

Pharmacoeconomics- Costs of Drug Therapy to Healthcare Systems

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ABSTRACT

Pharmacoeconomics is the description and analysis of the costs of drug therapy to healthcare systems and society. 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. The importance of pharmacoeconomic information to healthcare decision makers will depend upon the viewpoint from which the analysis is conducted.

The two fundamental components of Pharmacoeconomics 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; Cost-minimization analysis (CMA), Cost-effectiveness analysis (CEA), Cost-utility analysis (CUA), and Cost-benefit analysis (CBA). The results of pharmaceutical studies give a quantitative measure (cost/outcome achieved) that shows the most efficient allocation of limited resources among two or more competing alternative medications and services or where you can get the most improvement in outcomes for the money that is available to spend on drugs.

Keywords: Pharmacoeconomics, Cost-minimization analysis, Cost-effectiveness analysis, Cost-utility analysis ,Cost-benefit analysis .

INTRODUCTION

Pharmacoeconomics can be defined as the subdivision of economics that uses cost-benefit, cost-effectiveness, cost-minimization, cost-of-illness and cost-utility analyses to evaluate pharmaceutical products and treatment strategies [1]. 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[2]. Pharmacoeconomics adopts and applies the values and methodology of health economics to the ground of pharmaceutical policy. The significance of pharmacoeconomic information to healthcare decision makers will depend upon the view point from which the analysis is conducted. Pharmacoeconomic research in the managed care system is increasing. 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 [3].

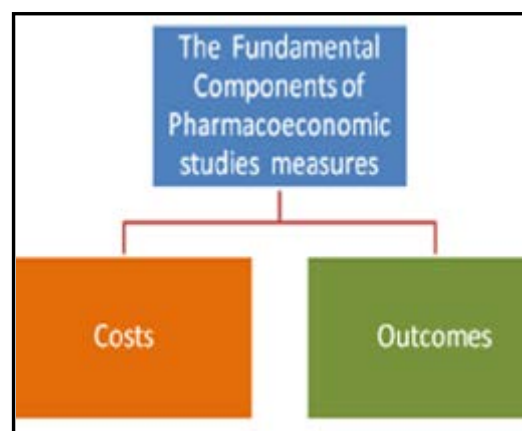


Fig 1. Components of Pharmacoeconomics Study

HISTORY

Over the last decade there has been notable interest in economic evaluations of healthcare programmers in the pharmaceutical field. Economic evaluations started about 30 years ago as rather basic analysis, in which the value of enhanced health was measured in terms of amplified labor production [4]. The term

pharmacoeconomics was used in public forum was in 1986, at pharmacist's meeting in Toronto, Canada, when Ray Townsend from the Upjohn company. 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 practitioners, a large research and application agenda, several journals and flourishing professional societies including the international society for pharmacoeconomics and outcomes research[5].

Pharmacoeconomics is the division of economics related to the most economical and proficient use of pharmaceuticals; economic approaches are applied to pharmaceuticals to direct the use of limited resources to yield highest value to patients, health care payers and society in general[6]. Cost-effectiveness studies are of supreme importance to justify expenditure in all fields of health care. There are several types of pharmacoeconomic evaluation:



FIG NO.2. Evaluation of Pharmacoeconomics

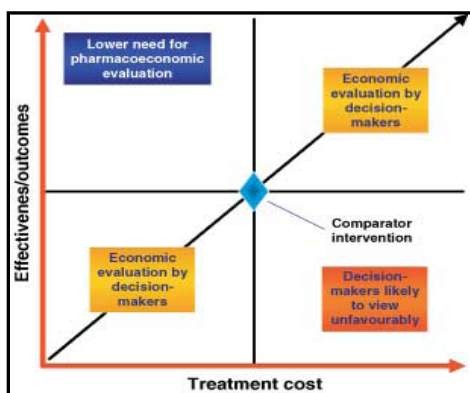


FIG No.3. Need of pharmacoeconomic

Pharmacoeconomics and onychomycosis:

The treatment of onychomycosis is costly. It has been estimated that the direct cost of treating onychomycosis for US Medicare patients is \$43 million per year. The availability of new drugs means that physicians now have a wide choice of possible treatment strategies.

• It is common practice to initiate treatment before confirming the diagnosis of onychomycosis. The evaluation of cost-effectiveness of diagnosis which compared the cost-effectiveness of initiating treatment, newer generation drugs are generally more expensive than older generation drugs. Given the increasing prevalence of fungal nail infections and the associated costs and burden to the healthcare systems. Therefore, several pharmacoeconomic studies have been carried out to compare the relative cost-effectiveness of various treatment

options to aid healthcare providers and patients in deciding which agent to use.

