

MAPPING OF HEALTH TECHNOLOGY ASSESSMENT IN SELECTED COUNTRIES

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Objectives: The aim of this study was to develop and apply an instrument to map the level of health technology assessment (HTA) development at country level in selected countries. We examined middle-income countries (Argentina, Brazil, India, Indonesia, Malaysia, Mexico, and Russia) and countries well-known for their comprehensive HTA programs (Australia, Canada, and United Kingdom). **Methods:** A review of relevant key documents regarding the HTA process was performed to develop the instrument which was then reviewed by selected HTAi members and revised. We identified and collected relevant information to map the level of HTA in the selected countries. This was supplemented by information from a structured survey among HTA experts in the selected countries (response rate: 65/385).

Results: Mapping of HTA in a country can be done by focusing on the level of institutionalization and the HTA process (identification, priority setting, assessment, appraisal, reporting, dissemination, and implementation in policy and practice). Although HTA is most advanced in industrialized countries, there is a growing community in middle-income countries that uses HTA. For example, Brazil is rapidly developing effective HTA programs. India and Russia are at the very beginning of introducing HTA. The other middle-income countries show intermediate levels of HTA development compared with the reference countries.

Conclusions: This study presents a set of indicators for documenting the current level and trends in HTA at country level. The findings can be used as a baseline measurement for future monitoring and evaluation. This will allow a variety of stakeholders to assess the development of HTA in their country, help inform strategies, and justify expenditure for HTA.

Keywords: Health technology assessment, Middle-income countries, Healthcare systems, HTA process

A systematic evaluation of the level and trends in development of health technology assessment (HTA) is lacking. Previous studies generally focus on the best way to *perform* HTA (1). These include initiatives that aim to support the development of co-operation among HTA institutions such as Eur-Assess (1994–97), HTA Europe (1997–99), ECHTA/ECHAHI (European Collaboration for Assessment of Health Interventions) project (1999–01), EUnetHTA Project (2006–08), EUnetHTA Collaboration (2008–09), EUnetHTA Joint Action 1 (2010–12), and the International Network of Agencies for HTA (INAHTA). For example, the ECHTA/ECHAHI project developed a best practice of the HTA process based on well-recognized and internationally agreed characteristics along with a common understanding of the HTA process (2;3). This guidance was further developed and implemented in the EUnetHTA Col-

laboration and its successors, EUnetHTA Joint Action 1 and 2 (4).

Complementary to these initiatives, the objective of our study was to develop and apply an instrument to map the level of HTA at country level in selected countries.

METHODS

Development and Adjustment of the Instrument

In developing the instrument we distinguished two key elements of HTA: (i) the institutionalization of HTA and (ii) the HTA process itself.

The main sources used include EUnetHTA tools such as the Handbook on Health Technology Assessment Capacity Building (3), the report on best practice in undertaking and reporting HTA of the ECHTA/ECHAHI project (5), guidance of the International Information Network on New and Changing Health Technologies (EuroScan) regarding effective early warning systems (6), the INAHTA checklist to present HTA information (7) and the principles for HTA programs in different countries of the International Working Group for HTA Advancement (8).

The draft instrument consisted of the following domains: (i) institutionalization of HTA; (ii) identification; (iii) priority setting; (iv) assessment; (v) appraisal; (vi) reporting; (vii)

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dissemination; and (viii) implementation of HTA in policy and practice. The categories ii–viii have been used in the EUnetHTA Collaboration to describe the HTA process (5).

For each domain a set of criteria was determined along with indicators on how to measure each criterion using the key documents stated above. For example, an indicator for institutionalization is membership of the international society for the promotion of HTA (HTAi) and membership of INAHTA. The latter requires that the agency is not-for-profit, funded at least 50 percent from public sources and has a national / regional function (3). However, not all countries have formal HTA programs in place. We therefore added two indicators that reflect a less well institutionalized situation. In addition, a simple scoring system for each criterion was developed consisting of a grading scale that differentiates between the different levels of HTA development in a country. For example, we decided that an established agency that is a member of INAHTA reflects a more institutionalized level of HTA than a government-advising group outside INAHTA or the presence of elements to establish a (formal) HTA program if no agency or group is in place. Therefore, the score of a country with at least one national or regional agency/organization that is a member of INAHTA is higher (25) than the score of a country without a formal HTA program (i.e., a government-advising group outside INAHTA (score: 20) or no agency or group but elements of establishing a formal program are in place (score: 24 at the maximum) (see Table 1).

