2011

The Effective Health Care Program Stakeholder Guide

AHRQ Effective Health Care Program

Stakeholder Guide

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Introduction

The extraordinary pace of medical innovation over the past few decades has created unprecedented opportunities to improve health care and health outcomes. To realize these opportunities, however, everyone with a stake in the health system—from patients to clinicians to policymakers—needs to have accurate, reliable, and accessible information on the diagnostic and treatment choices confronting them.

The Agency for Healthcare Research and Quality (AHRQ) is internationally recognized as a source of independent, high-quality scientific information, and as a leader in evidence-based medicine. In 2005 AHRQ launched the Effective Health Care (EHC) Program, a ground-breaking Federal initiative that compares the effectiveness of different health care interventions and services and translates research findings into practical decisionmaking guides for consumers, clinicians, and policymakers.

One of the unique aspects of the EHC Program is the involvement of a diverse range of stakeholders throughout the research process to ensure relevancy and transparency. Collaboration with a broad range of health care stakeholders is a cornerstone of AHRQ's research. AHRQ firmly believes that involving all stakeholders in the research enterprise from the beginning improves the end product and facilitates the diffusion and implementation of the findings by ensuring that the research findings reflect the various needs of all diverse users, are relevant to their unique challenges, and are applicable in real-world situations.

AHRQ defines a "stakeholder" as persons or groups who have a vested interest in the clinical decision and the evidence that supports that decision. Each has a unique and valuable perspective. EHC program stakeholders include:

- Patients, caregivers, and patient advocacy organizations
- Clinicians and their professional associations
- Institutional health care providers, such as hospital systems and medical clinics
- Government agencies
- Purchasers and payers, such as employers and public and private insurers
- Health care industry representatives
- Health care policymakers at the Federal, State and local levels
- Health care researchers and research institutions

This Guide is intended to facilitate stakeholder involvement in AHRQ's Effective Health Care Program research. The Guide reviews the purpose and the structure of AHRQ's EHC Program, outlines EHC Program activities, and describes opportunities for participation, which include nominating topics, refining key research questions, participating on technical expert panels to provide advice on research methodology, identifying priorities for future research, commenting on draft reports, helping translate research reports into decisionmaking guides, and dissemination of results. It may also be useful for anyone who is interested in using AHRQ reports and wants a better understanding of the research conducted by the EHC Program.

Get Involved!

- Nominate research topics.
- Comment on draft key questions before research has begun.
- Provide expert input or scientific information to inform a report. This includes a patient's experiential expertise.
- Comment on draft Research Reports and Comparative Effectiveness Reviews.
- Provide input on translation products.
- Disseminate research products.
- Participate in a listening session to provide focused comments on issues important to the EHC program, such as research topics, program structure, and scientific methods.
- Participate on the EHC Stakeholder Group to provide different perspectives on the Effective Health Care program.

Chapter 1

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

The Agency for Healthcare Research and Quality

The Agency for Healthcare Research and Quality (AHRQ) is a Federal agency under the United States 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 sponsored, conducted, and disseminated by AHRQ 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 from Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 that 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 communicate its findings widely to a variety of audiences. The Effective Health Care (EHC) program is the nation's first coordinated program of "***comparative effectiveness***" research. 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 what 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. Comparative effectiveness research seeks to overcome these limitations by gathering and analyzing the evidence from multiple sources on

What is comparative effectiveness research?

Comparative effectiveness research is designed to inform health-care decisions by providing evidence on the effectiveness, benefits, and harms of different treatment options. The evidence is generated from research studies that compare drugs, medical devices, tests, surgeries, or ways to deliver health care.

Learn more at www.effectivehealthcare.ahrq.gov

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 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.

EHC Research Priorities

The EHC program sets research priorities based on input from diverse stakeholders. All suggestions for research are carefully considered according to a standard set of criteria. Priority is given to research topics that focus on certain medical conditions. The current medical conditions given priority for research are:

- Arthritis and non-traumatic joint disorders
- Functional limitations and disability
- Cancer
- Infectious diseases including HIV/AIDS
- Cardiovascular disease, including stroke and hypertension
- Obesity
- Dementia, including Alzheimer's Disease
- Peptic ulcer disease and dyspepsia
- Depression and other mental health disorders
- Pregnancy including preterm birth
- Developmental delays, ADHD and autism
- Pulmonary disease/asthma
- Diabetes mellitus
- Substance abuse

These priority topics relate to health care products or services that (1) impose high costs on the Medicare, Medicaid, or Children's Health Insurance Program (CHIP); (2) may be over- or underutilized; (3) may significantly improve the prevention, treatment, or cure of diseases and conditions which impose high direct or indirect costs on patients or society; and (4) place a great burden on people, especially those who are "priority populations" as identified by AHRQ, including

- Low-income groups
- Minority groups
- Women
- Children
- The elderly
- Individuals with special health care needs, such as individuals with disabilities, in need of chronic or end-of-life care, or living in inner-city or rural areas

Getting the Work Done

The EHC Program achieves its goals by awarding grants and contracts to research centers and clinical investigators to conduct timely and relevant comparative effectiveness research. The program also supports the dissemination and implementation of the research findings.

