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INSTRUCTIONAL DESIGN AND ASSESSMENT

Parenterals Laboratory Course to Reduce Microbial Contamination Rates in Media Fill Tests Performed by Pharmacy Students

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Objectives. To evaluate microbial contamination rates of low- and medium-risk level media fill tests performed by pharmacy students near the beginning and end of a parenterals laboratory course in the second- professional year of a doctor of pharmacy (PharmD) program.

Methods. Students enrolled in a required parenterals laboratory class (N = 84) participated in this study. The aseptic technique procedures performed at the beginning of the course were identical to the procedures performed at the end of the course and included 3 low-risk level media-fill tests and a medium-risk level media-fill test. Single-strength trypticase-soy broth (TSB) was substituted for the drug and was used to detect microbial contamination for all manipulations.

Results. The baseline and end-of-course contamination rate was 21 of 504 syringes and 0 of 498 syringes, respectively ($p < 0.001$). Eighteen of 84 students at baseline and 0 of 83 students near the end of the course produced one or more contaminated syringes ($p < 0.001$). Of the 21 contaminated syringes at baseline, low-risk manipulations accounted for 14 and medium-risk manipulations accounted for 7. Of the low-risk procedures, the ampule produced the highest contamination rate (11 syringes), followed by the vial (2 syringes) and the reconstitution (1 syringe).

Conclusions. This study demonstrated a decreased rate of microbial contamination during the manipulation of parenteral products and a corresponding improvement in aseptic technique skills among pharmacy students enrolled in a parenterals laboratory course. The most sensitive tests for poor aseptic technique and bacterial contamination were medium-risk manipulations and low-risk manipulations involving an ampule.

Keywords: media fill tests, microbial contamination, USP Chapter 797, sterile products, aseptic technique, parenteral products

INTRODUCTION

The Parenterals Laboratory course teaching team at the Texas Tech University Health Sciences Center (TTUHSC) School of Pharmacy proposed a residency project designed to foster a data-driven assessment of the aseptic technique skills of second-professional year pharmacy students performing low- and medium-risk media-fill tests near the beginning and end of the parenterals course.

The importance of proper aseptic technique while manipulating parenteral products has been demonstrated in multiple studies conducted in the practice setting.[2-4] In one such study, contamination rates were compared between pharmacists and technicians. Each investigator prepared medium-risk intravenous (IV) admixtures according to United States Pharmacopeia (USP) chapter 797 guidelines in both a traditional practice site and a class 1000 cleanroom. TSB was substituted for the drug and the diluent and was used to detect contamination. Contamination rates did not significantly differ between the cleanroom and the traditional practice site ($p = 1.0$). There was, however, a significant difference in contamination rates, with pharmacists performing better than technician ($p = 0.012$). This emphasizes that the most important variable affecting contamination rates of sterile preparations was the aseptic technique of the investigator rather than the environment.[2]

A second study looked at bacterial contamination rates of an infusate in a simulation model of syringes prepared for continuous intravenous administration by nurses in the intensive care unit (ICU) compared with syringes prepared by pharmacy technicians working under standard aseptic conditions. [3] A difference in the rate

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of contamination was detected between syringes prepared from vials and syringes prepared from ampules, and in the rate of contamination between syringes prepared from ampules by ICU nurses and those prepared by pharmacy technicians ($p < 0.001$ for each, respectively). The syringes prepared from ampules by the ICU nurses had a median contamination rate of 22% while those prepared by pharmacy technicians had a median contamination rate of only 1%. Again, this study proves that contamination rates are often a reflection of the complexity of the compounding procedure, the quality of the environment, and the skill of the preparer.

Trissel and colleagues reported the results of aseptic technique tests performed by pharmacists and technicians over a 2-year period.[4] These medium risk level procedures included reconstitution of a dry growth medium; withdrawals of the growth medium from vials and ampules using syringes, needles, dispensing pins, and filter straws; and transfer of the growth medium into empty plastic intravenous bags. Technicians who routinely prepared sterile products exhibited a slightly higher rate of contamination compared to pharmacists (6.2% vs. 4.4%, respectively). The authors of this article concluded that the contamination rate was unacceptable. Bacterial contamination was attributed to inadvertent touch contamination while performing complex aseptic manipulations.

The goal of our study was to develop a skill assessment that measured the attainment of aseptic technique competency by second-professional year pharmacy students. This study was an evaluation of teaching effectiveness as it related to student mastery of specific skills (sterile manipulation of parenteral products). This study provided a summative assessment and subsequent feedback regarding mastery of these skills. Furthermore, this information can be used as a tool to improve instructional design. To our knowledge, this study would be the first to evaluate the aseptic technique skills of pharmacy students while performing media-fill tests in an academic laboratory setting. Furthermore, the initial aseptic technique test at the beginning of the course is a unique component of this study which enabled a baseline skill assessment from which progress could be measured.

