A Roadmap for State Policymakers to Use Comparative Effectiveness and Patient-Centered Outcomes Research to Inform Decision Making

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INTRODUCTION

Making informed decisions aimed at improving health care access and quality in a rapidly changing health care environment is hard. Recent interest by the federal government and others in funding comparative effectiveness research (CER) and patient-centered outcomes research (PCOR) will provide new resources to help inform decision making by policymakers and all involved in the health care system.¹ The purpose of this Roadmap is to guide policymakers in the use of CER and PCOR, as well as other research to support the decision-making process.

With support from the Patient-Centered Outcomes Research Institute (PCORI), the National Academy for State Health Policy (NASHP) has created this guide to support the use of various types of research in state policymaking. Authorized by the Patient Protection and Affordable Care Act, PCORI is funding research on the comparative effectiveness of different interventions but does not fund research examining cost-effectiveness.² Therefore, for the purposes of this Roadmap, we will not reference studies that solely examine cost-effectiveness.

Information for the Roadmap was obtained from several sources, including a national survey of 494 state health policymakers and a series of interviews with a variety of state policymakers including Medicaid, public health, worker’s compensation directors, state employee health benefits directors and others.³ All parts of this project were guided by an advisory group composed predominately of state policymakers (see Appendix A). Policymakers’ input on the benefits and challenges they face in using research, particularly CER and PCOR, and the steps they described in using evidence throughout the decision-making process were the foundation of this guide.

Findings from the national survey and calls with policymakers indicate many involved in crafting public policy are not familiar with CER and PCOR and could use additional information on the use of this evidence within the decision-making process. This Roadmap was created to help policymakers with varying levels of experience understand CER and PCOR and learn strategies to more effectively use this research to inform their work throughout their decision-making process from the earliest stages of first identifying an issue requiring a review of the research to the later evaluation of an implemented program.

HOW TO USE THE ROADMAP

As with other maps, we begin this document with a legend designed to help orient those who are new to using this research before they begin using CER and PCOR in their work on policy and program development. Readers who are more familiar with CER and PCOR can move ahead directly to the Roadmap and the steps provided. While the steps follow a general progression, they are not intended to be strictly linear. Within each step, we have organized strategies that range from short-term to long-term, understanding that states have varying degrees of resources and time available and, for those early in this process, may need different strategies from states with long-standing programs utilizing CER and PCOR.

Steps 1 through 3 of the Roadmap provide information to identify when CER and PCOR can inform policymaking and strategies to find and evaluate the available research. Steps 4 and 5 review approaches for using the evidence-based findings in designing the program or policy and communicating the findings after a decision has been made. Step 6 addresses the need to evaluate the program or policy and monitor new CER and PCOR as it becomes available. The section following is entitled Stories from the Road and provides several case studies of states’ use of CER in the decision-making process.
Throughout the Roadmap, the beginning of each section presents a list of key questions to consider as the material is reviewed. Text boxes are included to highlight both ‘at-a-glance’ resources and to present commentary from state policymakers that informed the project. In addition to the final case studies, readers are provided with examples of the application of the steps including three brief hypothetical scenarios referenced throughout the sections.

The appendices provide additional resource material for state policymakers. This material includes other sources of research, guides and tools (including glossaries and research appraisal tools), a list of suggested reading on CER, PCOR and evidence-based decision making, and an overview of conducting a systematic review that policymakers may find useful as a handout.

Unless otherwise noted, the views expressed in this guide are those of the authors.
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National Academy for State Health Policy

LEGEN D FOR TH E ROA DMAP

COMPARATIVE EFFECTIVENESS AND PATIENT-CENTERED OUTCOMES RESEARCH AND HOW THEY DIFFER FROM OTHER TYPES OF RESEARCH

Policymakers are increasingly expected to base their policy and program decisions on evidence showing the effectiveness of the selected intervention. In order to do so, policymakers are tasked with identifying, reviewing, and translating available research findings to fit specific program and policy needs. Many policymakers are familiar with the term ‘evidence-based practice’ , an approach defined by the Agency for Healthcare Research and Quality (AHRQ) as “applying the best available research results when making decisions about health care.”

Two other specific forms of research - comparative effectiveness research (CER) and patient-centered outcomes research (PCOR) - are often underutilized sources of evidence that can help inform policymaking.

Comparative Effectiveness Research

Definition: Comparative Effectiveness Research (CER) refers to research designed to compare the effectiveness of different interventions, examining the risks and benefits of several treatment interventions, supporting consistent and rational decision making, and improving the delivery of care.

Methodological approaches used in CER include studies designed to compare clinical, safety, or cost differences between two interventions, as well as studies reported as systematic reviews examining and comparing a number of different single-intervention studies. For example, a single study may directly compare the outcomes of two or more interventions designed to help obese individuals manage their weight (e.g., wellness programs, different medications); similarly, researchers may compare individual studies by conducting an systematic review of the existing literature on each intervention. The direct comparison of two or more interventions distinguishes CER from studies utilizing control groups or placebo as the comparison population. CER goes beyond simply validating one particular treatment and can be used to identify which of the myriad available treatments can best meet the needs of a population, particularly when given limited resources.

Examples of federal sources of CER include the Agency for Healthcare Research and Quality (AHRQ), the National Institutes of Health (NIH), the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). AHRQ, a leader in driving CER, has also developed Evidence-based Practice Centers (EPCs), housed in universities and non-academic research institutions. The American Recovery and Reinvestment Act of 2009 provided funding for the CDC to launch four new Prevention Research Centers, which conduct comparative effectiveness projects examining the benefits and harms associated with various public health interventions in community settings. State agencies and academic centers—either individually or through multi-state collaboratives—also fund and conduct such research (discussed further in Legend for the Roadmap). Additionally, private research organizations (e.g., RTI International, the Cochrane Collaborative, etc.) also conduct comparative effectiveness research.

Patient-Centered Outcomes Research

Definition: Patient-Centered Outcomes Research (PCOR) refers to research that assesses the benefits and harms of different interventions while also including an individual’s preferences and needs, focusing on those outcomes of most value to the patient.
PCOR is a relatively new field within CER, spurred in part by the creation of the Patient-Centered Outcomes Research Institute (PCORI) in Section 6301 of the Affordable Care Act. By identifying and selecting interventions that include the needs and preferences of patients, policymakers are more likely to address potential barriers to implementation and therefore design programs and policies in which patients will actively participate and achieve the desired health outcomes.

Current availability and use of PCOR, as strictly defined by PCORI, is still limited given the recent definition of this form of research. However, the field will likely flourish over the next few years; between 2012 and 2013, PCORI awarded $464.4 million to fund 279 patient-centered studies, and additional awards are made on a regular cycle. Projects funded by PCORI include research specifically aimed to improve healthcare systems, including five priority areas: assessment of options; improving healthcare systems; addressing disparities; communication and dissemination research; and improving PCOR methods and infrastructure. Examples of specific awards include: Using Technology to Deliver Multi-Disciplinary Care to Individuals with Parkinson Disease in Their Homes; A Toolbox Approach to Obesity Treatment in Primary Care; Optimizing Behavioral Health Homes by Focusing on Outcomes that Matter Most for Adults with Serious Mental Illness; and, Evaluating the Impact of Patient-Centered Oncology Care.

**How State Health Policymakers View Comparative Effectiveness and Patient-Centered Outcomes Research**

As part of the project that informed this document, NASHP conducted an online survey to better understand how state officials view and use research—CER and PCOR in particular—to inform their work. The survey was sent via email to 494 health policymakers in all 50 states, the District of Columbia, and select US territories. Recipients represented a wide variety of state offices and agencies, including governors’ health policy advisors, legislators, public health officials, Medicaid/Children’s Health Insurance Program (CHIP) directors, state employee/retiree health benefits administrators, workers’ compensation directors, and state insurance commissioners. Following the survey, NASHP conducted a series of semi-structured interviews with individuals and groups of state policymakers.

**Survey Results**

In total, 130 state officials representing 48 states and the District of Columbia completed the first set of questions (26 percent response rate), and 101 of those 130 (78 percent) completed the entire survey. The majority of respondents (55 percent) represented Medicaid, CHIP, or public health. Overall, state officials responding to the survey tended to report at least moderate familiarity with the concept of research evidence (92 percent), although they were relatively less familiar with the specific concepts of CER (73 percent) and PCOR (69 percent). Respondents were generally positive about the use of research to informing policymaking:

- 93 percent agreed with a statement that state health policymakers should use research to inform their work;
- 89 percent agreed with a statement that research should be used to determine health benefits coverage; and
- 89 percent agreed with a statement that research should be used to address the needs of patients with complex health issues.

The majority of respondents also agreed that research with a focus on outcomes identified by patients was considered important in their work on state health programs and policy (82 percent), making health
benefits coverage decisions (71 percent), and addressing needs of patients with complex health issues (71 percent).

Most respondents also agreed to statements that they would like to use research more often in their work (87 percent), to determine benefits coverage (74 percent), or address the needs of patients with complex health issues (76 percent). The most commonly reported barriers to using CER in their work included difficulty in finding CER (54 percent), difficulty translating CER to inform programs and policies (49 percent), and significant concerns that CER would be used to restrict patients’ freedom of choice (31 percent).

