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ISMP

Acute Care
ISMP Medication Safety Alert!®
Educating the Healthcare Community About Safe Medication Practices

Maximize benefits of IV workflow management systems by addressing workarounds and errors

Data submitted to the ISMP National Medication Errors Reporting Program (ISMP MERP) have repeatedly shown that manual verification of intravenous (IV) admixture ingredients by pharmacy personnel who prepare solutions and pharmacists who inspect the final products is not particularly effective in detecting and correcting errors.[1] Thus, the *ISMP Guidelines for Safe Preparation of Compounded Sterile Preparations*, originally published in 2013 and updated in 2016, recommend technology such as barcode scanning to verify all base solutions and ingredients during preparation and verification of compounded sterile preparations (CSPs). Since 2016, a recommendation to use barcode scanning and other technologies to assist in verification of CSPs has also been included in the *ISMP Targeted Medication Safety Best Practices for Hospitals* (# 11), particularly for high-alert medications, pediatric/neonatal preparations, pharmacy-prepared source/bulk containers, products administered via high-risk routes of administration (e.g., epidural, intrathecal), and other CSPs that an organization believes are high risk.[2]

Workflow Management Systems (WFMS)

To achieve this goal, increasing numbers of hospitals have implemented pharmacy IV workflow management systems (WFMS) that help automate the processes associated with preparing, verifying, tracking, and documenting CSPs. These systems not only require barcode scanning of each ingredient for positive identification before it is introduced in the compounding process, they can also help to standardize preparation steps; generate labels; automate calculations; assign beyond-use dates; display real-time electronic images of infusion bags, drug and diluent vials, and syringes throughout the verification process; track doses and minimize missing doses; reduce drug waste; and maintain an electronic record of the process. Some systems also add gravimetric analysis to verify the compounding accuracy of CSPs. Gravimetric analysis uses a known specific gravity or density of each ingredient to confirm the accuracy of the additives and base solution in a product based on its measured weight. During each step of the process, solutions are weighed on an electronic balance, and the results are compared to an expected weight stored in the system's database to verify the accuracy of the prepared volume and ensure it falls within an acceptable margin of error.[3]

ISMP is a staunch advocate of technology solutions (e.g., barcode scanning of ingredients, gravimetric verification of drug and diluent volumes, robotic image recognition) and strongly encourages their implementation to augment manual processes and provide additional safeguards during sterile compounding. Evidence suggests that barcode verification and gravimetrics coupled with real-time alerts created by WFMS can detect and prevent many potentially serious medication errors that would not have been recognized with traditional verification methods.[3-4] For example, evaluation of a WFMS at Boston Children's Hospital concluded that 23% of the errors detected by the system were undetectable by the pharmacy's previous verification practices.[5] In another study of a WFMS, nearly 9% of the intercepted errors could have resulted in patient harm.[6]

However, as with any new technology that introduces an element of change, we want you to know about the workarounds and errors we have learned about with WFMS and why they may be happening so you can be as prepared as possible to address them

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In deepest sympathy…

We were extremely saddened to learn of the August 27, 2017, death of **Dr. Kenneth N. Barker**, one of the earliest and most prolific researchers in the field of medication safety. Ken was best known for his scientific work in developing the observational method for detecting medication errors, which began in the early 1960s and brought national attention to medication errors in hospitals. The method was later developed into a commercial system known as AU MEDS, which is used in hospitals today to accurately detect medication errors.

Ken was one of the first researchers to identify that the unit dose system of drug distribution significantly reduced errors compared to other systems in use at the time, such as individual patient prescriptions combined with floor stock. With his colleague, the late Betsy Allan Flynn, he performed landmark research to show how control of lighting conditions, interruptions, distractions, and noise could reduce errors. They also extensively examined errors in community pharmacies. Ken and his family lived in Auburn, AL, where he was a professor and mentor to graduate students and head of the Pharmacy Care Systems Department.

ISMP is forever indebted to Ken for bringing the problem of medication errors to national attention.

SAFETY briefs

Please, no more teaspoon dosing.

Some community or ambulatory care pharmacists mistakenly believe it is helpful to "translate" prescription liquid dosing instructions for patients from metric (e.g., milliliters [mL]) to household measures (e.g., teaspoon). When they receive a prescription with dosing in mL, they change it to teaspoon dosing or list both teaspoons and mL

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when you assess or implement this technology. Some of these workarounds or errors are common to many other forms of healthcare technology.

