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ISMP
An ECRI Affiliate

Acute Care ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

A recurring call to action: Every healthcare organization needs a Medication Safety Officer!

Medication safety is a serious responsibility that is vital to the sustainability of healthcare organizations.[1] On average, hospitalized patients experience one medication error each day,[2,3] and preventable adverse drug events continue to be a frequent cause of hospital readmissions in older adults.[3,4] While many medication errors do not result in substantial patient harm, others may result in dire consequences for patients.

Since the Institute of Medicine (now called the National Academy of Medicine) report in 1999, *To Err is Human*,[5] years of focused efforts on medication error reduction have resulted in sizable progress. Despite these achievements, continuous changes in healthcare (e.g., changes in medications, team roles, staffing patterns, medication-related technologies, workflows, complex medication management systems) have introduced unintended consequences and new challenges that compromise medication safety. External forces such as drug shortages and competing demands from regulatory agencies, accrediting bodies, third-party payors, and patients further impact the efforts to prevent errors.[6] Additionally, the medication safety problem is much larger than what can be gleaned from reported errors, as evidenced by numerous studies that have uncovered vast underreporting of medication errors.[2-5] Thus, medication errors remain a significant contributor to preventable patient harm, and healthcare executives in virtually every US healthcare organization face the daunting task of enabling transformational change to result in sustainable medication safety improvements in their organization—yet they cannot do it alone.[3]

According to US hospitals (n = 807) that responded to our 2017-2018 *ISMP Medication Safety Self Assessment for High-Alert Medications*, about half (48%) have created a Medication Safety Officer (MSO) position to address ongoing medication safety challenges. This represents an increase in establishing an MSO position when compared to the results of our *ISMP Medication Safety Self Assessment for Hospitals* in 2011, when 40% of participating US hospitals had employed an MSO, and in 2000, when only 12% of participating US hospitals had employed an MSO. The initial catalysts for the MSO position included the escalation of the modern patient safety movement, an emerging cultural change unlike anything that had previously occurred in healthcare, a desire to bring recognition and leadership to medication safety programs, and the need for special education and skills to meet program requirements.

Who is an MSO?

An MSO is a dedicated clinical medication safety advocate armed with education, authority, and leadership skills, who serves as the organization's authoritative expert in safe medication use for the purpose of reducing patient harm.[3,7] Other titles used to describe this role include medication safety leader, medication safety manager, medication safety coordinator, medication safety clinical specialist, director of medication safety, and similar variations. Traditionally, the MSO may be a pharmacist, but nurses, physicians, and physician assistants with the requisite skills are also qualified to meet the responsibilities of an MSO. In fact, our 2018 self-assessment results show that hospitals with at least a part-time MSO scored, on average, significantly higher on their overall ability to safely manage high-alert medications than hospitals without an MSO, regardless of whether the MSO was a pharmacist, nurse, physician, or other healthcare practitioner.

continued on page 2 — Medication Safety Officer >

SAFETY briefs

HIGH-ALERT

Dispense unit dose syringes using the most appropriate concentration.

A wrong route error happened after an order for 2 mg of oral morphine was dispensed using a commercially available 15 mL bottle containing a 100 mg/5 mL (20 mg/mL) oral solution. An oral syringe that accompanies the 20 mg/mL morphine solution bottle has a mark for 5 mg as the lowest dose on the syringe scale (**Figure 1**). Because the 2 mg (0.1 mL) dose was not measurable using the provided syringe, a nurse prepared the dose using a 1 mL parenteral syringe. That allowed for the accidental connection of the parenteral syringe to the patient's intravenous (IV) line, and unfortunately, the oral solution was administered IV.

Figure 1. The lowest dose marking is 5 mg on the oral syringe that accompanies the morphine oral solution 100 mg/5 mL (20 mg/mL).

The practitioner who reported this event linked the error to not having a way to measure and administer doses under 5 mg using the accompanying oral syringe. He asked ISMP to advocate for adding "smaller markings" on the syringe. However, morphine 20 mg/mL solution is intended only for opioid-tolerant patients who would be receiving doses in line with the syringe markings or greater. For lower doses, an oral solution is available in a 2 mg/mL (10 mg/5 mL) concentration, which comes with a dosing cup. Thus, we will not be advocating for changes to the morphine 20 mg/mL syringes.

continued on page 3 — SAFETY briefs >

> Medication Safety Officer — continued from page 1

Why is an MSO needed?

