

Acute Care

ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

ISMP survey provides insights into pharmacy sterile compounding systems and practices



Millions of compounded sterile preparations (CSPs) are produced each year, many in hospital pharmacies. In our July 30, 2020 acute care newsletter, we invited pharmacists and pharmacy technicians who prepare or oversee the production of CSPs to participate in a survey on pharmacy compounding (www.ismp.org/ext/568). The purpose of the survey was to:

- Increase awareness of the best practices associated with pharmacy sterile compounding
- Assist pharmacy staff with identifying opportunities to improve the safety of sterile compounding
- Learn about the extent of implementing safe pharmacy compounding practices, the use of pharmacy compounding technologies, and the occurrence of pharmacy compounding errors
- Identify the most significant, perceived safety challenges related to pharmacy sterile compounding

An overview of the survey findings follows.

Respondent Profile

More than 600 (N = 634) pharmacy practitioners participated in our survey. Most respondents were pharmacists (80%) and pharmacy technicians (18%), although a few (2%) were pharmacy students/residents or medication safety officers (MSOs). Respondents were split regarding their position level, with 46% identifying as 'staff' and 47% identifying as a 'manager/director' or 'administrator.' Most of the remaining respondents (7%) listed their position as 'instructor,' 'lead,' 'coordinator,' or 'supervisor.' Most respondents work in a hospital pharmacy (87%). The remaining work in an ambulatory infusion center (5%); an outpatient/compounding pharmacy (3%); or in home infusion centers, specialty hospitals, home care, or research (5%). Only 4% of the survey respondents reported that their facility is registered as a 503B compounding pharmacy. In addition to 'sterile to sterile' compounding utilizing already manufactured prepared products in vials and bags, 19% of respondents also prepare 'non-sterile to sterile' compounded preparations utilizing active pharmaceutical ingredients as the starting material. 'Non-sterile to sterile' compounding accounts for approximately 10% (range of less than 1% to 30%) of all CSPs in these facilities.

Compounding Technologies

More than half of all respondents (57%, n = 361) reported using technologies when compounding sterile preparations, which include:

- Barcode verification systems without images (48% use this technology for approximately 75% [range of 10-100%] of all CSPs)
- Workflow systems that use barcode verification and images (47% use this technology for approximately 75% [range of 5-100%] of all CSPs)
- Automated multiple ingredient compounding devices (e.g., parenteral nutrition [PN] compounders) (46% use this technology for approximately 10% [range of 1-100%] of all CSPs)

continued on page 2 — **Sterile compounding** >

SAFETY briefs



Heparin-hypertonic saline close calls.

We recently received reports of two close calls between B. Braun 500 mL bags of heparin 25,000 units in 5% dextrose in water (D5W) and hypertonic sodium chloride 3% which look similar while in their overwraps (**Figure 1**). In one case, the similar-looking bags were stored next to each other on open shelving in the stockroom due to the large bag size. The wrong product was selected but thanks to pharmacy dispensing safety checks, the error never reached the patient.



Figure 1. B. Braun 500 mL bags of 3% sodium chloride (left) and 25,000 units of heparin (right) look very similar in their overwraps.

In the other case, involving heparin 20,000 units in D5W 500 mL and hypertonic sodium chloride 3% 500 mL, the similar clear plastic overwraps (covering an EXCEL IV container/bag), along with visual similarities in the labeling (e.g., same red and blue text, similar location of product name and strength) led a pharmacy technician to attempt to restock an automated dispensing cabinet (ADC) with the wrong solution. The technician was trying to restock the heparin product but was getting an incorrect barcode scan for the ADC location. The technician then realized that hypertonic saline, not heparin, was in hand.

continued on page 2 — **SAFETY briefs** >

> **Sterile compounding** — continued from page 1

- Image sharing or remote video supervision of the sterile compounding process (32% use this technology for approximately 50% [range of 5-100%] of all CSPs)
- Pharmacy workflow systems with images and barcode scanning and/or gravimetric verification (25% use this technology for approximately 50% [range of 1-100%] of all CSPs, mostly for antineoplastics and PN)
- Intravenous (IV) sterile compounding robot (8% use this technology for approximately 30% [range of 5-100%] of all CSPs, mostly for antineoplastics and PN)

