

Health-Care Systems and Pharmacoeconomic Research in Asia-Pacific Region

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Introduction

This article presents the state of pharmacoeconomics and outcomes research in eight countries in the Asia-Pacific region: China, Japan, South Korea, Singapore, Thailand, Pakistan, Malaysia, and India. To provide a better background, a summary table of the key attributes of the health-care system is also included within each of the eight countries. This summary table, as shown in Table 1, demonstrates a wide variation on most aspects of the health-care system, insurance programs, total health expenditures (THEs) per capita, and drug expenditures per capita among the eight countries. The range of some of the attributes was as follows: population: 4.25 million to 1.26 billion; Gross Domestic Product (GDP) in 2004: US \$620 to \$27,800 per capita; number of hospital beds per 10,000 populations: 6.8 to 127.7; number of physicians per 10,000 populations: 3.03 to 21.1; and number of pharmacists per 10,000 populations: 0.53 to 18.9. The ranges for health economics data were the following: health expenditure as percentage of GDP 3.7% to 8.89%; health expenditure per capita from US \$62 to \$2096; drug expenditure per capita from US \$7 to \$483.8; drugs as a percentage of total health-care spending from ~8% to 44.1%; and availability of local pharmacoeconomic data from an infancy phase to a better established stage.

Nevertheless, there are similarities among these countries. Western medicine is dominant in all health-care systems, while traditional medicine is still practiced in some countries. Drug pricing and reimbursement are mostly controlled by the government. No reference pricing system exists in any of the countries. Use of pharmacoeconomic data is only required in South Korea.

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This article is organized by country-specific sections, within each a description is presented to describe 1) health-care and financing systems; 2) drug use and its trends in expenditure; 3) drug expenditure management associated with the development of pharmacoeconomic guidelines; and 4) role of pharmacoeconomics and outcomes research in drug expenditure management.

China

Health-Care System and Health-Care Financial System

Universal coverage of health insurance is the future direction of health system reform in China. At present, the urban employees' medical insurance scheme covers about 170 million workers, and the new rural cooperative medical system (RCMS) covers about 726 million populations in 2451 counties by the end of 2007 [1]. Currently, the yearly premium of RCMS in most rural areas is set around 50 yuan (RMB) per insured, in which two-thirds of the contribution is paid by the central and local government, and is used to reimburse the partial cost of catastrophic illnesses.

Drug Management and Expenditures

Before the 1990s, under the planning economy, drug production, distribution, and price setting were totally controlled by the government. After the 1990s, about 8,000 pharmaceutical companies, 16,000 wholesale, and 11,600 retail pharmaceutical enterprises have flourished in China. As a result, price competition and differentials have occurred in the pharmaceutical industry and distribution system. The annual growth rate of pharmaceutical expenditure (11.2%) has exceeded that of GDP (10.3%).

According to data on national health accounts published by the Chinese Ministry of Health, the THE was 866 billion yuan RMB in 2005, which is 4.73% of the national gross domestic product. Based on these data, the health expenditure per capita is roughly 662.3 yuan (US \$83); and 44.1% of the sum, about 317 yuan (US \$40) per capita, was spent on pharmaceuticals [2].

Table 1 Health-care systems and pharmaco-economic research in Asia-Pacific region

Category	China (1\$ = RMB 8.0 yuan) (2004 data)	Japan (2004/2005 data) (2004 data)	South Korea (1\$ = ₩1120)	Singapore (2004 data)	Thailand (2003 data)	Pakistan (2004 data)	Malaysia (2004 data)	India (2004 data)
Demographics								
Size of nation (km ²)	9.60 million	378 k	98,585	699	514 k	804 k	330,252	5.34 million
Population – all	1.26 billion	128 million	47.8 million	4.25 million	65 million	162 million	25.6 million	1.08 billion
Percent age distribution	1–14 years, 20.3%; 15–64 years, 71.2%; ≥65 years, 8.5%	13.9% 66.4% 19.6%	20.0% 71.7% 8.3%	16% 75.9% 8.1%	23.9% 68.6% 7.5%	39.6% 56.3% 4.1%	32.9% 62.9% 4.2%	32.5% 62.3% 5.2%
GDP per capita in US dollars	US \$1109	US \$23,843 (JP¥2,861,182)	US \$12,651	US \$27,800	US \$2540 (GNI per capita, WDR 2004)	US \$736	US \$4631	US \$620
Health care								
Health care (i.e., traditional medicine, Western medicine)	Both are part of the health system. For instance, there were 18,703 hospitals in China in 2005, which included 2620 Chinese traditional hospitals, 194 combined traditional and western medicine hospitals, and 195 minority nations hospitals.	Western medicine	Western plus traditional medicine	Western medicine (dominant part of the health-care system) plus traditional medical practice	Western medicine is the dominant part of the health-care system, while traditional medicine is still practiced	Traditional and Western medicine. People approach the traditional system more than the Western system in rural areas	Western medicine is more dominant. Traditional medicine is more utilized in rural areas. Recently, alternative medicine is gaining popularity in the country.	Both Western and traditional systems of medicine are part of the health system.
Number of hospitals (<100 beds, 100–500, 500–1000, >1000 beds)	<100 beds: 11,156; 100–500 beds: 6523; 500–800 beds: 740; >800 beds: 284 (2005 data)	<100 beds: 3558; 100–500: 4983; 500–900: 418; >900: 67	Total: 1425	29 (13 public; 16 private)	NA	Public: 916; Private: 520	Public: <100 = 48; 100–500 = 61; 500–100 = 18; >1000 = 4 (total = 131) Private: <100 = 189; 100–500 = 29; (total = 218)	Public: 7,008
Number of hospital beds/10,000	24.5	127.7	71	29	21.65	6.8	19.1	46.9
Number of primary care clinics/10,000	NA	7.6	4.91	17 public polyclinics; 1480 private clinics	1.67	Public: 4554 dispensaries, 5290 basic health units, 522 rural health centers, 285 TB centers; Private: 340 dispensaries, 450 diagnostic clinics, 300 maternal and child health centers	1.2 (public) 2.0 (private)	Total number of health-care centers including subcenters, primary health centers, and community health centers is 163,181
Number of physicians/10,000	17.0	21.1	16	15	3.03	7.3	7.1	6.0
Number of pharmacists/10,000	0.99	18.9	0.53	3.0	1.17	3.4	1.4	0.8

Health-care insurance system (types)	There are two types of health insurance systems: basic insurance in urban China, which contains personal medical savings accounts (paid for ambulatory service) and a pooled fund (paid for inpatient and catastrophic illnesses). New type cooperative medical scheme in rural China (which has a pooled fund and/or family medical savings accounts). Other supplementary insurance schemes also exist.	Universal coverage (nationwide)	Universal coverage through social health insurance.	Public and private insurance available. (Public MedShield and IncomeShield Plan MA & MB.) MedShield is an opt-out scheme for all holders who are Singaporean citizens or permanent residents. IncomeShield Plan MA & MB offers higher claimable limits compared with MedShield, but also has higher deductibles.	Thailand achieved universal coverage in 2002. There are currently three public insurance schemes covering the whole population in Thailand. Social Health Insurance (SHI) for private sector employees; Civil Servant Medical Benefit Scheme (CSMBS) for public sector employees, pensioners, and dependents; the Universal Coverage (UC) scheme covers the rest of the population.	1. Private insurance (only 0.5% of GDP) 2. Employees Social Security Scheme covers 1.2 million individuals, which represent 3.06% of total workforce. 3. Smaller social health insurance, i.e., workers welfare fund, Zakat, Bait-ul-mal, employee's old age benefit, Guzara program, and workers participation fund.	Public: none Private insurance and employees benefit	The health insurance market covers about 10% of the total population. The schemes are 1) private for-profit schemes; 2) employer-based schemes; 3) insurance offered by NGOs/ community-based health insurance, and 4) mandatory health insurance schemes or government-run schemes (namely ESIS, CGHS).
% of population with insurance coverage	170 million employees covered by urban medical insurance, and 410 million rural residents covered by cooperative medical scheme. Both covered about 44.5% population in China at the end of 2006.	100% for Japanese	97.5%	>2 million contributors to MedShield in 1999	SHI, 13%; CSMBS, 10%; UC, 74%	3–5% approximately	25%	Approximately 10%
Reimbursement method	Including deductible, copayment and ceiling. There is a drug reimbursement list (A and B) for urban medical insurance system: rural cooperative medical system has its own reimbursement list at the county hospital and township health center.	Fee-for-service, but partly flat payment	Fee-for-service	Including deductible, copayment, and claim ceiling.	SHI—inclusive capitation for ambulatory care and admission, fee schedule for additional pay for high-cost care CSMBS—fee-for-service reimbursement UC—capitation for ambulatory care, and global budget and DRG for inpatient care	Out-of-pocket (98.35% of private expenditure on health (2002))	Mostly fee-for-service	
Health-care expenditure and controls Health expenditure (% of GDP); public/private	4.73% (2005 data)	8.89% (2004 data)	Public: 2.8%; Private: 2.8%	4.3% GDP (Public: 0.9%) 2002 data	4.4% GDP (2002); public: 70%; private: 30%	Public: 0.9%; Private: 3.2% (2002)	3.7% of GDP (public: 58%; private: 42%)	Public: 1.3%; Private: 4.8%

