

Paper PO-11

Integration of Scientific Writing into an Applied Biostatistics and SAS Programming Course for Pharmaceutical Sciences Graduate Students

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ABSTRACT

Background: Successful training of graduate students and young investigators requires a mixture of didactic and practice-based learning. Students routinely indicate that they would benefit from more training in scientific writing; however, this is often difficult to teach effectively in isolation from research-associated activities to a group of students with a diverse background and research focus. The core elements of a scientific report are the presentation and interpretation of findings from the study statistical analyses. Thus, in order to provide students with an opportunity to develop their skills in the written reporting of scientific findings, we have integrated a scientific-writing component into a previously existing course in applied biostatistics and SAS programming.

Methods: Graduate students in the UNC Eshelman School of Pharmacy are required to take a second-level 3-credit course in the application of biostatistics (DPET 831). Each week students attend a 2-hour lecture discussing the most common statistical procedures used in biomedical research. Subsequently, students attend a 2-hour recitation at which they are provided a related case assignment (background, hypothesis, raw data, and analysis plan) and are expected, individually, to carry out the required analyses using SAS® software in a supervised computer lab. After recitation students independently write a brief but formal report (<1,000 words) on a customized Microsoft Word (Redmond, WA) template, including: introduction, methods, results, and discussion sections, similar to the standard format for a scientific manuscript. The report is submitted and returned electronically for critique and grading.

Discussion: The key course objectives for students enrolling in DPET 831 remain instruction in statistical methods, SAS programming, and data interpretation. Nevertheless, with minor modifications to the assignment template and instructions, students can simultaneously learn biostatistics and efficiently develop scientific writing skills in a controlled environment with a consistent mechanism to monitor student progression. This combined training could also be expanded to other research-related activities (e.g., grant writing) expected of the young investigator. Finally, we believe this integrated model could be implemented at other academic institutions with courses in applied biostatistics that are training young investigators for careers in the biomedical sciences.

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INTRODUCTION

The ability to write scientifically persuasive, yet succinct, manuscripts is an essential skill for independent investigators in all disciplines of biomedical research(1,2). This skill is particularly important for young investigators, as the number and quality of publications are commonly used as metrics to evaluate job performance in order to inform decisions regarding promotion and career advancement.

Unfortunately, formal scientific writing instruction during education is typically lacking(3), and students instead receive 'ad hoc' training provided by graduate and post-doctoral mentors. This supervised training is routine and vitally important; however, it is an inefficient system that may not yield independent investigators who are proficient manuscript writers. When students in biomedical research are queried about major barriers to writing instruction, the lack of mentorship or concern for their mentors time availability is a common response(4). Moreover, while most mentors have become competent writers out of necessity, not all mentors are interested in or capable of teaching writing skills to students. Thus, much of scientific writing is learned through 'on the job' practice early in a researcher's career, a process that may yield scientific writing proficiency only after years of suboptimal production. Formal training, even at the assistant professor level, has demonstrated benefits to publication production(5), supporting the notion that formal training early in a researcher's career could be extremely beneficial.

Conceptually, a 'scientific writing course' for graduate students is an attractive training mechanism, in that a single, well-trained faculty member could teach multiple students simultaneously. Unfortunately, teaching such a course

through lecture-based pedagogy is often “dry” or “uninteresting” and typically provides limited actual ‘practice’ in writing, thus neglecting the most effective method of teaching these skills to students. Alternatively, a practice-based course could be highly effective in training students, but would be a tremendous burden on either the faculty or students, depending on its design. A course in which each student writes a manuscript on a topic in his or her individual area of interest would be exceptionally time-consuming and challenging for any individual course facilitator to oversee and evaluate. On the other hand, a course that requires all enrolled students to write a manuscript on a single topic maximizes efficiency for the course facilitators at the expense of a valuable opportunity for students to expand their knowledge within their research field and eliminates the possibility of publication. That being said, a well-designed course in which students actively write manuscripts could be a highly effective method for teaching scientific writing skills.

The fundamental components of a manuscript are the description, interpretation, and presentation of findings from a scientific experiment. Unfortunately, scientific writing courses are often taught in isolation from research activities. As a result, many young scientists continue to struggle to adequately convey their research findings, particularly with regard to the statistical methods employed and the appropriate interpretation of their data. This short coming may be particularly important in instances when a biostatistician is not involved in the study design or final manuscript preparation.

