

Reconceiving Health Care To Improve Quality

WILLIAM C. RICHARDSON

THE TANNER LECTURES ON HUMAN VALUES

Delivered at

University of California, Santa Barbara
January 29, 2001

WILLIAM C. RICHARDSON is president and chief executive officer of the W. K. Kellogg Foundation. He is also professor and president emeritus of the Johns Hopkins University. He was educated at Trinity College, Connecticut, and at the University of Chicago, where he received his Ph.D. He was executive vice president and provost of the Pennsylvania State University, and was dean of the Graduate School and vice provost for research of the University of Washington. He is a member of the Institute of Medicine of the National Academy of Sciences and a fellow of the American Academy of Arts and Sciences and the American Public Health Association. He has served in many capacities in the U. S. Department of Health, Education and Welfare, and the U. S. Department of Health and Human Services; on advisory committees for the Robert Wood Johnson Foundation, the Rockefeller Foundation, and the Pew Charitable Trusts; and on the board of trustees of the Henry J. Kaiser Family Foundation and the Glenmede Trust Company. He is currently serving on the board of the Council of Michigan Foundations and as chairman of the board of trustees of the Council on Foundations. He is the author of numerous articles, monographs, and reports on issues related to public health.

Good evening and thank you for the warm welcome.

Our society and economy have been undergoing some marked changes over the past twenty years. My topic this evening is envisioning a new set of relationships in health care and a degree of professional and organizational rearrangement that reflect these changes and that will, in the process, materially improve health care quality (Institute of Medicine 2000).

Let me begin with the basic premise of any encounter or relationship with a health care provider. We expect—at the very least—to be the better for it, and certainly no worse off. Since the days of ancient Greece, “First, do no harm” has been the first principle of medicine.

A little over a year ago, however, the Institute of Medicine of the National Academy of Sciences (which I will refer to as the IOM) released a groundbreaking report on medical errors that suggested we *are* doing harm (Institute of Medicine 2000). Although we have, in many ways, the world’s finest health care system, the report found a surprisingly high level of medical errors. And, although Americans are healthier and are living longer than ever, our over-stressed health care establishment too often fails to insure the basic safety of its patients.

The report received extraordinary media attention—two days of near-saturation coverage on the national networks and a great deal of local media coverage as well. Further, the story turned out to have what some refer to as “legs.” I don’t think there has been a week in the last year that there wasn’t some national coverage of the medical errors issue, except maybe the second week of November.

Naturally, much of the media’s attention focused on the statistics and personal stories related to medical errors. And these are certainly a vital aspect of the quality problem. But this evening I’d like to offer something of a sequel to the medical errors report. A range of pertinent demographic trends; technical, scientific, and societal developments; and changes in health care have been discussed by members of the IOM Committee that was responsible for the errors report. Based on these

This lecture draws heavily on the deliberations and contributions of members of the Committee on the Quality of Health Care in America, which I chair. The first report of this Institute of Medicine Committee is a key source, as are sections of our committee’s second report, available in the spring of 2001.

discussions, I will provide an overview of what a safer and more patient-centered health care system might look like. I think the ideas that are emerging can reduce medical errors but also lead to a much more effective and productive health care enterprise. Our report on these broader considerations should be out in early spring 2001 (Institute of Medicine 2001).

But first let me provide a brief recap.

In December 1999, along with several health care leaders, I joined President Clinton at the White House to discuss the implications of the medical errors report. As I said, the report had made headline news across the country, but as important to me was the groundswell of public interest that was prompted by its release. For weeks afterward the Institute of Medicine was flooded with calls from hundreds of people who had questions or personal stories to share. (The number I received personally was startling.) The report clearly touched a nerve with the American people. While health policy can be highly technical and obscure, everyone can relate to the tragedy of a serious medical mistake.

Local and national and private and public sector leaders have all taken notice. Many professional groups (such as the American Medical Association, American Nurses Association, American Hospital Association, American College of Physicians/American Society of Internal Medicine, American College of Surgeons, American Board of Medical Specialties, and the Accreditation Council for Graduate Medical Education, to name but a few) are taking action, including institutional practices, a careful examination of the roles of board certification and recertification, and undergraduate, graduate, and continuing health professions education in improving safety. The business community, including the Business Roundtable and the National Business Coalition on Health, has announced purchasing initiatives to promote patient safety. Last November the so-called Leapfrog Group unveiled a market-based strategy to improve safety and quality, including encouraging the use of computerized physician-order entry, evidence-based hospital referrals, and the use of intensive care units staffed by physicians credentialed in critical care medicine.

The Clinton administration and the Congress have also been active. The Senate held its first hearings on the issue within a few weeks of the report's release, and additional hearings were conducted by committees of both the House and the Senate. The administration launched an ambitious plan of federal action to reduce medical errors. In general, then,

there is broad bipartisan support for taking action, and I would be surprised if quality of health care were not a significant issue for the Bush administration.

