Improving State Medicaid Policies With Comparative Effectiveness Research: A Key Role for Academic Health Centers

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Abstract

After the Patient Protection and Affordable Care Act is fully implemented, Medicaid will be the largest single health care payer in the United States. Each U.S. state controls the size and scope of the medicine benefit beyond the federally mandated minimum; however, regulations that require balanced budgets and prohibit deficit spending limit each state's control. In a recessionary environment with reduced revenue, state Medicaid programs operate under a fixed or shrinking budget. Thus, the state Medicaid experience of providing high-quality care under explicit financial limits can inform Medicare and private payers of measures that control per-capita costs without adversely affecting health outcomes. The academic medicine community must play an expanded role in filling evidence gaps in order to continuously improve health policy making among U.S. states. The Drug Effectiveness Review Project and the Medicaid Evidence-based Decisions Project are two multistate Medicaid collaborations that leverage academic health center researchers' comparative effectiveness research (CER) projects to answer policy-relevant research questions. The authors of this article highlight how academic medicine can support states' health policies through CER and how CER-driven benefit-design choices can help states meet their cost and quality needs.

Medicaid is a state and federal partnership that is jointly funded but state-administered. After the Patient Protection and Affordable Care Act (PPACA) is fully implemented, Medicaid will become the largest single health care payer in the United States. Currently, Medicaid covers the selected low-income populations of children, pregnant women, and elderly and/or disabled adults on Medicare. In 2014, eligibility will extend to all individuals under age 65 with incomes under 133% of the federal poverty level ($14,404 for an individual in 2010).[1] Because U.S. states must balance their budgets each fiscal year and cannot deficit spend, the necessity of providing medical and behavioral health services for a larger population is increasingly challenging in a recessionary economy.

The Medicaid program has a federal match component, through which the federal government matches a portion of funds that states spend on Medicaid. This match will continue under the PPACA; nevertheless, many states face the dilemma of budget shortfalls, increased Medicaid enrollment, and increasing expenditures—the last are due in part to new treatments and health care technologies. Currently, state Medicaid programs consider three options to cut expenditures: (1) reducing the covered population by changing eligibility requirements, (2) reducing reimbursement for providers, and (3) reducing the scale and scope of liability by changing the benefits offered. Under the PPACA, states are not permitted to change eligibility requirements for adults until 2013 and for children until 2019 unless they give up federal matching funds.[1] Also, in 2013 and 2014, states must *in*crease reimbursements to primary care providers so that they match Medicare's primary care services reimbursement rates.[1] This leaves option number three—changing benefits—as the only lever in the face of budget cuts. Medicaid will seek to reduce costs by cutting benefits while still increasing or at least maintaining quality. Thus, there is an urgent need for academic medicine to play an expanded role in filling evidence gaps in order to continuously inform benefit decisions and to improve health policy making among U.S. states. This need is particularly important for Medicaid because the Medicaid population comprises primarily vulnerable populations who have largely been left out of the clinical research enterprise and who have often received the most fragmented care.[2] In this article, we discuss how state Medicaid programs are already using comparative effectiveness research (CER) to inform policy, and we outline ways that academic researchers can support states by developing and communicating targeted CER.

CER and Health Policy

A Federal Coordinating Council for Comparative Effectiveness Research report and an Institute of Medicine (IOM) report, both released in July 2009, defined and codified CER as a goal of health research.[3,4] The IOM defined CER as "the generation and synthesis of evidence that compares the benefits and harms" of methods to diagnose, treat, or

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monitor a clinical condition.[4] According to the IOM's report, "The purpose of CER is to assist patients, clinicians, purchasers, policymakers, and the public to make informed decisions that will improve health care at both the individual and population levels."[4] Federal funding made available in the American Recovery and Reinvestment Act rapidly accelerated the development of CER, and the PPACA emphasizes increasing the functioning and structure of CER.[3]

State Collaborations

Although "comparative effectiveness research" is a new name, several state Medicaid programs have used CER since 2003 to make benefit-coverage decisions under the auspices of two particular programs, the Drug Effectiveness Review Project (DERP) and the Medicaid Evidence-based Decisions project (MED). The experience of these states, which provide care under tight explicit financial constraints, can illustrate how some state Medicaid programs attempt to control per-capita costs without adversely affecting health outcomes. Because of Medicaid's role as a large health payer, Medicare and private payers could study and possibly copy Medicaid's approaches to the challenge of providing excellent care in a constrained fiscal environment.

