

## 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 that 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 alternative actions, choice, 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 professional. 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

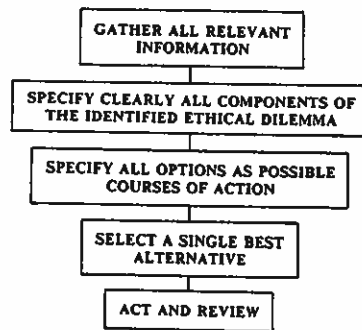


Fig. 1. Generic problem-solving model for ethical decision-making.

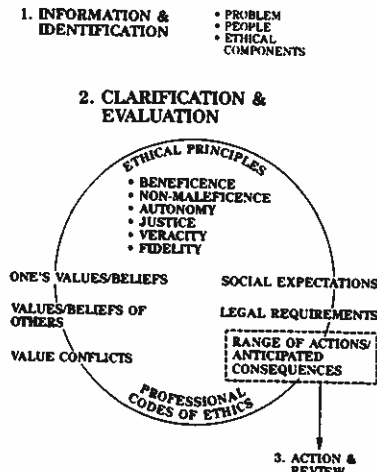


Fig. 2. Making an ethical decision. (Adapted from Storch JL, 1989: unpublished.)

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 Flaherty [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 deemed "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.).

- 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?

##### Step 2; identification of the problem or dilemma

We must specify clearly all components of the identified ethical dilemma. Consider all options and those that have been invoked in similar circumstances in the past. Consider why some options are favored over others; and why not. Note all of the issues that bear on the situation, and consider the values of both the major and the minor players. Remember the professional's value of the social good. Identify dilemmas. Where possible, initiate dialogue and communication among all stakeholders through soliciting the information necessary to clearly specify all the above components. Some specific questions include:

- What issues are at stake?
  - loyalty—competing interests?
  - autonomy of the researcher?
  - freedom vs submission?
  - truth-telling vs concealment?
  - lying or withholding truth vs obtaining informed consent?
  - duties conflicting with outcomes?
  - conflicting rights (privacy/confidentiality vs public interest)?
- What are the legal and ethical rights and duties of each person?
- Whose "best interest" is being served? (e.g. self-interest vs employer's interest vs public interest).

##### 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 component 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-

viduals. Carefully document responses to the following questions:

- What are the consequences of each course of action (including doing nothing) and what good/harm will result from each?
- Can the client/sponsor/subject understand the information? Can they act on the information once they are provided with it?
- Are these options consistent with the law and with the scientific method?

#### Step 4: making a choice

We are required to select a single best alternative from all of the options outlined under Step 3. To do this we should:

- Reconcile facts with ethical, legal and scientific principles, values, theories, and norms.
- Determine who does the selecting.
- Determine what are the values of those involved regarding possible actions.

#### Step 5: taking action and evaluating the action

The decision arrived at after going through the previous four steps is implemented. Remain sensitive to possible untoward consequences by a readiness to review, evaluate and take corrective action if necessary. Finally, generalize the experience and document it for posterity, so that others in the profession may benefit.

Action and appropriate review, which will involve an evaluation component, require an understanding of:

- What are the outcomes?
- At what stage are initial outcomes to be assessed?
- Were there any unforeseen outcomes?
- Is it possible to modify the protocol in the presence of unforeseen outcomes?
- Did the chosen solution meet identified objectives?
- What was learned from this situation?
- How would this help in a similar situation?

A point to be made in terms of case studies is that the American Association for the Advancement of Science, through its Scientific Freedom and Responsibility Programs Office in Washington, D.C., runs a Professional Societies Ethics Group. Membership in such a forum could assist in shaping ethics thinking among epidemiologists and also provide a forum in which to discuss our case studies. The latter will ensure that the resolution of duly resolved ethi-

cal situations will improve the quality of documentation to better serve posterity and to make better decisions more efficiently in the future [8, 9].

#### Case study

Case studies are useful to illustrate ethical principles and the process involved in resolving ethical dilemmas. Prior to this, however, some understanding of the widely used ethical principles is in order: *autonomy*, *beneficence*, *non-maleficence*, and *justice* are most commonly considered and have been addressed in earlier papers. In addition, however, *fidelity* (faithfulness)—promises, implied or expressed, that cannot be fulfilled, can pose an ethical dilemma; and, *veracity* (truthfulness)—the obligation to be truthful, and not to deceive people (e.g. peers, study subjects, employers, sponsors, etc.) are two more significant/important ethical principles.

#### Case study—The Consultant Critique

Consider the following hypothetical situation. This example has been generalized from a true experience. Its documentation is intended, consistent with the requirements of the discipline of professional ethics, to contribute to learning and hence for posterity. It is not intended to embarrass or to exact retribution.

A study is being completed for a large industry, a component of a national corporation, by a university-based epidemiology doctoral student. The study is to be the student's dissertation. A thorough investigation is made possible only because of access permitted to all workers' personnel records. Relationships between the industry management at the local site (whose population is being studied) has been cordial. At the corporate level, relationships have been excellent. Communication among student, university academic and administrative representatives, and the corporation have been open. It is generally agreed that a meticulous investigation is being conducted. In what were to have been the final weeks of the investigation, corporate headquarters employs a new manager of its epidemiology department. The student's dissertation is presented to the new manager, who then proceeds to take it upon himself to attempt to invalidate the findings of the study. As part of this attempt, you—as an external consultant epidemiologist—are asked to critique the study. The manager conveys his general misgivings to you. You are to be

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 Identified

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.
- The relevant scientific principle of free exchange of information and the sharing of knowledge is to be violated.

#### (2) Specify clearly 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."

Will the principle of beneficence be compromised?

- 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/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.

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### REFERENCES

1. Fromer MJ. *Ethical Issues In Sexuality And Reproduction*. Toronto: C. V. Mosby; 1983.
2. Alberta Association of Registered Nurses. *Guidelines for Bioethical Decision-Making in Nursing*. June 1987: 21.
3. Storch JL. Ethical principles and approaches to decision-making. Paper presented to the Community Health Nurses of British Columbia, 5 May 1989; Unpublished.
4. Veatch RM. *Case Studies in Medical Ethics*. Cambridge, Mass.: Harvard University Press; 1977: 420.
5. Beauchamp TL, Childress JF. Chapter 1, Morality and ethical theory. In: *Principles of Biomedical Ethics*, 2nd edn. New York: Oxford University Press; 1983.
6. Bergman R. Ethics concepts and practice. *Int Nurs Rev* 1973; 20: 140.
7. Curtin L, Flaherty MJ. In: Bowie MD, Ed. *Nursing Ethics: Theories and Pragmatics*. Englewood Cliffs, N.J.: Prentice-Hall; 1982: 61.
8. Frankel MS. Professional codes: why, how, and with what impact? *J Business Ethics* 1989; 8: 109-115.
9. Gellerman W, Frankel MS, Ladenson RF. The centrality of values and ethics to professional life. In: *Values and Ethics in Organization and Human Systems Development: Responding to Dilemmas in Professional Life*. San Francisco: Jossey-Bass Inc; 1990.