High-alert medication list... Relatively useless without risk-reduction strategies

Have you ever watched the 1993 movie, *Groundhog Day*. Bill Murray plays Phil Conners, a television news reporter who finds himself reliving the same day over and over again—a much-hated assignment covering the annual Groundhog Day event in Punxsutawney, PA.

Well, at times it feels like “Groundhog Day” when we hear about the same types of errors happening over and over again. Another patient with diabetes receives a 5-fold overdose of U-500 insulin after a nurse draws the dose into a U-100 syringe, and a double-check by another nurse fails to detect the error. Another hospitalized patient experiencing pain receives an overdose of intravenous (IV) HYDROMORPHINE after a physician prescribes the IV dose in the same amount as the oral dose that the patient had been taking at home; neither the pharmacist nor nurse captures the error. Another woman receives a rapid infusion of magnesium sulfate postpartum instead of oxytocin, despite staff awareness of prior mix-ups.

In many cases, events like these and others continue to happen in hospitals with medications that are on the hospital’s list of high-alert medications. High-alert medications are drugs that bear a heightened risk of causing significant patient harm when they are used in error. Although mistakes may or may not be more common with these drugs, the consequences of an error with these medications are clearly more devastating to patients. This is repeatedly borne out in the literature and by reports submitted to the ISMP National Medication Errors Reporting Program (ISMP MERP). High-alert medications repeatedly top the list of drugs involved in moderate to severe patient outcomes when an error happens.

The Joint Commission has a standard (MM.01.01.03) that requires hospitals to develop their own list of high-alert medications; to have a process for managing high-alert medications; and to implement that process. While most facilities meet the minimum requirements for The Joint Commission (i.e., any list, any process), some hospitals have neither a well-reasoned list of high-alert medications nor a robust set of processes for managing the high-alert medications on their list.

Instead, they have a hastily devised list of high-alert medications, which often are not well known to all clinicians, and they may rely on low-leverage risk-reduction strategies to prevent errors, such as staff education and high-alert medication labels on pharmacy bins. The hospital may also send memos to staff to increase their awareness of the risks or establish strategies that impact only one aspect of the medication use process—usually drug storage. In some cases, there are no safety nets in place at all, and hospitals are relying on staff vigilance to keep patients safe when receiving high-alert medications. In addition, some hospitals have not updated their list of high-alert medications since it was first mandated by The Joint Commission more than 10 years ago. A list of high-alert medications is relatively useless unless it is up-to-date, known by clinicians, and maintained. A list is only as useful as its content, and it is relatively useless without risk-reduction strategies. Continued on page 2—High-alert medication list.

National Nurses Week May 6–12, 2013

On May 6, 2013, the Institute for Safe Medication Practices (ISMP) is joining the American Nurses Association (ANA) in celebrating Delivering Quality and Innovation in Patient Care, as part of National Nurses Week, which is held May 6-12 every year. The purpose of the week-long celebration is to raise awareness of the value of nursing and to help educate the public about the role nurses play in meeting the healthcare needs of the American people.

In honor of the dedication, commitment, and tireless effort of the nearly 4 million nurses nationwide to promote and maintain the health of this nation, the ANA and ISMP are proud to recognize nurses everywhere during this week for the compassionate and quality work they provide 7 days a week, 365 days a year.

Safetywire

Don’t become opioid (misinformation) tolerant.

The Pennsylvania Patient Safety Authority has just published disquieting results of an opioid knowledge assessment of more than 1,700 prescribers, pharmacists, and nurses that uncovered the depth of misinformation surrounding the safe use of opioid medications. The Authority partnered with the Hospital & Healthsystem Association of Pennsylvania and the Pennsylvania Medical Society to develop an 11-question knowledge assessment tool for opioids (available at www.ismp.org/sc?id=173). ISMP and ECRI Institute assisted with this project. The lowest-scoring questions dealt with predictors of respiratory continued on page 2—Safetywire...
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tical staff, and accompanied by robust risk-reduction strategies that are more effective than simple awareness, manual double-checks, staff education, and appeals to “be careful.”

So, what does it mean if a drug is on your hospital’s high-alert medication list? Does the list serve only to increase awareness of the risk of harm with these medications, or has a robust plan been implemented for each drug or drug class to reduce the risk of errors? Hospitals need a well-thought-out list of high-alert medications and effective high-leverage processes to mitigate the risk of errors with these medications.

