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Health Economics and Outcomes Research: It's Swot (Strength, Weakness, Opportunities and Threats) Analysis for India

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ABSTRACT

The application of health economics reflects a universal desire to obtain maximum value for money by ensuring not just the clinical effectiveness i.e. outcomes research, but also the cost-effectiveness of healthcare provision. Outcomes research seeks to understand the end results of particular health care practices and interventions. Health economics and outcomes research**(**HEOR) now has become a vital part in some leading pharmaceutical companies abroad for demonstrating product value which encompasses aspects such as clinical efficacy, real-world data, budget impacts and cost effectiveness models, which eventually supports the allocation of resources for the acceptance and reimbursements of new products. Implementation of activities in this field has been possible in other countries because of Health insurance system that allows the use of data for research. Pricing pressure and regulatory restrictions across various health-care industries have called for more detailed evidence based on outcomes of healthcare products. Stakeholders including regulators and payers are increasingly relying on HEOR information to understand the product value and its potential in real-world clinical practice. So, the current work aims to study the scope of HEOR for the regulators and healthcare service providers in India and abroad. It emphasizes the role of everyone in health-care system including health insurance companies, benefits experienced by patients as well as pharmaceutical industries and challenges in the execution of this field in India and measures to overcome the roadblocks, which will benefit health-care systems in India.

Keywords: Health economics and outcomes research, health-care systems, insurance companies, pharmaceutical industries.

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INTRODUCTION

Health Economics and Outcomes research (HEOR)

In this world of limited resources, health economics is used to make proper decisions on which health treatments, medications or technologies to choose and which to avoid in order to improve the health of the overall population of a country.

Health economics has now become an important decision-making support science. It is a subset of the broader concept of health technology assessment (HTA), which includes not only drugs but also devices, medical and surgical procedures, diagnostics and the systems, processes and programmes that influence healthcare. Pharmacoeconomics[1, 2], which is a subset of health economics, focuses exclusively on pharmaceutical industries.

Defining the *value* of medicine is a common thread that unites today's healthcare practitioners. With serious concerns about rising medication costs and consistent pressure to decrease pharmacy expenditures and budgets, clinicians/prescribers, pharmacists, and other healthcare professionals must answer the question, "What is the value of the pharmaceutical goods and services I provide?"Pharmacoeconomics, or the discipline of placing a value on drug therapy,[1] has evolved to answer that question.

Consequence or outcome[1, 2] is defined as the effects or outcomes of the program of drug therapy of interest.Pharmacoeconomics research has become an essential tool in terms of resource utilization. The health care industry is facing a lot of problems with only a few ideas in the pipeline. The industry needs to address not only effective drug management, but also the wise and appropriate use of resources necessary to sustain the health care system.

Principles of HEOR

Pharmacoeconomics has been defined as the description and the analysis of the cost of drug therapy to healthcare systems and society. Pharmacoeconomics 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 e.g. comparing the value of alteplase (tPA) to streptokinase from a patient or community perspective, if a 1% reduction in mortality rate is observed in a large population, tPA may be the better alternative. However, in a small community hospital, streptokinase may present a better value, because it provides similar outcomes for less money[3,4].

The disciplines of pharmacoeconmics, outcome research and pharmaceutical care are interrelated. Outcome research is broadly defined as studies that aim to identify measure and

evaluate the results of healthcare services in general. Pharmacoeconomics is a division of outcome that can be used to determine the value of pharmaceutical services and products[5].

Perspectives

Assessing the value of a pharmaceutical product or service depends on the perspective of the evaluation. Common perspectives include those of the patient, provider, payer, and society. A Pharmacoeconomic evaluation can assess the value of a product or service from single or multiple perspectives. However, clarification of the perspective is critical because the results of a pharmacoeconomic evaluation depend heavily on the perspective taken. Once the perspective is clear, a full evaluation of the relevant costs and consequences can begin. Again, perspective is critical because the value placed on a treatment alternative will depend heavily on the point of view taken.

