global measures of satisfaction to assessing the patient’s perception of care, that is, the patient’s view of the technical and interpersonal aspects of his or her care.

Report cards have been touted as the means by which consumers will make informed choices. But research on how consumers understand the information provided in report cards has been discouraging (Jewett and Hibbard 1996). Consumers do not understand indicators very well and, in fact, interpret them in unintended ways. This is an area where thoughtful development of this technology needs to occur if report cards and performance indicators are to successfully differentiate poorly performing health plans from ones that are doing better.

CONCLUSION

Outcome measurement has come a long way in the last 50 years. Where once measurement was the province of educational and social psychology, the growth of the pharmaceutical industry has fueled the development of refined and sophisticated outcome instruments, finely tuned to expected symptom improvement. Parallel development efforts have produced more general, nonspecific measures of mental health and mental illness. These measures have encouraged others to study questions linked to health care policies. Understanding why each outcome measure was developed, the population for which it was developed, and its strengths and weaknesses will increase the likelihood that outcome effects, if they exist, will be demonstrated. The chapters in Part II should be a valuable resource in matching specific outcome instruments with specific clinical settings.

REFERENCES


CHAPTER 3

Linking Outcome Measurement With Process Measurement for Quality Improvement

Richard C. Hermann, M.D., M.S.

Although the principal focus of this book is outcome measurement, another important dimension of quality assessment—process measurement—requires discussion. After decades of debate over process versus outcome measurement, it is now becoming apparent that improving quality of care requires both types of measurement. (Brugha and Lindsay 1996; Hammermeister et al. 1995; Salzberg et al. 1997).

Recent changes in health care delivery have accelerated the development of methods for quality assessment. There is growing awareness of the variability in the quality of health care, including underuse, overuse, and

This work was supported by NIMH Grants K08-MH001477 and AHRQ R-01HS10303 to Dr. Hermann.
misuse of certain treatments (Chassin and Galvin 1998; Dickey et al. 1998; Hermann 1996). Cost-containment efforts such as utilization review have stirred concerns about quality and have added urgency to assessment efforts. Market forces in health care have greatly intensified competition among plans and providers. Measures are needed to ensure that plans compete not only on the basis of lower cost, but also on higher quality. Consolidation of providers and hospitals into large networks, combined with information-systems development, has provided new opportunities for addressing quality issues (Hermann et al. 2000c).

The resulting pressure for useful quality assessment methods has revealed the strengths and weaknesses of both outcome and process measurement. Their utility may lie in their complementarity: each is more useful and powerful when linked to the other. This chapter compares characteristics of process and outcome measures, explores this complementarity, and illustrates their combined potential for assessing and improving the quality of mental health care.

DEFINITIONS AND MEASURE CHARACTERISTICS

Drawing from Donabedian's (1980) paradigmatic triad, 1 Eddy (1998) described the roles of process and outcome in population-based quality assessment. In a given population, subgroups of patients are at risk for adverse health states, either by having risk factors for new disorders or by having existing conditions that are subject to recurrence, progression, or exacerbation. Often these conditions can be prevented or lessened through appropriate medical care. Assessing the quality of health care in populations takes one of two basic approaches. One approach is to compare the proportion of patients with an adverse health state (including its severity) before and after treatment; these are outcome measures. An alternative approach is to measure the proportion of patients who receive a clinical intervention consistent with evidence-based recommendations; these are process measures.

For example, patients with schizophrenia—a chronic relapsing condition—are at risk for acute episodes characterized by psychosis, disorgan-

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1 In addition to process and outcome, Donabedian's triad also includes "structure," i.e., the stable characteristics of patients, providers, facilities, and organizations that constitute a health care system. Many concepts discussed in this chapter with regard to process can also be applied to measures of structure, particularly the need to evaluate the significance and validity of such measures.
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zation, and decreased functioning. The frequency and severity of relapses can be reduced by the effective use of antipsychotic medications. An outcomes approach to quality measurement would be to assess the severity of psychotic symptoms, level of functioning, or quality of life of a group of patients before and after a pharmacologic intervention. In contrast, a process-based approach would measure aspects of the treatment patients receive or should receive, such as the type of medication and its dose or duration of action (Hermann et al. 2000a).

