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The role of health technology assessment on pharmaceutical reimbursement in selected middle-income countries

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ABSTRACT

Objective: Middle-income countries are often referred to as developing or emerging economies and face multiple challenges of severe financial stresses in their health care sectors, and high disease burden. The objective of this study is to provide an overview of how health technology assessment (HTA) is used and organized in selected middle-income countries and its role in the process of pharmaceutical coverage.
Methods: We selected middle-income countries where HTA activities are evident: Argentina, Brazil, China, Colombia, Israel, Mexico, Philippines, Korea, Taiwan, Thailand, and Turkey. We collected and reviewed relevant information to describe the health care and reimbursement systems and how HTA relates to coverage decision-making of pharmaceuticals. This was supplemented by information from a structured survey among professionals working in public and private health insurance, industry, regulatory authorities, ministries of health, academic units or HTA.
Results: All countries require market authorization for pharmaceuticals to be sold and most countries have a national plan defining which pharmaceuticals can be reimbursed. However, the use of HTA in reimbursement decisions is still in its early stages with varying levels of HTA guidance implementation.
Conclusions: The study provides evidence of the development of HTA in coverage decision-making in middle-income countries. Increased health care spending and the resulting access to modern technology give a strong impetus to HTA. However, HTA is developing with uneven speed in middle-income countries and many countries are building on the organisational and methodological experience from established HTA agencies.

1. Introduction

Every country has a structure of health policies that influences – and is influenced by – health technology. Health technology is a broad concept. It is defined by the International Network of Agencies for Health Technology Assessment (INAHTA) as "any intervention that may be used to promote health, to prevent, diagnose or treat disease or for rehabilitation or long-term care. This includes pharmaceuticals, devices, procedures, and organizational systems used in health care" [1].

The rapid diffusion of health technologies around the world provides challenges to governments to provide high quality care to meet their population health needs most effectively while managing health care budgets and safeguarding the basic principles of equity and accessibility of care [2]. This means that governments need to ensure accountability and value-for-money. There are several countries that have developed systems to identify health technology that provide the best value-for-money. For this purpose, health technology assessment (HTA) is increasingly used.

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Health technology assessment is defined as "the systematic evaluation of properties, effects, and/or impacts of health technology. It may address the direct, intended consequences of technologies as well as their indirect, unintended consequences" [1]. Its main purpose is "to provide structured, evidence-based input to policy-making to inform the formulation of safe and effective health policies that are patient-focused and seek to achieve best value. Despite its policy goals, HTA must always be firmly rooted in research and the scientific method" [3]. It is mainly used in relation to regulation of the health care system, quality of care, and payment for care (i.e. reimbursement decisions) [4].

Health technology assessment developed because of rising health care costs and limited health care budgets. It is known that the development of HTA correlates with gross domestic product (GDP) per capita [5]. As HTA is of growing interest to countries outside Europe, USA, and Oceania our aim is to provide an overview of how HTA is used and organized in selected middle-income countries and its role in the process of pharmaceutical coverage. Middle-income countries are often referred to as developing or emerging economies and face multiple challenges of severe financial stresses in their health care sectors, and high disease burden. The focus is solely on pharmaceutical coverage as the use of HTA information in the reimbursement of pharmaceuticals is currently the most advanced area of research in the discipline [6].

2. Methods

2.1. Selection of middle-income countries

Morgan Stanley's Capital International index (2006) was used to identify middle-income countries as investment information sources tend to offer a more dynamic classification than reliance on GDP per capita data. From the list of 25 countries [7] we focused on countries outside Europe and North America as HTA systems are set-up and active in (most of) these continents. On the basis of an internet based document review, we included the following countries that have current activities in HTA: Argentina, Brazil, China, Colombia, Israel, South Korea, Mexico, Philippines, Taiwan, Thailand, and Turkey.

2.2. Development of evaluation framework

On the basis of the document review described below we developed a template to describe the health care and reimbursement systems in the selected countries. The template used consists of four main components: characteristics of the health care system, regulation of pharmaceuticals, financing of pharmaceuticals, and reimbursement decisions. The organization of HTA and how it fits in the process of (pharmaceutical) coverage decision-making was also an element. We further included data on relevant socio-economic (health) indicators, including population, gross national income per capita, life expectancy at birth, total expenditure on health per capita, total expenditure on health as percentage of GDP, and out-of-pocket payments for health as percentage of total health expenditure.

