

# Recognizing Trust and Understanding as Twin Pillars of Statistical Ethics

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## An example to fix ideas (Belin and Normand 2009 *Psychiatric Annals*)

In an expensive government-funded randomized study on smoking cessation in cancer survivors, control group has higher rate of smoking cessation than active treatment.

Statistician asked to investigate further, revealing a covariate out of balance that, when included as covariate in analysis, reverses direction of estimated treatment effect, although effect remains non-significant.

# Ethical considerations

- Publicly-funded research—want answers that serve general public
- Scientific merits/imperatives of marginal analysis (favoring control) vs. conditional analysis (favoring active treatment), role of pre-specification
- What to report

## Mapping ethics into action

- The fact that marginal analysis was pre-specified was viewed as inducing imperative to report marginal analysis
- Report highlighted conditional analysis through table featuring logistic-regression findings, noting evidence of lack of balance on key covariate
- What would you have done?

# Another example: Research on RSVIG

- UCLA Clinical Research Center protocol, part of multi-site study of newly developed treatment for respiratory syncytial virus (or RSV, a common infection that places those with congenital heart disease at increased risk)
- Consent form for parents, approved by UCLA IRB, cited potential for reduced length of ICU stays and frequency of hospital stays
- Protocol noted that across three groups (control and two variants of active treatment) of previous patients, all 6 deaths were in active-treatment arms, but Fisher-exact p-value was 0.145.

# Research on RSVIG: Consent form language

“RSVIG is presently an investigational drug and its use for prevention of RSV infection is being studied. In a multi-center trial conducted from 1989 to 1992 RSVIG was found to significantly reduce the frequency and severity of RSV lower respiratory tract infections, it reduced the frequency of hospitalization due to RSV infection and reduced the number of days in the intensive care unit in comparison to children who received no RSVIG.”

# Research on RSVIG: Study background from Clinical Research Center application

“An earlier clinical trial of RSVIG-IV [intravenous] enrolled children with bronchopulmonary dysplasia, prematurity, and cardiac disease. Monthly high dose (750 mg/kg) infusions were found to reduce the frequency of RSV LRI [lower respiratory infection] in all high risk infants by 62% as compared to the no dose group and to reduce the severity of the disease. RSV hospitalizations were also reduced. In that trial, however, six study children died. Five children who died had congenital heart disease. On review it was evident that these deaths were related to surgical complications.”

Research on RSVIG: Summary from  
“Review of Pertinent Literature” in attached  
multi-site proposal from pharma company

“Six study children died during the period  
from the first RSVIG-IV infusion (or first  
scheduled visit in the control group) to four  
months after the last RSVIG-IV infusion or  
scheduled visit; three of the 81 (3.7%)  
patients in the high-dose group, three of the  
79 (3.8%) in the low dose group and none  
of the 89 patients in the no dose group  
( $p=0.15$ ).”



## Re-examination of study results

Group	0	1	2		Group	0	1
Lived	89	76	78		Lived	89	154
Died	0	3	3		Died	0	6
Total	89	79	81		Total	89	160
Fisher exact: $p = 0.145$ (2-tailed)					$p = 0.091$ (2-tailed) $p = 0.068$ (right tail)		

## Clinical Research Center protocol (cont'd)

- Protocol describes hiring of independent consultant to review each death, with consultant concluding that there was no clear mechanism through which active treatment would induce death
- Call to chair of Human Subjects Protection Committee reveals that some questions were asked and answered, after which approval was granted

## Clinical Research Center protocol (cont'd)

- Protocol also lists person who was hired as an independent consultant as a co-investigator on the current project
- Statistician submits review accompanied by letter disapproving of the project until concerns about consent form are addressed

## Clinical Research Center protocol (cont'd)

- Several months later, a conversation with a Clinical Research Center nurse reveals that the project was approved over the statistician's objection and that patients had already been enrolled and treated
- What should the statistician do?

# Ethical imperatives induced by human agency and the need to communicate

Rubin 1983 book chapter (“A Case Study of the Robustness of Bayesian Methods of Inference”):

“Statisticians have an obligation to provide the kinds of answers clients will assume are being provided....”

Commentary alludes to psychological appeal of Bayesian paradigm based on cognitive tendency of clients to interpret interval estimates as Bayesian HPD intervals, but interpretation here not limited to Bayesian perspective.

# The interests of statisticians in ethics

- Integrity of decisions
- Reputation
- Education
  - Development of curriculum
  - Professional identity development
- Public service

# Existing guidelines

ASA Board of Directors approved guidelines in 1999 that were developed through Committee on Professional Ethics

Contains preamble describing purpose (“intended to help statistics practitioners make and communicate ethical decisions”)

# Existing guidelines (cont'd)

Includes sections on:

- Professionalism
- Responsibilities to Funders, Clients, and Employers
- Responsibilities in Publications and Testimony
- Responsibilities to Research Subjects
- Responsibilities to Research Team Colleagues
- Responsibilities to Other Statisticians or Statistics Practitioners
- Responsibilities Regarding Allegations of Misconduct
- Responsibilities of Employers, Including Organizations, Individuals, Attorneys, or Other Clients Employing Statistical Practitioners



# Comments on existing guidelines

Strengths include:

- Identifying numerous stakeholders deserving of respect and good faith from statisticians
- Identifying numerous contexts in which ethical considerations are central

## Comments on existing guidelines (cont'd)

Criticisms include:

- Length of guidelines (~ 13 pages of text)
- Impossibility of enumerating relevant contexts
- Lack of awareness of their existence
- Risk of inducing vulnerability to manipulation by predatory operatives who play by different rules (e.g., political consultants, lawyers in adversarial settings, Hollywood filmmakers)

# Expert-witness example

- Context: Alleged Medicare fraud by health care facility based on artificially extending lengths of stay of patients
- Statistical question: Does the average length of stay of patients seen during the period of alleged fraud differ significantly from the average length of stay of patients before and/or average length of stay of patients after period of alleged fraud?

