

WASHINGTON

Health Technology Assessment

Process Evaluation

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August 2015



ACKNOWLEDGMENTS

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Suggested citation:

Pinson, N., Gordon, C., & Curtis, P. (2015). *Washington HTA Process Evaluation*. Portland, OR: Center for Evidence-based Policy, Oregon Health & Science University.

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Executive Summary

The Washington Health Technology Assessment (HTA) program was created in statute in 2006 to support the development of evidence-based coverage determinations that are binding upon state health care payers. The goal of the HTA is to ensure that state dollars are spent on health care tests and treatments that are safe, effective, and cost effective, and in addition, to support consistent coverage policies across state payers.

The HTA's statute and administrative costs establish a core framework and specific expectations for the processes by which coverage determinations are developed. This review examines HTA's implementation of these statutory and administrative requirements, and in addition, assesses stakeholder satisfaction with the HTA's processes. This review builds on the Stakeholder Engagement Project of 2011, and is part of an ongoing effort by the HTA to obtain feedback and develop processes that support transparent, independent, and evidence-based coverage determinations.

Review of HTA Process Requirements & Implementation

Since its inception, the HTA has established and modified processes to carry out its statutory mandate to support the development of evidence-based coverage determinations through a transparent and independent process. This review examines five core phases of the HTA's coverage determination process:

Topic Identification

The HTA facilitates the identification of topics through each of the potential sources identified by the HTA's statute and administrative rules: state agencies, members of the public, and consideration of the need to re-review previous determinations. Participating state agency medical directors recommend topics based on the HTA's prioritization criteria for new topics and re-reviews of previous determinations. Members of the public may nominate topics via the Interested Party Petition, available on the HTA website. Previous determinations are considered for review at least once every 18 months, based on whether new evidence may change the previous determination.

Topic Selection

As required by statute, the HCA Director selects technologies for review in consultation with state agencies and the Health Technology Clinical Committee (HTCC) based on priorities for new technologies (safety, efficacy, and cost concerns), and re-reviews (new evidence that may change previous determination). In addition, the Director has elected to seek public comment on potential technologies for review and re-review during a two-week comment period. Final topic selections are posted online, and include a summary of public comments and responses.

Topic Development

During topic development, the HTA facilitates submission of relevant information from interested parties and state agencies for consideration during the review, as required by statute. Interested parties may submit relevant information during a 30-day public comment period initiated upon final notice of topic selections. The program develops a review timeline and assigns topics to a contracted Technology Assessment Center (TAC), an independent evidence review vendor. The TAC drafts key questions based on the HTA's mandates to evaluate a technology's safety, efficacy, costs-effectiveness, and unique impacts on specific populations. Prior to posting final key questions, as required by administrative rule, the HTA releases draft key questions for a two-week public comment period. When possible, the HTA releases draft key questions to coincide with HTCC public meeting dates in order to provide members the opportunity to review and comment. Final key questions are posted online along with a summary of comments and responses prepared by the TAC.

Evidence Review

The HCA Director contracts with independent TACs to complete a systematic, evidence-based assessment of each technology, which must be initiated no sooner than 30 days from the public posting of final topic selections. The assessment must give the greatest weight to evidence determined to be the most valid and reliable, based on objective factors, and shall include consideration of

safety, health outcomes, and cost data submitted by state agencies, as well as evidence submitted by an interested party. In addition to meeting these requirements, the HTA has elected to seek public comment on draft evidence reviews during a 30-day public comment period. The TAC then addresses public comments, and makes changes where appropriate. All final evidence reports are posted online, in addition to a separate document summarizing public comments and the agency's response, including full copies of all comments received.

Coverage Determinations

The HTCC makes coverage determinations during public meetings held approximately six times per year. During HTCC meetings, members consider the systematic evidence assessment, public comments, and may consult with clinical experts on matters of clinical relevance. Coverage determinations result in one of 3 decisions: not covered, covered unconditionally, or covered under certain conditions. If covered under certain conditions, the HTCC will further develop the specific conditions of coverage. A quorum is required for voting, and determinations are made by the majority vote of HTCC members present. Draft *Findings & Decision* documents are posted on the HTA website for a two-week public comment period. The Committee reviews public comment and votes to adopt a final *Findings & Decision* document at the next HTCC meeting.

A process map detailing the statutory and administrative requirements, and the HTA's implementation of processes within each of these core phases, is provided in Appendix B. In addition, this review includes two case study coverage determinations—*Proton Beam Therapy* (2014) and *Vitamin D Screening and Testing* (2012)—to illustrate implementation of the HTA's processes (see Appendices C and D, respectively).

Stakeholder Satisfaction with HTA Processes

To assess stakeholder satisfaction with the HTA coverage determination processes, this review engaged a targeted group of program stakeholders. The review included key informant interviews and an in-person facilitated discussion with a total of 38 program stakeholders. Participating stakeholders represented a broad range of perspectives including: health care providers, industry representatives, state agency officials, HTCC members, clinical experts, evidence vendors, academic, patient advocacy, and other HTA peer organizations.

The goal of the current stakeholder engagement was to obtain specific and substantive insights into stakeholder experiences, perceptions, and knowledge of the HTA's

processes. This effort built on the 2011 Stakeholder Engagement Project, which gathered feedback from over 150 stakeholders regarding their knowledge, experience, and perceptions of the HTA overall.

Overall Project Findings

The HTA has developed robust coverage determination processes that align with the program's statutory and administrative process requirements. Overall, stakeholders are satisfied with program processes, and concerns and criticisms of HTA processes have abated since the 2011 Stakeholder Engagement Project. Key findings include:

- The HTA has established and modified processes to carry out its statutory mandate to support the development of evidence-based coverage determinations. The processes satisfy the HTA's statutory and administrative requirements, and in addition support stakeholder input and transparency throughout the coverage determination process.
- The HTA has been responsive to stakeholder feedback and made several changes since 2011 to improve stakeholder communications and increase program transparency. These changes include:
 - Increasing length of public comment period for draft evidence reviews from 2 weeks to 30 days.
 - Posting a summary of public comments and responses, as well as full copies of comments received, for potential technology topics, draft key questions, draft evidence reports, and draft findings and decisions.
 - Improving website usability.
 - Posting review topic timelines.
 - Holding a public conference call with state agency staff during Topic Selection.
 - Consulting with HTCC members on draft key questions during public meetings.
 - Reordering the HTCC meeting agendas to allow public comments to follow agency presentations.
- In 2011, stakeholders critiqued every component of the coverage determination process. During the current project, stakeholder perspectives were positive in overall tone, criticisms were focused on individual components in the process, and criticisms were made by a limited subset of two categories of stakeholders (industry and provider groups). Primary areas identified for improvement by stakeholders included:
 - Increased opportunities for stakeholders in the state agency topic identification process.

- Increased time for public testimony and order of testimony.
- Transparency and access to evidence during review process.
- Access to HTCC members.
- Expanded role of clinical experts.
- Increased stakeholder outreach by HTA staff.
- Improved clarity of processes to select topics for re-review.

Recommendations

The Washington HTA has developed robust processes that align with statutory and administrative process requirements, and support public input and program transparency. As the HTA continues to carry out its mandates, it may consider, in the context of program resources and capacity, the following recommendations based on this review:

Process Improvements

- Improve clarity of processes to select topics for re-review. As the HTA program ages, there will be increasing need for clarity around the processes and criteria for re-reviewing previous coverage determinations.
- Develop internal administrative “checklist” system to ensure consistent posting of all HTA materials and listserv distribution notices.
- Consider scheduling a consistent date or time of year for releasing potential technology topics and issuing final topic selections.
- Consider clarifying the role of clinical experts participating in HTCC meetings.

Stakeholder Communications

- Conduct ongoing stakeholder education to clarify topic identification process.
- Create visual diagram for topic review timelines.
- Update and consolidate website information about program processes.
- Provide high-level overview of theory and methods of systemic review of evidence.

Introduction

The Washington Health Technology Assessment (HTA) program was created in statute in 2006 to support the development of evidence-based coverage determinations that are binding upon state health care payers—including Department of Social and Health Services (Medicaid), the Department of Labor & Industries, and the Public Employees Benefits Board. In addition, the Department of Corrections participates voluntarily.

The goal of the HTA is to ensure that state dollars are spent on health care tests and treatments that are safe, effective, and cost effective, and in addition, to support consistent coverage policies across state payers. Annually, approximately 6 to 10 health technologies are selected for review based on criteria that include potential concerns for safety, efficacy, and costs. The HTA may also “re-review” existing coverage determinations in cases where new evidence has become available that may change the previous determination. Health technologies subject to review include medical and surgical devices and procedures, medical equipment, and diagnostic tests (RCW § 70.14.080), and coverage determinations address a variety of areas of medicine, such as cardiovascular, musculoskeletal, cancer, metabolic, endocrine, and nutrition (See Appendix A).

The HTA’s statute and administrative roles establish a core framework and specific expectations for the processes by which coverage determinations are developed. The HTA is situated within the Washington Health Care Authority (HCA) and facilitates the participation of several entities and groups in the coverage determination process. These include:

- **Health Technology Clinical Committee (HTCC)**
The HTCC is comprised of 11 independent health care providers appointed by the HCA Director in consultation with participating state agencies. The HTCC is authorized to make coverage determinations that are binding upon mandated participating state agencies.

- **Technology Assessment Centers (TACs)**
The HTA contracts with independent TACs to conduct systematic reviews of evidence. The HTA currently holds contracts with three TACs: Hayes, Institute for Clinical and Economic Review (ICER), and Spectrum Research.
- **Participating state agencies**
The Health Care Authority (Medicaid, Public Employees) and the Department of Labor & Industries are state agencies mandated to participate in the HTA. The Department of Corrections participates voluntarily¹.
- **External stakeholders**
External stakeholders, such as interested parties, beneficiaries, providers, and members of the public, have opportunity to provide public comment and participate at several points in the coverage determination process.

Since its inception, the HTA has established and refined processes to carry out its statutory mandate to support the development of evidence-based coverage determinations.

In 2011 the HTA undertook its first voluntary effort to assess how stakeholders are engaged in the HTA process. This effort included a review of national and international HTA programs designed to identify core components of successful programs, as well as a broad engagement effort to collect feedback from stakeholders regarding their knowledge, experience and perceptions of the HTA’s mandate and its core components. The review found the HTA aligned with other HTA programs and identified several areas for improvement, based on stakeholder feedback. The Stakeholder Engagement Report from 2011 may be found on the [HTA’s website](#).

As part of its approach to continuous improvement the HTA contracted with the Center for Evidence-based Policy (Center) at Oregon Health & Science University (OHSU) to evaluate implementation of the HTA’s coverage determination process requirements, and stakeholder

¹ Note: The HTA statute and administrative rules also identify the Department of Social and Health Services as a participating state agency, which had purview of Medicaid at the time the HTA was established in 2007. In 2011, Medicaid was transferred to the Health Care Authority, and the HTA statute has not been updated to reflect this.

satisfaction with the HTA processes.

Objective

The goal of this review is two-fold:

1. Examine the HTA's implementation of statutory and regulatory coverage determination process requirements.
2. Assess stakeholder satisfaction with the HTA's coverage determination processes.

The review builds on the Stakeholder Engagement Project of 2011, and is part of an ongoing effort by the HTA to obtain stakeholder feedback and develop processes that support transparent, independent, and evidence-based coverage determinations.

Project Methods

Methods for this project included 1) a review of statutory and administrative process requirements, HTA materials, and interviews with HTA staff to clarify understanding of the HTA's processes, 2) qualitative interviews with key stakeholders to assess stakeholder satisfaction with HTA processes, and 3) a half-day, in-person facilitated discussion with key stakeholders to validate findings from the review of the HTA's process requirements and implementation as well as stakeholder interviews.

