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## **A Brief Description of Pharmacoeconomics**

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### **ABSTRACT**

Pharmacoeconomics is a young science that will improve with application. Its need is undeniable, especially in developing countries. Pharmacoeconomics is a sub-discipline of the field of health economics, which itself is a relatively new sub-discipline of economics, only formerly appearing in the economics scientific literature since the 1960s. Accuracy of cost-effectiveness estimates depends on the quality of input variables; validity of surrogate end points; and appropriateness of modelling assumptions, including model structure, time horizon and sophistication of the model to differentiate clinically and economically meaningful outcomes. Economic analysis alongside pivotal clinical trials are often inconclusive due to the suboptimal collection of economic data and protocol-driven costs. The two fundamental components of pharmacoeconomic studies are measures of costs and measures of outcomes that are combined into a quantitative measure or ratio. It can be done using various methods like Cost-minimization analysis (CMA), Cost-effectiveness analysis (CEA), Cost-utility analysis (CUA), and Cost-benefit analysis (CBA). Cost involves all the resources that are used to produce and deliver a particular drug therapy. The need for pharmacoeconomic evidence has fundamentally changed the strategic imperatives of research and development (R&D). Therefore, professionals in pharmaceutical R&D have to be familiar with the principles of pharmacoeconomics, including the selection of health policy-relevant comparators, analytical techniques, measurement of health gain by quality adjusted life-years and strategic pricing of pharmaceuticals.

**Keywords:** Pharmacoeconomics, Cost effectiveness analysis, Drug therapy.

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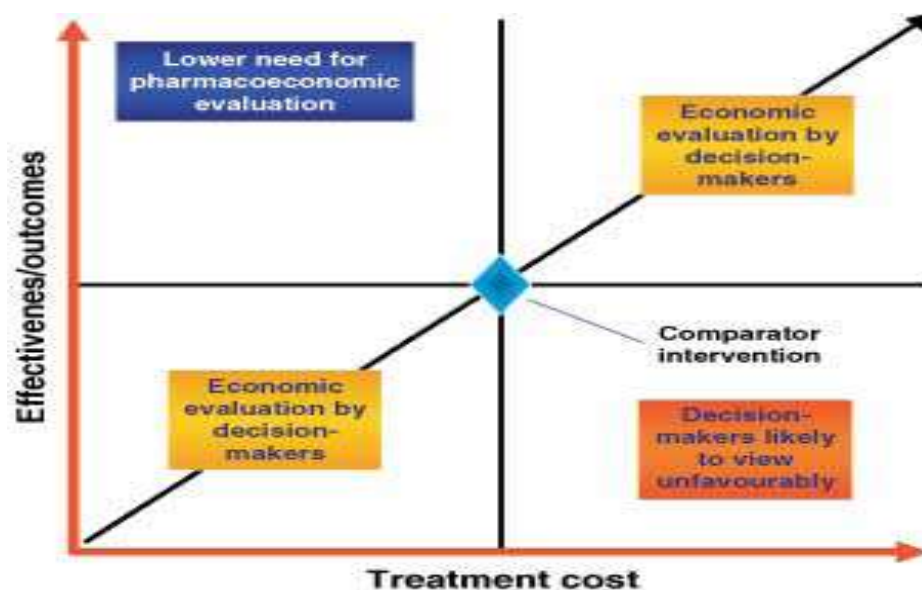
## INTRODUCTION

While the economic development in India has been gaining momentum over the last decade, our health system is at crossroads today. Even though Government initiatives in public health have recorded some noteworthy successes over time<sup>1</sup>, our achievements in health outcomes are only moderate by international standards; India is ranked 118 among 191 WHO member countries on overall health performance<sup>2</sup>. The Government's contribution to the total healthcare expenditure is only 20 percent, and therefore out-of-pocket expenditure is as high as 80 percent. The cost of healthcare is increasing rapidly. A large majority of our population cannot afford healthcare expenses. In India, there are five forms of healthcare insurance/private insurance, social insurance, employer-provided cover, community insurance schemes, and government healthcare spend. Only 3-4 percent of our population is insured. Advances in healthcare technology have led to significant improvements in the quality of healthcare and in population health and, in parallel, have contributed to increases in real health expenditure in most industrialized countries over the recent decades<sup>3</sup>. The expenses on drug therapy is a exact target for several reasons: the magnitude of the drug bill; the ease of measurement of pharmaceutical costs in segregation, in contrast to most other health care costs; confirmation of wasteful prescribing; and a perception that many drugs are overpriced and that the profits of the pharmaceutical industry are excessive<sup>4</sup>. It is currently being used to make formulary decisions, design disease management programs and calculating the cost-effectiveness of interventions and programs in managed care<sup>5</sup>. Economic analysis have been conducted to support decision makers regarding the cost of available therapeutic alternatives, aiming at providing efficient resource allocation to achieve maximum benefit in health care. Economic evaluations focus on the costs and the benefits of a new intervention over and above those provided by the current therapy. Pharmacoeconomics is a branch of health economics which particularly focuses upon the costs and benefits of drug therapy<sup>6</sup>. It is a new word; but economic interest in drug and other treatments of health problems is much older. Decisions about what treatments should be available within a health-care system have always been influenced by the resources available to pay for them<sup>4</sup>. Pharmacoeconomics adopts and applies the principles and methodology of health economics to the field of pharmaceutical policy<sup>7</sup>.

