ISMP Survey on Pharmacy Sterile Compounding

If you are a pharmacist or pharmacy technician who prepares or oversees the production of compounded sterile preparations (CSPs), please take our survey on pharmacy compounding! While compounding sterile preparations requires staff to follow standards to ensure sterility and stability of the final product, steps must also be taken to identify, reduce, and eliminate errors and their causative factors to minimize the risk of patient harm. You can help ISMP learn more about safe compounding practices, available pharmacy compounding technologies, and compounding errors by completing our survey by **September 18, 2020**, which can be found at: www.ismp.org/ext/526.

This survey is focused on <u>pharmacy</u> compounding. In the future, ISMP plans to conduct a related survey on compounding and admixture performed outside of the pharmacy.

Safe Compounding Practices

1 Please tell us the degree of implementation with the following safe compounding practices or conditions, considering all times/shifts throughout the day.

Key: Never = 0% of the time Rarely = 1 to 10% of the time Sometimes = 11 to 50% of the time Always = greater than 95% of the time

Best Practice or Condition		Degree of Implementation				
		Rarely	Some- times	Often	Always	Comments
a) 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 one another.						
b) During the verification process, it is easy to identify without uncertainty which drugs, diluents, and volumes were used (including the number of vials/ampules/bags used) to prepare each CSP.						
c) Bins are used during the compounding of each CSP (or each batch of identical preparations) to permit segregation (separation) from other CSPs.						
d) Only one CSP is prepared in a workbench/laminar flow hood/biological safety cabinet at a time.						
e) There are enough workbenches in the cleanroom/sterile compounding area to support only 1 staff member working at a time per primary engineering control device (e.g., laminar airflow workbench, biological safety cabinet, isolator).						
f) Standard operating procedures are defined <u>and</u> utilized by all staff during the compounding process.						
g) Standard operating procedures are defined <u>and</u> utilized by all staff during the verification/checking process for CSPs.						
h) Lighting and noise in all locations where CSPs are prepared <u>and</u> verified have been measured (e.g., lux, foot-candle, dBA) and is consistent with standards (e.g., USP: 1,000-1,500 lux, 50 dBA).*						
i) A standard workflow is followed for how final product labels are placed onto CSPs (e.g., location, flagging, label orientation).						
j) 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.						

Compounding Technologies

2	When you	mpound sterile preparations, do you use compounding technolog	ies?
	☐ Yes	□ No (skip to question #5)	

> Survey — continued from page 5

3	Please tell us which compound	na technologies are user	and the nercent of CSPs	prepared using these technologies.
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Compounding Technology	Yes	No	% of CSPs Prepared	Comments	
a) IV sterile compounding robot					
b) Workflow system that uses barcode and gravimetric verification and images					
c) Workflow system that uses barcode verification and images					
d) Barcode verification without images					
e) Image sharing or remote video supervision					
f) Automated multiple ingredient compounding device (e.g., parenteral nutrition compounders)					
If you use compounding technology that utilizes images to verify CSPs, are there any medications which you verify prior to completion of all compounding steps (e.g., does production stop for verification of the drug, diluent, and dose before compounding is complete)? □ No □ We do not use compounding technology that ultizes images □ Yes. If yes, which medications? □ No					
Sterile Compounding Errors					
Are you aware of any pharmacy sterile compounding errors during the past 12 months, including both those caught and corrected in the pharmacy, as well as those discovered after dispensing? Yes. Please specify the error type(s) (select all that apply) Issues, errors, and omissions with labeling CSPs Incorrect base solution Incorrect drug Omission of a drug Incorrect dose or concentration Incorrect reconstitution of a drug (volume or diluent) Wrong preparation technique (e.g., improper filtering, wrong tubing) Wrong timing (e.g., chemotherapy prepared on the wrong date) Expired drug vial, base solution, or CSP Error with solutions from 503B pharmacies used for pharmacy compounding Other (please specify): What is the biggest safety challenge or other concerns/comments you have related to pharmacy sterile compounding?					
About Your Facility and You					
 Does your pharmacy prepare non-sterile to sterile compounded preparations? ☐ Yes. If yes, what percent of all CSPs are non-sterile to sterile? ☐ No 					
Is your facility registered as a 503B compounding pharmacy? ☐ Yes ☐ No					
Please select the categories that best describe your profession, current position, and work profession: ☐ Pharmacist ☐ Pharmacy technician ☐ Other (please specify): Position: ☐ Staff ☐ Manager/Director ☐ Administrator Work setting: ☐ Hospital ☐ Ambulatory infusion center ☐ Outpatient/compounding			Other (please	specify): please specify):	