2.3. Document review

We have collected and reviewed relevant documentation by using multiple database searches, including: World Health Organization (WHO), Pan American Health Organization, European Observatory on Health Systems and Policies, Organization for Economic Co-operation and Development, the World Bank, Asian Development Bank, INAHTA, and PubMed/Medline. Search terms (<country> AND health system OR health care system, social care insurance OR health insurance, pharmaceutical strategy, reimbursement of pharmaceuticals, and health technology assessment) have been limited to publication dates from 2000 to 2008 (inclusive) that are available in English and in the public domain. In addition, the journals Health Affairs, Value in Health, Pharmacoeconomics, Health Policy, and the International Journal of Technology Assessment in Health Care were hand-searched for relevant articles. All identified documents have been examined and those that are relevant have been retrieved for inclusion in the study. Reference lists of retrieved documents have been hand-searched to identify additional publications. On the basis of the desk research that was performed between September 1st and October 15th 2008, we have drafted country studies that were reviewed by our senior expert (DB) who played an important role in the worldwide development of HTA in the past decades [8].

2.4. Web-based survey

To collect more in-depth information on the organisation and the role of HTA in the coverage decision-making processes we performed a web-based survey. The survey was aimed at key informants (including all heads of HTA agencies and/or key persons representing organisations involved in HTA/pricing and reimbursement of pharmaceuticals) in the selected countries. The survey consisted of 36 close-ended and open-ended questions and included six sections:

- General information about the survey respondent.
- The organisation of HTA in the respondent's country.
- The regulation of medicines in the health care system.
- The role of HTA in coverage decision-making in the respondent's country.
- The final two sections of the survey provided opportunities for further comments and also asked respondents to indicate what the key issues, trends or topics in the field of HTA that their country will face in the upcoming five years.

The survey (in English) was piloted with two potential respondents to ensure technical functioning, relevance and understanding of the questions.

We targeted 265 key informants in the field of HTA in the selected countries representing national health ministries, HTA agencies, university/research organisations, third party payers, medical device industries, pharmaceutical

Table 1
Breakdown of responses by country (>50% complete).

	National health ministry	HTA agency	University research organisation	Third party payer	Medical device industry	Pharmaceutical industry	Regulatory authority	Other	Total
Argentina		1	2						3
Brazil	3	1	5			1		1	11
China		1	2	1			1	1	6
Colombia			1						1
Israel	1	1	1						3
Mexico	3							1	4
Philippines			1					2	3
South Korea			1		1			1	3
Taiwan		2					1	1	4
Thailand	1	2	1	1					5
Turkey	1		1					1	3
Total	9	8	15	2	1	1	2	8	46

Other: State Health Authority of Rio Grande do Sul (Brazil), Medical doctor (China), Individual expert (Mexico), NGO (Philippines), Health think tank (Philippines), Independent organization under government (South Korea), Pharmacy Department (Taiwan), Social Security Institution (Turkey).

industries, regulatory authorities or other organisations. Potential respondents were identified by means of our own and the funding source networks, authors of relevant articles, attendees of relevant HTA conferences, and members of the network on the economic evaluation of health care programmes and its application in decision-making in Latin American countries. The online survey was distributed by email through CheckMarket (an online software platform that also helps with distribution and analysis of online surveys) to the targeted panel on September 24th 2008 and was live for completion until January 16th 2009. To maximize response rates two reminders were sent to respondents who had not or only partially completed the survey.

In the analysis, only surveys of which more than 50% of the questions were complete (i.e. $n = 5$ were excluded from the sample) were included. The survey responses (46/265, see Table 1) were analysed by country using cross-table analysis in SPPS (version 15.0 for Windows). The results were based on the information generated through the document review and the web-based survey and were reviewed by our senior expert (DB).

