INSTRUCTIONAL DESIGN AND ASSESSMENT

Design Considerations of a Compounded Sterile Preparations Course

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Objective. To design a comprehensive learning and assessment environment for the practical application of compounded sterile preparations using a constructivist approach.

Design. Compounded Sterile Preparations Laboratory is a required 1-credit course that builds upon the themes of training aseptic technique typically used in health system settings and threads application of concepts from other courses in the curriculum. Students used critical-thinking skills to devise appropriate strategies to compound sterile preparations.

Assessment. Aseptic technique skills were assessed with objective, structured, checklist-based rubrics. Most students successfully completed practical assessments using appropriate technique (mean assessment grade = 83.2%). Almost all students passed the practical media fill (98%) and gloved fingertip sampling (86%) tests on the first attempt; all passed on the second attempt.

Conclusion. Employing a constructivist scaffold approach to teaching proper hygiene and aseptic technique prepared students to pass media fill and gloved fingertip tests and to perform well on practical compounding assessments.

Keywords: compounded sterile preparations, laboratory, assessment

INTRODUCTION

It is critical to educate all pharmacists and regulators about appropriate compounding of sterile preparations (CSP) to prevent incidents in which contaminated sterile preparations cause the deaths of otherwise healthy recipients. The Accreditation Council for Pharmacy Education (ACPE), the American Association of Colleges of Pharmacy, and the National Association of Boards of Pharmacy have all promulgated competency statements related to CSP for pharmacy education, though none of these statements address the methodology for CSP instruction in the classroom or the cleanroom.

In modern health care systems, compounding pharmacies meet special patient care needs. However, while the role of compounding pharmacies continues to expand, the fundamental teaching of compounding has decreased. Reports show the utility of simulation in compounding education, but pharmacists require hands-on training to be competent in aseptic technique.

Previous surveys of schools and colleges of pharmacy report the frequency and depth of compounded sterile preparation education. Hellmus et al found that all respondent schools included some type of instruction on CSPs. Despite this promising response, only 70% (n=37) required students to compound on their own (rather than in groups or not at all), and only 21% (n=11) offered a standalone course on this topic. The majority of responding schools (88%) taught students about United States Pharmacopeia (USP) standards for sterile compounding (Chapter 797). It should be noted, however, that their study was conducted soon after USP 797 was published. Most schools at that point would only have been in the process of addressing the chapter. The current state of how USP 797 is covered in curricula is unknown.

The 2007 ACPE Accreditation Standards detailed the learning objectives for instruction regarding sterile admixture techniques, USP 797, stability and sterility testing, clean room requirements, and infusion devices and catheters. The 2016 Standards, however, only provide learning outcomes.

Extracting the detailed components of sterile preparations from the previous ACPE Standards 2007 and using them in combination with current ACPE Standards 2016 is necessary to develop an effective curriculum for pharmacy students. Furthermore, USP Chapter 800, which at the time of writing was under review, promulgates hazardous drug handling changes that will impact not only health-system pharmacy but community practitioners as well. Schools of pharmacy should anticipate the need to incorporate the latest handling procedures into their curriculum.

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While components of compounded sterile preparations education are reported in the literature, including grading rubrics, improvements in media fill test pass rates, the impact of prior experience on learning outcomes, and the importance of repeated testing to improve skills, no study has fully described the design considerations of such a course. A successfully designed course would be of value to the academic community as only 13% of schools of pharmacy (n=7) reported that they felt confident their students had adequate training in compounding sterile preparations prior to graduation. Additionally, few hospitals allow students to practice compounding in practice experiences.

Changing demands of the field may require schools of pharmacy to provide students with better opportunities to learn and practice aseptic techniques. Specialty pharmacy is a growing industry focused on high cost injectable and infused formulations. The scope of pharmacy practice continues to evolve throughout the country. Moreover, the paradigm shift of CSP oversight from the traditional health-system pharmacist to nontraditional expanded roles in specialty pharmacy necessitates the education of future pharmacists in CSP. To that end, this paper addresses design considerations of a comprehensive learning and assessment environment for the practical application of compounded sterile preparations.

DESIGN

Compounded Sterile Preparations Laboratory is a required 1-credit course with three contact hours per week; one hour of prelaboratory lecture and instruction followed by two hours of hands-on application. The instructors sought to make the laboratory practical, efficient, and cost-effective. The most pertinent design considerations were logistics, cost, student assessments, and time with “needle in hand.”

