Health Technology Assessment

Rapid Review

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About the Center for Evidence-based Policy and the Medicaid Evidence-based Decisions Project

The Center for Evidence-based Policy (http://www.ohsu.edu/policycenter) is a collaboration of academic and governmental entities with the mission of addressing policy challenges with evidence and collaboration. Established in 2003, the Center builds on lessons learned from improving public policy in the field of health care through innovation, collaboration, and use of best evidence.

The Medicaid Evidence-based Decisions (MED) Project is housed at the Center, and is a collaboration of state Medicaid programs and their state partners whose purpose is to make high quality evidence available to states to support benefit design and coverage decisions. The MED Project products include identification and synthesis of high quality systematic reviews and other studies, technology assessments of existing and emerging health technologies, and rapid evaluations of healthcare interventions. Additional information about the project can be found at the following link: http://www.ohsu.edu/xd/research/centers-institutes/evidence-based-policy-center/med/index.cfm.

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Executive Summary

Background

Health technology assessment (HTA) is defined by the International Network of Agencies for Health Technology Assessment (INAHTA) as "a multidisciplinary field of policy analysis, studying the medical, economic, social and ethical implications of development, diffusion and use of health technology" (2011b). Health technology assessments conducted through formal HTA programs can be instrumental in informing public and private payer coverage and policy decisions. Although there is little empirical evidence from which to guide a "gold standard" for all aspects of HTA programs, state public health care programs are interested in developing best practices for HTA programs that adhere to high standards for assuring safety, effectiveness, value, transparency, stakeholder involvement and fairness.

Methods

This report addresses the following Key Questions:

1. What are the components of public programs that allocate health resources using health technology assessment, in the US and internationally?

2. What are the goals of each of the components of the program or process?

This report describes well-developed HTA programs from the US, Canada, Australia and select European countries. Individual HTA programs were identified on the availability of having documents in English and/or that were discussed in the *International Journal of Technology Assessment in Health Care* 2009 supplemental volumes (Suppl 1 and 2) on HTA programs. In countries with multiple HTA programs the program with the most explicit link to public resource allocation/decision making was selected for review. Websites for each HTA program and published documents were hand searched to retrieve information on processes and structure. Appendix B of the full report provides a list of all HTA programs scanned for inclusion.

A full search of the MED clinical evidence core sources was carried out to identify systematic reviews (SRs), meta-analyses (MAs), and technology assessments (TAs) published after December 1999. A MEDLINE (Ovid) search was conducted to identify SRs and MAs as well as additional studies published between 2000 and 2010. Two supplemental volumes (Suppl 1 and 2) of the 2009 *International Journal of Technology Assessment in Health Care* (IJTAHC) and the 2009 Supplement 2 volume of *Value in Health* were hand searched for relevant articles.

Findings

This report highlights 14 key components of HTA programs that are used in public program decision making. These 14 components are drawn from a review of 12 national and international HTA programs. The following programs were reviewed:

- Australian Commonwealth HTA – Medical Services Advisory Committee (MSAC)
- Belgium – Health Care Knowledge Center (KCE)

- Canadian Agency for Drugs and Technology in Health (CADTH)
- Danish Center for Evaluation and Health Technology Assessment (DACEHTA)
- England[1] - National Institute for Health and Clinical Excellence (NICE)
- Germany – Institute for Quality and Efficiency in Health Care (IQWiG)
- Swedish Council on Health Technology Assessment (SBU)
- United States – Centers for Medicare & Medicaid Services, Coverage and Analysis Group (CMS-CAG)
- United States – Veterans Administration Technology Assessment Program (VATAP)
- United States – Minnesota Health Services Advisory Council (HSAC)
- United States – Oregon Health Resources Commission (HRC)
- United States – Washington Health Technology Assessment Program (WA-HTA)

The 14 key components of HTA programs were identified through a review of publically available HTA program information and HTA literature. The components are organized into six broad domains, as outlined below:

I. HTA Organization and Structure

1. *Program Purpose:* Role of HTA in relationship to policymaking.
2. *Governance:* Structure of HTA organization and review committees.
3. *Scope:* Types of technologies reviewed and key factors analyzed (e.g., clinical effectiveness, costs, social, ethical, legal and patient considerations).
4. *Products:* Types of reports and other products produced by program.
5. *Program Evaluation:* Use of program evaluation to inform program development.

II. Transparency

6. *HTA program transparency:* Efforts to provide information publically about how key aspects of the program are carried out.

III. Stakeholder Involvement

7. *Stakeholder* involvement: Opportunities for stakeholder involvement in HTA product development.

IV. Topic Nomination and Selection

8. *Topic Nomination:* Process to solicit topic nominations.
9. *Topic Refinement:* Process to develop key questions and refine topic nomination.
10. *Topic Selection:* Process to prioritize and select topics for review.

V. Evidence Synthesis

11. *Entities Conducting Reviews:* Internal or external groups that conduct evidence synthesis.
12. *Review Methods:* Extent and nature of review methodologies.

[1] Technically, the National Institute of Clinical Excellence serves England and Wales, but for simpilicity of presentation in this report, we will only state England.

VI. Use of HTA in Decision Making

13. *Public Program Decision Makers:* Use of HTA in public program decision making.
14. *Implementation:* HTA dissemination and implementation strategies.

This report describes each of the 14 key components and provides examples based on the 12 HTA programs reviewed. In addition, Appendices K through V of the report detail the components of each HTA program.

Strengths and limitations

This report is based on a structured qualitative review of 12 national and international HTA programs. Strengths of this review include a systematic process of identifying HTA programs for review, presentation of processes and components with examples from well-developed HTA programs, and a national and international perspective. Program information is based on publically available program information and resources, and a focused literature review. In some cases, program information was not identified about a particular component, which does not mean that program does not address that component. In addition, this review is limited to programs with publicly available information in English which excludes some well developed international HTA programs.

Background

Health technology assessment programs

Health technology assessment (HTA) has been defined by the International Network of Agencies for Health Technology Assessment (INAHTA) as "a multidisciplinary field of policy analysis, studying the medical, economic, social and ethical implications of development, diffusion and use of health technology" (2011b). Health technology assessments conducted through formal HTA programs can be instrumental in informing public and private payer coverage and policy decisions. The scope of technologies assessed by programs varies, but commonly includes pharmaceuticals, medical devices, procedures, diagnostics, and treatment strategies (Drummond 2008).

The process of health technology assessment and HTA programs themselves currently appear to be more developed in many European countries than within United States (US). However, many current program processes are grounded in the HTA program model of the US Office of Technology Assessment (OTA). The OTA was established in 1972 to provide the US Congress with impartial technology assessments in the fields of medicine, telecommunications, agriculture, materials, transportation, and defense. Funding for OTA was withdrawn in 1995 due to political pressure from industry and some controversy over report content. However, the OTA model was adopted by many of the current well-established international HTA programs, such as those in Denmark, Germany, United Kingdom (UK), Netherlands, and Sweden (O'Donnell 2009; Sullivan 2009).

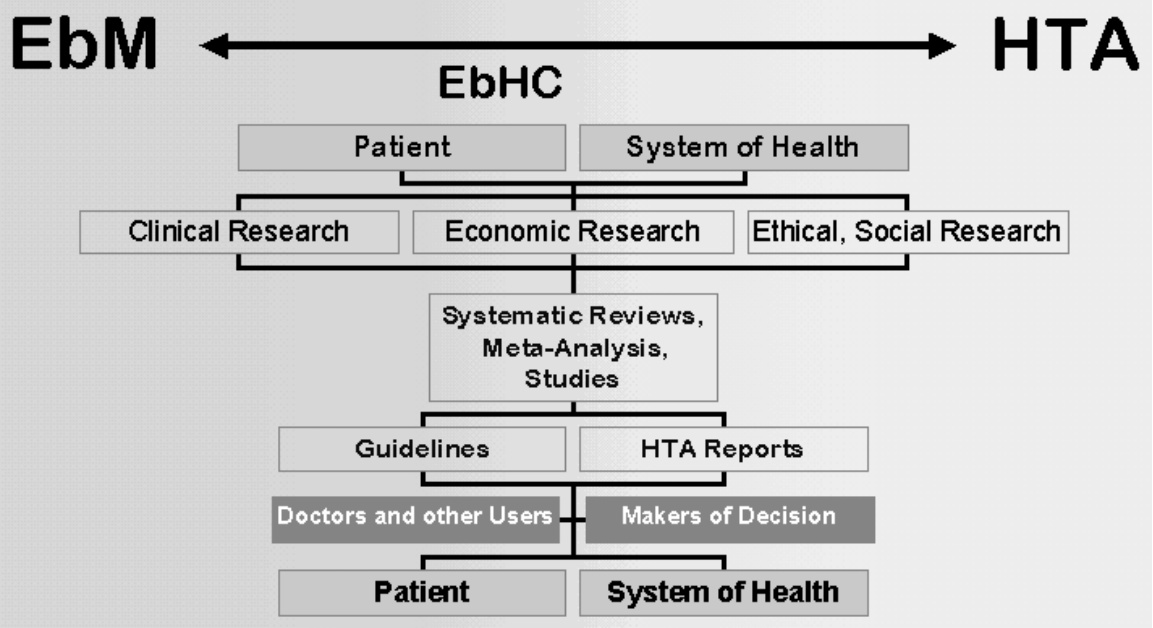
Collaborations in Europe have formed the basis for building awareness and interest in the use of research evidence among healthcare decision makers, including policy makers, clinicians, and the public (Banta 2009). The EUR-ASSESS project, which was initiated by the Netherlands, Sweden, France, UK, and Switzerland in 1994, was the first of four sequential European collaborations that focused on developing individual country HTA programs and exploring cooperation between HTA programs of European Union (EU) states (Banta 2009). The European Network for Health Technology Assessment (EUnetHTA) Collaboration was launched in 2008 as a sustainable and permanent HTA organization in Europe (EUnetHTA Collaboration 2011). Other international HTA collaborations include INAHTA, which was established in 1993 and includes 46 agencies from 24 countries (INAHTA 2011). The US member organizations collaborating in the INAHTA include the Agency for Healthcare Research and Quality (AHRQ) and the Veterans Affairs Technology Assessment Program (VATAP). Several of the HTA programs reviewed in this report are members of both EUnetHTA and INAHTA.

Evidence-based medicine compared to HTA

Health technology assessment overlaps and intersects with aspects of evidence-based medicine (EBM). While both use evidence as the basis for evaluation, HTA focuses on the broader impacts of a health technology at the system level, while EBM uses evidence to inform clinician decision making and care for individual patients or groups (See Figure 1). Sullivan (2009) suggests that a formal HTA process should include five domains: 1) horizon scanning; 2) topic determination and queuing; 3) collection and assessment of evidence; 4) appraisal; and 5) funding and policy implementation. In comparison with EBM, the fifth domain of funding and

policy implementation sets HTA apart. In addition, many HTA program processes go beyond EBM by applying outcomes, economic, cost-effectiveness and ethical/legal analyses to evidence (Eddy 2009).

Figure 1. How do HTA and EbM Differ from Each Other?



(German Institute of Medical Documentation and Information (DIMDI) 2010)

Comparison of national and international HTA programs

As discussed by Drummond (2008) and Neumann (2010), HTA programs around the world differ significantly based on decision making authority, scope of evidence reviews, longevity/experience, and in their program components. For example, many European HTA programs integrate economic data as a core component of their HTA reports. In contrast, some US HTA programs generally do not include analysis of cost or economic implications, and tend to focus more on clinical evidence review.

Nonetheless, international HTA programs in countries with single payer or other types of national health care systems can provide a useful reference point for states developing HTA programs. Although international HTA programs generally operate in health care systems that are dramatically different than the US system as a whole, the public nature of international healthcare systems and their use of HTAs underscore many important program characteristics of potential interest to developing state HTA programs. Most notably, public accountability, transparency, fairness, scientific quality, wise use of public resources and responsibility for a broader public good are among significant elements shared by national and international public payers using HTA to inform policy decisions.

Annual HTA program cost

The annual budgets of international HTA programs vary. One overview (Martelli 2007) of 24 HTA agencies reports that, in 2007, most HTA programs had an annual budget less than $1.6 million although some exceeded that amount and ranged from $1.5 million to over $19 million. The range of budgetary groups reported:

- $1.5 to $4 million (e.g., Centers for Medicare and Medicaid Services, Veterans Administration Technology Assessment Program);
- $5.5 million to $8 million (e.g., Danish Centre for Evaluation and Health Technology Assessment);
- $9.5 million to $19 million (e.g., Canadian Agency for Drugs and Technologies in Health , Swedish Council on Technology Assessment in Health Care); and
- Over $19 million (e.g., National Institute for Clinical Evidence).

Policy context

Public (and private) payers have historically relied on concepts of medical necessity, community standards, clinical practice guidelines developed by professional societies and others, legislative mandates, court advisories or rulings, and individual medical director decisions to determine the appropriateness of care and resource allocation. In recent years, however, increasing attention is being paid to the need for scientifically rigorous assessments of evidence relating to new and existing health care technologies given their contribution to rising medical costs, and their potential overuse, misuse or underuse (Congressional Budget Office (CBO 2007); Institute of Medicine (IOM 2009)).

In a landmark report, *Knowing What Works in Health Care: A Roadmap for the Nation*, the IOM stresses the importance of using unbiased, reliable information in health care to address persistent health policy challenges such as cost, geographic variation, improving quality, consumer-directed health care, and coverage decisions (IOM 2009). To produce such information, HTA is identified by the IOM as having "an organized process for determining which topics merit comprehensive study" (IOM 2009, p. 5) and HTA programs are able to provide systematic reviews, technology assessments and meta-analyses to summarize the clinical evidence on a topic (IOM 2009). This clinical effectiveness information can be used by public and private payers as the basis to form health care coverage decisions (IOM 2009).

Given the important and valuable role that HTA can play in policy decisions, public HTA programs in the US as well as in other countries are subject to inquiry from product manufacturers, consumers and other interested parties regarding the transparency and scientific legitimacy of HTA processes. Although there is little empirical evidence from which to derive a "gold standard" for all aspects of HTA programs, public payers are interested in developing best practices for HTA programs that adhere to high standards for assuring safety, effectiveness, value, transparency, stakeholder involvement and fairness. This report presents HTA program components from a diverse range of US and international HTA programs to assist state Medicaid agencies and other payers in developing and implementing HTA programs

within their unique organizational and legal contexts. The ultimate goal is to assist programs to establish "gold standards" for applicable components of public payer HTAs in the US.

Key Questions

1. **What are the components of public programs that allocate health resources using health technology assessment, in the US and internationally?**

2. **What are the goals of each of the components of the program or process?**

Methods

Search strategy

A full search of the MED clinical evidence core sources was carried out to identify systematic reviews (SRs), meta-analyses (MAs), and technology assessments (TAs) using the terms "health technology assessment", "health technology assessment program", "HTA", and "health technology evaluation". Searches of core sources were limited to citations which were published after December 1999. The core sources included: Hayes, Inc., Cochrane Library (Wiley Interscience), UK National Institute for Health and Clinical Excellence (NICE), Blue Cross/Blue Shield Health Technology Assessment (HTA) program, Veterans Administration TA program, BMJ Clinical Evidence, the Canadian Agency for Drugs and Technologies in Health (CADTH), Washington State HTA, US Preventive Services Task Force (USPSTF), and the Agency for Health Research and Quality (AHRQ).

A MEDLINE (Ovid) search was conducted to identify SRs and MAs as well as additional studies published between 2000 and 2010. Please see Appendix A for the full MEDLINE search strategy. The search was limited to publications in English.

Additionally, two supplemental volumes that summarize international programs (Suppl 1 and 2) of the 2009 *International Journal of Technology Assessment in Health Care* (IJTAHC) and the 2009 Supplement 2 of *Value in Health* were hand searched for relevant articles. Websites and published documents for each HTA program were hand searched to retrieve information on processes and structure.

Inclusion criteria

Individual HTA programs were identified based on the availability of program documents in English and/or were discussed in the *IJTAHC* 2009 supplemental volume (Suppl 1 and 2) on HTA programs. This report focuses on public programs that use HTA to allocate health resources.

Exclusion criteria

International programs were excluded if no information on the HTA process was available (e.g., China, Italy, Japan), if the available HTA documents were not in English (e.g., France, Netherlands, Poland, Spain), or if the available information in English was too limited to be able to pull HTA component information (e.g., Catalonia, Finland, Ireland, Israel, New Zealand, Norway, Singapore, Switzerland). Please see Appendix B for a full list of countries whose programs were scanned for inclusion. This report includes one HTA program per country. If

there were multiple HTA programs in a country, we included the program with the most explicit link to public resource allocation/decision making.

Studies and additional resources were excluded if they:

- Were not published in English
- Were published before 2000
- Did not have an identified link between the HTA process and public resource allocation/decision making

Individual HTA program review

This report uses a framework consisting of six categories (program organization and structure; transparency; stakeholder involvement; nomination and selection of topics; evidence synthesis; and use of HTA in decision making) to evaluate each included HTA program. For each category there are one to six HTA program review components for a total of 17 program review components. Please see Appendix C for a full description of the 17 review components. Data for all 17 program review components were abstracted for each HTA program (see Appendices K to V). In the body of this report, the program component information is synthesized into 14 key components.

This framework was developed based on work by Drummond and colleagues (2008) that outlines four overarching domains (structure, methods, processes for conducting HTA, and use of HTA in decision making) with a total of 15 key principles directed towards the improvement of HTA programs for resource allocation decisions. Neumann (2010) uses these key principles to evaluate a range of international HTA programs, and to compare and contrast the support for and implementation of Drummond's key principles. While Drummond's key principles are an initial attempt towards identifying integral components of HTA programs, they are not as process-oriented as needed for this report.

Findings

Included HTA programs

The MED Project core source search located 33 SRs and TAs relevant to this topic. The MEDLINE search retrieved 653 full citations. After a full review of citations and abstracts, we conducted a further online scan of HTA program components of 24 countries. Please see Appendix B for a full list of scanned HTA programs. Eight countries had websites with detailed HTA information in English available: Australia, Belgium, Canada, Denmark, England, Germany, Sweden, and the United States. In the US we identified the Centers for Medicare and Medicaid Services (CMS), the Veterans Administration/ Department of Defense (VA/DoD), and three state HTA programs (Minnesota, Oregon, and Washington). We included a total of seven international programs and five US based programs. We explicitly included HTA programs that linked technology assessment with a role in the decision making processes, either in an advisory capacity and/or used to inform decisions in a formal process. A detailed review of each program and its components from topic selection through decision making was conducted. Individual HTA program summaries are available in Appendices K through V. A summary comparison table of

included HTA programs is presented in Appendices E (international HTA programs) and F (US HTA programs).

Excluded HTA programs

Health technology assessment programs were included on the basis of whether there was detailed information in English about the HTA program structure, evidence synthesis process, and how HTA reports are used in decision making processes. Using these criteria, the Agency for Healthcare Research and Quality (AHRQ) was excluded based on not having a direct link to a decision making body. Scottish Intercollegiate Guidelines Network (SIGN) was excluded on the basis that it is primarily develops guidelines to inform clinical practice, which is distinct from HTA to inform policy decision. While both programs have HTA components that could be useful in developing a HTA program, (such as the AHRQ public topic nomination and selection process or the rigorous methodology used by SIGN to develop clinical practice guidelines), no direct link to public decision making processes was identified for either program.

The Germany Agency for Health Technology Assessment at the German Institute for Medical Documentation and Information (DAHTA@DIMDI) was excluded as the German Institute for Quality and Efficiency in Health Care (IQWiG) program has a more explicit and direct role in advising policy makers. The Dental and Pharmaceutical Benefits Agency (TLV) in Sweden, which rules on pharmaceuticals and dental benefits, was excluded given the lack of information in English about the program.

HTA Programs Reviewed

This report describes 12 national and international HTA programs to illustrate key components of these programs used in public decision making. Each program is portrayed briefly below, and Appendices K through V provide an overview of each program with respect to the components highlighted in this report.

1. Australia – Department of Health and Ageing, Medical Services Advisory Committee (MSAC)[2]
2. Belgium – Health Care Knowledge Center (KCE)
3. Canada – Canadian Agency for Drugs and Technology in Health (CADTH)
4. Denmark – Danish Center for Evaluation and Health Technology Assessment (DACEHTA)
5. England[3] – National Institute for Health and Clinical Excellence (NICE)
6. Germany – Institute for Quality and Efficiency in Health Care (IQWiG)
7. Sweden – Swedish Council on Health Technology Assessment (SBU)

[2] Several minister-appointed HTA committees advise the Australian Department of Health and Aging on the strength of evidence relating to safety, effectiveness and cost-effectiveness of technologies studied. These include the Medical Services Advisory Committee (MSAC), the Prosthesis & Devices Committee (PDC), and the Pharmaceutical Benefits Advisory Committee (PBAC). All health technologies must undergo an HTA evaluation to be eligible for funding. Information inthis report focuses on the MSAC process.

[3] Technically, the National Institute of Clinical Excellence serves England and Wales, but for simpilicity of presentation in this report, we will only state England.

8. United States – Centers for Medicare & Medicaid Services, Coverage and Analysis Group (CMS-CAG)
9. United States – Veterans Administration Technology Assessment Program (VATAP)
10. United States – Minnesota Health Services Advisory Council (HSAC)
11. United States – Oregon Health Resources Commission (HRC)
12. United States – Washington Health Technology Assessment Program (WA-HTA)

The Key Questions of this report address components and goals of public HTA programs that allocate health resources. In the following sections, we describe components of each HTA program using the following analytic domains:

I. Program structure;
II. Program transparency;
III. Stakeholder involvement;
IV. Topic nomination and selection;
V. HTA methods of evidence synthesis; and
VI. Use of HTA in each country's decision making.

I. Program Structure

Program Purpose

Health technology assessment programs play a variety of roles in relation to public program decision making. We classified these relationships into three categories:

1) advisory with respect to evidence conclusions only;
2) advisory with respect to both evidence conclusions and policy recommendations; and
3) prescriptive authority to issue public program health care benefit or coverage decisions.

Table 1. Role of HTA Programs in Relation to Public Decision Making

Role of HTA in relation to decision making	HTA programs
Advisory with respect to evidence only	Canada – CADTH Germany – IQWiG Sweden – SBU US – Oregon HRC US – VATAP
Advisory with respect to evidence and policy options	Australia – MSAC Belgium – KCE Denmark – DACEHTA England – NICE US – Minnesota HSAC
Authority to make coverage determinations	US – CMS-CAG US – Washington HTA

Ten of the 12 HTA programs reviewed play an advisory role to public program decision makers. Among these programs, five play an advisory role with respect to evidence conclusions only, and five advise public programs on evidence conclusions as well as policy recommendations. In HTA programs that maintain an advisory role, public program decision makers retain final authority to make policy decisions.

Only two HTA programs studied, Washington HTA and CMS-CAG, are vested with the authority to make coverage determinations that are binding. In Washington, technology assessments are conducted by external evidence-based technology assessment centers, and coverage decisions are made by an independent 11-member Health Technology Clinical Committee (HTCC) that is staffed by the WA-HTA. The HTCC's coverage determinations are binding on three state agencies (Health Care Authority, Department of Social and Health Services, Labor and Industries), and two state agencies participate voluntarily (Department of Corrections, Department of Veterans Affairs). Participating state agencies interact with Washington's HTA through an Agency Medical Director Workgroup, which identifies priority topics for study and serves as a liaison group between the program and the agencies. WA-HTA is singular among HTA programs in vesting binding coverage decision authority in an independent committee with no agency or public program membership.

The Centers for Medicare and Medicaid Services issues NCDs for 10 to 15 technologies per year. The agency's internal Coverage and Analysis Group (CMS-CAG) conducts technology assessments for the topics under review and issues coverage determinations. For topics that involve conflicting or complex medical information, the agency may request an independent evidence review by the Agency for Healthcare Research and Quality (AHRQ), and/or advice from a 15-member panel of representatives selected from the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC). When this more formal process is used, the evidence review and MEDCAC become advisory and the agency's internal Coverage and Analysis Group retains final decision authority similar to other advisory HTA programs.

While the primary purpose of many of the reviewed HTA programs is to inform pubic program decision makers, several also produce reports targeting a broad range of health care decision makers, such as health professionals, hospitals and other provider groups, patients and caregivers and the general public (e.g., CADTH, DACEHTA, IQWiG, MSAC, NICE, OR HRC, SBU). In comparison, other HTAs focus more exclusively on public program health care decision maker audiences (e.g., CMS-CAG, KCE, MN HSAC, VATAP, WA-HTA).

Governance and Organization

Nine of the 12 HTA programs reviewed are part of government agencies, and remaining three HTA programs are organized as independent non-profit or semi-governmental entities (CADTH, IQWiG, KCE). Of the nine government-based HTA programs, seven are part of agencies responsible for administering publically funded health care programs (CMS-CAG, MN HSAC, MSAC, NICE, OR HRC, VATAP, WA-HTA), and two are organized in government agencies independent from public health care programs (DACEHTA, SBU). The DACEHTA, for example, is part of a national agency that advises local and regional public health care program administrators.

The three HTA programs organized as independent bodies have explicit links to government programs. CADTH, for example, is funded by federal, provincial and territorial governments and governed by a 13-member board of directors that includes representatives of government, public health care programs, academia, and the general public. The Belgian KCE operates under the direction of the Minister of Public Health and Social Affairs, and is governed by an independent 13-member board representing government agencies, providers, and professional organizations.

Six of the seven HTA programs organized within or closely connected to public programs are guided by independent review committees (CMS-CAG, MN HSAC, MSAC, NICE, OR HRC, WA-HTA). The responsibility and composition of these review committees varies. For example, the Washington Health Technology Clinical Committee (HTCC) is responsible for making binding coverage decisions for three Washington public health care programs. The HTCC is comprised of clinical experts appointed by the administrator of the Washington Health Care Authority, and the committee does not include agency representatives. By contrast, NICE has four standing Appraisal Committees responsible for reviewing evidence and making coverage recommendations. Members of the Appraisal Committees are drawn from the NHS, patient and carer organizations, academia, and industry.

In addition, a number of HTA programs draw on scientific advisory committees comprised of clinical and scientific experts to review and advise on methodological or other evidence issues (e.g., IQWiG, OR HRC, SBU). Table 2 provides an overview of HTA program organizational governance structures, program roles and key committees involved in the programs.

Table 2. HTA Governance, Program Role and Committees

Organizational Governance	HTA Program Role and and Committees
Australia – MSAC MSAC is organized within the Australian Department of Health and Ageing, a public health care payer agency.	**HTA Program Role in Relation to Public Decision Makers** MSAC advises the Minister of Health and Ageing with respect to the strength of evidence and public coverage recommendations for public funding of services on the Medicare Benefits Schedule. **HTA Program Committees** *Medical Services Advisory Committee:* MSAC is an independent scientific committee with 21 members appointed by the Minister of Health and Ageing with expertise in clinical medicine, health economics and consumer issues. MSAC Sub-Committees include: the Evaluation Sub-Committee which provides advice on the quality, validity and relevance of evidence assessments being considered; and the Protocol Advisory Sub-Committee defines decision options or questions for public funding.
Belgium – KCE KCE is an independent, semi-governmental institution governed by a 13 member Board of Directors.	**HTA Program Role in Relation to Public Decision Makers** KCE produces studies and reports to advise the National Institute for Health and Disability Insurance, and Ministers of Public Health and Social Affairs with respect to the strength of evidence and policy options for coverage of healthcare technologies and services.

Organizational Governance	HTA Program Role and and Committees
Operates under the direction of the Ministers of Public Health and Social Affairs.	**HTA Program Committees** *None identified.*
Canada – CADTH CADTH is an independent, non-profit agency governed by a 13 member Board of Directors accountable to Canada's Conference of Deputy Ministers of Health.	**HTA Program Role in Relation to Public Decision Makers** CADTH produces technology reports to advise federal, provincial, and territorial ministries of health with respect to the strength of evidence supporting the use of drugs, devices and other health care technologies. **HTA Program Committees** *Drug Policy Advisory Committee:* provides advice to the CADTH Board on drug policy issues and topics. The Committee consists of 16 members from federal, provincial and territorial publicly funded drug plans, and health related organizations. CADTH also develops project-specific expert review panels.
Denmark – DACEHTA DACEHTA is organized within the National Board of Health, a government agency that is independent of public health care payers.	**HTA Program Role in Relation to Public Decision Makers** DACEHTA advises regional and local public program decision makers with respect to the strength of evidence and policy recommendations. **HTA Program Committees** *Strategic Advisory Board*: works to develop and coordinate the use of HTA in Denmark and is comprised of representatives of regions and municipalities, academia and government.
England - NICE NICE is part of the National Health Service, a public payer agency, and governed by an independent Board of Directors.	**HTA Program Role in Relation to Public Decision Makers** NICE produces evidence reports and makes recommendations for coverage of services for the National Health Service in England and Wales. **HTA Program Committees** *Technology Appraisal Committees:* 4 standing committees of 33 members each, drawn from the NHS, patient and caregiver organizations, academia, and the pharmaceutical or medical device industry. The Appraisal Committees consider evidence and formulate recommendations for the NHS on coverage.
Germany – IQWiG IQWiG is an independent scientific institution organized within the Foundation for Quality and Efficiency in Health Care, a non-profit foundation. The Foundation is governed by a 12 member Foundation Board and a 5 member Board of Directors.	**HTA Program Role in Relation to Public Decision Makers** IQWiG produces evidence reports to advise the German Federal Joint Committee with respect to the strength of evidence for services covered by the German public health insurance program. **HTA Program Committees** *Board of Trustee*s: may submit comments on recommendations issued by the IQWiG. Comprised of 30 members representing the Federal Joint Committee, health professional, patient and other relevant health system organizations. *Scientific Advisory Board:* advises IQWiG on scientific and research issues. Comprised of at least 6 and not more than 12 scientists.

Organizational Governance	HTA Program Role and and Committees
Sweden – SBU SBU is an independent governmental agency governed by a 10 person Board of Directors.	**HTA Program Role in Relation to Public Decision Makers** SBU regularly reports results of evidence assessments to the Ministry of Health. **HTA Program Committees** *Scientific Advisory Committee:* 15-member Committee appointed by the SBU director to oversee scientific aspects of work. Includes representation from basic and applied medical research, clinical medicine, nursing, epidemiology, economics, management, administration, and public health. *Alert Advisory Board:* determines methods and reviews draft Alert reports. Further information not identified.
US – CMS-CAG The Coverage & Analysis Group is an office organized within CMS, a public health care payer agency.	**HTA Program Role in Relation to Public Decision Makers** The CMS Coverage & Analysis group reviews evidence and issues Medicare national coverage determinations (NCDs) for 10 to 15 technologies each year. CMS-CAG may request formal HTAs conducted by AHRQ or advice from MEDCAC. **HTA Program Committees** *Medicare Evidence Development & Coverage Advisory Committee (MEDCAC)*: CMS-CAG may request evidence review and coverage advice from MEDCAC on certain NCDs. MEDCAC is an independent committee that consists of 100 members representing clinical and administrative medicine, biologic and physical sciences, public health, patient advocacy, health care data and information management, health economics, and medical ethics. CMS-CAG selects 15 members to serve per review panel.
US – VATAP VATAP is a program organized within the Office of Patient Care Services of the Veterans Health Administration, a public health care payer.	**HTA Program Role in Relation to Public Decision Makers** VATAP produces evidence summaries responding to information needs of senior VHA policy makers. The evidence summaries support evidence-based resource management by the VHA. **HTA Program Committees** *None identified.*
US – MN HSAC Minnesota HSAC is organized within and staffed by the Minnesota Department of Human Services, a public health care payer.	**HTA Program Role in Relation to Public Decision Makers** HSAC produces brief evidence summaries and makes coverage recommendations for DHS medical assistance programs. **HTA Program Committees** *Health Services Advisory Committee:* Independent committee staffed by state agency employees and comprised of 13 members appointed by the Commissioner of Human Services including physicians, physician specialists, non-physician professionals, consumer, and Commissioner's Medical director (as a non-voting member). HSAC reviews evidence summaries and makes coverage recommendations to the Department for public medical assistance programs.

Organizational Governance	HTA Program Role and and Committees
US – OR HRC Oregon HRC is organized within the Office of Health Policy and Research of the Oregon Health Authority, a public health care payer.	**HTA Program Role in Relation to Public Decision Makers** HRC produces evidence reports that advise OHA with respect to evidence conclusions on topics studied. **HTA Program Committees** *Health Resources Commission:* Independent committee staffed by state agency employees and comprised of 11 Governor-appointed members including four physicians, two pharmacists, and one representative from each of the following groups: hospitals, insurance, business, labor, and consumers. Reviews evidence assessments of technology subcommittee and pharmaceutical subcommittee and issues final HRC reports summarizing evidence conclusions. *Technology Subcommittee:* includes five physicians and one consumer representative. Ad-hoc experts are utilized as required. Reviews evidence and develops clinically relevant conclusions; defines topic scope; presents assessment to HRC. *Pharmaceutical Subcommittee:* seven members including three physicians, a nurse practitioner, a pharmacist, and two PharmDs, a consumer representative for mental health topics and ad-hoc clinical experts are utilized as required. Reviews evidence and develops clinically relevant conclusions; defines topic scope; presents assessment to HRC.
US – WA-HTA Washington HTA is organized within the Washington State Health Care Authority, a public health care payer.	**HTA Program Role in Relation to Public Decision Makers** WA-HTA produces evidence reports and binding coverage decisions for three state funded health programs. **HTA Program Committees** *Health Technology Clinical Committee:* Independent committee staffed by state agency employees and comprised of 11 members appointed by the HCA administrator including six practicing physicians, and five other licensed health professionals. The HTCC reviews an independently produced evidence report, public and agency input, and makes binding coverage decisions.

Scope

The scope of technologies reviewed by HTA programs range from a focus on medical procedures and services, to a broader concept of "technology" encompassing the organization and delivery of health care services, disease prevention and public health promotion efforts. For example, DACEHTA reports may evaluate how health care services are organized across government programs and multidisciplinary professions (e.g., a recent DACEHTA report provides advice on how brain injury rehabilitation can be organized across government agencies as well as the multidisciplinary professionals involved in providing these services). By contrast, other HTA programs, such as the WA-HTA, focus on assessment of medical and surgical devices and procedures, medical equipment, and diagnostic tests. See Table 3 for the

types of technologies reviewed by each program included in this review.

