

2018-2019 Targeted Medication Safety Best Practices for Hospitals

The purpose of the Targeted Medication Safety Best Practices for Hospitals is to identify, inspire, and mobilize widespread, national adoption of consensus-based best practices for specific medication safety issues that continue to cause fatal and harmful errors in patients, despite repeated warnings in ISMP publications. Hospitals can focus their medication safety efforts over the next 2 years on these best practices, which are realistic and have been successfully adopted by numerous organizations. While targeted for the hospital-based setting, some best practices may be applicable to other healthcare settings. The *Targeted Medication Safety Best Practices for Hospitals* have been reviewed by an external expert advisory panel and approved by the ISMP Board of Trustees. Related issues of the *ISMP Medication Safety Alert!* are referenced after each best practice.

ISMP encourages hospitals that have not implemented the 2016-2017 Targeted Medication Safety Best Practices for Hospitals to do so as a priority, while implementing the 2018-2019 best practices. Organizations need to focus on previous best practices 2, 3, 9 and 11 since these have the lowest implementation rate. **Two of the 2016-2017 Targeted Medication Safety Best Practices for Hospitals (number 4 and 7) have been revised for 2018-2019. Best practices number 12 through 14 are new for 2018-2019.**

BEST PRACTICE 1:

Dispense vinCRISStine (and other vinca alkaloids) in a minibag of a compatible solution and not in a syringe.

Rationale:

The goal of this best practice is to ensure that vinca alkaloids are administered by the intravenous route only. Vinca alkaloids (vinBLASStine, vinorelbine, vinCRISStine, and vinCRISStine liposomal) can cause fatal neurological effects if given via the intrathecal route instead of intravenously. VinCRISStine is particularly problematic, and the most frequently reported with accidental intrathecal administration, because it is often ordered in conjunction with medications that are administered intrathecally (e.g., methotrexate, cytarabine, and/or hydrocortisone). When vinca alkaloids are injected intrathecally, destruction of the central nervous system occurs, radiating out from the injection site. The few survivors of this medication error have experienced devastating neurological damage. Despite repeated warnings by various national and international safety agencies, deaths from this type of error still occur. The product labeling also carries a special warning (“For Intravenous Use Only—Fatal If Given by Other Routes”).

An effective prevention strategy that reduces the risk of inadvertently administering vinca alkaloids via the intrathecal route is to dilute the drug in a minibag that contains a volume that is too large for intrathecal administration (e.g., 25 mL for pediatric patients and 50 mL for adults). Many organizations have successfully switched to preparing vinca alkaloids in minibags, including pediatric hospitals, overcoming concerns of extravasation and other complications. There have been no reported cases of accidental administration of a vinca alkaloid by the intrathecal route when dispensed in a minibag. This best practice is supported by The Joint Commission,¹ the American Society of Clinical Oncology (ASCO),² the Oncology Nursing Society (ONS),^{2,3} the National Comprehensive Cancer Network, and the World Health Organization.⁴

References:

1. The Joint Commission. Eliminating vincristine administration events. *Quick Safety*. 2017;37:1-3. (www.ismp.org/sc?id=3035)
2. Neuss MN, Gilmore TR, Belderson KM, et al. 2016 Updated American Society of Clinical Oncology/Oncology Nursing Society Chemotherapy Administration Safety Standards, Including Standards for Pediatric Oncology. *J Oncol Pract*. 2016;12(12):1262-71.
3. Schulmeister L.: Preventing vincristine administration errors: Does evidence support minibag infusions? *Clin J Oncol Nurs*. 2006;10(2):271-3.
4. World Health Organization. Vincristine (and other vinca alkaloids) should only be given intravenously via a minibag. Information Exchange System, Alert No. 115, July 18, 2007. (www.ismp.org/sc?id=3034)

Related ISMP Medication Safety Alerts!:

September 5, 2013; February 23, 2006; December 1, 2005; April 5, 2000; September 23, 1998; May 20, 2010; August 14, 2008; July 26, 2007; May 18, 2006; May 1, 2003; February 6, 2003; April 5, 2000; November 4, 1998; June 18, 1997.

BEST PRACTICE 2:

a) Use a weekly dosage regimen default for oral methotrexate in electronic systems when medication orders are entered.

b) Require a hard stop verification of an appropriate oncologic indication for all daily oral methotrexate orders.

- For manual systems and electronic order entry systems that cannot provide a hard stop, clarify all daily orders for methotrexate if the patient does not have a documented oncologic diagnosis.
- Hospitals need to work with their software vendors and information technology departments to ensure that this hard stop is available. Software vendors need to ensure that their order entry systems are capable of this hard stop as an important patient safety component of their systems.

c) Provide specific patient and/or family education for all oral methotrexate discharge orders.

