

AMERICAN COLLEGE OF EPIDEMIOLOGY ETHICS GUIDELINES

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INTRODUCTION

This document, which is indebted to past efforts to develop ethics guidelines for epidemiologists and to the commentary that has accompanied such efforts, provides the first set of ethics guidelines for the American College of Epidemiology. These guidelines have been developed primarily for the North American context and thus do not supercede international guidelines nor those developed for a particular region. The background to and rationale for this effort, including the purpose and nature of ethics guidelines in epidemiology, have been discussed elsewhere.

Ethics guidelines are not static documents. They ought to reflect the changing role of epidemiologists in society. In addition, these ethics guidelines do not provide a step-by-step method for reaching decisions about ethical issues that arise in epidemiologic research and practice. Rather, they describe the core values, duties (obligations), and virtues that should serve as the basis for the thoughtful reflection and sound judgment that such decisions call for.

This document is divided into four parts. The first part provides an overview of widely held core values, duties, and virtues in epidemiology and provides concise definitions of these concepts. The second part provides general statements of the obligations that epidemiologists have to various parties. The third part is a more detailed discussion of these guidelines. The fourth part provides a summary, outlines some remaining issues, and draws some conclusions.

PART I - CORE VALUES, DUTIES, AND VIRTUES IN EPIDEMIOLOGY

In this section we define and discuss core values, scientific and ethical precepts widely held within the profession, as well as duties and virtues in epidemiology. We also relate core values to the mission of epidemiology: the pursuit of knowledge through scientific research and the improvement of public health through the application of that knowledge.

1.1 Definition and discussion of core values

Like other scientists, epidemiologists uphold values of free inquiry and the pursuit of knowledge. The goal of science, after all, is to explain and to predict natural phenomena.

Epidemiologists not only pursue knowledge about the distribution and determinants of health and disease in populations, but also uphold the value of improving the public's health through the application of scientific knowledge.

These core values underlie the mission and purpose of epidemiology. Here we are concerned with core values that are internal to the profession of epidemiology. As such, they are more restricted in scope than general ethical principles such as beneficence (which relates to the balancing of risks and benefits and the promotion of the common welfare). On the other hand, core values in epidemiology are more general (and more basic) than ethical rules and norms within the profession such as the need to obtain the informed consent of research participants. [Here and elsewhere in this document the term “research participants” is used instead of “human subjects” which is sometimes regarded as paternalistic; nevertheless, the term “participants” may incorrectly imply that there has been valid consent to participate which is not always feasible in epidemiologic studies.] Some differences of opinion about core values do exist, and core values may change or evolve over time. Core values and ethical rules about which it is possible to build a consensus are reflected in this document.

1.2 Definition and discussion of duties and obligations

Core values, including the above-described basic scientific and ethical values within epidemiology, can be distinguished from duties (obligations). Ethical duties are more general than ethical rules. Duties are those obligations epidemiologists have to various parties such as research participants, society, sponsors, employers, and professional colleagues. Thus, for example, the duties that epidemiologists have to rigorously protect the confidentiality of private and personally identifiable information are more general than the specific confidentiality safeguards (ethical rules) that epidemiologists ought to employ. Most of the remainder of this document (Parts II and III) relates to the ethical duties and professional responsibilities of epidemiologists. Also discussed are specific ethical rules that protect the welfare and rights of research participants and help to ensure that the potential benefits of epidemiologic research and practice are maximized and distributed in an equitable fashion.

1.3 Definition and discussion of virtues

Duties, or obligations, can be distinguished from virtues. The latter are motivational factors grounded in professional character (for instance, the need to treat colleagues and other parties with respect and courtesy). Virtues are character traits that dispose us to act in ways that achieve good things, whereas duties and obligations help define how and for whom we should act. An example is the virtue of benevolence. Among other things, it disposes us to provide benefits to socioeconomically disadvantaged persons in society. Other examples include honesty, prudence, excellence, and integrity, which can be cultivated by actions and experience. A distinction should be made between societal virtues and professional virtues. In this document, we are concerned with the latter. Professional virtues are those traits of character that dispose us to act in ways that contribute to achieving the good that is internal to the practice of epidemiology. The time that senior epidemiologists spend mentoring graduate students and junior investigators in the proper design and conduct of epidemiologic studies is an example of virtuous conduct in the profession. Virtues are complementary moral considerations to duties. For example, the appropriate attribution of scientific ideas in publications is consistent both with the virtuous conduct of epidemiology and with an ethical rule or professional obligation. Virtues do not replace ethical rules such as those specified in Parts II and III of this document. Rather, an account of professional ethics in epidemiology is more complete if virtuous traits of character are identified such as humility, fidelity, justice, patience, industry, and veracity.

