Advertisement

• acute porphyrias

Implementing USP <800> Guidelines in Pediatric Hospitals

January 19, 2024
Taylor Mackinnon, PharmD, MS, BCPS
Kristen Schaeffler, PharmD, MBA

View All

Publication *Article*

Pharmacy Practice in Focus: Health Systems
January 2024
Volume **13** Issue **1**

Protecting this vulnerable patient population requires specially designed strategies.

Implementing the *United States Pharmacopeia* (*USP*) <800> guidelines at a pediatric hospital presents unique challenges because of the vulnerable patient population, the need for specialized medication dosages and formulations, and differences in administration workflows compared with hospitals for adult patients. Insights into implementing *USP* <800> guidelines can be valuable for hospital pharmacy professionals in the pediatric setting. We present examples of these challenges and strategies from our work at the University of Michigan Health (UMH) Michigan Medicine CS Mott Children's Hospital and Von Voigtlander Women's Hospital (CW Hospital) in Ann Arbor.

USP <800>



Image credit: Pixel-Shot | stock.adobe.com

The *USP* <800> guidelines provide health care workers with standards for safely handling hazardous drugs in health care settings. The guidelines cover policies and procedures for receiving, storing, preparing, administering, and disposing of hazardous drugs. In addition, the guidelines detail how facilities must provide training and education programs for their workers. Starting November 1, 2023, this chapter had compendial applicability and, therefore,

enforceability by many state boards of pharmacy and the FDA.[1,2] Compliance with these guidelines will be necessary to maintain accreditation and to improve worker protections in response to the growing awareness of the potential health risks of handling hazardous drugs.

UMH had a hazardous drug handling program in place before the publication of *USP* <800> in 2016. However, the new chapter requires a more standardized approach to reviewing and classifying drugs used within the health care system. UMH established a multidisciplinary hazardous drug oversight committee (HDOC) in 2019 to provide consistency in drug classification, policies, and interdisciplinary education across the UMH enterprise.[3] Committee members included a medical doctor and representatives from pharmacy, nursing, safety management, environmental services, research, accreditation, occupational health, and infection prevention.

The HDOC classified medications into 4 hazardous categories: high or low biosafety, high hazard, modified hazard, and reproductive hazard **(Table 1)**.[4] Drug categorization was determined based on standardized criteria defining the type of toxicity and risk of exposure. This drug review resulted in an increase in medications classified as hazardous at Michigan Medicine by 119% (from 139 to 305) with the majority newly classified as hazardous. This translated to an 83% increase in hazardous drug doses administered per month in 2022, with 14,017 doses per month increasing to 25,687 doses per month.

TABLE 1. MEDICATION AND FORMULATION HAZARDOUS CLASSIFICATION[4]

New *USP* <800> classification		Previous classification		Ribociclib		
		HIGH	LOW	Non-HazD	NEW	NF
HazD total	305	139		-	-	-
Biosafety	4	4	0	0	0	0
High/modified	203	71	40	31	5	56
Reproductive	98	2	19	48	4	25
Non-HazD	0	1	2	0	0	0

Table 1: Medication and forumlation hazardous classification -- HazD, hazardous drug; new, new to market since the previous classification; NF, not evaluated due to nonformulary status; USP, United States Pharmacopeia.

CW Hospital Statistics

Approximately 2.1 million doses per year are dispensed from the inpatient pharmacy enterprise at UMH with approximately 44% of dispenses from CW Hospital **(Table 2)**. Because UMH is a pediatric hospital, the majority of the nonsterile dispenses (50% of total) are oral syringes (70% of nonsterile dispenses).

TABLE 2. MICHIGAN MEDICINE INPATIENT PHARMACY DISPENSES

FY	MM total	CW total	CW total/ MM total	Sterile dispenses (excluding TPN/lipids)	Nonsterile dispenses	Oral syringes
2021	2,082,141	826,703	39.70%	409,983	416,720	297,365
2022	2,108,263	911,916	43.30%	452,072	459,844	323,861
2023	2,029,930	987,538	48.60%	445,077	503,398	350,056
Total	6,220,334	2,726,157	43.87%	1,307,132	1,379,962	971,282

Table 2: Michigan medicine inpatient pharmacy dispenses -- CW, CS Mott Children's Hospital and Von Voigtlander Women's

Hospital; FY, fiscal year; MM, Michigan Medicine; TPN, total parenteral nutrition.