The prelaboratory sessions presented new material and demonstrations of the CSP for the week. They were developed using a constructivist approach, which allowed students to create new knowledge by building on the previous sessions’ concepts. Instructors provided the framework for success and expected students to apply that basic knowledge in the laboratory. While the constructivist approach was appropriate for teaching course concepts, a structured approach was more appropriate for the technical aspects of compounding sterile preparations. However, the constructivist philosophy still applied in the sense that students may have required modification of hand washing and aseptic technique based on hand size and manual dexterity. Therefore, students had to figure out what worked for them while maintaining the integrity of the process.

For the structured approach to this course, checklists similar to Objective Structured Assessment of Technical Skills used in surgical education and were designed and used for each of the assignments. Surgical checklists reduce morbidity and mortality by ensuring that important steps are not missed in the surgical procedure. The authors posited that this theory was transferrable to compounded sterile preparation education and that checklists would allow students to accurately perform required tasks. The checklist included each required step for the activity (Table 1). These activities can be transferrable to other schools looking to employ a checklist for teaching compounding sterile preparations. The checklist provides more specific feedback to students performing the assessment compared to published

<table>
<thead>
<tr>
<th>Upon Arrival:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arrives properly groomed</td>
</tr>
<tr>
<td>Has no rashes, weeping sores, sunburn, conjunctivitis, or respiratory infection</td>
</tr>
<tr>
<td>Long hair is pulled back or up in a bun</td>
</tr>
<tr>
<td>Beard/facial hair is neat and trimmed</td>
</tr>
<tr>
<td>No visible piercings</td>
</tr>
<tr>
<td>Wears no makeup</td>
</tr>
<tr>
<td>Wears no nail polish or artificial nails</td>
</tr>
<tr>
<td>Natural nails neat and trim</td>
</tr>
<tr>
<td>Wears clean, nonshedding clothing</td>
</tr>
<tr>
<td>Wears closed-toe shoes</td>
</tr>
<tr>
<td>Not chewing gum, eating, or drinking</td>
</tr>
<tr>
<td>Removes all jewelry and watches</td>
</tr>
</tbody>
</table>

The following must be done in order:

- Dons shoe covers properly – lifting off the sticky mat and placing on the floor – shoe covers should not touch sticky mat at any time until learner exits
- Dons hair cover/bouffant; hair does not stick out of the bouffant
- Dons beard cover if applicable
- Dons mask – blue side out
- Properly contours mask to face
- Ties mask appropriately – mouth not visible from side, no gaps or pockets
- Washes hands; see separate handwashing checklist
- Dons gown
- Washes hands with Avagard

Gloving

- Touches only the fold
- Does not cross over sterile area or let gown touch sterile area
- Pinches cuff with one hand
- Tips glove point downward
- Scoops remaining glove with gloved hand
- Tips of glove point downward
- Scoops glove over cuff of gown
- Rinses gloves with sterile 70% isopropyl alcohol
rubrics. Instructors can adapt this and assign percentages to checklist items as they see fit.

Compounded sterile preparation education in the workplace is typically conducted one-on-one. Incorporating the positive aspects of one-on-one education with the logistics of student enrollment numbers, laboratory space, and cost present the greatest challenges when designing this type of course. Seventy-five students were enrolled in the laboratory and were divided into three sections of 25 students. Based on hood space and logistics of observing students, each section of 25 was again divided into three groupings, forming a total of 9 groups with 8-10 students per group. Final groups were encouraged to select a team name and work as a cohesive unit. Based on these subdivisions, a minimum of three faculty members were required to run each session. The three groups in each 2-hour session rotated among the three faculty members, each of whom facilitated a 40-minute activity (see Table 2 for course outline). Each week, students spent one 40-minute session in the IV room, which required a full gown and garb and was supervised by the primary instructor. The other two sessions focused on technique necessary for the IV room session and/or topics applicable to CSPs.

Four overarching themes predicated the course design: (1) providing experiences similar to training in a health-system setting; (2) simulating USP 797 standard operating procedures; (3) threading other curricular competencies such as pharmaceutics and pharmacy calculations; and (4) scaffolding course material (see Table 3 for specific course objectives). The sequence of the course was similar to that of aseptic technique taught in a health-system setting. Before any compounding took place, students had to demonstrate the ability to appropriately wash hands, gown, garb, and clean and disinfect primary engineering controls (eg, laminar airflow hoods). The laboratory adopted the WHO 7-step hand washing technique. Online resources to help reinforce the WHO 7-step method were made available to students as supplementary material.

