Proposal for a State Health Technology Assessment Program

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ABSTRACT

Evidence suggests that a significant number of medical technologies are of little or no benefit to patients. Under current budgetary pressures, state health care programs cannot afford continued spending on unnecessary medical care without further cuts in enrollment. Limiting coverage of high-tech care only to indications supported by good clinical evidence would help save state health care dollars. However, there is currently no public process to formally evaluate new medical interventions in Wisconsin. In fact, new therapies often are introduced into clinical practice, and covered by state health insurance programs, even when there is weak or questionable evidence of clinical effectiveness. This article proposes the creation of a state Health Technology Assessment program in Wisconsin to systematically evaluate new tests or treatments, and to promote evidence-based coverage decisions. Such a program would help limit wasteful spending on unnecessary technologies, reinforce good clinical practice, and protect patients from the risks of interventions that have not been proven effective.

Defining what does and does not work in medicine is a professional responsibility of the highest order, one that physicians have resisted assuming.[1]

INTRODUCTION

The 2011-2013 Wisconsin state budget calls for more than $550 million in reduced Medicaid spending. A significant portion of the spending reductions will be in the form of enrollment and benefit cuts. The state budget includes numerous efficiency proposals, but its projected savings are far more modest. Missing from the list of efficiency proposals is the establishment of a State Health Technology Assessment (HTA) program. The omission is striking since a program of this sort, created by the state of Washington, was projected to save $31.8 million in 2011.[2] This figure vastly exceeds any of the projected savings expected from any of the Wisconsin Medicaid efficiency proposals, and does not involve cuts to enrollment or evidence-based care.

Researchers have identified significant variations in the use of high-tech interventions. Studies of physician behavior have shown that a variety of incentives, unrelated to the evidence, drive the use of technology: a subjective bias in favor of technology, financial incentives, anxiety regarding patient expectations, fear of lawsuits, clinical decision-making based on anecdotal experience, and an erroneous underestimation of the risks of high-tech interventions.[3] According to Deyo, "[v]ested interests, marketing, politics, and media hype often have more influence on how new medical advances get used than the best scientific evidence."[4] All of these factors have contributed to the inappropriate use of medical technologies and help explain why experts have found that 30% of medical care—including high-tech care—is of little or no clinical benefit.[5]

The challenge for health care policymakers is to have a reliable process for identifying unproven interventions and thus avoid premature or overly permissive coverage decisions. Three consequences of the current approach include (1) higher health care costs without proven benefit, (2) too much influence of marketing over coverage policy, and (3) an increased risk to patients, including the adoption of a more aggressive clinical approach.

All of these consequences are well illustrated by the rapid adoption of robotic-assisted laparoscopic prostatectomy (RALP) into clinical practice over the past decade.

Weak Coverage Policy and the Case of Robotic Prostatectomy

The US Food and Drug Administration (FDA) approved RALP (da Vinci Surgical System; Intuitive Surgical Inc, Sunnyvale, California) for radical prostatectomy in 2001. Since then, RALP has become the dominant approach to prostatectomy, increasing costs significantly. The robot used to perform RALP

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now costs over $2 million, plus more than $150,000 per year in maintenance fees. It adds more than $2000 to the cost of each surgery. But the widespread adoption of RALP occurred despite a lack of clear evidence that the use of robotic technology in prostate surgery produced better clinical outcomes.

