Some medication safety risks are painfully apparent in an organization, while many others lie dormant in the system until an error or adverse event draws attention to them. We thought it would be useful to describe selected medication safety risks for organizations to manage in 2016 that might otherwise fall off the radar screen. In Part I, published in our January 28 newsletter, we described one risk for five of ISMP’s Key Elements of the Medication Use System.

These risks were related to:

- Drug Storage, Standardization, and Distribution—Improper and unsafe vaccine storage

The proper storage and handling of vaccines is vitally important because their stability and efficacy are dependent on these factors. To maintain stability, most vaccines must be stored in a refrigerator or freezer, and many also require protection from light. Excessive heat or cold—even a single exposure in some instances—can reduce vaccine potency. These temperature deviations are often due to inadequate refrigeration or freezer units, faulty thermostat controls, and refrigeration/freezer units with inadequate space to allow good air circulation and consistent temperatures.

Improper and unsafe storage can also result in serious errors due to selecting the wrong vaccine, diluent, or other medication with a look-alike name and/or labeling and packaging. Unsegregated storage of vaccines has led to dispensing and administering the wrong vaccine or wrong form of vaccine (adult vs. pediatric). Storing vaccines with other medications in a refrigerator or freezer has led to serious adverse outcomes, particularly when the mix-up has involved a vaccine and a high-alert medication. For example, vials of insulin have sometimes been mistaken as influenza vaccine, and various neuromuscular blocking agents have been used to reconstitute vaccines or were mistaken as hepatitis B or influenza vaccine.

Unfortunately, when the product was reintroduced, for some unknown reason the nomenclature “opium tincture, 2%” was used in addition to “paregoric.” This is a problem for several reasons. First, “paregoric” is the official name; next, paregoric is NOT “opium tincture, 2%” and should never be confused as such. Here’s why: paregoric has 0.4 mg of morphine per mL (2 mg in 5 mL). A typical adult dose would be 5-10 mL, 1 to 4 times a day. A child would receive 0.25 to 0.5 mL/kg for each dose. But
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Store vaccines in stand-alone refrigerators or pharmacy grade/purpose-built refrigeration units (and freezers in the pharmacy), not in dormitory style or combination units that both refrigerate and freeze. Regular temperature monitoring is necessary. Technology is available to enable continuous temperature monitoring devices that can alert staff via electronic messages (e.g., email, pager) and audible alarms if a unit is outside of the specified range. Separate vaccines into labeled bins or other containers according to vaccine type and formulation, keeping vaccines with their corresponding diluents. Never store different vaccines in the same bin/container. Do not store vaccines with similar labels, names, or abbreviations, or vaccines with overlapping components, immediately next to each other or on the same shelf. Separate the storage areas of pediatric and adult formulations of vaccines. Label the specific locations where vaccines are stored to facilitate correct, age-specific selection and to remind staff that some vaccines have two components in separate vials that need to be combined before administration. Our March 26, 2015, newsletter1 contains additional strategies, as does a Vaccine Storage & Handling Toolkit available from the Centers for Disease Control and Prevention.2

7 KEY ELEMENT

Environmental Factors, Workflow, and Staffing Patterns—Poor quality lighting

Lighting is a crucial aspect of the physical environment that has been linked to medication safety.3 Poor quality lighting has often impaired the highly visual tasks associated with medication use, thus leading to medication errors. Examples include tubing misconnections due to low lighting in a patient’s room, infusion pumps that have been misprogrammed due to dim backlighting on the screens, and product selection errors in the pharmacy and patient care units caused by low lighting under a pharmacy hood or shadows around an automated dispensing cabinet (ADC).

Despite existing guidelines for lighting in healthcare, it’s been a challenge to implement optimal lighting conditions for prescribing, dispensing, and administering medications. Recent literature reviews found that little system-wide action has been taken to increase staff awareness of the problem or improve the lighting.4,5 This is largely because the tasks associated with medication use are varied, carried out under diverse physical conditions and in differing locations, and because there are differences in an individual’s light requirements based on their visual acuity and age. With an ever-increasing population of older healthcare providers, eye fatigue from computer work and task complexity, small font sizes on medication labels, poor background contrast, and glare or shadows have taken their toll on visual accuracy.4,5

