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A Review of Pharmacoeconomics and a Discussion on Branded, Branded Generics and Generics

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Abstract

Pharmacoeconomics is the emerging course which benefits Indian economy in many ways and also helps in minimizing other cost burden on the common people and make them affordable to the medicines which have equivalent therapeutic effectiveness. It can be calculated by four economic evaluation methods that are cost benefit, cost effective, cost utility and cost minimization analysis. There are many conflicts about branded and generics but in India there are other classes of drugs which are branded generics. Branded are the ones which are manufactured and marketed by innovator companies whereas generics are the ones which are sold under the name of therapeutic molecule but the other type of drugs which are branded generics are the ones which are marketed under some name or using the trade mark rather than the molecule name but after the expiry of the patent.

Introduction

Pharmacoeconomics is an emerging subject which deals with the costs of health care system and its outcomes. It has many different types to evaluations which are done to reduce the cost burden although providing best treatment outcomes to the patient. It has two types of evaluations but the most commonly used is economic evaluation which has four different methods as discussed below. This system is practiced in many developed countries and it provides treatment to a patient based on his/her economic status. This must be practiced and the methods are to be implemented in India for better patient treatment outcomes by improving medication adherence as many people belong to middle class who cannot afford the essential medicines.

Methodology

Definitions

Drug: According to Indian pharmacopoeia drug includes all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals including preparations applied on human body for the purpose of repelling insects like mosquitoes [1].

Such substance intended to affect the structure or any function of the human body or intended to be used for the destruction of venom or insects which causes disease in human beings or animals as may be specified from time to time by the central government by notification in the official gazette [1].

All substances intended for use as components as a drug including empty gelatin capsule [1].

Such devices intended for internal or external use in the diagnosis, treatment mitigation or prevention of disease and disorder in human beings or animals as may be specified from time to time by the central government by notification in the official gazette after consultation with the board [1].

There are different definitions in different countries to define brand drug and generic drug.

Branded drug

WHO defines branded drug as "Name given to a pharmaceutical product by the manufacturer. The use of this name is reserved exclusively to its owner as opposed to the generic name" [2].

In western countries branded is the one which is the innovator company [3].

In India there is no definition according to Indian Dug Regulations, but it means a drug product produced and marketed under a brand name. It does not correspond to the innovator drug of US.

According to Brazil a branded drug is categorized as a new medicine or originator medicine which is defined as "The product that is innovation and has patent protection". Brazil categorizes medicines into three types one as stated above i.e.

New medicine or originator medicines and the other two categories are similar production medicines and generic medicines [1].

Generic drug

Generic according to English dictionary is defined as a product not protected by trade mark, registration, non-proprietary or any product, as a food, drug or cosmetic that can be sold without a brand name. It pertains to the salt name or active ingredient of a drug delivery form [4].

Any drug manufactured should follow good manufacturing practice guidelines to market the product, it has to pass bioavailability and bioequivalent studies [4].

Innovator takes patent so that research and development needs in future can be taken care of and also for decent financial returns [4].

WHO defines a generic drug as a pharmaceutical product, usually intended to be interchangeable with an innovator product that is manufactured without a license from the innovator company and marketed after the expiry of the patent or other exclusive rights [4,5].

US FDA defines generic as a drug identical or bioequivalent to a brand name, drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use [6,7]. A generic drug is approved only after it has met rigorous standards established by the FDA with respect to identity, strength, quality, purity and potency. All generic manufacturing, packaging and testing process must qualify the standards of those of brand name drug. The manufacturer must prove the generic drug as bioequivalent to that of brand [3,6,7].

In Australia generics have different meanings like a product with INN or a product marketed under a different proprietary name [1].

In China generics are the drug which does not require clinical trials [1].

In Brazil as stated earlier a generic medicine is a medication like the innovator product after patent with same efficacy, safety and quality [1].

European Medical Agency defines generics as "A similar biological or biosimilar medicine is a biological medicine that is like another biological medicine that has already been authorized for us" [1,4].