Case Study: Choosing a Measurement Strategy

BCMHC Inc. is a nonprofit corporation operating five community mental health centers that serve severely mentally ill patients in a New England state. A new Department of Mental Health regulation was issued requiring centers to routinely assess and improve quality of care.

Individuals with schizophrenia constitute the largest proportion of BCMHC's patients. After several years of observation, the organization's chief medical officer had concerns that the quality of care for schizophrenic patients varied among the five centers. He wondered whether some centers were less likely to use state-of-the-art practices to prevent noncompliance and relapse, but he had no data to support his impressions. He resolved to make care for schizophrenia the focus of a quality assessment and improvement initiative. His first question was how to measure the quality of care for schizophrenia in the centers.

Strengths and Limitations of Outcome Measurement

The principal strength of outcome measures can be their clinical relevance. Although clinicians may dispute the best treatment for a given psychiatric disorder, most would agree on desired outcomes such as reduced symptoms, improved functioning, and enhanced quality of life. The importance of these outcomes can serve as a basis for motivating clinicians and other stakeholders to participate in quality improvement work.

Symptoms, functioning, and quality of life can be assessed from both the patient's and the clinician's perspectives. Other views can also be relevant. Employers may be interested in a functional outcome such as missed work days and may use this measure to assess the value of their health plan. A societal perspective might include outcomes within the criminal justice system, such as conviction rates among juveniles. A family perspective could include caregiver burden.

Outcome measurement is efficient, in that it assesses the aggregate impact of all care, whereas process measures provide information about specific interventions. For example, measuring changes in symptoms and
functional outcome in a cohort of schizophrenic patients assesses the impact of all treatment modalities: medication, therapy, patient and family education, and case management.

However, outcome measurement has its limitations, which current methodology has yet to surmount. A national system of "outcomes management," as envisioned by Ellwood (1988), remains more tomorrow's technology than today's. Some of the most definitive and routinely tracked outcomes (e.g., death) occur too rarely or too far downstream from treatment to be useful indicators of quality. Although the number of patients with schizophrenia who ultimately commit suicide has been estimated to be as high as 13%, only a small fraction are at risk during any specific point in time (Harkavy-Friedman and Nelson 1997). This limits the utility of suicide incidence as a quality measure in very large populations.

Perhaps the greatest problem in the field is that poor outcomes result from factors other than the treatment provided. Suicide, for example, could be a consequence of a schizophrenic patient's receiving poor care, but it could also occur for reasons unrelated to quality. Outcome measures may be confounded by a patient's clinical characteristics (such as illness severity and comorbid psychiatric, substance-related, and medical conditions) and factors outside the clinical realm, including whether the patient has housing or social support. Case-mix adjustment can provide a statistical means of controlling for non-treatment factors (e.g., characteristics of schizophrenic patients associated with a higher rate of suicide), but methods have not yet been adequately developed for many conditions and measures in mental health (Ferri et al. 2000a). A final problem with outcomes measurement is illustrated by the following case example.

**Case Study: Implementing Outcomes Measurement**

The chief medical officer implemented brief rating scales to measure symptoms and functioning levels among schizophrenic patients at the five centers. After training, clinicians administered the instrument to new patients at the start of treatment and at successive 6-month intervals. The results were collected and analyzed. Adjustments were made for some potentially confounding factors, such as age, gender, substance abuse, and homelessness. The results, illustrated in Figure 3-1, supported the chief medical officer's hypothesis of variation in patient outcome among the centers. Patients at three of the five centers showed comparable degrees of improvement at 6 months. On average, however, patients at clinic C showed greater improvement and those at clinic E showed less. Subsequently, the results were reviewed with the clinical staff at each site. The data interested the clinicians, particularly at clinic E, but did not provide guidance about the reasons patients at clinic E did less well or how to improve care and outcomes.