DESIGN

The Parenterals Laboratory course is a 16-week, 1 semester credit-hour course offered in the fall semester of the second-professional year. This course was added to the TTUHSC School of Pharmacy curriculum in 2001 based upon pharmacy employer and preceptor feedback and in order for graduates to meet the Texas State Board of Pharmacy requirements for intravenous (IV) certification.

The process of teaching aseptic technique skills in this course involves one 50-minute lecture session and one 2-hour laboratory session each week. Students participate in 14 didactic pre-laboratory lectures and laboratory sessions that cover the following subjects: safe handling of sharps and hazardous materials, aseptic preparation of parenteral products, laminar flow hoods, barrier controls, computer orientation, handwashing technique and laminar flow hood cleaning, pharmaceutical calculations, parenteral incompatibilities, low risk-level manipulations and single volume transfers, medium risk-level manipulations and dilutions, sterile powder reconstitution, infusion pumps/IV sets/IV ports, total parenteral nutrition (TPN) and TPN calculations, chemotherapy, application of regulatory issues, medication administration, and the aseptic technique skills tests. Each student in each laboratory session interprets, fills, calculates, and compounds 2 or 3 parenteral prescriptions. Students rotate through the cleanroom and prepare one of the prescriptions in the laminar flow hood each week. In addition, a midterm examination is conducted whereby student aseptic technique procedures are assessed by a faculty member through direct observation using a standardized checklist. The midterm consists of filling a parenteral prescription using the laboratory pharmacy operating system, compounding the prescription in a laminar flow hood, and properly labeling the prescription. Neither the laminar hoods nor the cleanroom in the parenterals course had been certified to meet USP 797 standards.

This study was approved by the TTUHSC Institutional Review Board. Students enrolled in a parenterals laboratory course ($N = 84$) performed an aseptic technique test near the beginning and at the end of this course. The procedures used for the 2 aseptic technique tests were identical and included 3 low-risk level media fill tests and 1 medium-risk level media fill test. All of the materials and devices used were sterile upon purchase and had not passed their expiration dates at the time of use. All procedures were performed at individual laboratory stations rather than in laminar flow hoods. The only instruction provided prior to the baseline assessment was focused on student laboratory safety. This instruction included TTUHSC laboratory safety procedures, proper handling and disposal of sharps, and personal protective equipment. Students in the parenterals course were not provided the opportunity to learn aseptic technique skills in either the classroom or laboratory setting before the baseline assessment. Students were provided powder-free vinyl gloves, a non-shedding disposable gown, protective eyewear, a bottle of 70% isopropyl alcohol, and 70% isopropyl alcohol pads for both the baseline and final assessments.

The low-risk level media fill test procedures included transfer of Valiteq TSB growth medium solution from a 10-ml vial to a 20-ml syringe; reconstitution of Valiteq tripticase-soy powder in a 20-ml vial with sterile water, and subsequent transfer from vial to a 20-ml syringe; and transfer of Valiteq TSB growth medium solution from a 10-ml ampule with a filter needle to a 20-ml syringe. The medium-risk level media fill test procedure involved multiple transfers of Valiteq TSB growth medium solution from vial to vial, via syringe and needle, and a final transfer of growth medium solution from vials to three 10 ml syringes in a manner consistent with USP Chapter 797 regulations.[5]

Each student produced 3 syringe products reflecting low-risk level manipulations and 3 syringes reflecting medium-risk level manipulations in each of the 2 separate aseptic technique tests. These syringes were sealed with sterile syringe caps, incubated at 25° C to 35° C for 14 days, and then evaluated for the presence of microbial contamination (solution turbidity). The presence or absence of microbial contamination for each product was recorded on a data collection sheet. All activities were supervised by faculty members.

All student data were de-identified and transferred from the data collection sheet into an electronic statistical database, SPSS Release 11.5 (SPSS Inc., Chicago, Illinois), by the primary investigator. Basic descriptive statistics including means, standard deviations, and percentages were produced. Inferential statistical tests involving nominal outcome variables were performed with the chi-square test.

ASSESSMENT

Eighty-four students (100% of class enrollment) in the *Parenterals Laboratory* course participated in the study. The average age of these students was 26 years and their age ranged from 19 to 55 years. Female students represented the majority of the class (56%). Before entering the *Parenterals Laboratory* course, 11% (9/84) of the students were IV certified technicians.

One student withdrew from the course, leaving only 83 students at the end of the semester who participated in the final aseptic technique examination. Therefore, the baseline assessment included 504 quarantined syringes and the final assessment included 498 quarantined syringes. Table 1 presents the contamination rate of syringes at baseline versus the end of the course. The overall contamination rate at the baseline assessment was 4.2% (21/504 syringes) versus 0 (0/498 syringes) at the final assessment ($p < 0.001$). The contamination rate was significantly lower at the final assessment for ampule and medium-risk manipulations ($p < 0.001$ and 0.015, respectively). The majority of contaminated syringes at baseline (14/21) resulted from low-risk manipulations.