Key players in the EHC Program include:

- The **Evidence-based Practice Centers (EPCs)** perform in depth reviews of existing evidence
- The **DEcIDE (Developing Evidence to Inform Decisions about Effectiveness) Research Network** generates new data on specific treatments and health care services
- The **Centers for Education & Research on Therapeutics (CERTs) conduct research and educate clinicians** and consumers about drugs, biologicals, and medical devices
- The **Scientific Resource Center provides scientific support** for the Effective Health Care Program
- The **John M. Eisenberg Center for Clinical Decisions and Communications Science organizes** the research results into guides and tools that are useful to clinicians, health care policymakers, and patients
- Individual investigators and their research groups at academic institutions and other research centers generate new evidence from original research in response to AHRQ grant opportunities.

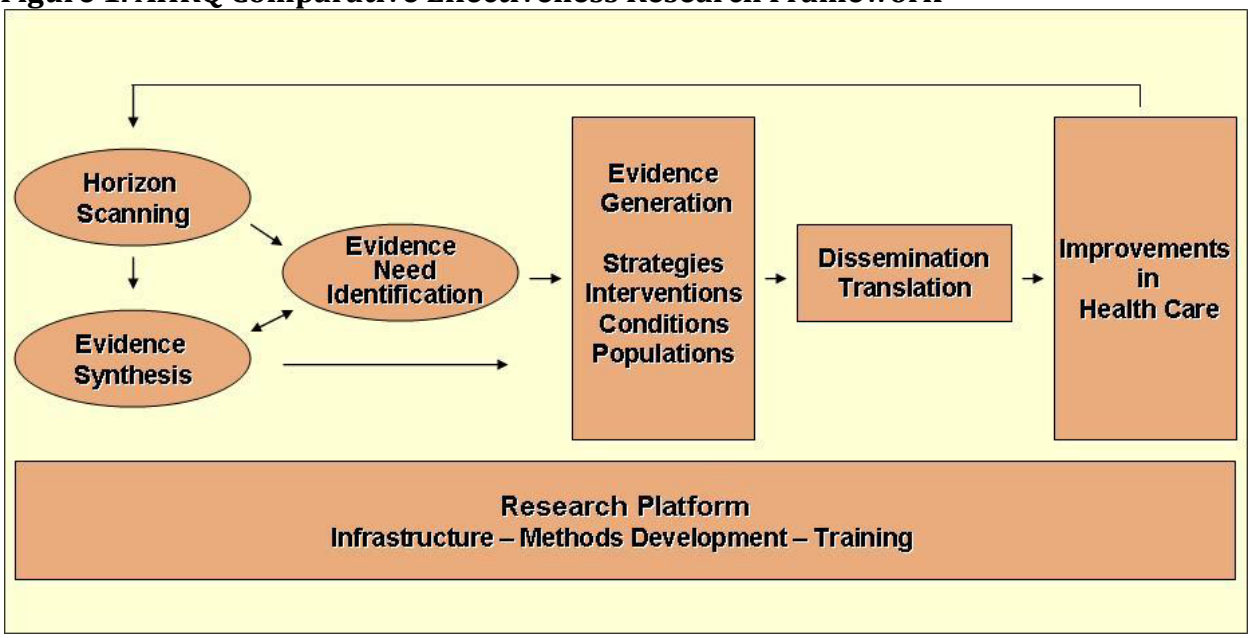
For more information about each of the EHC Program components, visit the Effective Health Care Web site at http://www.effectivehealthcare.ahrq.gov/index.cfm/who-is-involved-in-the-effective-health-care-program1/.

Chapter 2

Effective Health Care Program Activities

Core activities contribute to the conduct of comparative effectiveness research through the Effective Health Care Program and to the continuing development of an infrastructure to sustain and advance these efforts. These activities make up the integrated components of a national comparative effectiveness program in the United States—the first coordinated comparative effectiveness clinical studies program in our nation's history (See Figure 1).

Figure 1. AHRQ Comparative Effectiveness Research Framework



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 here.

Horizon Scanning

Some of the richest topics for comparative effectiveness research will likely be found at the frontier of new therapies that hold great promise but entail uncertain benefits and risks. Therefore AHRQ is in the process of establishing a horizon scanning program which is expected to begin operations in the fall of 2010. EHC researchers will scan the horizon to track emerging clinical interventions and investigate how these new interventions are likely to fit into current care pathways. These include important issues such as costs, possible risks, factors that may affect outcomes, and the availability of appropriate facilities and training.

Evidence Need Identification

Identification of evidence needs is a central, recurring activity that drives research and dissemination throughout the Effective Health Care Program. In order to gain the widest

perspective into what questions need to be answered, all stakeholders are encouraged to identify and suggest topics for research, including consumers, clinicians, policymakers, and other decisionmakers. (See Appendix C.) Research suggestions from all sources and all topic nominations are posted on the EHC Program Web site at http://effectivehealthcare.ahrq.gov. These suggestions are reviewed by AHRQ staff, based on a series of questions:

- How widespread and serious is the disease or problem proposed for study?
- What are the costs associated with the disease and available treatments?
- 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 and rural areas?

Evidence needs are also identified through issue forums, where stakeholders are brought together to discuss specific clinical areas and identify the most pressing questions of evidence. Finally, both evidence synthesis and evidence generation reports (described below) identify future research needs as part of the research process. In the case of Comparative Effectiveness 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 produces two types of evidence synthesis reports, Comparative Effectiveness Reviews (CERs) and Technical Briefs, depending on the nature and amount of evidence available for synthesis:

Comparative Effectiveness Reviews

Comparative Effectiveness Reviews are summaries of available scientific evidence that compare the benefits and harms of treatment options. CERs are designed to provide decisionmakers with accurate, independent, scientifically rigorous information for comparing the effectiveness and safety of various health care options. CERs 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 updates CERs 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. Technical briefs generally focus on interventions for which there is limited published information, or too few studies to support definitive conclusions. The 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 informational needs.

