

Research Article



Pharmacoeconomics: Principles, Methods and Indian Scenario

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ABSTRACT

The rising cost of healthcare delivery systems is a major concern to all patients, healthcare professionals, and the government. The demand for and the cost of health care are increasing in all countries as the improvement in and sophistication of health technologies. The increase in health care spending is mainly because of increased life expectancy, increased technology, increased standard of living and increased demand in health care quality and services. Medicines form a small but significant proportion of total health care cost. As the affordability of new medical technologies continues to be the subject of heated debate, attention is also increasingly focused on providing quality and cost-effective healthcare. Economic evaluation of pharmaceutical products, or pharmacoeconomics, is a rapidly growing area of research. Pharmacoeconomic evaluation is important in helping clinicians and decision makers to make choices about new pharmaceutical products and in helping patients obtain access to new medicines. Over the last few years, the scientific rigor of this field has increased. As a consequence of limited financial resources, health economics, and particularly pharmacoeconomic analyses, are becoming a frequently used criterion for decision making in modern health care policy. The purpose of this article is to provide an introduction of pharmacoeconomics, its various methods of evaluations such as cost minimization analysis, cost benefit analysis, cost utility analysis, cost effectiveness analysis and also discuss challenges, limitations and applications of pharmacoeconomics.

Keywords: Cost minimization analysis, Cost benefit analysis, Cost utility analysis, Cost effectiveness analysis, pharmacoeconomics.

INTRODUCTION

Pharmaceuticals and other therapeutic interventions have contributed to the important progress being made in the health status of the population. Corresponding to the introduction of new drug entities during the past several decades, the mortality rates for a number of diseases have declined substantially.¹ Drugs account for only a small proportion of the expenditures in hospital budgets, but drug therapy plays a crucial role in the management of hospitalized patients. An average hospitalized patient receives six to eight different drugs on a typical day. Effective drug therapy helps to partially explain why the mean length of stay in hospitals has decreased over the years.²

Despite the general evidence supporting the use of pharmaceuticals, few data exist regarding the actual costs and benefits attributed to specific drug therapies. A primary reason is the lack of defined methodologies to evaluate medical interventions. Perhaps the current focus on reducing expenditures of pharmaceuticals and pharmacy services to save costs to the total health-care system is inappropriate.³ Even though private health insurance and government programs cover a growing portion of drug expenditures; a sizable amount of drug costs is still paid directly by consumers. The costs of pharmaceuticals and pharmacy services have, therefore, become an important issue to patients, third-party payers, and governments alike.

Today, and in the future, it is necessary to scientifically value the costs and consequences of drug therapy.⁴

An interest in defining the value of medicine is a common thread that unites today's health care practitioners. With serious concerns about rising medication costs and consistent pressure to decrease pharmacy expenditures and budgets, clinicians/prescribers, pharmacists, and other health care professionals must answer about the value of the pharmaceutical goods and services they can provide. Pharmacoeconomics, or the discipline of placing a value on drug therapy, has evolved to answer this.⁵ Pharmacoeconomics has been defined as the description and analysis of the cost of drug therapy to health care systems and society.⁶ More specifically, pharmacoeconomic research is the process of identifying, measuring, and comparing the costs, risks, and benefits of programs, services, or therapies and determining which alternative produces the best health outcome for the resource invested.⁷

Pharmacoeconomics can be defined as the measurement of both the costs and consequences of therapeutic decision making.⁸ It is a part of the tool bag, pharmacist can be used to improve the efficiency of his profession. Pharmacoeconomics adopts and applies the principles and methodology of health economics to the field of pharmaceutical policy. Pharmacoeconomic evaluation therefore makes use of the broad range of techniques used in health economics evaluation to the specific context of medicines management.⁹

Pharmacoeconomics is the branch of economics that uses cost-benefit, cost-effectiveness, cost-minimization, cost-of-illness and cost-utility analyses to compare pharmaceutical products and treatment strategies.¹⁰ 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). Pharmacoeconomic research in the managed care system is growing. It is currently being used to make formulary decisions (complementing clinical data), design disease management programs and measuring the cost-effectiveness of interventions and programs in managed care.¹¹

DEFINITIONS

Economics is the study of the allocation of limited resources or inputs among alternative users to satisfy unlimited wants for outputs. The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) defines the terms health economics and pharmacoeconomics as follows.

Health economics: 'The field of study that evaluates the behaviour of individuals, firms, and markets in health care, and that usually focuses on the cost (inputs) and consequences (outcomes) of health care interventions, such as the use of drugs, devices, procedures, services and programs'.