Recognizing the importance of scientific writing to our students’ professional development and the inextricable link between data interpretation and scientific writing, we have integrated a formal writing component into an existing course in applied biostatistics. This course, which included a companion recitation for hands-on statistical analysis instruction using SAS® software, now requires students to complete assignments that possess the fundamental elements of writing a scientific manuscript.

ORIGINAL COURSE IN STATISTICAL ANALYSIS (DPET 831)

Since 2007, the UNC Eshelman School of Pharmacy’s Division of Pharmacotherapy and Experimental Therapeutics (DPET) core curriculum has included a 3-credit course in statistical methodology and application (DPET 831). The primary purpose of DPET 831 has been to teach pharmaceutical sciences graduate students how to analyze and interpret biomedical data. A weekly lecture taught by faculty and guest biostatisticians exposes students to issues related to proper trial design and examples of the application of the most commonly encountered statistical methodologies (Table 1). Students then attend a compulsory, companion recitation session where they use the statistical procedures and example SAS programming taught during that week’s lecture to analyze results from a case problem and dataset provided by the course director.

Table1 is a revised course outline for DPET 831:

Week	Lecture Topic	Recitation Assignment
1	Introduction (descriptive statistics, types of study designs, hypothesis testing, types of data)	Introduction to SAS programming (tutorial review; data entry; descriptive statistics)
2	Population sampling, sample distributions; Type I & Type II error; significance of “significance”	Review of case assignment expectations and grading
3	Analysis of continuous data (Student’s T-test, paired T-test); interval estimation	One-sample and paired t-tests; tests for normality; confidence interval estimation.
4	Correlation, simple linear regression; polynomial regression; regression-toward-the-mean;	Correlation & linear regression; polynomial regression
5	Analysis of variance (one-way ANOVA); multiple comparisons; dose-response analysis	Two-sample t-test; one-way ANOVA, multiple comparisons tests.
6	Two-way ANOVA & interaction; ANOVA for rand. block design; factorial experiments	Two-way ANOVA & interaction; multiple comparison tests (cont.)
7	Analysis of covariance (ANCOVA), interaction; repeated measures (mixed effects) ANCOVA	ANCOVA vs. ANOVA (baseline & covariates); test of interaction
8	Multiple linear regression; collinearity; centered regression, diagnostics	Multiple linear regression (model building); Diagnostics
9	Residual analysis; data transformation; outlier analysis	Exploratory data analysis (testing parametric assumptions: residual analysis, transformations)
10	Issues with statistics in genetic research; multiple comparisons in genome-wide analyses	Integration and interpretation of parametric statistical methods
11	Analysis of clinical pharmacology studies (bioavailability, food effect, & drug interaction)	Analysis of data from repeated measures or randomized block design
12	Analysis of categorical data (Chi-Squared test, McNemar, Mantel Haenszel, logistic regression)	Chi square; stratified chi square (Mantel-Haenszel); logistic regression

13	Analysis of ordinal data (Wilcoxon Rank Sum & Signed Rank, Kruskal-Wallis, Spearman's Rho)	Wilcoxon rank-sum; Kruskal-Wallis; ANOVA using rank data; Spearman rank test
14	Analysis of time-to-event (i.e., "survival") data (logrank, Cox Proportional Hazards)	Time-to-Event analysis: logrank test; Cox proportional Hazard
15	Response-surface analyses (manufacturing statistics – process engineering)	Guest Presentation: "SAS Use in Clinical Trials and other Applications"

Table 1. Spring 2012 Lecture and Recitation Outline

The recitation portion of DPET 831 would later provide a practical setting for us to incorporate scientific writing into the graduate curriculum. Each recitation case assignment (example - Figure 1) included the following: the study's purpose, methods, hypothesis, analysis plan, and raw data. During recitation, the students were expected to use SAS to complete the analysis of the provided dataset following the case problem instructions.