Potential Workarounds and Errors with WFMS

Inability to scan the barcode. Some barcodes are difficult to scan or are not recognized by the WFMS due to a change in product manufacturers, the use of an alternative drug during a shortage, or the use of a new drug on the market. If a new drug or alternative drug is being used, pharmacy staff would need to stop the compounding process to have the new drug entered into the system. These conditions may cause pharmacy staff to bypass the barcode scanning process for these products until the system has been updated.

Reluctance to scan the barcode. WFMS typically require barcode verification (and image capture) at each step of the compounding process to proceed forward. However, given the hurried pace in the pharmacy, particularly at certain times, some compounding staff may perceive the barcode scanning process as being too time-consuming, especially during the initial implementation phase given their comfort with compounding products before the WFMS was implemented. With competing demands on their time, pharmacy staff may be reluctant to follow the workflow process because they feel it will slow them down. In fact, workflow issues were listed as a major barrier to implementation of WFMS in a recent ISMP survey. Workflow issues, being hurried, and a low perception of risk may lead staff to work around the barcode scanning requirements at times.

Scanning just one vial. Most WFMS are designed to complete one CSP at a time. But when compounding multiple doses of the same drug, as during batching, or for CSPs requiring more than one vial of the same drug, staff may scan the same vial multiple times as a shortcut. They may not perceive the risk in scanning the package once to prepare multiple products, or scanning the same vial multiple times instead of each individual vial used. But such a practice defeats the safety benefits of WFMS.

Using a decoy for scanning or image capture. In some cases, when batching multiple doses of the same product, a spare "scanning bag and vial" are kept on the side and scanned for all doses. Similarly, the same syringe and IV bag may be used for image capture for all doses instead of each individual dose measured. Although perceived as more convenient, the WFMS would not be able to detect compounding errors this way.

Using the syringe pull-back method. Despite implementing WFMS, some operations continue to use the syringe pull-back method for image capture in which the user injects the drug into the bag first, and then takes a picture of an empty syringe pulled back to the volume one believes was injected. The syringe pull-back method defeats the purpose of being able to visualize the actual volume of additive *prior* to injection. For years, ISMP has discouraged reliance on the syringe pull-back method for verification, particularly for chemotherapy, complex electrolyte solutions, or CSPs with other high-alert medications. The syringe pull-back method requires too great of a leap of faith to ensure safety and is now prohibited by some State Boards of Pharmacy.

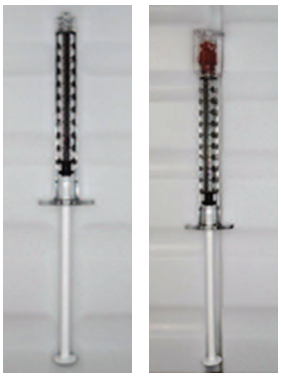

Figure 1. Volume in syringe may not be easily visualized. The syringe on the right is filled, while the syringe on the left is empty.

Blurry or missing digital images. Image verification with WFMS relies on the quality and type of pictures taken. Moniz et al. conducted an evaluation of an IV compounding WFMS in a pediatric hospital and found that during the initial months of implementation, nearly 36% of the rejected and reworked doses were related to blurry or missing images.[5] Unfortunately, the volume in the syringe may be too small to be visualized clearly from the picture taken, or the volume may not be clearly visible due to differences in the clarity of man-

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(in parentheses) on the label, believing most consumers are more familiar with household measures than metric dosing.

Unfortunately, pharmacy staff have inadvertently typed the number of mL in the teaspoons field, sometimes resulting in patient hospitalization. A close call occurred recently when **AUGMENTIN ES-600** (amoxicillin and clavulanate) suspension was prescribed for a child with otitis media. When the child's mother picked up the medication, a pharmacist provided counseling about how often to give each dose, to discard the medication in 10 days, and that it may cause diarrhea. However, the actual volume required for each dose was not discussed. Later, when the child's parent read the label at home, it said, "Give 5 teaspoons by mouth twice daily for 10 days." Wondering if this was accurate, she logged into an electronic patient portal to view a summary of her child's office visit and saw that the dose should have been 5 mL, not 5 teaspoons.

