American Journal of Pharmaceutical Education **2006; 70 (6) Article 132.**

RESEARCH ARTICLES

Retention of Compounding Skills Among Pharmacy Students

John G. Eley, PhD[a] and Christine Birnie, PhD[b]

[a]College of Pharmacy, Idaho State University
[b]Wegmans School of Pharmacy, St. John Fisher College

Submitted February 27, 2006; accepted May 26, 2006; published December 15, 2006.

Objective. To evaluate the competency of second-year pharmacy students to compound capsules from a prescription 12 months after completing a compounding course.
Methods. Students who completed the compounding course were given the same prescription they had been given 12 months earlier to compound metoprolol capsules. No warning of the second exercise was given and they were expected to prepare capsules and package and label the finished product. Performance was evaluated in an identical manner for both exercises based on the level of professional competency of a score of 80% or above.
Results. Eighty-seven percent fewer students achieved a score of 90% or more on the second exercise and 81% fewer students demonstrated the required competency.
Conclusions. Differences in scores on the first and second exercises indicate that pharmacy students' level of competency and retention of knowledge with respect to compounding capsules is not adequately retained after a 12-month hiatus.

Keywords: compounding, assessment, evaluation, curriculum

INTRODUCTION

Of 77,992 drug exposures reported in 2005 at a regional poison control center in Omaha, 0.05% were the result of pharmacy prescription errors. Of these, 50% were medication substitution errors, 42.5% were labeling errors, and 7.5% were compounding errors consisting of incorrect dilution or capsule preparation. Of these compounding errors, 100% resulted in overdose, 67% of which involved a drug prescribed to children and had the most serious outcomes of all pharmacy errors.[1] This same year, an incident in Texas involved a 1000-fold overdose of clonidine given to a 5-year old child.[2] The serum concentration of clonidine 17 hours post ingestion was 64ng/ml. The intoxication was traced to a pharmacy compounding error in which milligrams were substituted for micrograms.[2]

Flynn and colleagues conducted an observational study of the accuracy of intravenous admixture compounding, including total parenteral nutrition compounding, at 5 different hospitals in 5 regions of the country and rated in size from 400 to 815 beds. Errors were defined as: use of an unauthorized drug, wrong dose, wrong base solution and volume, omission of a component, wrong delivery form, wrong reconstitution procedure, and wrong technique of preparation. A total of 145 errors occurred out of 1679 parenteral doses prepared, for a mean overall error rate of 9%.[3]

Compounding errors are an emerging and serious problem particularly in the larger chain community pharmacies where the workload is high and mistakes are more likely to occur. With the employment of technicians in pharmacies to physically compound medications, pharmacists will need to take on a role that will require more administrative and logistic support in supervising the filling of prescriptions.

Pharmacists hold a unique position as health professionals who are formally trained in compounding medications and licensed to dispense them. Consequently, they are expected to possess the knowledge and skills necessary to compound extemporaneous preparations. In the last decade, the percentage of compounded prescriptions represented approximately 11% of all prescriptions dispensed, which is a tenfold increase in the percentage of such prescriptions dispensed in the previous decade, a trend that is likely to continue.[4] The requirement for individualized drug therapy for patients is being realized and is resulting in a rise in patient-specific prescriptions and the compounding of medications that are not commercially available.[5]

The Food and Drug Administration (FDA) has shown concern that compounded preparations are likely to be of lower quality than manufactured medicinal products.[6]

Corresponding Author: John G. Eley, PhD. Address: College of Pharmacy, Idaho State University, Pocatello, Idaho. E-mail johneley@otc.isu.edu

The general trend in academia (and within the PharmD courses) has been to concentrate on the role of the PharmD graduate towards clinical health care; however, 5 of the current 37 North American Pharmacist Licensure Examination (NAPLEX) competency statements in the Candidates Review Guide include the word ''compounding,''[7] which suggests this is an important competency area for students to achieve before graduation.

The 2004 Center for the Advancement of Pharmaceutical Education (CAPE) Outcomes recommends that health care providers, including personnel in pharmaceutical care, provide, assess, and coordinate safe, accurate, and time-sensitive medication distribution and improve therapeutic outcomes of medication use.[8]

The article ''Application of USP-NF Standards to Pharmacy Compounding'' clearly states that if pharmacists prepare medications named in the United States Pharmacopiea – National Formulary (USP-NF), these preparations must meet USP-NF standards for strength, quality, and purity, and this includes adherence to ingredient standards and/or recipes provided in the compendia for their preparation.[9]

Emphasis within the PharmD curriculum needs to be placed on the extent of practical compounding taught and also at what time within the 4-year PharmD program it should be placed. Compounding laboratories need to be an integral part of the first-year curriculum and span both semesters to ensure better retention.[1] This would lead to a greater understanding by creating an opportunity to enforce early learning which, as it stands, does not appear to be effective if there is a 3-year hiatus.

