



Stakeholder Guide 2014

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AHRQ Publication No. 14-EHC010-EF
Replaces Publication No. 11-EHC069-EF
February 2014

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Introduction

About This Guide

The Agency for Healthcare Research and Quality (AHRQ) has designed this Guide to encourage patients, researchers, clinicians, and others to become involved in its Effective Health Care (EHC) Program. The Guide highlights opportunities to take part in the program and describes what to expect throughout the process.

What Is the Effective Health Care Program?

Background

The extraordinary pace of medical innovation over the past few decades has created unprecedented opportunities to improve health care and health outcomes. To best realize these opportunities, all participants in the health system—from patients to clinicians to policymakers—must have accurate, reliable, and actionable information to help guide and inform their health care choices.

To support this goal, AHRQ launched the EHC Program in 2005 to increase the value of the health care Americans receive and, ultimately, to improve health outcomes. The EHC Program is the Nation's first coordinated program of comparative effectiveness research/patient-centered outcomes research, research that compares the benefits and risks of various approaches to health care. Patient-centered outcomes research investigates different drugs, devices, surgeries, and health care delivery arrangements to determine which approaches work best, for which patients, and under which circumstances.

EHC Program research includes reviews of published evidence, analysis of data to address new questions, and the design and conduct of studies comparing health care interventions or modes of service delivery. The EHC Program then translates research findings into practical materials for patients, clinicians, and policymakers. AHRQ works with a range of partners to implement the EHC Program (www.effectivehealthcare.ahrq.gov/index.cfm/who-is-involved-in-the-effective-health-care-program1).

Involving Stakeholders

Stakeholders are people or groups—each with a unique perspective—who have an interest in health care decisions. The EHC Program seeks the involvement of a wide range of stakeholders throughout the research process. AHRQ firmly believes that involving stakeholders from the beginning improves research results, and helps ensure that findings are relevant to users' distinct concerns and have applications in real-world situations.

Who Are the EHC Program Stakeholders?

EHC Program stakeholders include—

- Consumers, patients, caregivers, and patient advocacy organizations
- Clinicians and their professional associations

- Health care institutions, such as hospital systems and medical clinics, and their associations
- Health care policymakers at the Federal, State, and local levels
- Health care researchers and research institutions
- Health care industry and industry associations
- Purchasers and payers, such as employers and public and private insurers

How Can You Get Involved?

As a stakeholder, you can contribute to the EHC Program in a variety of ways. As discussed in this Guide, opportunities include—

- Suggesting a research topic
- Providing insights on research priorities
- Informing the refinement of research topics and the development of Key Questions
- Helping develop a research approach
- Reviewing draft research findings
- Improving research products and tools through evaluation and feedback
- Distributing research products and leading implementation

Not all types of stakeholders are involved in all stages of the EHC Program research; instead, the program calls on stakeholders where they can have the most impact. Some are approached to take part and others volunteer.

How To Use This Guide

This Guide is intended for all stakeholders. You can use it to help find out more about ways you can contribute to EHC Program research and what to expect (Figure 1).

Figure 1. Effective Health Care Program: Stakeholder roles



Chapter 1. The Agency for Healthcare Research and Quality and the Effective Health Care Program

AHRQ is a Federal agency under the U.S. Department of Health and Human Services. AHRQ is the lead Federal agency charged with improving the quality, safety, efficiency, and effectiveness of health care for all Americans. The research AHRQ sponsors, conducts, and disseminates provides information that helps people make better decisions about health care.

For more information about AHRQ, please visit our Web site at www.ahrq.gov.

The Effective Health Care Program

The EHC Program was created under Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which authorizes AHRQ to conduct and support research with a focus on comparing the outcomes and effectiveness of different treatments and clinical approaches, as well as communicating its findings widely to a variety of audiences. The EHC Program is the Nation's first coordinated program of comparative effectiveness research/patient-centered outcomes research (see Box 1). It is the Federal Government's leading effort to compare the benefits and risks of various approaches to health care—different drugs, devices, surgeries, and health care delivery arrangements—to determine which approaches work best, for which patients, and under which circumstances. The overall goal of this effort is to improve health outcomes and increase the value of the health care Americans receive.

Before the EHC Program was created, most available evidence-based information was about a single drug, medical device, or procedure tested on one group of patients. Groups such as the elderly, minorities, and individuals with complex medical problems often were not included in the research. These limitations made it difficult for clinicians and their patients to compare options and to select the treatment that was best for them given their unique circumstances. Patient-centered outcomes research seeks to overcome these limitations by gathering and analyzing the evidence from multiple sources on currently available treatment options, and focuses on the impact on real patients in real-world settings.

AHRQ has built the EHC Program around the guiding principles of strong involvement of stakeholders and the maintenance of transparency and public accountability. The EHC Program's

Box 1. What kind of research does the EHC program conduct?

Comparative effectiveness research/patient-centered outcomes research aims to compare the benefits and risks of various approaches to health care—different drugs, devices, surgeries, and health care delivery arrangements—to determine which approaches work best, for which patients and under which circumstances.

Learn more at www.effectivehealthcare.ahrq.gov.

research supports the overarching goal of providing health care decisionmakers (consumers, clinicians, policymakers, and others) with the best available scientific evidence to make informed health care decisions.

Getting the Work Done

All suggestions for research are carefully considered according to a standard set of criteria (Appendix A). The EHC Program achieves its goals by awarding contracts to research centers and clinical investigators to conduct timely and relevant research. The program also supports the dissemination and implementation of the research findings.

Key players in the EHC Program include the following:

- The Evidence-based Practice Centers (EPCs) (www.effectivehealthcare.ahrq.gov/index.cfm/who-is-involved-in-the-effective-health-care-program1/about-evidence-based-practice-centers-epcs) perform indepth reviews of existing evidence.
- The Centers for Education & Research on Therapeutics (CERTs) (www.effectivehealthcare.ahrq.gov/index.cfm/who-is-involved-in-the-effective-health-care-program1/about-certs) conduct research and educate clinicians and consumers about drugs, biologicals, and medical devices.
- The Scientific Resource Center (SRC) (www.effectivehealthcare.ahrq.gov/index.cfm/who-is-involved-in-the-effective-health-care-program1/about-the-scientific-resource-center1) provides scientific support for the EHC Program.
- The John M. Eisenberg Center for Clinical Decisions and Communications Science (www.effectivehealthcare.ahrq.gov/index.cfm/who-is-involved-in-the-effective-health-care-program1/about-the-eisenberg-center) organizes the research results into guides and tools that are useful to clinicians, health care policymakers, and patients.

For more information about each of the EHC Program partners, visit the Web site at www.effectivehealthcare.ahrq.gov/index.cfm/who-is-involved-in-the-effective-health-care-program1.

Chapter 2. Effective Health Care Program Activities

Core activities contribute to the conduct of comparative effectiveness research/patient-centered outcomes research through the EHC Program and to the continuing development of an infrastructure to sustain and advance these efforts. To ensure the relevance of the research to those making health care decisions, stakeholders are kept involved in all core activities at every stage of the research process. These core EHC activities are described below.

Horizon Scanning

AHRQ's Healthcare Horizon Scanning System began with funding under the American Recovery and Reinvestment Act of 2009. Its purpose is to conduct horizon scanning of emerging health care technologies and innovations in order to better inform AHRQ's investments in comparative effectiveness research/patient-center outcomes research through the EHC Program. The Healthcare Horizon Scanning System provides AHRQ a systematic process to identify and monitor target technologies and innovations in health care and to create an inventory of target technologies that have the highest potential for impact on clinical care, the health care system, patient outcomes, and costs. It is a tool for the public to identify and find information on new health care technologies and interventions. Any investigator or funder of research can use the AHRQ Healthcare Horizon Scanning System to select potential research topics.