Patient's perspective

Patient perspective is paramount because patients are the ultimate consumers of healthcare services. Costs from the perspective of patients are essentially what patients pay for a product or service that is, the portion not covered by insurance. If the pharmacoeconomic profile of a medicine is available, doctors can know and evaluate the additional benefits available from such a medicine over existing medicines and determine whether the incremental price is commensurate with the additional benefits claimed.

Physician's perspective

Performing an economic evaluation of a new medicine and comparing it with existing ones provides significant advantage from the viewpoint of medical practitioners. It will empower physicians to compare medicines on different pharmacological parameters including safety and efficacy.

Health Insurer's perspective

Pharmacoeconomics will prove to be an essential tool in preparing standardized list or formulary based on cost-effective analyses of drugs, which will benefit both patients and insurers in the process of reimbursement and impart further clarity and transparency to the health insurance system by helping insurers determine the clinical criteria for coverage. Till date, only 3% to 5% of Indians are covered under any form of health insurance. This includes those covered under the Central Government Health Scheme (CGHS; 4 million beneficiaries), the Railway Health Scheme (1.2 million) and the Employees State Insurance Scheme (0.3 million), all examples of social health insurance. On the other hand, private insurance covers about 11.2 million individuals. Nevertheless, private insurance is not the answer for India's objective of equity,

efficiency and quality in health because it tends to cater to the affluent classes, covering the healthiest and the wealthiest thereby resulting in limited social gain.

Government initiatives

In order to implement pharmacoeconomic studies in the reimbursement aspect of the Indian pharmaceutical industry, there is a need for the government to undertake a centralized insurance system like other countries in the Asia-Pacific region.

Govt. initiative 2003: An initiative was taken by the Indian government in 2003 to implement a Universal Health Insurance Scheme, the initiative failed because of its failure to cover the poor population.

Govt. initiative 2008: In April 2008, the Union Ministry of Labour and Employment in India launched a RashtriyaSwasthyaBimaYojna (RSBY) smart card to combat the so-called 'health-based poverty trap' in the country. The RSBY initiative provides health insurance coverage for below poverty line (BPL) families.

Current Status: There are currently, 28.6 million RSBY card holders and their 115 million family members across India. This initiative has proved to be beneficial for the poor in India. Pharmacoeconomic studies and its use may help to broaden its coverage across a wider population mass.

Researcher's perspective

Table: Stakeholders' perspectives and pharmacoeconomic solutions

Stakeholders Perspectives	Area of Stakeholders Concerns	Pharmacoeconomic Solution
Patient	Cost-benefit analysis of new medicine?	Access to cost benefit comparison between available medicines.
Physician	Evaluation of new medicines with respect to safety, efficacy etc?	Pros and cons analysis of old vs. new medicine
Insurer	Cost-benefit analysis to prepare a list or formulary of medicines for reimbursement eligibility?	Provision of drugs list and reimbursement eligibility.
Manufacturer	Documentation for regulatory authorities, justifying the proposed price and demonstrate therapeutic benefits?	Medicine pricing decision is possible.
Researcher	Retrospective evaluation of clinical trial data and develop a decision analysis model for economic evaluation?	Availability of new molecule economic evaluation.
Policy Maker	Policy framework to balance the economic imperative of industry growth and social need of providing an access to affordable medicines?	Use in policy framework for balancing industry, regulatory and consumer needs.

A recent trend indicates that clinical trial designs explicitly incorporate economic data collection. Some studies incorporate an element of modeling to either adapt the findings of the trial to other settings or to project costs and outcomes beyond the period observed in the trial. Several regulatory agencies are now evaluating the use of pharmacoeconomic parameters as a part of the drug regulatory process. A Pharmacoeconomics study from the researcher's perspective will usually consist of a decision analysis model containing an economic evaluation.[14]

Cost

Once a perspective is chosen, the costs and consequences associated with a given product or service can be identified and measured using Pharmacoeconomics methods. Cost[6] is defined as the value of the resources utilized by a health program or of treatment including hospital charges and hotel services such as meals and accommodation charges, heating and lighting overheads.

