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INSTRUCTIONAL DESIGN AND ASSESSMENT

A Virtual Clean Room to Teach USP 797 Regulations for Intravenous Medications

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Objective. To provide a virtual environment for pharmacy students to learn *United States Pharmacopeia* Chapter 797 (USP 797) requirements, while recognizing the role of pharmacists in the safe use of intravenous (IV) medications.

Design. A virtual laboratory was created that included stations for IV medications, product verification, medication safety, and patient cases pertaining to high-alert medications. Pharmacy students used 3-D glasses and a wireless controller to navigate through the session and identify violations of USP 797 regulations.

Assessment. Preassessments and postassessments were administered to students who completed the session in each of the 2 years it was offered. In the first year, 88% of students strongly agreed or agreed that the sessions met their expectation. Following their APPE clerkship, 92% of these students felt the virtual IV room prepared them for the IV clean room experience. In the second year, 88% of students felt the experience enhanced their understanding of clean room procedures. After session completion, 75% of participants perceived medication errors to be more significant. Written examinations also were administered and students' mean scores improved significantly compared to those of students' prior to implementation of the session (89.6% in year 0; 91.2% in year 1; and 96.1% in year 2).

Conclusion. The immersive virtual environment is a contemporary and effective way to teach USP 797 requirements and enhance the awareness of medication errors.

Keywords: virtual clean room, virtual learning, USP 797, sterile products, simulation, intravenous products

INTRODUCTION

Since the publication in 2000 of the Institutes of Medicine report "To Err is Human: Building a Safer Health System," medication safety awareness has increased.[1] Pharmacists serve a vital role in ensuring that the correct patient receives the correct medication as often only 1 step separates the pharmacist's verification of the product and administration of the medication to the patient. Pharmacists involved in sterile compounding have an error rate of approximately 10%.[2,3] Therefore, providing pharmacy trainees with adequate instruction to prevent medication errors is critical, including hands-on training within an IV room setting,[4] which is not always feasible for pharmacy students before they embark on APPEs.

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Although the use of virtual reality is not common for teaching pharmacy concepts, its use in health care is not new. Surgeons have demonstrated that using virtual reality in training residents can improve operating room performance significantly, resulting in fewer errors and injuries.[5,6] In April 2004, a Food and Drug Administration (FDA) panel voted to accept a proposal that virtual reality should be an important part of the training for carotid stenting.[6] Virtual reality is also being used to train nonpharmacy personnel in the virtual platform Pulse!! (Texas A&M University/United States Navy, Corpus Christi, TX) developed to help train and educate military health care providers prior to the occurrence of a catastrophic event.[7]

Due to the significance of patient safety, this virtual pharmacy laboratory focused on aseptic procedures and USP 797 regulations to cultivate student confidence in preparing IV medications appropriately. This session fostered the use of best practices and advancement of pharmacy education within an IV room environment.

To develop this session, specific curricular goals were set to evaluate the fundamental understanding of IV room procedures based on the Accreditation Council for Pharmacy Education (ACPE) Standard 11, Guideline 11.4, which states, "... development of innovative program pathways, courses, or teaching methods should be based on sound educational principles or the best evidence in educational practice. The college or school must evaluate the effectiveness of its curricular innovations through its assessment activities."[8]

DESIGN

The curriculum at Purdue University's College of Pharmacy includes a 2-credit hour Parenteral Products course for PY3 students in the doctor of pharmacy (PharmD) program. The virtual laboratory described here is an additional voluntary session that meets outside of scheduled class time. The overall Parenteral Products course remains unchanged, with students completing the established hands-on laboratory sessions throughout the course in which they are required to perform an IV dilution with multiple steps to assess sterile technique, dilution and transfer from a single vial, and filtration following the opening of a glass ampule.