Figure 1 is a sample recitation case problem and assignment:

Log Rank and Cox Proportional Hazard Tests

Research Problem: An experiment was performed to determine the antinociceptive effects of three doses of morphine compared to vehicle control. Rats (N=40) received a single dose of morphine (1, 3, or 6 mg/kg) or vehicle (0 mg/kg), using a 1:1:1:2 allocation ratio to treatment groups. Antinociception was evaluated using the hot plate assay (set at 55°C). Rats were placed on the hot plate and the time until the rats lifted their hind paw was recorded. Even if a rat had not yet lifted its hind paw, it was removed from the hot plate after 32 seconds (i.e., censored), to prevent injury to the animal. The weights of the rats (grams), treatment, dose, gender (1=female, 2=male), and time to lift hind paw (seconds) were recorded. Animals removed at 32 seconds were indicated by a "1" in the censor variable column. Three (3) animals also were censored before 32 seconds. When the experiment was being conducted, these animals appeared to lift their hind paw and so were removed from the hotplate. However, after reviewing the video of the experiments, it was determined that the 3 animals had been removed prematurely.

Assignment: Import the R14 Microsoft EXCEL dataset posted on Sakai. Calculate the mean, SD, and median values for weight and time for each dose level and treatment group. Use Proc Plot (not Proc GPlot) to plot time vs. dose. Next, conduct a log-rank test (Proc LIFETEST) to determine the effect of morphine dose on time to lift the hind paw. Test whether the global test of equality over strata (Logrank value, Z-Score) shows that there are statistically-significant differences in time among the four dose levels. It is expected that, with increasing doses, there will be a monotonic increase in response. Thus, include the TREND option to reflect the expected ordering of response. Also, compare each active morphine dose to control (i.e., dose=0) and adjust for the 3 pairwise comparisons using "Adjust=Dunnett Diff=control("0") after Strata=Dose / Test=Logrank."

Next, using the Cox Proportional Hazard model (Proc PHREG), determine whether there is a significant difference in time to lift the hind paw. For this portion of the exercise, only compare the 3 mg/kg and the 0 (vehicle) dose groups. For the Proc PHREG analysis, use a SET statement (rather than a WHERE statement) to create a new dataset and keep only the dose levels of interest. Perform a covariate-adjusted survival analysis for these two dose levels, by including weight and gender (along with dose) as independent variables. For this exercise ignore the interaction test. Ensure that, in the Class statement, the reference group for dose and gender is 0 (vehicle) and 1 (females), respectively, by putting Dose (ref='0') [and Gender(ref='1')] / param=ref, as was done with Proc Logistic (R13). Is there a difference between 3 mg and vehicle in the time that rats lifted their hind paw? Do either (or both) of these covariates significantly influence the time to lift the hind paw?

Finally, use the ODS html (graphics on) option to generate and retain the following 3 plots for the homework: 1) Proc LIFETEST-generated Kaplan-Meier curve for the 4 dose levels, 2) Proc LIFETEST-generated LLS ("hazard") plot supporting the proportional hazard assumption required to appropriately use the Cox procedure, and 3) the Proc PHREG-generated two-treatment survival curves. Summarize your findings from these analyses in a brief scientific report.

Figure 1. Example Research Problem and Recitation Assignment

Since these students were naïve SAS users, they were also given a Microsoft PowerPoint "SAS Crash Course" (example - Figure 2), which provided guidance and an explanation of the SAS coding procedures required to execute the analysis for each assignment. Recitations were overseen by both the course director as well as a secondary course facilitator, a senior teaching assistant, "senior TA," who typically was a 2nd or 3rd year graduate student who had previously completed and excelled in the course.

Figure 2 is a sample SAS Crash Course Slide:

SAS Crash Course: R14 (p.1-3)
PROC LIFETEST

- PROC LIFETEST runs the log-rank test

PLOTS=(Survival(test)) creates a Kaplan-Meier plot; **PLOTS=(LLS)** creates a log(-log(survival) vs. log(time) plot, which should be approximately linear and the lines parallel.

```
PROC LIFETEST PLOTS=(Survival(test))
PLOTS=(LLS) DATA=datasetname;
TIME yvariable*CENSOR(1);
```

CENSOR(1) indicates that censored values are coded with a "1" in the dataset

```
STRATA xvariable / Test=LogRank TREND
Adjust=Dunnett Control("0");
```

Title; **TREND** is used when there is an expected ordering to response. **Adjust=Dunnett Diff=control("0")** - tells SAS to only compare the 3 dose effects to vehicle, adjusting for the 3 comparisons using the **Dunnett-Hsu** procedure.

