
**Medicare: New Directions in Quality Assurance Proceedings**

Molla S. Donaldson, Jo Harris-Wehling, and Kathleen N. Lohr, Editors; Committee to Design a Strategy for Quality Review and Assurance in Medicare, Division of Health Care Services

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# Medicare

## New Directions in Quality Assurance

Proceedings of an Invitational Conference by the INSTITUTE OF MEDICINE
Division of Health Care Services

Molla S. Donaldson, Jo Harris-Wehling, and Kathleen N. Lohr, editors

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# Contents

# PART I

# Introduction

# 1

# Introduction

*Molla S. Donaldson, Jo Harris-Wehling, and Kathleen N. Lohr*

## QUALITY OF CARE AND QUALITY ASSURANCE FOR MEDICARE

At the twenty-fifth anniversary of the Medicare program, the Congress of the United States, the executive branch of the federal government, and indeed the entire country can be justifiably proud of the accomplishments of the program in expanding access to a generally high level of quality of care for the elderly. Near universal coverage by the Medicare program gives elderly people better access to health care than any other age group. Nevertheless, care is neither uniformly accessible nor uniformly good. Excessive care, underuse of services, and care of poor technical or interpersonal quality in hospital, office, and community settings continue to be reported. Some quality problems may be related to gaps or inadequacies in Medicare coverage.

Almost from the beginning, the federal government has tried to ensure that services reimbursed through the Medicare program are medically necessary, appropriate, and of a quality that meets professionally established standards. The two main efforts in this arena have been the Professional Standards Review Organizations (PSROs), in operation between 1972 and 1981, and the Utilization and Quality Control Peer Review Organization (PRO) program in operation since then. The success of those programs in meeting goals has been mixed, at best.

Since the implementation of Medicare's Diagnosis-Related Group (DRG) based prospective payment system (PPS) for hospitals in 1983, Congress has heard from many quarters that the quality of health care was being (or would be) undermined. To date, however, few data support or refute such claims.

In response to the concerns that quality of care might be deteriorating under PPS and that the PROs and other mechanisms for monitoring quality were inadequate, Congress included in the Omnibus Budget Reconciliation Act of 1986 a provision that directed the Department of Health and Human Services (DHHS) to request that the National Academy of Sciences "design a strategy for quality review and assurance in Medicare."

## THE INSTITUTE OF MEDICINE STUDY

In 1987, therefore, the Institute of Medicine (IOM) of the National Academy of Sciences appointed a committee to conduct the requested study, with funding from the Health Care Financing Administration (HCFA). The study committee interpreted the congressional charge as a call for a far-reaching strategic plan for developing a program throughout the next decade for assessing and ensuring the quality of medical care for elderly people. In March 1990 the IOM released the committee's two-volume report *Medicare: A Strategy for Quality Assurance.*[1] Volume I contains the IOM committee's recommendations for a comprehensive quality assessment and assurance strategy for Medicare. Volume II includes an extensive compilation of available information on quality measurement and assurance, and makes available many of the background technical analyses that supported the committee's deliberations.

The report concluded that the current Medicare system to assess and ensure quality is not very effective and may have serious unintended consequences. It pointed out, however, that opportunities are now emerging to set in place a comprehensive system of quality assurance that can address itself to improving the health of U. S. citizens.

The committee articulated several themes as the basis for the major redirection for a quality assurance program for Medicare. These included

- enhancing professionalism,
- strengthening organizational systems for quality improvement,
- improving patient and practitioner decisionmaking,
- introducing a patient outcomes orientation to quality measurement, and
- evaluating quality assurance activities.

Largely on the basis of the thrust of these new directions, the committee made ten major recommendations. Two recommendations proposed expanding the statutory mission of the Medicare program to include responsibility for quality of care for the elderly, with quality of care defined as "the

[1] Institute of Medicine. *Medicare: A Strategy for Quality Assurance*. Volumes I and II. Lohr, K.N., ed. Washington, D.C.: National Academy Press, 1990.

degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge." A third recommendation focused on the needs for research in areas of clinical evaluation (e.g., quality of care, outcomes, and effectiveness), and a fourth called for expanded training for health professionals in quality assurance and research. A fifth recommendation called for reorganizing the current PRO program into a Medicare Program to Assure Quality; two related recommendations addressed implementation of that new effort. Finally, three recommendations concerned public oversight, accountability, and evaluation of the new program.

An expanded mission for Medicare would aim to improve the quality of health care for Medicare enrollees, strengthen the ability of health care organizations and practitioners to assess and improve their own performance, and identify and overcome system and policy barriers to achieving good quality of care. A comprehensive system of quality assurance for Medicare would aim to develop tools to help providers improve the health of the elderly and to monitor their own performance, improve communication between clinicians and patients, broaden the concerns for the health and well-being of the elderly, and serve as a prototype for quality assurance systems for other parts of society.

## THE INSTITUTE OF MEDICINE CONFERENCE ON MEDICARE: NEW DIRECTIONS IN QUALITY ASSURANCE

The committee considered its final report only one important product of the study. Promoting discussion and provoking reactions from the intended audiences were equally important. With this in mind, an invitational conference was convened in May 1990 to give interested parties an opportunity to discuss the key themes of the report, address special implementation issues, examine research and training agendas, and comment on specific actions that might be undertaken in the public and private sectors in response to the report's recommendations. The remainder of this monograph comprises the papers, presentations, and discussions at the conference.

## THE CONFERENCE AGENDA

Rather than focusing the conference on the specific recommendations of the committee, the program agenda emphasized the underlying principles that can provide "new directions" in quality assurance, as noted above. Thus, parts of the conference addressed the following themes: "More Professionalism, Less Regulation"; "Organization- and System-Focused Quality Improvement"; "Improved Decisionmaking by Patients and Clinicians"; "A Patient Outcomes Orientation"; and "Public Accountability and Program

Evaluation." Each part was introduced by an IOM study committee member and included one major presentation by a committee member and a response by a ranking expert who had not been a member of the committee.

Two panels discussed implementation of study recommendations. The first panel examined special issues in understanding the epidemiology of quality problems, responding to legal concerns, and translating the IOM report strategy beyond the Medicare program. The second panel addressed the research, training, and capacity building agendas called for in the study report. In addition, "responses" to the report were heard from a diverse set of interested parties, including two members of the U.S. Congress and several national leaders in the health care professions.

We were fortunate in the insightful and thoughtful comments given by both the speakers and the participants at the conference. With this proceedings we invite our readers to join the discussion.

# 2

# The Institute of Medicine Report

*Steven A. Schroeder*

Welcome. We have a lot to do today. We are here to see whether this report (IOM, 1990) will sink like a stone, as some Institute of Medicine (IOM) studies do, or whether it will stimulate some reaction. The committee worked very hard on this project throughout the past two and a half years, and 15 of the 17 members of the committee are participating in this conference. To assess whether we should go further with this effort, we are going to need your reactions and comments, both to the IOM report itself and on what the next directions should be. To begin this process, I will summarize very briefly some of the highlights of this two-volume report.

## CHARGES TO THE COMMITTEE

We were asked by Congress to do a number of things:

- define quality of care,
- evaluate standards,
- describe current methods to measure, review, and assure quality,
- evaluate the adequacy of current methods for preventing, detecting and correcting problems of poor quality,
- set up a research agenda,
- consider how coordination and supervision of quality at the national level should be done, and
- look at criteria for allocation of funds and personnel.

To do this, the IOM put together a very interesting committee. Included on it were people from the research community, biostatistics, geriatrics, private practice of medicine, social work, nursing, hospital administration,

American Association of Retired Persons, labor, business and industry, health economics, law, and the Washington inside scene.

The focus of the study was deliberately broad. We looked at the beneficiaries. We looked at different settings of care. We excluded nursing homes in view of the fact that the IOM had just released a very comprehensive study on care in nursing homes. We looked at ambulatory care, both fee for service and in health maintenance organizations (HMOs). We said, "Let's take a long-term view and admit that under current conditions, we do not know what the financial or organizational structures are going to look like by the year 2000. Many things might happen, so let's have a strategy that is broad enough and flexible enough to respond to different and perhaps unforeseen developments."

## DEFINING QUALITY OF CARE

The first thing we did—and it took us a long time—was to come up with a definition: "Quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge." Let me walk through that definition a bit because it is important to understand its full interpretation.

First, the concept that quality is a probabilistic, not a dichotomous, concept is very critical. Second, we are talking about all people eligible for Medicare, not just those who check into a hospital and have something done to them. This is a very important criterion in examining what the data base should be for looking at quality. Third, desired health outcomes involve patient preferences. Fourth, health services must be consistent with current knowledge. Fifth, these latter two points imply that the medical care system and its practitioners are involved in a dynamic structure. We thought that this was a broader and a more compatible definition of quality than others that we could have chosen.

## FINDINGS

### Health Care and Health of the Elderly

What did we find? Regarding the elderly themselves, there were no big surprises. There are going to be more elderly, and they will constitute a larger proportion of the population. The good news is that people are living longer. Compared with most other Western countries, we may not do very well as regards the infant mortality rate, but we do pretty well once we hit age 65. Although it is not true for a U.S. infant, a 65-year-old in the United

States does relatively well in comparison with his or her German or French counterpart. An increasing number of elderly will be living with chronic illness and disabling conditions.

As regards Medicare and the elderly, the elderly have better access to health care than any other age group. Still, health care costs continue to rise, and pressures for cost containment continue to increase. Much health care has shifted out of the hospital into outpatient settings, long-term-care facilities, and the home. Gaps in coverage and financial barriers are going to pose increasing problems in terms of quality and access.

## Burden of Harm

To devise a program that looks at a problem, we have to know the nature of that problem. We spent quite a bit of time trying to see if we could quantify the burden of poor quality. The data here are surprisingly spotty.

The types of quality problems include poor technical quality, overuse, and underuse. We found that there is a lot of *poor performance*. From testimony we heard, it is spread throughout the population but is also concentrated in outliers. We know a moderate amount about technical problems, but we do not know as much about deficient interpersonal skills, although we suspect that this, too, is a major quality issue. *Overuse* is probably the best documented of the three quality areas. We know that a substantial amount of overuse exists in surgery, prescription drugs, and invasive diagnostic technologies, and because each instance of overuse carries a finite risk of patient harm, every unnecessary operation or drug or invasive diagnostic procedure is a quality problem. As regards *underuse*, the literature is just not that robust. We think there is a lot of underuse, but it is harder to measure. It does pose risks to patients.

The committee concluded that the burden of poor quality included all three of these categories. We cannot put a percentage on them, but we think it is very important that quality-of-care systems focus on all of them, not just on one, and we are afraid that much of the current scrutiny on quality of care focuses only on poor technical performance.

## Approaches to Quality Assurance

What have been the approaches to quality assurance? In terms of concepts, we do not think there is a single approach that will apply to every setting and each type of quality problem. So, the classic triad of structure, process, and outcome still makes a lot of sense. We heard a lot about the continuous improvement approach, and it was striking how conceptually appealing this approach is.

The practical state of development of this new approach, however, reminds me of a story in David Halberstam's *The Best and the Brightest* (1972). When Lyndon Johnson emerged from his first Kennedy cabinet meeting, he remarked to Sam Rayburn how awed he was by the intelligence of the assemblage: "Sam, these people are so bright I can't believe it." Rayburn listened for a time and then replied, "Well, Lyndon, that's all very good. I'd just feel better if one of them had ever run for sheriff."

We found that there is a tremendous amount of intellectual excitement and energy about the continuous improvement model, but it has yet to run for sheriff. So we are going to wait and see what happens when that model is applied in the field; if it is half as good as its proponents say it is, then we are in for an exciting time. However, we did not think, as a responsible committee, that the evidence was sufficiently good for us to declare it a definitive solution.

We concluded that different approaches were needed for different sites of care (e.g., hospital, home and ambulatory setting). Because incentives differ depending on how care is paid for and organized, we may need to be flexible and have different safeguards depending on whether patients are in HMOs or in fee-for-service settings.

Current quality assurance methods tend to focus on single events and single settings. They concentrate on what happens during hospitalization, rather than episodes of care or continuity of care. They are particularly deficient in diagnosing underuse or overuse of health services. If unnecessary bypass surgery is done with technical proficiency, that usually does not show up as a quality problem, particularly given the ambiguity in indications for bypass surgery.

Outliers account for a large proportion of the serious quality problems identified by the current methods. We heard some impressive testimony from two different states that a large proportion of the quality problems was traced to a relatively small cohort of practitioners and their hospitals. We heard, on the other hand, that once those problems were looked at, not much could be done to rectify them. As a system, our capacity to identify problems is much more advanced than our capability of remedying those problems. The current system of quality assurance does little to improve the behavior of the average provider.

## Peer Review Organizations

What about the function of the Medicare Peer Review Organizations (PROs), which are the statewide organizations that conduct review in the Utilization and Quality Control Organization Review program administered by the Health Care Financing Administration? We had an opportunity to visit many of them and talk with many of their representatives. We ac

knowledge the value of the infrastructure of the PROs, but we also concluded that some criticism is merited and that the PRO focus remains on utilization and cost more than quality. This reflects the language of the PRO legislation and the approach to funding PROs.

The PRO focus in terms of quality is on outliers, rather than on the average provider, and they were almost totally concerned with hospital care. The committee found that PROs were felt to pose an excessive burden on providers. It is our impression that a perception of bureaucratic harassment of practicing physicians—especially those in primary patient care—has served to diminish the attractiveness of the profession, and there was a sense that the PROs were part of the problem. Rather than having a two-tailed approach—to reward the virtuous and to try to correct those who are not—the PROs only looked at one tail of the behavioral spectrum, resulting in an adversarial and punitive process that did not work very well.

The kinds of funding arrangements that the PROs were working under were quite rigid. There was a lot of redundancy with other programs, particularly in the private sector. Finally, and perhaps most critically, there was no public oversight of the program to see whether it did what it was supposed to do, if it were possible to judge what it was supposed to do. So we felt that the opportunity was there to make explicit the goals and the directions of quality assurance.

### Capacity Building

We were also asked to set forth our recommendations for a national quality assurance structure. We said that at the present time, we were not sure that the nation has the capacity for a comprehensive and effective quality assurance system. We need to know more about the basic methods of detecting, and particularly of correcting, quality assurance problems. To do that, we needed to expand capacity in terms of generating the people with the requisite skills who are needed for the task. We also felt that it would be important to share national outcomes data with patients and health care workers so that patients could select the type of medical care they felt was most congruent with their desired outcomes.

## A STRATEGY FOR MEDICARE QUALITY ASSURANCE

We think a shift in emphasis needs to take place—from individual providers and events of care to episodes of care. The focus needs to be broadened from the hospital to all settings, particularly given the way that changes in economics and technology have altered the site of delivery of medical care. We need to have much more public oversight and evaluation of what we are doing and how we are doing it.

The current emphasis on regulation, inspection, and monitoring needs to focus as much as possible on the virtuous aspects of professionalism. A quality-of-care approach should appeal to the best side of health professionals to help them to carry out the mission that inspired them to enter health care. We should strive for improvement rather than inspection, turning the task as much as possible internally to let groups improve themselves. We should shift the focus more from just looking at the provider to examining patient interactions with providers. We should give the data collected in quality assurance efforts back to people working in the health care field so that they can make more informed decisions about what they are doing now and how they can do better in the future.

## Mission and Goals of Medicare Program

We thought it was very important to expand the mission of Medicare, to make explicit the responsibility of assuring the quality of health care for enrollees in Medicare. A virtue of our definition is that it looks at populations. For example, if 20 percent of the elderly population never get any health care and die or suffer adverse functional outcomes, this problem would not be detected by the PRO program, because it only measures what happens to people who enter the health care system.

Three explicit goals for the quality assurance system should be articulated: to improve continuously the quality of health care for enrollees; to strengthen the ability of health care organizations and practitioners to assess and improve their own performance; and to identify barriers to achieving quality of care and then see how we can overcome those barriers.

## Medicare Program to Assure Quality

To achieve these goals, we recommended restructuring the PRO program. We proposed renaming it the Medicare Program to Assure Quality (MPAQ). Its functions should be defined, and Medicare Conditions of Participation for hospitals should be consistent with these functions.

Let me give you the committee's rationale for thinking there needed to be a Quality Program Advisory Commission (QualPAC). One of the problems facing the way health care is looked at in this country is that it is divided up into neat little boxes, but the linkages across different territories are not done very well. So many aspects of health care affect the elderly that there needs to be an oversight group with the breadth, vision, and political independence to analyze data from every possible source and to say, in a nonpartisan, nonbureaucratic, nonterritorial way, "Here are the kinds of problems we should address." We were probably influenced by the two commissions that Congress has set forth, the Prospective Payment Assessment

Commission (PROPAC) and the Physician Payment Review Commission (PPRC), which have their own major assignments. This quality advisory commission ought to oversee the activities of the Medicare quality program and report periodically to Congress on how MPAQ is doing.

We also thought there should be a National Council, established within the Department of Health and Human Services (DHHS), to assist in implementation, operation, and evaluation of the MPAQ and to tackle difficult policy issues, for example, the release of quality data on individual hospitals or other providers. This is the kind of group that could take a look at that and say, "Yes, we think that the data are sufficiently strong to be released," or "No, let's reanalyze the data."

We recommend that the Secretary report to Congress on quality of care for Medicare beneficiaries and on the effectiveness of the Medicare Quality Assurance Program—how well it is doing in meeting those three goals I mentioned earlier—at least every two years.

The Health Care Financing Administration (HCFA) will have responsibility for the MPAQ and for the local organizations, the Medicare Quality Review Organization (MQROs), to carry out those functions with the assistance of contractors, if the organization needs them. The Department of Health and Human Services will have its National Council as well as outside technical advisory personnel, and Congress will have an Advisory Committee to take the broadest possible look.

More specifically, HCFA's responsibilities for the MPAQ are to set up both a short- and a long-term program. We are talking about a ten-year period to get the data that are required to do some of the outcome feedback we have talked about. There should be monitoring and evaluation of the local operations.

HCFA will also collect, analyze, and use the feedback process and outcome data to inform internal quality assurance programs. All this may be done by MQROs in some instances, or certain groups may decide to do much of the data collection and analysis on their own, but all providers groups, facilities, and the like will be assisted by feedback of pertinent data. Information will be reported back to the larger program in order to consider rewards, interventions and even sanctions if they seem necessary.

DHHS will have its National Council to advise on how this program is performing, what mid-course corrections need to be made, and what the next steps are. It will be assisted by a Technical Advisory Panel, again to enhance public oversight and evaluation.

Finally, responsibilities of the Congress will be to establish QualPAC, which will advise Congress on quality assurance and report on quality of care for the elderly. One of the responsibilities of the Congress will be to assure adequate funding for this program so that it can achieve the desired level of performance.

Finally, we need to improve the capacity of the system in terms of its research and knowledge base, and the kinds of personnel that will staff it.

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# PART II

# New Directions: More Professionalism, Less Regulation

# New Directions: More Professionalism, Less Regulation

## INTRODUCTION

*William S. Hoffman*

This part of the conference proceedings is entitled "More Professionalism, Less Regulation." The professionalism that the study committee described and discussed was not the aspect or dimensions of professionalism that are more associated with secret, perhaps elite, concerns that might be called trade association economics or the exclusivity of a profession. Rather, we were talking about the more virtuous aspects of professionalism—the assumption that an individual wants to grow not only as an individual, but with the science and in his or her commitment to patients. It is that kind of professionalism that we will be discussing. Committee member Leo M. Cooney, Jr., M.D., Humana Foundation Professor of Geriatric Medicine at Yale University School of Medicine, presents the committee's views; Lonnie Bristow, an internist in the private practice of medicine in California, offers a response. In much of the committee discussions there was a continuum of concerns. Commitment to individual growth, a collegial atmosphere, moving from legalism and detecting problems as opportunities for improvement—all of this ran through committee discussions. At the same time, none of us was comfortable enough to come out fully and say there are examples of quality assurance systems based solely on this notion of professionalism that will work throughout the whole system of health care. Generally, current quality assurance programs tend to place more emphasis on costs, utilization, and on detection and control, and less emphasis on professional growth, outcomes, and improvement of health. We have to find a point between rigid regulation at one end of the continuum and unexamined professionalism at the other.

# 3

# More Professionalism, Less Regulation: The Committee View

*Leo M. Cooney, Jr.*

Early in my career, I was given responsibility for overseeing the care provided by more than 100 interns and resident physicians at a large urban teaching hospital. I learned quickly that it was not easy to ensure that professionals will always perform to the best of their abilities. I could see that they were in the right place at the right time. I could review each chart to ensure that each fever was evaluated and each patient with anemia worked up, but too much badgering affected morale and performance. I learned at Boston City Hospital, however, that encouragement, peer pressure, motivation, and pride in a joint effort could result in a very high standard of care.

Now, many years later, I have a different experience with quality-of-care efforts in my dual responsibilities as director of utilization review at another large university hospital and as medical director of a skilled nursing facility. I now find myself spending hours worrying about the quality of records instead of the quality of patient care. Are the "verbal orders" signed, recreational therapy plans reviewed, or 30-day reviews completed? I see the adversarial relationship that has developed between our Peer Review Organization (PRO) and our hospital and medical staff. Numerous charts are photocopied and sent off in entirety because they fail "quality screens." Letters and accusations pass back and forth with virtually no impact on the way in which we practice medicine. The quality review burden on providers is exacerbated by the large number of agencies that review care, including the state health department, Medicaid agency, PROs, and the Joint Commission on Accreditation of Healthcare Organizations, yet these agencies are unable to share information or review in a coordinated fashion.

As I have participated in this Institute of Medicine (IOM) committee for the past two years, I have tried to understand why some review is helpful and effective and other reviews are so intrusive and often counterproduc

tive. I have concluded that a successful review is one in which you are treated as a professional, are challenged by your peers, and feel that you are a part of the process. Furthermore, there are both a clear understanding of why your work is being reviewed and a general trust in the experience and skills of those reviewing your work. This professional review is an essential component of American medicine, and it is reflected in morbidity and mortality conferences, tissue committees, clinical pathological conferences, and management reviews.

Most of the reviews that are generated by external agencies do not meet with the same level of understanding and cooperation that professional review receives. Most external reviews are designed to identify poor performance, not to elevate the general standard of care. Our present system subjects all providers to an increasingly burdensome and adversarial review to identify a small number of "outlier providers." Unfortunately, once these outlier providers have been identified, our review organizations have not been able to deal with them effectively.

We propose, in this IOM report (IOM, 1990), to move away from an often punitive review of the quality of records and process of care to a more substantive and innovative review of the actual results of care provided. We recognize that this review will be difficult and challenging, but it will conform to the standards of review that health care professionals have used for the past century to determine the effectiveness of various medical, surgical, and preventive maneuvers.

This emphasis on outcome will require cooperation and participation by health care professionals in the outcome process and analysis. Furthermore, we will supply these data to providers and, if necessary, we expect them to adjust their care to improve their results. We have seen how cooperatively and effectively institutions can deal with such problems as operative wound infections, nursery epidemics, and complications resulting from the use of new equipment and procedures. We would like to expand these efforts at continuous quality assurance by identifying those areas in which providers might attempt to improve their results.

We have made a major new assumption in quality review in this report, one that I believe heightens the "professional responsibility" theme of the report. We believe that, because providers must assume responsibility for the final outcomes of care, they must assure that all aspects of the health care system are properly applied. Thus, if one institution finds that a high proportion of its patients with fractured hips, though previously independent, are now immobile or institutionalized, that institution must look at all aspects of care. Whether the problem is poor surgical technique, postoperative care, in-house rehabilitation, discharge planning, or home or nursing home rehabilitation, the provider must identify the problem and address its correction. We have based our new approach on four characteristics of health

care providers: professionalism, responsiveness to outcomes, competitiveness, and pride.

## PROFESSIONALISM

Professionals must assume responsibility for a task and be accountable for all aspects of this effort. This concept recognizes that the health care professional is accountable not only for the care he or she delivers, but also for the continuum of care arranged for that patient, from consulting physicians to home care to skilled nursing facility care. An emphasis on the outcome for care highlights the responsibility of the professional to assure that all aspects of care delivered to his or her patient are of such quality and coordination that the outcome will be as good as possible.

## RESPONSIVENESS TO OUTCOMES

Health care professionals make many decisions throughout each day, decisions that are well-meaning and have substantial impact on the outcome of care. Medical research helps us with many of these decisions, such as giving us data about medical treatment versus observation for asymptomatic urinary tract infections.

There are many other decisions, however, for which traditional medical research has not been helpful. Which elderly patient might benefit from a total hip replacement, and which patient might become confused and experience a decline in health status during the hospitalization? Should patients with fractured hips receive their rehabilitation in an acute hospital, in a rehabilitation hospital, or in a skilled nursing facility? What is the outcome of care in the real world of community hospitals and community practitioners versus those results reported in the literature from university referral centers?

We believe that this information, fed back in an appropriately nonjudgmental manner, will have a positive effect on the way in which we practice care and on the outcome for our patients. Moreover, this emphasis on outcome will point out that exceptional technical care followed by poor rehabilitation is unsatisfactory, in that the health professional has the responsibility for ensuring the best possible final results of care for his or her patient.

## COMPETITIVENESS

Americans are, of course, very competitive, and we should use this characteristic to improve the quality of care. At present, hospitals compare themselves with other hospitals in terms of who has the most high-technology equipment, who is doing heart and liver transplants, and who has the best accommodations and menus. Few data are available to institutions to allow

them truly to know how they are doing. I believe that the natural instincts of the American marketplace will push these institutions to improve the outcomes for their patients with fractured hips, pneumonia, myocardial infarctions, and other medical and surgical conditions. They will do this only when they feel that these outcomes are an accurate reflection of the care that they arrange or provide. Internal steps designed to improve quality of care can and have worked extremely well when providers understand the importance of these maneuvers to improve the outcome for their patients.

## PRIDE

Most of us chose the health care professions as our career because of a strong ego. We want patients to come to us and to our institutions because they believe that we will provide the best care available. If we believe that the outcomes reported to us are a true reflection of the results of care given to our patients, we will do all in our power to make those results as positive as possible. We will make these efforts only if we believe in the value and integrity of those reviewing us and in the results they generate. This entire process will have positive outcomes only if professionals buy into it as a cooperative venture, producing results with which all can agree.

## CONCLUSIONS

In the final analysis, we believe that excellent medical care results from highly motivated, skilled, and energetic clinicians who feel that the system in which they work is responsive to the needs of their patients. Individuals will be encouraged to provide the highest standard of care if they see that these efforts result in improved outcomes for their patients. Furthermore, health care professionals have demonstrated the ability and desire to adjust their practice patterns when data point out the most effective patterns. We believe that the American health care system will achieve better results for its elderly patients if it encourages, stimulates, and rewards the motivation for caring that led many of us to enter the health care professions.

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# 4

# More Professionalism, Less Regulation: A Response

*Lonnie R. Bristow*

On behalf of the American Medical Association (AMA), I would like to congratulate the Institute of Medicine (IOM) for this important report (IOM, 1990). There is little doubt that Americans, including the elderly, generally receive high-quality medical care. Nevertheless, improvement in the quality of medical care is always possible, and we welcome effective strategies to accomplish this goal.

We have reviewed the IOM's report and have found the principles in that report to be generally consistent with existing AMA policies. In addition, the report proposes a number of changes in the Medicare review process that are also consistent with our long-standing goals, including greater emphasis on quality rather than cost concerns, on professional self-regulation, and on educational (as opposed to punitive) uses of review. I can find absolutely nothing with which to disagree in Dr. Cooney's initial statements (Cooney, 1991).

## PROGRAMMATIC CONSIDERATIONS

We do, however, disagree with some of the programmatic activities recommended in the IOM's report. For example, we believe that before considering recommendations regarding the complete elimination of utilization review as a component of Peer Review Organization (PRO) review activities, it is important to determine where and how utilization review will be conducted because, properly done, it does have value. Although there are many shortcomings in the utilization review activities of PROs, the utilization review processes used by PROs generally have been superior to those used by carriers.

The IOM's report calls for an expansion of PRO quality review activities with strong emphasis on data analysis and outcomes assessment. In assessing

the performance of PROs to date in detecting and addressing quality problems, it is helpful to keep in mind the relatively early stage of PRO activities in this area. Unfortunately, PROs too often have directed their attention primarily to utilization and cost containment rather than quality assurance. Therefore, we are pleased that quality review is becoming a more important focus of PROs, and we need to recognize that many of the techniques to identify cases of possible quality problems are still in their infancy.

Providing quality medical care is an enormously complex process in which many subjective as well as objective issues must be considered. For example, is there medical certainty in the relevant clinical area? What treatment options are available? What technology or specialized facilities are available? What are the patients expectations and are those expectations reasonable? What quality-of-life issues should be considered? What other factors should be integrated in the individual treatment decision? Although some of these issues can be quantified, many cannot.

In essence I am saying that there are precious few all black and all white decisions that are made. There are, instead, a great many gray decisions that have to be made.

We agree that ongoing research is essential to identify and improve techniques to collect and analyze data. Yet the limitations inherent in data analysis must be kept in mind. Data analysis will be an important adjunct to, rather than a substitute for, clinical judgment. Improved data and more sophisticated data analysis will be useful to quality assurance activities. However, the data will never substitute for clinical judgment or true medical peer review. Physicians must continue to have the flexibility to tailor medical care to meet individual patient needs.

## PRACTICE PARAMETERS

I would like particularly to commend the IOM's report for its emphasis on the role of practice parameters in improving quality and assuring appropriate utilization. Physician organizations have played a key role in the development of such practice parameters. Eight physician organizations had already developed certain practice parameters by 1980. Recently I heard an economist in another city discussing practice parameters, and he was recommending to a group of physicians that they really ought to use them. He presented the subject almost as though economists had invented practice parameters. At this time in 1990, 26 physician organizations have developed useful parameters, and at least 10 additional organizations of physicians are actively engaged in the development of other practice parameters.

Effective practice parameters are an important mechanism to improve quality. For example, the parameters for cardiac pacemaker implantation

developed by the American College of Cardiology have already contributed to significant improvement in the appropriate utilization of pacemakers.

Implementation of parameters for intraoperative monitoring developed by the American Society of Anesthesiologists has already significantly reduced the occurrence of hypoxic injuries in patients during surgery. In addition to their direct benefit to physicians, practice parameters will also provide a rational basis for the development of review criteria for quality assurance programs.

## AMERICAN MEDICAL ASSOCIATION (AMA) GUIDELINES FOR QUALITY ASSURANCE

Because of our deep commitment to improving the quality of medical care, the AMA has developed a set of guidelines for quality assurance that should be included in any medical peer review system. We have shared those guidelines with the Institute of Medicine during the preparation of its report, and we are extremely pleased to find that many of these principles are incorporated in the IOM's report.

Five of the key guidelines are as follows:

1. The general policies utilized in any quality assurance system should be developed and agreed upon by the physicians whose performance will be scrutinized and should be objectively and impartially administered. Such involvement and objectivity are critical to assuring continued physician participation and cooperation.
2. To the degree possible, quality assurance systems should be structured to recognize care of high quality as well as to correct instances of deficient practice. Quality assurance systems should explore methods to identify and recognize those treatment methodologies or protocols that consistently contribute to improved patient outcomes, and information on such results should be communicated to the medical community.
3. Feedback mechanisms should be established to monitor and document needed changes in practice patterns. You have heard many speakers say physicians want that sort of information, and that's absolutely correct. Linkages between quality assurance activities and quality assessment systems should allow the very important assessment of the effectiveness of any remedial activities that have been instituted.
4. Quality assurance systems should make available the appropriate educational resources required to effect desired practice modifications. It does little good to inform physicians about what needs to be done unless one provides the resources required to put that information in a useful and practical package.
5. Emphasis should be placed on education and modification of unacceptable practice patterns rather than on sanctions. The initial thrust of any

quality assurance activity should be toward helping practitioners correct deficiencies found in knowledge, skills, or technique.

## RESEARCH AND PEER REVIEW

We believe strongly that additional research should be conducted to improve quality assessment and quality assurance. Well-conducted research will improve quality assurance programs and provide a much better scientific basis for clinical management decisions.

We are also staunch advocates of effective medical peer review being an essential component of quality assurance. True medical peer review is the review of the clinical performance of physicians by other physicians of like training and specialty. We recognize the need for accountability in our actions and want that accountability to be based upon appropriate medical peer review.

## CONCLUSION

In conclusion, although Americans, including the elderly, in general receive high quality medical care, we must continue to expand our efforts to improve the quality of medical care. Improved systems of quality assurance are an important part of that effort. However, strategies to improve quality assurance must acknowledge the complexities inherent in the care of patients and the enormous variability that occurs among patients, in their clinical status as well as in their preferences. Although data analysis and outcomes assessment will be important, data analysis will never substitute for clinical judgment or for medical peer review. Physicians have long played an active role in efforts to improve the quality of medical care, and future efforts to improve quality assurance must involve physicians and physician organizations in every aspect of the planning and implementation of quality assurance systems.

Again, we applaud the IOM for its effort. The AMA looks forward to working with the IOM and others as the recommendations contained in the report are further evaluated, and to the extent that they conform to the five precepts previously articulated, you will find us very willing participants with you.

Finally, although quality assurance programs are essential, quality assurance systems will never substitute for or replace the one essential component of quality medical care: well-informed, caring physicians addressing the unique needs of individual patients to produce the optimal possible improvement in that patient's physiological status, physical function, emotional and intellectual performance, and comfort.

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# PART III

# New Directions: Organization- and System-Focused Quality Improvement

# New Directions: Organization- and System-Focused Quality Improvement

## INTRODUCTION

*Loring W. Wood*

This part of the conference proceedings examines the complex of methodologies subsumed under the generic heading of quality improvement, that issue so evocatively referred to earlier as not yet having "run for sheriff" (Schroeder, 1991). The theme of quality improvement, which is a transplant from industry, is a fact of everyday life in my own corporate environment. It incorporates organization-wide commitment to a customer focus through continuous improvement of all of the processes in the organization, to improving the average, and to moving the curve. Quality improvement appears in one form or another in several parts of the Institute of Medicine's committee report.

The second recommendation in the committee report states that Congress should adopt three goals for the quality assurance activities of the Medicare program. In an early draft of the report, the first of these three goals was given as ". . . improve the quality of health care for Medicare enrollees. . .". This implied moving quality from point A to point B over some unit of time. We added a single word to that—the word "continuously" at the beginning of the sentence—changing the entire meaning of this recommendation in the final report.

Quality improvement is one of a wide variety of methods of managing quality within and across organizations that we envision will be tested during our proposed 10-year strategy. In our committee discussions, professionalism was a central theme. One of the features of our strategy is that professionalism be allowed to grow in local organizations, institutions, and systems. Through the collection of information about the performance of those systems and of the physician as a component of those systems, a variety of methods of quality assurance and quality improvement can be evaluated. What really works will be the end point that will drive those evaluations.

The next two papers explore this idea of quality improvement from two perspectives. James Mortimer, a member of the IOM study committee, is President of the Midwest Business Group on Health (MBGH). Organized initially in 1980, the coalition now has about 180 member employers and spans a nine-state region. The MBGH is one of the major business coalitions in the country today and one of the few that is actively exploring quality-of-care issues on behalf of its members. Mr. Mortimer's paper explains the basis of the committee report, but with overtones of his extensive background in value-managed purchasing of health care services.

Chip Caldwell, President and Chief Executive Officer of the Hospital Corporation of America's West Paces Ferry Hospital in Atlanta, Georgia, represents a supplier of health services in one of the long-standing and successful programs of quality improvement in a hospital system. In November 1987, West Paces Ferry began implementing a quality improvement program under the Deming management method. Today the quality improvement program hosts six clinical teams, eight cross-functional quality improvement teams, and more than 20 functional teams. Drawing on this experience, Mr. Caldwell offers a "real-life" example of the directions in which a commitment to continuous quality improvement may take a health care institution.

