Infection Specialists and Pharmacists Share Responsibility for Ensuring Patient Safety

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Collaboration is a necessary component of successful compliance with USP, and technology can help.

The United States Pharmacopeia (USP), along with the American Society of Health-System Pharmacists (ASHP) and the Association for Professionals in Infection Control and Epidemiology (APIC), has identified collaboration between infection preventionists (IPs) and pharmacists as a necessary component of successful compliance with USP General Chapter <797>.1-3

There are several issues underscoring the need for this interdepartmental partnership, including accountability to government and accrediting organizations, IPs' expertise in environmental monitoring and mitigation, recognition of the role that the environment plays in infection transmission risk, and what is at stake when contamination of compounded sterile preparations (CSPs) occurs. Compliance with USP <797>, however, may increasingly require that this collaboration include reliance on emerging technologies to address environmental risk in the clean room.

High Stakes

The foundation of USP <797> is prevention of patient harm through contaminated or improperly formulated compounded medica- tions.1,2 The IP's role in USP <797> compli- ance is rooted in the prevention of microbial contamination.1,2

This is a critical undertaking because, as stated by USP <797>, CSPs pose an especially hazardous threat to patients “when administered into body cavities, central nervous and vascular systems, eyes, and joints, and when used as baths for live organs.”[1]

Outbreaks, such as the 2012 fungal infections caused by contaminated methyl- prednisolone preparations that resulted in 64 deaths and 793 illnesses across 20 states, highlight the contamination risk if proper environmental controls and monitoring are not in place.[4,5] In this instance, failures in environmental monitoring and mitigation within the compounding pharmacies were responsible for the subsequent devastating morbidity and mortality associated with the outbreak.[4]

USP <797> addresses CSP contamination risk through guidelines on the “quality status of the components incorporated, the process utilized, personnel performance, and the environmental conditions under which the process is performed.”[1]

The chapter provides detailed guidance on aseptic technique, engineering controls, environmental monitoring and quality assurance, and facility design. Both the ASHP and USP guidelines charge compounding personnel with responsibility for all elements of USP <797>, including cleaning and disinfection, environmental monitoring, and prompt corrective action for any unacceptable moni- toring or measurement results (see Table 1).[1] They also recommend, however, that the environmental elements be addressed in collaboration with infection prevention and control personnel.[1,2]

The ASHP further advises that clean room personnel consult the facility’s “appropriate authority [eg, the Infection Control Committee] on choice of cleaning and disinfection products and ensure a root cause-analysis, including participation by other facility experts such as infection control Personnel,” is completed for any actionable monitoring or measurement failures (see Online Table 2).[1]

This is critical not only for patient safety but because of the accountability standards to which health care facilities and practitioners are increasingly held.

Accountability

The USP sets standards for pharmacy practice, but it is not an enforcement body.

State pharmacy boards provide the primary oversight for compounding pharmacies, and an increasing number of them mandate compliance with USP <797>.[6,7]

A 2018 report by the Pew Charitable Trusts found that 32 state boards of pharmacy mandated compliance, with an additional 4 having pending policy changes regarding compliance.[6]

In turn, under Title 42, §482.25, the Centers for Medicare & Medicaid Services identifies adherence to state laws regarding compounding pharmacy practice as a condition of participation.[8] The Joint Commission accreditation similarly requires compliance with state law and, thus, compliance with USP <797> where mandated.[7]

Progress Snapshot

Although IP-pharmacist collaboration in the clean room may be an intuitive partnership in achieving compliance with governmental and professional standards

and ensuring patient safety, there is some evidence that challenges remain.[9,10]

In its most recent published survey of hospital pharmacists across the nation, the ASHP reported that 71% of pharmacists from 687 hospitals had used an environmental sampling program, and 83% reported preparing chemotherapy (ie, sterile) medications in their pharmacies.[9] This suggests that 12% of surveyed facilities might be compounding sterile preparations but not performing appropriate environmental oversight. Further, just 44% of those facilities performing environmental monitoring reported those sampling results through their organization’s quality reporting pathways.[9]

In a report on 2018 survey results from sterile medication compounding pharmacies, Robert Campbell, PharmD, the director of medication management for the Joint Commission Enterprise, noted that “there is a continuing trend of pharmacy leaders not reviewing their testing and certification reports in detail. As a result, important components of engineering

controls are undergoing testing, but are not in compliance with the required values; in some cases, they are not being treated at all."[10]

Emerging Environmental Technologies

The dramatic advancements in environmental technologies have been in direct response to the growing body of evidence demonstrating the inadequacy of manual cleaning and disinfection. As such, it has been a fail-safe of sorts, providing an added measure of certainty in mitigating environmental contamination risk. The aforementioned pharmacy survey statistics suggest that the clean room environment may need a fail-safe of its own, because of the reported suboptimal execution of environmental monitoring and mitigation strategies. Research has shown that environmental technologies, such as hydrogen peroxide vapor systems and ultraviolet-C light, can effectively reduce environmental bioburden as an adjunct to manual cleaning.[5] Evaluation of the method of disinfection (episodic versus continuous), impact on workflow, and compatibility with clean room materials are among the many factors that must be considered in choosing a technology, and are best assessed by integrating the IP's environmental risk expertise with the pharmacist's clean room operational expertise.

Case Report

Despite the statistics, there is evidence that collaboration can lead to successful outcomes. One such example is the partnership between the IP and the pharmacist at an inpatient hospital in Indiana, a state in which USP <797> compliance is mandated. Over a period of 2 and a half years, the IP and pharmacist collaborated to investigate and address recurring actionable air sampling results in the hospital's clean room (see Online Figure). Although the air and surface sampling within the actual intravenous (IV) hoods consistently yielded passing grades, there were continuing issues with viable growth in the air sampling in areas associated with IV mixing.

Investigations identified several environmental sources for the monitoring failures, including a faulty HVAC filter, personnel practices, and a water-damaged wall. Although these sources were individually addressed, the ongoing nature of these challenges made it clear to the team that an environmental mitigation strategy that could provide continuous bioburden reduction was needed. Aligning with the charge from both the ASHP and APIC that new technologies be

integrated where appropriate to achieve quality assurance,[2,3] the IP subsequently recommended the implementation of dry hydrogen peroxide (DHP) technology (Synexis), which in previous research had been shown to provide continuous and effective microbial reduction of air and surfaces in the health care setting.[11] The IP-pharmacist team determined that the ability of DHP technology to operate continuously would help address active shedding and contamination in real time without disrupting pharmacy workflow. Additionally, the DHP would be compatible with clean room surface materials as well as being safe. Deployment of the technology 24 hours a day, 7 days a week resolved the monitoring failures and enabled successful compliance with USP <797>.

Conclusion

IPs and pharmacists share responsibility for ensuring patient safety. In the clean room, this shared responsibility is achieved through the prevention of contaminated CSPs. Both professions are charged by their respective professional organizations, and increasingly by government mandate, to employ solutions that ensure the highest degree of quality assurance.[2,3,6-8] Environmental technologies are used in other health care settings for this purpose and should be similarly deployed in the clean room, particularly when evidence suggests environmental monitoring and mitigation processes are not being executed appropriately. Although the USP recently remanded the proposed changes to USP <797> to its Compounding Expert Committee, should the proposed revisions regarding more stringent monitoring frequencies and enhanced cleaning requirements be adopted, and the trend for more states demanding USP <797> compliance continue, collaborative deployment of these technologies may become even more imperative.[1,12]

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