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clinical evidence for the real world

Systematic literature review on international approaches to post-market reviews and technology re-assessment

Final Report

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Authored by Samara Lewis, Sue Campbell & Sarah Norris

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Abbreviations and acronyms

ACE	Agency for Clinical Effectiveness (Singapore)
ACG	Appropriate Care Guide (ACE, Singapore)
ACSQHC	Australian Commission on Safety and Quality in Health Care
AHRQ	Agency for Healthcare Research and Quality
AIFA	Agenzia Italiana del Farmac (Italy)
ANSM	Agence nationale de sécurité du médicament et des produits de santé (France)
ASMR	Amélioration du service médical rendu (HAS, France)
AVALIA-T	Galician Agency for Health Technology Assessment (Spain)
BIA	Budget Impact Analysis
CADTH	Canadian Agency for Drugs and Technologies in Health
CCATES	Collaborating Centre for Technology Assessment and Excellence in Health
CCG	Clinical Commissioning Group (England)
CCOHTA	Canadian Coordinating Office of Health Technology Assessment
CDR	Common Drug Review
CIS	Critical interpretive synthesis
Conitec	National Committee for Health Technology Incorporation (Brazil)
CUA	Cost-utility analysis
DERP	Drug Expenditure Rationalization Plan (South Korea)
DH	Department of Health (England)
DoH	Department of Health
DUSC	Drug Utilisation Subcommittee of PBAC
EMA	European Medicines Agency
FDA	Food and Drug Administration
FIMEA	Finnish Medicines Agency
FTA	Fast Track Assessment (NICE, UK)
G-BA	Gemeinsamer Bundesausschuss (Federal Joint Committee Germany)
GuNFT	Guideline for Not Funding Technology (Spain)
HAS	Haute Autorité de Santé (France)
HealthPACT	Health Policy Advisory Committee on Technology
HQC	Health Quality Council (Canada, Saskatchewan)
HQO	Health Quality Ontario (Canada, Ontario)
HSRIC	Horizon Scanning Research and Intelligence Centre (UK)
HTA	Health Technology Assessment
HTAC	Health Technology Assessment Committee
HTAi	Health Technology Assessment International
HTpA	Health Technology Performance Assessment
HTR	Health Technology Re-assessment
HTRG	Health Technology Reference Group
ICER	Incremental cost-effectiveness ratio
ICER	Institute for Clinical and Economic Review (United States)
INAHTA	International Network of Agencies for Health Technology Assessment
INESSS	Institut national d'excellence en santé et services sociaux
IT	Information technology
JBI	Joanna Briggs Institute
KT	Knowledge translation
LBI-HTA	Ludwig Boltzmann Institute for HTA (Austria)
LR	Literature review
MBD	Medicare Benefits Division
MBS	Medicare Benefits Schedule
MBSRTF	MBS Review Taskforce
MCDA	Multi-criteria decision analysis
MoH	Ministry of Health

MRFF	Medical Research Future Fund
MSAC	Medical Services Advisory Committee
MTA	Multiple Technology Appraisal (NICE, UK)
NA	Not applicable
NBA	National Blood Authority
NECA	National Evidence-based healthcare Collaborating Agency (South Korea)
NHMRC	National Health and Medical Research Council
NHS	National Health Service (UK)
NICE	National Institute for Health and Care Excellence (UK)
NIP	National Immunisation Program
NPL	National Product List
NR	Not reported
OECD	Organisation for Economic Co-operation and Development
OHTA	Office of Health Technology Assessment
OSA	Obstructive sleep apnoea
OSTEBA	Basque Office for Health Technology Assessment (Spain)
PAHO	Pan-American Health Organization (PAHO)
PBAC	Pharmaceutical Benefits Advisory Committee
PBMA	Program budgeting and marginal analysis
PBS	Pharmaceutical Benefits Schedule
PCR	Pre-Committee Response
PCT	Primary Care Trust (England)
PHARMAC	Pharmaceutical Management Agency (New Zealand)
PHI	Private Health Insurer
PICo	Policy problem, Intervention, Context
PL	Prostheses List
PLAC	Prostheses List Advisory Committee
PRAC	Pharmacovigilance Risk Assessment Committee (EMA, Europe)
PSCR	Pre-Subcommittee Response
PSD	Public Summary Document
QALY	Quality-adjusted life year
RCT	Randomised controlled trial
RedETS	Red Española de Agencias de Evaluación de Tecnologías Sanitarias y Prestaciones del Sistema Nacional de Salud (Spain)
RWD	Real-world data
RWE	Real-world evidence
SBU	Swedish Council on Technology Assessment in Health Care
SHARE	Sustainability in Health care by Allocating Resources Effectively
SHI	Statutory Health Insurance (France)
SHTG	Scottish Health Technologies Group
SMC	Scottish Medicine Consortium
SMR	Service médical rendu (HAS, France)
SNHS	Spanish National Health Service
SLR	Systematic literature review
SR	Systematic review
STA	Single Technology Assessment (NICE, UK)
SUS	Public health system (Brazil)
TAAD	Technology Assessment and Access Division
TC	Transparency Committee (France)
TLV	Swedish Dental and Pharmaceutical Benefits Agency
UK	United Kingdom
US	United States
WHO	World Health Organization
ZonMW	Netherlands Organisation for Health Research and Development

Glossary

Appropriateness	The proper or correct use of health services, products and resources (Maloney et al. 2017).
Disinvestment	The processes of (partially or completely) withdrawing health resources from existing health care practices, procedures, technologies or pharmaceuticals that are deemed to deliver little or no health gain for their cost, and thus are not efficient health resource allocations (Elshaug et al. 2007).
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 (Esmail et al. 2018).
De-adoption	The discontinuation or rejection of a clinical practice after it was previously adopted (Esmail et al. 2018).
Full HTA	Undertaking a health technology assessment that includes detailed consideration of all of the relevant HTA domains.
Health technology assessment (HTA)	A multidisciplinary field of policy analysis that examines the medical, economic, social and ethical implications of the incremental value, diffusion and use of a medical technology in health care (HTA Glossary, HTAi). In the current report it is used to denote assessments that are used to inform first-time decisions to list or fund a technology or service.
Health technology re-assessment (HTR)	A structured, evidence-based assessment of the clinical, social, ethical, and economic effects of a technology or service currently used in the healthcare system, to inform optimal use of that technology or service in comparison to its alternatives (Noseworthy and Clement 2012).
Health Technology Management	An umbrella term for the range of health technology assessment and re-assessment activities that can inform decisions regarding the introduction, use, refinement of use, and removal of technologies or services from the health system.
HTA domains	The broad aspects that are relevant to the consideration of any health technology or service, including the medical, economic, budgetary, and social and ethical implications associated with the use of a particular technology or service.
High-value care	An intervention in which evidence suggests it confers benefit on patients, or probability of benefit exceeds probable harm, or, more broadly, the added costs of the intervention provide

	proportional added benefits relative to alternatives (Elshaug et al. 2017).
Low-value care	An intervention in which evidence suggests it confers no or very little benefit for patients, or risk of harm exceeds probable benefit, or, more broadly, the added costs of the intervention do not provide proportional added benefits (Scott and Duckett 2015).
Obsolescence	The end of the lifecycle of a technology when it has been superseded by an alternative technology or service (Maloney et al. 2017).
Over-use	Provision of a service that is unlikely to increase the quality or quantity of life, that poses more harm than benefit, or that patients who were fully informed of its potential benefits and harms would not have wanted (Elshaug et al. 2017).
Post-market review	A systematic post-market approach to monitoring medicines, medical services or devices in use to inform decision-making at all levels throughout the cycle (from the registration right through to its use by consumers).
Rapid HTA	Undertaking a health technology assessment that is expedited by placing limits on the type of information included and/or the number of HTA domains considered.
Real-world data (RWD)	Observational or administrative data that provides information on the routine delivery of health care and the health status of the target population (HTA Glossary, HTAi).
Real-world evidence (RWE)	Evidence derived from the analysis of real-world data (HTA Glossary, HTAi).
Right care	Care that is tailored for optimising health and wellbeing by delivering what is needed, wanted, clinically effective, affordable, equitable, and responsible in its use of resources (Elshaug et al. 2017).
Standard HTA methods	Describes the preparation of a health technology assessment (a full or rapid HTA) using internationally accepted methods of critical appraisal, epidemiological analysis and health economic evaluation.
Under-use	Failure to deliver a service that is highly likely to improve the quality or quantity of life, that represents good value for money, and that patients who were fully informed of its potential benefits and harms would have wanted (Elshaug et al. 2017).

Executive Summary

Background

The Commonwealth Department of Health (DoH) commissioned a systematic literature review on international approaches to (post-market) reviews and disinvestment, reframed during scoping to focus on best practice approaches to health technology and service re-assessment.

Ensuring appropriate, affordable use of health technologies and services is a challenge for health systems around the world seeking both fiscal sustainability and high-quality care, or value for money. Health technology re-assessment (HTR) is a structured, evidence-based assessment of the clinical, social, ethical, and economic effects of a technology or service currently used in the healthcare system, to inform optimal use of that technology or service in comparison to its alternatives (Noseworthy and Clement 2012).

Although HTR may lead to 'full' disinvestment (i.e., the withdrawal of all funding for a specific technology or service), the policy outcomes of HTR are typically more nuanced, and may result in increased, decreased, or no change in funding for a specific technology or service. Ideally the outcome of an HTR is better targeting of the technology or service allowing HTR to address both over-use and under-use of technologies.

Research Question

The primary policy question for the review is comprised of the following three research questions:

1. What approaches are used internationally to identify and prioritise the re-assessment of health technologies that are currently funded?
2. What approaches are used internationally to re-assess health technologies that are currently funded?
3. What approaches are used to implement changes in funding after re-assessment?

Methods

A systematic literature review was conducted using the EMBASE.com and Cochrane Library electronic databases, supplemented with targeted searches of websites and extensive 'pearling' of reference lists to identify additional studies.

The inclusion of studies was an iterative process and no restrictions on study or report type, or date were pre-specified. Health technologies that are funded on an interim basis or under restricted conditions subject to the collection of additional evidence (i.e., 'managed entry' or 'coverage with evidence development' schemes) were out of scope for the current review. A critical interpretive synthesis was undertaken to compare the disinvestment approaches identified, taking into consideration the health system, health technology assessment (HTA) system and mechanisms for health funding within which they operate.

Findings

Ten international approaches to HTR were identified after excluding approaches that are unable to be linked to reimbursement or for which insufficient details were available. This included three guidelines for which no evidence of their application was identified (Guerra-Júnior et al. 2017; Ibargoyen-Roteta and Asua 2007; Ruano Raviña et al. 2007). It also included four HTA approaches that are not explicitly disinvestment initiatives, but rather standard HTA approaches which also consider existing technologies (National Institute for Health and Care Excellence [NICE] clinical guidelines, NICE Technology Appraisals, Canadian

Agency for Drugs and Technologies in Health [CADTH] Optimal Use Reports, and CADTH Rapid Response Reports). Therefore, only three of the included approaches are applied approaches to re-assessment. One of these was a pilot undertaken in British Columbia, Canada and only focused on identification and prioritisation (Soril, Seixas, et al. 2018). Of the two remaining, one is the French approach to ongoing drug re-assessments for which we have relied on secondary sources (Pant, Boucher, and Frey 2019; Parkinson et al. 2015) and the other is the National Health Service (NHS) England Evidence-Based Interventions Programme, a new program for which outcomes are not yet available.

Identification and prioritisation of technologies for re-assessment

The identification and prioritisation of technologies for re-assessment is the most widely addressed aspect of re-assessment approaches in the published literature. However, there was little evidence that it had been operationalised as a distinct re-assessment function, and several prioritisation approaches were used broadly (i.e., for both new and existing technologies).

The methods used to identify technologies as candidates for re-assessment include wide use of 'Choosing Wisely' or other 'low-value care' lists; recommendations from clinical practice guidelines; referrals from clinicians, patients, or government; and planned re-assessment at a fixed timepoint following an initial decision to list/fund a technology.

Prioritisation approaches employed multiple criteria such as: likely impact on patient-relevant health outcomes; impact on health care expenditure; the size of the population affected/using the technology; impact on equity; impact on related government policies; evidence of significant variation in use of a technology across the country; or the potential to resolve confusion or controversy regarding the use of a particular technology. While Canada uses a scoring system for prioritisation, it does not appear that any country uses formal multi-criteria decision analysis (MCDA) to prioritise technology re-assessments.

Approaches used for re-assessment

In general, most countries use standard HTA methods for re-assessments, with a reliance on administrative utilisation data, extended safety data collected for regulatory purposes, and the emergence of new or updated clinical evidence. The potential for using real-world evidence (RWE) to inform re-assessments is acknowledged by many countries but has not yet been widely adopted in a systematic manner.

A number of countries are implementing rapid HTAs; the extent to which these are used for re-assessment versus assessment is not clear. Rapid assessments typically focus on clinical evidence and often utilise existing secondary data (i.e., clinical practice guidelines, HTAs and systematic reviews). Economic analysis is rarely included.

Approaches to implementing decisions based on re-assessment

The approaches employed by countries to implement changed funding decisions based on HTR are generally poorly described in the literature (by contrast, there is much literature regarding the broader topic of initiatives to encourage 'appropriate' use of health care – but this aspect of implementation was beyond the scope of the current literature review). That said, there is general support for implementing a multifaceted approach when a listing changes, including activities such as providing patient and clinician information, developing a quality indicator, and tracking subsequent utilisation change(s).

One example of revised funding decision-making based on HTR is in France, where the relevant committee can modify the place of a medicine in the relevant 'therapeutic strategy' (i.e., its line of treatment) based on the findings from an HTR. Another example is Italy, where analyses of patient registry data are used to reduce the price paid for pharmaceuticals on the basis of lower effectiveness in practice than demonstrated in clinical trials.

The Evidence-Based Interventions Programme in England is taking a multifaceted approach to implementation and includes both statutory compliance – with the tools to monitor this – and patient and clinical education resources.

Limitations of the current review

HTR activities often occur in non-academic settings with no motivation for publication or public release (Leggett, Noseworthy, et al. 2012). Consequently, no matter how comprehensive the literature search, the information that is found is likely to be fragmented and incomplete due to reporting bias.

No evaluations of specific disinvestment or re-assessment initiatives were identified from any country. Consequently, it is difficult to determine the relative value of the different aspects of HTR, or the health system context in which the HTR occurs, that contribute to the success or failure of the overall approach.

Implications for Australia

Domains where the Commonwealth is already meeting best practice in HTA and HTR include: an ongoing commitment to methodological development; including assessment of value and affordability; and linking assessment to payment mechanisms within the health system.

Domains that are largely absent for HTA/HTR undertaken by the Commonwealth include: a focus on a disease area (rather than a single type of technology); use of aligned, co-produced, real-time data (rather than applicant-driven evidence submissions); use of processes that are agile and adaptive across the life cycle of a technology and which can be readily updated as new data become available or if other relevant changes occur within a health system.

Specific suggestions for transitioning towards a new HTA paradigm include a focus on patient-driven priorities; greater co-ordination of HTA/HTR with the production of clinical practice guidelines and quality indicators; use of information technology (IT) tools to support adaptive, responsive HTA/HTR; and greater support and use of real-world data to supplement clinical evidence.

1 Introduction

Ensuring appropriate, affordable use of health technologies and services is a challenge for health systems around the world. As noted in the 'Right Care' series of articles in the Lancet,[1] under-use of proven, high-value care and over-use of low-value care are causing serious physical, psychological and social harms, and significant misallocation of resources. Health technology assessment (HTA) is a multidisciplinary approach that can be applied to better inform health policy and financing decisions based on the comparative safety, effectiveness, cost-effectiveness, and budgetary, ethical and social impacts of a range of new or emerging health technologies and health services. Similarly, health technology re-assessment (HTR) is a structured, evidence-based assessment of the clinical, social, ethical, and economic effects of a technology or service currently used in the healthcare system, to inform optimal use of that technology or service in comparison to its alternatives (Noseworthy and Clement 2012).

Typically, the policy outcomes of HTA are 'binary' decisions to invest or not invest in specific technologies or services, often with use of the technology limited to those circumstances deemed to be cost-effective by the relevant payer. While the over-riding perception is that HTR is used to inform 'full' disinvestment (i.e., the withdrawal of all funding for a specific technology or service), the policy outcomes of HTR are typically more nuanced, and may result in increased, decreased, or no change in funding for a specific technology or service. Often the outcome of an HTR is better targeting of the technology or service such that use is reduced in some populations and increased in others (i.e., HTR is a mechanism to simultaneously address over-use and under-use of a health technology or service) and may propose a solution to a quality use of medicines issue.

The Department of Health (DoH) commissioned a systematic literature review on international approaches to (post-market) reviews and disinvestment. The purpose of the current literature review is not merely to describe international approaches to disinvestment, but to critically compare these approaches taking into consideration the health system, the broader HTA framework, and the mechanisms for health funding within which these re-assessment approaches operate. During the scoping phase for the literature review (undertaken to inform the research protocol for the project) it became apparent that the terms 'post-market review' and 'disinvestment' would not capture all of the potentially relevant international literature. Consequently, the primary policy question posed by the DoH was reframed as: **What are best practice approaches to health technology and service re-assessment and what enables such approaches to be implemented?**

1.1 Research questions

The primary policy question for the review is comprised of the following three research questions:

1. What approaches are used internationally to identify and prioritise the re-assessment of health technologies that are currently funded?
2. What approaches are used internationally to re-assess health technologies that are currently funded?
3. What approaches are used to implement changes in funding after re-assessment?

The outcome of the review is a critical analysis that seeks to:

I. Identify best practice in disinvestment

II. Compare approaches and the extent to which they meet best practice.

[1] https://www.thelancet.com/series/right-care

1.1.1 PICo criteria

For this review of health policy, PICo (Policy problem, Intervention, Context) criteria were used to clearly define the research question and assist with evidence selection (Munn et al. 2018). The following three elements have been defined in detail:

- the policy problem
- the intervention of interest, and
- the context for the policy.

These are described in detail in Table 1.1.

Table 1.1 PICo (Policy problem, Intervention, Context) criteria

PICo Criteria	Description
Problem	Health technologies, including medicines, medical or prosthetic devices (and the services associated with them) that are funded (by any type of payer i.e., Government, insurer) and where information has emerged to suggest that the health technology may no longer be acceptably cost-effective to that payer.
Intervention	Processes and methods used to identify, prioritise, re-assess and implement changes to the listing of currently funded health technologies.
Context	National, regional or local interventions were considered. Emphasis has been placed on health systems and approaches that share similarities with Australia and/or may be applicable to Australia.

2 Methodology

2.1 Search strategy

A comprehensive search of the peer-reviewed scientific literature was conducted to identify studies and other relevant information (including program evaluation reports) for inclusion in the literature review. The terminology to describe disinvestment is varied with no common terminology in widespread use (Gnjidic and Elshaug 2015). This presents a challenge for designing a search strategy that will capture the relevant literature without becoming unwieldy. The approach taken in this review was to design a narrower, more specific search and to utilise reference lists, grey literature searches and existing systematic reviews to identify additional studies (this is referred to as 'pearling' in the systematic review literature).

The EMBASE.com and Cochrane Library electronic databases were searched. In addition, a thorough search of the grey literature was undertaken, including targeted searching of the websites of HTA agencies and Health Technology Assessment International (HTAi). The reference lists of included studies were also scanned for any additional relevant studies that were not identified in the formal literature search.

Table 2.1 Databases and websites searched

Source of information	Database/website	Date limited and search terms
Electronic databases	EMBASE.com (concurrently searches EMBASE and Medline) Cochrane Library (Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effect [DARE], Health Technology Assessment Database)	2000 onwards Search terms in Table 2.2
Evidence synthesis repositories	Epistemonikos https://www.epistemonikos.org/ Health Systems Evidence https://www.healthsystemsevidence.org/ PDQ-Evidence http://www.pdq-evidence.org	Search terms based on Table 2.2
HTA network websites and Agency websites	Health Technology Assessment International (HTAi) https://htai.org Websites of not-for-profit members of HTAi (e.g., NICE, CADTH) as listed at https://htai.org/membership/organizational-members/ HTAi Vortal http://vortal.htai.org/index.php?q=home International Network of Agencies for HTA (INAHTA) http://www.inahta.org/ Websites of members of INAHTA as listed at http://www.inahta.org/members/members_list/ Websites of members of HTAsialink (website is currently down, previous list is available in Teerawattananon, 2018) European Network for Health Technology Assessment (eunethta) https://www.eunethta.eu/ ISPOR https://www.ispor.org/	Search terms based on Table 2.2

2.1.1 Search string

Table 2.2 EMBASE.com search string

#	Search terms
#1	'biomedical technology assessment'/exp
#2	((technology NEXT/1 assessment*):ti,ab,jt) OR hta:ti,ab
#3	budget*:ti OR cost*:ti OR expenditure*:ti OR expens*:ti OR pharmacoeconomic*:ti OR ((pharmaco NEXT/1 economic*):ti) OR pric*:ti OR reimburs*:ti
#4	'reimbursement'/exp
#5	'utilization review'/exp
#6	#1 OR #2 OR #3 OR #4 OR #5
#7	divest*:ti,ab,kw OR disinvest*:ti,ab,kw OR 'dis invest*':ti,ab,kw
#8	'low value':ti,ab,kw
#9	'de list*':ti,ab,kw
#10	'delist*':ti,ab,kw
#11	reassess*:ti,ab,kw OR 're assess*':ti,ab,kw
#12	deadopt*:ti,ab,kw OR 'de adopt*':ti,ab,kw
#13	#7 OR #8 OR #9 OR #10 OR #11 OR #12
#14	(health NEXT/1 technology NEXT/1 reassessment*):ti,ab,kw
#15	(postmarket NEXT/1 review*):ti,ab,kw OR ('post market' NEXT/1 review*):ti,ab,kw
#16	#1 AND #13
#17	#16 OR #14 OR #15
#18	#17 AND [2000-2019]/py

2.1.2 Eligibility criteria

Study/report eligibility were based on the PICo criteria outlined in Table 1.1 and no further formal eligibility criteria were specified. The inclusion of studies was an iterative process and no restrictions on study or report type, or date were pre-specified. It was agreed with the DoH that only studies or reports with an abstract or executive summary published in English would be included. It was agreed that if studies or reports were identified where the body of the publication was in a language other than English, and the report had a high likelihood of providing relevant information, the review team would contact the Department to discuss the potential value of seeking a translation of the document.

