Health Technology in Emerging Markets: A Framework and Examples

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Two Reports



Consulting Report

The Evolution of HTA in Emerging Markets Health Care Systems:

Analysis to Support a Policy Response

Adrian Towse, Nancy Devlin, Emma Hawe and Lou Garrison

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Health Technology Assessment in Low- and Middle-Income Countries: Findings from a Survey and Case Studies

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Source: Towse et al., OHE, 2011 UNIVERSITY of WASHINGTON

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Our Working Definition of HTA

Health technology assessment (HTA) is the structured analysis of health care technologies—medicines, vaccines, medical devices, diagnostics, healthcare procedures, and health systems—performed for the purpose of providing input into regulatory, coverage/formulary (including essential medicines lists), and/or reimbursement policy decisions.

Key Messages about Health Technology Assessment (HTA)

- Evolution—HTA is not new, but it has nearly 30 years of history—an evolutionary one.
- Globalization—HTA is being applied in more and more countries, and the number of competent practitioners is growing--globally.
- Variety—How HTA is used varies markedly, but depends on incentives to use the information.
- Challenge—HTA operates in the political sphere and its role and performance in any given country will depend on how it is institutionalized and organized.

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HTA as an Economic Production Process and Economic Good

- The process of HTA can usefully be thought of as a "technology" or production process.
 - As such, one can ask, whether it is "technically" efficient, obtaining maximum output given the resources used.
- The output of the process is "information"—a "public" good, in economic jargon. Indeed—a global public good
 - One can also ask whether the production is "economically" efficient, i.e., is it technically efficient, being produced a minimum cost, and in the right quantity?
- Public goods create incentive to be a "free-rider"

Economics says: "public goods" will be undersupplied by private markets. Incentives like patents and subsidies are needed.

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Another Separation of HTA Functions

- Marketing approval ("Registration")—usually for drugs and devices, an assessment of benefit-risk balance based on clinical trial or other data
- Coverage—inclusion as a covered service in health plan benefit package
- 3. Reimbursement—establishes plan payment level, perhaps considering "value of money" or budget impact, or via internal (therapeutic) reference pricing or via external (international reference pricing)
- **4. Clinical guidelines**—use HTA information use to support clinical guidelines in disease areas.

Objectives of the OHE Study

- To develop a categorisation of health care systems (HCS)
- To develop a categorisation of types of HTA in relation to the current and future healthcare systems of low and middle income countries.
- To combine these two strands (HCS and HTA) to examine the role for HTA in a health care system dependent on development stage and structure of that health care system;
- To understand the potential role of HTA processes in three emerging markets – Brazil, China and Taiwan

Six Building Blocks of a Health System

THE WHO HEALTH SYSTEM FRAMEWORK

SYSTEM BUILDING BLOCKS OVERALL GOALS / OUTCOMES SERVICE DELIVERY ACCESS **HEALTH WORKFORCE** IMPROVED HEALTH (LEVEL AND EQUITY) COVERAGE INFORMATION RESPONSIVENESS MEDICAL PRODUCTS, VACCINES & TECHNOLOGIES SOCIAL AND FINANCIAL RISK PROTECTION QUALITY FINANCING IMPROVED EFFICIENCY SAFETY LEADERSHIP / GOVERNANCE

Source: WHO, 2007

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The Four Functions of Health Care Systems