The instrument was adjusted by asking HTA experts with a strong interest in middle-income countries to give feedback. First, the instrument was sent by email to members ($n = 75$) of the interest sub-group on HTA in developing countries of HTAi (HTAi DC ISG) in June 2011. Second, the attendees (approximately 25) of the HTAi DC ISG meeting in Brazil (July 2011) were asked to review the instrument. Third, we asked a small sample of active HTAi members ($n = 10$), including HTAi DC ISG members as reviewers. In total, we received comments from six experts: two from India, two from Australia, one from China, and one from Poland. The respondents are well-known HTA experts in their respective countries. Their comments were used in developing the final version of the instrument.

Selection of Countries

To identify middle-income countries, we used the definition of the World Bank. Lower-middle-income countries are defined as countries with GDP/capita between \$1,006 and \$3,975 and upper-middle-income countries range between \$3,975 and \$12,275 (9). We aimed to include countries from different regions (Latin America and the Caribbean, Asia, and Europe) that undertake, according to our experience and knowledge at the start of the study, different levels of HTA activities. Argentina, Brazil (recently well developed HTA systems), Malaysia, Mexico (moderately developed HTA systems), India, Indonesia, and

Russia (no or some elements of HTA systems in place) were selected.

For benchmarking purposes three reference countries with well developed HTA systems from different regions (Asia-Pacific, North America, and Europe) were selected, namely, Australia, Canada, and the United Kingdom (England and Wales). These countries are often used in international comparisons of HTA systems.

Document Review

To map the level of HTA relevant information from the (gray) literature for each country was collected and reviewed. For some countries we had collected information in a previous study on the role of HTA in middle-income countries, including Argentina, Brazil, and Mexico (10). In the current study we used the same search strategy as published in 2010, avoiding overlap and duplication to the maximum. In addition, multiple databases were searched (World Health Organization, European Observatory on Health Systems and Policies, Organization for Economic Cooperation and Development, World Bank, and PubMed/Medline) to identify recent publications. Also, the International Journal of Technology Assessment in Health Care was searched for relevant articles. We used the following search terms: <country> AND health system OR healthcare system; health insurance; reimbursement of pharmaceuticals; and health technology assessment. Searches were limited to publications from 2000 to 2011 (inclusive) that are available in English and in the public domain. Moreover, an Internet-based review of wider information sources was performed (i.e., professional organizations at international level: INAHTA, HTAi, and International Society for Pharmacoeconomics and Outcomes Research regarding specific information on the selected countries) using the same search terms. Reference lists of retrieved documents have been hand searched to identify additional publications of interest. Articles or information that were targeted at either the institutionalization of HTA or elements of the HTA process were included in the study.

Web-Based Survey

A Web-based survey (in English) was distributed to key HTA experts in the selected countries. The survey consisted of forty-four close-ended and open-ended questions focusing on the main domains of the instrument. The final two sections of the survey provided opportunities for further comments on future developments regarding HTA in their country, as well as general comments on the survey.

Before launch the survey was piloted with two potential respondents (one from a middle-income country and one from a reference country) to ensure that it functioned properly from a technical point of view, as well as to confirm that the questions could be understood and were relevant. Some revisions were made after this step.