- Double-check all printed medication lists and discharge instructions to ensure that they indicate the correct dosage regimen for oral methotrexate prior to providing them to the patient.
- Ensure that the process for providing discharge instructions for oral methotrexate includes clear written instructions AND clear verbal instructions that specifically review the dosing schedule, emphasize the danger with taking extra doses, and specify that the medication should not be taken “as needed” for symptom control.
- Require the patient to repeat back the instructions to validate that the patient understands the dosing schedule and toxicities of the medication if taken more frequently than prescribed.
- Provide all patients with a copy of the free ISMP high-alert medication consumer leaflet on oral methotrexate (found at: www.ismp.org/AHRQ/default.asp).

Rationale:

The goal of this best practice is to prevent errors involving inadvertent daily dosing of oral methotrexate both in the inpatient setting and after discharge. Since early 1996, fatal errors have been reported to ISMP involving the accidental daily dosing of oral methotrexate that was intended for weekly administration.

Methotrexate is a folate antimetabolite used to treat different types of cancers. Since the drug's introduction, its labeled indications have expanded to include non-oncology uses. It is now used to treat a variety of autoimmune diseases (e.g., psoriasis, severe rheumatoid arthritis, lupus) and other disorders. When used for immunomodulation to treat disorders such as rheumatoid arthritis, the drug is administered weekly or twice a week.

Prescribing errors occur when physicians or other providers, who are familiar with prescribing many medications for daily administration, erroneously prescribe this medication daily instead of weekly. Dispensing errors occur in much the same way, when pharmacy technicians and pharmacists inadvertently select/approve daily instead of weekly administration during order entry or verification. While fatalities have occurred during hospitalization, many have occurred after discharge.

It is important for hospitals not only to ensure that the proper dosage regimen is administered during hospitalization, but also to implement effective, proactive strategies so that the proper dosage regimen is maintained after discharge. While all hospitals routinely provide discharge instructions to patients and/or families about the patients' medication use after discharge, extra attention is important with oral methotrexate so that the patient and/or family understands both the proper dosage regimen and potential toxicities when taking more than prescribed.

Related ISMP Medication Safety Alerts!:

September 19, 2013;
December 3, 2002;
April 3, 2002;
March 26, 2009;
December 13, 2007;
November 4, 2004.

BEST PRACTICE 3:

a) Weigh each patient as soon as possible on admission and during each appropriate* outpatient or emergency department encounter. Avoid the use of a stated, estimated, or historical weight.

- Have metric scales available in all areas where patients are admitted or encountered. Ensure the metric weight is documented in the medical record.
- Do not rely on a patient's stated weight, a healthcare provider's estimated weight, or a documented weight from a previous encounter.

* Appropriate encounters include all encounters where the patient is being seen by a licensed independent practitioner, excluding life-threatening situations where the delay involved in weighing the patient could lead to serious harm (e.g., major trauma). It is specifically meant to exclude laboratory and other services where medications are not prescribed or administered.

b) Measure and document patient weights in metric units only.

- If scales can measure in both pounds and kilograms/grams, modify the scale to lock out the ability to weigh in pounds.
- If purchasing or replacing scales, buy new scales that measure in, or can be locked to measure in, metric units only.
- Have conversion charts that convert from kilograms (or grams for pediatrics) to pounds available near all scales, so that patients/guardians can be told the weight in pounds, if requested.
- Ensure that computer information system screens, medication device screens (e.g., infusion pumps), printouts, and preprinted order forms list or prompt for the patient's weight in metric units only.
- Document the patient's weight in metric units only in all electronic and written formats.

Rationale:

The first goal of this best practice is to ensure, as much as possible, that the patient's actual weight is obtained upon each admission or appropriate encounter.* Many medication doses are based on the patient's weight. Relying on a stated, estimated, or historical weight can cause inaccurate dosing (both under- and overdosing).

The second goal is to standardize the measurement and communication of a patient's weight using only metric units of measure (grams [g] and kilograms [kg]). Official product labeling for medications provides weight-based dosing using only the metric system (e.g., mg/kg). Significant medication errors have occurred when the patient's weight was documented in non-metric units of measure (pounds and ounces) that have been confused with kilograms or grams. Numerous mistakes have been reported in which practitioners converted a weight from one measurement system to another, or weighed a patient in pounds, but accidentally documented the weight value as kilograms in the medical record, resulting in more than a two-fold dosing error.

