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An Overview of Outcomes Research and Measurement

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Rapidly rising healthcare costs, questions about effective medical intervention, and the need for efficient delivery of healthcare services have compelled organizations to focus on outcomes research, measurement, and management. Proponents of outcomes measurement predict that it will produce significant benefits, including improved physician and patient information, increased understanding of the effectiveness of different treatment interventions, and established guidelines for medical management. Multiple professional organizations, academic centers, and independent research laboratories, as well as government agencies, are now involved in the research and development of outcomes measurement tools. This article provides some insight into the outcomes phenomenon.

> "We pay dearly for the possession of the intricate machinery which gives us our vivid imagination, our retentive memory, and that power by which we are able to grasp at each moment all the threads of our past experience and to weave them into a new fabric for the service of the present. Mischief begins when the demands of this service cannot be properly met."
> —James J. Putman, MD, *Shattuck Lecture, 1899*
> (Ellwood, 1988, p. 1549)

Background

Continually escalating healthcare costs are generating more and more interest in the area of cost containment methodologies focusing on quality, cost-effective outcomes. As we move forward in this quest for more cost-effective, quality care, the healthcare preamble addresses the need to use outcome information to measure and demonstrate the effectiveness of healthcare practices.

Across the country, managed care organizations (MCOs), large employer groups, and other healthcare networks are using outcomes measurement tools to identify, measure, and evaluate the results of care. These organizations measure and evaluate their return on investment to make effective business decisions for the future. Purchasers and providers of healthcare are required to provide evidence of value in treatment and service. By performing outcomes studies, healthcare organizations are better able to determine which treatment or therapy offers the best clinical, humanistic, and cost-effective outcomes for their members and also to validate the outcome of care.

Programs focused on outcomes research, measurement, and management have emerged over the past decade as a result of rapidly rising healthcare costs, questions about the effectiveness of medical intervention, and the need for efficient delivery of care (Mowinski & Staggers, 1997). Clinicians, epidemiologists, clinical researchers, statisticians, and economists are among those who are becoming actively involved in the field of outcomes research and measurement to address these critical concerns. Many of these groups are designing outcomes tools that will measure the consequences of various therapeutic interventions. They are looking for effective and efficient treatments that produce positive outcomes when applied in day-to-day clinical practice.

Three areas, or domains, of outcomes measurement that evaluate the overall impact of care are clinical, economic, and humanistic measures. Clinical outcomes assess therapeutic results, such as blood pressure control, as well as morbidity and mortality statistics, to determine the effects of treatment. Economic outcomes analyze direct and indirect cost of care. In some instances, time missed from work is included as part of the economic equation. Also, as healthcare shifts toward managed care, consumer satisfaction has become an outcome with economic implications (Kane, 1997). Humanistic outcomes take into account the effects of treatment on the patient's quality of life and ability to function. This assessment includes the quality of care and services that are provided to the patient for a specific event that produces a specific outcome. The patient's perspective of his or her own health status is considered the most recent addition to the outcomes lexicon (Ware & Danes, 1995).

Outcomes can be measured in a variety of ways, depending on who the key stakeholder is: payer, provider, policy maker, researcher, regulatory organization, or government. Interestingly, they all have in common the desire for cost-effective, quality healthcare outcomes. To this end, the field of outcomes measurement has become a critical component of the healthcare industry.

Defining outcomes: An outcomes vocabulary has emerged in healthcare. However, there is no consensus to date on the best approach to defining and measuring outcomes. Without a precise translation of the word *outcome* in its application to healthcare, outcome means different things to different people.

In general, outcomes are the result of treatment or care. For the most part, the healthcare definition of outcomes is interpreted in terms of result, such as change in the patient's condition, the patient's status following intervention, and the effect of the intervention on how the patient functions. Outcomes also include resource consumption or costs, with claims data serving as the primary information source.

The terminology used by professionals and organizations involved in outcomes research and measurement is not standardized. Therefore the definition used by one organization or person can vary significantly from that used by other groups or individuals. Most often outcomes are categorized according to the perspective of the users of the data (Blaiss, 1997). MCOs choose outcomes that focus on cost-effective service in the appropriate setting, balancing cost and quality of care by improving the care delivery process. The National Committee for Quality Assurance (NCQA), the accrediting body for MCOs, considers how well these organizations screen their members for early detection of disease and what they provide for positive intervention. Physicians are interested in the clinical results. Patients focus on the impact of a specific treatment or medical intervention on their health, functional status, and quality of life.