Review of HTA Process Requirements & Implementation

Overview

This review examines the HTA's statutory and regulatory requirements and the program's implementation of processes to develop coverage determinations. Findings are presented below according to five core phases of the coverage determination process:

1. Topic Identification
2. Topic Prioritization and Selection
3. Topic Development
4. Evidence Review
5. Coverage Determination

A process map detailing the statutory and administrative requirements, and the HTA's implementation of processes within each of these core phases, is provided in Appendix B. In addition, this review includes two case study coverage determinations—*Proton Beam Therapy* (2014) and *Vitamin D Screening and Testing* (2012)—to illustrate implementation of the HTA's processes (see Appendices C and D, respectively).

Methods

Center staff reviewed the HTA statute (Revised Code of Washington §§ 70.14.080-140), HTA administrative rules (Washington Administrative Code, 182-55-005-055) and the bylaws of the Health Technology Clinical Committee. In addition, staff reviewed information on the [HTA's website](#) and communicated with HTA staff to confirm or clarify understanding of the HTA's processes.

Findings

Topic Identification

Statute & Rule

Program statutory and administrative requirements establish three potential sources of topics:

1. **State agencies:** The Health Care Authority (HCA) Director² shall consider nominations from participating state agencies (WAC 182-55-050).
2. **Members of the public:** The HCA Director may consider requests from interested parties for a technology review or re-review, submitted through a petition available on the program's website (WAC 182-55-050).
3. **Previous determinations:** All previous determinations shall be considered for re-review at least once every 18 months from the date of the previous determination based on the availability of evidence that has since become available that may change the previous determination (RCW § 70.14.100).

The HTA facilitates the identification of topics through each of the potential sources identified by the HTA's statute and/or administrative rules.

State Agencies

State agencies identify topics that raise potential concern for safety, efficacy and costs through a variety of methods. These include review of state utilization data, day-to-day agency experience and knowledge, and horizon scanning to identify emerging technologies that may impact state programs. Horizon scanning includes, for example, keeping abreast of medical journals and other publications, reviewing topics considered by other health technology

² The HTA statute and administrative rules refer to the HCA "Administrator," although this position title has since changed to HCA "Director."

assessment bodies in the United States or internationally, and tracking key sources of new technologies, such as the U.S. Food and Drug Administration’s approval pipeline of new drugs or devices.

Members of the Public

Members of the public may nominate topics via the Interested Party Petition, available on the [HTA’s website](#). The petition requests information addressing the HTA’s priority concerns for safety, efficacy, and costs, in addition to supporting references and other resources on the proposed topic. While this mechanism for public involvement has been available since 2007 it has rarely been used. The cause for lack of utilization is unknown.

Previous Determinations

Previous determinations are considered for re-review at least once every 18 months based on the availability of new evidence that may change the previous determination. New evidence impacting previous determinations may be identified by:

- Members of the public at any time, as well as during the opportunity to comment on proposed topic selections.
- HTA and state agency staff through the course of daily business and professional activities.
- Systematic search by a TAC to identify and analyze the impact of new evidence. This more intensive review is engaged for limited topics based on factors such as the complexity or rapidly evolving nature of the technology, as well as the HTA’s budgetary constraints.

Among the pool of technologies that are identified, the HCA Director selects approximately 6 to 10 technologies for review annually. To support these selections, the HTA has developed processes that satisfy the statutory and administrative topic selection requirements, and support stakeholder input and process transparency.

Consultation by State Agencies & HTCC

The HCA Director considers topics for review and re-review recommended by state agencies. Participating state agency medical directors recommend an annual list of proposed topics based on the HTA’s prioritization criteria for new topics and re-reviews of previous determinations. In addition, the HTCC may also provide input into topic selections when the Director publishes proposed topics for public comment.

Prioritization Criteria

The statute sets forth priorities to be considered in the selection of new topics and re-reviews of previous determinations. For new topics, the HTA has adopted prioritization criteria that reflect the statutory priorities as “primary criteria” and, in addition, identify “secondary criteria” that are commonly used across peer HTA organizations (Pinson, Thielke, & King, 2011) and may assist in prioritizing (see Selection of New Topics: Prioritization Criteria). For previous coverage determinations, the statute requires selection for re-review if evidence has since become available that may change the previous determination. Prioritization criteria are available on the [HTA website](#), and provided in the notice of proposed and final topic selections.

Topic Prioritization & Selection

Statute & Rule

The HCA Director shall select topics in consultation with participating state agencies and the HTCC. For new topics, priority shall be given to technologies based on concerns for safety, efficacy, cost-effectiveness, actual or expected high state expenditures, and the availability of adequate evidence to conduct the review. For previous coverage determinations, topics shall be selected for re-review if new evidence has since become available that may change the previous determination. The Director must provide public notice of technologies selected for review, indicating when the review will be initiated and how an interested part may submit evidence, or provide public comment, for consideration during the review (RCW §§ 70.14.100, 130).

Selection of New Topics Prioritization Criteria

- Primary criteria (statutory priorities)
- ✓ Concern for safety
 - ✓ Concern for efficacy
 - ✓ Concern for costs & cost-effectiveness
- Secondary criteria
- ✓ Number of persons affected annually
 - ✓ Severity of the condition
 - ✓ Policy related urgency
 - ✓ Variation in practice
 - ✓ Ethical concerns or impact on special populations

See: [WA HTA Prioritization Criteria](#)

Public Input & Transparency

The HCA Director has elected to seek public comment on potential technologies for review, and publishes a list of potential technology topics for a two-week public comment period. Over the past several years, in response to stakeholder feedback, the HTA has increased the level of information included in the release of potential topics for review. Potential HTA Technology Topics released for 2011, 2012, and 2013, for example, included only a basic list of topics for review. By contrast, in 2014 and 2015, the HTA provided additional information about the rationale and criteria for potential and final topic selections, including:

- Background information about HTA selection process and criteria.
- List of potential new technology topics, including ranking of each technology according to primary prioritization criteria, description of policy context and reason for selection.
- List of new technologies considered, but not proposed for review.
- List of previous determinations with new literature identified, including those proposed for re-review.
- List of previous determinations for which the HTA has not received or identified new evidence to support further review.
- Copies of surveillance reports in cases where the HTA has requested a systematic search and analysis of new evidence impacting previous determinations.
- Request for public comments on: proposed new topics, proposed re-reviews, and all topics eligible for re-review.

In 2015, during the two-week public comment period, the HTA also initiated a public conference call to allow stakeholders the opportunity to ask state agency staff directly about proposed topic selections. This conference call was initiated in response to stakeholder requests for two-way dialog regarding topics proposed for review.

As required by statute, the HTA provides public notice of final topic selections. The *HTA Selected Technologies* document includes:

- Letter from the HCA Director selecting technologies for review (new and re-reviews).
- All information included in the *Potential HTA Technology Topics* document (see above).
- Summary of written public comments and HCA responses, including any changes adopted.
- Copies of all written comments received.

Upon notice of final technology topic selections, the Director also initiates a 30-day comment period for interested parties to submit evidence for consideration during the review, as discussed next, under the Topic Development phase.

Topic Development

Statute & Rule

Upon notice of topic selection, HCA Director shall invite interested parties and participating state agencies to submit relevant information to be considered as part of the evidence review (RCW §§ 70.14.100, 130; WAC 182-55-055). The HCA Director shall provide all relevant information to the TAC, and post online along with the key questions for the review (WAC 182-55-055). Health technology assessments shall evaluate the technology's safety, efficacy, cost-effectiveness, and unique impacts on specific populations based on factors such as sex, age, ethnicity, race, or disability (RCW § 70.14.100).

During topic development, the HCA Director must provide interested parties and state agencies the opportunity to submit relevant information for consideration during the review. In addition, the TAC develops key questions.

Opportunity to Submit Relevant Information

Upon notice of topic selections, the HTA allows a 30-day public comment period for members of the public to submit evidence, or other relevant information for consideration during the review. In addition, the Director requests state agencies to submit relevant information, including administrative or utilization data on safety, health outcomes, or costs.

Key Questions

The TAC develops draft key questions based on the HTA's mandates to evaluate a technology's safety, efficacy, cost-effectiveness, and unique impacts on specific populations. HTA administrative rules require that key questions are posted publicly on the HTA's website. Prior to publication of final key questions, the HTA provides opportunity for public comment on the draft key questions during a two-week comment period. At this time, the HTA also creates a topic page on the HTA's website providing background information and key review dates and opportunities for public comment through the process.

Topic page on website includes:

- Key review dates and opportunities for public comments: draft and final questions, draft and

final evidence reports, and review by HTCC at public meeting.

- Topic summary and policy context.
- Topic ranking across primary prioritization criteria.
- Link to public documents posted, including prior review documents for previous coverage determinations on the topic.

Draft Key Questions document includes:

- Draft research key questions.
- Project scope (population, intervention, comparators, and outcomes).
- Policy context and concerns.
- Background information about the technology.

In order to provide the HTCC opportunity to review and comment on the draft key questions, the HTA times the release of draft key questions to coincide with HTCC public meeting dates, when possible.

Final Key Questions

Final key questions are posted online, in addition to a separate document summarizing public comments and TAC response.

Final Key Questions document includes:

- Final research key questions.
- Project scope (population, intervention, comparators, and outcomes).
- Policy context and concerns.
- Background information about the technology.

Draft Key Questions—Public Comments & Responses document includes:

- Summary and response to comments pertaining to draft key questions, project scope, or evidence review and TAC responses.
- Identification of all comment sources.
- Full copies of all comments received.

Evidence Review

Statute & Rule

The HCA Director shall contract for a systematic evidence-based assessment of each technology, to be initiated no sooner than 30 days from the public posting of the final topic selections. The assessment shall include consideration of safety, health outcome, and cost data submitted by a participating agency, and evidence submitted by an interested party. The assessment must give the greatest weight to evidence determined, based on objective factors, to be the most valid and reliable, considering the nature and source of the evidence, the empirical characteristic of the studies or trials upon which the evidence is based, and the consistency of the outcome with comparable studies. The assessment shall include consideration of safety, health outcome, and cost data submitted by a participating agency, and evidence submitted by an interested party. The Director shall post online access to the systematic technology assessment completed (RCW § 70.14.100, 130).

As required by statute, the HCA Director contracts with independent TACs to complete a systematic, evidence-based assessment of each technology, initiated no sooner than 30 days from the public posting of final topic selections. The assessment must consider safety, health outcome, and cost data submitted by state agencies, as well as evidence submitted by interested parties.

Draft Evidence Report

The statute requires that the HTA post the final evidence review on the agency website. Prior to posting the final evidence review, the HTA has elected to post draft evidence reports for a 30-day public comment period. Based on stakeholder requests for additional time for review and comment, this comment period was extended in 2012 from an original two-week comment period.

Draft Evidence Reports include at a minimum the following information

- Methods
- Quality assessment of studies
- Evidence findings addressing key questions
- Medicare and major private payer policies
- Clinical guidelines

Final Evidence Report

The TAC reviews and addresses public comments, and

makes changes where appropriate. All final evidence reports are posted online, in addition to a separate document summarizing public comments and the TAC's response, including full copies of all comments received.

