



United Regional Health Care System Case Study

Implementation of Simplist® Fentanyl Citrate Injection, USP 50 mcg per 1 mL

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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.

Case Study Results



86

Estimated annual time saved by nursing wasting*
(does not include waste verification time)



4,076

Estimated annual fewer opportunities for diversion*



62%

Estimated annual total reduction of Fentanyl waste*



17%

Increased space in dispensing system*

The Challenges

- Reduce delays in Fentanyl administration and reduce the time nurses spend wasting and/or verifying waste to increase their available time providing patient care
- Reduce narcotic waste and opportunities for diversion by more closely matching available product presentation to clinical practice
- Balance automated dispensing system (ADS) storage requirements for new products in the process

The Solution

- Adoption of Simplist® Fentanyl 50 mcg per 1 mL prefilled syringes to more closely match clinical practice
- Utilize Optilytics for product implementations

The Impact

- Decreased fentanyl waste by greater than 50%
- Increase in overall space in the automated dispensing system (ADS)

*Data provided by United Regional Health Care System and calculated with Fresenius Kabi's Narcotic Waste Calculator and Optilytics tool (automated cabinet analysis for Simplist prefilled syringes).

Fentanyl Citrate Injection, USP IMPORTANT SAFETY INFORMATION (continued)

CONTRAINDICATIONS

Fentanyl Citrate Injection is contraindicated in patients with a hypersensitivity to fentanyl.

WARNINGS AND PRECAUTIONS

- **Risks of Skeletal Muscle Rigidity and Skeletal Muscle Movement:** Manage with neuromuscular blocking agent. See full prescribing information for more detail on managing these risks.
- **Severe Cardiovascular Depression:** Monitor during dosage initiation and titration.
- **Opioid-Induced Hyperalgesia and Allodynia:** Opioid-Induced Hyperalgesia (OIH) occurs when an opioid analgesic paradoxically causes an increase in pain, or an increase in sensitivity to pain. If OIH is suspected, carefully consider appropriately decreasing the dose of the current opioid analgesic, or opioid rotation.

Please see continuing important safety information for Fentanyl Citrate Injection, USP on the following pages.

Introduction

United Regional Health Care System (URHCS), a 300 licensed bed hospital located in Wichita Falls, Texas, provides comprehensive medical care, including inpatient and outpatient services, advanced diagnostics, surgical specialties, and life-saving emergency care to a nine-county service area.

Simplist* is a platform of ready-to-administer prefilled syringes produced by Fresenius Kabi USA®. Simplist manufacturer prepared prefilled syringes require no assembly at the bedside and are associated with a 4x lower error rate* compared to traditional practice.

Fresenius Kabi is committed to supporting opioid stewardship and recently launched Simplist Fentanyl Citrate Injection, USP 50 mcg per 1 mL in a prefilled syringe to help hospitals more closely match clinical practice to available product presentation. Optimizing product size ultimately helps to eliminate narcotic waste and supports reduced diversion opportunities.

URHCS was an early adopter of Simplist ready-to-administer medications and used seven different medications in the portfolio, realizing the benefits of a ready-to-administer syringe from a trusted manufacturer.

With the launch of Fentanyl 50 mcg per 1 mL in the Simplist line of ready-to-administer medications, the URHCS pharmacy team was interested in utilizing the product to reduce waste associated with nursing time as well as reduce potential for diversion. After deciding to move forward with the product, URHCS used Fresenius Kabi's pharmacy support tool, called Optilytics®, to implement the product, increasing space in their automated dispensing cabinets by 17%. The results were annually projected to eliminate 86 hours of Fentanyl wasting for nursing, eliminating 4,076 opportunities for diversion, reducing Fentanyl waste by 62%.

"Limiting product waste and related documentation in the current environment is critical. Eliminating waste helps to streamline operations and free up staff time."

Nathan Wooten, PharmD – Director of Pharmacy at United Regional Health Care System

The Challenge

Opioid stewardship is an ever-important subject for hospitals and health systems. There are significant costs associated with proper controlled substance disposal, management, and regulatory compliance.² Given the high abuse potential of fentanyl, hydromorphone, and morphine, it is imperative that product waste is minimized.³

*A prospective, multisite, observational study of IV push medication preparation and administration compared the error rates between ready-to-administer products and traditional practice, including a cartridge-based syringe system and vial and syringe. Simplist was the only RTA delivery system used in the study. Study limitations include only a select number of sites (3) and steps observed.