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# 5

# Organization- and System-Focused Quality Improvement: The Committee View

*James D. Mortimer*

I have been honored to be part of this Institute of Medicine (IOM) study committee. I have learned a lot, and I have enjoyed the opportunity to meet and work with fellow panelists and the staff. The IOM report (IOM, 1990) is a comprehensive discussion of quality management in health care. In this brief paper, I will try to provide a picture of how quality improvement fits into this study and then discuss what role quality improvement might play in our proposed strategy.

As we use the term quality assurance in the report it includes quality assessment, quality assurance in a narrow sense, and quality improvement. Those are all terms for which people have varying definitions. In fact, quality improvement ideas are laced throughout the report, starting from the first goal in the committee's second recommendation and continuing through the rest of the report.

## QUALITY IMPROVEMENT AND OUTCOMES

In Chapter 2 of the IOM report, we explore patient outcomes and our understanding of the distribution of outcomes (Figure 5.1). This can be visualized as a bell curve of outcomes in any given situation.

On the left tail of the curve we have activity that is less than expected—lower outcomes than desirable—and on the right we have a better-than-expected outcomes. The region for quality assurance in the narrow sense is on the left, in looking at causes of less-than-expected outcomes. Here quality assessment and detection, the disciplinary kind of corrective measures, are contemplated as part of the report. On the other end, we have superior results, and we talk about studying these things, finding out why they happen, and rewarding the people involved in achieving these better-

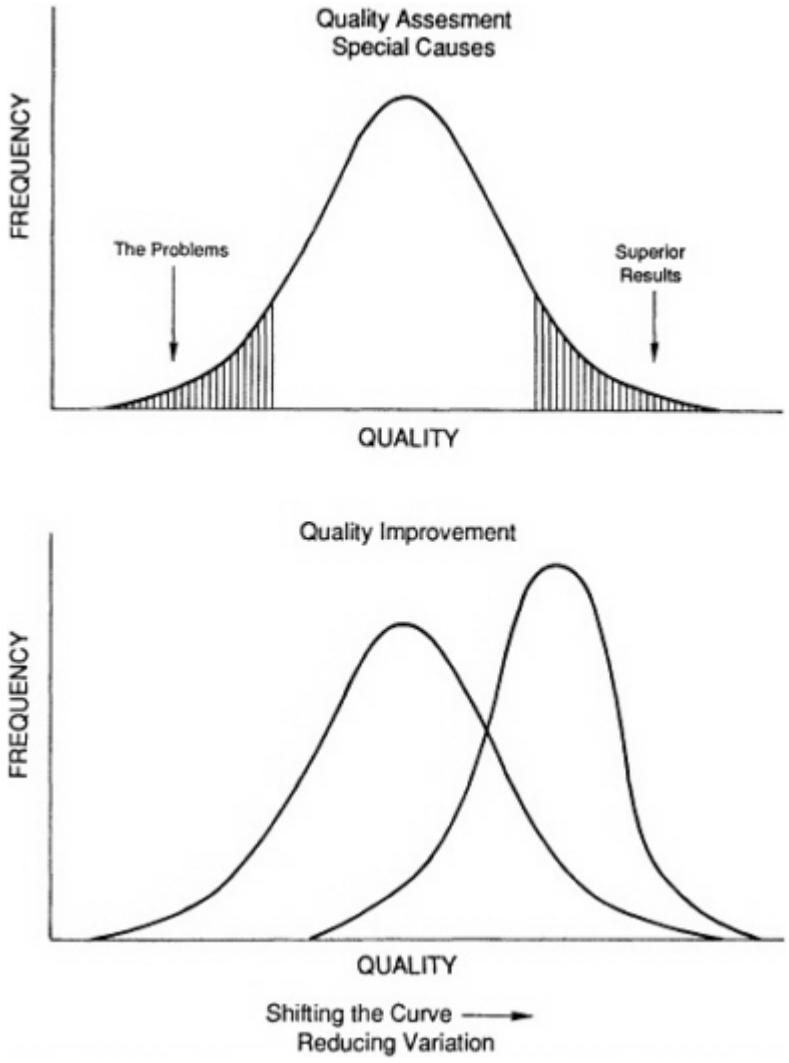


Figure 5.1
Quality of Care and Quality Improvement

than-expected results. Those have been the more traditional domains of quality assurance as we have used the term.

The middle of this distribution is the domain in which we focus on improving the basic processes of health care. Quality improvement ideas pertain here. As discussed by Leo Cooney (1991), much in the IOM report is based on professionalism; we are looking for professionalism to improve the process.

Using the terminology of quality improvement, we need another kind of understanding of the left tail of the curve—what we call "special causes." These are problems or disturbances that are not random and not part of a stable process. They are things that occur because of certain situations. They may be caused by an individual. They may be caused by an event. They are correctable or observable as individual episodes or as individual transactions.

Things that happen in the middle of the distribution curve are part of the normal process, that is, the way the system actually works. Seeing health care as a system, as a combination of stable and unstable processes, is also part of this new understanding. Variations in stable processes are random and cannot be corrected by working on specific incidents. Quality improvement techniques are used to change the shape of this curve. By moving it to the right, quality improvement leads to better results on the average, and makes the curve narrower by reducing variation. This is the conceptual structure that we wrestled with in Chapter 2 of the IOM report.

Committee members' views on quality improvement were divided. Some members said, "Quality improvement is new to health care, and we are not sure that it has a role." Others said, "It is not new to health care. We have been doing it all along—quality improvement is part of quality assurance. And so there is really nothing new here. Is it relevant? Is it effective outside administrative areas where it is first taking root? Is it a fad? Is there proof of results? Does it have staying power?" These are some of the areas of uncertainty with which the committee wrestled.

## THE ROLE QUALITY IMPROVEMENT PLAYS

I would like to show how we see the role of quality improvement in our proposed strategy for the Medicare program.

We talked in the later part of the report about three levels of quality assurance: the Medicare Program to Assure Quality (MPAQ) level, the Medicare Quality Review Organization (MQRO) level, and the provider level. These are shown in Table 5.1.

At the bottom of Table 5.1—the local provider level—we see quality improvement activity beginning. We anticipate that health care provider organizations will pursue quality improvement activities. The idea is that

TABLE 5.1. Relationships and Responsibilities of Main Constituents of the Medicare Program to Assure Quality

| Responsible Entity | Component Organizations | Information Flow | Quality Policy Deployment |
|---|---|---|---|
| Congress of the United States | Quality Program Advisory Commission (QualPAC) | Advise Congress on strategies for quality assurance in Medicare and report on issues relating to quality of care for the elderly. | Policy development and formation of goals and strategies |
| Department of Health and Human Services (DHHS) | National Council on Quality Assurance | Advise the Secretary of DHHS, the HCFA Administrator, and others on all aspects of MPAQ implementation, strategy, program planning, and operations. | |
| | Technical Advisory Panel (TAP) | Advise the Secretary of DHHS, the HCFA administrator, and others on public oversight and regular, formal evaluation of the MPAQ. | |
| Health Care Financing Administration (HCFA) | Medicare Program to Assure Quality (MPAQ) | Long-and short-term program planning (MPAQ) (e.g., of MQRO activities). Monitoring and evaluation of MQRO operations and performance. Aggregation, analysis, and reporting of quality-of-care data. | Program management |
| | Medicare Quality Review Organizations (MQROs) | Obtain, analyze, use, and feed back quality-related processes and outcome data to internal quality assurance programs of practitioners, agencies, and facilities providing care to the elderly. Report information to MPAQ. Initiate quality recognition interventions and sanctions as appropriate. | Information resources |
| | Technical assistance contractors | Give expert assistance in methods of quality assessment and assurance to MQROs and to internal quality assurance programs. | Training and facilitation resources |
| Participating health care providers | Quality assurance department, quality support department | Collect and report clinical and financial information to MQRO. | Quality improvement team selection and management |

the whole process should be very "permissive," that is, very supportive of quality improvement activity at the provider level. Both quality assurance and quality assessment activities will be conducted by the institution, and some interaction between quality assurance and quality improvement may occur. In other words, the problems and the difficulties that are detected in quality assurance may, in fact, become agenda material for improving the normal process of care delivery.

Moving up in the table to the Medicare Quality Review Organizations, we see data collection and data sharing where larger data sets and larger samples are being pulled together. We see risk-adjusted outcomes. This kind of information is produced for the health care provider organization, resulting in a feedback system. For quality assurance and quality improvement, we think that having that outside source of data is useful. There may be at this level some selection of diagnoses for study. Certain topics will be picked on a regional level and become selected input to the institutional level activity. Moving to the top of the table we see the major elements of the Medicare Program to Assure Quality. They are located in the U.S. Congress, the Department of Health and Human Services, and the Health Care Financing Administration. Their goals and activities are predicated in a definition of quality that does not exist today in the Medicare program in the explicit form we are recommending: *Quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge*. We also recommended capacity building, that is, training in quality assurance and quality improvement, and research in quality improvement effectiveness being mounted as national activities. Thus, many quality improvement activities are laced through the structure that we have envisioned in the proposed quality assurance strategy.

Looking at this table from the top, I could make the argument that this is a "quality policy deployment." At the federal level is a quality policy being put together—a definition, goals, attention to improving outcomes, and a customer (or patient) focus. At the MQRO level is quality management, where people are organized for, and decisions are made among, alternative kinds of activities. Deploying this quality policy down to the institutional level we have quality implementation, for example, quality improvement teams organized in a hospital.

How will this structure, in fact, work? Can it capture the favorable attention of the provider community? Those are key questions. As we gathered data in the study we found that much of what goes on today between government and health care does not have the favorable attention of the health care community. There is, in fact, defensiveness and a negative chemistry.

For quality improvement to work there needs to be a positive connection

—a partnership. Can this organizational structure form a partnership with the patient? Can it form one with the health care provider organization? These are the challenges: bringing this program closer to the needs of the patient, bringing it closer to the providers so that it is a positive connection.

This is, therefore, a major change in direction—one of several the report recommends. Indeed, "new directions" are the theme of this conference. As we wrestle with implementation of this strategy, we will begin to understand the full potential of the quality improvement model in health care.

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# 6

# Organization- and System-Focused Quality Improvement: A Response

*Chip Caldwell*

This paper addresses a management philosophy and a model referred to as organization-wide continuous quality improvement. It uses examples from one hospital that has implemented this mode to provide real-life examples of the theoretical structure Mortimer (1991) described in the previous chapter.

## QUALITY IMPROVEMENT POLICY AT WEST PACES FERRY HOSPITAL

I would introduce my hospital, West Paces Ferry Hospital, as a radically different place to practice medicine and to receive health care than it was before November 1987. I would introduce it as a place where employees in every position understand the mission of the hospital, the definition of quality, how we measure quality, and most important, their individual roles in improving quality. It is a place where every employee understands the tools necessary to measure and improve quality.

How do I know this is true? Let me offer several brief examples. I spent one hour and forty-five minutes with every employee in an orientation session that emphasizes exercises using quality improvement tools. Every department maintains an active Quality Improvement Team (QIT), and the QITs produce improvements so rapidly that we have difficulty tracking them. Finally, we have a systematic mechanism for measuring quality advances at every level of the organization. Our Patient Quality Trends increased from 77 percent in October 1988 to 88 percent by October 1989.

More specifically, the hospital-wide quality improvement process contains three components, Quality Improvement (QI) Policy, Quality Improvement Teams, and Quality Improvement in Daily Work Life. QI Policy answers those questions I first raised. What is the mission of our organization?

What are our definition of quality, the measures of quality, and the role of each individual and physician in the organization in improving quality? What are the tools necessary to measure and improve quality? The structure to implement QI Policy is through QI Teams and QI in Daily Work Life.

We are excited about what we are doing. Many questions remain about applying the continuous improvement model in health care and about using the techniques taught us through the Deming management method in clinical applications. We have some clinical successes, but as many questions remain to be answered as have been answered.

## RELATING QUALITY ASSURANCE TO QUALITY IMPROVEMENT

I was delighted with the ideas discussed by Mortimer (1991). A drawing similar to his Figure 5.1 was produced in early 1988 when a group of quality assurance directors within the Hospital Corporation of America (HCA)[1] met to debate the differences between quality assurance and quality improvement. Quality assurance identifies the 5 percent or so of problems evident in every process and seeks to reduce the bad outcomes. Quality improvement, by contrast, examines the entire spectrum of outputs and attempts to improve the entire process and reduce variation.

The first judgment of the HCA group was that quality assurance was bad. We have come a long way in our understanding since then. Quality assurance is not bad; it is just part of a quality improvement model. It is a subset of quality improvement, an activity we now call "quality alarms." All quality organizations we have studied—Florida Power and Light, Xerox, Baxter, Hewlett-Packard—have quality alarms and processes to attack those "special causes" of problems. Thus, we have begun to think about quality assurance in a very different way. There is reason to look at the 5 percent or so of bad outcomes and systematically reduce them, but what I think we have ignored for the past 30 years in health care is the opportunity to improve the entire system and to reduce variation. That becomes, then, the focus of our quality improvement efforts—to reduce variation. Examine variation in outcomes, and the underlying processes producing these outcomes, rather than just concentrating on quality alarms.

## THE INSTITUTE OF MEDICINE REPORT FROM A CONTINUOUS IMPROVEMENT PERSPECTIVE

What is the relation of our perspective to the recommendations of the Institute of Medicine (IOM, 1990) report? I am quite excited that the report

[1] Editors' Note: West Paces Ferry Hospital, Atlanta, Georgia, is a wholly owned subsidiary of the Hospital Corporation of America, Nashville, Tennessee

addresses continuous improvement as a model worth exploring. That conclusion is, nevertheless, associated with skepticism in many quarters about whether this continuous improvement can be applied to a health care system.

When I first began to see that continuous improvement was a better way to run hospitals, I had the same kind of skepticism about what we are doing now. I would begin with the question, Are this country's current models of quality assurance effectively improving the quality of health care in the United States? Perhaps, but the Japanese and more and more American companies are abandoning old ways for a continuous improvement approach. I embarked upon continuous improvement of quality not because of regulatory pressures, and not because of Joint Commission on Accreditation of Healthcare Organizations standards, but because I personally saw a better way to run hospitals and a better way to work cooperatively with our medical staff to improve quality. I also have many colleagues, both within the HCA and outside, who feel the same way and who are trying to make this work in their organizations. Many of us believe that quality of care can be improved if we can develop a mechanism in which we all learn and share together in the advancement of quality.

With that very brief orientation to a quality improvement program, I have five observations about the committee's work from a continuous improvement perspective. They are

1. a commitment to continuous improvement;
2. the power of locally developed initiatives;
3. widespread education about QI in schools of medicine, administration, and nursing;
4. the development of supportive methods of public review and oversight; and
5. community hospital as focal point of implementation.

## Continuous Improvement as a Preferred Model

First, an organization-wide continuous improvement model needs to be encouraged. I have had conversations with many people in sessions like these where it appears that attendees concluded that quality improvement is merely intensified quality assurance, simply a matter of degree of activity. That is not true. Continuous improvement is a matter of a distinction in fundamentals, not of degree of activity; it is organization-wide, and it calls for organization-wide commitment.

If we characterize HCA West Paces Ferry Hospital in 1988 as Hospital A, it is not in 1990 simply Hospital A plus quality improvement. Quality improvement is not just a management program. We in fact are experiencing a cultural transformation in which we are becoming Hospital B, a totally different organization in which the medical staff, employees, and the entire

management structure function around these measures of quality and the structures of QI in Daily Work Life. The hospital feeds itself on improvements.

### The Power of Locally Developed Initiatives

Second, it is important to recognize the power of locally developed strategies. I was fearful when I saw that one of the "new directions" for this conference included "system-focused" quality improvement, perhaps implying that an effort such as this must be mounted through a "system" such as HCA. HCA is a wonderful resource for us, and HCA leadership has ensured an environment that fosters the QI Culture. Furthermore, many people at this conference, of course, are not with HCA but have become very valuable resources to us as well. My point, though, is that it is the power of a local institution, its employees and physicians, and its local culture of continuous improvement that make QI happen. It is the very nature of our culture that becomes so important, I think, not some regulatory pressure.

That leads me to a parallel observation about research. We need careful examination of the incentives that are present in our system today. What incentives are there for physicians to work cooperatively for quality improvement? Equally important, what disincentives are present in our system today? How effective have our sanctioning regulations been? Should we not systematically remove those disincentives?

The science practiced in community hospitals like mine is often viewed as bad science. A corollary notion is that if science does not come from a major academic center it is not good science. We have seen in our efforts at West Paces Ferry, however, that there is so much to be learned from the individual practices of local physicians *if* our research is systematically structured. Physicians embrace research initiatives. One question I am often asked is, why are physicians willing to become involved in clinical process improvement? My answer is, they enjoy it. Physicians by and large enjoy research; that is not the issue. It is the issue of disincentives and incentives, I think, that dampens their enthusiasm.

The power of learning from local physicians about their practices may be the best way of addressing the issues of overuse and perhaps even underuse of health care resources. As we systematically examine variations in practice patterns and locally based initiatives, it is evident where overuse occurs. Locally developed strategies should be cultivated by our regulators.

### Quality Improvement Education

If the nation is to embark upon a transformation toward the widespread use of quality improvement in health care, many other things that have only been touched on will be fundamental to progress. One of these is the

exploration and publication of the best quality improvement practices. We need to develop mechanisms for learning from industry. For instance, one of our mentors is Florida Power and Light. We have learned tremendous things from them, but their tools are not universally applicable. Thus, in the past six months we have hired a physician to educate our medical staff in the use and modification of the seven statistical tools of the Deming method for their application in medicine. We are please with our success so far, but an accelerator to this progress would be better information and education about the best quality improvement practices that can be developed for use in health care.

More broadly, we need to learn how to teach this in schools of medicine, administration, and nursing. For instance, one early assignment for new department managers and employees at West Paces Ferry Hospital is complete reeducation regarding quality improvement. Why is variation important? What is a process? Within medical staffs, how can individuals work together and what is the role of continuous improvement in health care? It would be a tremendous accelerator and cost savings if physicians, nurses, and administrators came to the workplace in possession of these skills.

### Supportive Methods of Public Review and Oversight

My fourth observation is that we should develop supportive methods of public review and oversight. A lot of dialogue is necessary for us in the field to examine how existing and future methods can support and provide incentives for advancing continuous improvement. Often, as positive programs such as the Medicare peer review organization program and those mentioned by the earlier panel are implemented, they unintentionally evolve into punitive bodies. These public review and oversight mechanisms are taken as antagonistic and intimidating by providers, rather than as partners.

As a chief executive officer (CEO) of a large enterprise, it often strikes me that the greatest threat to productivity in our work force is intimidation and fear. In fact, one of Deming's Fourteen Points is "drive out fear." Yet it seems that, every time we establish regulations, they evolve to the point of intimidation. There is not a person in this room, I think, who is motivated best by fear of being singled out as a failure. Rather, motivation works because, as individuals, we like to feel a part of what we are doing and to enjoy our successes. By our very nature we like to advance quality and to be recognized for our achievements. Yet it seems that so often our regulatory practices and other initiatives are antagonistic and intimidating.

### Community Hospitals as Focal Points of Quality Improvement

The final observation I would make is that there is merit in considering the community hospital as a focal point for QI initiatives. There is no focal

point today, no mechanism to examine the effectiveness of care provided through a doctor's office, a hospital, or an outpatient setting, and to examine those patients three months, six months, or two years later.

I want to be careful that, because I am a CEO in a hospital, this point is not seen as an issue of control or power. Rather more importantly, the community hospital offers a mechanism, a meeting place or in quality policy deployment lingo, the community hospital offers a framework and structure for people to come together, including physicians, nurses, home care providers, and doctor's office personnel. We have a number of QI Teams where these kinds of initiatives are successful. One of these, our cesarean section team, for example, has been able to reduce the Cesarean-section rate at West Paces from about 22 percent to just over 18 percent.

As Dr. Relman (Relman, 1991) says, one thing absent in the IOM committee's recommendations is the focal point for physician office practices. I would like to suggest that the community hospital offers a mechanism through a continuous improvement model that looks at the extended process. There are other examples. We have a QI Team looking at operating room turnover. That team was able, in just a few months, to reduce the length of time in the holding area from 23 minutes to 16 minutes. The team also includes someone from a doctor's office, because as it looked for root causes of variation, it found that one major cause of variation was the absence of laboratory, x-ray, and electrocardiogram work. The team further examined root causes and found that the pre-admission process could facilitate efficiency. This team was expanded to include those people outside the boundaries of the hospital, and it increased the pre-admission rate from 17 percent to more than 80 percent.

## SUMMARY

West Paces Ferry Hospital, and others, have had numerous successes in implementing quality improvement to which I could point. What would be lost, in concentrating on the specifics of our exhaustive improvement diary would be the broader knowledge of the strength of the QI model, of having everyone in the organization involved in the continuous improvement of quality, of organizing the medical staff to work within that framework, and of the power of a culture in which improvements are commonplace.

Organization-wide continuous improvement has proven to be a necessary tool for America as we struggle to regain world dominance in the manufacture of industrial goods. It has proven effective in selected settings, such as HCA West Paces Ferry Hospital, in stimulating an environment in which quality improvement is a part of daily work life. Should we not capitalize on the creative energies of the thousands of Americans in health care professions dedicated to quality improvement, by giving them a supportive regulatory framework and an organization committed to continuous improvement?

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# PART IV

# New Directions: Improved Decisionmaking by Patients and Clinicians

# New Directions: Improved Decisionmaking by Patients and Clinicians

## INTRODUCTION

*Robert B. Copeland*

As the Institute of Medicine committee worked on a strategy for quality assurance in Medicare, my role was to offer perspectives from patients and providers at the primary care level. During this time, I had personal experiences with the new Medicare utilization review contractor in Georgia. This provided a dramatic example of how well-intended, but flawed and counterproductive, reviews of patient care services can be. For the past 17 months, Georgia has had utilization review by a for-profit company as mandated by the Health Care Financing Administration. The company was freed from many of the constraints of previous review programs. This unique experiment has decreased Medicare expenditures largely by rationing primary care services. This new plan's long-term negative effects on quality of care, access of Medicare enrollees to primary care physicians, and career decisions for primary care providers are far more significant than any short-term savings.

I mention this experience now to reinforce what we all must respect as we look at new strategies for Medicare quality assurance. That is, there is a critical need for broad reform that is data based, that takes a long-term view, and that will constructively remodel, not remuddle, assessment of quality in Medicare.

This part of the conference proceedings discusses another of the new directions that our committee identified as specific strategies—improved decisionmaking by physicians and patients. This is both an important and an obtainable goal. Aspects of those issues are discussed by two outstanding speakers. Paul F. Griner presents the committee's views on physician and patient decisionmaking, bringing to his paper the special perspectives of a clinician, hospital director, and medical educator. John Rother, the Director of the Legislative and Public Policy Division at the American Association of Retired Persons, provides the outside response, reflecting the orientation of a major patient-and population-oriented organization.

# 7

# Improved Decisionmaking by Patients and Clinicians: The Committee View

*Paul F. Griner*

Many people at the conference summarized by these proceedings are very knowledgeable about the issues on which I was asked to comment. Some of my observations, therefore, may seem superficial, and I apologize for that in advance. My intent in this paper, however, is to be more broad than deep.

I would like to begin by paraphrasing a point made elsewhere (Schroeder, 1991). In the opinion of the Institute of Medicine (IOM) committee, the assurance of quality of health care to the people of this country will be achieved through some combination of three things. First is knowledge—better knowledge of the effectiveness of specific medical practices. Second is the refinement of that knowledge in such a way that it is possible to make a decision about its appropriateness for the individual patient. Third is the flawless execution of the various diagnostic and treatment plans that are derived from new knowledge—flawless execution, not only by providers, but throughout the entire system in which the care is provided.

In the real world we know that not all of these criteria are achieved simultaneously. We have suggested in our report (IOM, 1990) that although the general level of care to Medicare recipients in this country appears to be quite good, there are major weaknesses. There are patients who are not receiving care—underutilization of services. There are patients, perhaps as many or more, who are receiving unnecessary or inappropriate care—overutilization. Then there is a middle group of patients who are receiving care that is both appropriate and necessary but by means that are flawed in one way or another. These are the reasons for one of the ten committee recommendations, namely, that Congress should direct the Secretary of the Department of Health and Human Services to support, expand, and improve research in and the knowledge base on efficacy, effectiveness,

and outcomes of care and to support a systematic effort to develop clinical practice guidelines and standards of care.

## FIRST-ORDER RESEARCH

Let us examine how we might address this recommendation through improved decisionmaking. We can start with what we might refer to as first-order research: the need for better knowledge of the relationships between treatments and outcomes of care. Some generic issues warrant attention. For example, better markers of outcomes of care are needed. Fortunately, most patients survive their treatments, and the majority do not have complications. The current markers that we have of morbidity and mortality are not sufficiently sensitive to give us the full spectrum of information needed to judge outcomes. The work by Greenfield and Ware[1] on measures of quality of life and functional status is a good example of current research that is helping to address this problem, and the IOM report indicates that more work of this kind is needed. Such markers immediately suggest opportunities to generate clinical data of a longitudinal nature, that is, observations over time and across settings. Disease-specific issues also arise. Given more than one approach to the management of a specific clinical problem, what are the outcomes associated with each approach, those that are good and those not so good? We will refer, in a moment, to the work that people such as Jack Wennberg[2] have done that points to the lack of knowledge of effectiveness as an explanation for the tremendous variation in patterns of medical practice across settings throughout the country.

How do we achieve such knowledge? We cannot expect to conduct classical randomized clinical trials (RCTs) to address very many of the outstanding questions; RCTs are too expensive and take too long. The report points to another alternative, and that is to take advantage of what David Eddy refers to as experiments of nature. The opportunity exists to look at the outcomes of care rendered to a large population of patients with a given condition in such a way that the outcomes of various treatment approaches can be compared among subgroups after adjustments for important variables.

[1] Editors' Note: The reference is to a long-running project, the "Medical Outcomes Study," begun at the RAND Corporation and now located at the New England Medical Center. The principal investigators include Sheldon Greenfield and John E. Ware, Jr.

[2] Editors' Note: The reference is to the body of research in geographic variations in use of health care services and outcome and effectiveness research pioneered by John Wennberg of Dartmouth Medical College. See also the papers in this monograph by Mulley (1991) and Wennberg (1991).

A few national clinical data bases do address this need. Two are very disease-specific and comprehensive. They have been developed over a period of 15 years. I refer to the medical information system of the American Rheumatism Association (ARAMIS) data base and to the Duke Cardiovascular Data Base. These systems have been helpful in addressing critical questions relating to the management of patients with rheumatologic and cardiovascular disorders respectively, but they are limited by being very disease-specific.

We can look at the other extreme of large data bases that cut across many diseases. These include the Medicare files of the Health Care Financing Administration (HCFA), regional Blue Cross data bases, and some of the state-mandated data bases such as the Statewide Planning and Research Cooperative System (SPARCS) in New York State. These data bases are excellent for administrative and business purposes, but they are not well developed for purposes of the clinical relationships that we are seeking. Thus, the IOM report includes a set of caveats concerning the need for comprehensive clinical data bases that can help address many of the questions that remain outstanding in medical practice for common clinical conditions.

As these data bases are developed, we need to remind ourselves of several essential elements. First is the amount of clinical information necessary to control for important variables, such as severity of illness and comorbidity. Second is longitudinality, the ability to capture outcome data over time. Third is flexibility to meet the needs of various oversight organizations as well as those involved in research and development. We have heard questions from Dr. Jencks[3] and Mr. Webber[4] about how one may apply a single data base in ways that will meet the need of multiple agencies. This is indeed a critical issue. To illustrate: there is at Mayo Clinic a large office that coordinates the pre-certification requirements for as many as 1,000 different payers throughout the United States, all of which have different pre-certification programs!

## APPLYING THE RESULTS OF EFFECTIVENESS RESEARCH TO PATIENT CARE

Let us move to the second area of research, the need to individualize the knowledge gained from effectiveness research. How do we accomplish

[3] Steven Jencks, M.D., Chief Scientist, from the HCFA Office of Research and Demonstrations.

[4] Andrew Webber, Executive Vice President, American Medical Review Association, the organization that represents the Medicare Peer Review Organizations.

this? For the sake of simplicity, we will assume that for a given number of patients with a specific medical problem, current knowledge permits us to say the following: for about one-third of the patients who are receiving a particular treatment, the treatment is clearly appropriate; another one-third are receiving the treatment for reasons that are not appropriate; and for the remaining one-third, we do not know what is appropriate. In this second-level research, the challenge is to increase the number in the first group, reduce the inappropriate number, and apportion more of those in the gray area to either the appropriate or the inappropriate category.

The obvious first step in addressing this challenge is to eliminate care that is already known to be inappropriate. The bigger challenge is to reduce the size of the gray zone. That can only come from better knowledge of the relationship between the processes and the outcomes of health care. It requires new knowledge that does not currently exist and reinforces once again the critical importance of the kind of work that people such as John Wennberg and others are doing in the area of effectiveness research.

## SHARED DECISIONMAKING

We need to add an important element here, and that is the personal variable. If we are truly to individualize the knowledge gained from outcomes research, we must engage the patient more effectively in the process of decisionmaking. Only the patient can assign value to the specific benefits and risks of a particular treatment option. The challenge here is to provide the information to the patient in a way that both educates and quantifies.

The IOM report comes back repeatedly to this objective. Its accomplishment may well be the most important contribution to health care over this decade. Successfully implemented, better practitioner-patient decisionmaking should improve patient satisfaction. It should reduce costs. It should temper the problem of medical liability. It should also improve physician satisfaction.

## BARRIERS AND INCENTIVES TO IMPROVEMENT

Up to this point, we have referred to the need for a better understanding of outcomes of treatments. We have talked about approaches that are needed to help individualize this knowledge. Next is the issue of the execution of care: the need to identify and address factors in the system that either help to achieve or prevent health care of good quality. Reimbursement is one. How health care is financed and reimbursed will influence the achievement of quality. Financing mechanisms that limit access to appropriate services will result in underuse and eventually constrain quality. Those that cover unnecessary procedures will result in overuse, as will reimbursement mechanisms that reward providers on the basis of the volume of services.

Another important challenge that the IOM report repeatedly addresses is how to make medical information regarding effective and appropriate strategies available to physicians and patients in a convenient fashion. The work of Mulley, Wennberg, and their colleagues with their prototype interactive video disk for patients to review options concerning the management of benign prostatic hypertrophy is an important step in this direction.

Are there incentives that will stimulate a change in physician behavior where needed? Education alone may not be sufficient. Careful study of the factors that influence physician behavior represents an additional area of inquiry recommended in the report.

Finally, the IOM committee stressed the need to develop systems to measure the quality of care across settings, and it put a particular emphasis on ambulatory care. Opportunities to improve quality are being lost through inability to assess and intervene early in the natural history of an illness in a patient whose hospitalization might have been prevented.

## SUMMARY

These, then, are the areas that warrant attention if we are to improve practitioner and patient decisionmaking: better understanding of the links between the process and outcomes of care; making the best possible use of current effectiveness research; engaging patients more effectively in decisionmaking about their own care; and overcoming several informational barriers and obstacles. The need is great to identify funds for the work required. For this, I look particularly to the Agency for Health Care Policy and Research, HCFA, perhaps private foundations, and possibly other private sector organizations such as insurance companies and industry.

I have not touched on the role of the consumer in addressing important issues bearing on health policy. How universal access can be achieved, how the organization and delivery of health services can be improved, how an equitable benefits structure can be derived from knowledge relating to appropriateness and effectiveness, and how best to make choices between competing priorities are all issues that demand consumer participation. The paper by Rother (Rother, 1991) comments more fully on these areas.

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# 8

# Improved Decisionmaking by Patients and Clinicians: A Response

*John Rother*

I begin by commending the Institute of Medicine (IOM) and this study for truly landmark work (IOM, 1990). On behalf of the American Association of Retired Persons (AARP), I welcome its findings and find much to support.

In this paper, I want first to share some patient perspectives on health care quality gleaned from AARP's extensive public opinion survey activities. Second, I want to address some patient information issues that the IOM report surfaces in its analytic and prescriptive chapters.

## PATIENT PERSPECTIVES ON HEALTH CARE QUALITY

AARP conducts numerous public opinion polls. Some of its findings with regard to health care issues are instructive as we examine options for a new quality assurance strategy for Medicare. Increasingly, the public, including Medicare beneficiaries, perceives health care to be a business; "customer" satisfaction is seen as a critical dimension of the system's performance. AARP's polls have found that about 80 percent of the population across the age spectrum say that they are generally satisfied with the quality of care they receive. At the same time, respondents voice fears about changes taking place in health care today, fears about costs that are skyrocketing, and fears that quality in health care is not going to be maintained in the future.

If we probe the polls' findings, we find that from a lay point of view people do not think of quality simply in terms of the physician-patient or hospital-patient interaction. They think of quality also in terms of this question: How does the health care system relate to me as a whole person? Is someone taking responsibility for my situation in its entirety?

In other words, when we ask people what they consider to be the most

important factor in choosing a primary care physician, the response is neither cost nor location; by far the factor that people cite most often is having a doctor who will take the time to explain things. I translate that into not just a desire for information that I, the patient, can get impersonally from books and other sources; it is also a desire to be treated by someone who relates to me as a whole person, who takes the time to understand my situation, as well as the social and medical-psychological aspects of care.

As important as health care outcomes are, I think these patient preferences argue for a focus on the processes of care as well. We know from other studies that trust in the process, the hope that the process will be successful, and the sense that one is being cared for—these intangibles—are often central to the likely success of medical intervention.

A corollary point is also pertinent. Just as the "whole" person is central to the idea of quality, a quality assurance mechanism must measure how the *whole system* relates to that person. Fragmentary quality assessment and quality assurance, in other words, are a problem. We need to look at quality across inpatient, outpatient, long-term, and home health care settings. A major source of a patient's frustration with the caregiving system today is the lack of coordination, the absence of a guide to help him or her through the health care maze. If we are serious about quality, we have to talk not only about reimbursement, but also about a coordinated system of care that allows us to look at quality as the patient experiences the various components of the delivery system. We must create a system that allows us to judge the entire spectrum of inputs, rather than just the input from a particular provider in a particular setting. Ultimately, I think, that leads to a call for some fairly major changes in the way our health care system is structured and financed.

In this connection, I should note that an effective, well-coordinated quality assurance program will itself require adequate initial investment and ongoing financial support. The benefit-cost payoff, however, in terms of overall health system savings promises to be substantial.

## INFORMATION NEEDS

Given the evolving nature of the doctor-patient relationship, the IOM is to be strongly commended for explicitly recognizing the centrality of patient interests and desires in its definition of quality. AARP believes that two major categories of information needs are pertinent to the achievement of greater patient autonomy and involvement in decisionmaking: treatment information, and individual provider and practitioner performance information.

With regard to the first category, treatment information, the section of the IOM report on capacity building is particularly welcome. The report's

emphasis on the federal funding, sponsorship, or production of audiovisual materials for distribution to Medicare beneficiaries—in the form of newsletters, brochures, television programs, tapes, and the like—is right on target. The interactive information system envisioned by the IOM is likely to require more time and greater sensitivity (particularly to differences among patients) on the part of practitioners. We believe that both patient and physician will benefit from increased patient participation in decisionmaking. Wennberg's recent interactive video experiments are encouraging examples of what can be achieved in this direction (see Wennberg, 1991).

It is easy to overestimate how well people can absorb and respond to printed material. In fact, the American public does not respond primarily to information in printed form; an estimated 70 percent of the population gets 100 percent of its information from television. Certainly, we need to look at a whole range of ways to increase the absorption of information. Moreover, people who are not themselves health care professionals often do not focus on information until a decision must be made. Therefore, information needs to be available to patients at decisionmaking times.