### **Need of Pharmacoeconomics**

Pharmacoeconomics has become more important over the past 20 years, due to an increased emphasis on efficient drug therapies for disease, which increase health costs, etc.

1. Rising health expenditure have led to the necessity to find the optimal therapy at the lowest price. Pharmacoeconomics is an innovative method that aims to decrease health expenditure, whilst optimizing healthcare results.
2. Pharmaceutical expenditure, which constitutes a large part of healthcare expenditure, has been increasing much faster than total healthcare expenditure.
3. Numerous drug alternatives and empowered consumers also fuel the need for economic evaluations of pharmaceutical products.
4. The increasing cost of healthcare products and services has become a great concern for patients, healthcare professionals, insurers, politicians and the public.
5. The increasing concern has prompted demand for the use of economic evaluations of alternative healthcare outcomes. This escalation in healthcare spending is due to increased life expectancy, increased technology, increased expectations, increased standards of living and an increased demand in healthcare quality and services.
6. Healthcare resources are not easily accessible and affordable to many patients; therefore pharmacoeconomic evaluations play an important role in the allocation of these resources (8).



**Figure.1: Need of Pharmacoeconomics**

Pharmacoeconomics is the description and analysis of the costs of drug therapy to healthcare systems and society. The importance of pharmacoeconomic information to healthcare decision makers will depend upon the viewpoint from which the analysis is conducted (i.e., including only costs that are relevant to managed care)<sup>9</sup>. Use of pharmacoeconomics is important in priority-setting between drug therapies since budgets are finite and there is great variance in

value for money for products in the market. Pharmacoeconomic evidence can help decision-makers judge whether the therapeutic benefits produced by a new drug are worth the extracosts<sup>10</sup>. In high-income countries pharmacoeconomic analysis is widely used to guide priority-setting decisions for pharmaceuticals<sup>11</sup>. National Institute of Clinical Excellence (NICE) in the UK and the Canadian Agency for Drugs and Technology in Health (CADTH) are examples of institutions which have been established for pharmacoeconomic evaluation of new pharmaceutical products and technologies<sup>12</sup>. Pharmacoeconomic evaluation has also gained acceptance at hospital level in formulary decision-making in these countries<sup>13</sup>.

### **Methods of Economic Evaluation**

Economic evaluation is the formal process of weighing benefits and costs in an incremental analysis. It is essentially a framework which draws up a balance sheet between costs and benefits to assist decision making. Within this framework are included the research methods related to cost-minimization, cost-effectiveness, cost–benefit, cost-of-illness, cost-utility, cost-consequences, and decision analysis, as well as quality-of-life and other humanistic assessments. There are several types of pharmaceconomic evaluation<sup>14</sup>, each of which is useful in different circumstances

**Cost-of-illness analysis** consider the costs of a given disease without considering the outcome. It measures the economic burden of disease and illness on society. It is often called burden-of-illness (BOI). The components of a pharmacoeconomic or cost-effectiveness analysis include costs and consequences. Costs can be divided into direct and indirect costs. Direct medical costs are those related to providing medical services, such as a hospital stay, physician fees for out patient visits, and drug costs (including the cost of the medication itself and any down stream adverse events that may arise as a result of drug administration). Direct nonmedical costs are those related to expenses, such as transportation costs, that are a direct result of the illness. Direct costs are most frequently included in a COI study, whereas indirect costs, those associated with changes of individual productivity, are often not included in a COI study, because they are difficult to obtain. Examples of indirect costs are lost time from work (absenteeism) and unpaid assistance from a family member. In addition, intangible costs, such as pain and suffering, may be included in the analysis. Analysis can be done from one or several perspectives, which will help in determining the distribution of disease costs across multiple stake holders. The societal perspective typically includes indirect, as well as direct, medical costs because these are costs to society, that is, as previously mentioned, lost time from work. COI analysis are used to aid in policy making; resource allocation—that is, prioritizing resource use for disease treatment and

prevention—and as baseline research from which to determine the potential benefit of new therapies<sup>15</sup>.