Final Evidence Report includes at a minimum:

- Methods
- Quality assessment of studies
- Evidence findings addressing key questions
- Medicare and major private payer policies
- Clinical guidelines

Draft Evidence Report: Public Comments & Response include:

- Summary of public comments and TAC response
- Identification of all comment sources
- Full copies of all comments received

Coverage Determination

Statute & Rule

The HTCC shall determine coverage of a technology reviewed, and if covered, criteria to determine medical necessity. The HTCC shall consider, in an open and transparent process, evidence regarding the safety, efficacy, and cost-effectiveness of the technology as set forth by the systematic evidence review, and shall provide opportunity for public comments. The Committee may also consider information it deems relevant, including other information provided by the Director, reports and/or testimony from an advisory group, and public comments. Committee determinations shall be consistent with Medicare policy and expert treatment guidelines, unless the committee concludes based on the review of the systematic evidence, that substantial evidence supports the contrary. All HTCC meetings are subject to Washington open public meetings law. The HCA Director shall provide online public access to HTCC determinations, and post final HTCC determinations online within 10 days of the final determination (RCW §§ 70.14.110-130, WAC 182-55-030, 040).

The HTCC reviews technologies and makes coverage determinations during public meetings held approximately six times per year. The HTA publishes Committee meeting agendas and materials two weeks in advance of the meetings. Meeting agendas are structured around five basic

components:

1. State agency presentation of technology and agency experience and recommendations
2. Scheduled and open public comment
3. Evidence report presentation
4. Committee questions and answers
5. Committee discussion, development of draft determination, and committee vote

The HTA recently re-structured the agenda so that public comments follow the state agency presentation, and allows the public to comment on information presented. Previously, public comment came at the beginning of the meeting.

The HTCC invites a clinical expert be present at the meeting. The role of the clinical expert is to provide information about the clinical context of the technology (e.g., current practice, clinical setting, technical details). Clinical experts complete a conflict of interest disclosure and agree not to advocate for a particular coverage decision and to be responsive to the Committee's questions. Clinical experts may be identified via by TAC expert consultants, external stakeholder volunteers, or through HTA staff outreach to medical associations and professional societies.

The HTCC votes on one of three coverage options: not covered, covered unconditionally, or covered under certain conditions. If the HTCC is considering coverage under certain conditions, Committee members outline these conditions. A quorum is required for voting, and determinations are made by the majority vote. The HTCC then directs HTA staff to prepare a Draft Findings and Decision document describing the coverage determination, any conditions of coverage, and the HTCC's voting results.

Draft Findings and Decision documents are posted for a two-week public comment period. At the Committee's next public meeting, the Committee reviews public comment and votes to adopt a final *Findings and Decision* document. The Director publishes final HTCC determinations on the HTA website within 10 days of the final determination.

Summary

The HTA has established and refined processes to carry out its statutory mandate to support the development of evidence-based coverage determinations. The processes that are in place satisfy the HTA's statutory and administrative requirements, and support stakeholder input and transparency throughout the coverage determination process.

The program has been responsive to stakeholder

feedback and made several changes since the Stakeholder Engagement Project in 2011. These changes include:

- Increasing length of public comment period for draft evidence reviews from 2 weeks to 30 days.
- Posting a summary of public comments and responses, as well as full copies of comments received, for potential technology topics, draft key questions, draft evidence reports, and draft findings and decisions.
- Improving website usability.
- Posting review topic timelines.
- Holding a public conference call with state agency staff during Topic Selection.
- Conferring with HTCC members during public meetings on draft key questions.
- Reordering the HTCC meeting agendas to allow public comments to follow agency presentations.

Stakeholder Satisfaction with Program Processes

Overview

Stakeholder engagement activities in the current project build on work of the [HTA's Stakeholder Engagement Report in 2011](#). The 2011 work was the first systematic effort the HTA had undertaken to collect feedback from stakeholders regarding their knowledge, experience, and perceptions of the HTA program. In the 2011 stakeholder engagement effort, there was a focus on attaining wide and broad participation from as many stakeholders as possible. This was achieved through an online survey, key informant interviews and two, in-person facilitated discussions. More than 400 stakeholders were invited to participate and 151 individuals responded to that opportunity.

The intent of the current project was to query stakeholders with deeper HTA experience in order to gain insights into stakeholder experiences, perceptions and knowledge of HTA processes. A total of 38 stakeholders responded to this opportunity out of a sample pool of approximately 80 individuals. Engagement activities included in-depth key informant interviews and an in-person facilitated discussion group. Methods and findings for the current project are discussed below.

Methods

Twenty-three stakeholder interviews were conducted between January 26 and May 19, 2015. In consultation with HTA staff, a list of approximately 80 potential participants was developed from an initial list of over 400. Since the goal of the interviews was to identify satisfaction with current HTA processes, a representative group of stakeholders who had experience engaging in the HTA program was identified. Table 1 identifies interview participants by category of stakeholder.

A seven-question, standardized interview guide was developed with a focus on stakeholder experiences and perspectives of HTA processes. The interview guide is in Appendix E. Respondents were asked to provide feedback on:

- Respondent background and experience with HTA
- HTA's performance in meeting legislative intent
- Overall satisfaction with HTA processes

- Consistency of application of coverage determinations
- Coverage determination impact on various stakeholder audiences
- Thoughts regarding specific topics reviewed in the past
- Any additional, open-ended comments the respondent wished to share

Table 1. Stakeholder Interview Participants

Stakeholder Category	Number
Academic, health expert	1
Clinical expert	2
Contractor	3
Health care provider, provider professional organization	4
Health industry, manufacturer, industry professional association	3
HTCC member	2
Patient/public advocacy	1
Peer organization	3
Washington State Agency, executive or legislative staff	4
TOTAL	23

Prior to each interview a list of questions and a brief description of the project were emailed to participants. Interviews were conducted by telephone and were digitally recorded with verbal consent. Interviews were between 30 and 60 minutes in length, depending on how much time and input participants had to offer.

All interview data were analyzed using Atlas.ti™ qualitative research software. Initial themes were compared to findings from the HTA's 2011 Stakeholder Engagement project to determine if there were changes or similarities in stakeholder knowledge, experience and perceptions. Analysis also included comparing "internal" (HTCC members, State Agency and legislative staff; 26%) stakeholder responses with those of "external" (all other stakeholder categories; 74%) stakeholders and comparing answers across stakeholder categories in order to identify sub-group comparisons. High-level themes were identified

and presented at a subsequent stakeholder discussion group for response and validation. Finally, interview data were compared with findings from the discussion group to identify similarities and differences.

Key Findings

Overall Satisfaction with Program Implementation

"I really admire the Washington HTA Program and the process and the fact that it actually uses evidence to support state coverage decisions. I think it's a very responsible program. I would love to see it have more national influence.... nationally we are spending billions of dollars on technologies that are not helping patients and are even harming them"

— R14 Clinical Expert

Most interview respondents are generally satisfied with HTA processes. Stakeholder concerns and criticisms of HTA processes have abated since 2011. Overall, the findings from this process evaluation are more positive in tone and the criticisms are more focused and measured than those from the 2011 Stakeholder Engagement Project. Previously, stakeholders critiqued every component of the review development process. Currently, respondent concerns were focused primarily on Topic Identification, Evidence Review and Coverage Determination and were limited to a small subset of stakeholders.

The HTA made several changes since the Stakeholder Engagement Project in 2011 to improve stakeholder communications and increase program transparency. These include:

- Improving website usability
- Posting review topic timelines
- Holding a public conference call with state agency staff during Topic Selection
- Posting responses to public comments on draft key questions
- Consulting with HTCC members on draft key questions
- Increasing length of public comment period for draft evidence reviews
- Reordering public comment segments during HTCC meetings
- Altered HTCC meetings schedule to align with payer

needs

A key finding from this review is that the higher level of stakeholder satisfaction expressed in 2015 is, at least in part, due to the responsiveness of the HTA to stakeholder suggestions for improvement.

"I think this has been an effective HTA that uses evidence and gets the right treatment to the right person at the right time. That is what we were aiming for. That gives it an A+ as far as I'm concerned."

— R4 Legislative Staff

HTA Intent & Overall Implementation

When asked if they thought the HTA was meeting its statutory intent, the majority of interview respondents (91%)¹ stated that they believed it was doing so. Two respondents, one industry representative and one provider representative responded negatively to this question citing concerns with HTA transparency and the perception that containing healthcare costs is the driving force behind all HTA technology assessments. Throughout the interview data, dissatisfied stakeholders consistently represented two stakeholder categories, providers and industry representatives, while other stakeholder groups both internal and external, expressed satisfaction with HTA processes overall. This distinction is not universal among all findings but it is significant enough to be considered a key finding.

Most respondents interviewed (78%) are satisfied with the HTA's implementation and processes overall. The group of satisfied respondents was a mix of internal and external stakeholders. Of these respondents eight were unequivocally satisfied and 10 provided mixed reviews, citing both areas of programmatic strength as well as areas where improvements could be made. An additional three respondents (13%) voiced overall dissatisfaction with the HTA.

HTA areas recognized by respondents as particularly strong included:

- Overall HTA model
- Integrity and independence of HTCC
- Integrity and independence of TACs
- Overall transparency of HTA processes especially when compared to other payers' coverage determination processes

¹ Respondents included a mix of both internal (33%) and external (67%) stakeholders.

- Overall opportunities for public involvement
- HTA is viewed as national leader in HTA

“From a process perspective I think they do a great job. The key elements were that it was going to be a public meeting, with an independent group of clinicians who were also expert in method review and they kind of hit all of the good procedural points.”

— R12 Peer Organization

HTA areas cited for possible improvement included:

- Increased transparency of topic identification process
- Increased time for public testimony and order of testimony
- Transparency and access to evidence during review process
- Access to HTCC members
- Expanded role of clinical experts
- Increased stakeholder outreach by HTA staff

Stakeholder Feedback on Specific HTA Processes

A Process Map was developed as part of this report to delineate the specific components of the HTA review process (see Appendix B). Interview respondents were asked to comment on their experiences and satisfaction with each review component described in the process map. The following sections identify interview respondent comments on each of the process components including a comparison to findings from the 2011 engagement effort.

“I know there has been some issue with transparency in the past. I know that when the committee determines which technology they are going to review that is not open to the public. So no one really knows how they come to the list they eventually come to. So I know that’s been a frustration.”

— R5 Industry

Topic Identification

Although most respondents interviewed (83%) are satisfied with Topic Identification processes, lack of transparency remains a concern for some external stakeholders. Topic Identification remains an unclear process to some stakeholders. These respondents requested more “sunshine” on the identification process overall and expressed disbelief in HTA explanations for how this process is conducted

internally (see Appendix B).

In 2011 there were relatively few comments about Topic Identification and concerns were focused more on Topic Prioritization and Selection. This shift in focus to the earlier process may be a result of greater stakeholder understanding of HTA processes overall and of Topic Selection in particular. In response to 2011 stakeholder feedback, the HTA increased efforts at stakeholder education on the selection criteria and process.

Current external stakeholders who voiced dissatisfaction (17%) were from two stakeholder categories, those representing providers and industry. Of greatest concern is the perception that cost is a key factor in identifying topics for review. In addition, respondents who expressed dissatisfaction voiced concern that state agency staff might require help assessing background evidence used in the Topic Identification process. These respondents suggested that they could provide the HTA with clinical experts to assist agency staff in evidence interpretation. These stakeholders also stated that one reason they wish to be engaged in Topic Identification is so that they might influence the process away from particular topics being reviewed.

“There might be flaws and inaccuracies and biases in their sources or interpretations of information that could trigger an unnecessary review. And so more transparency at the get go”

— R7 Industry

Topic Prioritization & Selection

As noted above, Topic Selection did not draw many comments in 2011, external stakeholders identified lack of transparency in Topic Selection as a major concern, particularly focusing on the need for greater transparency in the selection criteria and rationale for selection. HTA staff has worked since that time to improve overall communication strategies with stakeholders. By mandate, topic selection and prioritization criteria have been posted publicly on the HTA website as of the HTA’s implementation in 2007. Since 2011, changes were made to improve interface and usability of the HTA website in order to make this and other information more accessible to stakeholders. In 2015, stakeholder concerns shifted to the role cost plays in topic selection and the overall impact to a technology once it is identified for review.