It was agreed with the DoH that post-market reviews of health technologies that are funded on an interim basis or under restricted conditions subject to the collection of additional evidence (i.e., 'managed entry' or 'coverage with evidence development' schemes) were out of scope for the current review.

As the focus of the current project is on reimbursement/public funding, it was also agreed that post-market review or disinvestment programs relating to the supply of health technologies (i.e., regulatory reviews) were out of scope.

2.1.3 Data extraction

Data extraction was tailored to the types of studies, reports and other documentation retrieved. For each source identified, the following information is presented (where available):

- agency conducting the review
- starting year of program

- identification phase
- prioritisation phase (if applicable)
- assessment phase (including method of assessment)
- stakeholder involvement, including consumer consultation and Government involvement
- dissemination of results and implementation of recommendations
- length of process
- barriers and facilitators.

2.1.4 Quality assessment

It was agreed that quality assessment of included studies would be undertaken, as appropriate, according to standard accepted tools. For example, systematic reviews could be assessed using AMSTAR-II, randomised controlled trials (RCTs) using the Cochrane tool, and non-randomised studies using either ROBINS-I or the Newcastle-Ottowa scale. Alternatively, the series of tools developed by the Joanna Briggs Institute (JBI)[2],[3] might have been appropriate; for example, the *JBI Checklist for Quasi-Experimental Studies* for assessing quasi-experimental studies or interrupted time-series; or the *JBI Checklist for Qualitative Research* for studies reporting on barriers and facilitators to disinvestment approaches.

However, no 'studies' or formal evaluations of disinvestment programs were identified or included; all of the included source material is entirely descriptive in nature. Consequently, a formal quality assessment using the types of tools described above was not appropriate; the data have been analysed thematically and synthesised with a critical focus.

2.2 Evidence synthesis

It was agreed that a critical interpretive synthesis would be undertaken to compare the disinvestment approaches identified, taking into consideration the health system, HTA system and mechanisms for health funding within which they operate. The domains of information typically considered within a critical interpretive synthesis are shown in Table 2.3. The advantages and disadvantages of each approach to disinvestment will be discussed, with consideration of application to the Australian setting. Where available, standards of best practice are described.

Table 2.3 Domains considered within a critical interpretive synthesis (Entwistle et al. 2012)

Domain	Description
Purpose	To further understanding of a topic/question by drawing on broadly relevant literature to develop concepts and theories that interrogate those concepts. The topic might not be precisely bounded, and the initial question might be refined as the review progresses.
Process	The process of CIS is iterative, interactive, dynamic and recursive, with recognition of a need for flexibility and reflexivity. Searching, sampling, critique and analysis may happen concurrently.
Search strategy	Formal bibliographic searches may feature, but use will also be made of the research team's awareness of relevant literature from various fields and sources. The search strategy may evolve organically.
Sampling	Sampling of studies may be selective and purposive (not necessarily aiming for comprehensive identification and inclusion of all relevant literature). Inclusion criteria can be flexible and to some extent emergent. Reflexivity informs sampling. Ongoing selection of potentially relevant literature is informed by emerging theoretical framework.

[2] Tufanaru C, Munn Z, Aromataris E, Campbell J, Hopp L. Chapter 3: Systematic reviews of effectiveness. In: Aromataris E, Munn Z (Editors). *Joanna Briggs Institute Reviewer's Manual.* The Joanna Briggs Institute, 2017

[3] Lockwood C, Munn Z, Porritt K. Qualitative research synthesis: methodological guidance for systematic reviewers utilizing meta-aggregation. Int J Evid Based Health. 2015;13(3):179–187.

Domain	Description
Quality appraisal	Some formal appraisals of methodological quality may be appropriate, but judgements about the credibility and contribution of studies may be deferred until synthesis, as methodologically weak papers may still prove theoretically or conceptually insightful.
Data analysis	Inductive – aims towards the development of a synthesising argument. CIS involves an interrogation rather than aggregation of concepts and themes. Formal data extraction may be useful but is not essential to the approach.
Findings/results	CIS results in the generation of a 'synthesising argument' linking existing constructs from the findings to 'synthetic constructs' (new constructs generated through synthesis). This network of relationships and categories is submitted to rigorous scrutiny as the review progresses.
Discussion, contribution	CIS aims to offer a theoretically sound and useful account that has explanatory power and is demonstrably grounded in the evidence. It explicitly acknowledges the 'authorial voice' and that some aspects of its production will not be auditable or reproducible.

Abbreviations: CIS, critical interpretive synthesis.

3 Findings

3.1 The policy context

Health care expenditure is rising in many countries including Australia where in 2017–18, an estimated $185.4 billion was spent on health goods and services. This equates to an average of approximately $7,485 per person and constituted 10% of overall economic activity for this period (Health and Welfare 2019). While this may raise concerns regarding fiscal sustainability (Boxall, 2011), the large expenditure also merits ensuring that it is being spent on providing high-quality care, or value for money.

Recent reports from the Organisation for Economic Co-operation and Development (OECD; 2017) and the Lancet (Kleinert and Horton 2017) have highlighted the need to address both medical over-use and under-use, examining the extent of inappropriate care and approaches to reducing it.

The focus of the current review is post-market review and disinvestment. While the term 'post-market review' is used predominantly in Australia in the context of pharmaceutical re-assessment, disinvestment has come to be defined as 'the processes of (partially or completely) withdrawing health resources from existing health care practices, procedures, technologies or pharmaceuticals that are deemed to deliver little or no health gain for their cost, and thus are not efficient health resource allocations (Elshaug et al. 2007).'

A typology of disinvestment, specific to pharmaceutical reimbursement, is presented in Figure 3-1. It is useful to distinguish between passive and active disinvestment, as the focus of the current literature review is active disinvestment (where the main mechanisms are complete de-listing, restrictions on treatment, reductions in reimbursement/subsidy rates, or encouraging use of generics and biosimilar medicines). It is also useful to distinguish between disinvestment for drug and non-drug technologies.

It should be noted that activities listed as 'passive disinvestment' may trigger active disinvestment for related technologies. An example of this might be the withdrawal of a medical device due to safety concerns, which then triggers re-assessment of the incremental effectiveness and cost-effectiveness of the remaining medical devices in that group or class. Coverage with evidence development is excluded from consideration.

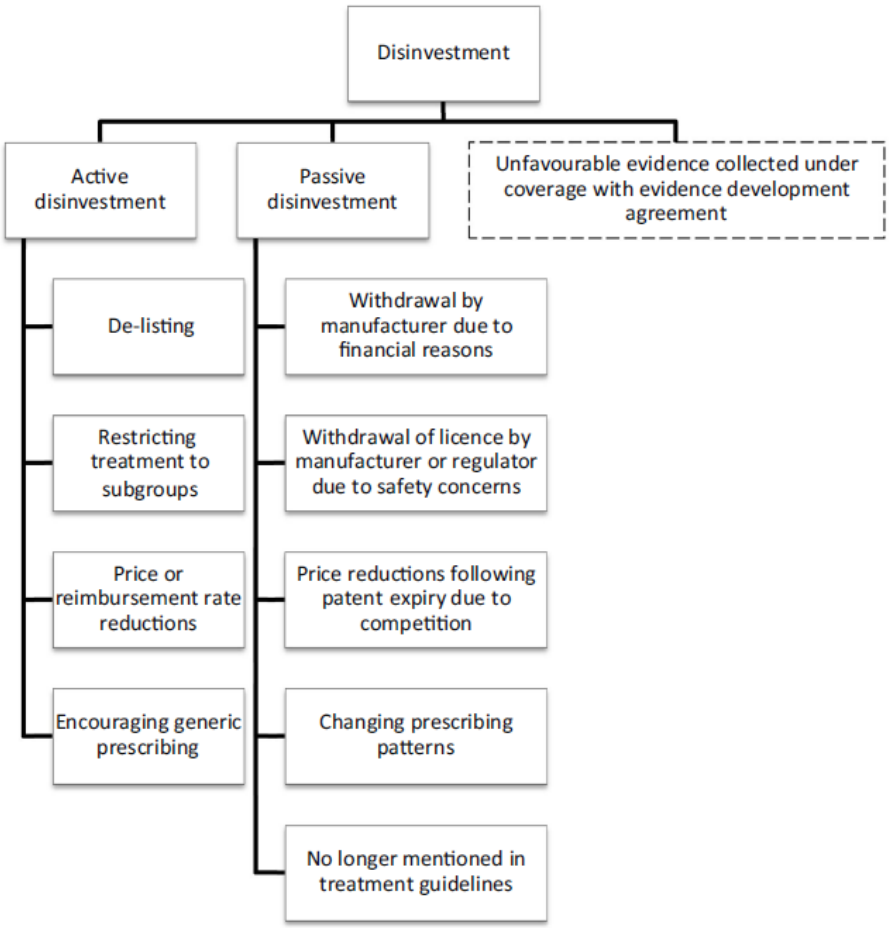

Figure 3-1 Drug disinvestment typology (Parkinson et al. 2015)

3.1.1 Health technology management: a technology lifecycle approach

Although the problem considered in this review is disinvestment, it is worth considering the wider lens of investment and disinvestment decision-making in health technology and services, with HTA (which is predominantly used for investment – not disinvestment – decisions) included as one tool within that frame.

These activities are now collectively referred to internationally as health technology management, as this more accurately reflects the range of activities that can occur to manage the introduction, use and removal of technologies and services from the health system. It also encourages a more inclusive collaborative lens in which health technology management is recognised as sitting under the umbrella of HTA but also the regular activities of safety and quality agencies.

Internationally, the Health Technology Assessment International (HTAi) policy forum published outputs in 2014, which noted that HTA needs to:

- be more agile and adaptive as well as more proactive in stating evidence requirements and in supporting evidence production
- provide inputs along the life cycle of the technology
- be timely
- go beyond the strict assessment of technologies to help the healthcare system use technologies in the most effective and efficient ways

- include other technologies that can contribute to system efficiency, e.g. aspects of care delivery such as nutrition and information technology solutions, to support more effective care delivery and patient engagement in their own care (Sampietro-Colom, Thomas, and Henshall 2015).

Building on this work, a more recent HTAi Policy Forum has presented a new HTA paradigm mapping out how HTA will need to innovate in order to best support health systems under fiscal constraint (Husereau et al. 2016) (Table 3.1). This reflects a broader view of HTA as an approach to investment and disinvestment decision-making and health care sustainability.

Table 3.1 Changing HTA paradigm (Husereau et al. 2016)

Current HTA approach	Innovating in HTA
Patient involvement	Patient-driven priorities
Focus on the technology (single and multiple technology assessments)	Focus on disease pathology and patient pathway
Unilateral stakeholder liaison (manufacturer–regulator), absence of service delivery	Multilateral stakeholder dialogue and collaboration, including health service delivery perspective
Focus on 'front end' innovation	Whole technology life cycle, from entry to exit
Scientific advice	Scientific dialogue
Review of submitted evidence	Aligned, co-produced, real-time, real-world data
Data/evidence for regulatory approval	Data/evidence for holistic value assessment (regulatory, payer and health service delivery)
Continued methodological development	Continued methodological development
HTA meaningful for regulators and payers	Translation of outputs of HTA in clinical practice (meaningful for clinicians and patients) Enhancing the reach of HTA to clinical practice
Analysing organisational implications	Better integration and information of service delivery issues and planning
HTA process complex and time consuming	HTA process agile and adaptive across the life cycle
Static HTA: a single episode at one point in life cycle	Dynamic HTA: continuous/updated assessment. System and resources keep pace as data become available and when/if things change during the life cycle
HTA confined to assessment of health technologies	HTA beyond the confines of traditional HTA using its approach to support and improve healthcare service
HTA and value of innovations	HTA and value and affordability of innovations (how health system can have the capacity to absorb the current and projected level of innovations)
HTA linked with payers	HTA linked with health system, with those responsible for allocating resources. HTA as a convenor of all parties on how health system needs to develop to get value from innovation
HTA in a budgetary and health system decision-making with a short-term perspective	HTA taking a medium long-term perspective in informing health system decision-making

This changing HTA paradigm is reiterated in an editorial (Bryan, Mitton, and Donaldson 2014) in which the authors note that HTA agencies, in particular those focused on reimbursement, are most likely to have a focus on adoption while healthcare delivery organisations tend to focus on management issues. Adopting a model of evaluation and assessment throughout the life cycle of health technologies with a disinvestment focus and tracking the validity of analysis predictions for the technology at the time of coverage (i.e., ongoing assessment of true effectiveness in relation to actual costs) may provide a solution to this misalignment. Recent work in Canada (for example, the formation of Health Quality Canada and the Canadian Agency for Drugs and Technologies in Health [CADTH]'s move to 'Health Technology Management'), and to a lesser extent at the National Institute for Health and Care Excellence (NICE), reflect

organisations making changes to encompass this broader investment/disinvestment approach to technology appraisal.

Recent work for the Australian government by the Menzies Centre for Health Policy conceptualises health technology management as encompassing five clear phases: (i) identification of the technology (and its prioritisation for some level of re-assessment); (ii) an initial investment decision for the technology; (iii) implementation of the conditions of use for the technology; (iv) monitoring and evaluation of the use of the technology; and (v) reconsideration of the investment decision in response to monitoring or the emergence of new information. The inter-relationship between these phases is shown in Figure 3-2.

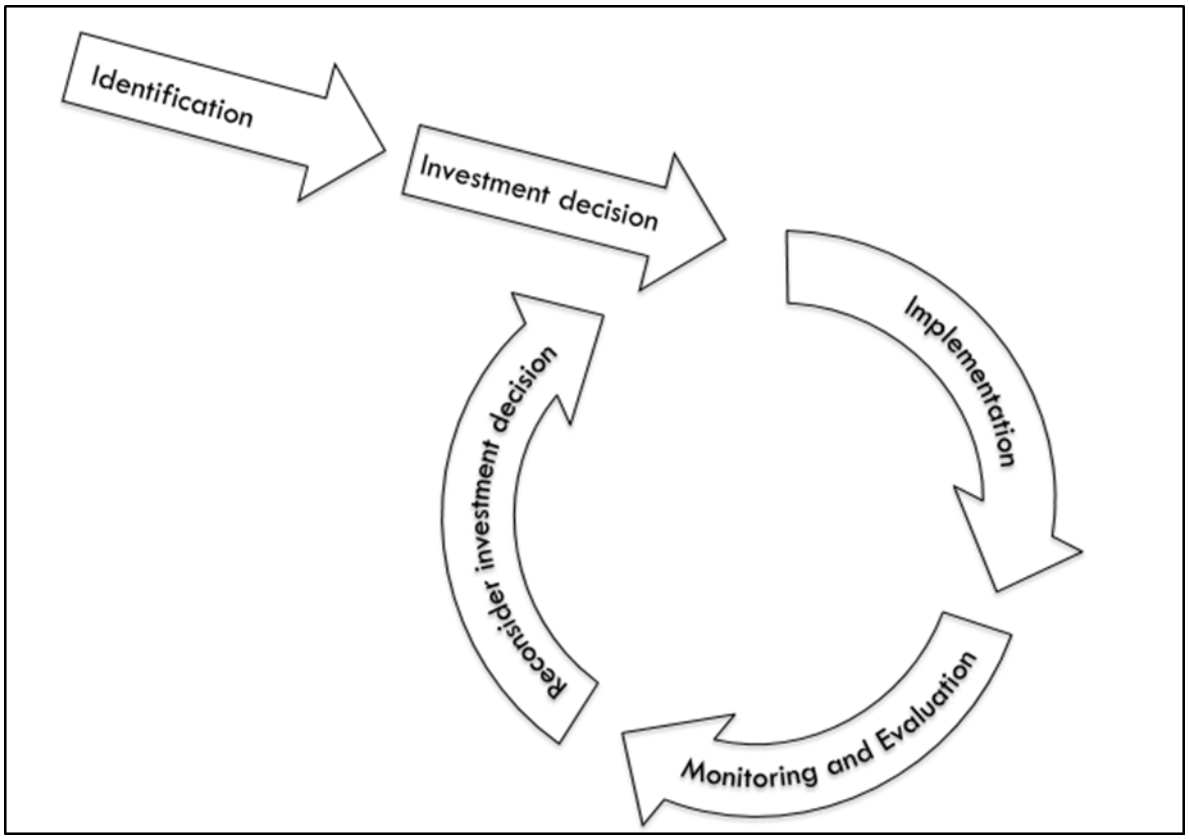

Figure 3-2 Cycle of health technology management

Previously, most re-assessment activities were reactive, occurring in response to triggers that emerged after a technology had been listed/funded – the *Monitoring and Evaluation* phase in the figure. But with a technology lifecycle approach there is the opportunity to prospectively plan data collection for future re-assessment from the time of the first investment decision.

Real-world evidence

With the increasing availability of data, its use has been widely discussed by HTA agencies and regulators. Real-world evidence (RWE), that is evidence derived from data collected during the routine delivery of healthcare, has the potential to provide information across the technology lifecycle, including informing the rational use of health technologies and reconsideration of investment decisions (Oortwijn, Sampietro-Colom, and Trowman 2019).

RWE presents both opportunities and challenges for HTA which are discussed in detail elsewhere (for example, Hampson et al. 2018); however, the ability to use RWE is likely to impact approaches to re-assessment and forms a component of several of the examples cited in this review.

Adaptive licensing and rapid access pathways

Regulatory approval and reimbursement have conventionally been distinct processes reflecting different mandates and, consequently, different evidentiary requirements. However, improved alignment and harmonisation of regulatory and reimbursement approaches within a jurisdiction has been proposed to improve patient care, innovation and system sustainability in particular by reducing duplication of effort and unnecessary use of resources while improving the quality of knowledge about the technology (Tsoi et al. 2013). There is also increasing pressure from many actors (consumers, medical practitioners, technology manufacturers) to provide faster access to new health technologies.

One approach to the harmonisation of regulatory and reimbursement processes is adaptive licensing, an approach that replaces single decision points with periodic or staged assessment and re-assessment using an evolving evidence base. An HTAi Policy Forum defined adaptive approaches as:

I. flexible and prospectively planned within and between key decision-makers,

II. intended to reduce uncertainty progressively to inform ongoing decisions on appropriate patient access and care,

III. intended to promote informed choices and improved outcomes and use of resources (Husereau, Henshall, and Jivraj 2014).

Adaptive licensing has also been referred to as 'medicine's adaptive pathways to patients (MAPPs)', 'staggered approval', 'progressive authorisation', or 'lifespan approach to licensing and reimbursement' and has similar goals to health technology management (Eichler et al. 2015) and clear implications for how disinvestment is implemented.

3.1.2 Terminology

The request for the current literature review used the terminology 'post-market review' and 'disinvestment.' It is noted in the methodology regarding the design of the search strategy that there are numerous terms to describe many interrelated concepts and that this presents a methodological challenge for literature reviews of this topic (Gnjidic and Elshaug 2015). However, the terminology used to describe a policy process can also have implications for the acceptability of that process and it is for this reason that much recent work within the HTA literature has adopted the term 're-assessment.'

Several authors have made the argument that 'disinvestment' assumes the result of the process before knowing the outcome, is polarising, implies cuts and rationing, and is in itself a barrier to gaining support for the process (Leggett, Noseworthy, et al. 2012; MacKean et al. 2013; Soril et al. 2017; Noseworthy and Clement 2012). All authors favour 'health technology re-assessment' as it is value neutral and doesn't presuppose a particular outcome and can be framed as optimising the use of technology with disinvestment as one possible outcome.

The current literature review did not identify any studies that used the term 'post-market review' nor was it listed amongst the 43 terms identified in a similar review by Niven et al. (2015).

3.2 Existing reviews of re-assessment activities

The current literature review identified 15 existing reviews or summaries of international disinvestment activities. The scope and methodologies of these reviews varied and included both formal systematic literature reviews, environmental scans, online surveys and targeted consultation. The aims, findings and conclusions of each are detailed in 0. These sources have been used to inform the current literature review by identifying specific approaches to disinvestment, by summarising barriers and enablers to disinvestment

or by providing guidance or frameworks. The individual contributions of each included published review are presented in Table 3.2. It is worth noting that eight of the fifteen reviews included Australia as a case study.

