STRIKING THE RIGHT LEVEL: “MICRO AND MACRO” HTA IN EMERGING MARKET HEALTH SYSTEMS

Findings from a study by the Office of Health Economics, London and Veritech / University of Washington, Seattle

Professors Adrian Towse ¹ and Lou Garrison ²

¹ Office of Health Economics ² VeriTech/UW

ISPOR Latin America: Mexico City, September 2011

Acknowledgements

• This project has been led by the Office of Health Economics (OHE) with the assistance of Professor Lou Garrison and his colleagues at Veritech Consulting and the University of Washington, Seattle

• Local researchers Michael Qin, Vanessa Teich, and Ivy Tsai have undertaken research and interviews in China, Brazil, and Taiwan respectively

• OHE / VeriTech would like to thank Stephanie Lane, formerly of PhRMA, who was the main industry point of contact for this work and her industry colleagues on the Project Steering Group
Agenda

- Objectives of the Study
- Understanding the challenges facing health care systems
- Categorisation of Health Care Systems (HCS) and HTA
- Links between HCS and HTA Evolution
- The Implications for Markets such as Brazil, China and Taiwan

The Objectives of the Study

- To develop a categorisation of health care systems (HCS) which can be accepted by key institutions and experts in the field (WHO, World Bank and academia);
- To develop a categorisation of types of HTA using definitions recognised by practitioners in the field. Inevitably these are based on the experiences of high income countries, but can be expressed in a form that can fit into policy development 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 set out these findings in a way that is helpful to understanding the potential role of HTA processes in three markets – Brazil, China and Taiwan
Agenda

- Objectives of the Study
- Categorisation of Health Care Systems (HCS) and HTA
- Links between HCS and HTA Evolution
- The Implications for Markets such as Brazil, China and Taiwan

The Four Functions of Health Care Systems

Source: Murray and Frenk, 2002
Six Building Blocks of a Health System

THE WHO HEALTH SYSTEM FRAMEWORK

SYSTEM BUILDING BLOCKS

- Service Delivery
- Health Workforce
- Information
- Medical Products, Vaccines & Technologies
- Financing
- Leadership / Governance

OVERALL GOALS / OUTCOMES

- Improved Health (Level and Equity)
- Responsiveness
- Social and Financial Risk Protection
- Improved Efficiency

Access

Coverage

Quality

Safety

Source: WHO, 2007

Applying Health Care System Frameworks

- The sophistication of “Financing” evolves slowly over time, with moves from predominantly out-of-pocket funding to elements of insurance through to more-or-less universal coverage varying from country to country.

- The element of Financing that arguably evolves the most slowly is Purchasing. Insurance cover typically develops around fee-for-service with the role of the third party payer being to passively pay the bills of the provider rather than actively decide what it is going to cover, who should provide it, and how they are to be paid?

- Over time more sophisticated mechanisms for incentivising and rewarding providers tend to be used, notably capitation payments and DRG type payments to hospitals.

- However, there can remain a misalignment of incentives which can give providers perverse incentives to provide inefficient but profitable services.
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)
What exactly is HTA?

• EUnetHTA (2008) report:
  • a health technology is ‘any [health] intervention that may be used to promote health, prevent, diagnose or treat disease, or for rehabilitation or long-term care. This includes pharmaceuticals, devices, procedures and organizational systems used in health care’

• We can categorise HTA into three types:
  • micro-level” HTA aimed at appraisal of individual technologies, or groups of related technologies
  • “micro-level” HTA aimed at developing clinical practice guidelines or the way in which individual technologies are combined within a delivery system to manage patients efficiently
  • “macro-level” HTA which is about the efficiency of the organizational systems or architecture of the health care system

What exactly is HTA? continued

• We term the first use of HTA as a focus on “micro-technologies”, such as new drugs, that are seen as incremental or “marginal” to the system.
• The second use for HTA is reviewing “macro-technologies” comprising elements of the architecture or framework such as how the system is organised (number and types of hospitals and physicians). This is not usually addressed by HTA organisations.
HTA as a “black box”

- Sørensen et al (2008) characterise HTA systems according to:
  - governance;
  - topic selection;
  - evidence and assessment methods;
  - dissemination /implementation
- This is a useful reminder of the elements that need to be explicitly understood in any use of HTA. In the early use of HTA by health care systems little systematic thought may be given to a number of these elements. The HTA process is a de facto “black box.”

