



Implications of Pharmacoeconomics for Iran National Health System

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Abstract

Like many other developing countries pharmacoeconomics and outcome research and its applications in national health system is a new but promising filed in Iran. Although decision makers of Iran national health system decided to use pharmacoeconomics in the decision making approach several hurdles including lack of reliable national data, lack of expertise and local experience are the main challenges in this filed. Recent activities in training graduate students in the field of health technology assessment in the universities could play a major role in advancing this field in Iran.

Key words: Pharmacoeconomics, Pharmaceutical Industry, Health system, Iran

Introduction

Pharmacoeconomics, a subdivision of health economics, is a new discipline for evaluation of health related interventions and most of the research data provided through application of pharmacoeconomics have been published since mid 1960's. Increasing health care costs and limited resources available in the health care sector have forced many countries especially those in developed world request evidence of cost effectiveness to convince decision makers to include a new medicine to their national medicine list. Therefore, in recent decades health technology assessment (HTA) has been extensively used

by policy makers to make rational decision on including medicines and other medical interventions to their basket of services. HTA is a multidisciplinary approach for systematic evaluation of newly introduced intervention in healthcare sector. Cost effectiveness studies are of utmost importance to justify expenditure in all fields of health care and to make the best choice among the priorities.

Iran Health Care System and its Financing Scheme

Iran is a country with more than 76 million population located in the Middle East. Iran has a young population and in past two decades country's population growth rate has been drastically reduced to about 1.2%. Iran GDP mainly depends on the oil revenue and its GDP per capita at purchasing power parity in 2012 reported to be over 13,000 USD. Iran Ministry of Health and Medical Education (MOH) is the main stewardship of the health system in Iran. However, at the same time MOH is also responsible for medical university education in the country.

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According to the Iran constitutional law, MOH has the mandate to make sure that all Iranian access the highest attainable level of the health. Based on the fact that any investment in improving health status of society will bring valuable return to the society in short and long term, in past three decades government of Iran has spend substantial resources in implementation primary and secondary health care facilities throughout the country. As a result, Iran health indicators have substantially improved in recent decades. Iran health system is now an advanced health care system with most of the advanced medical interventions and high tech medicines available to the patients. However, along with public foundations private sector also plays a major role in Iran health care system. Some of the main characteristics of Iran health system have been reported previously [1].

Providing universal health insurance system has been one of the main goals of Iran national healthcare system. However, despite the presence of different health insurance schemes in the country there are still several main hurdles for reaching to a universal national health insurance system. Health care system financing in Iran is a mixed financing system. Different insurance schemes and private and public funds are the main resources of public health system. Although MOH is responsible for regulating drug prices, reimbursement is under control of Ministry of Welfare and Occupation [2]. Due to lack of sufficient resources in public health sectors and national health insurance schemes, in recent years out of pocket payments of patients have substantially increased and has topped to over 60% of the costs of medical services [2]. It has also imposed catastrophic health expenses to some of the Iranian families.

Academic Education of Pharmacoeconomics

Like other developing countries attention to pharmacoeconomics and its application is new in Iran [3-5]. However, the introduction of pharmacoeconomics to Iran health sector

happens through the academic and not pharmaceutical industry. Although since early 2000s several short term training workshops along with short term courses in HTA as general and pharmacoeconomics and outcome research were held by educational centers, following approval of higher education system, since 2007a Ph.D. program for training of students in pharmacoeconomics and pharmaceutical management has been established in Iran's universities.

Two Tehran and Shaheed Beheshti Medical Science universities in 2007 enrolled 10 students in the Ph.D. discipline for pharmacoeconomics and pharmaceutical management. Since then every year 10 new students entered the program and in 2012 first of these students graduated from the discipline with a Ph.D. degree. Graduate training of the students in this discipline include course work and research activities. In their didactic training, students exposed to methodological focus on the concept and design of pharmacoeconomics analysis, resource allocation, cost effectiveness analysis and decision making policies in health systems. Students are expected to undertake an independent research project in the field of pharmacoeconomics or pharmaceutical management under supervision of the faculty members for their dissertations.

This post graduate educational program not only substantially contributed to the dissemination of the role of pharmacoeconomics in health care system, it has played a major role in increasing number of scientific papers published by Iranian authors in peer reviewed pharmacoeconomics journals. Some of the graduated students of the program have been employed by universities as academic members. However, majority of the first groups of the graduates have joined national drug regulatory system in MOH and decision making system in national health insurance systems. It is forecasted that this discipline will contribute greatly to application of health technology assessment methods as

general and pharmacoeconomics in particular in Iran national health system.

Some of the Iranian scientists have also established ISPOR (International Society for Pharmacoeconomics and Outcome Research) Iran Regional Chapter [6]. The mission of the ISPOR Iran Chapter is to:

- Provide an environment where researchers, health care practitioners, and decision-makers, interested in Pharmacoeconomics and outcomes research, can share knowledge at Iran level.
- Serve as a bridge between researchers, health care practitioners, and decision-makers, representatives of pharmaceutical industries and academia who have expertise in pharmacoeconomics and outcomes research.
- Act as a resource at a local level for individuals interested in pharmacoeconomics and outcomes research and their use in health care decisions.
- To promote local development and monitor implementation of guidelines in pharmacoeconomics and outcomes research.

