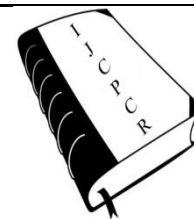




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PHARMACOECONOMICS IN INDIAN CONTEXT

Deepak Bhosle¹, Asif sayyed^{2*}, Shaikh Huzair³, Alimuddin Shaikh⁴, Vasundhara Bhople⁵,
Ayman Ali Khan⁶

Professor and H.O.D¹, Chief Resident^{2,5}, Resident^{3,6}, PhD scholar⁴,
Department of Pharmacology, MGM Medical College, Aurangabad (MS). India.

ABSTRACT

Pharmacoeconomics can be defined as 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. Economic evaluations provide healthcare decision-makers with valuable information, allowing optimal allocation of limited resources. However, pharmacoeconomics is based on long-term benefits; whereas physicians are typically forced to seek immediate savings. Australia was the first country to use pharmacoeconomics studies as part of decision making processes for development and use of new drugs. Pharmacoeconomics helps governments to make guidelines about reimbursing the cost of drugs. In many countries the governments on the basis of pharmacoeconomics makes the rules about using certain drugs. In some cases the guidance is against use of the drug at all, or for restricted use for a range of indications narrower than those mentioned in the license. For example anti-TNFs are reimbursed in most jurisdictions for rheumatoid arthritis, albeit with restrictions, like it should be used after patient has not responded to certain other drugs like Methotrexate etc. While in some other cases pharmacoeconomics helps make guidelines about the restricted use of drugs like while anti-TNFs are allowed to be used in rheumatoid arthritis after other drugs fails, they are not universally reimbursed if used in other conditions like Crohn's disease, psoriatic arthritis, and psoriasis. This article provides an overview about pharmacoeconomics, its application in the Indian pharmaceutical industry, and the growing insurance system in India. Pharmacoeconomic evidences can be used to formulate the guidelines about whether or not to license a particular drug for particular indication? If license is given then for which indication it can be used and the indications for which there should be a conditional use like when the patient is not responding to other first and second line drugs and when the concerned drug should not be used at all. It can also help in pricing and maintenance of formulary procedure of pharmaceuticals. With globalization the insurance sector is also expanding in India and with this expansion pharmacoeconomics is going to take a centre stage as a validating methodology for reimbursement by insurance companies. The role of Pharmacology graduates and postgraduates is expected to be of crucial importance in achieving this as they will be able to apply the principles of pharmacoeconomics in community and tertiary care hospitals.

Key words: Pharmacoeconomics, Drug licensing, Reimbursement, Indian perspective.

INTRODUCTION

With the exponential growth of health sector and improvement in preventive and social medicine as an important branch of medicine the focus now is shifting towards the prevention of diseases and complications. In this regard many of the chronic diseases which used to be diagnosed at a late stage when the patient had already developed complications is now fast becoming thing of the

fast and now the current trend is early diagnosis and prompt treatment. More and more patients of non-communicable disease requiring lifelong treatment ie diabetes mellitus, hypertension, rheumatic diseases and autoimmune disorders are being diagnosed at an early stages and treatment is being instituted at a very early stage of the disease. Early diagnosis and prompt treatment

Corresponding Author :- **Asif Sayyed** Email:- publicationmaster@gmail.com

obviously is going to affect the wellbeing of the patient. There is an important implication of this changed scenario that is now appraisal of healthcare services now goes beyond efficacy and analysis of adverse effects and economic analysis of the cost of treatment is fast emerging as one of the major concerns. The branch of pharmacology dealing with this aspect is pharmacoeconomics. It mainly focuses on costs and benefits of drug therapy and forms the basis of resource allocation and utilization. In western world it has been a major determinant of health policy decision-making. Although In developing countries like that of India it is relatively a young branch of pharmacology but its importance can't be overemphasized [1]. In fact it is more important in Indian context because of the huge population to which health care sector caters to and the relatively scarce health care resources available.