Outcomes are the results, or consequences, of care or lack of care. To determine the effects of care, an outcomes assessment is done. By virtue of the results of this assessment, the care delivery process can be evaluated. Outcomes now represent a new foundation for future clinical decisions about patient care.

Changing times: A whirlwind of change has occurred in the healthcare delivery system over the past decade. As the turbulence continues, so too will the changes necessary to survive. Perceptions and behaviors of payers, providers, government, and consumers are also changing as the healthcare system attempts to reorganize and take on a new image—that of a gatekeeper. The pressure to do more with less is dramatically affecting healthcare. This pressure is forcing the healthcare industry to restructure in order to be more efficient and cost-effective in delivering care.

In 1988, Ellwood proposed that a new technology, outcomes management, be used to evaluate, monitor, and ensure the provision of quality healthcare (Ellwood, 1988). MCOs, healthcare networks, large self-insured employer groups, and even government agencies are examining their "return on investment." They are measuring outcomes and the quality of care in a variety of ways to establish direction for the future. Because third-party payers are demanding information on results of treatment and services, partly as a result of escalating costs, outcomes research and management are flourishing. Consumers expect and are entitled to information for making decisions.

Outcomes Research

Outcomes research activities include, but are not limited to: (a) comparing the cost/benefit or cost/effectiveness ratios of different products, programs, and services, (b) examining the impact of new technologies on patients' health status (quality of life), and (c) identifying segments of a population at risk for certain disease conditions and developing strategies for optimal utilization of healthcare services (Kong & Wertheimer, 1998).

Outcomes research involves methodologically sound collection and analysis of health-related data on the application and results of therapeutic intervention in a specific population. The goal of outcomes research is to systematically analyze which interventions are most effective in terms of outcomes and cost (Mowinski & Staggers, 1997). A focal point of outcomes research is isolation of the effects of treatment on a specific group of individuals. Positive outcomes of treatment are the basis for development of guidelines for best practice.

As Greenfield stated at the twelfth annual meeting of the Society for Medical Decision Making, "If the outcomes field is going to be successful in helping with the creation of guidelines and trying to produce cost-effective care, and if guidelines and medical decision making are going to have any meaningful impact, the two need to be intricately linked and dealt with in every study" (Greenfield, 1990).

Because the results of outcomes research projects have a significant impact on clinical decisions, they must withstand close public scrutiny. Outcomes projects must meet the tests of reliability, validity, reproducibility, and trustworthiness of results to be exempt from skepticism.

Outcomes Measurement

Codman is widely credited with leading the first effort in outcomes measurement, which was direct measurement of clinical care in the 1910s (Campazzi & Lee, 1995). Five decades later, in 1966, Donabedian, one of the founders of contemporary medical quality management systems, proposed a three-tiered flowchart: (a) structure—the characteristics of a healthcare setting, (b) process—what is done to the patient, and (c) outcomes—how the patient does after healthcare intervention (Iezzoni, 1997). Outcomes are regarded by many as the most important measure of clinical care.

Outcomes measurement is defined as the systematic quantitative observation, at a point in time, of outcomes indicators. Outcomes measures are used to demonstrate that established patient goals have been identified and achieved. An outcomes indicator measures performance of functions, processes, and outcomes over time. Thus, the process of using outcomes indicators measures the improvement or lack of improvement after care has been provided.

The healthcare industry is focusing on outcomes information to build a system of accountability (Nash, 1997). Many different instruments have been and are still being developed for outcomes measurement. Although outcomes measures are continually evolving, they provide valid information that can assist clinicians in determining the best therapeutic plan for specific conditions and maintenance of good health.

Various types of outcomes measures include physical/clinical (mortality), performance/function (self care), economic (cost/benefit), and humanistic (quality of life) measurements.

Clinical measures now go beyond the traditional markers of morbidity and mortality; economic outcomes assess direct and indirect cost of care; and humanistic outcomes address the effects of treatment on the patient's quality of life and ability to function.

Types of Outcomes Measurement Tools

Over the past two decades, creators of outcomes measurement tools have greatly enhanced the parameters of generic health assessment (the dimensions of health that are measured). The definition of outcomes has expanded to include results of significance to patients, namely, patients' assessments of their own health and their evaluations of the quality of care and services provided (Ware & Davies, 1995). Researchers note that patients' perceptions of their health have been found to be an important indicator of health. They also note that the shorter and more succinct an outcomes instrument is, the better. Because shorter tools generate higher responses, brevity is recommended whenever possible.

