Teaching Statistical Ethics via Lectures, Group Discussions, and Peer Mentoring

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August 3, 2014

Acknowledgments: Dr. Kathryn Chaloner and various graduate students who have participated so well

Overview of My Own History of Scholarly Integrity/Ethics Training

- As a pre-doctoral trainee at Harvard
- As an MD/PhD mentor at the University of Iowa in the 1990's
- As Director of Graduate Studies in Biostatistics at Iowa from 2003-2012
- As a group facilitator of the class taught by our Graduate College, mostly to basic science students, post-docs, and fellows.
- As co-instructor of an supplemental course taught to our T32 trainees in Biostatistics.
- As instructor of an official biostatistics course (1 credit), accepted as a substitute for the Grad College class and approved by the Office of the VP for Research Data.

Format of the Grad College Class

- Each year a 4-hour “kick-off” was held the week before classes started (100s of students).
  - Mostly overview lectures, with some discussion at individual tables.
- Each semester, two 2-hour workshops were held in one of 4 areas.
  - Authorship & peer review – What is plagiarism, fabrication, falsification?
  - Fostering relationships with your mentors and collaborators – managing conflicts and grievances
  - Becoming an informed university scholar – human subjects, vulnerable populations, & the use of animals in research
  - Protecting scholarly endeavors & investments – intellectual property, conflict of interest, fiscal responsibilities
- Format of workshop was to be 15 minutes of lecture, and remainder of time in 8-person groups led by a faculty facilitator, discussing case studies.
- MS students required to do this for 2 semesters (0 credits)
- PhD students required to do this for 4 semesters (1 credits)

Reaction to the Grad College Class

- Too much emphasis on the culture/hierarchal structure in the basic sciences.
- Departments were told that all of their grad students who are on any NIH funds needed to take this course.
  - Unclear who made this decision ("Your mom really wants you to clean your room.")
  - Mandate to send students led to mandate to provide faculty, with little ownership of the curriculum.
- Too broad of an audience.
- Issues with vagueness of case studies.
- Unclear how to "count" the effort of the faculty member.
- Very strict attendance requirements.
- T32 reviewers suggested periodic review (~every 3 yrs)

Our Plan at the Univ. of Iowa

- Content delivered in 1 semester (probably second semester of grad program).
- For Biostat/Statistics Students
  - Can make the examples more relevant.
  - One faculty instructor/coordinator for entire semester (rather than a parade of stars).
  - Statistics faculty asked to give guest lectures.
- Required every 3rd year in Biostatistics.
  - Hence, a review for 4th year students.
  - 4th year students can be mentors, discussion leaders, etc.
- Class has lectures but emphasizes discussion.

Goals and Learning Objectives

At the end of the course the student will be able to:

- Understand the ethical importance of obtaining, managing, and storing high quality data.
- Document statistical analysis plans and organize computer programming code to assure integrity in the analytical aspects of the research process.
- Perform independent and collaborative research that maintains high standards of quality, integrity, and ethics.
- Communicate with their peers, supervisors, and future trainees more effectively, so that ethical issues can be proactively addressed in a timely manner.
- Reduce the occurrence of misunderstandings that may lead to unethical behavior.

In short, be a good statistician!!

Public Health Competencies

The following competencies in the MS and PhD Biostatistics programs of the College of Public Health will be addressed, in part, by this course:

- Effectively collaborate on a research team.
- Prepare reports and publications resulting from health science studies.
- Effectively communicate key statistical principles to a non-statistical audience.

NIH Competencies

1. Conflict of interest – personal, professional, and financial
2. Policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices
3. Mentor/mentee responsibilities and relationships
4. Collaborative research including collaborations with industry
5. Peer review
6. Data acquisition and laboratory tools; management, sharing and ownership
7. Research misconduct and policies for handling misconduct
8. Responsible authorship and publication
9. The scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research

Weekly topics, w/ NIH Competencies

- Overview: Ownership & Responsibility 4, 6, 9
- Documentation of Analyses 4, 6
- "The Lab" (ori.hhs.gov/thelab); Falsification of Data 7, 9
- Publication & Selection Bias, Type I/II Errors 8, 9
- Reproducible Research 3, 7, 9
- IRB Committees and Human/Animal Subjects 2
- Data confidentiality, Identifiers, Security 6
- Authorship, Peer Review, Intell. Property 5, 8
- Statistical review and errors in publications 5, 8
- Gender Bias 3, 7, 9
- Plagiarism, Copyright, Conflict of Int/Commit 1, 8
- Student/Mentor Comm & Relationships 3
- Conflict Resolution & Grievances 7
- Student Presentations (oral and written)

Student Projects

- Gender Bias (3)
- Publication/Media Bias (3)
- Vioxx Case Study (2)
- The Importance of Accommodating Correlations
- False Positive Findings—Ioannidis, 2005
- Sample Sizes of Phase I Studies/Regression Studies
- Data Encryption
- Ethical Issues with the Peer Review Process
- Use/Misuse of Journal Impact Factors
- Reducing Import Errors when Reading Multiple Datasets
- Case Studies of Unethical Research
- Autism/Vaccine Controversy

Final Thoughts / Future Directions

- Student evaluations were good
  - “Dr. Dawson was a good choice to teach this [because he is old enough to have lots of stories to tell about when things go wrong]”.
  - “Dr. Dawson did a good job on a course that would be difficult to teach.”
  - Somewhat low score on “I learned a lot” question.
- Emphasize what we want them to learn and what we have learned.
- Force more discussion/mixers earlier in semester.
- Students will have longer to present next time (~10 instead of 30 students).
- By 2017, we should have steady state of 10-15 new students and 5-6 advanced students.