**Cost-minimization analysis** compares the costs of interventions that provide the same outcome, with the ultimate aim of identifying the cheapest option. When two or more interventions are evaluated and demonstrated or assumed to be equivalent in terms of a given outcome or consequence, costs associated with each intervention may be evaluated and compared. This typical cost analysis is referred to as cost-minimization analysis. An example of this type of investigation regarding drug therapy may be the evaluation of two generically equivalent drugs in which the outcome has been proven to be equal, although the acquisition and administration costs may be significantly different<sup>16</sup>.

**Cost-effectiveness analysis** involves the comparison of cost per standardized unit of effectiveness for two or more interventions that provide varying outcomes. It provides a framework to compare two or more decision options by examining the ratio of the differences in costs and the differences in health effectiveness between options. The overall goal of CEA is to provide a single measure, the incremental cost-effectiveness ratio (ICER), which relates the amount of benefit derived by making an alternative treatment choice to the differential cost of that option. When two options are being compared, the ICER is calculated by the formula:

$$\frac{\text{COption 2} - \text{COption 1}}{\text{Effectiveness Option 2} - \text{Effectiveness Option 1}}$$

In medical or pharmacoeconomic cost-effectiveness analysis, health resource costs (the numerator) are in monetary terms, representing the difference in costs between choosing option 1 or option 2. In cost-effectiveness analysis, the differential benefits of the various options (the denominator) are non-monetary and represent the change in health effectiveness values implied by choosing option 1 over option 2. Typically, these health outcomes are measured as lives saved, life years gained, illness events avoided, or a variety of other clinical or health outcomes<sup>17, 18</sup>.

**Table 1: Basic Components of a Cost-Effectiveness Analysis**

<b>Component</b>	<b>Examples</b>
Options/comparisons	Existing program compared with new program
Perspective of the analysis	Societal, health system, patient
Time horizon	1 month, 5 years, lifetime
Scope of the analysis	Population affected, inclusion (or not) of secondary or collateral effects
Measuring and valuing costs	Cost categories included in the analysis are determined by the perspective taken
Measuring and valuing outcomes	Life years saved, illnesses avoided, cases found
Time preference	Discounting future costs and effectiveness
Analytic models	Clinical trial data, decision analysis model
Accounting for uncertainty	Sensitivity analysis

**Cost-utility analysis** aim to compare the cost per quality adjusted life-year for two or more interventions that provide varying outcomes. CUA is a special case of cost-effectiveness analysis (CEA), where the numerator of the incremental cost-effectiveness ratio (ICER) is a measure of cost (similar to other forms of CEA) and the denominator is measured typically using a metric called the *quality-adjusted life year* (QALY). A QALY accounts for both survival and quality of life (QoL) benefits associated with the use of a healthcare technology. The QoL component of the QALY is measured using a metric known as a *health utility*; hence, the term *cost-utility analysis* is used to describe this form of CEA. Given that the QALY can be used to measure the survival and QoL benefits of a healthcare technology, the QALY can serve as a common metric from which to compare the benefits of very different healthcare technologies (e.g., migraine pharmacotherapy versus angioplasty). Thus, one of the primary advantages of conducting a CUA is that the ICER theoretically can be considered a common metric from which to compare the relative value of one health care technology (e.g., drug) with a completely different healthcare technology (e.g., vaccine). This universal quality of a CUA is the primary reason many policy makers and reimbursement agencies prefer or require CUA when requesting a reimbursement dossier from a manufacturer. In fact, some reimbursement agencies have established ICER thresholds from which to determine whether a healthcare technology is cost effective. For example, the National Institute for Health and Clinical Excellence (NICE) has used the benchmark ICER of £ 30,000 per QALY gained as a threshold from which to judge whether a drug is cost effective for the National Health Service (NHS) in England<sup>19,20</sup>. In the United States, \$50,000 per QALY gained has been frequently used in cost-effectiveness analysis as a threshold<sup>21,22</sup>. From a global perspective, the World Health Organization (WHO) has established a cost-effectiveness criterion indicating that a healthcare technology is cost effective if the ICER

is less than three times the per capita gross domestic product (GDP) for a given country<sup>23</sup>. To summarize, CUA can serve as a general framework for conducting economic evaluations and a practical tool for decision-makers faced with making reimbursement decisions across widely different healthcare technologies.

