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Reviews and Commentary

EPIDEMIOLOGY: QUESTIONS OF SCIENCE, ETHICS, MORALITY, AND LAW

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The pursuit of truth is the tenet on which all scientific endeavor is based. This commentary is an attempt to show how the pursuit of truth in epidemiologic practice can be influenced by group interests. Examples from the recent past are used for emphasis.

It is argued that the principle of seeking truth—aside from the implications for scientific advancement—must be considered responsibly within the moral and legal value base of the culture within which the epidemiologist functions. Where the epidemiologist cannot subscribe to the moral

and/or legal basis of the culture within which he or she works, a primary focus of epidemiologic pursuit may be on influencing the value base of the culture itself (1).

It is argued further that a set of professional ethics guidelines forms a necessary (but insufficient) basis for the advancement of epidemiology; as the discipline matures, the ethics debate must be brought into the mainstream of epidemiologic literature so that the greatest possible input can be channelled toward developing ethics guidelines for epidemiologists. Thus, it is not the goal of this commentary to provide

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even a draft set of guidelines; rather, its goal is to further stimulate discussion on the topic.

EPIDEMIOLOGY: A MULTIDISCIPLINARY EMERGENCE

Practitioners of epidemiology emanate from a number of disciplinary bases, including epidemiology itself, medicine, nursing, public health, statistics, sociology, anthropology, philosophy, and demography. The research of these epidemiologists embraces a broad range of activity, from descriptive and analytic studies requiring access only to existing records, through experimental studies dependent for their success on human subjects and/or patient participation. The common denominator across all of the epidemiologist's activities is the focus on populations, and hence on questions of relevance to the public health (2).

Medically qualified epidemiologists, prior to their specialization in epidemiology, are usually required to subscribe under oath to a *medical* code of ethics. Because of this, physicians are regarded as a self-regulating profession (3-5). However, practitioners of epidemiology are not required to subscribe to a code of ethics and therefore cannot be considered a self-regulating profession. Even though physician-trained epidemiologists will have subscribed to a physician's code of ethics, the medical group's existing codes of ethics primarily relate to patient care, and thus are not directly relevant within the context of population-based research (2).

DISTINCTIONS BETWEEN ETHICS AND MORALITY

Ethics concern the "rules of conduct recognized in respect to a particular class of human actions or a particular group or culture" (6). On this basis, professional groups have established their respectability and credibility in the public eye and are relegated the responsibility by governments for self-regulation. *Morality*, on the other

hand, refers to "principles or habits with respect to right or wrong" (6) and relates to general interactions between persons in all facets of life. Legal safeguards, representing cultural norms based on prevailing values, often impose controls on extremes of moral action. Hence, distinct from self-regulation, questions of morality generally are entrenched through legislation.

Self-regulation and legislation interplay to ensure control over extremes of human conduct. Group interests and regional variations contribute to the degree of overlap between these two approaches to control. As a consequence, some professional groups are more self-regulating than others. Figure 1 schematically highlights the distinctions between the legislative and the self-regulation approaches to control.

Questions about ethics in epidemiologic practice first drew attention in 1977, when concerns were expressed in regard to the confidentiality (7), interpretation (8), and conduct (9) of studies. At that time, other medical, science, and engineering professional bodies already were self-regulating (or they recently have become self-regulating), a responsibility relegated by government in the interest of fewer imposed controls, particularly where the public interest is concerned (3, 4). Indeed, these other disciplines were already engaged in debate on intellectual questions dealing with ethical principles as they related to their respective disciplines. The lack of such debate among epidemiologists was first noted in 1984 (10), and the first text on the subject, specific to psychiatric epidemiology, was published in 1986 (11).

FUNDAMENTAL PRINCIPLES OF BIOETHICS

Principles of bioethics have evolved from about the 16th century B.C. (4). By 1520 A.D., the Royal College of Physicians of London had compiled a penal code for physicians, and, in 1543, this was renamed an "ethical code" (4). With the founding of the American Medical Association in 1847, the

1520 code of the Royal College was adopted. The code stressed behavior and etiquette. Revisions to the code were made in 1957 and 1980 (4). In 1948, the World Medical Organization adopted the Declaration of Geneva (4). The Nuremberg Code and the Declaration of Helsinki followed and dealt more specifically, however, with human experimentation (4). Despite a recent widening in 1975 of the scope of the Declaration of Helsinki (12), it continues to focus on responsibilities of the *medically* qualified researcher.

In essence, the fundamental principles of bioethics include four concepts (13-15): 1) *autonomy*, which requires of professionals a respect for individual rights and freedoms; 2) *beneficence*, which requires that professionals do good; 3) *non-maleficence*, which requires of professionals that they do no harm; and 4) *justice*, which requires

of professionals a fair and equitable allocation of resources without discrimination.

ETHICS IN THE PROFESSIONS

Many professional groups already have their own codes of ethics (3, 16). Medical associations around the world constitute one such example. Other examples in the North American context include associations of microbiologists, psychological associations, chemical societies, psychiatric associations, electrical and electronics engineering societies, societies for pharmaceutical therapeutics, and societies on aggression research, to name but a few (3). These professional organizations have affiliation with the American Association for the Advancement of Science, which has an active committee on scientific freedom and responsibility (3, 16). In addition, there are resource groups available to professional bodies interested in developing codes of ethics such as, for example, the Center for the Study of Ethics in the Professions (3).