The MSO position is not merely a title change for an existing position, and the role cannot be covered by other practitioners simply by adding "medication safety" to their job description. Of course, safe medication use is a shared responsibility among all healthcare practitioners who procure, prescribe, prepare, dispense, administer, and monitor medications. However, when healthcare executives hire a qualified, dedicated MSO, empower them to act on medication safety concerns, and position the MSO on the organizational chart where it will best enhance their ability to affect change, it helps to ensure that the organization will identify and learn from medication risks and errors (both internal and external), and implement high-leverage strategies to reduce or eliminate the negative consequences of medication errors.[3] An MSO can also make past safety achievements more robust, widespread, and sustainable, and they are well positioned to interact frequently with frontline clinicians to learn about system vulnerabilities. Without an MSO, medication safety tasks are rarely prioritized, and those with high impact are infrequently addressed.[6,7]

Furthermore, specialized training and/or practice experience in medication safety is vital to the success of the MSO.[6] For example, detailed knowledge of the science of patient safety and reliability, quality improvement principles, human factors, Just Culture, event investigation, system design, medication-related technologies, high-leverage error-reduction strategies, change management, and medication safety measurement are all essential to this role, as are an in-depth understanding of the entire medication use process and the ethics of transparency and disclosure. Additionally, an MSO requires a high level of communication, interpersonal, and leadership skills.[6] They must be a leader who earns the respect of those who can influence the behaviors of others, largely because the MSO's impact is made primarily through others.[1]

For a medication safety program to succeed, it is essential to have an innovative and highly visible MSO to set a vision and direction, identify opportunities for improvement, and coordinate the implementation of error-prevention strategies.[7] These safety leaders are said to be a "lifeline to patients and a life jacket for chief executive officers."[1] Similar to the evidence provided by successful infection control efforts in the US that are led by an infection preventionist,[8] the immense value of employing a qualified, dedicated MSO for the sole purpose of medication error surveillance and proactive error-control planning, is well supported by many professional organizations, including the National Academy of Medicine, the National Quality Forum, ISMP, ECRI, the Institute for Healthcare Improvement, and the American Society of Health-System Pharmacists (ASHP).

What are the Roles of an MSO?

It is critical for the role of the MSO to be custom designed to fit the vision and mission of the organization and to be tailored to the culture and values of the organization.[1] However, there are nine essential MSO roles that are key to achieving successful outcomes:[1,3]

① **Champion and Diplomat:** The MSO is a visible campaigner and an authoritative resource on medication safety. For example, on a typical day, an MSO might conduct leadership rounds on a clinical unit to listen to staff regarding current practices or systems that contribute to medication errors, as well as to reinforce a specific value of the organization or a medication safety initiative that is underway.

② **Information Steward and Communicator:** The MSO is a centralized expert on organizational medication safety-related evidence, information, and knowledge. During the course of a day, for example, an MSO might participate in a medication safety research project, conduct a literature search to capture ideas from external sources, disseminate new information to staff, write a medication safety-related newsletter, or provide a medication safety educational program for practitioners undergoing orientation.

continued on page 3 — Medication Safety Officer >

Resources for MSO Education and Networking

Sidebar

Consider the following resources for specialized education and networking for Medication Safety Officers (MSOs):

① ISMP Medication Safety Intensive (MSI) Workshops (www.ismp.org/node/127)

Several times a year, ISMP offers a 2-day, hands-on workshop (currently virtual) that is intended for practitioners with responsibility for medication safety oversight, including MSOs. During the workshop, faculty challenge attendees to see their organization through the eyes of leading medication safety experts. Since the start of the program, more than 1,600 enthusiastic participants have engaged in group discussions and problem-solving related to medication safety, data collection methods, culture, and the role of the MSO. Participants also have an opportunity to discuss the challenges and issues in medication safety oversight with two practicing MSOs.

② ISMP Practitioner in Residence (PIR) Mentorship (www.ismp.org/node/22697)

Several times a year, ISMP offers a week-long PIR program (currently virtual) designed for practitioners with oversight of medication safety. The program provides an enhanced learning experience that will impact the medication safety challenges in the participants' organizations. Participants focus on medication risk identification, error reporting and analysis, root cause analysis, medication safety team development, data collection and analysis, and strategic planning for medication safety. To date, nearly 50 participants have completed the program, which is limited to just a few participants during each session to allow customization of the mentorship to match the expressed needs of the participants.

③ ASHP-ISMP Medication Safety Certificate Program (www.ismp.org/node/770)

This self-guided eLearning program for healthcare professionals consists of 15 modules covering in-depth presentations, readings, and exercises covering the key aspects of medication safety, including risk

continued on page 3 — Sidebar >

> Medication Safety Officer — continued from page 2

③ **Strategist and Influencer:** The MSO is an influential voice establishing medication safety as a core value for both individuals and the organization. To accomplish this, an MSO might engage executive leaders, board members, or medical staff in a discussion about a complex medication safety challenge and confidently present the evidence for recommended high-leverage change strategies that will address the issue.

