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HIGH-COST DRUGS

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HTAsiaLink

NEWSLETTER TO STRENGTHEN COLLABORATION AMONG HTA AGENCIES IN ASIA

EDITORIAL

htasialink@hitap.net

Change is good. Health Technology Assessment itself is constituted of many change components starting from research, which is looking for evidence to change something, to decision-making, which is changing something from its previous state to a new one. With the half of 2017 gone by, many new changes have occurred. This issue tries to capture some of it through various experiences.

We would like to welcome the new members of HTAsiaLink – the Shanghai Health Technology Assessment Research Center, the Health Technology Assessment Program from Mahidol University,

and the InaHTAC (Indonesia Health Technology Assessment Committee), Ministry of Health, Republic of Indonesia. These members were approved by the HTAsiaLink Board during the Annual Conference which was held in Vietnam in April 2017. The theme for this year's conference was Health Technology Assessment in designing and implementing a benefits package so that it can help in achieving Universal Health Coverage. GEAR (Guide to Economic Analysis and Research), an online resource that guides researchers performing economic analysis research, was launched during the HTAsiaLink Conference. We also seized the opportunity to conduct an interview with the vice-minister of Vietnam.

This issue has stories from six countries that share their experiences about how HTA is being used to tackle the problem of 'High-cost drugs' back at home. We also introduced an international internship program at the Health Intervention and Technology Assessment Program (HITAP) which is aimed at helping researchers from Low-Middle Income Countries build their capacity in Health Technology Assessment.

We, the Editorial team, hope that you will enjoy reading this issue. We would also like to invite you all to the next HTAsiaLink Conference which is to be held in Thailand in early 2018.

Best wishes,
The Editorial Team

From the 6th to 7th *HTAsiaLink conference*



“Health Technology Assessment in designing and implementing Benefit Package for Universal Health Coverage (UHC).”

The 6th HTAsiaLink conference was held at La Than Hotel in Hanoi, Vietnam from 17th to 19th April 2017. Around 120 participants attended the conference and the theme was ‘Health Technology Assessment in designing and implementing Benefit Package for Universal Health Coverage (UHC)’. The Health Strategy and Planning Institute, Ministry of Health, Vietnam organized the conference beautifully and they were also wonderful hosts to all the participants who attended the.

The conference saw participation from almost all member countries. This year, we saw a lot of variety in terms of presentations ranging from broad health system research topics to detailed economic evaluation researches. The National Evidence-based healthcare Collaborating Agency also returned as the secretariat for HTAsiaLink network.

Professor Vicharn Panich from Thailand, who is the Chairman of the Board of HITAP, provided some closing remarks to sum up this year’s conference and he also welcomed everyone to Thailand for the following year’s.



Following the conference, the HTAsiaLink member’s meeting decided that the venue for the 2018 conference shall be Chiang Mai, Thailand and the theme chosen was ‘Sustainability and Independence of HTA Institution and Financing for HTA study’. Preparations have already begun in Thailand to make the upcoming conference a spectacular one. It will be organized jointly by HITAP, the Ministry of Public Health, Thailand, and Mahidol University, Thailand. HTAsiaLink members from Thailand have always maintained their reputation of mesmerizing participants with the way they present and promote their culture and we expect the same from this upcoming event.

Contributors



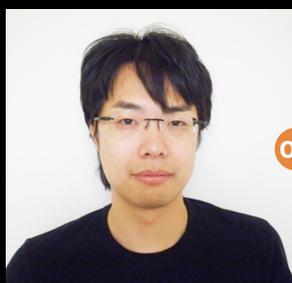
Jasmine Pwu, 01
Director of the National Hepatitis C
Program Office, MOHW, Taiwan

Ku Nurhasni 02
Malaysian Health Technology
Assessment Section,
Medical Development Division,
Ministry of Health Malaysia



Junainah Sabirin 03
Malaysian Health Technology
Assessment Section,
Medical Development Division,
Ministry of Health Malaysia

Noormah Mohd Darus 04
Malaysian Health Technology
Assessment Section,
Medical Development Division,
Ministry of Health Malaysia



Pempa 05
Laboratory Officer,
Essential medicine and technology
Division, Department of Medical
Services, Ministry of Health

Ryota Nakamura 06
Associate Professor,
Hitotsubashi University, Japan



Aamir Sohail 07
Medical Technology Advisory
Board Secretariat,
Department of Health Research,
Ministry of Health and Family
Welfare, Government of India

Laura Downey 08
Global Health and Development,
Imperial College London, UK



Anna Melissa Guerrero 09
MD, MPH (HTA) Division Chief,
Pharmaceutical Division



Author:

Dr. Jasmine Pwu,
National Hepatitis
C Program Office,
MOHW, Taiwan



Using HTA

to combat hepatitis C



“50% reduction in new infections, 50% reduction in HCV-related mortalities and over 50% coverage in access to treatment by 2025”

Hepatitis C is a major public health issue in Taiwan. The age-adjusted prevalence of hepatitis C virus (HCV) infections is about 3.6% of adults or nearly 450,000 patients. Patients diagnosed with HCV in Taiwan have the choice of using peginterferon/ribavirin, a treatment program which is reimbursed by the National Health Insurance since 2003. However, due to the possible side effects, patients are reluctant to receive the treatment. Alternatively, the recently developed directly-acting antivirals (DAAs) have high efficacy and safety profile but the price is high. The total financial impact would be overwhelming to the healthcare system when considering all HCV-infected patients.