Mix-ups between mL and teaspoon have been a longstanding problem, first discussed by ISMP in this publication in 2000. In recent years, there has been considerable movement toward the use of the metric system for all over-the-counter (OTC) and prescription liquid medications. Most oral dosing devices now display a mL scale, some exclusively. Thus, "translating" mL doses to teaspoons, or listing both teaspoons and mL on labels, should cease, as it is not helpful to patients and creates confusion. The National Council for Prescription Drug Programs (NCPDP) published *Recommendations and Guidance for Standardizing the Dosing Designations on Prescription Container Labels of Oral Liquid Medications* in 2014, calling upon stakeholders, particularly pharmacy leadership, to adopt mL dosing as the standard (www.ismp.org/sc?id=551). This is needed for all patient instructions on pharmacy labels and in computer systems. Also, always provide an appropriate metric dosing device, and ensure that patients or caregivers know how to measure the dose in mL, using "teach back" to confirm understanding.

Dramamine umbrella name confusing. The brand name **DRAMAMINE** is the latest example of a well-known, successful, over-

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ufacturers' plastic syringes (**Figure 1**). Staff may also forget to capture images of all the ingredients used or find it too time-consuming to take images of all containers (e.g., 5 vials used to prepare the product but 1 vial used for image capture). Pharmacists may not know if the other vials used were correct.

Lapses in technique. Use of WFMS touch screens can lead to touch contamination, especially when handling hazardous drugs. This and other lapses in hazardous drug handling and aseptic technique are not easily captured by the WFMS and may go unnoticed.

Interference with the scale. ISMP has received a report about a WFMS with gravimetric technology for which the scale would not work in a laminar airflow workbench/biological safety cabinet due to vibration. Every time the pharmacy technician needed to weigh a product, he or she had to turn off the hood. However, we have no further details regarding this potential problem. Another reported issue is that the airflow may interfere with the scale's ability to accurately weigh low volume products.

Other human errors. System entry errors and labeling errors have been reported. For example, the WFMS may allow users to enter the manufacturer's lot number and expiration date, which has led to transcription errors. Or, labeling errors have occurred if the system requires a printed label before dose preparation, and staff have not followed procedure and have kept several printed labels in the work area.[3] Labeling errors have also happened during reuse of products if one product at a time is not completed or if the reused product never gets relabeled (old label remains on container). Visual verification systems may also be prone to confirmation bias, where individuals see what they expect to see rather than what is present. For example, a syringe with 15 mL of fluid might be incorrectly verified as having 10 mL of fluid, because the observer is expecting 10 mL of fluid. This may occur even when no workaround is present.

Recommendations

To maximize the safety benefits of employing WFMS during sterile compounding, take these steps to help avoid new sources of error and the potential for process step deviations and workarounds.

Conduct an FMEA. Prior to introducing any technology, it is always a good strategy to perform a failure mode and effects analysis (FMEA) to identify potential risk points, and to plan interventions prior to technology implementation based on high potential severity and probability scores, and low detectability scores. Be sure to include representation from all pharmacy personnel who may be using the WFMS, including technicians. Conducting the FMEA prior to implementation of WFMS also allows a comparison of the current compounding process to the ideal process using the technology to identify and communicate anticipated improvements.

Use gravimetric analysis and barcode scanning when possible. A workflow that includes gravimetric analysis and barcode scanning will identify both wrong volumes and wrong drugs or products. In addition, the technologies combined may be better at steering staff towards the approved workflow than either technology alone.

Test barcodes. With new drugs, changes in the manufacturer of a product, or an alternative drug used during a shortage, test the barcode for scanning success using the WFMS and remedy any problems prior to their use. This test should be included in a checklist specifying the steps for setting up any new drug in all applicable technology platforms.

Maximize the clarity of photos. Choose syringes for compounding that make it as easy as possible to detect the actual volume in the syringe with digital images. Before use, test a sample syringe from a new vendor that will be used during sterile compounding for the clarity needed during the digital verification process.

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the-counter (OTC) drug name being recycled for use in products that contain a different active ingredient or ingredients that differ from those in the original product. The original Dramamine contains 50 mg of dimenhydrinate (**Figure 1**), which is also available in a chewable form, along with a children's formulation containing 25 mg. But there is now a Dramamine that contains meclizine 25 mg per tablet (**Figure 2**), and another formulation that only contains ginger root—Dramamine Non-Drowsy Naturals, a supplement (**Figure 3**). Packaging for all these products highlights the Dramamine name. When an "umbrella name" (brand-name extension) is used for products with varying ingredients, there is bound to be confusion regarding the product's ingredients, strength, and concentration. The wrong product or dose may be taken or the product may be used when contraindicated. Misleading product names can also cause confusion when treating side effects or accidental ingestion of these products. Although full ingredients are listed in the product's *Drug Facts* or supplement panel, this information may be overlooked due to confirmation bias.

