Simplist®

FRESENIUS KABI

Banner University Medical Center – Phoenix
Case Study

Saving Time and Resources by Reducing Narcotic Waste with Ready-to-Administer Prefilled Syringes

Case Study Results

78%

Reduction in overall Hydromorphone waste events*

73%

Reduction in overall Fentanyl waste events*

955

Nursing hours saved annualized*

The Challenges

- Numerous drug shortages
- Time required to appropriately dispense and waste controlled substances by nursing staff
- Maintaining chain of custody and performing waste transaction audits

The Solution

- Use Simplist MicroVault® ready-to-administer prefilled syringes to more closely match clinical practice for commonly used opioid medications, such as hydromorphone and fentanyl

The Impact

- Decreased hydromorphone and fentanyl waste by 78% and 73%, respectively, resulting in fewer opportunities for potential drug diversion
- Decrease time spent documenting waste transactions with a witness resulting in increased time spent performing patient care activities
- Reduce the time required for pharmacy staff to support the hospital's opioid stewardship program

**Data provided by Banner University Medical Center and analyzed by Fresenius Kabi's Simplist Support Team.*

Please see important safety information, including boxed warnings, for Dilaudid® (HYDROmorphone HCl) Injection, USP and Fentanyl Citrate Injection, USP at www.simplist-us.com/resources/#inserts.

Introduction

Banner University Medical Center Phoenix, the largest hospital in the state of Arizona, is a world-class academic teaching hospital with more than 750 beds. Part of the **Banner Health** system, which operates more than 30 hospitals across 6 states, Banner University Medical Center Phoenix offers specialty services including advanced heart care, organ transplantation, high-risk obstetrics, orthopedics, and other high-level surgical care. The medical center is also a Level I Trauma Center, providing 24-hour in-house surgical coverage across dozens of specialty service lines.

Fresenius Kabi USA is a global, integrated pharmaceutical company dedicated to bringing lifesaving medications and solutions to clinicians. For more than 100 years, the company has been a leader in providing high-quality, affordable medications for chronically and critically ill patients. Fresenius Kabi is one of the largest generic injectable suppliers in the United States, offering over 260 drugs in over 600 presentations.

The Challenge

> *"Diversion of drugs from legitimate to illicit use is being recognized with increasing frequency in the United States. Although the full extent of diversion from health care facilities is unknown and probably unknowable, our experience makes clear that it is a considerable and ongoing problem. Addicted HCWs who are diverting drugs from the health care facility workplace pose a risk to their patients, their employers, their co-workers, and themselves. It is essential that all health care institutions have a robust system in place to identify and investigate suspected diversion as rapidly and efficiently as possible and that they implement policies and procedures that enable a standardized and effective response to confirmed diversion."*
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> Mayo Clinic Proceedings – 2012[1]

To improve patient safety and more effectively combat drug diversion, hospitals, small and large, are looking for new ways to support their opioid stewardship programs. By doing so, they can help ensure the safe and effective use of opioid drugs across the hospital.

Banner University Medical Center Phoenix possesses a strong, multidisciplinary drug diversion committee to facilitate the institution's own drug diversion prevention efforts. Allison Mruk, PharmD, BCPPS, Associate Director of Pharmacy at Banner University Medical Center Phoenix, oversees the hospital's drug diversion prevention and response team, as well as the facility's controlled substance handling. She said she appreciates the fact that there's been a growing awareness surrounding the best practices of controlled substance management which positively impacts both her patients and employees at Banner Health. This translates to her colleagues being open to new opportunities to support the cause as well as the institution's refined program.

"Having not just a standard approach to identifying potential diversion events, but a proactive approach, helps us decrease the risk, which is beneficial for our hospital," she said. **"We take our drug diversion prevention efforts very seriously and we are always looking for ways to make improvements. This allows us to help ensure that controlled substances are being utilized appropriately and we are putting patient safety first."**

Wasting events can increase opportunities for diversion.[2] Banner University Medical Center Phoenix's pharmacy department identified a place to reduce wasting when faced with shortages of a commonly used drug, 100 microgram vials of Fentanyl. Mruk's colleague, Associate Director of Pharmacy Abe Charara, PharmD, BCGP, BCPS, recognized that, by stocking a different presentation size of this commonly used narcotic, he and the pharmacy team could both overcome the current supply chain challenges and reduce wasting events.

