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Health Technology Reassessment: An Overview of Canadian and International Processes

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Summary

Health technology reassessment (HTR) is defined as “a structured, evidence-based assessment of the clinical, social, ethical, and economic effects of a technology, currently used in the health care system, to inform the optimal use of that technology in comparison with alternatives.” Health technology assessment (HTA) agencies need to prepare for this emerging field. This Environmental Scan searched for information on HTR processes that have been developed or are being developed by Canadian HTA agencies as well as by eight international HTA agencies. Countries were selected for this investigation largely because of commonalities with the Canadian context. Out of the nine countries (Table 2) that were included in this Environmental Scan, some form of established process to support HTR was identified in four, i.e., UK (NICE); France (HAS), Australia (PBAC and MSAC) and Spain (OSTEBA and AVALIA-T). From these four, only HAS in France conducts a regular review of publicly funded technologies for a potential HTR. HTR-related reviews in the other three countries (UK, Australia, and Spain) take place only when requested by authorities. Processes related to topic identification or prioritization, were identified in all four countries. There was a general lack of details available in the public domain regarding the research process for these HTR related reviews. Of note, for UK, no HTR processes were identified for SMC and SHTG in Scotland. With respect to the other five countries, a formal framework for HTR was also not identified at CADTH (Canada), INESSS (Canada), ICER (US), AHRQ (US), G-BA (Germany), PHARMAC (New Zealand) and FIMEA (Finland). However, in Canada, an example of ad hoc HTR type of review was identified in the form of an Optimal Use project on Self-Monitoring of Blood Glucose (SMBG) completed in 2010 by CADTH. Further, a pilot project to identify and prioritize technologies for HTR was recently conducted in British Columbia.

Context

Health technology reassessment (HTR) is defined as “a structured, evidence-based assessment of the clinical, social, ethical, and economic effects of a technology, currently used in the health care system, to inform the optimal use of that technology in comparison with alternatives.”¹⁻⁴

The goal of both health technology assessment (HTA) and HTR is to ensure the “optimal use” of health technologies; “optimal” referring to the proposition of value for money of technologies. However, HTA and HTR are considered to be two distinct fields.⁵ HTA is related to technology adoption, whereas HTR is an ongoing policy-making process to inform technology use throughout its life cycle.^{4,5} Hence, HTR is concerned with technologies currently in use, and in particular, their scope of use.^{1,5} While HTR is generally based on principles and methods of HTA, the methodology also has to include the perspective of diverse users and recipients to account for the reality that the technologies being assessed are in current use.⁵

The goal of HTR is “to improve patient care and system efficiency through a reallocation of resources away from low-value care toward interventions and technologies of a higher value.”¹ Experts emphasize that the goals of HTR to optimize the value of care and increase appropriateness is contingent on a holistic process that includes collaboration with diverse stakeholders. HTR is distinct from concepts such as disinvestment, de-adoption and de-implementation (Table 1); (although these may be the results of a HTR).^{1,4}

Table 1: Definitions of Concepts Different From HTR¹

Disinvestment	The process of completely or partially withdrawing health care resources from currently funded areas that provide little benefit for their cost. Disinvestment can lead to full or partial withdrawal of a technology, contractual variation, restriction, or substitution and employs financial disincentives.
De-implementation	The process where the use of low-value care is reduced or stopped on a structural basis in a planned process that uses a set of activities, which can include financial disincentives, but also uses other activities such as data feedback, education, and system interventions.
De-adoption	The discontinuation or rejection of a clinical practice after it was previously adopted.

Resource reallocation through HTR is a result of cessation of inefficient or harmful treatments and practices to fund appropriate and new technologies within a fixed budget, rather than rationing or cutting of existing budgets. HTR can result in decreasing, increasing, or maintaining current levels of use, and in rare cases, even completely withdrawing the technology from the system (obsolescence).⁴

HTR is an emerging field, and some international HTA agencies have established or are currently developing processes for HTR. Even in the absence of a formal or standard HTR process, some HTA agencies have conducted ad hoc HTR for some health technologies. This Environmental Scan explores the HTR processes that have been established by national and international HTA agencies.

Objectives

The objective of this Environmental Scan is to identify the processes at national and international HTA agencies (Table 2) to conduct the reassessment of existing or currently funded health technologies, including single and multiple technologies, drugs, and medical devices. The Environmental Scan aims to address the following key question:

- What are the processes at national and international HTA agencies to conduct the reassessment of existing and currently funded health technologies (including single and multiple technologies, drugs, and medical devices) including processes related to:
 - topic selection
 - conduct of research and type of methods used
 - type of resources used, either internal or contracted by the HTA agency, to conduct reassessment projects?