All evidence synthesis reports are produced by the Evidence-based Practice Centers (EPCs). For more information on the EPCs, see the AHRQ Web site at http://www.ahrq.gov/clinic/epc/ or the EHC site at http://www.effectivehealthcare.ahrq.gov/index.cfm/who-is-involved-in-the-effective-health-care-program1/about-evidence-based-practice-centers-epcs/.

Evidence Generation

If there is not enough evidence to answer an important question, the Effective Health Care Program may sponsor new research. Original research reports are based on clinical research and studies that use health care databases and other scientific resources and approaches to explore practical questions about the effectiveness and safety of treatments. The reports are derived from studies of actual patients in clinical settings and are based on scientific methodologies. New research reports can focus on the comparative effectiveness, appropriateness, safety, and/or outcomes of health care services or treatments. They are produced by AHRQ grantees and researchers in the DEcIDE (Developing Evidence to Inform Decisions about Effectiveness) Network and the Centers for Education & Research on Therapeutics (CERTs).

The DEcIDE Network is comprised of research-based health organizations located throughout the U.S. with access to electronic health information databases and the capacity to conduct rapid turnaround research. DEcIDE research focuses on the outcomes, comparative clinical effectiveness, safety, and appropriateness of health care items and services, particularly prescription medications and medical devices. The CERTs program is comprised of research centers, each focusing on broad therapeutic themes relating to the optimal use of drugs, biologics, and medical devices. CERTs generally focus on areas where comparative information about the risks, benefits, and interactions of new and older treatments is limited. In addition, AHRQ has begun to invest significantly in investigator-initiated research through grant mechanisms. More information about ongoing grants and grant opportunities may be found at http://www.effectivehealthcare.ahrq.gov/index.cfm/comparative-effectiveness-research-grant-and-arra-awards/.

All research reports are available on the AHRQ Effective Health Care Program 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 the evaluation of 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.
- Trade-offs 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 lessons and examinations, slide sets for use by medical faculty, and electronic decision aids for clinicians and patients/consumers. Podcasts will also be developed to facilitate Web dissemination of EHC information. AHRQ also supports investigator-initiated efforts in translation and dissemination of EHC program 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 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. 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 review, retrospective studies, and clinical trials in comparative effectiveness research, and to develop data sources and other aspects of the research infrastructure.

Stakeholder Input and Involvement

The Effective Health Care Program gathers stakeholder input through the Stakeholder Group and the Citizen's Forum.

The Stakeholder Group

The EHC Stakeholder Group provides input to improve program quality and impact among users. This volunteer panel, which has included consumers, practicing clinicians, researchers, policymakers, industry representatives, private and public health care purchasers, and other health care leaders, brings unique experiences and perspectives to the table. The Stakeholder Group provides feedback on concerns such as program transparency, quality improvement of products and processes, types of products that will be most useful to health care decisionmakers, dissemination and implementation issues for EHC Program findings, and report content.

Citizens' Forum

The Citizens' Forum is an initiative funded by the American Recovery and Reinvestment Act (ARRA) to expand and systematize citizen and stakeholder engagement in AHRQ's comparative effectiveness research initiative (award anticipated in July/August 2010). The Citizens' Forum will develop and demonstrate deliberative methods and tools for obtaining informed public opinion as an input to decisions related to the conduct of comparative effectiveness research, as well as the application of research results in policy and practice.

As part of its activities, the Citizens' Forum will provide support for the Effective Health Care (EHC) Program Stakeholder Group, consistent with Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), which mandates broad and ongoing consultation with relevant stakeholders in AHRQ's comparative effectiveness research program. The Citizens' Forum will facilitate Stakeholder Group meetings, manage logistical requirements, improve methods and opportunities for stakeholder engagement, and work with the EHC program components to expand stakeholder involvement in EHC research processes and activities.

Stakeholder Involvement in Research

In addition to the formal involvement of stakeholders described above, the Effective Health Care Program offers many opportunities for stakeholders to get involved at all stages in the research process. This helps ensure that the program responds to the issues that are most pressing for health care decisionmakers and in ways that are accessible and useful. This is the subject of the next chapter.

Chapter 3

Getting Involved in the Research Process

The Agency for Healthcare Research and Quality (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 involved stakeholders 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, and then 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 Is a Stakeholder and Why Are Their Views Important?

AHRQ has defined a "stakeholder" as persons or groups who have a vested interest in the 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.

Stakeholders	**Stakeholders' Perspectives**
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 kind of presentation of research results is easiest to understand and act upon?
Clinicians and clinical professional societies	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?

Stakeholders	Stakeholders' Perspectives
Institutional health care providers, such as hospital systems and medical clinics	Many health care decisions are structured by the choices of institutional health care providers, and institutional health care providers often have a broader view of what is causing problems. What information would support better decisions at an institutional level to improve health outcomes?
Government agencies	The responsibility for the nation's health care is shared across several agencies. What research is or could be funded?
Purchasers of health care, 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 make the decision of what to pay for difficult? Where is new technology or new uses of technology raising questions about what is standard of care?
Health care industry representatives	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 on what works well and what doesn't. Comparative effectiveness 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.

