

Principles of Pharmacoeconomics Background

An economic evaluation is a study that compares the costs and results (outcomes) of two or more available interventions or services.

Assessing the clinical effectiveness (outcomes) of any new health care intervention, including medications, is paramount in determining the role of the new intervention in clinical practice. The **new** interventions may provide only a modest advantage (or no advantage) over existing treatment, usually at a **higher cost**. In the case of pharmaceutical interventions, pharmacoeconomics attempts to measure if the **added outcome** of one intervention is **worth the added cost** of that intervention⁽¹⁾.

Pharmacoeconomics has been defined as the description and analysis of the costs of drug therapy to health care systems and society. It identifies, measures, and compares the costs and consequences of pharmaceutical products and services.

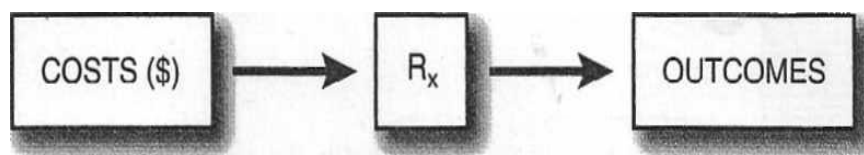


Figure 1. Basic pharmacoeconomic equation. Pharmacoeconomic studies compare the costs (left box) associated with providing a pharmacy product or service (represented as Rx) to the outcome of the product or service.

To show this graphically, think of two sides of an equation (Fig. 1.)⁽¹⁾. The left-hand side of the equation represents the **inputs (costs)** used to obtain & experience and use the pharmaceutical product or service. The right-hand side of the equation represents the **health-related outcomes** produced by the pharmaceutical product or service. The center of the equation, the drug product or service being assessed, is symbolized by *Rx*.

If just the left-hand side of the equation is measured without regard for outcomes, it is a **cost analysis** (or a partial economic analysis). If just the right-hand side of the equation is measured without regard to costs, it is a clinical or outcome study (not an economic analysis)⁽¹⁾.

To be a true pharmacoeconomic analysis, **both sides of the equation must be considered and compared**. Theoretically, at least two options must be compared in pharmacoeconomics, but some assessments consist of a "with or without" comparison, estimating what would occur if the product or service was provided (e.g., immunization or pharmacy clinic services) compared with no provision of the product or service⁽¹⁾.

Relationship of Pharmacoeconomics to Other Research

Health care economics encompasses a broad range of topics, including supply and demand for health care resources, the effects of health insurance, and manpower supply. Clinical or humanistic outcomes research is defined as the attempt to identify, measure, and evaluate the end results of health care services.

Consequences (results, benefits, outcomes)

Similar to costs, the outcomes or consequences of both (a disease and its treatment) are an equally important component of pharmacoeconomic analyses ⁽³⁾.

Depending on **perspective**, the outcomes of health care are multidimensional. The clinician has traditionally been most concerned with clinical outcomes of treatments. More recently, healthcare payers and administrators have focused on the resource use or economic outcome of healthcare decisions. Patients are increasingly knowledgeable and involved in decisions regarding their own health care and the humanistic outcomes of therapy. Patients want to know how their quality of life will be affected or how satisfied other patients with their condition have been with various treatments.

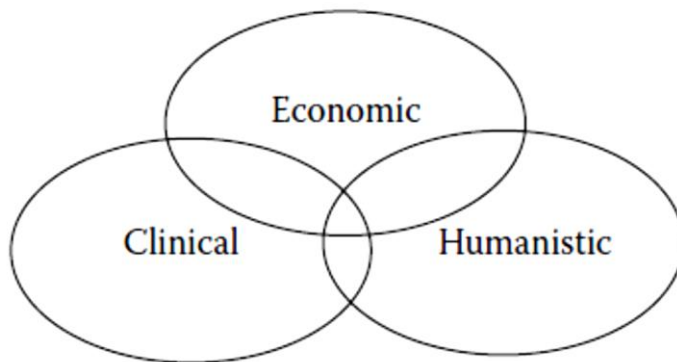
The consequences of medical care can be categorized into three categories: economic, clinical, and humanistic. *Economic outcomes* represent the **reductions** in costs of therapy. *Clinical outcomes* are the medical events that occur as a result of disease or treatment (e.g. safety and efficacy end points).

Humanistic outcomes are the consequences of disease or treatment on patient functional status or quality of life along several dimensions (e.g., physical function, social function, general health and well-being, and life satisfaction).

Assessing the economic, clinical, and humanistic outcomes (ECHO) associated with a treatment alternative provides a complete model for decision making⁽³⁾.

