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A Comparison between a Simulation-Based and Traditional Direct Patient Care Introductory Pharmacy Practice Experiences

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Abstract

Background: In the United States, the Accreditation Council on Pharmacy Education recently allowed the inclusion of simulation in the introductory pharmacy practice experience (IPPE) curriculum.

Aims: To compare the effects of a simulation IPPE on students' preparedness versus those enrolled in traditional IPPEs.

Methods: Twenty eight students were randomised to a simulation based IPPE and 60 to various practice sites. Students completed the 'Perception of their Preparedness to Perform'(PREP) survey, an agreement and a confidence survey. Students also completed a practical exam.

Results: There was no difference in the PREP survey. There was significant difference between the two arms in 9/13 items on the agreement survey and confidence in the 'use of drug information resources' and 'looking up information in a patient's record'(p=0.01). More students in the simulation arm passed the practical exam (67% vs. 52%).

Conclusion: The results of this study show that a simulation based IPPE is non-inferior to traditional IPPEs in providing select IPPEs.

Keywords: *Human patient simulation, introductory pharmacy practice experience, simulation*

Introduction

In the United States, the Accreditation Council on Pharmacy Education (ACPE) requires at least 300 hours of introductory pharmacy practice experiences (IPPE) prior to the advanced pharmacy practice experiences (APPE) (ACPE, 2007). The IPPEs can be one of the most important formative practice experiences in a pharmacy student's career. The IPPEs serve as the keystone experience which prepares students for their APPE and for future practice (Nemire *et al*., 2006; Chisholm *et al*., 2003; Ruehter *et al*., 2012; Crill *et al*., 2009; Wuller *et al*., 2008; Dennis *et al*., 2005; Turner *et al*., 2000; Turner *et al*., 2004; Turner *et al*., 2005; Turner *et al*., 2007). The IPPE curriculum can be an opportunity to provide a large variety of pharmacy practice experiences and to shape the student's professional outlook. In addition to this, the IPPEs can allow students to refine their practice skills and apply what they have learned in the didactic courses. For preceptors, the IPPEs can be an opportunity to provide formative feedback which can improve the student's skills. However, during some IPPEs, students may take on an observatory role and have little opportunity to apply didactic knowledge to develop care plans for patients (Chisholm *et al*., 2003). Sometimes, each student's experience within the IPPE curriculum can be disparate and the quality of the experience is largely dependent on the preceptor and practice site (Ruehter, et al., 2012). Crill and colleagues highlighted the high burden of IPPEs on practice sites which requires some innovative strategies to relieve the burden while providing meaningful learning experiences (Crill *et al*., 2009). One strategy as suggested by Chisholm and colleagues could be to restructure IPPE activities such that more activities are developed by the school versus practice-site (Chisholm *et al*., 2003). Another could be to structure more school-based discussion sessions where students have a chance to reflect and debrief on practice site patient care activities (Wuller *et al.,* 2008). Recent changes to the ACPE guidelines present another strategy to provide students with a consistent IPPE with formative feedback and opportunities for remediation. ACPE now allows the inclusion of simulation in the IPPE curriculum (ACPE, 2007). Guideline14.5 states:

> *"Colleges and schools may choose to include structured simulation as part of their overall introductory pharmacy practice experiences to meet their introductory pharmacy practice experiences program goals and objectives. Simulation, defined as an activity or event replicating pharmacy practice, can be utilized for no greater than 20% (e.g. 60 hours of a 300 hour requirement) of total introductory pharmacy practice experience time."*

