INSTRUCTIONAL DESIGN AND ASSESSMENT

A Decade of Teaching Pharmaceutics Using Case Studies and Problem-Based Learning

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Submitted May 10, 2003; accepted February 24, 2004.

Objectives. For the past decade, pharmaceutics at the University of Southern California has been taught using a case-study—driven problem-based learning (PBL) approach. In this paper, we document our experience with this teaching approach and describe the evolution of the course.

Methods. Over the 10-year period we have refined our teaching methodology based on the suggestions of students and faculty, and in response to changes in our teaching environment. Case studies have remained as the most important element of the pharmaceutics course, and the use of verbal assessment of student performance has also been consistently emphasized.

Results. There is a good relationship between student learning and case study performance in the PBL environment, as measured by grades for written case study reports and examination scores. This relationship holds from year to year, and applies equally to both stronger and weaker students.

Conclusions. A case study-driven PBL course with a large class size can be effective in enhancing student learning across a range of abilities, and verbal assessment by faculty and student peer review can play useful roles in this process.

Keywords: case studies, problem-based learning

INTRODUCTION

In the early 1990s the Department of Pharmaceutical Sciences at the University of Southern California School of Pharmacy made the decision to teach pharmaceutics in the PharmD curriculum using a problem-based learning (PBL) approach. The first offering of the Pharmaceutics I course in a PBL format was in the fall of 1993, and we have persisted with this format for each subsequent offering of the course, up to and including that in the fall 2002 semester. Hence, we now have 10 years of experience in the application of PBL in a basic science course with a large student enrollment.

The PBL approach is now widely applied in pharmacy education, and an excellent review of this area has been published. Teaching methodology and the concept of problem solving as an integral part of the pharmacy curriculum have been discussed for many years. Each PBL implementation differs in its details, but most contain common components. These include the solution of case studies, often as a group-based exercise, in which the role of the faculty is to facilitate, rather than to deliver material in a didactic manner. PBL courses may also include an element of peer review assessment and other, non-traditional forms of assessment, including assessment of students through verbal discussions and interviews. Increasingly, computerized PBL approaches are being reported, including computerized case studies and use of the Internet.

In their review of PBL in pharmacy education, Cisneros et al draw an important conclusion regarding the lack of quantitative information on the effectiveness of the PBL approach. From a broader search of the PBL literature across the biomedical sciences, a similar conclusion can be reached, although appropriate testing methods and the effectiveness of assessment in basic science PBL courses have been discussed. We also recently suggested that, given a careful approach to verbal assessment in PBL, scores from such assessments...
can correlate with written examination scores. Other studies have compared facilitator and peer assessment scores with examination results. Hmelo et al. have considered the effectiveness of PBL from a cognitive perspective and Naalsund has provided an interesting description of an approach to study the reliability of assessment and the effective educational outcome of a clinical therapeutics PBL course.

In 1998, we made our first presentation of the details of our implementation of PBL in the teaching of pharmaceutics, and we discussed some of our thoughts regarding the effectiveness of the PBL approach. In this article, we update the course description, and show how our approach has matured over the years. We describe how our particular implementation of PBL is driven by the practical considerations required for a large class size (170–190), but still has the critical components of a PBL course.

METHODS

Course Overview: PBL and Non-PBL Elements

The contents of the Pharmaceutics I course are typical of many pharmaceutics courses given in the PharmD curriculum. A detailed description of the course contents and structure until 1998 has been published. In general, the Pharmaceutics I semester is broken into 2 halves: in the first half, material relevant to solution formulation is discussed; the second half focuses on solid state formulation and a discussion of dissolution and passive absorption. Student learning occurs in both didactic and PBL modes. From the first meeting of the semester, we stress the relationship between the overall problems (of pharmaceutical formulation) and the “nuts and bolts” physical and organic chemistry (and clinical considerations) that underlie decisions made in formulation.

The key elements of the Pharmaceutics I course from 1993 to 2002 are shown in Table 1. These include case studies, group-based work, faculty-led discussion sessions, verbal assessment through interviews, and essay-based, problem-solving examinations. Case studies containing complex pharmaceutical formulation problems are used to drive the PBL elements of the course. Hence, students are challenged to problem solve in seeking answers to these case studies. This activity is facilitated by faculty-led small group discussions and assessed through student peer review and faculty assessment of students’ understanding in the discussions and in more formal “interviews.” Each of these components is further discussed below.

