

HTAi Asia Policy Forum 2019 Background Paper

**Sustainability of healthcare systems in Asia:
exploring the roles of horizon scanning and
reassessment in the HTA landscape**

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Executive summary

In order to support a sustainable health system, a balance needs to be found between the investment in new and innovative health technologies, and the reassessment of existing ones. A program for the identification of new health care technologies and clinical practices via horizon scanning run in parallel with a system of identifying existing practices as targets for reassessment may ensure that health systems can embrace innovation in a sustainable way.

Horizon scanning is a risk management tool that provides intelligence to policy-makers around the impact of the introduction of new, and potentially disruptive, health technologies. By gathering intelligence early, before a technology enters the health system, policy-makers are given forewarning in order to guide planning decisions, including not only financial capacity but infrastructure requirements such as physical structures and IT, workforce capability and training prerequisites. There is an appetite for more countries to embrace horizon scanning in the Asia region, with much to be learned from countries such as South Korea and Malaysia that have established, and Singapore who are in the midst of establishing, such systems.

In an ideal health system, existing clinical practices and technologies should be subject to ongoing review and continuous evaluation in order to identify ineffective, inefficient or costly clinical practices. Reassessment can improve quality and safety of care, and patient outcomes, in so doing, strengthen the sustainability of health system. However, reassessment is not easy and is associated with many challenges, the first and foremost being the sense of loss of services experienced by clinicians and patients. Other challenges include a lack of political, clinical and administrative will, vested interests from multiple stakeholders and the sensitivities around removing services that may be associated with vulnerable patient groups such as children, cancer patients or the elderly. In addition, issues such as a lack of resources, data and evidence makes successful reassessment difficult. Developing communication and education strategies is the key to collaboratively bringing all stakeholders, including policy-makers, clinicians and patients, on any successful reassessment journey. Part of this strategy is to emphasise that reassessment is a prioritisation of services, providing safe, effective and most importantly, appropriate health care for all patients. Reassessment is not just about cost-savings.

In summary, running a system of reassessment of existing health care practices in parallel with investment decision-making may improve the quality and safety of care, patient outcomes, and help build organisational resilience, strengthening the sustainability of health systems.

Introduction

In 2018, the HTAi Asia Policy Forum (HAPF) discussed the challenges and pitfalls of different post-regulatory mechanisms that may improve or enable access to high-cost technologies in the Asia region. A recurrent theme during these discussions and previous HAPFs, was the need to identify tools to enable decision-makers to prioritise technologies to invest in for benefit packages and reassess existing technologies, whilst delivering value for money. Health policy makers in the region are tasked with the challenge of ensuring the long-term sustainability of healthcare services, juggling the fine balance of reducing health inequalities and facilitating universal access to innovative healthcare all with limited budgets. Globally, health budgets are affected by major drivers of rising health care costs that include an ageing population (declining fertility concomitant with increased longevity), the increased utilisation of health care alongside the increasing prevalence of chronic disease such as diabetes, and the drive to invest in new devices, diagnostic tests, medical procedures and pharmaceuticals. Investment in innovative health care technologies may; however, deliver enormous benefits to patients and, importantly, to healthcare systems^{2,3}, with improved patient outcomes resulting in better patient flow through the system, which may result in reduced overall health system costs. In a resource-limited environment, governments recognise that tools such as health technology assessment (HTA) can assist them in the evidence-based decision-making process around priority setting, informing on the quality, safety and cost-effectiveness of new technologies. However, continuous investment in health innovation is not sustainable without a concurrent process for reassessing existing healthcare services. Whilst priority-setting for the investment of new healthcare technologies is of great importance, consideration must also be given to the reassessment of existing technologies that may have been superseded or those that are not as safe, effective or cost-effective as initially expected when used in real-world clinical practice. Continued investment without reassessment may lead to poorer health outcomes and wasted resources. Reducing expenditure on outmoded, low-value and potentially harmful health interventions can free up valuable resources to fund higher-value interventions elsewhere in the health system.³

As such, the 2019 HAPF will examine the role that horizon scanning (HS) and reassessment can play in the sustainability of health systems in the Asia region. This paper will introduce some general concepts around the life cycle of health technologies and present case studies of horizon scanning and reassessment activity from the region. This discussion will be informed and guided by the key messages from the 2018 HTAi Global Policy Forum meeting on HS, and what they might mean for the Asia region. Some of the important key messages from that meeting included that HS systems:

- need to identify unmet needs in order to drive innovation;
- should focus on specific disease areas and/or care pathways; and
- need to include all relevant stakeholders at an early stage.¹

Attendees of the 2019 HAPF may also like to consider joining HTAi's Disinvestment and Early Awareness Interest Group (DEA-IG), which is an international centre for sharing knowledge and expertise in methods for identification and prioritisation of emerging, new, obsolete or low-added-value technologies for HTA, and in the practical application of reassessment for health systems.

Life cycle of a health technology

Health systems usually consider the introduction or withdrawal of a health technology as a linear process: new technologies are introduced, and old technologies are made obsolete. More recently, the life cycle of a health technology has been depicted as an S-curve as described in Figure 1.

¹ *The International Information Network on New and Emerging Health Technologies, also known as EuroScan*

² *NICE = The National Institute for Health and Care Excellence*

³ *CADTH = Canadian Agency for Drugs and Technologies in Health*

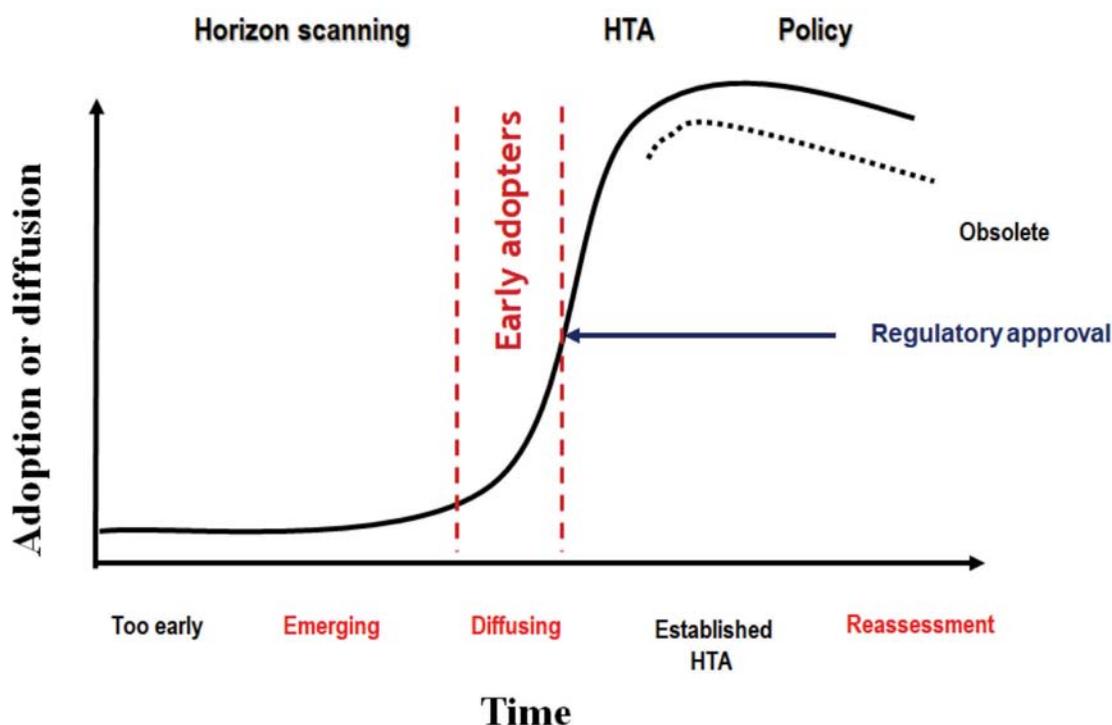


Figure 1 The typical life cycle of a health technology in a health system

Emerging, innovative technologies may be detected by horizon scanning or early awareness systems before widespread use, with these technologies picked up and used by early adopters as they begin to slowly diffuse throughout the health system. Regulatory approval tends to occur at the inflection point of the technology curve, after which diffusion of the technology may increase exponentially. A full health technology assessment is usually only conducted when approaching maximum growth and diffusion of the technology, towards the top of the technology curve, when the effectiveness and cost-effectiveness evidence base has matured sufficiently to inform and formulate health policy. The curve then moves into a period of technology management, where stabilisation occurs and use of the technology plateaus, which may also be associated with a concomitant reduction in price.⁴ Established technologies may then become outdated, inefficient or no-longer-effective and use of the technology may wane, becoming obsolete (dotted line) offering the opportunity for reassessment.

In reality, the introduction of a new and innovative health technologies does not fit nicely into a linear or curved line. The overlapping S-curve model in Figure 2 may more accurately describe the reality of health care, where the introduction of new technologies is a continuous, overlapping process. Technologies reach their limit of diffusion and plateau, or worse, begin to reduce value and patient outcomes. At the same time, other new technologies are introduced into the system and the process begins again.⁵

The challenge in healthcare is identifying the right time to invest in innovative and potentially disruptive technologies in order to value add to the existing health system, and to avoid using those technologies that may be outdated, inefficient or ineffective. A continual process of horizon scanning combined with a parallel process of reassessment using the tools of HTA is one way of achieving the overlapping S-curve technology life cycle.

