Helping Cancer Centers Make Rational Drug Purchasing Decisions

BY GEORGE A. SILBERMAN

Until relatively recently, the costs of therapy were largely irrelevant for making decisions about the best way to treat patients. If a treatment worked, it was used. If a newer treatment was found to work better, clinicians were quick to adopt it. By the mid-1980s, however, the combination of a growing demand for care from an aging population and startling advances in therapeutics created a "cost crisis" in the nation's healthcare system. The cost of care, once considered as an afterthought at best, suddenly became a central concern for many insurers who fought to incorporate it into coverage decisions. Their opposition came from a fragmented alliance of physicians, hospitals, and patients, who argued that the effectiveness of therapy should remain the only basis for clinical decisions.

Pharmacoeconomics: The Parent Discipline

Pharmacoeconomics was developed as a way to establish a common language between the "effectiveness" proponents and those who thought that cost should be taken into consideration when deciding on care. It did so by suggesting that the optimal basis for clinical decisions was one that took data for *both* costs and consequences and combined them into a single measure. The concept is quite simple and involves measuring all the costs associated with a therapy, all its health-related consequences, and then dividing the former (costs) by the latter (health-related consequences).

The resulting ratio of "cost per unit of outcome" is formally referred to as the *cost-effectiveness ratio* and serves as a measure of the therapy's value. The ratio makes it easier to compare alternative therapies by showing how much it costs each to achieve the same outcome. For example, consider a hypothetical new anti-cancer drug that costs $20,000 and leads to a disease-free survival interval of 5 years. Dividing $20,000 by 5 years yields a cost-effectiveness ratio of $4,000 per disease-free survival year. If a different drug for the same cancer offers disease-free survival at less than $4,000 per year, then the second drug has greater value. A drug that costs more for each year of DFS offers less value.

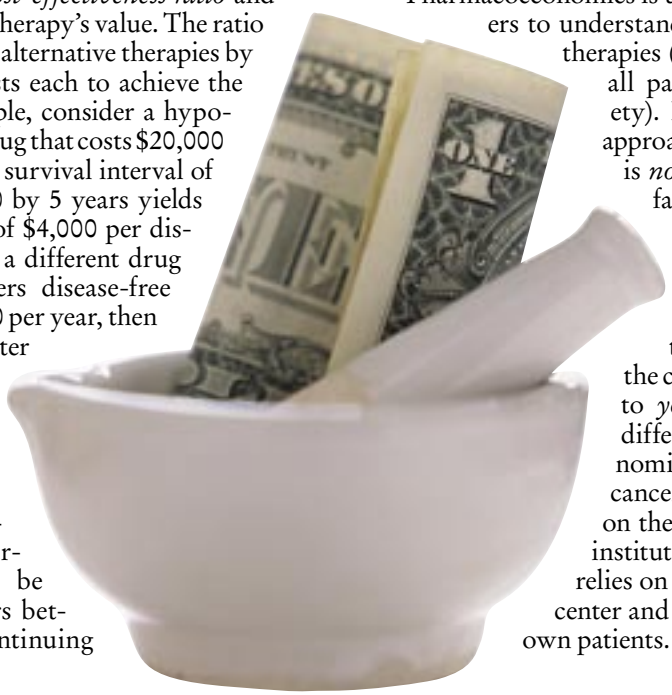
In many instances, however, a therapy will have a higher cost-effectiveness ratio than an alternative therapy but still be attractive because it offers better overall outcomes. Continuing with our example of an anti-cancer drug, imagine that the new drug costs $40,000 but offers 10 years disease-free survival while an alternative therapy costs $12,000 but leads to only a 4-year disease-free survival interval. The respective ratios are $4,000 and $3,000 per disease-free survival year. In this case most patients (and their physicians) would clearly prefer to be treated with the new drug because of its superior efficacy.

The measure used in such situations—where one treatment is both more expensive *and* more effective—is referred to as the "marginal cost-effectiveness ratio" and is defined as the "difference in cost per unit of outcome." (See Fig. 1 on page 38.) This ratio shows how much *additional* cost must be expected for each additional unit of benefit. In the case of our hypothetical drug, the marginal cost-effectiveness would be $1,000 per disease-free survival year. This is interpreted as the cost of extending disease-free survival by one year.

The marginal cost-effectiveness ratio is the "bottom line" of most pharmacoeconomic analyses because it shows clearly how much more it will cost to achieve a specific benefit—be it additional survival, better prophylaxis, shorter disease interval, or any health-related outcome. Armed with this number, physicians, payers, and patients can decide whether the additional benefits merit the additional costs.