We encourage hospitals to take the time to reassess their current list of high-alert medications and any plans that have been enacted to reduce the risk of errors and harm with these drugs. To guide this process, please consider the following:

** Develop/Update a Hospital-Specific List

Hospitals need a list of targeted high-alert medications that is comprehensive enough to address the most potentially harmful errors while not being so inclusive that the list is overwhelming. Many hospitals select medications from ISMP’s list of high-alert medications (www.ismp.org/Tools/institutionalhighAlert.asp), which is updated every few years based on error reports submitted to the ISMP MERP, reports of harmful errors in the literature, and input from practitioners and safety experts.

Based on national reports of harm to patients, we believe it is essential for every hospital’s list to include (when used): potassium chloride for injection concentrate, neuromuscular blocking agents, opioids (all, not just patient-controlled analgesia), anticoagulants, insulin, epidural or intrathecal medications, and chemotherapy. Other drugs from the ISMP list should be added if use is prevalent or there is a concern that the medication may not be used correctly.

Other medications to consider adding to the list may include new drugs with the potential to cause significant patient harm that are added to the formulary, potentially harmful drugs used temporarily during a shortage (which can be removed once the shortage is over), and medications involved in potentially harmful errors based on the hospital’s internal reporting process, even if the drug is not on the ISMP list. For example, after fatal wrong route errors were identified as a potential threat with the new drug EXPAREL (bupivacaine [liposomal] used for local anesthesia into surgical sites) due to its similar appearance to propofol, hospitals that added this drug to their formulary should have considered it for addition to their high-alert medication list.

Addressing drugs given by a certain route of administration (e.g., intrathecal, epidural) or in special populations (e.g., pediatrics) as high-alert can be effective as well. The hospital’s high-alert medication list should be updated as needed and reviewed at least every 1-2 years, and approved by the organization’s pharmacy and therapeutics (P&T) committee.

** Implement Risk-Reduction Strategies

The purpose of identifying high-alert medications is to establish safeguards to reduce the risk of errors with these drugs in all phases of the medication use process. The primary goals of implementing risk-reduction strategies are to: 1) prevent errors, 2) make errors visible, and 3) mitigate harm. To be effective, all of these interdisciplinary components are needed:

** Understand the causes of errors.

Effective strategies must address the underlying causes of errors with each type of high-alert medication or class of medications. To learn the causes of errors, review internal medication error-reporting data and the results of any applicable root cause analyses. Equally important, a search of the external literature should be completed to uncover reports of errors.

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depression, the definition of an opioid-tolerant patient, medications that can potentiate the effects of HYDROMorphone, and indications for using long-acting opioids. For example, only 22% of practitioners identified that the patient’s sedation level was the most important predictor of respiratory depression in patients receiving IV opioids; pharmacists scored lowest (16%) and attending physicians scored highest (33%). Only about a quarter (29%) of the participants were able to identify the correct example of an opioid-tolerant patient (patients who have received opioids regularly for approximately 7 days or more); medical residents scored the lowest (24%), and pharmacists scored the highest (41%) although more than half still did not know the correct answer. Only 67% knew that 0.4 mg of HYDROMorphone IV is equianalgesic to morphine 2 mg IV (HYDROMorphone is about 7 times more potent than morphine [www.ismp.org/Tools/Hydromorphone.asp]); pharmacists scored the highest (93%) and nurses (55%) scored the lowest. Only 57% of participants were able to correctly identify that long-acting opioids are indicated only if the patient is opioid-tolerant and has already been receiving an immediate release opioid prior to use. Errors with opioids have led to serious adverse outcomes ranging from failure to control pain to oversedation, respiratory depression, seizures, and death. Based on the results of the opioid knowledge assessment, organizations should consider educating and assessing the understanding of staff who care for patients receiving opioids. Implementing other high-leverage strategies, as mentioned in the feature article to the left on high-alert medications, should also be considered (see Table 1 on pages 4-5).
with high-alert medications that have occurred elsewhere. A failure mode and effects analysis or self-assessment tool also might help identify underlying risks associated with each high-alert medication/class of medications. This important first step should not be skipped—if you can’t describe the ways that errors have happened or could happen with the drug, your strategies may not lessen the risk of an error at all.

**Be sure actions are comprehensive.**
A single risk-reduction strategy for each high-alert medication is rarely enough to prevent harmful errors. The keys to success are as follows:

1) Numerous risk-reduction strategies must be layered together to address the targeted risk.

2) Risk-reduction strategies should impact as many steps of the medication-use process as feasible given the underlying causes (e.g., procuring, storing, prescribing, transcribing, preparing, dispensing, and administering the medication; monitoring the patient; preparing to treat [or recovery from] an adverse event if it occurs).

3) Low-leverage risk-reduction strategies such as staff education, passive information, and the use of reminders should be bundled together with high-leverage risk-reduction strategies such as forcing functions and fail safes, maximizing access to information, limiting access or use, constraints and barriers, standardization, and simplification. Table 1 (on pages 4 and 5) provides a description of key risk-reduction strategies listed roughly in descending order of effectiveness based on human factors.