Table 1. Syringe Contamination Rates Obtained by Second-Year Pharmacy Students at Baseline Versus Those Obtained at the End of a Parenterals Laboratory Course (N = 84)

Procedure	Baseline	End of Course[a]	*P*
Vial	2/84	0/83	0.497
Ampule	11/84	0/83	<0.001
Reconstitution	1/84	0/83	0.497
Medium-risk	7/252	0/249	0.015
Risk level totals			
Low-risk	14/252	0/249	<0.001
Medium-risk	7/252	0/249	0.015
Total combined	21/504	0/498	<0.001

[a]One student withdrew from the course

As shown in Table 2, significantly fewer students produced 1 or more contaminated syringes at the final assessment (0/83) versus the baseline assessment (18/84), $p < 0.001$. Of the 9 students who were IV certified technicians, none produced a contaminated syringe during either the baseline or final assessment. Eighteen of 75 students (24%) without IV certification produced a contaminated syringe at baseline.

DISCUSSION

To our knowledge, this was the first study to evaluate and report microbial contamination rates of aseptic technique tests performed by pharmacy students in an academic laboratory setting. When coupled with direct observation and evaluation of parenteral compounding procedures, the aseptic technique test described in this study provides a tool for assessing student competency with low- and medium-risk level parenteral manipulations. The aseptic technique test at the beginning of the

Table 2. Second-Year Pharmacy Students Who Produced One Or More Contaminated Syringes at Baseline and at the End of a Parenterals Laboratory Course (N = 84)

Category	Baseline Contamination Ratios	End of Course Contamination Ratios[a]	*P*
All students	18 of 84	0 of 83	<0.001
IV certified technicians	0 of 9	0 of 9	NS
Non-IV certified technicians	18 of 75	0 of 74	<0.001

Abbreviations: NS = not significant

[a]One student withdrew from the course

course enabled a baseline assessment of student skills. Nearly one fourth of the students without IV certification failed the baseline assessment by producing 1 or more contaminated syringes. Therefore, significant and potentially dangerous deficits in parenteral compounding skills were demonstrated in the baseline assessment. The significant improvement in aseptic technique demonstrated by the lack of microbial contamination at the final assessment provides an objective and measurable validation of the parenterals laboratory course design and instruction methods.

Faculty observation at the baseline assessment revealed frequent errors in aseptic technique that included lack of disinfection of the work surface, gloves, and critical sites, as well as inadvertent touching of critical sites. Based upon these observations and the fact that the same laboratory environment was used for both the baseline and final assessments, bacterial contamination was most likely the result of touch contamination. However, the cause of bacterial contamination could have been better determined by quantifying the observed technique errors at both the baseline and final assessments and then comparing these observations with the rate of product contamination. Identification of the bacterial organism in the contaminated syringes would have further helped to detect the source of the contamination.

The rate of contamination with the ampule to syringe manipulation exceeded that of the other low-risk parenteral compounding procedures. This observation was expected since the critical site of an ampule presents a larger surface area than vial to syringe manipulations. Surprisingly, aseptic technique tests involving the ampule were associated with a higher rate of contamination than medium-risk manipulations. This finding may suggest that the medium-risk procedure used in this study may have lacked sufficient sensitivity to detect all instances of poor aseptic technique. A more challenging method as described by Trissel and colleagues may be a better procedure for medium-risk aseptic technique assessment.[4]

A major limitation of this study is that the academic laboratory setting at the TTUHSC School of Pharmacy is not USP 797 compliant. For example, all manipulations in this study were performed in an unmonitored air quality environment. Therefore, the external validity of this study as it applies to pharmacies that provide parenteral compounding services is restricted. Despite this limitation, the assessment results at the end of this laboratory course are an important outcome to document in a student academic portfolio before the student begins experiential courses that involve parenteral compounding. Future plans include the requirement of this aseptic technique test with an opportunity for remediation if necessary during the final assessment in the *Parenterals Laboratory* course. The TTUHSC School of Pharmacy will also consider adding this aseptic technique test to the annual student assessment as described in previous publications.[6,7] This skill assessment could also be embedded in the required hospital experiential course. This would allow the aseptic technique test to be conducted in a USP 797 compliant cleanroom setting and for an evaluation of skill retention.

CONCLUSIONS

Improved aseptic technique as evidenced by a reduced rate of microbial contamination was demonstrated by pharmacy students upon completion of a 1-semester credit hour *Parenterals Laboratory* course. A significant difference in the rate of contamination from baseline to the end of the course was observed for ampule and medium-risk manipulations. However, vial and reconstitution manipulations had lower rates of contamination at baseline and were less sensitive tests for determining poor aseptic technique and bacterial contamination. The results of this study validate this assessment method as a tool for ensuring aseptic technique competency among pharmacy students.

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