THE STATISTICAL CONSULTANT

Section on Statistical Consulting
Christina M. Gullion, Editor
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IN THIS ISSUE

Announcement of Travel Awards Competition for 2002

The Section on Statistical Consulting invites proposals for Topic (Special) Contributed Paper Sessions for the 2002 Joint Statistical Meetings. Proposals submitted will compete for up to three travel awards, each consisting of $500 and a registration fee waiver for the organizer. Each organizer will be responsible for lining up speakers for the session and coordinating submission of abstracts in the fall of 2001.

A proposal should consist of 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. A list of possible speakers is helpful. The proposal submission deadline is September 1, 2001.

Send your proposal to: **Brenda Gaydos**
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Industry/Academic Statistics Collaborations

S. Stanley Young, GlaxoSmithKline

Statisticians can benefit greatly by forming a productive collaboration between university and industry. At its simplest level, industry has funds and industry statisticians have relatively little time whereas a university needs funds to fulfill its teaching, training, and research roles and faculty statisticians are expected to spend time on research. In addition, their graduate students need training in the research process.

Collaboration involves much more than funds going from industry to university. Statisticians in industry can identify problems worth solving and provide valuable insight into the nature of these problems. There is a current need for such collaborations, as many important problems confront industry (and society). Among these are an increasing number of worthwhile large data set problems, which call for skilled data mining, e.g. human genome, administrative records, high throughput screening for drug-development candidates, health care records.

What is needed to have a successful collaboration between industry and universities? I think the most important ingredient is a problem. Collaborators also need modest funding, a willingness to take time, tolerance for risk, freedom, and good collaborators – collaborators with a balance of talents. A review of three collaborations I've been involved in will clarify these points.

Problem: Multiple testing in carcinogenicity studies

In 1985, I was working in a toxicology laboratory that was testing tumor rates in rodents. A compound was administered for two years and pathologists examined tissues for a large number of tumor types.

The practice at the time was to test statistically every tumor and declare the compound a rodent carcinogen if there was a significant increase in any tumor. There was no adjustment for multiple testing. As many as 800 statistical tests might be conducted in the evaluation of a compound.

The compound-wise Type I error rate for this practice was large: at the time about half of the compounds tested had one or more significantly increased tumor rates. We did not have a satisfactory method for adjusting for the multiple tests. A simple multiplicity adjustment would be too conservative.

About this time, Peter Westfall (Texas Tech University) published a paper in Biometrics giving a method to construct simultaneous multivariate Bernoulli confidence bounds. It appeared that the resampling methods used by Westfall could be used to create multiplicity-adjusted p-values for the multivariate binomial-testing problem.

A collaboration involving several pharmaceutical companies was formed with Westfall. SAS Institute also contributed valuable resources. The collaboration lasted for two years. The pharmaceutical companies provided about $100,000 in direct funding. Statisticians on the industry side collaborated on problem definition, code testing, and evaluation, and they tested the methods and code on real, internal data sets. About twenty statisticians and computer scientists were involved at one time or another.

There were three important products of this research. The collaboration resulted in publications in the Journal of the American Statistical Association (1989) and Biometrics (1993) and the book *Resampling-Based Multiple Testing*. The methods were encoded into a SAS procedure (MULTTEST®), which was

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donated to SAS Institute, effectively making these methods available to all statisticians. Finally, these methods fundamentally changed the way that rodent carcinogenicity studies are evaluated.

Problem: Very large drug discovery datasets

In the mid 90s, the need for efficient analysis of very large, complex data sets became obvious. I had been working with Doug Hawkins (University of Minnesota) for some time on various problems, mostly outlier detection. He alerted me to work that he had done with Gordon Kass on recursive partitioning (RP).

In RP, a large data set is progressively divided into smaller data sets that are more homogeneous for some response variable. The best-known method at the time was CART (Classification and Regression Trees), developed by Breiman, Friedman, Olshen and Stone (1984). The Hawkins/Kass method uses statistical hypothesis testing for the splitting and has a great computational speed advantage over CART.

