HORIZON SCANNING METHODS AND PROCESS GUIDE

Version 2.0 March 2024



Record of updates

Date	Version	Summary of main changes		Summary of main changes	
September 2021	1.0	Publication of initial methods and process guide			
March 2024	2.0	 Updated HS process Inclusion of Annex A to outline industry notification of pipeline medical technologies Inclusion of Annex B to outline key points for consideration in ranking filtered technologies Other general modification to improve the clarity and flow of the guide 			

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Foreword

Established by the Ministry of Health (MOH), the Agency for Care Effectiveness (ACE) is the national health technology assessment and clinical guidance agency in Singapore. It produces evidence-based evaluations of health technologies (e.g. drugs, devices and medical technologies) to inform funding decisions by MOH committees, and publishes technology guidance documents for public hospitals and institutions in Singapore to promote the appropriate use of clinically effective and cost effective treatments. ACE also conducts horizon scanning to provide early alerts concerning new and emerging health technologies with the potential to significantly impact the healthcare system. Find out more about ACE at www.ace-hta.gov.sg/about

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 they are introduced into the local healthcare system. This guide intends to standardise and document the framework and methods that ACE follows for horizon scanning assessment, and to increase transparency of our processes and decision-making frameworks. It is not a comprehensive academic or technical document.

Alongside ACE, various Ministry of Health technology advisory committees may use this process guide, such as the Medical Technology Advisory Committee. However, they 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 it remains a useful resource for the Singapore healthcare system.

ACE would like to thank the following experts for their contributions to the development of the ACE horizon scanning system:

- Ms Linda Mundy, Royal College of Pathologists of Australia
- Dr Lesley Dunfield, Canadian Agency for Drugs and Technologies in Health
- Ms Leigh-Ann Topfer, Canadian Agency for Drugs and Technologies in Health

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 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 health technology assessment (HTA) and serves as a form of early HTA.

The Agency for Care Effectiveness (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 diffusion into the local healthcare system, especially for high-cost or disruptive technologies. This information allows for better preparedness of the healthcare system, by providing advance notice to policy makers and healthcare providers to aid in planning healthcare resource allocation. It further serves to support the uptake of innovative and effective technologies, while safeguarding patients from potentially unsafe or low-value technologies before their widespread adoption.

This document provides an overview of the ACE HS process and assessment framework. It introduces the general methodology underlying each stage of the HS process. The overall methodology was developed with reference to international best practice for HS, including the EuroScan International Network (now known as international HealthTechScan) HS toolkit, and in consultation with HS experts.

1.1. Scope and characteristics of health technologies

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

1.2. Overview of HS process

ACE HS is a systematic process that starts with the identification of new and emerging health technologies. This is followed by a detailed assessment of prioritised technologies, and culminates with the dissemination of recommendations by the Ministry of Health (MOH) Medical Technology Advisory Committee (MTAC) on the adoption of assessed technologies into the public healthcare system if locally available. The overall process is summarised in Figure 1. The following sections provide a detailed description of each step.

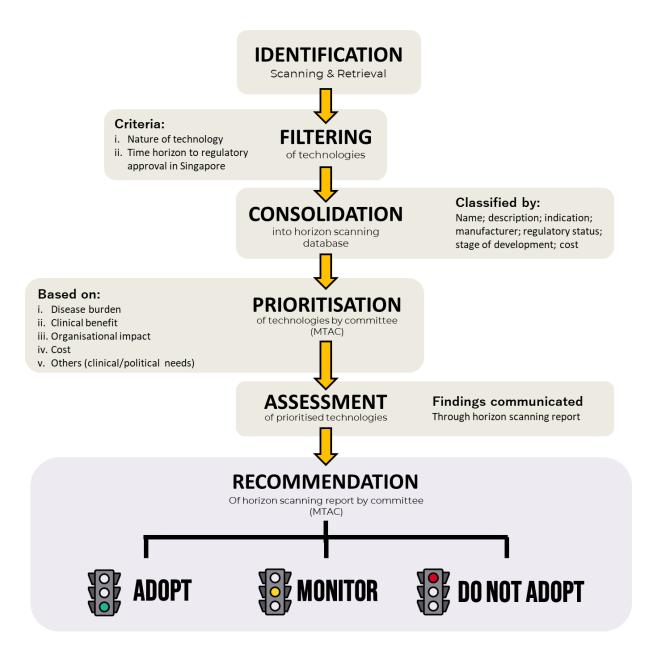


Figure 1: Overview of the ACE horizon scanning process. Abbreviation: MTAC, Medical Technology Advisory Committee.

