
American College of Epidemiology Ethics Guidelines: Foundations and Dissemination*

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ABSTRACT: *Epidemiology is a core science of public health, focusing on research related to the distribution and determinants of both positive and adverse health states and events and on application of knowledge gained to improve public health. The American College of Epidemiology (ACE) is a professional organization devoted to the professional practice of epidemiology. As part of that commitment, and in response to concerns for more explicit attention to core values and duties of epidemiologists in light of emerging issues and increased scrutiny of epidemiology, the College developed, adopted, and published a set of Ethics Guidelines. The structure of the ACE ethics guidelines is in four parts: (1) a brief statement of core values and duties of epidemiologists, coupled with the virtues important to professional practice; (2) concise statements of key duties and obligations; (3) exposition of the duties and obligations with more applications; and (4) a brief summary and conclusion. The Guidelines have been published on the ACE website and in the official College journal Annals of Epidemiology. The guidelines contain (and maintain) core elements that define the discipline of epidemiology and its fundamental duties, but they are also intended to be dynamic and evolving, responsive to a changing professional and social environment.*

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Introduction

A common definition of epidemiology is “the study of the distribution and determinants of health-related states or events in specified populations, and the application of this study to control of health problems.”¹ Epidemiology is “the ‘glue’ that holds public health’s many professions together;” the “mother science of public health.”²

Though its roots reach back more than two hundred years, perhaps even as far back as the Hippocratic school, epidemiology really emerges as a distinctive discipline in the post-World War II era.³ In that time its domain has enlarged to include a broad array of health outcomes and settings beyond public health, including clinical medicine and outcomes research. A similar historical development can be argued for bioethics, with roots in the ancient period, including the Hippocratic school, important foundations laid in the 18th century, but significant growth as a distinctive discipline over the last 50 years and only recent engagement with public health and other disciplines outside clinical medicine.⁴ All the more surprising, therefore, that there has been relatively little ongoing dialogue between the two disciplines until recently. (Note that the term *bioethics* has been used with regard to issues in environmental and ecological sciences and human survival as well as in clinical medicine and the health sciences.⁵ In this paper the term refers primarily to the latter tradition.)

Given the nature and scope of their research and the questions and challenges they have encountered, epidemiologists have turned their attention to ethics though few have significant training in ethical concepts and methods. In this respect they are not unlike other science professionals. A 1980 survey revealed “little attention and only minimal resources have been directed toward professional ethics” among AAAS constituent societies.⁶ More than a decade later a National Academy of Science report entitled *Responsible Science* found that ethical issues receive little attention in professional societies and called for greater efforts to enhance ethical sensitivity and competence.⁶⁻⁷

It is against that background that the American College of Epidemiology (ACE) turned its attention to the development of a set of ethical guidelines for epidemiologists. Since ACE first began to study the need for such guidelines in 1991, interest in research ethics and related issues has increased, especially in the aftermath of President Clinton’s apology concerning the Tuskegee Syphilis Experiment and the report by the President’s Advisory Committee on Human Radiation Experiments,⁸ though the latter events are indications of long standing problems.⁹⁻¹¹ Recently, there have been debates concerning military treatment and prevention regimens without consent;¹²⁻¹³ the ethics of placebo controlled trials in studies of schizophrenia¹⁴⁻¹⁷ and in prevention of vertical HIV transmission from mother to infant,¹⁸⁻²⁰ and allegations of misconduct regarding data collection, analysis, and ownership.²¹⁻²²

Additional impetus for studying ethical issues in epidemiologic research has occurred largely due to actions by the Department of Health and Human Services (DHHS). On June 6, 2000, DHHS created the Office for Human Research Protections (OHRP), replacing the National Institutes of Health (NIH) Office for Protection from

Research Risks (OPRR). At the same time, NIH propagated new guidelines concerning financial conflicts of interest and certification of training in the ethical conduct of research involving human subjects. The Office of Research Integrity of DHHS has issued a broader set of proposed guidelines concerning training in research ethics that would address issues from data acquisition through publication, and including collaborations and mentoring, in addition to traditional human subjects concerns.