CW Hospital pharmacy has increased the number of dispensed nonsterile oral syringes by 17% from fiscal year (FY) 2021 to FY 2023 **(Table 3)**. Of the total nonsterile oral solution medications dispensed from FY 2021 to FY 2023, approximately 6% would have been classified as hazardous, according to the new *USP* <800> guidelines. The legacy hazardous drug classification accounted for 2% of doses. Therefore, the new classification resulted in an increase of 200%. From FY 2021 to FY 2023, the hazardous medications classified under *USP* <800> as sterile and nonsterile have had diametric percentage changes. The sterile hazardous medications have decreased from 6.2% to 5.7%, whereas the nonsterile area medications have increased from 5.9% to 6.7%.

Table 3: UMH medications under new USP <800> category -- FY, fiscal year; HazD, hazardous drug; TPN, total parenteral nutrition, UMH, University of Michigan Health; USP, United States Pharmacopeia.

Training

Specialized training for health care workers on the safe handling of hazardous drugs for pediatric patients was performed by area pharmacy leaders and the HDOC. The HDOC sent out interdisciplinary education to providers, nurses, and pharmacy staff through multimedia forms such as e-learnings, posters, frequently asked questions documents, and presentations to affected groups. Area pharmacy leaders provided education through huddles, one-on-one training, and area-specific education materials. The pediatric-specific materials included the creation of a high-level overview of *USP* <800> changes with a Toy Story theme to enhance engagement and retention by placing characters in the area of most importance.

Initiatives geared toward transitioning staff from training to competency aim to bridge the divide between theoretical knowledge and practical application. These initiatives incorporate hands-on training, simulations, and real-life scenarios to help employees apply their skills in relevant contexts. Competency assessments, including performance evaluations, tests, and observations, gauge employees' proficiency in meeting defined performance standards and

attaining desired outcomes. UMH's technician trainer provides ongoing feedback, coaching, and mentoring to address areas of improvement and enhance employees' competence.

Dose Rounding/Prepacks

A dose rounding committee was established in 2020 to implement Lean Six Sigma principles and support the compliance transition to the new *USP* <800> guidelines. The committee consisted of pharmacy, nursing, and medical staff who collaborated to identify medications that could be rounded, establish rounding guidelines, and monitor the implementation process. The committee also ensured that the rounding process complied with *USP* <800> guidelines by incorporating safe handling practices, including that syringes should only be filled to only 75% of their calibrated volume. Implementing the doserounding program has significantly reduced medication waste, improved patient safety by decreasing the risk of errors associated with manipulating medication doses, and reduced workload through bulking prepackaged syringes. Through this initiative, 71 prepacks were created for those 3 hazardous medications **(Table 4)**.

Table 4: UMH prepacks -- UMH, University of Michigan Health

Lean Six Sigma principles also resulted in the conversion from a mixture of clear and amber syringes to exclusively amber ENFit syringes. This conversion has prevented errors in preparation (eg, medication requiring light protection being prepared in clear syringes) and administration (eg, giving oral medications in an intravenous line). The exclusive use of amber syringes resulted in cost savings through hard (cost) and soft (redispensed) savings. This change additionally supported Six Sigma's Kaizen 5S continuous improvement approach by eliminating protection-from-light materials and supportive manuals for the manual human error-prone process.

Batches

To increase efficiency, a new hazardous drug batch was created. For nonsterile hazardous medications, there are 2 categories of batches based on expiration dating **(Table 5)**.

One batch prints twice a day with medications that have extended expirations (majority) and covers 9- and 15-hour spans with a lag time (administration time to dispense time) averaging 14.25 hours. A second batch prints every 4 hours with medications with a short expiration and covers a 4-hour span with a lag time (administration time to dispense time) averaging 5 hours.

Table 5: UMH batches -- UMH, University of Michigan Health

Procedure

The process for preparing and checking nonsterile hazardous medications is as follows:

1. All nonsterile hazardous medication preparation, repackaging, and compounding must be completed in the designated nonsterile hazardous compounding room.
2. Medication label prints either as first dose or on designated hazardous batches.
3. Nonsterile hazardous medications must be prepared by a unit dose technician or by another identified technician if the unit dose technician is unavailable.
4. Hazardous medications will be checked by the pharmacist controller or by another identified pharmacist if the pharmacist controller is unavailable.
5. Technician takes label(s) along with other needed supplies to nonsterile hazardous room, gowns up appropriately, and enters compounding area to prepare medications.
6. Technician begins preparing all needed medications, prepacks, and/or compounds.
    1. Pharmacy controller (or other identified pharmacist if pharmacy controller is unavailable) enters nonsterile hazardous room to check prepared products.
        1. Pharmacist dons a minimum of gloves to check final products placed on checking counter that do not require pharmacists to cross red tape into hazardous compounding area.
        2. Medications requiring product checking within containment ventilated enclosure (CVE) require the pharmacist to don appropriate hazardous compounding garb.
    2. If the pharmacist is not in oral hazard room by the time the technician prepares medications, the technician uses the phone in oral hazard room to call pharmacist to enter room to check medications.