④ **Ethical Negotiator:** The MSO is a leader, leveraging process and system changes to embed safety and sustain improvements at the local and organizational level, all while maintaining the elements of ethics, transparency, and disclosure. For example, with every interaction and every person encountered, an MSO might demonstrate non-negotiable mutual respect that leads to an environment of trust and honesty that promotes error reporting and reliable system design.

⑤ **Cross-discipline Team Leader:** The MSO is a connector spanning boundaries to work across professional silos and hierarchies, engaging all in medication safety efforts. To accomplish this, an MSO might chair a medication safety committee and present relevant topics from the ISMP *Action Agenda* (www.ismp.org/node/645) or the *ISMP Targeted Medication Safety Best Practices for Hospitals* (www.ismp.org/node/160) for an interdisciplinary assessment, discussion, and development of a plan for improvement.

⑥ **Data Optimizer:** The MSO is a conduit for coordinating investigations of medication error-reporting data and analysis of technology data to ensure efforts result in tangible improvements. To achieve that level of optimization, an MSO might lead an event investigation, participate in a root cause analysis (RCA), or analyze medication-related technology data (e.g., from infusion pumps, bar-coding technology, automated dispensing cabinets) to inform a realistic and measurable action plan that is subsequently implemented and monitored to ensure plan effectiveness.

⑦ **Proactive Facilitator:** The MSO is often forward-looking, prospectively identifying preventable medication risks that could lead to patient harm, identifying the causes of risks, and implementing risk-reduction plans. To be proactive, an MSO might lead a team conducting a failure mode and effects analysis (FMEA) associated with a new smart infusion pump.

⑧ **Compassionate Just Culture Mentor:** The MSO is a fair and trusted colleague who guides others to make behavioral choices consistent with the organization's values, consoles individuals in cases of human error, encourages the reporting of medication risks and errors, and helps leaders design or redesign medication-use systems that eliminate or reduce the risk of errors. To be a compassionate mentor, an MSO might assist with developing, conducting, or reporting the results of an organization-wide culture survey; help a manager identify whether an employee's behavior during an event represents human error, at-risk behavior, and/or reckless behavior, and advise the manager how to respond; or show compassion for a patient and caregiver who were involved in system failures or human errors that caused or could have caused preventable harm.

⑨ **Agent of Change:** The MSO seeks to identify and understand challenges to medication safety, find creative solutions, and drive those solutions into action. For example, during the course of a day, an MSO might attend a pharmacy and therapeutics committee meeting, introduce a difficult and emotionally charged medication safety challenge, and guide the discussion towards respectful consensus on a viable solution.

Available Resources

If your healthcare organization does not employ one or more MSOs, there are many resources available to help you build a case to bring to executive leadership regarding the need for an MSO. Two resources in particular warrant your attention:

continued on page 4 — Medication Safety Officer >

> Sidebar — continued from page 2

identification, assessment, and investigation; human factors; Just Culture; risk-reduction strategies; and technology. A final module describes how to pull all the topics together to successfully implement and sustain safe medication practices. After completing all the modules, participants should be proficient in the fundamental concepts required for risk identification, medication error investigation, risk reduction, and actions required to sustain safe medication use. Participants who pass a comprehensive exam earn a professional certificate in medication safety.

④ Medication Safety Officers Society (MSOS) (www.medsafetyofficer.org)

The MSOS promotes a mission to advance excellence in medication safety by providing communication, leadership, direction, and education for its members (membership is currently free). With an interdisciplinary membership of nearly 3,000 practitioners, many of whom are MSOs, the MSOS offers an open forum for information sharing and collaboration, an active discussion board, and *MSOS Member Briefings* every other month that cover medication safety-related topics of interest. A recent *Briefing* included a presentation on establishing an MSO position in a rural setting. The *Briefings* are recorded and accessible to members.

