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Review

Pharmacoeconomics: An emerging branch in health sciences for decision making

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Increasing health care cost is a major concern in the developing world and has increased the individual economical burden for a common man. Patients are affected by the high pricing of drugs and though the symptoms improve, the poor patient's compliance sets in if the regimen is heavy on his/her pocket. Therefore, the concepts of pharmacoeconomics are essential for physicians to prescribe individualized drug therapy based on essential drug concept, STEP and R.U.D. criteria, with minimal costs to improve the cost-effectiveness of the drug therapy. Medical education is not purely technical in knowing about diseases and their treatment but also involves understanding socio-economic issues. Consumption decisions in health care are taken by the provider that is, the physician and not by the consumer – patient and these are driven by many factors including pharmaceuticals. Hence apart from professional, moral and ethical obligations as care providers, it is imperative to deliver quality care cost effectively. Pharmacoeconomics, a branch of health care economics offers important guidance for the management of limited health care resources and medical practice. The purpose of this article is to provide an introduction of pharmacoeconomics, its various methods of evaluations such as cost minimization analysis (CMA), cost benefit analysis (CBA), cost utility analysis (CUA), cost effectiveness analysis (CEA) and guidelines to delivering quality care cost effectively and also throw light on the limitations of pharmacoeconomics.

Key words: Pharmacoeconomics, cost minimization analysis (CMA), cost benefit analysis (CBA), cost utility analysis (CUA), cost effectiveness analysis (CEA).

INTRODUCTION

The demand for and the cost of health care are increasing in all countries as the improvement in and sophistication of health technologies. The increase in health care spending is mainly because of increased life expectance, increased technology, increased standard of living and increased demand in health care quality and services.(Thwaits et al., 1998). The escalation in health care spending is due to increased life expectance, increased technology, increased standard of living and increased demand in health care quality and services (Thwaits et al., 1998). Medicines form a small but significant proportion of total health care cost. The writing of a prescription is the most common therapeutic intervention in medicine. Cost of medicines are growing constantly as new medicines are marketed and are under patent law, preference of drug therapy over invasive therapy, discovering various off label uses of existing drugs (Cooke, 2003) and the irrational drug prescription. Pharmaceutical companies have to spend a lot of money and time to market any new chemical entity as a drug to fulfill various research requirements. Since 1961, pharmaceuticals are fallen under price regulation in India. A total of 343 drugs accounting for 85% of the drug market were under price control in 1979 (Godwin et al., 2007).

With successive polices, the number diminished and now a mere 15 - 20% of the drug market is under price control (Editorial: Essential Drug Monitor, 2003) Therefore drug prices are quickly spinning out of reach of the common man. All over the world patients are affected by high price of medicines. In a developing country like India 85% of total health expenditure is financed by house-hold out-of–pocket expenditure (Godwin et al., 2007). A major portion of the private health care spending goes to drugs and per capita private drug spending in India is estimated

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as US $16 (Able-Smith, 1994). Thus expenditure on drugs imposes a major financial burden on households, especially when it is met from the out-of-pocket expenditure due to total lack of health insurance and risk protection (Godwin et al., 2007).

Hence many poor people frequently face a choice between buying medicines or buying food or other necessities due to limited resources and high pricing of drug. So medicine prices do matter (Jana and Mandal, 2005).

FACTORS AFFECTING PRICES OF MEDICINE / DRUGS

Enumerable factors affect the prices of medicine; some of them are as follows:

1.) The sector in which medicines are purchased: The price is often higher in the private sector due to distilentor's costs and profiteering.
2.) The types of procurement agent: e.g. different prices may be paid for the same product by a public sector purchaser, such as Ministry of Health.
3.) The distribution route: A patient who purchases a medicine at a hospital pharmacy may have to pay more if the hospital pharmacy purchased the product from a local wholesaler than if it has been purchased by tender and supplied through public health sector distribution system. Many times hospital pharmacy may have limited stock of the generic drugs which one is cheaper than the branded drugs prescribed to the patient on routine basis and patient has to purchase the branded drugs in the emergency condition.
4.) The patient status: The price of patented medicine is often higher than that of their generic equivalent at least while the patient is in force (Myhr, 2003).