All of the included HTA programs evaluate the clinical effectiveness of the technology under consideration. With the exception of CMS-CAG and Oregon HRC, all included HTA programs also evaluate costs as part of their assessments. While costs are widely considered in HTA evaluations, inclusion of cost analyses has been a controversial topic among US HTA program efforts. CMS-CAG, for example, does not have authority to consider costs in its coverage decisions (Drummond 2008). In Oregon, cost are evaluated by the Oregon Health Authority (public payer program), but are not part of the HTA evaluation. US private sector HTA programs, however, all incorporate cost analyses into their evaluations (Drummond 2008).

Several of the included HTA programs also consider topics from broader social and ethical perspectives. DACEHTA's *Health Technology Assessment Handbook* outlines the Danish approach to evaluation of a technology's effectiveness, safety and risks, as well as broader analysis of ethical considerations, the organization of services, economic analysis, and patient-specific factors, such as preferences, needs and compliance (DACEHTA 2007).

Table 3. Scope of HTAs

HTA	Types of Technologies	Key Factors Analyzed
Australia – MSAC	Pharmaceuticals Diagnostic tests Medical devices Prostheses Medical procedures medical services Surgical interventions Public health efforts	Safety Clinical effectiveness Cost-effectiveness
Belgium – KCE	New health care technologies, treatments and drugs Health services organization and financing	Safety Clinical effectiveness Cost-effectiveness Patient considerations Organizational issues
Canada – CADTH	Drugs Medical devices Procedures Health systems for maintenance, treatment and promotions of health	Clinical efficacy Effectiveness Cost-effectiveness Service impact
Denmark – DACEHTA	Procedures and methods of prevention, diagnostics, treatment, care and rehabilitation, including equipment and medical drugs Supportive systems Health care organization	Technology (effectiveness) Patient (needs and challenges) Organization (administrative and delivery systems) Economy (cost and

HTA	Types of Technologies	Key Factors Analyzed
		economic analyses)
England – NICE	Pharmaceuticals Medical devices Diagnostic techniques Surgical procedures Therapeutic technologies Health promotion activities	Clinical effectiveness Cost-effectiveness
Germany – IQWiG	Drugs Non-drug interventions, e.g., surgical procedures Diagnostic and screening methods Treatment guidelines disease management programs	Benefit Cost-benefit
Sweden – SBU	Specific categories not stated	Benefits Risks Costs
US – CMS-CAG	Services covered by Medicare – specific types not specified	Effectiveness
US – VATAP	Vaccines Pharmaceuticals Devices Procedures Organizational and support systems	Medical Social Ethical Economic
US – MN HSAC	Health care services paid for by state program – specific types not specified	Effectiveness Cost
US – OR HRC	Pharmaceuticals Medical equipment and devices Medical or surgical procedures Supportive systems	Effectiveness
US – WA-HTA	Medical and surgical devices and procedures Medical equipment Diagnostic tests (review of prescription drugs are carried out by a separate state agency)	Safety Efficacy Cost-effectiveness

HTA Products

Health technology assessment program products encompass evidence reports, HTA program recommendations and/or decisions, and other types of resources such as clinician and patient summaries. There is no international standard HTA report type or product description; however, there is general consensus that HTA products should be designed to match the needs of key decision makers and target audiences.

Most of the HTA programs reviewed produce full evidence reports that provide detailed evaluation of the evidence. The DACEHTA, the SBU, and NICE delineate between a large scale HTA that might focus on a disease or complex issue (HTA – Broad; Yellow Report; and Multiple Technology Appraisal, respectively) and a focused HTA that concentrates on a single issue or technology (HTA – Focused; Alert Report; Single Technology Appraisal, respectively). While the broader HTA reviews may take between two to three years to complete, the focused reviews are designed to meet needs of policy decision makers on a more time sensitive basis and may be completed in a few months to a year. The DACEHTA, for example, estimates that HTA – Broad reports average about 200 pages in length and take one and a half to two and a half years to complete; HTA – Focused reports average around 100 pages in length and take one year to complete.

In addition to evidence reports, HTA programs may also produce reports documenting the evidence conclusions and/or policy recommendations or decisions of the HTA program. For example, NICE publishes its Final Appraisal Decisions documenting the program's evidence conclusions and policy guidance for use of the technology. Similarly, WA-HTA produces evidence reviews, as well as products documenting the HTCC's evidence findings and coverage decisions.

Some HTA programs also produce brief three to five page report summaries in addition to a full evidence review, targeted at specific stakeholders. The VATAP, for example, produces a one page Patient Summary that describes the issue, why it is important, what evidence exists on the topic, and what is being done to further evaluate the issue if needed. Minnesota's HSAC and Oregon's HRC also include executive summary documents and clinician summaries, respectively.

In addition, the DACEHTA and the SBU produce brief summary reports on new health care topics and important issues as they arise (Mini – HTA and White Reports, respectively). These reports are intended to inform and provide a starting point for future full systematic reviews. Denmark estimates that a Mini – HTA is four pages in length and takes approximately two to four months to complete.

Program evaluation

Program evaluation is a relatively new, but valuable step in the HTA program process that can help assess the use of HTA in decision making and identify areas for program development. Conducted internally or by an external vendor, program evaluation can provide validation that HTA program components are well developed, document evidence of need for a program, explore external perceptions of a HTA program, and help define program direction.

In this review, six HTA programs had undergone a formal program assessment or quality review within the last eight years (MSAC, KCE, DACEHTA, CADTH, NICE, and WA-HTA). Some programs, such as MSAC in Australia are actively integrating many recommendations resulting from a formal program evaluation. For example, in response to the 2010 HTA program evaluation, the Australian government redesigned the HTA topic nomination processes to have only one entry point for HTA nominations that staff then designate to an appropriate HTA committee (e.g.,

MSAC). Evaluations of HTA programs often recommend: (1) increased transparency; (2) stakeholder involvement; (3) increased report production efficiency; (4) consistency in HTA products; (5) continued integration of policy implications into HTA reports; (6) continued production of high quality services and products; and (7) increased adherence to organizationally specific standard report methods.

II. Transparency

For HTA products to be viewed as both useful and legitimate, they must be conducted with scientific rigor through a fair and transparent process. Transparency is a fundamental component that underlies the entire HTA process by providing information about how key aspects of the program are carried out. Program aspects involving transparency may include: the selection and prioritization of topics; formulation of research questions; inclusion or exclusion of studies; assessment of the quality of evidence; and documentation of the bases of HTA conclusions. The precise elements constituting transparency and fairness, however, are not well defined (Nielson 2009).

Because transparency is a broad concept that underlies numerous HTA program components, program transparency is addressed within the relevant HTA program components discussed in this report. With respect to overarching program efforts to support transparency, HTA programs reviewed in this report make evidence reports and program decisions publically available on their websites. These documents describe the methodological and research bases on which evidence conclusions, and in some cases policy recommendations, are made.

In addition, five of the 12 HTAs reviewed conduct their deliberations in public meeting settings (CMS-MEDCAC, MN HSAC, NICE, OR HRC, WA-HTA). Some programs have also developed comprehensive resources available on their websites describing the HTA program's processes from the beginning steps of developing topics to the final conclusions or decisions issued by the program. NICE, for example, has produced several guides outlining the program's appraisal process and methods, and has made these resources publically available on the program's website.

III. Stakeholder Involvement

Many HTA programs involve stakeholders in program processes to ensure that HTA products are useful and relevant to target audiences, and to strengthen stakeholder confidence in the integrity of HTA program's conclusions impacting public coverage decisions. While there is no single formula for what constitutes fair and appropriate stakeholder involvement, basic questions in relation to stakeholder involvement in HTA processes include 1) who to involve; 2) how to involve; and 3) in what aspects of the HTA process to involve stakeholders (Nielson 2009).

<u>Stakeholders: Who to involve</u>

In general, stakeholders may be defined broadly as "… individuals, groups, or organizations who have an interest (stake) and the potential to influence the actions or aims of an organization,

project or policy direction" (Nielson 2009). Stakeholders may, therefore, include a variety o groups, including public program policy makers, health professionals, consumer organizations, individual patients, and industry – all impacted by HTA program decisions or conclusions. However, in determining stakeholder involvement in the HTA processes, it is important to recognize the HTA programs' relationships and responsibilities to different stakeholder groups. For example, HTA programs that have a specific responsibility for producing reports for public program policy makers, may engage these decision makers in the HTA process more extensively to ensure that the products meet their needs.

With respect to patient and consumer involvement, a number of HTA collaborations are encouraging more attention to be paid on how to involve patients and their families in the HTA process. In response to a 2005 survey of INAHTA members, with 37 HTA agencies reporting, just over half (57 percent) of survey respondents involve patients, caregivers, and related organizations in some aspect of their HTA program, and 83 percent intend to involve consumers in the future (Hailey 2006). Of the 12 HTA programs included in this report, six include consumer representatives in HTA governance structures and/or advisory committees (CMS-CAG, IQWiG, MN HSAC, MSAC, NICE, OR HRC).

As described in *Consumer Involvement in Health Technology Assessment* (Hailey 2005a), for the Cochrane Collaboration, consumer involvement is important to "raise the difficult questions others may not have considered or do not give priority to; and challenge ideas, suggestions with which they do not feel comfortable" (p. 3). While identifying consumer stakeholders interested in participating in the HTA process can be difficult, programs may consider using formal alliance organizations, specific population-based groups, or condition-based groups to identify possible stakeholder participants (Hailey 2005a). At the same time, organized consumer groups may bring different interests to the HTA process than the perspectives of individual consumers.

<u>Stakeholders: How to involve</u>

Health technology assessment programs have developed a number of approaches for involving stakeholders in the HTA process, namely: opportunities to stay informed through transparent publication of key reports, decisions, and meetings; opportunities to provide input through oral and/or written comment periods; and opportunities to participate in HTA program committees.

With respect to opportunities to stay informed, HTA programs may publish documents describing key decision points in the HTA process, such as the schedule of public meetings, the selection of topics, key questions, draft and final evidence reviews, and draft and final HTA program decisions and/or recommendations. In some cases, these documents may also be open to stakeholder comment, as discussed further below.

Health technology assessment programs may also provide opportunity for stakeholders to submit oral and/or written comments to the program. A number of HTA programs, particularly in the US and UK, hold public meetings, with opportunity for public comment throughout the HTA process during the meetings. These programs provide meeting agendas or other materials in advance of meetings to enhance meaningful stakeholder participation. For example, NICE

makes meeting agendas available 20 working days prior to meeting dates and individuals must register to attend, with a maximum of 20 people allowed. By contrast, although the Minnesota HSAC posts meeting agendas and materials seven days prior to meeting dates, they do not require advanced registration or limit attendance. A number of HTAs also publish past meeting agendas, minutes and other meeting materials to their websites. See Appendix G for summary comparison of public meeting practices identified across programs.

HTA programs may also invite stakeholder written comments at specific points in the HTA process. IQWiG, for example, does not hold public meetings, but sets forth specific guidelines, comment forms, and conflict of interest statements on draft research protocols and draft reports to be submitted during four week public consultation. Programs generally notify stakeholders of these opportunities through stakeholder email listservs or newsletters, in addition to posting information on the program website. See Appendix G for summary comparison for public comment periods identified across programs.

Several programs incorporate stakeholders into HTA program committees or the HTA program governance structure. HTA programs organized as independent non-profit entities (e.g., CADTH, IQWiG, KCE), primarily government decision makers in addition to other stakeholders in their governance structures. CADTH's 13-member board of directors, for example, includes a regional distribution of federal, provincial and territorial representatives, representatives of health authorities, academia, and the general public.

Among programs that produce reports with evidence conclusions only, Oregon's 11-member HRC is an example of a program that involves stakeholders. The HRC is comprised of representatives of various stakeholder groups, including four physicians, two pharmacists, and one representative from each of the following groups: hospitals, insurance, business, labor, and consumers. The German IQWiG program, by contrast, includes a Board of Trustees comprised of 30 members representing the Federal Joint Committee, health professional, patient and other relevant health system organizations. This Board may submit comments on evidence conclusions issued by IQWiG, but is not responsible to deliberating and forming the evidence conclusions.

The MN HSAC and NICE are examples of programs that involve stakeholders in program committees that issue both evidence conclusions and policy recommendations. In England, NICE has four standing appraisal committees of 33 members each, drawn from the NHS, patient and caregiver organizations, academia, and the pharmaceutical or medical device industry. The Appraisal Committees consider evidence and formulate recommendations for the NHS on coverage. The MN HSAC reviews evidence summaries and makes coverage recommendations to the Department for public medical assistance programs. The HSAC is comprised of 13 members appointed by the Commissioner of Human Services including physicians, physician specialists, non-physician professionals, a consumer, and the Commissioner's Medical director (as a non-voting member).

The HTA programs reviewed that produce evidence reports and binding policy decisions involve stakeholders in program committees to a limited extent or not at all. The WA-HTA program, for

example, relies on an independent clinical committee, the HTCC, to issue binding coverage determinations. The HTCC is comprised of 11 clinical representatives and has no government agency, industry, consumer or other stakeholder representatives. Similarly, CMS-CAG makes coverage decisions based on decisions of internal staff with clinical backgrounds. However, for certain decisions CMS may request advice from the Medicare Evidence Development & Coverage Advisory Committee, which may review and judge the strength of available evidence and make coverage recommendations. MEDCAC is comprised of 100 members with backgrounds in science, clinical medicine, economics, public administration and ethics, and including six voting consumer representatives, and six nonvoting industry representatives. For each topic under review, CMS selects a panel of 15 MEDCAC members to review the evidence and provide recommendations. Final national coverage decisions are made by the CMS-CAG.

Other HTA programs that support public programs, such as NICE, have stakeholder committees or councils (e.g., The Citizens Council; The Partners Council) that provide advice on stakeholder perspectives to the program (Hailey 2005a). Stakeholder programs may also involve stakeholders in committees involved with implementation of HTA program findings and recommendations. The DACEHTA Strategic Advisory Board, for example, works to develop and coordinate the use of HTA in Denmark and is comprised of representatives of regions and municipalities, academia and government agencies. See Appendix G for summary comparison of the inclusion of stakeholders in governance or other HTA program committees.

<u>Stakeholders: When to involve</u>

The question of "when" to involve stakeholders may be considered in four phases of the HTA process: topic nomination and development; evidence review; development of HTA reports; and appeal or protest of HTA conclusions. Opportunities within each of these phases are discussed below.

Stakeholder input: Topic nomination and development

Some HTA programs solicit topic nominations from the public at large, while other programs focus more exclusively on topics requested by public program decision-makers. The Washington HTA and German IQWiG programs, for example, provide a public topic nomination form and guidance on their websites with regard to key information needed for topic nominations. Although these programs provide opportunity for public topic nominations, they are also designed to respond specifically to topic nominations developed by their target public program audiences. For example, the Agency Medical Director Workgroup in Washington develops topic nominations identified by different state agencies subject to WA-HTA decisions.

A number of HTA programs focus more exclusively on topics requested by public program decision makers. The US VATAP, for example, is located within the Veterans Health Administration and responds to needs of senior VHA policy makers. The Oregon HRC represents a hybrid approach, whereby Oregon's HRC discusses its technology topic selection at a public meeting and accepts public comment and suggestions for topics to be considered. The Oregon Health Authority (OHA) incorporates stakeholder input in the process of developing topic nominations and the HRC reviews the topics requested by the OHA.

In addition to topic nominations, several HTA programs involve stakeholders in developing key research questions to be addressed. For example, Australia's MSAC works directly with industry or health professionals applying for a HTA review to agree on key questions and a research protocol. (Note: HTA review in Australia is in order obtain public funding for any new health care technology or service.) In addition, MSAC makes a draft research protocol available for public comment for five weeks. The WA-HTA provides a 30-day public comment period on draft key questions. In England, NICE holds scoping workshops to provide a forum for HTA researchers and other key stakeholders to discuss the proposed scope of topics. While a number of programs seek stakeholder input into the topic development process, it is important to recognize that some HTA programs, such as Oregon HRC and Minnesota HSAC, may rely primarily on existing systematic reviews that include defined key questions. These HTA programs therefore have less control over this aspect of the HTA process. See Appendix G for a summary comparison of program efforts to involve stakeholders in the topic nomination and development process.

Stakeholder input: Evidence reviews

All included HTA programs make their evidence reviews, which include the methods, quality assessments, and inclusion and exclusion criteria, publically available on their websites. Publishing such reviews allow stakeholders to evaluate the methodological quality of these reviews, including potential biases and the validity of reviews.

Most HTA programs encourage stakeholders, including industry, provider organizations, patients and care givers, and other interested parties to submit relevant evidence to include in the HTA review. Some programs also invite stakeholders to comment on the evaluation of the quality and strength of evidence as a separate stage from comments on draft reports. In Australia, for example, an Evaluation Sub-committee evaluates and critiques the evidence review. Applicants for public funding of a technology under review may comment on the Evaluation Sub-committee's review, although a specific timeframe to submit these comments is not identified. Likewise, NICE provides approximately four weeks for external groups, including patient experts, to comment on evidence assessment reports. For external technology assessments commissioned by CMS-CAG, AHRQ provides a two-week opportunity for public comment on the draft technology assessments. In addition, AHRQ posts invited peer review and public comments on the draft technology assessment to its website within three months after the final technology assessment is released, along with author responses to comments.

Some HTA programs, such as Oregon HRC and DACEHTA, may also invite experts to comment or participate in an evidence review on an ad hoc basis. Most included HTA programs also incorporate expert or peer review of HTA reports. See Appendix G for comparison of program efforts to involve stakeholders in the evidence review process.

Stakeholder input: Development of HTA program reports

All included HTA programs make their HTA program reports, which include specific discussion of the bases for the program's evidence conclusions and in some cases policy recommendations or decisions, publically available on their websites. Publishing such reports allow stakeholders to evaluate the methodological quality of reports, including potential biases and the validity of

conclusions. In some cases, programs may combine the evidence review and HTA program conclusions and/or recommendations into the same document.

A number of programs have established a process for stakeholders to provide written comment on draft HTA program reports that outline the programs' evidence conclusions and potential policy recommendations or coverage determinations (e.g., CADTH, CMS-CAG, IQWiG, KCE, MSAC, NICE, WA-HTA). Program timeframes to submit comments on draft program decision and/or recommendation reports range from two weeks (e.g., CADTH) to a month (e.g., CADTH, CMS-CAG, IQWiG, NICE). HTA programs that conduct HTA processes that include public meetings also allow opportunity for stakeholder comment on reports during the course of those meetings. Minnesota's HSAC, for example, invites stakeholders to submit written comments three days prior to HSAC meetings and comments are distributed to committee members. See Appendix G for a comparison of program opportunities for stakeholder input on draft reports.

In addition to soliciting comments on draft reports, some programs make stakeholder written comments available for public review. National coverage determinations by CMS-CAG, for example, include a summary of public comments and CMS-CAG's response to those comments. In Minnesota, stakeholder comments submitted 10 days prior to HSAC meetings are posted to the website along with other meeting materials seven days in advance of meetings.

Stakeholder input: Appeal of HTA conclusions/decisions

We identified two HTA programs, NICE and CMS-CAG, with a formal process to appeal final HTA decisions. HTA programs that focus on a summary of evidence, or that have less direct influence over coverage determinations, generally did not identify appeals processes as these programs do not issue binding determinations. While the WA-HTA program makes coverage determinations, a separate legal process to challenge the WA-HTA decision was not necessary because the legislation creating the program indicates that individuals may file appeals through existing legal channels to challenge state public program coverage determinations. .

As a reference, the NICE appeal process is well detailed in its *Guide to the Technology Appraisal Appeal Process* (2010). Appeals are considered only on the following grounds: 1) NICE did not act fairly; 2) the guidance cannot be justified on the basis of the evidence submitted during the development process; and/or 3) NICE exceeded its power. They are considered by a separate Appeals Committee that has had no prior involvement with the HTA topic under appeal. Appeals may also only be submitted by organizations and individuals who have registered as consultees, and must be filed 15 working days from the time the final determination is issued. The *Guide to the Technology Appraisal Appeal Process* includes extensive information about the appeals process and should be consulted for further specifics.

IV. Topic Nomination and Selection

Topic nomination

Topic nomination processes of HTA programs differ; most programs have either an open or a focused nomination process. Of the included HTA programs, seven have an open nomination

process that accepts topic nominations from the public, in addition to nominations from specific state agencies and decision makers (e.g., CADTH, KCE, MSAC, NICE, OR HRC, SBU, WA-HTA). Programs differ in how an open nomination is carried out. Australia, for example, uses a single web-based portal to collect topic nominations that are then assigned to the respective HTA programs such as MSAC. Applications to the portal are accepted on a rolling basis and applicants do not need to specify which HTA program they are submitting their application to. The KCE in Belgium, in contrast, only accepts topic nominations once a year and most of these are submitted by private organizations, individual citizens, universities, scientific institutions, and the Federal Public Services – Public Health. In addition to public nomination, HTA programs such as CADTH, NICE, and SBU also identify topics through horizon scanning programs that conduct ongoing literature searches and communicate with members of their respective advisory committees to identify new areas for review.

Four of the included HTA programs have a focused nomination process that does not include public topic nomination (e.g., CMS-CAG, IQWiG, MN HSAC, VAHTA). Within these programs, topic nomination is conducted internally and in some cases in consultation with other agencies. In Minnesota, for example, the Department of Human Services recommends a list of topics to HSAC on an annual basis. While the HTA programs with a focused nomination process develop topics in response to policy makers' questions, some also internally nominate and develop topics. For example, IQWiG topics are developed by the Joint Federal Committee or the Federal Ministry of Health. However, IQWiG can also independently develop its own topics without approval from the Federal Joint Committee or Federal Ministry of Health.

Topic refinement

Topic development varies significantly between HTA programs depending on the topic nomination process. Some HTA programs work closely with the nominating author to define the research questions and to develop a research protocol (e.g., CADTH, MSAC, WA-HTA). Other programs work internally in project groups to establish the search protocol and scope of the topic (e.g., CMS-CAG, DACEHTA, IQWiG, KCE, MN HSAC, OR HRC, WA-HTA) and conduct an initial review of the literature as a preliminary assessment of the quantity of evidence available on a topic (e.g., CADTH, NICE, and SBU). As part of the public process, WA-HTA develops and reviews topics based on three primary and five secondary prioritization criteria (see Appendix V for more detail).

Topic selection

Due to the number and breadth of topics potentially subject to review, some HTA programs use criteria to prioritize and select topics. This is an important aspect of HTA programs to ensure transparency of topics selected for study and to avoid distortions in decision making about the investment and use of resources (Drummond 2008). A 2007 systematic review of HTA prioritization criteria, for example, identified 59 unique HTA priority setting criteria in 11 main categories (Noorani 2007):

- alternative technologies;
- budget impact;

- clinical impact;
- controversial nature of proposed technology;
- disease burden;
- economic impact;
- ethical, legal, and psychosocial implications;
- availability and relevance of evidence;
- level of interest (from government, health professionals and patients);
- timeliness of review; and
- variation in rate of use.

The HTA programs reviewed in this report reflect a range in types and use of prioritization criteria to select topics. On the more systematic end of the spectrum, CADTH has defined six core criteria to prioritize topics: disease burden, potential clinical impact, available alternatives, potential budget impact, potential economic impact, and available evidence. Each criterion is also weighted according to degree of importance. Topics that appear to address the core criteria are referred to a CADTH advisory committee for prioritization. The advisory committee then evaluates topics based on the weighted criteria which results in an overall score to determine topic selection (Husereau 2010).

Other HTA programs identify prioritization criteria, but use less systematic methods for applying them when selecting topics. NICE, for example, evaluates topics based on satisfying one or more of the following criteria:

- 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 (e.g., reduction in health inequalities)?
- Is the technology likely to have a significant impact on NHS resources (financial or other) if given to all patients for whom it is indicated?
- Is there significant inappropriate variation in the use of technology across the country?
- Is the Institute likely to be able to add value by issuing national guidance? (e.g., in the absence of such guidance is there likely to be significant controversy over the interpretation or significance of the available evidence on clinical and cost effectiveness?

Likewise, WA-HTA is required to select topics based on the following set of statutory criteria: (a) concerns about its safety, efficacy, or cost-effectiveness, especially relative to existing alternatives, or significant variations in its use; (b) actual or expected state expenditures are high, due to demand for the technology, its cost, or both; and (c) adequate evidence available to conduct the complete review [RCW 70.14.100]. In addition, Washington has identified a number of secondary criteria to consider, including: number of persons affected per year;

severity of condition treated by technology; policy related urgency/diffusion concern; potential or observed variation; and special populations/ethical concerns. (See Appendix V for more detail on the Washington "Prioritization Criteria and Tools" and "Health Technology Selection Process)

V. Evidence synthesis

Entities conducting reviews

Evidence reviews for HTA programs may be carried out by a group within the organization, and/or may also be commissioned to external entities. In the included agencies, for example, the Center for Health Technology Assessment within NICE develops HTAs and then contracts with external independent academic centers to conduct the evidence review. In Australia, MSAC also commissions full HTA reviews from external contractors. In Canada, CADTH assembles a multidisciplinary research team (including epidemiologists, economists, information and knowledge transfer specialists, expert clinicians, members of the Scientific Advisory Panel, as well as project managers) that can be comprised of CADTH employees and/or external research contractors. CADTH includes members of the Canadian Pharmaceutical, Devices and Systems Advisory Committees for project protocol development, but these members are not involved in the actual evidence review process. The SBU in Sweden forms a Project Group with members from the SBU staff, Scientific Advisory Board and others from outside the SBU, including epidemiologists, economists, and clinicians. All members of this Project Group receive training in systematic review and critical appraisal methods based on methods used by the Cochrane Collaboration.

Among US states, MN HSAC and ORHRC have public decision making bodies which review evidence syntheses. These reviews are conducted primarily by committee staff within the state health agency. The State of Washington contracts with an external research organization to conduct the HTA and has also nominated review topics to the AHRQ Effective Health Care Program. Within CMS, CAG requests HTA reviews from AHRQ who, in turn, might commission an Evidence-based Practice Center to conduct the evidence review or assign internal staff to carry out the work. The VA/DoD uses an internal Technology Assessment Program to conduct reviews. The internal team consists of staff with expertise in health and information systems, library science, project management and the clinical issue at hand.

Review methods

Although some of the included programs do not provide sufficient detail in public sources to fully describe their review methodology, the majority make extensive methodological documentation available. MSAC, SBU, CADTH, CMS-CAG and NICE all explicitly conduct systematic reviews as the basis of their HTA evidence process. These programs generally use established systematic review elements such as a PICO (population, intervention, comparator and outcomes) statement, key questions, prespecified inclusion and exclusion criteria, study quality assessment and data synthesis. The DACEHTA process evaluates whether a systematic review is needed and may do so if this level of research synthesis is needed. The VATAP uses existing systematic reviews, technology assessments and economic evaluations and supplements these with subsequently published primary studies that add to the evidence base.

VATAP reports evaluate the quality of included studies as well as the overall strength of evidence about a topic. The KCE method is similar to the VATAP process in that it incorporates existing HTA reports and systematic reviews in addition to primary studies and grey literature into their search strategy. The KCE process is supplemented with qualitative methodologies to appraise patient issues related to a technology. These methods may include interviews, focus groups or roundtables, and literature reviews of qualitative studies.

The Minnesota and Oregon HTA programs use "best evidence" methodologies for most of their reports. These methods incorporate existing systematic reviews and technology assessments as well as subsequent primary studies. Oregon's HRC conducts reviews using pre-approved "source" documents which detail the evidence sources (e.g., Cochrane Library, AHRQ, etc.) to be searched. The Minnesota HSAC also uses a set of defined evidence sources including PubMed or Medline, ICSI, the Medicaid Medical Directors' Learning Network and other sources. The State of Washington's evidence contractors conduct systematic literature searches for systematic reviews, technology assessments and additional studies relevant to the topic. Their reviews are based on an explicit PICO statement that informs a set of key questions to be addressed by the review. Oregon and Minnesota, in addition to Washington, on occasion nominate topics to AHRQ's Effective Health Care program and therefore provide full systematic reviews to help address some HTA topics.

VI. Use of HTA in Decision Making

Role of decision makers

The nexus between HTA programs and public program decision makers is a fundamental component of HTA programs. This relationship is critical in ensuring that evidence findings are translated into actionable policy and used by public programs. Important HTA processes in which to involve decision makers include topic planning and prioritization, topic refinement and development of key questions, and report preparation in order to ensure that HTA end products meet the needs of decision makers on a timely basis.

The INAHTA guidance sets forth responsibilities for both the HTA program and associated decision makers (Hailey 2010). The HTA program is responsible for carrying out competent evidence reviews, presenting clear and transparent findings, responding to questions that have been asked by decision makers within the needed timeframe, and following up with decision makers to inform them of conclusions reached (Hailey 2010). Decision makers are responsible for committing to the HTA process, which typically include a commitment of funds, intending to use HTA products, and ensuring continuous communication with the HTA agency (Hailey 2010).

The HTA programs reviewed in this report have a variety of relationships with public program decision makers. As discussed earlier, in some cases, HTA programs are part of public payer programs; in other cases, they are structured as entities independent of public payers, but with government representatives on the HTA program governance board. Regardless of the structure, HTA programs must in some way incorporate public program decision makers into their programs in order to ensure that reports are both useful and integrated into public program decisions.

Few included HTA programs identified describe explicitly how HTA products are used by public program decision makers. Programs that issue binding coverage determinations (CMS-CAG, WA-HTA) obviously have clear and direct influence over the use of HTA products in public program decision making. Likewise, some public programs, such as the NHS in England, are directed to incorporate NICE recommendations into NHS coverage decisions. Programs like VATAP, structured as a department within a public payer body, are also closely tied to decision makers.

For HTA programs without a direct or close tie to public program decisions, it is important to consider how to align and connect HTA activities with public program decisions. The CADTH Knowledge Transfer Program, for example, focuses on linking research with evidence-based decision making by federal, provincial and territorial health care decision makers. CADTH also includes a Liaison Program, which focuses on relationships with provincial and territorial jurisdictions to ensure that CADTH products are being used by and meeting their needs.

Implementation

While HTA products might be similar in scope, methods to implement them differ greatly across HTA programs. Implementation refers to how HTA products are disseminated to various stakeholders and how and in what format reports are available. Program scope might determine how HTA products are implemented and how widely they are disseminated. The VA VATAP reports, for example, are directly used by the Veterans Health Administration (VHA), but not directly implemented by other organizations or officially used beyond the VHA (although they are publically available and used by other organizations).

Conferences and facilitated discussions are another mode of HTA implementation. The HTA programs in Germany and Sweden hold annual symposiums where evidence and conclusions of HTA reports are actively shared. Additionally, both Germany and Sweden offer training sessions and seminars for targeted audiences interested in the HTA process. As mentioned above, CADTH has a dedicated knowledge transfer specialist (KTS) who works with project teams from topic inception to identify knowledge partners that are committed to using HTA reports in decisions and to develop strategies to enhance the capacity for knowledge uptake among decision makers.

The National Institute for Health and Clinical Excellence concentrates on a different aspect of HTA implementation, namely funding and cost support. The NHS is required to provide funding for technologies recommended through the NICE technology assessment program within three months of guidance publication date. Additional financial and audit support are provided as tools to help in the implementation of the guidance. NICE also provides summary documents for clinicians and patients or caregivers.

Discussion

As national and international HTA programs continue to grow and collaborate across programs, efforts are being made to develop commonly used key components in the HTA process. Collaborations such as the EUnetHTA and the INAHTA are actively working to compile and

define essential HTA components. While some have suggested "best practices" of HTA programs (Busse 2002), HTA programs vary widely in structure and practice, and so it is difficult to design a model HTA structure that would fit the diversity of needs of each HTA program (Henshall 2002). However, in the absence of empirically defined best practices, we identify four critical themes that underlie HTA components highlighted in this report for states or other public entities to consider in designing HTA programs.

HTA Independence

A fundamental consideration in designing and structuring a HTA program is the degree of independence between the HTA program and the public programs using HTA products to inform policy decisions. In order to achieve program autonomy, it is suggested that the "HTA process is best conducted independently of the body that ultimately will be responsible for adopting, paying and implementing the HTA decisions" (Drummond 2008, p. 247). In particular, it is important to develop an HTA organizational structure that reinforces offering an objective and scientific evaluation of evidence. At the same time, there should be close ties between an HTA program and public decision makers in order to ensure the usefulness and implementation of HTA reviews.

The HTA programs reviewed in this report address this balance between independence and integration with public program decision makers in a variety of ways. For example, some are structured as committees that are independent but supported by public program agencies (e.g., MN HSAC, OR HRC, WA-HTA). Others are set up as independent non-profit agencies that include public agency stakeholders in the HTA organizational governance structure (e.g., CADTH, KCE). In considering the variety of potential program structures, states should consider that the independence of HTA programs as an important underlying principle reinforcing the power and legitimacy of using HTA products to support evidence-based public program policy.

Transparency

International collaborations such as the INAHTA and the EUnetHTA identify transparency in the HTA process as a principle carrying equal importance to the use of scientific methods. As succinctly summarized by Nielsen, "HTA products are more likely to be accepted, and may thus impact on policy making, if stakeholders accept the scientific methodology upon which the results rest (corresponds to finding the arguments sound and understandable) and/or consider the production processes open and fair" (2009, p. 86). Transparency underlies the entire HTA process, from the organization and operation of the HTA program to the selection and prioritization of topics, formulation of research question, development of research methodologies, and documentation of the assessment of evidence and bases of conclusions. Nevertheless, precise elements of transparency are not well defined (Nielson 2009).

Scientific Validity and Process

The scientific validity of the HTA process is a core principle of HTA programs. HTA programs that allocate public monies have a fiduciary responsibility to their constituents to assure that the technology in question is assessed in a fair way, that decisions are transparent and that the needs of the population are considered. The HTA process should guard against conflicts of

interest on the part of either those who collect and synthesize the information or those who make decisions based on that information.

Once there is a refined policy question, HTA programs should generally develop a project protocol or plan before commencing research on a topic (Busse 2002). Protocols can be seen as guidelines for the project and define when and how to conduct a systematic review of the literature and available resources. Developing a comprehensive project protocol that includes decision maker input can help avoid external risks to a HTA program such as dissatisfied clients, criticism from external organizations and individuals, or possible loss of credibility for HTA products (Hailey 2005b).