The health care technologies and innovations of interest for horizon scanning are those that have yet to diffuse into or become part of established health care practice. These health care interventions are still in the early stages of development or adoption, except in the case of new applications of already-diffused technologies. Consistent with the definitions of health care interventions provided by the Institute of Medicine and the Federal Coordinating Council for Comparative Effectiveness Research, AHRQ is interested in innovations in drugs and biologicals, medical devices, screening and diagnostic tests, procedures, services and programs, and care delivery.

Identification of Evidence Needs

Identification of evidence needs is a central recurring activity that drives research and dissemination throughout the EHC Program. In order to gain the widest perspective into what questions need to be answered, all stakeholders—including consumers, clinicians, policymakers, and other decisionmakers—are encouraged to identify and suggest topics for research. Research suggestions from all sources and all topic nominations are posted on the EHC Web site at www.effectivehealthcare.ahrq.gov. The EHC Program reviews these suggestions based on a series of questions:

- How widespread and serious is the disease or problem proposed for study?
- How much controversy exists about treatment?
- What are the potential impacts for improving care and/or reducing costs?

- Would research results be relevant to Federal health care programs such as Medicare, Medicaid, or the Children’s Health Insurance Program (CHIP)?
- Would research results be relevant or helpful for vulnerable and underserved populations: low-income groups; racial/ethnic minorities; women; children; the elderly; individuals with special health care needs, such as those with disabilities; those who need chronic care or end-of-life care; or those who live in inner-city or rural areas?

In addition, evidence synthesis (described below) also identifies future research needs as part of the research process. In the case of systematic reviews, this includes a formal engagement with stakeholders to prioritize gaps identified during the review of research.

Evidence Synthesis

Evidence synthesis is a rigorous systematic research process that adheres to explicit scientific methods to analyze and summarize the existing scientific evidence on a specific topic. These methods are designed to reduce bias and allow research investigators to incorporate large amounts of information from different sources, while focusing on objective analysis and interpretation. The EHC Program produces two types of evidence synthesis reports, systematic reviews and Technical Briefs, depending on the nature and amount of evidence available for synthesis.

Systematic reviews. Systematic reviews are summaries of available scientific evidence that compare the benefits and harms of treatment options. They are designed to provide decisionmakers with accurate, independent, scientifically rigorous information for comparing the effectiveness and safety of various health care options. Systematic reviews have become a foundation for decisionmaking in clinical practice and health policy because they provide more reliable and less biased answers than individual studies. The EHC Program updates systematic reviews if new information becomes available and the topic is still of high clinical importance.

Technical Briefs. A Technical Brief explains what is known—and what is not known—about new or emerging health care tests or treatments. Technical Briefs provide an overview of issues related to emerging technologies or clinical interventions. They generally focus on interventions for which there is limited published information or too few studies to support definitive conclusions. Technical Briefs provide objective descriptions of the state of the science, potential frameworks for assessing the applications, implications of the interventions, summaries of ongoing research, and identification of future information needs.

All reports are produced by the EPCs. For more information on the EPCs, see www.effectivehealthcare.ahrq.gov/index.cfm/who-is-involved-in-the-effective-health-care-program1/about-evidence-based-practice-centers-epcs.

All reports are available on the EHC Web site, www.effectivehealthcare.ahrq.gov. Many reports are available in Spanish and audio formats. Free printed copies are available by calling 1-800-358-9295.

Translation and Dissemination of Research Findings to Diverse Stakeholders

AHRQ has a strong and long-term commitment to bridging the gap between research and practice by translating and disseminating findings on the comparative effectiveness of interventions for different audiences, including consumers, clinicians, and policymakers.

Summary guides translate complex scientific information into short plain-language publications for use by decisionmakers. The information in the summary guides can be used to assess options and help make informed decisions. Summary guides are developed for three targeted groups of decisionmakers—consumers, clinicians, and policymakers. They are designed to assist in evaluating the benefits and risks of health care interventions and services. Summary guides are available in both written and audio formats, and many are available in Spanish. The summary guides present information about—

- Strengths and limits of evidence
- Which interventions are supported by strong evidence and which options are less certain
- Tradeoffs between various decisions
- How to sort through the options
- Basic wholesale price information on medications (if relevant)

The John M. Eisenberg Clinical Decisions and Communications Science Center translates scientific reports into different summary guides, each tailored for practical use by consumers, clinicians, or policymakers. New types of summary guides are developed as the need is identified. The Eisenberg Center is developing Continuing Medical Education (CME) and Continuing Education (CE) lessons and examinations, slide sets for use by medical faculty, and electronic decision aids for clinicians and patients/consumers. Podcasts are developed to facilitate Web dissemination of EHC information. AHRQ also supports investigator-initiated efforts to translate and disseminate EHC products. All completed reports and summary guides, as well as many reports in progress, are available on the EHC Web site at www.effectivehealthcare.ahrq.gov.

Training and Development of Clinical Researchers

AHRQ builds the capacity for comparative effectiveness research/patient-centered outcomes research by providing support to institutions to boost their intellectual and organizational capacity for larger scale programs, and by providing for fellowship training opportunities. AHRQ funding supports the career development of clinicians and researchers on the doctoral level, who focus their research on the synthesis, generation, and translation of new scientific evidence, and on the development of analytic tools for comparative effectiveness research/patient-centered outcomes research. The goal of this training and development activity is to increase the Nation's research and methodological capacity for conducting and improving the quality of systematic reviews, retrospective studies, and clinical trials in comparative effectiveness research/patient-centered outcomes research, and to develop data sources and other aspects of the research infrastructure.

Stakeholder Input and Involvement

The EHC Program offers many opportunities for stakeholders to get involved at all stages in the research process. Stakeholder involvement, covered in Chapter 3, helps ensure that the program responds to the issues that are most pressing for health care decisionmakers in ways that are accessible and useful.

In addition, the AHRQ Community Forum, funded initially under the American Recovery and Reinvestment Act, develops tools and resources to support EHC stakeholder activities and methods to involve stakeholders and the public more broadly. These resources, available on the EHC Web site, address innovative methods for engaging stakeholders in research, supporting the involvement of patients and consumers, and using deliberative methods to obtain informed public input on complex topics (www.effectivehealthcare.ahrq.gov/tools-and-resources/how-to-get-involved-in-the-effective-health-care-program).

Chapter 3. Getting Involved in the Research Process

AHRQ relies on stakeholder involvement to ensure that research is relevant to, and useful for, decisionmakers. Stakeholder involvement also increases transparency in the research process, which is critical for maintaining the scientific integrity and credibility of AHRQ’s work. Finally, once research is produced, it is hoped that stakeholders who are involved in the process are more likely to actively use and disseminate the information that they helped produce.

This chapter describes the different types of stakeholders that AHRQ works with and why they are important. Then it outlines the opportunities for involvement in different EHC activities and what that involvement entails. Not all types of stakeholders are involved in all stages of research; instead they are targeted where they can have the most impact. If you have been asked to join a specific project activity, you can use this chapter to find a step-by-step description of the project and what is expected of you. If you are looking for opportunities to be involved, the shaded boxes in each section explain the different opportunities and which types of stakeholders are needed.

Who Are Stakeholders and Why Are Their Views Important?

