

# The Role of Education in Biostatistical Consulting with Medical and Health Science Researchers

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March 4, 2009

# Outline of Presentation

- Description of the role of education in biostatistical consulting, including consultant roles and client expectations
- Discussion of experiences connecting biostatistical consulting and training (research study with other biostatisticians)
- Review of recent work performed in this area

# Outline of Presentation (continued)

- Discussion of potential applications to Centers for Clinical and Translational Science (CCTS) and Comprehensive Cancer Centers (CCC)
- Presentation of ideas for a future prospective research study



# Introduction

- This research examines the role of biostatistical training during consultations with medical students, graduate students in health science fields, residents, postdoctoral fellows, medical faculty, and health science faculty.
- This research also reviews the characterizations of the connections between biostatistical consultation and education.

# Introduction (continued)

- Biostatistical consultation is often sought in conjunction with planned or current research and sometimes to clarify interpretation of research findings published in the medical literature.

# Introduction (continued)

- Those who have a need for this service include medical students (particularly those in their third or fourth year), graduate students (masters and doctoral) in health science fields, physicians during residency or postdoctoral training, health science postdoctoral trainees, and medical and health science faculty (Instructor, Assistant Professor, Associate Professor, Professor).



# Introduction (continued)

- The primary reason to collaborate with a biostatistician is to ensure adequately designed studies and scientifically sound findings.
- There is an apparent link between biostatistical consultation and training in study design and biostatistics.

# Reasons to Seek Biostatistical Advice

- Requests for biostatistical advice may be prompted by the following: grant or other funding application, research protocol development, randomization assignment, data analysis, interpretation of results, presentation of research findings at a conference or seminar, drafting a manuscript for publication, or responding to reviewer comments from a journal or grant review panel.



# Reasons to Seek Biostatistical Advice (continued)

- Other reasons to seek biostatistical advice include the following: a lack of knowledge about principles of study design, insufficient skills to analyze data or interpret results, or a lack of necessary technical expertise in more sophisticated or rigorous aspects of the research process even when an adequate background in the fundamentals is present.

# Modes of Biostatistical Training

- Diverse modes of biostatistical training may be available within a medical school (and other schools such as schools of public health or nursing) or teaching hospital environment. These include formal academic courses, intensive short courses, seminar series on biostatistical topics, self-paced textbook or computer learning, statistical references, guides, or compendiums, and one-on-one training.

# Modes of Biostatistical Training (continued)

- This presentation will focus on one-on-one training.
- How instruction takes place and in what settings will be described.
- A proposed model for plausible connections between biostatistical consulting and educational activities will be described.



# Linking Researcher Expectations with Biostatistical Training via Consultation

- Researchers who seek out biostatistical advice fall into one of three mutually exclusive categories.
  - (1) The researcher has sufficient knowledge to understand and apply the statistical information or results provided by the consultation. In this setting, no supplemental education is necessary.

# Linking Researcher Expectations with Biostatistical Training (continued)

(2) The researcher lacks the necessary knowledge and is aware of his or her insufficiency. In this setting, education is a critical component of consultation.

(3) The researcher lacks the necessary knowledge but is not aware of this gap in background. In this setting, biostatistical training becomes a vital part of the consulting process.

# Consultant and Client

- Consultant = Biostatistician
- Client = Medical student  
Graduate student  
Resident  
Postdoctoral fellow  
Faculty



