STUDY OBJECTIVE: To describe process of outcomes management (OM) and discuss barriers to its success.

DATA SOURCES: Relevant literature.

SELECTION: Not applicable.

DATA EXTRACTION: Not applicable.

DATA SYNTHESIS: Quality endeavors, such as outcomes management are receiving increased attention in the U.S. health care system. OM applies continuous quality improvement (CQI) techniques to medical care, assessing both the effectiveness of products and services and the quality with which they are provided. Linking the structure and process of care to the outcomes of care is critical to OM’s success. Sources of data for OM include claims databases, medical records, and patient surveys, each with inherent advantages and disadvantages that must be considered. A number of barriers to true outcomes management must be overcome before its full potential will be realized.

CONCLUSION: Outcomes management represents a simultaneous focus on costs, quality, assessment, and accountability. Sophistication of information systems, providers, purchases, and patients are key ingredients to its success.

KEY WORDS: Outcomes management, Quality of care, Managed care

In a 1994 survey of 102 managed care organizations (MCOs), 69% of respondents reported that price was the first or second most important factor in marketplace success. At the same time, 50% of respondents indicated patient satisfaction, and only 20% reported quality improvement processes as most important factors. While these findings are consistent with managed care’s historical focus on cost control, a growing emphasis is being placed on the quality of care.

This new focus is not a sudden development but the result of an evolutionary process. The U.S. health care system moved through eras of expansion (1940s-1960s) and cost containment (1970s-1990s) before turning the emphasis to outcomes, assessment, and accountability. This evolving focus has resulted, in part, because of the questionable quality of the U.S. health care system, as evidenced by wide practice variations and high levels of unnecessary care. For example, the rate of radical prostate surgery is 2.4 times greater in Boulder, Colorado, than the rest of the nation, while the likelihood of undergoing heart bypass surgery is 1.6 times greater in Joliet, Illinois. This simultaneous consideration of both cost and quality reflects a heightened interest in the value of medical care (Figure 1). While value typically is considered in other types of consumer purchases, this is the first time in history that the technology has been available to support the assessment of medical services’ values.

The dual emphasis on cost and quality is manifesting itself in a variety of forms. Familiar terms include pharmacoeconomics, treatment protocols, clinical pathways, evidence-based medicine, and demand management. While there are important differences between many of these activities, each is a tool in outcomes management, defined as “the analysis, evaluation, and dissemination of the results of medical processes or procedures intended to improve health.” Outcomes management attempts to

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Figure 1. Value in Health Care

<table>
<thead>
<tr>
<th>Variable</th>
<th>Examples</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical</td>
<td>death, stroke, heart attack</td>
<td>not intrusive, meaningful</td>
<td>rare confounders</td>
</tr>
<tr>
<td>Economic</td>
<td>cost per case screened, cost per life-year saved</td>
<td>accounts for costs</td>
<td>difficult to determine all the relevant costs</td>
</tr>
<tr>
<td>Humanistic</td>
<td>patient satisfaction, quality of life, daily functioning</td>
<td>patient-centered</td>
<td>patient burden confounders</td>
</tr>
<tr>
<td>Intermediary</td>
<td>cholesterol levels, can be meaningful, peak expiratory volume</td>
<td>link to outcome can be questionable, intrusive</td>
<td></td>
</tr>
</tbody>
</table>

OUTCOMES?

Outcomes are the end results of medical care; they represent what happened to the patient. It is important to distinguish between outcomes and intermediaries, which are measures used to assess the degree of disease (see Table 1). Examples of intermediaries include blood pressure measures, cholesterol levels, and forced expiratory volume. These measurements have no inherently intrinsic value but are only important based on the degree to which they relate to the outcomes of care. Accordingly, the stronger the relationship between the intermediary and some outcome of care, the more relevant the intermediary becomes.

Outcomes can take three different forms: clinical, economic, and humanistic. Clinical outcomes are medical events such as strokes, heart attacks, or broken ankles. Although mortality is perhaps the ultimate clinical outcome, it is not a commonly used measure of quality of care, mainly because it often is difficult to isolate the specific causes of mortality.

