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EXPANDING EVIDENCE-BASED TECHNOLOGY ASSESSMENT FOR COVERAGE IN WASHINGTON STATE

Erik J. Landaas
University of Washington School of Pharmacy
eriklⓐuw.edu

Gary Franklin
Washington State Department of Labor & Industries, Office of the Medical Director
University of Washington School of Public Health

Jeff Thompson
Willis Towers Watson

Dan Lessler, Josiah Morse
Washington State Health Care Authority

Robert Mootz
Washington State Department of Labor & Industries, Office of the Medical Director

Steven G. Hammond
Washington State Department of Corrections

Sean D. Sullivan
University of Washington School of Pharmacy

Objectives: We describe a new evidence-based method for screening and evaluating emerging medical technologies. Washington State agencies, under legislative direction, have granted authority to its agency Medical Directors and policy leaders to make coverage decisions on medical technologies using a "dossier" process. The dossier process is employed when technology advocates or manufacturers request Washington State healthcare purchasers to pay for new and emerging technologies. This offers the advocate an opportunity to submit scientific evidence and information classically associated with a more formal health technology assessment.
Methods: The submitted information is independently reviewed and summarized for Washington State's public healthcare purchasers allowing a more standardized coverage decision for all public purchasers in Washington State.
Results: This process has allowed Washington State to make twelve evidence-based coverage decisions at a fraction of the cost of classic technology assessment. To date, of twelve reviews over 6 years, one health technology was approved for coverage, ten were not covered and one did not require a coverage decision.
Conclusions: This evidence-based dossier process has yielded high-value coverage decisions of new and emerging medical technologies for public healthcare purchasers in Washington State.

Keywords: Health technologies, Devices, Evidence-based medicine, Coverage decisions, Technology assessment

Washington State has a rich history in developing and implementing evidence-based healthcare purchasing policies, including specific programs for drugs (1) and health technologies (2–4). All state agencies that purchase healthcare use an evidence language, in both statute and code, to support coverage decisions (5). In 2006, the Washington State Legislature enacted a law that created the health technology assessment (HTA) program (2). This Legislatively funded program is an effective tool that assists public healthcare purchasers seeking evidence-based coverage decisions on established and emerging healthcare technologies (3). The HTA program operates within the Washington State Health Care Authority and conducts rigorous assessments of healthcare technologies (surgery, devices, diagnostic tests, other interventions) to determine if they have evidence of effectiveness, safety, and cost-effectiveness to warrant coverage under State healthcare purchasing programs. The HTA program's estimated cost avoidance was $21 million within the first year at a cost of $1 million per year to operate (3).

At the direction of the Washington State legislature, the State's Agency Medical Directors Group (AMDG) have led evidence-based HTA efforts that inform coverage policies, purchasing and delivery strategies for the State's largest healthcare programs. The AMDG is an interagency work group comprised of medical directors and policy leaders from four state agencies that purchase and regulate healthcare services and policies (Medicaid, Public Employee Benefits, Workers Compensation, and Department of Corrections). This work group meets regularly to share information about coverage decisions, implementation issues regarding effectiveness, safety, quality, and cost of healthcare services. Each year the four agencies involved provide healthcare benefits to more than 2 million people at an estimated cost greater than $5.5 billion, or roughly 31 percent of the state budget. A highlight of these programs has been an emphasis on health technology assessment, including having conducted a federally funded national workshop on best practice of conducting HTAs (6;7).

Washington State's HTA program identifies healthcare technologies for consideration and then commissions comprehensive, evidence-based reviews of technologies that are conducted by established contractors. This program is highly effective; however, the number of technology reviews it can conduct

per year is limited. AMDG thus began to consider a new health technology assessment process to address health technologies that rapidly emerge but whose scientific evidence base might not rise to the level of a full technology assessment by the HTA body. In response to this need, a new, rapid HTA process was developed as an efficient alternative to the HTA program that the State can use when considering coverage of new and emerging technologies.

We have set out to describe Washington State's dossier program, a stand-alone evidence-based technology assessment and coverage decision process initiated in 2010. Manufacturers or other advocates of new and emerging medical technologies are asked to complete and return a detailed questionnaire and evidence supporting the safety and effectiveness of their technology to streamline coverage decision making. The information is used to inform a collaborative evidence-based decision across agencies that purchase health care for State programs. A key principle of the dossier program is that it places the responsibility for identifying, gathering, and providing the evidence on the technology representative or advocate rather than on the public payers.