AARP believes that an especially significant and useful source of patient information will emanate from current efforts to produce new practice guidelines. Patient experiences and preferences about treatment, outcomes, and patterns of care must be factored into both developing and updating these guidelines. In accordance with the intent of the statute mandating the development of these guidelines, they must be shared with the patient in a user-friendly form; patients need to know the potential risks and benefits of treatment options, and the potential consequences of taking no action.

With regard to the matter of individual provider and practitioner performance data, AARP believes that increased dissemination will further the goal of informed patient decisionmaking. It is important, of course, to continue to improve the measurement tools used to create consumer information. In particular, efforts to adjust raw data to account for the severity of illness should be intensified. Moreover, not every conceivable statistic on provider performance needs to be released immediately. What is critical is a commitment to a *policy* of disclosure of institutional, physician, PRO/MQRO,[1] and government-held data that include mortality rates, volume statistics, readmission rates, and other outcomes information as it becomes available, including considerations of functional status and quality of life.

The actual implementation of a data disclosure policy will occur along a time and validation continuum. Thus, outlier performance warranting PRO or state licensure board sanctions should be publicized quickly and clearly.

[1] Editors' Note: The reference is to the existing Medicare Peer Review Organizations (PROs) and the IOM's proposed Medicare Quality Review Organizations (MQROs).

At the same time, as the IOM study reminds us, it is important to publicly recognize examples of excellent quality. A publicized reward system can be just as important a driver on quality as a punishment system.

## ISSUES CONCERNING PATIENT INFORMATION

Viewing the IOM report as a whole, we detect some ambivalence about data disclosure. The committee states that although "a major principle of the MPAQ [Medicare Program to Assure Quality] is that reliable, valid, and useful data ought to be available to or placed in the public domain...a corollary is that misleading information and poorly presented data are harmful to providers, and ultimately, to the public. *We take the position that forestalling the latter takes precedence over accomplishing the former*" (emphasis added). In another vein, the report points out that "feedback and data reporting have three primary dimensions: information made available to internal quality assurance programs and practitioners, to the public, and to policymakers. Although making data available in a timely way to the latter audiences is an important goal, we believe that designing effective mechanisms for *giving information back to practitioners and provider institutions (feedback) is central to our proposed quality assurance program*" (emphasis added). Notwithstanding the need for *responsible* data collection, presentation, and dissemination, these kinds of statements have the collective effect of qualifying the committee's avowed view of the informed patient as *crucial* to a quality assurance strategy.

We should not be so paternalistic as to assume that people will fail to take into account the fact that mortality figures, for example, are a very rough indication of quality. Were we to decide to withhold data until we were absolutely satisfied that they were 100 percent accurate, we would be waiting a very long time. I would urge the IOM to adhere to the overall philosophy that data disclosure is an important goal, one that will work well only if there is broad dissemination, not only to providers but also to the public and to the policymaking community.

The IOM envisions one additional important dimension to the patient and consumer information strategy: quality assurance systems *themselves* need a healthy dose of informed consumer input and oversight to ensure accountability and credibility. This has been true with the Peer Review Organization program, and it will remain true with whatever mix of external and internal review emerges from current policy debates.

The Medicare population that we are going to be dealing with in the future consists of individuals whose attitudes and orientation to authority were shaped by the social and cultural forces of the 1950s and 1960s. These Medicare beneficiaries are likely, therefore, to insist upon a proactive

role in decisions that affect them personally; they are also likely to be willing to challenge traditional authority figures.

## SUMMARY

Realization of greater patient involvement in the decisionmaking process, a vision that the IOM and AARP share, holds much promise for fulfilling beneficiaries' hopes and meeting their needs. We look forward to working with the IOM, Congress, the administration, and the provider and beneficiary communities to achieve that end.

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# PART V

# New Directions: A Patient Outcomes Orientation

# New Directions: A Patient Outcomes Orientation

## INTRODUCTION

*Charles J. Fahey*

I would like to relate a personal experience and an underlying historical reality associated with it that have relevance for our efforts. Several times in the past few years, I have had the privilege to visit Monte Casino. Some of you are familiar with it, perhaps for no other reason than World War II. During the Italian campaign, the monastery became a symbol of resistance. What to do about it became the subject of contention among the allies. Although the presence of German troops on the slope on which the monastery was located was certain, it seemed they had refrained from entering the monastery or its immediate vicinity. However, its overarching presence became so much a symbol of the inability of the allied forces to move forward that it was decided to obliterate the abbey with intense air bombardment. Whether Germans were, in fact, inside the monastery is a moot point. However, following the destruction of the monastery, the rubble that remained became an even more formidable obstacle and was taken at a great loss of life.

Scruples about destroying the monastery came not only from the potential loss of life (many local civilians had sought sanctuary with the monks) and the beauty of the buildings and contents but also because of its place in history. You see, it was here in the sixth century that St. Benedict founded Western monasticism.

The approach to life of St. Benedict as articulated in his "rule" became a standard for virtually all communal religious life. At its heart was a commitment on the part of aspirants who wished to join this way of life to living in a spirit of poverty, chastity, and obedience with persons of like mind. When a period of training and testing were complete, the person stood before the community and made a public profession of his or her intent. This was known as making their profession.

In the Middle Ages, the guilds took upon themselves some of the responsibility for what religious communities had done. Those that were particu

larly involved in deeply human enterprises were known as professions, precisely because they had altruistic values of service to others about which they would hold themselves publicly accountable. Their service—although it meant a return, both psychological and pecuniary—also involved a commitment to competence, selflessness, and a concern for others. If ever there has been a word that has been corrupted it is "professional." Nevertheless, it continues to be an extraordinarily important word.

This part of the conference proceedings addresses personal and corporate professionalism in the sense of personal and corporate virtue. There are really two things that we are about. First, how do we know what is good, and how do we make that knowledge relevant to people on both sides of the transaction—the helper and the helped? Second, how do we all behave better? It is interesting how much of what we are talking about involves behavior and values. In this effort we have faced a dilemma that plagues all of society. What is the appropriate role of external oversight and sanctions as contrasted with dependence on people to act virtuously? How do you protect the vulnerable without instituting oppressive structures that demoralize?

By the same token, we have struggled with how to help people to be honest about their shortcomings without becoming unduly liable because of their honesty. How do we allow humility in our context? Humility is a very good word. How do we create an atmosphere in which we can be honest as individuals and as groups of people coming together to try to make good things happen? How do we help people to be virtuous?

Laws and regulatory techniques have their limitations. Whether we are on the left or the right, the tendency is to use law to enforce on everybody else our particular view of what is the good. Yet two such diverse persons as John Courtney Murray, the distinguished Jesuit who was chiefly responsible for the Vatican II *Decree On Religious Liberty*, and Oliver Wendel Holmes held that American democracy is predicated upon our being a virtuous people. Laws and regulatory activity are important, but ultimately our surviving as a people will depend on how virtuous we are. Much of our effort has been to carve out a role for government that allows it to protect those who are vulnerable but at the same time encourages personal and corporate moral agency and virtue.

Moving toward a world that enhances personal choice, decisionmaking, and responsibility calls for greater attention to patient outcomes, values, and preferences. The case for the "new direction" of a patient outcome orientation is made by committee member Albert Mulley, who is chief of the Division of General Internal Medicine at the Massachusetts General Hospital. The response is offered by John Wennberg, professor of epidemiology and community medicine at Dartmouth Medical College and pioneer of several critical areas of research in health services, effectiveness, and outcomes.

# 9

# A Patient Outcomes Orientation: The Committee View

*Albert G. Mulley, Jr.*

Others have reported the general findings and conclusions of the Institute of Medicine (IOM) Committee to Design a Strategy for Quality Review and Assurance in Medicare (IOM, 1990; Schroeder, 1991). The vision of a new quality assurance system for Medicare that the committee shares will require new directions, including increased emphasis on programs to enhance professional responsibility (Cooney, 1991), better systems to assure quality and make use of clinical practice as a source of information (Mortimer, 1991), and a sharper focus on health care decisionmaking (Griner, 1991).

The purpose of this paper is to make the committee's case for a shift from a provider and process orientation to a patient and outcome orientation. I will argue that this element of our overall strategy is central and, perhaps, the most critical to its success. Lest you think that we have been naively swept along with the current enthusiasm for outcomes, I will also share our concerns about the complexities and potential pitfalls of a quality assurance system that relies heavily on outcomes.

## PROCESSES, OUTCOMES, AND PATIENT CHOICES

The argument for more emphasis on outcomes is closely related to those for enhanced professional responsibility and patient involvement in decisionmaking. Simple building blocks can be used to demonstrate these relationships and then to broaden the argument to questions regarding the role of outcomes measurement in quality assurance. We will define "outcomes" precisely and relate them not only to the structure and process of health care, but also to the wants and needs of individual patients.

Figure 9.1 provides a caricature of how a patient interacting with the health care system produces an outcome. The patient might be bothered by

symptoms associated with prostate disease, a clinical example that has been studied extensively (Wennberg et al., 1987; Barry et al., 1988; Fowler et al., 1988; Mulley, 1989, 1990). The figure could also represent a patient with chronic angina, disabling osteoarthritis, or any number of other conditions. Symptoms that impair the quality of life prompt an encounter with the health care system. The box represents the structural elements—those that relate to the capacity of the system to deliver quality health care. The arrows represent alternative processes of care, that is, what may be done to and for the patient. The outcome is represented by a triangle, each side defined by measures of physical, psychological, and social functioning.

Seldom is only one process of care available to, or even appropriate for, a particular patient with a particular problem. There are choices. For the patient with prostate disease, it may be a choice among prostatectomy and watchful waiting; for the angina patient, a choice among bypass surgery, angioplasty, or medication; and for the patient with arthritis, a choice between joint replacement and anti-inflammatory drugs.

The manner in which these choices are made deserves careful scrutiny. Recognize that patient choice is central to the phenomenon of practice variation and to the IOM committee's concerns about underuse and, particularly, overuse of services as significant quality problems.

Consider the decision of the man with benign prostatic hyperplasia, which is represented in its simplest form in Figure 9.2. Quality of life has been diminished by bothersome urinary symptoms. The patient faces, with the help of his physician, a choice between two alternative treatment strategies. The first alternative, surgery, is a bit risky: the eventual outcome is uncertain and, although there is a good chance that it will produce the most valued outcome, there is also a chance that it will produce the outcome that is least valued, a complication leading to serious morbidity or even death.

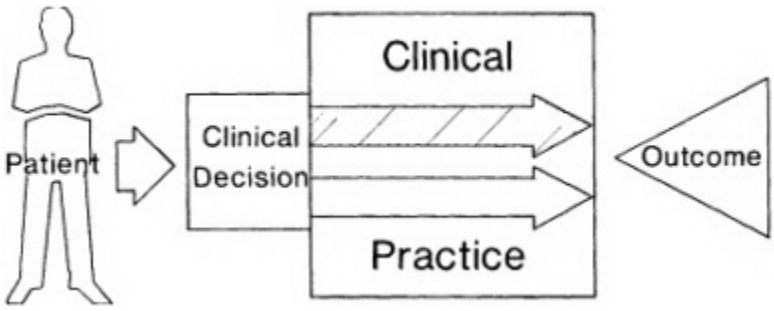


Figure 9.1
A patient faces a clinical decision about the process(es) of care most likely to produce desired health outcomes. See text.

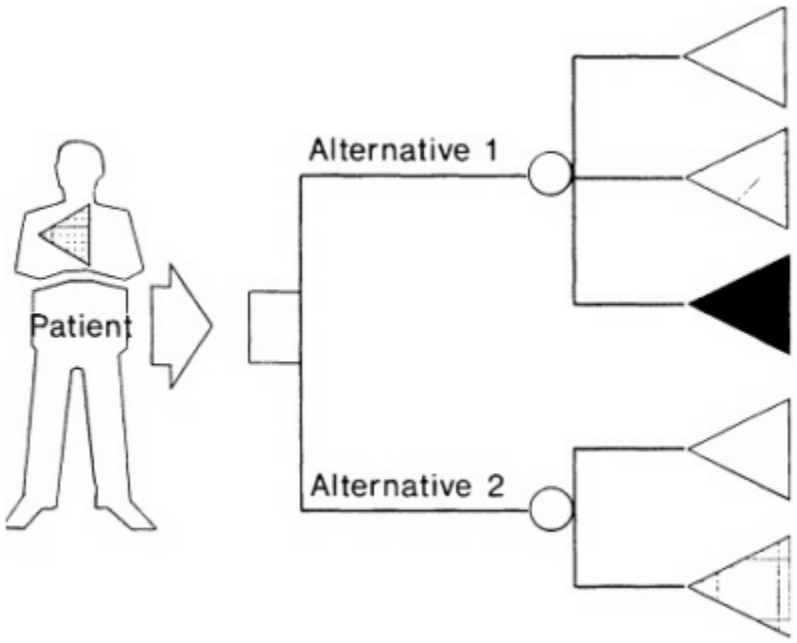


Figure 9.2
A simple representation of the decision faced by the man whose quality of life i s impaired
by symptoms of prostate disease. The square node represents a choice. The rou nd nodes represent chance events. The triangles represent outcomes. See text.

An intermediate outcome, such as impotence or incontinence following surgery, is also possible. The second alternative, watchful waiting, is less risky: the only possible outcomes are the most valued—symptom relief—and the patient's current health state. Note that some uncertainty about the outcome following either choice is inevitable. Therefore, a good decision for a particular patient can produce a bad outcome, and a bad decision can produce a good outcome. This clearly presents some dangers for those who would use outcomes to measure or monitor quality. This inevitable uncertainty also explains the term **"increased likelihood"** in the committee's definition of quality.

## INFORMED DECISIONMAKING

What do patient and doctor need to make this choice? First, they need to know how likely each of these outcomes will be if alternative 1 or 2 is

chosen. These probabilities can be depicted as pie diagrams (Figure 9.3). For the hypothetical patient who faces the decision (Patient A in the figure), alternative 1 has a 90 percent chance of producing the most valued outcome, a 1 percent chance of operative death, and a 9 percent chance of impotence and/or incontinence. Alternative 2, which looked so good without probability estimates, looks less promising with them: the odds are 9 to 1 that the health state bad enough to bring the patient to the doctor will persist. It can be said that knowledge is power because it confers the capacity to predict. Accurate estimation of outcome probabilities as represented in these simple pie diagrams captures the essence of professional knowledge relevant to the practice of medicine.

Where does this knowledge come from? The most obvious source of probabilities is the collective experience of previous patients. This constitutes the "clinical experience" of the provider that is so important to "clinical judgment." There are, however, real problems with this source of information. First, there are problems with the way clinicians characterize individual patients. Second, clinical practice is not standardized: interventions are not carefully defined and uniformly applied. Third, there is no routine mechanism to define outcomes with the appropriate level of detail or to aggregate and organize the information that could be derived from collective clinical experience. Without such systematic aggregation and analysis, the cognitive heuristics that we all use routinely may mislead the clinician's unaided intuitive estimates of outcome probabilities.

Recognizing these problems, the profession relies heavily on published clinical research when it is available. The randomized trial is the standard against which other clinical studies are measured. We can learn something about the complexities of using outcomes for quality assurance by considering the methodological requirements of valid research. Information about patients entering the trial is systematically collected. The group is made homogeneous by applying exclusion and inclusion criteria. The alternative interventions are carefully defined and their elements carefully segregated. Outcomes are carefully catalogued. The scientific requirements of research designed to determine the effectiveness of one intervention relative to another, which is nothing more than the relative outcome probabilities, include similarity of the initial states, integrity of the interventions, and similarity of detection or measurement of outcomes.

Even when well-conducted randomized trials are available, problems arise in using the results to estimate outcome probabilities. Clinicians may forget about real differences between the circumstances of the clinical trial and the circumstances of clinical practice. They may also forget about the patients excluded from the clinical trial. These exclusions are not trivial, commonly representing more than 90 percent of the patients for whom the intervention would be used in practice.

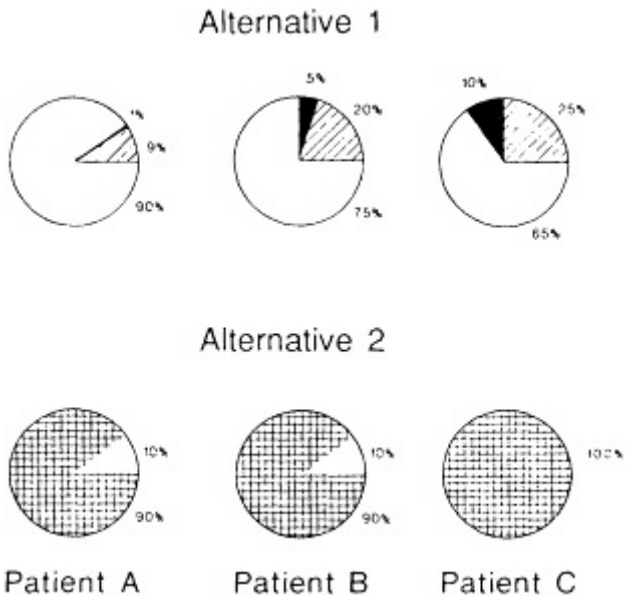


Figure 9.3
The pie diagrams represent different outcome probabilities for different patients.

The exclusions are important because different patients face different outcome probabilities even when the care rendered is identical. This is illustrated in Figure 9.3 by the three pairs of pie diagrams, each representing different outcome probabilities for a hypothetical patient. Clearly, a choice made by or for one of these patients should be based on probabilities derived from the experience of similar patients. Any inference about the effectiveness of a particular intervention must adjust for different mixes of patients with different outcome probabilities. Any inference about the quality with which an intervention is delivered is equally dependent on such adjustment.

## CLINICAL PRACTICE AS A SOURCE OF KNOWLEDGE

The IOM committee's proposed emphasis on outcomes can serve to make clinical practice a source of new knowledge that is very valuable to the professional and the patient. If we can effectively characterize patients by disease severity, comorbidity, and other variables that affect prognosis,

if we can characterize the processes of care, and if we can measure outcomes and relate them, for each patient subgroup, to the alternative care processes used, then we can give providers and patients the information they need to make informed decisions.

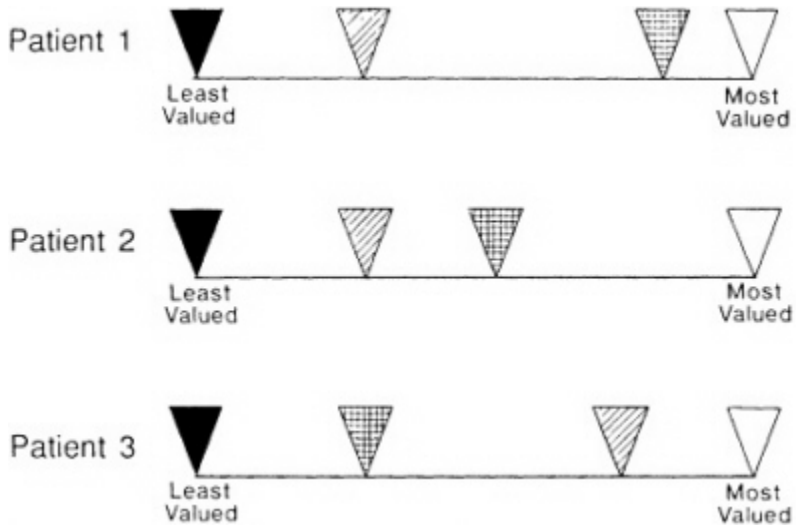


Figure 9.4
Three scales representing relative value of different outcomes for three different patients. See text.

This approach could dramatically improve our ability to estimate relevant outcome probabilities. The committee felt, however, that probabilities alone were insufficient. Whether the pie diagrams in Figure 9.3 represent probabilities of outcomes for a health care decision or a simple game of roulette, information about the likelihood of the outcomes must be accompanied by information about their relative values in order to be helpful to the person making the decision. Here is where the shift from a provider orientation to a patient orientation is most important and most challenging. This explains the reference to "desired health outcomes" in the committee's definition of quality.

The top bar in Figure 9.4 represents a scale on which we can register the value judgments of the hypothetical patient with prostate disease. It is anchored by the least and most desirable outcomes. The markings on the scale indicate that he prefers his current state to the one that would be imposed by a complication of alternative 1. This patient might, therefore, opt for the less risky alternative 2. The bottom two scales display different

value judgments for different hypothetical patients, similar enough to face the same outcome probabilities, but with different preferences. For the second patient, the same health state diminishes life's quality more; alternative 1 may be preferable despite the risks. For the third patient, alternative 1 would almost certainly be the best choice. The current health state is perceived as a serious hardship, and the state associated with a complication of alternative 1 is not.

## PATIENT VALUES

We know that patients' subjective responses to the same health states can be very variable. Doctors, too, have variable responses that may or may not be systematically different from those of patients. Information of this sort is scarce, but the tools to gather it are increasingly available. It is necessary information if we are to provide a context for the patient trying to make a health care decision, or if we are to measure quality using a definition that specifies desired health outcomes.

The conceptual model is illustrated in Figure 9.5. Aggregate outcomes

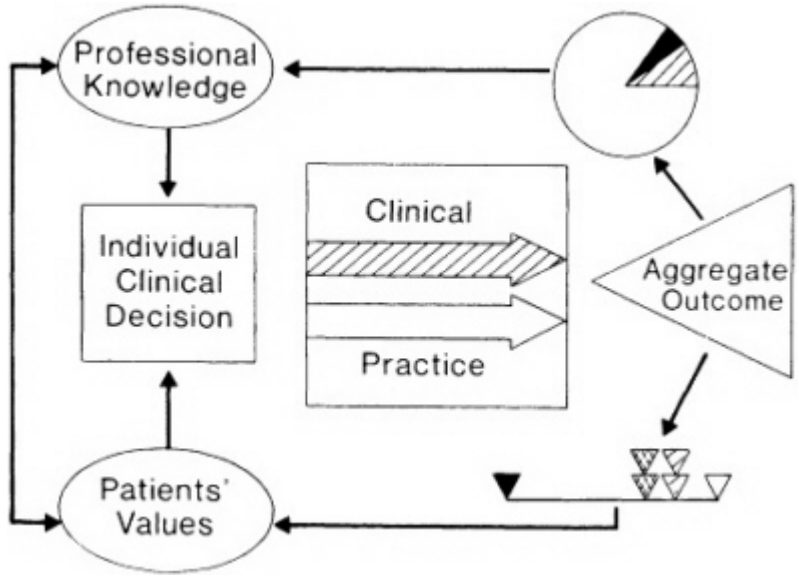


Figure 9.5
The role of aggregate outcomes in informing professional knowledge and patients' judgments about desired health outcomes.

serve as a source of information for the profession and patients, continuously improving the knowledge base on which decisions depend. Appreciate the pivotal role of outcomes: without outcomes, information most relevant to the patients' predicament and the providers' role is not captured. Without outcomes, therefore, professional knowledge may be disengaged from the decisionmaking process. Without outcomes, the patient orientation could be neglected.

## OUTCOMES AND QUALITY ASSURANCE

Clearly, this model assumes professional responsibility and patient involvement, elements of quality assurance that the IOM committee would like to promote. Yet what about quality assurance? How would we avoid depending too heavily on a presumption of virtuous professional behavior?

We complicate the model by acknowledging that not all providers are alike. Structural aspects of care vary from place to place. There are subtle and not so subtle differences in the processes of care. One provider may be more or less reluctant than another to use an intervention for a certain class of patients. When systematic treatment differences among providers occur, the outcomes may differ. Consider how valuable information about such differences would be not only to a patient, who could be expected to prefer the provider whose outcomes are better, but also to providers. Well-in-tended providers who discover that they do not achieve the best outcomes learn how to improve their processes from those who do. In the absence of such cooperation, which might seem naive or foolish to providers given incentives to compete with each other, they might at least be stimulated to examine their processes and improve them.

Such outcome rates would be a central product of our envisioned quality assurance program. Stimulating and enabling providers to characterize their patients, define their processes, and measure their outcomes would be a central task of the proposed Medicare Quality Review Organizations (MQROs). The Medicare Program to Assure Quality (MPAQ) would provide support, including technical assistance, and oversight. These tasks will not be easy. Because the knowledge, skills, and systems are not widely available, we will have to get there incrementally and make strategic choices. We have said that we would begin with discrete conditions that generally require hospitalization, then include forms of care that substitute for inpatient care such as ambulatory surgery. We would then extend the approach to ambulatory care, nursing homes, and eventually, home care.

## SUMMARY

The extended conceptual model can be described succinctly. Aggregate outcomes of care serve as a source of comparative information. That com

parative information must be credibly adjusted for the differences in patients. Its principal use would be to inform decisions and stimulate internal examination and quality improvement among providers. That examination and improvement would focus on the processes of care. Policymakers would also benefit from the comparative rates and the information about what patients value. These decisionmakers can influence the capacity of the system to provide different kinds of care, dealing with the structural elements of quality in a way that reflects desired health outcomes. To foster an enhanced sense of professional responsibility, we would see providers as the primary consumers of this information, but we also recognize that not all providers will make good and timely use of it. We see the eventual public disclosure of carefully validated outcome rates that have been generally accepted as valid by the professional community as a powerful stimulus for providers to improve or leave the marketplace. We also see the timely release of positive outcome rates as a welcome positive incentive for providers. Finally, we see this approach as the one most likely to bring providers, patients, and policymakers to recognize their common as well as conflicting interests in quality.

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# 10

# A Patient Outcomes Orientation: A Response

*John E. Wennberg*

First I would like to take this opportunity to thank Albert Mulley for doing so much work in this area. The whole idea of the interactive video disk approach as a means for informing patients about what happens was his idea. He hit upon it one night when we were walking in Santa Monica. His idea was to let the second opinion be the patient's. Since that time we have gone quite a long way toward clarifying the intellectual basis for involving the patient actively in the decisionmaking process. The more we engage this issue, the more optimistic I am that some of the major problems now confronting our medical policy have a solution that goes back to the question of patient demand. I have always been skeptical about the notion that our cost containment crisis was a product of patient demand and medical progress, being much more impressed by the features of supplier-induced demand and professional uncertainty about the value of medical treatments—the fact that physicians often disagree on what works in medicine. Perhaps, through outcomes research and communication with patients, we can learn what the demand for care really is.

## OUTCOMES OF CARE

One of the more important recent policy events, one that happened during the period of deliberations by this Institute of Medicine (IOM) committee, is that we now have a new agency called the Agency for Health Care Policy and Research (AHCPR). This agency offers, for the first time, a focus in government for the systematic evaluation of different medical theories. Much of our uncertainty about what works in medicine comes from the fact that we simply have not undertaken the kinds of studies that Mulley (1991) presents—studies to find out what the probabilities are for the various

outcomes given a particular course of treatment. By virtue of this neglect, physicians have not had the probability estimates at hand to inform patients about theft likely outcomes. A fundamental dimension in the IOM committee's definition of quality (IOM, 1990), namely the *likelihood of an outcome*, is not now understood in any systematic way. Because of the influence of the new agency, in the next few years we will come to understand much better what works in medicine; I will return to this point below.

The IOM committee's definition also includes the idea of a *desired health outcome*. I think we are now in a position to begin to learn what it is that patients actually want in medicine as opposed to what they have used. Most economists and policy analysts have in the past confused utilization with demand, as if the rate of service use expressed the wants of patients. Now we know from the small-area variation studies and from all we have learned about the scientific weaknesses in medicine that utilization does not necessarily indicate what patients want.

## APPROPRIATENESS OF CARE

In Paul Griner's paper (Griner, 1991), I am struck by the use of the word "appropriate." This word has always been a problem for me. When I was on the house staff at Johns Hopkins, my chief of medicine and other senior clinicians were always telling the house staff what was appropriate, which usually meant what they wanted us to do. Although their theories were very plausible, many were not tested; they were simply part of the conventional wisdom of the day. At that time, for example, it was appropriate, particularly at Hopkins where Dr. Halstead had invented the idea, to do a radical mastectomy for women diagnosed with breast cancer. We now know that this theory was hardly appropriate, if by the word appropriate we mean something that patients want based on knowledge about outcomes.

In our search for definitions, therefore, modification is needed. As a house staff officer, we thought the words appropriate care meant necessary care. If it is inappropriate, then it is unnecessary care. Now we know that medicine is much more complex, that there are multiple morbidities, multiple treatments, and multiple outcomes. Care is appropriate only if two conditions exist: (1) it works in some important dimensions of the multiple-morbidity, multiple-outcomes complex; and (2) patients prefer this treatment and these outcome probabilities among those offered by the alternatives. When these conditions are met, it seems fair to say that care is appropriate. Care that patients do not want is not appropriate, even though it may be effective.

## PATIENT VALUES

I want to elaborate a bit on this notion of choice between valid treatments. As we completed our assessment of watchful waiting and surgery as

options for treating benign prostatic hypertrophy (BPH), the predicament patients face became clear. Transurethral prostatectomy worked better than watchful waiting for relief of symptoms, but it has, as Mulley (1991) noted, its down sides. It causes death in some people; it causes incontinence and impotence in others. People will value these different possible outcomes differently depending on their life situations. The problem we faced was how to make this information available to patients in ways that allowed them actively to participate in their choice of treatment, in this case surgery. Our strategy in laying this out to patients was to try to make it crystal clear to them that they have an option. To do this we used interactive video disk technology, which allowed us to show specific patients what their outcome probabilities are, to inform them that they really do have a choice, and to show them vignettes of their possible futures through interviews with patients who had various outcomes. The heuristic we used to establish that the choice is up to the patient was to interview two physicians, both of whom were severely symptomatic. One chose surgery because of his particular attitude toward his symptoms and toward risk. The other, having similarly severe symptoms, was more concerned about incontinence than about his symptoms and he, therefore, chose watchful waiting.

Interactive disk technology works. When informed about the fact that they do have a choice, patients actively participate in the decision process. Some of our more successful experiences to date are among Veterans' Administration hospital patients, a group that many would suppose is uninterested in sharing decisionmaking. Virtually all patients, regardless of socioeconomic status, actively seek information. When they are empowered by the idea that they have a choice, they insist on participating in the decision. We have been very much gratified and somewhat surprised by that finding.

## FUTURE ADVANCES IN DECISIONMAKING

Over the next three or four years I think outcomes research will develop the probability estimates required to clarify the decision problems for 10 to 15 major choices, such as bypass surgery, joint replacement, hysterectomy, and back surgery. This will allow us to do for other common conditions what it has been possible to do for BPH, namely, to clarify the outcome probabilities and begin to bring that information to patients and physicians to improve the scientific and ethical basis of clinical decisionmaking. I predict that, as in the BPH example, most of the conditions will provide people with clear choices between treatments depending on their attitudes toward risk and their concern about various outcome states.

About 10 conditions represent well over 60 percent of inpatient surgery in the United States these days. If we begin to translate these data into information that patients can understand and present it to them in ways that they can act upon, we will begin to learn what demand really exists in

medicine for high-technology interventions. This should greatly assist the entire quality effort because it will provide a foundation for beginning to develop the methods for implementing this broadly in clinical practice.

On the basis of our work so far, I would not be at all surprised to see that the aggregate demand for surgery is less than the quantity now supplied. Our early results in the use of this approach show that patients tend to be more averse to risk than physicians; hence, they tend to select more conservative treatment. Whether this will be so in the long run is not clear, but at least we will learn what patients really want.

## OUTCOMES RESEARCH

The outcomes research agenda will help the quality agenda in one other important way, dealing with an entirely different kind of problem. This is one in which the capacity of the system influences the clinical thresholds that, in turn, affect the probability of hospital admission among various communities.

One of the more important insights of medical care epidemiology is that when the number of hospital beds varies between communities, as it does, for instance, between Boston (4.5 beds per 1,000) and New Haven (2.9 per 1,000), beds in higher-bed areas are used almost exclusively to treat patients with a set of medical conditions that I have come to call "high variation." Surgical procedure rates are not correlated with bed supply, nor are the admission rates for heart attacks, strokes, and acute gastrointestinal hemorrhages. The kind of admissions that are more frequent when beds are more common are pneumonias, bronchitis and asthma, otitis media, and hypertension. For example, the most important single reason for the difference in rates of use between Boston and New Haven is the number of hospital admissions for people with chronic back pain—not surgical patients but medical patients.

Associated with the increasing bed supply are three factors: (1) a tendency to put more resources into terminal illnesses (40 percent of people in Boston die in the hospital compared to 31 percent in New Haven); (2) to spend a lot more per case (the per capita cost for terminal illnesses in Boston is 2.5 times higher than in New Haven); and (3) to readmit people with chronic conditions. At least in the Boston-New Haven situation, outcomes research has already been able to show no detectable differences in mortality rates between these two communities despite their extraordinary differences in investment of resources. Further research will show whether there are differences in morbidity, differences in quality of life, or differences in symptom levels that can be associated with this extraordinary difference in resources. The null hypothesis may well hold, in which case there is a very interesting opportunity for massive reallocation of resources toward more effective services.

Remember that the theories that are associated with bed supply are implicit theories, theories that clinicians in New Haven do not even recognize as existing. Occupancy rates for the hospitals in New Haven are the same as in Boston, and New Haven physicians do not believe they are rationing or withholding care. Contrast this to the situation of Cody Howard in Oregon, who was a victim of the assumptions that medical progress and patient demand are at the heart of the cost containment crisis and that, therefore, we have to ration care. Contrast his situation where potentially lifesaving bone marrow transplantation was withheld on the basis that we could not afford it. Within three to four years we should know a good deal more about the outcomes of many of our common strategies for allocating resources, and we should be in a position to entertain seriously the idea of reallocation.

## QUALITY, RESOURCES, AND PRACTICE PATTERNS

When I read the IOM report, I agreed with its message, but I did not see in it mechanisms by which the quality movement could affect the overall aggregate supply in market areas. Yet, if we are going to achieve reallocation, we are going to have to pay close attention to the question of whether structural changes are actually harming patients. Inevitably, there will be disagreements and conflicts in the profession as these issues are dealt with more explicitly.

Finally, I want to draw attention to another observation I have made. In medical markets, theory and supply seem to be in dynamic equilibrium. The threshold effect of the use of hospital beds is a very good example of that. In areas where there are more surgeons who prefer, for example, endarterectomy theories for treating carotid stenosis, there will be more operations. In areas where there are more neurologists preferring aspirin treatment for that condition, there will be more medical management. We need to come to terms with the fact that the supply of resources and the theories that physicians use in practice are in dynamic equilibrium, and they both affect practice style. I bring this up at this point only to remind you that over the next few years we must learn how to deal explicitly with the capacity problem if we are going to make the gains that we want from our outcomes research and our efforts to improve the quality of care.

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# PART VI

# New Directions: Public Accountability and Program Evaluation

# New Directions: Public Accountability and Program Evaluation

## INTRODUCTION

*Marilyn Moon*

The Institute of Medicine report includes recommendations for increased public accountability and program evaluation. This reflects the desire by members of the committee to ensure that both the beneficiary and provider communities have opportunities to critique the quality assurance system. The concerns that prompted these recommendations can be placed into four general categories.

First, to promote professionalism and attention to the process of quality assurance, professionals must believe in the system. Physicians, hospital administrators, nurses, and other providers need to have opportunities to help shape the system over time. In this way, they will be more likely to "buy into" the process than if they have no input. Second, a formal role for public input also helps to ensure that the concerns of the users of health care are explicitly built into any quality assurance system. Third, a system for assessing and assuring quality will likely raise controversial and public issues over time—issues that ought to be discussed in a public forum. Finally, the committee felt strongly that it did not have all the answers and that a system needed to be designed with enough flexibility to change with the times. A formal role for accountability and evaluation establishes a structure to develop recommendations for change and adjustment.