Fentanyl Citrate Injection, USP

IMPORTANT SAFETY INFORMATION (continued)

- **Serotonin Syndrome:** Potentially life-threatening condition could result from concomitant serotonergic drug administration. Discontinue Fentanyl Citrate Injection if serotonin syndrome is suspected.
- **Adrenal Insufficiency:** If diagnosed, treat with physiologic replacement of corticosteroids, and wean patient off of the opioid.
- **Risks of Use in Patients with Increased Intracranial Pressure, Brain Tumors, or Head Injury:** Monitor for sedation and respiratory depression.

ADVERSE REACTIONS

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

Please see continuing important safety information for Fentanyl Citrate Injection, USP on the following pages.

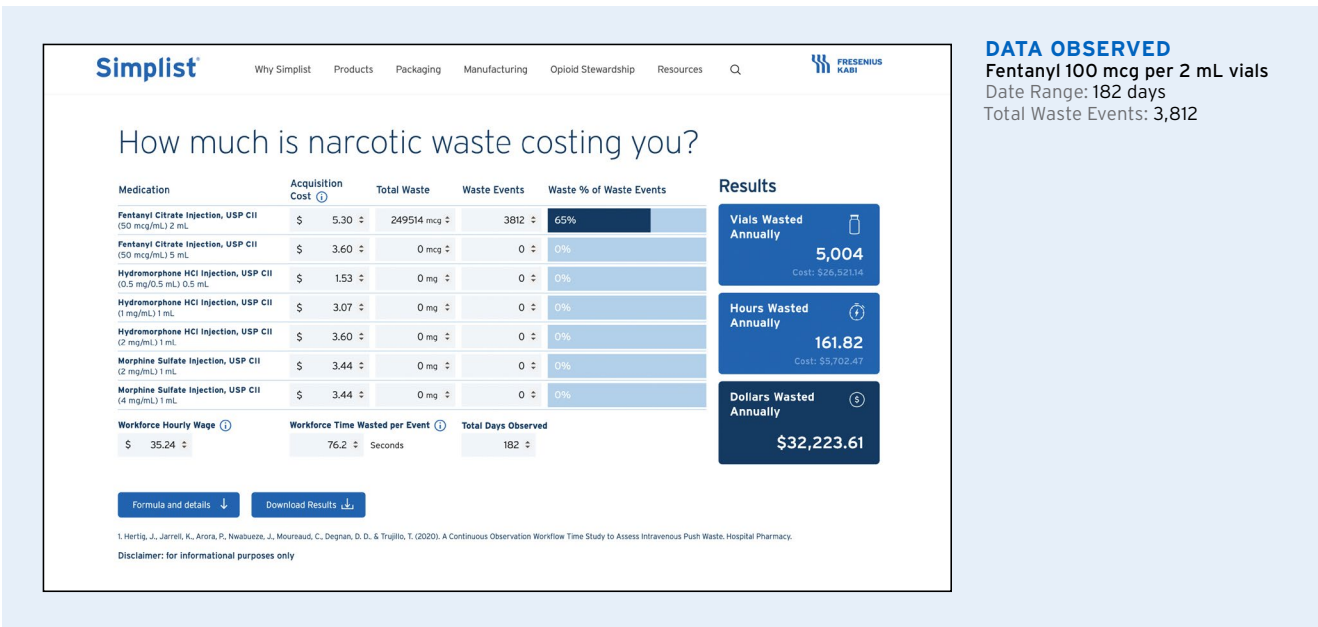
While pain control is an integral part of providing treatment to patients, doing so creates operational challenges for hospitals. Specifically, narcotic waste requires significant nursing time spent documenting. For example, one study ([Hertig](#)¹) estimated the amount of time each waste transaction requires is 76.2 seconds, not accounting for the waste witness (2nd RN) or pharmacy's time to reconcile discrepancies. Additionally, each waste event opens the door for narcotic diversion. As such, United Regional felt that reducing waste was in the best interest of their operations, and ultimately, patient safety.