Sixty-three percent of respondents who utilize images to verify CSPs stop production for verification of certain drugs, diluents, and doses before mixing the ingredients and completing the compounding process. In some cases, all medications require verification before mixing; however, for most of these respondents, only certain medications require verification prior to mixing, including the following:

- All or certain hazardous drugs (e.g., antineoplastics)
- All or certain high-alert medications (e.g., insulin, opioids/other controlled substances, epidural/intrathecal medications, epoprostenol)
- All or certain blood products (e.g., **KCENTRA** [prothrombin complex concentrate, [human]])
- All pediatric and/or neonatal medications
- Biologics including monoclonal antibodies
- Medications requiring dilution

continued on page 3 — **Sterile compounding** >

Table 1. Implementation of compounding best practices (in descending order based on overall level of implementation)

Best Practice	Degree of Implementation (%)			
	Never/Rarely	Sometimes	Often	Always
There are enough workbenches in the cleanroom/sterile compounding area to support only one staff member working at a time per primary engineering control device (e.g., laminar airflow workbench, biological safety cabinet, isolator).	7	5	15	73
Standard operating procedures are defined and utilized by all staff during the compounding process (including the verification/checking process).	3	7	34	56
During the verification process, it is easy to identify with certainty which drugs, diluents, and volumes were used (including the number of vials/ampules/bags used) to prepare each CSP.	3	10	35	52
A standard workflow is followed for how final product labels are placed onto CSPs (e.g., location, flagging, label orientation).	7	12	32	49
Only one CSP is prepared in a workbench/laminar flow hood/biological safety cabinet at a time.	5	14	34	47
When compounding a CSP, dose volume information is available on a preparation label, master formula record, or other approved document, so there is no need for calculations.	9	11	31	49
There is sufficient counterspace to gather and stage each component needed to prepare CSPs without the risk of intermingling/overlapping or the need to stage/store items on top of each other.	9	18	31	42
Bins are used during the compounding of each CSP (or each batch of identical preparations) to permit segregation (separation) from other CSPs.	21	9	16	54
Lighting and noise in all locations where CSPs are prepared and verified have been measured and are consistent with USP standards (i.e., 1,000-1,500 lux, 50 dBA).	44	11	11	34

Key: Never/Rarely = 0 to 10% of the time; Sometimes = 11 to 50% of the time; Often = 51 to 95% of the time; Always = more than 95% of the time

> **SAFETY briefs** cont'd from page 1

ISMP has contacted B. Braun about these packaging similarities and asked the company to consider changes to at least one of the products to help prevent mix-ups in the future. We also asked the company to review their other heparin products to minimize the potential for look-alike confusion. An actual mix-up between heparin and hypertonic saline could prove serious. Barcode scanning should catch an error; however, we have received complaints about how difficult it is to scan a barcode printed in white, such as the barcode on these products.



THRIV Coalition survey on IV workflow systems. THRIV Coalition, which, like ISMP, advocates that intravenous (IV) workflow management systems should be required for achieving compounded sterile product accuracy, has commissioned an independent researcher to conduct the **2020 Survey on IV Preparation Practices and Related Technology in US Hospital Pharmacies**. If you are a pharmacy director and did not receive the survey, please visit: www.ismp.org/ext/567. You will find a link to request a survey and/or to request that the survey be sent to the pharmacy director(s) in your organization. THRIV values your hospital's participation. ISMP is an organizational advocate of THRIV.



Mix-up between droperidol and dronabinol. A pharmacist received a call from a physician assistant (PA) requesting help with ordering a medication for a patient with nausea and vomiting. The PA told the pharmacist they were looking for dronabinol in the electronic health record (EHR) drug dictionary but could not find it. The pharmacist clarified the brand name (**MARINOL**) and the generic name (dronabinol) as well as the indication (nausea and vomiting). Finally, the pharmacist asked what dose was needed, to which the PA replied, "5 mg." It was not discovered until later that the PA had actually been looking for droperidol (formerly available as **INAPSINE**), not dronabinol, to treat this patient's nausea and vomiting.

