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INSTRUCTIONAL DESIGN AND ASSESSMENT

A Flowchart for Selecting an Ointment Base

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Objectives. To improve students' skills in selecting appropriate ointment bases through the development and implementation of a flowchart.
Design. A flowchart was designed to help students select the appropriate base for an ointment. Students used the flowchart throughout the semester in both dry and wet laboratory activities. At the end of the semester, students completed a dry laboratory practical that required them to select an appropriate ointment base and levigating agent.
Assessment. Student performance data from the year prior to implementation was compared to data for 2 years after implementation. Calculation, procedure, and labeling errors also were compared. Prior to implementation of the flowchart, 51 of 101 students selected the correct base. After implementation, 169 of 212 students selected the correct base ($p<0.001$). Calculation, procedure, and labeling errors were not significantly different.
Conclusion. Use of a flowchart to select an ointment base improved student performance when used in the context of a dry laboratory assignment.

Keywords: compounding, nonsterile compounding, ointment, decision-making flowchart

INTRODUCTION

As pharmacy practice evolves to meet the needs of patients and health care systems, extemporaneous compounding continues to be an essential tool in providing personalized pharmacy care. It is uncertain exactly how many prescriptions dispensed require compounding, but estimates of 1% to 2.3% have been made.[1] Thus, of the more than 3.7 billion prescriptions filled in 2011, approximately 3 million or more were compounded prescriptions.[2]

While compounding is regulated by state boards of pharmacy, the future of this practice is not entirely clear and it may eventually evolve into a specialty.[3] Regardless of the future of pharmacy compounding, all entry-level pharmacists are expected to have competence in basic sterile and nonsterile compounding. To ensure that pharmacy students are educated and trained to provide fundamental formulations, the National Association of Boards of Pharmacy (NAPB) and the Accreditation Council for Pharmacy Education have provided guidelines regarding coverage of this important skill in curricula.[4,5]

There is additional rationale for extemporaneous compounding to remain as a fundamental part of our curricula. A report of the American Association of Colleges of Pharmacy Council of Sections Compounding Task Force provides specific recommendations about the quantity of compounding education and resources needed, which are at least 4 credit hours and adequate budget to purchase supplies.[6] Compounding is a critical point where the basic and clinical sciences come together to create a customized product for a patient. It allows students to apply drug delivery concepts in a tactile experience. The practice of compounding connects pharmacy students to the history of pharmacy and an understanding of the role pharmacists have played and continue to play in providing customized medications. It is a multifaceted activity that requires more than a knowledge of basic compounding techniques. Attention to detail, calculations, and interpretation of medication orders are all skills that are concurrently reinforced while compounding. Acquisition and retention of these skills is challenging and compounding instruction can serve to facilitate students' learning.[7,8]

There are frequently several different ways to make an appropriate product, which leads to more than 1 correct answer, providing students with opportunities to problem solve and select the best of several possible options. The lack of a single process for compounding products, including semi-solids, and because most prescriptions will specify the active ingredients but leave the excipients and base selection to a pharmacist's discretion, poses

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challenges for students. Students often struggle when formulating an extemporaneous semi-solid product, particularly with the selection of an ointment base and a levigating agent. The goal of this study was to investigate if use of a flowchart for ointment base selection improved first-year pharmacy students' ability to select the appropriate ointment base for a dry laboratory activity.

DESIGN

The University of Minnesota pharmaceutical care skills (laboratory) course sequence consists of 5 semesters in a 4-year curriculum. All of the courses include sterile and nonsterile compounding and patient care skills development. The nonsterile compounding emphasis during the first semester of the course is on topical formulations. In first receiving any new prescription in this teaching laboratory setting, students are taught to verify (1) the need to extemporaneously prepare the product, considering the existence of the same or similar products that are commercially available; (2) the intended use and patient preferences that accompany this intended use, and (3) the appropriateness of the dose and dosage form. Following these steps, students determined the process for compounding the product, including selecting excipients that were consistent with the intended use, applicable patient preferences, and compatibility of the active ingredients. A flowchart was designed to help students make decisions about ointment base selection, through consideration of desired product properties, particle size reduction requirements, liquid/semi-solid compatibilities, and patient acceptance (Figure 1). The rationale for its creation was to help novice learners understand the various factors that needed to be considered when selecting an ointment base and making compounding decisions. The flowchart was reviewed by a pharmacist specializing in compounding and a pharmaceutics faculty member for accuracy, completeness, and practice validity.

