PHARMACOECONOMICS

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Summary

Economic evaluation of pharmaceutical products, or Pharmacoeconomics, is a rapidly growing area of research. Pharmacoeconomic evaluation is important in helping clinicians and managers make choices about new pharmaceutical products and in helping patients obtain access to new medications. Pharmacoeconomics is a subset of health care economics that compares costs and outcomes involving pharmaceutical products and services. Pharmacoeconomics focuses on the costs and benefits of drug therapy and Pharmacoeconomic evaluations provide a basis for resource allocation and utilization. The objective of Pharmacoeconomic studies is to examine the clinical and patient outcomes and cost-effectiveness of new medications relative to existing medication therapies. This review summarizes the methods, Analysis, Guidelines of Pharmacooeconomics.

Key words: Pharmacoeconomics, cost effective analysis, cost benefit analysis, cost minimization analysis, cost utility analysis.

Introduction

Pharmacoeconomics:

The emerging discipline of Pharmacoeconomics has become a health science discipline by the pharmaceutical industry, academic pharmaceutical scientists, and pharmacy practitioners worldwide. It is generally defined as the description and analysis of the costs and consequences of pharmaceuticals and pharmaceutical services and their impact on individuals, healthcare systems, and society. The research methods used by scientists in this discipline are drawn from many areas: economics, epidemiology, medicine, pharmacy, and social sciences. It is believed that Pharmacoeconomics analysis will have a significant impact on the delivery and financing of healthcare throughout the world. Furthermore, Pharmacoeconomics may influence healthcare and the practice of pharmacy at a magnitude equivalent to the impact of clinical pharmacy and pharmacokinetics. [1]

Pharmacoeconomics focuses on the costs and benefits of drug therapy and Pharmacoeconomic evaluations provide a basis for resource allocation and utilization. It is increasingly becoming important for health policy decision-making. A Pharmacoeconomic evaluation may be conducted as an economic assessment incorporated into clinical trials. Such trials should compare the new drug/procedure with an older drug or existing intervention. Four techniques are used for economic evaluation, namely, cost-minimization analysis, cost-effectiveness analysis, cost-utility analysis and cost-benefit analysis. The choice of the evaluation method depends on the nature of outcomes and the context in which the choices need to be made. Pharmacoeconomics is a young science that will improve with application. Its need is undeniable, especially in developing countries. [2]

The role of Pharmacoeconomics does not remain the same during the different phases of drug development. For example, during the early phases it helps to identify commercially viable options and find the market niche which could be commercially exploited, while at the later stages it performs the function of informing decision making with regards to appropriate use of the drugs which have been developed. [3]

History:

During the early 1960s, pharmacy began evolving as a clinical discipline within the healthcare system. It was during this time that the pharmaceutical science discipline such as pharmaceutics, clinical pharmacy, drug information and pharmacokinetics became a critical and integral part of pharmacy education and science. In the 1970s, Pharmacoeconomics developed its roots. In 1978, McGhan, Rowland and Bootman , from the University of Minnesota , introduced the concepts of cost- benefit and cost-effectiveness analysis. Bootman et al also published an early pharmacy research article in 1979 in which cost –benefit analysis was used to evaluate the outcomes of individualizing amino glycoside dosage in severely burned patients with gram-negative septicemia using sophisticated pharmacokinetic protocols. The actual term Pharmacoeconomics did not appear in the literature until 1986 when the first of a two- part presentation by Town send was published describing the need to develop research activities in this evolving discipline. To date, many of the efforts in this discipline have been directed toward the refinement of the research methods and their application to evaluating pharmaceutical services and specific drug therapies.[1]

Need and rational

- Pharmacoeconomics could be used as for selecting cheapest available formulation of particular drug**.**
- Enormous difference in the cost of newer agent compared to the older drug is realized**.**

- Facts such as long acting newly introduced drug is useful than shorter acting older counterpart are realized.
- Students are directly to the exposed to the cost effectiveness of the treatment and the economic reality of the prescription and drug therapies.
- Pharmacoeconomics (PE) plays vital role in the treatment of diseases, as it deals with both cost and consequences of therapeutic decision making.
- Prescribing medicine according to the principle of Pharmacoeconomics and ESPS data (Efficacy, Suitability, Price and Safety).
- The knowledge of cost consideration of therapy and will develop good prescription habits in their Carrer[3,4,5,6].