"I analyzed a download of all of our usage, including the doses that were most frequently administered," he said. **"When we looked at the average dose, we realized the most common dosage was 50 micrograms. Given those numbers, and the shortages we were facing, it made sense to move to a different product."**

The Solution

Per the American Society of Health System Pharmacists (ASHP), best practices for preventing the diversion of controlled substances include minimizing waste. In ASHP's 2022 *Guidelines on Preventing Diversion of Controlled Substances,*[2] they state, "when possible, controlled substances are [recommended to be] stocked in ready to-use form and in the lowest commercially available units for doses frequently prescribed for patients."

Banner University Medical Center Phoenix had already implemented automated dispensing systems to track their controlled substance use and wastage. After Charara's analysis, they moved to add Simplist ready-to-administer syringes from Fresenius Kabi in smaller presentations of opioid analgesics or controlled substances: Simplist Dilaudid® (HYDROmorphone HCl) Injection, USP 0.5 mg per 0.5 mL and Simplist Fentanyl Citrate Injection, USP 50 mcg per 1 mL.

"Our goal was to reduce waste transactions, and in the process, reduce potential opportunities for diversion by moving to these presentations," said Jeffrey Anderson, PHARMD, BCPS, FACHE, Banner University Medical Center Phoenix's Director of Pharmacy. **"We also appreciated that the packaging of the Simplist syringes came with tamper-evidence."**

See full Important Safety Information, including Boxed Warning

Dilaudid® (HYDROmorphone HCl) Injection, USP

IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS AND LIFE-THREATENING RISKS FROM USE OF DILAUDID INJECTION

Addiction, Abuse, and Misuse
Because the use of DILAUDID INJECTION exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death, assess each patient's risk prior to prescribing and reassess all patients regularly for the development of these behaviors and conditions.

Life-Threatening Respiratory Depression
Serious, life-threatening, or fatal respiratory depression may occur with use of DILAUDID INJECTION, especially during initiation or following a dosage increase. To reduce the risk of respiratory depression, proper dosing and titration of DILAUDID INJECTION are essential.

Risks From Concomitant Use With Benzodiazepines Or Other CNS Depressants
Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing of DILAUDID INJECTION and benzodiazepines or other CNS depressants for use in patients for whom alternative treatment options are inadequate.

Neonatal Opioid Withdrawal Syndrome (NOWS)
If opioid use is required for an extended period of time in a pregnant woman, advise the patient of the risk of NOWS, which may be life-threatening if not recognized and treated. Ensure that management by neonatology experts will be available at delivery.

Fentanyl Citrate Injection, USP

IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS AND LIFE-THREATENING RISKS FROM USE OF FENTANYL CITRATE INJECTION

Addiction, Abuse, and Misuse
Because the use of Fentanyl Citrate Injection exposes patients and other users to the risks of opioid addiction, abuse and misuse, which can lead to overdose and death, assess each patient's risk prior to prescribing and reassess all patients regularly for the development of these behaviors and conditions.

Life-Threatening Respiratory Depression
Serious, life-threatening, or fatal respiratory depression may occur with use of Fentanyl Citrate Injection, especially during initiation or following a dosage increase. To reduce the risk of respiratory depression, proper dosing and titration of Fentanyl Citrate Injection are essential.

Risks From Concomitant Use With Benzodiazepines Or Other CNS Depressants
Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing of Fentanyl Citrate Injection and benzodiazepines or other CNS depressants for use in patients for whom alternative treatment options are inadequate.

Cytochrome P450 3A4 Interaction
The concomitant use of Fentanyl Citrate Injection with all cytochrome P450 3A4 inhibitors may result in an increase in fentanyl plasma concentrations, which could increase or prolong adverse reactions and may cause potentially fatal respiratory depression. In addition, discontinuation of a concomitantly used cytochrome P450 3A4 inducer may result in an increase in fentanyl plasma concentration. Monitor patients receiving Fentanyl Citrate Injection and any CYP3A4 inhibitor or inducer.

Please see continuing important safety information for Dilaudid® (HYDROmorphone HCl) Injection, USP and Fentanyl Citrate Injection, USP on the following pages.