A few interview respondents (17%) representing industry and providers suggested that cost is the only concern of agency staff in forwarding technologies for review.

Other respondents acknowledged that assessing technology

cost-effectiveness and overall value is included in the primary selection criteria but questioned the methods used to determine this.

“There is an announcement made at the beginning of every HTCC meeting...that they are looking at safety and efficacy, but that cost determinations are not going to be a factor. In the two topics I have been involved with, if you look a little deeper, cost determination is the major driving factor.”

— R20 Provider

Current stakeholder concerns related to Topic Selection can be illustrated by the statement of one interview respondent who said that once a technology is placed on the Topic Selection list for the year, it becomes a “scarlet letter” for other local and national payers considering coverage changes.

“The evidence vendor is limited to looking only at the evidence that is defined in the key questions. Not all types of studies can be reviewed based on criteria in key questions. This needs to be more transparent to the public.”

— R22 Provider

Topic Development

Topic Development drew relatively few critical comments from interview respondents. While the development of key questions was of concern to both internal and external stakeholders in the 2011, it is of significantly less concern in 2015. Of greatest concern in 2011 was the variability in quality of key questions and lack of transparency as to the disposition of publicly submitted comments on draft key questions. Since then the HTA has adjusted this process so that the TAC, HTCC members, and clinical experts work with state agency staff and HTA staff to develop key questions that will lead to the identification and assessment of the best available evidence.

Five respondents commented on key question development during this year’s interviews. Some comments were positive, noting that the HTA’s key questions process had improved over time and that draft key questions are now shared with the HTCC prior to conducting the evidence review. Public comments submitted to the HTA are now posted on the website in their entirety with a disposition statement from the TAC. While this has increased transparency of the key question process, one provider respondent stated that his organization still feels their comments are ‘ignored’ by the HTA and the TAC when they do not result in suggested changes. Another provider respondent suggested that stakeholders are unaware of just how important key questions are in the subsequent inclusion and exclusion

of evidence and that the HTA should do more to educate stakeholders in this regard.

Evidence Review

Most respondents expressed satisfaction with the Evidence Review process. Internal interview respondents expressed high satisfaction with the quality and methods of TACs. Some external interview respondents (26%) representing industry and providers requested more access to evidence vendors during the review process and questioned inclusion/exclusion criteria.

“In terms of hiring an extremely competent evidence-based review group which produced a great report and in terms of the process for reviewing that report and coming to a conclusion I was extremely pleased with the whole process. It was a beautiful example of evidence-based public policy at work.”

— R15 Clinical Expert

In 2011, the source of greatest concern for stakeholders was the two week public comment period following posting of the draft evidence report. The HTA subsequently adjusted the comment period on draft reports from two weeks to 30 days. Also in 2011 stakeholders called into question the competence of the contracted evidence vendors noting wide variation in report quality and presentation skills. These criticisms were notably absent in 2015.

“The one thing we would like is the opportunity to look at the evidence that is being considered, earlier in the process. And get our surgeons to look at it earlier. I don’t know exactly how you would do that.”

— R8 Professional Association

However, one critique from the current review focused on the lack of clinical expertise on the TAC review team. Providers and industry representatives questioned the ability of clinical epidemiologists to grasp the clinical nuance of technologies they reviewed. Further stakeholder education on the methods of systematic evidence reviews including the roles of clinical epidemiologists may be of help to ongoing tensions regarding the Evidence Review process.

Coverage Determination

The statutorily mandated composition of the HTCC and the role of clinical experts continue to draw attention and concern from interview respondents. The majority of comments from interview respondents on the Coverage

Determination process involved the role of clinical experts during HTCC meetings. While this was also a theme from 2011 stakeholder input, both the intensity and number of comments were lower in 2015.

“I think it is excellent. We probably could not ask for a better run organized committee grappling with tough issues.”

— R21 Health Policy

The question of whether to include clinical experts on the HTCC made its way to the legislature as well. During the course of this project, a bill (SB 5145) requiring the HTCC to include at least one member who is a medical expert in the technology under consideration was introduced to the Washington State Legislature, although not passed during the 2015 legislative session.

Contracted evidence vendors may select one or more clinical experts at the time of scoping the systematic evidence review. These experts provide clinically relevant guidance for the duration of the evidence review, functioning as a Technical Expert Group similar to those used in other respected HTAs nationally and internationally (Pinson et. al., 2011). In addition these experts may be forwarded to HTA staff as candidates to serve as formal clinical experts to the HTCC during the public meeting. Interview respondents assert that clinical experts who consult for the HTA have too limited a role.

Additional Key Themes

“One thing that we have been advocating for forever is to have clinical expertise on the panel. Right now the panel is made up of health care providers, but they are not necessarily specialists, or they don’t necessarily have the expertise in the sometimes very complicated technologies that are being reviewed.”

— R7 Industry

Stakeholder Impact

Interview respondents were asked about their perceptions of the HTAs impacts on various stakeholder audiences. Many respondents were unsure what these impacts might be and were sometimes reluctant to give an answer for any stakeholder group other than the one they themselves represented. Others had a great deal to offer in way of comment on this topic. The percentage of respondents who commented on each group are in parentheses. Discussion of respondent perceptions of HTAs impact on stakeholders is summarized below.

“The question we need to answer now is ‘what is real value?’ How can we provide extraordinary value at the least amount of cost?”

— R1 Peer Organization

Impact on Patients (43%)

Both internal and external respondents identified lack of access due to coverage restrictions as the primary HTA impact for patients. However, some were quick to point out that restricting access to harmful or ineffective treatments, while distressing to individual patients, is actually positive. Interview respondents noted that the HTA is devoted to increasing value in healthcare purchasing and as a result actually serves all citizens by improving access to high quality, high value care.

Impact on Providers (52%)

HTA impacts to providers are viewed similarly to those of patients with the added element of potential decreased revenue depending on HTCC coverage decisions. Providers are also viewed as losing independence in selecting treatment course for individual patients based on population health data. Coverage determinations provide a clear roadmap of what are and what are not evidence-based treatments —and some respondents viewed this as a positive impact

Impact on Payers (65%)

The HTA is viewed as a high quality model by other states with HTAs or planning to develop health technology assessment programs. Internal stakeholders view this as a positive impact while external stakeholders, primarily industry, view this as a negative impact. No respondent cited evidence that HTA decisions are impacting private payers, especially large national payers, but there is conjecture that this is a likely HTA impact. Lack of transparency in private payer processes prevents assessing the accuracy of these beliefs.

Impact on Industry (26%)

Respondents thought impacts on technology manufacturers were the most obvious to identify. If the HTCC makes a non-coverage determination for a particular technology or a “covered with conditions” determination, declines in revenue for the manufacturer are likely a direct result. Respondents from industry also noted that coverage decisions made in Washington impact other payer’s decisions such as the Oregon Health Evidence Review Commission and other public or private payers.

Additional Themes

All respondents were offered the opportunity to provide comment on any topic of their choice. These comments resulted in additional themes that were outside the scope

of this review. Topics raised by stakeholders included the HTA appeals process, the Bree Collaborative, and tension between population health and individual health.

Summary

Overall, findings from stakeholder satisfaction interviews confirm that HTA responsiveness to stakeholder concerns is having a positive impact on stakeholder experience. Many of the concerns and criticisms heard in the 2011 stakeholder engagement effort were not voiced in 2015 or were voiced by fewer respondents and with less intensity. Most interview respondents are satisfied with HTA processes overall and identified areas that had improved over time such as longer comment periods, greater transparency in some processes and greater consistency in the quality of evidence reports. Analysis revealed a subset of interview respondents who expressed dissatisfaction with specific processes (Topic Identification, Evidence Reviews and Coverage Determinations) and the HTA overall and these were representative of just two stakeholder categories, industry and providers.

While the HTA has made progress in improving stakeholder communications, there are still some areas that could benefit from further efforts. Topic Identification remains unclear to interview respondents as do the differences between the basic principles of the systematic review of evidence, HTA and evidence-based medicine. Multiple comments from external respondents illustrated the confusion between HTA, which focuses on broader impacts at the system level and evidence-based medicine which uses evidence to inform clinical decision making and the care of individual patients or groups (Pinson et al., 2011).

High-level themes described above from the stakeholder satisfaction interviews, as well as findings from the process review, were presented to a facilitated discussion of 18 key stakeholders. The purpose of the facilitated discussion was to validate and adjust, if necessary, initial findings.

FACILITATED DISCUSSIONS

In order to validate findings from the stakeholder satisfaction interviews and the process mapping exercise, an in-person, facilitated discussion group was held with 18 stakeholders with significant experience engaging with the HTA program and its processes. Preliminary findings from interviews and process mapping were presented and discussed. Participants were also encouraged to share their experiences of HTA processes so that findings could be modified if necessary.

Methods

A half-day, in-person facilitated discussion was conducted

with stakeholders in Tukwila, Washington on May 21, 2015. Discussion participants were recruited from the same list that was used to recruit interview participants. No effort was made to control for equal representation among stakeholder categories allowing registration on a first-come, first served basis, therefore some categories were over-represented and some were under-represented. Group size was limited to 20 participants to ensure rich discussion. A total of 18 stakeholders attended (see Table 2).

Table 2. Facilitated Discussion Participants

Stakeholder Category	Number
Contractor	1
Health care provider, provider professional association	3
Health industry, manufacturer, industry professional association	6
HTCC member	2
Patient/public advocacy	2
Peer organization	1
Washington State agency, executive or legislative staff	3
TOTAL	18

Objectives of the facilitated discussion were to:

- Provide a brief overview of HTA and the current evaluation project
- Gather stakeholder feedback on HTA review process
- Validate preliminary findings with stakeholders

The discussion began with a welcome from the HTA Director, a brief overview of HTA processes and a review of methods used in the stakeholder interviews and process mapping. This was followed by an in-depth review of each of the five process components. High-level findings from stakeholder interviews were shared to highlight current and past satisfaction with each process component. Stakeholder discussion followed presentation of findings for each component, participants were asked to share their own experiences with the various processes and to comment on how closely their experience matched the description provided in the process mapping exercise. Ground rules for discussion were posted and reviewed to maintain optimal interaction among participants. The format was designed to allow for maximum interaction between participants to share perspectives, knowledge and experiences of the HTA.

Findings

One goal of the facilitated discussion was to validate findings from the Stakeholder Satisfaction Interviews. All key findings from the stakeholder interviews regarding

HTA processes were confirmed by the discussion group. Additional themes outside the scope of this project were collected but were not discussed during the in-person group due to issues of time and scope.

In general, external stakeholder participants were more vocal than their internal stakeholder counterparts and relatively few comments were shared regarding stakeholder experiences with the actual HTA process components. This was true even though each HTA process component was reviewed in-depth prior to opening the floor to participant discussion and participants were encouraged to share their experiences. A majority of comments were directed toward further programmatic changes stakeholders would like to see.

Overall, discussion participants had the most to say about Topic Identification and Topic Selection processes and relatively few comments on the current processes for Topic Development, Evidence Review and Coverage Determination, especially in comparison to the number of comments received on these components in 2011.