DERP

DERP is a multistate collaboration, comprising several Medicaid programs and the Canadian Agency for Drugs and Technologies in Health (CADTH; List 1).[5] Its genesis was in Oregon in 2001 after Medicaid drug expenditures were projected to increase by 60% over the next two years (2002–2004). Faced with this untenable trend, Governor John Kitzhaber (1995–2003, 2011–present) championed groundbreaking legislation. Overcoming pharmaceutical drug company objections, Kitzhaber—himself an emergency room physician by training—passed legislation that lifted a statutory ban forbidding Oregon Medicaid from using a preferred drug list. The goal of the new legislation was to increase price competition among suppliers. A key provision stipulated that drugs selected for the preferred drug list had to be first compared and only then—*if* their effectiveness was found to be similar—could the state select drugs by price.

List 1

States and Agencies Participating in either The Drug Effectiveness Review Project (DERP) or the Medicaid Evidence-based Decisions Project (MED), December 2010

DERP participants

1. Arkansas
2. Colorado
3. Idaho
4. Maryland
5. Missouri
6. Montana
7. New York
8. Oregon
9. Washington
10. Wisconsin
11. Wyoming
12. Canadian Agency for Drugs and Technologies in Health

MED participants

1. Alabama
2. Alaska
3. Arkansas
4. Minnesota
5. Missouri
6. New York
7. Oklahoma
8. Oregon
9. Washington
10. West Virginia
11. Wisconsin

Shortly after Kitzhaber passed the legislation allowing a preferred drug list, Oregon began a long-term relationship with researchers at Oregon Health & Science University. The state commissioned systematic reviews of the clinical literature comparing the effectiveness, safety, and effect on subpopulations of drugs within classes. Evidence synthesis through systematic reviews is an established academic activity often conducted by more junior researchers or established experts. As the state of Oregon completed the first four reviews, officials in Washington State and Idaho found the research to be superior to that which they were then using to inform their pharmacy and therapeutic committees, and these states' officials suggested an informal collaboration among the three states to fund four additional reviews of drug classes. Together, the three states' officials soon realized that additional classes of drugs needed study and that any reports (both those already completed and those to come) would require regular updating. In early 2003, the Center for Evidence-based Policy (CEbP), which Governor Kitzhaber created after his second term, began organizing a formal multistate collaboration that became known as DERP. (The CEbP, founded in 2003, is an independent entity located in the School of Medicine at Oregon Health & Science University that is funded through grants and contracts with local, state, and federal governments as well as private, not-for-profit organizations. Its staff of former state policy makers, researchers, and physicians work to "address policy challenges through evidence and collaboration" [CEbP mission statement].)

The DERP collaboration contracts with Evidence-based Practice Centers (EPCs) in Oregon, North Carolina, and California to conduct systematic reviews. The Agency for Healthcare Research and Quality (AHRQ) funds EPCs as five-year contracts awarded to institutions in the United States and Canada. EPCs review all scientific literature on clinical, behavioral, organizational, and financing topics relevant to health care in an effort to produce evidence reports and technology assessments of new discoveries or existing technology and therapies. As of February 2011, 11 states and CADTH had become members of the collaboration (List 1), and DERP had produced systematic reviews of 35 classes of drugs as well as numerous updates of reviews as new research was published (Table 1).