The commitment of the American College of Epidemiology (ACE) to the development of professional ethics guidelines has been longstanding. A previous publication²³ addressed the background, motivation, and process for the development of the new Guidelines. Briefly, the ACE was formed in the early 1980's as an organization committed to epidemiology as a profession. The College distinguishes between members and fellows, the latter status being determined by "significant and sustained contributions to the profession through research or through a leadership role in the practice of epidemiology." ACE is one of several epidemiology societies and, with about 800 members and fellows, by no means the largest. Other groups include the American Epidemiological Society, the oldest in the U.S. dating from 1927, the Epidemiology Section of the American Public Health Association dating from 1929, the International Epidemiology Association, the Industrial Epidemiology Forum, the International Society for Environmental Epidemiology (ISEE), and the largest independent group, the Society for Epidemiologic Research (SER).

Although examples of ethics guidelines already existed, it seemed appropriate for ACE, as the only organization specifically devoted to the professional practice of epidemiology, to have its own set of guidelines. The ACE ethics guidelines were written in part to stimulate ongoing discussion of ethics in the profession in light of emerging issues and increased scrutiny of epidemiology as well as other health related disciplines, fully recognizing that everyday issues and problems, rather than guidelines per se, are what primarily drive an interest in ethics.

Process: Creating the ACE Guidelines

It took about four years from the initial decision to move forward with the guidelines to publishing them in the ACE journal, the *Annals of Epidemiology* (Nov 2000).²⁴ The process began with a survey of ACE Members and Fellows in 1996 concerning the perceived need, uses, and content of ethics guidelines, followed the next year by formation of a writing group within ACE's Ethics and Standards of Practice Committee (ESOP). Draft guidelines were submitted to the full ACE ESOP Committee in summer 1998; a revised draft went to the ACE Board of Directors in September 1998; and a newly revised draft was provided to ACE membership the following month for their responses. Updates and revisions based on membership participation occupied almost a year, until summer 1999. Meanwhile, a paper on the background and rationale for the guidelines was published in the ACE journal.²³ Approval of a final version by ACE ESOP and then the ACE Board of directors took place in fall 1999. The approved guidelines were placed on the ACE Website URL in January 2000, followed by publication with an accompanying Editorial²⁵ in the November 2000 *Annals*.²⁴

Structure of the ACE Ethics Guidelines

The basic structure of the ACE ethics guidelines is in four parts: (1) a brief statement of core values and duties of epidemiologists, coupled with the virtues important to professional practice; (2) concise statements of key duties and obligations; (3) exposition of the duties and obligations with more applications; and (4) a brief summary and conclusion. The total length of the ethics guidelines document is about 25 double-spaced pages.

1. Core Values and Duties

The first section of the ACE ethics guidelines describes the core values of the discipline and the obligations to various parties that it recognizes. The core values are expressed in terms of the common definition of epidemiology cited above as the pursuit of knowledge concerning the distribution and determinants of health and disease in populations, enlarged by the value of improving the public's health through the application of scientific knowledge. This definition also describes the scope and practice of the profession within the context of more general bioethical principles.

The core duties are described in terms of obligations to various parties including research participants, society, sponsors, employers, and professional colleagues. These may seem obvious, but there is considerable debate within the discipline about the extent to which epidemiologists as epidemiologists should be involved as advocates or policy makers in the practice of public health or should remain insulated from such activities in order to safeguard the objectivity of science. In the latter view, epidemiologic research is the only domain of professional epidemiologic practice. In contrast to this position, the ACE Guidelines outline a broader perspective of the professional obligations of epidemiologists.

The initial section also includes a brief account of virtues, which were added for depth and to remind the professional practitioner that ethics is more than applying guidelines to cases or obeying rules; ethics is also about character and motivation with clear application to mentoring. Virtues can be defined as traits of character that dispose professional epidemiologists to act in ways that contribute to achieving those goods that are internal to the practice of epidemiology, which includes both the search for and acquisition of scientific knowledge as well as the application of that knowledge.²⁶ Some virtues mentioned in the document are: benevolence, honesty, prudence, excellence, and integrity. Others are humility, justice, patience, and industry.

2. Key Duties and Obligations

Part 2, which may be considered the heart of the ACE Ethics Guidelines, provides a very brief description of the duties and obligations of professional epidemiologists, in addition to other selected key issues. These duties, borrowed in large part from earlier guidelines, especially from the Industrial Epidemiology Forum,²⁷ are further elaborated in Part 3. There are eleven headings for duties described in this section, each given one or two sentences. The eleven headings are:

1. Professional Role of Epidemiologists,
2. Minimizing Risks and Protecting the Welfare of Research Participants,
3. Providing Benefits,
4. Ensuring an Equitable Distribution of Risks and Benefits,
5. Protecting Confidentiality and Privacy,
6. Obtaining Informed Consent,
7. Submitting Proposed Studies for Ethical Review,
8. Maintaining Public Trust,
9. Avoiding Conflicts of Interest and Partiality,
10. Communicating Ethical Requirements and Confronting Unacceptable Conduct, and
11. Obligations to Communities.