Related ISMP Medication Safety Alerts!:

August 26, 2010; December 1, 2011;
January 15, 2009; November 17, 1999;
www.ismp.org/pressroom/PR20110929.pdf

See also: *Emergency Nurses Association Position Statement (endorsed by American Academy of Medicine) 2012 – Weighing Patients in Kilograms.* www.ismp.org/sc?id=3036

BEST PRACTICE 4: (REVISED)

Ensure that all oral liquid medications that are not commercially available in unit dose packaging are dispensed by the pharmacy in an oral or ENFit syringe.

- Do not stock bulk oral solutions of medications on patient care units.
- Use only oral syringes that are distinctly marked “Oral Use Only.”
- Ensure that the oral syringes used do not connect to any type of parenteral tubing used within the organization.
- When ENFit syringes are used for administration of oral liquid medications, always highlight on the label, or affix an auxiliary label, “For Oral Use Only” on the syringe or highlight the statement if it is on the label.

Exception: If the pharmacy is employing unit-dose packaging automation that does not use oral syringes, unit dose cups/bottles may be provided in place of oral syringes. However, ensure that oral or ENFit syringes are available on nursing units in case patients cannot drink the medication from the cup or bottle.

Rationale:

The goal of this best practice is to prevent the unintended administration of oral medications via the intravenous route. ISMP continues to receive reports in which patients were inadvertently given an oral liquid medication intravenously. This happens most often when an oral liquid is prepared extemporaneously or dispensed in a parenteral syringe that connects to vascular access lines. Such errors have resulted in patient death. Fatalities have also occurred when the contents of liquid-filled capsules (e.g., niMODipine) were withdrawn for oral administration via a nasogastric or other tube with a parenteral syringe and then inadvertently administered intravenously. The oral and ENFit syringe tip is designed to be incompatible with vascular lines so it cannot be inadvertently attached.

Reason for the revision:

This best practice was updated to enhance clarity, reflect the release of ENFit syringes for oral and enteral use, and ensure consistency with an frequently asked questions (FAQ) that arose after initial publication.

Related ISMP Medication Safety Alerts!:

August 23, 2012; July 28, 2005;
May 30, 2013; August 12, 2010;
May 31, 2007; July 27, 2006;
June 15, 2006; July 28, 2005;
May 6, 2004; November 27, 2002;
August 25, 1999; January 13, 1999;
March 12, 1997; August 14, 1996;
May 8, 1996.

BEST PRACTICE 5:

Purchase oral liquid dosing devices (oral syringes/cups/droppers) that only display the metric scale.

Oral liquid dosing devices that only display the metric scale should be used. In addition, if patients are taking an oral liquid medication after discharge, supply them with (or provide a prescription for) oral syringes, to enable them to measure oral liquid volumes in milliliters (mL).

Rationale:

The goal of this best practice is to use liquid medication dosing devices (specifically oral syringes, cups, and droppers) that only display volume using the metric scale. ISMP has received more than 50 reports of mix-ups between milliliters (mL) and household measures such as drops and teaspoonfuls, some leading to injuries requiring hospitalization. Oral syringes, dosing cups, droppers, and other measuring devices have been involved. Use of the apothecary system has also caused confusion with mix-ups between drams and mL and other non-metric measurements such as ounces and tablespoons. ISMP first reported confusion in 2000, and has continued to receive reports of medication errors because of mix-ups between metric and non-metric units of measure.

The purchase and use of the current commercially available oral syringes, cups, and droppers that only display volume using an easy-to-read printed (rather than embossed) metric scale will help prevent these types of errors.

Related ISMP Medication Safety Alerts!:

June 28, 2000; September 20, 2012; November 1, 2012; June 14, 2012; December 1, 2011; September 22, 2011; March 22, 2007; March 6, 2003; February 26, 1997.

See also: ISMP statement on use of metric measurements to prevent errors. ISMP News Release. September 29, 2011. (www.ismp.org/pressroom/PR20110929.pdf)

BEST PRACTICE 6:

Eliminate glacial acetic acid from all areas of the hospital.†

Remove and safely discard this product from all clinical areas of the hospital (including the pharmacy, clinics, and physician office practices), and replace it with vinegar (5% solution) or commercially available, diluted acetic acid 0.25% (for irrigation) or 2% (for otic use).

† Laboratory use excluded if the laboratory purchases the product directly from an external source.

Rationale:

The goal of this best practice is to prevent harm from the use of glacial acetic acid applied directly to patients. The use of hazardous chemicals in pharmacy compounding or for special therapeutic procedures and diagnostics is common in many hospitals. Patient harm has occurred when toxic chemicals have been misidentified as oral products, or when a very concentrated form of a chemical has been erroneously used in treating patients.