Lastly, when considering the addition of new syringe products, automated dispensing space can become a challenge. Often, cabinets are close to capacity, and the larger bins, which accommodate ready-to-administer (RTA) syringes, are completely utilized. To help minimize this obstacle to implementation, URHCS leveraged the pharmacy support services offered by Fresenius Kabi.

The Process

Waste Analysis

To understand the impact of narcotic waste, URHCS utilized internal reports to determine where medication waste was happening in the hospital and the volume in which it was occurring.

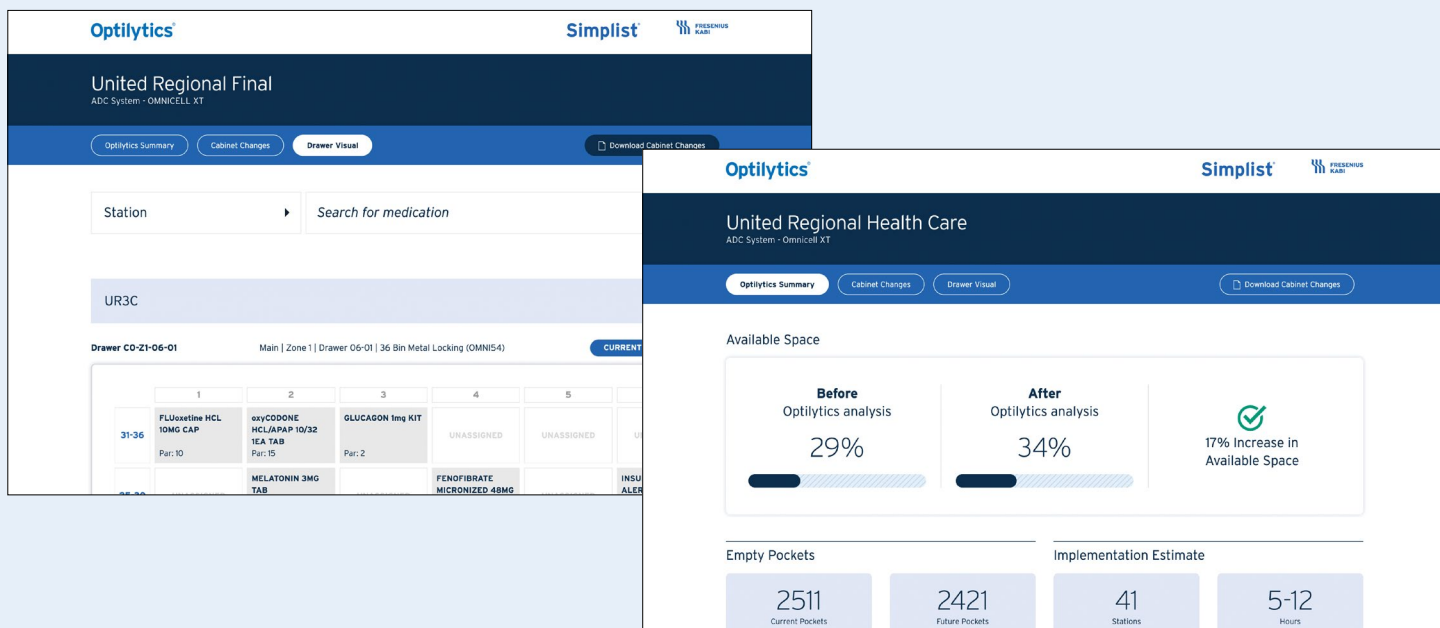


Fentanyl Citrate Injection, USP
IMPORTANT SAFETY INFORMATION (continued)

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.



Using Fresenius Kabi's Waste Calculator based on the framework demonstrated in [A Continuous Observation Workflow Time Study to Assess Intravenous Push Waste](#)², URHCS calculated that Fentanyl 100 mcg per 2 mL vial waste was demanding 162 hours of nursing time per year. That figure excludes accounting for waste witness and pharmacy operations time. The total waste amount was equivalent to 5,004 vials of Fentanyl 100 mcg per 2 mL per year. Using the average wholesale price for Fentanyl combined with workforce time wasted, the dollars wasted per year totaled \$32,223.61. This analysis supported that reducing the number of Fentanyl waste events would benefit URHCS from an operational cost perspective.