The training for aseptic procedures and USP 797 regulations occurs in a 2-credit hour, 1-semester course taught predominantly in a classroom setting. Student feedback has reflected satisfaction with the instructional course; however, they felt uncomfortable performing appropriate IV room procedures. Because many students have no experience working in an IV room prior to their APPEs, they lack practical experience and do not understand the importance of USP 797 regulations for optimizing patient safety, along with other concepts, such as what is considered appropriate IV room attire.

The goal of the virtual session was to help students feel comfortable and confident with the layout and special procedures associated with a clean room environment. This type of learning environment allowed for an enjoyable, interactive exercise similar to playing a video game. The learning objectives for the first offering of the session stated that by the conclusion, students should be able to:

- List the proper attire for the IV room. (Knowledge)
- Apply USP 797 standards for an IV room to evaluate a virtual IV room. (Application)
- Evaluate a product preparation for accuracy. (Evaluation)
- Select the appropriate product for IV preparation. (Evaluation)
- Generate a recommendation for IV fluids based on the provided patient case information. (Synthesis)

For the second offering, objectives remained the same with the last objective changed to:

- Produce a final recommendation for the preparation and administration of an IV product that is safe and accurate, based on an assigned medication problem. (Synthesis)

Creation of the Virtual Laboratory

The virtual IV laboratory required approximately 2 years for development and implementation with collaboration among senior computer technology and pharmacy students. Three computer technology and 2 pharmacy students worked for approximately 1 year to design the layout, which was researched by visiting various Indiana hospital sites and merging aspects of each IV room to create the final virtual IV room. Medications were incorporated into the environment based on digital pictures of available IV products. The virtual IV room environment was a multi-wall immersive environment which worked on wall-sized panels as well as a portable display system, such as a computer. The equipment included 3-D glasses and a wireless controller that students used to navigate throughout the virtual IV room. In addition, to portray a more realistic virtual environment, a head-tracking device adjusted the view of the students, allowing the image on the wall-sized panels to change based on the direction that he or she was facing. The tracker also permitted detailed viewing, even allowing students to see information printed on a small medication vial. The complexity of the 3-D technology was similar to that of a television screen; however, due to the faster rate of shuttering, the glasses worn by the students allowed for a 3-dimensional image to appear. The virtual IV room set the foundation for the sessions. To ensure that key concepts were retained during the session and to refine students' knowledge, 3 other stations were developed for use during the first offering. These stations included product verification, medication safety, and patient cases pertaining to high-alert medications. Overall, the virtual IV room and the 3 stations covered important learning concepts necessary for confident hospital pharmacists.

Virtual Laboratory Sessions

First Offering. For the first offering of the virtual IV laboratory in 2009, students were assigned to 1 of 10 sessions, with approximately 20 students assigned to each session, and subgroups of 5 students each, allowing small group interaction, discussion, and application of instructional material. To complete the session, a minimum of 4 instructors was needed (1 for each of the following stations: virtual IV room, product verification, medication safety, and patient cases). The session required the use of a virtual technology room and an additional classroom. A

variety of standard IV room materials were used including: clean room attire, syringes, IV fluid bags, IV stock solutions, labels, and medication vials. Additionally, patient cases relating to high-risk medications were created.

To create a realistic IV room experience, the students were required to dress in appropriate IV room attire. To follow appropriate aseptic technique, the students were instructed to dress in the following order: shoe covers, hair cover, gown, face mask, and gloves. Students were not able to wash their hands during this process, but were instructed when and how hand washing should occur. The rationale regarding the importance of appropriate order and technique for dressing also was presented, helping the students to understand the value of these procedures. Once the students were dressed appropriately, they were ready to enter the virtual IV room.

For the first offering, the laboratory was conducted over a 1-hour 50-minute session, beginning with a preassessment to collect general student demographics relating to experience within an IV room setting. This test also evaluated the students' knowledge on pharmaceutical mathematics, general therapeutics, and drug information. The session ended with a postassessment to evaluate the same information gathered in the preassessment, with the addition of questions relating to student expectations and comments about the laboratory session.