⁴ Health Technology Incorporation Esplanada dos Ministérios

⁵ Center of Healthcare Quality Assessment and Control, Russian Ministry for Health

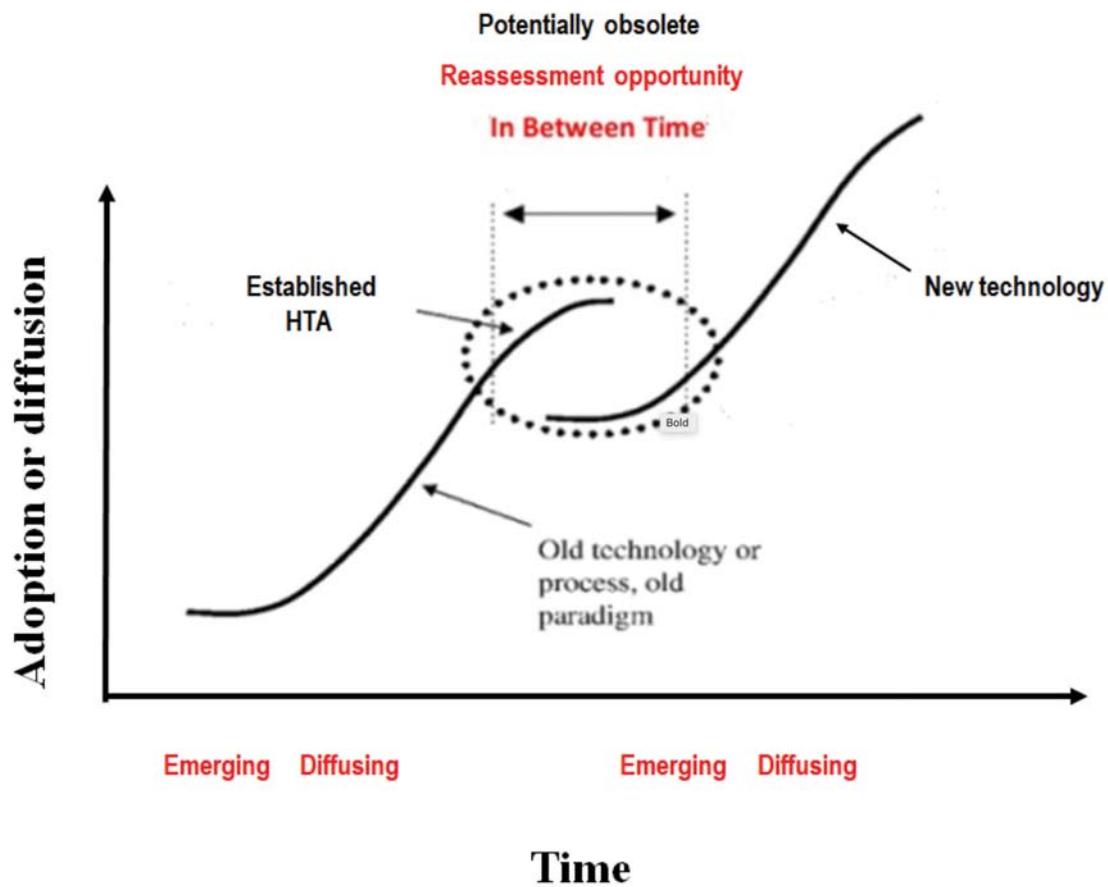


Figure 2 The overlapping S curves of health technology's life cycle in a health system (adapted from 5)

Horizon Scanning

Horizon Scanning (HS) is a risk management tool that is not unique to healthcare and is used in many fields such as the environment, law, business, industry, defence, taxation and national security to reduce uncertainty, inform on future trends, enable planning to facilitate appropriate adoption, and in so doing, provide some element of future proofing. Essentially any sector employing an HS methodology wants to have advance warning and knowledge of any:

- Threats: What is coming over the horizon that could adversely affect your sector of interest?; and
- Opportunities: What does the intelligence gathered mean for your sector and what advantage could it deliver?⁶

In the case of healthcare, HS may deliver information and intelligence around both new and emerging, innovative health technologies, as well as identifying new uses for existing technologies.⁷ In addition, the scanning methodology of HS may provide a means of identifying targets for reassessment that may benefit patients and improve the delivery of health care.⁸ The greatest benefit of HS is that it delivers intelligence on potentially disruptive technologies to policy makers that may be used to guide future investments and assist in all aspects of health care planning that are not just confined to questions of financial capacity but consider infrastructure requirements (physical structures, IT requirements etc), workforce capability and training prerequisites. HS may also help to build organisational resilience

⁶ Center for Innovative Global Health Technology (H-SIGHT)

⁷ Malaysia Health Technology Assessment Section

⁸ Chinese Taipei CDE = Center for Drug Evaluation

by assessing the implications of a new technology to ensure that health systems are able to embrace innovation in a sustainable way before the technology enters either the system. HS may prove to be an invaluable tool in providing information on risks and benefits as health systems move to embrace high-cost health technologies such as gene technology, cellular therapies and oncological pharmaceuticals, innovative technologies such as wearables, implants and E-health technologies⁹, and new models of health care delivery such as integrated care and home-based therapies.

In the early 1990s Banta and Gelijns recognised that the sustainability of health systems could not be maintained by simply reacting to developments in health care technologies, and that a proactive approach was needed to provide advance notice to policy makers to inform rational, evidenced-based decision-making. They recommended a systematic approach to the identification and early assessment of new health technologies, now known as early awareness and alert systems (EAA) or HS.^{7,10} European countries embraced this new methodology and in 1999 the EuroScan International Network was formed to provide a platform for information sharing via a web-based database, most of which is publicly available. This collaborative approach to the early assessment of innovative healthcare technologies reduces duplication of effort for members; however, it is reliant on agencies all participating equally. Although focussed heavily on European HTA agencies, with founding members coming from the Netherlands, Sweden and Denmark, other major contributing agencies included the UK's National Horizon Scanning Centre, that conducted HS on behalf of NICE, and CADTH.⁷ EuroScan has expanded and strengthened its membership and now has 24 members (3 individual) who are committed to sharing information and providing advice and support to organisations considering setting up EAA systems.^{7,11} Relatively new members such as CONITEC from Brazil and Rosmedex from Russia, and established members NECA H-SIGHT from South Korea and MaHTAS from Malaysia may be able to offer valuable assistance, leadership and insights to countries in the Asia region wanting to develop an HS system.

The type of HS or EAA framework adopted is heavily dependent on the type of health system in place in each country, their financing and reimbursement policies, the degree of public subsidisation, the level of health insurance, the types of services offered, and the size and strength of the private sector. Not every country will, like Malaysia (see later case study), want to conduct HS across the board for all types of health care technologies. Some countries may choose to focus on highly innovative and high-cost technologies such as cellular and gene therapies that will be targeted by Singapore's HS system (see later case study), whilst Chinese Taipei's Center for Drug Evaluation (CDE) only focuses on HS for pharmaceuticals. Developing an HS system according to specific needs is nicely illustrated by research conducted in Australia, which unlike the majority of EuroScan members, conducts HS on all health technologies bar pharmaceuticals. Comparisons of the time taken for regulatory approval and public reimbursement for drugs identified by HS in countries with comparable health systems (UK and Canada) found that there was no difference in the time to market access between all three countries. This finding indicated that an EAA system for pharmaceuticals in Australia would neither improve access to new drugs nor better inform decision makers than the system already in place,¹² underlining that the value of EAA activity is entirely dependent on the health system it is trying to support.¹³

9 A new technology can be defined as a drug, medical device or procedure that is newly approved by Health Sciences Authority (HSA) or is in the early adoption phase in the Singapore health care system. An emerging technology can be defined as a drug, medical device or procedure that is under clinical evaluation in trials (Phase II/III), or is expected to obtain regulatory approval in Singapore within 3 years. Both new and emerging technologies may refer to existing technologies that are being developed for a new indication.

10 Gene therapies treat diseases by modifying or introducing an individual's genes. They are usually one-time treatments that result in a cure or life-long benefit, and target severe conditions with very limited treatment options. The cost of such therapies are hence correspondingly high.

11 From Choosing Wisely Australia: Q1 Do I really need this test, treatment or procedure? Q2: What are the risks? Q3 Are there simpler, safer options? Q4 What happens if I don't do anything? Q5 What are the costs?

The actual process of HS will not be discussed in-depth in this background paper; however, the EuroScan International HS Network has a freely available toolkit that provides an overview of the HS methodology which can be adapted to form the basis for an HS system in any country's health system.¹⁴ In addition, the HS handbook developed by MaHTAS is freely available on their website. Other good sources of HS information for agencies is the recent systematic review on HS methodologies by Hines et al (2019) and a report by PWC describing HS in the Asia region.^{9,15}

The basic steps involved in conducting HS may vary between countries and agencies; however, the essential elements remain the same and, briefly, consist of identification, filtration, prioritisation and assessment (Figure 3).

Agencies setting up an HS system first need to identify their primary stakeholders. These may include health department or hospital policy-makers, regulatory agencies, clinicians or patient groups. The next important step is to define the time horizon that the system will operate under. This may be a difficult concept and should be defined by the stakeholders needs. Some systems may want to identify technologies just before regulatory approval, whilst others will want to be informed about technologies just before they enter the health system.

A key message from the 2018 GPF was that HS systems need to include all relevant stakeholders at an early stage.¹

Sources used to identify technologies will vary according to country and types of target (drugs, devices etc) and may include a mix of primary sources, such as direct contact with manufacturers or research institutes, or more commonly secondary sources such as the peer reviewed literature, medical media such as Medscape and clinicians. Sources used should be an iterative process over time, with adoption of new sources or rejection of old ones being informed by success rates in identifying relevant technologies, and changes in trends and the priorities of stakeholders. Agencies in the region should consider using sources that are pertinent and relevant to their own health system needs, and a regional information network may be helpful in sharing this type of information.

Importantly an agency's framework should include scanning for groups of technologies in a clinical care pathway rather than just single technologies. This approach may offer more in the way of health system planning opportunities, especially for those diseases with a high burden of disease such as diabetes. Good examples of this include assessments conducted to identify technologies to treat chronic obstructive pulmonary disease¹⁶ and retinal disease.¹⁷ Depending on the disease, these types of horizon scans can map technologies across all stages: prevention, diagnosis, treatment and even rehabilitation. Technologies in each category can also be mapped to their stage of development: current, emerging (medium term < 3 years) and innovative (long term >3 years). See Figure 4 for an example of this mapping technique for stroke technologies. These types of scans can be kept "live" in that they can be added to as new technologies come to market, or when technologies move from one category to another e.g. moving from innovative to emerging.

A key message from the 2018 GPF was that HS systems should focus on specific disease areas and/or care pathways.¹

In many cases, the filtration step can be conducted at the same time as identification, depending on the structure of the HS team, using simple questions such as: Is the technology new? Does it fit the time horizon? Is it an old technology for a new indication? Is it relevant to the health system in question? Does the technology have potential to impact on the healthcare system? What benefits to the health system does this new technology bring compared to current practice? This step requires a degree of familiarisation with the process and may benefit from a team approach at first, before being practised at the individual level.

