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EXPERT OPINION

Generating productive dialogue between consulting statisticians and their clients in the pharmaceutical and medical research settings

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Abstract: Due to the ever-increasing complexity of scientific technologies and resulting data, consulting statisticians are becoming more involved in the design, conduct, and analysis of biomedical research. This requires extensive collaboration between the consulting statistician and nonstatisticians, such as researchers, clinicians, and corporate executives. Consequently, a successful consulting career is becoming ever more dependent on the statistician's ability to effectively communicate with nonstatisticians. This is especially true when more complex, nontraditional analytical methods are required. In this paper, we examine the collaboration between statisticians and nonstatisticians from three different professional perspectives. Integrating these perspectives, we discuss ways to help the consulting statistician generate productive dialogue with clients. Finally, we examine how universities can better prepare students for careers in statistical consulting by incorporating more communication-based elements into their curriculum and by offering students ample opportunities to collaborate with nonstatisticians. Overall, we designed this exercise to help the consulting statistician generate dialogue with clients that results in more productive collaborations and a more satisfying work experience.
Keywords: statistical consulting, nontraditional analysis, communication

Introduction

> The beginner in experimentation too often finds himself supplied with a pair of elaborate mechanisms. In the one hand is a mass of data demanding simplification and interpretation, [while the other holds] complex statistical methodology. How shall the two be geared together?[1]

Since the days of Snedecor,[1] the current widespread availability of statistical software packages allows nonstatisticians to efficiently apply traditional analyses to their data. However, rapid advances in experimental and biological technologies (for example, the use of robotics and data mining/machine learning techniques) have resulted in increasingly complex research projects that often require nontraditional statistical analysis. As a result, nonstatisticians (ie, clinicians, scientists, and so on) may not recognize or understand the need for such analysis and risk missing a potentially important insight. On the other hand, these more complex projects require the statistician to have a reasonable understanding of the subject matter and methodology before he or she can appropriately analyze the data. Thus, our role as consulting statisticians is evolving from that of a service provider to a scientist, to a true collaborator who helps the scientist both understand and address the question of interest.[2] While this is a potentially exciting and rewarding prospect, it also presents new challenges. How do we convince researchers

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to utilize complex or innovative statistical methods that they may not fully understand? In the corporate sector, how do we convey the importance of these methods to executives that may not come from a scientific background? Hence, the need for effective communication skills that supplement a broad and strong applied statistical background has never been more important.

In this paper, we examine the collaboration between statisticians and nonstatisticians from three different professional perspectives. These perspectives come from a preclinical statistician, a clinician–scientist, and a statistician working among corporate executives. Integrating these perspectives, we demonstrate that successful collaborations are a direct result of productive dialogue between the statistician and their clients. For the consulting statistician, these perspectives highlight the benefits of effective communication. Indeed, Lachenbruch[2] focused his presidential address to the American Statistical Association on the importance of communication. However, despite the efforts of Lachenbruch[2] and others,[3,4] many statisticians may still be hampered by an inability to effectively communicate with colleagues outside the field. The statisticians should not be the only bearer of this responsibility, as communication is a two-way stream, and scientists at least need to learn skills to be able to describe their research questions effectively.

In the discussion, we provide the consulting statistician with a few simple guidelines to help generate productive dialogue with his or her clients. In addition, we examine ways in which universities can better prepare students for careers in statistical consulting by incorporating more communication-based elements into their curriculum and by offering students ample opportunities to collaborate with nonstatisticians.

Perspectives

The preclinical statistician's perspective

Preclinical statisticians work on all aspects of pharmaceutical development prior to the initiation of a clinical trial including early screening processes, pharmacology and toxicology studies, and assays relating to quality and stability issues during the manufacturing process. As such, we collaborate with chemists, biologists, toxicologists, chemical engineers, and clinicians, each of whom have distinct expectations and goals. This diversity presents a challenge since, as preclinical statisticians, we must understand each of these goals, develop solutions to achieve these goals, and manage the expectations of our various collaborators.

Often, a simple discussion with the researcher is sufficient to overcome these challenges. For example, a researcher may request a simple analysis comparing multiple doses of a drug against placebo, with the expectation of gaining information concerning the drug's efficacy. Further discussion, however, reveals that the researcher's specific goal is to determine whether higher doses result in increased efficacy. Though he or she expected a specific analysis, the researcher must be convinced that a different analysis, such as a dose–response trend test in this instance, would be more pertinent.

