

Statistical Consulting and its Challenges

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Introduction

Statistical consulting, the provision of statistical advice and/or services to those who request it, applies statistical methodology to problems in other disciplines. Consultants assist with design and conduct of the study, including randomization of subjects, data collection, and data analysis. They help to report the results of the study and to ensure that conclusions reached are supported by the data. The consultation may range from a five-minute chat in a hallway, involving only advice about some aspect of the study, to a many years' collaboration on a project. Although the terms consulting and collaboration are often used interchangeably, a collaboration implies more responsibility and involvement, both intellectual and time, by the statistician. In a collaborative relationship, a statistician is a full-fledged member of the team of investigators conducting the study, has more authority, receives credit for contributions made, and coauthors the research paper reporting the project. This is a relationship most conducive to statistical contribution. To connote a broad range of services, some statisticians now refer to the practice of statistics, meaning the communication of statistical information across disciplinary boundaries by persons who have training in statistics and related quantitative fields.

Biostatistical consulting is the application of statistical expertise in the biological or health sciences. Within the arenas of medicine, dentistry, and public health, biostatisticians work with physicians, basic scientists, dentists, nurses, pharmacists, epidemiologists, and other health professionals. A biostatistician may be a faculty member in a school of public health or a professor in a quantitative sciences department in a medical or dental school or at a medical research center [3]. In this capacity, they teach graduate courses in biostatistics while working collaboratively on research grants, jointly with medical colleagues. In addition, the biostatistician might perform analyses for reports, manuscripts, and presentations for medical clients. In many universities, consulting biostatisticians belong to a statistical consulting unit [5], often within a biostatistics department that offers statistical and computing services. Some universities and schools of public health have statistical or clinical trials centers in which biostatisticians have a primary role [1]. Some biostatisticians work in cancer centers or other disease-specific research centers that may be part of a larger network [8]. Such centers are usually in a university setting; others may be independent entities.

Biostatistician in a Medical School

Working with physicians and other medical investigators within a collaborative setting, biostatistician offers advice and provides statistical input for the design and analysis of clinical trials. When the trials are being designed, the clinician meets with biostatistician and investigators from pharmaceutical companies. In designing the trials, biostatistician considers both statistical and clinical factors. He seeks to understand the clinical issues in these studies; he provides sample size calculations, input on study design, advice on interim analyses, and randomization schedules. He usually writes the statistical portions of the study protocol. As the trial progresses, he works with junior statisticians to monitor the trial and supervises the analysis. When the trial has been completed, many manuscripts reporting various aspects of the study are produced, for which biostatistician specifies the appropriate statistical methods and supervises the analysis by junior biostatisticians.

Biostatistician's greatest strengths as a consultant are his ability to listen intently and to explain statistical design and methodology principles to physicians clearly. In addition, he often conducts research conferences for a mixed audience of physicians, statisticians, trial coordinators, and other team members in the organization. His ability to speak systematically and to present statistical ideas simply make him sought after as a lecturer. He also teaches a class of physicians and other health professionals who are enrolled in a biostatistics training program to obtain a master's degree. In all aspects of his varied role, he communicates effectively with physicians, health professionals, and other statisticians, in a group setting or individually.

Biostatistician in a Governmental Agency

Grace leads a biostatistical group in one of the National Institutes of Health. Because her Institute recognizes the value of statistics in the design, analysis, and interpretation of medical studies, the group of biostatisticians finds itself in constant demand. Grace sees her consulting role divided into three quite different functions – intramural consulting, participation in discussions on issues related to funding, and collaboration with nongovernment investigators. For the intramural scientists within the Institute, she serves as an ad hoc statistical consultant, with all the excitement and frustration that role entails. The investigators, often postdoctoral fellows, look to statisticians as the purveyors of small P values, those precious tickets to publication. Grace's first contact with an investigator may

be a frantic call demanding immediate statistical input for an abstract that is complete “except for a few numbers”. She recognizes that these encounters afford an opportunity for teaching young researchers about the value of statistical collaboration. Moreover, a fruitful short-term statistical fix may lead to long-term collaboration with an investigator who has become convinced that statistical thinking enhances scientific research. Grace’s consulting spans a wide range of activities. Like any effective biostatistical consultant, she must understand the studies with which she is involved; she must be aware of new biostatistical methodology, and she must be poised to develop new techniques. What distinguishes her role from that of other biostatistical consultants is the perception that when she expresses an opinion, she is speaking for the government.