In Indian context it's a huge challenge to provide healthcare to all with relatively scarce resources. The healthcare budget of India is far less than that of developed countries which makes it imperative to implement healthcare programs, treatment protocols and policies which are economically feasible and efficient. One important sector which is concerned about these pharmacoeconomics dynamics is health care insurance sector which is concerned about evidence that can help it make decisions that can help determining whether or not to purchase, contract and include new medications in the recent formularies. Pharmacoeconomics is concerned with this long term benefit of use of a particular drug rather than immediate effects. Analysis of this long term benefit and economic worth is what influence most about the decision regarding a particular drug or treatment protocol [2]. The nature of socialized medicine is very complex. The complexity is in the fact that the medicines are prescribed by doctors, consumed by patients who need the medicine, paid by the government with the money of taxpayers who are healthy or not deriving any benefit whatsoever from this treatment. Pharmacoeconomics deals with these aspects of cost of healthcare measures and benefits it is expected to provide to the patients and to the society as a whole [3]. Pharmacoeconomics deals with all aspects of drug from research, clinical trials, production, marketing, adverse effects and benefit etc. At all of these steps pharmacoeconomics plays a major role in deciding whether or not the drug should be introduced and if introduced then for what purposes it can be used [4]. It is for this reason that Professionals related with or working in pharmaceutical research and development process must be familiar with the advantages, pitfalls, methods and principles of pharmacoeconomics which includes analytical techniques and measurement of impact of particular drug and its use on overall health of those for whom it is intended to be used [5].

DISCUSSION

The definition of pharmacoeconomics as given by

The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) is "the field of study that evaluates the behavior 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"[6]. In early 1970 the concept of pharmacoeconomics started taking shape [7]. The concept of cost benefit and cost effectiveness was first published by McGhan, Rowland, and Bootman from the University of Minnesota [8]. In our country where only 10-15% of the population is insured by health care insurance approximately 90% of the population remains at the risk of developing severe financial crisis if anyone of them gets struck by a major illness. In this scenario application of cost benefit and cost effective analysis becomes more critical in comparison to western countries where most of the population is covered by health care insurance [9].

Pharmacoeconomic Analysis:

The Expenditure, Clinical and therapeutic outcomes, morbidities and mortalities associated with different forms of management is studied by pharmacoeconomics. The study helps in giving emphasis to more cost effective drugs and one with greater impact on public health. The medicine having greater public health implications even if costly may be given priority over the drugs dealing with rare disorders. There are four important types of pharmacoeconomic analysis [10].

1. Cost-minimization analysis:

According to World health organization "Cost-minimization analysis is a method of calculating drug costs to project the least costly drug or therapeutic modality [11]. Cost minimization analysis is most commonly done to compare two drugs that are supposedly equivalent in dose and therapeutic effects. The rationale behind this analysis is that when a new drug is licensed for marketing is similar to an old drug in its therapeutic benefits and side effects etc then the price should arguably be same as that of old drug. But in reality it is not as simple as it sounds to be because of the fact that sound trial-based information of both drugs are needed for coming to such a conclusion which is always not the case. And for this very reason the critics of cost-minimization analysis have argued against using cost-minimization analysis as a useful tool of pharmacoeconomics studies. In fact some of the authors had been so critical of cost-minimization analysis so as to declare "the death of cost-minimization analysis". They are of the view that "it is inappropriate for separate and sequential hypothesis tests on differences in effects and costs to determine whether incremental cost-effectiveness (or cost-utility) should be estimated" [12].