Echoing the WHO’s call for action on the global efforts of eliminating hepatitis by 2030, Taiwan’s Ministry of Health and Welfare (MOHW) has set the goal of “50% reduction in new infections, 50% reduction in HCV-related

mortalities and over 50% coverage in access to treatment by 2025”. In order to achieve this goal, the “National Hepatitis C Program (NHCP) Office” was set up in December 2016 with the main tasks of coordinating the already-existing prevention, screening, health promotion, treatment, and research/development functions in different ministerial administrations.

In the initial phase, the NHCP office firstly recruited experienced HTA experts (Dr. Grace Wu and Wen-Wen Yang, who are longtime HTAsiaLink-enthusiastic colleagues). We have already connected with different government functions, different sectors (economics, pharmaceutical companies, the hepatology society, epidemiology, ICT industry, outcomes research, etc.). Early this year (2017), the National Health Insurance Administration (NHIA) started to reimburse DAAs for patients with certain criteria (8,000 patients in the first year). The NHCP office has also assisted with estimating the number of patients for reimbursement as well as the registry system in the NHIA. Furthermore, we set up a more aggressive safety monitoring/feedback system in order to help hematologists detect safety signals more rapidly.

Among all these, the design of a national strategy and its financing will be the most challenging one. Health technology assessment will be the key to our success.

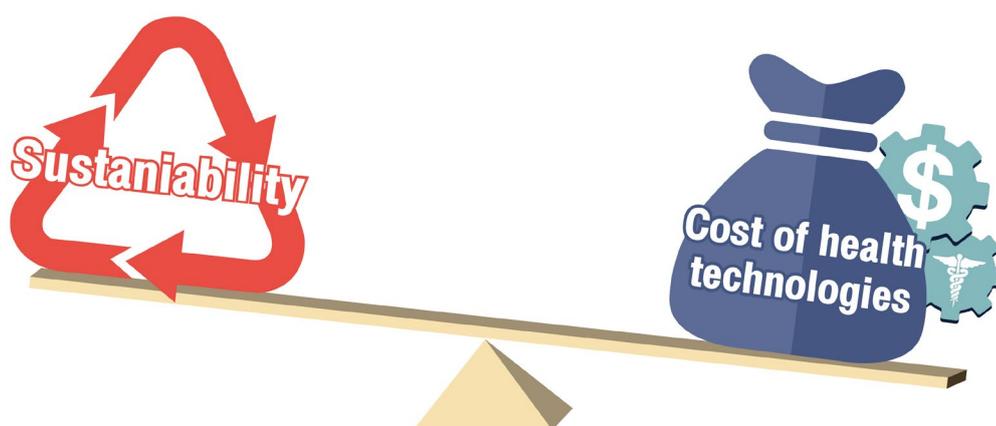


Enzyme Replacement Therapy: HTA role



Author:

Ku Nurhasni
Ku Abd Rahim,
Junainah Sabirin,
Noormah Mohd Darus,
Malaysian Health
Technology
Assessment Section,
Medical Development
Division, Ministry of
Health Malaysia



Global healthcare is now facing the escalating costs of health technologies and the sustainability of healthcare services are at risk. Making a decision for the healthcare coverage under uncertainties is not only a challenge but also a responsibility in improving the efficiency of resource allocation. Selective and careful consideration in choosing the treatment wisely for the patient may be the key to effective healthcare delivery. According to the 11th Malaysia Plan Main Theme, the focus for health is to ensure people achieve universal access to affordable and good quality national healthcare services. Therefore, one of the strategies is to improve ground level services via the fast rollout of high impact and appropriate lower-cost interventions.¹

In Malaysia, the development of clinical practice guidelines and assessment of emerging and existing health technologies is under the realm of the Malaysian Health Technology Assessment Section (MaHTAS); a section under the Medical Development Division, Ministry of Health. For instance, the assessment of enzyme replacement therapy (ERT) in metabolic diseases in government hospitals has been requested and the findings have been successfully delivered to policy makers. A huge amount of financial resources became the major hurdle in providing access to patients in need despite the evidence of effectiveness. Following these findings and after deliberation among the stakeholders, the Malaysian Government, through the Ministry of Health, has approved the funding for Enzyme Replacement Therapy Program for Lysosomal Storage Diseases (LSDs) on a case-to-case basis. A Technical Committee on ERT consisting of experts in metabolic disorders has been set up to develop the guidelines to ensure consistency and sustainability of the program.^{2,3} Priority was given to those deemed to benefit most from ERT. Until 2016, this strategy has benefited 28 patients in Malaysia through various funding mechanisms.

¹ Ministry of Health Malaysia. TGP Inspirational Leadership Podium No 1/2016. MOH/S/IPK/18.16(BK).

² Ministry of Health Malaysia. Guidelines for Treatment of Lysosomal Storage Diseases by Enzyme Replacement Therapy in Malaysia..2012. MOH/P/PAK/216.11(GU)

³ Health Technology Assessment Report, 2008.MOH/P/PAK160.08 (TR),

“Global healthcare is now facing the escalating costs of health technologies and the sustainability of healthcare services are at risk.”