Topic Identification

Discussion group participants echoed the concerns of the interview respondents. Participants requested more information about when and how topics are identified by agency staff and requested opportunities for input during this earliest phase of the review process. There was also a request for more information regarding when and how re-review is determined to be necessary. Although the HTA has established a process for anyone to nominate topics, few participants had nominated a topic for review. Participants also struggled with the distinction between topic identification and topic selection. This is an ongoing point of confusion for external stakeholders, and they may benefit from greater educational efforts on the part of the HTA to clarify the review process.

Topic Selection

Similar to findings in the interviews, concerns regarding Topic Selection revolved around transparency and the rationale for forwarding topics for review. In addition, discussion participants requested that more outreach be conducted to affected stakeholders prior to the list being posted in order to afford less engaged stakeholders an opportunity to comment. Discussion participants identified the addition of a public conference call with HTA staff and agency medical directors as helpful in this stage of review. Participants noted that once a technology appears on the Topic Selection list that is considered a “scarlet letter” and other payers follow the direction of the HTA.

Topic Development

Almost all comments on the Topic Development process related to key question development and expertise of TAC staff. Some participants noted that the process has improved and become more transparent over time and that this has resulted in higher quality key questions. Based on comments during discussion, there is still confusion among stakeholders as to the actual HTA processes. Stakeholders would like the opportunity to assist in the actual writing of the draft key questions, not just on commenting on already drafted questions during the public comment period. Suggestions included allowing professional societies or other stakeholders to nominate experts to assist the TAC. Another suggestion was that the HTA holds a public conference call to discuss draft key questions (similar to the newly instated call on proposed topic selection list).

Evidence Review

Participant comments on the HTA's Evidence Review process were similar to those heard in 2011. Two consistent critiques raised by some stakeholders are related to systematic review methods. Stakeholders complain that the evidence selected for inclusion in HTA reviews is outdated and does not always reflect current practice. Stakeholders also object to the selection criteria used by TACs to identify high-quality studies for reviews. These critiques reflect the ongoing tensions between the experience of individual practitioners and the rigorous methods of systematically reviewing large bodies of the highest grade of available medical evidence. Scoping of the systematic review along with inclusion and exclusion criteria remains controversial with external stakeholders.

Discussion highlighted general lack of understanding about the methods and process of evidence reviews. For example, one discussion participant raised the issue of redundancy of HTA efforts with those of the FDA. Further discussion clarified that the HTA conducts comparative and post-market analyses of effectiveness as well as an assessment of cost-effectiveness. These three important activities are beyond the scope of FDA assessments, which focus on pre-market safety and effectiveness, but do not compare new technologies' effectiveness with existing technologies or consider the relative value of the technology for consumers and purchasers.

Coverage Determination

Discussion participants shared thoughts on the HTCC and its processes for coming to coverage determinations. Similar to comments from interview respondents, discussion participants raised concern about the role of clinical experts in HTCC proceedings. Of particular concern is the procedure of hearing from the clinical expert only when Committee members have a question regarding clinical

contents. Some participants requested that experts be placed on equal standing with Committee members up to and including voting rights.

In response to previous stakeholder feedback, the HTA changed the order of presentation at the HTCC meeting to lead with State Agency staff, followed by members of the public and ending with the TAC presentation of the evidence review. Some discussion participants would now like the opportunity to follow the TAC, or to “bat clean up” as one participant described it. In that way, members of the public would have the opportunity to respond to all comments and data presented to the Committee.

Additional Themes

Many stakeholders wanted to discuss topics that were outside the scope of the current review. These themes were collected for potential future discussions and comments are summarized below. Topics raised included the HTA appeals process, and tension between population health and individual health.

Summary

Findings from the discussion group were consistent with findings from the stakeholder satisfaction interviews. Participants expressed appreciation for the opportunity to share their experiences and concerns and to provide feedback on HTA processes. Relatively few participant comments directly addressed the content of either the process map or themes from the interview data. Rather, most comments were focused on additional changes stakeholders would like to see made to current processes and frustration with specific topics reviewed prior to 2011. In addition, participants confirmed the finding from the interviews that there is a need for further education and clarity of HTA processes to address ongoing areas of stakeholder confusion. Areas needing further clarification are Topic Identification and Topic Selection and the basic precepts of the systematic review of medical evidence and clinical epidemiology.

A weakness of the program that was identified by stakeholders is the lack of specific clinical expertise on the part of TACs and HTCC members. This stakeholder concern is related to the overall misunderstanding of the precepts of systematic review methods and clinical epidemiology skills. While interview respondents identify the lack of specific clinical expertise in the review topic as a weakness, the opposite can and is argued by experts in the field of systematic evidence review. As the field matures, more bodies are recognizing the need to limit the participation of individuals such as experts who may have significant conflicts of interest in the treatment or technology being assessed (Baumann, Lewis, & Gutterman,

2007; Institute of Medicine, 2009; Rosenfeld & Shiffman, 2009). The American College of Chest Physicians has been a particular leader in this area and has developed rigorous methods to identify and exclude conflicted participants in their clinical guideline development process. Using experts to clarify matters of practice nuance while strictly controlling the amount of influence that a given expert can exert on the bodies' decision-making processes is a common design element of evidence-based policy bodies like the HTCC.

Coincidentally, the interview respondents concerned with this point do not mention the significant clinical epidemiologic expertise of the TACs and the HTCC. It is unknown whether this is born of a misunderstanding of the basic skill set of clinical epidemiology or an attempt to influence the process with non-evidence based techniques.

Overall Findings & Recommendations

Overall Findings

The Washington HTA program has established robust processes that satisfy statutory and administrative requirements to support the development of evidence-based coverage determinations by an independent clinical committee. HTA processes are open and transparent with multiple opportunities for public input throughout five core phases of the coverage determination process: Topic Identification, Topic Prioritization and Selection, Topic Development, Evidence Review, and Coverage Determination. These program processes and components are also consistent with other well-established national and international HTA programs (Pinson et al., 2011).

The HTA has a history of and commitment to engaging stakeholders in a meaningful way. Stakeholders are invited to provide input at numerous points in the HTA process and in efforts of continuous improvement such as this project. The HTA not only requests stakeholder feedback, but also when possible, makes programmatic adjustments to increase stakeholder satisfaction and improve efficiencies and outcomes. Most stakeholders who participated in qualitative interviews are satisfied with program processes overall. A small subset of stakeholders, representing industry and provider categories, was the exception to this finding. These stakeholders requested more transparency for the topic identification process; public access to the studies reviewed by TACs; an expanded role for clinical experts; and recognition and assessment of standards of care in the community prior to coverage determination.

The following represent key findings from the three activities of this project (review of program statute and rule, interviews with key stakeholders and a facilitated discussion).

- The HTA has established and modified processes to carry out its statutory mandate to support the development of evidence-based coverage determinations. The processes that are in place satisfy the HTA's statutory and administrative requirements. The HTA also provides multiple opportunities for public input which are not required by statute or rule.

- The program has been responsive to stakeholder feedback and made several changes since the Stakeholder Engagement Project in 2011 to improve stakeholder communications and increase program transparency. These changes include:
 - Increasing length of public comment period for draft evidence reviews from 2 weeks to 30 days.
 - Posting a summary of public comments and responses, as well as full copies of comments received, for potential technology topics, draft key questions, draft evidence reports, and draft findings and decisions.
 - Improving website usability.
 - Posting review topic timelines.
 - Holding a public conference call with state agency staff during Topic Selection.
 - Consulting with HTCC members during public meetings on draft key questions.
 - Reordering the HTCC meeting agendas to allow public comments to follow agency presentations.
- In 2011, stakeholders critiqued every component of the coverage determination process. During the current project, stakeholder perspectives were positive in overall tone, criticisms were focused on individual components in the process, and criticisms were made by a limited subset of two categories of stakeholders (industry and provider groups). Primary areas identified for improvement by stakeholders included:
 - Increased opportunities for stakeholder participation in the state agency topic identification process.
 - Increased time for public testimony and order of testimony.
 - Transparency and access to evidence during review process.
 - Access to HTCC members.
 - Expanded role of clinical experts.
 - Increased stakeholder outreach by HTA staff.

- Improved clarity of processes to select topics for re-review.

Recommendations

The WA HTA program has developed robust processes that align with statutory and administrative requirements, and support public input and program transparency. As the HTA continues to carry out its mandates, it may consider, in the context of program resources and capacity, the following recommendations based on this review:

Process Improvements

- Improve clarity of processes to select topics for re-review. As the HTA program ages, there will be increasing need for clarity around the processes and criteria for re-reviewing previous coverage determinations.
- Develop internal administrative “checklist” system to ensure consistent posting of all HTA materials and listserv distribution notices.
- Consider scheduling a consistent date or time of year for releasing Potential Technology Topics and issuing final Topic Selections.
- Consider clarifying the role of clinical experts during HTCC meetings.

Stakeholder Communications

- Conduct ongoing stakeholder education to clarify Topic Identification process.
- Create visual diagram for topic review timelines.
- Update and consolidate website information about program processes.
- Provide high level overview of theory and methods of systematic review of evidence.

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Appendix A Washington HTA Coverage Determinations by Topic

HTA Coverage Determinations by Topic	Review Date
CANCER	
Novocure	Review open
Proton Beam Therapy	May 2014
Stereotactic Radiation Surgery & Stereotactic Body Radiation Therapy	Nov 2012
Intensity Modulated Radiation Therapy	Sep 2012
CARDIOVASCULAR	
Cardiac Stents (Re-review)	Review open
Cardiac Nuclear Imaging	Sep 2013
Carotid Artery Stenting	Sep 2013
Catheter Ablation Procedures for Supraventricular Tachyarrhythmia (SVTA), Including Atrial Flutter, Atrial Fibrillation	May 2013
Calcium Scoring	Nov 2009
Computed Tomographic Angiography	Nov 2008
EAR, NOSE & THROAT	
Tympanostomy Tubes in Children	Review open
Cochlear Implants: Bilateral versus Unilateral	May 2013
Upper Endoscopy for GERD & GI Symptoms	May 2012
METABOLIC, ENDOCRINE & NUTRITION	
Bariatric Surgery	May 2015
Testosterone Testing	Mar 2015
Screening & Monitoring Tests for Osteopenia/Osteoporosis	Nov 2014
Vitamin D Screening & Testing	Nov 2012
Glucose Monitoring	Mar 2011
Pediatric Bariatric Surgery	Aug 2007
MENTAL & BEHAVIORAL HEALTH	
Nonpharmacologic Treatments for Treatment-Resistant Depression	Mar 2014
Applied Behavioral Analysis Therapy for Autism	Jun 2011

MUSCULOSKELETAL

Lumbar Fusion (Re-review)	Review open
Hip Resurfacing (Re-review)	Nov 2013
Hyaluronic Acid/Viscosupplementation (Re-review)	Nov 2013
Cervical Spinal Fusion for Degenerative Disc Disease	Mar 2013
Bone Morphogenic Proteins for Use in Spinal Fusion	Mar 2013
Microprocessor-Controlled Lower Limb Prosthetics	Nov 2011
Osteochondral Allograft & Autograft Transplantation	Nov 2011
Femoroacetabular Impingement (FAI) Syndrome	Sep 2011
Vertebroplasty, Kyphoplasty, & Sacroplasty	Dec 2010
Knee Joint Replacement or Knee Arthroplasty	Oct 2010
Bone Growth Stimulators	Aug 2009
Artificial Discs	Oct 2008
Arthroscopic Knee Surgery	Aug 2008
Discography	Feb 2008

NEUROLOGY & PAIN MEDICINE

Functional Neuroimaging for Primary Degenerative Dementia or Mild Cognitive Impairment	Jan 2015
Facet Neurotomy	Mar 2014
Spinal Injections	Mar 2011
Spinal Cord Stimulators	Aug 2010
Electrical Neural Stimulation	Oct 2009
Vagal Nerve Stimulation	Aug 2009
Implantable Infusion Pumps	Aug 2008