Countries listed in Table 2 were selected largely because of commonalities as compared with the Canadian context, including geography and regulatory HTA or reimbursement processes.

Table 2: National and International Health Technology Assessment Agencies

Country	HTA Agencies
Canada	<ul style="list-style-type: none"> • CADTH: <ul style="list-style-type: none"> ◦ Common Drug Review (CDR) ◦ Pan-Canadian Oncology Drug Review (pCODR) • Institut national d'excellence en santé et en services sociaux (INESSS)
UK	<ul style="list-style-type: none"> • National Institute for Health and Care Excellence (NICE) • Scottish Medicines Consortium (SMC) • Scottish Health Technologies Group (SHTG)
France	<ul style="list-style-type: none"> • Haute Autorité de Santé or French National Authority for Health (HAS)
Germany	<ul style="list-style-type: none"> • Gemeinsamer Bundesausschuss or Federal Joint Committee (G-BA)
Australia	<ul style="list-style-type: none"> • Pharmaceutical Benefits Advisory Committee (PBAC)
New Zealand	<ul style="list-style-type: none"> • Pharmaceutical Management Agency (PHARMAC)
US	<ul style="list-style-type: none"> • Institute for Clinical and Economic Review (ICER) • Agency for Healthcare Research and Quality (AHRQ)
Spain	<ul style="list-style-type: none"> • Galician Agency for Health Technology Assessment (AVALIA-T) • Basque Office for Health Technology Assessment (OSTEBA)
Finland	<ul style="list-style-type: none"> • Finnish Medicines Agency (FIMEA)

Methods

The Environmental Scan is based on limited literature search, as well as consultation with key informants at national and international HTA agencies. Key informants at the HTA agencies were consulted to identify relevant publications or documents; the latter may not necessarily have been available in the public domain. Relevant published literature was identified primarily through a targeted MEDLINE search; Grey literature was retrieved through a focused Internet search. The literature search was limited to English-language documents published between January 01 2008, and October 16 2018. Only citations retrieved before December 1, 2018 were incorporated into the report.

Findings

The Environmental Scan presents information on any existing HTR process at the national and international HTA agencies described in Table 2. The scan is focused on HTR that are conducted to inform formulary and reimbursement policies. Reports, guidelines, and evaluation frameworks from HTA organizations located in the countries listed in Table 2 were reviewed to gather the relevant information.

The following sections present the information on the processes at national and international HTA agencies to conduct the reassessment of existing and currently funded health technologies. Results are grouped by countries where these agencies are located.

Canada

A formal framework for HTR was not identified at Institut national d'excellence en santé et en services sociaux (INESSS). A formal framework for HTR was also not identified at CADTH, neither in the Common Drug Review (CDR) nor the pan-Canadian Oncology Drug Review (pCODR) programs.

Example of ad hoc HTR

An example of an ad hoc HTR project was identified in the library of reports of CADTH. Indeed, CADTH's Self-Monitoring of Blood Glucose (SMBG) Optimal Use project, completed in 2010, could be considered as an example of HTR as it led to limiting the use of SMBG in low-value clinical situations, e.g., regular blood glucose testing in patients with type 2 diabetes treated only with oral medications.⁶ The following process was followed for the SMBG Optimal Use project.

Topic Selection: The topic was selected based on the recommendation of CADTH's Canadian Optimal Medication Prescribing and Utilization Service (COMPUS) Advisory Committee (CAC) to review the clinical and economic evidence relating to the optimal prescribing and use of SMBG.⁷

Research Process: The research process included clinical evaluation (systematic reviews); economic evaluation (cost-effectiveness, cost-utility, and cost consequence analyses); current utilization analysis; current practice analysis; identification of practice and knowledge gaps; and identification of barriers to optimal use.⁷

Output: The clinical and economic evaluations were used by the COMPUS Expert Review Committee (CERC) to generate recommendations for the optimal prescribing and use of SMBG. The recommendations were developed to inform formulary and reimbursement policies, as well as clinical practice. Several knowledge mobilization efforts including development of implementation support tools were made to ensure the appropriate implementation of the recommendation.^{6,8}

Pilot program in British Columbia (prioritization process for HTR)

A model for prioritizing technologies for HTR was piloted by the British Columbia Ministry of Health's Health Technology Assessment Committee (HTAC). It should be noted that this model only represents the initial step of the HTR process, which is prioritization; it is nonetheless a model of interest. HTAC conducts assessments of new non-drug health technologies (e.g., devices, diagnostics, and/or medical procedures) and the reassessment of technologies already used within the health system.⁹

