FRESENIUS KABI

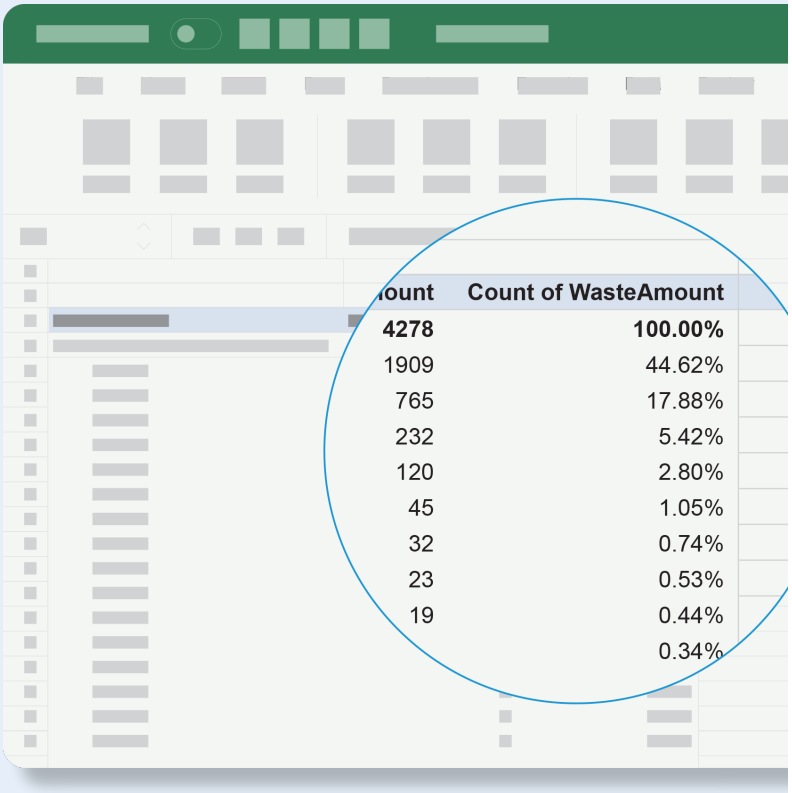
For Pharmacists

Identifying Intravenous Push Waste Transactions in Your Institution

How to use Microsoft Excel to analyze Automated Dispensing System (ADS) data

Learn to:

- ☐ Download reports from your automated dispensing system
- ☐ Use Microsoft Excel to identify waste practices and opportunities to optimize product selection
- ☐ Identify automated dispensing cabinets with the most waste transactions

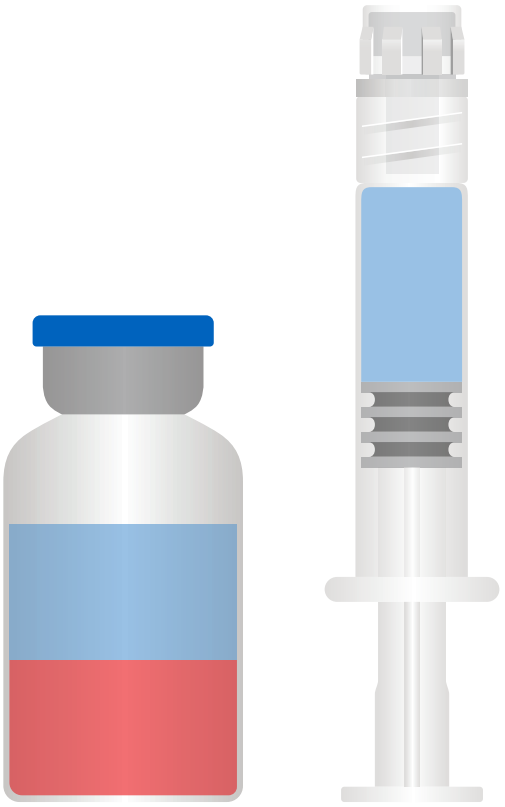


Scan the QR code to watch the tutorial video

www.simplist-us.com/waste-analysis-tutorial

Introduction

Benefits of optimizing product size, taking special note to match product availability that closely aligns with commonly ordered doses of controlled substances include:



Less product waste

Less turnover of controlled substance waste disposal systems

Less time wasted

Less pharmacy time devoted to reconciling discrepancies and waste, and less nursing time devoted to wasting process

Less diversion risk

Fewer waste events, which helps minimize the risk of diversion

Common dose

Excess drug waste

Illustration above is for demonstration purposes only and not representative of all vial and syringe sizes.

Use the table below to determine which waste events you may eliminate by matching product size to your practice.

Opportunities to reduce waste transactions		
Current Product	**Waste Amount**	**Optimal Product Size**
Fentanyl 100 mcg per 2 mL	50 mcg	Fentanyl 50 mcg per 1 mL
Hydromorphone 0.5 mg per 0.5 mL	0.3 mg	Hydromorphone 0.2 mg per 1 mL
Hydromorphone 1 mg per 1 mL	0.5 mg	Hydromorphone 0.5 mg per 0.5 mL
Hydromorphone 1 mg per 1 mL	0.8 mg	Hydromorphone 0.2 mg per 1 mL
Hydromorphone 2 mg per 1 mL	1.8 mg	
Hydromorphone 2 mg per 1 mL	1.5 mg	Hydromorphone 0.5 mg per 0.5 mL
Hydromorphone 2 mg per 1 mL	1 mg	Hydromorphone 1 mg per 1 mL
Morphine 4 mg per 1 mL	2 mg	Morphine 2 mg per 1 mL

In the following example we analyze waste from Fentanyl 100 mcg per 2 mL injection.

For hydromorphone and morphine you will want to analyze the products seen in this table and the corresponding waste amounts. If you don't use all of these strengths, you can eliminate those from your analysis.