Table 1 Continued

Category Country/region	China (1\$ = RMB 8.0 yuan) (2004 data)	Japan (2004/2005 data) (2004 data)	South Korea (1\$ = ₩120) (2004 data)	Singapore (2004 data)	Thailand (2003 data)	Pakistan (2004 data)	Malaysia (2004 data)	India (2004 data)
Health expenditure per capita: public/ private	¥662.3 (US \$83) (2005 data)	US \$2096 (JP¥251,500) (2004 data)	US \$348	US \$1105 per capita (Public: \$307 per capita) 2002 data —US \$75 per capita	PPP \$321 US \$90 (2002)	US \$62 (2002)	RM 380/ per capita RM 220, public RM 160, private	US \$71, public expenditure; US \$4, private Data not available
Drug spending per capita	¥317 (US \$39.6) (2005 data)	US \$393 (2002, OECD) US \$483.8 (JP¥58,059) (2004 data)		—US \$75 per capita	115.69 PPP\$ (2002)	US \$7 (2004) US \$32.44 (2002)	US \$27	
Drug spending of total health expenditure (%)	44.1% (2005 data)	23.2% (2004 data)	28%	—8% (estimated)	36. %	80% of the total health expenditure on buying medicines	17%	15%
National drug budget	No data. Nevertheless, the total drug expenditure was ¥414.21 billion (2005 data)	US \$62 billion (JP¥74,418 billion) (2004 data)		No data available. Total drug expenditure: US \$311 million	Integrated in capitation budget for SHI and UC scheme. No drug budget ceiling for CSMBs.	US \$298,350 (2004– 2005). The Drug Controller Budget, Ministry of Health (MOH).	RM 963	The estimated expenditure on health and family welfare is INR 102.8 million
Pricing/reimbursement	Government control	Government control	Government control	No specific reimbursement for drugs as included in DRG and global budget for public hospitals or polyclinics.	No specific reimbursement for drugs in SHI and UC as drug expenditure are included in the capitation for ambulatory care, and global budget and DRG for inpatient care. Beneficiaries covered by CSMBs reimburse drugs for OP and IP based on hospital price list, general cost plus 15% margin.	Price control with the government according to laws that are in the process of being amended. Reimbursement for the minority that comes under insurance coverage.	Government control in the public sector	Data not available
Reference pricing— international	No	No	No	No	No	No	No	No
Reference pricing— national clusters	No	No	No	No	Reference price for the National List of Essential Drugs (NLED) was promulgated for purchase by government hospitals, according to procurement regulation.	No	No	No
Use of pharmacoeconomics	Yes, but has not been required by the government in registering new drugs. Recently, pharmacoeconomic evaluation guidelines are under prepared by pharmacoeconomists.	Yes, but no government requirement (recommendation only)	Recommended, but not required	No legal requirement, but implicitly used in the selection of drugs for inclusion into Standard Drug List maintained by the MOH.	Increasing application of evidence from pharmacoeconomics for the revision of NLED as NLED is referred as the minimum drug package for all public insurance schemes. Not applied at the hospital level.	No	Very limited but developing	Data not available

Copayments	10% of annual salary as deductible, 10% and more than for drugs, based on HI categories. Ceiling usually set on four times of the annual salary and wages in urban medical insurance system.	30%	Yes	Public sector health-care institution heavily subsidized for citizens and permanent residents. Copayments for standard drugs in public institutions.	No copayment for drugs in SHI and UC; beneficiaries covered by CSMBs have to pay in full for drugs outside the NLED.	No	Yes in public sector, but subsidy is up to 80–90% of cost	No
Profit/revenue controls	No. Some cities now are conducting hospital global budget control and revenue capping.	No	No	Singapore has a mixed health-care market with free-market private providers. Public hospitals are allowed to keep a portion of profits. Profit control in public hospitals by requiring the returning of excess profit once a limit is reached.	Free market for private hospital sector; government hospitals are allowed 15% margin for drug sales.	No	No	No
Clinical practice guidelines	Some, but not required by the government	Some, but not required by the government	Partially	Well developed by MOH and updated regularly.	Well developed by the Royal Colleges, but lack of enforcement mechanisms, or other incentive structure fostering the use of CPG.	No	Yes	Guidelines available in few (6–8) of the states. No national guidelines.
Drug budgets/ financial incentives aimed at prescribing doctors	Usually, there are strong incentives in public hospitals to prescribe high-price drugs in order to increase hospital revenue.	No	No	Block budget in public hospitals with no separate drug budget account to encourage prudent and rational drug prescribing.	In the future, the CSMBs will have a policy to harmonize payment mechanism with the other two schemes (SHI and UC), namely, capitation for ambulatory care, and global budget with DRG for inpatient care. Capitation and global budget send a strong signal toward the efficient use of diagnostic and therapeutic services, including drugs.	No	No	No
Availability of local pharmaco-economic data	Yes, from some Chinese studies	Yes, from Japanese literature, but limited	Yes	Limited	At an infancy phase	No	Very limited	At an infancy stage

GNI, gross national income; WDR, World Development Report; NA, not available; ESIS, Employees' State Insurance Scheme; CGHS, Central Government Health Scheme; DRG, diagnosis-related group; IP, Indian Pharmacopoeia; OP, outpatient; HI, health insurance; CPG, clinical practice guideline.

The share of China in the global pharmaceutical market is increasing very rapidly. In 2004, the value of global pharmaceutical sales was US \$9.5 billion, which was ranked ninth in the global pharmaceutical market. The annual growth rate of 28% was much higher in China than the average growth rate of 9% in the world.

Pharmacoeconomics and Outcomes Research Guidelines

Although pharmacoeconomics is a newly developed discipline in China, the principles of pharmacoeconomics have been widely noted in health economics, clinical epidemiology, evidence-based medicine, and health technology assessment (HTA). Many health professionals have applied pharmacoeconomic evaluation methods into clinical trials in the phase II, III, and IV stages. Pharmacoeconomic research findings have been applied occasionally in the field of drug price policy, essential drug (ED) listing for reimbursement purpose, drug marketing, and rational use of drug. In addition, pharmacoeconomics has also been increasingly applied in the areas of disease burden, cost analysis, cost-effectiveness, and economic evaluation. A recent search shows 506 pharmacoeconomic articles published in 126 journals, and 2034 pharmacoepidemiology articles published in 43 journals between 1993 and 2002, respectively. In 2006, the first *China Journal of Pharmaceutical Economics* was published with the mission to promote the application of pharmacoeconomics in the management of drug expenditures, health insurance, and rational use of drugs.

To better understand the scope of pharmacoeconomic research in China, a systematic review of 380 pharmacoeconomics and outcomes research articles retrieved from the Chinese journal database and literature published before 2003 was conducted recently [3]. The retrieved articles were evaluated according to study design, comparator selection, cost, effectiveness measurement, and economic evaluation method. From the study design, 42% of the articles were prospective studies, while 28% were retrospective studies; 25% were literature reviews, and 5% were of a mixed study design.

Regarding the methodology used in the published studies, 75% of the publications applied cost-effectiveness analysis, followed by cost-minimization analysis (12%). Less than 5% of the publications used cost-utilization analysis. Cost analyses were calculated from different perspectives, e.g., patient, hospital, health insurance, or government. In most of the literature (44.4%), direct medical cost was used when conducting cost analysis, followed by drug expenditure cost (24.2%), and by both direct and indirect costs (23.1%). Only 4.6% of the publications considered social costs. Markov model was rarely used in these

publications because of lack of parameters from clinical and epidemiological studies in China.

