Drug Monograph Project as an Effective Active Learning Exercise in a Drug Information Course

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Abstract

Background: Ability to critically analyze health sciences literature and accurately communicate evidence-based therapeutic recommendations is a competency essential for successful professional performance. The objective of this study was to assess the effectiveness of a drug monograph project (DMP) in preparing pharmacy students for formulary activities in the setting of a simulated health system P&T committee meeting in a drug information course.

Methods and findings: Effectiveness of the exercise was assessed through a-9-item student perception survey and 5 knowledge-based multiple-choice questions (MCQ) designed by the authors of this study and based on the course and DMP objectives. Both assessments were administered before and after the DMP. Fifty-nine students (69.4%) responded to the pre-DMP survey, and 77 students (90.5%) completed the post-DMP survey.The results of the post-DMP student perception survey showed statistically significant increase in mean scores for all nine survey questions. The response rate for the pre-DMP knowledge assessment was 65.9% and 91.7% post. The post-DMP knowledge scores were significantly higher on 4 of 5 items. Overall, post-DMP student feedback was positive. Students commented on the practical value of the DMP in creating drug monographs, increased understanding of the role of a P&T committee, and working as a team.

Conclusion: This study demonstrated the effectiveness of a drug monograph project as an active learning exercise on pharmacy students preparedness for formulary activities. A significant improvement in students' readiness was observed. Drug monograph projects should be incorporated into drug information courses as an essential component.

Keywords: Drug information; Drug monograph; Pharmacy practice

Introduction

Ability to critically analyze health sciences literature and accurately communicate evidence-based drug information is a pharmacy practice competency essential for successful professional performance in any pharmacy setting [1,2]. Exercise in preparation of a formulary drug monograph for presentation at a Pharmacy and Therapeutics (P&T) committee is an important educational activity aimed at the attainment of this competency [3].

The concept of active learning relates to student engagement in higher-order thinking such as analysis, synthesis, and evaluation [4]. Active learning practices have been widely accepted by pharmacy educators as reflected in the survey conducted by Stewart et al. [5]. However, a mock P and T committee meeting as an active learning exercise has been reported by only 7% of ninety schools of pharmacy [6]. The published reports of mock P&T committee meetings describe exercises in pharmacoeconomics or P&T activities other than preparation and presentation of drug monographs [7-10]. The objective of this study was to assess the effectiveness of a drug monograph project (DMP) as an active learning exercise in preparing pharmacy students for formulary activities in the setting of a simulated health system P&T committee meeting.

Method

Eighty-five second year pharmacy (P2) students, enrolled into a required 2-credit Drug Information and Pharmaceutical Informatics course, were randomly assigned into groups of 8-9 members and were given eight weeks to create a drug monograph for presentation at a mock health system P&T committee meeting. Prior to the assignment, a didactic lecture covering composition and format of drug monographs, methodology of formulary drug product evaluation, and the role of drug monographs in formulary management was delivered. Each group prepared a monograph addressing one indication for a drug approved by the FDA within the past 6 years. Students were provided with a required monograph format, formulary scenario, sample drug monograph, and grading rubric.

They were expected to discuss clinical data from only one randomized controlled clinical trial since at this point in the curriculum, students had not been yet exposed to pharmacoeconomics and pharmacoepidemiology in depth. Task distribution within each student group was not influenced by faculty in order to foster student collaboration, teamwork and collective decision-making in preparation of formulary recommendation(s). Groups were required to submit their documents to a shared folder two weeks prior to presentation to allow for adequate review time.

Presentations occurred during class time in the last week of the course. Each group was allotted 7 minutes for their presentation to P&T members and class followed by a question and answer (Q&A) session. The mock P&T committee consisted of three faculty members role-playing P&T membership (e.g. physicians, nurses, pharmacy directors etc.). All faculty had extensive hospital and health system experience including participation in P&T committee meetings.The Q&A session utilized the Socratic method intended to stimulate analytical and critical thinking.

Effectiveness of the exercise was assessed through a 9-item student perception survey and 5 knowledge-based multiple-choice questions (MCQ) designed by the authors of this study and based on the course and DMP objectives. Both assessments were administered before and after the DMP. The assessments had not been previously validated. The survey measured student's confidence in preparing and presenting a drug monograph on a 5-point Likert scale ranging from "strongly agree (5)" to "strongly disagree (1)." A free-text item was added to the post-DMP survey where students could enter their comments and suggestions regarding future delivery of the project and the course. Five MCQs tested students' knowledge on the role of drug monograph in formulary management and P&T activities. Means were compared using paired t-test and proportions using the chi-square test. The study received exempt status from the University's Institutional Review Board (IRB).

Results

The pre-DMP student perception survey was completed by 69.4% of the students, and 90.5% responded to the post-DMP survey. The results of the post-DMP survey showed a statistically significant increase in mean scores for all nine items **(Table 1)**.

Table 1: Student Perception Survey.