The course also includes some elements that are not necessarily found in a “pure” PBL course. Hence, we do have a didactic component, and some class time is spent on formal lectures. Given our large class size, we consider this element to be essential in providing a basic framework for each student. Lectures are given in which key concepts in a given subject area are discussed. The goal is to define the scope of the subject area. We also use written examinations as part of our assessment.

<table>
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<th>Fall Semester Enrollment*</th>
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<th>Students / Group</th>
<th>Final Examination</th>
<th>Midterm Examination</th>
<th>Case Studies</th>
<th>Case Study Reports</th>
<th>Discussion Schedule</th>
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<td>Case Groups</td>
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<td>Final Examination</td>
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*The number of students who completed every element of the course. The numbers for 1993 and 1994 are estimates.†Two case studies in the semester, but each student only performed one of these.
Although such examinations may not be typical of a pure PBL course, class size again precludes complete reliance on peer review and verbal assessment. Furthermore, through the use of essay-based, problem-solving question on examinations, we are able to maintain PBL principles as much as possible.

The changes in content and emphasis on particular elements (Table 1) have occurred in response to several factors, including increasing class size, student feedback, faculty perceptions of the effectiveness of PBL, concerns regarding peer assessment, financial considerations, and limitations on faculty time. These factors are likely to be present in the environment of any teaching or research/teaching institution, and they can have a significant effect on the potential to deliver a PBL course. Although some aspects of the course have changed significantly, many of the most important elements have been maintained in a relatively unchanged format. Given this continuity, we feel that we can compare and contrast data from different years, and that we can sensibly interpret trends that have emerged over the 10-year period.

The Case Study
The case study is the most important mechanism that drives the PBL in the course. Case studies are performed by groups of 6 to 8 students (Table 1). The students are randomly allocated to groups at the beginning of the semester, and these groups are not changed during the semester. The group size is dictated by the class size and the number of faculty members available to hold group discussions. The case studies are sufficiently complex (see Appendix 1) that significant group effort is required. This involves exchange of information between students, the development of a group-working strategy, the meeting of internal deadlines, organization of group meetings outside of scheduled class time (this is a necessary element for completion of the case study), and completion of a group report, for which each student in the group receives the same score. A case study takes place over a period of ~4 weeks. At its conclusion, each student provides a brief written assessment of and peer review score for each group member, and this score forms part of the case study grade for each student.

A typical case study is shown in Appendix 1. The course faculty members have developed many other similar case studies over the 10-year period, and the particular case study in Appendix 1 is representative of the approach that we find works most effectively in stimulating PBL in the course. Following a brief introduction, a list of required information is provided. This is then followed by an outline of the kind of approach and the type of data that will be needed to answer the case study. Finally, we provide a set of objectives that need to be completed by 3 deadline dates. The case study would typically be distributed ~2 weeks before the first of these deadlines. Each student group receives the same information, but applies it to a related but different pair of molecules (not shown in Appendix 1). A single case study cannot cover every issue associated with, for example, solution formulation. Nonetheless, the case studies are detailed and do cover considerable ground. Furthermore, our goal in giving a case study is to promote the kind of critical thinking and problem solving that will allow students to apply this ability to other areas.

A faculty member interviews each group at the end of the case study. The entire group is present for the interview, but individual questions are directed to one student at a time, with some additional general questions posed for anyone in the group to answer. The interview period lasts for an average of 5 minutes for each student in the group. Each student is asked to answer questions on a specific area of the case study, and the interviewer begins by asking which student will take a given area. To encourage and reward broader understanding of the case study, the questioning of each student is broadened as the student shows the ability to answer simpler questions. The students are not formally advised prior to the interview about the key areas on which the interview will focus or which students will be responsible for which area. Further details of our interview approach have been published elsewhere.19