IMAGING

Imaging for Rhinosinusitis	May 2015
Appropriate Imaging for Breast Cancer Screening in Special Populations	Jan 2015
Position Emission Tomography (PET) Scans for Lymphoma	Sep 2011
Routine Ultrasound for Pregnancy	Oct 2010
Breast MRI	Aug 2010
Virtual Colonoscopy or Computed Tomographic Colonography (CTC)	Feb 2008
Upright/Positional MRI	May 2007

OTHER

Hyperbaric Oxygen (HBO ₂) Treatment for Tissue Damage	Mar 2013
Robotic Assisted Surgery	May 2012
Sleep Apnea Diagnosis & Treatment in Adults	Mar 2012

Appendix B HTA Coverage Determinations Process Map

Statute & Rules

The HTCC reviews and develops coverage determinations for health technologies, defined as “medical and surgical devices and procedures, medical equipment, and diagnostic tests.” Health technologies subject to review do not include prescription drugs which are governed by a separate statute. RCW § 70.14.100

The HTA statute and rules establish three sources for identifying potential health technologies for review:

- **State agencies:** The Health Care Authority (HCA) Director shall consider nominations from participating state agencies. WAC 182-55-050
- **Members of the public:** The HCA Director may consider requests from interested parties for a technology review or re-review, submitted through a petition available on the HTA’s website. WAC 182-55-050
- **Previous determinations:** All previous determinations shall be considered for re-review at least once every 18 months from the date of the previous determination based on the availability of evidence that has since become available that may change the previous determination. RCW § 70.14.100

I. Topic Identification

HTA Process Implementation

The HTA facilitates the identification of topics through each of the potential sources identified by the HTA’s statute and/or administrative rules.

- State agencies identify topics that raise potential concern for safety, efficacy and costs through a variety of methods. These include review of state utilization data, day-to-day agency experience and knowledge, and horizon scanning to identify emerging technologies that may impact state programs.
- Members of the public may nominate topics via the Interested Party Petition, available on the [HTA’s website](#).

- Previous determinations are considered for re-review at least once every 18 months based on whether new evidence may change the previous determination.

Statute & Rules

The HCA Director shall select topics in consultation with participating state agencies and the HTCC. For new topics, priority shall be given to technologies based on concerns for safety, efficacy, cost-effectiveness, actual or expected high state expenditures, and the availability of adequate evidence to conduct the review. For previous coverage determinations, topics shall be selected for re-review if new evidence has since become available that may change the previous determination. The HTCC may select topics for review or re-review nominated via an interested party petition that are not selected by the Director. The Director must provide public notice of technologies selected for review, indicating when the review will be initiated and how an interested party may submit evidence, or provide public comment, for consideration during the review. RCW §§ 70.14.100, 130.

II. Topic Selection

HTA Process Implementation

Consultation by State Agencies & the HTCC

The HCA Director considers topics for review and re-review recommended by state agencies. Participating state agency medical directors recommend an annual list of proposed topics based on the HTA’s prioritization criteria for new topics and re-reviews of previous determinations (See: Washington HTA Prioritization Criteria). For each proposed topic, participating state agency medical directors assign a ranking (low, medium, high) for each of the primary and secondary prioritization criteria. In addition, the HTCC may provide input on potential technology topics during the two-week period when the Director publishes the potential topics for public comment.

Public Comment Opportunity on Potential HTA Technology Topics (two-week comment period)

The HCA Director releases an annual list of Potential

HTA Technology Topics (New and Re-review), and seeks public comment during a two-week comment period. The HTA posts this list to the program website and notifies stakeholders. In 2015, the HTA also hosted a public conference call to provide stakeholders the opportunity to ask questions about the potential technology topics. The Potential HTA Technology Topics (New and Re-review) document includes the following:

- Background information about HTA and selection process and criteria
- List of new proposed technologies, including ranking of each technology according to primary prioritization criteria, description of policy context and reason for selection
- List of new technologies considered, but not proposed for review
- List of previous determinations with new literature identified, including those proposed for re-review
- List of previous determinations for which the HTA has not received or identified new evidence to support further review
- Copies of surveillance reports in cases where the HTA has requested a systematic search and analysis of new evidence impacting previous determinations
- Two-week public comment period seeking comment on: proposed new topics, proposed re-reviews, and new evidence impacting previous determinations to consider for re-review

Final Topic Selections

The HCA Director selects approximately 6 to 10 topics for review on an annual cycle, based on state agency recommendations, HTCC recommendations and public comment. The HTA publishes an annual list of final topic selections on the website, and notifies stakeholders. The final HTA Selected Technologies document includes:

- Letter from the HCA Director selecting technologies for review (new and re-reviews)
- All information included in the Potential HTA Technology Topics document (see above)
- Summary of written public comments and HCA responses, including any changes adopted
- Copies of all written comments received
- Initiation of 30-day comment period providing interested parties opportunity to submit relevant information or evidence for consideration as part of review

Washington HTA Prioritization Criteria

New Topics

New topics are considered for selection based on the HTA's prioritization criteria. These criteria were developed based on the program's statutory priorities (primary criteria), in addition to other important factors to consider in the selection process (secondary criteria).

Primary criteria (statutory priorities)

- ✓ Concern for safety
- ✓ Concern for efficacy
- ✓ Concern for costs & cost-effectiveness

Secondary criteria

- ✓ Number of persons affected annually
- ✓ Severity of the condition
- ✓ Policy related urgency
- ✓ Variation in practice
- ✓ Ethical concerns or impact on special populations

Re-reviews

Previous coverage determinations are selected for re-review on the basis of whether new evidence may change the previous determination. New evidence may be identified by:

- ✓ HTA and state agency staff through the course of daily business, horizon scanning and professional activities
 - ✓ A TAC systematic search and analysis of new evidence (e.g. signals search) for complex or rapidly evolving topics, based on program resources.
 - ✓ Members of the public may submit a request for re-review at any time as well as during the comment period on topic selections.
-

III. Topic Development

Statute & Rules

Upon notice of topic selection, HCA Director shall provide interested parties the opportunity to submit evidence and other relevant information to be considered as part of the evidence review. In addition, the Director shall request state agencies to provide relevant information for consideration during the review, including state data on safety, health outcome, and costs. The HCA Director shall contract for a systematic evidence-based assessment of each technology, to be initiated no sooner than 30 days from the public posting of the final topic selections. The HCA Director shall provide all relevant information received to the TAC for consideration as part of the review. RCW §§ 70.14.100, 130; WAC 182-55-055

Health technology assessments shall evaluate the technology's safety, efficacy, cost-effectiveness, and unique impacts on specific populations based on factors such as sex, age, ethnicity, race, or disability. The HCA Director shall post key questions on the program website. RCW § 70.14.100, WAC 182-55-055

HTA Process Implementation

Opportunity for Public to Provide Relevant Information for Consideration During Review (30-day comment period)

With the notice of technology selections, the HCA Director initiates a 30-day public comment period inviting interested parties to submit evidence or other relevant information for consideration in the review. This opportunity is consistent with HTA's statutory and administrative requirements to provide interested parties the opportunity to submit evidence or relevant information for consideration during the review, and to initiate evidence reviews no sooner than 30 days following the notice of final topic selections.

Request for Information from State Agencies

The HTA requests state agencies to submit information relevant to the health technology, including agency administrative and utilization data on safety, health outcomes or costs, for inclusion in the evidence report.

Development of Annual Work Plan

The HTA develops an annual work plan and review timelines, assigns topics to TACs, and provides information submitted by state agencies and interested parties for consideration as part of the review.

Development of Draft Key Questions

The TAC develops Draft Key Questions and review protocol, in consultation with HTA and participating state agency medical directors. The Draft Key Questions are designed to address the HTA's statutory priorities regarding concern for the technology's safety, efficacy, and cost-effectiveness, and effect on special populations.

Opportunity for Public Comment on Draft Key Questions (two-week comment period)

The HTA posts Draft Key Questions on program website for a two-week public comment period, and notifies stakeholders. In addition, the HTA creates a topic page on the website for each topic, providing background information, key review dates, and opportunities for public comment throughout the process. In order to facilitate HTCC input on the Draft Key Questions, the HTA times the release of Draft Key Questions to coincide with HTCC public meeting dates, when possible.

Draft Key Questions document includes:

- Background information about the technology
- Policy context and concerns
- Draft research key questions
- Project scope (population, intervention, comparators, and outcomes)
- Two-week comment period on Draft Key Questions

Topic page on website includes:

- Key review dates and opportunities for public comments during process
- Topic summary and policy context
- Topic ranking across primary prioritization criteria
- Links to all public documents posted, including prior review documents for previous coverage determinations on the topic

Final Key Questions

The TAC reviews public comment and modifies the Draft Key Questions as appropriate. In addition, the TAC prepares a summary and response to all comments received that pertain to the Draft Key Questions, project scope, or evidence review. The HTA responds to comments that relate to HTA process or other program-related matters. The HTA posts Final Key Questions and Draft Key Questions: Public Comments and Responses on the program website, and notifies stakeholders.

Final Key Questions document includes:

- Background information about the technology

- Policy context and concerns
- Final research key questions
- Project scope (population, intervention, comparators, and outcomes)
- Link to Draft Key Questions - Public Comments & Responses (below)

Draft Key Questions - Public Comments & Responses document includes:

- Summary of public comments and TAC response
- Identification of all comment sources
- Full copies of all comments received

- Evidence findings addressing Key Questions
- Medicare and major private payer policies
- Clinical guidelines summary
- 30-day comment period on Draft Evidence Report

Final Evidence Report

The TAC reviews public and peer comment and modifies the Draft Evidence Report, as appropriate. In addition, the TAC prepares a summary and response to all comments received that pertain to the evidence review. Comments related to HTA process or other matters are acknowledged by inclusion. The HTA posts the Final Evidence Report and the Draft Evidence Report: Public Comments and Responses on the program website, and notifies stakeholders.

Final Evidence Report includes the following major components:

- Methods
- Quality assessment of studies
- Evidence findings addressing Key Questions
- Medicare and major private payer policies
- Clinical guidelines summary

Draft Evidence Report: Public Comments & Response include:

- Summary of public comments and TAC response
- Identification of all comment sources
- Full copies of all comments received

IV. Evidence Review

Statute & Rules

The HCA Director shall contract for a systematic evidence-based assessment of each technology, to be initiated no sooner than 30 days from the public posting of the final topic selections. The assessment shall include consideration of safety, health outcome, and cost data submitted by a participating agency, and evidence submitted by an interested party. The assessment must give the greatest weight to evidence determined, based on objective factors, to be the most valid and reliable, considering the nature and source of the evidence, the empirical characteristic of the studies or trials upon which the evidence is based, and the consistency of the outcome with comparable studies. The Director shall post online access to the systematic technology assessment completed (RCW §§ 70.14.100, 130).

HTA Process Implementation

Draft Evidence Report

The TAC conducts a systematic evidence review based on the final Key Questions, and includes consideration of evidence and other relevant information submitted by interested parties and state agencies.

Public Comment Opportunity on the Draft Evidence Report (30-day comment period)

The HTA posts Draft Evidence Reports online for a 30-day public comment period, and notifies stakeholders. In addition, the TAC requests peer review of Draft Evidence Report from clinical and methods experts.