Author:

Mr. Pempa,
Essential medicine and
technology Division,
Department of Medical
Services, Ministry of
Health



Economic evaluation of pneumococcal conjugate vaccine

Pneumococcal disease is the leading vaccine-preventable killer amongst young children worldwide (Source: World Health Organization). The latest annual health bulletin of the Ministry of Health (MOH) of Bhutan indicated that pneumonia is one of the top 10 killer diseases. The incidence rates of pneumonia and otitis media, especially in children under the age of 5, are found to be relatively very high. The National Committee for Immunization Practice proposed the introduction of pneumococcal conjugate vaccines PCV10 or PCV13 into the routine immunization of the country. However, since Bhutan is no longer eligible for the 'GAVI the vaccine alliance' funding for the vaccine, the High-Level Committee of the MOH called for a Health Technology Assessment to make evidence-based decisions when the government is to make such huge investment.

“MOH called for a Health Technology Assessment to make evidence-based decisions when the government is to make such huge investment.”

Our staffs lack capacity in economic evaluation; therefore, we sought technical support from HITAP, Thailand in carrying out this project. Through various consultations, it was decided that cost-utility analysis for PCV10 and PCV 13 versus no vaccine using a Markov model will be applied from a government perspective. QALY will be used as one of the main determinants to find out cost-effectiveness.

We used the 2016 annual health bulletin to obtain incidence and mortality rates. Health centers were categorized into 3 levels and the cost of drugs, consumables, diagnostic tests, patient diet, and human resources incurred were calculated for treating each disease at the various level of health facilities. For vaccine efficacy and herd protection, we did a literature review and for serotype coverage, we used data available to the central laboratory at the National Referral Hospital.

The study is still ongoing and the study may reveal findings on the incidence and mortality rates of each pneumococcal disease, the efficacy and herd protection of both the vaccines, the percentage of serotypes prevalent in the country, the cost of treatment of each pneumococcal disease, and the cost for introducing the vaccine program. Eventually, we hope we will be able to compare value for money for PCV10 and/or PCV13 against the no vaccine scenario and also against each other.





Author:

Ryota Nakamura



High-cost drugs and HTA implementation in Japan

It is probably fair to say that Japan has a long history of HTA. In the early 90s, HTA was introduced in a limited way for the drug pricing process in the public healthcare system, where manufacturers could provide the government with economic evaluations of their new products if they wished to; however, they were not essentially used for drug pricing by the government.

Recently, high-cost drugs—in particular, the innovative new drugs for hepatitis C and certain types of cancer—triggered active public debate about whether the country needs a new measure for drug pricing that would make the healthcare system sustainable. Under the current scheme, the initial reimbursement prices of drugs were set to be exceptionally high. For example, a new cancer drug cost about 320,000 USD per patient per year at its launch. The price of the same drug in the United Kingdom was just about 20% of the Japanese price. Soon after the launch, the government decided, almost politically, to give a 50% price cut for the drug.

The “scandal”, combined with long existing concerns about rapidly increasing healthcare expenditure, has now led to **strong public support for the full introduction of HTA or decisions informed by cost-effectiveness evidence**. The government is now provisionally implementing HTA for 13 existing technologies which include the high-cost drugs mentioned above, and the results will be reflected in new reimbursement prices in the next round of the comprehensive price revision in 2018; although, it is yet to be decided how to do so.

“Concerns about rapidly increasing healthcare expenditure, has now led to strong public support for the full introduction of HTA or decisions informed by cost-effectiveness evidence.”

