

sources, and new benefit designs. Recommendations should be submitted for Congressional approval, but they must be adopted or rejected as a package, rather than picked apart piece by piece. The latter approach provides maximal opportunity for lobbyists for special-interest groups to determine the outcome, whereas a congressional “yes” or “no” vote on a total reform package would allow the public interest to play a larger role.

Health care spending has grown 2.7% faster than the rest of the economy over the past 30 years, primarily as a result of new technology.<sup>3</sup> Some of the new drugs, tests, and procedures have contributed to longer, high-quality lives. Many have not. Currently, there is no institution that has been established with the specific aim of evaluating the value of new technologies (or of new applications of older technologies). It is not feasible for individual physicians or physician groups to carry out the necessary analyses and disseminate findings throughout the health care community. To accomplish this task, Congress should create a quasi-independent institute for technology assess-

ment with steady, ensured funding, such as a fixed percentage of annual Medicare expenditures.<sup>4</sup> The assessments performed by this institute will initially be particularly valuable to the expert commission that is charged with making Medicare payment methods more efficient and more equitable.

One omission from these recommended reforms is a proposal for dramatically increasing the number of insured Americans. I favor increased coverage and have advocated universal coverage, financed by a value-added tax that is dedicated to funding basic health care for all. To be sustainable, expanded coverage must be accompanied by adequate new revenues and by changes in the organization and delivery of care that will predictably lower costs. The proposals that are currently being considered for expanding coverage do not meet that test. Indeed, I believe the proposed expansion of employment-based insurance (through employer mandates) and the expansion of income-tested insurance such as Medicaid (through raising the income threshold for eligibility) are the wrong way to go. These

inefficient and inequitable methods contribute to our present problems and must eventually be replaced.

I believe that the four reforms proposed here have more chance of doing good than harm, will lower rather than increase the deficit, and will reinforce one another. Given the complexity of health care, that's the most that we can expect until comprehensive change in the financing and organization of care becomes politically possible.

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From Stanford University, Stanford, CA.

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## Implementing Evidence-Based Health Policy in Washington State

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.<sup>1</sup> 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 ex-

penditures — 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, en-

acted 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.<sup>2</sup> 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.<sup>2</sup>

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 agen-

cy'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.<sup>3</sup>

The uniqueness of the HTA program rests on a number of key characteristics.<sup>2</sup> 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).<sup>4</sup> Five of the decisions resulted in non-coverage because the evidence of effectiveness, safety, cost-effectiveness, or some combination of these was deemed insufficient.<sup>4</sup> 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.

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 admin-

## Coverage Decisions from the Washington Health Technology Assessment Program.\*

Technology	Decision	Estimated First-Year Cost Savings (\$)	Potential Effects on Quality of Care and Outcomes
Upright or positional medical resonance imaging	Not covered: accuracy unproven	2.99 million	Prevention of additional unnecessary tests or inappropriate treatment
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	Control of surgical risk; agencies may use as preconditions that surgery is performed at centers of excellence and that patients demonstrate dietary compliance
Lumbar fusion for uncomplicated degenerative disk disease	Covered with conditions: agencies may mandate structured, multidisciplinary pain services before fusion	5.24 million	Agencies have been prompted to develop new policies and incentives for structured, multidisciplinary pain programs; reduction of surgical risk
Diskography for uncomplicated degenerative disk disease	Not covered: accuracy and effectiveness unproven	324,000	Avoidance of lumbar fusion and artificial disk procedures on the basis of diskography results
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	—	Lumbar: same as for lumbar fusion Cervical: reduction of off-label use (e.g., for multiple levels or in patients >60 yr of age)
CT colonography	Not covered: less cost-effective than colonoscopy	11.1 million	Decision based on cost-effectiveness, since colonoscopy must be done if polyp found; avoidance of redundant procedures
Arthroscopic surgery for osteoarthritis of knee	Not covered: proven ineffective	1.8 million	Reduction of operative and postoperative complications; avoidance of unnecessary procedures
Implantable drug-delivery systems for chronic, non-cancer-related pain	Not covered: unproven effectiveness, safety concerns	—	Avoidance of complications
Coronary CT angiography	Covered with conditions: low-to-intermediate risk; acute angina in emergency department or hospital; CT with at least 64-slice technology	—	Avoidance of small but definite risks of radiation from unnecessary tests and of incidental findings that could lead to further, inappropriate interventions

\* Information is from the Washington Health Technology Assessment Program.<sup>4</sup> CT denotes computed tomography, and FDA Food and Drug Administration.

istrative 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.<sup>1,5</sup> 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.

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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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