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SPECIAL REPORT

New Ethics Guidelines for Epidemiology: Background and Rationale

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In the past decade, at least four sets of ethics guidelines for epidemiologists have been prepared by various national and international organizations. None, however, have been officially adopted by the American College of Epidemiology (ACE). Recently, the ACE asked its Ethics and Standards of Practice (ESOP) Committee to produce ethics guidelines. In this paper, we explain the context and rationale for this effort, describe the purpose and content of ethics guidelines in epidemiology, and discuss their strengths and weaknesses. Three issues that are central to the mission of ACE–education, policy, and advocacy–are inadequately addressed in existing ethics guidelines. In addition, ethics guidelines are not static documents; they should reflect the changing role of epidemiologists in society, including issues arising in emerging subspecialty areas. New, more dynamic, guidelines that emphasize core values, obligations, and virtues, may help to further define and legitimize the profession of epidemiology and will provide a foundation for the discussion of specific ethical issues in the classroom and in professional practice. Guidelines however, do not provide the final word on ethical issues. Specific °cisions in particular cases require judgments made upon reflection of the core values, obligations, and virtues described in the guidelines. From our review, we conclude that a new set of guidelines is reasonable and warranted.
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INTRODUCTION

Nearly a decade has passed since epidemiologists, ethicists, and legal scholars began concerted efforts to write professional ethics guidelines for epidemiologists (1–3). During this time, guidelines have been prepared by the Industrial Epidemiology Forum (IEF) in 1989 (4), the Council for International Organizations of Medical Sciences (CIOMS) in 1990 (5), the International Epidemiological Association in 1990 (6), and for the International Society for Environmental Epidemiology in 1996 (7). Recently, the American College of Epidemiology (ACE) asked its Ethics and Standards of Practice (ESOP) Committee to produce ethics guidelines (8). In this commentary, we provide the context and rationale for such an effort, describe the purpose and content of guidelines, and discuss their strengths and weaknesses.

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WHY WRITE ANOTHER SET OF GUIDELINES?

Perhaps the most obvious reason for a new set of guidelines is that the organization has not developed its own, although ACE members hardly practice within an ethical void. They are guided by other guidelines (4–7), recent books on ethics in epidemiology (9, 10), a growing number of journal articles, and formal courses (11). A more compelling reason for writing new guidelines is that three issues central to the mission of ACE–education, policy, and advocacy–are inadequately considered in existing ethics guidelines. Ethics education in graduate training programs for epidemiologists or as part of continuing professional education is barely addressed in existing guidelines. Ethical issues concerning the important role of epidemiology in health policy are also inadequately discussed. For the issue of public health advocacy, existing guidelines provide inconsistent recommendations on the extent to which epidemiologists should engage in this aspect of professional practice (12). Finally, existing guidelines focus more on the equitable distribution of the burdens of research than on the equally important notion of the just distribution of the benefits of research (13).

A further reason for revisiting and refining existing guide-

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Selected Abbreviations and Acronyms

ACE = American College of Epidemiology
IEF = Industrial Epidemiology Forum
CIOMS = Council for International Organizations of Medical Sciences
IEA = International Epidemiological Association
ISEE = International Society for Environmental Epidemiology

lines is that issues arising in subspecialty areas of epidemiology are inadequately addressed. For example, the guidelines do not address issues that can arise in molecular epidemiology such as those surrounding the use of banked biological specimens for DNA testing (14) and those concerning biomarkers (15). Existing guidelines also do not deal adequately with ethical issues arising in field epidemiology and other areas of public health practice such as outbreak investigations, surveillance systems, and evaluation studies (16). In addition, a re-examination of the issues of privacy, confidentiality, and data security may be warranted in this age of enhanced information technologies.

Beyond these practical reasons lies another justification for new ethics guidelines. These are not static documents. As the needs and values of professionals change, so should the guidelines to reflect the changing roles of epidemiologists in society (17). Epidemiology has undergone increasing scrutiny from the media and from the courts. Likewise, epidemiologists are increasingly challenged by their newfound relationships with regulatory bodies, the legal profession, and employers, such as managed care organizations. Dynamic guidelines require occasional updating and revising (18). Still, the framers may find good reason to reaffirm core values, principles and rules of professional conduct that may remain relevant because they are rooted in a common morality such as the universal precept of "truth-telling," accepted by all moral persons in all moral traditions. In this context, universal does not mean absolute. Even a universally accepted ethical rule may have exceptions, especially when it conflicts with some other such rule (19).