Based on this model, a five-step methodological process was developed. First, a list of low-value technologies was compiled based on NICE (UK) "Do Not Do" recommendations (please see Section below on UK for more details), low-value technologies in the Australian Medical Benefits Schedule (MBS), and Choosing Wisely Canada (note: Choosing Wisely Canada is a list-making initiative of low-value clinical practices based on expert consensus exercises related to systematic and non-systematic reviews of the literature). This list included a total of 1,350 low-value technology recommendations. Secondly, the low-value recommendations were reviewed and coded using the appropriate coding systems for the administrative health data. Based on the review, 1,276 low-value technology recommendations were excluded based on factors such as language or qualifiers not identified in administrative data (i.e., clinically nuanced recommendations); technologies not publicly funded within the British Columbia health system (e.g., complementary and alternative treatments); and as they were drug technologies (as drug coverage falls outside the scope of HTAC). The third and fourth steps involved querying administrative data to examine frequencies of use and costs of 74 included low-value technologies. Among these, 47 low-value technologies were observed in at least one of the administrative health databases (i.e., any frequency and cost) between April 1, 2010 and March 31, 2015. This information was used to rank potential candidates for HTR based on high annual budgetary impact; that is, costs greater than \$1 million in a fiscal year. Based on this assessment, a total of nine potential candidate technologies were prioritized for HTR; six were used in-hospital (that is, identified in the hospital database) out of which

three were concomitantly identified within the physician claims data. The three remaining technologies were identified only in the physicians and laboratory claims data. As the fifth step, clinical experts reviewed the ranked technologies before broad dissemination and stakeholder action.⁹

Following this same model, a draft list of seven prioritized candidate health technologies was developed for potential HTR within the context of Alberta Health. (Dr. Fiona Clement, Director, Health Technology Assessment Unit, University of Calgary, Calgary, AB: personal communication, 2018 Dec 20).

United Kingdom

NICE

The UK's National Institute for Health and Care Excellence (NICE) has three established processes to support HTR; technology appraisal, recommendation reminders, and commissioning guidelines.^{2,10}

Topic Selection or Prioritization Process: NICE applies the same health technology appraisal criteria for both HTA and HTR; additional criteria may also be considered. These include claimed additional benefit to patients, claimed health care system benefits, patient population, disease impact, cost considerations, and sustainability. Further, criteria for HTA prioritization include the consideration of budget impact, existing alternatives, improved patient safety, vulnerable populations, small benefit, and close risk/benefit ratio.¹⁰ NICE also developed the Cochrane Quality and Productivity topics; these are based on Cochrane reviews to identify low-value practices that can be reduced (or stopped) to allocated resources for more effective practices. In addition, NICE has clinical practice guidelines to identify candidates for disinvestment.^{3,10}

Research Process: Similar to its HTA projects for investment, NICE applies a rigorous approach to evidence, meaning reliable data from high-quality studies are required to make any decision to reduce or eliminate funding for specific technologies, thus to conduct HTR projects.¹⁰ The Technology Appraisal Committee (TAC) makes decisions on disinvestment. Committee members include members from the National Health Service (NHS), patient and caregiver organizations, academia, as well as pharmaceutical and medical device industries. Commentator organizations include the manufacturers of comparator technologies, National Health Service Quality Improvement Scotland, the relevant National Collaborating Centre (a group commissioned by NICE to develop clinical guidelines in areas such as cancer and mental health), and research groups working in the area.¹⁰

During the process of guidance development, NICE independent advisory bodies often make "Do Not Do" recommendations; that is, they identify low-value NHS clinical practices that should be discontinued completely or should not be used routinely.³

Output: The recommendation reminders are released monthly and summarize any new recommendations for the use of an existing technology. The "Do Not Do" list, recommendation reminders and Commissioners' Guidance list all of the health technologies that NICE suggests avoiding or using sparingly.^{2,3,10}

The "Do Not Do" list has been in effect since 2007, and is available in the form of a searchable database. Each "Do Not Do" recommendation includes additional information regarding the intervention, health topic, the guidance it is based on, any related "Do Not Do" recommendation; as well as the health care setting that describes the main clinical environments in which the intervention or investigation may be initiated.³