Dronabinol is a synthetic oral cannabinoid that comes in capsules (2.5, 5, and 10 mg strengths) and as an oral solution (5 mg/mL, brand name **SYNDROS**). Droperidol, continued on page 3 — **SAFETY briefs** >

> **Sterile compounding** — continued from page 2

Safe Compounding Practices

ISMP identified nine best practices associated with pharmacy sterile compounding and asked survey respondents to evaluate their degree of implementing these best practices (**Table 1**, page 2). Respondents reported the highest level of implementation (73% *always*, 15% *often*) with ensuring that there are enough workbenches in the cleanroom/sterile compounding area to support only one staff member working at a time per primary engineering control device (e.g., laminar airflow workbench, biological safety cabinet, isolator). For respondents who reported lower compliance with this best practice, comments suggest that the degree of implementation is dependent on the pharmacy's location (central vs. satellite), time of day, urgency of preparing the CSP, and overall workload.

More than half of all respondents (56%) reported that standard operating procedures are defined and *always* followed during the compounding process (including the verification/checking process). Another one-third (34%) of respondents reported that the procedures are defined and *often* followed. However, pharmacy technicians tended to report higher compliance with always following compounding procedures than what was perceived by pharmacists (62% vs. 54%, respectively). Ten percent of respondents reported that standard procedures are *never*, *rarely*, or *sometimes* defined and followed. Comments suggest that the procedures might be well defined but that shortcuts may be taken to improve efficiency and production numbers. Numerous examples of at-risk procedural violations were provided (e.g., hand hygiene, jewelry, makeup, nail protocols not followed; verification process from the doorway). A few comments suggested that pharmacists and technicians utilize their own process rather than following standard procedures.

Alarmingly, only 52% of respondents reported that it is *always* easy to identify with certainty which drugs, diluents, and volumes were used (including the number of vials/ampules/bags used) when verifying the preparation of each CSP. However, again, pharmacy technicians tended to report higher confidence with *always* being able to identify which drugs, diluents, and volumes were used to prepare each CSP than was perceived by pharmacists (62% vs. 48%, respectively). Respondents with high confidence in identifying drugs, diluents, and volumes during verification indicated that cameras, image capture, verification software, and/or pharmacy workflow systems were used. However, many respondents commented on technology limitations (e.g., picture quality) or shortcuts (e.g., bypassing technology) that raised concerns. Respondents with the lowest confidence in the verification process tended to cite weaknesses in the outdated and error-prone post-production syringe pull-back method of verification. Numerous respondents commented that diluents were not easy to identify, particularly if they had been withdrawn from bulk stock bags or bottles that stayed in the hood and for which a syringe drawn back to the diluent volume was not even included for verification. Others noted that vials and syringes sometimes get mixed up if there is a large array of CSPs on a cart to verify.

Almost half of all respondents (49%) reported that they *always* follow a standard workflow for how final product labels are placed onto CSPs. Pharmacy technicians tended to report higher compliance with *always* following a standard process for label placement on CSPs than perceived by pharmacists (58% vs. 46%, respectively). Almost one in five respondents (19%) reported wide variation in label placement, and most of the survey comments noted that there is no standard process in place.

Slightly less than half of all respondents (47%, *always*) also reported that only one CSP is prepared at a time. Respondents' comments noted exceptions for products that take a long time to dissolve or reconstitute (20-30 minutes), stating that these products are put aside while preparing another CSP. A few respondents commented that they also keep partially used vials of medications and bags of diluents in the hood.

continued on page 4 — **Sterile compounding** >

> **SAFETY briefs** cont'd from page 2

however, is an antipsychotic that plays a role in reducing nausea and vomiting by blocking dopamine stimulation in the chemoreceptor trigger zone. It is available as a solution for injection (2.5 mg/mL). Hearing the PA request a dose of "5 mg," a reasonable starting dose for both medications, likely played a role in confirmation bias, making both the PA and pharmacist believe they were talking about the correct drug. Unfortunately, neither the pharmacist nor the PA clarified the route of administration for the medication being ordered, and the PA did not recognize the discrepancy when the pharmacist clarified the brand name of Marinol.

During verbal communication of medication orders, speak clearly and always follow through with readback to ensure there is no miscommunication. Spell out sound-alike drug names when reading back a verbal order. Specify all portions of the medication order when prescribing and during readback (e.g., patient's name and identifiers, drug name, strength, dose, dosage form, indication, frequency, route, provider). If either party had clarified the route of administration, it is likely the mix-up would have been caught earlier. Incidentally, ISMP is considering the use of tall man lettering for these drugs because they look very similar. We plan to update our tall man letter list early in 2021.