Evolution of the Course: 1993–1999
In hindsight, our initial implementation of PBL in 1993 and 1994 reflected an overly optimistic view of the practical conduct of a PBL course. We chose not to include formal examinations and relied exclusively on case studies for grading of the course (Figure 1), with the case study grade itself based exclusively on peer review (Figures 2 and 3). This model is perhaps the closest to a “pure” PBL model, but it proved unsatisfactory in a large class environment. In particular, it led to an inability to fairly assign grades, with a lack of reward for those students who put additional effort into the case study. For this reason, in 1995 we reduced the number of case studies to 2 and introduced a comprehensive final examination (Table 1). From 1995 to date we have used the 2 case studies to define 2 halves of the semester, with the first case study focused on solution state formulation problems and the second focused on solid state formulation.
From 1995 to 1999 the case studies and the final examination comprised 60% and 40% of the course grade, respectively (Figure 1). The case study grade had 2 components, a group report score and an individual score, with the ratio of these scores remaining similar from 1995 to 1999 (Figure 2). The basis for the individual score, however, did change. We significantly reduced, but did not eliminate, the peer assessment component after 1995 (Figure 3). This change was initially made based on only anecdotal evidence that the peer assessment method was less reliable than potential verbal assessment methods conducted by faculty members. This is now supported by the peer assessment data collected since 1995 and discussed later in this paper. It is further supported by the good correlation we have found between verbal assessment scores given by faculty members and final examination results.\(^\text{19}\) In particular, an interview of each group (see above), with individual scores assigned to each student, was introduced in 1996. We find that this is a particularly good form of assessment, and we have continued to increase the contribution of the interview to the overall individual score (Figure 3).

In 1997 we made one further important change regarding the interrelationship of lectures and small group, faculty-led discussion sessions. Prior to 1997, discussion sessions had been held once a week to complement the lecture that had been delivered earlier in that particular week. Although this method had some advantages in providing immediate reinforcement of the material discussed in the lecture, it also resulted in fragmentation of the course material, rather than encouraging integration of the material. In 1997 we altered the course format such that the discussion sessions were held in blocks (6 discussion meetings over 3 weeks, with 2 such 3-week periods in a semester) and this format has proven to be successful. The discussion periods of the semester are timed to coincide with the time the case study is being solved, and so they provide direct facilitation of the case study process. In this context, they allow integration of material from different lectures, and student participation is generally very good because the need to complete the case study report provides a direct incentive to use the discussion sessions as learning vehicles.

In 2000, the Pharmaceutics I course was significantly altered from that of the previous 5 years (Table 1). An increasing class size caused concern regarding the increased faculty time required to facilitate a PBL course appropriately. Furthermore, we had consistently received feedback from students that a midterm examination would help them in determining how well they were dealing with the PBL approach. For this reason, an essay-based midterm examination was introduced (Figure 1). Case studies were performed in the same way...
as in the previous 5 years (Table 1), but no report was collected and no individual grading (peer or faculty-based assessment) occurred (Figure 1). This proved to be a largely unsatisfactory model. The reduction in importance of the case studies, from a student perspective, resulted in decreased effectiveness in the case-study—driven PBL elements of the course. A noticeable decrease in the quality of discussion sessions occurred because there was no grade incentive for student to perform the case study to the highest level. Although many students recognized that developing an understanding of the case studies would have a positive effect on their midterm and final examination results, many others took a short-term view and perhaps devoted more attention to other courses.

In 2001 we returned to a format close to that used prior to 2000. Case study reports were reintroduced, but these were now due in 3 separate parts, once a week for 3 weeks. This requirement forced each case study group to address the case study in a more balanced way, spreading their effort over a longer time period. Case study reports were also required only in an electronic form. The increased computer literacy of almost all students and the increasing availability of software for document preparation encouraged us to introduce this requirement. The quality of the case study reports, which was already high, has increased further as students have developed their document preparation skills.

In the 2002 Pharmaceutics I course the PBL components of the course remained largely unchanged, but for one important adjustment that resulted in each student only performing one of the 2 case studies. This change has allowed us to begin to evaluate PBL in a somewhat more objective manner, and the results of this approach will be discussed in a future publication.