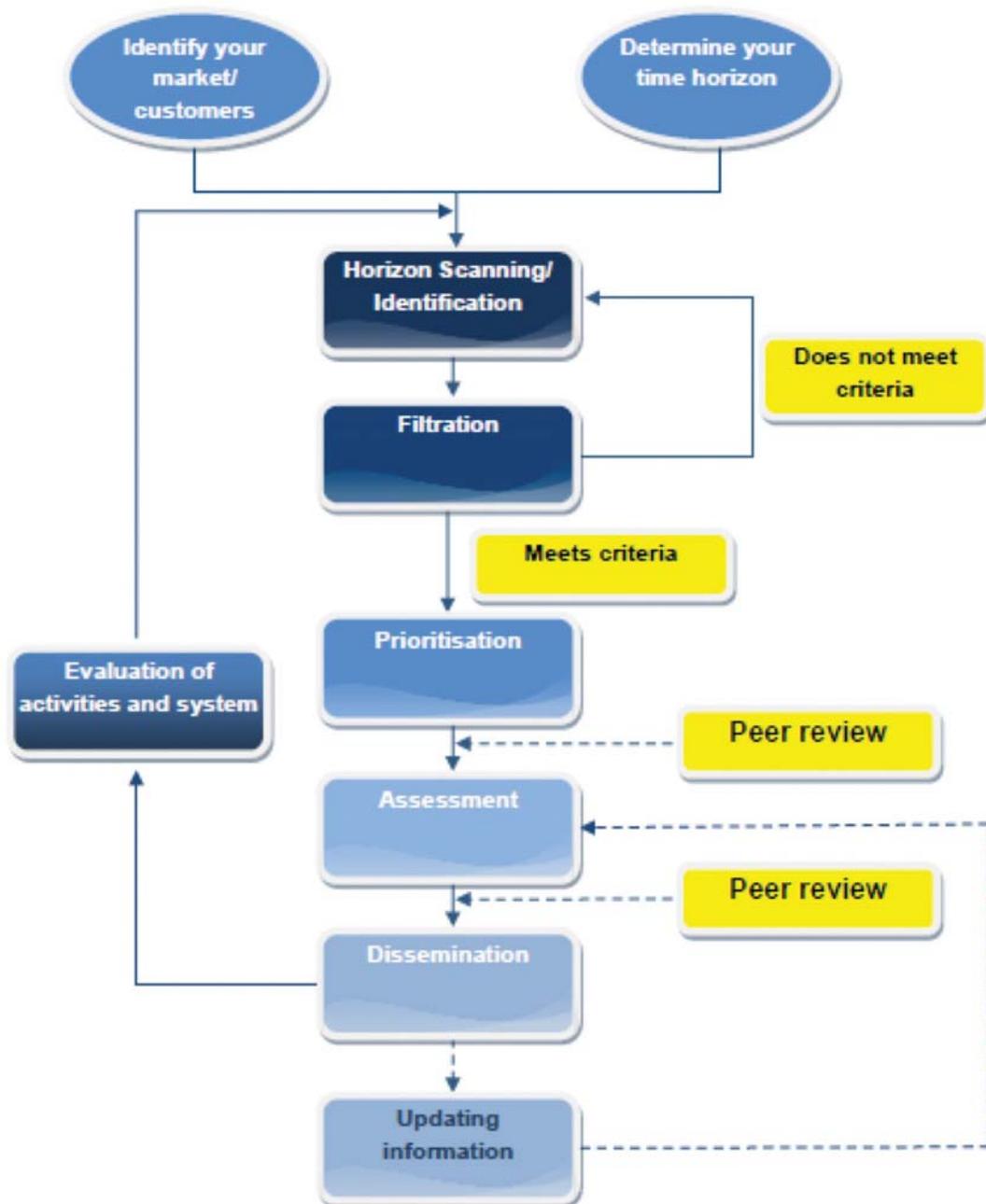


Figure 3 Basic steps involved in the horizon scanning process¹⁴

Each HS system should formulate a series of prioritisation criteria that are designed to be applied to relevant technologies once filtration has been completed in order to prioritise the system's capacity for assessment or evaluation. These criteria may be applied in-house by the HS team or by an expert panel that may consist of a mix of policy makers, clinicians and HTA experts. Again, these criteria will be specific to the HS system in question but may include technologies that address a high burden of disease (high morbidity or mortality), rarity of disease (few alternative treatment options available) or chronic disease. Other criteria may consider technologies that are high-cost, associated with safety concerns or ones that are rapidly diffusing in the health system and have not yet been assessed. It is important that the structure of the health system in question is considered with the formulation of prioritisation questions, especially factors such as the level of patient out-of-pocket payments required and the subsequent disparities in patient access to care that might result.

A key message from the 2018 GPF was that HS systems should identify unmet needs in order to drive innovation in technology development.¹

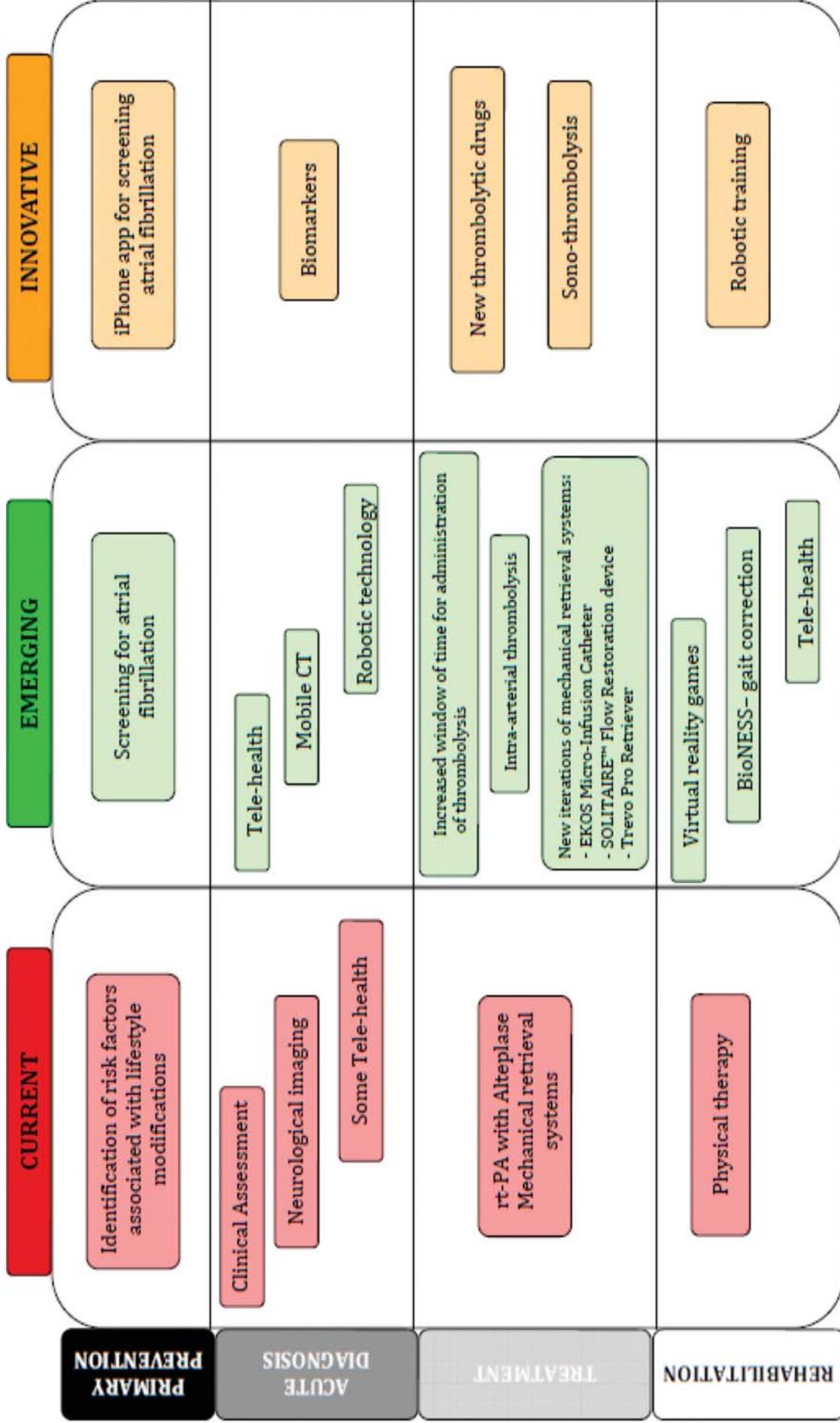


Figure 4 Mapping of stroke technologies in the Australian health system¹⁸

Once a technology has been prioritised, the type of assessment conducted, and the mode of dissemination, will again depend on the stakeholders needs. Assessments may be rapid (3-4 pages), brief (6-10 pages) or in-depth (up to 50 pages) depending on requirements and the extent of the evidence-base. Some agencies will prefer that assessments remain confidential and only disseminated to decision-makers, whilst others will be required to make assessments publicly available. The value of an information sharing network in the region may depend on a country's requirements for dissemination, although it may be possible to share a redacted version (i.e. any financial/commercial-in-confidence matters) with other agencies in an effort to reduce duplication of effort.

To assess the level of horizon scanning activity in the region, a short survey of countries and agencies participating in the 2019 HAPF was conducted.

Summary of the results from the agency horizon scanning survey

A total of 14 public sector agency participants from 11 countries responded to the survey representing China (Beijing, Shanghai and Hong Kong), India, Indonesia, Japan, Malaysia, the Philippines, Singapore, South Korea, Chinese Taipei (2 agencies), Thailand and Vietnam. The main results of this survey are summarised in Table 1.

Of the 14 agencies, three have been conducting horizon scanning for at least 3-years (South Korea, Malaysia and Chinese Taipei- CDE) and two are in the process of developing an HS system (Singapore and Shanghai). The development of Singapore's HS system will be detailed later in a case study. Shanghai gave no further details of the scope of its intended HS system. Eight of the remaining nine agencies are interested in developing an HS system, with only Hong Kong not interested in developing HS at this moment in time. Of the five agencies who are either currently conducting HS or developing an HS system, four were interested in forming an information sharing HS network similar to the EuroScan network. Five of the eight agencies interested in developing an HS capacity expressed an interest in forming such a network (3 agencies did not answer the question). Formation of such a network would not only provide a forum for information sharing, reducing duplication of effort, but may also provide a platform for collaboration with industry in the region.

Of the established HS systems, Malaysia has the most comprehensive, aiming to identify all types of new and emerging health care technologies that may impact on the Malaysian health system (see case study), whilst South Korea identifies new devices, diagnostics and medical procedures. Chinese Taipei's CDE, as would be expected for an agency for drug evaluation, only identifies new pharmaceuticals. All three HS systems are primarily proactive, that is they actively identify new and emerging health technologies from a range of sources, rather than being reactive, where they would respond to requests and information provided by stakeholders such as clinicians. In addition, all three agencies currently identify single technologies rather than a range of technologies involved in a clinical care pathway. Interestingly, Malaysia and Chinese Taipei would consider using the HS methodology to identify potential disinvestment/reassessment targets.

The typical time horizon before technologies were thought to impact on the health system was more than 3-years, with only Chinese Taipei considering technologies 12 months away from health system entry. All three agencies used HS to inform policy-makers at the health department level, with South Korea and Malaysia also using it to inform hospital policy-makers, clinicians and patients. HS in Malaysia was also used to inform the medical device and pharmaceutical regulatory bodies. There was great variation between the agencies regarding HS sources with Malaysia having the most comprehensive range of primary and secondary sources (see Table 1).