> SAFETY briefs

cont'd from page 1

Although lack of a smaller dose marking on the syringe scale may have contributed to the nurse preparing the dose with a parenteral syringe, the way to minimize the risk of an error and patient harm is to use the most appropriate concentration of oral solution available. The hospital investigated obtaining the lower concentration but found that only the 20 mg/mL concentration was available from their wholesaler. While wholesalers need to make both concentrations available, this lower concentration can be obtained from other suppliers. Furthermore, the pharmacy should dispense patient-specific, ready-to-administer doses in labeled oral or ENFit syringes, rather than dispensing a 15 mL bottle that contains 150 doses (2 mg each). The hospital is adding an "ORAL USE ONLY" comment on the medication administration record. Barcode scanning could verify the drug and concentration, particularly if both concentrations are available.

continued on page 4 — SAFETY briefs >

> Medication Safety Officer — continued from page 3

① A Call to Action: The Case for Medication Safety Officers (MSO)[3] (www.ismp.org/node/1132)

In 2018, ISMP published a white paper explaining why an MSO is necessary in every healthcare organization, describing the optimal role of the MSO, and challenging healthcare executives to be accountable to their patients, staff, and communities by:

- Hiring an MSO with the requisite skills, knowledge, and attitudes
- Providing the MSO with the ability to act on safety concerns
- Accepting the responsibility to enable the MSO position to succeed
- Freeing the MSO from selected frontline responsibilities to lead the incremental hard work of transforming the medication management system into one that is highly reliable and safe

The white paper also recommends placing the MSO on the leadership team and making the position one of rank in the organization so the MSO has the authority to act and remove barriers to change. The MSO position requires strong, consistent support from executive leaders to transform the organization as needed to achieve medication safety.

② Medication Safety Officer Full-time Employee Justification Toolkit[6] (www.ismp.org/ext/644 [ASHP members-only access])

The ASHP Inpatient Care Practitioners' Section Advisory Group on Medication Safety identified that health systems attempting to justify a dedicated MSO or expand the number of MSOs in an organization lacked guidance on how best to approach this type of request. The group created a toolkit, which includes a document intended to be used as a template for an MSO proposal or to organize the beneficial elements in an MSO proposal. While every health system is likely to utilize its own full-time equivalent (FTE) justification template, this resource, which includes actual examples from previously submitted FTE justifications as well as a medication safety gap analysis, can help support these efforts in your organization.

Included in the template are background information related to medication safety and supporting evidence highlighting the value of creating a dedicated MSO position. There are preformatted sections that can be inserted directly into the proposal as well as sections that should not be replicated but rather reproduced using organization-specific data. The examples in the tool are not an all-encompassing list of activities that can be used for justification of an MSO but are intended to trigger thought regarding the position request.

If your organization already employs one or more MSOs, several additional resources associated with specialized MSO education and networking can be found in the **Sidebar** that appears in the right column on pages 2 and 3.

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> SAFETY briefs cont'd from page 3

Silicone-free syringes required. A hospital alerted us to an issue with dose preparation of **BERINERT**, a concentrate of C1 esterase inhibitor (human) indicated for the treatment of acute abdominal, facial, or laryngeal hereditary angioedema (HAE) attacks. HAE is a rare condition, and dose preparation of this drug was a new process in this hospital. Pharmacy and nursing staff had been educated about proper dosing, preparation, and administration; however, a crucial piece of information in the product labeling was missed: the manufacturer requires silicone-free syringes for reconstitution and administration of the drug.

The product, packaged as a kit, contains a single-use Berinert vial, a 10 mL vial of sterile water for injection, a **Mix2Vial** filter transfer set, and an alcohol swab; however, a silicone-free syringe is not included. Since the drug is very expensive and must be protected from light, it was kept in the original packaging and was not opened prior to use. Staff assumed a syringe was in the carton, as it is with other kits requiring silicone-free syringes, such as **ORENCIA** (abatacept). Since the required use of a silicone-free syringe was not known, the product was prepared using a syringe with silicone, and the drug was administered to the patient.

According to the company, it is important to use silicone-free syringes because particulate matter or visible protein flakes may appear when siliconized syringes are used. Since the syringe is not part of the Berinert kit, pharmacies and patients must purchase silicone-free syringes from one of four companies that sell this product:

- Air-Tite Products Co (HSW NORM-JECT Syringes)
- B. Braun (Injekt Syringes)
- West Pharmaceutical Services (Daikyo Crystal Zenith Luer Lock Syringes)
- Thomas Scientific (HSW NORM-JECT Luer Lock Syringes)

CSL Behring, the manufacturer of Berinert, does not recommend the use of a specific silicone-free syringe, and they have not tested the syringes listed above with Berinert. We believe the manufacturer should include a silicone-free syringe with the drug. Also, with this drug, the intention

continued on page 5 — SAFETY briefs >

Error-prone concentrations of ibuprofen suspensions

Parents who are told to give their child or infant over-the-counter ibuprofen oral suspension may not be aware that there are two different concentrations available. An infant's formulation (for infants 6-23 months or weighing 5.5-10.5 kg [12-23 lbs]) contains 50 mg/1.25 mL (40 mg/mL). This is twice as concentrated than the children's formulation (for children 2-11 years or weighing 10.9-43.1 kg [24-95 lbs]), which contains 100 mg/5 mL (20 mg/mL). Retail locations routinely stock both concentrations. Also, the labeling and packaging of the two concentrations can sometimes look similar.