Financing

Revenue collection

Fund pooling

Purchasing

Provision

Personal health services

Non-personal health services

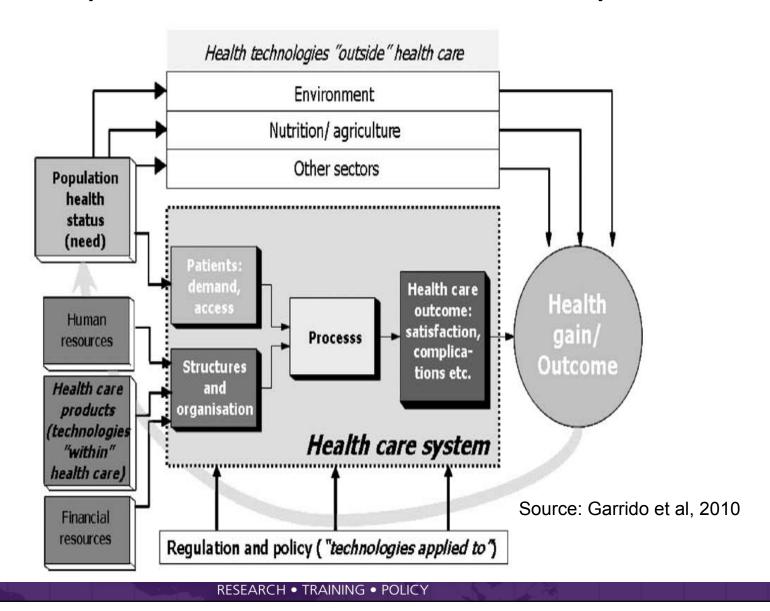
RESOURCE GENERATION

Source: Murray and Frenk, 2002

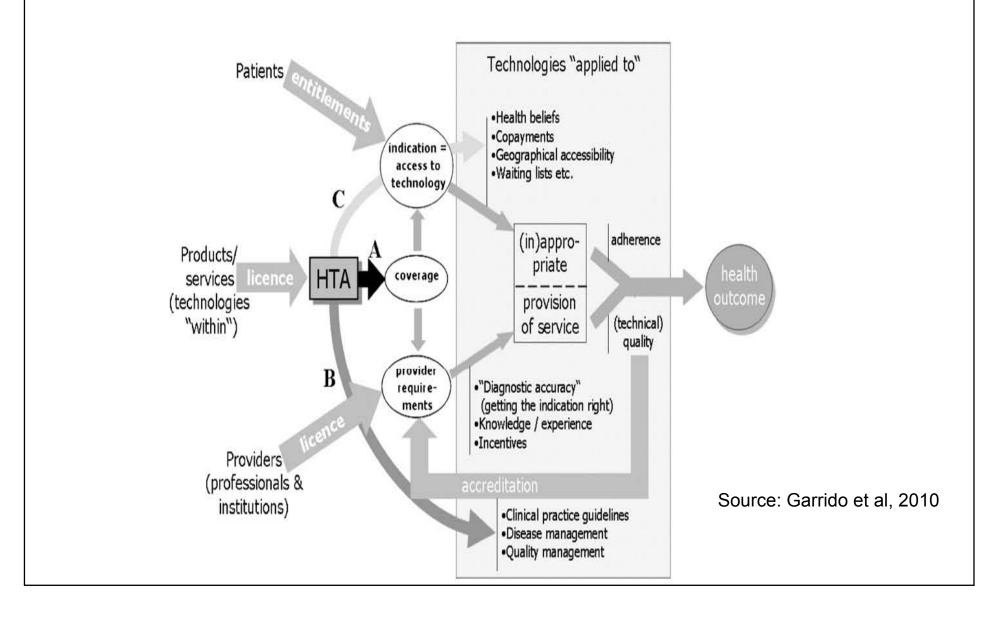
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Input-output model of the healthcare system



HTA within the healthcare system: current application to coverage decisions (A) and proposed expansion of HTA role (B and C)



Natural History of HTA (Battista and Hodge, 2009)

- Two particular points are of note.
 - HTA initially seems to emerge as an "ideas transfer" from academics and policy practitioners based in more developed health care systems and can appear to be a "product" without an obvious market.
 - an early interest is often in its use to review expensive technologies
 (usually medical devices). This is because these technologies are seen
 as cost-drivers challenging the financial sustainability of emerging
 insurance systems or public subsidies to providers. Yet the real
 concern is cost containment rather than identifying value.
- Not obvious that HTA is initially used in an effective way