Cost-effectiveness of diagnosis:

• Diagnostic testing vs. initiating treatment without diagnostic testing in 688 patients. They found that pretreatment diagnostic testing led to a saving of \$159 per patient. Furthermore, confirming diagnosis before treating avoids unnecessary exposure to antifungals and thus reduces the risk of adverse effects.

General retrospective pharmacoeconomic studies:

• Humphrey et al. performed a retrospective analysis to compare the cost-effectiveness of terbinafine, tioconazole, amorolfine and griseofulvin.

• By calculating direct treatment costs (drugs, medical consultations, minor surgery, etc.) and mycological and clinical cure rates (based on the results of a previous multinational study), they found that terbinafine was the most cost effective option.

• This study also presented a flaw leading to an incorrect conclusion.

Most of the early pharmacoeconomic studies in the field of dermatology were flawed; newer studies are of a higher standard. Older studies directly transposed clinical figures into comparisons without making any adjustments for what would really happen in practice. There is a need for studies conducted in standardized conditions, subject to internationally validated principles. An appropriate mathematical model, such as a Bayesian model, needs to be applied. The National Institute for Clinical Excellence (NICE) guidelines are often taken into account in countries other than Britain. In UK, all costly treatments have to be approved by NICE. NICE is beginning to look at dermatology products to decide which are acceptable and which are not regulatory and licensing bodies are often asked to see cost benefit data, but no such studies are available in onychomycosis. NICE wants cost-utility data to determine what would happen to other diseases if a given treatment is reimbursed.

There is increasing pressure on doctors to not prescribe drugs and to consider their annual budget. This makes doctors reluctant to prescribe costly treatments.

The availability of generics may manipulate prescribing habits. For instance, a generic drug accessible in Colombia was found to have a bioavailability of just 3.5% compared to the original drug. This situation is likely to worsen as price is often the only criterion considered by governments and regulatory bodies. As in Germany, topical treatments are not reimbursed in Italy. The outcome is that mild cases are often left untreated. These mild cases may then become moderate or severe meaning that oral treatment is required. Thus, it could be argued that more cost-effective treatment at an early stage, especially as disease severity affects the success rate. Adverse events and medical management (consultations, mycology, liver function and hematology tests) mostly with oral treatments need to be taken into account when performing pharmacoeconomic analyses.

The cost of adverse event management is generally considered less than 10% of the total regimen cost, as most treatments are relatively safe with few serious adverse events. On the other side, medical management represents a considerable part of total regimen costs. Drug costs represent around 70%. Other factors that make it difficult to compare previous studies are differences in study design. For example, efficacy rates are higher in open studies than in randomized controlled trials. It is also important to define severity and patient inclusion criteria. For example, success rates are considerably higher in studies with a

small number of patients than in the majority of studies. Cure rates come into view low in UK, this is probably because GPs treat mild cases and only severe cases are referred to specialists (patients cannot consult specialists without a referral from their GP in UK). It is important that the severity of the disease in the study population be specified, otherwise data that should not be pooled may be pooled in meta-analyses. Other terms that need defining include: clinical cure, mycological cure and total cure.

Pharmacoeconomic data can be used to influence drug choice. It could be useful to apply such data before initiating treatment. The case of elderly subjects who are already being treated with numerous drugs. In such cases, the patient often chooses to leave the prescribed medication in the back of the cupboard rather than risking the occurrence of drug interactions. Prescribing practices are often affected by one's opinion of the importance of onychomycosis. Regulatory bodies often consider that it is no more than a cosmetic problem, whereas some patients consider it a very important problem and others do not even notice that they are infected.

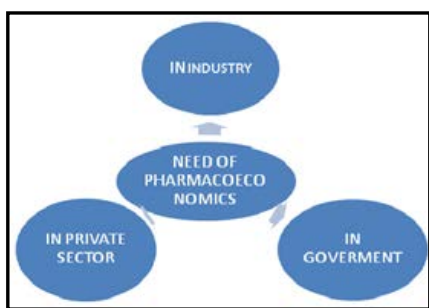


Fig. 4. Need of Pharmacoeconomics [7]

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 used by the people.

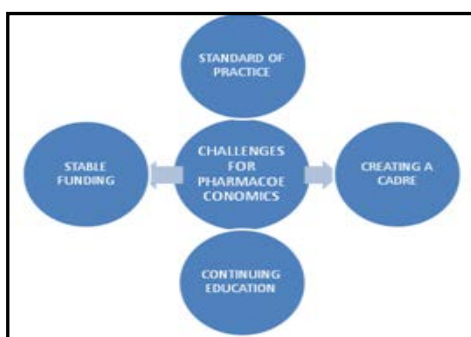


Fig.5. Challenges for Pharmacoeconomics

Pharmacoeconomic Evaluation [8,9].