Staff at children's hospitals might be familiar with this and have often made it a point of emphasis to educate parents about this issue at discharge. However, for many reasons, staff have told us about mix-ups that sometimes occur after discharge. One reason is that some hospital computer systems sometimes convert oral liquid doses to a metric volume to help parents measure each dose using a dosing cup or oral syringe. However, the concentration parents might purchase or already have at home is often unknown.

One hospital reported a close call involving a child who was discharged from an ambulatory surgery unit. The child's mother was concerned because she was familiar with giving her 8.6 kg child less than 2 mL of ibuprofen, as per the manufacturer's label instructions. However, the discharge instructions said to give 4.3 mL, or 86 mg of the 100 mg/5 mL concentration. After confirming that the mother had the 50 mg/1.25 mL and not the 100 mg/5 mL concentration at home, the hospital was able to tell the mother the appropriate volume of ibuprofen to administer to her child for each dose.

In another case, a child was prescribed ibuprofen 70 mg every 6 hours. The child's mother was told to give 3.5 mL of the medication for each dose, with the expectation that the 100 mg/5 mL suspension would be used. However, the child's mother purchased ibuprofen suspension 50 mg/1.25 mL (200 mg/5 mL) and gave her child 3.5 mL per dose as instructed. So, instead of receiving 70 mg, the child received 140 mg per dose. Fortunately, we are not aware of any serious adverse outcome as a result of this 2-fold overdose, but the possibility of side effects is likely increased. An overdose might lead to nausea, vomiting, diarrhea, headache, stomach bleeding, and kidney damage.

This situation is similar to an issue that has since been resolved with oral liquid acetaminophen (**TYLENOL**) products, which, for many years, existed in two concentrations: a more concentrated liquid (100 mg/mL) for infants, and a less concentrated liquid (160 mg/5 mL) for children. When the 100 mg/mL concentrated product was accidentally administered to children in volumes appropriate for the 160 mg/5 mL product, there were accidental deaths and serious injuries to children. Faced with this evidence, manufacturers voluntarily withdrew the more concentrated infant's product and agreed to only provide the 160 mg/5 mL concentration that is available today (some manufacturers label their products as 500 mg/15 mL concentration).

Due to the potential for harm and the ongoing nature of these ibuprofen errors, we have interacted with the US Food and Drug Administration (FDA) and asked the agency to look into the matter to determine if the more concentrated product is truly necessary. One of the children's hospital nurses who we spoke with queried colleagues about this, and the overwhelming response was, "Why isn't there just one concentration of liquid ibuprofen similar to acetaminophen?" Ideally, Johnson & Johnson Consumer Health, the original sponsor of infant's and children's **MOTRIN** (ibuprofen), would modify the infant's concentration to match the children's concentration, as was done for acetaminophen, with other ibuprofen manufacturers to follow. For now, we recommend that healthcare providers counsel parents about the availability of the two liquid ibuprofen strengths, and that the 100 mg/5 mL strength includes "children's ibuprofen" in the name, while the more concentrated 200 mg/5 mL (50 mg/1.25 mL) strength is referred to as "concentrated infant drops." Ensure parents understand that the dose in mL (volume) must be based on which concentration they are using.

> SAFETY briefs cont'd from page 4

is for the patient/caregiver to prepare doses for self-administration at the onset of an HAE attack. Thus, pharmacies that dispense this drug should provide one of the four syringes mentioned above for use in the hospital. It is also important to educate patients and provide these special syringes upon discharge. Discharge planning/care management staff should ensure these syringes are available for patients after discharge.

Special Announcements

Become an ISMP Fellow

You still have time to apply for an ISMP fellowship, which can help you grow in your career and make major contributions to medication safety! ISMP is accepting applications until **March 31, 2021**, for three unique fellowship programs that begin this summer/fall. For more information, visit: www.ismp.org/node/871.

FREE ASPEN webinar

The current shortage of intravenous (IV) multivitamins has become a critical healthcare issue. To learn more about this issue, register for a **FREE** webinar being held by our safety partners at the American Society for Parenteral and Enteral Nutrition (ASPEN), ***Optimizing Patient Care During a Multivitamin Shortage***, which will be presented on **March 4, 2021**, from 4:00-5:30 p.m. ET. To register, visit: www.ismp.org/ext/646.

To subscribe: www.ismp.org/node/10

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