Outcomes measurement must take into account economic considerations while focusing on acceptable clinical and humanistic outcomes. The true value of healthcare interventions, programs, and policy can be assessed only if **all three** dimensions of outcomes are measured and considered ⁽²⁾.

ECHO Model: Economic, Clinical, and Humanistic Outcomes



Positive versus negative consequences

These outcomes can be further categorized as positive or negative. An example of a positive outcome is a desired effect of a drug (efficacy or effectiveness measure), possibly manifested as cases cured, life-years gainedetc⁽³⁾.

Since all drugs have adverse effects, negative consequences also can occur with their use. A negative outcome is an undesired or adverse effect of a drug, possibly manifested as treatment failure, an adverse drug reaction (ADR), a drug toxicity, or even death. Pharmacoeconomic evaluations should include assessments of **both types** of outcomes. Evaluating only positive outcomes may be misleading because of the potential **detriment** and **expense** associated with negative outcomes⁽³⁾.

(The nature and assessment of costs, in healthcare)

Identifying costs:

It is important to take into account **all the costs** associated with an intervention, not just acquisition market prices. Calculation of true economic cost is difficult, but it is essential to make sure that cost information reflects true economic cost as closely as possible. For example, prescribing the highly effective anticoagulant heparin for a person with a thrombotic event does not just incur the costs of buying the drug. Heparin can have serious side effects, and so regular blood monitoring tests have to be carried out in all patients. Therefore, these monitoring costs must be taken into account when the economic implications of using heparin are being assessed. A very small number of patients go on to experience serious side effects that require hospitalization and treatment, and these costs must also be identified and measured ⁽⁴⁾.

Types of costs

Economic studies use a range of costs. It is important to be able to distinguish between the different types of costs that are used. Costs are usually divided into direct, indirect and intangible depending on perspective (Figure 2)⁽⁴⁾ and table 1 ⁽¹⁾.