Table 3.2 Existing reviews of disinvestment activities and their contribution to the current report

Author (year)	Title	Case studies	Barriers/ enablers	Guidance/ frameworks
Gerdvilaite and Nachtnebel (2011)	Disinvestment: overview of disinvestment experiences and challenges in selected countries	✓ England, Spain, Australia, Canada	×	×
Leggett, Noseworthy, et al. (2012)	Health technology reassessment of non-drug technologies: current practices	✓ Australia, Denmark, Norway, Scotland, Spain, Sweden, England, USA	×	×
Leggett, Mackean, et al. (2012)	Current status of health technology reassessment of non-drug technologies: survey and key informant interviews	×	✓	×
Polisena et al. (2013)	Case studies that illustrate disinvestment and resource allocation decision making processes in health care: a systematic review	× Mostly PBMA	×	×
Niven et al. (2015)	Towards understanding the de-adoption of low-value clinical practices: a scoping review	×	? List of studies that examine barriers & enablers	✓ New framework & list of existing frameworks
Parkinson et al. (2015)	Disinvestment and value-based purchasing strategies for pharmaceuticals: An International review	✓ Australia, Canada, France, NZ, UK	×	×
Mayer and Nachtnebel (2016)	Disinvesting from ineffective technologies: lessons learned from current programs	✓ Spain, UK, Sweden, Australia	✓	×
Seo, Park, and Lee (2016)	A systematic review on current status of health technology reassessment: insights for South Korea	✓ UK, Canada, Australia, Spain	✓	✓ For Korea
Agirrezabal et al. (2017)	Status of disinvestment initiative in Latin America: results from a systematic literature review and a questionnaire	×	×	×
Chambers et al. (2017)	A review of empirical analyses of disinvestment initiatives	✓ Australia, Canada, Denmark, France, NZ, Scotland, Spain, UK, USA	✓	×
Orso et al. (2017)	Health technology disinvestment worldwide: Overview of programs and possible determinants	✓ Australia, Canada, Italy, Netherlands, Spain, Sweden, UK, USA	×	×
Maloney et al. (2017)	Drug disinvestment frameworks: components, challenges and solutions	×	✓	×
Calabrò et al. (2018)	Disinvestment in healthcare: an overview of HTA agencies and organizations activities at European level	✓ Austria, Italy, Spain, UK	×	×

Author (year)	Title	Case studies	Barriers/ enablers	Guidance/ frameworks
Polisena et al. (2019)	Disinvestment Activities and Candidates in the Health Technology Assessment Community: An online survey	×	✓	×
Pant, Boucher, and Frey (2019)	Health technology reassessment: An overview of Canadian and international processes	✓ Canada, UK, France, Germany, Australia, NZ, USA, Spain, Finland	×	×

Abbreviations: HTA, health technology assessment; NZ, New Zealand; PBMA, program budgeting and marginal analysis; UK, United Kingdom; USA, United States of America.

3.3 Approaches to re-assessment

The literature search and the existing reviews failed to identify many examples of approaches to disinvestment, particularly those that had been operationalised, and there are few reports in the peer-reviewed literature of the processes undertaken to approach disinvestment. This information was also not widely available on the websites of HTA agencies. The information herein is presented by country (arranged alphabetically), with relevant individual initiatives within these countries considered separately where appropriate.

3.3.1 Austria

Two of the existing systematic reviews were developed by the Austrian HTA agency, the Ludwig Boltzmann Institute for HTA (LBI-HTA) (Gerdvilaite and Nachtnebel 2011; Mayer and Nachtnebel 2016). In addition, a report on the impact of HTA from the LBI-HTA includes analysis of four full HTAs and two rapid assessments used for disinvestment decisions, which found some role in reducing volumes (Zechmeister and Schumacher 2012). However, the LBI-HTA is not a decision-maker so its ability to implement disinvestment is limited.

3.3.2 Brazil

In Brazil, the National Committee for Health Technology Incorporation (Conitec) was established in 2011 to improve the decision-making process in HTA. The primary purpose of this committee is advising the Ministry of Health on decisions related to the adoption, disinvestment or changes in the use of health technologies in the public health system (SUS), as well as the development or update of clinical protocols or therapeutic guidelines (Pereira, Barreto, and Neves 2019).

A recent study identified 47 technologies re-assessed by Conitec over the period 2012 to 2017 out of a total of 333 assessments. Of these, 41 were initiated by the public sector and six by the private sector and 44 (93.6%) were for drugs. The reason for the requests varied; the most common reason was the exclusion of a specific indication (n=19, 40.4%) followed by an extension of use (n=14, 29.8%) and de-listing (n=12, 25.5%). The process undertaken for these assessments was not standardised; just over half included data on the disease (epidemiology, treatments etc.) (n=65, 55.3%) and the same number included scientific evidence regarding efficacy, effectiveness or safety (n=26, 55.3%). Reports that didn't include such evidence all related to exclusion of the technology (either wholly or for a specific indication) and were justified based on clinical protocols (n=14), obsolescence (n=7), unavailability (n=2) or stability/storage (n=1). Seven reports included an economic analysis, 13 included a budget impact analysis, and 13 underwent a public consultation. Data extracted from the SUS database on the performance of the drug over 10 years was used for a single technology, interferon beta for treatment of multiple sclerosis (Pereira, Barreto, and Neves 2019).

Methodological Guidelines for the conduct of Health Technology Performance Assessment (HTpA) have also been produced in Brazil[4]. Released in 2017, the guidelines were produced by the SUS Collaborating Centre for Technology Assessment and Excellence in Health (CCATES) in collaboration with international experts and the support of the Pan-American Health Organization (PAHO) and the Department of Management and Incorporation of Technologies from the Brazilian Ministry of Health. The objective of the Guideline was to establish the monitoring of funded technologies using RWE to assess their performance and update clinical guidelines (Guerra-Júnior et al. 2017).

The guidelines cover identification, prioritisation, assessment and implementation. It is noted that during development of the guidelines the objective expanded from evaluating disinvestment to institutionalising the continuous monitoring of funded health technologies in routine clinical care. This allows a distinction between the HTA activities undertaken for incorporation of new technologies, typically focused on randomised trials, to HTR activities that monitor technologies, including the use of RWE, and strive to continuously update clinical practice guidelines. The barriers to such a system are the costs required and the need for improved data collection and storage (Guerra-Júnior et al. 2017).

Process diagrams for HTpA for technologies assessed at listing and technologies never assessed are presented in Figure 3-4 and Figure 3-5 respectively. Prioritisation criteria used in the guidelines were adapted from CADTH (see Table 3.4 and Table 3.5) (Husereau, Boucher, and Noorani 2010) and Australia (Elshaug, Moss, et al. 2009) and are listed in Table 3.3. It is not clear from information in the public domain if, or to what extent, HTpA has been incorporated into the technology assessment processes in Brazil.

Table 3.3 Criteria for prioritisation of listed health technologies for HTpA (Guerra-Júnior et al. 2017)

Criteria	Explanation
Safety issue	Among the identified technologies, the ones related to health risks should be prioritised.
Cost of service	High cost per procedure, high cost due to the volume, or an aggregate measure of both.
Probable impacts	• Related to health care: e.g., gross estimate of quality-adjusted year of life. • Related to costs: e.g., gross estimate of savings per patient; release of additional resources, etc. • Overall assessment of the maintenance of equity in care, if the finances of health care technology are modified (e.g., access for subgroups of patients).
Cost-effective alternative	Priority should be given to technologies for which there are cheaper alternatives with equivalent or better results.
Burden of disease	Conditions associated with low disability or morbidity, or low mortality rates (excluding orphan diseases) can influence the prioritisation of different health conditions with high disability/morbidity or mortality. Low burden conditions may reduce the potential for dispute; high burden diseases can represent a greater scope for reinvestment / reallocation of resources.
Sufficient evidence available for disease	Rigorous assessment requires robust evidence. Typically, the evidence is not 100% conclusive, but they must be suitable to be useful in decision-making.
Possibility to generate evidence for decision-making	Time and budget possibility of conducting a study to support decision-making when there is little evidence available.
Futility	An intervention that probably does not result in “significant survival” or benefit can be prioritised.
Possible political impact	Interventions in areas where there is political engagement should be carefully evaluated, because this can be considered of more or less priority depending on the political moment.
Rate of release of new technologies	Technologies used for diseases that are the focus of scientific and industrial interest should be prioritised. New technologies are often released in the market (greater possibility of replacement technology).

[4] https://htai.org/wp-content/uploads/2018/02/2017_DIRETRIZ_AdTS_FINAL_INGLES_ISBN.pdf

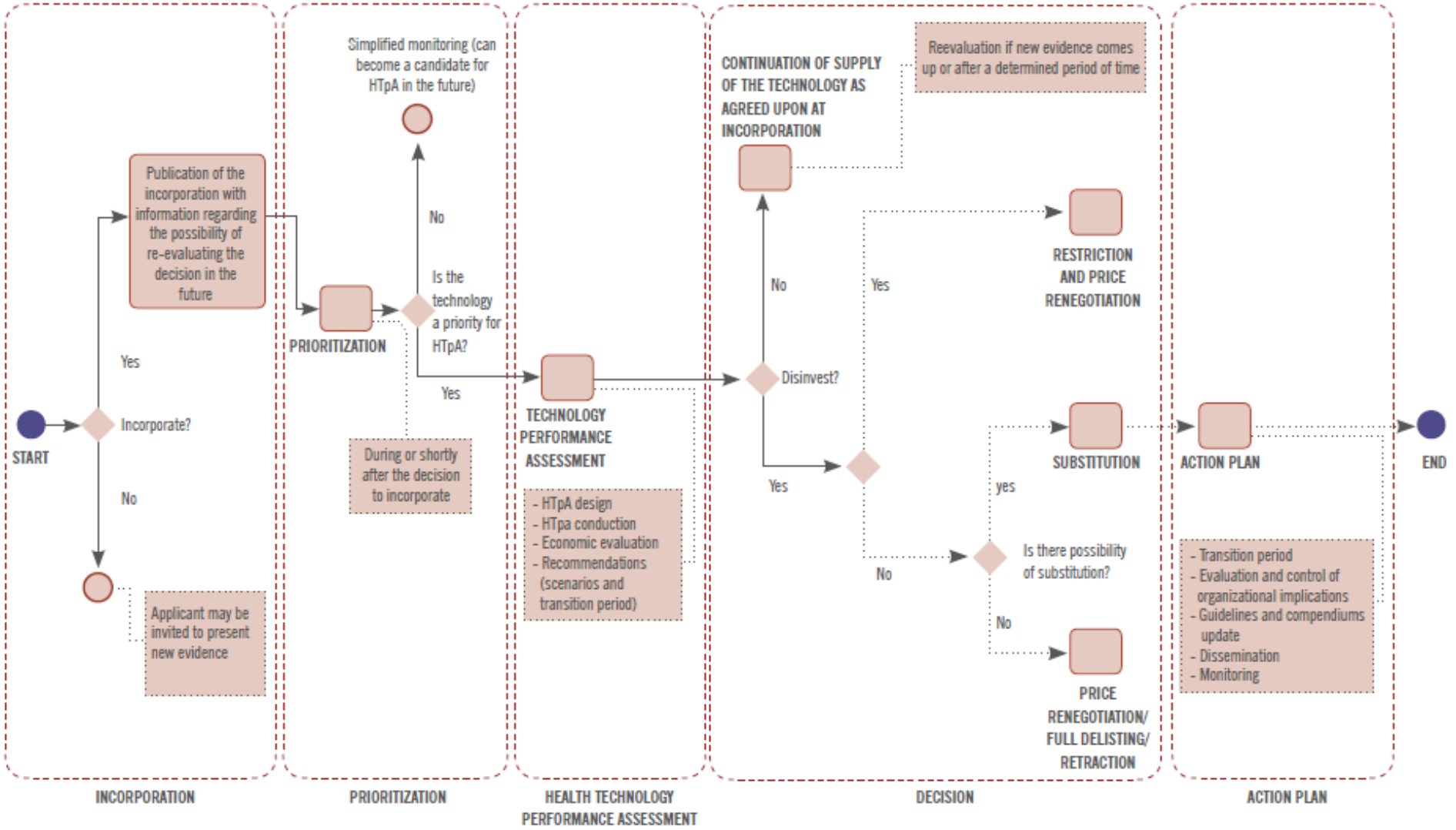

Figure 3-3 Health Technology Performance Assessment process diagram in Brazil for technologies assessed at incorporation

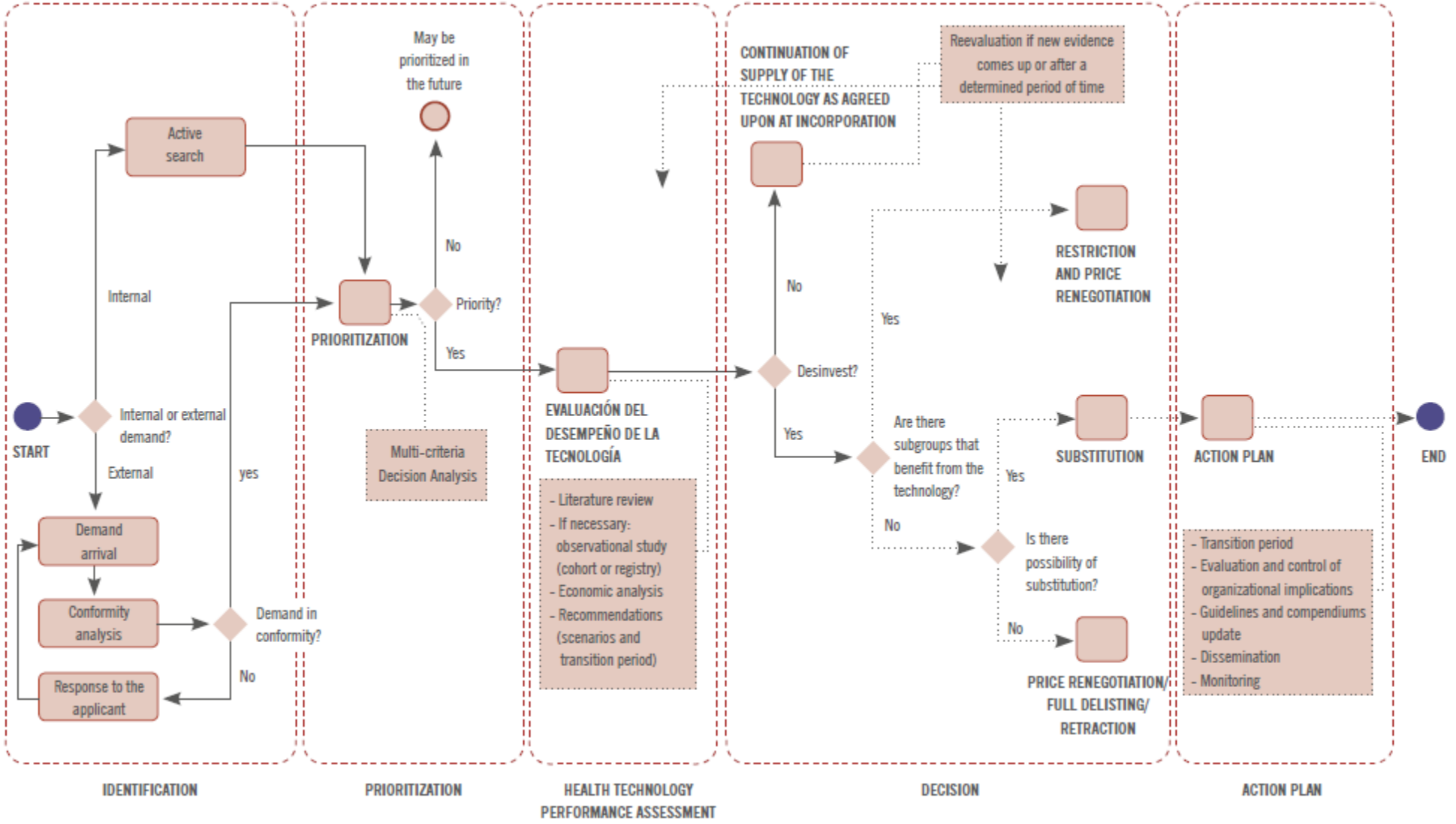

Figure 3-4 Health Technology Performance Assessment process diagram in Brazil for technologies not previously assessed

3.3.3 Canada

Canada has a federal publicly funded, national health care system designed to ensure access to health care services regardless of ability to pay. The system is decentralised with health insurance plans in each individual province and territory making their own decisions on organisation, management and delivery of health care services (Menon and Stafinski 2009). Often these decisions are then further decentralised to the local or municipal level.

The Canadian Coordinating Office of Health Technology Assessment (CCOHTA) was established in 1989 with the primary mandate of co-ordinating HTA activities across Canadian jurisdictions; however, it also undertook the role of producing HTA, particularly for provinces that lacked their own systems. Renamed CADTH in 2006, and funded by the provincial, federal and territorial governments (excluding Quebec), the agency is now the largest producer of HTA in Canada. In addition to the national body, many provinces also have government funded HTA bodies that produce HTA products for provincial-level decision-making.

CADTH

CADTH has produced policy documents exploring disinvestment and/or HTR but does not yet have an established framework. The documents identified are:

- Policy Perspectives on the Obsolescence of Health Technologies in Canada. (Discussion paper) (Elshaug, Watt, et al. 2009a)
- Reassessment of Health Technologies: Obsolescence and Waste. (Discussion paper) (Joshi, Stahnisch, and Noseworthy 2009)
- Health Technology Reassessment: An overview of Canadian and International Processes. (Environmental Scan) (Pant, Boucher, and Frey 2019).

In its 2017-18 Business Plan, CADTH outlined the intention to transition to a health technology management enterprise, and this is a core element of the 2018-2021 Strategic Plan which has three goals:

1. Close the gap between evidence, policy and practice
2. Adopt a life cycle approach to HTA
3. Anticipate health system and technology trends and develop agile management strategies.

Within the second goal, the following objectives are specified:

- Align drug and medical device review processes with federal, provincial, and territorial priorities throughout all phases of the technology life cycle
- Implement programs for re-assessment and disinvestment
- Advance initiatives across the health technology life cycle that will improve access, appropriate use, and affordability[5].

Although CADTH's own review states that it does not have a formal framework for HTR (Pant, Boucher, and Frey 2019), it is already within the agency's remit to conduct reviews of both new and existing technologies and this does occur.

Priority setting at CADTH has a relatively long history (Husereau, Boucher, and Noorani 2010; Noorani et al. 2007) and uses a MCDA approach.

[5] https://www.cadth.ca/sites/default/files/corporate/planning_documents/CADTH_2018-2021_Strategic_Plan.pdf

Topic suggestions come from a variety of sources, including the public, and are all added to a master list. These are then reviewed to ensure they are within CADTH's mandate. Topics that are within the mandate are then considered for appropriateness (Table 3.4). Topics with a weighted score of 200 or more are moved onto the topic prioritisation list, while those that score less than 200 may be considered for a rapid review or remain on the master list for prioritisation in the future.

Table 3.4 Criteria for the assessment of appropriateness of a topic[6]

Criterion	Definition and weight	Score	Score definition
Duplication of effort	Is another organisation undertaking a review or considering a review on the same topic? 30%	3	No duplication foreseen
		2	Partial duplication is possible, which may allow brokering or collaboration
		1	Another organisation is considering this topic
		0	Another organisation is currently working on this topic
Need	How important is the policy, purchasing, or practice decision for which this evidence is needed? 40%	3	Decision with substantial impact on patient care
		2	Decision with moderate impact on patient care
		1	Decision with limited impact on patient care
		0	No decision to be made in the foreseeable future, or decision with no impact on patient care
Stage of diffusion	Is the technology available in Canada? 30%	3	Currently approved or in use in Canada
		2	Currently not approved or used in Canada, but likely to be approved or used in the next year
		1	Currently not approved or used, and unlikely to be approved or used in the next year
		0	Currently not approved or used and will not be considered for approval or use in the next year (i.e., not approved in any other countries)

A scoping brief is prepared for all topics on the prioritisation list. This brief contains the information required to assess the topic against the criteria for prioritisation and also outlines related policy issues and provides an overview of the existing evidence through a rapid response approach. These scoping briefs are then used to score topics (Table 3.5) and a ranked list is produced that is used to make a decision about which reviews to undertake.