**RESULTS**

**Effectiveness of the Case Study as a Learning Vehicle**

In Figure 4 we show the relationship between the case study report grade for a group and the average final examination score for the students in that group. The data in Figure 4 comprise 7 years of case study reports and final examination scores. In each of these years we observed a consistent relationship in which a higher group report grade tended to lead to a higher average examination score (data not shown). Collectively, these data suggest that a 25% difference in the scores on case-study—reports may lead to a 10% difference (about a letter grade) in average examination score (Figure 4). Although the correlation coefficient is modest \(r = 0.32\), the trend is consistently apparent from year to year. Grading of case study reports is a difficult and relatively subjective process, and several different faculty members have independently performed it over the years of the course. Of equal importance, the examination results reflect the performances of 6 to 8 students in each group and also reflect independent grading of examination questions by different faculty members.

We performed further analysis of the case study report and final examination scores in which we considered the average of the 2 highest examination scores in each group, the average of the 2 lowest examination scores in each group, and the average of the scores of all other students in each group. These averages were plotted against the group case study report scores (Figure 5). The results were similar for the 3 groups of students, with high, intermediate, and low examination scores. This result was particularly encouraging to us, because it suggests that even those students who did not perform particularly well on the final examination had benefited from being part of an effective case study group. A concern with groups is that the strongest students in the group will perform most of the work and only they will benefit, leaving other students in a weaker position from which they do not learn the course material. The data in Figure 5 suggest that an alternative, much more positive group dynamic is occurring. Certain students with stronger backgrounds may tend to dominate a group-working environment, and this is certainly our anecdotal experience. However, it seems that positive group functioning and presumably increased learning (as reflected in a high score on a case study report) can have an impact throughout the group, and lead to a generally improved performance on the examination by all students in the group.

**Effectiveness of Peer Assessment**

Peer assessment scores for individual students were compared with final examination scores (Figure 6). These data were taken from the 6 years during which both a peer assessment score and a final examination score were used as part of the grading criteria (Figure 1). Most of the peer assessment scores were in the 90% to 100% range, reflecting a general satisfaction of students with the efforts of their peers, but also a possible unwillingness to grade peers harshly. However, as seen in Figure 6, the tail on the data does not support the latter possibility. Of the 98 students who received peer scores of 80% or less, 68 of these students received a lower than average examination score. Hence, qualitatively we
believe that peer assessment may be effective in identifying students who are perceived by their peers as not putting sufficient effort into the group case study, and this lack of effort may be reflected in the relatively weak performance of these students on the final examination.

Effectiveness of Faculty-Based Verbal Assessment

We have recently published a detailed analysis of the effectiveness of verbal assessment as part of the PBL approach. A comparison of the verbal assessment scores (comprising only faculty-led discussion and interview scores) for individual students with final examination scores from 1996 to 1999 showed a relationship in which a 30% difference in the verbal assessment score was predictive of a 20% difference in the final examination score.

DISCUSSION

PBL approaches are being widely used across the basic and clinical sciences, but there is limited information on their effectiveness and quantitative information is particularly limited. In this paper we have used final examination scores as a measure of student learning, and discussed their relationship with case study report scores, peer assessment scores, and faculty assessment scores. Based on these data and our many qualitative experiences from a decade of PBL teaching, we draw the
following conclusions on the implementation of PBL in pharmaceutics and, more broadly, in a large-enrollment basic science course.

Group-based working is one of the key elements of most PBL courses and is important in facilitating the exchange of information and ideas between students. We believe that asking students to work in small groups allows for the development of many skills that will ultimately be invaluable in the workplace and in society, as well as providing the students with a forum to critically discuss the course material. Two criticisms often associated with group-based assignments and PBL courses, compared with the lecture/examination approach, are (1) that only a few students in a group will actually do the work, leaving the remaining students less well educated than they would have been through a didactic approach; and (2) that individual effort within the group cannot be assessed to as satisfactory a level as with a standardized examination, and so group working cannot be used as a basis to assign individual grades. We agree, in part, with the first of these criticisms. In most groups there is an imbalance in activity among the students, and in faculty-led discussion groups often only 3 or 4 out of 7 or 8 students actively participate in the discussion. However, our quantitative data relating group case-report scores to examination performance suggest that effective group working (as manifested in a higher report score) leads to higher examination scores (hence, more evidence of learning) over the entire range of student abilities within the group. Hence, it may be that students who are highly motivated and have strong backgrounds appropriate for the course can have a positive effect on the learning of the students with less appropriate backgrounds.