PART II - ETHICS GUIDELINES

This section provides a concise set of ethics guidelines for epidemiologists. Later in this document, in Part III, we describe and clarify these duties of epidemiologists.

2.1. The Professional Role of Epidemiologists

The profession of epidemiology has as its primary roles the design and conduct of scientific research and the public health application of scientific knowledge. This includes the reporting of results to the scientific community, to research participants, and to society; and the

maintenance, enhancement, and promotion of health in communities. Other professional roles in epidemiology include teaching, consulting, and administration.

2.2. Minimizing Risks and Protecting the Welfare of Research Participants

Epidemiologists have ethical and professional obligations to minimize risks and to avoid causing harm to research participants and to society. The risks of non-research public health practice activities also should be minimized.

2.3. Providing Benefits

Epidemiologists should ensure that the potential benefits of studies to research participants and to society are maximized by, for example, communicating results in a timely fashion. Steps should also be taken to maximize the potential benefits of public health practice activities.

2.4. Ensuring an Equitable Distribution of Risks and Benefits

Epidemiologists should ensure that the potential benefits and burdens of epidemiologic research and public health practice activities are distributed in an equitable fashion.

2.5. Protecting Confidentiality and Privacy

Epidemiologists should take appropriate measures to protect the privacy of individuals and to keep confidential all information about individual research participants during and after a study. This duty also applies to personal information about individuals in public health practice activities.

2.6. Obtaining the Informed Consent of Participants

Epidemiologists should obtain the prior informed consent of research participants (with exceptions noted below in Section 2.6.3), in part by disclosing those facts and any information that patients or other individuals usually consider important in deciding whether or not to participate in the research.

2.6.1 Elements of informed consent

Information should be provided about the purposes of the study, the sponsors, the investigators, the scientific methods and procedures, any anticipated risks and benefits, any

anticipated inconveniences or discomfort, and the individual's right to refuse participation or to withdraw from the research at any time without repercussions.

2.6.2 Avoidance of manipulation or coercion

Research participants must voluntarily consent to the research without coercion, manipulation, or undue incentives for participation.

2.6.3 Conditions under which informed consent requirements may be waived

Requirements to obtain the informed consent of research participants may be waived in certain circumstances, such as when it is not feasible to obtain the informed consent of research participants, in some studies involving the linkage of large databases routinely collected for other purposes, and in studies involving only minimal risks. In such circumstances, research participants generally need protection in other ways, such as through confidentiality safeguards and appropriate review by an independent research ethics committee (often referred to as institutional review boards in the United States or as ethics review boards in Canada). Informed consent requirements may also be waived when epidemiologists investigate disease outbreaks, evaluate programs, and conduct routine disease surveillance as part of public health practice activities.

2.7. Submitting Proposed Studies For Ethical Review

Epidemiologists should submit research protocols for review by an independent ethics committee. An exception may be justified when epidemiologists investigate outbreaks of acute communicable diseases, evaluate programs, and conduct routine disease surveillance as part of public health practice activities.

2.8. Maintaining Public Trust

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.

2.8.1 Adhering to the highest scientific standards

Adhering to the highest scientific standards includes choosing an appropriate study design for the scientific hypothesis or question to be answered; writing a clear and complete protocol for the study; using proper procedures for the collection, transmission, storage, and analysis of data; making appropriate interpretations from the data analyses; and writing up and disseminating the results of the study in a manner consistent with accepted procedures for scientific publication.

2.8.2 Involving community representatives in research

To the extent possible and whenever appropriate, epidemiologists should also involve community representatives in the planning and conduct of the research such as through community advisory boards.

2.9. Avoiding Conflicts of Interest and Partiality

Epidemiologists should avoid conflicts of interest and be objective. They should maintain honesty and impartiality in the design, conduct, interpretation, and reporting of research.

2.10. Communicating Ethical Requirements to Colleagues, Employers, and Sponsors and Confronting Unacceptable Conduct

Epidemiologists, as professionals, should communicate to their students, peers, employers, and sponsors the ethical requirements of scientific research and its application in professional practice.

2.10.1 Communicating ethical requirements

Epidemiologists should provide training and education in ethics to students of the discipline as well as to practicing scientists. They should demonstrate appropriate ethical conduct to colleagues and students by example.

2.10.2 Confronting unacceptable conduct

Epidemiologists should confront unacceptable conduct such as scientific misconduct, even though confronting it can be difficult in practice. Steps should be taken to provide

protections for persons who confront or allege unacceptable conduct. The rights of the accused to due process should also be respected.

