

Washington State Health Technology Assessment Program

Stakeholder Engagement Project

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January 2012

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Suggested Citation:

Curtis, P., Gordon, C., Slaughter-Mason, S., & Thielke, A. (2012). *Washington State Health Technology Assessment Program: Stakeholder engagement project*. Portland, OR: Center for Evidence-based Policy, Oregon Health & Science University.

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Executive Summary

The primary purpose of Washington Health Technology Assessment (WA HTA) Program is to ensure medical treatments and services paid for with state health care dollars are safe and proven to work. The WA HTA serves as a resource for state agencies purchasing health care by contracting with independent external vendors to produce scientific, evidence-based reports about the safety and efficacy of select medical devices, procedures, and tests. An independent clinical committee of health care practitioners uses the reports to “determine the conditions, if any, under which” programs should pay for the medical device, procedure, or test [Revised Code of Washington 70.14.080 (2006)]. Participating state agencies include the Health Care Authority; Department of Social and Health Services (Medicaid); Labor and Industries; Department of Corrections; and Department of Veterans Affairs.

Little research is available on “gold standard” components of health technology assessment (HTA) programs and their processes. To assess how the WA HTA compares with the structure and processes of other HTA programs, and to assess stakeholder understanding and perception of the WA HTA, the Center for Evidence-based Policy (Center) at Oregon Health & Science University (OHSU) was engaged to conduct a “Stakeholder Engagement Project” (the Project). The Project had two primary components:

- 1) a review of common components of national and international HTA programs, conducted through a collaboration of ten states (the Medicaid Evidence in Decisions project); and
- 2) an assessment of stakeholder perceptions of the WA HTA relating to these common components and the WA HTA program’s legislative mandate.

The Project was not a formal program evaluation of the WA HTA, nor did it undertake an outcome evaluation of the Program.

Review of International and National HTA Programs

The International Network of Agencies for Health Technology Assessment defines health technology assessment as “a multidisciplinary field of policy analysis, studying the medical, economic, social and ethical implications of development, diffusion and use of health technology” (2011). 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).

A full search of the Center’s core clinical evidence sources was conducted to identify systematic reviews, meta-analyses, and technology assessments published after December 1999. Twenty-four HTA programs were identified and searched, and 12 national and international HTA programs were selected for review. Across these programs, fourteen core components were identified and organized into six broad categories:

1. HTA Organization and Structure
2. Transparency

3. Stakeholder Involvement
4. Topic Nomination and Selection
5. Evidence Synthesis
6. Use of HTA in Decision Making

Overall, from the Center’s review of HTA programs, the Washington HTA Program’s mandates and processes are consistent with many of the core components of other well-established national and international HTA programs. Examples include: the Washington HTA Program maintains an open topic nomination process, uses an independent review committee with authority to make coverage determinations, is based on evidence synthesis, solicits public comment at common points in the topic research process, and has publically available reports, coverage decisions, and program process documents. With few exceptions, the methods employed by the WA HTA Program are similar to other publically funded HTA programs.

Assessment of Stakeholder Experience

Engaging stakeholders in public policy processes has been increasingly called for as a component of health services research and health care reform. As a second component of the Stakeholder Engagement Project, feedback was solicited from a full range of stakeholders regarding their knowledge and perceptions of, as well as experience with, the Program’s core components and its processes. The goal was to assess stakeholder understanding and perception of the WA HTA Program’s mandate and processes. A multimodal approach was used to gather feedback, allowing for a diverse range of feedback, while including opportunities for more focused discussion. Three methods were employed:

- an online survey,
- key informant interviews, and
- facilitated discussions.

Each method builds on the findings of the one(s) preceding it. This approach is designed to assess stakeholder perception and to understand areas of concern. The process identified areas of stakeholder satisfaction and concern with the Program. However, only areas of concern were explored in-depth.

Findings from all three modes of engagement efforts were similar. Stakeholders expressed support of the Program and its processes. Stakeholders understand the mandate and are supportive of an independent, decision making body. Stakeholders acknowledged and supported the HTCC’s use of evidence to make decisions. They indicated that WA HTA seems interested in stakeholder perspectives and is attempting to be transparent. Processes are perceived as defined and transparent, although information, including how processes are structured, may need to be more clearly communicated and user friendly. Stakeholders discussed the need for a consistent and explicit definition of “evidence” and expressed confusion about under which circumstances which types of evidence would be “good enough.” There was also a call for clear standards and definitions, as well as for the Program to provide additional clinical and cost context for the evidence reviews.

Overall Project Findings (Review of HTA Programs and Assessment of Stakeholder Experience)

Since its inception in 2007, the WA HTA Program has established a solid foundation in the national and international world of evidence-based health care assessment. The Stakeholder Engagement Project found that the majority of stakeholders responding to request for feedback are satisfied the Program is successfully meeting its mandate and that current processes are fair and unbiased. The Program is at a natural point in its development to look at opportunities for continuous improvement. This Project provides valuable information that the WA HTA Program can use in ongoing improvement activities.

Key findings include:

- The Washington HTA Program maintains processes or generates products in that are consistent with the 14 core components of other well-established national and international HTA programs.
- The purpose of the HTA is supported, its mandate is understood, and there is support for an independent, coverage decision-making body.
- The Program’s processes are transparent, but are not well understood, particularly by “external” stakeholders¹. The Program currently publishes most of the information that stakeholders are interested in, but it is not always easy for stakeholders to find. Program areas that lack stakeholder understanding primarily include:
 - a. Topic nomination and selection;
 - b. HTCC member and evidence vendor selection; and
 - c. Opportunities for public input or involvement.
- Stakeholder concerns and suggested improvements are generally focused on three areas:
 - a. Timelines for review of draft reports;
 - b. Opportunity for public input to the HTCC; and
 - c. Access to public comment and their disposition.
- There is a need to provide context for the evidence reports, including clinical background and cost information.
- Tension between program timelines, evidence synthesis and decision mandates was evident from the various stakeholder voices in this Project.

¹ WA HTA Program staff does not make the distinction between “internal” and “external” stakeholders. However, when analyzing project data, it became clear that this is a real distinction in terms of Program knowledge, experience, and perceptions.

Recommendations

Based on the findings in this report, the Center for Evidence-based Policy recommends the WA HTA consider eight modifications relevant to the areas of stakeholder communication, program processes and evidence reports. These suggestions should be considered in light of the WA HTA mandate and resources.

1. Improve usability of the WA HTA website, making information of importance to stakeholders clear and available within a limited number of clicks.
2. Create simple, user-friendly diagrams and documents that summarize important Program information.
3. Conduct additional outreach to individuals and organizations, particularly patients, patient groups and providers.
4. Publish a timeline for the estimated completion of each report.
5. Review timelines for public comment of draft reports. The need for extending comment periods may be alleviated by additional public engagement in topic selection and topic refinement processes, and publication of timelines. Consider extending the comment period for draft reports.
6. Publish information regarding the disposition of public comments.
7. Clearly communicate purpose and role for each opportunity of stakeholder involvement.
8. Include contextual information by:
 - a. Providing clinical background for the topic; and
 - b. Providing cost data, when available, for a topic.

Introduction

The Washington State Health Technology Assessment (WA HTA) Program was established in 2006 by governor-sponsored legislation. The goal is to promote the purchase of excellent health care by investigating and paying for tests and treatments proven safe, effective, and cost effective. The statutory mandate changed the process used by public agencies to make coverage decisions for medical and surgical devices and procedures, medical equipment, and diagnostic tests. Prior to the inception of the WA HTA Program, agency medical staff at Labor and Industries, Department of Corrections, Health Care Authority, Department of Social and Health Services (Medicaid) and Department of Veteran's Affairs, along with expert consultants, made independent coverage decisions. Since becoming operational in 2007, the WA HTA Program provides coverage determinations on selected health technologies through evidence-based systematic reviews and an independent clinical committee. These State agencies must implement these determinations, resulting in more consistent coverage decisions. The Program contracts with independent external vendors through a public bidding process to produce these reports.

The WA HTA works to achieve better health care outcomes for enrollees and beneficiaries of state programs by paying for health technologies that are proven to work. However, little research is available on "gold standard" components of health technology assessment (HTA) programs and their processes. To address this gap, the WA HTA contracted with the Center for Evidence-based Policy (Center) at Oregon Health & Science University (OHSU) to review common components of HTA programs (through the Medicaid Evidence-based Decisions (MED) project) and to assess stakeholder understanding and perception of the current WA HTA program and its processes. The Program was also interested in better understanding common components of public HTA programs, and identifying common practices in alignment with the legislative mandate, including:

- Evidence and analysis;
- Decision process;
- Transparency; and
- Stakeholder engagement.

As a result, the "Stakeholder Engagement Project" (the Project) had two primary components: 1) a review of common components of national and international HTA programs; and 2) an assessment of stakeholder perceptions of the WA HTA program relating to these common components and the program's legislative mandate. The Project was not a formal program evaluation of the WA HTA, nor did it undertake an outcome evaluation of the Program.

This report provides a brief overview of the WA HTA and its purpose. It reviews the purpose, methods and findings of the two Project components (review of HTA programs and assessment of stakeholder perceptions). Based on the Project findings, this report also provides recommendations for the WA HTA to consider as the program evolves. The complete review of HTA components is available as a separate report (<http://www.ohsu.edu/xd/research/centers-institutes/evidence-based-policy-center/med/index.cfm>).

Program Purpose and Legislative Mandate

The primary purpose of WA HTA is to ensure medical treatments and services paid for with state health care dollars are safe and proven to work. The Program serves as a resource for state agencies purchasing health care by contracting for scientific, evidence-based reports about whether certain medical devices, procedures, and tests are safe and work as promoted. An independent clinical committee of health care practitioners utilizes the reports to determine if state agencies should pay for the medical device, procedure, or test. Participating state agencies include the Health Care Authority; Department of Social and Health Services (Medicaid); Labor and Industries; Department of Corrections; and the Department of Veterans Affairs.

The statutory mandate [Revised Code of Washington 70.14.080-70.14.140 (2006)] requires the program to:

- Contract for impartial, peer reviewed evidence-based reports to support better decision-making;
- Use the expertise of an independent committee of practicing health care providers to review the reports and make health care coverage decisions;
- Maintain an open process for nominations of health technologies and information gathering about selected technologies; and
- Support a centralized transparent process to communicate program timelines and products.

The Program was required to select six technologies in its first year and eight technologies in the second year for evaluation and coverage decisions. Currently, the Program assesses approximately eight technologies per year utilizing systematic reviews of the best available evidence. Technologies are selected for review based on state agency concerns about whether they are safe, whether they work as intended, whether they are cost-effective (especially when compared to alternatives), and/or where there is a variation in how they are used. State agency medical directors identify potential health technologies of concern based on these criteria. Topics are prioritized based on the Program's mandate and standardized criteria that are widely used by other HTA programs in setting topic review priorities. Agency recommendations are sent to the Health Care Authority Administrator for preliminary and final selection. Any interested party may also petition for a technology to be reviewed, and the same prioritization criteria are applied.

To consider the structure of the WA HTA program in the context of other HTA programs doing the same or similar work, and to identify common components and processes, a review of national and international HTA programs was completed (see Chapter 1).