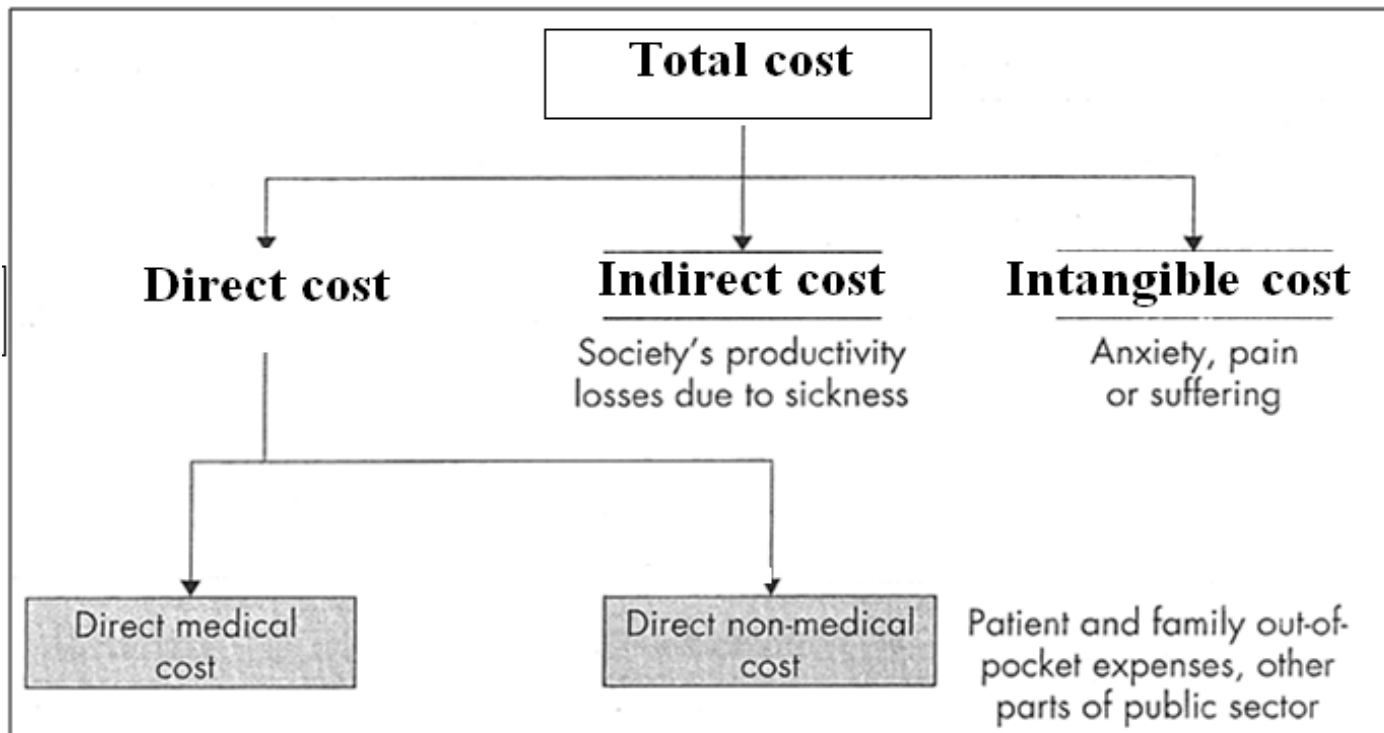


Figure 3 types of costs⁽⁴⁾

TABLE 1. EXAMPLES OF TYPES OF COSTS	
Type of Cost Category	Examples
Direct medical costs	<ul style="list-style-type: none"> • Medications • Medication monitoring • Medication administration • Patient counseling and consultations • Diagnostic tests • Hospitalizations • Ambulance services • Nursing services
Direct nonmedical costs	<ul style="list-style-type: none"> • Travel costs to receive health care (bus, taxi or airplane) • Hotel stays for patient or family for out-of-town care • Child care services for children of patients
Indirect costs	<ul style="list-style-type: none"> • Lost productivity for patient • Lost productivity for unpaid caregiver (e.g., family member, neighbour, friend) • Lost productivity because of premature mortality
Intangible costs	<ul style="list-style-type: none"> • Pain and suffering • Fatigue • Anxiety

1-Direct Medical Costs

Direct medical costs are the most obvious costs to measure. These are the medically related inputs used directly to provide the treatment. Examples of direct medical costs include the costs associated with the pharmaceuticals, diagnostic tests, physician visits, pharmacist

visits, emergency department visits, and hospitalizations.

Example: during chemotherapy treatment, direct medical costs may include the chemotherapy products themselves, other medications given to reduce side effects of the chemotherapy, intravenous supplies, laboratory tests, clinic costs, and physician visits⁽¹⁾.

2-Direct Nonmedical Costs

Direct nonmedical costs are costs to patients and their families that are **directly associated with treatment but are not medical in nature**. Examples of direct nonmedical costs include the cost of traveling to and from the physician's office, clinic, or the hospital; child care services for the children of a patient; and food and lodging required for the patients and their families during out-of-town treatment.

Using the example of chemotherapy treatment, patients may have increased travel costs related to traveling to the clinic or hospital. They may also have to hire a babysitter for the time they are undergoing treatment⁽¹⁾.

3-Indirect costs

Indirect costs are incurred by the **reduced productivity** of a patient and their family, resulting from illness, death or treatment. They may include time off work or; time spent going to healthcare providers; time spent caring for the patient by relatives ⁽¹⁾. Only the following indirect costs can be calculated reliably from data:

A-Time off work due to sick leave

B-Early retirement

C-Reduced productivity at work.

The significance of indirect costs depends upon the particular illness and treatments involved. Diseases such as asthma, migraine and depression affect working age groups, whereas other diseases, such as Alzheimer's, do not.

Indirect costs are difficult to measure and sometimes are underestimated in certain patient groups like children, housewives, nonworking and the elderly. Because of the difficulties concerning indirect costs, they are not often included in economic studies. However, they should always be considered, if not measured⁽⁴⁾ because they have a dramatic effects on the results of economic analysis.

4-Intangible costs

Intangible costs are difficult or impossible to measure, but they still occur and it is of value to identify them. They can include **anxiety, pain or suffering** from an illness or treatment⁽⁴⁾.

Fixed, semifixed and variable costs ⁽⁴⁾

The costs of healthcare can be split into fixed costs & variable costs. There is an intermediate category called semifixed costs.

1- Fixed costs

These costs are incurred whether patients are treated or not. These costs include two major components: overhead & capital costs. Examples of capital costs are building hospitals or

counseling rooms, costs of equipments & instruments.

2- Variable costs

These costs are incurred from patients' treatment. They include disposable equipments, drugs, blood products & investigations.

3- Semifixed costs

These costs virtually refer to staffing costs. Staff costs may vary directly with activity and here they can be considered as variable costs. However, staff costs may increase only when there is a large increase in activity and here they can be considered as semifixed costs.

What costs need to be included in an economic evaluation⁽⁴⁾

It is important to state the **perspective** of the study, as this determines which costs are included. Health economics is based on welfare economics, and so it is concerned with society's welfare, not just the welfare of individual patient groups or healthcare providers. Therefore, the ideal perspective is considered to be the societal perspective because it is the widest perspective and looks at the costs from the viewpoint of society as a whole. The societal perspective includes direct, indirect and intangible costs.