

**A RAND NOTE**

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of Methods for Monitoring the Results of  
Medical Care**

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**RAND**

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# The Medical Outcomes Study

## An Application of Methods for Monitoring the Results of Medical Care

Alvin R. Tarlov, MD; John E. Ware, Jr, PhD; Sheldon Greenfield, MD; Eugene C. Nelson, DSc; Edward Perrin, PhD; Michael Zubkoff, PhD

The Medical Outcomes Study was designed to (1) determine whether variations in patient outcomes are explained by differences in system of care, clinician specialty, and clinicians' technical and interpersonal styles and (2) develop more practical tools for the routine monitoring of patient outcomes in medical practice. Outcomes included clinical end points; physical, social, and role functioning in everyday living; patients' perceptions of their general health and well-being; and satisfaction with treatment. Populations of clinicians (n = 523) were randomly sampled from different health care settings in Boston, Mass; Chicago, Ill; and Los Angeles, Calif. In the cross-sectional study, adult patients (n = 22 462) evaluated their health status and treatment. A sample of these patients (n = 2349) with diabetes, hypertension, coronary heart disease, and/or depression were selected for the longitudinal study. Their hospitalizations and other treatments were monitored and they periodically reported outcomes of care. At the beginning and end of the longitudinal study, Medical Outcomes Study staff performed physical examinations and laboratory tests. Results will be reported serially, primarily in THE JOURNAL.

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THE MEDICAL care system in the United States is being restructured, with the goal of containing rising health care expenditures. Cost-containment strategies, which have included diagnosis related groups, prepaid health plans, preferred provider organizations, and professional review organizations, have as their major purpose restraining the use of high-cost medical services. Yet little attention has been paid to how

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patients' health and level of functioning in everyday activities are affected by these and other strategies.

The Medical Outcomes Study (MOS) was a 2-year observational study designed to help understand how specific components of the health care system affect the outcomes of care. The MOS has two purposes: (1) to relate variations in patient outcomes to differences in the system from which the patient receives care, clinician specialty training, the intensity of resource use, and clinicians' technical and interpersonal styles and (2) to develop more practical tools for monitoring patient outcomes, and their determinants, in routine practice. We are particularly interested in improving methods for identifying key features of medical care that are associated with favorable patient outcomes, so that these features can be preserved despite the constraints imposed by an increasingly cost-conscious health care environment.

The study examines variations in use of resources, the clinicians' technical and interpersonal styles, and outcomes

for patients with one or more of four chronic conditions that commonly affect adults: hypertension, coronary heart disease, diabetes, and depression. The project includes both cross-sectional data based on a single observation and longitudinal data based on observations repeated during 2 years. Among a number of noteworthy features, the MOS (1) assesses a broad array of patient-reported outcomes (physical, mental, and social/role functioning; general health perceptions; and satisfaction with care), in addition to traditionally measured clinical end points; (2) emphasizes information obtained directly from patients in addition to that obtained from clinicians and the medical and financial records; (3) uses results of independent physical and laboratory examinations performed at the beginning and end of the study to verify diagnoses, severity, and comorbidity; (4) measures and adjusts for differences in patient case mix across practices; (5) evaluates patients so as to estimate the effects of physician specialty and system of care on their outcomes; and (6) was replicated in three sites (Boston, Mass; Chicago, Ill; and Los Angeles, Calif).

This article introduces the conceptual framework and major study variables of the MOS, identifies the major research questions, explains the rationale for the study design, and presents an overview of planned analyses that will be reported serially. Two companion articles<sup>1,2</sup> present cross-sectional findings on the effects of chronic medical and psychiatric conditions on functional status and well-being.

### CONCEPTUAL FRAMEWORK, STUDY VARIABLES, AND RESEARCH QUESTIONS

A useful approach to thinking about ways to monitor the results of medical care is to begin with outcomes and then to examine variations in both the pro-

cesses of care and the structural features thought to be most important in explaining and determining those outcomes.<sup>3,4</sup> Figure 1 illustrates this framework and lists the major structural, process, and outcome variables studied in the MOS.