The commissioning guides are practical guidelines that help NHS commissioners carry-out NICE recommendations; and also include cost models which will allow commissioners to calculate savings and costs associated with a change in service.² NICE's HTR activities are considered to be "passive" HTR, that is, it results in recommendation and guidance that clinicians may choose to follow.^{2,10,11}

SMC and SHTG

A standard framework for HTR was not identified at the Scottish Medicines Consortium (SMC) and the Scottish Health Technologies Group (SHTG). SMC has recently introduced a mechanism to fund a technology on an interim basis for medicines that have received conditional marketing authorizations by the European Medicines Agency (EMA); that is, a medicine can be accepted for use subject to ongoing evaluation and reassessment once further evidence is available that has been requested by the medicines regulatory authority the EMA.¹² However, this process is beyond the scope of this Environmental Scan, as the technology is not yet fully accepted (funded), and can be considered to be still in the early stages of its life cycle (that is, technology adoption stage). SHTG is currently in the process of redefining its range of HTA procedures and products. The new approach will be published online in early 2019, and will take into consideration opportunities for reassessment of health technologies. (Edward Clifton, Scottish Health Technologies Group – Unit Head, Healthcare Improvement Scotland, Glasgow: personal communication, 2018 Dec 18).

France

The Transparency Committee (TC) at the Haute Autorité de Santé (HAS), or French National Authority for Health, reassesses the clinical benefit ("service médical rendu" [SMR]) and/or the clinical added benefit (amélioration du service médical rendu [ASMR]) of the product in the following two situations described below (Dr. Anne d'Andon, Chef du service Évaluation des Médicaments, Haute Autorité de Santé, Paris: personal communication, 2018 Dec 18).

Regular HTR of medicinal products available in the pharmacy (outpatient)

Topic Selection Process: France has a mandatory requirement (by law) to reassess the medicinal products listed on the "national health insurance," that is, medicines available in the pharmacy (outpatient); every five years after the date of the first inscription of the medicine in the list (Dr. Anne d'Andon, Chef du service Évaluation des Médicaments, Haute Autorité de Santé, Paris: personal communication, 2018 Dec 18).

Research Process: Every five years, the TC of HAS assesses the new clinical data available on the medicine; including efficacy and safety data: new clinical trials, observational studies, pharmacovigilance data, safety concerns from EMA such as new assessment by the Pharmacovigilance Risk Assessment Committee (PRAC), the Agence nationale de sécurité du médicament et des produits de santé (ANSM), or the US FDA. The TC also assesses any modifications since the listing of the medicine, related to the place of the medicine in the therapeutic strategy. For example, if a recently assessed new medicine has been granted a high clinical added value as compared with an older one, the new medicine will be recommended as a first-line treatment instead of the old one (Dr. Anne d'Andon, Chef du service Évaluation des Médicaments, Haute Autorité de Santé, Paris: personal communication, 2018 Dec 18).

As such, every five years, the TC assesses the clinical benefit (SMR), which is a recommendation for reimbursement and according to its level, impact the reimbursement rate. (Dr. Anne d'Andon, Chef du service Évaluation des Médicaments, Haute Autorité de

Santé, Paris: personal communication, 2018 Dec 18). Of note, there are four reimbursement rates (i.e., one is “not included in the positive list”; the three other rates are 15%, 30%, 65%). These are determined based on the actual benefit level assigned to the drug (i.e., insufficient, mild, moderate, important).¹³ Accordingly, based on the reassessment, the SMR can be modified every five years. The key objective of this reassessment approach is to determine whether a medicine should still be reimbursed or not. Companies have to submit to HAS a file containing the new clinical data for the reassessment. If major concerns are not identified, the file follows a simplified procedure in order to quickly produce an opinion for the renewal of the reimbursement. For a total of 834 opinions of the TC in 2017, 209 were for the five-year reassessment of the inscription on the list. For 206 among those 209 opinions, the opinion was positive for the renewal of the reimbursement of the product of the same conditions (i.e., the same rate of reimbursement) (Dr. Anne d’Andon, Chef du service Évaluation des Médicaments, Haute Autorité de Santé, Paris: personal communication, 2018 Dec 18).

Ad hoc reassessment requested by the ministry of health, pharmaceutical company, or by HAS.

Topic Selection Process: The TC may reassess every medicinal product at the request of the ministry of health, the pharmaceutical company, or by its (HAS) own volition. The scope of these reassessments is quite large and can concern the SMR, the ASMR (which has an impact on the price of the product) but also the target population, the comparators, and the impact on public health. This reassessment can take place at any moment in the life cycle of the medicine. If the reassessment is conducted by request of the ministry of health or by HAS itself, it can concern only one product or several products (with the same indication and/or belonging to the same therapeutic class). These reassessments have to be justified by new substantial information (Dr. Anne d’Andon, Chef du service Évaluation des Médicaments, Haute Autorité de Santé, Paris: personal communication, 2018 Dec 18).