3. Results

3.1. Characteristics of the health care system

Most of these countries have health care problems related to both equity and efficiency. The trend in all countries is toward public sector programs covering the entire population. Most countries have a mix of insurance systems but differ in the share of public and private insurance, the degree of decentralization, and populations covered (e.g. urban/rural population). In China, for example, a distinction is made between urban area insurance covered by the New Cooperative Medical scheme and rural area insurance, which is covered by city-based social health insurances [9]. Brazil established a health system based on decentralized universal access, with municipalities providing comprehensive and free health care to each individual in need financed by the states and federal government [10].

Based on socio-economic indicators we observed a positive association between gross national income and total health expenditure per capita. Countries with more developed economies like Israel and South Korea, spent an average of international $ (I$) 2263 and I$ 1487 per capita respectively in 2006. Middle-income countries with rapid-growth health economies, such as Brazil and China, spent an average of I$ 765 and I$ 342 per capita respectively in 2006. Low- and middle-income countries have spent an average of I$ 413 per capita in 2005, more than double the amount (I$ 189) per capita spent in 1995 (constant dollars). Health expenditure in these countries has overall been growing at a rate of 8.1% per year [11].

Out-of pocket expenses are common in the observed countries despite increasing government expenditures on health. Based on WHO figures (2006) we found ranges between 6% (Colombia) and 54% (China). Socio-economic status is inversely associated with disparities (i.e. income proportion used by lower socio-economic groups is greater). In other words, as socio-economic status improves, the health system becomes more equitable with the aim of reducing disparities in access and health outcomes [11,12].

In the observed countries the market for pharmaceuticals is – in terms of the volume of sales for products – mostly dominated by domestic players producing generic, less expensive pharmaceuticals. Branded imported pharmaceuticals from predominantly foreign pharmaceutical companies tend to dominate the value of sales for products.

In Table 2 we summarise the key characteristics of the health care systems studied.

3.2. Regulation and financing of pharmaceuticals

Regulation of the health care system in the observed countries is either centralized or a combination of regulation by central and local governments. With regard to the regulation of pharmaceuticals the Ministry of Health holds responsibility but in most countries regulatory tasks (e.g. testing of medicine samples, quality control, post-market surveillance, and promotion) have been designated to a national regulatory authority (see Table 3). All governments require market authorization for pharmaceuticals to be sold.

Table 2
Characteristics of selected middle-income health care systems.

Characteristics	Argentina	Brazil	China	Colombia	Israel	Mexico	Philippines	South Korea	Taiwan	Thailand	Turkey
Health care system (public, private, mixed)	Mixed	Mixed (large public system)	Mixed-depending on the location	Mixed	Public	Mixed	Public	Public	Public	Mixed (large public system)	Mixed
Gross national income per capita, PPP (current international $, 2007)	12,990	9,370	5,370	6,640	25,930	12,580	3,730	24,750	16,230	7,880	12,350
Total expenditure on health per capita (PPP int. $, 2006)	1,665	765	342	626	2,263	756	223	1,487	964	346	645
Out-of-pocket expenditure for health as percentage of total health expenditure (2006)	23.9	33.3	53.8	6.4	24.1	52.5	48.4	36.9	34.4	27.3	20.0
Obtaining pharmaceuticals through domestic production and/or import	Mainly domestic pharmaceutical production of generic drugs, branded drugs are imported	Mainly domestic pharmaceutical production of generic drugs, branded drugs are imported	Mainly domestic pharmaceutical production of generic drugs, branded drugs are imported	Around 70% of the market is supplied by the well-developed domestic industry, which is dominated by multinationals partly due to the fact that the domestic industry is heavily dependent on imports of raw materials	Substantial domestic pharmaceutical production of generic drugs, branded drugs are imported	Mainly domestic pharmaceutical production of generic drugs. Branded medicines will increasingly be imported	Parallel imports of inexpensive generic drugs from India and Pakistan. Foreign firms take up largest part of the market with branded expensive drugs	Mainly domestic pharmaceutical production of generic drugs, branded drugs are imported	Mainly domestic pharmaceutical production of generic drugs, branded drugs are imported	Large domestic productions of drugs, but main ingredients are imported. The Government Pharmaceutical Organisation (GPO) maintains a semi-monopolistic position	Domestic production and imports, only branded original and branded generic drugs are available

Table 3
Key characteristics of regulation and financing of pharmaceuticals in selected middle-income countries.