The students participating in the first offering of the laboratory were split into 4 groups of approximately 5 students each. Each group remained in the virtual theatre for approximately 20 minutes, where each student spent 5 minutes navigating through the virtual IV room. Throughout the anteroom, chemotherapy preparation room, and clean room were items for students to identify, similar to a scavenger hunt (Table 1). Each student identified 1 item per room, not to be repeated by a subsequent student within the group.

To reinforce key learning concepts pertaining to an IV room and hospital pharmacy, all groups in the first offering were required to visit each of the following stations for approximately 20 minutes:

Product Verification. All students were asked to evaluate 1 of 4 IV preparations. Each preparation had a label, syringe(s), medication vial(s) and stock solution(s) for the checking process. After the students reviewed the preparations for accuracy, based on the prepared label and products, the instructor discussed requirements for the label as well as the necessary steps to check a product.

Medication Safety. Students were given labels and required to pick the necessary products for preparation from a shelf. In addition, the students were expected to identify the proper expiration date of each product. The labels contained look-alike/sound-alike medication names or an unapproved abbreviation. Once the students picked the medication, the instructor discussed the Joint Commission requirements for use of standard concentrations and other methods to decrease risk of error.

Patient Cases with High-Alert Medications. Four patient cases were provided to students. The first case asked students to locate IV compatibility information using various online drug resources. The remaining cases involved patients with electrolyte abnormalities requiring replacement with high-alert medications. Students were asked to provide recommendations for IV bag concentrations and infusion rates. Emphasis was placed on fluids that should never be run alone, and on safety issues of these high-alert medications.

Second Offering. During the second offering of the virtual IV laboratory, students were assigned to 1 of 20 sessions, with the option of attending a different session, if desired. Approximately 8 students were assigned to each session to allow for small group interaction, discussion, and application of instructional material. To complete the session, a minimum of 2 instructors was needed. The session required the use of a virtual technology room and clean room attire.

Based on feedback received from the students who completed the first offering of the session and the additional functionality built into the virtual environment, the session was modified to focus more directly on medication safety within the virtual environment. For the second offering, the laboratory was conducted over a 1-hour session, beginning with a preassessment to collect student opinions regarding the role of pharmacists and medication errors. The session ended with a postassessment to evaluate the same information, with the addition of questions relating to

Table 1. Virtual IV Room Scavenger Hunt Items

Anteroom	Chemotherapy Room	Clean Room
Trissel's Handbook	Spill on floor	Drink in refrigerator
Advantage bags	Vancomycin bottle in hood	Overflowing sharps container
Linezolid vial	Cigarette in hood	Cardboard boxes
Large volume IV fluid (lactated ringers or dextrose 5% in 0.45% normal saline)	Syringe laying by edge of hood	Stock bottle blocking syringe in hood

the virtual clean room experience and comments about the laboratory session. Because the laboratory session activities changed from the first offering to the second, the pre- and postassessment evaluations were modified to reflect the changes. The knowledge assessed during the first offering was not reassessed during the second offering due to the shift in focus towards medication errors.

Students who participated in the first offering of the session indicated that more time in the virtual environment was desired. Therefore, for the second offering, problems were developed that allowed the students to simulate IV product preparation within the virtual clean room, instead of using the 3 non-virtual clean room stations from the first offering. Students remained in the virtual theatre for the entire hour-long session, with each student given the chance to navigate through the virtual IV room. Each student was asked to identify an inappropriate item within the environment (Table 1). These items remained the same as in the first offering of the laboratory. After identifying at least 1 inappropriate item, the students navigated into the clean room where they were instructed to select the appropriate medication vial and diluents to prepare the product from their preassigned question (Table 2). Following feedback from the students participating in week 1, some of the products were modified to present higher risk preparations. Once in the clean room, students were faced with 2 sets of shelving that contained medication vials and diluents. Students were instructed to select the appropriate vial and diluent by using a joystick to hover over the item they had wanted to use. A verbal explanation of how the IV product was to be prepared and administered also was required from the students. After the complete explanation was presented, the instructor provided verbal feedback about the appropriateness of the selections and whether patient harm may have occurred as a result.