What the report found, after an exhaustive review of the literature, was a staggering number of medical errors. Based on the findings of one major study, about 44,000 patients die each year from medical errors in hospitals alone (Thomas et al. 2000). Another study puts that figure even higher, at 98,000 patients a year (Leape et al. 1991). Even if we use the 44,000 patient figure, medical mistakes in hospitals rank eighth in the United States among the leading causes of death. More people die each year in the United States from medical errors, for example, than from traffic accidents, breast cancer, or AIDS.

Within a short time of the report's release, some began to question the numbers. "Could the problem really be this serious?" they asked. We will never know the exact number of medical errors, but there is little doubt that the evidence is strong and consistent. Let me take a moment to point out several things about the nature of the evidence base. First, the conclusions of the IOM Committee were not based on just these two studies. There are two large studies—the Harvard Medical Practice Study using about 30,000 medical records and a study in Colorado and Utah (Thomas et al. 2000; Leape et al. 1991) based on about 15,000 records—and more than thirty others (chapter 2 in Institute of Medicine 2000) in leading peer-reviewed journals in the last ten years.

Second, in some ways, we have really only looked "under the lamp post" for errors. Nearly all studies focus on hospital settings, yet most care is delivered in doctors' offices, ambulatory surgery centers, clinics, patients' homes, and nursing homes. Granted, most would concur that the hospital is a higher-risk environment for errors, because patients in hospitals are generally receiving more medical interventions and more drugs, sometimes under hurried or critical circumstances. But we have seen a steady migration of many procedures such as some laparoscopic surgery to ambulatory settings. One study has found that some 7,000 patients die each year just from medication errors that occur both in and out of hospitals (Phillips et al. 1998).

Third, most studies identify errors from information that is documented in handwritten medical records. It is likely that many errors never get documented in medical records. Providers are acutely aware of liability concerns. In addition, some errors are not recognized or noticed by clinicians. Studies that rely on "automated signals" to detect errors

(such as abnormal or unexpected laboratory test results) reveal higher rates of errors than do studies that rely on the documentation or reporting of errors by clinicians (Classen et al. 1991).

At this point, anyone who is not familiar with the report might gather that it is an indictment of health professionals. But this is not at all the case. Indeed, a main conclusion of the report is that no particular group or entity is to blame. A fundamental conclusion is that this is not a “bad apple” problem. And indeed that pinpointing and placing blame is actually a counterproductive exercise. To reduce medical errors and improve patient safety we need to recognize this as a systems problem.

The comprehensive strategy put forth by the IOM report calls for action by government, industry, consumers, and health care providers. The report notes that it may be human to err, but it’s also human to create solutions, find better alternatives, and devise new approaches for the challenges ahead. In order to meet these challenges, however, we must first face facts. Our health care system is a decade or more behind other high-risk industries in its attention to ensuring basic safety. The ordinary risk of dying in a domestic airline flight or at the workplace has declined dramatically in recent decades. That is due in part to increased attention by industry efforts, and in part because federal agencies were created to improve safety. Drawing on these models, my colleagues and I urge several courses of action, which are detailed in the report. Let me just quickly summarize them here before moving on to the topic of quality of health care more broadly defined.

First, we urged Congress to create a national center to set national safety goals, track progress in meeting them, and support research to learn more about preventing errors. It would also act as a clearinghouse—an objective source of the latest information on patient safety for the nation. I am pleased to say that prompt action has been taken.

We also recommend that a nationwide, mandatory public reporting system be established by the states. Currently, only about one-third of the states have reporting requirements. And yet, this information is critical if we are to learn, in any systematic way, about practices that lead to serious injury or death. It’s not unlike our being required to report serious traffic accidents or deaths from workplace accidents. During the last year, the National Academy for State Health Policy has convened leaders from both the legislative and executive branches of the states to discuss approaches to improving safety and with the support of private foundations has recently completed an inventory of current state report-

ing initiatives (National Academy for State Health Policy, forthcoming).

At the same time, we also recommend federal legislation to protect the confidentiality of certain information. This protection would cover medical mistakes that do not result in harm—so-called near misses—where information is collected and analyzed solely to improve safety and quality. Such legislation would encourage the growth of voluntary, confidential reporting systems so that practitioners and health organizations can correct problems before serious harm occurs. Without such legislation, a doctor or hospital may be afraid to gather such information, for fear that it would be subpoenaed and used to establish a pattern of error in a subsequent lawsuit.

Again, the majority of errors in hospitals do not result from impaired professionals or recklessness. Most mistakes occur because of basic flaws in how elements of the health system are designed and organized. For example, equipment controls that vary from one manufacturer to another, or from year to year, can contribute to errors. Stocking patient care units with drugs that are potentially lethal unless they're diluted has led to deadly overdoses. And, because of illegible handwriting in medical records, patients have been given drugs in wrong doses or given drugs to which they have a known allergy.

