



Continuing Education



Outcomes: Studies and management

Learning Objectives

Describe cost, resource utilization and pharmaco-economic analyses.

Define health-related quality of life and explain how it is measured.

Describe how different outcome areas are managed, and identify major stakeholders in outcomes management.

Describe the role of outcomes studies in developing and maintaining clinical practice guidelines.

Explain how outcomes research is used in disease management.

This second article in a three-part series discusses different types of outcomes studies, health-related quality-of-life measurements, outcomes management and its major stakeholders, the relationship of outcomes studies to clinical practice guidelines, and how outcomes research is used in disease management.

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Outcomes studies involving cost, resource utilization and pharmaco-economic analyses are essential for managed care organizations to remain competitive.

Cost analyses are primarily concerned with the cost of inputs or resources rather than their consequences. These analyses might help an MCO answer questions such as:

- How much money are we spending?
- Where are we overspending or underspending?
- Are there areas where we can allocate resources more efficiently?

Resource utilization analyses (also known as utilization reviews) have been a central part of the cost-containment strategies of MCOs for many years. Much of the information required for utilization reviews can be found in administrative data. A review of the MCO resources being utilized might include average length of hospital stay, number of hospital days per 1,000 members, number of patient referrals to specialists per 1,000 members and number of office visits per 1,000 members.

Pharmacoconomics is the study of the costs and

consequences of pharmaceutical products and services and is a component of pharmaceutical outcomes research that provides methods for assessing economic efficiency. Rather than focusing only on product cost, pharmacoconomics also examines the total cost impact – balanced against some outcome or endpoint – that a pharmaceutical product or service has on the healthcare system. The major types of pharmaco-economic analyses are:

Cost-benefit analysis. This compares both costs and health outcomes in terms of dollars. These types of analyses are often used when comparing the value of dissimilar programs where the outcomes are in different units.

Cost-effectiveness analysis. This compares the costs (in dollars) of an intervention with a nonmonetary measure of its net effect on health outcomes. The outcome of this analysis is expressed as a ratio of dollars per unit of effectiveness. This type of analysis has several variants, including:

- Cost-consequence, which compares individual costs and their health outcomes without aggregating the comparisons into ratios.
- Cost-minimization, which compares the costs

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associated with two or more alternatives that have equivalent health outcomes.

Cost-utility analysis. This compares costs (in dollars) per quality-adjusted life-year (a measure of utility that combines life-years gained as a result of a health intervention with a judgment about the quality of those years).

Quality-of-life measures

The use of health-related quality-of-life (HRQOL) measures offers a way to monitor the effects of disease and the impact of treatment in terms that are relevant to patients and that reflect the quality of their lives. Quality of life is a multidimensional concept that encompasses a variety of factors, including health, economic status, housing and occupation. HRQOL encompasses only those aspects of life that are dominated or significantly influenced by personal health or activities performed to maintain or improve health.

Validity. This refers to the capability of an instrument to measure what it is supposed to measure. The three types of validity are:

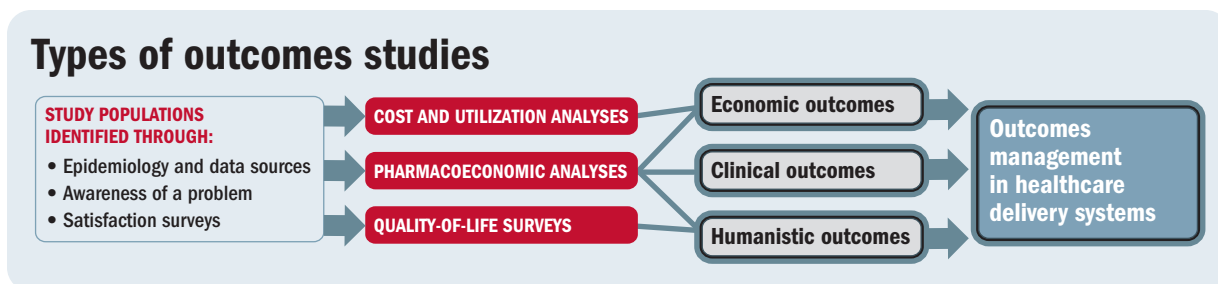
- Content validity (how well the sample of questions reflects the domain the instrument is attempting to address).
- Construct validity (the extent to which an instrument actually measures the concept under consideration).
- Criterion validity (how well the results obtained correlate with other standard measurements).

Sensitivity. This refers to the ability of an instrument to detect clinically important changes in quality of life when they occur.

Outcomes management overview

Outcomes management is the systematic collection and application of outcomes data to improve health status through better decision-making and delivery. Providers coordinate both structure and process to achieve optimal outcomes in the areas of economics, clinical results and health-related quality of life.

Management of economic outcomes. Since today's healthcare providers are sometimes paid through capitation, it is in their best inter-



Both general and disease-specific instruments (standardized questionnaires) can be used to measure HRQOL. General instruments can be used to compare HRQOL across patients with various disease states, across different medical treatments and across a variety of populations. Dimensions measured include physical functioning, social and role functioning, mental health, and general health perceptions. Disease-specific instruments are more sensitive to a particular disease and can measure subtle changes resulting from the disease or its treatment.

There are three types of scoring systems for measuring HRQOL:

- Health profile, which provides an array of scores for individual HRQOL dimensions.
- Health index, which produces a single score based on an aggregation of scores from its composite dimensions.
- Health battery, which consists of scores from separate HRQOL instruments that may include both general and disease-specific measures.

HRQOL instruments are evaluated on the basis of reliability, validity and sensitivity.