In India there is no exact definition for generic drug, but it can mean as they defined under Section 3(b) of the Drug and Cosmetics Act, 1940. It means a drug product manufactured and sold in the market under its pharmacopoeial or chemical or generic name [1].

Branded generic

A generic product manufactured and sold under a brand name, these are generics for trade but branded for patients as they as sold at the price as that of branded [1].

In Brazil there a category of medicine named 'similar production' which is defined as a product manufactured after its expiry with brand name with similar composition as innovator but may vary in size, shape, colour etc. [1]. It is similar to branded generic in India.

According to US FDA, branded generic is an Indian criterion to distinguish generics from the generics of other companies. Thus, a generic drug marketed under a brand name is a branded generic [3].

International Non-proprietary Name (INN)

A common generic name selected by designated experts for the unambiguous identification of a new pharmaceutical substrate. These are used worldwide [2].

A comparative evaluation was done between generics and branded generics by a team of experts and they were found to be identical in terms of identification, uniformity of weight, assay, uniformity of contents and dissolution. Hence the common misconception that the substandard generics are of inferior quality can be misplaced [8].

After expiry of patency the cost of branded drug goes down by 30-40% initially lasting up to 90% finally due to competition [8]. Branded generics are ten times costlier to that of unbranded on an average. The term "Affordable Medicines for All" can be justified only when the misconception about the quality and efficacy of unbranded over branded generics are misplaced and when the prescriptions are written in generic names or the medicine and also quality assurance programmes have to be improved [8]. Medicines account for 90% of health care, which is spent by poor people. Excessive costs can lead to decreased access to healthcare [9,10]. In India costs of medicines are highly variable and not affordable for the economically poor. Thus, modification is made to be done urgently in National Pharmaceutical Policy [10]. 60% of population that is approximately 499-649 million does not have access to essential medicines though India holds 13th rank in world production and produces 8% of medicines available globally [10].

Out of pocket expenditure is the main source of health funding in India were 60-90% spending of health care is on medicines. It is the poor patient who has to bear the medical and economic consequences of these formulations [10,11]. The reasons for the price variations are existence of pricing policy for medicines. Maximum allowable post manufacturing expense (MAPE) is permitted for medicines under price control are 100% and ceiling prices have been fixed for these [10]. Price differences between the highest and lowest selling prices and MRP was found to be 32.7%. Expenditure on health in rural area is 77% and in urban areas is 74%. Thus, there is a need for generic substitution [10].

Pharmacoeconomics

It has been defined as the description and analysis of the cost of drug therapy to health care system and society. It is the division of outcomes research that can be used to quantify the values of pharmaceutical care products and services [1,9,12].

Pharmaceutical care is defined as the responsible provision of drug therapy for the purpose of achieving definite outcomes [1].

Cost: It is defined as the values of the resources consumed by a program or a drug therapy of interest [1].

Consequence: It is defined as the effects, outputs or outcomes of the program or drug therapy of interest [1].

The differentiation between different Pharmacoeconomic evaluation methods is done by considering costs and consequences.

Perspectives to be included: Patient, Provider, Payer and Society. Thus, the result of Pharmacoeconomic evaluation depends on the perspective taken.

Patient: This is considered when assessing the impact of the drug therapy on quality of life or if a patient will pay out of pocket expenses for a healthcare service.

Provider: Hospitals, managed care organization, private practice physicians can be some examples of provider. This perspective includes direct costs such as drugs, hospitalization, laboratory tests, supplies and salaries of health care professionals which can be identified, measured and compared.

Payers: They include insurance companies, employers or the government. It includes charges for healthcare products and services allowed or reimbursed by the payers.

Society: They include patient morbidity and mortality and the overall cost of giving and receiving medical care.

Costs

Direct medical costs

These are the costs which are incurred for medical products and service used to prevent, detect and/or treat a disease.

E.g. Costs of drugs, medical supplies and equipment's, laboratory and diagnostic tests, hospitalization and physician visits.

It can be divided into two groups

- Fixed costs: these are overhead costs. E.g. Heat, rent, electricity.
- Variable costs: These change as functional volume. E.g. medications, fees for professional services and supplies.

