Matrices of Decision Making in Cardiology

John Ross Jr., MD

With the increasing focus by university deans, hospital directors, and chairs of departments of medicine on cardiology as a high-income clinical service, many of us who work in medical schools are beginning to wonder how our academic position can be preserved. Maintaining a high profile in basic research becomes increasingly difficult under such conditions. On the other hand, clinical research activity is possible in all work settings, and important contributions have and still are being made by clinical observation and even by library research.

It was such nonfederally funded clinical observations in the era before World War I that led to James Herrick’s description in 1912 of the clinical syndrome of nonfatal acute myocardial infarction. Herrick was a practicing internist and, in 1915, the first president of the Chicago Society of Internal Medicine. Although survival after coronary occlusion had been occasionally suggested by postmortem studies, Herrick’s account of the clinical picture with survival for as long as 20 days was convincing and highly influential on subsequent practice. His 1912 article was remarkably insightful and described in detail the clinical findings in several patients (one with autopsy); of course, no electrocardiographic confirmation was available. Based on postmortem studies, in those days there apparently was no question that coronary thrombosis was the problem, and Herrick discussed different syndromes to be expected from occlusion of different vessels, the role of the collateral circulation, and the effects of disease in other nonoccluded vessels.

The term “matrix” refers to a place or an element within which something forms or develops, and as such a matrix gives shape to that which it encloses. In considering matrices for decisions in cardiology, a very broad matrix can be identified; this includes virtually all societal, cultural, and other factors that influence our decisions as to what kind of a person and medical specialist we want to be, how good a physician in the sense of doctor as patient-colleague we become, and how well educated and aware of our own decision-making processes we remain. But I would like to focus primarily on a somewhat smaller medical matrix that includes government and fiscal policies but in particular encompasses the ethical, legal, and scientific forces that ultimately shape a clinical decision.

Among the societal and fiscal issues, I will mention only two: management of care and cost. Many experts believe that the 1990s will be the era of growth in managed care. By managed care, they do not mean care managed by physicians. Let me quote briefly some excerpts from an insurance company document:

“Utilization management will be central to containing costs as businesses become more willing to challenge physicians’ decisions regarding patient care. . . . Managed care is the wave of the future. Consumers will increasingly be willing to accept managed care systems which restrict their freedom at the point of purchasing care. . . . and fewer people will have the “family doctor” of yesteryear, due to greater mobility and physician specialization; thus they will appreciate the continuity of care found in HMOs [health maintenance organizations] and PPOs [preferred provider organizations] which use the primary care physician to coordinate the patient’s care. Doctors will lose influence. In the future, many physicians will face heightened conflicts, experience less job satisfaction, and earn lower incomes.”

What is behind these macroforces that will have an important influence on the microenvironment within which we practice cardiology? One major factor, as you know, is cost. Health care as a percentage of the gross national product has increased from 5.9% in 1965 to 12.5% in 1990, and it is still growing. This figure is higher by 3% or 4% than that in countries such as Canada, England, and Sweden that have national health insurance. The main driving force for a fiscal change in the United States appears to be increasing costs to the purchasers of health care, many of whom are employers—that is, our major industrial corporations. One consequence of these forces has been the development of the resource-based relative value scale that will take effect in 1992 for Medicare, with third-party payers likely to follow, leading to an increase in payments for primary care.
and cognitive services and a decrease in payments for specialists.

The consequence of these trends is that reimbursement will be changing, and managed care will be placing increasing constraints on practice patterns. They are likely to limit access to specialty care, which many of us believe will lead to reduced quality of care. Budget-driven decisions by the primary care provider or gatekeeper will often replace those based on individual physician judgment of optimum patient care, particularly those of specialists such as cardiologists. Like any business venture, providers and users will be seeking quality at a reasonable cost, thereby providing a rather broad fiscal matrix around clinical decision making.

If we as cardiologists truly believe in what we are doing, we must take a very active role in setting standards for care as well as in informing the public, government, other physicians, and the purchasers of care about the value of what we do. A good start in the direction of setting standards has occurred with the simultaneous, ongoing publication in *Circulation* and the *Journal of the American College of Cardiology* of guidelines for medical procedures developed jointly by the American College of Cardiology, the American Heart Association, and the American College of Physicians. Nevertheless, much more needs to be said about the value of specialized cardiovascular treatment to a much wider audience.

