

INSTRUCTIONAL DESIGN AND ASSESSMENT

Development and Implementation of a Scoring Rubric for Aseptic Technique

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Objective. To assess students' development of aseptic technique skills through the use of a scoring rubric.

Design. A scoring rubric was developed to assess students in 6 skill areas of parenteral preparation. Areas were assessed as "likely harmful," "needs improvement," or "acceptable" according to developed criteria. Students were assessed at baseline and at the end of the fall and spring semesters.

Assessment. Of 624 ratings given to 104 students at baseline and at the end of the spring semester, respectively, 51.1% and 88.9% were "acceptable," 17.9% and 7.6% were "needs improvement," and 30.9% and 3.5% were "likely harmful" ($p < 0.001$ vs baseline). The percentage of students receiving one or more likely harmful ratings decreased from 85.6% at baseline to 18.3% ($p < 0.001$).

Conclusion. Use of the rubric successfully documented student improvement. It also identified areas that need additional emphasis in the curriculum.

Keywords: aseptic technique, rubric, United States Pharmacopeia, parenteral preparation, assessment

INTRODUCTION

Aseptic technique and the compounding of sterile preparations have received much attention in the profession of pharmacy since the January 2004 release of Chapter 797 in the United States Pharmacopeia (USP).¹ Various works have been published describing the influence of Chapter 797 on the preparation of sterile products in practice settings.²⁻¹⁰ USP Chapter 797 has also heightened the attention paid to teaching and assessing sterile product preparation in the Pharmaceutical Care Learning Center, our College's practice skills teaching laboratory.

There are many components to the adequate training of students in the broad scope of USP Chapter 797, including maintenance of the preparation environment, personal preparation and garb, the product manipulation process, and quality assurance processes. While our Learning Center provides education on all of these areas, since the release of USP Chapter 797, special attention has been paid to the development of personal preparation and product preparation skills.

Other tools have previously been developed and implemented to assess sterile product preparation technique. The American Society of Health-Systems Pharmacists (ASHP) has developed and published a 3-page

template for the assessment of aseptic technique knowledge and skills.¹¹ This document, although helpful to many institutions, did not provide an optimal evaluation tool for our Learning Center's educational needs because (1) it relied simply on rating grouped skills as "yes" (possess skill) or "no" (does not possess skill), (2) it was too long for efficient formative and summative feedback of multiple students in a short period of time, and (3) it provided no clear areas for qualitative feedback or comments. Consequently, an aseptic technique scoring rubric was developed and incorporated into students' aseptic preparation assessment. The purpose of this manuscript is to describe the improvement in students' performance over an academic year as measured by the scoring rubric. It also highlights areas that the rubric identified as being particularly challenging for students.

DESIGN

The Pharmaceutical Care Learning Center's curriculum consisted of a 5-semester sequence designed to build students' pharmacy practice skills. Students enrolled in the second year of the Learning Center's sequence rotated through blocks of activities focused on nonsterile compounding, sterile compounding, and patient care. With some minor variations, students participated in 1 parenteral-focused session, 1 non-sterile compounding-focused session, and 2 clinical-focused sessions every 4 weeks. The parenteral-focused activities and the respective

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Table 1. Parenteral Activities and Prepared Products

Block*	Activity Focus	Products	Comments
1	Febrile Neutropenia	1. Syringe (subcutaneous) 2. Small volume parenteral (SVP)	Baseline technique evaluation
2	Review of Technique and Expiration Dating	3. SVP	1-on-1 practice session
3	Cytotoxic Agents and Adjuvant Therapy	4. SVP 5. Syringe (IV push)	"Cytotoxic agent" is actually methylene blue
4	Lab practical	6. SVP	End-of-Fall semester technique evaluation
5	Compatibility and Stability 1	7. SVP 8. Syringe (intramuscular)	Purposefully incompatible products made to demonstrate presence/ absence of visual clues to incompatibility
6	Compatibility and Stability 2	9. SVP	Focus on photosensitivity
7	Technique practice session	Variable – students' choice (both syringe and SVP prescriptions available)	Required for students receiving "Likely harmful" rating on Block 4 technique, optional for others
8	Lab practical	10. Syringe (intramuscular or intravenous push) 11. SVP	End-of-Spring semester technique evaluation

*Blocks 1-4 were in Fall semester, 5-8 were in Spring. All 104 students rotated through the activity in each block (group sizes 6-10). Block lengths ranged from 2 to 4 weeks as necessary to fit in Learning Center's overall schedule

parenteral products are summarized in Table 1. When possible, the topics of these parenteral activities coincided with topics covered in the College's *Pharmacotherapy* course series. They also focused on further development of drug delivery, compatibility, and stability issues covered in the students' previous year of traditional classroom preparation. Throughout the year, students engaged in learning activities that addressed broad issues related to the preparation, administration, and clinical management of parenteral medications. Within these activities, students prepared a total of 11 parenteral products – 7 small volume parenterals and 4 syringe preparations.