Under such background, pharmacoeconomics plays vital role in the treatment of diseases, as it deals with both cost and consequences of therapeutic decision making (Gautam, 2005).

AIMS AND OBJECTIVES OF PHARMACOECONOMIC (PE) EVALUATION

1) The aim of this article is to provide an overview of the issues and theory which lie at the heart of pharmacoeconomics.
2) To show how it can be applied in practice to decisions about drug therapy.
3) In future, how implementation of PE helps to reduce monetary burden on the consumers (by insuring global pricing strategy) for the effective management of health care system as the principle of PE is to make more efficient use of limited resources for maximization of health care benefit at loser cost.

TERMINOLOGIES RELATED WITH PHARMACOECONOMICS

1.) Pharmacoeconomics; This can be defined as a branch of health economics which deals with the measurement of both the costs and consequences of therapeutic decision making (Cooke, 2003). Thus it:

a) defines; measures and compares the cost and conesquences of pharmaceutical products as well as services.
b) describes economic relationship involving drug research, drug production, distribution, storage pricing and use of medicine by the people (Cooke, 2003).

Pharmacoeconomics runs through the thread of our socio-economic system thus it provides a guide for decisions makers on resource allocation.

2.) Cost of drug: This is the total resources consumed in producing the drug or drug formulation. It is the amount paid to the suppliers.

To evaluate the economics of drug therapy, cost is categorized into:

i. Direct cost.
ii. Indirect cost.
iii. Intangible cost.

Direct cost

i.) Direct medical cost
ii.) Direct non medical cost.

Direct medical cost: This is what is paid for specialized health resources and services. It includes the physician's salaries; the acquisition cost of medicine; consumables associated with drug administration; staff time in preparation and administration of medicines; laboratory costs of monitoring for effectiveness and adverse drug reactions.

Direct non medical cost: This includes cost necessary to enable an individual receive medical care such as lodging, special diet and transportation; lost work time (important to employers) such as acute *Otitis media* in pediatric patients with professional parents who lost work time during the treatment of their kid.

Indirect cost

This is the cost incurred by the patient, family, friends or society. Many of these are difficult to measure, but should be of concern to society as a whole (Wally and Haycox, 1997). This includes productivity loss in the society; unpaid care givers; lost wages; expenses of illness borne by patients, relatives, friends, employers and the government and; loss of leisure time.

Intangible costs

These are costs related with the patient's pain and suffering; worry and other distress of the family members of a patient; effect on quality of life and health perceptions. For example patients of rheumatoid arthritis, cancer or having terminal illnesses in which quality of life is suffered due to adverse reactions of the drug treatment. These are difficult to measure in monetary terms but represent a considerable concern for both doctors and patients.

Quality adjusted life year (QALY) is one method by which intangible costs can be effectively integrated in PE analysis (Wally et al., 1997).

3.) Quality adjusted life years (QALY): This is a summary of quality and quantity of life. It is measured on a scale of 0 - 1 like a visual analog scale, from poor to excellent health.

For example, a patient with a rare cancer will live for only 2 years without treatment. A new treatment increases life expectancy by 2 years however; it is associated with adverse effects which decrease the quality of life by 25%. The QALYs is calculated thus;

Life expectancy = 2 (survival without treatment) + 2 (gain in life years due to treatment) = 4 years.
Adverse drug reactions due to treatment = 0.25%
Hence decrease in quality of life = 2 x 0.25 = 0.5 years.
Thus net gain is 2 - 0.5 = 1.5 or 1.5 QALYS.

Thus the net gain with the new treatment is 1.5 QALYs rather than 2 years.

4.) Utility units: It measures changes in a patient's satisfaction, or sense of well being in an attempt to evaluate the satisfaction derived from moving from one state of health to another as consequences of the application of drug therapy. It is based upon some measurement of quality of life.

5.) Quality of Life: It includes physical as well as psycho-social dimension of the life. Physical dimension includes presence or absence of pain, immobility while psychosocial includes level of anxiety, depression experienced and hence the reduced ability of the patient to cope with problems (Wally and Haycox, 1997).

METHODS / TYPES OF PHARMACOECONOMICS EVALUATION

Health care economic evaluation offer important guidance to the management of limited health care resources and medical practice (Detsky, 1990). Health care economics is intended to help decision makers make choices which are compared with respect to expected consequences resulting from the adoption of one strategy over another (Tan et al., 2006).