Practical Economics: Adapting Pharmacoeconomics for the Community Cancer Center

Pharmacoeconomics is used by regulators and policy-makers to understand societal implications of different therapies (i.e., how much benefit is there for all patients at what total cost to society). However, the pharmacoeconomic approach to measuring costs and benefits is *not* the only legitimate approach. In fact, while evidence on societal costs and benefits is certainly important, it can be misleading at the institutional level. Knowing the costs to the U.S. healthcare system is very different from knowing the cost to *your* cancer center or the cost to *your* patients. Practical economics differs from traditional pharmacoeconomics in that it is structured to provide cancer center personnel with evidence on the value of therapies from their own institution's perspective. The approach relies on measuring the costs specific to the center and the benefits specific to the center's own patients. (See Table 1.)



PHOTOGRAPH/PICTUREQUEST

Table 1: Pharmacoeconomics Vs. Practical Economics

Dimension	Pharmacoeconomics Study	Practical Economics Study
Cost	How much will it cost society to offer Drug X to all patients with Condition Y?	How much will it cost our hospital to treat our patients with Condition Y with Drug X?
Health Consequences	What is the expected improvement in outcomes for all patients with Condition Y if they are treated with Drug X?	What is the expected improvement in outcomes for patients at our hospital with Condition Y if they are treated with Drug X?

Practical economics also differs from traditional pharmacoeconomics in that it recognizes that community cancer centers rarely have the resources available to conduct intensive studies of each new drug. While the evidence practical economics provides may not be as rigorous as that derived from fully-executed, formal pharmacoeconomic analyses, the data is more relevant. After all, knowing the total societal costs of a drug is less relevant for a hospital's pharmacist, physician, or finance officer than understanding the costs of that drug to the hospital.

The sections that follow detail the steps involved in conducting a practical economic analysis for any drug of interest.

Practical Economics: Measuring Cost

The starting point for determining your hospital's costs for drug therapy is with the purchase price of the drug. To do so your cancer must ***determine the acquisition price*** for each anti-cancer drug. Use the following steps to determine this price:

1. Establish the standard dose of the drug. If the dosing for the drug is highly variable, use the average dose given to patients at your institution (defined as the total volume of drug given divided by the number of times the drug was given).
2. Determine the number of doses used in a typical treatment episode. For example, if 10 mg antibiotic is usually prescribed for daily use for a 21-day period, the dose per treatment episode of this drug would be 210 mg.
3. Determine the number of doses contained in all shipments of the drug from the wholesaler in the most recently completed quarter.
4. Sum the invoice prices for the shipments, exclusive of volume-dependent rebates.
5. Divide the total invoice price by the total number of doses to obtain the per-dose acquisition price.
6. Multiply the per-dose acquisition price times the number of doses in a treatment episode.

The second step in estimating costs is to ***determine the ancillary costs***, which includes all staff resources needed to support the use of the drug. The general approach to estimating these costs is to:

1. Identify the relevant staff. Pharmacists (for preparation) and nurses (for administration of IV and injectables) are the personnel most likely to devote meaningful resources to drug-based therapy.
2. Obtain an estimate of the time needed to prepare/deliver/prescribe/explain a single dose of the drug. Subjective estimates will suffice where there is general agreement among those queried.
3. Multiply time by staff's hourly rate by the number of doses in a treatment episode and sum across all staff.

Although many pharmacoeconomic analyses extend measurement of the cost dimension to include indirect costs, we do not recommend this step for a practical economic analysis unless a meaningful disparity in indirect costs exists between the two drugs under consideration.

Combining acquisition price and the costs for consumed ancillary resources completes the expenditure side of a drug's cost. Expenditures for a drug and its costs are exactly the same in four situations:

- *Inpatient use.* The drug is given to a patient whose inpatient stay is reimbursed under a fixed rate.
- *At-risk patients*. The drug is given to a patient for whom your hospital accepts a fixed premium and then provides care without charging for specific services.
- *Uninsured patients*. The drug is given to a patient who is both uninsured and does not have the capability to pay for care.
- *Uncovered use*. The drug is not covered by the patient's insurer, and the patient does not have the ability to pay.

Determine revenue from reimbursement. When a drug is reimbursed, this revenue must be included in the calculation of cost. Failure to do so leads to a distorted view of the actual costs of a drug to your hospital. Two of the most typical cases where reimbursement must be considered are o*utpatient use of covered drugs*, e.g, a drug is given to patients receiving care in your outpatient department and it is covered by their insurers; and *charge-based care* e.g., the drug is given to inpatients covered by plans that reimburse based on services (rather than DRGs) or the patient is self-paying.