Pharmacoeconomics: 'The field of study that evaluates the behaviour of individuals, firms and markets relevant to the use of pharmaceutical products, services and programs, and which frequently focuses on the costs (inputs) and consequences(outcomes) of that use'.¹²

History

Over the last decade there has been tremendous interest in economic evaluations of healthcare programmes, especially in the pharmaceutical field. Economic evaluations started about 30 years ago as rather crude analysis, in which the value of improved health was measured in terms of increased labour production.¹³ The term Pharmacoeconomics was used in public forum in 1986, at meeting of pharmacist in Toronto, Canada, when Ray Townsend from the Upjohn company, used the term in presentation. Ray and few others had been performing studies using the term pharmacoeconomics within the pharmaceutical industry. Since the early eighties 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.¹⁴

Pharmacy was finally recognized as a clinical discipline within the healthcare system in the early 1960s. At this time, disciplines within the pharmaceutical sciences such as clinical pharmacy, drug information, and pharmacokinetics became an important part of pharmacy education and sciences. Pharmacoeconomics developed its roots in 1970s. The first book on health economics was published in 1973 and in 1978; McGhan, Rowland, and Bootman from the University of Minnesota introduced

the concept of cost-benefit and cost effectiveness analysis. Utilizing sophisticated pharmacokinetic protocols, Bootman published an early pharmacy research article in 1979 in which cost-benefit analysis was employed to appraise the outcomes of individualizing aminoglycoside dosages to severely burned patients with gram-negative septicaemia. In 1983, Ohio State University College of Pharmacy initiated a specialized pharmacy academic program with the objective of providing an overview of the application of cost benefit and cost effective analysis in healthcare, with emphasis on their application to the delivery of pharmaceutical care.

Initially, defined as "analysis of the costs of drug therapy to healthcare systems and society", the actual term "pharmacoeconomics" first appeared in the literature in 1986 when Townsend's work was published to highlight the need to develop research activities in this new discipline. In 1992, a journal named "Pharmacoeconomics" was launched.¹⁵

PHARMACOECONOMICS: ITS NEED AND SCOPE

The demand for and the cost of health care are increasing in all countries as the improvement in and sophistication of health technologies. The increase in health care spending is mainly because of increased life expectance, increased technology, increased standard of living and increased demand in health care quality and services. Medicines form a small but significant proportion of total health care cost. All over the world, patients are affected by high price of medicines. In a developing country like India, 85% of total health expenditure is financed by house-hold out of pocket expenditure. Many poor people frequently face a choice between buying medicines or buying food or other necessities due to limited resources and high pricing of drug. There are enumerable factors which affect the drug pricing like the sector in which medicines are purchased i.e private or government sector and often the price is higher in private sector due to distilentor's costs and profiteering. Another factor is the types of procurement agent: e.g. different prices may be paid for the same product by a public sector purchaser. Also the distribution route and the patient status will also influence the drug pricing. So medicine prices do matter.¹⁶ 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. Pharmacoeconomics identifies, measures and compares the cost and consequences of pharmaceutical products and services and describe the economic relationship involving drug research, drug production, distribution, storage, pricing and use by the people. Basically the pharmacoeconomics is needful in following manner; In Industry, it is useful in deciding among specific research and development alternatives. In Government-Determining program benefits and prices paid and in Private Sector it can be used for designing insurance benefit coverage.¹⁷



SCOPE OF PHARMACOECONOMICS

To Pharmaceutical manufacturers

Pharmacoeconomics can be a very useful tool long before a drug is approved for use by the FDA. Pharmaceutical manufacturers need to spend enormous resources in the drug development process. If proper pharmacoeconomic research is conducted the manufacturers can avoid spending vast resources to the development of a drug that does not provide competitive advantage. Competitive advantage in the present healthcare environment may be defined as a drug that is cost-effective. Cost effective can mean a drug that is less costly and at least as effective as an alternative; more effective and more costly than an alternative, but improved health outcomes justify additional expenditures, or less effective and less costly than an existing alternative, but a viable alternative for some patients.

The potential for an investigational new drug to leave the laboratory is a function of its expected safety and efficacy, which are both factors comprised of several specific measures or evaluations (e.g., toxicology, adverse reaction, teratogenicity and pharmacology). An additional factor worth considering is the expected pharmacoeconomics of the investigational drug. That factor also would be comprised specific evaluation such as societal and individual costs of the illness for which the drug is indicated, the costs and consequence of existing treatment methods, and the impact of the disease and existing treatment on the patients quality of life(QOL). Having such information very early in the development of a drug would help reduce uncertainties and contribute to the knowledge base used to decide whether to further evaluate a treatment via prospective clinical trials. Cost efficacy and QOL components can be incorporated into appropriate phase III studies to provide additional information regarding a drugs impact on patient outcome. If such parameters are applied systematically to all new treatment candidates, the scientific basis of drug therapy decision making will increase substantially.