This research progressed on two fronts. We developed very fast algorithms and more efficient memory management methods for handling very large, high-throughput screening data sets. Our RP code can easily analyze hundreds of thousands of cases with over two million compound binomial descriptors. A single split takes less than one minute on a typical UNIX workstation. Modest data sets, twenty thousand observations and ten thousand descriptors, can be analyzed in seconds.

A number of papers resulted from this research, e.g., one by Hawkins, Rusinko, and Young in *Quantitative Structure-Activity Relationships* (1997, Vol. 16). Funding was provided to Bret Musser for thesis research at the University of Minnesota.

The resulting thesis provides insight into multiple recursive partitioning trees. More than one tree can be constructed on a data set, and it has been shown that the multiple trees can be used to give better predictions than a single tree.

Understanding how to construct and interpret multiple trees has great utility. Research was also conducted at the National Institute of Statistical Science on the use of multiple trees for the analysis and prediction of biological potency of compounds.

Problem: Experimental designs to cover heterogeneous mechanisms

The major problem with large data sets is that the objects in the data set may be responding to rather different mechanisms. For example,

- Compounds may bind to proteins in different places or in different orientations. The characteristics of compounds that bind in different places are expected to differ, so the modeling process needs to build multiple models.

- Patients on a clinical trial may have heterogeneous etiologies for the disease for which a treatment is being tested, e.g. high blood pressure. A drug that works for one subtype of the disease is not expected to work for another.

How are experimental designs executed when multiple mechanisms are expected? If we are selecting representative compounds for initial screening, it turns out that we need to select a diverse set. We also need to select a large number of compounds to densely cover the chemical space. We know that *very* similar chemical compounds are likely to act similarly, but compounds that are only modestly different structurally are unlikely to act the same in a bioassay. So the question that needs to be addressed is how to select objects to uniformly and densely saturate a high dimensional space.

Again, this collaboration has spanned an extended period. Initially, I worked with Randy Tobias (SAS Institute). In the collaboration, I provided real data sets that were large

and complex. Together we considered space-filling algorithms and various compromises to increase the speed of the design construction. The result was the addition of space-filling options to the SAS/QC procedure for optimal design of experiments, PROC OPTEX®.

Lately we have revisited the problem of space-filling designs through collaboration with Ray Lam and Will Welch (University of Waterloo). The problem we are working on now is efficient coverage of high-dimensional (D) spaces. It is not possible to cover a high-D space densely as it takes too many design points. For example, if we are working in 10D and we need to cover all deciles of each dimension, then we would need 10^{10} design points.

We chose to cover all the 1D, 2D, and 3D projections. Fast exchange algorithms were developed so that large designs from very large candidate lists can be constructed. A typical problem involves selecting 10,000 compounds from a list of 100,000 compounds. This work is reported in Lam, Welch, and Young, "Uniform Coverage Designs for Molecule Selection" (submitted to *Technometrics*).

Risks vs. Payoffs

In each of these examples, it is easy to describe the problem. In the first two cases, it is also easy to understand that a solution would be valuable.

In the case of *multiple testing* of carcinogenicity in rodent studies, a false positive result can stop the development of a proposed drug. The development cost of a new drug can be hundreds of millions of dollars.

In the case of *recursive partitioning*, it costs about one dollar to screen a compound. In the course of drug discovery for a new biological activity, hundreds of thousands of compounds are typically screened. It has been common practice to simply sort the compounds by their assayed activity and follow up on a few of the most active compounds, ignoring the vast majority of the data and any information that might be therein. The question is simple: How can we extract useful information from these large, high-throughput screening data sets?

The case of *space-filling designs* is more problematic. There is no assurance that a space-filling design will beat a simple random design. On this question, the jury is still out. Some of our work, plus extensive work at Pfizer, indicates that compounds carefully selected for diversity give about the same hit rate as compounds selected at random. Freedom to explore, given or taken, is the issue. Often it is worth risking time and funds on research where we are not sure of the utility.