Direct non-medical costs

These are the costs which are for non-medical services that are results of illness or disease but do not involve purchasing medical services.

E.g. Transportation charges, tips to emergency department, child or family care expenses, special diets and other out of pocket expenses.

Indirect non-medical cost

These are the costs of reduced productivity. These results from (E.g.: missing work) and mortality (E.g. years lost as a result of premature death)

Techniques used to estimate indirect non-medical costs

Human capital: It values morbidity and mortality losses based on individuals earning capacity using standard labor wage rates.

Willingness to pay methods

It values indirect and intangible aspects of a disease.

Intangible costs

These are those of other non-financial outcomes of disease and medical care.

E.g. pain, suffering, inconvenience and grief.

Opportunity costs

These are the economic benefits forgone when using one therapy instead of the next best alternative therapy.

Incremental costs

These are the additional costs that a service or treatment alternative imposes over another compared with the additional benefit or outcome it provides.

Categories of outcomes

There are 3 types of categories of outcomes [1].

- This category is on the basis of economic, clinical and humanistic outcomes. Economic outcomes include direct, indirect and intangible costs. Clinical outcomes include medical events that occur as a result of disease or treatment. Humanistic outcomes include consequences of disease or treatment on patient quality of life.
- This category has outcomes based on affects like positive and negative outcomes. Positive outcomes are the desired effects of drugs. Negative outcomes are undesired effects of drugs
- This category has outcomes like intermediate and final outcomes. Intermediate outcomes are the ones in which only the drug is seen rather than curing the disease.

Final outcomes are those where complete cure of the disease is seen.

Methods of pharmacoeconomics

There are two types of methods for the evaluation of Pharmacoeconomics [1].

- Economic evaluation
- Humanistic evaluation

Economic evaluation

It identifies, measures, value and compares the costs and consequences of alternative treatment.

Economic evaluation is of two types

Partic economic evaluation

It compares the costs of 2 or more alternatives without regard to outcome.

Full economic evaluation

It includes cost minimization, cost benefit, cost effectiveness, cost utility analysis [1,9,12].

Cost Minimization Analysis (CMA): It determines the least costly alternative when comparing two or more treatment alternatives, when two alternatives are assumed to be equal in safety and efficacy [1].

It is a financial strategy that aims to achieve the most cost-effective way of delivering goods and services to the required level of quality [13].

It can be done when outcomes of the procedures under consideration are the same [9].

CMA shows only a "cost savings" of one program or treatment over another. It is appropriate when comparing two or more therapeutically equivalent agents or alternate dosing of the same agent.

It can be applied to "me too" products and generic competition in the pharmaceutical market place. The costs should extend beyond a comparison of acquisition cost and include costs of drug preparation, administration and storage. Other costs can also be included such as costs of physician visits, number days hospitalized, the least expensive agent considering all these costs should be preferred.

Applications include comparisons of drugs within the same therapeutic class and the delivery of the same medication in different settings [12].

Cost Benefit Analysis (CBA): It is a method that allows for the identification, measure and comparison of the benefits and costs of a program or treatment alternative [1]. The benefits obtained are compared with that of costs and both costs and benefits are converted

to monetary values which finally give a benefit to cost ratio [1,9,12]. The alternative with greater B:C ratio is selected [1].

B:C ratio is >1 indicates benefits outweigh costs

=1 indicates benefits equal to cost

<1 indicates cost overweigh benefits

It can be employed only when both costs and benefits can be measured in monetary values. But it is difficult to conduct as everything cannot be converted to monetary values.

Cost Effective Analysis (CEA): Values and outcomes in non-monetary values are measured.

E.g.: lives saved, cases cured, life expectancy, drop in blood pressure.

It is of two types (I) ACER (II) ICER

ACER

ACER = Total healthcare costs ($) ÷ Clinical outcomes (not in $)

In which least cost or outcome gained is selected.