THE PURPOSE OF GUIDELINES

New guidelines may serve to further define and legitimize the profession of epidemiology. Indeed, guidelines serve the same purpose for any profession (17), each of which is characterized by a specialized body of knowledge and skills, by lengthy education and training, and by the services it provides. Professions are autonomous and self-regulating bodies that *profess*, i.e., affirm their willingness as learned practitioners of their discipline, to provide services. Just as physicians profess (or declare publicly) to treat illness in patients and teachers pledge to educate students, so epidemiologists profess to prevent disease in populations through studying the distribution and determinants of disease and applying that knowledge for the public's benefit (12). The knowledge required to meet epidemiology's commitment to society through science and public health is broadly conceived and supported by theory, methodology, and practical experience in research and practice. Education and training programs in epidemiology, which are now widely recognized and proliferating, are correspondingly broad and deep. In sum, epidemiology *is* a profession as the ACE explicitly recognizes. A new set of ethics guidelines may underscore the College's commitment to that idea.

It follows that ethics guidelines also alert the public (including employers of epidemiologists) to what they may and may not expect from a professional epidemiologist. Nevertheless, the primary users of a new set of ethics guidelines are the epidemiologists themselves, who are provided with a general description of the moral aspects of their work as well as a guide to moral decisionmaking in cases of moral uncertainty (20).

THE CONTENT OF GUIDELINES

We draw a distinction between moral (i.e., ethics) guidelines, which address a range of general professional obligations, and what Spicer (17) calls "quasi-moral" guidelines, or rules of etiquette for professionals. The latter emphasize procedural matters, such as the proper procedures for consultations or the process for adjudicating disputes. We also recognize the importance of guidelines for good scientific practices within epidemiology, although such guidelines do not focus specifically on the ethics of epidemiologic research. Nevertheless, there is a close relationship between good epidemiology practices and ethical norms in the field (e.g., having a written protocol and submitting that protocol to an independent committee for ethical review).

We also draw a distinction between ethics guidelines and more specific policy statements that have sometimes been drafted by professional societies and consensus committees. For example, a working group formed by the National Institutes of Health and the Centers for Disease Control and Prevention recently offered specific recommendations for the use of repository materials (e.g., DNA obtained from banked tissues, blood, or other biological specimens) for genetic testing, such as when requirements to obtain the informed consent of subjects can be waived (14). Additional policy statements of interest to molecular and genetic epidemiologists have been drafted by groups such as the American Society for Human Genetics (21) and the American College of Medical Genetics (22). Like the more general ethics guidelines, such policy statements on specific issues concerning human subjects need to be periodically revisited and revised, in part because of the rapid advance of scientific technology in molecular genetics and other fields.

We focus here on ethics guidelines, and in this section consider their basic components: core values, duties, and virtues. Core values are the central objectives of the profession of epidemiology, that reflect what the profession stands

for and promotes through its work (7). Duties are those obligations epidemiologists hold to various parties, whether broadly or specifically conceived. Obligations and their implications have been emphasized in published guidelines. Virtues can also be considered a component of ethics guidelines (17). Virtues–such as honesty, prudence, integrity, and truthfulness–are distinct from core values and obligations. Virtues reflect issues of character for professionals and are important in all aspects of professional practice, including our willingness to use ethics guidelines in everyday professional activities (23). Although good character does not ensure good conduct (as defined in the existing guidelines), it does affect the ways in which epidemiologists are perceived by society and forms the moral basis of the motivation of professional practitioners to use the guidelines.

WHAT GUIDELINES CAN AND CANNOT DO

The strength of guidelines is that they not only maintain, promote, and protect professional prestige, but also provide a foundation for the discussion of specific ethical issues in the classroom and in professional practice (1). When faced with an ethical dilemma, or to some other ethical conflict or challenge, a practitioner may refer to guidelines for general guidance in decisionmaking. Specific answers to discrete ethical questions, however, should not be expected from any set of guidelines; they are not typically structured to consider the complexity and richness of detail that comprise everyday decisionmaking at the level of specific cases such as those found in a recent text (24).

Guidelines do not provide the final word on ethical issues; as noted above, they are rather general discussions. Also, they do not provide an organizational framework, such as policies and procedures, for dealing with ethics violations. Rather, they can be considered the standard of practice regarding general ethical issues. Specific decisions in particular cases will involve reflection and judgment (19).