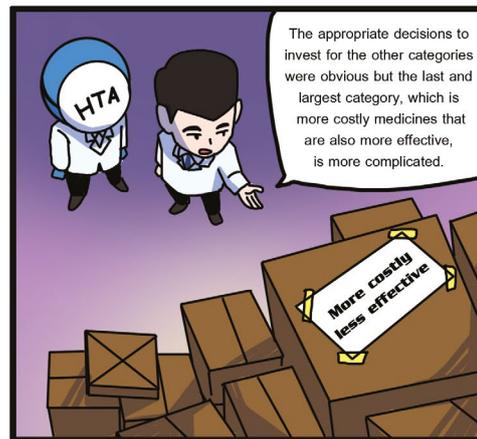
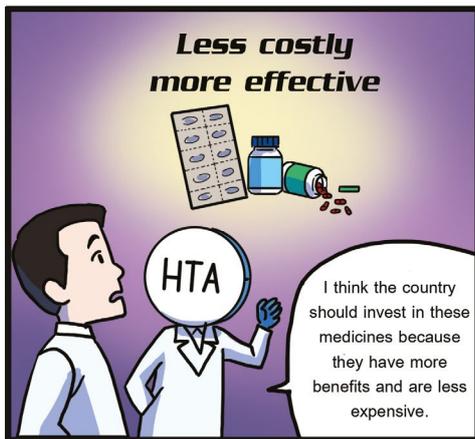
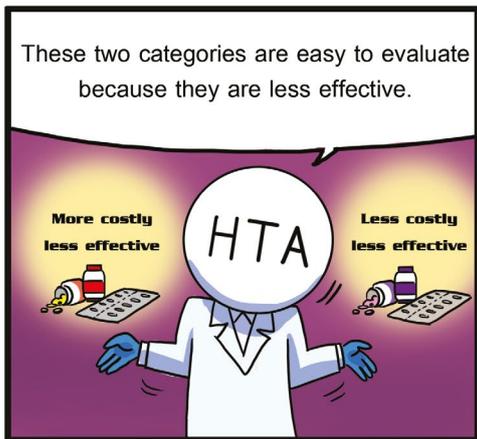
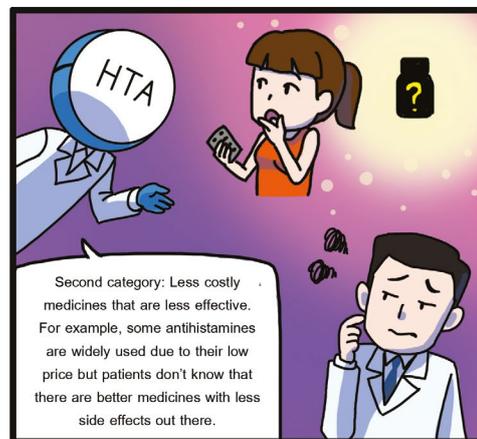
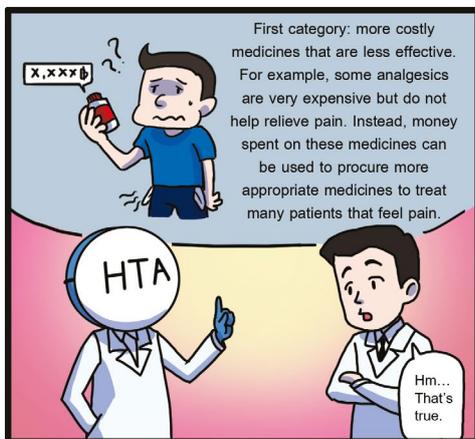
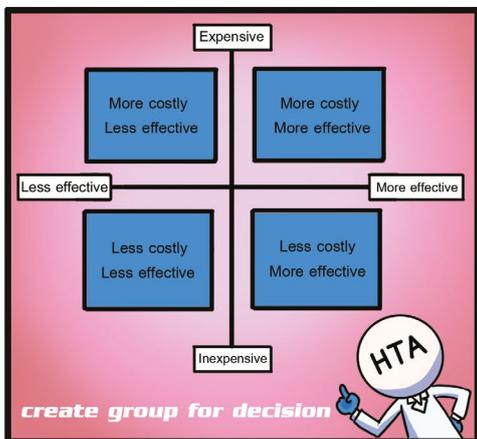
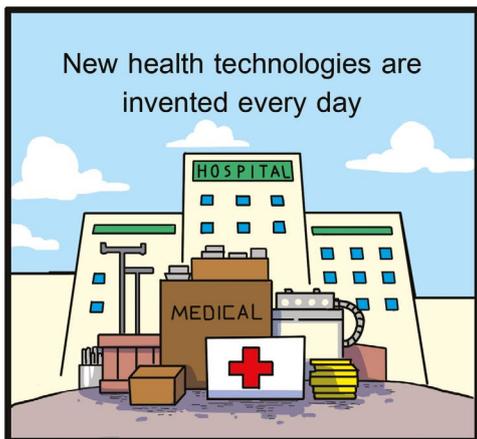
Moreover, there is a longer-term plan for implementing HTA for pricing and reimbursement of new (as well as existing) drugs. There are, however, pressing challenges for implementation, including but not limited to: how to conduct the appraisal of cost-effectiveness evidence and value judgement; capacity building; and development of the national database for costs and outcomes.



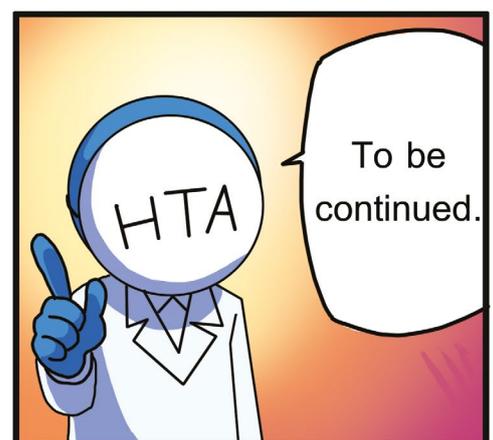
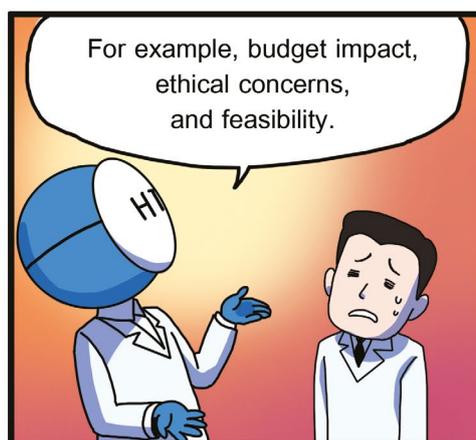
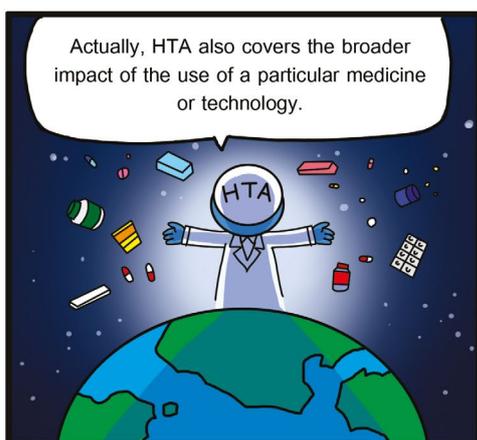
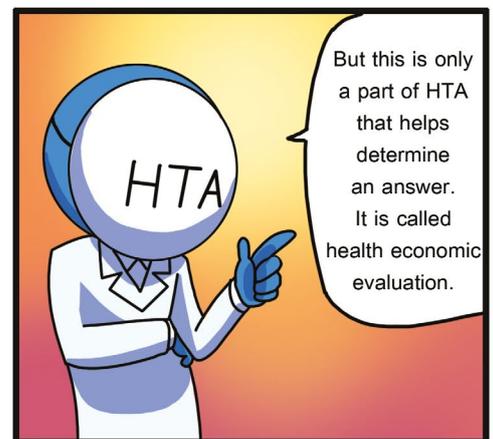
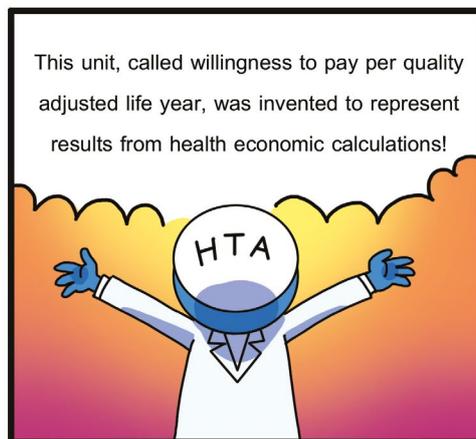
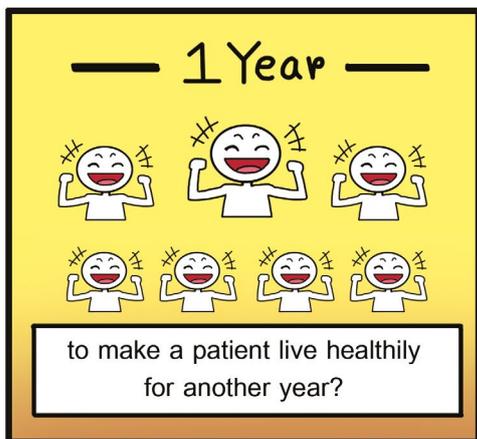
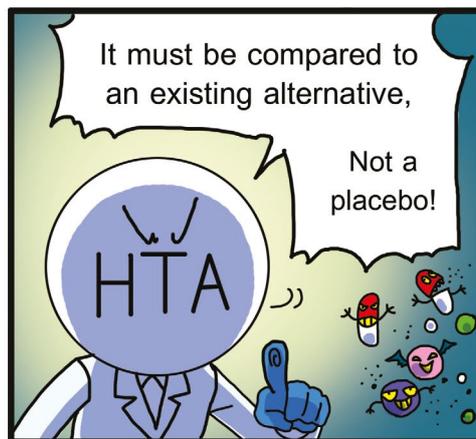