Marketing of the device has been particularly aggressive. According to Turner, the early adoption of RALP by hospitals and urologists was driven more by "[c]ompetitive market pressures and our enduring hope that somehow the latest, greatest and best will help us beat the odds."[6] Some of the marketing used by hospitals to promote RALP was reviewed in a study of 400 hospital websites. The study found that 86% of websites declared that RALP was clinically superior, and 32% claimed that it resulted in improved cancer control.[7] But there was no conclusive evidence of clinical superiority or improved cancer control at the time. In fact, Andriole concluded that "in this particular instance, with this particular robot, there hasn't been a quantum leap in anything."[8]

When the widespread adoption of a new medical technology precedes adequate vetting, there can be increased risks to patients. For instance, some early studies found that RALP was associated with higher rates of the 2 most feared complications of prostatectomy—impotence and incontinence.[9,10] These higher rates likely were due, in part, to the long learning curve required to achieve consistently low complication rates. Some studies found that surgeons needed to perform at least 250 RALP procedures to achieve consistently low rates of impotence and incontinence, but others have found that 1000 to 1500 surgeries are needed to assure consistently low complication rates.[11] The minimum number of procedures necessary to assure an optimal level of expertise has not yet been established or validated. Interestingly, more than 70% of RALP surgeries are performed by urologists who do fewer than 100 cases per year.

An additional risk to patients is that the technological imperative associated with new techniques can itself lead to increased rates of aggressive intervention. A study of 52 Wisconsin hospitals found that, between 2002 and 2008, 23% of the hospitals studied purchased robotic technology for prostate surgery. In hospitals that did not acquire robotic technology, prostatectomies decreased, consistent with the general trend in Wisconsin and across the country of decreasing prostate cancer rates. But, despite a decreased incidence of prostate cancer, prostatectomies increased by 25.6% in hospitals that acquired robotic equipment.[12] These findings suggest that purchase of the robotic technology seems to have incentivized Wisconsin urologists to perform more surgeries than they would have performed had they not been using RALP. In other words, the availability of the new technology, rather than any specific clinical factor, appears to have contributed to increased rates of aggressive surgery.

The lack of convincing evidence of clinical benefit at the start of the robotic era should have led policymakers to classify the procedure as essentially investigational. Instead, most public and private carriers—including Medicare—chose a more passive approach. They chose to cover robotic prostatectomies, but without additional reimbursement for use of robotic assistance. However, when no additional reimbursement is offered for new interventions, hospitals will routinely shift costs to other areas. In addition, surgeons will tend to increase the volume of procedures performed, as reflected by the increased rates of prostatectomies in Wisconsin hospitals that acquired robotic technology. All of these strategies increase health care costs for everyone, and allow unproven technologies to prematurely diffuse into clinical practice before they have been adequately evaluated.

BACKGROUND

Other developed countries have established national technology assessment programs. England's National Health Service (NHS), for example, established the National Institute of Clinical Excellence (NICE) in 1999 to set standards for the use of medical technologies and procedures.[13,14] Since 2002, NHS has been required to pay for technologies recommended by NICE. Those therapies not recommended by NICE are not usually covered. NICE also prepares public health policy recommendations and produces clinical guidelines. There is a strict conflict of interest policy which does not allow employees, NICE directors, or the chairs of advisory committees to have financial relationships with industry.[15] This is in sharp contrast to the United States, where up to 90% of clinical guideline authors have financial conflicts of interest.[16]

US Attempts to Establish a National HTA Program

Attempts to establish a national technology assessment program in the United States have been fragmented and frequently undermined by manufacturers and the medical profession.[17] The Office of Technology Assessment (OTA), established in 1972, acted as an advisory board to Congress on a broad range of health care issues, but was abolished by Congress in 1994. Nevertheless, the OTA became the model used by countries such as Denmark, Germany, the United Kingdom, the Netherlands, and Sweden to establish their national HTA programs.[18]

In 1978, the National Center for Health Care Technology was given a mandate to oversee research on health care technology. The center conducted a number of evaluations of surgical procedures, and issued about 75 recommendations to the Medicare program. The agency was abolished 3 years later due

to funding cutbacks by the Reagan administration and pressure from the American Medical Association and the Health Industry Manufacturers Association.[19]

