INSTRUCTIONAL DESIGN AND ASSESSMENT

Development and Evaluation of a Required Patient Safety Course

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Objectives. To develop, implement, and assess a required patient safety course for second-year doctor of pharmacy students.

Design. A patient safety course was developed that included didactic lectures, case studies, in-class activities, and reading assignments. Written examinations and essays were used to evaluate student learning. In addition, a modified minute paper and a pre- and post-intervention student self-assessment survey were used to assess course outcomes.

Assessment. Results examining the utility of the course teaching format and the relevance of the material in meeting the course outcomes are presented and discussed. The self-assessment course survey indicated major improvements in the students' knowledge and skills, readiness for knowledge application, and commitment to improve patient safety.

Conclusion. The course provided pharmacy students with an increased level of understanding of the principles and concepts of patient safety.

Keywords: patient safety, medication errors, medical errors

INTRODUCTION

The number of patients experiencing morbidity and mortality each year from medical and medication errors is not precisely known.^{1,2} Although the likelihood of a serious adverse event occurring in an individual is small, in the population as a whole, thousands of events occur each year. In 2000, the overall cost of one type of medical error, the drug-related morbidity and mortality, exceeded \$177 billion, greater than the overall national costs associated with initial drug therapy.^{3,4}

The Joint Commission of Pharmacy Practitioners' (JCPP) 2004 vision statement assigns the role of optimizing medication therapy outcomes to pharmacists.⁵ Medical errors disrupt efforts aimed at improving public health.^{1,2} To date, a pharmacist's active involvement in improving therapeutic outcomes has been limited.⁶ There are many possible explanations for why pharmacists lack active and sustainable roles in this crucial area. Deficiencies in or insufficient emphasis on skill development in the pharmacy curriculum have been suggested as major obstacles to pharmacists attaining key roles in improving patient therapeutic outcome.^{7,8}

In 2001, a descriptive survey of the quality and quantity of medication error instruction in the curricula of US pharmacy schools illustrated the lack of a structured process for teaching patient safety to graduate and undergraduate pharmacy students.⁹ Effective July 1, 2007, the Accreditation Council for Pharmacy Education (ACPE) identified patient safety as a core element of the pharmacy curriculum.¹⁰

This article describes how a patient safety course was developed, and conducted, and examines to what extent the course educational outcomes were achieved. Measurements of formative assessment and summative course evaluations are also provided.

DESIGN

In 2007, a 2-credit course, *Patient Safety and Medication Errors*, was required during the spring semester of the second year of an accredited 3-year doctor of pharmacy degree program. Three major goals were identified for the patient safety course: first, to introduce pharmacy students to the longstanding, unresolved debate in the US health care system over patient safety; second, to provide pharmacy students with a background that would allow the reliable translation of the science of preventable medical errors into practice; and finally, to prepare pharmacy students for a future role in improving patient safety.

The patient safety course included didactic lectures, case studies, in-class activities, reading assignments, written essays, and 2 examinations. No lecture notes were

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offered and no textbook was required for the course. Readings from the current literature were assigned to provide background, emphasis, and relevancy to the lecture's conceptual topics. Additional readings for written assignments were required to ensure the application of knowledge and to enhance students' critical thinking and analytical skills.

The outline for the course was developed based on 2 public health reports published by the Institute of Medicine (IOM) involving major patient safety issues in the United States,^{1,2} a medication errors textbook,^{11,12} and numerous published articles involving patient safety.¹³⁻²³

Patient safety web sites of government agencies and private organizations were also consulted for teaching materials.²⁴⁻²⁷ The course lecture topics are listed in Table 1.

A weekly case study involving recent medical errors which received significant media coverage helped the students to remain current. Sessions were conducted using a structured deliberation format. By adapting this format, students were exposed to an escalated level of complexity in analyzing the causes of the medical error being studied and suggesting potential resolutions to prevent future incidents.

