



Review Article

Emerging role of pharmacoeconomics into clinical trials and its outcomes: An overview

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ABSTRACT

The expenses of health services are expanding in all the nations as the enhancement in and alteration of wellbeing advances every day. Pharmacoeconomics evaluation of clinical trials plays a vital role in assisting clinicians and researchers to take the decision over the economic and clinical outcomes of new health intervention and in helping patients to access new health interventions in affordable expenses. Incorporating pharmacoeconomics into clinical trials offers a clinical research organization to developed, design, and conduct a clinical trial to gain the most reliable data with possible minimum expenses.

A literature search was done using Medline electronic database with PubMed. MeSH terms such as 'Pharmacoeconomics', 'Cost-effectiveness Analysis', 'Cost-minimization Analysis', 'Cost-utility Analysis', 'Cost-benefit Analysis', 'Health economics', 'Quality of Life', 'Cost-analysis', 'Clinical trials', 'Healthcare' etc. were used.

We found that most randomized clinical trials have been assessed for economic evaluation. Pharmacoeconomics data generated from clinical trials gives insight to researchers and industries to estimate the economic burden of trials, decide to provide reimbursement to participants, and allocating funds to clinical trial/health research.

Key Messages: The economic assessments of trials offer health organizations to decide policymaking and providing health insurance whereas regulatory bodies over approval and pricing of new health intervention. The researchers need to develop, design, and conduct an economic assessment of the initial phase of clinical trials which provide the basis to conduct an economic evaluation for further trial development phases.

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1. Introduction

Increasing expenses of health insurance frameworks is a notable worry to all patients, human services experts, and the governing body. The increase in health services expense is a result of expanded life expectancy, extended innovation, altering way of life, and amplified interest in social insurance quality and administrations. Medicine is a small however significant parameter for overall health cast. As the affordability of new health intervention advances keeps on being the subject of warmed discussion, consideration is progressively centered on giving quality and cost-effective

health services.¹ Monetary assessment of pharmaceutical items, or pharmacoeconomics, is rapidly developing in the field of medical research.²

Pharmacoeconomics is described as the descriptive analysis of the costs of the intervention (drug/device) to the healthcare system and society and it is used to identify, measure, and compares the cost and consequences of pharmaceutical products and health services. The pharmacoeconomics study includes the research methodology related to cost-minimization, cost-effectiveness, cost-benefit, cost-utility, and decision-analysis, and quality of life.^{1,3} The pharmaceutical industry spent billions of dollars over new drug development. Now the aim is to collect pharmacoeconomic data in the initial stage of drug development to estimate clinical outcomes of

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new health intervention.³ Pharmacoeconomics assessment plays a vital role in assisting clinicians and leaders with making decisions about new pharmaceutical items and in helping patients acquire access to new health interventions.¹ Pharmacoeconomics data can be utilized to help to build up the efficacy of pharmaceutical items in the medication endorsement process, to furnish information to help value arrangements with national pharmaceutical buyers, set up signs for explicit items, and positioning health interventions against the therapeutic equivalent drug.⁴ Another point of view to conduct the monetary assessment of drug is to support those researchers, physicians, clinicians, epidemiologists, and other health care professionals who effectively occupied with multi-disciplinary research, or wish to add a financial viewpoint to their examinations of health service and health intervention.⁵ The drug development process is known to be a complicated, expensive, and time-consuming process. In this way, there is a need to incorporate pharmacoeconomics in the drug development beginning stage to properly allot resources.⁶

However, the developing global enthusiasm for pharmacoeconomics has provoked the incontestably visit consideration of financial appraisals inside worldwide clinical preliminary.⁷ As medical practitioners progressively more demand confirmation of economic value for new treatment therapy. Researcher assisted economic evaluation in conjunction with clinical studies is desirable because they expand the scope of information existing in a specific drug/device, and can give data over design, analysis, and validity in a time-dependent manner. Pharmacoeconomic evaluation needs to explore to assess the value for money of the interventions under clinical trial. Presently the pharmacoeconomics studies are progressively being incorporated in a clinical trial.⁸

2. Relationship between Clinical Trials and Pharmacoeconomic Evaluations

Clinical trials are being led to assess the safety and effectiveness of therapeutic interventions and pharmacoeconomic information can be gain by these clinical trials. The economic evaluations of clinical trials in real-world data disclose the actual information on the effectiveness and efficacy of new health intervention in a clinical trial.