MED

The CEbP began MED in 2005 at the request of Medicaid administrators from several states who were seeking access to studies that were similar to those produced by DERP, but which covered topics beyond the comparative effectiveness of drugs. MED examines the myriad of other coverage and benefit-design decisions routinely made by Medicaid programs. MED reviews clinical literature on diverse topics including the risks and benefits of various high-technology imaging procedures, the appropriate use of vacuum wound closures, the comparative effectiveness of treatments for substance abuse, and the efficacy of various dental interventions. MED also reviews the health services research literature on programs and

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Table 1

Reports and Updates of Drug Classes or Drugs to Treat Specific Diseases Completed by the Drug Effectiveness Review Project (DERP), 2002–2010

Drug class	Original report (MO/YR)	Last update (MO/YR)
Alzheimer drugs	4/05	6/06
Angiotensin converting enzyme inhibitors (ACE)	10/02	6/05
Angiotensin II receptor antagonists (ARB)	9/04	2/06
Antiepileptics	12/04	5/08
Antidepressants—second generation	11/04	2/11
Antiemetics—newer	1/06	1/09
Antihistamines—second generation	11/04	5/10
Antiplatelets	11/05	6/11
Asthma controller drugs	11/08	4/11
Atypical antipsychotics	1/05	7/10
Inhaled beta agonists	11/06	None
Beta andrenergic blockers	9/03	7/09
Calcium channel blockers	9/03	3/05
Diabetes combination drugs	11/07	None
Constipation drugs	9/07	None
Diabetes drugs (incorporated into diabetes combined update report, below)	8/08	None
Diabetes combined update report	2/11	None
ARB and ACE inhibitors	12/09	None
Drugs to treat attention deficit hyperactivity disorder	9/05	10/11
Drugs to treat fibromyalgia	4/11	None
Hepatitis C drugs	5/07	None
Hormone therapy (formerly estrogens)	3/03	11/07
Inhaled corticosteroids (incorporated into asthma controller drugs, above)	1/05	1/06
Long-acting opioid analgesics	11/02	7/11
Multiple sclerosis drugs	7/07	8/10
Nasal corticosteroids	6/06	6/08
Neuropathic pain	10/07	6/11
Quick-relief medications for asthma	11/06	10/08
Newer insomnia drugs	12/05	10/08
Nonsteroidal anti-inflammatory drugs	5/02	11/10
Oral hypoglycemics	3/03	5/05
Overactive bladder drugs	2/03	3/09
Proton pump inhibitors	11/02	5/09
Skeletal muscle relaxants	4/03	5/05
Statins	4/02	11/09
Targeted immune modulators	12/05	3/11
Thiazolidinediones (incorporated into diabetes combined update report, above)	5/06	9/08
Topical calcineurin inhibitors	10/08	None
Triptans	3/03	6/09

disease management products (e.g., data analysis programs designed to improve disease control of diabetic clients) that are aggressively marketed to Medicaid. As of February 2011, MED comprised 11 collaborating states (List 1), had completed 170 reports, and was in the process of writing 29 more (examples in List 2). These reports are not necessarily full systematic reviews; rather, they are summaries of the best available evidence including not only randomized trials but also any available systematic reviews that are superlative. MED routinely searches for new primary studies related to existing reviews, and when such studies are found, MED evaluates the effect the *new* research has on the review's *existing* conclusions and, if needed, adds updates.

Lessons Learned to Successfully Link State Medicaid Policy to Academic Medicine Through CER

Despite the extensive resources DERP and MED already provide to help inform Medicaid policy, there is seemingly unlimited need for CER, especially with respect to the populations of pregnant women, children, and disabled and/or elderly adults whom Medicaid covers. Using CER to inform benefit-design in a systematic way would assist all Medicaid programs. Yet, bridging the policy and research worlds is a multitiered challenge that involves the creation and analysis of evidence coupled with the navigation of preferences and constraints of policy makers.[6] On the bases of the lessons we learned from the DERP and MED collaborations and on our roles as academic researchers who have conducted policy-relevant research for Medicaid, we believe that four steps are key to creating the productive, collaborative, and sustainable relationships between state policy makers and academic researchers that can leverage CER to produce actionable results.