By: Warut Lertsarawut (warut.l@hitap.net)

Bittersweet 4TH Directions



Key Decisions of decisions



Author:

Aamir Sohail¹ &
Laura Downey²



¹ Medical Technology
Advisory Board Secretariat,
Department of Health
Research, Ministry of
Health and Family Welfare,
Government of India

² Global Health and
Development, Imperial
College London, UK

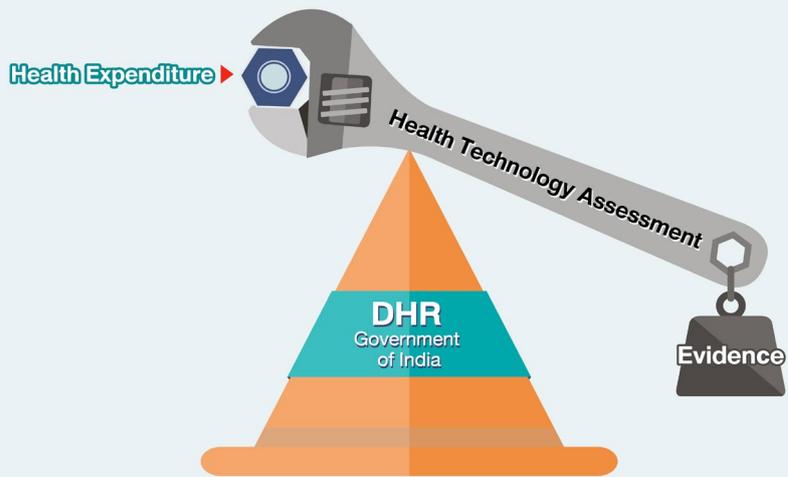


Using HTA as a tool for price negotiation and health policy decision making in the Indian Health System

Sixty-three million Indians are pushed into poverty by catastrophic health expenditure each year, and the cost of drugs is cited as the primary contributing factor to this (Jordan L, 2016). Drugs such as Sovaldi (used to treat Hepatitis C, Pollack A., 2015), Temozolomide (an anti-cancer drug, The drugs prices control order, 2013), and antiretroviral drugs used to treat HIV are highly expensive within the Indian market and as such are unobtainable by the majority of citizens.

Health Technology Assessment (HTA) is a tool that considers clinical and cost-effectiveness of a given intervention alongside the ethical and social consequences of implementation to inform health resource allocation decision-making (Velasco et al., 2010). The Government of India, via the Department of Health Research (DHR), has undertaken measures to formally establish a Medical Technology Assessment Board (MTAB) in India that will conduct HTA in collaboration with technical partners and stakeholders to inform health policy decisions (Downey et al., 2017).

“HTA could also provide an additional role in relation to high-cost drugs”



Ahmad A. et al (2015), Drug pricing policies in one of the largest drug manufacturing nations in the world: Are affordability and access a cause for concern? *Journal of Research in Pharmacy Practice*. 4(1):1-3. doi:10.4103/2279-042X.150043.