There is no single solution sufficient to bring about the degree of needed change. Rather, we should think and act systemically, to create an environment where safety will become a top priority for health care organizations and providers. The goal here is not to blame individuals or to seek retribution. Instead, we want to design new systems that prevent, detect, and minimize hazards and the likelihood of error. In short, we want to create a new culture of safety in the American health care system. We want a system in which it is hard to make a mistake.

We are not, however, calling for a nationwide master plan to solve the problem of patient safety. The American health system doesn't work that way. There are too many markets and too many variables. What works well for the Henry Ford Health System in Detroit may not be applicable in Santa Barbara—much less in Maine.

While the findings on medical errors are sobering, perhaps more sobering is the realization that medical errors are but one manifestation of an even larger problem. Medical errors, the failure to execute a care plan as intended, are not the only type of "system weakness." There is ample and growing evidence that much of health care is not strongly

science-based (Schuster et al. 2001). In many instances, patients don't receive effective care. That is, many people receive services for which the potential risks exceed potential benefits—some call this “overuse.” Others do not receive services from which they would likely benefit—generally called “underuse.”

The most extensive reviews of the literature on quality have been conducted by colleagues at RAND (Schuster et al. 1998). The RAND review now includes over 100 publications in leading peer-reviewed journals documenting overuse, underuse, and errors (Schuster et al. 2001). Overuse of health services is common. Examples include performance of surgery for hysterectomy, coronary artery bypass graft, and other procedures without appropriate reasons; provision of antibiotics for the common cold and other viral upper respiratory tract infections for which they are ineffective; and insertion of tubes in children's ears in the absence of clinically appropriate indications.

Underuse is also a serious concern for all types of clinical conditions. In a study of approximately 3,700 Medicare patients with a diagnosis of heart attack and eligible for treatment with beta blockers, only 21 percent received beta blockers within 90 days of discharge. The adjusted mortality rate for patients with treatment was 43 percent less than that of patients without treatment (Soumerai et al. 1997). Another study found that an estimated 18,000 people die each year from heart attacks because they do not receive effective interventions (Chassin 1997).

Overall, it is not an overstatement to say that the health care delivery system is unable to provide consistently high-quality care. Or said another way, many people simply do not benefit from what medicine has to offer. There is a large “quality gap.” Several expert panels in recent years have come to this conclusion (President's Advisory Commission 1998; Chassin et al. 1998). One example would be the IOM National Cancer Policy Board. Its report *Ensuring Quality Cancer Care* (Institute of Medicine 1999) examined the quality of cancer care in depth and concluded that there is a large gap between what care should be and the care that many patients actually experience.

The significance of the report *To Err Is Human* (Institute of Medicine 2000) was not that it reinforced the messages of these other reports, but that it focused on one readily understandable aspect of quality—medical errors—and it communicated this problem effectively to a very broad audience, including the lay public.

These panels, of course, are not the only groups that have been rais-

ing issues about quality. The Institute for Healthcare Improvement, the National Committee for Quality Assurance, the Foundation for Accountability, many local institutions (such as the Institute for Clinical Systems Improvement in Minnesota), and others have been calling for action to address quality concerns for some time.

All of these efforts have contributed to what I think is a “sea change” in the way health care leaders, policymakers, purchasers, physicians, nurses, and, increasingly, consumers view quality. This range of activity has achieved widespread recognition that quality in health care is not what it should be and that this is a problem that must be dealt with. We have in many ways turned a corner, with much change now possible that wasn’t possible just a few years ago.

Not only is there increased recognition that we have a serious problem, but there is also recognition that we cannot address it successfully by simply tweaking today’s health care system. Telling providers to work harder on coming up with more quality measurement tools just isn’t going to be enough. Fundamental change is needed in how we organize and deliver health care; and for this to happen, we need far-reaching changes in the culture of medicine and in the environment in which health care is provided.

As we chart a course for the redesign of health care, it is helpful to understand some of the major technological and demographic forces that are currently shaping it and will continue to do so in the future. There are three that I would like to highlight—the rapidly expanding knowledge base; demographic changes, leading most notably to the prevalence of chronic disease in the population; and information technology.

The quality gap is attributable in part to the extraordinary increase in medical knowledge and technology in recent decades. Starting in the mid-1960s and continuing to this day, investment in biomedical research, public and private, has increased in inflation-adjusted dollars (National Institutes of Health 2000). These investments have clearly paid off in terms of new knowledge, procedures, drugs, and medical devices. For example, laparoscopic surgery has dramatically changed the functional impact of many procedures, such as cholecystectomy; and thrombolytic therapy has had a major influence on the treatment of persons with heart attacks.