Healthcare costs can be classified into several categories[7, 8, 9, 10]

1. Direct medical costs
2. Direct nonmedical costs
3. Indirect nonmedical costs
4. Intangible costs
5. Opportunity costs

1. Direct medical costs[12] - Direct medical costs account for medical products and services to detect, prevent and/or treat a disease e.g. costs of medicines, diagnostic tests and hospitalization. Direct benefits are estimates of savings on direct costs.
2. Direct nonmedical costs - These are any costs for nonmedical services due to consequences of illness but do not involve actual medical services e.g. costs of transportation and hotel rooms near a health centre.
3. Indirect nonmedical costs[12-14]- These are the costs of less productivity due to morbidity and mortality. They are in the form of lost earnings and productivity in the absence of health program in question. Indirect nonmedical costs are very difficult to measure.
4. Opportunity costs - These represent the economic benefit lost when using one therapy instead of the next best alternative therapy. The concept of opportunity cost is central to economics and identifies the value of opportunities which have been lost by utilizing resources in a specific service or health technology. This can be estimated as the benefits that have been forgone by not investing the resources in the best alternative fashion. Opportunity cost identifies that there are limited resources available for utilizing every treatment and therefore the rationing of health care is inevitable.

5. Intangible costs – Intangible costs can be defined as the psychological costs of a disease. These costs comprise other financial outcomes of disease and medical care, which cannot be appropriately expressed in a currency value e.g. pain, suffering and distress and hence, these costs are very difficult to measure.

Outcome

Consequence or outcomes of medical care can be classified in the following ways: [3, 4, 5, 11]

1. Economic outcomes: These can be described as the financial burden in the form of direct, indirect and intangible costs compared to the consequences of medical treatment alternatives.
2. Clinical outcomes: These are the medical events that occur as a result of disease treatment e.g. safety and efficacy endpoints.
3. Humanistic outcomes: Humanistic outcomes are the consequences of disease or treatment on patient's functional status or quality of life determined by several parameters e.g. physical ability, social welfare, general well-being and life satisfaction.

Outcomes of medical care can also be classified as follows:

a. Positive outcomes: These are the desired consequences of a drug treatment, characterized as efficacy and effectiveness.
b. Negative outcomes: These are the desired consequences of a drug treatment e.g. failure of therapy due to adverse drug reactions.

Pharmacoeconomic methods

The method of Pharmacoeconomics evaluations can be categorized as follows[11]

A. Economic methods[15,16,17,18]

1. Cost of illness analysis (COI)- It estimates the overall cost of a particular disease for a defined population. It involves measuring the direct and indirect costs. This method is usually used to estimate the financial burden of a disease.
2. Cost benefit analysis (CBA) - It is a method that identifies, measures and compares the costs and benefits of a treatment program and its alternatives. CBA can be useful in making high level strategic decisions on health care programs, e.g. estimation of resource utilization can be made for successful run of a national level immunization program. CBA can be used to measure the reduced morbidity and mortality that occur as a consequence of the program.CBA can also be used for comparing the value of different programs where the outcomes are in different units e.g. a given hospital or health

centrecan measure the cost benefit of having a child care program versus a cardiac rehabilitation program.

3. Cost minimization analysis (CMA) - It aims to determine the least costly alternative when comparing two or more therapeutically equivalent treatment alternatives.
4. Cost effectiveness analysis (CEA)- It can be defined as comparison of the costs of two or more clinical interventions which have the same outcome that can be measured in physical units e.g. disabilities prevented, life years added or lives saved. CEA may provide useful information to support drug policy formulary development and individualized drug therapy decisions.
5. Cost utility analysis (CUA) - This type of analysis takes into account the patient's preferences for a particular treatment program with respect to patient's state of well being and health related quality of life (QOL). CUA can be best used for evaluating the utility of treatment programs and their alternatives that are life extending (which produce reduction in morbidity rather than mortality) e.g. treatment of arthritis and cancer chemotherapy. Thus, CUA is reserved for comparing interventions wherein the primary goal is improving the quality of life.