Characteristics	Argentina	Brazil	China	Colombia	Israel	Mexico	Philippines	South Korea	Taiwan	Thailand	Turkey
Actors involved in the regulation of pharmaceuticals	Ministry of Health and Social Action (MSAS) through the Superintendence of Health Services	National Health Surveillance Agency (ANVISA), Drug Market Regulation Council (CMED), Commission for Incorporation of Technologies (CITEC), Ministry of Health (Secretariat for Science, Technology, and Strategic inputs (SCTIE)– Department of Science and Technology (DECIT))	State Food and Drug Administration (SFDA, plus affiliated agencies), Centre for Drug Evaluation (CDE), Ministry of Public Health, National Development and Reform Commission (NDRC), Bureau of Drug Policy Administration (BDPA)	Health care Regulating Commission (CRES)	Ministry of Health	Federal Commission for the Protection against Sanitary Risks for licensing drugs, Inter-institutional Commission of the Basic Formulary of Inputs of the Health Sector for the development of Basic Formularies	Department of Health (DOH), Bureau of Food and Drugs (BFAD), Bureau of Health Facilities and Services (BHFS), Bureau of Health Devices and Technology (BHDT)	Ministry of Health and Welfare	Department of Health (DoH), Bureau of Pharmaceutical Affairs (BPA), Bureau of National Health Insurance (BNHI), Centre for Drug Evaluation (CDE)	Ministry of Public Health (MoHP), Thai Food and Drug Administration (TFDA)	Ministry of Health, General Directorate of Pharmaceuticals and Pharmacies (GDPP)
Reimbursement lists	National formulary	National list of essential drugs	State Essential Drug List (SEDL)	National list of essential drugs	The Israeli National List of Health Services (NLHS)	Basic Formulary and Catalogue of Inputs	Philippine National Drug Formulary (PNDF)	A mix from old drugs reimbursement listing (21,000 drugs), with a positive list system since 2008	National formulary	National Essential Drug List	Positive drug list/non-official formulary, formularies under social insurance (Social Security Institution (Sosyal Sigortalar Kurumu, SSK))

Forms of reimbursement	Decisions on the broad allocation of resources and priority setting are the responsibility of the Provincial and Municipal Health Secretariats and the Social Works through the Superinten-dence of Health Services. This institute is specifically in charge of a compulsory minimum coverage package to be included in the health insurance plan of every single health-care institution	Municipalities are responsible for providing a set of basic health care services for their respective populations. They receive capitation payments, which are transferred from the Ministry of Health to the Municipal Health Funds	Fee-for-service, per diem and capitation	National Social Health Insurance	All residents are entitled to receive services from the NLHS from their health plans (HMOs)	The law stipulates that the package must be progressively expanded and updated annually on the basis of epidemiological trends, technological developments, and the availability of resources. Drugs are free of charge if the institution or pharmacy has the product in stock	Fee-for-service scheme, plus Relative Value Scale, capitation	Cash/directly to claimant	Fee-for-service, per diem, capitation, diagnosis-related groups (DRGs), global budgets, or linked to clinical outcomes	Capitation and diagnostic related group (DRG), fee-for-service payments under CSMBS	There is no unified reimbursement system in place. Reimbursement used to be driven by prices. However, any drug not included in the formularies will not be reimbursed, pharmacists are paid on a regressive margin basis from health insurance funds and fee-for-service

Table 4
Organisation and role of HTA in reimbursement decisions in selected middle-income countries.