Although the structural characteristics of medical care have traditionally been considered relatively stable,<sup>4</sup> in recent times they have become the tools of cost containment. By sampling providers and patients from the dominant systems of care in the United States, including solo and group practices, as well as prepaid and fee-for-service (FFS) arrangements, the MOS provides an opportunity to estimate the influence of a number of structural features, including organization of practice, physician specialty mix, financial incentives for providers and patients, work load, and the accessibility and convenience of services. Other important structural variables are measured, including characteristics of providers and patients that might account for some of the variation in process and outcomes (Fig 1).

In defining process of care, we distinguish two distinct components of practice style: technical and interpersonal.<sup>4,5</sup> *Technical style of care* refers to the specific services used and the way in which episodes of treatment are managed, including considerations of continuity of care and its coordination. We measure the quantity of health care resources used in terms of visit rates, medications prescribed, referrals made, tests ordered, and hospitalization rates.<sup>6,8</sup> These measures can be analyzed separately or aggregated in terms of charges to allow us to address the economic implications of different practice styles.<sup>6</sup>

*Continuity of care* refers to the extent to which patients see the same provider(s) on successive visits and whether a patient identifies a principal-care physician. *Coordination of care* refers to the extent to which a patient's principal-care physician is aware of all treatments a patient is receiving and communicates with all other providers.

*Interpersonal style* includes many aspects of the way clinicians relate to patients. It encompasses friendliness, courtesy, respect, and sensitivity; the extent to which patients participate in making decisions and share responsibility for their treatment; whether the clinicians counsel patients about their health habits, the need to comply with treatment recommendations, and personal and emotional problems; and the overall level of communication.

A hallmark of the MOS is its reliance on a broad array of outcome measures, including parallel assessments of dis-