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These changes to ACPE guidelines allow faculty members to develop experiences that would otherwise not be guaranteed during direct patient care IPPEs. These experiences could include, but are not limited to, special patient populations such as pediatrics, emergent situations, seasonal conditions, and exposure to adverse effects from medications. Besides, unique experiences, simulation-based training could allow faculty members to create experiences which focus on specific skills acquisition such as communication, technical, and clinical skills (Seybert *et a*l., 2008; Mieure *et al*., 2010; Seybert *et al*., 2007; Tofil *et al*., 2010; Marken *et al*., 2010; Benedict *et al*., 2010; Zagar *et al*., 2010; Chen *et al*., 2008; Vyas *et al*., 2012). However, currently there is limited evidence to recommend the replacement of direct patient care IPPEs with a simulation based experience. Vyas and colleagues described an IPPE which augmented direct patient care experiences with three clinical high fidelity simulations (Vyas *et al*., 2010). This study found that there was an increase in student knowledge when comparing post-simulation quiz to pre-simulation quiz scores ($p<0.05$). The study also found that the majority (76%) of students felt more confident "making clinical recommendations to a healthcare provider" after completing the simulation series ($p=0.01$). However, to our knowledge there have been no published studies describing an IPPE that solely utilizes simulation-based techniques. The evidence from the last few years has shown that simulation techniques are a useful tool for training pharmacy students when used to supplement didactic classroom materials (Vyas *et al*., 2010; Seybert *et al*., 2008; Mieure *et al*., 2010; Seybert *et al*., 2007; Tofil *et al*., 2010; Marken *et al*., 2010; Benedict *et al*., 2010; Zagar *et al.,* 2010; Chen *et al*., 2008; Vyas *et al*., 2012). However, there is little evidence in the experiential arena.

Rationale and Objectives

The purpose of this paper is to describe a pilot study comparing the effects of a simulation IPPE on students' preparedness for APPEs, student self-perceived confidence, and clinical skills versus those students enrolled in direct patient care IPPE sites. We hypothesized that the students enrolled in the simulation IPPE would perform just as well on the various outcome measures as those students enrolled in direct patient care IPPEs.

Methods

This study was approved by the Independent Institutional Review Board Inc. This was a randomised controlled trial of IPPE training at a simulated clinical site versus traditional IPPE sites within the community. The students in the direct patient care sites served as the control group.

Educational Environment

Twenty eight students in their 3rd year of pharmacy school were randomised into the simulation-based IPPE while the remaining 60 students were enrolled in various direct patient care IPPEs in the region. All but one student were enrolled in hospital IPPEs at various community hospitals. The one student was enrolled in a clinical rotation with the Department of Health Care Services. Prior to this IPPE, all students had completed 200 hours of IPPE experiences in both community and institutional settings and received equivalent didactic coursework at baseline.

Content

The simulation IPPE offered 60 hours of pharmacy practice experiences in various arenas (Table I). The course instructors developed experiences that would otherwise not be guaranteed during IPPE. Each week, students enrolled in the simulation IPPE were engrossed in intensive clinical situations which required them to use appropriate clinical judgment, demonstrate practice skills, respond appropriately to emergency situations, and demonstrate competency in dealing with multi-layered problems.

Table I: Simulation Scenarios

DAY*	SESSION TOPIC	SIMULATION MODALITY
1	American Society of Health-System Pharmacists (ASHP) Basics of Aseptic Compounding Technique	Mock Pharmacy
2	Basics of aseptic technique and skills laboratory	Mock Pharmacy
3	Vaccine scenarios with subsequent emergencies	Standardized Patients
4	Health assessment skills	Standardized Patients
5	Medication therapy management	Standardized Patients
6	Chemotherapy scenarios/Aseptic technique	Mock Pharmacy
7	Asthma exacerbation	High Fidelity Simulators
8	Acute overdose and toxicity	High Fidelity Simulators
9	Diabetic ketoacidosis with a pulmonary embolism	High Fidelity Simulators
10	Emergency contraception and ethics scenarios	Standardized Patients
11	Emergency scenarios in the community	Standardized Patients
12	Congestive heart failure	High Fidelity Simulators
13	Advanced cardiac life support (ACLS)	High Fidelity Simulators
14	Wrap –up and reflection	Not applicable

*Each day was 4-6 hours resulting in a total of 60 hours of contact time

Expected Outcomes and Learning Objectives

A panel of five faculty members determined the minimal competencies that students needed to achieve prior to APPEs. This was based on the pre-APPE minimal core domain abilities and competencies as outlined by ACPE (ACPE, 2007).The emphasis of this IPPE was on the patient safety core domain. The aspects of this are discussed in a previous publication (Vyas *et al*., 2010).