Biostatistician in a Department of Biostatistics and Director of a Consulting Unit

Smith, a professor in a department of biostatistics at a major university, teaches two categorical data courses, mentors numerous doctoral dissertations, and directs a biostatistical consulting laboratory staffed by students in the department. The role of the laboratory, which provides statistical consultation primarily to investigators from the university’s Schools of Medicine, Dentistry, and Public Health, is to provide funding and training for students in academic biostatistics programs and to encourage practice oriented statistical research, particularly for master’s degree papers and doctoral dissertations – and, of course, the investigators benefit by having the statistical aspects of their research problems solved. In addition to clients within the university, Smith also arranges cooperative agreements between the laboratory and sponsors in the biopharmaceutical industry.

Smith has created a structure for consultation that fosters learning and teaches teamwork. The doctoral students have a direct liaison with him, delegate projects to master’s and undergraduate students, and mentor them. The doctoral students are responsible for meeting deadlines and writing and reviewing statistical reports. The master’s students work with the doctoral students for large projects and manage databases, write programs and reports, and learn to handle smaller projects directly with clients. They also mentor the undergraduates. The undergraduates perform support services including data entry, word processing, and basic programming. The benefits for students of this arrangement include mentoring by Smith, reinforcement of course work, practice in communication skills and report writing, publications, and thesis topics. A wide variety of projects are available to students in the consulting laboratory.

Characteristics of a Successful Biostatistical Consultant

A successful biostatistical consultant possesses many skills [4,6,7]. The consultant must have a solid technical background in biostatistics, good knowledge of the subject matter area, excellent computing skills, and the ability to apply – or develop if necessary – statistical methods innovatively in a variety of settings. A successful biostatistical consultant should be aware of his or her limitations and know when to ask for assistance from a statistical or subject matter colleague or to learn about the appropriate statistical methodology in the literature. Other important characteristics are enthusiasm in participating as a member of a team of research investigators; the capability of

formulating problems in statistical terms; a proclivity for problem-solving; and excellent communication skills, both oral and written.

Being a good consultant requires skills beyond ability in mathematics and knowledge of the theory and methods of statistics. Any investigation requires high-quality data, so the successful consulting biostatistician should become familiar with data collection procedures and methods for assuring the quality of the data. He or she should be genuinely interested in the subject matter area in order to become aware of issues that may have important statistical implications. Many clients fear mathematical and statistical ideas, but it is crucial that the client understand the statistical aspects that the consultant is discussing. Thus, a successful biostatistical consultant should be a good teacher who is willing to explain the statistical aspects of design and analysis in terms that a client can understand.

Working effectively on several research projects simultaneously means that the consultant should manage time efficiently and meet appropriate deadlines. Sometimes, the consultant should aim to achieve an acceptable solution to a problem when an ideal solution would require too much time, effort, and expense. Having good interpersonal skills is essential, since many personalities are encountered; sometimes the biostatistical consultant functions as an expert, while at other times he or she is a strategist or confidant. A willingness to admit mistakes and learn from failures helps a consultant in working on subsequent projects with clients.

Challenges of Consulting

Consultations are complex interactions in which the biostatistician may use many skills simultaneously. The successful biostatistical consultant often listens to the client’s problem and constructs a statistical formulation. If the client brings data to be analyzed, the consultant should assess the statistical design of the project, explore the assumptions of statistical tests, discuss limitations of the analyses, and suggest appropriate solutions. After arriving at a statistical solution, the consultant should write a coherent report that is understandable to the client. Delivery of raw

computer output or an uninterpreted set of tables does not serve either medicine or statistics. The consultant biostatistician should be aware that the nontechnical aspects of consulting may be at least as important as the technical aspects [2,10]. Projects often have deadlines and budgetary constraints. Some clients apply pressures to achieve a favorable outcome, but the biostatistician must deal ethically and provide an honest report of the study. The best clients are those who understand that an honest report of the project is in the highest interest of science. Excellence in communication is another essential skill for the consulting biostatistician. Adequate technical knowledge is simply not sufficient if the biostatistician is poor at communicating ideas to clients. Often, biostatisticians must learn to listen and to ask questions that gradually lead to a revelation of the client’s problem. This is especially important when the client is unfamiliar with statistics. Being able to discuss problems in the language of the client is a definite aid to communication. Being knowledgeable in the client’s discipline, and being supportive and willing to educate the client, are attitudes that are most helpful in establishing good client–biostatistician relationships. Therefore, while a basic technical knowledge is necessary and presumed for consulting, the nontechnical as-