Pharmacoeconomics and National Pharmaceutical Industry

Despite presence of a long history of traditional medicine, current Iran pharmaceutical market is mainly dominated by Western medicines [7-8]. Iran national pharmaceutical industry has about half century history. However, following 1979 Islamic revaluation in Iran all of the pharmaceutical companies in Iran were nationalized. In 1980s pharmaceutical market in Iran was tightly controlled by the government and the nationalized pharmaceutical companies mainly produce small molecule generic medicines [7]. Despite the fact that based on new economical policy of the Iran government in past decade, ownership of the Iran pharmaceutical industry

has shifted from state owned to semi government and pseudo private sector, attitude of the traditional managers of the industry has not changed substantially. Therefore, even in these companies, competition and free market rules have not yet fully implemented. Although in recent years some signs of application of knowledge based approaches could be seen in some sections of Iran national pharmaceutical industry, use of Pharmacoeconomics experts in this industry is still rare.

Logically pharmaceutical industry should also pursue projects which are not only health oriented but economically feasible. Therefore, pharmacoeconomics studies could be an effective tool for pharmaceutical industry in order to decide when and where a project should go forward [9]. That is why nowadays many pharmaceutical companies have established a pharmacoeconomics expert group in their research and development (R&D) department. In these companies pharmacoeconomics experts play crucial role in R&D projects from starting point up to marketing and even post marketing survey of the new products. Pharmacoeconomics could assist internal decision-making and resource allocation during drug development procedure. Clearly, these experts directly involve in selecting candidate drugs to develop, designing clinical trial, pricing approval for national health system, formulary listing and even reimbursement of new medicines. Strategic planning, marketing strategy, sales revenue, decision making in R&D and controlling R&D costs are also among the expertise fields of pharmacoeconomics experts.

Iran national pharmaceutical industry is a non innovative industry which mostly produces generic medicines. Therefore, until recently Iran national pharmaceutical industry never feel to use tools such as pharmacoeconomics in a non competitive pharmaceutical market of Iran [7]. However, in order to change the market strategy since 2002 Iranian policy makers introduce the

concept of brand generics and promote production of new, high tech and brand medicines in the country. Since then and along with privatization of state owned pharmaceutical companies in Iran, introduction of a semi free market regulations have drastically changed Iran pharmaceutical market [8]. Pharmaceutical industry in Iran has now realized that pharmacoeconomics could help them to optimize their resources and provide them a better understanding of cost components of their R&D projects and marketing strategies. Although, so far none of the pharmaceutical companies has established an independent pharmacoeconomics expert group, some of them have recruited experts graduated from pharmacoeconomics and pharmaceutical management disciplines to advise them on selecting economically sound projects. It is forecasted that this trend will be increased in coming years. This strategy will clearly contribute to improving efficiency of the national pharmaceutical industry in Iran.

Pharmacoeconomics and National Regulatory System

Although traditionally acceptable safety, quality and efficacy have been the main parameters for including new medicines to the national formulary, limited resources and increasing demands have forced decision makers to include cost effectiveness as a fourth hurdle for expanding their national medicine lists. Nowadays, policy makers in many countries use pharmacoeconomics considerations to conclude if the added benefit of a newly introduced medicine is worth the extra costs impose to the health care system. Therefore, decision makers can use the pharmacoeconomics methods to evaluate and compare the total costs of a new medicine versus the outcomes and utilities provided by this new medicine.

Iran pharmaceutical market is a regulated market and all aspects of medicines including production, importation, distributions, and administrations of medicines in Iran is fully regulated and are under authority and control

of Iran MOH. Iran Food and Drug Organization (FDO) has all functions required for regulation of the market. All medicines should receive registration and marketing authorization before entering the Iran market. Iran Drug Selection Committee as an expert forum in FDO is the main core for developing Iran Drug List. The Committee which comprises of experts and high level managers of FDO and other experts meets regularly to discuss possible updating the national medicine list. Although, traditionally acceptable safety, quality and efficacy have been the main concern of the committee for evaluation of new application, in recent years cost effectiveness data becomes a routine requested amendment to the application. The committee requires pharmacoeconomics evaluation of any submission file for new medicine. However, clinical aspects of the submission is still the main concern of the committee and it will be some times in the future when fully integration of pharmacoeconomics appraisal of the new medicines happens in working procedure of the committee.

In conclusion it should be mentioned that despite all of its limitations, pharmacoeconomics could provide a valuable tool for Iran national pharmaceutical industry and policy makers to make the most appropriate decision for their most prior objectives in national health system. Hence, it is expected that due to the recent investment in the field of pharmacoeconomics in Iran its application will be widely spread in national health system in coming years.

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