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TEACHERS' TOPICS

A Root Cause Analysis Project in a Medication Safety Course

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Objective. To develop, implement, and evaluate team-based root cause analysis projects as part of a required medication safety course for second-year pharmacy students.

Design. Lectures, in-class activities, and out-of-class reading assignments were used to develop students' medication safety skills and introduce them to the culture of medication safety. Students applied these skills within teams by evaluating cases of medication errors using root cause analyses. Teams also developed error prevention strategies and formally presented their findings.

Assessment. Student performance was assessed using a medication errors evaluation rubric. Of the 211 students who completed the course, the majority performed well on root cause analysis assignments and rated them favorably on course evaluations.

Conclusion. Medication error evaluation and prevention was successfully introduced in a medication safety course using team-based root cause analysis projects.

Keywords: medication safety, root cause analysis, pharmacy education

INTRODUCTION

Approximately 100,000 people die each year as a result of preventable medical errors.[1] This is more than the number of deaths caused by motor vehicle accidents, breast cancer, and acquired immune deficiency syndrome combined. These deaths result in more than $30 billion in direct healthcare expenses and indirect income losses each year.[1] As a result of these statistics, hospitals and regulatory agencies, such as The Joint Commission, have reevaluated the importance of patient safety in healthcare. Also, these agencies have recommended that medication and patient safety principles be introduced early in the education of healthcare professionals.[2] For example, the Institute of Medicine, the Association of American Medical Colleges, the American Association of Colleges of Nursing, and the Accreditation Council for Pharmacy Education (ACPE) have all advocated for and emphasized greater inclusion of patient safety principles and competence in the curriculums of their academic institutions.[3-6] The ACPE's accreditation guidelines, in particular, stress patient and medication safety as core elements of pharmacy education and specifically state in Standard 9 that a pharmacy curriculum must prepare graduates to ensure optimal patient safety.[3]

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As a means to fully address ACPE accreditation standards and prepare students to be proficient in the skills of patient safety, the Jefferson School of Pharmacy developed a required medication safety course for second-year doctor of pharmacy (PharmD) students. This course is designed to establish the principles of medication safety through classroom lectures and out-of-class readings, as well as to facilitate the application of newly learned skills in teams using structured root cause analysis activities. A root cause analysis is an essential tool for evaluating safe medication use in healthcare settings and can be used to analyze and identify faulty medication-use systems implicated in errors using a systematic approach. In the medication safety course at the Jefferson School of Pharmacy, the root cause analysis also serves as a measure of students' comprehension and ability to apply essential medication and patient safety skills. This article describes the design and implementation of a root cause analysis activity in a required medication safety course.

DESIGN

Medication Safety is a 2-credit course required for second-year PharmD students delivered in 12 weekly 2-hour class sessions in the fall semester. The first part of the course (classes 1-5) was designed to introduce students to essential medication safety principles, including the culture of medication safety, agencies dedicated to safe medication practices, drug safety legislation, error-reporting systems, and common errors associated with poor packaging and labeling, inappropriate dose expressions,

and unapproved abbreviations. These concepts were reinforced as students were asked to complete out-of-class reading assignments from the current medication safety literature and answer open-ended questions in online quizzes that were designed to assess students' ability to apply baseline medication safety knowledge to contemporary issues. The delivery and reinforcement of these principles were necessary to prepare students for the second part of the course (classes 6-12) in which the model for evaluating individual medication errors or root cause analysis was emphasized.

The root cause analysis used in this course followed the approach described by the Institute for Safe Medication Practices (ISMP),[7] which emphasizes that the cause of a medication error is rarely the fault of a single person practicing within the vast and complex medication-use process. Rather, medication errors are often the result of a breakdown of at least 1 of 10 key elements that affect medication use. These key elements are interrelated subprocesses of the 5 core steps in the medication-use process: medication prescribing, order processing, dispensing, administration, and monitoring. When performing a root cause analysis, the following 10 key elements[7] that affect the core medication use steps should be thoroughly evaluated to determine the cause of the error:

- Patient information that is accessible and accurate
- Drug information that is accessible, accurate, and usable
- Communication between providers that is consistent and not complicated
- Drug labeling and packaging that facilitates safety and the consistent use of appropriate nomenclature
- Drug storage and stock that facilitates appropriate distribution with standardized drug concentrations and administration times
- Drug device acquisition methods that ensure proper use and monitoring
- Work environments that provide an appropriate workload and limit unfavorable conditions such as poor lighting, noise, and interruptions
- Staff competency that is assessed and can be improved with opportunities for continuing education
- Patient education that is accurate and provided consistently
- Medication use processes that are evaluated for quality and can be redesigned to improve safety