Of particular concern is glacial acetic acid. Accidental topical application of "glacial" (greater than or equal to 99.5%) acetic acid has repeatedly resulted in serious patient harm, including severe pain and serious tissue damage, third-degree burns, and in one case, bilateral leg amputation. Often in these cases, this item was either accidentally purchased or used in place of a much more diluted form of acetic acid, such as vinegar or a commercially available 0.25% acetic acid solution.

Related ISMP Medication Safety Alerts!:

January 24, 2013; May 5, 2005; September 20, 2012; June 30, 2005.

BEST PRACTICE 7: (REVISED)

Segregate, sequester, and differentiate all neuromuscular blocking agents (NMBs) from other medications, wherever they are stored in the organization.

- Eliminate the storage of NMBs in areas of the hospital where they are not routinely needed.
- In patient care areas where they are needed (e.g., intensive care unit), place NMBs in a sealed box or, preferably, in a rapid sequence intubation (RSI) kit.
- If NMBs must be stored in automated dispensing cabinets (ADCs), standardize the storage practices throughout the organization by keeping them in lock-lidded pockets.
- Segregate NMBs from all other medications in the pharmacy by placing them in separate lidded containers in the refrigerator or other secure, isolated storage area.
- Place auxiliary labels on all storage bins and/or ADC pockets and drawers that contain NMBs as well as all final medication containers of NMBs (e.g., syringes, IV bags) that state: **“WARNING: PARALYZING AGENT — CAUSES RESPIRATORY ARREST — PATIENT MUST BE VENTILATED”** to clearly communicate that respiratory paralysis will occur and ventilation is required.‡

Exception: Excludes anesthesia-prepared syringes of NMBs.

‡ Other acceptable alternatives to labeling storage bins and/or ADC pockets is to affix an auxiliary warning label (in addition to the manufacturer’s warning on the cap and ferrule) directly on all vials and/or other containers stocked in storage locations, or by displaying a warning on the ADC screen, which must be acknowledged prior to removal of a NMB.

Rationale:

The goal of this best practice is to prevent errors related to the accidental administration of NMBs to patients, especially those not receiving proper ventilator assistance. Because the respiratory muscles are paralyzed by these agents, errors in the compounding, dispensing, and administration of these agents instead of other drugs have resulted in death or serious, permanent injury. Even with patients requiring ventilator assistance, severe psychological trauma can occur if the NMB is accidentally administered prior to sedation.

ISMP has received well over 100 reports concerning accidental administration of NMBs and has discussed the hazards of these agents since 1996. Most errors with the use of these agents have been the result of using or compounding a NMB in error instead of the intended drug. In 2014, a widely publicized death caused by compounding a NMB solution by accident instead of a fosphenytoin solution received national attention. Inadequate labeling or unsafe storage has been the root cause of most of these errors. Segregation in storage areas and the use of proper warning labels can be an effective means of preventing mix-ups with NMBs.

Reason for the revision:

This best practice was updated to be consistent with the new ISMP Medication Safety Self Assessment® for High-Alert Medications, specifically the last bullet. Other changes were made based on organization feedback – specifically clarification that elimination of storage is only for areas where NMBs are not routinely needed; elimination of routine auxiliary labeling of manufacturer vials, if storage locations are labeled; and adding an exception for anesthesia-prepared syringes of NMBs.

Related ISMP Medication Safety Alerts!:

September 22, 2005; June 5, 1996; October 23, 1996; April 9, 1997; May 20, 1998; October 7, 1998; August 25, 1999; May 1, 2002; December 18, 2002; January 9, 2003; April 4, 2003; May 30, 2007; December 4, 2008; January 14, 2010; November 15, 2012; January 30, 2014; September 25, 2014; December 18, 2014

BEST PRACTICE 8:

Administer high-alert intravenous (IV) medication infusions via a programmable infusion pump utilizing dose error-reduction software.

- This best practice applies to all hospital settings, both inpatient and outpatient (e.g., in magnetic resonance imaging [MRI], emergency department, outpatient infusion clinics), and to all situations in which high-alert medications are infused by the IV route, including anesthesia use and patient-controlled analgesia (PCA). The only exception is for small volume vesicant infusions (i.e., chemotherapy vesicants) which, when administered via the peripheral route, should only be infused by gravity and NOT by an infusion/syringe pump. For a list of recommended high-alert medications, visit: www.ismp.org/Tools/institutionalhighAlert.asp.
- Ensure that dose error-reduction software is employed on all pumps with this feature (i.e., smart pumps). Specifically, ensure that drug libraries are built and installed on all smart pumps and that staff are using the error-reduction software.
- If smart pumps are not already in use in all areas, ensure the capital equipment budget includes the purchase of this technology as soon as possible.
- Require periodic maintenance, updating, and testing of the software and drug library for all smart pumps.
- Evaluate the alerts regularly and determine if staff are responding to them appropriately.