Regarding course structure, our experience in 1993–1994 in eliminating final examinations and in 2000 in eliminating case reports suggests that both of these components are essential to providing sufficient motivation for learning through the performance of the case study. Furthermore, we believe that dividing the case report into 3 parts, due in 3 successive weeks, is effective because it (1) allows students to appreciate each individual section of the case study without becoming overwhelmed by the whole; (2) ensures that the group work for the case study is performed equally over the ~1 month in which the case study is active; and (3) allows a linking of faculty-led discussion sessions to the part of the case study for which a report is due, thus providing increased motivation to participate in these discussions. However, we do not advocate the formal division of the case study itself into small, unrelated sections. We believe that the complexity of the case study is important in forcing students to make connections between various parts of the course material, and we emphasize that answers provided in the second and third sections of the report must be consistent with and developed upon those in earlier sections.

Assessment of the case study reports and the individual contributions to these reports is a difficult problem. Our data suggest that our approach to assessment of the reports themselves is satisfactory, in that it correlates with examination performance of the students in a given group. Peer assessment of individual efforts also appears to be a valuable component, but we do not believe that it should form a major part of the grade. Most students will either be unwilling or unable (due to insufficient information) to grade their peers accurately. Most peer scores are close to 100% of the maximum score and frequently groups “conspire” to give everyone in the group a 100% score. We do not discourage this. If the group is functioning well and this is the perception of every member, then this score is reasonable. The peer score is valuable for students who want to express their frustration at the lack of effort (real or perceived) of another member of their group, and the peer assessment data suggest that some of the lower scores given are reflective of students who ultimately performed at a less than average standard on the final examination. Students’ scores for verbal responses to faculty questions appear to be correlated with examination performance. In particular, the interview given to each group at the end of each case study seems to be particularly effective in determining each student’s general level of understanding of the case study and the course material.

CONCLUSIONS

The data presented here address the effectiveness of PBL. However, they are unable to provide an objective assessment of PBL, and it remains unclear whether the case-study—based approach to pharmaceutics is significantly better at enhancing student learning, compared with a didactic lecturing approach. To address this, we have used conclusions drawn from both the quantitative data and our experience over the last decade to design a PBL pharmaceutics course that might allow for this objective comparison to be made. This course was first offered in the fall of 2002, and the results may provide further insights into the real value of case-study—driven PBL courses.

ACKNOWLEDGEMENTS

We thank the faculty members who have contributed to the teaching of the Pharmaceutics I course from 1993 to
2002: Drs. John Biles, Michael Bolger, Eric Chambers, Vincent Lee, Suman Mukherjee, and Curtis Okamoto. We also thank the almost 1800 students who have taken the Pharmaceutics I course over the past decade.

REFERENCES
Appendix 1: A Typical Pharmaceutics I Case Study

Helicobacter pylori plays an important role in peptic ulcer disease and eradication of the bacterium decreases the risk of ulcer reoccurrence. Omeprazole is an antiulcer agent that is used in combination with amoxicillin against the bacterium. Your group are part of a research team that is developing a novel aqueous solution combination formulation of an omeprazole derivative and a β-lactam antibiotic (see page 3 for your molecules). The omeprazole substituents were chosen based on similar substituents examined for molecules with similar properties to omeprazole (Terauchi et al., J. Med. Chem. 1997, 40, 313-321).

In the initial stage of formulation development, you need to determine if the solubility of the 2 molecules is suitable. However, you suspect that the omeprazole derivative may not be sufficiently soluble and you have decided to derivatize the drug with further chemical functionality, in order to increase its solubility. You propose to do this by adding a carboxylic acid group. You are not restricted by synthetic chemistry issues and you can propose any molecule containing the additional carboxylic acid group (and any additional aliphatic chain). However, you should try to avoid disrupting the mechanism of action of the omeprazole derivative.

The formulation of the COOH-modified omeprazole derivative and the β-lactam antibiotic must contain the following:
1. An aqueous solution of the molecules buffered at an appropriate pH.
2. A volume consistent with the shelf-life and reflecting the required doses of the drugs.
3. Any other components you feel to be necessary.