Purpose of Pharmacoeconomics

The purpose of Pharmacoeconomics (PECON) is to describe and analyze the costs and consequences of pharmaceutical products and services and the impact of pharmaceutical products and services on individuals, healthcare systems and society [4]. PECON is a very focused area of outcomes research that uses research methods and analytical tools from multiple disciplines, such as economics, epidemiology, medicine, pharmacy and the social sciences, most of the theoretical models upon which PECON studies are based come from economics and the social sciences. Since PECON is an evolving field, however, there is a constant and dynamic dialogue on PECON methods and applications. Thus, it must be borne in mind that currently, none of the techniques used in PECON evaluations are flawless and there is ongoing debate about the techniques. Nevertheless, it is agreed that the theories, methods and analyses used by PECON must be held to the same rigorous scientific standards as the disciplines from which they are derived. [5]

Pharmacoeconomic methods

The major analytical tools used in PECON research are costeffectiveness analysis, cost-utility analysis, cost-benefit analysis and cost-minimization analysis. PECON research must compare the efficacy of alternative interventions (i.e., drugs and services) with a value assigned to both costs (e.g., resources used) and outcomes (e.g., survival). [5]

Pharmacoeconomic Analysis:-

Pharmacoeconomics may be defined as balancing the cost with the consequences (outcomes) of pharmaceutical therapies and services. As a type of outcomes evaluation, Pharmacoeconomics looks beyond just the direct or acquisition cost of a pharmaceutical by including its impact on total health resource utilization and costs. [7] Economic analyses have become increasingly important in healthcare in general and with respect to pharmaceuticals in particular. If economic analyses are to play an important and useful role in the allocation of scarce healthcare resources, then such analyses must be performed properly and with care. Every analysis should have an explicitly stated perspective, which, unless otherwise justified, should be a societal perspective. Cost minimisation, cost-effectiveness, cost-utility and cost-benefit analyses are a family of techniques used in economic analyses. Cost minimisation analysis is appropriate when alternative therapies have identical outcomes, but differ in costs. Cost-effectiveness analysis is appropriate when alternative therapies differ in clinical effectiveness but can be examined from the same dimension of health outcome. Cost-utility analysis can be used when alternative therapies may be examined using multiple dimensions of health outcome, such as morbidity and mortality. Cost-benefit analysis requires the benefits of therapy to be described in monetary units and is not usually the technique of choice.

The technique used in an analysis should be described and explicitly defended according to the problem being examined. For each technique, the method of determining costs is the same; direct, indirect, and intangible costs can be considered. The specific costs to be used depend on the analytical perspective; a societal perspective implies the use of both direct and indirect economic costs. A modelling framework such as a decision tree, influence diagram, Markov chain, or network simulation must be used to structure the analysis explicitly. Regardless of the choice of framework, all modelling assumptions should be described. The mechanism of data collection for model inputs must be detailed and defended. Models must undergo careful verification and validation procedures. Following baseline analysis of the model, further analyses should examine the role of uncertainty in model assumptions and data. [8]

Cost-minimization analysis

When two interventions are believed to yield equivalent outcomes, they may be analyzed on the basis of cost alone; this is a cost-minimization analysis. This study was designed as a cost-benefit analysis, but after the agents proved to be equally effective, they were evaluated on the basis of direct cost alone. Cost-minimization analysis is the simplest of the four types of Pharmacoeconomics analysis because the focus is on measuring costs and the outcomes is assumed to be the same (or is found to be the same). But this method has limited use because it can only compare alternatives with the same outcomes. [9,10]