Given that medicinal products only available at hospital pharmacies (that is, included only in the “hospital list”) do not fall under the mandatory five-year reassessment program (described above), they may instead be reassessed through the ad hoc reassessment mechanism. For example, the ministry of health has requested the reassessment of approximately 30 drugs on the Diagnostic-Related Group (DRG) list to determine whether they should still pay more than the hospital flat rate (Dr. Anne d’Andon, Chef du service Évaluation des Médicaments, Haute Autorité de Santé, Paris: personal communication, 2018 Dec 18).

The TC can also decide to reassess one or several medicines, in case of new substantial clinical data becoming available (for example safety data, new phase III efficacy data, or modification to the therapeutic strategy) (Dr. Anne d’Andon, Chef du service Évaluation des Médicaments, Haute Autorité de Santé, Paris: personal communication, 2018 Dec 18).

In addition, the company can request the TC for a reassessment of one of their products to obtain a better level of reimbursement (that is, at a better clinical benefit level) or a better ASMR (which also impacts the price of the product), based on new data available (Dr. Anne d’Andon, Chef du service Évaluation des Médicaments, Haute Autorité de Santé, Paris: personal communication, 2018 Dec 18).

Research Process: In the context of reassessment on the request of the ministry of health or by the pharmaceutical company or of the TC itself, the company has to submit to HAS a file containing all the clinical data with a justification of the SMR and/or the ASMR, depending of the request. The file follows the same process as a new request for an inscription on the list(s) (Dr. Anne d’Andon, Chef du service Évaluation des Médicaments, Haute Autorité de Santé, Paris: personal communication, 2018 Dec 18).

The final step is the diffusion of an opinion containing the reassessment of the SMR and/or the ASMR (depending of the original request) for the concerned product(s) (Dr. Anne d'Andon, Chef du service Évaluation des Médicaments, Haute Autorité de Santé, Paris: personal communication, 2018 Dec 18).

On a total of 834 opinions of the TC in 2017, 29 concerned a reassessment of the SMR and/or the ASMR (depending of the request). Among these, 11 were requested by a pharmaceutical company and 18 were requested by the ministry of health or HAS, itself) (Dr. Anne d'Andon, Chef du service Évaluation des Médicaments, Haute Autorité de Santé, Paris: personal communication, 2018 Dec 18).

Germany

A formal framework for HTR was not identified at the Gemeinsamer Bundesausschuss or Federal Joint Committee (G-BA). In general, G-BA is entitled to reassess established technologies if necessary. G-BA may conduct reassessments to modify the indication when new evidence becomes available; mostly for drugs, and occasionally for medical devices too; however, this rarely happens. G-BA has in the past suspended assessment processes for new or controversial technologies, and has made decision only after new evidence became available (PD. Dr. med. Matthais Perleth, MPH, Federal Joint Committee (G-BA), Berlin: personal communication, 2018 Dec 18). However, such a 'suspended review' would not fall under the scope of HTR, as the technology is not yet currently fully funded.

Australia

No formal process for HTR was identified in Australia. However, there are examples of ad hoc "delisting" reviews, utilization reviews and systematic post-market approach to monitor medicines throughout its life cycle; all of which can be considered to be a form of the HTR process.¹⁴⁻¹⁶

Examples of ad hoc delisting reviews.

PBAC

In 2015, upon request from the minister, PBAC provided advice regarding delisting specific drugs that are listed on the Pharmaceutical Benefit Scheme (PBS), which are also available for over-the-counter purchase. This process involved consultation with diverse stakeholders such as physicians and consumers. Based on the PBAC review, more than 17 over-the-counter medicines were reported to be delisted from PBS.^{14,17}

Medical Services Advisory Committee

Along with conducting an appraisal of, and providing recommendation on new medical services proposed for public funding, the Medical Services Advisory Committee (MSAC) may also consider amendments and reviews of existing services funded on the Medical Benefits Schedule (MBS) or other programs (for example, blood products or screening programs). Of note, MSAC is an independent non-statutory committee established by the Australian Government Minister for Health. MSAC appraises new medical services proposed for public funding, and provides advice to government on whether a new medical service should be publicly funded (and if so, its circumstances) on an assessment of its comparative safety, clinical effectiveness, cost-effectiveness, and total cost, using the best available evidence.¹⁸ These reviews and amendments are referred to MSAC by the minister for health or under Australian Health Ministers' Advisory Council arrangements.¹⁴ No separate method for evaluating existing medical services (than the method used for the appraisal of new medical services) were identified; and no formal ongoing review of medical services once listed, were identified.