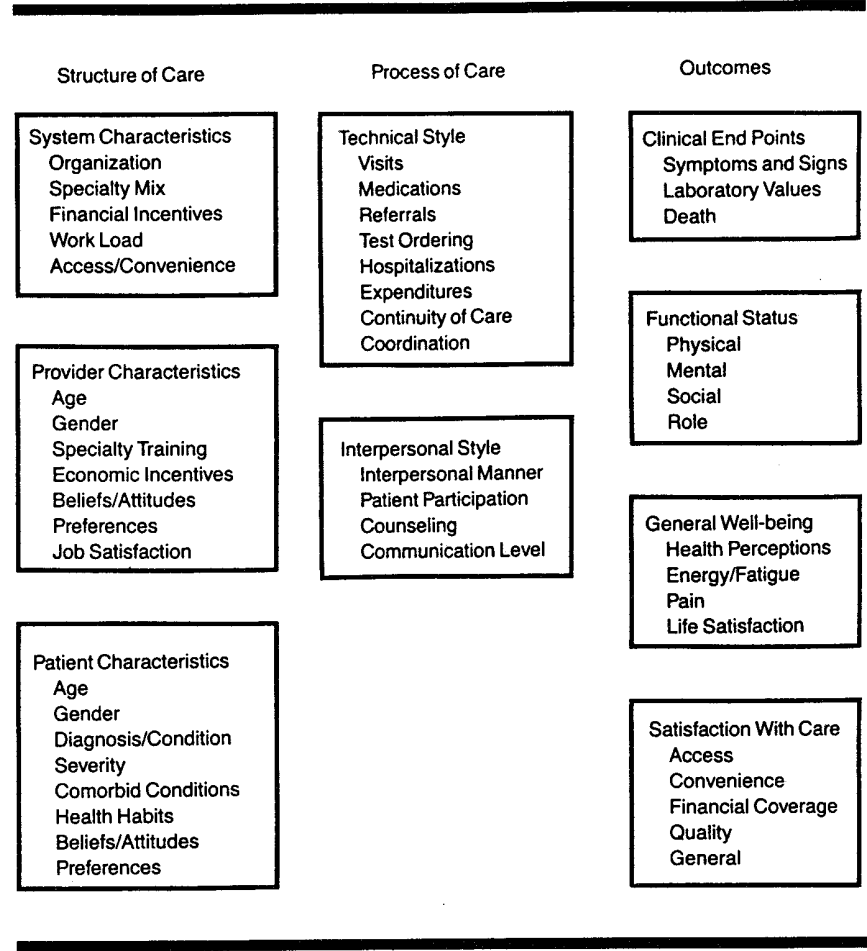


Fig 1.—The Medical Outcomes Study's conceptual framework.

Table 1.—Major Study Questions

<b>Systems of care</b> How do patient outcomes vary across systems of care that differ in organizational and financial arrangements? What is the relationship between system of care and style of practice and intensity of use of medical care resources?
<b>Styles of practice</b> What is the relationship between patient outcomes and style of practice and intensity of use of medical care resources?
<b>Specialty issues</b> How do patient outcomes, practice style, and use of medical care resources vary when care is managed by providers trained in different specialties? What are the differences in case mix for patients treated by various specialty groups in different systems of care?
<b>Outcomes for the poor and elderly</b> Do differences in practice styles and health outcomes across systems of care vary for key population subgroups (Medicare and Medicaid)?
<b>Advancing the state of the art of outcome assessment</b> What is the impact of chronic disease on patient functioning and well-being and what factors account for variations in these outcomes? What methods work best in monitoring patient outcomes in general medical practice?

ease-specific clinical end points traditionally measured by clinicians as well as generic measures of functional status, well-being, and satisfaction with care as reported by patients. Our emphasis on the patient's perspective about the results of medical care is consistent with an emerging trend in clinical and health policy studies.<sup>9,13</sup> We hypothesize that this more encompassing

assessment of outcome increases the likelihood of detecting the consequences to patients of policies that modify the structure of the health care system or the process of care. Measuring disease-specific end points, as well as a common set of generic health outcomes for various conditions, will also contribute a new database that will allow physicians to inform patients about the trade-offs

Table 2.—Systems of Care\*

System of Care	Practice Organization	Physician Specialty Mix	Patient Payment Arrangement
Prepaid group practice form of HMO	Group	Mixed	Prepaid
Large multispecialty group—prepaid	Group	Mixed	Prepaid
Large multispecialty group—FFS	Group	Mixed	FFS
Solo FFS practice	Solo	Single	FFS
Independent practice association	Solo	Single	Prepaid

\*HMO indicates health maintenance organization; and FFS, fee for service.

they may experience with different treatment options.<sup>14</sup>

Eight major research questions guided the design of the MOS (Table 1). They address the implications for patient outcomes of differences in systems of care, styles of practice, and physician specialty. Other questions are related to the study objective of advancing the state of the art of outcome assessment as a tool in health policy evaluation, clinical research, and medical practice.

## STUDY DESIGN

The study was designed to ensure meaningful comparisons between medical care processes and outcomes as they are affected by system of care and clinician specialty, as well as by patients' diagnoses and levels of illness severity. Implementation of the study involved a five-step process: (1) selection of appropriate geographic sites; (2) selection of systems of care; (3) selection and recruitment of clinicians; (4) selection and recruitment of patients; and (5) data collection.

## Site Selection

The three study sites met the following criteria: (1) presence of a health maintenance organization (HMO) with at least 100 000 enrollees that has been in existence for at least 3 years; (2) presence of numerous multispecialty groups, with at least 10 physicians in each, that have been in existence for at least 3 years and that include a mixture of prepaid and FFS payment arrangements; and (3) willingness of HMOs and multispecialty groups and physicians in solo practice to participate in the study.

Sites from three of the four US census regions were chosen: Boston, Chicago, and Los Angeles. Participants from these sites included two of the largest HMOs in the United States that employ salaried physicians and one of the largest independent practice association networks. Two of these cities are among the top five in terms of patient enrollment in independent practice associations, another form of HMO.