Some colleges and schools devote 1 academic year to compounding skills while others devote only 1 semester in the first year of the PharmD program and that is the only formal training provided. This lack of compounding experience for a period of 3 years or more is sometimes compensated for by students receiving additional training related to compounding in their experiential programs and postgraduation.

Based on these concerns, the objective of this study was to determine whether students retain competency in compounding a particular medication 1 year after successfully completing the required compounding component of a PharmD curriculum. Our hypothesis was that students do not retain the required professional knowledge and competency in compounding after 1 year because they are not exposed to elements within this discipline throughout the pharmacy curriculum.

METHODS

Students from the compounding course were given an exercise to prepare metoprolol capsules from a prescription—the same laboratory exercise given to them 1 year earlier. All needed chemicals and equipment were such that could be found in a college or school of pharmacy compounding laboratory. Class III prescription balances (The Torsion Balance Co., Clifton, NJ), were used for weighing. Metoprolol tartrate tablets, Lopressor, 50 mg (Novartis, Cambridge, Mass), clear gelatin capsules, size 0, 1, and 2 (Eli Lilly & Co, Indianapolis, Ind) and anhydrous lactose (Spectrum Chemicals, Gardena, Calif) were provided. The project was approved by the Institutional Review Board of Palm Beach Atlantic University under the code of Federal Regulations 45 CFR 46.

During the previous year, while taking a 14-week course entitled *Pharmaceutical Care Laboratory*, 62 students successfully completed a laboratory session on metoprolol capsule preparation. One year later, 30 students from the compounding course, now in their second-professional year, volunteered to participate in a study involving a compounding exercise. The volunteers had no knowledge of the purpose of the study. The exercise was held during a free period and was not part of the curriculum.

The students were given the same exercise on metoprolol capsule preparation and the same instructions they had been given the previous year. During the allotted 90 minutes, the students were expected to translate a prescription, prepare capsules as indicated, package and label the finished preparation, and write a report. The report should have included accurate calculations required to produce the metoprolol capsules, the size of gelatin capsule required, a description of the actual method of compounding and weighing necessary, a description of the finished product, a label and a suitable packaging process, instructions to the patient, and any subjective comments the student might think relevant. The prescription and procedure to be followed were the same as for the first exercises except the time allowed for completing the second exercise was 50% longer (90 minutes instead of 60 minutes) because the students were given no warning. Also, the initial exercise had been preceded by a pre-laboratory instructional period on capsule preparation, whereas the second exercise was not.

The prescription contained the following relevant information: ''Rx. Metoprolol, 15 mg; Dtd Caps #4; Sig 1 cap BID.'' A table comparing drug substance to capsule size and capacity was provided as well as the following written instructions: ''You receive a prescription for metoprolol capsules, 15 mg, #4. The commercial tablet (Lopressor) contains 50 mg of metoprolol tartrate. You are to prepare enough powder for 4 capsules using lactose as an excipient and choose a suitable size capsule.'' Students were then expected to adhere to the following

general procedure, which also constituted the final report: (1) calculate the number of metoprolol tartrate tablets required and reduce to powder; (2) calculate and weigh the lactose required; (3) choose a capsule size; (4) calculate the amount of powdered tablet plus lactose for each capsule to give a strength of 15 mg metoprolol and weigh out; (5) fill and weigh capsules; and (6) dispense in the appropriate container with a label. Students were given access to textbooks in the laboratory library.

Evaluation of the final preparation and report was conducted in a manner consistent with the first exercise. The evaluation tool consisted of the finished preparation, label, written compounding directions, and documented calculations, each of which counted 20% of the overall grade. A documented use of the drug contributed 4%, prescription documentation contributed 6%, and the remaining 10% was given for the completion of the report and preparation within the time allotted. Points were deducted for each error. The participants were familiar with this documented format and the percentage of points allotted for each section. The total scores from each exercise were compared and analyzed. Statistics were obtained using *Sigma Plot 2000* software (Systat Software, Inc., San Jose, Calif, 2000). The standard deviation, standard error, and confidence intervals used to compare exercises 1 and 2 have been included. Student *t* test was used to determine whether the means were significantly different.