It involves explicit measurement of inputs (costs) and measure outcomes. Perspectives are the key point that is to be considered for any economic evaluation. The evaluation should be considered, from the health service perspective or the societal perspective. Usually the societal perspective is considered but the health managers facing problem of low budget concentrates on health service perspective.

Costs : Costs concerned in pharmacoeconomic evaluation can be chiefly separated into financial cost and economic cost (resource for which no mandatory payment is made) opportunity cost is the benefit foregone when selecting one therapy substitute

over the subsequently best alternative. Measuring cost: several costs can be measured when weighing up the cost of any invention. This cost may be, Direct: paid by the health service (including staff costs, capital costs, and drug acquisition costs). Indirect: cost experienced by patient (family, friends).

The cost can be measured in following ways,

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

Outcomes (benefits): The second fundamental factor of a pharmacoeconomic study is outcomes. In assessing outcomes, it is also important to take into account both positive and negative outcomes. Positive outcome is a measure of the drug's efficacy. Negative outcomes include side effects, treatment failure, and the development of drug resistance.

Methods of Pharmacoeconomic Evaluation: There are fundamentally 4 categories of pharmacoeconomic studies.

- Cost-effectiveness analysis (CEA)
- Cost-minimization analysis (CMA)
- Cost-benefit analysis (CBA)
- Cost-utility analysis (CUA)

Cost effectiveness analysis (CEA): The term cost effectiveness is often used loosely to refer to the whole of economic evaluation, but should properly refer to a particular type of evaluation, in which the health benefit can be defined and measured in natural units and the costs are measured in money. It therefore compares therapies with qualitatively similar outcomes in a particular therapeutic area. CEA is the most commonly applied form of economic analysis in the literature, and especially in drug therapy. It does not allow comparisons to be made between two totally different areas of medicine with different outcomes.

Cost minimization analysis (CMA): This involves measuring only costs, usually only to the health service, and is applicable only where the outcomes are identical and need not be considered separately. An example would be prescribing a generic preparation instead of the brand leader.

Cost benefit analysis (CBA): The benefit is measured as the associated economic benefit of an intervention, and hence both costs and benefits are expressed in money. CBA may ignore many intangible but very important benefits not measurable in money terms. However the virtue of this analysis is that it may allow comparisons to be made between very different areas, and not just medical, e.g. cost benefits of expanding university education (benefits of improved education and hence productivity) compared to establishing a back pain service (enhancing productivity by returning patients to work).

Cost utility analysis (CUA): This is similar to cost effectiveness in that the costs are measured in money and there is a defined outcome. But here the outcome is a unit of utility.

Handling The Results Of Economic Evaluations [10] :Consider the four possible results arising in a CEA (FIG NO 6). First, if costs are lesser and health benefits higher for one drug comparative to another, the former is said to control 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 judgment 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.

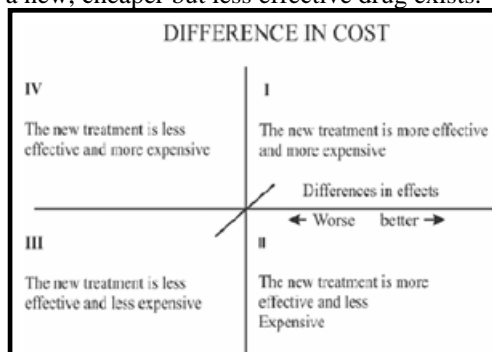


Fig. 6. Handling the results of Economic Evaluations

LIMITS OF PHARMACOECONOMIC EVALUATION:

The entire procedure may be open to bias, in the option of comparator drug, the assumptions made, or in the selective reporting of outcome. This distrust arises because the majority studies are conducted or funded by pharmaceutical companies. Variation in costs, diversity in effects work are fascinated in the results, and there is a publication bias towards those studies constructive to sponsoring companies. Doctors may tend to equate health economics with rationing or cost cutting, and many therefore reject on principle the whole process as unethical. Since resources are limited within health services, wasting them by inefficiency is wrong, as it reduces the clinician's ability to give the best possible care to his patients. It therefore seems unethical not to consider the economics of a medical intervention. A key problem is our ability to implement the results of a study. No matter how good a study is, and how cost effective a therapy compared to existing treatment, it may not be possible to achieve its potential benefits because of the existing cumber some management structures. Three problems are common: first, a short term outlook which restrictions the application of economic evaluations showing extended savings for the health service in return for increased spending now a days. Second, lots of budgets activate in isolation, and it is not easy to move money between them: for instance, prescribing in primary care is often funded separately from hospital services, so any rised spending on drug therapy in primary care cannot be just funded from a future reduction in hospital admissions. Third, a new interference may purely not be affordable no matter how cost effective it. Health economics and pharmacoeconomics is a juvenile science and is slowly developing and testing its methodologies.