AHRQ has defined “stakeholders” as persons or groups that have a vested interest in a clinical decision and the evidence that supports that decision. Stakeholders may be patients, caregivers, clinicians, researchers, advocacy groups, professional societies, businesses, policymakers, or others. Each group has a unique and valuable perspective (Table 1).

Table 1. Stakeholder groups

Consumers, patients, caregivers, and patient advocacy organizations	It is vital that research answer the questions of greatest importance to those experiencing the situation that the research addresses. Which aspects of an illness are of most concern? Which features of a treatment make the most difference? Which kinds of presentation of research results are easiest to understand and act upon?
Clinicians and their professional associations	Clinicians are at the heart of medical decisionmaking. Where is lack of good data about diagnostic or treatment choices causing the most harm to patients? What information is needed to make better recommendations to patients? What evidence is required to support guidelines or practice pathways that would improve the quality of care?

Table 1. Stakeholder groups (continued)

Health care institutions, such as hospital systems and medical clinics, and their associations	Many health care decisions are structured by the choices of institutional health care providers, and institutional health care providers often have a broad view of what is causing problems. What information would support better decisions at an institutional level to improve health outcomes?
Purchasers and payers, such as employers and public and private insurers	Coverage by public or private purchasers of health care plays a large role in shaping individual decisions about diagnostic and treatment choices. Where does unclear or conflicting evidence cause difficulty in making the decision of what to pay for? Where is new technology or new uses of technology raising questions about what constitutes a standard of care? What research is or could be funded?
Health care industry and industry associations	The manufacturers of treatments and devices often have unique information about their products.
Health care policymakers at the Federal, State, and local levels	Policymakers at all levels want to make health care decisions based on the best available evidence about what works well and what does not. Comparative effectiveness research/patient-centered outcomes research can help decisionmakers plan public health programs, design health insurance coverage, and initiate wellness or advocacy programs that provide people with the best possible information about different health care treatment options.
Health care researchers and research institutions	Researchers gather and analyze the evidence from multiple sources on currently available treatment options.

Identification of Evidence Needs

Identifying a need for evidence is the beginning of any comparative effectiveness research/patient-centered outcomes research process. This presents an opportunity for stakeholders to have a significant impact by nominating a topic for research. Once a topic has been nominated, it is further clarified through a process of topic development, which may allow further opportunities for input from the nominator and possibly other stakeholders.

Topic Nomination

The EHC Program accepts topic nominations from all individuals or organizations (see Box 2). Nominations can be submitted by anyone using the Web site (www.effectivehealthcare.ahrq.gov) and clicking the “Submit a Suggestion for Research” tab. For those who do not have access to a computer or the Internet, nominations may be submitted by mail (see Appendix B). The nomination form requests information about the importance of the topic being proposed, patients affected by the issue, and specific questions that research could help answer.

Box 2. Get involved as a nominator

Any individual or organization can nominate a topic at any time using the EHC Web site: www.effectivehealthcare.ahrq.gov. Nominations may be submitted anonymously.

The nominator is asked to—

- Describe a well-defined question related to the topic of interest (see Appendix C for tips on developing strong research questions).
- Provide as much information as possible in order to guide the process for selecting which nominations will go forward for research.

Be as specific as possible, particularly regarding the health care intervention or service of interest, the population of interest, and how you expect this research to affect health care. Providing more information initially will help guide the process for selecting research topics.

Submit the nomination by mail or email, or by completing the nomination form through the Web site (www.effectivehealthcare.ahrq.gov/index.cfm/submit-a-suggestion-for-research/). Include any supporting documentation.

It is not mandatory that you provide your contact information, but it is often helpful to contact the nominator when clarification about the research question is needed. This is known as topic development. Clinical or other experts may also be consulted during this process.

Consider serving in other roles (described below) if the topic goes forward for research.

Topic Development

When nominations are under review, the nominator may be asked to provide further information for clarification. Clinical or other experts may also be consulted to ensure that the context of the nomination is accurately considered. This process of clarification, known as topic development, is conducted by the EHC Program and typically takes 3 to 4 months. Once the topic nomination is fully developed, the EHC Program selects topics based on a set of predefined criteria (Appendix A).

Anyone can check the status of a nomination at any time on the EHC Web site.

Evidence Synthesis

The EHC Program produces two types of evidence synthesis reports: systematic reviews and Technical Briefs. Both offer opportunities for stakeholder involvement, although each report follows a slightly different process, as described below.

Systematic Reviews

Topic Refinement

If a nominated topic has been selected to move forward as a systematic review, AHRQ will assign the topic to one of the EPCs for topic refinement. Topic refinement is the process of clarifying the scope of a topic and defining the questions so that it is ready to undergo research. Refinement requires several steps.

Kickoff Call

Once an EPC is assigned a topic for refinement, a kickoff call is scheduled for key staff from the EPC, AHRQ, Eisenberg Center, and Scientific Resource Center to organize and discuss the

research plan. The kickoff call is facilitated by the EPC with guidance from a staff person assigned by AHRQ, known as a Task Order Officer. The kickoff call is intended to help develop a common understanding of the task at hand, as well as to establish agreement on the methods, plans, and timeline for completing the research. The nominator may be asked to participate in this call to help clarify the intent of the topic and to communicate important contextual information.

Developing the Key Questions

Good research requires a good set of research questions. The key research questions for each systematic review are formulated and refined with the help of Key Informants to ensure that research addresses the questions important to decisionmakers, represents an accurate scope of issues, and produces the most valuable product (see Box 3). Key Informants often include the nominator as well as other decisionmakers who can contribute to defining the scope and Key Questions of a research report. Key Informants may include patients and caregivers, clinicians (including both generalists and experts in relevant specialties), representatives of relevant professional and consumer organizations, insurers and health plan representatives who make coverage and benefit decisions, public policymakers, and others with experience in making health care decisions relevant to the topic. During the topic refinement process, the focus of the original nomination may be narrowed, expanded, or shifted depending on the input received from the Key Informants.

This input is gathered through Key Informant calls, which are scheduled and coordinated by the EPC assigned to do the research. One or several calls may be held. The “Guide for Key Informants,” including roles, responsibilities, and what to expect, is shown as Appendix D.

Box 3. Get involved as a Key Informant for a systematic review

Key Informants are stakeholders with direct experience with the topic being researched as patients or caregivers, clinicians, policymakers, insurers, or other health care decisionmakers. Key Informants offer unique perspectives that help to refine Key Questions before the research begins. They also provide context, as well as help direct questions for specific considerations such as side effects, benefits, harms, and quality-of-life issues.

The EPC assigned to a research topic will invite approximately six to eight individuals to participate in the topic refinement process as Key Informants. The nominator of the topic will often be invited to participate to address the original intent of the nomination and to increase the likelihood that the end products will meet the originating need. All Key Informants must complete disclosure-of-interest forms, and they may be asked to submit a short description of their experience with the topic. The requirement of disclosure bolsters transparency, assists in mitigating bias, and helps create a balance of perspectives among the Key Informant group.

Once Key Informants are approved by AHRQ to participate, the EPC is responsible for scheduling and coordinating conference calls and/or other opportunities for input. The number of calls or methods used to collect input will vary depending on the complexity of the topic. It is recommended that calls include as many of the identified Key Informants as possible to foster more robust discussions. In the event that this is not possible, it may be necessary to schedule individual calls, schedule calls with subsets of the identified Key Informants, or use other methods for soliciting input from Key Informants.