**Semi-Structured Interviews with Policymakers**

Following the survey, NASHP conducted a series of semi-structured interviews with individuals and groups of state policymakers. Participants were selected from those who indicated an interest in follow-up calls when completing the survey and others who were identified through NASHP’s database. Over the course of seven calls, 24 state policymakers were interviewed, and several provided additional information through follow-up emails and individual calls. The common themes identified through these calls, with guidance from our advisory group, were used to develop the action steps and considerations included in the Roadmap that follows. Key differences across agencies were also identified, such as the unique considerations that arise from being both a policymaker and a health care purchaser (e.g., Medicaid).

**HOW STATE POLICYMAKERS USE COMPARATIVE EFFECTIVENESS AND PATIENT-CENTERED OUTCOMES RESEARCH**

The state health policymakers that responded to our survey reported a much lower use of CER and PCOR compared to use of evidence in general. While 63 percent of respondents replied “almost always” or “often” when asked whether they use research to inform their work, only 35 percent of respondents replied using CER and 31 percent of respondents replied that they used PCOR with regularity. For policymakers that use CER and PCOR to inform their work (e.g., to set preferred drug lists or determine coverage for a new treatment), the research may be collected, analyzed, and implemented in a number of different ways, such as using advisory groups or committees, specific programs, or in collaboration with other agencies or states. Additional information on various programs states may use to incorporate this research into their work is available through a companion document entitled Programs Used by State Policymakers to Leverage Comparative Effectiveness Research and Patient-Centered Outcomes Research developed as part of the same NASHP project.13

**Advisory Groups and Committees**

State agencies often form advisory groups and committees to help policymakers identify and review evidence-based solutions to pressing issues. Depending on the agency for which they serve, membership may range from a panel of clinicians to a multi-stakeholder group including legal advisors, epidemiologists, consumers and other experts. Members’ familiarity and understanding of CER and PCOR can vary widely. While many of these groups are standing committees that meet regularly, policymakers may also field an ad hoc workgroup to examine specific issues. For example:

- A legislative ruling in 2007 resulted in the California Division of Worker’s Compensation forming a committee to inform decision making. The California Worker’s Compensation Medical Evidence Evaluation Committee is a closed, multi-disciplinary committee composed of members of the medical community. It is responsible for ranking the evidence and advising the Medical Director on
how to adopt and update medical treatment guidelines. Clinicians are required to use the adopted
guidelines, and must present a higher level of evidence when requesting to use another approach.
Contractors perform the studies to inform policy decisions on guidelines.\textsuperscript{14}

\textbf{State Health Technology Assessment Programs}

Several states have created formal health technology assessment (HTA) programs to support program
and policy decisions within their states. The key components of HTA programs include multi-disciplinary
stakeholder involvement, transparency, the review of evidence of selected topics, and the promotion of
the use of HTA in decision making.\textsuperscript{15} For example:

- The Oregon Health Evidence Review Commission (HERC) is responsible for conducting CER of
  health technologies or treatments and developing or identifying evidence-based guidelines to be
  used by the state’s clinicians, consumers and purchasers of health care.\textsuperscript{16} HERC maintains a list of
  health services showing the comparative benefits of each service. The Commission is made up of
  volunteer members of the health care community, including physicians, nurses, pharmacists and
  consumer representatives, and emphasizes a transparent process to include input from the public
  and those impacted by the decisions. Using HERC findings, the Oregon State Employee Benefits
  Board has built additional charges into their benefit design for those services that do not have
  good HERC research to support their effectiveness.

\textbf{Cross-Agency Collaboratives}

States have also created formal research and evaluation bodies to provide recommendations to multiple
agencies separate from those qualifying as HTA programs. For example:

- The Washington State Health Care Authority maintains a State Prescription Drug Program, in
  which the Washington State Pharmacy and Therapeutic Committee reviews and evaluates the
  comparative safety, efficacy and effectiveness of drugs within a therapeutic class. The Committee
  then makes recommendations to the state to develop the Washington State Preferred Drug List,
  which is used by the Public Employees Benefits Board, Medicaid, and the Worker’s Compensation
  Administration.\textsuperscript{17,18}

\textbf{Multi-State Collaboratives}

Many states participate in national and/or regional multi-state research collaborations. Depending on
the organization, comparative effectiveness studies may be made available for public review or may be
restricted to those states participating in the collaborative. For example:

- National: The Center for Evidence-based Policy at the Oregon Health & Science University
  (OHSU) administers two multi-state research collaboratives: the Drug Effectiveness Review
  Program (DERP) and the Medicaid Evidence-based Decisions Project (MED).\textsuperscript{19} Nine states
currently participate in DERP, which provides comprehensive systematic reviews of drug safety and
effectiveness,\textsuperscript{20} and 13 states participate in MED, which provides Medicaid agencies with tools
and resources to help make evidence-based decisions and share best practices.\textsuperscript{21} Two examples of
state use include Colorado’s Pharmacy and Therapeutic Committee using DERP findings in their
review to make recommendations on the efficacy and safety of different insulin groups and Texas
Medicaid’s use of MED resources in their work on health homes, payment reform, telemedicine
and chronic conditions.
• **Regional:** The New England Comparative Effectiveness Public Advisory Council (CEPAC), managed by the Institute for Clinical and Economic Review (ICER), is an independent group of physicians and other experts tasked with assisting policymakers and other stakeholders apply comparative effectiveness information to “improve the quality and value of healthcare in the region.” Reports have included comparative effectiveness on treatments for attention deficit disorder, breast cancer screening, depression, and on the use of community health workers.
Identifying When Comparative Effectiveness and/or Patient-Centered Outcomes Research can Inform Policymaking

- What are the desired outcomes for the intervention under consideration?
- Would comparative effectiveness or patient-centered research help in understanding the best course of action to reach the desired outcomes?
- Do stakeholders, experts, and colleagues recognize the utility of CER and PCOR in their work?

Finding Research and Other Relevant Resources

- What types of research and resources are needed to help make an informed decision?
- Where can the relevant research and resources be found?
- Who can help find relevant research and resources?
- Has another agency or state already conducted or reviewed research for a similar policy or program decision?
- What can be done when research or other resources are not currently available?

Evaluating the Evidence

- How were the patients or participants selected?
- Was the approach used to analyze the results valid?
- Was the study “patient-centered” and did it include the patient perspectives and priorities?
- What studies besides specific comparative effectiveness research studies might be useful to compare the impact of different interventions?
- How can studies with conflicting findings be evaluated?
- Has enough evidence been found to make an informed decision?
- Who can help evaluate the research findings?

Using The Evidence To Design A Program Or Policy

- What local, regional, or state data should be used to inform your decision?
- Is implementation of a specific intervention feasible given political or cultural pressures?
- Are there time or resource constraints that will impact feasibility?
- Is there enough buy-in from leadership and stakeholders that this intervention can be successfully implemented?

Communicating And Disseminating The Decision

- How will different stakeholders react to this decision?
- What information is most important to provide the various stakeholder groups?
- How should the information be presented and delivered to reach different groups?
- Who are the most appropriate representatives to communicate the decision?

Monitoring And Evaluating New Research As It Becomes Available

- What information is needed to evaluate the effectiveness of the selected intervention?
- How can new research be used to impact an existing program or policy?
- How can policymakers build flexibility into programs and policy decisions to ease the use of new research evidence to make modifications?
Consider the following scenarios:

- Public health officials want to address the leading preventable causes of death in their state and are presented with statistics showing a rapid increase of opioid-related deaths.
- A member of the Senate Standing Committee on Health must determine whether to support a colleague’s bill that increases nurse practitioners’ scope of practice.
- A Medicaid official must determine which treatments for childhood autism should be covered under a state plan.

In each of these scenarios, state policymakers are presented with making a policy decision for which there may be multiple interventions available. This Roadmap will provide policymakers with guidance from the initial consideration on whether to review comparative effectiveness or patient-centered outcomes research to the evaluation of new research once a program or policy is put in place. Over the next six sections, the Roadmap will provide strategies for how states can increase the frequency and efficiency of using these types of research in policymaking and, when possible, will present these considerations as short-, medium-, and long-term strategies depending on the time and resources involved.

A key component of each of the steps includes, whenever possible, broad stakeholder engagement and a transparent decision-making process. Making decisions behind closed doors may create animosity or skepticism among some stakeholders—particularly on controversial or “hot-button” issues—which later can potentially create challenges prior to or during implementation of a new program or policy. In these cases, a transparent process and the dissemination of the research and materials being used to make the decision is of particular importance.
Step 1: Identifying When Comparative Effectiveness and/or Patient-Centered Outcomes Research Can Inform Policymaking

The use of comparative effectiveness research (CER) and patient-centered outcomes research (PCOR) to inform decision making may help counter pressures from advocates, lobbyists, other stakeholders, and colleagues by ensuring policies are patient-centered and grounded in evidence rather than as a result of anecdotes, emotion, or agenda. Though policymakers are often faced with short deadlines and significant pressure to support a specific intervention, recognizing when CER and PCOR may be useful in the decision-making process may also prevent selecting an intervention unlikely to achieve the desired outcomes.

**SHORT-TERM STRATEGIES**
Examine whether the issue being addressed lends itself to CER. Comparing the effectiveness of several different interventions may add considerable strength to your decision-making process. When there is little or no opportunity to use CER—for instance when a decision has been mandated—a review of CER may still provide valuable information on the anticipated effectiveness of the intervention. Reviewing CER may also offer ideas of how to amend or modify an intervention along the way so that it reflects the best available research.

