

**HTAi Conference, Vancouver, June 2018
Strengthening the Evidence-to-Action Connection**

Panel Session Report

**Multi-stakeholder Dialogues Addressing Needs,
HTA Requirements and Good Practices
in Emerging Countries**

Key points

- All stakeholders involved in health care are under pressure and face complex problems. In such times, collaboration among stakeholders is essential to engage, reflect, listen and develop understanding of issues, so that solutions can be developed together.
- Multi-stakeholder collaboration is a journey during which trust must be built to openly discuss difficult issues. It can lead to mutual understanding and development of solutions that benefit all parties.
- Stakeholder involvement needs to be organized in a transparent way that considers which stakeholder is involved in what way in each phase of the HTA process and this needs to be adequately resourced.
- A range of mechanisms exist in the World Health Organization that enable effective multi-stakeholder collaborations and for HTA these include establishment of partnerships to build capacity in HTA.
- Emerging countries need to work in collaboration with other jurisdictions that have established systems to understand good practices and adapt them for the local context. Once organizational systems are established, wider multi-stakeholder engagement is possible.
- More efforts are needed to foster trust and credibility among stakeholders so that understanding can become a reality. This includes development of frameworks and rules for engagement to address issues such as conflict and undue influence.
- HTA could be seen as a focal point that can align stakeholders to identify effective health technologies in as efficient a manner as possible.
- HTAi offers a “safe harbour” for multi-stakeholder discussions, providing expert support and clear rules for engagement. This enables open conversations within limits that helps develop understanding and build relationships.

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About HTAi

Health Technology Assessment international (HTAi) is the global scientific and professional society for all those who produce, use, or encounter HTA. HTAi has members from over 65 countries and embraces all stakeholders, including researchers, agencies, policy makers, industry, academia, health service providers, and patients/consumers. HTAi is the neutral forum for collaboration and the sharing of leading information and expertise. This panel was judged by three reviewers and selected for presentation at the 2018 annual meeting by the International Scientific Program Committee.

Status of this report

This report has been prepared by an independent consultant, Karen Facey and approved by all presenters to become a public record of the HTAi panel session.

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Multi-stakeholder Dialogues Addressing Needs, HTA Requirements and Good Practices in Emerging Countries

1. Introduction and Industry Perspective

**Dr Alicia Granados, Head Global Health Technology Assessment
Scientific Strategy, Sanofi Genzyme**

Introduction

As moderator, Dr Granados explained that dialogue processes are developing in emerging countries, which go beyond the traditional low level one-way engagement of providing advice about technical issues to multi-stakeholder and two-way dialogue about wider challenges. This panel includes speakers from organisations that support dialogue among stakeholders in relation to health policy and HTA in emerging countries. They will explain the processes that support stakeholder engagement in specific initiatives, implementation challenges and good practices to support multi-stakeholder dialogues that are emerging. It is hoped this may lead to feasible actions for the future.

In 2014, the World Health Organization (WHO)¹ acknowledged the critical role of HTA in relation to Universal Health Coverage (UHC) and sustainability of health systems. It emphasized that rigorous and structured research methodology and transparent and inclusive processes could help address the need for reliable information to guide rational policy and professional decisions and practices in developing countries, where capacity for assessment of technologies is inadequate.

HTAi supports this work as a collaborating center with WHO. It recognizes that the lack of HTA, or very heterogeneous HTA approaches and lack of resources is a challenge in many regions, particularly those in emerging countries. In these regions, HTAi has sought ways to develop multi-stakeholder dialogues to further HTA, through using the model of the Global Policy Forum. So, it has established regional Policy Fora in Asia and Latin America that involve health policy makers, HTA bodies and industry representatives. These have discussed evolving needs, HTA requirements, capabilities, principles and good practices.

While recognizing the multifactorial needs and HTA practices across these two regions, the presentations from the HTAi Latin America and Asia Policy Fora in this conference have shown there are some commonalities, particularly in relation to needs. Furthermore, these multi-stakeholder interactions continue to develop in different ways and so it is a good time to reflect on:

- how these processes have evolved and the commonalities across the regions
- how a more collaborative and multi-stakeholder approach can be developed to support implementation of HTA and UHC.

This panel will discuss:

1. the reversible elements and barriers that prevent HTA implementation and consider how should they should be addressed
2. the role of multi-stakeholder dialogues in terms of determining health needs, HTA requirements, principles and good practices
3. the next steps to improve future collaboration and influence HTA policy shifts.

¹ World Health Organization. Health intervention and technology assessment in support of universal health coverage. WHA67.23 24 May 2014.

Industry perspective

Dr Granados stressed that industry is a part of the healthcare system and that the entire system is under pressure – both those providing for and paying for care and those developing health technologies. This is a complex problem, with no simple solution. Multi-stakeholder dialogues are the most innovative approach to solve complex issues in healthcare. Although there was a somewhat adversarial relationship between industry and the healthcare system in the past, this has evolved to a more transparent and ethical collaboration. Industry has initiated several workshops in Asia and Latin America and this has been a very enriching experience. Such fruitful collaboration enables different stakeholders to engage, reflect, listen and develop understanding of issues to develop solutions for the future together.

2. Experience in the HTAi Asia Policy Forum

Professor Adrian Towse

Former Scientific Secretariat, HTAi Asia Policy Forum

Director of Office of Health Economics, UK

Professor Towse shared his experiences of working with the HTAi Asia Policy Forum as its Scientific Secretary during 2013-2016 and set out its work in 2017.

The HTAi Asia Policy Forum held its first formal meeting in Seoul in 2013 under the chairmanship of Dr Chris Henshall. It has evolved its ways of working over the past six years, holding meetings in Manila, Singapore, Kuala Lumpur and Beijing, and is now chaired by Professor Brendon Kearney.