Box 3. Get involved as a Key Informant for a systematic review (continued)

The topic refinement process is expected to take 4 months. Key Informants should expect to—

- Submit a completed disclosure-of-interest form.
- Submit a brief description of their experience with the topic.
- Participate in at least one, and possibly several, phone calls with the EPC and other Key Informants. Typically, calls last 1 hour and use a toll-free number. Often it is necessary to schedule multiple calls.
- Be available to answer questions if the research team requires additional information.
- Help guide the formation of Key Questions, which may involve the use of a patient, intervention, comparison, outcome (treatment and setting) [PICO(TS)] format. For more information on formulating questions using PICO(TS), please see Appendix C.
- Have their names and contact information shared with the EHC Program for potential consultation on future work, unless otherwise requested.

Key Informants who are also nominators should anticipate that the original nomination may be altered or changed during the topic refinement process in order to ensure the greatest possible application and relevancy.

The EHC Program assists EPCs in identifying and supporting Key Informants in the topic refinement process. To indicate interest in participating as a Key Informant, contact the EHC Program at 301-427-1502 or at EffectiveHealthCare@ahrq.hhs.gov.

Once Key Informants have provided input into the development of research questions, the EPC develops a draft set of Key Questions. The draft questions are then posted on the EHC Web site for public comment (see Box 4). The final key research questions, along with an analytic framework and research abstract, will guide the research process.

Box 4. Get involved by providing public comments on the Key Questions

Anyone may comment on draft Key Questions, and the assigned EPC will consider incorporating feedback in the final Key Questions. It is critical that the questions posed for these documents reflect the concerns and dilemmas of consumers, clinicians, policymakers, and other health care decisionmakers. Public posting is another opportunity for involvement of the whole range of stakeholders and a way to ensure that the research report has the broadest possible relevancy.

The public comment period lasts 3 weeks. Those who wish to comment on the Key Questions should expect to—

- Post their comments through the Web site within 3 weeks at www.effectivehealthcare.ahrq.gov/index.cfm/research-available-for-comment.
- Have their names and contact information shared with the EHC Program for potential consultation on future work, unless otherwise requested.

You can sign up at www.effectivehealthcare.ahrq.gov/index.cfm/join-the-email-list1 to receive alerts when Key Questions are posted for clinical areas that interest you.

Conducting a Systematic Review

A systematic review involves carefully reviewing the literature and analyzing the quality of existing studies and data. This process can take up to 12 months to complete, during which time scientific investigators thoroughly and methodically examine information. During the conduct of a report, there will not be opportunity for communication with the institution conducting the research. All communication regarding the topic at this phase must go through AHRQ in order to ensure that the investigators remain as objective as possible. The process does include an opportunity for stakeholder involvement through Technical Expert Panels and during peer and public review.

Technical Expert Panels

Technical Expert Panels provide expert advice about the clinical specialty being studied as well as advice about research methods. Therefore, Technical Expert Panels are primarily comprised of clinical, research, and methodological experts who can provide information and guidance on technical aspects of the review. (See Box 5.) Technical Experts are assembled by the EPC assigned to the report. The AHRQ Task Order Officer is available to help identify participants for Technical Expert Panels if needed.

Box 5. Get involved as part of a Technical Expert Panel

Participation on Technical Expert Panels is usually limited to researchers, clinical experts, statisticians, and specialists who can help ensure the methodological rigor of the research report. Generally comprised of five to eight members, Technical Expert Panels help focus the literature search, identify inclusion/exclusion criteria, and assist in the evaluation of available evidence. The size and composition of the Technical Expert Panel are intended to create a balance between content and methodological expertise. The assigned EPC is responsible for convening the Technical Expert Panel, with approval from the AHRQ Task Order Officer.

The research process is expected to take up to 12 months. Technical Experts should expect to—

- Submit a completed disclosure-of-interest form.
- Submit a brief description of their experience with the topic.
- Participate in at least one, and possibly several, phone calls with the EPC and other Technical Experts. Typically, calls last 1 hour and use a toll-free number. Often it is necessary to schedule multiple calls.
- Be available to answer questions if the research team requires additional information.
- Have their names and contact information shared with the EHC Program for potential consultation on future work, unless otherwise requested.

Peer and Public Review

Once the EPC has completed a draft of the systematic review, a peer review panel is assembled to provide additional and technical review of the report (see Box 6). The peer review process is coordinated through the Scientific Resource Center.

Box 6. Get involved in the peer review process of a systematic review

Research products undergo a peer review process to ensure the scientific integrity and quality of research reports. AHRQ, the Scientific Resource Center, and the assigned EPC identify Peer Reviewers for specific topics. Decisionmaker organizations (such as professional societies) are encouraged to suggest experts to participate in peer review. Suggestions for Peer Reviewers can be made during the topic nomination, topic development, and topic refinement processes by contacting EffectiveHealthCare@ahrq.hhs.gov. The Scientific Resource Center coordinates the peer review process, which typically lasts 3 months. The EPC considers all peer review comments and modifies the final report as appropriate.

Peer Reviewers should expect to—

- Complete their review of the draft research review within 4 weeks.
- Have their names and contact information shared with the Scientific Research Center for potential consultation on future work, unless otherwise requested.

While the draft report is undergoing peer review, it is posted on the EHC Web site for public comment (see Box 7). An announcement is sent through the EHC Program listserv that the draft is available for comment. Reports are typically available online for public comment for 4 weeks. To sign up for EHC Program listserv notification, go to the EHC Web site (www.effectivehealthcare.ahrq.gov) and click “Join the Email List” in the lower left corner.

Box 7. Get involved by providing public comments on the draft report

Anyone may comment on the draft report, and the assigned EPC will consider incorporating feedback in the final report. It is critical that the questions posed by these documents reflect the concerns and dilemmas of consumers, clinicians, policymakers, and other health care decisionmakers. Public posting is another opportunity for involvement of the whole range of stakeholders and a way to ensure that the research report has the broadest possible relevancy. Those who wish to comment on the draft report should expect to—

- Post their comments through the Web site during the 4-week posting period at www.effectivehealthcare.ahrq.gov/index.cfm/research-available-for-comment/.
- Have their names and contact information shared with the EHC Program for potential consultation on future work, unless otherwise requested.

You can sign up at www.effectivehealthcare.ahrq.gov/index.cfm/join-the-email-list1/ to receive alerts when draft reports are posted for clinical areas that interest you.

After all public and peer review comments have been received, the final report is prepared. The process of responding to and addressing Peer Reviewer, Technical Expert, and public comments can take up to 3 months. The final report is then posted on the EHC Web site at www.effectivehealthcare.ahrq.gov. A notice of availability is also sent to individuals and organizations who have signed up through the AHRQ listserv to receive announcements.

Disposition of Comments

AHRQ supports and is committed to the transparency of its review processes. Therefore, within 3 months after a final report is posted, all comments received from Peer Reviewers,

Technical Experts, and the public, and all the responses made by the authors of a draft report to the public comments (i.e., the “disposition of comments”) are posted on the EHC Web site. Each comment is listed with the name and affiliation of the commentator, if such information is provided. Public commentators are not required to provide their names or affiliations to submit suggestions or comments, but contact information will be used to communicate with commentators if there are questions about submitted comments.

Future Research Needs

A Future Research Needs paper is a document produced by an EPC, usually the one preparing the main research report. After completing a research review, including identification of evidence gaps, the EPC convenes a group of stakeholders, including investigators, funders, and others, to prioritize future research needs as they relate to the research topic (see Box 8). The results of these discussions and prioritization are summarized in a separate Future Research Needs paper.

Box 8. Get involved identifying needed research

Methods of involving stakeholders in the development of the Future Research Needs papers are being tested. Research institutions consult with decisionmakers regarding how and what type of research should be prioritized to meet the identified evidence gaps.