## Selection of Systems of Care

To represent the five systems of care shown in Table 2, populations of clinicians were sampled according to practice organization (group vs solo), physician specialty mix within a group, and the payment arrangements of their patients (prepaid vs FFS). One prepaid group practice form of HMO was selected in each city. Physicians and patients were recruited from the main facility of each HMO and from 23 of their satellite facilities. Multispecialty groups were limited to practices that represented family medicine or general internal medicine, cardiology, or endocrinology and formally trained mental health specialists (eg, psychiatrists, clinical psychologists, and social workers) who practiced independently in these settings. Included were 25 multispecialty group facilities serving the same areas as the HMOs.<sup>15</sup>

These types of practices were sampled because they are among the organizational forms most likely to dominate the provision of health services in the coming decade. Comparisons of outcomes for patients treated on a prepaid vs FFS basis in large multispecialty groups and for patients treated on a prepaid vs FFS basis in solo practices will be particularly interesting because they provide a pure test of the effect of payment arrangements, holding constant both physician and practice setting.

## Selection and Recruitment of Clinicians

Populations of physicians were sampled according to specialty training, age, and experience. The study was limited to physicians in family practice, general internal medicine, cardiology, endocrinology, and psychiatry and to clinical psychologists and other mental health professionals who treat patients with the four chronic conditions selected for study.

Physicians between the ages of 31 and 55 years were eligible. Thus, internists and subspecialists in the study were

trained at the same time as family physicians. To participate in the study, generalists (n = 285) had to have completed 3 years of training in their specialty and subspecialists (n = 140) 2 years of training; both had to be board certified or board eligible. Clinical psychologists (n = 74) and other nonphysician mental health professionals (n = 24) had to be licensed for independent practice. All providers (n = 523) had to have had at least 3 years of practice experience and patient care as their principal activity.

The success of this study depended in large part on the endorsement of professional organizations and their active involvement in the recruitment and retention of individual providers. A network of prominent leaders of the American Academy of Family Physicians, the American College of Physicians, the American Psychiatric Association, and the American Psychological Association personally contacted eligible providers on behalf of the MOS.

We attempted to recruit all 266 eligible clinicians practicing in HMO and large multispecialty group facilities. Of these, 245 (92.1%) completed clinician background questionnaires and 225 (84.6%) contributed patients. To sample the population of eligible clinicians from solo practices within the areas served by the groups, a multistage selection process was used. A random sample of clinicians was selected from lists provided by national professional associations. We were able to contact 1525 (68.8%) of these clinicians to verify their practice location and to determine their eligibility. Those contacted did not differ from those not contacted in terms of age, gender, or foreign training. Of those contacted, 511 were eligible and agreed to further selection interviews. Of these, 338 (66.1%) completed clinician background questionnaires and 298 (58.3%) contributed patients to the study. Participants did not differ from nonparticipants in terms of age, gender, site, specialty training, foreign training, or percentage of FFS patients. However, participants were likely to spend more time in direct patient care. Additional details regarding the sampling of clinicians are reported elsewhere.<sup>15</sup> The representativeness of the study sample will be discussed further when results are reported.

## Selection and Recruitment of Patients

We sampled populations of adults with selected chronic conditions or "tracers." Simply defined, tracers are "specific health problems that when combined in sets, allow health care evaluators to pinpoint the strengths and

weaknesses of a particular medical practice setting or an entire health service network by examining the interaction between providers, patients, and their environments."<sup>16</sup> This evaluation strategy is analogous to the use of radioactive tracers to evaluate bodily function. The MOS monitors how patients with these conditions "flow through the system," including how they are managed and the outcomes that are produced. We assume that the management of these conditions and the outcomes that are produced together indicate the overall quality of each system of health care provision.