Exporting an automated dispensing system report

To start, you will need to export a report from your automated dispensing system. To download the report, follow these instructions:

Pyxis

Report needed: **Waste Activities**

Located in BD Knowledge Portal, under the Audit tab

- Run for 90-180 days worth of data
- Download as a CSV
- Open CSV file in Excel, and save it as an Excel workbook

  The Excel workbook will enable you to create multiple worksheets to summarize large amounts of data

Omnicell

Report needed: **Transaction Details by Item**

Located in Omnicenter, under the reports tab

- Click the select button under **Date Range** to choose the desired date range; 90–180 days of data is recommended
- Change your report filter to waste transactions only
- Export as Excel document

These systems occasionally update their reports. If you are unable to find the report using these instructions, look for a report that includes all waste transactions and the amount of drug wasted.

Dilaudid® (HYDROmorphone HCl) Injection, USP

WARNING: ADDICTION, ABUSE, AND MISUSE; LIFE-THREATENING RESPIRATORY DEPRESSION; NEONATAL OPIOID WITHDRAWAL SYNDROME; and RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS

Fentanyl Citrate Injection, USP

WARNING: RISK OF ADDICTION, ABUSE, AND MISUSE; LIFE- THREATENING RESPIRATORY DEPRESSION; CYTOCHROME P450 3A4 INTERACTION; and RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS

Morphine Sulfate Injection, USP

WARNING: ADDICTION, ABUSE, AND MISUSE; LIFE-THREATENING RESPIRATORY DEPRESSION; NEONATAL OPIOID WITHDRAWAL SYNDROME; AND RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS

Step 1

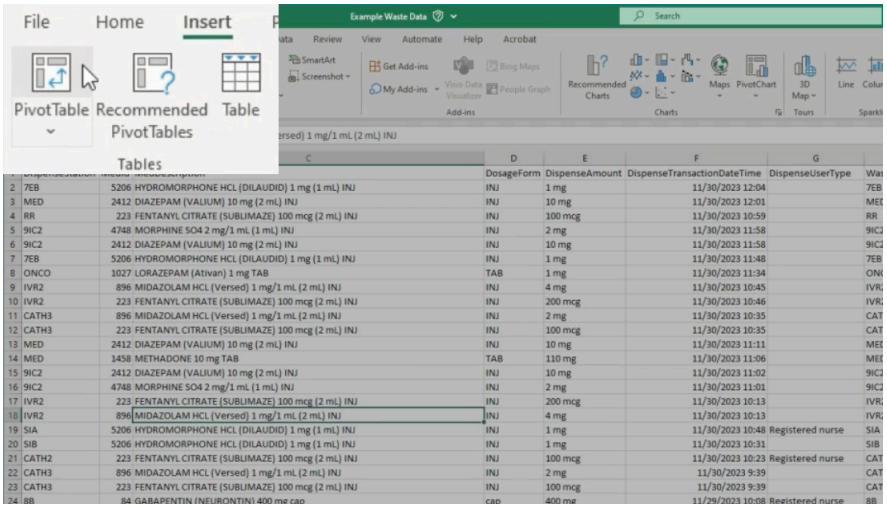
Insert a Pivot Table

Now that you have your raw data in an Excel workbook, you will insert a Pivot Table.

To do this, click on any cell within the data set and then navigate to the **Insert** tab.

Under the Insert tab, select **PivotTable** to summarize the information in the worksheet.

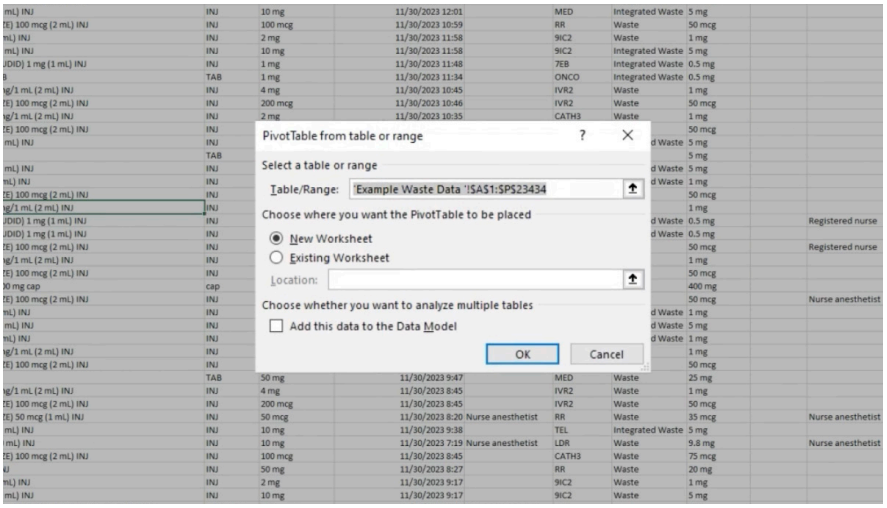
Note: If you're using an earlier version of Excel, **PivotTables** may be under Table or Data along the top navigation rather than **Insert**.



A **Create PivotTable** dialog box will appear.

Table/Range is pre-populated showing that you have selected the entire data set.

For where to place your PivotTable select **New worksheet** and click **OK**.