The "natural" history of HTA development

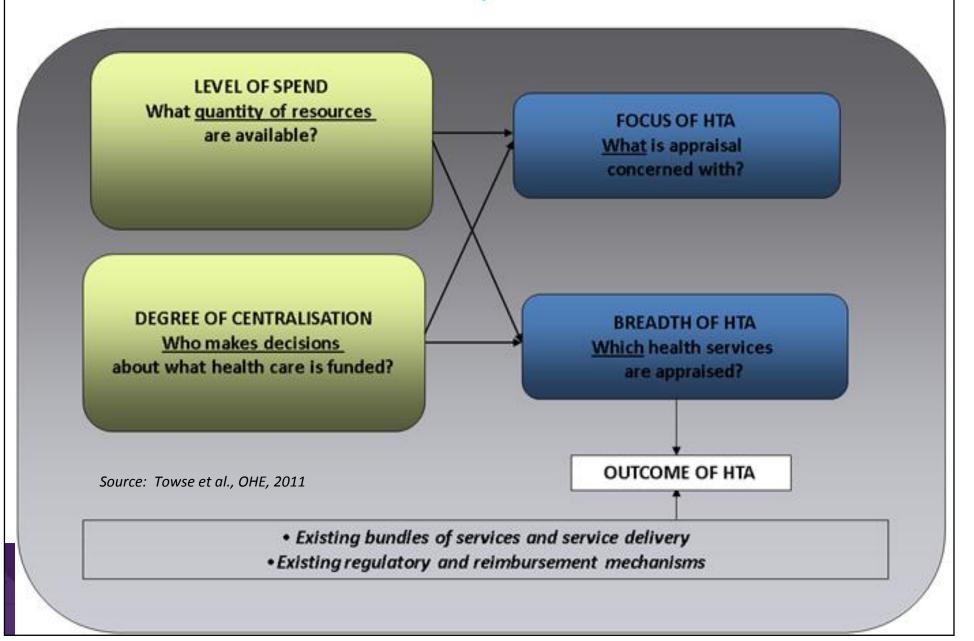
	Emergence	Consolidation	Expansion
Why?	 Convergence of needs, demands, and supply 	 Early successes attract interest of more decision makers 	 HTA as part of official political discourse
	 Key individuals are "Champions" of HTA 	 Expansion of demand for HTA products 	 Increased demand for diversified products
	 Receptive policy/political environment 	 Formalized priority setting process 	
What?	 Narrow interpretation of health technology Focus on high intensity 	 Broadening of scope of HTA Possible addition of pharmaceuticals 	 Further broadening of scope of HTA (pharmaceuticals, public health, delivery models, social
	technology (Imaging) • Exclusion of pharmaceuticals	 Shift from specific technologies to care processes for the management of health conditions 	 services) Existing practices and new interventions
How?	 Modest resources, at times project or deliverable specific Minimal scientific capacity 	 Expansion of scientific team Modest addition of resources Research partnerships sought 	 Significant increase in resources Expansion of scientific team and partnerships Diversification of products
and, Then What?	Knowledge translation minimal Efforts directed to policy makers,	 Progression of knowledge translation efforts 	 Clinical practice guidelines Consolidation of multiple target audiences
	often by means of personal communication	Broadening of target audiences	 Specialization of KT instruments Increased proportion of resources to KT

Source: Battista and Hodge, 2009

What exactly is HTA?

- HTA can be categorized into three types:
 - "micro-level" HTA aimed at <u>appraisal of individual</u> technologies, or groups of related technologies
 - "micro-level" HTA aimed at developing <u>clinical practice</u> <u>guidelines</u> or the way in which individual technologies are combined within a delivery system to manage patients efficiently
 - "macro-level" HTA which is about the <u>efficiency of the</u> organizational systems or architecture of the health care <u>system</u>

The conceptual model



Several Issues Become Apparent (i)