2. Identification

The ACE HS process begins with the identification of new and emerging health technologies that address locally relevant indications, focusing on the top disease burden in Singapore at the time. A range of primary, secondary and tertiary sources are used, including new regulatory approvals from key overseas regulatory bodies such as the US Food and Drug Administration (FDA), overseas reference HS agencies and news media channels (Table 1). Other sources include scientific journals, clinical trial registries, commercial websites and technology transfer offices. In addition, ACE may also seek inputs from key stakeholders including industry (see <u>Annex A</u>), policy makers and clinical experts to identify new and emerging health technologies, especially those with a shorter innovation cycle or a higher rate of potential diffusion.

Health technologies that are found to be registered with HSA at this stage may be shared with the relevant ACE technical team, such as the Medical Technology Evaluation team, for potential inclusion in the HTA topic prioritisation pipeline for subsidy evaluation. This may allow the early evaluation of a newly registered technology to guide its appropriate diffusion before it is well-entrenched into the healthcare system. More information on ACE's methodology for the evaluation of medical technologies can be found in the *Medical Technologies Evaluation Methods and Process Guide* on the website (https://www.ace-hta.gov.sg/resources/process-methods).

Table 1: Identification sources and 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. 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. CADTH, PCORI, NIHR Innovation Observatory)	Quarterly
Others	Industry notification	Annual
	Nominations from local clinicians, policy makers, consumers	Ad-hoc

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

3. Filtering

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

The scope of the technologies for the filtering process can include, but is not limited to, novel technologies, existing technologies with new indications (e.g. incremental innovation), or technologies that are of political interest. The novelty of a technology is determined based on several factors, such as the breakthrough device designation or de novo clearance granted by the FDA, or technologies that are identified and/or assessed by other reference HS agencies. The registration status in overseas key regulatory bodies such as the FDA 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 these regions. The time horizon can vary based on the type of health technology and the length of the product lifecycle, typically averaging two to three years before market access.

4. Consolidation

The filtered health technologies are consolidated into a database, where relevant information such as indication(s), current stage of development, local and overseas regulatory status, cost and funding status is collated, when available. This provides a consolidated list of key information for prioritisation.

5. Prioritisation

The consolidated list of filtered health technologies is prioritised for further assessments based on a set of pre-defined criteria that are approved by MOH decision-making advisory committees (e.g. MTAC). The prioritisation criteria intend to determine the relative potential of the technology to patients and the healthcare system. In addition, requests and feedback from relevant key stakeholders (e.g. policy makers and clinical experts) are taken into consideration to ensure that the prioritised health technologies are in line with local needs.

5.1. Key prioritisation criteria

In line with overseas HS systems, the core prioritisation criteria adopted by ACE include disease burden, benefit, organisational impact and cost of the technology. Where applicable, local political need and available assessment from overseas reference HS agencies may serve as additional considerations in prioritising particular technologies.

5.1.1. Disease burden

Amongst the filtered health technologies, those that address conditions with greater disease burden will generally be prioritised for assessment. Key considerations include the size of the target population based on local prevalence or incidence of the condition of interest, disease severity, and the availability of effective management strategies (refer to Section 6.2.1 for more information).

5.1.2. Benefits

As these new and emerging health technologies are generally early in their product lifecycle, published clinical evidence to support its claimed benefits may be sparse. A high-level assessment of each filtered health technology is performed to determine its benefits for patients and/or the health system, including safety, clinical- and cost-effectiveness and any other relevant outcomes (refer to Section 6.2.3 for more information).