An aseptic technique scoring rubric (Table 2) was developed to evaluate parenteral technique. The rubric measured 6 skill development components: (1) personal preparation, (2) disinfecting the hood, (3) manipulation of vials, ampules, and syringes, (4) working in airflow, (5) inspecting the product, and (6) disposal of materials. A student's performance for each of these 6 components was rated as "likely harmful" or "acceptable." Two of the 6 components, manipulation and airflow, also include a possible rating of "needs improvement." The rubric included descriptions of techniques that corresponded to each rating to assist evaluators in assigning scores. For each student's activity, the overall rating was summarized as S+ (all acceptable ratings), S ("Satisfactory" – no

likely harmful ratings but at least 1 needs improvement rating), or S- (1 or more likely harmful ratings). This method of assigning scores was used rather than numeric ratings to avoid correlating an arbitrary number to skills critical to the provision of safe patient care. For all but the baseline assessments, individual ratings influenced the students' final grades. Students were given a copy of the rubric at the beginning of the year. In addition, the rubric was available to students on the course web site.

Pharmacy practice residents, graduate students, and third- or fourth-professional year PharmD students served as evaluators. Evaluators were trained to use the rubric as part of a 1½-hour live, hands-on training session that reviewed proper and improper technique. Further review of the rubric was done throughout the year at subsequent training sessions just prior to the start of the next activity. Evaluators formally scored students with the rubric on 3 occasions: a baseline assessment and at the end of the 2 semesters during semester-ending assessments (Table 1). Students were asked to work with a partner during the other 5 course activities, scoring each other's aseptic technique using the same rubric. Students' peer ratings were immediately returned to their peer as formative feedback and did not influence students' activity or course grades. The evaluators' ratings were recorded and then returned to each student so they could learn from their ratings and comments.

Table 2. Aseptic Technique Scoring Rubric

Component	Ratings		
	Likely Harmful	Needs Improvement	Acceptable
Personal preparation	Jewelry not removed OR hands washed for less than 30 seconds OR germicidal soap is not used OR faucet is turned off without using toweling OR gloves not donned	N/A	Jewelry removed AND hands washed for at least 30 seconds with germicidal soap AND handles of faucet turned off with toweling AND gloves donned
Disinfecting hood	Hood not wiped with isopropyl alcohol and sterile 4x4s OR hood wiped in a manner that does not move from cleanest area to dirtiest area OR some area of hood missed during process	N/A	Hood wiped with isopropyl alcohol and sterile 4x4s from cleanest to dirtiest area without missing any area
Manipulation of materials	Access points on vials and bags are not properly swabbed prior to entry OR access point on vial or bag is touched after swabbing OR shaft of needle is touched OR filter needle is not used with ampule OR dose is drawn from vial before dissolution complete	Hub of needle is touched OR shaft of plunger is touched OR needle is capped without use of scooping technique	All access points are properly swabbed, critical areas (needle shaft and hub, plunger shaft, and access points) are not touched, filter needles are used with ampules, and needle is capped using scoop technique
Working in airflow	Airflow from HEPA filter across access points or needle is routinely blocked (student blocks airflow and does not quickly correct) OR manipulations occur within first 6 inches of hood	Airflow from HEPA filter across access points or needle is rarely but occasionally blocked (student blocks airflow but quickly corrects)	Airflow from HEPA filter across access points and needle is never blocked
Inspecting product	Product is not deliberately agitated for complete mixing and then inspected	N/A	Product is deliberately agitated for complete mixing and then inspected for particulate matter and discoloration
Disposal of materials	Needle is placed in non-sharps container	N/A	Needle is placed in sharps container

The primary educational goal of parenteral technique training was to avoid likely harmful ratings and maximize acceptable ratings. The primary educational outcome was the improvement in performance between each student's baseline and end-of-spring semester technique assessment. Secondary educational outcome measures were the change in performance from baseline to end of fall semester, the change in performance from end of fall to end of spring semester, the change in number of likely harmful ratings on activities, and the types and frequencies of technique errors. Outcomes comparing overall technique were analyzed using the McNemar test for paired categorical data. Change in number of likely harmful ratings were analyzed with the paired *t* test. Other data were analyzed with descriptive statistics.