The primary objective of the dossier program is to ensure medical treatments and services are safe and proven to improve health outcomes and not cost significantly more when compared with similar technologies. Participating State agencies collaborate and use the systematic evidence-based dossier process to inform more consistent coverage decisions across public payers. This results in more consistent coverage policies, a common decision-making process shared by multiple agencies, and reduced administrative burden for medical providers.

PROGRAM DEVELOPMENT

The dossier process is a rapid, low cost decision support tool that assists Washington State's public healthcare purchasers in their review of proposed technologies regarding their potential benefits, harms, and costs. Each review is conducted in a timely manner, with a coverage decision on average occurring typically within approximately 3 months of receipt of materials. In contrast, a full HTA can take up to a year or more. The dossier process is not resource intensive in that it does not require dedicated staff. The dossier program contracts with health technology assessment experts at the University of Washington (UW) to review the evidence submitted by manufacturers, evaluate the completeness and accuracy of the submission, and summarize the evidence submitted to the AMDG.

New and emerging technologies are identified for a dossier review in two ways: (i) most commonly when a provider or manufacturer requests coverage for a new medical technology, and (ii) through an annual review of recently approved technologies by the national committees that advise the Centers for Medicare and Medicaid Services (CMS). When an emerging technology is identified by either of these methods, the manufacturer is sent a copy of the dossier application that explicitly states, "If you would like to have your technology considered for payment in Washington State, please complete our dossier application."

There are many important reasons for public payers to use evidence-based research as a foundational element in the coverage decision-making process and balancing healthcare outcomes with cost-effectiveness. Without the HTA and dossier programs, many issues of value to healthcare purchasers would go unanswered. How can healthcare payers objectively determine the value of new and emerging medical technologies? Should the latest diagnostic test or new device that promotes cost savings and improved health outcomes be paid for? How can healthcare purchasers respond to the pressures from technology manufacturers and advocates that are trying to leverage new and emerging technologies for which cost-benefit concerns are unknown?

There is no doubt that new innovations in medicine have improved the health and lives of patients, yet some have come at a cost in terms of a poor safety profile adversely affecting member health, and have little evidence of effectiveness or cost-effectiveness. Healthcare purchasers are frequently faced with prioritizing allocation of limited resources for many important healthcare needs. As healthcare costs increase, it is clear that some emerging technologies may not produce better outcomes for patients and in some cases may even cause harm. New medical technologies and treatments are not always introduced or approved with objective evidence about their safety indications, demonstrated effectiveness, or any substantial evidence about how the benefits are better than that of existing technologies. The vast majority of new health technologies in the United States, for example, are approved based on substantial equivalence to a similar technology approved before 1976 (6).

The HTA and dossier programs operate independently. However, because Washington State has the benefit of both programs, the HTA and dossier programs complement each other by leveraging both the intensive resources required for a full HTA and the less intensive needs of the dossier program. Annual environmental and horizon scans allow the AMDG to determine if a technology's attributes and evidence-base require the full HTA or the dossier process. When a technology is identified for consideration, the medical directors and staff evaluate the evidence-base, potential population, and cost impacts and the likelihood of rapid usage, among other factors, to determine the most effective evidence-based decision-making processes including the dossier process. Theoretically, a dossier could be conducted on a very new health technology, and subsequently referred for full HTA as the technology diffuses in medical practice. Since starting the program, however, none of the technologies reviewed through the dossier process has later been reviewed by the HTA program. Table 1 summarizes the essential differences between the full HTA program and Washington State's dossier program.

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Table 1. Health Technology Assessment Versus Dossier Program

	HTA	Dossier
Purpose	Develop policies for selected health technologies to ensure that covered technologies are safe and proven to work	Evaluate evidence on technologies with new codes or new requests for coverage
Scope	Health technologies including devices, tests and procedures	Health technologies including devices, tests, procedures
Product(s)/output	Complete HTAs, coverage determinations, records of all meetings and public comments	Agency coverage determination
Transparency	Public process	Internal agency process
Stakeholder involvement	Broad	Specific to requesting entity (e.g., manufacturer or provider
Topic identification and selection	Selected by Health Care Authority Director in consultation with participating state agencies and the Health Technology Clinical Committee. Anyone may nominate a topic for consideration	Identified through (i) annual review of recently approved technologies by the national committees that advise the Centers for Medicaid and Medicare Services (CMS) (ii) request for coverage by product representative or provider
Evidence synthesis/review methods	Independent contactor	Evidence provided by requesting entity. Review and verification of evidence by a contracted expert (UW)
Decision process	Independent committee	Decision of agency medical directors/chief medical officers

THE DOSSIER PROCESS

Step 1: Selection

A workgroup of the AMDG meets regularly to discuss new and emerging technologies. Agency staff periodically conducts horizon scans to identify technologies that do not fall into existing policies and/or do not have coverage decisions. Additionally, staff collects information from medical and claim staff regarding new or emerging technologies on a case by case basis for which coverage decisions are not clear. The Agency Medical Directors along with clinical and policy staff also review new codes and technologies as they gain Federal approval and/or are provided codes through (CMS). The program also considers previously uncovered technologies for re-review if new evidence has been published. The dossier program prioritizes the technologies being considered and makes decisions each month regarding which technologies will be reviewed. See Figure 1 for dossier process flow chart.