To Healthcare Practitioners

One of the primary uses of pharmacoeconomics in clinical practice is to aid clinical and policy decision making. Complete pharmacotherapy decisions should contain three basis evaluation components; clinical, economic, and humanistic outcomes. No longer can drug selection decisions be based solely on acquisition costs. This strategy is misleading because of the inability to capture potential costs associated with diminished safety and efficacy profiles. Through the appropriate application of Pharmacoeconomic principles and methods incorporating these three critical components into clinical decision can be accomplished.

Pharmacoeconomic data can be a powerful tool which supports various clinic decisions, including effective formulary management, individual patient treatment,

medication policy, and resource allocation. For example, Pharmacoeconomics can provide critical cost-effectiveness data to support formulary addition or removal. The formulary is a regularly revised collection of pharmaceuticals based on current clinical judgment and helps the medical staff of a given institution and experts in the diagnosis and treatment of disease. Pharmacoeconomic data can support the inclusion or exclusion of a drug on or from the formulary and support practice guidelines that promote the most cost-effective or appropriate utilisation of pharmaceutical products. Various strategies can be used to incorporate pharmacoeconomics into formulary decision making. These include using published pharmacoeconomic studies and economic modelling techniques, and conducting local pharmacoeconomic research. Pharmacoeconomic assessments of formulary decisions help to ensure that the agents promoted by our formularies yield the highest outcome per dollar spent.¹⁸ In fact, the pharmacoeconomic assessment of formulary action is becoming a standardized part of many pharmacy and therapeutic (P&T) committee decision making process, if based on sound pharmacoeconomic data, when competing for hospital resources, pharmacoeconomics can provide the data necessary that a pharmacy service maximizes the resources allocated to it by hospital administration.

Evaluating the impact a drug has on a patient's health-related quality of life can be useful when deciding between two agents for an individual patient treatment decision.

In the past, inclusion of economic outcomes (costs) in clinical decisions seemed to necessitate compromise in the quality of care delivered. However, when used appropriately, pharmacoeconomics can assist in balancing cost with patient outcome (quality of care), often resulting in maintaining or improving quality of care, with potential cost savings. Best valued drugs will be those with optimal patient outcome per rupee/ dollar spent compared to competitors. In the cost conscious environment, Pharmacoeconomic research is important to the healthcare practitioner.

To Pharmacists

Drug use evaluation is one of the important services provided by pharmacists. Ideally, that value should be translated into patient and financial outcomes. Apart from concentrating on inappropriately prescribed therapy and overprescribing, drug use evaluation focuses on the most cost-effective therapy. A high degree of sophistication is required in order to make such determination fairly, considering patient factors, disease factors, and other issues.

Drug formulary services, Pharmacy and therapeutics committees are viewed as a means of reducing drug budgets and have had some value in encouraging drug therapy cost considerations, but they do not provide



incentives to take into account overall medical costs, nor do they necessarily consider all consequences such as potential drug interactions, adverse reactions, and treatment response rates. Conducting cost-effectiveness studies allows an evaluation of total costs and consequences from various perspectives.¹²

Methods of Pharmacoeconomics

The basic task of economic evaluation is to identify, measure, value, and compare the costs and consequences of the alternatives being considered. The two distinguishing characteristics of economic evaluation are as follows: (1) Is there a comparison of two or more alternatives? and (2) Are both costs and consequences of the alternatives examined?¹⁹ A full economic evaluation encompasses both characteristics, whereas a partial economic evaluation addresses only one. Pharmacoeconomic evaluations conducted in today's healthcare settings can be either partial or full economic evaluations.

Partial economic evaluations can include simple descriptive tabulations of outcomes or resources consumed and thus require a minimum of time and effort. If only the consequences or only the costs of a program, service, or treatment are described, the evaluation illustrates an outcome or cost description. A cost-outcome or cost-consequence analysis (CCA) describes the costs and consequences of an alternative but does not provide a comparison with other treatment options.²⁰ Another partial evaluation is a cost analysis that compares the costs of two or more alternatives without regard to outcome.

Full economic evaluations include cost-minimization, cost-benefit, cost-effectiveness, and cost-utility analyses. Each method is used to compare competing programs or treatment alternatives. The methods are all similar in the way they measure costs (in dollars) and different in their measurement of outcomes. Although a full economic evaluation generally provides higher quality and more useful information, the time, resources, and effort employed are also great.