These innovations in medicine have significantly, and positively, affected the health of the population. Yet they also pose a challenge for health care practitioners who want to keep their skills up to date. Just

reading about advances—let alone active training in or experience with new techniques—is a daunting task. For instance, the number of citations reporting on randomized controlled trials has increased from an average of 509 annually in the 1970s to over 10,000 annually today (Chassin 1998). Although no practitioner needs to follow advances across all areas of medicine and surgery, rapid expansion of knowledge is occurring even within specific areas. I have been told that the number of randomized controlled trials published on diabetes in these same periods, the 1970s to the 1990s, increased from a few (less than ten) per year to well over 150 per year.

The process of diffusing knowledge and new tools is also quite slow. The lag between discovery of more efficacious forms of treatment and their incorporation into routine patient care is in the fifteen- to twenty-year range (Balas and Boren 2000). And if we can't keep up now, how will we respond to the extraordinary advances that will emerge during this new century?

Another consequence of advances in medical science, technology, and health care delivery is that people are now living longer. Although health care is by no means the only factor that affects morbidity and mortality, innovations in medical science and technology have contributed greatly to the increase in life expectancy. As a result of changing mortality patterns, those age sixty-five and over constitute an increasingly large number and proportion of the U.S. population. In 1994 this age group accounted for approximately one in eight persons, or 13 percent of the population (National Center for Health Statistics 1999). In 2030, when the large baby boom cohorts have become elders, one person in five, or 20 percent, is expected to be in the sixty-five and over age group. The very old, of course, are also growing in numbers and as a proportion of the population.

The increasing likelihood of survival due to scientific and technologic advances will continue to result in larger proportions of people with continuing morbidity and disability. Chronic conditions are now the leading cause of illness, disability, and death and account for about 70 percent of care (Hoffman et al. 1996). Almost 100 million people in the United States have one or more chronic conditions (Robert Wood Johnson Foundation 1996).

These demographic changes have very important implications for the organization of the health care delivery system, but we have yet to address them in any significant way. In many cases we are organized for

and oriented to acute care, while the majority of health care resources are now being devoted to the treatment of chronic disease. There is a dearth of clinical programs with the infrastructure to provide the full complement of services needed by people with heart disease, diabetes, asthma, or other common chronic conditions. Most people with these conditions require care from multiple providers and across multiple settings over long periods. Effective and efficient care of this population necessitates a well-organized program, which would include:

- an interdisciplinary team,
- mechanisms for ongoing communication and coordination of services across providers and settings,
- education programs and communication mechanisms directed at patients, their families, and other informal caregivers,
- a formally organized care process designed to achieve best practice, and
- the ability to measure both medical care process and patient outcomes for purposes of quality improvement.

And providing state-of-the-art health care to a mostly chronically ill population is further complicated by the fact that many have co-morbid conditions. About 44 percent of those with a chronic condition have more than one chronic condition (Robert Wood Johnson Foundation 1996).

Our challenge, then, is to move from the highly decentralized, often cottage industry that we have now to one that can provide excellent tertiary intervention and care, both primary and preventive care, and, increasingly, the necessary “packages” of services that are needed for care of the chronically ill. We fall particularly short in this last category.

It is true that the health care sector is more complex than other industries. I think it is probably the most complex industry. There are large number of conditions and ailments, and in some important respects each patient is unique.

But I would suggest that the heavy focus in health care on the clinical needs of individual patients has in some ways blinded us to some of the principles that have guided the development of better systems in other industries. The so-called 80/20 rule should apply to health care.

For example, a study at one health maintenance organization found that 78 percent of direct medical costs were attributable to just twenty-five acute and chronic conditions and that three cardiovascular conditions (ischemic heart disease, hypertension, and congestive heart failure) accounted for 17 percent of these costs (Ray et al. 2000).

The Agency for Health Care Research and Quality in its work on the Medical Expenditure Panel Survey identifies a limited number of “priority conditions” (Medical Expenditure Panel Survey 2000). These conditions account for a sizable proportion of the national health burden. They include cancer, diabetes, emphysema, and hypertension. If we were to make it a *priority* to develop well-organized care programs based on “best practices” for this limited number of conditions, we would be well on our way to addressing many quality problems.

In following the 80/20 approach, we determine what work is routine and design a simple, standard, and low-cost process to perform this work efficiently and reliably. This not only results in safer, higher-quality, and more reliable health care for common conditions but frees up resources and the time of highly skilled clinicians to focus on the more unusual, complex cases. Standardizing care processes doesn’t mean “one size fits all.” As I said a moment ago, patients are not the same. They have a range of preferences, and some have special needs. In other industries, we use what is called mass customization to standardize common services needed by many patients, while customizing or tailoring other aspects of services to respond to particular preferences and needs.

