American Journal of Pharmaceutical Education **2013; 77 (3) Article 58.**

INSTRUCTIONAL DESIGN AND ASSESSMENT

Assessment of the Accuracy of Pharmacy Students' Compounded Solutions Using Vapor Pressure Osmometry

William M. Kolling, PhD, and Timothy B. McPherson, PhD

School of Pharmacy, Southern Illinois University Edwardsville, Edwardsville, Illinois

Submitted May 31, 2012; accepted October 23, 2012; published April 12, 2013.

Objective. To assess the effectiveness of using a vapor pressure osmometer to measure the accuracy of pharmacy students' compounding skills.

Design. Students calculated the theoretical osmotic pressure (mmol/kg) of a solution as a pre-laboratory exercise, compared their calculations with actual values, and then attempted to determine the cause of any errors found.

Assessment. After the introduction of the vapor pressure osmometer, the first-time pass rate for solution compounding has varied from 85% to 100%. Approximately 85% of students surveyed reported that the instrument was valuable as a teaching tool because it objectively assessed their work and provided immediate formative assessment.

Conclusions. This simple technique of measuring compounding accuracy using a vapor pressure osmometer allowed students to see the importance of quality control and assessment in practice for both pharmacists and technicians.

Keywords: assessment, compounding, pharmaceutics, osmolality

INTRODUCTION

While pharmacists no longer compound individualized prescriptions to the extent that they did in the 1940s and 1950s, they are still called upon to manipulate commercially available products. For example, an infant may need a powder paper dosage form of a drug, while a child may require a special solution, and an adult may need an extemporaneous capsule.

The Joint Commission of Pharmacy Practitioners document on the Future Vision of Pharmacy Practice explicitly states that pharmacists will be responsible for providing patient care that ensures optimal medication therapy outcomes.[1] Because compounded drug products will always be a part of the therapeutic armamentarium, especially in subpopulations like pediatric and geriatric patients, pharmacists must have the necessary skills to fulfill their professional obligations to society. The contemporary professional focus on patient-centered care demands that the pharmacist demonstrate not only technical competence, but also personal responsibility for accuracy in these operations.

One of the *deep-learning* objectives in the Pharmaceutical Skills and Techniques course at Southern Illinois University Edwardsville School of Pharmacy was for students to understand the impact of unit operations on ultimate product quality. Deep-learning has been described as, "meaningful understanding of the material being studied."[2] Patient-centered care requires the pharmacist to take responsibility for optimizing patient outcomes, and therefore, even the simplest compounded preparation must be of the highest quality. To help meet this objective, in 2008 the faculty began using a vapor pressure osmometer for both formative and summative assessments of compounded solution compounding. This paper describes the implementation and use of the vapor pressure osmometer within the course over a 4-year period and its impact on course outcomes. One purpose of this formative analysis was for students to develop the skills necessary to compound solution dosage forms and to verify their quality. Another purpose was to provide immediate feedback to all students on their performance in order to maximize the educational impact of the exercise. Finally, this exercise inculcated in students the steps necessary to check the work of another pharmacist, or more likely, a technician assisting them.

Corresponding Author: William M. Kolling, PhD, School of Pharmacy, Southern Illinois University Edwardsville, 220 University Park Drive, Edwardsville, IL 62026. Tel: 618 650-5140. Fax: 618 650-5145. E-mail: wkollin@siue.edu

DESIGN

The Pharmaceutical Skills and Techniques course was first offered in 2008 to provide first-year pharmacy (P1) students with an introduction to the kinesthetic manipulation skills required of pharmacists. This required course is offered during the spring semester of the P1 year to approximately 80 students. The course consists of

2 arms: a calculations component (classroom based) and a laboratory component. Students participate in one 2-hour laboratory session each week. The laboratory arm focuses on the fundamental tasks of appropriate balance use, correct measurements of liquids with varying viscosity, powder mixing, and proper aseptic technique for parenteral manipulations. To ensure continuity in learning, relevant sections from the calculations component are incorporated into the laboratory exercises.