With these concerns in mind, the committee proposed several specific organizations as a means of implementing a review and evaluation component of the system. Maxwell Mehlman, director of the Law-Medicine Center at Case Western Reserve University and a member of the IOM panel, discusses more fully the goals and implications of these recommendations. Duncan vB. Newhauser, professor of epidemiology at Case Western Reserve University, offers a commentary and response, with a particular focus on broad programmatic change within the entire Medicare program.

# 11

# Public Accountability and Program Evaluation: The Committee View

*Maxwell J. Mehlman*

Of the ten major recommendations of the Institute of Medicine (IOM) committee, three are devoted to the issue of public accountability and program evaluation (IOM, 1990). Although several recommendations are broad in scope, somewhat general, and perhaps difficult to achieve, this was an area in which we felt we could make several specific recommendations that would be fairly easy to carry out. This paper discusses our findings and recommendations in this arena.

## BACKGROUND

In our deliberations we examined the existing mechanisms for facilitating public accountability and for evaluating the Medicare quality assurance system. We saw that the Peer Review Organizations (PROs) themselves do some of this in the sense that they have a limited reporting function, particularly to facilitate the review by the Health Care Finance Administration (HCFA) of their ability to fulfill their contracts. HCFA itself, of course, performs program evaluation and is to some extent publicly accountable. We learned about the "PROMPTS-2" system and again found that it focuses primarily on whether the individual PROs have fulfilled their contract requirements.

SuperPRO is another evaluative mechanism, and we learned about some of the recent changes that have enhanced the role of SuperPRO, such as HCFA's selecting cases for review itself rather than relying on PRO-selected cases and the more formal role that SuperPRO evaluation is playing in the HCFA evaluation of PRO performance. This also seemed to be focused primarily on whether the PROs were fulfilling their contract obligations with HCFA.

The Office of Inspector General (OIG) of the Department of Health and Human Services (DHHS) and the General Accounting Office have done some systemwide evaluations of the quality assurance program, but they focused on fairly specific issues. Potentially or indirectly a number of other entities might play this role—the Office of Management and Budget, the Office of Technology Assessment, the Prospective Payment Assessment Commission (ProPAC), the Physician Payment Review Commission (PPRC), and of course, Congress itself. This area of public accountability and program evaluation is clearly a very diverse and multi-layered system, but one that the members of the committee thought might be improved in several ways.

Our study of these entities gave rise to several concerns. First we asked how well suited these entities are to reflect the emphasis on quality that we have recommended. None of these entities really focuses exclusively on quality as distinct from containing the costs of care, which was a major concern during the committee's deliberations. We felt it was important to be able to assess quality independent of cost concerns. This is reflected in the struggle we had over the definition of quality itself. If we are going to make trade-offs between quality and cost, we want to be clear that is what we are doing. This seemed to us to call for an independent, high-level body that focused exclusively on the quality of care delivered to Medicare beneficiaries.

Another concern we had with the existing mechanisms for public accountability and evaluation was the lack of a sufficient, ongoing, systematic evaluation of how well the Medicare system was assuring quality of care. The Office of Inspector General's report (OIG, 1989), for example, tells us that 6 percent of Medicare admissions demonstrate or suggest quality deficiencies, but is this good or bad? We do not know. Is it getting better or worse? This would seem to be a simpler inquiry, but again, we do not know. So we saw a need for a continuous evaluation of the quality of care under Medicare and also of Medicare's mechanisms for assuring quality.

In addition to evaluating quality, we also perceived the need to report the results of this evaluation to the public and to bodies that are publicly accountable. Here again we found no formal systematic reporting to Congress about how well the program assures quality. We also found only limited effort by the PROs and by the OIG to document and demonstrate their own impact on quality. In some respects this seemed to be a lack of proclaiming the benefit and success of those programs themselves.

It was very difficult for the committee to get a clear picture of the extent of quality problems within the Medicare system, or of how those problems had been detected and dealt with by the PROs and by the OIG. We eventually obtained some information on this, but it is only the numerator of the equation—the number of cases that were detected and that were responded to by the system. It tells us nothing about the denominator, what is out there. In addition, it deals only with the subset of poor-quality providers.

It does not address the rest of the quality question—that is, whether quality as a whole has improved or declined.

The committee was also concerned about the extent to which HCFA taps into expertise on quality assessment and assurance that might be available outside of the agency and the extent to which the Medicare quality assurance system is in a position to change and grow, or contract, in light of new research findings. To respond to these concerns, we made several recommendations.

First, we recommended the establishment of a congressional commission that we call QualPAC, the Quality Program Advisory Commission. We felt that Congress seemed to work very well with the Prospective Payment Assessment Commission and the Physician Payment Review Commission and took those as our models for this recommendation. QualPAC would be established on a par with those other commissions. The purposes would be (1) to provide advice to Congress about how well the Medicare Program to Assure Quality (MPAQ) is doing and how it might do its job better; (2) to stay on top of quality problems systemwide by identifying them and charting their progression; (3) to conduct studies to support policy evaluations and recommendations; (4) to integrate new research on quality assurance into the quality assurance program; and (5) to serve as a sounding board for groups interested in quality assurance. QualPAC should have a staff comparable to the other congressional commissions and be funded by Congress separately from MPAQ.

We also recommended the establishment of a National Council on Medicare Quality Assurance. This would be within the executive branch, whereas QualPAC would have reporting responsibility to Congress itself. The purpose of the National Council, somewhat reminiscent of the council for the former Professional Standards Review Organization program, would be to advise the key entities within the executive branch (DHHS, HCFA, and the Health Standards and Quality Bureau in HCFA) on the MPAQ and how well it is doing, and to afford the executive branch access to the expertise and viewpoints of diverse groups involved with Medicare quality assurance, particularly from the research and quality management communities.

We also recommended an additional body within the executive branch, a Technical Advisory Panel. It would advise the DHHS how to evaluate the MPAQ program and help to prepare a report to Congress, which we recommended occur at least every two years.

These recommendations do not reflect all of the elements in our report that deal with public accountability and evaluation. We also endorsed the recommendations of the Administrative Conference of the United States (Jost, 1988) encouraging the use of formal, publicly accessible rulemaking proceedings in adopting Medicare policies and policy changes and increasing the access of the public to Medicare written materials and documents.

We also recommended the release of appropriate quality information to the public. Many of us believe that this is potentially one of the best methods for assuring public accountability.

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# 12

# Public Accountability and Program Evaluation: A Response

*Duncan vB. Neuhauser*

One of the good things about this Institute of Medicine report (IOM, 1990) on Medicare quality is that it looks toward a 10-year time horizon. Let me go beyond that to consider a 20-year horizon. This desire comes partly from being infected by continuous quality improvement ideas, such as constancy of purpose, and partly from recently observing several small companies destroy themselves by being concerned only with maximizing the next quarter's profits. If we voters do not express our concern for the future, Washington will never get the message.

## NEED FOR CHANGES

Using this long time horizon leads me to believe that the classic form of health insurance on which Medicare is based, that is, paying for units of care and relying on inspection for quality control, is on its way to extinction. There is going to have to be a major massive involvement by the federal government in improving the quality of the services Medicare pays for, or Medicare as we now know it will simply become a dinosaur.

One measure of the depths of the problem we are dealing with relates to the well-known film on prostate surgery by John Wennberg and his colleagues. Videos such as this should be available to everyone. Seeing them should be the minimum standard of informed consent prior to surgery. Medicare apparently is unable to create such a requirement and to promote the development of other such films. That is a problem of the first order.

In my city of Cleveland, as elsewhere, health maintenance organizations (HMOs) and preferred provider organizations (PPOs) are taking over much of the market for medical care. Our local business coalition, called the Health Action Council, has the potential to organize sensible care for its employees

and their families through provider-payer-user partnerships. Along with Kaiser Permanente, Blue Cross and other PPOs, and Medicaid HMOs, most people in this area are entering managed care plans. Medicare in my city is becoming the major stumbling block to reorganizing high-quality and efficient care, because it has a lack of capacity and a lack of levers to move care in a more sensible direction. Medicare is becoming more and more part of the problem rather than part of the solution.

Managers of one Blue Cross plan in a nearby state were considering stopping payment for bypass surgery in 40 hospitals doing fewer than 100 procedures a year. Could Medicare do this if it wished to? Employers and unions are talking about developing ongoing working groups with physicians (partnerships) to improve specific categories of care such as substance abuse and low back pain. These partnerships would meet and go on continuously. The Kingsport, Tennessee, model should received more attention. Could Medicare do these things? Not as it is currently structured. Medicare is being left behind.

I think that ultimately the medical model for care of the elderly, the health insurance model, will be on its way out and that it will be replaced by a social support model of care for the elderly. I think we will keep coming back to more of those bizarre creatures, such as Social-HMOs, On Lok Senior Health Services, and even medieval Beguines. We will eventually move to the very different view that social support is the major model for helping the elderly. The medical model will become a subsidiary perspective.

## PROGRAM EVALUATION

Once there were the Foundations for Medical Care. They begat EMCROs. EMCROs begat PSROs. PSROs begat PROs, and they are about to beget MQROs.[1] PROs are based on inspection, as far as I can tell. By the way, this violates one of Edwards Deming's 14 principles of total quality management and, therefore, from his point of view should be done away with altogether.

About 1978, I met with a dozen managers of PSROs, and we talked about how to evaluate their performance. Could we find out and demonstrate what good work they were doing? The general response from these executives was that they were not very interested. If somebody else would do it, and if it would cost them neither money nor effort, they would perhaps go along with it—reluctantly. They were sure that they were doing good

[1] Editors' Note: The reference is to the successive Medicare peer review and quality assurance efforts: Experimental Medical Care Review Organizations (EMCROs), Professional Standards Review Organizations (PSROs), Utilization and Quality Control Peer Review Organizations (PROs), and the proposed Medicare Quality Review Organization (MQROs).

work and that, with a little more money, they certainly could do better. They were very busy implementing their programs, and they certainly did not have time, thank you very much.

As you probably know, and if you do not know you should, the standards for what makes good evidence of health outcomes were laid down in the first 21 verses of the biblical book of Daniel. The PSRO directors failed to follow the wise example of Daniel. Rightfully the PSROs were found wanting, and their kingdom was divided among the Medes and the Persians, and those PSRO managers have all lost their jobs. Can we say whether the PRO managers have learned to listen and heed the advice of the prophet Daniel? Are they carefully evaluating what they are doing to demonstrate the usefulness of their activities? They probably are not.

There are now about 50 PROs. Would it not be a marvelous thing if we could randomly choose 10 PROs and assign them to John Wennberg to run according to his philosophy? Another randomly chosen 10 could be given to Robert Brook and Jacqueline Kosecoff[2] for them to run. Randomly choose another 10 and give them to the people involved in Deming's continuous quality improvement. We could watch and see what happens, and maybe on that basis we could choose one of the more sensible approaches.

I am a great believer in management by randomization as opposed to rigid uniformity in government systems. Governments tend to prefer standard, uniform, monolithic systems. This is true for the British National Health Service, for the Costa Rican health services in rural areas, for the Department of Veterans Affairs, and for Medicare. We pay a disastrous price for having single monolithic institutions. This is a simpleminded, one-style-fits-everybody philosophy as opposed to a massive commitment to experimental changes.

If this IOM report creates a vehicle for evaluating care, it ought to be empowered to provide systematic randomized changes in many aspects of the Medicare program. Then the managers of this program can produce a long menu of possible answers when the next political crisis comes along, with the next set of politicians whose future orientation does not exceed the next election two years from now. It ought to be a vehicle for good management that should help guide a longer-term view of things, rather than what the British call redisorganization.

## CONCLUDING REMARKS

I am very much pleased with the report and its proposals. We are living in wonderful times in terms of quality assurance improvement and evaluation. Today there are more exciting things being tried in these areas than at

[2] Editors' Note: Health services researchers who have published widely in the field of quality assurance.

any time since the death of Ernest Avery Codman. We ought to cheer on these efforts. This is exactly the wrong time to set any one of these approaches in concrete and make it mandatory for everybody. This is certainly the time to ask many questions, to continue discussion, to debate and comment, and to evaluate. I think that is exactly what this report has proposed to do. Therefore, three cheers.

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# PART VII

# Confronting Special Implementation Issues

# Confronting Special Implementation Issues:

## INTRODUCTION

*Mark R. Chassin*

This part of the conference proceedings addresses three issues that our report deals with only indirectly (IOM, 1990): the epidemiology of quality problems, legal concerns, and the relationship of Medicare's quality efforts to those of other sections of the health care system. They are taken up, respectively, by R. Heather Palmer, a pediatrician by training who is now a Lecturer at the Harvard School of Public Health and Director of the Center for Quality of Care Research and Education; Alice G. Gosfield, a practicing attorney in Philadelphia with long experience in medicolegal issues, particularly those pertaining to peer review; and James S. Roberts, a physician with many years of work in the quality-of-care field and currently Senior Vice President of the Joint Commission on Accreditation of Healthcare Organizations.

These issues form a major part of the environment in which the Medicare quality assurance strategy that we have laid out in such detail must be implemented and played out. We considered each of the three areas, but—unlike topics covered in the earlier presentations—we did not make specific recommendations that pertained directly to them. Rather, we clearly identified them as very important components of the system either as constraints, as obstacles, or simply as facts that quality assurance has to take into account.

The remainder of this brief introduction gives the context in which the committee saw these issues and then raises some of the questions each of them poses. I doubt we are going to have very many answers, but we do need to ask the questions.

On the epidemiology of quality problems it was clear to us early on that in trying to set a strategy for quality assurance it would be nice to know what quality problems existed out there and, in fact, what the burden of harm of these quality problems was. Particularly in considering just the major categories that we identified—overuse, underuse, and misuse or

improper use—it is quite critical to the rational allocation of quality assurance resources to know something about the relative distribution of those problems. Each of them requires very different measurement techniques. If, for instance, you are measuring underuse, you have to look at populations. If you are measuring overuse, you have look at specific incidents of care. They also require very different means of intervention and different monitoring mechanisms.

To even begin to set up a quality assurance strategy—a real quality assurance program—one would like to know what the distribution of those problems is and, even more specifically, within each of those domains what are the most common, what are the most difficult, what are the most burdensome problems? Well, we learned very early that very little is known about that distribution. The question is how do we proceed in the absence of such data? Clearly, it is not responsible to say we have to wait until the research findings roll in over the next 20 years, if in fact they will, because we will always have incomplete information. So the problem that Medicare faces, indeed that all quality assurance programs face, is how to proceed in the absence of those kinds of data.

Second, legal concerns form a major part of the environment. Those concerns arise in a number of different domains. As the committee gathered its data, certainly we heard a lot from Medicare Peer Review Organizations (PROs), from state health departments, and from state licensing boards about how difficult it is, even after identifying a "bad apple," to sanction that aberrant provider unless he or she is a drug addict or sell drugs as a physician. I read the California licensing board's deliberations every month, and they are virtually all (certainly 90 percent of them) about acts of sexual deviance or acts of drug addiction or drug selling. Very few instances of quality of care become the basis for licensing board sanctions. Why is it that sanctioning providers is so extraordinarily difficult? was the recurrent theme. Is it a process problem? Is it simply an obstacle in the environment that will never be made any easier? What can we learn about how that process can be improved?

What about malpractice concerns? Can we get physicians to give up defensive medicine? This constitutes some finite fraction of overuse although we know very little about exactly what proportion it constitutes. Can we really expect physicians to give that up unless the tort system is completely dismantled and completely reformed, as Relman (1991) suggests? Relman also mentions antitrust as another force in the environment that makes physicians very reluctant to undertake, at the local level, at the hospital staff level, or even at the organizational level, sanctions against providers who may be misbehaving.

Other presentations note that the report calls for a massive amount of new information about outcomes that are physician specific and that are

hospital specific. How are these sensitive data going to be handled? What about confidentiality? How are they going to be released? To whom? Under what circumstances?

Last on our list of "simple problems" is, How does the Medicare strategy relate to everything else that is out in the environment—to the other players in quality assurance? Another repetitive theme the committee heard was that providers are excessively burdened by the multiple agencies involved in quality assurance independently demanding the same information in an uncoordinated fashion. So the final issue of this set of three special topics concerns how the Medicare strategy fits into what everybody else is doing.

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# 13

# Confronting Special Implementation Issues: The Epidemiology of Quality Problems

*R. Heather Palmer*

One full chapter of the Institute of Medicine (IOM) report concerns the "epidemiology of quality," in other words, the pattern of occurrence of quality problems (IOM, 1990). This paper expands upon the implications of those patterns.

## THREE TYPES OF QUALITY PROBLEMS

The IOM report analyzed the extent to which harm created for patients by quality problems is caused by overuse of services, by poor technical quality, or by underuse. An example of overuse would be performing an unnecessary coronary angioplasty. An example of poor technical quality might be perforating the bowel during an abdominal operation or administering a drug other than the drug ordered by the physician. An example of underuse might be neglecting to prescribe an effective drug, that is, a drug that could cure a patient.

The IOM committee sought to define the magnitude of each of these because it believed that the three different types of problems must be detected and corrected by using different methods. For example, overuse can be identified by reviewing procedures performed on Medicare beneficiaries that are believed to be subject to overuse. The corrective intervention would be denial of payment for the procedure.

Poor technical quality is also studied among recipients of care. In the Medicare Peer Review Organization (PRO) program it is detected primarily by the use of written criteria called "generic quality screens." Nurse reviewers read patients' records, using these criteria to identify adverse events occurring to patients. A physician reviews all cases of adverse events to determine whether the cause was poor quality of care. The intervention used for

repeated or flagrant instances of poor quality is to sanction the physician who is responsible. Poor technical quality, of course, may also provoke a malpractice suit.

Underuse is more difficult to measure. It may occur among recipients of care, but to get a complete picture one must also study nonrecipients who may have been unsuccessful in getting access to care. The Medicare program currently addresses underuse only in capitated settings, and it does not pursue the issue vigorously even there. Presumably if underuse of a serious nature were discovered in a health maintenance organization (HMO), the result of the intervention would be a sanction. Underuse, including omission or delay in matters of diagnosis or treatment, is also becoming a common cause of malpractice suits.

## Evidence of Quality Problems

Evidence for the prevalence of these three types of problems is provided in the IOM report. Information on overuse comes primarily from data comparing rates of use of procedures and admissions in apparently comparable populations, although there is seldom any assurance that the populations are truly comparable. Wide variations in the use of procedures are often found, especially for procedures and types of admissions where there is little scientific evidence to guide physician decisions. It was widely believed that the difference in rates of use between a high-use and a low-use area was created by overuse in the high-use area, but we know now that the situation is more complex. Chassin et al. (1987) and Leape et al. (1990) report studies in which criteria chosen by expert panels to define appropriateness of a procedure were applied to data from medical records of Medicare beneficiaries. They show that overuse certainly occurred for procedures where clinical indications are in dispute. For instance, Chassin et al. (1987) found that 32 percent of carotid endarterectomies were unnecessary. Leape et al. (1990) found small geographic areas where up to 67 percent of carotid endarterectomies were unnecessary. Surprisingly, however, the differences in overuse between high-use and low-use areas were small. In other words, the proportion of inappropriate use did not explain most of the difference between high- and low-use areas.

Overuse is a major target in Medicare because its elimination can save money without lessening quality. Providers generally agree that overuse is a problem for the Medicare program, although the IOM committee found that elderly beneficiaries seldom complained of it.

The committee found evidence of poor technical quality from several sources. These included reports of sanctions initiated by PROs against physicians or hospitals, reports of license withdrawals by state licensing boards, and reports of malpractice claim settlements. None of these sources

permits comparing the distribution of poor quality across states because the procedures for invoking a sanction, withdrawing a license, or settling a malpractice claim are highly variable from state to state. From these data, however, it emerged that a small number of physicians account for a large proportion of quality problems.

Information on poor technical quality comes also from record reviews done by the PRO program or by hospital risk management personnel to identify patients who experience adverse events. Adverse events are common. The California Medical Insurance Feasibility Study of 1977 showed that in 4.65 percent of hospital admissions, adverse events occur that are "potentially compensable" because they were caused in part by poor technical quality (Mills, 1977). Adverse events occur most commonly with more complex procedures and with sicker patients.

Underuse was the problem for which the committee found the least information, although Medicare consumers complained often of it. Some of the complaints of failure to provide service concerned services that the Medicare program has made a conscious decision not to cover. As noted earlier, Medicare concerns itself only with underuse in capitated settings. In fee-for-service settings, underuse may also occur, less for financial reasons than for physical, psychological, and logistical reasons. Perhaps the federal government and third-party payers are not anxious actively to promote use of services, even those deemed necessary, because that would result in their paying for more care. If so, this is a shortsighted point of view. Investment in early intervention and prevention services may save costs in the long run. We do not know, and desperately need to know, the extent of these potential savings.

It is noteworthy that the committee found evidence of underuse primarily for what we might call "nonglamorous" conditions, such as incontinence, depression, or gait problems, and for simple types of services, such as the time and attention of providers, particularly nonphysicians including nurses.

The IOM report did not find enough information to decide that any one of the three quality problems should take precedence. An interesting pattern emerges in the report: overuse and quality problems are primarily cited in the area of "high-technology" medicine and underuse in the area of "low-technology" medicine. This must surely derive from the present pattern of benefits coverage and reimbursement, which favors performance of high-technology procedures. Three other issues deserving comment include the overlap between overuse and poor technical quality, ways to discourage overuse while overcoming underuse, and ways to improve technical quality.

### The Overlap Between Overuse and Poor Technical Quality

First, let us consider the relationship between overuse and poor quality. Table 13.1 provides a framework for discussing this relationship. Unnecessary

care, even if perfectly implemented, worsens the patient's outcome (net benefit) because it provides little or no gain in health while potentially causing unavoidable complications and side effects, discomfort, anxiety, and use of patient time. Obviously, then, overuse is bad for both cost and quality reasons.

TABLE 13.1 Probability of Good Outcome for Patients According to Competent Implementation and Necessity of Health Services

| Is the Service Competently Implemented? | Is the Service Necessary? | |
|---|---|---|
| | Yes | No |
| Yes | Good | Bad |
| No | Bad | Worst |

The report quotes data to show that Americans have more procedures than any other nation on earth. For instance, the U.S. rate for hysterectomy is three times higher than that in England and Wales. As another example, coronary bypass surgery is done at the rate of 19 per million in France and 483 per million in the United States. Many more American than French individuals, then, have complex procedures that put them at risk for poor quality.

Overuse may also adversely affect outcomes because a high volume of output, and the spread of procedures or other types of care to less well-prepared provider teams, may lead to less competent implementation of those services. Poor implementation in turn harms patients and necessitates still more services to repair the damage; for instance, high rates of surgery bring with them an increased need to treat nosocomial infections. By doing many procedures and therefore having to do them in less well-prepared settings, problems with poor technical quality increase. Obviously, poor technical quality is most disturbing or troubling if the procedure was unnecessary in the first place. The patient will not benefit and is put at risk for serious harm. An inevitable conclusion seems to be that problems with poor quality in the United States would decline substantially if overuse could be controlled.

### Discouraging Overuse and Overcoming Underuse

Second, to control overuse we must first define and detect it. The two scenarios in Table 13.2 show how complex this can be.

TABLE 13.2 Two Scenarios for Considering "Necessity" (Probability of Net Benefit) of a Procedure

| Scenario Dimensions | Heroic Procedure | Perfectionist Procedure |
|---|---|---|
| Patient status | Very sick | Very healthy |
| Probability of benefit | Low | High |
| Risk | High | Low |
| Outcome likely with or without procedure | Bad | Good |

In the first scenario we have what is described as "the heroic procedure": the patient is very sick, there is a low probability of benefit, but the benefit could be very great. The procedure is much more risky in so sick a patient and in fact the outcome is likely to be bad whether or not the procedure is done. Is this overuse?

The second scenario shows another potential type of overuse. The patient undergoing "the perfectionist procedure" is very healthy: there is high probability of some benefit but that benefit is very small because the patient is not very sick in the first place. The procedure is low risk in such a healthy patient. Do "perfectionist procedures" constitute overuse? A good outcome is likely, with or without the procedure. We can envisage, of course, even worse scenarios, such as when the patient is very sick and has a low probability of small benefit, so that a worse outcome is virtually certain from doing the procedure.

When a new procedure is introduced—a common event these days—it is used first in the heroic mode. As providers get accustomed to the procedure, its riskiness declines. Providers then tend to recommend the procedure for less and less sick patients. As that happens, the probability of benefit to the patient fails; it may even fall below the probability of harm. This is likely to occur because new procedures are done at first in specialized settings: as the procedure moves out into less well-prepared settings, such as smaller hospitals with less experienced surgeons and staffs, the risk of harm rises. So then, appropriateness is not an invariable property of a procedure. It depends on the patient's characteristics and on where and by whom the procedure is done.

Diffusion of new techniques to unsuitable patients and settings is a problem of overuse. Failure to diffuse techniques that are effective in improving patients' health is, however, a problem of underuse.

Until recently, we commonly assumed that discouraging overuse could best be done by concentrating on areas where rates of performance of a procedure were high. Now we recognize that the task requires a more sophisticated approach because the rate of inappropriate use in areas with

low usage rates is similar to that in areas with high usage rates. In other words, in both high- and low-use areas there is a mixture of over- and underuse occurring.

A sophisticated approach to judging the appropriateness of a procedure is needed—one that adjusts for factors such as those in the scenarios shown in Table 13.2. It requires empirical knowledge of the benefits and risks of procedures in many different patient circumstances and many different care settings. Producing knowledge of this kind is the objective of the Agency for Health Care Policy and Research (AHCPR) Patient Outcome Research Teams (PORTs) and the Agency's outcomes, effectiveness, and practice guidelines program (MEDTEP).

Knowledge of the net benefit of a procedure to the patient is not enough, however. The IOM report emphasizes the need to consult the patient's own preferences to incorporate judgments about the value of particular health states. This view is in keeping with the trend toward consumerism in our society. For health care financed by third parties, however, some way must be found to incorporate societal values into the decision to do a procedure or provide another type of service, because societal resources are being consumed. For instance, whatever the net benefit to the patient, should scarce resources be used for a heart transplant on a 90-year-old patient? If we say no, is that ageism and underuse, or is it prudent purchasing? How might the decision change if we knew the patient also had Alzheimer's disease?

Judging appropriateness, then, is complex and is itself expensive. Given the observation made earlier that high-technology care is overused and low-technology care is underused, could we achieve more by changing the reimbursement methods that have encouraged this maldistribution of resources? The Hsiao resource-based relative value system for physician payment, for instance, is moving in this direction (Hsiao et al., 1988). The IOM report suggests that beneficiaries might not support this, since they did not complain about overuse. The shift of resources to low-technology care might, however, encourage doctors to take time to explain to their patients the dangers of overuse. The Medicare program may also be reluctant to encourage more use of any kind of service. To overcome this tendency to think only of short-term costs, we desperately need information on what the "net cost" impact would be if we dealt with underuse of low-technology care and of prevention and early intervention services. A shift to more of this kind of service could in the long run produce greater benefit at less cost than our current system of heavy use of high-technology procedures.

### Improving Technical Quality

Third, since the committee report appeared, more evidence is available on the issue of poor technical quality. It comes from a study, called the

Harvard Medical Practice Study (1990), of care in New York hospitals in 1984. Using a carefully standardized process of peer review, the investigators identified all adverse events, that is, unintended injuries to patients caused by medical management, and all negligent adverse events, that is, those that result from failure on the part of the physician to provide reasonably careful management or to reach the standard of care.

Because these data came from representative sampling, the investigators could generalize their findings to the total population of hospital patients in New York State. The resulting estimates were startling. Of all hospital admissions, 3.7 percent had adverse events, and 1 percent had negligent adverse events. Adverse events were estimated to be primarily responsible for more than 13,000 deaths in 1984 in New York hospitals, and negligent adverse events for nearly 7,000 deaths.

The authors also studied risk factors for adverse events and negligent adverse events. They found both to be statistically significantly more likely to occur in persons over the age of 65. The distribution of adverse events differed from that for negligent adverse events. For instance, simple adverse events occurred significantly more often in teaching hospitals where, of course, there are more complex procedures and sicker patients. The percentage of adverse events that were negligent was significantly higher, however, in nonteaching hospitals. This higher occurrence of negligence represents lower quality of care than in the teaching hospital environment. Technical quality in hospitals is clearly an important problem. Efforts must be directed to preventing each and every adverse event, irrespective of whether an individual provider's negligence was the primary cause.

## CONCLUSIONS

There is sufficient information to conclude that deficiencies in quality of care impose a substantial burden of harm. This challenges providers, purchasers, and patients to commit themselves to quality improvement. How should this be done? Table 13.3 lists some recommendations for action.

First, curbing overuse would also help with the problem of poor technical quality. We must recognize that new procedures are constantly being developed in centers of excellence and then diffusing to settings where the ratio of benefit and harm to patients is quite different. We should stop being surprised by that. We need a system for managing the introduction of new technologies and procedures. This would include determining the indications for performing the procedure and specifications about how and by whom the procedure can be safely performed. This would be a step toward ensuring that the probability of harm to the patient is not greater than the probability of benefit whenever and wherever the procedure is used.

Second, it is time to pay attention to the potential long-term negative

consequences of underuse. There is great danger that the Medicare program will make bad decisions about allocation of resources because it lacks information about whether better coverage might in the end reduce costs. Shortsighted decisionmaking is likely to produce worse quality at higher cost in the long run.

TABLE 13.3 Recommendations for Action to Improve Quality of Care

| |
|---|
| 1. Curb overuse, which will help also to limit harm from poor technical quality. |
| 2. Adopt policies for coverage and reimbursement that promote cost-effective prevention and early intervention services. |
| 3. Manage health programs and the introduction of new health care technologies to improve technical quality. |
| 4. Stimulate continuous quality improvement by health care providers and organizations. |
| 5. Intervene for physicians and hospitals with serious quality problems. |

Third, we need a direct campaign against poor quality. This will require a commitment to quality management as a personal responsibility of every health care provider, manager, and worker. Senior clinicians and managers must provide the leadership to harness these individual efforts to the common goal of continuous improvement.

What should the federal government do about quality assurance in the Medicare program? Two major thrusts of the IOM committee's recommendations are reflected in the fourth and fifth points in Table 13.3. Fourth, the Health Care Financing Administration (HCFA) should become an active partner in promoting and facilitating continuous quality improvement among all physicians, nonphysician health professionals, and health care organizations. This is a change from an earlier mode of operation in which HCFA adopted a punitive and adversarial approach toward health care providers. It is gratifying to hear HCFA announce that it had already and independently adopted this positive and facilitative role (Morford, 1991).

This new approach requires that HCFA hold providers responsible for their own quality improvement. It is important to emphasize this because some advocates interpret any external pressure to hold providers accountable as counterproductive to internal quality improvement. It is doubtful, however, whether American companies would have embarked upon continuous quality improvement if their customers had not started buying Japanese products. There is an external stimulus in the free market—customer preference—and that stimulus has encouraged American industries to change their ways. In health care, since the end users, that is, patients, cannot fully judge the quality of the care they receive, the proposed new Medicare Quality Review Organizations are needed to fill that role.

Fifth, the IOM committee recommends that HCFA retain its role of preventing harm to patients from providers who are not maintaining acceptable standards of quality. The PRO evidence suggests that a relatively small number of physicians contribute disproportionately to problems in overuse, underuse, and poor technical quality. The Harvard Medical Practice Study suggests that the same is true for hospitals. Incompetent providers should receive special attention. The challenge for the federal government is for all its agencies that become involved with seriously substandard providers to cooperate with one another.

The evidence from the IOM report is clear: there is a need to "manage for quality" in the Medicare program. It justifies a major increase in effort in the next decade.

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# 14

# Confronting Special Implementation Issues: Legal Concerns

*Alice G. Gosfield*

The Institute of Medicine (IOM, 1990) study presents a 10-year strategy for revamping Medicare's approach to quality assurance. To address in the very limited space available the myriad legal concerns it raises would be impossible. Given the restrictions imposed by the forum, format, and space, I will address three specific themes: (1) using the law as a means to motivate provider behavior in conformity with quality assurance goals; (2) how "due process" figures in a quality assurance strategy, particularly as implicated by a continuous improvement model; and (3) legal issues surrounding the data-based components of a quality assurance strategy. Even having selected these three discrete issues, however, there is no question that the overarching legal concern for all players in the quality assurance arena is the issue of malpractice liability exposure, not only for those who seek to adhere to quality assurance guidelines, but also among those who participate in peer review.

## MALPRACTICE

Over the almost 20 years of my practice, to the extent it has addressed these issues as distinct from other health law concerns, I have worked with individual physicians, institutional providers, groups of physicians, and managed care entities across the country. I find that the single greatest source of anxiety for physicians—and therefore the primary barrier to aggressive, systematic, and pervasive quality assurance activities—arises from deeply ingrained fears of malpractice litigation.

A recent experience that I had in the heartland of America illustrates this phenomenon. I had just concluded a presentation on the Medicare Peer Review Organization (PRO) program in Indiana to a large medical staff. A

young urologist approached me after the presentation and sought my counsel on the following dilemma: "I'm trying to decide which of two groups to affiliate with when I finish my fellowship. One consists of two physicians. The other is a group of six physicians. Do you think, from a malpractice perspective, that I would be better protected joining the larger group or the smaller group?" I was stunned. Rather than quality-of-life issues or working environment concerns, a major decision point for this physician, despite presumed insurance protection, was exposure to malpractice liability. Here was a physician just starting out in practice, about to make an absolutely critical determination in terms of his professional life, based on something that as far as I am concerned should have been tangential to his primary focus.

I believe that one of the reasons that malpractice looms as such an incredible presence to physicians is in part the nature of the activities in which they engage. Given imperfect data, as well as highly detailed and technical training, in which the limits of knowledge are decidedly finite but the expectations of the patient and society frequently are not, the consequences of their actions are life and death—often literally. To perform in this environment, many physicians must learn to believe that they can control what is imperfect, accept the limits of their knowledge, and nevertheless act with supreme confidence. Their patients expect that confidence and rely on it.

Out of this constellation of factors, for reasons others are surely better equipped than I to elucidate, I observe that physicians as a group completely self-identify in terms of their professional roles. Asked to complete the following statement, "I am a good_____," the vast majority of physicians will instinctively respond, "I am a good doctor," and they will believe it. Given this complete self-identification with their profession and belief in their own competence, any question that is raised about how they have performed is received in a way that goes far beyond what those of us who work in the system would think is appropriate. I generally characterize this overreaction by saying that most practicing physicians would be happier to see an FBI agent standing on their front doorstep with a gun and a badge telling them they broke some rule unrelated to their professional practice than to get a letter from a PRO posing a routine question about a specific quality issue.

Within this frame of reference, medical technology, technique, and knowledge are improving. Societal expectations about performance are also increasing. Malpractice litigation crystallizes for physicians these inherent unresolved tensions and focuses on their own imperfections, with results that they perceive as personally threatening and singularly unfair. At the same time, health care policy development is at a moment in history of intense demands

for self-scrutiny and peer review, external regulation of health care performance, and quantification and measurement of behavior with consequences such as data consortia, severity indices, and increased reporting and interagency data exchange. The creation of a National Practitioner Data Bank and the increased liability of institutions and organizations for the actions of their independent medical staffs are producing more probing, investigatory credentialing procedures (Shields and O'Kelly, 1989; Smith, 1990).

In this developing environment, a malpractice lawsuit against a physician is no longer a private experience. Its consequences can be career threatening. Physicians confronting these issues frequently ask me why lawyers are apparently exempt from similar treatment. My answer is that society does not value the services of lawyers as highly as it does those of physicians. The very fact of the IOM study, congressional attention, and even publicly financed health care amply underscore this value.

In the context of proposing and developing an achievable quality assurance strategy, I raise this issue to focus on the need for a clearly articulated, credible policy effort devoted to this new and different malpractice crisis. Similarly, there must be an acknowledgment that physician acceptance of new initiatives and incentives may be hard won and realistically will need to be a long-term goal.