Proper illumination improves both the accuracy and efficiency of medication-related tasks. Fluorescent cool-white lamps or compact fluorescent lamps should be used in areas where critical tasks are performed, including on mobile medication carts, near ADCs, and in patients’ rooms for nighttime administration of medications.6,7 Administration of medications at night under low lighting to avoid disturbing the patient is an unsafe practice and should be avoided. Adjustable 50-watt high-intensity or task lights are recommended when difficult-to-read prescriptions and product labels are encountered.7 Illumination levels for computer order entry areas should be at least 75 footcandles (fc), while 100-150 fc are needed when interpreting handwritten orders.7 Medication preparation areas, medication verification areas, and patient counseling areas should have illumination levels between 90-150 fc.7 Medication rooms should provide illumination at 100 fc.7 Lighting levels should be increased if the workforce has an average age above 45 years. A magnifying glass and task light together can also significantly improve accuracy4 and should be used on mobile medication carts (including those used with barcode medication verification systems)7 and near ADCs.

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opium tincture is an entirely different product. Also known as laudanum, opium tincture contains 10 mg/mL (1%) of anhydrous morphine. A typical adult dose is 0.6 mL, 4 times daily; a child would receive just 0.005 to 0.02 mL/kg for each dose. A 10 kg child might get 5 mL of paregoric (anhydrous morphine 2 mg), but using opium tincture in error would result in the administration of an equivalent of 50 mg of morphine.

Confusion between paregoric and opium tincture has been a longstanding problem because paregoric was previously known as “camphorated tincture of opium,” which is easily confused with opium tincture, as happened with the Hi-Tech labeling error in Figure 1 (page 1). Fatalities have been associated with mix-ups between these products (www.ismp.org/sc?id=1661). The official name of “camphorated tincture of opium” was changed to “paregoric” to reduce the likelihood of mix-ups. It’s unclear where “2%” on the Hi-Tech label came from, but that would be 20 mg/mL, or twice the amount in actual opium tincture and 50 times the amount in paregoric. We contacted Hi-Tech and FDA to request immediate action to relabel the product as paregoric 2 mg/5 mL (0.4 mg/mL). Until then, if you have this product, add labels to the bottles so they are not confused with opium tincture.

The FDA drug approval process would have prevented labeling errors like this. To get FDA approval, a company must provide FDA with evidence that its unapproved product is safe and effective. Such evidence doesn’t always entail conducting clinical trials. For example, phenylephrine injection was unapproved for more than 30 years, but in 2012, West-Ward submitted an application (NDA 203826) for the drug and received approval. The support for effectiveness and safety was derived from the literature.

New bendamustine product avoids CSTD issues. BENDeka (bendamustine hydrochloride) was approved in December 2015. Unlike TREANDA, also bendamustine hydrochloride, a Teva company spokesperson told us that their product, Bendeka, is

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Two seemingly harmless practice habits that breach aseptic technique might lead to contamination of sterile injection equipment and increase the risk of a healthcare-associated infection (HAI) of the bloodstream or tissues: 1) failing to place a sterile cap on the end of a reusable intravenous (IV) administration set that has been removed from a primary administration set, saline lock, or catheter hub, and left hanging between use; and 2) failing to properly disinfect the port when accessing needless valves on an IV set. In the first instance, the tip of the IV administration set is exposed to potential contaminants, which could lead to infection if the contaminated IV set is reconnected to the patient’s IV access. In the second instance, the port is exposed to potential contaminants that can be pushed into the patient’s IV line once the port has been accessed by tubing or a syringe.

These risks may be unintended consequences of needleless IV system implementation. Before needleless systems, practitioners typically replaced the needle used to connect the infusion to the IV tubing with a new sterile, capped needle to prevent contamination when the line was hanging between use. Now it appears that practitioners are not considering the risk of contamination and are not placing a sterile cap on the exposed tubing. Some have speculated that the lack of a needle or cannula on a syringe, or at the end of the tubing, may suggest that protection and disinfection are not required.

It is imperative that facilities develop procedures that incorporate manufacturer recommended disinfection protocols for their needleless connectors, and to place a sterile cap on the end of the IV tubing between intermittent infusions. This disinfection process should specify the disinfecting agent, the method for disinfection (e.g., scrub the access surface), and the duration. “Looping”—attaching the exposed end of IV tubing to a port on the same tubing—is not recommended. Both processes (disinfection, capping) should be observed during competency assessments related to medication administration for new and existing practitioners. At-risk behaviors that breach aseptic technique require coaching and education, as well as continued monitoring by organizational leadership.