Table 1. The Mapping Instrument

Domain: Institutionalization	Score (on country level)
Criterion: Level of institutionalisation	
Indicators:	
At least 1 national or regional agency/organisation that is a member of INAHTA (since. . .) and a) reports to a Minister of Health/human resources or other authorities such as social security institutions; b) produces and/or endorses HTA reports and c) informs decisions about introduction, reimbursement and disinvestment from health technologies.	Yes = 25 No = 0
[Please note that a country might have several agencies that are member of INAHTA, e.g. the Netherlands, Spain] – the requirement for becoming an INAHTA member is to have at least 50% public funding	
At least 1 government-advising group outside INAHTA and a) reports to a Minister of Health/human resources or other authorities such as social security institutions; b) produces and/or endorses HTA reports and c) informs decisions about introduction, reimbursement and disinvestment from health technologies.	Yes = 20 No = 0
Presence of fulfilment of elements needed to establish a (formal) HTA programme if no agency or group is in place:	Per element:
● Interest in HTA expressed by government/policy makers which can be retrieved in <i>official documents</i>	Completely present = 3
● Commitment towards HTA from government/policy makers and it is expressed in <i>official documents</i>	Largely present = 2
● <i>Public</i> money (funding) is allocated to HTA as expressed in official documents	Present to some extent = 1
● Willingness to commit <i>public</i> money (funding) to HTA as expressed in official documents	Not present = 0
● Support for HTA from several stakeholders, including, the medical profession as expressed in publicly available documents	
● Organisational structure and institutional set-up in place. The achievement of legal support (i.e., policy statement or a specific law providing for the institution of a new body or giving HTA functions to an existing organisation) is important in formalising HTA activities	
● International network strategy available	
● Availability of human resource development:	
○ Capability to carry out HTA, including medical disciplines, public health specialists, including epidemiologists, statisticians, psychologists, biomedical engineers and economists [number]	
○ An ability to review international literature, including expertise in searching the internet	
○ HTA training opportunities are available	
Number of memberships of HTAi	More than 10 members = 3 5–10 members = 2 1–5 members = 1 0 members = 0
Domain: Identification	
Criterion: Early warning system of horizon scanning system in place	
Indicators:	
At least one agency/organisation in the country is a member of the International Information Network on New and Changing Health Technologies - Euroscan (since. . .)	Yes = 4 No = 0
Presence of fulfilment of primary characteristics of early warning systems as described in a publicly available document:	Per characteristic:
● Information is targeted to stakeholders	Completely present = 3
● Independent of commercial and industrial influence	Largely present = 2
● Clearly defined pathway	Present to some extent = 1 Not present = 0
Monitoring system(s) to identify technologies in need of assessment in place (e.g. registries, structured and standardized questionnaires, databases)	Completely present = 3 Largely present = 2 Present to some extent = 1 Not present = 0
Other activities involving identification are performed – e.g. reviewing medical journals to identify technologies in need of assessment etc.	Completely present = 3 Largely present = 2 Present to some extent = 1 Not present = 0

Table 1. Continued

	Score (on country level)
<p>Domain: Priority setting</p> <p>Criterion: System for setting priorities for HTA exists</p> <p>Indicators:</p> <p>Presence of fulfilment of characteristics of priority setting process for HTA as described in a publicly available document:</p> <ul style="list-style-type: none"> ● Explicit and transparent process is in place that is replicable (criteria and procedures are well described) ● Process reflects the goals of the programme ● Stakeholder involvement is included ● Information on priorities is set ● Processes and outcomes of priority setting are evaluated <p>System(s) in place to review the international evidence base (literature) to set priorities (knowledge of what has already been done)</p>	<p>Per characteristic:</p> <p>Completely present = 3</p> <p>Largely present = 2</p> <p>Present to some extent = 1</p> <p>Not present = 0</p> <p>Completely present = 3</p> <p>Largely present = 2</p> <p>Present to some extent = 1</p> <p>Not present = 0</p>
<p>Domain: Assessment</p> <p>Criterion: The goal and scope of the HTA should be explicit and relevant to its use</p> <p>Indicator:</p> <p>Clear description (e.g. in a start document/work plan) of</p> <ul style="list-style-type: none"> ● health care problem(s) ● patient population ● practitioners or users ● health care setting(s) of care <p>Criterion: HTA should include alternative technologies</p> <p>Indicator:</p> <p>Description and technical characteristics of health technology under study (e.g. pharmaceuticals, devices, procedures, diagnostics, public health interventions and treatment) and its alternatives as well as current use - should be part of guideline on how to undertake the planned HTA</p>	<p>Completely present = 3</p> <p>Largely present = 2</p> <p>Present to some extent = 1</p> <p>Not present = 0</p> <p>Completely present = 3</p> <p>Largely present = 2</p> <p>Present to some extent = 1</p> <p>Not present = 0</p>
<p>Criterion: HTA should assess safety and efficacy/effectiveness at the minimum</p> <p>Indicator:</p> <p>Description of the aspects of the problem to be addressed should be part of guideline on how to undertake the planned HTA:</p> <ul style="list-style-type: none"> ● safety and clinical effectiveness ● cost and cost-effectiveness (economic considerations) ● ethical analysis ● organizational analysis ● social-cultural aspects ● legal aspects <p>Criterion: HTA should incorporate standardised methods for assessing aspects under study</p> <p>Indicators:</p> <p>Collection of new primary data should be part of guideline on how to undertake the planned HTA</p>	<p>Per aspect:</p> <p>Completely present = 3</p> <p>Largely present = 2</p> <p>Present to some extent = 1</p> <p>Not present = 0</p> <p>Completely present = 3</p> <p>Largely present = 2</p> <p>Present to some extent = 1</p> <p>Not present = 0</p>
<p>Performance of systematic review / meta-analysis of all available evidence - should be part of guideline on how to undertake the planned HTA</p>	<p>Completely present = 3</p> <p>Largely present = 2</p> <p>Present to some extent = 1</p> <p>Not present = 0</p> <p>Completely present = 3</p> <p>Largely present = 2</p> <p>Present to some extent = 1</p> <p>Not present = 0</p>