The HTAi Asia Policy Forum involves three core stakeholder groups:

- HTA representatives
- Ministry of Health/decision-makers/payers
- industry.

Dialogue amongst each of these stakeholders is key, as the biggest challenges may not be between industry and HTA, but between HTA and the decision-makers.

In 2017, 11 jurisdictions were represented: China, Indonesia, Iran, Japan, Korea, Malaysia, Philippines, Singapore, Taiwan, Thailand, Vietnam. A similar number of companies (pharmaceutical or medical device) was invited to ensure a balanced discussion.

Typically, surveys have been sent out in advance of the meeting to HTA agencies and ministries, and more recently to industry. In 2016, the pre-meeting survey asked about approaches to assessing value and budget impact and to financing high cost technologies. In 2017, two pre-meeting surveys were conducted on uses of real-world evidence and issues and challenges in implementing universal healthcare. These surveys have not only been useful to collect data about processes in the jurisdictions, but also to generate awareness of the upcoming meeting.

In addition, feedback questionnaires are issued to all participants after the meeting, to enable HTAi to improve the meeting process to continue to develop the collaborative approach. These feedback surveys have consistently shown that individuals found the meetings very helpful and they wanted to participate in a future meeting. The most important aspects of the meetings were the opportunities to interact and network with various stakeholders and to engage in open discussion of relevant topics.

To illustrate how the multi-stakeholder dialogues have developed in the HTAi Asia Policy Forum over this five-year period, it is helpful to review the themes arising from each meeting, with key issues underlined.

Further information about the Asia Policy Forum and its papers can be found at this website. <https://htai.org/policy-forum/asia-policy-forum-2/>

2013: How can the available resources be used most effectively to deliver high quality HTA that can be used by health system decision makers?

Key points from the meeting:

- *HTA can be positioned as a ‘bridge between scientific evidence and the needs of policymakers’.*
- *HTA is a tool to help improve the allocation of resources, but it cannot solve all problems.*
- *Decision makers in the region see potential for the use of HTA and are pushing for greater use.*
- *Decision makers may prefer “good enough” HTA advice on a range of questions, rather than “perfect” advice on a smaller number.*

Feedback: “The opportunity to meet for open discussions between HTA agencies, leaders of health system payer/coverage agencies and leaders of industry market access functions was valuable.”

2014: Transferability of HTA

Key points from the meeting:

- *HTA agencies/decision makers reported that they search for external HTA reports when developing their own.*
- *External reports were mainly used for information on methodology and data inputs, rather than transfer of decisions.*
- *Transferability of HTA may represent an efficient approach to building the local HTA evidence base, particularly when countries (like many in the Asia region) have limited capacity or expertise.*
- *Transferability is also important for industry: models must be adapted to different contexts. Assessment (scientific data) is more transferable than the appraisal (value systems and decision making).*

Feedback: “The Forum provided a useful space for discussing key issues and learning from international colleagues.”

This meeting was interesting, because it was a revelation to each stakeholder that they had similar views - that transferability of evidence was important. It was a surprise to some that HTAs begin by systematically searching HTA agency websites to identify relevant HTA reports that they can build on to add in the context relevant elements for their own jurisdiction.

2015: How can HTA meet the needs of health system and government decision makers?

Key points from the meeting:

- *There are inefficiencies in the current system – it is necessary but not sufficient for HTA to look at new drugs and technologies*
- *HTA is not the end goal in itself – the goal is improved outcomes and efficiency, and HTA is just one tool which could help achieve this.*
- *Payers and HTA representatives reported that HTA is considered to be a key tool in achieving UHC – mainly used at technology level*
- *For manufacturers, the decision-making process can seem like a black box. Transparency is crucial in all decisions.*

Feedback: “The group reported that the meeting was useful and well organised; the flow and the depth of the discussions were good. Time for networking/informal discussion is particularly useful.”

2016: Assessing value, budget impact and affordability to inform discussions on access and reimbursement²

Key points from the meeting:

- **HTA agencies** pointed out that measurement and benchmarking are challenging for wider value elements (how much should we pay for a day back at work?)
- **Decision makers** highlighted that a high cost does not automatically signal an innovative or curative therapy; value considerations must still take centre stage.
- **Industry** reported that Asian patients get later access to many medicines and argued that budget impact analysis should be used to decide the extent to which innovative financing arrangements are required (rather than whether or not to finance the technology).

Feedback: “The meeting was felt to be helpful in bringing important issues to light, including how budget impact analysis methods need development and how these analyses can complement, rather than replace, HTA.”

Everyone accepted that budget impact should be estimated. However, it was clarified that the analytical methods are not very reliable and the data needed for the calculations are often not available (epidemiology etc). As decisions are made on the basis of budget impact, this is a major issue and all agreed that more needed to be done to improve these calculations.

² <https://htai.org/policy-forum/asia-policy-forum-2/background-papers/>

2017: Overcoming the barriers to achieving universal health coverage in the Asian region using HTA and real-world data

Key points from the meeting:

- *Access to UHC can be viewed as an efficiency gain, but healthcare systems in the Asian region are experiencing huge pressures and are striving to achieve UHC.*
- *Barriers to implementing UHC included affordability, the lack of political will, and the cultural issue of deference to expert opinion instead of using evidence-based assessments.*
- *Asian social values and context need to be taken into consideration when making benefit package decisions, as well as incremental cost-effectiveness ratios.*
- *There is a disconnect between what real-world data (RWD) the HTA agencies and industry have knowledge of, and access to.*
- *There is a lack of collaboration and trust between agencies and industry on access to and use of RWD.*
- *Countries have conservative approaches to RWD access*

The key challenge raised here was that HTA agencies may do an evidence-based assessment but that Ministries may take greater notice of expert advice.