The findings of this systematic review suggested that approaches and methods of conducting pharmacoeconomic evaluation are not standardized in China. In addition, pharmacoeconomic data have not been widely employed in rational use of drugs and in management of hospital formulary. Nevertheless, even though the data of pharmacoeconomic information have not been adapted as a criterion of decision-making for reimbursement, increasing number of pharmaceutical companies in China, especially the international ones, started using pharmacoeconomic evaluation as a supportive evidence in the areas of new drug reimbursement applications, pricing decision, and marketing approach.

Japan

Health-Care System and Health-Care Financing System

In 1961, the Japanese government established a universal coverage of health-care insurance for all Japanese, which has played an important role in providing and maintaining an equal opportunity for people to access the health-care system in Japan [4].

The Japanese health-care insurance system is complex with about 5000 insurers classified into two broad categories: Employees' Health Insurance (EHI) covering 60% of the population, and National Health Insurance (NHI) for nonemployees, covering the remaining 40%. A patient holding either an EHI or NHI card issued by the government is entitled to access any hospital depending on the needs of the patient. The accounting and payment of treatment costs, including drug costs, is performed according to the fee-for-service (FFS) principle. Patients must contribute 30% of the total expense as a copayment at the point when a service is provided in a hospital while the rest is reimbursed to the hospital by the government. The medical expenditures are determined by the medical-fee scores and a set of reimbursement rates, which are uniformly determined and biennially revised by the Ministry of Health, Labor and Welfare (MHLW) [4].

Despite continuing revisions to maintain the system under the current financing arrangement, the system is increasingly facing financial stress under increasing demand for better quality of health care from the population. The major problem comes from the changing demographic feature of a rapidly aging Japanese society, which is accelerating the shift of insured from EHI into NHI. Such a shift makes the NHI financially more vulnerable because of the dual effects of increasing number of elderly population to cover, and a higher demand for health care for the group relative to the younger generation. This aging effect of society leads to a soaring progression over time of national health-care expenditure, which stood at JPY30 trillion (US

\$250 billion), representing an 8.89% of Japanese GDP in 2004. The annual rate of increase in health-care expenditure is approximately 1 trillion JPY (US \$8 billions) per year. In addition to the effect of an aging population, excessive care in practice inappropriately induced by FFS is another factor contributing to the increase [5].

Responding to public concerns about soaring national medical expenditures, former Prime Minister Koizumi repeatedly reduced medical-fee scores with decreases of 2.7%, 1.0%, and 3.16% in 2002, 2004, and 2006, respectively. The latest reductions in medical-fee scores, by the Koizumi administration, of 3.16% comprised of 1) a reduction of 1.36% of the “maximal cutoff” of medical service fee since the implementation of the FFS system in 1961; and 2) a reduction of 1.8% in fees of medical products, of which the reduction was 1.6% for drugs and 0.2% for medical devices. Against this discounting of the medical-fee scores, the Japan Medical Association expressed their concerns about a decline in the quality and safety of health-care services in practice. The claim is that physicians with less incentive might deliver inappropriate health care and malpractice, which eventually decreases the benefit to patients. The other concerns raised include the following: 1) hospital managers might provide more patients with admission beyond the capacity of a hospital to save worsening finances, consequently; 2) patients might report less satisfaction of the services delivered because of more crowded hospitals; 3) competitive capability on business of companies might be eroded because of lower profits; and 4) the government could be too optimistic for the cost-containment policy in health care.

Regarding the future of improving health financing, three challenging reforms have been implemented by the MHLW. These include 1) Long-term Care Insurance (LCI) (i.e., Nursing Care Insurance) since 2000; 2) Diagnosis-Procedure Combination (DPC) since 2003; and 3) The Health care Systems Reform Act in July 2006.

Long-term/nursing care insurance. In the LCI, elderly people more than 65 years old are insured and supported with compulsory premium payments by persons more than 40 years. The features of LCI include 1) public subsidization with flat rates of payment by the government according to the grades (six categories) accredited by the MHLW on the basis of patient needs; 2) care at home, which would provide patients with the “benefit” of nursing on-site by health-care workers; and 3) a “free-to-choose” contract between the insured and a care provider/company. The objective of LCI launched in 2000 was not only building a new nursing home system for an aging society, but also segregating its high-risk finance for the elderly from lower-risk finance in ordinary

health care for younger generations. As anticipated, financial concerns did arise after the launching of the LCI system, and LCI was subsequently revised in 2005 to make it more robust against increasing costs.

Diagnosis-procedure combination. This is a new case-mix-based payment (flat payment) program for diagnosis-procedure combinations of 1860 categories, based on the ICD-10, for treatment of patients in acute care in hospitals. After the MHLW introduced the DPC program in 82 national hospitals in 2003, the number of hospitals participating in the program increased to 150 in 2004, and 300 in 2005. The DPC was intended to shift from the FFS maximizing revenues process of a hospital to a diagnosis-related group (DRG)-like mechanism minimizing expenditures. Currently, sufficient evidence is still lacking to evaluate the cost-saving influences that could have been caused by DPC on the national medical expenditures. Nevertheless, it certainly aroused consciousness of cost-effectiveness in health care, and also the need for evidence-based or standardized practice employing clinical pathways. Nevertheless, there are concerns about declines in quality care, which might be induced by the flat payment.

The Health care Systems Reform Act in July 2006. This reform aims to achieve three objectives: 1) prevention against lifestyle-related diseases; 2) implementation of a new health-care program in 2008 for elderly people more than 75 years old, with nursing hospitals downsized from total facilities of 380,000 to 150,000 by the year 2012, with a resultant saving of about 4 trillion JPY by the year 2025; and 3) re-pricing of health-care fees downward by 3.16%. Despite this reform, the government is not optimistic in terms of the amount of cost-saving. The cost-saving estimated by the reform is only JPY275 billion per year, although the medical expenditure would increase by JPY800 billion in the fiscal year of 2006 without any reform.

Drug Use and Expenditure

Regarding drug use, the Japanese market is huge with an annual expenditure of about JPY7 trillion. An MHLW report estimated JPY7441.8 billion for drugs in 2004 (US \$62 billion). Ninety percent of the sales (i.e., JPY6737.6 billion) is attributed to pharmaceuticals prescribed in hospitals. The proportion of pharmaceuticals prescribed in hospitals among all drug sales increased over time initially from 50% when the universal coverage of health-care insurance was implemented in 1961. The OECD Health Data 2005 reported the drug expenditure per capita in Japan in 2002 of US \$393 (JPY56,592; 1\$ = JPY144 in 2002). For 2004, the drug expenditure per capital is estimated to be approximately US \$484 (JPY58,059; 1\$ = JPY120 in 2004) [6].

As a proportion of total national health-care expenditure, drug expenditure was reported to constitute 23.3% of the total expenditure in 2004 by the MHLW. In comparison, the market size of generic drugs is only 5.2% in sales and 16.6% in quantity basis, which is not as large as in the United States, United Kingdom, or Germany where generic sales are greater than 50%. Another interesting issue for drug management is the projection of the drug expenditure after the introduction of the DPC program in the future. It is estimated to be more than US \$8 billion after all the hospitals participate in the program, of which about 80% of the expenditures would be pharmaceuticals including injections [6].

Drug Management and Pharmacoeconomic Guidelines

Subsequent to the zigzag performance since the 1980s, the First ISPOR Asia-Pacific Conference in Kobe 2003 opened the door in several Asian countries and provided the second stage of pharmacoeconomic study in Japan. To address issues raised at the First ISPOR Asia-Pacific Conference, the ISPOR Japan Chapter was established in September 2005. Also, the MHLW funded a research group to draft the pharmacoeconomic guidelines in 2005 to 2007. The Ministry of Economy, Trade and Industry (METI), another government entity, expressed an interest in pharmacoeconomics for medical device and diagnostics, and has organized the Preliminary Committee to develop the pharmacoeconomic guidelines for medical device and diagnostics in 2005 with a first draft planned for 2008. There is a substantial need for continuing efforts to improve how to finance all sectors of health care in Japan. Cost reduction becomes the first approach; however, this approach alone may result in a decline of quality care in Japanese hospitals and communities. Although the MHLW launched several initiatives for health-care reform, many professionals in every health sector recognize a need for new approaches, such as pharmacoeconomics, to implement sustainable reform, by shifting the mindset of "health finance" to the view of "value-based health care" in Japan.

