ISMP Medication Error Report Analysis

Selected Medication Safety Risks to Manage in 2016—Part II

Methylergonovine Errors in Obstetrics

Michael R. Cohen, RPh, MS, ScD, and Judy L. Smetzer, RN, BSN†*

These medication errors have occurred in health care facilities at least once. They will happen again—perhaps where you work. Through education and alertness of personnel and procedural safeguards, they can be avoided. You should consider publishing accounts of errors in your newsletters and/or presenting them at your inservice training programs.

Your assistance is required to continue this feature. The reports described here were received through the Institute for Safe Medication Practices (ISMP) Medication Errors Reporting Program. Any reports published by ISMP will be anonymous. Comments are also invited; the writers' names will be published if desired. ISMP may be contacted at the address shown below. Errors, close calls, or hazardous conditions may be reported directly to ISMP through the ISMP Web site (www.ismp.org), by calling 800-FAIL-SAFE, or via e-mail at ismpinfo@ismp.org. ISMP guarantees the confidentiality and security of the information received and respects reporters' wishes as to the level of detail included in publications.

SELECTED MEDICATION SAFETY RISKS TO MANAGE IN 2016—PART II

In this column last month (May 2016), we described selected medication safety risks that might fall off the radar screen unless an adverse event happens to draw attention to them. In part I, we selected 1 risk for each of 5 of the 10 key elements of the medication use system. These included management of patient information, drug information, how information is communicated to staff, how medications are labeled and packaged prior to administration, and how patients are educated. This month in part II we'll cover a topic for the remaining 5 key elements associated with medication storage, the environment, medication devices and technology, human resources, and culture.

6. Drug Storage, Standardization, and Distribution: Improper and Unsafe Vaccine Storage

The proper storage and handling of vaccines is vitally important because it affects their stability and efficacy. 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 the selection of the wrong vaccine, diluent, or other medication with a look-alike name and/or labeling and packaging. Unsegregated storage of vaccines has led to the wrong vaccine or wrong form of vaccine (adult vs pediatric) being dispensed and administered. The storage of 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

*President, Institute for Safe Medication Practices, 200 Lakeside Drive, Suite 200, Horsham, PA 19044; phone: 215-947-7797; fax: 215-914-1492; e-mail: mcohen@ismp.org; Web site: www.ismp.org. †Vice President, Institute for Safe Medication Practices, Horsham, Pennsylvania.

to reconstitute vaccines or were mistaken as hepatitis B or influenza vaccine.

Store vaccines in stand-alone refrigerators or pharmacy grade, purpose-built refrigeration units (and freezers in the pharmacy), not in dormitory style refrigerators or combination units that both refrigerate and freeze. Regular temperature monitoring is necessary. Continuous temperature monitoring devices are available to enable staff alerts via electronic messages (eg, e-mail, 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, and keep vaccines with their corresponding diluents. Never store different vaccines in the same bin or 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 2 components in separate vials that need to be combined before administration. *ISMP Medication Safety Alert!*¹ (March 26, 2015) contains additional strategies, as does a Vaccine Storage & Handling Toolkit available from the Centers for Disease Control and Prevention (CDC).²

7. Environmental Factors, Workflow, and Staffing

Patterns: Poor Lighting Quality

Lighting is a crucial aspect of the physical environment that has been linked to medication safety.³ Poor lighting quality has often impaired the 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 health care, it has been a challenge to implement optimal lighting conditions for prescribing, dispensing, and administering medications. Recent literature reviews found that little systemwide action has been taken to increase staff awareness of the problem or to improve the lighting.^{4,5} This is largely because the tasks associated with medication use are varied and are carried

out under diverse physical conditions and in differing locations. There are also differences in light requirements based on an individual's visual acuity and age. In an ever-increasing population of older health care 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 under low lighting at night 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 foot-candles (fc), whereas 100 to 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 and 150 fc.⁷ Medication rooms should provide illumination at 100 fc.⁷ Lighting levels should be increased if the average age of the workforce is above 45 years. A magnifying glass and task light together can also significantly improve accuracy⁶ and should be used on mobile medication carts (including those used with barcode medication verification systems)⁷ and near ADCs.

8. Medication Device Acquisition, Use, and Monitoring:

Failure to Disinfect Ports and Use Sterile Caps

Two seemingly harmless practices that breach aseptic technique might lead to contamination of sterile injection equipment and increase the risk of a health care-associated infection (HAI) of the bloodstream or tissues: (1) failure 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) failure to properly disinfect the port when accessing needleless 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 uses. Now it appears that practitioners are not considering the risk of contamination, and they 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 place a sterile cap on the end of the IV tubing between intermittent infusions.⁸ This disinfection process should specify the disinfecting agent, the method for disinfection (eg, 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.

9. Staff Competency and Education: IV Practices Based on Inherited Knowledge

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.⁹ The causes of these errors are diverse, but one contributing factor is that pharmacists and nurses are ill prepared to take on these tasks upon graduation from schools of pharmacy and nursing.

In recent years, pharmacy practice has moved toward a more clinical focus. Partly as a result, core practices such as sterile compounding and IV admixture are not given much attention during training.^{10,11} 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 these procedures from practicing pharmacists, who may or may not carry out the procedures safely, depending on how they were taught.

It is much the same for graduate nurses, although for different reasons. Oftentimes, student nurses are not permitted to administer IV infusions or IV push medications during rotations in clinical areas. Even if they are allowed, their 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.^{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.

10. Quality Processes, Risk Management, and Culture: Human Resource Policies that Conflict with a Just Culture

As health care organizations move toward 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.

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 they reach 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 a 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 policies and procedures cannot guarantee that the desired actions will be realized in practice, they are a critical step in building an organizational foundation for success. Punitive policies create the risk that the organization will slip back into an unjust culture. As organizations align actual practice with a Just Culture, they also need to align supporting policies and procedures.

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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. 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 postpartum hemorrhage.

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 ampuls of phytonadione. We are also aware of an event in which a nurse administered methylergonovine to a newborn infant instead of the mother due to a series of verbal miscommunications. The error was not caused by a mix-up between methylergonovine and phytonadione but rather was due to the confusion regarding who was supposed to receive the prescribed methylergonovine. In this case, the infant died.

Separating newborn medications from those used for mothers in perinatal areas reduces the potential for errors. If an 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 ampuls of methylergonovine. Finally, hospitals should implement processes in which infants are reliably banded with an identification bracelet immediately after birth. Then barcode scanning of drug containers can eliminate dangerous mix-ups like this one. ■