Rationale:

The goal of this best practice is to utilize dose error-reduction technology to prevent infusion-related medication errors, which can cause harm to patients, especially when high-alert medications are administered. High-alert medications are drugs that bear a heightened risk of causing significant patient harm when used in error. Although mistakes may or may not be more common with these drugs, the consequences of an error are clearly more devastating to patients. Infusion-related medication errors expose patients to a higher risk of harm.

Programmable infusion pumps with dose error-reduction software help to avert these potentially harmful errors by “remembering” the large number of “rules” (hospital-defined dosing limits and other clinical advisories) entered into the drug library, and applying those “rules” during pump programming to warn clinicians about potentially unsafe drug therapy. Although this technology has been available for more than 10 years, many healthcare organizations still do not utilize smart pumps in all settings. In addition, the dose error-reduction software is not always employed on smart pumps. While the use of smart pumps is advantageous in preventing medication errors with all drugs given IV, the use of this technology when administering high-alert medications will have a significant impact on reducing harmful errors.

Related ISMP Medication Safety Alerts!:

April 19, 2007; August 23, 2007;
September 18, 2002; May 6, 2004;
April 7, 2005; June 14, 2007;
September 20, 2007; August 28, 2008;
April 8, 2010; October 7, 2010;
May 5, 2011; February 23, 2012;
April 9, 2015.

See also: Proceedings from the ISMP Summit on the Use of Smart Infusion Pumps: Guidelines for Safe Implementation and Use. (<http://www.ismp.org/Tools/guidelines/smartpumps/default.asp>)

BEST PRACTICE 9:

Ensure all appropriate antidotes, reversal agents, and rescue agents are readily available. Have standardized protocols and/or coupled order sets in place that permit the emergency administration of all appropriate antidotes, reversal agents, and rescue agents used in the facility. Have directions for use/administration readily available in all clinical areas where the antidotes, reversal agents, and rescue agents are used.

- Identify which antidotes, reversal agents, and rescue agents can be administered immediately in emergency situations to prevent patient harm.
- Use this list to develop appropriate protocols or coupled order sets to ensure that the above best practice is met.

Rationale:

The goal of this best practice is to ensure that when an antidote, reversal agent, or rescue agent is known for a drug that has a high potential to cause an adverse reaction, or if a toxic dose is inadvertently administered, the agent is readily available and can be administered without delay. Some medications have a high potential to cause an adverse reaction even when the appropriate dose is administered (e.g., iron dextran.) Adverse effects can also occur if an overdose of a medication is accidentally administered. In both cases, the reaction can be life-threatening, and sometimes immediate intervention is needed. For some drugs, an antidote, reversal agent, or rescue agent may exist to counteract the reaction. For example, naloxone counteracts the effects of opioids, flumazenil counteracts benzodiazepines, lipid emulsions counteract the cardiotoxic effects of local anesthetics, and uridine triacetate counteracts the toxic effects of fluorouracil.

ISMP has received reports of death and serious harm because there was a delay in the administration of the appropriate antidote, reversal agent, or rescue agent (e.g., **EPINEPH**rine for anaphylaxis.) Known antidotes, reversal agents, and rescue agents must be routinely available and, in certain situations, stored in areas where these high-risk medications are administered. In addition, it is important to have standardized protocols or coupled order sets so qualified staff can treat the reaction/overdose without waiting for an order from the prescriber. Also, the directions for use should be available near where these agents are stored to avoid a delay or improper use and administration of the agent.

Related ISMP Medication Safety Alerts!:

September 10, 1999; November 3, 1999; December 14, 2006; January 11, 2007; February 22, 2007; March 11, 2010; April 8, 2010; July 1, 2010.

BEST PRACTICE 10:

Eliminate all 1,000 mL bags of sterile water (labeled for “injection,” “irrigation,” or “inhalation”) from all areas outside of the pharmacy.

- Use alternatives to avoid the storage and use of 1,000 mL (1 liter) bags of sterile water for injection, irrigation, or inhalation in patient care areas. For example, replace all 1,000 mL (1 liter) bags of sterile water for injection, irrigation, or inhalation with 2,000 mL (2 liter) bags of sterile water for injection, irrigation, or inhalation, or bottles of sterile water for irrigation or vials.
- Establish a policy that 1,000 mL bags of sterile water can only be ordered by the pharmacy.
- The pharmacy needs to work with respiratory therapy and other relevant departments of the hospital to establish guidelines regarding the safest way to provide large volumes of sterile water when needed for patient care.