- As third party funding develops, it is in the insured group's interest to ensure that claims on those funds are justified. HTA is a tool to do this. However, it may be some time before insurers actively manage providers.
- The early interest in the use of HTA for new technologies is driven by a concern about cost rather than any system-wide focus on achieving value.
- HTA can be seen as a "black box" with little thought given to appropriate processes to ensure the involvement of stakeholders.
- HTA can be a "product" without a customer if there is a lack of understanding of how it can be used or practical obstacles to its use to change the way in which patients are treated;

Source: Towse et al., OHE, 2011

Several Issues Become Apparent (ii)

- There can be a lack of distinction between the different elements of government stewardship of the health care system, in particular as regulator of entry to the system and as a payer or employer operating within the system
- The potential importance of evidence-based clinical practice guidelines in managing chronic disease in a decentralised health care system may be neglected.
- The conventional focus is on the use of HTA for "microtechnologies" rather than other "macro" aspects of system architecture which may yield higher gains
 - Other elements of system architecture such as incentives to prescribe and the importance of trading margins are not being addressed

Source: Towse et al., OHE, 2011

Level of Spend

	Population (m)	% GDP Health	GNI per Capita (PPP\$)
China	1345	4.5%	\$6,020
Brazil	193	8.4%	\$10,070
Taiwan	23	6.2%	\$28,005

- Each is struggling (in different ways) to reconcile rapidly rising expectations regarding health care with what is currently available given budgets.
- HTA is seen as one means by which these tensions may be reconciled
 - Although where, as appears to be the case in Brazil in 2010, limits on the resources to conduct the reviews result in substantial delays in access, which is unlikely to be a satisfactory response in the longer term.

Degree of Centralisation (i)

- In all three markets the degree of centralisation is relatively high or increasing:
 - Brazil has public and private systems but the private system is centrally regulated. There is regional and local control of the public system, but there is a constitutional right to health care, and the three major pharmaceutical programmes are national entitlements;
 - China is increasing central control through an expansion of its three public schemes. National oversight is shared with Provincial administration;
 - Taiwan introduced a single payer system in 1995, and operates a national benefit package.
- In all three countries, however, there appears to be little "active third party purchasing"

Degree of Centralisation (ii)

- A side effect of "fee-for-service" as used in China and Taiwan is an incentive to provide additional services, especially those on which additional income can be earned
- If artificially low prices are set for 'basic services' this creates strong incentives for overuse of technologies where providers are free to set higher prices.
- In Taiwan, differences between drug acquisition cost and reimbursement payments provides strong incentives to overprescribe medications.
- The wider 'architecture' of the health care system, in terms of reimbursement and corresponding incentives for providers and patients, is distorting behaviours resulting in "second-best" outcomes.

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Natural History—Three Cases

- China is at the "Emergence" category, with an interest expressed and now
 a modest investment of resources, notably in the new initiative with NICE
 around clinical practice guidelines. These are likely to focus on efficacy and
 relative effectiveness.
- Brazil is between "Emergence" and "Consolidation" with CITEC (in 2011; CONITEC in 2012) appraising pharmaceuticals and other procedures. The focus of HTA is cost-effectiveness and the breadth is new technologies. However, resources are modest and the priority setting process is informal.
- Taiwan is at the "Emergence" stage, albeit with an exclusive focus on pharmaceuticals, but with modest resources and minimal scientific capacity. Use seems to be to establish the degree of innovation by an examination of relative efficacy and then to use reference pricing to establish a price for the product.

Source: Towse et al., OHE, 2011 UNIVERSITY of WASHINGTON

Observation 1—Incomes and Expectations

- Observation 1: Incomes are growing in emerging markets, but resulting increases in funding for health care are likely to be out-paced by rising demands and expectations.
 - In such situations, HTA may have a role in assisting the health care system to reconcile rapidly expanding demand with more slowly expanding resources. HTA can provide a potential means of handling this in a more explicit and transparent way, and in promoting public debate about priorities.

OHE Report, 2011

Source: Towse et al., OHE, 2011

Observation 2—Bad Incentives

- Observation 2: HTA of individual technologies is not a substitute for the reform of health care systems. Where health care systems create obviously bad incentives, this type of micro-HTA is unlikely to compensate for these failings.
 - HTA should not be approached out of context. HTA should be tied, in a caseby-case way, to what else is going on in the health care system.