Storage Optimization

At URHCS, Fentanyl 100 mcg per 2 mL vials were found to be stored in 41 automated dispensing cabinets. The pharmacy team hoped to implement the Simplist Fentanyl 50 mcg per 1 mL prefilled syringes by matching par levels of the Fentanyl 100 mcg per 2 mL vials. While implementing the new syringes, the URHCS team reduced their current Fentanyl 100 mcg per 2 mL vial inventory by 50%. The pharmacy support team at Fresenius Kabi has a unique offering to support customers. They use a proprietary analytics tool called Optilytics®, which is complimentary for Simplist customers.

Optilytics is a tool that analyzes each cabinet to create space for customers to implement Simplist®. The storage team utilized a couple of standard reports from URHCS's ADS and generated a plan to fit the new product. The pharmacy support team came onsite to help the pharmacy team implement the product.

Fentanyl Citrate Injection, USP IMPORTANT SAFETY INFORMATION (continued)

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.

Please see continuing important safety information for Fentanyl Citrate Injection, USP on the following pages.

The Results

Reduction in Narcotic Waste

By adding Fentanyl 50 mcg per 1 mL Simplist® prefilled syringes, URHCS reduced the amount of Fentanyl waste by 62%, and overall Fentanyl waste events by 53% in the observed time period. Data analyzed included all hospital automated dispensing system (ADS) stations, even those without the new Simplist product.

WASTE DATA OBSERVED: PRODUCT OPTIMIZATION OPPORTUNITIES

Before Fentanyl 50 mcg per 1 mL		After Fentanyl 50 mcg per 1 mL	
Presentations Observed (182 days):		Presentations Observed (47 days):	
Total Fentanyl Waste	249,514 mcg	Total Fentanyl Waste	24,376 mcg
Total Waste Events	3,812	Total Waste Events	465
Annualized Waste	503,164 mcg	Annualized Waste	189,303 mcg
Annualized Waste Events	7,687	Annualized Waste Events	3,611

ANNUAL PROJECTIONS

313,861 mcg (62%)

Reduction in overall Fentanyl waste

4,076 (53%)

Reduction in overall Fentanyl waste events

Fentanyl Citrate Injection, USP

IMPORTANT SAFETY INFORMATION (continued)

Indication and Usage (continued)

Fentanyl Citrate Injection is indicated for:

- 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.

It is notable that by adding Simplist Fentanyl 50 mcg per 1 mL, this represents a projected 4,076 fewer waste events. While this has operational benefits, it also means more nursing time with patients, and an estimated 4,076 fewer opportunities for narcotic diversion.

Increased Storage Capacity

The pharmacy support team used Optilytics to help with ADS storage. Optilytics found that space could be increased in the ADS by 17% while adding Simplist® Fentanyl 50 mcg per 1 mL syringes across 41 cabinets. Implementation of Fentanyl 50 mcg per 1 mL Simplist® syringes took on average 11 minutes per cabinet.

Overall Results

United Regional Health Care System implemented Simplist Fentanyl 50 mcg per 1 mL. Doing so reduced their overall narcotic wasting rate. Additionally, by utilizing Optilytics, they implemented a ready-to-administer product efficiently and increased ADS storage space in the process.

"It was incredible how easy the pharmacy support team made it to implement Simplist. Optilytics helped fit Simplist efficiently and was easy to use."

Nathan Wooten, PharmD – Director of Pharmacy at United Regional Health Care System

Fentanyl Citrate Injection, USP

IMPORTANT SAFETY INFORMATION (continued)

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. Hertig, John B. PharmD, MS, CPPS*; Degnan, Daniel D. PharmD, MS, CPPS, CPHQ*; Scott, Catherine R. CPHQ*; Lenz, Janelle R. PharmD*; Li, Xiaochun PhD, MSct; Anderson, Chelsea M. PharmD, MBA, BCPS* A Comparison of Error Rates Between Intravenous Push Methods: A Prospective, Multisite, Observational Study, Journal of Patient Safety: March 2018 - Volume 14 - Issue 1 - p 60-65 doi: 10.1097/PTS.0000000000000419. 2. Hertig, J., Jarrell, K., Arora, P., Nwabueze, J., Moureaud, C., Degnan, D. D., & Trujillo, T. (2020). A Continuous Observation Workflow Time Study to Assess Intravenous Push Waste. Hospital Pharmacy.



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