While health care providers traditionally have focused on clinical outcomes and intermediaries, there is an increasing customer focus, which means a greater emphasis on economic and humanistic outcomes. Economic outcomes are the comparison of all costs of treating the disease with the clinical and/or humanistic outcomes.

The field of pharmacoconomics is devoted to assessing the economic outcomes of care. Familiar terms include cost per life-year saved, cost per quality-adjusted life year, and cost per case treated. Examples of humanistic outcomes include quality of life, functional status, health risk, patient satisfaction, and productivity. Employer groups are becoming increasingly interested in issues of patient functional status and quality of life as they impact work productivity.

While all three types of outcomes ideally would be considered in any resource allocation or clinical decision, this is not always possible or practical. Different groups have varying interests in these outcomes, and which outcomes are used to measure/manage clearly depends on the objective of the program. For example, providers may concentrate on a patient's
clinical intermediates and outcomes, while patients may be more concerned with the humanistic aspects.

Certainly, because resources are scarce, the payor will consider the economic outcomes. The outcomes emphasized also may vary by disease state. For example, in the case of pediatric asthma, the focus may be on minimizing acute exacerbations to prevent emergency and hospital visits, while quality of life and work productivity may be of greatest concern in the treatment of migraines.

Other factors to consider when deciding which outcome(s) to measure include the definiteness, timing, and directness of the outcome. Definiteness refers to the objectivity of measuring the event. Whereas death is definite and can be objectively determined, quality of life or patient satisfaction are subjective measures, making them more difficult to meaningfully measure and assess. Timing refers to the length of time needed to observe the event; clearly, some outcomes take longer to observe than others. Directness refers to the relationship between the structure and process and outcomes of care.

**STRUCTURE, PROCESS, AND OUTCOME**

Critical to the success of any outcomes management endeavor is the measurement of the structures and processes of care and the ability to link these factors to the outcomes of care. Structure refers to the tangible and intangible systems used to provide care. It includes the sources, personnel, and policies and procedures (Table 2). In a pharmacy setting, measures of structure may include the number and qualifications of the pharmacists, the number and quality of the computer system(s), and the procedures in place for completing the dispensing function. For a pharmacy benefit manager (PBM), examples of structure measures include the number and qualifications of the clinical staff, the availability of on-line edits, and whether a procedure is in place for receiving prior authorization of a nonformulary medication.

Process refers to the interactions that occur between practitioners and patients or what was done to the patient—in other words, how the structures are used in the provision of care. Process measures can include both the technical and humanistic dimensions of care. Examples in a community pharmacy would include the percentage of patients counseled per day and the number of dispensing errors as a percentage of prescriptions dispensed. For a PBM, a process measure may include the number of patients switched to a preferred product.

While there has been much debate about which of these measures should be used as indicators of the quality of care, historical quality assurance techniques have focused on measuring the structure and processes of care, primarily because they are much easier to measure than the outcomes of care. However, a study released by the General Accounting Office (GAO/HEHS-95-201) found that consumers and employers want standardized information that focuses on the outcomes of care rather than the structure or processes of care.

The greater emphasis on outcomes does not lessen the importance of measuring the structure and processes of care. In fact, each has no meaning except in the context of the others. It is only important to evaluate the process of care because it affects the outcome, and outcomes indicate quality only if they can be linked to the process and structure of care and do not result from some outside factor, such as an environmental contingency. As one provider stated, "the primary goal of outcomes is quality improvement, not outcomes; outcomes are only a tool to achieve that goal."

**MEASURING OUTCOMES**

There are two key questions in the measurement of outcomes. First, what types of outcomes will be measured? And second, what type(s) of data will be used? The three major sources of outcomes data—claims databases, medical records, and patient surveys—are discussed here.

**Claims databases**

The desire to examine clinical, economic, and humanistic outcomes usually is limited by practical considerations, such as financial and time constraints, as well as concerns about patient privacy. Given these realities, most outcomes management activities will utilize a claims database for some or all data collection. Claims databases offer a number of important advantages for conducting outcomes management. Most important, unlike randomized controlled trials (RCTs), they reflect routine clinical practice (Table 3). RCTs include carefully selected populations of particular ages and disease severity with few or no comorbidities. In addition, the procedures and protocols are not often representative of routine clinical care. Patient compliance typically is greater in RCTs than in the "real world" because of the support services available to treat adverse effects and the tendency of RCT participants to be more compliant than the population at large.