Outcomes measurement tools fall into three major categories: general health/generic measures, disease-specific measures, and functional status measures.

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General health measures: General health measures have historically been used to assess the health status of large populations. Today, the emphasis of general health measurement tools is on the positive aspects of physical, social, and emotional well-being. Generic measures can be particularly useful for surveys that attempt to document the range of disability in a general population or a patient group; however, general health profiles may be unresponsive to changes in specific conditions.

The Medical Outcomes Study Short Form 36 (SF-36) is a general health measure (Ware & Sherbourne, 1992). Because its concepts are not specific to any age, disease, or treatment group, it enables comparisons of the relative burden of different diseases or the relative benefits of different treatments. The SF-36 can be used for comparison across diseases and across settings. The scale assesses the following eight health concepts:

1. Limitations in physical activities because of health problems
2. Limitations in usual activities because of physical health problems
3. Bodily pain
4. General health perceptions
5. Vitality (energy and fatigue)
6. Limitations in social activities because of physical or emotional problems
7. Limitations in usual activities because of emotional problems
8. Mental health (psychological distress and well-being).

Sample questions from the SF-36 are provided in **Table 1.** The SF-36 measures health status and outcomes from the patient's point of view.

SF-36, the 36-item survey of mental and physical functioning and well-being, is used internationally. John Ware, who is principal investigator of the SF-36, said, "This is a very powerful tool for comparing the burdens of disease and the benefits of treatment" (Youngs & Wingerson, 1996, p. 55). [*Editor's Note: An interview with Dr. Ware appears in the September/October issue of* JHQ, *p. 12.*]

Generic health status measures such as the SF-36 cast a wide net but are lacking in sensitivity and specificity (Kane, 1997). Disease-specific symptoms and problems are not included in the SF-36. In fact, many generic tools lack the precision required to enhance effective healthcare decision making.

In addition to the SF-36, other generic tools include the following:

- Child Health Questionnaire (CHQ)
- Nottingham Health Profile

Table 1. Sample Questions from the SF-36

Q2. Compared to 1 year ago, how would you rate your health in general now? Would you say it is
1. Much better now than 1 year ago
2. Somewhat better now than 1 year ago
3. About the same as 1 year ago
4. Somewhat worse now than 1 year ago
5. Much worse now than 1 year ago

Q13. During the past 4 weeks, have you had to cut down the amount of time you spent on work or other regular daily activities as a result of your physical health?
Yes
No

Q18. During the past 4 weeks, have you accomplished less than you would like as a result of any emotional problems, such as feeling depressed or anxious?
Yes
No

Q29. How much of the time during the past 4 weeks have you felt downhearted and blue?
1. All of the time
2. Most of the time
3. A good bit of the time
4. Some of the time
5. A little of the time
6. None of the time

Q35. I expect my health to get worse. Would you say that's
1. Definitely true
2. Mostly true
3. Don't know
4. Mostly false
5. Definitely false

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- Quality of Well-Being Scale (QWB)
- EuroQol
- Health-Related Quality of Life (HRQoL)
- Duke Health Profile
- Consumer Assessment of Health Plans Survey (CAHPS).

Disease-specific measures: Disease-specific measures focus on individual outcomes unique to a specific disease entity. Disease-specific measures are of greatest interest to the patients themselves and to the clinicians who treat them, whereas generic measures, because they permit comparisons across conditions and populations, are of greatest interest to policy and decision makers (Guyatt et al., 1993). Generic measures exhibit breadth but not depth. Conversely, disease-specific measures exhibit great depth but little breadth.

The following are examples of disease-specific measurement tools:

- Adult Asthma QoL Questionnaire (AQLQ)
- Pediatric Asthma Quality of Life Questionnaires for patients (PAQLQ) and caregivers (PACQLQ)
- Sydney Asthma Quality of Life Questionnaire (adult)
- BASIS-32 (Outcomes of Mental Health Treatment)
- Medical Outcomes Survey–HIV Health Survey
- Kidney Disease and Quality of Life SF (KDQOL-SF)
- Prostatism Typology of Patient Experience
- Quality of Life after Myocardial Infarction (QLM)
- "HASSLES" Diabetes-Specific Health Status Measure.

Functional status measures: Functional status measures focus on various aspects of individual patients' performance associated with specific activities. Functional assessment instruments such as the Functional Independence Measure (FIM) tend to focus on treatment outcomes associated with individual rehabilitation performance, whereas general health measures tend to focus on the entire gamut of health status.