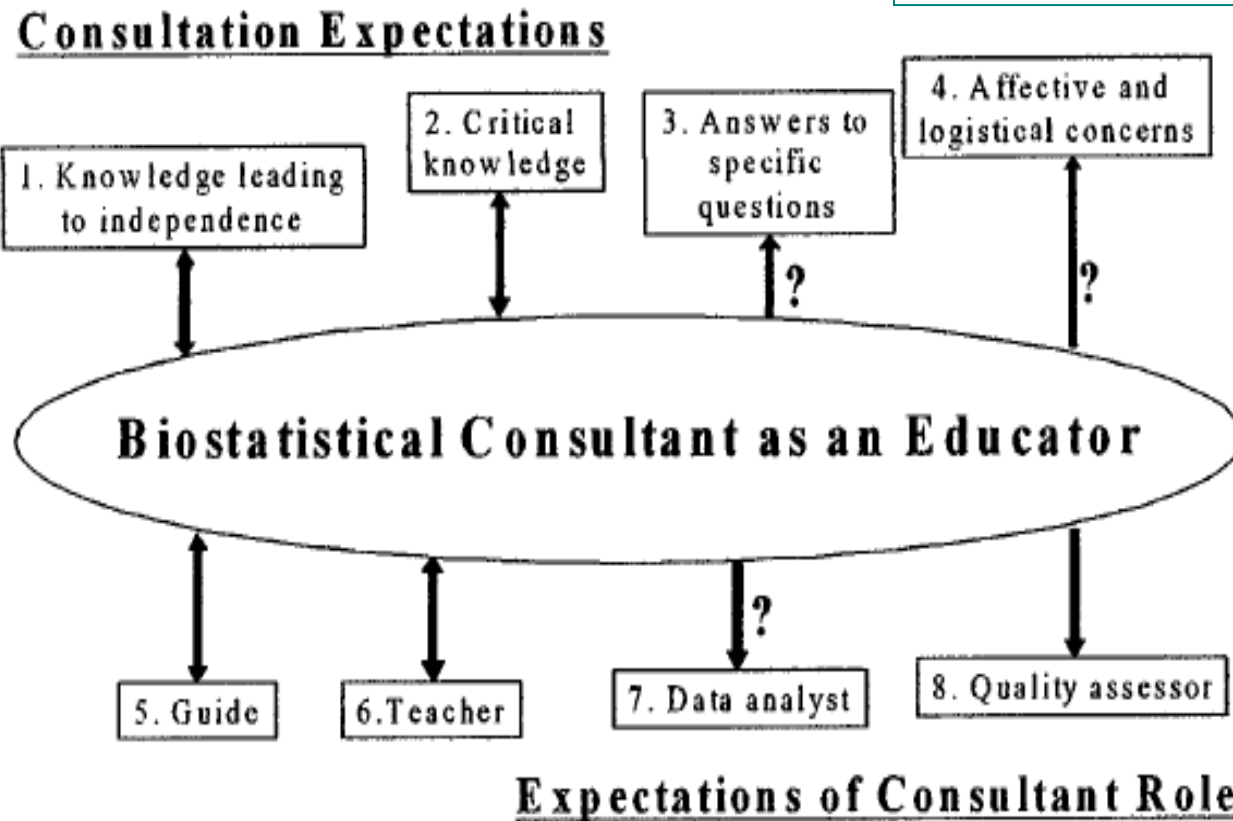


Figure 1. Link between researcher expectations of biostatistical consultation (Boxes #1–4) and consultant's role (Boxes #5–8) with the biostatistical consultant's position as an educator (Ellipse). Arrows pointing towards the ellipse show automatic anticipation of training; arrows pointing away from the centre are likely to include training during the consultation; question marks show possible training.

# Client Expectations (top part of the oval)

- (1) Knowledge leading to independence: to acquire information about statistical analysis for independent future use.
- (2) Critical knowledge: to understand why a procedure is used and what problems might be associated with it.
- (3) Answers to specific questions: to receive only the answer to a specific statistical problem and not more than that.
- (4) Affective and logistical concerns: to demand a fast turn-around to meet a deadline or maintain research momentum. Timing is important, and patience is required.

# Consultant Roles

## (bottom part of the oval)

- (5) Guide: to help choose a statistical strategy to analyze data and answer research questions.
- (6) Teacher: to explain why an analytical procedure is appropriate for a given scenario and how it works.
- (7) Data Analyst: to number-crunch and manipulate data.
- (8) Quality Assessor: to check accuracy and integrity and to point out errors or problems in the project.



# Experiences Connecting Biostatistical Consulting and Training (Methods)

- Biostatisticians with consultation activities at separate academic research institutions recorded characteristics of the consultations, focusing on the presence and types of teaching efforts.
- This included maintaining logs of in-person, e-mail, and telephone consultations over a period of time and determining if some degree of training in study design or biostatistics took place during the consults.
- Most of the data were collected in real time, although some were compiled after reviewing hard copy, computer files, and notes from consultations.

