Respecting the risks of sterile compounding

An audio interview that supplements the information in this article is available on AJHP’s website at www.ajhpvoices.org.

National headlines have been riddled with cases in which questionable sterile-compounding practices caused harm to patients. A number of industry dynamics may be potentiating the increased prevalence of these incidents. These dynamics include new regulatory requirements, ongoing medication shortages, and evolving drug-delivery modalities that necessitate changes to current pharmacy compounding practices. Pharmacy must address the remaining gaps in sterile compounding practices. We must also appreciate the expertise needed to oversee sterile-compounding operations, especially those involving high-risk preparations.

Before the release of United States Pharmacopeia (USP) chapter 797 in 2003, a detailed national standard for sterile compounding in the acute care setting was lacking. Before the approval of the Drug Quality and Security Act in 2013, differentiation between compounding and manufacturing was unclear. Further, it was unclear what regulatory agency was responsible for monitoring and ensuring safe practices of those engaged in compounding and manufacturing.

Pharmacy’s ongoing focus on internal sterile-compounding practices and on compliance with USP chapter 797 seems to have resulted in fewer instances of contaminated preparations originating in hospitals’ cleanrooms. Yet cases like the one that prompted the study by Moulton-Meissner et al. in this issue (see page 1285) continue to be reported. That case, which involved bacterial contamination of parenteral nutrient solutions, was an example of health systems relying on a compounding facility and thus reducing their ability to directly ensure that the competence and diligence applied during compounding were commensurate with the complexity of that activity.

The inability to purchase commercially manufactured medications has led hospital and compounding pharmacies to seek alternative products to address their clinical needs. In some instances, these alternatives involve high-risk compounding in which nonsterile ingredients are used to prepare sterile products. Most hospital pharmacies are equipped to prepare low- and medium-risk sterile products. Facilities engaged in compounding high-risk products must appreciate and appropriately manage the increased potential for causing harm.

Pharmacy leaders contemplating the preparation of high-risk products must determine if the facility in question is capable of such activity; they must also evaluate the risk:benefit ratio of engaging in this practice. If a desired formulation of a medication becomes unavailable, is it better to switch to a commercially available product of a different concentration or to prepare a high-risk sterile compound? The answer could depend on the clinical scenario, available drug-delivery devices, and the capabilities of the facility and personnel involved in compounding the product.

If a pharmacy is equipped to compound high-risk products, it must have the proper risk-mitigation processes in place. Hospitals delegating medication preparation to compounding facilities must be fully informed about and capable of evaluating the facilities’ ability to comply with the relevant practice standards, including state and federal regulations. For example, employees responsible for high-risk sterile compounding must be well versed in USP chapter 797 and understand the importance of prefiltering, performing bubble-point integrity tests on 0.2-µm filters, and observing appropriate equipment-sterilization processes.

Finally, pharmacy should evaluate how sterile-compounding competencies are established and maintained. There is no universal standard for credentialing health systems or certifying personnel involved in sterile compounding. Although 96% of pharmacy schools provide some level of training in compounding sterile products, the depth of this training varies. ASHP’s accreditation standards for postgraduate year 1 pharmacy residencies do not specifically require proficiency in sterile compounding. Perhaps the time has come for the profession to develop a nationally recognized certification or other credential to validate expertise in the practice of sterile compounding as a requirement for personnel involved in high-risk compounding.


Ross W. Thompson, B.S.Pharm., M.S., FASHP, Director of Pharmacy Services
Tufts Medical Center
Boston, MA
rthompson@tuftsmedicalcenter.org

Caryn Belisle, B.S.Pharm., M.B.A., Director of Pharmacy
Regulatory Compliance, Quality, and Safety
Brigham and Women’s Hospital
Boston, MA

The authors have declared no potential conflicts of interest.

DOI 10.2146/ajhp150313