## Expert-witness example (cont'd)

- Data delivered in Excel spreadsheet
- TRB analysis: One-way analysis of variance on length-of-stay data, supplemented by analysis of all pairwise comparisons using Bonferroni, Tukey, and Scheffe multiple-comparison procedures
- After report submitted, lawyer who retained TRB reported errors in original Excel spreadsheet, asked TRB to produce new report using updated data set

## Expert-witness example (cont'd)

From cross-examination (in substance):

“Dr. Belin, did you undertake any investigation into the accuracy and validity of the data you analyzed?”

“No, sir, I did not.”

“Now Dr. Belin, don't you think you had an ethical obligation to determine the accuracy and validity of the data you analyzed?”

## Expert-witness example (cont'd)

“Absolutely not.”

Reasoning: I was not asked to do so. I was only asked to provide my best professional judgment about whether the mean of one set of numbers was significantly different from the mean of two other sets of numbers. If I had been given a different set of numbers, I could have done another analysis. I was charging a premium rate for my time, and it would have been inappropriate for me to charge for something someone else could have done at much less expense to my client.

# Comments on expert-witness example

- Ability to replicate findings as a core element of science
- Lawyers known to lay traps, luring witnesses into acknowledging external authority (e.g., ethical obligations) that can then be used to shred witness's credibility
- Of course, in the context of scientific research for publication, one does have an ethical obligation to ensure the accuracy and validity of the data being analyzed
- Heinz Pagels (*The Dreams of Reason*, 1986): “Draw distinctions where there are important distinctions to be drawn”

# Comments on expert-witness example

- John Rawls (*A Theory of Justice*, 1971): Justice conceptualized using game-theory formulation where the rules of the game are devised before anyone knows the labels of where anyone resides in the system
- Ethical guidelines should induce meaningful constraints on professional activity but should not make it impossible to function or amount to a mandate to commit professional suicide when confronted with a dilemma induced by interaction with non-statisticians



# A complementary framework built on “trust” and “understanding”

As opposed to trying exhaustive enumeration of relevant contexts, can identify core principles to serve as the foundation of a thought experiment when values clash

Existence of true but misleading statements argues against treating “truth” as foundation for thought-experiment test (as opposed to principles that effectively require truthfulness)

Proposal: Anchor ethics on principles of “trust” and “understanding”

# Motivations growing out of philosophical principles

Spinoza: Self-preservation instinct implies

- virtue in considering self-preservation of others,
- injunction to do no harm to others

Hume: We are bound to recognize regular conjunctions of events as well as to remain skeptical in interpretations since we cannot directly perceive source of connection

Key principle: “Draw distinctions where there are important distinctions to be drawn” (Heinz Pagels, *The Dreams of Reason*)

## Trust as a Core Value

Sissela Bok in *Lying: Moral Choice in Public and Private Life*

“I believe that we must at the very least accept as an initial premise Aristotle’s view that lying is ‘mean and culpable’ and that truthful statements are preferable to lies in the absence of special considerations....”

## Trust as a Core Value (cont'd)

Sissela Bok: “I would like ... to refer to the ‘principle of veracity’ as an expression of this initial imbalance in our weighting of truthfulness and lying. It is not necessarily a principle that overrides all others, nor ...sufficient by itself—witness the brutal but honest regime or the tormentor who prides himself on his frankness.”

## Trust as a Core Value (cont'd)

Sissela Bok: “Rather, trust in some degree of veracity functions as a *foundation* of relations among human beings; when this trust shatters or wears away, institutions collapse.”

# Potential for audiences to be misled

Subtle differences in premises can give rise to wildly different conclusions

Consider adversarial proceeding regarding injury to a large number of people, where aggregate damages estimated by evaluating damages to a few hundred people

Statistician A: Summarize damages utilizing sample mean plus or minus multiple of standard error

Statistician B: A lurking variable might exist that makes proposed estimate too high or too low

# Potential for audiences to be misled (cont'd)

What would a lay judge or juror think?

What if sample came from individuals with the most visits to medical clinics, as opposed to being a random sample?

Statement about lurking variable might be true, but does it justify dismissing any and all attempts to arrive at a single summary of damages?

# Other examples

- Biotech company mischaracterizing findings from statistical analyses in press releases
- Being denied authorship of NEJM article relying on multiply imputed data sets developed pursuant to written agreement that pledged co-authorship
- Student misconduct on exams
- Plagiarism by students
- Words and their meaning, e.g., “smoking-related deaths”
- Standards for fetal tissue research
- Ethics as a structured logical framework to guide decisions not determined by scientific imperatives



# Comments

- Statisticians have an excellent foundation upon which to build a reputation for integrity
- Viewing ethics as central to professional identity is rewarding
- An effort to elevate ethics in the statistics profession has to build on expanded awareness yet recognize limits in people's attention spans: Checklist of scenarios? Thought experiment based on trust and understanding? Some other framework?
- All feedback welcome! (tbelin@ucla.edu)