# Experiences Connecting Biostatistical Consulting and Training (continued)

- Education and training were defined as providing technical didactic background information or supplemental details about a topic in study design or biostatistics beyond simply defining a term or reporting a result.
- In addition, for teaching to have taken place, an investigator had a need to understand the topic of instruction to fully make use of the material provided in response to the investigator's request for assistance.

# Experiences Connecting Biostatistical Consulting and Training (continued)

- Participating biostatisticians were solicited from the Association of General Clinical Research Centers (AGCRC, an NCRR-funded resource for human-oriented medical research) Statisticians listserv and include all who responded positively and furnished data.
- There were four sites: 1) University of California, San Diego (UCSD), 2) Brigham and Women's Hospital, Boston (BWH), 3) University of Pittsburgh (Pitt), and 4) University of Alabama at Birmingham (UAB).



# Experiences Connecting Biostatistical Consulting and Training (continued)

- Data were obtained retrospectively from overlapping time periods of varying durations. However, all time periods occurred from 1999 through 2005.
- Approvals or exemptions by the local institutional review boards were obtained prior to the inclusion of any data in the project.
- All statistical analyses were descriptive. These analyses included point estimates and exact 95 per cent confidence intervals for the percentage of consultations involving training.

# Biostatistical Consultations

	<u>With Training</u>	<u>Without Training</u>	<u>Total</u>
Overall	186	51	237
By Site			
UCSD	39	17	56
BWH	57	0	57
Pitt	43	21	64
UAB	47	13	60
By Position of Investigator			
Faculty	120	41	161
Fellows & Residents	31	8	39
Medical Students	10	0	10
Other	25	2	27

# Biostatistical Consultations with Education

	<u>Percent</u>	<u>95% Exact Confidence Interval</u>
Overall	78	73 – 84
By Site		
UCSD	70	56 – 81
BWH	100	94 – 100
Pitt	67	54 – 78
UAB	78	66 – 88
By Position of Investigator		
Faculty	75	67 – 81
Fellows & Residents	79	64 – 91
Medical Students	100	69 – 100
Other	93	76 – 99



# Medical Fields of Investigators

Anesthesiology

Clinical Nutrition

Family Medicine

Geriatrics

Internal Medicine

Oncology

Pediatrics

Renal

Sleep Medicine

Cardiology

Emergency Medicine

Gastroenterology

Hematology

Neurology

Orthopedics

Psychiatry

Reproductive Medicine

Surgery

Cardiothoracic Surgery

Endocrinology

Genetics

Infectious Disease

Neurosurgery

Pathology

Radiology

Rheumatology

Thyroid

# Biostatistical and Study Design Topics

ANOVA, ANCOVA, MANOVA

Area under the curve

Binomial test, McNemar's test

Bland–Altman plot

Categorical *versus* continuous data

Chi-square and cell counts

Collinearity

Confidence intervals and precision

Continuous *versus* binary data

Correlation: Pearson and Spearman

Covariates

Cox regression

Cross-over design

Data coding

Data entry

Data transformation

Database design

Diagnostic testing

Dispersion

Dunnett's test

Equivalence

Exact confidence interval

Fisher's exact test

Form design

Friedman test

Hierarchical regression

Imbalance

Intent-to-treat

Inter-observer agreement

Interaction

Interim monitoring

Inter-observer variability

Kaplan–Meier plots, Logrank test

Kappa

Likert scales

Logistic regression

Longitudinal data

Mantel–Haenszel test

Marginal effects

Missing values, imputation

Mixed models

Model assumptions, model building

Multiple comparisons

Nonparametrics

Odds ratios

Outliers

*P*-value *versus* confidence interval

Partial correlation analysis

Phase III clinical trial design

Pilot study

Poisson regression analysis

Polynomial trends

Power

Psychometrics

ROC curves

Random coefficient modelling

Randomization

Raw data *versus* summarized data

Reliability coefficients

Repeated measures

Residuals

Sample size

Simon's two-stage design

Simple effects

Slope comparisons

Standard error of the mean *versus* standard deviation

Statistical genetics

Study design

Survey data analysis

Survival analysis, censoring

*T*-tests: two-group and paired

Technical writing

Time-dependent proportional hazards

Transformations

Trends

Variance test

Wash-out

Wilcoxon rank sum test

Wilcoxon signed rank test

# Discussion

- The level of understanding and retention of biostatistical skills taught in the classroom are often inadequate for tackling design and analysis challenges that occur in subsequent clinical research efforts.
- The pattern of linking each expectation to an instructional outcome illustrates the need and also opportunities for biostatistical education within the context of a consultation initiated by researchers.