This was the first meeting where actions were agreed for the Forum Members to develop:

- a standardised methodology for the prioritisation of technologies
- a catalogue of public and private data that is available across countries in the region
- a policy statement about a common approach to the release of data that agencies can use.

Agreeing these actions was possible given the trust that had developed among participants over the previous five years, the honest sharing of issues among all stakeholders and recognition that everyone wanted a solution to the same challenges.

Reflecting over the development of these meetings, multi-stakeholder collaboration is a journey, creating trust and willingness to talk openly and discuss difficult issues. This will not happen at the first meeting, it takes time. The journey leads to more willingness to engage openly and address difficult issues. This leads to better mutual understanding and the possibility of some possible ways forward.

3. Experience in HTAi Latin America Policy Forum – Main Challenges and Ways Forward

Professor Andrés Pichon-Riviere, HTAi Latin America Scientific Secretariat; Director of HTA and Health Economics, Institute for Clinical Effectiveness and Health Policy (IECS)

Professor Pichon-Riviere presented the work of the HTAi Latin America Policy Forum meetings to reflect on the challenges and opportunities for multi-stakeholder collaboration in the region.

To provide some context, 10 years ago Drummond et al. (2008)³ published 15 principles that sought to improve the conduct of HTA. Principle 10 was “those conducting HTAs should

³ Drummond MF, Sanford Schwartz, Joensson B et al. Key principles for improved conduct of health technology assessments for resource allocation decision. *Int J Technol Assess Health Care*. 2008; 24:244-258.

actively engage all key stakeholder groups”. In the following year, IECS, worked with Professor Drummond to review whether those principles were relevant and useful for HTA in Latin America and to what extent they were being applied⁴.

A survey was issued in 2009 and 1,142 responses were received from individuals in 19 Latin American countries. The general conclusion of the survey was that the 15 principles on HTA were relevant for Latin America, but that the level of application of the principles at that point in time was low. The principles were graded in terms of relevance and the five with the highest level of relevance were appropriate methods for assessing costs and benefit, characterization of uncertainty, monitor implementation of HTA findings, timely HTA, transparent link between HTA findings and decision-making (Figure 1).

Figure 1. Latin-America views of relevance* of international principles for HTA in 2009

	<i>1: The Goal and Scope of the HTA Should Be Explicit and Relevant to Its Use</i>	<i>2: HTA Should Be an Unbiased and Transparent Exercise</i>	<i>3: HTA Should Include All Relevant Technologies</i>
Structure of HTA programs	4: A Clear System for Setting Priorities for HTA Should Exist	5: HTA Should Incorporate Appropriate Methods for Assessing Costs and Benefits	6: HTAs Should Consider a Wide Range of Evidence and Outcomes
	7: A Full Societal Perspective Should Be Considered When Undertaking HTAs	8: HTAs Should Explicitly Characterize Uncertainty Surrounding Estimates	9: HTAs Should Consider and Address Issues of Generalizability and Transferability
Processes for conducting HTA	<i>10: Those Conducting HTAs Should Actively Engage All Key Stakeholder Groups</i>	<i>11: Those Undertaking HTAs Should Actively Seek All Available Data</i>	12: The Implementation of HTA Findings Needs to Be Monitored
	13: HTA Should Be Timely	14: HTA Findings Need to Be Communicated Appropriately to Different Decision Makers	15: The Link Between HTA Findings and Decision-Making Processes Needs to Be Transparent and Clearly Defined

Relevance*

Most relevant
Intermediate
<i>Less relevant</i>

Principle 10 about engaging stakeholders was in the group that were of lowest relevance. The survey also explored the degree of application of each principle at that point in time. This also showed that “actively engaging with all stakeholder groups” had a lower level of application.

Over the past decade, this situation has changed.

⁴ Pichon-Riviere A, Augustovski F, Rubinstein A, Martí SG, Sullivan SD, Drummond MF. Health technology assessment for resource allocation decisions: Are key principles relevant for Latin America? *Int J Technol Assess Health Care*. 2010; 26:421-7.

In 2016, the first HTAi Latin America Policy Forum was held in Costa Rica. Following the format of the other HTAi Policy Fora, it was organized to provide an environment where senior representatives from the public and private sector and keynote speakers could engage in strategic discussions about the present state of HTA, its development and implications for health care systems, industry, patients and other stakeholders with specific relevance to the region. To enable optimal networking in this region, the meeting is held in Spanish.

This meeting progressed the work on application of principles undertaken in 2009 and had objectives to:

- identify which of the HTA good practice principles proposed at the international level would be the most relevant and of highest priority for application in Latin America
- identify barriers faced by the region in fostering their uptake
- formulate recommendations to health systems for improving HTA and its use in decision making in the region.

The conclusions were that international good practice principles are valid and potentially applicable in Latin America. The main recommendation was to find appropriate HTA processes and methodologies, adapted to the context of each country. These need to allow for gradual improvements in the links between HTA and decision making, without trying to impose, in the short-term, excessively high standards set by the international principles. To ensure that these conclusions were shared among all stakeholders a paper summarizing the meeting was published in a Spanish and an English journal⁵.

In these Latin America Policy Forum discussions in 2016, five principles for HTA were identified as important and with the greatest potential to be applied or strengthened in the region. This now included “involvement of relevant stakeholders in the HTA process”. Some of the groups felt that this principle should be implemented immediately because it is essential to legitimize the HTA and decision-making processes and thereby reduce the risk of conflicts and/or judicial appeals. However, other participants felt that this principle was not such a high priority because it can be complex to implement, expose HTA to undesirable influences and produce an excessive workload that causes delays to HTA.

