

Pharmacoeconomics guidelines: The need of hour for India

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Abstract

Although the government pays for approximately 20% of drugs used in India, private out-of-pocket expenditure in India on health-care is one of the highest in the world. Preparing pharmacoeconomics guidelines will be an important step in order to establish Health Technology Assessment (HTA) in India. Areas in which HTA could be applied in the Indian context include, drug pricing, development of clinical practice guidelines and prioritizing interventions that represent the greatest value within a limited budget. All this calls for action, both by government and civil-society organizations, to make access to essential medicines a priority.

Key words: Drug pricing, essential medicines, health technology assessment, pharmacoeconomics

INTRODUCTION

The role of health economics is well-recognized for efficient and equitable health system.^[1] In developing countries, though challenges faced by the health care system are slightly different from developed countries, health economics tools are equally applicable.^[2] Access to healthcare is a fundamental human right, safeguarded internationally and recognized by governments throughout the world.^[3,4]

In October 2010, the Planning Commission of India constituted the High Level Expert Group on universal health coverage with the mandate of developing a framework to provide easily accessible and affordable health-care for all Indians.^[5] As a first step, the federal government instituted a policy to provide free medicines for all persons attending a government health facility and the first phase was to start by October 2012.^[6] This government initiative was a step in the right direction to provide access to affordable essential medicines^[7] and was in line with

fulfilling the United Nations Millennium Development Goals (MDGs).^[8] Unfortunately, however, the federal government has already delayed implementation of this policy.

Medicines account for 20-60% of health care spending in developing and transitional countries,^[9] compared with 18% in countries of the Organization for Economic Co-operation and Development.^[10] Up to 90% of the population in developing countries purchase medicines through out-of-pocket payments,^[11] making medicines the largest family expenditure item after food. As a result, medicines are unaffordable for large sections of the global population and are a major burden on government budgets. Up to 90% of the population in low- and middle-income countries pay for medicines from out-of-pocket due to lack of social insurance and inadequate publicly subsidized services.^[12,13]

Niëns *et al.*^[14] assessed affordability among 11 Asian countries after taking into account household expenditures on health-care in terms of the proportion of the population being pushed below poverty levels because of the purchase of medicines. The results illustrated that substantial proportions of the population would be pushed into poverty as a result of medicine procurement, implying that in many countries affordability of these treatments is low. Although the government pays for approximately 20% of drugs used in India,^[15] private out-of-pocket expenditure in India on health-care is one of the highest in the world. It is estimated that 20 million people in India fall below the poverty line each year because of indebtedness due to health-care needs, which is mainly associated with the high cost of medicines.^[16]

Pharmacoeconomics has been defined as “the description and analysis of the cost of drug therapy to health-care systems

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and society.”^[17] Pharmacoeconomic (PE) research identifies, measures, and compares the costs (i.e., resources consumed) and consequences (i.e., clinical, economic, humanistic) of pharmaceutical products and services. This framework includes the research methods-related to cost-minimization, cost-effectiveness, cost-benefit, cost-of-illness, cost-utility, cost-consequences, and decision analysis, as well as quality-of-life and other humanistic assessments. In essence, PE analysis uses tools for examining the impact (desirable and undesirable) of alternative drug therapies and other medical interventions.

The International Society for Pharmacoeconomics and outcomes research (ISPOR) is preparing proposal for PE guidelines to be followed in India. The health-care delivery in each country is influenced by local and global politics.^[15] In all countries, the Ministries of Health are generally responsible for approval of health technologies through various agencies like the Central Drugs Standard Control Organization in India, Bureau of Food and Drugs for medicines and Bureau of Health Devices and Technology for medical devices in the Philippines, the National Pharmaceutical Control Bureau, Health Technology Assessment (HTA) Unit and Medical Device Bureau in Malaysia, and the Drug Control Organization in Pakistan. These organizations evaluate the product dossiers while taking decisions.^[15]

Australia was the first country in this region where data related to PE and outcome research (OR) were made mandatory for health-care policy decision making. In recent years, PE and OR have emerged as important for decision-making in health policy in various countries of the Asia-Pacific region including Taiwan, Thailand, South Korea, China, Japan, and Singapore.^[15]

Resource scarcity in health-care delivery, as in other sectors of the economy, is a globally common phenomenon. Among the contributing factors to resource scarcity in healthcare, prime factors are the introduction of new health technologies (NHT), an individual’s growing awareness of better health status, and population aging. The issues resulting from resource scarcity raise deep concerns for Asian policymakers and stakeholders in health-care.^[18]

Preparing PE guidelines will be an important step in order to establish HTA in India. Areas in which HTA could be applied in the Indian context include drug pricing, development of clinical practice guidelines and prioritizing interventions that represent the greatest value with in a limited budget.^[19]

New health technology developers view Asia as very attractive for two reasons: First, it is already a big market with a large population size, and second, it is a growing market with relatively higher economic growth rates and comparatively greater speed of population aging. As HTA policy has been formulated in various parts of this region in recent years, NHT developers have become keenly interested in their policy contents and their impact on business. By attending HTA meetings and exchanging dialogue,

NHT developers hope to learn how to cope with the changes brought on by HTA adoption.^[18]

The results of the study by Niëns *et al.*^[14] has shown that high medicine costs can push large groups of patients into poverty. These results call for action, both by governments and civil society organizations, to make access to essential medicines a priority, and not only to ensure access to necessary medicines, but also as a component in the context of reducing poverty.

The possible lines of action include:

- Developing, implementing, and enforcing sound national and international price policies by formation of the advisory committee at national and international level.
- Promoting the use of quality-assured, low-cost generics, for example, through preferential registration procedures, is also an important strategy.^[20]
- In the public sector, ensuring availability of essential medicines, at little or no charge to the poor is critical.
- In the long term, establishing health insurance systems with outpatient medicine benefits seems crucial to avoid poverty due to health shocks (and poor health due to poverty).
- Medicine prices can be reduced by eliminating duties and taxes on medicines.
- Development of HTA in association with the PE guidelines.
- Innovative approaches, such as using private distribution systems to supply subsidized medicines to chronic disease patients.
- Pharmaceutical companies should be encouraged to differentially price the life-saving products such as anticancer medicines, antimalarials and antiretrovirals.^[21]

When resources are limited, those in greatest need, such as people suffering from chronic disease whose earning is less, should be benefited from state and national policies and actions. Biological and supply side models of health-care are not capable of coping with the emerging challenges of the health care system in India. Government should seriously consider a shift in the objectives of the health policy toward quality and length of life. Programs yielding higher benefits with least cost to the society should be prioritized in resource allocation. Following such rules can control cost, improve quality and access to healthcare. It will simultaneously account for the interest of healthcare providers, the government and the patient.

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