Downey L. et al (2017) Institutionalising Health Technology Assessment: Establishing the Medical Technology Assessment Board in India. *BMJ Global health*, in press

Jordan L. (2016) 63 million Indians are pushed into poverty by health expenses each year—and drugs are the chief cause. *Center for Disease Dynamics, Economics & Policy (CDDEP)*. Link: http://www.cddep.org/blog/posts/63_million_indians_are_pushed_poverty_health_expenses_each_year%E2%80%94and_drugs_are_chief_cause#sthash.eAXoiYUZ.dpbs

Pollack A. (2015) High Cost of Sovaldi Hepatitis C Drug Prompts a Call to Void Its Patents. *New York Times*. Link: <https://www.nytimes.com/2015/05/20/business/high-cost-of-hepatitis-c-drug-prompts-a-call-to-void-its-patents.html>

Thailand's health ambitions pay off. (2014) *Bulletin of the World Health Organization*. 92(7):472-473. doi: 10.2471/BLT.14.030714.

The drugs (prices control) order, 2013. (Notified by SO 1221 (E) dated 15.05.2013 and as amended up to vide SO 1192(E) dated 22-03-2016). Link: http://nppaindia.nic.in/DPCO2013_03082016.pdf

Velasco et al. (2010) Developing health technology assessment to address health care system needs. *Health Policy*. 94: 196-202. doi: 10.1016/j.healthpol.2009.10.002.

The primary aim of establishing the MTAB in India will be to utilize HTA to engage in explicit priority-setting of health resources towards the goal of providing universal health. HTA could also provide an additional role in relation to high-cost drugs through enabling negotiation with manufacturers for strategic purchasing and procurement. For example, HTA analysis of the HPV vaccine in Thailand carried out by HITAP enabled the Thai government to determine the price at which the HPV vaccine was good value for Thai resources (\$60 unit cost), and negotiated with the manufacturer to reduce the unit cost (originally \$150) down to this price (Bulletin of the World Health Organization, 2014). In this same vein, HTA can have a role in India by providing a tool for Indian policy makers to negotiate with manufacturers to secure high-cost drugs at a reduced price for the Indian market based on a price that is deemed a cost-effective use of Indian health resources. As home to one-sixth of the global population, improving the coverage of essential health services in India through utilizing HTA to ensure effective resource allocation will have a resounding impact not only for the Indian population but for global health.



Taking aim on high cost drugs

(When thresholds are not enough)



Author:

Anna Melissa Guerrero, MD, MPH (HTA), Division Chief, Pharmaceutical Division



Pricing of drugs and the significant out-of-pocket spending of patients for medicines are currently issues of high policy concern in the Philippines. In a country that continues to see extreme drug price differentials when compared with other Asian countries, tension is mounting especially as patients and health providers increasingly demand new treatments for illnesses such as cancers, chronic hepatitis, kidney failure, and orphan disease.

We have seen it, for example, in the recent proposals of oncologists to approve new cancer drugs in the national formulary whose total treatment cost per patient per year ranges from Php 540,000 for Nimotuzumab, a drug for head and neck cancers, to Php 1,940,000 for Regorafenib, a treatment for colorectal malignancy.¹ In March 2016, the Philippines saw the passing of the Rare Diseases Act, effectively mandating the government to expand the universal healthcare program to patients with rare genetic and metabolic disorders that often require lifelong treatment at costs that are unlikely to be cost-effective.

And yet, there is – in every health system – the human rights argument to be fair and inclusive, making it difficult for decision-makers to deny patients access to treatment whether that treatment is truly life-saving or only modestly effective. However, the healthcare budget is inevitably stretched to its limit even with the significant increases from tobacco sin taxes in recent years. Prioritizing high-cost drugs for a few will mean spending less on other diseases that affect many or resources taken away from hiring needed doctors and nurses, building new primary care clinics or launching mass campaigns to curb obesity and smoking.



The industry argues that we must keep the status quo of giving new drugs patent monopolies to recoup the costs of R&D that make them more expensive than if they were sold with competition from generics.² Further, there is pressure on the government to consider higher willingness-to-pay thresholds, particularly for treatments of severe and fatal diseases even though such thresholds may not reflect the real cost of production to bring them to the market. This approach has proven to be unaffordable to patients as well as costly and unsustainable for the health system.

In the Philippines, the new government has identified several strategies to address the issue of the high prices of medicines.

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“Reducing out-of-pocket spending, particularly for medicines, is one of the twelve legacies targeted under the Philippine Health Agenda. The current administration is determined to maximize the instruments provided in the Cheaper Medicines Law and undertake reforms to ensure that we bring prices down for consumers overall and increase government subsidy that will ease the burden of our patients,” declared Health Secretary Paulyn Jean Rosell-Ubial during a patient forum held in March.

The Health Secretary also enumerated several strategies being planned by the Duterte Administration such as the expansion of the list of drugs under the mandatory drug price reduction scheme; the revival of the government-run community pharmacies to provide free medicines; centralizing the purchasing of essential drugs for government hospitals; use of the competition policy in the pharmaceutical industry, and building economic zones for generics companies to enhance the domestic capacity to supply essential medicines and improve market competition and drug affordability.

“The Philippines is not a rich country and it is impossible to afford and sustain spending for new expensive drugs even with the increased healthcare budget, especially when they cost hundreds of thousands to millions per patient per year. We need to push for a more fair and sustainable system not only for patients but also the government,” said Secretary Ubial.

Legislative and governance reforms are currently under way to ensure better affordability of medicines in recognition that this is fundamental in achieving the nation’s agenda to attain Universal Health Coverage.