latest Studies : One of the studies showed the efficacy of Sildenafil, its side effects ,drug interactions, and socioeconomic factors involved in its use, with a focus on specific patient populations (prostate cancer, diabetes mellitus, ischemic heart disease, spinal cord injuries, neurological disorders). Sildenafil is an useful first-line therapy for erectile dysfunction in men. The decision to prescribe this agent should include such considerations

as the cost-risk benefit balance, patient access, drug distribution pathways, and prescription drug coverage.

The efficacy, complications, and costs associated with low-dose , Alteplase (tissue plasminogen activator [t-PA]) versus Urokinase for the catheter-directed treatment of acute peripheral arterial occlusive disease (PAO) and deep vein thrombosis (DVT). Outcome variables included initial and total drug doses, infusion time, success rates, complications, and estimated drug costs, which were compared with the Student t test for continuous data and analysis for dichotomous data. The regression analysis of thrombolytic complications showed the P value of less than 0.05 which was considered to be statistically significant. Pharmacoeconomic analysis showed t-PA was nearly 15 times less expensive than Urokinase overall. The safety, efficacy, and pharmacoeconomics of low-dose Alteplase compared with Urokinase for catheter-directed thrombolysis of arterial and venous occlusions [11].

The previous work from the United States, Canada, Europe and Asia on the pharmacoeconomics of alcohol, tobacco and illicit drug abuse, indicates that as cost decreases, abuse increases. The concept that lowering the price of prescription drugs with abuse liability will increase their therapeutic use has never been tested, but there is a significant world-wide literature on the influence of price on the use of prescribed medications. For example, it has been shown across the world (e.g. Europe, North America and Japan) that price limits the therapeutic use of 15 different non-opioid classes of therapeutic agents to a very significant extent[12].

According to economic theory, the shift from full coverage to the co-payment and coinsurance plus deductible policies for older individuals would have caused patients to purchase fewer inhalers if those patients were sensitive to prices. It seems plausible that older patients with chronic obstructive pulmonary disease (CORD), emphysema, or asthma, who reduced their use of inhaled medications, may be at increased short-term and long term risk of health-related outcomes that lead to increased physician use, hospitalizations, and mortality. The costliness of inhalers (particularly steroids) and the potential for short-term adverse outcomes made CORD and asthma patients an ideal high-risk group in which to study the early effects of the policy changes. It appears that structuring coverage according to income reduced treatment cessation among inhaled steroid users with lower incomes which is a concern with other drug policies. Older inhaled-steroid users were more resistant to cessation treatment than were younger patients, which may have been the result of incomplete adjustment for disease severity in the model. Ettinger et al presented the a cost effectiveness study of Ibandronate, Alendronate, and Risedronate in the treatment of postmenopausal osteoporosis at the 2005 Annual Meeting of the American Society for Bone and Mineral Research. They incorporated rates of persistence with medication into a cost-effectiveness analysis. The persistence rates used for the weekly Bisphosphonates Alendronate and Risedronate were 36% in year 1 and 24% in years 2 and 3; the persistence rates used for monthly Ibandronate were 51% in year 1 and 39% in subsequent years. The model was based on a 10-year horizon and 3-year duration of therapy. All 3 Bisphosphonates were assigned a class effect for vertebral, hip, and wrist fracture reduction. Based on these assumptions, the analysis indicated that Ibandronate was associated with a lower fracture-care cost per patient compared with Alendronate and Risedronate.