Another US government initiative was the Agency for Health Care Policy and Research (AHCPR). The AHCPR was established in 1989 to enhance the quality, appropriateness, and effectiveness of health care services. In 1994, it published an evidence-based back pain clinical guideline demonstrating poor or insufficient evidence to support many back surgeries. In response to pressure from orthopedists, neurosurgeons, and the medical device industry, unhappy with the findings of the clinical guideline, Congress nearly abolished the agency. The agency survived, but Congress redirected its focus away from evaluative research and changed its name to the Agency for Health Care Research and Quality (AHRQ).[20]

AHRQ technology assessments are sometimes used by the Centers for Medicare and Medicaid Services (CMS) to guide coverage decisions. Based in part on AHRQ technology assessments, the CMS Coverage and Analysis Group (CMS-CAG) issues 10 to 15 National Coverage Determinations (NCDs) each year. CMS-CAG also has the option of requesting advice from the Medicare Evidence Development and Coverage Advisory Committee (MedCAC). MedCAC is an independent committee that includes 15 members with knowledge specific to the topic in question. Based on a systematic review of the evidence, MedCAC makes coverage recommendations to CMS-CAG. However, recent decisions suggest that the separation of MedCAC's advisory role from CMS-CAG's coverage policymaking authority has made it easier for special interests to derail evidence-based coverage decisions.

For example, in 2005, CMS-CAG requested that MedCAC review the evidence for the use of cardiac computed tomography angiography (CCTA) and provide coverage recommendations to CMS-CAG. After an exhaustive review of the evidence, in May 2006 MedCAC recommended that CMS-CAG issue an NCD for CCTA. The recommendation was based on the finding by the committee that "the relevant data were limited to small, single-center studies of selected populations and did not demonstrate a benefit with regard to outcomes."[21] However, pressure from cardiologists, radiologists, and industry representatives led CMS-CAG to essentially ignore the MedCAC recommendation.[22] CMS-CAG issued no NCD, resulting in widespread coverage of CCTA by Medicare. Three years after that CMS decision, the National Institutes of Health (NIH) agreed to fund a multimillion dollar randomized control trial (RCT) of 10,000 patients to help determine the proper clinical role for CCTA. Paradoxically, the relevant clinical effectiveness research is being performed after, instead of before, widespread coverage of the test.

Comparative Effectiveness Research (CER)

Despite setbacks, there is evidence that CMS is tightening its evidentiary requirements for new technologies.[23] In addition, the Patient Protection and Affordable Care Act (PPACA) of 2010 established an independent, trust-endowed, not-for-profit corporation named the Patient-Centered Outcomes Research Institute (PCORI) to support the production of well-validated scientific evidence, particularly comparative effectiveness research (CER). CER probably will account for an increasing portion of the US research enterprise, and will provide the high quality evidence necessary for future technology assessments and evidence-based coverage decisions.

PCORI will create and manage a national CER agenda, giving preference to the Agency of Healthcare Research and Quality (AHRQ) and the National Institutes of Health (NIH). It is not yet clear how CER results will be used to make coverage decisions at the state or national level. In fact, the PPACA legislation explicitly states that CER findings by themselves cannot be considered sufficient to determine coverage policy. CMS-CAG (or a state HTA program) would need to include CER findings in its assessments, and make independent decisions based on all of the evidence.

State HTA Programs must Complement Federal Efforts

It remains to be seen whether the establishment of PCORI will be accompanied by an increased number of CMS technology assessments and NCDs. An average of 10 to 15 NCDs per year is insufficient to adequately address the large volume of new technologies entering the market every year. But it will take time for the federal HTA process to evolve and expand. In the meantime, increasing budgetary pressures at the state level are forcing states to find ways to address these issues sooner.