3. Technician remains in oral hazardous room while pharmacist checks products whenever possible to assist with fixing incorrect doses and bagging.

7. Pharmacist completes all required checks on all prepared hazardous medications. Once medications are checked, technician and pharmacists together bag all hazardous medications into appropriate hazardous bags.

Although crushing/dissolving solid oral dosage forms within a pouch containment system and oral liquid repackaging activities are not required to occur within a CVE, these workflows were simplified to prevent staff confusion with added safety benefits **(Table 6)**.

Table 6: UMH patient-specific process -- UMH, Univeristy of Michigan Health

Role of Pharmacists

To prevent manipulation of medications before administration, prescribers were educated to avoid ordering formulations of hazardous medications that need additional manipulation, such as crushing tablets or opening capsules, whenever possible. Additionally, pharmacists were empowered through policy to change hazardous medications to liquid formulations if solid dosage forms were inappropriate for the patient.

Simplifying the process of ordering pediatric dissolved tablets involves several key considerations. Firstly, only pharmacists have access to the order, ensuring enhanced control and accuracy. To minimize errors, common hazardous medications are prepared at a predetermined concentration. Opting for prebuilt options maintains a consistent concentration, eliminating the need for dilution adjustments. Changes in dosage automatically adjust the desired volume accordingly. Tablet strength for dilution is now fixed to ensure precise dose calculations using the electronic health record Epic. For instance, clobazam (Onfi) consistently uses 10-mg tablets for dilution, requiring two 10-mg tablets for a 15-mg dose. In cases involving uncommon hazardous medications with nonstandard concentrations, the pharmacist manually enters the volume for each dose adjustment, following the existing process.

The order system intelligently populates with either the “pharmacy to dilute” or “nursing to dilute utilizing RxCrush” option, depending on the patient’s assigned unit. Currently, the “nursing to dilute utilizing RxCrush” feature is under development and not yet active, intended for testing on select units. Patients assigned to the “pharmacy to dilute” option receive labels for shortdated hazard batches, whereas “nursing to dilute using RxCrush” allows for tablet printing during cart filling or automated delivery to the BD Pyxis dispensing system if the medication is stored there.

If a patient transfers units, reordering the medication from scratch as separate electronic prescriptions becomes necessary to switch between “pharmacy to dilute” and “nursing to dilute utilizing RxCrush,” or vice versa. However, once the transfer is complete, the relevant section in the order will automatically update. Presently, there is no established process for indicating this transfer before nursing contacts the pharmacist to facilitate the switch. Addressing this gap becomes essential if units adopt the use of RxCrush.

The labels for the “pharmacy to dilute” option maintain a similar appearance to the current process but now include concentration information associated with the title in Epic **(Figure)**. These enhancements aim to improve medication safety, streamline processes, and promote accurate dosing throughout the ordering and administration of pediatric dissolved tablets.

Figure: Nonsterile hazardous room work procedure reference -- C&R, compounding and repackaging; CVE, containment ventilated enclosure (hazardous compounding hood); HD, hazardous; HD counter, nonsterile hazardous checking counter; oral HD room, nonsterile hazardous compounding room; pharmacy, general 10Rx pharmacy; QS, quantum satis; RPh, pharmacist.

Patient-Specific Impact

Due to the prevalence of patients following a ketogenic diet, a pill-crushing system was purchased for the manipulation step in single-dose administration. Manipulation includes opening capsules, crushing or splitting tablets, or the dissolution of solid oral dosage forms for immediate administration to a

patient. This pill-crushing system is compatible with ENFit syringes for nurses and midnight pharmacy staff to utilize.

The ketogenic diet is a popular therapeutic option for pediatric patients with epilepsy, neurodevelopmental disorders, and mitochondrial disorders, but providing inpatient pharmacy services can be challenging because of various barriers. Given the strict macronutrient ratios crucial for maintaining a state of ketosis, individuals on a ketogenic diet must carefully navigate the availability and safety of medications, especially those that contain hidden sources of carbohydrates or other additives that can disrupt their dietary goals. From FY 2019 to FY 2023, CW Hospital averaged 107 patients on a ketogenic diet with an average length of stay of 4.4 days. Medication formulation can be problematic for children who have difficulty swallowing capsules or tablets. *USP* <800> has further complicated the process of providing therapy to these patients because many of the formulations cannot be manipulated bedside without proper personal protective equipment and other equipment due to the new hazardous classification. When a patient is placed on a ketogenic diet, an order set provides medication decision support for fever, seizure, and fluid management.