Review of PBS listings

The PBAC and the minister can request reviews of medicine use, cost-effectiveness, and other aspects of quality use of medicines of PBS-listed medicines.¹⁹ These reviews include post-market reviews, cost-effectiveness reviews, and reviews of the utilization of specific medicines or groups of medicines.

Utilization Reviews

The Drug Utilization Sub-Committee (DUSC) reviews medicines that have been listed in the PBS for 24 months. DUSC selects individual medicines or groups of medicines to be reviewed as well as undertakes ad hoc reviews as requested by the PBAC or the minister. Both sponsors and consumers are engaged in the review process, and are allowed to provide their comments regarding the review; these are submitted as “stakeholder responses.” The report on the utilization of the medicines (DUSC report), stakeholder responses and DUSC minutes are then referred by DUSC to the PBAC for consideration. DUSC may also provide specific advice for PBAC to consider. Based on the DUSC report, PBAC can make a number of different recommendations to the minister, including revising the restriction wording; revising the category of the listing or type of approved prescriber; requesting DUSC to revise the utilization review report, as specified by the PBAC; requesting further consultation; or advising the minister for health that a post-market review is warranted. DUSC reports are published, and are available for public access.¹⁶

Post-Market Review

Post-market reviews are aimed to improve patient safety, and avoid preventable wastage or inappropriate prescribing, among other concerns. Post-market reviews can be initiated at any time, and proceed only after ministerial approval. The main drivers of post-market reviews are recommendations by the PBAC or issues identified through DUSC’s routine monitoring processes (as discussed above). These reviews are initiated when there are concerns related to the quality use of a medicine, cost-effectiveness, clinical effectiveness, higher than predicted utilization, and/or international differences.

A review takes approximately 12 months, but the time frame may vary depending on the complexity of the review. After the ministerial approval of the review, PBAC sets the Terms of Reference for the review, which also has to be approved by the minister. The evidence evaluation may include a literature review, utilization analysis, economic analysis and more. Stakeholders such as consumers organizations, sponsors of the medicine, and other relevant organizations can also participate during the review process; that is, during public consultation on the draft Terms of Reference, the public submission process; a stakeholder forum; and by providing comments on the draft report. A Reference Group is formed for each post-market review to provide independent, expert advice on specific clinical and consumer issues; including advice to PBAC on issues associated with use of the medicine(s) of interest, the medicine(s) place in clinical practice, sources of evidence and data analyses that should be used, the quality and implications of gathered evidence, and issues raised by stakeholder. Based on the review, PBAC may make a range of recommendations including taking no action; making changes to PBS restrictions; taking measures to improve cost-effective use; updating clinical guidelines; and providing education for health professionals or consumers to improve quality use of medicines. PBS related recommendation (such as listing and pricing) is implemented as per PBAC standard process. A complete framework for the post-market review process and information regarding current and completed post-market reviews is available on the PBS website.^{20,21}

New Zealand

A formal framework for HTR was not identified at the Pharmaceutical Management Agency (PHARMAC).

US

A formal framework for HTR was not identified at the Institute for Clinical and Economic Review (ICER) or the Agency for Healthcare Research and Quality (AHRQ).

Spain

The Galician Agency for Health Technology Assessment (AVALIA-T) and the Basque Office for Health Technology Assessment (OSTEBA) have developed guidelines and tools to support HTR in Spain at the regional level. Spain also has regulatory support for HTR at the national level, such as the Royal Decree 1030 which stipulates that HTR should take place when there is evidence of a lack of efficacy, effectiveness, or efficiency or unfavourable risk-benefit; the technology has lost health care interest due to a technological or scientific development or the technology no longer meets current legislation.^{2,10}

In 2010, OSTEBA developed the Guideline for Not Funding Technology (GuNFT) to guide its HTR process. The model divides HTR into the following seven phases: "a) identification, b) validation of applications, c) prioritization (if necessary), d) assessment of applications, e) decision-making, f) development of an action plan and g) diffusion of the decision."²²

