2018-19 Targeted Medication Safety Best Practices for Hospitals Webinar – January 18, 2018 Questions and Answers

GENERAL

Q: Regarding the electronic health record (EHR), I feel like I would be much more effective if I were an "Informatics Medication Safety Officer" instead of just a Medication Safety Officer, as EHR resources are so short. Are you finding that common across healthcare?

A: Since so many medication safety efforts hinge upon automation and the electronic health record, MSO's need to be knowledgeable about the basics of informatics at their organization as well as have a good rapport and working relationship with the informatics team. While there is some overlap, there are clearly different responsibilities and focus in the two positions – more than can be fulfilled by one person. We believe that the MSO position should not be diluted by informatics responsibilities unrelated to medication safety. Fortunately, we have not seen (based on our surveys) a combination of these roles.

Q: What disciplines were respondents to the survey for this data?

Q: How many respondents representing how many different organizations participated in the survey?

A: There were 338 respondents. 92% of the respondents were pharmacists, 7% were nurses and 1% were "other." We do not have data on how many different organizations were represented. However, we asked for only one respondent from each organization to complete the survey.

BEST PRACTICE 1

Q: We are using a closed system transfer device that eliminates the potential for intrathecal administration with vinCRIStine and Bortezomib. If we lock out the ability to procure the intrathecal adapter, would this meet the best practice for vinCRIStine?

A: While locking out the ability to procure the intrathecal adapter is a good additional precaution, it does not meet our best practice. The best practice required that vinCRIStine and other vinca alkaloids be administered via a minibag and not a syringe, so any use of the syringe, regardless of other safeguards in place, would be contrary to the best practice.

Q: The pushback we get on the vincristine best practice is that the "since the med is prepared in 30 mL syringe, NO ONE would administer that intrathecally" Any comment on that?

A: While most people would understand that this should not be done, you cannot rely on all providers recognizing that the syringe volume would be too large for intrathecal administration. Unfortunately, we have received reports of individuals who have tried to administer medications in a 50-mL syringe intrathecally. Counting on practitioners to "catch" this potentially fatal error is far riskier than taking steps to "prevent" the error in the first place.

BEST PRACTICE 7

Q: Does that mean that you are no longer recommending placing auxiliary labels on manufacturer products? It is acceptable to place in a bag or other container, if the manufacturer labeling is clear?

A: Yes, we are not recommending placing auxiliary labels on the manufacturer's vial or other medication container if the vial/container is already labeled with the warning. However, we do recommend placing an auxiliary label on all storage bins, automated dispensing cabinet (ADC) pockets/drawers, and final medication containers (syringes/IV bags). We still recommend that any bag or container in which the vial is placed also contain an auxiliary warning label.

Q: Regarding NMB anesthesia syringes. I have seen issues with medications such as neostigmine in the almost same identical syringe as the NMBs (succinylcholine). Is there any pressure being put on the 503b's to address this issue since many times these are stored in anesthesia carts in open matrix drawers?

A: Although ISMP works with sterile compounders (and manufacturers) to improve labeling, we have no ability or regulatory authority to exert pressure. When we are notified of an issue, we communicate with the company and make recommendations for improvement. Whether they choose to follow our advice is up to them. We encourage practitioners to submit their concerns and comments to us.

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BEST PRACTICE 8

Q: To meet this best practice, do we have to have infusion rate limits for chemotherapy in the pump library? We've struggled with developing limits for chemotherapy since the dosing is so variable.

A: We are not specific as to include infusion rate limits in the best practice, as this can be dependent on the drug/fluid being administered. We do, however, require that organizations determine the parameters (e.g. dose limits, rate limits and other "rules") that should be built into the infusion pump library to ensure that when certain drugs/fluids, especially high-alert medications, are administered using a smart infusion pump that staff are alerted to unsafe conditions or situations.

BEST PRACTICE 9

Q: Do you have a list of antidotes or reversal agents that we should prioritize first, since many organizations are suggesting it is taking much time and resources to fully implement?

A: Due to the large variety of products/antidotes or reversal agents available and variability of use within facilities, we cannot provide a universal list. One listener recommended referring to the *Expert Consensus Guidelines for Stocking of Antidotes in Hospitals That Provide Emergency Care*. Ann Emerg Med. 2017; 1-12

BEST PRACTICE 13

Q: What is the reason for eliminating promethazine?

Q: Why is IV promethazine such a concern?

Q: Other than the risk of necrosis from iv administration what are the additional reasons for eliminating this drug fully from the formulary?

A: Serious tissue injuries and amputations from the inadvertent arterial injection or IV extravasation of injectable promethazine have occurred and continue to occur. The US Food and Drug Administration (FDA) requires the manufacturer to include strong warnings about the risk of inadvertent intraarterial injection or perivascular extravasation of this drug in the package insert. Because there are many suitable alternatives, limiting access is a much stronger strategy to prevent patient harm in this circumstance than asking every practitioner in an organization to take special steps to use it safely, with no guarantee that they will be taken.