Draft Evidence Report includes the following major components:

- Methods
- Quality assessment of studies

V. Coverage Determinations

Statute & Rules

The HTCC shall determine coverage of a technology reviewed, and if covered, criteria to determine medical necessity. The HTCC shall consider, in an open and transparent process, evidence regarding the safety, efficacy, and cost-effectiveness of the technology as set forth by the systematic evidence review, and shall provide opportunity for public comments. The HTCC may also consider information it deems relevant, including other information provided by the Director, reports and/or testimony from an advisory group, and public comments. All HTCC meetings are subject to Washington open public meetings law. The HCA Director shall provide online public access to HTCC determinations, and posts final HTCC determinations online within 10 days of the determination (RCW §§ 70.14.110-130, WAC 182-55-030, 040).

HTA Process Implementation

HTCC Meetings

The HTCC meets approximately every other month, with meeting dates and locations posted on the HTA's website. Meetings are typically held in person at a regional meeting or conference center for a full or half day. Individuals may also join meetings by phone. All HTCC meetings are public and subject to Washington's public meetings laws. During HTCC meetings, the Committee reviews evidence and other relevant information, and determines coverage of the technology (as outlined below).

Meeting Materials Published Two Weeks in Advance

The HTA publishes HTCC meeting agendas and materials two weeks in advance of the HTCC meetings, and notifies stakeholders. Meeting materials include the following:

- Meeting agenda
- Previous meeting business materials including draft minutes, draft findings and decisions, and public comments on draft decisions
- Public comments and presentations received in writing in advance of meeting and conflicts of interest disclosures
- State agency presentation of technology and agency utilization, current state policies, and agency recommendations
- Clinical expert curriculum vitae and conflicts of interest disclosure
- TAC presentation of evidence
- HTCC Coverage and Reimbursement Determination Analytic Tool
- Other materials to be reviewed (e.g. Draft Key Questions)

HTCC Review

The HTCC reviews technologies during public meetings and develops a draft coverage and reimbursement determination. Meetings agendas structure discussion of technologies around five basic components:

- State agency presentation
- Scheduled and open public comment
- Evidence report presentation
- HTCC questions and answers
- HTCC discussion, development of draft determination, and vote

The HTCC generally requests that a clinical expert is present at the meeting. The role of the clinical expert is to provide information about the clinical context of the technology (e.g. current practice, clinical setting, or technical details). Clinical experts sign a conflicts of

interest disclosure and agree not to advocate for a particular coverage decision and to be responsive to the Committee's questions.

The HTCC votes on one of three coverage options: not covered, covered unconditionally, or covered under certain conditions. If the HTCC members are considering coverage under certain conditions, Committee members outline those conditions. A quorum (majority of HTCC members) is required for voting, and determinations are made by the majority of voting HTCC members present. The HTCC addresses the rationale for any inconsistency between its determination and Medicare policy and clinical expert guidelines. The HTCC directs HTA staff to prepare a Draft Findings and Decision document describing the coverage determination and the HTCC's voting results. The HTCC uses the Coverage and Reimbursement Determination Analytic Tool as a guide for the coverage decision process.

Public Comment Opportunity on Draft Findings & Decision (two-week comment period)

The HTA posts Draft Findings and Decision documents for a two-week public comment period, and notifies stakeholders. The HTA publishes public comments as part of the meeting materials released two weeks in advance of the next HTCC meeting.

The Draft Findings and Decision document includes:

- Draft Coverage Determination
- Draft Reimbursement Determination (outlines conditions of coverage)
- HTCC voting results and formal actions
- Link to meeting transcript documenting rationale for the decision

HTCC Final Adoption of Findings & Decision

At the HTCC's next public meeting, HTCC members review public comments and vote to adopt a final Findings and Decision document. The HTA posts the HTCC Findings and Decision document online within 10 days of the final determination, and notifies stakeholders.

The HTCC Findings and Decision document includes:

- Final Coverage Determination
- Final Reimbursement Determination (outlines conditions of coverage)
- HTCC voting results and formal actions
- Link to meeting transcript documenting rationale for the decision

Agency Implementation

Upon publication of the HTCC Findings and Decision, participating agencies will implement the HTCC's determination according to each agency's statutory, regulatory or contractual process, unless the determination conflicts with federal or state law.

Appendix C Case Example: *Proton Beam Therapy*

Proton Beam Therapy is a form of radiation therapy that focuses delivery of radiation to a target tumor and may reduce toxicity associated with normal tissue damage. The HTCC reviewed Proton Beam Therapy and issued a decision in July 2014 to cover the technology under specific conditions. Below is a review of the key process steps carried out by the program to reach this coverage determination.

I. Technology Identification

For the 2013 topic selection cycle, state agencies recommended Proton Beam Therapy for review based on concerns for the technology's safety, efficacy, and cost-effectiveness. While recognizing that Proton Beam Therapy may offer an important therapeutic option for specific cancers, state agencies recommended the technology for review based on the following rankings of the program's priority concerns: safety=medium, efficacy=high, and cost=high.

II. Technology Selection

The HCA Director selected Proton Beam Therapy as part of the 2013 selection cycle. Key process steps carried out to support this selection decision included:

1. *Consultation by state agencies and the HTCC:* The HCA Director considered the state agencies' recommendation to review Proton Beam Therapy based on safety, efficacy, and costs concerns. In addition, the Director sought HTCC member input during the public comment opportunity on the potential technology topics.
2. *Public comment opportunity on Potential Technology Topics:* The HCA Director proposed Proton Beam Therapy as part of the list of 2013 Potential Technology Topics (New and Re-review), and sought public comment during a two-week period (November 19, 2012 - December 3, 2012)

Note: In more recent topic selection cycles (2014 and 2015), the HCA Director, in response to stakeholder requests, has significantly increased the level of information provided as part of the release of Potential Technology Topics (New and Re-review). In addition to the list of topics proposed for review and re-review,

the Potential Technology Topics document now includes information regarding the rationale and ranking of prioritization criteria for each topic (see Appendix B Process Map for further detail).

3. *Final topic selections:* The HCA Director issued final topic selections on December 6, 2012, notified stakeholders and posted on the HTA website. Proton Beam Therapy was 1 of 9 technologies selected for review (7 new reviews, 2 re-reviews).

Note: In more recent topic selection cycles (2014 and 2015), the HCA Director now includes information regarding the rationale and ranking of prioritization criteria for each topic, a summary of comments and HCA response, and full copies of all comments received (see Appendix B Process Map for further detail).

III. Topic Development

During topic development, the HTA facilitated submission of relevant information from interested parties and state agencies for consideration during the review. In addition, the HTA supported the development of Key Questions by the TAC to guide the review. Key process steps carried out during topic development included:

1. *Public comment opportunity to submit evidence:* Upon notice of the 2013 Technology Selections, the HCA Director initiated a 30-day public comment period (December 6, 2012 through January 7, 2013) inviting interested parties to submit evidence or other relevant information for consideration during the review of Proton Beam Therapy (as well as other topics selected).
2. *Request for state agency information:* The HTA requested state agencies to submit relevant information, including administrative or utilization data on safety, health outcome, and costs, for inclusion in the evidence report.
3. *Public comment opportunity on Draft Key Questions:* The TAC developed Draft Key Questions focused on the Proton Beam Therapy's safety, efficacy, and cost-effectiveness, and effect on special populations. The HTA posted Draft Key Questions for Proton Beam Therapy on the program website for a two-week public comment period (September 20, 2013 - October 7,

2013). The Proton Beam Therapy Draft Key Questions included:

- Draft key questions
- Topic background and policy context
- Project scope (population, intervention, comparators, and outcomes)
- Analytic framework given the anticipated evidence base

The HTCC reviewed and provided input on the Draft Key Questions at their September 20, 2013 meeting. With the release of Draft Key Questions, the program also created a Proton Beam Therapy topic page on the program's website with background information about the topic and key review dates.

Thirty-two individuals submitted comments addressing the Proton Beam Therapy Draft Key Questions or related evidence, and an additional 764 individuals submitted general comments.

4. *Final Key Questions:* The TAC reviewed public comments and modified the Draft Key Questions, as appropriate. The Director posted the Final Key Questions on the program website and notified program stakeholders on November 19, 2013.

In addition to the Final Key Questions, the program published a Draft Key Questions: Public Comments & Responses. This document included a summary of comments and the TAC responses on the Draft Key Questions, including identification of changes made³.

IV. Evidence Review

1. *Draft Evidence Report:* The TAC conducted a systematic review of evidence for Proton Beam Therapy, and developed a Draft Evidence Report addressing the Key Questions defined.
2. *Public comment opportunity on the Draft Evidence Report:* The HTA published the Draft Evidence Report on the program website for a 30-day public comment period (February 7 – March 10, 2014).
3. *Final Evidence Report:* The TAC reviewed and responded to peer and public comments on the Draft Evidence Report. Two parties submitted comments. The program published the Final Evidence Report on the program website on April 11, 2014. In addition, the program published a Proton Beam Therapy – Draft Report Public Comments and Response with the release of the final evidence report. This document included a summary of public

comments and TAC responses³.

V. Coverage Determination

1. *Meeting materials published in advance:* The HTA published meeting materials for Proton Beam Therapy two-weeks in advance of the May HTCC meeting. Materials specific to the discussion of Proton Beam Therapy included:

- Public commenters registered in advance, including conflict of interest disclosures and comments received
- Clinical expert qualifications and conflicts of interest disclosure
- State agency presentation slides
- TAC presentation slides

2. *HTCC Review:* At the May 2014 HTCC public meeting, the Committee reviewed Proton Beam Therapy and issued a draft decision to cover with conditions.

The meeting agenda structured discussion as follows:

- *Scheduled and open public comments:* Nine parties presented public comments representing providers, proton beam therapy centers, and patients.
- *Agency presentation:* The Health Care Authority Chief Medical Officer presented the state agency utilization rates for proton beam therapy, current state policies, and the medical directors' recommendations for coverage.
- *TAC Presentation:* The TAC (Institute for Clinical and Economic Research) presented the evidence review.
- *HTCC Q & A:* The HTCC discussed and asked questions of TAC and state agencies. In addition, a clinical expert from the University of Washington School of Medicine (Department of Radiation Oncology, Department of Neurological Surgery) was available to address HTCC member questions regarding current practice and the clinical context for use of Proton Beam Therapy.
- *Committee Discussion and Decision:* The HTCC deliberated and worked toward a decision regarding coverage. The HTCC members submitted 10 votes in favor of coverage with conditions (one committee member was absent). The Committee directed program staff to prepare a Draft Findings and Decision document

³ This review noted a few instances in which program documents did not include certain information that was intended (e.g., copies of full comments received). These issues did not involve mandatory aspects of the process, and were noted for purposes of process and program improvement opportunities.

reflective of the Committee vote and conditions of coverage developed.

Note: We identified that as compared to the current process, meeting agendas are now structured to allow public comments to follow the state agency presentation. This change was made in response to stakeholder requests to allow opportunity for public comments to respond to information presented by state agencies (see Appendix B Process Map for further detail).

