



High-Alert Medications: Best Practices

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Note: All dosages given are for adults unless otherwise stated. The information on medications contained in this course is not meant to be prescriptive or all-encompassing. You are encouraged to consult with physicians and pharmacists about all medication issues for your patients.

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Suzan Miller-Hoover, DNP, RN, CCNS, CCRN

Purpose and Objectives

The purpose of *High-Alert Medications: Safe Practices* is to define the process by which the Institute for Safe Medical Practices (ISMP) identifies high-alert medications; discuss how healthcare facilities identify which of these medications are incorporated into the high-alert medication policies, and how safe medication practices effect pharmacy and nursing workflows.

After successful completion of this course, you will be able to:

1. Discuss the purpose for designating medications as high-alert medications.
2. Define the process the ISMP uses to designate high-alert Give examples of recommendations to improve safety with high-alert medications.
3. Discuss the list of high-alert medications and how your institution designates the medications to be handled as high alert medications.

Introduction

The Joint Commission (TJC), the Institute for Safe Medical Practices (ISMP), the Institute for Healthcare Improvement (IHI), and the United States Pharmacopoeia (USP) routinely review and identify medication errors that most often result in injury or death. These findings identify high-risk or high-alert medications which have a heightened risk of patient harm when used in error.

High-alert medications are defined as medications which have the highest risk for causing injury when misused. These medications have narrow therapeutic indexes or small margins of safety; that is, there is a small difference between a therapeutic dose and a harmful dose.

High-alert medications include high and low frequency medications such as insulin, heparin, warfarin, narcotics, sedatives and chemotherapy. In fact, researchers have reported that 2/3 of emergency admissions for adverse medication reactions were related to warfarin, insulin, oral antiplatelet agents and oral hypoglycemic agents (Budnitz, Lovegrove, Shehab, & Richards, 2011).

To enhance patient safety, it is important that healthcare facilities review the ISMP High-Alert Medication List routinely and compare facility based occurrence reports to designate those medications that should be included in the healthcare institutional policy.

Did You Know?

Mistakes may or may not be more common with these drugs; however, the consequences of an error are clearly more devastating to patients.

Check your Knowledge:

True or False

The most commonly designated high-alert medications are rarely used medications.

Answer: False

Rationale: High-alert medications include high and low frequency medications such as insulin, heparin, warfarin, narcotics, sedatives and chemotherapy. In fact, researchers have reported that 2/3 of emergency admissions for adverse medication reactions were related to warfarin, insulin, oral antiplatelet agents and oral hypoglycemic agents (Budnitz, Lovegrove, Shehab, & Richards, 2011).

Why Focus on Reducing Harm from High-Alert Medications

1. High-alert medications are more likely than other medications to be associated with harm
2. The harm leads not only to patient suffering, but also increases healthcare costs
3. Known safe practices can reduce the potential for harm

The Joint Commission, the Institute for Safe Medical Practices, the Institute for Healthcare Improvement, and the United States Pharmacopoeia have joined forces to develop resources for healthcare facilities to decrease preventable harm to patients.

The Institute of Medicine (IOM) Committee on Identifying and Preventing Medication Errors estimates; that, at least 1.5 million preventable adverse drug events (ADEs) occur each year in the United States.

Several studies have identified ADEs as the most frequent single source of health care mishaps, continually placing patients at risk of injury.

Based on a rate of 400,000 ADEs per year in hospitalized patients, the IOM Committee estimated that ADEs accounted for \$3.5 billion (in 2006 dollars) of additional costs incurred by hospitals.