Worth repeating...



More mix-ups between ePHEDrine and EPINEPHrine

A hospital discovered vials of **ADRENALIN (EPINEPHrine)** injection (1 mg/mL, PAR Pharmaceutical) mixed together with ePHEDrine (50 mg/mL, Amneal Pharmaceuticals) in an operating room (OR) automated dispensing cabinet (ADC). ISMP has previously reported similar mix-ups with these products, most recently in our May 3, 2018 issue. In that instance, the ePHEDrine product was **AKOVAZ** (Avalide Pharmaceuticals).

Although we do not know for certain how this error originated, it is possible that OR staff could have returned these products to the wrong location in the ADC after a

continued on page 4 — **Worth repeating** >

> **Sterile compounding** — continued from page 3

Nearly half of all respondents (49%) reported that dose volume information is *always* available on a preparation label, master formula record, or other approved document, so there is no need for calculations. However, again, technicians tended to report higher full compliance than perceived by pharmacists (58% vs. 46%, respectively). One in five respondents (20%) reported that this best practice is followed half of the time or less. Most comments suggested that prep labels are not ideal, and calculations may be necessary to determine the volume of ingredients if the label only expresses the dose in mg (or g, units, etc.). A few respondents reported that the total volume is not always provided on labels. Quite a few respondents noted that they double check all calculations on prep labels, noting specific label errors in some cases.

Best practices associated with sufficient counterspace to gather and stage each CSP, the use of bins to permit separation of CSPs, and measurement of lighting and noise to ensure consistency with USP standards scored lowest in our survey based on overall level of implementation. Comments from respondents laid bare their pervasive concerns about pharmacy space limitations, inconsistent use of bins to separate each CSP, and the lack of knowledge around measurement and standards related to noise and lighting levels in the pharmacy.

continued on page 5 — **Sterile compounding** >

Table 2. Examples of biggest safety challenges related to pharmacy sterile compounding (n = 505)

Challenge	Percent of Comments	Brief Description
Lack of direct verification of the CSP process	13	No direct observation by a pharmacist of the compounding process; still using the post-production syringe pull-back method for verification; pharmacist cannot see the actual drug/volumes prepared; unable to observe aseptic technique
Difficulty meeting USP standards	11	Difficulty meeting USP <797> and USP <800> standards related to sterility, cleaning, environmental monitoring, beyond-use dating, garb worn during preparation, and safe handling of hazardous drugs
Insufficient staff training and competency	10	Technicians: Inexperienced; do not fully understand sterile compounding; no certification required (certain states); competencies not evaluated; high turnover Pharmacists: Inexperienced; supervising CSP process but have inadequate knowledge to properly verify; rotating staff not highly skilled
Insufficient technology	8	Lack of hardware, software, cameras, gravimetric systems, workflow systems, bar-coding technology; concerns about electronic health record capabilities
Space limitations	6	Lack of space; lack of required rooms; architecture/design issues
Insufficient staffing	6	Often related to staffing shortages, high turnover rate of pharmacy technicians
Variation in practices	6	Variations in workflow; not following standard operating procedures; lack of follow-through with details (e.g., putting product in light-protective bags, applying warnings)
Excessive workload	6	Increasing CSP numbers; demand and expected turnaround unsustainable; unrealistic expectations
Lack of time	6	Often rushed; focused on speed over safety
Technology limitations	5	Unreliable technology that requires frequent maintenance; automation downtime; lack of information technology (IT) support; specific limitations (e.g., workflow system gaps, images unclear, camera not wireless, unable to receive wireless signal in cleanroom)
Interruptions/distractions	2	Phones; music; frequent questions; multitasking
Bypassing available technology	2	Technology workarounds; bypassing warnings; not scanning each container; not utilizing workflow systems for required CSPs
Leadership failure	2	Failure of leadership to recognize and provide resources to reduce CSP risks
Lack of supervision	2	Pharmacist not always available to supervise/oversee the CSP process

> **Worth repeating** cont'd from page 3

procedure. Or perhaps it was stocked incorrectly by pharmacy staff. The 1 mL vial sizes and similar purple cap color could have contributed to the stocking error (**Figure 1**). Fortunately, the mix-up was recognized before an error reached a patient.