These are the key duties and obligations of professional epidemiologists, which are augmented by several concerns. In some instances, two or three subheadings are also provided, each with a sentence or two of text. For example, paragraph 2.8 on Maintaining Public Trust reads, “To promote and preserve public trust, epidemiologists should adhere to the highest ethical and scientific standards and follow relevant laws and regulations concerning the conduct of these activities, including the protection of human research participants and confidentiality protections.” Part 3 then elaborates upon this very basic statement. There are then two additional subheadings: 2.8.1: Adhering to the highest scientific standards, and 2.8.2: Involving community representatives in research.

Examples of other duties include Obligations to Communities (2.11), which reads, “Epidemiologists should meet their obligations to communities by undertaking public health research and practice activities that address health problems including questions concerning the utilization of health care resources, and by reporting results in an appropriate fashion.” There are then additional subheadings: 2.11.1: Reporting results, 2.11.2: Public health advocacy, and 2.11.3: Respecting cultural diversity. These examples illustrate the user-friendly structure, accessibility, and directness of the ACE ethics guidelines; straightforward expressions of key obligations and concerns with no discussion or clarification.

3. Exposition of Duties

In Part 3, the concise statements of duties are discussed and clarified with a brief exposition. This section constitutes the bulk of the text of the guidelines. Thus, Part 3 is the first step taken towards applying these more general considerations to the professional practice of the discipline. It remains, nevertheless, at a level of generality “above” that of case studies, but with further specification of the obligations than the mere listing of obligations and duties described in Part 2.

4. Summary and Conclusion

Part 4 concludes the guidelines. Here the reader finds caveats and a plea for application and further consideration. Indeed, framers of these guidelines were

persistently concerned about the possibility that the document would end up “on a shelf” ignored and underutilized. They were convinced that awareness of the guidelines, participation in their formulation, and continued dissemination and implementation were key to their acceptability and applicability.

Dissemination and Use

As noted, the primary means of dissemination of the ACE Ethics Guidelines has been publication on the ACE Website (www.acepidemiology.org) and in the society journal, *Annals of Epidemiology*.²⁴ In addition, the guidelines have been featured at the ACE Annual Meeting in roundtables, papers, and the annual debate. The ACE ESOP Committee intends to stimulate submission of papers and case studies related to ethical issues in epidemiology, and hopes to make the Guidelines a common point of reference for such discussions, both in print and in practice. Representatives of schools of public health were informed of the guidelines at a May 2000 workshop on “Teaching Ethics in Schools of Public Health” sponsored by the Association of Schools of Public Health, with support from the U.S. Health Resources and Services Administration. Outreach to the broader scientific community has begun with a presentation at the AAAS Conference on Research Integrity,⁶ and we hope to present the guidelines in a suitable forum at a future annual meeting of the principal bioethics organization, the American Society for Bioethics and Humanities.

The intention is, first, to inform the ACE membership and the broader epidemiological and public health community of the guidelines’ existence and to encourage discussion of their content and applicability to real-life professional decisions and scenarios (case studies). Unfortunately, epidemiologists are not well versed in ethics. Interest tends to be episodic, reactive to crises or adverse events, such as the abuses noted earlier or the criticism of questionable research publications. It remains to be seen whether the new federal guidelines from DHHS concerning training in research ethics are forthcoming, and what they will mean for the quality of ethics education, continuity in reflection on current and emerging ethical issues, and basic competence in ethical reasoning. It is our hope that the Guidelines can provide a focal point for continuing attention to and discussion of ethical issues in the field of epidemiology. Though the guidelines contain (and maintain) core elements that define our discipline and its fundamental duties, they are also intended to be dynamic and evolving, responsive to a changing professional and social environment. The ACE ESOP committee is committed to developing processes for dissemination and education to achieve those ends.