In addition, the other members of the research team (who do not have training in pharmacy, but are scientifically and chemically literate) have asked you to supply the following information:
(a) A description of the mechanism of action of omeprazole against Helicobacter pylori and peptic ulcer.
(b) A description of the physicochemical properties of the omeprazole derivative, the COOH-modified omeprazole derivative and the β-lactam antibiotic. This should include identification of all the functional groups in each molecule, the pKa values of any ionizable functional groups, the calculated intrinsic aqueous solubility of each molecule, an estimation of the pH dependence of the solubility of each molecule, the potential degradation reactions, and an estimation of the potential degradation rate as a function of pH.
(c) The shelf-life of the formulation at room temperature, and appropriate storage conditions.
(d) A complete description of the experimental aqueous formulation, including all the weights of the components to be included.

To perform this task, you first need to understand the physicochemical properties of the molecules. After finding this information, you will then be in a position to assess the viability of creating aqueous formulations of each molecule, to describe the difficulties associated with doing so, and to determine possible approaches to dealing with these difficulties. You will also be in a position to determine the most appropriate pH for your combination formulation, which in turn will allow you to identify the most appropriate buffer solution. With all this information, you will be able to calculate or estimate a shelf-life, and then determine the most appropriate storage conditions.

To approach the problem, you need the following information:
(1) An identification of the functional groups of the molecule.
(2) A list of the pKa values for each drug. These should be obtained from the literature directly, or by analogy with a similar drug (with an explanation of the analogy), or from Hammett-Taft equations.
(3) The water solubility of each drug. This information may be in the literature, or you may need to estimate the pH dependence of the solubility from literature data for other molecules. You have an Excel spreadsheet for calculation of the intrinsic solubility.
(4) A description of the possible degradation reactions the molecules might undergo in aqueous solution, as a function of pH, and an assessment of which of these reactions is likely to be of most importance. A rate constant for the degradation reaction(s) will be necessary to calculate the shelf life.
(5) The pKa values of the weak acids of several buffer solutions. This will help in your final choice of pH for the formulation and in your choice of which buffer solution to use.

The answer to the case study is due in 3 parts, on the dates indicated below. For each deadline, the list below gives the required parts of the answer and a suggestion of the number of pages for each section. Answers should be written in 12-point font, single spaced. All material should be presented in electronic form only by 9 p.m. on the deadline date.
Thursday, Sept. 26th:
(a) An explanation of the mechanism of action of omeprazole. (0.5 pages)
(b) A list of the functional groups of the omeprazole derivative and the ß-lactam antibiotic. (0.5 pages)
(c) The pKa values for the omeprazole derivative and the ß-lactam antibiotic, including literature citation and/or
details of the estimation or calculation of the pKa values. (1 page)
(d) A calculation of the intrinsic solubility of the omeprazole derivative, with a brief explanation. (0.5 pages, also
provide the Excel spreadsheet)
(e) A proposed structure for the COOH-modified omeprazole derivative, with an explanation of the choice, and a
calculation of its intrinsic solubility. (0.5 pages, also provide the Excel spreadsheet)
(f) A discussion of the pH-dependent solubility properties of the ß-lactam antibiotic. (0.5 pages)

Thursday, Oct. 3rd:
(a) An estimation of the pH vs. solubility curve for the COOH-modified omeprazole derivative and an explanation
of the basis for the estimated curve. (1 page)
(b) A discussion of the potential degradation reactions of the molecules. (0.5 pages)
(c) An estimation of the pH rate profile of the COOH-modified omeprazole derivative and an explanation of the
basis for the estimated profile. (0.5 pages)
(d) A quantitative discussion of the pH dependence of degradation of the ß-lactam antibiotic. (0.5 pages)
(e) A discussion of the overall degradation properties of the formulation. (0.5 pages)

Thursday, Oct. 10th:
(a) A discussion of the choice of the pH of your formulation. (1 page)
(b) A discussion of the choice of the buffer solution and a calculation of the weights of the buffer components. (1
page)
(c) A discussion of the shelf-life and the appropriate storage conditions. (0.5 pages)
(d) A list of the components of the formulation, including the weights of each component. (0.5 pages)