Opportunities for Involvement

A. Evidence Need Identification

Identifying a need for evidence is the beginning of any comparative effectiveness 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 though 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. Nominations can be submitted by anyone using the Web site (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.

Get Involved as a Nominator

Any individual or organization can nominate a topic at any time using the EHC Program Web site: www.effectivehealthcare.ahrq.gov. Nominations may be submitted anonymously, although if the nominator includes contact information, an EHC Program representative may follow-up with the nominator if there is a need to clarify or further develop the nomination.

The nomination process typically takes 3-4 months. The nominator is asked to:

- Describe three to five specific, well-defined questions related to the topic of interest (see Appendix D 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.
  - Include any supporting documentation with the nomination by mail or email, or by uploading electronically through the website nomination form.
- Be available to answer questions or further clarify the nomination, if needed. This is known as "topic development." Clinical or other experts may also be consulted during this process.
- Consider serving in other roles if the topic goes forward for research (described below).

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 the context of the nomination is accurately considered. This process of clarification is known as "topic development," and is conducted by one of the Evidence-based Practice Centers

(EPCs). Once the topic nomination is fully "developed," it is discussed by the AHRQ Topic Selection Committee which decides whether the nominated topic is appropriate for an evidence synthesis, should be considered for evidence generation, or whether it will not be pursued at this time based on of the following questions:

- How widespread and serious is the disease or problem proposed for study?
- What are the costs associated with the disease and available treatments?
- 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)?

An explanation of the Topic Selection Committee's decision is provided to the nominator and posted on the EHC Program Web site at effectivehealthcare@ahrq.gov. Anyone can check the status of a nomination at any time on the EHC Program Web site.

B. Evidence Synthesis

The Effective Health Care Program produces two types of evidence synthesis reports: Comparative Effectiveness Reviews and Technical Briefs. Both have opportunities for Stakeholder involvement, although each report follows a slightly different process as described below.

Comparative Effectiveness Reviews

Topic Refinement

If a nominated topic has been selected to move forward as a Comparative Effectiveness Review, AHRQ will assign the topic to one of the Evidence-based Practice Centers (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:

Kick-Off Call

Once an EPC is assigned a topic for refinement, a kick-off call is scheduled for key staff from the EPC, AHRQ, Eisenberg Center, and the Scientific Resource Center (SRC) to organize and discuss the research plan. The kick-off call is facilitated by the EPC with guidance from a staff person assigned by AHRQ. This staff person is known as a "Task Order Officer" (TOO). The kick-off call is intended to help develop a common understanding of the task at hand, as well as 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 Comparative Effectiveness Review are formulated and refined with the help of **key**

informants to ensure research addresses the questions important to decisionmakers, represents an accurate scope of issues, and produces the most valuable product. **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 that 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. There may be one or several calls held. The *Guide for Key Informants*, including roles and responsibilities, and what to expect is included in Appendix E.

Get Involved as a Key Informant

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 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, 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 forms. (Conflict of Interest policy is available at Appendix F.)
- 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 PICO(TS) format. For more information on formulating questions using a PICO(TS) please see Appendix D.
- Have their names and contact information shared with the Effective Health Care 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 Effective Health Care 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 Effective Health Care Program at (301) 427-1502 or 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 Program Web site for public comment. The final key research questions, along with an analytic framework and research abstract, will guide the research process.

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 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 the broadest possible relevancy of the research report.

The Public Comment period lasts for 4 weeks. Anyone who wishes to comment on the Key Questions should expect to:

- Post their comments through the Web site within 4 weeks at http://effectivehealthcare.ahrq.gov/index.cfm/research-available-for-comment/.
- Have their names and contact information shared with the Effective Health Care Program for potential consultation on future work unless otherwise requested.

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

Research Review

Developing a Comparative Effectiveness Review involves systematically 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 development 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 of developing a research report, however, 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 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 as it is completed. **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.

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 forms (Conflict of Interest policy available at Appendix F).
- 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 Effective Health Care Program for potential consultation on future work, unless otherwise requested.

Peer and Public Review

Once a draft of the research review has been completed by the EPC, a peer review panel is assembled to provide additional and technical review of the report. The peer review process is coordinated through the Scientific Resource Center.

Get Involved in the Peer Review Process

Research products undergo a peer review process to ensure 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 SRC for potential consultation on future work unless otherwise requested.

The draft report undergoing peer review is posted simultaneously on the EHC Program 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 Program website (www.effectivehealthcare.ahrq.gov) and click "Join the E-mail List" in the lower left corner.

Get Involved by Providing Public Comments on the Draft Report

Anyone may comment on draft report, and the assigned EPC will consider incorporating feedback in the final key questions. 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 the broadest possible relevancy of the research report. Anyone who wishes to comment on the Key Questions should expect to:

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

You can sign up at http://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 public comments can take up to three months. The final report is then posted on the EHC Program 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.

The Agency for Healthcare Research and Quality supports and is committed to the transparency of its review processes. Therefore, the following are posted on the EHC Program Web site within 3 months after a final report is posted: (1) all comments received from the public, and (2) all the responses made by the authors of a draft report to the public comments (i.e., the "disposition of comments"). Each comment will be 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. Contact information will be used to communicate with commentators if there are questions about submitted comments.

