Integration of Pharmacy Practice and Pharmaceutical Sciences in Developing an Elective Course in Contemporary Compounding

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ABSTRACT. A 3-quarter-hour elective course in compounding is offered to third-year pharmacy students. The objective for this course, which involves a lecture component and extensive laboratory experience, is to strengthen students' proficiency in prescription compounding. Dosage forms compounded include troches, lipbalms, suspensions, gels, ointments, suppositories, ophthalmics, and IV admixtures. Topics discussed target the need for compounding, compounding versus manufacturing, and legal aspects involved. Each student is given an independent formulation project. Students utilize library resources to prepare a written report, order required supplies, and compound the product. Approximately 92% of the students surveyed after taking the course felt more competent in their compounding skills and knowledge after taking this course. Students agreed that a combination of lectures, laboratories, and project

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helped them gain a better understanding of the subject. [Article copies available for a fee from The Haworth Document Delivery Service: 1-800-342-9678. E-mail address: getinfo@haworthpressinc.com]

INTRODUCTION

The Chicago College of Pharmacy (CCP) was founded in 1991 and is a college of Midwestern University, a private, health-professions institution located in the western suburbs of Chicago, Illinois. CCP offers both a three-year Bachelor of Science in Pharmacy degree and a four-year Doctor of Pharmacy degree.

The objectives of the CCP curriculum include the following:

- to provide a comprehensive background in the basic pharmaceutical sciences as a foundation for practice,
- to provide experiential instruction in the art and science of pharmacy,
- to sensitize students to the high ethical standards of a pharmacist as a member of a health-care team,
- to provide the students with an appreciation of the need for life-long learning to maintain professional competence, and
- to provide students with elective opportunities that strengthens preparation for practice in the varied environments.

Extemporaneous prescription compounding has historically been considered as a cornerstone in the professional practice of pharmacy, as pharmacists have been compounding prescriptions for centuries. The mortar and pestle are universally recognized as a symbol of the pharmacy profession. Compounding patient-specific and commercially unavailable dosage forms allows the pharmacist to provide optimal patient care and improve compliance. Pharmacists acquire these unique skills through extensive training and education obtained in pharmacy school regarding pharmaceutical dosage forms, chemical structures of drugs, drug stability and interactions, incompatibility information, and storage.

At CCP, pharmacy students take courses in their first and second professional year in which they acquire basic skills in pharmaceutical compounding; course outlines for these courses are included in Appendix A. The courses include:

Pharmacy 360 (Pharmaceutical Calculations), Pharmacy 361 (Pharmaceutics I), and Pharmacy 362 (Pharmaceutics II): The students take these courses in their first professional year. The students in the two

Desai et al. 41

pharmaceutics courses take a total of ten 4-hour formulation design and compounding wet labs.

Pharmacy 482 and 483 (Applied Pharmaceutical Care): The students take these courses in their second professional year. The students participate in four 2-hour compounding wet labs preparing nonsterile dosage forms and five 2-hour wet labs preparing sterile dosage forms.

Due to the recognized importance of pharmaceutical compounding in the professional practice of pharmacy and to meet the stated objectives of the CCP curriculum, an elective course entitled "Contemporary Compounding" (Pharmacy 564) was developed. During the fall quarter of their third professional year, students are offered this ten-week, 3-quarter-hour elective course which is taught jointly by the faculty in the departments of pharmacy practice and pharmaceutical sciences.

COURSE DESCRIPTION

Contemporary compounding was designed for students who wish to develop an expertise in the field of extemporaneous compounding. The course's stated objectives include strengthening the students' proficiency in prescription compounding by utilizing hands-on experience, stimulation of critical-thinking by the student, and development of problem-solving skills. The course includes a one-hour weekly lecture discussing topics and issues in pharmaceutical compounding and four hours of wet lab per week.

Classroom Discussion: Topics of current interest in pharmaceutical compounding and other topics that help develop student confidence in compounding are discussed with the students in a lecture cum dialog format. The topics include:

- the need and importance of pharmaceutical compounding
- · legal aspects related to pharmaceutical compounding
- compounding versus manufacturing
- · formulation and procedural development
- general guidelines for compounding nonsterile and sterile dosage forms
- chemical incompatibilities
- stability and expiration dating for compounded prescriptions
- · review of pharmaceutical calculations

During the one-hour lecture the students receive the prescriptions which are to be compounded in the following week in the laboratory. The

students are required to complete all calculations and determine the optimum compounding procedure, labeling instructions, and expiration date prior to coming to the laboratory. The objective of this approach was to give the student autonomy and practice in retrieving pharmaceutical compounding information from suggested reference books.