Rationale:

The goal of this best practice is to prevent the accidental administration of an intravenous (IV) infusion of sterile water to a patient. Administering large quantities of hypotonic sterile water IV has resulted in patient harm, including death, from hemolysis. ISMP has received reports of mix-ups between the 1 liter bags of sterile water for injection, irrigation, and inhalation with 1 liter bags of dextrose 5% (D5W) and 0.9% sodium chloride (normal saline [NS]). These products look very similar in size, shape, and type of flexible plastic bag used for distribution.

Respiratory therapy staff may need to use bags of sterile water for inhalation in patient care units for humidification with ventilators or continuous positive airway pressure (CPAP) devices. In addition, due to the large volume of sterile water needed to reconstitute traditional dantrolene, sterile water bags for injection may need to be stored in malignant hyperthermia (MH) carts in the perioperative and procedural areas of the hospital. Unfortunately, if the sterile water bag is not used, it may be returned to the wrong storage area where IV bags are routinely kept (e.g., medication rooms, on IV poles). Therefore, when large volume bags of sterile water must be used outside of the pharmacy, the best approach is to use 2 liter bags, or bottles of sterile water, to prevent mix-ups because the larger volume or shape of the container will differentiate these products from 1 liter bags of D5W and NS. Also, use of the concentrated suspension of dantrolene, which can be reconstituted with a small amount of sterile water from vials, eliminates the need for large volume sterile water bags on the MH cart.

Related ISMP Medication Safety Alerts!:

September 11, 2014; September 18, 2003; November 30, 2006.

BEST PRACTICE 11:

When compounding sterile preparations, perform an independent verification to ensure that the proper ingredients (medications and diluents) are added, including confirmation of the proper amount (volume) of each ingredient prior to its addition to the final container.

- Specifically, eliminate the use of proxy methods of verification for compounded sterile preparations of medications (e.g., the “syringe pull-back method,” checking a label rather than the actual ingredients).
- Except in an emergency, perform this verification in all locations where compounded sterile preparations are made, including patient care units.
- At a minimum, perform this verification for all high-alert medications (including chemotherapy and parenteral nutrition), pediatric/neonatal preparations, pharmacy-prepared source/bulk containers, products administered via high-risk routes of administration (e.g., intrathecal, epidural, intraocular), and other compounded sterile preparations that the organization believes are high-risk.
- Use technology to assist in the verification process (e.g., barcode scanning verification of ingredients, gravimetric verification, robotics, IV workflow software) to augment the manual processes. It is important that processes are in place to ensure the technology is maintained, the software is updated, and that the technology is always used in a manner that maximizes the medication safety features of these systems.

Rationale:

The goal of this best practice is to prevent medication errors during sterile compounding of drugs, especially for high-alert medications, that are not detected with proxy checks, such as the “syringe pull-back method.” Between 2004 and 2011, ISMP has reported serious compounding errors involving 16 patients, 9 of whom died, mostly due to wrong concentration/strength, or wrong product or diluent. Many of these would have been identified prior to dispensing if preproduction checks or sterile processing technology would have been utilized.

ISMP continues to receive reports of errors resulting in serious harm and death that were specifically attributed to a failed check system when using the “syringe pull-back method.” This error-prone method has been used in pharmacies during the sterile compounding process for years. Using this method, an ingredient is injected from the syringe into the final container, and the plunger is then pulled back to the amount on the syringe that was injected. It is this “pulled-back” syringe which is checked to determine the accuracy of the amount injected. Errors may not be detected if the syringe does not reflect the actual amount added or when the pulled-back syringes are partnered with the wrong container of medication. Since 2010, ISMP has repeatedly warned against using this method of verification, especially for high-alert and pediatric medications. The practice also may be illegal in some states (e.g., Minnesota).

Related ISMP Medication Safety Alerts!:

July 1, 2010; July 11, 2013; January 15, 2015; August 23, 2000; April 23, 2009; April 21, 2011; June 2, 2011; October 18, 2012; October 9, 2014; December 18, 2014; March 12, 2015.

See also: Guidelines for SAFE Preparation of Sterile Compounds. (<http://www.ismp.org/Tools/guidelines/IVSummit/IVCGuidelines.pdf>)

BEST PRACTICE 12:

Eliminate the prescribing of fentaNYL patches for opioid-naïve patients and/or patients with acute pain.