2.11. Obligations to Communities

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.

2.11.1 Reporting results

All research findings and other information important to public health should be communicated in a timely, understandable, and responsible manner so that the widest possible community stands to benefit.

2.11.2 Public health advocacy

In confronting public health problems, epidemiologists sometimes act as advocates on behalf of members of affected communities. Advocacy should not impair scientific objectivity.

2.11.3 Respecting cultural diversity

Epidemiologists should respect cultural diversity in carrying out research and practice activities and in communicating with community members.

PART III - DISCUSSION AND CLARIFICATION OF GUIDELINES

In this section, a more detailed discussion of the ethics guidelines appearing in Part II above is provided. The professional duties and obligations are clarified along with key epidemiologic virtues.

3.1. The Professional Role of Epidemiologists

Epidemiology is the study of the distribution and determinants of health and disease in human populations. Collectively, individuals who practice epidemiology constitute the professional group of epidemiologists. It has been suggested that epidemiology is a set of methods employed in a variety of professions and disciplines (for example, medicine, health

services administration, clinical trials, and environmental health). The proponents of this argument have held that epidemiology is therefore not a distinct profession. It is increasingly accepted, however, that a distinction should be made between the methods of epidemiology and those who are engaged in the application of these methods as a primary activity. It is asserted here that epidemiologists are members of a profession. Hence, this set of ethics guidelines is intended for epidemiologists rather for "epidemiology" per se. Epidemiologists have organized themselves into various national, international, and subspecialty organizations and in North America have established the American College of Epidemiology to further their professional interests in this region. It is for this professional group of epidemiologists that these guidelines are particularly intended.

The profession of epidemiology has at its foundation the maintenance, enhancement and promotion of public health by better understanding the determinants of disease. To this end, epidemiologists can be employed in government positions engaged directly in either research or practice, in university research and teaching roles, in private consulting practice, or elsewhere in the private sector. In addition, epidemiologists increasingly have a role as expert witnesses in courts of law and in the discovery process.

Although epidemiologists do not need a license to practice, individual members of this profession should be accountable for the work that they perform. Professional organizations such as the American College of Epidemiology have a role in the maintenance and encouragement of professional standards through continuing education and through the development of policy statements and guidelines. [Although there is some overlap between standards of practice and ethics guidelines, standards of practice deal more directly with accepted norms for the proper scientific design, conduct, and analysis of epidemiologic studies and do not cover all important ethical issues. Standards of practice are further discussed in Section 3.8.] While such statements about standards of practice ought to strive to avoid restricting the development of innovative research or surveillance methods, or otherwise hindering scientific creativity and innovation, they should provide a framework in which scientific quality, rigor, and

accountability are enhanced and maintained. Scientific excellence, validity, and creativity can be considered epidemiologic virtues that should be nurtured.

3.2. Minimizing Risks and Protecting the Welfare of Research Participants

In carrying out their research, epidemiologists should abstain from conduct that may injure or jeopardize the welfare of study participants either through intentional or unintentional behaviors or actions (e.g., negligence or unjustified departure from study protocols or standards of practice) or omissions. Epidemiologists need to consider and weigh any known or potential risks which individuals or populations may encounter as a result of their research or practice. Consideration of risks includes attention not only to physical risks as a result of direct contact with participants but also to psychological, economic, legal, or social risks. The risks associated with epidemiologic research and practice may be subtle.

No consideration of the potential harms and risks of epidemiologic research and practice would be complete without a consideration of the measures that epidemiologists ought to employ to protect personal privacy and safeguard the confidentiality of information (e.g., income and history of disease) collected as part of studies and practice activities. Although the protection of confidentiality and privacy are discussed in detail in Section 3.5, we provide a brief overview here.

Individuals' privacy and confidentiality of information need to be ensured unless there is an overriding moral concern (e.g., health or safety) justifying the release of such information or if such release is required by law. If privacy or confidentiality must be breached, the epidemiologist should first attempt to inform participants of such required infringements.

To minimize risks, epidemiologists should protect individuals' privacy by storing personally identifying information securely. For example, with the use of a unique study number, the names of research participants can often be removed from medical record abstract forms and questionnaires before the forms are given to data entry personnel and then stored separately. Epidemiologists should restrict access to personal information and store this information in secure environments (e.g., locked file cabinets) including offsite locations for any

back-up documents. To ensure confidentiality of information (including self-reported and biologic data), epidemiologists should gather, store and present data in such a manner as to prevent identification of study participants by third parties. No potentially identifying information should be given to third parties without the express written permission of the participant unless required by law.

