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2010 Innovations Awards Application

DEADLINE EXTENDED: MARCH 15, 2010

ID # (assigned by CSG): 10-W-18WA

Please provide the following information, adding space as necessary:

State: Washington

Assign Program Category (applicant): Health Services (Use list at end of application)

1. Program Name: Health Technology Assessment Program
2. Administering Agency: Health Care Authority
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9. Please provide a two-sentence description of the program.

This is a first-in-the-nation public program that uses unbiased evidence reports, an independent clinical committee, and a public and transparent process to determine which medical tests and treatments have evidence that they work, are safe, and have value to patients. Decisions are binding across several state-purchased health care programs, including public employees and retirees, injured workers, and Medicaid beneficiaries.

10. How long has this program been operational (month and year)? Note: the program must be between 9 months and 5 years old on March 1, 2010 to be considered. Jan.2007 (3yrs3mos)

11. Why was the program created? What problem[s] or issue[s] was it designed to address?

- The state's budgetary share of costs for health care continues to rise; studies show that outcomes are not improving and as much as one-third of health care spending is wasted on procedures, drugs, or treatments that neither improve quality of life or extend life.
- Governor Gregoire's 5-point health care strategy and concurrent legislative priority included emphasis on evidence-based medicine. The Health technology assessment program was created to improve state health care purchasing decisions by paying for what is proven to work.

12. Describe the specific activities and operations of the program in chronological order.

The Health Technology Assessment program uses an evidence report and the recommendations of a clinician panel to make decisions about whether agencies should fund certain medical procedures and tests based on evidence of three criteria: safety, efficacy, and cost-effectiveness.

- The Administrator selects topics (eight per year), appoints the committee, and staffs the program.
- The program contracts for an unbiased review of evidence of selected medical procedures, devices, or equipment.
- The report is then used by an independent clinical committee of eleven practicing health care providers to make recommendations.
- The program must be transparent: post topics for comment, hold public meetings, and post decisions publicly.
- The decisions apply to the Health Care Authority, Labor and Industries, and the Department of Social and Health Services. The Department of Corrections and Veterans Affairs participate voluntarily

13. Why is the program a new and creative approach or method?

Health care services and benefits are typically determined by internal clinical staff or boards, often based on expert opinion or lobbying; this has contributed to payment for treatment and test without proven efficacy, safety and cost. The explicit use of unbiased, science based reports; an external, independent panel, and a public process are new. Statutory criteria for coverage decision that required evidence on safety, efficacy, and cost-effectiveness are new.

14. What were the program's start-up costs? (Provide details about specific purchases for this program, staffing needs and other financial expenditures, as well as existing materials, technology and staff already in place.)

Staff needs below; first 6 months to operationalize had 2 staff

15. What are the program's annual operational costs?

\$1 million annually covers three full-time employees and one contracted clinical consultant; the contracted evidence research firms are paid per report, and the clinical committee is reimbursed per diem.

16. How is the program funded?

General state tax revenue

17. Did this program require the passage of legislation, executive order or regulations? If YES, please indicate the citation number.

Yes. WA 2006 ESSHB 2575.

18. What equipment, technology and software are used to operate and administer this program?

None other than office software and the Internet.

19. To the best of your knowledge, did this program originate in your state? If YES, please indicate the innovator's name, present address, telephone number and e-mail address.

Yes. It was a collaborative effort based on agency, executive, and legislature. Governor Chris Gregoire; Representative Eileen Cody and Senator Karen Keiser; agency medical directors - Gary Franklin, MD; Jeff Thompson, MD; and Nancy Fisher, MD.

20. Are you aware of similar programs in other states? If YES, which ones and how does this program differ?

The Center for Medicaid and Medicaid Services (CMS)-funded Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) is similar, but it does not include cost and value considerations. Other states have staff that use evidence and reports; several states participate in the Medicaid Evidence Based Decisions (MED) run by the Oregon Health & Science University; but still make internal decisions and do not publish criteria.

21. Has the program been fully implemented? If NO, what actions remain to be taken?

Yes

22. Briefly evaluate (pro and con) the program's effectiveness in addressing the defined problem[s] or issue[s]. Provide tangible examples.