Role of Pharmacoeconomics

Japan recognizes the key role of pharmacoeconomics and the value of its related studies in health care at the early stage of their development. The Japanese Society for Clinical Economics, which is a renowned entity for pharmacoeconomic study in Japan, has been established for almost 30 years. The key ideas and methods for pharmacoeconomics were advocated to the stakeholders in industry and the government in the International Symposium on Clinical Economics, Tokyo, 1988. Responding to the growing interest in such studies, in the early 1990s, the MHLW recommended appending pharmacoeconomic data to the dossier for new drug applications.

Despite the early recognition of the importance for pharmacoeconomics, in Japan, research and education in the field has not matured enough to build an era of the use of cost-effectiveness information in health-care decisions because of skepticism raised from clinicians, health-care industry, and health-care decision-makers. Research activities on economic evaluations are still very limited in Japan, compared to the United States or Europe [7].

South Korea

Health-Care System and Health-Care Financing System

Korea has undergone remarkable social changes over the last four decades. The unprecedented high economic growth rates from the 1960s through the 1990s have been accompanied by industrialization, urbanization, and most conspicuously, democratization. Along with these social changes came the development of the health-care system, which was largely influenced by Western medicine. The most noticeable change in the Korean health-care system was the establishment of the NHI system. It was implemented in stages over 12 years, and each stage was achieved with little political, economic, or social resistance. The expansion of health insurance coverage toward the whole population was a popular issue and received a strong political support from voters.

NHI is the central organizing mechanism of the Korean health-care system, through which resources flow among the government, consumers, corporations, and service providers, under a relatively weak governance structure. In most situations, patients are given a choice of hospitals and clinics. To establish patient referral channels, regulations were introduced in 1989 to partially restrict the choice of providers available through the NHI. Nevertheless, the regulations were not enforced by the hospitals because they feared the loss of revenues, and most patients do not abide by these rules.

Providers are paid by FFS for services covered by the insurance. These fees are paid in part by the National Health Insurance Corporation (NHIC), and the rest by patients' out-of-pocket (OOP) payments. NHI, in turn, is financed by premium contributions paid by consumers and employers, along with government subsidy. The government raises this subsidy through tax revenues.

The work of health-care delivery is performed mostly by the private sector. The private sector, which was dominant in Korea before the insurance plans were introduced, has grown further with the increase in per capita income and the expansion of health insurance coverage. Health-care providers are tiered into general hospitals, local hospitals, and clinics. In 2003, public local hospitals accounted for only 7% of all local hospitals, public general hospitals accounted for

Table 2 Trend of national health insurance financial status

	1993	1994	1995	1996	1997	1998
Revenue	4,116	4,608	5,435	6,326	7,297	7,849
Expenditure	3,363	3,869	5,054	6,413	7,679	8,709
Annual balance	752	739	382	-88	-382	-860
Accumulated surplus	3,432	3,926	4,121	4,002	3,785	3,036
	1999	2000	2001	2002	2003	2004
Revenue	8,692	9,529	11,642	13,890	16,823	18,500
Expenditure	9,561	10,538	14,051	14,651	15,744	16,941
Annual balance	-869	-1,009	-2,409	-761	1,079	1,599
Accumulated surplus	2,244	919	1,811	2,572	1,492	668

Source: National Health Insurance Corporation, 2005 (unit: billion Korean Won).

20% of all general hospitals, and clinics are 100% private. There are 7.1 hospital beds per 1000 Koreans [8], 87% of which are in private hospitals and clinics [9].

Drug Use and Expenditure

Development of the modern Korean health-care system, however, is not without costs. Financial sustainability is under heavy scrutiny at the moment. Statistics show that total insurance expenditure increased by about 20% annually from 1993 to 2004 [10], mostly because of increasing treatment costs. These increases in treatment costs can be explained by several factors, some demand-driven and some supply-driven: expansion of coverage, fee increase greater than the consumer price index (CPI) increase, population aging, and aggressive use of new technologies. Nevertheless, the most important factor has been the use of the FFS payment method, coupled with nearly unregulated use of new technologies, which structurally ensures that the system's resource requirements are open-ended. The natural consequence of this is the NHI's financial deficit (Table 2).

Since 1996, the NHI system had run an annual deficit each year with the size of the annual deficit continuously increasing until 2001, which was the first year in which the NHI had a cumulative deficit. A cumulative deficit was projected in 2003, but it happened earlier than expected because of the abrupt physician and pharmacist fee increases at the end of year 2000. The cumulative deficit had made the financial stability of NHI a national priority by the Korean health authorities. Various actions have been taken to relieve the deficits including greater government contributions from general tax revenues, higher premiums, a newly introduced cigarette tax, control of fee increases, and stricter monitoring of medical fraud in claims processing. The annual deficit significantly declined in 2002, and annual surpluses in both 2003 and 2004 helped to erase the cumulative deficit by the end of 2004.

There have been speculations and discussions about the role of pharmaceuticals in this budget instability phenomenon. Researchers argue that the most contrib-

uting factor toward financial unsustainability is the use of new drugs and the ever-increasing drug expenditures, and as long as the limited management of insurgent new medical technologies (equipment, devices, and drugs) remains as it is, the projected financial sustainability for NHI is somber.

To confirm this argument, a closer look into the trend of pharmaceutical expenditure was made. The data reveal that drug expenditure has been rising very rapidly in Korea. Over the 4-year period of 2001 to 2005, pharmaceutical expenditure in nominal figures has nearly doubled, and the real expenditure has increased by 50%. The issue within the policy arena is that the rationality of drug expenditure, which accounts for more than one-quarter of total NHI expenditures (more than 29% in 2005), has never been seriously questioned at any level.

From a policy perspective, researchers and policymakers point out that the rapidly increased pharmaceutical expenditure was probably due to not only so many drugs are enlisted in the reimbursement list, but also these new drugs are adopted very quickly in the Korean market [11]. Early adoption of new entering drugs could be seen as a problem from the efficiency perspective, as drugs are enlisted in the reimbursement list with little consideration of budget impacts and/or cost-effectiveness.

Drug Management and Pharmacoeconomic Guidelines

The NHI Act's "Guidelines for Determining and Adjusting New Medical Technologies" stipulates the use of economic evaluations for decisions regarding the use of new medical technologies including drugs, equipment, and diagnosis. Because a significant portion of the increase in NHI expenditure is attributable to the extensive use of new medical technologies, which are usually cost-increasing rather than cost-saving, the Ministry of Health and the NHIC are considering the use of economic data in reimbursement decisions regarding newly introduced technologies. The first target is pharmaceuticals. For example, at the moment, almost all drugs that receive market approval by Korea Food and Drug Administration (KFDA) are automatically listed as insurance-reimbursed drugs,

without consideration of their cost-effectiveness and budget impacts. The result is that over 21,000 drugs are on the Korean NHI reimbursement list, in stark contrast to the 3000 to 8000 drugs in the insurance formulary of most OECD countries. One likely outcome of having a long list of reimbursable drugs and many substitutable drugs for one treatment category is that many small pharmaceutical companies will compete heavily for product promotion and market sales, often using undesirable promotion and sales strategies, a phenomenon the Korean pharmaceutical market is currently displaying. For example, in an effort to promote sales, various types of promoting tools are provided to service providers and pharmacists by pharmaceutical companies or wholesalers.

To take the cost-effectiveness and budget impacts of newly entering drugs into consideration of reimbursement decisions, the Health Insurance Review Agency (HIRA) recently prepared the Korean version of the pharmacoeconomic guidelines (KPEG). KPEG provides pharmaceutical companies with instructions on how economic data are to be prepared before a drug is submitted for reimbursement and pricing. Its objective is to give more consideration to cost-effectiveness before adopting new drugs into the health insurance domain.

Use of economic data in reimbursement decisions can be extended to other technology areas as well, namely, medical equipment and diagnosis technology. Nevertheless, how soon and how widely it will be extended is still undecided, because there are many stakeholders with strong interests in this issue, both within and outside Korea; the subject easily becomes an international trade issue, which is often raised by medical technology-exporting countries.