A consideration of the potential harms and risks of epidemiologic research also relates to the need to obtain the informed consent of participants as discussed in detail in Section 3.6. Disclosure of known and potential risks should occur prior to requesting study participants' participation. Risks should be considered and disclosed with respect to their probability of occurring and their estimated magnitude.

Epidemiologists may not always be able to prevent all risks for study participants. For example, clinical trials may pose greater risks (and benefits) for individuals in the treatment or intervention arm of the trial in comparison to those in the control or placebo arm (or vice versa). Thus, the epidemiologist must ensure that the risks are reasonable in relation to the anticipated benefits before initiating the study.

3.3. Providing Benefits

Epidemiologists have obligations to maximize the potential benefits of research studies to participants and to society. The potential benefits of epidemiologic research are partly societal in nature and include obtaining new information about the etiology, diagnosis, treatment or preventive aspects of causes of morbidity and mortality, and about the costs, cost-effectiveness and utilization of health care resources. Although the individuals who participate in epidemiologic studies may derive no direct benefit from the research, opportunities sometimes exist for individuals who consent to research to receive some personal gain from participation, such as when previously unrecognized treatable disease is detected during health examinations and individuals are then referred for treatment. In addition, many epidemiologists are engaged in clinical trials or practice activities that may provide direct benefits to participants.

Epidemiologists provide societal benefits and advance the profession by carrying out studies and improving research methods. Improvements in practice activities (for example, enhanced surveillance systems) also provide benefits to society. Epidemiologists should employ the means available to them to contribute to scientific findings and techniques so as to provide benefits to society and advance the profession.

The potential benefits of epidemiologic research include providing scientific data that policy makers can use to formulate sound public health policy. The responsibilities of epidemiologists to facilitate the development of health policy include publishing objective research findings in a form that can be utilized by policy makers. The publication of both positive and negative research findings is important, since it helps to prevent publication bias and allows for additional benefits to be gleaned through meta-analyses.

Epidemiologists should submit their methods and findings to peer review (for example, review for publication). Peer review plays an important role in improving research protocols and scientific reports. Such measures contribute directly to the potential benefits of epidemiologic studies to the scientific community and to society. Contributions to the peer review process, such as service on a grant review panel or as a reviewer for a scientific journal, are consistent with virtuous conduct in epidemiology.

Research methods that involve greater community participation and collaboration are more likely to provide long-term benefits to research participants and to the community. As part of some population-based studies, it may be feasible to impart some health care advantage to the community following completion of the study, such as epidemiologic research that leads to the establishment of a local disease registry or the training of members of a community in basic methods of population research, or a health care services program. Such indirect benefits of epidemiologic studies may be particularly important to consider in planning and carrying out studies in socioeconomically disadvantaged populations.

3.4. Ensuring an Equitable Distribution of Risks and Benefits

A further obligation is the need to ensure that the potential benefits and burdens of epidemiologic research are distributed in an equitable fashion. Persons and groups ought to be treated equally, although the equal distribution of benefits and burdens may be modified by considerations of special need or merit. For example, vulnerable classes of persons in society and those in special need may merit additional benefits (while bearing fewer burdens). The potential benefits of epidemiology extend to all groups of persons in society including those who are socioeconomically disadvantaged. The identification of disparities in health or the maldistribution of health services across groups defined by race, ethnicity, class, and many other characteristics as diverse as age, gender, sexual orientation, homelessness, and rural residence can serve as a basis for health planning and policy making and, thereby, contribute to improving the health of those who are less well-off in society. Carrying out studies and practice activities that provide benefits to socioeconomically disadvantaged and underserved persons in society is a part of the virtuous conduct of epidemiology.

3.5. Protecting Confidentiality and Privacy

Privacy is concerned with the right of individuals to be left alone and not be forced to provide information about themselves except when, how, and to those to whom they choose to reveal this information. Confidentiality is concerned with preventing disclosure of information in ways that are inconsistent with the understanding under which the information was obtained. Epidemiologists should respect the right to privacy and aggressively protect confidentiality. Exceptions are justified in both epidemiologic research and in public health practice only if there is an overriding moral concern such as a health emergency or a legal requirement.

An individual's reasonable expectation of privacy regarding access to and use of his or her personal information should be assured. The law sometimes requires invasions of privacy, especially under conditions of a threat to public health and safety. When under a legal obligation to make disclosures that invade privacy, the epidemiologist should carefully weigh an obligation to the law against the moral importance of preserving the privacy of research participants. If an

epidemiologist must infringe upon the commitment to maintain privacy, those involved should be informed of the reasons and of their rights in the circumstances. A decision to violate privacy should be made only after consultation with administrative superiors, ethics committee chairs, and/or other persons qualified by nature of expertise and responsibilities.