![Figure 3-1. Example of measured treatment outcomes of schizophrenia at five community mental health centers. Not shown in this illustrative example, but important for actual use, are data on sample sizes, confidence intervals, and specifications of the case-mix adjustment.](image)

**Strengths and Limitations of Process Measurement**

Process measurement involves the assessment of the interaction between patients and the health care system, including interpersonal and technical aspects of care. Interpersonal processes, such as the quality of clinician-patient communication and the respect accorded to patients during the delivery of care, are often evaluated by surveying patient satisfaction (Hermann et al. 1998). Technical process measures examine treatment content and are typically expressed as the proportion of patients with a given condition who receive an appropriate treatment.

Process measurement is in many ways the inverse of outcomes measurement. Rather than being rare, as are some significant outcomes, treatment processes are common. In contrast to many outcomes, processes can be evaluated concurrently with the delivery of care. Process measures can help clinicians determine where to focus quality improvement efforts, by identifying processes that show significant variance between actual practice and standards of care.

By relying on previously collected data, such as billing claims or pharmacy records, process measurement can be less costly and burdensome to implement and maintain. However, some process measures also require the collection of new data, for example, from medical records or patient surveys.
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The chief medical officer implemented brief rating scales to measure symptoms and functioning levels among schizophrenic patients at each site. After training, clinicians administered the instrument to new patients at the start of treatment and at 6-month intervals. The results were collected and analyzed. Adjustments were made for potentially confounding factors, such as age, gender, substance abuse, and homelessness. The results, illustrated in Figure 3-1, supported the chief medical officer’s hypothesis of variation in patient outcome among the centers. Patients at three of the five centers showed comparable degrees of improvement at 6 months. On average, however, patients at clinic C showed greater improvement and those at clinic E showed less. Subsequently, the results were reviewed with the clinical staff at each site. The data interested the clinicians, particularly at clinic E, but did not provide guidance about the reasons patients at clinic E did less well or how to improve care and outcomes.

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By relying on previously collected data, such as billing claims or pharmacy records, process measurement can be less costly and burdensome to implement and maintain. However, some process measures also require the collection of new data, for example, from medical records or patient surveys.
Process measures are generally less susceptible to confounding variables—and a need for case-mix adjustment—than are outcome measures. Many processes—such as whether a schizophrenic patient is evaluated for substance abuse during an initial assessment—rely on the clinician’s performance rather than a patient’s characteristics, and thus are less influenced by differences among patients. However, some treatment processes depend both on provider practice and patient compliance, and thus measurement results may differ based on the characteristics of the population treated by the clinician. For example, one measure of medication treatment is the proportion of patients with schizophrenia who continue taking an adequate dosage of antipsychotic medication throughout a 6-week acute treatment period. Conformance with this measure depends on both the clinician’s practice and the patient’s agreement and ability to comply. Mediating factors—such as the severity of the patient’s thought disorder and the level of social support—may confound results.

The limitations of process measurement lie less with their implementation than with their significance. There has been little study of their validity, which is thought to be highly variable. Although some measures are derived from research-based evidence, others are not and are based on consensus judgments or clinical opinion (Hermann et al. 2000b). The latter measures may represent high-quality practices, but they can also be arbitrary and can rely existing practice rather than promote higher quality. Process measurement may also promote micromanagement by implicitly recommending how to achieve desired clinical results, whereas outcome measures enhance accountability but leave decision making to clinicians.

**OPPORTUNITIES FOR SYNERGY**

Combining process and outcome measures can serve quality improvement more completely than can either alone.

**Case Study: Integrating Process and Outcome Measurement**

Comparing patient outcomes among the five centers had the desired effect of focusing clinicians on the quality of their care. Initially, clinic E’s staff scrutinized the data, convinced that they would show that their patients were sicker than those at other centers, thus explaining the poorer outcomes. Finding no such evidence, they turned to examine their practices.

