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A Second Call for Invited Sessions for JSM 2001

In the last newsletter, a call for invited sessions sponsored by the Statistical Consulting Section for 2001 was announced. Session ideas that have surfaced include statistical consulting and the internet as well as the incorporation of spatial statistics methods into consulting issues related to design and analysis.

I am still looking for additional inputs into these areas as well as other ideas on invited sessions that potential organizers would like to develop. The invited sessions need to be fairly well developed before the JSM 2000 meetings

in Indianapolis.

Please contact me as soon as possible if you are willing to organize a session and have an idea of potential interest to Section members and others. I would also welcome any suggestions on ideas that could be co-sponsored by other Sections. Sessions addressing technical issues of broad interest are particularly sought.

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The Changing Role of Statistical Consulting in the Pharmaceutical Industry

Rocco Brunelle, Eli Lilly and Company*

The surprise coldness of a single bead of sweat cascades down your back. This meeting is not going as planned.

The project manager is creating a time line that is not only aggressive but also gives you very little time to do your analyses. There is not enough time to perform a detailed analysis, and there is not enough time to work with the clinician and the rest of the team to review and refine the analyses.

The above scenario is becoming typical, as the way statisticians work in the clinical areas within the pharmaceutical industry changes. Statisticians have increasing responsibility to provide a high quality analysis in a very brief period. This is in addition to being responsible for the statistical portions of a clinical trial, including accepting the database, approving all tables and figures, and reviewing all inferences within the final report.

The Old Model

In the past we often could carefully analyze the data and take the time to work closely with the clinicians and other team members to better understand the clinical trial findings. This would lead to refinements of the analyses and models until we arrived at what we felt was the most appropriate analysis of the study results. Time lines were always present, but were often secondary to producing a high quality analysis and final report.

In this model the statistician was often part of a self-managed work team. Initially, the team consisted of the MD, CRA (Clinical Research Administrator) and the statistician. Representatives from systems, data manage-

ment and other areas would join the team as the project moved ahead.

A physician would come into my office with a new study, and we might take months discussing the objectives, hypotheses and possible study designs. We would check the literature and talk to other experts from the medical and statistical areas, both within and outside the company.

Slowly a fine tuned, efficient protocol would emerge. I recall going to the gym during lunch with one physician, two or three times a week, and discussing various protocols while weight lifting. I guess one could say that this had the opportunity to be a “powerful” study!

The New Model

With the advent of project management and very aggressive time lines, the old model no longer exists.

The clinical teams all try to minimize time to approval of each new drug, especially the time from last patient visit to a completed final report. This includes the time to perform the analysis.

The clinical team expects the analysis to be completed within days of the final datalock. However, delays in the final analysis can be caused by re-analysis because of bad source data, a database that is not in the right form or was entered incorrectly, additional analyses requested by the team and physicians, and statistical assumptions that are not satisfied.

Under this new model, the statistician must re-engineer how a statistical analysis is done. One way to meet the more aggressive goals is to do some serious up front planning. In addition, the statistician needs to work care-

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fully with the physician and the clinical team to insure that all of the required analyses are identified early.

Advance planning should include the following steps:

Step 1. Put together a detailed analysis plan before you see any data. A good time to do this is shortly after the study has started. Work closely with the physician and team members when developing this plan. Also, use the International Conference on Harmonisation (ICH) guidelines (ICH: Guidance on Statistical Principles for Clinical Trials, 63 FR 49583) as a template to check for completeness.

The detailed analysis plan should contain the exact format of each table, graph, listing and analysis. It should be reviewed by another statistician and approved by the clinical team. The analysis plan should become a blue print or contract for the analysis.

Step 2. Obtain a test dataset as soon as possible after the start of the study. Use real data if possible in a blinded fashion. Check assumptions and use this data to test the programs. It has been my experience that testing in real data is far better than in fictitious data.

Step 3. Review the reporting database carefully before datalock. Check for outliers. Validate all calculated fields.

If feasible, have data management staff validate the data using the case report forms from a few patients. Better yet, work with the data management staff to perform a database quality review. Careful examination of the data will obviate the need to redo the analysis due to bad source data or mistakes in the database.

Step 4. Have all programs validated and reviewed prior to datalock. This is necessary to successfully reduce the time between datalock and the completion of the analysis to a minimum.

I typically give myself two weeks to perform this task. It should only take a few days

to run the programs but invariably something happens and one or two of the programs no longer work with the new locked database.