The contents of USP 797 can be distilled into three distinct parts: environment, personnel, and equipment. While aseptic technique and the preparation of CSPs are important and have been the traditional focus, preparation for practice requires an understanding of these components. For example, weekly quality assurance checks, such as temperature and simulated pressure differential monitoring in the clean room area familiarized students with some of the regulatory compliance issues. Values outside of normal

<table>
<thead>
<tr>
<th>Week</th>
<th>Lecture Topic</th>
<th>IV Room</th>
<th>Session 1</th>
<th>Session 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Orientation</td>
<td>Garbing</td>
<td>Hand Washing</td>
<td>Surgical Scrub</td>
</tr>
<tr>
<td>2</td>
<td>Personal Hygiene</td>
<td>Hood Cleaning</td>
<td>Hand Washing/Surgical Scrub</td>
<td>Garbing</td>
</tr>
<tr>
<td>3</td>
<td>Hood Anatomy and Cleaning</td>
<td>Basic Syringe technique</td>
<td>IV Catheters</td>
<td>Stability (“Trissels” and King)</td>
</tr>
<tr>
<td>4</td>
<td>Expiration Dating and Labeling Requirements</td>
<td>Hand Washing, Surgical Scrub, Gloved Fingertip Assessment, and Hood cleaning</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Admixture, Working in a Hood, Syringes and Needles</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>USP 797</td>
<td>LVP/SVP</td>
<td>USP 797</td>
<td>Video Technique Review</td>
</tr>
<tr>
<td>7</td>
<td>Stability and Compatibility</td>
<td>LVP/SVP</td>
<td>Administering IV</td>
<td>NIOSH/OSHA</td>
</tr>
<tr>
<td>8</td>
<td>Mid-term Examination</td>
<td>Sterility Testing and Media Fill Assessment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Pediatrics and Preservatives</td>
<td>Pedi Dilutions</td>
<td>IV Errors</td>
<td>Patient Controlled Analgesia</td>
</tr>
<tr>
<td>10</td>
<td>Ophthalmic Preparations</td>
<td>Ophthalmic Preparation</td>
<td>Isotonicity</td>
<td>Video Technique Review</td>
</tr>
<tr>
<td>11</td>
<td>Parenteral Nutrition</td>
<td>TPN</td>
<td>Osmolarity</td>
<td>Rate Calculations</td>
</tr>
<tr>
<td>12</td>
<td>Home Infusion</td>
<td></td>
<td>Product Preparation Assessment</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>Work Practices Regarding Hazardous Drugs</td>
<td>Chemo Practice</td>
<td>Chemo Regimen Prep</td>
<td>HazMat Introduction</td>
</tr>
<tr>
<td>14</td>
<td>Hazardous Drug Disposal and First Aid</td>
<td>Chemo Regimen Prep</td>
<td>HazMat Spill</td>
<td>Video Technique Review</td>
</tr>
<tr>
<td>15</td>
<td>Chemotherapy</td>
<td></td>
<td>Chemotherapy Assessment</td>
<td></td>
</tr>
</tbody>
</table>

IV=intravenous; LVP=large volume parenteral; SVP=small volume parenteral; NIOSH=National Institute of Occupational Safety and Health; OSHA=Occupational Safety and Health Administration; TPN=total parenteral nutrition; Pedi=pediatrics; USP=United Stated Pharmacopelia; HazMat=hazardous materials
After taking this course, the learner should be able to:

1. Demonstrate the proper procedures and techniques required for aseptically compounding sterile preparations.
2. Prepare proper documentation and labeling of products.
3. Identify potential sources of medication errors.
4. Analyze methods to prevent contamination of sterile product preparations.
5. Describe principles of quality assurance in sterile compounding within United States Pharmacopeia Chapter 797.
6. Compare the relationship of dosage form to stability, storage, compatibility, and handling procedures.

Table 3. Learning Objectives for the Compounded Sterile Preparations Course

The laboratory syllabus included strict language requiring adherence to USP 797 guidelines for attire. Similar to an actual compounding set-up, any learner arriving not in adherence to the attire policy would not be allowed into the laboratory.

The laboratory provided the opportunity to thread the application of concepts learned in other courses such as pharmacy calculations and drug information. For example, students calculated nutritional requirements and subsequently compounded a total parenteral nutrition bag. Students investigated the compatibility of compounds and used critical-thinking skills in interpreting that information.