Students used the flowchart throughout the first semester in both dry and wet laboratory activities. Each student was required to complete three 2-hour laboratory sessions in which they made 1 or 2 products. One dry laboratory activity was completed as a formative assessment at mid-semester. At the end of the semester, students completed a dry laboratory practical (they did not actually make the product) that required them to evaluate a prescription, perform calculations, document their procedure, including selection of an appropriate ointment base and levigating agent, and produce a label for the product. The prescription order was for a powder (zinc oxide) and aqueous solution (rose water) to be incorporated into an ointment base, which students needed to select. The instructors anticipated that students would select an anhydrous hydrophilic absorption base. Students were allowed to use their textbook and the flowchart as references during the dry laboratory assessment. The dry laboratory practical was evaluated using a rubric evaluating 3 components: calculations, procedure, and label. This was an abbreviated rubric adapted from a rubric students had used throughout the semester that also contained criteria for the documentation section (where the ingredients, lot numbers, and expiration dates were recorded) and for the product. As this exercise was a dry laboratory activity and the students did not make the actual product, these sections were not included. Each component was rated as exceptional, professionally acceptable, needs improvement, or likely harmful. Errors that could lead to a rating of "likely harmful" being assigned included any error that could have been detrimental to patient care. The evaluation data were collected via an online grading interface. If a "likely harmful" rating was assigned, the grader was required to note the specific error that was made. The grader also indicated what ointment base the student had selected if it was incorrect. To evaluate if the use of the flowchart impacted the students' selection of ointment base, this analysis compared student performance by 1 cohort who had not been given a flowchart (historical control group) with 2 cohorts of students who were given the flowchart. To assess if use of the flowchart resulted in other changes in student performance, label errors, procedure errors that did not involve base selection or levigating agent, and calculation errors between the groups were also compared as controls. Performance by students who were provided with the flowchart were compared to the previous year's class who were not provided with a flowchart using a chi-square analysis (SPSS, version 21, IBM, Armonk, NY). This study was determined to be exempt by the investigational review board.

EVALUATION AND ASSESSMENT

Performance data on the dry laboratory final examination from the first semester of the pharmaceutical care skills course was available for 3 years of students (313). One hundred ten of the students were enrolled in the course the year prior to implementation of the flowchart and served as the control group. In the subsequent 2 years, 212 students used the flowchart throughout the semester and served as the study group. For all years, the prescription order requested that students make an ointment, but also required the incorporation of water. The ratings of exceptional, professionally acceptable, and needs improvement on the calculations, procedure, and label portions of the assignment were collapsed together and compared using chi-square analysis to the number of likely harmful ratings. Reasons for assigning a likely harmful rating

