Simplist®

FRESENIUS KABI

Middlesex Health Case Study

Reducing Waste and Ensuring Accountability: A Case Study with Simplist® and Data Analytics Tools

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Case Study Results

85%

Reduction in overall Hydromorphone waste events*

55%

Reduction in overall Fentanyl waste events*

410

Nursing hours saved annualized*

The Challenges

- Identifying and investigating potential drug diversion incidents
- Inefficient clinician workflows related to dispensing and wasting controlled substances

The Solution

- More closely match clinical practice for commonly used opioid medications
- Utilize AI Diversion Software to identify potential drug diversion events through pattern recognition

The Impact

- Decreased hydromorphone and fentanyl waste by 85% and 55%, respectively, resulting in fewer opportunities for diversion
- Reduced the time nurses spend counting and wasting controlled substances
- Reduce the time required for pharmacy staff to investigate discrepancies and potential diversion events

**Data provided by Middlesex Hospital 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

Middlesex Health, a Mayo Clinic Care Network member, is a fully connected, comprehensive network of expert health care providers in Middletown, Connecticut, serving Middlesex County and the Connecticut state shoreline. At the heart of this network is Middlesex Hospital, with 275 licensed beds, which provides inpatient medical, surgical, and emergency services, as well as vital outpatient care, including diagnostic, rehabilitation, behavioral health, disease management, radiology, laboratory, cancer care, home care, wound and ostomy care, surgical services, urgent care, and an extensive network of primary care practices.

To support its clinical operations and medication stewardship goals, Middlesex Health implemented an integrated set of clinical data analytics and monitoring tools designed to help identify patterns in medication use, monitor dispensing and waste activity, and streamline investigation workflows. These tools use automated analysis and pattern recognition software to surface potential areas of concern in controlled substance handling, reducing the need for time-intensive manual review of disparate reports. By combining clinical data with automated alerts and dashboards, Middlesex Health aimed to free up pharmacy and nursing staff to focus more on direct patient care and safer clinical workflows.

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 produces **Simplist®,** a single-unit-dose prefilled syringe platform. Designed for efficient medication delivery and ease of use, Simplist may help reduce waste potential and eliminate steps where errors can occur.[1,2]

The Challenge

> *"In every organization, drug diversion is a potential threat to patient safety. Risks to patients include inadequate pain relief and exposure to infectious diseases from contaminated needles and drugs, compounded by impaired performance. Furthermore, diversion may cause undue suffering to patients who don't receive analgesic relief, can be costly to an organization by damaging its reputation, and may lead to major civil and criminal monetary penalties."*
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> Drug Diversion and Impaired Health Care Workers: April 2019[3]

In response to the opioid crisis, hospitals across the country are taking a more strategic approach to opioid stewardship. Doing so better ensures the safe and effective use of opioid drugs—not only reducing potential patient safety issues but also potential opportunities for drug diversion.

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While pain management remains an important part of treating patients, the use of narcotics presents a number of operational challenges. Research studies indicate that roughly 10 percent of American healthcare workers abuse controlled substances, a number that matches the abuse rate within the general population.[4] Several high-profile cases of drug diversion at U.S. hospitals have resulted in costs adding up to millions of dollars. As a result, an increasing number of hospitals are now implementing narcotic diversion platforms, leveraging the power of analytics, to identify potential diversion patterns in the ordering, dispensing, and wasting of narcotics within the institution. The goal is simple: to ensure controlled substances are used appropriately — and, equally important, to quickly identify potential diversion events.

Advanced diversion analytics programs can analyze narcotic use records to quickly identify potential diversion through pattern recognition informed by historical diversion events, reducing the need for pharmacy staff and nursing supervisors to manually review multiple reports. These systems also provide visibility into the volume of narcotic waste — an operational metric that is often correlated with increased diversion risk and inefficiencies in medication handling.

> *"One of the biggest challenges we face is reconciliation of opioid waste. We work hard to make sure that we're checking all the boxes and investing in high impact projects that can help support our opioid stewardship. But we were spending a lot of time looking for discrepancies in waste reporting that could be better spent elsewhere."*
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> Jason Zybert — Director of Pharmacy at Middlesex Hospital

Zybert also noted that controlled substance waste at Middlesex Hospital required significant nursing hours. Two nurses are required to be present to document any waste, but even so, it's well known that such wasting events can increase opportunities for diversion.[3]

The Solution

As noted in the *ASHP Guidelines on Preventing Diversion of Controlled Substances, August 2022*,[5] "Policies and procedures should define how waste will be accounted for, tracked, and disposed of to prevent unauthorized access. To minimize waste, 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."

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To enhance narcotic stewardship and operational efficiency, Middlesex Health adopted a combination of automated analytics and clinical workflow tools to identify usage patterns and potential discrepancies in controlled substance handling.

Key elements of the solution included:

- Implementing data analysis software that continuously reviews dispensing and waste records to identify anomalous patterns and potential risk areas, reducing the need for manual reconciliation and repetitive reporting tasks.
- Integrating automated reporting and alert systems that notify pharmacy and nursing leadership about unusual trends or outliers in medication dispensing, facilitating faster investigation and resolution.
- Combining these software capabilities with the deployment of ready-to-administer prefilled syringes sized to more closely match common clinical dosing practices. By better aligning product sizes with everyday use, the hospital reduced unnecessary preparation and waste — and in turn, minimized opportunities for handling errors and diversion.