Characteristics	Argentina	Brazil	China	Colombia	Israel	Mexico	Philippines	South Korea	Taiwan	Thailand	Turkey
Organisation mainly involved in HTA	IECS – Institute for Clinical Effectiveness and Health Policy	DECIT-CGATS – Secretaria de Ciência, Tecnologia e Insumos Estratégicos, Departamento de Ciência e Tecnologia	Department of Science and Education (DSE)	CTMT-Technical Committee of Medications and Technology Evaluation	ICTAHC-Israel Center for Technology Assessment in Health Care	CENETEC-Centro Nacional de Excelencia Tecnológica en Salud	PhilHealth	HIRA-Health Insurance Review Agency	CDE-Center for Drug Evaluation	HITAP-Health Intervention and Technology Assessment Programme	Social Security Institution
Type of organisation	Private not-for-profit agency. IECS has a HTA unit that comprises of 10 researchers (epidemiologists, health economists, social scientists and a librarian)	DECIT is part of the Ministry of Health. CGATS is tied to DECIT and currently consists of 15 professional in-house staff (e.g., pharmacist, nutritionists, physiotherapists, medical doctors, and economists) and supported by about 40 external consultants	Part of Ministry of Health	Advisory body of the National Council on Social Security in Health (CNSSS), including one medical/pharmaceutical chemist, pharmacologist, biomedical engineer, epidemiologist and health economists. The Ministry of Social Protection in collaboration with PAHO is currently organizing a HTA agency with the active participation of the academic sector	Independent research center. It is a multidisciplinary unit, comprised of physicians, nurses, pharmacists, economists, and other professionals (permanent number of staff: 8)	Part of Ministry of Health focusing on three areas: medical equipment and devices, health technology assessment and e-Health	Government-owned and controlled corporation attached to the Department of Health. The HTA Committee consist of an expert panel on clinical epidemiology, family medicine, internal medicine, health economics, medical devices, pharmacology and toxicology, EBM, surgical procedures, quality assurance improvement, biostatistics and health management, planning and policy; representatives from PhilHealth's Quality Assurance Group, Program Management of Claims, Claims Review Office, and Accreditation Department; and a secretariat	Independent but under supervision of the government. Number of staff is 23. Recently, the committee for new HTA (CNHTA) is established. This is a national independent HTA organization that will take over the functions of the HTA Center of HIRA but not the evaluation of drugs	Established by the Department of Health. HTA unit consists of 9 permanent staff (including physician, economists)	HITAP has no legal authority but serves as a technical agency for all public health authorities at the national level. Permanent number of staff: 34	Part of Ministry of Labour and Social Security

Formal HTA programme	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	No
Role of HTA	IECS analyses the clinical, economic and social impact of drugs, devices, practices and health care services to inform policy-makers, health professionals, patients and users	DECIT monitors and assesses HTA studies produced by academic institutions. Also, it produces reports for dissemination of HTA studies, with the aim to support decision-making	The new health reform proposal (October 2008) mentioned that health economic studies will be gradually requested when drug companies apply for new drug approval. The increasing number of pharmacoeconomic and pharmaceutical outcome research studies has had some impact on policy-making	CTMT is incorporating scientific and economic evidence-based decision-making	ICTAHC advises the Ministry of Health on national policy in technology management. The considerations are mainly clinical-epidemiological (life saving, improvement quality of life, number of patients), expected budget impact, co-payment by the patient and family, acceptability and importance to the clinical practice	Pharmaceuticals are scrutinized for efficacy, safety and cost-effectiveness to decide on the inclusion/exclusion of services in the health insurance package	Effectiveness, safety and cost-effectiveness of new drugs in comparison with standard treatment such as the formulary drug are assessed by the HTA Committee that PhilHealth may reimburse and it develops recommendations on the indications for their use	Reimbursement of drugs includes the use of economic data. The HIRA has developed a set of pharmacoeconomic guidelines providing pharmaceutical companies with instructions on how to prepare economic data before submitting a drug for reimbursement and pricing	CDE performs regulatory evaluation of clinical trial protocols, marketing application dossier of new drugs and medical devices, and provides advice to the Department of Health	HITAP focuses on capacity building, methodological standard setting, development of guidelines for economic evaluation, priority setting for HTA and conducting economic evaluations	The drug reimbursement decisions concerning placement on positive lists are taken by the SSK drug committee, based on therapeutic need, added value, and financial burden issues
Provision of information of industry to regulatory authority:											
Copy of market authorization, sales permission, price approval or patient leaflet	Yes	Yes	Yes	Not clear	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Comparative clinical evidence	Yes	Yes	Not clear	Not clear	Yes	Yes	Not clear	Yes	Not clear	Yes	Yes
Pharmacoeconomic data	No	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Reimbursement decisions/situation in other countries	Not clear	Yes	No	Not clear	Yes	Yes	Not clear	Yes	Yes	Yes	Yes