As we struggle to address this challenge, we must also keep in mind that the health care industry is changing at an extraordinary rate. Our efforts to narrow the quality gap will be far more successful if they are congruent with the ways in which the industry is being transformed by information technology and consumerism. As the saying goes, it is easier to ride a horse in the direction it is going.

The Internet places us on the threshold of a change that is reshaping virtually all aspects of society, including health care delivery. The Internet supports rising consumerism, with greater demands for information and convenience in all areas of commerce. The effect of these trends on health care will likely be a fundamental transformation in how services are organized and delivered and how doctors and patients interact with each other.

To better understand how information technology can contribute to

quality improvement, our IOM Committee convened a special workshop. The participants identified five key areas where information technology can make a difference.

The first area is translating science into practice. Through more effective use of the Internet, we can help providers gain better access to the medical science base. The Internet has opened up many new opportunities to make evidence, both primary publications and secondary analyses, more accessible to clinicians. The efforts of the National Library of Medicine, through Medline, are particularly promising. Medline contains more than 9 million citations and abstracts to articles drawn mainly from professional journals (Miller et al. 2000). In June 1997 the Library of Medicine made Medline on the Web available free of charge. Usage jumped about ten-fold, to 75 million searches annually (Lindberg and Humphreys 1998).

Second, information technology also facilitates consumer access to health information. Patients and their families will be far more effective caregivers (and team members) if they are knowledgeable about their health conditions, options for treatment, and expected outcomes. Some 77 million Americans retrieve health-related information annually (Morrison 1999), but the volume of health-related information can be overwhelming. There are some 61,000 web sites that contain information on breast cancer and about 40,000 for diabetes (Boodman 1999; National Research Council 2000). This information is of varying quality—some is incorrect and some is misleading. In 1998 the Library of Medicine started Medline Plus, a web site for consumers. Medline Plus includes information on more than 300 health topics and also contains links to reputable web sites maintained by professional associations and other government agencies.

The third area is the collection and sharing of clinical information. Perhaps the single most important contribution of information technology will be to supplement paper medical records, which are so often illegible or incomplete. Handwritten orders are a major source of medical errors. Paper records are often unavailable, which contributes to many unnecessary services, especially repeat laboratory and radiology services. I realize there are important confidentiality and data security issues to be resolved, but we can and must work our way through them. We shouldn't deny patients the very important benefits of automated clinical information, which include improved quality, safety, convenience, and efficiency.

Fourth, information technology can help reduce errors by standardizing and automating certain decisions and by identifying errors before they occur—errors such as adverse drug interactions. Computerized drug prescribing has great potential to have a positive impact on dosing calculations and scheduling, drug selection, screening for interactions, monitoring and documenting adverse side effects, and other areas. Yet comprehensive medication order entry systems have been implemented in only a limited number of health care settings.

Fifth, information technology can change the way individuals receive care and interact with their providers. Instead of a \$65 office visit and a half-day off work, a ten-minute e-mail communication could meet the patient's needs. Similarly, patients will be able to go online to get test results, inform their physicians about how they are doing, participate in interactive disease management services, and receive after-care instructions. Touch and face-to-face interaction will always be important. The essence of high-quality health care is a "healing relationship." But in many instances face-to-face encounters are neither needed nor wanted by the patient or clinician.

Of course, there are challenges we must confront to take advantage of the many beneficial applications that information technology (IT) has to offer. First and foremost are privacy considerations. The public have been given little information to help them evaluate the many benefits of IT, while at the same time they have heard potential horror stories that can come from automated personal health information. There is a very real need to open the dialogue and inform public debate in this area. For an interesting example of how public concerns about privacy can halt efforts to advance our use of IT, we need only look back two years, when the Department of Health and Human Services halted plans to establish a unique patient identifier in response to public outcry over potential violations of medical privacy (Goldman 1998).

Second, the lack of national standards for the collection, coding, and sharing of data is also viewed by many as an impediment to moving forward. The efforts of the National Committee for Vital and Health Statistics are very important in moving us forward in this area. Progress has been slow.

Third, significant financial investments in IT will be needed—far greater than the current investments being made by most health care organizations. Capital will be required to purchase and install new technology. The installation of new computerized systems often produces

temporary disruptions in the delivery of patient care. Considerable specialized training and education will be needed to help the workforce adapt to a new environment. These capital decisions must be made in an environment where benefits are hard to quantify. Unlike capital investments in new medical technology, which immediately generate revenues under our predominantly fee-for-service system of payment, IT investments to automate clinical data have only an indirect effect on the bottom line.

Lastly, not all patients will take advantage of the opportunities afforded by information technology. There will be a need to operate the “old” and the “new” delivery systems in parallel.

It is not possible to foresee all the new organizations, forces, technologies, needs, and relationships that will develop in the health care system over the coming decade. The IOM Committee is attempting to specify some general *aims* that the system should try to achieve and what might be called some rules for the road. Our framework is based on an understanding of systems that can self-organize to achieve a shared purpose and improve by adhering to well-thought-out general rules.