One of the primary goals of the course was for students to demonstrate proficiency in weighing and measuring skills. Historically, a student's compounding skills were assessed by evaluating a product's label and packaging, the organoleptic properties of the dosage form, and the student's written report. Analytical verification of the product contents was not performed. Thus, an exploitative student could turn in a sham product, thereby circumventing the objectives and goals of the compounding exercise. Furthermore, students had no useful feedback on their performance. Therefore, we designed laboratory exercises that could be objectively assessed.

The solution dosage form was used in developing the quantitative standards for the pharmaceutical skills course because it provides a great degree of pedagogical and assessment flexibility. Further, approximately 2.3% of prescriptions dispensed by independent community pharmacies are compounded and the most frequently compounded dosage form is the solution.[3,4] How a particular solution prescription is written determines the extent of calculation necessary to make the solution. The number and types of solution components determine the specific manipulations and equipment required for an accurate product. Three example solutions of increasing complexity are shown in Appendix 1.

Vapor pressure osmometry was chosen as the analytical method to quantitatively assess solution dosage forms. Osmolality is a measure of overall solution quality, as the total concentration of all solutes determines the osmolality value for a solution. The instrument is easier to maintain and much less costly than high-performance liquid chromatography systems. The fact that a single method is applicable to a wide range of solutions is another advantage of vapor pressure osmometry.

The vapor pressure osmometer functions by measuring vapor pressure depression via thermocouple hygrometry. It is a passive technique that relates electrical current and heat transfer. Vapor pressure depression is a function of the molar concentration of dissolved molecules or ions. The extended range instrument is accurate from 0 mmol/kg to 3500 mmol/kg, with a resolution of 1 mmol/kg. We learned that high viscosity solutions (some syrups) rapidly contaminated the sensor wire. The analytical head had to be removed from the instrument and thoroughly cleaned with the provided solutions prior to each laboratory session. It took approximately 1 hour to remove, clean, reinstall, and recalibrate the head.

The vapor pressure osmometer provided the osmolality value of the solution in mmol/kg directly. Therefore, no further interpretation on the part of the student was necessary. Students were required to calculate the theoretical osmotic load of the solutions they prepared for the purpose of self-assessment. When calculated correctly, this value was the absolute upper limit of the measurement. Students were reminded that solutions that were more concentrated than approximately 0.02 M had lower measured osmolality than the calculated theoretical value, so they could correctly interpret product labeling, especially on parenteral electrolyte products.

Laboratory Assignments

Two weeks of laboratory time were spent on developing students' solution compounding skills. Prior to the start of the laboratory section, the students were reminded that all of the handouts and instructional videos were available online. Students were expected to collaborate with each other and double-check all calculations, including the theoretical solution osmolality. It was emphasized that they must understand the physical meaning of osmolality, as the calculation served to guide students in self-assessing their laboratory skills. Questions, or other unresolved issues, could be addressed with the instructor during office hours, or at another convenient time.

After an introduction to the balance and the United States Pharmacopeia (USP) methods of assessing balance performance, students were introduced to the concepts of solution preparation. Students prepared 3 solutions, similar to the examples in Appendix 1, in each laboratory period. Solution components were chosen because of their favorable solubility parameters, low impact on local water toxicity, and financial cost. Because the osmometer requires only 10-microliters to perform an analysis, students were provided with 2 mL disposable mini-centrifuge tubes to contain aliquots of their solutions.

A faculty member calibrated the vapor pressure osmometers each week using solutions purchased from Wescor, Inc (Logan, UT). Students analyzed their own solutions with the vapor pressure osmometer and were able to obtain immediate feedback from the professor on their solution quality. (A streaming video link on the use of the vapor pressure osmometer is available at http://streaming.siue.edu/player/RGmkS2Ave1eC.) A professor-prepared solution served as the analytical standard for the students' compounded solutions. After performing the analysis, the students compared their measured solution osmolality with

the theoretical value and the instructor-prepared standard solution value. Students whose values were not within the acceptable range of ± 7% of the standard solution osmolality analyzed their procedures to ascertain where they may have erred. After determining the most likely source(s) of error, students prepared another solution for analysis using the vapor pressure osmometer.

