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Assessment and Recommendations of Compounding Education in AACP Member Institutions

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In August 2009, the American Association of Colleges of Pharmacy (AACP) Council of Sections established a Task Force to assess the current status of compounding education at its member institutions and to provide recommendations for future direction. The Task Force conducted a survey in late June 2010 of faculty members enrolled in the AACP Pharmaceutics and Pharmacy Practice sections to gain qualitative information of the current state of compounding education. The survey results were then organized around eight curricular topics for which the Task Force members provided interpretations and recommendations. A final report was sent to the AACP Council of Sections on February 15, 2011. This publication provides the information contained in that final report to the professional community.

Keywords: education, compounding, pharmaceutical care laboratory, skills lab

INTRODUCTION

Compounding has long been an essential component of pharmacy practice that provides individualized dosage forms for patients. The art and science of compounding is unique to the pharmacy profession, and for this reason, Colleges and Schools of Pharmacy often include practical compounding laboratory experiences in the curriculum to ensure that students will be competent in this area. Each College or School of Pharmacy has developed its own unique "configuration" of compounding exercises to train and enhance the techniques and skills of their students. These configurations are undoubtedly the end result of a blending of factors such as 1) the culture of the student body, 2) availability of physical and monetary resources, 3) expertise and interest of faculty, and, 4) the culture and needs of the community where the institution is located.

The American Association of Colleges of Pharmacy (AACP) Council of Sections convened a Compounding Task Force in August 2009 to evaluate compounding education within the curriculum of its member institutions. The impetus for this assessment was a result of the Pharmaceutics Section's special focus on the status of compounding in academic pharmacy in 2009. It should also be noted that no standardized compounding curriculum exists, though some insights to select compounding activities at a limited number of Schools of Pharmacy have been published.[1-7]

The AACP Council of Sections provided the Compounding Task Force with three charges:

1. Assess the status of compounding education (didactic, lab and experiential).
2. Determine if the level of basic compounding education is appropriate for an entry-level pharmacist.
3. Develop a compounding curriculum for basic and advanced compounding.

The leadership of the Task Force (hereafter referred to as "the authors") was selected in October 2009, and members were in place by March 2010. The authors used the following work plan to address the three charges: 1) develop a survey to poll Schools of Pharmacy about various aspects of compounding education; and 2) deploy

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the survey in late June, 2010 using the AACP Pharmaceutics and the Pharmacy Practice Section list serves. The plan to administer the survey in June, 2010 allowed time to prepare and present an interim report to the Council of Sections at the AACP Annual Meeting July 10-14, 2010 in Seattle. Thus the survey was subjected to limited testing by the authors. During the Fall 2010, the resulting qualitative information was organized around eight curricular topics to which the authors provided interpretations and recommendations (Table 1). An Executive Summary and Final Report were delivered to the Council of Sections (COS) on February 15, 2011. This publication provides the information contained in the COS Final Report to the professional community.

METHODS

The survey was designed to answer two primary questions: (1) what was the general opinion of the importance of inclusion of compounding education in a pharmacy curriculum? and (2) what was the status of compounding education at AACP member institutions? The survey was a twenty-two item questionnaire. Questions were formatted as follows: single answer, multiple answer, and free text response. The survey was designed to capture respondent opinions or "ideal" for compounding education in addition to the current status of compounding at each of their institutions. Authors developed questions about the current time (e.g., semester and contact hours) devoted to compounding; laboratory facilities; lab budgets; FTEs devoted to compounding education; and specific formulations taught to students. For the formulation question, specifically, the authors developed a list of compounded preparations used in their own institutions, and asked respondents to indicate if they compounded similar preparations in their programs. The respondents were also asked to indicate if the preparation was compounded in their required course or an elective course, since the authors were interested in learning if more advanced compounded preparations were only available in elective courses.

Table 1. Eight Curricular Topics Utilized to Categorize the Respondent Data

1. Definition and importance of including compounding education in the curriculum
2. Time commitment to compounding education
3. The laboratory facility
4. Laboratory instructional content
5. Current financial investment in the lab
6. Staffing and time
7. Assessment of student work
8. Elective course

After a pre-announcement was sent to members of the AACP Pharmaceutics and Pharmacy Practice Sections, the survey was deployed on-line by AACP staff via Formsite. The survey was open from June 25, 2010 through July 5, 2010. One reminder was sent before the survey was closed. Survey responses were kept anonymous and no attempt was made to identify any individual respondent's section membership.

