CAPS® Sterile Compounding Review: Three Challenges Commonly Reported by Hospital Pharmacists

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There are countless different workflows and workloads that make up the sterile compounding programs across the United States, but there is at least one common safety concern on the minds of many pharmacists—***the challenge to know everything being signed for, when verifying a compounded sterile preparation (CSP).***

In a survey on sterile compounding practices, conducted in July 2020, the Institute for Safe Medication Practices (ISMP) revealed that 74% of all pharmacy respondents were aware of at least one pharmacy sterile compounding error in the last 12 months; some of which had been caught and corrected and others that had been dispensed to patients.[1] "Incorrect dose or concentration", "incorrect base solution", and "incorrect base solution volume" were the more common errors reported in the survey.

To gain additional insights about these compounding oversights, the ISMP survey asked respondents to list the biggest challenges they face related to pharmacy sterile compounding. In this latest issue of our sterile compounding newsletter we will discuss the three greatest challenges reported in the survey.

The Most Reported Challenge

The number one most reported challenge was the inability for a pharmacist to accurately verify prepared CSPs if using an indirect process. Pharmacists who are unable to directly engage with the actual sterile compounding inside the cleanroom, will rely on an indirect verification process to approve the finished CSP.

One commonly practiced form of indirect verification is known as the "post procedure pull back method". As unreliable as its name sounds, in the pullback method the pharmacist inspects an empty syringe, "pulled back" to the additive amount, after the additive has already been added to the base solution. This method is somewhat akin to accepting an empty dinner plate as proof of someone finishing all their vegetables.

Over half of the survey respondents preferred an IV workflow system, rather than the pullback method. An IV workflow system usually includes some combination of workflow management software, ingredient bar code scanning, and gravimetric checking. We will always applaud IV workflow systems and believe that they are champions in patient safety. For example, a recent report from Pharmacy Practice News[2] describes yet another sterile compounding program that cut down their dispensing errors through ingredient barcode scanning.

Some workflow systems may also stream selected images to an outside pharmacist, to help capture any errors during the compounding process. Although pictures may add another element of improvement over the outdated and unsafe practice of syringe

pullback, we can't help but wonder what types of oversights may get missed when pharmacists routinely sign for CSPs from a workstation outside the cleanroom.

Second Most Reported Challenge

The second most reported group of challenges listed in the ISMP survey were all related to USP <797> and USP <800> standards. These included an array of responses related to sterility, cleaning, environmental monitoring, beyond-use dating, garb, and the safe handling of hazardous drugs.

It remains unseen by us if pharmacists can fully oversee USP compliance exclusively through streamed images. After all, how many snapshots will it take to capture someone retrieving a fallen item off the floor, wearing a facemask under a nose, or crossing over a line of demarcation in cleanroom garb?

No matter what method of verification is used, it is the person in authority—the licensed pharmacist—who has the ultimate responsibility for the safety and the quality of the patient's CSP. It is an enforceable requirement written in many states' pharmacy regulations. For example, the state of California states that "a pharmacist shall be responsible for all activities of pharmacy technicians to ensure that all such activities are performed completely, safely and without risk of harm to patients"[3] and in Ohio the pharmacist is always responsible for drugs that are compounded with the assistance of qualified pharmacy technicians.[4]

Given that many pharmacists must rely heavily on technicians to help balance their crushing workloads, it would make sense that pharmacies first prepare their sterile compounding personnel through proper training, before entrusting those same personnel to prepare a patient's CSP. Many respondents in the survey, however, reported otherwise.

Third Most Reported Challenge

The third most reported challenge in the ISMP survey was the ability to properly train both technicians and pharmacists to prepare and/or verify CSPs. Survey respondents listed CSP compounding by inexperienced technicians, supervision of CSP compounding by inexperienced pharmacists, and pharmacist coverage by a rotating staff, as concerns related to proper training.

We often receive comments and questions sent to our newsletter about similar issues related to sterile compounding. In one recent email to us, a 3rd year pharmacy student stated that "sterile compounding and the guidelines involved are hit on very briefly" in her pharmacy school. Both the ISMP survey, and the comments emailed to us, suggest that sterile compounding knowledge is often obtained from other individuals already working in the cleanroom.

Many times, the greatest challenge when training a newly hired pharmacist or technician is "un-teaching" them any of the poor practices they may have acquired from someone else. Even worse is when new employees pick up bad habits from any of your existing personnel who may follow different standards which depend upon who's supervising. Therefore, until everyone in the pharmacy uses the same "gold" standard to continuously keep each other in check, we wouldn't put much stock on perfect scores achieved during a training period.

In conclusion, although it is unlikely to capture every type of sterile compounding practice in one survey, it is possible to pinpoint certain types of practice settings that share common concerns, and it is notable that 80% of the respondents in the ISMP survey were pharmacists and 87% worked in a hospital pharmacy. Perhaps, many of these respondents also perform daily order entry, drug utilization, disease state management, and more, while overseeing their sterile compounding program.

If workload imbalance leads you to have similar concerns, or if your health-system's demand for clinical services has over-consumed your pharmacy's resources, we hope this discussion will make a good case for putting some expert and authoritative eyes back into your cleanroom. You will be amazed at the level of oversight.





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CAPS Consulting℠ is a team of pharmacy experts who are proficient in sterile compounding. We perform USP <797>, USP <800>, and 503B outsourcing compliance tests each and every day, year round, at 22 regional 503A pharmacies and three 503B outsourcing facilities across the United States. Our consulting team is ready to share this expertise with you.

To learn more about CAPS Consulting contact Eric.Bauer@CAPSPharmacy.com

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1. ISMP Survey Provides Insights into Pharmacy Sterile Compounding Systems and Practices. Institute for Safe Medication Practices. www.ISMP.org (October 22, 2020)
2. Wild, David "Planning and Execution Key to Successful Barcode Implementation" Pharmacy Practice News March 1, 2021.
3. 16 CCR § 1793.7 (e) Requirements for Pharmacies employing Pharmacy Technicians; California Code of Regulations
4. 4729-16-03(E)(1) Drugs compounded in a pharmacy; Ohio Administrative Code

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