Recently, extensive benchmarking at GlaxoSmithKline indicates that hit rates from screening can be improved by our new space-filling algorithms. Our results indicate that we can cut screening in half and find the same number of active compounds. The payback for this research promises to be good, but the research was conducted at great risk and cost. This research extended over five years at a cost of over $100,000.

What Makes Collaborations Work

Latitude in research is important. It does not make sense in an industrial setting to pursue questions with no obvious utility. It does make sense to expend some resources on high-risk, potentially high-payback projects. In the case of statistics, the actual costs are not great. Time (salary) and computers are the main costs. Experimenters need to be involved to pose useful questions, to help guide the process, and to provide timely experimental data to help test the resulting methods.

Often upper management understands and actively supports the research. Just as often, a statistical researcher should be prepared to go out on his/her own to try out a potentially useful idea or follow up on a promising result.

I should say at this point that I typically have five or so research interests/projects going at any one time. About half of our projects are successful in that in that we obtain useful results. Many projects die for lack of time or

skill to solve the problem. But when things work out, and we find a method that makes a real difference in how work is done, there is typically great joy among all involved.

Good problems are typically complex, even though they may not be complex to state. Insight can come from any of many sources. Good collaborators make all the difference. Multiple inputs from several people almost always lead to better results than the lone inventor toiling away in isolation, no matter how gifted the individual is.

We typically try to have a subject matter expert, a statistician, and a computer scientist involved. We use brainstorming methods as a matter of course. In an ideal world, we would have the team in close geographic proximity. We are very fortunate in Research Triangle Park to have three universities close by, so that students from chemistry, statistics and computer science can work on site together. Travel, e-mail, videoconferencing, etc. facilitate distance research, but it is not easy and it is less likely to be successful.

A Golden Age for Statistical Applications?

I suppose there have always been good problems to work on, but the present seems like a golden age for statistical applications and methods development. There is automated collection of very large data sets. Computers are "cheap and plentiful" as agricultural specialists used to say. Questions with potentially very valuable answers are showing up everywhere. The main problem is selecting from the bounty.

To support my "golden age for statistics" proposition, I list some of the high-utility, technically interesting problems that have been generated as a result of advances in genomics alone:

1. A variety of genes might be involved in a disease process or in the metabolism of a drug. Many thousands of genetic markers, or single nucleotide polymorphisms (SNPs), can be assayed on each patient. Analysis will be complicated by having to address *many questions on a clinical trial* rather than the typical one main question about efficacy.

2. Differences between people can cause different responses to treatment. How do we design and analyze clinical trials recognizing that *unknown subgroups of patients will give differing results*? Can we find *patterns of SNPs* associated with treatment success/failure? Associated with side effects? How do we *pinpoint the genes that are up-regulated and down-regulated*?

3. How do we address *data quality in a gene chip assay*? There may be one hundred thousand DNA spots on a chip. Each gene is replicated several different times and in different ways. And there may be spatial effects.

4. *How do these genes interact*? It seems obvious that a human's thirty thousand genes cannot be working independently. If you know the networks, you can design drugs to apply selective pressure to influence health.

5. Screening compounds to find starting points for atom-by-atom drug optimization is an expensive trial and error process. Usually we screen individual compounds. Screening of pools offers the possibility of improved efficiency and is practiced by some screeners. *How should pools be structured*?

In addition, there is the whole area of analysis of large data sets, i.e., data mining, in which intellectual competition is fierce. Statisticians have much to offer here. Pharmaceutical companies have large data sets that contain potentially useful information. Computer scientists are innovative and obviously have computer skills. Teams of subject matter experts,

statisticians, and computer scientists could be very productive.

How to proceed

I hope that I have interested you in the possibility of collaborative research between industry and universities. There are several ways for a statistician in industry to develop collaborative research. Hiring summer interns is a way to start [*Ed. Note:* cf. *The Statistical Consultant*, 2000, 17(2)]. If there is a university nearby with a statistics department, you might consider funding a graduate student to work on a topic of interest. Again, expect to spend time as well as money. In this type of research, you are in for the long term.