The role of a stakeholder at this point is to participate in discussions to describe and prioritize research needs.

Stakeholders involved in identifying research needs should expect to—

- Read and review portions of the research report.
- Review suggestions and draft language regarding the prioritization of research gaps and needs for additional evidence.
- Provide comments in individual conversations or in group settings, such as dedicated meetings or conference calls.
- Have the process take up to 2 months.

In a transparent and systematic formal process, all stakeholders, including clinicians, funding agencies, and researchers, consider the gaps between available medical knowledge and the needs of clinical practice that are identified in the systematic reviews. Participants in the discussion include the researchers who worked on the individual review where the gap was first identified, stakeholders with interest in the topic, clinicians with particular expertise in the topic area, and agencies with funds for potential future research. Also involved are researchers with expertise in the clinical area and in study design, who can help identify evidence needs and develop new research projects based on the findings of the systematic review. It is hoped that this process will help shape future research plans and set priorities for a national investment in new research.

Inputs to the evidence gap identification process include nominations and recommendations of stakeholders by groups such as the Federal Coordinating Council for Comparative Effectiveness Research and the Institute of Medicine’s project on Priority Setting for Comparative Effectiveness Research, as well as AHRQ’s systematic review process.

Technical Briefs

A Technical Brief is a rapid report, typically on an emerging medical technology, strategy or intervention. It provides an overview of key issues related to the intervention—for example, current indications, relevant patient populations and subgroups of interest, outcomes measured, and contextual factors that may affect decisions regarding the intervention. Although Technical Briefs generally focus on interventions for which there are limited published data and too few completed protocol-driven studies to support definitive conclusions, the decision to request a Technical Brief is not solely based on the availability of clinical studies. The goals of the Technical Brief are to provide an early objective description of the state of the science, a potential framework for assessing the applications and implications of the intervention, a summary of ongoing research, and information on future research needs. In particular, through the Technical Brief, AHRQ hopes to gain insight on the appropriate conceptual framework and critical issues that will inform future comparative effectiveness research/patient-centered outcomes research.

Key Informants

Since Technical Briefs are assessments of the current state and implications of new medical technologies, Key Informant interviews are an important resource for identifying how the technology in question is currently used, the major issues and controversies surrounding the technology, and strategies for acquiring information on the technology. Therefore, an integral part of the research process for Technical Briefs is interviewing subject matter experts and end-users of the technology, such as patients and caregivers, practicing clinicians, relevant professional and consumer organizations, purchasers of health care, and others with experience in making health care decisions relevant to the topic.

This input may be gathered through Key Informant calls, which are scheduled and coordinated by the EPC assigned to do the research, or the EPC may carry out individual interviews, depending on the topic (see Box 9).

Box 9. Get involved as a Key Informant for a Technical Brief

Key Informants are stakeholders with direct experience with the topic being researched as patients or caregivers, clinicians, policymakers, insurers, or other health care decisionmakers. Key Informants offer unique perspectives that help to refine Key Questions before the research begins. They also provide context, as well as help direct questions for specific considerations such as side effects, benefits, harms, and quality-of-life issues. They may provide information on how a technology, strategy, or intervention is used; the clinical context in which it is used; and so on.

The EPC assigned to a research topic will invite approximately six to eight individuals to participate in the topic refinement process as Key Informants. The nominator of the topic will often be invited to participate to address the original intent of the nomination and to increase the likelihood that the end products will meet the originating need. All Key Informants must complete disclosure-of-interest forms, and they may be asked to submit a short description of their experience with the topic. The requirement of disclosure bolsters transparency, assists in mitigating bias, and helps create a balance of perspectives among the Key Informant group.

Box 9. Get involved as a Key Informant for a Technical Brief (continued)

Once Key Informants are approved by AHRQ to participate, the EPC is responsible for scheduling and coordinating conference calls and/or other opportunities for input. The number of calls or methods used to collect input will vary depending on the complexity of the topic. It is recommended that calls include as many of the identified Key Informants as possible to foster more robust discussions. In the event that this is not possible, it may be necessary to schedule individual calls, schedule calls with subsets of the identified Key Informants, or use other methods for soliciting input from Key Informants.

The topic refinement process is expected to take 4 months. Key Informants should expect to—

- Submit a completed disclosure-of-interest form.
- Submit a brief description of their experience with the topic.
- Participate in at least one, and possibly several, phone calls with the EPC and other Key Informants. Typically, calls last 1 hour and use a toll-free number. Often it is necessary to schedule multiple calls.
- Be available to answer questions if the research team requires additional information.
- Help guide the formation of Key Questions, which may involve the use of a patient, intervention, comparison, outcome (treatment and setting) [PICO(TS)] format. For more information on formulating questions using PICO(TS), please see Appendix C.
- Have their names and contact information shared with the EHC Program for potential consultation on future work, unless otherwise requested.

Key Informants who are also nominators should anticipate that the original nomination may be altered or changed during the topic refinement process in order to ensure the greatest possible application and relevancy.

The EHC Program assists EPCs in identifying and supporting Key Informants in the topic refinement process. To indicate interest in participating as a Key Informant, contact the EHC Program at (301) 427-1502 or at EffectiveHealthCare@ahrq.hhs.gov.

Peer and Public Review

Once the EPC has completed a draft of the Technical Brief, a peer review panel is assembled to provide an independent and unbiased technical review of the report. Peer Reviewers agree to be named in the report, although the report is not intended to represent their opinions. Peer review comments are published with a disposition of comments, although individual comments of invited Peer Reviewers are not directly attributed. The peer review process is coordinated through the Scientific Resource Center (see Box 10).

Box 10. Get involved in the peer review process for a Technical Brief

Research products undergo a peer review process to ensure the scientific integrity and quality of research reports. AHRQ, the Scientific Resource Center, and the assigned EPC identify Peer Reviewers for specific topics. Decisionmaker organizations (such as professional societies) are encouraged to suggest experts to participate in peer review. Suggestions for Peer Reviewers can be made during the topic nomination and topic development processes by contacting EffectiveHealthCare@ahrq.hhs.gov. The Scientific Resource Center coordinates the peer review process, which typically lasts 3 months. The EPC considers all peer review comments and modifies the final report as appropriate.

Peer Reviewers should expect to—

- Complete their review of the draft research review within 4 weeks.
- Have their names and contact information shared with the Scientific Research Center for potential consultation on future work, unless otherwise requested.

While the draft report is undergoing peer review, it is posted on the EHC Web site for public comment. An announcement is sent through the EHC Program listserv that the draft is available for comment. Reports are typically available online for public comment for 4 weeks. To sign up for EHC Program listserv notification, go to the EHC Web site (www.effectivehealthcare.ahrq.gov) and click “Join the Email List” in the lower left corner.

Preparation of Final Report

After all public and peer review comments have been received, the final report is prepared. The process of responding to and addressing public comments can take up to 3 months. The final report is then posted on the EHC Web site at www.effectivehealthcare.ahrq.gov. A notice of availability is also sent to individuals and organizations who have signed up through the AHRQ listserv to receive announcements.

AHRQ supports and is committed to the transparency of its review processes. Therefore, within 3 months after a final report is posted, all comments received from the public and all the responses made by the authors of a draft report to the public comments (i.e., the “disposition of comments”) are posted on the EHC Web site. Each comment is listed with the name and affiliation of the commentator, if such information is provided. Public commentators are not required to provide their names or affiliations to submit suggestions or comments, but contact information will be used to communicate with commentators if there are questions about submitted comments.