Examine whether the issue being addressed lends itself to PCOR. PCOR may provide a valuable perspective in shaping policy decisions that are dependent on achieving outcomes important to patients. If PCOR is not relevant to the intervention under consideration, recognize the potential value of patients’ input into the process and consider other opportunities to include the patients and their families in the decision-making process.

**Identify the key outcomes the intervention intends to impact.** After determining that CER/PCOR is relevant to your decision-making process, the next step is to focus on desired outcomes. For example, when a legislator examines whether to expand nurse scope-of-practice laws, the legislator may focus...
on the impact of this change on access to primary care, emergency department utilization, or chronic illness management. Selecting the desired outcomes will make it easier to find the research (Step 2). For instance, drawing from our previous example, the legislator may want to compare the outcomes of patients seen by physicians only, patients seen by nurse practitioners supervised by a physician, and patients seen independently by nurse practitioners.

**Ask for help to assist in determining whether CER or PCOR would be useful.** State policymakers have ample opportunity to bring other policymakers, stakeholders and experts together to provide guidance about whether CER/PCOR would be useful to the decision-making process and to help make the entire process more objective.

**Medium-Term Strategies**
Anticipate opportunities for the inclusion of CER and PCOR in decision making. The engagement of different individuals knowledgeable about CER and PCOR will vary widely by agency and state and may require effort to identify and involve in the process.

- Review existing advisory group or stakeholder group memberships and add someone knowledgeable about CER and PCOR to the group. If this is not possible (for instance, if the membership is closed), consider strategies to increase stakeholders’ as well as the general public awareness of CER and PCOR.
- Invite experts, local thought leaders, and patients and advocates to open meetings to further promote an understanding of CER and PCOR and how this research may be impacting the decisions being made.
- Post research findings related to the intervention(s) being considered on state or agency websites for public review.
- Ask an expert from PCORI, AHRQ, or other organization to speak at a webinar or conference call to brief state policymakers on the use of CER or PCOR.
- Convene focus groups to include consumer representation and the review of CER and PCOR. Engaging patients and consumers in the process may also help offset the lack of formal patient-centered outcomes research and provide the needed patient perspective on the implementations being considered.
- Circulate pertinent journal articles to help educate colleagues. The Agency for Healthcare Research and Quality, for example, sponsored the January/February 2005 issue of *Health Affairs*, which focused on “putting evidence into practice.”

**Long-Term Strategies**
Create state entities to raise awareness and promote the use of CER and PCOR across state agencies. Many issues, for example autism treatment and the impact of opioid addiction, would benefit from a multi-agency collaboration and approach to review CER and PCOR when decisions for different populations or programs are being considered.

- Form workgroups of cross-agency leaders and experts to share differing perspectives on the interventions being considered and examine the potential for use of CER and PCOR.
Form long-term commissions such as health technology assessment (HTA) programs through private or legislative support to examine the potential for use of CER and PCOR. See page 7 for a description of the Oregon Health Evidence Review Commission (HERC).

Establish formal relationships with other states that are leaders in using CER and PCOR to inform their work. States may not be able to establish a state-specific entity to serve as a support in identifying if CER or PCOR would be useful for an intervention under consideration and therefore cross-state collaborations might be useful.

- Reach out and engage with colleagues from states that are further along in their use of CER and PCOR, especially those states that have similar programs, cultures and politics.
- Enlist help from associations or organizations representing state officials, including the National Association of Medicaid Directors, a bipartisan, nonprofit organization, providing information and expertise across the states on issues pertinent to Medicaid.
- Join or form a multi-state collaborative (described on page 7). These collaboratives can engage different states through conference calls, webinars, etc. to develop a vision of how the decision-making process may be better informed. The Drug Evaluation Research Program (DERP) is one example of a paid membership program and is described on page 7.

Promote a vision within and across state agencies on the value of CER and PCOR in the design of health programs and policies. Barriers to recognizing when to use CER and PCOR in decision making may require a long-term effort to raise awareness and promote a culture of using evidence-based findings. For this report, a third of survey respondents noted that a significant barrier for their use of CER included a specific concern that CER may be used to restrict access to different interventions.24 In addition, PCOR, patient engagement, or patient-centered outcomes may be concepts unfamiliar to policymakers.

- Develop an agency mission statement or strategic priorities that emphasize the use of best available evidence including CER and PCOR in policy decisions.
- Develop interagency agreements that promote the consideration of CER and PCOR in policy decisions.
Step 2: Finding Research and Other Relevant Resources

Questions to ask during this step:

- What types of research and resources are needed to help make an informed decision?
- Where can the relevant research and resources be found?
- Who can help find relevant research and resources?
- Has another agency or state already conducted or reviewed research for a similar policy or program decision?
- What can be done when research or other resources are not currently available?

As discussed in the Legend section, state health policymakers face significant barriers in finding research to inform policymaking, particularly comparative effectiveness research (CER) and patient-centered outcomes research (PCOR). Despite these reported difficulties, a myriad of sources and strategies are available that can be adapted to meet short- and long-term needs.

**Short-Term Strategies**

**Become familiar with sources of available research.** For the purpose of this section, research refers to published information or studies that examine the impact of a given intervention. Research may be available as findings on individual interventions, findings on research designed to compare two or more interventions, or as reviews or compilations of the individual research reports. Currently, research materials are available from a number of sources, including journals, national organizations and federal and state resources (see textbox At-A-Glance: Key Sources of Research).

**Focus the search for research on outcomes the intervention intends to address.** A targeted approach to finding the research begins with knowing the questions the research should address and outcomes the intervention intends to achieve. A legislator may need to focus on short-term outcomes for an opioid treatment program, for example, to show a rapid return on investment and obtain support from other state legislators.

"Developing our own guidelines…quickly proved to be unmanageable, which is why so many states end up adopting other guidelines. It is hundreds of thousands of dollars to look at original literature and do a comprehensive review."

- Worker’s Compensation Official
**Key Sources of Research**

### Peer-Reviewed Journals

Include both health policy and medical journals. Examples include *Health Affairs* and the *American Journal of Managed Care*. Leading medical journals include the *New England Journal of Medicine* and the *Journal of the American Medical Association*. Policymakers may utilize online databases such as MEDLINE® and PubMed® to find relevant journal articles. Subscription fees may apply.

### Grey Literature

Includes materials such as issue briefs, policy reports, white papers, and industry reports that are not published in peer-reviewed journals. Sources of grey literature may include both non-profit research organizations (National Academy for State Health Policy, Institute for Healthcare Improvement, AcademyHealth, etc.) and non-profit health foundations, (such as The Commonwealth Fund, Robert Wood Johnson Foundation, etc.). These materials are more likely to be found by using general web searches on specific topics, although the New York Academy of Medicine maintains a bimonthly *Grey Literature Report*. Most resources available at no cost.

### Federal Resources

Include materials available from various agencies, for example:

- **Agency for Healthcare Research and Quality (AHRQ):** Evidence-based Practice Centers Program; National Guideline Clearinghouse
- **Centers for Disease Control and Prevention (CDC):** Prevention Research Centers
- **Centers for Medicare & Medicaid (CMS):** Research, Statistics, Data & Systems
- **Food and Drug Administration (FDA):** Scientific Publications
- **Health Resources and Services Administration (HRSA):** Maternal and Child Health Research & Data; Rural Health Research Centers
- **National Institutes of Health (NIH):** Clinical Trials Registry; National Information Center on Health Services Research and Health Care Technology; National Library of Medicine
- **Substance Abuse and Mental Health Services Administration (SAMHSA):** Center for Integrated Health Solutions Research; National Registry of Evidence-based Programs and Practices

### Quasi-public entities

Include organizations such as the National Quality Forum or the Patient Centered Outcomes Research Institute (PCORI). PCORI is an independent agency created by the Affordable Care Act specifically charged with funding research that “provide[s] information about the best available evidence to help patients and their health care providers make more informed decisions.” As a relatively new entity, the research funded may not yet be available; however, information on each study funded by PCORI is available on their website.

### International Clearinghouses

Include the International Network of Agencies for Health Technology Assessment (briefs available at no charge) and the Health Systems Evidence Database (free registration required) and McMaster Health Forum (no cost) at McMaster University in Hamilton, Ontario, Canada.

### Private Programs

Are available to provide access to research either free to the general public or for a fee. Institute for Clinical and Economic Review (ICER), for example, is an independent non-profit research firm that conducts CER, organizes groups to review and discuss research, and supports the dissemination and implementation of evidence-based best practices. Additional organizations such as the Cochrane Collaborative and Hayes, Inc. are a resource for obtaining information through systematic reviews and evaluations of medical technologies.

### National Membership and Professional Organizations

Are a resource for state policymakers interested in reviews of available research. The National Governors Association, for example, houses a Center for Best Practices and the National Association for Insurance Commissioners oversees the Center for Insurance Policy and Research. Similarly, national professional and trade organizations—as well as their state chapters—may play a similar role in providing resources specific to their constituency.