Thus healthcare practitioners and clinicians also find it necessary to employ various partial economic evaluations.²¹

Costs

Costs involved in pharmacoeconomic evaluation can be mainly divided into financial cost (mandatory cost) and economic cost (resource for which no mandatory payment is made).

Opportunity cost is the benefit foregone when selecting one therapy alternative over the next best alternative. The first step in any cost analysis is identification of the various costs. These are direct, indirect and intangible.

Direct i.e. costs from the perspective of the healthcare funder: including staff costs, capital costs, drug

acquisition costs. It includes physicians' fees, cost of administering the medication, costs of treating an adverse drug reaction, etc.

Indirect i.e. costs from the perspective of society as a whole: for example, these might include loss of earnings, loss of productivity, loss of leisure time, due to the illness, and cost of travel to hospital etc). This would include not just the patient themselves but also their family and society as a whole.

Intangible i.e. the pain, worry or other distress; which a patient or their family might suffer. These may be impossible to measure in monetary terms, but are sometimes captured in measures of quality of life.

The cost can be measured in following ways:

- Cost / unit
- Cost / treatment
- Cost / person
- Cost / person / year
- Cost / case prevented
- Cost / life saved
- Cost / DALY (disability-adjusted life year)

Outcomes

The second fundamental component of a pharmacoeconomic study is outcomes or benefits. The expected benefits might be measured in:

A. "Natural" units e.g. years of life saved, strokes prevented, and peptic ulcers healed etc.

B. "Utility" units - Utility is an economist's word for satisfaction, or sense of well being, and is an attempt to evaluate the quality of a state of health, and not just its quantity. Utility estimates can be obtained through direct measurement (using techniques such as time trade off or standard gambles, or by imputing them from the literature or expert opinion. They are often informed by measures of quality of life in different disease states.¹⁶

Application of economic evaluation methods to healthcare products and services, especially pharmaceuticals, might increase their acceptance by healthcare professionals and society.²¹

Cost-of-Illness Evaluation

A cost-of-illness (COI) evaluation identifies and estimates the overall cost of a particular disease for a defined population. This evaluation method is often referred to as burden of illness and involves measuring the direct and indirect costs attributable to a specific disease. The costs of various diseases, including diabetes, mental disorders, and cancer, in the United States have been estimated.

By successfully identifying the direct and indirect costs of an illness, one can determine the relative value of a treatment or prevention strategy. For example, by



determining the cost of a particular disease to society, the cost of a prevention strategy could be subtracted from this to yield the benefit of implementing this strategy nationwide. COI evaluation is not used to compare competing treatment alternatives but to provide an estimation of the financial burden of a disease. Thus the value of prevention and treatment strategies can be measured against this illness cost.²²

Cost-Minimization Analysis

Cost-minimization analysis (CMA) involves the determination of the least costly alternative when comparing two or more treatment alternatives. With CMA, the alternatives must have an assumed or demonstrated equivalency in safety and efficacy (i.e., the two alternatives must be equivalent therapeutically). Once this equivalency in outcome is confirmed, the costs can be identified, measured, and compared in monetary units (dollars).

CMA is a relatively straightforward and simple method for comparing competing programs or treatment alternatives as long as the therapeutic equivalence of the alternatives being compared has been established. If no evidence exists to support this, then a more comprehensive method such as cost-effectiveness analysis should be employed. Remember, CMA shows only a "cost savings" of one program or treatment over another.

Employing CMA is appropriate when comparing two or more therapeutically equivalent agents or alternate dosing regimens of the same agent. This method has been used frequently, and its application could expand given the increasing number of "me too" products and generic competition in the pharmaceutical market.²³

Cost-Benefit Analysis

Cost-benefit analysis (CBA) is a method that allows for the identification, measurement, and comparison of the benefits and costs of a program or treatment alternative. The benefits realized from a program or treatment alternative are compared with the costs of providing it. Both the costs and the benefits are measured and converted into equivalent dollars in the year in which they will occur. Future costs and benefits are discounted or reduced to their current value.

Cost-benefit analysis (CBA), sometimes called benefit-cost analysis (BCA), is a systematic approach to estimating the strengths and weaknesses of alternatives that satisfy transactions, activities or functional requirements for a business.

It is a technique that is used to determine options that provide the best approach for the adoption and practice in terms of benefits in labor, time and cost savings etc. The CBA is also defined as a systematic process for calculating and comparing benefits and costs of a project, decision or government policy (hereafter, "project").

Broadly, CBA has two purposes:

1. To determine if it is a sound investment/decision (justification/feasibility),
2. To provide a basis for comparing projects. It involves comparing the total expected cost of each option against the total expected benefits, to see whether the benefits outweigh the costs, and by how much.