The remaining 60 students completed 60 hours of instruction at either hospital or other specialty IPPEs in the region. Each IPPE varied greatly between site and preceptor; however, preceptors were instructed to meet the global objectives of the IPPE course. The objectives of the IPPEs are summarized in Table II.

Typical IPPE session.

A variety of simulation modalities were used including a mock pharmacy, standardized patients (SPs), and high fidelity simulators. During the scenarios which utilized high fidelity simulators, SPs serving as a nurse and physician were employed to provide an interdisciplinary experience. Students were divided into 10 teams of 2-4 students each (most scenarios were individual and not team-based). Two students/teams ran parallel through the entirety of the 90-minute simulation experience, sharing the case preparation room, then separating into 2 identical simulation rooms, and finally reconvening in the debrief rooms. During the case preparation period, students were given the patient's history and physical with instructions to develop an assessment and plan.

After case preparation, student/teams went to the simulation room where the scenario unfolded. Students were oriented to the room and instructed to remain within their role as a pharmacy intern. All simulations were dynamic and introduced new information which would change the student's treatment plan.

The last step of the simulation was the debrief period. The debrief period provided the opportunity to reflect as well as an opportunity for closure. During the debriefing, a pharmacy faculty member shared clinical pearls from the scenario, and answered questions posed by the students regarding the scenarios. Students also reflected on and discussed their role within the simulation.

After each debrief period, students were asked to complete documentation on that day's simulation. Documentation could include a SOAP (subjective, objective, assessment and plan) note, history and physical exam note in the patient's chart, a Food and Drug Administration (FDA) MedWatch form for a drug adverse event, or submission of a report in the Vaccine Adverse Event Reporting System (VAERS). For simulations in which none of these documentation types were applicable, students completed a self-reflection on their performance in the simulation. Students were free to leave after they submitted their assignment for the day.

Both arms completed the Perception of their Preparedness to Perform (PREP) survey adapted from Ried *et al.* (2002). The PREP survey is a measure of student readiness to perform during the APPEs. It was developed by Ried and colleagues with the objective of measuring student readiness on 41 different survey items which

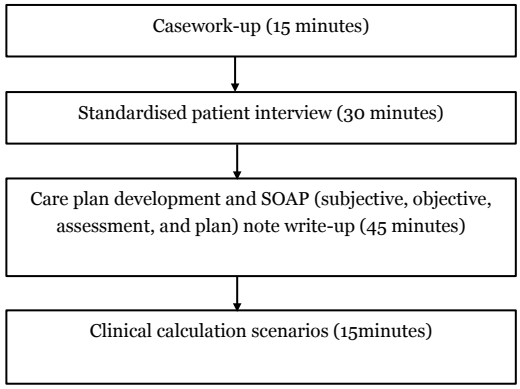
Table II: Introductory Pharmacy Practice Experience (IPPE) Learning Objectives

	Simulation Based IPPE	Hospital IPPE	Specialty IPPE
Knowledge	– Identify medication errors. – Recall appropriate dosages of select medications. – Identify drug-drug interactions. – Describe physiologic effects of drugs on the human body.	– Demonstrates understanding of the distribution of patient specific medications in the pharmacy. – Demonstrates understanding of inventory control in the pharmacy.	– Demonstrate the understanding of the core function(s) for the preceptor within this setting. – Demonstrate the understanding of the basic operational issues of the practice site.
Skills	– Demonstrate the ability to compound drugs. – Display aseptic technique when making intravenous preparations. – Create a care-plan for a patient. – Utilize drug information resources to find appropriate answers. – Communicate with patients, physicians, and nurses. – Calculate correct drip rates for intravenous medications. – Write medication orders in a patient chart. – Identify lab abnormalities. – Apply evidence based treatment guidelines to clinical situations. – Educate patients and caregivers about pharmacologic and non-pharmacologic issues. – Respond to an emergency.	– Formulate sound evidence-based, pharmacotherapy plans. – Evaluate a patient's disease and response to drug therapy. – Optimize a patient's pharmacotherapy outcomes. – Select specific medications based on therapeutic bio-equivalence. – Implement strategies for improving medication adherence. – Communicate effectively with patients, health care professionals, and caregivers. – Incorporate new scientific developments into practice. – Formulate strategies for promoting health, wellness, and disease prevention. – Work effectively as a member of the inter-professional team.	– Formulate sound evidence-based, pharmacotherapy plans. – Evaluate a patient's disease and response to drug therapy. – Optimize a patient's pharmacotherapy outcomes. – Select specific medications based on therapeutic bio-equivalence and cost-effectiveness. – Implement strategies for improving medication adherence. – Communicate effectively with patients, health care professionals, and caregivers. – Work effectively as a member of the inter-professional health care team. – Incorporate new scientific developments into pharmacy practice to improve patient care.