Health outcomes are consequences that affect the well being or quality of life (Tan et al., 2006). There are four types of health care evaluation, all of which can be applied to pharmaceutical products. The ultimate objective of all four methods is to compare the cost and out come of alternative regimens. The nature of outcome measurement is the important factor determining the level of complexity and sophistication as well as the reliability and validity of a comparison of alternative regimens.

The methods/types of pharmacoeconomics evaluation are: cost minimization analysis (CMA); cost benefit analysis (CBA); cost utility analysis (CUA) and; cost effectiveness analysis (CEA).

Cost minimization analysis (CMA)

It evaluates cost and ignores outcome. Such analysis should only be used where health benefits obtained from two alternative therapies are identical and therefore need not be considered separately. The objective of this method is to select the least costly among multiple equivalent interventions. One of the examples is to introduce generic prescribing rather than by brand name which would achieve the same level of benefit at reduced cost. It cannot be used to evaluate programmes or therapies that lead to different outcomes (Wally and Haycox, 1997).

Cost benefits analysis (CBA)

In this cost of therapy and consequences, both are measured in monetary terms and this will involve evaluating intangible cost in monetary value attached to different state of health e.g. physical, emotional and psychological distresses associated with being ill versus being healthy. Determining the economic value of saving a life is especially problematic, which is the chief reason that cost benefit analysis is used more commonly in a setting where determining the monetary value of a human life is not required (Tan et al., 2006). It allows comparisons to be made between cost and benefits arising in very different areas. It can be useful in making strategic decisions on health care programme. For example nationwide immunization programmes can be fully costed in terms of resource utilization consumed in running the programme. This can be valued against reduced mortality and morbidity that occurred as a result of the programme (Cooke, 2003).

Cost utility analysis (CUA)

The outcome of the study and cost to reach that outcome

is measured in monetary terms. The outcome is measured in terms of changes in the patient's well being. Analysis of QALY as a health outcome measured along with the inclusion of intangible cost has also stirred debate (Maetzel, 2005).

Cost effective analysis (CEA)

This is the most common type of analysis. The choice of a health outcome measure depends on the disease context. Such analysis compares the unit of effectiveness that is, number of years of life saved, number of lives saved, and percentage lowering of glucose level amongst others with the cost of treatment (Wertheimer, 2003). The results are then plotted and those treatments along the effectiveness frontier which have the lowest cost and highest effectiveness will be given preference. The treatment can be referred to being cost effective if it has an outcome that is worth its corresponding cost in relation to alternative therapies. For example the diuretic hydrochlorothiazide may be the most inexpensive treatment for hypertension, but it often requires a potassium supplement. The additional cost involved in the therapy means this drug is not always the most cost effective therapy (Wertheimer, 2003). This method of cost outcome analysis is the most frequently utilized method. Health outcome is measured in terms of QALY. A key advantage of using QALY as a health outcome measure is that it enables the comparison of cost effective estimates from different disease setting.

RESULT

The steps in calculating cost analysis are as follows:

a) Define the objective: Which drug is the preferred alternative for treating particular disease?
b) List the drugs\ methods available to achieve the objective.
c) Identify and measure the cost of each option: e.g. acquisition cost, pharmacy cost, nursing cost, laboratory services among others.

GUIDELINES FOR PHARMACOECONOMICS EVALUATIONS

Currently, the accepted guidelines for the practice of economic evaluation of drug treatments are:

1. The perspective of the study should ideally be applicable to the society.
2. Demographic characteristics of the target population should be identified.
3. Conceptual and practical reasons for choosing the comparator should be set out and justified.
4. Treatment paths of the options being compared should be identified and fully described.
5. The study should use recognized techniques of analysis and should be justified.
6. Clinical outcome measures should be identified.
7. All relevant costs should be identified, collected and reported.
8. Discounting should be undertaken considering the time lapse.
9. Sensitivity of analysis should be conducted and reported.
10. Comparisons with results from other studies are handled with care (Ramesh, 2006).

DISCUSSION

The task of translating health care economic comparison research to the practice of clinical medicine is challenging for many reasons and is itself, an area of continuing discussion and debate (Maetzel, 2005).