CBA is related to, but distinct from cost-effectiveness analysis. In CBA, benefits and costs are expressed in monetary terms, and are adjusted for the time value of money, so that all flows of benefits and flows of project costs over time (which tend to occur at different points in time) are expressed on a common basis in terms of their "net present value."

These costs and benefits are expressed as a ratio (a benefit-to-cost ratio), a net benefit, or a net cost. A clinical decision maker would choose the program or treatment alternative with the highest net benefit or the greatest benefit-to-cost (B: C) ratio. If the B:C ratio is greater than 1, the program or treatment is of value. The benefits realized by the program or treatment alternative outweigh the cost of providing it.²⁴

- If the B:C ratio equals 1, the benefits equal the cost. The benefits realized by the program or treatment alternative are equivalent to the cost of providing it.
- If the B:C ratio is less than 1, the program or treatment is not economically beneficial. The cost of providing the program or treatment alternative outweighs the benefits realized by it.

CBA should be employed when comparing treatment alternatives in which the costs and benefits do not occur simultaneously. CBA also can be used when comparing programs with different objectives because all benefits are converted into dollars. CBA also can be used to evaluate a single program or compare multiple programs. However, valuing health benefits in monetary terms can be difficult and controversial. The expression of some health benefits as monetary units is neither appropriate nor widely accepted. Therefore, unless the benefits of a program or treatment alternative are expressed appropriately in dollars, CBA should not be employed.

CBA can be an appropriate method to use in justifying and documenting the value of an existing healthcare service or the potential worth of a new one. For example, when a clinical pharmacy service is competing for institutional resources, CBA can provide data to document that the service yields a high return on investment compared with other institutional services competing for the same resources. However, the relative magnitude of the costs and benefits for the service must be considered when making this resource-allocation decision.²⁵

Cost-Utility Analysis

Cost-utility analysis (CUA) is a method for comparing treatment alternatives that integrates patient



preferences and HRQOL. CUA can compare cost, quality, and the quantity of patient-years. Cost is measured in dollars, and therapeutic outcome is measured in patient-weighted utilities rather than in physical units. Often the utility measurement used is a quality-adjusted life year (QALY) gained. QALY is a common measure of health status used in CUA, combining morbidity and mortality data. Results of CUA are also expressed in a ratio, a cost-utility ratio (C:U ratio). Most often this ratio is translated as the cost per QALY gained or some other health-state utility measurement. The preferred treatment alternative is that with the lowest cost per QALY (or other health-status utility). QALYs represent the number of full years at full health that are valued equivalently to the number of years as experienced. For example, a full year of health in a disease-free patient would equal 1.0 QALY, whereas a year spent with a specific disease might be valued significantly lower, perhaps as 0.5 QALY, depending on the disease. This method is used to compare treatment alternatives that are life extending with serious side effects (e.g., cancer chemotherapy), those which produce reductions in morbidity rather than mortality (e.g., medical treatment of arthritis), and when HRQOL is the most important health outcome being examined. CUA is employed less frequently than other economic evaluation methods because of a lack of agreement on measuring utilities, difficulty comparing QALYs across patients and populations, and difficulty quantifying patient preferences.

Cost-Effectiveness Analysis

Cost-effectiveness analysis (CEA) is a form of economic analysis that compares the relative costs and outcomes (effects) of two or more courses of action. Cost-effectiveness analysis is distinct from cost-benefit analysis, which assigns a monetary value to the measure of effect. Cost-effectiveness analysis is often used in the field of health services, where it may be inappropriate to monetize health effect. Typically the CEA is expressed in terms of a ratio where the denominator is a gain in health from a measure (years of life, premature births averted) and the numerator is the cost associated with the health gain. The most commonly used outcome measure is quality-adjusted life years (QALY). Cost-utility analysis is similar to cost-effectiveness analysis. Cost-effectiveness analyses are often visualized on a cost-effectiveness plane consisting of four-quadrants. Outcomes plotted in Quadrant I are more effective and more expensive, those in Quadrant II are more effective and less expensive, those in Quadrant III are less effective and less expensive, and those in Quadrant IV are less effective and more expensive.

Cost-effectiveness analysis (CEA) is a way of summarizing the health benefits and resources used by competing healthcare programs so that policymakers can choose among them. CEA involves comparing programs or treatment alternatives with different safety and efficacy profiles. Cost is measured in dollars, and outcomes are

measured in terms of obtaining a specific therapeutic outcome. These outcomes are often expressed in physical units, natural units, or non dollar units (e.g., lives saved, cases cured, life expectancy, or drop in blood pressure).