**Cost-benefit analysis** compare the costs and benefits of two or more interventions that provide varying outcomes, where outcome is measured in monetary terms. It is a basic tool that can be used to improve the decision-making process in all location of funds to health care programs. Although the general concept of cost-benefit analysis is not overly complicated, many technical considerations require a degree of explanation and interpretation understand how it can be or has been applied. Cost-benefit analysis consists of identifying all of the benefits that accrue from the program or intervention and converting them into dollars in the year in which they will occur. This stream of benefit dollars is then discounted to its equivalent present value at the selected interest rate. On the other side of the equation, all program costs are identified and allocated through a specific year and, again, the costs are discounted to their present value. Then, if all relevant factors remain constant, the program with the largest present value of benefits less costs is best in terms of its economic value. Ideally, all benefits and costs resulting from the program should be included. This presents considerable difficulty, especially on the benefits side of the equation, as many benefits are either difficult to measure, difficult to convert to dollars, or both. For example, the benefits of improved patient quality of life, patient satisfaction with the health care system, and working conditions for the physician are not only difficult to measure, but are extremely difficult to assign a dollar value to. This problem has been addressed by many researchers in health economics, but has not been completely resolved. Generally the analyst or researcher will convert as many benefits as possible into monetary units. The remaining variables are labeled as “intangible benefits” and left to decision-makers to include in their final deliberations. Cost-benefit analysis often has been used when comparing the value of dissimilar programs where the out comes are in different units (eg, cost-benefit of having an neonatal care program vs a cardiac habilitation program)<sup>24</sup>. In essence, pharmacoeconomic analysis uses important tools for examining the outcomes or impact of drug therapy and related healthcare interventions.

### **Handling the Results of Economic Evaluations**

Consider the four possible results arising in a CEA (figure 2). First, if costs are lower and health benefits higher for one drug relative to another, the former is said to dominate and would be the

preferred treatment (quadrant II). Second, the opposite applies, i.e. the new drug is more expensive and less effective, and thus is considered inferior and not recommended (quadrant IV). The third and most common case is where the new drug is both more effective and more expensive than the standard (quadrant I); on the basis of ICERs, a judgement must be made regarding whether the additional benefits are worth the extra costs of the new drug and, therefore, whether it is 'cost-effective'. This might be defined by a previously agreed ICER threshold value. The fourth case is similar to the third, with the roles of the new therapy and the standard reversed (quadrant III); the question now is whether the extra benefits provided by the standard justify the additional costs of retaining it as the preferred treatment when the option of a new, cheaper but less effective drug exists.