The dossier program assigns a lead Medical Director for each unique technology review. The role of the lead Medical Director is to be the subject matter expert for the technology for the AMDG. The lead Medical Director may also assign staff and dedicate in kind resources to better support the AMDG's process and decision.

Step 2: Sending the Application to the Manufacturers

The application is sent to manufacturers or advocates of the healthcare technology that is being considered for coverage. The application requests responses in nine dimensions of evidence assessment (see Table 2). Five of the nine evidence questions in Table 2 were identified and adapted from the Blue Cross Blue Shield Center for Clinical Effectiveness (CCE) (8). Earlier iterations of the dossier application provided extensive guidance to the applicants on topics such as how to grade the evidence. Recently the AMDG has made the application more clear and concise with limited guidance. One of our lessons learned is to ensure that the dossier application is provided to the most appropriate individual within the requesting organization. As expected, we have had more organized and higher quality evidence that has come from corporate offices rather than from sales and marketing. Applicants frequently ask clarifying questions and AMDG staff provide support to promote higher quality applications. One of the best dossier applications came from a local provider group.

Step 3: Evidence Review by the University of Washington (UW)

Evidence submitted by the applicant is reviewed by expert University of Washington staff, including supplementary literature searches to assess if the application is complete and representative of the peer-reviewed evidence. The University of Washington submits a letter summarizing the adequacy of responses in the submitted dossier, including: description of the technology; evaluation of the quality and the completeness of the submitted scientific evidence; and a careful review of nine evidence-based questions in the dossier questionnaire (Table 2). The University of Washington letter is submitted to the dossier program and reviewed by the AMDG workgroup.

Step 4: Coverage Decision and Meeting

The dossier application and the UW review are provided to the AMDG workgroup. UW experts who prepare the review discuss the results with the AMDG workgroup and answer questions that may arise. Based on the application and

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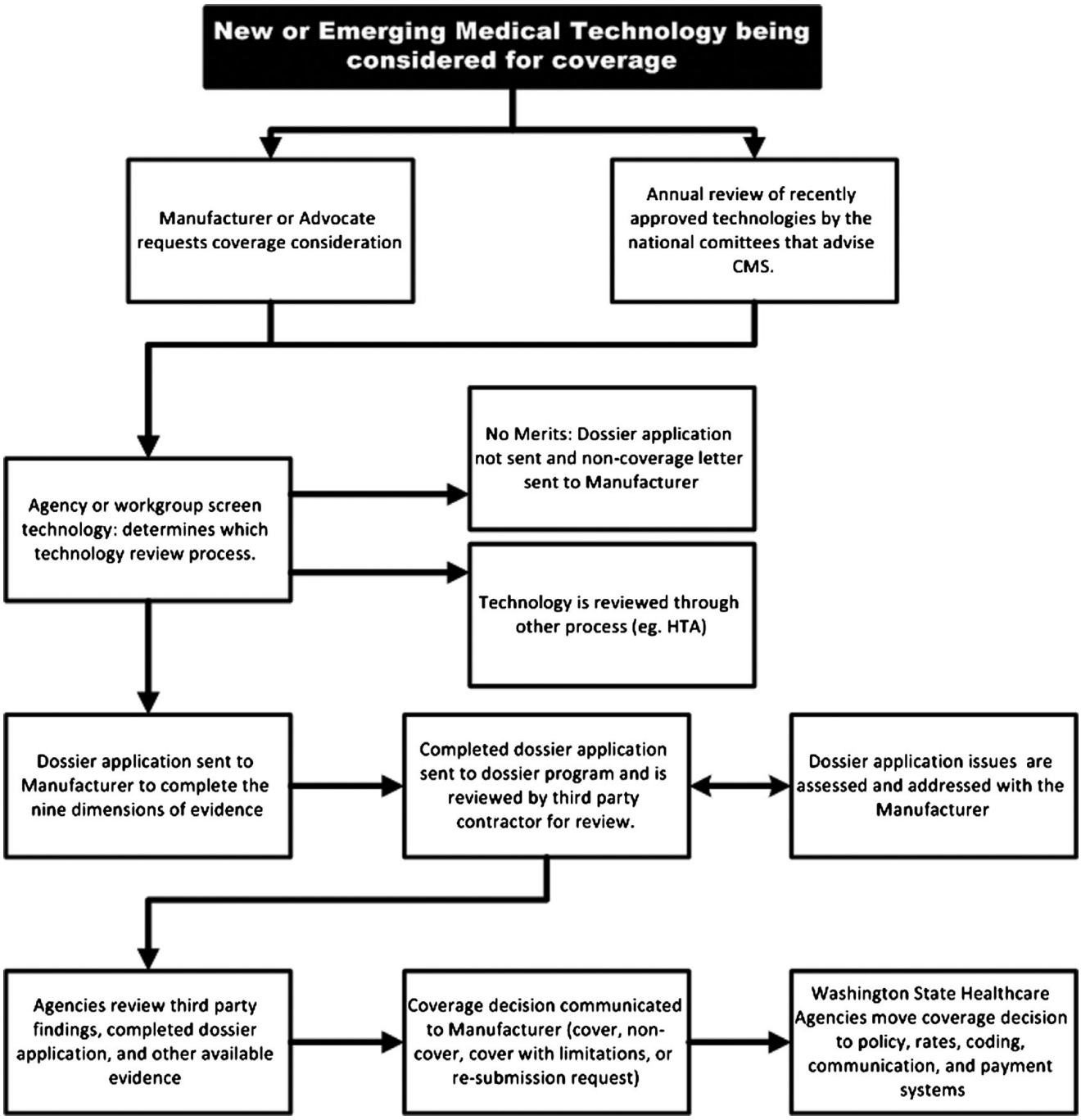