## LEGAL INCENTIVES TO PERFORMANCE

### Positive Inducements

Having elaborated these major concerns, I remain convinced that in any quality assurance strategy, significant energy needs to be devoted to the carrots that might be available in the system rather than to the sticks. Positive inducements can take a variety of forms in law. Federal law currently provides a malpractice exemption in the PRO program. It comes directly out of the Professional Standards Review Organization law, and provides that no practitioner and no provider can be held civilly liable on account of any action taken by him in compliance with, or reliance upon, PRO norms, criteria, and standards, provided that he or the institution exercises due care (Gosfield, 1975, 1989a). Contractually reduced malpractice premiums for those who participate in quality assurance on a good faith basis—in the same way that continuing medical education credits are applied in the medical licensure environment—is another inducement. Using focused review for those who really need attention can be incorporated into the law, thereby lightening the burdens of review on those who are performing appropriately.

The use of accreditation might also be an area to be explored as a posi

tive incentive. Some courts have taken judicial notice of the Joint Commission's[1] standards as the standard of care for hospitals. Judicial notice is an approach to evidence in which the court on its own initiative takes as proven a fact that is so incontrovertible it can be accepted into evidence as true without the necessity for any arguments about its probative value. Although other courts have not been so persuaded by the Joint Commission's standards, the concept merits some evaluation. In the managed care environment, we currently see much more competition among accrediting organizations, and no single group's standards are likely to be acknowledged soon for judicial notice.

In contrast with my hopes for a strategy of positive inducement reflected in law, I tend to be very cynical about the prospects for dealing with this issue through tort reform. Combating defensive medicine through tort reform will take on vested interests whose power goes well beyond the ability of those concerned about health care quality assurance to be able to mount an appropriate and successful campaign. A strategy with more laserlike precision will be based in regulation and contracts using techniques such as malpractice exemption.

The absence of case law to date construing the PRO malpractice exemption ought not be seen as a strategic failure. Rather, one of the reasons the exemption has not been used is that most lawyers who engage in personal injury defense work have no knowledge of the Social Security Act in which the exemption appears. In developing a national quality assurance strategy expressed through the law, the failure of the personal injury bar to focus on these efforts may be an advantage. Policy can then develop without the spotlight focused on generalized tort reform and the inevitable, convulsive debate that the subject engenders.

To achieve the goals of a major new quality assurance strategy, policy must also confront one of the major complaints of practicing physicians in dealing with quality assurance systems and utilization management controls: the "paper chase" aspect of it all. Formalistic, nonvalidated, externally imposed, detailed requirements in the law will be met with cynicism and resistance. Physicians decry policymakers' lack of real-life understanding of what physicians have to deal with in the trenches, making imperfect decisions based on imperfect information, with not enough time to do everything demanded of them.

If the policy value on quality assurance and peer review is sufficient to merit the kind of attention we are devoting to it in this forum, then perhaps we should look at approaches requiring that practicing physicians participate in these activities—in much the same way some would impose on lawyers

[1] Joint Commission on Accreditation of Healthcare Organizations.

a requirement to do pro bono work as a condition of their continued licensure as attorneys. To my knowledge, at this point we do not know whether broad-based participation would improve the quality of the review process or its outcomes. Yet, motivating broad-based participation might be an effective approach to the frequently asserted, yet rarely supported, position of some subjects of these processes that they are implemented by physicians who are out of touch, out of practice, or unaccountable to those who are the objects of their actions—whether patients or other physicians.

## Protection for Peer Review

In confronting legal concerns in quality assurance by those who do accept their mandate to participate, another issue concerns the obligations and liabilities of those who participate not only in formal government sanctioned peer review but in self-regulation mechanisms as well, when they find egregious problems the review mechanism is not designed to address. When one of these quality failures is discovered, are the reviewers supposed to report this to someone? To whom are they supposed to report their findings? What will happen to them if they do make such a report?

Today, in my law practice, in the few instances in which well-motivated reviewers have raised these concerns with me, I have had very little I can give them by way of guidance. I am loath to recommend that they bring their concerns to a licensure board. I am not sure I think that is appropriate, given the level of evidence they may have at the point at which their concerns are raised. The risks to the reported physician in the current environment are substantial. Balancing these concerns is difficult and essentially unaddressed in current law. Appropriate interventions and sanctions frequently are not available.

## Interventions and Sanctions

The IOM report offers a remarkable compilation of a plethora of material dealing with relatively obvious ways of confronting quality assurance concerns to date. The study addresses the range of regulatory efforts that exist and some self-regulatory approaches. One area that has not been addressed, however (because it is rarely discussed in this frame of reference), is other laws that Congress enacts for other purposes that relate directly to quality assurance concerns. In particular, I am talking about fraud and abuse laws.

Many civil money penalties are based on efforts to assure administrative control. Examples include a provision that a failure to put ICD-9-CM[2]

codes on a claim form may result in a $2,000 civil money penalty to the physician for each such instance. A physician who fails to issue to the patient undergoing elective surgery that entails a fee of more than $500, a written disclosure statement providing the anticipated charge, the Medicare allowance, and the deductible and co-insurance, incurs potentially a $2,000 civil money penalty. Although these two examples may not appear to have much to do with quality, other provisions in the law state that if a physician renders services to patients substantially in excess of the patients' needs, or not in accord with professionally recognized standards of quality, or provides information to a patient that might lead to a premature discharge, that physician may be excluded from the Medicare program (Teplitzky et al., 1989).

Legitimate efforts at quality impacts are lost in a sea of detail and requirements that reduce these ministerial and major policy concerns to the same plane for physicians. At the same time, physicians are acutely aware of significantly increased enforcement in this area. The proposed regulations issued by the Inspector General of the Department of Health and Human Services on April 2, 1990 are a remarkable policy statement about the perceptions and approaches of government enforcers regarding fraud and abuse by health care practitioners and providers. These regulations address exclusionary activities by the Inspector General based on new authorities under the Medicare and Medicaid Patient and Protection Act of 1987. Some exclusions are mandatory under the law based on a criminal conviction elsewhere. Some exclusions are "permissive" and may be overcome by the potentially excluded party providing a sufficient basis to reject exclusion. Still further exclusions are referred to as "derivative permissive exclusions."

The current regulatory environment in which all health care providers, whether institutions, practitioners, or suppliers, must operate is replete with these punitive rules, and all believe that they are at risk. If you examine the bases for these actions closely, you see that they are frequently based on quality concerns, but rarely do they provide any standards at all to inform those affected by the rules what the rules are. This approach creates substantial uncertainty and in the long run undermines the ability of providers to respond to other more well-intentioned activities aimed at improved quality performance.

## DUE PROCESS

Within the legal environment of sanctions and interventions is the issue of due process. Many people complain about how long it takes and how difficult it is to impose penalties or other corrective action for poor quality performance. My standard retort to this complaint is, "Where you stand depends on where you sit." When I work with physicians who are on

[2] International Classification of Diseases, ninth revision, clinical modification.

hospital medical staff committees, trying to implement good quality assurance programs and corrective action, their primary question to me is, "We all know where the problem is, why do we have to go through all this clue process?" In contrast, however, whenever a question is raised about an individual physician's behavior, the first thing he asks me is, "Where is my due process?"

I believe that in the context of the legal issues raised by a quality assurance strategy, we need to devote more attention to the role of clue process in all of these systems. I have recently begun to describe due process to physicians as the lawyer's version of the scientific method. When someone comes forward with evidence, there must be some kind of testing and validation of that evidence in order for it to be viewed as credible. Nonlawyers frequently forget that under the constitution, "due process" is that process which is clue. It is not a uniform standard of behavior. It varies in terms of what is due, depending on the nature of the judgment at issue. Due process tries, in the crucible of cross-examination, expert testimony, questioning, and struggling to identify the truth, to produce an ultimate reality that can be supported. This procedure takes time in the same way that the scientific method and double-blind studies take time.

Within the context of a quality assurance strategy, a significant amount of attention ought to be devoted to the current socialization of physicians, which cuts at cross-purposes with the legal environment within which they operate. Physicians—and peer reviewers—are socialized to the consensual intellectual considerations of grand rounds. This is not a good model for due process. Physicians are uncomfortable with adversarial process. Peer reviewers need training about how to develop and present evidence supporting findings of poor quality. Early PRO efforts at sanctions were frequently rejected by the Inspector General for these and other technical and procedural failures.

Another variable in the character of a sanction hearing or discussion at the PRO level is the type of attorney representing the PRO. A corporate attorney advising a PRO will run one kind of meeting. A technical health lawyer, to the extent we exist as a breed, will take a different approach. Still further, a personal injury defense lawyer will create a different environment. These issues have not been addressed in terms of evaluating what types of procedures the law will impose. The guidance given a group of physicians trying to exercise control over their peers will influence the nature of the process that emerges and therefore will also influence the outcome of that process.

Arbitration techniques, contractual approaches, and intermediate interventions are examples of more creative uses of the legal system. Some energy from the legal community in this direction would probably advance the state of the art if not ameliorate the fundamental mistrust of the legal

system and lawyers, which is the outcome of the new malpractice crisis addressed above.

### Shifting Standards of Behavior

As part of the issue of due process, it must be stated that the continuous improvement model proposed in the IOM study is one that necessarily entails, as part of its conceptual underpinnings, the notion that standards for performance will constantly shift. Once identified outlier problems have been solved, new outliers will be identified as we continuously improve the environment. This will create an inherent uncertainty in the system.

If a continuous improvement model is adopted, there will always be physicians who complain that the rules are in flux, the standards always shifting, and measures of proper performance unclear. This tension is acceptable provided it is clearly understood by all players. The continuous improvement model will have legal consequences: there will forever be a temporal parallax in the system, because the standard of performance at the time the care was rendered will not necessarily be the standard that has most recently been articulated or the standard applied at the time the behavior is judged.

## DATA PROTECTION AND RELEASE

Another significant legal concern arising from the quality assurance strategy proposed in the IOM study emanates from the tensions between the protection of and the availability of data pertaining to performance. All of the quality assurance methodologies addressed in the study—whether pre-admission or concurrent, whether focused on quality assurance or utilization management—are data driven. Data—whether profiles of provider behavior, outcome statistics, quantitative definitions of outliers, or even just the medical record—are at the core of all quality assurance and utilization management activities. The necessity for accurate data on which to base judgments is so critical in the PRO system that federal law provides an explicit legal obligation for proper documentation by providers and practitioners. Failure to conform to this obligation can result in fines or even exclusion from Medicare. At the same time, the law, both state and federal, protects the confidentiality of patient-identified data.

On the other hand, laws protecting the confidentiality of data considered and produced by review processes and reviewers have not evolved as rapidly as the proliferating systems and requirements to conduct review. Most of the peer review protection laws in existence today were enacted in the mid-1970s during the last malpractice crisis. They tend to be hospital-focused and sometimes extend to insurance claims review, but they reflect the quality

assurance and utilization management world as it existed 15 years ago. Many of these laws are ill equipped to deal with the scope of activities in existence today (McCann, 1989), let alone as contemplated over the 10-year strategy in the IOM study.

Many HMOs today permit fundamental decisions regarding quality, medical necessity, and coverage of services to be made by a single individual functioning as the medical director. Some case law has found that judgments made by an individual as distinct from a committee do not obtain the confidentiality protections of the law. Some case law has said that an infection control committee is not a peer review committee under state law.

To address the legal concerns in implementing a comprehensive quality assurance strategy, attention needs to be devoted to these problem areas as well. With regard to a continuous improvement model, many practitioners and providers are vitally concerned about the conclusions that can be drawn from the data necessary to the conduct of such a quality assurance program. Some will argue that the continuous improvement model inherently creates the ammunition that will feed the malpractice fire. Even the Joint Commission's required quality assurance monitors have been critized by some on the same basis: the point of the Joint Commission's requirements is that an institution must be unearthing and documenting problems. The failure to identify problems in and of itself will result in a Joint Commission deficiency because the requirement assumes that every institution can be better (Gosfield, 1987).

The early motivation of peer review protection acts, to encourage and foster aggressive self-criticism, has by no means diminished. If anything, the pressure for these activities has increased. The law should be addressed to keep pace with these requirements.

Although this need for protection is essential to foster careful review, it exists in the middle of a trend toward vastly increased access to previously protected information. The government's continuing release of hospital morbidity and mortality data, as well as nursing home data, and the appropriateness and effectiveness initiative (Gosfield, 1989b) are responses to society's firm acceptance of the public's right to know.

Yet these tensions have not been well examined to date. A good recent example is the proposed PRO substandard quality denial notice. Since 1986, federal law has provided for Medicare payment denial for poor quality. When proposed regulations were issued they provided for notice to the patient of the basis for the denial—poor quality—before any appeal rights had been exercised. Significant fears regarding malpractice exposure from the notice were expressed by the provider community. To date no final regulations have been issued, but in 1989 Congress passed an amendment to specify what language must be included in the notice. Reference was made to care not being "acceptable" rather than to care of poor quality. Although the new language was intended to remove some of the sting from

the notice, consternation continues regarding the implications of the statement in an individual case. Many practitioners and providers believe that the procedures that produce the substandard determination are themselves vulnerable to significant criticism. Similarly, the quality intervention plan imposed by the federal government through the PRO Third Scope of Work mandates that when a PRO identifies a quality problem of sufficient severity to garner a score of 25, the PRO must consider reporting the findings to the appropriate licensure boards. Yet, at that point there will have been no external validation or objective review of the underlying judgments prior to reporting the finding (Gosfield, 1989b).

## CONCLUSIONS

From the multiplicity of legal concerns raised by a comprehensive quality assurance strategy, I have selected those that might not be obvious. Other concerns abound; they range from highly technical legal concerns such as enforcement problems in utilizing a "deeming" mechanism in the Medicare program based upon Joint Commission accreditation, to issues of the implications of antitrust exposure in quality assurance activities based on a peer-conducted approach. As the programmatic requirements for quality assurance are refined and expressed in the law, the law can either impede or advance more rapid progression toward a better system. To ignore these issues can only retard the ultimate goal of improvement.

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# 15

# Confronting Special Implementation Issues: Translating the Institute of Medicine Report Strategy Beyond Medicare

*James S. Roberts*

My responsibility is to discuss the translation and deployment of the ideas contained in the Institute of Medicine (IOM, 1990) report beyond the Medicare program. To do so I need to start by noting what I think the report says: the major themes, the directions it would take us, and the objectives it establishes for the next step in the evolution of approaches to improving the quality of care in this country. Although I will not comment on the suggested restructuring of the Peer Review Organization (PRO) program, I will say that it is nice to see "MQROs" back.[1] Much of what we were trying to do early in the 1970s with the EMCRO program is reflected in this report. I hope that this version will make it further down the road than our earlier model did.

The proposed restructuring of the PRO program represents the IOM committee's suggestion for implementation of its ideas within the context of the Medicare program. My charge is a different one. When one goes beyond the Medicare program, the evidence is clear that other payment programs will use a variety of means to address the ideas contained in the report. PROs will not be the vehicle that will be used uniformly.

## MAJOR THEMES OF THE INSTITUTE OF MEDICINE REPORT

So my task is to concentrate on pursuit of the themes of the report—not on the organizational form in which the pursuit will occur. Let me start by

[1] Editors' Note: The reference is to the proposed Medicare Quality Review Organizations, or MQROs, in the IOM report. The acronym harkens back to the Experimental Medical Care Review Organization, or EMCRO, program of the early 1970s.

discussing the report's basic themes. Understanding these themes will help us grasp the deployment challenge.

### Antecedent Processes and the Outputs of Health Care

The overarching theme of this report is a bit hidden. Although the point is not brought together in one place, the report strongly emphasize that the outputs of health care are the combined results of several important antecedent processes. Thus, outputs for a population of patients, or for an episode of care, are dictated not just by clinical care but by a much more complex interplay of practitioner, patient, and organizational factors and by a variety of forces external to the organization.

Figure 15.1 depicts this reality. In the quality improvement world, this is called a "cause and effect" or "fish-bone" diagram. It is used to understand the many causes of a measured effect. Using any measure of output one wishes to explore—a patient outcome, a change in functional status or psychological status, mortality rates, morbidity rates, a measure of value (cost and quality)—at the head of the fish-bone diagram, one can easily identify the many potential determinants of these outcomes.

As the Joint Commission on Accreditation of Healthcare Organizations (Joint Commission) and health care organizations have worked with this tool it has become clear (as noted in Figure 15.1) that the activities of practitioners, governing boards, and managerial and support staff all have a potentially powerful influence on patient outcomes.

At the interface between these internal influences and the external world is the manner in which the results of clinical research are synthesized and disseminated to health care practitioners and then used to influence day-to-day practice. Here we are talking about the work of the research community in conducting and reporting clinical and health services research; the professional associations in their work efforts to develop and disseminate useful practice guidelines; and the educational community in its use of continuing education mechanisms. All have a critical, though often unmeasured, impact on quality. "Health policy" (Figure 15.1) is broadly construed to include such matters as the availability of insurance coverage and the structure of insurance plans, the imposition of nonproductive standards by accreditors and by government, the level of resources made available to health care organizations, the use of price-based selective contracting, the stimulation of aggressive competition within local markets, and professional liability law and practice. All have a potentially powerful effect on the outputs of the system. So government, accrediting organizations, unions, insurers, and purchasers of care all influence outcomes.

Before leaving my discussion of this overall theme, let me return to the health care organization. Most believe, or at least most act as though, the

exclusive determinant of quality is the physician. It is as if mortality rates and complications are caused solely by the presence of (or lack of) physician knowledge and skill. Such is not the case. Outcomes are also determined by nursing care, by the work of other practitioners, and by the ability of practitioners to work together in teams. The quality of support services has been seen principally as an issue of safety and quality control of test results. Largely ignored are the important interactions that should go on between practitioners and support services staff concerning the specific nature of the patient's problems and the precise type of service that best meets those needs. For the most part, quality evaluations have ignored the important roles that boards and the management of health care organizations play in the ability of the organization to produce desired outputs.

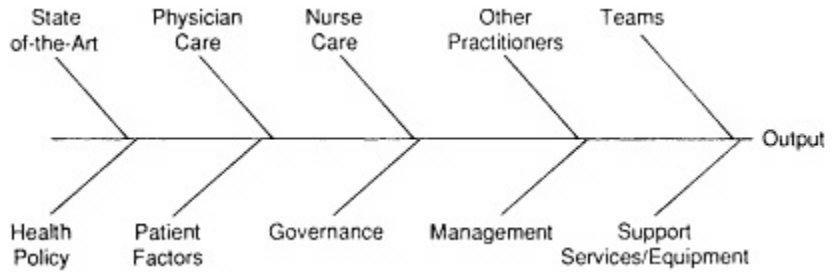


Figure15.1
A "fish-bone" diagram of potential determinants of organizational outputs as they relate to quality improvement.

The message in this conceptualization is that we are all in this quality business together. We have, in fact, a shared responsibility and accountability for the quality of care. So rather than painting the quality scene as one in which external organizations tell hospitals and doctors what they have to do, and rather than these same outside agencies demanding a variety of data from health care organizations or from doctors and then making judgments about performance, the notion here is that we are all part of the problem and, thus, must all be part of its solution.

The production of appropriate, efficient, and effective health care must become the combined effort of everyone represented in Figure 15.1. It is both a shared responsibility and a shared accountability. All of us—accreditors, government, insurers, businesses, patients, practitioners, and health care managers—must understand that we are accountable for what we do. If the outputs of health care are not at a level that is desired, the cause is unlikely to be confined to inadequate hands-on care; it may also be poorly designed health care plans, ill-conceived standards of care, misguided management, or the poor or inadequate use of practice guidelines.

By focusing on factors beyond the practitioner, I do not mean to excuse

poor care. Government and accreditors should have tough requirements and should apply them well. They must, however, be grounded in the best available information and must facilitate good care. Nor am I saying that corporations should not design their health benefits plans in a businesslike fashion. They have to; that is a fact of life. What I am saying is that the decisions these outside agencies make must reflect careful attention to their potential impact on patient outcomes—the effect that these decisions have on the level of performance of the health care system. That, it seems to me, is the overarching theme of this report.

## Seven Derivative Themes

In addition, several other themes are largely derivative of the first. They are summarized in Table 15.1.

The first is the absolute need to rekindle professional instincts for constant improvement. Here I do not confine myself to physicians. The same imperative exists for nurses, other health care practitioners, and managers of health care organizations. Quality assurance, as currently performed, simply does not make sense to most people involved in the day-to-day delivery of health care. It has deadened the natural interest in and inclination toward constant learning and fact-based improvement in performance.

The second is that we need to focus review activities on quality. Much attention was given to this point during the conference on which this monograph is based. I simply echo the point and emphasize the importance of focusing on the use of outcome measures as windows into weaknesses in the design and performance of key processes.

Third, as we address quality we must recognize the importance of continuity of care—the coordination of care among practitioners and departments within organizations and across organizational boundaries within a geographic community—and of educating the patient and his/her family and of their engagement in clinical decisionmaking.

TABLE 15.1 Key Themes of the Institute of Medicine Report

- Rekindle the professional instincts for constant improvement
- Focus review activities on quality
- Recognize the importance of continuity and of patient and family involvement
- Address the critical, if currently hazy, link between processes and outcomes
- Build a better substrate for evaluation and improvement
- Foster improvement in internal quality assurance and quality improvement
- Enhance coordination and communication among external organizations

The fourth theme is the need to address the critical but oftentimes hazy link between processes and outcomes of care. If you think about the various "bones" of the fish-bone diagram, you should see that each represents a series of processes. We need to understand how those processes are linked to desired (or undesired) outcomes. The IOM report suggests that they be addressed both at a national level, through better and more targeted research and the development of practice guidelines, and within health care organizations. As Caldwell (1991) discusses the latter point, each organization should understand how its performance of key processes influences the outcomes achieved by the patients it serves.

Fifth, I would add that there must be a better understanding of the regulatory, accrediting, and insurance processes as they play through to patient outcomes, partly through a better foundation for evaluation and improvement. Often ignored, these evaluative processes can either stimulate or obstruct the provision of appropriate, effective patient care. The organizations involved in such activities must do much more to align their objectives and requirements with those of well-intentioned health care organizations. They must also do more to bring order to the current cacophony of demands they make on health care organizations.

Sixth, we must foster substantial enhancement in internal quality assurance and quality improvement mechanisms. Any external organization that does not have this as one of its principal priorities is abdicating its responsibilities. Such organizations are part of the problem, not part of the solution. Seventh, there must be better coordination and communication among the many external organizations. Those who demand things of health care organizations have an obligation to get their own act together among themselves.

These, then, are the themes of the IOM report. Now I want to talk about how to take those good ideas and make them real. I will do so by focusing first on the health care organization and what it needs if these suggested changes are going to become operational.

## NEEDS OF HEALTH CARE ORGANIZATIONS

The needs of health care organizations fall into the categories shown in Table 15.2. First they need models for the creation of positive, improvement-oriented internal cultures. There is a lot of talk about the need to change the way we think about quality in health care. The most compelling theme is the need to create a more improvement-oriented culture. Yet it is not clear how one makes the transition from the current punitive atmosphere to a much more positive one. Expressing the need for such a change does not necessarily turn on the light bulb. How do you get a fast moving train onto a different track? We need some models for this switch and, fortunately, some are being constructed. They are developing very organically day after

day within a growing number of enlightened health care organizations. We need to learn from the experience of these leaders.

TABLE 15.2 Needs of Health Care Organizations

- Models for the creation of a positive, improvement-oriented internal culture
- Synthesized state-of-the-art information and models for, or indicators of, their use
- Practical models for process description, measurement, and improvement
- Public policy that more clearly differentiates "tail-of-the-curve" practice from the more universal need for continual improvement
- Coherent and coordinated external expectations and improvement-focused use of information

Health care organizations also need well-synthesized state-of-the-art information and, most importantly, guidance on how to translate it into day-to-day practice. Whether one calls such information "practice guidelines," "clinical parameters," "branching logic trees" (or "thickets" as one conference participant put it), there is a lot of it around. Although we certainly need such material, the most critical obstacle is the lack of a practical understanding of how to use it. How do we translate information contained in practice guidelines into improved patient care? How do we use continuing education programs and quality improvement programs to assure the effective incorporation of such information?

A key part of the strategy must be well-conceived indicators that tell whether such material is being used and used well. The objective is not a punitive one. Rather we must measure whether guidelines are being used, and if not, why not? Are they unclear, incomplete, irrelevant? Are there weaknesses in implementation strategies?

An additional need is for practical models for process description and improvement. If, as noted earlier, process knowledge is the key to improved outcomes, we must give organizations models for describing their performance of these key processes. How do you take the flow of medication use or the care of the trauma patient across departments and professional groups and describe it for yourself, for your organization? What measures do you use to judge whether these processes are effective? How do you use outcome measurement as a window into process improvement? Organizations know they have problems; they have reams of data that tell them that they are weak, but they literally do not know what to do next.

Health care organizations also need public policy that clearly differentiates tail-of-the-curve practice from the more universal need for continual improvement. As I noted earlier, health care organizations deserve coherent and coordinated external requirements and improvement-oriented use of

information—not more information to do more sanctioning, but better information to prompt improvement.

## STRATEGIES FOR DIFFUSION

### Gain Acceptance of Shared Responsibility

Beyond meeting these needs of health care organizations, what strategies must be followed if the themes of the IOM report are to have their maximum impact? I believe three strategies must be pursued. The first (Table 15.3) is to gain understanding and acceptance of the notion of shared responsibility and shared accountability discussed earlier. Imagine, for example, collaborative efforts that focus on a key output, by using the mechanism of placing that output on the far end of a fish-bone diagram and then engaging in a collective examination of the various roles that the actors on the branches of that diagram play in either fostering high levels of performance or obstructing high levels of performance.

Might such an exercise (possibly in the context of a community-based examination of its health care system) improve the manner in which we deal with each other and modify the current finger-pointing nature of such efforts?

Might it also be instructive to take this approach with current population-based research studies? Consider, for example, large-scale data base studies with shared responsibility as the paradigm. That is essentially the route, it seems to me, that John Wennberg and his colleagues are taking with their prostatectomy studies. It is the concept that underlies the comparisons of the New Haven and Boston health care systems. These studies raise important questions about how these communities operate their health care systems.

Should we convene some conferences that have "shared responsibility and accountability" as the theme and explore the practical ramifications? How would the new mindset change the data demands that accreditors, that government, and that businesses are expecting of health care organizations? What would it do to quality assurance requirements? How would insurance coverage determinations change? The practical ramifications of this idea

TABLE 15.3 Gain Acceptance of Shared Responsibility

| |
|---|
| • Case studies of the determinants of patient outcomes |
| • Reanalysis of population-based studies using shared responsibility as the paradigm |
| • Conferences that posit this theme and explore its practical ramifications |
| • Identification and celebration of models |

might be played out profitably in a conference or two. Finally, we need to identify and celebrate models. There are models—in Kingsport, Tennessee, for instance, and Rochester, New York. These experiements and models ought to be held up for praise and evaluation.

### Remove Major Barriers

The second strategy (Table 15.4) is the removal of barriers. Without going too far, we need to temper expectations for constant perfection or the assurance of quality. What we are talking about here is quality "improvement" not quality "assurance"; some say we are talking about "value" improvement. Maybe the common ground—the shared interest of all major actors—is continual improvement in the value of health care, the value we get for the money we invest. We need to refocus leadership attention on fostering constant enhancement in value.

We need to increase and refocus health services and clinical research and development (R&D). This is a fundamental recommendation in the IOM report, although it does not emphasize sufficiently the need to devote much of this R&D to the *practical* needs noted in Table 15.2. It would be instructive to compare this list with the research agendas of the Agency for Health Care Policy and Research, the Joint Commission, and individual health services research centers to examine how well they match. Does this research answer these needs? If, as I suspect, the match is inadequate, we must reorder our research priorities in the context of the real-world needs of those who have to take the IOM themes and operationalize them.

Next, barriers that are created by aggressive competition need to be identified. I am not against competition, but I can tell you that many health care professionals are distressed by its effect on their ability to share experiences and to learn from each other. Before the recent push for significant competition within local markets, many important community-based professional

TABLE 15.4 Remove Major Barriersa

- Temper expectations for perfection or assurance of quality. QI is not QA, or is it VI?
- Refocus organizations to QI and their leaders to fostering quality and value
- Increase R&D and focus it on practical needs. Assure wide dissemination of resulting models
- Identify the barriers created by aggressive competition and remove them
- Shrink the sanctions net and expand the search for improvement opportunities

[a] QI is quality improvement; QA is quality assurance; and VI is value improvement; R&D refers broadly to research and development.

networks existed. The engineers, the quality assurance people, the chief executive officers, the medical staff leaders, the nursing directors, and others would get together in informal ways and share experiences, exchange ideas, celebrate successes, and discuss common problems. Now these colleagues are seen as enemies. They are literally afraid to meet with each other and to share these ideas with the "bad guys." There is a chill on basic information sharing, and I think that is unfortunate.

Finally, we need to shrink the sanctions net. We catch lots of dolphins in this net; it needs to be narrowed. At the same time, we need to expand the search for improvement opportunities.

### Develop and Disseminate Models

The third strategy is shown in Table 15.5: the development and dissemination of models. Health care organizations are starving for good models, particularly those that have undergone real-world testing. We do not need theoretical models; we need operational models. Important activities are under way at national, regional, and local levels and within individual health care organizations. It would be helpful to have a resource center that systematically gathered these models and disseminated them. We must hear about both the successes and the failures. Nobody likes to talk about his or her failures, but they are very instructive, maybe more useful than the success stories. Most of these stories will not appear in refereed journals as they now operate. New sections of such publications should be created, and educational conferences focused on real-world needs would be helpful.

TABLE 15.5 Develop and Disseminate Models

- Health care organizations are starving for models
- The need is for approaches that have received real-world testing
- There are activities under way in all areas of necessary change
- Both successes and failures must be made known
- This is not always the material sought by refereed journals

### Enhancing Coordination

Finally, it is important that we enhance coordination among external actors, such as government agencies, PROs, accreditors, insurers, and the long list of other folks that are external to health care organizations (Table 15.6). One way to make that happen is for everybody to create it as an expectation. All of us listen to the constant expectations of those we affect—or we should. An area the Joint Commission is beginning to explore

involves the extent and implications of fragmented, external requirements. Hospitals now have 10, 20, 30, even 50 requests for a significant volume of data concerning various segments of their patient population. What is the cost of answering these demands? If data are defined differently, how much waste does this create? We need to improve on existing forms of coordination among external agencies, and new forms need to be created.

TABLE 15.6 Enhance Coordination Among External Agencies

- Keep expressing this as an expectation
- Provide practical information on the implications of fragmentation
- Identify and strengthen current models
- Use existing forums to foster coordination
- Identify statutory, philosophical, and other barriers and remove them
- Drop stereotypes and destroy pigeonholes

The Institute of Medicine, the Joint Commission, business groups, and government each have forms that they could use to talk about these IOM themes and their implementation. We need to identify statutory and other barriers to rational action. I would particularly comment on the first recommendation of the IOM report.[2] I am concerned about statutorily giving to any one group in this system the "responsibility" for quality. It cuts against the basic notion of shared responsibility—that particular recommendation ought to be considered carefully.

## CLOSING REMARKS

Let me close by saying that if quality is to be enhanced, we must drop stereotypes and destroy all these pigeonholes into which we tend to put each other. This field is awash with stereotypes. Doctors are put here; hospitals are put there; governments are put in that pigeonhole; accreditors are put in yet another one. These stereotypes chill innovation and make coordination difficult. If government and professional leaders are prevented by these destructive stereotypes from exploring more rational, integrative,

[2] Editors' Note: The reference is to the opening recommendation of the IOM committee, which states: Congress should expand the mission of Medicare to include an explicit responsibility for assuring the quality of care for Medicare enrollees, where quality of care is defined as the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.

innovative approaches to quality, then we all lose, and the good ideas contained in the Institute of Medicine report simply will not be realized.

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# PART VIII

# New Directions: The Research, Training, and Capacity Building Agendas

# New Directions: The Research, Training, and Capacity Building Agendas

## INTRODUCTION

*Edward B. Perrin*

The Institute of Medicine (IOM) committee report includes two recommendations that are aimed at increasing and broadening support for the research and training activities necessary for achieving the objectives of the quality assessment and assurance program outlined by the committee. One (Recommendation No. 8) suggests that Congress should direct the Secretary of the Department of Health and Human Services (DHHS) to support, expand, and improve research in the effectiveness and outcome of care and to support a systematic effort to develop clinical practice guidelines and standards of care. The other (Recommendation No. 9) recommends that Congress direct the Secretary of DHHS to establish and fund educational activities designed to enhance the nation's capacity to improve the quality of care. In the papers that follow, we consider more closely the nature of the research, training, and capacity building agendas needed to support the quality assurance program under Medicare.

Harold Luft, professor of economics at the University of California, San Francisco and its Institute for Health Policy Studies, first presents the IOM committee's views about the need for movement in these areas and the directions that such movement might take. Sheldon Greenfield, Senior Scientist, The New England Medical Center, and Edward W. Hook, Physician-in-Chief, University of Virginia Hospital, then offer their outside observations and responses to, respectively, the issues of research and capacity building.

# 16

# Research and Capacity Building: Issues Raised by the Institute of Medicine Report

*Harold S. Luft*

The chapter on research, training, and capacity building in the Institute of Medicine (IOM, 1990) report outlines in substantial detail the research agenda and questions concerning capacity building, so I will take this opportunity to give my perspective of the rationale behind these recommendations. My view is that this is not just the usual researchers' tag line at the end of the paper that reads "and more research is needed." From my perspective, it really arises from frank fear and terror concerning the implications of our larger agenda and the problems facing the national implementation of a quality assurance program.

The fear and terror arise from the gap between "policy-relevant research" and something ready for routine implementation. Research always needs to narrow the focus, to select the cases, to look at the underlying signal, and not to get confused by random, extraneous noise. We were reminded during the conference that in the data base on patients undergoing cardiac catheterization, only 6 to 12 percent would have met the criteria for inclusion in the usual randomized controlled trials. Researchers need to focus on homogeneous populations to evaluate in a reasonable fashion, with constrained research dollars, the effectiveness of a new treatment or approach. Narrowing the focus increases the ratio of "signal to noise." That is the research role.

Practitioners, however, are faced with large amounts of noise and a little bit of signal underneath. They cannot say, "Well I won't treat you because you are not in the 6 percent that meets the criteria of a controlled trial." They have to treat the whole population.

In an analogous sense, much of what has informed the IOM committee in its efforts to come up with suggestions for changing the way quality assessment and quality assurance are done, is based upon research results. However, we always remember deep in our guts—I would not say our hearts neces

sarily—that such research results are usually based on those carefully designed studies of relatively homogeneous populations in one or two settings. The question of generalizability, validity, reliability, and applicability to the real world of 5,000 or 6,000 hospitals, 400,000 physicians, and several million nurses and other health care practitioners has not been tested. It is a little bit scary to think about implementing a proposal based upon such a "thin" body of research.

In fact, if someone gave me a magic wand and offered me a choice—take your chances with the Congress and a 10-year agenda and maybe have the strategy go through (or maybe not), or wave the magic wand and have the whole program implemented tomorrow—I would take my chances with the Congress because I am not sure it would work as we outlined it. The committee was not sure it would work; that is why we identified a 10-year agenda with substantial vagueness and many unanswered open questions. In essence we were saying that we do not know the specifics, and it is going to take at least 10 years to get from here to a point where we might have something ready for "prime time."

## VARIABILITY

To get ready for prime time we need to look at tasks that might be usefully categorized under the headings of basic research, applied research, and dissemination. Then we can move to capacity building. The conference discussions often turned to variations—everybody knows that there is wide variability in how certain kinds of procedures and techniques are applied; what we do not yet know is what accounts for that variability.