Step 2

Edit Your Pivot Table Fields

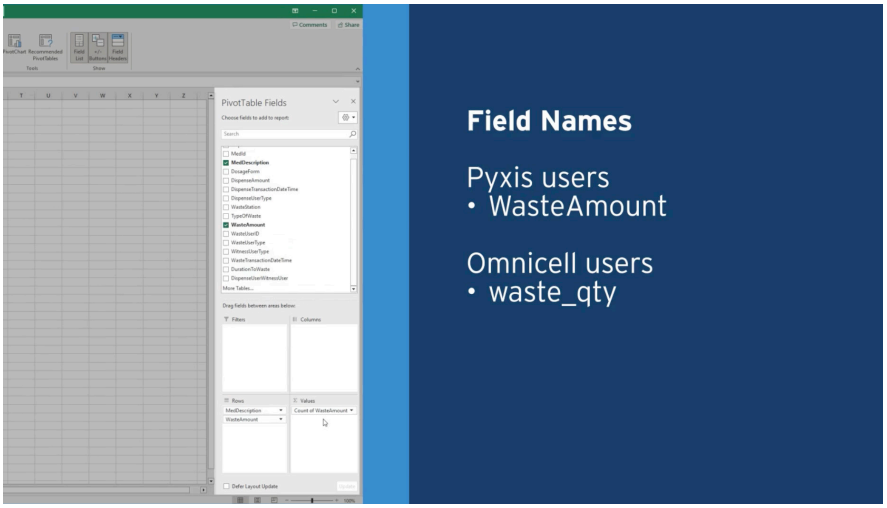
You will notice a **PivotTable Fields** pane where you can edit and customize your pivot table. In this pane, you select the appropriate data headers to manipulate the data by dragging and dropping any of your existing table fields into one of the four fields in the pane.

First, select the **MedDescription** field name and drag it down into the **Rows** field.

Next, select the **WasteAmount** field name and drag it down into the **Rows** field.

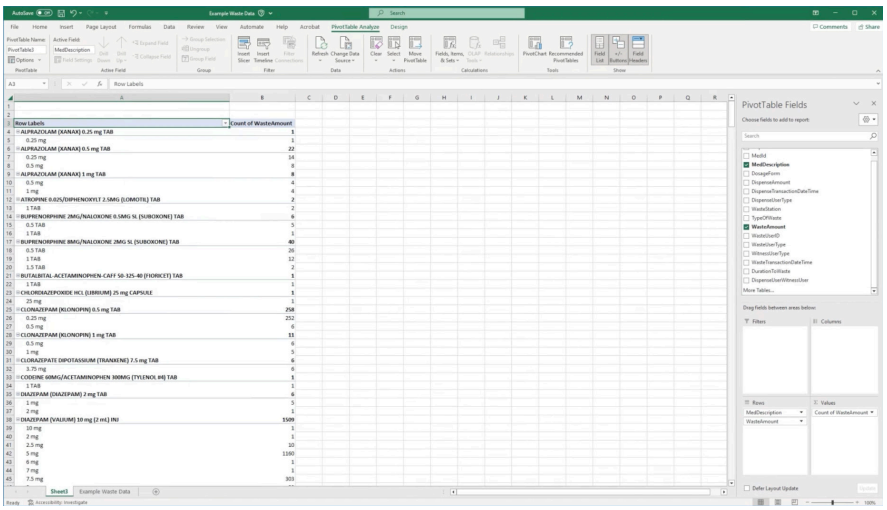
Then, select the **WasteAmount** field name again and drag it down into the **Values** field.

Please note, this example uses Pyxis data. The table shows the corresponding Omnicell fields needed.



Adding the **WasteAmount** in the **Values** field will calculate the frequency of different waste amounts.

Now, you can see the different waste amounts for each drug and how often they occur.



Step 3

Filter Drug Name & Waste Amount

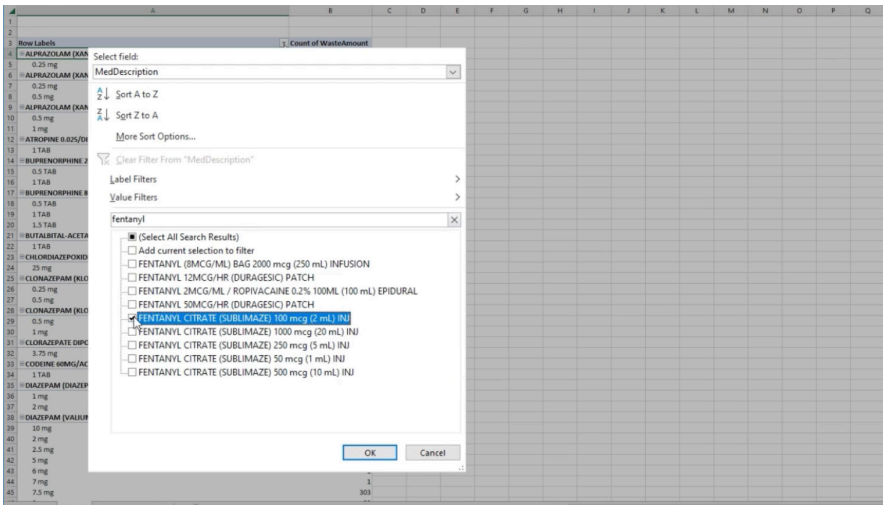
In this example, we are looking for fentanyl 100 mcg per 2 mL products.

First, click the dropdown arrow for the **Row Labels** column.

Then, search fentanyl. Deselect all products except fentanyl 100 mcg per 2 mL.

The drug naming conventions may vary in your system, so search for either 50 mcgs per mL and then a 2 mL injection. The drug name may be listed as the total drug strength. In this case, it's the fentanyl 100 mcg per 2 mL.