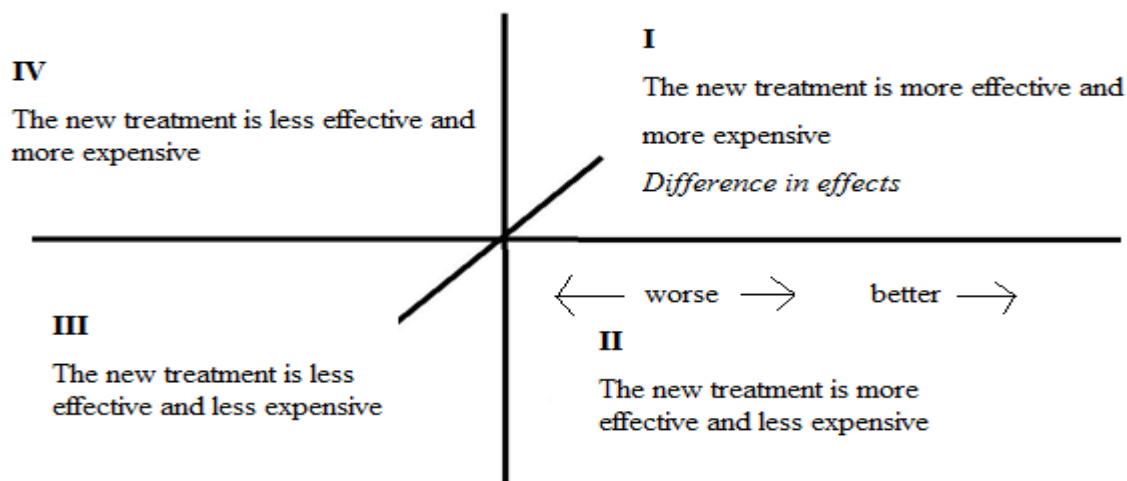


Figure 2: Difference in Costs

### Historical Perspective

The emerging discipline of pharmacoeconomics has become a health science discipline by the pharmaceutical industry, academic pharmaceutical scientists, and pharmacy practitioners worldwide. Their search methods used by scientists in this discipline (e.g., cost-effectiveness, cost-utility, quality-of-life evaluations) are drawn from many areas: economics, epidemiology, medicine, pharmacy, and the social sciences. During the early 1960s, pharmacy began evolving as a clinical discipline within the health care system. In the 1970s, pharmacoeconomics developed its roots. In 1978, McGhan, Rowland, and Bootman, from the University of Minnesota, introduced the concepts of cost-benefit and cost-effectiveness analysis<sup>25</sup>. The actual term "pharmacoeconomics" did not appear in the literature until 1986 when the first of a two-part presentation by Towns end was published describing then end to develop research activities in this evolving discipline. To date, many of the efforts in this discipline have been directed toward the refinement of their search methods and their application

to evaluating pharmaceutical services and specific drug Therapies<sup>26</sup>. The term pharmacoeconomics was used in public forum was in 1986, at meeting of pharmacist in Toronto, Canada, when Ray Townsend from the Upjohn company, used the term in presentation. Ray and few other had been performing studies using the term pharmacoeconomics within the pharmaceutical industry since the early eighties today pharmacoeconomics research is a flourishing industry with many practioners, a large research and application agenda, several journals and flourishing professional societies including the international society for pharmacoeconomics and outcomes research<sup>27</sup>.

### Challenges

The main challenges for pharmacoeconomics continue to be:

- Establishing guidelines or standards of practice.
- Creating a cadre of trained producers and consumers of pharmacoeconomic work.
- Continuing education on the relevant features of this discipline for practitioners, government officials, private sector executives.
- Stable funding to support applied pharmacoeconomic research<sup>28</sup>.

#### Pharmacoeconomic Guidelines

- Researchers and evaluators continue to develop and refine guide lines for pharmacoeconomic analysis. The uses and subject of the proposed guidelines are as follows:

1. Methodologic guidelines would guide researchers to appropriately design, conduct, analyze, and report economic and humanistic evaluations.

2. Reimbursement and pricing guidelines would outline the content, presentation, and evaluation of pharmacoeconomic data to determine or justify the price or reimbursement of a pharmaceutical product.

3. Approval guidelines would set the standards acceptable to a particular government to obtain approval to market a new product.

4. Promotional guidelines would set the criteria for the use of pharmacoeconomic data in support of pharmaceutical promotion to prescribers and consumers. Although the intent of the call for guidelines is under standable, at present, the science of pharmacoeconomic research is still developing. It would not be desirable to implement guidelines that would limit the development of knowledge in this area. Suffice it to say that the substance of any guidelines involving research must be well grounded in appropriate methodology and sound scientific principles<sup>29</sup>.

### Limiting Factors for Pharmacoeconomic Evaluation

- a) Choice of the drugs is given according to the marketed pressure. Pharmacists give drugs as per their will (alternative drugs for prescribed medicine).
- b) Drugs are prescribed under promotional pressurizing activities of marketing executives of pharmaceutical firms. Incentives and gifts offered by these firms to doctors have a major impact on prescribing brands.
- c) For chronic diseases, bio-availability consideration can have an upper- hand over pharmacoeconomics.

To overcome these limitations, the following steps should be taken:

- 1) State associations should buy medicines directly from the firm/industry and sell to retailers who are associated members. These drugs would cost 30 - 40% lesser than current prices.
- 2) Retailers should lower their profit margins. There are three layers between drug makers and purchasers; super stockiest, authorized stockiest and semi-wholesalers. Dealing directly with the drug firm and availability of drugs through affiliated drug retailers would lower prices by 10 - 12%.
- 3) Hospitals can buy expensive drugs for cancer and HIV directly from drug firms and sell through their pharmacies. To purchase the drug, select the firm having good marketing practices (GMP) and invite technical bids from them. Avoid the firm selling drugs with very low prices as this does not mean cost -effective drugs.
- 4) Sensitization of students of health sciences on pharmacoeconomics during their formative years is needed as they are future prescribers. The revised undergraduate medical curriculum stresses on the importance of the essential drug concept and to prescribe a drug tailored to individual needs based on safety, tolerability/suitability, efficacy and price (STEP). The students should be sensitized during their under graduate course to consider the cost of the medicine they would be prescribing.
- 5) Creating awareness of concepts and principles of pharmacoeconomics in existing physicians should also be done. Whether this carries implications for day-to day clinical decision making directly or through clinical practice guidelines formulated by a panel of experts, requires for clinician to understand various methods of evaluations and also to develop skills to interpret and critique results<sup>30</sup>.

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