OHE Report, 2011

Source: Towse et al., OHE, 2011

Observation 3—Importance of the Purpose of HTA

- Observation 3: 'One size fits all' HTA processes and methods are unlikely to be appropriate for emerging markets. There needs to be clarity over the purpose of HTA and the methods and processes which are adopted need to be fit for purpose.
 - HTA is not an objective 'tool kit' that is transferable to any setting.
 - "Value" of new drugs varies, and is subjective and based on local preferences and other values.
 - Real value depends in a "second-best" world on the match between costs and the value of all other inputs (hospitals, physician, nurses, equipment, etc.).

OHE Report, 2011

Source: Towse et al., OHE, 2011

Observation 4—HTA and Pricing

- Observation 4: HTA and pricing regulations work hand-in-hand: the approach to HTA should be appropriate to, and work sensibly in combination with, the particular approach to pricing technologies.
 - For example, HTA based on reimbursement levels ignores what providers actually have to pay for new drugs. This would tend to under-estimate realworld cost-effectiveness.

OHE Report, 2011

Source: Towse et al., OHE, 2011 UNIVERSITY of WASHINGTON

Observation 5—HTA Evolution

- Observation 5: There is no single prescription for HTA methods and processes which will be welfare-increasing in all contexts.
 - Further, trade-offs between competing objectives are likely if not inevitable; and health care systems may differ in the relative value placed on them, for example, the achievement of equity goals; technical efficiency; cost containment; and patient choice.
 - Every health care system is on a slightly different trajectory: as it develops, and as spending increases, the way that HTA evolves will be a reaction to the possibilities and pressures that new technologies present.
 - A key message is that the relevance and positioning of any role for HTA in a health care system depends on the development stage and structure of that health care system.

OHE Report, 2011

Source: Towse et al., OHE, 2011

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UW HTA Landscape Survey in LMICs

- We received 12 out of 16 completed surveys.
- The respondents reported on: DRC, Ethiopia, Namibia, Rwanda, Swaziland, Kenya, Afghanistan, Dominican Republic, Bangladesh, Jordan, South Africa, and Vietnam.
- Also, three case in-depth studies—Kenya, South Africa, and Vietnam

	Population (m)	% GDP Health	GNI per Capita
Kenya	40.5	4.3%	\$467
South Africa	50.0	8.5%	\$3745
Vietnam	86.0	7.2%	\$722

Survey Results: Presence of HTA Ordered by Govt. Effectiveness

Country	Population, totalWDI	GDP per capita (constant 2000 US \$)WDI	Government Effectiveness - Percentile Rank WB-Governance Indicators	Written guideline or established process for HTA in country	Formal process in place to identify technologies for HTA review
South Africa	49991300 (2010)	3745.34 (2010)	65.07 (2010)	Yes	No
Namibia	2283289 (2010)	2666.91 (2010)	59.33 (2010)	Yes	Yes
Jordan	6047000 (2010)	2534 (2010)	57.42 (2010)	No	No
Rwanda	10624005 (2010)	338.27 (2010)	54.07 (2010)	Yes	Yes
Ethiopia	82949541 (2010)	220.89 (2010)	42.58 (2010)	Yes	Yes
Swaziland	1186056 (2010)	1556.15 (2010)	36.36 (2010)	No	Unknown
Kenya	40512682 (2010)	467.47 (2010)	35.89 (2010)	No	No
Dominican					
Republic	9927320 (2010)	4049.04 (2010)	31.58 (2010)	No	No
Bangladesh	148692131 (2010)	558.06 (2010)	21.53 (2010)	No	Unknown
Afghanistan	34,385,068 (2010)	410 (2012)	4.78 (2010)	No	No
DR Congo	65965795 (2010)	103.85 (2010)	1.44 (2010)	No	No

- One-third have written guidelines or established processes for HTA in their country.
- Three countries have a formal process in place to identify technologies for HTA review.
- The level of government effectiveness is correlated with having an established guideline for HTA.