ICER

ICER = Cost(A) - Cost(B) ($) ÷ Effectiveness A(%) - Effectiveness B(%)

In which the additional cost and effectiveness gained when one treatment is compared with the best treatment alternative.

It is a method of cost optimization rather than cost reduction. It helps in determining which treatment alternatives represent the best health outcome per dollar spent.

Cost Utility Analysis (CUA): It is the method used for comparing treatment alternatives that integrates patient references and HRQOL. It can compare cost quality and the quality of patient years [1]. Cost in monetary units and outcomes in QALY gained results expressed in a ratio of C: U [1,9].

C: U ratio = Cost ÷ QALY gained

Lowest C: U ratio is selected. This method is used in comparing programs and treatment alternatives that are life extending with serious side effects.

Importance of Economic Evaluation

Measurements and comparisons of outputs and inputs, we have little criteria on which to base any judgment about the value of money and resource investment. The optimal use of technology would be achieved when the marginal cost is equal to marginal benefit. Economic evaluation is useful when it overcomes efficacy, effectiveness and availability problems.

Humanistic evaluation

It is based on patient quality of life [1].

E.g. Physical, emotional and social effects of patient which are achieved by questionnaires.

Applications of pharmacoeconomics

- Aid clinical and policy decision making
- Powerful tool to support various clinical decisions ranging from the level of patient to the level of entire health care system
- Formulary management based on costs and its outcomes
- Drug use policy and guidelines
- Disease management
- Resource allocation
- Future application is providing quality care with minimum resource

Discussion

In India there is no national health service hence payment for medical care is mainly from out of pocket spending for majority of population. As per a survey 90% of population purchase medicines through out of pocket payments making medicines largest family expenditure item after food. Medicines account for 20-60% of health spending in developing and transitional countries, compared with 18% in countries of the organizations for economic co-operation and development. Health care costs are more increasing day by day and 63 million people are faring poverty every year due to health care costs.

Conclusion

Although India produces drugs at a low cost but still 1/3rd of population is unable to afford to the health care services due to unawareness about the availability of quality medicines at low cost and also due to their low-income occupations. Thus, there is an emergence in the country to make aware the population about the availabilities of government provided schemes and other development programs.

References

1. Dipiro JT. Pharmacoeconomics: Principles, methods and applications, Pharmacotherapy: A pathophysiologic approach, 8th edition. http://acesspharmacy.mhmedical.com/content.aspx?bookid-462&sectionid-41100767#7965155

2. WHO definitions of generics. http://gabionline.net/generics/general/WHO-definition-of-generics

3. Anup soans (2017) Quality, Not Price, is the Key Issue When Prescribing Generic Drugs in India. https://thewire.in/130498/drugs-generics-branded-health/

4. Dhamija P, Sharma PK, Kalra S (2015) Only generics(drugs/names); Is India ready?, Indian J Endocrinol Metab 19: 541-545.

5. Karan B. Thakkar, Gauri Billa (2013) The concept of Generic drugs and potential drugs vs. brand name drugs and non-proprietary (generic) name drugs, Front Pharmacol 4: 113.

6. http://shodhganga.inflibnet.ac.in/bitstream/10603/6852/7/07_chapter%203.pdf

7. Alfonso-Cristancho R, Andia T, Barbosa T, Watanabe JH (2015) Definition and Classification of Generic Drugs Across the World, Appl Health Econ Health Policy 205; 13: 5-11.

8. Injeti Srinivas (2014) The Myth of Branded Generics, Economics and Political Weekly. 38.

9. Rajat Kumar (2013) Health economics and cost-effectiveness research with special reference to hemato-oncology. Med J Armed Forces India 69: 273-277.

10. Roy V, Gupta U, Agarwal AK (2012) Cost of medicines & their affordability in private pharmacies in Delhi (India), Indian J Med Res 136: 827-835.

11. Hogan P, Dall T, Nikolov P, American Diabetes Association (2003) Economic costs of diabetes in the US in 2002, Diabetes Care 26: 917-932.

12. http://www.pharmideas.com/pharmacoeconomics

13. http://www.tutor2u.net/buisiness/reference/cost-minimization