Role of Pharmacoeconomics

In using economic data for drug reimbursement decisions, the objective is not to reduce the drug expenditures, the number of drugs in the list (formulary), nor to reduce drug prices; rather, by using economic data as a tool in decision-making, the goal is to gain in rationality in the use of scarce health-care resources. Like other countries, Korea is in a situation where the level of resource scarcity is ever increasing with growing consumer demands and insurgent new technologies.

Through the practice of emphasizing cost-effectiveness and rational use of scarce resources, there is little question that consumers will be better off with improved access to cost-effective pharmaceuticals. Population health will also be better in the long run.

For pharmaceutical companies, submitting economic data would mean additional financial burden for data preparation and a prolonged period to obtaining approval for reimbursement decisions. These could be transmitted as added production costs

to the firms. Nevertheless, there will be a long-run efficiency gain for the firms through healthy competition of price and outcomes (effectiveness) of the products. Over time, producing better product with improved outcomes through R & D will be the keyword among the firms in the industry. The Korean pharmaceutical industry will be better shaped in the sense that only efficient firms survive, and firms would rely less on undesirable product advertising and promotion. If the Korean government thinks the growth of pharmaceutical industry is one strategy for a prosperous national economy in the 21st century, use of economic data for reimbursement decisions would certainly contribute to such a national goal in the long run, albeit indirectly so.

By counting the cost-effectiveness of drugs, the insurance authority ultimately purchases health outcomes, not products themselves. This is a way to maximize health outcome for a given set of resource constraints. Scarce financial resources would be allocated more efficiently, and rationality of drug expenditure would also be enhanced.

Singapore

Health-Care System and Health-Care Financing System

The health-care delivery system in Singapore can be divided into the public and private sectors, with the bulk of primary care being delivered through the private sector, and the bulk of hospital care being delivered through the public sector health-care institutes.

The health-care system is financed by a mixture of taxation, compulsory saving through the Medisave scheme, employee medical benefits, insurance, and OOP payments. The main principle of the Singaporean government in maintaining the health-care system is provision through a balance between the public and private with a mixture of health-care services. This is augmented by compulsory savings through the Medisave program, and insurance through the MediShield program. At the same time, a safety net is available through the MediFund program for those financially disadvantaged who cannot afford to pay for their medical expenses with sufficient fund from their Medisave accounts. A more detailed description of the operation of the Medisave, MediShield, and MediFund programs has been previously described [12], and an update of these programs is described in another published article [13]. The fundamental philosophy is that individuals should have the responsibility to take care of their own health-care expenditure, but no citizen should be denied of health care because of financial difficulties, and the government is organizing different measures to help the citizens to achieve these goals.

Drug Expenditure, Drug Management, and Pharmacoeconomic Guidelines

The annual drug expenditure in Singapore is around SGD 600 million (which is approximately US \$375 million). This works out to be US \$75 per capita, and as a proportion of public spending, this constitutes 8% of public health expenditure.

In the public health-care system in Singapore, drug management is through the Standard Drug List, which is maintained by the Ministry of Health (MOH). The Standard Drug List comprises of two parts, Standard Drug List 1 and Standard Drug List 2. The difference between the two lists is that drugs that are included in the Standard Drug List 1 are heavily subsidized by the government, while those included in the Standard Drug List 2 are subsidized at only 50% of the drug acquisition cost.

No formal pharmacoeconomic guidelines are available at present, but the concept of cost-effectiveness has been implicitly applied in the deliberation of drugs considered for government subsidy through the public health-care institutes (including polyclinics and hospitals).

Role of Pharmacoeconomics

The level of awareness and application of pharmacoeconomic information has increased since the last review was written and published in 2004. Nevertheless, because of the nature of the health-care system and the management philosophy of health care, progress may not be as quick as researchers in the field would like it to occur. Despite the slower progress, there are concerted efforts from researchers and health-care administrators and professionals in promoting pharmacoeconomic research in Singapore.

Throughout the past few years, there have been several major conferences being organized by local public health institutes with special themes on cost-effectiveness in health-care delivery. The latest one was organized by the SingHealth Postgraduate Medical Institute in October 2006. In general, these conferences were well attended, with delegates coming from many different countries in Asia-Pacific and afar. In addition, there are efforts by the two Singaporean hospital clusters to organize training workshops to equip their staff in acquiring skills in assessing the cost-effectiveness of health-care delivery.

In terms of formal training, there is still no formal accredited courses being conducted locally by the tertiary education institutions to provide specialized training in pharmacoeconomics. Nevertheless, at the National University of Singapore, pharmacoeconomic research is being taught at the introductory level as part of the pharmacy curriculum. At the graduate level, there is a very active, although small by staff size, research group in the department of pharmacy engaging in various aspects of pharmacoeconomic research

in collaboration with various clinical researchers who have interest in this area of research. The group also has the capacity to provide consultative services to the government and pharmaceutical industry in the area of pharmacoeconomic research. Recently, a Health Services Research Center has been established at the National University of Singapore. It is therefore envisaged that there will be more resources available to pursue in research projects in the area in the foreseeable future. Overall, the capacity and resources available for pharmacoeconomic research have improved since we last visited this issue.

Regarding the application and use of pharmacoeconomic research in decision-making, there is a Pharmacoeconomic Evaluation and Drug Utilization (PEDU) Unit set up at the Center for Drug Administration, Health Sciences Authority with funding provided by the MOH. Any drug that has been put up for consideration for inclusion into the SDL would need to go through the application process where the evaluators at the PEDU will provide an abridged report outlining the cost-effectiveness of such drugs and the financial impact to the governmental drug budget for deliberation by the Drug Advisory Committee (an advisory body with members from various medical disciplines and pharmacy, and the membership is by appointment by the MOH). The use of a relatively simplified cost-effectiveness evaluation is really a trade-off considering the available staff level at the Pharmacoeconomics and Drug Utilization Unit, and the level of acceptance and understanding of pharmacoeconomic concepts by the members of the Drug Advisory Committee. Nevertheless, there always exists the option that the Drug Advisory Committee can request for a more detailed pharmacoeconomic evaluation to be performed by the PEDU for specific drugs.

Thailand

Health-Care System and Health-Care Financing Systems

Thailand has a pluralistic public and private mixed system for financing and service provision although public financing and provision still plays a dominant role. Thailand has provided a universal health-care coverage (UC) through a tax scheme since 2001. The scheme protects the 45 million population who are not eligible for Civil Servant Medical Benefit Scheme (CSMBS), which covers the government and state enterprise employees and their dependents, or Social Health Insurance (SHI), which is a mandatory health insurance for private sector employees in companies employing more than one employee [14]. As a result, 96% of the total 64 millions of Thai population was covered by one of these three public insurance schemes. Table 3 describes the key characteristics of these major insurance schemes.

Table 3 Health insurance schemes, 2002

Scheme	CSMBS	SHI	UC scheme
Year of introduction	1960	1990	2001
Beneficiaries	Government employees, dependents, and pensioners	Private sector employees, no dependents covered	The remaining population who are not covered by CSMBS and SHI
Population coverage	10%	13%	74%
Source of finance	Government budget, noncontributory scheme	Tripartite payroll contributions by employee, employer, and the government	Government budget (general tax revenue)
Payment to health facilities	FFS reimbursement	Capitation inclusive outpatient and inpatient services	Capitation for outpatient, disease prevention, and health promotion services. A global budget with case-base payment, i.e., (DRG) for inpatient service

CSMBS, Civil Servant Medical Benefit Scheme; SHI, Social Health Insurance; UC, Universal Coverage; FFS, fee-for-service; DRG, diagnosis-related group.

Overall resources devoted to health care have gradually increased recently. The THE per capita per year was 2160 baht (US \$86) at current year price in 1994, and had increased to 3974 baht (US \$98) in 2005 [15]. In 1994, private sources of financing played a major role, 55% of THE. As a result of financing reform, in 2005, public source played the major role; 64% of THE.

Budget constraints in health systems prompt stakeholders to be rewarded for priority setting [16]. Senior administrators, hospital directors, and health professionals have all realized the fact that it is impossible that the UC benefit package covers all medicines and interventions available in the market; thus, use of cost-effectiveness comparisons and rationing is inevitable. This requires the trust of the public on the application of a well-structured and evidence-based approach to generate this information.

