[Ethical Guidelines for Statistical Practice: Report of the Ad Hoc Committee on Professional Ethics]: Comment

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The American Statistician, Vol. 37, No. 1. (Feb., 1983), pp. 8-9.

Stable URL:
http://links.jstor.org/sici?sici=0003-1305%28198302%2937%3A1%3C8%3A%5BGFSPR%3E2.0.CO%3B2-E

The American Statistician is currently published by American Statistical Association.

I believe the primary justification for ASA's ethical guidelines is educational. As such, the functions of the guidelines will be to increase the general awareness concerning significant issues, to inform statisticians of competing values and incentives affecting ethical behavior, and to spread knowledge of desirable procedures. Although as written the guidelines are primarily aspirational, they present an opportunity and mechanisms for introducing more educational material of the type suggested by Jowell—in the procedures for extending the guidelines and for adding guidelines for specific areas of application, and in the establishment of the Ad Hoc Committee on Professional Ethics as a continuing committee of the Association. It is my hope that the committee will stimulate discussions of a variety of ethical issues in *The American Statistician* and elsewhere during the three-year trial period.

It is possible that the guidelines may also serve to assist individual statisticians in maintaining ethical standards in confronting employers, sponsors, or clients in specific instances. A statistician will be able to point to the guidelines as a considered statement of appropriate behavior that has been accepted by the profession.

REFERENCE

JOWELL, ROGER (1981), "A Professional Code for Statisticians?: Some Ethical and Technical Conflicts," invited paper, plenary session of the International Statistical Institute's 43rd Biennial Session, Buenos Aires, 1 December 1981.

Comment

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The guidelines should serve as an excellent starting point in the evolution of ethical standards within the statistical profession. In a profession that is known to many through Disraeli's phrase "there are lies, damn lies, and statistics," there should be no need to emphasize the importance of a set of guidelines. I became aware of this early in my medical consulting career when, in a cooperative venture to organize some data for presentation in a legal case, a physician suggested calculating the average survival time of a group of cancer patients using the data from dead patients only.

These guidelines provide norms of behavior for practicing statisticians and inform the statistical consumer of what to expect from a consulting relationship. In the context of professional training, the guidelines could be one of the foundations for a teaching program in ethics. The study of ethics should be a fundamental part of the professional training of a statistician, especially consulting statisticians. The committee has proposed collecting a series of case studies that could be used to sharpen the formation of ethical judgment just as biostatistical casebooks have been used in the development of consulting and statistical judgment. This is an excellent idea.

As one with more than 20 years' experience as a consulting statistician in a medical environment, perhaps I could be useful by discussing briefly some situations in which having ethical guidelines could influence behavior. In medical statistical consulting, one often becomes involved in the design of experiments, especially clinical trials. Levine and Lebacqz (1979) have identified "six ethical norms for research involving human subjects: (1) good research design, (2) balance of harm and benefit, (3) competence of the investigator(s), (4) informed consent, (5) equitable selection of subjects, and (6) compensation for research-related injury. While not all of these norms have been recognized as either compelling or applicable at all times, there is a growing consensus that adherence to each norm is a necessary condition for the ethical conduct of clinical trials." A simple ethical guideline concerned with research design is that a statistician should not propose any design involving human subjects if he is not willing to be a participant in the study, assuming that he met the conditions for entry. This is closely related to the statement of Atkins (1966): "If we would allow a member of our own family to enter the trial, it is ethical; if not, it is not ethical."

A consulting medical statistician may sometimes be asked to coauthor a publication concerning a project that he has had little connection with or, in fact, where he may disagree with some of the major conclusions drawn. For some medical research investigators, having a statistician as a coauthor provides an imprimatur and justifies the methodology used and the conclusions expressed. The experienced consulting statistician, Cuthbert Daniel, has warned of the dangers of "publishing *and* perishing." Statisticians should be cautious about permitting use of their names on medical research papers; my own guideline is to ask that my name be removed when I believe that the data do not support one or more of the major conclusions in the paper. Unfortunately, in these days of multi-authored papers, it is not always possible to implement this, since sometimes one's name is used as a coauthor or in an acknowledgment without prior approval. (The ethics of this practice is questionable.)