Recognizing the various types of training received by epidemiologists, it becomes evident that many practicing epidemiologists have never studied ethics, nor have they ever subscribed to a code of ethical conduct. The physician-trained epidemiologist, with or without a Master's or Ph.D. degree, may have been exposed to some ethics teaching in the undergraduate medical curriculum, and will have subscribed to a code of ethics pertaining to medical practice. However, for the non-medically-trained epidemiologist whose background may be from sociology, anthropology, philosophy, or the like, the question of ethics is only possibly referred to in these other programs that produce practicing epidemiologists; certainly no code of ethics exists to which they are expected to abide.

Only in nursing programs has ethics traditionally been more consistently taught than in medical curricula. Despite physician or nurse epidemiologists having at one time been subjected to aspects of ethics training, any codes that exist for these

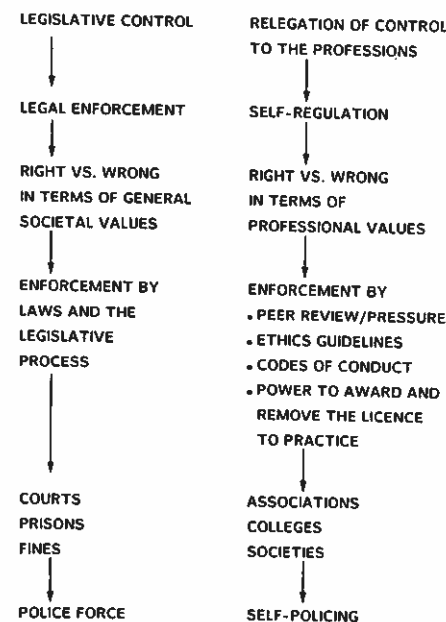


FIGURE 1. The societal accordance of legislative control versus the relegation of control to the professions.

professions tend to have a patient-care focus and are not directly relevant to population-based research questions or to public health practice in general (2). Indeed, from an economist's view, "individualistic" ethics have superseded "societal ethics"; it becomes important to recognize this contrast in the interests of resolving questions of equitable resource allocation (17).

ADVANCEMENT OF THE DISCIPLINE

Adherence to the scientific method provides the basis for the systematic advancement of knowledge. The extent to which epidemiologists can adhere to the scientific method depends on their ability to approximate experimental studies in the context of human subjects. The less experimental an epidemiologic study, the more open it becomes to bias and hence to interpretational influences. Indeed, difficulties associated with the interpretation of observational studies common in epidemiologic research can be exploited to support arguments for or against a given set of findings.

Any deliberate misuse—as opposed to the poor use—of science, tends to raise questions of personal morality or integrity as well as questions of scientific competence. The *deliberate* incorporation of methodological deficiencies or systematic error, respectively, in the design or conduct of epidemiologic research—indeed, the use of fraud or deceit in any aspect of science (18–20)—would constitute immoral conduct. Questions of morality fall within the jurisdiction of professional disciplinary bodies where these exist, and also within the judicial system. Non-premeditated flaws would constitute poor science. The responsibility for ensuring that the conduct of poor science is minimized is first that of teachers and supervisors of students in epidemiology and second that of the peer review system for the maintenance of standards.

The maintenance of standards, despite the foregoing, remains a function of the ability and integrity of those charged with

ensuring the standards. Yet, epidemiologists continue to allow themselves to be placed, wittingly or unwittingly, in conflict of interest situations. For example, in the context of social anthropology, Fetterman (21) has pointed to hazards of a researcher undertaking contract research, i.e., acting as an intermediary between informants (subjects) and sponsors (the body funding the research). Conflicting roles emerge which confer many responsibilities on the researcher (21). Any compliance on the part of consultant reviewers, or contract researchers, with the manipulation of science to support vested interests falls within the realm of ethical conduct, and may be labelled "unethical".

Since the science of epidemiology impacts directly, for example, on the setting of standards for the regulation of population exposures to possibly hazardous substances, and hence on interpretations and rulings in matters of law, epidemiologists have a public responsibility perhaps even more significant than that of other scientists (22, 23).

EPIDEMIOLOGY AS A PROFESSION

Based on the foregoing and, in particular, on a review of figure 1, it becomes evident that the only self-regulation among epidemiologists is that imposed through peer review. In fact, unlike other professional groups, epidemiologists have no ethics guidelines, no code of conduct, and there is no organization or association among epidemiologists that has the power to discipline or to award and remove the licence to practice.

In defense of the lack of ethics guidelines specific for epidemiology, a comparison with the development of codes of ethics among other professions is warranted. In essence, codes of conduct were developed initially among the more mature and long-standing professions. Epidemiology, relatively speaking, is at best in its adolescence; a code of conduct may have to await the attainment of greater maturity of the profession. It is this author's view, however,

that consideration should be given to ethics guidelines now.

In the absence of adequate self-regulation, epidemiologists may find themselves placed in professionally undefined roles. When an epidemiologist is asked, for example, to serve as an expert witness in a court of law, the epidemiologist enters the court of law to provide a "professional/expert opinion" as expected by the judiciary which deems the professions to be self-regulating (24, 25). In the absence of self-regulation, however, what then is the epidemiologist masquerading as under this scenario?

This commentary brings into the literature of mainstream epidemiology the need for broad concern about professional ethics, including concerns about conflicts of interest. It encourages the development of guidelines, first promoted in 1984 (10, 26), to forearm epidemiologists with the ability to recognize, above all, the scientific, ethical, moral, and legal implications of their work.