Table 3.5 Criteria and scoring for topic prioritisation[7]

Criterion	Definition and Weight	Score	Score Definition
Clinical Impact	Potential for the technology to have an impact on patient-related health outcomes (benefits and harms) 25%	3	Major potential improvement in clinical outcomes
		2	Moderate potential improvement in clinical outcomes
		1	Little potential improvement in clinical outcomes
		0	No expected change in clinical outcomes
Budget Impact	Impact of the technology on health care spending 25%	3	Major cost savings or expense (> $ 50 M)
		2	Moderate cost savings or expense (> $10 M to $50 M)
		1	Limited cost savings or expense ($1 M to $10 M)
		0	No cost savings or expense (< $1 M)
Population Impact	The size of the population that would be affected by the technology 15%	3	Affects 5% of more
		2	Affects from 1% to < 5%
		1	Affects from 0.05% to < 1%
		0	Affects < 0.05%

[6] https://www.cadth.ca/sites/default/files/pdf/HTA_OU_Topic_ID_and_Prioritization_Process.pdf
[7] https://www.cadth.ca/sites/default/files/pdf/HTA_OU_Topic_ID_and_Prioritization_Process.pdf

Criterion	Definition and Weight	Score	Score Definition
Jurisdictional Interest	The number of provincial, territorial, or federal programs with a CADTH customer (such as hospital, regional health authority, or Ministry of Health) facing a decision on the technology, and which could use the HTA to inform a decision or change 20%	3 2 1 0	Interest from >7 jurisdictions Interest from 5 or 6 jurisdictions Interest from 2 to 4 provincial jurisdictions Interest from <2 jurisdictions
Equity	The technology has the potential to introduce, increase, or decrease equity in health status 15%	3 2 1 0	Major potential to affect equity in health status Moderate potential to affect equity in health status Minor potential to affect equity in health status Will not affect equity in health status

Although CADTH can review existing technologies across many of its products, Optimal Use Reports are of particular relevance as they are intended to encourage appropriate coverage, prescribing, and utilisation of drugs and other health technologies. Rapid Response products are also widely used for existing technologies. Recent examples of reviews of established technologies include:

- Dioctyl Sulfosuccinate or Docusate (Calcium or Sodium) for the Prevention or Management of Constipation: A Review of the Clinical Effectiveness[8]. This was a rapid review that found little evidence to support the use of docusate and it was subsequently removed from the formularies in eight jurisdictions[9]
    - This was a 'rapid response – summary with critical appraisal', which consisted of a limited literature review, critical appraisal and consideration of policy implications. Timelines are 30 days from topic finalisation (without peer review) or 2-3 months (with peer review). No consultation is undertaken, but the reviews are usually conducted for a provincial 'customer'.
    - Two implementation tools were also released: a letter for long-term care residents and a prescription pad.
- Caesarean Delivery for Pregnancies in the Second Stage of Labor: Clinical Effectiveness and Guidelines[10]. This rapid review found no relevant literature or evidence-based guidelines.
    - This was a 'rapid response – summary of abstracts', which consisted of a limited literature review, a list of included studies organised by study type and a summary of their findings from the abstract only. Timelines are 15 business days from topic refinement.
- Interventions for insomnia disorder[11]. This Optimal Use Report included three components:
    - a clinical evaluation (overview of systematic reviews), registered in PROSPERO on 20 July 2017[12], report published September 2018
    - a review of caregivers and patient experiences (rapid response – summary with critical appraisal)
    - a current practice analysis (online survey of current primary healthcare service providers)

[8] https://www.cadth.ca/sites/default/files/pdf/htis/nov-2014/RC0561%20Stool%20Softeners%20Final.pdf
[9] https://www.cadth.ca/sites/default/files/pdf/CADTH_2017_2018_at_a_glance_infographic_e.pdf
[10] https://www.cadth.ca/sites/default/files/rr/2019/RB1394%20Caesarean%20Delivery%20Second%20Stage%20Final.pdf
[11] https://www.cadth.ca/interventions-insomnia-disorder
[12] https://www.crd.york.ac.uk/PROSPERO/display_record.php?RecordID=72527

A brief plain-language summary was also published.

- CADTH methods for therapeutic reviews state that stakeholder feedback is solicited at the following stages:
  - Proposed project scope (including existing recommendations from the Common Drug Review [CDR] program for drugs to be included for review if applicable)
  - List of included studies
  - Draft Therapeutic Review Science Report
  - Draft Therapeutic Review Recommendations Report
  - Proposed revisions to existing recommendations from the CDR program (if applicable).

Although CADTH appears to frequently review existing technologies, it is not a decision-making body and therefore can only make recommendations on appropriate technology use; it cannot implement any active disinvestment.

British Columbia

The British Columbia Ministry of Health's Heath Technology Assessment Committee (HTAC) makes evidence-informed decisions about which health technologies (devices, diagnostics and clinical procedures) should be publicly provided in the province. Its remit includes new or existing non-drug, non-IT technologies expected to have a significant patient and/or health system impact. The HTAC currently has three technologies listed for re-assessment:

- Open retropubic radical prostatectomy vs. minimally invasive prostatectomy
- Polypropylene surgical mesh
- Same-day total hip replacement[13].

In 2016, HTAC reviewed hip implants for total primary hip replacement.[14] The extensive review included:

- review of patient experiences conducted by CADTH (rapid review – summary with critical appraisal)[15]
- patient focus groups
- telephone or email feedback from surgeons
- jurisdictional scan – request for policy information from each jurisdiction
- systematic literature review
- economic analysis
- budget impact analysis.

The timeframe was not reported.

The HTAC has piloted an approach to prioritising technologies for re-assessment using a five-step methodological process (Figure 3-5) (Soril, Niven, et al. 2018). A list of low-value technologies was compiled from the NICE 'Do Not Do' recommendations, Choosing Wisely Canada, and the list of low-value Medical

[13] https://www2.gov.bc.ca/gov/content/health/about-bc-s-health-care-system/partners/health-authorities/bc-health-technology-assessment/health-technology-assessments#current
[14] https://www2.gov.bc.ca/gov/content/health/about-bc-s-health-care-system/partners/health-authorities/bc-health-technology-assessment/health-technology-assessments/hip-implants-for-total-primary-hip-replacement
[15] https://www.cadth.ca/meaning-and-impact-benefits-and-harms-total-hip-replacement-review-patient-and-caregiver-0

Benefits Schedule items (Elshaug et al. 2012). The list included 1,350 recommendations, of which 1,276 were excluded because they were drug technologies, not publicly listed in British Columbia, or the language was too nuanced, and they could not be quantified.

Use of the technologies was then queried in administrative databases over the period 2010 to 2015 and this information was used to rank potential candidates for re-assessment based on high budgetary impact (defined as more than $1 million in a fiscal year). This produced a draft list of nine candidate technologies that were then discussed with the expert advisory committee (Soril, Niven, et al. 2018). Although there were nine candidates prioritised, different prioritisation criteria could have produced a different list as frequencies and costs for 47 technologies were listed.

The authors note several limitations to the work. Firstly, 552 technologies were excluded because of 'clinically nuanced' language; that is, the recommendation contained language or qualifiers that could not be identified in the administrative data. Further clinical consultation could resolve some of these difficulties and identify additional candidate technologies for re-assessment. Secondly, due to the aggregated data, geographic and provider variations in technology use were not considered. Under-use of high-value technologies was also not considered. Finally, the pilot was an approach to the identification and prioritisation of low-value technologies, and as such represents only the initial steps in a disinvestment program (Soril, Niven, et al. 2018). Alberta Health (see below) has followed the same model as British Columbia to draft a list of seven candidate health technologies for potential re-assessment (Pant, Boucher, and Frey 2019).

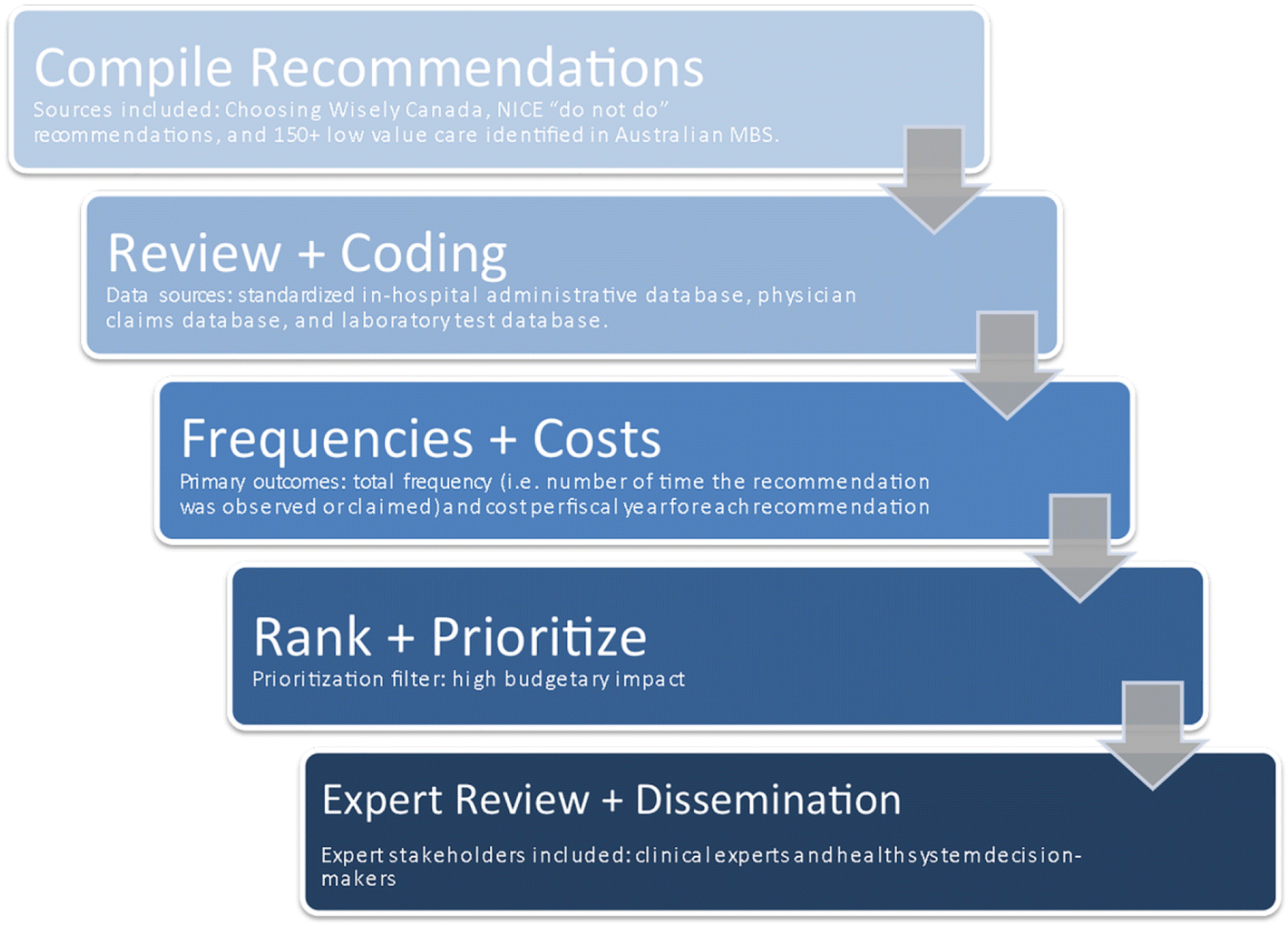

Figure 3-5 **Methodological process in Canada for selecting candidate technologies for HTR (Soril, Niven, et al. 2018)**

Ontario

Ontario's provincial HTA agency, the Medical Advisory Secretariat within Ontario's Department of Health and Long-Term Care became part of Health Quality Ontario (HQO). HQO was established as an agency of the Ontario government by the Excellent Care For All Act 2010. The agency incorporates HTA and the development of quality standards and performs the following tasks:

- monitor and report on how the health system is performing
- provide guidance on important quality issues
- assess evidence to determine what constitutes optimal care
- engage with patients and give them a voice in shaping a quality health system
- promote ongoing quality improvement aimed at substantial and sustainable positive change in health care.

This new agency explicitly takes a health technology management approach. HQO conducts reviews of existing technologies to support Choosing Wisely Canada recommendations[16].

Alberta

A framework published in 2017 'Maximising the impact of HTA: the Alberta framework' details an approach to HTA in which scope is expanded beyond single technology adoption questions to provide advice on optimal technology use. The framework is explicit about including technology re-assessments and has a focus on implementation[17]. An example of a re-assessment conducted in Alberta is a review that considered the appropriate use of antipsychotics in long-term care facilities[18]. The methodology included a review of existing clinical practice guidelines updated and/or supplemented with five de novo systematic reviews. A review of economic evidence found no studies and a budget impact analysis was not found to be feasible.

Atlantic provinces

The Atlantic provinces (Prince Edward Island, Newfoundland and Labrador, Nova Scotia, and New Brunswick) have an Atlantic Common Drug Review within which there is an explicit review mechanism. The goal of the process is to ensure that the drugs covered are current and based on the best available evidence, and the process may also result in disinvestment. A review can be launched in response to changes in the scientific evidence, regulatory status, cost-effectiveness or budget impact related to changes in the drug cost or the cost of its comparators. Each province can still make its own reimbursement decisions based on the review recommendations (Parkinson et al. 2015).

Saskatchewan

Saskatchewan developed an Appropriateness of Care framework in 2015, with a focus on clinical engagement and quality improvement. The work is ongoing, led by clinicians and a partnership between the Ministry of Health and the Health Quality Council (HQC). A part of this work is the co-ordination of work for Choosing Wisely Saskatchewan[19].

[16] https://www.hqontario.ca/Evidence-to-Improve-Care/Health-Technology-Assessment/Other-Publications/Choosing-Wisely-Canada
[17] https://open.alberta.ca/dataset/39ddae93-8840-49a3-aee2-9a88702a7e06/resource/b117e72d-eaec-4010-a5dc-1005dc9f8680/download/hta-framework-2017.pdf
[18] https://open.alberta.ca/publications/best-practices-in-the-management-of-behavioural-and-psychological-symptoms-of-dementia
[19] https://hqc.sk.ca/what-we-do/ensuring-patients-get-appropriate-care

3.3.4 England

NICE and the NHS

Universal health coverage is provided in England by the National Health Service (NHS) in the Department of Health and is predominately funded by general taxation. Approximately 85% of the NHS budget in England is distributed to Primary Care Trusts (PCTs) that are responsible for providing health care and health improvements within a local area. NICE, a non-departmental public body, was established to ensure equitable healthcare access, but has had its areas of responsibility broadened over time to include public health and social care. Its current role is:

- Producing evidence-based guidance and advice for health, public health, and social care practitioners.
- Developing quality standards and performance metrics for those providing and commissioning health, public health, and social care services.
- Providing a range of information services for commissioners, practitioners, and managers across the spectrum of health and social care[20].

Technology appraisals

NICE produces numerous outputs and in most cases adoption and implementation decisions are made locally, noting that the NHS is legally obligated to provide funding for technologies recommended in technology appraisals (Drummond and Sorenson 2009).

Although the NHS in England is required to implement NICE recommendations arising from Technology Appraisals, NICE's remit had not included taking account of the budget impact or the affordability of its recommendations. This task falls to the local level where implementing a NICE recommendation typically leads to a reduction in the availability of existing services as a consequence of fixed local budgets. This misalignment has been long understood (Burke 2002). Consideration of the budget impact by NICE was introduced in April 2017, although this appears to be primarily to guide commercial negotiations rather than to prioritise investment decisions[21].

In 2006, a pilot 'Ineffective Treatments' program was conducted through the technology appraisal program. However, after a series of scoping workshops in early 2007, NICE concluded that a designated technology appraisal program was not warranted, with several challenges identified:

- NICE was already issuing 'do not do' recommendations
- there were few opportunities for total disinvestment, and
- there was insufficient data to guarantee the estimated savings (Garner and Littlejohns 2011).

It was concluded that disinvestment opportunities could be identified through existing programs, particularly through clinical guidelines (discussed below). Nevertheless, the lack of a formal disinvestment framework at NICE continues to attract criticism (Hughes, Wood, and Tuersley 2015) and NICE's methods for assessing candidates for disinvestment are the same as those for investment.

Technology appraisals assess the clinical and cost-effectiveness of new and existing health technologies, including medicines, medical devices, diagnostic techniques, surgical procedures and health promotion activities and can be either single technology appraisals (STAs, based on company-submitted evidence) or multiple technology appraisals (MTAs, based on assessment by an academic group). NICE has recently introduced a Fast Track Appraisal (FTA) for technologies where:

[20] https://www.nice.org.uk/about/what-we-do
[21] https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/budget-impact-test

- the company's base-case incremental cost-effectiveness ratio (ICER) is less than £10,000 per quality-adjusted life year (QALY) gained
- it is likely that the most plausible ICER is less than £20,000 per QALY gained, and it is highly unlikely that it is greater than £30,000 per QALY gained.

These are unlikely to be used for existing drugs and only four had been conducted as at May 2019[22]. The time taken for these assessments was 32 weeks compared to 42 weeks for an STA.

There is an extensive topic selection process in place for technology appraisals. Once an appraisal is considered eligible, and the availability of appropriate evidence has been confirmed, the following prioritisation criteria are applied:

- Is the technology likely to result in a significant health benefit, taken across the NHS as a whole, if given to all patients for whom it is indicated?
- Is the technology likely to result in a significant impact on other health-related Government policies?
- Is the technology likely to have a significant impact on NHS resources if given to all patients for whom it is indicated?
- Is there significant inappropriate variation in the use of the technology across the country?
- Is NICE likely to be able to add value by issuing national guidance? For example, without such guidance is there likely to be significant controversy over the interpretation or significance of the available evidence on clinical and cost-effectiveness?[23]

A suggested timeframe for review is specified in each appraisal, or an appraisal can be labelled as static because the evidence base is not likely to change substantially. Data on the number of technology assessments undertaken of existing technologies is not readily available, but it is clearly skewed towards new technologies with most technologies receiving positive recommendations (82% positive since 2000)[24].

A study of negative and restrictive technology appraisals from 2000 to 2004, found that the guidance did not reduce prescribing in 97% of cases (Dietrich 2009) suggesting NICE Technology Appraisals may have a very limited role in disinvestment. A more recent study considered the use of 'innovation' as a value in NICE's decision-making, concluding that this was 'substantially considered' by decision-making committees in 68% of appraisals between 2013 and 2018. However, concerns were raised that 'innovation' as a social value is not well balanced with the goals of promoting health and equity (Charlton and Rid 2019).

Clinical Guidelines

NICE guidelines make evidence-based recommendations on a wide range of topics, from preventing and managing specific conditions, improving health and managing medicines in different settings, providing social care to adults and children, and planning broader services and interventions to improve the health of communities. Although recommendations are not mandatory, they are considered the best place for NICE to consider both disinvestment and investment as they involve strong clinical collaboration and review of an entire clinical pathway rather than focusing on a single technology (Drummond 2016).

One output from NICE clinical guidance has been a searchable 'Do Not Do' list, which was initiated in 2007 to identify low-value interventions. The list no longer appears to be available on the website, replaced by a summary of 'cost-saving guidance'[25] which identifies guidance that could be cost-saving when implemented.

[22] https://www.source-he.com/single-post/2019/05/29/Is-the-NICE-FTA-process-resulting-in-faster-access-to-the-most-cost-effective-therapies
[23] https://www.nice.org.uk/process/pmg19/chapter/selecting-technologies
[24] https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/data/appraisal-recommendations
[25] https://www.nice.org.uk/about/what-we-do/into-practice/cost-saving-guidance

The extent to which clinical practice guidelines can impact disinvestment is not clear. A study of NICE recommendations made in 2004 regarding the discontinuation of two fertility procedures and caesarean section found no decline in the use of the procedures (Chamberlain et al. 2013).

NICE produces a range of other outputs, including the production of quality standards and indicators, designed to measure and improve quality of care and which can be used to track variations in care.

Evidence-Based Interventions Programme

In the absence of a formal disinvestment framework at NICE, the NHS has developed a program commencing in 2017 the goals of which are to:

- Reduce avoidable harm to patients. With surgical interventions, there is always a risk of complications. Weighing the risks and benefits of appropriate treatments should be co-produced with patients.
- Save precious professional time, when the NHS is severely short of staff, professionals should offer appropriate and effective treatment to patients.
- Help clinicians maintain their professional practice and keep up to date with the changing evidence base and best practice.
- Create headroom for innovation. If we want to accelerate the adoption of new, proven innovations, we need to reduce the number of inappropriate interventions. This allows innovation in healthcare, prescribing and technology to improve patients' ability to self-care and live with long-term conditions.
- Maximise value and avoid waste. Inappropriate care is poor value for the taxpayer. Resources be focused on effective and appropriate NHS services (NHS England 2019).

The Evidence-Based Interventions Programme is a collaboration between the NHS, NICE and the Academy of Medical Royal Colleges. The focus of the program is on interventions while another similar program has a focus on medicines ('Items which should not be routinely prescribed', see below). In both cases, the output is a list of interventions or medications that should not be used in routine care.

The development of the list was undertaken by initially identifying recommendations from NICE guidance, Choosing Wisely, academic studies and local Clinical Commissioning Groups (CCGs) work. This large group was then shortlisted by working with stakeholders (clinical groups, clinical commissioners, patients), considering variation and ease of implementation, and alignment with other national programs (NHS RightCare and NHS Improvement's Getting It Right First Time). The draft shortlist went to public consultation, following which the 17 interventions were finalised.

The Evidence-Based Interventions Programme has produced patient leaflets and videos for all interventions and sits within the broader goal of embedding personalised care across England, and facilitating shared decision-making between patients and clinicians (Markham 2019). However, the guidance is statutory, and compliance is mandated.

There are two categories of interventions:

- Category 1 Interventions - interventions that should not be routinely commissioned or performed.
- Category 2 Interventions - interventions that should only be routinely commissioned or performed when specific criteria are met.