We highly encourage hospitals to reference this table whenever risk-reduction plans are being developed.

4) To help inform the planning process, the literature should be searched to identify risk-reduction strategies that have been proven effective, recommended by experts, or implemented successfully elsewhere.

5) Strategies need to be applicable in various practice settings (e.g., emergency department, operating room).

6) When implementing strategies, there must be a balance on how resources will be impacted by the change.

7) Strategies must be sustainable over time.

**Assess the Effectiveness of Strategies**

Both outcome and process measures should be established and data should be collected routinely to determine the effectiveness of risk-reduction strategies for high-alert medications. The results should be shared regularly in meetings with pharmacy and nursing leadership, the medication safety committee, the pharmacy and therapeutics committee, and other appropriate committees. Reviewing the effectiveness of safeguards and extending the reach of all your risk-reduction strategies are important to ongoing success within your organization.

**References**


### Table 1. Key Safety Strategies for Safeguarding High-Alert Medications

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<tr>
<th>Key Strategies</th>
<th>Description</th>
<th>Examples</th>
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| **FMEA* & Self Assessments**       | Proactively identify the ways that processes or medication-related equipment can fail, why it might fail, how it might affect patients, and how it can be made safer; assess current systems and practices against best practices | - Perform an FMEA* on a new high-alert medication before initial use  
- Perform an FMEA* on a new infusion pump being considered for purchase (see ISMP FMEA tool: [www.ismp.org/Tools/FMEA.asp](http://www.ismp.org/Tools/FMEA.asp))  
- Perform an FMEA* on a high-risk process associated with medication use  
- Perform an FMEA* on the use of alternative medications during a drug shortage |
| **Forcing Functions & Fail Safes**  | Employ procedures or equipment design features that will:  
- Prevent something from happening until certain conditions are met (forcing function)  
- Prevent malfunctioning or unintentional operation by reverting back to a predetermined safe state if a failure occurs (fail safe) | - Use of oral syringes that cannot be connected to IV tubing ports  
- Use of epidural tubing without ports  
- Use of infusion pump sets with an automatic clamping mechanism to prevent free-flow if the tubing is removed from the pump  
- Engineering features that stop a process from moving forward or require the entry of key information (e.g., allergies) before proceeding |
| **Limit Access or Use**             | Use constraints to restrict access to certain medications or error-prone processes; require special education or conditions for prescribing, dispensing, or administering a particular drug; require special authorization for participation in certain tasks | - Sequester neuromuscular blocking agents in separate containers or a locked-lidded ADC® drawer to limit access  
- Require special education/credentialing for the ordering, preparation, and use of certain high-alert medications (e.g., chemotherapy)  
- Carefully select the drugs, concentrations, and quantities of medications in floor stock/ADCs® (e.g., restrict stock of liquid concentrated oral opioids to certain units)  
- Establish parameters to change IV therapy to oral therapy as soon as possible to limit IV access  
- Limit the administration of certain medications unless certain criteria are met (staffing, monitoring) |
| **Maximize Access to Information** | Use active, not passive, means of providing staff and patients with necessary information at the appropriate time while performing critical tasks | - Use of smart infusion pumps with dose checking software enabled  
- Use of concurrent data monitoring software systems that notify practitioners with critical monitoring information (e.g., labs)  
- Deploy clinical pharmacists in patient care units for immediate consultation when needed  
- Use of electronic prescribing systems with clinical decision support, thus providing immediate warnings if unsafe orders are entered |
| **Constraints & Barriers**         | Use of special equipment or environmental conditions to prevent a hazard from reaching a target | - Use of personal protective equipment to reduce employee exposure to hazards  
- Use of a biologic safety cabinet to prepare chemotherapy  
- Use of a needleless system to administer medications and fluids, or for other procedures involving a potential risk of exposure from contaminated sharps |
| **Standardize**                    | Create clinically sound, uniform models of care or products to reduce variation and complexity | - Employ evidence-based, standard order sets (one for each care process)  
- Standardize concentrations, container sizes, and drugs used to treat specific conditions  
- Use scales that only weigh patients in kg, and document weight only in kg |
| **Simplify**                      | Reduce the number of steps, handoffs, and options without eliminating crucial redundancies | - Use commercially available products instead of preparing solutions  
- Dispense oral and parenteral medications in the most ready-to-use form  
- Use electronic prescribing to eliminate transcriptions  
- Consult dosing charts instead of manually calculating infusion rates |
| **Externalize or Centralize Error-Prone Processes** | Transfer error-prone tasks to an external site or centralized area to help ensure they are completed in a distraction-free environment by those with expertise, with appropriate quality control checks in place | - Use commercially available products  
- Have a centralized pharmacy IV admixture service prepare all IV solutions under sterile conditions as specified in USP <797>  
- Use a specialized external service (outsourcer) to prepare complicated solutions such as PN® or cardioplegic solutions |