Chapter 1. Review of National and International HTA Programs

In 2010, the MED project, a collaboration of 11 state Medicaid and public-employee benefits agencies, selected health technology assessment (HTA) as a topic for an evidence review. Washington and Oregon nominated the topic to provide information about how their programs were similar and different to other HTA programs. Other states were interested in the review as a resource in the development of potential HTA programs in their jurisdictions. The review was conducted in the spring of 2011 with the final public report published August 2011. A copy of the full report is available at <http://www.ohsu.edu/xd/research/centers-institutes/evidence-based-policy-center/med/index.cfm>. This section provides a brief overview of this HTA review, references relevant appendices of the full report, and includes highlights of how the Washington HTA Program compares with other national and international HTA programs.

Overview

The International Network of Agencies for Health Technology Assessment defines health technology assessment as “a multidisciplinary field of policy analysis, studying the medical, economic, social and ethical implications of development, diffusion and use of health technology” (2011). 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).

Objectives and Key Questions

The objective of the *Review of National and International HTA Programs* was to review state or public payer programs that allocate health resources and to identify the processes used by those programs to determine the benefits and harms, costs and cost-effectiveness, and coverage policies of health technologies. Following this objective, the report focused on two key questions:

1. What are the components of public programs that allocate health resources using health technology assessment, including both US and international HTA programs?
2. What are the goals of each of these program components or process?

Methods

A full search of the MED clinical evidence core sources² 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 journal volumes (Suppl 1 and 2) of

² The Center for Evidence-based Policy uses a collection of high quality, independent evidence sources that are referred to as “core sources.” Examples of databases and resources included in the “core sources” include the Cochrane Collaboration (Wiley Interscience), Hayes, Inc., Agency for Healthcare Research and Quality, National Institute for Health and Clinical Excellence in England and Wales, Blue Cross/Blue Shield Health Technology Assessment Program, Veterans Administration Health Technology Assessment Program, British Medical Journal Clinical Excellence, Canadian Agency for Drugs and Technologies in Health, Washington State Health Technology Assessment Program, and US Preventive Services Task Force.

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.

Individual HTA programs websites were searched and selected for inclusion based 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 their 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.

Findings

Of the 24 HTA programs searched, 12 national and international HTA programs were selected for review:

- 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)
- England³ - 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 report highlights 14 key components of HTA programs that are used in public program decision-making. The key components were identified through a review of publically available HTA program information and HTA literature. The components can be organized into six broad domains, as outlined below. Appendices K through V of the full report detail the components of each HTA program.

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).

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

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 stakeholders to engage 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.

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.

Overall, the Washington HTA Program mandates and processes are consistent with the core components of other well-established national and international HTA programs. For example, the Washington HTA Program has an open topic nomination process, uses an independent review committee, has authority to make coverage determinations, is based on evidence synthesis, solicits public comment at various points in the topic research process, and has publically available reports, coverage decisions, and program process documents. Compared with other national and international HTA programs reviewed, the WA HTA publically provides equal amounts, and in some cases more detailed information on the implementation of many of the core program components; it has less detailed methods in place for communicating its processes to stakeholders. Table 1 summarizes the Washington HTA program components compared to the other 11 programs reviewed. The full HTA report compares and contrasts the included HTA programs across all 14 components.

Various national and international HTA programs are utilizing many of the components identified in this review. However, there is very little published literature on what constitutes “best practices”

for each of these components and how to measure their outcomes. The literature is also relatively silent on what specific components are necessary in developing a well designed HTA program.

As programs such as the WA HTA continue to evolve, more work will be needed to further develop program components and measurement tools to evaluate the effect of individual components and the HTA program on a whole. Efforts have begun in Europe with a collaboration of programs (EUnetHTA) to develop a HTA Core Model. The work of EUnetHTA 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).

Strengths and Limitations of the HTA Review

This review of HTA programs is based on a structured qualitative review of 12 national and international HTA programs. Strengths of this review include a systematic process to identify HTA programs for review, presentation of processes and components with examples from well-developed HTA programs, and a national and international perspective. Detailed HTA 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 a program does not address that component. In addition, this review is limited to public HTA programs, and those with publicly available information in English, which excludes some well-developed international HTA programs.

Table 1. Comparison of HTA Programs Across Components

Component	Washington HTA Program	Examples from National or International HTA Programs ⁴
I. HTA Organization and Structure		
1. Program Purpose	Authority to make coverage determinations [makes coverage (payment) determinations for state public programs]	Advisory with respect to evidence conclusions only (5 programs) Advisory with respect to evidence conclusions and policy recommendations only (5 programs) Authority to make coverage determinations (1 program)
2. Governance	Government-based agency	Government-based agency (8 programs) Non-profit / semi-governmental entity (3 programs)
2a. Governance and Advisory Committees	Independent review committee for coverage decision	Independent review committee (5 programs) Scientific advisory committee (3 programs) Variety of other advisory committees
2b. Committee Membership	Appointed by Government Agency head	Appointed by program director, umbrella agency director (e.g., Minister of Health, Commissioner of Human Services), or the governor
2c. Committee Composition	11 member composed of six practicing physicians and five other licensed health professionals	Size varies from 6 to 33 member committees. Composition ranges from representatives from regional government, academia, industry, patient or other relevant organizations, providers, insurance, business, and labor
3. Scope	<u>Technologies:</u> Medical and surgical devices and procedures, medical equipment, diagnostic tests <u>Factors analyzed:</u> safety, efficacy, cost-effectiveness	<u>Technologies:</u> range from specific medical technologies to broad health promotion activities <u>Factors analyzed:</u> range of safety, clinical effectiveness, cost-effectiveness, patient considerations, service impact, administrative and delivery systems, and organizational issues
4. Products	Focused evidence reports HTCC evidence findings and coverage decisions	Range of HTA reports (from focused on single technology or issue to reports on diseases or multiple technologies) Evidence conclusions and policy recommendations Report summaries (patient, provider, executive)

⁴ Where possible, the number of programs identified with the particular component example is noted. These numbers indicate total number of programs, where possible, excluding WA HTA.

Component	Washington HTA Program	Examples from National or International HTA Programs ⁴
		Brief summaries on new topics (not enough literature for full evidence review)
5. Program Evaluation	Last conducted in July 2008	5 programs have conducted a program evaluation within the last 8 years
II. Transparency		
6. HTA program transparency	Public topic nomination Public topic refinement (key question development) Public comment on reports Public comment on coverage decisions Publicly available reports and coverage decisions Publicly available process descriptions Public HTCC meetings	Public topic nomination (6 programs) Public topic refinement (key question development) (4 programs) Public comment on reports (7 programs) Public comment on coverage decisions Publicly available reports and coverage decisions Publicly available process descriptions Public meetings (4 programs)
III. Stakeholder Involvement		
7. Stakeholder involvement	Public meeting agendas published in advance Oral and written comments Publication of evidence reports Non-agency stakeholders on HTCC Topic nomination and development Use of peer review Comments on HTA reports	Public meeting agendas published in advance (5 programs) Oral and written comments Publication of evidence reports Non-agency stakeholder in HTA program committee or governance structure Topic nomination and development (7 programs) Use of peer review Comments on HTA reports (7 programs) Consumer representatives in HTA governance structure and/or advisory committee (6 programs) Appeal of HTA conclusions (2 programs)
7a. Comment period length	Topic Proposal: 2 weeks Topic Selection: 4 weeks Key Questions: 2 weeks	Key Questions: 4 to 5 weeks Draft reports: 2 to 4 weeks Final report: 3 months

Component	Washington HTA Program	Examples from National or International HTA Programs ⁴
	Draft reports: 2 weeks Findings and Decisions: 2 weeks	Program decisions: 2 to 4 weeks
IV. Topic Nomination and Selection		
8. Topic Nomination	Open nomination process	Open nomination process (6 programs) Focused (agency directed) nomination process (4 programs) Horizon scanning (3 programs)
9. Topic Refinement	Work with nominating authors Internal project group	Work with nominating authors (2 programs) Internal project group (6 programs) Initial literature review (3 programs)
10. Topic Selection	Prioritization criteria	Prioritization criteria (2 programs)
V. Evidence Synthesis		
11. Entities Conducting Reviews	External	External (5 programs) Internal (2 program) Mixed review team (internal and external) (4 programs)
12. Review Methods	Systematic reviews “Best evidence” reports	Systematic reviews (6 programs) “Best evidence” reports (5 programs) Review of industry evidence – dossier process (3 programs)
Use of HTA in Decision Making		
13. Public Program Decision Makers	Binding coverage determinations	Binding coverage determinations (1 program) Knowledge Transfer Specialist (1 program) Liaison Program (1 program)
14. Implementation	Public reports available on website Coverage decisions implemented by state agencies	Public reports available on website (11 programs) Funding and financial support (1 program) Publication of findings in professional and scientific journals (1 program) Conferences and facilitated discussion on HTA report findings (2 programs) Training sessions and seminars about HTA process (2 programs) Summary documents for patients, clinicians, and policy makers

Chapter 2. Assessment of Stakeholder Experience

Background

Engaging stakeholders in public policy processes is increasingly recognized as a critical component of health services research and health care reform. As a second component of the Stakeholder Engagement Project, the Center solicited information on stakeholder knowledge and perceptions of, as well as experience with, the Program and its processes. The goal was to assess stakeholder perception and understanding of the WA HTA Program's mandate and processes. A multimodal approach was used to gather feedback, allowing for a diverse range of feedback, while also including opportunities for more focused discussion. Three methods were used, with each building on the findings of the one(s) preceding it:



For more information on the rationale and process used in selecting these involvement methods please see Appendix A. The approach was designed to assess stakeholder perception and to understand areas of concern. The process also identified areas of stakeholder satisfaction, but did not explore them in-depth. This section provides an overview of the methods and findings of the survey, interviews and discussions.

Online Survey

The initial method for gathering information from stakeholders was through an online survey. The goal of the survey was to gather broad and diverse feedback from as many stakeholders as possible, and to identify areas that could be further investigated through the more in-depth approaches of key informant interviews and focused discussions.

Methods

The survey instrument (see Appendix B) consisted of 42 quantitative and qualitative questions, spanning six program areas based on common HTA components identified in the *Review of National and International HTA Programs*:

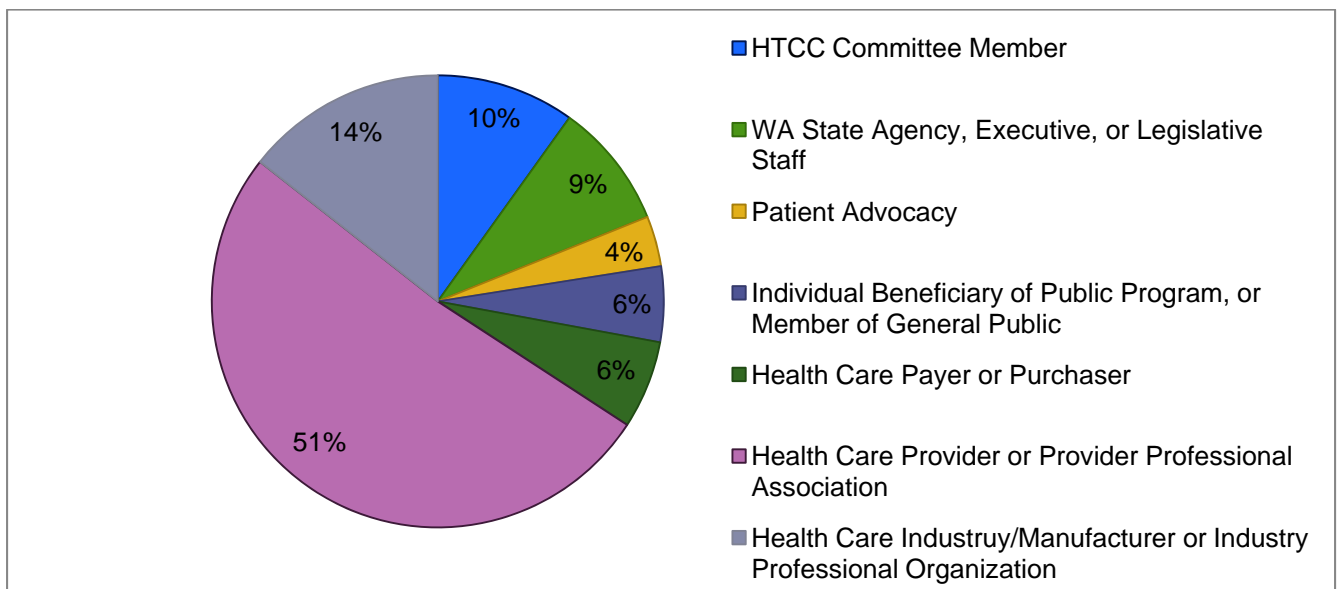
1. Program purpose and legislative mandate;
2. Topic nomination and selection;
3. Evidence reports;
4. Health Technology Clinical Committee (HTCC) and its coverage decisions;
5. Program transparency; and
6. Public engagement.

