ETHICAL DECISION-MAKING IN EPIDEMIOLOGY:
THE CASE STUDY APPROACH

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Abstract—The experience of other health professions that have been concerned with professional ethics over the past number of years can be directly applied in epidemiology. A schematicized model, adapted from Storch and based on the nursing experience, provides a synthesis of those considerations necessary for ethical decision-making. An example demonstrates the process by which the model can be used. While a checklist procedure is regarded as neither useful nor appropriate for making an ethical decision, the existence of professional ethics guidelines is deemed a prerequisite, because it embodies the profession’s values and social responsibilities. The place of professional ethics guidelines in making an ethical decision is central to the model and is shown to be fundamental to continued ethical conduct among epidemiologists.

Ethics Professional Epidemiology

INTRODUCTION

I hope that my 20-minute slot will usefully demonstrate how everything we have learned over the past day-and-a-half about ethics can indeed (to use Doug Weed’s term) be merged with epidemiologic research and practice.

But, before I proceed, I want to thank the IEF, the du Pont de Nemours and Company Inc., William “Bill” Fayerweather and the planning committee for hosting and organizing this milestone conference. Those of you who are aware of my keenness, over the past 5 years, to see epidemiologists begin an open, honest dialogue on ethics, can appreciate how pleased I am to be here, participating in this very special event and particularly in the session on approaches for the future. Thank you again.

Ethical decision-making is the process of using rational thought, based on a set of principles, to make decisions about which course of action is morally preferable in a given situation [1]. As epidemiologists look to the future, I suggest that not only must we collectively become involved in formulating the ethics guide-

lines for our profession, but we must integrate ethics’ principles into our individual professional daily practices as an aide to making ethical decisions. This paper focuses on the process of making ethical decisions rather than on the development of the necessary guidelines per se. The process, as I hope to demonstrate, serves to uncover ethical dilemmas and provides a strategy for resolving them. It is intended to provide a basis, taken from the nursing profession [2, 3], for the philosophical, but nevertheless practical analysis of ethical issues experienced in epidemiologic research and practice.

A caution is needed. At first glance, it may be construed that in providing any kind of basis for ethical decision-making—be it in the form of a “framework” or a “schematic”—a checklist approach is being recommended. This is not so; checklist approaches have no place in resolving ethical dilemmas, because:

(1) the meaning of and assumptions behind those points comprising a checklist cannot be appreciated/interpreted equally
by all who have to apply them now or in the future; and
(2) a checklist can become an end in itself rather than the means to that end.

The significance of this caution will become evident by the end of this paper. For now, suffice it to say that ethical decision-making cannot be short-circuited; it is a process that means to challenge our very rationale every step of the way when we make both research and practice-based epidemiological decisions. The end lies in making an ethical decision.

We will see the means towards making an ethical decision draw on all of those principles that have been discussed at the conference, and perhaps also on others. Ethical principles are derived from moral philosophy and are based upon the "rightness" or "wrongness" of behavior (2, 4, 5). Ethical decision-making requires a clear understanding of what the situation is, and of the principles relevant to the dilemma (2).

BELIEFS PERTAINING TO EPIDEMIOLOGIC RESEARCH AND PRACTICE

Before we plunge into ethical decision-making, however, epidemiologists will need first to affirm the following three beliefs (pertaining to the profession, the individual and one's own situation) as fundamental to being an ethical epidemiologist, because these beliefs will influence the ethical decision-making of the epidemiologist.

(1) The Profession will have to develop a code of ethics/ethics guidelines, which will include standards of practice, to which the professional epidemiologist will subscribe. Subscribing to such guidelines, the epidemiologist will recognize the normative values and responsibilities of the professional to society, peers, the profession, sponsors, employers, students and subjects. In addition, it should be recognized that professional competence is essential to ethical research and to the practice of epidemiology.

(2) The individual will clarify his/her personal values when making ethical decisions. Ethical decisions are influenced by the beliefs, values, and experience of those individuals involved in a situation. It is the study of ethics and ethical situations that can assist the epidemiologist to recognize the presence of conflicts or tensions, and enable him/her to make reasoned decisions rather than intuitive responses.

(3) The situation within which epidemiology operates can present ethical dilemmas which involve a choice between competing, and usually equally negative or positive, alternatives. Each ethical dilemma is unique and identifies the parameters of conflict which are not solvable, but which can be resolved.

Thus, presupposing the existence of ethics guidelines for epidemiologists, there are five steps to be worked through in a generic problem solving model to ensure a more ethical decision (see Fig. 1). Although the actual steps in ethical decision-making models may vary, they all require analysis which includes: data collection, identification of the problem, identification of alternatives, choices, and action and evaluation. The epidemiologist is not unfamiliar with this approach in research. The same problem-solving skills apply in an ethical analysis.

The nature of ethical decisions involves choice between competing alternatives, whatever the disciplinary base of the profession. Therefore, all models for ethical decision-making incorporate an examination of the values of the participants (e.g. the researchers, sponsors, agency engaging in epidemiologic activity, study subjects, consultants, society, government, or any other interested party), and a high degree of commitment and accountability. The model adapted from Storch and presented here (Fig. 2) has been selected for its clarity as a schematic which shows the interconnectedness of the numerous principles required for ethical decision-making. Storch's model synthesizes the relevant deliberations for ethical decision-making and reduces the 5-step generic model into 3 steps, essentially by consolidating the middle 3 steps of Fig. 1. Other models do exist (e.g. Bergman [6], Curtin and Faherty [7]). Regardless of which model is selected, its role is to provide guidance in deciding what ought to be done. The model should, however, not be termed a "checklist." In what follows, the generic problem-solving five-step approach is used.