pects of consulting are often the most challenging. Consultation may have a negative side, for the biostatistician may not receive sufficient recognition by the client and by the institution or organization in which the consultant is employed. In universities, promotions and tenure are based primarily on research, followed by teaching and service or practice-oriented research. Consulting, which usually falls into the category of supportive practice-oriented research, often is not valued greatly. Extremely active consultants who are consulting with a variety of disciplines simultaneously may not publish enough methodological research in peer-reviewed statistical journals [9]. The biostatistician spends a lot of time learning the discipline of the investigators and communicating with them regularly, particularly in large, long-term projects. The lack of recognition of consulting activities by academic departments when discussions are held about promotions and tenure, coupled with the lack of time for methodological research compounds the frustration of an academic consultant. In addition, some clients believe that payment for services is sufficient recognition for a consultant's efforts. When the biostatistician has devoted substantial time and energy to a project, the client's failure to acknowledge the intellectual contribution, in the form of authorship, also frustrates the consultant. Even when consultants are authors, rarely are they first authors. Since first authorship is given greater emphasis during reviews for promotion, consulting contributions tend to be undervalued. Some frustrations may be eliminated when there is a discussion with the client prior to the initiation of the project concerning authorship of papers and charges for statistical services. Some academic institutions realize that consulting biostatisticians contribute substantively to publications and subject matter areas and consider this during reviews for promotions. Many contributions to statistical methodology have arisen through consulting projects. Also, as more attention is given to utilization of appropriate statistical methodology in research papers, perhaps academic institutions will award more credit when a biostatistician is the coauthor of a medical paper. Challenges may be different in other settings. In an organization in which consultation constitutes the primary role of the biostatistician, it may be difficult to satisfy the requests of several clients simultaneously in a manner consistent with the priorities of the organization. Often, the ideal analysis of a set of data may require more time and money than has been allocated to the project. The challenge to the biostatistician is to set priorities firmly and complete projects in a timely manner, subject to budgetary constraints. Whatever the setting, biostatistical consultants must stay current with the statistical literature while maintaining their other responsibilities. In addition, they must maintain their computing skills in the face of evolving technology and a plethora of software packages. It is challenging to stay abreast of these developments in the field while simultaneously meeting work demands.

Special Challenges of Consulting with Physicians

A biostatistician working with physicians faces many challenges. Some problems are universal issues that occur with clients from all fields, and others seem to derive from differences in mind-set, approach, or inherent differences in physicians and statisticians. Physicians are trained to produce quick responses when presented with a set of patient characteristics; indeed, the patient usually expects an immediate assessment. In some clin-

ical specialties, these decisions are made in a life-threatening situation. Physicians may weigh the results of several tests or factors as they make the decision. If most of the evidence leads to a certain conclusion, they often do not quibble over slight vagaries. In the clinical setting, physicians need and want the best answer in the shortest length of time. On the other hand, biostatisticians tend to be meticulous. They examine the data check for discrepancies and outliers, test assumptions, and often approach questions from several angles. They like to do a thorough job. When physicians bring their clinical mind-set to the statistical consultation, they sometimes complain that biostatisticians are overly conscientious. And biostatisticians frequently complain that physicians want conclusions before the relevant data have been fully analyzed and interpreted! Each party should recognize the inherent differences in style and modify their approaches somewhat, moving toward a more "central" position. "Differences" seen in this light allow better understanding between physicians and biostatisticians.

Another complication that often surfaces when biostatisticians work with physicians is the psyche of the physician. Physicians are used to being "in charge". When coming to a biostatistician for assistance, they can feel either a lack of control because of a lack of familiarity with biostatistics or a need to dominate the biostatistician about what "statistics" should be done. Sometimes, physicians who do not understand the statistical arguments adopt a passive-aggressive stance, accepting with question the results presented by the biostatistician. This situation is usually stressful for the biostatistician and physician alike. Often this can be alleviated by a frank characterization of the situation and a statement by the biostatistician of their commitment to work with the physician, perhaps suggesting an ongoing collaboration. This, combined with some respectful coaching of the physician on statistical terms and practice by the consultant, can mollify the situation.

Many physicians and biostatisticians develop extremely productive collaborations that continue for years. This occurs most often when the physician has come to value the impact that the biostatistician has had on their work in terms of efficiency and accuracy of methodology, leading to an increase in the number of grants or papers accepted for publication. And that usually occurs when the biostatistician has taken the time to become educated in the discipline of the physician and has fostered the relationship. In these long-term relationships, biostatisticians often have concentrated their consulting efforts in an area of medicine and become "experts" in the analyses that are used most often in that area.

Incentives for Biostatistical Consulting

Consultation has many rewards for a biostatistician. The skills required may match those of the individual, whereas a career spent entirely in teaching and research may be less rewarding. A biostatistical consultant will almost surely design an experiment and analyze data, whereas many academic biostatisticians may have no real experience in these areas. In addition, many problems encountered in consulting relationships are challenging. Since most new statistical methodology arises from realistic problems, being a consulting biostatistician is a way to learn about new projects requiring advances in statistical methodology. Also, there is the excitement of participating as a collaborating member of a team on a research project that is addressing an important scientific or health related question.

Another incentive is that financial benefits accruing to the biostatistical consultant is often greater than for those participating only in academic work. Additional benefits derive from being coauthors on medical publications, making presentations at scientific meetings, and contributing generally to the betterment of society.

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