Using *chronic* tracer conditions to assess outcomes for patients has a number of advantages. First, adults with chronic conditions account for a substantial proportion of health care visits and expenditures. Second, patients with chronic conditions have more to gain or lose from the changes being made in the health care system than healthy adults. Third, studying very similar groups of patients with the same diagnoses makes possible more valid comparisons between systems of care and specialty groups.

We commissioned critical reviews of 12 potential tracers, including 9 that affect adults and 3 that affect children. The reviewers evaluated the extent to which each fulfilled study requirements. These reports were, in turn, critiqued by independent experts.<sup>15</sup> The four chronic conditions that were selected met the following requirements: (1) a high prevalence in the general population; (2) straightforward case finding; (3) inexpensive and noninvasive ways to measure severity; (4) documented variations in typical treatments; (5) treatments of known efficacy; and (6) the conditions and treatments have a substantial impact on patients' functional status and well-being, the principal MOS outcomes.

Study participants were sampled from those adult patients who visited an enrolled MOS health care provider during a 9-day period beginning in February 1986. Adults seen during this period were asked to complete a 42-item screening form ( $n = 22\,785$ ). For 96% of these patients, their clinicians also completed a 32-item form that included diagnosis, information about the purpose and content of the visit, and variables useful in adjusting for differences in case mix. These physician reports were used to identify patients with hypertension, diabetes, and coronary heart disease. A different method was used to identify depressed patients (see below).

Hypertensives were selected on the basis of systolic and diastolic blood pres-

Table 3.—Sources of Data for Major Study Variables

	Providers	Patients	Medical Record	Clinical Examination
Diagnosis, severity, and medical comorbidity	X	X	X	X
Other patient characteristics		X		X
Provider characteristics	X	X		
System characteristics	X	X	X	
Technical style	X	X	X	X
Interpersonal style	X	X		
Outcomes		X	X	X

sure readings reported by participating physicians. To confirm the diagnosis and severity for this subsample, blood pressure readings and information about medications were obtained during the independent clinical examination conducted by MOS staff.

Patients with diabetes were selected on the basis of physician reports of current diabetes, age of onset, and complications. These reports were checked and the severity of diabetes was determined by physical examination and laboratory tests performed by MOS staff.

The coronary heart disease subsample consisted of two groups: those who had suffered a myocardial infarction within 12 months prior to initial screening for the MOS and had returned to the care of their physicians and those who had congestive heart failure with or without a recent myocardial infarction. For those who had recently had a myocardial infarction, their hospital records are being abstracted to determine risk factors and severity. Confirmation of congestive heart failure was made at the clinical examination.

Because of the low rate of recognition of depressive disorders, we identified depressed patients using an independent two-stage screening procedure consisting of a patient-completed form followed by a structured psychiatric interview for those who exceeded a cutoff on the patient form.<sup>17-20</sup> During the clinical examination, a trained interviewer updated their current status and documented any psychiatric comorbidity. Two subgroups of patients with depression were sampled: those with current unipolar affective disorder (major depression and/or dysthymia) according to the *Diagnostic and Statistical Manual of Mental Disorders, Third Edition*, and those with current depressive symptoms but no current depressive disorder. Additional details are presented in a companion article.<sup>2</sup>

Patients in these four tracer groups ( $n = 2349$ ) were enrolled in the longitudinal portion of the study. Patient participation rates varied with the differ-

ent phases and areas of study. For example, in the accompanying depression study,<sup>2</sup> completed questionnaires were obtained for 74% of group practice patients and 65% of FFS patients. In contrast to most clinical trials, participation was not limited to patients with only one of these four conditions. Inclusion of patients with more than one of these conditions and other comorbidities allowed for a more generalizable study and permitted analysis of the extra patient burden resulting from comorbidity as well as the unique demands these patients place on the medical care system and providers.<sup>1,2</sup>