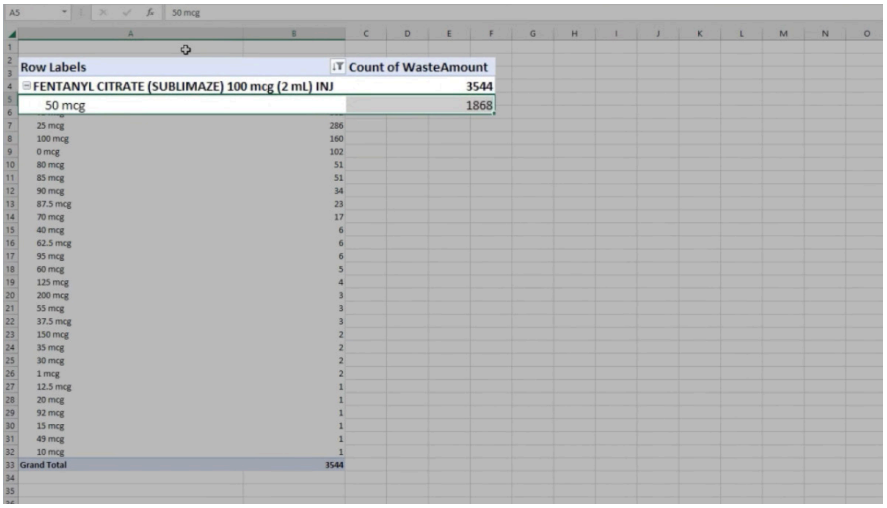
Once you have selected the appropriate drug, hit **OK**.



Now you can see a list of waste amounts sorted from smallest to largest.

To sort the list in order of the waste amount happening most frequently, right-click the cell in the **Count of WasteAmount** column and select **Sort** followed by **Sort Largest to Smallest**.

The waste amount that occurs most frequently is at the top; in most cases, it is 50 mcgs.



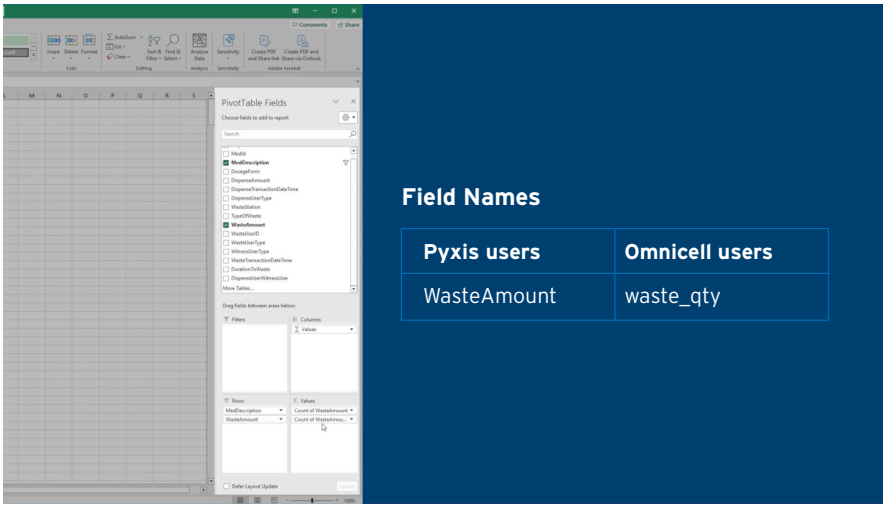
We are looking for a waste amount of 50 mcg, which would indicate that the dose was 50 mcg. Since there is a 50 mcg per 1 mL product on the market, using a 50 mcg product here theoretically could eliminate all of these waste transactions because the ordered dose matches the product being dispensed.

Step 4

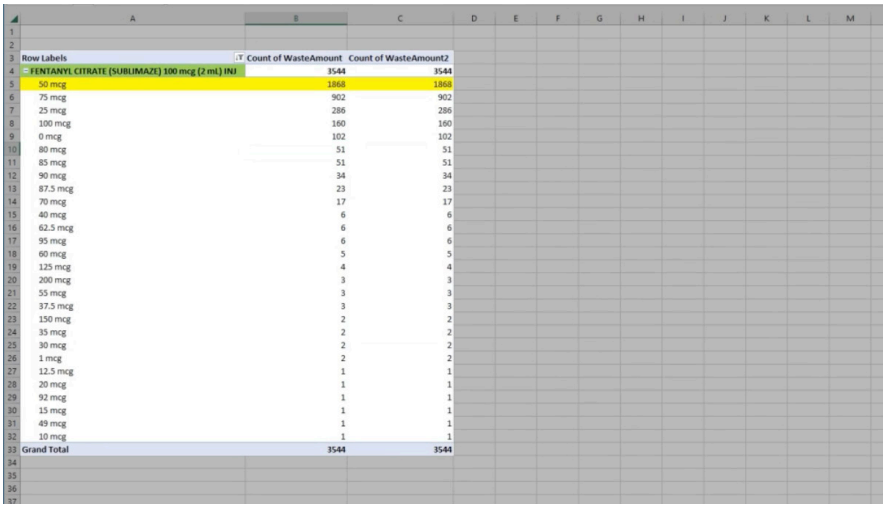
Calculate Percentage of Waste Transactions

One additional value that is beneficial to know is the percentage of all waste transactions 50 mcgs represents.

To calculate the percentage represented by 50 mcgs, return to the Pivot Table Fields, select the **WasteAmount** from the Field Name list, and drag it to the **Values** field.