The program has been operational since January 2007.

- 15 comprehensive evidence reports complete
 - Over 6,000 potential articles identified; average of 18 critically appraised per topic
- 15 coverage decisions
 - 8 technologies - Not covered due to evidence that the technology does not work or evidence does not yet show net health benefit
 - 7 technologies covered under certain conditions where evidence demonstrated benefit
- Over \$27 million annually in avoided costs on health care that is unproven, unsafe, or ineffective. For example, cardiac stents costs differ by up to \$3,600.00. For every premium stent we buy, if we had used the lower cost version, we would meet the medical needs of the heart patient where studies show no difference in heart attack or death rates between stent types and we could provide a full year's worth of fully subsidized coverage for one person on Basic health.
- Comparative effectiveness is rated by Commonwealth, IOM and others as leading approach to improve quality and reduce cost.

Results of tough decisions include some unhappy stakeholder/industry/providers:

These are hard choices that require commitment from both the executive and legislative branch. Change is hard - we are used to having an expert-driven system with everyone getting what they want or believe they need, but we know that this has led to an untenable amount of waste and a not insignificant amount of harm in our system. In order to improve quality and lower cost, we are going to have to say no to certain things and focus more on those proven, value-added services. The decisions require courage because there will be lobbying and unhappy stakeholders, and a desire to gravitate to expert opinion. Key program components to rely on are using standardized (and enhanced) HTA processes, unbiased clinical evidence, and independent clinicians who work in our health system and see patients regularly and are convinced that the tough choices that they make are best for patients and our health system.

23. How has the program grown and/or changed since its inception?

N/A

24. What limitations or obstacles might other states expect to encounter if they attempt to adopt this program?

- **Resource (time and cost) Intensive**
 - Collecting evidence is in a systematic way and using an open process is time consuming and expensive
- **Change in Policy Decision-Making Model (must engage stakeholders and be transparent)**
 - Changing to a requirement to use evidence or explicit criteria is a new model of "Proof" instead of Persuasion via lobbying, marketing, or expert based decisions
 - Industry/Provider/Patient view is important but is difficult to integrate into a model based on unbiased evidence
- **Policy Decisions Requires Additional Considerations**
 - Clinical evidence alone does not usually point to one answer - Alternatives, criticality and burden of condition are examples of additional considerations that must be weighted
- **Information Gap (develop common values)**
 - Targeted topics are generally not already well studied (because no need for process), so many reports describe a low level or quality of information, but decisions must still be made for complex/controversial issues

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2010 Innovations Awards Application Program Categories and Subcategories

Use these as guidelines to determine the appropriate *Program Category* for your state's submission and list that program category on page one of this application. Choose only one.

Infrastructure and Economic Development

- Business/Commerce
- Economic Development
- Transportation

Government Operations and Technology

- Administration
- Elections
- Information Systems
- Public Information
- Revenue
- Telecommunications

Health & Human Services

- Aging
- Children & Families
- Health Services
- Housing
- Human Services

Human Resources/Education

- Education
- Labor
- Management
- Personnel
- Training and Development
- Workforce Development

Natural Resources

- Agriculture
- Energy
- Environment
- Environmental Protection
- Natural Resources
- Parks & Recreation
- Water Resources

Public Safety/Corrections

- Corrections
- Courts
- Criminal Justice
- Drugs
- Emergency Management
- Public Safety

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Nancy J. Vickers, National Program Administrator
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Implementing Evidence-Based Health Policy in Washington State

Posted by [NEJM](#) • October 28th, 2009 • [Printer-friendly](#)

Gary M. Franklin, M.D., M.P.H., and Brian R. Budenholzer, M.D.

