

POLICY NOTE

Key Findings

- I. The Health Technology Assessment Program (HTA) was created in 2006. The decisions of the agency effect 763,000 people in state-purchased feefor-service health care programs.
- 2. Provider satisfaction and compliance are unknown, although there is anecdotal evidence of dissatisfaction within some specialty groups.
- 3. Comparative effectiveness research (CER) raises important ethical concerns for doctors.
- 4. Used properly, CER could be an effective program to protect taxpayers from over-paying for entitlement health care and can help with cost-effective decision making.
- 5. The HTA program must allow for thorough patient and provider input and must be responsive to new technologies. It must be transparent and must utilize expert testimony.
- 6. Although it is only three years old, the HTA program in WA has the potential to be a national model. The fact that millions of patients throughout the country may be effected by the HTA decisions adds a greater level of responsibility to the program and the need for reforming it.

Comparative Effectiveness Research in Washington State

The Health Technology Assessment Program

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November 2010

Introduction

Medical research is the foundation of the modern era of medicine. Doctors and other providers spend their entire careers deciding the best treatments for their patients based on scientific research and their own experience. Health care providers are trained to identify patient variations and to offer individualized treatments from a selection of treatments and medicines.

However, these providers are not trained to know the cost of the treatments they offer. This has led to huge variations in health care expenditures across the nation. 1 It is now estimated that because of these treatment variations, almost 30 percent of health care spending in the United States offers no value to patients.² Taxpayers at both the state and federal levels have paid for an ever increasing amount of health care since the passage of Medicare and Medicaid in 1965.

Congress observed the escalating costs of these government programs and in 1989 elected to fund an agency to provide cost-effective, clinical guidelines for practitioners. This agency, now called the Agency for Healthcare Research and Quality (AHRQ), was reorganized in 1999 and currently has a budget of \$330 million and a staff of 300 federal employees.3

These clinical guidelines are based on a practice called comparative effectiveness research (CER). CER seeks to answer three basic questions. First, is a medical treatment effective? In other words, does it work and is it safe? Second, does a chosen treatment work better than possible alternatives? And third, is a chosen treatment cost-effective when compared to the possible alternatives. CER also applies to diagnostic procedures and uses the same questions.

Comparative Effectiveness Research in Washington State

In 2006, Governor Gregoire's Blue Ribbon Commission on Health Care made a number of recommendations, including creation of a state-based agency to undertake CER.4 Legislation to do so was passed by unanimous votes in both

¹ "The Implications of Regional Variations in Medicare Spending, Part 1: The Content, Quality, and Accessibility of Care," and "Part 2: Health Outcomes and Satisfaction with Care," by Elliott S. Fisher et. al., *Annals of Internal Medicine* 138, no. 4, February 18, 2003. ² "Expert Voices: More Care is not Better Care," by Elliott S. Fisher, National Institute for Health

Care Management, no. 7, January 2005.

³ http://www.ahrq.gov, accessed August 20, 2010.

⁴ http://www.leg.wa.gov/JointCommittees/HCCA/Documents/Final%20Report.pdf, accessed August 20, 2010.

the House and Senate.⁵ State-wide medical organizations, such as the Washington State Medical Association and the Washington State Hospital Association, as well as large provider groups were firmly in support.

The agency was established in 2006 and is called the Health Technology Assessment Program (HTA). The decisions of the agency effect 763,000 people in state-purchased fee-for-service health care programs, including Medicaid, state employees and retirees, Department of Labor and Industry, and patients in state prisons. The HTA was added to a number of existing programs (for example the Prescription Drug Program, the Surgical Care Outcomes Assessment Program, and the Patient Decision Aids) and together these programs are called "Health Care that Works".

The primary goals of the HTA program are to make:

- Health care safer by relying on scientific evidence and a committee of practicing clinicians.
- Coverage decisions of state agencies more consistent.
- State purchased health care more cost-effective by paying for medical tests and procedures that are proven to work.
- Coverage decision processes more open and inclusive by sharing information, holding public meetings, and publishing decision criteria and outcomes.

Four components make up HTA's decision-making process. First, the agency staff selects the technology to be reviewed. They collect data and input from other state agencies and the public. Officials at the Health Care Authority (HCA) make the final selection.

Second, a thorough five to eight month review of all pertinent research literature is undertaken by a non-government consulting company. This company determines the quality of the research papers and does not make specific recommendations for or against the procedure under review. The public can provide input during two comment periods.