The goal is to minimize the time to perform the analysis after datalock. This can be accomplished by carrying out most of the procedures needed to perform the analysis before the database is locked. There will always be some additional analyses that are needed after the final results are obtained, but this should be held to a minimum.

Finally, I would like to offer a few axioms I have discovered when working on both protocol development and analyses for a clinical trial, which others may find useful.

Axiom 1: Statisticians always make people think. This tends to slow the process especially during protocol development.

Axiom 2: Thinking always improves the process. Taking time to think through the entire process typically finds flaws and improves the final product.

Axiom 3: There is a strong inverse relationship between the amount of time spent planning and the amount of time in execution. Minimizing the time spent in the development of the protocol or analysis plan maximizes the time needed to resolve the confusion created by rushing. A corollary is that there is an inverse relationship between the time spent with the client and the time spent in performing the analysis.

Axiom 4: There is a direct relationship between the quality of a product and the time spent performing reviews. Nothing improves the quality of the final product more than a good, detailed review.

A well-conducted clinical trial is a difficult task. Rushing the protocol development and final analysis adds to the complexity and increases the chance of creating a poor quality study.

The statistician can greatly reduce the amount of time needed to perform the analysis by increasing the time spent in planning for the analysis. In addition, working carefully with the clinician and the clinical team helps to insure that the analyses are all well defined before the end of the study.

This is a challenge. The statistician needs to take charge and accept the ownership of the analysis and insure that the inferences are accurate and unbiased. Careful planning, teamwork and leadership will assure that the study is done quickly with high quality.

Comments from the Section Chair

Brian S. Yandell, University of Wisconsin-Madison*

Y2K started with a bang for *us*, anyway. Eli Lilly and Co., headquartered in Indianapolis, has offered to host the section mixer at JSM 2000. This promises to be a much larger affair than we have had in the past, and I encourage all members to drop in, sample the food and say hello. Oh. . . don't forget about the fabulous door prizes.

In the next issue of *The Statistical Consultant*, you will see the fruits of the diligent efforts by Program Chair Ron Wasserstein to build an excellent set of sessions for JSM 2000. These serve our charter mission, to foster increased and improved use of statistics through effective consulting interchanges. Thanks, Ron, for your continuing commitment to this section. Ideas for JSM 2001 should be forwarded to Rob Tempelman, the Program Chair for next year (see announcement elsewhere in this issue).

Our section has volunteered to participate in a new initiative to go electronic with proceedings. It is too early to tell how this will

progress, or even if the process will be ready for JSM 2000. However, the members of the Executive Committee feel this would be both cost-effective and better serve our outreach mission. If you have comments about this, please contact me or Nancy Berman, Publications Officer (berman@gcrc.humc.edu).

The section web pages have been in flux, for which I and the Executive Committee apologize. Very soon, thanks to the hard work of Elaine Allen and her son Chris Seaman, our website will consist of newly refurbished pages that sit directly on the ASA web site (www.amstat.org/sections). Once these are in place, it will be much easier to keep them up to date—and they won't move again!

We are always looking for volunteers to help build our section. Do you have consulting ideas just itching for release? Please contact one of us to work informally, or let Janice Derr know that you would like to be nominated for an office next time around. Take charge of your section, and come visit us in Indianapolis.

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Written Communication Skills for Consulting Statisticians: Creating a Collaborative Environment with Clients

Nancy M. Fenn Buderer, St. Vincent Mercy Medical Center*

Introduction

In today's world of computers, electronic mail and facsimile machines, our ability to communicate effectively depends on our ability to write effectively. The human moment—"the authentic psychological encounter than can only happen when two people share the same physical space" (Hallowell 1999, p. 59)—is no longer the primary method for communicating.

For consulting statisticians, skills in written communication are critical (Boen & Zahn 1982, p. 22). Our written reports document not only the results of data analyses for our clients, but also reflect our professionalism and our contribution to a project or collaborative team (Baskerville 1981, p. 122).

The written report is an essential final step in the consulting process (Boen & Zahn 1982, p. 194; Marquardt 1981, p. 218). Key points can often be communicated more clearly, and with less danger of loss, by writing them down (Boen & Zahn 1982, p. 194). Deming (1965, p. 1893) stated that "the aim of a statistical report is to protect the client from seeing merely what he would like to see; to protect him from losses that could come from misuse of the results."

What and how we write influences the collaborative environment shared among statisticians and their clients. Jonas Ellenberg wrote "Better communication will likely make us stronger collaborators. Assuredly, and perhaps more importantly, it will raise the level of respect with which statisticians are viewed . . . if we start communicating like professionals, perhaps we will end up being treated as

professionals" (Ellenberg 1999, p. 9).

