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Foreword

The Agency for Care Effectiveness (ACE) is the national health technology assessment (HTA) agency in Singapore residing within the Ministry of Health. It conducts technical evaluations to inform subsidy decisions for health technologies such as drugs, devices and medical services, and produces guidance on their appropriate use for public hospitals and institutions in Singapore. ACE also conducts horizon scanning to provide early alert on new and emerging health technologies with significant impact on the healthcare system.

The ACE Horizon Scanning Methods & Process Guide outlines the core framework and processes underpinning the identification, filtering, prioritisation and early assessment of new and emerging health technologies before its introduction into the local healthcare system. This guide is not intended to be a comprehensive academic document nor to describe all the technical details relating to the horizon scanning process and assessment. Rather, the intention of this guide is to standardise and document the framework and methods that ACE follows for horizon scanning assessment, and increase transparency of our processes and decision-making frameworks.

While this document forms an important part of the Ministry of Health (MOH) Medical Technology Advisory Committee's (MTAC) process guide for the horizon scanning of new and emerging health technologies, it is only a guide – ACE and MTAC are not bound to adhere to it in every detail, or in every case.

Information in this guide may also be useful for relevant stakeholders who provide advice or input to support ACE's horizon scanning assessments, where applicable. ACE will continue to review and update this guide to ensure that it remains a useful resource for the Singapore healthcare system.

Find out more about ACE at www.ace-hta.gov.sq/about

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1. Introduction

Horizon scanning (HS), also known as early awareness and alert system, is an established approach in healthcare to identify new and emerging health technologies and trends. Given the challenges to alter well-entrenched healthcare practices, HS can be used as a tool to keep abreast of new and emerging health technologies with potentially high impact at an early stage of their development. HS represents a continuum of HTA and serves as an early HTA.

The ACE HS System aims to identify, filter and prioritise new and emerging health technologies, or new uses of existing interventions, to assess their potential impact on health or the healthcare system before its introduction into the local healthcare system, especially for high cost and disruptive technologies. This allows for better preparedness of the healthcare system by providing advance notice to policymakers and healthcare providers to aid in planning for healthcare resources allocation. It further serves to support the uptake of innovative and effective technologies while safeguarding patients from potentially unsafe technologies before its widespread adoption.

This document provides an overview of ACE's HS process and framework. It introduces the general methodology underlying each stage of the HS process. The overall methodology was developed with reference from the EuroScan International Network (now known as international HealthTechScan) HS toolkit and in consultation with HS experts from Canada and Australia.

1.1 Scope and characteristics of health technologies

ACE's scope of HS can include, but is not limited to, medical devices, diagnostics, medical services and procedures. New and emerging health technologies refer to technologies that are early in their product lifecycle, generally in the developmental, launch or early pre-marketing stages. In the local context, they can include technologies that are not yet registered with the Health Sciences Authority (HSA), and are not yet widely adopted by the local healthcare system.

2. Identification

ACE's HS process begins with the identification stage to identify new and emerging health technologies that address high disease burden in medical conditions such as cardiovascular diseases, cancer and neurological disorders (Figure 1). These technologies can be identified from a range of primary, secondary and tertiary sources (Table 1). Amongst these, the main sources of identification include new regulatory approvals from overseas regulatory bodies such as the US Food and Drug Administration (FDA) or European Medicines Agency (EMA), overseas reference HS agencies and news media channels. Other supplementary sources include scientific journals, clinical trial registries, commercial websites and technology transfer offices. In addition, ACE may also seek inputs from clinical experts and the industry to identify new and emerging health technologies, especially those with a shorter innovation cycle or a higher rate of potential diffusion.

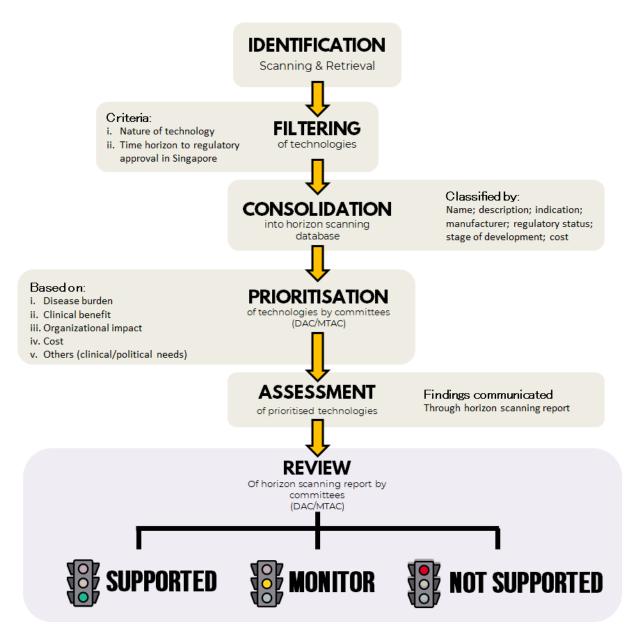


Figure 1: Overview of ACE's horizon scanning system

Table 1: Identification sources and its scanning frequency

Type of information source	Source	Scanning frequency
Primary	Trial registries (e.g., Clinicaltrials.gov)	Bi-annually
	Commercial developer websites	As required
Secondary	Regulatory authorities (e.g., US FDA, EMA)	Quarterly
	Medical technology or pharmaceutical news media	Weekly
	Scientific journals	Weekly
	Conference proceedings	Annually
Tertiary	Reports from reference horizon scanning agencies (e.g.,	Quarterly
	CADTH, PCORI, NIHR Innovation Observatory)	