Third, after at least thirty days, a committee of eleven people makes the final decision on whether the medical treatment or diagnostic procedure will be provided to people receiving health care through state programs. This committee, by law, is composed of six physicians and five non-doctor professionals. The physicians are not necessarily specialists in the medical area under review. The committee examines eight to ten items per year and holds scheduled quarterly meetings to take public comment and to debate the efficacy, cost and safety of the medical treatment or procedure they are reviewing.

The committee calculates the cost of a procedure, or conversely the potential savings to the state, by determining the number of times the state paid for that procedure in the preceding year and multiplying the cost of each procedure. The cost to the state of the procedure that is recommended is not taken into account. For procedures that are not used often, the committee compares national usage to the population served by the HTA program and determines an estimated state usage.

The fourth and last component is implementation. Once a medical treatment or diagnostic procedure has been rejected by the committee, the state will

⁵ http://apps.leg.wa.gov/billinfo/summary.aspx?bill=2575&year=2005, accessed August 15, 2010.

⁶ http://www.hta.hca.wa.gov, accessed August 16, 2010.

no longer pay a doctor or hospital for using that treatment or procedure to treat a patient's illness. If a provider feels strongly that the patient should receive the specific treatment the state will not pay for, the doctor and medical facility have to absorb the cost. The state law says all committee decisions must be consistent with nationally-recognized clinical practice guidelines and with Medicare decisions.

Table I shows the current list of items review by the HTA committee and its assessment.

		Evidence			Decision	Medicare Alignment		State Impact	Utilization
Торіс	Date	Safe	Effective	Cost- Effective	Coverage	Medicare National Coverage Dec?	Consistent w/ Medicare NDC	Utilization Change Expected	Impact (annual figure)
Upright MRI	May-07	Equal	Insufficient	Less	No	No decision	n/a	Decrease	\$2,990,000
Ped Bariatric Surgery < 18	Aug-07	Insufficient	More	Insufficient	No	No decision for ped.	n/a		\$0
Ped Bariatric Surgery 18-21	Aug-07	Less	More	Insufficient	Yes/ Conditions	(adult conditions similar)		Increase	\$589,485
Lumbar Fusion	Nov-07	Less	Equal/ More	Less	Yes/ Conditions	No decision#	n/a	Decrese	\$5,240,639
Discography	Feb-08	Insufficient	Insufficient	Insufficient	No	No decision	n/a	Decrease	\$324,000
Virtual Colonoscopy (CTC)	Feb-08	Equal	Equal/ More	Less	No	No decision/not covered*	n/a Yes	Same	\$11,100,000
Intrathecal Pump for chronic noncancer pain	Feb-08	Insufficient	Insufficient	Equal	No	Covered w/ conditions	No - less	Decrease	\$691,326
Arthroscopic Knee Surgery	Aug-08	Less	Equal	Less	No	No coverage	Yes	Decrease	\$400,000
Artificial Disc Replacement	Nov-08	Equal	Equal/ More	Insufficient	Yes/ Conditions	Lumbar, not covered over 60, Cervical no policy	No-more n/a	Increase	0**
Computed Tomographic Anglography (cardiac)	Nov-08	Equal	Equal	Equal/ More	Yes/ Conditions	No decision#	n/a	Same	\$5,063,928
Cardiac Stents	May-09	Equal	Equal/ More	Less	Yes/ Conditions	No decision	n/a	Decrease	\$966,760
Vagal Nerve Stimulator	Aug-09	Equal/ Insufficient	More/ Insufficient	Equal/ Insufficient	Yes/ Conditions	Covered for epilepsy w/ conditions	Yes	Same/ Decrease	
Bone Growth Stimulator	Aug-09	Equal	Insufficient	Insufficient	Yes/ Conditions	Covered with conditions ^	Yes	Increase	
Transcutaneous Electrical Neural Stimulation (TENS)	Oct-09	Equal	Insufficient	Insufficient	No	Covered with conditions	Yes	Decrease	
Calcium Scoring for Cardiac Disease	Nov-09	Insufficient	Insufficient	Insufficient	No	No decision	n/a	Decrease	
Hip Resurfacing	Nov-09	Insufficient	Equal	Insufficient	Yes/ Conditions	No decision	n/a	Increase	
									\$27,366,13

^{**}Not enough information to calculate conservative estimate.