First, for clinicians who regard that demanding the best possible care for every patient whatever the cost is their professional responsibility, there is the reluctance to allow monetary considerations to enter into the management of the patient's care at all (Detsky, 1990). A counter argument to this position, however, is that physicians' decisions have consequences for the use of limited resources affecting other patients suffering from common diseases subsidized from the drug quota in public sector hospitals. Hence, the role of economic evaluation in clinical medicine may be justified on the grounds that medical decisions on health care professionals have opportunity costs that fall upon all patients as a whole (Tan et al., 2006). Opportunity cost is a term from economics meaning the value of the best available alternative to a given decision (Varian, 1992).

A second issue is resistance to the increasing relative prominence of evidence based medicine "the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patient" (Sackett et al., 1996) compared with the more traditional practice of medicine grounded in a physician-patient relationship and the seasoned judgment and expertise of medical practitioners earned through experience in clinical settings.

A common concern is that the study populations in published studies of evidence-based medicine in controlled trials do-not resemble the typical individual patient who is under a physician's care (Charlton, 1997). Another concern is that evidence-based medicine encroaches upon a physician's autonomy and patient's choice (Sleigh, 1997). The same issues are relevant to all health care economic evaluations because these evaluations belongs to the body of current best evidence on which evidence-based medicine is founded (Tan et al., 2006).

LIMITING FACTORS FOR PHARMACOECONOMIC EVALUATION

a) Choice of the drugs is given according to the marketed pressure. Pharmacists give drugs as per their will (alternative drugs for prescribed medicine).
b) Drugs are prescribed under promotional pressurizing activities of marketing executives of pharmaceutical firms. Incentives and gifts offered by these firms to doctors have a major impact on prescribing brands.
c) For chronic diseases, bio-availability consideration can have an upper- hand over pharmacoeconomics.

To overcome these limitations, the following steps should be taken:

1) State associations should buy medicines directly from the firm/industry and sell to retailers who are associated members. These drugs would cost 30 - 40% lesser than current prices.
2) Retailers should lower their profit margins. There are three layers between drug makers and purchasers; super stockiest, authorized stockiest and semi-wholesalers. Dealing directly with the drug firm and availability of drugs through affiliated drug retailers would lower prices by 10 - 12%.
3) Hospitals can buy expensive drugs for cancer and HIV directly from drug firms and sell through their pharmacies. To purchase the drug, select the firm having good marketing practices (GMP) and invite technical bids from them. Avoid the firm selling drugs with very low prices as this does not mean cost -effective drugs.
4) Sensitization of students of health sciences on pharmacoeconomics during their formative years is needed as they are future prescribers. The revised undergraduate medical curriculum stresses on the importance of the essential drug concept and to prescribe a drug tailored to individual needs based on safety, tolerability/suitability, efficacy and price (STEP). The students should be sensitized during their under graduate course to consider the cost of the medicine they would be prescribing (Jana, 2005).
5) Creating awareness of concepts and principles of pharmacoeconomics in existing physicians should also be done. Whether this carries implications for day-to day clinical decision making directly or through clinical practice guidelines formulated by a panel of experts, requires for clinician to understand various methods of evaluations and also to develop skills to interpret and critique results.

Conclusion

Medical education is not purely technical in knowing about diseases and their treatments but it also involves understanding socio-economic issues (Supe, 2004). Consumption decisions in health care are taken by providers that is, the physician and not by the consumer –patient and these are driven by many factors including pharmaceuticals. In a country like India with scarce resources, the responsibility of the physician is much more. Pharmacoeconomics, a branch of health care economics offers important guidance to managing limited health care resources and medical practices for decision makers in health sciences.

The purpose of this article is to provide an introduction of pharmacoeconomics its various methods of evaluations and guideline so that:

1) Clinicians will investigate the relationship between cost and health consequences of medical decisions so that if implemented, would be helpful towards prescribing a rational drug therapy.
2) Medical students (future prescribers), would appreciate the cost effectiveness of drug therapies they would be prescribing in future which ultimately reduces the economic burden on the patient.
3) Pharmacist, the bridge between patients and doctors, will dispense as well as help in purchasing drugs for hospital pharmacies. This would help in reducing the monetary burden on institutions.

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