After categorization by type of error and outcome of 317 preventable ADEs in an adverse drug reaction database; the analysis of this data revealed that three categories of drugs accounted for 50% of all reports:

1. Anticoagulants
 - a. Overdose of anticoagulants or insufficient monitoring and adjustments was associated with hemorrhagic events
2. Opioids
 - a. Overdosing or failure to adjust for drug-drug interactions of opiate agonists was associated with somnolence and respiratory depression
3. Insulins
 - a. Inappropriate dosing or insufficient monitoring of insulins was associated with hypoglycemia

(The Institute of Safe Medicine Practice (ISMP), 2012)

The number of ADEs can be reduced significantly by implementing recognized safety measures, such as standardizing and simplifying core medication processes in known high-risk areas, redesigning delivery systems using proven human factors principles, partnering with patients, and creating safety cultures that minimize blame and maximize communication.

The ISMP periodically provides the “ISMP Medication Safety Self-Assessment® for Hospitals”; the latest survey was sent out in 2011. This assessment allows healthcare facilities to voluntarily evaluate the safe medication practices that have been placed into effect. The results, if sent in to the ISMP are compiled, and the individual facilities can compare results.

A copy of the 2011 ISMP Medication Safety Self-Assessment® for Hospitals can be accessed by clicking on the following link:

<https://www.ismp.org/selfassessments/Hospital/2011/pdfs.asp>

Check your knowledge

Reducing the risk of “preventable harm” reaching the patients may be attained by which of the following? Choose all that apply

- A. Standardizing orders
- B. Standardizing procedures
- C. Reducing the number of drug concentrations
- D. Utilizing “just culture” methods when evaluating errors

Answer: All of the above

Rationale: The number of ADEs can be reduced significantly by implementing recognized safety measures, such as standardizing and simplifying core medication processes in known high-risk areas, redesigning delivery systems using proven human factors principles, partnering with patients, and creating safety cultures that minimize blame and maximize communication.

Lists of High-Alert Medications

The Institute for Safe Medical Practices periodically updates a list of medications determined to place patients at a higher risk of harm if the medication is used in error. The list is lengthy and includes categories of medications that are routinely used and those used only in specialized settings; such as anesthetics, chemotherapeutic agents, dialysis solutions, neuromuscular blocking agents, and radiocontrast agents. Additionally, specific medications may be listed due to the dosage utilized in specialty areas, such as Labor & Delivery.

For a printer friendly copy of the latest "ISMP List of High-Alert Medications in Acute Care Settings" click on the link below

<http://www.ismp.org/tools/institutionalhighAlert.asp>

The Institute for Healthcare Improvement, based on data collected from participating hospitals has developed a How-to-Guide which focuses on the following four medications categories:

1. Anticoagulants
2. Narcotics and Opioids
3. Insulins
4. Sedatives

Additionally, the harm caused by these four categories of drugs includes:

1. Bleeding
2. Hypotension
3. Hyperglycemia
4. Delirium
5. Lethargy or over sedation

For the complete "How-To-Guide: Prevent Harm from High-Alert Medications" click on the link below:

<http://www.ihi.org/resources/Pages/Tools/HowtoGuidePreventHarmfromHighAlertMedications.aspx>

2011 ISMP Medication Safety Self-Assessment[®] for Hospitals Results

The results of the 2011 survey were similar to past versions of the survey. Chemotherapy remains the highest rated high-alert medication, while the others listed below moved around in the standings.

The adoption of safety precautions for most of the drugs/classifications of the ISMP High-Alert Medication List increased since the 2007 survey.

MOST Common Drug or Drug Class Treated as High Alert Medications According to the 2011 ISMP Medication Safety Self-Assessment [®] for Hospitals	% of Respondents Identifying as High-Alert
Chemotherapeutic agents, parenteral	93%
Antithrombotic agents	93%
Insulin, IV	93%
Potassium chloride for injection	89%
Insulin, SQ	84%
Neuromuscular blocking agents, such as succinylcholine	83%
Epidural or intrathecal medications	82%
Potassium phosphates injection	80%
LEAST Common Drug or Drug Class Treated as High Alert	% of Respondents