EPINEPHrine and **ePHED**rine share a number of similar letters in their names. Not only do these drug names look similar, but their use as vasopressors or vasoconstrictors makes storage of both products in clinical settings likely. Both products also may be packaged in 1 mL ampules or vials and may have the same color caps. Mix-ups between **EPINEPH**rine and **ePHED**rine can be dangerous (www.ismp.org/node/1033).

It is important to use barcode scanning when restocking these medications and/or prior to administration if barcoding is available in the area. If you happen to have vials of **EPINEPH**rine and **ePHED**rine that look alike, store these medications apart in the pharmacy and used locked-lidded drawers for storage in ADCs. However, as pointed out in our earlier article, purple happens to be the standard color for vasopressors for user-applied labels in anesthesia. Since several manufacturers provide **ePHED**rine injection in vials with other cap colors, consider using a different brand for the **ePHED**rine product to reduce the potential for mix-ups. To the extent possible, use prefilled **EPINEPH**rine syringes from an outsourcer or have pharmacy prepare infusions and bolus doses for these drugs except in emergencies.



Figure 1. Similar vial shape, size (1 mL), and cap color likely contributed to a stocking error between Adrenalin (**EPINEPH**rine) and **ePHED**rine vials.

> **Sterile compounding** — continued from page 4

Sterile Compounding Errors

Nearly three-quarters (74%) of all survey respondents were aware of at least one pharmacy sterile compounding error that had occurred during the past 12 months, including those caught and corrected in the pharmacy as well as those discovered after dispensing. A higher percentage of pharmacists (79%) were aware of these errors than technicians (67%). The types of reported pharmacy compounding errors included:

- Incorrect dose or concentration (58%)
- Incorrect base solution (51%)
- Incorrect base solution volume (43%)
- Issue or error (including omission) with labeling of a CSP (41%)
- Incorrect reconstitution of a drug (volume or diluent) (36%)
- Incorrect drug (35%)
- Wrong preparation technique (e.g., improper filtering, wrong tubing) (26%)
- Expired drug, base solution, or CSP (16%)
- Wrong timing (e.g., preparing an antineoplastic on the wrong date) (12%)
- Omission of a drug (5%)

Examples of other error types reported (7%) include coring of vials on robots, using the wrong port or container, and wrong patient errors. Only 4% of respondents reported awareness of errors associated with CSPs purchased from 503B compounding pharmacies.

Biggest Safety Challenges

ISMP received more than 600 comments from survey respondents when asked about the biggest challenge they face related to pharmacy sterile compounding. We have aggregated most of the comments into various categories and presented the most common in **Table 2** (page 4). While the reported challenges are diverse and unique to each individual respondent, the most commonly cited challenge was the inability for a pharmacist to accurately verify prepared CSPs if using an indirect process such as the post-procedure syringe pull-back method. The second most common challenge was associated with meeting USP <797> (*Pharmaceutical Compounding – Sterile Preparations*) and USP <800> (*Hazardous Drugs – Handling in Healthcare Settings*) standards. The ability to properly train both technicians and pharmacists to prepare and/or verify CSPs was listed as the third biggest challenge, followed by the lack of purchasing and utilizing various sterile compounding technologies, such as cameras, workflow systems, gravimetrics, and bar-coding technology. Additional environmental, human resource, technology, human factors, process, procurement, and leadership issues were described as other pharmacy sterile compounding challenges, as noted in **Table 2** (page 4).

Conclusion

ISMP wants to sincerely thank each and every person who participated in our survey. Your responses provided an in-depth look at current pharmacy sterile compounding practices, which substantially contributed to our shared learning. We plan to utilize and share more detailed survey findings in the future to drive improvements in sterile compounding.

We hope that pharmacies will use the results of this survey to prompt internal discussions about improvements that may be needed in their sterile compounding practices to reduce the risk of errors. If your pharmacy did not participate in this survey, you may want to download it (www.ismp.org/ext/568), distribute it internally, and take the survey to pinpoint your vulnerabilities and to establish a plan for improvement. You can also utilize the **ISMP Guidelines for Safe Preparation of Compounded Sterile Preparations** (www.ismp.org/node/101) to guide your discussion and to identify practical ways to improve your CSP preparation process.