The pharmacoeconomics data can be acquired form clinical trial in the three-way such as the first is to collect pharmacoeconomics data from the clinical trial as a primary objective, second is to collect pharmacoeconomics data as secondary objective where the primary objective is to collect safety and effectiveness data and the last is to perform pharmacoeconomics as a retrospective study from the past clinical trial. Besides, pharmacoeconomics evaluation is a system to screen or assess the utilization of health resources, productivity lost through bleakness and/or unexpected death and the effect of disease and treatment on quality of life.⁹

Previously, most of the pharmacoeconomics studies had been conducted such as cost-effectiveness analysis, cost-utility analysis, cost-benefit analysis and quality of life in a randomized controlled trial (RCTs), factorial RCTs, multicentre and multinational as well as long term clinical trial.^{7,10–17}

3. Incorporating Pharmacoeconomic Evaluation into the Clinical Trial

Incorporating pharmacoeconomics into the clinical trials (Table 1) offers a clinical research organization to developed, design, and conduct a clinical trial to gain the most reliable data with possible minimum expenses. The uses of pharmacoeconomics model into clinical trial ensure decision-makers to gain knowledge for cost and effectiveness of trial intervention.¹⁷ Pharmacoeconomics analyses help to estimate sample size and to select a comparator drug and trial site; and data over clinical trial provide a scheme for reimbursement, drug pricing and making drug policy.^{10–23}

4. Economic Assessment of Trial Development Phase

The economic assessment of clinical trial in the development phase (Table 2) such as phase I give an idea of whether the trial should be assessed or not in further trial phases for the economic and clinical outcome.²⁴ Now economic evaluation of clinical trials is a center of attention for most of the researchers to assess the effectiveness and efficacy of health intervention in the development phase.^{2,25} However economic assessments of the trial development phase undergo various issues such as concern about the trial result, bias, etc.^{26,27}

i) Phase I trials (Human Pharmacology Phase): At this point, the cost of illness studies should be conducted which confirms the further need for pharmacoeconomics study on a later phase. Thus there is a need to develop and design a more strategic economic evaluation of clinical trials.⁴

ii) Phase II trials (Explanatory Phase): In phase II trials, the drug is administered to a limited number of patients with the target disease. At this phase, the cost of illness assessment provide more information over the clinical aspect of intervention.^{26,28}

iii) Phase III trials (Confirmatory Phase): At this phase, the pharmacoeconomics data is a crucial factor that decides the marketability of drugs that might be time-consuming and may delay the new drug application process, they should be done unless the drug is very novel and has no other alternative.^{28–30}

iv) Phase IV trials (Post-marketing Surveillance): Prospective as well as retrospective studies can implement the monetary assessment that provides information about cost and outcomes of drugs in real-life scenery, unlike clinical trials that are conducted in prohibited conditions.²

Table 1: Economic evaluation of clinical trials

S. No.	Pharmacoeconomics Evaluation	Trial Design
1	Cost-Effectiveness Analysis	Multi-centric, Multinational trial ^{15–17}
2	Cost-Effectiveness Analysis	RCTs ¹⁹
3	Cost per Patient-Year	RCTs ²⁰
4	Cost-Benefit Analysis	RCTs ¹¹
5	Cost-Utility Analysis	RCTs ¹⁰
6	Costs, Effects, and C/E-Ratios	RCTs ²¹
7	Incremental net benefit	RCTs ²²
8	Quality of Life (QOL)	RCTs ¹²
9	Cost Data of patients after withdrawal	RCTs ²³
10	QOLYs and Cost/patient	Factorial RCTs ¹⁴
11	Total costs and QALYs	Partial factorial trials ¹³

C/E Ratio-Cost- Effectiveness Ratio, QOL- Quality of Life, QOLYs- Quality of Life Adjusted in Years, RCTs-Randomized controlled trial

The clinical trials and pharmacoeconomic evaluations can be conducted together in the following way:

1. Safety and efficacy in clinical trials followed by pharmacoeconomics evaluation.
2. A clinical trial with the objective of pharmacoeconomics evaluation.
3. Pharmacoeconomics evaluation of Clinical data either prospectively or retrospectively.