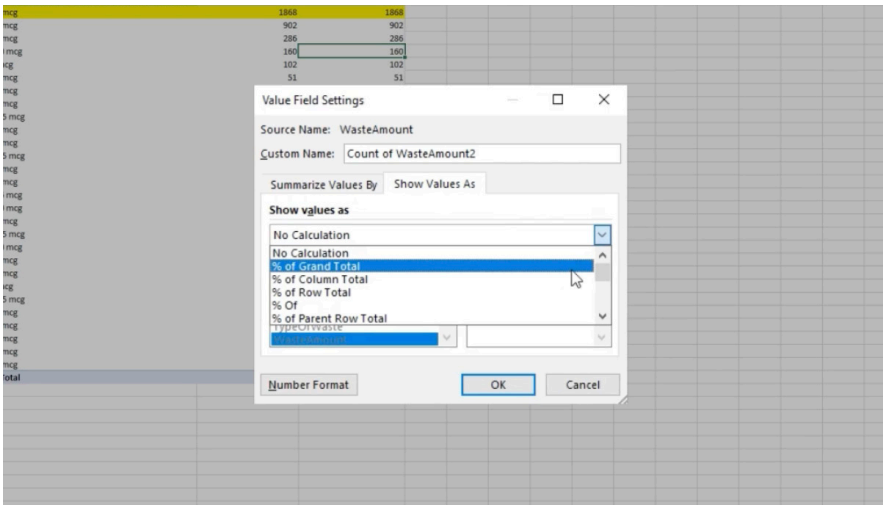
You now have a new column that duplicates what you already have.



Row Labels	Count of WasteAmount	Count of WasteAmount2
FENTANYL CITRATE (SUBLIMAZE) 100 mcg (2 mL) INJ	3544	3544
50 mcg	1868	1868
75 mcg	902	902
25 mcg	286	286
100 mcg	160	160
0 mcg	102	102
80 mcg	51	51
85 mcg	51	51
90 mcg	34	34
87.5 mcg	23	23
70 mcg	17	17
40 mcg	6	6
62.5 mcg	6	6
95 mcg	6	6
60 mcg	5	5
125 mcg	4	4
200 mcg	3	3
55 mcg	3	3
37.5 mcg	3	3
150 mcg	2	2
35 mcg	2	2
30 mcg	2	2
1 mcg	2	2
12.5 mcg	1	1
20 mcg	1	1
92 mcg	1	1
15 mcg	1	1
49 mcg	1	1
10 mcg	1	1
Grand Total	3544	3544

Step 4 continued

To see what the waste events represent as a percentage, go to the new column added, right-click one of the value cells, and select **Value Field Settings**. In the dialog box, choose **Show Values As**, select **% of Grand Total** from the dropdown, and click **OK**.

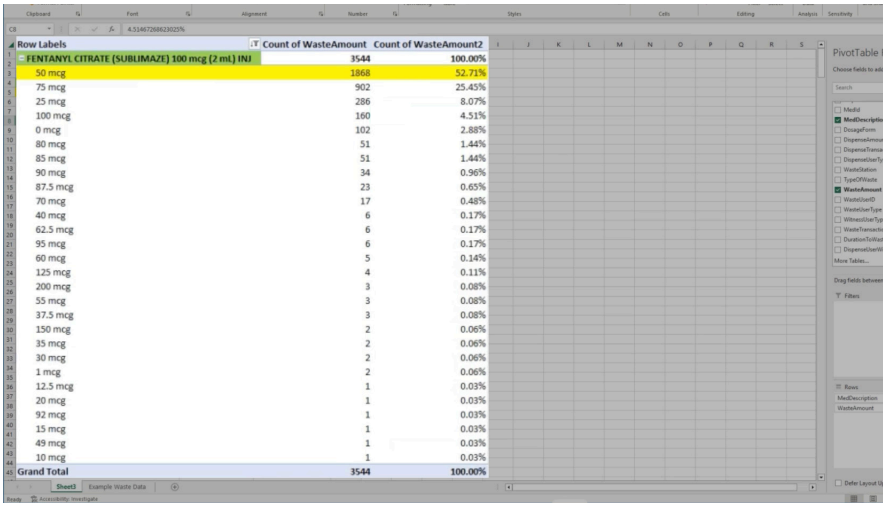


The field has been updated to display the percentage of each waste transaction compared to the total amount. Within the given time frame, there were 3,544 waste transactions in total.

Out of those, the 50 mcg waste transactions accounted for 52.71% of all the transactions.

Waste transactions can be eliminated by using products that more closely align with clinical practice.

In this example, using a 50 mcg per 1 mL syringe may eliminate 52.71% of the waste generated by the 100 mcg product.



Row Labels	Count of WasteAmount	Count of WasteAmount2
FENTANYL CITRATE (SUBLIMAZE) 100 mcg (2 mL) INJ	3544	100.00%
50 mcg	1868	52.71%
75 mcg	902	25.45%
25 mcg	286	8.07%
100 mcg	160	4.51%
0 mcg	102	2.88%
80 mcg	51	1.44%
85 mcg	51	1.44%
90 mcg	34	0.96%
87.5 mcg	23	0.65%
70 mcg	17	0.48%
40 mcg	6	0.17%
62.5 mcg	6	0.17%
95 mcg	6	0.17%
60 mcg	5	0.14%
125 mcg	4	0.11%
200 mcg	3	0.08%
55 mcg	3	0.08%
37.5 mcg	3	0.08%
150 mcg	2	0.06%
35 mcg	2	0.06%
30 mcg	2	0.06%
1 mcg	2	0.06%
12.5 mcg	1	0.03%
20 mcg	1	0.03%
92 mcg	1	0.03%
15 mcg	1	0.03%
49 mcg	1	0.03%
10 mcg	1	0.03%
Grand Total	3544	100.00%