There was a great deal of consistency between the three agencies when asked what criteria were used to prioritise identified technologies, with all agencies considering the burden of disease a priority, as well technologies that may be associated with any safety concerns. All agencies considered the potential impact of the technology on costs, whether that be increased costs or savings to the health

system, technologies that require a large capital outlay, or technologies that might require out-of-pocket payments for patients. Aligned with these concerns, all agencies prioritised those technologies that would have an impact on existing services that may require reorganisation or structural changes, have staff training requirements, be associated with learning curves or require quality assurance procedures. In addition, technologies that would impact on patient morbidity, mortality and quality of life were also a priority for all agencies. Identified technologies are prioritised either by the in-house HS team (South Korea and Chinese Taipei) or by a panel of clinical experts (Malaysia).

All three agencies produce reasonably in-depth assessment briefs that would typically consist of a description of the technology, regulatory information and include an assessment of the evidence on the safety and effectiveness of the new technology from several studies. Due to the newness of technologies it is highly unlikely that any cost-effectiveness analysis would be identified; however, a summary of basic costs including infrastructure and training requirements would be presented. Assessments briefs would typically be 8-12 pages long and would take 1-2 weeks to produce. Only Malaysia has a Rapid Brief product that is approximately 1-3 pages produced in 24-48 hours, which provide a brief overview of technology including costs and any evidence if available. These rapid briefs may not have sufficient evidence for investment decision making but they are important to alert policy makers to potential disruptive technologies that may have a great impact on the health system in the near future.

Table 1 Horizon scanning survey results from payer agencies

Currently conducting horizon scanning (HS)	3/14 (21.4%)
Not conducting HS but developing an HS system	2/14 (14.3%)
Not conducting HS but interested in developing an HS system	8/14 (57.1%)
Not conducting HS and not interested in developing an HS system	1/14 (7.1%)
Interested in forming a network similar to EuroScan	Yes: 9/14 (64.3%) No: 2/14 (14.3%) Abstain: 3/14 (21.4%)
Answers from the 3 established HS agencies	
How long has your HS system been active?	Chinese Taipei: 3 years South Korea: >3 years Malaysia: >3 years
What types of technologies is your HS system intended to identify?	Chinese Taipei : Drugs South Korea: Devices, diagnostics, medical procedures Malaysia: Drugs, devices, diagnostics, medical procedures, vaccines, gene or cellular technologies, public health programs

Does your HS system identify single technologies or all technologies in a clinical care pathway?	Chinese Taipei: Single technologies South Korea: Single technologies Malaysia: Single technologies
Is your HS system proactive or reactive?	Chinese Taipei: Proactive South Korea: Proactive Malaysia: Proactive
Would you use HS methodology to identify potential disinvestment/ reassessment targets?	Chinese Taipei: Yes South Korea: No Malaysia: Yes
What is the time horizon of your HS system?	Chinese Taipei: 12 months South Korea: 1-3 years Malaysia: 1-3 years
Technologies identified through HS will be used to inform	Health department policy-makers: Chinese Taipei, South Korea, Malaysia Hospital policy-makers: South Korea, Malaysia Clinicians: South Korea, Malaysia Patients: South Korea, Malaysia Other (Medical device authority & National Pharmaceutical Regulatory Agency): Malaysia
What sources are routinely scanned for technologies by your agency?	<p>Primary sources</p> <p>Commercial developers: Malaysia, Chinese Taipei Clinical trials registries: Malaysia, Chinese Taipei Patents: Nil</p> <p>Secondary sources</p> <p>Peer reviewed international journals: Malaysia, South Korea Regional (Asian) peer reviewed journals: Nil Google search alerts: Nil Medical media (e.g. Medscape): Malaysia Other HS agencies (e.g. CADTH or EuroScan): Malaysia Grey literature (e.g. newspapers): Malaysia Conference proceedings: Nil Commercial developers: Malaysia, South Korea Regulatory authorities: Malaysia, South Korea, Chinese Taipei Clinical experts: Malaysia</p>

<p>What criteria are used to prioritise identified technologies for assessment?</p>	<p>Based on health system priorities</p> <p>Burden of disease: Malaysia, South Korea, Chinese Taipei</p> <p>Rarity of disease: South Korea</p> <p>Associated morbidity or mortality: Malaysia, South Korea</p> <p>Treatment options available (rare diseases): Malaysia, South Korea</p> <p>Characteristics of disease (acute vs chronic): South Korea</p> <p>Impact of technology on</p> <p>Costs: Malaysia, South Korea, Chinese Taipei</p> <p>Patients: Malaysia, South Korea, Chinese Taipei</p> <p>Services and organisation: Malaysia, South Korea, Chinese Taipei</p> <p>Ethical issues: Malaysia, South Korea, Chinese Taipei</p> <p>Technology is</p> <p>Rapidly diffusing & has not be assessed: South Korea</p> <p>Associated with safety concerns: Malaysia, South Korea, Chinese Taipei</p> <p>New use of an existing technology: Malaysia, South Korea, Chinese Taipei</p>
<p>Who applies these criteria?</p>	<p>HS team – in-house experts: South Korea, Chinese Taipei</p> <p>Clinical expert panel: Malaysia</p>
<p>What type of HS assessment does your agency produce?</p> <p>Rapid brief: brief overview of technology, limited if any evidence but important to alert policy makers, typically 1-3 pages produced in 24-48 hours</p> <p>Assessment brief: more in-depth assessment covering safety, effectiveness, cost and impact, typically 8-12 pages produced in 1-2 weeks</p>	<p>Rapid brief: Malaysia</p> <p>Assessment brief: Malaysia, South Korea, Chinese Taipei</p>
<p>How are your assessments disseminated?</p>	<p>Website: Malaysia, South Korea</p> <p>Newsletters (electronic or printed): Malaysia, South Korea</p> <p>Social media (Twitter and Facebook): Malaysia</p> <p>Word of mouth, seminars: Malaysia</p> <p>Journal articles: South Korea</p> <p>Other: Confidential brief for policy-makers: Chinese Taipei</p>

Case studies

Case study 1: An established horizon scanning system: Malaysia

In 1995, the Ministry of Health (MoH) in Malaysia established its HTA unit, MaHTAS, in order to support coverage or purchasing decisions for health technologies using an evidence-based approach. The use of HTA was viewed as an effective mechanism to use for this purpose especially during a time of rapid economic growth which had resulted in an increased demand from clinicians for introducing new technologies into the health system.¹⁹ MaHTAS would receive ad hoc requests for rapid assessments from a number of sources including the MoH hospitals but also from other government agencies. In order to facilitate these requests, and with an increase in the development of innovative and high-cost technologies, the Medical Development Division proposed that an HS unit be developed within MaHTAS. In 2013 an exploratory survey was conducted on the needs and expectations of HS within the MoH and a pilot project was conducted in 2015, along with the development of an HS manual.¹⁹ The HS unit within MaHTAS has been operating at full strength since 2016, with five full time staff and one information specialist employed to conduct scanning and assessments.

The remit of the unit is to provide timely advice to the MoH on health technologies that have potential to impact on health, health services, and/or society. In so doing, this early warning system facilitates budgetary planning by enabling the appropriate implementation and/or adoption of new and innovative health technologies. Although policy-makers within the MoH are the primary stakeholders, others include hospital level decision makers, clinicians and patients as well as the government agencies of the Medical Device Authority and the National Pharmaceutical Regulatory Agency. The unit also has relationships with the Ministry of Health Innovation Unit and other government agencies related to innovation, as one of the more interesting roles of the HS unit is that it prioritises assessments and promotes awareness of local Malaysian healthcare innovations.

The range of assessments conducted within the MaHTAS HS unit is one of the broadest of all HS agencies, encompassing all types of technologies: pharmaceuticals, devices, diagnostics, surgical interventions, medical procedures, care pathways, community care, vaccines and public health interventions. Traditional and complementary medicines are also part of the unit's remit; however, these assessments are rare due to the paucity of evidence. As such, the technology assessments produced address all levels of the health system: community and primary care, secondary (allied health), tertiary hospital care, as well as informing national, system-wide policy.

The HS unit is primarily proactive, identifying potential new technologies from a range of sources, as summarised in Table 1. In particular, the unit has found conferences and local media good sources for identifying local innovations. Sources have changed and evolved since the unit's inception with a database being maintained that tracks the number of positive 'hits' identified from each source. The database is reviewed every year in order to refine the sources used. New sources are always being sought, especially local ones. In particular, the unit has tried to foster links with universities but have encountered a level of suspicion, especially regarding intellectual property. The unit also provides a forum for reactive assessments, responding to requests primarily from clinicians but also from industry. Links have also been fostered with industry via engagement with the Pharmaceutical and Medical Device Associations. This has enabled a two-way communication, with a mutual understanding that MaHTAS must follow MoH guidelines and operate at arm's length to maintain the integrity of the unit whilst still enabling the exchange of information around new technologies.

Scanning is conducted on a continual, rolling basis, with each staff member assigned several sources that are scanned on a daily, weekly or monthly basis depending on publication of the source. Clinical trial registries are searched weekly, focusing on diseases that are a national priority. The HS unit then conducts an in-house meeting to apply the filtration criteria to identified technologies. Technologies must be innovative (preference to local), address a priority disease area (high burden of disease) and expect to be introduced into the market within 24 months i.e. before regulatory approval.

Technologies that meet these requirements are sent to a multi-disciplinary clinical expert panel to be prioritised for assessment. This panel meets three times per year, with meetings scheduled to coincide with HTA/CPG Council meetings, as all assessments need to be endorsed by the council prior to dissemination. The expert panel apply a number of prioritisation criteria and each technology receives a score depending on how many criteria are satisfied. Technologies prioritised for assessment must score at least 70%; however, it has been acknowledged that, at times, scoring is difficult when there is limited information about new technologies, especially around ethical and legal issues. Figure 5 describes the scoring system, with each criterion worth a maximum of 10 points. Technologies that are considered innovative and of interest but don't quite meet the prioritisation threshold may be monitored for further information in 12 months, or when a clinical trial is expected to be finalised.

Please score on a scale of 1 to 10 [score 1-3 (low priority), score 4-7 (moderate priority), score 8-10 (high priority)], for each of the sub-criteria below. The total score is 70.