In some countries governments use price controls as a short-term cost containment measure. The Philippines is an interesting example of how efforts are made to decrease the prices of essential medicines by at least 50%. The Department of Health has set-up a low-cost drug programme implemented by the state procurement agency, the Philippine International Trading Corporation (PITC). The PITC procures inexpensive parallel imported branded drugs (mainly from India and Pakistan) to the Department of Health, and hospitals and accredited privately operated retail drugstores nationwide. In China, the National Development and Reform Commission is mandated to approve and regulate the prices of new products that are suggested by the manufactures based on so-called self-reported costs [13]. Current government policy in China focuses primarily on trying to control drug spending through price regulations at selected levels of the supply chain [14].

Most countries have a national plan defining which pharmaceuticals can be reimbursed. For a drug to be eligible for reimbursement it has to be included in, what is often called, the National Formulary (or National List of Essential Drugs). However, the requirements (e.g. information on efficacy, safety, and pharmacoeconomic data) to be included in the formulary differ by country. Also, the reimbursement of pharmaceuticals is arranged differently by country ranging from the highly centralized (e.g. Turkey) to the fragmented (e.g. Argentina). In Turkey, pharmacists are paid on a regressive margin basis from health insurance funds and a fee-for-service scheme. Fee-for-services schemes are also observed in China, Philippines, Taiwan, and Thailand. In Argentina, for example, drugs are reimbursed by the Local Health Secretariat in the provinces and municipalities through the department of purchases in the public sub-sector, as well as individual social works (see Table 3).

Another distinction can be observed between social health insurance schemes that fully reimburse pharmaceuticals for patients in hospitals (e.g. Argentina, Turkey), and those schemes that only cover medicines on the national essential drug list (e.g. Israel and Colombia) (see Table 3). In most of the countries pharmaceuticals for persons receiving out-patient care are only partially reimbursed by the social health insurance schemes and co-financed by the beneficiary.

3.3. The organisation and role of HTA in reimbursement decisions

The development of health technology plays an essential role in promoting health and developing health systems. Evaluation of the introduction and use of health technology can support decision-making addressing problems related to both equity and efficiency. This means that HTA can contribute to the allocation of scarce resources, to the selection of cost-effective health technology, to greater efficiency and more effective services, and to quality assurance in care [15].

In all the countries under study the use of HTA was relatively undeveloped; however, the increasing establishment of HTA organisations indicates that HTA is gaining interest and attention. For example, the INAHTA had 27 members in 1998 [16], and it has now 46 member agencies from 26 countries. Of the eleven countries under study six organisations are a member of INAHTA (Argentina, Brazil, Israel, Mexico, South Korea and Taiwan). The Israel Center for Technology Assessment in Health Care became a member in 1998. All other organisations became a member after 2004 (Argentina and Mexico in 2005, Brazil in 2006, Taiwan in 2008 and Korea in 2009) [17].

HTA activities are evident in Argentina, Brazil, China, Israel, Mexico, South Korea, Philippines, Taiwan, and Thailand (i.e. funding is from private, government, and/or international agencies). Colombia is in the process of establishing an HTA agency [18]. The role of HTA agency/organization can be either seen as advisory or mandatory in regard to national reimbursement. The methods that are mostly used in HTA according to the survey respondents include economic evaluation, expert opinion (mentioned by the majority of respondents from all countries) and systematic reviews (all countries except the majority of the Turkish respondents mention not using it). Budget impact analysis is used as a method in HTA in the majority of the countries while qualitative analysis, post-market surveillance and clinical trials are used in HTA in some countries. The document review and the survey results show that efficacy is almost always included in HTA followed by safety and effectiveness. Cost aspects are included most of the time, followed by effectiveness and cost-effectiveness. The demand and additional effects of technology are sometimes included in HTA.

In Table 4 we present an overview of the organisation and role of HTA in reimbursement decisions in the selected countries.