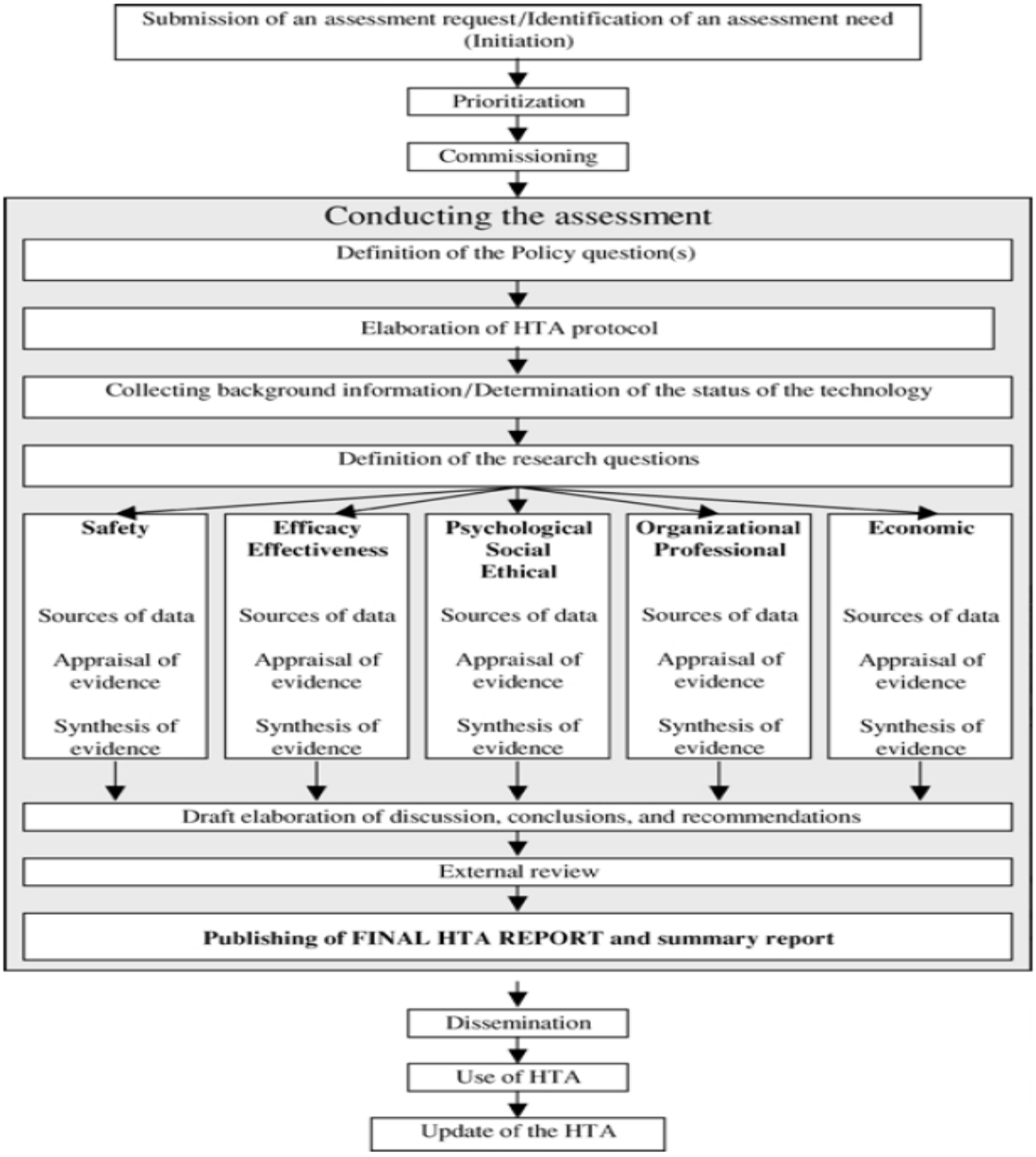
Upon completion of a project protocol, best practices in TA development suggest: first, gathering background information to help translate the initial policy question into specific research questions that can be addressed through systematic literature reviews; and second, documenting literature search methods, inclusion and exclusion criteria, quality assessment of included articles, and the process for information synthesis (often in the form of evidence tables) (Busse 2002). This will help demonstrate the report's transparency and proactively mitigate risks to the HTA program (Busse 2002; Hailey 2005b). See Appendix I for a suggested literature selection process flow diagram produced by the EUR-ASSESS Workgroup 4 (Busse 2002). The INAHTA has developed a checklist for HTA reports to assist in the development of more transparent and consistent HTA products (see Appendix J). As with the risk assessment checklist (Appendix H), the INAHTA HTA assessment is based on expert opinion regarding best practices, and the collaborative work of INAHTA members rather than on empirical outcome evidence or evaluation. However, since evidence-based standards for systematic reviews and meta-analyses are available, incorporating these methods into HTA processes will raise the scientific rigor of the evidence synthesis process (IOM 2011; Moher 2009).

Use of HTA in Decision Making

The INAHTA guidance points out that HTA programs and decision makers have a shared role in the HTA process that requires regular communication and a commitment to engage in the process. This commitment requires an HTA program to be responsive to the needs of decision makers as well as requiring decision makers to engage in the HTA process (Hailey 2010). Including decision makers and stakeholders in HTA topic development can help mitigate external risks to a HTA program (Hailey 2005b; 2010) (see Appendix H for a model HTA risk checklist). When external stakeholders are involved, the likelihood increases that HTA products are applicable and relevant to decision makers' needs and a process is likely to have been created that is transparent and approachable by stakeholders. When an HTA report is driven by an initial policy question, it follows that it will directly address the needs of decision makers (Busse 2002; Hailey 2005b, 2010). Figure 2, developed from the EUR-ASSESS Workgroup 4 (Busse 2002), illustrates how the policy question lays the groundwork for all subsequent work in the assessment process. Discussions defining the policy question should include decision makers and address the context of the report, the scope of the assessment, and the urgency and level of detail needed (Hailey 2010). Additionally, individuals conducting the assessment will no doubt have a stronger understanding of the pathways used by decision

makers, and thus focus their assessment on decision makers needs. In the initial stages of the HTA process, this model HTA structure requires regular communication between the HTA program and decision makers (Hailey 2010).

Figure 2. HTA Assessment Process (developed by EUR-ASSESS Workgroup 4 (Busse 2002))



Effective dissemination of information to a broad spectrum of decision makers and stakeholders is also strongly encouraged by the INAHTA, and including a summary document

targeted at consumers and decision makers that includes a concise lay translation of the HTA findings (Busse 2002; Hailey 2005a, 2005b, 2010). Some HTA programs, such as the SBU and NICE, also develop patient handbooks. These patient materials are easily accessible online and/or in pharmacies, clinics and hospitals (Hailey 2005a). Additionally, the SBU uses the Ambassador Program, which draws on local opinion leaders to disseminate HTA findings to change clinical practice (Hailey 2010).

As a final note, it is difficult to ignore the value and strength of collaboration in developing standard HTA process and practices. European HTA programs have a long history dating back to 1994 of working together to develop high quality HTA methods and to reduce the level of duplicative efforts in HTA program process development. Through collaboration of HTA programs in Europe, resources and international organizations such as the INAHTA, Health Technology Assessment international (HTAi), and *IJTAHC*, have been developed and continue to work toward creating best practices for HTA (Banta 2009). As an example, the EUnetHTA, a current collaboration built from multiple country HTA development projects, recently proposed a HTA Core Model which could increase the international applicability of country specific HTA reports, reduce the international duplication of HTA reports, and promote well developed HTA methods and processes (Kristensen 2009; Lampe 2009). As a note, the core model does not include specific recommendations on technology use, as international health care policy and settings widely differ (Kristensen 2009). However, the Core Model does represent a tool meant to foster international collaboration around HTA and to define and strive for best practices (Lampe 2010).

Strengths and limitations of the evidence

This report is based on a qualitative review of 12 national and international HTA programs selected because of their explicit roles to inform public program decision makers. Strengths of the review include a systematic process of identifying HTA programs for review, presentation of the HTA processes and components used by a representative group of well-developed HTA programs, and a national and international perspective. Information included in the review relies heavily on information available through HTA program public websites. This approach underscores the extent of transparency in program processes and information that is available to external audiences. At the same time, the information may be limited based on what was identified on program websites. Where we identify that information is not available does not mean that a program does not have a process in place. In addition, we limited the review to programs with information in English. This excluded some well-developed HTA programs, such as the HTA program in France.

Policy Considerations

This section outlines key policy considerations and options for each HTA program component highlighted by this report. While the policy considerations identified are not exhaustive for all options for structuring an HTA program, they provide a comprehensive overview of national and international program approaches to HTA components. This outline below may help guide public programs in considering options of how to structure a new HTA program, revise an

existing program, or make optimal use of available HTA products in their own decision making contexts.

Program Purpose: Role of a HTA program in relationship to policy making.

The program purpose for a HTA program needs to be explicit. The options available include:

- Evidence advisory role;
- Evidence and policy advisory role; **or**
- Authority to make coverage determinations.

Governance and Organization**:** Structure of HTA organization and review committees.

Different governance models are used by HTA programs. An HTA program structure can be one of the following:

- Independent agency / non-profit; **or**
- Government-based agency.

HTA committees and advisory committees can help guide HTA processes, ensure independence, and reinforce scientific review. Types of committees may include:

- Board of directors / Strategic advisory board;
- Scientific or technical advisory committee;
- HTA report evaluation committee; and
- Protocol or methods advisory committee.

Scope**:** Types of technologies reviewed and key factors analyzed.

Depending on the needs of decision makers, the scope of an HTA program can vary. However, the scope of most HTAs can be defined as:

- Limited (focus on medical procedures and services), **and/or**
- Expanded (includes medical procedures and services, organization and delivery of health care services, disease prevention and public health promotion).

Note: For example, a HTA program may review a single technology (limited scope) and subsequently review another technology in the context of the healthcare delivery system, and public health promotion (expanded scope).

The following is a list of possible *technology factors to analyze*. Not every HTA program addresses all of the following components:

- Safety;
- Clinical effectiveness;
- Cost- benefit;
- Cost-effectiveness;
- Patient considerations (needs and challenges);

- Health service impact;
- Organization (administrative and delivery systems); and
- Ethics.

HTA Products**:** Types of reports and other products produced by a HTA program.

Available products from HTA programs can include:

- Focused HTA report (single issue or technology);
- Large scale HTA report (disease specific or complex issue);
- Technology alerts (brief summary of an emerging health technology); and
- Patient and clinician summaries, clinical pathways, guidelines, performance measures and other implementation tools.

Program Evaluation**:** Use of program evaluation to inform HTA program development.

Program evaluation is a useful tool to assess current HTA processes and products and establish new directions for a program. Program evaluation can be conducted through an:

- Internal HTA program assessment; and/or
- External HTA program assessment.

Stakeholder Involvement**:** Types and processes for stakeholder involvement in the HTA process.

Stakeholders and decision makers can be involved at several stages of the HTA process. Key considerations about stakeholder involvement include:

- Who to involve as stakeholders (e.g., policy decision makers, consumers, clinicians, industry);
- How to involve (public meetings, committee and advisory groups);
- What aspects of HTA should have stakeholder involvement:
    - Topic nomination and development (public topic nomination process; stakeholder involvement in key question development);
    - Evidence and experts (industry or patient/disease advocacy groups encouraged to submit evidence/dossiers; peer review process);
    - Draft HTA reports (comments on draft reports); and
    - Appeal of HTA conclusions.

Topic Nomination: Process to solicit topic nominations.

Topic nomination can be either:

- Agency directed (includes decision maker and governmental nominations); **or**
- Public (includes nominations from the public, in addition to governmental, and decision maker nominations).

Topic Refinement: Process to develop key questions and refine topic nomination.

Topic refinement can include one or more of the following:

- Work with topic authors to define research question(s) and define research protocol;
- Project groups develop research protocol;
- Conduct initial review of literature/evidence; and/or
- Use public topic review criteria.

Topic Selection: Process to prioritize and select topics for review.

Topic selection criteria are an important way to prioritize topics for reviews. Many HTA programs use:

- Topic prioritization criteria (e.g., disease burden, potential clinical impact, available alternatives, potential budget impact, potential economic impact, and available evidence); and/or
- A process to apply prioritization criteria to the topic selection process (i.e., systematic approach to apply prioritization criteria to topic selection).

Entities Conducting Reviews: Internal or external groups conduct evidence synthesis.

Review of health technologies may be conducted internally or externally. HTA programs will often use one or more of the following entities to conduct a review:

- Internal project team;
- External contractors; or
- Mixed internal / external research team.

Review Methods: Extent and nature of review methodologies.

Multiple types of review methodologies can be incorporated into an HTA program, such as:

- De novo full systematic reviews (review of primary studies and existing systematic review and technology assessments);
- Incorporation of existing systematic reviews, technology assessments, primary studies, and grey literature; and/or
- Use of "best evidence" (incorporation of existing systematic reviews and recent primary studies).

Public Program Decision Makers: Use of HTA in public program decision making.

The relationship between public program decision makers and HTA programs is fundamental component in the sustainability of a HTA program and should include:

- Decision makers committed to HTA process through:
    - Commitment of funds;
    - Intention to use HTA products; and
    - Continuous communication with the HTA program;
- HTA programs responsible for:
    - Competent evidence reviews;
    - Clear and transparent presentation of findings;

- Responding to decision makers' questions; and
- Following up with decision makers to inform them of conclusions reached.

Implementation: HTA dissemination and implementation strategies.

Program information and HTA products are implemented and disseminated through multiple pathways. While not all HTA programs apply the same methods for dissemination and implementation of information, possible methods include:

- Funding and financial support for dissemination, implementation and/or evaluation;
- Knowledge transfer;
  - HTA training sessions for targeted audiences;
  - Facilitate communication between decision makers and HTA program;
- Dissemination
  - HTA reports available on public websites;
  - Publication in scientific and professional journals (e.g., *International Journal of Technology Assessment in Health Care*);
  - Conferences; and
  - Facilitated discussions.

Summary

This report reviews 14 key components of HTA programs used by public health care programs to allocate health resources. The key components are described based on 12 well-established national and international HTA programs, and are organized within six domains: program structure, program transparency, stakeholder involvement, topic nomination and selection, HTA methods of evidence synthesis, and use of HTA in each country's decision making. The report discusses four consistent themes – HTA independence, transparency, scientific validity and process, use of HTA in decision making – that state or other public entities may consider in designing HTA programs. In addition, policy options and implementation tools are identified in the report and Appendices H through J to assist state public programs considering the development of HTA programs.

Appendix A. Updated Search Strategy

1. exp Technology Assessment, Biomedical/
2. exp "Outcome and Process Assessment (Health Care)"/
3. exp Program Evaluation/
4. 1 and 3
5. 1 and 2
6. ((health$ or medic$ or biomed$ or telemed$ or teleheal$) adj3 technol& adj5 (assess$ or evaluat$)).mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
7. hta.mp.
8. 6 or 7
9. 3 and 8
10. 4 or 0
11. (program$ adj5 (evaluat$ or assess$ or judg$ or comar$)).mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
12. 1 and 11
13. 10 or 12
14. 8 and 11
15. 13 or 14
16. 5 or 15
17. limit 16 to English language
18. limit 17 to yr="2000-Current"

Appendix B. HTA Program Scanning

Country	Website / Materials in	Include (y/n)	Comments
Australia (MSAC)	y	y	Detailed information about structure and process
Belgium (KCE)	y	y	Limited information about organization, good report on methods/process information
Canada (CADTH)	y	y	High quality methods – part of core sources
Catalonia (Spain region)	y	n	Limited information about product or process
China	n/a[4]	n/a	No primary information available
Denmark (DACEHTA)	y	y	Detailed information about products, stakeholder involvement, program structure
England (NICE)	y	y	High quality methods – part of core sources
Finland (FINOHTA)	y	n	Limited information about product or process
France	n	n	Program overview in English, all methods and product descriptions are in French
Germany (DAHTA@DIMDI)	y (some)	n	Good overview information, methods are in German, excluded
Germany (IQWiG)	Y	y	Good overview information, direct link to decision makers
Ireland	y	n	Formal HTA process in development
Israel (ICTAHC)	y	n	No information on process or structure
Italy	n/a	n/a	No national HTA program identified
Japan	n/a	n/a	No national HTA program identified
Netherlands	n	n	No primary information available
New Zealand	y	n	Very limited information about structure. No info on process
Norway (NOKC)	y	n	Very limited information about structure. No info on process
Poland (AHTAPol)	n	n	No primary information available

[4] n/a – in our scoping, no national HTA website was identified.

Scotland (SIGN)	y	n	High quality methods – part of core sources, not an HTA
Singapore	y	n	No primary information available
Spain (AETS)	n	n	Limited detailed information in English
Sweden (SBU)	y	y	Some detailed information about process and structure
Switzerland	y	n	No national HTA program identified
United States			
AHRQ (EPC, DEcIDE)	y	n	High quality methods – not an HTA
CMS-CAG / MEDCAC	y	y	High quality methods – part of core sources
VA HTA (TAP, TAAG)	y	y	Developed HTA process, refer to Luce (2009)
Minnesota	y	y	Developed HTA process
Oregon	y	y	Developed HTA process
Washington	y	y	Developed HTA process

Appendix C. HTA Program References

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Appendix D. HTA Program Component Description

Health Technology Assessment Program Structure

1. Program purpose
    - Program purpose / goal, including primary audience (countries, government agencies)
    - Types of decisions informed (coverage, guidelines, etc.)
    - Source of program authority (statutes, regulations, etc.)
2. Organization and governance
    - Program management
    - Evidence review entity
    - Coverage / policy decisions entity
3. HTA program scope
    - Definition of HTA (e.g., systematic review of technology's safety, efficacy, and cost-effectiveness)
    - Types of technologies reviewed (drugs, devises, treatments, health promotion, and public health efforts; old and new technologies)
4. Program transparency
    - Overall transparency of program decisions (extent of stakeholder involvement, open versus closed process, conflict of interests policies, program independence)
5. Stakeholder input
    - Opportunities for stakeholders to provide input into topic nominations and selection
    - Opportunities for stakeholders input into evidence reviews (e.g., submission of studies, comments on draft and final reports)
    - Opportunities to provide input into coverage decisions and timeframes
    - Information made public
6. Target audience

Nomination and Selection of Topics

7. Topic nomination process
    - Process to solicit topic nominations, including sources, frequency and timeframes
    - Topic re-review process
8. Topic development
    - Process to develop key questions and refine topic nomination
9. Topic selection
    - Process to select topics for review, including groups consulted, frequency and timeframes
    - Priorities for selecting topics
    - Number of topics reviewed per year

Evidence Synthesis

10. Entit(ies) conducting reviews
    - Description of evidence review entity (public, private, academic, overall credentials)
    - Internal or external to the HTA program
    - Relationship to decision makers
    - Process of assignment, and timeframes from start and finish of reviews
11. Review methods
    - Search methods and scoping
    - Types of evidence considered
    - Assessment: standards to rate evidence, validity of evidence, outcomes considered
    - Economic analysis methods
    - Statistical techniques and applicability
    - Expert or peer review of products

Use of HTA in Decision Making

12. Decision making bodies
    - Description of entit(ies) with decision making power and relationship to HTA program
13. Decision making processes and criteria
    - Process for making decisions
    - Factors on which decisions must be based
    - Timeframes in which decisions are made
14. Appeal process
    - Process to appeal coverage decisions

Program Products and Dissemination

15. HTA products
    - Primary HTA product structure, conclusions, ratings
    - Derivative products, such as tools for providers and patients to use HTA
16. Implementation
    - Dissemination of HTA products
    - Monitoring direct and indirect impacts of program
17. Program evaluation
    - Evaluations of HTA program outcomes or performance measure

Appendix E. Summary comparison of HTA programs – International

HTA Component	Australia (MSAC)	Belgium (KCE)	Canada (CADTH)	Denmark (DACEHTA)	England (NICE)	Germany (IQWiG)	Sweden (SBU)
Program Structure							
Program Purpose	Advisory with respect to evidence and policy options	Advisory with respect to evidence and policy options	Advisory with respect to evidence only	Advisory with respect to evidence and policy options	Advisory with respect to evidence and policy options	Advisory with respect to evidence only	Advisory with respect to evidence only
Organizational Governance and HTA Program Committees	*Organizational Governance* Government agency (part of public payer agency) *HTA Program Committees* Medical Services Advisory Committee; Evaluation Sub-Committee; Protocol Advisory Sub-Committee	*Organizational Governance* Semi-governmental institution *HTA Program Committees* No information identified	*Organizational Governance* Independent non-profit *HTA Program Committees* Advisory Committee on Pharmaceuticals; Devises and Systems Advisory Committee	*Organizational Governance* Government agency (independent of public payer agency) *HTA Program Committees* Strategic Advisory Board	*Organizational Governance* Government agency (part of public payer agency) *HTA Program Committees* Technology Appraisal Committees (four standing committees)	*Organizational Governance* Independent non-profit *HTA Program Committees* Scientific Advisory Board	*Organizational Governance* Government agency (independent of public payer agency) *HTA Program Committees* Scientific Advisory Committee; Alert Advisory Board
Scope	*Reviewed Technologies* Pharmaceuticals (including vaccines), diagnostic tests, (including pathology), medical devices, surgically implanted prostheses, medical procedures and services, surgical interventions, and public health interventions *Key Factors Analyzed* Safety, clinical effectiveness, and cost-	*Reviewed Technologies* New health care technologies, treatments, and drugs; health services organization and financing *Key Factors Analyzed* Safety, clinical effectiveness, cost-	*Reviewed Technologies* Drugs, medical devices, medical procedures, and health systems used in the maintenance, treatment and promotion of health *Key Factors Analyzed* Clinical efficacy, effectiveness, cost-	*Reviewed Technologies* Procedures and methods of prevention, diagnostics, treatment, care and rehabilitation, including equipment and medical drugs, supportive systems and organizations within the health care system *Key Factors Analyzed* Technologies (effectiveness), patient	*Reviewed Technologies* Pharmaceuticals, medical devices, diagnostic techniques, surgical procedures, therapeutic technologies, and health promotion activities *Key Factors Analyzed* Clinical effectiveness, cost-effectiveness	*Reviewed Technologies* Drugs, instruments, devices, medical and surgical procedures, supporting systems, organizational and management systems *Key Factors Analyzed* Benefit Cost-benefit	*Reviewed Technologies* Specific technologies not stated *Key Factors Analyzed* Benefits, risks, costs

HTA Component	Australia (MSAC)	Belgium (KCE)	Canada (CADTH)	Denmark (DACEHTA)	England (NICE)	Germany (IQWiG)	Sweden (SBU)
	effectiveness	effectiveness, patient considerations, and organizational issues	effectiveness, and service impact	(needs, challenges), organization (admin and delivery systems), economy (cost, economic analyses)			
Stakeholder Input	*MSAC committees:* Include clinical experts and consumer representatives *Topic nomination and selection:* open to all applicants for public funding *Research protocol:* Work with applicant/industry and public comment *Evidence review:* Applicants may comment *MSAC draft assessment report:* Applicants may comment	2010 study of the impact of the KCE program found that there are no systematically applied procedures regarding the involvement of stakeholders (Poortvliet 2010, commissioned by KCE) *Board of Directors:* Representation by government policy makers and health professional groups *Topic nominations:* Open to public, annual process *Evidence review:* KCE generally consults with industry for submission of evidence and review of draft reports	*Topic nominations*: Open to public, topics refined with nominator *Evidence review*: Information solicited from manufacturers, report authors, & other experts *Implementation*: Knowledge Transfer Program focuses on linking research with decision makers; includes Liaison Program	Project manager primarily assesses which stakeholders are most relevant to involve Use of stakeholder "reference group" to seek input from stakeholders with conflicts of interest	Stakeholders involved at each step in HTA process Consultees invited to submit statements and participate as consultant to HTA process (includes for example, national groups representing patients, industry, health care professionals, Department of Health) Commentator organizations, with interest in technology, also invited to participate in HTA process	*Topic nominations and development*: Open to the public; public may also comment on draft research plans *Evidence review*: Invites industry to submit unpublished studies Solicits external expert review *Draft reports*: Open to public comment for four weeks; comments published on website; evaluation of comments included in final report	*No information identified*

HTA Component	Australia (MSAC)	Belgium (KCE)	Canada (CADTH)	Denmark (DACEHTA)	England (NICE)	Germany (IQWiG)	Sweden (SBU)
Target Audience	Australian Department of Health and Ageing, health professionals, hospitals, consumers	National Institute for Health and Disability Insurance, Ministers of Public Health and Social Affairs, professionals, general public	Federal, provincial, and territorial health ministries including drug plans; regional health authorities and hospitals, clinical practice	Regional and local public program decision makers, hospital and department level management, politicians, industry, clinicians, general public	NHS for England and Wales, clinicians, patients, and carers	Federal Joint Committee, Federal Ministry of Health, general public	Ministry of Health, administrative, county and municipal level decision makers, quality improvement teams, county drug review committees, patients
Nomination and Selection of Topics							
Topic Nomination Process	Open to public	Open to public	Open to public	Focused nomination process (decision makers)	Open to public	Focused nomination process (decision makers)	Open to public
Topic Refinement	Works with nominating author to refine topic and develop search protocol	Internal project group refines topic and develops search protocol	Works with nominating author to refine topic and develop search protocol; conducts preliminary literature assessment	Internal project group refines topic and develops search protocol	Internal project group refines topic and develops search protocol; conducts preliminary literature assessment	Internal project group refines topic and develops search protocol	Internal project group refines topic and develops search protocol; conducts preliminary literature assessment
Topic Selection	Department of Health and Ageing determines whether proposed service for review is clinically relevant professional service	Board of Directors selects topics based on prioritization criteria	Topics approved and prioritized by Advisory Committees and Board of Directors based on six core criteria	*No information identified*	UK Department of Health refers technologies for HTA based on prioritization criteria	The Federal Joint Committee and the Ministry of Health commission reports	Board of Directors and Scientific Advisory Committee select topics and report type based on priority areas
Evidence Synthesis							
Entit(ies) Conducting Reviews	External contractors	HTAs may be conducted internally or externally	Combined internal project group and external contractor	*No information identified*	Independent academic centers	Internal staff and external contractors	Work group including Scientific Advisory Committee, Board of Directors, staff, clinicians, economists, epidemiologists
Review Methods	Systematic review (full systematic literature review and	Incorporation of existing HTA reports, systematic reviews,	Systematic review	Systematic review	Systematic review	*No information identified*	Systematic review

HTA Component	Australia (MSAC)	Belgium (KCE)	Canada (CADTH)	Denmark (DACEHTA)	England (NICE)	Germany (IQWiG)	Sweden (SBU)
	modeled economic evaluation)	primary studies and grey literature					
Use of HTA in Decision Making							
Decision Making Bodies	Australian Department of Health and Ageing	National Institute for Health and Disability Insurance, Ministers of Public Health and Social Affairs	Federal, provincial, and territorial health ministries	Regional and local public program decision makers	NICE	Federal Joint Committee	Ministry of Health
Decision Making Process and Criteria	MSAC advises Minister of Health and Ageing whether new medical service should be publically funded	KCE advises policy makers with respect to strength of evidence and policy options for coverage of healthcare technologies and services	CADTH advises regarding the strength of evidence supporting coverage of drugs and health care technologies	DACEHTA advises policy makers with respect to strength of evidence and policy options	Appraisal Committee issues the final appraisal determination NICE distributes the determination to NHS in England and Wales	IQWIG advises policy makers with respect to strength of evidence	SBU advises policy makers with respect to the strength of evidence
Appeal Process	*No appeal process identified*	*No appeal process identified*	*No appeal process identified*	*No appeal process identified*	15 business days for consultees to appeal	*No appeal process identified*	*No appeal process identified*
Program Products and Dissemination							
HTA Products	Technology Assessments; Public Summaries	Scientific report with executive summary	Technology Reports; Technology Overviews; Health Technology Update Issues in Emerging Health Technologies; Emerging Drug List	Focused (single issue or technology) ; Large-scale (multiple technologies or diseases); Brief summary reports	Focused (single issue or technology); Large-scale (multiple technologies or diseases)	Detailed Reports; Rapid Reports; Dossier assessments within framework or early assessment of drugs; Health Information; Working Papers	Focused (single issue or technology) ; Large-scale (multiple technologies or diseases); Brief summary report
Implementation	HTA reports available on comprehensive website (in English)	HTA reports available on comprehensive website (in English)	HTA reports available on comprehensive website (in English); knowledge transfer specialist (KTS)	HTA reports available on comprehensive website (in English); facilitated utilization; conferences; publication in scientific and professional journals; published debating points in daily newspapers;	HTA reports available on comprehensive website (in English); development of implementation tools; costing and audit support	HTA reports available on comprehensive website (in English); project status available on website	HTA reports available on comprehensive website (in English); newsletter; publication in scientific and professional journals; free online subscription to SBU website & news;

HTA Component	Australia (MSAC)	Belgium (KCE)	Canada (CADTH)	Denmark (DACEHTA)	England (NICE)	Germany (IQWiG)	Sweden (SBU)
				Media press releases			regional & national conferences; exhibitions; educational activities & seminars for targeted audiences
Program Evaluation	Evaluation conducted – 2010	Evaluation conducted – 2010	Evaluation conducted – 2010	Evaluation conducted – 2003	Evaluation conducted - 2008	*No information identified*	*No information identified*

Appendix F. Summary comparison of HTA programs – United States

HTA Component	United States (CMS-CAG)	United States (VA/DoD)	United States (MN)	United States (OR)	United States (WA)
Program Structure					
Program Purpose	Coverage determination decision maker	Advisory with respect to evidence and policy options	Advisory with respect to evidence and policy options	Advisory with respect to evidence only	Coverage determination decision maker
Organizational Governance and HTA Program Committees	*Organizational Governance* Government agency (part of public payer agency) *HTA Program Committees* Medical Evidence Development & Coverage Advisory Committee	*Organizational Governance* Government agency (part of public payer agency) *HTA Program Committees* No information identified	*Organizational Governance* Government agency (part of public payer agency) *HTA Program Committees* Health Services Advisory Committee; Dental Sub-Committee A	*Organizational Governance* Government agency (part of public payer agency) *HTA Program Committees* Health Resources Commission; Pharmaceutical Subcommittee; Technology Subcommittee	*Organizational Governance* Government agency (part of public payer agency) *HTA Program Committees* Health Technology Clinical Committee
Scope	*Reviewed Technologies* Services covered by Medicare – specific types not specified *Key Factors Analyzed* Effectiveness	*Reviewed Technologies* Vaccines, pharmaceuticals, devices, procedures, organizational and support systems *Key Factors Analyzed* Medical, social, ethical, economic	*Reviewed Technologies* Health care services paid for by state program – specific types not specified *Key Factors Analyzed* Effectiveness, cost	*Reviewed Technologies* Pharmaceuticals, medical equipment and devices, medical or surgical procedures, supportive systems *Key Factors Analyzed* Clinical effectiveness, safety	*Reviewed Technologies* Medical and surgical devices and procedures, medical equipment, diagnostic tests *Key Factors Analyzed* Safety, efficacy, cost-effectiveness

HTA Component	United States (CMS-CAG)	United States (VA/DoD)	United States (MN)	United States (OR)	United States (WA)
Stakeholder Involvement	*Committees*: MEDCAC includes industry and consumer representatives , and external subject area experts *Topic nomination:* public may request NCDs or comment on proposed NCDs *Draft reports*: 2 week public comment period on draft reports *Final report*: peer review and stakeholder comments and authors' responses posted 3 months after final report is released *Meetings:* MEDCAC meetings are public *Draft decisions:* proposed NCDs open to public comment *Appeals*: formal process to appeal NCD decisions	*No information identified*	*Committees*: HSAC includes health care professional and consumer representatives *Meetings:* HSAC meetings are public and provide opportunity for comment on program subjects, such as draft reports, topic nomination or selection	*Committees*: HRC includes physician, pharmacist, hospitals, insurance, business, labor, and consumer representatives; consumer representatives are also on subcommittees *Topic nomination and selection*: OHA incorporates stakeholder input into topic refinement and selection; topic selections posted to website 1 month prior to technology subcommittee meeting reviewing topic *Evidence review*: Invite experts to comment on topics *Draft report*: Technology subcommittee draft report posted on web prior to HRC meeting and open to public comment during meeting *Meetings*: All HRC and subcommittee meetings are public	*Topic nomination and selection:* open to the public, nominations may be submitted according to standardized nominations form; potential topics for review open to public comment for 2 week period *Topic refinement*: 30-day public comment period on draft key questions *Draft reports*: two-week public comment period on draft report *Final reports* final report, peer review, stakeholder comments and authors' comments posted 30 days prior to public meeting *Meetings:* Stakeholders written comments provided in public meeting package for HTCC; HTCC meetings are public and include opportunity for oral public comment *HTCC draft finding and decisions*: Stakeholders may provide written comment on draft decisions *Appeals*: No appeals of HTCC decisions
Target Audiences	CMS – Medicare Coverage Decisions	Senior VHA decision makers	Department of Human Services	Oregon Health Authority, decision makers responsible for coverage decisions by state agencies and public programs, public and private health plans, clinicians, and consumers	State direct purchased health care programs (WA public employees and retirees, Medicaid, and Worker's Compensation); Dept. of Corrections and Veterans Affairs participate voluntarily

HTA Component	United States (CMS-CAG)	United States (VA/DoD)	United States (MN)	United States (OR)	United States (WA)
Nomination and Selection of Topics					
Topic Nomination Process	Focused nomination process (decision makers only)	Focused nomination process (decision makers only)	Focused nomination process (decision makers only)	Open to public nominations	Open to public nominations Considers nominations of public agencies subject to HCA decision and HTCC recommendations
Topic Refinement	Internal project group refines topic and develops search protocol	*No information identified*	Internal project group refines topic and develops search protocol	Internal project group refines topic and develops search protocol with approved evidence vendors	Works with nominating author to refine topic and develop search protocol Internal project group refines topic and develops search protocol with evidence vendor
Topic Selection	CMS-CAG requests HTAs for NCDs where there is conflicting or complex medical and scientific literature available, or when it is believed an independent analysis of literature will be helpful for coverage decisions	*No information identified*	HSAC reviews and prioritizes topics to study Topics prioritized based on impact to health and budget, availability of literature, and political relevance	OHA selects topics for review. The topic selection process takes into account factors such as utilization (including overall utilization, trends and variability in utilization) and costs (including overall costs as well as cost variability)	HCA Administrator selects topics for review, may also consider nominations by interested parties, and must select topics based on technology review priorities established in law
Evidence Synthesis					
Entit(ies) Conducting Reviews	AHRQ conducts full HTAs CMS Coverage and Analysis Group	Internal staff	Internal staff and approved external evidence sources	External contractors and approved evidence sources	External contractors
Review Methods	Systematic reviews (AHRQ)	Defined search strategies to locate applicable evidence	Incorporation of "best evidence" into decisions	Incorporation of "best evidence" into decisions	Systematic reviews and targeted "best evidence" reviews
Use of HTA in Decision Making					
Decision Making Bodies	CMS-CAG policy makers make coverage decisions	VHA policy decisions makers	Department of Human Services	OHA programs including OHP through DMAP and HSC for use in Prioritized List of health services and developing clinical guidance Will also share with PEBB and OEBB & other state agencies	HTCC: Coverage decisions are made by the HTCC and are binding on the participating state agencies