The Outcomes Management System (OMS), a set of measurement tools designed to collect standard data about patients' medical experiences across large populations, was developed by the Health Outcomes Institute (HOI) of Bloomington, MN. OMS has two basic components: (a) a 39-item Health Status Questionnaire that asks patients about their health, functional status, and sense of well-being and (b) TyPE, a separate questionnaire that collects extensive data about patients' medical conditions. There are currently 17 TyPEs available from HOI: angina, asthma, carpal tunnel syndrome, cataracts, chronic obstructive pulmonary disease (COPD), chronic sinusitis, depression, diabetes, hip fracture, hip replacement, hypertension/lipid disorder, low-back pain, osteoarthritis of the knee, prostatism, rheumatoid arthritis, stroke, and substance abuse (Youngs & Wingerson, 1996).

Functional status measures originated in the rehabilitation setting, focusing on different aspects of individual patients' performance associated with a specific activity. These measures give healthcare providers standardized criteria for assessing patient performance. Functional status measures have also been used to examine financial barriers that ultimately may have an impact on the outcome of rehabilitation (Stanton, 1997). Functional status measures do not encompass quality-of-life measures or project the impact of environmental or societal barriers on independence when the patient returns to the community. For this reason, it is important to combine a functional status assessment with other tools to capture the patient's full spectrum of needs.

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Outcomes that include patient satisfaction, clinical outcomes, functional health status, and cost provide a comprehensive approach to assessing outcomes (Schriefer, Urden, & Rogers, 1997). Ware and Davies (1995) noted that multi-item scales generally provide greater score variability and higher reliability and validity than single-item measurements. In the future, multi-item scales will be more likely to capture information on patient satisfaction, clinical outcomes, functional health status, and cost, in order to be all-encompassing. These instruments usually have several domains, or dimensions. A domain, or dimension, refers to the area of behavior or experience being measured (e.g., communication, mobility level, nutrition).

Examples of functional status measures are the following:

- London Handicap Scale
- Sickness Impact Profile (SIP)
- McMaster Health Index Questionnaire
- Functioning and Well-Being Profile
- Functional Status Questionnaire
- Seattle Angina Questionnaire (SAQ)
- Minnesota Living with Heart Failure Questionnaire.

Attributes of well-defined outcomes measurement tools: The list of attributes from the Instrument Review Criteria of the Medical Outcomes Trust Scientific Advisory Committee (Weaver et al., 1997) includes the following:

- Conceptual and measurement model (scale and subscale structure)
- Reliability
  - Internal consistency (Cronbach's alpha or KR-20)
  - Reproducibility (test-retest/interobserver)
- Validity
  - Content
  - Construct
  - Relationship to criterion measure
- Responsiveness or sensitivity to change
- Interpretability
- Burden
  - Respondent
  - Administrative
- Alternative forms
- Language and/or cultural adaptations.

Collection of Outcomes Data

To capture outcomes information adequately, data need to be collected, aggregated, and measured correctly. Defining uniform standards for data collection is of critical importance, inasmuch as different methods of data collection can yield different outcomes information.

Without a prototype to delineate the basic components of outcomes management studies, data may be riddled with inaccuracies and misrepresentations. Setting time lines for data collection that will not confound the relationship of severity of illness with complications of the intervention is critical for accurate outcomes reporting. Documenting the patient's condition before therapy or treatment is initiated and comparing the patient's condition after therapy or treatment are essential steps in accurate measurement of outcomes (Blackwell, 1997).

It is important that the measuring, monitoring, and managing of outcomes occur with full awareness of the different levels of analysis and the implications of each. Individual, group, facility, and community outcomes might each be studied by using different conceptual levels, different operational definitions, different parameters, and different techniques.

Outcomes Management and Quality Improvement

The Institute of Medicine defines healthcare quality as "the degree to which health services for individuals and populations increases the likelihood of desired health outcomes that are consistent with current professional knowledge" (Lohr, 1990, p. 21). With more healthcare organizations focusing on cost-effective, quality healthcare, the emphasis on outcomes has intensified. When evaluating outcomes measurement, one must also evaluate the process of care by which the outcome is measured. Measuring the relationship between the process and the outcome is essential for quality improvement; that is, to ensure that the quality of patient care is not compromised, the focus of quality improvement efforts should be directed at the outcome of care.

Outcomes assessment information can help answer the question "What makes a difference?" Another important question is "Does the program function according to the intended design?" Outcome variance may be due to any number of factors, including variances in the way the program is applied.