3.5.1. Maintaining confidentiality

Except under unusual circumstances (e.g., mandated by a court of law), information obtained about individuals during an epidemiologic study should be kept confidential. Protection of confidentiality is required not only to follow the ethical principle of respecting persons, but also because the disclosure of certain information to third parties may cause harm to an individual, e.g., discrimination in employment, housing, and health insurance coverage. Identities and records of research participants should remain confidential whether or not confidentiality has been explicitly pledged.

Epidemiologists should take appropriate measures to prevent their data from publication or release in a form that would allow individuals to be personally identified. Confidentiality can be violated even without the release of personal identifiers such as names or social security numbers. For example, the release of information about a physician in a small town could “identify” an individual patient in that community even though no name or social security number was given. Therefore, it should be standard practice to aggregate data in such a way that individuals cannot be deduced without additional information. For highly sensitive information or where there is danger of retribution for having some characteristic, data from research studies should be presented in such a manner that no identifiable person is placed at such risk. Where group confidentiality cannot be maintained or is violated, the investigators should take steps to avoid contributing to the stigmatization of the group or discrimination against its members.

As detailed in the Council for International Organizations of Medical Sciences (CIOMS) International Guidelines for Ethical Review of Epidemiological Studies (Appendix), information about research participants is generally divisible into:

Unlinked information, which cannot be linked, associated or connected (even by deduction) with the person to whom it refers. Since this person is not known to the investigator and cannot be known, confidentiality is not at stake.

Linked information, which may be:

anonymous, when the information cannot be linked to the person to whom it refers except by a code or other means known only to that person, and the investigator cannot know the identity of the person;

non-nominal, when the information can be linked to the person by a code (not including personal identification) known to the person and the investigator; or

nominal or nominative, when the information can be linked to the person by means of personal identification, usually the person's name.

Epidemiologists should unlink personal identifiers as soon as they are no longer needed. Identifiable personal information should not be used when a study can be conducted without personal identifiers, unless discarding personal identifiers would preclude personal health benefits for the participants. If personal identifiers must remain linked to study records, a clear and compelling justification should be given to the ethics review committee (institutional review board or ethics review board) along with a description of how confidentiality will be adequately protected.

The obligation to protect confidential information does not preclude obtaining confidential information. Confidential medical and other vital records that identify individuals are essential to epidemiologic research and practice, and identification of persons whose records have been obtained may be needed to prevent those individuals (or others who have contact with them) from developing disease or to identify the disease at an early stage.

Recent advances in computer technology, the development of large data sets and the ability to link different data sets which contain personal identifiers have created great concern about our ability to maintain confidentiality of information about an individual's health. In response, various governmental bodies are considering or have enacted strict laws regarding the

confidentiality of health information. Epidemiologists should be alert to and comply with state, provincial, and national (federal) laws regarding confidentiality and privacy, including those pertaining to data sharing or pooling of data.

Recent developments in genetics also have heightened concern about the confidentiality of, and the inappropriate use of, genetic information, e.g., using confidential genetic information to refuse someone employment or deny health insurance. Laws are being proposed to restrict how genetic information can be used. Epidemiologists should remain alert to developments in this area. In addition, epidemiologists who understand genetics can make important contributions to the field by helping to establish procedures which will ensure that genetic information can be protected from inadvertent or intentional inappropriate disclosure.

3.5.2. Maintaining security

In order to assure confidentiality, epidemiologists should use all appropriate physical safeguards (e.g., locked file cabinets, locked rooms) and security measures (e.g., password access, encryption) to protect records from unauthorized access. Backup files/tapes and archived records should be subjected to the same measures. Staff training and periodic audits should be conducted to reinforce the importance of confidentiality safeguards.

3.5.3 Certificates of Confidentiality

In the United States, researchers can further address confidentiality concerns by requesting certificates of confidentiality from the Department of Health and Human Services agency that funded the research (or, if the research is not federally funded, from the National Institutes of Health). Subsection 301(d) of the Public Health Service Act, added in 1988, provides authority for the issuance of certificates of confidentiality for health research projects. The certificate relieves the holder (for example, investigators carrying out genetic testing as part of a research protocol) from the obligation to comply with some categories of compulsory legal demands for disclosure such as court subpoenas for individual research records.