RECENT HISTORY OF ETHICS IN EPIDEMIOLOGY

The first epidemiologists to address in a profound way the issue of ethics in epidemiology, particularly with regard to the scientific method, were Susser (8) and Susser et al. (9) in 1977 and 1978, respectively. They dealt with problems regarding the choice of research questions and design, and the use of human subjects in research. Their paper on ethics per se (9) was published in the *Annals of the American Academy of Political and Social Science*. At that same time, Gordis et al. (7) had addressed the question of access to data, data privacy, and the limitations imposed on epidemiologic research through inaccessibility to data sources. Prior to this, various countries had legislated the need to protect data. For example, in 1970, the State of Hessen, Federal Republic of Germany, was the first (27) to legislate data protection; the United States enacted such legislation in 1974 (28). In 1973, the British Medical Research Council issued a statement on responsibility

in the use of medical information for research (29).

During 1980, various documents expanded on and refined the developments made through the 1970s (30–32). In the United States, refinements were made in 1981 concerning the data systems of the National Center for Health Statistics (33). In Britain, the Data Protection Act of 1984 (34), was followed in 1985 by an update (35) of the Medical Research Council's 1973 guidelines (29). By 1985, in the United States, the privacy laws had been found to be an impediment to the conduct of epidemiologic research, resulting in a formal report on the problems (36). Questions of data privacy thus have been extensively legislated in the United States, and responsibilities of researchers in dealing with data have been widely discussed.

In 1983, Stolley delivered to the Society for Epidemiologic Research his presidential plenary session remarks on the subject of "Faith, Evidence and the Epidemiologist" (37), subsequently published in the *Journal of Public Health Policy* (38). Stolley drew attention to scientific controversy involving epidemiologists over the past decade. He pointed to an inability (or, was it more an unwillingness?) on the part of epidemiologists to synthesize available data coming from all fields that bear on the problem at hand; instead, Stolley noted, they place extraordinary importance on small defects in study designs. In referring to the positive relation reported between toxic shock syndrome and the use of highly absorbent tampons, Stolley stated, "a group of investigators, either acting independently or hired by the company, began a kind of 'witch-hunt' for alleged bias and confounding in order to challenge these findings." Stolley reflected, "Biases that may be only postulated are somehow given a reality before their actual existence is even demonstrated" (38).

In 1982, Feinstein and Horwitz (39) published in *The New England Journal of Medicine* a paper on "Double Standards, Scientific Methods, and Epidemiologic Re-

search" in which they appealed to epidemiologists to ensure in their design (and in reporting research based on observational studies) that adequate techniques are included to assist the person reviewing, interpreting, and (especially) critiquing studies to assess questions of validity. They pointed to biases inherent in and difficult to control in observational research peculiar to epidemiologic study designs—as opposed to experimental research typical in, say, toxicologic studies.

Interest group influences

Miles W. Lord (40), Judge of the United States District Court for the District of Minnesota, in a keynote address on corporate ethics and environmental pollution, pointed out that: "Corporations create 80 per cent of our gross national product. They, of all entities working, have the most potential for good or evil in our society" (40). It is for this reason that many more examples emerge that relate to the influence of corporations and "big business" on epidemiologic practice. Of course, examples also exist that demonstrate questionable professional conduct among epidemiologists representing the constituencies of any interest group. In the late 1970s, Epstein (41), in his book, *The Politics of Cancer*, exposed the role of scientific experts employed by industry "to advocate its position in professional journals" and thereby delay or prevent effective government regulations. Epstein cited examples where epidemiologists had adopted a pro-industry advocacy role in questions of occupational exposure to asbestos, vinyl chloride, bis-chloromethylether, saccharin, and other chemicals, which then had been recently accepted as being carcinogenic.

Clayson and Halpern (42) in 1983 drew attention to the fact that in the United States: "Corporations are buying into basic laboratory science, toxicology, epidemiology and other areas of public health ... they 'lease scholars.' These new generations of students, lured by the ample fellowships, new programs and large research

grants, will rarely think twice about the social and political implications of their fascinating scientific work." (More recently, this sentiment was echoed in Britain (43).) Clayson and Halpern (42) pointed out that, "Industry's offensive against the regulation of health and safety hazards uses academics to downplay or deny the seriousness of the hazards ..."

As noted above, situations analogous to those described by Epstein (41) and by Clayson and Halpern (42) as typical of industrial apologists, apply equally readily in perhaps every area of epidemiologic endeavor. Indeed, apologists or advocates can be found in any activities involved with policy questions—be they government, granting agency, health agency, union, industry, academia, Royal Commissions, or any possible policy-impacting body. In all these areas, the risk exists of playing the tune called by the piper.

Indeed, Rothman (44), in a satirical thought piece, has cynically prognosticated the decline of epidemiology through the last two decades of the 20th century. He foresees, due primarily to overregulation, a reduction in the academic base of the discipline, with epidemiologists found more often "representing vested interests on one side or another of the ever-controversial issues" (44). Recognizing the vested interest role of the epidemiologist requires a parallel recognition of those human frailties that do a disservice to and undermine the profession. This awareness should encourage the compilation of a set of ethics guidelines out of which a code of ethical conduct eventually might emerge. For developing the guidelines, epidemiologists from all interest areas of application will need to actively participate. In this way, epidemiology more likely will rise rather than decline in the status accorded to it by society.