Figure 1. New or emerging medical technology being considered for coverage.

the UW review, the AMDG decides if the evidence supports coverage of the technology for each agency program.

Step 5: Decision Completion and Feedback to the Advocate or Manufacturer

The lead Medical Director develops a coverage decision letter based on the dossier submission, the review by the UW, any necessary clarifying information from the requestor and discussion with agency medical director colleagues. The lead Medical Director sends the coverage decision letter to the manufacturer or advocate and the state public purchaser adapt the new coverage decision into policy and payment methods that are then adopted by all state health payers in Washington State (Medicaid, state employees, workers' compensation, Department of Corrections).

DISCUSSION

Between January 2010 and May 2015 Washington State's dossier program requested an application from twenty manufacturers and received and completed twelve dossier reviews.

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Table 2. Nine Dimensions of Evidence Assessment

1) The technology must have final approval from the appropriate governmental regulatory bodies (e.g., FDA).
    a. What are the indications and/or intended use of this technology?
    b. Does the technology have FDA approval and what process was employed (e.g., 510(k), PMA, IDE)?
    c. Submit the approval letter from the FDA.
2) The scientific evidence must permit conclusions concerning the effectiveness of the technology on health outcomes.
    a. Summarize the scientific evidence that supports the effectiveness of the technology on health outcomes that matter to patients.
3) Compare the effectiveness of your technology with that of established technologies.
   What are the Safety Outcomes and Harms for this technology?
    a. Summarize the scientific evidence that supports the safety of the technology in the target patient population.
    b. Compare the safety of your technology with that of established technologies.
    c. Describe any important adverse events related to your technology.
4) The technology must improve the net health outcome.
    a. How would this technology increase the quality of care for Washington State patients (e.g., injured workers, Medicaid beneficiaries, state employees)?
    b. How does this technology improve care and patient outcomes (e.g., return to work and/or reduce hospital stays)?
    c. What specific safety issues does this technology raise or solve?
5) The technology must be as beneficial as any established alternatives.
    a. How is this technology (1) different from and (2) more efficacious and/or effective than technologies that currently address the medical conditions for which this technology has been approved?
    b. If this is a diagnostic technology, how does it compare to established gold standard diagnostic technologies?
6) The improvement must be attainable outside the investigational settings.
    a. Specify which, if any, of the enclosed articles look at the clinical effectiveness of the technology and its impact on health outcomes (e.g., return to work of injured workers, reduced disease progress or medical costs).
7) Summarize the scientific evidence that supports the fiscal impacts of the technology to the target population.
    a. What is the total cost for the technology (e.g., the price of the technology plus the costs of related physician services, outpatient hospital services or other services that patients using the technology will need)?
    b. What HCPCS or CPT® codes will be used to bill for this technology?
    c. Compare the cost of the technology with the cost of established technologies.
8) Which Workers' compensation programs, Medicaid, Medicare or private Health Plans reimburse for use of this technology? List payers with established billing codes, fees, guidelines and/or policies.
9) List and describe relevant, published evidence based guidelines on this technology?