¹ The estimated treatment cost includes only the total cost of the medicines taken at full course and excludes other cost components of providing services for cancer patients such as doctor’s fees, hospital admission, and laboratory tests. The costs reflect the current final price-to-patient as reflected in the submissions of professional medical societies.

² The pivotal Report of the UN High Level Panel on Access to Medicines released in September 2016 called for alternative approaches to redress the current situation of monopolistic high drug prices resulting from the current market-driven model of funding innovation of healthcare technologies. Key recommendations include the maximization of TRIPS flexibilities for developing countries; enhancing drug price transparency to reflect taxpayer’s funding for medical research; the use of competition policy to ensure that markets work for the benefit of patients and consumers; and new funding models to delink the cost of R&D from the final prices of medicines and to target unmet global health needs

An insight on the use of HTA and its role in curbing the expenditure on high-cost health technologies



Author:

Prof. Pham Le Tuan –
An interview with
the Vice Minister,
Ministry of Health,
Vietnam



A health policy maker's responsibility is to make life and death decisions, particularly those who work in countries that have already implemented the Universal Health Coverage (UHC). These countries are faced with difficult decisions such as choosing between investments in new medical equipment or in new pharmaceuticals to cure specific diseases. Both of these have their pros and cons.

In Vietnam, the Health Insurance Law was established in 2008 with the expectation that all Vietnamese citizens will be covered by 2020. However, there are many decisions yet to be made.

During the HTAsiaLink conference in Vietnam held from 17th to 19th April 2017, we had the opportunity to conduct an exclusive interview with Prof. Pham Le Tuan, the Vice Minister, Ministry of Health, Vietnam regarding the development of their UHC and decision-making, particularly for high-cost drugs.



We are trying to work on decreasing out-of-pocket expenditure and aim to bring it down by 40%.



Q: The development of UHC in Vietnam.

A: I am happy to inform you that not only the government but even the central parties (political) have now committed to setting up health insurance coverage for our people with the expectation to cover at least 90% of our population by 2020. I am also glad to inform that in 2016 achieved 81.7% of the population under health insurance coverage. We are also comfortable in saying that we achieved it 5 years before the target date. The Vietnamese Prime Minister also approves of this objective and proposal to expand services at the grassroots level in the first dimension and then to the second dimension. The PM also approved one project proposal to strengthen our services at the grassroots level, meaning the provision of our services widely even in the mountainous and difficult terrain areas which we call the second dimension. We have also created a financial strategy to effectively control our budget and demonstrate how we develop and implement UHC. **We are trying to work on decreasing out-of-pocket expenditure and aim to bring it down by 40%.** By having a health benefits package at the grassroots level, we will be able to use our budget more efficiently.



Q: Challenges faced in implementing UHC in Vietnam.

A: Even though we have good service coverage from the central to the provincial to the district levels and have community health centers and volunteers working in villages, the places that are difficult in terms of accessibility, for example, mountainous areas, face challenges in the areas of human resources and limited infrastructure; these factors hinder the provision of services. We found that 20% of our people do not even have health insurance and this group is left out because they are mostly from the informal sector. Another challenge is that out-of-pocket payment is still more than 40%. In addition to these challenges, the quality of the HIS (Health Information System) is not so good as of now. We would like see the HIS strengthened, for example, creating a method of payment. Those who live uphill and in remote areas do not have equal opportunities to access such services.