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*aFMEA: failure mode and effects analysis  
bADC: automated dispensing cabinet  
cPN: parenteral nutrition*
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| **Differentiate Items**         | Modify the packages and labels of medications to help distinguish them from other medications with look-alike packaging or look- and sound-alike names | - Affix auxiliary labels to call attention to important information (e.g., “oral use only”)
- Use color or a pen/marker to draw out or circle important information (e.g., strength, epidural) on labels or paper MARs
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- Purchase look-alike medications from different manufacturers to maximize label differences in appearance
- Use tall man lettering with drug names on labels, MARs, and computer screen drug listings to call out differences in look-alike drug names |
| **Redundancies**                | Implement multiple pathways so if the first pathway fails, a second pathway may detect the error and be successful | - Employ automated check systems such as barcode scanning or smart pumps to warn when conditions are unsafe or selections are erroneous
- Require a time-out process to verify the patient, treatment plan, and drugs prior to a procedure
- Require a manual independent double-check to verify a crucial aspect of prescribing, dispensing, or administering a high-alert medication (use should be limited)
- Require the verification of two unique patient identifiers to verify patient identity before prescribing, dispensing, or administering medications or before a procedure
- Require both mg/kg dose (or mg/m², etc.) and the final calculated dose for pediatric or chemotherapy drug orders to facilitate a double-check on calculations |
| **Use of Affordances**          | Take advantage of generally held knowledge about how things work, thereby suggesting how to interface with the object | - Have numerical keys of infusion pumps arranged in the same pattern as phone keypads
- Medication labels that provide drug information in the same manner/order as the MAR (how the nurse expects to see the order; no interpretation needed) |
| **Situational Awareness & Critical Thinking** | To enhance an accurate understanding of the environment in order to understand how information, events, and one’s own actions will impact patient safety and other goals, both immediately and in the near future; a strategy used to reduce drifting into unsafe practice habits | - Use simulations to expose staff to common risk and to teach them to identify and manage the risks
- Coach staff to recognize the specific risks associated with their behavioral choices that were not seen or misread as being insignificant or justified
- Teach and encourage self-briefings before critical tasks to reinforce memory cues and knowledge, and to seek answers to questions
- Implement team huddles with a specific focus to communicate and share information concurrently with a care team |
| **Positive Performance Shaping Factors** | An aspect of the human’s individual characteristics, environment, task, or organization that specifically improves human performance, thus decreasing the likelihood of human error | - Limit distractions in the environment and multi-tasking when staff are carrying out critical and/or complex tasks
- Provide hands-on experiences and/or simulation training to rehearse and reinforce new skills and knowledge
- Establish realistic workloads; avoid global productivity quotas
- Establish staffing patterns and workflow that guard against fatigue
- Promote a Just Culture to foster reporting and learning |
| **Checklists & Reminders**      | Provide a list of items for comparison, verification, or to assist with remembering important steps or information; provide additional alerts or warnings to make important information highly visible (overuse of reminders can lead to desensitization and alert fatigue) | - Label IV and other access lines and tubing
- Use checklists for complex tasks (e.g., surgical checklist, checklist for setting up automated IV compounders in the pharmacy)
- Build reminders for special monitoring into order sets or protocols
- Set visual and audible alarms on monitoring equipment
- Apply an auxiliary label on epidural medications stating, “Epidural Use Only”
- Use allergy alert bracelets |
| **Education & Competency Validation** | A baseline strategy intended to impart upon staff and patient, specific knowledge (what they know) and skills (the ability to apply the knowledge) about medications and their safe use, and verifying their knowledge and skills | - Provide patients discharged on a high-alert medication with written information regarding the types of errors that have happened with the drug and how to avoid them
- Educate staff about each high-alert medication/class of medications on the hospital’s high-alert medication list, how errors happen, the steps the hospital is taking to avoid errors, and the staffs’ role in error-reduction |
| **Recovery**                    | Recognize that, despite efforts, an error might occur, so enhance the ability to detect the initiating event and correct it before significant patient harm can occur | - Monitor the patient’s level of sedation, vital signs, respiratory quality, pulse oximetry/capnography, and pain level when receiving opioids
- Monitor drug levels and dose-dependent lab values (e.g., INR) regularly
- Establish a well-rehearsed resuscitation protocol with lipid emulsion to treat the effects of bupivacaine toxicity |

*MARs: medication administration records*