# Discussion (continued)

- The investigator's lack of familiarity with relevant biostatistical topics and study design issues often prompts a detailed tutorial to fill the gaps.
- More than 75% of documented biostatistical consultations included varying levels of instruction in biostatistical topics or research study design. This evidence supports that this type of informal teaching makes up an integral part of the consulting process. Investigators will benefit from this type of consultation since the newly gained knowledge should carry over to improved skills in critical evaluation of the medical literature.

# Limitations

- There was no attempt to discriminate between consultation sessions for large, complex, rigorous projects and sessions addressing more routine, less complicated studies.
- The study reflects consulting experiences of only four biostatisticians.
- There was no assessment of the degree that the consulting experiences are representative of sessions with other biostatistical consultants nor if they reflect the experiences of investigators at other institutions.

# Generalizations

- The broad spectrum of research in diverse fields of medicine may support the generality of the findings.
- The broad span of positions of the four biostatisticians may allow generalization of the results.
- The fact that at least 67% of biostatistical consultations at each site included a training component suggests that these training opportunities are consistently offered.
- Consulting experiences of the four biostatisticians are consistent with consulting experiences of colleagues in different areas of the country providing active consulting efforts based on informal discussions.



# Inferences from Research Study

- Motivation to master research skills may be lacking during medical school or even during postgraduate medical training.
- Education in study design and biostatistics is more fully appreciated later in the researcher's career.
- It is sensible and convenient for a consulting biostatistician to nourish and expand upon the client's training in study design and biostatistics.

# Inferences from Research Study (continued)

- Institutional support for educational efforts in biostatistical training should be encouraged to sustain and enhance the educational mission of the institution.
- Learning opportunities for researchers during biostatistical consultations add value to this resource.

# Collaborators

Reena Deutsch –

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Janine Janosky –

University of Pittsburgh

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# Recent Related Work – Cho et al.

- The focus of this work is on institutional research ethics consultation services for biomedical scientists.
- Several models of ethics consultation are described. These models range from “moral community” (large group) models, where all of the scientists involved in the research project as well as representatives of the research participants, would be involved in every consultation for that project, to “single expert” models, where a single individual with the necessary knowledge and skill set to address any ethical issues that arise in a particular case carries out the consultation.

# Recent Related Work – Cho et al. (continued)

- The authors specifically mention that “biostatistics and design consultants” follow the “single expert” model in their consultations.
- The authors present a model that they developed. This model is a hybrid approach which combines elements of individual consultation and group consultation. The core team consists of three academics with training in philosophy, law, and biology, and is responsible for the initial response to consultation requests. Other academics with different areas of expertise are available if needed. An individual consultant triages the case either to a single individual or to the core team.

# Recent Related Work – Cho et al. (continued)

- Five areas that contain unresolved questions:
  - (1) Scope – the range of issues (very specific to very broad) that researchers might bring to a research ethics consultation.
  - (2) Composition – the composition of the consultation team. Committees with a range of backgrounds will be needed. Internal and external consultants may be needed for the request.
  - (3) Core competencies – should each consultant possess a specific set core competencies (knowledge areas).



# Recent Related Work – Cho et al. (continued)

(4) Conflicts of interest – these include the location of the consultation service within the research institution, the funding of the service with either intramural or extramural support, and the nature of the role of the consultants.

(5) Purpose of the consultation – is it primarily for scholarly research or for providing a service. The structure of the consultation is affected by the purpose.

# Recent Related Work – Weber and Cobaugh

- The authors describe practical approaches to successful implementation and execution of practice-based research projects.
- Included are descriptions of the project research question and specific aims, project team establishment, research timeline and progress tracking, methods and instrument development, data management and analysis plans, IRB approval, resource allocation, grant submissions, research implementation, ensuring quality control, and presentation and publications of findings.