2. Cost-effectiveness analysis

Cost-effectiveness analysis (CEA) is a form of

economic analysis that compares the relative costs and outcomes (effects) of different courses of action. Cost-effectiveness analysis is distinct from cost-benefit analysis, which assigns a monetary value to the measure of effect [13]. In context of healthcare which deals with life of human being cost-effectiveness analysis is appropriate rather than cost benefit analysis because life cannot be monetized. It is most appropriate in analysis of cost of drugs used for various diseases because it is difficult to put a value on outcomes but where the outcomes can be compared like for example analysis of effects of different lipid lowering agents on serum lipid levels or in prevention of episodes of strokes etc [14]. The best example of cost-effectiveness analysis is the use of oral rehydration solution for the treatment of acute diarrheal illness in developing countries. It is a well known fact that oral rehydration solution is not the treatment of diarrhea or it does not have any bearing on the etiopathogenesis of diarrhea but it prevents dehydration which is the primary cause of hypovolumic shock in patients especially patients of pediatric age group. The fact that proper oral rehydration therapy can prevent deaths in children can be proved scientifically and cost effectiveness analysis can further prove that the negligible cost of oral rehydration therapy is something which can be promoted as a public health policy. The inference drawn from cost effectiveness analysis can be used to decide the re-allocation of health care resources so that more number of life years can be saved [15].

3. Cost-benefit analysis

World health organization states that “Cost-benefit analysis is used to value both incremental costs and outcomes in monetary terms and therefore allows a direct calculation of the net monetary cost of achieving a health outcome. A gain in life-years (survival) may be regarded as the cost of the productive value to society of that life-year using, for example, the average wage” [16]. It is one of the least popular and most controversial methods utilized in the studies of pharmacoeconomics because it values health outcome in terms of monetary gain which itself is not an appropriate approach. Second factor which influences cost-benefit analysis is the use of this technique of analysis when long term effects are the ultimate consideration but the analysis is usually done on short term effects for example the effectiveness of a hypoglycemic drug in lowering blood sugar level can be demonstrated in short term studies but its effectiveness in delaying end-organ damage can only be demonstrated in long term studies spread over years or decades. For these pitfalls cost-benefit analysis is not a popular method of cost-benefit analysis especially in context of health care delivery system [17].

4. Cost-utility analysis

This is one of the most useful methods of evaluation in context of health care setup. This analysis

compares the costs of different interventions with their outcomes measured in "utility based" units—this unit can be level of wellbeing of the patient or level of possible activity of a patient. Quality adjusted life year (QALY) is one of the most common units used for such an analysis [18]. Cost in terms of utilities is determined by this method of analysis. Quality of life is one of the method of analysis or determinant of outcome of such an analysis. Some authors have termed it to be controversial because to put a value on improvement in health status is a very subjective feeling and cannot be objectively quantified [19]. The classical example is that of psoriasis. The skin lesions of psoriasis can involve any part of the body and a person who is having a facial lesion may be more distressed by psoriasis than one who may have it over unexposed part of bodies and improvement in the condition of these 2 patients may have an entirely different influence on quality of life which cannot be objectively quantified. Nonetheless it is one of the useful model of the study of pharmacoeconomics and especially useful when comparing healthcare outcomes [20].

In Indian context the pharmacoeconomics is an important aspect because millions of household live below poverty line in India and it is of critical importance to allocate the healthcare resources properly so that it can have maximum effect on the quality of life of the people. Every individual who is part of health care delivery system should be aware of the concept of pharmacoeconomics. In this regard policymakers, pharmaceutical companies, pharmacology experts and doctors should have sound knowledge of the methods of pharmacoeconomics which will help them choose the optimal therapy with lowest price. Unlike in developed world it is of critical importance in developing countries where resources are scarce and its of utmost critical importance to properly allocate the health resources to have maximum benefit to the large population [21]. On negative side of it pharmacoeconomics may post a hurdle in using some drugs even when their efficacy is established for example use of rituximab for autoimmune hemolytic anemia is well established but for economical reason some countries may adopt guidelines that it should only be used when other drugs are not effective. Such a condition may be useful for some economical consideration but it puts an unreasonable restriction on treating hematologist who may be more inclined to use rituximab in a patient of autoimmune hemolytic anemia based upon his experience. Such eventuality will defeat the very purpose of health care delivery system when the treatment options and decision are based not upon the expert opinion but on economical consideration [22].

CONCLUSION

Pharmacoeconomics is a useful method of economic evaluation of various treatment options. As more expensive drugs are being developed and licensed it has become imperative especially in context of developing

countries where resources are scarce to apply the principles of pharmacoeconomics for various drugs and treatment

options so that maximum improvement in quality of life can be achieved in minimum cost.

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