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Navigating the Path to Safe Compounding in Health Systems

Thomas Pile

Craig Kimble

Alberto Coustasse

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Drug shortages have led to increased use of compounding pharmacy.

THOMAS PILE, PHARMD, CDCES; CRAIG KIMBLE, PHARMD, MBA, MS, BCACP; AND ALBERTO COUSTASSE, DRPH, MD, MBA, MPH

ABOUT THE AUTHORS

THOMAS PILE, PHARMD, CDCES, is a clinical assistant professor in the Department of Pharmacy Practice, Administration, and Research at Marshall University School of Pharmacy in Huntington, West Virginia.

CRAIG KIMBLE, PHARMD, MBA, MS, BCACP, is an associate professor and chair of the Department of Pharmacy Practice, Administration, and Research, as well as the director of the Office of Experiential Learning at Marshall University School of Pharmacy in Huntington, West Virginia.

ALBERTO COUSTASSE, DRPH, MD, MBA, MPH, is a professor in health care management and administration at Marshall University Lewis College of Business in Huntington, West Virginia.

ACROSS THE COUNTRY, health systems are facing increasing drug shortages that are forcing pharmacists to rely far more heavily on compounding to meet the needs of patients.[1,2] Additionally, several high-profile compounding incidents have helped highlight the importance of ensuring best practices are followed during sterile and nonsterile compounding to support patient safety and high-quality care.[3]

Specifically, in 2022, 160 drug shortages were reported in pharmacies. From January 1, 2023, to March 31, 2023, 47 drug shortages were reported, 55% of which were for injectables.[4] In response, compounding has increasingly become a solution to bridge that gap.

One area where drug shortages have raised particular concerns is with diabetes and weight-loss medications. The unauthorized versions of glucagon-like peptide 1 receptor agonists, such as those of semaglutide (Ozempic and Wegovy; Novo Nordisk), surfaced amidst the current wave of drug shortages.[5] Although compounding pharmacies create versions of commercially available drugs under certain circumstances, state regulators have raised concerns about using unapproved forms of drugs such as semaglutide.[6]

State regulators in Louisiana, Mississippi, North Carolina, and West Virginia have taken notice of these unauthorized compounded versions and have issued warnings to pharmacies, urging them to cease compounding of unapproved forms of these drugs or face legal and/or regulatory action.

The primary concern raised by these regulators is that the use of semaglutide sodium salt, a modified version of the compound, is intended for scientific research and not for use in humans. This unauthorized form raises potential safety risks and lacks FDA approval.[6]

In January 2023, pharmacy organizations such as the American Pharmacists Association, the National Community Pharmacists Association, and the Alliance for Pharmacy Compounding addressed the shortages of acetaminophen and ibuprofen in oral suspension form in a letter to the FDA.[7] They highlighted difficulties that caregivers of ill children face in finding these products and emphasized the need for immediate action. Further, these organizations urged the FDA to allow pharmacies to compound medications to meet high demand, suggesting the addition of these suspensions to the FDA drug shortage list and issuing temporary guidance for compounding until adequate supply resumes.[7]

Best Practices Are Key

Sterile compounding requires meticulous attention to detail and strict adherence to protocols. It also involves maintaining a sterile environment, implementing aseptic techniques, and following stringent hand hygiene practices. To this end, personal protective equipment requirements should be strictly followed to minimize the risk for introducing contaminants. Proper facility design, equipment maintenance, and calibration are all crucial for this purpose.[8-10]

In nonsterile compounding, guidelines and regulations must be strictly followed to ensure product consistency, accuracy, and safety. Accurate calculations and meticulous measurement of ingredients are imperative to minimize dosing errors. The selection and preparation of vehicles and bases should consider factors such as solubility, stability, and compatibility. Hazardous substances can

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introduce additional challenges that require a thorough understanding of risk assessment and containment strategies.[9]

Regular audits and inspections help identify potential risks and ensure adherence to best practices. In addition, establishing robust standard operating procedures promotes consistency, accuracy, and safety throughout the compounding process. Further, establishing a comprehensive adverse event reporting system encourages health care professionals to report any issues, allowing for timely intervention and prevention of potential harm to patients. Lastly, continuous professional development, including ongoing education and training, is essential for compounding personnel to stay updated with current guidelines and best practices.

Looking to the Future

Compounding practices will continue to evolve, and addressing evolving regulations and compliance requirements is essential. Further, staying abreast of regulatory updates and maintaining compliance with changing standards continue to be a challenge during the evolution of these regulations. The emergence of modern technologies, such as robotics and artificial intelligence, also present opportunities for advancements in compounding safety and efficiency.

Adhering to best practices in compounding ensures patient safety and quality. Further, the ongoing prevalence of drug shortages highlights the crucial role of compounding pharmacy in meeting patient needs. By following guidelines and best practices, pharmacy teams can help prevent patient harm and provide the best possible care. ■

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