This discussion led to the topic for the 2017 HTAi Latin America Policy Forum that was held in Peru. Its aim was to debate the best way for HTA agencies in the region to improve stakeholder involvement, in terms of conceptual frameworks, methodological and operational aspects.

This meeting included 41 participants in 10 countries from HTA agencies, the social security and health care sector, industry and academia. The discussion took place with joint recognition that many of the countries in the region do not have fully operational HTA agencies, explicit benefit packages and clear processes to incorporate technologies. So, this is a very different context to the Global Policy Forum and this impacts the way the multi-stakeholder dialogues develop.

⁵ Pichon-Riviere A, Soto NC, Augustovski FA, García Martí S, Sampietro-Colom L. Health Technology Assessment for decision making in Latin America: Good practice principles. *Int J Technol Assess Health Care*. 2018; 34:241–247.

Pichon-Riviere A, Soto NC, Augustovski FA, García Martí S, Sampietro-Colom L. Evaluación de tecnologías sanitarias para la toma de decisiones en Latinoamérica: principios de buenas prácticas]. *Rev Panam Salud Publica*. 2018 Feb 19;41:e138. Spanish. PubMed PMID: 29466522.

The meeting began with an overview of the involvement of patients and industry in the 10 countries involved in the Forum. This showed a heterogenous picture ranging from countries where there are no formal mechanisms to involve stakeholders to those where there is some systematic involvement. However, even in these countries, the involvement is limited to certain stakeholders at certain phases of the HTA.

During this Forum meeting, many concerns were raised and several participants expressed concern over potentially negative consequences of stakeholder involvement in HTA. Some of the main fears were that certain groups could have an excessive influence on setting the agenda for prioritization of technologies to be assessed towards those that have a “sponsor” rather than those that are deemed to have highest need by the health system. Some Forum attendees feared that stakeholders could inappropriately influence assessment and decision-making and referred to pressure received from patient groups highly associated with industry. This concern was more pronounced in countries with a lower level of HTA institutionalization where HTA mechanisms and structures are weaker or just developing.

Country representatives were also concerned that stakeholder involvement would increase demand to a point exceeding available resources, thereby causing delays in the HTA process. It was argued that this could be readily applied in large countries with assessment structures equipped to respond to such demands, but for smaller countries, this would not be feasible.

Other barriers to stakeholder involvement in the process HTA were identified as:

- lack of trust among stakeholders
- fragmentation of health systems
- patients’ lack of education and awareness about HTA
- lack of culture for involving citizens in policy development and no clear mechanisms to promote citizen participation in HTA
- judicialization of HTA related decisions through individual-based appeals.

As a result of these discussions, many participants felt that principles and conditions (as outlined in Box 1) should be used to facilitate appropriate involvement of stakeholders in HTA. Given the lack of HTA processes in some countries in the region, these included mechanisms to guide the assessment and decision-making processes and to ensure that the HTA process is not exposed to excessive “external” influences.

Box 1. Principles and mechanisms to support stakeholder involvement in HTA in Latin America⁶

- Transparency in the HTA process
- Clear links between HTA and decision-making, with criteria and values explicitly based in social preferences.
- Appropriate technical staffing and resourcing of HTA agencies
- Mechanisms to assure the prioritization of assessment topics aligns with real needs and is not unduly influenced by stakeholders
- Methodological guidelines outline the technical aspects of the HTA process and identify where and how different stakeholders can participate

⁶ Adapted from Pichon-Riviere A, Soto N, Augustovski F, Sampietro-Colom L. STAKEHOLDER INVOLVEMENT IN THE HEALTH TECHNOLOGY ASSESSMENT PROCESS IN LATIN AMERICA. International Journal of Technology Assessment in Health Care. Cambridge University Press; 2018;34(3):248–53.

This meeting concluded that given the legitimization of HTA and decision-making processes in the Latin America region it is important to promote stakeholder involvement, but the form and timing of involvement must be adapted to the local context and type of stakeholder. To achieve this, the entire system of assessment and decision-making needs to be appropriately resourced and organized taking account of the key principles in Box 1. Over and above this, efforts need to be made to foster trust and credibility among stakeholders so that involvement can become a reality.

4. Perspective from World Health Organization (WHO)

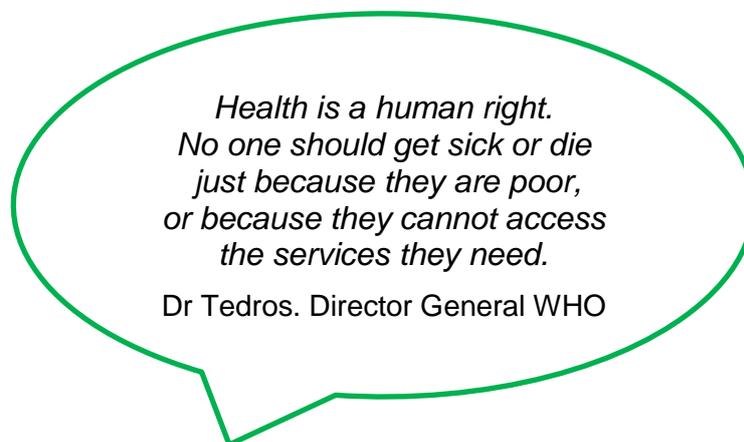
Dr Sarah Garner, Coordinator - Innovation, Access and Use; Essential Medicines and Health Products, WHO.

WHO mechanisms to foster collaboration

Dr Garner presented mechanisms to foster dialogue among stakeholders to engage in the work of WHO and new developments in WHO in relation to HTA.

WHO was created as the directing and coordinating authority on international health, enabling the nations of the world to act together for the health of all people. It has a 70-year history that includes catalyzing major accomplishments, such as the eradication of smallpox or the rapid scale-up of treatment against HIV infection. However, WHO has also experienced periods of crisis.

