in previous research found significant costs were associated with proper disposal and management of controlled substances
- Research was needed to better understand the financial and workforce costs of controlled substance waste on inpatient hospital units
  - Limited direct-observation studies in peer-reviewed literature



Hertig JB, Jarrell K, Arora P, Nwabueze J, Moureaud C, Degnan D, Trujillo T. [A Continuous Observation Workflow Time Study to Assess Intravenous Push Waste](#). *Hosp Pharm*. Published online ahead of print. 2020 May.

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## Holistic Costs of Waste: Research

### “A Continuous Observation Workflow Time Study to Assess Intravenous Push Waste”

**Principal Investigator: John B. Hertig, PharmD, MS, CPPS, FASHP**

Associate Professor and Vice-Chair of Pharmacy Practice  
Butler University, Indianapolis, USA

Hertig JB, Jarrell K, Arora P, Nwabueze J, Moureaud C, Degnan D, Trujillo T. [A Continuous Observation Workflow Time Study to Assess Intravenous Push Waste](#). *Hosp Pharm*. Published online ahead of print. 2020 May.



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# Quantifying the Holistic Costs of Controlled Substance Medication Waste

## Study Objectives

- **Primary:** quantify the total waste associated with administering fentanyl, hydromorphone, and morphine via the intravenous push route; evaluate two categories of waste:
  - The quantity (mg/μg) of medication disposed (“pharmaceutical/product waste” or PW)
  - Workforce time associated with the waste disposal process (workforce time waste or WTW)
- **Secondary:** collect the number of distractions (interruptions), and average time to document PW



Hertig JB, Jarrell K, Arora P, Nwabueze J, Moureaud C, Degnan D, Trujillo T. [A Continuous Observation Workflow Time Study to Assess Intravenous Push Waste](#). *Hosp Pharm*. Published online ahead of print. 2020 May.

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## Methodology

- A workflow time study design was adopted
- A data collection tool was developed
  - Used by research observers to capture data in real-time
- Study measures:
  - Fentanyl, hydromorphone, and morphine wasted (Product Waste = PW)
  - Time spent wasting fentanyl, hydromorphone, and morphine (Workforce Time Waste = WTW)
  - Cost (USD) in average wholesale pricing (AWP) associated with fentanyl, hydromorphone, and morphine PW
  - Time-cost (USD) related to PW procedure
- The number of assessments, total values, and mean values were reported separately for each drug; descriptive statistics used



Hertig JB, Jarrell K, Arora P, Nwabueze J, Moureaud C, Degnan D, Trujillo T. [A Continuous Observation Workflow Time Study to Assess Intravenous Push Waste](#). *Hosp Pharm*. Published online ahead of print. 2020 May.

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## Results (1)

- 669 distinct waste observations met inclusion criteria
  - Collected during a study period of 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)
- Only two doses of morphine collected during study period – “optimized” –

**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. [A Continuous Observation Workflow Time Study to Assess Intravenous Push Waste](#). *Hosp Pharm*. Published online ahead of print. 2020 May.

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## Results (2)

- 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 were 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
<b>Total</b>	669	\$1115.88	\$489.51	\$1605.39	



Hertig JB, Jarrell K, Arora P, Nwabueze J, Moureaud C, Degnan D, Trujillo T. [A Continuous Observation Workflow Time Study to Assess Intravenous Push Waste](#). *Hosp Pharm*. Published online ahead of print. 2020 May.

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# Quantifying the Holistic Costs of Controlled Substance Medication Waste

## Quantifying Medication Waste

Partner with nursing and pharmacy to leverage real-world data from your institution via automated dispensing cabinet reports



Leverage reports that capture actual volumes and expenses by medication



Identify medications with potential to reduce waste by optimizing strength/volume used by clinicians



Identify average waste per dose and quantify the medication waste expense using Average Wholesale Price (AWP) from historic purchase data



Quantify all direct costs per dose including labor expense and disposal of drug waste



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## Pharmaceutical Waste Disposal Costs

- As of August 21, 2020, the EPA has banned sewerage of controlled substance medications
  - Federal Resource Conservation and Recovery Act (RCRA)
- Controlled substances to be “rendered irretrievable” if any waste exists after administration
- Health care facilities have had to purchase controlled substance waste disposal bins where excess drug can be disposed of appropriately in accordance with EPA and other Federal/State regulations
  - The antiquated method of “free” sewerage of controlled substance waste in 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 in the cost of drug waste



American Journal of Health-System Pharmacy, Volume 77, Issue 7, 1 April 2020, Pages 574–582, <https://doi.org/10.1093/ajhp/zx3380>

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## Added Indirect Costs of Medication Waste

- Increased burden on medical and health care staff to monitor and witness medication waste
- Additional oversight required by pharmacy for waste-related activities and diversion prevention
  - Increased auditing expense per mL wasted
- Medication safety errors and costs associated with diversion could be significant

LABOR COST



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## Key Takeaways

- Drug diversion is expensive, resulting in societal, human, and financial costs
- Controlled substance waste is significant, especially in areas of high use
  - There are high financial costs associated with wasting product AND workforce
- Consider total cost of delivering safe IV drug therapy
  - Use evidence-based literature and guidelines to implement diversion and waste reduction programs



Improved patient  
experience



Prioritizing  
health  
professional  
time



Ensuring  
patient safety



Establishing a  
compliant practice



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## Questions?

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