RESULTS

The grades obtained in the original exercise and the second exercise are shown in Figure 1. A minimum score of 80% on the second exercise indicated that the student had maintained competency. In the first exercise, 16 students (53%) achieved a score of 90% or higher, while in the second exercise, only 2 students (7%) achieved this score, an 87% reduction. Furthermore, 11 students (36%) achieved a score betweeen 80% - 89% in the first exercise, while only 3 students (10%) achieved this score in the second exercise, a reduction of 72%.

In both exercises, 2 students achieved a score between 70% - 79.5% (C grade). In the first exercise, no students received a score between 60 % - 69.5 % (D grade), whereas in the second exercise 10 students had scores in this range, an increase of 33%. While only 1 student failed exercise 1, 13 students failed exercise 2, an increase of 92% and an overall 43% failure rate in exercise 2.

Only 5 students (17%) demonstrated a competency level of 80% in the second exercise, while 27 students (90%) demonstrated this competency level during the first exercise, an 82% reduction in the number of students whose compounding skills were adequate.

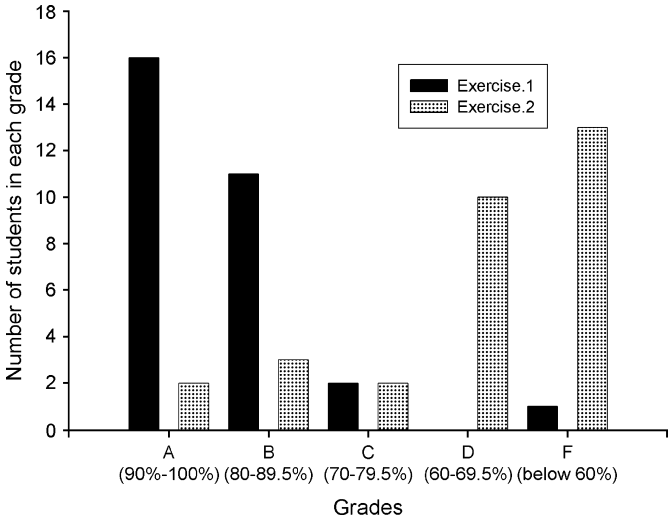

Figure 1. Comparison of grades PharmD students received on the same compounding assignment completed while taking a compounding course (exercise 1) and after a 12-month hiatus from compounding instructions (exercise 2).

The mean score was 89.0 ± 10.5 for the first exercise and 63.0 ± 13.7 for the second exercise. Confidence levels of 99% were 5.3 and 6.9 for the first and second exercises, respectively. Student *t* test values were 8.2, indicating a probability of less than 0.001, evidence of a significant difference between the means.

Overall, during the second exercise, most of the errors students made were in preparing an accurate dose for each capsule. Since the drug source was a manufactured tablet, 41% of students neglected to take into account the excipients within the commercial tablet formulation. Additionally, 32% of students did not accurately assess the amount of lactose to be added to each capsule, which resulted in an incorrect quantity in each capsule and an unsatisfactory final product.

DISCUSSION

The first capsule compounding laboratory exercise was given during the second semester for P1 students as part of a 12-week compounding course. The second exercise was given approximately 1 year after completion of that course. The students were, therefore, in the second semester of their second year and none were on a practice experience when the second exercise was conducted.

In a session completed during their compounding laboratory course the year before, students had prepared 14 capsules containing 15 mg pseudoephedrine, 4 containing 200 mg ferrous sulfate, 5 containing 50 mg propranolol, and 4 containing 81mg aspirin (from 325 mg aspirin tablets). They also attended a pharmaceutical calculations course that included instruction in capsule preparation.

They were exposed to the use of excipients throughout their pharmaceutics course in lectures and laboratories, which included capsule compounding calculations.