Special Announcements

Virtual MSI workshop

Don't miss a unique opportunity to maximize your error prevention efforts and look at your organization through the eyes of leading safety experts! Register for the first virtual **ISMP Medication Safety Intensive (MSI) Workshop on December 3-4, 2020**, and learn how to establish a medication safety program and use data for sustained improvement. For details, please visit: www.ismp.org/node/13788.

ISMP's on-demand library

Educational programs available on ISMP's on-demand library are a convenient way for practitioners to stay ahead of new trends in medication safety and access ISMP's collection of webinars and symposia. Some programs provide continuing education credits for pharmacists, technicians, and nurses. For additional details, please visit: www.ismp.org/node/22.

FREE FDA webinar

The US Food and Drug Administration's (FDA) Division of Drug Information is presenting a **FREE** webinar, **FDA Drug Topics: Labeling Made Simple: The How, What, and Where of Drug Interactions in Prescribing Information**, on **October 27**. This webinar will provide an overview of key regulations impacting drug interaction content in the prescribing information. For details, visit: www.ismp.org/ext/30, and to register, visit: www.ismp.org/ext/31.

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



ISMP Medication Safety Alert! Acute Care (ISSN 1550-6312) © 2020 Institute for Safe Medication Practices

(ISMP). Subscribers are granted permission to redistribute the newsletter or reproduce its contents within their practice site or facility only. Other reproduction, including posting on a public-access website, is prohibited without written permission from ISMP. This is a peer reviewed publication.

Report medication and vaccine errors to ISMP:



Call 1-800-FAIL-SAF(E) or visit our website at: www.ismp.org/report-medication-error. ISMP guarantees the confidentiality of information received and respects the reporters' wishes regarding the level of detail included in publications.

Editors: Judy Smetzer, BSN, RN, FISMP; Michael Cohen, RPh, MS, ScD (hon), DPS (hon), FASHP; Ann Shastay, MSN, RN, AOCN; Russell Jenkins, MD; Ronald S. Litman, DO, ML. ISMP, 200 Lakeside Drive, Suite 200, Horsham, PA 19044. Email: ismpinfo@ismp.org; Tel: 215-947-7797; Fax: 215-914-1492.


ISMP Medication Safety Alert!® ActionAgenda

One of the most important ways to prevent medication errors is to learn about problems that have occurred in other organizations and to use that information to prevent similar problems at your practice site. To promote such a process, the following selected items from the July - September 2020 issues of the *ISMP Medication Safety Alert!* have been prepared for leadership to use with an interdisciplinary committee or with frontline staff to stimulate discussion and action to reduce the risk of medication errors. Each item includes a brief description of the medication safety problem, a few recommendations to reduce the risk of errors, and the issue number to locate additional information. Look for our high-alert medication icon under the issue number if the agenda item involves one or more medications on the *ISMP List of High-Alert Medications* (www.ismp.org/node/103). The Action Agenda is also available for download in a Microsoft Word and Excel format (www.ismp.org/node/21034) that allows expansion of the columns in the table designated for organizational documentation of an assessment, actions required, and assignments for each agenda item. Continuing education credit is available for nurses at: www.ismp.org/nursing-ce.