A somewhat smaller medical matrix surrounds our clinical decisions and involves ethical, medicolegal, and scientific matters. Ethical issues are receiving increasing attention at many levels ranging from activities by physicians serving in professional and lay organizations to research to clinical care. At the service level, after several years on the Ethics Committee of the American College of Cardiology, I have become aware that many cardiologists have invested in commercial firms in the health-care field. Our committee recently developed guidelines for potential financial conflicts of interest with regard to service on College committees, the first principle, of course, being disclosure. This concept allows the individual (and others) to decide whether his or her participation in a discussion or decision might be tainted, consciously or unconsciously, by the potential for personal financial gain or other less direct benefits.

To my knowledge, Dr. Joe Reeves in his Herrick lecture of 1984 was the first to clearly state that an ethical issue is present in self-referral by cardiologists. That is, the cardiologist performs a diagnostic medical workup and then referrals the patient to himself or herself for a therapeutic procedure, which is often well remunerated. Our surgical colleagues joined in pointing out the potential ethical conflict of interest because they generally obtain their referrals from other physicians. The problem certainly has not been solved since Dr. Reeves enunciated it, although it may be alleviated by having an additional medical opinion in the decision loop. The issue has recently become even more complex, however, and current practice now involves the question of informed consent.

Informed consent is a highly complex medicolegal issue, and a number of subtleties have developed since the legal concept of informed consent was established in 1955, when only a simple statement by the physician was required. This approach evolved into a physician-oriented disclosure standard. Under most current laws, a physician must describe three things to the patient: the benefits of, the risks of (including the risk of not undertaking a certain treatment), and the alternatives to the treatment. The "persuasion effect" is well recognized legally; that is, which procedure a physician emphasizes and which risks he or she chooses to emphasize will affect the patient's decision. Should a legal problem arise, the benefits, risks, and alternatives described by a physician during the informed consent procedure will, of course, be compared with those that other physicians will testify should have been given.

However, this physician-oriented procedure is now changing in many areas of the country to a patient-oriented disclosure standard, and this standard may soon dominate. In 1972, in *Canterbury vs Spence*, the notion of informed consent was expanded to include what a reasonable person would want to know and now, in some rulings, to what a particular patient would want to know, so the patient's education and knowledge about his or her specific illness enter the equation. It also appears likely that in the future the patient may have to be informed of potential economic constraints such as what is and is not available as a diagnostic or therapeutic procedure in a health maintenance organization, and be provided with information on institutional success rates for procedures.

On the economic side, it is interesting that a recent legal decision in California held that the physician, not the state or hospital, was responsible for complications after an early hospital discharge, despite funding guidelines and hospital pressure for the early discharge. Physician accountability will be further emphasized by the new national data base, which will track adverse outcomes and malpractice claims regardless of whether they go to court.

The increasing recent trend to perform percutaneous transluminal coronary angioplasty (PTCA) procedures during a single cardiac catheterization that includes the diagnostic study illustrates and complicates all of these principles concerning informed consent, and if we add the potential use of a stent, laser, or atherectomy device, meeting the standards for informed consent becomes even more difficult. Thus, in current interventional cardiology practice in particular, the ethical issue of self-referral blends into the medicolegal issue of what constitutes adequate informed consent.

A related ethical problem concerns physician equity interest in a commercial firm that manufactures cardiovascular equipment (e.g., positron emission tomography imaging equipment, or laser devices). Sometimes, the physicians carrying out the initial
clinical research on such devices have an equity interest in the company and also are directly involved in deciding which patients should undergo the procedure, occasionally with rather loose criteria for patient selection. This sets the stage for an ethical dilemma as to how to ensure that offering use of the new device, even with consent, to a particular patient is not unconsciously affected by self-interest in a given clinical setting. As an editor, I encounter a similar issue in deciding whether interpretation of the data might be biased in a research study by investigators with financial interests in a device under study. Perhaps the clinical dilemma could be approached by having very well defined criteria for patient selection and by having physicians who do not have a financial interest in a device involved in patient selection and obtaining informed consent.

This is not to say that we should not continue clinical research on new devices or that other areas of research do not deserve equally close scrutiny. Rather, attention should be drawn to the important links among personal clinical decision making, the informed consent procedure, research goals, potential conflicts of interest, and related ethical matters.

Scientific issues are the last element that I will mention in the matrix that directly influences the choices made in patient care. Here, our own career interests and the knowledge base that we maintain through continuing education and research come together in deciding on initiation of or change in treatment in the individual patient.