3.6. Obtaining the Informed Consent of Participants

The purpose of informed consent provisions in epidemiologic research is to ensure that research participants fully understand the purpose and nature of the study, the identities of the investigators and sponsors, the possible benefits and risks, the scientific methods and procedures, any anticipated inconveniences or discomfort, the voluntary nature of participation, and the opportunity to withdraw at any time without penalty. Institutions view informed consent as providing legally valid authorization to proceed with the research. The focus is on both the obligation of researchers to disclose information about risks and potential harms and the quality of the consent of the research participant.

Investigators are obligated to disclose information that patients or other individuals usually consider important in deciding whether to participate in research. Potential participants in epidemiologic research should be told the extent to which confidentiality can be protected and the intended and potential uses of data which contain personally identifying information. Additional disclosures may be necessary depending on the circumstances. Steps should be taken to ensure that the participants (including minors) understand the information provided; obtaining informed consent is a process, and informed consent statements must be understandable to a lay person. Although research participants sometimes receive compensation for their participation in studies (for example, reimbursement for transportation costs or lost earnings), they must voluntarily consent to the planned intervention without coercion, manipulation, or undue incentives for participation.

Requirements to obtain the informed consent of research participants may be waived in certain circumstances, such as when it is impractical and there are only minimal risks, although review by a research ethics committee is a necessary safeguard. For example, it is not feasible to obtain the informed consent of individuals in some epidemiologic studies and surveillance programs involving the linkage of large databases routinely compiled and maintained for other purposes. In such circumstances, confidentiality safeguards and other measures should be employed to ensure that no harm can result from the research. Informed consent requirements

may be loosened or waived when epidemiologists investigate disease outbreaks or evaluate programs as part of public health practice activities. However, even in outbreak investigations it is often feasible and desirable to disclose information about the purpose of the investigation.

3.7. Submitting Proposed Studies for Ethical Review

Investigators have a professional responsibility to evaluate the ethics of a study and to ensure its ethical adequacy throughout its term. It is also necessary, however, to ensure that studies involving human research participants be submitted for review by a research ethics committee. The requirement that proposals for epidemiologic studies be submitted to ethical review applies irrespective of the source of the proposals--academic, governmental, health care, commercial, or other. Sponsors should recognize the necessity of ethical review and should facilitate the establishment of ethics review committees. These committees may be created under the aegis of national or local health administrations, national medical research councils, or other nationally representative health-care bodies. They help to ensure the conditions which safeguard the rights, safety, and well-being of the study participants.

If an untoward event occurs during the course of a study, such as an adverse drug reaction in a clinical trial or an adverse psychological response during an observational study, the event should be promptly reported to the research ethics committee so that they may help to determine if and how the study should proceed.

Protocols for collecting data for population-based or community studies should be submitted to the local health authorities where the study is to be conducted (e.g., State and local health departments in Canada or the United States and ministry of health in many developing countries).

Issues surrounding the scientific review of research protocols are discussed in Section 3.3 (providing benefits).

3.8. Maintaining Public Trust

Public trust is essential if epidemiologic functions, such as disease surveillance, outbreak investigation and control, and research are to continue to be supported by the public. Trust is an

expression of faith and confidence that epidemiologists will be fair, reliable, ethical, competent, and nonthreatening. To promote and preserve public trust, epidemiologists should adhere to the highest ethical standards and follow relevant laws and regulations concerning the conduct of epidemiologic research and practice activities, including the protection of human research participants; confidentiality protections; and disclosure or avoidance of conflicts of interest.

Maintaining public trust is especially important in planning and carrying out community studies. In identifying public health problems to be studied, and their priority for study, epidemiologists should take into account the perceived importance of the problem to the people living in a community after information about the problem has been provided. However, if epidemiologists perceive that a health problem exists but is being ignored or its existence denied by the community, it may well be appropriate to proceed with a study of a health problem (or an outbreak investigation that must be initiated without delay to address an urgent public health concern) while simultaneously working with the community to gain their confidence and support.

Epidemiologists are frequently drawn to the problems of unempowered communities and may require special sensitivity in dealing with them. To promote public trust, especially in unempowered communities, epidemiologists should consider adopting a "participatory" approach to a research project. Involving community members beyond just recruiting them as research participants might promote trust and provide other benefits. Care should be taken to ensure that community participation in studies does not adversely affect scientific objectivity. The establishment of a community advisory board may be helpful. In planning and conducting occupational epidemiology studies, it is desirable to obtain input from workers or their representatives.