States are well-positioned to establish effective HTA programs.[24,25] Even if the United States ultimately adopts a more robust federal HTA effort, it will not eliminate the need for state or regional HTA programs. There are important differences between the Medicare and Medicaid populations. CMS tends to focus more on technologies that have the greatest impact on elderly populations, but state budgets are equally affected by technologies that impact their younger Medicaid patients. In addition, state HTA programs will be crucial in translating future CER findings into coverage decisions that take into account local health care needs and structures.[26]

CURRENT APPROACH TO STATE COVERAGE POLICY

In the absence of a formal state HTA program, most state coverage policy decisions rely on an ad hoc process, based as much on what others are doing as on a systematic review of the evidence. State health policymakers typically start by assuring

that new technologies have been cleared by the Food and Drug Administration (FDA). Yet, recent FDA failures have demonstrated that FDA review is sometimes an inadequate indicator of safety. The next step for policymakers usually is to establish whether a new intervention is considered to be the standard of care. But there is no accepted clinical measure for determining the standard of care. In practice, state policymakers frequently base their coverage decisions on a review of other public and private insurer policies rather than conducting their own formal technology assessment.

Limits of FDA Regulation

In 1976, Congress mandated that the FDA begin regulating medical devices.[27] The law created 2 pathways to FDA approval. The premarket approval (PMA) pathway was designed especially for high-risk medical devices and required the review of at least some trial data. A quicker pathway for approval, called the 510(k) provision or exemption, was designed for lower risk devices, such as tongue depressors and crutches. It required only that manufacturers claim that a device be substantially equivalent (SE) to a previously approved device.

The 510(k) provision was never intended for high-risk devices, but over 98% of all new medical devices are now cleared using the 510(k) provision, including many high-risk devices. The most frequent recalls for high-risk devices are for cardiovascular devices. It would seem prudent to require that high-risk cardiac devices undergo review through the PMA pathway, but a striking two-thirds are cleared using the 510(k) exemption. Furthermore, a review of FDA medical device recalls for life-threatening or very serious hazard found that 81% had been approved through the 510(k) provision.[28] These and other findings have led the Institute of Medicine to recommend eliminating the 510(k) exemption altogether.[29]

There is evidence that even the PMA review process is inadequate to assure the safety of high-risk devices. A study of high-risk cardiac devices undergoing PMA review found that less than one-third had been studied in a randomized control trial (RCT), and only 5% had been evaluated by 2 or more RCTs.[30] However, even if FDA reforms improve the safety review process, policymakers ultimately are interested in knowing which interventions are clinically effective. In the absence of clear guidance regarding clinical effectiveness, policymakers often base coverage decisions on the standard of care. But the standard of care is difficult to define and it is not always a reliable indicator of clinical effectiveness.

Limits of Relying on Standard of Care

The factors that lead physicians to adopt new technologies have been a frequent subject of social science research. Published findings from the University of Wisconsin show that science is often overshadowed by the strong influence of local consensus, and that "[t]he scientific literature fails for a number of reasons to speak persuasively to the practitioner."[31] Since the 1980s, evidence-based medicine (EBM) has focused more attention on some aspects of clinical practice, but it has had remarkably little effect in changing the way physicians adopt new technologies. In addition, the skills required to perform technology assessments go well beyond basic EBM principles.[32] As mentioned earlier, factors such as reimbursement incentives, biases in favor of technology, fear of lawsuits, and anxiety over patient expectations still play a significant role in physicians' use of technologies.

New interventions are often promoted on the basis of clinical efficacy trials, which are typically industry sponsored. Physician proceduralists, the medical device industry, and other technology enthusiasts often argue that it is unethical to wait for more evidence when initial trials demonstrate potential benefit. In the previously discussed case of CCTA, these groups even argued that using Medicare's Coverage with Evidence Development (CED) policy would have been unethical because it would have denied access of the new imaging modality to patients not enrolled in a clinical trial. Proponents of new technologies often argue that rigorous evidentiary requirements such as those preferred in HTA evaluations are too onerous and hamper innovation.