Table 1. Continued

Domain: Assessment**Criterion: HTA should incorporate standardised methods for assessing aspects under study****Indicators:**

Literature searches in different languages – using key HTA databases - should be part of guideline on how to undertake the planned HTA:

- HTA Database
- Medline/PubMed
- Cochrane Library
- Database of Abstracts of Reviews of Effects (DARE)
- Search engines
- HTA reports

Score (on country level)

Completely present = 3
 Largely present = 2
 Present to some extent = 1
 Not present = 0

Criterion: Use an explicit and systematic approach to classify and critically appraise the quality of the available studies**Indicator:**

Use of guidelines for systematic reviews (e.g., developed by the Centre for Reviews and Dissemination at the University of York) - should be part of guideline on how to undertake the planned HTA

Completely present = 3
 Largely present = 2
 Present to some extent = 1
 Not present = 0

Criterion: HTAs should consider and address issues of generalizability and transferability**Indicator:**

Addressing generalizability and transferability - should be part of the guideline on how to undertake the planned HTA (e.g. EUnetHTA adaptation toolkit)

Completely present = 3
 Largely present = 2
 Present to some extent = 1
 Not present = 0

Domain: Appraisal**Criterion: Transparent and deliberative system for appraisal in place****Indicator:**

Presence of fulfilment of characteristics of appraisal process as expressed in a publicly available document:

- Explicit and transparent process is in place that is replicable (procedures are well described)
- Specification of stakeholder involvement
- Mechanism(s) for appeal are in place

Per characteristic:
 Completely present = 3
 Largely present = 2
 Present to some extent = 1
 Not present = 0

Domain: Reporting**Criterion: HTA should be an unbiased and transparent process****Indicator:**

Use of guideline on best practice in undertaking and reporting HTA (ECHTA report) or INAHTA checklist for HTA reports

Completely present = 3
 Largely present = 2
 Present to some extent = 1
 Not present = 0

Criterion: Publications**Indicators:**

Number of HTA reports per year produced (total last year) and per institute)

More than 12 (on average 1 per month) = 4
 6–12 = 3
 1–6 = 2
 0 = 0
 Yes = 1
 No = 0

[If a country does *not* produce reports] Use of HTA reports produced by other countries

Table 1. Continued

<p>Domain: Reporting Criterion: Publications Indicators: Number of HTA reports (total last year) that are produced by those who apply for reimbursement (i.e., paid for by a for profit organization) and of which the quality is checked by another organization/institute)</p>	<p>Score (on country level) More than 12 (on average 1 per month) = 4 6–12 = 3 1–6 = 2 0 = 0</p>
<p>Domain: Dissemination of findings and conclusions Criterion: HTA should be performed in a timely manner Indicator: Information (HTA report) is disseminated to decision makers before the decision on a particular technology is made</p>	<p>Always = 3 To a large extent = 2 To some extent = 1 Never = 0</p>
<p>Criterion: HTA findings need to be communicated to decision makers Indicator: Presence of fulfilment of characteristics of a publicly available dissemination strategy as expressed in a publicly available document:</p> <ul style="list-style-type: none"> ● what is to be said, to whom it should be said, what way of communication should be used? (e.g. clear recommendations for target groups) ● Starting with the selection of the subject ● Involvement of advisory groups 	<p>Per characteristic: Completely present = 3 Largely present = 2 Present to some extent = 1 Not present = 0</p>
<p>Domain: Implementation in policy and practice Criterion: HTA should inform policy and practice Indicators: Legal mandate of the HTA agency/organisation involved in HTA in the health care system</p>	<p>Yes = 1 No = 0</p>
<p>Existence of an administrative framework/ link to regulatory process as described in a publicly available document</p>	<p>Completely present = 3 Largely present = 2 Present to some extent = 1 Not present = 0</p>
<p>Availability of one or more implementation plans with attention to factors that influence implementation of HTA such as financial incentives, regulation, physicians preferences, patient preferences</p>	<p>Completely present = 3 Largely present = 2 Present to some extent = 1 Not present = 0</p>
<p>Criterion: Measuring impact of HTA Indicator: System(s) in place to monitor and evaluate the impact of HTA</p>	<p>Completely present = 3 Largely present = 2 Present to some extent = 1 Not present = 0</p>