Product Translation and Dissemination

The John M. Eisenberg Center for Clinical Decisions and Communications Science produces and disseminates user-friendly actionable summaries of systematic reviews and other reports for health care consumers, clinicians, and policymakers. These guides are designed to facilitate effective communication and decisionmaking about test or treatment choices between clinicians and patients, and to provide evidence-based decision tools for policymakers.

Translation

To ensure that translations of EHC Program research accurately reflect the needs of audience members as well as the science itself, the Eisenberg Center is involved throughout the systematic review process, listening carefully to Key Informants and Technical Expert panelists as they

interact with EPCs, and interacting with investigators as they review public comments and refine reports. The Eisenberg Center also engages its own medical content experts to better understand the factors that both patients and clinicians must consider when making medical decisions on specific topics and to assist the Center in producing scientifically accurate translations of research findings.

Translation of research into practical decisionmaking tools for consumers, clinicians, and policymakers is a pivotal aspect of AHRQ's overarching goal to support the practice of evidence-based medicine. Effective translation of research is critical to ensuring that decisionmakers have access to high-quality evidence and tools for making informed decisions.

Input from patients, their caregivers, clinicians, and policymakers guides the creation of summaries and decision tools by providing a context for decisionmaking as well as feedback on the tools themselves. For each topic, a consumer panel, clinician panel, and policymaker panel are created early in the process. Panel members may participate in several group and individual conversations conducted by the Eisenberg Center or its associates.

Providing Information on the Context for Decisions

Consumer, clinician, and policymaker panelists can first participate in focus groups or an individual interview that explores the context of a specific topic currently under systematic review. During these interviews, panelists may be asked to share their experiences with the condition or certain treatment choices, their values and preferences in information-seeking and decisionmaking, and their challenges in deciding the best choice for themselves or others. This information is used to guide the Eisenberg Center in developing contextually relevant materials that speak directly to decisionmaking needs and situations among a broad audience base. The Center is careful to ensure that all panelist information is kept confidential. Patient/caregiver panelists who have personal experiences with the condition being studied are sought for these conversations. Clinician and policymaker panelists who have experience treating or setting policies on the test or treatment being studied are also sought for these conversations. Chosen panelists are paid for their time (see Box 11 for information on decision-context groups).

Box 11. Get involved in groups describing the context for decisions

The role of a panelist is to participate in interviews or group discussions to provide context and experience related to a specific health condition, and to test product messages. Panelists should expect to—

- Participate in a 30- to 45-minute conversation with an Eisenberg Center associate, either in person or over the telephone and either alone or with other consumers, clinicians, or policymakers. This conversation is recorded and transcribed, although individual panelist names are not included in the transcript or reported.
- Discuss their own health and medical experiences, their values and preferences, and their habits of information collection, whether it be from brochures, magazines, television, radio, Internet, or other sources.
- Discuss the challenges faced and strategies used concerning the specific condition being studied as a patient, provider of clinical treatment, or policymaker.
- Provide informed consent for their participation following a full disclosure of possible risks and benefits of participating in the interview.
- Receive compensation for their time spent in conversation.
- Have their names and contact information shared with the EHC Program for potential consultation on future work, unless otherwise requested.

Summary Guide Review

The Eisenberg Center consults with AHRQ and the Scientific Research Center to identify and invite individual representatives of decisionmaker organizations to review and provide feedback on draft information products and decision tools. The purpose of these reviews is to ensure the scientific accuracy of the products and to confirm the contextual relevancy of the content. Reviewers include individuals who have been involved throughout the research process, as well as those who have not been involved and can provide a “fresh eye” on decisions made throughout development. Feedback received from reviewers of these products is used to revise and improve the content or graphics of the guides. Product reviews generally take less than an hour for reviewers to complete (see Box 12).

Box 12. Get involved in summary guide review

The role of a product reviewer is to provide review and comment on specific draft products. Product reviewers should expect to—

- Receive information products and decision tools by mail or electronic delivery for review.
- Receive a set of instructions and a formal review form to assist in the product review process.
- Receive a clear timeline and return path for the submission of comments.
- Receive compensation for their time spent reviewing products.
- Have their names and contact information shared with the EHC Program for potential consultation on future work, unless otherwise requested.

Product User Feedback

Once draft summary guides are developed and reviewed, the Eisenberg Center invites consumers, clinicians, policymakers, and other decisionmakers who are potential users of the

products to provide feedback on their ease of comprehension, usefulness, and actionability. Feedback received from potential users of these products is used to revise and improve the content or graphics of the guides. Often, panelists may encounter several “rounds” of products to confirm that changes are leading to a more understandable and useful information product or decision tool. Length of time involved in these interviews is between 60 and 90 minutes (see Box 13).

Box 13. Get involved by providing user feedback

The role of a user panelist is to participate in interviews or group discussions to test products. Panelists should expect to—

- Receive samples of draft information products/decision tools in either print or electronic version to read, or attend a session where Eisenberg Center associates can observe the panelists’ interaction with the information product/decision tool to understand their initial interaction process with these products.
- Answer specific questions about their interaction with the guides as they experience them.
- Provide honest feedback and suggestions on making the guides more understandable or useful.
- Provide informed consent of their participation following a full disclosure of possible risks and benefits of participating in the interview.
- Receive compensation for their time spent in conversation.
- Have their names and contact information shared with the EHC Program for potential consultation on future work, unless otherwise requested.

Dissemination

Having stakeholders distribute and talk about EHC Program research products and summary guides, model their use, and report outcomes from the use is critical to maximizing the understanding of how the work of the EHC Program improves the quality of health care decisionmaking. AHRQ and the Eisenberg Center employ a variety of strategies to disseminate products, including distribution of resources through consumer and professional organizations, societies, and associations, and through databases such as the National Library of Medicine and electronic clinical decision support services (see Box 14).

Box 14. Get involved in product dissemination

Stakeholders can get involved in dissemination by—

- Distributing products to their organization's members or clients.
- Sharing information about the EHC Program and its products in their organization's newsletters or other communication.
- Participating in efforts to measure the use and impact of the products, programs, or policies derived from EHC reports.
- Linking to the EHC Web site and/or the EHC products.
- Making presentations to their organization or other audiences regarding the EHC Program or any of its products, including successes they have had from using them.

To obtain EHC products or tools, visit the Web site at www.effectivehealthcare.ahrq.gov or request copies by calling 1-800-358-9295.

Chapter 4. Using Research

AHRQ's research products are used by Federal and State agencies, patients, caregivers, clinicians, professional associations, consumer organizations, health delivery systems, payers, policymakers, and others committed to evidence-based health care. AHRQ research products provide health care decisionmakers the best available scientific evidence without making specific recommendations or evaluating cost.

EHC Program research products can be used in myriad ways. For example—

- Patients may use consumer summary guides to evaluate health care options, initiate discussions with their health care providers, and be actively involved in their health care decisions.
- Public and private-sector organizations may use research reviews as a basis for developing clinical practice guidelines, performance measures, educational materials, and quality or operational improvement tools.
- Clinicians may use research reviews or clinician summary guides to evaluate health care options, initiate discussions with their patients, and deliver high-quality evidence-based care.
- Clinicians may provide consumer summary guides to patients to help explain health care options or reinforce health messages.
- Payers and insurers may use research reviews or policymaker summary guides to inform benefit and coverage decisions.
- Professional societies may use research reviews to develop professional guidelines.
- Policymakers may use summary guides to design evidence-based policies that improve access to high-quality care.
- Health care organizations may use research reviews or summary guides to develop and implement clinical decision support tools or other evidence-based practice tools.
- Academic medical centers and universities may use EHC products to develop academic or continuing education curriculums.