All of these arguments were used in the late 1980s and 1990s when, based on small clinical trials, oncologists, industry representatives, and hospitals promoted the use of autologous bone marrow transplantation (ABMT) for the treatment of late stage breast cancer. Although there had been no RCT to demonstrate its effectiveness, by 1989, almost 80% of oncologists considered it a recommended treatment for advanced breast cancer.[4] At the time, the cost of the procedure was about $150,000 and increased to $500,000 if there were complications, which were common. Use of the procedure grew exponentially throughout the 1990s. Finally, by the end of the decade, 4 RCTs had shown that ABMT was an ineffective therapy for advanced breast cancer, associated with more toxic effects and deaths than standard treatment.[33] Approximately 42,680 women were subjected to unnecessary ABMT procedures, and at least $1.7 billion in excess costs were incurred.[34]

The ABMT episode is just one of many examples of technology overuse and misuse in the United States. Other examples include the ongoing inappropriate use of pulmonary artery catheters, spinal fusion surgery, vertebroplasty, drug eluting stents, percutaneous coronary intervention (PCI), coronary artery bypass graft (CABG) surgery, and arthroscopic knee surgery for osteoarthritis. In comparison to other developed coun-

tries, the United States performs on average 1.9 times the rate of PCIs, 1.4 times the rate of cardiac catheterizations, and 1.9 times the rate of knee replacements.[35] But the ABMT example is especially useful to illustrate what happens when there is no formal HTA program in place to systematically evaluate the evidence for new technologies. It also highlights the risks of relying too heavily on the advice of influential specialists or idea champions who may err on the side of promoting treatments that have not been adequately proven.[31] The point is not that expert opinion should be ignored, but that it is inadequate in the absence of a formal HTA framework to evaluate and characterize the level of evidence for clinical effectiveness.

COVERAGE POLICY BASED ON HTA PRINCIPLES

Part of the problem is that the medical profession lacks a consensus definition for clinical effectiveness. As a result, experts often refer to evidence that speaks to safety or efficacy, but not to clinical effectiveness. One of the primary benefits of establishing a formal technology assessment program is that it compels physicians to use an explicit methodology for establishing clinical effectiveness. Clinical or comparative effectiveness studies are the most useful in conducting technology assessments. They measure hard clinical outcomes, make comparisons with standard therapies, evaluate real-world settings, and involve long-term follow-up. Hard clinical outcomes include death, functional status, or quality of life, and provide the most direct evidence of clinical effectiveness.

Most of the industry-sponsored studies used to promote the early adoption of unproven technologies are clinical efficacy trials. Clinical efficacy studies are much weaker than effectiveness trials, but easier to perform. They often use surrogate outcomes, comparisons with placebo, investigational settings, and short-term follow-up. Surrogate outcomes are clinical indicators or biomarkers such as blood pressure, lipid levels, glucose levels, or prostate specific antigen levels. Surrogate outcomes are attractive because they are easier to measure than clinical outcomes, but they often have not been well validated.[36] Furthermore, some experts warn that our over-reliance on surrogate outcomes has led to poor clinical practices and has helped promote false innovations that are often later proven ineffective or harmful.[37]

The Institute of Medicine has identified HTA as the best approach to evaluate new treatments.[38] HTA is defined by the International Network of Agencies for Health Technology Assessment (INAHTA) as "a multidisciplinary field of policy analysis, studying the medical, economic, social, and ethical implications of development, diffusion, and use of health technology."[39] International experts in the field have identified 15 key principles of HTA that can be divided into 6 broad categories: (1) organization and structure, (2) level of transparency, (3) stakeholder involvement, (4) topic nomination and selection, (5) evidence synthesis, and (6) use of HTA in decision making.[40]

States that establish HTA programs will be better positioned to adopt evidence-based coverage policies and save health care dollars by eliminating wasteful spending on ineffective technologies. Three states—Minnesota, Oregon, and Washington—have established HTA programs. But the Minnesota and Oregon HTA programs are limited to an advisory role. The Washington HTA program is the only program that combines technology assessment responsibilities and coverage decision-making authority within the same committee. As we have seen in the case of MedCAC and CMS-CAG, separating the advisory role from policymaking authority can lead to weaker coverage decisions that are poorly aligned with the evidence. Because the Washington HTA program provides a stronger framework for implementing evidence-based coverage policy, it merits closer consideration.

