ABSTRACT

The concept of “cost effectiveness” is based on general economic theory. Pharmacoeconomics is a sub-branch of cost-effectiveness analysis that is applied to the field of healthcare delivery. In pharmacoeconomics, cost-outcome analysis studies measure the costs of an intervention over time and compare them to the outcomes. Although these studies are used by healthcare decision-makers to determine how to allocate healthcare resources, cost-outcome analyses are rarely, if ever, the only factor driving a policy recommendation or decision. Cost-outcome analyses must consider the costs, benefits, and perspective from which the study is conducted. These analyses are based on effectiveness studies of an intervention (i.e., the efficacy of an intervention as it is used in the “real world”), but they do not rely solely on economic theory as their gold standard. Cost-outcome analyses are only as good as the underlying effectiveness study. For nurses, the results of cost-outcome analyses can have far-reaching implications in determining their salaries and how to allocate their time. As cost-outcome analysis studies become more prevalent, it is important for all healthcare providers to understand the information on which resources are allocated. This article describes the most common types of cost-outcome analysis studies to provide an understanding of pharmacoeconomic methods. Specific study examples from the literature and our work at the Johns Hopkins Hospital are also offered.


Pharmacoeconomics is taking on greater prominence in our healthcare system as costs continue to increase rapidly. Cost-outcome analyses in pharmacoeconomics measure the costs of an intervention over time. Healthcare decision-makers (e.g., hospital administrators, the government, health insurance companies, employers, or other benefit providers) use cost-outcome analyses to help determine which interventions provide the most benefit per dollar spent. However, cost-outcome analysis is rarely, if ever, the only factor to drive a policy recommendation or decision. It provides a framework on which a dollar value can be placed on outcomes, such as health benefits.

GOOD COST-OUTCOME ANALYSES: MORE THAN JUST GOOD ECONOMICS?

Cost-outcome analyses are based on clinical studies of efficacy or effectiveness. Before a cost-outcome analysis is performed, the clinical issue (e.g., symptom management) must be identified and potential solutions measured for effectiveness. Pharmacoeconomics has a set of gold standards for these analyses, but a cost-outcome analysis is only as good as the underlying effectiveness study. Efficacy refers to the benefits of
an intervention in a clinical trial, in which the patient population is tightly controlled. Effectiveness refers to the benefits of an intervention when used in the “real world,” where patients may have other coexisting conditions, take other medications, or may not be as compliant. Once a cost-outcome analysis is published, decision-makers address the ethical and political issues that shape how the analysis will be used.

ARE COST-OUTCOME ANALYSES ALL THERE IS TO ECONOMICS?

Pharmacoeconomics, also known as health economics, is a sub-branch of cost-effectiveness analysis, which is based on general economic theory and applied to the healthcare industry. It can be used to ask a wide range of questions beyond cost versus outcomes, such as consumer (patient) behavior and producer (clinician) behavior. Pharmacoeconomics provides a paradigm for asking, “Which program is more efficient?,” or “Do people behave the way you predict they would using our economic theory?”

PERSPECTIVE

In cost-outcome analyses, it is also necessary to define the perspective of the study. For example, a patient will have different priorities than an insurance provider. The perspective helps determine whose costs and whose benefits are relevant for the study. Perspective can include society, the healthcare system (overall or for a specific clinic or hospital), the insurer/payer, an employer, or the patient. Societal costs are recommended as the gold standard for cost-outcome analyses but, in practice, this perspective is not very helpful and not often used by decision-makers. The societal perspective considers all costs and all benefits, not just those of interest to a particular group. The advantage of using the societal perspective for all studies is it ensures that decision-makers are all “playing by the same rules” when justifying their allocation of resources.

COSTS

Costs are clearly an important component of cost-outcome analyses, thus it is critical to understand how costs are defined. The costs of an intervention include the quantities of the intervention used, the price of the intervention, the “labor” in administering the intervention, preparation and evaluation, and other ongoing costs. The quantities and prices are determined by inventories. Labor costs include the salary or hourly wages and fringe benefits of each healthcare provider and the direct provider time spent on the intervention, which will vary by provider type. Traditionally, costs for hospital nurses have been folded into general hospital costs at the “room rate” but, in the future, nurses’ time may be coded and costed separately because of their different duties and specialties. There are several methods to measure healthcare provider time, including direct observation of service duration (often not feasible), random observations of provider activities, time diaries completed by providers (often not reliable), or patient flow analysis. Labor costs also include the salary and benefits for administrative and support staff. A difficult provider cost to calculate is that of volunteers. Questions arise regarding what perspective is represented if volunteer or unpaid care providers’ (eg, friends and family) time is calculated, even if it does not cost the payer. It is difficult to assign a dollar value to the services of these providers.