For category 1 interventions, there is no reimbursement, and they can only be accessed with an Individual Funding Request. For category 2 interventions, clinicians must demonstrate that patients meet the criteria specified in the guidance. The guidance specifies the activity levels expected for the 17 interventions, and

this will be facilitated with a data dashboard on activity, audits to review compliance and the development of an indicator to measure performance.

Table 3.6 Interventions that should not be routinely used and their activity levels

Category	Intervention	Total activity (2017/18)	Variation (n fold variation)[1]	Activity reduction opportunity	Remaining activity
1	Intervention for snoring (not OSA)	812	-[2]	812	0
1	Dilatation & curettage for heavy menstrual bleeding	236	-[2]	236	0
1	Knee arthroscopy with osteoarthritis	3,437	11.3	3,437	0
1	Injection for nonspecific low back pain without sciatica	13,165	31.4	13,165	0
2	Breast reduction	2,388	8.4	829	1,559
2	Removal of benign skin lesions	116,255	4.1	45,589	70,666
2	Grommets	8,669	6.2	3,259	5,410
2	Tonsillectomy	32,238	3.0	7,454	24,784
2	Haemorrhoid surgery	8,474	4.3	2,801	5,673
2	Hysterectomy for heavy bleeding	27,660	3.3	6,536	21,124
2	Chalazia removal	6,026	29.7	4,326	1,700
2	Shoulder decompression	13,930	9.1	6,807	7,123
2	Carpal tunnel syndrome release	44,497	5.3	14,950	29,547
2	Dupuytren's contracture release	14,376	4.1	4,113	10,263
2	Ganglion excision	6,219	6.4	2,509	3,710
2	Trigger finger release	7,789	5.7	2,582	5,207
2	Varicose vein surgery	28,846	8.0	8,633	20,213

Abbreviations: OSA, obstructive sleep apnoea

Notes: 1. the ratio between the 10th highest and 10th lowest age-sex standardised rate between Clinical Commissioning Groups (CCGs). 2. There are CCGs with no activity so can't be calculated.

Source: NHS England (2019)

The Evidence-Based Interventions Programme is a relatively new approach to disinvestment in England and therefore there is not yet any evaluation of its effectiveness. There has been published criticism of the approach, citing the threat to clinician-patient dialogue and autonomy and inconsistency between treatment criteria and NICE recommendations for some interventions (Puntis 2019).

Items that should not be routinely prescribed

The guidance on items that should not be routinely prescribed was first published in November 2017 and updated in June 2019. It includes 17 items (of 18) from the 2017 list, and an additional seven items. Unlike the interventional guidance, this guidance is general as opposed to statutory, with no changes to financial arrangements (Lacobucci 2017). However, dashboards have been developed to monitor prescribing patterns for each item and a Low Priority Prescribing indicator is being developed.

A clinical working group considered items for inclusion if they were:

- Items of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns.
- Items that are clinically effective but where more cost-effective products are available, including products that have been subject to excessive price inflation.

- Items that are clinically effective but, due to the nature of the product, are deemed a low priority for NHS funding.

There was a period of public consultation on the draft guidance before the final guidance was published. The guidance is due to be reviewed at least annually (NHS England and NHS Improvement 2019). Brief (4-9 pages) rapid evidence summaries were produced for several of the items.

Initial data suggests the list may have reduced some prescribing in general practice[26].

3.3.5 France

The French healthcare system is a mixed type, with a single public payer. The Statutory Health Insurance (SHI, Sécurité Sociale) covers almost 100% of the resident population, but only about three-quarters of health spending, with the remainder including patient out of pocket costs and supplementary health insurance (Parkinson et al. 2015).

The Transparency Committee (TC) at the Haute Autorité de Santé (HAS), or French National Authority for Health, assesses a drugs clinical benefit ("service médical rendu" [SMR]) and the added clinical benefit (amélioration du service médical rendu [ASMR]) to decide whether a drug should be included on the reimbursable list and to set prices. Reimbursement rates vary between 0% for 'no or inadequate therapeutic value', 15% for low therapeutic value, 35% for 'moderate therapeutic value' and 65% for 'major or considerable therapeutic value.' Disinvestment mainly involves de-listing or price reductions (Parkinson et al. 2015).

Between 2000 and 2004, the TC comprehensively re-evaluated 4,490 drugs on the market, and those with an SMR rating of 'insufficient' (n=835) were removed from the list. The 'insufficient' drugs included those that had been superseded, those considered dangerous, and those no longer considered effective. An additional 617 drugs had their reimbursement rate reduced from 65% to 35%, but the changes were heavily contested by industry resulting in re-evaluation of 763 drugs in three waves between 2003 and 2006 (Parkinson et al. 2015).

Following these reviews, France has implemented a mandatory requirement (by law) to re-assess the clinical benefit (SMR) of listed drugs every five years after the date of first listing to determine whether the medicine should still be reimbursed and at what level. 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, and safety concerns from the European Medicines Agency (EMA) such as a new assessment by the Pharmacovigilance Risk Assessment Committee (PRAC), the Agence nationale de sécurité du médicament et des produits de santé (ANSM), or the United States Food and Drug Administration (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. For the re-assessment, companies submit new clinical data; if major concerns are not identified the assessment follows a simplified process (Pant, Boucher, and Frey 2019).

In addition to these systematic re-assessments, the TC may also undertake *ad hoc* re-assessments requested by the Ministry of Health, a pharmaceutical company, or by HAS. The scope of these re-assessments can include the SMR, the ASMR (which has an impact on the price of the product) and also the target population, the comparators, and the impact on public health. If the re-assessment is conducted at the request of the Ministry of Health or HAS, it may relate to only one product or to several products (with

[26] http://www.pulsetoday.co.uk/clinical/clinical-specialties/prescribing/analysis-gp-prescriptions-drop-by-almost-one-million/20037057.article

the same indication and/or belonging to the same therapeutic class) (Pant, Boucher, and Frey 2019). Two examples of class re-assessments are drugs for hypertension and 3rd generation oral contraceptives [27].

Drugs only available at hospital pharmacies (that is, included only in the 'hospital list') do not fall under the mandatory five-year re-assessment program (described above). They may instead be re-assessed through the *ad hoc* re-assessment mechanism (Pant, Boucher, and Frey 2019). In 2017, the TC re-assessed 209 drugs under its systematic process, of which 206 remained unchanged. In contrast, in the same year, 25 drugs were re-assessed on an *ad hoc* basis (11 at the request of the pharmaceutical company), of which 16 had a change in reimbursement, showing a higher yield in the *ad hoc* than the mandatory re-assessments[28].

3.3.6 Italy

An Italian methodological project was undertaken concluding in 2015 with the aim of developing a systematic and integrated approach to identify obsolete (non-drug) health technologies and to plan the implementation of new technologies (Calabrò et al. 2018). The report is not published in English, and it is not clear whether further work has been undertaken or the extent to which disinvestment activities are ongoing in Italy.

With respect to the reimbursement of drugs, this is managed by the Italian National Health Service, and a national medicines agency (Agenzia Italiana del Farmac; AIFA) is responsible for making reimbursement decisions. Two features of the Italian approach are noted (Palozzo and Messori 2016) in relation to the disinvestment of pharmaceuticals: firstly, most innovative drugs in Italian hospitals are assigned to national patient-level registries in which clinical indications and outcomes are recorded. The registries are managed by AIFA as part of a mandatory surveillance program and can be used for disinvestment decisions, mostly a reduced payment due to lower effectiveness than suggested in clinical trials. Secondly, in 2012, a national regulation was issued in Italy under which local tenders for drugs belonging to the same pharmacological class were no longer allowed within the Italian National Health Service, unless AIFA certifies that the agents are therapeutically equivalent. The law was initially problematic for disinvestment, as it limited the ability of hospitals to select a single drug in a pharmacological class. However, the law also led to methodological developments in determining equivalence, which has supported disinvestment (Palozzo and Messori 2016).

3.3.7 Netherlands

An early example of priority setting was the Dutch Investigative Medicine Program, which in 1997 produced a list of 126 existing technologies of doubtful efficacy based on cost-effectiveness and societal relevance (burden of disease, clinical uncertainty, potential benefits and impact) (Orso et al. 2017).

A more recent identification and priority setting project has been undertaken as part of an ongoing Dutch Program 'To Do or Not To Do' run by the Dutch Federation of University Medical Centers and The Netherlands Organisation for Health Research and Development (ZonMW)[29]. The identification was undertaken by reviewing Dutch Clinical Practice Guidelines. The review identified 1,366 low-value services from 193 guidelines (from 2010 to 2015). The list was compared with NICE's 'Do Not Do' list and found to contain more services (Wammes et al. 2016).

The 'To Do or Not To Do' program has three goals:

- identify what care is of low value
- study how low-value care can be reduced sustainably
- reduce low-value care in clinical practice.

[27] https://www.has-sante.fr/upload/docs/application/pdf/2014-03/pricing_reimbursement_of_drugs_and_hta_policies_in_france.pdf
[28] https://www.has-sante.fr/upload/docs/application/pdf/2018-07/rapport_activite_commission_transparence_2017.pdf
[29] https://www.doenoflaten.nl/en/

It has conducted a series of demonstration projects, some involving RCTs, considering the effectiveness of implementing strategies to reduce low-value care. The projects do not appear to have included formal de-listing, but focused on strategies such as education, feedback, clinical champions and patient information.

3.3.8 Scotland

The Scottish Health Technologies Group (SHTG) conducts HTA for non-drug technologies in Scotland and has undertaken some work in disinvestment, establishing a steering group in April 2011, MaCSWise 'Making Choices, Spending Wisely,' (Leggett, Noseworthy, et al. 2012); however, information on the output of this group is no longer available.

In their current action plan, SHTG states an intent to "develop processes to support HTA throughout the technology life cycle; for example, re-assessment, disinvestment and review of previous work[30]" but no further details were identified.

Scotland has also developed a program of work around 'Realistic Medicine' which focuses on six core principles:

1. building a personalised approach to patient care
2. changing style to shared decision-making
3. reducing harm and waste
4. tackling unwarranted variation in practice and outcomes
5. managing risk better
6. becoming improvers and innovators in healthcare (Fenning, Smith, and Calderwood 2019).

The approach appears to be a passive one, not involving active disinvestment. A similar initiative has been developed in Wales called 'Prudent Healthcare,' and, at arm's length from the NHS, in England called 'Rethinking Medicine' (Marshall, Cornwell, and Collins 2018).

3.3.9 Singapore

Singapore has a mixed public-private healthcare system in which the public sector delivers 80% of acute care and 20% of primary care, with the balance of care delivered by private sector providers (Pearce et al. 2019). The Agency for Clinical Effectiveness (ACE) was established in 2015 to consolidate and expand national HTA capacity, taking on roles previously conducted by the Ministry of Health (Pearce et al. 2019).

The ACE does not have a formal disinvestment program or framework, however its methodological guidance notes that drugs recommended for subsidy will be reviewed after 3 years[31] and technologies after 2-5 years[32]. In both cases, the process outlined is a literature search by the technical team to determine whether there is any new clinical evidence or cost information which may affect the decision or guidance. Where new information has been published, the topic is scheduled into the work plan for re-evaluation.

In addition to this review process, the ACE produces Appropriate Care Guides (ACGs), which 'provide concise and evidence-based recommendations on care practices and pathways to guide specific areas of clinical practice.' Topics are shortlisted for development based on the following:

1. alignment with national health priorities

[30] http://www.healthcareimprovementscotland.org/our_work/technologies_and_medicines/shtg/about_shtg.aspx
[31] http://www.ace-hta.gov.sg/public-data/our-process-and-methods/ACE%20methods%20and%20process%20guide%20for%20drug%20evaluation%20(5%20Feb%202018).pdf
[32] http://www.ace-hta.gov.sg/public-data/our-process-and-methods/ACE%20methods%20and%20process%20guide%20for%20medical%20technologies%20evaluation%20(1%20Oct%202018).pdf

2. disease burden
3. evidence of suboptimal outcomes
4. practice variation
5. knowledge gap
6. potential impact on patient outcomes[33].

ACGs are also developed as an extension of drug and non-drug technology guidance.

A local disinvestment project has been conducted in Singapore involving two hospitals, one specialist centre and nine primary care institutions, which form a regional public health system cluster (Lim et al. 2018). The objectives of the disinvestment program were:

a) to create awareness of opportunities to disinvest health technology that deliver no or low health gain for its cost
b) to optimise patient care by ensuring effective, safe and cost-effective use of a health technology
c) to contribute towards a sustainable healthcare through the efficient use of resources.

The four key processes were:

1. identifying disinvestment opportunities
2. establishing prioritisation processes
3. assessing evidence on low-value health technologies and practices
4. implementing and evaluating disinvestment.

The approach utilised existing lists of low-value technologies and practices, which identified 314 candidates relevant to the local context which then underwent stakeholder engagement and prioritisation. The prioritisation criteria (clinical impact, clinical use [i.e., variation], financial impact and timeliness of evidence review) were considered by a panel of senior clinicians and key opinion leaders and nine technologies underwent re-assessment. Evidence appraisal was undertaken using rapid HTA methods, utilising existing clinical practice guidelines and HTAs in the first instance, followed by targeted searches. Stakeholders disseminated and implemented the recommendations and pre- and post- evaluations were conducted.

Three case studies were presented in the paper (Lim et al. 2018): routine monitoring of statin therapy; routine sodium valproate level monitoring in bipolar disorder; and routine neuroimaging in first-episode psychosis. For all three, a reduction in usage and savings were demonstrated. The authors identified stakeholder engagement in every stage as crucial. The use of information technology also appears to have been important, with changes made to drug or test ordering systems in two cases.

3.3.10 South Korea

Korean health insurance is a single-payer system (National Health Insurance Corporation) and mandates health insurance for all, levied from taxation. Before a positive list system was introduced in 2006, there was a negative list system in which almost all the drugs were listed automatically after being approved by the Korea Food and Drug Administration and prices of drugs were determined without considering cost-effectiveness. In 2006, a Drug Expenditure Rationalization Plan (DERP) was started in Korea in response to high and increasing drug expenditure. The DERP introduced a positive list system, listing only drugs evaluated as therapeutically superior and cost-effective, and planned to re-assess drugs listed prior to the DERP (Lee and Kim 2012).

[33] http://www.ace-hta.gov.sg/our-process-and-methods.html#acg

Initially about 4,000 items which had never been produced or prescribed were delisted, leaving 16,000 items for re-evaluation. Two pilots were initially undertaken of hyperlipidemia and migraine drugs, with other efficacy groups scheduled to follow. However, the assessments lagged behind schedule and encountered significant opposition. As a result, the evaluation framework was changed totally from an economic evaluation to an across-the-board price reduction so as to complete the re-evaluation project for listed drugs as soon as possible and remove the administrative burden placed on all stakeholders including government. The outcome failed with respect to disinvestment and also is not expected to have significant cost-saving impacts. It is hoped the ongoing high drug spending in Korea will lead to a new approach to re-evaluations using a cost-effectiveness approach (Lee and Kim 2012).

The National Evidence-based healthcare Collaborating Agency (NECA) was established in 2008 to take charge of HTA and economic evaluation research of non-drug technologies in South Korea and has also undertaken some work in disinvestment. Informed by a systematic review of international approaches (Seo, Park, and Lee 2016), a four stage HTR model was developed involving identification, prioritisation, re-assessment and decision. Two pilot re-assessments were undertaken in 2015: small bowel capsule endoscopy for patients with suspected small bowel disease; and safety and efficiency analysis of steroid intradiscal therapy[34]. The agency has also undertaken work to develop an information system and legal framework to support HTR and has undertaken 10 HTRs[35] (although details of the these are unavailable in English).

3.3.11 Spain

The Spanish National Health Service (SNHS) is a decentralised public health insurance system with universal coverage. It provides free health care to every resident in all 17 Spanish regions or autonomous communities. The SNHS is managed at a regional level, and there are seven regional HTA agencies in Spain. In 2012, a national HTA network, the Spanish Network for Health Technology Assessment and Services of the National Health System (Red Española de Agencias de Evaluación de Tecnologías Sanitarias y Prestaciones del Sistema Nacional de Salud [RedETS]) was created (Serrano-Aguilar et al. 2019).

Two regional HTA agencies, OSTEBA and Avalia-T, undertook a disinvestment program in 2007, which produced two main outputs: the Guideline for Not Funding Technology (GuNFT, developed by OSTEBA); and the PriTech tool, part of a guideline developed by Avalia-T.

The Avalia-T guideline was developed using a nominal group technique (Ibargoyen-Roteta, Gutiérrez-Ibarluzea, and Asua 2010) and includes consideration of an action plan, whereas the GuNFT focusses on identification, prioritisation and assessment (Ruano Raviña et al. 2007; Ibargoyen-Roteta and Asua 2007).

Accompanying the guidelines was a body of work undertaken to develop a prioritisation tool, PriTech. The tool was designed to undertake side-by-side assessment of technologies and score them in terms of population/users, benefit/risk and cost/other implications (Leggett, Noseworthy, et al. 2012). PriTech was originally available free online although it is no longer available at the cited website.

No studies or reports on the implementation or evaluation of the GuNFT have been identified and the extent to which they are used is not clear. A report on the activities of RedETS noted that an ongoing challenge was “reinforcing HTA on disinvestment and its impact assessment given that most current RedETS efforts are addressed toward the assessment of new/emerging technologies (Serrano-Aguilar et al. 2019).”

[34] https://www.neca.re.kr/lay1/program/S1T11C145/report/view.do?seq=263
[35] https://www.neca.re.kr/lay1/program/S1T11C216/tech_report/list.do

3.3.12 Sweden

The Swedish Council on Technology Assessment in Health Care (SBU) was established in 1987 and has a history of considering appropriate use and identifying research gaps but does not have a specific model or framework (Leggett, Noseworthy, et al. 2012; Mayer and Nachtnebel 2016).

The Swedish Dental and Pharmaceutical Benefits Agency (TLV) is a government agency responsible for pricing and reimbursement decisions for pharmaceuticals. In 2002, the agency began re-assessing the value of 2,000 medicines that were already reimbursed, with the objective of making more efficient use of resources. The existing medicines have been divided into 49 groups, and a final report specifies which products should continue to be reimbursed in all or some populations. The decision is instigated immediately (Wettermark et al. 2008). The approach has been found to have a positive effect on antihypertensive prescribing (Wettermark et al. 2010); however, more recent initiatives at TLV were not identified in the literature. The review of existing drugs is an ongoing activity[36].

3.3.13 Summary of disinvestment approaches

A summary of the key disinvestment approaches identified in the current review is presented in Table 3.7. The table excludes approaches that are unable to be linked to reimbursement or for which insufficient details were available. The table includes three guidelines for which no evidence of their application was identified (Guerra-Júnior et al. 2017; Ibargoyen-Roteta and Asua 2007; Ruano Raviña et al. 2007). It also includes four HTA approaches that are not explicitly disinvestment initiatives (NICE clinical practice guidelines, NICE Technology Appraisals, CADTH Optimal Use Reports, and CADTH Rapid Response Reports). Therefore, only three of the included approaches are applied, of which one was a pilot (Soril, Seixas, et al. 2018). Of the two remaining, one is the French approach to ongoing drug re-assessments for which we have relied on secondary sources (Pant, Boucher, and Frey 2019; Parkinson et al. 2015) and the other is the NHS England Evidence-Based Interventions Programme for which little published evidence is available.

