MEDICAL TECHNOLOGY ASSESSMENT PROGRAM [MedTAP][1]

INTRODUCTION

The eleven-member, Governor-appointed Oregon Health Resources Commission (HRC) consists of four physicians, two pharmacists, and one representative each of hospitals, insurers, business, organized labor, and consumers. Its purpose is to encourage the rational, responsible and appropriate allocation and use of health technology in Oregon by informing and influencing decision makers, including consumers, through the collection, analysis, synthesis and dissemination of information concerning the use, effectiveness and cost of health technologies and their impact on health care of Oregonians. Its major activity is to conduct a medical technology assessment program (MedTAP) that addresses the introduction, diffusion and utilization of health technologies.

Medical Technology includes the equipment and devices, drugs or other pharmaceuticals (including vaccines); medical, surgical, or other procedures used to screen, prevent, diagnose, and treat disease; as well as the health systems (such as electronic health records) which support these activities.

Advances in health technology create a steady stream of new diagnostic and treatment options that may improve the quality of health care in Oregon. However, the rapid pace of innovation and the increasing complexity and cost of health technologies also create new challenges. In order to identify technologies that will improve health outcomes and deliver value for every health care dollar invested; health policy makers, administrators and professionals need clear answers to difficult questions such as: Does a technology offer clinical advantage over the alternatives? What is the balance of benefit and risk? Is it cost-effective? Are incremental health benefits worth the cost? What conditions/ patients would benefit from its use? What conditions/patients should be excluded?[2]

OVERVIEW

The Commission has limited resources to assess medical technologies in depth annually. The process for identifying, screening and selecting medical technologies for assessment seeks out those that have the highest likely impact on the health and health care of Oregonians, the cost of that care, and the Oregon Health Plan's goal of achieving universal access to an adequate level of high quality health care at an affordable cost.

The actual conduct of an assessment is open to the public, and involves both technical and policy components. For each medical technology assessed, the Commission appoints a Technical Advisory Panel (TAP) of experts who volunteer

[1] HRC Policy 1994
[2] Shaded sections are updated proposed HRC Policy January 2006

to perform the technical component by reviewing available existing evidence from published and unpublished sources following a protocol developed by the HRC.

TECHNICAL ADVISORY PANEL REPORT

Members of a TAP include both specialized and primary care physicians, other health care professionals, and health services researchers, all of whom are appointed by the Commission in consultation with statewide or local professional, trade, or academic associations. The Commission will attempt to achieve representation from major geographic regions of the state and from metropolitan and non-metropolitan communities on each TAP

Members of the TAP are required to complete a Conflict of Interest questionnaire and recuse themselves from voting on any issue for which they have a vested financial interest. Each TAP prepares a written report and recommendations to the Commission regarding the science behind the assessed medical technology, its appropriate indications for use, its benefits and risks and its clinical effectiveness relative to alternatives, factors affecting its effective and efficient provision, and advisory clinical practice guidelines for its use; the TAP then presents its report to the Commission at a public meeting.

After accepting a TAP's report, the Commission conducts the policy and cost-effectiveness component of the medical technology assessment at a public meeting by considering available policy-relevant information and evaluating the medical technology's broader health care, social, and economic impacts. The Commission next combines the technical and policy components of the assessment, evaluates the medical technology's performance based on the Commission's assessment criteria, and reaches recommendations regarding the medical technology's utilization in Oregon.

DISSEMINATION

Once an assessment is finalized, it is made available on our web site at http://www.ohpr.state.or.us/DAS/OHPPR/HRC/index.shtml to health care providers, payers, purchasers, policy makers, and the public to foster informed decision making and policy development. Thus, the MedTAP helps practitioners and their patients make clinically and cost-effective treatment choices, helps providers make responsible and cost-effective technology acquisition, helps payers and health plans make reasonable and prudent coverage and payment decisions, and helps public agencies make sound public policy about the value of the technology in the face of limited resources.

To help assure the cost-effectiveness of the Oregon Health Plan, the Commission shares the results of a medical technology assessment with the Health Services Commission for its use in revising its Prioritized List of health services. Similarly, the Commission notifies the Department of Human Services

(DHS), Oregon Medical Assistance Plan (OMAP), and other health-related state agencies regarding its findings and recommendations.

MONITORING

Working cooperatively with Oregon Health Policy and Research (OHPR) data division, the Commission seeks to obtain Oregon data needed to monitor the utilization of an assessed medical technology and its effects on the health system. The results of this monitoring are periodically shared with the same groups to whom the assessment was disseminated. These results also provide evidence that the Commission can use in deciding whether or not to reassess a medical technology.