- Ensure the organization has a process in place to routinely document the patient's opioid status (naïve vs. tolerant[§]) and type of pain (acute vs. chronic) in the health record or prescriber orders.
- Implement a process to verify and prevent orders for fentaNYL patches in patients who are opioid-naïve or with acute pain. Examples include the use of hard stops during order entry, electronic alerts, automatic interchange, and pharmacy interventions with prescribers.
- Eliminate the storage of fentaNYL patches in automated dispensing cabinets or as unit stock in clinical locations where acute pain is primarily treated (e.g., in the emergency department, operating room, post-anesthesia care unit, procedural areas).

§ **Opioid-tolerant patient:** Opioid tolerance is defined by the following markers: Patients receiving, for 1 week or longer, at least: 60 mg oral morphine/day; 25 mcg transdermal fentaNYL/hour; 30 mg oral oxyCODONE/day; 8 mg oral HYDROmorphone/day; 25 mg oral oxyMORphone/day; 60 mg oral HYDROcodone/day; or an equianalgesic dose of another opioid, including heroin and/or non-prescribed opioids.

Rationale:

The goal of this best practice is to prevent death and serious harm from the inappropriate use of fentaNYL patches to treat acute pain in patients who are opioid-naïve. FentaNYL patches are ONLY to be used in patients who are opioid-tolerant and are ONLY indicated for persistent, moderate to severe chronic pain that requires continuous, around-the-clock opioid administration for an extended period of time that cannot be managed by other means.

FentaNYL patches were the highest-ranking drug involved in serious adverse drug events (ADEs) reported to the US Food and Drug Administration (FDA) from 2008 through 2010. Since then, ISMP continues to receive reports, including fatalities, due to the prescribing, dispensing, and administration of fentaNYL patches to treat acute pain in opioid-naïve patients.

Related ISMP Medication Safety Alerts!:

June 28, 2007; January 26, 2017;
October 20, 2016; November 6, 2014;
October 17, 2013; June 17, 2010;
October 8, 2009; November 6, 2008;
July 12, 2007; August 11, 2005;
May 20, 2004; April 18, 2001

BEST PRACTICE 13:

Eliminate injectable promethazine from the hospital.

- Remove injectable promethazine from all areas of the hospital including the pharmacy.
- Classify injectable promethazine as a non-stocked, non-formulary medication.
- Implement a medical staff-approved automatic therapeutic substitution policy to convert all injectable promethazine orders to another antiemetic.
- Remove injectable promethazine from all computerized medication order screens, and from all order sets and protocols.

Rationale:

The goal of this best practice is to eliminate the risk of serious tissue injuries and amputations from the inadvertent arterial injection or IV extravasation of injectable promethazine. ISMP brought attention to this serious issue in August 2006 and conducted a survey to determine the prevalence of the issue. Of the nearly 1,000 responses to the survey, 1 in 5 reported awareness of such an occurrence in his or her facility during the prior 5 years. The US Food and Drug Administration (FDA) requires the manufacturer to include strong warnings about the risk of inadvertent intra-arterial injection or perivascular extravasation of this drug in the package insert. Intravenous promethazine has been included on the *ISMP List of High-Alert Medications in Acute Care Settings* (www.ismp.org/Tools/institutionalhighAlert.asp) since 2007.

In 2009, ISMP recommended removal of injectable promethazine from an organizations' formulary, if possible, and use of safer alternatives such as 5-HT³ antagonists (e.g., ondansetron). However, these products were significantly higher in cost at the time. Since then, these alternative injectable antiemetics have become available as a generic product and are significantly less costly. Thus, injectable promethazine has been used less frequently, and for safety, should now be removed from all hospitals.

Related *ISMP Medication Safety Alerts!*:

August 10, 2006; June 27, 2013;
October 8, 2009; September 24, 2009;
October 9, 2008; November 2, 2006

BEST PRACTICE 14:

Seek out and use information about medication safety risks and errors that have occurred in other organizations outside of your facility, and take action to prevent similar errors.

- Appoint a single healthcare professional (preferably a medication safety officer) to be responsible for oversight of this entire activity in the hospital.
- Identify reputable resources (e.g., ISMP, The Joint Commission, ECRI, patient safety organizations, state agencies) to learn about risks and errors that have occurred externally to improve.
- Establish a formal process for monthly review of medication risks and errors reported by external organizations, with a new or existing interdisciplinary team or committee responsible for medication safety. The process should include a review of the hospital's current medication use systems (both manual and automated) and other data such as internal medication safety reports to determine any potential risk points that would allow a similar risk or error to occur within the hospital.
- Determine appropriate actions to be taken to minimize the risk of these types of errors occurring in the hospital.
- Document the decisions reached and gain approval for required resources as necessary.
- Share the external stories of risk and errors with all staff, along with any changes that will be made in the hospital to minimize their occurrence, and then begin implementation.
- Once implemented, periodically monitor the actions selected to ensure they are still being implemented and are effective in achieving the desired risk reduction. Widely share the results and lessons learned within the facility.