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REFERENCES

1. Last, J.M. (1995) *A Dictionary of Epidemiology*, 3 ed., Oxford University Press, New York.
2. Institute of Medicine, Committee for the Study of the Future of Public Health (1988) *The Future of Public Health*, National Academy Press, Washington, DC.
3. Susser, M. (1985) Epidemiology in the United States after World War II: The revolution of technique, *Epidemiologic Reviews* 7: 147-177.
4. Wolf, S.M. (1994) Shifting Paradigms in Bioethics and Health Law: The Rise of a New Pragmatism, *American Journal of Law & Medicine* 20: 395-415.
5. Callahan D. (1995) Bioethics, in: Reich, W.T., ed. *Encyclopedia of Bioethics*, Rev. Ed. MacMillan, New York, Vol 1, pp. 247-256.
6. DuMez, E. (2000) The role and activities of scientific societies in promoting research integrity, *Professional Ethics Report* 8: 1,7-8.
7. Panel on Scientific Responsibility and the Conduct of Research, Committee on Science, Engineering, and Public Policy, National Academy of Sciences, National Academy of Engineering, Institute of Medicine. (1992) *Responsible science: ensuring the integrity of the research process*, National Academy Press, Washington, D.C.
8. President's Advisory Committee on Human Radiation Experiments. (1996) *The Human Radiation Experiments: Final Report of the President's Advisory Committee*, Oxford University Press, New York.
9. Beecher, H.K. (1966) Ethics and Clinical Research, *The New England Journal of Medicine* 274: 1354-1360.
10. Brandt, A.M. (1978) Racism and Research: The Case of the Tuskegee Syphilis Study, *Hastings Center Report* 8: 21-29.
11. Katz, J. (1987) The Regulation of Human Experimentation in the United States – A Personal Odyssey, *IRB* 9: 1-6.
12. Annas, G.J. (1992) Changing the consent rules for Desert Storm, *New England Journal of Medicine* 326: 770_3.
13. Grodin, M.A. and Annas, G.J. (1996) Legacies of Nuremberg. Medical ethics and human rights. *JAMA* 276: 1682_3.
14. Carpenter, W., Jr. (1997) The Risk of Medication-free Research, *Schizophrenia Bulletin* 23: 11-18.
15. Fins, J.J. and Miller, F.G. (1997) The call of the sirens: Navigating the ethics of medication-free research in schizophrenia, *Archives of General Psychiatry* 54: 415-6.
16. Lehrman, N.S. and Sharav, V.H. (1997) Ethical Problems in Psychiatric Research, *Journal of Mental Health Administration* 24: 227-250.
17. Shore, D. (1996) Ethical Principles and Informed Consent: An NIMH Perspective, *Psychopharmacology Bulletin* 32: 7-10.
18. Angell, M. (1997) The Ethics of Clinical Trials in the Third World, *New England Journal of Medicine* 337: 847-849.
19. Lurie, P. and Wolfe, S.M. (1997) Unethical Trials of Intervention to Reduce Perinatal Transmission of the Human Immunodeficiency Virus in Developing Countries, *New England Journal of Medicine* 337: 853-856.
20. Varmus, H. and Satcher, D. (1997) Ethical Complexities of Conducting Research in Developing Countries, *New England Journal of Medicine* 337: 1003-1005.
21. Fisher, B., Costantino, J.P., Redmond, C.K., Fisher, E.R., Wickerbaum, D.L., and Cronin, W.M. (1994) Endometrial Cancer in Tamoxifen-Treated Breast Cancer Patients: Findings From the

- National Surgical Adjuvant Breast and Bowel Project (NSABP) B-14, *Journal of the National Cancer Institute* **86**: 527-537.
22. Youngner, J.S. (1998) The Scientific Misconduct Process: A Scientist's View From the Inside, *JAMA* **279**: 62-64.
 23. Weed, D.L. and Coughlin, S.S. (1999) New ethics guidelines for epidemiology: Background and rationale, *Annals of Epidemiology* **9**: 277-280.
 24. American College of Epidemiology. (2000) Ethics Guidelines, *Annals of Epidemiology* **10**: 487-497.
 25. McKeown, R.E. (2000) American College of Epidemiology Ethics Guidelines: Filling a Critical Gap in the Profession, *Annals of Epidemiology* **10**: 485-486.
 26. Weed, D.L. and McKeown, R.E. (1998) Epidemiology and Virtue Ethics, *International Journal of Epidemiology* **27**: 343-348.
 27. Beauchamp, T.L., Cook, R.R., Fayerweather, W.E., Raabe, G.K., Thar, W.E., Cowles, S.R. and Spivey, G.H. (1991) Ethical Guidelines for Epidemiologists, *Journal of Clinical Epidemiology* **44**: 151S-169S.