Medications According to the 2011 ISMP Medication Safety Self-Assessment® for Hospitals	Identifying as High-Alert
Sterile Water for injection/inhalation/irrigation (100 mL or greater)	24%
Oral Hypoglycemic agents	31%
Liposomal forms of drugs	38%
Adrenergic antagonist, IV	44%
Dialysis solutions	44%
Radiocontrast agents, IV	46%
Epoprostenol, IV	47%
Promethazine, IV	49%

To view the entire results of the “2011 SMP survey on High-Alert Medications: Differences between nursing, pharmacy, and risk/quality/safety perspectives” click on the following link <http://www.ismp.org/Newsletters/acutecare/showarticle.aspx?id=15>

The ISMP periodically surveys nurses, pharmacists, and risk/quality/safety managers concerning high-alert medications. The survey asks which medications the respondents think should be high-alert medications and which medications the respondents’ facilities have designated as high-alert medications (ISMP, 2012).

It is interesting to note that these professionals do not always agree on what drugs should be considered high risk medications. The reasons for the differences in perception may be that:

1. Nurses may feel more vulnerable to harmful errors, particularly since the pharmacy may not prepare all doses/infusions of these medications, thus requiring nurse preparation. Nurses may also have witnessed transient harm with these drugs in critical care settings, providing greater awareness of the potential for harm associated with these drugs
2. Pharmacists may have greater awareness of the risk of harm associated with errors involving these medications than nurses
3. Quality Management staff often have additional knowledge regarding the drugs that have caused patient harm, which often stems from internal and external error-reporting databases, malpractice claims and judgments, patient complaints, and publications about sentinel

Utilizing a multidisciplinary consensus approach to determining which medications should be listed on the facilities high-alert medication list ensures that all concerns are identified and addressed comprehensively. Additionally, these participants can also help limit the number of medications on the list so as not to encourage “high-risk medication fatigue”.

System Strategies to Prevent Harm Related to High-Alert Medications

The regulatory strategies recommended for decreasing errors include:

1. Limit the concentrations of these medications that are available
2. Stock small vials of high-alert medications
3. Differentiate high-alert medications with warnings, including warnings on automatic dispensing cabinet screens and medication labels, such as NOTE CONCENTRATION
4. Standardize orders that permit use of a limited number of concentrations
5. Standardize protocols for use of reversal agents
6. Limit the possibility of error related to decimal places
 - a. Requiring rounding off whenever possible
 - b. Use leading zeros (.2 should be 0.2)
 - c. Eliminate trailing zeros (0.20 should be 0.2)

7. Institute forcing functions impose requirements that prevent errors
 - a. Stop order entry or programming of a pump when preset limits are exceeded
 - b. Require use of a preprinted height/weight/body surface area chart for ordering chemotherapy
8. Include information about appropriate monitoring parameters in the order sets and protocols
9. Eliminate the need for calculation through use of tables
10. Reduce the number of steps in processes
11. Alert staff members to look-alike/sound-alike medications
 1. Use of FDA and ISMP recommended tall man letters
(www.ismp.org/Tools/confuseddrugnames.pdf)

Did You Know

In 2010, the look-alike/sound-alike requirement from the National Patient Safety Goals (NPSG.02.02.01) was moved to the Joint Commission Standards and can be found at Medication Management standard MM.01.02.01, EP1 (The Joint Commission, 2012).

Did You Know

The TJC National Patient Safety Goals prohibit trailing zeros in medication orders (The Joint Commission (TJC), 2012).

Reporting Medication Errors

In addition to implementing error prevention strategies, it is important to review any medication related incident that happens within the facility. Utilizing the Agency for Healthcare Research and Quality (AHRQ) “just culture” concepts can encourage self-reporting and reporting of medication errors (Agency for Healthcare Research and Quality (AHRQ), 2001). Taking the time to complete a root-cause analysis helps ensure that the system issues are removed from the staff issues and that solutions are found to correct the situation.

During a root-cause analysis time and effort is devoted to finding where the process broke down.

Causes often fall within the following five categories

1. Human Factors
2. Physical Environment
3. Leadership
4. Communication
5. Assessment

Check your knowledge

Can you identify the 3 root-causes of medication errors nurses can have a direct impact on?