We targeted 449 key informants, representing Ministries of Health, HTA agencies, university/research organizations, third party payers, medical device industry, pharmaceutical industry, and regulatory authorities. Potential respondents were identified by means of our own networks, the survey database from our for-

mer study (10), the HTAi annual meeting in Brazil (2011), HTAi Membership Directories (2010, 2008, and 2007), authors of relevant articles, presenters at relevant conferences, and members of NEVALAT (thematic network on the economic evaluation of healthcare program and its application in decision making

Table 2. Response Rate per Country

Country	No. of invitees	Total no. of responses	No. of complete responses	Response rate
Argentina	18	2	2	11.1%
Brazil	72	19	18	26.4%
India	44	5	5	11.4%
Indonesia	27	2	1	7.4%
Malaysia	29	4	4	13.8%
Mexico	40	4	3	10.0%
Russia	20	4	4	20.0%
Australia	43	7	7	16.3%
Canada	51	12	12	23.5%
United Kingdom	41	6	5	14.6%
Total	385	65	61	16.9%

in Latin American countries). After correcting for bounces and invitations sent to people with no or limited knowledge of the subject, the final panel consisted of 385 persons.

The survey was distributed by email through Check Market on September 30th 2011 and was live for completion until November 4th 2011. To maximize response rates two reminders were sent to respondents who had not or only partially completed the survey. Responses with at least 50 percent of the survey completed were considered as partial and included for analysis. The survey responses (65/385, see Table 2) were analyzed by country using IBM SPSS Statistics (version 19.0 for Windows).

Determining the Level of HTA

The information from the document review and Web-based survey was used to determine the score for each criterion (see Table 1). The scores were assigned by the lead author (WO) on the basis of the answer given by the majority of the respondents in a country, in conjunction with the evidence found in the literature. The scoring was reviewed by another researcher (PB). Any disagreement was resolved in a consensus meeting. These scores were then added resulting in a total score per domain. These scores were reviewed by the other members of the project team (H.V. and D.B.). We used this score for determining the level of HTA in the countries selected and for benchmarking purposes.

RESULTS

Institutionalization of HTA

The level of institutionalization is the highest in the reference countries. These countries all obtained the maximum score of 28. Brazil has a comparable degree of institutionalization. The institutionalization of HTA in Argentina, Mexico, and Malaysia

is lower, as these countries have a limited number of HTAi members. Institutionalization is lowest in Russia, Indonesia, and India as indicated by the lack of a formal HTA program, the limited number of HTAi members, as well as lack of political commitment to HTA (see Table 3).

In the countries with a formal HTA program, there is at least one organization that is a member of INAHTA. They differ, however, in the way these agencies interact with providers and purchasers of health care. Canada is complex, with several programs at federal, provincial, and local levels. Also, in Latin America (Argentina, Brazil, Mexico), more actors are involved in decision making (11). In the countries where no formal HTA program exists, decision making about the adoption and use of health technologies may be carried out by health authorities and health service providers. Decisions, however, are frequently based on interests of individuals or “gut feelings.” At best, decisions take into account experience generated in other countries or selective expert advice. The challenge is to shift to a decision-making process that follows the principles such as those of evidence-based medicine, cost-effectiveness, and patient centered services (5). With regard to institutional set-up, both Indonesia and Russia have made some progress. There is some, but limited, capacity available to search the Internet and review international literature. In addition, there are several training opportunities regarding pharmaco-economics and outcomes research in India and Russia.