Key:  — ISMP high-alert medication

Issue No.	Problem	Recommendation	Organization Assessment	Action Required/Assignment	Date Completed
Intravenous (IV) workflow systems ensure accuracy and prevent errors with compounded sterile preparations (CSPs)					
(16) 	When preparing a dose of IV fluconazole for an infant, a technician selected a minibag of potassium chloride (40 Eq/100 mL) that had been incorrectly returned to the fluconazole (200 g/100 mL) bin since both minibags look similar. The pharmacy had just installed a pharmacy IV workflow system, so when the bag was scanned before preparation of the syringe, the error was caught.	To ensure accuracy during CSP preparation, use IV workflow management systems interfaced with electronic health record (EHR) systems. This includes barcode scanning technology along with imaging and/or gravimetrics to verify ingredients and final preparations. Additional recommendations can be found in the <i>ISMP Guidelines for Safe Preparation of Compounded Sterile Preparations</i> (www.ismp.org/node/101).			
Errors with VEKLURY (remdesivir, Gilead) after Emergency Use Authorization (EUA) from the US Food and Drug Administration (FDA)					
(18)	To treat severe COVID-19, FDA issued an EUA for remdesivir, which is supplied in 100 mg/20 mL (concentrated solution) and 100 mg (lyophilized powder) vials. Incorrect storage and preparation of both formulations have led to wrong dose or formulation errors or discarding improperly prepared/stored products.	Review details about correct dosing, administration, preparation, and storage in the <i>Fact Sheet for Health Care Providers</i> (www.ismp.org/ext/541). Use standardized order sets, alerts, and/or a hard stop to enter patients' weights to ensure the appropriate formulation and dose are selected and used.			
Set the drug search feature to 5 letters in Omnicell automated dispensing cabinets (ADCs)					
(13) 	Using only the first 2 or 3 characters to search for a drug in an ADC can lead to errors (e.g., verapamil or vecuronium administered instead of the intended drug, VERSED [a former brand of midazolam]), especially if the drug is removed from the cabinet via override, thus enabling access to all medications.	The Omnicell XT ADC can be programmed to address safety so that at least 5 letter characters must be entered to select a drug via override. We encourage those who have Omnicell XT ADCs to make sure this important feature is set to require a 5-character search for drugs obtained via override.			



© 2020 ISMP

Issue No.	Problem	Recommendation	Organization Assessment	Action Required/Assignment	Date Completed
Errors in paramedicine (prehospital care delivered through emergency medical services [EMS])					
(19)	Rapid changes in ill or injured patients provide challenges that increase the risk of medication errors. EMS errors are related to common themes: clinical assessment and management errors, therapeutic product use errors, errors in communication during transitions of care, and errors related to inventory management.	When stocking EMS vehicles or aircraft, choose products that do not look alike and are ready to administer in standard concentrations. Stock medications with the front label facing outward. Gather a complete medication history from each patient and communicate that to the provider who assumes care. Use standardized checklists for verbal hand-offs.			
NRFit neuraxial connectors comply with the International Organization for Standardization (ISO) standard to prevent misconnections					
(14)	ISO developed standards to make small-bore connectors dissimilar for different clinical applications to prevent tubing misconnections and wrong-route errors. After ENFit, ISO-compliant enteral connectors, the next phase is implementation of NRFit, ISO-compliant neuraxial connectors, which are incompatible with the Luer system.	Assemble a team to coordinate transition from the Luer connector to NRFit for neuraxial applications (currently available from B. Braun and Smiths Medical). Provide education to staff and update related procedures and order sets. Review the <i>NRFit Connector Transition Checklist for Nurses and Clinicians</i> (www.ismp.org/ext/514).			
Use brand names to differentiate tacrolimus formulations					
(14)	Immediate-release tacrolimus was dispensed instead of the extended-release formulation (ASTAGRAF XL). All tacrolimus products were in the same pharmacy drop-down menu. Astagraf XL, ENVARUSUS XR , and PROGRAF (and generics) are all different formulations of tacrolimus and are not substitutable.	Display the brand name of tacrolimus extended-release formulations (i.e., Astagraf XL, Envarsus XR) on computer screens to help differentiate them from immediate-release tacrolimus (i.e., Prograf, generics). Avoid using the modifier “IR” for immediate-release products.			
Confusion between LYUMJEV and HUMALOG (both insulin lispro by Lilly), which have different onsets of action					
(14) 	Dispensing errors have occurred with Lyumjev and Huma LOG when searching for either product using only insulin lispro and/or failing to include the brand name on prescriptions. These insulin lispro formulations are not substitutable. Lyumjev contains ingredients that make it faster acting than Huma LOG .	Order entry systems and container labels should include both the brand and generic name. Practitioners should confirm the brand name if it is not on the prescription. Also, patients should be aware of the differences between these insulins and confirm that they received the correct insulin from their pharmacy.			