REASSESSMENT

Given the continuous evolution of medical technologies and how they are used, single-point-in-time assessments must be periodically reevaluated and updated. As significant new information and evidence regarding an assessed medical technology becomes available to the Commission, or when the scheduled reassessment date for that technology as specified in its assessment is reached, the Commission will evaluate the need for, and feasibility of, reassessing that technology.

THE 10 STAGE PROGRAM

STAGE 1: Identifying Potential Candidate Technologies

In order to identify potential candidate technologies for assessment by the Commission, staff reviews the health care literature; discusses technology developments with biomedical, clinical and health services professionals and researchers; monitors regional, national and international technology assessment efforts; and organizes and manages a process to gather potential candidate technology nominations/recommendations from the following sources:

(1) Physicians and other licensed health care professionals licensed to practice in Oregon, especially through their local and statewide professional associations and specialty societies;
(2) Health care payers licensed in Oregon or participating in the various programs of the Oregon Health Plan, especially through their medical directors;
(3) Hospitals and other health care facilities licensed to operate in Oregon and any Oregon-based health system/integrated delivery network of which such facilities are members or any other health care provider (see definitions) not elsewhere specified;
(4) Oregon State agencies and programs, boards and commissions, councils, executive branch officials, and Legislative Assembly members or

legislative or committee staff, especially those with health-related functions;
(5) Health plan purchasers which sponsor or provide health care coverage for Oregon residents, especially through coalitions or consortiums of such purchasers;
(6) Health industry manufacturers and or pharmaceutical manufacturers, especially through their statewide and national associations;
(7) Oregon health care consumers and their advocacy organizations.

STAGE 2: Screening Potential Candidate Technologies

At a public meeting of the Commission, staff presents the list of potential candidate technologies identified through Stage 1. The Commission then evaluates them against the following screens:

(1) Is there significant debate or disagreement among health care providers or payers, or in the health care literature, regarding the indications for use and/or the clinical or cost-effectiveness of this technology? Is their geographic or specialty variation in utilization within Oregon?
(2) Is this technology likely to have a significant impact on the cost or quality of or access to health care in Oregon?
(3) Is this technology strongly recommended in Stage 1 by one or more nominating sources as a potential candidate for assessment?
(4) Is this technology assessment likely to meaningfully address any significant clinical, social, ethical or legal issues?

Those medical technologies to which the Commission can answer 'Yes' on all four of these screens become candidates for selection in Stage 3.

STAGE 3: Selecting Technologies for Assessment

As previous assessments are completed and new ones started, the Commission designates a public meeting to prioritize the candidate technologies successfully passing the Stage 2 screens. The Commission reviews information supplied by staff regarding these technologies and, depending on the resources the Commission can commit to starting new assessments at that time, selects one or more of them for assessment.

STAGE 4: Conducting the Assessment

4 a. Key Questions

The MedTAP develops Key Questions built upon the model used by the Drug Effectiveness Review Project (DERP) that includes the following basic key questions
:

(1) What is the comparative efficacy or effectiveness of the therapeutic intervention compared to other therapies?
(2) What is the comparative safety of the therapeutic intervention compared to other therapies?
(3) Are there sub-groups of patients based on co-morbidity that would compare differently in efficacy, effectiveness, or safety from the average?

Furthermore, the HRC will add Key Questions for the policy phase based on:
(1) What is the cost-effectiveness of the therapeutic intervention compared to other therapies?
(2) What is the affordability, equity and value of specific benefits and harms?

The Key Questions, scope of the review including patient inclusion and exclusion criteria, relevant clinical outcomes, and study designs will be determined by the TAP and approved by the HRC.

4 b. Search Strategy and grading of evidence

Staff will identify and critically appraise the literature looking for systematic reviews from Cochrane, AHRQ, NICE, TEC but if no fair-good systematic reviews are available, staff will access pertinent peer-reviewed articles of the best available evidence using the OH&SU EPC methods[3]. For quality of evidence the MedTAP will take into account the number of studies, the total number of patients in each study, the length of the study period, and the end points of the studies. The MedTAP will utilize the EPC's ratings of "good, fair or poor" for grading the body of evidence and excludes "poor" evidence. Overall quality ratings for an individual study will be based on the internal and external validity of the trials.

4 c. Validity

The internal validity of each trial will be based on:
(1) Methods used for randomization
(2) Allocation concealment and blinding
(3) Similarity of compared groups at baseline and maintenance of comparable groups.
(4) Adequate reporting of dropouts, attrition, and crossover
(5) Loss to follow-up
(6) Use of intention-to-treat analysis

External validity of trials will be assessed based on:
(1) Adequate description of the study population
(2) Similarity of patients to other populations to whom the intervention would be applied
(3) Control group receiving comparable treatment

[3] McDonagh MS, Santa J, and Seolver D "Drug Class Review on Agents for Overactive Bladder", December 2005, Oregon Evidence-based Practice Center Oregon Health & Science University. P 5-7

(4) Funding source that might affect publication bias.