The new Director General of WHO, Dr Tedros, is changing the direction of WHO at all levels (global, regional and country). He has stated that access to services (medicines, devices, assistive technologies) is a human right, which puts this high on the political agenda.

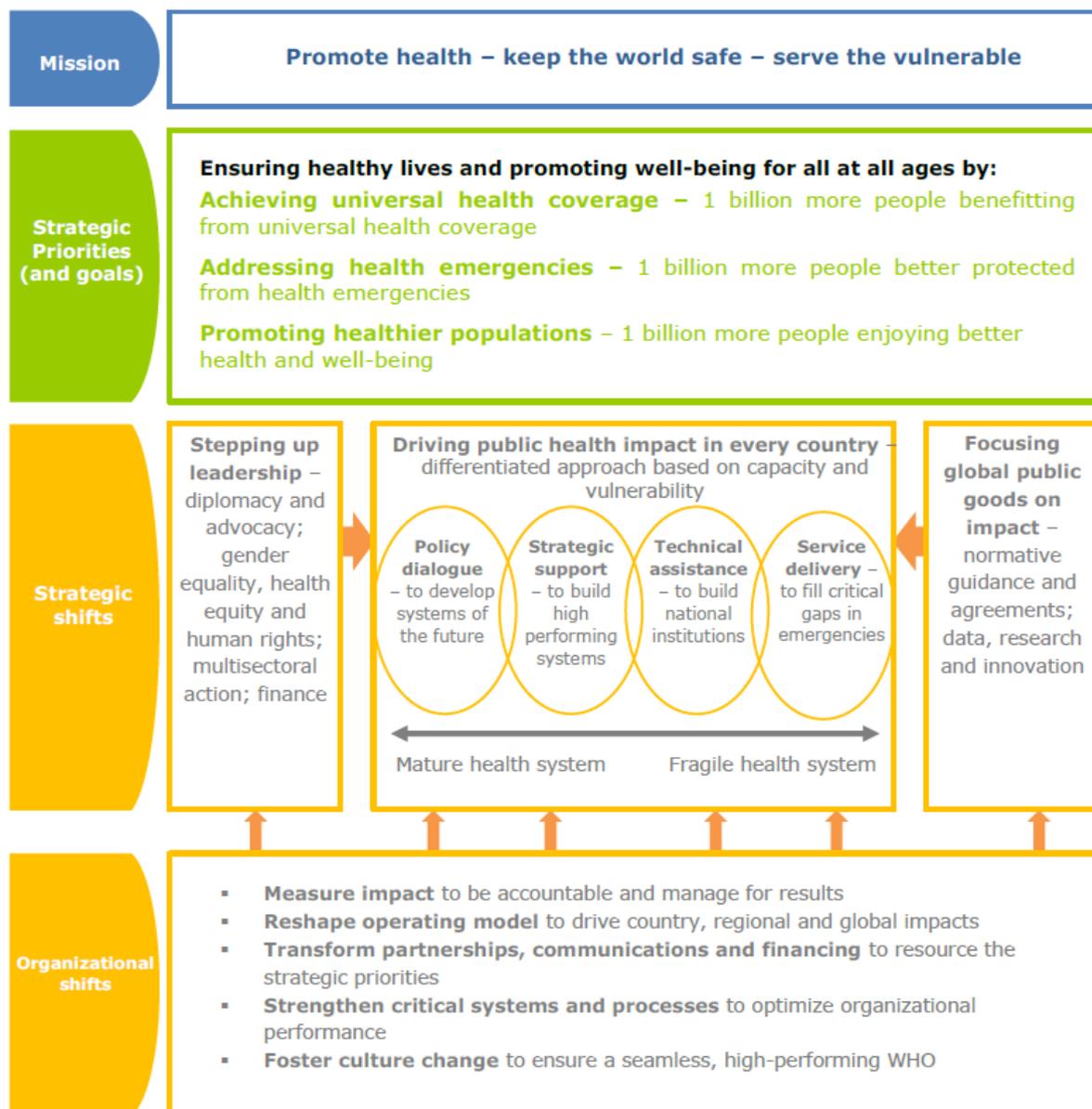


This has influenced the strategic direction of WHO as outlined in its new global program of work 2019-2023⁷ and shown in Figure 2. The new WHO work programme aims to build on past achievements and respond to new challenges, while continuously learning and improving. WHO is embarking on an ambitious journey that will not only transform the Secretariat, but also global health.

⁷ Draft thirteenth general programme of work, 2019-2023. Seventy-first World Health Assembly. World Health Organization. 5 April 2018. http://apps.who.int/gb/ebwha/pdf_files/WHA71/A71_4-en.pdf?ua=1 Accessed 25 July 2018.

In relation to multi-stakeholder dialogues, one of the key “strategic shifts” shown in the work programme is to differentiate how WHO will operate with its Member States (MS), depending on their stage of development and the needs in that country. This differentiated approach will influence the policy dialogue, strategic support, technical assistance and service delivery offered to each country, based on its capacity and vulnerability. To enable this, WHO is stepping up its leadership in a number of areas; enhancing diplomacy and advocacy, promoting equality and human rights and encouraging multi-sectorial action. In terms of “organizational shifts” the opportunity to “transform partnerships” is of particular relevance to this discussion.

Figure 2. Overview of WHO’s draft thirteenth general programme of work 2019–2023: strategic priorities and shifts⁸



WHO is developing its approach to partnership working with citizens, research institutions, and the private sector. To address concerns raised about these partnerships (for example regarding conflicts of interest), there have been extensive discussions amongst the WHO leadership and in MS. This has led to *the Framework of Engagement with Non-State Actors* (FENSA)⁸, which was adopted by the World Health Assembly (WHA) in 2016 (WHA69.10).