RUN;

Figure 2. Example "SAS Crash Course" Slide

At the end of the recitation period, each student was expected to have finished the coding and generated the necessary SAS output to complete the assignment. The assignments were then critiqued and returned to the students electronically before the next recitation period to ensure ample time for students to reflect on facilitator feedback.

A crucial component of the recitation assignment was the creation of a customized, expandable template in Microsoft Word. This template, provided at the beginning of the course, ensured a uniform final product produced by each student and greatly streamlined the assignment critique and grading processes. The original DPET 831 template included a designated area to be populated with the assignment, the final SAS code, the relevant SAS output, and any plots and figures that were generated. The template

also included a brief interpretation section with general directions for describing the statistical procedures used and summarizing the results obtained, again, representing the fundamental elements of a scientific manuscript.

ADDITION OF SCIENTIFIC WRITING COMPONENT TO DPET 831

In 2010, recognizing the unique opportunity to integrate a formalized scientific writing component into an existing course in data analysis and interpretation, the DPET 831 recitation was modified, a transformation process that continues to evolve annually. The modification necessitated only minor changes to the existing course. For example, the total amount of biostatistics material covered during class time did not increase, nor did the total time that students spent in either lecture or recitation.

The primary changes to the course were adjustments made to the interpretation section of the template (Appendix 1). Originally, the interpretation section required many components (e.g., statement of a research problem and hypothesis, execution of data analysis, and interpretation of statistical output) that are fundamental aspects of scientific manuscript writing. However, the interpretation section was not structured in a way that reflects standard manuscript writing format. Adapting the template to formalize the scientific writing objective was straight-forward. Students are now expected to write a brief Introduction using the information provided in the expanded case assignment. Because the main objectives of the course remain instruction in applied biostatistics and statistical methodology, the required Statistical Methods section is *more* thorough than that typically found within a manuscript. Students are expected to comment in detail on the descriptive and inferential statistical tests employed, test assumptions, appropriateness of those tests given the type of data, and explicitly state the null and alternative hypothesis for each individual analysis. In the Results section, students report the results of both the descriptive and inferential statistics derived from the SAS output (including: the test statistic(s), df, p-value, magnitude of effect, and a concise statement concerning rejecting or accepting the null hypothesis). Finally, a Discussion/Conclusions section requires students to succinctly interpret their findings, note any unexpected results, and, if appropriate, comment on the generalizability of their results.

BENEFITS OF REPEATED, GUIDED PRACTICE IN SCIENTIFIC WRITING

By integrating formal manuscript writing practice into an existing course in applied biostatistics, we have developed an efficient framework for hands-on training in the preparation of the fundamental components of a scientific manuscript. Importantly, because students typically complete 12 assignments over the course of the semester, they are exposed to a wide range of statistical procedures across an array of different study types, representing the spectrum of biomedical research from *in vitro* studies through clinical trials. As the course progresses and students master simpler concepts, more advanced statistical techniques are introduced and writing expectations increased, to ensure that students continue to develop their skills.

Aside from weekly practice, the success of this initiative to teach scientific writing has been contingent upon guidance and feedback, both during the recitation and outside of class time. The senior TA, by virtue of grading numerous uniform reports each week, can easily identify major issues for a single student, or a pattern in a group of students, and address these issues in the appropriate individual or group setting. For example, one semester a pattern of

students presenting results that were not described in the Methods section was identified early on. The students were each given written feedback on their individual assignments, and this was also reviewed with the whole class at the beginning of the next recitation. The senior TA can also monitor each student's understanding of the feedback they receive and oversee individual student improvement throughout the semester.

INCORPORATION INTO AN EXISTING COURSE IN BIOSTATISTICS IS HIGHLY EFFICIENT

The inclusion of formal manuscript writing techniques into the assignment shifts the focus from simply reporting data to a paradigm based more on critical thinking skills, thus requiring students to interpret and provide context for their findings. Not surprisingly, the expanded interpretation requirements have increased the time students spend completing the assignments. Similarly, the workload was increased for the senior TA, due to critiquing and grading the expanded interpretation and providing feedback. The total weekly workload and time commitment for the course director also was slightly increased, due to a need to find more applicable cases and to adapt or expand certain sections of the case problem.