1. Constructing relationships

The first prerequisite to using CER in a Medicaid agency is to create an environment in which the right relationship between a core of qualified researchers and the policy makers within the Medicaid program can develop. Researchers will likely do well when they approach a public–private collaboration as participatory research. That is, researchers should not unilaterally develop the questions to be answered; rather, they should work with the agency to derive the most important, relevant, and timely questions. Cooperatively developing such questions can be challenging simply because of the "language" barrier that exists between researchers and policy makers. Even the nomenclature "translational science" highlights this barrier; one approach to a question requires some "translation" to be useful and relevant for

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List 2

Representative Medicaid Evidence-based Decisions Project (MED) Reports Completed and In Progress, December 2010

Completed

1. Role of Percutaneous Coronary Intervention (PCI) in Patients with Stable Angina
2. Outcomes and Cost Effectiveness of Standard vs. Reduced Intensity Stem Cell Transplantation
3. Behavioral and Other Interventions for Treatment of Autism in Childhood and Adolescence
4. Wheelchair Cushions Comparison, All Codes
5. Genetic Screening Algorithm for Covering or Not Covering Genetic Testing
6. Extended Office Hours in Primary Care Practices to Increase Quality and Cost Effectiveness
7. Effectiveness of Weight Management Programs in Children and Adolescents
8. Insulin Pumps versus Multiple Daily Injections for Type 1 and 2 Diabetes
9. Spinal Surgery for Back Pain: Spinal Fusion and the use of Artificial Intervertebral Discs
10. Caries Risk Assessment and Topical Fluoride Application in Primary Care Settings
11. Buprenorphine and Methadone in Opiate-addicted Pregnant Women
12. Substance Abuse Treatment During Pregnancy*

In progress

1. Effectiveness of Twice Yearly Preventive Dental Visits
2. Efficacy of Residential Psychiatric Treatment Centers for Children
3. Prior Authorization (PA) Strategies for Medical Imaging
4. Bilateral Cochlear Implants vs. Unilateral Cochlear Implants
5. Wearable Cardio-Defibrillator (WCD) and Implantable Cardio-Defibrilator (ICD)
6. 1st Line, 2nd Line and Palliative Chemotherapy

* Indicates a report that is publicly available.

practitioners of another. In particular, researchers often lack the knowledge of what policy makers really need, and their unique jargon, training, and experiences further complicate communication with policy makers. The DERP and MED collaborations have surmounted this difficulty by including in the first steps of any collaboration careful questioning, listening, and reasoning by researchers in order to identify the central problems prompting policy makers to seek research support. This process can be time-consuming; nevertheless, building trust, sharing a common vision of the research questions, and communicating larger knowledge goals are crucial first steps.

Specific differences that collaborators must negotiate include professional incentives and timetables. External funding sources that require long lead times and journal publications that require review and revision can put academic medical researchers on a slower pace than policy makers who often face legislative review on very short schedules. In addition, policy makers may need research to be outcomes focused rather than process based in order to ensure an improvement in population health. For example, researchers may use surrogate end points, such as hemoglobin A1C in diabetes—instead of a health outcome measure, such as time to dialysis, which not only has a clearer link to population health but also provides a concrete outcome that policy makers can support.

2. Constructing questions

Investigating a question that is directly relevant to policy is often enough to spark the interest of a researcher, but simply asking policy makers what they want to know will not guarantee a researchable question. Policy makers often start their thinking at a very general level; for example, they might ask, "What does the research show about the appropriateness of percutaneous coronary interventions (PCI)?" Only further exploration will uncover the concern that limited tax dollars are spent on PCI, which does not always result in better health outcomes. Thus, policy makers may really want to know whether PCI is obtaining significant health value for the expenditures. Initial literature scans may reveal that in many cases, such as suspected myocardial infarction or unstable angina, the research clearly shows the benefit of the procedure. Policy makers and researchers may then agree that the final question should center on the appropriateness of the use of PCI in cases of stable angina, for which credible treatment options exist and for which the net benefit of the PCI intervention is not clear. Using the standard PICO (population, indication, comparator, outcome) framework to guide this conversation can assist in question development.

In addition, understanding the perspective for the analysis is critical. Collaborators should know whether the question will be answered from the perspective of the patient or population, the payer, the Medicaid program broadly, or society because the benefits and costs differ according to each of these perspectives.[7]

3. Constructing answers

Policy makers and researchers commonly focus on elusive "actionable results," which occur when a policy change or coverage decision directly improves population health, but actionable results can be difficult to achieve. Further, a definitive finding of comparative effectiveness or cost-effectiveness does not necessarily dictate the policy approach or the clinical decision. Thus, although research is a valuable tool, it is not a panacea. Conducting relevant research to inform a policy decision takes work and disciplined question formation. Even after such an effort, the result may only be to better define the gap of knowledge about a given intervention. All collaborators must accept that the "answer" may simply be new, more focused questions.

