

TO: ASA Committee on Professional Guidelines
 TOPIC: ASA Ethical Guidelines for Statistical Practice. (March AMSTAT News)
 ISSUE: Are these guidelines suitable to the breadth of ASA membership?

CONCLUSION: No! These guidelines are not adequate! This document does an outstanding job of describing the responsibilities of those statisticians who do experimental research, but it is woefully inadequate in describing the responsibilities of those statisticians who deal with observational studies.

In this document, page 1 recommends additional principles of professional responsibility. Page 2 applies these principles to an actual study. Page 3 gives reasons why these recommendations are so important.

Kinds of studies [Preamble, Part B. Statistics and Society]

Findings: Experiments are mentioned; observations are mentioned. Observational studies are not.

Recommendation: Regroup the activities listed as either experimental or observational.

General Reporting Responsibilities of Statisticians [Section on Ethical Guidelines; A. Professionalism.]

A. Bias

Findings: No comprehensive mention of bias.

Recommendation: Add something about guarding against bias in general -- measurement bias, sampling bias, non-response bias, etc. And if there is significant uncontrollable non-response, identifying whether any steps were taken to see if this contributes to measurement bias. To mention only subjective bias and omit measurement bias seems odd. In surveys based on voluntary responses, there should be some mention of human response bias (the ability to lie). If possible, the study should indicate the influence of a bias.

B. Reporting Responsibilities in Helping Readers Interpret the Statistical Conclusions:

Findings: Nothing very explicit on reporting responsibilities.

Recommendation: Add the following.

1. Statisticians have a professional responsibility to assist readers in interpreting the meaning of the statistical results and to use tables, graphs and summaries that present the data so that its meaning is not misrepresented.

C. Reporting Responsibilities involving Observational Studies:

Findings: There is nothing in the entire document about observational studies.

Recommendation: Add four paragraphs on observational studies.

1. Researchers must clearly identify whether the study was an experiment or an observational study. All too often "controlled studies", "clinical studies", "medical studies" and "government studies" are taken by unwitting readers to be experiments when in fact they are observational studies. Experiments in which subjects randomly assigned to the treatment group can and do quit based on their knowledge of the treatment should be treated as observational studies.
2. In reporting on observational associations, statisticians have a professional duty to note the following. (1) such associations are always subject to confounding, (2) these associations may be changed in both magnitude and in direction (Simpson's Paradox) after taking into account the influence of confounding factors and (3) it is impossible in observational studies to control for all confounding factors.
3. In reporting the results of observational studies, statisticians have a professional duty to present plausible potential confounders, to indicate how they might confound, to identify those that were not included in the study, to indicate why these were not included and to measure the strength of observed confounders. If the association between the variable of interest and the measured confounders is larger than the reported associations, then all the associations should be reported hierarchically with the most important predictor(s) first and then broken out by secondary predictors.
4. Statisticians have a responsibility to protest when they find that others, in summarizing their work, have ignored the influence of substantial confounding factors that were identified in the original report.

One example of professional irresponsibility in dealing with observational studies is found in "Health, United States, 1998 with Socioeconomic Status and Health Chartbook": a comprehensive 460 page publication of the U.S. Dept of Health and Human Services. In terms of its goals, this study is exemplary: unlike simple descriptive studies, this study seeks to explain health in terms of socioeconomic causes.

The first two outcomes analyzed in this book were low birth-weight and infant mortality. The authors found strong associations between these two outcomes and two predictors: income and education.

On page 4, "Low birth-weight and {higher} infant mortality were more common among children of less educated mothers than among children of more educated mothers; for example, in 1995, infants born to non-Hispanic white mothers with less than 12 years of education were 2.4 times as likely to die in the first year of life as those (infants) whose mothers had at least 16 years of education."

The study identified three plausible potential confounders of this observed association:

1. prenatal care during the first trimester
2. smoking during childbirth
3. pregnancy involving a teen-age mother.

The study presented measurements of the strength of association between confounders and predictors..

On page 4, "Mothers with more education are more likely to have received early prenatal care than less educated mothers; in 1996, mothers with 16 or more years of education were 40% more likely to obtain first-trimester prenatal care than those with fewer than 12 years of education. Mothers with less than 12 years of education were almost 10 times as likely to smoke during pregnancy as mothers with 16 or more years of education, in 1996." On page 58, they presented data showing a strong association (three times as likely) between being a teen-age mother and low-income (poverty). They even reported the association between teen-age pregnancy and the teen-age mother having been born to a teenager.