The guideline expressed in Statement II.C concerns the assumptions, methodology, and data processing

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used in statistical work. In my experience, equal or possibly even more importance should be given the data used in an inquiry. In clinical trials, one could perform analyses on one or all of the following groups of patients: all patients registered in the study; all patients registered who were eligible for the study; all registered and eligible patients who received the appropriate treatment and at least some adequate course(s) of the treatment; and all registered, eligible patients who received all of the appropriate courses of treatment as outlined in the protocol. In some clinical trials in which I have participated, the last-named subgroup of patients constituted less than 50 percent of the total patients registered. A scientific and ethical question arises when the relative merits of the treatments depend on which of the subgroups of patients received primary focus in the analysis. The most ethical approach is to analyze all of the various subgroups and, when conclusions differ among them, the study should be reported as inconclusive.

When writing up the results of some studies, a delicate problem arises in the emphasis to be given to reporting "known inaccuracies in the data." Giving too much detail about problems can supply critics with a basis for arguing that results must necessarily be invalid. Not divulging problems would be a cover-up. The only ethical approach is to report problems and inaccuracies, and to evaluate the effect that these might have had on the major conclusions of the study.

Any statement of guidelines developed within the ASA and approved by the Board of Directors could only apply to ASA members. However, the guidelines clearly should apply to all practicing statisticians and could be submitted to other statistical societies for their consideration. Legally, the guidelines can be used to delineate what is acceptable practice in the statistical profession. However, as written, the guidelines are more useful to a practitioner than if they had been written in the formal language of the law.

REFERENCES

LEVINE, R.J., and LEBACQZ, K. (1979), "Ethical Considerations in Clinical Trials," *Clinical Pharmacology and Therapeutics*, 25, 728–741.

ATKINS, H. (1966), "Conduct of a Controlled Clinical Trial," *British Medical Journal*, 2, 377–379.

Comment

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I feel strongly that an officially recognized set of ethical guidelines for statistical practice is urgently needed; the American Statistical Association is to be commended for taking the initiative in developing and sponsoring the guidelines. The statement that has been prepared serves this purpose well. The guidelines apply appropriately to the practice of statistics generally; they are not and should not be limited in application to statisticians, however defined, or to members of the Association. And while some may consider these moral precepts clear and obvious, they are not necessarily so to everyone, and all statistical practitioners, but especially those first entering the field, need to be reminded of the ethical standards the profession expects of them.

No consideration should be given at this time to establishing sanctions for violators or setting up enforcement procedures, and the time may never come when we would want to do that. The guidelines will have their effect through moral suasion, and this should be enough. While I do not believe there would be any direct legal implications, surely the courts would take the Association's guidelines into account in considering any allegations of fraudulent statistical behavior.

There is one particular change I would urge be made in the document. The statistical practitioner does not need all the information about the charge to the Committee on Ethics. Such material detracts from the statement and should be deleted. All the practitioner needs to know in this regard is that there is a Committee on Ethics, that it will reconsider the guidelines for changes from time to time and after three years will determine whether to recommend that they be made permanent, and that any comments about the guidelines should be sent to the Committee on Professional Ethics by a specific date.

I hope the guidelines will get widespread distribution. Federal agencies such as ours will find the guidelines a valuable supplement to such publications as the *Statistical Policy Handbook* of the Office of Federal Statistical Policy and Standards. We shall see to it that all of our statisticians and analysts have a copy of the guidelines to use along with such sources as our *National Center for Health Statistics Staff Manual on Confidentiality*. The guidelines will also be invaluable in the universities and in the private sector.

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