3. *Public comment opportunity on Draft Findings and Decision:* Program staff developed a Proton Beam Therapy Draft Findings and Decision document and published for a two-week public comment period (June 2, 2014 - June 16, 2014). Five parties submitted comments.
4. *HTCC Final Adoption:* At the July 11, 2014 public meeting, HTCC members reviewed the Draft Findings and Decision and public comments, and clarified terminology. After review, the Committee members voted 10 in favor to approve the Findings and Decision document (one member was absent). The HTA published the final Findings and Decision document on the program website within 10 days of the final determination, including the following information:
 - Final Coverage Determination
 - Final Reimbursement Determination (outlines conditions of coverage)
 - HTCC voting results and formal actions
 - Link to meeting transcript documenting rationale for the decision

11. [HTCC Meeting Agenda \(July 11, 2014\)](#)
12. [HTCC Meeting Material, Proton Beam Therapy Timeline Overview \(July 11, 2014\)](#)
13. [HTCC Meeting Material, Proton Beam Therapy Drafting Finding and Decision with Edits \(July 11, 2014\)](#)
14. [HTCC Meeting Minutes \(July 11, 2014\)](#)

Resources

1. [WA HTA, Proton Beam Therapy, Topic Page](#)
2. [2013 Technology Selections](#)
3. [Final Key Questions: Proton Beam Therapy](#)
4. [Proton Beam Therapy, Draft Key Questions: Public Comments & Response](#)
5. [Draft Report Comments and Response: Proton Beam Therapy](#)
6. [Final Evidence Report: Proton Beam Therapy](#)
7. [Findings and Decision: Proton Beam Therapy](#)
8. [HTCC Meeting Agenda, Proton Beam Therapy \(May 16, 2014\)](#)
9. [HTCC Meeting Materials, Proton Beam Therapy \(May 16, 2014\)](#)
10. [HTCC Meeting Minutes \(May 16, 2014\)](#)

Appendix D Case Example: Vitamin D Screening & Testing

The Health Technology Clinical Committee reviewed Vitamin D Screening and Testing and issued a decision in March 2013 to cover the service under specific conditions. The case study below summarizes of the key process steps carried out to reach this coverage determination.

I. Technology Identification

Vitamin D Screening and Testing may be performed for a variety of concerns including Vitamin D insufficiency, risk of poor bone health, presence of conditions resulting in malabsorption or altered metabolism, and suspected toxicity. Assessing Vitamin D levels may be useful to influence diagnostic or treatment decisions in some circumstances, though the usefulness of testing is uncertain in others, especially among healthy subjects. State agencies determined the need for further evaluation of evidence regarding the usefulness of Vitamin D Screening and Testing, particularly with increasing state spending on this testing. For the 2012 topic selection cycle, state agencies recommended Vitamin D for review based on the following rankings of the program's priority concerns: safety=low, efficacy=high, and cost=high.

II. Technology Selection

The HCA Director selected Vitamin D Screening and Testing as part of the 2012 selection cycle. Key process steps carried out to support this selection decision included:

1. *Consultation by state agencies and the HTCC:* The HCA Director considered the state agencies' recommendation to review Vitamin D Screening and Testing based on the following rankings of the program's priority concerns: safety=low, efficacy=high, and cost=high. In addition, the Director sought HTCC member input during the public comment opportunity on the potential technology topics.
2. *Public comment opportunity on Potential Technology Topics:* The HCA Director proposed Vitamin D Screening and Testing as part of the list of 2012 Potential Technology Topics (New and Re-review), and sought public comment during a two-week period (November 1, 2011 – November 15, 2011).

Note: In more recent topic selection cycles (2014 and 2015), the HCA Director, in response to stakeholder

requests, has significantly increased the level of information provided as part of the release of Potential Technology Topics (New and Re-review). In addition to the list of topics proposed for review and re-review, the Potential Technology Topics document now includes information regarding the rationale and ranking of prioritization criteria for each topic (see Appendix B Process Map for further detail).

3. *Final topic selections:* The HCA Director issued final topic selections on November 29, 2011, notified stakeholders and posted on the HTA website. Vitamin D Screening and Testing was 1 of 10 technologies selected for review.

Note: The current process includes a summary of comments and HCA response, in addition to a full copy of all copies received, with the notice of final topic selections. This information was not included as part of the 2012 topic selection cycle. At the time of the Vitamin D Screening and Testing review, comments on the Potential Technology Topics were addressed as part of the response to comments on the Draft Key Questions (see Appendix B Process Map for further detail).

III. Topic Development

During topic development, the HTA facilitated submission of relevant information from interested parties and state agencies for consideration during the review. In addition, the HTA supported the development of Key Questions by the TAC to guide the review. Key process steps carried out during topic development included:

1. *Public comment opportunity to submit evidence:* Upon notice of the 2012 Technology Selections, the HCA Director initiated a 30-day public comment period (November 29, 2011 through December 29, 2011) inviting interested parties to submit evidence or other relevant information for consideration during the review of Vitamin D Screening and Testing (as well as other topics selected).
2. *Request for state agency information:* The HTA requested state agencies to submit relevant information, including administrative or utilization data on safety, health outcome, and costs, for inclusion in the evidence report.

3. *Public comment opportunity on Draft Key Questions:* The TAC developed Draft Key Questions focusing on the safety, efficacy, and cost-effectiveness, and effect on special populations for Vitamin D Screening and Testing. The HTA posted Draft Key Questions for Vitamin D Screening and Testing on the program website for a two-week public comment period (April 27, 2012 – May 14, 2012). The Vitamin D Screening and Testing Draft Key Questions included:

- Draft key questions
- Topic background and policy context
- Project scope (population, intervention, comparators, and outcomes)

One organization submitted comments (Northwest Alliance of Multiple Sclerosis Centers) on the Draft Key Questions. The TAC prepared a summary and response to these comments. The TAC noted that references would be considered for inclusion in the review. No changes to the key questions were needed. With the release of Draft Key Questions, the program also created a Vitamin D Screening and Testing topic page on the HTA's website with background information about the topic and key review dates.

Note: By comparison to the current process, the HTCC did not review the Draft Key Questions during a public meeting, although the HTCC had the opportunity to review during the public comment period (see Appendix B Process Map for further detail).

4. *Final Key Questions:* The Director posted the Final Key Questions on the program website and notified program stakeholders on June 6, 2012.

In addition to the Final Key Questions, the program published a Draft Key Questions: Public Comments & Responses. This document included a summary of comments and the TAC responses on the Draft Key Questions, including full copies of comments received.

IV. Evidence Review

1. *Draft Evidence Report:* The TAC conducted a systematic review of evidence for Vitamin D Screening and Testing, and developed a Draft Evidence Report addressing the Key Questions defined.

2. *Public comment opportunity on the Draft Evidence Report:* The HTA published the Draft Evidence Report on the program website for a 30-day public comment period (August 31– October 1, 2012). One individual submitted comments on the Draft Evidence Report.

3. *Final Evidence Report:* The TAC reviewed and

responded to peer and public comments on the Draft Evidence Report. The program published the Final Evidence Report on the program website on October 8, 2012, and notified stakeholders.

In addition, the program published a Vitamin D Screening and Testing – Draft Evidence Report Public Comments and Response with the release of the final evidence report. This document included a summary of public comments and TAC responses, addition to a full copy of comments received⁴.

V. Coverage Determination

1. *Meeting materials published in advance:* The HTA published meeting materials for Vitamin D Screening and Testing two-weeks in advance of the November 2012 HTCC meeting. Materials specific to the discussion of Vitamin D Screening and Testing included:

- Public commenters registered in advance, including conflict of interest disclosures
- Clinical expert qualifications and conflicts of interest disclosure
- State agency presentation slides
- TAC presentation slides

2. *HTCC Review:* At the November 16, 2012 HTCC public meeting, the Committee reviewed Vitamin D Screening and Testing and issued a draft decision to cover with conditions. Eleven committee members voted in favor of coverage with conditions.

The meeting agenda structured discussion as follows:

- *Scheduled and open public comments:* Two individuals representing the NW Alliance of Multiple Sclerosis Centers scheduled time for the public comment. No open public comments were presented.
- *Agency presentation:* The Chief Medical Officer, Department of Corrections, presented the state agency utilization rates for Vitamin D Screening and Testing to the committee, current state policies, and the medical directors' recommendations for coverage.
- *TAC presentation:* The TAC (Hayes, Inc.) presented the evidence review.
- *HTCC Q & A:* The HTCC discusses and asks questions of TAC and state agencies. In addition, a clinical expert from the University of Washington (Department of Medicine;

⁴ This review noted a few instances in which program documents did not include certain information that was intended (e.g., copies of full comments received). These issues did not involve mandatory aspects of the process, and were noted for purposes of process and program improvement opportunities.

Radiology, Pathology and Orthopedics) was available to address HTCC member questions regarding current practice and the clinical context for use of Vitamin D Screening and Testing.

- *Committee Discussion and Decision:* The HTCC deliberated and worked toward a decision regarding coverage. The HTCC members submitted 11 votes in favor of coverage with conditions. The Committee then directed program staff to prepare a Draft Findings and Decision document reflective of the Committee vote and conditions of coverage developed

Note: Under the current process, meeting agendas are now structured to allow public comments to follow the state agency presentation. This change was made in response to stakeholder requests to allow opportunity for public comments to respond to information presented by state agencies (see Appendix B Process Map for further detail).

3. *Public comment opportunity on Draft Findings and Decision:* Program staff developed a Vitamin D Screening and Testing Draft Findings and Decision document and published for a two-week public comment period (December 7, 2012 – December 21, 2012). No comments were submitted.
4. *HTCC Final Adoption:* At the March 22, 2013 public meeting, HTCC members reviewed the Draft Findings and Decision. No public comments were received. Committee members voted nine in favor of approving the Findings and Decision document (two members were absent). The HTA published the final Findings and Decision document on the program website within 10 days of the final determination, including the following information:
 - Final Coverage Determination
 - Final Reimbursement Determination (outlines conditions of coverage)
 - HTCC voting results and formal actions
 - Link to meeting transcript documenting rationale for the decision

Resources

1. [WA HTA, Vitamin D Screening and Testing, Topic Page](#)
2. [2012 Technology Selections](#)
3. [Final Key Questions: Vitamin D Screening and Testing](#)
4. [Draft Key Questions Public Comments: Vitamin D Screening and Testing](#)
5. [Draft Report Comments and Response: Vitamin D Screening and Testing](#)
6. [Final Evidence Report: Vitamin D Screening and Testing](#)
7. [Findings and Decision: Vitamin D Screening and Testing](#)
8. [HTCC Meeting Agenda, Vitamin D Screening and Testing \(November 16, 2012\)](#)
9. [HTCC Meeting Material, Vitamin D Screening and Testing \(November 16, 2012\)](#)
10. [HTCC Meeting Minutes \(November 16, 2012\)](#)
11. [HTCC Meeting Agenda \(March 22, 2013\)](#)
12. [HTCC Meeting Minutes \(March 22, 2013\)](#)
13. [HTCC Meeting Material, Previous Business \(March 22, 2013\)](#)

Appendix E Stakeholder Interview Guide

1) Can you briefly tell me a little about yourself and your experience as it relates to the WA HTA Program?

2) The WA HTA Program is mandated to:

- *Review selected technologies and make coverage determinations using scientific evidence*
- *Contract for independent evidence-based reports to support 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 technologies for review or re-review*
- *Provide transparent processes and opportunity for public input/comment*
- *Develop and maintain a centralized, public internet site to:*
 - *Provide notification of topic selection and review schedules*
 - *HTCC determinations, processes and effective dates*
 - *Evidence-based reports used in HTCC determinations*

What are your thoughts regarding how well the Program is doing in terms of meeting this mandate?

3) Overall, how satisfied are you with current Program processes?

4) The WA HTA Health Technology Clinical Committee makes coverage decisions that are implemented by multiple state agencies. These include:

- Medicaid
- Uniform Medical Plan

- Labor and Industries
- Department of Corrections (voluntary policy adoption)

In your opinion, are the uptake patterns within these departments similar? If not, what variations do you see?

5) What do you think has been the impact of HTA decisions on various stakeholder audiences? Please begin with the impact, on your own organization or group and then we can talk about other groups.

6) What are your thoughts regarding specific HTA decisions of the past? Which decisions have you perceived as having resulted in significant changes to coverage? Health outcomes? Utilization? Cost? Other?

7) Is there anything else you would like to add?