Other costs include preparation and evaluation program costs and ongoing program costs. Preparation and evaluation costs can include educational materials, training costs, and outside consultant services. Evaluation costs also include the cost of documentation and tracking results, the analysis of results, and incorporation of conclusions into future implementation. The challenge is to determine if these costs are part of the research program or part of the regular duties of the providers. Ongoing program costs can include supplies, materials, and laboratory costs associated with each type of service provided, drug costs, facilities (eg, rent and utilities), equipment, maintenance for facilities and equipment, and transportation and travel expenses. If the intervention is not the only service being provided in the facility, it is necessary to determine what proportion of the costs are devoted to the intervention to establish costs for rent, utilities, maintenance, and equipment. Clearly, cost calculations need to be transparent in a published cost-outcome analysis because determining which costs to include can significantly affect the results.

There are many sources of cost data, including Medicare reimbursement data, public and private data sets (eg, a managed care company database), and hospital records. When another source is not available, a panel of experts can estimate costs, although this is the
least preferred option. In these studies, costs differ from charges applied by physicians or institutions providing services, which are presumed to have a mark-up. Medicare receives a discount from charges that are assumed to be higher than cost and not closely related to cost, thus the Medicare data are thought to more accurately represent true cost. The amount paid by a payer for services rendered represents the cost from the payer's perspective, but this may still differ from the charge.

Costs to study participants also must be calculated in an intervention and are almost always gathered through a survey. These costs are determined by asking the participant questions, such as:
- How far did you travel for this intervention?
- How much time did you spend receiving the intervention?
- What other costs (eg, childcare, bus fare, and parking) did you incur to get to the intervention site?

These costs can be large or small, stable or variable across participants. Therefore, certain assumptions are made to calculate a cost estimate.

For a long-term intervention or analysis of long-term outcomes, researchers must take costs over time into consideration, such as the cost of dietary and exercise changes in a 25-year-old to prevent heart disease later in life. This process, referred to as discounting, is a systematic and consistent way to compare the value of money spent today with its future value. For example, discounting reflects the fact that a person can spend $1000 next year with approximately $990 in the bank today. Although similar to inflation, discounting is different; it is often used in everyday applications, such as retirement accounts (eg, “How much do I need to save today to have $1 million when I retire?”).

**Benefits**

Benefits can be defined not only by improved health outcomes (eg, less pain) but also by the decreased incidence of disease, dollars saved by prevention (decreased healthcare resource use), increased productivity, improved quality of life, more years lived, and many other outcomes. The benefits will depend on the perspective from which the study is done. For example, productivity may be part of the decision-making process for health insurance providers or a particular employer, but it may be less important to a particular physician.

**Types of Cost-Outcome Analysis Studies**

For the practicing nurse evaluating cost-outcome analysis studies, it helps to understand the different types of studies and the information they provide. The Table provides a summary of some of the types of cost-outcome analysis studies, which also are described in more detail later in this article. Although they represent a sample of the different cost-outcome analyses that can be performed, these are the types most often found in the literature.

**Cost-of-Illness Study**

Cost-of-illness studies measure the lifetime cost for an incident case of a condition (ie, the cost over a life-