5.1.3. Organisational impact

The introduction of new health technologies may require significant changes at multiple levels to the healthcare system, especially for novel and disruptive technologies. Assessment of potential organisational impacts of the filtered health technologies can alert key stakeholders and decision-makers to incoming technologies that may require organisational level changes such as service or infrastructure modification, if introduced in the healthcare system (refer to Section 6.2.5 for more information).

5.1.4. Cost

The cost of the filtered health technologies is considered in the prioritisation process to identify technologies that may significantly impact the national healthcare budget. Early visibility of such technologies will allow the healthcare system to better manage resources required for the potential adoption of such technologies, if deemed appropriate.

5.2. Ranking system

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

Based on the results, higher ranking technologies will generally be proposed for prioritisation and further assessment, with the approval from MTAC. Those not selected will be pooled together with other technologies in subsequent topic prioritisation exercises.

6. Assessment

HS assessments are conducted for the prioritised technologies. They aim to assess each technology early in its lifecycle, focusing on potential clinical, economic and organisational impacts, and any other considerations that are of importance to the stakeholders. The assessment outcome for each prioritised technology is in the form of an HS report which will inform MTAC when making their adoption recommendation.

6.1. Horizon scanning outputs

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

- Horizon Scanning Brief is a targeted and in-depth technical report, focusing on a single or a
 few clinical applications of a new or emerging health technology. It serves to provide an early
 assessment on the potential impact of a technology in the indication(s) of interest.
- Horizon Scanning Overview is a high-level assessment focusing on multiple or all clinical uses
 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 applications for more in-depth assessment.

In addition to the main assessment reports, HS also produces other outputs to meet the diverse demands of stakeholders.

- *Innovation Report* provides a trend analysis of top health technologies anticipated to disrupt local healthcare practices in the next three to five years.
- Environmental Scan provides a landscape analysis to understand the internal and external environment of a particular topic, providing input into strategic thinking, decision making, and planning.

• *HSalert* is a summary document that offers a brief overview of various health technologies that have been assessed, along with the corresponding recommendations from MTAC (see Section 7).

6.2. Key assessment domains

The HS reports provide an assessment of a health technology from various aspects, including the clinical need for that technology, its impact on patient or system outcomes, and the potential organisational and resource implications to the local healthcare system if adopted.

6.2.1. Disease burden

When assessing the burden of the disease addressed by a health technology, the following key areas are considered:

- Size of the target population (e.g. how widely a target condition impacts on the population in terms of its local prevalence or incidence rate, if available)
- Disease characteristics (e.g. severity of the disease in terms of its impact on quality-of-life, morbidity, or mortality; acute or chronic nature)
- Clinical need for the technology (e.g. whether there is any unmet need in the management of the target condition, taking into account the availability and effectiveness of current interventions)

6.2.2. Description of health technology

When providing a holistic overview of a health technology the following key areas are included:

- A brief description including its function, mode of action and novelty
- Details of local or overseas regulatory and funding status, where available
- The state of diffusion in local clinical practice
- Place of the health technology in the current clinical management pathway of the target condition

6.2.3. Summary of evidence

The impact of a health technology on patient health outcomes and the healthcare system is assessed using published literature from bibliographic databases including, but not limited to, PubMed, Embase, Cochrane Library and international HTA databases. The scope of the assessment is based on a pre-determined PICO criteria that outlines the population, intervention, comparator and outcome measures for the health technology. Key assessment domains include the following:

- Safety (e.g. adverse events, procedural or device-related events)
- Clinical effectiveness (e.g. impact of health technology on net health outcomes)
- Cost-effectiveness of the technology (e.g. incremental cost-effectiveness ratio or cost saving information), if available
- Healthcare system benefits arising from the introduction of new health technologies (e.g. improved workflow and efficiency, reduced or optimised resource use)

Ongoing trials for the health technology are also summarised to provide insights into the future availability of new evidence, together with anticipated completion date to better inform decision-making.