Our report on twenty-first-century health care will be released early this spring, so this is still a work in progress; but I can share with you some of our thinking. First, let me again emphasize that fundamental change is needed. The American people should get a much higher return on their investment in health care than they currently do.

The IOM Committee has identified six Aims for Improvement—six dimensions of quality where, we believe, today’s health system functions at far lower levels than it should. Health care should be:

- Safe: avoiding injuries to patients from the care that is intended to help them.
- Effective: providing services based on scientific knowledge to all who could benefit and refraining from providing services not likely to benefit (avoiding overuse and underuse).
- Patient-centered: providing care that is respectful and responsive to individual patient preferences, needs, and values; and assuring that patient values guide all clinical decisions.
- Timely: reducing waits and sometimes harmful delays for both those who receive care and those who give care.
- Efficient: avoiding waste, including waste of equipment, supplies, ideas, and energy; and

- **Equitable:** providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, or socioeconomic status.

A health care system that achieves major gains in these six dimensions would be a great benefit for patients.

The culture of medicine and the roles of physicians, nurses, and other clinicians and the clinician/patient relationship are all likely to change substantially over the coming decade.

To help guide this transition, we have been formulating ten “simple” rules in our IOM Committee work.

First, care should be based on continuous healing relationships. In today’s health system the product of health care is the visit or hospital episode. In the future the product of the health care field will be the “healing relationship.” In the current framework of health care delivery, interaction and relationship are regarded more as a toll on health care than as one of its goals or products. The system today often acts as if interactions and relationships were an added burden for the real care process. In the twenty-first-century health system, interaction is not the price of care, it is care. In practical terms, care based on continuous healing relationships means that the health care system should be responsive at all times. It also means that care should be provided in many forms, including over the Internet and by telephone, not just through face-to-face visits.

Second is customization based on patient needs and values. I’ve already mentioned the concept of “mass customization” in other industries. In health care, customization means that the system of care should be designed to meet the most common types of needs but have the capability to respond to individual patient preferences and choices.

Third is the patient as the source of control. Patients should be given the necessary information and opportunity to exercise the degree of control they choose over health care decisions affecting them. Throughout most of the twentieth century the physician has served as the principal care provider, exercising a great deal of authority and autonomy. In the twenty-first century the role of the physician, in addition to providing highly technical services, will more likely be that of a “care partner” and coach. The notion is sometimes called “patient-centered care,” and it means that control over care and choices resides more in the patient. To

be sure, it takes time for patients to be included as partners in care, and they'll often need to be coached in this new role. However, in settings where this has occurred, its value has been shown by medical research. In sixteen of twenty-one studies published in recent years, patients who partnered with physicians were more likely to follow treatment advice (Stewart 1995). This held true for a range of health problems, including breast cancer, diabetes, hypertension, headaches, and gastrointestinal disease. This rule is not intended to imply that patients should be forced to share decision-making, only that it should be possible for them to exercise the degree of control they wish.

Fourth is shared knowledge and the free flow of information. Patients should have unfettered access to their own medical information and to clinical knowledge. This rule goes hand in hand with the preceding ones. It recognizes that information is the key to the patient-clinician relationship and that in most instances the exchange of information is the essence of the healing relationship.

Fifth is evidence-based decision-making. Patients should receive care based on the best available scientific knowledge. I've already discussed the importance of moving toward science-based practice. Another general rule is best practice based on systematically acquired evidence. In the twentieth century a commitment to autonomy of clinical decision-making has been a fundamental health care value. In the future a commitment to excellence—standardization to the best-known method, given the patient's circumstances—should be preeminent.

Sixth is safety as a system property. Threats to patient safety are the end result of complex causes such as faulty equipment, system design, and the interplay of human factors such as fatigue, limitations on memory, and distraction. The way to improve safety is to learn about causes of error and to use this knowledge to design systems of care to prevent error when possible, to make visible those errors that do occur (so that they can be intercepted), and to mitigate the harm done when an error does reach the patient.

Seventh, transparency is necessary. The health care system should make information available to patients and their families that allows them to make informed decisions when selecting a health plan, hospital, or clinical practice or choosing between alternative treatments.

Eighth is anticipation of needs. The health system should anticipate patient needs, rather than simply reacting to events. Our current health care system works largely in a reactive mode. The twenty-first-century

system should organize health care to predict and anticipate need based on knowledge of patients, local conditions, and the natural history of illness.

Ninth, waste should be continuously reduced. The health system should not waste resources or patient time. Members of the committee do not believe that increased value will come by stressing the current system—that is, by asking people to work harder, faster, and longer. Rather, increased value will come from systematically developed strategies that focus on the six Aims for Improvement of the health care system.

