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The Academy of Managed Care Pharmacy's *Concepts in Managed Care Pharmacy*

Outcomes Research

What Is Outcomes Research?

Outcomes research is a facet of research that measures results of various medical treatments and/or interventions in patient populations. The purpose of outcomes research per the Patient Centered Outcomes Research Institute (PCORI) is to assist patients, clinicians, purchasers and policy makers in making informed health decisions by advancing quality and relevance of evidence. The Agency for Healthcare Research and Quality (AHRQ) defines the purpose of outcomes research as a tool to provide evidence about benefits, risks, and results of treatments so clinicians and patients can make more informed decisions. The process involves identifying, measuring and evaluating effects of care provided to patients. Results of outcomes research, which consider clinical, economic, and humanistic outcomes, can guide health care decision makers in selecting the most effective treatment and/or procedural strategy or to improve upon current treatments and medical interventions. Those involved in making decisions about care may include the patient, the health care professional, or the payer of health care. Examples of some outcomes that can be measured are cure rates for certain diseases, patient functional status and activities of daily living, respiratory function, or the rate of hospital admission or outpatient visits.

Any organization with an interest in evaluating results in certain patient populations and with access to the appropriate data can conduct outcomes research. This includes health plans and insurers, government agencies, academic institutions, pharmaceutical research firms, and medical groups. Pharmacists, economists, physicians, nurses, other researchers, and health care professionals participate in this type of research. If an organization does not have internal expertise to conduct such research, it may consider using consultants in academic, institutional, government, or pharmaceutical industry settings.

Types of Outcome Research

Outcomes research can be economic (pharmacoeconomics), clinical (comparative clinical effectiveness research) or humanistic (health-related quality of life). Pharmacoeconomics is “the scientific discipline that assesses the overall value of pharmaceutical health care products, services, and programs.”¹ The costs associated with economic evaluation methods are derived from many different sources and include both direct and indirect costs, some of which are difficult to measure. These might include medical, pharmacy, patient productivity, and level of

activity costs, *to name a few*. Comparative clinical effectiveness research is research evaluating and comparing health outcomes and clinical effectiveness, risks and benefits of two or more medical treatments, services or items.² Health-related quality of life, typically used to measure the effects of chronic illness, treatments and disabilities, is a multi-dimensional concept that focuses on the impact health status has on quality of life.³

Importance of Outcomes Research

The fast-paced changes in health care have heightened awareness of the costs of new therapies and sometimes the additional costs associated with established therapies. Though cost-containment is an important objective, quality of care is the first priority. It is important to be able to describe the *value* of health interventions in terms beyond simple cost. Outcomes research incorporates economic considerations into evaluations which also focus on clinical and humanistic results. These results establish and support clinical and administrative decisions. For example, economic analyses can be used to demonstrate that the least expensive alternative is not always the most economical, and that it may not produce an optimal outcome both for the patient and the health plan. The results of outcomes research studies can support policy decisions, provider treatment decisions, formulary drug selection, treatment protocols, and other processes within a health care system.

Organizations such as the National Committee for Quality Assurance (NCQA), the Joint Commission, and the Foundation for Accountability (FACCT), require outcomes evaluations as evidence of achieving healthy populations. Various government agencies such as the Centers for Medicare and Medicaid Services (CMS) require similar documentation.

Components of Outcomes Research

Many steps are involved in performing outcomes research. The manner in which they are conducted is variable, depending upon the group conducting the study (i.e., the perspective taken) and the type of drug or disease intervention being evaluated.

The design of the study for an outcomes evaluation first requires the researcher to establish the perspective from which conclusions will be reached, particularly related to costs and consequence. The results of an evaluation will vary greatly depending upon the perspective established. For example, the research would be very different if researchers took societal perspective vs. a patient's perspective. Other perspectives could be that of a payer (such as an insurer or the government) or an individual institution (such as a hospital or medical group). Additionally, the alternatives within an evaluation need to be established and weighted appropriately based on their respective probabilities of occurring. These probabilities can be derived from expert panels, a literature review, or clinical trial data.

After data are collected and analyzed, a sensitivity analysis is conducted to compensate for uncertainty. A sensitivity analysis incorporates a "what if" process to test the assumptions or estimates made within the study process when precise input values could not be acquired.

Role of the Pharmacist in Outcomes Research

Pharmacists are important contributors in conducting outcomes research processes with roles in the following areas:

1. Identifying topic areas for outcomes evaluation.⁴

Through standard processes such as drug utilization evaluation, or the tracking of undesirable drug reaction trends, pharmacists are in a pivotal position to identify areas to evaluate.