These key elements and the proper systematic method for evaluating them during a root cause analysis were introduced to students in a lecture in class 6. This lecture was supplemented by out-of-class reading assignments of literature from ISMP. During class 7, at the midpoint of the course, students were separated into teams of 5 to 6 students, with each team receiving a unique medication error case to complete in class. All medication error cases assigned to students were based on real medication errors reported in the medical literature. Within their teams, students had to provide a complete written assessment of their case by first identifying the medication error present (ie, wrong drug, wrong dose, wrong route, etc) and then evaluating each of the 10 key elements to determine the root cause(s) of the error. A written description of how the identified elements contributed to the error also had to be completed.

Following completion of the case, instructors provided timely, verbal feedback to student teams outside of class on their performance and presented them with a second unique case to be completed outside of class. For the second case, the same student teams were given 4 weeks to perform a root cause analysis by identifying the medication error and the contributing key elements. In addition, students were asked to critically evaluate these contributing elements, identify ways to correct them and ultimately synthesize a plan for preventing the error from occurring in the future. Error prevention strategies were the focus of in-class lectures and out-of-class readings during this time period (classes 8-10). Emphasis was placed on preventing errors in special healthcare populations (ie, oncology and pediatrics) and when using high-alert medications. For their final assessment held during classes 11 and 12, student teams formally presented their findings to their instructors and peers.

EVALUATION AND ASSESSMENT

Two structured grading rubrics, 1 for each of the root cause analysis assignment, were designed to evaluate student performance and competency. Each rubric assessed student teams on achievement of the course objectives specific to medication error evaluation. These included the abilities to identify the medication error in a patient case and to identify systematically and describe deficiencies in any of the 10 safe medication-use elements contributing to the error (Table 1). The rubric for the second root cause analysis also assessed the student team's ability to develop a plan to improve or eliminate identified deficiencies in an effort to prevent the medication error from recurring. Within their teams, students also evaluated their peers on their contributions to each root cause analysis project.

Three classes of pharmacy students (n = 211) completed the Medication Safety course from 2009 to 2011 (37 total teams of 5 to 6 students each) and 74 root cause

Table 1. Learning Objectives for a Medication Safety Course

Discuss the history and evolving culture of medication safety.
Identify internal and external programs for the reporting of adverse drug events, near misses, and dangerous situations.
Describe the role of specific agencies in the evaluation of medication errors and the implementation of safe medication practices.
Classify medication errors according to their source and determine the causes of errors through the use of a root cause analysis.[a]
Define the ten key elements provided by the Institute for Safe Medication Practices that impact safe medication use.[a]
Given a medication error case, systematically identify and evaluate any deficiencies among the ten key safe medication use elements contributing to the error.[a]
Given a medication error case, develop a plan to prevent the medication error from recurring.[a]

[a]This objective was specifically addressed by the root cause analysis assignments.

analysis assignments were assessed. Overall performance on both root cause analysis assignments was high in each class (Table 2), with all teams demonstrating the ability to identify the medication error present in each assignment. Furthermore, 28 (76%) of the 37 teams received full credit on the first assignment for their identification and evaluation of key elements contributing to the medication error (average team score 92%, range 83%-100%). Performance on the second root cause analysis was also high, with 9 (24%) teams receiving full credit for all components including error identification, key element evaluation, and error prevention plan development (average team score: 90%, range: 82%-100%).

One hundred sixty-nine (80%) students evaluated the course and assignments. Students consistently rated the root cause analysis projects as positively contributing to their learning comprehension and ability to apply medication safety principles. Approximately 98% of students agreed or strongly agreed that the course improved their medication safety skills (1.5% neither agreed nor disagreed, 1% disagreed) and 98% agreed or strongly agreed that the root cause analysis assignments contributed to their learning (2% neither agreed nor disagreed).