Analysis of survey results using descriptive statistics and summary of free text responses was conducted by the authors. Free text responses that were not relevant to the question asked or left blank were excluded from further analysis. During the analysis of the survey, responses to the two primary questions were subdivided into eight curricular topics since multiple questions pertained to similar topics (see Table 1). Each author was assigned one topic area, and was asked to summarize the questionnaire information and provide an initial recommendation for the entire team's consideration. The results section is formatted around these eight curricular topics.

Tabulation of the single and multiple answer responses were straightforward. The free text responses were summarized into groups as appropriate for the question asked.

RESULTS

AACP membership in the Pharmaceutics Section was 260 and Pharmacy Practice was 1,361 at the time of the survey. The survey was completed by 137 respondents which equals a 8.5% response rate. It should be noted that AACP members may belong to more than one section so there may be overlap in the section membership, so the response rate may be more representative than 8.5%. Also of note, not all 137 respondents answered every question in the survey. The results are detailed in each of the curricular areas below.

Definition and Importance of Including Compounding Education in the Curriculum

There was unanimous support from all 137 respondents for inclusion of compounding education in the curriculum. However there was quite a bit of variation when respondents were asked to define compounding. Twenty-one percent (21%) of the respondents did not answer this question. This suggests that even though 100% of respondents thought compounding education should be in the curriculum, there is some uncertainty of how to define compounding. The submitted responses were variable and were categorized into four areas by the authors:

- General preparation/dispensing (51%): Responses referred to only the processes of preparation and/or

dispensing compounded preparations, and did not mention "specific patient need" or the "compounding triad."

- Special preparation (24%): Reponses referred to meeting "specific patient need" or "provider request" with compounded preparations.
- Secundum Artem or professional prerogative (8%): Responses addressed the role pharmacists have in providing compounding as an "essential skill fundamental to being a pharmacist."
- Legal definition of compounding (4%): Respondents cited the legal USP-NF definition.

Respondents were then asked to provide their opinion about which year(s) of the curriculum should contain compounding education. The question allowed multiple responses since it was expected that compounding experiences would be desired in more than one professional year. The respondents indicated that the majority of compounding education should be contained in the PY1 (63.5%) and PY2 (53.2%) year vs. PY3 (24.8%) or PY4 (7.2%) years. In a follow-up question, "For each year(s) you indicated, how many credit hours should involve compounding education," a programming glitch prevented respondents from entering multiple responses and respondents were left with answering the question through the text box. Analysis of the raw data allowed the authors to determine the number of credit hours that should be involved in a curriculum, but not the number of credit hours per semester. Respondents proposed that an average of 3.5 credit hours (range 0.1-12) be available in the curriculum for compounding education.

Time Commitment to Compounding Education

According to this survey, compounding education is included in an average of 2.2 semesters. However, responses varied, from zero (0) up to 6 semesters. Thirty-one point two percent (31.2%) of respondents had one semester of activity, 42.7% had two semesters, and 12.5% had three semesters. Five percent (5%) of the respondents each indicated 4, 5, or 6 semesters of compounding activity.

The number of credit hours currently allotted to each semester averaged 1.66, but ranged from 0.2 (14.6%) to 5 (2.1%) credit hours. A majority of respondents (41.7%) indicated 1 credit hour per semester, 16.7% indicated 2 credit hours, and 14.6% indicated 3 credit hours. The average number of credit hours per curriculum was determined to be 3.3. This value is markedly similar to the number of credit hours that respondents suggested should be in a curriculum (3.5).

The current number of student contact hours per semester was used as a final measure of time commitment to compounding activities. According to respondents, 40.4% assigned between 1-16 contact hours per semester, 52.1% assigned between 20-50 contact hours, and 7.5% were assigned more than 60 contact hours per semester.

In corollary to the current number of student contact hours, the authors wanted to learn the approximate amount of time students spend completing a single compounding laboratory exercise. Eleven percent (11.0%) of respondents reported 2.5 hours or less were needed, 28.0% reported 3 hours, and 18.3% reported 4 hours were needed to complete a single compounding laboratory exercise. Twenty-nine point two percent (29.2%) of respondents reported that 6 or more hours were needed for a single compounding exercise.

The authors were also interested in learning if compounding education was typically a standalone course or course sequence, or was it part of an integrated experience within a larger Pharmaceutical Care Laboratory sequence. A majority of respondents (68%) indicated that compounding education was integrated within another course.