Rationale:

One of the most important ways to prevent medication errors is to learn from errors that have occurred in other organizations and to use that information to identify potential risk points or practices within your organization to prevent similar errors. Experience has shown that a medication error reported in one organization is also likely to occur in another. Seeking out external sources of risk and errors prompts the evaluation of similar risks within the organization that may otherwise be hidden, lying dormant for years before they cause an adverse outcome.

Because there's a natural human tendency to "normalize" errors that happen elsewhere, believing they will never happen within the organization, leaders must convey that these external risks and errors offer valuable and necessary learning opportunities and must be sought out and reviewed regularly. They must convey that the organization is vulnerable to errors, and that they consider external errors to be a "clear and present danger" in their organization for which steps must be taken to prevent a similar occurrence.

To establish a process for learning from external risks and errors, organization leaders must identify reliable sources of information, establish a systematic way to review this information, assess the organization's vulnerability to similar events, and determine a workable action plan to address any vulnerabilities. To facilitate such a process, ISMP publishes the **Quarterly Action Agenda** in January, April, July, and October to summarize important topics published in the **ISMP Medication Safety Alert!** during the previous 3 months. The Agenda is prepared for leadership to use at an interdisciplinary committee meeting and with frontline staff to stimulate discussion and action to reduce the risk of medication errors. Each Agenda item includes a brief description of the medication safety problem, a to reduce the risk of errors, and the issue number to locate additional information.

Related *ISMP Medication Safety Alerts!*:

February 25, 1998; January 13, 2005; November 29, 2007; November 6, 2008; February 9, 2017; March 23, 2017

BEST PRACTICE 14 (NEW BEST PRACTICE) continued:

Rationale continued

Other credible sources of information about risks and errors that can be used to proactively address known medication safety issues that could otherwise lead to harmful patient outcomes include The Joint Commission **Sentinel Event Alert**; advisories from the US Food and Drug Administration (FDA), and the Centers for Medicare & Medicaid Services (CMS); patient safety organization publications (e.g., **Pennsylvania Patient Safety Advisory**); peer-reviewed journals and newsletters; and other reliable publications.

It should be noted that it is a requirement of CMS that hospitals “need to be aware of external alerts to real or potential pharmacy-related problems in hospitals” and “must take steps to prevent, identify, and minimize these errors.”¹

Reference:

1. Centers for Medicare and Medicaid Services. Revised Hospital Guidance for Pharmaceutical Services and Expanded Guidance Related to Compounding of Medications. S&C 16-01-Hospital. October 30, 2015.

HOSPITAL EXPERT ADVISORY PANEL

David T. Caron, Jr., RPh, PharmD

Director of Pharmacy
Martha's Vineyard Hospital
Oak Bluffs, MA

Frank Federico, RPh

Vice President, Senior Safety Expert
Institute for Healthcare Improvement
Cambridge, MA

Rita K. Jew, PharmD, MBA, FASHP

Director of Pharmacy
UCSF Medical Center Mission Bay
San Francisco, CA

Patricia C. Kienle, RPh, MPA, FASHP

Director of Accreditation and Medication Safety
Cardinal Health
Wilkes Barre, PA

Steven B. Meisel, PharmD, CPPS

System Director of Patient Safety
Fairview Health Services/HealthEast Care Systems
Minneapolis, MN

Mikaela Olsen, APRN-CNS, MS, AOCNS, FAAN

Oncology and Hematology Clinical Nurse Specialist
Sidney Kimmel Comprehensive Cancer Center
Johns Hopkins Hospital
Baltimore, MD

Deborah A. Pasko, PharmD, MHA

Director, Medication Safety and Quality
Center for Safety and Quality
American Society of Health-System Pharmacists
Bethesda MD

Georgene Saliba, RN, BSN, MBA, CPHRM

Sr. Director Corporate Risk - Acute Division
Universal Health Services of Delaware
King of Prussia, PA

Debra Simmons, PhD, RN, CCNS

Senior Vice President and Chief Quality Officer and
ISMP Board of Trustees member
St. Luke's Episcopal Health System
Houston, TX

William R. Simpson, RPh

Director of Pharmacy
Clarion Hospital
Clarion PA

For more information about the ISMP Targeted Medication Safety Best Practices for Hospitals including Frequently Asked Questions, Educational Programs and Surveys, see:

www.ismp.org/tools/bestpractices/.