The survey instrument was developed by the Center with input from WA HTA Program staff. The survey allowed respondents to remain anonymous, and provided opportunity for open-ended

feedback. It utilized the online tool *SurveyMonkey*, and was open from August 30 to September 14, 2011. All stakeholders registered on the WA HTA listserv⁵ were invited to participate. Potential respondents were sent an email invitation and provided with a direct link to the survey. Each stakeholder received at least three notifications – one directly from the Program, and two from the Center. Invitations were extended to over 400 stakeholders, with 115 individuals participating in the survey.

While a diverse range of stakeholders were invited to participate in the survey, the majority of respondents self-identified as providers (51%). Figure 1 shows the proportion of respondents by stakeholder category.

Figure 1. Respondents by Stakeholder Category



Findings

A summary of quantitative findings from the survey, along with a brief description of qualitative comments, follows for each of the six program areas.

Program Purpose & Legislative Mandate

The majority of respondents indicated that they understood the legislative mandate (79%), and many thought the program is achieving its stated purpose (56%). Additionally, over half of respondents indicated that, compared to coverage decisions prior to the existence of the program, public agency coverage decisions are more transparent, independent and evidence-based (58%). This was echoed with comments indicating overall satisfaction with program components such as

⁵ The HTA listserv is promoted and maintained by the Health Care Authority and can be accessed on the WA HTA website. The listserv is open to any interested person or organization, by providing basic contact information. Interested parties can also sign-up for the listserv at public meetings, in reply to emailed comments and phone calls, or at Program presentations. All Program updates and meeting announcements are released via email distribution through the HTA listserv.

the HTCC and its processes, and the WA HTA prioritization criteria, website, listserv, and Program staff. However, the qualitative comments indicated that there were specific areas about which stakeholders were confused or concerned. These concerns were described using the terminology of ‘transparency’ and program processes (see Program Transparency below).

Topic Nomination & Selection

The majority of respondents had not nominated a topic to the WA HTA Program, but had provided comments on potential or selected topics. Similar numbers of respondents were satisfied (47%) and dissatisfied (41%) with the topic nomination process. This finding indicated the need for further investigation through key informant interviews and facilitated discussion. Further, approximately half of respondents expressed satisfaction with the Program’s topic prioritization process and its selection criteria. Approximately 30% did not have an opinion about these program components, and approximately 20% indicated dissatisfaction.

Evidence Reports

Respondents also provided divergent opinions about the methods and quality of evidence reports. Almost half were satisfied with the quality of the reports (51%) and the methods used to develop them (48%). A similar number of participants reported dissatisfaction with report quality (41%) and methods (42%). Open-ended comments indicated potential concerns with bias, vendor expertise, and appropriate scope of evidence for inclusion in reports. Participant comments further illustrated a lack of common understanding about “evidence” in the context of the Program, a desire for more consistent approaches to evidence reviews, and indicated that report quality may have improved over time. Comments also referenced the need for clinical context or expertise in relation to evidence reports. These findings indicated a need for further information gathering on the use and methods of evidence reports through the key informant interviews and facilitated discussions.

Health Technology Clinical Committee (HTCC) and its Coverage Decisions

The majority of respondents (67%) had not attended a meeting of the HTCC, but expressed understanding of the committee’s role (98%). Close to half of respondents (49%) were satisfied with the process and criteria used by the HTCC to make coverage decisions, and 41% were dissatisfied (11% did not have an opinion). Almost half (48%) were satisfied with the consistency of coverage decisions across state agencies, and 24% were dissatisfied (29% expressed no opinion). Stakeholder concerns were illustrated by comments in the areas of public meeting processes, public access, and communication with stakeholders about coverage decisions. These comments indicated limited stakeholder understanding about HTCC processes (including how members are selected), and warranted further information gathering through the key informant interviews and facilitated discussions.

Program Transparency

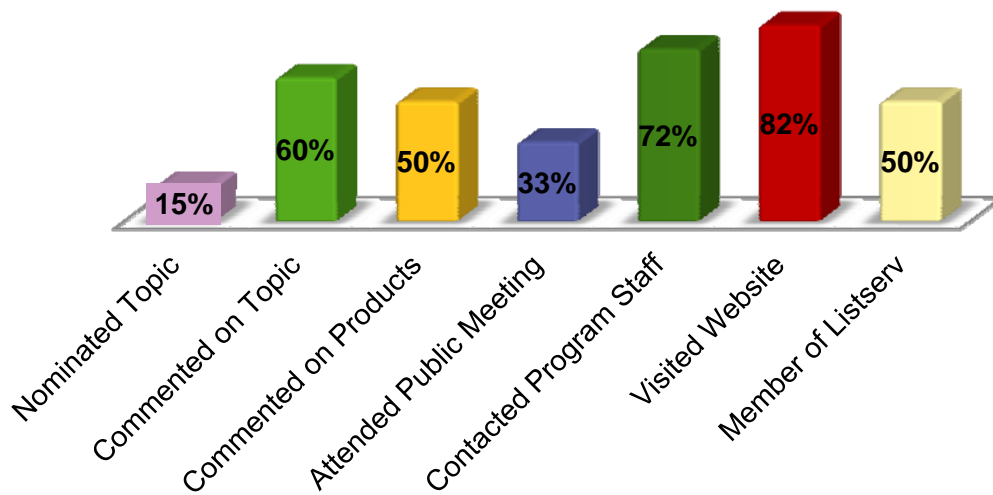
Over half of respondents (57%) expressed satisfaction with program transparency. However, some qualitative comments indicated concerns with transparency. This program area was the only section of the survey with which the majority of respondents expressed dissatisfaction, namely a lack of opportunity to provide public input on program processes, including concern about

disposition of public input (59%). This dissatisfaction generated comments concerning length of public comment periods and opportunities for testimony at HTCC meetings. This finding indicated need for further information gathering through the key informant interviews and facilitated discussions.

Public Engagement

There are multiple opportunities for stakeholders to engage with the WA HTA Program: nominating a topic, commenting on a topic or product, attending a public meeting, contacting program staff, visiting the website, or receiving updates from the listserv. Respondents' experiences with these opportunities varied. Most respondents had visited the Program's website, while only 15% had nominated a topic. Figure 2 illustrates the percentage of respondents indicating they had engaged in each activity. Some respondent's comments called for additional outreach, focused on patients, patient advocates, providers, and professional provider groups as further methods for stakeholders to be engaged in the WA HTA Program.

Figure 2: Stakeholder Points of Engagement



Summary

The online survey provided a brief, yet broad review of stakeholder perceptions of six program components. Several key themes emerged across the qualitative and quantitative information gathered through the survey:

- The HTA mandate is well understood and accepted.
- The purpose of the HTA is supported, and there is support for an independent, coverage decision-making body.
- There is overall satisfaction with program staff, the listserv, and website.
- The HTCC makes clear, transparent, and fair decisions.

- The public input process is the largest area of concern.
- There is interest in more closely linking the HTCC with clinical expertise.
- Desire was expressed for a standardized approach to evidence reviews.
- Stakeholders are interested in more outreach by the Program, particularly to consumers.

Overall, stakeholders were satisfied with program processes and components; however, there were several areas that warranted further analysis to better understand concerns or comments of stakeholders. Survey areas with diverse respondent opinion or clear dissatisfaction, were further explored with key informant interviews.

Key Informant Interviews

The second phase of stakeholder data collection used semi-structured key informant telephone interviews with representatives from seven stakeholder categories (Table 2). The key informant interviews sought to gather additional information on Program components where there was divergent stakeholder opinion in the online survey. The interviews also explored the one clear area of dissatisfaction identified through the survey: public input on Program processes. The goal was to gather information to better understand the underlying reasons for the diversity in opinions or dissatisfaction. Findings from the survey indicated stakeholder satisfaction with the HTA mandate, use of an independent coverage decision-making body, the Program staff, website and listserv, and the clarity and fairness of HTCC decisions. These areas of satisfaction were not explored in the key informant interviews.

Table 2. Key Informant Participants by Stakeholder Category

Stakeholder Category	Number
Academic, Health Policy, Research	2
Health Industry, Manufacturers, Industry Professional Association	3
Health Payer, Purchaser	2
Health Care Provider, Provider Professional Association	2
HTCC Member	3
Patient/Public Advocacy, General Public	3
Washington State Agency, Executive or Legislative Staff	3
TOTAL	19

Methods

Data analysis of the overall Project was designed to be iterative in nature. Each phase of data collection was designed to go in more depth than the previous step in understanding areas of stakeholder concern or dissatisfaction, and to build on the previous step(s) findings. Areas of clear support or satisfaction were not explored further. Initial analysis of survey findings (see above) informed the development of the key informant interview guide (Appendix C). Key informant interviews only explored areas with diverse stakeholder opinion (e.g., topic nomination, evidence methods), strong dissatisfaction (e.g., disposition of public comments), and areas where there may

be misunderstanding of Program processes or mandate limitations (e.g., role of clinical experts, HTCC processes, public access).

WA HTA Program staff identified potential participants, across seven stakeholder categories, based on their depth and breadth of experience with the Program. An initial list of 30 potential respondents and 11 alternates (total of 41 potential respondents) were identified. Due to scheduling and response rate, a total of 19 interviews were completed, between October 3 and October 26, 2011. Interviews were approximately 30 to 40 minutes, and were audio-recorded with verbal consent from participants. Participants were informed that no information would be personally identified, but information may be identified as representative of stakeholder categories. Interview participants were asked seven questions across four topic areas. These questions were based on questions from the online survey that had responses with either divergent stakeholder opinion or dissatisfaction. Respondents in the interviews were also given opportunity to provide open-ended comment. Interview topic areas included:

1. Program transparency, particularly in relation to topic nomination, topic selection and selection of members/vendors;
2. Evidence reports, including methods, quality, qualifications of vendors, and use of clinical experts;
3. Health Technology Clinical Committee processes, including public comment; and
4. Public access.

Findings

Over the course of the interviews, a distinction between the views of “internal stakeholders” and “external stakeholders” became clear.⁶ “Internal” stakeholders included HTCC members and Washington State agency, executive, or legislative staff. “External” stakeholders included all other stakeholder categories (e.g., industry, providers, patients). This distinction between groups was not made at the outset of the interviews, and did not persist across all topics. However, the delineation between the opinions of these two stakeholder types was clear in multiple findings, as indicated below. A summary of the qualitative data from the stakeholder interviews was categorized according to HTA program components and is provided below.