In his 1949 book, Memories of Eighty Years, Herrick indicates that he was an active practitioner most of his life as well as a teacher—at first a general practitioner and later a specialist. He said, “After 1912, when I reported my observations on thrombosis of the coronary artery I was, willy nilly, a ‘heart specialist.’ I fought against having this term pinned on me.” He goes on to quote a colleague who said that his patients would now suffer from “special attention and general neglect.” “Yet,” he says, “I had to admit that no matter how hard I tried, it was impossible to keep pace with the rapid strides made by medicine and the cognate sciences.” And he later quotes Dr. Bois-Raymond, who said, “I would much prefer a scholar who investigates and does excellent work in a limited field, to one whose knowledge may be extensive but who has accomplished nothing remarkable in any particular line.” This credo undoubtedly has something to do with our own motivation to be subspecialists.

As such, we must be able to advise concerning the very best means (whether it be invasive, surgical, medical, or only a change in life-style) for relieving symptoms, delaying the progress, or reversing the course of cardiovascular disease and, above all, selecting the safest course for the patient at a given stage of disease. Not uncommonly, all four approaches are needed but at widely different points in time during the trajectory of a given patient’s illness; it is not only the appropriateness but, like many things, also the timing of such decisions that requires the specialist’s knowledge and cognitive skills as well as his or her technical capabilities. For example, many scientific issues must be considered in choosing between PTCA and coronary bypass surgery. Perhaps the most basic data base for such a decision is a local one. We should be aware in an ongoing way of mortality and morbidity rates at our hospitals for invasive and surgical procedures, and these should be within the acceptable ranges as determined from recent large reported series.

Not only are we entering an age of managed care, but we are also in an era of clinical trials, and the scientific outcomes of such trials are increasingly being carried directly to the bedside. However, we need to keep in mind that a scientific basis for comparing PTCA with coronary bypass surgery in multivessel coronary disease is not available, whereas long-term follow-up after coronary bypass alone has been reported. A number of major studies are under way that compare these two modalities: the Randomized Intervention Treatment of Angina (RTI; in UK) and the Coronary Artery Bypass/Revascularization Investigation (CABRI; in Europe). In addition, there is the German Angioplasty Bypass Investigation (GABI), the Emory Angioplasty/Surgery Trial (EAST; in the United States), and the Bypass Angioplasty Revascularization Investigation (BARI), the largest of the studies (supported by the National Heart, Lung, and Blood Institute). Also, there is the ongoing angioplasty versus medicine trial (ACME) of the Veterans Administration, which involves patients with single vessel disease. These trials focus on various end points, ranging from symptom relief, or evidence of ischemia, to morbidity and mortality to quality of life to costs over time. Even so, it is doubtful that the trials will address certain more subtle factors, such as patient preference for a 1- or 2-hour balloon dilation procedure to a thoracotomy with vein harvesting.

We must also keep in mind the need to actually use criteria employed in clinical trials when we select patients for treatment based on the outcomes of such trials. Frequently we do not, as Michael Stadius and Ed Alderman point out in an important recent editorial in Circulation. They indicate that most clinicians still do not use caliper techniques in assessing coronary artery stenoses despite clear evidence that visual inspection is poorly reproducible and biased, overestimating the severity of lesions greater than 50% and underestimating that of lesions less than 50%, compared with the use of caliper or computerized methods, and they strongly urge a change in current clinical practice.

Regarding symptomatic single vessel coronary disease, in a thoughtful editorial comment in Circulation, Bud Friesinger discusses the dilemma of intervention in such patients. It has been known for a number of years, of course, that the long-term outlook for survival in younger patients with stable one-vessel disease is extremely good with medical
therapy; although they are ideal candidates for surgery, the outlook for survival is not improved by surgery. However, a substantial proportion of PTCA procedures continue to be done in patients with one-vessel disease despite a lack of information on long-term effects, including quality of life and cost. Only two of the ongoing trials, RITA and ACME, involve patients with single vessel disease. In weighing potential risks and long-term benefits of PTCA or coronary bypass surgery versus medical therapy alone in such patients, we need to be very careful in our decisions. Perhaps firmer selection criteria should be developed concerning patient stability, responses to optimum medical treatment, degree of inducible ischemia, and atherosclerotic lesion characteristics; certainly, whatever the decision, a strict approach to reduction of risk factors should also be implemented.

Let me summarize briefly by emphasizing how complicated our decision making has become. The elements of the matrix were always there: the clinical picture, ethical and legal boundaries, the extent of scientific knowledge, the patient's right to know, and monetary factors. However, today our decisions are more complex, and, of importance, they are being increasingly scrutinized by others. Therefore, the need is obvious for each of us to be self-analytical and fully conscious of our own decision-making processes and to ensure that all relevant issues are carefully considered.

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J Ross, Jr

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