Results

It is too early to know the impact of the HTA program. The legislation allowed for an administrative cost of \$3.5 million and officials estimate the savings to taxpayers are in the \$27 million to \$30 million range. Again, this is based on historic utilization and on current and future cost avoidance. It does not consider, and subtract, the cost of procedures that are actually used. Although \$30 million is

^{*}later decision, CMS cited WA-HTA

[#]CMS reviewed, issued no decision

 $[\]hat{\ }$ committee followed CMS, per current statue, even though insufficient evidence

not an insignificant amount of money, it represents just 0.25 percent of the \$12.2 billion Washington state spent on health care in 2009.

Provider satisfaction and compliance are unknown, although there is anecdotal evidence of dissatisfaction within some specialty groups. CER is also known as "best practices" or to many physicians, "cookbook medicine." Providers treat every patient as an individual and consequently they strongly object to a system that makes patients seem uniform and that dictates how doctors can practice medicine.

CER raises important ethical concerns for doctors. Trained to treat the sick, and obligated by the moral standards of their profession to make their best efforts on behalf of each patient, providers are now required to consider restrictions imposed by a third party. Decisions made by a distant committee may deny patients access to treatments or medicines their doctor would otherwise prescribe. Doctors are trained to think of their patients' well-being first and cost second, so for many doctors the state's CER process further disrupts the doctor/patient relationship and the ethical practice of medicine.

Patient satisfaction has not been measured as it specifically relates to the HTA program. Medicaid patients in general, however, are finding it more difficult to access health care because of poor provider reimbursement from the government. Further restriction of patient treatment and diagnostic options will need to be monitored to insure patients covered by state-funded health care programs have the chance to receive the best quality of care.

Drug and medical device manufacturers have expressed a number of concerns with the process of the HTA program. They question the use of non-technology specific expertise, the limited amount of time allowed for public and provider participation, the lack of nationally-recognized clinical guidelines, the actual number of procedures used in Washington state and the timeliness of reviewing relevant data. They also question the cost-savings projections. Their concern is that the anticipated savings are flawed and too simplistic because the numbers don't include the cost of the actual procedure or test used.

Analysis

Everyone, including taxpayers, wants to get the most value for their money. CER, if done properly, could be an effective program to protect taxpayers from over-paying for entitlement health care. The program makes financial sense if the cost versus savings is truly about ten percent (\$3 million cost versus \$30 million saved). This assumes that health outcomes would be the same even if certain treatments are disallowed.

Patients who accept state tax-payer funded health care under the current system must rely on bureaucratic decisions to guide their care. If patients had control of their own health care dollars, for example through a voucher program, they would have a vested interest in treatment and diagnostic alternatives from a financial standpoint. Conversely, if all patients lose control of spending their own health care dollars, for example through a single-payer government program, potentially all medical decisions would be made by government committees using CER.

Most providers do not have an understanding of health care costs. Used properly, CER can help with cost-effective decision making. On the other hand, physicians spend four years in medical school and four to eight years in specialty

⁷ http://www.usgovernmentspending.com/Washington_state_spending.html, accessed August 25, 2010

training to be able to evaluate medical research. Having a government committee tell providers what treatments and diagnostic tools to use is, from a medical standpoint, arrogant, condescending and not in the best interest of patients.

Drug and medical device manufacturers have valid concerns. The HTA program must allow for thorough patient and provider input and must be responsive to new technologies. It must be transparent and must utilize expert testimony.

Although it is only three years old, the HTA program in Washington state has the potential for being a national model.8 Other states, as well as the federal government, may very well use the researched data already provided by the HTA program. The fact that millions of patients throughout the country may be effected by the HTA decisions adds a greater level of responsibility to the program and the need for reforming it.

Recommendations

- Track and regularly publish actual savings from the HTA program and have the state auditor evaluate the program.
- Allow sufficient public input and publish these comments.
- Rely on specialty-trained provider expertise in the decision process.
- Allow enough time for public and provider review of the data.
- Establish a mechanism to promptly review new data and incorporate this into the decision process.
- Insure that the HTA program follows nationally-recognized clinical guidelines.

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⁸ "Implementing Evidence-Based Health Policy in Washington State," by Gary M. Franklin, M.D., M.P.H. and Brian R. Budenholzer, M.D., *New England Journal of Medicine*, October 29, 2009.