Criteria	Sub-criteria	Explanation	Score
Population/end-user	Disease burden	The impact of the disease in terms of number of people affected, morbidity, mortality and other indicators. (Higher priority for diseases with higher burden)	
	Current options for patients	Are there already other treatment regimen available for this specific indication or is this technology is a completely new therapy? Will the technology replace the current treatment or is it an add on? (Higher priority for novel technologies and if there is no treatment regimen available)	
Potential impact of technology	Patient	Clinical impact such as morbidity, mortality, quality of life, diagnosis. Comparison with current treatment (Higher priority for technologies that may reduce morbidity, mortality, improve quality of life and diagnosis)	
	Cost	Such as increase cost or savings, large capital outlay, direct and indirect costs for patients and society (Higher priority for expensive technologies)	
	Service/organisation	Increase or decrease utilisation of service, structural changes and staff training (Higher priority for technologies which leads to increase use of service, needs changes in infrastructure and required training)	
	Societal or ethical	Societal reaction or acceptability towards the technology, ethical issues that may surface (Higher priority for technologies with higher impact to the society or ethics)	
	Safety/adverse events	Invasiveness of the technology and the associated adverse events (Higher priority for technologies with higher safety risk)	
Total score			

Decision: Prioritised
 Not prioritised

Figure 5 Scoring system used by MaHTAS expert clinical panel to prioritise technologies

When the HS unit first began operations, it aimed to produce eight assessments per year (produced 5, 9 and 8 HS Briefs in 2016, 2017, 2018 respectively) but with added operational capacity, this number is likely to increase in the future. A relatively new product, TechScans (rapid reviews) are produced, which are typically 4-6 pages and usually conducted in response to a specific request from a stakeholder about an emerging technology. Horizon scanning briefs (TechBrief), that are a more detailed assessment of approximately 6-20 pages in length are produced for prioritised technologies. More in-depth assessments are likely to be handled by the HTA team. All assessments follow a standard template as described in the HS manual, and these templates are reviewed regularly by the expert Committee to identify any strengths or weaknesses, ensuring they remain fit for purpose. Not all assessments currently go out for external review, but the HS unit plans to undertake this in the near future to ensure quality control. Industry is, however, given the opportunity to provide feedback on assessments within a two-week period. In addition, MaHTAS would also like to measure the impact of the HS assessments in a manner similar to that adopted for measuring impact of HTA reports.¹⁹ Currently MaHTAS seek feedback on the usefulness of the HS products from stakeholders and whether assessments have changed policy or clinical practice.

Assessments are all made publicly available and widely disseminated using a range of platforms including the MoH website, MOH Malaysia Web site, International Network for Health Technology Assessment (INAHTA) database, MaHTAS mobile app (myMaHTAS) for android and IOS application, the Academy of Medicine Malaysia, some Malaysian professional medical society web sites (CPGs only) and extracts of reports and news are highlighted in the biannual newsletter. Although MaHTAS products are accessible through all of these channels, creating awareness among the public on ineffective health technologies and more to empower them on informed decision making is still a major challenge. To facilitate communication with a wider audience including the public social media is being used to disseminate news, especially on the MaHTAS Facebook page.

On a final note, the HS unit are interested in developing their HS methodology in order to identify potential reassessment targets and a workshop was held recently to engage with clinicians to this end.

Recent assessments include those that have targeted diseases with a high burden of disease in Malaysia in addition to showing promising clinical impact:

- intranasal Esketamine
- low dose radiotherapy for early breast cancer post breast conserving surgery
- Brolocizumab for age-related macular degeneration (AMD)
- Entrectinib for NTRK fusion-positive, locally advanced or metastatic solid tumours; and metastatic ROS1-positive non-small cell lung cancer
- Signature by Natera for early detection of breast cancer relapse (on-going assessment)
- NeuVax Vaccine (Nelipepimut-5) (on-going assessment).

One of the biggest challenges setting up and maintaining the HS unit has been human resources: training and maintaining skilled staff when staff turnover has been high. In addition, getting “buy in” from stakeholders, especially regulators, was challenging at first but the relationship has improved over time.

Case study 2: A developing horizon scanning system: Singapore

Since 2015, Singapore's Agency for Care Effectiveness (ACE) has been performing HTA for drugs and medical technologies to inform subsidy recommendations. The majority of ACE's evaluation topics are selected from annual nominations from the public healthcare institutions (PHIs) and generally reflect established technologies already in routine clinical practice in the health system. As such, the current practice is reactive, with technologies that may have a large clinical, financial and organisational impact on the overall health care system only being assessed by ACE once they have begun to diffuse in the PHIs. To challenge this entrenched practice, ACE is currently developing an HS system that will operate in tandem to the existing HTA system to proactively identify and provide advance notice of new and emerging health care technologies⁹ that may have a significant impact on the Singapore health system *before* they diffuse. This may be in terms of budgetary and financial impact, infrastructure, workforce or training requirements in addition to safety or efficacy concerns associated with the use of the technology. It is expected that the new HS system will become fully operational by 2020 and it will primarily aim to inform policy makers at both the health care decision maker and hospital level, as well as clinicians. The system will target innovative, potentially disruptive high-cost technologies where there is considerable growth in clinical need and health care expenditure, and will initially focus on gene therapies.¹⁰ Once the HS system has been established and scanning processes are in place, other technologies will be added to the system over time. It is also hoped that the system will identify and assess all potential technologies in a clinical care pathway, rather than assessments of single technologies.

In establishing the new HS system, ACE conducted a systematic review of horizon scanning methodologies, and examined the HS systems of the key reference countries: Canada, Australia, the UK and South Korea in addition to EuroScan's HS toolkit. Figure 6 describes the HS framework that was developed by ACE in alignment with international methodological standards.

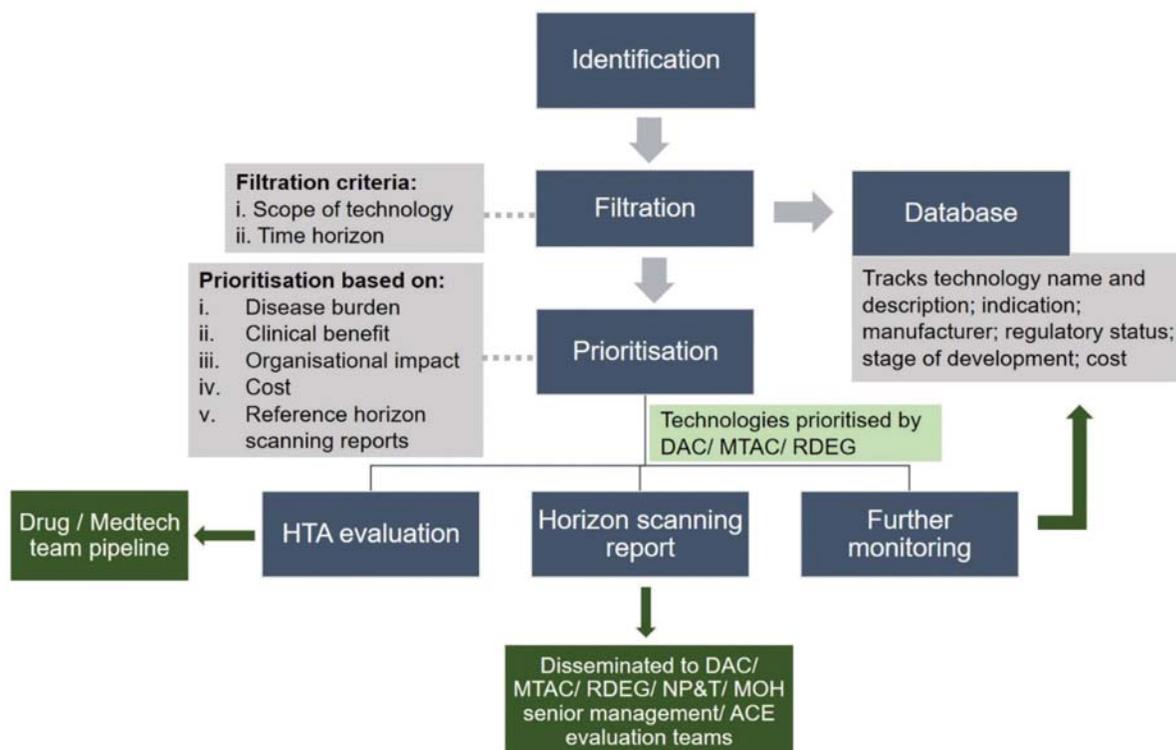


Figure 6 HS framework developed by ACE

To identify potential targets, the HS system will initially scan a number of primary and secondary sources at regular intervals as outlined in table 2. In addition, local health care professionals and clinical experts will be consulted whenever relevant.

Table 2 Proposed scanning sources and frequency for Singapore HS system

Type of information source	Source	Scanning frequency
Primary	Trial registries eg. clinicaltrials.gov	Bi-annually
	Company websites	As required
Secondary	Regulatory authorities eg. FDA, EMA	Quarterly
	Medical technology/ pharmaceutical news sources	Weekly
	International and Asia region peer reviewed literature	Weekly
	Conference proceedings	Annually
Tertiary	Other HS organisations eg. CADTH, NIHR Innovation Observatory, Health Technology Reference Group (Australia), EuroScan members	Quarterly

After identification, the filtration step will prioritise technologies that fit the ACE remit and are in the limits of the defined time horizon of technologies that are up to 3-years away from regulatory approval in Singapore, which is considered a sufficient lead-time to prepare the health system for the introduction of these high impact technologies.

As per Figure 6, a number of criteria will be used to prioritise the identified technologies for assessment. Topics will be prioritised by an in-house HS team as well as by relevant Committees such as the Ministry of Health's Drug Advisory Committee, the Medical Technology Advisory Committee or the Rare Disease Expert Group, based on existing prioritisation criteria for the evaluation of drugs and medical technologies. In addition, consideration during prioritisation will be horizon scanning reports from reference agencies, including CADTH (Canada), Health Technology Reference Group (Australia), the NIHR Innovation Observatory (UK) and NICE Medtech Innovations (UK). Preference will be given to technologies that address significant health system priorities such as conditions with a high burden of disease, diseases with high levels of associated morbidity or mortality, as well as technologies that provide treatment options where few options exist e.g. for rare diseases. Other prioritisation criteria include the impact of the technology on:

- health system costs (e.g. potential savings, large capital costs, out-of-pocket payments for patients etc); or
- patients (e.g. increased or decreased morbidity or mortality, quality of life); or
- services and organisations (e.g. reorganisation, structural changes, staff training requirements, learning curves, quality assurance procedures).