Additionally, the patient's allergy list is updated with a dextrose allergy to provide a best practice advisory alert. Because it is essential to avoid sugar-containing medications, the pharmacist carefully verifies that the hospital's medication supply is sugar free and can be made with sugar-free products. This requires evaluating compounding recipes using either compounding and repackaging or using all UMH compounding recipes.

Further, the pharmacist should ensure that all new compounded bottles for the patient during admission are made using sugar-free ingredients, which can be noted with a specific medication label added to the compounded bottle. If there is no sugar-free solution, partial/aliquot doses of medications can be used to achieve optimal therapeutic outcomes. To use this methodology, a generic orderable was created and made available to providers, whereas an additional medication-specific orderable was created but was only available to pharmacists.

The generic orderable was available to providers and pharmacists to allow for flexibility in ordering. The medication-specific orderable was only available to pharmacists to allow for preselected strength/drug products that automatically

populate ordered doses, fixed drug-to-volume ratio, and easy dose titration. This was not made available to providers because of the possibility of mismatched ordering, modification of drug-to-volume ratios, and inability to combine tablets of multiple strengths. Finally, the pharmacist pays special attention to the "ketogenic diet" notification on patient labels and bolds this comment on both Epic and medication labels to make it more noticeable during product checking.

Conclusion

Implementing *USP* <800> guidelines at the UMH CS Mott Children's Hospital required a customized approach that addressed the unique challenges associated with the care of pediatric patients. The hospital successfully overcame these challenges by conducting a comprehensive assessment of its medication-handling practices, providing specialized training to health care workers, investing in specialized equipment and facilities, implementing policies and procedures promoting the safe handling of hazardous drugs, and involving parents and caregivers in the implementation process. By adopting these strategies, UMH CS Mott Children's Hospital ensured the safety of health care workers, patients, and the environment while providing the highest quality care to its patients.

References

1. Hazardous Drugs—Handling in Healthcare Settings. The United States Pharmacopeial Convention. Last updated November 1, 2023. Accessed December 9, 2023. https://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare
2. *Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act*. US Department of Health and Human Services, FDA, Center for Drug Evaluation and Research. June 2016. Accessed December 5, 2023. https://www.fda.gov/media/94393/download
3. Tharp J.Develop a hazardous drug oversight committee. *Pharmacy Purchasing & Products*. 2022;19(9):8-15. Accessed December 5, 2023. https://www.pppmag.com/article/2985
4. Penzien C. Safe handling of biosafety drugs and live virus vaccines. *Pharmacy Purchasing & Products*. 2023;20(4):12-15. Accessed December 5, 2023. https://www.pppmag.com/article/3067

About the Authors

Taylor Mackinnon, PharmD, MS, BCPS, is a pharmacy manager at CS Mott Children's Hospital and Von Voigtlander Women's Hospital in Ann Arbor, Michigan.

Kristen Schaeffler, PharmD, MBA, is a pharmacy manager at CS Mott Children's Hospital and Von Voigtlander Women's Hospital in Ann Arbor, Michigan.

Carrie Penzien, PharmD, BCSCP, is a pharmacist specialist team lead for the Department of Pharmacy compounding compliance team at Michigan Medicine and adjunct clinical faculty at the University of Michigan College of Pharmacy in Ann Arbor.

Ashley Sauro, PharmD, BCPS, is a clinical pharmacist, pediatrics, at CS Mott Children's Hospital and Von Voigtlander Women's Hospital in Ann Arbor, Michigan.

Download Issue PDF Download RIS

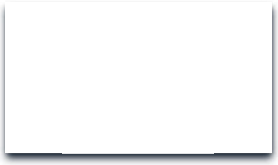
Articles in this issue



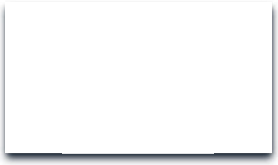


Implementing USP <800> Guidelines in Pediatric Hospitals

Related Videos



Navigating CLL Management: Insights from a Clinical Pharmacist at Mount Sinai Hospital



Guiding Principles in the Management of cGVHD



Navig
Optimi

Related Content



Updating Hospital Policies to Improve Inpatient Care for Patients With Parkinson Disease

January 19th 2024

Article

Pharmacy Focus: A Glimpse into Independent Prescribing

January 8th 2024

Podcast



Gender Gap in NIH-Awarded Research Grants Persists in the Field of Nonmalignant Hematology

January 19th 2024

Article

Public Health Matters: A Pharmacist's Journey in Global Public Health

December 21st 2023

Podcast

All it Takes is a Conversation: Deprescribing Benzodiazepines in Older Adults

January 19th 2024

Article

Standardized Onboarding Reduces Turnover of Pharmacy Technicians

January 19th 2024

Article

2 Commerce Drive
Cranbury, NJ 08512

609-716-7777

© 2024 MJH Life Sciences™.
All rights reserved.