FENSA aims to:

- strengthen WHO engagement with Non-State actors (i.e. non-governmental organisations (NGOs), private sector entities, philanthropic foundations and academic institutions)
- protect its work from potential risks such as reputational risks, conflicts of interest and undue influence from external actors.

FENSA also facilitates and enhances transparency and accountability in WHO's engagement with Non-State actors and provides an online register of Non-State actors.

Before engaging with WHO, Non-State actors submit to due diligence and each proposed project undergoes a risk assessment and an agreement must be signed. It is still fairly new in terms of implementation and so it is currently being operationalized on a case-by-case basis.

WHO uses a mechanism of "official relations", which is a privilege that the Executive Board may grant to Non-State actors that have had and continue to have a sustained and systematic engagement in the interest of WHO. There are currently 214 Non-State actors registered as official relations. These organisations are invited to participate in sessions of WHO's governing bodies, such as the World Health Assembly. As an official relation, an organization has the opportunity to make a statement on request or by permission of the Chairman. It also includes the possibility to submit the statement in advance of the debate and this will be posted on a dedicated website. This is a great opportunity to make a clear statement to senior leaders in the MS and inform stakeholders.

In the field of HTA, HTAi, Euroscan and INAHTA are seen to have official relations. For industry, all engagement is via the official trade bodies, not individual companies and so IFPMA and IGBA are official relations.

In addition to being registered as an official relation, there are a number of other ways to work with WHO:

- via the United Nations system
- through partnerships, where WHO is an equal partner (e.g. the TB alliance), but the partnership is managed elsewhere
- as a WHO collaborating center
- on WHO expert panels and committees.

WHO collaborations in relation to HTA

Dr Garner has been providing leadership on HTA, working with colleagues to consider what WHO needs to do at global, regional and country level. The first step is to recognize that the use of the term HTA may itself be a barrier. However, setting it in the context of UHC, as "access to services for all" could be more helpful. As access to essential medicines and health products is at the heart of UHC and is supported by five other elements that are essential for healthcare delivery (financing, governance, workforce, information systems, service delivery and safety).

⁸ WHO. Framework of Engagement with Non-State Actors. World Health Assembly. May 2016. http://www.who.int/about/collaborations/non-state-actors/A69_R10-FENSA-en.pdf?ua=1

Political support for using HTA to improve health was first seen in 2005, when Mexico proposed a resolution *about the waste of resources resulting from inappropriate investments in health technologies that do not meet high-priority needs, are incompatible with existing infrastructures, or are irrationally or incorrectly used*. This resolution on Health Technologies was endorsed by Thailand and the Netherlands.

Two years later, in 2007, the WHA approved the resolution and MS were required to:

- formulate, as appropriate, national strategies and plans for the establishment of systems for the assessment, planning, procurement and management of health technologies in particular medical devices, in collaboration with personnel involved in health technology assessment and biomedical engineering”;
- provide support to its Member States in establishing mechanisms to assess national needs for health technologies, assure their availability and use, and implement policies on health technologies, especially for priority diseases according to different levels of care in developing countries.

The process is non-binding but it provides a tool that can be quoted and used to drive forward change.

In 2009 and 2010, Memoranda of Understanding were signed with HTAi, INAHTA and EuroScan to support the implementation of the resolution as a means to disseminate knowledge about HTA (particularly in low and middle-income countries), evaluate innovative technologies and exchange information.

A key HTA related activity in WHO is the Essential Medicines List, which is a tool that seeks to expand access to medicines, by identifying medicines that are deemed essential for addressing the most important public health needs globally. It focusses on clinical effectiveness and can consider unlicensed indications if they may be used for public good. The List currently includes 433 medicines and this year new medicines for hepatitis C, HIV and leukemia were added. Likewise, an In Vitro Diagnostics List is published in 2018.

Another group relevant to HTA, is the WHO Health Systems team, which manages the WHO CHOICE programme. This supports analysis of costs, cost-effectiveness and strategic planning to determine the “best buys” for the MS health system.

One of the challenges has been to work out how to bring these two programmes on clinical effectiveness and cost issues together and bring in other elements that are known to be important in decision-making, such as social values, to create a coherent approach. This whole-systems approach has been fostered by the development of the Innovation, Access and Use team that brings together the work on the essential lists of products, pricing etc.

Dialogues are underway with the regions and countries to clarify their needs in relation to HTA. This will be used to develop a strategy and mobilise resources. An important element of this will be to work will be to develop partnerships to use good work that is already underway and identify the specific role for WHO.

At the World Health Assembly in March 2018, two decisions were endorsed that have implications for how the WHO will organise its work in future and they could both be vehicles for collaboration on HTA issues:

1. Endorsement of WHO to create a roadmap to address shortage of, and access to, medicines, vaccines and health products.
2. Global strategy and plan of action on public health, innovation and intellectual property.

In particular, the global strategy on public health includes reference to HTA and notes that the WHO Secretariat will develop and share good practices on evidence-based selection and HTA for health products for national use and support bilateral and regional collaboration between countries.

WHO has a huge agenda, so the African proverb seems apt that “If you want to fast, go alone. If you want to go far, go together.”, but within the framework of the FENSA agreement!

Public-private partnerships

Dr Garner also reflected on the potential for dialogue in public-private partnerships, reflecting on her past involved in a number of Innovative Medicines Initiative (imi)⁹ projects, when she worked at NICE. These public-private partnerships enable HTA bodies to interact with stakeholders in a different way and have been instrumental in changing the perceptions of all those involved. They have shown that stakeholders can work together on general issues where there are no conflicts of interest, agreeing plans of work and outcomes, but this is a journey that will continue.