Certain challenges, particularly those necessitating complex or nontraditional methods, will require more than simple discussion before they are resolved. In the mid-1990s, for example, a researcher asked for assistance in designing experiments based on deoxyribonucleic acid microarrays. Specifically, the researcher wanted to know how many microarrays needed to be analyzed to obtain statistically significant results. As this was new technology at the time, literature describing microarray analysis did not exist and the resulting data made the direct application of conventional statistical methods problematic. It took, in fact, many months of discussion and research before we could provide any truly meaningful contributions to the design and analysis of these experiments. However, by demonstrating an interest in the question at hand, thinking outside the box, and clearly articulating our statistical points to the scientists, we developed a toolbox of context-specific data preprocessing and analysis approaches.[5]

Lastly, it is often the case – especially in biological experiments such as genomics – that the data have been processed and prefiltered in various ways by automated software. These automatic data manipulation methods make a variety of assumptions and can sometimes hide more interesting features and important signals in the "raw" data. Therefore, it is important in some cases that the original data be explored.

The clinician's perspective

On superficial examination, there seems to be little common ground upon which to develop collaboration between pharmaceutical industry statisticians, whose focus concerns the development and registration of a drug, and clinician–scientists, whose focus is on the optimal care of patients. The analyses related to the development and registration of a drug, for example, do not necessarily translate into clinically useful information, and these analyses are difficult to incorporate into clinical practice. Despite these divergent interests, however, it is possible for the clinician–scientist and statistician to form a productive collaboration that yields valuable scientific information and enhances patient care.

The field of neuropathic pain changed substantially in the late 1990s with the first modern clinical trials of an orally-administered pain drug. These trials compared treatment versus placebo over an 8-week time period, with patients recording their daily mean pain score in a diary on a scale of 0 (no pain) to 10 (worst pain imaginable). Today, all industry-sponsored pain trials include efficacy endpoints such as numeric pain score, global patient impression of change, and the number of patients with a ≥30% improvement over baseline. While these data may be necessary for drug registration and approval, they do not address all the concerns of clinicians and patients. Patients want to know if they will get better, how long will it take to get better, and how long the drug's beneficial effects will last. To answer these patient-centered questions in collaboration with pharmaceutical industry statisticians, we used a standard statistical method in a nontraditional way. We used time-to-event analysis to calculate the likelihood and time to obtain a clinically-significant, one-point improvement in pain score that was sustained to the end of the study, thereby providing information that directly influences decisions in patient care.[6]

Modern clinical trials also focus on the occurrence of adverse effects in response to drug treatment, but researchers simply report the frequency of these events. The clinician and patient, however, are more interested in knowing the following: the likelihood of experiencing an adverse event; how long the adverse event lasts if it does occur; the probability of the event ceasing once it starts; and the probability of the event recurring once it ceases. Again, after discussing the patient's concerns with our statisticians, we were able to estimate the transitional probabilities in a Markov chain model for each specific adverse event and provide the patient with clinically meaningful information (Freeman and Emir, unpublished manuscript).

The perspective of a statistician working among corporate leaders

Marquardt,[7] in his presidential address to the American Statistical Association, had a vision of statisticians as entrepreneurs and leaders in the workforce. Statisticians in the corporate arena, however, often face the unique challenge of collaborating with executive leaders who may not possess a scientific background. While statisticians must be able to clearly explain methods and results to these executives, they must also demonstrate the value of their analytical work and explain how it contributes to the company's success. Establishing a successful collaboration with these executives, therefore, requires the statistician to develop a more corporate mindset that, at first, may seem foreign.

Each service we provide has value that must be articulated to the client. The notion of value, however, may differ greatly from one client to the next. When discussing the benefits of an analysis plan to scientists or clinicians, for example, we highlight how the primary and secondary endpoints will yield clinically-relevant information that can be applied to patient care. While this information is certainly of interest to a corporate executive, their primary focus is more likely on the registration, marketing, and sales of a drug. Therefore, when discussing this same analysis plan to executives, we highlight how its design will meet federal registration requirements, cut costs, and get their product approved and on the market more quickly than anticipated. We highlight these aspects because executives, many of whom come from business or finance backgrounds, realize that all the work involved in developing a drug is not economically valuable to their company unless it is prescribed by the doctor and paid for by the patient.

Conversely, the corporate mindset, however, does not solely place its focus on economics. We aim to proactively identify a client's statistical and information needs, develop innovative solutions, manage expectations, and influence decision making.[7–9] However, as Grieve[8] states, statistics "cannot influence, cannot persuade, cannot design studies, cannot analyze data, cannot interpret results, and cannot report results." This is true, as only statisticians, not statistics, do all these. However, only the statistician possessing excellent communication skills will be able to influence and persuade executive decision-makers and establish successful collaborations in the corporate world.