Step 5

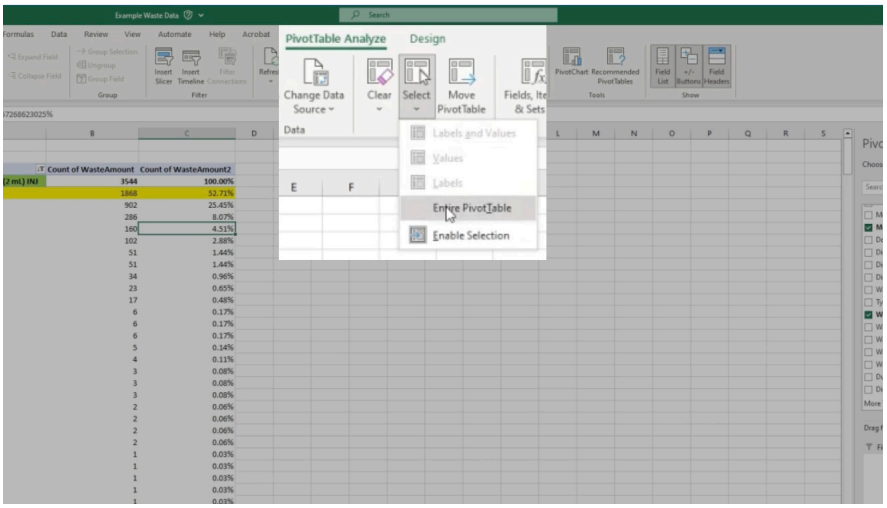
Identify Waste at the Cabinet Level

To utilize this data to create an inventory implementation plan for your new products, you will want to determine where this waste is happening in your hospital.

First, let's select the entire pivot table and copy it.

To copy an entire PivotTable, select anywhere within the PivotTable and then go to the **PivotTable Analyze** tab. From the **Select** dropdown, choose **Entire PivotTable**. Once the Pivot Table is selected, use **Ctrl** + **C** to copy and **Ctrl** + **V** to paste anywhere on the sheet.

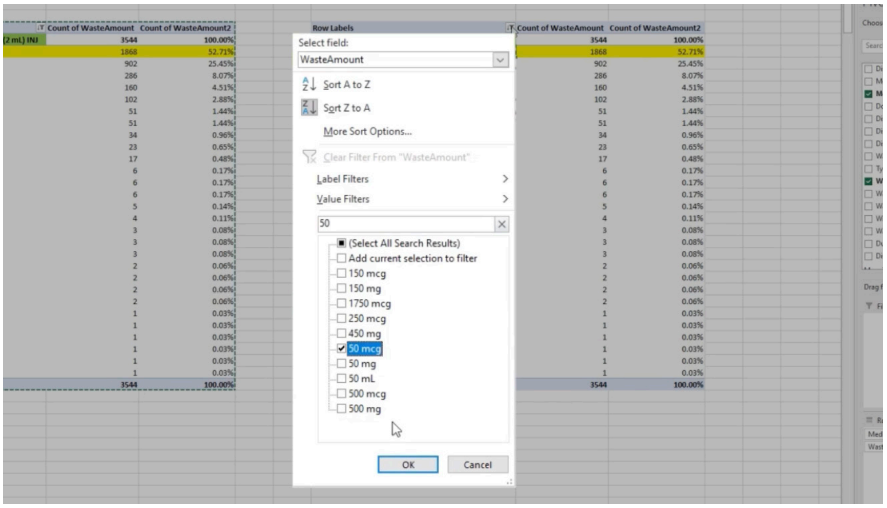
Note: To expand columns, double-click between each.



Next, you should filter the data in the copied table to focus only on transactions that involve 50 mcgs and identify where they occurred within the hospital.

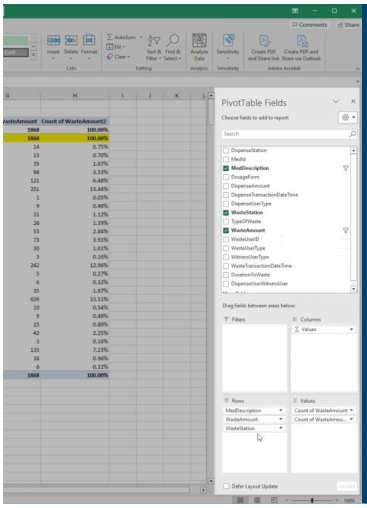
To do this, select a cell in the **WasteAmounts** column and apply a filter.

Then, deselect all options except the 50 mcgs to view the relevant data.



To identify where this waste is occurring, return to your **PivotTable Fields**.

Select **WasteStation** and drag it into the **Rows** section.