These artificial circumstances have important implications…
Table 3. Advantages and Disadvantages of Various Data Sources

<table>
<thead>
<tr>
<th>SOURCE</th>
<th>ADVANTAGES</th>
<th>DISADVANTAGES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Claims</td>
<td>inexpensive, timely, reflects routine clinical practice, flexibility</td>
<td>diagnosis uncertainty, uncontrolled confounders, missing data</td>
</tr>
<tr>
<td>Medical Records</td>
<td>depth of clinical information</td>
<td>expensive, timely, time-consuming, unknown quality of record</td>
</tr>
<tr>
<td>Patient Surveys</td>
<td>relevance</td>
<td>expensive, timely, time-consuming, methodologically difficult</td>
</tr>
</tbody>
</table>

for clinical care. For example, a recent meta-analysis of antidepressant pharmacotherapy concluded that there was no evidence that the selective serotonin reuptake inhibitors (SSRIs) offered any advantage over the less expensive tricyclic antidepressants that justified the additional costs of the SSRIs.\(^2\) This conclusion is not particularly surprising given that this meta-analysis included only randomized controlled trials and overlooked other forms of research that reflected routine clinical practice. Had the issues of frequency of dose titration, management of side effects,\(^2\) organizational structure, and physician specialty been taken into account,\(^2\) different conclusions may have been reached.

A second advantage of claims databases is that they are not influenced by patient or provider biases.\(^2\) In addition, they are unobtrusive and relatively inexpensive to use once the information system is in place.\(^2\) Further, databases provide a timely means of analyzing a problem.\(^3\) Answers can be found in days or weeks, rather than months or years. Finally, databases offer a great deal of flexibility.\(^4\) Rare diseases or specific subpopulations can be researched, or a problem can be approached in a number of different ways.

Claims databases allow for the measurement of clinical and economic outcomes (e.g., hospital and emergency room visits). Beyond such high-level outcome measures, the availability of the diagnosis, procedure, and revenue codes allow for further specification of a patient's outcome. ICD-9-CM (International Classification of Diseases, 9th Revision) codes provide diagnostic information allowing for identification of patients with a particular diagnosis or combination of diagnoses. CPT-4 codes (Physicians' Current Procedural Terminology, 4th Edition) identify procedures that are used to bill physician and other professional services. For example, CPT-4 codes could be used to determine whether a depressed patient received hypnotherapy. The Health Care Financing Administration Common Procedural Coding System (HCPCS) can be used to provide further information on physician and nonphysician services that are not included in the CPT-4, such as whether a patient obtaining care in a physician's office for asthma received an injection of epinephrine.

The processes of care also can be assessed from a claims database. For example, the number of physician visits might be considered a good measure of the quality of care in depressed patients, as could whether a patient received care from a specialist. Procedure codes allow for the measurement of additional processes of care such as whether or not asthmatic patients are receiving annual pulmonary function tests. Whether or not an asthmatic is using an inhaled steroid is a measure of the process of care, which is purported to affect outcomes such as hospitalizations for asthma and quality of life.

Figure 2. Possible Relationships Between the Structures, Processes, and Outcomes of Care for Asthma
Most measures of the structure of care are not found in the database itself but within the patient benefit manual or other records held by the MCO. Important examples include copay amount, formulary coverage of specific drugs, prescription quantity limits, and limits on mental health benefits.

While using a claims database to actually measure the various processes and outcomes of care can be difficult, often more challenging is linking the variations in outcomes to recognized variations in the processes and structures of care. As shown in Figure 2, there are multiple processes of care in the treatment of asthma; these processes often influence each other, making it even more difficult to isolate the relevant component. Despite these inherent difficulties, isolating the “cause” of suboptimal outcomes is essential to developing successful interventions to improve these outcomes.