Topic Selection and Prioritization: The GuNFT outlines the following criteria that should be met for a technology to undergo HTR: the technology should be used in the centre (hospital, health system) where the HTR is conducted, the technology status is known to the applicant, alternative treatment options are available, and disinvestment does not lead to absence of care. The guideline notes that a prioritization system needs to be established when a high number of technologies need to be assessed. GuNFT refers to the prioritization criteria established by other researchers and organizations. One example is the prioritization criteria set by the guideline on the identification, prioritizing, and evaluation of obsolete technologies. These criteria, developed by AVALIA-T, are related to the population and users of the technology, the balance between risks and benefits of the technology, and the costs, organizational aspects as well as other implications linked to the technologies to be prioritized.²²

Research Process: The guideline emphasizes the need for relevant, high-quality scientific studies to aid the decision-making process. The following three fundamental criteria are considered when making the assessment: the centre's health care services package and strategic objectives of the centre, the balance between the advantages and disadvantages of adopting the proposal, and, the ability of the centre or health care setting to assume the proposal. The guideline provides a detailed questionnaire to facilitate the assessment.²²

Output: The results of the HTR process include the possibilities of disinvestment as per the terms proposed, disinvestment not approved, but could take place in future, and disinvestment is not possible. Following the decision, an implementation strategy is developed. This strategy includes informing relevant stakeholders, and monitoring the impact of disinvestment and that of the technology that was implemented as replacement.²²

Finland

A formal framework for HTR was not identified at the Finnish Medicines Agency (FIMEA).

Limitations

The method used in this Environmental Scan was pragmatic. As such, there may be some limitations to this report. In particular, findings are based on a limited literature search of publicly available information as well as targeted personal communications to attempt to obtain further information from international HTA agencies. As it was not possible to establish contacts with all international HTA agencies, and that some of these agencies may not post all of their processes online, some relevant information may not have been captured. On the other hand, it was possible to obtain personal communication from several contacts to support statements on unpublished information. As such, this Environmental Scan may provide information that is unavailable in other similar reports.

Conclusion

HTR is an emerging field; some international HTA agencies have nonetheless established processes to support HTR. Out of the nine countries that were included in this Environmental Scan, some form of established process to support HTR was identified in four, i.e., UK (NICE); France (HAS), Australia (PBAC and MSAC), and Spain (OSTEBA and AVALIA-T). From these four, only HAS in France conducts a regular review of publicly funded technologies to form the basis for a potential HTR. HTR related reviews in the other three countries (i.e., UK, Australia, and Spain) take place only when requested by authorities. Processes related to topic identification, or prioritization, were identified in all four countries. There was a general lack of details available in the public domain regarding the research process for these HTR related reviews. Of note, for UK, no HTR processes were identified for SMC and SHTG in Scotland.

With respect to the other five countries included in this Environmental Scan, a formal framework for HTR was not identified at CADTH (Canada), INESSS (Canada), ICER (US), AHRQ (US), G-BA (Germany), PHARMAC (New Zealand) and FIMEA (Finland). However, in Canada, an example of ad hoc HTR type of review was identified in the form of an Optimal Use project on SMBG completed in 2010 by CADTH. Further, a pilot project to identify and prioritize technologies for HTR was recently conducted in British Columbia. The same was proposed in another Canadian province, Alberta. In the absence of a formal HTR process, key informants from international HTA agencies identified other related processes such as “suspended reviews” (G-BA) and “interim funding decisions” (SMC). However, for the purpose of this Environmental Scan, these processes are not considered HTR as decisions are related to technology adoption as opposed to the reassessment of existing and currently funded technologies.