[36] https://www.tlv.se/lakemedel/omprovning-av-lakemedel.html

Table 3.7 Summary of key re-assessment initiatives identified

Agency conducting the review	Program	Scope	Starting year of program	Identification phase	Prioritisation phase	Assessment phase	Stakeholder involvement	Dissemination of results	Length of process	Barriers and facilitators
AVALIA-T (Spain) (Ruano Raviña et al. 2007)	Identification, prioritisation and assessment of obsolete health technologies: a methodological guideline	Health technologies	2007	Direct search of biomedical literature Review of HTA reports Horizon scanning databases Stakeholders Databases	PriTech tool	Systematic literature review	Work group and panel of experts	NR	NR	Identification of technologies likely to have genuine impact
CADTH (Canada)	Optimal Use Reports	Drugs, diagnostic tests, surgical/ medical/ dental devices, and procedures (excludes health system issues)	NR (approx. 2012)	Can be suggested by any source. Must meet appropriateness criteria: duplication, impact on patient care, available in Canada	Clinical impact Budget impact Population impact Jurisdictional interest Equity	Standard HTA methods Full HTA and may include additional analysis e.g., utilisation, patient survey etc.	Feedback at multiple points (scope, list of studies, draft) Inclusion on committee	Website and knowledge mobilisation tools including plain-language summary	NR Variable depending on methodology	NR
CADTH (Canada)	Rapid Response Reports	Drug, diagnostic test, medical device, medical, dental and surgical procedures	2005	Request from Canadian decision-makers which meets criteria for rapid response	NA	Targeted literature search Output ranges from list of relevant studies to summary of abstracts with critical appraisal	Follow up with customer. Rapid reports do not undergo consultation but the jurisdiction requesting it may conduct its own consultation.	Available on website. Knowledge transfer sometimes created.	5-10 days from topic refinement (list) 2-3 months from topic refinement (critical appraisal of abstracts with external peer review)	NR

Agency conducting the review	Program	Scope	Starting year of program	Identification phase	Prioritisation phase	Assessment phase	Stakeholder involvement	Dissemination of results	Length of process	Barriers and facilitators
HAS (France)	TC Re-assessments (HAS)	Drugs	2000	Mandatory re-assessment *Ad hoc* identification requested by MoH, industry or HAS	'Substantial new information'	Industry submitted evidence plus independent assessment	Industry involvement Others NR	NR	90 days	Few drugs in mandatory re-assessment result in change to reimbursement
HTAC (Canada) (Soril, Seixas, et al. 2018)	HTAC Pilot	Non-drug technologies	2017	NICE 'Do Not Do' recommendations Choosing Wisely Canada List of low-value MBS items	High budgetary impact (defined as more than $1 million in a fiscal year)	NA	Expert advisory committee	Academic paper	NR	Limited clinical consultation Inability to consider clinical variation
MoH Brazil (Guerra-Júnior et al. 2017)	Health Technology Performance Assessment (HTpA)	Health technologies (non-drug [unclear])	2017	Identified by: Horizon scanning Prospective search External demands Inadequate in one of: Safety Effectiveness Cost Cost-effectiveness Disuse Inappropriate use Logistics Availability Acceptability Adequacy Contraindications	Expert panel applying criteria using a matrix: safety, costs, impacts, alternatives, burden of disease, sufficient evidence, possibility of evidence generation, futility	HTA process plus inclusion of additional data on economic resources and clinical results. Also, indicators of access, organisational and logistical aspects	Health professionals, patient organisations, manufacturers and managers useful	Consideration of implementation: engineering (update guidelines etc), education, economy (financial incentives) and enforcement Develop dissemination strategies, particularly patient-relevant	NR	NR

Agency conducting the review	Program	Scope	Starting year of program	Identification phase	Prioritisation phase	Assessment phase	Stakeholder involvement	Dissemination of results	Length of process	Barriers and facilitators
NHS England, NICE, Academy of Medical Royal Colleges	Evidence-Based Interventions Programme	Surgical interventions	2017	NICE Guidance, Choosing Wisely, Academic Work, CCGs	Variation, ease of implementation, stakeholder consultation (clinical, commissioners, patients), alignment with other programs	Existing guidelines (NICE and NICE accredited specialist society guidelines)	Identification and prioritisation conducted with specialist medical groups, patients and commissioners. Open public consultation on draft guidance.	Statutory guidance for CCGs, patient and clinician resources	NR. Consultation from July-Sept 2018. Guidance released Nov 2018 (updated Jan 2019)	NR
NICE (England)	Technology Appraisals	Medicines, medical devices, diagnostics, surgical procedures, therapeutic technologies, systems of care, screening tools	1999	Primarily HSRIC Formal referral required from Secretary of State for Health	Significant health benefit Significant impact on NHS resources and other government policies Inappropriate variation in use across the country	Standard HTA methods Full HTA Clinical and cost-effectiveness (CUA), BIA	Representation on committees, formal consultation, ability to appeal decisions	Publication on website	STA: 61 weeks minimum MTA: 78 weeks minimum FTA: 30 days	Only positive (investment) decisions are mandatory for implement-ation
NICE (England)	Clinical practice guidelines	Condition-specific care and services	2001	Topic oversight group	Discussion between NHS England, DH and Public Health England	Standard HTA methods Full HTA for key questions but not all Clinical and cost-effectiveness, BIA	Representation on committees, formal consultation, ability to appeal decisions	Publication on website May be other strategies including patient information	12-27 months	No ability to implement directly

Agency conducting the review	Program	Scope	Starting year of program	Identification phase	Prioritisation phase	Assessment phase	Stakeholder involvement	Dissemination of results	Length of process	Barriers and facilitators
OSTEBA (Spain) (Ibargoyen-Roteta and Asua 2007)	Guidelines for Not funding (GuNFT)	All health technologies	2007	Application by stakeholders	Criteria proposed by Elshaug, Moss, et al. (2009)	Systematic literature review	Unclear	Action plan (inform applicants, inform patients, inform media, plan for change)	NR	NR

Abbreviations: BIA, budget impact analysis; CCG, Clinical Commissioning Group; CUA, cost-utility analysis; DH, Department of Health; FTA, Fast Track Appraisal; HAS, Haute Autorité de Santé (France); HSRIC, Horizon Scanning Research and Intelligence Centre; HTA, health technology assessment; HTAC, Health Technology Assessment Committee; MBS, Medical Benefits Schedule; MoH, Ministry of Health; MTA, multiple technology appraisal; NA, not applicable; NHS, National Health Service; NICE, National Institute for Health and Care Excellence; NR, not reported; STA, single technology appraisal; TC, Transparency Committee.

3.4 Excluded approaches

Several approaches were excluded from the current literature review but are included within some of the reviews listed in Table 3.2. These excluded approaches are described briefly below.

3.4.1 Choosing Wisely

The systematic review identified nine studies on Choosing Wisely (Colla et al. 2018; Collado 2014; Grover et al. 2016; Grover, McLemore, and Tilburt 2016; Harris et al. 2019; Hines et al. 2013; Howard 2016; Morden et al. 2014; Roth et al. 2018) and there are likely many more. The Choosing Wisely initiative began in the USA in 2012 and aims to promote conversations between clinicians and patients to help choose care that is:

- supported by evidence
- not duplicative of other tests or procedures already received
- free from harm
- truly necessary[37].

The approach has been adopted internationally and now includes over 550 recommendations. It is not an active disinvestment approach, relying on patient and clinician education; however, it is a source for identifying technologies for disinvestment, and could be complementary to other approaches.

3.4.2 Program budgeting and marginal analysis

Eight studies in the literature review considered Program budgeting and marginal analysis (PBMA) (Anderson 2017; Ball, Kemp, and Fordham 2009; Charles et al. 2016; Edwards et al. 2014; Goodwin and Frew 2013; Lim and Anderson 2011; Mortimer 2010; Tsourapas and Frew 2011). These studies were excluded as the approach is an economic approach to assist decision-makers under a fixed budget, which was out of scope.

3.4.3 Clinical practice guidelines

Clinical practice guidelines are discussed in the context of NICE (Drummond 2016). Like Choosing Wisely, they were frequently reported as a source for identifying technologies for disinvestment; however, their intent is not disinvestment. Many countries and clinical specialities produce national clinical practice guidelines that could play a role in re-assessment, either directly or indirectly.

3.4.4 Atlas of Variation

The OECD has identified ten countries with atlases of healthcare variation, and these are considered useful tools to identify and prioritise low-value services and track the effectiveness of interventions to reduce variation (OECD 2017). The merging of HTA and quality and safety functions in both Canada and, to some extent England, is designed to assist in taking a technology lifecycle management approach and has implications for the ability to re-assess and potentially disinvest in technologies.

[37] http://www.choosingwisely.org/our-mission/

3.5 Best practice in post-market reviews and re-assessment

Based on three existing pieces of work (Leggett, Noseworthy, et al. 2012; Leggett, Mackean, et al. 2012; MacKean et al. 2013), a Canadian group has proposed 11 guiding principles for HTR:

1. HTR should be conceptualised as a Mode 2 knowledge-generation activity.
2. HTR is best integrated with other evidence-informed decision-making processes, such as the development of clinical practice guidelines and/or high-value care pathways, and overall quality improvement initiatives.
3. HTR should not be viewed as a separate initiative but rather as a broadening of the scope of traditional HTA.
4. HTR requires high-level political support.
5. The language used to describe HTR is critically important and must be defined.
6. A HTR model must be context-specific and flexible, with an expectation that it will evolve over time.
7. Stakeholders must be meaningfully engaged and ideally embedded within any HTR process.
8. Feasibility assessment, done collaboratively with stakeholders, must be done early in the HTR process.
9. Cost accounting of real savings must be robust and accurate.
10. Monitoring and evaluation are essential and need to be integrated into the HTR process.
11. Monitoring and evaluation processes must be flexible and robust enough to capture unintended consequences (Soril et al. 2017).

The authors also developed a three phase (six step) conceptual model of HTR. There are two foundational components – meaningful stakeholder engagement and ongoing knowledge exchange – which must be engaged throughout the entire process. The model is presented in Figure 3-6.

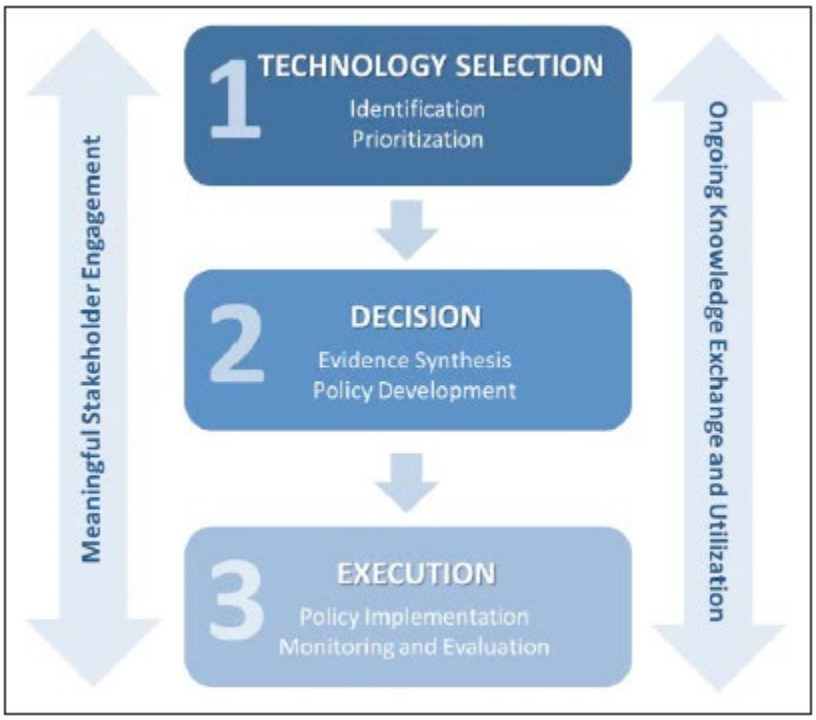

Figure 3-6 A proposed model for HTR (Soril et al. 2017)

Extending on these concepts, the same group has developed a schematic to frame HTR under six major domains each with a specific question to be addressed (Figure 3-7).

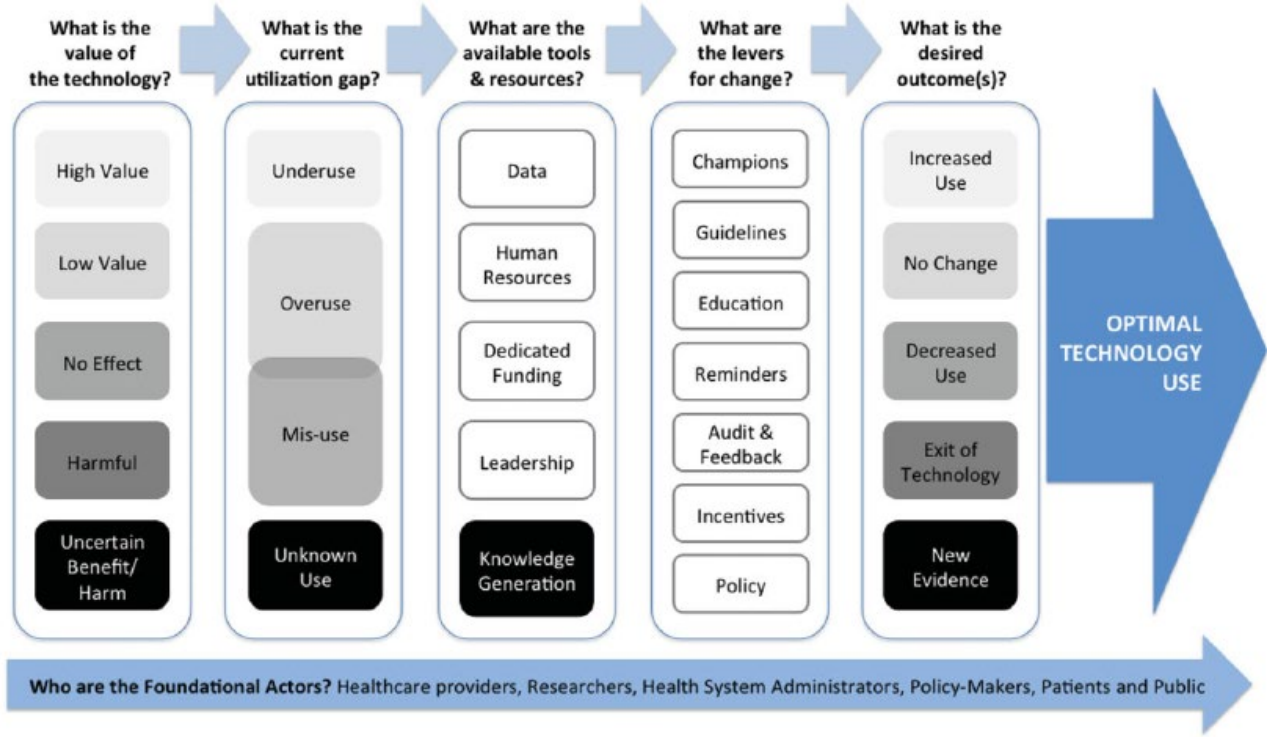

Figure 3-7 Structured framework for optimal technology use (Soril, Niven, et al. 2018)

In CADTH's 2009 policy paper, seven elements of a proposed approach to implementation of a disinvestment program were proposed:

- **Element 1**: High-level decision and commitment is required to make disinvestment an explicit, formal, and resourced policy agenda. This would involve the development of partnerships involving government (provincial and federal), professional colleges, and relevant stakeholder groups including patient and citizen groups to further a disinvestment agenda by fostering awareness raising, collaboration, and improved health outcome data generation and reporting.
- **Element 2**: A regulatory framework for disinvestment decision-making is required that is transparent and removed from vested interests. This may be parallel to existing processes for new and emerging technologies. Elements of the framework may include explicit consideration of formally decommissioning old technologies and practices as new items are approved if there is adequate evidence.
- **Element 3**: Given the strain that exists on committees responsible for new and emerging technologies and practices, consider either (a) additional resources and capacity for those committees to consider existing items in parallel, or (b) the establishment of new, parallel committee(s) to consider existing items.
- **Element 4**: Regulatory support should be provided for HTA recommendations for (a) removing, or (b) reducing reimbursement, or (c) restricting use of a comparator technology if a new or existing item has better clinical or cost-effectiveness for a given indication. These analyses and decisions are dependent upon the maintenance of equity in care.
- **Element 5**: To ensure a maximally productive approach, any process for selecting health care practices with a view to evaluating them for displacement should follow a protocol with a pre-specified, transparent selection criteria. Funding could be allocated to support a centralised 'horizon scanning' style approach that would facilitate the systematic and transparent identification of existing, potentially ineffective practices on which to prioritise candidates for assessment as to their safety, clinical effectiveness, and, where appropriate, cost-effectiveness. The process could be jointly funded by all relevant stakeholders but centrally administered, with an HTA group resourced to undertake identification and assessment and to liaise with clinicians, consumers, and funding stakeholders. Final HTA reports of chosen candidates could be disseminated to provincial regions for contextualisation to the local environment.
- **Element 6**: There is panoply of options in terms of guideline and/or reimbursement levers to effect disinvestment. Debate is essential among all relevant Canadian decision-making stakeholders as to which of these mechanisms, or combinations thereof, are most appropriate within a given jurisdiction at impacting effective disinvestment. However, international experience of the impact of HTA processes strongly supports the need for leverage at the reimbursement level to effect positive and lasting reform.
- **Element 7**: A dedicated stream of funding for capacity building in research and policy development in disinvestment is required. An explicit disinvestment agenda will require the development of new and transparent methods to dovetail with existing HTA capacity. This will require initial capital input to support stakeholder consultations, a working disinvestment development and implementation plan, and policy reform. Pilot funding should be provided to a Canadian organisation with appropriate skills, knowledge, and broad-based oversight to commence this work (Elshaug, Watt, et al. 2009b).

3.6 Barriers and facilitators

A comprehensive discussion of barriers and facilitators to HTR with a particular focus on knowledge translation is presented in Table 3.8, categorised according to a World Health Organization (WHO) classification scheme from the work of Esmail et al. (2018).

In interviewing key informants, the key barriers frequently cited included:

- a poor evidence base
- political push back
- a large investment of work and time for relatively small cost savings
- influence of industry
- difficulty communicating with a variety of audiences.

Many methods for mitigating these barriers were proposed with the top two being stakeholder engagement and champion involvement (Leggett, Mackean, et al. 2012).

The review for the LBI-HTA conducted in 2011, identified the following challenges to disinvestment:

- Terminology: wide variation in terms to describe disinvestment
- Resources: both financial and expertise
- Framework: no evaluation of methodologies and no understanding of what best practice is
- Availability of evidence: often lacking for existing technologies
- Duplication of effort: particularly likely in decentralised systems
- Local priorities and multiple interests: including the influence of clinicians, patient groups, suppliers etc. (Gerdvilaite and Nachtnebel 2011)

Table 3.8 Barriers and facilitators to HTR, disinvestment, de-implementation and de-adoption as reported in Esmail et al. (2018)

Modified WHO Classification	Sub-categories	Barriers	Facilitators
Climate and Context Individual's negative attitudes, overall sense of political will, and openness to research	Health Care Providers	Physicians are reluctant to dismiss outmoded devices and procedures Lack of incentives to decrease or remove technologies	Use of clinical champions Involve clinicians to increase buy-in Address perceived net benefit to patients
-	Patients/Public	Removal of technologies and procedures may cause concern for health professionals and patients who will view the exercise as a reduction of available health services	Shared dialogue
-	Political/Social/ Decision-makers	Political and social barriers/push back Absence of political drive Lack of support from decision-makers Lack of collaboration	Political support Government interest Local/national relationships Policy regulations and restrictions Encouragement of political discussion and raising awareness before and during implementation

Modified WHO Classification	Sub-categories	Barriers	Facilitators
Linkage and Exchange Underlying linkage and exchange between researchers and knowledge users, policy makers and stakeholders	-	Lack of a well-planned implementation strategy that involves all stakeholders and is aligned with the initial goal of the program Absence of strong leadership Concept of low-value care not understood Cost savings viewed as unfavourable	Broad and early stakeholder engagement Meaningful stakeholder engagement and ongoing knowledge exchange A dissemination strategy tailored to target groups Consideration of local contexts Use of clinical champions Address perceived net benefit to patients Public representative's involvement in the process to increase knowledge of the HTR process Shared dialogue Do not frame as 'waste' but focus more on 'harm' and staged testing and treatment Co-ordination/collaboration/professional understanding
Research Evidence, a Structured HTR Process, and Resources Timeliness, relevance and local applicability of research	-	Lack of methods to identify technologies with uncertain cost-effectiveness Lack of understanding and expertise of HTR Lack of approaches to conduct an HTR that are transparent Lack of relevant evidence of the technology itself	A structured evidence-based process that includes transparent methods for identification, prioritisation, and assessment of ineffective health technologies Good evidence base for identification and recommendations Mitigate with clear identification and prioritisation criteria Additional human and financial resources for sustainable implementation
Role of Researchers and HTR The role of researchers is facilitating the transfer of research which includes views of their own role, communication skills, and packaging of the research results	-	Researchers may not understand their role Financial resources for HTR Lack of resources and human resources to support HTR Large investment in work and time required for HTR Difficulty in communicating with a variety of audiences and public perceptions	Capacity building in KT and change management Understanding KT theories, models and frameworks and use of effective and multifaceted KT interventions Development of a KT strategy to ensure uptake of HTR recommendations

Abbreviations: HTR, health technology re-assessment; KT, knowledge translation.

4 Synthesis of findings

4.1 Synthesis of findings

As outlined in Section 1, the primary policy question for the current literature review (What are best practice approaches to health technology and service re-assessment and what enables such approaches to be implemented?) was comprised of three sub-questions. The findings from the literature review are discussed below by sub-question, followed by a discussion of the limitations of the current review, and an analysis of the extent to which best practice approaches in re-assessment could be adopted in Australia.

4.1.1 Identification and prioritisation of technologies for re-assessment

The identification and prioritisation of technologies for re-assessment is the most widely addressed aspect of re-assessment approaches in the published literature. Brazil, Canada, England, France, the Netherlands, Singapore, South Korea, Spain and Sweden were found to have documented processes for identifying technologies for re-assessment. Six of these countries (Brazil, Canada, England, the Netherlands, Singapore, and South Korea) also have documented processes or methods for prioritising re-assessments. However, the extent to which these processes for identification and prioritisation have been operationalised in each country is difficult to ascertain from the published literature.

Approaches to identification

The methods used to identify technologies as candidates for re-assessment include: wide use of 'Choosing Wisely' or other 'low-value care' lists; recommendations from clinical practice guidelines; referrals from clinicians, patients, or government; and planned re-assessment at a fixed timepoint following an initial decision to list/fund a technology. Broader horizon scanning to anticipate health system and technology trends (as recommended by CADTH) does not appear to be an integral part of the identification process in any of the countries covered in the literature.