Laboratory Exercises: Laboratory exercises included the preparation of topical products, oral solutions, suspensions, capsules, troches, suppositories, ophthalmic drops, IV medications, and cosmetics such as antidandruff shampoo and fluoride toothpaste gel. The products along with the write-ups were to be submitted at the end of each lab period for evaluation of calculations, compounding procedure, product quality, and accuracy of the label. If there was a significant error in either the product or label, the student was required to fill out an Incident Report Form explaining the error (Appendix B). In order to give the student practice in documentation, the student is required to keep an extensive compounding log book and record information such as prescription number, the date of making the product, initials of the compounder, expiration date of the product, as well as the name and amount chemicals used, the manufacturer or the source of the chemical, and its expiration date. Appendix C includes an outline of the various laboratory topics covered in the course.

Assessment of Student Performance: Student performance is assessed based on laboratory assignments, a laboratory practical, workshops, class assignments, and a midterm and a final examination. Laboratory work and projects constituted approximately 66% of the grade. The midterm and final examinations as well as other assignments were given to students as take-home exercises.

Practice Assignments/Workshops: The purpose of the assignments/ workshops was to improve the students problem-solving skills and expose the students to questions on a variety of topics in compounding, compatibility issues, and calculations which are considered important in practice. These assignments would also aid the students in studying for the state board licensing examination. One of the workshops given to the students was intended to give students experience in identifying legal or documentation errors and omissions on prescriptions. Another workshop dealt with IV incompatibilities and was designed to give the student practice in retrieving IV compatibility information from reference books. Students were responsible for identifying and correcting the incompatibility in the prescriptions and compounding the final product after incorporating the necessary changes after checking with the prescriber (instructor).

Laboratory Practical: During the third week of the course, students were given an independent project and assigned a prescription for their

Desai et al. 43

laboratory practical. The student was responsible for researching and developing a compounding procedure, ordering all the necessary supplies needed to formulate, compounding and dispensing the product, and developing a pricing strategy to charge for the final product. This was done in order to allow the students to develop critical thinking and problem-solving skills. This product would be compounded as the final laboratory exam exercise during the tenth week of the course.

STUDENT EVALUATION OF THE COURSE

Contemporary compounding has been offered as an elective course since the fall of 1994. At the end of the quarter, the students were asked to evaluate the course through written comments and rating scales to determine the usefulness of the course and the ability to meet its stated objectives. The course was found to be very enjoyable and interesting by over 90 percent of the students.

Question: Why did you decide to take this elective course?

Responses:

- To improve skills in the area of extemporaneous compounding
- To increase confidence in the area of extemporaneous compounding
- To broaden the knowledge base and learn how to prepare different types of dosage forms
- To review pharmaceutical calculations
- To prepare for the NAPLEX examination

Question: What were some of the strengths of this course?

Responses:

The course:

- Enhanced skills and techniques in the area of compounding
- Increased confidence in this area
- Provided experience with a wide range of prescriptions
- Provided good preparation for professional practice and the NA-PLEX examination
- Provided good practice with calculations
- Had convenient and appropriately scheduled laboratories and lectures and adequate amount of time was given to complete the laboratory exercises

Question: What were some of the areas that needed more emphasis? Responses:

- Documentation skills
- Literature searching
- Selection of preservatives and excipients
- Incompatibilities
- General compounding procedures
- End-of-laboratory discussion and conclusion

Student responses to other selected questions is presented in Tables 1-3.

TABLE 1. Evaluation of Course Content.

Questions Percentage of Re		Respo	esponses		
	SA*	Α*	N*	D*	SD*
Did the course provide practice with relevant clinical examples?	38	54	5	3	0
Did the course stimulate critical thinking?	46	46	5	3	0
Was the course intellectually challenging?	49	43	3	5	0

*SA A N D SD SD Strongly Agree Agree Neutral Disagree Strongly Disagree

TABLE 2. Evaluation of Learning Objectives.

After taking this course		Percentage of Responses			
	SA*	Α*	N*	D*	SD*
I feel more sure of my compounding skills.	26	68	6	0	0
I feel more confident in calculations.	34	60	6	0	0
I feel better prepared to take the licensure exam.	23	57	20	0	0
I have a better understanding of the legal requirements.	11	49	40	0	0
I know how to approach a compounding prescription.	14	77	9	0	0

*SA A N D SD Strongly Agree Agree Neutral Disagree Strongly Disagree

Desai et al. 45

TABLE 3. Evaluation of Time Dedicated to Specific Compounding Topics.