Table 2. Virtual IV Room Pre-assigned Questions

Week 1: How would you prepare the following orders? If not appropriately ordered, what would need to be changed to be correct?
IV insulin 100 units/100 mL, titrate to appropriate response
Potassium chloride 20 mEq/ 100 mL IV, infuse over 15 minutes, to be given via peripheral line
Heparin 25,000 units/ 500 mL, infuse over 1 hour
A 90 kg patient requires a dose of gentamicin 3 mg/kg/day (in 50 mL), dosed every 8 hours
Norepinephrine 16 mg/ 500 mL IV, titrate to appropriate response, to be given via central line
Amiodarone 150 mg/ 100 mL IV bolus, infuse over 10 minutes
Diltiazem 125 mg/ 125 mL, titrate to appropriate response
Methylprednisolone 500 mg/ 250 mL IV
Week 2: How would you prepare the following orders? If not appropriately ordered, what would need to be changed to be correct?
IV insulin 100 units/100 mL D5W, infuse over 1 hour
Potassium chloride 20 mEq/ 100 mL IV, infuse over 15 minutes
Heparin 25,000 units/ 100 mL, titrate to appropriate response
A 90 kg patient requires a dose of gentamicin 3 mg/kg/day IV (in 50 mL), dosed every 8 hours
Vinblastine 10 mg, to be given intrathecally
Cisatricurium 300 mg QS 300 mL, titrate to appropriate response
Diltiazem 125 mg/ 100 mL, titrate to appropriate response
Methylprednisolone 500 mg/ 250 mL IV

EVALUATION AND ASSESSMENT

Our assessment was approved as exempt by the Institutional Review Board.

Preassessment

For the first offering, the virtual IV room experience was centered on 2 learning objectives, knowledge of and application of aseptic procedures and USP 797 regulations. To assess the students' baseline knowledge, the instructors distributed a preassessment which included demographic questions, such as, "Have you ever been in an IV room?" and "Do you currently or have you worked in a hospital? If yes, for how long?" In addition, the preassessment included technical questions, such as "What type of IV hoods have you worked with?" "What are the 5 items required to be worn before entering the clean room?" and "How many inches inside the hood does a syringe need to be in order to follow aseptic technique?" For general pharmacy knowledge applicable to the IV room, the preassessment included pharmaceutical mathematics, general therapeutics, and drug information questions. The students were allowed approximately 20 minutes to complete the preassessment.

The experience for the second offering remained focused on the 2 learning objectives from the first offering, with additional emphasis on medication errors. The preassessment took approximately 5 minutes to complete and included 3 items using a Likert scale that ranged from strongly disagree to strongly agree. No experience-related demographic information was collected. The items assessed were: (1) Medication errors can significantly impact patient outcomes; (2) The likelihood of a highly skilled pharmacist making an error is low; (3) My potential for making a medication error upon entering practice is low.

Postassessment

The postassessment included the same questions as the preassessment, with the addition of 3 questions to evaluate student perceptions of the laboratory session. For the first offering of the laboratory, these questions asked, "Did the virtual IV room meet my expectations?" and "Why or why not?" Two open-ended questions included, "What did you like most about this lab session?" and "What did you like least about this lab session?" For the second offering of the laboratory, the additional items were: "I perceive medication errors to be more significant after completing this lab; My experience in the virtual clean room has enhanced my understanding of clean room procedures; The problem assigned for this lab reinforced my understanding of order processing within the clean room setting." These questions were rated based on the Likert scale, allowing both qualitative and quantitative measurement of satisfaction.

Outcomes/Findings

First Offering. Out of the 156 student in this class, 150 students (96%) attended the elective sessions. Fifty-nine percent of the students stated they had no experience in an IV room before attending the session. Of the 41% with IV room experience, 26% (39 students) stated that they had worked or were currently working in a hospital IV room. The years of experience in an IV room varied, ranging from 1 day to 5 years. In addition, the type of IV hood used differed among the students who worked in a hospital setting. Students had the most experience with a laminar flow hood, followed by a chemotherapy hood, and had the least experience with an isolator hood.