HTA Component	United States (CMS-CAG)	United States (VA/DoD)	United States (MN)	United States (OR)	United States (WA)
Decision Making Process and Criteria	MEDCAC provides advisory recommendations Primary factors for making national determinations about what care is "reasonable and necessary" include whether a technology was safe, effective, and appropriate, and whether it led to improved health outcomes	*No information identified*	HSAC uses the summary documents as a starting point for discussion, drawing an assessment based on the evidence and their clinical expertise	HRC shares results of HTAs within OHA, PEBB, OEBB, DOC State agencies are encouraged, but not required, to use the HRC reports in their coverage decisions	The HTCC must make coverage decisions based on the health technology assessment, as well as information provided by the HCA administrator, an advisory group, and submissions or comments from the public; HTCC decides whether evidence demonstrates that the technology is safe, effective, and cost effective The committee gives the greatest weight to the evidence determined, based on objective factors, to be the most valid and reliable; as well as additional evidentiary valuation factors such as recency (date of information); relevance (the applicability of the information to the key questions presented or the participating agency programs and clients); and bias (presence of conflict of interest or political considerations)
Appeal Process	MEDCAC decision not subject to appeal (advisory) The public may request "reconsiderations" of NCDs	*No information identified*	Coverage determinations can be appealed	HRC conclusions not subject to appeal (advisory)	There is no right to appeal HTCC decisions directly Individuals subject to state agency coverage and benefits have appeal rights/processes
Program Products and Dissemination					
HTA products	Systematic review conducted by AHRQ; CMS NCDs	Brief Overview; bibliography	Evidence summary, including proposed coverage decision	Evidence summary (with clinically relevant conclusions); Brief Clinician Summaries	Health technology assessments; findings and coverage decisions

HTA Component	United States (CMS-CAG)	United States (VA/DoD)	United States (MN)	United States (OR)	United States (WA)
Implementation	HTAs are available through NCD process	VATAP reports used by VHA	Evidence summaries and legislative reports are available on the HSAC website	The Commission shares the results of the medical technology assessments with relevant state agency decision makers	Participating agencies required to comply with HTCC decision; unless decision conflicts with law or agency provides coverage under experimental and investigational policy with IRB approval
Program Evaluation	*No information identified*	*No information identified*	*No information identified*	*No information identified*	Quality assessment of program (July 2008) Program Review report developed and available on the WA-HTA website

Appendix G. Summary comparison of stakeholder involvement

	Australia MSAC	Belgium KCE	Canada CADTH	Denmark DACEHTA	England NICE	Germany IQWiG	Sweden SBU	US CMS-CAG	US VATAP	US MN HSAC	US OR HRC	US WA-HTA
Public Meetings												
Public meetings	No Meetings are held quarterly, but not public	No No meeting information available on website	No No meeting information available on website	No	Yes Appraisal Committee	No	*No information identified*	Yes MEDCAC public meetings 4-8 times per year; MEDCAC meetings only held for select NCDs Must register to attend in person or via webinar 3 days prior to meeting	*No information identified*	Yes HSAC public testimony disclosure form on website	Yes Monthly meetings, agendas and minutes are posted on website and distributed by e-mail to interested subscribers	Yes HTCC Public meetings 4-5 times/year; agendas and meeting materials are posted on website and distributed by e-mail to stakeholders 1 week prior to public meeting
Advanced notice of meeting agenda and materials	Yes Timeframe not specified	No	No	No	Yes Agenda published on website at least 20 working days before the mtg (public must register for mtg; up to 20 people allowed)	No	*No information identified*	Yes 60 days advanced notice of meeting agendas published in federal register and on website Must register and provide materials for oral	*No information identified*	Yes Website & list serve	Yes Timeframe subject to topic area	Yes Schedule of public meetings published annually on website Draft meeting agendas posted on website 30 days prior Final

	Australia MSAC	Belgium KCE	Canada CADTH	Denmark DACEHTA	England NICE	Germany IQWiG	Sweden SBU	US CMS-CAG	US VATAP	US MN HSAC	US OR HRC	US WA-HTA
								presentation 30 days prior to meeting				agendas and meeting materials are posted on website and distributed by e-mail to stakeholders 1 week prior to public meetings
Invite written comments prior to meetings	No	No	No	No	*No information identified*	Yes Opportunity to comment on draft research plans and draft reports (see below)	*No information identified*	Yes Written comments must be submitted 30 days prior to meeting	*No information identified*	Yes	Yes May submit written or oral comments at public meeting	Yes May provide written comment for inclusion in advanced meeting materials
Meeting minutes and other materials published	Yes Not current (updated as of 3/2008)	No	No	No	Yes Within 15 working days of mtg	No Publish minutes of private scientific debate with commentators	*No information identified*	Yes MEDCAC minutes and transcript, TA reviewed, written comments, presentations, and committee "score-sheet" posted on website	*No information identified*	Yes	Yes	Yes Minutes, draft and final decisions published to website
Topic Nomination and Selection												
Public topic nomination solicitation	Yes Open	Yes Nominations	Yes Nominations	No	Yes	Yes Public may	Yes	Yes The public	No	No	Yes OHA	Yes Nominations

	Australia MSAC	Belgium KCE	Canada CADTH	Denmark DACEHTA	England NICE	Germany IQWiG	Sweden SBU	US CMS-CAG	US VATAP	US MN HSAC	US OR HRC	US WA-HTA
	application for HTA review in order to receive public funding	open to the public and occur annually	open to public; however, guidance not available on website			submit via email through website; no guidance or form for nomination		may propose NCD topics; no public input regarding CMS-CAG request for AHRQ technology assessment or MEDCAC review			incorporates stakeholder input into topic refinement and selection	open to the public and may be submitted according to standardized nomination form available on website
Public comments to develop topics/key questions	Yes MSAC works with applicants to agree on research protocol 5 weeks for public comment on draft research protocol	No No formal process identified	No Topics refined with nominator, but not open to public comment	No May use stakeholder "reference group" Specific opportunities for input unclear	Yes 20 working days; publishes draft KQ's & scope on website 5 days after sending to consultees & commentators; scoping workshop (6-8 wks after start of consultation process)	Yes Public comment on draft research plan, and any changes, for period of 4 weeks	*No information identified*	No No public process identified to comment on key questions	No	Yes In HSAC meetings	No Program draws on existing systematic reviews and does not have control over key questions	Yes 30-day public comment period
Stakeholder notice of topics selected	Yes 6 weeks public notice in advance of beginning assessment Assessments in process	Yes Website lists planned studies Timeframe for notice to public not specified	No	No Website identifies ongoing projects, but no notice prior to start of assessment	Yes Website	Yes Opportunity to submit comment on research plan; ongoing projects listed	Yes Website	Yes 60 days advanced notice MEDCAC meeting agendas and topics under review	No	*No information identified*	Yes Topic selections posted one month prior to first Tech Sub-committee meeting	Yes Website lists selected topics; inform all stakeholders by e-mail all nominated and selected

	Australia MSAC	Belgium KCE	Canada CADTH	Denmark DACEHTA	England NICE	Germany IQWiG	Sweden SBU	US CMS-CAG	US VATAP	US MN HSAC	US OR HRC	US WA-HTA
	posted on website											topics
Evidence Reviews												
Stakeholder opportunity to submit evidence	Yes Applicants for HTA review submit evidence No timeframes specified	Yes Specific timeframe unclear	Yes Information solicited from industry, report authors and other experts No timeframes identified	No May use stakeholder "reference group" Specific opportunities for input unclear	Yes Week 9 once appraisal begins – have 2 wks to submit; clarification on manufacturer or sponsor's submission - by week 12 (STA) or week 14 (MTA)	Yes Invites industry to submit unpublished studies	*No information identified*	No No public process to submit evidence identified May submit evidence via MEDCAC public comment opportunity	*No information identified*	Yes	Yes Stakeholders may submit evidence through the evidence review process conducted by approved vendors	Yes May submit evidence during public comment opportunities
Stakeholder opportunity to comment on evidence synthesis	Yes Applicant comment on evidence review No time-frames specified	Yes Specific timeframe unclear	No Information not available on website	No May use a stakeholder "reference group" Specific opportunities for input unclear	Yes 4 weeks consultation for consultees & commentators; 3 weeks (online) for non-consultees & non-commentators	No	*No information identified*	Yes Stakeholders may comment on draft AHRQ technology assessment during 2 week comment period	*No information identified*	*No information identified*	Yes Stakeholders may provide comment at public meetings or in writing prior to the meetings	Yes Stakeholders may provide comment on draft report for 2 weeks
Expert reviews	Yes Assessment reviewed by	Yes Program consults	Yes	Yes Use ad hoc expert	Yes	Yes Posts solicitations	Yes	Yes AHRQ TA includes	No	*No information identified*	Yes Use as needed	Yes Experts invited to

	Australia MSAC	Belgium KCE	Canada CADTH	Denmark DACEHTA	England NICE	Germany IQWiG	Sweden SBU	US CMS-CAG	US VATAP	US MN HSAC	US OR HRC	US WA-HTA
	Evidence Sub-Committee	with experts and obtains external validation of reports		groups, and external peer review		for external expert review on website		invited peer review MEDCAC may invite experts			Must complete conflict of interest forms	provide comment Health technology assessments includes invited peer reviews and available on website
Reports												
Stakeholder review/ comments on draft reports/ decisions	Yes Applicant comment on draft MSAC assessment	Yes Consultation with industry only Specific timeframes for comment unclear	Yes 2 wks for Recommendation report; 4 weeks for discussion paper	No May use a stakeholder "reference group" Specific opportunities for input unclear	ACD circulated to consultees & commentators within 15 working days of AC mtg; published on website 5 working days after circulation w/comment facility; consultees & commentators have 20 working days to submit comments in writing, preferably by email, but cannot	Yes Public comment on draft report for period of at least 4 weeks; Require conflicts of interest disclosure and standardize form	*No information identified*	Yes Comments and invited peer review posted w/ final report along with author responses within 3 months after final report released	*No information identified*	Yes	Yes Posted on website 2-4 weeks prior to HRC public meeting	Yes Draft report posted to website for 2 week public comment period Final report, peer review, stakeholder comments, and authors' responses posted 30 days prior to public meeting HTCC findings and decisions posted to website for two week public comment

	Australia MSAC	Belgium KCE	Canada CADTH	Denmark DACEHTA	England NICE	Germany IQWiG	Sweden SBU	US CMS-CAG	US VATAP	US MN HSAC	US OR HRC	US WA-HTA
					use website comment facility							period after public meeting
Stakeholder review/comments on final reports	No	No	No	No May use a stakeholder "reference group" Specific opportunities for input unclear	Consultees receive FAD & ACD as to consider whether to appeal; Commentators only receive FAD	No Comments and response to comments are included in final report	*No information identified*	Yes Public may comment on proposed NCDs	*No information identified*	*No information identified*	No	Yes Stakeholder comments and response to comments published in final report
Reports posted on website	Yes Posted after accepted by Minister	Yes	Yes	Yes Ongoing projects and final reports	Yes 5 days after circulating FAD	Yes	Yes	Yes AHRQ final reports and NCDs	Yes	*No information identified*	Yes	Yes Draft and final reports posted to website
Organizational Involvement (committee representation, stakeholder groups)												
HTA Committee Stakeholder Representatives	Consumer representatives, health professionals, and health Ministry reps (ex officio) included on MSAC and Sub-committee	Policy makers and health professional groups represented on Board of Directors	Board comprised of public decision making bodies	No	Appraisal committee comprised of government agency reps, patient/carer orgs, academia, industry	Board of Trustees comprised of consumer, industry and government representatives	*No information identified*	MEDCAC comprised of 100 members, including 6 patient advocates, and 6 nonvoting industry reps	*No information identified*	*No information identified*	HRC comprised of consumer, hospital, business, labor, and insurance representatives	HTCC membership by law is comprised of 11 practicing clinicians not employed by state or industry manufacturers
Stakeholder committee or liaison groups	No	No	Knowledge Transfer Program – focus on linking research and public	Strategic Advisory Board coordinates use of HTAs among local decision	No	No	No	No	No	No	No	No HTCC has authority to establish an ad hoc temporary advisory group

	Australia MSAC	Belgium KCE	Canada CADTH	Denmark DACEHTA	England NICE	Germany IQWiG	Sweden SBU	US CMS-CAG	US VATAP	US MN HSAC	US OR HRC	US WA-HTA
			decision making	makers May form a stakeholder "reference group" to provide during HTA process								if specialized expertise or inputs are needed
Stakeholders targeted	Focus on consumers and applicants (e.g., industry and health professionals)	Focus on government policy makers No consumer outreach or representation	Focus on government decision makers No consumer outreach or representation	Focus on government decision makers Patient groups may be part of reference group	Consultee and commentator organizations	Focus of government decision makers Statutory obligation to inform public as well	*No information identified*	Medicare coverage decisions	*No information identified*	*No information identified*	Focus on government decision makers Also consumers, clinicians, public at large	State agencies purchasing health care
Other Resources	*No information identified*	*No information identified*	Newsletter	*No information identified*	*No information identified*	*No information identified*	Newsletter	*No information identified*	*No information identified*	*No information identified*	Website, stakeholder e-mail distribution list	Website, stakeholder e-mail distribution list
Overall timeframe to conduct evidence review	18 months	12 months	454 reports produced in 2008-09	Varied based on product: 2 months – 2.5 years	Single TA (37 weeks) Multi- TA (54 weeks)	*No information identified*	*No information identified*	*No information identified*	*No information identified*	*No information identified*	*No information identified*	Varies based on product scope
Note: **Yes = information identified on HTA program website** **No = information not indentified on HTA program website**												

Appendix H. HTA Risk Checklist (Hailey 2005b, p. 21-22)

		Project Stage					
Program Activity	**Area of Risk**	**Planning**		**Product Preparation**		**Dissemination**	
		Risk Level	Review Date	Risk Level	Review Date	Risk Level	Review Date
Question formulation	Problem/topic definition						
	Assessment scope						
	Decline or modify request						
	Time frame						
HTA product	HTA quality						
	Consultation – expert advice						
	Public/external development						
	Misleading information						
	Sensitivity regarding findings						
	Product review						
Dissemination	Summary message						
	Dissemination to primary target						
	Sensitivities from other parties						
	Secondary dissemination - targets						
	Use of dissemination vehicles						
Contractors	Form of contract						
	Timelines for deliverables						
	Quality of deliverables						
	Confidentiality						
	Unacceptable interests						

Appendix I. Literature Selection Process Flow Diagram (Busse 2002, p. 373)

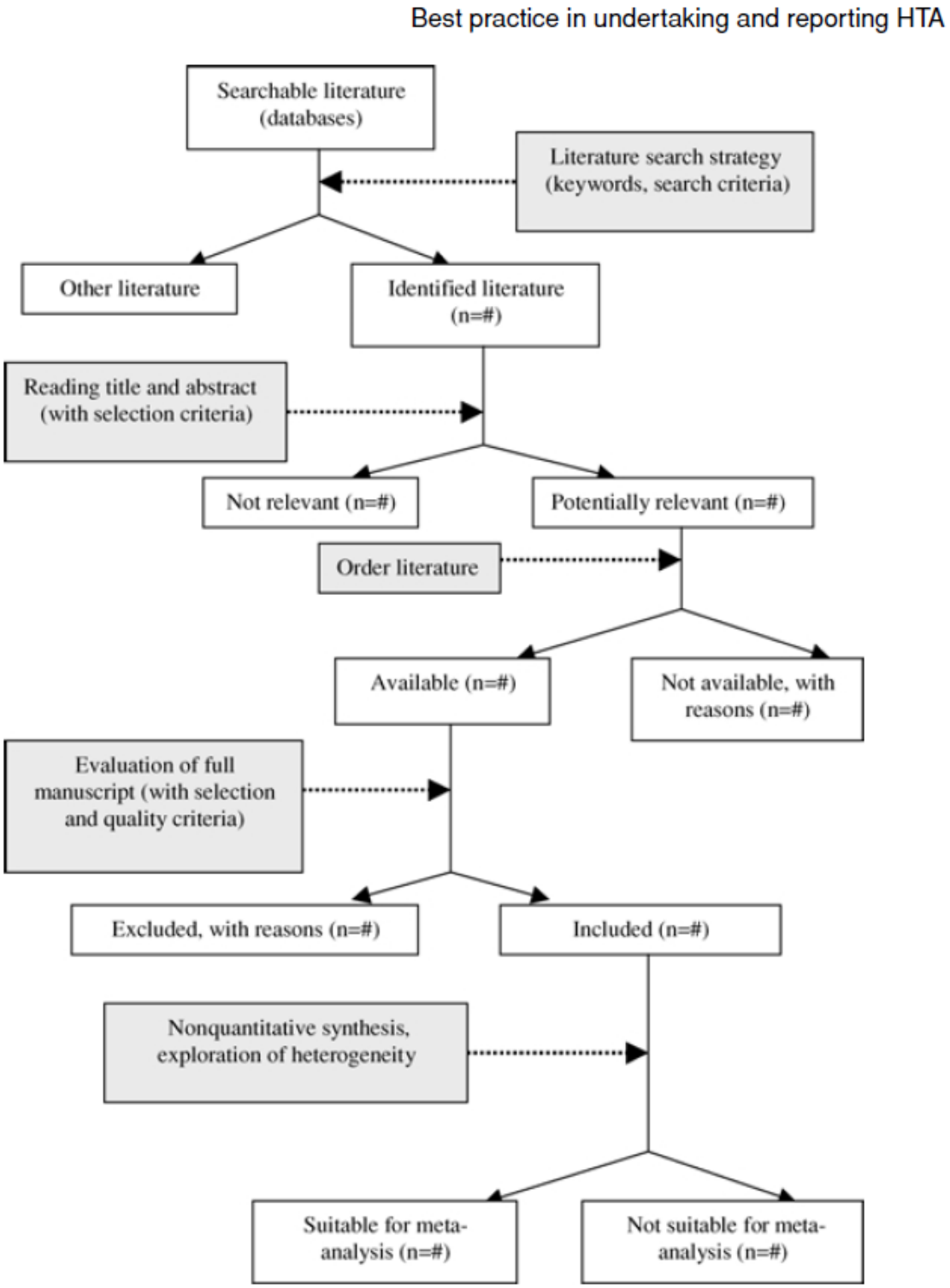


Figure 2. Flow diagram of literature selection process (adapted from Khan et al. (3b).)

Appendix J. INAHTA Checklist for HTA Reports (INAHTA 2007)

Introduction

Objective

This checklist has been prepared as an aid to furthering a consistent and transparent approach to health technology assessment. A general theme is the clear identification in an HTA report of what has been done in an assessment and of any significant limitations in the analysis. A key to improving the usefulness and generalisability of HTA reports is to aim for transparency in the assessment process. Assessments will vary considerably in their depth and scope of analysis, given differences in the types of problem being addressed, policy requirements and the time and resources available for assessment. However, readers of an HTA report need to be able to easily obtain information on the purpose of the assessment, the methods used, assumptions made and conclusions reached.

Intended audience

The checklist is intended as a guide both for those who use HTA reports as a source of information and for those who prepare such documents.

For those reading reports prepared by other organisations, the checklist gives guidance on what to look for in an HTA report and in assessing the reliability of the information provided.

For those undertaking HTA, the checklist gives points that should be considered during the planning, conducting and reporting of the assessment. It is hoped that this guidance will help to improve the quality of HTA reports.

Context of material in the checklist

The checklist contains only brief details of a number of important points relating to HTA reports and is intended for initial guidance. The checklist should be seen as complementary to the authoritative guidelines for assessment of health technologies that have been prepared by a number of agencies.

It is stressed that an HTA report may be a valid and useful source of information even if it does not include a number of elements from the checklist. It is not essential for an HTA report to include all the attributes given in the checklist.

The checklist will help those reading and preparing HTA reports in consideration of which elements have been included and which omitted. The significance of any omissions in an HTA report will depend on how it is to be used by the reader. Those needing further assurance of the nature and quality of an assessment may well have to contact those who prepared the HTA report.

Contents of the checklist

The checklist includes 14 questions to be considered by those reviewing or preparing an HTA report.

One additional question is concerned with the context of the technology assessment and relates to issues that may not be addressed in some reports (i.e., medico-legal implications, economic impact, ethical and social implications and the wider community perspective).

The core 14 questions deal with matters that should be considered for all HTA reports. Some of these questions cover provision of basic information; others refer to the steps taken in performing the assessment. Those dealing with selection and appraisal of information are followed by additional points for consideration, whose application will vary, depending on the scope of the report under review.

Under most of the questions, some further points and suggestions have been added in italics.

At the end of the checklist is a summary sheet that may be helpful for recording conclusions regarding the content of an HTA report.

The checklist

Preliminary information

1. Are there appropriate contact details for provision of further information?

Include a contact person or position with appropriate addresses.

2. Are those who prepared the HTA report identified as authors or in other ways?

Approaches and conventions will vary, but it will be desirable to have a clear indication of persons who were involved in preparing the report and of their roles. These persons may include authors, committee members (if that has been the approach used) and persons providing technical or administrative support.

It may be helpful to include a statement to the effect that the assessment has drawn on available published material and expert comment and is intended to be current at the date of publication.

3. Is there a statement regarding conflict of interest?

Conflict of interest is of concern here because of the perception that it could lead to unreasonable bias in an HTA report. A statement on conflict of interest would refer to those who prepared the report. There may be a need only to indicate there is no conflict of interest. It will be appropriate for reports to indicate whether funding for the assessment has been provided by sources other than those responsible for the author agency's usual budget.

It should be noted that conflict of interest may arise in relation to non-financial matters.

4. Is there a statement on whether the report has been externally reviewed?

External review of a report is generally regarded as a measure that improves its quality and credibility. Details provided regarding the review process will vary, but it is helpful to include names and affiliations of persons who have provided comment or information during preparation of the report.

5. Is there a short summary that can be understood by the non-technical reader?

This is a highly desirable feature of an HTA report. Many of the policy makers and other non-technical recipients of the report will only read the summary. This is a major aid to getting the message of the assessment across to a wider audience. The summary might cover the purpose and scope of the assessment, refer to the approach taken, give leading results and include clear conclusions. It should preferably not exceed two pages
— longer summaries tend not to be read.

It is highly desirable for non-English language HTA reports to include an English version of the summary.

Inclusion of a structured abstract can be a helpful approach to concise presentation of essential details.

Why the assessment has been undertaken

6. Is reference made to the policy question that is addressed?

It is important to describe the rationale for undertaking an HTA report in order to explicitly identify factors that may have influenced the report such as health system policies and priorities, social and political influences.

Reports should specify why an assessment has been undertaken and, where appropriate, who

has requested this work.

7. Is reference made to the research question(s) that is/are addressed?

It is important to clearly define the research question(s). How is this health technology to be assessed? A well-constructed research question should contain elements of the criteria for including studies, specifically the population for whom the technology is intended, the technology or intervention of interest, the comparator (or related health services and technologies) against which the technology will be evaluated, and the outcomes that will be used to assess the technology. For example, "Is MRI screening of women at high risk of breast cancer more effective at reducing breast cancer mortality than film-screen mammography?"

8. Is the scope of the assessment specified?

The report should indicate which attributes of the technology are addressed and preferably also clearly indicate areas that are not included in the assessment.

9. Is there a description of the health technology that has been assessed?

A short description of the technology will be helpful for the general reader. Details of what the technology does and how it works will be useful but should be concise - a text book approach is not needed. Brief reference to alternative or competing technologies may also be helpful.

How the assessment has been undertaken

10. What sources of information have been used?

- Details of the literature search should be provided. These should include key search terms and combination of search terms, databases used, years covered, and any language restrictions.
- Details of the use of primary data and other sources of information should also be given.
- Details of the source and basis of any cost data should be given, preferably with comment on their accuracy.
- Inclusion and exclusion criteria should be provided. The report should indicate who has undertaken the selection and how this processing was done.
- A complete reference list of included studies/bibliography should be included.
- A list of studies that met the inclusion criteria but were eventually excluded, and reason for exclusion, should be provided.

Some reports will include more extensive details of the literature search. It is suggested that full details of the literature search should be available on request, but not necessarily included in the report. Quality and relevance of cost data will vary with their source and nature, which may range from administrative data collected for other purposes to a bottom up approach specifically directed towards the assessment being undertaken. If arbitrary values have been assigned to costs, appropriate justification should be provided.

Material may be selected for inclusion in the report to address the following:

- *Technical issues*
  (If these are addressed, include the source of material, and the basis for selection.)

- *Safety (For example, regulatory decisions; information on adverse effects. The basis for selection of material should be indicated.)*

- *Efficacy/effectiveness (Details of the basis for selection should be given — for example, consideration of study design, numbers of subjects. Is it made clear why the selected papers have been chosen and not others?)*

Some attributes (for example, safety of the technology) may not be covered in some reports.

Usually, only references selected for inclusion in the analysis or commentary will be cited in the report. However, details of rejected references should be available on request. Use of an internationally recommended diagram (e.g., CONSORT) to summarise what has been included and excluded in the literature selection process would be a helpful feature.

11. Is there information on the basis for the assessment and interpretation of selected data and information?

- Has the method of data extraction been described? *Accuracy and consistency in data extraction are extremely important. Errors can be minimised by designing data extraction forms with clear instructions and using at least two reviewers to perform data extraction independently.*
- Has the critical appraisal method (for quality assessment of the literature) been provided? *Appraisal of the quality of the available material should be an important component of an HTA report. Assessment of quality of life studies should consider whether valid instruments have been used. For these and other types of study attention should be paid to whether there is good comparison between groups.*
- Has the method of data synthesis been described? *There will be a synthesis from the analysis of the material selected for assessment — quantitative or non-quantitative. Details of the method should be described.*
- Are the results of the assessment clearly presented, (e.g., in the form of evidence tables)? *Tabular presentation of material is a commonly used and helpful approach.*

  Absolute values should be presented, not just relative values. Estimates or indications of uncertainty and potential bias should be included.

Context *(may or may not apply to each HTA)*

- Are medico-legal implications considered?

  Have the medico-legal implications of using this particular health technology been considered? Information on litigation risks and professional indemnity insurance may be of relevance in this section, should it be discussed.
- Is an economic analysis provided?
  Has there been an analysis of the economic impact? May include cost or economic studies of similar applications; the basis for selection should be given.

  The approach to any synthesis and extrapolation of results from the literature selected should be described. If the HTA report includes cost or economic analysis, details of methods used and assumptions made are required. The quality of available studies should be considered. There should be adequate sensitivity analysis.
- Are ethical implications considered?
  Any specific issues relevant to the technology should be included. This may include issues of access, equity and informed consent concerning use of the technology in the local health care system and community. There should be a description of what has been done in the analysis, including the arguments and approaches used. The basis for discussion should be clearly outlined.

- Are social implications considered?
  Any specific issues relevant to the technology should be included. This may include issues of the impact of this technology on carers, family dynamics, social isolation, ability to stay in the home longer, early return to work, relevance of particular sub-cultures, likelihood of employment, "disease labelling", among others.
- Is a wider perspective (stakeholders, patients, consumers) considered?
  Any organisational issues specific to the national, regional or local health care system that are related to the acquisition, implementation and operation of the technology may be discussed. This might include the impact of the technology on hospital provision of services, provision of services in rural and remote areas, or workload and workforce implications. Issues regarding training and credentialing of people operating the technology, along with patient compliance and uptake might also be considered. Sources of information should be clear and analysis transparent.

What then? - Implications of the assessment results and conclusions

12. Are the findings of the assessment discussed?

Discussion of the findings should include:

- The relationship of the results obtained to the question being addressed by the assessment. (Information from the literature may help only to a limited extent.)
- There should be a clear interpretation of the results. It will be helpful to include comment on their likely relevance to clinical practice and to the health care system.
- Comment on missing or uncertain information, and the reliability of the analysis (This may perhaps be brief.)
- The basis for the opinions and conclusions in the report. (Do the assessment findings follow from the data? Are additional assumptions or opinions contributing to the position taken? If so, what are they? Has the report addressed all the potential benefits and disadvantages of the intervention? Have the objectives of the assessment been met?)

The discussion should be bringing earlier components of the report together in the context of the question that has been asked.

Frequently, judgements will have to be taken in the absence of definitive data on the performance of a technology. The nature and basis of such judgements should be made explicit. As in other parts of the report, transparency should be a key feature. The reader should be given a clear account of what has been done, what has been assumed and what has not been done.

13. Are the conclusions from the assessment clearly stated?

The report should reach clear conclusions, which will make reference to the question addressed by the assessment and, where appropriate, its context. The conclusions should flow from the evidence that has been reviewed.

Some HTA reports will include recommendations. Not all agencies will have a mandate to make explicit recommendations, but the conclusions of the assessment should be clear to the reader.

14. Are there suggestions for further action?

It may be helpful for the HTA report to include discussion of current research/ information gaps, directions for future research and assessment and approaches to dissemination of findings.

It may be useful for HTA reports to address the implications of their findings for policy, where such analysis is within the mandate of the assessment organisation.

A checklist for HTA reports

This summary form is intended as an aid for those who wish to make a record of the extent to which a health technology assessment report meets the 14 questions given in the checklist.

It is NOT intended as a scorecard to rate the standard of HTA reports — reports may be valid and useful without meeting all the criteria that have been listed.

Item	**Yes**	**Partly**	**No**
Preliminary			
1. Appropriate contact details for further information?			
2. Authors identified?			
3. Statement regarding conflict of interest?			
4. Statement on whether report externally reviewed?			
5. Short summary in non-technical language?			
Why?			
6. Reference to the policy question that is addressed?			
7. Reference to the research question(s) that is/are addressed?			
8. Scope of the assessment specified?			
9. Description of the assessed health technology?			
How?			

10. Details on sources of information and literature search strategies provided?

Search strategy	Databases	Year range	Language restriction	Primary data	Other kind of information resources
O	O	O	O	O	O

Complete reference list of included studies	List of excluded studies	Inclusion criteria	Exclusion criteria
O	O	O	O

11. Information on basis for the assessment and interpretation of selected data and information?

Method of data extraction described?	Critical appraisal method (for quality assessment of the literature) described?	Method of data synthesis described?	Results of the assessment clearly presented, e.g. in the form of evidence tables?
O	O	O	O

Context? *(may or may not apply to each HTA)*

(Medico-) legal implications considered?	Economic analysis provided?	Ethical implications considered?	Social implications considered?	Other perspectives (stakeholders, patients, consumers) considered?
O	O	O	O	O

What then?	**Yes**	**Partly**	**No**
12. Findings of the assessment discussed?			
13. Conclusions from assessment clearly stated?			
14. Suggestions for further action?			