Q: Can you provide resource information on eliminating promethazine and fentanyl (i.e., hospitals that have already done so)?

Q: Can you provide examples of pediatric hospitals that removed promethazine?

Q: Any there any special considerations for pediatric hospitals related to this best practice?

A: Injectable Phenergan is a non-formulary, non-stocked item across the entire 10 hospital health-system at OhioHealth. For more information, contact Kelly Besco, PharmD, FISMP, CPPS, Medication Safety Officer at Kelly.Besco@ohiohealth.com. Pediatric hospitals were taken into consideration. We received a report from the Pharmacy Safety and Quality Coordinator at Children's Hospital of Orange County in Irvine CA that they have recently removed injectable promethazine from their hospital. For more information contact: Shannon Bertagnoli at Seetagnoli@choc.org. NOTE: ISMP did not recommend eliminating fentanyl from your hospital, only injectable promethazine.

- Q: One of our physicians wants to know the incidence or rate of harm per/1000 patient days.
- Q: Regarding promethazine, what is the rate of harm in the US?
- Q: Does ISMP have data regarding the frequency of promethazine injuries?
- Q: is there data for incidence of adverse effects with IV promethazine? This will make pleading the case easier.

A: To our knowledge the incidence of harm for promethazine is unknown throughout the world, as healthcare organizations and ISMP rely on voluntary error reporting to capture events, many of which have been shown in the literature to be unreliable source for error rates. Like other error types, we believe these events to be under-reported. In 2006, ISMP conducted a national survey to gauge the prevalence of

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patient harm related to this issue. Of the nearly 1,000 responses to the survey, 1 in 5 practitioners reported awareness of such an occurrence in his or her facility during the prior 5 years. Due to repetitive reports of patient harm, the US Food and Drug Administration (FDA) requires the manufacturer to include a strong warning statement in its package insert, suggesting they too believe the rate of harm is significant. However, as several listeners commented: "Even one case of serious harm in a patient deserves precautionary measures."

Q: Since the risk of the promethazine appeared to be limited to IV injections, is there a problem with a facility limiting it to IM administration only?

A: While IM administration does not cause serious harm, we still do not recommend using the drug IM, since it must be administered in a syringe and the potential for accidental administration by IV push is possible. One listener commented on the inappropriate use of the IM administration of the drug in their hospital, it was frequently administered in the deltoid muscle instead of a large muscle. In addition, we do not recommend using the drug by dilute IV infusion, as this practice requires that vials are available in patient care areas (e.g., automated dispensing cabinets) for urgent use, again resulting in the potential for accidental administration by the IV push route. We believe the best systems approach to preventing harm from injectable promethazine is to remove it from the hospital entirely.

Q: Regarding promethazine injection, given that drug shortages are so rampant right now, many fear removing things from the formulary.

A: One cannot justify failing to implement practices that can reduce serious harm to patients based on the unknown possibility of a drug shortage in the future.

BEST PRACTICE 14

Q: Would a quarterly review about ISMP newsletters with the Pharmacy and Therapeutics (P&T) committee, or similar group suffice? I believe you listed "monthly".

A: Quarterly review would be acceptable. The goal is to review the medication errors and risks reported by other external organizations to evaluate your own current medication systems to determine the potential risk points in your organization. We used "monthly" because in many cases that represents the frequency when most similar organizational committees meet. If you prolong the review too long (e.g. annually) and do not have a regular process, then the amount of data and information to review can become too onerous to properly and thoroughly review at a single meeting.

Q: Are there any tangible resources to tap into regarding the best practice of learning from the mistakes of others?

Q: Are there any resources other than ISMP that acts as a repository for general medication errors?

Q: Can you elaborate on HOW to seek out medication safety risks and errors that have occurred in other organization outside of my facility?

Q: Where are the best places to find information on errors outside of our facility.

A: There are several formal and informal sources of valuable medication safety stories from external entities. ISMP's semi-monthly newsletter *Medication Safety Alert!* and its Quarterly Action Agenda in the newsletter are a good source. Other formal sources include: The Joint Commission *Sentinel Event Alert*; advisories from the US Food and Drug Administration (FDA), and the Centers for Medicare & Medicaid Services (CMS); publications from patient safety organizations (e.g., *Pennsylvania Patient Safety Advisory*); peer-reviewed journals and newsletters; and other reliable publications. One listener suggested the AHRQ website: https://psnet.ahrq.gov/webmm. Health organizations with several associated facilities are wise to share deidentified error types and contributing factors as they work together on prevention strategies. Hospitals and health systems that belong to a Patient Safety Organization (PSO) or a Health Information and Innovation Network (HIIN) also may gain external safety knowledge about errors that have happened at other organizations. In addition to these, there are informal sources such as the Medication Safety Officers Society and ASHP Medication Safety listservs. ISMP recommends that you develop a list of resources that you can use on a formal basis for review.