Cost-benefit analysis

Cost-benefit analysis is the description and analysis of costs and outcomes when all relevant outcomes are reported as a monetary value. Using this tool, competing interventions are analyzed on the basis of their relative cost-to-benefit or benefit- to-cost ratio. The assumptions of this and indeed all of the PECON techniques (except cost-minimization analysis) are that the value of the competing interventions is different. For some time, cost-benefit analysis in healthcare has been looked down upon because it assigns a monetary value to outcomes. The techniques used in PECON originated from economic theory, which makes use of the principles of optimization. This means that, the ultimate object of the analysis is to provide services by optimizing the resources available because "according to economic theory, the consequences of a program should be measured as the willingness to pay of the individuals who bear the consequences." The Principles of social choice theory implies that "the value of health improvements should be based on individuals own willingness to pay for those improvements." The willingness-to-pay method is a way to value health outcomes in monetary terms for cost-benefit analysis. The method quantifies or values individual (or societal) preferences for optimizing resources. It attempts to measure what people are willing to give up to get something needed, wanted, or desired. The primary methods used to assign a monetary value are the human capital method, the revealed preference method and the direct elicitation method (i.e., contingent valuation). In the revealed preference method, references are measured indirectly using multiple sources of economic productivity. The magnitude of the willingness-to-pay for a particular outcome in one market is extrapolated to a resource of comparable magnitude in the healthcare market and the magnitudes of the two choices are compared. A revealed preference method that has gained attention recently is the method of contingent valuation. This method uses survey research to elicit preferences regarding the use of resources or individual willingness to pay. [10]

Cost-effectiveness analysis

Cost-effectiveness analysis is the description and analysis of costs and of relevant outcomes that are expressed in natural units (e.g., life-years gained). Competing interventions are compared on the basis of their relative cost-to-effectiveness ratios. As an example of this approach, a cost-effectiveness analysis was used to evaluate taxane treatment in patients with advanced breast or

ovarian cancer. The conclusions drawn from this cost-effectiveness analysis by the National Health Service Research and Development Health Technology Assessment Programmes were then used to guide national priorities for health technology. [10] Cost-effectiveness analysis (CEA), part of the discipline of health economics, plays a crucial role in helping decision-makers allocate scarce funds efficiently, i.e., to health interventions that yield the most improvement in outcome for the least amount of expenditure. The volume of cost-effectiveness studies has increased dramatically in the past 10 years [11, 12, 13]

Cost-utility analysis

Cost-utility analysis is the description and analysis of costs and of relevant outcomes that are measured in terms of quantity and quality of life. Competing interventions are compared on the basis of their relative cost-to-utility ratios (e.g., cost per quality adjusted by life-years gained). Many consider cost-utility analysis to be an extension of cost-effectiveness analysis because the utility aspect should be gauged on the basis of the final outcomes (i.e., survival) rather than intermediate outcomes (i.e., blood pressure decrease).[9,10] Cost–utility analysis, allows the comparison of different health outcomes (such as prolongation of life, prevention of blindness or relief of suffering) by measuring them all in terms of a single unit — the quality-adjusted life-year (QALY). To do this, any state of health or disability is assigned a utility on a scale ranging from 0 (immediate death) to 1 (a state of perfect health). The outcome of any health intervention can then be calculated as the product of the increase in utility that it may cause and the time in years over which it may be enjoyed [14, 15, 16]

Pharmacoeconomics evaluation:

Economic evaluation of pharmaceutical products, or Pharmacoeconomics, is a rapidly growing area of research. Pharmacoeconomic evaluation is important in helping clinicians and managers make choices about new pharmaceutical products and in helping patients obtain access to new medications.[17]To date, decision trees and Markov models have been the most common methods used in Pharmacoeconomic evaluations. Both of these techniques lack the flexibility required to appropriately represent clinical reality. However one more alternative which is natural way to model clinical reality is discrete event simulation. A discrete event simulation represents the course of disease very naturally, with few restrictions. Neither mutually exclusive branches nor states are required, nor is a fixed cycle. All relevant aspects can be incorporated explicitly and efficiently. Flexibility in handling perspectives and carrying out sensitivity analyses, including structural variations, is incorporated and the entire model can be presented very transparently. The main limitations are imposed by lack of data to fit realistic models. Discrete event simulation, though rarely employed in Pharmacoeconomics today, should be strongly considered when carrying out economic evaluations, particularly those aimed at informing policy makers and at estimating the budget impact of a pharmaceutical intervention. [18]