loaded onto five different factors. Both arms also completed an agreement survey and a self-perceived confidence survey. The agreement and self-perceived confidence survey was developed by the faculty panel.

All students also completed a milestone exam, a diagnostic annual exam offered to third year PharmD students at the beginning of the Autumn semester. The milestone exam comprised of a practical and written exam. The sequence of the practical exam is described in Figure 1. The exam was developed by an independent faculty panel and consisted of items that would allow the faculty to measure minimal competency in certain elements of the pre-APPE core domains. The student was required to demonstrate competency in the following tasks: 1.) Interview a patient with appropriate communication technique; 2.) Conduct a limited physical assessment and identify abnormalities; 3.) Order laboratory tests; 4.) Order new medications based on the physical exam and laboratory data; 5.) Counsel a patient on new and existing medications; and 6.) Develop a treatment plan and document the plan by writing up a SOAP note.

Figure 1: Practical Exam Sequence



Faculty members were recruited to serve as observers to evaluate the students. All observers used a standardized checklist to score the student's performance. Observers were blinded to which students were enrolled in the simulation versus those in direct patient care IPPEs. Faculty observers could give a bonus point, if deemed appropriate. Based on the student's performance in the exam room, the faculty observer were instructed to checkmark 'pass or no pass' on the checklist. This was based on the observer's subjective analysis of the student's performance. SPs were also provided a checklist to score the student's performance especially with regard to communication skills.

The written exam comprised of 120 multiple choice questions which reflected material emphasized in each course offered in the previous academic year. The exam had three separate components: 1.) pharmacy calculations; 2.) a comprehensive case study; and 3.) mock board exam questions. The questions were written by a panel of faculty members and not the study investigators.

Statistical Analysis

SPSS version 19 was used for all statistical tests. Data from the PREP survey, the agreement survey, and the self-perceived confidence survey was analysed using the paired student t-test. Results from the Milestone exam were analysed using the independent samples *t*-test.

Results

Table III: Agreement Survey*

Question	*p*-value (0.05)	Mean Control/ Simulation
My IPPE** was stressful	<0.001	1.87/2.95
My IPPE helped reinforce didactic course materials	0.038	2.89/3.18
I better understand the physiologic effects of the medications because of my IPPE	0.002	2.69/3.14
I am now more aware of medication errors because of my IPPE	0.002	2.69/3.14
IPPEs are a helpful tool for training for PharmD students	0.28	3.26/3.41
My IPPE was a positive experience	0.93	3.26/3.27
Compared to standard team based learning, I learned clinical patient care better in my IPPE	<0.001	2.65/3.45
It is easy to make medication errors in pharmacy	0.002	3.09/3.55
My IPPE helped me realize the importance of patient safety training	0.02	3.24/3.55
My IPPE helped me realize the importance of providing patient centered care	0.01	3.22/3.59
I learned more new information in my IPPE	0.007	3.11/3.5
My IPPE reinforced previously learned concepts in a manner that was meaningful	0.06	3.11/3.36
I would recommend my IPPE to other pharmacy students	0.22	3.21/3.41