Over the course of several meetings, clinicians from all five centers discussed their schizophrenia treatment practices. They developed a list of key areas where their practices varied; prioritizing those that they believed may explain differences in outcome. Drawing on the work of Lehman and Steinwachs (1998) and others, these practices were translated into process measures:

- The proportion of patients with schizophrenia assessed for substance abuse and, if positive, referred for treatment
- The proportion of patients with unremitting psychotic symptoms given a trial of clozapine
- The proportion of patients with poor medication compliance given a trial of depot antipsychotics
- The proportion of patients with multiple hospital admissions enrolled in an assertive community treatment or intensive case management program

These measures were further specified to ensure that the same data sources and measure specifications would be used at each site. At the next 6-month assessment interval, the process measures were implemented in conjunction with the outcome scales.

**Developing a Measurement Strategy**

With limited resources and a nearly infinite number of measurable processes and outcomes, a necessary step is the development of an assessment strategy. Rather than using measurement to monitor existing practice, clinicians should focus on known or suspected problems (also known as opportunities for improvement). The problem selected for improvement should have a high priority—that is, that it affects patients, has important clinical implications, is under the control of the clinicians and staff, and is meaningful to quality improvement participants.

Although advocating for fewer measures over many, Kaplan and Norton (1992) suggest the use of a “balanced scorecard” of performance measures. This approach can unify an organization around a handful of measures in key domains: processes, outcomes, cost, and patient satisfaction. Adding cost recognizes the need for health care organizations to monitor financial performance and acknowledges that clinical decision making allocates limited health care resources. Adding measures of patient satisfaction reflects a customer-focused perspective that is becoming essential in a competitive environment. Figure 3–2 illustrates an example of a balanced approach by the community mental health centers in the case study, using a compass metaphor developed by Nelson et al. in 1996.

**Improvement Methodology**

Among the many emerging models for quality improvement in health care, one of the most developed is continuous quality improvement (CQI). Berwick et al. (1990) outlined some of its key principles:
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### Improvement Methodology

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After the interventions, remeasurement of these processes informed them whether the interventions had successfully changed clinical practice. Remeasurement of outcomes determined whether their patients' clinical and functional status had improved.

NEEDS FOR THE FUTURE

For process measurement to become more useful in quality improvement, it will be necessary to improve the meaningfulness, feasibility, and actionability of these measures.

Validating Process Measures

Validity is a primary consideration in improving the meaningfulness of process measures. A valid measure is one that represents true quality of care. Because there is no gold standard for quality, validity is assessed through indirect means. Face validity can be established by informed judgments of relevant stakeholders (e.g., consumers, clinicians, researchers, and payers). Predictive validity can be determined by establishing a statistical association between conformance with the process measured and subsequent improvement in patient outcome. Linking process measures to clinical outcomes combines their strengths: process measures' ease of use and the evident importance of improved outcomes (Owen et al. 1999).

Statistical analyses of such process-outcome links are few and technically difficult. Large sample sizes are needed, as are accurate measures and multivariate analysis to control for confounding factors. A few preliminary analyses of mental health measures have been conducted. Druss and Rosenheck (1997) studied a Health Plan Employer Data and Information Set (HEDIS) 2.0 measure of ambulatory follow-up after hospitalization for depression, finding the measure to correlate poorly with other proxies for outcome. Melfi et al. (1998) found that adherence to a guideline recommendation for the duration of antidepressant treatment (a HEDIS 3.0 measure) was significantly associated with lower rates of relapse. Owen et al. (1999) determined that patients with schizophrenia who were prescribed lower-than-recommended dosages of oral antipsychotic drugs (a Schizophrenia Patient Outcomes Research Team [PORT] measure) were less likely to respond to treatment than were patients whose dosages were within the recommended range.