Appendix K. Australia – HTA Components - Commonwealth HTA system (MSAC)

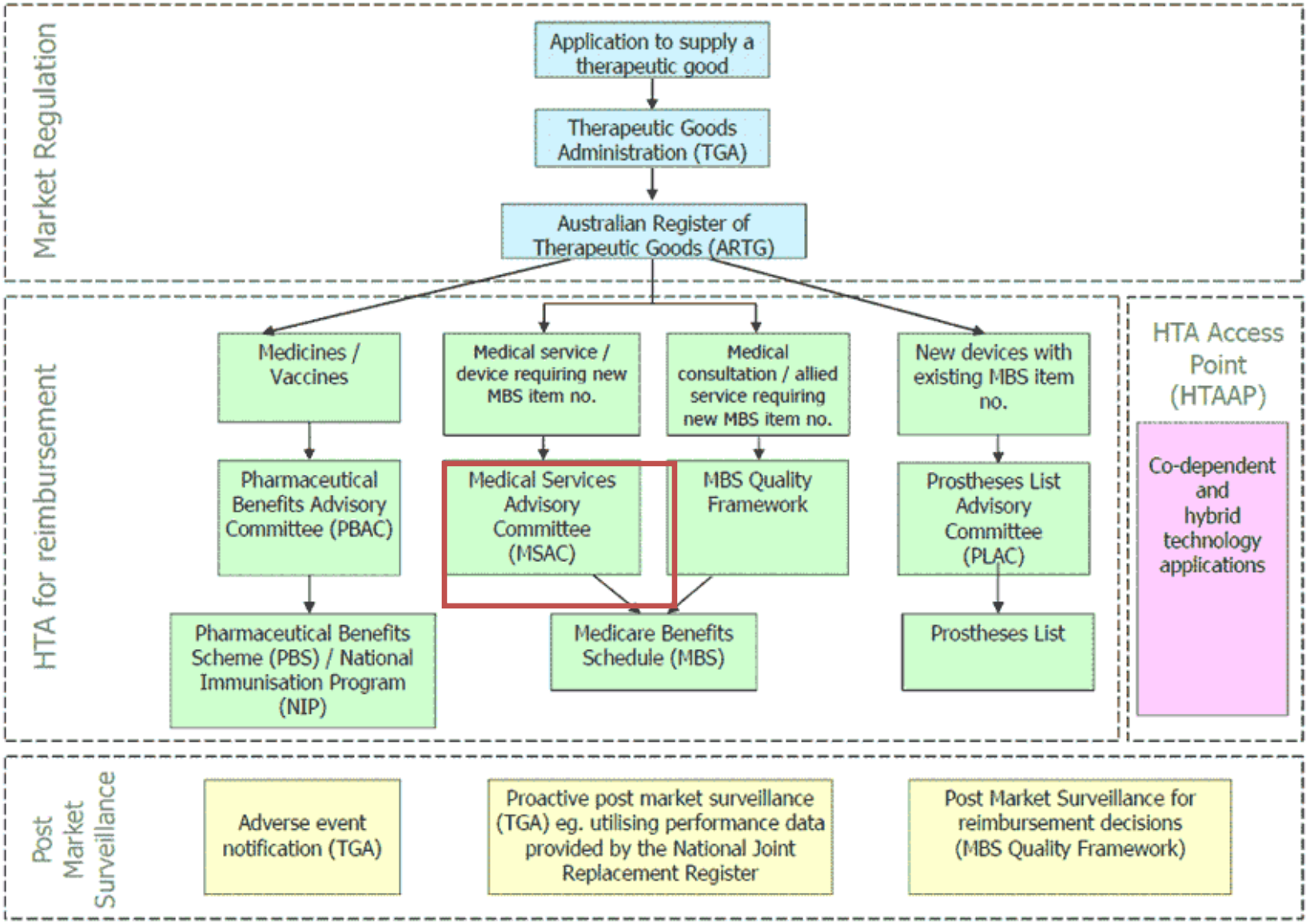
Structure of HTA Program	HTA Organization
Program Structure	
1. Program purpose	Several minister-appointed HTA committees advise the Australian Minister of Health and Ageing. These include the Medical Services Advisory Committee (MSAC), the Prosthesis List Advisory Committee (PLAC), and the Pharmaceutical Benefits Advisory Committee (PBAC). Because the HTA committees each have discrete roles and functions, this report focuses on MSAC's role and program components. MSAC advises the Minister for Health and Ageing with respect to the strength of evidence addressing the comparative safety, effectiveness, and cost-effectiveness of medical services that involve new or emerging technologies, and whether these services should be publically funded. All medical services must undergo a HTA evaluation to be eligible for public funding.
2. Organizational Governance and HTA Program Committees	*Medical Services Advisory Committee:* MSAC is an independent scientific committee appointed by the Minister for Health and Ageing. The Committee is comprised of members with expertise in clinical medicine, health economics and consumer issues. MSAC's size and composition is determined by the Minister of Health and Ageing. As of January 1, 2011, the committee includes 21 members (two of which are ex officio). MSAC's role is to evaluate the strength of evidence and advise the Minister for Health and Ageing on whether a new medical service should be publicly funded. • *Evaluation Sub-committee* is a standing sub-committee of MSAC with health economics, epidemiology, public health, consumer and clinical expertise. Its focus is to provide advice on the quality, validity and relevance of internal and external assessments for applications being considered by MSAC. • *Protocol Advisory Sub-committee* is a standing sub-committee of MSAC with membership including decision analysis, health economics, epidemiology, public health, consumer and clinical expertise. Its focus is on the task of determining Decision Analytic Protocols – that is, defining the decision option(s) or question(s) for public funding of a proposed new medical technologies and procedures prior to final lodgment of an application for its consideration by MSAC. The Department contracts with independent firms to prepare reports assessing the strength of evidence. MSAC then reviews evidence reports and other input to prepare advice to the Minister of Health and Aging regarding the strength of evidence and coverage of the technology. The Minister of Health and Ageing then makes a decision within the context of broader government priorities about whether the proposed medical service should be funded. Note: In February 2010, a Review of Health Technology Assessment in Australia made sixteen recommendations aimed at setting new directions for HTA in Australia, of which 13 were accepted by the Australian Government for implementation. These recommendations aim to support better health care for all Australians, and to reduce unnecessary regulatory burdens on the

Structure of HTA Program	HTA Organization
	sector while providing timely access to new and improved technologies and treatment modalities. Recommendation 9 from the HTA Review specifically focuses on the role of the Medical Services Advisory Committee (MSAC) to both streamline its operations and improve the flexibility of its processes. *See Figure 1. Map of Current Australian Government Processes for Market Entry and for Reimbursement Processes* *See Figure 2. Overview of New MSAC Process*
3. Scope of HTAs	*Types of technology reviewed:* Pharmaceuticals (including vaccines), diagnostic tests (including pathology), medical devices, surgically implanted prostheses, medical procedures, medical services, surgical interventions, and public health interventions. *Key factors analyzed:* safety, clinical effectiveness, and cost-effectiveness
4. Program Transparency	Advice from MSAC to the Minister for Health and Ageing is confidential until the Minister has noted the advice and agrees to its public release. Once the advice is noted, Public Summary Documents explaining the rationale for the advice, and the printed Assessment Report are made publicly available on the MSAC website. MSAC's website includes: a list of applications that are in progress, draft protocols, and final assessment reports (which are released after advice is noted by the Minister), and public summary documents.
5. Stakeholder Involvement	MSAC identifies opportunities for stakeholder input by applicants (industry or medical professionals) and by consumers. (See: Proposal for Changes to the MSAC Process for Applications for Public Funding, Attachment 5: Stakeholder Input) • *MSAC committees:* Consumers representatives are included on MSAC, as well as the Evaluation Sub-committee and the Protocol Advisory Sub-committee. • *Topic nomination and selection:* Application for a technology assessment can be submitted by the medical profession, medical industry and others with an interest in seeking Australian government funding for a new medical technology or procedure. MSAC works with applicants to determine the eligibility of the service to receive a MSAC assessment. Applications for public funding may be submitted on an ongoing basis. Specific timeframes for applicant input and comment are not identified. Consumers are also notified 6 weeks in advance of MSAC's intent to conduct an appraisal. • *Research protocol:* The Protocol Advisory Sub-committee works with applicants directly to agree on a research protocol. In addition the Protocol Advisory Sub-committee releases a Public Feedback Survey to solicit public comment on the Draft Protocol. Draft protocols are open for public comment for five weeks. • *Evidence review:* Applicants may comment on the Evidence Sub-committee's evaluation and critique of the evidence review. Timeframes for comment are not identified. • *MSAC draft assessment report:* Applicants may comment on the draft Assessment Report by MSAC. MSAC meetings are not public. Meetings are held up to four times per year, with dates and agendas of meetings posted on the website. There is no timeframe identified for advanced notice of meeting agendas. Meeting minutes of past meetings are

Structure of HTA Program	HTA Organization
	posted on the website, although the most recent meeting minutes posted are dated March 2008.
6. Target Audience	Policy-makers, funders, health professionals, hospitals, and consumers
Nomination and Selection of Topics	
7. Topic Nominations Process	Application for a technology assessment can be submitted by the medical profession, medical industry and others with an interest in seeking Australian government funding for a new medical technology or procedure. Applications may be initiated on an ongoing basis.
8. Topic Refinement	The Protocol Advisory Sub-committee works with applicants directly to agree on a research protocol. The PASC consults with trade groups, the public and clinical experts in defining the protocol (see public feedback survey indentified in opportunities for stakeholder input). The protocol will be the basis for developing an assessment of the evidence.
9. Topic Selection	The principal eligibility criteria for MSAC review is whether the proposed service constitutes a clinically relevant professional service within the meaning of the *Health Insurance Act 1973*. In addition, the Department has identified "fit for purpose" eligibility criteria.
Conduct of Evidence Reviews	
10. Entit(ies) conducting reviews	MSAC commissions full HTA (systematic literature review and modeled economic evaluation) from external contractors.
11. Methods of Reviews	Sample Methods from MSAC review of *Middle ear implant for sensorineural, conductive and mixed hearing loss* (2010) • PICO developed with assistance of the Advisory Panel • Key questions developed • Electronic databases searched (PubMed, EMBASE, Cochrane) • Established inclusion/exclusion criteria • Eligible full text articles reviewed by one reviewer, a second reviewer assessed articles in doubt, a third reviewer independently assessed the article • Bibliographies of all included studies were hand searched • Included studies quality assessed using the National Health and Medical Research Council (2000) definitions
Use of HTA in Decision Making	
12. Decision Making Bodies	MSAC formulates advice to the Minister of the Health and Ageing to determine public funding for technologies reviewed.
13. Decision Making Process and Criteria	MSAC formulates advice regarding circumstances in which public funding should support technologies review based on: the report assessing the evidence, the Evidence Sub-committee report on the evidence, any feedback on the reports provided by the applicant and/or other relevant parties, as well as the individual expertise of MSAC members. The Minister for Health and Ageing notes MSAC's advice and authorizes the publication of the advice and the assessment report. The Minister, in acting on MSAC positive advice may direct the Department to conduct further consultation leading to

Structure of HTA Program	HTA Organization
	policy and costing advice on which the Minister may make a fully informed decision in relation to public funding. Additionally the Australian Government considers community views of a technology or intervention, affected patient groups, the severity or impact of the disease being treated, and availability of effective alternative treatments.
14. Appeal Process	*No information identified.*
Program Products and Dissemination	
15. HTA Products	*Technology Assessments* – A detailed report documenting evidence reviewed and the basis of advice to the Minister. *Public Summaries* – Brief 1-3 page documents that summarize the evidence conclusions and coverage recommendations.
16. Implementation	MSAC is part of the Department of Health and Ageing and reports directly to the Minister of the Department. The Minister's makes final coverage decisions, and directs implementation.
17. Program Evaluations	In 2009, a Review of Health Technology Assessment in Australia made sixteen recommendations aimed at setting new directions for HTA in Australia, of which 13 were accepted by the Australian Government for implementation. Recommendation 9 from the HTA Review specifically focuses on the role of the Medical Services Advisory Committee (MSAC) to both streamline its operations and improve the flexibility of its processes. MSAC submits Performance Reports to the Minister annually.

Figure 1. Map of Current Australian Government Processes for Market Entry and Reimbursement Processes



(*Source*: http://www.health.gov.au/internet/hta/publishing.nsf/Content/commonwealth-1)

Figure 2. Overview of New MSAC Process

Overview of New Process

Stage : Pre-lodgment

Prior to applicants submitting a request for eligibility consideration the Department holds a pre-lodgment meeting with them. Representatives from relevant areas of the Department (including other advisory committee secretariats) also attend. This ensures the applicant is aware of the process, the likely pathway and evidence expectations.

Stage : Eligibility

MSAC eligibility criteria may vary depending on final requirements for fit-for-purpose pathways and approaches. This stage involves consideration by the Department to determine eligibility for a fit for purpose pathway and where required, protocol development. The principal eligibility criterion will remain whether the proposed service constitutes a clinically relevant professional service within the meaning of the *Health Insurance Act 1973*. Any need for submission to the Therapeutic Goods Administration (TGA) will also confirmed at this stage. The Department will determine if all fit for purpose pathway requirements have been met and agree the pathway under which the application will be progressed.

Stage : PASC Protocol development

Where indicated in a pathway, this stage requires the Protocol Advisory Subcommittee (PASC) to further develop decision analytic and resource usage templates submitted by the applicant. The PASC will undertake consultation with craft groups, the public and clinical experts. At the end of this stage the applicant and department and MSAC Executive will have an agreed protocol to undertake a systematic review of the evidence and generate an economic evaluation/model.

Stage : Assessment – PASC protocol based

The agreed PASC protocol will be the basis for the applicant developing an assessment of the evidence for formal lodgment. The PASC protocol stage will be required for proposals for public funding and for submission based applications. With submission based application the applicant funds the review of evidence whereas in the case where a proposal for public funding is the agreed pathway, the department contracts an assessment group to undertake development of the assessment report. Reports must meet the requirements of an agreed template which will be the same for both submission based and for contracted assessment reports.

Stage : LODGEMENT Evaluation - ESC

For submission based reports the department will commission a critique of evidence. In the case of a departmentally contracted report the applicant will be invited to comment, and that comment will be provided to MSAC. Following submission of protocol based review of existing evidence the report is provided to the MSAC Evaluation Subcommittee (ESC) which considers the report, critique or applicant comments. ESC's role is to review the report and comments against a pre-determined template for identifying the gaps and levels on uncertainty in the evidence and summarizing issues mapped against the range of options MSAC routinely considers in formulating advice on public funding.

Stage : MSAC Appraisal
In formulating its advice MSAC considers a wide range of information, including the report assessing the evidence, the critique of the report, ESC report on the evidence, any feedback on the report provided by the applicant and/or other relevant parties, as well as drawing on the individual expertise of MSAC members.
Stage : MSAC Advice to Minister
MSAC prepares advice to the Minister on the circumstances under which public funding should be supported based on the strength of the evidence of safety, clinical effectiveness and cost-effectiveness of the new technology or procedure. Where current evidence is inconclusive, but MSAC considers the potential for health benefit to warrant Interim Funding MSAC may consider advising the Minister on interim funding.
Stage : Minister/Government Decision
The Minister for Health and Ageing notes MSAC's advice and authorizes the publication of the advice and the assessment report. The Minister, in acting on MSAC positive advice may direct the Department to conduct further consultation leading to policy and costing advice on which the Minister may make a fully informed decision in relation to public funding.
Stage : Implementation
Once a Government decision has been made to provide public funding to a new service the Department is directed to implement the decision. Where public subsidy is related to a new item on the MBS the necessary changes are made to the Medicare Benefits Schedule that describe the service and the fee on which Medicare benefits will be based. The Department undertakes routine reporting to government on MBS costs to the health care system. In some instances the government may also direct that further reporting requirements be established. This has been the case in the past for some MBS items established through the 3C determination process for interim MBS funding based on MSAC advice.

(*Source*: http://www.msac.gov.au/internet/msac/publishing.nsf/Content/msac-application-process-lp-1)

Appendix L. Belgium – HTA Components - KCE

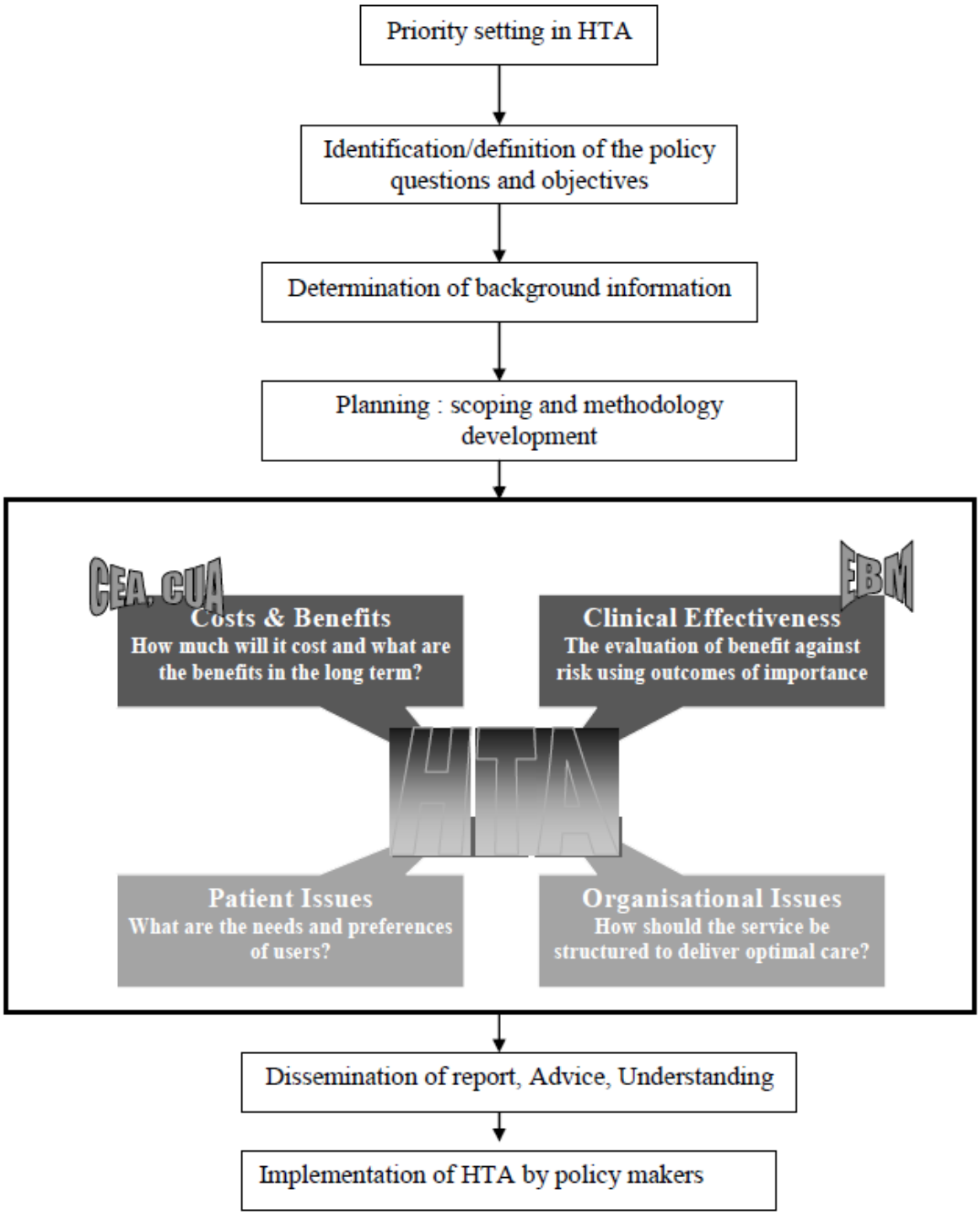
Structure of HTA Program	HTA Organization
Program Structure	
1. Program purpose	The Belgian Health Care Knowledge Centre (KCE) produces studies and reports to advise policy-makers with respect to the strength of evidence and policy options for coverage of healthcare technologies and services. KCE is legally obliged to perform studies for at least the following governmental institutions: National Institute for Health and Disability Insurance, and Ministers of Public Health and Social Affairs. The KCE is active in three major research fields: • Analysis of clinical practices and development of recommendations of good practice (Good Clinical Practice) • Assessment of health technologies and drugs (Health Technology Assessment) • Healthcare financing and organization (Health Services Research)
2. Basic organization and governance	The Belgian KCE is a semi-governmental institution, established by law in 2002. KCE is governed by a 13-member Board of Directors, with representatives from government agencies, professional organizations, providers, among other groups. KCE operates under the direction of the Minister of Public Health and Social Affairs. Members on the board represent: • Minister of Public Health • Minister of Social Affairs • National Institute for Health and Disability Insurance • Federal Agency for Medicinal and Health Products • Intermutualist Agency • Council of Ministers • Hospital Association • Physicians' professional organizations • Social partners representatives • Nurses' professional organizations • Chamber of Representatives Research projects are performed by internal experts or contracted to an external partner. The KCE Board then reviews all reports before they are disclosed publicly. *See Figure 1. Schematic presentation of HTA process* *See Appendix 1. Description of all steps in the HTA process (full HTA)*
3. Scope of HTAs	*Types of technologies reviewed:* new health care technologies, treatments and drugs. KCE also conducts Health Services Research involving the organizing and financing of health care services.

Structure of HTA Program	HTA Organization
	Key factors analyzed: • Clinical effectiveness: benefits and risks of the technology, expressed in for the patient relevant outcomes • Cost-effectiveness: comparative analysis of the cost-effectiveness/cost utility of alternative courses of action • Patient issues: needs and preferences, patient information, compliance, obstacles and fears related to the use of the technology. • Organizational issues: optimal organization of the health care infrastructure, diffusion of the technology, professional requirements, quality control, budget impact, legal issues
4. Program Transparency	*Reports:* The KCE website identifies ongoing and planned studies. All reports are posted on the KCE website.
5. Stakeholder Input	*Overall:* A 2010 study of the impact of the KCE program found that there are no systematically applied procedures regarding the involvement of stakeholders (Poortvliet 2010, commissioned by the KCE). *Stakeholder groups:* Focus on industry and health professionals. The program does not proactively seek consumer or patient input. *Topic nominations:* Topic nominations may be submitted by the public and topics are nominated once per year. The program provides a standard topic nomination form on its website that solicits information about nominations according to program priorities. Most of KCE's activities are commissioned by the Ministry of Public Health and Social Affairs and the National Health and Invalidity Insurance. *Evidence reviews:* • *Submission of evidence by industry:* KCE generally consults with industry for submission of evidence and review of draft reports. The "Description of All Steps in the HTA Process (Full HTA)" in Appendix 1 indicates that consultation with stakeholders to submit evidence occurs within the general timeframe allocated for a search of evidence and data of 10 weeks (a specific timeframe for industry submission of evidence is not noted). • *Expert review:* The program seeks expert review of evidence synthesis. • *Industry comment on evidence synthesis/draft report:* According to the 2010 impact study, forming expert groups is generally the only way in which KCE involves stakeholders during the research process (Poortvliet 2010). The evidence synthesis and the draft report appear to be one and the same. • *External validation:* KCE submits reports for external validation after external experts and industry have commented on the synthesis of evidence.
6. Target Audience	Primary target audience for KCE studies are defined by law to include: National Institute for Health and Disability Insurance (NIHDI), Federal Public Services Health, Federal Public Services Social Security, and the Cabinet of the Minister of Social Affairs and Public Health.
Nomination and Selection of Topics	
7. Topic Nominations Process	Proposals for research topics may be submitted by the public. Most of KCE's activities are commissioned by the Ministry of Public Health and Social Affairs and the National Health and Invalidity Insurance. Nominations are submitted once per

Structure of HTA Program	HTA Organization
	year.
8. Topic Refinement	In order to assess whether topics will be taken into account, the KCE evaluates the following criteria: 1. Does the proposed topic belong to KCE's activity domains (i.e., Good Clinical Practice, Health Technology Assessment or Health Services Research)? Studies that require a funding of diagnostic or therapeutic interventional studies will always be excluded. 2. Were all items of the form completed clearly and thoroughly so as to a priority can be assigned based on the criteria mentioned below? 3. Did the KCE receive the nomination form by the deadline? After assessment with the above criteria, topics are further refined by defining the objective(s) of the review, defining the PICO, specifying the databases that will be searched, and selecting the search terms and the selection criteria for studies.
9. Topic Selection	The KCE will assess the priority of the topics based on the following criteria: • Importance of the research topic (frequency, severity, room for improvement) • Policy relevance • Feasibility For the 2011, topic nominations were due by April 29th. An internal KCE jury will classify the admitted proposals according to priority in May 2011. • This priority assessment will be presented to KCE's Board of Directors in June 2011. The Board will select a shortlist of topics for 2012. In July 2011 the initiators will be informed that their proposal was or was not retained in this shortlist. • Between July and September 2011 the KCE will create a pre-project form for each selected topic. This will imply an assessment of the methodological feasibility and the availability of data (if applicable) and an estimation of the workload. This assessment will finally result in a concrete work plan for 2012 in which only those proposals of the shortlist are retained that are truly feasible, taking into account time and budget constraints. • In October 2011 this work plan will be presented to the Board of Directors that will eventually establish the work plan for 2012. In November 2011 the initiators will be informed whether their proposal was selected for KCE's 2012 work plan.
Conduct of Evidence Reviews	
10. Entit(ies) conducting reviews	HTA can be conducted internally or externally.
11. Methods of Reviews	*Steps for locating studies*: • Search for HTA studies (published or ongoing) • Search for Systematic reviews • Search for Primary studies • Search for Evidence-based Guidelines

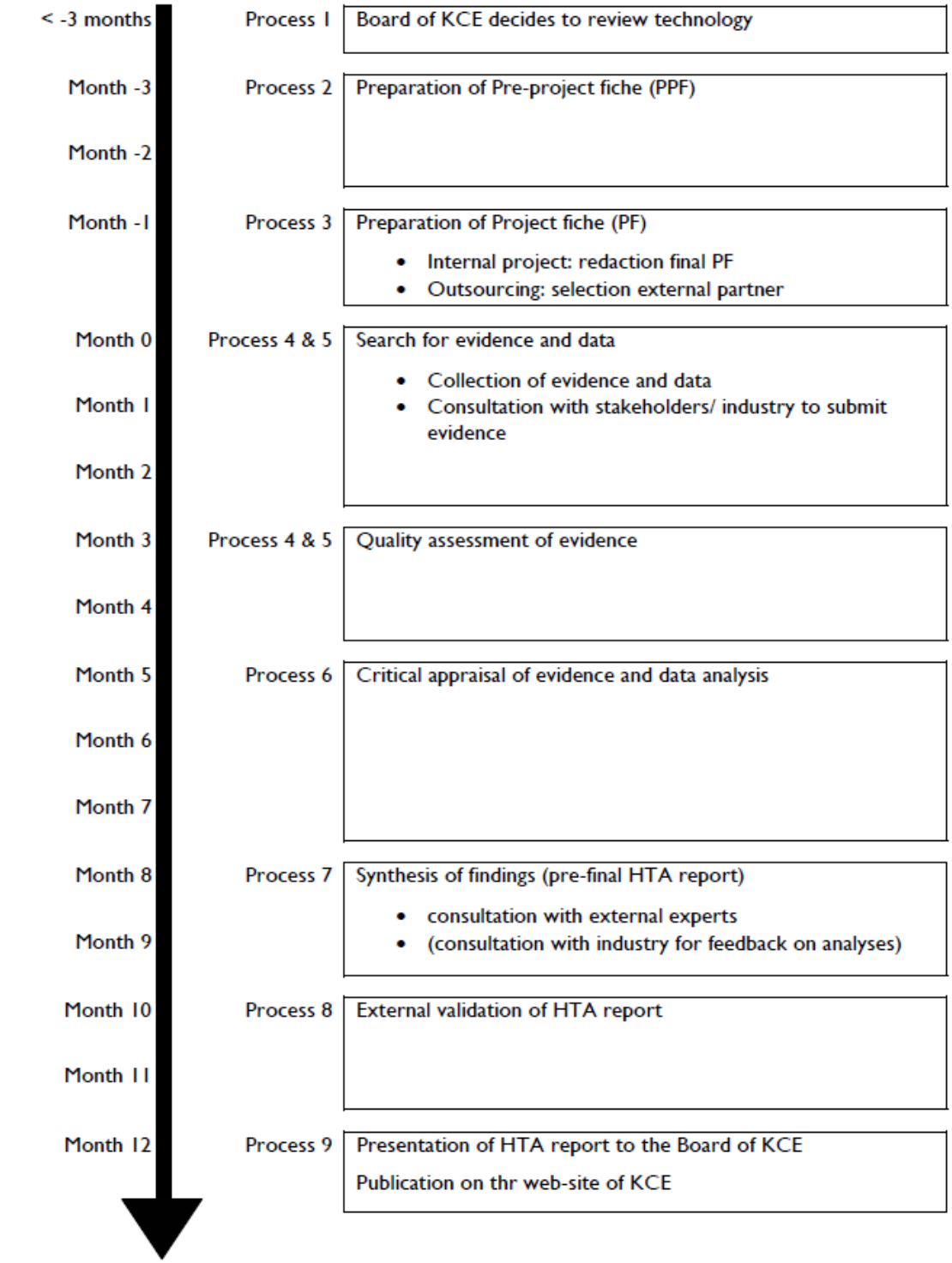
Structure of HTA Program	HTA Organization
	• Search for (ongoing) trials • Search additional resources: grey literature, government publications, registration agencies, professional associations, hand searching, web searching *Study selection* • Studies should be selected based on selection criteria resulting from the review questions, and that have been piloted to check that they can be reliably applied. • Study selection is a staged process involving sifting through the citations located by the search, retrieving full reports of potentially relevant citations and, from their assessment, identifying those studies that fulfill the inclusion criteria. • Parallel independent assessments minimize the risk of errors of judgment. If disagreements occur between reviewers, they should be resolved according to a predefined strategy using consensus and arbitration as appropriate. • The study selection process should be documented, detailing reasons for inclusion and exclusion. To appraise the patient issues related to a technology, several qualitative methodologies could be used to retrieve the kind of information needed: • Literature review • Search on the Internet • Interviews or focus groups • Roundtables
Use of HTA in Decision Making	
12. Decision Making Bodies	*No information identified.*
13. Decision Making Process and Criteria	*No information identified.*
14. Appeal Process	*No information identified.*
Program Products and Dissemination	
15. HTA Products	Scientific report with executive summary.
16. Implementation	*No information identified.*
17. Program Evaluations	KCE publishes annual reports on its activities. Reports are sent to the Chamber of Representatives and published on the KCE website in Dutch or French. The program also commissioned *A Study into the Impact of the Belgian Health Care Knowledge Centre* (April 2010), available on the program's website.

Figure 1: Schematic presentation of an HTA process



(*Source*: Cleemput 2007, p. 2)

APPENDIX I: DESCRIPTION OF ALL STEPS IN THE HTA PROCESS (FULL HTA)



(*Source*: Cleemput 2007, p. 17)

Appendix M. Canada – HTA Components – Canadian Agency for Drugs and Technology in Health (CADTH)

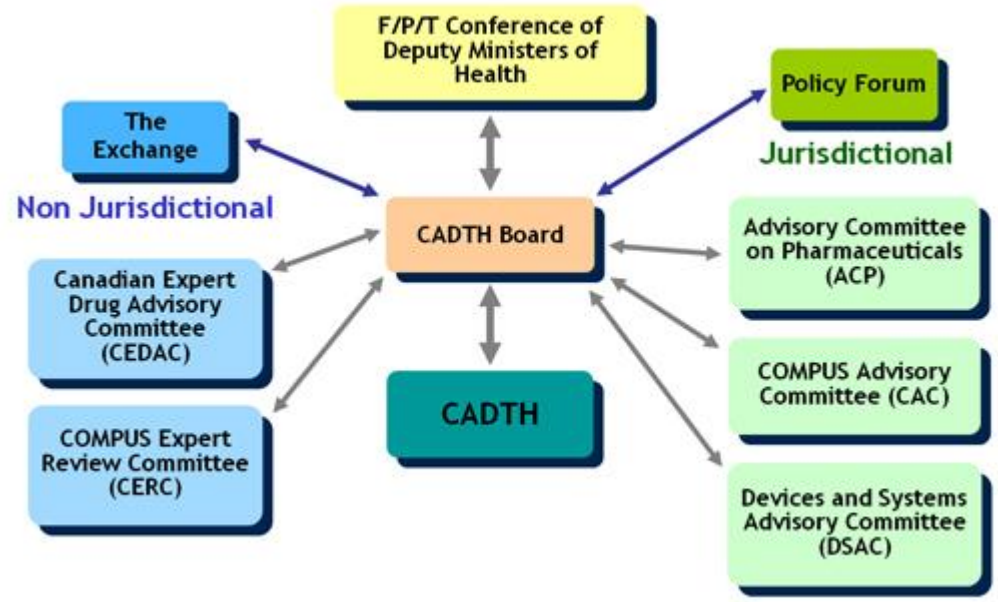
Structure of HTA Program	HTA Organization
Program Structure	
1. Program purpose	CADTH provides advice about the strength of evidence supporting the use of drugs and other health technologies to Canada's federal, provincial and territorial ministries of health and their constituents. HTA is one of CADTH's three main programs: • Health Technology Assessment: assessing drugs and health technologies • Common Drug Review: conducting drug reviews and providing formulary listing recommendations. • Canadian Optimal Medication Prescribing and Utilization Service (COMPUS) The HTA program provides three main services: • *Health Technology Assessment (HTA)* **-** provides health care decision makers with a comprehensive, objective, evidence-based analysis of the clinical effectiveness, cost-effectiveness and broader impact of drugs, medical technologies and health systems. HTA examines technologies at all stages of their life cycle, from development through to maturity and obsolescence. • *Health Technology Inquiry Service (HTIS)* – responds to inquiries on drugs, devices, diagnostic tests, and medical and surgical procedures, considering the urgency and potential impact of request. The HTIS is available to Canadian health care decision makers in the federal government, provincial health ministries, Local Health Integration Networks, regional health authorities, hospitals, and national and federal health care programs in CADTH-area jurisdictions. • *Environmental Scanning Service* - alerts decision makers to new and emerging health technologies that are likely to have a significant impact on the delivery of health care in Canada. Environmental scanning also involves taking a more comprehensive look at the health care environment and maintaining a pulse on how evidence is being used to inform practice and policy decisions. CADTH is also pursuing a pilot project to develop policy guidance based on research findings relating to non-drug technologies. The pilot is focusing on policy recommendations an evidence review of hip protectors for residents in long-term care.
2. Basic organization and governance	CADTH is an independent, not-for-profit agency funded by Canadian federal, provincial, and territorial governments and governed by a 13-member Board of Directors with an independent chair; a regional distribution of jurisdiction federal, provincial, and territorial representatives; non-jurisdictional representatives from health authorities, academia, and general public. CADTH's board is accountable to Canada's Conference of Deputy Ministers of Health. CADTH is assisted by several advisory bodies. • *Drug Policy Advisory Committee* provides advice to the CADTH Board on drug policy issues and topics. The Committee consists of 16 members from federal, provincial, and territorial publicly funded drug plans, and health related organizations.

Structure of HTA Program	HTA Organization
	• The Canadian Expert Drug Advisory Committee and the COMPUS Expert Review Committee also provide ongoing expert advice to CADTH. • CADTH also develops expert review panels to support specific projects. Evidence reviews may be conducted internally or by external review entities. Project teams include researchers in medicine, pharmacy, pharmacology, basic sciences, bioethics, or health services; a project manager; economists; epidemiologists; an information specialist; a knowledge transfer specialist; and two or more expert clinicians. *See Figure 1. CADTH Governance Committee Structure*
3. Scope of HTAs	*Technologies reviewed:* drugs, devices, diagnostic agents, equipment, and medical and surgical procedures. The definition also includes organizational and service systems that provide health care, such as telehealth. *Key factors analyzed:* clinical effectiveness, cost-effectiveness, and "broader impact" of technologies.
4. Program Transparency	*HTA products*: provide detailed, reproducible and transparent description of scientific methods used and the evidence related to a health care technology. All reports and other products are publicly accessible.
5. Stakeholder Input	Topic Nominations: • Topic nominations may be submitted by the public. Topic suggestions are received from Canadian policy makers; medical directors and managers; health care providers; professional associations; and the public. • A standardized topic nomination form or other guidance is not available through the CADTH website. • Topic nominations are refined with the nominator and CADTH Advisory Committees. Evidence Reviews: • Submission of evidence: Information is solicited from technology manufacturers, report authors, and other experts during the evidence review phase. No timeframes identified. • Expert review: Every Health Technology Assessment report is peer-reviewed, first by a senior HTA staff member, and then by at least two external experts, including clinicians, methodologists, and economists. The project team addresses all reviewer comments, and modifies the report as necessary. Implementation • *Knowledge Transfer Program* focuses on linking research and evidence-based decision making by federal, provincial and territorial health care decision makers. Includes a Liaison Program, which works with provincial and territorial jurisdictions.
6. Target Audience	Target audience: federal, provincial, and territorial health ministries, including drug plans, regional health authorities and hospitals, and clinical practice.