References

1. Esmail R, Hanson H, Holroyd-Leduc J, Niven DJ, Clement F. Knowledge translation and health technology reassessment: identifying synergy. *BMC Health Serv Res.* 2018;18(1):674.
2. Leggett L, Noseworthy TW, Zarrabi M, Lorenzetti D, Sutherland LR, Clement FM. Health technology reassessment of non-drug technologies: current practices. *Int J Technol Assess Health Care.* 2012;28(3):220-227.
3. MacKean G, Noseworthy T, Elshaug AG, et al. Health technology reassessment: the art of the possible. *Int J Technol Assess Health Care.* 2013;29(4):418-423.
4. Soril LJ, MacKean G, Noseworthy TW, Leggett LE, Clement FM. Achieving optimal technology use: A proposed model for health technology reassessment. *SAGE Open Med.* 2017;5:2050312117704861.
5. Noseworthy T, Clement F. Health technology reassessment: scope, methodology, & language. *Int J Technol Assess Health Care.* 2012;28(3):201-202.
6. Self-monitoring of blood glucose. Ottawa: CADTH; 2010: <https://cadth.ca/self-monitoring-blood-glucose>. Accessed 2018 Nov 10.
7. Optimal self-monitoring of blood glucose Ottawa: CADTH; 2009: <https://cadth.ca/sites/default/files/pdf/C1109-Project-in-Brief-final-e.pdf>. Accessed 2018 Nov 10.
8. Systematic review of use of blood glucose test strips for the management of diabetes mellitus Ottawa: CADTH; 2009: https://www.cadth.ca/media/pdf/BGTS_SR_Report_of_Clinical_Outcomes.pdf. Accessed 2018 Nov 10.
9. Soril LJJ, Seixas BV, Mitton C, Bryan S, Clement FM. Moving low value care lists into action: prioritizing candidate health technologies for reassessment using administrative data. *BMC Health Serv Res.* 2018;18(1):640.
10. Seo HJ, Park JJ, Lee SH. A systematic review on current status of health technology reassessment: insights for South Korea. *Health Res Policy Syst.* 2016;14(1):82.
11. Mayer J, Nachtnebel A. Disinvesting from Ineffective Technologies: Lessons Learned from Current Programs. *Int J Technol Assess Health Care.* 2015;31(6):355-362.
12. Interim acceptance decision option. Glasgow: Scottish Medicines Consortium; 2018: <https://www.scottishmedicines.org.uk/how-we-decide/interim-acceptance-decision-option/>. Accessed 2018 Nov 11.
13. Pricing & reimbursement of drugs and HTA policies in France. Saint-Denis (FR): National Authority for Health (Haute autorite de sante); 2014: https://www.has-sante.fr/portail/upload/docs/application/pdf/2014-03/pricing_reimbursement_of_drugs_and_hta_policies_in_france.pdf. Accessed 2018 Nov 15.
14. McCreanor V. Active disinvestment in low-value care in Australia will improve patient outcomes and reduce waste Deakon ACT: Australian Healthcare and Hospitals Association (AHHA). Deeble Institute; 2017: https://ahha.asn.au/system/files/docs/publications/171004_issues_brief_no_23_disinvestment_2.pdf. Accessed 2018 Nov 5.
15. Post-market reviews of pharmaceutical benefits subsidised medicines. Canberra: Australian Pharmaceutical Benefits Scheme; 2015: <http://www.pbs.gov.au/info/reviews/subsidised-medicines-reviews>. Accessed 2018 Nov 15.
16. Drug utilisation sub-committee review (Section 9.1). Canberra: Australian Pharmaceutical Benefits Scheme: <http://www.pbs.gov.au/info/industry/listing/procedure-guidance/9-review-pbs-listings/9-1-dusc-review>. Accessed 2018 Nov 15.
17. Conifer D. Government to remove paracetamol, aspirin, other common drugs from Pharmaceutical Benefits Scheme. 2015; <https://www.abc.net.au/news/2015-11-03/government-to-scrap-paracetamol-from-pbs/6907222>. Accessed 2018 Nov 11.
18. MSAC Terms of Reference. Canberra: Australian Medical Services Advisory Committee; 2016: <http://www.msac.gov.au/internet/msac/publishing.nsf/Content/msac-terms-of-reference>. Accessed 2018 Nov 10.
19. Review of PBS listings (Section 9). Canberra: Australian Pharmaceutical Benefits Scheme: <http://www.pbs.gov.au/info/industry/listing/procedure-guidance/9-review-pbs-listings/9-review-of-pbs-listings>. Accessed 2018 Nov 15.
20. Pharmaceutical Benefits Scheme post-market reviews : Stakeholder information. Canberra: Australian Pharmaceutical Benefits Scheme: <http://www.pbs.gov.au/reviews/subsidised-medicines-reviews-files/post-market-review-framework-10-2014.pdf>. Accessed November 10, 2018.
21. Reviews. Canberra: Australian Pharmaceutical Benefits Scheme; 2018: <http://www.pbs.gov.au/info/browse/reviews>. Accessed 2018 Nov 10.
22. Ibarra-Goyen-Roteta N, Gutiérrez-Ibarluzea I, Asua J. Report on the development of the GuNFT Guideline. Guideline for not funding existing health technologies in health care systems. Quality plan for the NHS of the MHSP. Vitoria-Gasteiz (ES): Basque Office for Health Technology Assessment (Osteba); 2009: https://www.osakidetza.euskadi.eus/contenidos/informacion/2010_osteba_publicacion/es_def/adjuntos/e_10_11_report_GuNFT.pdf. Accessed 2018 Nov 12.