Helen Baker (1993, p. 1291) said "Every correspondence not only includes the content of the communication, but also enhances or hurts the relationship between the author and the recipient."

Although many authors in the statistical consulting literature have emphasized the importance of written communications skills, few offer specific advice on writing. This article offers an approach for writing the results of data analyses that fosters a collaborative environment between statisticians and their clients.

General Tips

Tone. The most important consideration in creating a collaborative environment through writing is the tone of your words. "All communications should be designed both to communicate effectively and to build morale and relationships" (Baker 1993, p. 1294). "The tone of this relationship is determined by the personal attitudes and professional abilities of both the consultant and the client" (Strickland 1996, p. 3).

In general, put in writing only what you would say face-to-face. Marlene Caroselli (1990) suggests the following: Think about whether any of your words can come back to haunt you. Is there something you should avoid saying? Is there anything that will offend others? Avoid sexist language. Is there anything that might be misinterpreted? Think twice about what you put in writing.

Therefore, write tactfully, respectfully, non-judgmentally. One of the ways to do this is to avoid words that turn readers off. Ex-

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amples of negative words include: not, never, couldn't, wouldn't, shouldn't, can't, don't, won't, should, allege, claim, complain, wrong, fail, fault, inadequate, insist, demand, misinform, mistake, neglect, overlook, oversight, must (SkillPath 1992, p. 9).

“If your intent is to operate in an atmosphere of mutual respect and good will, remain polite . . . write polite phrases, such as ‘Please’ and ‘Thank you’, particularly in circumstances that do not require such niceties” (Baker 1993, p. 1291).

Professionalism. Treat everything you write as a professional product. The report you present to the client should be neat and organized.

With modern technology, there is no excuse for handwritten reports, misspelled words or sloppy computer output. Type all reports. Use spell check and a current dictionary. Proofread and check every number before releasing a report to the client.

Use proper grammar and punctuation (Horner, Webb, & Miller 1994). One way to do this is to avail yourself of lists of incorrect word choices (affect/effect, lay/lie, among/between) (Horner, Webb, & Miller 1994). Also, “Memorize the grammar rules you use often. Research the grammar rules you use only occasionally. Forget the grammar rules that make your writing or speech awkward to your audience” (SkillPath 1992, p. 8).

Language. An effective writer uses language that is understandable to the reader. Some clients are very knowledgeable of statistics while others do not know what a standard deviation is. By knowing your client's level of statistical literacy, you can provide the appropriate explanations of statistical concepts, jargon and methods. Regardless of their statistical competence, it is best to “avoid formulaic complexity” (Ellenberg 1999, p. 8).

Style. Write scientifically, not socially. Avoid repetition. Vary sentence structure. Use short sentences and paragraphs. Use active, rather

then passive voice. Recommended style guides include Caroselli (1990), Horner, Webb, & Miller (1994), Strunk & White (1979), Zinsser (1985) and Freeman & Bacon (1990).

Follow-up. It is a disservice to the client to email him a fifteen-page report without any oral explanation or follow-up. It is especially useful to follow-up with a telephone call to the client after mailing the report. Arrange a time with the client to discuss the report: put the “human moment” back into statistical consulting (Hallowell 1999).

An Example

The following text was the first paragraph of a report summarizing the statistical analysis on data from a medical research study. As you read it, imagine how the client may have reacted.

“Hello and how are you? As you may very well know, in this study, there were several empirical deficiencies regarding sample size and inconsistencies in validity and reliability of data collected. Fortunately, this is an exploratory project or an ad hoc research in terms of the numerous methodological challenges, because I would have recommended the data be recollected using more sound data collection methods.”

Several of the tips are ignored in this example.

The tone is offensive. “Hello and how are you?” is social writing, not scientific or professional. “As you may very well know” shows disrespect for the client. If they knew their study design was inadequate they would not have done it in the first place.

Negative words are used: *deficiencies* and *inconsistencies*. Statistical jargon is given without an explanation of how it applies to the study, including *empirical*, *validity* and *reliability*.

Non-specific language leads to confusing statements like *empirical deficiencies* and

methodological challenges. It is not helpful to say “*recollected using more sound data collection methods*” without suggesting alternative methods or offering to help the client. Grammar and punctuation need help.