Tenth is cooperation among clinicians. Clinicians and institutions should actively collaborate and communicate to assure appropriate exchange of information and coordination of care. The current system shows too little cooperation and teamwork. Each discipline and type of organization tends to defend its authority at the expense of the total system's function—a problem known as suboptimization. Patients suffer through lost continuity, redundancy, excess costs, and miscommunication. The new rule asserts that cooperation in patient care is more important than professional prerogatives and roles.

Although I have used the term “simple rules” to refer to the guiding principles, our committee recognizes that adhering to these rules will be very challenging. Some of these rules bump up against professional norms and behaviors, while others will require major cultural changes in health care organizations. And there are environmental barriers that must be overcome as well. Legal liability, payment policies, regulatory systems, and other external forces that influence health care must be changed to encourage the types of behavior consistent with quality improvement.

How do we get from here to there? Changes will be needed at two levels: the care delivery and the environmental level.

Although we cannot foresee the range of new organizations, relationships, and technologies that will emerge over the coming decade, there are certain functions that organizational structures—whether virtual or bricks and mortar—will need to perform. Quality health care cannot be delivered through a cottage industry any longer. Well-designed care processes that are based on sound clinical and engineering principles and make the best use of information technology and human resources are essential.

Health care today is more and more an interaction between the sys-

tem and a person who needs help from that system. To be sure, the physician plays a critical role, but his/her effectiveness is increasingly determined by the characteristics of the system within which practice takes place.

Changes will also be needed in the environment of care. Current payment policies do not adequately encourage or support the provision of quality health care. Although payment is not the only factor that influences provider and patient behavior, it is a very important one. Too little attention has been paid to the careful analysis and alignment of payment incentives with quality improvement. The current health care environment is replete with examples of payment policies that work against the efforts of clinicians, health care executives, and others to improve quality. For example, a safety improvement initiative that reduces adverse drug events may also reduce payments for physician visits or shift hospital patients into Diagnosis Related Group categories that are less complicated and generate less revenue. Similarly, under current visit-based payment systems, clinicians have little incentive to communicate with patients through e-mail.

There will also need to be changes in health professional education and training programs. The traditional emphasis in clinical education, particularly medical education, has been on teaching a “core of knowledge,” much of it focusing on the basic mechanisms of disease and patho-physiologic principles. Given the expansiveness and dynamic nature of the science-base in health care, this approach should be expanded to include knowledge management as a means to support clinical decision-making. Similarly, as more care is provided in teams, more opportunities for interdisciplinary training should take place.

In order for innovative programs to flourish, our regulatory environments will also need to adapt. In general, regulation in this country can be characterized as a dense patchwork of federal and state requirements that are slow to change. One of the key regulatory issues affecting the workforce and how it is used is licensure and scope of practice acts, implemented at the state level. One effect of these acts is to define how the health care workforce is deployed. Although scope of practice acts are motivated by the desire to establish minimum standards to ensure the safety of patients, they also can make it difficult to use alternative approaches to care delivery, such as telemedicine, e-visits, nonphysician providers, and multidisciplinary teams.

These are but a few examples of some of the far-reaching changes

that will be necessary. In short, the need for leadership has never been greater—organizational leadership, physician/clinician leadership, and community participation. The transformation of the health care system will not be an easy process. But the potential benefits are tremendous.

This field has changed over time as the society has changed and as its capabilities have developed. It was only a century ago that care got complex enough, capital-intensive enough, and successful enough to warrant the middle class even wanting to be in a hospital. Physicians who volunteered in indigent clinics at hospitals applied for privileges. What was the privilege? To admit their private patients to the hospital and provide them care.

Today we're at the dawn of a new era of complexity, capital requirements, and potential effectiveness. The privilege for us in this new era will be to support development of new sets of organizational and financial capacities, just as we did during the last century, to make the most of these opportunities for all of our people.

REFERENCES

- Balas, E. Andrew, and Suzanne A. Boren. 2000. Managing Clinical Knowledge for Health Care Improvement. In *Yearbook of Medical Informatics*, pp. 65–70. Bethesda, Md.: National Library of Medicine.
- Boodman, Sandra G. 1999. Medical Web Sites Can Steer You Wrong: Study Finds Erroneous and Misleading Information on Many Pages Dedicated to a Rare Cancer. *Washington Post*, August 10, Health-Z07.
- Chassin, Mark R. 1997. Assessing Strategies for Quality Improvement. *Health Affairs* 16, no. 3: 151–61.
- . 1998. Is Health Care Ready for Six Sigma Quality? *Milbank Quarterly* 76, no. 4: 575–91.
- Chassin, Mark R., Robert W. Galvin, and the National Roundtable on Health Care Quality. 1998. The Urgent Need to Improve Health Care Quality. *Journal of the American Medical Association (JAMA)* 280, no. 11: 1000–1005.
- Classen, David C., Stanley L. Pestonik, Scott Evans, and John P. Burke. 1991. Computerized Surveillance of Adverse Drug Events in Hospital Patients. *JAMA* 266, no. 20: 2847–51.
- Goldman, Janlori. 1998. Protecting Privacy to Improve Health Care. *Health Affairs* 17, no. 6: 47–60.
- Hoffman, Catherine, Dorothy P. Rice, and Hai-Yen Sung. 1996. Persons with Chronic Conditions: Their Prevalence and Costs. *JAMA* 276, no. 18: 1473–79.