Figure 1

Figure 2

Figure 3

Figures 1-3. Dimenhydrinate (1), meclizine (2), and ginger (3) are all "Dramamine" products.

Dimenhydrinate is an OTC monograph drug, which is not specifically approved by the US Food and Drug Administration (FDA) via direct application but is legally marketed under regulations established through the FDA's OTC Drug Review. Monograph drugs are "generally recognized as safe and effective" for their intended uses.

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Avoid the syringe pull-back method of verification. Proxy methods of verification of ingredients, including the syringe pull-back method, should be avoided. Instead, verify all ingredients prior to their addition to the final container (in-line verification), or use digital images of syringes and containers of ingredients that were taken during the process before mixing to retrospectively verify the final preparation.

Use a prospective check for certain medications. Require a prospective verification of ingredients for certain high-alert medications that triggers a halt in the process prior to preparation (in-line verification) so a pharmacist can check and approve the ingredients (in person at the hood or remotely) prior to mixing. This may also prevent waste and delays caused by rework.

Conduct a robust final inspection. Despite the WFMS's ability to detect compounding errors,[4-8] pharmacists also play an important role in error prevention during final verification of the products. Several studies have shown that, while the WFMS detects the lion's share of compounding errors, approximately a quarter of the errors detected when using WFMS were captured by pharmacists during the final product verification.[6,7] In one study, the greater-than-expected number of errors detected by pharmacists at the end of the process despite the WFMS were attributed to staff failure to follow standard processes and the implementation of workarounds.[7]

Reject untrustworthy CSPs. Pharmacists should reject CSPs with incomplete documentation, missing digital images, or when anything seems amiss or questionable with its preparation or the final product.

Educate compounding staff. Provide compounding staff with a clear understanding of the WFMS and its immense value and impact on safety, productivity, and costs if used properly. Initial staff instructions for new technologies should include didactic and hands-on training. Be sure all compounding staff understand the importance of following standard processes as designed, the most common causes of errors and workarounds, and to report any problems that might lead to an error or workaround as soon as they arise.

Coach staff and remove barriers to work. Pharmacists who verify final compounded products should be trained to recognize if staff who prepared the products skipped an important step in the process (e.g., barcode scanning) or deviated from the correct procedure (e.g., scanning just one vial when multiple vials were used, using a decoy for scanning images, accumulating labels under the hood, one-piece workflow not followed, choosing not to take all the required pictures). If these unsafe practices are identified, understand why they are happening, and then coach staff to help them recognize that the risk of deviations is significant and not acceptable, even in a hurried environment. Importantly, take steps to remove any barriers to following the WFMS process steps as designed to prevent the workarounds. Remind staff that you expect them to report any problems that may encourage workarounds so they can be corrected.

Audit process. Pharmacists should regularly observe sterile compounding steps performed using WFMS. To serve this purpose, an auditing method that utilizes video observation can be an effective tool.[9] Observation can identify when staff are not practicing aseptic technique, make errors, or have drifted from the designated workflow into unforeseen unsafe practices that occur with the workarounds previously mentioned. It is essential for pharmacy managers and staff engaging in sterile compounding to understand the vulnerabilities of WFMS and safeguard the system to avoid errors and the use of workarounds that bypass intended safety features.

Remedy equipment problems. Work with vendors of laminar airflow workbenches/biological safety cabinets and WFMS to remedy equipment problems (e.g., vibrations, airflow interference) that may affect proper use of the systems.