© 2020 ISMP

Issue No.	Problem	Recommendation	Organization Assessment	Action Required/Assignment	Date Completed
Inappropriate prescribing of transdermal fentaNYL patches for opioid-naïve, elderly patients					
(13) 	FentaNYL patches have been inappropriately prescribed for opioid-naïve, elderly patients discharged from the emergency department (ED) to treat acute pain or due to an “allergy” to codeine that was only a minor drug intolerance. Prescribing information recommends fentaNYL patch use only in opioid-tolerant patients for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment.	Document each patient’s opioid status (Best Practice #15, www.ismp.org/node/160), build interactive alerts to confirm opioid tolerance when prescribing fentaNYL patches, and distinguish between true allergies and drug intolerances when collecting allergy information. A Risk Evaluation and Mitigation Strategy (REMS) for long-acting opioids strongly encourages practitioner training about the safe use of opioids.			
Test patients should not be created in live electronic health records (EHRs)					
(18) 	At the request of a surveyor, a nurse ordered alteplase for a test patient, who was accidentally “admitted” to a different hospital within the system. The alteplase was almost prepared for a real patient. The pharmacist questioned the real patient’s nurse about the dose. That nurse re-entered the order, believing it had been entered incorrectly. However, the physician never intended for the real patient to receive alteplase.	Use a test environment, not a live EHR, to create test patients. If creating a test patient in a live EHR is necessary, use an obviously fake name (e.g., “Test Patient”). Do not allow one hospital to impact the workflow of another hospital within the same health system. Provide staff with clear instructions and procedures to follow when demonstrating workflows to surveyors.			
Wrong-route tranexamic acid errors					
(18) 	Three cases of inadvertent spinal tranexamic acid administration instead of a local anesthetic were reported. Prior mix-ups have occurred between tranexamic acid and bupivacaine or ropivacaine. All three products are available in vials with blue caps, which are often stored upright making labels difficult to read. These products are typically used in areas where barcode scanning is not utilized (e.g., operating room, labor and delivery).	Purchase these products from different manufacturers to help differentiate appearance and/or consider alternate preparations (e.g., premixed bag, pharmacy prepared syringes or infusions). Store tranexamic acid separately and avoid upright storage to ensure labels are always visible. Use an auxiliary label over the cap to indicate vial contents. Use barcode scanning prior to dispensing or administering.			

© 2020 ISMP

Issue No.	Problem	Recommendation	Organization Assessment	Action Required/Assignment	Date Completed
Time to end vinCRISStine syringe administration					
(13) 	Accidental intrathecal injection of vinCRISStine has resulted in more than 140 deaths worldwide when the drug was dispensed and administered in a syringe. No cases of accidental intrathecal administration have been reported when the drug was diluted and administered in a flexible plastic container or minibag.	Pfizer revised the package insert, which now states: To reduce the potential for fatal medication errors due to incorrect route of administration, vinCRISStine sulfate injection should be diluted in a flexible plastic container and prominently labeled as indicated “FOR INTRAVENOUS USE ONLY—FATAL IF GIVEN BY OTHER ROUTES.” All reference to preparation and administration in an intravenous (IV) syringe has been removed. Pharmacies should adjust preparation procedures to align with the new labeling.			
The US Food and Drug Administration (FDA) revises labeling for methotrexate tablets					
(15) 	ISMP has received numerous reports about fatal oral methotrexate errors when the weekly dose was divided into 3 doses given 12 hours apart but mistakenly taken daily every 12 hours for numerous days in a row.	FDA has required the removal of divided doses from official labeling, which now recommends a single weekly dose for nononcologic indications. Inform staff about this change and make sure any patient educational materials you provide reflect this change. For additional strategies to prevent errors with methotrexate, follow Best Practice #2 in the <i>ISMP Targeted Medication Safety Best Practices for Hospitals</i> (www.ismp.org/node/160).			
Confusion between the numbers 15 and 50					
(17)	After talking to an endocrinologist, a medical resident ordered 50 units of insulin glargine for a pediatric patient. A pharmacist confirmed the high dose with the resident, who mentioned that the endocrinologist seemed tired when they spoke. Upon investigation, the endocrinologist stated he ordered 15, not 50, units during the phone consultation.	When verbalizing medication orders, state the dose the way pilots state numbers (e.g., “15 units” stated as “one-five units”). Always follow through with readback, where the listener documents what is heard and then reads it back to the speaker to ensure the order was heard and transcribed correctly. When possible, remove a mask and face shield when speaking by phone.			

© 2020 ISMP