BRIEF

Instructional and Assessment Redesign of a Sterile Compounding Course Using Immersive Simulation

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Objective. To revise a traditional sterile compounding course to include content, competencies, and immersive simulations relevant to the current practice of sterile compounding pharmacy.

Methods. Faculty and staff at the University of North Texas System College of Pharmacy made significant revisions to an existing sterile compounding course. Instruction was provided in didactic and laboratory sessions and delivered in three modules: fundamental skills, integration of skills and knowledge, and exceptions and specialty topics. Integration laboratory sessions consisted primarily of repetitive but increasingly difficult simulations that included both technician and pharmacist activities. Assessment methods included checkpoint assessments, a mock objective structured clinical examination (OSCE), a written examination, and a final comprehensive OSCE. Effectiveness of the course redesign was assessed by comparing student performance on assessments, overall course performance, and student perceptions extracted from the student course evaluation.

Results. Of the 364 students enrolled in the sterile compounding course across four terms, 156 were in the pre-implementation cohort (cohort 1) and 208 were in the post-implementation cohort (cohort 2). Two hundred twenty-eight students completed the course evaluation. Course evaluations significantly demonstrated students' improved perceptions related to seven of 11 survey elements, most notably, critical thinking, integration of concepts, and students feeling challenged. Student performance on laboratory summative assessments also improved. However, written examination scores did not change.

Conclusion. This novel sterile compounding course provided a practice-oriented blueprint for instruction and assessment of sterile compounding.

Keywords: sterile compounding, simulation, objective structured clinical examination, laboratory, assessment

INTRODUCTION

Sterile compounding courses are designed to provide pharmacy students with the education and skills necessary to prepare compounded sterile preparations (CSPs) using aseptic technique. The ability of pharmacists to properly prepare CSPs in an aseptic manner is of utmost importance to ensure patient safety. Additionally, pharmacists are expected to be the experts in other aspects of sterile compounding, including formula development, beyond use dating, and intravenous drug compatibility. With the proper integration of both aseptic technique and professional judgment exercises,

sterile compounding courses can improve the simulation and reality of pharmacy practice skills in this setting.

Pharmacy schools across the country must be intentional about the design and effect of sterile compounding courses in their curricula. As of 2019, 70% of Doctor of Pharmacy (PharmD) programs in the United States require students to be able to independently compound sterile preparations prior to starting advanced pharmacy practice experiences (APPEs), but only 20% of pharmacy schools offer a standalone course devoted to sterile compounding.^{1,2} To reinforce current United States Pharmacopeia (USP) standards pertaining to sterile compounding, most notably those contained within USP chapter <797>, the vast majority of instruction time is spent teaching and assessing aseptic technique, hand washing and garbing, and pharmaceutical calculations.²

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Proper training of future pharmacists is fundamentally important for the safety of patients. In 2012, poor compounding practices at the New England Compounding Center (NECC) resulted in an outbreak of fungal meningitis that infected over 753 people and resulted in 64 deaths across 20 states.^{3,4} Many state boards of pharmacy responded by developing new or more stringent rules and regulations for pharmacies and pharmacists compounding sterile preparations. In the state of Texas, board rules concerning sterile compounding were greatly expanded to include verbatim language from USP <797>, strict rules concerning in-process checks, more frequent inspections, and specific licensing requirements for pharmacies engaged in sterile compounding.⁵

Several studies have shown that failing to administer or repeat follow-up testing after pharmacy students complete a sterile compounding course can lead to a decline in students' ability to prepare sterile products using proper aseptic techniques.⁶⁻⁹ This is further complicated by the fact that not all students are provided hands-on sterile compounding practice during APPEs, with only 79% of practice sites allowing students to prepare sterile compounds.¹⁰ Considering this limitation, it may be necessary for colleges of pharmacy to expand and enhance sterile compounding coursework to ensure all students are competent in these skills before starting their APPEs.