Our goal was to have at least 1800 patients who would be alive and actively participating in the study after 2 years. A sample of this size or larger has at least an 80% power to detect a difference of about 5% in visit rates, 20% in hospitalization rates, and two points in health outcomes as measured by the 0 to 100-point General Health Rating Index, one of the MOS health outcome scales.<sup>15</sup> This goal has been exceeded. In February 1989, two thousand fifty-six patients (87.5% of those enrolled) were still alive and had completed data collection for the 2-year panel study. Additional details regarding sampling methods, refusal rates, the representativeness of study participants, completion rates for longitudinal assessments, and statistical power for hypothesis testing are presented elsewhere.<sup>15</sup>

## DATA COLLECTION

Planned MOS analyses required the collection of information about patient case mix, variations in technical and interpersonal styles of practice, and provider and patient characteristics that might explain those variations, as well as patient functioning and other outcomes. Such information is not routinely noted in medical records, insurance claim forms, or any other readily available source. Further, no one source of information can be considered a "gold standard." We therefore implemented a complementary set of data collection



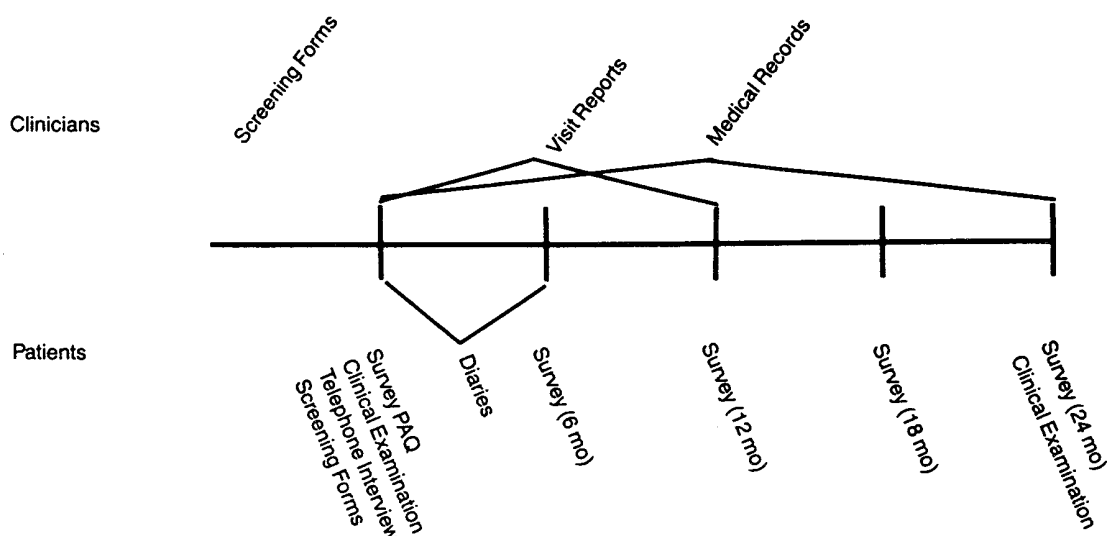


Fig 2.—Schedule of data collection. PAQ indicates patient assessment questionnaire.

strategies to evaluate the usefulness of each as a source of information about variations in style of practice and outcomes of care and to test the sensitivity of conclusions to analyses of different data sources. As summarized in Table 3, the MOS relied on information from clinicians, patients, the medical record, and independent clinical examinations for data on major study variables, which were assessed using data from at least two of those sources. Given the importance of detailed information about case mix, diagnosis, disease severity, and medical and psychiatric comorbidity, these and other case-mix variables were assessed using data from all four sources. In keeping with its emphasis on the patient's point of view, patient assessments of all major variables were collected at baseline and throughout the study.

We used several methods to collect data from providers and patients. For providers, we conducted telephone interviews and collected self-administered questionnaires and forms. For patients, we used self-administered questionnaires and diaries, telephone interviews, face-to-face interviews, and clinical examinations (including physical and laboratory tests) by MOS staff. In addition, hospital records are being abstracted for episodes of inpatient care.