While there was a modest increase in invested time for the students and instructors, we strongly believe that the benefits to our students of repeated, guided scientific writing practice are sufficient to warrant this increase. By incorporating scientific writing into an applied biostatistics course, we have maintained the crucial link between sound statistical reasoning and written communication of experimental findings. Moreover, integrating scientific writing in this format circumvents the potential inefficiencies and shortcomings inherent in teaching scientific writing which we discussed earlier. In part, the efficiency of this method is due to the incorporation of scientific writing practice into a core course already required for the students. From the instructor's perspective, the uniformity of a singular case, dataset, analysis plan, and SAS crash course, ensures that all students will have highly consistent code and results, yielding similar discussion/conclusion sections across the class. This allows the course director, working directly with the senior TA, to produce a single set of expectations and grading rubric, which enables the senior TA to execute the vast majority of the grading. Finally, because the template is provided, submitted, and returned electronically, no printing is needed throughout the lifecycle of the assignment, saving the School potentially substantial printing costs. Thus, we believe that we have been able to efficiently integrate scientific writing into the core curriculum with minimal additional burden on the students, faculty, or the UNC Eshelman School of Pharmacy.

LIMITATIONS OF OUR APPROACH

Though we are pleased with our experience to date with the incorporation of scientific writing into DPET 831, we recognize that there are a number of limitations to this approach in addition to the previously-discussed requirement that all students must work on the same assignments.

1. We recognize that the scientific writing experience in DPET 831 is somewhat limited in that the recitation assignments only require authoring primary research manuscripts, and thus ignore many other forms of scientific writing (i.e. systematic reviews, commentaries, letters to the editor, or grant writing). While it is possible to envision the extension of this process to include some forms of scientific writing (i.e. abstracts, posters), it is unlikely that others (i.e. reviews and commentaries) could be incorporated into this format.
2. The required brevity of the reports, in terms of word limit and time for completion, preclude inclusion of the literature review customarily found in a scientific manuscript as well as limiting the depth of interpretation that is possible within any given assignment.
3. No matter the setting or course structure, the effectiveness of training in scientific writing is limited by the skills and experience of the individuals critiquing the documents. While we feel confident in our abilities as writing supervisors, we accept that another reviewer may have different comments on any given report. It is the concept of integrating scientific writing with biostatistics and SAS programming, and not the report itself that we believe to be the novel insight underlying this manuscript.
4. Finally, no single course can create a well-qualified scientific writer. However, hopefully this course provides foundational scientific writing skills, particularly the analytical components, which the student can further develop through on-the-job practice.

CONCLUSIONS

Despite the above limitations, we believe that the integration of scientific writing into DPET 831 addresses an important need in the training of our students at a low investment cost to the UNC Eshelman School of Pharmacy. As previously discussed, we continue to collect student feedback and expect to further improve the course each year. We recognize that there is still great potential to expand the scientific writing skills taught to students, both within and outside the context of manuscript writing. Nevertheless, we view the integration of scientific writing with biostatistics and data analysis as both an efficient, and an effective way to teach scientific writing to students and young investigators who engage in biomedical or statistical research.

Appendix 1. Revised Blank Template for Completing and Submitting Recitation Assignment