### State Resources

States may find that other states may be a rich source of relevant research. Other state programs, such as Health Information Technology Assessment programs (see page 7), may publically report research of relevance to multiple agencies and states. More informal approaches include networking at meetings and contacting the state agencies directly. More formal sharing may occur through membership organizations such as the National Association of Medicaid Directors, a bipartisan, nonprofit organization representing Medicaid directors.
Use available staff to find and review research. Designate staff in your agency or department skilled in research analysis to find research; cultivate their skills through staff development opportunities.

Use other entities within your state as a source of available research. Other entities in your state may have researched the same issue and be a resource to you. For example, the California Division of Workers’ Compensation research and the Minnesota Health Services Advisory Council (HSAC) are both charged with being a source for finding research to support policymakers in their states.

Use “off-the-shelf” guidelines that can either be adapted en masse or modified to fit local needs. For example, the American College of Physicians has guidelines based on best practices with recommendations for management of different conditions. Many states’ workers compensation offices have subscribed to the Evidence-Based Medical Treatment and Return to Work Guidelines (also known as Official Disability Guidelines or ODG) developed by the Work Loss Data Institute and either adopted the guidelines entirely or used them to supplement their own standards. The use of standard guidelines may avoid the potentially costly process of determining a new set of guidelines for a particular issue.

Develop contacts both inside and outside of academia to assist with finding research. Local academic settings—particularly schools of medicine and schools with public health or policy-related centers—may provide faculty and researchers knowledgeable of the current research findings in a specific field, as well as have resources to help find and interpret the research. Outside of academia, local thought leaders or other agencies with extensive experience with the issue can be an additional resource and may aid in locating available research.

**Medium-Term Strategies**

Establish ongoing partnerships with local colleges or universities, particularly in agencies with limited resources. Academic institutions can serve as an ongoing resource to either find needed research or provide the support needed to translate evidence-based findings into a format usable by policymakers.

- Contact heads of academic departments with graduate programs to develop partnerships with faculty and access to graduate students. You benefit from having a pool of researchers to tap into and the students benefit from getting experience working with policymakers.
- Request academic centers provide training for agency staff on evidence-based practices, CER and PCOR.

Find an AHRQ Evidence-based Practice Center near you. These centers are housed in multiple universities and are available as a resource to the health care community, including policymakers. For example, reports created for North Carolina by the RTI, International-University of North Carolina Evidence-based Practice Center examined the impact of a Medicaid funding cut for a maternity care coordination project run through a local public health department. See page 15 to locate these centers.

Coordinate with other agencies to pool resources to find research. Connecting with other state agencies makes sense when several are working on similar issues. Finding research to support decisions for the coverage of autism therapies, for example, was cited as a need by multiple agencies impacted by the
issue including legislators, public health, state employee health plans and Medicaid. Though agencies may have different goals or priorities, colleagues in another agency may have valuable information to share having already used research to inform their decisions.

**Long-term Strategies**

**Contract for services from independent research organizations when you cannot find needed CER and PCOR.** Private contractors and independent research organizations may also be of value to states when needed research cannot be found. Alabama’s Bureau of Children’s Health Insurance utilized tools from Truven, a for-profit organization that conducts CER, to consider coverage for HPV vaccine, resulting in a recommendation to the State Health Officer to cover the vaccine.

**Identify academic partners to conduct novel research and evaluations.** When research is not available, states can also build partnerships with existing research entities or develop entirely new entities. For these relationships to be successful, both policymakers and researchers must learn to work in the other’s space, which typically includes recognizing and addressing significant differences in “professional incentives and timetables.”

- Pass legislation to establish research centers to conduct CER and PCOR. The Evidence-based Practice Institute (EBPI) at the University of Washington was established by the legislature in 2007. EBPI acts as a resource to help the state identify, evaluate and partner with the community to use evidence-based practices and offers trainings and consultations on their use.

- Establish agreements with local universities. Partnerships between state agencies and academic centers can either be informal or codified through contract or statute. University of Alabama at Birmingham conducts specific health services research at the request of the Alabama Department of Public Health. Examples of special studies include whether successive years of insurance coverage decrease asthma-related emergency use or hospitalizations, as well as how access to more preventive dental visits may impact subsequent dental visits and costs.

- Form public and quasi-public state entities charged with using research to inform health policy at the state level. Examples of such entities include the Kentucky Office of Health Policy within the Kentucky Cabinet for Health and Family Services and the independent Massachusetts Health Policy Commission.

**Other long-term strategies to consider to help find research:**

- Create health technology assessment (HTA) programs to identify CER and PCOR and support other decision-making steps. See description in Legend section on page 7.

- Establish formal multi-stakeholder collaboratives within a state. The Washington state legislature, for example, established the public/private Robert Bree Collaborative composed of 24 members that includes purchasers, employers, plans, and clinician organizations. The intent of the Collaborative is to annually study topics “for which there are substantial variation in practice patterns or high utilization trends…without producing better care outcomes for patients [or] are indicators of poor quality and potential waste in the healthcare system.” Though the Collaborative has no authority to implement the recommendations, findings are made available to the public and various state agencies, employers, clinicians, and health plans. A report on obstetrics care and early C-section, for example, led to state purchased health plans adopting the recommended strategies and contributed to changes in the state payment policies for deliveries.
• **Obtain support and funding for membership in existing multi-state collaboratives to help find research and support other decision-making steps.** See description of multi-state collaboratives on page 7.

• **Create or join an independent regional group to help find research and support other decision-making steps.** See page 8 describing the New England Comparative Effectiveness Public Advisory Council.
Step 3. Evaluating the Evidence

**KEY QUESTIONS**

Questions to ask during this step may include:

- How were the patients or participants selected?
- Was the approach used to analyze the results valid?
- Was the study “patient-centered” and did it include the patient perspectives and priorities?
- What studies besides specific comparative effectiveness research studies might be useful to compare the impact of different interventions?
- How can studies with conflicting findings be evaluated?
- Has enough evidence been found to make an informed decision?
- Who can help evaluate the research findings?

The various design methodologies used by researchers can be overwhelming to state officials trying to evaluate different studies and determine if they are useful in the decision-making process. Strategies to successfully evaluate evidence are provided below and, depending on a state’s resources, may range from accessing research already vetted by a reliable source to establishing formal educational programs for policymakers to better use CER in their decision-making process.

**SHORT-TERM STRATEGIES**

Determine Whether Evidence on Different Interventions Has Already Been Evaluated by a Reputable Source. In addition to research expertise, evaluating research takes time and resources—all valuable and limited commodities for state policymakers. States may not have the resources or staff to fully evaluate available research to compare different interventions or include patient needs and priorities.

- Consult with reputable sources such as academic institutions, and programs such as MED and DERP (see Legend).

**NOTABLE QUOTE**

“For a lot of these policies, the evidence is not particularly strong either way. You do evidence-informed decision making and it gives you some clues. You need to be able to interpret what the evidence is or is not. There are a lot of studies that claim to be evidence but when you look at them there are all sorts of issues. Need to make sure not to take something and run…Need to look under the hood.”

- Medicaid Official
• Use external research organizations including, for example, organizations such as Hayes, Inc. to provide a review for a fee or use the Cochrane Collaboration’s Cochrane Database of Systematic Reviews, which includes more than 8,000 reviews and protocols on various health care issues available at a range of costs (see Step 2).

Use multiple sources to obtain information for use in the decision-making process. The existence of a research study or an article on the web or in a publication alone does not guarantee the findings presented are valid or will be useful to include in the decision-making process. While single sources or research collaboratives may ease the burden of reviewing the evidence, you risk potential pushback from some stakeholders. Utilizing multiple sources of research during the decision-making process may alleviate these concerns.

Encourage policymakers to develop a basic understanding of research methodologies including CER and PCOR. Policymakers need to recognize different research methodologies examining the same intervention can result in different outcomes depending on specific aspects of the methodology. For example, a study with patients randomly assigned to receive different treatments may result in different findings than a study where patients are allowed to choose the treatment they prefer, potentially resulting in a concept known as selection bias. In addition, preference should be given to studies with larger sample sizes and longer study periods. The success of an opioid treatment, for example, for a six-month period may report a success rate that differs significantly from the same program evaluated one year after treatment.

• Use tools similar to the Agency for Healthcare and Research Quality Glossary on research terminology (see text box At-a-Glance: Examples of Key Terms) and the George Health Policy Center’s “Blue Book” created for legislators reviewing research and replicated by a number of other state programs.

Evaluate the source of the research to examine any risk for real or potential bias. A research report on an intervention provided on the web or through a special interest group does not necessarily mean the findings have been reviewed by peers in the field or is reproducible and reliable. Even peer-reviewed journals or organizations may suffer from some bias. In particular, clinical practice guidelines face scrutiny for potential conflicts of interest; a 2013 review found that on average, 30 percent of type-2 diabetes guideline authors had a disclosed financial interest in manufacturers of the recommended drugs. Though no association was shown between the drugs recommended and specific authors, the researchers raised the concern about the credibility of the guidelines based on the potential for conflicts of interest.

• Select data from an independent third-party source when available. It is more likely to be viewed as trustworthy by stakeholders when compared to research or reports where the researcher, publisher, or reviewer may appear to have a personal or financial interest in demonstrating a certain result.