A more systematic approach to collaborations is now available. The National Institute of Statistical Sciences (NISS) has an affiliates program (visit `www.niss.org/affiliates/affiliatesmain.html` or see *Amstat News*, December 2000, p. 8). For a modest fee, companies and universities can become affiliates of NISS. This brings the industrial and university statisticians employed at these institutions into a community of collaborative statisticians, including fellows and graduate students at NISS. It also gives them access to and a voice in regular meetings to set research priorities.

The bottom line: modest inputs of time and money (and some risk-taking) can lead to very good financial returns and professional satisfaction.

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Member Survey in Final Stage

A survey of the members of the Statistical Consulting Section is currently underway. Every member should have received a survey questionnaire, "Survey of Statistical Consultants", in December.

This survey is being carried out in order to provide the Executive Committee and section members with a better idea of the characteristics of members. The aim is to aid in planning section activities that are relevant to the members. In addition, there has been no survey of statistical consultants in quite a while, and in-

formation on what we do and where we are employed is of interest to the ASA.

Over 500 responses have been received from the approximately 1,500 members of the Section. If you intend to participate, please send your response in the postage-paid return envelope as soon as possible. It should take only about 10 minutes to complete.

The survey questionnaire was developed by Nancy Berman, past Section Publications Officer, and Christina Gullion, Section Newsletter Editor, who will be responsible for analyzing and reporting the results. Their goal is to have results to report at JSM this year.

Welcome from New Section Chair

Ron Wasserstein, Washburn University

I look forward to serving you, the members of the Statistical Consulting Section, as your section chair for 2001. Alongside me will be the hard-working members of the Section Executive Committee.

Before talking about plans for this year, I would like to thank several people who have provided excellent leadership to our section. First, let me thank my dear friend and colleague, Janice Derr, who on January 1 signed off the Executive Committee as outgoing past-president. Janice has meant and continues to mean a great deal to the Section and to me personally. It has been my great pleasure and privilege to work with Janice and to count her as a friend.

Many thanks as well to my immediate predecessor, Brian Yandell, who served and led our Section well this past year, and whose contributions to both the Section and the Association are enormous. I don't know where Brian finds the time, but I am sure grateful for his work and for his fine leadership.

The rest of the committee (Rob Tempelman, Roy Tamura, Elaine Allen, Chris Gullion, Sam Lowe, Tom Loughin, Nancy Fenn-Buderer, Stuart Gansky, Barbara Mann, Matilde Sanchez, and Brenda Gaydos) will be of service to you in many ways during the course of the year, and I am very grateful for their efforts. All of us are eager to make the operation of the Section as effective and as efficient as we can.

My number one priority as chair will be to explore with the Executive Committee and with you ways we can increase service to our membership. Our membership survey will provide some ideas for this, so I encourage you, if you haven't already, to respond. In addition, we will need to brainstorm to see how we can continue to add value to Section membership. I hope that we will add and retain Section members, as well as serve them better, as a result of these efforts.

Some additional things I plan to look at in the coming year include:

- How to build interest in the travel award
- Finishing the revision of the section logo
- Direct email contact with new members and lapsed members
- Development of a history of the Section
- Developing a process for nominating Section members for ASA Fellow

Please feel free to contact me or any of the Executive Committee members with your ideas and suggestions. Any of us can be reached via the Section website (`www.amstat.org/sections/cnsl/`). We're here to serve!

Washburn University, Academic Affairs, 1700 College, Topeka, KS, (`ron@washburn.edu`)

Call for Invited Sessions for JSM 2002

The Section on Statistical Consulting can qualify for 2 or 3 invited sessions for the JSM 2002 meetings, if section members submit attractive proposals.