At our institution, sterile compounding is a required course in the fall semester of the second professional (P2) year of a traditional four-year doctor of pharmacy professional program. The course is taught throughout a 16-week semester and includes 2.8 hours weekly of both didactic and laboratory components. Prior to the 2016-2017 academic year, the course roadmap was similar to that of other programs, focusing primarily on the development of technical skills, most notably aseptic technique.^{1,2} Student knowledge and skills were assessed using a laboratory practicum that evaluated aseptic technique and preparation accuracy, and administering a written examination. In spring 2016, the course team was changed to include the addition of a pharmacist and technician who had 25 years of combined experience in sterile compounding. Upon review, the existing course was found to focus exclusively on acquisition of technical skills and administrative knowledge. Consequently, there was minimal instruction in the knowledge and skills required by pharmacists practicing in sterile compound practice settings. Additionally, the course team recognized an opportunity to include immersive (eg, realistic and true-to-practice) simulation, which has been demonstrated to improve long-term retention of complex skills.¹¹ This prompted a course revision for the 2016-2017 academic year, the purpose of which was to provide

more instruction in pharmacist-specific activities, improve retention of skills through immersive simulation, and improve the student experience.

METHODS

Course changes were evaluated through a retrospective comparison of student performance, student feedback, and laboratory expenses incurred before and after the course revision. The course team compared data among two cohorts: cohort 1 included students enrolled in the course during the 2014-2015 and 2015-2016 academic years (prior to course revision), whereas cohort 2 included students enrolled in the course during the 2016-2017 and 2017-2018 academic years (after course revision). The numerous changes that comprised the course revision were categorized as either changes to instruction or changes to assessment. Changes to instruction included any changes to content delivered, teaching techniques, or course structure. Changes in assessment included any changes to formative or summative assessments including content assessed or assessment methods and modalities (ie, examinations, practicums, and simulations).

Following course revision, the course content for cohort 2 was broken into three modules: fundamental skills, rules, and knowledge; integration of skills, rules, and knowledge; and advanced and specialty areas. Fundamental skills were categorized as either technical or analytical. Technical skills included calculations, hand hygiene and garbing, and aseptic technique with vials, powders, and ampules. Analytical skills included evaluation and application of compatibility and stability data, determination of beyond-use date (BUD), synthesis of administration recommendations based upon compatibility, and parenteral access. Fundamental technical skills were taught primarily in the laboratory, whereas analytical skills were primarily taught during didactic sessions. Throughout the fundamental skills module, individual skills were taught one-at-a-time prior to integrating them into the entire sterile compounding process. For example, in the fundamental skills module, students practiced aseptic technique at their desktop, rather than in the laminar airflow hood; were not required to complete calculations; and were not required to select their own supplies or products until the integration module.

During the integration module, students worked in pairs throughout four laboratory sessions that simulated workflow within an actual sterile compounding pharmacy. Each activity was similar in structure, but involved preparation of different types of CSPs. One student assumed the role of the compounding technician while the other assumed the role of the pharmacist; then the students switched roles. For each simulation, the "technician"

partner performed hand hygiene, donned garb, cleaned the laminar flow hood, performed calculations while in the buffer room, and prepared two CSPs using the labels provided. As part of their immersive simulation, students were required to select the correct compounding ingredients from an inventory of over 50 different simulated drugs of varying concentrations and 10 different formulae of IV solutions. Upon completion, the “technician” partner presented their CSPs to their “pharmacist” partner for quality check and labeling. The “pharmacist” partner inspected integrity, verified accuracy, assigned a BUD, and labeled both CSPs. Laboratory instructors kept track of student errors, but allowed “pharmacist” partners the opportunity to catch compounding errors prior to intervening. “Pharmacist” partners were also given a case in which they applied and integrated their knowledge of IV compatibility and administration principles. At least three faculty members with training and experience in sterile compounding supervised students in the laboratory; this provided continuity and standardization of student experiences and assessments. If areas of variation were identified, course team huddles were conducted to reconcile instruction and messaging to student learners.

During the advanced and specialty modules, students were instructed in the preparation of parenteral nutrition solutions, prepackaging/batching of CSPs, preparation of hazardous CSPs in a vertical flow hood, and hazardous spill cleanup. For example, immersive simulation was used to provide instruction in hazardous drug preparation and hazardous spill cleanup. Students were provided with a simulated spill and a commercially available chemotherapy spill kit. Working in pairs and using information taught in a didactic session, one student searched for the material safety data sheet (MSDS) to discover any special exposure considerations, and then guided the other student on how to clean up the spill. Although detached from the rest of the course, the experience was another example of immersive simulation that was implemented in the revised course.