The results of CEA are also expressed as a ratio—either as an average cost-effectiveness ratio (ACER) or as an incremental cost-effectiveness ratio (ICER). An ACER represents the total cost of a program or treatment alternative divided by its clinical outcome to yield a ratio representing the dollar cost per specific clinical outcome gained independent of comparators.

$$\text{ACER} = \frac{\text{health care costs (\$)}}{\text{clinical outcome (not in \$)}}$$

This allows the costs and outcomes to be reduced to a single value to allow for comparison. Using this ratio, the clinician would choose the alternative with the least cost per outcome gained. The most cost-effective alternative is not always the least costly alternative for obtaining a specific therapeutic objective. In this regard, cost-effectiveness need not be cost reduction but rather cost optimization.

Often clinical effectiveness is gained at an increased cost. Incremental CEA can be used to determine the additional cost and effectiveness gained when one treatment alternative is compared with the next best treatment alternative. Thus, instead of comparing the ACERs of each treatment alternative, the additional cost that a treatment alternative imposes over another treatment is compared with the additional effect, benefit, or outcome it provides. The ICER can be summarized as follows:

$$\text{ICER} = \frac{\text{cost}_A (\$) - \text{cost}_B (\$)}{\text{effect}_A (\%) - \text{effect}_B (\%)}$$

This formula yields the additional cost required to obtain the additional effect gained by switching from drug A to drug B.

CEA is particularly useful in balancing cost with patient outcome, determining which treatment alternatives represent the best health outcome per dollar spent, and deciding when it is appropriate to measure outcome in terms of obtaining a specific therapeutic objective. In addition, CEA can provide valuable data to support drug policy, formulary management, and individual patient treatment decisions. Globally, CEA is being used to set public policies regarding the use of pharmaceutical products (national formularies) in countries such as Australia, New Zealand, and Canada.²⁶

The cost-effectiveness analysis (CEA) ratio can be a more practical tool for decision making than CBA in that it involves the comparison of the costs of achieving a particular non-monetary objectives; such as lives saved, health improvement, or quality of life. CEA ratios can be applied when the costs are expressed in money and the benefits are in specific health outcomes. Benefits can be expressed in any unit of measure (asthma free days,



hospitalizations, etc.) but can only be reliable and meaningful when the output units are consistent across projects or models. The goal of applying CEA is to allow for comparison of a variety of interventions in terms of non-monetary (health) gains at a given cost, keeping the comparators in the same terms or units of measure. In essence, different entities are compared once common measure of the outcome is established, and a common cost has been determined as a means of assigning relative effectiveness to different modes of treatment or intervention. Future CEA applications in formulating health policy are controversial. Recent legislation in the USA (i.e., the Patient Protection and Affordable Care Act) explicitly prohibits the use of cost-utility analysis, specifically QALY, in directing recommendations about healthcare technologies, treatment and services²⁷. The study of cost-effective analysis will continue to gain importance and credibility as there is greater confidence in measuring such intangible, albeit real, consequences or outcomes; such as functional status and feelings of health.

There is a growing consensus in healthcare-related literature emphasizing the benefits of cost-effectiveness analysis and other related methods of determining incremental cost effectiveness ratios. Medical literature, both nationally and internationally, supports the role of CEA and CER in ability to identify and rank treatments in terms of their social welfare effects.²⁸

General Steps in Designing an Economic Evaluation

The prerequisite for conducting or evaluating a pharmacoeconomic evaluation is advanced knowledge of research methods and biostatistics, both of which are essential to design a protocol or evaluate the validity of a published.

The basic steps in designing the pharmacoeconomic study are as follows.

- *Define the problem* - This step is self-explanatory. What is the question that is the focus of the analysis? The important thing to remember in this step is to be specific.
- *Determine the study's perspective*- It is important to identify from whose perspective the analysis will be conducted. Is the analysis being conducted from the perspective of the patient or from that of the hospital, clinic, insurance, company or society? Depending on the perspective assigned to the analysis different results and recommendations based on these results may be identified.
- *Determine specific treatment alternatives and outcomes*- In this step, all the treatment alternatives to be compared in the analysis should be identified. This selection should include clinical options and/ or options that are used most often in that setting at the time of study. If a new treatment option is being considered, comparing it with an out-dated

treatment or a treatment with low efficacy rates is a waste of time and money. This new treatment should be compared with the next best alternative it may replace. The alternatives may be drug treatments or non-drug treatments.