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<thead>
<tr>
<th>Study</th>
<th>What Is Measured</th>
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<tr>
<td>Cost of illness</td>
<td>The lifetime cost for an incident case of a condition (ie, the cost over a life</td>
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<td></td>
<td>time for individuals having a condition, even if the condition is not life-long).</td>
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<tr>
<td>Cost minimization</td>
<td>Two or more treatment options that achieve the same (or at least a defined</td>
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<td>minimum) outcome to determine which treatment costs less.</td>
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<td>Cost consequence</td>
<td>Costs of an intervention versus the consequences (outcomes), but the</td>
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<td></td>
<td>consequences are not assigned a monetary value (eg, money spent/outcome) and</td>
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<td>there is no summary measure; each outcome is considered separately.</td>
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<td>Cost effectiveness</td>
<td>The dollar spent per outcome achieved, in which the outcomes (ie, effectiveness)</td>
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<td>are measured in “natural units.”</td>
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<td>Cost utility</td>
<td>Two interventions, based on preferences for different health states (quality</td>
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<td></td>
<td>adjusted life years); it is a type of cost-effectiveness analysis.</td>
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<td>Cost benefit</td>
<td>Determines whether the dollar value of the benefits is larger than the dollar</td>
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<td>value of the costs.</td>
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time for individuals with a condition, even if the condition is not lifelong). These studies are different from burden-of-disease studies, which measure the cost of treating prevalent cases (ie, the cases existing this year only, regardless of the year they started). A cost-of-illness study may ask, “What is the lifetime cost for a person with heart disease?” (eg, medications, doctor visits, and time off from work), or “If it can be prevented, what are the lifetime savings?” However, a burden-of-disease study would ask, “How much does it cost to treat everyone in the United States with heart disease this year?” For example, a study in Germany compared current treatment patterns and costs, including resource use, in the management of patients with severe hemophilia with inhibitor therapy. Children and adults were studied from a third-party payer’s perspective.

**COST-MINIMIZATION STUDY**

Cost-minimization studies compare 2 or more treatment options that achieve the same or a defined minimum outcome. These studies ask, “Which treatment costs less?” For example, this type of study can compare psychotherapy versus antidepressant medication for patients suffering from depression after surgery. These studies help insurers to decide which treatment to cover. Another example of a cost-minimization study is a comparison of the effect of an early morning fast-track triage endoscopy unit on the cost and length of stay of a general gastrointestinal inpatient population. The results show that early morning scheduling with a reserved time and space for inpatient endoscopy is a cost-minimizing factor that preserves optimal patient outcomes.

**COST-CONSEQUENCE STUDY**

Cost-consequence studies compare the costs of an intervention with the consequences or outcomes; however, the consequences are not considered based on monetary value (eg, dollars spent per outcome), and there is no summary measure. Each consequence is considered individually. Ideally, an intervention would have only 1 consequence, but this is often not the case. For a condition with multiple symptoms, a researcher can choose to measure only 1 symptom. This type of study is useful when several types of changes beyond health status are being assessed, such as attitude changes (based on an exercise program), knowledge changes (based on a diabetes education course), or behavior changes (based on patient information on high-fat diets). Because there is no easy way to summarize these different types of outcomes, cost-consequence studies are used. An example of a cost-consequence study is the comparison of fondaparinux versus enoxaparin in patients after orthopedic surgery. In this study, the costs of the treatments are compared to avoided venous thromboembolism (VTE) events, in addition to prevention, diagnosis, and treatment of VTE and its complications.

**COST-EFFECTIVENESS STUDY**

Cost-effectiveness analysis is a broadly used term, inside and outside the healthcare community. In pharmacoeconomics, these studies measure dollars spent per outcome, in which the outcomes (ie, effectiveness) are measured in “natural units,” such as the number of cases of visual impairment prevented or the number of months of increased breastfeeding. Cost-effectiveness studies often compare a new intervention with the current usual care to see if the new intervention offers an economic advantage with the same outcome. For example, this type of analysis would not be used to compare the number of cases of visual impairment prevented versus the number of months of increased breastfeeding. Therefore, cost-effectiveness studies are best used to analyze interventions with a limited number of effects. The determination of an intervention being “cost effective” is a judgment call. For example, the question of whether the extra cost of $500 per month on an education program is worth the increased rates of breastfeeding. If we compared $500 per month for breastfeeding improvement to $1500 per month per heart attack prevented, which is more valuable? An example of a cost-effectiveness study is the comparison of 2 antiemetics for prevention of postoperative nausea and vomiting. The study shows that the incidence of postoperative nausea and vomiting and the use of rescue antiemetics are significantly more reduced with 1 drug as compared to the other. The costs are based on the cost of the preventive and rescue antiemetics. The outcomes are measured based on the incidence of nausea and vomiting and use of rescue medication.