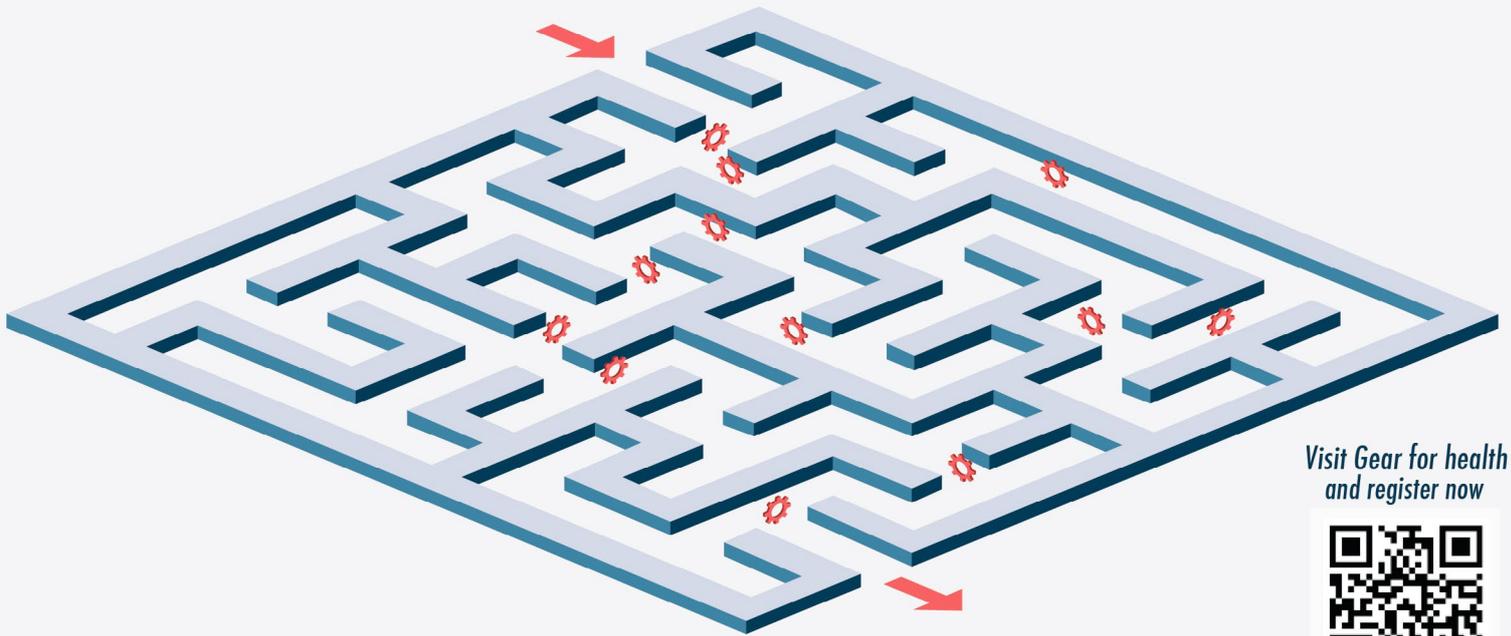


Q: The use of HTA evidence to support policy decision-making in establishing the Vietnam benefits package, especially for the high-cost drug.

A: In developing Vietnam's benefits package, I would like to thank HITAP and the Ministry of Public Health, Thailand as we have sent many delegates and team members to study in Thailand and gain experience. We also participated in short courses, training, and workshops as they are core activities that educate us about the different cases in different countries. From HITAP, what we learned is the use of HTA as it is a very powerful method for developing the health benefits package. Apart from the experience in developing the health benefits package, we learned a lot from experiences and recommendations from different countries and international organizations. We now use HTA to assess high-cost medicines and services in terms of their effectiveness. The HSPI (Health Strategy and Planning Institute) is the main office in Vietnam for all HTA-related activities. The current benefits package has many things in it and is very huge but we are now using HTA to streamline it and we are also trying to define the health services package with a focus on the grassroots level. For Vietnam, we have found the solution to creating efficient medical packages for all grassroots level services as it is the most important level in the Vietnamese health system. The people who fall under the grassroots level receive 100% payment coverage from the health insurance.

Vietnam is currently in the process of implementing its own UHC and there are many challenges we face during this period. However, one sure thing is that our policy makers are committed to moving forward and initiating better health care for all Vietnamese citizens.

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July – December 2017

July
3-5

Event: 9 Asiapacific Global Summit on Healthcare
Event date: 3-5 July 2017
Venue: Kuala Lumpur, Malaysia, Kuala Lumpur, Malaysia
Organizer: Conference series LLC
See more: <http://bit.ly/2ngnGmv>

July
3-5

Event: The 2017 Government Health Care Congress Event
date: 18-19 July 2017
Venue: Sheraton Tysons Hotel Washington, DC
Organizer: GHCC
See more: <http://www.worldcongress.com/events/GHCC/#sthash.2G2zWTV6.dpuf>

Sep
15-17

Event: ISPOR 6th Latin America Conference
Event date: Sep 15- 17, 2017
Venue: Sao Paulo, , Brazil
Organizer: ISPOR
See more: <https://www.ispor.org/Event/index/2017SaoPaulo>

Sep
13-16

Event: Global Evidence Summit
Event date: 13 – 16 September, 2017
Venue: Cape Town, South Africa
See more: <https://www.globalevidencesummit.org/>

Sep
29-30

Event: Annual Health Econometrics Workshop
Event date: Sep 29 – 30 2017
Venue: Washington University in St. Louis, St. Louis MO
Organizer: AHEW

Oct
13-14

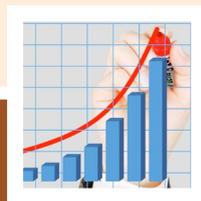
Event: 18th Annual Southeastern Health Economics Study Group Conference
Event date: October 13 – 14, 2017
Place: Owen Graduate School of Management, Vanderbilt University, Nashville, Tennessee.
See more: <https://medschool.vanderbilt.edu/health-policy/18th-annual-southeastern-health-economics-study-group-conference>

Nov
30

Event: The Health Technology Assessment Course – Trends & Opportunities in Europe with Prof. Dr. Lieven Annemans
Event date: Nov 30, 2017
Venue: Brussels, Belgium,
Organizer: C.E.L.forpharma
See more: <http://www.celforpharma.com/course/health-technology-assessment-course>

Dec
12-13

Event: Real world data for competitive advantage summit
Event date: Dec 12- 13 2017
Venue: Philadelphia, PA, USA
See more: http://www.worldcongress.com/events/PB17027/?utm_source=healthconomics&utm_#sthash.qLOYsmfY.dpuf



HTAsiaLink Newsletter

Health Intervention and Technology Assessment Program (HITAP)

6th Floor, 6th Building, Department of Health, Ministry of Public Health, Tiwanon Rd., Muang, Nonthaburi 11000, Thailand
Tel : +662-590-4549, +662-590-4374-5 Fax : +662-590-4369 Email: htasialink@hitap.net

Lead editor: Deepika Adhikari

Editorial team: Sirirat Varamali, Apinya Mattadet, Thanchanok Bhorntus

Graphic designer: Warut Lertsarawut

HTAsiaLink is a network to support collaboration between Asian health technology assessment (HTA) agencies. It focused on facilitate HTA research by accelerating information and resources sharing and developing an efficient methodology for HTA in the region.

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Contact: HTAsiaLink secretariat (NECA)

E-mail: int@neca.re.kr Tel: +82-2-2174-2748