Appendix A. Standardized Selection Criteria for Topics

Appropriateness

- Represents a health care drug, intervention, device, or technology available (or soon to be available) in the United States.
- Relevant to Medicare, Medicaid, CHIP, and other Federal health care programs.

Importance

- Represents a significant disease burden; affects a large proportion of the population or a priority population (e.g., children, elderly adults, low-income, rural/inner city, minorities, or other individuals with special health care or access issues).
- Is of high public interest; affects health care decisionmaking, outcomes, or costs for a large proportion of the U.S. population or for a priority population in particular.
- Was nominated/strongly supported by one or more stakeholder groups.
- Represents important uncertainty for decisionmakers.
- Incorporates issues surrounding both clinical benefits and potential clinical harms.
- Represents important variation in clinical care or controversy in what constitutes appropriate clinical care.
- Represents high costs due to common use, high unit costs, or high associated costs to consumers, patients, health care systems, or payers.

Duplication

- Avoids potential for redundancy (i.e., is not already covered by an available or soon-to-be available high-quality systematic review by AHRQ or others).

Feasibility

- Effectively utilizes existing research and knowledge by considering—
 - Adequacy (type and volume) of research for conducting a systematic review.
 - Newly available evidence (particularly for updates or new technologies).

Potential Value

- Has potential for significant health impact:
 - To improve health outcomes.
 - To reduce significant variation in clinical practices known to be related to quality of care.

- To reduce unnecessary burden on those with health care problems.
- Has potential for significant economic impact:
 - To reduce unnecessary or excessive costs.
- Has potential for change:
 - The proposed topic exists within a clinical, consumer, or policymaking context that is amenable to evidence-based change.
 - A product from the EHC Program could be an appropriate vehicle for change.
- Has potential risk from inaction:
 - Unintended harms from lack of prioritization of a nominated topic.
- Addresses inequities and vulnerable populations (including issues for patient subgroups).
- Addresses a topic that has clear implications for resolving important dilemmas in health and health care decisions made by one or more stakeholder groups.

Appendix B. Suggesting a Topic for Effective Health Care Research

The EHC Program researches available health care tests and treatments to determine whether there are significant advantages or disadvantages with different approaches. The results of this research can help people make better decisions about what health care they want to have, and can help clinicians and health care purchasers to focus on the best tests and treatments.

The process of identifying, selecting, and developing important research topics for research reviews or new research is a key aspect of the EHC Program. The process is enhanced by strong involvement of stakeholders, maintaining transparency and public accountability, and striving for continuous self-evaluation and improvement. The program uses an established set of criteria to guide the process of topic selection (www.effectivehealthcare.ahrq.gov/index.cfm/submit-a-suggestion-for-research/how-are-research-topics-chosen).

We would like to understand important aspects of the health care service you are interested in, including to whom it applies, what benefits or harms are of greatest interest, and the other health care services or tests with which you think it should be compared. **Your answers to the questions as part of the topic nomination process will help us phrase your suggestion as one or more research questions that could be answered through AHRQ EHC products.**

Nominate a Topic

To nominate a topic for research in the EHC Program, please complete the online form at www.effectivehealthcare.ahrq.gov/index.cfm/submit-a-suggestion-for-research and click on “submit” at the end. If you prefer to submit a paper copy, instructions are available at the same Web site. If you have any supporting documents you would like to include with your nomination, you can include them (if mailing), send them as additional attachments (if emailing), or upload them while submitting the online form.

View Topics Nominated by Others

All topic nominations, including those submitted on paper, will appear in the Read Suggested Topics for Research section (www.effectivehealthcare.ahrq.gov/index.cfm/submit-a-suggestion-for-research/read-suggested-topics-for-research).

Appendix C. Research Questions and PICO(TS)

Systematic reviews are a type of research review that synthesizes the available scientific evidence on the comparative effectiveness, benefits, and harms for a variety of diagnostic, treatment, and health care delivery decisions. They provide syntheses of relevant evidence to inform real-world health care decisions for consumers, clinicians, and policymakers.

Systematic reviews are designed to answer a set of questions. The questions may be about how different tests or treatments work, or how they compare with one another. These Key Questions direct the researchers on what to look for in the evidence. Key questions help to ensure that the research stays focused on the findings that consumers, clinicians, and health care policymakers need to make good decisions.

For example, investigators studying the evidence about different treatments available for people with acid reflux disease will engage a team of patients, clinical experts, researchers, and others to think through the important issues for people with this condition. The team then develops a list of questions that are most relevant to consumers, clinicians, and policymakers. They will make sure the questions reflect as many of the available treatments for acid reflux disease as possible, the benefits of these treatments for different groups of people, and the possible side effects of each treatment for different groups of people.

Typically these questions are generated during the topic refinement process. However, Key Questions can be suggested as part of a topic nomination. Key Questions generally use a patient, intervention, comparison, outcomes (treatment and setting) [PICO(TS)] format to maximize the usefulness of the final report. Public comment on a set of draft Key Questions helps researchers continue to think about what is most important to ask so that the research report can be as useful as possible. PICO(TS) stands for the following:

Patient, Population, or Problem: The “P” in PICO(TS) is a description of the patient(s) of interest. It includes the condition(s), populations or subpopulations, disease severity or stage, comorbidities, and other patient characteristics or demographics.

Intervention or Exposure: The “I” in PICO(TS) refers to the specific treatments or approaches with the patient or population. It includes dose, frequency, method of administering treatments, and so on.

Comparison: The “C” in PICO(TS) describes what is being compared with the intervention. It includes alternatives such as placebo, drugs, surgery, and lifestyle changes.

Outcome: The “O” in PICO(TS) describes the specific results of interest. It refers to short, intermediate, and long-term outcomes, and includes specific areas such as quality of life, complications, mortality, and morbidity.

Timing (If Applicable): The “T” in PICO(TS) describes the duration of time that is of interest for the particular patient outcome, benefit, or harm to occur (or not occur).

Setting (If Applicable): The “S” in PICO(TS) describes the setting or context of interest. Setting can be a location (such as primary, specialty, or inpatient care) or health policy that frames or restricts the important questions to be answered.

The carefully drafted questions for a systematic review are strengthened by incorporating stakeholders and end-users in their development. For example, patients can offer specific and important insights about the benefits and harms of a treatment or drug. Clinicians or policymakers can describe real-world treatment and coverage dilemmas that the review may help to resolve. These points of view are invaluable in the early phases of research and help ensure that the final products are relevant and useful.

When developing Key Questions, investigators use the PICO(TS) approach described above, as well as the involvement of stakeholders, to help them identify three to five specific well-defined questions. A strong question is one that helps guide the research and can be addressed by a review of the evidence. Questions inappropriate for systematic reviews include those that involve clinical judgment, seek recommendations for an individual patient, are vague or limited to a single procedure, or ask about general approaches to treatment.

The examples in Figure C-1 are listed to illustrate the difference between questions that are considered “strong” or “weak” in their appropriateness for systematic reviews. Examples are listed for clinical questions, as well as for the organization and delivery of health care.

Figure C-1. Guidance for Key Questions

✓ **Use questions that ask about indications for multiple procedures**

Weak	What are the appropriate indications for arthroscopic surgery?
Strong	Does arthroscopic surgery improve [certain outcomes] for [certain types of] patients?
Strong	For what types of patients is there strong evidence that arthroscopic surgery improves [certain outcomes]?

✓ **Ask questions that are specific about effectiveness and evidence**

Weak	Can [test Y] be used as a screening for hypertension?
Strong	How effective is [test Y] as a screening for hypertension?