CADTH, Canadian Agency for Drugs and Technologies in Health; EMA, European Medicines Agency; FDA, Food and Drug Administration; NIHR, National Institute for Health Research; PCORI, Patient-Centered Outcomes Research Institute.

3. Filtering

Following the identification stage, identified technologies are filtered to select for those that are relevant to the local healthcare system based on the scope of technology and time horizon to regulatory approval in Singapore. The scope and interest of the technologies selected in the filtering process will evolve and remain fit-for-purpose in line with the prevailing national healthcare priorities and are determined with inputs from policy makers and local healthcare experts.

The scope of the technologies selected in the filtering process can include, but is not limited to, high cost technologies, novel technologies, or existing technologies with new indications (e.g., incremental innovation). The registration status in overseas countries such as the United States and Europe is used as an indicator for the time horizon of potential health technologies poised to enter the Singapore market in the near future, given that health technologies are generally approved earlier in those countries. The time horizon considered can vary based on the type of health technologies and their different length of product lifecycles.

4. Consolidation

The filtered health technologies will be consolidated into a database, where the relevant information of the technologies such as its indications, current stage of development, local and overseas regulatory status, cost and funding status will be collated. This provides a consolidated list of key information for prioritisation to be conducted.

5. Prioritisation

The consolidated list of filtered health technologies will be prioritised for further assessments based on a set of pre-defined criteria in agreement with the requirement of key stakeholders (e.g., MOH's Medical Technology Advisory Committee, policy makers and clinical experts) to ensure congruity in the process. The prioritisation criteria allow the relative potential of each filtered health technology to the healthcare system to be determined. In addition, requests from relevant stakeholders can be taken into consideration in the prioritisation process to ensure that the health technologies prioritised are in line with the local needs.

5.1 Key prioritisation criteria

In line with overseas HS systems, the key prioritisation criteria adopted by ACE include disease burden, clinical benefit, organisational impact and cost of the technology. Where applicable, clinical and political needs may be used as additional considerations for the prioritisation process.

5.1.1 Disease burden

The disease burden of the condition indicated by the particular health technology is assessed to consider the size of the target patient population, disease severity and current treatment or diagnostic options. Key considerations can include the following:

- Size of the target population (e.g., local prevalence or incidence rate, if available)
- Disease characteristics (e.g., severity, acute or chronic, quality-of-life, morbidity, mortality)

• Clinical need (e.g., availability and effectiveness of current interventions)

5.1.2 Clinical benefit

As these new and emerging health technologies are generally early in their product lifecycle, there may be a sparsity of published or available clinical evidence. Assessment of clinical evidence for each filtered health technology can include the following:

- Clinical effectiveness (e.g., direction and magnitude of effect, clinical meaningfulness of the effect)
- Safety (e.g., adverse events, procedural or device-related events)

5.1.3 Organisational impact

The introduction of new health technologies may lead to changes in organisational requirements to the healthcare system, especially for novel and disruptive technologies. Assessment of the potential organisational impact of the filtered health technologies can serve to pre-empt key stakeholders and decision-makers on incoming technologies that require organisational level changes if introduced in the healthcare system. Additionally, healthcare system benefits arising from the introduction of new health technologies are also considered. Key considerations can include the following:

- Healthcare system benefits (e.g., improved workflow and efficiency, reduced or optimised resource use)
- Implementation barriers (e.g., service reorganisation, training or credentialling requirements, major infrastructure upgrades)

5.1.4 Cost

The cost of the filtered health technologies are considered in the prioritisation process to determine technologies that may potentially have a greater impact to the national healthcare budget. Early visibility of such technologies will allow the healthcare system to better manage and allocate resources for the potential arrival of these technologies. Direct cost of the technology is considered and key considerations can include the following:

- Cost of the health technology
- Associated cost from the use of the technology (e.g., additional cost required for the technology to be used, cost arising from organisational changes required for the technology to be adopted)
- Cost-effectiveness of the technology, if available

5.2 Ranking system

In general, a qualitative ranking approach is adopted where each of the above-mentioned key prioritisation criteria is ranked as "high", "moderate", "low" or in-between rankings (i.e., "moderate-high" or "moderate-low") for every filtered health technology.