The attention that epidemiologists give to standards of practice (as discussed in section 3.1) also helps to maintain public trust. The importance of adhering to the highest scientific standards (for example, by choosing an appropriate study design; writing a clear and complete protocol; using proper procedures for the collection, transmission, storage, and analysis of data;

and properly interpreting and reporting results) is highlighted in standards of practice that have been developed in the field. Reports of epidemiologic findings should include sufficient data (in aggregate form) and sufficient information about the study methods to ensure that interpretations and conclusions made from the findings can be independently corroborated by others. Full information should be reported about the response rate and other potential sources of bias.

Measures for the secure storage and transmittal of confidential information (Sections 2.5 and 3.5), including the development and retention of coding manuals, are also addressed in standards of practice for epidemiologists. Similar issues arise in efforts to provide societal benefits by maximizing the potential benefits of epidemiologic research (Sections 2.3 and 3.3).

Other measures that epidemiologists should take to maintain public trust are discussed in Sections 2.9 and 3.9 (avoiding conflicts of interest), Sections 2.10 and 3.10 (confronting unacceptable conduct), and Sections 2.11.1 and 3.11 (reporting results).

3.9. Avoiding Conflicts of Interest and Partiality

It is incumbent upon epidemiologists (as members of the broader scientific community) to ensure that objectivity prevails at every step of the research process. Partiality can arise through a scientist's own biases and preconceived notions about a problem being investigated. Maintaining honesty and impartiality in the design, conduct, interpretation, and reporting of research findings is essential. Truth-telling and objectivity are professional duties and they can also be thought of as virtues.

Reports of epidemiologic findings should be free of distortions that might be introduced by preconceptions or organized efforts, irrespective of whether the research was conducted by private or public funds. Partiality can arise when pressure is brought to bear on the researcher by any parties that have an interest in seeing the research results favor their particular interests. Epidemiologists should not enter into contractual obligations that are contingent upon reaching particular conclusions from a proposed study.

Investigators should disclose any potential material conflicts of interest to their study collaborators, sponsors, research participants, journal editors, and their employer. Full disclosure

can be helpful in ensuring transparency for identifying conflicts of interests and preventing them. Epidemiologists should take care to distinguish the perceived conflicts of interests of others from actual conflicting interests.

3.10. Communicating Ethical Requirements to Colleagues, Employers, and Sponsors and Confronting Unacceptable Conduct

Epidemiologists, as professionals, should provide training and education in ethics to students of the discipline. This includes the mentoring of junior investigators outside of classrooms and structured learning environments. The goal should be to communicate the core values and obligations of a professional epidemiologist (i.e., ethics guidelines) and to provide an ethical foundation so that students can deal appropriately with ethical challenges that they will face in their future practice.

Epidemiologists should demonstrate appropriate ethical conduct to colleagues by example. Modeling ethically appropriate conduct while mentoring students and junior colleagues is particularly important. It provides another opportunity to offer training in the ethics and science of the discipline. Examples of virtuous conduct in interacting with colleagues include avoiding personal attacks and appropriately citing the work of others.

Epidemiologists should communicate to their colleagues (including those who are in other disciplines) the ethical requirements of epidemiologic research and its application. Such communication may be by direct negotiation of the particulars of issues such as authorship, consent, and interpretation of the results with regard to public health importance.

Addressing and, if necessary, reporting or confronting unethical or unacceptable conduct such as scientific misconduct are essential actions for safeguarding the integrity and reputation of the profession. Such actions have potentially severe consequences and should be undertaken and carried out with great discretion and appropriate consultation. Scientific misconduct itself can also have potentially severe consequences for public health, for health professions, and for individual researchers. In addressing such issues, epidemiologists should give due consideration to the complexity of many ethical issues and attempt, where possible and appropriate, to educate

rather than to confront. Agencies, institutions, and research sponsors should accept responsibility for adjudicating situations of alleged unethical and/or unacceptable conduct fairly, objectively, and in a manner that maintains or restores the integrity of the research process, while preserving the rights of the accused and protecting an accuser acting in good faith from retribution and other adverse treatment.

3.11. Obligations to Communities

Obligations to communities are central to any account of the professional role of epidemiologists. Epidemiologists meet their obligations to communities by undertaking public health research and practice activities that address causes of morbidity and mortality or utilization of health care resources, and by reporting results in a timely fashion so that the widest possible community stands to benefit. These measures help to build and maintain public trust (Section 3.8). Providing community service (for example, providing scientific expertise to community-based organizations) is an epidemiologic virtue.

The optimal time to disseminate the findings of epidemiologic studies is not always easy to discern. Both premature and unnecessarily delayed release of research findings can be more beneficial than harmful to individuals and to society. Study findings should be interpreted and made available to the public in accordance with the current scientific thinking about the utility and validity of the information. Nevertheless, it may be difficult to strike the right balance between the need to cautiously communicate findings to other scientists with appropriate peer review and validation of findings, and the need to expeditiously communicate results to other interested parties without undue delay. The appropriate peer review, replication and validation of study findings, and other safeguards to assure scientific validity are important, but they require time.