The Laboratory Facility

All respondents reported a hands-on laboratory experience associated with their Schools' compounding education. However, the type of laboratory facilities varies widely. The largest percentage (77.8%) reported a completely equipped laboratory for nonsterile compounding (i.e., USP <795>), and 27.0% of these respondents also have sterile compounding facilities (i.e., USP <797>). The remainder of respondents indicated less than basic laboratory equipment and supplies. Interestingly, two institutions use PCCA (Professional Compounding Centers of America) and UHCOP (Univ. of Houston COP) instructional facilities for their compounding facilities.

Laboratory Instructional Content

The respondents were asked to identify, by name, the textbooks, reference books, online resources, and other learning tools used in the compounding education experience. The results are reflected in Table 2.

The authors identified what compounded preparations were being emphasized in the member institutions. Table 3 indicates the number of respondents that included the listed dosage form in either their required or elective compounding education laboratories for the 2009-2010 academic year. There appeared to be substantial consensus in the types of compounded preparations between member institutions.

Current Financial Investments in Compounding Labs

Including compounding education as part of the overall education experience does require additional resources.

Table 2. Laboratory Instruction Content Tools

Textbooks (43.5%)	Reference Books (17.6%)	Online Resources (17.6%)	Other Tools (21.1%)
• A Practical Guide to Contemporary Compounding	• Remington's • Martindales	• Paddock Labs • Compounding Today	• International Journal of Pharmaceutical Compounding
• Compounding Sterile Preparations	• Handbook of Pharmaceutical Excipients	• PCCA videos: Secundum Artem, UNC Pharmaceutics and Compounding Laboratory	• Pharmaceutical Calculations • Merck Index
	• PCCA teaching materials		• USPDI
• The Art, Science and Technology of Compounding	• Trissel's Handbook of Injectable Drugs		• USP
• Pharmaceutical Compounding and Dispensing	• Secundum Artem		
• Applied Pharmaceutics in Contemporary Compounding	• Trissel's Stability of Compounded Formulations		
	• Pharmaceutical Dosage Forms and Drug Delivery		

PCCA = Professional Compounding Centers of America

Many costs are associated with such an endeavor beyond the space needed for a compounding laboratory. For example, there is the cost of supplies, equipment purchases, equipment maintenance, teaching assistants (TAs), faculty, compliance costs, etc. The authors were interested to learn what compounding education experiences cost (in real dollars) at member institutions.

The operational cost was subdivided into two parts: (1) the purchase/inventory of equipment; and (2) the costs associated with supplies, equipment maintenance, compliance, and TAs per year. The authors were aware that TAs were used in a large number of compounding laboratory exercises, and wanted to include TA stipend costs into the cost of operating a compounding education experience. Table 4 indicates the initial equipment costs and annual operational cost reported by the respondents.

Staffing and Time

In addition to the cost of supplies and equipment, indirect costs such as faculty and TA time must be considered in a compounding education program. The authors wanted to assess the current usage of these resources in member institutions' programs. It was found that the majority of the programs (70%) had 3 or less faculty involved in compounding education, and 25% had 4 or more faculty. Within the programs that utilized 3 or less faculty, 16.1% reported having 1 faculty involved in compounding education, 35.5% reported having 2 faculty, and 18.3% reported having 3 faculty involved.

A substantial number (75%) of respondents indicated that TAs were involved in the compounding education experience while 25% of respondents reported having no TA involvement. The authors were interested in understanding what type of TA was being utilized in the compounding education program, and this information is tabulated in Table 5.

The survey did not identify if faculty members were assigned to compounding instruction as their only educational responsibility, or if faculty members provided compounding instruction in addition to other educational responsibilities. Regardless of how faculty's responsibilities were structured, additional support (e.g., TAs) was deemed to be essential and was frequently provided.

Assessment of Student Work

A fundamental requirement of any compounding education program is the assessment of students' compounding competency. Assessment tools include physically observing the student while performing a compounding operation, reviewing a "lab report" type document where the student documents what was done, evaluating the compounded preparation for proper labeling, conducting a lab practical exam under test conditions, conducting an analytical procedure of the finished compounded preparation, or a combination of these .

The authors were interested in the tools used by the member institutions to assess both student work and techniques, and the quality of the preparation compounded. The most common (35.7%) assessment method of student performance was direct feedback by faculty and/or TAs while observing student work. Sixteen point seven percent (16.7%) of the respondents used a practicum exam to asses student work, and 6.5% of the respondents used a checklist.