Survey Question	Pre-DMP Mean (n=59)	Post-DMP Mean (n=77)	P-value
I understand the definition of a drug monograph.	3.69	4.47	p<0.001
I understand the role of drug monographs for use in formulary decision-making.	3.42	4.47	p<0.001
I am comfortable in identifying appropriate drug information resources in drug monograph creation.	3.56	4.42	p<0.001
I understand how to evaluate evidence for drug monograph preparation.	3.08	4.35	p<0.001
I am comfortable in creating a drug monograph.	2.69	4.13	p<0.001
I am comfortable presenting formulary recommendations in a P&T committee setting.	2.81	3.91	p<0.001
I understand how to apply informatics in the setting of formulary recommendation.	2.88	4.12	p<0.001
I am comfortable working in a team environment on a project.	3.9	4.19	p=0.011
I understand the role of a P&T committee in formulary management.	3.76	4.49	p<0.001

The lowest mean scores for pre-DMP were for the items involving creating a drug monograph (2.69), presenting formulary recommendations (2.81), and applying informatics in the setting of formulary recommendations (2.88). Pre-DMP, students seemed most comfortable with items involving the definition of a drug monograph (3.69), understanding the role of P&T in formulary management (3.76), and working in a team environment (3.9). Post-DMP, the lowest mean score was for the item presenting a formulary recommendation (3.91). The highest mean scores were for items involving the definition of a drug monograph (4.47), role of drug monographs for use in formulary decision-making (4.47), and understanding the role of P&T committee in formulary management (4.49).

The response rate for the knowledge assessment was 65.9% (pre-DMP) and 91.7% (post-DMP). The post-DMP scores were significantly higher on 4 of 5 MCQs **(Table 2).**

The pre-DMP MCQ with the lowest percentage of correct answers was the first question having to do with drug monograph structure and formulary recommendations (16.07%). The pre-DMP MCQ with the highest score of correct responses was the fourth question related to a case scenario involving the formulary review process (78.57%). In the post-DMP knowledge assessment, the lowest performing question was again the first question having to do with drug monograph structure and formulary recommendations (33.33%), although the increase compared to pre-DMP was significant (p=0.029).

The highest performing post-DMP question was the third question related to formulary decision-making (92.31%).

Table 2: Drug information assessment.

Assessment Question	Pre-DMP Correct Response (n=56)	Post-DMP Correct Response (n=78)	P-value
Which of the following statements is true? • A drug added to the formulary with monitored use means the drug will be monitored via a quality assurance study • A drug evaluation monograph allows a structured method to review major features of a drug • REMS information from the FDA should be included in the therapeutic indication section of a drug monograph	0.1607	0.3333	0.029
Which of the following statement(s) is/are true regarding a pharmacy and therapeutics committee (P&T)? • It is an advisory committee responsible for managing a formulary system • It educates health care professionals about optimal medication • It monitors adverse drug reactions and medication errors	0.625	0.8462	0.004
Which of the following statements is true? • Formulary inclusion of a drug is based on practitioner experience with the drug in his/her patients. • Formulary recommendation is based on the need for medication, outcome data, adverse effects, and cost. • The least costly decision for the institution should be recommended to the pharmacy and therapeutics (P&T) committee. • Members of a pharmacy and therapeutics (P&T) committee consist of representatives from pharmacy and nursing.	0.75	0.9231	0.007
You are a recent graduate who just completed a PGY1 residency. You have accepted a position at a local hospital medical center as a clinical pharmacist. One of your first assignments is to prepare and present a medication monograph on a new oral direct thrombin inhibitor that was just approved by the FDA. You will have 10 minutes to present at the next pharmacy and therapeutics committee meeting that will be held next week. The only piece of information that you are given is the non-formulary request to add this drug to formulary. All medications are reviewed for the outpatient pharmacy as well. Having reviewed the non-formulary request, what are the steps to add this drug to the formulary? • Review available literature to evaluate clinical evidence. • Seek input from specialists who have knowledge of the product. • Determine financial implications of product addition by reviewing cost information from purchasing agent.	0.7857	0.8846	0.15
Which of the following is/are source(s) of information used to develop a drug monograph? • Current package labeling for the drug • Current published clinical studies and abstracts • Online patient discussion forum for patients who have used the drug	0.625	0.8718	0.002

Discussion

Professional communication and health information retrieval and evaluation are two required elements of the didactic pharmacy curriculum according to Accreditation Standards. Drug information courses often focus on developing these skills. Reports on the impact of a drug monograph project on pharmacy students' preparedness for formulary activities is limited. This study evaluated the effect of a drug monograph project on student self-perception of skills and comfort level related to formulary-related activities and student performance on knowledge-based assessment. This study demonstrated the drug monograph project was effective in increasing pharmacy students' perceived preparedness for formulary activities and knowledge related to formulary-related content. This drug monograph project was in the setting of a simulated health

system P&T committee meeting embedded in a drug information course. It allowed students the opportunity to develop skills in identifying useful drug information resources for creation of a drug monograph, presenting a drug monograph, and working in a group setting. All items in the student perception survey demonstrated significantly increased mean scores when comparing the results of pre-and post-DMP student perception survey. Interestingly, significant increases were observed even for survey items that had fairly high mean scores pre-DMP such as the definition of a drug monograph and understanding the role of P&T committee in formulary management.