Drug Use and Expenditure

Data on drug utilization in Thailand suffer from incomplete databases. For example, the underreporting by manufacturers and importers to the Thai Food and Drug Administration (TFDA), the magnitude of

drug distribution through various channels including self-medication to the end users, and the percentage markup by these channels are examples of where good data are lacking. Nevertheless, the best estimate of total drug expenditure is 36.04% of THE in 2002, or 1152 baht per capita (US \$27). Over time, imported drug products revealed an increasing trend in market share by sales (Fig. 1) [17].

Health-care services outside the terms and conditions (e.g., bypassing the contracting providers for UC and SHI members to private hospitals and clinics including drugs) are subject to full direct payment by households. In 2004, the monthly household expenditure for self-medication, mostly through private pharmacies, was 83.6 baht, on average, which is 0.9% of the total consumption expenditure [18]. Private pharmacies are licensed by the TFDA for nonprescription, prescription, and traditional medicines.

The drug benefit for all public insurance schemes (CSMBS, SHI, and UC schemes) was referenced to the medicines quoted in the National List of Essential Medicines (NLEM). A prescription of the nonessential drug (non-ED) is covered if deemed necessary. The ED List is periodically updated by a subcommittee of the

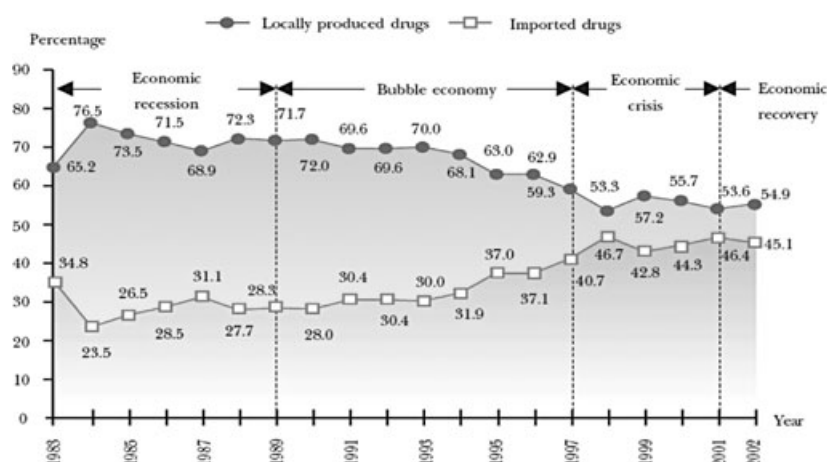


Figure 1 1983–2002 market penetration of imported drug products share of total sales. Source: [17].

National Drug Committee. The current NLEM (AD2004 version) has 882 items. Customary, dispensing non-ED list drugs is subject to full pay by any beneficiaries.

In a closed-end provider payment, such as capitation and global budget with DRG in SHI and UC schemes, the providers have an incentive to dispense the lower-cost generic products to make a margin from the capitation. In contrast, empiric evidence indicates that CSMBS beneficiaries were more likely given the expensive single-source drug products than those in other schemes [19,20], as CSMBS applies FFS payment.

On price control, a reference price was applied only to drug products covered by NLEM, according to the Procurement Regulation, but only enforced in the public hospitals when purchasing ED. After the 1997 economic crisis, the Ministry of Public Health “good health at low cost” policy enforced a mechanism to purchase drugs at the lowest possible price, given good quality and standards. Main elements of this policy are common drug list, collective bargaining, and bulk purchasing at provincial level, although this is not strongly enforced currently.

Drugs prescribed by private clinics and hospitals have higher markups. Charges in private pharmacies are subject to price control by the Ministry of Commerce in theory; in practice, however, the manufacturer or wholesale price depends largely on market segmentation and differential classes of trade, whereas the retail price depends on the competitiveness of the market.

Drug Management and Pharmacoeconomic Guidelines

Application of new drugs for registration to the TFDA is governed by the Drug Act, whereby approval is based on submitted documents on safety and clinical efficacy [21]. Real-world effectiveness and efficiency are not considered evidence by the TFDA for market approval, although attempts have been made to include efficiency into the revision of the Drug Act.

Application of drugs to be considered as national EDs is governed by regulations set by the subcommittee on NLEM revisions under the National Drug Committee. Presently, Thailand does not have a standard guideline for conducting health economic evaluation, and the subcommittee has not yet developed the selection criteria based on pharmacoeconomic evidence. Nevertheless, there is an implicit application of cost and efficiency dimensions [22]. For example, all drugs applying for ED status would be assessed on the following criteria: 1) completeness of clinical information submitted; 2) evidence on safety; 3) evidence on ease of administration and related restrictions; 4) evidence on frequency of drug administration; and 5) evidence on clinical efficacy. The composite score (0–1) of the five criteria would reflect the efficacy score of each drug.

Only drugs that pass 50% of these criteria would be considered by the subcommittee. An Essential Medical Cost Index (EMCI) is then estimated. This is the ratio of the cost of drug daily dose and the efficacy score. This index reflects the relative cost and efficacy of each drug, an implicit score of cost-effectiveness. Other criteria, such as availability of drugs in the market, are also considered.

Role of Pharmacoeconomics

Given the fact that more people are living longer, the increasing incidence of chronic noncommunicable diseases (NCDs), and the advancement in health technology, particularly pharmaceuticals, the rapid rise in health-care costs is one of the major policy concerns of the Thai government. Evidence on cost-effectiveness generated from pharmacoeconomic assessment is an important tool for decisions on allocation of scarce health-care resources. Nevertheless, pharmacoeconomics is a relatively new discipline in Thailand, which has not yet been widely applied in policy decision. Current policy dialogues stress the need for institutional capacity strengthening to provide pharmacoeconomic evidence to guide decisions on drug registrations by TFDA and adoption of drugs into the ED.

A systematic literature review revealed that there were very limited economic evaluation studies in Thailand, especially compared to countries where economic evaluation has been accepted for formal use in policy decision-making [23]. This review found that none of these publications address interventions for the top 20 burden of diseases (BOD) as measured by disability adjusted life year (DALY) loss [23]. The challenge is to minimize fragmentation and competition among research and funding agencies. A comprehensive and systematic approach is required to prioritize areas for future economic evaluation, e.g., guided by BOD profiles, or areas of controversy in interventions or clinical practices. Furthermore, in-depth interviews with policy actors at the national level, hospital directors, health professionals, and academic found that there was limited knowledge and understanding of concepts and applications of economic evaluation, and lack of training in health economics, with the exception of the academic group [16]. Without an improved understanding among these partners, the application and acceptance of economic evaluation to guide decisions is unlikely.

In the past, it was not possible to apply economic evaluations for setting priority and resource allocation because of several constraints. These limitations were due to limited research capacity to generate evidence, an absence of a national guideline for conducting economic evaluation, limited knowledge and understanding on the tools of economic evaluations, and a lack of

awareness among decision-makers and health professionals to support economic evaluation.

Nevertheless, given a better understanding of these limitations and opportunities of an increasing human capacity and commitments, a medium-term program for further capacity building and institutionalization of a national body for HTA was approved by multi-partners in Thailand with full funding support. It is hoped that economic evaluations (pharmacoeconomics) would be institutionalized and would better contribute to decision-making. Recently, the government has decided to invest in a medium-term program on HTA, namely Health Intervention and Technology Assessment Program (HITAP), aiming at capacity building, methodological standard settings, guideline for economic evaluation, priority setting for HTA and conducting economic evaluation for interventions, which address priority BOD, including pharmaceuticals, medical devices, and health promotion and prevention program. This would, at the end, establish the National Health Technology Institute to meet increasing challenges and guide resources allocation decisions.