Approaches to prioritisation

A number of different approaches were found for prioritising technologies for re-assessment. Each approach employed multiple criteria such as: likely impact on patient-relevant health outcomes; impact on health care expenditure; the size of the population affected/using the technology; impact on equity; impact on related government policies; evidence of significant variation in use of a technology across the country; or the potential to resolve confusion or controversy regarding the use of a particular technology. While Canada uses a scoring system for prioritisation, it does not appear that any country uses formal MCDA to prioritise technology re-assessments[38]. NICE in England has been criticised for using the same criteria to prioritise technology assessments for disinvestment decisions as for investment decisions.

4.1.2 Approaches used for re-assessment

Types of HTA reports

Based on the findings from the literature review it appears that the majority of countries undertake full HTAs, at the time of re-assessment. Although a number of countries are implementing rapid HTAs, the extent to which these are used for re-assessment versus assessment is not clear. The CADTH rapid HTAs exclude economic analyses. One exception to this is France, where re-assessments of medicines follow a

[38] Although Brazil cites the use of 'MCDA' it does not appear to be a formal MCDA process, but a listing of the criteria on which judgements may be based.

simplified process if no major concerns with the medicine have been identified. Rapid assessments typically focus on clinical evidence and often utilise existing secondary data (i.e., clinical practice guidelines, HTAs and systematic reviews). Whether or not other HTA domains are included in the simplified assessments is not clear from the literature.

HTA methods and data sources

In general, it would appear that most countries use standard HTA methods for re-assessments, with a reliance on administrative utilisation data, extended safety data collected for regulatory purposes, and the emergence of new or updated clinical evidence. The potential for using RWE to inform re-assessments is acknowledged by many countries but has not yet been widely adopted in a systematic manner. The exceptions to this are: Brazil, which has published a framework for the prospective collection of RWE for the purpose of informing future re-assessments; and Italy, which has a requirement for most innovative pharmaceuticals to be included within patient-level registries to track any differences between clinical trial-based efficacy and real-world effectiveness. None of the literature identified herein referred to specific guidelines for the use of RWE within HTR.

4.1.3 Approaches to implementing decisions based on re-assessment

The approaches employed by countries to implement decisions based on HTR are generally poorly described in the literature (by contrast, there is much literature regarding the broader topic of initiatives to encourage 'appropriate' use of health care – but this aspect of implementation was beyond the scope of the current literature review). That said, there is general support for implementing a multifaceted approach when a listing changes, including activities such as providing patient and clinician information, developing a quality indicator, and tracking subsequent utilisation change(s).

One example of revised funding decision-making based on HTR is in France, where the relevant committee can modify the place of a medicine in the relevant 'therapeutic strategy' (i.e., its line of treatment) based on the findings from an HTR. Another example is Italy, where analyses of patient registry data are used to reduce the price paid for pharmaceuticals on the basis of lower effectiveness in practice than demonstrated in clinical trials.

The Evidence-Based Interventions Programme in England is taking a multifaceted approach to implementation and includes both statutory compliance, with the tools to monitor this, and patient and clinical education resources.

4.2 Limitations of the current review

4.2.1 Presence of reporting bias

Although our literature search used a range of relevant search terms and synonyms for disinvestment and re-assessment and made use of pearling techniques and the grey literature, it is possible that not all relevant information was included. As noted in previous systematic reviews of this topic, HTR activities will be missed if they occur in non-academic settings with no motivation for publication or public release (Leggett, Noseworthy, et al. 2012). This will be particularly true for countries where HTA and HTR is undertaken predominantly by government, where key aspects of the assessment activities may be confidential or not available publicly. Consequently, no matter how comprehensive the literature search, the information that is found is likely to be fragmented and incomplete due to reporting bias.

4.2.2 Lack of quality appraisal of included literature

As described in Section 2, quality appraisal of included studies was planned, but was judged to be inappropriate given the descriptive, non-comparative nature of the included literature.

4.2.3 Absence of evaluation of HTR approaches

No evaluations of specific disinvestment or re-assessment initiatives were identified from any country. Consequently, it is difficult to determine the relative value of the different aspects of HTR, or the health system context in which the HTR occurs, that contribute to the success or failure of the overall approach.

5 Application of findings to Australia

In order to apply the findings from the current literature review to the Australian context, we first present a summary of current post-market review and re-assessment activities across multiple arms of government, and we then present an analysis of the extent to which current approaches in Australia align with internationally-recognised best practice in HTA (using the HTA domains mapped out by the HTAi Policy Forum). Finally, we identify opportunities for Australia to adopt or adapt best practice approaches within specific HTA domains.

5.1 Summary of current re-assessment approaches in Australia

Although a detailed description of current Australian post-market review and re-assessment activities is beyond the scope of this report, a summary of key features of different approaches is summarised in Table 5.1. This summary is presented using the same descriptors used for the international approaches described above. The summary of Australian approaches is based on information in the public domain, the authors' knowledge of Australian Commonwealth Government processes, and additional information provided by Departmental officers.

The summary focuses on activities within the Health Financing Portfolio of the Commonwealth DoH, but it is noted that activities within other portfolios (e.g., the Health Systems Policy and Primary Care Portfolio) could potentially encompass HTA and HTR principles, and/or may be able to provide relevant cross-portfolio advice for HTA/R undertaken within the Health Financing Portfolio.

Furthermore, it is noted that HTR is known to occur at the jurisdictional and local level in Australia, and there might be 'hospital-based HTA' findings that could be usefully applied in the Commonwealth context. For example, the Centre for Clinical Effectiveness at Monash Health has published a series of papers describing the development of the Sustainability in Health care by Allocating Resources Effectively (SHARE) program (Harris, Allen, Brooke, et al. 2017; Harris, Allen, King, et al. 2017; Harris, Allen, Waller, and Brooke 2017; Harris, Allen, Waller, Dyer, et al. 2017; Harris, Allen, Waller, Green, et al. 2017; Harris, Green, and Elshaug 2017; Harris, Green, et al. 2017b, 2017a; Harris, Ko, et al. 2017). The aim of the SHARE Program was to establish organisation-wide, systematic, integrated, transparent, evidence-based systems and processes for decision-making about disinvestment in the context of resource allocation at Monash Health. The series of papers provide a very detailed description of the program, and barriers and facilitators to its implementation, and are designed to provide practical information to inform and assist others.

Table 5.1 Examples of current re-assessment activities within the Commonwealth Department of Health

Part of government conducting the review	Program/ section	Scope	Starting year of program	Identification phase	Prioritisation phase	Assessment phase	Stakeholder involvement	Dissemination of results	Length of process
TAAD; Commonwealth Department of Health	DUSC	PBS-listed drugs	1988	Routine monitoring at 24 months for major listings Other *ad hoc* reviews of a class or category	Budget impact Population impact	Analysis of PBS utilisation data	Sponsor and peak body/clinician feedback	Public report on website[39]	variable
TAAD; Commonwealth Department of Health	Post-market Reviews	PBS-listed drugs	2013	Recommended by the PBAC due to concerns related to the quality use of a medicine, cost-effectiveness, clinical effectiveness, higher than predicted utilisation and/or international differences	Clinical impact Budget impact Population impact Jurisdictional interest Equity Requires Ministerial approval	Full HTA • Literature review • Utilisation analysis • Economic analysis • Other	Feedback at multiple points • public consultation on draft Terms of Reference • public submission process • a stakeholder forum • comments on draft report	Public report on website[40]	~12 months
TAAD; Commonwealth Department of Health	Immuno-globulin Review; Post-market Reviews	NPL-listed immuno-globulin	2018-	Review of local utilisation data	Clinical impact Budget impact Population impact Jurisdictional interest Equity	Full HTA • Literature review • Utilisation analysis (Blood STAR) • Economic analysis • Other	Feedback at multiple points • public consultation on draft Referral • sponsors provided with ratified PICO for input to the contracted assessment • public consultation on draft report	Public report on website[41]	~18 months

Abbreviations: DUSC, Drug Utilisation Subcommittee; HTA, Health Technology Assessment; NPL, National Product List; PBAC, Pharmaceutical Benefits Advisory Committee; PBS, Pharmaceutical Benefits Schedule; PICO, Population, Intervention, Comparator, Outcomes; TAAD, Technology Assessment & Access Division

[39] http://www.pbs.gov.au/info/industry/listing/participants/public-release-docs/dusc-utilisation-public-release-docs
[40] http://www.pbs.gov.au/info/browse/reviews
[41] https://www1.health.gov.au/internet/main/publishing.nsf/Content/ig-review-pilot-process

5.2 Transitioning to the new HTA paradigm in Australia

The 'new HTA paradigm' described by the HTAi Policy Forum is essentially a summary of best practice approaches to health technology assessment and re-assessment. The paradigm takes a technology lifecycle approach, and promotes a more collaborative, patient-centred approach to HTA.

Based on our analysis of the findings from the literature included here, no country is currently implementing best practice across all the domains of HTA, but a number of countries are developing or have introduced best practice approaches for one or more HTA domains.

Opportunities for Australia to adopt or adapt specific international approaches are discussed in the following section, with reference to the specific HTA domains mapped out by HTAi.

As discussed in Section 3.1.1, a 2016 HTAi Policy Forum presented a new HTA paradigm describing how HTA needs to innovate in order to best support health systems under fiscal constraint (Husereau et al. 2016) (Table 3.1). This new paradigm reflects a broader view of HTA as an approach to investment and disinvestment decision-making and health care sustainability.

It is worth noting that many of the 'innovative' HTA approaches listed by the HTAi Policy Forum are already employed within one or more of the HTA processes of the Australian government. The table below details our understanding of how the different HTA approaches listed by the HTAi Policy Forum are currently used within Pharmaceutical Benefits Advisory Committee (PBAC), Medical Services Advisory Committee (MSAC) and/or Prostheses List Advisory Committee (PLAC) processes. The shading in the right-hand column of the table indicates the following:

- Green: the particular HTA approach is already well-addressed or incorporated within Australian government HTA processes.
- Yellow: the particular HTA approach is partially addressed or incorporated within one or more Australian government HTA processes.
- Red: the particular HTA approach is currently absent from all Australian government HTA processes.

Table 5.2 How the changing HTA paradigm applies to Australia

Established HTA approach	Innovating in HTA	Current status of HTA and HTR in Australia
Patient involvement	Patient-driven priorities	HTA Consumer Consultative Committee, and Consumer Engagement Unit within the OHTA is already established and exploring approaches for enhanced consumer engagement with HTA, and the appropriate inclusion of the patient perspective and patient-relevant outcomes; but most HTAs are industry- or clinician-driven, and most HTRs are government-driven.
Focus on the technology (single and multiple technology assessments)	Focus on disease pathology and patient pathway	HTAs tend to focus on single technologies because the HTA processes are sponsor-driven; most (but not all) HTRs tend to focus on a class or group of related technologies rather than all management options for a specific clinical condition; there is little to no planned co-ordination between Australian clinical practice guideline development and Australian HTA and HTR.
Unilateral stakeholder liaison (manufacturer–regulator), absence of service delivery	Multilateral stakeholder dialogue and collaboration, including health service delivery perspective	Most HTAs by the PBAC and MSAC are predominantly unilateral (applicant–government) except for PLAC considerations which explicitly include a (private) health system perspective within the assessment process; HTRs tend to be multilateral but do not always include a health service delivery perspective.
Focus on 'front end' innovation	Whole technology life cycle, from entry to exit	HTR processes for PBS- and MBS-listed items are well established with a commitment to adopt best practice methods; HTR processes for PL-listed items are nascent.
Scientific advice	Scientific dialogue (during specific HTAs)	Scientific dialogue is evident during PBAC and MSAC processes (PSCRs, PCRs, PSDs) and is under development for PLAC processes; additional opportunities for scientific dialogue also provided as required via PBAC/MSAC Pre-submission Meetings, Hearings, and Stakeholder Meetings.
	Scientific dialogue (outside specific HTAs)	There are examples of HTA committees being proactive in stating evidence requirements and supporting evidence development after an HTA received a negative assessment (e.g., alignment of HTA information gaps and targeted calls for research via the MRFF); limited government-initiated dialogue with sponsors and patients/consumers regarding evidence requirements outside of specific HTAs.
Review of submitted evidence	Aligned, co-produced, real-time, RWD	HTA and HTR is still largely based on review of submitted clinical evidence and/or clinical evidence collated by contracted HTA groups; there is limited production or use of local RWD (real-time or not) other than PBS or MBS data, or Australian patient registry data.
Data/evidence for regulatory approval	Data/evidence for holistic value assessment (regulatory, payer and health service delivery)	PBAC and MSAC processes already include assessment of data and evidence beyond TGA requirements, with clear articulation of payer perspectives(s); similar approaches are in development for PLAC processes.
Continued methodological development	Continued methodological development	Established commitment to ongoing updates to technical guidelines for PBAC, MSAC and PLAC; government already supports the development of new methodologies to support HTA (e.g., establishing equi-effective doses for pharmaceuticals; using linked evidence for investigative tests; evidence for assessing monitoring tests; developing methods for assessing the clinical utility of testing for inherited genetic mutations).

Established HTA approach	Innovating in HTA	Current status of HTA and HTR in Australia
HTA meaningful for regulators and payers	Translation of outputs of HTA in clinical practice (meaningful for clinicians and patients) Enhancing the reach of HTA to clinical practice	Longstanding web publication of PSDs for PBAC and MSAC advice and of HTRs, more recently with the inclusion of lay summaries for non-technical audience; rationale for HTA or HTR decisions often poorly understood and/or contested by clinicians, consumers or health service providers.
Analysing organisational implications	Better integration and information of service delivery issues and planning	PBAC and MSAC HTAs already include assessment of implementation issues from a broader health system perspective and similar approaches are in development for PLAC processes; assessment of de-implementation issues associated with disinvestment decisions is not as well established for any committee.
HTA process complex and time consuming	HTA process agile and adaptive across the life cycle	Further improvements in the timeliness of Australian government HTAs and HTRs is limited by the Department's reliance on static, document-based assessments (see below); truly agile and adaptive processes require appropriate IT investment to leverage efficiencies from a digital-database approach to the accumulation of data and evidence (i.e., 'living systematic reviews').
Static HTA: a single episode at one point in life cycle	Dynamic HTA: continuous/updated assessment	HTA and HTR in Australia still largely a reactive sequence of static assessments at defined points in time, with the exception of planned comparisons of predicted versus actual PBS or MBS utilisation.
	System and resources keep pace as data become available and when/if things change during the life cycle	It is a challenge for HTA/HTR processes to keep pace with new developments as there is no systematic approach to horizon scanning beyond the (limited) medical device surveillance activities of the HTRG (formerly HealthPACT).
HTA confined to assessment of health technologies	HTA beyond the confines of traditional HTA using its approach to support and improve healthcare service	MSAC already uses HTA to assess health care services which do not necessarily involve the use of a specific technology (e.g., consultations, surgical procedures); HTA not used routinely to inform decisions regarding primary prevention interventions.
HTA and value of innovations	HTA and value and affordability of innovations	PBAC and MSAC HTAs and HTRs already include detailed consideration of the value and affordability of new technologies and services from the perspective of the PBS and MBS.
	(how health system can have the capacity to absorb the current and projected level of innovations)	HTA and HTR are undertaken predominantly for technologies and services funded through the PBS, NIP and MBS (and more recently the NPL); HTA and HTR that encompasses impacts at other levels of the health system (private and public payers) is limited.
HTA linked with payers	HTA linked with health system, with those responsible for allocating resources	All HTAs and HTRs undertaken by Australian government already include direct links to payers and payment mechanisms (e.g., PBS, NIP, MBS, PL).
	HTA as a convenor of all parties on how health system needs to develop to get value from innovation	To a limited extent the HTRG acts as a convenor of federal and jurisdictional co-considerations of technologies and services within the broader health system.

International approaches to post-market reviews and technology re-assessment

Established HTA approach	Innovating in HTA	Current status of HTA and HTR in Australia
HTA in a budgetary and health system decision-making with a short-term perspective	HTA taking a medium to long-term perspective in informing health system decision-making	HTAs and HTRs undertaken by the PBAC and MSAC typically take a 5- to 6-year perspective for budgetary considerations; longer term perspectives could be adopted when considering the adoption of technologies or services with significant impacts on workforce, training and/or infrastructure.

Abbreviations: HealthPACT, Health Policy Advisory Committee on Technology; HTA, health technology assessment; HTR, health technology re-assessment; HTRG, Health Technology Reference Group; MBS, Medicare Benefits Schedule; MRFF, Medical Research Futures Fund; MSAC, Medical Services Advisory Committee; NIP, National Immunisation Program; NPL, National Product List; OHTA, Office of Health Technology Assessment; PBAC, Pharmaceutical Benefits Advisory Committee; PBS, Pharmaceutical Benefits Schedule; PCR Pre-Committee Response; PL, Prostheses List; PLAC, Prostheses List Advisory Committee; PSCR, Pre-Subcommittee Response; PSD, Public Summary Document; RWD, Real-World Data; TGA, Therapeutic Goods Administration.

Based on Table 5.2, considerations and options for developing a technology lifecycle approach in which re-assessments are included within Australian HTA processes are discussed. Taking this 'best practice' approach to HTA also necessitates taking a broader view such that the overall goal is of managing technology use with the aim of encouraging best practice in health care, within the context of expenditure priorities and policy objectives of governments at all levels. It is acknowledged that HTA is only one tool used to achieve this goal, working in tandem with safety and quality agencies, regulatory agencies and other stakeholders.

5.2.1 Identification and prioritisation of topics for re-assessment

Patient-driven priorities

The majority of initial technology assessments by the PBAC, MSAC and PLAC are driven by manufacturers or clinician groups, whereas the majority of HTRs are driven by government. It is also noted that the Commonwealth does not appear to be using formal horizon scanning or prioritisation processes in the selection of technologies or services for HTA or HTR.

Although the Commonwealth HTA processes are likely to remain sponsor-driven, there is room for greater patient involvement in the selection of technologies and services for HTR. If a review prioritisation process was introduced that explicitly considers the patient perspective, this could serve as a mechanism for incorporating patient-driven priorities in HTR.

Using HTA to support and improve healthcare

With the broader goal of delivering best practice health care, there are specific triggers that could be used to identify technologies that might be suitable for re-assessment. For example, the Atlases of Variation produced by the Australian Commission on Safety and Quality in Health Care (ACSQHC) are a means of identifying clinical variation for which a formal re-assessment may be a useful step towards better targeting of the technology.

Whenever a new technology is compared with an existing technology that has not itself had its cost-effectiveness assessed, this could trigger a HTA for the comparator technology and/or the broadening of the HTR to consider the value of both the new technology and the grandfathered item.

Focus on disease area and using HTA to support and improve healthcare

The best practice HTA approach has a focus on disease areas or pathways, rather than a narrow focus on single technologies. Such approaches are more common in clinical practice guidelines than HTAs. Australian clinical practice guidelines can show discordance with technologies assessed as cost-effective (or not cost-effective) by the PBAC and/or MSAC, and greater co-operation and earlier discussion between the Office of Health Technology Assessment (OHTA) and guideline developers could lead to greater overall impact within the health system. There could be a role for the National Health and Medical Research Council (NHMRC) to facilitate a two-way dialogue between the Department and guideline developers.

As noted, the overall goal of HTA is to improve health care. Sponsor-driven, single technology assessments focused on investment do not provide the necessary broad view needed to achieve this. There is the opportunity to use HTR as a means to take a different approach that is informed by more stakeholders, especially patients (see above), and which takes a disease pathway approach.

The ability to re-assess a clinical pathway or area rather than specific items is challenging given the output of HTA in Australia is directed towards the reimbursement of individual items (e.g., via the Pharmaceutical Benefits Schedule [PBS], National Product List [NPL], Medicare Benefits Schedule (MBS) or Prostheses List [PL]). Post-market Reviews tend to occur by indication, and can include multiple technologies, but these

tend to be multiple technologies of the same type (e.g., drugs only). There is also *ad hoc* communication between the different HTA areas (e.g., the MSAC may be alerted to recent or concurrent decision-making by the PBAC in a relevant disease area). However, a true disease focus for the Commonwealth requires planned co-ordination of activities across the PBAC, MSAC and/or PLAC to capture the use of multiple types of technologies and services to manage a disease or condition. It is recognised that such co-ordination may not be possible within current Commonwealth HTA and HTR arrangements.

5.2.2 Approaches used for re-assessment

Focus on disease area

An approach to enable better consideration of technologies within a specific disease area could be the development of a reference economic model for specific diseases, which could be funded by the Department and used prospectively within and across the PBAC, MSAC and PLAC. Such models would enable the incorporation of additional data and evidence as it becomes available over time – and could therefore expedite a HTR when it does occur. Indeed, reference models could be used at the time that second- and subsequent-market entrants are considered by a HTA committee – and could be used to inform re-assessment of the first market entrant as well as to inform consideration of the relative cost-effectiveness of the later entrants. Such models would be most useful and cost-efficient (in assessment terms) for clinical areas with a high population burden and/or high budget impact.

Dynamic and adaptive HTA across technology life cycle

Ideally re-assessments would build on HTA work already undertaken, such that new evidence can be integrated into existing work, and also enabling work undertaken by one committee or jurisdiction to be used for assessing a related technology in another committee. To enable this, it would be necessary to explore the use of digital/IT technologies to store and collate evidence (clinical, economic, and real-world, see below) in a standardised way across HTA pathways, facilitating data retrieval, and real-time comparisons between technologies as submissions are received, as well as the addition of evidence for HTR as it becomes available.