WA-HTA PROGRAM MODEL

The WA-HTA program was established in 2006 with strong bipartisan support. The nearly unanimous vote in the state legislature was backed by statewide medical groups, including the Washington State Medical Association. The mission of the WA-HTA is to assure that "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 determinations."[41] The WA-HTA review board, composed of 6 physicians and 5 other practicing health care professionals, reviews all pertinent research prepared as an HTA report prior to voting on coverage decisions. It makes coverage decisions affecting about 763,000 people in state-purchased fee-for-service health care programs including Medicaid, the workers' compensation program, the state government employee benefit plan, and the corrections department. Any coverage decision reached by the WA-HTA committee must be followed by all state payers.

The WA-HTA program maintains a web-based portal that allows the public to make comments about ongoing assessments and view final health technology reports and decisions. At present, the website has more than 30 completed technology assessments.[42] About half of the completed assessments include decisions to stop coverage of specific tests or interventions including arthroscopic knee surgery for osteoarthritis, calcium scoring, spinal cord stimulators, therapeutic medial branch nerve block injections, intradiscal injections and facet injections. Other reports, for example those regarding the use of ultrasound in pregnancy and hip resurfacing, outline specific evidence-based coverage criteria.

Not surprising, some of the coverage determinations have been criticized, especially by industry representatives and physicians adversely affected by the decisions. However, this is a normal component of the HTA process, and it is why 2 of the 6 broad categories for any HTA include stakeholder involvement and level of transparency. The WA-HTA program also provides the opportunity for public comment on: topic nomination; submission of evidence for consideration; draft reports; coverage decision meetings; and draft coverage decisions. The coverage determinations are made in a public forum, and the committee members are independent of state agency payers and industry stakeholders. The WA-HTA program represents a model that other states should strongly consider.[24]

CONCLUSION

One estimate from the nonpartisan Wisconsin Legislature Fiscal Bureau calculates that up to 65,000 people, including 29,000 children may lose BadgerCare coverage due to budget cuts. Before further enrollment cuts are made, it would seem appropriate to establish a state HTA program in Wisconsin that can help identify and eliminate wasteful spending on unproven or ineffective medical technologies. Such a program would also improve the state's ability to align coverage policy with the findings of what will be a growing body of comparative effectiveness research to be published in the coming years.

Wisconsin could integrate a formal state HTA program with other state initiatives such as the Wisconsin Network for Health Research (WiNHR). A Wisconsin HTA program also could provide guidance to new Accountable Care Organizations (ACOs) in their attempts to bend the cost curve. It could help the Wisconsin Collaborative for Healthcare Quality (WCHQ) develop metrics for inappropriate medical technology utilization. The expertise gained through a state HTA program could be used to develop global capitation and other payment models that offer higher reimbursement schemes for the most clinically effective interventions and to stop rewarding volume over value in health care.[43] Finally, a Wisconsin state HTA program could work collaboratively with other federal and state HTA programs to avoid duplicating efforts when possible.

Albert Einstein once said, "[n]o problem can be solved from the same level of consciousness that created it." The consciousness that created our current problem is one that has failed to take a more scientific approach toward determining what works and does not work in health care. It is also a consciousness that has allowed interests other than science to have far too much influence in shaping clinical practice and has failed to emphasize physicians' professional responsibility for the stewardship of scarce health care resources.[44,45] A Wisconsin HTA program would represent a different consciousness with regard to coverage policy, one that is more evidence-based and sorely needed to address the problem of health care technology misuse and overuse.

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