5. Evidence of Incorporating Pharmacoeconomics into the Clinical Trial

We found that a higher number of studies have been reported from china followed by India and Russia in the searched literature of respective countries (Figure 1). In India, the majority of studies conducted for economic evaluation have been objected to quality of life followed by cost-effectiveness analysis (Figure 2). The data in Figure 1 and Figure 2 obtained from the literature search form the PubMed database between the duration of 2010 to 2019 (such data included research studies and trials both). The economic assessment of the clinical trials in real-world data reveals the actual information on the effectiveness and efficacy of health intervention in a clinical trial. It gives insight to health researchers to decide the need for the economic evaluation of clinical trials. Several trials had been assessed for economic evaluation in the field of coronary artery disease, cancer, spinal disorders, HIV, skin infection, etc(Table 3).^{31–45}

6. Impact of Integrating Pharmacoeconomic into Clinical Trial

The design and successful completion of clinical trials is not an easy task as it requires huge resources, cost, and manpower. These costs include drug cost, patients incentive, data collection, accrual, data management, clinical overhead, finance invoicing, reporting result etc.⁴⁶ Currently, many health care systems in developed countries

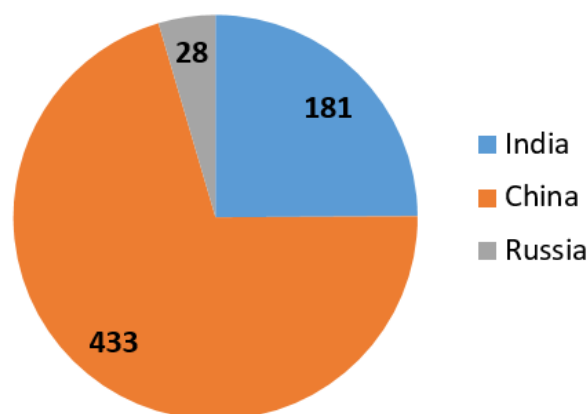
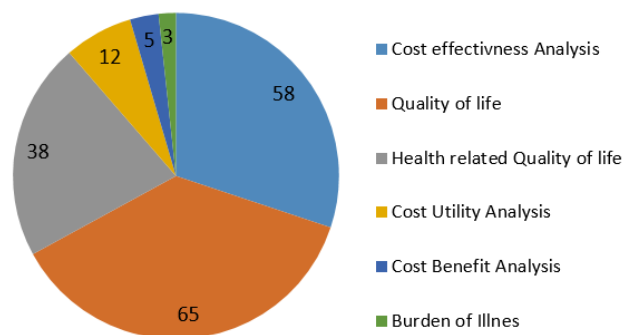
No. of Pharmacoeconomic Studies**Fig. 1:** Number of studies over Pharmacoeconomics in India, China, and Russia**No. of Pharmacoeconomics Studies in India****Fig. 2:** Number of studies over Pharmacoeconomics in India

Table 2: Economic assessment of trial development phase

S. No.	Trial Phase	Pharmacoeconomics study	Outcomes
1	Phase I	Cost-effectiveness	Provide a basis to conduct economic analysis in new drug development ⁴
2	Phase II	Cost of care of patients, Quality of life	Help to provide an estimate for patient care as well as obtain burden of data collection in Phase III ⁴
3	Phase II	Total expected, cost-per patient	Need sensitive analysis before conducting an economic evaluation of large multi-centric clinical trial ²⁶
4	Phase II	QOL	Outlined strategy for collecting pharmacoeconomics data ²⁸
5	Phase III	Total care cost and Hospital cost in Alzheimer's disease	Consideration must be paid to structuring pharmacoeconomics strategies to estimate the anti-dementia disease-modifying therapy can be conveyed to all concerned ²⁹
6	Phase III	QOL	Outlined strategy for collecting pharmacoeconomics data ²⁸
7	Phase III (Multinational)	Total cost, Clinical outcomes, Cost and Outcomes comparison, QALYs	Economic study is a complex process and required a set of strategies to take the decision. Phase III offers large data collection to help to set cost and clinical outcome ³⁰
8	Phase III	Survival, Quality of life and health economics	Separate strategies and studies ought to be utilized to assess economic value and expenses ²⁵
9	Phase IIIA	Cost-effectiveness Efficacy data	Acquire pharmacoeconomics data for registration of dossier, drug pricing, reimbursement and negotiation ²
10	Phase IIIB	Effectiveness data and efficiency data	Development of drug formularies, reimbursement, and negotiation, comparison of health interventions alternatives ²
11	Phase IV	Effectiveness data and efficiency data	Formularies development, reimbursement, and negotiation, health alternative comparison ²