ASSESSMENT

One hundred four students completed both the fall and spring semesters of the second-professional year and were included in the analyses. Figures 1, 2, and 3 show the percent of students receiving acceptable, needs improvement, and likely harmful ratings for each component on the baseline and end-of-semester assessments. The number of students receiving acceptable ratings on all 6 components of the assessment increased from 1 student (0.96%) at baseline to 43 (41.3%) on the end-of-fall assessment and 51 (49%) on the end-of-spring assessment ($p < 0.001$ baseline vs both end-of-semester assessments, $p = 0.35$ fall vs spring). The number of students receiving one or more likely harmful ratings decreased from 89 (85.6%) at baseline to 26 (25%) on the end-of-fall assessment and 19 (18.3%) on the end-of-spring assessment

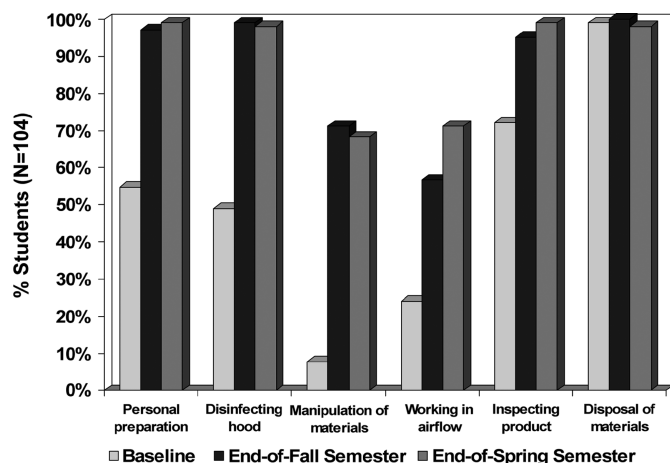


Figure 1. Percent of students receiving acceptable ratings at baseline and end-of-semester aseptic technique assessments.

($p < 0.001$ baseline vs both end of semester assessments, $p = 0.337$ fall vs spring). Of the 19 students receiving one or more likely harmful ratings on the end-of-spring assessment, all had received at least 1 likely harmful rating at baseline and 3 had received 1 or more likely harmful ratings on the fall assessment.

Of the 624 total ratings per activity, the number of total likely harmful ratings decreased from 193 (30.9%) at baseline to 29 (4.6%) on the end-of-fall assessment and 22 (3.5%) on the end-of-spring assessment. The mean number of likely harmful ratings per student decreased from 1.9 at baseline to 0.2 on the end-of-spring semester assessment ($p < 0.001$). When just considering the 89 students at baseline and the 19 students on the end-of-spring semester assessment who received 1 or more likely harmful ratings, the mean number of likely harmful ratings per student fell from 2.2 at baseline to 1.2 when assessed at the end of spring semester ($p < 0.001$), suggesting that students improved even when they continued to receive at least 1 likely harmful rating. By the end of spring semester, only the components “manipulation of materials” and “working in airflow” received more than 2 likely harmful ratings among all 104 students.

Table 3 summarizes the most frequent errors for each assessed activity. At baseline all components had areas that proved to be problematic for students, but in the end-of-semester assessments, airflow and manipulation were the only components that still presented challenges.

Figure 4 shows the number of students who received at least 1 likely harmful rating on a given component, followed by the number of students who repeated any error for the same component resulting in a second likely harmful rating. Only 1 student made a likely harmful error on the component, “Disposal,” prior to the assessment at the end of the spring semester; unfortunately the student