Research Needs Development

The development of a research needs document is a relatively new phase for the Effective Health Care Program. The research needs document will be produced by the EPC preparing the main research report. After completing a research review, including identification of evidence gaps, the EPC will convene a group of stakeholders, including investigators, funders, and others to prioritize future research needs as they relate to the research topic. The results of these discussions and prioritization will be summarized in a separate research needs document.

Get Involved Identifying Needed Research

As this process is new, methods of involving stakeholders in the development of the research needs document are being tested. Research institutions will 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.

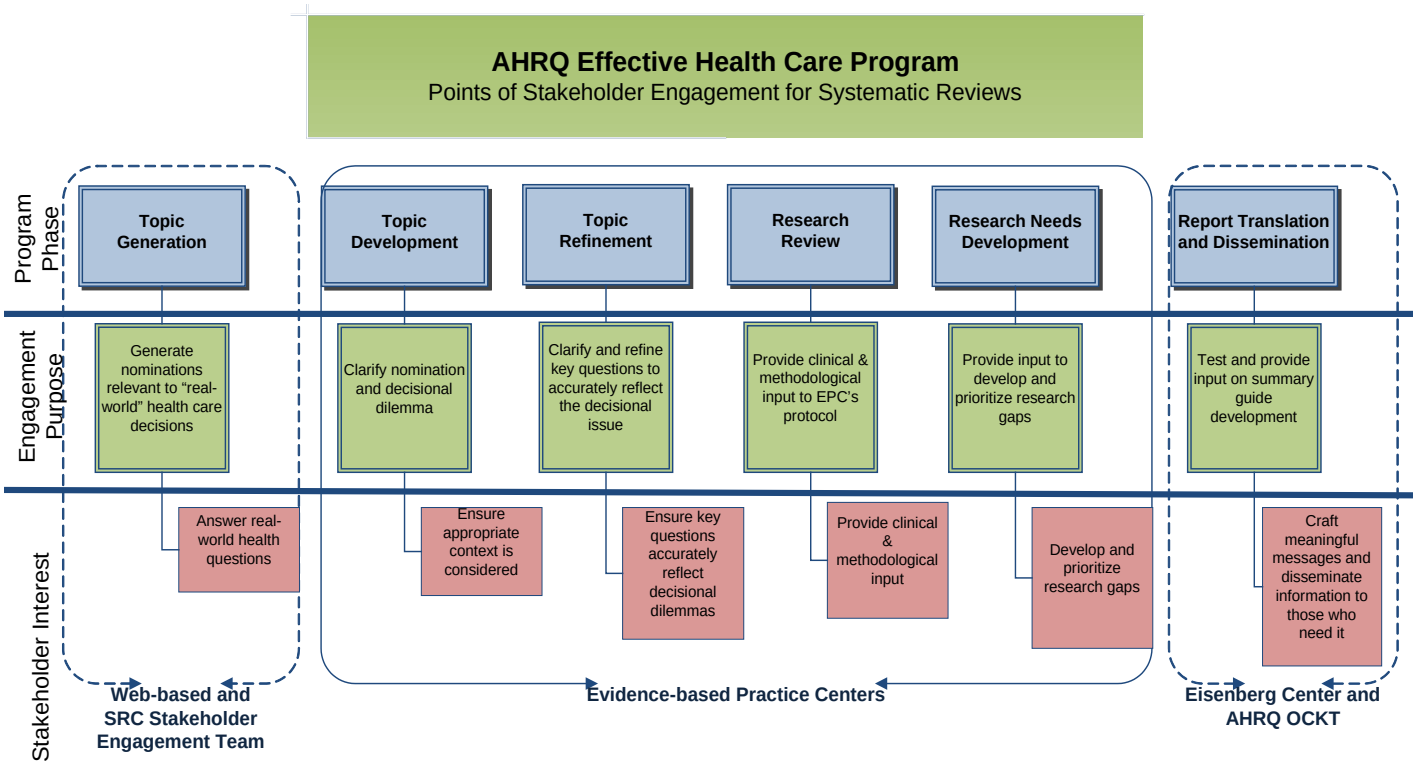
Stakeholders involved in identifying research needs should expect to:

- 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 identified in the systemic research reviews between available medical knowledge and the needs of clinical practice. 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 comparative effectiveness 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 like 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.

Figure 2. Points of Stakeholder Engagement for Systematic Reviews



Technical Briefs

Technical Briefs are rapid reviews of what is known about a specific medical intervention rather than comprehensive evaluations and therefore do not undergo Topic Refinement but proceed directly from the Kick-off call to the Research Review. Because one of the objectives of Technical Briefs is to identify future research needs, the Technical Brief process does not include the production of a separate Future Research Needs document.

Research Review

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 interviews with subject 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.

Get Involved as a Key Informant

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 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, calls with subsets of the identified key informants, or use other methods for soliciting input from key informants.

The research phase of a Technical Brief is expected to take 4 months. **Key informants** should expect to:

- Submit a completed Disclosure of Interest forms.
- Submit a brief description of their experience with the topic.
- Participate in at least one phone call with the EPC, either individually or with 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.
- Have their names and contact information shared with the Scientific Resource Center 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 Effective Health Care 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 Effective Health Care Program at (301) 427-1502 or EffectiveHealthCare@ahrq.hhs.gov.

Peer and Public Review

Once a draft of the research review has been completed by the EPC, a peer review panel is assembled to provide additional and technical review of the report. The peer review process is coordinated through the Scientific Resource Center.

Get Involved in the Peer Review Process

Research products undergo a peer review process to ensure 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 Effective Health Care Program for potential consultation on future work unless otherwise requested.