EVALUATION AND ASSESSMENT

Solution Compounding

Students were required to prepare a solution during the summative assessment laboratory period. The solution prescriptions were similar to those prepared during the practice sessions. Students were not expected to prepare solutions with any ingredients that were not commonly available during the earlier sessions. Sample tubes were submitted, and the professor or laboratory assistants analyzed the solutions. Students whose solution osmolality values agreed within ± 7% of the instructor-prepared standard solutions passed the assessment and were excused from further testing. Students whose values fell outside of the ± 7% range had to participate in remedial instruction and underwent another round of summative assessment. When the student passed, they were excused from further testing. If the student failed a second time, then remedial instruction over the summer was required.

Outcomes

From 2008-2011, approximately 320 students completed the laboratory section of the course. The first-time pass rates of students varied over the 4-year period, ranging from 85% to 100%. Overall student performance is summarized in Table 1. In comparison with the instructor-prepared standard solution, the average student performance over the 4-year period was 98.2% ± 5.5%. In other words, the average percent error was -1.8%. All of the students who were required to repeat the summative assessment were successful on their second attempt.

Student Survey

Students were surveyed using a simple questionnaire regarding their opinion on the overall laboratory assessment. Students were asked the extent to which they agreed with several statements regarding the ease of use and utility of the osmometer as a laboratory quality control instrument. Over the 4-year period of this study, approximately 90% of students agreed that the instructional video enhanced their ability to use the instrument and lowered their anxiety level regarding the use of the instrument. Approximately 85% of students reported that the instrument was valuable as a teaching tool, especially because formative assessment was immediately obtained. Approximately 13% of the students were neutral regarding their use of the instrument, while approximately 2% did not like using the instrument (reasons not stated).

Table 1. Pharmacy Students' First Time Performance On Summative Assessment of a Compounded Solution

% Error[a]	% of Students
≤ 7	89.6
7.01 – 10.00	7.9
10.01 – 15.00	0.8
> 15	1.7

[a] Absolute value

DISCUSSION

The course syllabus clearly stated that all of the solutions made during the laboratory sessions would be quantitatively analyzed. Initially, we planned on the analyses being used primarily for grading. However, upon deeper reflection, we concluded that a summative approach contributing to the final grade would be, in a sense, punitive, and would not achieve the desired learning outcome. Further, a grading policy that allows a student to progress without meeting the stated course objective is antithetical to the principles of patient-centered care. Our decision to accept osmolality values within ± 7% provided the students a degree of latitude, taking the USP requirements and instrument variation into account.[5] We did not expect perfection, just competence. We wanted the students to develop confidence in these basic manipulation skills and concentrate on internalizing correct procedures instead of focusing on a particular outcome summarized by a number.

Common errors that lead to an aberrant solution osmolality value include weighing out an incorrect mass of solid, weighing out the correct mass but of an incorrect solid, measuring an incorrect volume, measuring the correct volume of an incorrect liquid, miscalculating a required mass or volume, producing an incorrect final volume, and failing to adequately mix the solution prior to sampling. We observed all of these errors singly and in various combinations over 4 years of using this assessment procedure. For example, some students incorrectly selected sodium chloride from the laboratory bench when potassium chloride was needed. This resulted in a 22% error in osmolality (ratio of molecular weights of sodium chloride to potassium chloride). The inadvertent selection of propylene glycol for glycerin resulted in a 17% error, based on respective solution densities, 1.03 versus 1.25. Students have incorrectly selected the grain readings rather than the gram reading on the class A torsion balance dial. For example, setting the rider dial at 3 grains when 0.3 grams was desired resulted in a 35% error in mass. Combinations of errors can lead to larger or smaller errors than those specifically mentioned.

While there are many potential sources for error and it is impossible to deduce with absolute certainty from a vapor pressure osmometer measurement what was the exact source, many students were able to identify the errors they made in solution compounding. We believe this is, at least in part, because the memory of the procedure was still fresh in their minds. This may not be the case if a full week elapsed between preparation submission and feedback in laboratory.