Pakistan

Health-Care System and Health-Care Financing System

Pakistan is the sixth largest country in the world on the basis of population with a projected population of 162 million. One-third of the population lives below the poverty line (i.e., meaning, they may not have three meals a day) [24]. The Pakistan government has recognized the need and has tried to provide for these people, but lacks funds and infrastructure, and subjected to unstable political environment. Pakistan is an emerging economy with improving parameters and a per capita income of more than \$700, which may not reflect the true progress that is always offset by the annual growth rate of more than 2%. The government of Pakistan has been spending 0.6 to 1.19% of its GDP and 5.1 to 11.6% of its development expenditure on health over the last 10 years [25]. It is a developing country, which is developing from an agriculture-based to an industry-based economic system. It is this industrial transition that has subjected its population to a double BOD. The Western world has passed the transitional stage so that NCDs are the major health burden over communicable disease (CD) like infections. Nevertheless, in Pakistan, CDs and NCDs are both emerging neck and neck simultaneously, and it is predicted that NCDs will overtake CDs by the early quarter of this century [26]. Thus, there is a need for Pakistan to have cost-effective evidence for decision-making at the central level.

Pakistan's health policies are being reviewed and revised by thought leaders from academia, health technology, and government. The government has already launched the "National Action Plan" to counter the

emerging epidemic of NCDs. The early results are promising, but the long-term results need to be assessed [26].

Because of poor funding and patronage, the government health-care facilities at the primary care level are understaffed, and lacking material and medicines. This causes a shift of patients to low-quality private clinics or to the secondary and tertiary care facilities, which are then inundated with primary care problems, thus diluting the tertiary care service. This produces a compromised health-care delivery system. The present government has realized these issues and has changed the long-held health finance system. Pakistan is divided into four provinces and two federally administered areas. The central or federal health departments develop the policies, and the provincial health departments deliver health care. Previously, the funding remained with the provincial governments, but now, the funds have been allocated to the district level governments with the result that the funds are being allocated to the community-based programs. Currently, resources are channeled to tertiary care for treatment of diseases. Nevertheless, preventive care programs at the community level may be the answer to the burgeoning NCDs such as cardiovascular disease.

Drug Use and Expenditure

Health-care finances in Pakistan are mostly patient OOP payments. More than 80% of the THEs are for drugs. Drug expenditures are large with annual sales of US \$1.2 billion and an annual growth rate of 10% to 15%. The pharmaceutical industry comprises 411 local and 30 multinational companies, which produce 125 categories of medicines [27]. Ninety-five percent of the raw material used in drug manufactures is imported, thus adding to the total imported drug expenditures. In 2005, the drug imports were US \$257 million, and the exports were US \$50.4 million. The total drug expenditure was US \$353 million. The local production was US \$1 billion, and the local consumption was the same. The local drug share was 47% versus 53% share by multinational companies. There was an increase in the export of pharmaceuticals of about 17% [28]. The pharmaceutical industry is robust and developing to serve the 162 million people in the country. A few of the local drug companies are also exporting to other countries in the region, and it is time to consider developing a forum to bring the industry, the academia, and the government on the same platform to improve meeting the health needs of the people.

In 1993, prices were deregulated to encourage competition, which resulted in a huge price hike (up to 400% for some). This caused the imposition of a freeze in prices, which exists even today, but despite the freeze, drug prices continue to rise. In 1997, the national drug policy was announced but has yet to deliver benefits to the people in terms of enhanced

access to quality-assured EDs [29]. The Drugs Control Office has published the third revision of the National Essential Drug List (NEDL), which contains 452 drugs. This makes it the largest NEDL in the South Asian region. The MOH requires that all drugs purchased by health department are on the NEDL [30].

Drug Management and Pharmacoeconomic Guidelines

Drug management and pharmacoeconomic guidelines currently do not exist in Pakistan. With the situation described, it seems an important consideration that Pakistan should use pharmacoeconomics as a tool for decision-making in the future. Because of paucity of health resources, it is only prudent that the use of drugs and devices be evidence-based and economically viable. As far as research goes, the state of affairs has been unsatisfactory. There has been a dearth of local data, which is very much needed for the country. Despite the Pakistan Medical Research Council (PMRC) that was created very early after the inception of Pakistan, there has been little significant research effort. Pakistan has relied mostly on evidence accumulated from foreign sources, which, at times, make the application to the local populace and demographics very difficult. Most of the research has been conducted by generating retrospective statistical data of variable quality rather than original research. Very few projects have optimal public health impact. The PMRC has funds, which go unutilized because of lack of proposals and a tedious process of applying. In short, the atmosphere is not conducive for research as there is a lack of infrastructure, funding, and academic incentives. Furthermore, data that are available are not provided to or is not used by the decision-makers in creating a positive impact on the population. Decisions are often based on unbalanced anecdotal experience or skewed by biased selection of the team of decision-makers. We are currently far from the point where we can implement pharmacoeconomic guidelines. Nevertheless, with the participation as an active member in the Asia consortium of ISPOR, the seeds have been sown, and the will has been mobilized; the results of which hopefully will be seen in the near future.

Role of Pharmacoeconomic Research

The challenge is to encourage evidence-based practice, to curb irrational drug prescribing and irresponsible dispensing in the community, and to control self-medication and noncompliance by the consumers. Being a developing economy with poverty as a major public concern, there is a need to impart knowledge to make usage of drugs economically efficient. All actions need to be governed by laws for smooth and harmonious functioning, and laws to regulate drugs need to be implemented and updated. In doing all of these, the process needs to be as transparent as possible.

There needs to be an awareness created for the subject of pharmacoeconomics in the country, especially at the university level. This will help build capacity through trained manpower. Pharmacoeconomic research needs to be fast tracked to generate local economic information, especially original research in priority areas. Evidence-based educational, managerial, and regulatory interventions are needed. This will help in developing and strengthening the management/control of drug expenditures, especially at the local level. Pakistan is at the infancy of pharmacoeconomics and needs not only to learn from other countries, which have developed guidelines, but also countries in the region, which are developing pharmacoeconomic infrastructure and guidelines.

Malaysia

Health-Care System and Health Financing System

Malaysia consists of 13 states and a federal territory covering an area of 330,252 square kilometers. The population of Malaysia in 2005 was estimated to be 25.6 million with an annual growth rate of 2.1%. Bumiputra forms 65.1% of the population; Chinese, 26.0%; Indians, 7.7%; and 1.2% others. Sixty-two percent of the population lives in the urban areas. The population is relatively young with 32.9% between the age of 0 to 14 years, 62.9% between 15 and 64 years, and only 4.2% more than the age of 65 [31].

Public and private sector providers play an important role in the provision of health-care services in Malaysia. In the public sector, the MOH is the main government agency responsible for providing health-care services in the country. Other ministries that also provide health-care services in the countries are the Ministry of Higher Education, Ministry of Defense and Ministry of Internal Affairs, and Ministry of Women, Family, and Community Development. The health system is highly centralized with most planning and organization of health services being carried out centrally.

The lowest level of health services in the hierarchy is at the district level, each with a population of about 100,000 to 200,000. Every district is served by a number of rural health units, each covering a population of around 50,000. In each rural health unit, there are two types of health facilities: health centers and community clinics. There are four types of hospitals in the public sector under the MOH: district hospitals, state general hospitals, national referral center and special institutions, and non-MOH hospitals. The district hospitals typically have between 100 and 200 beds, and are normally run by 6 to 10 medical officers. State general hospitals have 500 to 1500 beds. Each state has one state general hospital except for the state of Sabah, which has two. These hospitals provide outpatient and inpatient care in general surgery, pediat-

rics, medicine, obstetrics and gynecology, and psychiatry. Services are provided by both specialist and nonspecialist medical officers.

The National Referral Center is the highest level of hospital in the hierarchy. This hospital has 2800 beds and is located in Kuala Lumpur. Although it receives referrals from other parts of the country, especially for cases which need specialized care not available in state general hospital, such as neurosurgery and radiotherapy, it also provides outpatient and inpatient care for the surrounding population.

There are seven special medical institutions that provide inpatient services for specific diseases in the country: the National Tuberculosis Center, the Hospital for Leprosy, and five mental hospitals. Private health providers in Malaysia can be divided into four main groups: private practitioners, private hospitals, private nongovernmental organizations, and practitioners of traditional medicine.

Private practitioners are registered doctors who provide services through private clinics. Currently, there are 5642 private general practitioners clinics and 535 private specialist clinics in Malaysia [32]. Private hospitals are licensed under the Private Hospital Act of 1971 and defined as any private facility with more than one bed. There were great variations in the size of the hospitals in the country, ranging from 2 to 406 beds in 2004. The number of private hospital beds remains stagnant over the past 5 years to about 20% to 22% of the total hospital beds in the country. Most of these private hospitals were located in the cities and in the more developed states of Malaysia. In 2004, 48.4% of all doctors, 54.1% of dentists, and 76.2% of pharmacists in the country were employed in the private health sector [33].