Because of the change in content delivery, there were significant changes to formative and summative assessments for cohort 2 (Table 1). Similar to most sterile compounding courses, the initial offering of the course used a written examination to assess the didactic elements of the course and a practicum to assess hand hygiene/garbing technique, aseptic technique, and compounding accuracy.¹ For cohort 2, three checkpoint assessments of fundamental skills were conducted, including a calculations examination, hand hygiene and garbing, and glove tip and media fill test. Successful integration of fundamental skills was assessed using a formative mock

objective structured clinical examination (OSCE) in the last laboratory session, followed by a summative final OSCE two weeks later. Two traditional written examinations were administered throughout the course to assess students’ retention of the didactic material.

The mock and final OSCE were identical in structure and delivery to minimize non-cognitive influencers on students’ performance on the final OSCE. However, different case scenarios and CSPs were used in each OSCE to ensure the accuracy of the assessment. Each OSCE consisted of five stations. Stations, as depicted in Figure 1, included: staging and instructions (station 1), hand hygiene and garbing (station 2), compounding of two CSPs (station 3), checking and labeling of one CSP (station 4), and providing an intravenous (IV) compatibility or administration recommendation to a nurse (station 5).

At station 1, students received instructions and gathered garbing supplies for the OSCE. At station 2, students were required to demonstrate proficiency in hand hygiene and garbing. At station 3, students prepared one low-risk level CSP and one medium-risk level CSP. Similar to the integrated laboratory sessions, students were provided with two labels and then required to select the correct compounding ingredients and complete all calculations prior to compounding. Upon completion, students exited the buffer room, turned in their CSPs, and removed all garb. At station 4, students were provided a previously prepared, standardized “CSP” that was ready to be checked and labeled. Students were allowed electronic access to two drug information databases and provided 20 auxiliary labels from which to choose. Prior to labeling the final CSP, students were expected to verify the accuracy of the CSP, determine the microbial contamination risk level, and interpret available compatibility data to assign the most appropriate BUD. At the final station, each student entered a room with a standardized “nurse” who posed a standardized and internally validated administration question to the student. After being provided access to two drug information databases, the student had to ask the nurse clarifying questions and correctly interpret the data provided to arrive at the correct response.

All graded OSCE elements were assessed in real-time by teams of health-system pharmacists and technicians with sterile compounding experience. Two graders assessed hand hygiene and garbing (station 2), eight graders assessed aseptic technique via hood cameras (station 3), one grader assessed accuracy and presentation of the student-compounded preparations (station 3), and one grader assessed labeling accuracy

Table 1. Instructional Roadmap for a Sterile Compounding Course in a Doctor of Pharmacy Program Before and After Course Revision

Cohort 1 (Before Revision)	Cohort 2 (After Revision)
Didactic Sessions	
Course Introduction	Introduction to Parenterals
Calculations (3 weeks)	Calculations (2 weeks)
Hand Washing, Garbing, Hood Cleaning	Calculation Exam
Aseptic Technique	Aseptic Technique and Primary Engineering Controls
Compatibility & Microbial Risk Levels	Parenteral Access
Facilities & Environment	Stability, Sterility, & Compatibility
Personnel Duties & Responsibilities	Application of Stability, Sterility & Compatibility
Quality Assurance	Written Exam 2
Hazardous Drugs	Parenteral Nutrition
Parenteral Nutrition	Hazardous Drugs
Final Written Exam	Quality Management
	Written Exam 3 (Final Written Exam)
Laboratory Sessions	
Laboratory Safety	Laboratory Safety
Calculations (3 weeks)	Calculations (2 weeks)
Hand Washing, Garbing, Hood Cleaning	Hand Washing, Garbing, Hood Cleaning
Aseptic Technique	Basic Vial Technique
Aseptic Technique	Basic Ampule & Powder Technique
Compounding Sterile Preparations	Mock OSCE
Compounding Sterile Preparations	Media Fill Test
Media Fill Test	Low-Risk CSP, Beyond Use Date, Labeling
Chemotherapy CSPs	Medium-Risk CSP, Beyond Use Date, Labeling
Parenteral Nutrition	Chemotherapy CSPs, Chemo Spill Kit
Final Practical	Medium Risk CSP, BUD, Compatibility
	Final OSCE