Example: Asthma is a topic area that could be identified via tracking of medication use trends inconsistent with national treatment guidelines. In addition, asthma might be identified in a population where emergency room admissions for acute attacks are higher than national averages.

2. Evaluating the published literature.

For the pharmacist, reading and using the published results from outcomes research studies is similar to using the results from any research. The pharmacist must make a critical assessment of the research methods, limitations, potential for bias, and the validity of the study's conclusions.

Example: A review of the literature would be conducted to assess current research on the treatments for diabetes. A literature review would also identify those study strategies that have been successful or unsuccessful, and aid in designing the project.

3. Designing evaluations.

Special training (i.e. residency or fellowship trained Pharm.Ds) is required to design valid outcomes evaluation studies and analyze the findings. Individuals who have expertise in this discipline (i.e. pharmacoeconomists, statisticians) may be used to assist with study design, analysis, and sensitivity testing. Understanding the population served by the health care system is essential to the design process and assures that the evaluation, its results, and the implementation of correction strategies are of value to the patient population and the system conducting the evaluation.

Example: Evaluation studies for the treatment of asthma could involve a detailed study of a group's demographics. In this case, a study for a population of pediatric patients would have a significantly different design and set of validation tools than a study for adult patients. For example, a follow-up questionnaire to pediatric patients must not only be statistically validated, but it must also be in appropriate language for a child, the parents, or guardians to understand in order to elicit accurate information.

4. Analyzing and assessing results.

While good design may ensure results will be useful, the ability to critically analyze the results in light of study objectives is an important step. Analyzing the results of the research requires assessing the possible reasons for the conclusions reached. Determining which results are most important will establish the need to move to the next step

Example: If the research showed that although there were higher than the national average of acute asthma attacks in a hospitals' pediatric population, there is a higher than normal asthma population in the city where the research was conducted.

5. Identifying and executing intervention strategies.

Once the study results have been completed, the pharmacist is an integral part of the team of health care professionals who take responsibility for making sure that corrective action is taken.

Example: An intervention strategy for pediatric patients with asthma may involve setting up small groups of patients/caregivers with pharmacists to discuss medication use regimens and appropriate use of inhalers. For adults, this might include a quarterly newsletter to highlight lifestyle changes and encourage compliance with medications.

6. Monitoring the results of those strategies.

A re-evaluation of the outcome assessed is an essential part of the intervention strategy. It assures that the initial problem has been resolved and acceptable outcomes, within reasonable cost ranges, are achieved.

Example: After the asthma interventions have been in place for a year, assessments should be made to evaluate the outcomes and economic impact on the patients and the health plan. These might include an evaluation of the change in drug use patterns by the asthmatic patients and/or a change in emergency room admissions. In addition, a statistically validated survey might be used to determine changes in patients' knowledge of asthma and their control of their disease state.

7. Presenting results.

To assure continuous improvement in the evaluated therapeutic areas, pharmacists should present results of successful outcomes evaluations to peer organizations.

Example: A presentation of the results of the asthma program could be made to the state pharmacist's organization.

8. Repeating the evaluation process.

To assure that an effective intervention maintains efficacy over time, the entire evaluation process may need to be repeated.

Example: New asthma guidelines may be published or new therapies may become available and may require a change in the recommendations that resulted from the research conducted. The evaluation process may need to be repeated to determine if any changes are warranted.

Conclusion

To assure that quality care is provided economically, managed health care systems must attempt to achieve numerous goals, including improving the appropriate use of medications, enhancing favorable patient outcomes, and improving the cost-effectiveness and cost-efficiency of health

care. The high-quality decisions necessary to implement strategies to achieve these goals must be based on credible, relevant outcomes research. As the use of outcomes research increases, pharmacists, by virtue of their training, are well positioned to be among the most effective professionals to design and implement programs and policies to influence the practice of prescribers and pharmacists and to evaluate the effect of these programs on patient outcomes.

¹ Health Care Cost, Quality, and Outcomes: ISPOR Book of Terms. *Lawrenceville, NJ: International Society for Pharmacoeconomics and Outcomes Research; 2003:180-2.*

² *Patient Protection and Affordable Care Act, Public Law 111-148*, March 23, 2010.
http://www.pcori.org/assets/PCORI_EstablishingLeg.pdf (accessed March 28, 2012).

³ HealthyPeople.gov. Health-related quality of life and well-being.
<http://www.healthypeople.gov/2020/about/qolw/about.aspx> (accessed March 28, 2012)

⁴ Academy of Managed Care Pharmacy, *Catalog of Quality Indicators*, v. 2.0, 2006.
<http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=9273> (accessed March 28, 2012).