

Teaching and Learning in Compounding Course: Instructional Design, Assessment, and Reflection in the Pharmacy Practice

Cindy Ngoc Chau, PharmD Candidate 2024; Karina Mendez Cordero, PharmD Candidate 2024; Ayesha Rahman Ahmed, PhD

Washington State University, College of Pharmacy and Pharmaceutical Sciences (Spokane, Washington)



WASHINGTON STATE UNIVERSITY
College of Pharmacy and
Pharmaceutical Sciences

Introduction

Compounding pharmacy is an important element of pharmacy practice. The compounding technique involves the preparation of individualized medications that are not commercially available for patients. The importance of pharmaceuticals-related concepts to pharmacy practice regarding pharmaceutical calculations and compounding is well documented. Therefore, knowing how to appropriately compound medications to prevent harm due to a poor-quality product is essential. Watson et al. identified 63 compounding errors while screening 2155 reports. Of these 63 errors, 21 were concentration errors that predominantly resulted from compounding a prescription for a single patient, 27 were contamination errors mainly due to the bulk distribution of compounded medications for parenteral use and affected more patients, and 15 were unidentified errors². The burden of compounding errors in the pharmacy ultimately becomes the responsibility of the government, pharmacy industry, and medical providers to reduce the risk of harming patients. The registered pharmacist is expected to be proficient in both sterile and non-sterile compounding; therefore, compounding skills are required for pharmacy graduates. This technique is also vital for pharmacy students to learn for their North American Pharmacist Licensure Examination (NAPLEX) as well as real-life applications.

Through compounding lab, therapeutic needs are met for the prescriptions including patients allergic to given excipients, adjusted dosing for the pediatric patients, and medicines for the orphan drugs. The objective is to identify and improve the skills and tools necessary among pharmacy students, to adopt accuracy and appropriate techniques when preparing non-sterile compounding medications.

Materials and Methods

The non-sterile compounding lab included completing the compounding record based on the master formulation record of the drug product, completing the quality control worksheet, turning in the drug product, and a reflection worksheet. The compounding involves the evaluation and documentation process to determine the weighing, measurement, and manipulation of the components along with the beyond-use dates, labeling, packaging, and dispensing to the patients in the appropriate containers and instructions, as referred to in USP 795. The reflection worksheet, compounding record, and quality control worksheets measure the learning, retention, and competency to pass the lab course.

The overall purpose of the learning was to apply the theoretical principles of the selected pharmaceutical analysis technique involved in the compounding pharmacy, understand the fundamental aspects and develop an understanding of the compounding of the non-sterile drug products as specified in the United States Pharmacopeia, integrate and apply the theoretical principles to compounding in the real world, completed the laboratory exercises with a focus on the calculations of the different dosage forms for the specific patients, plan, organize the lab activity, evaluate their performance and retention, think critically about the extent and complexity of compounding different drug products and decision making in the application as a healthcare provider, and lastly to evaluate the importance of the pharmaceutical analyses on drug compounding and pharmacy practice.

Results

During the first weeks of the non-sterile compounding course, learners were provided readings and an introduction lesson on the expectations for the upcoming weeks of the components required during each week of the non-sterile compounding lab. During these weeks, we instructed the learners on ten different components of a master compounding record, which includes master formulation record information, formulation ingredient table, equipment needed for preparation, method of preparation, calculations, compatibility/stability, storage/packaging, labeling information, quality control, and accurately citing references. To track the learners' progress, we considered the number of learners that got the different components correct and followed this throughout the following weeks as the lesson facilitators to assess areas of improvement. The first component was the ability for learners to retain the vital information required to be included on a master formulation record, such as the manufacturer number, the date when the product was formulated, and the total amount needed to be made. The second element was the formulation ingredient table. We wanted to assess if the learners could identify the purpose of each ingredient and label them correctly. The third element was if the learners could list the equipment they will use to prepare for their non-sterile compounding. The fourth element assessed whether the learners could accurately and legibly record each step in preparing each product. The fifth element was the calculations of preparing each product, which, as student pharmacists, is an important skill that the learners were expected to master. The sixth and eighth element was the learner's ability to indicate the correct compatibility/stability of the product and the auxiliary labels required for the products made; the seventh element was the learner's ability to indicate the correct storage/packaging of the completed product. Figure one depicts the errors or missing components of the compounding record worksheet by the end of week 10 assessment.