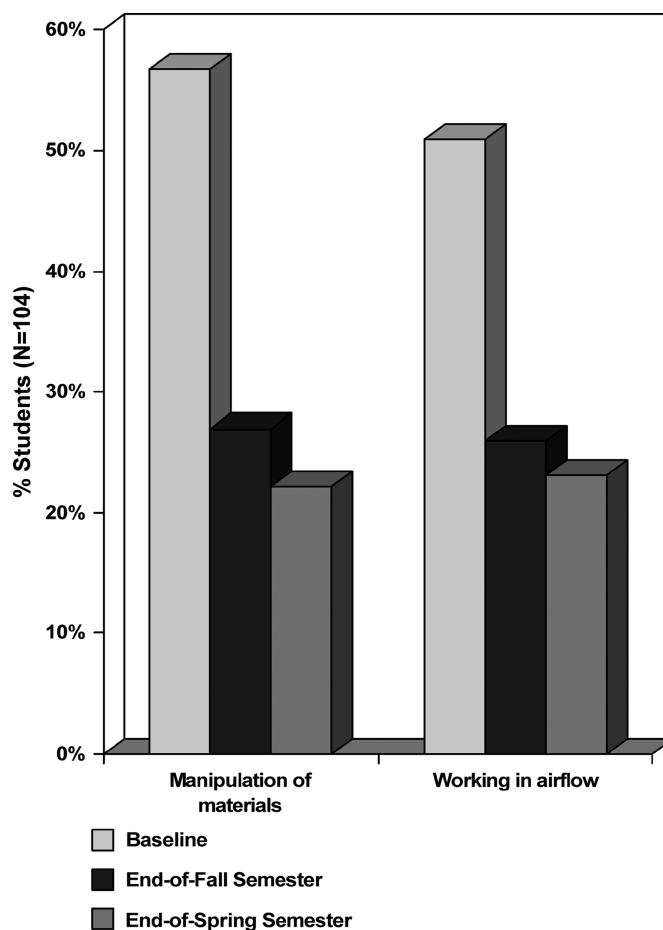


Figure 2. Percent students receiving needs improvement ratings at baseline and end-of semester aseptic technique evaluations. Note: Needs Improvement ratings were only options for the Manipulation of Materials and the Working in Airflow components. Other components could only be rated as Likely Harmful or Acceptable. See Table 1 for details.

repeated the same error on the final assessment. About one third of students received a second likely harmful rating on the “Airflow” component of the assessment at the end of the spring semester. For the other 4 components, more than 89% of students avoided repeating the same likely harmful error.

DISCUSSION

Chapter 797 focuses both on the environment in which products are prepared and the techniques employed by preparers of aseptic products.¹ While learning about the management of the “environment” is likely more practically accomplished during students’ experiential education, aseptic technique is commonly introduced prior to the experiential component of a college of pharmacy’s curriculum.

Before the development and implementation of this scoring rubric, we questioned the degree to which

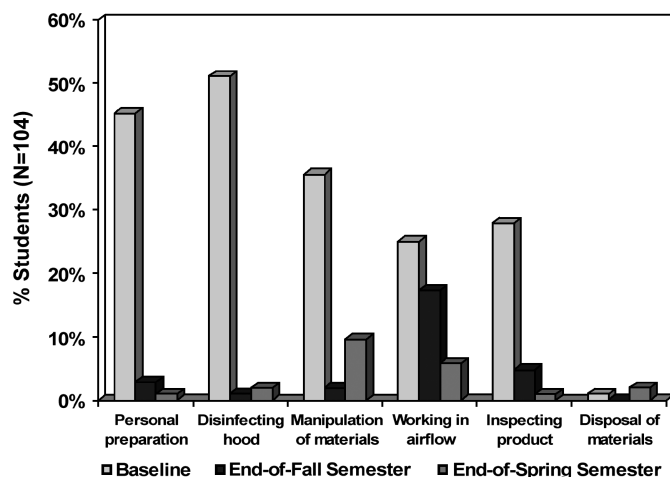


Figure 3. Learning from harmful errors.

students were achieving desired outcomes related to sterile product preparation. Students were engaging in several learning activities that were focused on sterile product preparation skill development; however, we found it challenging to quantify the degree to which improvement was occurring among students. We could observe that, generally, students' skills were improving, but we did not know whether students were mastering all areas of product preparation or whether they were learning from mistakes made early in their skill development. Moreover, we could not identify class-wide challenges that might guide instructional improvement efforts.

The development and implementation of the rubric successfully addressed these challenges. It has given us the ability to longitudinally track student performance in 6 different areas that contribute to optimal patient care. With its implementation, we have documented student

improvement in aseptic technique throughout a course and their ability to learn from the feedback delivered through this tool. At the same time, we have learned that students continue to struggle with some of the skill areas (most notably, considerations with airflow and manipulation).

One of the strengths of the scoring rubric is that the evaluation "scores" utilize a taxonomy that is based on professional standards. Rather than attempting to convert abilities to an arbitrary number, it maintains evaluative terminology (such as "likely harmful") that correlates with patient outcomes. As a result, when students receive feedback, they can clearly link the nature of their performance with expectations set for practitioners.