The business case for developing new therapies for Alzheimer disease and related disease (ADRD) is compelling. The most rapidly growing population in developed societies is the 75 age group, 25% of whom have cognitive impairment. In the USA alone, there are an estimated 4 million sufferers of ADRD. The potential market has expanded with the recognition of more subtle forms of cognitive impairment in old age. The economic impact of ADRD is considerable. ADRD is the third most costly disease to society after heart disease and cancer, costing the USA alone over US\$100 billion dollars in 2002 in direct and indirect costs. ADRD is estimated to cost US businesses US\$33 billion per year, US\$26 billion going to employed caregivers suffering depression, lost days of work and increased healthcare costs. Mild cognitive impairment (MCI) is a recently described entity affecting perhaps 8 million older people in the USA with isolated memory loss who do not suffer the more global cognitive impairments (such as disorders of language and abstract reasoning) that characterize dementia. Fifteen percent of MCI patients progress to AD each year, making MCI an important advance for drug development as a model for prevention and rate of progression clinical trials. Even more common, and estimated to affect 16 million people over 50 years of age in the USA, is age-associated memory impairment (AAMI), which is a syndrome that generally describes normal cognitive aging. AAMI is important because it provides a clinical paradigm for drug development to develop therapeutics to treat the slowed speed of processing, word retrieval and other cognitive difficulties associated with normal aging, just as we treat presbyopia.

Clinical studies have shown efficacy of cholinesterase inhibitors (e.g. donepezil) in mild to moderate Alzheimer's disease (AD). However, there are limited studies examining the impact on health care costs of cholinesterase inhibitors prescribed in routine clinical practice. The purpose of this study was to estimate the impact of donepezil use on health care costs and utilization in patients with mild to moderate AD and related dementias. A patient's prescription-drug coverage might affect health care costs by two mechanisms. First, more comprehensive coverage would be expected to increase prescription-drug use and, in turn, overall cost. Second, more comprehensive coverage would be expected to increase access to prescription drugs, which, in turn, would decrease total cost by preventing hospitalizations and other health care utilization that would occur without treatment [13]. In this case-control study in patients with predominantly mild to moderate AD and related dementias enrolled in a medicare managed care plan, patients receiving donepezil therapy prescribed in routine clinical practice had lower total health care costs compared with a control group of matched patients not receiving therapy over a period of 12 months. Although donepezil-treated patients had higher costs or utilization as measured by outpatient hospital costs, prescription-drug costs, and physician's office visits, these costs were substantially offset by the lower costs for hospital, post-acute SNF, and home health care services. Thus, in addition to improved clinical outcomes, donepezil use might reduce health care costs and utilization.

The new recombinant human parathyroid hormone Teriparatide (hPTH), including its clinical pharmacology, mechanism of action, pharmacokinetic properties, clinical efficacy, safety profile, potential drug interactions, contraindications and warnings, dosage and administration, and pharmacoeconomics. The average wholesale cost of Teriparatide is \$20.81/d. Therefore, the estimated total 2-year cost of

Teriparatide is >\$15,000.11 Compared with other medications that are currently on the market for the management of osteoporosis, Teriparatide exceeds the monthly amount a patient would pay compared with the other medication alternatives. Teriparatide is calculated as costing 8-fold more a month than other available medications, which can be a growing concern for many patients who choose this as a treatment option.

New technology for the treatment of end-stage renal disease will need to be pharmacoeconomically persuasive in reducing the life-cost of treatment to obtain entry into the market. Increased automation, with closed-loop sensing technology, will occur in the near term. Clearance-based terminology for quantifying performance of equipment will give way to direct quantification of toxin removal. In the short term, there will be a steady progression toward more user-friendly and efficient blood cleansing methodology, with commonality of need drawing the equipment into a single multifunctional device. Preparation of sterile pyrogen-free dialysis fluid will be extemporaneously compounded, with closed-loop sensors driving the system to provide the prescribed quantity and composition of dialysate to achieve prescriptive goals of body content of important solutes, such as sodium, hydrogen, etc. Longer-term molecular biological tools will permit a far more convenient solution to the problem of ESRD. Access problems for hemodialysis will yield to a short-term fix that will involve novel shunt hardware. Longer-term biomedical engineering of tissues (vascular endothelium) with a return to fistula technology will occur. Peritoneal access improvement will involve improvement of the rosthesis-tissue interface. Initially, this will result from material selection and surface configuration changes. Subsequently, these changes will be coupled with tissue engineering to provide increased infection resistance and decreased atheroma formation. In conclusion, the future for renal replacement therapy is bright with promise. Our revolutionary new tools for creating biological/physiological change have clear applications to the problem of ESRD and can be expected to provide a much needed improvement in its treatment.

CONCLUSION

As the healthcare sector making headway slowly the need to develop Pharmacoeconomics area is must. Healthcare segment is not just a small area but it became an industry now. It has more extent to explore. Patients also get benefit out of Pharmacoeconomics findings. The value added care provided to the patients by individual healthcare institution needs to be further researched due to increase in health care cost. The pharmacist has to implement the principles of economics in daily basis practice in community and hospital pharmacy. The development of pharamcoeconomics is at an early year's in India at the moment, in spite of the rapid growth of clinical research.

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