“I actually don’t hear much about this [the WA HTA Program]. I wouldn’t even know that they had a website. It may be perfectly transparent on the website information but how would I connect with that?” (Provider)

⁶ WA HTA Program staff does not make this distinction when referring to Program stakeholders. However, when analyzing the data from interviews, it became clear that this is a real distinction in terms of Program knowledge, experience, and perceptions and proved a valuable coding system when analyzing the qualitative data from the interviews.

Program Transparency

Transparency refers to efforts to provide the public with information about how key aspects of a program are carried out. The key informant interviews explored the concerns voiced by stakeholders regarding transparency in the online survey. The interviews revealed that stakeholder concerns were less related to transparency and more related to lack of communication and stakeholder engagement efforts. Respondents indicated that the Program was not well known by its various stakeholder communities or with the general Washington public. They further indicated interest in the Program conducting more general outreach to provider and patient organizations affected by Program decisions. These requests included greater efforts at publicizing processes to the public and provider communities.

“There seems to be enough lead time so if you aren’t prepared it’s your own fault. I’m not sure why anyone who has had to defend technology would think that this was any less transparent than any of the alternatives that’s out there. It’s way more transparent.”
(Industry)

State agency staff and HTCC members were clear about Program processes, believed them to be transparent, and thought they are working well as currently designed. These “internal stakeholders” voiced support of current Program processes while remaining open to the possibility that there is room for improvement. One respondent speculated that transparency concerns voiced by stakeholders are reflective of a larger, underlying issue of stakeholder ability to influence the decision-making process. This respondent suggested that

current WA HTA process and coverage determinations are more transparent and evidence-based than the previous process and that some stakeholders are not able to exert the same kind of influence that they had become accustomed to.

Topic Nomination & Selection

Although Program process explanations and information are publically available on the website, some “external stakeholders” continue to struggle with understanding the Program’s topic selection, topic refinement, and other processes. Based on interview responses, concerned individuals had attempted to utilize the website, or inquired of colleagues or other stakeholders about the WA HTA process, but were unable to find what they needed. This was primarily true of “external stakeholders” who were unclear or held perceptions about Program processes, such as topic selection, that differed from the legislative mandate. For example, there was a common perception voiced by external stakeholders that topics were selected by the Program based solely on cost concerns and not on safety or effectiveness. In contrast, the mandate calls for topics to be identified based on concerns with safety, efficacy and cost effectiveness. These criteria, as well as a detailed description of the selection process, are available on the WA HTA website.

“I’ve never been part of any process that was more transparent than this one. ... I know there is a desire by people who are affected by these decisions to control them, but I think the purpose of the process is to make decisions based on evidence, and the evidence isn’t always going to provide the answers that people want. People are phrasing their desire to control the process in different terms.” (HTCC Member)

Many key informants stated that the WA HTA Program is transparent in its topic nomination and selection processes and should be commended for its efforts and commitment in this area. One respondent stated that compared to other programs, the WA HTA Program is actually more transparent than many other state HTA processes. Other respondents indicated an understanding of topic selection, but would like modification to provide more open exchange of information between stakeholders and Program decision-makers.

Key Question Development

Throughout the key informant interviews there was comment regarding the importance of well-written, clinically informed key questions. “External stakeholders” believed the WA HTA key question development process to be a relatively closed process, leading them to suspect that bias might be introduced through the phrasing of key questions. Respondents expressed interest in making this process more transparent, particularly in the

“Having high quality key questions is the first step whenever you are doing an evidence review. If the key questions are flawed or blurred you have a problem. In repeated instances I found that the key questions were not phrased adequately, or were politicized.”(Provider)

methods for receiving and responding to public comments. In addition, “external stakeholders” voiced concerns about how public comments are considered, or if they are considered at all, in the revision of key questions. “Internal stakeholders” cited past topics where the areas addressed by the key questions did not align with the evidence in the assessment report, causing frustration on the part of committee members, agency directors, and the public. All stakeholders agreed that the framing of the key questions determines the usefulness of the end product.

HTCC Member Selection & Evidence Vendor Selection

The issue of transparency arose in relation to the selection of HTCC members and evidence vendors. “External stakeholders” expressed interest in published information on how potential committee members are identified, nominated and selected, and rationale for candidate selection processes. Stakeholders also suggested publically providing committee members stated conflicts of interest. Similarly, more information was requested on how evidence vendors are identified, selected, and the criteria for their selection. One respondent suggested that the Program expects the public to trust external vendors conducting the evidence-reviews, without providing publically available information on vendors’ expertise, credentials, or conflicts, and with that the Program is expecting “a leap of faith.” Of particular concern is the disclosure of economic interests.

“There are two currencies, one is financial the other is academic. Credentials must be transparent including a statement of economic interest. This would be the most likely source of bias or lack of neutrality...if it has to do with my salary.”(Provider)

Evidence Reports

Quality & Methods

Both “internal” and “external stakeholders” commented on the variability in the quality of WA HTA reports over the history of the Program. Most noted that quality appeared to be improving over time and

concerns were more focused on reports early in the Program’s history. Some respondents tied the variability and quality issue to lack of standardized methods across vendors. Others suggested lack of expertise or bias on the part of the vendors toward perceived outcomes preferred by Program staff. “Internal stakeholders” suggested that problems were related to scoping of reviews and development of key questions. They highlighted the issue of the quality of the answers in the evidence reviews being dictated by the quality of the underlying evidence base. This further illuminated the lack of agreement on what constitutes ‘good enough’ evidence. For example, “external stakeholders” raised the issue that evidence for devices and other technologies will never be as good as that of pharmaceuticals. These same stakeholders argue that the Program needs to consider less robust forms of evidence, such as case series and expert clinical opinion. “Internal stakeholders”, however, want the Program to look at the best possible evidence available and to use standard, transparent evidence grading.

“If clinical experts bring evidence I think they should be used more. If clinical experts bring anecdotal information I don’t think it adds to the conversation at all.” (Industry representative)

Expertise of Vendors

The issue of expertise of the vendors was commonly discussed. Underlying the issue of “expertise” seems to be conflict of interest and whether evidence vendors are biased toward certain outcomes. This was an area of disagreement among “internal” and “external” stakeholders. “External stakeholders” voiced concern regarding the expertise of the

vendors selected to conduct the reviews. Some questioned the credentials of evidence vendors and suggested that the Program relies on the reputation of the organizations within which vendors are employed. There was a desire for more transparency regarding vendor credentials as well as disclosure of conflicts of interest. “Internal stakeholders” felt confident with the level of expertise of evidence vendors. They noted that the particular expertise required of the evidence vendor is not necessarily as sub-specialist medical providers but rather as experts in systematic evidence review, grading, and synthesis. Several respondents commented on the need for impartiality, including the need for evidence expertise separate from clinical expertise, and disclosure of the conflict of interest from those who have a stake in a product or technology raising the need for additional expertise.

“Who are these people and how do we know they are evidence experts? At a public meeting the vendor appears and announces themselves expert and presents evidence. But where is the oversight scrutiny of the work that has been conducted? How do we know they are of the same objective stripe that OHSU as an academic institution is? Stated simply, we don’t know who these people are, they comport to be experts but where would I go as an interested stakeholder to find out who they are? Is it posted on the website? Is there something that tells me who they are?” (Provider)

Clinical Experts

Although there were no questions included in the online survey regarding the use and role of clinical experts, the subject arose frequently in open-ended survey responses and was therefore explored in the interviews. Respondents from all stakeholder categories believed that the Program

has under-utilized clinical experts. Both “internal” and “external” stakeholders agreed that clinical experts are important to the process and quality of reports; however, they disagreed about

“A lot of the comments from stakeholders are based on industry funded studies and they are not high quality studies.” (HTCC Member)

appropriate limits on the use of clinical experts.

“External stakeholders” suggested more liberal and frequent utilization of clinical expertise in all phases of the Program, while “internal stakeholders” suggested clinical experts be utilized in a consultative role.

“Internal stakeholders” did not agree with the assertion made by “external stakeholders” that one must be an expert in the clinical area of practice in order to accurately assess the evidence. In addition, respondents from both groups agreed that while clinical expertise was helpful in order to accurately assess the evidence, it also may be a source of bias if not carefully managed.

Most stakeholders agreed with the need to manage conflict of interest on the part of clinical experts. “Internal stakeholders” cite the mandate as limiting participation of individuals with significant financial conflicts. One committee member stated that in the past, when “external stakeholders” suggested experts for Program participation, those individuals were not eligible due to consulting agreements they had with device manufacturers.

HTCC Processes

Overall, comments about the Health Technology Clinical Committee (HTCC) were positive. Even those stakeholders who were critical of committee processes were quick to point out their respect for the committee members and the work they are doing. However, there were a few HTCC processes that received frequent comment.

Public Comment

“External stakeholders” stated that the length of time allotted for public testimony at the HTCC meetings is inadequate to make meaningful comment on an evidence report that may be several hundred pages in length. The process is perceived as ‘unfair’ to “external” stakeholders in that they are allotted a limited time (3 to 5 minutes) to testify while agency directors and external evidence vendors are allotted 20 to 30 minutes, respectively. The order of public testimony was also raised as a concern. Industry and provider groups would like the opportunity to present testimony after agency directors in order to comment and respond to issues brought to the

“They finally hear the full public comment on the same day they are forced to make the decisions on the therapy. That seems like a terrible circumstance. If someone’s public comment is really swaying your thinking it seems like there should be a period of deliberation where there is more discussion.”
(Patient Advocate)

committee in agency presentations. These respondents also noted that when experts provide public testimony at HTCC meetings they are not allowed dialogue with the committee regarding new evidence they submit at that time or other points addressed in their testimony. “Internal stakeholders” value public testimony and believe it to be an important part of the process. However, they also point out that committee members in their decision-making must give the greatest weight to the evidence that is most valid and reliable. “External stakeholders” expressed

frustration about public comment timelines. Some comment periods seem too brief while other comment periods seem too long.

Disposition of public comment

A common complaint among “external stakeholders” was the lack of Program response to written comments submitted during the multiple opportunities for public input. Stakeholders expressed frustration that thoughtful comment based on sound evidence and clinical context, either from the perspective of patient or clinician, have been met with silence or possibly even disregarded. Some stakeholders questioned whether their written feedback was seen or addressed by the HTCC. One patient/advocate cited a topic where time and care was invested to provide written comments, but when attending the HTCC public meeting were asked to present the same information again, as though the committee members were not aware of the previous written submission. The exception to this perception by stakeholders is when comments on the draft evidence reviews are forwarded to the evidence vendor, summarized and addressed in the final report. However, it was noted that even some comments handled by evidence vendors might not address the stakeholder input provided.

Public Access

Patient/advocate and provider stakeholders were unique in sharing concerns about public access to HTCC meetings. Industry representatives and internal stakeholders did not share this concern. Providers noted that meetings are held during normal patient contact hours. This is a barrier to those with a busy practice and for whom attending a meeting would require cancelling a clinic day. Location of meetings was of concern for patient/advocate respondents. Patient/advocate respondents felt that while the Seattle/Tacoma airport may be easily accessible to people with private transportation options, the same may not be true for individuals who have disabilities or who are dependent on public transportation.

