Quality-of-Care Research
Internal Elegance and External Relevance

Much of quality assessment is based on approaches that have been around for the better part of the 20th century. Even the focus on outcomes dates back more than 80 years to the exhortations of Ernest Codman.1 The inclusion of patient opinion is not new either; consumerism dates back almost half a century and the literature on consumer attitudes and satisfaction has a long history.2 The President’s Advisory Commission on Consumer Protection and Quality in the Health Care Industry spent more than a year discussing the challenges. Its report made more than 50 recommendations to “advance the purposes of continuously reducing the impact and burden of illness, injury, and disability and to improve the health and functioning of the people of the United States.”3 These recommendations focused primarily on using the results of research to improve patient care, as well as building an “ongoing research agenda and capacity for achievement.”

In this issue of THE JOURNAL, the National Roundtable on Health Care Quality of the Institute of Medicine4 identifies important issues related to measurement, assessment, and improvement of quality of care in the United States and concludes that a national focus on improving health care quality is imperative. The roundtable calls for involvement by health care professionals, consumers, and policymakers and points out the importance of increasing research on quality measurement and improvement. While the overwhelming imperative is to assess and improve the quality of health care services, little attention has been devoted to assessing the quality of the research endeavors that support them.

In an insightful contribution to the quality debate, Blumenthal5 called for a “new set of measures and technologies that we have hardly conceived up to this point.” Developing new measures and technologies provides challenges to researchers, clinicians (and the organizations in which they work), and community-oriented and public health personnel, as the boundaries between clinical care and population-focused care increasingly blur.6 Two types of considerations deserve attention, the relevance of research questions and the elegance of the research itself.

Relevance of Research Questions

Quality of care usually encompasses the adequacy of clinical interventions, including the recognition of patients’ needs and their biological, social, and environmental determinants; procedures involved in making a diagnosis; management strategies; and reassessment to judge outcomes. Timeliness, appropriate-ness, and inappropriateness are relevant considerations. From the vantage of policy and populations, a broader concept of quality is needed. Effectiveness, efficiency, and equity of the services become paramount and always involve consideration of characteristics in addition to the clinical interventions themselves.

The “gold standard” for evidence supporting evidence-based medicine has been the randomized, controlled, clinical trial. Unfortunately, this type of study is unable to adequately address these additional characteristics. The extension of quality concerns beyond the clinical context involves new questions, new measures, new technologies, and new standards for adequacy of evidence. Thus, the current concerns regarding elegance of research (study design and methods) need to be balanced with consideration of the relevance of the research.

The issue is not only whether certain interventions are better than others for given conditions, but how research questions are chosen. For instance, research relevant to the elderly will focus policy efforts on the elderly. Moreover, the penchant of US quality efforts for clinical research involving technology (and thus a focus on populations for which technology plays a prime role in averting death) leads to the neglect of topics with much greater potential for saving lives in the long run and improving health both in the short and long term. Black and Roos7 posed the issue starkly: “Were there other patients not considered who could have benefited more?” and “Were there other problems for which greater gain might have been achieved?” These questions are rarely asked by researchers who choose research priorities or those who fund the research. Some important issues are currently underrepresented in the research literature.

Importance of Patients’ Problems.—At least partly because of a heavy focus on the elderly and especially on the hospitalized elderly, a preponderance of research attention is directed at the management of specific diseases or diagnoses. Missing from all but a handful of studies is the essential first step in the clinical assessment process, recognition of patients’ problems and needs. Almost all studies of quality of care start with a diagnosis, a suspected diagnosis, or a particular indicated preventive intervention, and evaluation of quality of care is directed at that particular condition. This is a professionally specified definition of patients’ needs, not a patient-specified definition.8 Good medical care requires that clinicians recognize the problems that patients bring to them, yet this approach fails half the time.9 Available and well-tested classification systems make it possible to focus attention on patients’ problems and their resolution, not simply on morbidity as conceptualized by clinicians. Focusing on patients’ problems makes it possible to include all individuals in quality assessments. Health problems are found at all ages and in all population subgroups, although their particular natures may differ. Study designs that start with patient-defined problems and follow them up through diagnosis, management, and outcomes assessment are an important complement to research strategies that start with professionally specified diagnoses.
The current paradigm of disease-focused quality assessment is more appropriate for specialty-oriented health care services than for primary care, in which people present with problems across the illness spectrum. Patients often have multiple problems, and many of them result in no specific diagnosis. For such challenges to quality of care, new approaches are needed. Particularly relevant in this regard are assessments of the adequacy of outcomes that are generic; ie, they are considerations common to all health problems rather than specific to a disease. The development of tools to assess quality of life is an important contribution, but these tools are not enough. From the viewpoint of quality interventions, it is important to ascertain whether the problems that patients are experiencing are improved. This is what Codman thought should be done and what Mushlin and Appel did in their interesting work in the 1970s. In the latter, patients seen for a variety of conditions in the ambulatory setting were sent postcards after a period of weeks to determine the extent to which their problem had improved. Little has been done to substantially develop this method of assessing quality of care.