In addition, policy makers must be prepared to accept findings of an independent research protocol, even if the findings do not match their prior expectations or curry political favor. They must recognize that the policy process is strengthened by the independence and quality of the research they employ. If the question is well formed and the research process is credible (using, for example, internationally accepted methods), then honoring the results of the research gives policy makers the foundation for making and sustaining the sometimes politically difficult decisions required to gain maximum value from their public expenditures.

As policy makers must accept results that may not be politically expedient,

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academic researchers must accept resources and methods they do not typically employ. Academicians may be familiar with Medicaid claims databases (resources that represent a substantial up-front investment of time for organizing and structuring large amounts of data but which can pay off in many years of policy-relevant research studies[8]); however, these researchers must allow for some research norms that are *un*familiar or uncomfortable. A state generally requires a quicker research pace—involving timelines measured in weeks or months—than is common in the academic process. This faster pace also means that researchers must be comfortable sharing research results quickly—even before publication.

Finally, transparency in research protocols is key to ensuring not only the *trust* of policy makers and the general public who may review research findings and policy decisions, but also the *adoption of new protocols, interventions, or medications* by these stake holders. Time and budgets may limit what is feasible in a policy context, so policy makers and the public must be aware of and understand the limits of any research or research findings used in the policy process. Often in Medicaid processes, benefits are discussed in a public forum so that all stakeholders and clients can provide input into a policy. For this reason, another peculiarity of the policy process is that researchers must adapt to include the need to translate results into lay language, as we discuss next.

4. Constructing messages

Communicating findings to stakeholders—be they policy makers, consumers, voters, or health providers—can be described in terms of implementation and dissemination research. This research is also known as adoption and diffusion studies, risk communication, or, more broadly, health literacy (which is itself defined as the ability to translate medical jargon and the results of the study into usable information). Even if in a CER study one treatment has a clear advantage in net health benefit over another, what action stakeholders should take and how to proceed with that action can remain unclear and, in turn, become the basis for another step in the research process.

If CER collaborators construct messages that effectively communicate the results of their research to the appropriate institutions and governing bodies, CER may result in changed and better policies. On the basis of our observations of consumer behavior, we believe that many Americans have a particularly strong conviction that more and newer health care interventions are better than the existing options. In many cases, this belief leads to widespread adoption of interventions for which researchers have never clearly demonstrated that benefits exceed harms at a societal level. This widespread adoption occurs in part because payers are expected to pay for an intervention *unless* it has been proven to be *in*effective. This expectation is illustrated in the FDA's requirement that manufacturers show efficacy in a placebo-controlled randomized trial in a highly selected population. Efficacy should be proven through CER—that is, through trials in usual care settings with head-to-head comparisons with alternative treatments for new drugs in a class. Indeed, some widespread practices once rigorously evaluated, such as hormone replacement therapy in postmenopausal women, have been found to convey no benefit at best—and to cause harm at worst. Thus, effective CER that shows proof of benefit in a given population *before* widespread adoption could result in a substantial shift in benefit policies. In addition, proof that an intervention is more effective or less risky than existing alternatives could also have an impact. Indeed, the potential for better health outcomes and mitigated costs, which CER promises, is based on gaining and effectively disseminating such knowledge.