Structure of HTA Program	HTA Organization
Nomination and Selection of Topics	
7. Topic Nominations Process	Anyone can nominate a topic (e.g., CADTH Board of Directors (who represent F/P/T ministries of health), advisory committees, staff, other organizations, clinical and methodological experts, industry and the general public (via the website)) Topics also identified through Horizontal Scanning Program (ongoing literature scanning, establishing and maintaining networks with key stakeholders) Proposed topics prioritized & filtered by CADTH's Advisory Committee on Pharmaceuticals and Devices and Systems Advisory Committee
8. Topic Refinement	Topics revised with CADTH Advisory Committees (Committee on Pharmaceuticals, Canadian Optimal Medication Prescribing and Utilization Services (COMPUS) Advisory Committee, Canadian Expert Drug Advisory Committee, COMPUS Expert Review Committee), originator of topic suggestion, other relevant decision makers • Knowledge gaps, relevant issues, and policy-related questions identified Pre-assessment of existing evidence for each selected topic is prepared by staff. Objectives and research questions are defined for each selected topic with the assistance of advisory committee members and clinical experts as necessary
9. Topic Selection	Topics approved and prioritized by the advisory committees and then the Board Each topic designated as internal, external, or a blend. If external, a RFP is issued and circulated
Conduct of Evidence Reviews	
10. Entit(ies) conducting reviews	Multidisciplinary Project teams (researchers, project manager, economists, epidemiologist, information specialist, knowledge transfer specialist, and two or more expert clinicians (all authors must satisfy established authorship criteria). • Two members of the Scientific Advisory Panel (SAP) appointed to project team • Members of the Pharmaceutical and Devices and Systems Advisory Committees are part of the research team up to and including the protocol phase, but not beyond this phase • Teams can consist of CADTH employees and external contractors Authors prepare the first draft of the report, final report is prepared, submitted and receives a final review by research and communications staff.
11. Methods of Reviews	Search protocol developed by authors, describing how information (clinical and economic) will be quality assessed, abstracted and synthesized Protocol internally reviewed & modified according to feedback Information specialist searches literature to identify all relevant existing (published or unpublished) evidence

Structure of HTA Program	HTA Organization
Use of HTA in Decision Making	
12. Decision Making Bodies	Federal, provincial, and territorial health ministries, including drug plans, regional health authorities and hospitals, and clinical practice. *Knowledge Transfer Program* focuses on linking research and evidence-based decision making by federal, provincial and territorial health care decision makers. Includes a Liaison Program, which works with provincial and territorial jurisdictions.
13. Decision Making Process and Criteria	*No information identified.*
14. Appeal Process	*No information identified.*
Program Products and Dissemination	
15. HTA Products	The Health Technology Assessment Program offers a full range of evidence-based reports and information products to meet the needs of various decision makers. The products are tailored to the amount and type of evidence that is available on a given technology or service. The reports follow a standardized format to make the information readily accessible. Overview of CADTH reports: • Technology Reports: represent the comprehensive assessments of health care technologies and services. These reports examine more mature technologies, for which there is a larger and higher quality body of evidence available. • Technology Overviews • Health Technology Update: a newsletter published twice a year covering new and emerging health care technologies. • Issues in Emerging Health Technologies: four- to eight-page bulletins indexed in PubMed (MEDLINE) and peer-reviewed and w*eb-posted.* • Emerging Drug List In 2008-09, CADTH produced 454 reports, as discussed in the CADTH Annual Report.
16. Implementation	Knowledge transfer specialist (KTS) works with project team from topic inception to identify knowledge partners that are committed to using HTA reports to make decisions. KTS also develops strategies to facilitate interaction and collaboration with health care decision makers to enhance the capacity for knowledge uptake.
17. Program Evaluations	Yes, contracts for evaluations of CADTH (EKOS Research Associates 2007) Annual Reports are also conducted (most recent report is 2008-09)

Figure 1. CADTH Governance Committee Structure



(*Source*: http://www.cadth.ca/index.php/en/cadth/corporate-profile/governance)

Appendix N. Denmark – HTA Components - DACEHTA

Structure of HTA Program	HTA Organization
Program Structure	
1. Program purpose	DACEHTA advises regional and local public program decision makers with respect to the strength of evidence and policy recommendations.
2. Basic organization and governance	DACEHTA is part of the National Board of Health, which is independent of public health care programs administered at the regional and local levels. DACEHTA is served by the Strategic Advisory Board which is comprised of representatives from regions & municipalities, the Faculties of Health Science, the Danish Agency for Science Technology and Innovation, and Ministry of Health and Prevention. The role of the Strategic Advisory Board is to develop and coordinate the use of HTAs in Denmark. Evidence reviews are carried out internally and through external contractors.
3. Scope of HTAs	*Types of technologies reviewed:* procedures and methods of prevention, diagnostics, treatment, care and rehabilitation, including equipment and medical drugs. Supportive systems and organization within the health care system may furthermore be regarded as health technology. *Key factors analyzed:* four main domains of evidence analysis: the technology (effectiveness), the patient (needs and challenges), the organization (administrative and delivery system) and the economy (cost and economic analysis). *See Figure 1.2. The Danish HTA model*
4. Program Transparency	*No information identified.*
5. Stakeholder Input	The DACEHTA *2007 HTA Handbook* sets forth a framework for conducting HTAs with stakeholder involvement (see below). However, specific opportunities for stakeholder input are not identified and there does not appear to be a systematic and uniform process of involving stakeholders. According to the *HTA Handbook*, "stakeholders can be involved in different ways – adapted to the need within the individual project." Specific opportunities for stakeholder input identified, include: • *Reference group:* For stakeholders with conflicts of interest, the Handbook suggests involvement of stakeholders in a "reference group" as way to follow the project and contribute comments. • *Evidence:* DACEHTA uses ad hoc expert groups, as well as external peer review. • *Implementation:* DACEHTA is served by the Strategic Advisory Board which is comprised of representatives from regions & municipalities, the Faculties of Health Science, the Danish Agency for Science Technology and Innovation, and Ministry of Health and Prevention. The role of the Strategic Advisory Board is to develop and coordinate the use of HTAs in Denmark. *HTA Handbook – Process to involve stakeholders:* Stakeholders are identified by discussing who initiated the HTA, who will use the HTA results, who must approve the HTA results, who funds the HTA process, who will be affected by the HTA results, and who has

Structure of HTA Program	HTA Organization
	knowledge on the HTA topic and could contribute. Project manager primarily assesses which stakeholders are most relevant to involve, especially those who are close to the decision or planning process surrounding the results and recommendations of the HTA.
6. Target Audience	Audiences for HTAs include: Regional and local public program decision makers, politicians and officials at national or regional level; planners at regional and hospital level as well as municipality level; management at hospital and department level; organizations and companies; clinicians in the health care system and the primary sector; and the general public.
Nomination and Selection of Topics	
7. Topic Nominations Process	Policy or planning questions are clarified. HTA questions developed into 4 domains (technology, patient, organization and economy). Weight should be given to information needed by decision makers.
8. Topic Refinement	Project manager (with project team) prepares project description to be approved by project owner (should include background, target group/stakeholder, objective, method, analytical framework, presentation, project organization, time frame, and budget)
9. Topic Selection	The *2007 HTA Handbook* discusses the importance of prioritizing topics for HTA, but does not identify specific prioritization criteria used by DACEHTA.
Conduct of Evidence Reviews	
10. Entit(ies) conducting reviews	*Approaches in assessing HTAs* (an assessment could include a combination or all approaches) • Technology-oriented (assess the importance of a specific health technology, e.g., the clinical, social or economic importance of population-based screening for prostate cancer) • Problem-oriented (to find solutions or strategies for solution of medical problems, for which there are several different alternative technologies available, e.g., planning of dementia assessment, including the development of a basis for clinical guidelines) • Project- or organization-oriented (to assess how a specific technology can be fitted into a specific institution, program or project)
11. Methods of Reviews	*Clarify methods at beginning of process* (is evidence available, how the literature review should be conducted (systematic review, meta analysis, syntheses of quality of research), if primary research is needed) *Plan search process* (clarify object, scale and time horizon of search) • Develop search protocol (include background and presentation of problem, focused questions (PICO), inclusion and exclusion criteria, information sources, search strategy and results for each information source, strategy for reviewing and selecting literature) *Identify ethically relevant characteristics* (i.e., presentation of ethical problem, ethical assessment) *Document searches* (sources, search period, search terms, date of search) Quantitative studies • Divide literature into primary (can be further subdivided into study design) and secondary studies

Structure of HTA Program	HTA Organization
	See Table 4.1 Hierarchy of scientific literature • Quality assessment of important articles – two readers assess independent of each other, and then compare to checklists (SIGN, NICE, GRADE) • Assess internal and external validity of studies <u>Qualitative studies</u> • use to gain new insights, make generalizations based on synthesis of results of several qualitative studies, and/or reach a level of conceptual and/or theoretical development reaching beyond what is achieved in every individual empiric study <u>Synthesis</u> *See Figure 10.1. The synthesis process*
Use of HTA in Decision Making	
12. Decision Making Bodies	*No information identified.*
13. Decision Making Process and Criteria	According to the Danish National Strategy for HTA, which has been the basis for the development of HTA in Denmark, the HTA should contribute with information for decision making at *all* levels in the health care system. HTA thus affects political, administrative and clinical decision makers. Depending on 1) the policy question, 2) the level of decision making and 3) the time frame, HTA aims to improve the basis for decision making with results from either broad or more focused types of HTA projects. The HTA framework may also be useful as a "way of thinking", i.e., without major analyses. An example is the mini-HTA providing decentralized decision support, e.g., in hospital departments. Target audience needs to be defined early in the project to verify that the topic is relevant and is connected to decision making. Ongoing dialogue about project schedule and scope is recommended with the target audience
14. Appeal Process	*No information identified.*
Program Products and Dissemination	
15. HTA Products	*All HTAs need to include patient aspects* **(**e.g., patients' knowledge and experiences of a technology; patients' preferences, needs and expectations of a technology; patients' visions and requirements concerning a technology, economic aspects and organization; how customs, attitudes and traditions influence patients' experiences, preferences; what importance the technology in question has or may have for the patient's everyday life; how patients' self-care and/or empowerment resources are best exploited, and what opportunities and limitations apply to self-care/empowerment) HTA Products can also include: • patient-experience quality • organizational analysis • administrative analysis (structures for decision making and coordination across levels)

Structure of HTA Program	HTA Organization
	• economic evaluations (cost-benefit analysis (CBA), cost-effectiveness analysis (CEA), cost-utility analysis (CUA), and cost minimization analysis (CMA) *See Table 3.3 Lifecycle of technologies and HTA products* *See Table 9.1. Choice of type of economic analysis* *See Table 9.2. Types of resource consumption and costs in an economic analysis* **HTA – broad [**Based on complex problem or, for instance, area of disease. Broad and general approach; may include alternative technologies] Aim: Input for political-administrative and clinical decisions at all levels; • Time frame: 1½ – 2½ years; Quality assurance: External peer review; Extent of report: 200 pages; Link/examples: DACEHTA. Publications: "Type 2 diabetes" **HTA – focused** [Based on delineated problem; focus on one technology] Aim: Input for decisions as above provided they can be made within a short time frame. • Time frame: 1 year; Quality assurance: External peer review; Extent of report: 100 pages; Link/examples: DACEHTA. Publications: "Reduction in the risk of cervical cancer by vaccination against human papillomavirus (HPV)" **HTA – cancer drugs** [Based on delineated problem; focus on one technology] Aim: Input for decisions as above which are to be made within a very short time frame. • Time frame: 3 months; Quality assurance: Expert consensus; Extent of report: 4 -15 pages; Link/examples: New cancer drugs: "Tarceva", "Avestin" *HTA products which integrate foreign work* **Foreign HTA with comments** [Based on foreign HTA report which is related to Danish conditions] Aim: Input for decisions in the health care system within a short time frame. • Time frame: 3-6 months; Quality assurance: Expert assessment; Extent of report: 10-25 pages of summary and comments; Link/examples: DACEHTA. Publications "Chronic paradontitis" (in Danish) **Core HTA** [Based on problem which is of current interest in several European countries] Aim: Input for decisions in the health care system within a short time frame. • Time frame: 6 months; Quality assurance: Undecided; Extent of report: 50 -100 pages; Link: Still in the development phase as part of the EUnetHTA project **Mini HTA** [Based on question framework with HTA questions. Prepared internally within the individual hospital (operational-orientated tool).

Structure of HTA Program	HTA Organization
	Aim: Input for decisions at local level (department, centre and hospital level). Concerns proposals for new treatments, changes, etc., in relation to the cost. • Time frame: Only completion of questionnaire: 5-15 hours; incl. Literature review: 1-2 months; Quality assurance: No peer review; Extent of report: 3 -5 pages; Link: mini-HTA **Early warning*** [An information system which early on in the "life cycle" of the technology warns decision makers of future technologies that may have to be introduced.] Aim: Input for decisions and planning nationally as well as locally in hospitals. • Time frame: 2-4 months; Quality assurance: Expert assessment; Extent of report: 4 pages; Link/examples: Technology alerts Timeframes: • Broad (1.5-2.5 yrs) • Focused (1 yr) • Cancer drugs (3 mo) • Foreign (3-6 mo) • Core HTA (6mo) • Mini HTA (1-2 mo) • Early warning (2-4 mo)
16. Implementation	*The utilization of HTA may be facilitated on several levels* - Top political and administrative level (one possibility is to try to link the HTA to existing decision making processes) - Institutional level (possible to work on ensuring that employees are familiar with the HTA and are thus aware that the HTA can be used in decision making) - HTA project level (task of the project team to bear the prospects for utilization in mind during the course of the project and to consider specific possibilities for utilization and implementation as part of the final phase of the HTA.) *See Figure 10.2. The two phases of utilization of HTA* *A health technology assessment should be communicated actively*, such as at: conferences; articles in scientific journals; articles in professional journals; debating points in daily newspapers; or press releases for electronic media.
17. Program Evaluations	*Recommended follow-up evaluation* of how HTA results are integrated into the health care system and any resulting changes

Figure 1.2. The Danish HTA model

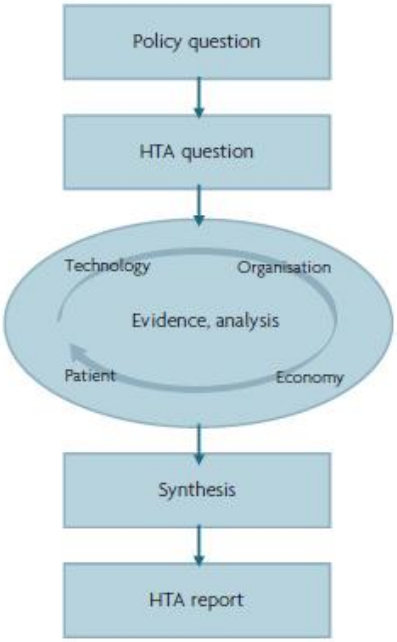
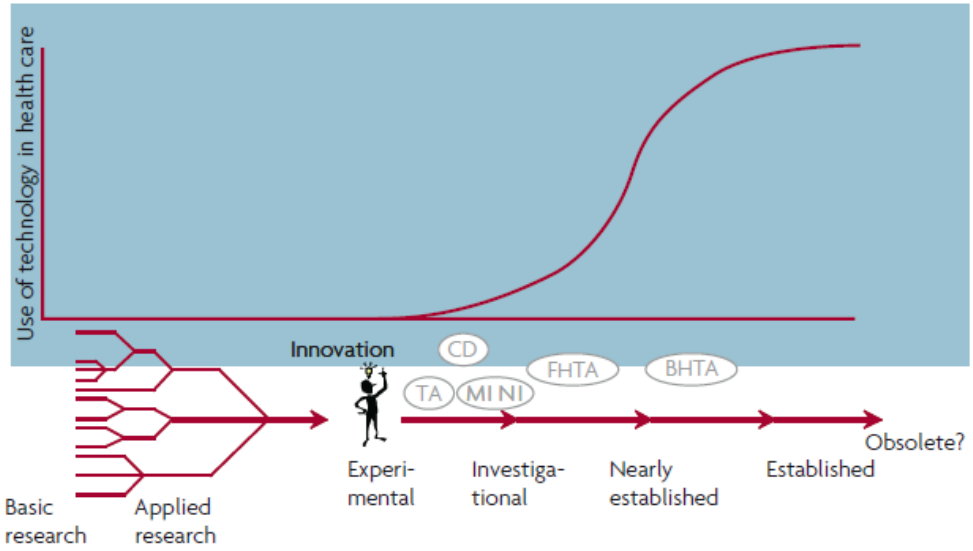


Figure 3.1. Life cycles of technologies and HTA products



Note: TA = Technology Alert (early warning); MINI = Mini-HTA; CD = Cancer Drug HTA; FHTA = Focused HTA; BHTA = Broad HTA; (see Section 1.2.4).

(*Source* (both Figures): http://www.sst.dk/~/media/Planlaegning%20og%20kvalitet/MTV%20metode/HTA_Handbook_net_final.ashx)

Table 9.1. Choice of type of economic analysis

Type of economic analysis	When should the individual type of analysis be chosen?
Cost minimization analysis	1. When the technologies compared are equally effective – then it is only necessary to collect data about costs
⇓	
Cost-effectiveness analysis	1. When activities with the same purpose and measure of effectiveness are compared 2. When the effectiveness of the technologies compared is different, i.e. the difference in costs must be weighed against the difference in effectiveness
⇓	
Cost-utility analysis	1. When health-related quality of life is an important outcome 2. When activities across the health care sector are compared
⇓	
Cost-benefit analysis	1. When non-health effects are also important, e.g. the treatment process itself, the utility of information, etc. 2. When only one technology is assessed (net benefit) 3. When lives are to be valued in monetary units (e.g. € or $) 4.When activities across society are to be compared

Table 9.2. Types of resource consumption and costs in an economic analysis

Perspective			Type of costs	Resource consumption
Society	Health care sector	Hospital	Direct costs: - in hospital	Health personnel, medicine, utensils, tests, capital equipment (plant & buildings), in-patient stay(hotel), outpatient visits, overheads (food, lighting, heat, etc.), (research & training)
			Direct costs: - in the primary health care sector	Consultation with general practitioner, practising specialist, physiotherapist, etc., prescription medicine (the Danish National Health Insurance Service's share), public surveys
			Direct costs: - in other sectors	Home care & home nursing, social events, including support for medicine (municipal grants), aids
			Direct costs: - for patient & family	User payment (medicine, dentist), transport, time spent on investigation/treatment, (unpaid) time spent by family or friends in caring for patients
			Production loss/gain in society	Changes in patients' temporary absence through sickness, reduced ability to work due to sickness and disability, or lost production in the case of premature death
			Future costs	Future unrelated costs including health costs generated as a result of a patient's lifetime being extended or shortened

(*Source* (both Figures): http://www.sst.dk/~/media/Planlaegning% 20og%20kvalitet/MTV%20metode/HTA_Handbook_net_final.ashx)

Figure 11.1. Peer review process

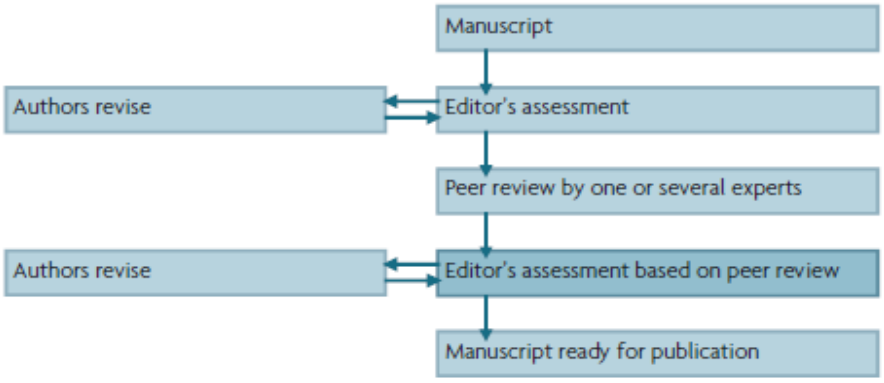
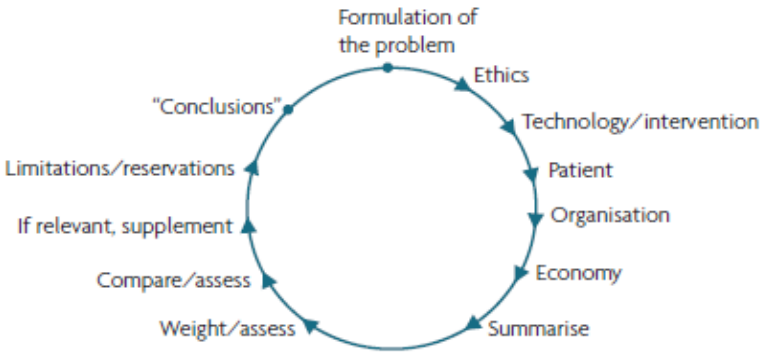
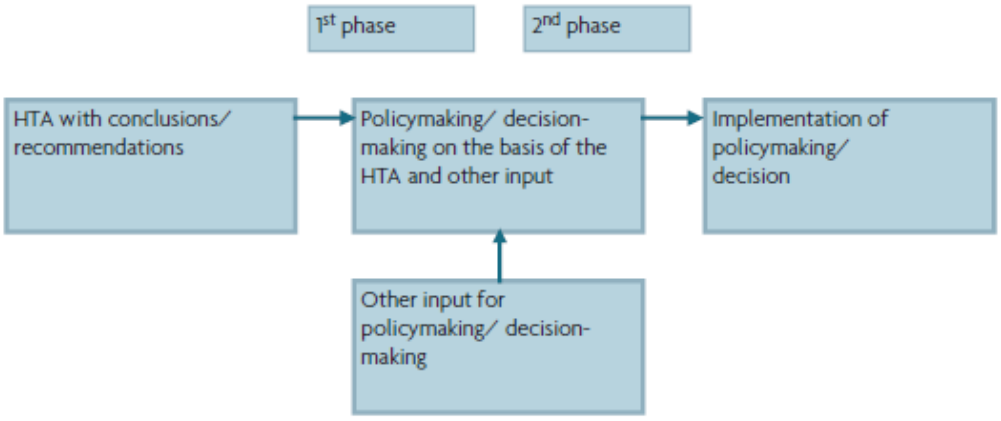


Figure 10.1. The synthesis process



Figur 10.2. The two phases of utilization of an HTA



(*Source* (all Figures): http://www.sst.dk/~/media/Planlaegning%20og%20kvalitet/MTV%20metode/HTA_Handbook_net_final.ashx)

Appendix O. Germany – HTA Components – Institute for Quality and Efficiency in Health Care (IQWiG)

Structure of HTA Program	HTA Organization
1. Program purpose	*Program purpose* IQWiG works on issues of fundamental importance for the quality and efficiency of the services performed within the framework of the statutory health insurance (SHI) system as an independent scientific institution of the Foundation for Quality and Efficiency in Health Care, in particular in the following areas: 1. Search for, assessment, and presentation of current scientific evidence on diagnostic and therapeutic procedures for specific diseases; 2. Preparation of scientific reports and expert opinions on quality and efficiency issues of SHI services, taking age, gender, and personal circumstances into account; 3. Appraisal of evidence-based clinical practice guidelines on the epidemiologically most important diseases; 4. Issue of recommendations on disease management programs; 5. Assessment of the benefits and costs of drugs; 6. Provision of easily understandable information for all citizens on the quality and efficiency of health care services, as well as on the diagnostics and treatment of diseases of high epidemiological relevance. IQWiG support the Federal Joint Committee in carrying out its statutory responsibilities. IQWiG also has a statutory mandate to inform the public, which it fulfills through information provided on the website (www.informedhealthonline.org). The website includes information based on IQWiG's own scientific publications and on topics it chooses. The website will also include items of patient information commissioned by the Federal Joint Committee or Federal Ministry of Health.
2. Basic organization and governance	IQWiG is an independent scientific institution of the Foundation for Quality and Efficiency in Health Care, a non-profit foundation. The Foundation is governed by a Foundation Board and Board of Directors. • Foundation Board: comprised of 12 members, including 6 representatives of the Central Federal Association of Health Insurance Funds, and 6 representatives from the following groups: the Board of Directors or the management of the National Association of Statutory Health Insurance Physicians, the German Federal Association of Sick Fund Dentists, and the German Hospital Federation. • Board of Directors: The Board of Directors consists of 5 members. Four members are appointed by the Foundation Board for a term of 4 years, one member is appointed by the Federal Ministry of Health. IQWiG is under scientifically independent management. Advisory committees of the institute are the Board of Trustees and the Scientific Advisory Board. • The Board of Trustees: comprises 30 members, including ten members from each of the follow groups: 1. the bodies of

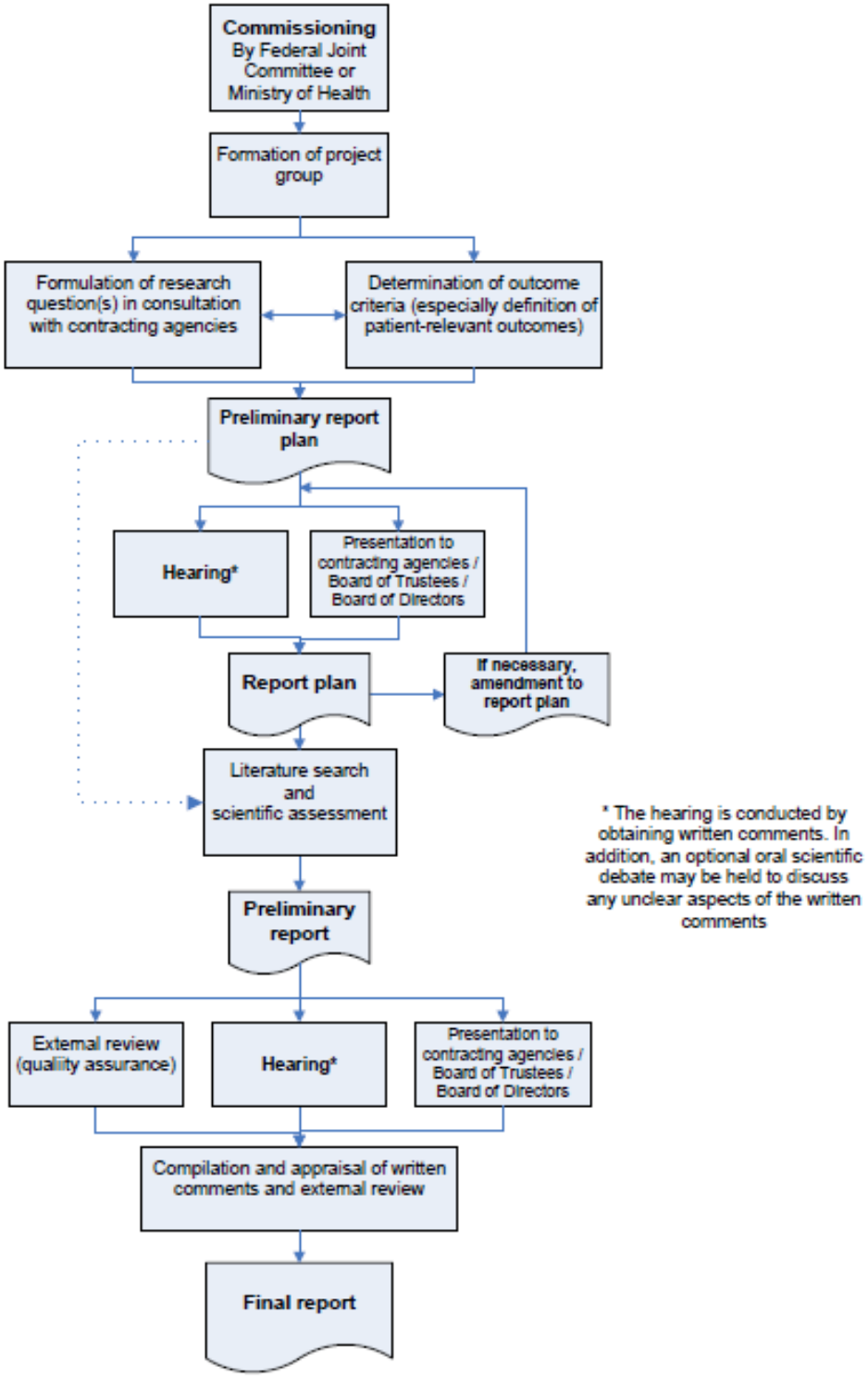
Structure of HTA Program	HTA Organization
	self-administration of the governing organizations of the Federal Joint Committee; 2. relevant health professional associations; 3. other organizations relevant to the health system, 6 of which are representatives of patients and self-help of chronically ill and disabled persons, as well as the Federal Government Commissioner for Patients' Affairs. • Scientific Advisory Board: comprises at least 6 and not more than 12 scientists. Appointed by the Foundation Board of Directors.
3. Scope of HTAs	*Technologies reviewed* Drugs, non-drug interventions (e.g., surgical procedures), methods for diagnosing and screening, treatment guidelines (CPGs) and disease management programs (DMPs)
4. Program Transparency	*See Stakeholder Involvement*
5. Stakeholder Involvement	IQWiG identifies several opportunities for manufacturers, professional societies, and patients to provide input. These include: *Topic nominations and development* • Individuals may email topic ideas. There is no standardized nomination form. • The public may comment on draft report plans (research plans), and any changes to those plans. Draft report plans, and any changes, are posted on the website for public comment during a period of at least four weeks from the date published on the website. IQWiG provides standardized comment guidelines, comment submission forms, and conflict of interest statements that must be submitted. • If comments are unclear, IQWiG may invite commentators to an oral scientific debate on comments. The debate is not open to the public. Participants will be informed 10 working days in advance of the debate. • Comments as well as the meeting minutes of a scientific debate and a response to comments will be published. • Patient perspective: When assessing benefit, IQWiG applies criteria that are important to patients. The Institute generally consults patient representatives in order to establish these criteria (patient-relevant outcomes). *Evidence reviews* • Submission of data: IQWiG invites industry to submit unpublished studies. IQWiG has developed a sample contract in collaboration with the Association of Research-based Pharmaceutical Companies for the submission of unpublished studies. • Involvement in early benefit assessment of drugs [further detail not available in English] • External experts: IQWiG posts solicitations for external expert review on its website. *Draft reports* • Comments on draft reports: Draft reports are posted on the website for public comment for at least four weeks. IQWiG

Structure of HTA Program	HTA Organization
	provides standardized comment guidelines, comment submission form and conflict of interest statement that must be submitted. • If comments are unclear, IQWiG may invite commentators to an oral scientific debate on comments. The debate is not open to the public. Participants will be informed 10 working days in advance of the debate. • Comments as well as the meeting minutes of a scientific debate will be published to the website. An evaluation of comments will be included in the final report. *Conflicts of Interest – Disclosure Policy* External scientists working for the Institute are therefore obliged to disclose contacts (particularly with industry). Participants in the comments procedure are similarly required to disclose any contacts. The following must be disclosed: paid employment, consultancy activities, payments received, financial support received for research activities and patent applications, other financial or cash-value payments, and the possession of shares, share options or other company shares.
6. Target Audience	The Federal Joint Committee, the Federal Ministry of Health, and the public at large
Nomination and Selection of Topics	
7. Topic Nominations Process	The Federal Joint Committee and the Federal Ministry of Health commission reports. The public may submit topic ideas via email through the IQWiG website. IQWiG may also select topics for scientific evaluation independently.
8. Topic Refinement	The project group formulates the scientific research question and the outcomes for the project in agreement with the contractor and also with external experts, if necessary
9. Topic Selection	*No information identified.*
Evidence Synthesis	
10. Entit(ies) conducting reviews	*Production of the report plan:* In this step a preliminary report plan is drawn up. This project outline provides a summary of the main planning stages for the rest of the project. The draft of the report plan is published, so that all interested parties have the opportunity to submit comments. These comments are then incorporated into the report plan version 1.0, which forms the basis of future work
11. Methods of Reviews	*Information acquisition and scientific evaluation:* In this step information based on the criteria laid down in the report plan is gathered and its reliability evaluated. *Publication of the results:* The results of the search and the scientific evaluation are then initially published as a preliminary report (preliminary result), and comments can again be submitted. The preliminary report is revised taking the comments into consideration and is published as a final report together with the documentation of the comments. *See Tables 1-4 for Product Processes* *Quality assurance of IQWiG products* IQWiG closely monitors both staff members and external experts to make sure they have no conflicts of interest that could give

Structure of HTA Program	HTA Organization
	rise to prejudice. Everyone who is involved in working on an Institute product must disclose all relationships which could influence the work and the result. All products, including intermediate products such as the report plan, undergo several internal reviews. In addition to a content and biometry review, this also includes a review of information acquisition. External experts are involved at an early stage of project planning in almost all commissions. Additional external experts are invited to review the products. Scientists, industry and patients are also given the opportunity to offer their expertise by submitting comments. The methods, recorded in the Institute's Methods papers, are monitored and updated at regular intervals.
Use of HTA in Decision Making	
12. Decision Making Bodies	*Federal Joint Committee*
13. Decision Making Process and Criteria	*No information identified.*
14. Appeal Process	*No information identified.*
Program Products and Dissemination	
15. HTA Products	Detailed reports (benefits assessments or evaluation of the cost-benefit relation of medical interventions) -Single commission by Federal Joint Committee or Federal Ministry of Health - Aim: provide up-to-date information on relevant, current topics, as well as on research questions not targeted towards policy decisions of the Federal Joint Committee Rapid reports - Single commission by Federal Joint Committee or Federal Ministry of Health - Aim: provide up-to-date information on relevant, current topics, as well as on research questions not targeted towards policy decisions of the Federal Joint Committee Dossier assessments within the framework of early assessment of drugs - Commissioned by the Federal Joint Committee. Based on comprehensive dossiers submitted by pharmaceutical companies to the Federal Joint Committee (for early benefit assessment) - Must be published 3 months after effective date of dossier submission Health information (easily understandable information for patients and consumers) Working papers on relevant developments in health care and on the methodological work of the Institute
16. Implementation	Reports and project status available on website