In addition to prioritisation, these committees will recommend the type of assessment required:

- **Monitor:** technologies still in an early phase of development with an immature evidence base should be monitored for more information in 12-24 months; or
- **HS report:** an assessment of more mature technologies encompassing safety, effectiveness, cost and impact. See Table 3 for an example of the fields of a typical report. The evidence base may consist of several studies, and the size of the report will typically be up to 10 pages; or
- **HTA evaluation:** either a full or expedited evaluation would be considered especially if the technology is close to regulatory approval in Singapore. These evaluations would be included in the relevant ACE HTA team's work plan.

HS assessments will not be made publicly available but will be disseminated to the relevant national committee, Ministry of Health divisions or public health institutions.

In August 2019, ACE's HS team completed their first assessment.

Two main challenges were encountered by ACE when setting up their HS system in Singapore:

- A great deal of clinician engagement and expertise was required to prioritise identified technologies. Consultations with clinicians to understand local patient numbers, current treatment practices and the potential disruptive impact of new technologies to the healthcare system was required to inform prioritisation scores for most of the filtered technologies. Such information was not readily available.
- The scope of horizon scanning was not easily defined. While ACE received suggestions from MOH Advisory Committees on potential topics for horizon scanning, they were broad and covered a wide range, for example, precision medicine could include anything from companion diagnostics, genetic screening, artificial intelligence methods for imaging/sequencing, and autologous stem cell therapy.

The value of the HS outputs to key stakeholders remains to be seen at this point in time. There may be limited evidence for identified technologies for stakeholders to assess impact, and added to that are other uncertainties such as whether manufacturers would launch the technologies in the relatively small Singapore market.

Table 3 *Horizon scanning report template*

Summary
Background
Description of disease / disease aetiology
Burden of disease
Clinical need
Technology
Description of technology
Novelty of technology
Regulatory Status
Details of local and overseas regulatory or development status
Fast track designations, if any
Brief details of any commercial arrangements
Treatment Pathway
Patient pathway
Current treatment options
Changes with new technology
Available Evidence
Safety and efficacy – summary of available trial information
Cost
Actual cost if available or estimated cost based on pricing information in other major markets
Implementation
Foreseeable issues with implementation in the local setting e.g. limited safety and efficacy data, cost and coverage of treatment, accessibility of treatment etc.
Concurrent Developments
Similar technologies in development
References
Horizon scan reports or guidance from other reference agencies
Other references

Reassessment

Tools such as HTA are needed to increase the efficiency of the health system, ensuring it provides value for money and is fit for purpose, enabling it to provide optimum care for all patients. In an ideal health system, existing clinical practices and technologies should be subject to ongoing review and continuous evaluation in order to identify instances of poorly coordinated care, duplication or gaps in service delivery, practices that encourage over-treatment or over-diagnosis, ineffective practices or systemic waste.²⁰ In most health systems, some existing clinical practices have never undergone assessment, and any review of their performance tends to be slow, whilst in comparison, the investment in new technologies tends to occur rapidly. Harris et al (2017) summarised the many reasons, which are not always budgetary, why health technology reassessment (HTR) should be conducted (Table 4).²⁰ Health systems should consider undertaking HTR activities in parallel with the uptake of new clinical practices and technologies in order to continue to offer value for money healthcare.²¹

HTR has been previously referred to as 'disinvestment'; however, this term is generally disliked by clinicians and consumers alike due to its negative connotations around the implied withdrawal or 'taking away' of a service believed to be beneficial.²⁰ Reassessment is one of the preferred terms, along with prioritisation, optimisation or the appropriate use of health care, which have a more positive connotation.²¹ In essence, these terms can be defined as the evidence-based process of withdrawing health resources, partially or completely, from existing healthcare practices (procedures, devices, diagnostics, programs or pharmaceuticals) that are deemed to deliver no or low health gain for their cost, representing an inefficient allocation of health resources.²² However, it should be remembered that a multi-faceted approach is required for acceptance of HTR by all stakeholders. Assessment of the traditional metrics of HTA (safety, effectiveness and cost-effectiveness) is not sufficient during an HTR process, where a more holistic approach is required with consideration needed to be given to people, structures and values.²¹

Reassessment was defined by Leggett and Noseworthy (2012) as '*A structured, evidence-based assessment of the clinical, social, ethical & economic effects of a technology currently used in the health care system, to inform optimal use of that technology in comparison to its alternatives.*'²³

Table 4 Potential reasons for reassessment in the local healthcare setting²⁰

External	Economic
<ul style="list-style-type: none"> • To address political priorities • To meet legislative, regulatory or accreditation requirements and professional standards • To meet national recommendations • To address legal and ethical issues • To be sensitive to the environment 	<ul style="list-style-type: none"> • To maximise benefits from resource use • To improve efficiency • To maintain quality without extra expenditure • To remove a technology or clinical practice with unacceptable cost per QALY
Financial	Patient care
<ul style="list-style-type: none"> • To save money to meet budget cuts • To find money to spend on something else • To prioritise where money is spent • To redistribute within or between budgets • To support investment in new technologies • To support continued investment • To get value for money 	<ul style="list-style-type: none"> • To improve patient health outcomes • To reduce patient harm • To target populations or indications for best results • To improve patient flow and reduce waiting times • To improve patient satisfaction or reduce inconvenience • To improve patient access and equity of service provision • To reduce unnecessary tests or treatment

Evidence based practice	Social judgement
<ul style="list-style-type: none"> • To ensure practice is consistent with current evidence • Identify evidence of harm or lack of effect & remove technologies or clinical practices • To update evidence-based guidelines and protocols 	<ul style="list-style-type: none"> • To ensure public funds are spent wisely • To reduce public funding on discretionary services eg some cosmetic procedures
Organisational	Health technology, clinical practice or service
<ul style="list-style-type: none"> • To meet strategic goals and priorities or address specific problems • To ensure sustainability • To increase productivity • To work within organisational capacity • To work within staff capability • To rationalise services eg provide orthopaedics at hospital A and oncology at hospital B • To enable system redesign • To reduce health service utilisation • To reduce risk to staff, finances or reputation • To reduce waste 	<ul style="list-style-type: none"> • To keep equipment up-to-date • To remove obsolete or superseded technology • To remove or restrict technologies or clinical practices that are harmful • To remove or restrict technologies or clinical practices that have little or no value • To replace technologies or clinical practices with alternatives of greater benefit • To remove services that are not performing as intended • To remove services that are not meeting the needs of the target population

Investment in new clinical practices and technologies can passively render existing ones obsolete through natural attrition, although new and old technologies often co-exist together in the system for some time. This passive approach may be achieved simply by education and disseminating information without the need for direct intervention from policy-makers, with clinicians often making the decision to stop using a technology because a better alternative is available.²⁰ Natural attrition is often observed in surgical interventions, where incremental changes in technique are made, or old techniques are superseded by clearly more superior ones. In addition, medical devices may become obsolete due to industry's ability to develop new iterations. Natural attrition should lead to improved patient outcomes, but it may be difficult to directly attribute savings, which is still the measurement most policy makers use to gauge the success of a program, to this process. The term reassessment does imply an explicit or active process that is attractive to policy makers as it is easier to attribute direct savings to, and therefore measure its value to the health system; however, this approach does run the risk of disenfranchising stakeholders.^{20, 21}

Challenges and issues of HTR

Although HTR may appear to be an obvious requirement for a health system, it is not an easy process, as unlike the investment in healthcare, there is no validated methodology or framework for health systems or HTA agencies to follow. Note: In 2017 a series of papers (11) were developed by the Sustainability in Health care by Allocating Resources Effectively (SHARE) program in Australia. These papers describe concepts, opportunities, methods and implications for evidence-based investment and reassessment in health technologies and clinical practices in a local healthcare setting. The papers in this series are targeted at clinicians, managers, policy makers, health service researchers and implementation scientists working in this context. Although describing the experience of a more mature health system in terms of universal health care, this series of papers may offer some valuable insights into the issues and challenges around HTR. The lack of methodology may in part explain the difficulty that the HTR process has in gaining traction and 'buy in' at all levels of the health system. An explicit, transparent process may be more acceptable to stakeholders rather than the *ad hoc*, seemingly random process of HTR currently operating. Much research on methodology has been conducted with a recent review by Harris et al (2017) identifying 15 frameworks and models related to HTR, resource allocation and priority setting; however, most were in the concept phase and were, as such, untested.²⁰

Some of the other challenges and issues around successful HTR include:

- difficulties with identifying low-value services (see next paragraph);
- poor quality evidence (a lack of evidence does not equate to evidence of a lack of effectiveness)^{22, 24}
To overcome stakeholder resistance, HTR requires evidence of at least no risk, or of a benefit, when removing or limiting a technology's use²⁵;
- a lack of resources, in particular HTA practitioners;
- a lack of political, clinical and administrative will to evaluate established technologies²⁴;
- some clinical practices and technologies may be associated with sensitivities (e.g. those used to care for children, cancer patients, and people at the end of life);
- multiple stakeholders;
- vested interests from manufacturers and some clinicians;
- a perceived lack of clinical autonomy with clinical advocates for healthcare practices who may be reluctant to change²⁴; and
- a lack of data, data linkage and post-market surveillance (e.g. registries for surgical procedures and medical devices). Good data is required to determine what is currently happening in clinical practice in order to identify potential HTR targets.²¹

Identifying potential HTR targets

Various methods for identifying and prioritising reassessment opportunities have been described. Initiatives such as the US Choosing Wisely Program (also in Australia and Canada) and the NICE 'Do-Not-Do' list have been good starting points in identifying ineffective practices; however, many of these recommendations either describe clinical practices where evidence of effectiveness has always been lacking (i.e. x-rays for acute lower back pain or arthroscopy of the knee) or are simply guidelines that describe good clinical practice, such as the reducing the number of prescriptions for antibiotic prophylaxis. It should be noted; however, that it would be rare for programs such as these to identify a clinical practice that should be completely withdrawn, with most recommendations aimed at reducing widespread, inappropriate use whilst directing care to appropriate patients. One of the most important functions of these lists is not so much the guidance given to clinicians, but the encouragement and empowerment given to patients to ask questions about their care.^{11, 26} There have been few reports on the impact of these lists, with early research suggesting modest changes in clinician behaviour, with some clinical practices decreasing in use but with some actually increasing. The authors of this research concluded that additional interventions rather than just the provision of information may be required to affect change.²⁷

In practice, a multi-pronged approach is often needed, combining a top-down (with policy consisting of incentives and clear messages) and a bottom-up (involving empowering clinicians and patients) approach.

Top-down approaches (usually aimed at health system efficiencies) include identifying:

- high cost, high-volume clinical practices and technologies;
- low volume clinical practices;
- substitution opportunities; or
- clinical redesign and changed management looking at every step in the patient journey.