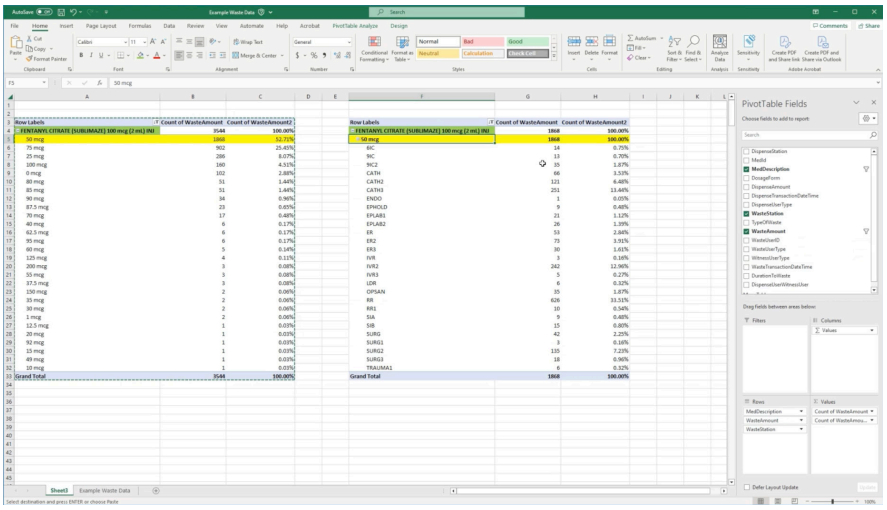


Field Names

Pyxis users	Omnicell users
WasteStation	omni_stid

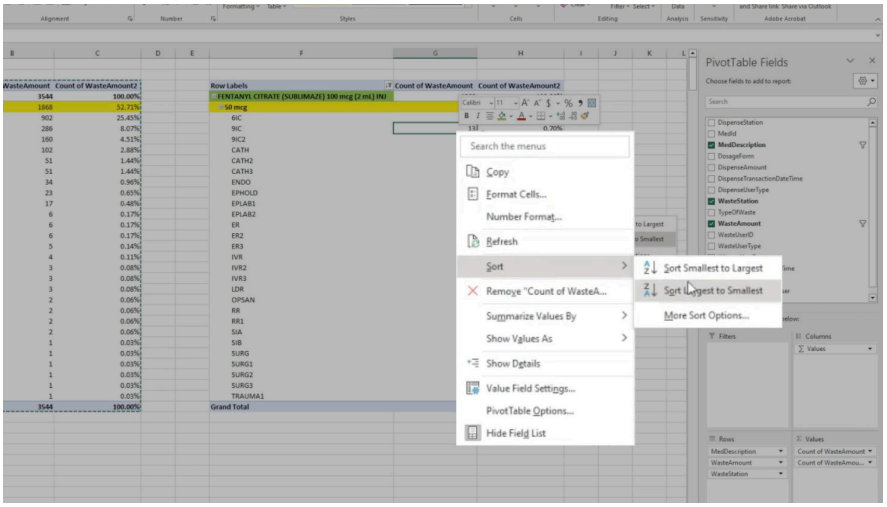
Step 5 continued

You will now see the cabinet locations within the hospital where you use a 50 mcg dose.



Next, you need to sort the values to identify the areas with the most significant impact to help you operationalize a change in your hospital.

To view waste events by areas of impact, right-click on the **Count of Waste** column, choose **Sort**, and then select the **Largest to Smallest** option.

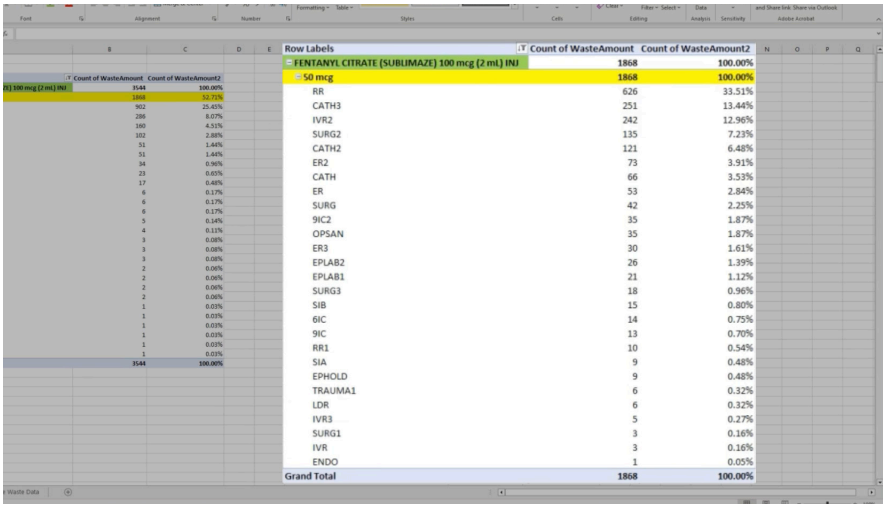


By doing this, you will be able to see where transactions with 50 mcgs of waste occur more frequently.

You can see that 1,868 is a portion of the Total Waste Transactions from that fentanyl 100 mcg.

We then take those 1,868 Waste Transactions and break them down to the cabinet level to identify where the waste occurs.

You can use this information to help you decide what you want par levels to be for your new product.



Row Labels	Count of WasteAmount	Count of WasteAmount2
FENTANYL CITRATE (SUBLIMAZE) 100 mcg (2 mL) INJ	1868	100.00%
50 mcg	1868	100.00%
RR	626	33.51%
CATH3	251	13.44%
IVR2	242	12.96%
SURG2	135	7.23%
CATH2	121	6.48%
ER2	73	3.91%
CATH	66	3.53%
ER	53	2.84%
SURG	42	2.25%
9IC2	35	1.87%
OPSAN	35	1.87%
ER3	30	1.61%
EPLAB2	26	1.39%
EPLAB1	21	1.12%
SURG3	18	0.96%
SIB	15	0.80%
6IC	14	0.75%
9IC	13	0.70%
RR1	10	0.54%
SIA	9	0.48%
EPHOLD	9	0.48%
TRAUMA1	6	0.32%
LDR	6	0.32%
IVR3	5	0.27%
SURG1	3	0.16%
IVR	3	0.16%
ENDO	1	0.05%
Grand Total	1868	100.00%

Step 5 continued

To extrapolate these waste transactions into an annualized estimate you can use the following calculation.

Waste Transactions Calculation

(**Waste Transactions** ÷ **Data Set Time Frame**) × 365 days per year =
Annualized Waste Transaction Calculation

Fentanyl Example Reviewed

(**1,868 transactions** ÷ **183 days**) × 365 days per year =
3,726 transactions per year

You can also determine nursing time associated with this waste with the following calculation.

This calculation only accounts for one nurse. To account for the waste witness you can double this time.

Nursing Time Calculation

(**Annualized Waste Transaction Calculation** × 76.2 seconds*) ÷ 3,600 =
Nursing Time Associated with Waste (Hours)

Fentanyl Example Reviewed

(**3,726 transactions** × 76.2 seconds) ÷ 3,600 =
79 Hours**

* 76.2 seconds is based on Nursing staff time associated with the wasting process from the Hertig study: Hertig J, Jarrell K, Arora P, et al. A Continuous Observation WorkflowTime Study to Assess Intravenous Push Waste. Hospital Pharmacy. Hosp Pharm. 2021;56(5):584-591

**To account for waste witness you can double this time.

Important Safety Information

Dilaudid® (HYDROmorphone HCl) Injection, USP

IMPORTANT SAFETY INFORMATION

WARNING: ADDICTION, ABUSE, AND MISUSE; LIFE-THREATENING RESPIRATORY DEPRESSION; NEONATAL OPIOID WITHDRAWAL SYNDROME; and RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS

Addiction, Abuse, and Misuse
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 DILAUDID INJECTION and monitor 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. Monitor for respiratory depression, especially during initiation of DILAUDID INJECTION or following a dose increase.