# Recent Related Work – Weber and Cobaugh (continued)

- The role of the biostatistician on the project team is specifically discussed. This is regarding study design, sample size calculations, selection of appropriate statistical tests, and financial resources required to support the biostatistician.
- The authors state that “one of the biggest frustrations for new investigators is engaging in technical dialogue with the statistician” and then recommend that new investigators consider reviewing a statistics primer.



# Recent Related Work – Weber and Cobaugh (continued)

- The authors recommend that investigators consult a biostatistician early in the design phase and go on to say that “many new investigators make the fatal error of consulting with the biostatistician when data collection is complete and analysis is required”.
- My thought – there are clearly opportunities to provide statistical education to investigators during the planning and execution of their research projects.

# Potential Applications to CCTS

- There are many opportunities to provide biostatistical consultation to a wide variety of investigators.
- BERD = Biostatistics, Epidemiology, and Research Design
- At UAB, the overall goal of the BERD component is to provide experienced methodological investigators to collaborate with clinical and translational researchers in the areas of epidemiology, biostatistics, outcomes and health services research, and data management.
- The emphasis is on assisting researchers with pilot and nascent studies.

# Potential Applications to CCTS (continued)

- Current educational efforts of the UAB BERD include participating in the MSPH in Clinical Research Program and fostering a seminar series in clinical research (primarily for junior physician-researchers).
- We submitted a Summer Institute in Biostatistics (SIBS) proposal entitled "Summer Institute for Training in Clinical Trials and Statistical Genetics/Genomics". This is to be a "crash course" in biostatistics with emphasis on clinical trials and statistical genetics/genomics.



# Potential Applications to CCTS (continued)

- The national BERD evaluation subcommittee has developed evaluation guidelines for BERD components. One part of this involves evaluation of educational activities that the BERD is involved in, including evaluation of effectiveness of teaching and overall course satisfaction.
- Completion of residual responsibilities and commitments made under the auspices of the former GCRC often involves an educational component. For example, our GCRC trainees work on projects for their theses and dissertations that are related to or in support of GCRC-approved research studies.

# Potential Applications to CCC

- There are many opportunities to provide biostatistical consultation to Cancer Center investigators.
- There are four ways that the UAB Biostatistics and Bioinformatics Unit provides statistical education to Cancer Center researchers.
  - (1) Through routine consultation on proposed research studies submitted for Cancer Center approval and also for scientific manuscripts based on approved studies.
  - (2) Through seminars given as part of the Cancer Center Seminar Series (which includes all aspects of cancer research).

# Potential Applications to CCC (continued)

(3) Through involvement in the Clinical Trials Review Committee (CTRC) – providing thorough statistical reviews of study protocols and participating in the committee meetings.

(4) Through participating in the Clinical and Translational Research Concepts Meeting – providing statistical advice to investigators who present a draft of their proposed research study prior to submitting it to the CTRC for approval or a draft manuscript prior to submitting / resubmitting it to a peer-reviewed journal.



# Ideas for a Future Study

- Perform a prospective study
- Obtain consulting experiences from a substantially greater number of biostatisticians
- Obtain consulting experiences from a substantially greater number of institutions
- Use a more clearly defined and uniform time period (perhaps a one-year period) for the consulting experiences that are reported

# Ideas for a Future Study (continued)

- Discriminate between consultation sessions for large, complex projects and sessions addressing more routine, less complicated studies
- Attempt to obtain funding for this study (one of the reviewers of the completed study said that it was probably the best that can be done without a grant)
- Offer an incentive to biostatisticians that participate

# Ideas for a Future Study (continued)

- Encourage participation from GCRC and CCTS biostatisticians
- Perhaps include a measure of the client's satisfaction with the consultation



# References

- Deutsch R, Hurwitz S, Janosky J, Oster R. The role of education in biostatistical consulting. **Statistics in Medicine 2007; 26:709-720.**
- Cho M, Tobin S, Greely H, McCormick J, Boyce A, Magnus D. Strangers at the bedside: research ethics consultation. **The American Journal of Bioethics 2008; 8:4-13.**
- Weber R, Coughlin D. Developing and executing an effective research plan. **American Journal of Health-System Pharmacy 2008; 2058-2065.**