The Results

After integrating the new Simplist ready-to-administer syringes into their existing medication management system, Banner University Medical Center Phoenix met their goals of reducing controlled substance waste across the facility – supporting the hospital's overarching drug diversion prevention program. **The addition of ready-to-administer syringe products that more closely aligned with the clinical practice numbers uncovered by Charara's analysis reduced hydromorphone and fentanyl waste by 78% and 73%, respectively.**

> *"I was proud to present these results at our quality and safety council meeting earlier this year and show the reductions. The team was blown away. Nursing loved the impact the change had made in waste reduction and the potential labor reduction, as well."*
>
> Jeffrey Anderson, PHARMD, BCPS, FACHE – Director of Pharmacy at Banner University Medical Center Phoenix

WASTE DATA OBSERVED: PRODUCT OPTIMIZATION OPPORTUNITIES

Hydromorphone Before	
Presentations Observed (171 days):	
Hydromorphone 1 mg per 1 mL, Hydromorphone 2 mg per 1 mL	
Top Waste Events by Quantity:	
0.5 mg	10,157
0.75 mg	320
1 mg	184
Waste Events	**11,169**

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Hydromorphone After	
Presentations Observed (192 days):	
Hydromorphone 0.5 mg per 0.5 mL, Hydromorphone 1 mg per 1 mL, Hydromorphone 2 mg per 1 mL	
Top Waste Events by Quantity:	
0.5 mg	1,370
0.25 mg	608
0.3 mg	226
Waste Events	**2,734**

Fentanyl Before	
Presentations Observed (138 days):	
Fentanyl 100 mcg per 2 mL Ampule & Vial	
Top Waste Events by Quantity:	
50 mcg	8,798
75 mcg	3,217
25 mcg	1,305
Waste Events	**13,693**

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Fentanyl After	
Presentations Observed (178 days):	
Fentanyl 100 mcg per 2 mL, Fentanyl 50 mcg per 1 mL	
Top Waste Events by Quantity:	
25 mcg	4,027
50 mcg	454
37.5 mcg	111
Waste Events	**4,748**

The switch to the smaller presentations Simplist prefilled syringes also helped to reduce both drug costs and nursing time. Based on the framework demonstrated in *A Continuous Observation Workflow Time Study to Assess Intravenous Push Waste (2020),*[3] both product waste and nursing workforce time waste were calculated for the waste amounts observed before and after the Simplist ready-to-administer syringes in the new presentations were adopted.

The change resulted in a savings of 955 hours of nursing time when annualized. The cost of the waste reduced was calculated to be approximately $154,200 per year when annualizing the product cost and wasted workforce time.

Anderson said the results, taken together, help to show his nursing colleagues how the organization is working to improve clinical workflows for these vital clinicians.

"It's important to us that we can show our nursing team that we are working hard to improve the quality of their work life and make things easier for them," he said. **"With less product waste, there are fewer trips to the Pyxis machine. Fewer witnesses required. And that means there's more time for them to be with their patients."**

Dilaudid® (HYDROmorphone HCl) Injection, USP
IMPORTANT SAFETY INFORMATION (continued)

ADVERSE REACTIONS

Most common adverse reactions are lightheadedness, dizziness, sedation, nausea, vomiting, sweating, flushing, dysphoria, euphoria, dry mouth, and pruritus.

To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Kabi USA, LLC at 1-800-551-7176 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- Serotonergic Drugs: Concomitant use may result in serotonin syndrome. Discontinue DILAUDID INJECTION if serotonin syndrome is suspected.
- Monoamine Oxidase Inhibitors (MAOIs): Can potentiate the effects of hydromorphone. Avoid concomitant use in patients receiving MAOIs or within 14 days of stopping treatment with an MAOI.
- Mixed Agonist/Antagonist and Partial Agonist Opioid Analgesics: Avoid use with DILAUDID INJECTION because they may reduce analgesic effect of DILAUDID INJECTION or precipitate withdrawal symptoms.

USE IN SPECIFIC POPULATIONS

Pregnancy: May cause fetal harm.

OVERDOSAGE

Acute overdose with hydromorphone can be manifested by respiratory depression, somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, constricted pupils, and, in some cases, pulmonary edema, bradycardia, hypotension, hypoglycemia, partial or complete airway obstruction, atypical snoring, and death. Marked mydriasis, rather than miosis, may be seen with hypoxia in overdose situations.

