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TASK FORCES

Task Force I: Background and General Principles

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Introduction

The growing attention to ethical issues, especially in politics, business and medicine (1–14), has been particularly evident in the arena of cardiovascular disease. Physicians today face a host of environmental, societal, religious, legal and economic pressures that provide potentially conflicting responses to ethical issues. These issues include, but are not limited to, patient rights, animal welfare, limited reimbursement for patient care, the role of industry in shaping cardiovascular medicine as well as instances of scientific fraud, conflict of interest, limited resources and a resulting decline in the public's perception of the physician as a virtuous professional. Because of the special pressures these developments bring to bear on cardiovascular medicine, it is appropriate that the American College of Cardiology review some of these issues and offer guidelines for dealing with them.

As a professional organization the American College of Cardiology has a substantial interest in the problems of medical ethics as they relate to cardiovascular specialists. Over the past few years the membership has brought its interest in and desire for guidance on ethical issues to the attention of the Executive Committee, the Ethics Committee and the Strategic Planning Committee of the College. The Ethics Committee was recently reconstituted and given a new charge: "The Committee shall address ethical issues in cardiovascular medicine. The Committee shall bring to the attention of the Board of Trustees issues of particular significance relative to ethical behavior, and propose forums and/or actions to address such issues. In addition the Committee shall review and respond to any concerns regarding ethics brought to their attention from other areas."

An important prelude to this dialogue on ethics occurred at the Annual Scientific Session of the American College of Cardiology held in Anaheim, California in March 1989. At a symposium especially designed to discuss ethical issues in cardiovascular medicine there was a receptive response from a capacity crowd. This response emphasized a major interest in the development of guidelines for the practicing cardiovascular specialist.

For these and other reasons the Bethesda Conference Committee singled out ethics as the focus of the 21st Conference. It was clear from the outset that all the pertinent issues could not be reviewed in a conference or publication of this limited size. Accordingly, only a few specific topics were selected. Further, we acknowledge that this report is only a first step and that definitive solutions are not yet available for many pressing problems.

Because the task force approach has worked well in previous Bethesda Conferences, this format was adopted. An attempt was made to have broad-ranging participation from a number of organizations throughout the country and to include persons representing government, industry, medical groups and the public. This consensus report represents a summary of the topics presented and discussed at the 21st Bethesda Conference. Of considerable importance was the charge to each task force to offer guidance on ethical issues to members of the American College of Cardiology and other health care professionals. We trust that this will be the beginning of a continuing dialogue that will assist the cardiovascular specialist and the public in ethical decision making.

General Principles

Dr. Edmund Pellegrino (1) has suggested that the moral core of medicine originates in the fact of illness and the act of profession. Individuals ask physicians to help them with health problems and physicians *profess* to be morally and technically competent to help. The ideal of ethical medical practice is reflected in establishing voluntary and uncoerced physician-patient relations, where a joint decision is reached that an individual patient will place his or her care in the hands of a particular physician and where the physician affirms his or her ability to care for this patient (2).

The ethical practice of medicine is realized in the process of patient-doctor decision making, which aims for a right and good therapeutic decision and action for a particular patient. The question, "What is best for the patient?" is the beginning point in any medical ethical discussion. This question implies a judgment by the physician of the primary medical needs and wishes of the patient and a determination of what can be achieved. Primacy of a patient's needs over a physician's personal gain is closely linked to this question.

In general patients and physicians pursue similar goals that vary with clinical circumstances, and these goals may include

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Table 1. Principles Guiding Physician Behavior

A commitment to relieve pain and suffering and, when possible, to heal both body and mind
A respect for human life and human dignity
An appreciation of patients' best interests and the right to free choice
A responsibility for service to others and a willingness to be fit for qualified service
A responsibility to teach and to share new knowledge with colleagues and students
A concern for the creation of adequate health care for all and a special concern for the indigent, oppressed and infirm
Personal moral integrity in patient care, scientific research and relations with the community and industry

the prevention of disease and untimely death, cure of disease, relief of pain and suffering, prevention of disability and maintenance of the patient's dignity and control. The initial transaction between patient and doctor creates responsibilities for each. It establishes both the goals of the clinical encounter and the process through which patient-doctor decision making will occur.

This decision-making process must take account of potential conflicts about goals that may emerge among physicians, patients, families, institutions and society. Medicine must offer both procedural and substantive solutions for resolving such conflicts in view of the need to make a clinical decision. Of course, postponing a clinical decision is itself a decision.