The objective of Pharmacoeconomic studies is to examine the clinical and patient outcomes and cost-effectiveness of new medications relative to existing medication therapies. Pharmacoeconomic evaluations examine the impact of different pharmacologic interventions on patient psychopathology, functioning, and well-being and on medical costs. [19]

Guidelines for Pharmacoeconomic analysis:

Pharmacoeconomic research is used to identify, measure, and compare the costs, risks, and benefits of programs, services, or therapies and determine which alternative produces the best health outcome for the resources invested. Each Pharmacoeconomic method measures costs in monetary terms; the differences lie in the valuation of outcomes. In cost-minimization analysis, the outcomes are considered to be equal and therefore are not measured. Cost-benefit analysis measures outcomes

in dollars, whereas cost-effectiveness analysis measures outcomes in nonmonetary units. In cost-utility analysis, outcomes expressed in nonmonetary units are adjusted for health-related quality of life. A well-designed Pharmacoeconomic analysis involves 10 steps: (1) defining the problem, (2) determining the study's perspective, (3) determining the alternatives and outcomes, (4) selecting the appropriate Pharmacoeconomic method, (5) placing monetary values on the outcomes, (6) identifying study resources, (7) establishing the probabilities of the outcomes, (8) applying decision analysis, (9) discounting costs or performing a sensitivity or incremental cost analysis, and (10) presenting the results, along with any limitations of the study. By adhering to the analytic steps described, the pharmacist undertaking a Pharmacoeconomic evaluation has the greatest likelihood of obtaining valid and useful results [20]. Researchers in countries around the world are now conducting PECON analyses and as a result, many countries and professional organizations have developed guidelines for conducting these analyses. Some countries have mandated guidelines for the health economic evaluation of pharmaceutical products and require an evaluation prior to reimbursement. According to Hjelmgren a comparative summary of current PECON guidelines from North America, Europe and Australia have been classified into three groups:

• Formalized or mandatory guidelines (a requirement prior to reimbursement)

• Informal or voluntary guidelines (a recommendation prior to reimbursement)

• Guidelines for health economic methods designed to improve methodology in health outcome evaluations

There are 25 guidelines according to their methodological aspects (perspective, resource use/costs, outcome measurement, type of analysis, incremental or average cost-effectiveness, treatment comparator, methods of data capture, modeling, time horizon, discounting, sensitivity analysis, reporting of results and financial implication for society). The three groups of guidelines were found to be in agreement in terms of 75% of the methodological aspects. However, the formal guidelines were more homogeneous than the informal guidelines or guidelines for health economic methods. Disagreement was found in the resources and costs to be included in the analysis, the choice of perspective and the methods of evaluating the resources used. Since PECON is a relatively new and developing discipline, the guidelines should eventually merge and a consensus should be reached. [21, 22, 23, 24, 25]

Conclusion

Pharmacoeconomics may be defined as balancing the cost with the consequences (outcomes) of pharmaceutical therapies and services. Pharmacoeconomics is a tool of management which should be applied to strategic and operational decisions about pharmaceutical development, production or consumption. The focus of emphasis in the earliest phase is on informing decisions about product development whilst the emphasis at the later stage shifts to rational prescribing and utilisation. The choice of the evaluation method [cost-minimization analysis, cost-effectiveness analysis, cost-utility analysis and cost-benefit analysis] depends on the nature of outcomes and the context in which the choices need to be made. The aim throughout is to ensure the most efficient use of limited resources. On the whole Pharmacoeconomics should be thought of as an ongoing process which not only bridges the existing gap between the R&D and marketing departments of the pharmaceutical companies, but perhaps more importantly, is likely to change the structure of the industry from within.

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