Adaptive approaches may also involve greater use of rapid or fit-for-purpose approaches, relying on evidence syntheses undertaken by others (HTAs, systematic reviews and clinical practice guidelines) and/or existing economic models, and focusing on contextualising these to local contexts to reach decisions. However, the use of rapid approaches to evidence review and economic modelling should only be undertaken when there is a clear understanding of the trade-off in methodological rigour for a particular HTA. In addition, rapid approaches are only feasible when the policy or practice question aligns with how the reviews and models developed by others have been framed.

Use of co-produced real-world data

The collection and monitoring of data has great potential to assist in the improvement of health care. The introduction of a new technology is an ideal time to consider what data would assist future re-assessment of the appropriate and effective uptake into the health system. There is the opportunity to specify data collection at the time of listing, either using specific PBS or MBS data, patient registry data or alternative approaches. This data collection is envisaged not as a formal managed access scheme but as a forward-planning approach to enable future re-assessments to answer relevant questions on access, health outcomes, utilisation, and budget impact.

5.2.3 Implementing decisions based on re-assessments

Multilateral stakeholder involvement

As noted in Table 5.2, the PBAC and MSAC HTAs already include an assessment of implementation issues from a broader health system perspective; however, assessment of de-implementation issues associated with disinvestment decisions is not as well established – noting that de-implementation is typically a greater issue for the MSAC than for the PBAC due to implications for workforce and infrastructure planning.

That said, as noted above, there are opportunities to use multiple policy levers to support the implementation of decisions based on HTR: co-ordinated changes to national clinical practice guidelines, development of quality indicators, and the development of audience-specific communication materials.

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Appendix A - Summary of existing reviews of re-assessment/disinvestment activities

Table App 1 Data extraction table: Existing reviews (including surveys) of re-assessment/disinvestment activities

Author (year)	Title	Aim	Method [N studies included]	Inclusion/exclusion criteria	Results	Authors' conclusion
Gerdvilaite and Nachtnebel (2011)	Disinvestment: Overview of disinvestment experiences and challenges in selected countries	This report investigates internationally used concepts of disinvestment, existing frameworks and guidelines for identification, assessment and dissemination of results of disinvestment recommendations. Four countries (England, Spain, Australia and Canada) are analysed as specific examples of disinvestment-related research and practices.	SLR [283 retrieved; 31 included]	Articles on methodology focusing on disinvesting in obsolete or potentially obsolete technologies in general or providing an overview on one of the four selected countries.	An overview of disinvestment activities in England, Spain, Australia and Canada shows that disinvestment policies are at the developing/piloting phase. Only Spain has a formal methodological framework – the Guideline for Not Funding existing health technologies. The National Institute for Health and Clinical Excellence in England is recognised as already issuing mandatory disinvestment advice; however, this might change after a new legislation will be passed (Health and Social Care Bill 2011). Active discussion towards implementation of disinvestment policy was found in Canada and Australia, but actual projects are still in the piloting phase at regional level.	Six generalised challenges are recognised from the experiences of these four countries. The main problems for a slow disinvestment process were identified as lack of resources and published evidence, lack of methodological framework, multiple interests and potential duplication of disinvestment efforts.

Author (year)	Title	Aim	Method [N studies included]	Inclusion/exclusion criteria	Results	Authors' conclusion
Leggett, Noseworthy, et al. (2012)	Health technology reassessment of non-drug technologies: Current practices	To identify and summarise international HTR initiatives for non-drug technologies.	SLR [482 retrieved; 17 papers + 19 grey literature documents included]	Inclusion criteria: • Published in English • Title or abstract must mention some aspect of HTR and/or reinvestment • Document must contain information relevant to either current practices or theoretical knowledge in HTR and/or reinvestment of non-drug technologies • Document available between January 2000 and April 2011 Exclusion criteria: • Material exclusively focused on PBMA or economic analysis without placement of such methods in the context of re-assessment and/or reinvestment • Case study documents reporting on a single re-assessment without context within a model, framework or program • Material centred on reallocation without emphasising identification or prioritisation or cost-ineffective technologies	One model for re-assessment was identified; however, it has never been put into practice. Eight countries have some evidence of past or current work related to re-assessment; seven have shown evidence of continued work in HTR. There is negligible focus on monitoring and implementation.	HTR is in its infancy. Although HTRs are being conducted, there is no standardised approach. Future work should focus on developing and piloting a comprehensive methodology for completing HTR.
Leggett, Mackean, et al. (2012)	Current status of health technology reassessment of non-drug technologies: Survey and key informant interviews	To summarise experience-based information gathered from international experts on the development, initiation and implementation of a HTR program.	Online survey and interviews [2,123 emailed survey; 95 responded]	N/A	Ninety-five individuals responded to the survey: 49 were not discussing HTR, 21 were beginning to discuss HTR, nine were imminently developing a program, and 16 participants had programs and were completing re-assessments. The survey results revealed that methods vary widely and that although HTR is a powerful tool, it is currently not being used to its full potential. Of the 16 with active programs, nine agreed to participate in follow up interviews. Interview participants identified early and extensive stakeholder engagement as the most important factors for success. A lack of top–down support and financial and human resources are inhibiting program development.	HTR is in its infancy. Although HTRs are being conducted, there are no standardised approaches. However, much can be learned from current international work. Future work should focus on developing a comprehensive methodology, reporting the processes of re-assessments and sharing successes and challenges in a common platform.

Author (year)	Title	Aim	Method [N studies included]	Inclusion/exclusion criteria	Results	Authors' conclusion
Polisena et al. (2013)	Case studies that illustrate disinvestment and resource allocation decision making processes in health care: A systematic review	To systematically review and catalogue the application of frameworks and tools for disinvestment and resource allocation decision-making in health care.	SLR [2,963 retrieved; 14 case studies included]	Articles that provided a case scenario for the application of a framework or tool that support decisions on disinvestment in a real-world health context. Eligible articles included those that presented information on the framework or tool used; health technologies and service assessed; the criteria considered for disinvestment decisions, including resource allocation; and the rationale behind and impact of disinvestment decisions; and strengths and limitations of framework or tools based on individuals who participated in the process. Reports that did not present a list or categories of candidate health services or technologies for disinvestment or the criteria considered during the decision-making process or were published in a language not spoken by any of the co-authors were excluded from the review.	Most studies described the application of PBMA, and two reports used HTA methods for coverage decisions in a national fee-for-service structure. Numerous healthcare technologies and services were covered across the studies. We describe the multiple criteria considered for decision-making, and the strengths and limitations of these frameworks and tools are highlighted.	Disinvestment and resource allocation decisions require evidence to ensure their transparency and objectivity. PBMA was used to assess resource allocation of health services and technologies in a fixed budget jurisdiction, while HTA reviews focused on specific technologies, principally in fee-for-service structures. Future research can review the data requirements and explore opportunities to increase the quantity of available evidence for disinvestment and resource allocation decisions.

Author (year)	Title	Aim	Method [N studies included]	Inclusion/exclusion criteria	Results	Authors' conclusion
Niven et al. (2015)	Towards understanding the de-adoption of low-value clinical practices: A scoping review	To systematically review the literature on de-adoption, document current terminology and frameworks, map the literature to a proposed framework, identify gaps in our understanding of de-adoption, and identify opportunities for additional research.	SR [26,608 retrieved; 109 included]	English-language citations that referred to the de-adoption of any clinical practice in adults (mean age ≥ 18 years) with medical, surgical, or psychiatric illnesses. All original and non-original quantitative and qualitative research citations were eligible; however, we excluded citations that exclusively described the adoption of practices or appropriateness of resource use (e.g., selected use of antimicrobials, appropriate use of surgical procedures, appropriate use of lumbar spine radiography among patients with lower back pain).	There were 43 unique terms referring to the process of de-adoption—the most frequently cited was "disinvest" (39% of citations). The focus of most citations was evaluating the outcomes of de-adoption (50%), followed by identifying low-value practices (47%), and/or facilitating de-adoption (40%). The prevalence of low-value practices ranged from 16% to 46%, with two studies each identifying more than 100 low-value practices. Most articles cited RCTs (41%) that demonstrate harm (73%) and/or lack of efficacy (63%) as the reason to de-adopt an existing clinical practice. Eleven citations described 13 frameworks to guide the de-adoption process, from which we developed a model for facilitating de-adoption. Active change interventions were associated with the greatest likelihood of de-adoption.	This review identified a large body of literature that describes current approaches and challenges to de-adoption of low-value clinical practices. Additional research is needed to determine an ideal strategy for identifying low-value practices and facilitating and sustaining de-adoption. In the meantime, this study proposes a model that providers and decision-makers can use to guide efforts to de-adopt ineffective and harmful practices.
Parkinson et al. (2015)	Disinvestment and value-based purchasing strategies for pharmaceuticals: An International review	To review how reimbursement policy decision-makers have sought to partially or completely disinvest from drugs in a range of OECD countries (UK, France, Canada, Australia and New Zealand) where they are publicly funded or subsidised.	SLR [5000 retrieved; N included NR]	Relied heavily on the judgement of the authors as experts in the field	Historically, countries have relied on 'passive disinvestment'; however, due to (1) the availability of new cost-effectiveness evidence, or (2) 'leakage' in drug utilisation, or (3) market failure in terms of price competition, there is an increasing focus towards 'active disinvestment'. Isolating low-value drugs that would create headroom for innovative new products to enter the market is also motivating disinvestment efforts by multiple parties, including industry. Historically, disinvestment has mainly taken the form of price reductions, especially when market failures are perceived to exist, and restricting treatment to subpopulations, particularly when a drug is no longer considered value for money.	There is considerable experimentation internationally in mechanisms for disinvestment and the opportunity for countries to learn from each other. Ongoing evaluation of disinvestment strategies is essential, and ought to be reported in the peer-reviewed literature.

Author (year)	Title	Aim	Method [N studies included]	Inclusion/exclusion criteria	Results	Authors' conclusion
Mayer and Nachtnebel (2016)	Disinvesting from ineffective technologies: Lessons learned from current programs	To analyse processes and experiences of programs for identifying ineffective health technologies. The goal of this study was to elucidate factors that facilitate implementation.	SLR Survey [593 retrieved; 120 included references, 7 programs]	Published in English or German that contained information either on specific programs used to identify ineffective technologies or on general issues concerning methods for disinvestment/HTR and/or resource reallocation, were included. No limitation regarding the design of articles was applied. Programs were excluded if they (i) lacked a detailed description of the objectives, methods, applied criteria and outputs; (ii) did not focus on the identification of potentially ineffective, unsafe, or inefficient health technologies for optimising resources.	Seven programs were identified that include identification, prioritisation and assessment of ineffective health technologies and dissemination of recommendations. The programs are quite similar regarding their goals, target groups and criteria for identification and prioritisation. Outputs, mainly HTA reports or lists, are mostly disseminated by means of the internet. Top–down and bottom–up programs both have benefits in terms of implementation of recommendations, either as binding guidelines and decisions or as nonbinding information for physicians and other stakeholders. Crucial facilitators of implementation are political will, transparent processes and broad stakeholder involvement focusing on physicians.	All programs can improve the quality of health care and enable cost reduction in supportive surrounding conditions. Physicians and patients must be continuously involved in the process of evaluating health technologies. Additionally, decision-makers must support programs and translate recommendations into concrete actions.
Seo, Park, and Lee (2016)	A systematic review on current status of health technology reassessment: Insights for South Korea	To systematically investigate the current status and methodology of HTR in various countries to draw insights for the healthcare system in South Korea.	SLR [20,395 retrieved; 45 included studies]	Studies reporting the current status of HTR activities or HTR process including the HTR agencies, candidate technology identification and priority setting, HTR methodologies, stakeholder involvement, and political support for implementation. Only studies published in English or Spanish were included.	Informed by the literature review, and complemented by informant interviews, we focused on HTR activities in four jurisdictions: the UK, Canada, Australia, and Spain. There were similarities in the HTR processes, namely the use of existing HTA agencies, re-assessment candidate technology identification and priority setting, stakeholder involvement, support for reimbursement coverage, and implementation strategies. Considering the findings of the systematic review in the context of the domestic healthcare environment in Korea, an appropriate HTR model was developed. This model included four stages, those of identification, prioritisation, re-assessment and decision.	Disinvestment and reinvestment through the HTR was used to increase the efficiency and quality of care to help patients receive optimal treatment. Based on the lessons learned from other countries' experiences, Korea should make efforts to establish an HTR process that optimises the National Healthcare Insurance system through revision of the existing Medical Service Act.

Author (year)	Title	Aim	Method [N studies included]	Inclusion/exclusion criteria	Results	Authors' conclusion
Agirrezabal et al. (2017)	Status of disinvestment initiative in Latin America: Results from a systematic literature review and a questionnaire	To identify disinvestment initiatives in Latin American countries.	SLR Questionnaire [350 retrieved; 11 included]	Being published in English, Portuguese, or Spanish; reporting a comparison of the efficacy, effectiveness, cost-effectiveness, or safety of two or more health technologies; reporting a disinvestment-related activity.	Of the eleven articles identified, none provided a comprehensive description of a disinvestment initiative, such as explaining the approach taken for identification, evaluation, and prioritisation, the actual challenges faced during its implementation, the results, and current situation.	Many challenges need to be overcome for a disinvestment initiative to be successful and sharing particular experiences with the international community would increase the chances of positive outcomes. The present study highlights the need for publication of such experiences in Latin American countries.
Chambers et al. (2017)	A review of empirical analyses of disinvestment initiatives	To identify international experience with disinvestment initiatives and to review empirical analyses of disinvestment initiatives.	LR [N retrieved NR; 26 unique initiatives included, 18 empirical evaluations]	Included studies that described or evaluated national disinvestment initiatives that addressed any type of healthcare service, including drugs, medical devices, diagnostic imaging and screening tests, surgical procedures, and so on. We excluded strategies that were not national disinvestment initiatives, for example, those limited to individual hospitals. We also excluded studies that described PBMA programs. Empirical analysis defined as those that compared the use of a low-value service before and after the implementation of the disinvestment initiative.	We identified 26 unique disinvestment initiatives implemented across 11 countries. Nineteen addressed multiple intervention types, six addressed only drugs, and one addressed only devices. We reviewed 18 empirical analyses of disinvestment initiatives: 7 reported that the initiative was successful, 8 reported that the initiative was unsuccessful, and 3 reported that findings were mixed; that is, the study considered multiple services and reported a decrease in the use of some but not others. Thirty-seven low-value services were evaluated across the 18 empirical analyses, for 14 (38%) of which the disinvestment initiative led to a decline in use. Six of the seven studies that reported the disinvestment initiative to be successful included an attempt to promote the disinvestment initiative among participating clinicians.	The success of disinvestment initiatives has been mixed, with fewer than half the identified empirical studies reporting that use of the low-value service was reduced. Our findings suggest that promotion of the disinvestment initiative among clinicians is a key component to the success of the disinvestment initiative.

Author (year)	Title	Aim	Method [N studies included]	Inclusion/exclusion criteria	Results	Authors' conclusion
Orso et al. (2017)	Health technology disinvestment worldwide: Overview of programs and possible determinants	To describe the state of the art of health technology disinvestment around the world and to identify parameters that could be associated with the implementation of disinvestment programs.	SR Statistical analysis based on socio-economic indicators [1456 retrieved; 38 included studies, 15 programs]	Primary study describing an implemented disinvestment program or a structured experience encompassing methods used to identify, prioritise, and assess obsolete technologies and disseminate the results. Also included disinvestment programs focused on resource reallocation and appropriate use of technologies. Only articles written in English or Italian Excluded: SRs, narrative reviews, overviews; letters, editorials, poster presentations; qualitative studies, model studies.	The majority (12/15) of disinvestment programs began after 2006. As expected, these programs were more common in developed countries, 63 percent of which had a Beveridge model healthcare system. The univariate analysis showed that countries with disinvestment programs had a significantly higher level of Human Development Index, Gross Domestic Product per capita, public expenditure on health and social services, life expectancy at birth and a lower level of infant mortality rate, and of perceived corruption. The existence of HTA agencies in the country was a strong predictor ($p = 0.034$) for the development of disinvestment programs.	The most significant variables in the univariate analysis were connected by a common factor, potentially related to the overall development stage of the country.
Maloney et al. (2017)	Drug disinvestment frameworks: Components, challenges and solutions	To describe disinvestment framework process components for drugs and to report on framework components, challenges, and solutions.	SLR [4774 retrieved; 40 included]	Literature was included if it pertained to health technology disinvestment for drug technologies and contained information relevant to practices or theory of disinvestment of drug technologies. Literature was excluded if it was focused on budgeting or economic analysis without context to disinvestment or reported on case studies without context to a model and/or framework or program for disinvestment.	This review finds that stakeholders lack the political, administrative, and clinical will to support disinvestment and that there is not one disinvestment framework that is considered best practice.	Drug technology disinvestment components and processes vary, and challenges are numerous. Future research should focus on lessening value assessment challenges. This could include adopting more neutral framework terminology, setting fixed re-assessment timelines, conducting therapeutic reviews, and modifying current qualitative decision-making assessment frameworks.

Author (year)	Title	Aim	Method [N studies included]	Inclusion/exclusion criteria	Results	Authors' conclusion
Calabrò et al. (2018)	Disinvestment in healthcare: An overview of HTA agencies and organizations activities at European level	To investigate the extent of application of HTA in disinvestment at the level of HTA agencies and organisations located in Europe.	Search of HTA agencies websites [61 retrieved; 10 included]	Retrieved deliverables were considered eligible if they reported methodological projects/frameworks, case studies, dissemination initiatives focused on disinvestment in healthcare and if they were published in English or Italian. Deliverables were not considered eligible if disinvestment was not the major topic or was addressed only in a narrative way.	Eight methodological projects/frameworks, one case study and one dissemination initiative were found starting from 2007. With respect to methodological projects/frameworks, two were delivered in Austria, one in Italy, two in Spain and three in UK. As for the case study and the dissemination initiative, both came from UK. The majority of deliverables were aimed at making an overview of existing disinvestment approaches and at identifying challenges in their introduction.	Although several projects were carried out in different countries, most remain constrained to the field of research. Disinvestment is a relatively new concept in HTA that could pose challenges also from a methodological point of view. To tackle these challenges, it is necessary to construct experiences at international level with the aim to develop new methodological approaches to produce and grow evidence on disinvestment policies and practices.
Polisena et al. (2019)	Disinvestment activities and candidates in the health technology assessment community: An online survey	To collect data and information by means of a survey of disinvestment candidates and ongoing disinvestment projects in the HTA community.	Online survey [362 Invitees; 24 responses]	N/A	The disinvestment candidates identified represented a range of health technologies. Evidence or signalling of clinical ineffectiveness or inappropriate use typically led to the nomination of disinvestment candidates. HTAs and HTRs were usually conducted to evaluate the technology in question, and decisions usually led to the limited use of the technology. Barriers to disinvestment decisions included the strength of interest and advocacy groups, insufficient data for assessments, a systematic decision process and political challenges, while obstacles to their implementation were clinicians' reluctance and insufficient funding and incentives.	The survey results suggested that disinvestment activities are occurring in the HTA community, especially in the public sector. Future research can further investigate the processes and methods used to reach and implement disinvestment decisions from our survey respondents and explore the formation of closer ties between the HTA and clinical communities.

Author (year)	Title	Aim	Method [N studies included]	Inclusion/exclusion criteria	Results	Authors' conclusion
Pant, Boucher, and Frey (2019)	Health technology reassessment: An overview of Canadian and international processes	To identify the processes at national and international HTA agencies to conduct the re-assessment 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 re-assessment 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 re-assessment projects?*	Environmental scan (limited literature search and key informant consultation) [N retrieved & included NR]	English-language documents published between 01 January 2008, and 16 October 2018	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 prioritisation, were identified in all four countries. 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).	HTR is an emerging field; some international HTA agencies have nonetheless established processes to support HTR. There was a general lack of details available in the public domain regarding the research process for these HTR related reviews.

Abbreviations: AHRQ, Agency for Healthcare Research and Quality; AVALIA-T, Galician Agency for Health Technology Assessment; CADTH, Canadian Agency for Drugs and Technologies in Health; FIMEA, Finnish Medicines Agency; G-BA, Gemeinsamer Bundesausschuss (Federal Joint Committee Germany); HAS, Haute Autorité de Santé; HTA, health technology assessment; HTR, health technology re-assessment; ICER, Institute for Clinical and Economic Review; INESSS, Institut national d'excellence en santé et services sociaux; LR, literature review; MSAC, Medical Services Advisory Committee; N/A, not applicable; NICE, National Institute for Health and Care Excellence; NR, not reported; OECD, Organisation for Economic Co-operation and Development; OSTEBA, Basque Office for Health Technology Assessment; PBAC, Pharmaceutical Benefits Advisory Committee; PBMA, program budgeting and marginal analysis; PHARMAC, Pharmaceutical Management Agency (New Zealand); RCT, randomised controlled trial; SHTG, Scottish Health Technologies Group; SLR, systematic literature review; SMC, Scottish Medicine Consortium; SR, systematic review; UK, United Kingdom; US, United States.