EXISTING ETHICS GUIDELINES IN EPIDEMIOLOGY

The events that led to the development of ethics guidelines for epidemiologists have been reviewed elsewhere (1). Descriptions of the four sets of guidelines that are currently available to professional epidemiologists follow. These have appeared in various publications in a six year window from 1990 through 1995.

IEF Guidelines

These guidelines emphasize the obligations of epidemiologists to four distinct groups: research subjects, society, funding agencies and employers, and professional colleagues. For example, obligations to research subjects include: protecting their welfare, obtaining informed consent, protecting privacy, and maintaining confidentiality, and reviewing research protocols. Obligations to society include: avoiding conflicting interests, avoiding partiality, widening the scope of epidemiology, pursuing responsibilities with due diligence, and maintaining public confidence. Obligations to funders and employers as well as those to colleagues are similarly specified. The IEF guidelines also contain commentary sections on the nature and purpose of guidelines and a detailed discussion of specific components of each general obligation. In addition, the moral foundation of the guidelines is briefly described, which relies primarily (but not exclusively) upon four principles of bioethics: autonomy, nonmaleficence, beneficence, and justice. Other principles that are relevant for making moral judgments are acknowledged, including fidelity and conscientiousness. Finally, the authors of these guidelines note that the nature and goals of epidemiology–i.e., the core values–are inadequately addressed. Virtues are not mentioned. In sum, the IEF guidelines primarily provide a detailed (and well-organized) description and discussion of professional obligations.

IEA Guidelines

Ethics guidelines drafted by the IEA were never officially adopted and are only available in draft form. They are organized around nine basic points: the first two discuss the definition and purposes of epidemiology and the nature and (core) values of epidemiology. Following these is a section on basic principles of biomedical ethics–autonomy, beneficence, nonmaleficence, and justice–which also mentions the Helsinki Declaration. The next three sections discuss obligations to individuals, obligations to communities, and access to information. The last sections discuss scientific integrity, professional standards, and cultural variations in values. Virtues are not mentioned. A paragraph on education and training is provided under the heading of professional standards. In sum, the IEA guidelines are rather brief and appear to be a draft document to be used as a starting point for discussion.

CIOMS Guidelines

Like the IEF and IEA guidelines, the CIOMS guidelines were intended to provide a guide to help those who have to deal with ethical issues that arise in epidemiology. Unlike the IEF and IEA guidelines, the CIOMS guidelines are not obligation-based. Rather, they emphasize the review of epidemiological studies; a prominent section describes cross-sectional, case-control, cohort, and experimental study designs. The structure of the guidelines is based on the (same) four principles of bioethics applied to epidemiological studies and uses the following major subheadings: informed consent, maximizing benefit, minimizing harm, confidentiality, and conflict of interests. The final section of the guidelines is a discussion of ethical review procedures.

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ISEE Guidelines

These guidelines were prepared for but not officially adopted by the ISEE. They are based directly upon the IEF guidelines and even use the precise language of the earlier effort. The authors of the ISEE guidelines add core values and a definition of environmental epidemiology. They also provide additional components to the general obligations featured in the original IEF guidelines. For example, under the obligation to colleagues, the IEF guidelines proposed the following components: reporting methods and results, confronting unacceptable behavior and conditions, and communicating ethical requirements. To these, the ISEE guidelines added: publishing methods and results. It should be noted, however, that issues in publication were also addressed in the commentary section of the IEF guidelines.

CONCLUSIONS

From our review of the nature and scope of existing ethics guidelines for epidemiologists, we conclude that an effort to provide a new set of guidelines under the auspices of the American College of Epidemiology is reasonable and warranted. Beyond the idea that it is important to revisit ethics guidelines periodically because professional values and needs change with time, our reasons include the fact that existing guidelines do not carefully examine nor clearly state the obligations and components of obligations involved in three areas central to the ACE: education, policy, and advocacy. Another reason for composing a new set of ethics guidelines is that no current set addresses the topic of professional character (i.e., virtues). Finally, it is not clear the extent to which the concerns and needs of the members of the profession were considered in drafting some of these guidelines; the ISEE guidelines, however, were informed by an international survey of environmental scientists.

Our concerns should not be construed as critical of the framers of previous guidelines nor of the documents themselves. We fully appreciate the effort that was expended to create the existing guidelines and the accompanying commentary. We also understand that other groups such as the Italian Epidemiological Association have undertaken efforts to develop new or refined sets of ethics guidelines. All guidelines remain important, even vital, milestones in epidemiology's search for its ethical foundations.

We look forward to meeting the needs of the American College of Epidemiology with a new set of ethics guidelines for the profession.

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