Reliability. This is a measure of the extent to which an instrument produces the same score when used by different investigators or when administered repeatedly to a person whose health status has not changed over time.

est to make the most of available resources. Examples of ways that economic outcomes can be managed include reducing the number of emergency room visits or hospitalizations, decreasing the average length of stay, and conducting return-on-investment analyses.

Management of clinical outcomes. MCOs seek to demonstrate the high quality of the medical services they provide while reassuring plan members that the processes in place for controlling resource use will not adversely affect patient outcomes. Examples of ways that clinical outcomes can be managed include disease management programs, clinical practice guidelines and comparisons of therapeutic interventions.

Management of HRQOL outcomes. The impact of health-related quality-of-life outcomes may be important in selecting a treatment alternative and assessing its effect on the condition being studied. For example, there are many different types of drugs available that will effectively lower high blood pressure, but each of these drug classes has an adverse effect profile that affects physical functioning, social activities and work capabilities in different ways.

Besides healthcare organizations, physicians, employers, insurers and patients, there are other important stakeholders involved in the development, practice and success of outcomes management, including:

- The federal Agency for Healthcare Research and Quality, which now supports the development of evidence-based reports and the distribution of evidence-based guidelines.
- Many trade and business groups involved in developing clinical practice guidelines, such as the American College of Physicians, the Kaiser Permanent Medical Care HMO and the American Pharmaceutical Association.
- Pharmacy benefit management companies, which have the patient

databases and information system capabilities to perform outcomes studies in large populations.

Clinical practice guidelines

Clinical practice guidelines are systematically developed statements or specifications that assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances. The use of clinical practice guidelines has potential clinical, economic and humanistic benefits.

The first step in the development of guidelines is to use a large database to establish a monitoring system. Through this monitoring system, variations in outcomes in different areas and differences in procedures or interventions that are associated with the differences in outcomes can be identified. Researchers then analyze the data and incorporate the results into guidelines. Education and feedback are used to modify the behavior of physicians and patients to comply with the guidelines. Throughout the process, patient care is monitored with the goal of modifying the initial guidelines over time as physician practices change and new technologies are developed.

Often, physicians trust guidelines that they or their peers with medical knowledge and experience have developed (although there may still be some healthy skepticism). Guidelines developed by insurers or pharmaceutical companies are trusted the least. For this reason, many pharmaceutical companies have partnered with well-respected professional societies or medical societies, who develop the guidelines and lend their name to them. These guidelines and programs are then marketed by the pharmaceutical company sales force to other healthcare organizations and employers.

There are some drawbacks to clinical practice guidelines. The development of comprehensive clinical practice guidelines based on outcomes research is expensive and time-consuming. Therefore, they may be justifiable only for common procedures or those that have a substantial impact on cost or outcome. Also, the effectiveness of clinical practice and evidence-based guidelines often depends on the active participation of patients, who may need special motivation or incentives to make these types of behavior or lifestyle modifications.

Disease management

Disease management is an approach to outcomes management that is based upon outcomes research. Disease management focuses on the entire continuum of a disease, including prevention, early screening, diagnosis, appropriate treatment, patient compliance and monitoring, and outcomes assessment. The key elements of a comprehensive disease management program include patient demographics, clinical practice guidelines, patient data monitoring and outcomes assessments.

Article Summary

- Outcomes studies involving cost, resource utilization and pharmacoeconomic analyses are essential for managed care organizations to remain competitive.
- Types of pharmacoeconomic analyses include cost-benefit, cost-effectiveness and cost-utility.
- Health-related quality of life measures offer a way to monitor the effects of disease and the impact of treatment in terms that are relevant to patients and that reflect the quality of their lives.
 - Both general and disease-specific instruments can be used.
 - HRQOL instruments are evaluated on the basis of reliability, validity and sensitivity.
- Outcomes management is the systematic collection and application of outcomes data to improve health status through better decision-making and delivery.
 - Providers coordinate both structure and process to achieve optimal outcomes in the areas of economics, clinical results and health-related quality of life.
- Clinical practice guidelines are systematically developed statements or specifications that assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances.
- Disease management is an approach to outcomes management that is based upon outcomes research.
 - The key elements of a comprehensive disease management program include patient demographics, clinical practice guidelines, patient data monitoring and outcomes assessments.

Patient demographics. These statistics include age, gender, race, socioeconomic factors, lifestyle factors (such as smoking) and health profiles. Using this information, an MCO can target a particular disease state where patients are at high risk and would benefit from more aggressive intervention and management. Data sources include enrollment data, medical claims, prescription claims and patient surveys.

Clinical practice guidelines. Clinical practice guidelines are a mechanism to reduce variance in how physicians treat disease. They should not be interpreted as a means to govern and regiment all physician decision-making. The current trend is to monitor the patient outcomes achieved through guideline application to determine if the guidelines actually result in improved patient health or if there are aspects of the guidelines that require refinement.

Patient data monitoring. By monitoring patients throughout the treatment process, MCOs can gather data on health outcomes and the total costs involved in the treatment. Patient data can be obtained through physical examinations, self-assessment surveys, home visitations, telephone communication, postal surveys or laboratory tests. An integrated information system for gathering and analyzing the information obtained from these data sources is vital for interpreting patient outcomes.

Outcomes assessments. The data for various outcome categories are collected, analyzed and balanced against one another to evaluate a particular treatment. These aggregated results can then be compared with other treatment alternatives for which similar data have been gathered and analyzed. Thus, gathering outcomes data allows the cost-effectiveness, clinical effectiveness and health benefits of various treatments for a specific disease to be compared.

The final article in this series will focus on outcomes in the marketplace.