A particular randomized trial may receive two different ratings: one for efficacy and another for adverse events. The overall strength of evidence for a particular key question will reflect the quality, consistency and power of the body of evidence relevant to that question. Consideration of publication bias will be reported when available.

Stage 5. Technical Report

MedTAP meetings will be public and conducted in a manner consistent with the HRC's evidence-based drug reviews. After discussing the best evidence, the HRC appointed TAP will draw conclusions as to overall importance of beneficial effects, side effects, and compliance. If consensus is not possible, the decision will be by majority vote, with a minority opinion expressed in the report. The TAP is expected to complete its technical component of an assessment and prepare a written consensus report with recommendations to the Commission within 3-4 months. At a minimum, a TAP's report will contain:

(1) a description of the assessed medical technology and the science which underlies it;
(2) the recommended clinical indications for use of the assessed medical technology based on technical considerations
(3) an assessment of the medical technology's technical performance: its clinical benefits and risks (including safety and efficacy considerations and required regulatory approvals); its risk/benefit ratio; and its relative clinical effectiveness in achieving intended preventive, diagnostic, therapeutic, and/or rehabilitative outcomes for the indicated use(s) compared to established alternatives for the same indication(s);
(4) the factors affecting the quality, effectiveness, and efficiency in providing or using the assessed medical technology;
(5) the relevant clinical practice guidelines for the use of the assessed medical technology;
(6) any other technical advice regarding the assessed medical technology as specifically requested by the Commission;
(7) an evaluation of the quality and sufficiency of available evidence for assessing the technical performance of the medical technology, along with recommendations for improving inadequate or insufficient evidence;
(8) the strength of the recommendations and the confidence in the conclusions reflecting the power of the evidence.
(9) the recommendation regarding the frequency and circumstances that the assessed medical technology should be reassessed.

The MedTAP's Report will be available on the web for public review prior to presentation at the HRC meeting. The TAP then presents its report and recommendations to the Commission at a public meeting where testimony will be

entertained. The Commission discusses the report in view of any testimony heard and either accepts the report or defers its acceptance pending further requested information or clarification.

Stage 6. Policy Report

After accepting a TAP's assessment of a medical technology, the Commission will conduct the policy component of the report during public meeting(s) designated for this purpose. One or more epidemiologists, biostatisticians, medical economists, health services researchers or other similar professionals who are experts in research methodology may be appointed as needed to facilitate their decisions. The Commission will consider policy-relevant information from the following sources: staff reports and analyses; policy relevant material from the TAP's report; public testimony it specifically solicits regarding the medical technology; recommendations from any consumers/consumer advocates, medical directors of payer organizations, and/or health industry or pharmaceutical manufacturers; and any other policy-related information that bears on the public interest. Factors that the Commission considers during the policy component of a medical technology assessment include:

(1) the TAP's recommended indications for use of the medical technology
(2) the estimated current and projected future relative cost of providing the medical technology in Oregon compared to providing alternative established technologies
(3) the medical technology's relative cost-effectiveness compared to that of alternative established technologies for improving the desired health outcomes for recommended indications
(4) the likely relative overall net health, health care, and social and economic consequences and impacts of providing and using the medical technology in Oregon
(5) any special patient population that would be effected by the policy recommendations
(6) any significant social, ethical, and legal issues bearing on the medical technology and its use in Oregon
(6) the quality and sufficiency of the available policy-relevant evidence regarding the medical technology.

STAGE 7: HRC Recommendations

Based on the technical and policy components of the assessment of a medical technology, the Commission reaches final conclusions regarding the introduction, diffusion, distribution, and use of that technology in Oregon. The Commission then incorporates its determinations into the advisory HRC recommendations it develops for the medical technology. The Commission solicits public testimony to gather public input regarding its plan for this medical technology's use in Oregon.

The written HRC Recommendations includes the following:

(1) The Commission's recommendations regarding the technology's appropriate indications and utilization

(2) The Commission's determination of the current and 5-year projected utilization in Oregon for any indicated uses of the medical technology;

(3) The Commission's estimation of the appropriate provision and use of the medical technology provided at an affordable cost in Oregon;

(4) Any additional determinations or recommendations the Commission believes are relevant to meeting the indicated need for the medical technology in Oregon;

(5) The Commission's recommendations regarding monitoring the impact of the medical technology in Oregon

(6) The Commission's plans for disseminating the Medical Technology Assessment and associated Health Resources Plan to inform and influence health care decision making regarding the medical technology and its use in Oregon; and

(9) The Commission's recommendation regarding when and/or under what conditions the medical technology should undergo reassessment along with an expiration date for the current Medical Technology Assessment and HRP.

