

## ETHICAL ISSUES IN EPIDEMIOLOGY

University of Miami Department of Epidemiology and Public Health

**Course, meetings:** EPH 525-GY; 3 credits; Calder Library 046; Wednesdays 2:30-5

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### Introduction

This course will identify and review leading ethical issues in public health practice and epidemiological research.

For some time now, epidemiologists have recognized that their work raises a number of interesting and important ethical issues. Some of these issues will be familiar to those with an acquaintance with, or background in, bioethics and research ethics: informed consent, confidentiality, patient-subject rights, conflict of interest, and so forth. Nevertheless, epidemiology often offers – or, rather, demands – a different or broader set of problems under these headings. For instance, what are a researcher's obligations in terms of informed or valid consent in cultures where family or village leaders are by custom expected to provide "consent by proxy" for kin or community? Other cultural differences pose an ensemble of interesting challenges for epidemiologists.

Other issues of concern to epidemiologists are rarely addressed in general bioethics. These include, but are by no means limited to, the notion of "ethical imperialism," the danger of social and ethnic stigma arising from epidemiological findings, and the tensions surrounding decisions whether and to what extent to reveal public health risks to study communities.

Fortunately, there is an emerging literature that focuses on these and other issues.

The course has the following overarching goals:

- To help students identify ethical issues, problems and conflicts in epidemiology and public health.
- To examine the ways in which ethical issues in epidemiology are either like or unlike ethical issues in other health sciences.
- To provide a decision procedure, including an evaluation metric, for approaching ethical issues, problems and conflicts.
- To make plain epistemological-ethical linkages, i.e., the connections between sound science and (ethically and socially) responsible science.

We will make use of case studies to illuminate issues. Students are strongly encouraged to submit cases for class discussion.

### **1. Ethical Principles, Rules and Ideals**

This component will provide an introduction to two leading approaches to applied bioethics, namely the Principlism of Beauchamp and Childress and Gert's moral rule-and-ideal approach. We will include a brief review of the ethical theories of utilitarianism and deontology.

### **2. Duties, Responsibilities and Practice Standards**

What are the various credible goals for epidemiologists? This section will evaluate the relation between science and ethics, and the scientific, social and financial motivations of researchers in academic, government and industrial epidemiology. The potentially conflicting roles of epidemiologists and the following entities will be reviewed: colleagues and other researchers, other individuals, communities, societies, businesses, universities, governments, health policy institutions and others.

### **3. Valid Consent and Refusal**

One of the most difficult problems facing epidemiologists is that of valid consent to participate as a subject in research. This course component will address the following points and issues:

- Minimal criteria for valid consent.
- The nature and context of valid refusal.
- Embedded criteria addressing questions such as the competence requirement in psychological, psychiatric, drug use and like studies; the level of detail that is minimally required for informing potential subjects about risks; whether monetary and other inducements constitute coercion; etc. Relatedly,
- Special problems that attach to informed consent forms and their readability; and the relation of readability to the criterion of "adequate information."
- Circumstances under which informed consent is or might not be necessary.
- The role, function and constitution of institutional review boards or their analogues.
- The potential need for community consent.

### **4. Privacy and Confidentiality**

People expect that details about their personal lives will not be made public, and that they have a right not to have intruders learn about those details inappropriately. As information gathering and storage techniques progress, however, these presumptions are increasingly under strain. The following points and issues will be reviewed:

- Privacy and the degree to which it must be protected; and circumstances under which privacy may be violated.

- Confidentiality and minimal criteria for keeping linked records from publication or other disclosure. Relatedly,
- Standards for database security and access, addressing criteria for legitimate demands for access.
- The relatively free use of unlinked information (where data and a person's identity are decoupled); the relation of this to contexts in which valid consent is presumed unnecessary.
- The need for explicit and rigorous justifications for use or maintenance of any linked records.

## **5. Risks, Harms and Wrongs**

The distinction among risks, harms and wrongs is an important one, and epidemiologists should be given standards for evaluating the following:

- The notion of "acceptable risk."
- What constitutes a harm, and how this may vary by culture, community or even individual.
- What constitutes a wrong.
- The need to eliminate or minimize – and steps for eliminating or minimizing – risks, harms and wrongs.
- What constitutes a risk, harm or wrong to a group or community, including the problem of research-related stigma.
- Relationship between risks, harms and wrongs and their inclusion in informed consent documents and processes. Relatedly,
- The need for and role of truth telling by observers and experimenters.
- Role of disease prevention and issues in mass screening.