“I found it very disappointing that credible, reasonable responses...based on methodological concerns were simply ignored and not at all heeded in either process changes or specific topic based approaches. I received no feedback and saw no resonance whatsoever.” (Provider)

Summary

Findings from the key informant interviews were consistent with findings from the online survey. Overall, stakeholders understand and support the mandate of the WA HTA, and think that the

“The meeting is at the airport, you have to pay for parking, and location is not ideal. Having another forum in another part of the state or at different times or in the Seattle area would be helpful. Something a bit more local.” (Patient Advocate)

Program is fundamentally on sound footing. Survey findings indicated stakeholder concern regarding Program transparency. However, on closer examination through the key informant interviews, concerns were more focused on the lack of program process information and the need for better and clearer Program communication and outreach.

Generally, respondents internal to the Program had differing perspectives than those external to the Program. “Internal stakeholders” had more clarity and insight regarding the Program’s purpose, goals, and processes. Responses from “external stakeholders” revealed confusion regarding the actual processes of the Program versus perceptions of these processes from the ‘outside looking in.’ This latter finding indicates a need for clear communication about the WA HTA and its processes.

The key informant interviews helped to clarify points of the WA HTA process where there may be a need for clearer communication. These included:

- Topic refinement;
- Timelines for public comment;
- Disposition of public comment;
- Quality of evidence reviews, including;
- Role and utilization of clinical experts; and
- Access to public meetings.

Per the methods of this Project, these areas were further explored with two focused and facilitated discussions using a representative sample of stakeholders.

Facilitated Discussions

The final phase of stakeholder information gathering involved small, focused discussions with a representative group of stakeholders (Table 3). The facilitated discussions sought to review initial themes from the online survey and key informant interviews, and to substantiate, alter, or add to findings. The objectives of the facilitated stakeholder discussions provided stakeholders:

- An overview of health technology assessment (HTA) programs;
- An overview of the Washington HTA Program;
- An overview of the Assessment of Stakeholder Experience and findings to date; and
- An opportunity to discuss, and gather feedback on WA HTA Program strengths, and potential areas to improve processes.

Methods

Two, six hour, in-person facilitated discussions were held with a representative group of stakeholders. Participants were randomly selected from the full list of stakeholders (excluding those who participated in key informant interviews) registered to receive information from the Program, using electronically generated random number assignment. Minor adjustments were made to ensure balanced representation across diverse stakeholder categories. Discussions were held in Olympia on December 7, 2011 and Seattle on December 8, 2011. Group size was limited to 25 participants to facilitate rich stakeholder discussion. Agendas and discussion format were identical for both days, and included an introduction to the Program by the Director of the WA HTA, a presentation of findings of the *Review of National and International Programs*, a presentation of

the Assessment of Stakeholder Experience findings to date, and participant discussions. Participants were asked to identify potential areas of concern with Program processes and to suggest possible solutions that may increase stakeholder satisfaction while maintaining alignment with the Program mandate. As in the key informant interviews, areas of satisfaction with the WA HTA Program were noted, but stakeholder concerns were the focus of the meetings. Discussions were facilitated, using a professional facilitator, and allowed for direct interaction with Program staff and knowledge exchange among all participants.

A total of 17 stakeholders participated. While effort was made to create balanced representation in the groups, participants were allowed to self-select the location of the discussion in which they participated. Given that one of the discussions took place in the state capitol, this session was over-represented by state agency stakeholders. While this may have been a limitation to discussion design, data were aggregated between the two groups for the purposes of analysis. In addition, findings were consistent across the two groups, as well as with previous data collection activities (online survey and key informant discussions).

Table 3. Facilitated Discussion Group Participants by Stakeholder Category

Stakeholder Category	Number
Academic, Health Policy, Research	0
Health Industry, Manufacturers, Industry Professional Association	4
Health Payer, Purchaser	1
Health Care Provider, Provider Professional Association	3
HTCC Member	2
Patient/Public Advocacy, General Public	2
Washington State Agency, Executive or Legislative Staff	5
TOTAL	17

Findings

In addition to being similar to each other, findings from the two discussion groups were similar to findings from the online survey and key informant interviews. Participants raised many of the same concerns in this process as in the other data collection formats. This served to validate the findings of the previous data collection phases as no significant new themes were raised in either of the discussion groups. Information from participants in the facilitated discussions fell into two overall categories: program processes (including transparency), and evidence. Key discussion points are summarized below.

Program Processes

Overall, stakeholders expressed support of the Program and its processes. They indicated that WA HTA seems interested in stakeholder perspectives and is attempting to be transparent. Discussion participants thought that WA HTA processes are defined and transparent, and the Program is not trying to “hide information”. However, participants were in agreement that information, including how processes are structured, may need to be more clearly communicated and user friendly.

Several stakeholders also acknowledged that the Program is small (three FTEs) and has limited resources. Changes to the Program, such as more robust stakeholder outreach, will need to be realistic and balanced with available resources. Concerns expressed by participants in the facilitated discussions about program processes included:

Timelines

Identical to survey and interview findings, there was a call for increased public comment periods for draft reports. There was also a call for the publication of timelines for the production of each report, so that stakeholders could anticipate when comment periods would occur. Many stakeholders emphasized the need to extend the comment period for draft reports due to the large volume of information presented in these reports. Compared to some national and international HTA programs, the WA HTA has a shorter timeline for comment on reports. This window of comment was viewed as more important than the timeline for comment on topic selection (which is mandated to be 30 days). As a result, the potential need to adjust overall timelines to accommodate any change was also discussed. See also Topic Selection and Refinement sections below.

Public Input

Similar to findings in earlier stakeholder data collection activities of the Project, participants in the facilitated discussions voiced concerns regarding public comment processes. Primary points of discussion were the length and order of public testimony allotted in the HTCC meetings. Stakeholders were interested in having additional time to testify. They acknowledged that the Program uses techniques similar to other public bodies, such as the Washington State Legislature, regarding public testimony (where length of time available for testimony is divided among the number of individuals wishing to testify). They also discussed modifications that would balance how much time is allotted to speakers at the public meetings. Some stakeholders suggested that individuals interested in providing feedback should provide written information prior to the meeting. Others suggested that testimony be focused on evidence, as that is what committee members are required to use in the decision-making process. Industry and some provider stakeholders would like to engage Committee members in dialogue during the public HTCC meeting.

Stakeholders also discussed the order of public testimony. There was not agreement on this issue across the two discussion groups. Some suggested that public input should be last so that commenters could respond to information presented by agency directors or evidence vendors. Others suggested public comment should be first so that HTCC members could keep input in mind while listening to agency rationale and evidence. Many did agree, however, that they would support public comment following agency director presentations.

Stakeholders also discussed comments on draft reports and key questions, and making their disposition public. Stakeholders expressed frustration that submitted written comments are not acknowledged or responded to. Stakeholders requested that written comments be posted in their entirety on the website rather than be summarized by the evidence vendors. Individuals providing comment would also like direct feedback from the Program as to disposition of their comments.

Communication

A recurring theme in the facilitated discussions, and the Project overall, was the need to improve general outreach and communication with stakeholders. The Program currently publishes most of the information that stakeholders are interested in, but some stakeholders struggle to find it. Some national and international HTA programs have products focused specifically at communicating with stakeholders. Suggestions for improving communication in the facilitated discussions included making the website more user friendly, especially for non-technical stakeholders.

Stakeholders agreed on the need for proactive efforts to reach out to individuals and groups affected by HTCC decisions (beyond those on the listserv or who typically attend HTCC meetings) in order to inform them of the Program and decisions that may affect them. Suggestions included conducting outreach with patient and provider groups, and ensuring those organizations are included in stakeholder lists. Stakeholders discussed that this outreach work might be especially important with non-profit patient organizations that may have limited resources to search for evidence or HTA information on their own. Other suggestions included:

- Better information about program purpose, emphasizing that safety and effectiveness are primary goals and all taxpayers share in the efficient and effective use of resources;
- Increase information about processes used to select HTA topics;
- Expand time and location of public meetings around the state;
- Make products more ‘user friendly’ by including plain language summaries that would be accessible to wider audiences;
- Provide information on the impact of decisions and implementation; and
- Publish descriptions of the processes and criteria for committee member selection, vendor selection and credentials and conflicts of each.

Evidence

One of the core components of HTA programs nationally and internationally is the use of evidence synthesis. Stakeholders discussed the need for a consistent and explicit definition of “evidence” and expressed confusion about under which circumstances which types of evidence would be “good enough.” Some suggested the need for clear standards for evidence grading and review, including assurance that vendors are consistently applying them. Others discussed the need for additional context for the evidence reviews (e.g., numbers of patients potentially impacted, private payer coverage). A standardized and rigorous approach to including cost information in the reports was also called for. Overall, stakeholders acknowledged and supported the HTCC’s use of evidence to make decisions.

Topic Selection & Topic Refinement

Across the facilitated discussions, there were two areas where stakeholders called for Program enhancement: topic selection and refinement, and use of clinical experts. Stakeholder questions centered on how topics are nominated, prioritized, and selected. Of particular concern was the weighting of selection criteria and the perception that cost was the most important consideration in

selection. The WA HTA has required criteria for identifying and selecting topics. Program staff clarified that agency medical directors nominate and prioritize topics according to established criteria and the Health Care Authority Director makes the final decision about which topics will move forward for review in the WA HTA process. While increasing cost or utilization may trigger a topic for review, the driving prioritization criteria are concerns related to effectiveness and safety. Stakeholders called for more public engagement in topic selection and topic refinement processes, suggesting that this may alleviate the need to extend comment periods for draft key questions and draft evidence reports. There was also discussion about the need for robust cost-effectiveness data including comparative analyses of alternative treatments when a non-coverage decision is made. It was noted that vendors look for cost effectiveness data but information on cost effectiveness in the literature is rare.

Use of Clinical Experts

“Internal” and “external” stakeholders initially disagreed on the role and use of clinical experts. There was also not clear differentiation between clinical decisions and policy decisions. The HTCC is charged with making binding coverage (policy) decisions, and the WA HTA clearly addresses the role of clinical experts and the importance of managing conflict of interest. However, stakeholders are concerned with how the Program has operationalized this to date. Currently, evidence vendors make recommendations for clinical experts. It can be difficult to find interested participants since they are minimally reimbursed. The need to balance expertise with conflict of interest was acknowledged. Ultimately, stakeholders agreed that the role of clinical experts should be to provide clinical context to the committee (vs. opinion regarding assessment of the evidence). Participants suggested that the Program take guidance from how clinical experts are used in other programs nationally and internationally. They also suggested that the process would be more efficient and valuable if experts were local and able to attend meetings in person.

Summary

Participants in the facilitated discussions validated the perspectives gathered from stakeholders in the online survey and key informant interviews. They also refined and provided more detailed information about these findings. Facilitated discussion participants expressed support of the Program and its processes. They recommended extending timelines for review of draft reports, providing access to public comment and their disposition, and increasing opportunity for the public to provide input to the HTCC. Stakeholders also suggested reaching out to affected organizations and individuals, and communicating program processes and products with “user friendly” documents and descriptions. Stakeholders called for increased involvement by the public in topic selection and refinement, and by clinical experts to provide context for evidence reports.

In addition, participants in the facilitated discussions were asked to provide comments that would help evaluate the Stakeholder Engagement Project. They were asked to provide a ‘plus’ (positive) and a ‘wish’. Comments reflected satisfaction, appreciation and support for the Project, and a desire that the Program build on its efforts to engage stakeholders (See Appendix D for complete comments).