A recent example of profound governmental bias relates to acquired immunodeficiency syndrome (AIDS) research (45, 46). Many governments have been slow to respond adequately to the AIDS crisis and

have been reluctant to fund such research. Even more recently, governmental bias against educational intervention demonstration and research programs has been evident in the United States and Canada, and such bias has been particularly marked in certain African countries, despite advice and appeals from epidemiologists in public health.

An example where one branch of government obstructed research recently was alleged by the National Institute for Occupational Safety and Health against the US Office of Management and Budget (47-49) regarding a proposal to study the health effects of video display terminals. This exemplifies the lack of protection of any group when vested interests lobby for their own cause and have an impact on those in decision-making positions.

Axelson and Hardell (50) in 1986 described an experience in which they had been invited to serve as expert witnesses on an Australian Royal Commission examining the health effects of 2,4,5-T herbicide use on Australian veterans. This example (see later under "Essential Debate", p. 13) served to demonstrate the susceptibility of a Royal Commission to interest group influences. It is only when actual abuses of the science are brought to the attention of their peers (51-54) that epidemiologists can become sensitive to the issues of ethical conduct as professionals. Two quotations serve to underscore this point. "In our time, when science is being employed most conspicuously as an adjunct of politics and strategic national purposes, a vacuum of internal values tends to be invaded by prevailing external values" (55). Therefore, "academically-based professionals must work to establish within their universities a code of ethics and public accountability to expose and correct any conflict of interest resulting from industry financing of research" (42).

In 1984, Hickey (56) complained that numerous US Government agencies relied on linear extrapolation from high- to low-dose health effects, declaring this to be

"bogus 'science'". Such extrapolations, he stated, "rely on opinion, not on science," to the possible detriment of the public health. Hickey claimed that malpractice exists when "there are subcultures of epidemiologists, physicians, administrators, and politicians who are not qualified to practice biostatistics, but who, nevertheless, do practice it." A code of ethics for epidemiologists will need to address such concerns.

In 1985, this author (26) drew attention to interconnections among epidemiologic research, interest groups, and the review process, in a paper published in the *Journal of Public Health Policy*. An example was given which suggested corporate subterfuge because of alleged attempts by elements within a corporation to ensure that the results of an epidemiologic study (57) should not be published. One lesson from this experience is that epidemiologic consultants paid to review the work of other such consultants might serve science, ethics, and the profession better if the purpose of the review (or critique) is understood by all those concerned. Producing a balanced review with a summary that is comprehensible to both epidemiologists and business managers would be better than a technical critique that points, for example, only to potential biases (26).

A longstanding case of unethical research recently was reported from Auckland, New Zealand (58). An overzealous gynecologist who had an academic appointment at the major teaching hospital for women for more than 20 years had denied state-of-the-art treatment to a large series of patients with carcinoma in situ of the cervix. The interest of the "investigator" was in proving some rigidly-held bias that to maintain fertility was the proper (better?) course of treatment. The influence of this clinician extended over generations of now graduated trainees. Exposés of this type beg the question "for every situation that is exposed, how many lie hidden?" Being a clinical investigator, the gynecologist in question would have been bound by existing codes of medical ethics. It does, however, raise

additional questions about the review process and journal editorial policy, in that numerous manuscripts from this unethically conducted study had been successfully published (58).

Evidence of support for ethics guidelines

Is there support among epidemiologists for the proposal to establish ethics guidelines? It would appear so. In 1984, at the International Epidemiological Association Meeting in Vancouver, British Columbia, this author presented a paper titled, "Research, Interest Groups, and the Review Process" (10). So great was the support and encouragement received from that presentation, that a fuller embellishment of that paper was published in June 1985, as noted above (26).

In order to consider the question of how much support exists among epidemiologists for a set of ethics guidelines, early in 1985, this idea was formally proposed to a group of 34 epidemiologists in the upstate New York/Southern Ontario region; 96 per cent supported the idea to at least explore the need for and development of a set of ethics guidelines.

In June 1985, a proposal for a committee to examine the need for ethics guidelines was presented to the Society for Epidemiologic Research Annual Business Meeting in Chapel Hill, North Carolina. It required a two-thirds majority vote to be carried, since the proposal had not been previously circulated. It almost secured the required majority, but failed marginally, perhaps because some members felt that a code was being proposed to stifle criticism (59). This was not so: no code should inhibit scientific criticism.

Later in 1985, at the American College of Epidemiology Business Meeting in Santa Monica, the College's incoming president, Dr. Lewis Kuller, agreed, after a large majority vote among delegates present, to create an ethics committee. An analogous proposal to that presented to the Society for Epidemiologic Research and that had failed

(see Appendix) was presented at the American College of Epidemiology meeting. As of September 1988, however, no word has been received on the establishment of the proposed committee; neither was an announcement of any such committee's formation and activities made to the membership at the College's 1986 meeting in New Haven, nor at the 1987 meeting in New Orleans. Given the recent creation of the College, it may be that its directors would prefer not to assume any appearance of imposing criteria for self-regulation. Perhaps the above facts support the earlier impression of the adolescent stage of epidemiology as a profession in evolution.