Do the variations reflect uncertainty, in other words, a lack of science? Put another way, God has not told us that one of these two techniques really works better. Do the variations reflect unmeasured clinical factors? Even when you include only 6 percent of a population in a randomized trial, unmeasured clinical variables account for differences in outcomes. That is, is one technique truly better than the other when appropriately applied for the right criteria and conditions, but we do not yet know what those conditions are? That would appear to be random noise, looking as though it is sometimes better, sometimes worse. Do variations reflect patient preferences, or do they reflect variable competencies of providers? Finally, some patients really like one approach rather than another, as Albert Mulley (1991) pointed out.

Most of the things we are looking at are not single shots of penicillin produced under a very tightly controlled manufacturing process. Instead, they are interventions applied by people in organizations with varying levels of quality. Most of them would be considered reasonably good, but some

are better than others. If so, you would naturally expect different kinds of outcomes.

In fact, variations in outcomes are probably not due to any *one* of those four factors reflected in the above; rather, variations are most likely due to some combination of those four things, and we need to determine their relative importance. Furthermore, the relative importance of the several explanations probably depends on the setting, the intervention, and other circumstances. That is a lot of research when you consider the number of different procedures and the number of different medical conditions to which they can be applied. The answer for one problem is not going to be the same as the answer for another in terms of the relative importance of scientific uncertainty, patient variability, patient preferences, and provider quality. We know that there may be different relative weights, but we do not know what the weights are.

## PROCESS MEASURES

There is a long history of using process-of-care measures as the yardstick for quality measurement. We certainly need to look at technical aspects of quality—whether the procedure was done appropriately—but that requires explicit criteria. How do we develop clear, valid, reliable, flexible, and clinically adaptable standards? Sheldon Greenfield has done a lot of work on criteria mapping, narrowing down the problem by using branching logic to give us a better handle on aspects of good quality care. The question is, now that we know it can be done for certain things, what proportion of all patients can be criteria-mapped into a category such as "yes, this is good"; or "no, it is not"? It is one thing to know that it can be done. It is another thing to go into a Medicare Peer Review Organization (PRO) and say, "Okay, here's the list; apply it to all the patients."

## ART OF CARE

The art of care is extremely important, and it is not just warm, fuzzy stuff—I know; I am from California. There is good evidence for the placebo effect, that is, that patients react to sugar pills as well as to real medicine. There is also anger and frustration with a medical care delivery system, even a system that is just not delivering the food warm enough, that may have an impact on the patient's biological outcome. This is not just patient satisfaction, but we are uncertain how to measure it. I suspect patient satisfaction directly affects patient outcomes, as well as being a separate measure that patients talk about.

## OUTCOMES

### Severity Adjustment

If we are going to look at outcomes, we need to have severity adjusters. Here is a substantial policy problem. As you start looking at outcome measures, anybody who ends up on the wrong end of the quality assessment measure says, "Well, you didn't appropriately adjust for severity. Of course, every case is different." At some point we may have sufficiently accurate severity adjusters to satisfy everyone, but I doubt it.

We have to recognize that severity adjustment is not just a problem for former econometricians who use big data sets. Severity adjustment is needed even in the classic randomized trial. All randomization buys is the lack of a consistent nonequivalence between the two groups, the control and the experimental. If you run a study a thousand times with a thousand patients, on average you will wash out all of the nonequivalence. If you do this study only once, the groups can be nonequivalent, even with the best randomization, so you have to look at age, gender, and all of the other things that could potentially account for differences. That is severity adjustment, even in the context of a randomized trial, and it could very well be that inconsistent results across various studies may in fact be a consequence of nonequivalence of the underlying populations.

### Health Status

We need improved measures of health status and functional outcomes beyond dead or alive. For some patients, it is not clear which is better, and one needs to look carefully at this. (For example, some hospitals with high death rates claim that they are sent patients who are terminally ill.) There are several good measures of functional status, but more are needed, especially for subgroups of particular importance to the Medicare population such as the frail elderly and the homebound. We also need conceptual work on developing summary scores and comparing different measures.

These are not simple problems. For example, consider something as clear and as objective as evaluating automobiles. *Consumer Reports* comes out with rankings of cars every year, but the *Consumer Reports* rankings are different than the ones developed by *Road and Track*. The rankings depend on what sort of car you like and how you like to drive. Likewise, patient reports of, or preferences for, level of health may be very different when different scales are used.

## CONTINUOUS IMPROVEMENT

During the IOM committee deliberations (and this conference) we have heard about continuous improvement models. I was very pleased to hear Chip Caldwell's discussion of the program at West Paces Ferry Hospital (Caldwell, 1991). We now know that one operating model really exists; earlier we did not. That is important because, as Alain Enthoven is fond of pointing out, economists are very good at spending a lot of time proving theoretically that certain things cannot happen. What an empiricist does is bring one into the room and show you that it exists. So, yes, there is a continuous improvement model program at West Paces Ferry. What we do not know is, how important is the selection effect associated with its presence? I am sure that if we went back two years ago, we could have found, somewhere in the country, another hospital that was doing something that looked like a continuous improvement model without the same terminology. There may be good managers and not so good managers. Can the continuous improvement model be transferred outside of the Hospital Corporation of America without transferring those people, with that corporate culture and with that environment? Can it be implemented effectively in a random sample of hospitals, not a self-selected one?

How do we take the special circumstances of the medical care system with its substantial regulatory overlay—licensing, for example, and certain publicly designed rules and regulations about how organizations and individuals are expected to behave—and superimpose a continuous improvement model that by its very nature is saying, "Let's change the way we do some things?" A continuous improvement model might lead a hospital to decide that it is better to have nurses do certain things that physicians previously have been doing because, even though they are not licensed to do those things, they nontheless do them better. Should the hospital try it? What risks is it exposing itself to? Alternatively, should the hospital say, "We can't accept this continuous improvement model because its logic would lead us to want to do certain things that, however reasonable, are illegal under current regulations"? What would happen if "radical" changes were implemented under a continuous improvement model and there was a malpractice suit because of the deviation from standard practice?

## LINK BETWEEN PROCESS AND OUTCOME

There is a wide range of issues in the area of applied research. What is the linkage between process and outcomes? Sometimes when doing quality assessment, we are going to want to focus on one (e.g., processes) rather than the other. It is very hard to think about applying outcome measures to

individual physician office visits because they are usually a small part of a large episode of care. We can, however, look at the process to see if it makes some sense. By contrast, we might use outcomes for population-based measures or for long periods of care, such as home care settings.

However, once we start to employ multiple measures, how do we apply them with an even hand? For example, if we are going to sanction a practitioner or provider for poor care, is it fair to sanction one group based on process measures and another based on outcome measures? How much poor process is considered equivalent to an excess number of deaths?

## PRACTICE GUIDELINES

As the IOM committee was finishing its report, the U.S. Congress mandated the Agency for Health Care Policy and Research to explore the area of practice guidelines. Many questions can be posed at this juncture. What are the criteria for choosing guidelines? How applicable will they be to the broad range of clinical practice? Is the health services research community going to be able to deliver? (Probably not, but we could ask that they be held to no stricter standards than the Congress with respect to Gramm-Rudman-Hollings.)

How will these guidelines be implemented? Informing the practitioner community about them can be done through publication in the *Journal of the American Medical Association* or somewhere else, but how do you then encourage *behavior* change? What if information alone is not enough? That then gets to the question of how best to change and modify professional behavior. This means taking into account the problems of applying guidelines to clinically diverse patients, assuming that optical disks filled with specific indications down to the individual patient level are not a realistic option. If you cannot do that, then you must draw guidelines more broadly to account for wide variability in severity, indications, comorbidities, and similar factors. As you do that, the guidelines become broad enough to allow an enormous variability in practice for situations that really should be handled in the same way. How do you deal with that kind of conflict?

What is the most appropriate method for the diffusion of guidelines? What is the value, positive or negative, of a government or professional society label on a guideline? What are the antitrust issues when one applies guidelines at a local level? Only a relatively small number of communities have a very large number of hospitals, for instance, New York, Chicago, Los Angeles, and Philadelphia. Once you start getting below that in size, you are getting into medical care communities in which everyone knows everyone else. They are all competing with each other. Fifty thousand people can be designated a metropolitan area, and there are over 200 such

areas with fewer than five hospitals. How do you apply guidelines and assessment in that kind of environment while encouraging everybody to compete?

## SPECIAL SETTINGS

### Ambulatory Care

Research needs to be done on the assessment and assurance of quality in different kinds of settings. Ambulatory care is far more difficult to assess than hospital care, yet that is where more and more of the action is taking place. We are not just talking about the standard office visit for an upper respiratory infection, but also, for example, free-standing cardiac catheterization units. Until several years ago, cardiac catheterization was always done in a hospital setting. Questions of appropriateness, poor technical quality, and the like can be just as important in such settings, but the organizational structure for quality assessment and assurance is very different.

### Long-Term and Community-Based Care

Our committee did not look at the nursing home area because the IOM had earlier released a study on that topic. That does not mean, however, that these topics of long-term and community-based care do not need to be examined further and incorporated into an integrated system. Home health care is a major priority. We looked at it briefly, but partly because there is so little evidence, much more research needs to be done. One of the special problems in this area is the collection of data; no detailed routine medical record exists that can be unobtrusively reexamined after the fact. Moreover, the actual collection of outcome data—asking patients how they are doing—may, in fact, be a wonderful intervention and make them feel better. The "Hawthorne effect" may actually be a desirable outcome.

### Health Maintenance Organizations

Health maintenance organizations (HMOs) have often done quality assurance activities on their own, but one needs to take into account the different practice styles, different admission rates, and different kinds of settings in which HMOs deliver care. What is a fair comparison between an HMO practice and a fee-for-service practice? Maybe we should evaluate HMOs on a population basis, because they are responsible for populations, and similarly evaluate fee for service on a population basis and say, for instance, that "the fee-for-service practitioners in Philadelphia are just not

doing a very good job relative to the HMOs there. You, the health care professionals, need to figure out what the problem is and work it out."

### Rural Settings

Rural health care has a set of unique problems partly because there are few providers. This factor causes access problems, about which we heard repeatedly, but it also causes problems for quality assurance. How, for instance, would you get a reasonable external opinion when there are only two neurologists in the whole state? They are likely to be either partners or competitors, so whom do you get to review the other's charts? If you go out of state, then you have out-of-state standards, a situation that is often resented by those few practitioners or providers. In many instances, hospitals are so small that effective internal peer review may be impossible.

## FINANCING

We also need to look at the effect of organization and financing issues on quality assurance. How well do various quality assurance methods work under different kinds of settings? For example, are they equally applicable in open-staff and closed-staff hospitals? What if the hospital starts marketing its services in competition with its medical staff?. What about the integration of incentive systems, pulling together Medicare Part A and Part B payments in an HMO or under selective contracts. For example, how would things change if the Health Care Financing Administration started selectively contracting for coronary artery bypass surgery and other specialized care and said, "We'll give you a lump sum. You handle both medical and hospital costs *and* quality assurance as the whole package."

## DIFFUSION

There are also research issues in diffusion. We need to think about data systems and hardware. How can we pull together a wide variety of data and make them equally reliable and valid, so that, in fact, data are being recorded in the same fashion?

These are not idle questions. As part of another study, some colleagues and I examined discharge abstract data from California and found that for one hospital, 51 patients undergoing cardiac bypass surgery had exactly 13 procedures listed; few had either 12 or 14. Somebody must have been running a protocol, and all patients received 13 procedures during their stay, or at least they were all recorded as having had 13 procedures. Aberrant patterns such as this are sure to cause problems when analyzing data across hospitals.

## CAPACITY BUILDING

We also need substantial efforts to build capacity because we do not have the human resources to get answers to these questions, both in terms of the underlying research side and in terms of applying them at the local level. What should be the role of continuing medical education courses? What should be the role of professional associations in encouraging careers in quality assessment and quality assurance? We need to identify a viable career path for people who really want to do quality assessment and assurance, rather than treating it as just a side issue done over a sandwich once a month as part of a medical staff commitment.

We need to figure out how to add courses to undergraduate medical, and other professional education curricula to encourage health care providers to look at patterns of care, to think about patient preferences, to consider variability in outcomes—and to do so as a normal, routine activity rather than considering everything as an individual situation.

We also need to consider how to educate patients by using various forms of media—to encourage them to ask questions, to point them to information resources, and to help them become accustomed to viewing outcomes as a probabilistic phenomenon. People need to move away from the notion that they are definitely going to get better or that this is too dangerous an operation because they may die. Rather, they need to develop an understanding of what it means to have a 2 percent risk of death. Most people do not understand that at all in any intuitive sense. Yet, we are now saying physicians have to inform patients about risks. Risks are not yet information, they are data. What we need to do is think about how to provide usable information rather than data.

## FUNDING

In terms of funding, we are talking here about approaches, issues, and problems that are not just Medicare oriented. Our charge was to focus on quality assessment and quality assurance in the Medicare program, but the basic tools, the capacity building issues, the underlying research that needs to be done, are really a public good. They will affect all patients in all settings, with perhaps some minor exceptions—if you focus on Medicare models, you are not going to do a lot on pediatrics, but one needs to take a broader perspective. The notion of the research and capacity building for quality assurance being a public good means these activities will be underfunded if they are left to private sources. Consequently, there needs to be a federal commitment to doing more in this area. We have already seen an increased commitment. What we need to keep in mind is that this is a long-term agenda. We need to build the capacity. We need to start doing the basic

research. It will take time for the results to come out. It cannot all be done immediately, but we need to begin somewhere. We have tried in this IOM report to outline an agenda to help point us toward where we should begin.

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# 17

# The Research Agenda: An Outside View

*Sheldon Greenfield*

My charge is to answer two questions: Is the glass half full or is it half empty? Have the enormous advances in research directed at understanding how to measure and improve quality of care given us, at this time, an adequate capability to erect quality assurance systems that make judgments, or do we know so little that we should be wary of making judgments on infirm grounds? I will address our overall progress to date and directions for the future by underscoring six issues that have been raised in Chapter 11 of the Institute of Medicine (IOM, 1990) report.

## THE NEED FOR RESEARCH

Some questions can be asked now only because of past research findings. With respect to outcomes, for example, if physicians or organizations are going to interpret outcome information, can they be sure that the outcomes are not attributable to differences in case mix? Can they be sure that outcomes are not distorted by assessing the outcome too early or too late, such that new events befall patients—events that had nothing to do with the receipt of care? Will we get into the problems that we did with the mortality data, where statistical considerations make it such that one or two cases move some doctors or organizations above or below the line? When you give information back to physicians, do they know what to do with it? These are all questions that now need to be addressed and researched.

Roberts (1991) and Luft (1991) outline questions that need to be dealt with in respect to, among other things, practice guidelines. These are downstream questions that now can be asked because the state of the art of guideline development is rather sophisticated. We now have to ask, as we are asking in a study in Boston: Will physicians use guidelines? How will they use

them? Will guidelines save money? If they save money, will they hurt patients? Asked another way: Are the guidelines effective in bringing about more good than harm? Are physicians happy with guidelines? Are patients happy under a system in which guidelines are a pan of day-to-day medical care?

With respect to continuous quality improvement, the questions include: What is it, really? What are the basic invariable elements that make the most difference? What elements are more critical in different situations? Will continuous improvement, a phrase that resounds like a heavenly trumpet blast, have any impact on compliance with process and with outcomes, which is the way we know whether we have improved?

I think that the agenda and the program set out in the IOM report are the way to approach future quality issues. I emphasize that quality assessment and assurance are not a one-shot thing. If priorities are set, future directions can flow from past research, and ways to attack the problems of quality can be handled in an orderly fashion. The IOM program is going to need imaginative and not erratic funding, not only from the government and foundations, but from private sources, a point to which I will return. These private practice organizations will gain in both the short and the long run from getting involved in quality research.

Thus, point number one is the need for research. I think there is a lot of agreement about that. Many questions are settled; most are not.

## JOINING BASIC AND APPLIED RESEARCH

Point number two relates to the issue of basic versus applied research. A table in Chapter 11 of the IOM report makes this useful distinction. I would argue that, in the future, researchers and practitioners need to get together. All too often researchers study quality-of-care methods in a vacuum. I know this from very hard personal experience; researchers perform a study in a practice organization and then disappear. Nothing ever happens to the quality measures developed in that study. Much more often, every day in this country, thousands, millions of dollars are being spent in windowless lower floors of hospitals and other places on quality assurance activities that nobody can learn anything from. The two need to be combined in a way that I will liken to post-marketing surveillance. Drugs are never completely studied even when they are approved by the Food and Drug Administration. New side effects turn up all the time, but only when, and if, good surveillance follows the approval.

Private sources such as health maintenance organizations, independent practice associations, preferred provider organizations, and insurance companies will benefit. They can put quality programs into place with the promise that results will be somewhat tentative and inconclusive now because

the methods are basically sound but need further development. Over the next five years, as these measures are in place, better answers will be forthcoming and practitioners will be able to learn from their experience, if they work with researchers who have the time and methodological sophistication to reject poor methods and improve promising ones. We need to take the field of quality and put it where it belongs, which is in practice, and to perform research and develop methods that come from practice instead of creating them in isolation.

## STRUCTURE, PROCESS, AND OUTCOMES

Issue number three, as has been raised by others, involves the relationships among structure, process, and outcome. Processes and guidelines are not useful unless they have been shown to have an impact on outcomes. Outcomes are invalid and meaningless if they are not relatable to process. We all know that being dead is a health state that is in itself valid; however, to those in the health system, it has no meaning unless it is linked to something that has to do with the prior receipt of care. Despite the fact that ten years of extraordinary research has now allowed us to determine the health status of people, that health status may have relatively little to do with what we do in everyday practice until we establish the link. Finally, with respect to structure or continuous improvement, we need to know whether outcomes affect continuous improvement, whether continuous improvement affects processes and outcomes, and so forth.

In the IOM End-Stage Renal Disease Study, we are trying to put together some quality indicators. I will give you one illustration of how process and outcome need to be united. It might be asserted, for example, that with new drugs and transfusions, patients undergoing dialysis should have a hematocrit of 30 as a proximate outcome. They might also feel better and function better. If those outcomes are not achieved, the process needs to be examined to see whether the four or five other competing causes of anemia are present, whether the patient refused treatment, or whether care was suboptimal. Process also needs to be examined because putting someone on erythropoietin can cause depletion of iron stores. That consequence of care would not show up in an ordinary outcome assessment, because it is relatively rare.

What I have just described is a set of potential indicators of process and outcome that can be validated only by putting them in place and seeing how they work. There is no other way; it is not magic. We cannot, as the definition of quality implies, go beyond the state of our professional knowledge.

## GENERALIZABILITY

Point number four is generalizability: what works in one place does not necessarily work in other places. It is not that the principles are not valid; it

is just that the tailoring of methods from one situation to another will in itself make some methods invalid, and then they need to be retested. This is not a trivial matter. Taking methods off the shelf and applying them requires more than just a simple application. It has to do with understanding both the methods and the specifics of the context in which they are applied. That needs to be done for poor people's care; it needs to be done in outpatient settings and inpatient settings, long-term care, and so forth. In my view, for example, outcomes are going to be a better measure of quality of care in the office practice of medicine than process. That assessment must be tested to determine which is better in which circumstances.

## PATIENT AND PHYSICIAN PARTICIPATION

Points number five and six are ones that, as my four-year-old Nintendo-playing son says, take us into some new worlds: World V and World VI. World V for me is the new world of the patient that has been amply and, in a visionary way, alluded to in the IOM report. In a recent book chapter, two of my colleagues discuss patients as (1) the raters of their health (that is, satisfaction), (2) the reporters of health (health status), and (3) the participants in their health care (preferences) (Kaplan and Ware, 1989). All three of these roles, and others that may arise, must be fleshed out, quantitatively and understandably. It is not just a matter of doing what the patient wants. None of us ever gets exactly what we want at the time we want it, and patients are not going to get that either. Negotiation or compromise first demands understanding the patient's role and how to measure and agree as to when the optimal role of the patient is fulfilled.

Finally, World VI is the doctor's world. There is a great deal of work to do here. Many programs including, I would argue, measures of cost- effectiveness and cost-containing initiatives have foundered because physicians have not been brought into the equation. That has been amply emphasized in the IOM report.

I think we need to test all kinds of incentives and to refashion the training of physicians so that they incorporate quality assessment into everyday practice, much as they have integrated billing into their lives. Many of you remember the days when office practices were not as high powered in terms of their automated billing systems. I think that we have to be imaginative about ways to get physicians involved in the quality assurance effort, without making them sullen, difficult, and unhappy.

## SUMMARY

These are just six issues that I chose as an overview to this discussion of research and capacity building. I would like to see the kind of program proposed in the IOM report take hold. I know it is somewhat vague, but to

me it has, in fact, quite a lot of teeth in it compared to other proposals that we have seen over the years. I would like to see this program implemented over an extended period. I think it will not only serve to integrate a lot of the disparate and fragmented players in the health care field, but also result in the improvement of quality of care not only in the Medicare population, but for all of us.

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# 18

# The Training and Capacity Building Agendas: An Outside View

*Edward W. Hook*

I, too, wish to congratulate the Institute of Medicine (IOM, 1990) committee on this carefully constructed proposal designed to improve the quality of the health of our people. Because of its magnitude and the many unknowns, I see the committee's 10-year implementation plan as a very wise decision. Like others, I have learned much in reviewing the proposal and have gained more than I could possibly give in commenting on the report.

My charge was to review the section on capacity building, focusing principally on training and on education. Having just indicated that I am very positive overall about the report, I can state my main criticism: the report has very little information, insufficient information in my opinion, on who will do the job and how they will be trained. For example, there is no assessment of our present capacity to implement the recommendations of the report, although it was emphasized that our present capacity was inadequate. There is no assessment of the requirements for new personnel or the magnitude of the retraining and educational effort that will be required. Considering the detail given to structure and function of the program, and the emphasis placed on specific research needed to correct information deficits, I found the lack of emphasis on manpower development and training programs inconsistent.

## PERSONNEL TRAINING

The types of personnel that will be needed fall into two major categories. The first includes persons required to staff and operate the quality assurance program—that is, from top to bottom, from the oversight to the provider

organizations, especially in the MQROs[1]. The second consists of investigators who will carry out the research. The investigators themselves fall into two main groups: those who would work to strengthen the weak knowledge base of the methods and the impact of quality assurance, and those who do the research that will provide data on effectiveness and outcomes of various interventions or alternatives that constitute the information base for much of the quality assurance process.

Regarding the operation of the program, the report appropriately emphasizes the fundamental importance of a core of professionals prepared to provide both technical skills and leadership. There seems to be general agreement in the committee that at present we lack an adequate number of professionals to staff a nationwide program and that establishing training programs to prepare these professionals should be a high-priority item. The committee apparently envisioned that these educational programs would require a year of study—I see the period of training as very variable—and that such programs could be built on existing programs in epidemiology, health care research, and biostatistics. Re-education of existing staffs and senior professionals already working in the area will facilitate implementation of the program until organized training programs that would include field experience could be developed to prepare this new cadre of health workers with the tools needed to collect and apply information for quality assurance.

## CURRICULUM DEVELOPMENT

The professional staff required for the program will require a diverse group of individuals with many different skills, including persons trained for leadership roles, as managers, in data acquisition and analysis, evaluation, record abstraction, information science, questionnaire development, ethics, and so forth. Much work remains to be done in identifying the types and numbers of such persons who will be needed to establish a nationwide network for quality assurance.

Because of the diversity of the group, it seems inevitable that the type and duration of training will vary greatly. Curriculum development for the types of personnel that will be required is a high priority. Some experimentation through demonstration projects might be advisable to define the optimum staff for the MQROs and other components of the system. I very much like

[1] Editors' Note: The reference is to Medicare Quality Review Organizations (MQROs), "local" organizations proposed by the IOM committee as part of its Medicare Program to Assure Quality (IOM, 1990).

Dr. Relman's ideas (Relman, 1991) as well as the committee's views about incremental implementation before going big.

In the report and the other conference presentations, two related messages recur. First is the need for research—and then more and more research. The research is required to fill extensive knowledge gaps and to define what works and what does not, what people want and what they need. Second is the need for research specifically in quality-of-care issues—how to measure it, how to apply such measures efficiently, how to address deficiencies, and how to evaluate the effort.

The training of researchers who will focus on quality assurance, outcome, and related issues will require that they gain varying levels of proficiency in experimental design, biostatistics, clinical epidemiology, decision analysis, and perhaps other nonbiological disciplines. Those planning a research career in the area would probably be M.D.s, Ph.D.s, or degree nurses, and they would need a period of study of no less than two years, perhaps even three. For the M.D.s this would come after clinical training of sufficient duration to achieve board eligibility. The characteristics of training sites would need to be carefully defined and would certainly have to include adequate faculty to cover all of the disciplines or areas that I mentioned earlier. The training site should also be an active site for research in quality assurance and technology assessment, outcomes research, and health services research broadly defined.

When the committee or other responsible group comes to grips with designing the goals, the objectives, and the characteristics of the research training program, it might profit by calling on the experience of the Robert Wood Johnson Foundation's Clinical Scholars Program. This program has been the country's premier program in producing qualified clinician investigators in health services research, technology assessment, and the like. The program was designed to allow young physicians from all clinical specialties to undertake two years of graduate-level study and research to acquire competence in one or more of a number of nonbiological disciplines that bear on medicine and health affairs. These disciplines include epidemiology, biostatistics, economics, management sciences, ethics, anthropology, and occasionally others. To date there have been more that 500 graduates of this highly successful program, many of them in full-time investigative roles and many of them working on problems related to quality assurance, outcomes of care, and the like.

## RELATED TRAINING NEEDS

The IOM report, by design, did not address technology assessment, health services research, or research into access to care and continuity of care. Nevertheless, as the committee emphasized, these areas are critical to qual

ity assurance. The number of persons properly trained to carry out research in these areas, and especially those with satisfactory clinical backgrounds, is inadequate despite increasing interest in the field in recent years and the current prospects for increased funding in the new Agency for Health Care Policy and Research. I am disappointed, however, by the apparently limited research training capabilities of that agency; at least that is my interpretation of the emphasis on research reflected in the remarks by Dr. Demlo (Demlo, 1991) at the conference. Thus, I see the serious need for expanded opportunities for research training, not only for those professionals who will focus on research specifically on quality-of-care measurement and quality assurance, but also for those who will do health services research, technology assessment, and other research providing data on effectiveness and outcome—the information base for much of quality assurance.

## PATIENT EDUCATION

Finally, let me comment briefly on the issue of patient education. I accept completely the recommendation that we educate the public and our patients about matters of health and, of course, I respect the right of the public and patients to be involved in decisionmaking about their health. Yet what we decide to communicate to the public might be quite different from what we communicate to our patients. First things should come first. Before communicating morbidity and mortality figures of uncertain value to the public, I would like to use our resources in an educational effort extolling the virtues and the importance of having a primary care physician or providing more information on preventive practices of known value.

In contrast to this type of broad public education, there is interaction between the patient with a significant problem and his or her physician. In this interaction, balancing the alternatives with morbidity and mortality data and any other information that is available becomes more meaningful and very helpful in the decisionmaking process. Of course the model that we discuss so much is Dr. Wennberg's prostatic hypertrophy model, which I think is an extremely good one (Mulley, 1991; Wennberg, 1991).

In terms of capacity building, the question becomes who is going to make this patient and public educational effort and by what means? Newsletters, video disks, television programs, and tapes were all mentioned in the report, but priorities were not defined. Obviously, appropriately trained educators are central to this effort, and experimentation in this area is certainly in order.

## SUMMARY

The goals of the program proposed by the IOM offer exciting possibilities for the continued, even continuous, improvement of the health of our

people. Adequately trained professionals are a prerequisite for success. Specific, detailed plans for training of these professionals should be initiated as a high-priority item early in the development of the program.

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# PART IX

# Response to the Institute of Medicine Report Recommendations

# Response to the Institute of Medicine Report Recommendations:

## INTRODUCTION

*Molla S. Donaldson, Jo Harris-Wehling, and Kathleen N. Lohr*

Throughout the conference, health care policymakers, and observers of health policy, commented on the recommendations presented in the Institute of Medicine (IOM, 1990) report. This part brings together the papers given by two legislators, Senator David F. Durenberger and Representative J. Roy Rowland; a physician, Arnold S. Relman; two administration spokespersons, Linda K. Demlo of the Agency for Health Care Policy and Research (AHCPR) and Thomas G. Morford of the Health Care Financing Administration (HCFA); and a representative of the Medicare Peer Review Organizations (PROs), William H. Moncrief, Jr.

From his vantage point on the Finance Committee, the Labor and Human Resources Committee, and the Environment Committee, Senator Durenberger responds to the IOM report and its recommendations in the context he views as a fragmented national health care policy, with particular attention to health insurance reform. Congressman Rowland, who serves on a number of health-related committees including the Energy and Commerce Committee, the Veteran's Affairs Committee, and the Select Committee on Children, Youth and Families, has offered a wide range of legislation ranging from drug abuse to the environment, transportation, economic development, disabled veterans, and health care. As one of two physicians in the House of Representatives he brings the special perspective of both a lawmaker and a family physician who practiced in middle Georgia for 28 years and who is acutely aware of the current climate of medical practice.

Dr. Relman, who provides a physician's response to the IOM report, is the editor-in-chief of *The New England Journal of Medicine.* He has been an outspoken observer of the American health care system and has commented widely on the effects of regulation and financial matters on professionals.

Dr. Demlo is the Director of the Office of Program Development at

AHCPR, an agency that was created in November 1989. She provides an overview of the plans of the new agency and how they correspond with the IOM report's broad recommendations concerning basic, applied, and diffusion of research.

Mr. Morford, Director of HCFA's Health Standards and Quality Bureau and an experienced federal bureaucrat, gives the response for the agency that is presumptively most affected by the IOM report. He focuses on new directions of the PRO program as they reflect recommendations and implications of the IOM report.

Dr. Moncrief is President and Medical Director of California Medical Review, Inc. (the California PRO) and President of the American Medical Peer Review Organization; before holding these posts he had a long career in the practice of surgery. His authoritative view of the reaction of the PRO community reflects support for the "new directions" proposed in the IOM report, but it also stresses the continuing need for individual record review and for retaining sanctions in cases where they are needed.

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# 19

# A Legislator's Response to the Institute of Medicine Report

*David F. Durenberger*

I would like to begin with an explanation of the badge I am wearing. It is a picture of Jacob Wetterling, one of more than 4,000 children who have been abducted in recent years. Jacob was 11 years old when he was abducted about seven months ago. He was with his mother and his little brother on a rural road when the abductor, wearing a ski mask, took Jacob. They have not heard from him since.

We are talking about the quality of health care in America at this conference. If one defines health care in a comprehensive manner (as I think we must), the abduction is a quality-of-health care issue. Quality is a lot more than just what goes on in the doctor's office. It is doing something about the health problems that caused Jacob to be parted from his family.

## THE INSTITUTE OF MEDICINE REPORT

It is hard to know where to start in responding to the Institute of Medicine (IOM, 1990) report other than with a compliment—and that is always a nice place to start. I think the effort of the committee is more than worthwhile; the product is very, very good. I hope it will be understood by many of my colleagues.

I trust that in the process of implementation, many sessions, like this conference, will be held to bring together people who are making growing contributions to our understanding of the quality assurance field. It is important that we keep using this kind of process, rather than just the political process, to implement quality assurance strategies.

As the person who accepts the responsibility for converting the Professional Standards Review Organization (PSRO) program to the Utilization and Quality Control Peer Review Organizations (PRO) program, I agree

with the comments in the summary of the committee's report about the need to build on and strengthen the existing PRO infrastructure for quality assurance. The criticisms noted in the summary on the PRO program are all appropriate, but I am not going to blame the individual PRO organizations for that. We in the Congress structured the program poorly and we, along with the Health Care Financing Administration, were negligent in attending to essential details. For example, we did not provide space for the individual PROs to breathe, grow, and adjust to reality at an individual state level as I intended when we first started the program. Thus, we now have a structure that gives primary attention to utilization rather than quality, focuses on outliers rather than the average provider, concentrates on inpatient care, imposes excessive burdens on providers, and does not use positive incentives to alter performance. It follows, of course, that almost every doctor perceives the program as adversarial and punitive.

For the last five years or so, we have listened to similar complaints about the PROs without doing anything to correct the problems. The IOM critique is an accurate critique. Furthermore, the committee's conclusion to build on the infrastructure that is in place—to learn from what we know—is also an appropriate conclusion.

I do not consider it my task today to comment in depth on the specifics of the 10-year implementation plan. I would like to make a general comment, however. The IOM and the study committee are to be complimented on the repeated emphasis in the implementation plan on the engagement of providers, patients, and consumers in quality assurance. That theme is present throughout the report. I agree with the importance of keeping the lines of communication and understanding open.

## ADDRESSING PROBLEMS OF UNDERUSE

Problems of access and underuse are quality-of-care issues. However, the IOM was not charged by Congress through this study to focus on those problems. Thus, it is not a surprise that the report does not give equal attention to quality issues of the uninsured or underserved. Congress requested that the IOM undertake this study because of concern about the quality assurance program of Medicare—thinking in particular of the existing PRO program, which only monitors the quality of care provided or delivered to the Medicare beneficiary. The study was also supported by members of Congress who acknowledge that a price is paid for achieving advances in medicine: paying for new medical technology means less is available for the uninsured or underserved. We felt that we first needed to know how to assure the quality of care that is delivered; we needed to know how to determine if and where we are spending more than is necessary to have quality care.

Until we as a society come to grips with some basic issues of values, outcomes in health care, and quality of care, we will be limited in the resources we have available for health care. Special taxes such as tobacco taxes or liquor taxes will not solve the financing problem. We must confront our value system and determine if quality care can be provided more efficiently to those who are in the health care system. We can address the needs of the underserved only by closely examining where our monies are going now and by making the current health care delivery system more efficient and effective.

## FUTURE DIRECTION OF HEALTH POLICY

I would like to make a few comments on where public policy is going in the future, some of which relate to this IOM study. I have recently completed working on the Pepper Commission (The National Bipartisan Commission on Comprehensive Health Care), which did not really solve any problems. In this country, health reform will take a fairly long time to define the problem before we define the solution in its larger sense. During this period we will be working on prospective pricing, outcomes measures, and practice guidelines. We will be conducting activities on an incremental basis similar to those recommended by IOM.

We are not the revolutionaries; we are the reformers. Revolutionaries usually want to get things done quickly; that is not possible. The health policy reform process could possibly be speeded up through the multiple efforts of developed nations focusing on the same problems and thereby bringing about quicker solutions.

The first step is to define the problem; that means we have to define health. We have to define health in the context of Jacob's abductor—in America we must approach health in the larger context. I am on the Finance Committee, the Labor and Human Resources Committee, and the Environment Committee. I am dealing with tax policy. I am also dealing with Medicare, with Medicaid, with maternal and child health, and even with Title XX (the Social Security Act); I am the author of several parts of the Clean Water and Clean Air Acts. I am also the author of the Safe Drinking Water Act and of legislation relating to leaking underground storage tanks.

*All* of these are related to health—any place but in America. In America we have Medicare over here, the tax subsidy over there, and clean air someplace else. The only place they ever meet is in a room like this, where I can see the heads nodding in agreement.

How are we going to redefine health? We will not be able to do so until the public and the political leadership in this country make up their minds that they are going to define health in different terms. I would hope that perhaps a year from now the President of the United States will make a

speech along this line, which will in effect help us to define health. We will then be in a position to begin the process of reforming our health policy.

We cannot reform the components of the health care system—the medical, financial, or delivery parts of the system—until we all understand it in this much larger context. Nobody is going to give up what they have; each coalition has a narrow stake and the price is high.