A majority of respondents (33.5%) evaluated a student's compounded formulation by direct observation. An additional 13.8% of the respondents indicated that compounded preparations were submitted for qualitative

Table 3. Types of Dosage Forms Compounded During 2009-2010

Formulation Compounded in 2009-2010	Required Course	Elective Course
aqueous solution	80	3
nonaqueous solution	58	4
saturated solution	42	5
suspensions	76	2
alcohol soluble gel	37	11
water soluble gel	50	9
gel for controlled release capsule	12	11
troche	45	12
medication stick	39	12
suppository	78	4
ointment by incorporating an ingredient	78	1
ointment by forming the base	55	4
intravenous solution (large volume parenteral)	72	2
intravenous solution (small volume parenteral)	69	3
chemotherapy in biological safety hood	28	9
effervescent powder	17	10
capsule	81	4
PLO emulsion	48	10
tablets	35	11
nasal spray solution	22	9
magic mouthwash suspension	29	3
otic solution	22	8
ophthalmic solution	33	9
radiopharmacy	2	16

analysis. Only 8.0% of the respondents indicated that a quantitative analysis was used to assess the compounded formulations.

Availability of Elective Courses

The authors were aware that some member institutions had required instruction in compounding education, other institutions offered only elective instruction in compounding, and some institutions had both required and optional elective courses available for their students. The survey indicated that 43.5% of the respondents had elective compounding education at their institution. The authors did not attempt to differentiate institutions that offered a required course and an optional second elective from institutions that offered only optional compounding education. However, the question was asked, "If the elective is in addition to a required course, what was the percentage of students that take the compounding elective." Nineteen point four percent (19.4%) of the respondents indicated that less than 10% of the students took the elective, while 41.7% and 33.3% of the respondents answered that 10-19% and 20-30% of the students took the elective, respectively. A small percentage of respondents (5.6%) indicated that greater than 50% of the students took the elective. Also, when analyzing the formulations data it was not possible to determine if more complicated preparations were only compounded in elective courses as some institutions only have an elective course in compounding and therefore would include every preparation in that course.

RECOMMENDATIONS

The 137 respondents to the survey unanimously indicated their support for having compounding education within a School of Pharmacy curriculum. Based on the data of this survey and the authors' personal experiences, we concur. The stated outcomes for such education should be centered on the development of compounding skills and an understanding of how pharmacy professionals can meet specific patient needs utilizing this unique skill.

The respondents' data shows a consensus of >3.0 credits of compounding education should be included in the curriculum. There was strong indication that compounding education should be included in each semester of the first two years of the curriculum, with some respondents suggesting compounding experiences beyond that time. These suggested values are markedly similar to time commitments currently utilized in member institutions. The authors also noted that many of the respondents have compounding education as part of an integrated course,

Table 4. Initial Equipment Costs and Annual Operational Cost

Purchase/Inventory of Equipment (based on original purchase price)		Operation Cost Per Year (supplies, maintenance, TA stipends)	
Dollars	**% of Respondents**	**Dollars**	**% of Respondents**
500-15,000	30.8	1,000-9,000	53.7
20,000-49,000	28.2	10,000-18,000	16.7
50,000-99,000	17.9	20,000-49,000	16.7
100,000-217,000	23.1	50,000-100,000	12.9

Table 5. Type of Teaching Assistants Utilized in Compounding Laboratory Exercises

Educational Pursuits of Teaching Assistants	
Discipline	**% of Respondents**
Professional pharmacy student	24.4
Graduate student	37.2
Community pharmacist	16.7
Pharmacy residents	13.3
Pharmacy technicians	5.1

making it difficult to assign a strict "number of credit hours per number of semesters" rule but based on data obtained from this survey recommend that 4 credit hours per curriculum be dedicated to compounding education.

It appears that the time necessary for each individual compounding exercise was not as a significant consideration as the number of credits. However, the authors recommend that individual compounding exercise not exceed 4 hours in length.

The authors recommend that adequate and appropriate space for compounding education activities should be provided such that each student has their own workstation. In addition, a library of reference materials should be available for the student to use as part of the compounding education experience. If students have a required text for the compounding instruction, additional materials should still be available for reference.

The authors note that only 27% of the respondents report having compounding education facilities for sterile compounding. The authors stress the importance of member institutions having these sterile compounding facilities in order to appropriately train students in this critical area. This deficiency takes on new urgency given the expanded requirements of USP-NF Chapter <797>.

The authors recommend that dosage forms contained in Table 2 selected by greater than 25 Required Course respondents should be included in an institution's compounding education experience. Institutions are encouraged to include other dosage forms based on the desired outcomes of individual programs.