A possible breakthrough for the more formal discussion of ethics was made when the Society for Epidemiologic Research Executive Committee resolved in June 1987 to create two committees to examine, respectively: 1) conflicts of interest; and 2) access to data by third parties. The Executive Committee, interested in moving with deliberation and focus, had felt that it was important to narrow the focus initially, since ethics in general was seen to be too broad and daunting a task. A symposium on conflicts of interest then was to take place in June 1988 at the Society's annual meeting in Vancouver, Canada. It is noteworthy that the said committee nevertheless saw fit to broaden its mandate. A plenary session on "Ethical problems of epidemiologists" (Chair: Dr. Paul D. Stolley) took place at the annual meeting.

While the Society for Epidemiologic Research's committee on conflicts of interest was being formed, a real breakthrough took place at the International Epidemiological Association's three-yearly Scientific Meeting in Helsinki, Finland in August 1987. First, a session on ethics was held. One of five papers dealt specifically with the question of a code of ethics for epidemiologists (60). Second, the Council of the Association undertook, over the subsequent three years, to formulate a draft set of ethics guidelines and present them for discussion at the next Association meeting scheduled for 1990.

This activity is in process under the stewardship of Dr. John M. Last.

WHY ETHICS GUIDELINES ARE NEEDED

Gordis (61) has stressed the need for creativity among epidemiologists as being the most important challenge over the next decade. He states that epidemiologists should be willing to tolerate the unorthodox and take risks with new ideas, and believes there is a danger that excessive methodological criticism could stifle creative research. Have creative approaches in the past indeed provided the "witch-hunt"-inclined with their ammunition to undermine the credibility of studies so that they should never see the light of day—and, thus, never be subjected to broader review and discussion? With such a threat, creativity well could be stifled.

It is clear that the "right" and "wrong" in epidemiology is not always "black" and "white" and that the "dos" and "don'ts" of epidemiology also are not clearcut. As far back as 1950, Pigman and Carmichael (62) suggested "an ethical code for scientists," recognizing the "big business" nature inherent in modern science. Epidemiology is a relatively new and important science, and there is no doubt about the special interests of growing numbers of groups in specific types of research and in the interpretation of evidence that the research generates. The potential for conflict-of-interest situations is great and, directly or indirectly, the epidemiologist is involved.

In 1984, Baram (63), in an article on the corporate management of health risks, wrote that "no panaceas are at hand for corporate health professionals" (including epidemiologists) who need to infuse the risk assessment decision-making process with a strong sense of "personal and professional ethics." How can this be achieved in the absence of any documented ethics guidelines for epidemiologists? Professions tend to be self-regulating and self-regulation cannot be achieved satisfactorily in the absence of documented guidelines. Epidemiology, as with other branches of science,

has its own special requirements for ethics guidelines or a code of ethics. The peculiar population-based focus of epidemiology makes its needs distinct.

Process needs

In developing guidelines, vigorous debate to sensitize and educate epidemiologists worldwide must occur. All epidemiologists should have the opportunity to provide input, whatever their application area, to the development of a professional code.

Ongoing and vigorous discourse is encouraged to heighten awareness of issues and situations that are faced by practitioners of epidemiology. Such discourse should serve to sensitize epidemiologists and their students to the issues; it should imbue them with a set of values based on the pursuit of truth, independent of any vested interests. It is proposed that by such action, the credibility and professional status of the discipline will be enhanced; the advancement of both epidemiologic knowledge and the science itself will be more assured.

WHAT A CODE MIGHT INCLUDE

It took six years (1979–1985) for the International Statistical Institute to develop and adopt its "Declaration on Professional Ethics" (64). This international declaration specifically was intended to enable the statistician's individual ethical judgments and decisions to be informed by shared values and experience, rather than to be imposed by the profession. The declaration therefore sought to document widely-held principles of statistical enquiry and to identify the factors that obstruct their implementation. Hence, this international body's declaration is to provide guidance rather than regulation, and is to promote knowledge and interest in professional ethics among statisticians worldwide.

Since there are many equivalents between the practice of statistics and the practice of epidemiology, it might be prudent, in the interests of expediting the development of a set of professional ethics guidelines for epidemiologists, to scrutinize

the International Statistical Institute's experience in this regard. Since the closest disciplinary analogue to epidemiology could be said to be the methodological principles of statistics, the experience of that organization might serve as a model that epidemiologists could adapt to their own specific needs.

The International Statistical Institute declaration comprises four major categories: 1) *obligations to society*, including being mindful of conflicting interests, widening the scope of the discipline, and pursuing objectivity; 2) *obligations to funders and employers*, including clarification of obligations and roles, assessing alternatives impartially, not pre-empting outcomes, and guarding privileged information; 3) *obligations to colleagues*, including maintaining confidence in the discipline, exposing and reviewing methods and findings, and communicating ethical principles; and 4) *obligations to human subjects*, including the avoidance of undue intrusion, obtaining informed consent, modifications to informed consent, protecting the interests of subjects, maintaining confidentiality of records, and inhibiting the disclosure of identities (64). These major content areas are clearly also directly relevant in the practice of epidemiology.

The schematic adopted by the International Statistical Institute is consistent with that recommended by the American Association for the Advancement of Science's Professional Ethics Project (3). This should not be surprising, in part because the American Statistical Association is affiliated with the American Association for the Advancement of Science. Because at present no epidemiologic group is so affiliated, consideration might be given to the benefits of affiliation by epidemiologic organizations. Such affiliation could assist epidemiologists in achieving par with the other professions in North America in terms of professional ethics development.