Although epidemiologists cannot always prevent the media or other parties from sensationalizing research results, epidemiologists should strive to ensure that, at a minimum, research findings are interpreted and reported on accurately and appropriately. The goal should

be to communicate research findings in ways that allow full use of the information for the public good.

Thus, all information important to public health should be communicated in a timely, understandable, and responsible manner. The significance of the findings should neither be understated nor overstated. Epidemiologists should put the strengths and limitations of their research methods into proper perspective. The results of studies in progress should not be reported to the media or others if such reporting could jeopardize the scientific integrity of the study or mislead the public. There may be occasions when it becomes necessary to terminate a study early and release its findings in order to protect the public's health. Early terminations should occur only after due consultation with scientific peers and the study's oversight committee. Reasons for the early release of results should be clearly articulated.

Epidemiologists have an obligation to communicate with communities directly or through community representatives to explain what they are doing and why, to transmit the results of their studies, to explain their significance, and to suggest appropriate action, such as the provision of health care. This suggests the need for formal communications training for epidemiologists so that they can better communicate research findings.

In confronting public health problems, epidemiologists sometimes act as advocates on behalf of affected communities. Care must be taken to ensure that such advocacy does not impair scientific impartiality in designing and interpreting new research and implementation efforts pertinent to the public health problem in question. Indeed, epidemiologists who advocate should be open to the possibility of changing their views as new evidence or other relevant information becomes available. An impartial advocate should keep in mind that the core value of improving the public's health through the application of scientific knowledge relies upon the ideas that the acquisition of knowledge is dynamic and that knowledge itself can improve.

Epidemiologists should respect cultural diversity in carrying out research and practice activities and in communicating with community members. To do this effectively, epidemiologists should be well-informed about the history, circumstances, and perspectives of

groups within the community. They should form relationships with formal or informal leaders in the community and consider the relevance of the epidemiologic research agenda to perceived community needs.

Other obligations that epidemiologists have to communities are discussed in Section 3.8 (maintaining public trust).

PART IV - SUMMARY AND CONCLUSIONS

The goal of these guidelines is to provide a useful account of the ethical and professional obligations of members of the American College of Epidemiology as they engage in professional activities and the application and dissemination of information to colleagues and the public. As such, these guidelines identify and record ethical rules and professional norms in the field and should therefore be viewed as normative. However, these guidelines do not provide an exhaustive account of professional duties and ethical concerns in epidemiology. Additional issues that might be addressed in future guidelines, in policy statements, or in standards of practice include ethical rules and standards of practice for the long-term retention of data in data archives, data audit, and data sharing; ethical issues in placebo-controlled trials; ethical issues arising in genetic research; consideration of the broader social and environmental consequences of epidemiologic research; and human rights considerations relevant to epidemiology.

Although these ethics guidelines focus both on epidemiologic research and on public health practice activities such as outbreak investigations, surveillance systems, and program evaluations, we acknowledge that there are many professional duties and ethical concerns in public health practice that are not directly addressed by these guidelines. These guidelines also do not provide a comprehensive account of professional duties and ethical concerns in epidemiology subspecialty areas such as molecular epidemiology, genetic epidemiology, clinical epidemiology, reproductive and perinatal epidemiology, pharmacoepidemiology, and psychosocial epidemiology. Ethics guidelines for environmental epidemiologists and practice guidelines for pharmacoepidemiologists have been proposed.

Finally, we note that ethics guidelines do not provide the final word on issues of ethical concern. Rather, specific decisions in particular circumstances require judgments made upon reflection of the core values, obligations, and virtues described in these guidelines. Suggestions for improving future versions of these guidelines can be sent to the American College of Epidemiology's Ethics and Standards of Practice Committee in care of the ACE national office.

These guidelines were prepared by the Ethics and Standards of Practice (ESOP) Committee on behalf of the American College of Epidemiology (ACE). The members of the writing group were (alphabetically) Germaine Buck, Steven S. Coughlin (Chair), Rosanne B. McTyre, Dixie E. Snider, Jr., Colin L. Soskolne, and Douglas L. Weed. Other individuals including several current and previous members of the ESOP Committee, ACE Board and Executive Committee and several other ACE members provided helpful comments on an earlier draft of this document. Initial comments were kindly provided by Gina Etheredge, Kenneth Goodman, and John Last.

APPENDIX

SUGGESTIONS FOR FURTHER READING

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