5. Perspective from a Health Authority in Latin America

Dr. Rabel Eduardo Ventura, Programa de Medicamentos de Alto Costo, Ministerio de Salud Pública República Dominicana

Dr Ventura gave an overview of challenges related to the reimbursement of medicines in the Dominican Republic, which is an upper-middle income developing country. He presented how approaches have been developed over the past seven years in collaboration with other stakeholders.

The Dominican Republic is the second largest country of the Caribbean islands with 10.6 million inhabitants. Healthcare is provided in the public and private sectors, with limited primary care gatekeeping. There is coverage for high cost diseases, of 1 million pesos (~US\$20,000). The coverage for outpatient medicines for the whole year has been increased from 3,000 pesos (US\$60) to 8,000 pesos (US\$120).

There is no HTA system in the Dominican Republic. In 2011, the government created a Protective Medicines’ Programme, to provide patients with assistance to buy their prescriptions. However, the demand for medicines was high, as were the costs, so in 2015 the programme of high-cost medicines and direct medical aids was created. It aimed to contribute to equitable and sustainable access to high quality, safe and cost-effective medicines. The medicines included in the programme were selected based on the best scientific evidence (including HTA reports from other countries) and prioritization criteria that considered the financing capacity of the Dominican State, the national drug policy, patient needs and patient out-of-pocket expenses.

Over time, a large number of medicines was included in the Programme, but the budget was insufficient and so there was a long waiting list for patients to get their medicines. So, a different process was needed to make better decisions about what should and should not be included in the Programme.

⁹ <https://www.imi.europa.eu/>

In 2015, the process was refined to create specific criteria for high cost drugs. This identified medicines that must remain in the list, according to three priorities:

- 1: those in the WHO / PAHO Essential Medicines List
- 2: those in the list developed by the Councils of Ministers of Health of Central America and the Dominican Republic
- 3: not included in the previous lists, but with scientific evidence that supports its use.

All these priorities were ratified by a group of clinical experts.

This reduced the list of approved medicines in the Programme, but these would still have costed more than the budget available. So, economists used Pareto analysis to identify the medicines on the list that would provide the largest health gain.

For patients who were given prescriptions in private sector hospitals for medicines that were not included in the Programme, partnerships were established with public sector hospitals and health services, who re-evaluated the prescriptions. In many cases the prescription could be altered to a medicine that was on the approved list.

There was also collaboration with other government departments to transfer their budget to health services.

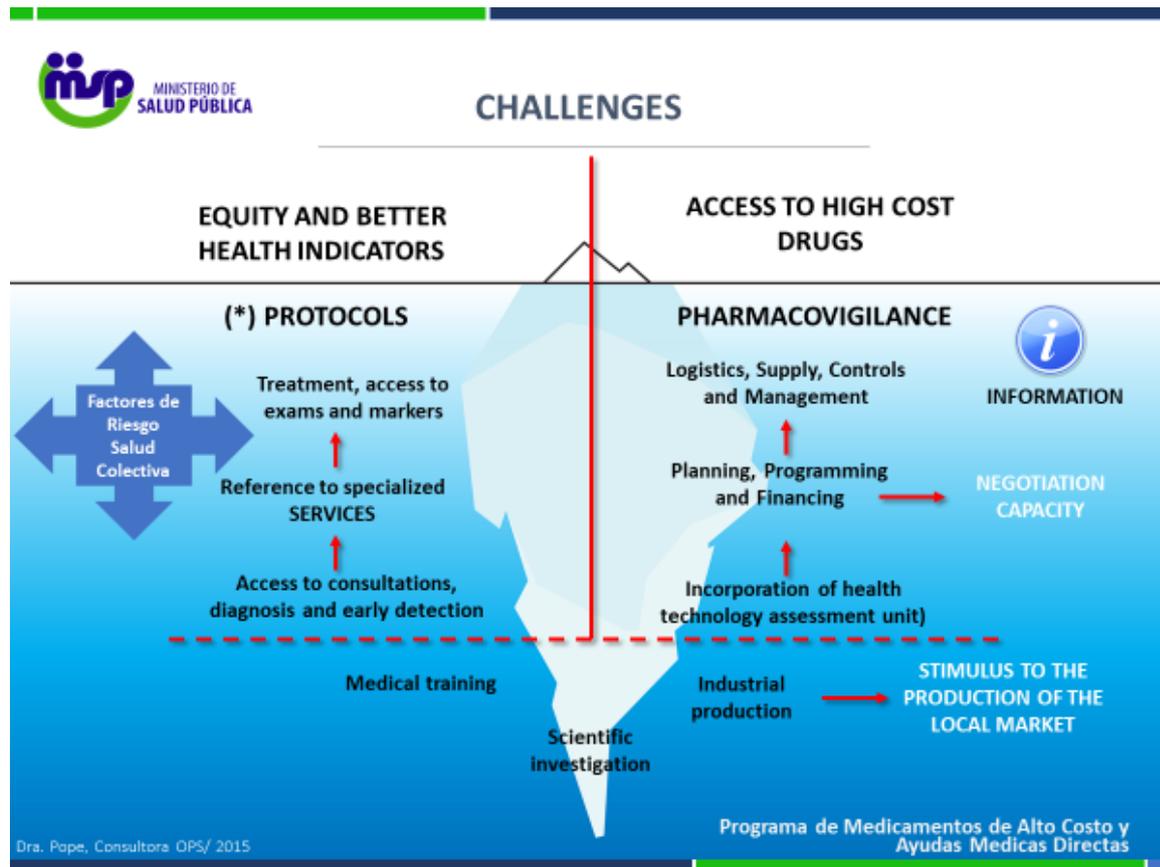
This process has now developed into the High Cost Drug Management System that is publicly available on the web. It is a sophisticated system that keeps track of individual patients, the hospitals they attend and when they pick up their prescriptions. With these improvements it has been possible to increase coverage in the health system from 8,753 patients in 2015 to 19,310 patients in 2018.