Simultaneous with the draft report's undergoing peer review, it is posted on the EHC Program 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 Program website (www.effectivehealthcare.ahrq.gov) and click "Join the E-mail List" in the lower left corner.

Get Involved by Providing Public Comments on the Draft Report

Anyone may comment on a draft report, and the assigned EPC will consider incorporating feedback in the final key questions. 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 the broadest possible relevancy of the research report. Anyone who wishes to comment on the Key Questions should expect to:

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

You can sign up at http://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 public comments can take up to 3 months. The final report is then posted on the EHC Program 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, the following are posted on the EHC Program Web site within 3 months after a final report is posted: (1) all comments received from the public, and (2) all the responses made by the authors of a draft report to the public comments (i.e., the "disposition of comments"). Each comment will be 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. Contact information will be used to communicate with commentators if there are questions about submitted comments.

C. Evidence Generation

Research Reviews, developed by Evidence-based Practice Centers, represent synthesis of existing literature, most of which is already published, while the Research Reports, developed by the DEcIDE (Developing Evidence to Inform Decisions about Effectiveness), are original research. Since the Research Reports are usually submitted for publication to medical journals, AHRQ honors standard journal embargo policy for original research, which generally does not allow pre-release of study results before they are published. This

policy allows for independent review of a study by journal peer review as well as the opportunity to disseminate study results through the journal publication. Hence, the main opportunity for comment on Research Reports is similar to other original research funded at AHRQ and the National Institute of Health (NIH); i.e., as letters to the editor, invited editorials, etc. In the future, AHRQ may allow for comment on the study questions for Research Reports but currently we are working directly with stakeholders to identify and refine research questions.

Peer Review

Once a draft of the research report has been completed by the DEcIDE Center, a peer review panel is assembled to provide additional and technical review of the report. The peer review process is coordinated through the Scientific Resource Center.

Get Involved in the Peer Review Process

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 DEcIDE identify peer reviewers for specific topics. Suggestions for peer reviewers can be made by contacting EffectiveHealthCare@ahrq.hhs.gov. The Scientific Resource Center coordinates the peer review process, which typically lasts 3 months. The DEcIDE Center 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 Effective Health Care Program for potential consultation on future work unless otherwise requested.

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 Program 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.

D. Product Translation and Dissemination

The John M. Eisenberg Center for Clinical Decisions and Communications Science produces and disseminates user-friendly, actionable summaries of research reviews and 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 their own medical content experts to better understand the factors that must be considered by both patients and clinicians 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.

Topic Decision—Context Groups

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, and that information gathered is never identified as from a specific individual. Patient/caregivers panelists who have personal experiences with the condition being studied, particularly those who represent one of AHRQ's priority populations (see page 6), 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.

Get Involved in Topic Decision—Context Groups

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/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 or information collection, whether it be from brochures, magazines, television, radio, internet, or other sources.
- Discuss the challenges faced and strategies used—as a patient, as a clinician providing treatment, or as a policymaker—with respect to the specific condition being studied.
- Provide informed consent of their participation following a full disclosure of all 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 for potential consultation on future work unless otherwise requested.

Summary Guide Review

The Eisenberg Center consults with AHRQ and the SRC 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 relevance of the content. Reviewers include individuals that 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.

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 Effective Health Care 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 if 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.

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 all 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 Effective Health Care Program for potential consultation on future work unless otherwise requested.

Dissemination

Having stakeholders distribute, talk about, model usage, and report outcomes from the use of EHC Program research products and summary guides 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 databases such as the National Library of Medicine and electronic clinical decision support services.

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 Program Web site and/or the EHC Program products.
- Making presentations to their organization or other audiences regarding the Effective Health Care Program, or any of its products, including successes they have had from using them.

To obtain EHC Program 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.

Effective Health Care (EHC) Program research products can be used in myriad ways. Some examples include:

- 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 can 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 can use EHC Program products to develop academic or continuing education curricula

Appendix A
Examples of Research Products

Research Reviews

Comparative Effectiveness of Therapies for Clinically Localized Prostate Cancer
Final Research Review published *5 Feb 2008*

Comparative Effectiveness of Second-Generation Antidepressants in the Pharmacologic Treatment of Adult Depression
Final Research Review published 24 Jan 2007

Comparative Effectiveness of Treatments to Prevent Fractures in Men and Women with Low Bone Density or Osteoporosis
Final Research Review published 17 Dec 2007

Technical Brief: Particle Beam Radiation Therapies for Cancer
Draft Research Review published 15 Jul 2008

New Research

Addressing Knowledge Gaps in the Treatment of Depression
Research Abstract published 23 Oct 2008

Comparative Safety of Analgesics for Arthritis
Research Abstract published 27 Oct 2008, Research in Progress

Methods for Studying Dementia Treatment and Outcomes in Observational Databases
Final Research Report published 22 May 2008

Infrastructure to Monitor Utilization and Outcomes of Gene-Based Applications: An Assessment
Final Research Report published 21 May 2008

Medicare Prescription Drug Data Development: Methods for Improving Patient Safety and Pharmacovigilance Using Observational Data
Final Research Report published 26 Aug 2008

To view all EHC Program research publications visit the Effective Health Care Program Web site at www.effectivehealthcare.ahrq.gov.

Appendix B

Topic Nomination Form

Suggesting a Topic for Effective Health Care Research

The Effective Health Care Program compares available health care tests and treatments to determine whether there are significant advantages or disadvantages with different approaches. The results of this comparative effectiveness 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.