Strengths and Limitations of the Assessment of Stakeholder Experience

The Assessment of Stakeholder Experience was not a formal program evaluation of the WA HTA, nor did it undertake an outcome evaluation of the Program. The Project was limited in its focus on understanding stakeholder perception about whether the WA HTA was meeting its mandate and had effective processes in place. The findings of the Project are based on a qualitative evaluation of the WA HTA Program by its registered stakeholders. Strengths include the iterative nature of the design where each subsequent data collection phase built on the findings from the prior phases, and the open and transparent conduct of the Project. The Project allowed for both broad and deep input by stakeholders. All of the processes for the stakeholder engagement activities involved self-selection by Program listserv members. These findings may or may not be generalizable to the actual stakeholder audience, which includes all of the citizens of the State of Washington. In addition, self-selection may skew data in a particular direction based on the characteristics and interests of those responding. The Project was conducted by the Center for Evidence-based Policy, which is also an evidence vendor for the WA HTA Program. Steps were taken to address conflicts of interest, including: an independent team of staff with stakeholder engagement expertise, who do not work on evidence reports, conducted the data collection from stakeholders and Project management; a separate evidence team conducted the review of national and international HTA programs; and data collected from stakeholders were kept separate from the evidence team (Center staff assigned to complete evidence reports for the WA HTA were not allowed access to the stakeholder data of this Project and vice versa).

Chapter 3. Overall Project Findings and Recommendations

Since its inception in 2007, the WA HTA Program has established a solid foundation in the national and international world of evidence-based health care assessment. The components of the WA HTA compare favorably with all 14 core components of well-established national and international HTA programs. The Stakeholder Engagement Project found that the majority of stakeholders responding to request for feedback are satisfied the Program is successfully meeting its mandate and that current processes are fair and unbiased.

Stakeholder concerns and suggestions for improvements illustrate the tension present across evidence-based decision processes. Stakeholders were primarily concerned with three areas of public input:

- 1) timelines for review of draft reports;
- 2) opportunity for public input to the HTCC; and
- 3) access to public comment and their disposition.

The WA HTA current processes in these areas are consistent with national and international HTA programs – although some other programs allow a longer timeline for review of draft and final reports. Generally, these findings highlight the competing tensions experienced by HTA programs. Most HTA programs are required to meet their mandates and base decisions on best evidence. Many programs include stakeholders in their processes to increase relevance and utility of their work, and have established stakeholder involvement procedures to do so. The inclusion of stakeholders within the HTA process allows for public comment on evidence reports and program processes. Research has also documented that stakeholder engagement can enhance processes by bolstering the relevance of products (Innvaer, Vist, Tommald & Oxman, 2002), knowledge exchange between decision makers and stakeholders (Graham, 2006), application (Graham, 2006), real-world context (Whitlock et al., 2009; Keown et al., 2008), and opportunities for dissemination (Keown et al., 2008).

Despite these myriad benefits, engaging stakeholders can be a challenging endeavor. While many stakeholders provide useful insight, there is a perception that some use opportunities for input to try to influence the process and its outcome. As a result, stakeholder involvement needs to be balanced with evidence synthesis, specific timelines and decision mandates. Tension between these areas was evident from the various stakeholder voices in this Project. Developing a clear framework for stakeholder participation, including articulation of expectations and limitations of each area, as well as definition of stakeholder role in processes, has the potential to reduce tension, minimize misperception or misunderstanding, and improve overall program quality.

The WA HTA is at a natural point in its development to look at opportunities for continuous improvement. A review of national and international HTA programs, as well as feedback from stakeholders, have highlighted that the WA HTA is on sound footing, but needs to more clearly communicate its processes with stakeholders. Findings of the Stakeholder Engagement Project

need to be considered in conjunction with the WA HTA mandate, Program goals and Program commitments. Key findings include:

- The Washington HTA Program’s mandates and processes are consistent with many of the core components of other well-established national and international HTA programs.
- The purpose of the HTA is supported, its mandate is understood, and there is support for an independent, coverage decision-making body.
- The Program’s processes are transparent, but are not well understood, particularly by “external” stakeholders. The Program currently publishes most of the information that stakeholders are interested in, but the information is not always easy for stakeholders to find. Lack of understanding primarily involves:
 - a. Topic nomination and selection,
 - b. HTCC member and evidence vendor selection, and
 - c. Opportunities for public input or involvement.
- Stakeholder concerns and suggested improvements are focused on three areas of public input (see above).
- There is a need to provide context for the evidence reports, including clinical background and cost information.

Recommendations

Based on the findings detailed and summarized in this report, the Center for Evidence-based Policy recommends the WA HTA consider modifications in the WA HTA Program in the areas of stakeholder communication, program processes and evidence reports. These suggestions should be considered in light of their impact on the WA HTA mandate and current Program commitments.

Stakeholder Communication

- Improve usability of the WA HTA website, making information of importance to stakeholders clear and available within a limited number of clicks.
- Create simple, user-friendly diagrams and documents that summarize important information. Examples, based on stakeholder feedback, include:
 - Opportunities for involvement;
 - “How to” get involved;
 - Topics under review and timeline for review; and
 - Findings of evidence reports.
- Clearly communicate purpose and role for each opportunity of stakeholder involvement.
- Reach out to affected individuals and organizations, particularly patients, patient groups and providers.

Program Processes

- Publish a timeline for the estimated completion of each report.
- Review timelines for public comment of draft reports. The need for extending comment periods may be alleviated by additional public engagement in topic selection and topic refinement processes, and publication of timelines.
- Publish information regarding the disposition of public comments.

Evidence Reports

- Include contextual information by:
 - Providing clinical background for the topic; and
 - Providing cost data, when available, for a topic.

These recommendations were generated from a synthesis of findings from the two components of this Project: 1) a review of HTA programs nationally and internationally; and 2) an assessment of the experience and perspectives of multiple stakeholder groups. The WA HTA was found to be a sound example of HTA programs nationally and internationally, and is consistent with to the 14 core components of these programs. Stakeholders providing feedback through this project expressed support of the Program, its processes, and its efforts to make transparent evidence-based health purchasing decisions. The Program's mandate has provided a strong foundation that is well understood by stakeholders. Future continuous improvement efforts could maintain and build on this foundation by clearly communicating and further developing opportunities for public input.

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Appendix A: Overview of Stakeholder Engagement in Health Care Research

Background

Engaging stakeholders in public policy processes has become increasingly recognized as a critical component of health services research and health care reform. The Cochrane Collaboration noted that stakeholder involvement is critical 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” (Hailey, 2005). The World Health Organization (WHO) also recommends stakeholder inclusion in their work (Legare et al., 2009; Fretheim et al., 2006; Schunemann et al., 2006) and the National Institute for Health and Clinical Excellence (NICE) mandates active stakeholder membership in all guideline development (Harding et al., 2010; NICE, 2004). Nationally, the Institute of Medicine’s report on initial priorities for comparative effectiveness research (2009) states that the program “should fully involve consumers, patients and their caregivers in key aspects of CER, including strategic planning, priority settings, research proposal development, peer review, and dissemination.” Although stakeholder engagement has been identified as a valuable and important aspect of research, there is not yet clear consensus among experts regarding best practices, standard definitions, effective methods, and approaches to engagement.

Exploring stakeholder involvement in health technology assessment (HTA) agencies is increasingly a priority (Gauvin et al., 2010). In 2006, 57-percent of 37 HTAs, internationally, involved stakeholders in “some aspects of their programs” and 83-percent intended to do so (Hailey & Nordwall, 2006). Although the body of literature on engagement of stakeholders in research is growing (Staley, 2009; Avalere Health, 2008; National Working Group on Evidence-based Health Care, 2008a & 2008b), few studies employ rigorous methodologies to evaluate the impact of their involvement (Boote et al., 2010; Nilsen et al., 2010; Mitton et al., 2009). Additionally, due to the nature of HTAs as both research and policymaking organizations, stakeholder involvement must serve dual roles to address scientific standards and policymaking needs (Gauvin et al., 2010).

Stakeholder Engagement

Strategic stakeholder engagement can enhance processes by bolstering the relevance of products (Innvaer, Vist, Tommald & Oxman, 2002), knowledge exchange between investigators and stakeholders (Graham, 2006), application (Graham, 2006), real-world context (Whitlock et al., 2009; Keown et al., 2008), and opportunities for dissemination (Keown et al., 2008). Despite the myriad benefits, engaging stakeholders can be a challenging endeavor. Developing a clear framework for thinking about stakeholder participation is at the core of designing effective participatory processes (Macfarlane, 1996).

In health care, the desire to engage stakeholders may be related to quality improvement, provision of care, broader aims of transparency, or policy decisions. Regardless of the intent, it is essential that those leading the process clearly communicate the goals of engagement and adequately structure processes to achieve those goals. Developing a clear framework of the research or

decision processes, and opportunities for involvement will assist with the strategic engagement of stakeholders.

Involvement Methods

There is no one size fits all method for engaging stakeholders, however, effective engagement incorporates considerations such as stakeholder interests, familiarity with the program, resources necessary to participate, topic complexity, understanding of the context and value of participation, and type of feedback desired (O’Haire et al., 2011; Curtis & Joplin, 2009). Potential goals of engaging stakeholders could include: 1) educating the public about the program and its value; 2) increasing transparency and legitimacy of program decision-making processes; 3) ensuring the responsiveness of the program to the needs and values of its stakeholders; 4) establishing or strengthening relationships with particular populations or representatives; 5) increasing the program’s understanding of its stakeholders’ needs and values to guide or design program changes, future direction, or other aspects (Gauvin & Abelson, 2006).

As Gauvin et al. (2010) note, stakeholder engagement is not appropriate for all aspects of research, and different stakeholders “may seek different levels of involvement at different moments and for different reasons.” Not all stakeholder interests will align to help achieve the objective of each point in the research process, nor will all points in the process be valuable to all stakeholders. For example, public stakeholders have demonstrated more interest in involvement in deliberative processes concerning policy, resource allocation, or programmatic decisions than individual level decisions (Litva et al., 2002). Additionally, meaningful participation is more likely to occur when stakeholders are engaged in processes for which the sponsoring organization has an ability to adopt or change a course of action (Chafe et al., 2009).

There are numerous strategies and methods for engaging stakeholders. For all methods, identifying desired outcomes and clearly communicating intent, while allowing flexibility to accommodate diverse stakeholder needs, will assist with ensuring an effective process (O’Haire et al., 2011). Methods for engaging stakeholders include, but are not limited to:

Citizens’ Jury: Participatory action research utilizing a representative stakeholder sample, or “jury,” that listens to presentations by and questions experts, or “witnesses,” about specific issues. The jury collaboratively develops and may present recommendations after deliberation. An advisory committee often helps facilitate the process and works to limit bias.

Benefits: Random selection helps ensure representativeness, while carefully balanced expert witness testimony provides a range of information about the specific topic – ensuring educated and informed stakeholder decision makers. The process is deliberative and allows all stakeholder participants’ input to be considered.

Challenges: The process requires considerable time investment from all participants, can be resource intensive, and hinges on the information provided to stakeholder participants being accurate, reliable, unbiased, and appropriate.

Focus Group: A qualitative research method utilizing facilitated group interview about stakeholder knowledge, perceptions, beliefs, or opinions regarding specific topics. Stakeholders interact with the facilitator as well as other stakeholder participants. There are several methods and formats for conducting focus groups however, effective facilitation is essential to successful implementation.

Benefits: Provides opportunity for direct stakeholder interactions and validation, and builds rapport with researchers and stakeholders. Allows for sampling of multiple stakeholders within a limited timeframe.