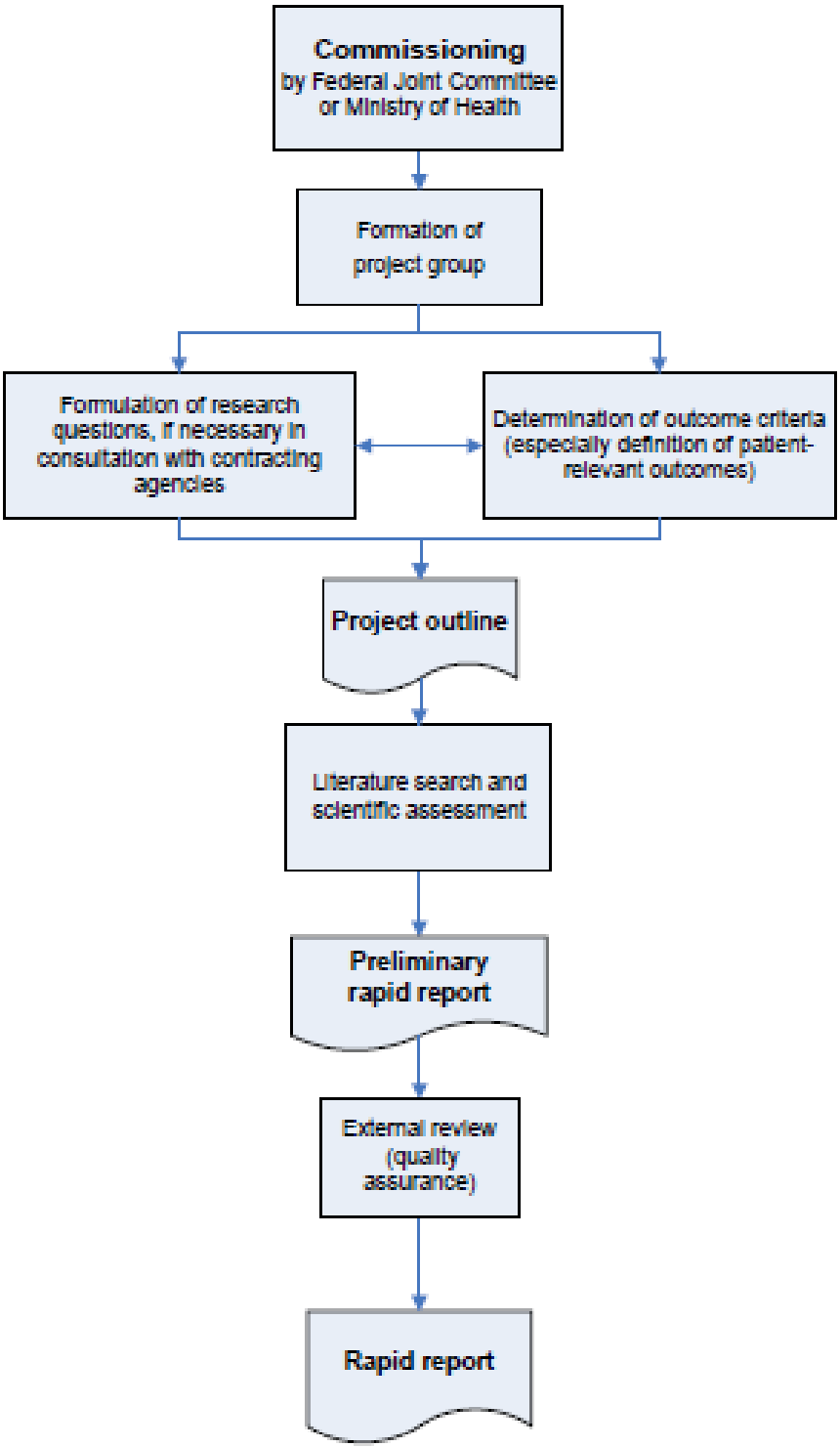
Structure of HTA Program	HTA Organization
17. Program Evaluations	*No information identified.*

Table 1. Flow Chart for Reports



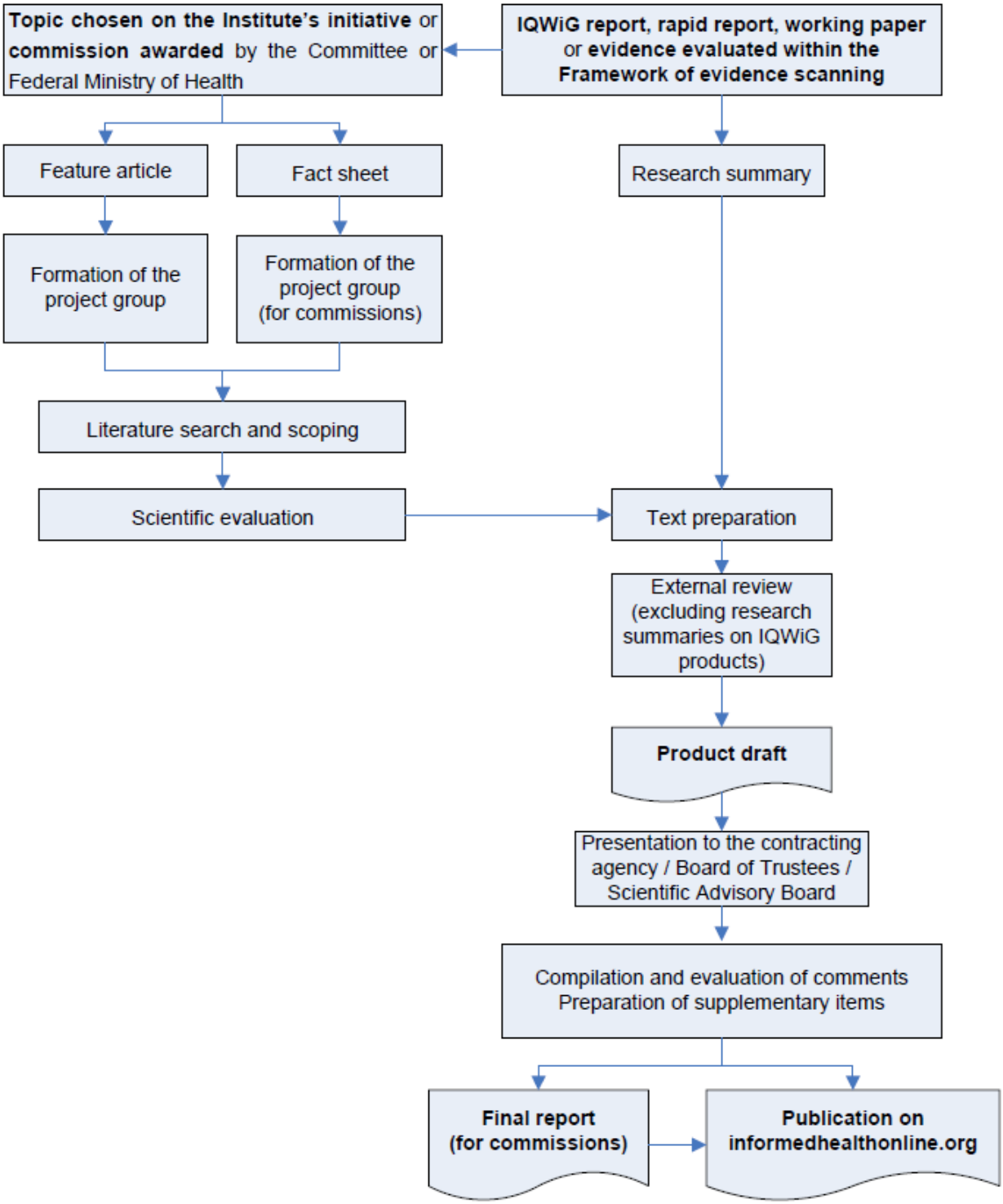
(*Source*: https://www.iqwig.de/download/IQWiG_General_methods_V-3-0.pdf)

Table 2. Flow Chart for Rapid Reports



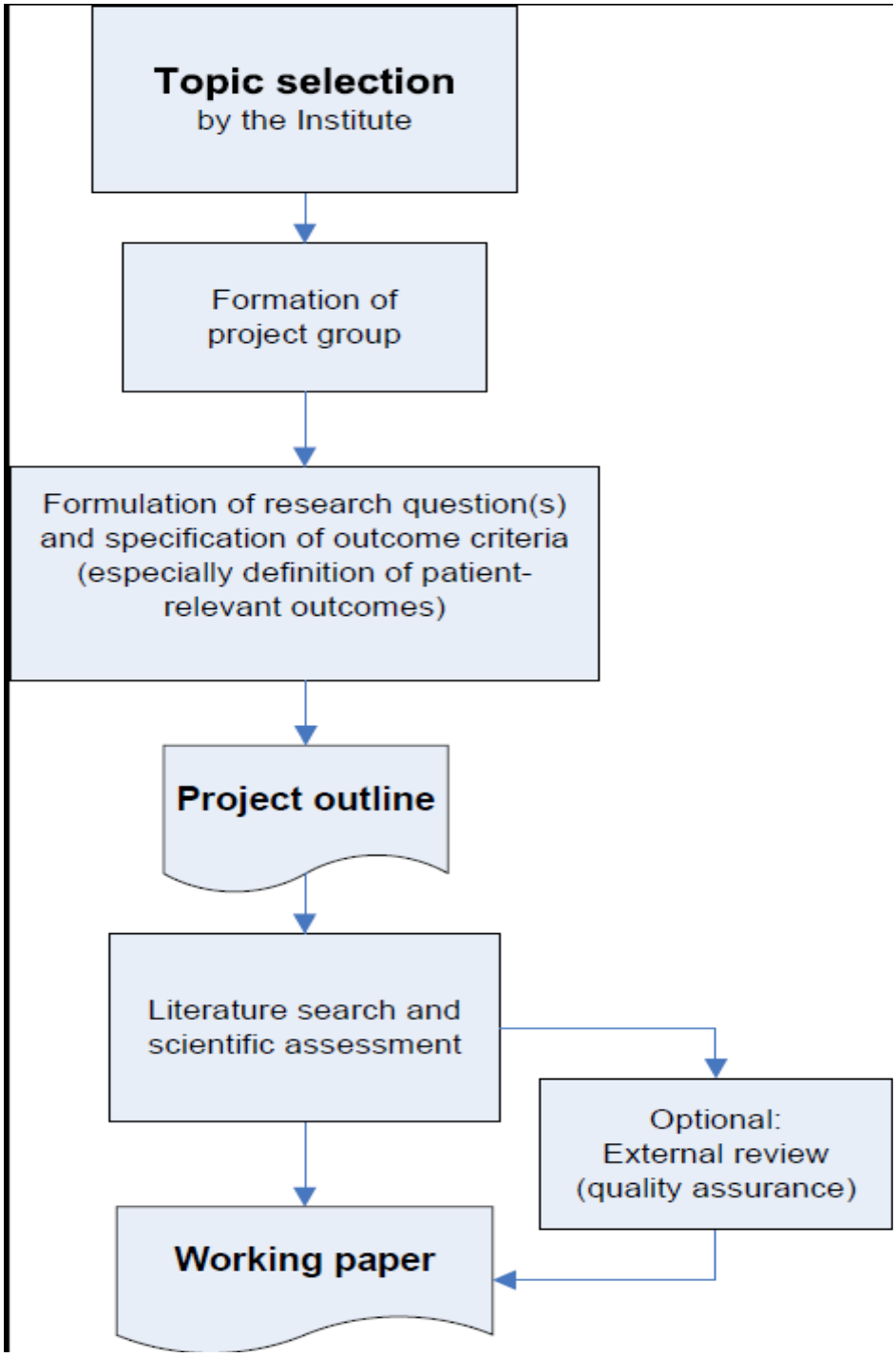
(*Source*: https://www.iqwig.de/download/IQWiG_General_methods_V-3-0.pdf)

Table 3. Flow Chart for Health Information



(*Source*: https://www.iqwig.de/download/IQWiG_General_methods_V-3-0.pdf)

Table 4. Flow Chart for Working Papers



(*Source*: https://www.iqwig.de/download/IQWiG_General_methods_V-3-0.pdf)

Appendix P. Sweden – HTA Components - SBU

Structure of HTA Program	HTA Organization
Program Structure	
1. Program purpose	SBU has a government mandate to comprehensively assess healthcare technology from medical, economic, ethical, and social standpoints. SBU regularly reports results of its assessments to the Ministry of Health. Additional target audiences include professional caregivers, healthcare administrators, planners, patients and their families.
2. Basic organization and governance	SBU is an independent governmental agency headed by a 10-person Board of Directors with a government mandate to comprehensively assess healthcare technology from medical, economic, ethical and social standpoints. SBU regularly reports results of its assessments to the Ministry of Health. The Board of Directors includes representation from clinical, scientific, management, and heath care policy-making communities. In addition, a fifteen-member Scientific Advisory Committee appointed by SBU's director oversees scientific aspects of work. The Scientific Advisory Committee includes representation from basic and applied medical research, clinical medicine, nursing, epidemiology, economics, management, administration, and public health. To conduct reviews, a working group of 10 to 15 members is selected, including clinicians, economists, epidemiologists, SBU staff, and individuals from the Board and Scientific Advisory Committee. This group's task is to systematically review the entire body of scientific literature in the field. The literature review usually takes about two to three years to complete. The group's report is then reviewed by external reviewers and by the Board and Scientific Advisory Committee. In addition, SBU has developed an Alert program to produce shorter timeframe assessments (usually 6-12 months) of new innovations in health care. The Alert Advisory Board guides the program, which is a collaborative between SBU, the Medical Products Agency, the National Board of Health and Welfare, and the Swedish Association of Local Authorities and Regions.
3. Scope of HTAs	*Types of technologies reviewed:* specific technologies not identified. *Key factors analyzed:* benefits, risks, and costs
4. Program Transparency	*No information identified.*
5. Stakeholder Input	*No information identified.*
6. Target Audience	*No information identified.*
Nomination and Selection of Topics	
7. Topic Nominations Process	Proposals for assessment projects are received from many sources (e.g., individuals, organizations, government agencies, and other decision making bodies) The SBU Scientific Advisory Committee, which represents a broad range of professions in health care, recommends topics for new

Structure of HTA Program	HTA Organization
	projects. The Board and the Scientific Advisory Committees prioritize the technologies to be assessed.
8. Topic Refinement	Before initiating an assessment project, SBU examines the scope of scientific literature available on the topic. An exploratory study shows whether or not it is feasible to draw conclusions based on scientific evidence, or whether major gaps in knowledge need to be filled.
9. Topic Selection	The Board of Directors and the Scientific Advisory Committee determine which of the proposed subjects should receive further assessment and be published by SBU as a Yellow Report, Alert Report, etc. Generally, the topics selected are of major importance to public health and quality of life. These issues are of great concern, involving common health problems and technologies with major economic consequences. Some projects focus on conditions for which treatment and medical outcomes vary throughout the country. Ethically controversial issues and interventions that require major changes in organization or staffing also command high priority. Evaluates new and existing technologies. SBU Alert Reports focus on new technologies.
Conduct of Evidence Reviews	
10. Entit(ies) conducting reviews	A working group of 10 to 15 members is selected, including clinicians, economists, epidemiologists, SBU staff, and individuals from the Board and Scientific Advisory Committee. This group's task is to systematically review the entire body of scientific literature in the field. The group must pass an SBU course on systematic and critical reviews, based on the Cochrane Collaboration model. The literature review usually takes about two to three years to complete. The group's report is then reviewed by external reviewers and by the Board and Scientific Advisory Committee.
11. Methods of Reviews	*Yellow Reports* **-** A project group, often including more than ten members, is formed for each major SBU project. Initially, the members are trained in systematic literature searching and critical analysis of the literature identified. After that, the work generally includes the following phases: <u>1. Define the topic</u> First, the purpose of the assessment is defined. As the project begins, the group decides on the issues to be included and excluded. <u>2. Set the standards for quality</u> Inclusion criteria are established for the quality and relevance of the studies. Only the results from research that is sufficiently rigorous will be used. SBU's list of common pitfalls provides examples of unacceptable results. In some cases, project groups may decide to include studies of lower quality or relevance if the material presents unique information. <u>3. Collect relevant research findings</u> All available research findings addressing the important issues are systematically searched in computerized databases and by manually scanning reference lists in professional journals and scientific reports. Searches may identify several thousand articles if

Structure of HTA Program	HTA Organization
	the assessment concerns a broad area, for instance, common methods to treat obesity or substance abuse. 4. Select studies of acceptable quality Since the quality of research may range from high to low, project groups must separate the 'wheat from the chaff'. Each research report is carefully reviewed and evaluated. The project groups evaluate every study for quality and relevance. At times, the groups use standardized checklists in this process. Research reports that do not meet the predetermined criteria for quality and relevance are eliminated in this step of the review process. 5. Weigh the results Results from the selected studies are summarized in tables, scrutinized, and used to form the body of evidence. As with searching and selecting the literature, weighing the evidence must also be systematic and rigorous. All conclusions drawn must have scientific support. It is important to address not only the medical effects of different methods, but also the prevalence of the problem, current practices in Sweden, and the economic, social, and ethical aspects. 6. Summarize the evidence and draw conclusions Before SBU publishes its findings, the manuscript is evaluated by external experts and by experts from the SBU Scientific Advisory Committee. Manuscripts are always carefully edited, and the language is revised prior to publication. The SBU Board of Directors and the Scientific Advisory Committee approve the conclusions drawn from the evidence and consider the findings in a broader context. As a rule, the strength of the scientific evidence is noted for each conclusion by using the SBU evidence grading scale. *The SBU Alert Work Process* Identification of new methods Many sources provide SBU Alert with suggestions about new methods needing assessment, for example: • employees within the health care system • organizations, for example the National Board of Health and Welfare, the Medical Products Agency and the county councils • the Alert Advisory Board and the staff of SBU • international counterparts of SBU Alert and the joint network EuroScan Prioritization of methods The Alert Advisory Board decides which of the suggested methods that should be assessed by Alert. The methods that Alert assess must have been tested on patients. The results must have been published in a scientific journal or presented at a conference. The method should not already be well-studied or widely used in health care. However, Alert may assess an established method that will be used for a new indication. Furthermore, the method should be expected to have a major impact on health services, for example, they may: • represent a medical breakthrough • affect a large group of patients

Structure of HTA Program	HTA Organization
	• influence the structure of health delivery • result in controversy or have ethical and/or social implications • have a substantial economic impact <u>Review</u> • One or more experts are appointed, sometimes at the recommendation of the Swedish Society of Medicine. • A draft, based on a standardized format, is prepared by the appointed expert in collaboration with SBU. • The draft is reviewed by at least one additional expert, the Alert Advisory Board and the SBU working committee. Where appropriate, manufacturers are asked to comment on the draft. • The report is updated when new, relevant, scientific documentation becomes available. <u>Assessment of the scientific evidence</u> An SBU Alert report begins with summary and conclusions, which includes grading of scientific evidence concerning patient benefits and cost-effectiveness. <u>Dissemination</u> • The SBU Alert report is published on the SBU home page • The summary and conclusions is translated into English • A newsletter is sent to SBU's email subscribers when the report is published. Subscribe to the Newsletter
Use of HTA in Decision Making	
12. Decision Making Bodies	*No information identified.*
13. Decision Making Process and Criteria	*No information identified.*
14. Appeal Process	*No information identified.*
Program Products and Dissemination	
15. HTA Products	*Yellow Reports* – assessments carried out by SBU project groups. These comprehensive reports are based on systematic reviews of the existing body of scientific literature in a subject area. External experts and the SBU Scientific Advisory Committee review the manuscripts. The Yellow Reports include an executive summary and conclusions that have been formally approved by the SBU Board of Directors and the SBU Scientific Advisory Committee. *Alert Reports* – early assessments of single, new methods that are being developed and disseminated in health care. These assessments also include a systematic literature review. However, in contrast to the Yellow Reports, each Alert Report addresses a single intervention only. The SBU Board of Directors and the Alert Advisory Board formally approve the findings.

Structure of HTA Program	HTA Organization
	White Reports – information on the "state of the art" exploring topics in health care that may need to be assessed. These documents address important issues and may be the starting point for future systematic literature reviews. White reports are reviewed by the project groups and external experts only. Many SBU reports are translated into other languages and published in international scientific journals or books. SBU's findings reach a diverse audience, and several reports have received international acclaim *SBU Alert* A system for identification and early assessment concerning new methods in health care (EWS – Early Warning System). The Alert program is based at the SBU and is a joint effort by SBU, the Medical Products Agency, the National Board of Health and Welfare and the Swedish Association of Local Authorities and Regions. The Alert reports concisely describe the new methods and their effects. The drafts are prepared in collaboration with appointed experts. SBU's summary and conclusions, which includes grading of evidence concerning the method in question, is translated into English and published on the SBU home page.
16. Implementation	*SBU Newsletter – Science & Practice* (over 100,00 copies per issue) published in the Journal of the Swedish Medical Association and other medical journals *Reports* – published in full text on SBU website *Media*- often reports on scientific findings of the SBU *Free internet subscription service*- alert reports and other news on the SBU website is disseminated through this service *Dissemination activities* SBU's reports are disseminated on a large scale to predefined target groups (clinicians, politicians, administrators), to the media, and to the general public. The reports are frequently published in English as supplements to scientific journals. A summary is always published in the Swedish Medical Journal and in the *Journal of Technology Assessment in Health Care*. All summaries of the Alert reports are translated into English and published on the website. Other means of dissemination include regional and national conferences, workshops, exhibitions, and educational activities and seminars for targeted groups, (e.g., medical journalists). SBU also distributes a quarterly information bulletin, "Medical Science and Practice" (circulation of 86,000 copies). SBU is also disseminating findings through "Ambassadors" in special entities in the county councils to provide face-to-face information about recent HTA findings at staff meetings, seminars, and conferences. SBU publish versions of the reports for the general public. Web page: www.sbu.se.
17. Program Evaluations	*No information identified.*

Appendix Q. United Kingdom – HTA Components - NICE

Structure of HTA Program	HTA Organization
Program Structure	
1. Program purpose	The purpose is to appraise the health benefits and costs of technologies as referred by the Secretary of State for Health and to make recommendations on use of the technology to the National Health Service (NHS) in England and Wales.
2. Basic organization and governance	NICE is part of the NHS. The Centre for Health Technology Evaluation (CHTE), within NICE, develops HTAs. Two types of HTAs are undertaken by the CHTE on behalf of NICE: The Multiple Technology Assessment (MTA) process is designed to assess single or multiple products, devices, or other technologies with one or more indications. NICE seeks information from a variety of sources and organizations and an academic "Assessment Group" carries out the HTA. Additional information is sought from Consultees, clinical experts, patient experts and the NHS. The Single Technology Appraisal (STA) process is designed to appraise a single product, device or other technology with a single indication. The process generally involves new technologies and aims to produce guidance soon after the technology is introduced into England. The main evidence for the appraisal is submitted by the manufacturer/sponsor of the new technology and the evidence review group (an independent, external academic organization) reviews the evidence. Additional information is provided by Consultees, clinical experts, patient experts and the NHS.
3. Scope of HTAs	NICE undertakes appraisals of new and established technologies, as formally requested by the Department of Health. Health technologies referred to NICE include: pharmaceuticals, medical devices, diagnostic techniques, surgical procedures, other therapeutic technologies, and health promotion activities.
4. Program Transparency	Documents and decisions from all parts of the HTA process are posted on a publically available website.
5. Stakeholder Input	Stakeholder involvement at each step of process, from start of assessment through any appeal prior to finalization of decision. NICE Appraisal Committee membership drawn from the NHS, patient and carer organizations, academia, and pharmaceutical and medical device industries. NICE invites Consultees to submit statements and participate in consultation on the HTA. Consultees include the following groups: national groups representing patients/carers; organizations representing healthcare professionals; manufacturers/sponsors of the technology; Department of Health; Welch Assembly Government; specialized commissioning groups; primary care trusts and local health boards. NICE also invites Commentator organizations, with an interest in the technology, to participate. They include: manufacturers/sponsors of comparator technologies; NHS Quality Improvement Scotland; relevant National Collaborating Centers (commissioned by NICE to develop guidelines); related research groups (e.g. Medical Research Council); other groups (e.g., NHS Confederation, NHS Purchasing and Supplies Agency, etc.)
6. Target Audience	The NHS for England and Wales and the clinicians, patients and carers who are affected by appraised technologies.
Nomination and Selection of Topics	
7. Topic Nominations	Topics come from several sources, including healthcare professionals, the general public, the Department of Health's national

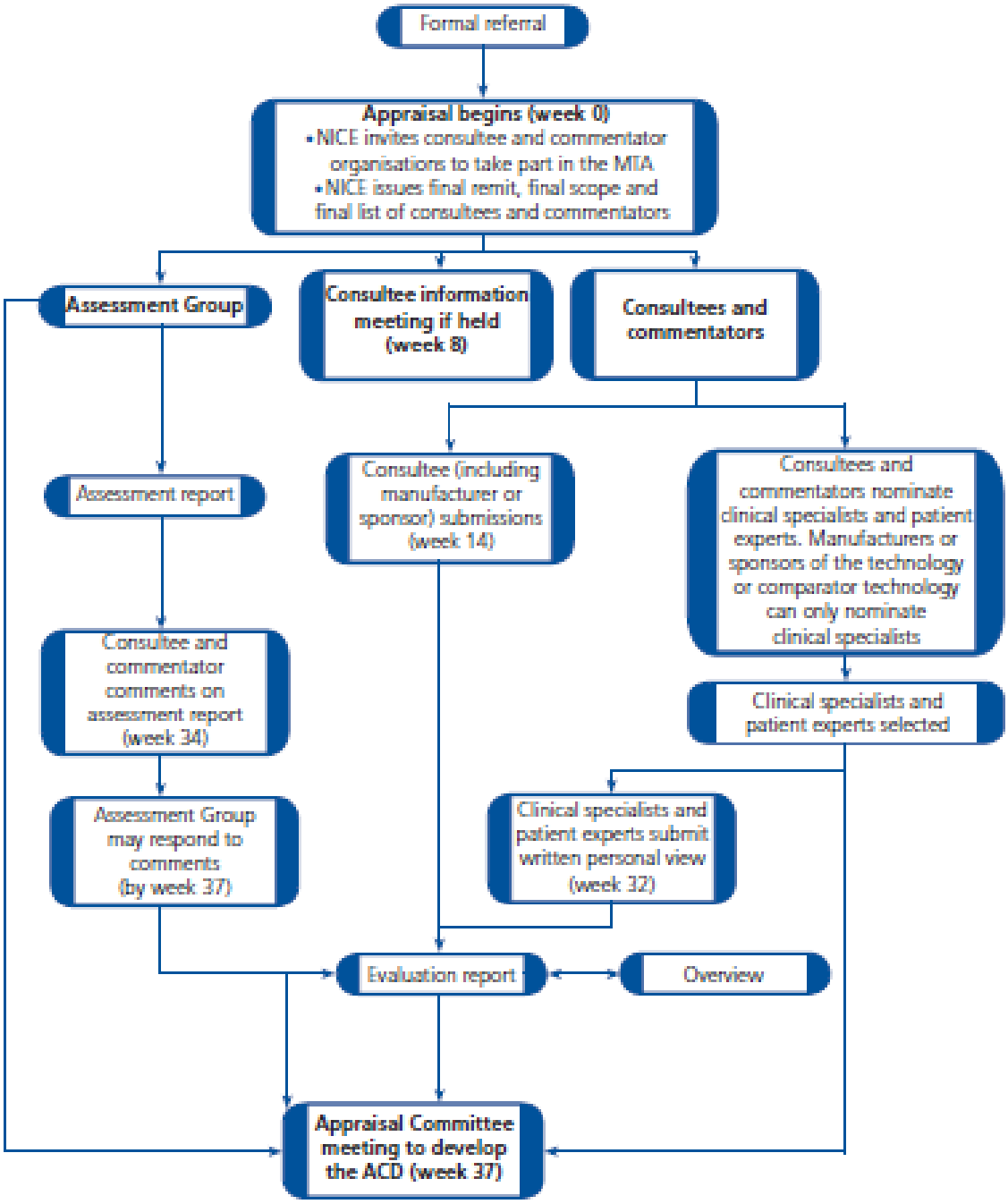
Structure of HTA Program	HTA Organization
Process	clinical directors and policy teams, and the National Horizon Scanning Centre. Ministers at the Department of Health have responsibility for the final decision about which topics are referred to NICE.
8. Topic Refinement	NICE determines the specific questions to be addressed for each HTA during a scoping process. The scope defines the issues of interest (e.g., population, comparators and potential subgroups) as clearly as possible for considering the clinical and cost effectiveness of the technology. Stakeholders are consulted during the scoping process and NICE revises the scope in response to comments received and develops a final scope for the HTA and the issues that will be investigated.
9. Topic Selection	The UK Department of Health refers technologies for HTA based on one or more of the following criteria: • 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 (for example, reduction in health inequalities)? • Is the technology likely to have a significant impact on NHS resources (financial or other) 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 the Institute likely to be able to add value by issuing national guidance? For example, in the absence of such guidance is there likely to be significant controversy over the interpretation or significance of the available evidence on clinical and cost effectiveness?
Conduct of Evidence Reviews	
10. Entit(ies) conducting reviews	The Centre for Health Technology Evaluation (CHTE), within NICE, conducts the HTA.
11. Methods of Reviews	NICE commissions a systematic evaluation of the relevant evidence available on a technology. The assessment generally consists of two components: a systematic review and an economic evaluation. Evidence review is conducted by an independent assessment group (the Evidence Review Group). For MTAs, the assessment includes an independent systematic review and economic analysis. For STAs, the submission provided by the manufacturer or sponsor of a technology is reviewed and the Evidence Review Group provides a critique of the submission. The Evidence Review Group may recommend that NICE request additional analyses from the manufacturer or sponsor. The review may include sensitivity analysis to explore alternative scenarios and uncertainty in the cost-effectiveness results.
Use of HTA in Decision Making	
12. Decision Making Bodies	The HTA Appraisal Committee issues the final appraisal determination (FAD). NICE distributes the FAD for the use of the NHS in England and Wales.
13. Decision Making Process and Criteria	The "Appraisal Process" involves consideration of the reports and analyses alongside additional information supplied by Consultees and other involved in the review and comment process. The Appraisal Committee considers the available evidence and then makes a decision, applying judgments on the importance of a range of factors which it determines are most appropriate for each HTA. NICE states that, "Although there is a boundary between assessment and appraisal, it is not precisely defined and judgment in the assessment process about, for example, choice of outcome measures to be investigated will

Structure of HTA Program	HTA Organization
	influence the appraisal process."
14. Appeal Process	The appeal process is detailed in NICE publication *Guide to the technology appraisal appeal process*, August 2010. Appeals are considered by a separate committee and can only be filed by organizations and individuals who have been previously registered as Consultees for the HTA. Appeals must be registered within 15 working days from the time the final determination is issued. Appeals are considered only on the following grounds: 1) NICE did not act fairly; 2) the guidance cannot be justified on the basis of the evidence submitted during the development process, and/or 3) NICE exceeded its power. The chair of the appeals committee decides if there is reasonable cause for an appeal and whether a written or oral process is most appropriate. Appeals are heard by a five member panel drawn from members of the Appeal Committee who have had no prior involvement with the HTA under appeal. Appeal panels include representatives with experience in the relevant industry and those affected by the decision. Oral hearings are held within 8 weeks of the appeal and written appeals within 10 weeks. After the hearing, the panel sends its final determination to NICE usually within 15 working days. The panel can uphold the appeal and either return the HTA to its development committee or request changes without further consideration by the committee. The panel may also dismiss the appeal and at that point the final decision is published and the only further challenge possible is at the level of the High Court. The *Guide to the technology appraisal appeal process* includes extensive information about the appeals process and should be consulted for further specifics about the process.
Program Products and Dissemination	
15. HTA Products	The FAD forms the basis of NICE guidance on the use of the technology. The guidance is published on NICE's website.
16. Implementation	The NHS, under direction of the Secretary of State for Health, provides funding and resources for technologies that are recommended through the NICE HTA program. NICE provides advice and tools to support the local implementation. Audit support and costing tools are produced for all technology appraisals. Additional implementation support tools are produced for selected technology appraisals. The NICE document, *'How to put NICE guidance into practice'*, gives more information and advice about implementation.
17. Program Evaluations	A full evaluation of NICE was conducted by the House of Commons Health Committee and published 10 January 2008. Internal to NICE, an audit staff person is assigned to each topic from the division of NICE responsible for implementation. Audit measures and electronic audit tools are provided with the final published technology appraisals.