- Institute of Medicine. 1999. *Ensuring Quality Cancer Care*. Ed. Maria Hewitt and Joseph V. Simone. Washington, D.C.: National Academy Press.
- . 2000. *To Err Is Human: Building a Safer Health System*. Ed. Linda T. Kohn, Janet M. Corrigan, and Molla S. Donaldson. Washington, D.C.: National Academy Press.
- . 2001. *Crossing the Quality Chasm: A New Health System for the Twenty-first Century*. Washington, D.C.: National Academy Press.
- Leape, Lucian L., Troyen A. Brennan, Nan M. Laird, et al. 1991. The Nature of Adverse Events in Hospitalized Patients: Results of the Harvard Medical Practice Study II. *JAMA* 324, no. 6: 377–84.
- Lindberg, Donald A. B., and Betsy L. Humphreys. 1998. Updates Linking Evidence and Experience—Medicine and Health on the Internet: The Good, the Bad, and the Ugly. *JAMA* 280, no. 15: 1303–4.
- Medical Expenditure Panel Survey. 2000. MEPS HC-006R: 1996 Medical Conditions. Online. Available at <http://www.meps.ahrq.gov/catlist.htm> (accessed December 7, 2000).
- Miller, Naomi, Eve-Marie Lacroix, and Joyce E. B. Backus. 2000. MEDLINE-plus: Building and Maintaining the National Library of Medicine's Consumer Health Web Service. *JAMA* 88, no. 1: 11–17.
- Morrison, J. Ian. Healthcare in the New Millennium: The Promise of the Internet. 1999. New York: Presentation at Internet Health Care II: Health Care in Transition—Preparing for an Interactive Future, October 12.
- National Academy for State Health Policy. Forthcoming. *State Systems to Track Adverse Events*. Portland, Maine: National Academy for State Health Policy.
- National Center for Health Statistics. 1999. *Health, United States, 1999: With Health and Aging Chartbook*. Hyattsville, Md.: U.S. Government Printing Office.
- National Institutes of Health. 2000. An Overview. Online. Available at <http://www.nih.gov/about/NIHOverview.html> (accessed August 11, 2000).
- National Research Council. 2000. *Networking Health: Prescriptions for the Internet*. Washington D.C.: National Academy Press.
- Phillips, David P., Nicholas Christenfeld, and Laura M. Glynn. 1998. Increase in U.S. Medication-Error Deaths between 1983 and 1993. *Lancet* 351: 643–44.
- President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry. 1998. Quality First: Better Health Care for All Americans. Online. Available at <http://www.hcqualitycommission.gov/final/> (accessed September 9, 2000).
- Ray, G. Thomas, Tracy Lieu, Bruce Fireman, et al. 2000. The Cost of Health Conditions in a Health Maintenance Organization. *Medical Care Research and Review* 57, no. 1: 92–109.

- Robert Wood Johnson Foundation. *Chronic Care in America: A Twenty-first Century Challenge*. Princeton, N.J.: Robert Wood Johnson Foundation, 1996. Available at <http://www.rwjf.org/library/chrcare/>.
- Schuster, Mark A., Elizabeth A. McGlynn, and Robert H. Brook. 1998. How Good Is the Quality of Health Care in the United States? *Milbank Quarterly* 76, no. 4: 517–63.
- Schuster, Mark A., Elizabeth A. McGlynn, Cung B. Pham, Myles D. Spar, and Robert H. Brook. 2001. Appendix A: The Quality of Health Care in the United States: A Review of Articles since 1987. In Institute of Medicine, *Crossing the Quality Chasm: A New Health System for the Twenty-first Century*. Washington, D.C.: National Academy Press.
- Soumerai, S. B., T. D. McLaughlin, E. Hertzmark, G. Thibault, and L. Goldman. 1997. Adverse Outcomes of Underuse of Beta-Blockers in Elderly Survivors of Acute Myocardial Infarction. *JAMA* 277: 115–21.
- Stewart, Moira A. 1995. Effective Physician-Patient Communication and Health Outcomes: A Review. *Canadian Medical Association Journal* 152, no. 9: 1423–33.
- Thomas, Eric J., David M. Studdert, Helen R. Berstin, et al. 2000. Incidence and Types of Adverse Events and Negligent Care in Utah and Colorado. *Medical Care* 38, no. 3: 261–71.