*Survey based on a Likert scale of 1-4. 1 being "Strongly Disagree" and 4 being "Strongly Agree"
** IPPE: Introductory Pharmacy Practice Experience

There was no statistically significant difference in the PREP survey results. Simulation students felt just as prepared for APPEs as the control arm. There was a statistically significant difference in the level of agreement on 9 out of 13 items on the agreement survey (Table III). Of note, more students in the simulation group agreed with the statement "I learned new information in my IPPE" (mean 3.5 for the simulation group versus 3.0 for the control group, p=0.007). Student agreement with the statement "My IPPE helped me realize the importance of patient safety training" was significantly higher for the simulation group compared to the control group (mean 3.55 for the simulation group versus 3.24 for the control group, p=0.02). Results indicated statistically significant difference existed between the two groups on their self-perceived confidence on 2 separate items, 'use of drug information resources' and 'looking up patient information in a medical record' (Table IV).

Table IV: Self-Perceived Confidence Survey

Question	*p*-value	Mean Control/ Simulation
Using drug information resources	0.01	1.82/2.5
Identifying medication errors	>0.05	2.63/2.83
Communicating with a physician and nurse	>0.05	2.32/2.58
Working up clinical cases in a limited time frame	>0.05	2.86/2.88
Writing drug orders in a patient chart	>0.05	2.82/2.83
Looking up patient information in a patient's medical record	0.01	2.14/2.54
Calculating drip rates for intravenous medications	>0.05	2.6/3
Identifying drug-drug interactions	>0.05	2.89/2.92
Identifying physiologic effects of drugs on the human body	>0.05	2.68/2.88
Creating a care-plan for a patient	>0.05	2.79/3.08
Perform advanced cardiac life support on a patient in acute cardiac arrest	>0.05	2.87/2.92
Performing aseptic technique in an intravenous hood	>0.05	2.56/2.46
Calculating the amount of dose required to reconstitute a drug given the concentration in a vial or ampule	>0.05	2.55/2.83
Administer a vaccine taking into account contraindications, drug-drug interactions	>0.05	2.65/2.79
Counsel a patient on birth control and emergency contraception	>0.05	2.24/2.33
Identify the main side effects associated with drugs	>0.05	2.75/3
Perform physical assessment on a patient	>0.05	2.62/2.75

Survey based on a Likert scale 1 being "Not confident" and 4 being "Very confident."

More students in the simulation group passed the practical exam versus the control group as subjectively determined by the faculty observer (67% vs. 52% respectively). Students in the simulation group had significantly higher faculty observer scores (based on the standardized checklist) on the practical exam compared to the control group (52% vs. 44% respectively, p=0.02). The score given by the actor was not statistically different between the 2 arms (57% vs. 54%, p=0.528). Performance on the SOAP note score was also similar between the 2 arms (78% vs. 71%, p=0.065). Simulation students had significantly higher calculation scores compared to the control group students (52% vs. 35% respectively, p=0.007). More students in the simulation group received a bonus point for excellent performance (48% vs. 34% respectively).

There was no difference in the written exam results for students in the simulation group compared to those in the control group. Simulation students had higher cumulative overall scores versus the control group students (68% vs. 64% respectively, p=0.075). Simulation students also had higher scores on the mock board exam questions (79.42% vs. 86.69%, p=0.039). There was no statistically significant difference in scores for the calculation and comprehensive case study sections.

Discussion

The requirement for IPPEs in the PharmD curriculum is relatively new. The majority of the 300 hours of IPPEs should be completed in institutional and community practice settings. During the IPPEs, students should be exposed to various areas such as developing care plans and monitoring drug therapy, SOAP note documentation, professional and interprofessional communication, and practice improvement. IPPEs should also emphasize areas such as ethical reasoning, problem solving, medication system improvement, and continuous quality improvement. However, for each year of the PharmD curriculum, appropriate levels of responsibility have not been established. Additionally, ways to integrate the didactic PharmD curriculum with IPPEs to achieve optimal competency-based student outcomes have not been determined. There are several challenges facing pharmacy educators with regard to IPPE provision and simulation represents one of multiple ways in which improvement might be achieved.