Identification of Health Technologies

We determined if a country has an early warning or horizon scanning system in place. If not, we mapped the extent to which early warning activities are carried out. The maximum score that could be obtained was 19. Australia, Canada, and the United Kingdom have an early warning system(s) or horizon scanning system(s) in place. For India, Mexico, and Russia, we found no literature on identification of health technologies. Of the survey respondents from the middle-income countries, 75 percent answered that at least one monitoring system to identify technologies is in place in their respective countries. For Argentina and Brazil, we found evidence of such a system but not for Indonesia and Malaysia. In Mexico and Russia, half of the respondents do not think that such a monitoring system is present in their country. More than half (55 percent) of the respondents confirm the presence of other identification activities (such as review of medical journals) described in a publicly available document.

Priority Setting

We collected information on the existence of a priority setting process including: (i) An explicit and transparent process that is replicable (criteria and procedures); (ii) A process that reflects the goals of (national, regional, local) health policy; (iii) Attention to stakeholder involvement; (iv) Explicitly stated

Table 3. Level of HTA Development per Domain

Domain	Country									
	Argentina	Brazil	India	Indonesia	Malaysia	Mexico	Russia	Australia	Canada	UK
Level of institutionalization	26	28	7	8	26	26	11	28	28	28
Identification of health technologies	3	4	1*	1	2	1*	1*	11	13	13
Priority setting	3	11	6*	6*	10	8	6*	11	12	18
Assessment	12	22	7*	13	22	23	10	26	28	31
Appraisal	0	4	0*	3	3	3*	0*	7	6	9
Reporting	7	9	2*	5*	4	7*	6*	11	11	11
Dissemination	4	6	1	4*	5	5	1*	8	8	11
Implementation	5	5	0*	4*	4	4	0*	7	7	8

*Scoring mainly based on survey.

information on priorities; (v) and An evaluation of processes and outcomes.

In addition, we identified countries that have a system for reviewing international evidence (literature) to set priorities. For each indicator, a maximum score of 3 could be obtained, resulting in a total maximum score of 18.

We found a mixed picture with regard to the different elements of a priority setting process (see Table 3). An explicit system exists in Australia, Canada and the United Kingdom, as well as in Brazil and Malaysia. We found limited evidence in the literature on priority setting in India, Indonesia and Russia. The majority of the survey respondents in all countries believe that the process reflects the goals of health policy, that there is, at least to some extent, stakeholder involvement and that the information on priorities set is available. It appears that evaluation is often not performed in the countries under study, except in the United Kingdom and Brazil. This observation also applies to the presence of a system for reviewing the international evidence base.

Assessment

A document describing a clear goal and scope of HTA is available in Australia, Canada, the United Kingdom, as well as in Malaysia and Mexico. All countries except India provide a clear description of the safety and clinical effectiveness of the technology in their assessments. Cost and cost-effectiveness information are well described in the reference countries, Brazil and Mexico. The other aspects (ethical, organizational, social, and legal aspects) are less examined, as in the rest of the world.

Argentina, Brazil, India, Indonesia, Mexico, and Russia score low with regard to an explicit and systematic approach to classify and critically appraise the quality of available studies. Generalizability and transferability are not well described in Argentina, Indonesia, Russia, and Mexico.

According to the survey results, the collection of new primary data is well described in Australia, the United Kingdom, as well as in Brazil. Conducting systematic reviews / meta-analysis is covered in the reference countries and in Brazil and Mexico. This also applies to literature searches in different languages, which are also described in Malaysia (see Table 3). For each of the 13 indicators reflecting the assessment phase, a maximum score of 3 could be obtained. This means that in total each country could obtain a score of 39.

Appraisal

The concept of appraisal was consolidated and formalized with the establishment of the National Institute of Health and Clinical Excellence in 1999. Appraisal is a consideration of the outputs of the assessment process within the context of additional information supplied by relevant parties. Although appraisal is often not separated from the assessment phase, we tried to identify whether a transparent and deliberative system exists. In total, countries could obtain a maximum score of 9. It appears that the reference countries all have appraisal systems in place, although there is some criticism regarding transparency of these systems in Canada. Also, Brazil is taking steps toward a more explicit process of decision making. Argentina, India and Russia do not have a clear and transparent system in place. Indonesia, Malaysia, and Mexico have some elements of an appraisal system (see Table 3).