For an epidemiologic declaration, however, content areas specific to the nature of epidemiologic practice likely will be needed,

in addition to those areas common to other professions. These might include: 1) the choice of research questions; 2) access to data; 3) the advocacy and expert witness roles; 4) the duty to inform subjects of a study's findings; and 5) ensuring that the list of questions included in the Appendix is addressed by any guidelines.

The question of deciding whether or not to publish the findings of a study has been discussed by Shapiro (65). The publication of medical research in general has been discussed by others (66, 67).

In Britain, the Medical Research Council set out its views on the conditions under which information about identified patients may be obtained and used for research (29). This statement recently was revised (35) to protect confidential personal information. Hence, two themes are addressed: 1) "a concern to avoid causing harm or distress to any individual or his family"; and 2) "a concern to respect the doctor/patient relationship". Such guidelines could be helpful in the pursuit of guidelines specific for epidemiologists.

A number of papers have discussed the proper conduct of epidemiologic research (39, 68, 69), while others have discussed institutional review boards (70-74) and the impact of overregulation on epidemiologic investigation (44, 70, 71), confidentiality (7, 11, 31, 32, 36), the more recent questions of access to existing data (75-77) and/or of recontacting subjects (78), and questions of authorship, editorship, the review process, and publication (65-67, 74). All of these contributions to epidemiologic thought and practice provide a partial basis from which an encompassing set of ethics guidelines for epidemiologists could be developed.

Ethical dilemmas have been raised in the areas of primary prevention, public health, and health promotion by Lappé (2) and by Last (79), and in two texts edited by Doxiadis (80, 81). Others have addressed particular aspects in terms of the principles of autonomy (82, 83), paternalism (84), social justice (85, 86), the protection of privacy (85-87), the problem of conflicting loyalties

(86), and the question of mores and values in the context of education needed to contain the spread of human immunodeficiency virus (HIV), the putative cause of AIDS (79, 88).

Large-scale interventions have been addressed by Weed (89) in the context of chemoprevention trials, which can be associated with untoward side-effects. Weed recommended that agreements to restore to health and to make adequate financial awards to harmed subjects be incorporated into the consent document. Such concerns for review boards and researchers can be extended to any mass intervention and to epidemiologic practice in general, including vaccination and screening programs. In the latter situations, government epidemiologists may have a significant role to play in ensuring analogous compensation to people harmed through mass intervention programs.

Skrabanek (90, 91) argues from the public health practice perspective that epidemiologists must limit themselves to *informing* the public, and he maintains that: "they have no right to *tell* people what they *should* do. If they start advising government on 'population measures,' they declare themselves as agents of social control, they become preventionists for whom the interests of the state override the interest of the individual." These concerns have relevance also to workplace health promotion (86, 92), and could be in conflict with the economist's view (17) of "societal ethics".

Most recently, Weed et al. (93) examined an ethical dilemma central to epidemiology in asking the question, "Must epidemiologists await the discovery of biologic explanations of interaction before using observed statistical interactions for the public health?" Weed and Trock (94) provide part of the answer to this dilemma by showing that neither the additive nor the multiplicative models represent a reasonable *threshold* level for public health application of causal interaction or of preventive interaction, respectively. Clearly, further discussion is needed to clarify the epidemiologic

gist's role in, and appropriate ethical responses to dilemmas posed by direct involvements in public health.

In addressing the role of epidemiologists as reviewers in criticizing a piece of work, two definitions for the word "criticize" warrant consideration: 1) "to consider the merits and demerits of and judge accordingly: evaluate" (6); and 2) "to stress the faults of" (6). It is the first of these two definitions that this author encourages epidemiologists to adopt in providing critiques.

Four further points that then might be considered for inclusion in a set of ethics guidelines, specifically pertaining to the *consultant* role of epidemiologists, are: 1) be aware of the use to which a critique is to be put; 2) provide some balance in the critique by identifying both strengths and weaknesses of the study under review; 3) explore as part of any critique the basis and possible direction of any bias that may be postulated; and 4) provide a definitive summary of the critique within a general epidemiologic perspective, relating the critique to the results of the study under review. The summary should be comprehensible to business managers who may be the initiators of consultant reviews and who have the responsibility of translating scientific recommendations into policy and practical action. Scientists who assume that their work is not open to abuse by those with special interests are naive. A definitive summary statement may reduce the likelihood of managers being selective in their interpretation from among the scientific detail forming the bulk of a consultant's critique.

The vain attempts for over 40 years in the International Statistical Institute to codify the statisticians' professional ethics are described by Jowell (95) in a way that could help epidemiologists avoid significant delays in their own ethics deliberations. The American Statistical Association's influence on the Institute's deliberations, together with their own regionalized debate that has not yet been concluded (95-97), provide a lesson for how regional epidemi-

ologic organizations may choose to proceed in relation to the International Epidemiological Association's movement toward developing a set of ethics guidelines for epidemiologists. As the International Statistical Institute did, epidemiologists may do well to devise a code that serves an educational function rather than producing a code that attempts to regulate the profession.

The authors responsible for drafting or for contributing to a set of ethics guidelines would do well not only to examine the relevant experiences of those professions mentioned throughout this commentary, but also to examine the experiences of as many other professions as possible. For example, the experience of a cancer hospital (98), the World Health Organization's guidelines on studies in environmental epidemiology (99), the guidelines to the code of practice of the Canadian Health Record Association (100), and an examination of say, the code of ethics of the Canadian Medical Association (101) could contribute to the necessary thinking among epidemiologists if a set of guidelines is the goal. In addition, the services of a professional ethics group could assist in the process.