Outcomes are often judged by the goals that are met or unmet as the goals are translated into outcomes indicators. **Table 2** lists the questions used to develop an outcomes indicator tool.

Table 2. Developing an Outcomes Indicator Tool

What is the goal?
What will be measured?
When will it be measured?
How will the data be collected?
What is the method of data analysis?
What is the indicator?

From this assessment, quality improvement strategies can be developed and implemented, with hopes of future improvement. The outcome indicator is reevaluated after a period of time to assess the outcome.

The effects of well-monitored quality improvement initiatives should be reflected in measurable improvements in outcomes.

Contemporary outcomes management encompasses three components: (a) outcomes measurement—the systematic quantification, at a single point in time, of outcome indicators, (b) outcomes monitoring—repeated measurement of outcomes indicators over time to support casual inferences about how the outcomes were produced, and (c) outcomes management—the use of information gained from monitoring care to achieve optimal outcomes through improved clinical decision making and delivery of quality care. The major goal of outcomes management is to utilize collected data to improve the quality of care rendered in the future. The effects of well-monitored quality improvement initiatives should be reflected in measurable improvements in outcomes.

Outcomes Management and Disease State Management (DSM)

Disease state management (DSM) is the continuous process of identifying and delivering, within selected patient populations, the most efficient combination of resources for the treatment or prevention of disease (Todd & Nash, 1997). Proponents of the DSM approach believe that it holds substantial promise toward improving health outcomes and reducing costs. Outcomes research and healthcare economics are important tools for the ongoing evaluation of the effectiveness and efficiency of disease state management initiatives. Programs cannot be implemented if data are not available to identify problem areas and measure outcomes as interventions are implemented.

Outcomes are examined in relation to interventions for a particular disease or condition. An example of a program goal for asthma management is: reduce the organization's cost of treating asthma patients by improving the process of care while improving patients' health-related quality of life and satisfaction with the healthcare services (Kozma, Kaa, & Reeder, 1997).

DSM brings together outcomes research and clinical management of diseases to provide efficient and cost-effective quality care to patient populations in the continuous quality-improvement environment of disease management. Efforts are focused on identifying diseases for which costs can be reduced while health outcomes are maintained or improved. Outcomes must be measured before, during, and after a DSM program has been initiated in order for the health system to determine whether the clinical, functional, and quality-of-life outcomes have worsened, remained the same, or improved (Armstrong, 1996).

MCOs as well as other health systems have become more interested in DSM programs because of their focus and clarification of the cost-to-outcome relationship in disease management. In the future, the ultimate extension of disease and health management will focus on optimizing health, keeping the patient well, and preventing disease-related complications.

Summary

Outcomes research and measurement have entered an era of unprecedented growth. Proponents of outcomes measurement predict significant benefits, including improved physician and patient information, increased understanding of the effectiveness of different treatment interventions, and established guidelines for medical management. Over the past two decades, creators of outcomes measurement tools have greatly expanded the dimensions that these tools measure.

Although there are no right or obvious guides to determine which point in time is best for examining outcomes, decisions must be made about whether outcomes will be used to reflect inpatient care, an episode of care that bridges inpatient and outpatient care delivery, preventive care, or the management of an entire chronic illness such as congestive heart failure or diabetes (Mowinski & Staggers, 1997). The ultimate goal of outcomes research is to provide insights that lead to greater efficiency and higher quality of care.

Today, outcomes are measured through a series of variables obtained in a variety of ways. Functional status, disability assessment, emotional health, social interaction, general health perception, and cognitive function are among the series of variables that are captured and measured for outcomes assessment. Existing outcomes indicators can be categorized as reflecting diseases, patients, providers, or organizations. The most sophisticated, complete, and useful reflection of outcomes will be derived from a balance of indicators representing a variety of outcomes categories.

The healthcare delivery system is heavily weighted toward the attainment of defined outcomes to evaluate care. To that end, outcomes assessment information can help answer the fundamental questions "Is the patient truly better off as a result of the intervention?" and "What makes a difference?"

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Kate Maloney is director of nursing, OptiCare Health Systems, Norwalk, CT. Ms. Maloney has also worked as a healthcare consultant for several large organizations doing quality improvement, utilization management, and risk management, and as manager of clinical network services for one of the largest medical information systems companies in the country, as case manager for a large managed care organization, as business manager for a large home health agency, as an elected board of health official, and as clinical leader in the operating room of a large teaching hospital.

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