In recent years, pharmacy practice has moved into a more clinical realm. Partly as a result, core practices such as sterile compounding and IV admixture do not receive as much attention as that given to clinical pharmacy roles during training. Schools of pharmacy often do not adequately teach students sterile compounding nor prepare them to verify compounded sterile preparations and oversee processes they have never carried out themselves. Instead, sterile compounding procedures are typically handed down from one pharmacist to another, often with little scientific merit. New pharmacists learn via inherited knowledge taught by practicing pharmacists, who may or may not carry out the procedures safely, depending on how they were taught.

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**Medication Device Acquisition, Use, and Monitoring—Failure to disinfect ports and use sterile caps**

It’s critically important to prepare for a serious adverse reaction when administering drugs with a high potential to cause such reactions or when a toxic dose may be inadvertently administered. That’s why we have included Best Practice #9 in the new 2016-2017 Targeted Medication Safety Best Practices for Hospitals (TMSBPs). As noted in the rationale for this Best Practice, we’ve received reports of preventable deaths and serious harm due to a delay in administering an appropriate antidote, reversal agent, or rescue agent (e.g., EPI-NPHrime for anaphylaxis). These agents must be readily available and, in certain situations, stored in areas where high-risk medications are administered. Learn more about this Best Practice at: www.ismp.org/sc?id=1659.

We hope your hospital is following through to ensure staff are prepared for these adverse events. To address this issue, one hospital system has coupled rescue/reversal agent orders with their standard order sets so that nurses have appropriate orders available to rescue patients should it be necessary. Including orders for antidotes, rescue agents, or reversal agents allows a

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**Staff Competency and Education—IV practices based on inherited knowledge handed down from one practitioner to another**

Parenteral drug administration often poses risks because of its complexity and the multiple steps required to prepare, measure, and administer medications. A systematic review determined an overall probability of 73% for a practitioner to make at least one clinical error during IV preparation and administration. While the causes of these errors are diverse, one contributing factor is that pharmacists and nurses are ill prepared to take on these tasks upon graduation from schools of pharmacy and nursing.
For graduate nurses, it is much the same although for different reasons. Oftentimes, student nurses are not permitted to administer IV infusions or IV push medications during rotations in clinical areas. If they are allowed, the experiences are few and far between. New graduate nurses need to quickly get up to speed and learn these skills. But again, the procedures are handed down from one nurse to another.\textsuperscript{12,13} Most training is prefaced with, “Here’s how I do it,” resulting in wide variability due to individual preferences. Furthermore, nurses receive little feedback on performance in this area due to lack of defined policies and procedures to outline expectations.

Training of all pharmacists and nurses new to the organization should follow a documented standard process that outlines the steps associated with sterile compounding (including IV admixture) and IV drug administration according to well-designed, evidence-based protocols. Variability in practice and individual preferences should be discouraged. Specific training modules should be developed and standardized, and competency evaluation via observation should occur at least annually. All practitioners should be carrying out all processes the same way—the safest way—every time.

As healthcare organizations move towards a Just Culture, one of the areas potentially overlooked is the organization’s human resource-related policies and procedures. Because these policies and procedures typically describe staff expectations, individual accountability, and disciplinary processes, they must be reviewed and often revised to ensure alignment with the tenets of a Just Culture. Otherwise, the journey will be long and unsuccessful if the policies are in conflict with a Just Culture.

In a Just Culture, human resource-related policies and procedures regarding safety should hold all individuals equally accountable for the quality of their behavioral choices and should not focus on errors (which are not a behavioral choice) except for the expectation to report them. The policies and procedures should reflect a tone that is proactive toward risk identification rather than reactive to errors and adverse outcomes. They should define human error as inadvertent, with a response of consoling individuals and conducting an investigation to determine how to redesign systems to prevent the errors or detect them before reaching the patient. Policies and procedures should describe how to investigate a procedural violation to determine its causes and scope, and how to coach staff who have engaged in at-risk behaviors under the mistaken, but good faith, belief that the risks were insignificant or justified. For outcome-based duties related to sda business code of conduct, such as arriving to work on time and wearing identification badges, policies should be clear about expectations and the actions that will be taken when they are not met. When describing reckless behavior (actions involving a conscious disregard of what an individual knows is a substantial and unjustifiable risk), remove any reference to “negligent” or “criminal” conduct as the basis for disciplinary action. Regrettably, mere human error can result in legal action (criminal negligence), but human error is never reckless behavior. Also ensure that event reporting and investigation policies and procedures support the tenets of a Just Culture.