The ethical practice of medicine is closely related to the standard of care. That standard of care has increasingly come to represent decisions reached jointly by competent adult patients and physicians after the physicians have communicated clearly their recommendations based on the best technical considerations. At the same time it must be acknowledged that there are occasions when the physician must take an authoritative stand because the patient may be incapable of making a decision.

When considering first principles of ethical behavior, physicians should remember that their profession is a high calling that involves responsibility for the life and health of patients. In attempting to formulate principles to meet that calling it is clear that each individual should have a guiding moral framework and background. That background may be a product of religion, societal influence, personal experience or other factors. However, regardless of the background of the physician, the principles of ethical behavior must stress the best interests of the patient and the patient's right of free choice. Table 1 lists some of the principles that guide physician behavior.

An Approach to Ethical Decision Making in Medicine

The Establishment of Medical Goals and Clinical Possibilities

The physician's responsibility for technical competence. The practice of ethical medicine must begin with technical competence. When an ill person voluntarily consults a physician, the physician's primary clinical and ethical obligation is to be sufficiently technically competent to determine the patient's diagnosis, prognosis and the range of alternative clinical interventions (including their risks and benefits) and to be sufficiently attentive to the patient to establish the patient's goals and preferences. The physician should offer a clinical recommendation that takes into account the nature of the medical problem, the risks and benefits of alternative clinical strategies and the patient's biologic and personal characteristics. The clinical recommendation offered to a particular individual should result from the rigorous application of clinical knowledge, clinical judgment and scientific principles. Thus, physicians have a responsibility to be involved in continuing medical education to keep their medical knowledge current. They are also expected to demonstrate moral integrity in their work, including honesty, fairness, trustworthiness, fidelity, maintenance of confidentiality and compassion for the sick person who has requested medical care.

This first step in the decision-making process is based on the ethical principle of providing the patient a benefit insofar as this is accepted by the patient or the patient's surrogate decision maker. The physician's obligation is to use medical knowledge to help the person as much as possible and to do as little harm as possible. Thus, the physician has a duty to recommend medically validated interventions that have a reasonable probability of attaining the patient's goals, to provide those interventions whose benefits outweigh risks and to refrain from interventions that would be futile. In the words of the Hippocratic writings, "As to diseases, make a habit of two things—to help, or at least to do no harm."

The Clarification of Patient Preferences

The patient as the source of authority. The preferences of an adequately informed, competent adult patient are a major ethical consideration in clinical decision making.* Although both patients and physicians have responsibilities, competent patients have the ethical prerogative and legal right to accept or reject clinical recommendations on the basis of their personal goals and preferences. Physicians therefore have several key obligations: to adequately inform patients of medical alternatives and possibilities, to assess whether a particular adult patient is competent, to respect the decisions of informed adult patients who are competent and, after ensuring that appropriate and continued care is provided, to withdraw from cases in which the physician cannot in good

*The 21st Bethesda Conference did not consider the morally and legally complex issue of reaching clinical decisions, particularly about life and death matters, for patients who lacked or would never recover decision-making capacity. This matter has been considered by a President's Commission (7) and will continue to be debated vigorously in clinical, judicial and legislative arenas.

conscience act according to the expressed wishes of the competent patient. The doctrine of informed consent acknowledges the rights of patients to make decisions about the medical interventions they wish to accept and which they will reject.

The ethical principle underlying patient preferences is the recognition that patients are the usual source of authority regarding what is done to them. The legal counterpart of the moral principle is the common law right of self-determination. This principle has particular importance in a pluralistic culture such as ours. As Justice Cardozo wrote in 1914 (*Schloendorff v. Society of The New York Hospital*): "Every human being of adult years and of sound mind has a right to determine what shall be done with his body." Informed patient preferences are the legal and moral center of the physician-patient relation and of medical decision making. Adequate information implies that physicians should communicate effectively and truthfully with patients and that they should avoid any form of deception.

The physician's contribution to the patient's decision. In view of the importance of patient preferences, it might be asked why this consideration is listed second rather than first in the proposed decision-making system. The answer to this question is derived from the nature of medicine and how it functions in our society. In general patients enter the health care system by choice after deciding that they want help. Patients and physicians tend to share common goals, such as the pursuit of health or the relief of discomfort, and they pursue these goals jointly. The physician as a technical expert must first evaluate the patient to determine what is wrong and what can be done and then assess the patient's goals and explain the means available to achieve those goals. Thus, chronologically and logically, the patient's informed preferences necessarily follow the physician's recommendations, which in turn are based on the physician's evaluation of the patient's medical problems and goals. *Simply put: patients cannot express truly informed preferences or informed refusals until they are provided with sufficient information about their medical problem and what the physician thinks can be done for it.* However, some patients do not want full information and may legitimately request that a surrogate decision maker be utilized or that the physician assume responsibility for some therapeutic decisions. Moreover, some patients may decide not to establish a physician-patient relation and therefore withdraw from treatment altogether.