In 2018, Middlesex Hospital introduced Dilaudid® (HYDROmorphone HCl) Injection, USP 0.5 mg per 0.5 mL Simplist syringes. When Simplist Fentanyl Citrate Injection, USP 50 mcg per 1 mL was released in 2021, Middlesex Hospital also switched to these syringes to support their efforts to curtail narcotic waste. These combined efforts aligned with professional guidelines recommending the use of ready-to-use formats and data-driven monitoring to both improve efficiency and prevent controlled substance misuse.

"We wanted to implement solutions that could help us better match our clinical practice while also helping to reduce waste, reduce nursing time, and reducing our overall diversion risk," said Zybert.

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)
Advise pregnant women using opioids for an extended period of time of the risk of Neonatal Opioid Withdrawal Syndrome, 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 implementing the integrated analytics and workflow enhancements alongside ready-to-administer prefilled syringes, Middlesex Hospital observed significant improvements in narcotic stewardship and operational performance.

Reduction in narcotic waste:
By optimizing product presentation and using analytics to refine workflows, the hospital reduced hydromorphone waste by approximately **85%** and fentanyl waste by approximately **55%** compared with prior periods.

Estimated cost savings:
Using the financial framework demonstrated in *A Continuous Observation Workflow Time Study to Access Intravenous Push Waste (2020)*[2], Middlesex Health estimated $46,309.88 in annual savings from reduced narcotic waste costs.

WASTE DATA OBSERVED: PRODUCT OPTIMIZATION OPPORTUNITIES

Hydromorphone Before	
Days Observed	183
Wastes Per Day	56.15
Waste Events	**10,276**

Hydromorphone After	
Days Observed	153
Wastes Per Day	8.3
Waste Events	**1,271**

Fentanyl Before	
Days Observed	364
Wastes Per Day	9.53
Waste Events	**3,470**

Fentanyl After	
Days Observed	358
Wastes Per Day	4.3
Waste Events	**1,538**

"Having the product sizes that better matched our clinical practice helped us reduce waste and make a big impact throughout our stewardship program," said Zybert.

Time savings for clinical staff:
The reduced waste and streamlined reporting saved an estimated **410 nursing hours annually,** freeing nursing staff to spend more time on direct patient care rather than on administrative tasks.

Improved operational workflows:
Nursing and pharmacy teams reported more efficient processes, driven by reduced preparation requirements and simplified documentation for controlled substance handling.

"Our nurses like the product because it's ready to use. They don't have to draw from a vial to administer the medication. They can just pull it out of the packaging and have the medication ready. And, my opinion is when you can reduce waste, you decrease the risk of diversion," Zybert said. **"On the pharmacy side, we see benefits in the tamper-evident packaging, especially when diversion is suspected. It makes it much clearer whether something has happened with an individual product or something else may be going on."**

Overall, by focusing on maximizing opioid stewardship through data review and waste reduction, Middlesex Hospital improved its operations and reduced the time nursing and pharmacy staff spent documenting and handling it.

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

CONTRAINDICATIONS
DILAUDID INJECTION is contraindicated in patients with:
- Significant respiratory depression.
- Acute or severe bronchial asthma in an unmonitored setting or in absence of resuscitative equipment.
- Known or suspected gastrointestinal obstruction, including paralytic ileus.
- Known hypersensitivity to hydromorphone, hydromorphone salts, sulfite-containing medications, or any other components of the product.

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

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

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

WARNINGS AND PRECAUTIONS

- 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.
- Life-Threatening Respiratory Depression in Patients with Chronic Pulmonary Disease or in Elderly, Cachectic, or Debilitated Patients: Monitor closely, particularly during initiation and titration.
- Adrenal Insufficiency: If diagnosed, treat with physiologic replacement of corticosteroids, and wean patient off of the opioid.
- Severe Hypotension: Monitor during dosage initiation and titration. Avoid use of DILAUDID INJECTION in patients with circulatory shock.
- Risks of Use in Patients with Increased Intracranial Pressure, Brain Tumors, Head Injury, or Impaired Consciousness: Monitor for sedation and respiratory depression. Avoid use of DILAUDID INJECTION in patients with impaired consciousness or coma.
- DILAUDID INJECTION contains sodium metabisulfite. There is a risk of anaphylactic symptoms and life-threatening asthmatic episodes in susceptible people.

ADVERSE REACTIONS
Serious adverse reactions associated with DILAUDID INJECTION include respiratory depression and apnea and, to a lesser degree, circulatory depression, respiratory arrest, shock, and cardiac arrest.

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

Opioid-induced esophageal dysfunction (OIED): Cases of OIED have been reported in patients taking opioids and may occur more frequently in patients taking higher doses of opioids, and/or in patients taking opioids longer term

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. Toxic leukoencephalopathy has been reported after opioid overdose and can present hours, days, or weeks after apparent recovery from the initial intoxication.

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. For clinically significant respiratory or circulatory depression secondary to hydromorphone overdose, administer an opioid overdose reversal agent such as naloxone or nalmefene. Because the duration of opioid reversal is expected to be less than the duration of hydromorphone in DILAUDID INJECTION, carefully monitor the patient until spontaneous respiration is reliably reestablished.

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, misuse, overdose, and death, which can occur at any dosage or duration, and persist over the course of therapy, reserve opioid analgesics, including DILAUDID INJECTION for use in patients for whom alternative treatment options are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.

Do not rapidly reduce or abruptly discontinue DILAUDID INJECTION in patients who may be physically dependent on opioids

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

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

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.
- 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.

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

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