Although databases offer a number of advantages for conducting outcomes management, they are not without their limitations. It is widely recognized that the diagnosis found in databases is not always valid and or reliable. While some overcoding does occur, in most cases undercoding of actual diagnoses is more common. Undercoding is an even bigger problem with chronic diseases, which are notoriously underreported. Given these limitations, it is helpful to know for which disease states the coding is insufficient, calling for a review of the medical record. Unfortunately, there is no published research to provide guidance on this issue.

Another important consideration is patients’ severity-of-illness. The goal often is to compare the outcomes of care for persons receiving different treatments or receiving care from different types of providers. However, there may be important differences in the patients being compared that cannot be measured or controlled when using the information in the database. An example of the difficulty of interpreting outcomes analyses comes from the Health Care Financing Administration (HCFA)’s efforts to compare the quality of care provided by hospitals using hospital-specific, age-adjusted mortality rates for selected conditions. HCFA found difficulty in isolating outcomes resulting from quality of care versus those due to adverse patient selection. While a number of organizations offer proprietary severity-adjustment software, one researcher compared 10 of these programs and found that comparisons of individual hospitals varied according to the software program used.

Medical record

The medical record provides a wealth of information on clinical outcomes and intermediaries. However, while the medical record sometimes is considered the “gold standard” for patient medical information, this is not necessarily the case. The primary concern with medical records is whether one is measuring the quality of care or the quality with which the care was recorded. Additionally, gaining access to medical records can be difficult, and it is expensive and time-consuming to collect data from them.

As for the types of data that can be collected, medical records allow for the examination of clinical outcomes and intermediaries as well as many of the processes of care, such as the frequency with which certain diagnostic procedures are being performed.

Patient surveys

Patient surveys represent the absolute consumer focus, but they can be expensive to conduct. Self-administered surveys may cost as little as $5 per person, while face-to-face interviews can cost upwards of $50. These surveys put a burden on patients and the MCO risks offending them, regardless of its good intentions. In addition, it is sometimes difficult to reach a representative sample of the MCO’s population. This is particularly true with Medicaid patients. Finally, there always is the question of whether patients can provide relevant, reliable, and valid information about their medical care. Nonetheless, research suggests that these surveys can be useful if they are constructed carefully.

While surveys allow for measurement of clinical, economic, and humanistic, they probably are most useful for measurement of humanistic outcomes. In fact, the only means of gathering most humanistic outcomes (e.g., patient satisfaction, quality of life, etc.) is by surveying the patient. Used in isolation, surveys do not easily allow for the linkage of outcomes to the structure and process of care in most cases.

Automated collection of patient information is the ultimate goal and the ideal for MCOs. An institution that has taken a major step in this direction is the University of Utah Hospital and Clinics’ sports medicine and physician therapy center. The center asks that patients use a touch-screen computer to complete a health-assessment survey during their first visit and after their last visit. Satisfaction with care is also surveyed at the final visit. Neither assessment takes more than 10 to 15 minutes to complete, and the survey results are used to make treatment decisions.

In summary, one should not view a single type of data source as superior to the others. Rather, each has advantages and disadvantages, and each can and should play an important role in managing patient outcomes. Understanding the inherent limitations and benefits of each source so that the potential of each alternative will be maximized is essential.

GETTING STARTED

The first step in developing an outcomes management program is defining the goal(s). While the general goal is always to improve the value of medical care, more specific goals should be developed. A good approach is to start simple. Rather than attempting to identify specific links between the processes and outcomes of care, an initial step would be to simply describe variation. For a particular disease state, group of patients, or providers the trends and patterns of outcomes may be desired. Once variations have been established, epi-
and purchaser groups are becoming more sophisticated in evaluating the quality of care, this limitation is rapidly diminishing.

**CONCLUSION**

Certainly, a sensitivity to costs will always exist in health care, but as the information systems advance MCOs will have the ability to manage the entire medical system rather than controlling each component in isolation. Only then can MCOs conduct the research and quality assurance activities needed to provide truly cost-effective care.

Some have asked whether outcomes management is a passing fancy. Regardless of the label attached to it, the focus on value, accountability, and systematic management of outcomes is here to stay. The interesting questions are how long will it take to fully realize the potential and who (i.e., providers, type of institutions, specific organizations) will be successful in the new environment.

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**References**