Calculating the revenue obtained from reimbursement can be complicated, largely because reimbursement can differ dramatically from one insurer to the next. Calculating revenue from reimbursement also requires a conversion from dose to billing unit as the unit of measurement. Five specific steps are necessary to estimate revenue from reimbursement (see Table 2).

First, determine the volume listed for the drug in the narrative description of its HCPCS number. This number is

Table 2: Five Steps to Measure Drug Costs

1. Determine the acquisition cost.
2. Determine ancillary costs.
3. Combine acquisition and ancillary costs.
4. Calculate drug revenue from reimbursement.
5. Calculate difference between expenditures and reimbursement.

the drug's billing unit. The billing unit can approximate the standard dose but may be completely unrelated to dose.

Second, divide the dose per treatment episode by the billing unit.

Third, using the most recent quarter for which your cancer center has data, determine patient volume for each major insurer.

Fourth, determine reimbursement rates for the drug from each insurer. These amounts may either be fixed by a fee schedule (as they are by Medicare) or set as a percentage of charge.

Finally, multiply the expected reimbursement by the patient volume percentage and sum across all insurers. This amount is the gross revenue for the drug.

The cost of the drug to your hospital is then determined by calculating the difference between expenditures and its reimbursement.

Practical Economics: Measuring Health-Related Outcomes

Although the costs of a therapy vary considerably based on the perspective (for example, the costs of a drug to the insurer differ from those to the patient), the same is usually not true for the health consequences. Drugs that are aimed at extending survival, reducing emesis, or limiting the need for inpatient care have those same objectives for everyone—patients, payers, and providers alike. Because of this mutuality of objectives, the health benefits of a drug in published reports can often be used in your practical economic analysis. Further, because all drugs require rigorous studies of efficacy before they are approved for marketing, a practical economic analysis of any drug always begins with a careful study of the health-related outcomes in the published literature.

However, a drug's effects can vary substantially across populations. Therefore, for measuring health-related consequences, you must first determine whether the population of patients seen at your hospital differs in any meaningful way—in a way that is likely to be related to effectiveness—from those patients treated in the controlled studies. Two types of differences must be considered.

The first of these is *differences in outcomes*. Your hospital's population may differ from the general population in some way that influences outcomes. Biological differences (age and gender) are the most common reasons for different outcomes, but socioeconomic factors that are strongly related to compliance can also result in a drug having less efficacy than expected.

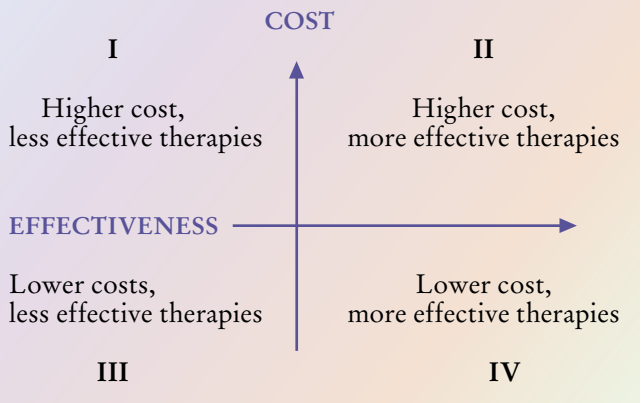
The second variable is *differences in valuation of outcomes*. In many cases, drugs achieve multiple outcomes. When multiple outcomes occur, the importance that is placed on each outcome can affect the perceived value of the drug. For example, if an anti-cancer drug is exceptionally effective at offering symptomatic relief but extends survival only slightly, it would be highly valued by those patients primarily interested in improving their quality of life and discounted by those most interested in extending life. Complex methods have been developed for assessing the value that an outcome has for patients (called *patient utilities*) and that allow you to sum across multiple outcomes. However, in choosing drugs for your own institution, it is important that the priorities given to drugs by the general population match those your own patients would have.

If there is reason to assume that either of these factors might influence the effectiveness of a drug, both quantitative and qualitative adjustments can be made. Our recommendation is that adjustments be made by a panel of at least three clinical staff, who review the available evidence and then jointly decide on reasonable adjustments of the published efficacy. For example, this panel might decide to reduce the general estimate that a drug offers 5 years disease-free survival by 10 percent (or any other amount) because its hospital's patients are considerably older than the patients enrolled in the clinical trials. While this approach is certainly imprecise, it both forces explicit assessment of efficacy and is also preferable to no analysis whatsoever.