## **6. Sponsorship and Conflict of Interest**

The question of professional allegiance finds its most difficult context in the arena of research sponsorship. The following topics will be addressed:

- Criteria for identifying (in)appropriate sponsorship.
- Obligations, and limits to obligations, to sponsors and employers.
- What constitutes a conflict of interest.
- The need to avoid the appearance of a conflict of interest.
- Contexts in which potential or real conflicts should be revealed to subjects and others.

## **7. Communication, Publication, Intellectual Property and Education**

Unpublished research cannot easily advance the primary goal of improving public health. But publication of scientific results is sometimes problematical. The following considerations will be evaluated:

- Duties to communicate, and problems in communicating, study results to subjects, communities, sponsors, etc.
- Difficulties in accurate and balanced communication of risks, harms and wrongs.
- Obligation to publish study results. Effects of publication. Responsibility to colleagues and "science."
- Issues in data management.
- Issues in publication and authorship, including overpublication and redundant publication.
- "Ownership" of results, as by a corporate sponsor; and nature of intellectual property in epidemiology.
- Need to educate government officials, communities, subjects and others; and standards for education, including topics to be covered, complexity and accessibility of media. Role of popular news media.

## **8. Advocacy and Intercultural Conflict**

While the primary epidemiological goal of improving public health is straightforward enough, less clear is the appropriate stance researchers should take in attempts to apply their findings. That is,

- Under what contexts, if any, should epidemiologists become advocates for a particular health policy?
- How should epidemiologists *qua* advocates address issues of cultural difference? What if sincere health policy advocacy conflicts with values prevalent in a study community?
- To what extent is it realistic and proper to demand of researchers a measure of sympathy and respect for values and customs, for instance, that they find objectionable? Contrarily, is it appropriate to use study results to advocate change in values or customs?

## **9. Conclusion**

The ethical theories and standards introduced at the outset will be revisited with the goal of achieving a synthesis that describes appropriate goals and techniques in epidemiology. In other words, we will obtain closure on the preceding topics by associating scientific decisions with ethical decisions, and showing how each informs and shapes the other. It will be suggested that one cannot do good epidemiology without good ethics, and, given public health as the goal, vice versa.

## 10. Assignments and Grades

The course will be conducted in the manner of a seminar. Students are expected to be prepared for and to participate in class discussions. This will include maintaining familiarity with current events in science and science policy (including medicine and public health). This familiarity must be deeper than that conferred by television. It is strongly recommended that students subscribe to *The New York Times* for this purpose. It is assumed that students regularly consult the *American Journal of Public Health* and related professional journals.

There are two other formal assignments:

- Students will make a class presentation on a topic of their choice in ethics and epidemiology. While wide latitude will be given in choice of topics, students should confer with the instructor before beginning work on a particular problem. Students will make a 10-15 minute presentation and field questions from classmates and the instructor. Additionally, oral presentations must be accompanied by a typed abstract of no more than 500 words. As appropriate, a case study should be used to illustrate the points being made.
- Students will write a final paper on a topic of their choice in ethics and epidemiology. Here, too, topics should be discussed with the instructor. (Note that some class time will be devoted to discussions of appropriate topics for the presentation and paper.) As appropriate, a case study should be used to illustrate the points being made. The papers must be typed or typeset using double spacing and a standard text, annotation and bibliographic style of the writer's choice. Provide a cover page with salient information; otherwise, do not devote any resources to fancy presentations, folders, etc.

Assignment	% of final grade
Class participation	25
Oral presentation and abstract	25
Final paper	50

## 11. Texts

Coughlin, S.S., ed. *Ethics in Epidemiology and Clinical Research: Annotated Readings*. Newton, Mass.: Epidemiology Resources Inc., 1995

Coughlin, SS, Beauchamp TL, eds, *Ethics and Epidemiology*, New York: Oxford University Press, 1996

Plus various articles as assigned or distributed.