To nominate a topic for research in this program, please complete this form. We need 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 with what other health care services or tests you think it should be compared. Your answers to the following questions will help us phrase your suggestion as one or more research questions that could be answered through comparative effectiveness research. At the end of this form, you will also have the chance to phrase your own research question based on your answers.

Thank you for participating in the program!

To nominate a topic for research in this program, please fill in the form below as completely as possible and click on "submit" at the end. If you prefer, you may fill out the rich text format (rtf) version of the form, which can be edited in any text editing program (e.g., MS Word, Wordpad), and email the completed form to effectivehealthcare@ahrq.hhs.gov, or you may print out the completed form and mail it to:

Michelle Eder
AHRQ Effective Health Care Program
c/o Scientific Resource Center at Oregon EPC
Center for Health Research
3800 N Interstate Avenue
Portland, OR 97227-1110

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 you will be given an opportunity to upload them after submitting the online form. All topic nominations, including those submitted on paper, will appear in the public reading room.

Topic Nomination

1. Your Nomination — Briefly describe a specific question, or set of related questions, about a health care test or treatment that this program should consider.

Examples:

- For patients with low bone density, what is the comparative effectiveness of exercise versus drug therapy to treat or prevent osteoporosis?
- For adult patients with a major depressive disorder (MDD), what are the comparative risks and benefits of older versus newer antidepressants?
- In patients with cystic fibrosis, what is the effectiveness of recombinant human growth hormone (rhGH) in improving intermediate health outcomes, such as pulmonary function and nutritional status?

2. Does your question include a comparison of different health care approaches? (If no, your topic will still be considered)

2a. If yes, explain the specific technologies, devices, drugs, or interventions you would like to see compared:

Examples:

- Calcium versus biphosphonates for the prevention of vertebral fractures
- Core needle biopsy versus open surgical biopsy for diagnosing breast lesions
- Antireflux medication versus diet and exercise for the control of acid reflux symptoms

3. What patients or group(s) of patients does your question apply to? (Please include specific details such as age range, gender, coexisting diagnoses, and indications for therapy)

3a. Are there subgroups of patients that your question might apply to? (For example, an ethnic group, stage or severity of a disease)

4. Describe the health-related benefits you are interested in. (For example, improvements in patient symptoms or problems from treatment or diagnosis)

5. Describe any health-related risks, side effects, or harms that you are concerned about.

Appropriateness for EHC Program

6. Does your question include a health care drug, intervention, device, or technology available (or likely to be available) in the US?

7. Which priority area(s) and population(s) does this topic apply to? (Check all that apply.)

Priority Conditions

- ❑ Arthritis and nontraumatic joint disorders
- ❑ Functional Limitations and disability
- ❑ Cancer
- ❑ Infectious diseases, including HIV/AIDS
- ❑ Cardiovascular disease, including stroke and hypertension
- ❑ Obesity
- ❑ Dementia, including Alzheimer's Disease
- ❑ Peptic ulcer disease and dyspepsia
- ❑ Depression and other mental health disorders
- ❑ Pregnancy, including preterm birth
- ❑ Developmental delays, attention-deficit hyperactivity disorder, and autism
- ❑ Pulmonary disease/asthma
- ❑ Diabetes mellitus
- ❑ Substance abuse

Priority Populations

- ❑ Low income groups
- ❑ Minority groups
- ❑ Women
- ❑ Children
- ❑ The elderly
- ❑ Individuals with special health care needs including individuals with disabilities or who need chronic care or end-of-life care

Federal Health Care Program

- ❑ Medicaid
- ❑ Medicare
- ❑ State Children's Health Insurance Program (SCHIP)
- ❑ Other

Importance

8. Describe why this topic is important.

9. What specifically motivated you to ask this question? (For example, you are developing a clinical guideline, working with a policy with large uncertainty about the appropriate approach, costly intervention, new research you have read, items in the media you may have seen, a clinical practice dilemma you know of, etc.)

10. Does your question represent uncertainty for clinicians and/or policy-makers? (For example, variations in clinical care, controversy in what constitutes appropriate clinical care or a policy decision)

10a. If yes, please explain:

Potential Impact

11. How will an answer to your research question be used or help inform decisions for you or your group?

11a. Describe the timeframe in which an answer to your question is needed.

12. Describe any health disparities, inequities, or impact on vulnerable populations your question applies to.

Technical Experts and Stakeholders

13. Are there health-care-focused, disease-focused, or patient-focused organizations or technical experts that you see as being relevant to this issue? Who do you think we should contact as we consider your nomination? This information will not influence the progress of your suggestion through the selection process, but it may be helpful to those considering your suggestion for further development.

a. List organizations:

b. List individual experts:

Examples:

- American Heart Association and American College of Cardiologists
- Mental Health America
- Association of American Indian Physicians
- Depression and Related Affective Disorders Association
- Gerontological Society of America
- National Lipid Association
- Nominator Information

14. In order to help us to understand the context of your health care question, it would be helpful to know more about you. The answers you give will not influence the progress of your suggestion.

a. Choose a description that best describes your role or perspective: (You may select more than one.)