The team-based learning during in-class hands-on experience evaluated the impact and performance of learners in the compounding lab. The learners provided the feedback and self-experience survey that clarified the pharmacy learners' perspectives regarding the pedagogy change and how comfortable or confident they felt preparing the compounded medications and working with the assigned worksheets. Through the assignment's competency scores and active participation, the learner's engagement, performance, and retention were analyzed. The learners feedback results revealed students agreed or strongly agreed that compounding lab was enjoyable with the weekly products practice, created a conducive learning environment, and improved their perceived knowledge, communication skills, and confidence.

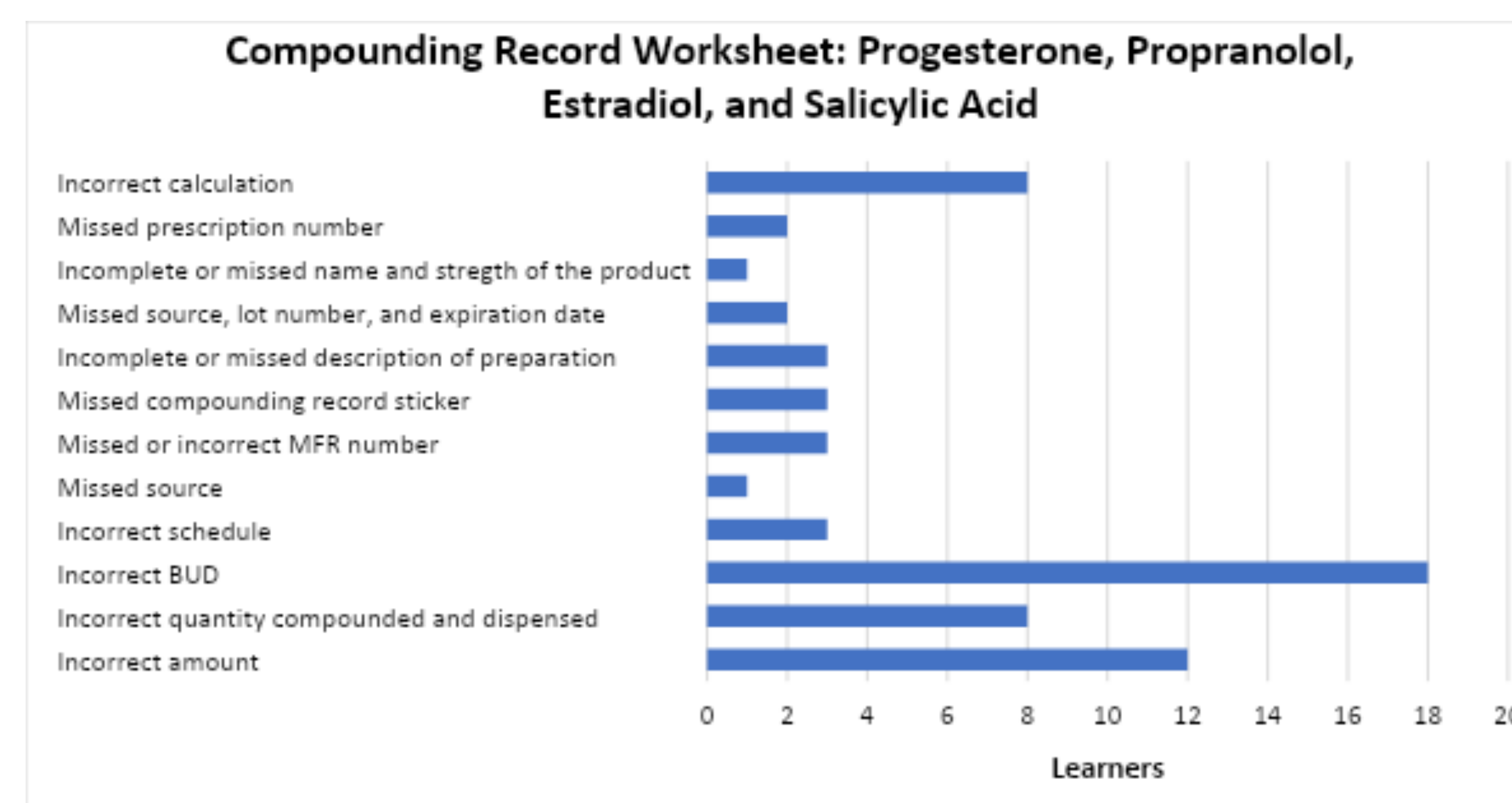


Figure 1. Errors or missing parts of the progesterone, propranolol, estradiol, and salicylic acid compounding record worksheet during the week ten assessment.