The technologies and coverage decisions are listed in Table 3. One technology was approved for coverage, ten were not, and one had no formal recommendations.

The dossier application that did not require a decision was a request to increase the number of allowable hemodialysis treatments for patients with renal failure. It was not a new technology; however, a provider organization had requested state agencies to increase the standard frequency of dialysis. The dossier process with independent review of the evidence provided clearer insight and better understanding of the advocate's issues. The whole process improved communications between State healthcare payers and providers, led to updating some internal protocols allowing for some exceptions to the standard dialysis frequency allowed based on new evidence, and improved care for individuals requiring hemodialysis in Washington State.

The one technology that passed muster by the dossier program and is now covered by Washington State public payers is a genotype test of node-negative women to determine the efficacy of chemotherapy for women with breast cancer. The manufacturer's original dossier application was denied coverage because it was outdated and requested coverage for both node-positive and node-negative breast cancer. After review of current literature, the AMDG asked the manufacturer to re-submit evidence for node-negative women only because the available evidence was higher quality when compared with that for node-positive women.

The AMDG has not systematically conducted a prospective evaluation of the impacts of the dossier process; and there is not an evaluation plan aimed at comparing the HTA program with the dossier program because they address technologies at very different stages of health technology development. Most of the full HTA reviews are conducted following wide adoption and dissemination of technologies. Technologies evaluated by the dossier process were either not covered or had been marginally used. Because of this difference, the HTA program can more

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Table 3. Dossier Program Reviews and Coverage Decisions, 2010–2015

Description of technology	Coverage: yes/no
Wearable vest defibrillator	No
Skin substitute, porcine biologic implant	No
Positive and negative node assays to determine the efficacy of chemotherapy for women with breast cancer	No- asked for updated dossier
Hysteroscopic sterilization procedure	No
Negative node assay to determine the efficacy of chemotherapy for women with breast cancer	Yes
Percutaneous tibial nerve stimulation	No
Digital performance capacity exam (PCE)	No
Policy revision to determine the value of increased frequency of hemodialysis	No decision necessary
Provides clinical knowledge on drug metabolism to help predict medications and dosing for individual patients	No
Assists in emptying bowels or anal irrigation Sent application on 24 September 2013 and no response	No
Skin substitute: human derived allograft	No
Neuro-visual rehabilitation or vision therapy[a]	No

[a]There are limited cases where vision therapy is covered under certain circumstances.

effectively estimate financial savings based on prior years costs and usage following noncoverage decisions, whereas the technologies reviewed by the dossier program do not have the benefit of existing usage data on the technologies reviewed; therefore, we have yet to develop an effective methodology to conduct a cost analysis on the dossier reviews.

Although directly aimed at assisting the state to make better-informed decisions about covering emerging medical technologies, the dossier process also is informative for proponents to better understand the increasing role evidence plays in covering new services as well as the demands for accountability among healthcare purchasers.

The dossier application process has grown and matured since the inception of the dossier program. As such, other states and organizations have begun to use Washington State's dossier model to develop similar screening approaches for new and emerging technologies. For example, the New York Medicaid system recently implemented a dossier program that was based on Washington State's model.

The benefits to Washington State's public health purchasers from its dossier process have included: (i) efficient use of limited resources to systematically review evidence for new and emerging health technologies; (ii) enhanced opportunities for new technology proponents to provide information supporting their devices and procedures; (iii) enhanced clarity and transparency for proponent, providers, and patients regarding what goes into making evidence informed coverage decisions; (iv) assurance that state purchased healthcare technologies are effective, safe and of reasonable value, thus achieving meaningful outcomes for public monies; (v) increased consistency in coverage decisions across the State's public healthcare purchasers.

Washington State's experience demonstrates how the inclusion of new tools for evidence-based medicine could contribute to improving health outcomes for individuals as well as assuring healthcare funds are spent appropriately for medical services. Using research regarding medical effectiveness can help payers, states, and the Federal government allocate resources more wisely (9).

CONCLUSION

The dossier program has been used effectively for 6 years in Washington State and could be easily replicated by other states, Federal healthcare purchasers, or private health insurers. The key components of the program include a body of medical experts (e.g., Medical Directors and policy staff) to evaluate applications and reviews and make recommendations for coverage decisions; staff to organize the process, convene meetings and identify technologies for consideration; identify and contract with an independent evaluator (e.g., UW experts); and adapt or use Washington State's dossier application.

CONFLICTS OF INTEREST

The authors have not conflicts to declare.

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