Compare the study population to the population impacted by the intervention under consideration. Lack of external validity—the application of research findings to a broader population—may make the research findings irrelevant for the program or policy being considered. An understanding of important features of the population likely to impact the success of an intervention—for example, geography, demographics, and culture—will also provide important information as to whether research findings being considered are realistic to pursue.
MEDIUM-TERM STRATEGIES

Utilize tools from academic and research organizations to develop formal processes for ranking the strength of evidence found. Once research evidence has been gathered, strategies can be used to rank the different findings for specific criteria such as safety, effectiveness and impact on a specific outcome.46

- Become familiar with examples of tools including hierarchies developed by the Centre for Evidence-Based Medicine at the University of Oxford.37 Thomas Jefferson University illustrated a similar hierarchy as a pyramid (see text box At-a-Glance: The Heirarchy of Evidence).48
- Find tools at the Centre for Evidence-Based Medicine. They have developed a number of tools to help individuals find, evaluate, and make decisions using evidence, including critical appraisal sheets. These tools can be adopted or adapted to assess and compare individual studies and systematic reviews.49
- Check out references to tools and resources state health policymakers may wish to use included in Appendix B at the end of this document.
- Conduct a systematic review of the findings from multiple single-intervention studies. In the absence of formal CER, policymakers should evaluate and compare the evidence on different interventions including their effectiveness and emphasis on patient-centered outcomes.
- Use “Five Steps to Conducting a Systematic Review” (see At-a-Glance text box and Appendix D). This reference cites an example facing public health officials making a decision on public water fluoridation.50 A careful systematic review provides the policymaker with both a thorough understanding of research available to inform their decisions and provides information to potentially address concerns regarding the selection of one intervention over another.

AT A GLANCE

The Hierarchy of Evidence

1. Meta-analysis* (Best)
2. Systematic Reviews*
3. Randomized Control Trials
4. Cohort Studies
5. Case Control Studies
6. Case Reports

*Both meta-analyses and systematic reviews use statistical techniques to combine the findings of separate studies; however, not all systematic reviews include such analysis.

Adapted from The Evidence Pyramid, Thomas Jefferson University (November 2008); available at: http://jeffline.tju.edu/Ask/Help/Handouts/evidence_pyramid.pdf

For more information on the difference between a meta-analysis and a systematic review please visit: http://www.cochrane-net.org/openlearning/html/mod3-2.htm

AT A GLANCE

Five Steps to Conduct a Systematic Review

1. Frame Questions that Must be Answered
2. Identify Relevant Materials
3. Assess the Quality of the Research
4. Summarize the Evidence Found
5. Interpret the Findings

Adapted from Khan et al, Five Steps to Conducting a Systematic Review
**Long-Term Strategies**

Establish opportunities to educate policymakers and others on the use of research for decision making. Learning needs vary and groups will need to be evaluated for their familiarity with research methods and designs, as well as the barriers they face in translating findings to use for their particular program or policy decisions. For example, training a lay advisory group on how to compare different medical treatment options would require a different approach than ensuring a medical advisory committee consisting primarily of physicians uses available comparative effectiveness research.

- Refer to handbooks or glossaries created by states that translate key terms used in health care policy and research into lay language (see suggested glossaries in Appendix B).

Collaborate with local partners to develop the training curriculum for policymakers. Training stakeholders to use research will better prepare them to help review the evidence, understand the differences between different interventions, and be more informed participants throughout the decision-making process.

- Refer to the Georgia Health Policy Center’s Legislative Health Policy Certificate Program, an example of a training program specifically targeted to state legislators. A unique tool includes a computer simulation model embedding the research evidence that allows legislators to see the impact of different decisions on key outcomes. (See Stories from the Road).  

- Adopt or adapt the Centers for Disease Control and Prevention online guide to using evidence-based approaches in public health training programs.
### Examples of Key Terms

Unless otherwise noted, the definitions have been adapted from the Agency for Healthcare Research and Quality Glossary, found at: [http://effectivehealthcare.ahrq.gov/index.cfm/options/glossary/](http://effectivehealthcare.ahrq.gov/index.cfm/options/glossary/)

**Bias:** Any factor that distorts the findings of a study; bias may influence observations, results, or conclusions, and may make the study less accurate or believable.

**Blinding** (sometimes referred to as Masking): A way to ensure that the participants, clinicians, or researchers do not know which participants have been assigned to one of a study’s intervention or control groups.

**Clinical Practice Guidelines** *(from www.pcori.org/about-us/glossary)*: Systematically developed statements or recommendations to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.

**Cohort Study:** A research study in which people with a common condition or treatment plan are followed over time and compared with a group of people who do not have the same condition or treatment plan.

**Comparative Effectiveness:** A type of research that compares the results of one approach for managing a disease to the results of other approaches, usually comparing two or more types of treatment for the same disease.

**Evidence-Based Practice:** Applying the best available research results when making decisions about health care.

**External Validity:** The extent to which research applies to broader populations. A study has external validity if the results can be generalized to the larger population.

**Internal Validity:** The extent to which the results of a study are not biased.

**Meta-Analysis:** A way of combining the findings from multiple research studies.

**Patient-Centered Outcomes Research** *(from www.pcori.org/about-us/glossary)*: Research that helps patients and their caregivers communicate and make informed healthcare decisions, while allowing their voices to be heard in assessing the value of healthcare options.

**Publication Bias:** The tendency to publish findings that have a positive result, while not publishing findings when results are negative or inconclusive.

**Randomized Controlled Trial:** A controlled study where participants are randomly assigned to two or more groups.

**Selection Bias:** A type of bias where the way in which participants are assigned to intervention and control groups create differences in the groups in ways that may affect the study’s outcome.

**Statistical Significance:** A mathematical technique to measure the likelihood of whether a study’s results occurred due to chance instead of the intervention.

**Systematic Review:** A critical assessment and evaluation summarizing the current research available on a specific topic.
After collecting and evaluating research comparing the different interventions under consideration, the next step is to determine how the findings can be used to develop and implement a program or policy. Geography, culture, and available resources influence a selected intervention’s feasibility and success, and—as discussed in the previous section—what worked for one population may not necessarily translate to success elsewhere. Similarly, the feasibility of implementing a particular program may even vary across different agencies or regions within a single state. Several strategies are presented to aid in translating the research into policy.

**SHORT-TERM STRATEGIES**

**Secure and maintain involvement from multiple stakeholders throughout the process.** Sharing the evidence and keeping the process transparent when possible will help inform the design of the program or policy, promote the use of evidence, and identify potential challenges early on regarding the feasibility of implementing a potential approach. Policymakers should keep in mind that different stakeholder groups may need different information—or the information presented in different ways—for the resources used to be understood and useful (discussed in Step 5).

- Engage and educate advisory groups during the design period.
- Provide opportunities for public comment, such as public hearings, comment periods, or focus groups.
- When appropriate, include various state professional groups. For example, when considering expanding the nurse practitioner’s role, including clinicians in the discussion will provide a valuable perspective on the practical considerations for how the clinicians and potentially local or state communities may be impacted.

**Use data to assess whether the intervention is a ‘good fit’ and would be feasible to implement within a given state or agency.** A careful review using relevant data will both identify interventions less
likely to be successful and provide opportunities to adapt and modify certain interventions to better fit a state or agency’s needs.

- Request and leverage local and state data (e.g., claims/encounter data or public health registry data) and use experts to compare local demographics or available resources with those described in evidence-based reports. Using data will help translate whether the research being reviewed is applicable to the targeted population.

Examine local, regional and state data for any similarities that can inform applicability across state lines. As discussed in Step 2, other states can be a valuable source for information about how to address a pressing health issue. However, citing evidence from the success of another state’s program or policy to support an intervention may raise concerns from some stakeholders that the outcomes are meaningless due to real or perceived differences.

- Explore potential similarities between two populations before determining that an intervention taking place in a “dissimilar” state would not translate to your state.

Focus on agency-specific needs and goals when comparing evidence on interventions. Different state agencies may have similar goals, but the interventions to reach the goals often differ and may require the use of different research. For example, a state employee health plan smoking cessation program implemented within a workforce environment will likely differ significantly from a program available to the Medicaid population within a local community health care site. Given the differences in the two populations, different agencies may also select interventions targeting different places within the system. For example, state employee benefits agencies may be more likely to attempt solving issues by changing the behavior of the beneficiaries and not involve the health care system (e.g., workplace wellness programs) while Medicaid may attempt to make a program change at the clinician-level through payment reform or enhanced clinician requirements.

MEDIUM-TERM STRATEGIES

When possible, educate stakeholders on the value of using comparative effectiveness research and patient-centered outcomes research in the decision-making process. Providing data or strong research evidence may not be sufficient to influence the selection of one intervention over another. Cost and limited resources may be key priorities during the selection process and may need to override the findings from a review of the evidence. Different stakeholders may also have differing priorities or agendas for resisting the inclusion of findings from CER. Depending on the issue and the environment, an agency or state may need to increase support for the education of policymakers and other stakeholders on the potential value of CER and PCOR.

Assess your local infrastructure and analyze the readiness for program implementation. Local, regional, or state resources to support the intervention need to be evaluated and, when not available, put in place. Implementing an opioid treatment program within a rural community, for example, may require the training of local community clinics or an assessment of transportation support for the population engaged in the program.

Obtain leadership buy-in for a new policy or program. Recommendations from expert advisory groups, for example, may be of limited value if leaders with decision-making capacity are not convinced of the value of a selected intervention.