The Commission next prepares a preliminary written document combining the Medical Technology Assessment and associated HRC Recommendations for a medical technology. This document includes the TAP's Report and Recommendations as an appendix.

Even though the HRC Recommendations and the assessment on which it is based are advisory rather than regulatory, the Commission adheres to Oregon's Administrative Procedures Act by providing interested parties reasonable time and opportunity to comment on the draft report. The Commission makes the draft document available to interested parties and solicits testimony from them regarding the assessment and recommendations. The Commission then reviews and considers the testimony and comments received, solicit or invite any additional testimony it believes it still needs for finalizing the preliminary document, and then revise the draft document. The finalized written MedTAP and associated advisory recommendations are then disseminated during Stage 8.

STAGE 8: Disseminating the MedTAP and HRP

The Commission widely disseminates the results of a MedTAP and its associated recommendations to inform and influence health care decisions and policy on the part of health care providers and provider networks, payers, purchasers, consumers, and policy makers.

Commission staff works with various entities including public agencies; public and private health and medical educational institutions, programs and foundations; associations and membership groups of health care professionals and managers; payers, health plans and provider systems and networks; purchasing groups and alliances; consumer advocacy groups; and local news media to disseminate MedTAPS and their associated recommendations. Staff also makes appropriate use of telecommunications and electronic media, including the Commission's internet website, in this dissemination effort.

To help assure the cost effectiveness of the Oregon Health Plan, the Commission shares the results of MedTAPs and their associated recommendations with the Health Services Commission (HSC) and requests that it take them into account when revising the Prioritized List of services for the Oregon Health Plan. Similarly, the Commission notifies OMAP and its Medical Directors from the participating health plans.

The Commission also notifies the results of its MedTAP and associated recommendations to other appropriate state agencies and programs including: the Workers Compensation Division, the Insurance Division, the Health Division, the Office for Oregon Health Policy and Research, the Health Policy Commission, the Insurance Pool Governing Board, the Oregon Medical Insurance Program, the Family Health Insurance Assistance Program, the Public Employees Benefits Board, the Public Employees Retirement System, and members and staff of appropriate legislative committees and recommends that they take them into account in developing public policy regarding that technology.

STAGE 9: Monitoring and Evaluating Outcomes

Relying to the greatest extent possible on currently available data systems, the Commission will work cooperatively with OHPR and appropriate public and private sources to monitor and evaluate the net health and health system (access, quality and cost) outcomes resulting from the use of an assessed medical technology in Oregon. The results of this monitoring are periodically shared with those receiving the MedTAP and associated recommendations to help inform and influence their decisions and policies regarding that technology.

STAGE 10: Reassessing Technologies

Given the continuous evolution both of the research evidence regarding a medical technology's performance and of the technology itself and how it is used, single-point-in-time assessments must be periodically reevaluated and updated to reflect this new evidence.

This stage links the end of the assessment process with its beginning: the information sources consulted during Stage 1 to help identify potential candidate medical technologies for initial assessment also provide information regarding

new evidence and developments for previously assessed medical technologies. When significant evidence and/or developments accumulate that potentially warrant the reassessment of a medical technology, or when the reassessment date or conditions specified in a previously assessed medical technology's Health Resources Plan are reached, staff brings this information to the attention of the Commission along with other Stage 1 information, and the candidate for reassessment is evaluated, screened, and prioritized along with any other candidates for assessment.

If the Commission chooses *not* to reassesses a medical technology before the expiration date for that technology's Health Resources Plan is reached, the recommendations become obsolete unless the Commission extends its expiration date in the absence of significant new evidence or developments regarding the technology.

If the Commission chooses to reassesses a medical technology, depending on the nature and extent of the new evidence or developments and their bearing on the technology's existing assessment and recommendations, the Commission may perform the reassessment by:

> (1) reconvening the original TAP and conducting the full assessment process described in Stages 4 and 5, leading to major revision of the medical technology's assessment and HRP
> (2) appointing a limited TAP and conducting a partial or abbreviated reassessment, leading to moderate revision of the Medical Technology Assessment and recommendations, or
> (3) the HRC conduct a limited reassessment on its own through consultation with technical experts, but without appointing a TAP, leading to only minor revision of the assessment and recommendations.