For example, students were asked to watch the ABC News 20/20 investigative report "Medication Errors in Community Pharmacy" that was broadcast on March 30, 2007, for the following week's class discussion.²⁸ A case summary was conducted at the beginning of the class to inform students who were unable to watch the program and to keep the class focused on certain aspects of the report. After a brief discussion, the students were asked to identify failed areas within the medication-dispensing system and major contributing factors to the incident. The students were asked to rank the contributing factors in accordance with their significance. By deliberating the issue, students were able to reach a consensus regarding the major factors that led to the incident and the needed changes to minimize future incidents. Indicators to monitor and/or predict system failure were also discussed. The American Society of Health-System Pharmacists (ASHP) press release in response to the 20/20 report was also part of the discussion.²⁹

The class met twice a week for a 100-minute conceptual lecture and a 50-minute case study. The case study was selected to emphasize the learning objectives of the preceding conceptual lecture. Students were also required to complete weekly reading assignments and submit a half-page essay. The basis for the students' course grade were the 2 examinations counting for 30% and 40% (mid-term and final, respectively), and written assignments comprising 30% of the final grade. The course was

Table 1. Lecture Topics of the Patient Safety and Medication Errors Course

Lecture Title and Topics
1. Introduction to patient safety
The leading cause of death and injury in the US health care system
The epidemiology of errors in the health care system
Why do errors occur?
Factors that contribute to errors
The cost of errors
2. Medication-related errors in health care
The epidemiology of medication errors
Types of Medication errors
Why do medication errors occur?
Research on human factors
Research on system factors –
Identifying systems failures
System Analysis of an adverse event – The Root Cause Analysis Approach
3. Standards for patient safety
Standards for performance and expectations
Quality standards
Quality indicators
Standards for health professionals
4. Standards for drugs and devices
The FDA approval standards
The FDA regulatory authority
5. Error reporting systems
Review of the existing error reporting systems in health care
The FDA's adverse events reporting system
Voluntary versus mandatory error reporting system - ethical and legal issues for considerations
6. Recommendations to improve patient safety
The IOM 2006 report on drug safety -Summary Report
The FDA Response to IOM's 2006 report
The future of patient safety

^aTopics are listed in order of presentation

predominately taught by 1 faculty member. Four faculty members from the Department of Pharmacy Practice were asked to review the lecture contents and provide recommendations.

Upon completion of the course, students were expected to have basic knowledge of the science of medical errors and to identify the basis of safe practices. Participating in case study sessions, students were also expected to apply their knowledge and skills to real-world work situations.

The course educational outcomes included:

- Students' acquisition of the knowledge and skills that are consistent with current patient safety science concepts:
 - System failure
 - Error contributing factors
 - Role of the front line workers
 - Role of team work
 - Required leadership and management skills
 - Students' application of the acquired knowledge and skills:
 - Identify high-risk areas within the healthcare system
 - Assess the working conditions of a selected area
 - Analyze a specific incident
 - Propose changes to prevent errors
 - Measure results by identifying indicators that are highly specific for system performance
 - Students' commitment to improve patient safety
- Students' feedback was solicited using 2 approaches, minute papers and the course survey.

To ensure that students were able to grasp the teaching material and the instructor was able to identify confusion or learning misconceptions early in the course, students were asked to provide immediate feedback at the end of each conceptual lecture using the "minute paper" method.³⁰ Each student was asked to report what he/she had learned, any confusing concept, and any learning concerns. Two additional items regarding learning difficulties and students' satisfaction with lecture content were incorporated into the original minute paper format.

Course outcomes related to the ultimate goal of future pharmacists' involvement in improving patient safety were assessed. A retrospective survey, conducted at the end of the course, included the following course outcomes: students' acquisition of knowledge and skills consistent with current patient safety science concepts; students' readiness to apply knowledge and skills in real-world work situations, and students' commitment to improve patient safety. Using a Likert scale of 1 to 5, students were asked to anonymously rank their level of likelihood of active involvement, agreement, or familiarity, with survey statements. The survey also included an overall course evaluation. (Table 2).

Survey items were adapted from a report on the effectiveness of a pilot training curriculum on patient safety for healthcare professionals.³¹

ASSESSMENT

The students' scores generated a typical bell-shaped curve. The average score on the final examination was $81.9\% \pm 8\%$. Ninety-nine of 129 students (77%) scored

80% or higher. The overall average grade for the course was $83.8\% \pm 4.8\%$

The minute papers were readable and easy to tabulate. Most students were able to grasp the major learning concepts. A decision to conduct an in-class review was made if more than 5 students considered a specific concept to be confusing, otherwise e-mail was used to address individual student questions. On 2 occasions, 5-10 minutes of in-class review involving the previous week's material was necessary to clarify concepts that students' considered confusing. On a scale from 0 to 10, on which 0 = total waste of time and 10 = very beneficial, the students' average level of satisfaction with gaining new knowledge from the lectures was 7.24.