- Ensure key leadership understands the intervention selected and key features of the research supporting the design or selection of the program or policy once a decision is made. Even
commissioners and directors may need to secure the support of the governor or the legislature before implementation can begin.

- Have back-up options lined up when the first choice is likely to face significant resistance.

**LONG-TERM STRATEGIES**

**Secure support for using an intervention shown to be more effective.** Policymakers may not always be able to select an intervention solely based on its effectiveness - even with strong CER available. A state’s budget, for example, may influence willingness to support or continue supporting a program or policy that is not expected to produce a rapid improvement in outcomes and yield a strong return-on-investment.

- Explore multi-stakeholder processes to focus on key, high impact topics. For instance, the Massachusetts Prevention and Wellness Trust Fund provides an example of a state entity focusing on four conditions found likely to have an immediate impact or produce short-term returns on investment within four years: pediatric asthma, hypertension, tobacco use, and falls among older adults. Applicants were allowed to propose interventions for other conditions, but were required to address at least two of the priority conditions in their proposal to show a short-term impact.

- Educate policymakers on the potential value of investing in interventions likely to show results over a longer period of time and result in a more efficient use of resources.

**Pursue private and federal funding sources to support the use of CER and PCOR in the decision-making process.** Given that many states and agencies may have limited funding, agencies can use public and private sources to both create supports within their state to use CER and PCOR and to pilot and evaluate programs using this research.

- Explore private foundations or organizations such as the Patient-Centered Outcomes Research Institute, Robert Wood Johnson Foundation or private insurers.

- Explore federal grants opportunities including, for example, the Centers for Medicare and Medicaid Innovation State Innovation Models grants which provide significant opportunities to integrate evidence-based practices and offset the cost to the state or agency.

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**NOTABLE QUOTE**

“I look at the infrastructure we already have to see what our readiness is. So it is not just the data, but do we have the stakeholders and their buy-in? Do we have the resources to effectively implement this? Is it what people are ready to do?”

- Public Health Official
Step 5: Communicating and Disseminating the Decision

**Key Questions**

Questions to ask during this step may include:

- How will different stakeholders react to this decision?
- What information is most important to provide the various stakeholder groups?
- How should the information be presented and delivered to reach different groups?
- Who are the most appropriate representatives to communicate the decision?

Recognizing that stakeholder groups are often motivated by different priorities is essential to successfully securing buy-in both prior to and during implementation of the program or policy decision. When the Oregon Public Employees’ Benefits Board adopted value-based insurance design for coverage for state workers, for example, communication of the change was found to be incredibly important, both in “crafting the message” and “managing the reaction.” Several strategies policymakers may use to communicate and disseminate the decision are presented below.

**Strategies**

Communicate policy decisions using content that is both real and relevant to those impacted by the decision. Ultimately, a successful communications strategy will address the concerns of the different target audiences and may require different information depending on the stakeholder group.

- Keep experts and those impacted by the decision engaged throughout to provide valuable insight into what information is of most importance to stakeholders.
- Tailor the message to fit the audience. For example, physicians and academics would likely prefer the information comparing the interventions reviewed be presented in clinical and research terms, while the public or media would likely

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**Notable Quote**

“Regardless of how good the idea, concept, or program is, if it’s not properly communicated and implemented it lacks ultimate effectiveness.”

- State Employee Health Plan Official

**Notable Quote**

“When you are in a position of implementation, you have to be very practical about how you use literature, how you communicate to folks that you need to get on board.”

- Medicaid/CHIP Official
need to receive information in lay terms. Similarly, legislators often short on time may prefer high-level information or a review of the resources needed and potential return on investment, while physicians would value a greater level of clinical information.

- Leverage the communication process and advance the use of CER and PCOR when informing consumers and others of the value of using this research evidence to make more informed decisions. To accomplish this, states may be able to leverage the materials developed through Choosing Wisely®, a program led by the American Board of Internal Medicine Foundation in which family medicine and specialty organizations developed lists of questions that physicians and patients should ask regarding many common tests and treatments.55

**Use different formats and venues to deliver the information on the selected intervention to different audiences.** Different audiences are likely to want—and need—different approaches to learn about selected programs or policies and why they were chosen. Informing the public on the benefits of participating in a selected tobacco cessation program, for example, will require a different approach than those used to engage insurers and clinicians to promote the program through their organizations and offices.

- Tailor the format: press releases, short ‘elevator’ speeches, talking points, fact sheets, and data reports are all useful depending on the time and place.
- Vary information by length, level of detail, terminology used and issues. For example, some audiences may be better reached by information that emphasizes considerations of a condition’s burden or impact on health while others focus on quality outcomes or safety.
- Identify novel approaches to disseminate information to ensure the target audience can find the information; policymakers may find value in using social media or other venues when providing information to consumers.

**Determine the best level(s) of leadership to communicate the decision.** An important consideration in disseminating a program or policy decision is identifying the appropriate individual(s) and the appropriate venue to communicate the decision to the public and others impacted. In many cases, it makes sense for the spokesperson to be the person within the agency that made the decision, such as the public health commissioner. Alternatively, if the decision is part of a larger state agenda, it may be appropriate for the messaging to come from a higher office, potentially the health secretary or even the governor’s office.

**Recruit stakeholders external to state government to communicate support for decisions when appropriate.** Trusted community leaders or other non-governmental parties may be in a position to meet with and address specific questions and concerns raised by their constituencies—especially if they were engaged in the decision-making process. These spokespersons may be of particular importance for those decisions likely to create resistance from particular groups of stakeholders. A patient may experience receiving information from a well-informed patient or clinician differently, for example, than from a state official when a treatment option is no longer available due to a review of the evidence.
Step 6: Monitoring and Evaluating New Research as It Becomes Available

**Key Questions**

Questions to ask during this step may include:

- What information is needed to evaluate the effectiveness of the selected intervention?
- How can new research be used to impact an existing program or policy?
- How can policymakers build flexibility into programs and policy decisions to ease the use of new research evidence to make modifications?

The rapid growth in medical and healthcare research—particularly comparative effectiveness research (CER)—has created an ever-changing body of evidence for policymakers to inform their decision making. Evaluations of programs and policies will provide important information on their effectiveness and provide opportunities to incorporate findings from new CER and PCOR and modify if needed.

**Strategies**

Create an evaluation process for the selected program or policy. To determine the impact of a program or policy and recognize when modifications may be needed, an evaluation component should be included in the design of the program. The evaluation component may be brief with specific measures collected through basic methods or may be more comprehensive requiring an investment of skilled personnel and resources. Though a selected intervention may initially appear to be a 'good fit,' evaluating key outcomes will provide specific information on the effectiveness of the intervention and suggest when modifications are necessary.

Review new research findings including CER and PCOR as they become available.

Numerous policies and programs are put in place with limited research to support their effectiveness. As discussed in earlier sections, establishing formal processes to review CER and PCOR in the decision-making process will create or strengthen a culture to continue to evaluate established programs and policies. Additional CER and PCOR studies could impact, for example, current payment methodologies aimed to enhance the delivery of comprehensive and coordinated care or a revision of established guidelines for the coverage for bariatric surgery for morbid obesity. As mentioned in previous steps, this includes:

**Notable Quote**

"Since evidence changes, we want to give flexibility to best practices and new evidence."

- State Legislator
• Designate staff in your agency or department to perform ongoing monitoring of new relevant CER and PCOR.

• Establish relationships with reputable sources such as academic institutions or research collaboratives such as MED and DERP to learn of new research as it becomes available. (Discussed in Legend)

• Use external research organizations such as the Cochrane Collaboration, described in **Step 2**. The Cochrane Collaboration maintains a Cochrane Database of Systematic Reviews and conducts evidence-based systematic reviews of different interventions and added 516 new reviews and 685 new protocols to their Cochrane Library over a 14-month period (2013-2014); another 603 reviews were updated in that time period, and 141 of those 603 included changed conclusions.56

• Explore federal sources, including the Centers for Medicare and Medicaid Services, the Agency for Healthcare Research and Quality, and other federal agencies posting research findings (See **Step 2**).

• Review research findings reported by the Patient-Centered Outcomes Research Institute (See **Step 2**).

• Join a multi-state collaboratives and/or look to associations or organizations representing state officials for assistance with review (described in **Step 3**)

**Build a process that allows for some flexibility to modify a program or policy, particularly when minimal evidence was available to support the decision.** The lack of evidence may discourage policymakers from relying on research to inform decision making, particularly when facing pressure from stakeholders or colleagues to implement specific interventions. Evidence can change rapidly—sometimes faster than it takes to fully implement a new policy or program after a decision. Acknowledging that new—and potentially conflicting—research is likely to be released in the near future, policymakers can anticipate and prepare for these changes and avoid unnecessary delays in implementing promising practices (e.g., needing to pass new legislation or re-authorizing an advisory group).