Consider the following alternative paragraph. The tone is helpful, respectful, professional and positive. *Validity* and *reliability* have been replaced with words the client may better understand: *accuracy* and *reproducibility*.

“I have reviewed your research proposal and offer suggestions regarding the sample size and data collection methods. Enclosed is a revised sample size calculation for your consideration. Also enclosed is an example of a data collection tool that may improve the accuracy and reproducibility of your data.”

Formatting

Letterhead. Baker (1993, p. 1293) suggests you “always use letterhead for outside communications, even with your closest friends”. However, in some situations, the formality of letterhead may undercut your team player image. Whether or not you choose to use letterhead, provide your contact information on the first page including telephone and facsimile numbers, postal and email addresses.

To: First name, Last name, degree(s). Address the report to the person with whom you are working most closely, and possibly to other team players. In addition, consider copying the boss and/or the person paying the bill. To be on the safe side, ask the person you are working with to identify the individuals who should be listed on the report.

Show your respect for clients by spelling their names correctly, avoiding nicknames and including their academic degrees. Baker suggests that “to further emphasize the ‘team’ approach, list names in alphabetical order, rather than listing the ‘most important’ person first” (Baker 1993, p. 1292).

From: Your name, degree(s). If you did the work, then use your name in the “From” section of the report. Take ownership. The ASA Committee on Professional Ethics suggests you “identify who is responsible for the statistical work if it would not otherwise be apparent” (ASA Ethics 1999, p. 14). List others’ names only if they have contributed to the work and have read the report.

List your name, with academic degree(s), as you would want it to appear in a publication. However, Baker suggests that “when dealing with people who are aware of your degrees and titles but who don’t have such impressive credentials themselves, no need is served by repeating your titles” (Baker 1993, p. 1292).

Today’s date.

Re: Subject. Use an informative yet brief subject line. Use bold type or color for attention, for example, “***Final Analysis of Nursing Study Data.***”

Content

Design your report as though it were a manuscript for a peer-reviewed journal (Day 1998, International Committee of Medical Journal Editors 1997, Hawkins & Sorgi 1993, Horner, Webb, & Miller 1994). Include the following sections, in order:

- Introduction
- Methods
- Results
- Tables
- Limitations
- Summary
- References

Introduction. “Get to the point promptly. The first paragraph should clearly and succinctly state the issue being addressed” (Baker 1993, p. 1290). For example, you might write,

“This report contains the results of the statistical analyses I performed to address each of the study’s specific aims.”

Re-state the aims. Number each aim and follow this order throughout the other sections of the report. For example, *“As I understand your study, the specific aims were 1) To . . . , and 2) To Secondly you were interested in knowing. . . .”*

Providing explanations or background helps build a collaborative environment. For instance, if you intend to do more work on the project before you next meet, then reassure the clients that you have more to do and what it is. Tell them when is a good time to reach you and if you are going to be out of town.

To ensure follow-up with a client, a standard paragraph you might include on the first page of each report is as follows:

“If you have any questions while you are reading this report, please call me (800-555-5555). After you have had a chance to review these materials I would like to meet with you to discuss the analyses, answer any of your questions and address other research questions you may have. Thank you.”

Methods. Provide enough details in each of these areas to demonstrate your understanding of the study:

- **Design.** Use design buzzwords, as defined in several texts (Lang & Secic 1997, International Committee of Medical Journal Editors 1997, Bailar & Mosteller 1986). Mention randomization, blinding and controls. For example: *“This was a prospective, randomized, double blind, placebo-controlled clinical trial.”*

- **Participants / Units of Observation.** State the unit of observation and briefly mention the inclusion/exclusion criteria. Give the details of subjects or groups you omitted from analyses and why. For example: *“Motorcycle riders were excluded from the analyses of patients involved in motor vehicle collisions.”*

- **Interventions / Procedures.** Briefly explain the study procedures, including any

follow-up visits and timing.

- **Main Outcome Measures.** The primary endpoints are listed here. They should correspond to the primary aims as stated in the Introduction.

- **Operational Definitions.** In this section explain any variables you created and how. For example: *“The group ‘Children’ includes cases that were of age less than 14 years at randomization.”*

- **Statistical Methods.** Following the order of the aims stated in the Introduction, explain the statistical approaches you used to address each of the client’s research questions. “Report statistical and substantive assumptions made in the study. Account for all data considered in a study and explain the sample(s) actually used. Report the data cleaning and screening procedures used, including any imputation” (ASA Ethics 1999, p.14).