**Inappropriate Prescribing.**—Approaches that are not disease specific would open up another heretofore neglected type of research area, inappropriate prescribing. The attention to inappropriate use of antibiotics, with consequent and alarming increases in antibiotic resistance, has focused on the justifiability of particular medications for particular diagnoses. A few health systems, for example in Spain and the United Kingdom, go far beyond this in their systematic and concerted attempts to define and monitor rates of prescribing, at least in primary care practice. These efforts start not with the diagnosis that is associated with the prescription but with the prescribed medications. Where rates of prescribing are high, either overall or for specific categories of medications, practitioners must consider whether their practices are justifiable. Although many quality assessment activities (particularly in managed care organizations) consider medication prescribing as a cost containment issue, little concerted systematic research has been devoted to it.

**Generalizability of Research Findings.**—Research is usually considered exemplary largely because of its methodologic elegance. For example, a recent article selected 6 prototype articles to provide justification for directing health care policy. All 6 articles dealt with specific clinical entities that primarily affect the elderly, the most costly health care challenge. Moreover, all but 1 of the articles involved predominantly male or white patient populations. Basing policy on these studies would lead to a strategy that focuses on elderly men, even though this is the only age group for which the United States already performs well among its peer industrialized nations with regard to life expectancy at age 80 years. Where the United States falls short is with other age groups, particularly children and young adults. A continued focus on the elderly hardly seems appropriate when there are so many concerns for quality in other age groups. The availability of an administrative database (ie, the Medicare files) has greatly facilitated research involving the elderly, but it does not provide a good rationale for decisions about what research is needed. If concern for justice should inform the choice of research topics, then the greater relative needs of the young in the United States should receive increased attention in the design of research studies.

The current vogue for evidence-based medicine, laudable as it is, neglects the fact that the adequacy of evidence for policy-making is only as good as the relevance of the studies that produced it. Unfortunately, internal elegance rather than external relevance characterizes most research, including controlled clinical trials that, on average, succeed in enrolling only 15% to 30% of eligible subjects. Even those who are eligible are usually highly selected by virtue of where they receive care, their sociodemographic characteristics (including social class), and the absence of comorbidity. Thus, a critical feature of ethical quality of care, equity in its delivery, is poorly served by a focus on such trials, at least in their current form, as the sole means of getting it. The topics for study and those who participate in studies are so highly selected that the research falls far short of representing the composition and needs of the population.

**Elegance of Research Designs**

New areas of research are documenting the importance of clinically relevant but nonclinical determinants of health status. Omission of these important determinants from research investigations compounds the problem of inadequate research questions. Many, if not most, studies of quality of care fail to include relevant sociodemographic and ecological variables, the effect of health system characteristics on outcome, the role of consumer experiences, and attention to adequacy of available information. Although the limitations of the biomedical model are well recognized, this recognition has not led to an increased inclusion of social variables in research designs.

Epidemiological teaching about the importance of including age in all analyses has not been accompanied by the routine inclusion of variables related to social characteristics such as family income, even though these are among the most important determinants of health and responsiveness to medical intervention.

**Ecological Characteristics.**—Although the literature on social determinants of health is old and its relevance to policymaking heightened by the publication of major policy documents, insights into the importance of relative (rather than absolute) material deprivation within societies are relatively new and are a good example of the need to consider not only the characteristics of individuals but their position relative to those in their milieu. The admonition to avoid ecological fallacy is blinding researchers to the need for consideration and inclusion, where appropriate, of these ecological characteristics, ie, the context in which people live and work.

**Role of Health Care Services Organization.**—The way in which health care services are organized and delivered is another clinically relevant but nonclinical determinant of health outcomes. Health policies, through their influence on the organization of health care services, have a major impact not only on what clinicians do but also on their effect in improving health (also L. Shi, Barbara Starfield, MD, MPH, B. Kennedy, I. Kawachi, unpublished data, 1998). For example, the importance of characteristics such as freely chosen primary care physicians or requirements for co-payments receive attention in the health care services research literature but are rarely included as relevant characteristics in studies of quality of care, even though these factors influence outcomes.

**Consumer Experiences.**—The literature on patient satisfaction is not new in the health care services research literature. What is new, however, is the implication that satisfaction surveys provide a reasonable measure of the quality of care and consumer input into decision making. Satisfaction with care is an important consideration because it is known to be related to adherence to prescribed regimens. However, it is
not a substitute for patients' experiences. Moreover, satisfaction surveys are among the less effective methods of consumer input, at least when compared with strategies to enhance consumer influence on decisions about budgets and resource allocation. Meaningful choice of health plans and practitioners is far more effective as a mechanism of consumer input than are satisfaction surveys. However, in the presence of evidence that most individuals with employer-provider insurance have little choice, satisfaction surveys serve primarily to help employers make paternalistic decisions about the best options for the employees, who have limited ability to freely choose their health plan or health care practitioner. This is why consumer "report cards" are more useful as a marketing strategy than as a strategy for evaluating quality of care. As a strategy for understanding quality of care and outcomes, consumer experiences make more sense as research variables.

Need for Better Information.—The absence of relevant data items is compounded by problems of poor data quality. More adequate information systems will facilitate better research only if they contain the information that is needed to address current deficiencies in knowledge. The imperative to develop standards for the electronic medical record, through the Health Insurance Portability and Accountability Act of 1996, provides an excellent opportunity to rethink the nature of clinical and clinically relevant data and how new approaches to obtaining and recording it could overcome the current problems with incomplete and inaccurate information. More widespread acceptance of the importance of key data elements in enrollment and encounter data sets, with their standardization, should go a long way in remedying the deficits in current information systems, whether used for clinical purposes or for research. If this opportunity is missed it may be another century before new and effective ways of thinking about improving quality emerge.

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