B. Humanistic methods

1. Quality of life
2. Patient preferences
3. Patient satisfaction

Humanistic evaluation methods aim to evaluate the impact of a treatment program on patient's health related quality of life (QOL), patient preferences, and patient satisfaction and these are also gaining wide acceptance in pharmacotherapy decision making. Current trend is thus, to focus on evaluation of humanistic outcome of the treatment alternatives. The number of healthy years added within life extensions is one of the most important aspects of QOL research. The QOL extra years added in life ought to be adjusted in order to reflect whether this addition leads to full, healthy years or includes some dysfunctional adjustment too.

Health economics and outcomes research around the globe

Pharmacoeconomic data is currently used for reimbursement and other financial decisions and most of the European countries are currently making the maximum use of it and also have introduced pharmacoeconomics guidelines in their countries. In comparison with European countries, Australia has a relatively well-developed pharmacoeconomic structure. Countries in the North American continent, South American continent and South Africa have introduced the

concept of Pharmacoeconomics and outcomes research data lately but its full introduction is not visible until today. Countries in Asia like China, Hong Kong, Japan, Korea and Singapore have a well-developed Pharmacoeconomics and outcomes research structure. However, the Indian healthcare system has not yet undertaken research in Pharmacoeconomics and outcomes[19].

Current scenario for the development of HEOR in India

The Indian pharmaceutical industry (IPI) is the world's fourth-largest by volume and leading manufacturing sector in India. The Indian Patent Act in 1970 gave an impetus for the development of manufacturing unit in India. This has created tremendous job opportunities mainly in the field of clinical research, thus making way for health outcomes research[15]. In addition, many governments worldwide are now using generics to curb their soaring prescription drug costs, thus giving importance to cost-effectiveness and cost-benefit analysis studies. 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. Hence, in order to develop outcomes research and pharmacoeconomic analysis in India it is necessary to have a proper database system to be used for comparative effectiveness research. Being a generic nation and having the health care system governed by many private organizations, the concept of Pharmacoeconomics in India 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.

Challenges in using HEOR[19]

1. In a diversified country like India various factors like socioeconomic development and population size makes it difficult to adapt the concept.
2. Lack of knowledge and appreciation of the prospective importance and relevance of Pharmacoeconomics studies.
3. Poor technical skills of healthcare professionals, especially of pharmacists.
4. Lack of appropriate database of the healthcare system in order to bring about research adaptation from another country.

Benefits of HEOR[19]

1. Optimal use of finances for pharmaceutical expenditure.
2. Provision of job opportunities in the clinical, health economic and market research sectors.

3. Helps in pointing out and identifying cost barriers and thus finding a suitable way for reimbursement.

4. With respect to high cost diseases it gives a perspective in knowing and understanding the outcomes.

5. Cost management for medical therapies.

6. Understanding resource utilization.

Implementing the HEOR concept in India[20]

The following measures can be undertaken to extend Pharmacoeconomics practice in India

1. Introducing the concept of Pharmacoeconomics and outcomes research at the undergraduate level.

2. Workshops/Seminars on implementation of the concept of Pharmacoeconomics in pharmacy practice.

3. Use of cost-effectiveness data in the pharmaceutical industry for reimbursement and other financial decisions that could influence pharmaceutical expenditure.

4. Encouragement of pharmacy students to present posters and participate in the student chapters of International Society of Pharmacoeconomics and Outcomes Research (ISPOR).

5. Creation of health economic and reimbursement body at government level that can develop guidelines, standardize definitions and terminology relevant to HEOR.