About eighteen learners wrote the incorrect beyond-use date during all three compounding record worksheets. Also, twelve learners used the incorrect amount of active ingredient or other agents to create the drug assigned, eight had the incorrect quantity compounded and dispensed, and another eight included the incorrect calculations.

On the other hand, twelve different learners should have included the compounding record sticker on the worksheet, included an incomplete or missed description of the preparation, cut or wrote the incorrect MFR number, and lastly, had the incorrect schedule of the agents. In addition, four different learners still need to include the prescription number and source, lot number, and expiration date.

Lastly, another two different learners missed the source and needed an incomplete or missing name and strength of the product.

However, regarding the quality assurance worksheet, just one learner needed more information on physical appearance in the assignment. The rest of the learners completed the quality assurance worksheet without errors.

Discussion

The course objective is to provide learners with the skills, critical thinking, and learning experience on compounding non-sterile preparations to develop the necessary tools when encountering similar situations in the real world. Having students learn compounding terminology, stability and quality control information, compounding techniques, and calculations will be helpful for learners when performing similar tasks each week with different medication dosage forms and gain confidence with the compounding techniques. This exposes learners to constant repetition and critical thinking under different scenarios, leading to retention and skill-based performance improvement. In addition, we evaluated the quality and accuracy of the non-sterile preparations using the USP Chapter <795>, which is an essential part of compounding since it could lead to patient harm if inappropriately prepared. Therefore, we believe that the continued exposure and constant repetition of pre-class readings, calculations, compounding equipment, and methods will enhance the learners' understanding and performance each week. This learner approach learning environment has encouraged learners to ask questions about the material being taught each week. This lab course also benefits learners long-term since most of the material learned will be on their NAPLEX at the end of their pharmacy program. This study aims to evaluate the quality of compounded non-sterile products and the learners' retention and skills learned during the compounding lab course.

Learners could retain most of the skills and applications from the previous weeks and apply them in the assessment. Some parts, such as assigning beyond use date, amount, or doing calculations, are more challenging for learners to apply. However, in a class of 52 learners, most learners successfully retained and applied the skills learned in the lab. Also, learners successfully applied the skills they learned in class and had a quality control worksheet without errors. Providing learners with continuous practice, returning them the worksheets, and seeing what they got wrong can help them continue to improve during the weeks.

Conclusion

The safety and accuracy in the compounding of drug products are essential for healthcare providers, including pharmacists and pharmacist technicians. The ability to prepare and dispense drug products with the correct identity of the ingredients, along with their purity, strength, and sterility, is essential.

The immense responsibility of educating pharmacy students on the baseline competencies related to sterile product preparation is recognized by the Accreditation Council for Pharmacy Education (ACPE), specifically articulated in Appendix 1 of the 2016 revision of the ACPE Standards. The training of future pharmacists is fundamentally crucial for the safety of the patients.

The mass manufacturing of drugs has increased over the last few years and has made the compounding of drugs an important aspect of pharmacy practice. The compounding of the drugs is a relevant technique for pharmacy students to learn, as it applies to pharmaceutical care, patient-centered care, and home health care. The current pharmacy graduates are educated to be in multiple healthcare roles, including but not limited to team-based patient care, management of patient health, patient-centered care plans, and the preparation and dispensing of medications.

This research will help prepare future students for the North American Pharmacist Licensure Examination (NAPLEX) and real-life applications by providing different scenarios to apply their knowledge acquired each week during the hands-on experience of the compounding lab

The strengths of our research were the consistent teaching model we provided each week and the various medications that learners were exposed to for practicing. The future areas of improvement would be implementing a larger sample size and a longer study duration. Additional research should be conducted to quantify student engagement and active attendance within similar courses.

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Disclosures

All authors of this project have no relevant financial relationships to disclose.