**COST-UTILITY STUDY**

Cost-utility analysis is a specific type of cost-effectiveness analysis in which 2 interventions are compared based on preferences for different health states.
Utility is a term used in general economic theory; in pharmacoeconomics, it refers to a level of preference for outcomes or health states. The health states are measured by morbidity and mortality. Morbidity is defined based on quality-of-life measures and, for cost-utility studies, morbidity is combined with mortality to create a quality adjusted life year (QALY). This is a measure of how long a study subject is alive in a health state and how a reduced quality of life decreases the value of each remaining year of life for the patient. The QALY measures not just how long someone survives, but is also adjusted based on their quality of life. Therefore, cost-utility studies compare dollars spent per QALY gained by asking patients to choose between health states (e.g., “Would you prefer to have a longer survival with cancer, but more sickness caused by chemotherapy, or have shorter survival, but less time being sick after surgery?”). Cost-utility studies are now considered state-of-the-art cost-effectiveness studies as standards are being developed.

A threshold for willingness to pay has been reported in the literature as $50,000. In other words, if an intervention costs $50,000 to improve a QALY, it is considered to be worthwhile. Those interventions costing more than $100,000 are considered not worthwhile, and those interventions costing $51,000 to $99,000 are in a less well-defined area. However, this is just one interpretation of what is considered to be a “worthwhile” intervention.

As an example, a cost-utility study compared long-term, high-intensity exercise classes with usual care in patients with rheumatoid arthritis to determine the cost per QALY. It was determined that high-intensity exercise classes provide insufficient improvement in the valuation of health (QALY) to justify the additional costs. Cost-benefit studies provide the most direct comparisons of costs with benefits, but they can also be the most controversial. All outcomes are valued in dollars, thus the study asks whether the dollar value of the benefits is larger than the dollar value of the costs. Therefore, cost-benefit studies may place dollar values on medical care costs saved, in addition to days off from work, days of reduced productivity at work because of illness (“presenteeism”), or infections avoided. For example, a study calculated the cost savings for Medicare from a program using hip protectors in the nursing home. The study found that as a result of the reduced risk of hip fracture with the hip protectors, Medicare saved $223 per resident when these protectors were used. Hip protectors cost $151 per resident annually, thus they were deemed to be a cost-saving intervention.

**A CASE STUDY**

Our group is performing a cost-effectiveness analysis of a Breastfeeding Support Study in Baltimore, Maryland, conducted by Dr Linda Pugh of the Johns Hopkins University School of Nursing. The program involves a peer counselor and community health nurse visiting a new mother 3 times, along with follow-up phone calls, to help with breastfeeding issues. The peer counselor is also responsible for additional phone contacts. These visits involve some education on breastfeeding from the nurse, in addition to providing support for breastfeeding from someone who is considered to be a peer and expected to be at a communication advantage. This program is designed to help low-income mothers avoid the pain and fatigue associated with breastfeeding and increase the duration of breastfeeding. Some examples of items for which prices and quantities are needed are the peer counselor and community health nurse time for home visits and phone calls, the mileage for peer counselors and nurses during home visits, and breast pumps. It was difficult to separate research time (i.e., time spent on the study intervention) from practice time because they would be visiting the patients anyway as part of their job description. The goal is to differentiate time spent collecting data and giving the intervention from their normal activities with the patient. The study began in 2003 and will continue to collect data until 2006; therefore, the costs will need to be discounted to determine the cost of this program for 6 months in 2007, should it be implemented. The outcomes simply could include an increased number of weeks of breastfeeding. However, the outcomes also may include medical care costs savings, such as fewer physician or emergency department visits; fewer hospitalizations; fewer infections, thus decreased drug costs for antibiotics; decreased formula costs for the mother; possible decreased time for feeding; and possible improved developmental outcomes and mother-child bonding.
CONCLUSIONS

Pharmacoeconomics and cost effectiveness are based on general economic theory, but applied to the field of healthcare delivery. A basic understanding of the common types of cost-outcome analyses is an important endeavor for professional nurses. As cost-outcome analysis studies become more prevalent in the literature and are increasingly used by decision-makers, it is important for all healthcare providers to understand the information on which resources are allocated. For nurses, this information can have far-reaching implications on how their salaries are determined and their time is allocated.

REFERENCES