Bottom-up approaches include:

- timely and broad stakeholder engagement and consultation, especially involving clinicians is critically important to achieving a wider acceptance of the HTR process. A lack of early engagement of clinicians may result in little change in practice. Consumer/patient involvement and education is also important;
- an evidence-based assessment of quality and safety of clinical practices and technologies that

should also include an ethical dimension. Good evidence to support HTR may be lacking as there may have been little evidence supporting the initial investment. Registries may provide a means of providing ongoing monitoring and identification of high-risk medical devices or surgical procedures and could be used to identify potential targets;

- investment in new clinical practices and technologies as a means of driving HTR of existing clinical practices and technologies; or
- assessment of variations in clinical practice, e.g. regional or geographic variation, changes in practice over time, variations in patterns of use between clinicians, variations between institutions (e.g. public versus private).²¹

Scanning the peer-reviewed literature using an HS methodology may be a useful source of identifying potential HTR targets, with reports of outmoded practices or inappropriate care.⁸ However, this method may lack currency as it is associated with a significant publication lag- time. A more effective method may be to identify and foster 'clinical champions', key clinical groups or influential experts who can be pivotal in driving acceptance of change. In addition, at a local level, intelligence can be gathered and shared from clinicians who have attended conferences and may provide useful information regarding new technologies and practices gleaned from presentations by their peers.²¹

Another method of identifying targets is through the use of clinical redesign methodology, which is primarily a service improvement tool, but it may have a secondary benefit of providing a means of reassessment by identifying and eliminating waste, resulting in improvements to patient flow. The redesign process tracks performance of an organisation or service and provides a framework for change and future decision making. Clinical redesign should be a systematic and methodical approach led by clinical staff, with the result being entirely patient-focused.²¹

HTR can be driven by a combination of evidence, incentives and high-level support. Change is more likely to be accepted by both clinicians and consumers if the focus is firmly placed on quality and safety, or put simply, the appropriate care for the appropriate patient at the appropriate time. HTR decisions may be interpreted as a foregone or lost benefit for some, and for these individuals, an evidence-based decision alone will not drive change; therefore, incentives may need to be identified to affect clinically appropriate change.²¹

Incentives can, but not always be financial. At a local level, incentives may be offered to clinicians in the form of trade-offs. There is anecdotal evidence that this so-called 'carrot and stick' approach works in some cases, with the best time to reassess the value of a health care practice being when investing in a new service or technology. That is, approval may only be granted for the investment in a new technology when a clear return on investment can be demonstrated via the identification of an HTR target that the new technology or service would replace.²⁸ Following on from this process, another important incentive for effective HTR is to make the freed resources available to fund more appropriate services in the same program or hospital. Investment in new technology may drive HTR of an existing practice and deliver a return on investment. Released resources from the outmoded practice may then be more efficiently allocated by re-investing in clinical practices elsewhere in the health system, in so doing, optimising patient outcomes.²⁰

Case study 3: An experienced reassessment program: South Korea

The South Korean HTA agency NECA is one of the most experienced agencies in the region in terms of HTA, horizon scanning and health technology reassessment. The results of the HTR survey show that South Korea has an active HTR program that primarily focuses on diagnostics and medical procedures. Potential HTR targets were identified by several means including: stakeholder engagement, usually clinician driven; the investment in a new technology that then required a reassessment of an existing technology; the technology was a low volume clinical practice; or a variation in practice had been noted (e.g. regional or geographic variation, changes in practice over time, variations in patterns of use between clinicians, variations between institutions e.g. public versus private.)

Seo et al (2016) conducted a systematic review of HTR in several countries, including the United Kingdom, Australia, Canada, Spain, Sweden, Denmark, and the United States of America, in order to inform the HTR process in South Korea.²⁵ Of particular interest was methodologies around the identification of candidate HTR technologies, priority setting, stakeholder involvement, support for reimbursement coverage, and strategies for the implementation of HTR.

The review identified several criteria that were used in these countries to identify potential HTR targets including the availability of new safety, effectiveness and cost-effectiveness evidence; variation in healthcare service utilisation and variation from clinical practice guidelines. Prioritisation of potential HTR targets used similar criteria as decision-making around the investment in new technologies including cost and the impact on the total healthcare budget, the benefit of the technology, the burden of disease and alternative options available. Once identified and prioritised, the review found that HTR methodology did not differ greatly from that of HTA. An important difference was that in order to overcome stakeholder resistance, HTR required a higher level of convincing evidence demonstrating at least no risk, or of a benefit, in removing or limiting access to the technology. Although acknowledged as being more difficult than assessments of new technologies, the review concluded that health system data was an invaluable source of real-world evidence that could be used to support HTR decision-making. The review also concluded that stakeholder involvement, especially the education of patients, was extremely important at all stages of the HTR process, and that the HTR decision-making process needs to be transparent and supported by robust evidence., around the decision-making process. A key development of HTR in South Korea has been recognising that a national registry for HTR should be created to investigate the influence of health technologies on health outcomes, as well as to analyse existing national health insurance claims data from the Health Insurance Review & Assessment Service and National Health Insurance in Korea. In so doing, evidence to support the implementation of HTR of existing technologies could be generated.²⁵

Two HTR pilot projects were initiated in South Korea, beginning in April 2014. These projects aimed to assess the feasibility of the introduction and implementation of an HTR program, to refine the objectives of the HTR for reimbursement coverage or (partial/complete) disinvestment, and to set prioritisation criteria according to the objectives of the HTR program. A four-stage Korean HTR model was developed, including “identification”, “prioritisation”, “reassessment” and “decision” (see Figure 7). Criteria were developed to facilitate the practical implementation of HTR in South Korea:

- seven for “identification”: (i) safety, (ii) controversial efficacy, (iii) proposal from Department of Health, Korean Medical Association and patient related associations, (iv) new evidence on effectiveness, (v) significant changes in the utilisation frequency of technologies, (vi) changes in the cost-effectiveness of a technology, and (vii) variation in use (either regional or by provider).
- seven “prioritisation” criteria and weighted values: (i) safety, (ii) efficacy, (iii) volume on evidence, (iv) burden of disease, (v) potential impact of reassessment, (vi) utilisation of technologies and (vii) cost-effectiveness; and
- four “reassessment” criteria (i) safety, (ii) efficacy or effectiveness, (iii) efficiency or cost-effectiveness, and (iv) infrastructure of the healthcare system.²⁵

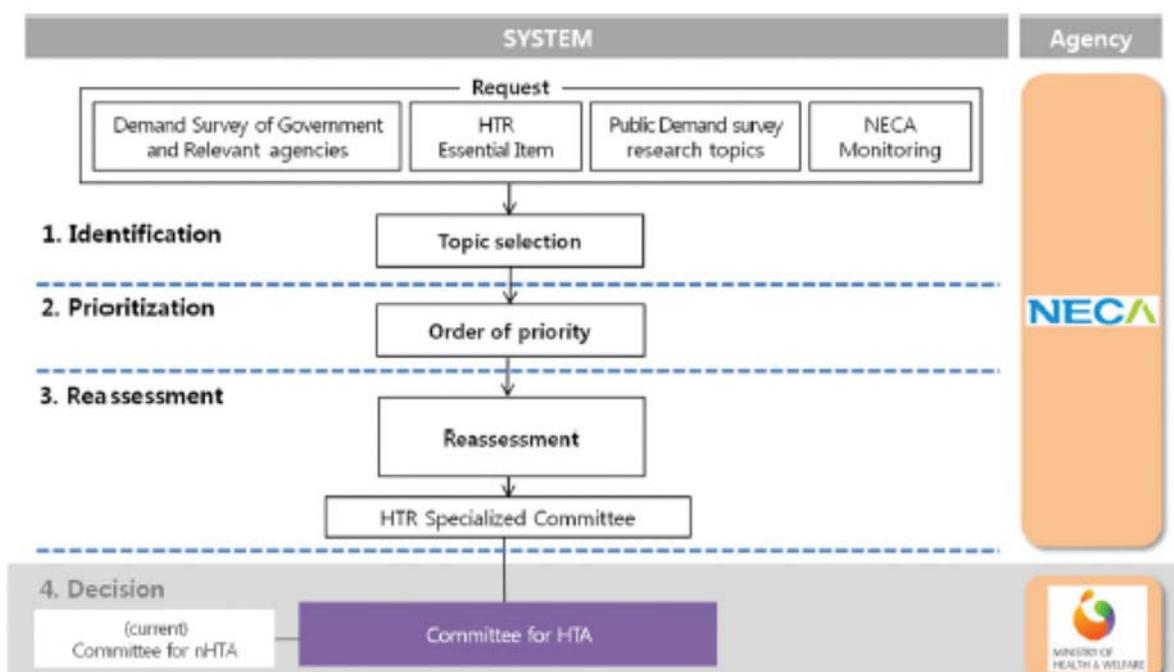


Figure 7 The health technology reassessment process in South Korea²⁵

Once a technology has undergone reassessment the Health Technology Assessment Committee makes a decision based on the evidence and other criteria, in addition to advice from the HTR Specialised Committee. This reassessment model was first implemented on intestine capsule endoscopy and intra-disc steroid injections.²⁵

To assess the level of HTR activity in the region, a short survey of countries and agencies participating in the 2019 HAPF was conducted.

Summary of the results from the agency HTR survey

All 13 agencies responded to the HTR survey with the results summarised in Table 5. Six (42.9%) agencies reported having some experience with the reassessment of a technology with a view to either partially, or completely, disinvest from it (Chinese Taipei (CDE), South Korea, Vietnam, India, Malaysia and China – Shanghai). Although Japan reported no experience with reassessment thus far, the new HTA system introduced in 2019 has an expectation that technologies may be reassessed in the future when new important clinical evidence is published in the peer-reviewed literature, or importantly, if costs of the technology are higher than expected once the technology is in routine clinical practice. Most agencies reported that they would be interested in forming a regional information sharing network around reassessment activities.

Of the six agencies with experience of HTR, Chinese Taipei (CDE) and South Korea reported that their agencies had an active HTR program. As expected, Chinese Taipei's CDE routinely reassessed pharmaceuticals, whilst South Korea has conducted reassessments of diagnostics and medical procedures. Three countries (Vietnam, India and Malaysia) have had experience of reassessment on a more *ad hoc* basis, initiated either by clinician engagement or by noting a variation in clinical practice. As with their HS activities, Malaysia has wide ranging experience in reassessment covering pharmaceuticals, devices, vaccines and public health programs. The China – Shanghai agency conducted the reassessment of a pharmaceutical as a result of a clinical redesign program.

As might be expected, the majority of agencies had experience of clinician-driven identification of potential targets; however, it was interesting to note that five agencies identified reassessment targets due to a variation in practice. This practice may increase with the increasing use of data linkage and real-world data as discussed in previous HAPFs. Of note, three agencies conducted HTR of technologies that were identified as high-volume and high-cost.