Include the level of significance (*“A level of 0.05 was set as the criterion for a statistically significant difference between the two groups”*), adjustments for multiple testing and one or two-tailed testing.

Consider providing the client with two statistical methods sections, one in lay terms and one in technical terms suitable for a professional journal. You might also offer to help write this section in the client’s manuscript by stating, *“I would be glad to help you write the Statistical Methods section of your manuscript.”*

Results. Because this section is dependent on the type of analyses performed, it is beyond the scope of this article to provide detailed advice on what to write. In general, you should describe the number of subjects and their characteristics. Address each aim following the order of the Introduction. Explain the results mostly in words, leaving statistics and *p*-values in the Tables. Lang & Secic (1997) do an excellent job explaining appropriate presentations for various types of statistical analyses in their book *How to Report Statistics in Medicine*.

Tables. Structure the tables in the format suggested in the targeted journal's Instructions for Authors. In general, round p -values to two significant digits, with nothing smaller than $p < 0.001$.

Use a number of significant digits appropriate to the precision of the measuring instrument. Include units of measurement. Label columns. Include a title and table number. Name statistical tests. Again, I refer the reader to Lang & Secic (1997) for additional details.

Limitations. This is the section where you discuss the generalizability of the results and power and sample size considerations. It is important to be tactful, not discouraging, but honesty is necessary.

“Report the sources and assessed adequacy of the data. Clearly and fully report the steps taken to guard against bias and assure objectivity. Similarly, address the suitability of the analytic methods and their inherent assumptions relative to the circumstances of the specific study. When reporting analyses of volunteer data or other data not representative of a defined population, include appropriate disclaimers. Report the limits of statistical inference of the study and possible sources of error, both random and systematic” (ASA Ethics 1999, p. 9).

Summary. This section gives the client a brief synopsis of the results for each of the study aims. It is most useful to the client if he can go to this section and understand the study results without re-reading the full report. Be short yet informative. Leave the details to the Results section.

References. Many peer-reviewed journals require statistical methods to be referenced. Therefore, provide a reference for each of the statistical methods you used with a citation from a standard statistical text and specific page numbers.

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Request for Statistical Consultants for FDA Committees

Theresa Riley, the Executive Secretary to the Dermatologic and Ophthalmic Drugs Advisory Committee and the Drug Abuse Advisory Committee at the Food and Drug Administration (FDA), is seeking statisticians interested in participating as members, consultants, and experts for FDA committees. These committees provide independent expertise and technical assistance related to the development and evaluation of products regulated by FDA.

The Agency is committed to diligent pursuit of ethnic, gender, and geographic diversity and is required by law to be "fairly balanced in . . . the points of view represented and the functions to be performed." Rigorous conflict of interest checking is conducted prior to each meeting. Anyone interested in working with

the committees should be aware of this (sometimes very frustrating) requirement.

The process of recruitment is ongoing; however, at this time several vacancies urgently need to be filled.

If you have questions about the advisory committee process, feel free to call Theresa at 301-827-6788. Please forward CVs or letters of nomination to:

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Announcement of Travel Awards Competition

The Section on Statistical Consulting is soliciting ideas for Special Contributed Paper Sessions for the 2001 Joint Statistical Meetings to be held in Atlanta, Georgia, August 5-9, 2001.

Up to 3 travel awards will be given to organizers of these sessions; each award consists of \$500 AND a registration fee waiver. Each organizer will be responsible for lining up speakers for the session and for coordinating submission of abstracts in the fall of 2000.

To submit a proposal, prepare a short (one page) description of the session, including a

description of the session theme, the types of papers or discussions to be included, and the intended audience. The proposal submission deadline is September 1, 2000.

Send proposals to:

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As in the previous issue, Rob Tempelman asks for ideas for the 2001 meeting. The interest and value of JSM reflects the creativity and initiative of members willing to share their research and professional experience. If you have been working or thinking about something that interests you, it might interest your colleagues too. Why not check it out?!

The feedback I am getting indicates that people enjoy reading the newsletter, which is very encouraging. I hope that this newsletter continues to stimulate and inform you.

I welcome comments on anything pub-

lished in the newsletter. You may address them to me privately or frame them as a Letter to the Editor for publication.

In addition, if you would like to share your ideas or experience in some aspect of statistical consulting with the other members of the section, please contact me about writing an article. Submission deadlines for future issues are May 1, and October 1, 2000.

Many thanks to Karla Hommertzheim, who did the L^AT_EX markup and layout for this issue while recovering from her MA oral exam. Go, Karla!!

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