Battista, Hodge 2009: Natural History of HTA

- 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
Agenda

- Objectives of the Study
- Categorisation of Health Care Systems (HCS) and HTA
- Links between HCS and HTA Evolution
- The Implications for Markets such as Brazil, China and Taiwan

Health care system typology: two key attributes/variables and levels

**LEVEL OF SPEND**

What **quantity of resources** are available?
- Low spend per capita
- Medium spend per capita
- High spend per capita

**DEGREE OF CENTRALISATION**

Who makes decisions about what health care is funded?
- Out of pocket spend dominates
- Emergence of insurance /collective funding; decisions localised
- Active third party purchasing
Degree of Centralisation

- The extent to which there is third party coverage and so an interest in the use of both “micro” and “macro” technologies that goes beyond the provider-patient relationship that dominates an out-of-pocket spend environment.

- The extent to which there is active rather than passive purchasing by the third party insurer. Related to this is the degree of national level regulation as to what is included in the insurance package offered to enrollees.

HTA typology: key HTA system attributes/variables and levels

**FOCUS OF HTA**
What is appraisal concerned with?
- Efficacy/safety
- Relative effectiveness
- Cost-effectiveness (C-E)
- C-E and broader issues

**BREADTH OF HTA**
Which health services appraised?
- Basic preventative services and minimum care packages
- New technologies
- All technologies/services
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;
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 “micro-technologies” 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.

Agenda

- Objectives of the Study
- Categorisation of Health Care Systems (HCS) and HTA
- Links between HCS and HTA Evolution
- The Implications for Markets such as Brazil, China and Taiwan
Level of spend

• Brazil is spending around 8% of GDP on health as compared to 4% for China and 6% for Taiwan. Brazil is closest to the OECD average of 10% in 2008 (OECD Health Database, 2010). China is seeking to increase spending on health rapidly to around 6% of GDP.
• 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, 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.

Observations (i)

• 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.
  • However, addressing ‘rationing’ in this way requires a willingness to engage in active debate about ways of addressing demand and supply.
  • Such a debate will inevitably refer to the appropriate balance between national procurement and individual clinician decision making.
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 over-prescribe 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.
The “natural” history of HTA development

<table>
<thead>
<tr>
<th></th>
<th>Emergence</th>
<th>Consolidation</th>
<th>Expansion</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Why?</strong></td>
<td>Convergence of needs, demands, and supply</td>
<td>Early successes attract interest of more decision makers</td>
<td>HTA as part of official political discourse</td>
</tr>
<tr>
<td></td>
<td>Key individuals are “Champions” of HTA</td>
<td>Expansion of demand for HTA products</td>
<td>Increased demand for diversified products</td>
</tr>
<tr>
<td></td>
<td>Receptive policy/political environment</td>
<td>Formalized priority setting process</td>
<td></td>
</tr>
<tr>
<td><strong>What?</strong></td>
<td>Narrow interpretation of health technology</td>
<td>Broadening of scope of HTA</td>
<td>Further broadening of scope of HTA (pharmaceuticals, public health, delivery model, social services)</td>
</tr>
<tr>
<td></td>
<td>Focus on high intensity technology (imaging)</td>
<td>Possible addition of pharmaceuticals</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Expansion of technologies</td>
<td>Shift from specific technologies to care processes for the management of health conditions</td>
<td></td>
</tr>
<tr>
<td><strong>How?</strong></td>
<td>Modest resources, at times project or deliverable specific</td>
<td>Expansion of scientific team</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Minimal scientific capacity</td>
<td>Modest addition of resources</td>
<td></td>
</tr>
<tr>
<td>and, Then What?</td>
<td>Knowledge translation immature</td>
<td>Progression of knowledge translation efforts</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Efforts directed to policy makers, often by means of personal communication</td>
<td>Broader use of target audiences</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The “natural” history of HTA development

- 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 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.
Observations (ii)

• 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 case-by-case way, to what else is going on in the health care system.

• 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.).

Observations (iii)

• 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 real-world cost-effectiveness

• 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.
  - The 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.
Particular issues in Brazil

• In Brazil, the CITEC works slowly and appears to be under-resourced. This has the effect, intentional or otherwise, or delaying reviews of, and decisions on, access to new technologies.
• Aspects of the HTA process that could be improved, notably around transparency of process and of selection criteria.
• It is also unclear how the role of CITEC fits alongside a constitutional right of access to healthcare (which is clearly not consistent with the levels of funding available) and regulation by the ANS of the minimum requirements of the private insurance package.