The plans for these sessions need to be well-developed by the time of the Joint Statistical Meetings (JSM) in August 2001. If you have an idea for a session that you are willing to organize, please contact Brenda Gaydos as soon as possible to discuss it with her.

The theme of the 2002 JSM is *Statistics in an Era of Technological Change*. Any ideas related to that theme are particularly welcome. Also welcome is any other topic that you believe would be of potential interest to Section members. Sessions addressing technical issues of broad interest are always well-attended. In addition, suggestions for sessions that could be co-sponsored with other ASA sections increase our chances of being awarded an invited session.

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There have been continuing discussions in the Section Executive Committee about the logistical and liability aspects of establishing a page at our website where Section members could post their availability for consulting assignments and/or clients could post their need for a statistical consultant. I encourage any member who has used this kind of online service at another website to write about it for the newsletter.

As always, short articles (1000-2500 words) on any aspect of statistical consulting are welcome. Please submit via e-mail. The deadline for the next issue is May 1.

Many thanks to Karla Genter, who continues to do the LaTeX 2_ε markup of the newsletter (and rein in my stylistic vagaries).

Client Perceived Pitfalls in Statistical Consulting: An Ethnographic Study

Holmes Finch, Department of Statistics

A statistical consultant, whether in industry or a university setting, works with clients from a variety of disciplines and with varying degrees of statistical sophistication. Clients come to the statistician with varying, sometimes complex, expectations as well. Of particular relevance is the clients' perception of potential pitfalls in the consulting process, with respect both to themselves and to the consultant.

This article reports the interview responses of fourteen graduate student clients of a university statistical consulting lab, who were asked to describe their anticipations regarding pitfalls in a scheduled consultation with a statistician. The methods and sample are described in Finch (1999).

The interview responses were classified into those that were associated with communication between the client and the consultant, and those that involved non-communication aspects of consulting.

Communication-related pitfalls

Prior to their first interaction with a Lab consultant, subjects expected the statistician to be more likely than the client to create communication-related pitfalls. Almost half of the subjects cited statistician miscommunication as a serious potential pitfall for consulting.

Statistician ignorance. Subjects were concerned that the statistician wouldn't understand the underlying content-specific issues and would thus make recommendations for analysis that were inappropriate. One doctoral student commented:

> *... If the consultant doesn't have a very [clear] picture of what the researcher is doing, I don't think that he [will] understand the research questions...*

Another anticipated reason for not understanding is lack of interest on the part of the consultant:

> *[A problem is] somebody that doesn't listen well, that can't hear you, that has too narrow a scope of expertise.*

One doctoral student had a bad experience with a previous statistical consultant. She believed he did not take the time needed to understand her study. Eventually the student went to someone else for help in developing an analysis plan, which delayed her work by several weeks. This experience colored her expectations of statisticians and of future consultations.

Statistician miscommunication. Another concern among subjects was that the consultant would not communicate effectively with the statistically naive client. They thought it was realistic to anticipate that the statistician would use jargon or assume a level of sophistication in the clients that was not justified. As one client described statistics in general:

> *... it always seemed like in stats I thought I was right and they changed the words just slightly and I couldn't understand the difference between them a lot of times...*

Another client seemed frustrated by what she perceived to be overly complicated descriptions of ideas that masked ideas she really understood:

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...when we actually got through and I saw that this is...basically a proportion,...it didn't seem so hard, but it's using those words...and actually one of my colleagues, who has been teaching at the university level for six years,...said, "well you collapse the data in a chi square"...why couldn't [the consultant] just say that?

In addition to the use of jargon, some clients feared that the statistician would assume more statistical knowledge on their part than they had, and would explain things at too high a level. A doctoral student observed:

You [the consultant] need to come down to my level. You have to draw things for me sometimes to understand it. Even if you do, there's still no guarantee that I'll really get it.

Another aspect of miscommunication is negative nonverbal communication on the part of the statistician. As one doctoral student put it:

...if [the consultant] said yeah, they can crunch the numbers, but the nonverbal said they're not really interested,...that would affect it [success of the consultation] too...