Challenges: Recruiting representative samples of stakeholders; addressing stakeholder constraints such as scheduling, time commitment, transportation, childcare, etc.; lack of anonymity when discussing sensitive or personal issues; and potential facilitator bias.

Workgroup/Committee: A small group of stakeholder participants, usually interdisciplinary, dedicated to collaborating on a specific topic or issue over an extended period of time. Workgroups and committees can be supported by skilled facilitators and other administrative staff.

Benefits: Provides ongoing opportunity for stakeholder discussion and deliberation supports relationship building between researchers and stakeholders, and provides an opportunity to engage “expert” stakeholders.

Challenges: The limited number of participants restricts the ability to recruit a truly representative sample of participants, selection bias, and skilled facilitation and attention to group dynamics and processes are essential to establishing success.

Survey/Questionnaire: A systematic tool for collecting information from stakeholders. Survey delivery methods include in-person, telephone, online, and mail.

Benefits: Standardized approach to data collection with ability to more easily extract quantitative data in addition to qualitative data. Allows stakeholders to participate at their convenience. Provides efficient opportunity to solicit information from large groups of diverse stakeholders at low cost.

Challenges: Identifying and recruiting participants and achieving necessary response rates, maintaining internal and external validity, and challenges with collecting second-order feedback.

Web Conference/Webinar: An online format for presentations and/or discussions that allows stakeholders to access and participate from geographically disperse locations.

Benefits: Accessible by any stakeholder with internet access, low cost, features such as polling and virtual whiteboards provide additional feedback methods, some technologies emulate face-to-face interactions, immediate feedback.

Challenges: Participation is limited to stakeholders with sufficient internet access, some web conferencing technologies can be difficult to use for both moderator and participant and may require additional time for preparation in the form of downloading plug-ins, or learning how to operate new systems. Additionally, facilitating conversations in this format is critical and requires different skills than traditional, in-person facilitation.

Conference Call: A telephone call in which multiple parties are able to access and participate from geographically disperse locations.

Benefits: Accessible by any stakeholder with a telephone, low cost, minimal time investment, immediate feedback, and some services provide recording and transcribing services.

Challenges: Participation is limited to stakeholders with telephone access, is inherently less personal than in-person interactions, does not allow for shared viewing of materials, possibility of background noise and other disruptions. Additionally, facilitating conversations in this format requires different skills than traditional, in-person facilitation.

Workshop/Conference: A single meeting bringing together stakeholders to present and discuss specific topics in an extended timeframe. Conferences may include panel presentations with moderated discussion, round table debates, and workshops for interactive knowledge exchange or facilitated learning opportunities.

Benefits: Convenes group of stakeholders for longer period of time with foci on specific issues; provides networking and relationship building opportunities for stakeholders and researchers; and allows multiple tracks or activities to occur simultaneously, while maintaining group dynamic and participation.

Challenges: Resource intensive and requires complex logistical coordination. Stakeholder participation is limited depending on requirements for participation (cost, schedule, location, etc.). Neglecting group processes can negatively impact outcomes and outputs. Maintaining stakeholder energy, momentum, and focus for extended period time requires innovative design and facilitation.

One-on-One Meeting: A meeting, either by phone or in person, between a researcher or facilitator and a single stakeholder.

Benefits: Provides ease of scheduling, privacy and confidentiality of stakeholder responses, and allows the opportunity to focus on stakeholder answers and ask follow-up questions for more in-depth feedback.

Challenges: Omits interaction with other stakeholders than can be validating, informative, or inspire additional thoughts and suggestions. Limits the number of stakeholders involved and decreases representativeness and diversity of perspectives.

Whatever method is chosen, researchers and policymakers must be ready and willing to respond to stakeholders' needs to ensure engagement is accessible and relevant (Hashagen, 2002). Advanced planning and preparation, clear roles and expectations, flexibility, and expert facilitation will help support this objective.

Considerations

In addition to the strategies outlined above, research suggests that successful stakeholder engagement will consider the following (Curtis & Joplin, 2009):

- The depth of public input and feedback that is desired and appropriate and how stakeholder input will be utilized and incorporated in the program.
- Engaging stakeholders can be a resource intensive activity. Ensuring the skills, resources, and capacity are available to dedicate to stakeholder engagement processes is critical.
- Stakeholders need to understand the context and value of their involvement, and what role their input will have in relation to specific decisions.
- Sponsoring organizations should consider the needs, perspectives, and challenges of their stakeholders.
- Aligning specific stakeholder interests and capacity with appropriate engagement opportunities is essential to providing positive stakeholder experiences.
- Keeping stakeholders informed of research progress beyond their own involvement additionally aids in the development of long-term relationships. Determine what mechanisms will be used to maintain accountability and communicate how stakeholder input was utilized.

In order for program products to be viewed as credible and applicable, processes must be rigorous and transparent. Neilson (2009) asserts that including a balance of stakeholder engagement helps support transparency. In addition, strategic and effective stakeholder engagement can result in more applicable products, greater uptake and implementation, and increased dissemination. Although more evidence is needed on the impact of specific methods of engagement, research suggests there are several key factors to successful engagement. Clearly articulating the goals of

stakeholder engagement, developing strategic plans for engagement, allowing flexibility in the process, and utilizing skilled facilitation are all essential to positive engagement outcomes.





The Washington Health Technology Assessment Program has been operational for four years and seeks to utilize stakeholder input to inform and improve program processes. Given these aspirations, the Center for Evidence-based Policy recommended a multifaceted approach to gathering feedback from stakeholders about the Program and its efforts to gather and apply input. The following process allowed for a broad and diverse range of feedback, while including opportunities for more focused discussion.

Appendix B: Washington State Health Technology Assessment Program Stakeholder Survey

Washington State Health Technology Assessment Program Stakeholder Survey

Survey Introduction and Purpose

The purpose of this survey is to inform the Washington Health Technology Assessment (WA HTA) Program's work. The program has been operational for four years and is conducting a program review with stakeholder feedback about their experiences with the program. The findings from this survey will inform the development of in-depth structured interviews and facilitated group discussions of key stakeholders. All findings will be summarized in a Program Review Report to be disseminated at the end of this process.

-  This survey will take approximately 20-30 minutes to complete.
-  This survey is anonymous. No personally identifiable information will be collected.

Demographics

Please take a minute to tell us about yourself.

1. In relation to the WA HTA Program, please indicate your primary role/organizational setting/affiliation.
 - a. HTCC Committee Member
 - b. WA State Agency, Executive, or Legislative Staff
 - c. Patient Advocacy
 - d. Individual Beneficiary of Public Program or Member of general public
 - e. Health Payer or Purchaser
 - f. Health Care Provider or Provider Professional Association
 - g. Health Industry/Manufacturer or Industry Professional Association

2. What Washington geographic region do you represent?
 - a. Northwest Washington
 - b. Southwest Washington
 - c. Central Washington
 - d. Eastern Washington
 - e. Statewide
 - f. Other (please specify)

Program Purpose and Legislative Mandate

The WA HTA Program was established in 2006 by legislative mandate. This legislation changed the process used to decide whether public agencies will pay for certain health tests and treatments. Prior to the HTA Program, agency medical staff and expert consultants made informed coverage decisions based on their training and research. Now, about 10 tests/treatments are assessed by the Program each year utilizing evidence-based reports prepared by external experts. The goal is to promote the purchase of excellent health care by investigating and paying for tests and treatments proven safe, effective, and cost effective. The earlier process is still in place for coverage decisions which are not selected for assessment by the Program. The Program achieves the mandate stated above by:

- Selecting medical tests or treatments where there are concerns about safety, effectiveness, and/or costs
- Contracting for impartial, evidence-based reports that review and rate the quality of clinical evidence about a selected medical service
- Selecting and staffing an independent committee of practicing health care providers (Health Technology Clinical Committee), that:
 - review the reports and comments
 - make a binding decision on whether, and under what condition evidence supports agency payment for the medical service
- Making coverage decisions transparent by publishing information, criteria, and rationale and holding public meetings.

This survey will ask questions about each of the above activities and the HTA Program overall. Please indicate how much you agree or disagree with the following statements:

3. The WA HTA Program mandate outlined above closely reflects my previous understanding.
 - a. Strongly agree
 - b. Somewhat agree
 - c. Neither agree nor disagree
 - d. Somewhat disagree
 - e. Strongly disagree

4. Compared to coverage decisions that were made prior to the existence of the WA HTA Program, public agency coverage decisions now are more transparent, rely on independent clinicians, and are evidence based.
 - a. Strongly agree
 - b. Somewhat agree
 - c. Neither agree nor disagree
 - d. Somewhat disagree
 - e. Strongly disagree

5. The WA HTA Program satisfactorily achieves its stated purpose.
 - a. Strongly agree
 - b. Somewhat agree
 - c. Neither agree nor disagree
 - d. Somewhat disagree
 - e. Strongly disagree

6. Please provide any additional comments related to Program purpose and mandate.

Topic Nomination and Selection

The WA HTA Program assists state agencies with coverage decisions where there are questions about the safety, efficacy, or cost of a medical test or treatment. By law, topics can be nominated by agencies or the public and are selected by the Administrator of the Health Care Authority. Potential and selected topics are posted online for public comment. The Program uses eight prioritization criteria in selecting topics for assessment. These include three primary criteria* (which are legislative mandates) and five secondary criteria:

- Potential patient harm/safety concerns*
- Concerns about therapeutic efficacy or diagnostic accuracy and appropriateness of outcomes for patients*
- Estimated total direct cost per year*
- Number of persons affected per year
- Severity of condition treated by technology
- Policy related urgency/diffusion concern
- Potential or observed variation
- Special populations/ethical concerns.

The following questions ask about your past participation with the WA HTA Program's topic nomination and selection processes. You will be asked to rate your satisfaction with these activities and for ideas on how to improve them.

Please rate your overall level of satisfaction with the WA HTA Program's efforts at transparency.

7. Have you participated in nominating a topic?
 - a) Yes
 - b) No

8. How satisfied are you with the topic nomination process?
 - a. Very satisfied
 - b. Somewhat satisfied
 - c. Neither satisfied or dissatisfied
 - d. Somewhat dissatisfied

- e. Very dissatisfied
9. Have you participated in providing comments on potential/selected topics?
- a. Yes
 - b. No
10. How satisfied are you with the nomination and selection public comment process?
- a. Very satisfied
 - b. Somewhat satisfied
 - c. Neither satisfied or dissatisfied
 - d. Somewhat dissatisfied
 - e. Very dissatisfied

Please indicate how much you agree or disagree with the following statements:

11. I am satisfied with the Program's prioritization criteria.
- a. Strongly agree
 - b. Somewhat agree
 - c. Neither agree nor disagree
 - d. Somewhat disagree
 - e. Strongly disagree
12. I am satisfied with the Program's topic prioritization process.
- a. Strongly agree
 - b. Somewhat agree
 - c. Neither agree nor disagree
 - d. Somewhat disagree
 - e. Strongly disagree
13. Do you have any comments or suggestions for the Program's topic nomination and topic selection processes? Please specify:

Evidence Reports

The WA HTA Program is a public program charged with making coverage determinations on selected health technologies which are based on science. The Program 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 evidence-based technology assessment. HTA evidence reports search and summarize the clinical evidence, coverage decisions and treatment guidelines in addition to other information provided by agencies and the public.