Abbreviations: CSP=compounded sterile preparation, BUD=beyond use date, OSCE=objective structured clinical examination

and pharmaceutical elegance of the standardized CSP (station 4). For station 5, health-system pharmacists served dual roles as both the grader and standardized “nurse”; these pharmacists assessed the students on communication skills, accuracy, and the practicality of their responses. Throughout the OSCE, course faculty members were available for graders’ questions and graders were provided with an internally validated rubric to ensure standardization and consistency in grading. For the final OSCE, students were required to complete every station with a minimum passing score of 75%. Students were allowed a single opportunity to remediate the station they failed at a later date.

After completion of each course and prior to the release of final grades, students completed a standardized questionnaire. This questionnaire, which was internally developed and validated for use in all courses at the university, consisted of 11 statements which students ranked using a five-point Likert scale (5=strongly agree, 4=agree, 3=neutral, 2=strongly disagree, and 1=disagree). In addition, students were allowed to provide open-ended comments. Completion of the course evaluation was voluntary

and incentives were not provided. Per university policy, student responses were de-identified and reported in aggregate.

The research protocol was designed by the authors and approved by the University of North Texas Institutional Review Board. To evaluate the impact of course changes on student competency, student performances were compared between the two cohorts on the following assessments: final written examination, hand hygiene and garbing practicum, and common elements between the pre-revision comprehensive practicum and post-revision OSCE. Furthermore, investigators compared course evaluations between cohorts to understand the impact of the course redesign on the student experience. Investigators also compared both cohorts in terms of laboratory expenses to evaluate the impact of course changes on direct student costs. Student performance on assessments, questionnaire responses, and laboratory expenses were collected using Excel. Means were calculated using Excel and all other statistical analyses were conducted in SPSS Statistics 24 (IBM, Armonk, NY). Two-sample *t*-tests were used to compare numerical data using an alpha of

Abbreviations: PEC=primary engineering control, CSP=compounded sterile preparation, BUD=beyond use date.

Figure 1. Roadmap for an Objective Structured Clinical Examination in Sterile Compounding

0.05. Open-ended comments from the student questionnaire were analyzed using thematic coding to cluster semantically similar statements.

RESULTS

Cohort 1 included 156 students and cohort 2 included 208 students. All of the students in both cohorts completed the required didactic and laboratory assessments. The majority of students completed the voluntary student course questionnaire (57% [89/156] of students from cohort 1 and 66% [139/208] of students from cohort 2).

As expected, there were changes in student performance after the course revision. Student performance on the hand hygiene and garbing practicum improved slightly, but grade variability as measured by standard deviation decreased by 81% ($p=.04$) (Table 2). While there were changes to the instruction of handwashing and garbing, no changes to the assessment tool were implemented for cohort 2. Additionally, mean student performance and variability on the final laboratory assessment (ie, practicum for cohort 1; OSCE for cohort 2) also improved ($p=.007$). However, the retrospective review did not detect any improvements in cohort 2's performance on the final written examination ($p=.45$).

Revisions made to the sterile compounding course reflected significant improvements in seven of 11 survey elements, most notably: student involvement and interaction were encouraged ($p=.04$), students felt challenged ($p=.03$), and students had the ability to analyze and critically evaluate ideas, materials, and/or concepts ($p=.004$). Students' perspective on all other elements

remained similar throughout all four terms (Table 3). Overall, results from the course evaluation questionnaire indicated that students' satisfaction increased when revisions to the course were implemented. In response to open-ended comments on the questionnaire, 36 and 39 participants in cohorts 1 and 2, respectively, provided elaboration on the positive and negative aspects of the course. The following were identified as strengths of the revised sterile compounding course: it was well-organized, the instructors provided timely and effective feedback, the students showed interest in and understanding of sterile compounding, and the students gained improved practical experience. Areas for improvement included standardization of teaching aseptic technique, a need for more open-laboratory practice time, and more individualized observations and feedback during laboratory sessions.