Reporting

With regard to the reporting of HTA information, we examined whether reporting is unbiased and according to a transparent process. Also, we identified the total number of HTA reports produced annually using public resources and the total number of HTA reports produced by applicants for reimbursements. With regard to these indicators, countries could obtain a maximum score of 11.

In all countries, except for India and Russia, it appears that there is at least one agency/organization that uses (some sort of) guidelines on reporting (e.g., ECHTA report or INAHTA checklist for HTA reports). In Australia, Canada, and the United Kingdom, several HTA reports (i.e., more than twelve reports per year) are published on an annual basis, which is likely due to a well-established HTA infrastructure in those countries. This also includes a relatively high number of reports produced by applicants for reimbursement (i.e., more than twelve reports per year) (see Table 3). We found similar results for Brazil.

Dissemination

HTA information needs to be timely and effectively communicated to be valuable for decision makers. A publicly available dissemination strategy is important. We, therefore, examined whether the information (HTA report) is disseminated to decision makers before the decision on a particular technology is made (see Table 1). The maximum score for each of the indicators was 3, which totals the maximum score to 12 for this domain.

Dissemination strategies are well developed in the reference countries, and to a lesser extent in Brazil, Argentina, Malaysia, Mexico, and Indonesia. This might be due to the existence of HTA agencies or HTA unit(s) in those countries. More than 80 percent of survey respondents state that clear recommendations for target groups are at least to some extent present in publicly available dissemination strategies. Clear information on dissemination strategies in India and Russia is lacking (see Table 3).

Implementation in Policy and Practice

HTA tends to have a higher profile in coverage decision making when these processes are explicit, deliberative and formalized (i.e., HTA is integrated and enforced by law). We examined whether (a) at least one organization involved in HTA has a legal mandate in the healthcare system, (b) there is a link between HTA and the regulatory process, and (c) an implementation plan is used. In addition, we looked at the extent to which the actual impact of HTA is measured.

Almost 63 percent of the survey respondents believe that HTA organizations in their countries have a legal mandate. In the literature, we found evidence for such a mandate in the reference countries, Argentina, Brazil, Indonesia, and Mexico.

There is a clear link between HTA and a regulatory framework in the reference countries as well as in Argentina, Brazil, and Malaysia. The other countries showed divergent outcomes, although the majority believes that there is a link between HTA and the regulatory process, with the exception of Russia and India. This was also confirmed by the literature.

Regarding implementation plans, almost 90 percent of the respondents state that factors influencing the implementation of HTA are taken into account when HTA is used in their country,

at least to some extent. However, this does not apply to India and Russia (see Table 3).

Measuring the impact of HTA is becoming more frequent in the HTA community. However, only a few studies have been undertaken to better understand the issue (1,10). Measuring HTA impact by using monitoring systems is currently most advanced in the reference countries.

For this domain, a maximum score of 10 could be obtained (see Table 1).

DISCUSSION

With this study, we go beyond previous studies on the organization of HTA by focusing on a more systematic evaluation of the level and trends in HTA development at *country level*, taking into account the characteristics of the healthcare system. Of particular interest is Brazil, which is developing rapidly toward the standards of best practice in HTA. Political commitment in Argentina and Mexico will determine how quickly these countries can further develop and how the actions already undertaken will have an impact. For Malaysia, the main challenge is to sustain the established HTA framework while training (new) personnel. Indonesia has taken some steps toward developing HTA capacity, although the focus is mainly on pharmaco-economics. India and Russia are still at the very beginning of introducing HTA in their countries. Political will is obviously important for introducing and maintaining HTA in a country.

There are strengths and weaknesses to our approach. A strength is that we received minor comments from relevant stakeholders and respondents during the development and adjustment phases of the instrument. These focused on the level at which HTA should be mapped in each country: national and/or provincial level and/or local (e.g., Canada).

One of the restrictions of this research lies in the scope of the literature retrieved (limited to publications that are available in English). A Web-based survey was performed to collect additional information for each country to support and enrich the profiles with information which is not publicly available.