14. How satisfied are you with the methods used to develop the evidence reports?

- a. Very satisfied
- b. Somewhat satisfied
- c. Neither satisfied or dissatisfied
- d. Somewhat dissatisfied
- e. Very dissatisfied

15. How satisfied are you with the quality of the evidence reports?

- a. Very satisfied
- b. Somewhat satisfied
- c. Neither satisfied or dissatisfied
- d. Somewhat dissatisfied
- e. Very dissatisfied

16. Do you have comments or suggestions for improvement of evidence reports? Please specify:

Health Technology Clinical Committee (HTCC) and Coverage Decisions

The WA HTA Program selects and staffs the Health Technology Clinical Committee (HTCC). The HTCC is an independent committee of eleven practicing clinicians (at least six physicians and five other licensed health professionals). The committee meets in public, reviews evidence reports and other topic related information and makes coverage decisions for the Program.

17. I understand the role of the HTCC in the WA HTA Program.

- a. Yes
- b. No

18. Please explain your answer to question #17.

19. Have you attended a public meeting of the HTCC?

- a. Yes
- b. No

20. [If answer to Question #19 was "No"] Please tell us why you have not attended a public meeting of the HTCC.

- a. No interest in attending
- b. Meeting occurs at inconvenient time
- c. Unable to travel
- d. Other (please specify)

21. How satisfied are you with HTCC's public meeting process?

- a. Very satisfied
- b. Somewhat satisfied
- c. Neither satisfied or dissatisfied
- d. Somewhat dissatisfied
- e. Very dissatisfied

You are approximately half way done with the survey.

Please indicate how much you agree or disagree with the following statements:

22. I am satisfied with the HTCC's selection process and membership.

- a. Strongly agree
- b. Somewhat agree
- c. Neither agree nor disagree
- d. Somewhat disagree
- e. Strongly disagree

23. I am satisfied with the process and criteria used by the HTCC to make coverage decisions.

- a. Strongly agree
- b. Somewhat agree
- c. Neither agree nor disagree
- d. Somewhat disagree
- e. Strongly disagree

24. I am satisfied with the Program's consistency of coverage decisions across state agencies.

- a. Strongly agree
- b. Somewhat agree
- c. Neither agree nor disagree
- d. Somewhat disagree
- e. Strongly disagree

25. I am satisfied with the Program’s post-decision coordination and support of implementation processes.

- a. Strongly agree
- b. Somewhat agree
- c. Neither agree nor disagree
- d. Somewhat disagree
- e. Strongly disagree

26. Do you have comments or suggestions for improvement of the HTCC’s process or coverage decisions? Please specify:

Program Transparency

One goal of the WA HTA Program is to make “more transparent coverage decisions by publishing information, criteria, and rationale and holding public meetings”. The Program is required to maintain a website that provides:

- notice of selected topics
- indicates how individuals can submit evidence or comments to be considered in the review
- notice of decisions and the basis of the decision
- access to evidence reports
- notice of public meetings.

The following questions ask you to rate your satisfaction with the Program’s transparency. You will also be asked for ideas on how to improve these activities.

27. Have you visited the WA HTA Program website?

- a. Yes
- b. No

28. How satisfied are you with the WA HTA Program website?

- a. Very satisfied
- b. Somewhat satisfied
- c. Neither satisfied or dissatisfied
- d. Somewhat dissatisfied
- e. Very dissatisfied

29. Have you provided comment on a WA HTA product (e.g. evidence report, website, coverage decisions)?

- a. Yes
- b. No

30. How satisfied are you with the WA HTA public comment methods and process?

- a. Very satisfied
- b. Somewhat satisfied
- c. Neither satisfied or dissatisfied
- d. Somewhat dissatisfied
- e. Very dissatisfied

31. Overall, how satisfied are you with the transparency of the WA HTA Program?

- a. Very satisfied
- b. Somewhat satisfied
- c. Neither satisfied or dissatisfied
- d. Somewhat dissatisfied
- e. Very dissatisfied

32. Please provide any suggestions or comments about the WA HTA Program's transparency, website and/or comment process.

Please specify:

Public Engagement

In addition to requirements for transparency, the WA HTA Program strives to engage stakeholders by providing multiple opportunities and means of participation. The following questions ask you to rate your satisfaction with the Program's current public engagement activities. You will also be asked for ideas on how to enhance these activities.

33. Are you a member of the WA HTA Program listserv?

- a. Yes
- b. No

34. How satisfied are you with the content and timeliness of the information you receive from the Program listserv?

- a. Very satisfied
- b. Somewhat satisfied
- c. Neither satisfied or dissatisfied
- d. Somewhat dissatisfied
- e. Very dissatisfied

35. Have you contacted the WA HTA Program staff?

- a. Yes
- b. No

36. How satisfied are you with the responsiveness of the WA HTA Program staff to your inquiries.

- a. Very satisfied
- b. Somewhat satisfied
- c. Neither satisfied or dissatisfied
- d. Somewhat dissatisfied
- e. Very dissatisfied

37. Have you attended, or has your organization requested, a presentation by WA HTA Program?

- a. Yes
- b. No

38. How satisfied are you with the content of the presentation(s) by WA HTA Program?

- a. Very satisfied
- b. Somewhat satisfied
- c. Neither satisfied or dissatisfied
- d. Somewhat dissatisfied
- e. Very dissatisfied

39. Overall, how satisfied are you with the public engagement/stakeholder outreach activities of the WA HTA Program?

- a. Very satisfied
- b. Somewhat satisfied
- c. Neither satisfied or dissatisfied
- d. Somewhat dissatisfied
- e. Very dissatisfied

40. Do you have any comments or suggestions for improvement of the Program's public engagement activities? Please specify:

Additional Ideas

41. If you have additional comments, suggestions, and/or ideas about improving the WA HTA Program please describe them below. Please feel free to include references to other programs or decision models. Please specify:

Thank you for taking the time to fill out this survey. Your feedback is invaluable.
If you have any questions, or concerns please contact Samantha Slaughter-Mason at (503) 494-6063, or slaughsa@ohsu.edu

Appendix C: WA HTA Key Informant Interview Guide

Questions:

- 1) One of the findings of the online survey was that there was dissatisfaction voiced about the Program's transparency regarding topic nomination, topic selection and the disposition of public comments. Can you tell me about your experiences with these processes?
 - ✚ PROBE: Do you have any insights into why this might have been a finding?
 - ✚ PROBE: The statutory mandate for the Program says that it will achieve transparency on coverage decisions by holding public meetings and publishing information, criteria and rationale for those decisions. How would you recommend the Program meet this mandate?

- 2) Now I would like to hear your thoughts regarding the quality the evidence reports and the methods employed in the development of the evidence reports. One of our findings from the online survey was that there was wide variation in the satisfaction with the scientific methods used to produce evidence reports. Can you tell me what you think about the quality of the WA HTA reports?
 - ✚ PROBE: What are your thoughts regarding the methods used by vendors to create reports?
 - ✚ PROBE: Do you have specific ideas or recommendations to improve the quality of the evidence reports?
 - ✚ PROBE: How do you define 'evidence', what is good (enough) evidence?
 - ✚ PROBE: What does it take to produce good evidence?
 - ✚ PROBE: The Program mandate requires the State to contract for "impartial evidence-based reports that review and rate the quality of clinical evidence about a selected medical service." In your view, are improvements needed in the areas of methodology, process or both? Please explain.

- 3) Now I would like to hear what you think about the various parities who play important roles in HTA processes. In the online survey, there were many comments about evidence vendors. Some respondents asserted that vendors were biased or lacking in the appropriate expertise necessary to be providing information to the HTCC. What are your thoughts on this?
 - ✚ PROBE: In your mind, what is the role of the vendor? Is it the same or different than the HTA's role of making coverage decisions?

- 4) Now let's talk about the role of clinical experts, there were numerous comments in the survey about the need to include more input from clinical experts in the work and deliberations of the HTCC. What are your thoughts about this?
 - ✚ PROBE: How could clinical experts most effectively be engaged?

- ✚ PROBE: The HTA is mandated to be “evidence-based” How should the HTA meet its mandate and balance clinical expertise and evidence expertise?
- 5) In the last question, we explored Program roles. There were also comments in the online survey about “neutrality”, particularly in reference to evidence vendors. I now want to hear your thoughts about neutrality. The HTA is required to be neutral and to manage conflicts of interest. What would indicate to you that they have engaged neutral members, clinical experts and evidence vendors?
- ✚ PROBE: What are the characteristics of neutrality?
- 6) So, another area that drew many comments on the online survey was regarding the processes of the HTCC. Can you tell me what your thoughts are on this topic?
- ✚ PROBE: The HTCC meets quarterly in a public meeting. What suggestions do you have that might address concerns about the HTCC process?
 - ✚ PROBE: Do you think the processes of the HTCC are transparent? If not, how would you suggest they be improved?
- 7) I would like to shift our focus now to issues of public access. Some respondents to the online survey felt that there were barriers to full public access to the Program and particularly to public meetings. What does “public access” mean to you?
- ✚ PROBE: Do you think the WA HTA is committed to and successfully facilitating public access to the Program’s activities including public meetings?
 - ✚ PROBE: How could the Program improve public access? P
 - ✚ ROBE: Have you ever attended a public meeting?
 - ✚ PROBE: Have you ever nominated a topic?
 - ✚ PROBE: How might the Program better engage patients/consumers?
- 8) Thank you very much. Those are all the questions I had for you today. Do you have anything you would like to add?

Appendix D: Comments on Stakeholder Engagement Project from Facilitated Discussion Groups

Positives	Wishes
Processes like these can be intimidating to consumers but today was very comfortable and I learned a lot	Will be important to make the common person feel that they are heard as part of the process through continuing outreach efforts to expand that voice
Systematic and iterative design of the engagement process was brilliant	Would like to see an increase in efficiency on background and an increase in the give and take between stakeholders and Program
Appreciated the opportunity to provide feedback in an unrestricted voice	Would like to see processes developed or altered so everyone feels that it is fair
This was a great opportunity to hear a lot of interesting information about the Program and other HTA Programs	Hopeful that this project can assist in CQI (continuous quality improvement) processes for the Program now and in the future
Appreciated hearing a diversity of views today	Would like to see the HTA 'build the bridge between evidence and policy' as sturdy and useful as possible
Appreciated all of the different perspectives present in the group today	Hoping that the Program finds some of the suggestions from this project to be implementable in order to help improve Program processes
Appreciated the diversity of perspectives and the discussion for solutions or Program improvements	Know more about the HTA programs internationally and improve our program
Appreciated the opportunity to talk about concerns and to express frustrations about the Program directly to staff.	Would like to see even more stakeholders present in this sort of discussion group
Important to highlight that Washington State is a leader in this area. Solid model for the rest of the country.	That Program always keep in mind the lives affected by Program decisions
Have a new realization of the value of the Program	Program keeps in the foreground the tenet that transparency is essential to credibility
Meeting did a good job of addressing stakeholder concern about the Program 'rationing' care	Continue education efforts and outreach to the public
Found it helpful to discuss issues around evidence and the use of evidence in Program	Would like to see how decisions are applied/more about implementation

Appreciate this discussion process today	Increase understanding that evidence is a better way to assess technology
Presentations today have led to a better understanding of program	Hopeful that I will have more time for involvement with the Program in the future
WA took leadership to start HTA	Would like to see the Program continue in evidence-based practices and to move toward including providers through focused education and outreach efforts
Today's meeting is an example of the Program's commitment to transparent processes	Hope that this will assist everyone to "see through the haze" that surrounds questions of how best to deliver safe and effective healthcare