In terms of laboratory fees, enhancements to laboratory sessions resulted in an increase in total course expenditures of \$85.12 per student (Table 4). New expenses incurred for cohort 2 included: increased variety of syringes, simulated solutions, powders, ampules, intravenous solutions, mini-spikes, equipment to create vials, and materials for hazardous drug simulations.

DISCUSSION

Overall, revisions to this sterile compounding course provided students with an enhanced learning experience beyond traditional sterile compounding courses as evidenced by student course evaluations. However, there were several concerns with the addition of new content and competency areas, which the course team sought to

Table 2. Comparison of Doctor of Pharmacy Students' Performance in a Sterile Compounding Course Before and After Course Revision

Item	Cohort	N	Mean (SD)	p-value
Final written examination	1	156	81.0 (9.9)	.45
	2	208	81.8 (9.7)	
Hand washing practicum	1	156	97.0 (12.0)	.04
	2	208	99.0 (2.3)	
Final OSCE/practicum	1	156	90.6 (14.9)	.01
	2	208	94.0 (5.7)	
Final grade	1	156	96.0 (4.1)	<.001
	2	208	93.1 (4.5)	

^a Two-sample *t*-tests were used to determine significant differences between cohort 1 and cohort 2. Significance was defined as *p*<.05

mitigate for cohort 2. In particular, the course team wanted to ensure that there was no loss in core competencies, such as aseptic technique, and also wanted to ensure that the content volume was not excessive. To mitigate these concerns, investigators adjusted content and modified teaching methods. In terms of content, instruction time in areas pertaining to quality assurance, facilities, hazardous drugs, and parenteral nutrition was

reduced, thereby allowing the course team to allocate more time to activities that student pharmacists were likely to experience during APPEs or in practice (ie, conducting quality checks and addressing compatibility questions).

Skills and knowledge associated with sterile compounding are complex, with multiple interacting elements, and possess a high intrinsic cognitive load that

Table 3. Comparison of Pharmacy Students' Evaluation Survey Results in a Sterile Compounding Course Before and After Course Revision

Item	Cohort ^a	Rating ^b (SD)	p value
The content (subject matter) was organized in a way that facilitated my learning.	1	4.2 (0.8)	.12
	2	4.3 (0.8)	
The instructional design encouraged student involvement and interaction.	1	4.4 (0.7)	.15
	2	4.5 (0.6)	
The stated goals and objectives of this course were met.	1	4.3 (0.7)	.04
	2	4.5 (0.6)	
This course used appropriate instructional technologies to enhance my learning experience.	1	4.3 (0.7)	.68
	2	4.3 (0.8)	
The exams were representative of materials and objectives presented in the course.	1	3.9 (1.1)	<.001 ^c
	2	4.4 (0.7)	
This course challenged me to think and learn.	1	4.4 (0.7)	.04 ^c
	2	4.5 (0.6)	
Attending course activities facilitated my learning.	1	4.4 (0.7)	.06
	2	4.6 (0.5)	
This course advanced my ability to analyze and critically evaluate ideas materials and/or concepts.	1	4.2 (0.8)	.004 ^c
	2	4.5 (0.6)	
This course demonstrated the integration of key concepts of basic biomedical science.	1	4.2 (0.7)	<.001 ^c
	2	4.5 (0.6)	
Student involvement and interaction were encouraged in this course.	1	4.4 (0.7)	.04 ^c
	2	4.6 (0.6)	
The time allocated for this course was sufficient for me to learn and apply the assigned material.	1	4.1 (1.0)	.01 ^c
	2	4.4 (0.8)	

^a For cohort 1, N=89; for cohort 2, N=140. Not all students in cohort 2 responded to all items (n=138-140)

^b Course evaluation score ranges from 0 to 5

^c *p*<.05. Two-sample *t*-tests were used to determine significant differences between cohort 1 and cohort 2

Table 4. Comparison of Laboratory Expenses Incurred in a Sterile Compounding Course Before and After Course Revision