Implementing the survey highlighted several challenges. First, we address the issue of identifying key persons working in the HTA field. For countries with more established HTA activities (e.g., Brazil), it was easier to identify a large number of contact persons compared with countries with less established HTA activities (e.g., Malaysia, Indonesia, India, and Russia). Second, the initial response rate of the survey was relatively low. We found that this was partly due to the fact that our survey was likely distributed as SPAM (with survey as a trigger word). Efforts have been made to ensure a good response rate, with reminder emails sent 10 days after the first invitation was launched to all those stakeholders who had not responded to the survey. Reminders were also sent to stakeholders on the panel who had only partially responded to the survey, 1 day

after their survey was received. A subsequent reminder was sent to all stakeholder panel members who had not responded as we suspected that our survey had been filtered as SPAM. After sending the reminder, we expected the response rate to increase. As we encountered no significant increase in response rate, we decided to search for additional contact information. After sending a second reminder through our own system, it was found that a large number ($n = 52$) of the initial email addresses were bounced. As a result, we decided to send a final reminder to contacts from countries with a very low response and to contacts with corrected email addresses ($n = 82$). Furthermore, the nonresponse in most countries with less established HTA activities was relatively higher than in other countries. This might be explained by a lack of interest for the subject or people considering themselves not 'qualified enough' to answer the survey. Another issue related to the relatively low response rate could be the language barrier (e.g., in Argentina, Brazil, Malaysia, Mexico, Russia, and Indonesia). Also, a few respondents indicated that they had difficulties with the phrasing of the questions. In addition, we found that the results of the survey demonstrated sometimes contradictory views regarding several questions and often conflicted with the evidence retrieved from other sources, especially for the developing countries. For some of these countries, HTA activities are rather new (e.g., India, Indonesia, and Russia). In other cases, the number of survey respondents was relatively low for some of the countries (e.g., Argentina, India, Indonesia, and Mexico). In general, the survey scores for Canada appeared to be relatively low compared with the other reference countries. This might be explained by the fragmentation in the HTA process in Canada; it was not always clear whether the respondent related to the federal or provincial perspective. The low number of respondents has implications for the reliability of the findings from the survey. For future use, it is necessary to require a minimum number of informants per country.

Another limitation of the study is the assignment of scores using desk research and survey as main sources. Although for some indicators the evidence is clear (e.g. membership of IN-AHTA, EuroScan), for others (e.g., (elements of a) system for priority setting) it was less clear. In these cases, we used the experiences of the project team, but this might result in an over- or underestimation of the score for each country. Taking these limitations into account, we base our summarizing conclusions mainly on the findings from the document review.

CONCLUSIONS

Mapping of HTA at the country level is feasible and can be done by focusing on the level of institutionalization and the process of HTA. This includes the identification, priority setting, assessment, appraisal, reporting, dissemination, and implementation of HTA results in policy and practice.

The results of this first mapping exercise can be used as a baseline measurement for future evaluation. It would be beneficial to evaluate how the different selected countries would score on the different indicators after 3–5 years (especially those countries that have announced healthcare reforms and changes in the HTA processes). Ideally, progress should be monitored on a regular basis to identify trends in the indicators (e.g., publication of reports and HTAi memberships could be monitored on a yearly basis). This can help different actors (governments, HTA organizations, industry, other stakeholders) to assess the development of HTA at country level, help inform HTA strategies, and justify expenditure for HTA.

The selection of countries includes both lower-middle-income countries and upper-middle-income countries from different regions. This strengthens the argument that the instrument can be applied to other middle-income countries and probably low-income countries too. Before applying the instrument to other countries, it needs, however, further validation.

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CONFLICTS OF INTEREST

Wija Oortwijn reports consulting fees, travel support and payment for writing to her institution from GSK and Novo Nordisk International Operations A/S; and employment at and stock or stock options from Ecorys Nederland B.V. Pieter Broos reports consulting fees, travel support and payment for writing to his institution from GSK and Novo Nordisk International Operations A/S. Hindrik Vondeling reports consulting fees, travel support and payment for writing to his institution from Ecorys Nederland B.V., partly provided by Novo Nordisk International Operations A/S. David Banta reports consulting fees and payment for writing to his institution from Ecorys Nederland B.V., partly provided by Novo Nordisk International Operations A/S. Lora Todorova reports support for travel from Novo Nordisk International Operations A/S which is her employer.

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