While human resource-related policies and procedures cannot guarantee that the desired actions will be realized in practice, they are a critical step for building an organizational foundation for success. Old punitive policies risk slipping back into an unjust culture. As organizations align actual practice with a Just Culture, they also need to align supporting policies and procedures.

References appear at the bottom of page 5—Safety risks >
Methylergonovine errors in obstetrics

A woman underwent a scheduled induction of delivery at 41 weeks gestation. Shortly following delivery, her newborn daughter was given methylergonovine maleate (discontinued brand METHERGINE) injection by mistake instead of phytonadione (vitamin K1) injection. The infant developed seizures and altered mental status requiring a neonatal intensive care unit (NICU) admission for several days. Fortunately, the baby recovered and is developing normally. The methylergonovine had been brought into the delivery room in case it was needed, due to the patient’s history of post-partum hemorrhage.

In the past, we have published mix-ups that involved methylergonovine injection and hepatitis B vaccine, both of which are available in obstetrical areas, and mix-ups between adult and neonatal ampu of phytonadione. We are also aware of an event in which a nurse administered methylergonovine to a newborn infant instead of the infant’s mother due to a series of verbal miscommunications. The error was not caused by a mix-up between methylergonovine and phytonadione but rather confusion regarding who was supposed to receive the prescribed methylergonovine. Sadly, the infant died.

Separating newborn medications from those used for mothers in perinatal areas reduces error potential. If an automated dispensing cabinet (ADC) must be shared between units, a locked, lidded storage bin should be used for pediatric products, and the selection screen should highlight which medications are for the mother and which medications are for the infant. If possible, infant medications should be administered in an area that is separate from where medications are administered to the mother. This strategy may not be workable in hospitals where mothers and babies room together. However, many infants are initially evaluated in a newborn nursery setting, so administration of some medications after birth, including phytonadione injection, may be delayed until the baby is in the nursery. Bringing only the medications that are needed to the bedside is also a strategy to limit unnecessary access to medications without a current order or identified need. Also, neonatal phytonadione is available in a prefilled syringe, which can help to differentiate it from ampu of methylergonovine. Finally, hospitals should implement processes in which infants are reliably banded with an ID bracelet immediately after birth. Then barcode scanning of drug containers can eliminate dangerous mix-ups like this one.

> Safety risks — continued from page 4

References
2) CDC. Vaccine storage & handling toolkit. May 2014. www.ismp.org/sc?id=1663
5) Graves K. Nurses’ decision making processes about lighting during medication administration. A dissertation submitted to Texas Woman’s University College of Nursing. May 2014.
Safe Medication Management Fellowships

ISM is now accepting applications for two unique Fellowship programs

**ISM Safe Medication Management Fellowship**

**Location and Term:** The 12-month Fellowship commences summer 2016 at the Pennsylvania (near Philadelphia) office of ISM. Relocation to the Philadelphia area is required.

**Description:** The Fellowship offers a nurse, pharmacist, or physician with at least 1 year of postgraduate clinical experience an unparalleled opportunity to learn from and work with some of the nation’s experts in medication safety. Now in its 24th year, the Fellowship allows the candidate to work collaboratively with practitioners in various healthcare settings to assess and develop interdisciplinary medication error-prevention strategies.

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**Description:** The Fellowship, open to a healthcare professional with at least 1 year of postgraduate clinical experience, is a joint effort between ISM and FDA’s Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, and Division of Medication Error Prevention and Analysis. The Fellowship allows the candidate to benefit from ISM’s years of experience devoted to medication error prevention. At FDA, valuable regulatory experience is gained by working with the division focused on medication error prevention.

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**How to Apply**

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Applications can also be requested by calling 215-947-7797.

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Please join us on March 2, 2016, at 1:00 p.m. ET for a special, live conference call about the Fellowship programs. Current and past Fellows will describe their Fellowship experiences as well as their post-Fellowship careers. They will also be available to answer any questions you may have about the Fellowship. To attend, please send an email to: fellowship@ismp.org.

The application deadline for all Fellowship Programs is March 31, 2016.