RISKS IN THE ABSENCE OF A CODE

In the absence of ethics guidelines, a disservice to epidemiology could arise in at least four ways: 1) methodological innovation will be discouraged for fear of providing sponsors with arguments which could be used to attack or defend future findings; 2) the credibility of epidemiologists may be diminished if opinions favored by an interest group are seen to be purchasable; 3) no framework or basis exists within or against which to develop ethics curricula, so necessary in epidemiologic teaching programs; and 4) the professional status of epidemiology could be questioned and/or undermined.

ADVANTAGES OF A CODE

In the presence of ethics guidelines, employers of epidemiologists (regardless of

their constituency) can be informed of the professional basis on which the epidemiologist conducts him/herself, minimizing the risk of competing loyalties. Employer expectations, particularly in relation to the ethic of beneficence, then may be more inclined toward reasonableness, especially when one recognizes that this ethic must be interpreted as "doing good" for the *common good* rather than "doing good" for the employer's short-term gain. In addition, when actions, inconsistent with professional ethics, are expected of an epidemiologist, the employee then can bring the professional code to the attention of the employer. If needed, the professional organizations could be called upon to mediate, to provide support, and/or to provide guidance in difficult situations.

Indeed, the utility of a written code for epidemiologists is great. In addition to the above uses, documented guidelines also could serve for posterity, a hallmark of civilization; for teaching purposes and as a framework within and around which to debate the issues; as a benchmark in the evolution of the discipline; as a guide to which to adhere in everyday practice and to turn to in times of uncertainty; to demonstrate the maturity of epidemiology as a profession; to support the professional status of epidemiology; to minimize risks of infringements that could be damaging to the advancement of knowledge; to enhance the credibility of the profession; as a basis for self-regulation and hence to legitimize its professional status; and as evidence for state-of-the-art conduct in cases brought before the courts for questions of professional competence (102).

ESSENTIAL DEBATE

The debate on ethics in epidemiology is well-started. Coye (103) has published a set of operational guidelines (or ethical principles) to form the basis for an ethics code for occupational medicine research and for review and approval of research projects. These codes embrace the need to communicate research plans and results of re-

search studies to the worker populations that form the basis of such studies.

Goldsmith and Israeli (104), in a paper on ethical problems in occupational epidemiology, stress the need for open debate of the issues and conflicts facing occupational epidemiologists, rather than the need for ethics guidelines per se. Certainly, ongoing discussion is essential.

As noted earlier, in 1986, Axelson and Hardell (50) brought to the attention of epidemiologists the blatant disregard not only for unwritten, but generally accepted ethical standards, but also to the questionable morality of those involved in misquoting, distorting, plagiarizing, and falsifying data to suit their own ends. The need for ethics guidelines indeed has been raised and discussed since 1984 at numerous scientific sessions and business meetings.

Most recently, Hessel and Fourie (105) have contributed to the ethics debate with their ideas on a code of ethics for epidemiologists practicing in Southern Africa.

RECOMMENDATIONS AND CONCLUSIONS

Epidemiologists have been invited to formulate their own experiences regarding ethical conduct, and to use the *Epidemiology Monitor* as the best available medium at present to promote understanding of the subtleties and incentives in issues covering the broad range of epidemiologic endeavor. In this way, the appeal of O'Berg (106) that "we each need to examine our motives and guard against letting them drive us" will gain permanence in the day-to-day functioning of epidemiologists.

A catalogue of questions that a code of ethical conduct might serve to address was presented to the 1985 American College of Epidemiology Meeting and it appears in the Appendix. The questions catalogued in the Appendix require that responses to them be developed. Should these responses be developed individually, through the College, the International Epidemiological Association, the Society for Epidemiologic Research, and/or other regional/national epidemiologic associations/societies? The

optimum might be for all interested groups of epidemiologists to act together in this regard.

Corbett (107) has stated, "Essences of right and wrong can be hard to calibrate, hard to determine. However, there is a gauge that not only evokes the best in human spirit, but is as practical as any ethical gauge can be. It is called the Golden Rule. Essentially, it tells us to treat others as we would want them to treat us or our loved ones. It tells us not only to do our level best, but also to assert ourselves if we find someone else who has done ill."

In conclusion, a quote from Yoder (108) succinctly expresses the sentiments of this paper: "Any group that calls itself professional must be concerned with ethics and must attempt to define ethical conduct for the group." It is with such conviction that epidemiologists might be motivated to develop for themselves a set of professional ethics guidelines as a basis for a possible, duly documented, code of ethical conduct. Professional self-regulation would presuppose the existence of such a code.

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APPENDIX

Text of motion submitted by the author to the American College of Epidemiology (ACE) Annual Business Meeting, Santa Monica, CA, September 20, 1985.

Re: Establishment of a committee to explore the need for ethics guidelines for epidemiologists

Anecdotes abound of questionable ethical conduct involving epidemiologists. Such experiences may be occurring with greater frequency and with increased severity. Historically, the relatively few practicing scientists that existed had cultivated a code of professional tradition and ethics, largely in unwritten form, to advance their disciplines. Today, there are greater numbers of scientists having more complex interrelationships with government, industry and society than had existed previously. Opportunity for infringement of unwritten codes thus continues to grow. Since the late 1970s, some scientific disciplines have developed codes of ethical conduct specific to their needs. Others are developing codes.