On the postassessment, 132 (88%) strongly agreed or agreed that the laboratory had met their expectations (Table 3). The 3 students (2%) who disagreed stated that the laboratory exceeded their expectations. Fifteen students (10%) did not return the postassessment, therefore their perception of the sessions was not documented. Resurveying the students following their APPEs via an e-mailed survey link found that 92% of participating students felt the virtual experience was helpful to their understanding prior to the real experience of working in an IV clean room. Before completing the survey instrument all students had completed at least 4 to 8 weeks of hospital operations APPEs.

Table 3. Pharmacy Students' Response to the Statement That a Virtual IV Room Laboratory Exercise Met Their Expectations

Level of Agreement	Number of Students (% of Attendants)
Strongly Agree	66 (44)
Agree	66 (44)
Disagree	3 (2)
Disagree Strongly	0 (0)
No Response	15 (10)

Second Offering. One hundred percent (157) of the students in the second offering attended the voluntary virtual laboratory session. Based on the pre- and postassessments, an increased number of students disagreed/strongly disagreed with the statement, "The likelihood of a highly skilled pharmacist making an error is low." (Table 4). On the preassessment, 57% of students disagreed/strongly disagreed with this statement, while this increased to 64% of students following their experience in the virtual environment. Overall, there was no difference in the number of students that disagreed/strongly disagreed with the statement, "My potential for making a medication error upon entering practice is low." For both the pre- and postassessment, 73% of students disagreed/strongly disagreed with the statement. On both the pre- and postassessment, 96% of students felt that medication errors can impact patient outcomes significantly.

Additionally, the postassessment from the second offering of the virtual IV room sessions showed that 88% of students felt that the virtual clean room experience enhanced their understanding of clean room procedures. After completing the session, 75% of participants felt they perceived medication errors to be more significant, and 90% of students felt the assigned problem reinforced their understanding of order processing within the clean room setting.

Written Examinations

Part of the assessment of the Parenteral Product course included multiple written examinations to evaluate various concepts. A post hoc analysis of the sterile technique written examination scores using the Tukey test was completed. Three years of examination scores were analyzed: year 0 (prior to implementation of virtual IV room session), year 1 (first offering of virtual IV room sessions) and year 2 (second offering of virtual IV room sessions). The scores improved from a mean of 89.6% $\pm$ 7.3% in year 0 to 91.2% $\pm$ 7.5% in year 1 and 96.1% $\pm$ 4.4% in year 2 (Table 5). The change from year 0 to year 1 was not significant ($p > 0.05$), but there was a significant improvement ($p < 0.001$) between year 2 and year 0. There was also a significant improvement in the results from year 2 to year 1 ($p < 0.001$).

DISCUSSION

As innovative technology becomes more accessible in pharmacy education, faculty members are given new opportunities to be creative with learning methodologies. Technology is changing constantly, and many pharmacy students want new technologies to be implemented in the classroom. Recognizing this, an immersive virtual

Table 4. Pharmacy Students' Responses to Pre- and Postassessment Statements (Second Offering)

Statement	Preassessment (% of Students)	Postassessment (% of Students)
Medication errors can significantly impact patient outcomes	96.0[a]	96.2[a]
The likelihood of a skilled pharmacist making an error is low	57.3[b]	64.3[b]
My potential for making an error upon entering practice is low	73.3[b]	72.6[b]
I perceive medication errors to be more significant after completing this lab	N/A	75.2[a]
My experience in the virtual clean room has enhanced my understanding of clean room procedures	N/A	87.9[a]
The problem assigned for this lab reinforced my understanding of order processing within the clean room setting	N/A	90.4[a]

[a] agree/strongly agree
[b] disagree/strongly disagree

environment was created to train pharmacy students on aseptic procedures and the USP 797 regulations surrounding an anteroom, a chemotherapy preparation room, and a clean room, with emphasis on the safe preparation of IV products.