Neonatal Opioid Withdrawal Syndrome
Prolonged use of DILAUDID INJECTION during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated, and requires management according to protocols developed by neonatology experts. If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available.

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.**
- **Limit dosages and durations to the minimum required.**
- **Follow patients for signs and symptoms of respiratory depression and sedation.**

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, even at recommended doses, reserve DILAUDID INJECTION for use in patients for whom alternative treatment options [e.g., non-opioid analgesics or opioid combination products]:

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

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.

Use the lowest effective dosage for the shortest duration consistent with individual patient treatment goals. Individualize dosing based on the severity of pain, patient response, prior analgesic experience, and risk factors for addiction, abuse, and misuse.

Warnings and Precautions:
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: 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.

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.

Pregnancy: May cause fetal harm.

Overdosage: Acute overdose with DILAUDID INJECTION 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, partial or complete airway obstruction, atypical snoring, and death. Marked mydriasis, rather than miosis, may be seen with hypoxia in overdose situations.

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

Fentanyl Citrate Injection, USP

INDICATIONS AND USAGE
Fentanyl Citrate Injection, for intravenous or intramuscular use, 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.

IMPORTANT SAFETY INFORMATION

WARNING: RISK OF ADDICTION, ABUSE, AND MISUSE; LIFE- THREATENING RESPIRATORY DEPRESSION; CYTOCHROME P450 3A4 INTERACTION; and RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS

See full prescribing information for complete boxed warning.

- **Fentanyl Citrate Injection exposes users to risks of addiction, abuse, and misuse, which can lead to overdose and death. Assess patient's risk before prescribing and monitor regularly for these behaviors and conditions**
- **Serious, life-threatening, or fatal respiratory depression may occur. Monitor closely, especially upon initiation or following a dose increase.**
- **Concomitant use with CYP3A4 inhibitors (or discontinuation of CYP3A4 inducers) can result in a fatal overdose of fentanyl.**
- **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 for use in patients for whom alternative treatment options are inadequate; limit dosages and durations to the minimum required; and follow patients for signs and symptoms of respiratory depression and sedation.**

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

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.

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.

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.

Concomitant Use of CNS Depressants: May decrease pulmonary arterial pressure and may cause hypotension. See full prescribing information 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.

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.

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

Morphine Sulfate Injection, USP

IMPORTANT SAFETY INFORMATION

WARNING: ADDICTION, ABUSE, AND MISUSE; LIFE-THREATENING RESPIRATORY DEPRESSION; NEONATAL OPIOID WITHDRAWAL SYNDROME; AND RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS

Addiction, Abuse, and Misuse

Morphine Sulfate 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 Morphine Sulfate Injection, and monitor 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 Morphine Sulfate Injection. Monitor for respiratory depression, especially during initiation of Morphine Sulfate Injection, or following a dose increase. Because of delay in maximum CNS effect with intravenously administered morphine (30 min), rapid IV administration may result in overdosing.

Neonatal Opioid Withdrawal Syndrome

Prolonged use of Morphine Sulfate Injection during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated, and requires management according to protocols developed by neonatology experts. If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available.

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 Morphine Sulfate Injection and benzodiazepines or other CNS depressants for use in patients for whom alternative treatment options are inadequate.**
- **Limit dosages and durations to the minimum required.**
- **Follow patients for signs and symptoms of respiratory depression and sedation.**

INDICATIONS AND USAGE

Morphine Sulfate Injection is an opioid agonist indicated for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

Use the lowest effective dosage for the shortest duration consis¬tent with individual patient treatment goals.

Individualize dosing based on the severity of pain, patient response, prior analgesic experience, and risk factors for addiction, abuse, and misuse. Do not stop Morphine Sulfate Injection abruptly in a physically dependent patient.

Limitations of Use: Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve Morphine Sulfate 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.

Morphine Sulfate Injection is contraindicated in patients with:

- Significant respiratory depression.
- Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment.
- Concurrent use of monoamine oxidase inhibitors (MAOIs) or use of MAOIs within the last 14 days.
- Known or suspected gastrointestinal obstruction, including paralytic ileus.
- Hypersensitivity to morphine.

Warnings and Precautions

Cardiovascular Instability: High doses are excitatory. Have Naloxone Injection and resuscitative equipment immediately available.

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 Morphine Sulfate 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 Morphine Sulfate Injection in patients with impaired consciousness or coma.

Adverse Reactions

The most serious adverse reactions encountered are respiratory depression, apnea, circulatory depression, respiratory arrest, shock and cardiac arrest. Common frequently observed adverse reactions include: sedation, lightheadedness, dizziness, nausea, vomiting, constipation and diaphoresis.

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 Morphine Sulfate Injection if serotonin syndrome is suspected.

Mixed Agonist/Antagonist and Partial Agonist Opioid Analgesics: Avoid use with Morphine Sulfate Injection because they may reduce analgesic effect of Morphine Sulfate Injection or precipitate withdrawal symptoms.

Pregnancy: May cause fetal harm.

Overdosage: Acute overdose with Morphine Sulfate Injection 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, partial or complete airway obstruction, snoring, and death. Marked mydriasis rather than miosis may be seen with hypoxia in overdose.

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

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Please see package insert for full prescribing information at www.simplist-us.com.