The reform process is going to have to confront a variety of issues. One of them is defining responsibility. Certainly if you have first-dollar health care coverage, you do not have any responsibility. You basically have a blank check. Most of us are aware that blank checks produce irresponsibility. So just defining responsibility in America in a new way is very, very important.

Making a commitment to choice is also extremely important in this country. Freedom of choice promotes responsibility, affects outcomes, and is important to quality. By making choices we express our values. What is going on in Oregon[1] must go on in Washington, D.C. We need a process of expressing and then implementing our societal values from time to time, and this is the place it has to go on. The folks in Oregon are just sending us a message. They are like Paul Revere and the lantern in the church steeple, but their message applies to all of us. A somewhat similar system must be put in place at the national level, but we can do it only if everybody in this country is willing to take responsibility—to step up and do something with their choices. The President talks about consumer choice in child care and in education, but he is going to have to add health care to the list. People are going to have to play a role in reforming the system.

There is not one system of quality or value for everybody, even if there are national standards. Some things will be equal: access will be equal, information systems should be equally available to all, and the choices certainly ought to be fair. The financing mechanisms ought to be in place. I may make a different choice about health care than somebody else does. If I make the wrong choice, I ought to be penalized for it, and if I make the right one, I ought to be rewarded. This philosophy is so basic and essential to our American heritage, but we know that it is not applied in many public services.

## ASSURING QUALITY OF CARE IN THE FUTURE

Who should be responsible for assuring quality of care in the future? I do not have any easy answers to that question. First, providers certainly

[1] Editors' Note: A controversial approach being taken to expand Medicaid coverage by limiting the types of services the program will pay for.

would be the most reliable source to assure me of quality. Second, I would probably play a role in it as a consumer as well.

Third, the people who currently should be playing a greater role in quality assurance are the employers of this country. We are at a point in time in which the company, in a sense, brings some level of comfort or assurance or security to a lot of people. Currently, however, they are the least well equipped to participate actively in health care quality assurance, even though they are exploring things such as case management and managed care. The employer's role is not yet developed.

I think the employers of this country have an obligation—as yet unmet—not to provide coverage for a mandated set of benefits through health insurance (because I oppose that notion) but to deal with that important security relationship between management and labor. In so doing, the appropriate and very important role of employers in quality assurance will be more clearly defined.

## Insurance Reform

The fourth place where we might find quality assurance is in what I would call the insurer of care management. This relates to what will be the next phase of my efforts to reform the health care system: oversimplified, I call it insurance reform. My link to the health insurance system today is a piece of paper that I buy from the Federal Employee Health Benefit Plan, which pays part of my bills. This system increases my insensitivity to my own responsibility and clouds my judgment about what it is I am buying.

By insurance reform I mean that it is essential for us to define the product that we are putting on the market between the consumer and the provider. One product is insurance, catastrophic protection against catastrophic loss. That is an important product. If we have that protection, the other decisions we need to make, which presently are cloaked in health insurance, can be more wisely made.

These other decisions (and the financing of them) have nothing to do with insurance per se. I am talking about decisions such as adopting personal life-styles for health promotion and disease prevention or, when you do get sick, deciding where to go, whose advice to take, and how much to pay for it. What role will a third-party payer play in financing those decisions? That is the undefined area, the area where we hope that care management and similar concepts will be part of the health policy reform package.

I believe that it is appropriate at the national level to provide a basic health care service benefit package that reflects our national values. I do not know exactly what we as a society might include in such a benefit package—perhaps some health promotion and disease prevention services, some inpatient and outpatient services, and some mental health and chemi

cal dependency services. I visualize that the basic benefit package would be subsidized in some manner and include some prescribed cost sharing. Any other health services purchased beyond the basic benefit covered package would be the individual's or employer's particular choice.

Having a national-level benefit package means that all persons are covered, including those who may be heavy users of the health care system. This, in itself, would address many of the currently unresolved access problems for the uninsured or for those who have high-cost illnesses and diseases and are unable to obtain coverage for pre-existing conditions.

My reform package begins with catastrophic coverage. We learned through the unsuccessful efforts to add catastrophic coverage to Medicare that we need to educate the public on what they are buying through insurance and to make them aware of what they are not buying. Americans need to understand the role they are playing—through purchasing insurance products with extensive benefit packages—in supporting and promoting the high cost of health care in America. The dissatisfaction with health care cost is as much my problem as a consumer as it is the problem of the insurance companies, the doctors, the hospitals, or anybody else. Until we, the consumers, understand that we are all part of the problem, we, the reformists, are not really going to be able to do all of the things we need to do to correct the problems.

## CLOSING REMARKS

We need happy doctors in order to have quality care. Doctors must feel that they are doing what attracted them to practice medicine in the first place. For this to happen, the consumer—the patient—needs to better understand his or her role in the health care system.

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# 20

# A Legislator's Response to the Institute of Medicine Report

*J. Roy Rowland*

May I tell you how pleased and honored I am to have been invited to be a part of this conference to discuss some of the work that you have been doing. I know that your charge was to look at the Medicare system and to think about quality assurance in that program, but one really cannot separate the Medicare system from the rest of health care delivery in our country, because what happens in one system is going to affect other systems. So, although the Institute of Medicine (IOM, 1990) report centered on the 30 million Americans who get their care through Medicare, I am very much concerned about the other 200-odd million people in the country and the quality of their care, and some of my remarks will reflect that broader concern.

## ACCESS FOR MEDICARE ENROLLEES

When you talk about the quality of care for Medicare, are you talking about the quality of care for people who are eligible for Medicare, or are you talking about the quality of care for people who get into the system who are sick? Both of those need to be examined. If you look at the quality of care for people who are eligible for Medicare, who are not sick, I think it is important to realize that those people are very concerned about whether they are going to be able to get medical care when they need it. I hear this frequently at town meetings.

Most of these people, you say, have access to care if they are covered by Medicare. In listening to people in my district and elsewhere, I know that is not necessarily so. In fact, more recently I have been hearing from people who are concerned that they will not have a doctor when they need one. I am hearing more and more from physicians that they are not as

inclined to participate in the Medicare program as they were at one time, and this is causing a great deal of concern on the part of patients.

Access to care is also affected by the cost of the care. Medicare is not a totally free program. There are some people for whom copayments and deductibles are a real hardship. If they are not eligible, if they are not at that specified income level where they become eligible for Medicaid to pay for their deductible and copayment, then they are somewhere in that gray area of never-never land, and they have trouble getting their copayment and deductible together. Just as you keep hearing that some 30 million Americans do not have any health insurance at all, when you talk about quality of care, you have to talk about the people who are eligible for care before they get sick and the concerns that they have.

## A COMPREHENSIVE STRATEGY

I want to commend the Institute of Medicine (IOM) for the excellent study the committee and staff have done. Two very ambitious and challenging objectives have been laid out. The first is to establish a comprehensive theoretical framework for the development of quality assurance; the second is to implement an integrated strategy for improving the quality of care in the Medicare program.

I am optimistic that Congress is going to work with this and is going to do the very best that it can to make some of these recommendations come true. Members of Congress will give a great deal of thought to it, because they are very concerned about a long-range strategy in health care, too. Nevertheless, a word of caution is needed. I think that Congress is afraid right now to be doing anything with our health care delivery programs after the catastrophic health insurance legislation (the Medicare Catastrophic Coverage Act of 1988) that we passed and then repealed under a barrage of objections. So, the members of Congress are somewhat wary right now about doing almost anything.

## CONCERN ABOUT COST CONTAINMENT AND MEDICARE

I have been deeply concerned for some time about the Medicare program and our health care system in general, and in particular about the way that Medicare is influencing the practice of medicine and having mixed effects on our patients and our physicians. The constant budget cuts in Medicare over the last 10 years, which now total about $40 billion, have a considerable impact on the program. This has produced an undesirable context and frame of mind for the administration of this program. Efforts to assure quality of care and to maximize the value of enormous investments in our health care are most welcome. However, crude efforts to control utilization

or reduce payment just for the sake of cost containment represent a disregard for this program. In that regard, it is distressing to me to see the Congress go every year to the Medicare program to get money to meet the Gramm-Rudman-Hollings deficit reduction targets. Not only is this putting individual physicians and providers of health care in a bind, it is also putting hospitals in a terrible bind, particularly hospitals in rural areas and those teaching hospitals in urban areas that have a large number of Medicare patients.

I called this morning to talk with a hospital administrator of the largest, not-for-profit hospital in my district. I knew that he was having a difficult time with respect to the Medicare program and that it was costing him money, and he gave me some figures that are astounding. The last five years have seen a steady loss of revenue from the Medicare program there. It is made up by shifting costs to the private sector. For 1989, there were 6,140 Medicare discharges from the Medical Center of Central Georgia, and his Medicare reimbursements relative to the cost of that care revealed a difference of over $30 million. Of course, he has to make that up. This cannot help but affect the quality of care adversely.

Some of the people with whom I have talked in the Veterans Administration (VA) over the years say that the screws in the VA hospital and health care delivery system have been tightened more and more. Individual hospital directors have had increasing difficulty in meeting their responsibilities. It is natural and warranted for us to ask if these budget cuts adversely affect the quality of care available to the elderly, and I really think they do.

The problem is that we are not in a position to answer that question empirically and authoritatively to prove what we sense is the case. We have not developed sufficient tools to evaluate the quality of care, and we do not have a baseline against which we can measure today's level of quality. Those factors go to the very heart of the matter, and they are one reason for the Congressional mandate for the IOM study. It is my hope and expectation that the study will finally put quality assurance for Medicare on the right track to be able to answer these very important questions.

## CONGRESSIONAL INTEREST

We in the Congress are typically concerned with proposals to change the policies that structure the Medicare program. All too frequently we deal with these in an episodic, knee-jerk manner. We respond to pressures from our constituents. Often this response is very narrow, and we have been less attentive to evaluating implementation of these policies and trying to understand in a comprehensive manner how the administration of the program, including the interpretation and implementation of our policies, can either advance or derogate our good intentions.

The Subcommittee on Health and Environment (of the House Committee on Energy and Commerce) recently held a field hearing in Atlanta about Part B Medicare. The instigation for the hearing grew from problems encountered with medical review and utilization review after a rather abrupt changeover in Medicare carriers. It was apparent at the hearing, however, that the issue we were discussing was not just narrowly framed or local to the State of Georgia but was something that is pertinent to our whole country. We are hearing increasingly from patients and physicians that the program is too complicated, the rules are too arcane or obtuse, the red tape is too tightly wound, and the administration is really not responsive. The emphasis is too much on utilization control at the expense of quality assurance. The prevailing attitude seems to be one of finding a culprit rather than promoting efficient health care. Physicians and patients are complaining about the "hassle factor" and the difficulty of obtaining administrative remedies.

## CONCERNS ABOUT PRACTICING PHYSICIANS

I used to be a practicing physician in Georgia, in family medicine, and I have seen how the practice environment has been changing. The complaints come not just from the few disgruntled or what we might call "bad actor" doctors. Rather, I know many physicians of very high caliber and great integrity who have been working to provide quality care in a compassionate manner. They are very distressed about what is taking place, and many of them are talking about dropping out of the Medicare program. Their complaints lie not in being inadequately paid, but rather in not being able to provide the care that they know is needed without having repeatedly to justify their decisions about the services they render.

I received a copy of a letter just yesterday written by a doctor in Georgia to those in charge of the Medicare carrier program about some problems that he was having with a couple of patients in dealing with the Medicare program. One part caught my attention: "The next person has been my patient for 20 years after having had a myocardial infarction at a very early age. If your utilization system was more sensible and dealt with outcomes, I would get accolades for taking good care of him for two decades, helping him stay productively employed, out of the hospital, and on minimal medications." The phrase that really caught my eye was "if you...[had] dealt with outcomes...." So many times the powers that be do not deal with outcomes. They deal with something else, cost containment or whatever.

The physicians I have been talking about have the knowledge that they need to practice good medicine, but they know there are some changes taking place in the environment. I saw my last patient in January 1982, and I was beginning to see some changes taking place then that I did not think

were in the best interest of quality. Physicians now are going to have to accept the legitimacy of the concerns about overutilization and ineffective care; there is some of that out there. They have to face the reality of cost containment, because whenever health care comes up at town meetings I hear about the inordinately high cost of medical care or particular things such as medications.

However, these physicians need to be dealt with in a supportive and understanding manner. They need to be dealt with as colleagues and not as antagonists.

Much of the IOM report discusses the current peer review program. It calls for a better balance between the task of catching so-called bad apples and the effort of improving the overall effectiveness of health care, and I agree with this. We will, of course, always need some watchdog function to screen out those who fail to meet an acceptable standard of competency or integrity. That will always create some level of contentiousness in the program. However, we should be putting greater emphasis on the potential for PROs to provide education and leadership for the improvement of health care.

To realize this potential, we must invest more heavily in research, both basic and applied, to develop more sophisticated tools and better information. We need an applied technology for quality assurance. The IOM report has laid out a strategic framework for that, but a great deal of work must be done to develop specific criteria and standards and the data management systems necessary to carry it out.

## ADDITIONAL CONCERNS

We took a giant stride forward last fall when we enacted legislation creating a new Agency for Health Care Policy and Research. We gave it a broader mission than its predecessor agency. We placed a special emphasis on patient-oriented, clinically based research, and we authorized the doubling of the resources previously devoted to these activities. I look to this agency to invest heavily in the promotion of the strategy laid out in the IOM report.

Along with better information and tools, we also need to improve the professionalism of those with whom we entrust the task of quality assurance. I hear from physicians who are reviewed that they are reviewed by someone who really does not know a great deal about their particular area of medicine. For example, a neurosurgeon may be reviewed by somebody who practices obstetrics and gynecology. We need to do something to enhance the professionalism of people who are involved in the review process as well, including better training and enhanced stature. Maybe better career opportunities need to be considered.

## CONGRESSIONAL RESPONSIBILITY

I expect the Congress to respond favorably to this report. The role and responsibility of the Congress at this point is clear. First, we must articulate clear objectives and priorities for quality and quality assurance in the Medicare program and lay out a long-range strategy for that achievement. Second, we must provide adequate resources to implement that strategy. In this era of cost containment, there is a serious risk of underfunding the administration of the program generally and quality assurance, in particular. This would be a serious mistake. Here, as in so many things, we will get what we pay for. Third, we must hold parties accountable much more than we have in the past for carrying out quality assurance provisions properly and for providing quality care throughout the program.

Those are some of the thoughts I have about what is going on in our system. I appreciate what you have done in focusing on quality in our Medicare system. You have done a great work here, and I am happy to be a part of this challenging product.

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# 21

# A Physician's Response to the Institute of Medicine Report

*Arnold S. Relman*

I am very pleased to have the opportunity to participate in this meeting and to give you my reactions to this report (IOM, 1990).

First, let me make it clear that I speak purely as an individual. *The New England Journal of Medicine* and its owners, the Massachusetts Medical Society, take no public position on policy issues through the *Journal*, and I do not express the views of any organization. I express my own personal views for what they are worth.

Second, I want to say that I have read the Institute of Medicine (IOM) report and I must say I was impressed. I have been around this institution for a while. I have chaired other studies. I have been involved in the production of reports. I have been on the Executive Council of this organization, so I know something about how it works, and I must say this is a superb job. I congratulate all involved, the committee and the staff. It is a superb job, well thought out, well written, reflecting an enormous amount of hard work and an enormous amount of available information. It is scholarly, comprehensive, and thoughtful.

I learned a lot from reading all the facts. It puts everything together. If you want to know what is known and what is not known about quality assurance in this country, there it is. So it is an enormously valuable contribution, and I agree basically with the conceptual analysis.

## CONCERNS ABOUT THE PROPOSED STRATEGY

My concerns about your proposals are similar to your concerns about the continuous improvement model: How might it play out? The ideas are very sound. It is hard to argue against the very sensible and reasonable approach

you take. However, as I try to think about how it would play out and what impact it would have on the practice of medicine, I have some reservations.

It all comes down to changing the behavior of physicians. From what I know about the way physicians work and what motivates them. I am concerned that we may be trying to overstructure and overorganize the doctor-patient relationship. The interaction among provider institutions, medical professionals and patients must have a certain degree of autonomy and independence for things to work properly.

## ECONOMIC ASPECTS OF QUALITY CONCERNS

Having said that, let me be a little more specific. I do not think that this report gives sufficient emphasis to the obvious historical fact that concern about quality, the whole quality agenda, comes basically from concern about cost. Yes, it is true that there has always been a concern about the incompetent or the impaired practitioner but basically the reason that the Congress asked the IOM to do this study was not so much worry about bad doctors or bad decisions, but about expensive doctors and expensive decisions. So this is first of all an economic issue. We ought to be paying more attention to economic solutions.

The two big problems are, first, the cost of our health care system, and second, the fact that we do not adequately identify, monitor, or prevent poor quality medical care.

The first problem of expense is mainly a problem of overuse. We have much more data—good hard information—about overuse being a big problem. I agree with Steven Schroeder (Schroeder, 1991) and his colleagues that underuse is also a problem, but we do not have any data on this. We have the uncomfortable feeling that underuse may be a problem because of the way prepaid health care is structured and the incentives that are involved in prepaid health care, but I do not think that this will turn out to be a major issue except when it comes to limited access. Underuse, as I see it, is mainly an access problem. It is true that we have the extraordinary example of Cody Howard, a child who had leukemia. His was the famous case in Oregon where the third party payer—Medicaid—decided not to provide a useful but high technology medical service, bone marrow transplantation. That is a dramatic headline-catching example of what may well be going on at a much lower technology level in prepaid health care arrangements. Nevertheless, I do not think that this dramatic example is as much a concern as the problem of people who have no insurance coverage who never get into the system at all. For them, the third party payer has no decision to make at all, because those people have no third party coverage.

So basically, overuse and underuse are economic problems. How do we deal with that? First, and foremost, we need more information about outcomes

and better evaluation of new technology. Second, we must have more information about what works and what does not, what is cost-effective and what is not. Finally, we have to have more information about what people want, and how they value certain outcomes. I am not going to steal John Wennberg's thunder, because that is the sermon he has been preaching for a long time (Wennberg, 1991), and I totally endorse it. As we look at what works and what does not, what is cost-effective and what is not, and what people want or do not want, it will become clear that much of what we do is not necessary, puts patients at risk, and wastes money. The problem is to organize and fund that kind of research and to make it available to influence doctor behavior.

To do that you have to think about the future of medical practice. I do not believe one can very effectively feed back information about outcomes and technology assessment, or assure quality very effectively, through office practice settings. That is true now, and it is going to be true in the future. It is difficult to envision how a really effective quality assurance program could be applied to the office practice of medicine without being terribly expensive and terribly intrusive.

I do not see a solution to that problem. Therefore, we have to imagine that an effective quality assurance program will be based largely on physicians practicing in groups. That is my major suggestion for an economic approach to the overuse problem. If we have doctors practicing in groups, then information can be generated about what is done. Better records can be kept. Standards can be applied. Feedback can be much more effective, and professional peer oversight is facilitated.

## PROFESSIONALISM

In groups, furthermore, professional values will have a better opportunity to work. Doctors who are practicing alone are thrown back on their own consciences and their own personal values, their own economic imperatives, and their own psychological needs. Very good doctors, practicing alone, may practice superb medicine, but the average doctor and the less-than-average doctor, practicing alone, are not likely to practice as well as if they were practicing in company with at least a few colleagues, where they can talk to one another, look at one another, report on what they do, and where professional standards and values occur.

Professionalism flourishes best when doctors work collegially. Steven Schroeder and I have lived all of our professional lives in a group setting. Of course, each doctor takes care of his or her own patients in an office, and there is a certain private element in the doctor-patient relationship that you cannot do without. I am not saying that patients should be taken care of by a committee of doctors. Medical care should involve one patient and one

doctor at a time. Yet good medical care also requires doctors to be close to their colleagues, to be able to call colleagues in for consultation, to have colleagues look at what they do, to report to their colleagues on what they are doing, and to have collegial judgment and professional standards influence the private interaction between doctor and patient.

That is why I believe that one key to improving the quality of health care in the future is to encourage group practice. At the present time I think that less than 5 percent of Medicare is provided through prepayment and group arrangements. We should try to increase that percentage, and we should try to be developing quality assurance methods that focus on doctors practicing in groups. That is where quality assurance is going to be effective, whereas doctors practicing privately and individually in their own offices are going to be very difficult to deal with.

Fee-for-service reimbursement along with the technology explosion is a major factor in increasing costs and overuse of services. We have to face that fact. I am not suggesting we outlaw or restrict fee for service. It is not possible legally, and I am opposed to it in principle. The fee for service option is going to be with us for the foreseeable future, but subsidized insurance (Medicare, Medicaid, and all employer-subsidized health insurance) should move toward capitated arrangements and prepayment arrangements with a group practice. Fee for service should be an option available to those who want and can afford it.

I liked the emphasis in this report on professionalism rather than regulation, and that is discussed in other papers (Bristow, 1991; Cooney, 1991). The way to implement any quality assurance program is to involve physicians and to hold them collectively responsible for what they do. However, the intrusion, the regulation, the administrative forms, and the paperwork should be minimal. Doctors are fed up with the increasingly intrusive regulation they experience. You cannot manage doctors beyond a certain point without jeopardizing morale, esprit, and professional commitment. When you have a sullen, resentful, demoralized medical profession, you have got bad care. At some point, then, regulation and excessive external concern for quality care become counterproductive because doctors become resistant and angry. I do not want to be taken care of by an angry, sullen, demoralized doctor, nor does anyone.

## LEGAL ISSUES

One big problem the IOM report did not touch on sufficiently is the legal impediments to quality assurance. Two branches of government are telling the medical profession very different things. One branch of government, the executive is saying, "We want you to be concerned about quality; we want you to be more professional; we want you to be more concerned about

improving the doctor-patient relationship; and we want you to act like doctors should." The other branch of government, the judiciary, is saying, "You doctors are fundamentally businessmen. We are going to apply antitrust law to you, just like businessmen. You had better not collude; you had better not get together and worry about standards; you had better not tell your competitors how to conduct their business." These mixed messages—and the legal ramifications of misinterpreting or ignoring them—are a big problem indeed.

Medical organizations are afraid of antitrust actions whenever they contemplate disciplinary actions against individual doctors. The fact is that most doctors I know are reluctant to participate in peer review and quality assurance activities because of the legal implications. I know that new legislation is supposed to be protecting them, but the perception and the feelings are that "antitrust law will get you if you do not watch out."

## COST OF THE NEW PROGRAM

I am also concerned about the cost of the program proposed by the IOM committee. Steven Schroeder mentions that it would cost more money (he does not know how much), but it would be worth it (Schroeder, 1991). It will cost a lot of money and require a very large administrative machinery, but my feeling is that we ought to start small. The ideas in this report are excellent, but I would be afraid to start out by applying them wholesale, setting up this new organization, this Medicare Program to Assure Quality (MPAQ). (By the way, the only major criticisms I have of this report are these ghastly new acronyms.) I am concerned about the cost and size of the administrative machinery that would have to be set up, and I am concerned about how you would get all this administrative machinery to work without ruining the morale of the medical profession and ending up with a dispirited, sullen, resentful doctor who says, "I have had it. I am being regulated too much. I went into medicine because I like to take care of patients, and now everyone is telling me what to do."

What you have to do is set up mechanisms that rely on doctors to regulate themselves as much as possible. The only way that you can make sure they do this is to have them practice in groups so they can be responsible as groups, manage their own quality assurance, and be accountable for that. In any case, we ought to try out some of the IOM's ideas on a small scale, in demonstration projects and small trials, rather than in a new national program all at once.

At the same time, we have to deal with the problem of incompetence, which clearly exists. We are going to hear from the Harvard School of Public Health Liability Study that approximately 3 or 4 percent of all hospital admissions lead to one or more adverse events, and about 20 or 25 percent

of those adverse events, or about 1 percent of all hospital admissions, are associated with negligence. Now that is a big problem.

The way to deal with that problem is through a no-fault compensation approach coupled that with a very rigorous and fair system of professional review. We are going to have to set up panels and machinery linked to the occurrence of adverse events for identifying poor practitioners and impaired physicians, and for dealing with them in some way.

## SUMMARY

The quality problem is largely a matter of overuse, limited access, underuse, and incompetence. Limited access and underuse, as they relate to insurance coverage, were clearly not the responsibility of the IOM study committee. We all know that we have got to have a system that provides adequate insurance for all Americans, but that is a separate problem.

The overuse problem can be dealt with through an outcomes and effectiveness approach, like that pioneered by John Wennberg, linked to a gradual movement away from solo practice and fee for service to group practice and capitation. We should make groups responsible for managing the care that they provide, based on the information that will come from a greatly expanded national program of technology assessment outcomes and effectiveness research. We need to put a lot of money into these efforts, and it will be an excellent investment. Although there is no time to discuss this here, a reform in the fee scale would also be helpful in reducing overuse of specialized services.

The problem of incompetence is not being effectively dealt with by the tort liability system. The Harvard study confirms an earlier study in California and doctors, of course, do not need convincing. Doctors have believed for a long time that the tort system was just not working, and the new evidence supports that view. It is not serving patients; it is not serving the profession; it is not serving the public; it is serving the trial lawyers. We should replace it with a no-fault system of some kind and couple that to a very carefully thought-out system for identifying adverse events, negligent practitioners, and impaired practitioners and dealing with them in a way that the public can accept.

In short, I like your report. I think it is conceptually correct. My concern is how your recommendations would play out. The risk is that we would be overadministered and overorganized, and doctors would feel even more harrassed than now. Therefore, I would like to see you start more modestly with demonstration products while working toward making doctors take more responsibility for managing their own care.

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# 22

# An Administration Response to the Institute of Medicine Report from the Agency for Health Care Policy and Research

*Linda K. Demlo*

In reviewing the Institute of Medicine (IOM, 1990) report on quality assurance in the Medicare program, I was struck by the magnitude of the undertaking. The report demonstrates a mastery of the complexities of conceptualizing and measuring quality, as well as the intricacies of operationalizing quality review that is truly impressive. I predict it will serve as a valuable reference for years to come.

## THE AGENCY FOR HEALTH CARE POLICY AND RESEARCH

I will confine my comments to those portions of the report that deal primarily with research, since those functions are most germane to the mission of the Agency for Health Care Policy and Research (AHCPR). The agency was created last December by the Omnibus Budget Reconciliation Act of 1989. Its primary mission is to enhance the quality, appropriateness, and effectiveness of health care services and to improve access to such services. It accomplishes this by establishing a broad base of scientific research and by promoting improvements in clinical practice and in the organization, financing, and delivery of health care services.

The agency replaces the former National Center for Health Services Research and Health Care Technology Assessment, which had traditionally been the primary funder of investigator-initiated health services research. Many of the studies of quality assurance noted in the IOM report were funded by the center. This would include support for the early Experimental Medical Care Review Organizations (EMCROs); various approaches for measuring and improving the quality of patient care; development of measures of disability, health status, and severity of illness; and computerized

medical information systems to monitor patients and assist health care providers in diagnosing and treating illness.

The new agency continues to support investigator-initiated general health services research. This is a fundamental component of our mission. What sets AHCPR apart from its predecessor is an increased attention to clinical practice and medical effectiveness and an explicit legislative charge to promote improvements in clinical practice and the organization, financing, and delivery of services. This is reflected in our mandate to stimulate the development of clinical practice guidelines and to expand our dissemination activities.

We view the creation of the agency and its expanded mission as an opportunity to make quality assurance an important component of the Public Health Service agenda and to continue collaborative activities with the Health Care Financing Administration, other public and private organizations, and professional and consumer groups. The analyses and recommendations of the IOM report will be very instructive as we go about these tasks.

For the remainder of my time, I would like to review our Medical Treatment Effectiveness Program (MEDTEP) and discuss some planned research and demonstration activities that focus on quality measurement and improvement and on medical liability. MEDTEP, in particular, has already been the beneficiary of helpful guidance and counsel from the IOM. We hope to be able to call upon many of you both individually and collectively for future assistance.

## MEDICAL TREATMENT EFFECTIVENESS PROGRAM

AHCPR is responsible for implementing the Department of Health and Human Service's MEDTEP, which supports research to address fundamental questions about what difference medical care makes. Do patients benefit? What treatments work best? Are health care resources well spent? The goal of MEDTEP is to improve the effectiveness and appropriateness of health care services and procedures through a better understanding of the effects of health care practices on patient outcomes.

MEDTEP is built on studies conducted during the past two decades that reveal wide variations in the type and amount of health care provided to apparently similar patients. Those outcomes analyses, combined with evidence that providers will change their behavior when they are given pertinent information about practice patterns and patient outcomes, support the belief that more effective health care is achievable. Toward this goal, we are working collaboratively with other public and private entities to learn more about the effectiveness of health care and to put the results of that research into practice.

MEDTEP has four components. The first is health services research on the outcomes, effectiveness, and appropriateness of health care services and pro

cedures. The second is data base development. Third is the development of clinical practice guidelines, and fourth is the dissemination of research findings. We are currently funding five patient outcome research teams to develop and test methods to reduce inappropriate variations in the treatment of low back pain, heart attacks, cataracts, prostate gland enlargement, and knee replacement. About 26 other research projects address other issues pertaining to outcomes and effectiveness, and we expect these activities to grow over time.

Facilitating the development of clinical practice guidelines, standards, and performance measures is the responsibility of our Office of the Forum for Quality and Effectiveness in Health Care. Here, it is important to emphasize our facilitation role. The results of these efforts will not be practice guidelines developed by federal employees. Rather, they will be developed by representatives of the professional community. Our role is to manage the process for facilitating guidelines development.

The guidelines will be created by practicing physicians; be based on science; and be practical, explicit, and subject to revisions as needed. We expect this process to include the full participation of professional and specialty organizations, scientific bodies such as the IOM, academic medical centers, standard-setting and quality measurement organizations, and research institutions. Consumer groups must also be involved to ensure that the program's processes and guidelines are relevant and understandable from the patient's perspective.

Our current activities include developing a methodology for guideline formulation to foster consistency in the development process and putting in place a set of activities to involve the practicing community in generating guidelines. We are legislatively required to develop an initial set of three guidelines by January 1991.

As patient outcomes research and guidelines are completed, the results will be widely disseminated through journal publication, information networks, and conferences. We will also utilize the resources and expertise of the National Library of Medicine and the Health Resources and Services Administration. In particular, the Bureau of Health Professions will convey appropriate information to geriatric education centers, family medicine departments, general internal medicine departments and the wider network of area health education centers. We will also explore new approaches to health professional education to ensure that research findings are incorporated into academic curricula, continuing education, and other professional education activities.

## QUALITY EVALUATION AND IMPROVEMENT INITIATIVE

Let me now turn to some proposed activities dealing with quality improvement and evaluation. We believe that the effectiveness of ongoing

quality assurance programs is influenced by many factors in addition to clinical practice guidelines. Therefore, we propose to mount a major research and demonstration initiative on methods for health care quality evaluation and improvement. Here again, the IOM report on quality assurance will be most helpful.

A major portion of what the IOM refers to as basic research will be encompassed by the research supported as part of our MEDTEP program. This would include research on patient outcomes and the effectiveness and appropriateness of medical care. One might add to that the generation of basic information on the distribution of quality problems and the "burdens of harm," to use the IOM phrase, including information on the extent of poor technical and interpersonal quality, overuse, and underuse. Such information can guide choices about optimal approaches and emphases in the design of quality assurance programs.

We plan an increased emphasis on applied or operational research aimed at developing tools and methods for ongoing quality assurance and evaluating their effects. Topics that warrant investigation include the relative effects of generic quality screens versus condition-specific review criteria; the integration of treatment information and claims data across multiple providers, payers, and health care settings; the effects of incentives versus sanctions in changing provider behavior; the roles of internal continuous improvement models of quality assurance versus external monitoring in sustaining changes in overall levels of quality over time; and the utility of the continuous improvement model in dealing with clinical problems encountered in ordinary medical practice, such as poor physician decisionmaking. We would also be interested in examining operational links between quality assurance and utilization management and review, considering both prospective and retrospective review criteria and areas of complementarity and disagreement. The effects of the use of clinical practice guidelines would also be important. For example, we would be interested in examining whether quality of care has improved, whether cases are properly classified as exhibiting good or poor quality, what the effects are on malpractice, the feasibility and likelihood of "gaming," the effects on cost, and various systems design and operational issues.

We plan to convene a working conference in late fall or early winter to help develop a research and demonstrations agenda with the expectation that the funded projects will be about evenly split between research and demonstration activities. Our intent is to bring together the "doers" of quality assurance and the research community and see whether we can help to move the field forward.

## MEDICAL LIABILITY PROGRAM

Finally, we are initiating another research and demonstration program in the area of medical liability. I do not need to note the widespread concern

that the current system for resolving claims of medical malpractice is not working well. Concerns focus on the escalating cost of liability insurance, the patient-provider relationship, and the inadequacy of the civil court system to resolve conflict. Many states have enacted tort reforms, which may be expected to have a positive impact on the medical liability problem. However, changes are occurring in health care delivery itself that may further alter the liability environment. Here I have in mind, for example, the potential conflict between malpractice law and cost containment. As physicians respond to declining reimbursement by limiting the performance of procedures once considered necessary, they may be exposed to liability unless legal standards shift to accommodate these new constraints and new standards of practice. As increasing competition drives hospitals and physicians to engage in joint ventures and in joint risk management programs, this sharing of cost, risk, and responsibility raises legal issues such as participation in peer review activities versus possible antitrust exposure and the locus of responsibility for institutional risk management.

To address these and other issues, we will initiate a program of research and demonstrations intended to improve the malpractice liability system. We are interested in supporting activities such as demonstrations and evaluations of the effects of tort reform on medical liability claims, studies of the results of medical effectiveness research as they may pertain to medical liability, and systematic analyses of claims for medical negligence to determine the types of events that lead to bad outcomes, the settings in which they occur, and the circumstances surrounding their occurrence.

## SUMMARY

To summarize, the Agency for Health Care Policy and Research has already charted a course intended to expand the knowledge base about the outcomes, effectiveness, and appropriateness of health care and of systems assessing and improving the quality of care. We see the IOM report as an extremely valuable contribution along this path. We look forward to continuing discussions.

## REFERENCE

Institute of Medicine. *Medicare: A Strategy for Quality Assurance*. Volumes I and II. Lohr, K.N., ed. Washington, D.C.: National Academy Press, 1990.

# 23

# An Administration Response to the Institute of Medicine Report from the Health Care Financing Administration

*Thomas G. Morford*

I am pleased to represent the views of the Health Care Financing Administration (HCFA) on the Institute of Medicine (IOM, 1990) study. We at HCFA are used to being studied, and I always delight in having the opportunity now and then to give the agency's reaction to some of these efforts. I would like to lay out a brief picture of where we have been and where we are going, at least from the HCFA perspective, with the Peer Review Organizations (PROs).

## PROBLEM AREAS IDENTIFIED BY THE HEALTH CARE FINANCING ADMINISTRATION IN THE PAST

At the beginning of my involvement with the PRO program four years ago, we identified three major problem areas that were of sizable proportion.

The first was that we lacked fundamental stability in the program, both within the HCFA and within the PROs themselves. Our policy development was somewhat haphazard; our communications were limited and really more focused on internal operations.

The second was what I viewed as a lack of capability in all the PROs. At that time we simply did not have the talent—the capacity administratively or medically—to run some 50 organizations throughout the United States in the manner that we had set out to do and in the manner that the Congress intended.

The third major area that is critical to the issues in the IOM report was the waste and inefficiency of the case-by-case review process. It is not systematic; consequently, it is subject to wide variation and a waste of resources. We pay $300 million a year for nurse reviewers to look at unending numbers of medical records, which in turn have been xeroxed by

the many hospitals and health maintenance organizations throughout the United States. That nurse reviewer, with a massive set of instructions from HCFA, goes through each medical record, makes appropriate notes, and makes all sorts of initial judgments on quality and appropriateness of care. Because there are 50 PROs times "X" number of nurse reviewers, you get variation in review. In addition, no data are captured. When the nurse reviewer reviews a case and the finding is no problem, the review is wasted in terms of clinical information captured for future use, and the case is shredded. Only those cases with a problem or a potential problem really begin to move along in the system. Consequently, we preserve data for only a brief time from the problem cases and pay little attention to good practices.