According to these clients, the consultant must eschew statistical jargon and work to express herself in a way that is clear to the client. She must be open to alternative methods of communication, including presenting ideas using graphs and pictures so that clients understand what is being discussed, and she must be careful not to assume anything about clients' statistical expertise.

Client ignorance. Some interviewees believed that client ignorance of statistics could also cause problems in the consulting process. A lack of understanding of what the consultant is doing can result in an incorrect analyses. Obviously, this notion is related to the failed communications described above. However, in this context, the subjects did not blame the statistician for doing a poor job of communicating, rather they were concerned that their own lack of knowledge would result in a poor interaction with the statistician.

Non-communication-related pitfalls

Other potential difficulties mentioned by the interviewees included the timing of meetings, disagreements over statistical analyses, and the "myopia" of either the client or the consultant.

Time issues. This was the most frequently cited pitfall. In cases where the client reported relying heavily on a statistician, time became a major issue, particularly as they waited for an opportunity to meet or have some work completed. A doctoral student reported that she really needed:

...relatively timely feedback, because it's really hard to stop the progress of the study, and if you can get the feedback in a timely way, it can keep you on a good path.

In addition to concerns over the timing of meetings with the statistician, some individuals were concerned about the small number of meetings that the Lab made available to them.

Myopia. A second concern voiced by several individuals was that the researcher and/or the statistician could be prone to myopia, failing to see beyond his or her respective discipline. One client shared his view of statisticians as:

...people who are very, very good at one thing but they have a hard time dealing with other things.

Another commented that

... different professionals... just come to each question with a different frame of reference. And statisticians place such an emphasis on the numbers. I mean that's really what it's all about. And I guess I feel like sometimes those numbers have limitations and if you're just looking at statistical output then you're missing a bigger part of the picture.

Another subject acknowledged that this view might not be completely accurate:

I guess they knew what to do with equations and stuff, but I didn't realize that there were people who really knew a lot about... the experiments themselves and help me to figure out...

Some of the subjects believed that the client could also be a victim of his or her own version of myopia. One subject described her difficulties in talking with the statistical consultant.

... when you're deep down in your study it's very hard to come out of it, surface out of it and just be very clear [and] succinct from the beginning.

Disagreements over statistical analysis. A third type of anticipated non-communication pitfall in the consulting process involves differences between the statistician and the client in expectations for the statistical analysis. While both parties may agree that the statistician is the expert in his/her field, some clients feel that they not only have the prerogative but also the responsibility to challenge the recommendations of the consultant. This viewpoint might originate in what the client perceives as the limitations of statistics to adequately capture what they are interested in:

... then I was forced to... squeeze it into numbers and I felt like by the time I got finished doing that, that I'd lost [the study subjects], the voice was gone of [the study subjects].

In the case of graduate student clients, disagreements over analysis strategies may also occur between the consultant and the client's dissertation or thesis committee.

These graduate students anticipated that the result of a disagreement over analysis could be as severe as the dissolution of the consulting relationship with the client.

What if you [the statistician] had this great suggestion for an analysis and the [researcher]... said, "No, I don't want to do that." Well, then you have to decide whether you want to keep going... If the statistician wouldn't believe that it would even be valid, he or she would have to pull out... It gets to be moral at that point.

This client recognizes that both parties have ethical boundaries. The researcher has a responsibility to be true to his or her data and answer the appropriate research questions. The statistician must also be true to his profession, and might have to stop working with someone if the requested analysis were invalid.

Implications for consulting practice

- Clients may come to a statistical consultant concerned that the statistician will not understand the contextual issues of their study or will have difficulty communicating statistical principles effectively.
- Timely feedback may be very important to some clients. Therefore, the consultant should follow-up with clients in a timely manner, and communicate clearly a schedule to which they can adhere.
- The statistician needs to be aware of the possibility of myopia with respect to statistics, and to recognize narrowness of research focus in their clients.

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