6.2.4. Estimated cost

The estimated cost of an assessed health technology is reported, based on publicly available pricing information from either local or other major markets, to inform the potential resource requirement if adopted. Key information can include:

- Direct costs of the health technology
- Associated costs from use of the technology (e.g. training costs required to use the technology, costs arising from organisational changes for the technology to be adopted)

6.2.5. Organisational impact

Potential barriers to, and resource implications from, the adoption of a health technology into local public healthcare systems are also assessed. This information provides decision-makers with insights into the challenges and requirements associated with integrating the technology into existing care pathways and the infrastructure changes needed, if any. Key considerations can include:

- Workflow changes (e.g. service reorganisation)
- Staff training or credentialing requirements
- Infrastructure requirements (e.g. physical or information technology infrastructure modification)
- Data management (e.g. changes to existing data management systems)

6.2.6. Concurrent developments

Other alternatives to the technology of interest that are in ongoing development are also summarised to provide an overview of competing technologies that may enter the local market. This information may be obtained from general search, clinician feedback and technologies previously identified through the HS process.

6.3. Clinician review and feedback

Clinicians who are domain experts for the prioritised health technology are identified and consulted during the assessment process, to help with defining the scope of the assessment and providing feedback for the final report. At the scoping stage, clinical feedback focuses on the appropriateness of the PICO criteria, the position of the technology in the current clinical pathway and the local need of the technology.

While finalising the HS report, the clinical experts are again consulted, and encouraged to provide valuable inputs on all aspects of the assessment, with particular focus on the applicability of evidence to the local settings and potential organisational issues associated with the introduction of the technology. Their inputs will be considered and reflected in the final HS report, where applicable.

7. Recommendation

7.1. Decision-making committee

ACE reports to key decision-making advisory committees within the MOH, such as the MTAC, to seek recommendation on adoption of health technologies assessed in the HS reports.

MTAC mainly serves to provide funding recommendations for medical technologies. It consists of senior clinicians from public healthcare institutions, healthcare finance and regulatory authority representatives from the MOH and HSA. The terms of reference of MTAC can be found in the *Medical Technologies Evaluation Methods and Process Guide* on the ACE website (https://www.ace-htta.gov.sg/resources/process-methods).

Each HS report is presented to MTAC for their review and advice on adoption of the assessed technology by the local public healthcare system. In contrast to other HTA evaluations, the committee's recommendation on HS topics is advisory in nature and does not translate into a funding decision. MTAC's recommendation intends to provide early alert to the healthcare system on the potential introduction and, if appropriate, any necessary changes required for the successful adoption of new and emerging health technologies.

7.2. Committee recommendation

Based on the HS assessment, MTAC will deliberate on the potential of the assessed health technology for future adoption in the local healthcare system. The decision-making process is guided by a 'traffic light' system to either adopt, monitor or not adopt the health technology based on a holistic assessment of various factors, mainly clinical need, available evidence, cost and organisational considerations (Table 2). Additional factors will be considered when deemed necessary.

Table 2: Guiding principles for decision-making for the HS report

Decision	Guiding principles	
Adopt (Green)	The technology addresses a local clinical need, shows significant potential benefits, with manageable cost.	
Monitor (Yellow)	 The technology addresses a local clinical need, however there is insufficient evidence to substantiate its claimed benefits at the time of the review. Additional evidence that may allow a firm conclusion to guide decision-making is anticipated to emerge within a reasonable timeframe, generally within the next two to three years. 	
Do not adopt (Red) ^a	 The technology is unlikely to address local clinical need (if any), with unclear benefits, prohibitive cost or implementation issues. Substantial evidence is not expected in the near future (e.g. next two to three years) 	

^a This decision serves to advise against the adoption of new health technology in the next three to four years.

7.2.1. Adopt

Health technologies recommended for adoption by MTAC generally address an unmet local clinical need, with sufficient evidence demonstrating that, if introduced, they may bring significant benefits to either patients or the healthcare system. There are no significant implementation issues, including costs, identified to adopt the technology into local clinical practice.

7.2.2. Monitor

Health technologies recommended for further monitoring by MTAC are promising and generally address a local clinical need, however current evidence is insufficient for a definitive decision. If emerging evidence is expected in the near future, generally within the next two to three years, that may allow a firm conclusion to guide decision-making, then these technologies are tracked and a status update conducted at an interval of approximately two years to update the evidence base. When substantial clinical evidence emerges, the original reports will be updated and presented to MTAC for review.