Discussion

Integrating the three perspectives

A successful consulting career requires much more than technical mastery. Unwin,[4] for example, describes the complexity of the "human side" of consulting and asserts that effective consulting depends on the social skills of the statistician. We examined collaborations between statisticians and non-statisticians from three different perspectives: a preclinical statistician; a clinician; and a statistician working with executive leaders. Each of these perspectives illustrated that the success of these collaborations depends on much more than the ability of the statistician to analyze data. These examples demonstrated that, aside from analyzing data, the statistician must be able to identify the needs of a client, influence the client to implement an appropriate solution, and manage the client's expectations of that solution. These are required of the statistician regardless of their environment, whether it is preclinical research, clinical research, or even work

outside the biomedical field. More importantly, all require the statistician to be an effective communicator. From the perspective of a preclinical statistician, effective communication is required to understand and develop solutions to a wide variety of problems related to both drug development and manufacturing. In clinical research, the statistician must communicate with the clinician to understand what information is clinically relevant to patients and suggest the appropriate analytic tools to extract this information from registration trial data. In the corporate sector, the statistician must convince executive decision-makers that their work addresses all the client's needs and plays an important role in the company's success.

The question, then, is how does the statistician initiate or improve communication with his or her clients? Here we offer a few guidelines, based partly on the perspectives examined, to help the consulting statistician generate productive dialogue with his or her clients.

A short consulting checklist

As each of the perspectives demonstrated, productive dialogue cannot be achieved unless the statistician adequately understands the underlying biology and ultimate goals of the research. Therefore, if your knowledge of the field is insufficient, it is important to work with the client to gain an adequate level of understanding of the science. It may also be possible to partner with a statistician who has a strong background in biology and extensive biomedical research experience. He or she will be a valuable asset to both yourself and the client as you work to understand the research. Once you understand the biology and goals of the research, you can determine if the client's question or approach will ultimately address the goals of his or her experiment. If not, explain to the client why asking a different question or using a different analysis will lead to more pertinent information. As Tukey[10] noted, it is "far better an approximate answer to the right question, which is often vague, than an exact answer to the wrong question, which can always be made precise." These types of discussions demonstrate to the client that you understand the goals of his or her research and are committed to its success. As such, thoughtful interactions will inspire confidence in your clients and are the building blocks of a successful collaboration.

There are other basic discussions the statistician can initiate to illustrate his or her interest in a project and inspire confidence in the client. For example, the statistician can ask for all the details of the experiment and explain to the client that a detail that may be regarded as trivial might actually be quite important to the selection of an appropriate analysis. Similarly, the statistician may ask for all the raw data and explain to the client that preprocessed data often hides subtle trends or other relevant information. Using the raw data, begin with an initial exploratory analysis and explain to the client that such an analysis will demonstrate whether more complicated, time-consuming, and potentially expensive analyses will be worthwhile. When proposing an analytical plan to the client, use less complex analyses whenever possible. Do not, however, sacrifice a useful complex analysis merely because of its complexity. As Breiman[11] noted, the goal of an analysis "is not interpretability, but accurate information." In all cases, it is beneficial to use graphics to visualize the data and results since this will help the client understand the data and analyses more thoroughly, enabling him or her to incorporate the findings into practice more efficiently and effectively. Tukey[12] has often reiterated the old maxim, "a picture is worth a thousand words." For less complex projects, provide the client with customized, easy-to-use, data analysis software. This will allow the client to effectively analyze subsequent data themselves, and this helps to maintain the established collaboration. Finally, always get involved with the project as early as possible. You can provide the client with constructive ideas on the design of the experiment and outline approaches to efficiently utilize a dataset. These tips, summarized in Table 1, will help generate productive dialogue with your clients and are the basis for cultivating successful collaborations. In addition, these techniques will demonstrate the expertise and value you bring to a research team or company.

Preparing students for a future in consulting

"The future of data analysis can involve great progress, the overcoming of real difficulties, and the provision of a great service to all fields of science and technology. Will it?"[10] The answer to "will it" depends largely on our ability to recruit and train students for careers in the field of statistics.

Table 1 A short consulting checklist

- ✓ Get involved early in the project.
- ✓ Understand the underlying biology and goals of the research.
- ✓ Determine if the questions being asked address the goals of the research.
- ✓ Get all the experimental details.
- ✓ Get all the raw data.
- ✓ Begin with a simple exploratory analysis.
- ✓ Use simple analyses whenever possible, and tables/graphs to visualize the results.