1. Human Factors
2. Physical Environment
3. Leadership
4. Communication
5. Assessment

Correct answer: Human factors, communication, and assessment

Rationale: Usually multiple root-causes contribute to a single sentinel event. Nurses can have a direct impact on three of the five root-causes frequently identified in medication-related sentinel events: human factors, communication, and assessment.

Nursing/Pharmacy Strategies to Prevent Harm Related to High-Alert Medications

In addition to system strategies, nursing and pharmacy should institute the following whenever possible:

1. Institute independent double-checks
 - a. Each provider should independently of each other:
 - i. Review the medication order
 - ii. Review the medication label
 - iii. Calculate the dose and rate
 - b. Both providers should:
 - i. Compare results
 - ii. Review medication label
 - iii. Review pump settings for infusion medication
2. Identify patient and medication at bedside
3. Limit verbal orders
4. Heed alarms on automatic medication dispensing cabinets, pumps, and other devices equipped with alarms
7. Utilize smart infusion pump technology
 - a. Guardrails
 - b. Unit or department based drug libraries (e.g. critical care, acute care)
8. Utilize barcoding technology

There is a sense of false security when facilities require a double signature to indicate in the medical record that safety checks for high-alert medications have been completed. In reality, many facilities across the nation realize that this practice of double signatures does not prevent medication errors from happening. Multidisciplinary medication safety teams across the nation are struggling to find a solution that is practical and efficient.

Check Your Knowledge

Independent double checks include which of the following? Choose all that apply.

- A. Double signature
- B. Independently reviewing the order, calculating the dose and rate, reviewing the medication label
- C. Barcode use
- D. Verifying pump settings

Answer: B & D

Rationale: Institute independent double-checks

- a. Each provider should independently of each other:
 - i. Review the medication order
 - ii. Review the medication label
 - iii. Calculate the dose and rate
- b. Both providers should:
 - i. Compare results
 - ii. Review medication label
 - iii. Review pump settings for infusion medication

Can You Help?

In the ideal world there would be enough time and staff for every medication to be independently

double checked. Each smart pump would have every medication and concentration listed. Barcoding would be available and work correctly every time. Double signatures would truly indicate that the medication was checked and given to the right patient, at the right time, in the right dose etc.

However this world we work in is not the ideal world, and we are short staffed, are caring for sicker patients, new medications are continuously being introduced, barcoding is not always available, smart pumps do not have enough memory for every drug and every concentration we use.

Do you have a system that works? Do you have suggestions to make the work flow more efficient? Do you have a low ADE rate?

If you do, share it! Help find the solution to thwarting preventable harm reaching patients.

High-Alert Medications

The latest ISMP survey identified the following drugs/drug categories as the high-alert medications that are most commonly on facility high-alert medication lists across the nation.

Chemotherapeutic agents, parenteral
Antithrombotic agents
Insulin, IV
Potassium chloride, IV
Insulin, SQ
Neuromuscular blocking agents, such as succinylcholine
Epidural or intrathecal medications
Potassium phosphates, IV

Recommendations for High-Alert Medication Safety

1. Utilize written evidence-based policy and protocols
2. Utilize evidence-based standardized order sets
3. Utilize independent double-checks
4. Use oral unit-dose, prefilled syringes and pre-mixed IV preparations
5. Use products specifically designed for children
6. Prepare all medications in the pharmacy
7. Utilize pharmacy run drug monitoring programs
8. Spell out unit of measure or use hospital approved abbreviations
 - a. mL instead of cc
 - b. unit instead of u
9. Utilize tall man lettering
10. Use smart technology infusion pumps
11. Label tubing and pumps
12. Verify medication, pump, and tubing to vascular access with change of caregiver
13. Utilize age-appropriate pain and sedation scales
14. Provide patient and family education that includes:
 - a. The importance of follow-up monitoring
 - b. Compliance
 - c. Drug-food interactions
 - d. The potential for adverse drug reactions and interactions

(TJC, 2011; IHI, 2012)

Case Study 1

On an acute care floor a postoperative patient was admitted after surgery. The postoperative management of this patient included the use of a PCA pump delivered medication. The facility's policy required that two licensed staff members independently double check the orders, medication, and pump programming.