6. Establish thresholds for cost data and introduce requirements for doing such analysis as part of the drug dossier.

Government's Role in development of HEOR concept:[5]

For the application of HEOR department in India it is necessary to operate the entire healthcare system under a single roof. At present, there is no definite healthcare system followed in India; there is no nationalized prescription service as well. In India, the drugs are not purchased via centralized systems such as state associations thus encouraging middlemen and increasing the price a common man would pay had the drug been brought by the pharmacies from this associations at a much cheaper rate. All these increase the common man's health expenditure. This indirectly increases the expenditure on the healthcare system of the country.

The government can play a major role by including Pharmacoeconomics in the healthcare system by taking the following measures:

1. A government-operated centralized healthcare system is required that would regulate the government hospitals and also pharmaceutical drugs and services. This action would entertain

the usage of pharmacoeconomic studies in evaluating the drugs for its cost-effectiveness and cost minimization, thus optimizing the health expenditure of the country.

2. State governments should undertake measures of supplying pharmaceutical drugs to local pharmacies by its direct purchase from the pharmaceutical industries or manufacturers. This would avoid middlemen like super-stockists, authorized stockists and semi-wholesalers, thus lowering the overall cost of the drug in the market.
3. Currently the approval of new drugs for marketing is the function of the Central Drugs Standard Control Organization (CDSCO) headed by the Drug Controller General (India). Before approval basic information on chemistry, physicochemical information, complete monograph specifications and data on the formulation including quality control data, animal pharmacology and toxicology and human/clinical pharmacology are reviewed. During the review process of the new drug by DCGI, pharmacoeconomic evaluation studies should be requested from the manufacturing company, thus giving an idea of cost-effectiveness and cost utility of the newly submitted drug. This would ensure long-term benefits of the newly introduced drug in the market.

When we want to develop the pharmaceutical sector which makes use of interpretive data and which focuses on patient related outcomes for the betterment of the society, it is imperative that we introduce important stake holders who play critical role in developing HEOR as a department which already is in existence in developed countries. This article mainly focuses on how implementation of HEOR will be beneficial for the health care sector in India.

Table: The effectiveness of HEOR model

Strength	**Weakness**	**Opportunities**	**Threats**
Optimal use of finances	Huge amount of human force required	Job Opportunities	Sometimes discouraging for researchers since large amount of money invested in research.
Cost-benefit analysis data helps in selection of medicines for patients by physicians and insurer for reimbursement eligibility	Extensive data handling systems	Introducing the concept at the undergraduate level	
	Lack of full appreciation of the concept		

CONCLUSION

The majority of research in India involves different segments of preclinical or clinical trials, with little or no inclusion of outcomes research. One reason for this may be the lack of access to quality primary data. There exists a vast amount of data, but they are not suitable for secondary database research. Regulation of drugs and medical devices requires adequately trained technical individuals who are capable of applying evidence in policy decisions. Additionally, they should be familiar with related policies and procedures. In the region under discussion, one of the priority areas that the different regulatory agencies would benefit from is human resource development to facilitate this process. Support from the government in terms of higher budgetary allocation and stronger legislation is also needed to strengthen the regulatory functions of the concerned agencies. An area of concern across the region is the paucity of regulation of devices. It is also necessary to promote inter-country cooperation to allow the sharing of best practices as well as to harmonize practices across the region. Because complementary medicines (including strong local traditional medicines like Ayurveda in India) are very popular there is a need to promote the concepts of PE and OR in these areas as well. Business models to sustain the operations of these regulatory agencies must be explored. Nevertheless, this should be done in a manner that will maintain the integrity and credibility of the processes. .Time and money can only be spent once- choice is inevitable. Whether done unconsciously or with a consistent process, health care professionals are constantly evaluating patient care choices & acting on them. Pharmacoeconomics and outcomes research can enhance the quality of your practice by strengthening your evaluation process and increasing the probability that you deliver better value in patient care.

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