Based on the ranking results, technologies with higher ranks will be selected and proposed to be prioritised for further assessment. The technologies that are not selected will be pooled together with other technologies in the next topic prioritisation exercise.

6. Assessment

HS assessments will be conducted for the prioritised technologies. It aims to provide an early stage technological, clinical, organisational, social and ethical assessment of the health technology in the form of a HS report.

6.1 Horizon scanning report

There are two main types of horizon scanning reports that ACE may produce based on the nature of the request and the purpose of the report.

- Horizon Scanning Brief is a more targeted and in-depth report, focusing on a single or a few
 clinical applications of a health technology. It serves to provide an early assessment on the
 potential impact of a technology in the application(s) of interest.
- Horizon Scanning Overview is a high-level assessment focusing on multiple or all clinical use of
 an emerging technology. It serves to provide an overall summary of the current clinical
 applications of a technology and its potential benefits. The Overview can also be used to
 identify potential clinical application for more detailed assessment.

Generally, the HS reports provide an evaluation of the proposed patient population, burden of disease, clinical need, description and current developmental stage of the technology, proposed position of the technology in the current care pathway, benefits of the technology over currently available alternatives, and potential financial and organisational impact to the local healthcare system. Current available evidence to support the safety, effectiveness and cost-effectiveness of the technology, where available, will be summarised.

6.2 Clinical expert consultation

Clinicians who are domain experts for each prioritised health technology will be identified and consulted during the assessment process, including feedback for the final report. Clinical experts can provide valuable inputs on the position of the technology in the care pathway, its viability, benefits and risk over current alternatives, and any implementation, training or organisational issues with the potential introduction of the technology. Their inputs will be considered and reflected in the HS report, where applicable.

7. Review

7.1 Decision-making committee

ACE will leverage on key decision-making committee within the MOH – the Medical Technology Advisory Committee (MTAC) – to seek advice and recommendation on the health technologies assessed in the HS reports.

MTAC serves to provide funding recommendations for medical technologies and consists of senior clinicians from public healthcare institutions, healthcare finance and regulatory affairs representatives from the MOH, and is chaired by the MOH Director of Medical Services (DMS). The terms of reference of MTAC can be found in the *Medical Technologies Evaluation Methods and Process Guide* on ACE's website.

The HS report will be presented to MTAC for their review and recommendation on the potential for the prioritised technology to be introduced into the healthcare system. In contrast to HTA evaluations, the committee's recommendation does not translate into subsidy decision. It serves to provide early alert to the healthcare system on the potential introduction and, if appropriate, any necessary changes required for the successful introduction of new and emerging health technologies.

7.2 Recommendation

Based on the HS report, MTAC will deliberate on the potential of the prioritised health technologies for future adoption in the local healthcare system. The decision-making process is guided by a 'traffic light' system to either Support, Monitor or Not to support the health technology based on available evidence (Table 2).

Table 2: Guiding principles to guide decision for the HS report

Decision	Guiding principles	
Supported (Green)	There is sufficient evidence to support uptake of the technology	
Monitor (Yellow)	Further monitoring is required due to insufficient evidence available at the time of the review but the technology looks promising and additional evidence may provide useful information	
Not supported (Red)	The uptake of the technology is currently not supported due to concerns regarding its benefits	

7.2.1 Supported

Health technologies that are supported by MTAC would generally have sufficient evidence to support its uptake, indicating that these technologies may bring significant benefits to either the patients or the healthcare system if introduced.

7.2.2 Monitor

Health technologies that are recommended for further monitoring by MTAC will be earmarked for ongoing tracking of emerging evidence. The current evidence generally indicates that the technologies are promising. However, the evidence is insufficient for a definitive decision and further monitoring of emerging evidence will be required. Updates on these technologies will be conducted at an interval of approximately two years when new substantial clinical evidence is available, and the updated results will be presented to MTAC for review.

7.2.3 Not supported

Health technologies that are recommended as "Not supported" generally refer to low value technologies that are not encouraged to be adopted in the local healthcare system at the time of review. This may be attributed to technologies with inferior clinical benefits or present safety issues. In addition, this decision may also apply to technologies at an earlier stage of development and thus

would require a much longer interval (e.g., more than three or four years) before any meaningful reassessment.

8. Dissemination

The HS reports for the health technologies recommended to be supported by MTAC can be disseminated to policy makers and other relevant stakeholders to provide advance notice and anticipation of a technology's arrival and adoption in the local healthcare system. This would provide ample lead time for the healthcare system to prepare for necessary changes such as staff training, infrastructure upgrades or resource allocation to enable the successful introduction of the technology.

Conversely, HS reports for health technologies that received a negative recommendation (i.e., not supported) can also be disseminated to policy makers and other relevant stakeholders to provide advance warning for these technologies before they enter into the local healthcare system.

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