Topics	Percentage of Responses			
	NE*	S*	TM*	
Oral Liquids	3	97	0	
Ointments	8	92	0	
Suppositories	6	94	0	
Aseptic Technique	14	78	8	
Lip Balms/Troches	3	97	0	
Expiration Dating	25	75	0	
Excipients	44	56	0	

*NE S TM
Not Enough Sufficient Too Much

CONCLUSION

"Contemporary Compounding" (Pharmacy 564) was received well by the students and met its stated objectives. This elective course is being offered every year to the third-year students who wish to fine-tune their compounding skills.

REFERENCE MATERIAL USED FOR COURSE DEVELOPMENT

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APPENDIX A

COURSE OUTLINES

Pharmacy 360 (Pharmaceutical Calculations) and Pharmacy 361 (Pharmaceutics I)

Filanti	Pharmacy 360 (Pharmaceutical Calculations) and Pharmacy 361 (Pharmaceutics i					
Week	Lecture Topics	Laboratory/Workshop Topics				
1	Introduction Chapter 1: "Some Fundamentals of Measurement and Calculations"* Chapter 2: "Interpretation of the Prescription," Appendix A: "Common Systems and Intersystem Conversion"	Workshop, Chapter 1 Workshop, Chapter 2 and Appendix A				
2	Chapter 4: "Calculation of Doses" Chapter 5: "Reducing and Enlarging Formulas" Chapter 7: "Percentage and Ratio Strength Calculations"	Workshop, Chapter 4 and Chapter 5 Workshop, Chapter 7				
3	Chapter 7: "Percentage and Ratio Strength Calculations" Chapter 6: "Density and Specific Gravity" Chapter 8: "Dilution and Concentration"	Workshop, Chapter 7 Workshop, Chapter 6				
4	Chapter 8: "Dilution and Concentration" Dosage Form Development and GMP Dosage Form Design	Workshop, Chapter 8				

Week	Lecture Topics	Laboratory/Workshop Topics
5	Chapter 12: "Some Calculations Involving Units, mg/mg, and Other Measures of Potency," Chapter 13: "Some Calculations Involving the Use of Prefabricated Dosage Forms" Chapter 9: "Isotonic Solutions" Dosage Form Design Preformulation	Workshop, Chapter 12 and Chapter 13
6	Chapter 9: "Isotonic Solutions" Chapter 10: "Electrolyte Solutions" Intermolecular Forces of Attraction, Solubility Dissolution	Workshop, Chapter 9 and Chapter 10
7	Chapter 10: "Electrolyte Solutions" Dissolution, Polymorphism Partition Coefficient and Diffusion	Workshop, Chapter 9 and Chapter 10
8	Chapter 1: "Some Fundamentals of Measurement and Calculations (Least Weighable Amount and Aliquot Method of Calculation)" Acid/Base Chemistry and Buffer Systems	Workshop, Chapter 1 Laboratory, Use of Prescription Balance Rx: Dusting powders
9	Stability Kinetics	Laboratory, Analytical Techniques
10	Introduction to Statistics in the Medical Sciences	Workshop, Acid/Base Chemistry and Stability Kinetics

^{*}Chapter numbers refer to the specific chapters in: Stoklosa MJ, Ansel HC, *Pharmaceutical Calculations*, 10th ed. Malvern, PA: Williams and Wilkins, 1996.

Pharmacy 362 (Pharmaceutics II)

Week	Lecture Topics	Laboratory Topics
1	Course Introduction and Lab Introduction Prescription Standards Solid Dosage Forms/Oral Products	Diazepam Oral Powder Hydralazine Oral Powder
2	Solid Dosage Forms/Oral Products Solid Dosage Forms/Dissolution Testing Liquid Dosage Forms/Single Phase System	Theophylline and Ephedrine Sulfate Oral Capsules Capsule Filling by Machine (Video Demonstration)
3	Liquid Dosage Forms/Interfacial Phenomena Liquid Dosage Forms/Multiple Phase System Liquid Dosage Forms/Rheology	Potassium Chloride Oral Syrup Hydrochlorothiazide Oral Suspension
4	Liquid Dosage Forms/Suspensions Liquid Dosage Forms/Emulsions	Castor Oil Oral Emulsion Mineral Oil Oral Emulsion
5	Semisolid Dosage Forms Rectal/Vaginal/Urethral Products	Hydrophilic Petrolatum USP Hydrophilic Ointment USP
6	Nasal/Aural Products Sterile Dosage Forms/Parenteral	Sulfur in Hydrophilic Ointment USP ZnO/Calamine in White Petrolatum Urea in Hydrophilic Petrolatum USP
7	Sterile Dosage Forms/Parenteral Sterile Dosage Forms/Ophthalmic	Progesterone/PEG Suppositories Aspirin/Cocoa Butter Suppositories Sterile Product Demonstration
8	Oral Sustained Release Dosage Forms Transdermal Products Ocular Insert/Implants/IUD	Epinephrine Eye Drops Novel DDS Product Demonstration
9	Nanoparticles/Liposomes Biotechnology Products	Cold Cream Gel
10	Radiopharmaceuticals	Compounding Laboratory Practical