DISCUSSION

Ensuring safe medication use is a critical role of pharmacists. However, formal courses dedicated to the principles of medication safety and error prevention are not present in all pharmacy college and school curricula. A 2001 survey found little structure or uniformity in the delivery of medication safety principles among US colleges and schools of pharmacy.[8] They also found that in many cases there was no instruction provided on identifying several major safety elements such as human errors, medical errors, and medication errors. Furthermore, only 38% (13/34) of respondents provided instruction on evaluating medication errors using root cause analysis, and most of those (9/13) occurred through classroom lecture rather than through applied skills training. A 2007 study of the integration of the "science of safety" into pharmacy curriculums found that basic medication error principles are not taught consistently to pharmacy students.[9,10] The document also identifies several gaps in safety education including medication error identification, the application of error-evaluation skills using root cause analysis, and discussion of medication safety organizations such as ISMP.[9,10]

Given the important role pharmacists play in medication safety, gaps present in the education of pharmacy students should be addressed. The medication safety course described in this paper addresses these gaps and more specifically facilitates the application of essential medication safety skills using root cause analysis assignments. Both root cause analysis assignments were designed to challenge students to critically evaluate the causes of medication errors using the systematic approach outlined by ISMP. The second root cause analysis also allowed for the synthesis of new information as students developed a plan to prevent error recurrences. These skills are essential to pharmacists and help students newly introduced into pharmacy practice better understand the medication use system. Understanding the key elements to safe medication use and medication error prevention enhances a student's ability to ensure safe medication practice now and after graduation and licensure.

The root cause analysis assignments were structured activities that placed students in the role of a pharmacist on a medication safety team. The structure of the activity combined with prompt assessment and feedback from instructors contributed to effective learning and retention of information and skills.[11] In addition, students learned to communicate effectively and work within a team. While this strategy attempted to mimic "real world" medication safety practice, all of the students were pharmacy students, as opposed to the more common multidisciplinary medication safety committees found in healthcare settings.

Overall, students performed well on root cause analysis assignments and rated the activities high on course evaluations. While limited by the retrospective design of a final course evaluation, the findings demonstrate a consistent appreciation for the opportunity to apply safety knowledge and prevention skills to real medication error

Table 2. Major Elements Assessed in Root Cause Analysis Assignments and Associated Team Outcomes (N = 37)

Outcome	No. (%) of Teams That Achieved the Outcome	
	Assignment 1	**Assignment 2**
Error identification		
Group has provided a complete identification of the error	37 (100)	37 (100)
Group has provided a partial identification of the error	0	0
Group has not identified the error	0	0
Identification of error sources (key elements)		
Group has completely identified all sources of the error	32 (86)	35 (95)
Group has identified nearly all sources of the error	5 (14)	2 (5)
Group has identified a portion of the error sources	0	0
Group made no effort in identifying sources of the error	0	0
Evaluation of error sources (key elements)		
Group has completely evaluated all identified sources of the error	28 (76)	32 (86)
Group has partially evaluated identified sources of the error	9 (24)	5 (14)
Group has minimally evaluated identified sources of the error	0	0
Group made no effort in evaluating sources of the error	0	0
Strategies for error prevention[a]		
Group has identified error prevention strategies addressing all identified sources of the error	NA	28 (76)
Group has identified error prevention strategies addressing nearly all of the identified sources of the error	NA	6 (16)
Group has identified error prevention strategies addressing a portion of the identified sources of the error	NA	3 (8)
Group has not identified any error prevention strategies	NA	0
Potential problems with error prevention strategies[a]		
Group has identified potential problems with all error prevention strategies	NA	24 (65)
Group has identified potential problems with nearly all of the error prevention strategies	NA	10 (27)
Group has identified potential problems with a portion of the error prevention strategies	NA	3 (8)
Group has not identified potential problems with any error prevention strategies	NA	0

Abbreviations: NA = not assessed (ie, element was not assessed in assignment 1).
[a]Note: These elements were only assessed on the final root cause analysis assignment.

cases. In fact, the inability to apply safety skills to real error cases was a limitation to a previously described patient safety course.[12] In contrast, placing students in a community or health-system pharmacy to conduct medication error reduction projects has had some success.[13]

It is difficult to assess the overall impact this course will have on students' ability to contribute to medication safety as practicing pharmacists. While the course does provide a comprehensive overview of several essential principles and facilitates the application of error evaluation and prevention skills, its overall application is limited by the inclusion of only pharmacy students. Medication safety is a multi-disciplinary practice and future courses should seek to include medical students as well as other health professions students.

CONCLUSION

Ensuring safe medication use is an essential function of pharmacists. The development of a required medication safety course with a particular emphasis on the application of error evaluation and prevention skills can contribute to meeting ACPE standards and prepare graduates to ensure optimal patient safety.

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