Given the large number of new technologies that are coming into the health system in the Dominican Republic, there is a need for an HTA-like system to help use the limited resources wisely to maximize the health of the population. Protocols (clinical guidelines) are being developed to identify optimal care pathways and use of health technologies. This is another area where HTA would be valuable. However, there are some challenges that the system faces including supply of medicines and financing as shown in Figure 3.

Currently, the Ministry of Public Health is promoting the development of a proposal for the creation of a Regional HTA unit, drawing on established HTA bodies in the region, like Columbia and Argentina, to create regional HTA reports that could be adapted for use in individual countries. These regional reports will be piloted in the Dominican Republic. This will include use of real-world evidence to monitor and evaluate use of new technologies.

To develop HTA in the Dominican Republic, there needs to be collaboration among all stakeholders within the country and internationally to understand good practices that can be adapted to the local context.

Figure 3. Challenges in Health Service Development in the Dominican Republic



6. Discussion

Dr Granados thanked the panelists for their interesting contributions and asked the audience for their comments.

Adham Ismail, Regional Adviser (WHO Regional Office for the Eastern Mediterranean). There are other partners and WHO collaborating centres such as the Middle East/North Africa Health Policy Forum (MENA HPF), which can contribute to the progress of HTA in this region. Last year they conducted a meeting for regional HTA policy makers. Issues raised during discussions addressed similar issues to those presented by Dr Riviere. It would be good to include a presentation about their work in future discussions. Since the African context is different, sessions regarding the progress in MENA region should be included in future events.

In terms of engagement with stakeholders, we need to think about the form of engagement. There are three levels of engagement:

1. Consult
2. Involve
3. Partnerships.

We need to create a framework that considers which stakeholders, at what stage, at what level of engagement. This would prevent conflicts of interest and help engagement with industry, according to a clearly defined framework.

AG - Sometimes when seeking to develop the conceptualisation of an issue like collaboration, it is helpful to reflect on a practical example. A previous conference session presented the discussion of this year's HTAi Asia Policy Forum on real world evidence. This showed that there were areas that were easier to collaborate on, such as epidemiology, natural history etc and that working together on such issues is for the public good not just for industry, or HTA. Does the audience think there is potential for greater collaboration to address such public health needs?

EV – It would be interesting to see if countries in a region could collaborate to see if they can share real world evidence, to share the burden for analysis and then localize it.

AG – In HTA there are some aspects that can be shared, but some that are context dependent. In terms of stakeholder collaboration, there are good practices emerging for patient involvement. Do you think that any of these could be implemented in Asia or Latin America?

AT – There is a wide diversity in views among countries and regions about the role which patients should play in the development of health care and this affects policy leaders' views on how patients should be involved in HTA.

APR – Latin America is heterogeneous, but involving stakeholders in HTA and decision-making requires time, methodologies, processes, resources and training. In countries that do not even have a basic package of care and are just starting to evaluate effectiveness of health technologies, it is very difficult to involve stakeholders. At these very early stages of HTA development, processes are still being developed and it is not possible to be fully transparent about them as they may evolve rapidly. However, if you consider well-established HTA bodies, like in Brazil, Columbia, or Mexico, stakeholder involvement is a reality.

AG – There are some basic requirements that are needed before stakeholders can be involved, such as established processes, trust, evaluation of impact of involvement. What else is needed?

Katja Berg (Market Access, Sanofi) – It is important to find a common purpose for stakeholders to align on – then we can be clear about what we are trying to achieve through the stakeholder involvement.

AG – HTA could actually be seen as the focal point that aligns stakeholders to identify effective health technologies in as efficient a manner as possible, taking account of key principles that everyone can agree with like transparency, inclusiveness, right to appeal etc. HTAi and WHO have helped foster discussions to develop this alignment and we need to think about what we need to do now to improve stakeholder collaboration in all regions.

Katja Berg – HTA should be an enabler for access for medicines to patients. That is the greater goal and should be the common priority.

AT – Is it true that in the initial meeting of the HTAi Latin America Policy Forum there was a certain amount of friction between the HTA bodies and industry, but that over the years the multi-stakeholder dialogue has built trust and understanding?

APR – The group is indeed learning how to engage in dialogue with different stakeholders to discuss difficult issues and we see the atmosphere changing year on year. (This year a patient representative was included for the first time and this worked very well.)

AG – One of the important elements is that the Policy Fora are hosted by HTAi, which offers neutral territory (a “safe harbour”) for discussions and provides clear rules for engagement. This enables open conversations within limits, which helps develop understanding and build relationships.

Dr Granados thanked all who had contributed to the panel. This session has shown the magic of dialogue that even if groups have different interests and purposes, they can often find a common goal. For us it is how to facilitate access to patient to the most appropriate technology at the right time.

Glossary

FENSA	Framework of Engagement with Non-State Actors
HIV	Human Immunodeficiency Virus
HTA	Health Technology Assessment
IECS	Institute for Clinical Effectiveness and Health Policy
IFPMA	International Federation of Pharmaceutical Manufacturers
IGBA	International Generic and Biosimilar Medicines Association
INAHTA	International Network of Agencies for HTA
MS	Member State
NGO	Non-Governmental Organization
NICE	National Institute for Health and Care Excellence
PAHO	Pan-American Health Organization
RWD	Real-World Data
TB	Tuberculosis
UHC	Universal Health Coverage
WHA	World Health Assembly
WHO	World Health Organization