Pharmacy 482 (Applied Pharmaceutical Care II)

Week	Lecture Topics	Laboratory Topics
1	Introduction Pharmacy Ethics	Rx Errors and Omissions Patient Assessment: Pharmacy Ethics
2	Pain Management Geriatric Counseling	Patient Assessment: Arthritis/Pain Management Patient Profile Review
3	Top 200 Quiz/Computer Lab Review (Capsules, Emulsions, and Expiration Dating)	Compounding: Capsule Rx, Patient Profile #15, Computer
4	Patient Assessment Pediatric Overview	Patient Assessment: Allergy/Vital Signs Compounding: Emulsion Rx
5	EENT The Fatal Swallow	Patient Assessment: Pediatric/EENT Compounding: Lozenges Rx
6	Top 200 Quiz/Lab Review Preservatives and Excipients	Compounding: Ophthalmic Rx, Patient Profile #16 with Phone Rx
7	Hypertension	Patient Assessment: Hypertension
8	Standard/Universal Precautions Lab Practical review	Patient Assessment: Psychiatric disorders
9	Compounding Laboratory Practical Top 200 Quiz	Blood Pressure Evaluations Patient Profile #13 with Phone Rxs
10	Rx Jeopardy Course Review	Patient Assessment: Physical Assessment Exam

Pharmacy 483 (Applied Pharmaceutical Care III)

Week	Lecture Topics	Laboratory Topics
1	Overview Reference Review	Home Health Care
2	IV Incompatibility	IV Incompatibility
3	Aseptic Technique	Aseptic Preparation
4	Reference Review Top 200 Quiz	Patient Assessment: Asthma Case Asthma Equipment and Technique Medication Profile Review
5	Nutrition	Patient Assessment: Nutrition/TPN
6	TPN Preparation Top 200 Quiz	TPN and IV Preparation
7	Patient Assessment: MI	Patient Assessment: Diabetes Equipment and Technique Medication Profile Review
8	Infectious Disease	Patient Assessment: ID/Pharmacokinetics Medication Profile Review
9	Neoplastics Chemotherapy Preparation	Chemo Preparation
10	Rx Jeopardy Course Review	Evaluation of IV Preparations Hospital Pharmacy Stations and Compatibility Stations Top 200 Quiz

APPENDIX B

PRESCRIPTION INCIDENT REPORT

1.	PHARMACIST, STORE NAME, AND ADDRESS:					
2.	PATIENT'S NAME:					
	Approximate Age: Sex: Phone No. ()					
	If patient is a minor child, provide names of both mother and father:					
	· · · · · · · · · · · · · · · · · · ·					
	Address: City, State, and Zip Code:					
	What was patient told by pharmacist or pharmacy personnel?					
3.	PRESCRIPTION NO Date Filled:					
	Prescription called for:					
	(NOTE: medication, strength, regimen)					
	Did patient take any of the medication?					
	If so, how much?					
	Patient's attitude/comments:					
4.	PHYSICIAN'S NAME:Phone No					
	Was the Physician (Instructor) contacted?					
	Physician's comments:					
5.	DESCRIBE THE INCIDENT:					
	What action has been taken to prevent a recurrence of this incident?					

APPENDIX C

COURSE OUTLINE

Pharmacy 564 (Contemporary Compounding)

Week	Lecture Topics	Laboratory Topics
1	Introduction to the Course and to Laboratory Exercises	Topical Products/Applicator Sticks Lip Balms Medisticks
2	Need for Compounding Legal Requirements	Topical Products Carbopol Gels Lotions
3	Topical Products	What is wrong with these Rxs? Identify and correct errors in some of the prescriptions and modify them. Compound these modified Rxs.
4	Oral Products	Oral Suspensions using tablets, capsules, solutions as the source of the active ingredient
5	Workshop: Identify Legal Errors	Troches and Lozenges (containing PEG or gelatin)
6	Rectal and Vaginal Products	Suppositories
7	Ophthalmic Drops	Ophthalmic Drops: Aseptic Technique
8	Aseptic Technique/Compatibility Issues	IV Preparations Detect the incompatibility (if any), correct the Rx and prepare it.
9	Cosmetics	Shampoos and Toothpastes Working with chemicals that may be hazardous
10	Compounding vs. Manufacturing	Lab Project and Practical