References appear in the upper right column >

References

1) ISMP. ISMP guidelines for safe preparation of compounded sterile preparations. 2013 [original publication], 2016 [revised]. www.ismp.org/sc?id=183
2) ISMP. 2016-2017 targeted medication safety best practices for hospitals. 2016. www.ismp.org/sc?id=417
3) Reece KM, Lozano MA, Roux R, Spivey SM. Implementation and evaluation of a gravimetric i.v. workflow software system in an oncology ambulatory care pharmacy. *Am J Health Syst Pharm.* 2016;73(3):165-73.
4) Terkola R, Czejka M, Bérubé J. Evaluation of real-time data obtained from gravimetric preparation of antineoplastic agents shows medication errors with possible critical therapeutic impact: results of a large-scale, multicentre, multinational, retrospective study. *J Clin Pharm Ther.* 2017;42(4):446-53.
5) Moniz TT, Chu S, Tom C, et al. Sterile product compounding using an i.v. compounding workflow management system at a pediatric hospital. *Am J Health Syst Pharm.* 2014;71(15):1311-7.
6) Speth SL, Fields DB, Schlemmer CB, Harrison C. Optimizing i.v. workflow. *Am J Health Syst Pharm.* 2013; 70(23):2076,2078-80.
7) Deng Y, Lin AC, Hingl J, et al. Risk factors for i.v. compounding errors when using an automated workflow management system. *Am J Health Syst Pharm.* 2016;73(12):887-93.
8) Davis SJ, Hurtado J, Nguyen R, et al. Innovations in medication preparation safety and wastage reduction: use of a workflow management system in a pediatric hospital. *Hosp Pharm.* 2017;52(1):54-9.
9) Connor TK, Lim JH, Hinton TM. Auditing sterile compounding competency with video observation. *Am J Health Syst Pharm.* 2017;74(16):1218-9.

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20th Anniversary of the ISMP Cheers Awards

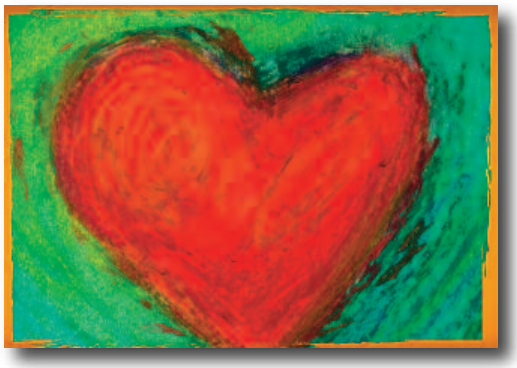
Celebrating the Heart & Soul of Medication Safety

Join ISMP on Tuesday evening, **December 5, 2017**, at 6:00 p.m. for the 20th **Annual Cheers Awards** at **B.B. King's Blues Club** in Orlando, FL. The special anniversary gala will commemorate two decades of advancing medication safety by honoring an outstanding group of healthcare leaders and showcasing their innovative programs. You can demonstrate that your **heart and soul** are dedicated to medication safety as well by making a donation and/or attending the awards dinner (www.ismp.org/Cheers/support.aspx).

Lifetime Achievement Award

Bona Benjamin, BS Pharm

Bona Benjamin is a safety leader who has had a significant impact on clinical practice, accreditation issues, and regulatory standards. She has managed crucial national-level projects to help reduce drug shortages and improve the safety of sterile compounding. In 2011, ISMP honored her, along with two of her colleagues, with a **Cheers Award** for her advocacy in addressing drug shortages and helping to bring together a group of stakeholder organizations to examine the problem and recommend solutions. Ms. Benjamin also has served on several of the Institute's advisory boards, and provided input into the development of the ISMP Targeted Medication Safety Best Practices. Before her recent retirement, she was Director of Medication Use Quality Improvement for American Society of Health-System Pharmacists.



Keynote Speaker

Michael R. Cohen, RPh, MS, ScD (hon), DPS (hon)

Michael Cohen is the President and co-founder of the Institute for Safe Medication Practices (ISMP) and has dedicated his career to advocating for medication error prevention. During the 20th anniversary of the **Cheers Awards** celebration, Mike will provide a unique perspective on the amazing journey toward safer medication practices—a journey that many have joined. A nationally and internationally known speaker on the topic of medication safety, Mike will chronicle our achievements and disappointments as a nation, and pave the way for the next 10 years of the journey. Mike has received numerous awards and honors, including being recognized as a MacArthur Fellow by the John D. and Catherine T. MacArthur Foundation.

Support the Awards

Your donation or attendance helps ensure the future of the **Cheers Awards** and allows ISMP to continue its lifesaving work in preventing medication errors. As this is an important anniversary year, all **Cheers** supporters will receive special recognition in ISMP's many communication avenues, including publications and social media. To make a tax deductible donation or to register for the awards dinner, please visit: www.ismp.org/Cheers/support.aspx.