<h2 style="margin: 0;">DPET 831 Recitations ²⁰¹²</h2> <h3 style="margin: 0;">Quantitative Methods in Clinical Research</h3> <p>UNC-DPET Instructor: Heyward Hull, PharmD, MS (jhull@unc.edu, 966-7590) Teaching Assistants: John Doe (JDoe@unc.edu, XXX-XXX-XXX) Recitation time and location: Thursdays 3-5 pm – Basement Computer lab. Office Hours: By appointment. Email address for Homework Submissions: see TA above. Important: Please rename your attachment in the following format: R01(name).doc</p>	<h3 style="margin: 0; background-color: black; color: white; padding: 2px;">Current Homework Assignment</h3> <p style="margin: 5px 0;">By my name below, I pledge that I have neither given nor received any aid on the interpretation section of this assignment.</p> <p style="text-align: center; margin: 10px 0;"> RXX: Student's Name Recitation Date: X/XX/2012 </p>												
<h3 style="margin: 0; background-color: black; color: white; padding: 2px;">Late Submission Policy</h3> <p style="margin: 5px 0;">Each homework must be turned in no later than 10 am on the Monday after the Recitation class. There is a penalty for late homework: After 10 am - 1 point; beginning 12:00am Tuesday- 2 additional points are taken off for each day late. If you cannot work on the homework due to matters beyond your control, please contact one of us <u>beforehand</u> and we can make an exception to these rules.</p>	<h3 style="margin: 0; background-color: black; color: white; padding: 2px;">Grade</h3> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="padding: 2px;">SAS Code/Output</td> <td style="width: 10%;"></td> <td style="width: 10%; text-align: center;">3</td> </tr> <tr> <td style="padding: 2px;">Interpretation</td> <td></td> <td style="text-align: center;">7</td> </tr> <tr> <td style="padding: 2px;">Programming Questions</td> <td style="text-align: center;">n/a</td> <td style="text-align: center;">n/a</td> </tr> <tr> <td style="padding: 2px;">TOTAL</td> <td></td> <td style="text-align: center;">10</td> </tr> </table>	SAS Code/Output		3	Interpretation		7	Programming Questions	n/a	n/a	TOTAL		10
SAS Code/Output		3											
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<h3 style="margin: 0; background-color: black; color: white; padding: 2px;">I. SAS Research Problem</h3> <p style="margin: 5px 0;">please click here to paste your sas research problem.</p>													
<h3 style="margin: 0; background-color: black; color: white; padding: 2px;">SAS Programming Code</h3> <p style="margin: 5px 0;">please click here to paste your sas code.</p>	<h3 style="margin: 0; background-color: black; color: white; padding: 2px;">Comments</h3> <p style="margin: 5px 0;">This column is for grading and comments from the instructor.</p>												
<h3 style="margin: 0; background-color: black; color: white; padding: 2px;">SAS Output</h3> <p style="margin: 5px 0;">please click here to paste your sas output.</p>													
<h3 style="margin: 0; background-color: black; color: white; padding: 2px;">Plots / Graphs</h3> <p style="margin: 5px 0;">please click here to paste your sas plots.</p>													
<h3 style="margin: 0; background-color: black; color: white; padding: 2px;">Interpretation</h3> <p style="margin: 5px 0;">This field is for your (brief) report of the study or experiment. <u>Do not paste SAS Output in this section!</u> Please make sure that you address the points (listed below), unless not relevant for a given assignment. Note: You cannot collaborate with others in writing your interpretation of the data, and should confirm this commitment by agreeing to the "pledge" in the upper right corner of this document.</p> <ol style="list-style-type: none"> 1. Please write a brief <u>Introduction</u> to the study as if you were writing a (brief) manuscript for publication. Include general comments about the population, the study design, and the purpose of the analysis. 2. Write a <u>Statistical Methods</u> section that explicitly states first the <u>descriptive</u> statistical tests and next the <u>inferential</u> statistics that were performed. Comment on whether the scales of measurement (type of data) and properties of the sample data are consistent with the assumptions necessary for use of the statistical tests. Include the null and alternative hypotheses for each statistical test. 3. Write a <u>Results</u> section. First, describe the <u>descriptive statistics</u> from the SAS Output for the experiment or study. Include means (\pm SD) or medians (range), and/or frequency data that represent appropriate summaries of the particular variable data. If helpful, create a table to organize these data. 4. Next, in the <u>Results</u> section, report the findings from the <u>inferential statistics</u>. Include all relevant information for each of the statistical tests carried out. This should include the mean treatment effects (\pm SD), test statistic values (e.g., $t_{27\text{ df}} = 2.05$ and the p-values associated with your test statistics. Report whether these results allow you to reject the null hypotheses. 5. Include a brief summary (<u>Discussion/Conclusions</u>) with your interpretation of the statistical results, as they relate to the specific questions of the study. If there were any questions posed in the assignment respond to them in this section. Finally, if there are any unusual findings from the analysis, please comment. Comment on the study limitations and/or generalizability of your findings (e.g., to other populations). <p style="margin: 10px 0;">please click here to type your brief study report.</p>	<h3 style="margin: 0; background-color: black; color: white; padding: 2px;">Comments</h3> <p style="margin: 5px 0;">This column is to be left blank for comments, corrections, and suggestions by the instructor or by the TA.</p>												

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ACKNOWLEDGMENTS

We would like to gratefully thank Berk Zafer who was of invaluable help with the development of the customized template in Microsoft WORD for DPET 831. DH, DC, JT, and KT were supported by fellowships from the American Foundation for Pharmaceutical Education (AFPE) while serving as teaching assistants for DPET 831.

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