It was estimated that the country spent 3.7% of its GDP on health care in 2004. This figure is quite low compared to most developed nations. The government financed most of the resources in health care, spending 58.3% of the total national health expenditure. Private expenditure accounts for the remaining 41.7% of the expenditure.

Public health services are financed mainly from taxes on earned income. Other sources of financing for health services are private voluntary insurance, social security, and user fees. Private voluntary insurance is gaining popularity now because there is no compulsory insurance or NHI in Malaysia yet at the moment. It is estimated at least one-quarter of the population is covered by some form of voluntary health insurance in Malaysia [34]. The government is currently in the process of establishing the National Health Financing Scheme. A working committee has been formed, and the MOH has officially announced that the scheme will be established within the next 2 years [35].

Highly subsidized user fees are charged for inpatient and outpatient services in all public hospitals.

Under the MOH fee schedule, patients are charged RM 1.00 for treatment in general outpatient clinic, and RM 5.00 for specialist care in public hospitals. Services in the health centers of rural health units are free of charge. Charges for inpatient care are capped at the maximum of RM 500 per admission in third class wards of public hospitals.

Drug Use and Expenditure

Data on drug use and expenditure are only available in the public sector. In 2004, the MOH spent 10.7% or RM 963 million of its budgets on drugs. Using the estimates from national health accounts, the national spending on drugs is about RM 1666 Million. Therefore, the per capita expenditure in the public sector for drugs is about US \$27. In Malaysia, the drugs provided to patients in public facilities are highly subsidized. The cost of drugs is bundled together with the user fees. For example, in public hospitals, user fees of RM 1 charged to patients includes drugs, consultations, and basic laboratory investigations. It was estimated that the actual cost of outpatient treatment in public hospitals is between RM 20 to RM 25 per visit. In the private sector, private practitioners provide consultations and also dispense drugs to patients. Typically, patients in private clinics were charged between RM 30 and RM 35, which includes drugs and consultations [36]. Doctors in private clinics usually get more income by drug dispensing than providing consultations. Recently, there were calls to remove the dispensing rights from private clinics. Nevertheless, the Malaysian Medical Association opposed the proposals on the grounds of patient convenience and inadequate number of pharmacy outlets in the country [37].

Drug Management and Pharmacoeconomic Guidelines

The Drug Control Authority (DCA) is the agency responsible for the licensing and registration of all drugs in the country. Established as an executive body under the Control of Drugs and Cosmetics Regulations 1984, the agency has the task to ensure the safety, quality, and efficacy of pharmaceuticals, health, and personal care products that are marketed in Malaysia. The National Pharmaceutical Control Bureau of the MOH serves as the secretariat to the DCA. The bureau undertakes the daily operations of drugs and cosmetics registration together with monitoring and surveillance activities delegated by the DCA.

Under the MOH, drug costs are controlled by various mechanisms. In the national drug formulary, drugs are grouped into three categories. List A are very expensive drugs and are allowed to be prescribed only by specialists. List B drugs are moderately priced drugs, which are allowed to be prescribed by medical doctors only. List C consists of very cheap drugs, which are allowed to be prescribed by nurses and other paramedics. The government purchased the drugs cen-

trally in bulk to reduce the price. Clinical practice guidelines have been developed for selected groups of illness in government hospitals to reduce the variations in drug usage, to control drug costs, and to improve the quality of care. Since 1995, the MOH established the HTA Unit, which carries out the evaluation of expensive technology including pharmaceuticals. Nevertheless, the unit plays only an advisory role and produces guidelines on the introductions of new drugs. Lack of trained human resources is the main obstacle faced by the HTA Unit to function effectively to control drug costs in the country [38].

Role of Pharmacoeconomics

Pharmacoeconomics and outcomes research is very new in the country. As other research activities in the country, the government is the main funding agency. The Ministry of Science and Innovation provides research grants under Intensified Research in Priorities Area (IRPA) mechanisms for all research areas including pharmacoeconomics. Every year, the grants are open for applications. In public universities and institutions of higher learning, the Ministry of Higher Education provides limited funding under a short-term grant for academic staff and postgraduate students to undertake research projects. Research projects carried out in the country in the area of pharmacoeconomics were mostly related to clinical trial funded by pharmaceutical companies. Drug-costing studies, and studies on cost-effectiveness and cost benefit are becoming more popular study types being funded by pharmaceutical companies.

Major obstacles to pharmacoeconomic research in Malaysia include inadequate funding and trained human resources. Other limitations in research and development in Malaysia include the lack of protected time for researchers in institutes of higher learning and universities. Limited access to data and information for research purposes is another challenge faced by the researchers. Dissemination of research findings is also limited by the lack of publication skills among the researchers, and made worse by the control on publication by relevant authorities. Another major obstacle is the inability to turn research output into policy and practice for a number of reasons including the lack of skills among policymakers to make full use of research findings, and the lack of innovations among policymakers.

India

Health-Care System and Health-Care Financing System

In India, allopathic (western) and complementary and alternative medicine health-care practices (ayurveda, unani, siddah, and homeopathy) operate side by side.

Many patients switch from one practice to another when relief is not adequate. Higher-quality public health-care system exists only in larger cities, but is virtually nonexistent in villages. The private health care, although unaffordable for many, is booming. The challenge before India is to make health care accessible for the majority of its people. Allopathic health care has emerged as one of the largest service sectors in India. In 2004, the national health-care spending equaled about 5.2% of nominal GDP, or about US \$34.9 billion. Health-care spending in India is expected to rise by 12% per annum from 2005 to 2009, and to scale up to about 5.5% of GDP, or US \$60.9 billion, by 2009. As far as the ratio of doctors and nurses to the population is concerned, it is 5.9 doctors, 0.8 nurses, and 0.47 midwives for 1000 people, which adds up to 1.86 health workers for every 1000 people. According to the Union Ministry of Health and Family Welfare's Health Information of India, the country had 67,576 government doctors, meaning, each doctor was serving roughly 15,980 people in 2004 [39].

Of the total US \$24 million spent on health care in India, the private sector health-care spending is approximately 77% of the total amount (US \$18,643 million). Of this, 86% is OOP expenditure. Public sector expenditure is 21% (US \$4953 million), and the external aid accounts for 2% (US \$565 million) [40].

The proportion of insurance in health-care financing in India is very low. The extent of coverage as well as the type of coverage is key issues related to insurance penetration. Only around 10% of the population is covered through health financing schemes. Selection criteria by suppliers often restrict the poor (and more likely to be ill) from affordable prepayment schemes. The voluntary health insurance market, which is estimated at Rs 4 billion (US \$86.3 million) currently, is growing fast. Industry estimates put the figure at Rs 130 billion (US \$2.8 billion) [41].

Drug Management, Expenditure Pharmacoeconomic Guidelines

The pharmaceutical sector is growing at a rapid pace, next to the information and technology (IT) sector. The pharmaceutical sector has grown by about 100 times to about US \$10,000 million during the last 15 years. Likewise, pharmaceutical exports have increased to US \$35,000 million. It is estimated that by 2010, the pharmaceutical industry has the potential to achieve US \$20,000 million in formulations, and US \$6,000 in bulk drugs. This rapid growth of pharmaceuticals has led to the revision of the National Drug Policy of 2002 into the National Pharmaceuticals Policy of 2006 [42].

Because India is a highly populated and vast country, health is a state subject. Although there is an NLEM most recently published in 2003, it serves only as a model list. Each state is developing its drug policy.

Some of the states have developed policies such as EDs list, formulary, treatment guidelines, and monitoring and evaluation system. Nevertheless, the difficult part is the implementation of the policy in majority of the states. One state that has succeeded is the state of Delhi through public-private partnership effort (Delhi Society for Promotion of Rational Use of Drugs). The success in other states is meager [43].

Role of Pharmacoeconomics

The role of pharmacoeconomics in India is in infancy at present, although clinical research organizations are being formed rapidly. Several multinational pharmaceutical companies and research organizations find India a good destination for their studies. The India Chapter of ISPOR has been formed, but it needs to develop the platform for pharmacoeconomics. Nevertheless, methodology, training, and initiatives are needed for its development.

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