The use of HTA in reimbursement decisions is still in its early stages with varying levels of HTA guidance implementation. We also found that gradually, pharmacoeconomic evidence and clinical data are required for drug applications. For example, in South Korea, Taiwan, Brazil and Mexico the HTA organisation has developed pharmacoeconomic guidelines providing pharmaceutical companies with instructions on how to prepare economic data before submitting a drug for reimbursement and pricing. Submission of pharmacoeconomic evidence is a mandatory requirement. In Mexico, economic evaluation studies are conducted to decide on the inclusion/exclusion of services in the health insurance package by the Directorate of Finance of the Mexican Institute of Social Security [19]. In China HTA is not yet used by the Chinese State Food and Drug Administration but the new health reforms (October 2008) state that pharmacoeconomic studies will be gradually requested when pharmaceutical companies apply for new drug approval from 2012.

4. Discussion and conclusions

Restrictions of this research lie in the scope of the literature retrieved (limited to publications that are available in English) and the implementation of the survey. For countries with more established HTA activities (e.g. Brazil) it appeared easier to identify, and get a response from, a large number of contact persons than for those countries with less established HTA activities (e.g. Turkey). Via our

network we were able to send the survey to HTA experts and other public health experts in Colombia and Mexico. Although our action has increased the response rate from these countries, the representativeness of these responses could be questioned. For this reason we have analysed the survey sample including responses from this source and excluding these responses to identify major differences in our findings. We found no significant differences in the findings using the two samples. Second, the initial response rate of the survey was relatively low due to the language barrier in several countries (e.g. Spanish speaking countries and Turkey). We therefore translated the invitation letters in Spanish and Turkish. We have not translated the complete survey, which might have helped to increase the response rate even further. Also, we believe that the fact that the survey was not anonymous could have been a potential barrier for responding. Therefore we have decided that the additional survey invitees could provide their responses anonymously.

Currently, HTA plays an increasingly important role in health care systems by supporting decision-making in health care policy and practice. Although HTA is most advanced in industrialised countries, there is a growing community around the world that is interested in developing and using HTA.

We found that a number of the publicly funded programs for payment of health services, such as PhilHealth in the Philippines, also sponsor HTA studies to support their decisions. However, public services play a limited role in funding HTA in the selected countries. When there are more public services, publicly funded HTA will also increase.

It seems that increased health care spending and the resulting demand for access to modern technology gives a strong impetus to HTA. The assessment and regulation of drugs are advanced in relation to other technologies. Also, the use of guidelines for HTA can help facilitate transparency of the process, especially if the guidelines are clear, comprehensive and standardized. Transparency of both the process and the methods used in HTA are of great importance for stakeholders (i.e. accountability) and can facilitate the effective use of HTA information in decision-making [20]. In many industrialized countries, as well as in some of the countries studied, these issues are addressed through external advisory committees or external experts (e.g. Brazil) [21].

In conclusion, HTA is developing with uneven speed in middle-income countries as some of these countries are building on experience and evidence from developed countries (for example Taiwan explicitly evaluates evidence reports from the HTA agencies in United Kingdom, Canada and Australia) [22]. Increasing levels of health care expenditure and the demand for new technologies gives a strong impetus to HTA. The lack of HTA in middle-income countries is often assumed to be due to the absence of formal HTA agencies. Therefore proposals are sometimes made, for example in South Korea, to establish a national agency along the lines of an embryonic National Institute for Health and Clinical Excellence [23]. This is an over-simplified view that does not take into account the complexity of local health care needs, service delivery arrangements and mechanisms available to implement guidance within the clinical community.

How can HTA be (further) developed in middle-income countries? A first priority area is to promote the understanding of the concept of HTA by sharing of expertise and experiences in middle-income countries among professionals, policy-makers, academia, industry, health insurance sector, patients, consumer organizations, and people in general.

Another priority is capacity building since most countries lack the capacity of trained and experienced personnel for carrying out, interpreting, and using the results of HTA. Recently, the Catalan Agency for Health Technology Assessment and Research has published a handbook on capacity building, as part of the European Network for HTA project. The book provides practical guidance and support on how to establish HTA activities, especially in countries with limited HTA capacity [4]. In addition, on-the-job training of persons from countries with no or limited HTA activity by HTA agencies abroad has been successful [24].

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