In case of overdose, priorities are the reestablishment of a patent airway and protected airway and institution of assisted or controlled ventilation, if needed. Employ other supportive measures (including oxygen and vasopressors) in the management of circulatory shock and pulmonary edema as indicated. Cardiac arrest or arrhythmias will require advanced life-support measures.

INDICATIONS AND USAGE

DILAUDID® INJECTION (hydromorphone hydrochloride) for intravenous, intramuscular, or subcutaneous use, is an opioid agonist indicated for the management of pain severe enough to require an opioid analgesic and for which alternate treatments are inadequate.

Limitations of Use:
Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration, reserve Hydromorphone Hydrochloride Injection for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or opioid combination products):

- Have not been tolerated or are not expected to be tolerated.
- Have not provided adequate analgesia or are not expected to provide adequate analgesia.

DILAUDID INJECTION should not be used for an extended period of time unless the pain remains severe enough to require an opioid analgesic and for which alternative treatment options continue to be inadequate.

Use the lowest effective dosage for the shortest duration consistent with individual patient treatment goals.

This Important Safety Information does not include all the information needed to use DILAUDID safely and effectively. Please see accompanying full prescribing information, including Boxed Warning, for DILAUDID INJECTION. Also available at www.simplist-us.com.

Fentanyl Citrate Injection, USP continued
IMPORTANT SAFETY INFORMATION (continued)

ADVERSE REACTIONS

The most common serious adverse reactions were respiratory depression, apnea, rigidity, and bradycardia.

To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Kabi USA, LLC, at 1-800-551-7176 option 5 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- Concomitant Use of CNS Depressants: May decrease pulmonary arterial pressure and may cause hypotension. See FPI for management instructions. For post-operative pain, start with the lowest effective dosage and monitor for potentiation of CNS depressant effects.
- Mixed Agonist/Antagonist and Partial Agonist Opioid Analgesics: Avoid use with Fentanyl Citrate Injection because they may reduce the analgesic effect of Fentanyl Citrate Injection or precipitate withdrawal symptoms.

USE IN SPECIFIC POPULATIONS

- Pregnancy: May cause fetal harm.
- Lactation: Infants exposed to Fentanyl Citrate Injection through breast milk should be monitored for excess sedation and respiratory depression.
- Geriatric Patients: Titrate slowly and monitor for CNS and respiratory depression.

INDICATION AND USAGE

Fentanyl Citrate Injection is indicated for:

- analgesic action of short duration during the anesthetic periods, premedication, induction and maintenance, and in the immediate postoperative period (recovery room) as the need arises.
- use as an opioid analgesic supplement in general or regional anesthesia.
- administration with a neuroleptic as an anesthetic premedication, for the induction of anesthesia and as an adjunct in the maintenance of general and regional anesthesia.
- use as an anesthetic agent with oxygen in selected high-risk patients, such as those undergoing open heart surgery or certain complicated neurological or orthopedic procedures.

Fentanyl Citrate Injection should be administered only by persons specifically trained in the use of intravenous anesthetics and management of the respiratory effects of potent opioids. Ensure that an opioid antagonist, resuscitative and intubation equipment, and oxygen are readily available.

This Important Safety Information does not include all the information needed to use Fentanyl Citrate Injection, safely and effectively. Please see full prescribing information, including Boxed Warning, for Fentanyl Citrate Injection at www.simplist-us.com.

Contact us

To learn how narcotic waste is impacting your hospital, contact your Sales Representative or call Customer Service at 1.888.386.1300

www.simplist-us.com

References: 1. Lanier, MD, William L. "A New Era in Journal Stewardship." *Mayo Clinic Proceedings 2012,* vol. 87, Mayo Foundation for Medical Education and Research. Published by Elsevier Inc., Jan. 2012, pp. 1–6, doi:https://doi.org/10.1016/j.mayocp.2011.12.001. 2. American Society of Health-System Pharmacists. ASHP Guidelines on Preventing Diversion of Controlled Substances. *Am J Health-Syst Pharm.* 2022;79:2279-2306, doi: https://doi.org/10.1093/ajhp/zxac246 3. Hertig J, Jarrell K, Arora P, et al. A continuous observation workflow time study to assess intravenous push waste. Hosp Pharm. 2021;56(5):584-591.

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