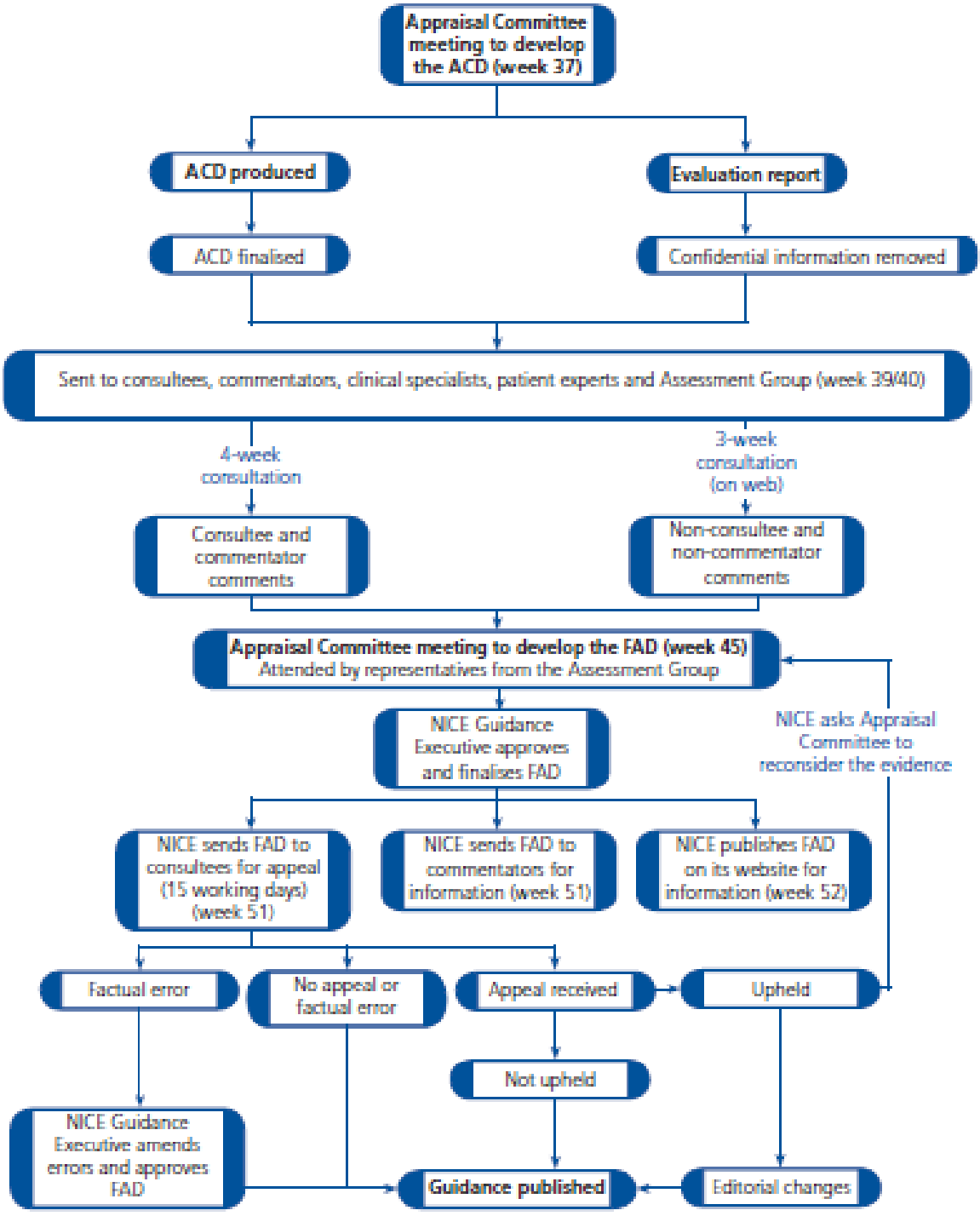
Table 1. Comparison of NICE STA & MTA Timelines

Step	Component	MTA Timeline (weeks)	STA Timeline (weeks
Step 1	NICE invites organizations to participate in the [MTA or STA] as consultees or commentators	0	0
Step 2	NICE receives submissions from consultees	14	8 (evidence submissions and statements)
Step 3	NICE sends submissions from consultees to the Assessment Group	15	(10-11 NICE requests clarification on the evidence submission)
Step 4	NICE invites selected clinical specialists, NHS commissioning experts and patient experts to attend the Appraisal Committee meeting and asks them to submit a written personal view	16	10
Step 5	NICE receives the assessment report	28	-
Step 6	NICE sends the assessment report to consultees and commentators for comment	30	18 (for fact checking)
Step 7	Selected clinical specialists, NHS commissioning experts and patient experts submit written personal views	32	18
Step 8	NICE receives comments on the assessment report from consultees and commentators	34	-
Step 9	NICE compiles the evaluation report and sends it to the Appraisal Committee	35/36	19
Step 10	Appraisal Committee meeting to develop and ACD attended by clini8cal specialists, NHS commissioning experts and patient experts	37	21
Step 11	The ACD is produced. NICE distributes the ACD and publishes it on the website 5 working days later	40	24
Step 12	Fixed 4-week consultation period on the ACD	40-43	24-28
Step 13	Appraisal Committee meeting to consider comments on the ACD from consultees and commentators, and comments received through the consultation on the NICE website. Appraisal Committee agrees the content of the FAD	45	29
Step 14	The FAD is produced. NICE distributes the FAD and publishes it on the website 5 working days later	51	34

Figure 2 Summary of the MTA process



(*Source*: NICE MTA Timelines (NICE 2004, p. 32, 41))



(*Source*: NICE MTA Timelines (NICE 2004, p. 32, 41))

Appendix R. United States (CMS) – HTA Components

Structure of HTA Program	HTA Organization
Program Structure	
1. Program purpose	CMS issues Medicare national coverage determinations (NCDs) each year for 10 to 15 technologies. In some cases, CMS may request formal HTAs conducted by AHRQ, or input from the Medicare Evidence Developments and Coverage Advisory Committee (MEDCAC).
2. Basic organization and governance	CMS's Coverage and Analysis Group (agency staffed) is responsible for evaluating evidence and issuing NCDs. CMS may request additional advice and input through independent HTAs conducted by the Agency for Healthcare Research and Quality (AHRQ) when there is "conflicting or complex medical and scientific literature available, or when [CMS] believe[s] an independent analysis of all relevant literature will assist us in determining whether an item or service is reasonable or necessary" (68 Fed. Reg. 55639). In addition, or alternative to formal HTAs conducted by AHRQ, CMS may request that MEDCAC review and evaluate medical literature, technology assessments, and other information and provide independent guidance and expert advice to CMS on specific clinical topics and related coverage decisions. The primary role of MEDCAC is to provide independent, expert advice and assistance to CMS in making sound coverage decisions based on the reasoned application of scientific evidence (68 Fed. Reg. 55640). MEDCAC is comprised of up to 100 experts appointed by DHHS, of which 94 are voting members, and 6 are nonvoting members representing industry. Six of the 94 voting members include representatives of patient advocates. MEDCAC members include backgrounds in clinical and administrative medicine, biologic and physical sciences, public health administration, patient advocacy, health care data and information management and analysis, health care economics, and medical ethics. DHHS selects 15 members with knowledge specific to the topic in question to serve on the panel for each MEDCAC meeting. CMS makes final coverage determinations. Coverage determinations must be made within 6 months of the date of request, or 9 months if CMS seeks recommendations from MEDCAC.
3. Scope of HTAs	*Types of Technologies Reviewed:* Services covered by Medicare [specific types not identified] *Key factors analyzed:* effectiveness, clinical benefits and harms.
4. Program Transparency	*See Stakeholder Input*
5. Stakeholder Input	*Topic Nominations:* • The public may request NCDs, as well as comment on proposed NCDs. CMS determines whether a formal HTA or MEDCAC review is needed. There is no public input into whether CMS requests a formal HTA or review by MEDCAC.

Structure of HTA Program	HTA Organization
	• No process for public input to develop topic key questions identified. *Evidence Review:* • "Public comments sometimes cite the published clinical evidence and give CMS useful information. Public comments that give information on unpublished evidence such as the results of individual practitioners or patients are less rigorous and therefore less useful for making a coverage determination" (Decision Memo for Computed Tomographic Angiography, CAG-00385N). • Non-MEDCAC members who have relevant expertise may be asked to provide additional input to panel members and invited experts may make formal presentations to the MEDCAC. *Draft Evidence Reviews:* • AHRQ posts draft and final evidence reviews on its website for public review. The agency provides notice to public email distributions lists that a draft evidence review will be posted 1 week prior to posting the draft evidence review. The draft evidence review will be available for public comment for 2 weeks. • Invited peer review and public comments are posted to the website within 3 months after the final evidence review is posted, along with author responses to comments. • MEDCAC "score sheets" evaluating the quality of evidence and clinical effectiveness of technologies reviewed are posted with records of past meeting materials. The score sheets generally consist of a series of questions specific to each technology requesting MEDCAC members to rate the confidence in which they believe evidence supports the clinical effectiveness of the technology under review. *Public meetings:* • MEDCAC meetings are public and there is opportunity to comment at meetings. In general 45 minutes is allocated at meetings for public comment. (See March 11, 2011 Federal Register notice for May 11, 2011 MEDCAC meeting). • Notice of MEDCAC meetings with agendas are posted 60 days in advance of meetings. • Written comments must be submitted 30 days in advance of meetings. • Oral presentations and materials must be submitted 30 days in advance of meetings. • Individuals may attend in person or via webinar, and must register 3 business days in advance of meeting. • MEDCAC will deliberate topics publicly, but allows for public comment only during the topic allocated, unless otherwise requested by Chairperson. • MEDCAC minutes and transcript, TA reviewed, written comments, presentations, and committee "score-sheet" posted on website. *MEDCAC:* • CMS generally uses MEDCAC to allow for additional expert and public input on coverage topics. Specific areas of input include: expert clinical and technical review of TA methods and conclusions about the health outcomes of

Structure of HTA Program	HTA Organization
	technologies under review; expert advice on factors not directly related to evidence review but important to the NCD; and a forum for formal public input and advice. *Coverage Decisions:* • The public may comment on proposed NCDs.
6. Target Audience	CMS – Medicare Coverage Decisions
Nomination and Selection of Topics	
7. Topic Nominations Process	The public may propose topics for CMS NCD review. HTAs and/or MEDCAC reviews are conducted at request of CMS.
8. Topic Refinement	CMS identifies a framework of issues/questions for consideration by MEDCAC (Charter, pp. 2). [The process for developing key questions for HTAs conducted by AHRQ for CMS is not available on the website or in other CMS policy.]
9. Topic Selection	In 2003, in the CMS policy issued for the NCD process, CMS requests HTAs based on when there is "conflicting or complex medical and scientific literature available, or when we believe an independent analysis of all relevant literature will assist us in determining whether an item or service is reasonable or necessary" (68 Fed. Reg. 55639). According to 2006 policy outlining factors CMS considers in commissioning formal external HTAs, other considerations include: • The body of evidence to review is extensive, making it difficult to complete an internal technology assessment by CMS within the 6-month statutory timeframe; • An independent formulation of the appropriate assessment questions and methodological approach to an issue is desirable given the complexity or conflicting nature of the medical and scientific literature available; • Significant differences in opinion among experts concerning the relevant evidence or in the interpretation of data suggest that an independent analysis of all relevant literature will be of value; • The review requires unique technical and/or clinical expertise not available within CMS staff at the time of the review; • The review calls for specialized methods (e.g., decision modeling, meta-analysis) in health technology assessment; • The topic under consideration will be referred for consideration to the MCAC; or • Relevant non-proprietary but unpublished data could be collected and analyzed. CMS may refer a topic to MEDCAC based on a variety of circumstances, including: • Significant controversy among experts. • Methodological flaws of studies. • Lack of research

Structure of HTA Program	HTA Organization
	• Conflicting results of published studies. • Request for greater public input • Controversial use of technology among the public • Dissemination of technology would have major impact on Medicare program • Decisions informed by broad societal perspective of factors not directly related to scientific review of evidence but nevertheless relevant to the decision. (See Factors CMS considers in Referring Topics to MEDCAC).
Conduct of Evidence Reviews	
10. Entit(ies) conducting reviews	CMS staff within the Coverage and Analysis Group conduct evidence reviews. CMS may request independent, external HTAs by AHRQ for topics that involve conflicting or complex medical literature. In addition, CMS may also request MEDCAC assess the evidence and advise CMS on a reasoned application of the evidence. AHRQ may conduct formal HTAs internally or through one of the AHRQ Evidence-based Practice Centers.
11. Methods of Reviews	CMS details it methodology in the body of its National Coverage Determination decisions. The following Methodological Principles, for example, were stated in the Decision Memo for Computed Tomographic Angiography (CAG-00385N): *General Methodological Principles* When making national coverage decisions, CMS evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding that an item or service falling within a benefit category is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. The critical appraisal of the evidence enables us to determine to what degree we are confident that: 1) the specific assessment questions can be answered conclusively; and 2) the intervention will improve health outcomes for patients. An improved health outcome is one of several considerations in determining whether an item or service is reasonable and necessary. A detailed account of the methodological principles of study design that the agency utilizes to assess the relevant literature on a therapeutic or diagnostic item or service for specific conditions can be found in Appendix B. In general, features or clinical studies that improve quality and decrease bias include the selection of a clinically relevant cohort, the consistent use of a single good reference standard, and the blinding of readers of the index test, and reference test results. **AHRQ** TAs are also based on a systematic review of literature, along with appropriate qualitative and quantitative methods of synthesizing data from multiple studies.
Use of HTA in Decision Making	
12. Decision Making Bodies	CMS issues national coverage decisions each year for 10 to 15 technologies. MEDCAC and AHRQ provide advisory

Structure of HTA Program	HTA Organization
	information to CMS. CMS makes final determinations.
13. Decision Making Process and Criteria	CMS details the bases of its decisions in Decision Memos issued on topics reviewed (see e.g., Decision Memo for Computed Tomographic Angiography).
14. Appeal Process	The public may request "reconsiderations" of NCDs, or may challenge NCDs. Neither of these processes are described on CMS's website. The processes are referenced in a September 23, 2003 federal register, Medicare Program; *Revised Process for Making National Coverage Determinations*.
Program Products and Dissemination	
16. HTA Products	AHRQ produces HTAs for CMS. These reviews are included or available through the CMS's NCD. CMS produces NCDs.
17. Implementation	NCD decisions are binding Medicare coverage decisions.
18. Program Evaluations	*No information identified.*

Appendix S. United States (VA / DoD) – HTA Components

Structure of HTA Program	HTA Organization
Program Structure	
1. Program purpose	VATAP responds to the information needs of senior VHA policy makers by carrying out systematic reviews of the medical literature on healthcare technologies to determine "what works" in healthcare, and to support evidence-based resource management by the VHA.
2. Basic organization and governance	VATAP is located within the VHA's Office of Patient Care services. VATAP conducts the evidence reviews. Reports are targeted to needs of VHA senior policy makers.
3. Scope of HTAs	*Types of Technologies Reviewed:* vaccines, pharmaceuticals, devices, procedures, and the organizational and support systems within which health is protected and maintained. *Key factors analyzed:* medical, social, ethical, and economic implications of interventions used in health care. .
4. Program Transparency	VATAP does not invite external parties to participate in the technology assessment process. VATAP reports are available on the program's website. Reports identify authors, contact information, and a statement of no conflicts of interest among contributors
5. Stakeholder Input	There is no process for external stakeholder input into topics reviewed. VATAP does not seek external input into technology assessments. VATAP does not provide opportunity for external parties to comment on HTA reviews.
6. Target Audience	*No information identified.*
Nomination and Selection of Topics	
7. Topic Nominations Process	VATAP researches topics at request of VHA policy makers. A formal topic nomination and selection process is not available through the VATAP website.
8. Topic Refinement	*No information identified.*
9. Topic Selection	Topic selection criteria not available on website.
Conduct of Evidence Reviews	
10. Entit(ies) conducting reviews	VATAP conducts reviews
11. Methods of Reviews	Methods include defined search strategies, and study inclusion and exclusion criteria. Reports evaluate quality of evidence, and identify strength of conclusions.

Structure of HTA Program	HTA Organization
Use of HTA in Decision Making	
12. Decision Making Bodies	VATAP reports can inform VHA policy decisions with respect to appropriateness criteria, benefit design or modification, case management, equipment acquisition, quality management, risk management.
13. Decision Making Process and Criteria	*No information identified.*
14. Appeal Process	*No information identified.*
Program Products and Dissemination	
15. HTA Products	VATAP produces two types of products: Brief Overview and Bibliography. *Brief overview:* usually comprises a 2 to 10 page review of evidence on a topic, and assumes sufficient existing knowledge regarding clinical context and technology issues by its readers to omit these components of other VATAP products. *Bibliography:* is a selection of quality-filtered references of about 3 to 5 pages in length, not subject to external review. In addition to a reference list, it includes a brief synopsis about the policy issue at hand, background on the topic to provide clinical context, and search and retrieval methodology, but it does not include in-depth analysis.
16. Implementation	VATAP reports are used by VHA decision makers to support policy decisions with respect to appropriateness criteria, benefit design or modification, case management, equipment acquisition, quality management, risk management.
17. Program Evaluations	*No information identified.*

Appendix T. Minnesota – HTA Components – HSAC

Structure of HTA Program	HTA Organization
Program Structure	
1. Program purpose	Established by statute, the Health Services Advisory Council (HSAC) advises the Commissioner of Human Services regarding evidence conclusions and policy recommendations for health services and coverage policies of medical assistance, general assistance medical care, and MinnesotaCare programs. In addition, HSAC recommends criteria for verifying centers of excellence for specific aspects of medical care.
2. Basic organization and governance	The HSAC has 13-members appointed by the Commissioner, including: 7 voting physicians, 2 voting physician specialists, 2 voting non-physician health care professionals, 1 voting consumer, and the Commissioner's medical director who shall serve as a nonvoting member. Members of the Council are not employed by the Department of Human Services, except for the medical director. Voting members receive a $200 honorarium plus travel reimbursement for each meeting. Council members serve staggered 3-year terms. HSAC also includes a dental subcommittee, comprised of dental providers, health plan and county and public representatives, health researchers, and consumers. Additionally, ad-hoc subgroups of HSAC can be created for specific purposes. An example of this is the Perinatal Practices Advisory Group, which met to develop policy recommendations related to elective inductions of labor. Minnesota Department of Human Services (DHS) staff researches, writes, and present the HSAC and DSAC reports. DHS Medical Director oversees the HSAC and DSAC processes, and edits the draft reports before they are presented to the committees. The DHS commissioner chooses to accept or reject the HSAC recommendations.
3. Scope of HTAs	*Types of technologies reviewed:* health care services paid for by state programs [specific types not specified] *Key factors considered:* effectiveness and cost
4. Program Transparency	All HSAC meetings are public. Meeting minutes and agenda's are posted on HSAC's website. HSAC encourages stakeholder comments at meetings. Written comments must be submitted 3 days prior to HSAC meetings, and all comments are distributed to committee members in advance of the meeting. Meeting materials are posted on the website 7 days prior to HSAC meetings. Comments must be submitted to staff 10 days in advance of meetings in order to be posted to the website with other meeting materials. Additionally, HSAC distributes meeting information to a stakeholder listserve via email at the same time information is distributed to committee members. HSAC invites relevant clinical experts to meetings as needed by the complexity of the subject matter under discussion.

Structure of HTA Program	HTA Organization
	Stakeholders may recommend experts to invite.
5. Stakeholder Input	Stakeholders can provide public comment about topic nomination and selections as they are discussed by HSAC during public meetings. HSAC agendas are put on the website 1 week before HSAC meetings. Additionally, HSAC distributes meeting information to a stakeholder listserve via email at the same time information is distributed to committee members. Stakeholders have opportunity to submit evidence. External review of reports is done on an as-needed basis. This can be requested by stakeholders, and voted on by HSAC, and/or as determined to be needed by staff and the medical director. External reviewers must complete a conflicts of interest disclosure form. Stakeholders may always request a copy of the draft report, and can comment on it. The reports are posted when they are finalized. HSAC meeting are public. A schedule of meetings, agendas and minutes are posted on HSAC website. Stakeholders may request meeting background materials in advance by contacting DHS via phone. Stakeholders may comment at meetings. There is an HSAC public testimony disclosure form on website.
6. Target Audience	*No information identified.*
Nomination and Selection of Topics	
7. Topic Nominations Process	DHS recommends a list of topics to HSAC on an annual basis.
8. Topic Development	Staff and the medical director discuss the topics internally, and also discuss more formally with HSAC. In some cases, report topics may be modified after the literature is better understood and issues are identified.
9. Topic Selection	HSAC reviews and prioritizes topics to study. In general, topics are prioritized based on factors such as impact to health, impact to budget, availability of literature, and political relevance (for example, if there is a coverage mandate). However, there is no written process or criteria to prioritize topics.
Conduct of Evidence Reviews	
10. Entit(ies) conducting reviews	HSAC reviews Evidence Summaries compiled by DHS staff.

Structure of HTA Program	HTA Organization
	HSAC has had two staff persons – one with a master's degree in public policy, and one with a master's degree in public health. The staff are employed by DHS, and interact on a regular basis with the DHS medical director. An evidence summary can be done in as little as two months, or can take longer, depending on DHS priorities and the need for external review. Typically, 3 to 4 evidence summaries are being developed at a time.
11. Methods of Reviews	DHS staff prepare Evidence Summaries to present to HSAC. Evidence summary documents include brief background/context of clinical issue, the amount, quality and reliability of the evidence, and a proposed action to be taken by HSAC. Evidence summaries are based on defined sources: Medicaid-specific collaborations (MED Project, AHRQ Medicaid Medical Directors' Learning Network); Keyword searches of AHRQ National Guidelines Clearinghouse, the Cochrane Library, PubMed and Medline; Resources accessed directly including AHRQ Evidence-Based Program, Institute for Clinical Systems Improvement, and TAs by BCBS, ECRI, and ICSI. (See appendices in each report "HSAC Process for Summarizing Evidence." Sources are reviewed with preference for clinical practice guidelines, meta-analyses and systematic reviews, and supplemented by quality peer-reviewed primary articles. Preference is given to most up-to-date evidence. Quality of evidence is evaluated using AMSTAR (for systematic reviews) and Cochrane Collaboration (for individual studies).
Use of HTA in Decision Making	
12. Decision Making Bodies	HSAC advises DHS on coverage decisions. See description of HSAC above.
13. Decision Making Process and Criteria	HSAC uses the summary documents as a starting point for discussion, drawing an assessment based on the evidence and their clinical expertise.
14. Appeal Process	Coverage determinations can always be appealed, regardless of whether they were based on HSAC documents. Minnesota has found that having an HSAC report as the basis of a coverage decision has influenced appeals judges to uphold a denial decision.
Program Products and Dissemination	
15. HTA Products	Evidence summary documents include brief background/context of clinical issue, the amount, quality and reliability of the evidence, and a proposed action to be taken by HSAC.
16. Implementation	Evidence summaries and legislative reports are available on the HSAC website, and are available on request.
17. Program Evaluations	*No information identified.*

Appendix U. Oregon – HTA Components - HRC

Structure of HTA Program	HTA Organization
1. Program purpose	Established by the Oregon Legislature in 1991, the Health Resources Commission (HRC) conducts assessments of the effectiveness of medical technologies through the Medical Technology Assessment Program. The HRC's technology assessments inform decision makers responsible for coverage decisions by state agencies and public programs. Technology assessments are also intended to inform health care decisions by policy makers, public and private health plans, clinicians and consumers.
2. Basic organization and governance	The HRC is a volunteer commission appointed by the Governor and staffed by the Office for Oregon Health Policy & Research (located within the Oregon Health Authority (OHA), the state agency with purview of Oregon's Medicaid program). The HRC is comprised of 11-members with the following statutorily defined representation: four physicians, two pharmacists, one representative from each of the following groups: hospitals, insurance, business, labor, and consumers. The HRC has two subcommittees: *Technology Subcommittee:* The HRC has appointed a Technology Subcommittee comprised of five physicians and one lawyer. The Technology Subcommittee may employ experts as needed to review and develop clinically relevant conclusions with respect to evidence. The HRC may contract with research entities to conduct literature review and assess quality of evidence using standardized methods. The Subcommittee submits its assessment to the HRC for review and final recommendations. *Pharmaceutical Subcommittee:* The HRC has appointed a Pharmaceutical Subcommittee comprised of seven members including three physicians, a nurse practitioner, a pharmacist, and two PharmDs, a consumer representative for mental health topics and ad-hoc clinical experts are utilized as required. Reviews evidence and develops clinically relevant conclusions; defines topic scope; presents assessment to HRC. The HRC's work informs Oregon's Health Services Commission (HSC), the entity responsible for maintaining the Prioritized List of conditions and treatments covered by the Oregon Health Plan (OHP). State agencies (The Public Employees Benefit Board (PEBB), the Oregon Educators Benefit Board (OEBB), the Department of Corrections and the OHA) are encouraged, but not required, to use the HRC reports in their coverage decisions.
3. Scope of HTAs	*Types of technologies reviewed:* pharmaceuticals, medical equipment and devices, medical or surgical procedures, and health systems (such as electronic health records) that support these systems. *Key factors analyzed:* clinical effectiveness
4. Program transparency	*See stakeholder input.*
5. Stakeholder input	*Topic nominations:* The OHA develops topic nominations, and conducts public process to seek stakeholder comments on nominations.

	Topic selection: The HRC posts topic selections to its website at least a month prior to the first meeting of the Technology subcommittee reviewing the topic. *Evidence Review:* - All source documents are peer reviewed. - The Technology Subcommittee may use experts as needed. All expert reviewers are approved by HRC and must complete a conflict of interest form. - Technology Subcommittee meetings are public. Stakeholders may submit evidence during public meetings. *Draft Reports:* The Technology subcommittee draft report will be available on the HRC website for public review prior to presentation at the HRC meeting (timeframe currently under review, and may be 2 to 4 weeks). The report is presented to the HRC at a public meeting with time for public comment. *Public meetings:* All HRC and Subcommittee meetings are held in accordance with public meeting laws. HRC and Technology Subcommittee meetings are scheduled monthly. Meeting agendas and minutes are posted on website. *HRC composition:* includes consumer, hospital, business, labor, and insurance representatives.
6. Target Audience	The HRC's technology assessments inform decision makers responsible for coverage decisions by state agencies and public programs. Technology assessments are also intended to inform health care decisions by policy makers, public and private health plans, clinicians and consumers.
Nomination and Selection of Topics	
7. Topic Nominations Process	The OHA develops topic nominations, and conducts public process to seek stakeholder comments on nominations.
8. Topic Refinement	HRC draws on existing systematic reviews related to nominated topics and generally does not have control over key questions framed.
9. Topic Selection	The OHA selects topics. In general, topics are selected based on those that have the "highest likely impact on the health and health care of Oregonians, the cost of that care, and the Oregon Health Plan goals of achieving universal access to affordable care" (MEDTap Overview, n.d.) The HRC may reassess technologies based on the availability of new evidence and as deemed appropriate by the Commission.
Conduct of Evidence Reviews	
10. Entit(ies) conducting reviews	The HRC assigns topics to a Technology Subcommittee to evaluate the evidence in clinical context and formulate a report. The subcommittee meetings are held in public and adhere to all applicable public meeting laws. The HRC utilizes publically available source documents and may contract with an external firm to identify the scope of literature and assess quality of studies, using standardized methods.

	The Subcommittee presents its assessment to the Commission at a public meeting. The HRC may accept the report, make edits, or return the report to the Subcommittee for further work.
11. Methods of Reviews	Reviews are conducted using an HRC-approved "source document" which includes the scope of evidence to be reviewed. The report will contain an evaluation of the quality and sufficiency of available evidence for assessing the clinically relevant technical performance of the medical technology and the confidence in the conclusions reflecting the power of the evidence. Depending on available evidence the report may contain information regarding the science behind the assessed medical technology, its appropriate indications for use, its benefits and risks and its clinical effectiveness relative to alternatives.
Use of HTA in Decision Making	
12. Decision Making Bodies	The Commission shares the results of the medical technology assessments within the OHA programs including the OHP through the Division of Medical Assistance Programs (DMAP) and the HSC for its use in revising its Prioritized List of health services and developing clinical guidance. It will also share its findings with other health-related programs in the OHA, including other public purchasers such as PEBB and OEBB, as well as health-related programs in other state agencies regarding its medical technology recommendations. State agencies are encouraged to use HRC reports, but the HRC findings are not binding.
13. Decision Making Process and Criteria	No information identified with respect to how state agencies use HRC reports in coverage decisions.
14. Appeal Process	HRC conclusions are advisory and therefore do not involve an appeal process. At later stages in the policy making process, there is opportunity for public comment.
Program Products and Dissemination	
15. HTA Products	The HRC produces reports that summarize available evidence and provide clinically relevant conclusions based on evidence addressing the topic being evaluated. In addition, the HRC prepares brief clinician summaries highlighting key conclusions from the full reports. All reports and clinician summaries are available on the HRC website.
16. Implementation	The Commission shares the results of the medical technology assessments with relevant state agency decision makers.
17. Program Evaluations	No evaluations are available on the HRC website.

Appendix V. Washington – HTA Components – WA-HTA

Structure of HTA Program	HTA Organization
Program Structure	
1. Program purpose	Established by state law in 2006, the Washington Health Technology Assessment Program (WA-HTA) conducts health technology assessments and makes coverage determinations that are binding on three state government agencies purchasing health care: the Department of Social and Health Services (Medicaid), the Health Care Authority, and the Department of Labor and Industries. The Department of Corrections and the Department of Veterans Affairs also voluntarily participate in the program. WA-HTA conducts approximately 10 HTAs per year. The initial review and decision process takes between 6 and 12 months.
2. Basic organization and governance	WA-HTA is located within the Washington Health Care Authority (HCA), a state agency with purview over several state health care programs (not including Medicaid). Agency staff provide operation support for the program and the committee. The Administrator (head) of the HCA appoints committee members and selects technologies. The program contracts with an evidence-based technology assessment centers to conduct HTAs. Coverage decisions are made by an independent Health Technology Clinical Committee (HTCC) comprised of 11 members – including six practicing physicians licensed by the state, and five other practicing health professionals. Participating state agencies interact with WA-HTA through an Agency Medical Director Workgroup (AMDG) comprised of medical director representatives from each agency. The AMDG provides input into the program's decisions, HTCC membership, topic nominations, and agency experience and utilization information.
3. Scope of HTAs	*Types of technologies reviewed*: medical and surgical devices and procedures, medical equipment, and diagnostic tests. Health technology does not include prescription drugs, which are governed by a separate state evidence-based prescription drug program. *Key factors analyzed:* safety, efficacy, and cost-effectiveness. A list of HTAs completed and in progress is available on WA-HTA's website at: http://www.hta.hca.wa.gov/assessments.html
4. Program Transparency	WA-HTA provides opportunity for public participation and/or comment in: topic nominations; submission of evidence for consideration in the HTA review; draft reports; coverage decision meetings, and draft coverage decisions. Interested parties receive notices of opportunities for public input via a stakeholder email list and postings to the program's website. Overall, the program operates according to a public process and makes decisions based on published criteria. The HTCC coverage determinations are made in a public forum, and the committee members are independent of state agency payers and industry stakeholders. Committee members must not have substantial financial conflicts of interest in a

Structure of HTA Program	HTA Organization
	health technology company, and must disclose conflicts annually.
5. Stakeholder Input	Interested parties may nominate topics using a standardized form available on WA-HTA's website which outlines questions according to WA-HTA's topic selection priorities. Proposed and final topic selections and key questions are posted on WA-HTA's website with a 30-day public comment period. The primary goal of this comment period is to gather information and evidence from interested parties to consider in the evaluation. The program also provides interested parties also a 30-day period to comment on draft reports. Interested parties may submit written comments in advance to the HTCC, or provide oral comments at the public meetings where HTCC deliberations and coverage decisions take place. The HTCC may establish an ad hoc advisory group if specialized expertise is needed, or to seek input from enrollees or clients of state purchased health care programs. Draft findings and decisions of the HTCC are posted to the website for public comment, prior to a final decision at the following public meeting of the HTCC. Final committee decisions, rationale and the evidentiary basis are posted on the program's website within 10 days.
6. Target Audience	State agencies subject to the binding coverage decision have specific opportunities for input outlined above. *No information identified on other specific stakeholders.*
Nomination and Selection of Topics	
7. Topic Nominations Process	Topics are selected for review based on nominations by participating agencies and recommendations of the HTCC. Interested parties may nominate topics via a standardized form on the program's website. All HTAs conducted by the program are subject to re-review at least every 18 months or earlier based on the availability of new evidence.
8. Topic Refinement	Topic nominations by the participating agencies are developed collaboratively by participating agencies through the Agency Medical Director Workgroup. All topic nominations – whether from the agencies, HTCC or interested parties – are developed and reviewed according to eight publicly-defined prioritization criteria, based on the program's legislative mandates and secondary criteria defined by the program:

Structure of HTA Program	HTA Organization
	Primary criteria – legislative mandates 1. Potential patient harm/safety concerns 2. Concerns about therapeutic efficacy or diagnostic accuracy and appropriateness of outcomes for patients 3. Estimated total direct cost per year *Secondary criteria* 4. Number of persons affected per year 5. Severity of condition treated by technology 6. Policy related urgency/diffusion concern 7. Potential or observed variation 8. Special populations/ethical concerns (See "Prioritization Criteria and Tools" and "Health Technology Selection Process Background" accessed 1/7/2011 at www.hta.hca.wa.gov/about.html)
9. Topic Selection	The HCA Administrator selects topics for review, based on nominations from the participating agencies and recommendations by the HTCC. The Administrator may also consider nominations by interested parties. The Administrator must select topics based on three technology review priorities set forth by statute: (a) Concerns about its safety, efficacy, or cost-effectiveness, especially relative to existing alternatives, or significant variations in its use; (b) Actual or expected state expenditures are high, due to demand for the technology, its cost, or both; and (c) Adequate evidence available to conduct the complete review (RCW 70.14.100). Interested parties that nominated topics that were not selected by the HCA Administrator may submit a request to the HTCC to conduct a review or re-review. The HTCC must then select topics based on three program priorities set forth in statute, outlined above.
Conduct of Technology Assessments	
10. Entit(ies) conducting reviews	The HCA must contracts with an independent evidence-based practice center designated by the federal Agency for Healthcare Research and Quality (AHRQ), or other appropriate entity, to conduct the technology assessment. Assessments usually take between two and six months to complete.
11. Methods of Reviews	The HCA uses systematic reviews, meta-analysis, and targeted "best evidence" reviews. The HTAs search and summarize the clinical evidence, coverage decisions, and treatment guidelines, and information provided by agencies and the public. The HTAs do not include recommendations related to coverage decisions.
Use of HTA in Decision Making	
12. Decision Making Bodies	Coverage decisions are made by the HTCC, an independent committee comprised of 11 members – six practicing physicians

Structure of HTA Program	HTA Organization
	licensed by the state, and five other practicing health professionals – and are binding on the participating state agencies. Committee members serve for three-year terms, and may serve for additional three-year terms for a maximum of nine years total.
13. Decision Making Process and Criteria	The HTCC meets quarterly, and meetings are subject to the state public meetings law, which authorizes private executive sessions to consider proprietary or confidential information. The HTCC must make coverage decisions based on the health technology assessment, as well as information provided by the HCA administrator, an advisory group, and submissions or comments from the public. The committee shall give the greatest weight to the evidence determined, based on objective factors, to the most valid and reliable considering the nature and source of the evidence, the empirical characteristic of the studies or trials upon which the evidence is based, and the consistency of the outcome with comparable studies. The committee may also consider additional evidentiary valuation factors such as recency (date of information); relevance (the applicability of the information to the key questions presented or partici8pating agency programs and clients); and bias (presence of conflict of interest or political considerations.) WAC 182-55-030 The HTCC must determine the conditions, if any, under which a health technology will be covered. In addition, the HTCC must specify criteria for agencies to use in deciding whether a technology is medically necessary or proper. Agencies may make certain exceptions to these coverage determinations for experimental or investigational treatment, services under clinical investigation approved by an institutional review board, or health technologies that have a humanitarian device exemption from the federal Food and Drug Administration.
14. Appeal Process	There is no right to appeal HTCC decisions directly.
Program Products and Dissemination	
15. HTA Products	WA-HTA produces health technology assessments, and HTCC Findings and Coverage Decisions, which are available on the program's website.
16. Implementation	Participating agencies are named in the legislation and must implement the coverage decision, unless very narrow statutory exceptions are met. The agencies must also develop methods to report on the implementation of coverage decisions with respect to health outcomes, frequency of exceptions, cost outcomes, and other matters deemed appropriate by the administrator.
17. Program Evaluations	The program conducted a quality assessment of itself in July 2008, and developed a Program Review report available on the WA-HTA website. The program gathered input from the HTCC, stakeholders, agencies, legislators and legislative and governor staff with respect to 1. Public engagement and transparency; 2. State agency coordination and support; 3. Technology selection and evidence review; 4. Clinical committee staff support and coverage decisions; and 5. Internal program operations.

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