It is proposed that epidemiologists now consider the need for a formal code of ethical conduct and then set about developing such a code if so indicated.

Successful development may require joint participation of existing epidemiological societies, associations, sections and groups (national and international) as well as the American College of Epidemiology.

NOTING THAT:

1. There has been a call for a code of ethical conduct for epidemiologists;
2. No code of ethical conduct or set of ethics guidelines exists that has relevance to epidemiologists from either a science and/or a medicine background;
3. No code should be developed that restricts scientific criticism;
4. Students are rarely exposed in their epidemiology programs to a course on ethics;
5. The effects of disregard for those scientific traditions based largely on unwritten ethical standards can have a profoundly negative effect on the advancement of science;
6. Since the late 1970s, numerous affiliated societies and academies of the American Association for the Advancement of Science (AAAS) have seen fit to work jointly in developing codes of ethical conduct specific to their respective branches of science;
7. The AAAS itself addresses ethical problems related to science and technology which cut across disciplinary lines;

8. Each AAAS-affiliated society and academy of science acts independently both in its own specialist field and/or geographical area;
9. Areas of current concern to epidemiologists include the need for guidelines on how epidemiologists might respond:
 - a) to serving as expert witnesses in courts of law;
 - b) to interest group pressure for a desired interpretation of epidemiologic findings;
 - c) to the media's need for information, the public's right to know, and the epidemiologist's risk of being perceived as lobbying for research funding;
 - d) to interacting with Institutional Review Boards;
 - e) to the establishment of steering committees involving joint participation of unions, management, academics and any other relevant group;
 - f) to conflict of interest allegations;
 - g) to funding needs and limitations from any source;
 - h) to any limitations imposed on the epidemiologist's autonomy and/or academic freedom by any agency/funding source;
 - i) to review committees, whose composition is *exclusively* of people whose philosophic approach is known to be diametrically opposed (or at best indifferent) to the approach under review;
 - j) to reviewers known to be both ignorant and/or inexperienced on the subject matter under review, or to requests to serve on review panels on topics that the epidemiologist knows himself/herself to be ignorant and/or inexperienced in;
 - k) to demands of management that require the withholding of criticism provided by consultants from the colleague whose work is being critiqued;
 - l) to the pressure to publish;
 - m) to demands or pressures or inducements to conduct or continue studies with the prior knowledge that statistical power is inadequate;
 - n) to pressure to conduct research with inadequate funding;
 - o) to pressure to conduct a "token" study so that the funding body can be seen to be active in an area knowing that, at best, equivocal results only will be found;
 - p)* to falsification of evidence as presented before Royal, Congressional or other Commissions;
 - q)* to political directives issued by the Office of Management and Budget to amend studies rendering them of questionable scientific usefulness (see points m) and o) above);
 - r)* to the requirement for the pooling of resources between public bodies and interest groups (see point e) above);
 - s)* to the need to engender community support and the confidence of human subjects for their participation in research;
 - t)* to the role of epidemiologists in promoting not only public health, but of social awareness (e.g., minorities in most exposed jobs);
 - u)* to the use of ethics for other purposes, such as political posturing;
 - v)* to the use of subpoena or other legal manoeuvres through study populations;
 - w)* to the obligation, if any, to inform cohort subjects of study results that may modify individual disease risk;
 - x)** to ethics committees (IRBs) who, in the absence of the mandate and/or the scientific expertise, assess methodologic aspects of a research proposal as a part of the "ethics review";
 - y)** to the publication of papers based on unethically conducted research;
 - z)*** to the need for collective informed consent (e.g., union, headman/chief, community/group leadership) prior to individual informed consent;
 - aa)*** to the need to protect the interests of a study population (e.g., oppressed or stigmatized groups such as, for example, South African blacks, or homosexual men) from governmental manipulation or economic exploitation that could arise as a consequence of information published from epidemiologic studies;
 - bb)*** to the pressure from salaries and promotions committees to publish research papers in international prestige journals, against the knowledge that publication in local journals will be more likely to have practical impact on questions of health policy.

* These points arose from the paper presented by Dr. Axelson and questions from the floor, Los Angeles, CA, September, 1986.

** These points arose from discussions at the International Epidemiological Association Meeting in Helsinki, Finland, August 8-13, 1987.

*** These points arose from a seminar given in the Department of Community Health, University of the Witwatersrand, Johannesburg, South Africa, March 24, 1988.

BE IT RESOLVED THAT:

The ACE establish a committee to explore the need for ethics guidelines for epidemiologists.

Suggested Ethics Committee Interim Mandate:

The Committee define its own terms of reference and objectives to include possibly the following:

1. The Committee encourage the joint participation of epidemiologists from all areas of epidemiologic endeavor;
2. The Committee investigate those codes of conduct already developed by AAAS-affiliated societies and academies and consider the desirability of such an approach for epidemiologists;
3. The Committee explore the possibility of affiliation of the ACE with the AAAS and examine any potential advantages and disadvantages of such affiliation;
4. The Committee should identify resource groups such as the Center for the Study of Ethics in the Professions;
5. The Committee could prepare a report with recommendations to the ACE membership before the 1986 Business meeting which should be contained in the final program mailing. The report should include the Committee's defined mandate should it recommend its continuation beyond its initial year of operation.
6. Any new terms or amendments as the Committee may determine from time to time.