The Obama administration's infusion of stimulus funds into enhanced comparative-effectiveness research (CER) is in keeping with the conclusion of a recent Commonwealth Fund report that, of the top 15 ways of bringing health care costs under control, CER promises the greatest short- and long-term savings.¹ In addition, the report notes, CER efforts are the most likely to reduce the out-of-pocket health care costs of ordinary households. To address the unsustainable increase in overall health care expenditures — a matter made more urgent by the financial challenge of providing health care coverage for all citizens in the state — the Washington State legislature and successive governors Gary Locke and Chris Gregoire have, since 2003, enacted a set of statutory policies related to the use of evidence-based principles in improving the quality of care, reducing overuse and underuse of health care services, and determining what benefits should be covered by the state's public payers. These payers — Medicaid, the workers' compensation program, the state government employee benefit plan, and the corrections department — provide \$2.9 billion in benefits annually to approximately 773,000 Washington citizens through direct fee-for-service plans. The state government's authority to use evidence-based methods now extends to all major types of health care products and services: drugs (whether brand-name or generic, including those used off-label), devices, surgical procedures, diagnostic tests, medical equipment, and advanced imaging procedures.

A centerpiece of this effort is the Health Technology Assessment (HTA) program.² The statute authorizing this program, which was supported by the Washington State Medical Association, was passed with only one "nay" vote by the Washington State legislature in 2006. The HTA program is an unusual initiative in the United States: a government-sponsored program in which formal methods are used to conduct critical appraisals of surgical devices and procedures, medical equipment, and diagnostic tests and to translate the results of those evaluations into coverage recommendations.²

Assessing these types of products and services is particularly challenging. Whereas the Food and Drug Administration adheres to the standard of the randomized, controlled trial for the approval of drugs, the agency's approval standards for devices are lower, and thanks to Section 510(k) of the Food, Drug, and Cosmetic Act, the vast majority of devices are approved on the basis of the demonstration of substantial technical equivalence to devices that were on the market before May 1976. Since surgical procedures are not specifically regulated, the evidence available for their critical appraisal is generally very limited — and usually comes in the form of case series, most of which are not prospective and do not include an independent assessment of outcomes. Even some surgical procedures that have been in use for decades

have never been subjected to a well-performed randomized trial; for instance, the first such randomized trial on thymectomy for myasthenia gravis, a procedure that has been used since 1912, is just now under way.³

The uniqueness of the HTA program rests on a number of key characteristics.² The program's assessments are based on a thorough, systematic review of the evidence related to the effectiveness, safety, and cost-effectiveness of a product or service, with each type of evidence examined separately. After considering the "most valid and reliable" evidence on all three of these dimensions, the health technology clinical committee — which must be made up of practicing clinicians — arrives at one of three recommendations: covered without conditions, covered with conditions (such as criteria defining medical necessity), or not covered. The entire process must be transparent. Any recommendation the committee issues must be followed by public payers in Washington State (unless it conflicts with a state or federal statute), although investigators conducting clinical trials that have been approved by the relevant institutional review board may be exempted from adherence to a given coverage decision. If the committee determines that a technology should not be covered, that recommendation supersedes any determination of medical necessity — public payers in Washington State simply cannot cover it.

Of the nine health technology assessments that have been completed under Washington's program thus far, six were of surgical devices or procedures and three were of advanced imaging procedures (see table).⁴ Five of the decisions resulted in noncoverage because the evidence of effectiveness, safety, cost-effectiveness, or some combination of these was deemed insufficient.⁴ The other four decisions resulted in coverage with conditions (as summarized in the table). Thanks to a rigorous prioritization process, reviews are conducted only for technologies thought to have a high likelihood of substantial overuse or underuse or those about which there are substantial concerns related to safety or cost-effectiveness. Thus far, no assessments have resulted in coverage without conditions.

Coverage Decisions from the Washington Health Technology Assessment Program		
Technology	Decision	Estimated First-Year Cost Savings (\$)
Upright or positional medical resonance imaging	Not covered: accuracy unproven	2.99 million
Pediatric bariatric surgery	Not covered for patients <18 yr of age: effectiveness unproven, safety concerns Covered with conditions for patients 19–21 yr of age: laparoscopic adjustable gastric banding only	589,000
Lumbar fusion for uncomplicated degenerative disk disease	Covered with conditions: agencies may mandate structured, multidisciplinary pain services before fusion	5.24 million
Diskography for uncomplicated degenerative disk disease	Not covered: accuracy and effectiveness unproven	324,000
Lumbar and cervical artificial disks	Covered with conditions: for patients ≤60 yr of age and single level only, and FDA criteria must be met; concern about longer-term outcomes	—
CT colonography	Not covered: less cost-effective than colonoscopy	11.1 million
Arthroscopic surgery for osteoarthritis of knee	Not covered: proven ineffective	1.8 million
Implantable drug-delivery systems for chronic, non-cancer-related pain	Not covered: unproven effectiveness, safety concerns	—
Coronary CT angiography	Covered with conditions: low-to-intermediate risk; acute angina in emergency department or hospital; CT with at least 64-slice technology	—

* Information is from the Washington Health Technology Assessment Program.⁴ CT denotes co Administration.