Hand washing and garbing served as the foundation for scaffolding aseptic technique and theory throughout the semester. For each assessment, expectations were built on this foundation and increased as the semester progressed (see nested hand washing assessment in the second column of Table 1). For example, for one to succeed in the sterility testing assessment, the student first needed to demonstrate the ability to wash hands and gown, don gloves, and clean the primary engineering control before they would be able to start the sterility testing assessment.

EVALUATION AND ASSESSMENT

The laboratory evaluation was comprised of four practical assessments, one midterm examination, one final examination, weekly quizzes, and participation points. The assessments were designed so the class would have at least two guided practice sessions before being assessed on a competency.

In addition to instructor feedback on technique, some of the 40-minute laboratory sessions were devoted to students filming their technique with the college’s laptop video program and personal smart phones. The students could then compare their technique and process with the rubrics. The rubrics were similar to the ones published by Brown in 2006; however, they were augmented with step-by-step checklists for appropriate aseptic technique. Per USP 797 requirements, a media fill sterility test and a gloved fingertip test constituted the second assessment. In practice, passing three of each is required to prepare CSPs; however, for time and financial reasons, students completed one of each. We used tryptic soy broth media for the sterility test and tryptic soy agar for the gloved fingertip test. A remediation was provided for students whose preparations yielded any microbial growth. Media fill test pass rates at the midpoint of this course were similar to those in previous studies that measured contamination rates at the end of course (Table 5). In theory, this indicated an earlier proficiency and allowed for students to spend more time perfecting their aseptic technique. All unsuccessful students passed the media fill and gloved fingertip test on remediation (Table 5: media fill remediation cohort 1: n=2; cohort 2: n=1/gloved fingertip remediation cohort 1: n=8; cohort 2: n=13).

Subsequent practical assessments included a practical preparation of a large (cohort 1) or small (cohort 2) volume parenteral product as well as a chemotherapeutic regimen (see Table 2 for description of assessments). The use of standardized rubrics and checklists allowed faculty members to identify thematic issues with knowledge or technique and address as needed. For example, instructors were able to identify that 10 students in cohort 2 were inappropriately spraying sterile isopropyl alcohol toward the HEPA filter during the first assessment. Instructors were able to redirect students prior to the next session, resulting in correct alcohol spraying in the subsequent assessment. Grades for each of the practical assessments are presented in Table 4. Most students performed well, and the average assessment grade was usually a B (80%) or better.

DISCUSSION

This course design provides a framework for other schools of pharmacy looking to rework or add a CSP laboratory. Material cost is a factor for institutions designing similar laboratories. Although tryptic soy broth and agar are major costs, performing at least one media fill and gloved fingertip test provides students with a realistic experience. Instructors may want to budget for extra tryptic soy products for remediation, as well as calcium and phosphate containing products to demonstrate what a precipitate looks like.

There are a number of pearls that pharmacy schools can take away from our experience creating this course. During the initial offering, instructors provided fresh
The tenets of aseptic technique do not change, but the execution is different. The course was designed so weekly assignments and participation points would be easily attainable. However, from the student perspective, this proved to be difficult. The course was offered during the same semester that students started their therapeutic classes. The juxtaposition of a CSP laboratory with therapeutics did not bode well for perceptions of the course. Students thought it was too much work for a 1-credit class, and many questioned its utility in the curriculum. The dress code was wildly unpopular. However, the instructors felt strongly that in a professional setting, students should be able to adhere to simple standards relevant to compounded sterile preparations.

Future directions of the course include incorporating an electronic medical record (EMR) for hi-fidelity simulation of order processing. In the absence of an EMR, students could be assigned a preparation when entering the cleanroom to better simulate receiving an order in a hospital. Additionally, the authors plan to incorporate hood-mounted cameras to assist with grading and feedback.

**SUMMARY**

Employing a constructivist scaffold approach to teaching proper hygiene and aseptic technique prepared students to pass media fill and gloved fingertip tests and to perform well on practical compounding assessments. While the creation of a standalone CSP course is a challenging undertaking for any school of pharmacy, the effort better prepares students for future practice. Students completed the CSP laboratory with an understanding of the details of USP 797 so they could monitor environment, personnel, and equipment in an IV room. Such a course ensures student success in a compounding setting and prepares new pharmacists to minimize contamination risks.
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REFERENCES