Distributive Justice

An additional ethical principle to be considered is that of distributive justice—the justifiable ways in which benefits and burdens are distributed in a society under prevailing conditions of economic scarcity. This principle requires giving to each what is due and has been interpreted by the President's Commission Report *Securing Access to Health Care* (13) to involve ensuring that all will receive equitable access to health care. In addition, physicians as members of a learned profession should through their professional and specialty associations provide the public with the information needed to establish through democratic procedures the scope of what will be deemed an adequate level of health care.

Many problems of distributive justice arise in the health care system, from clinical issues such as the availability of intensive care unit beds or of organs for transplantation, to broad social issues such as access to and methods of paying for health care. In the context of limited resources and continually expanding technology, physicians and institutions face increasingly difficult decisions as they attempt to use available medical resources in a technically and ethically justifiable way to ensure appropriate care for patients. The same considerations apply as physicians strive to ensure that adequate medical care is available and accessible to all.

Societal Responsibilities

Physicians have the responsibility to protect the health interests of society in general, as well as of individual members of society who are not their patients. When responsibilities to the patient and to society are in conflict, patient responsibilities take primacy unless there are overriding and exceptional circumstances.

Goals of This Conference Report

Focusing on guidelines rather than rules. A major goal of the 21st Bethesda Conference is to stimulate a heightened level of awareness of ethical issues and to facilitate thoughtful discussion of unsettled topics. The Conference is meant as only an initial step in the ongoing effort to deal effectively with the complex, rapidly changing issues that will confront us all in the years ahead. Because recommendations in individual cases nearly always have to be based on reasoned judgments rather than on rote application of an encyclopedic set of rules, our attention should focus on guidelines rather than rules. Excessively detailed and stringent recommendations can be counterproductive. In some ways the situation is similar to that of a cardiologist grappling with a difficult clinical problem. Because very few cases are exactly the same, the physician's challenge is to place available data and therapeutic options in the context that is most proper for the individual patient and setting. ACC members readily recognize the judgmental elements involved in this sort of decision making, as well as the time and effort required if proper decisions are to be reached and unfavorable outcomes minimized.

The role of oversight groups and ethics committees. In any conflict of interest the primary responsibility of each of us is to be true to our moral convictions and to maintain personal integrity. No set of rules or guidelines can justify our

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proceeding in a manner that we find to be morally unacceptable. However, many of our activities as physicians involve public as well as personal responsibilities. Mistakes in judgment, which any of us can make, can undermine the public trust essential to our effective functioning and can taint the public view of cardiologists and physicians as a group. Accordingly, even when we personally believe that a conflict of interest is not present, we will sometimes need to submit our judgments to an ethics committee or another peer group for review and consultation. Such action may provide some degree of protection for the individual patient and physician as well as reassurance to the public.

Many of us from time to time will also have to serve on such oversight groups or committees. Whether the group is an ethics committee of a professional society, a hospital committee reviewing a specific problem, a committee of a university or a government agency representing the public, the integrity of the oversight process requires that inquiries be thorough, balanced and dispassionate. Substantial time and effort are almost always needed to reach a judgment in an individual case. Oversight groups and ethics committees must also ensure that parties involved in their inquiries are accorded respect and that full attention is given to protect their interests.

Using the Bethesda Conference guidelines. Within this framework, it is suggested that physicians carefully consider the recommendations of each Task Force relative to their individual behavior. It is hoped that a thoughtful review of these principles and guidelines will assist decision making in any circumstance in which ethical issues may be involved.

Included in the Appendix are a variety of case studies developed by each Task Force to serve as a basis for discussion by physicians. In such circumstances, these case studies can provide a good basis for free discussion, using the ethical principles and guidelines of this Conference as a framework.

General Perspectives on Ethical Issues in Cardiovascular Medicine

1. Cardiovascular physicians must recognize the central importance of morality in health care delivery.
2. Cardiovascular physicians must recognize that value conflicts occur in the daily practice of clinical cardiology and cardiovascular research and must be prepared to deal with these conflicts in a fair, honest and consistent manner.
3. The cardiovascular physician must recognize the importance of the free choice of the patient in health care decision making and that this choice may at times be in conflict with the goal of achieving the best medical interests of the patient.
4. Cardiovascular physicians must be knowledgeable about such ethical issues in health care as informed consent, respect for persons, confidentiality and conflicts of interest.
5. The just allocation of health care resources requires the cooperation of physicians, patients and society.

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