The implementation of the scoring rubric posed unique challenges. The real-time technique assessment activities required an increase in staffing from 1 to 2 evaluators per 8 students per session. One could imagine minimizing the number of evaluators needed through the use of video capture technology, although the cost of this technology could be prohibitive, particularly if it was retrofitted into instructional hoods. However, such technology could also allow for (1) self-assessment, (2) improved peer assessment, and (3) multiple evaluators to examine inter-rater reliability, and may be pursued in the future for these reasons. The use of additional teaching assistants also increased the amount of coordination required for consistent instructor training. In the future, Web-based training modules may increase training efficiency.

This single year of the rubric's implementation has identified areas requiring attention. Although students' improvement in performance was positive, there are

Table 3. Most Common Harmful Errors Detected by a Scoring Rubric for Aseptic Technique (N =104)

Component	LH Error	Frequency (%)
Baseline		
Personal prep	Did not dry from fingertips to elbow	46 (44.2)
Disinfecting hood	Wiped surfaces in incorrect order	46 (44.2)
Inspection	Product not thoroughly inspected during/after preparation	28 (26.9)
Manipulation	Touched sterile vial top, needle, or other critical areas	24 (23.1)
Airflow	Hand routinely blocked airflow across needle/access point	21 (20.2)
Disinfecting hood	Wiped in-and-out, not cleanest-to-dirtiest	17 (16.3)
Fall Practical		
Airflow	Hand routinely blocked airflow across needle/access point	9 (8.7)
Airflow	Swabbed bag port not facing airflow	8 (7.7)
Airflow	Worked over sterile materials, risking "fallout" contamination	6 (5.8)
Spring Practical		
Manipulation	Used exposed (non-sterile) luer-tip cap	10 (9.6)
Airflow	Materials in hood blocked airflow to critical/sterile area	3 (2.9)

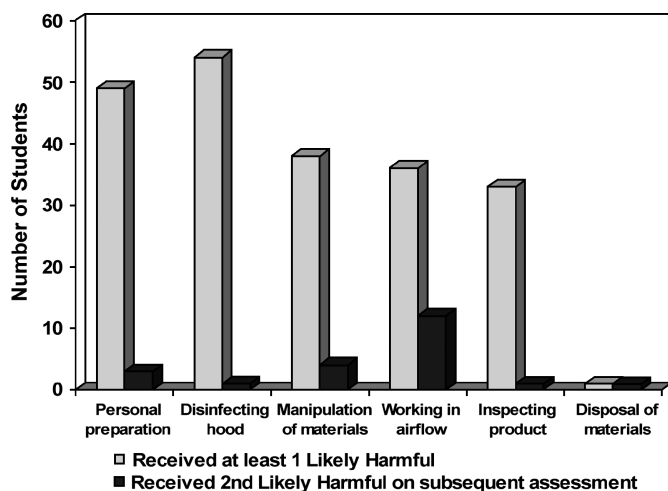


Figure 4. Learning from harmful errors.

several areas that continued to challenge students; most notably, manipulation and airflow considerations. Future educational offerings will target these areas to try to improve students' performance and minimize the number of repeat errors for these components. Informal discussions with students suggested that the implementation of the rubric was well received. However, formal survey of students' perspectives did not occur, and this should be investigated in the future as well. USP 797 continues to evolve. At the time of this publication, revisions to USP 797 were proposed that likely will dictate changes to the criteria used in the scoring rubric (ie, acceptable, needs improvement, and likely harmful).

Much of the work pharmacists do in practice in the areas of sterile product preparation involves supervising pharmacy personnel. While the focus of our instructional activities will continue to be students' technique, further work preparing students for this supervisory role is warranted. The rubric has been used in peer evaluations but the results have not been captured or evaluated systematically. Such efforts would help build students' abilities to detect suboptimal technique, providing an educational experience that better represents the scope of pharmacists' responsibilities in this practice area.

As experiential sites work to fully integrate Chapter 797 requirements, it is possible that fewer sites will provide students actual product preparation opportunities in their early or advanced pharmacy practice experiences. This trend has begun to some degree in our region; eg, some sites have been reluctant to invest hours training and certifying a student for 1 month or less of product preparation opportunities. Liability issues have further compounded the situation. As a result, colleges and schools of pharmacy need to work diligently to ensure students have adequate parenteral product preparation education

and feedback, including assessment methods such as the rubric described here. This needs to occur both within the pharmacy practice experiences and in prepractice experiences. The assessment tool may also be of utility to experiential education host sites.

CONCLUSION

The aseptic technique scoring rubric provided an objective, quantitative assessment tool for instructors to use when fostering the development of students' aseptic technique. It also provided a mechanism to archive student performance and allow for identification of the most challenging areas. Future work in this area will continue to investigate methods of minimizing potentially harmful errors and repeated errors.

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