7.2.3. Do not adopt

Health technologies not recommended for adoption generally refer to technologies with major safety concerns, or low-value technologies with unproven benefits over their comparator. It also includes technologies with significant implementation issues or that are markedly more costly than current standard of care. This recommendation is time-bound and is generally intended to guide adoption over a three to four year period, after which re-assessment may be conducted if deemed appropriate based on new evidence. The reassessment may also be conducted earlier if requested by a stakeholder.

8. Dissemination

The HS assessment reports with MTAC's recommendation on adoption are disseminated to policy makers, clinicians and healthcare administrators. These reports serve to:

- Provide advance notice for beneficial health technologies that received a positive recommendation on their adoption into 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 adoption of the technology, if locally available.
- Provide advance warning for low value health technologies that received a negative recommendation on their adoption before they enter into the local healthcare system.

The HS reports are also made publicly available on the ACE website: https://www.ace-hta.gov.sg/healthcare-professionals/ace-horizon-scanning. Similarly, other HS products will be disseminated to relevant stakeholders for information.

References

Wong WQ, Lin L, Ju H, Ng K. Towards greater impact in health technology assessment: horizon scanning for new and emerging technologies in Singapore. *Int J Technol Assess Health Care*. 2020 Jun 22:1-7. doi: 10.1017/S0266462320000343

EuroScan International Network, A toolkit for the identification and assessment of new and emerging health technologies, 2014, EuroScan International Network: Birmingham.

Annex A: Industry notification of pipeline medical technologies

As part of ACE's horizon scanning (HS) identification process, companies are invited to share their regulatory pipeline for medical technologies that are intended to be introduced into Singapore. This enables the healthcare system to be privy to incoming medical technologies anticipated to enter the local market for the purpose of early resource planning.

While not mandatory, companies who participate in the industry notification process provide early visibility of their technologies to MOH. This may be used to assist in the early planning and, if appropriate, their early adoption into the local public healthcare institutions. There are no immediate funding implications resulting from HS assessment, if any, of the submitted technologies.

Scope of medical technologies

The scope of medical technologies includes:

 Medical devices, diagnostics, services, procedures or medical-related digital health technologies (e.g. mobile apps, online tools, artificial intelligence software) intended to be introduced locally or have been submitted to the Health Sciences Authority (HSA) for regulatory approval

The following medical technologies are <u>excluded</u> from the scope of submission:

HSA approved medical technologies

Submission details

The annual submission window is open from 1st May to 31st May each year, both dates inclusive. Announcement will be made on ACE's website (https://www.ace-hta.gov.sg) one week prior to the submission window. Companies may share their pipeline technologies with ACE through the notification form and all submissions should be made to the ACE's HS team at ACE_HS@moh.gov.sg within the submission window. All submitted information will be treated as confidential.

Companies who have questions may write to the ACE's HS team at ACE HS@moh.gov.sg.

Annex B: Considerations when ranking filtered technologies

Key	Ranking				
prioritisation criteria	High	Moderate	Low		
Disease burden	 Large target population, or debilitating disease with poor prognosis Major limitations with standard-of-care 	 Moderate target population, or disease with less than favourable prognosis Some limitations with standard-of-care 	 Low target population, or large population with favourable prognosis Efficient standard- of-care 		
Benefit	 Low/no safety issues Evidence of significant benefits to patients and/or healthcare system Strong potential to bring healthcare savings 	 Some safety issues Evidence of some benefits to patients and/or healthcare system Some potential to bring healthcare savings 	 Significant safety issues Unclear benefits to patients and/or healthcare system Unlikely to bring healthcare savings 		
Organisational impact	Major organisational changes required	Some level of organisational changes required	Technology can be easily adopted		
Cost	 High cost, or significantly higher cost over standard care 	Considerably higher cost over standard care	Low cost, or unclear cost information		

Note: The rankings provided are intended as a guide and should be adapted to specific contextual considerations.