• Use legislation or administrative rules to ease implementation of revised policies or programs. Minnesota, for example, used the confidence-with-evidence development (CED) approach when designing their program policy on autism treatment coverage, given limited research to support a specific intervention (see Stories from the Road). CED includes a process to make conditional payments for providing the intervention while also collecting data to show their impact on specific outcomes.57

• Include either mandatory review periods or use permissive ‘may’ language instead of mandatory ‘shall’ language when codifying specific program elements in statute or regulation. For example, the regulations governing the operation of the California Division of Worker’s Compensation grants the division’s administrative director, in consultation with the medical director, the authority to revise, update, and supplement the medical treatment utilization schedule (MTUS) as necessary; furthermore, the division’s Medical Evidence Evaluation Committee is required to meet at least four times annually, presenting ample opportunities to adapt the MTUS as new CER or PCOR becomes available.58
MINNESOTA: USING COMPARATIVE EFFECTIVENESS RESEARCH TO INFORM AUTISM LEGISLATION

Multiple states are struggling to determine appropriate benefits for the treatment of autism spectrum disorders (ASD). In 2013, the Minnesota Legislature passed legislation for coverage of an “early intensive intervention” benefit for treating children diagnosed with ASD and enrolled in Minnesota’s public health care programs. This case study offers a snapshot of Minnesota’s use of research, including comparative effectiveness research (CER), to impact this policy change and pass legislation built on evidence. The Minnesota case study also provides an excellent example of how the Roadmap can be used to inform the decision-making process. (In 2013, Minnesota passed separate ASD legislation pertaining to children covered by commercial health plans and insurers. This summary pertains only to the benefit provided in public health care programs, not commercial policies).

Throughout the process, ample opportunities were provided for public comment. In 2012, the Department of Human Services (DHS) assembled an ASD Advisory Council that includes parents, clinicians, county workers, service providers, educators, and state employees. The Council was convened to provide input on the successful implementation of early intervention services for children with ASD. DHS also convened a clinical/professional focus group, a parent focus group, and an advocate focus group to obtain patient and consumer perspectives in the decision-making process. To date, the ASD Advisory Council continues to meet to further develop the benefit and communicate updates and the minutes from related meetings and public comments are made available on a state website.59

Step 1: Identifying When Comparative Effectiveness and/or Patient-Centered Outcomes Research Can Inform Policymaking: The existence of numerous treatments for autism spectrum disorders (ASD) but a paucity of strong scientific evidence demonstrating effectiveness made ASD treatment a ripe issue for the application of CER. In 2012, the Minnesota Legislature directed the Health Services Advisory Council (HSAC), which provides external, evidence-based, clinical advice to the Minnesota DHS, to review the evidence concerning treatments for ASD to inform coverage recommendations.60

Step 2: Research and other Relevant Resources: The HSAC was the primary entity responsible for reviewing research and other relevant resources to inform a coverage recommendation. HSAC included a review of CER studies published by AHRQ as well as further research from the Medicaid Evidence-based Project Initiative collaborative (MED).61 62

Step 3: Evaluating the Evidence: Based on their review of different treatments, the committee concluded that, although there was less evidence than was desired, Early Intensive Behavioral and Developmental Interventions (EIBDI) had the best strength of evidence.63

Step 4: Using the Evidence to Design a Policy: The HSAC developed a final report delivered to the Minnesota DHS Commissioner that included recommendations for the selected early intensive intervention benefit. Minnesota Legislature had also specifically allowed HSAC to make recommendations that included ‘coverage-with-evidence development’ (CED). CED includes a process to make conditional payments for providing the intervention while collecting data to show the impact on specific outcomes. 64 A lack of strong evidence to support coverage for one particular treatment for children with ASD also resulted in...
DHS adopting an approach that gives patients and clinicians some flexibility in choosing the specifics of a treatment plan.

**Step 5: Communicating and Disseminating the Decision Made:** DHS let the existing ASD Advisory Council take the lead in disseminating and communicating information on the selected early intervention benefit. The ASD Advisory Council continues to hold open meetings, allowing the public to sit in and learn about updates to the benefit.

**Step 6: Monitoring and Evaluating New Research as It Becomes Available:** Acknowledging a dearth of research providing conclusive and consistent results on autism treatments, including EIBDI, Minnesota plans to collect outcomes data, monitor new research as it becomes available and adjust policies as necessary. The legislation specifically contains a provision for the “revision of treatment options” and allows the commissioner to “revise covered treatment options as needed based on outcome data and other evidence.”

**Georgia: Educating Legislators on the Use of CER**

The George Health Policy Center (GHPC) was formed in 1995 in partnership with business leaders, donors, clinicians and others to provide objective evidence-based research to policymakers and help inform their decisions on health policy and programs in their state. Recognizing their state legislature only was in session 40 days each year, GHPC aimed to provide legislators with the research and support needed to make fully informed decisions within the limited time available.

Several levels of learning needs among legislators were identified and resulted in the recognition of four different broad categories of learners:

- **Group 1:** Novice legislators
- **Group 2:** Legislators interested in the “hot” and controversial topics but who required concise summaries of material due to time constraints.
- **Group 3:** Legislators, often on health-related committees, with an understanding of nuances and an interest in better understanding how pieces fit together.
- **Group 4:** Legislators in leadership positions seeking understanding at high-level to recognize the implications of the policy and resource decisions in the broader context.

Recognizing the range of needs among legislators, GHPC has developed several specific tools on health policy interventions. Included in these materials, for example, is the *Little Blue Book, A Health Glossary*, a resource created by GHPC and adapted by other states as well (see Appendix B). Two structured programs are key to educating legislators: the Legislative Health Policy Certificate Program and the Advanced Health Policy Institute. The Legislative Health Policy Certificate Program is designed for those in Group 3 and helps legislators develop an approach to policy issues through systems thinking: examine the big picture, and consider multiple factors and possible high-leverage interventions. The Advanced Health Policy Institute is a three-day course for legislators to develop a higher-level understanding of issues and approaches to examining solutions; per diem is covered by the state.

**GHPC Childhood Obesity Model for State Legislators**

As part of the Legislative Health Policy Certificate Program for Georgia policymakers, GHPC developed a childhood obesity model to provide Georgia legislators with a systemic perspective on childhood obesity using research findings and help them understand policy impacts. This model was designed
by a collaborative team comprised of state legislators, legislative staff, and experts in nutrition, exercise physiology, epidemiology pediatric medicine, economics, and system dynamics. The team designed a computer-based tool that allowed policymakers and stakeholders the opportunity to rapidly explore health impacts of specific policy changes prior to enacting them. The model relied on epidemiological data, a review of the research literature on childhood obesity, and structure from a similar tool previously developed by the Centers for Disease Control and Prevention. The six policy areas that were modeled were:

1) Ensuring safe routes to school
2) Improving school food options
3) Improving school physical education
4) Improving nutrition/physical activity education in preschool programs
5) Improving nutrition/physical activity education in after school programs
6) Reimbursing Medical Nutrition Therapy for obese children insured by Medicaid

The simulation occurred in a real-time, hands-on learning lab environment with legislators and their staff. Following the simulation, participating legislators commented that the model informed their deliberations during the legislative session and contributed to the passage of HB 229, requiring fitness testing and stricter enforcement of physical education requirements in Georgia’s school system.

The model and the collaborative model-building process facilitated more rigorous discussions among legislators, their staff, and nutrition and physical activity experts. The computer simulation model provided an opportunity to learn about the consequences of actions before policies are set in motion. Further, the model creates a transparent framework for organizing published evidence and expert assumptions in a way that makes research accessible to, and easily understood by, legislators.

Massachusetts: Implementing Evidence-Based Community Interventions through the Prevention and Wellness Trust Fund

Massachusetts established the Prevention and Wellness Trust Fund in Chapter 224 of the Acts of 2012, which is administered by the Massachusetts Department of Public Health (DPH). Designed to reduce the prevalence and costs of chronic diseases, the Trust Fund provides funding for a competitive grant program for community-based partnerships to implement targeted evidence-based public health interventions. Grants were awarded in January 2014.

Advocates were instrumental in ensuring the Prevention and Wellness Trust Fund was included in the omnibus health care legislation. Once passed, the Massachusetts DPH held four listening sessions across the state to engage stakeholders and communities in informing program development. Additionally, the legislation established an Advisory Board charged with assisting DPH in administering and allocating the Fund. The Advisory Board, appointed by the governor, included broad expert and stakeholder representation, including a public health economist, a health equity expert, local health officials, and payer/clinician representatives. The Massachusetts case study also provides an excellent example of how the steps in the Roadmap can be used to inform the decision-making process.

Step 1: Identifying When Comparative Effectiveness and/or Patient-Centered Outcomes Research Can Inform Policymaking: For the most part, the evidence that informed the development of the program included single-intervention studies; meta-analyses were used when available. Patient-centered outcomes research was not specifically prioritized.
Step 2: Finding Research and other Relevant Resources: DPH staff conducted a literature review and consulted with external experts to identify additional research. The Cochrane Database of Systematic Reviews was one tool used to identify relevant meta-analyses.

Step 3: Evaluating the Evidence: Content experts, including those on the Advisory Board and other members of academia, were asked to rank the evidence found using an existing “A, B, C” grading system. DPH also worked with a non-profit organization (Social Finance US) to conduct analyses.

Step 4: Using the Evidence to Design the Program: Chapter 224 of the Acts of 2012 requires the Commission on Prevention and Wellness to complete an evaluation of the program, including a recommendation on whether to continue the program beyond 2016, by June 30, 2015. Given the short timeframe, the Advisory Board and DPH developed four priority conditions that had a significant evidence-base of producing results in a short timeframe: pediatric asthma, hypertension, tobacco use, and falls among older adults. Applicants were also able to propose interventions for diabetes, substance abuse, oral health, and mental health/depression, but at least two of the priority conditions had to be included as well.