But the study did not analyze the marginal effect of education and income on the outcome variables (low birth-weight and infant mortality) once/after one had controlled for (taken into account) these three plausible confounders. The study failed to treat the problem in a regression-style format with income, education, prenatal care, smoking and teen-age mother as five independent predictors and with low birth-weight and infant mortality as the predicted outcomes..

The study did not even measure the strength of association between the outcome variables (low birth-weight and infant mortality) and the plausible confounders (prenatal care, smoking and teenage mothers). The study presented only qualitative comparisons on these associations.

On page 60, "infants whose mothers smoke during pregnancy are more likely to be born with low birth-weight". On page 58, "Children born to teenage mothers have higher infant mortality rates". On page 4, "These maternal risk factors [lack of early prenatal care and smoking] are likely contributors to the higher incidence of low birth-weight and infant mortality among the infants of less educated mothers." By neglecting to present the strength of these associations, the study implied (by omission) the following. The outcome variables (low birth-weight and infant mortality) are more highly associated with the reported predictors (income and education) than with any of the three measured confounders (prenatal care, smoking and teenage pregnancy). Of these five factors, the best predictors of low birth-weight and high infant-mortality are low income and inadequate education.

Finally, the study noted a strong association between the two outcome variables, (page 9)

"In 1995, mortality for low birth-weight infants was 22 times that for infants of normal weight or more." But by treating the outcomes as parallel rather than treating low birth-weight as an intervening or preceding factor, there was a reduced visibility for the paths by which the predictors influenced the outcomes.¹

By identifying three plausible confounding factors and by measuring their association with other predictors, these authors are to be praised for their professionalism. By neglecting to measure or analyze the influence of these confounders on the outcome variables and by treating the two outcome variables as parallel rather than sequential, these authors are professionally irresponsible.

¹ Davis, James A. (1985). *The Logic of the Causal Order*. Sage Publications #55.

The ASA Ethical Guidelines must include the reporting responsibilities of statisticians in dealing with observational studies! Omitting this kind of professional duty in reporting the results of observational studies is the biggest loophole in the current draft of the ASA Ethical Guidelines. Adding something of this sort could have a strong effect on the dissemination of observational statistics by the government and by the press.

In an observational study, if data is obtained on several plausible confounders, a statistician has a professional responsibility to indicate the strength of association between the confounders and the variable(s) of interest. In dealing with data obtained in an observational study, statisticians have a professional responsibility to present the resulting association after controlling for all those confounding influences that are found to be more important.

Including this one admonition could do more to upgrade the level of professionalism among statisticians than almost any other item currently listed in the proposed "Ethical Guidelines for Statistical Practice". Instead of limiting statistics to applied probability (variability due to chance), the guidelines would be endorsing a wider view of statistics: analyzing the sources of variation: indeterminate (chance) and determinate (e.g., bias and confounding factors). By remaining silent on the issue of confounding in observational studies, the ASA is limiting its influence to experimental studies where chance and bias are most important and confounding is almost never encountered. By explicitly taking on observational studies, the ASA will be moving into areas where confounding and bias are, in many cases, more important than chance in explaining the variation in the data.

If we are to live up to Past-President David Moore's JSM-98 theme, "Statistics – a Guide to Public Policy", we must include observational studies. Consider some common kinds of statistical associations found in the daily news: "Accident rates higher for car-phone users." "Death rates higher for those living in houses with higher radon levels." "Test scores higher among those attending Head Start." In each case, the study is observational. In each case, the primary issue is confounding. Is there some other factor that explains the outcome better than the variable presented? Is there some other confounding factor that actually explains the observed association? This is the area in which statistics gets a bad reputation (you can use statistics to prove anything). This is the area that the ethical guidelines must address if we are to improve our image. Addressing observational studies would also set a standard of professional conduct for those who communicate statistics (journalists, news commentators, etc.). Addressing observational studies would even influence how statistics is taught at the introductory level.

At the next JSM of the ASA in Baltimore, there is a special contributed session for the Section on Statistical Education entitled "Statistical Literacy and Observational Studies." John Bailar agreed to chair the session (based on the views he expressed in his recent AMSTAT article). Don Rubin (Harvard), Tom Wonnacutt (Ontario), Victor Cohn (former Washington Post science reporter) and I will be addressing the importance of observational studies and their relation to causality.

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I do hope the ASA Committee on Professional Ethics will think deeply on this matter. I know this comment is submitted late in the process. I know the Board of Directors has commented favorably on what you have done to date. But the role of observational studies within our profession is too big to be left unstated in these guidelines: guidelines that should include all statisticians – not just those who do experiments.

Having taught both Business Ethics and introductory statistics for many years, I do think this topic is critically important. I appreciate your consideration of this matter. If I can be of further assistance, I'd be happy to contribute in any way I could.

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