A STEPWISE APPROACH TO ETHICAL DECISION-MAKING

Step 1: data collection
The analysis commences by gathering all relevant background information. Some specific questions include:
—Who is involved in the situation?
—Who are the interested parties?
—What is the scope of their authority and responsibility?
—What is the purpose behind the question being asked?
—Whom will the outcome affect?
—What information is required? Determine the relevance.
—What facts are known about each party's interest in the question being asked? (e.g. scientific interest, financial interest, values, beliefs, philosophy, etc.)

Step 2: clarification and evaluation

Fig. 2. Making an ethical decision. (Adapted from Storch JL, 1989: unpublished.)

—How does each party view the situation? (e.g. calm, upset, objective, etc.)
—How free is each party/person to make a decision?
—Is the work able to be given due priority? Are adequate resources being provided to address the question?
—What are the relevant legal and scientific principles?
—What are the time frames?
—How much financial gain/loss is involved to each party?

Fig. 1. Generic problem-solving model for ethical decision-making.

Step 3: identification of alternative actions
We are required to specify all options as possible courses of action to be taken. This step requires that we evaluate each option under Step 2, and consider the range of possible actions and anticipate the likely consequences of each. Re-formulate the problem, if necessary; re-focus the problem and attempt to achieve consensus among all interest groups and indi-
compensated for your report which is not to be shared either with the student or his academic advisors.

This scenario will now be subjected to ethical analysis as described in the first part of this paper.

Ethics Principles

Autonomy
Beneficence
Non-maleficence
Veracity

The five problem-solving steps follow:

(1) Gather all relevant information

There are a number of interested players: the student, the university, local industry management, corporate management, the scientific community, and the consultant. The academic's role is to advance knowledge; industry is to make a profit; the consultant is to earn a living.

A suggested purpose behind the assignment is to invalidate the findings of the study.

The finding of a flawed study will affect the student negatively. Science and the workers will be spared poor research. The manager will be praised for killing a poor study.

On the other hand, the finding of general support for the study will affect the student positively. Knowledge will be advanced and the health of workers can be protected. The manager may be demoted; the consultant may not see future work from that source.

The finding of some strengths and some weaknesses is the likely finding from a competent review of a carefully conducted study.

(2) Specify all components of the identified ethical dilemma

Will the principles of autonomy and veracity be compromised?

- Will the consultant be free to provide an objective, scientific report?
- Free communication in science vs concealment
- Bias vs objectivity in reporting that which is "commissioned."

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- Ethical duty of the professional corporate manager to the social good vs the corporate good.
- Ethical duty of the professional consultant to the social good vs personal self-interest.

Will the principle of non-maleficence be compromised?

- Corporate interests are being given priority over the public interest, the student and science.

What are the legalities of the contract?

- Once the agreement is made, the consultant has an obligation to be loyal to it.

(3) Specify all options as possible courses of action, and likely consequences

(a) Decline the assignment. A consequence could be that the manager finds another consultant willing to support him in his goal.

(b) Accept the assignment. Real flaws may justify the invalidation of the study. A consequence could be the exclusion of such a study from peer review; student fails to graduate.

(c) Accept the assignment and ensure objectivity by producing a balanced and understandable report, providing a clear summary statement as to the credibility of the findings to the manager. This could serve to make the manager's case less defensible.

(d) Accept the assignment and ensure objectivity by producing a balanced and understandable report. Then, provide a clear summary statement of the credibility of the findings to corporate management, under separate cover from the manager's report that you had contracted to provide to him directly. This, however, could constitute a breach of contract between the consultant and the manager.

(e) Accept the assignment only if all interested parties can be consulted in the process of the review. A consequence could be the advancement of knowledge to the satisfaction of all interested groups. The consultant could win or lose the contract. The manager may fail the test of "industrial apologist."
(f) Educate: advise the manager, in writing, with a copy to his manager, of the ethical dilemma that his request poses to you. Risk winning or losing the contract. The manager may be censured within the corporation. Future contracts may not be offered to you as a consultant reviewer by the said manager.

(4) Select a single best alternative

Reconciling facts with ethical, legal and scientific principles, values, theories and norms would, it would seem, prefer the last two options. Ideally, consensus agreement of all interested parties could be achieved, assuming that their values and beliefs permit such a discussion. Perhaps an institutional review board approach to selecting the best alternative would be optimal. Of course, to select the best alternative, the normative basis for making an ethical decision presupposes professional self-regulation, based on the existence of a statement of the profession's normative ethical principles; i.e. a set of ethics guidelines or a code of ethical conduct.

(5) Act and review

Depending on the course of action selected, a number of possible outcomes are likely. Ideally, the consultant obtains the contract and no harm is caused to any interested party. Whatever is learned, including the process, should be duly documented for posterity. Such case studies will serve as a benchmark for future reviews of the professional code of ethics itself. This concludes the ethical analysis.

CONCLUDING REMARKS

This paper has attempted to demonstrate the centrality of ethics guidelines to ethical conduct in epidemiology. A case study, analyzed in accordance with professional ethics guidelines, has served to illustrate the process through which the epidemiologist's thinking is to proceed in making an ethical decision. The documentation of such deliberations is for epidemiologic posterity.

Acknowledgements—Dr Janet L. Storch is gratefully acknowledged for providing resource material and collegial discussion which has advanced this author's thinking in the subject area. Her editorial assistance also is appreciated. Treasure Whaley provided technical assistance.

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