This is the first pilot study measuring the impact of a simulation-based IPPE compared to direct patient care IPPEs. During this simulation IPPE, faculty members were able to design each module of simulation to focus on the minimal pre-APPE competencies as outlined by ACPE. Each module integrated training and assessment of ethical reasoning, problem solving, medication system improvement, and clinical aptitude. The IPPE also exposed to students acute medical problems such as anaphylactic shock, diabetic ketoacidosis, heart failure, and drug overdose.

This study found that the simulation-based IPPE was non-inferior to direct patient care experiences. Students in the simulation IPPE were not at a disadvantage as far as skills acquisition and overall felt just as prepared for APPEs as those enrolled in direct patient care sites. The students in the simulation IPPE performed better on some aspects of a standardized practical exam and felt more confident using drug information and reviewing a patient chart than those in the traditional IPPEs. The results from this study are consistent with other published studies on the impact of simulation training. Seybert and colleagues showed improvements in students' ability to measure blood pressure after simulation- based training while Tofil showed significant improvements in knowledge pre and post simulation (average scores 4.1 ± 1.2 out of 9 on pre-test and average 7.0 ± 1.5 out of 9 on post-test p<0.0001.) (Seybert *et al*., 2007; Tofil *et al*., 2010) Marken and colleagues showed improvements with student attitudes regarding difficult conversations (Marken *et al*., 2010).

The systematic pre-simulation and post-simulation assessments provided valuable first-hand information for regarding students' strengths and weaknesses. The overall pass rate on the practical exam for both study arms exposed deficiencies in student skills particularly in the area of clinical calculations, history taking, and physical assessment. It is worth noting, that the overall scores achieved by the students in either arm is similar to those found by other studies which have used a practical exam format (Kirton published average scores of 62.9% ±

10.9% while Salinitri showed average scores of 68.8% ± 7.4%; range 48.6% to 83.9%) (Kirton *et al*., 2011; Salinitri *et al*., 2012). However, from an institutional perspective, the results from both the formative and summative assessments have been relayed to the faculty members in charge of the related courses and several changes have been adapted in the designing of respective courses. For example, longitudinal pharmacy calculation training and assessments have been added and emphasized in the therapeutics series. Team based objective structured clinical exams have also been integrated in the therapeutic courses.

One limitation of this study is the small sample size which precludes the investigators from making any solid conclusions about the impact of a simulation-based IPPE. Another limitation of this study's methodology is that the practical exam is not a validated tool and may not completely establish a student's clinical competency. Additionally, since the overall scores from the practical exam were based on the checklists completed by the faculty observers and SPs, there was potential for inter-rater variability. It is also unclear whether the performance on the practical exam is a true reflection of a student's performance in direct patient care interactions. Preceptor evaluations from APPEs may provide better insight however evaluations can be unreliable and may not provide objective data regarding the student's performance. A more appropriate tool would be to directly observe and measure a student's competency in the practice setting during the APPEs or even after graduation. This presents an obvious physical challenge as students are scattered in various practice sites throughout the country. An inherent limitation of this study design is that the investigators could not guarantee that the direct patient care IPPEs would provide equivalent experiences to the simulation IPPE. However, this is an on-going issue with IPPEs as there is sometimes inconsistency in the types/levels of experiences that are offered to students (Ruehter *et al*., 2012).This may have put the control arm at a disadvantage with regard to the practical exam. However, since these students had equivalent didactic coursework which emphasized those skills, it was expected that students would be able to perform the activities highlighted in the practical exam.

This study suggests that simulation teaching can be a reliable strategy to create focused experiences to teach and assess minimum competencies required for PharmD students prior to their APPEs. The results of this study show that a simulation based IPPE is non-inferior to traditional IPPEs in providing select IPPEs.

Summary

More rigorous studies need to be performed in this arena to truly establish the role of simulation in providing IPPEs; however, this first study is encouraging and should provide some confidence that a simulation-based IPPE will not put the student at a disadvantage compared to those enrolled in traditional IPPE sites.

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