The authors recommend that institutions should be prepared to invest $10,000-20,000 per year in operation costs per year which would include supplies, equipment maintenance, or compliance costs. If TA stipends are to be considered cost of the compounding education program, then those costs will need to be added to the proposed cost. The authors recommend that institutions should be willing to establish and maintain at least a $50,000 equipment inventory. This inventory would be for items needed for the proper equipping of the compounding facility, for specialized compounding equipment, and for the analysis of compounded preparations.

The authors recommend that three faculty members with TA support be associated with the curriculum's compounding activities. This can be accomplish through a variety of means including part-time faculty, full-time faculty who are involved in other courses, or adjunct faculty serving as practitioners from the community. TAs should be PY2/PY3 students who have completed the curriculum's compounded courses, or graduate students. While the authors do feel that those involved in the compounding instruction need to be in a dedicated position, they strongly feel that all involved should have adequate experience in compounding to be useful in the laboratory setting.

The authors believe student compounding techniques should be evaluated by direct observation of faculty or TAs who are aware of the subtleties of compounding. The authors also recommend that some form of quantitative analysis of the compounded preparation be performed.

A compounding elective in addition to a required compounding course was not seen as an essential by the authors. However, it is recommended that a required compounding course become part of the institution's curriculum. The decision to offer an elective course would be at the discretion of the institution.

CONCLUSION

Member institutions should ensure their curriculum includes distinct hands-on compounding training, offering at least four (4) credits of required laboratory training, including all of the primary sterile and nonsterile dosage forms discussed. A minimum of 3 faculty in addition to TAs should be used to conduct the laboratories, adjusting the number accordingly to the number of students enrolled in the course. Student assessment should be conducted by direct observation, written documentation, and some form of quantitative analysis. School administration should be willing to allocate sufficient space and funds ($10,000 minimum) to accommodate such laboratories and the initial equipment appropriate to adequately train students on nonsterile as well as sterile products. Space and funds should be evaluated often and should be adjusted accordingly to account for the number of students registered in the course and significant changes in practice.

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Appendix 1. Task Force on Compounding Education Questionnaire

1. Do you think compounding education should be included in the curriculum? (Yes/No)

2. If yes, which year(s) of the curriculum should contain compounding education (PY1, PY2, PY3, PY4)?

3. For each year(s) you indicated, how many credit hours should involve compounding education?

4. How do you define compounding?

5. Which best describes the compounding education at your institution?
   - stand-alone required course
   - integrated instruction in a required course
   - If none of these explain your situation, please describe.

6. How many semesters during the pharmacy curriculum is compounding education offered?

7. How many credits hours are assigned to each semester of compounding education? (If a stand-alone course, how many credit hours for the course. If an integrated part of another course, give approximate credit hours dedicated to compounding education.)

8. How many student contact hours in compounding education are conducted in each semester?

9. Is there a hands-on laboratory experience associated with the compounding education?

10. If there is no laboratory experience, please explain how compounding education is accomplished.

11. What laboratory facilities are present for students to complete the compounding education?

12. How many faculty are involved?

13. Are there TAs involved in the course? If so, please state their current position (e.g., graduate student, hospital resident, community pharmacist)?

14. Where do you get reference material for your compounding education instruction?
   - textbooks – please list which
   - reference books – please list which
   - online resources – please list which
   - virtual learning tools – please describe
   - others – please describe

15. How many compounded formulations do students make during the curriculum?

Formulation Compounded in 2009-2010	Required Course	Elective Course
aqueous solution		
nonaqueous solution		
saturated solution		
suspension		
alcohol soluble gel		
aqueous gel		
modified release gel		
troche		
medication stick		
suppository		
ointment by incorporating an ingredient		
ointment by forming the base		
intravenous solution (LVP)		
intravenous solution (SVP)		
chemotherapy in biological safety hood		
effervescent powder		
capsule		
PLO emulsion		
tablets		
nasal spray solution		
"magic mouthwash" type suspension		
otic solution		
ophthalmic solution		
radiopharmacy		

16. How do you assess a student's compounding technique?
    - direct observation and feedback from faculty or TAs
    - checklists
    - practicum exam
    - others – please describe

17. How do you assess a student's formulation?
    - qualitative analysis
    - observation
    - quantitative analysis
    - others – please describe

18. Approximately how many hours are needed for a single compounding exercise for laboratory set-up, formulation and student assessment, equipment maintenance, etc.?

19. Is there an elective available at your institution related to compounding?

20. If an elective is available, what percentages of students who complete the required compounding education take the elective?

21. What is your institution's operational cost for compounding education per year (please include TA costs, supply costs, equipment maintenance costs, etc., but not the purchase of new equipment)?

22. What is the approximate inventory value of equipment used in your institution's compounding education (use original purchase price in US dollars)?