The vision for Purdue University's College of Pharmacy was to create a representative IV room environment seen in many hospitals across Indiana to allow PY3 students to feel prepared when starting APPEs. The goal was to help students feel comfortable and confident with the layout and special procedures associated with an IV room, while emphasizing safe medication practices. To make this possible, the college took an interdisciplinary approach. With collaboration from the Rosen Center for Advanced Computing and Information Technology at Purdue University, the college was able to create a virtual IV room environment for training students using technology similar to that of a video game.

To determine whether this type of learning experience existed, a literature search was performed on virtual technology used within colleges and schools of pharmacy for IV room training. After performing this search, we determined that this type of learning activity is the first of its kind for pharmacy education, even though virtual reality is commonly used in training other health care professionals. In addition to its use in health care training, virtual reality has become an integrated part of the training of other professions ranging from armed services members to aircraft inspectors.

Cost and other limitations, including the lack of work experience, prevent pharmacy students from hands-on IV room training prior to APPEs. The ability to bring the clean room environment into the classroom increased student confidence when working in an IV room and fostered a greater appreciation for the role pharmacists have in promoting safe IV product preparation not achieved through the traditional course format. The virtual IV room and additional stations used during the first offering of the laboratory provided a hands-on method for reinforcing materials learned during instructional sessions. Using preassigned problems and simulated IV preparation during the second offering of the laboratory allowed students to gain an enhanced appreciation for the risk of medication errors with IV products. Postassessment evaluations showed that students viewed this session positively, and felt it was a beneficial addition to the parenterals course.

Post hoc statistical analysis showed an improvement in written examination scores assessing sterile technique with the implementation of the virtual IV room session. After the first offering of the laboratory, there was a positive trend in test scores compared with scores prior to implementation. Following the second offering of the laboratory, test scores improved significantly compared to scores prior to the virtual IV room implementation and scores from the first offering of the laboratory. During the second offering of the laboratory, greater emphasis was placed on product preparation, which may have improved scores as well as increased the comfort of instructors working with the technology.

As with the implementation of any new teaching methodology, challenges were presented by the implementation and development of the virtual clean room sessions. Each

Table 5. Comparison of Sterile Technique Written Examination Scores

Year	Mean Percentage (SD)	*p*
0 (Prior to introduction of laboratory)	89.64 (7.3)	> 0.05
1	91.17 (7.5)	< 0.001 (Year 0 Comparison)
2	96.05 (4.4)	< 0.001 (Year 1 Comparison)

year, the largest challenges revolved around providing a quality educational experience for 150 students that included time spent within the virtual environment, while also working within the limits of the technology (ie, not all vials were labeled for the first offering of the laboratory). Relying on technology as the backbone of a lesson can be problematic if the technology does not function appropriately. One group of students in each year experienced technical difficulties within the virtual theater session, but they were able to reschedule on another day to gain the experience of the virtual environment. Additional challenges included finding a suitable facility on campus to host the sessions, accessing knowledgeable individuals to validate the virtual environment's compliance with USP 797 standards, and securing the technical assistance required for initial and updated programming.

SUMMARY

A virtual laboratory session allowed pharmacy students to gain hands-on training to increase their confidence within an IV room setting. The pre- and postassessments permitted evaluation of the students and their perceptions of the sessions. During the IV room exercise, the students were asked to identify improper procedures and explain how proper USP 797 requirements should be employed, as well as identify products for safe and appropriate preparation of IV products. This type of learning environment provided an enjoyable, interactive exercise similar to playing a video game. As a result, the pharmacy students were satisfied with the sessions. Besides providing an enjoyable exercise, the addition of the virtual IV room sessions also corresponded to a significant improvement in examination scores related to sterile techniques. Overall, the immersive virtual environment was a progressive and effective way to teach aseptic procedures and USP 797 requirements for a hospital IV room, with the goal of improving patient safety.

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