- *Select the appropriate pharmacoeconomic model*- The pharmacoeconomic model selected will depend on how the outcomes are measured. When all outcomes for each alternative are expected to be the same, CMA is used. If all the outcomes for each alternative considered are measured in monetary units, CBA is used. When outcomes of each treatment alternative are measured in the same nonmonetary units, CEA is used. When patient preferences for alternative treatment are being considered, CUA is used.
- *Measure inputs and outcomes*- All resources consumed by each alternative should be identified and measured in monetary value. The cost for each alternative should be listed and estimated. When evaluating alternatives over a long period of time (eg: greater than 1 year). The concept of discounting should be applied. Measuring outcomes can be relatively simple (eg; cure rates] or relatively difficult (eg; QALYs). Outcomes may be measured prospectively or retrospectively. Prospective measurements tend to be more accurate and complete, but may take considerably more time and resources than retrospective data retrieval.
- *Identify the resources necessary to conduct the analysis*- The availability of resources to conduct the study is an important consideration. Data may be obtained from a variety of sources, including clinical trials, medical literature, medical records, prescription profiles or computer databases.
- *Establish the probabilities for the outcomes of the treatment alternatives*- Probabilities for the outcomes identified should be determined. This may include the probability of treatment failures or success or adverse reactions to a given treatment or alternative.
- *Construct a decision tree* – Decision analysis can be a very useful tool when conducting pharmacoeconomic analysis. Constructing a decision tree creates a graphic display of the outcomes of each treatment alternative and the probability of their occurrence. Decision analysis is the application of analytical method for systematically comparing different decision options. This method of analysis assists in making decisions when the decision is complex and there is uncertainty about some of the information.
- *Conduct a sensitivity analysis* – Whenever estimates are used, there is a possibility that these estimates are not precise. These estimates may be referred to as 'assumptions'. A sensitivity analysis allows one to



determine how the results of an analysis would change when these assumptions are varied over a relevant range of values.

- *Present the results* - The results of the analysis should be presented to the appropriate audience, such as P & T committees, medical staff, or third party payers. The steps outlined in this section should be employed when presenting the results. State the problem, identify the perspective, and so on. It is imperative to acknowledge or clarify any assumptions.¹²

Pharmacoeconomics – A Tool for Pharmacists

Pharmacoeconomics helps us to make decisions about the use of medicines. Most pharmacoeconomic studies in health care are cost-effectiveness studies set out to demonstrate how to achieve an objective with the least use of resources. This should not be confused with efficiency, which measures how well we use resources in order to obtain the desired outcome.

Pharmacoeconomics is used at all stages in the development of medicines by the pharmaceutical industry, when medicines are researched, produced and marketed. Some countries insist on pharmacoeconomic evaluations as part of the licensing process. Most hospital pharmacists use pharmacoeconomics to assist with making decisions involving formularies and how medicines can be used in a more cost-effective or cost-beneficial manner.

Knowledge of health economics coupled with political insight is essential to understand resource allocation and expenditure in a modern health care system. Pharmacists, with their unique knowledge of medicine, are crucial in using pharmacoeconomic analysis to influence expenditure and distribution of resources on medicines. The basis of financing secondary care is currently changing. Under “payment by results”, providers of care are paid for each patient spell according to a national tariff, which is based on a national average cost for a particular patient spell. As foundation trusts increase, the number of hospitals that depend on tariff payments for their income also grows.

Therefore, using the most efficient methods of working to reduce cost and maximize benefits is becoming increasingly important. Pharmacoeconomics is part of the tool bag pharmacists can use to improve the efficiency of their hospital.

In theory, if hospitals improve their efficiency and deliver increased activity the trust will make a profit, which should then be invested in improving health care. In some medical disciplines the medicines element to the overall tariff price can be considerable, and savings on costs of medicines can make the difference between a profit and loss for the trust. The application of pharmacoeconomics to improve the efficient use of medicines is a key component in this productivity drive.

Although the clinical role of the profession is appreciated, it is the role of the pharmacist in advising on medicines expenditure and ensuring economical use of medicines that has increased demand for their services. In many directorates the only person with the required knowledge, experience and expertise to manage the medicines budget is the directorate pharmacist. Medicines management technicians are now also seen as essential to the overall improvement in efficiency and reduction on Medicines expenditure. Knowledge of health economics and application of its techniques is essential to today's pharmacist.²⁹

Pharmacoeconomics – Indian Scenario

The Indian pharmaceutical industry (IPI) is the world's fourth-largest by volume and is likely to lead the manufacturing sector in India. The Indian Patent Act in 1970 played a major role in developing a base for the manufacturing unit in India. The change in law in 2005 has created opportunities for both international firms and local Indian companies for sharing expertise. This has certainly created tremendous job opportunities mainly in the field of clinical research, thus making way for health outcomes research.