Step 5: Communicating and Disseminating the Decision: After DPH released the grant application, advocates provided a great deal of feedback on the program, particularly the list of priority conditions, the number of available grants, and the focus on return-on-investment. DPH developed a communication strategy that used the evidence to address stakeholders concerns, including that return on investment can translate into reduced utilization and better public health.

Step 6: Monitoring and Evaluating New Research as It Becomes Available: The grants provided under the Prevention and Wellness Trust Fund included three phases: capacity building, implementation, and sustainability. DPH continued monitoring and evaluating evidence during the capacity building phase to support grantees implement best practices. In April 2014, DPH provided grantees with an updated set of potential evidence-based interventions tiered by the strength of evidence.
The use of evidence comparing the effectiveness of different interventions when developing state programs and policies is increasingly a priority for state and federal policymakers. Interventions being considered may range from treatment for mental or physical conditions, the best use of the health care workforce, or methods to pay physicians for care delivery. Multiple approaches may need to be considered, each with varying amounts of research on their effectiveness and safety. Including patients in research and engaging them in their health care decision making is also an increasing priority within the health care system. When faced with options, policymakers will benefit from reviewing comparative effectiveness research (CER) and patient-centered outcomes research (PCOR) to select the program or policy more likely to be effective for a given investment of resources. This guide provides information and strategies for policymakers to support their use of CER and PCOR from the initial stage of recognizing issues that would benefit from a review of available CER and PCOR to using CER and PCOR to evaluate and maintain a policy or program already in place.
APPENDIX A: ROADMAP ADVISORY GROUP MEMBERS

Gregory Allen, Director of the Division of Program Development and Management, Office of Health Insurance Programs, New York State Department of Health

Alison Beam, Policy Director, Pennsylvania Insurance Department

Jane Beyer, Assistant Secretary for Behavioral Health and Service Integration, Aging and Disability Services Administration, Washington Department of Social and Health Services

Ted Cheatham, Director, West Virginia Public Employees Insurance Agency

Russell Frank, Former CHIP Director, Department of Vermont Health Access

Leah Hole-Marshall, Medical Administrator, Office of the Medical Director, Washington State Department of Labor and Industries

Laurie Jinkins, State Representative, 27th District, Washington State House of Representatives

Joan Kapowich, Former Administrator, Oregon Public Employees’ Benefit Board and Oregon Educators Benefit Board

Laura Kelly, State Senator, 18th District, Kansas State Legislature

Judy Lee, State Senator, 13th District, North Dakota State Legislature

Doris Lotz, Medicaid Medical Director, New Hampshire Department of Health and Human Services

Sheena Olson, Assistant Director, Medicaid Programs and Provider Management, Division of Medical Services, Arkansas Department of Human Services

Gail Propsom, Director, Bureau of Long-Term Support, Wisconsin Department of Health Services

Linda Sheppard, Special Counsel and Director of Healthcare Policy and Analysis, Kansas Insurance Department

Jeanene Smith, Chief Medical Officer, Oregon Health Authority

Nan Streeter, Director, Maternal and Child Health Bureau, Utah Department of Health

Robert Zavoski, Medical Director, Connecticut Department of Social Services

Judy Zerzan, Chief Medical Officer/Clinical Services Office Director, Colorado Department of Health Care Policy and Financing
APPENDIX B: ADDITIONAL SOURCES OF RESEARCH AND TOOLS

SOURCES OF RESEARCH
Agency for Healthcare Research and Quality, Evidence-based Practice Center Reports: http://www.ahrq.gov/research/findings/evidence-based-reports/a-z/index.html
Center for Integrated Health Solutions, Research: http://www.integration.samhsa.gov/research
The Cochrane Library: http://www.thecochranelibrary.com/
ECRI Institute, Library of White Papers, Resources and Other Perspectives: https://www.ecri.org/Forms/Pages/default.aspx
Grey Literature Report: http://www.greylit.org/
International Network of Agencies for Health Technology Assessment (INAHTA), Publications: http://www.inahta.org/Publications/
National Institutes of Health, Clinical Trials Registry: http://www.clinicaltrials.gov/
Partnership to Improve Patient Care, CER Inventory: http://cerdatatracker.org/?q=content/search
Patient-Centered Outcomes Research Institute, Funding Awards: http://pfaawards.pcori.org/
Rural Health Research Center, Rural Health Research Gateway: http://www.ruralhealthresearch.org/
Substance Abuse and Mental Health Services Administration, National Registry of Evidence-based Programs and Practices: http://www.nrepp.samhsa.gov/
U.S. Food and Drug Administration, Recent Scientific Publications: http://www.accessdata.fda.gov/scripts/publications/

GUIDES AND TOOLS
Communication Guides

**Glossaries**


**Guides to Conducting Systematic Reviews**


Khalid S Khan et al., “Five Steps to Conducting a Systematic Review,” *Journal of the Royal Society of Medicine* 96, no. 3 (March 2003): 118–121. (See Appendix D)

**Research Appraisal Tools**


APPENDIX C: SUGGESTED READING

Policymakers who want to learn more about using research in policymaking may wish to consider the following articles and resources, many of which were included or referenced in the Roadmap.

Background and Overview


Jonathan E. Fielding and Peter A. Briss, “Promoting Evidence-Based Public Health Policy: Can We Have Better Evidence And More Action?” *Health Affairs* 25, no. 4 (July 1, 2006): 969–978.


### Evaluating Evidence


### Implementing Evidence-based Programs


**Patient-Centered Outcomes Research**


APPENDIX D: HANDOUT

STEPS FOR A SYSTEMATIC REVIEW (KHAN ET AL.)71

Step 1: Framing questions for a review
The problems to be addressed by the review should be specified in the form of clear, unambiguous and structured questions before beginning the review work. Once the review questions have been set, modifications to the protocol should be allowed only if alternative ways of defining the populations, interventions, outcomes or study designs become apparent.

Step 2: Identifying relevant work
The search for studies should be extensive. Multiple resources (both computerized and printed) should be searched without language restrictions. The study selection criteria should flow directly from the review questions and be specified a priori. Reasons for inclusion and exclusion should be recorded.

Step 3: Assessing the quality of studies
Study quality assessment is relevant to every step of a review. Question formulation (Step 1) and study selection criteria (Step 2) should describe the minimum acceptable level of design. Selected studies should be subjected to a more refined quality assessment by use of general critical appraisal guides and design-based quality checklists (Step 3). These detailed quality assessments will be used for exploring heterogeneity and informing decisions regarding suitability of meta-analysis (Step 4). In addition they help in assessing the strength of inferences and making recommendations for future research (Step 5).

Step 4: Summarizing the evidence
Data synthesis consists of tabulation of study characteristics, quality and effects as well as use of statistical methods for exploring differences between studies and combining their effects (meta-analysis). Exploration of heterogeneity and its sources should be planned in advance (Step 3). If an overall meta-analysis cannot be done, subgroup meta-analysis may be feasible.

Step 5: Interpreting the findings
The issues highlighted in each of the four steps above should be met. The risk of publication bias and related biases should be explored. Exploration for heterogeneity should help determine whether the overall summary can be trusted, and, if not, the effects observed in high-quality studies should be used for generating inferences. Any recommendations should be graded by reference to the strengths and weaknesses of the evidence.
1 Justin W Timbie et al., “Five Reasons That Many Comparative Effectiveness Studies Fail to Change Patient Care and Clinical Practice,” Health Affairs (Project Hope) 31, no. 10 (October 2012): 2168–2175.

2 The Patient Protection and Affordable Care Act. PL 111-148. 3-23-2010.

3 See Appendix for Roadmap Advisory Group members


13 Barbara Wirth and Felicia Heider, Programs Used by State Policymakers to Leverage Comparative Effectiveness Research and Patient-Centered Outcomes Research, in press.


32 National Academy for State Health Policy personal communication with Cathy Caldwell, Alabama CHIP Director, 4/15/2014.

33 Judy T Zerzan, Mark Gibson, and Anne M Libby, “Improving State Medicaid Policies with Comparative Effectiveness Research: A Key Role for Academic Health Centers,” Academic medicine: journal of the Association of American Medical Colleges 86, no. 6 (June 2011): 695–700.


35 National Academy for State Health Policy personal communication with Cathy Caldwell, Alabama CHIP Director, 4/25/2014.


39 For an example of one of the Bree Collaborative’s reports, please see: http://www.hca.wa.gov/bree/Documents/spine_lbp.pdf

40 National Academy for State Health Policy personal communication with Leah Hole-Curry, Medical Administrator, Office of the Medical Director, Washington State Department of Labor and Industries, 4/12/2014.


55 For additional information, please visit: http://www.choosingwisely.org/about-us/

56 “About the Cochrane Library,” accessed April 30, 2014, http://www.thecochranelibrary.com/view/0/AboutTheCochraneLibrary.html (Note: This figure is updated after each issue—the figures represent the changes between Issue 2 in 2013 and Issue 3 in 2014).


69 National Academy for State Health Policy personal communication with Rachel Ferencik, Georgia Health Policy Center Senior Research Associate, 4/3/2014.
70 National Academy for State Health Policy personal communication with Massachusetts Department of Public Health staff (Laura Nasuti, Bonnie Andrews, and Thomas Soare), 4/17/14.