## THE HEALTH CARE FINANCING ADMINISTRATION'S STRATEGY FOR PEER REVIEW

Seeing those three major problems, particularly the last in terms of the waste and inefficiency, I have been fond of telling the PROs for the last two years that we are not going to spend $300 million a year to catch a few bad guys and process gobs of medical records. The same issue that faced us four years ago faces us today. At HCFA we believe that we have resolved it and are moving the PRO program in a specific direction.

We have developed a very concrete, very particular strategy to change the approach to peer review in the United States. It had to be done in a very directed, cautious manner and over some reasonable amount of time. First, obviously, we had to stabilize our internal operations and to some extent improve the accountability of both the PROs and ourselves. Three or four years ago we did not know what kinds of quality interventions PROs were taking. We had no data system. If a PRO found a problem, we did not know the severity of the problem. Was it a little problem—was it dotting the i's in the medical record? Was it somebody who had actually done considerable harm? We had no way to get at those issues. One of the primary concerns was to bring some order and accountability to the management of the program.

Second, we wanted to shore up some of the PROs. We knew that they needed technical assistance. We did not have the capacity to run the program as intended, and it took some time. I am also candidly not satisfied yet that in all 50 PROs we have that capacity. Nonetheless, from my parochial perspectives, we have done a great deal to accomplish these two objectives: improving our own management and improving the capability of the PROs.

The other thing that we have begun to do is to develop within the PROs the capability and the data bases to accomplish some of the fundamental changes that we have talked about: to focus on the movement of the program from

case-by-case review with its wasted resources to an examination of outcomes and of patterns of care based on clinical data. This is not simply a "blue sky" notion. This is a very concrete plan we laid out about three and a half years ago, and we have been moving steadily on course to accomplish it.

Plans are great, but you have to fasten the nuts and bolts to get there. There is nobody but HCFA able to accomplish this in the United States. We have seen the ashes of the PSRO[1] program; we have gone through difficulties with the PROs; and we have learned that fundamental steps have to take place for these processes to work. The PROs must have the capacity to analyze the data. They must have the infrastructure, the data systems, and the staff capability. They must have reasonably stable management and an ordered scope of work to be able to make these kinds of changes. Otherwise we have another health services researcher's dream, and a great plan with little hope of ever really accomplishing it.

So we have now fastened the nuts and bolts, and we are moving the program. We are developing and testing a variety of analytic tools, data bases, and hardware configurations to support the kind of transition into a more systematic approach to the assessment of quality of care. The objective of all these efforts is to equip the PROs with the skills and the tools to examine patterns of care and outcomes, to draw inferences about performance, and to share that information with the medical community and with the consumer community.

I want to add a point of emphasis here. We should not forget that the consumer movement is a very important part of this. Although we embrace the notion of continuous quality improvement and our plans for the PROs will clearly foster it, there needs to be by statute and by common sense some kind of concern about patient protection. Although we clearly acknowledge that there are only a very few cases of aberrant providers, that most physicians in the United States are good practitioners, and that most hospitals are good, Congress demands, the consumers demand, and common sense demands that we have some protection against the aberrant provider. It need not be the whole program or cost $300 million a year to catch a few bad guys. That $300 million a year needs to be spent in an orderly process to move toward the collection of data and toward the analysis of data and the kinds of outcomes that we have talked about.

## THE UNIFORM CLINICAL DATA SET ACTIVITY

We have available summaries of the numerous activities we have undertaken to change the course of PRO review (see appendix to this chapter).

[1] Editors' Note: The Professional Standards Review Organization (PSRO) program preceded the current PRO program.

These activities, currently underway within the PRO program, encompass essentially all the IOM recommendations other than those pertaining to oversight and advisory mechanisms.

I want to emphasize one activity that I think is the key to the future of the program: the Uniform Clinical Data Set. Contrary to some popular rumor, we have developed it with extensive advice and assistance from academicians and health services researchers, as well as practicing physicians. This project was started two and a half years ago, and we are in the final stages of field testing it right now. We will begin to implement it in the PROs in the fall. This project forms the basis for fundamental changes in the PRO program. PROs will abstract all of the hospital records they review under current program requirements according to well-documented rules and procedures. That is roughly 20 percent. We are going to capture the data from the medical records.

The data that are collected have two applications. First, to achieve greater consistency and accuracy in PRO review, the abstracted information will be screened by a computerized screening expert system that will identify cases to be reviewed by PRO physicians. These are two critical points. We are going to make the review of the cases consistent and stable. We are going to try to eliminate much of the independent decisionmaking by the nurse reviewers in interpreting our massive instructions. We are going to computerize this front-end process, but we are not going to have the computer make the medical decisions. The purpose of the computerization is to have a uniform, consistent application and then to take the cases as they are appropriately identified to the peer reviewers.

Second, and obviously at least equally important, when linked to currently available claims data the abstracted clinical data will establish an epidemiologic data base that will enable the PROs and HCFA to characterize patterns of care, adjusted for sociodemographic characteristics and risk-adjusted patterns of outcomes, and provide information to the medical community and to the consumer community. This is the data base that we have talked about. This is the data base that everybody would have loved to have had for the last 25 years, and I guess, to put it bluntly, we are going to do it because I am sick of talking about it, and I am sick of listening to the health services research community say, "Gee, it would be great to have the data, then we could analyze the outcomes." It is not going to be perfect by any means, but we are going to use the PROs to abstract the data and develop these sizable data bases. We will be able to share them across the country, with specialty societies for standard setting, with practitioners, and with the health services research community.

In this context, two principal advantages of having the PROs do this are (1) they are reviewing about 20 percent of 12 million discharges in the United States, and we are not going to let that data simply be wasted; and

(2) they are uniquely situated around the country. They are state-based. If they are managing their organizations properly in accordance with the scope of work, they will have strong local roots and be able to interact with the medical and the consumer communities within those states. We are going to provide them the data to be able to do that.

## OTHER ACTIVITIES SPONSORED BY THE HEALTH CARE FINANCING ADMINISTRATION

Just to name a couple of other projects, we have engaged with seven PROs to design an approach to the assessment of quality of care in the noninstitutional setting. We are supplying the PROs analyses of small area variations across the country. We have contracted with the Medical College of Wisconsin and with the Wisconsin PRO to develop a data management and analysis infrastructure to enable the PROs to analyze existing large Medicare claims data bases as well as those other data bases that are emerging. We are currently negotiating a project through the New Hampshire PRO with the Dartmouth School of Medicine to develop the analytic software and supporting hardware for PROs to use in assessing quality of care provided in the area of internal medicine. Those are just several examples, I say with some pride, of an extensive laundry list of the kinds of things that we are in the process of developing.

## CONCLUDING REMARKS

We are moving the program to where we think it ought to be; to where we have heard the research community say it ought to be; to where we have heard organized medicine, as well as practitioners, say it ought to be. I conclude by saying that I appreciate the Institute of Medicine study's having endorsed the plan we unveiled about three and a half years ago. I think it will continue to supply us momentum and the kind of support we need to make these kinds of improvements.

## REFERENCE

Institute of Medicine. *Medicare: A Strategy for Quality Assurance*. Volumes I and II. Lohr, K.N., ed. Washington, D.C.: National Academy Press, 1990.

## APPENDIX QUALITY ACTIVITIES OF THE HEALTH CARE FINANCING ADMINISTRATION

Listed below are seven current activities that support a transition from the current Peer Review Organization (PRO) program to a more systematic approach to assessment of the quality of care. The objective of these efforts is to equip the PROs with skills and tools to enable them to characterize patterns of care and patterns of outcomes in their jurisdictions and, from their correlations, draw inferences about patterns of performance of providers of medical services. For PROs to be able to perform these functions they need an adequate and cost-effective data management infrastructure and the epidemiologic and biostatistical skills to make effective use of the data.

1. We have developed, with extensive advice and assistance from the academic and practicing medical communities, a Uniform Clinical Data Set. This project has been underway for two and a half years and forms one basis for our proposed changes in the PRO program. PROs would abstract, according to well-documented rules and procedures, all of the hospital records they review under current program requirements. The data so collected have two applications. First, to achieve greater consistency and accuracy in PRO review, the abstracted information would be screened by a computerized screening "expert system," which would identify cases to be reviewed by PRO physicians. Second, the abstracted clinical data, when linked to currently available claims data, will establish an epidemiologic data base that will enable the PROs and the Health Care Financing Administration (HCFA) to characterize patterns of care, adjusted for sociodemographic characteristics and risk-adjusted patterns of outcomes.
2. We are currently engaged in a complementary project involving seven PROs to design an approach to the assessment of quality of care in the noninstitutional setting. Here also, the objective is to develop a methodology to characterize patient populations, the patterns of care they receive, and the effects of the care on their health, by recognizing the need to span periods of time and constellations of services. The project focuses on 16 medical areas and will enable PROs to evaluate trends and variations in effectiveness among interventions and among providers to offer useful feedback and stimulate continuing improvement in care. This project began in May 1989 and will last three years.
3. In 1987, we began a $2.6 million project with the American Medical Review Research Center and 12 PROs to use the small-area analysis tool developed by the Codman Research Group and John Wennberg. The project provided PROs with data and software to analyze variations in service use and outcomes in hospital market areas in their states. The objective of this

project was to begin to develop in the PROs the capability to feed back data on patterns of care and of outcome to the provider community and to evaluate the impacts of such an educational activity on practice.

4. We have contracted with the Medical College of Wisconsin, through the Wisconsin PRO, to develop a data management and analysis infrastructure to enable the PROs to analyze the existing large Medicare claims data bases as well as the emerging clinical data bases. The hardware configuration has been designed, the software is being written at this time, and the testing of the system in four PROs will begin shortly.
5. We are currently negotiating a project with the New Hampshire PRO and the Dartmouth School of Medicine to develop epidemiologic and analytic software and supporting hardware for PROs to use in assessing care provided in the area of internal medicine. The products here, as in the previous project, would be made available to PROs and would be in the public domain.
6. We are currently in the process of producing analytic information for PROs on 38 different procedures and/or diagnoses. The information would be analyzed nationally and by state, Metropolitan States Statistical Area, county, and hospital market area. We will present mortality, readmission, and expenditure information. The information would be risk-adjusted for a variety of demographic, socioeconomic, and patient characteristic variables. This is another example of the kind of analysis that PROs could eventually conduct for themselves with software that HCFA would provide.
7. We have undertaken several collaborative analytic efforts with academic medical centers making use of the HCFA claims and clinical data bases. The intent is to stimulate greater academic involvement with the PRO program and bring to it the biostatistical and epidemiologic skills necessary for a successful transition of the program. These efforts have involved the University of Maryland School of Medicine, the University of Pennsylvania College of Medicine, the Dartmouth School of Medicine, Boston University Hospital, and the Medical College of Wisconsin. The latter two have resulted in a joint effort with the PRO of Wisconsin (project 2 above). In addition, proposals have been received from several PROs to conduct evaluations of the quality of care in collaboration with Northwestern University, the Harvard School of Public Health, the University of Minnesota School of Public Health, the University of Michigan School of Public Health, and the RAND Corporation.

# 24

# A Peer Review Organization Response to the Institute of Medicine Report

*William H. Moncrief, Jr.*

The Institute of Medicine (IOM, 1990) report is—I will not say it is the greatest thing since sliced bread—but I think it has affected the Medicare Peer Review Organization (PRO) program positively. In addition to the IOM report, one of the good things to happen to the PRO program has been Thomas Morford for his consistent and positive support and direction for the program (see Morford, 1991). This is the same way that the PRO community looks at the IOM report. It leads us in a positive direction and focuses renewed attention on the quality-related issues that are within the Medicare program. As is mentioned in several papers, there are quality issues in the delivery of care to the Medicare beneficiary.

I would like to emphasize quality issues because in the PRO lexicon a quality issue is a perception by the PRO that there is a problem with the care that the beneficiary has received, but it is not a quality problem until we have discussed the issue(s) with the practitioner or with the provider. So when I say that there are quality issues in the Medicare program, I think these are based on the data that we have and the review that we do. One of the interesting things is that as the Medicare program goes, so goes the private sector. I see the IOM report as setting a course of action that will assure quality of care for all consumers, not only the Medicare population.

## NEW DIRECTIONS SUPPORTED BY THE PRO COMMUNITY

The definition of quality of care is excellent and well reasoned; it includes not only the individual but also the community of patients, the community of consumers. Certainly any quality assurance program must be able to assess the impact of a medical intervention on patient health status.

The PRO community strongly supports the call for the development of a comprehensive patient outcome data base. Historically, as Morford (1991) mentions, the PRO data base has been fragmented and incomplete, and the changes in the focus of the review have further fragmented the PRO data base. This has not permitted the PRO community to come up with any concept of outcomes, nor has it allowed for the development of an efficient or effective patient care review methodology across the continuum of care.

Historically the PRO community has been extremely uneasy with looking at a snapshot of care as we have for the last several years. The emphasis in the IOM report on the continuum of care is to be applauded. In the Third Scope of Work the PRO community is beginning to look outside the acute hospital environment. As it develops expertise in the non-acute hospital review, the PRO community could make a definite contribution to the data accumulating on non-acute hospital care.

The PRO community likewise applauds the shift from focusing on the single event, and on the outlier, to looking at patterns of care. In looking at patterns of care the PRO can focus on institutions, hospital administrations, and hospital medical staffs as deliverers of care, rather than focusing on the single practitioner.

The PRO community certainly agrees that an internal institutionally based quality assurance program must be encouraged and that, at a minimum, good performers should be rewarded with less review. Particularly in the Third Scope of Work the PRO program clearly identifies the problems in the acute hospital environment; problems will be assigned to the hospital, as well as to the practitioner, no matter the source. This is an effort in the PRO program to look at institutionally based delivery of care and to look at patterns of care rather than focusing on the practitioner or the "bad apple."

The development of a comprehensive Medicare outcome data base is not going to come easy. I am pleased to hear, according to Morford (1991), that we will be able to implement the Uniform Clinical Data Set in the near future. However, I think we have to be very careful about using data alone to make judgments about practitioner and provider performance. The American Medical Peer Review Association (AMPRA) believes that, both in the transition period when the data base is being developed and in the long term when the data base is operational, local physician peer review of medical records must continue to play a significant role in the program's ability to validate outcomes and to make final determinations about practitioner and provider performance. Moreover, as Morford (1991) mentions, the PROs have a statutory obligation to take appropriate action in individual cases of unnecessary and poor quality care. The PROs will greatly appreciate a broad data base because it will help them target their review of suspected deficiencies and should lead to a more efficient and effective external monitoring system that is less intrusive on the provider community.

## CONTINUING NEED FOR RECORD REVIEW

The PRO community is concerned about the perception among the media and in some portions of organized medicine that, by emphasizing use of a data base to focus on providers and practitioners, individual case record analysis will be abandoned. We are going to have to continue to review individual case records. The PRO community recognizes its lack of expertise in statistical analysis—that is, the in-house, biostatistical, epidemiological, and other expertise that is required to evaluate the data that the PRO community is accumulating. Thus, we would encourage the capacity building and, indeed, would endorse it enthusiastically.

Historically in the PRO community, practitioner involvement has been almost a pro bono effort. It is very difficult to get the cardiovascular surgeon, the invasive cardiologist, or the neurosurgeon to take a course in epidemiology, health statistics, or similar studies so that he or she can make a better, more scientific contribution to analysis of the PRO data. As we move into this capacity building effort, we hope we will be able to build on those practitioners who are involved in the PRO program and retain them in the PRO program. The PRO community is finding that as we develop practitioners who are skilled in analysis we are losing them to the private sector. We cannot retain them, just as we cannot retain the good review nurses. This is a major problem.

AMPRA and the PRO community are not wedded to the QualPAC and the Council concept.[1] We have endorsed and have encouraged and are on record as saying that HCFA and its Health Standards and Quality Bureau (HSQB) should have readily available to them outside advice and counsel on management of the PRO program. I think that HSQB does take advantage of this. Sometimes I wonder if the expertise that HSQB calls on is quite as constructively critical of the PRO program as it should be. I think that HCFA and HSQB would benefit from outside expertise, and we recommend that a mechanism be found to ensure consistent and frequent input.

The PRO community does not agree with the total IOM report. Although AMPRA supports the self-monitoring and internal organizational improvement, the report also suggests that external regulation and inspection of the type characterized by the existing PRO program is incompatible with or a hindrance to such a goal. The PRO community strongly disagrees with this portion of the report. On the contrary, AMPRA believes that the primary

[1] Editors' Note: The reference is to the IOM recommendation concerning the establishment of an independent expert advisory body for Congress (the Quality Program Advisory Commission or QualPAC) and for the Department of Health and Human Services (the National Council for Medicare Quality Assurance).

impact of the PRO program to date has been to encourage institutions to develop good quality assurance programs. As the PROs implement the Third Scope of Work where providers (hospitals) are assigned quality problems, no matter the source, we will see further movement in this direction. One of the problems with institutions developing an effective, efficient quality assurance program has been that such programs are resource intensive.

The PRO program currently is designed to feed back identified quality concerns to hospitals and direct the institution to take corrective action. We feel that the PRO program is an important stimulant rather than an obstacle to fostering professional self-monitoring and internal organizational movement to this end.

One other issue remains. The study suggests in several points that consideration be given to transferring PRO utilization review activities to other HCFA contractors. AMPRA does not support this idea. We believe that issues of quality and utilization are inextricably linked. Utilization management is very much a quality issue. We also believe that considerable efficiencies are possible when a single entity reviews care for both medical necessity and medical quality.

## SUMMARY

In summary, AMPRA believes that establishing a long-term strategy for Medicare quality assurance is a policy imperative, one that all parties must now work together to achieve. The IOM study has made a valuable contribution to designing a framework and setting a direction for the future. The challenge, as AMPRA sees it and as the study concludes, is not to start over but to strike an appropriate balance between adding new tasks and responsibilities and retaining the best features of the current system.

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# PART X

# Where Do We Go From Here?

# Where Do We Go From Here?

## INTRODUCTION

*Molla S. Donaldson, Jo Harris-Wehling, and Kathleen N. Lohr*

The final part of the proceedings asks about the next steps in implementing the recommendations of the Institute of Medicine report. In closing the conference, two presenters, Ceylon S. Lewis, Jr. and Jerome H. Grossman, provided thoughtful and vigorous support for the report.

Dr. Lewis, who is in the private practice of internal medicine in Tulsa, Oklahoma, also serves on the Board of the Joint Commission on Accreditation of Healthcare Organizations. In his commentary, he reviews major mechanisms in place in the private and public sector to maintain high quality of care such as medical education, board certification, and hospital accreditation. He also comments on the IOM's 10 recommendations and how these might be accomplished by joint efforts of the public and private sectors.

Dr. Grossman is the Chairman and Chief Executive Officer of the New England Medical Center in Boston. He sees the strategy as a "mid-course correction" in the Medicare program, and the maturation of outcomes and health status measures and the involvement of patients in their care as critical to making the shift to a broader definition of quality and outcome. He calls for a long-term investment in quality to develop a national strategy beyond Medicare.

# 25

# Where Do We Go From Here?

*Ceylon S. Lewis, Jr.*

The Institute of Medicine (IOM, 1990) report *Medicare: A Strategy for Quality Assurance* is a challenging and, in my opinion, excellent analysis of the current state of the art of quality monitoring, evaluation, and improvement in the delivery of health care. It is a timely subject that represents a concern of many people in our country. The positions taken in the report that the quality of health care has been, and may continue to be, negatively influenced by cost containment pressures and that, therefore, quality should be addressed in a positive manner are an excellent beginning.

I would like to review briefly the major mechanisms that are in place at present in the private sector and to some degree in the public sector to address the issue of maintenance of high quality of care. I would then like to comment on the ten recommendations in the IOM report.

## CURRENT MECHANISMS FOR ASSURING QUALITY CARE

### Medical Education and Board Certification

The medical profession has in place a number of mechanisms to assure appropriate training and clinical competence of physicians. Other health professions have similar programs in place. Webster's *Third International Dictionary* defines a profession as

> a calling requiring specialized knowledge and often long and intensive preparation, including instruction in skills and methods, as well as in the scientific, historical or scholarly principles underlying such skills and methods, maintaining by force of organization or concerted opinion high standards of achievement and conduct and committing its members to continued study of a kind of work which has for its prime purpose the rendering of public service.

The Liaison Committee on Medical Education (LCME) oversees the standards for curriculum in medical schools and for the maintenance of adequate resources and environment for medical student education. The Accreditation Council for Graduate Medical Education (ACGME) coordinates the activity of the 24 Residency Review Committees that oversee and approve curriculum, resources, and faculty for residency education and carry out an accreditation program based on periodic survey. The American Board of Medical Specialties (ABMS) oversees the 24 specialty boards that are members of the ABMS, and each specialty board oversees the training requirements for eligibility to sit for the examination by the board and for certification by the board.

The ongoing stimuli for maintenance of quality of physicians in terms of clinical competence and knowledge consists of time-limited certification, professional organizations that stress continuing medical education, and the availability of high-quality continuing medical education. These mechanisms do not guarantee cost containment. However, a large amount of data supports the thesis that high-quality care is more cost-effective than low-quality care. Continuing effort to increase and update medical information for health professionals is one of the most potent means of assuring continual improvement in quality of care per se, but society will have to make the difficult decisions on the apportionment of resources to care for our citizens in the future, such as prenatal care compared to terminal care.

## Hospital Accreditation

The environment for providing medical care, particularly for the hospitalized patient, is monitored and accredited primarily by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). In addition to monitoring quality of care through quality assurance and quality improvement mechanisms, the JCAHO is in the process of revamping the standards and monitoring capabilities through a series of approaches under the general term "Agenda for Change." The JCAHO is reducing the complexity of standards and focusing them on key governance, management, patient care, and support functions within the hospital organization. Standards are being created to provide a foundation for continual improvement in quality of care. To monitor performance capabilities more effectively, a method has been created to develop useful performance measures. This method is now being used to formulate sets of indicators related to performance of key functions that will be measured in each institution. The data will be transmitted to the JCAHO for analysis and feedback. This will form the basis for a national data base that incorporates standards, compliance information, and performance data.

One important aspect of the Agenda for Change is to develop an attitude of seeking continual improvement in the quality of care through cooperative

activities of the medical staff, the administration, and the trustees of each health care organization. Greater emphasis will be placed on the role of leaders within each of these components to ensure continued improvement.

Performance indicators that are being developed will be used in measuring results of patient care activities, to identify potential problem areas, and thereby lay a foundation for correcting any problems that may be present. Two groups of indicators—for obstetrics and for anesthesia—have been field-tested for over a year. Later in 1990 they will be field tested in 400 hospitals in the country, with data collection, feedback, and evaluation procedures being tested for general application to all institutions. In addition to these measures, pilot testing is being started this year on indicators for oncology care, cardiovascular care, and trauma care.

In summary, the JCAHO is refocusing standards on key processes to include medication usage, infection control, systematic monitoring by using key indicators, and matching individual credentials with demonstrated performance. The traditional assessment of compliance with specific standards will continue and will be complemented by the collection, analysis, and feedback of data that reflect the actual performance of accredited organizations in undertaking key activities.

## COMMENTS ON THE INSTITUTE OF MEDICINE RECOMMENDATIONS

Recommendation No. 1 in the IOM report calls for an expansion of the mission of Medicare to include an explicit responsibility for assuring the quality of care for Medicare enrollees. One means of doing this might well be by deemed status or by other types of cooperative efforts between government and the private sector. Deemed status is now applied to hospitals that are accredited by the JCAHO and are therefore deemed to have met the Medicare requirements. The IOM report strongly endorses deemed status.

Recommendation No. 2 in the IOM report calls for continuous improvement in the quality of health care and strengthening the ability of the organization and practitioners to assess and improve their performance, to identify barriers, and to generate options to overcome these barriers. This, again, is an excellent recommendation and could be well covered by a deemed status mechanism as noted above.

Recommendation No. 3 calls for restructuring the Medicare Peer Review Organization program to shift the responsibility of the program to monitoring quality of care rather than cost containment. This would be an excellent development, in my opinion, because I think it would do much more to enhance improved quality of care than the current censuring program that has been mandated. Efforts should be made to better coordinate this activity with accreditation.

Recommendations Nos. 4,5,6, and 7 in the IOM report call for structuring the agencies to oversee a program of continued improvement; this certainly appears to be necessary.

Recommendations Nos. 8 and 9 call for adequate resources through the office of the Secretary of the Department of Health and Human Services to provide research funds to support development of clinical practice guidelines and adequate educational activities to enhance the nation's capacity for improved quality of care. Funds are urgently needed at this time to support the development and testing of performance indicators.

Recommendation No. 10 calls for appropriate funds to carry out the recommendations.

The primary suggestion that I have is to develop a strategy to encourage government agencies and private agencies, such as the JCAHO, to work together —much as the Health Care Financing Administration and the JCAHO work together at present with a deemed status mechanism or as the LCME, the Residency Review Committees, and the specialty boards in the private sector carry out the quality assurance functions in medical education. I believe this would produce better results than government working alone.

The patients cared for in hospitals that are not currently accredited by the JCAHO represent a special problem. It may best be addressed as suggested in the report with cooperative efforts, particularly between the private sector JCAHO and government agencies, to develop and utilize a mechanism for nonaccredited institutions to be monitored through performance standards that employ clinical indicators.

## SUMMARY

I think this is an excellent report and believe it points in the right direction: improvement on a continuing basis by using clinical indicators and monitoring methods to provide for our citizens the highest quality of health care that is possible. The next steps should be (1) to develop a strategy to enable adequate funding for development and testing of performance; (2) to develop a strategy for utilizing the private sector initiatives (e.g., JCAHO, ABMS, ACGME) in a combined effort to maintain and improve the quality of care; and (3) to develop a strategy to address the societal issues of resource application in health care.

## REFERENCE

Institute of Medicine. *Medicare: A Strategy for Quality Assurance*. Lohr, K.N., ed. Washington, D.C.: National Academy Press, 1990. (See especially Volume I, Chapter 5 for a discussion of the Joint Commission's accreditation activities and Volume I, Chapter 12 for an explication of the IOM committee's recommendations.)

# 26

# Where Do We Go From Here?

*Jerome H. Grossman*

At the beginning of the conference Steven Schroeder (Schroeder, 1991) asked whether we were going to launch the ship. I am here with a bottle of champagne, and we are going to crack it over the bow of this ship as we put it in the water. This is a terrific report (IOM, 1990). It is the only one I have read that gets better each time I read it. Why does it get better? I think that it comes at a particular moment, and it does two very important things. First, it offers the basis of what I would call a mid-course correction in the Medicare program. It has the intellectual base that brings together what has been fermenting, and it incorporates the beginnings of cultural change in the last decade and gives them form and substance.

Second, the report gives a specific set of recommendations and a program for implementation that I think superbly reflect the realities of public program and government operation. When people ask whether we should just tinker and work on the margins, my answer is no. I would never have said that five or ten years ago. I now understand that there is a legislative and administrative context in which to carry out a program.

With that as background or overview, you may be asking, "Where do we go from here?" The answer is that there are buses outside with placards and lists of Congress people. Each of you will be ending up with a small walk around the White House at four o'clock.

## WHERE TO GO FROM HERE?

These Institute of Medicine (IOM) findings (and recommendations) need to be distributed, reviewed, corroborated, supported, and altered by the critical groups out there. I will come back to this a little bit later. Furthermore, with appropriate corroboration and support, a consortium of parties needs to

come together to press for the legislative and administrative changes called for.

Why should such an effort be undertaken? If it is undertaken, will it succeed? Why should it be supported? I think the shift of definition of purpose —to achieving outcomes for patients—is very important. It needs to be understood, internalized, and externalized, and I have come to understand that this shift in purpose represents a major cultural change. It does not come overnight. It does not come because we all sit here and agree with one another. The changes need a broad and public appreciation and understanding.

## PATIENT OUTCOMES

The shift to outcomes is not just a technical process. The more I look at this, the more I think we have been obsessed in this country with reducing risk through accuracy and data collection. We have gotten so carried away that we believe that if it is not measurable, it is not real. The fact that we now have outcomes and health status measures that are broader than our physiologic measures is, I think, critical to our ability to make the shift to a broader definition of quality and outcome. We can measure things now—accurately, reliably, and repeatedly—that simply were not available in the past to be measured and incorporated into a quality assurance effort.

Within the issue of outcomes, functional status, and satisfaction is another critical shift—namely, a redressing of the balance between those of us who give care and those of us who receive it. There must be a growing understanding that this is a partnership and that we cannot do it alone. Patient preferences, patient control, and levels of patient compliance do affect outcomes. That is one important theme that must be more broadly understood as well as written into legislation.

## EMPHASIZING PROFESSIONALISM

I believe that we need to understand the culture of physicians and hospitals with the objective of getting medical care providers to internalize this broader view of their objectives and roles. Someone asked whether hospitals were willing to look at outcomes. I must say I was a bit taken aback by that. I think many of us have been struggling with it as our purpose for being here. Some might resist, but I cannot imagine that they are very many in number.

The report calls for re-recognizing the role of the professional, re-recognizing some assumptions that people do have positive, virtuous goals. Yes, there are "bad apples," but let us not concentrate all of our time and energy on them because as Relman (1991) says, "We have a lot of sullen people

out there." They are sullen because every morning they wake up, and they think someone is saying, "We know you are committing fraud and abuse. We just have to find out how you're doing it and how much you're doing it." In appealing to providers of care we also need to understand that we tend to like trendy work. During the conference discussions someone suggested that this notion of continuous quality improvement has the feel of a religion. It does to some extent, but that does not make it any less valid. I know we cannot get it written into legislation if it is a religion, so we call it something else.

## LONG-TERM STRATEGIES

One characteristic of past strategies has been an unrelenting focus on cost containment, to which I would add "unrelenting *but unsuccessful* focus on cost containment." In some way, the suggestions and findings of this report reflect what we are learning in American society. Namely, you must keep in mind the long run; you have to be looking out for the long haul. Investment in quality is the lowest cost way of achieving improved health status outcomes. My view of what is proposed here represents the best strategy for cost containment as well as for improved outcomes that we presently have.

How do we make the transition? I have learned that you can have wonderful ideas about what happens ten years from now, but you also have to stay in business every year. We learned that at the Harvard Community Health Plan. I was its first employee. We started it with wonderful ideas about what it should be. In 1969 when we opened, we had the staff ready to take care of 10,000 people. We had fewer than 100 sign up. We had just a little excess capacity, and we lost big, big dollars. So, we have to understand that we have to get from here to there while making it through this—and every—year. I think the IOM committee's ideas about 10 years, about transition, and about mid-course corrections offer just the right tone and reality.

## RESEARCH, TRAINING, AND CAPACITY BUILDING

The report and the conference discussion also featured research, training, and capacity building. To me, this is part of another general theme. We have done a terrific job in this country on physiologic and biologic research. This last decade makes the previous ones look like small potatoes. The wonderful results that will come out of current molecular biology and genetics research are glorious stuff.

We forgot, however, to do the second half of research and development (R&D). Palmer (1991) says it so well: how the system is organized and

operated needs the same R&D—the same phases of implementation, evaluation, and correction. We have done almost no work to bring either the hard or the soft social sciences to stand side by side with what we do in academic medicine. In Japan and in Europe, advances in techniques of production belong to the private sector. In the United States, we do not have a private sector that is sufficiently organized to have that sort of dedication. It is either in the public domain or, in our wonderfully American way, in the voluntary, not-for-profit, academic, collegial environment where we do this work. This begins to focus on that incredibly important piece of work that we are just beginning to do, to improve our understanding of the production process and to make it a more receptive environment for the quality management process.

## UTILITY OF THE STRATEGY

The question I would then turn to is whether this plan and this methodology are intellectually sound. There is no doubt about that. We talked about that at this conference, and I heard no one disagree on that point. Is this approach practical? That clearly comes next. My strong belief is that it is and that it needs to be done. Medicare is a program that has enormous implications beyond itself. It sets national standards. What we do here inevitably affects the tone and quality of life in American medicine. My understanding is that the Health Care Financing Administration (HCFA) says, "Well, we're really doing this stuff already. We don't need legislation, we don't need another 'PAC smack,' another commission. All these people just bother us—let's have smaller government and get on with it." I say no, there is another overarching theme here, and that is that we can no longer be adversarial. It is indeed "getting to yes," and we need all the parties at the table. Both of the proposed entities (QualPAC and the National Council)[1] have the potential to bring together around the same table those who receive, those who provide, and those who pay for care.

Computer systems have allowed us to create computer star wars. With the current "system"[2] the providers sit there while the payers lob 800-

[1] Editors' Note. The reference is to the recommendations for Congress to establish (1) a Quality Program Advisory Commission (QualPAC) for congressional advice and oversight of the proposed Medicare Program to Assure Quality and (2) a National Council for Medicare Quality Assurance for the Department of Health and Human Services.

[2] Editors' Note. The reference is to computer-aided procedures by which physicians and hospitals call an 800 telephone number to receive precertification to admit a patient to the hospital to ensure later payment by the patient's insurance company.

numbers at us. They have their people at their green screens. What do you think that we have—our people at our green screens. If it is this 800-number, this is the right answer. They find that they are not denying enough so they have to change their questions, right? And our guys are sitting there trying to figure out how can I get the next right answer? Well, this is hopeless; it just will not work. The practical utility here is indeed bringing together the parties. Why is the timing so good for this? Because we have reached a magic moment: everybody is miserable.

It took us time, but now we are there. It has got to be better to sit down and talk than to keep going on this way. This report represents a very thoughtful way of bringing those parties together to have that discussion, because while my view of quality and your view of quality and my view of outcomes and yours may be different, we now have the methods, the ability, and the desire to get some resolution. Each of these proposed councils represents a vehicle to send out a very important cultural message.

Gosfield (1991) discusses guidelines, due process, and the scientific method. The development of guidelines really is due process because there is not any scientific basis for developing them. It is due process in which all the parties come together and talk about what they think is appropriate and how it might be done. Until we have the scientific basis, until this research really turns out work 5, 10, and 15 years from now, we need to come to agreement about what we are going to try, the basis on which we are going to try it, and how we are going to assess how it is working. That is a critical part of the agenda. As you propose here, we need to resist the definition of guidelines as part of the process and create the organizational framework in which to carry out these discussions. You set out some principles that bring appropriate methodology and reprofessionalize the process around the organizations, their implementation, evaluation, and correction.

Finally, the IOM highlights the need to conduct sponsored research, to build appropriate capacity, and to train appropriate people. There is a wonderful analogy to the National Institutes of Health. We do not hear about the success of government-sponsored research and training efforts, but we do hear about wonderful science. I do not have any doubt that we can also do wonderful work in the social and behavioral sciences and in the science of management and organization. It will be enormously less expensive than biologic research, and we are on the way, building on efforts begun in the last decade or so. Like that research, it will be supported by a combination of public and private funding. I am less worried about course development and its sponsorship because I think it is attracting good people already.

To build on Heather Palmer's comment, what attracts someone to a career in this research is some belief that 5, 10, or 20 years from now, he or she can continue that career. It is more than the dollars themselves. The

*continuous* funding of this work at an appropriate level is what will attract the best and brightest to that career, and that kind of funding probably has to be public. The mandate has to be there and exist by law, as I think it is beginning to do.

## CONCLUDING REMARKS

I will end as I started, with my affirmation of the IOM's good work. I have my champagne bottle to break across the bow of the bus that we are all going to get on to head up to Congress to get this work done.

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