In addition, many governments worldwide are seeking to curb their soaring prescription drug costs by greater use of generics, thus giving importance to cost-effectiveness and cost-benefit analysis studies. In other words, they are implementing the concept of Pharmacoeconomics. Unfortunately, even after the availability of tremendous data on health sciences and clinical research, this data is not used for outcomes research and pharmacoeconomic analysis, the reason for this being the quality of primary data available and its suitability for secondary database research. Therefore, the centre point for the future of outcomes research and pharmacoeconomic analysis in India is the development of a proper database to be used for comparative effectiveness research. In India, the concept of Pharmacoeconomics is still not used by the government in order to make reimbursement decisions. Furthermore, the concept of Pharmacoeconomics is not being used in academic research though cost effectiveness studies have been performed in various parts of India.

Pharmacoeconomics is yet to make an appearance in India where majority of healthcare spending is done by patients out of their own pockets, unlike medical insurance policies in most developed countries. It is important that Pharmacoeconomic researches should be introduced strongly in the India and should be performed from the clinical trial onwards so that the government can ensure that money spends in the right direction and also reduce the financial burden on patients.

As third largest producer of drugs by volume, Indian pharmaceutical industry has diversity of medicines; yet, brand name prescriptions are the rule of the day. Formulary system is very weak and treatment protocols



exist only in theory. The resources are scarce and competing programs are plenty in healthcare. The concept of healthcare insurance is yet to be popularized in the country. Given the issues prevalent in the Indian healthcare system, pharmacoeconomics has many applications. Pharmacoeconomics can aid in decision making when evaluating the affordability of and access to the right medication to the right patient at the right time, comparing two drugs in the same therapeutic class or drugs with similar mechanism of action, and in establishing accountability that the claims by a manufacturer regarding a drug are justified.

Practicing pharmacists in community, hospital, and clinical settings in India can benefit considerably from the application of the principles of pharmacoeconomic into their normal practice settings. Proper application of pharmacoeconomics will empower the pharmacy practitioners and administrators to make better and more informed decisions regarding products and services they provide. Pharmacotherapy decisions traditionally depended solely on clinical outcomes like safety and efficacy, but pharmacoeconomics teaches us that there are three basic outcomes to be considered clinical, economic, and humanistic in drug therapy. It is accepted by all that appropriate drug selection decisions could not be made today based on acquisition costs only. Applied pharmacoeconomics can help in decision making, in assessing the affordability of medicines to the patients, access to the medicines when needed, and comparing various products for treatment of a disease. It will provide evidence contraindicating the promotion of certain types of high-cost medicines and services.

Pharmacoeconomics has use in health policy decision making and can be applied by a number of healthcare professionals such as policy makers, primary healthcare providers, health-care administrators, and health managers.

Available in large quantities, Indian primary care providers are often bombarded with many new drugs of the same category, in addition to the existing drugs. Introduction of new drugs can confuse the doctors and administrators for the judicious selection and rational use of medicines.

When introducing new medications, its outcome should be equal or more effective compared to the existing drug and shall have some economic or related advantage.

Evidence about pharmacoeconomics can aid pharmacists and policy makers in the decision-making process about the use of medications and healthcare services.³⁰

Challenges

The main challenges for Pharmacoeconomics are:

- 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.
- Lack of full appreciation of the potential importance and application of Pharmacoeconomics studies.
- Poor technical skills of healthcare professionals, especially of pharmacists.
- Lack of appropriate database of the healthcare system in order to bring about research adaptation from another country.³¹

CONCLUSION

Pharmacoeconomics evaluation has become an important area of interest to find the optimal therapy at the lowest price as healthcare resources are not easily accessible and affordable to many patients. Numerous drug alternatives and empowered consumers also fuel the need for economic evaluations of pharmaceutical products. In a country like India the PE can help the poor and middle class Indians to obtain well health care services because many households are below poverty line, unaffordable for private health care. Costs of the medicines are growing constantly. In Asian countries with scarce resources and an ever growing population with diverse health care needs, innovative method called, pharmacoeconomic evaluation plays an essential role in determining the delivery of reasonable and cost-effective health services.³²

By understanding the principles, methods, and application of pharmacoeconomics, pharmacists will be prepared to make better, more-informed decisions regarding the use of pharmaceutical products and services, that is, decisions that ultimately represent the best interests of the patient, the health care system, and society. PE can be applied to any therapeutic area like hospital pharmacy, using a variety of application strategies. As the healthcare sector is progressing day by day the need to develop Pharmacoeconomics area is must. Healthcare sector is not just a small area but it became an industry now. It has more dimensions to explore. Patients also get benefit out of Pharmacoeconomics findings. Pharmacoeconomics research should be strongly supported in a country like India where majority of health care spending is done by the patient's themselves.

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