The MD ordered

- Fentanyl PCA
- 50 mcg/mL concentration
- 10 mcg demand dose
- 6-minute lockout interval
- Clinician boluses of 20 mcg every 5 minutes X 3, repeat every 4 hours as needed

Two nurses were present when the nurse began programming the pump
However, one left to take a telephone call.

The patient nurse programmed:

- Concentration: 1 mcg/mL
- Demand dose: 0.10 mcg

1. Did you find any "process" errors?
 - a. Two nurses were present at the beginning but one left the room
2. Did you find any "nursing" errors?
 - a. The pump settings were programmed incorrectly

The second nurse returned and checked the pump settings and the patient nurse started the medication delivery. No changes in the settings were made. Both nurses signed in the medical record that the double check was done.

The next shift arrived several hours later and the patient complained of being in severe pain with no relief since the PCA was started.

The nurse received orders from the physician to deliver a 20 mcg bolus; which, she did.

1. Did you find any process errors?
 - a. The independent double check was not done multiple times:
 - Between the patient nurse and the second nurse on set-up
 - Between the two nurses at shift change
 - Between two nurses when giving the bolus

Ramifications:

1. The delivered demand dose was 5 mcg not 50 mcg ordered dose
2. The patient remained in severe pain
3. The 20 mcg bolus became a 1000 mcg bolus

- a. The concentration of 1 mcg/mL delivered 20 mL of 50 mcg/mL medication
4. The patient was found unresponsive and transferred to a higher level of care

Case Study 2

A 19-year-old post-surgical patient was admitted to an acute care surgical floor. For pain management, the physician ordered: Morphine 4 to 8 mg IV push every 15 minutes - 2 hours PRN. The policy had just been changed to allow nurses on units outside the critical care areas to administer IV push opioids. The policy gave guidance for vital sign frequency but did not require post IV push pain and sedation evaluation utilizing age-appropriate pain and sedation evaluation tools.

The nurse administered doses in smaller amounts than ordered; however a total of 32 mg of IV morphine was given over a six hour period. After the last dose, the patient was sleeping soundly and snoring lightly.

1. Did you find any “process” errors?
 - a. The order for the morphine was a range order and did not have all the required elements of a safe order.
 - No pain score or evaluation of when to give the medication
 - The order had two sets of ranges with no clear indication of how to decide when to use the two different ranges
 - b. The policy changes did not provide guidance to use pain and sedation scales after each administration of medication
2. Did you find any “nursing” errors?
 - a. The nurse did not clarify the order set
 - b. The nurse gave doses of medication not in the order set

Ramifications:

1. The patient became unresponsive and cyanotic
2. The patient died after an unsuccessful resuscitation attempt

Summary

As with any other skill used by the multidisciplinary healthcare team, competency validation is essential to reducing preventable patient harm. Routinely scheduled competency validation for medication administration with a focus on harm prevention is crucial.

Reviewing policy and procedures to ensure that evidence-based best practices are included,

standardizing concentrations, standardized order sets and protocols are all tantamount to patient safety.

Limiting the number of high-alert medications that require special handling, such as double signatures, can decrease frustration and decrease complacency and work arounds; thus, increasing patient safety.

Does your organization participate in the “ISMP Medication Safety Self-Assessment® for Hospitals”? If not, you should encourage your organization to do so. Learning where gaps exist will help your facility refine practices and reduce preventable patient harm.

Reducing “preventable harm” is essential to safe and effective patient care. Identifying a limited list of “high-alert medications” and developing a system of accountability when administering these drugs will make reducing “preventable harms” a realistic and obtainable goal.

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