	Cost per Student	
	Cohort 1 (n=156)	Cohort 2 (n=208)
Supply Categories		
Garbing supplies	\$69.30	\$69.30
Hand washing and cleaning supplies	\$23.05	\$23.05
Syringes and needles	\$8.47	\$12.87
Simulated drugs	\$1.50	\$18.95
Vials and ampules	\$29.48	\$30.10
IV solutions	\$16.60	\$36.15
Media fill supplies	\$13.10	\$13.10
Other compounding supplies	\$5.50	\$6.35
Hazardous drug supplies	\$5.50	\$42.25
Total per student	\$167.00	\$252.12
Total per cohort	\$26,051.22	\$52,440.96

taxes students' working memory.¹² The limiting effects of cognitive load were minimized by providing partial instruction on performing challenging skills early in the course before integrating them later. By progressing content in this manner, the new course promoted students' long-term retention of core skills.¹² By contrast, professional judgment exercises (ie, compatibility, literature evaluation) were successfully taught using a whole task scaffolding model that allowed learners to gain competency through exposure to increasingly difficult cases with decreasing instructor guidance.¹³ Lastly, the addition of immersive simulation allowed for more experiential learning to occur, contributing to the observed performance improvements on summative laboratory assessments.^{11,14} The lack of change in written examination scores indicates that modifications made to instructional methods did not positively or negatively impact retention of didactic content. This is surprising, as it is well established that active and experiential learning experiences improve content retention.¹⁴

There are several important limitations to the study of this course revision. First, interpretation of the comparison of student performance on the final practicum (cohort 1) and the final OSCE (cohort 2) is challenging, and conclusions on this result are difficult to draw because the assessment methods varied. Also, the major changes in assessment may have made a valid comparison between cohorts impossible. Additionally, the focused use of formative assessment (eg, mock OSCE), which was purposefully designed to improve student performance by reducing the influence of non-cognitive factors, may be viewed as a confounder.¹⁵ Lastly, although the study was conducted across four academic years, applicability of results may be limited by the fact that it was conducted at a single institution.

In general, the transition of a traditional laboratory course to one that incorporates immersive simulation provides numerous benefits.¹¹ First, that team performance is adversely effected by poor understanding of other team members' roles is well established in the literature.¹¹ By allowing students to assume either a pharmacist or technician role in each simulation, students gain deeper understanding of the role each plays in ensuring the preparation of safe and accurate CSPs. Another potential beneficial change is the addition of compatibility and stability learning activities, which required students to interpret imperfect data and exercise professional judgment. The use of immersive simulation to train students in professional judgment can establish a foundation for students' future development of these skills during their APPEs. Finally, many high-risk, high-impact professions, including the military, airline industry, and healthcare have found immersive simulation to be beneficial in reducing errors and reinforcing a culture of safety.¹¹ Inclusion of simulated pharmacist checks, in which students checked CSPs prepared by their peers, allowed students to gain experience in identifying and rectifying compounding errors prior to APPEs, thereby allowing them to learn from their mistakes in a consequence-free environment.¹¹

There are several considerations that should be pondered before other programs implement similar changes. While cohort 2 responded positively to the revised course, course evaluation data and comments indicated that cohort 2 found the revised course more challenging than did cohort 1. This is likely because of an increase in complex assessments (eg, mock OSCE) and the addition of course content (eg, application of professional judgment). This hypothesis is supported by the majority of student comments related to the delivery and conduct of both laboratory and didactic assessments.

Furthermore, enhancements to simulation resulted in a direct cost increase to students in terms of supplies and an indirect cost increase in terms of instructor time. Despite increases in direct and indirect costs, student performance and feedback support that these additional expenses added value to the student experience.

Current literature indicates that students require additional instruction in sterile compounding during APPEs. As such, colleges of pharmacy should reevaluate how content in sterile compounding is taught and assessed.⁶⁻¹⁰ Sterile compounding course teams should consider reducing instructional time spent on administrative topics in favor of more pharmacist-specific activities. Such changes may also promote learning in the areas of problem-solving and professional judgment. However, when implementing such changes, course teams should be aware of additional associated costs.

CONCLUSION

This revision of a traditional sterile compounding course to include instruction in pharmacist-specific roles and the use of immersive simulation, resulted in improved student satisfaction and practical performance, despite an increase in rigor. The revised course described here provides a practice-oriented blueprint for instruction and assessment of sterile compounding. Future directions for research should focus on evaluating the impact that similar courses have on APPE performance and practice readiness as it pertains to sterile compounding.

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