Table 5 Reassessment survey results from payer agencies

Has your agency ever reassessed a technology/practice and “disinvested” from it either partially or completely?	Yes: 6/14 (42.9%) No: 8/14 (57.1%)
Was this reassessment	Part of an active program of routine reassessment: Chinese Taipei (CDE), South Korea A one off, ad hoc reassessment: Chinese Taipei (CDE), Vietnam, India, Malaysia Part of a review of clinical practice guidelines As a result of a clinical redesign program: China – Shanghai
Was the technology a	Pharmaceutical: China – Shanghai, Chinese Taipei (CDE), Vietnam, Malaysia Device: Vietnam, Malaysia Diagnostic including precision medicine: South Korea Medical (surgical) procedure: India, South Korea Vaccine: Malaysia Public health programs: Malaysia Gene or cellular therapy
How was the technology identified as a reassessment target?	Through the peer reviewed literature Through horizon scanning activities Stakeholder engagement (i.e. a clinician driven): China-Shanghai, Chinese Taipei (CDE), Vietnam, Malaysia, South Korea Change in clinical practice guidelines: Chinese Taipei (CDE) Technology was high volume and high cost: Chinese Taipei (CDE), Vietnam, India Technology was a low volume clinical practice: South Korea Investment in a new technology required a reassessment of existing technology: China-Shanghai, South Korea A variation in practice had been noted, e.g. regional or geographic variation, changes in practice over time, variations in patterns of use between clinicians, variations between institutions (e.g. public versus private): China-Shanghai, Chinese Taipei (CDE), India, Malaysia, South Korea
How are the results of your reassessments disseminated?	Website: China-Shanghai, India, Malaysia Word of mouth, seminars, clinical forums: India, Malaysia, Vietnam Policy document: China-Shanghai, Malaysia, Vietnam, Chinese Taipei (CDE), South Korea Press release: South Korea Newsletters (electronic or printed): China-Shanghai, India, Malaysia RSS feeds Social media including Twitter and Facebook: Malaysia Journal articles: China-Shanghai, India, South Korea



Potential talking points for during the Forum, especially during the breakout sessions, in relation to the challenges and issues of horizon scanning and reassessment.

- What do agencies hope to realise by establishing a framework for horizon scanning or reassessment?
 - Should reassessment be conducted on a structured or more ad hoc basis?
 - Can horizon scanning be conducted in parallel with reassessment in your agency?
- What are the common themes and key differences of HS or reassessment activities between agencies?
- What role can industry play in HS or reassessment activities in the region?
- How can existing HS and reassessment programs share information with agencies in the region?
 - Should a network like EuroScan be established to share information?
 - What would this network look like?
 - Is there a role for industry in this network?
- What are some of the key challenges you envisage when embarking on a program of reassessment?
 - Lack of HTA resources?
 - Difficulty identifying targets?
 - Access to data or lack of data?
 - Stakeholder “buy in”, especially clinicians? Political will? Limited commitment from policy-makers, funders and clinicians?
 - Inertia and failure to acknowledge that current practices aren’t working?
 - Lack of clear processes or incentives to sustain change?

Appendix 1 Horizon scanning and reassessment activity survey

Horizon scanning is a systematic methodology used for the identification and early assessment of new and emerging health technologies that may have a significant impact on health systems. By providing evidence-based advice on emerging technologies, horizon scanning is used to inform policy makers and health service organisations to assist in the managed introduction of new health technologies, including pharmaceuticals, medical practices and devices. Advance notice of an emerging technology can assist financing and planning decisions, ensure processes are put in place to support and monitor clinical development, and that technologies are evaluated before widespread diffusion. In so doing, horizon scanning supports the uptake of innovative, cost effective health technologies, whilst at the same time protecting patients from potentially ineffective or unsafe health technologies.

This part of the survey aims to capture the state-of-play of horizon scanning in the Asia region.

1. Which country does your agency represent?

- | | | |
|------------------------------------|--------------------------------------|---|
| <input type="checkbox"/> China | <input type="checkbox"/> Indonesia | <input type="checkbox"/> South Korea |
| <input type="checkbox"/> Beijing | <input type="checkbox"/> Japan | <input type="checkbox"/> Chinese Taipei |
| <input type="checkbox"/> Shanghai | <input type="checkbox"/> Malaysia | <input type="checkbox"/> Thailand |
| <input type="checkbox"/> Hong Kong | <input type="checkbox"/> Philippines | <input type="checkbox"/> Vietnam |
| <input type="checkbox"/> India | <input type="checkbox"/> Singapore | <input type="checkbox"/> |

2. Is your agency (please choose the most appropriate option)

- A: Currently conducting horizon scanning (HS)
- B: Not currently conducting HS but currently developing an HS system
- C: Not currently conducting HS but interested in developing an HS system
- D: Not currently conducting HS and not interested in developing an HS system

3. For those agencies conducting/developing HS, would you be interested in forming an information sharing network in the Asia region similar to the EuroScan network?

- Yes
- No

Only continue with HS survey if you clicked A or B in Q2.

If you clicked C or D, please go to Reassessment survey Q17

4. If your agency has an HS system, how long has it been active for?

- Less than 12 months
- 1-3 years
- >3 years

5. If your agency is developing an HS system, how long before it becomes fully operational?

- Less than 12 months
- 1-3 years
- >3 years

6. If your agency is currently conducting HS, or developing an HS system, are you scanning/plan to scan for new and emerging (click all that apply)

- Pharmaceuticals
- Devices
- Diagnostics including precision medicine
- Medical (surgical) procedures
- Vaccines
- Gene or cellular therapies
- Public health programs

7. Does your HS system/ will your HS system identify

- Single technologies
- All technologies in a clinical care pathway e.g all new pharmaceuticals for prostate cancer or new technologies for the treatment of stroke

8. Would you consider using your HS methodology to identify potential disinvestment/reassessment targets?

- Yes
- No

9. Is your HS system/will your HS system be

- Proactive: where a range of sources are searched for information on new and emerging health technologies.
- Reactive: where stakeholders, health professionals, developers and/or consumers to inform the system on new and emerging health technologies.

10. What is/will be the time horizon of your HS system (at what stage of development will technologies be identified)?

- 6 -12 months prior to regulatory approval
- 12 months before the technology will enter the health system
- 1-3 years before the technology will enter the health system
- 3-5 years before the technology will enter the health system

11. Will technologies identified through HS be used to inform:

- Policy-makers at the health department level
- Policy-makers at the hospital level
- Clinicians
- Patients
- Other (please specify)

12. What sources do you scan/plan to scan from to identify potential topics? Please click all that apply

Primary sources such as

- Commercial developers
- Clinical trials registries
- Patents

Secondary sources such as

- International English language peer reviewed journals (BMJ, Lancet, NEJM)
- Regional (Asian) peer reviewed journals
- Google search alerts
- Medical media - electronic newsletters (e.g. Medscape)
- Other HS agencies (e.g. CADTH) or network such as EuroScan
- Grey literature including TV news, newspapers
- Conference proceedings
- Commercial developers
- Regulatory authorities
- Clinical experts

13. What criteria are used/will be used to prioritise identified technologies for assessment?

Please tick all that apply

- Based on health system priorities
 - burden of disease
 - rarity of disease
 - associated morbidity or mortality
 - alternative treatment options available (rare diseases)
 - characteristics of disease (acute vs chronic)
- Impact of technology on
 - costs – increased costs or savings to the health system, large capital outlay, out-of-pocket payments for patients, direct and indirect costs for society
 - Patients - impact on morbidity, mortality, QoL, diagnosis, safety
 - Services and organisations - increased or decreased use, service reorganisation, structural changes, staff training requirements, learning curves, quality assurance procedures, safety concerns
 - Ethical issues
- Technology is rapidly diffusing and has not be assessed
- Technology is associated with safety concerns
- New use of an existing technology

14. Who applies these criteria?

- Horizon scanning team – in-house experts
- Clinical expert panel
- Health service policy makers
- Patients or consumer groups

15. What type of HS assessment does your agency typically produce?

- Rapid brief: brief overview of technology, limited if any evidence but important to alert policy makers, typically 1-3 pages produced in 24-48 hours
- Assessment brief: more in-depth assessment covering safety, effectiveness, cost and impact, more mature evidence base may consist of several studies, typically 8-12 pages produced in 1-2 weeks

- Report: HTA assessment, mature evidence base (past the horizon?) typically 30-50 pages produced in 3 months
- Other (please specify)

16. How do you disseminate your assessments?

- Website
- Newsletters (electronic or printed)
- RSS feeds
- Social media including Twitter and Facebook
- Word of mouth, seminars
- Journal articles
- Other (please specify)

This part of the survey aims to capture the state-of-play of reassessment in the Asia region.

Traditional HTA methodologies have become established practice when health systems seek to invest in and implement new clinical practices and technologies; however, reassessment methodologies are lacking. With increasing restraints on health system budgets, reassessment is viewed as a necessary part of the lifecycle of a technology. Reassessment of ineffective, inefficient or harmful clinical practices and technology presents opportunities to enhance patient and operator safety and improve quality of care that can also result in health system savings.

17. Has your agency ever reassessed a technology/practice and “disinvested” from it either partially or completely?

- Yes
- No

18. If NO to Q17, would you be interested in a regional information sharing network around reassessment?

- Yes
- No

19. If YES to Q17, was this reassessment (please click all that apply)

- part of an active program of routine reassessment
- a once off, ad hoc reassessment
- part of a review of clinical practice guidelines
- as a result of a clinical redesign program

20. If YES to Q17, was the technology a (please click all that apply)

- Pharmaceutical
- Device
- Diagnostic including precision medicine
- Medical (surgical) procedure
- Vaccine
- Public health programs
- Gene or cellular therapy

21. If yes to Q17, how was the technology identified as a potential reassessment target? (please click all that apply)

- through the peer reviewed literature
- through horizon scanning activities
- stakeholder engagement (i.e. a clinician driven)
- change in clinical practice guidelines
- an investment in a new technology required a reassessment of existing technology
- a variation in practice had been noted, e.g. regional or geographic variation, changes in practice over time, variations in patterns of use between clinicians, variations between institutions (e.g. public versus private)
- technology was high volume and high cost
- technology was a low volume clinical practice

22. If YES to Q17, how do you disseminate your reassessments? (please click all that apply)

- Website
- Word of mouth, seminars, clinical forums
- Policy document
- Press release
- Newsletters (electronic or printed)
- RSS feeds
- Social media including Twitter and Facebook
- Journal articles
- Other (please specify)

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