Particular issues in China

• In China, there are a number of reforms to health system architecture underway and others are needed.
• Where HTA seems to be emerging as important is in the key area of clinical practice guidelines. The initiative with the UK NICE appears to be targeted at generating evidence-based clinical practice guidelines.
• HTA in the sense of appraising the cost-effectiveness of individual drugs is not used. There is interest in HTA in all three Ministries (MoH, MoHRSS, NRDC) and leading academics continue to promote dialogue on guidelines for good practice.
• To our knowledge there is no use of HTA for other individual technologies outside of drugs.
Particular issues in Taiwan

- In Taiwan, the role of HTA appears to be exclusively in the area of drug reimbursement;
- Even here it is unclear how it fits logically alongside an international reference price system.
- There are also some issues around the “black box” nature of the process such as:
  - the degree of transparency of the assessment;
  - the relationship between the assessment and the drug licensing process, given that expertise for pharmacoeconomic assessments is drawn from the licensing body
- Other elements impacting on cost and prices such as incentives to prescribe and trading margins are not being addressed

Macro-HTA: Tackling health system inefficiencies

- 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 over-prescribe 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.
- In all three countries, there appears to be little “active third party purchasing”
“Macro-HTA” example: The Ningxia Province Experiment

- Collaboration between the provincial government and the central government 2009-2013 to tackle most prevalent health problems including:
  - chronic (e.g. hypertension, and diabetes),
  - infectious (e.g. TB, Hepatitis B, and dysentery) and
  - common ailments (e.g. the common cold, UTI, and gastritis)
- Improvements in delivery to tackle these health problems include:
  - Developing clinical protocols;
  - Defining the role and function of the three-tiered delivery system: village clinics, THCs, county hospitals;
  - Designing provider payment method to incentivise providers to follow the best-practice, including referral. This raises the question as to how to re-train and/or retain qualified village doctors?
  - Designing benefit package to reduce financial barrier to access care and to motivate patients to use primary-based care
  - Using technology (e.g. mobile phone) to improve patient compliance.
  - Conducting patient education program on prevention, healthy lifestyle and best-practice care

"Macro-HTA” example: The Experiment in Ningxia Province

- There are 2 intervention counties, 3 comparison counties, a total of 1.8 million people. The study design is within county: blocked randomization across townships and villages with phased in interventions. It covers five years: 2009-2013, and uses:
  - Longitudinal household survey in baseline and followed up every year.
  - Patient cohort study
  - Provider survey
  - Direct linkage to claims data for NCMS reimbursement
  - Data base created by mobile phone technology

- Source: Yip (2009)
Implications

• The PhRMA, EFPIA, and IFPMA principles for good practice in HTA and Evidence-based Medicine provide a consistent approach to “micro HTA” and continue to provide a solid framework for approaching “micro HTA” issues globally including the three markets.

• We have sought to develop a framework for putting such a position into the context of health care system development and HTA evolution.

• Our key points are that 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”.

Thank you

atowse@ohe.org
www.ohe.org
lgarrisn@uw.edu
Key Points from Industry Principles

- HTA should not just be applied to medicines but to all health technologies and interventions. It should be undertaken as part of a broad agenda to improve health care quality and efficiency, rather than used as a cost containment tool. Likewise “silos budgeting,” where medicines are put into a separate cost bucket, runs counter to optimising health gains across the system;
- A broad perspective of value should be used including the impact on productivity, and on caregivers and personal time, and societal health priorities, for example in terms of disease burden, should be recognised.
- HTA when applied to determine access to or reimbursement for pharmaceuticals should be kept separate from marketing authorisation.
- HTA should be inclusive, open, transparent and balanced, involving external experts and all stakeholders. It should include rights of appeal. The evaluating body should be independent of the payer.
- Payers should commit to rewarding value. Positive HTA appraisals should attract the budgetary resources necessary to fund use.
- Appraisals should recognise that value emerges through use and additional evidence over the product life cycle and recognise the need to include new data. To this same point, uncertainty around cost-effectiveness has to be dealt with in a flexible way, including the use of in-market data collection, which requires putting in place the necessary infrastructure. A full range of types of evidence including observational data can play an important role. It is important that patients get speedy access to new technologies.
- Patient preferences and needs matter in any choice of medicine. HTA guidance should give clinicians enough freedom to address individual clinical situations. In this context, the incremental nature of innovation should be recognised as should the importance of having multiple treatment options.