The consequences of the technological developments in the last quarter century have revolutionized how statistics are generated and used. Statistical methods are no longer confined to those found in a software package and computer code can be generated to develop innovative, nontraditional methods to analyze a particular dataset. Thus, statistical modeling is driven by science and not by the software, which is an important distinction. This concept is a result of increased collaboration between academic institutions and the pharmaceutical industry. This new environment allows statisticians to really delve into problems and collaborate with scientists to come up with new, innovative statistical approaches.

Aspiring students are trained in all the classical statistical methods and, in addition, they learn the newest, most advanced data mining techniques and computer simulations. Still, however, students are often ill-prepared for this new collaborative environment. These students may be great statisticians but often they lack the necessary communication skills, both written and verbal, to successfully collaborate with scientists. How, then, can these essential skills be successfully incorporated into a given curriculum so that students are more prepared for the real world?

To address this problem, universities have begun to stress the importance of effective communication skills to their students. While this may seem trivial to some, essential communication skills were not an area of focus in the past. Cabrera and McDougall[3] describe the model that was followed at Rutgers University (NJ, USA) to create a statistical consulting course in collaboration with the Office of Statistical Consulting and a group of industrial statisticians who brought their knowledge and experience to the classroom. In this model, students learned the basics of technical writing and were required to submit clear and concise reports throughout the year. To develop verbal skills, students were periodically required to give oral presentations or to conduct one-on-one interviews with a research scientist. In addition to these basic skills, students learned how to communicate effectively and, more importantly, persuasively. Often, effective and persuasive communication requires much more than basic written or verbal skills; therefore, students are taught the importance of nonverbal communication as well, which includes elements such as proper attire, body language, eye contact, and facial expressions. This process benefits greatly from the use of audiovisual equipment, which makes the student more aware of their strengths and weaknesses during the communication process.

Recently, numerous articles have eloquently addressed the issues and concerns regarding the teaching of statistics (Brown and Kass,[13] Easterling,[14] Hoerl and Snee,[15] and Kotz[16]). We agree that too much emphasis is placed upon teaching statistical methods, and that more emphasis should be placed upon teaching the concept of "statistical thinking". Though several definitions of statistical thinking exist, each involves the idea of using scientific and statistical principles to address and solve real-world problems in a practical manner. To broaden the students' knowledge from a singular focus on the teaching of statistical methods, to more substantial science based coursework, such as medicine, biochemistry, and/or finance, should be required of students. This additional learning is designed to help the student realize the need to adapt his or her statistical knowledge base to a real-world working environment (for example, when the statistician is part of a biomedical research group). To help students in this process, all statistics departments should offer a statistical consulting course or consulting lab that works in conjunction with research labs, such as those found at Rutgers University and Columbia University (NY, USA), and arrange summer internships for students so they can get hands-on experience in an actual research environment. In addition to Rutgers University and Columbia University, the authors have experienced consulting in other universities such as Iowa State University, Princeton University (NJ, USA), the University of New Mexico, the University of Washington at Seattle, and the University of Pittsburgh. Through these opportunities, students learn how to apply statistical thinking to generate practical solutions to a variety of real-world problems and make significant contributions to projects in a team-oriented research environment. In addition, the frequent interaction with researchers will help the students develop the communication/social skills needed to successfully collaborate with nonstatisticians once they enter the workforce.

The more advanced a statistical consultant's education, the more important it is that the consultant trains with real life cases. However, consulting education should not be limited only to graduate students. Senior-level undergraduates enrolled in a statistics major should also attend consultancy-oriented classes. These, topped with "mentoring", are key factors in the development of a novice statistician's career.

We will close by mentioning an important issue: a disagreement between the scientist and the statistician may arise. The statistician needs to have good communication skills to clearly explain his/her reasons for disagreeing with the scientist, why the statistician's perspective may be appropriate, and he or she also needs to gain a full understanding of the collaborator's perspective. The statistician also needs to gain the trust of the scientist. This can be accomplished through

dialogue about the source of disagreement and sensitivity to communication cues. If the problem still persists, a more senior, mentor, or expert statistician can assist by smoothing out the discussion, helping to explain certain points, and making clarifications.

Conclusion

By examining the partnership from three different professional perspectives, we showed that communication is the foundation of successful collaborations between consulting statisticians and their clients. Recognizing this point, we offered guidelines to help the statistician generate productive dialogue with their clients, and then examine ways in which students in statistics programs can be prepared to communicate and collaborate more effectively with biomedical researchers.

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Disclosure

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