Eighty-one (63%) students completed the course survey. The results are presented in Figures 1, 2, and 3. For the purpose of this article, the survey results are interpreted as follows: a reported score that is 2 or less represented a low level; 2.1 to less than 3 represented a moderately low level; 3 represented a neutral level; 3.1 to less than 4 represented moderately high level; and 4 or more represented a high level.

Items 1 and 2 of the survey asked students to rank the changes in their pre- and postintervention exposure. Statement 1a was designed to reflect the extent to which the students agree that medical errors represent a serious problem. Responding to the statement, students reported a high level of agreement. According to the Wilcoxon signed rank test, the increase in students' awareness was significant ($p < 0.05$). Students reported an overall low level of agreement with system-related patient safety misconceptions. A decline in the students' level of agreement with the stated statements reflected knowledge and skills improvements. This decline was significant for 2 out of 4 survey statements ($p < 0.05$).

Students reported an overall moderately high level of familiarity with major patient safety concepts. The increase in students' level of familiarity was significant ($p < 0.05$) (Figure 1).

Items 3 and 4 of the survey asked the students to rank the level of their agreement or the likelihood of their active involvement in improving patient safety. Students reported a moderately high level of agreement with statements designed to reflect their readiness to apply their knowledge and skills in real-world work situations (mean $\pm$ SD = 3.8 ± 0.1). However, responding to statement 3a, the students were almost neutral when asked whether they anticipated any significant barriers (3.1 ± 1.1).

Assessing the students' commitment to patient safety, they reported a moderately high level of the likelihood of active involvement to improve patient safety (3.7 ± 0.0 ; Figure 2).

Table 2. Patient Safety Course Survey

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1. Indicate the extent to which you disagree or agree with the following statements. Note: your perceptions are required for both *before* the course and for your perceptions *today*.
 - 1a) Medical errors represent a serious problem within the health care system.
 - 1b) Medical errors can generally be prevented by retraining or firing a few individuals.
 - 1c) A certain number of medical errors are simply inevitable.
 - 1d) It is generally not worthwhile for hospitals to try to achieve error rates any lower than those seen at similar hospitals.
 - 1e) Highly vigilant individuals will generally not produce medical errors.
 2. Answer the following question about the degree to which you were/are *familiar* with the following skills and/or concepts. Note: your perceptions are required for both *before* the course and for your perceptions *today*.
 - 2a) Understanding how systems work.
 - 2b) Careful observation of system operation.
 - 2c) Root cause analysis of an incident.
 - 2d) The importance of team-based problem-solving approach.
 3. Indicate the extent to which you agree or disagree with the following statements.
 - 3a) In my future professional work, there are likely to be significant barriers to my ability to use patient safety and medication errors knowledge/skills.
 - 3b) With what I know today, I am confident that I can overcome barriers that I might encounter in putting patient safety and medication errors knowledge/skills into practice.
 - 3c) The course helped me to identify resources in my future workplace that might allow me to address barriers to use of skills.
 - 3d) In my future workplace, I would feel comfortable approaching a professional peer in order to discuss an unsafe practice he or she was engaging in.
 - 3e) In my future workplace, I would feel comfortable approaching a manager, administrator, or supervisor in order to discuss an unsafe practice.
 - 3f) As a pharmacy student, this course, generally speaking, presented material that was beneficial to my future career.
 4. Please rate the likelihood of your active involvement in the following activities during the next year.
 - 4a) Read a report or other patient safety publications.
 - 4b) Talk to a preceptor about an unsafe practice.
 - 4c) Talk to a pharmacy technician about an unsafe practice.
 5. Indicate the extent to which you agree or disagree with the following statements.
 - 5a) The course was good.
 - 5b) The course met my expectations.
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Students reported a moderately high levels of agreement that the patient safety course was helpful and beneficial (3.4 ± 0.9 and 3.3 ± 1.1 , respectively). However, the students level of agreement that the course was good and met their expectations was neutral and moderately low (3.0 ± 1.1 and 2.8 ± 1.2 , respectively). (Figure 3)

DISCUSSION

Patient safety and medication errors are not infrequent topics for the lay media and often involve pharmacists. This media scrutiny, sometimes negative, has focused public attention on the role of the pharmacist in the drug distribution system. This has made patient safety a high priority for inclusion in pharmacy curricula.