QOL-Quality of Life, QOLYs-Quality of Life Adjusted in Years

are utilizing pharmacoeconomics assessment to decide on reimbursement of new health interventions.^{47,48} Alone economic data is not sufficient to decide the cost of therapy and intervention in a clinical trial, the clinical outcome should be conducted along with economic data enable health researchers to improve public health. Many pharmaceutical companies and researchers are controversial with the adequacy of data, inappropriate termination, and appropriate use of economics in new drug development. However, to date, researchers have recognized the fact and impact of incorporating economic assessment in new drug development. Yet, there is a sturdy justification for incorporating pharmacoeconomic assessment which provides a strong decision approach in new drug development in the initial stage. As the economic obstacles for new drug keep on rising, pharmacoeconomics study plays an important role in completing a research work in a well-organized manner in possible low cost and provide

a cost-effective drug with excellent clinical outcomes.²⁴

However, it does not necessary to conduct pharmacoeconomics study for all kinds of clinical trials as it makes unnecessary burdens over clinicians, researchers, and sponsors. Thus scientific strategies should be utilized to incorporate pharmacoeconomics study for proposed clinical trials.⁵

The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Randomized Clinical Trials Cost-Effectiveness Analysis Task Force has commenced the challenging duty of preparing and issuing a good research practice guidance document relevant to cost-effectiveness analysis along with clinical trials.⁴⁹ Optimistically, guidelines will be provided for the implementation of economic evaluations “based on” clinical trials, where the regulatory and reimbursement needs to be fully merged.⁵⁰

Table 3: Evidence of incorporating pharmacoeconomics into the clinical trial

S. No.	Pharmacoeconomics study	Trial design	Evidence
1	Cost-Effectiveness, Cost-Utility, Cost-Minimization, and Cost-Benefit Analysis	RCTs	Spinal Disorder ³¹
2	Effectiveness study	Pragmatic cluster RCTs	Web-based pharmaceutical treatment reduces inappropriate prescribing in older patients ³²
2	Cost-Effectiveness Analysis	RCTs	Fetal fibronectin screening ³³
3	Cost-Effectiveness Analysis and Cost-Utility Analysis	RCTs	sHCR compared to CABG in coronary arteries disease ³⁴
4	Cost-effectiveness and Budgetary Consequence Analysis	RCTs	Durvalumab Consolidation therapy in Stage III Non–Small Cell Lung Cancer after chemoradiotherapy ³⁵
5	Health Related-Quality of life	Meta-Analysis	HAART, HIV Infected Patients ³⁶
6	Cost-Effectiveness Analysis, Cost-utility Ratio	RCTs	Cardiovascular Medicine for a surgical and medical purpose ³⁷
7	Cost of Medical Care	RCTs	Cancer Patients(BMT and Breast cancer) ³⁸
8	Cost-Effectiveness Analysis, Cost of Medical Care	RCTs	CABG and PTCA ³⁹
9	Cost per cure for patients	Randomized, multinational, open-label, clinical trial	Linezolid versus Vancomycin in Complicated Skin and Soft-Tissue Infections ⁴⁰
10	Productivity Loss	Randomized, Double-Blind, Placebo-Controlled Clinical Trial	Effectiveness of Sumatriptan on Migraine ⁴¹
11	Cost-Effectiveness Analysis	RCTs	tyrosine kinase inhibitors erlotinib or afatinib for non-small cell lung cancer ⁴²
12	Cost-Effectiveness Analysis	RCTs	sunitinib as first-line therapy in metastatic renal carcinoma ⁴³
13	incremental cost per quality-adjusted life-year	RCTs	pazopanib versus sunitinib for metastatic renal cell carcinoma ⁴⁴
14	Cost-Minimization Analysis	RCTs	Oxaliplatin and oral capecitabine for metastatic colorectal cancer ⁴⁵

BMT- Bone Marrow Transplant, C/E Ratio-Cost-Effectiveness Ratio, CABG-Coronary Artery Bypass Surgery, HAART- Highly Active Antiretroviral Therapy, HIV-Human Immune Virus, PTCA- Percutaneous Transluminal Coronary Angioplasty, RCTs- Randomized controlled trial, sHCR- Simultaneous hybrid coronary revascularization.

7. Conclusion

Mostly, randomized clinical trials had been assessed for economic evaluation. Implementing pharmacoeconomics evaluation in trials result a ‘Value-Based Drug’ in terms of safety, effectiveness, and cost. The researchers need to develop, design, and conduct an economic assessment of the initial phase of clinical trials which provide the basis to conduct an economic evaluation for further trial development phases.

8. Source of Funding

None.

9. Conflict of Interest

None.

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