Figure 2 summarizes the schedule of data collection from clinicians and patients. Physicians were asked to complete a 1-minute screening form for all

patients in the cross-sectional study and visit-report forms for each of their patients included in the longitudinal study. Patients in the cross-sectional study completed a separate 12-minute screening form. A sample of those thought to be eligible for the longitudinal study were interviewed by telephone and received a clinical examination by MOS staff at the beginning of the study. Patients in the longitudinal study completed a comprehensive patient assessment questionnaire at baseline and at 6-month intervals for 2 years. During the first 6 months, they also reported acute disability, symptoms, use of health care services, and charges in monthly diaries. The independent clinical examination was repeated at the end of 2 years.

#### COMMENT

In light of recent political and socioeconomic developments,<sup>21,22</sup> the salience of the major MOS research questions has increased since the planning of the study began more than 5 years ago. Pressures to control rising health care costs have escalated, yet the impact of cost-containment strategies on the outcomes of care remains unknown.

Outcomes in different systems of care may well vary for the poor and the non-poor and for those among them who differ in severity of illness.<sup>9,10,24</sup> In an era of cost containment, the poor and elderly with chronic conditions may be at greatest risk. Recognizing the federal government's interest in cost-containment

strategies for the Medicare and Medicaid populations,<sup>25</sup> these subgroups will be analyzed separately.

As in all studies of naturally occurring variations and their effects, the interpretation of MOS results will depend on a thorough understanding of whether differences in outcomes reflect variations in practice styles or differences in the case mix of patients treated. Key elements of the MOS case-mix control strategy include (1) sampling by chronic tracer condition; (2) assessment of the severity of tracer and comorbid conditions using newly developed case-mix measures; (3) measurement and testing of case-mix models using data from multiple sources; and (4) use of statistical methods to control for observed differences in case mix. The MOS database was constructed to facilitate formal statistical tests of the adequacy of alternative case-mix models for purposes of estimating variations in use of health care resources, practice styles, and health outcomes. For each kind of analysis, we will examine the sensitivity of conclusions to differences in case-mix specification.

The MOS emphasizes patients' perspectives regarding health outcomes and satisfaction with their care. Our secondary objective is to advance the state of the art of methods for monitoring these perspectives in medical practice. Our first steps included development and refinement of the MOS Short-Form Health Survey and the COOP Function Charts, which are both practi-

cal methods for assessing functional status and well-being.<sup>25,26</sup> The second step was to address fundamental assumptions underlying the use of these generic measures to monitor patient outcomes; namely, that such measures are sensitive to the impact of disease and treatment. The impact of chronic disease on functional status and well-being is the subject of two companion articles,<sup>1,2</sup> which demonstrate noteworthy variations in health profiles for patients with different chronic medical and psychiatric conditions, as well as the usefulness of the MOS Short-Form Health Survey in detecting those differences. We are now testing the usefulness of these and other short-form measures in detecting changes in patient health over time.

There are good reasons for developing more practical tools for monitoring patient functioning and well-being in office practice and in clinical research.<sup>11,13,18,27-29</sup> Such routine assessments would be useful in detecting and explaining decreased functional capacity, keeping track of changes in function over time, making it possible to consider the patient's total functioning better in choosing among therapies, guiding the efficient use of community resources and social services, and predicting more accurately the course of chronic disease.<sup>25</sup>

The MOS is a new paradigm for monitoring the results of medical care. As

such, it required a new database. We have demonstrated the feasibility of collecting the necessary data in a number of diverse practice settings in three cities. The stage is now set for us to evaluate the usefulness of this database in increasing our understanding of how health care policies affect medical management decisions and patient outcomes.

The MOS has been sponsored by grants from the Henry J. Kaiser Family Foundation, The Robert Wood Johnson Foundation, the Pew Charitable Trusts, the National Center for Health Services Research and Technology Assessment, the National Institute on Aging, and the National Institute of Mental Health and by The RAND Corp and the New England Medical Center from their own research funds.

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