An Example of CER-Informed Policy

One area of policy that CER can influence is prescription drug coverage. State Medicaid programs spent approximately $234 billion in 2008 on prescription drugs, yet few CER studies examine medications.[9,10] In high-impact journals, only a third of the studies evaluating the effectiveness of medications were CER studies, and only a few focused on medication versus nonmedication therapies.[10] Colorado Medicaid offers an example of a program that currently uses DERP and other available CER to manage prescription drugs: The policy makers who set the Colorado Preferred Drug List use DERP's systematic reviews in a public process to select drugs for benefits coverage. The case of proton pump inhibitors (PPIs) in particular illustrates the effective use of CER. PPIs are the third-highest prescription drug class sold in the United States. In Colorado, Medicaid spent over $2 million on PPIs in the last year, and about 10% of patients had an ulcer diagnosis, which is the clearest indication for PPI use. While these medications can prevent gastrointestinal bleeding and treat ulcers, the studied indications and benefits are narrower than their current use. New studies suggest that long-term use of these medications can cause harm by increasing the risk of osteoporosis, pneumonia, and clostridium difficile.[10,11] The DERP report has helped identify the risks of, the benefits of, and the indications for using PPIs as well as alternative treatments including the "stepped-down" therapy of h-2 blockers. Colorado is using the DERP report in conjunction with published guidelines and literature to create a policy requiring providers to complete a prior authorization form before prescribing a PPI to a patient long-term. The policy is meant to change the pervasiveness of PPIs and to encourage providers to carefully consider whether long-term use of PPIs is really necessary for all patients.

A Specific CER Opportunity

Another example of the potential use of CER is the use of antiepileptic drugs. Antiepileptic drugs and other neuropsychiatric medications represent a large and growing portion of Medicaid expenditures. Antiepileptic drugs are a class comprising more than 20 individual agents labeled for use in preventing and treating seizures. These drugs, which have varying mechanisms of action, varying drug-to-drug interactions, and varying adverse effects potential, include brand name and generic drugs with respective differences in costs to U.S. states and consumers. New formulations, such as long-acting and slow-release forms, promise better efficacy and fewer side effects, yet there is limited comparative evidence for use among populations of the young and old who most commonly use these drugs. Indeed, according to the draft of a CER protocol, the Effective HealthCare Program of the AHRQ reached the conclusion, after a systematic review and examination of all available evidence, that the best therapy, be it a brand name or

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generic drug, for people with seizures remains unknown.[12] Antiepileptics, and psychotropic medications more generally, are examples of areas ripe for CER that, with effective messaging, could inform Medicaid policy.

Going Forward

There is an urgent and important need for academic health centers (AHCs) to lead the way in generating innovative and policy-relevant CER for state Medicaid programs to use in making benefit decisions. AHCs can provide assistance to state Medicaid programs in a number of ways. First, students and trainees can complete systematic reviews to begin to fill knowledge gaps that may be of interest to policy makers. Second, junior faculty, including the AHRQ Mentored Clinical Scientist Comparative Effectiveness Program scholars, along with more established researchers, can work on constructing relationships with state Medicaid agencies to inform their (the researchers') research interests and projects. These relationships, benefiting researchers, policy makers, and state Medicaid programs and their beneficiaries, can be long-lasting. To illustrate, after DERP started, researchers in Oregon whose research interests related to Medicaid issues formed a collaborative open to researchers from any university in the state as well as to state policy makers. This group continues to meet two to six times a year to develop research questions and share findings. Finally, academic faculty can present at Medicaid pharmacy and therapeutics meetings or other public meetings that focus on Medicaid benefits to share their research and knowledge about a topic area.

The impetus is not only on AHC researchers; state policy makers can reach out to their local AHCs to ask for literature reviews or for research projects that could employ Medicaid claims data to answer a pressing policy question.

The great promise is that CER is a way to reduce costs while improving health outcomes. Although much of the focus on CER is on improving care at the patient–clinician decision-making level, public payers and policy makers may also use CER to get the most value out of limited taxpayer dollars.[13] Payers and policy makers can encourage the use of evidence at the point-of-care to lead to better care at the system level. The Medicaid changes mandated in the PPACA will provide new opportunities for CER because state Medicaid programs will cover larger, more general populations, and states will, in turn, need to find new ways to deliver high-quality and cost-efficient health care with the best health outcomes to these populations. State policy may be the harbinger of things to come, as Medicare will also have to limit services if health expenditures continue to increase. As the successful model of state and researcher collaboration in both DERP and MED demonstrate, U.S. states can together formulate policy questions and then collaborate with AHC researchers to find the best evidence to inform health care resource utilization.

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