Using Core Measure Sets

More than 300 process measures have been proposed by professional groups (e.g., the American Psychiatric Association), managed care organi-
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zations, government agencies (including the Center for Mental Health Services), purchasers, accreditation groups (e.g., the National Committee for Quality Assurance's HEDIS initiative), and researchers (particularly RAND's quality-of-care studies and the University of Maryland's Schizophrenia PORT).

Having numerous measures allows for assessment of multiple domains of quality—such as detection of illness, access to care, and appropriateness of treatments—as well as varied patient populations. But the variety of measures also limits the feasibility of their use. Currently, providers must use different measures to meet requirements of each payer, accreditor, and regulatory agency. Even a single measure, such as readmission rates, can have different specifications, requiring reanalysis for each report.

A solution is the development of one or more core sets of measures with established specifications. Core sets could be used by multiple stakeholders and providers, which would reduce the reporting burden, allow for comparisons across sites, and provide a greater pool of data for benchmarking and case-mix adjustment. A number of organizations, including the American College of Mental Health Administration, the Substance Abuse and Mental Health Services Administration, and the National Association of State Mental Health Program Directors, have launched efforts to develop consensus among stakeholders on measures, but to date this has not been achieved.

The U.S. Agency for Health Policy Research has funded the National Inventory of Mental Health Quality Measures, which is cataloguing the properties of existing process measures (e.g., numerator, denominator, rationale, data source, population, sampling, risk adjustment, validity, reliability, scientific basis, norms, and standards) (Hermann and Palmer, in press; Hermann et al. 2000b, in press). This information will allow areas for future measure development and testing to be identified, enable potential users to access measure information, and provide a foundation from which core sets can be developed. The inventory will be disseminated via the Internet by the Center for Quality Assessment and Improvement in Mental Health at Harvard Medical School (http://www.cqaimh.org).

Acting on Measurement Results

Several factors affect a quality measure’s "actionability," that is, the capacity of a clinician (or other measure users) to act on a result that may reflect a problem with quality. First, only 20% of proposed measures are in routine use, providing a limited pool of results (Hermann et al. 2000b). Wider use can lead to the identification of norms (average values) and benchmarks (standards reflecting best practices), allowing users to interpret their results—for example, as excellent, average, or inadequate—and if the latter, to set goals for improvement. Ideally, norms and benchmarks should be specific to geographic regions and relevant patient subpopulations. Second, there is a need for a typology among measures by user and purpose. Different measures are needed to drive quality improvement within a hospital than those needed for regulatory oversight by a governmental agency. Still other measures are needed to inform consumers in their selection of clinicians and purchasers in selecting among plans.

CONCLUSION

No single instrument or method will adequately assess the quality of mental health care. A combination of methods—including process and outcomes measurement, satisfaction surveys, and surveillance for errors and adverse events—will be needed to improve care in the increasingly complex health care system. Many measures, scales, and surveys have been developed. The next step is to identify the most promising for further development and rigorous testing, separately and in combination.

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CHAPTER 4

Validity, Reliability, and Other Key Concepts in Outcome Assessment and Services Research

Alisa B. Busch, M.D., M.S.

Consumers, health plans, and payers are concerned with purchasing quality mental health services. This, in addition to the desire of clinicians to provide high-quality care, provides impetus for clinicians to measure what we do, assess and define our effectiveness, and use those assessments to improve care. We are in the midst of an explosion of new treatments in pharmacotherapy and psychotherapy, as well as new ways of delivering services. Although many psychiatric treatments have been tested in rigorous

Supported by a postdoctoral training grant from the National Institute of Mental Health. The author would like to thank Paul Cleary, Ph.D., Arnold Epstein, M.D., Richard Frank, Ph.D., Shelly F. Greenfield, M.D., M.P.H., Sharon-Lise Normand, Ph.D., and Lloyd I. Sedler, M.D., for their helpful advice on outcomes assessment and comments on earlier drafts of this chapter.