This study cannot be completed again at this particular school of pharmacy because the element of surprise would be lost, ie, students might attempt to prepare for the exercise. Although the results of the study were not surprising, the number of students who failed the second exercise is of concern. Students' comments made in an open discussion held 1 week after participating in the second exercise indicated that they found the exercise was fair although unexpected. They thought that this method of testing their retained knowledge was of value. Calculations required to complete the prescription caused difficulty and without the drug/capsule comparison table for reference, some would have been unable to complete the task. The table proved vital in helping students remember the procedure they had completed a year earlier. Once students had assessed the situation with reference to textbooks and tables, they were able to make a reasonbable attempt at completing the exercise. It was suggested that a similar exercise be conducted each year. Although the element of surprise would be lost, the exercise could still serve as an important measure of students' knowledge retention throughout the curriculum. Such a procedure could be included in yearly assessment examinations.

If our hypothesis is extrapolated from compounding capsules to other compounding procedures a significant number of pharmacy students do not retain the expected and required level of professional competency in pharmaceutical compounding 1 year after their formal training. Only 16.6% retained the required competency grade of 80% or above in the second exercise.

It must be stressed that this was a limited study carried out by one institution and to extrapolate our results may not be generally viable due to exceptions with individual students and individual colleges and schools of pharmacy. Nevertheless, it raises important questions about how much and how often pharmacy students need to be exposed to compounding exercises. A primary concern being the hiatus of practical compounding for at least 3 years before a pharmacy student becomes licensed to practice. Although students may receive additional compounding experience through experiential and on-site training after they graduate, it may be necessary to evaluate whether the amount of training in the curriculum is appropriate to adequately train PharmD students in this most basic, traditional, and exclusive skill. Inevitably a certain amount of knowledge is lost over a period of time, but it was not apparent that such a dramatic decrease in knowledge would occur after only 12 months.

Based on our results, and assuming similar results would be obtained in a large percentage of pharmacy schools, curriculum schedules and course content should be evaluated to ensure adequate competency in compounding is maintained throughout the entire PharmD curriculum. Emphasis on medicinal compounding would ensure adequate training of pharmacy students and it may be necessary in the future to include a compounding evaluation in each of the professional years at specific institutions. Alternatively the example already set by some pharmacy schools could be followed by interjecting compounding laboratories throughout the length of the professional curriculum.

Based on our findings, colleges should consider including instruction in compounding throughout the professional curriculum or place it towards the later part of the curriculum. This might cause problems with curriculum management, but would be advantageous in closing the time interval between the end of compounding laboratories and the beginning of actual practice.

CONCLUSION

Significant differences in scores on a laboratory exercise conducted 1 year after completing the same exercise as part of a compounding course suggest that pharmacy students do not adequately retain compounding knowledge and skills. Only 17% of the students were able to score the required competency grade of 80% or above when completing the second exercise in compounding metoprolol capsules. The results suggest that the same situation exists with respect to compounding other medications; however, there is no empirical evidence of this. Maintenance of a closer association with compounding and required calculations throughout the professional PharmD curriculum is recommended.

ACKNOWLEDGEMENTS

This project was completed at Palm Beach Atlantic University, School of Pharmacy. The authors wish to thank the University for their support of this project.

REFERENCES

1. Seifert SA, Jacobitz K. Pharmacy prescription filling errors reported to a regional poison center. *Acad Emerg Med.* 2006;9:400.
2. Romano MJ, Dinh A. A 1000-fold overdose of clonidine caused by a compounding error in a 5-year-old child with attention-deficit/hyperactivity disorder. *Pediatrics.* 2006;108:471-2.
3. Flynn EA, Barker KN, Carnahan J. National observational study of prescription dispensing accuracy and safety in 50 pharmacies. *J Am Pharm Assoc.* 2003;43:191-200.
4. Gosselin R. Pharmaceutical care: part of TQM? *Drug Topics.* 1995;139:10.

5. Allen LV. The art, science and technology of pharmaceutical compounding. 2nd ed. Washington DC: American Pharmaceutical Association; 2002:xvi-xvii.
6. Subramaniam V, Sokol G, Zenger V. Survey of drug products compounded by a group of community pharmacists. Food and Drug Administration; 2002. Available at: http://www.fda.gov/cder/pharmcomp/communitypharmacy/default.htm. Accessed October 20, 2002.
7. Newton DW. Compounding paradox: taught less and practiced more. *Am J Pharm Educ.* 2003;67:Article 5.
8. Bormel G, Valentino JG, Williams RL. Applications of USP-NF Standards to pharmacy compounding. *Int J Pharm Compounding.* 2003;7:361-3.
9. Beck DE. Pharmacy education: make a bet on the trends and wager a successful future career. ASHP Midyear Clinical Meeting. 2005. http://www.aacp.org/CAPE Accessed May 12, 2006.