✓ **Be specific about the aspect of health care that is of interest**

Weak	What are the effects on health care of defined-contribution models?
Strong	How does the utilization of previously covered health care services change when employers offer defined-contribution models to their employees?

✓ **Ask questions that are specific to reviewing available evidence**

Weak	Should patients with severe mental illness be placed in community-based care or treated in inpatient settings?
Strong	What is the evidence that placing patients with severe mental illness in community-based care yields the same or better access, effectiveness [on certain outcomes], and costs compared with placement in inpatient treatment settings?

✓ **Ask questions that will provide a basis for determining relative performance**

Weak	Do high-volume hospitals provide superior cardiac care?
Strong	Are physicians practicing at academic medical centers or hospitals designated as “centers of excellence” for cardiac care more likely than those at other acute care hospitals to provide beta blockers to patients who have had heart attacks?

Appendix D. Guide for Key Informants

Evidence-based Practice Center

Evidence-based Practice Centers (EPCs) are the research centers that the AHRQ EHC Program contracts with to conduct the research. One or more investigators from the EPC participate in the Key Informant calls. The EPC schedules and facilitates the call(s), develops the agenda, takes and distributes meeting minutes, and incorporates input from the Key Informants to develop the clear, precise draft Key Questions that will be posted on the Web for public comment. They also develop the analytic framework that guides the research.

Key Informant

Approximately six to nine Key Informants—patients and caregivers, policymakers, practicing clinicians, relevant professional and consumer organizations, purchasers of health care, and others with experience relevant to the topic—are identified to participate in the call(s). The role of the Key Informant group is to provide feedback on the preliminary research questions. These questions should address the issues most important to patients, caregivers, clinicians, potential guideline developers, policymakers, and other stakeholders. The input of Key Informants is used to develop Key Questions that guide a systematic review on a particular topic. Individual Key Informants are selected because they represent a particular perspective (e.g., patient, clinician, guideline developer). Key Informants are asked to represent this particular perspective throughout the topic refinement process in order to ensure a broad range of input.

AHRQ Task Order Officer

The Task Order Officer (TOO) is assigned to the topic by AHRQ and participates in all topic refinement calls. The role of the TOO is to oversee the work assignment, process, and products. The TOO is available to answer process questions and provide input regarding topic scope and definition.

John M. Eisenberg Clinical Decisions and Communications Science Center

The Eisenberg Center uses the systematic reviews to develop plain-language summary guides for clinicians, consumers, and policymakers. At least one Eisenberg Center representative participates in the Key Informant call(s). The Eisenberg Center representative(s) may provide input regarding topic scope and definition, as well as other aspects of topic refinement that may relate to the development of the final translational documents. The involvement of the Eisenberg Center at the topic refinement stage is intended to firmly connect the final translational documents with the initial topic refinement process. This enhances the utility of the translational products and increases alignment between nominator intent, actual research, and final translational products.

Scientific Resource Center

The Scientific Resource Center provides methodological guidance to the EPCs and conducts the initial nomination development and selection process.

Appendix E. Comparative Effectiveness Overview for Key Informants

Definition

Systematic reviews are summaries of available scientific evidence in which investigators collect, evaluate, and synthesize existing research. They use organized, structured, explicit, and transparent methodology to conduct this work. Systematic reviews are designed to provide decisionmakers with accurate, independent, scientifically rigorous information for comparing the effectiveness and safety of various health care options. Systematic reviews have become a foundation for decisionmaking in clinical practice and health policy. To play this important role in decisionmaking, they must address questions that are relevant to patients and clinicians.

Analytic Frameworks and Key Questions

Analytic frameworks are used to describe the clinical concepts and logic underlying beliefs about how interventions may improve health outcomes. Figure E-1 depicts an analytic framework for evaluating studies of a new enteral supplement to heal bedsores. There is a Key Question (KQ1, KQ2, KQ3, or KQ4) associated with each of the arrows in the analytic framework. An analytic framework helps to—

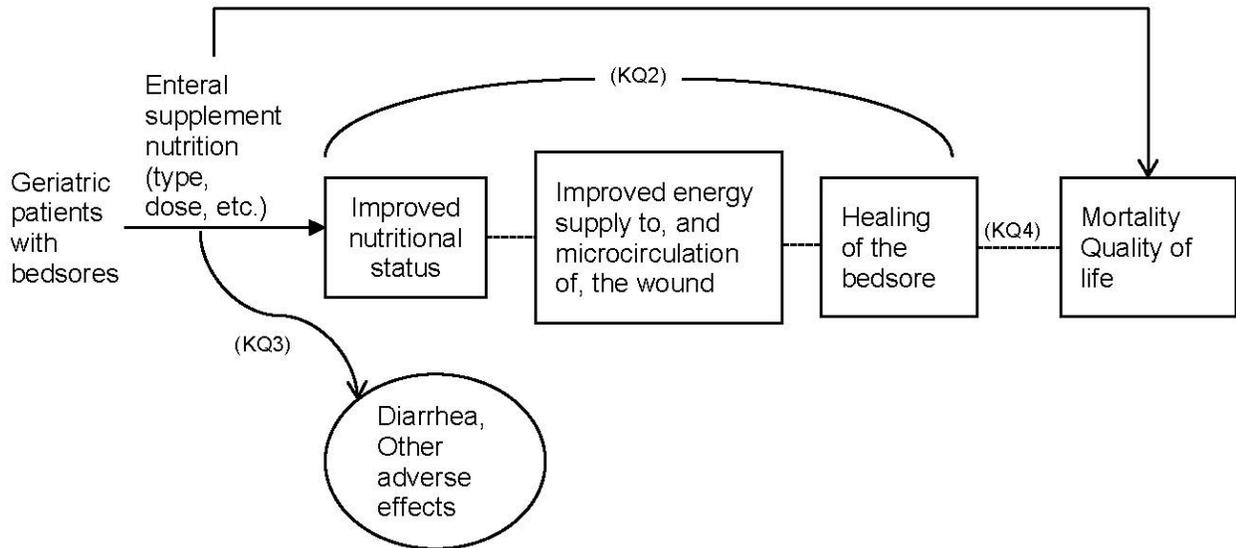
- Clarify assumptions about benefits from health care interventions, including long-term effects on quality of life, illness, and mortality
- Be explicit about the reasoning behind clinical theories that link intermediate outcomes with outcomes of interest to patients, clinicians, and other health care decisionmakers
- Understand the context in which clinical decisions are made and illuminate any disagreements about logic

When available, evidence that directly links interventions to the most important health outcomes is more influential than evidence from other sources. (See KQ1 of Figure E-1.) Input from Key Informants assists with identifying and clarifying the important intermediate and long-term outcomes and the KQs that relate to those outcomes.

The KQs in the following analytic framework (Figure E-1) are—

- | | |
|------|---|
| KQ1: | Does enteral supplementation improve mortality and quality of life? |
| KQ2: | Does enteral supplementation improve wound healing? |
| KQ3: | How frequent and severe are side effects such as diarrhea? |
| KQ4: | Is wound healing associated with improved survival and quality of life? |

Figure E-1. Analytic framework for a new enteral supplement to heal bedsores
(KQ1)



More Information

For more information about comparative effectiveness or the Effective Health Care Program, please visit the Web site at www.effectivehealthcare.ahrq.gov.

A useful glossary of terms used in comparative effectiveness research/patient-centered outcomes research is available on the EHC Web site. Please go to www.effectivehealthcare.ahrq.gov/index.cfm/glossary-of-terms/ to access the glossary.