Decision Rules

Once both cost and effectiveness have been estimated, some decisions about optimal drug choices can be easily made while others present more of a dilemma (see Fig. 1). Two situations offer clear choices. First, if two (or more) drugs have equivalent cost, the one that offers the best outcomes (or minimizes bad outcomes) should be selected. Second, if two drugs offer equivalent outcomes, the one with the bet-

Figure 1: Drug Cost versus Drug Effectiveness



Why Practical Economics

Regulators and policy-makers must understand the societal implications of how healthcare is delivered. Providing valid and reliable evidence about those implications is the objective of pharmacoeconomics. Your hospital's ability to provide quality healthcare services to patients, however, depends more on the specific costs of those services to you than on the costs to society at large. Practical economics was developed to address this need.

ter cost profile for your institution should be selected.

If competing drugs differ in both costs and outcomes, the decision about which drug to use becomes more difficult. In these instances, the marginal cost-effectiveness of the more efficacious drug should be computed. The relevant clinical team should then make a recommendation regarding whether that ratio merits use of the drug. A generally accepted benchmark of "value" is the ratio of $50,000 per life-year saved; however, this dollar amount is based on societal costs and must be considered in light of the financial health of the hospital. Any resources expended will ultimately impact your institution's ability to provide care across the full spectrum of patients, so the recommendation for which drug to use should include an estimate of budgetary impact.

The other difficulty faced in deciding between drugs is the obligation that hospitals have to their patients. Sometimes the more expensive drug will also be the one that offers the best value. Since these drugs also require higher co-pays from patients, consider the implications of the co-pay on your patient population before selecting these products. Special attention should be given to the question of whether the size of the co-pay will present a meaningful barrier to use for some patients. If a drug has a high co-pay, you may want to have the clinical team explicitly address the question of value with patients and offer them the choice of drugs.

Finally, you should recognize that in many instances, the drug that is optimal from the hospital's perspective will not be the one that offers the best value from a societal perspective. This difference in perspective arises because costs can be radically different when they account for reimbursement (as they should from the hospital's perspective) and when they do not (when measuring cost from the societal perspective). The conflict that results is that hospitals are often forced to choose between what is in their interests and what is in the interest of the entire healthcare system. We cannot offer concrete guidelines on how to make this choice but suggest that the decision is best made with a clear understanding of the true costs to your institution.

Practical Implications

The most important consequence of adopting a practical economic perspective for evaluating drugs is that it can lead to the exact opposite conclusion about a drug's value to that presented in pharmacoeconomic studies. As should be clear, the different conclusions will result largely from the inclusion of reimbursement on the "cost" side of a practical economic analysis and its exclusion from the traditional pharmacoeconomic study.

The impact of including reimbursement in the analysis has another implication. A practical economic analysis is likely to yield different findings about a drug's relative value based on whether the drug is used in the inpatient or outpatient setting. Generally, the worse the financial profile of a drug for inpatient care, the better its profile for use in the outpatient setting. Stated more directly, when effectiveness is equivalent, the more expensive a drug, the lower its value in the inpatient setting (where there is no reimbursement) and the greater its value in the outpatient setting (where reimbursement often reduces true cost to zero).

The lesson is that you must understand how and where a drug will be used and adjust your assessment of costs accordingly. A uniform policy of assuming that cost is equal to acquisition price is likely to have a deleterious effect when a hospital uses a significant volume of drugs for outpatient care.

The need to incorporate the setting of care into the process of choosing drugs is especially important for oncology drugs. One obvious reason is because these drugs constitute a significant portion of your hospital's drug purchases. More immediately, however, choosing oncology products that offer the best value will become increasingly important because hospital outpatient departments are likely to see a dramatic increase in the demand for medical oncology services in the near future. This demand is predicted because of the imminent reduction in reimbursement to office-based physicians for medical oncology services. The expectation is that many smaller or less efficient offices will need to close because of the 2005 payment cuts. Should this scenario happen, many patients will be forced to seek care in hospital outpatient departments.

The decisions that you will need to make about the medical oncology drugs that offer the best value to your hospital and its patients require a practical economic analysis. Without it—especially if there is a continued perception that the price of a drug is the only relevant factor in determining its cost—your institution will likely make less than optimal choices.

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Author's note: The term 'therapy' is used in this article in the broadest sense of the word and is meant to include any attempt to improve health status. Examples would include prevention programs (smoking cessation or change in diet), palliative care (grief counseling), national screening programs, and such.