Using the minute paper method in this course allowed for the close monitoring of students' progress in attaining the course outcomes and identifying potential misconcep-

tions at the earliest possible time. This was extremely valuable in eliminating any perceived weaknesses in connecting concepts presented in the course lectures. To what extent this method was effective in improving the course outcomes was not measured. The students' learning perceptions was examined by averaging the level of their satisfaction with the conceptual lectures. The students found the presented material beneficial.

The results of the course survey suggest that the course outcomes were met. An important section of the survey assessed the students' acquisition of knowledge and skills that are consistent with current patient safety science concepts. The students grasped the course educational material and their misconceptions appeared to have been corrected.

The students felt they were ready to apply their acquired knowledge and skills to professional practice

Figure 1. Students' acquisition of knowledge and skills.

situations. Students also believed that the course resulted in their becoming committed to the ideal of patient safety in the future.

In the course evaluation section of the survey, the students found the new, required patient safety course to be helpful and beneficial, although they indicated that the course did not fully meet their expectations. During the course, the students expressed a desire for more case studies. This may be an indication that the students desired more real-world examples.

Survey evaluations are always open to criticism on the basis of subjectivity and this is certainly true for the one used in the patient safety course. The retrospective nature of the survey may have introduced a recall bias. However, using this method may have better captured the students' impressions of what they had learned by reducing changes over time in their evaluative standards, a common bias with the traditional pre- and post- intervention exposures.³²

Figure 2. Students' readiness to apply in real-world situations and the students' commitment to improve patient safety.

Figure 3. Patient Safety course evaluation.

The responses on the self-assessment survey indicate that the course outcomes were met but the course can be improved. One section of the survey dealt with students' commitment to patient safety in their future practices. A majority of students believed that patient safety was an important issue and stated that they were willing to implement concepts of patient safety in their future professional careers. This may reflect the fact that after pharmacy students were initially exposed to the depth and scope of medical errors and avoidable injuries in the healthcare system their reaction, predictably, would be to commit to improving patient safety.

We may be relying too heavily on and continuing to measure invalid surrogates for educational outcomes. With regard to the patient safety course, or any intervention to improve patient safety, the only valid measure will be a system in which errors can be captured and methodically analyzed and the effect of these interventions measured.

Another limitation of our survey was a relatively low response rate of 63%. The extent to which possible response bias accounted for the results is unknown.

Useful comments and suggestions for future modification of the course were received during the preparation and outside review of this article. One of the most important suggestions was the inclusion of more case studies, in particular, cases involving inappropriate and off-label prescribing, and the Food and Drug Administration (FDA) drug approval process. Overarching this suggestion are the possible roles for future pharmacists. These ideas are being incorporated into the course.

Other comments were critical of using definitions for the course from the IOM's *To Err is Human* report. There appears to be a lack of consensus on definitions of terms applied to medication errors and patient safety. The IOM definitions were chosen because of the relatively high public awareness of the report.

There is a range in categories of drug-related errors discussed in the course including dispensing errors, prescribing errors, and the off-label prescribing. The later, arguably in our view, is the most important from a patient safety perspective and is the area that had received the least attention in our curriculum until the addition of the patient safety course.

It is difficult to estimate to what extent, if any, this course will ultimately contribute to the societal goal of improving patient safety. An examination of the progress made in patient safety since the release of the IOM's *To Err is Human* report indicates lack of measurable improvement.¹³ The addition of more cases to the course, including cases of historical importance, may give students a broader historical context for drug safety issues and show that the efforts made to date to improve patient safety have largely failed. Hopefully, understanding the past will spur students to explore other possible causes and resolutions for the patient safety problems.

The new ACPE requirement to include patient safety in its standards should produce a number of innovative ideas and courses by pharmacy educators.

CONCLUSION

Based on a number of educational course outcomes, this new, required patient safety course is an important addition to the pharmacy curriculum.

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