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Landscape Survey Results: HTA Challenges

- The need for consensus building among the stakeholders and raising awareness of the importance and use of HTA, prior to starting a process to strengthen HTA
- Building capacity and an increased quantity and quality of human resources for HTA
- Development of standards and policies to enforce the use of HTA.

HTA Survey and Interview Results--Kenya

- No formal national program for HTA in Kenya
- HTA performed to a limited extent in Kenya:
 - Pharmacy and Poisons Board reviews medicines for registration in the country
 - Drug and Therapeutics Committee performs some assessments when creating the EML

Health System Challenges and the Future of HTA in Kenya

- Healthcare system has many challenges:
 - Resource constraints
 - Health workforce problems
 - Stakeholders think liberalization of the pharmaceutical sector is a problem given limited regulatory capacity and small number of welltrained pharmacists
- HTA can help improve the use of scarce resources by improving efficiency of use of health technologies
- Relatively good knowledge among different stakeholders of the potential role of HTA and vibrant interest in learning HTA tools and methods
- HTA will likely play increasingly significant role in Kenya in the coming years as the health system moves to a higher proportion of insured patients and the country's economy transitions in low middle-income status

HTA Survey and Interview Results—South Africa

- The development of HTA in South Africa mirrors the two-tier healthcare system of the country as a whole:
 - The medical schemes (covering about 18 percent of the population) that provide private insurance coverage for the relatively well-off workers have had sophisticated tools to measure health care utilization for at least a decade. Although it is not clear the extent to which they have been relying upon formal pharmacoeconomic analysis, it is clear that they have been making careful and considered buying decisions about the medicines and services they provide for many years.
 - The public sector has had a limited amount of HTA in the past, but has recently promulgated proposed pharmacoeconomic guidelines for the assessment of new medicines. (Adopted in 2013.)
- Drug HTA is being done for regulatory purposes, but performance has been criticized for being slow and inefficient.

HTA Survey and Interview Results--Vietnam

- Vietnam currently does not have a formal national program for HTA.
- According to a landscape survey response, HTA is in the concept stage in Vietnam. There
 have been informal discussions among academic institutions and health care professionals;
 however, HTA has not been placed in the institutional agenda.
- Based on the literature review, HTA activities are evident and its use is relatively underdeveloped in Vietnam.
 - For example, economic evaluation is not a part of the formal development of the social health insurance benefit package, the reimbursement drug list, and selection of medical services.
- Hospitals currently use the reimbursement drug list as a basis for choosing drugs to include
 in specific drug lists for different hospital departments and units. The list is also used as a
 reference for insurance reimbursement of health services.
 - However, it is unclear how drugs are removed or added to the reimbursement drug list and guidance is not well defined.
- In addition, communications with several stakeholders outside of the MOH in Vietnam indicated poor understanding of HTA and its purpose.

Conclusions—UW Study

- The use of HTA in the surveyed low- and middle-income countries is extremely limited for the most part.
- Other than broad health system reform evaluations (i.e., macro HTA), micro-HTA tends to focus on medicines and related guidelines.
- Having local, trained professionals is a necessary condition for the development and implementation of HTA.
- Other than for regulatory review, micro-HTA is probably not that helpful or necessary in the absence of functioning public health insurance delivery and insurance system.

Final Observations

- The impact of HTA and cost-effectiveness information on health system resource allocation depends on:
 - Incentives to use the information
 - Insulation from political influence

(--or at least a fair and workable system of checks and balances)

• HTA is resource-intensive and that an appropriate initial focus for skilled people may well be on "macro HTA" or other health system issues rather than on a very resource intensive use of "micro HTA".

Important question to ask:

What would be "efficient" HTA? From a both a country's and global perspective--Short-term (static) vs. long-term (dynamic)?

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Thank you!

Questions?

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