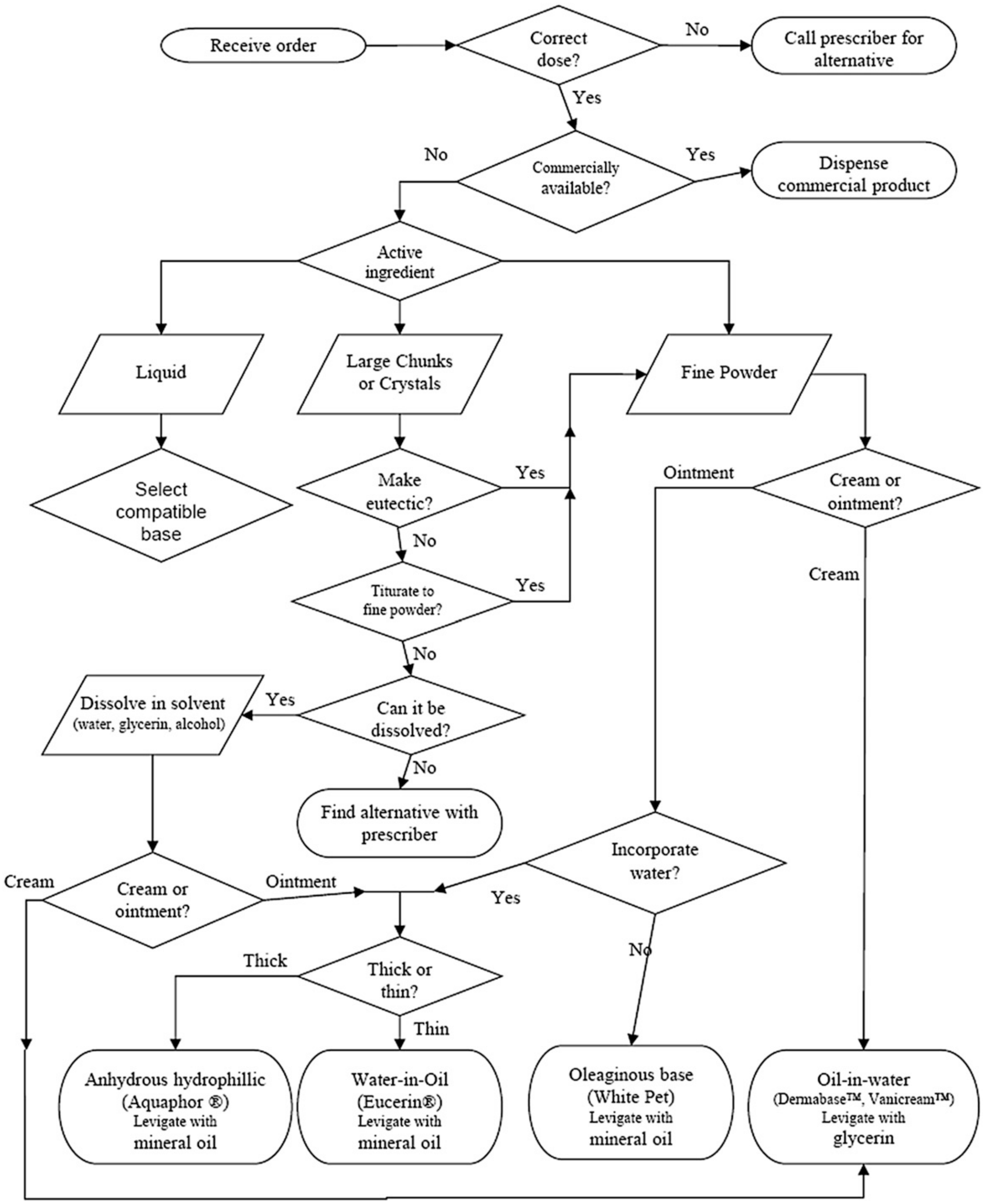

Figure 1. Ointment Base Selection Flowchart.

included unsafe writing practices (naked decimal points, trailing zeros), incorrect calculations, incorrect patient directions on the label, and an expiration date that was too long. When the wrong base was selected, students chose white petrolatum, which received a likely harmful rating because white petrolatum would not have been able to absorb the aqueous solution in the base. If the student chose an oil-in-water emulsion cream base (such as DermaBASE), a "needs improvement" rating was given because the product could have been compounded but it would have resulted in a water-washable cream rather than an ointment. For the analysis of the correct base selection, oil-in-water emulsion cream base and white petrolatum were collapsed together and compared to the number of students who selected the correct base (an anhydrous, hydrophilic absorption base such as Aquaphor) using chi-square analysis.

Fifty-one students (50.5%) in the control group correctly selected anhydrous hydrophilic ointment as the base. Of the 212 students in the study group who were given the flowchart to use, 169 (79.7%) selected the correct base ($p<0.001$). There were no significant differences between the groups for errors on calculations (7.9% control group vs 8.5% study group), procedures (19.8 control group vs 12.3% study group), or labeling errors (24.8% control group vs 21.7% study group).

DISCUSSION

The use of a flowchart to guide students through decision making is one method for scaffolding learning as pharmacy students develop their extemporaneous compounding skills.[9] It provides novice learners with some of the initial questions they should consider as they learn the science and techniques necessary to compound topical ointments. A challenge in helping students learn compounding principles is that there are usually multiple ways to create a pharmacologically usable product. The flowchart provides some direction and consistency to the expectations within a course and provides guidance to the teaching assistants and instructors responsible for grading. The flowchart does not encompass all considerations required for extemporaneous compounding, including determining if the active ingredient is stable, how the drug may be released in a given base, or how ingredients with unique properties might be incorporated (eg, eutectic mixtures). While not included in this version of the flowchart, these considerations were part of the course overall. Student learning may be enhanced if the flow chart is updated to include a broader scope of these and other excipient selection considerations. We plan to incorporate these features in the next version of the flowchart.

The decision to allow students to use their textbook and the flowchart during the dry laboratory assessment reflects the expectation that students should be able to access reference information in a timely fashion to devise a plan to compound a product. With the trend in pharmacy practice toward centralizing compounding to specialty centers, many pharmacists do not compound frequently and therefore it is an appropriate and realistic expectation that they will need references and resources to perform this skill in practice.

As students master basic compounding concepts and skills, they should be able to transfer their knowledge and skills to more complex compounded products. However, that was not tested in this project and would require additional assessment of student performance later in the sequence of skills courses or during the drug delivery course. One limitation to this study is the inability of the activity and data to assess whether the use of the flowchart increased retention of these concepts. Additionally, this study did not collect data to test if the use of the flowchart impacted student performance in other pharmaceutics courses that provided instruction on concepts of topical drug formulation. Prior to flowchart use in for laboratory practicals, the course director revised it to improve usability and clarity based on questions and comments from students. There were no substantial alterations to the dry laboratory practical assignments that provided the data for this analysis.

SUMMARY

The ointment-base selection flowchart improved student performance when used in the context of a dry laboratory assessment. This difference didnot appear to be the result of other factors as the rates of errors in calculation, procedure, or labeling were similar for students in the control and study groups.

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