This program faces several challenges. First, industry can apply substantial pressure throughout the process, including having patients testify that they have obtained personal

benefit from a given technology. Political pressure, on the other hand, has been limited, probably because the authorizing statute was passed nearly unanimously by the legislature, the statutory language and underlying administrative rules are very specific, and the process is transparent.

Second, since there is little precedent for synthesizing the three key dimensions of evidence (effectiveness, safety, and cost-effectiveness) into a coverage decision, that step has been difficult to achieve operationally.

Third, it is challenging to predict the program's results in terms of specific cost savings and precise effects on the quality of care and health outcomes. It has been conservatively estimated that the program would result in first-year savings of \$21 million, at a cost of \$1 million. Some decisions, such as the recommendation about artificial disks, will probably lead to increased costs. It is difficult, however, to generate accurate projections, in part because estimating downstream cost savings — for example, from avoiding an inappropriate procedure that would have been performed had an inaccurate test remained a covered benefit — will require a much longer follow-up and probably a formal evaluation.

Fourth, despite the appearance of several articles about the HTA program in regional newspapers, patients and consumers are probably not keenly aware of the program or of its significance in terms of improved value — and they continue to be driven toward greater use of expensive health technologies by direct-to-consumer advertising and by physicians who prize their decision-making autonomy and have a financial interest in ordering or performing tests and procedures.

And fifth, though all public payers in Washington come under the program's authority, it has proved challenging to extend coverage decisions to the minority of patients who are covered under public-payer–contracted health plans. These carriers are excluded in the authorizing legislation.

In addition to reducing the use of products and services that are of questionable value, the HTA program has the potential to increase the use of currently underutilized health care services. There is a widely recognized need to improve the quality of U.S. health care and to realign the allocation of health care resources. Programs like Washington's HTA program hold promise for achieving these goals on a population-wide basis; however, more comprehensive approaches that shift delivery-system incentives will also be required to improve the integration and efficiency of care and the system's accountability for health outcomes.^{1,5} Only with both types of strategies are we likely to see a sustained decrease in cost escalation that is sufficient to balance the long-term costs of health care reform. Clearly, improved strategic communication with the public about the value of these programs will be required as the federal government and states move forward.

No potential conflict of interest relevant to this article was reported.

Source Information

From the Department of Environmental and Occupational Health Sciences, University of Washington School of Public Health, Seattle (G.M.F.); the Washington State Department of Labor and Industries, Olympia (G.M.F.); the Washington Health Technology Assessment

Clinical Committee and the Washington Health Technology Assessment Program, Olympia (B.R.B.); and Group Health Cooperative, Spokane, WA (B.R.B.).

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1. Schoen C, Guterman S, Shih A, et al. Bending the curve: options for achieving savings and improving value in U.S. health spending. New York: Commonwealth Fund, December 2007. (Accessed October 8, 2009, at <http://www.commonwealthfund.org/Content/Publications/Fund-Reports/2007/Dec/Bending-the-Curve-Options-for-Achieving-Savings-and-Improving-Value-in-U-S-Health-Spending.aspx#>.)
2. Washington State Legislature. HB 2575 — 2005-06: establishing a state health technology assessment program. (Accessed October 8, 2009, at <http://apps.leg.wa.gov/billinfo/summary.aspx?bill=2575&year=2005>.)
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4. The Washington Health Technology Assessment Program. Health technology assessment findings. (Accessed October 8, 2009, at <http://www.hta.hca.wa.gov/assessments.html>.)
5. Shortell SM, Casalino LP. Health care reform requires accountable care systems. *JAMA* 2008;300:95-97. [[Free Full Text](#)]

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