Although there was a significant improvement in student comfort level in presenting formulary recommendations in a P&T committee setting, the mean score for this survey item was still below 4 in the post-DMP survey. It was the survey item with the lowest mean score for both the pre-DMP and post-DMP

surveys. This finding indicates that students are generally not as confident in presenting their recommendations in comparison to other activities. The finding demonstrates the importance of continuing to offer this activity within this course and the need for more active learning exercises like the one described throughout the pharmacy curriculum.

In the knowledge-based assessment, the majority of items demonstrated a significantly increased percentage of students who answered the questions correctly indicating an increase in knowledge. The knowledge-based question with the worst student performance was the first question related to drug monograph structure. This indicates an area for improvement in the didactic lecture for expanding the explanation for each section of a drug monograph. In addition, the survey allowed students to provide free text feedback regarding the drug monograph project and any suggested areas for improvement. Overall, post-DMP student feedback was positive **(Table 3).**

Table 3: Post-DMP student feedback.

"It was really helpful that the questions were asked by the committee which made us think about the material."
"I think more time will be required to present the drug monograph project (at least 10 minutes)."
"I enjoyed working in a team to complete this project as well as learned how to search and use different types of sources to obtain information."
"This project was very helpful and I now fully understand the concept of a drug monograph and how a P&T committee works."
"This project prepared me for my winter IPPE rotation in the hospital setting."
"I do feel in the future it would be helpful for students to have an idea of the type of questions that are going to be asked during the presentation."
"One of the most practical assignments we've completed to date."

Students commented on the practical value of the DMP in creating DMs, increased understanding of the role of a P&T committee, and working as a team. Student feedback included recommendations to expand student presentation duration and provide more guidance on the types of questions that may be asked by the faculty panel representing the mock P&T committee. One of the limitations of this study was the lower response rate for the pre-assessment and student survey before the DMP. Also, cost analysis was omitted from the DMP rubric due to placement of this course prior to courses such as pharmacoeconomics in the pharmacy curriculum. In future delivery of this course, consideration will be given to expanding the student DM presentation duration, allotting increased class time for student presentations, and providing more guidance on questions to anticipate from the faculty panel.

Conclusion

This study demonstrated the effectiveness of drug monograph project as an active learning exercise on pharmacy students' preparedness for formulary activities. Requiring a presentation of a drug monograph in the setting of a simulated P&T committee meeting was beneficial for students. A significant improvement in both students' confidence and knowledge was observed. Presenting formulary recommendations was a skill that was scored lower by students' self-report indicating a need

to continue incorporation of this essential activity into future deliveries of this course.

References

1. Accreditation Standards and Key Elements for the professional program in pharmacy leading to the Doctor of Pharmacy degree,Accreditation Council for Pharmacy Education. Chicago, Illinois (2015)

2. Guidance for the Accreditation Standards and Key Elements for the professional program in pharmacy leading to the Doctor of Pharmacy degree.

3. Wang F, Troutman WG, Seo T, Peak A,Rosenberg JM (2006) Drug Information Education in Doctor of Pharmacy Programs. Am J Pharm Educ 70 :51.

4. Bonwell C, Eison J (1991) Active Learning: Creating Excitement in the Classroom. Washington, D.C.: School of Education and Human Development, Washington, USA.

5. Stewart D, Brown S, Clavier C, Wyatt J (2011) Active-Learning Processes Used in US Pharmacy Education. Am J Pharm Educ 75: 68.

6. O'Sullivan T, Phillips J, Demaris K (2016) Medical literature evaluation education at US Schools of Pharmacy. Am J Pharm Educ 80: 5.

7. Fujisaki B, Marcus K (2008) Simulating a pharmacy & therapeutics committee meeting as a capstone for a course in drug policy.

109th Annual Meeting of the American Association of Colleges of Pharmacy. Chicago, IL, USA.

8. Law A, Jackevicius C, Bounthavong M (2011) A monograph assignment as an integrative application of evidence-based medicine and pharmacoeconomic principles. Am J Pharm Educ 75: 1.

9. Cavanaugh TM, James L, Buring S, Cluxton R (2012) A pharmacoeconomics and formulary management collaborative project to teach decision analysis principles. Am J Pharm Educ 76: 115.

10. Keller D, O'Dell D, Skochelak S, Cochren GL, Schull SJ, et al. (2004) Teaching the basics of clinical pharmaceutical care: innovative pharmacy workshops at the University of Wisconsin and the University of Nebraska. Fam Med 36: S89-92.