For example, the measured osmolality value of one student's solution was much lower than the calculated value and not explainable as a difference between a real and ideal solution. When asked to assess his procedure, the student realized that he had become confused when using the rider dial on the torsion balance and read the apothecary scale instead of the metric scale. Another student was absolutely certain that she accurately weighed and measured all components of the solution and was surprised that her measured value was much lower than those of other students. Examination of the graduated cylinder clearly showed the presence of swirl lines, indicating incomplete mixing. She admitted that she thought the solution diffusion process was almost instantaneous, so mixing the solution after bringing to final volume was unnecessary. A measure of solution concentration reflected by a mmol/kg value was thus able to reinforce the importance of adequate mixing as a routine procedure in solution compounding. Clearly, the students' ability to internalize a process is more important than obtaining a pass/no pass grade based on the comparison between 2 numbers. By having every solution analyzed, the students obtained immediate feedback on that particular preparation. They were able to use this information to develop a level of confidence in their ability that might be missing if they had only received a pass or no pass grade for their solution, or if feedback were delayed by a week or more.

The implementation of vapor pressure measurements in the laboratory was straightforward and we believe it to be a useful quantitative technique. However, there are some limitations associated with its use in our particular situation. There is the initial cost to consider. The Wescor vapor pressure osmometer costs approximately $8,900, so the purchase of 2 instruments is a substantial investment. In addition to the instruments, 3 sets of calibration solutions and a 10 microliter pipette are needed. Supplies cost an additional $100 to $200 per year—a reasonable amount for a robust analytical technique usable by all students. Other potential limitations to consider include the time necessary to analyze 1 sample. It takes 80 seconds of instrument time to cycle through the process. Overall, with student operation, the throughput is approximately 1 sample every 2 minutes. For this reason, we ultimately purchased 2 instruments to service 30 students per laboratory session.

The implementation of the osmometer measurements in the laboratory course went smoothly. Because the laboratory course is approximately aligned with classroom instruction in pharmaceutical calculations, the devices are helpful in reinforcing concepts like milliequivalents, millimoles, and milliosmoles.

SUMMARY

The addition of analytical quantitative assessment to a pharmaceutics skills course proved to be a valuable pedagogical component. Students receive immediate feedback on their calculations and technique. By comparing the calculated theoretical osmolality of their compounded solutions to the measured value, students experience the importance of quality control and careful checking of their work – a skill required of pharmacists working in all practice environments. We believe the assessment plan also serves to instill in students the confidence to perform basic unit operations when compounding solutions. The use of vapor pressure osmometry is simple and robust, allowing faculty members to use this marker of student performance for formative and summative laboratory assessment.

ACKNOWLEDGEMENT

The authors acknowledge former Dean Philip Medon and the SIUE Excellence in Undergraduate Education program for providing financial support for the purchase of the vapor pressure osmometers. We acknowledge the valuable directed comments on assessment graciously provided by Dr. Catherine Santanello. We thank Professor David Sill for valuable discussions on pedagogy. The authors thank Mr. Henry DiRuscio of DiRuscio and Associates for the semester-long loan of an additional VPO instrument.

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Appendix 1.

i)	Sodium chloride		50 mg/teaspoonful
	Water	qs	60 mL

The student was required to calculate and weigh the total mass of powder to be used. After the salt was dissolved in an aliquot of water, the solution was brought to final volume in an appropriately selected volumetric cylinder.

ii)	Lactose	5%	
	Potassium chloride		5 mEq
	Water	qs	60 mL

The student was required to weigh a mass of powder calculated from the percentage and required volume. This reinforces the concept of weight/volume concentration. Another mass unit, the milliequivalent (or millimole), was used to provide the students practice working with this unit. As in the previous example, the solution was brought to final volume in an appropriately selected volumetric cylinder.

iii)	Potassium gluconate		15 mEq
	Propylene glycol		4.5 g
	Cherry syrup		5 mL
	Water	qs	60 mL

The student worked with milliequivalents with the added dimension of accurately measuring the volume of 2 liquids with viscosities different from water. Furthermore, the student was required to convert the mass of propylene glycol into a measurable volume by the use of the density term. Propylene glycol and cherry syrup were chosen to show the student that volumetric measurement of viscous liquids is most accurately accomplished using oral syringes.