- ❑ Patient/consumer
- ❑ Continuous Quality Improvement group
- ❑ Physician
- ❑ Health benefits plan/insurance carrier
- ❑ Nurse/nurse practitioner/physician assistant
- ❑ Administrator (hospital or other)
- ❑ Pharmacist
- ❑ Health care payer/purchaser (employer, Federal government)
- ❑ Other health care professional
- ❑ Health care industry (device, drug, or other manufacturer)
- ❑ Professional society
- ❑ Researcher
- ❑ Public policymaker/legislator
- ❑ Other

b. Are you making a suggestion as an individual or on behalf of an organization?

c. If an organization, please state the name of the organization: (optional)

d. Your name and contact information: (optional)

Your personal identification will not be displayed in the public reading room, nor will it influence your nomination for EHC research. It will only be used to contact you for additional information about your nomination if necessary. It is not mandatory that you provide your contact information, but it is often helpful for us to contact the nominator when we need clarification about a research question.

Your First Name:

Your Last Name:

Your Title:

Your Organization:

Your email address:

Appendix C

Standardized Selection Criteria

A. Appropriateness

1. Represents a health care drug, intervention, device, or technology available (or soon to be available) in the United States.
2. Relevant to Medicare, Medicaid, SCHIP, or other Federal health care programs.
3. Represents one of the priority conditions designated by the Department of Health and Human Services.

B. Importance

1. Represents a significant disease burden for a large proportion of the U.S. population or for a particular priority population.
2. 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.
3. Was nominated/strongly supported by one or more stakeholder groups.
4. Represents important uncertainty for decisionmakers.
5. Incorporates issues around both benefits and potential harms.
6. Represents important variation in clinical care, or controversy in what constitutes appropriate clinical care.
7. Represents high costs due to common use, to high unit costs, or to high associated costs to consumers, to patients, to health care systems, or to payers.

C. Feasibility/Desirability of New Research

1. 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).
2. Would not be redundant; (*i.e.,* the proposed topic is not already covered by available or soon-to-be available high-quality systematic review by AHRQ or others.)

D. Potential Value

1. Potential for significant health impact:
    - To improve health outcomes.
    - To reduce significant variation in clinical practices known to be related to quality.
    - To reduce unnecessary burden on those with health care problems.

2. Potential for significant economic impact: to reduce unnecessary or excessive costs.
3. 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.
4. Potential risk from inaction: unintended harms from lack of prioritization of a nominated topic.
5. Addresses inequities, vulnerable populations (including issues for patient subgroups).
6. 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 D

Research Questions & PICO(TS)

Comparative effectiveness reviews (CERs) are a type of systematic review, which 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.

CERs are designed to answer to a set of questions. The questions may be about how different tests or treatments work, or how they compare to one another. These key questions tell the researchers 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 all 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.

Most 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.

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 sub-populations, disease severity or stage, co-morbidities, 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 doses, frequency, methods of administering treatments, etc.

Comparison:

The "C" in PICO(TS) describes what is being compared with the intervention described above. It includes alternatives such as placebo, drugs, surgery, lifestyle changes, etc.

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, morbidity, etc.

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 CER 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 final CER may help to resolve. These points of view are invaluable in the early phases of research and help ensure the final products are relevant and useful.

When developing key questions, investigators will 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 CER include those that involve clinical judgment, seek specific recommendations, are vague or limited to a single procedure, or that ask about general approaches to treatment.

The following examples are listed to illustrate the difference between questions that are considered "strong" or "weak" in their appropriateness for CER. Examples are listed for clinical questions, as well as the organization and delivery of health care.

✓ ***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 the [test Y] be used as a screening for hypertension?
Strong	How effective is the [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 to 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 other acute care hospitals to provide beta blockers to patients who have had heart attacks?

Appendix E
Guide for Key Informants

Topic Refinement Process: Roles and Responsibilities—A Guide for Key Informants

Evidence-based Practice Center (EPC)
EPCs are the research centers that are contracted by the AHRQ Effective Health Care (EHC) Program to conduct the research. One or more investigators from the EPC will participate on the key informant calls. The EPCs will schedule and facilitate the calls; develop the agenda; take and distribute meeting minutes; incorporate input from the key informants to develop the clear, precise draft key questions that will be posted on the Web for public comment. They will also develop the analytic framework that guides the research.

Key Informant
Approximately six to nine key informants, including patients and caregivers, policymakers, practicing clinicians, relevant professional and consumer organizations, purchasers of health care, and others with experience relevant to the topic will be 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 will be used to develop key questions that will guide a comparative effectiveness review on a particular topic. Individual key informants are selected because they represent a particular perspective (i.e., 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 (TOO)
The 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 (EC) uses the comparative effectiveness reports to develop plain-language summary guides for clinicians, consumers, and policymakers. At least one EC representative will participate in the key informant call(s). The EC representative(s) may provide input regarding topic scope and definition, as well as other aspects of the topic refinement that may relate to the development of the final translational documents. The involvement of the EC at the topic refinement stage is intended to connect firmly the final translational documents to 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 (SRC)

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

Comparative Effectiveness Overview for Key Informants

Definition

Comparative effectiveness reviews (CERs) 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. CERs are designed to provide decisionmakers with accurate, independent, scientifically rigorous information for comparing the effectiveness and safety of various health care options. CERs have become a foundation for decisionmaking in clinical practice and health policy. To play this important role in decision making, CERs 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. The figure below depicts an analytic framework for evaluating studies of a new enteral supplement to heal bedsores. There is a key question (KQ1, KQ2, KQ3, and KQ4) associated with each of the arrows in the analytic framework. An analytic framework helps to:

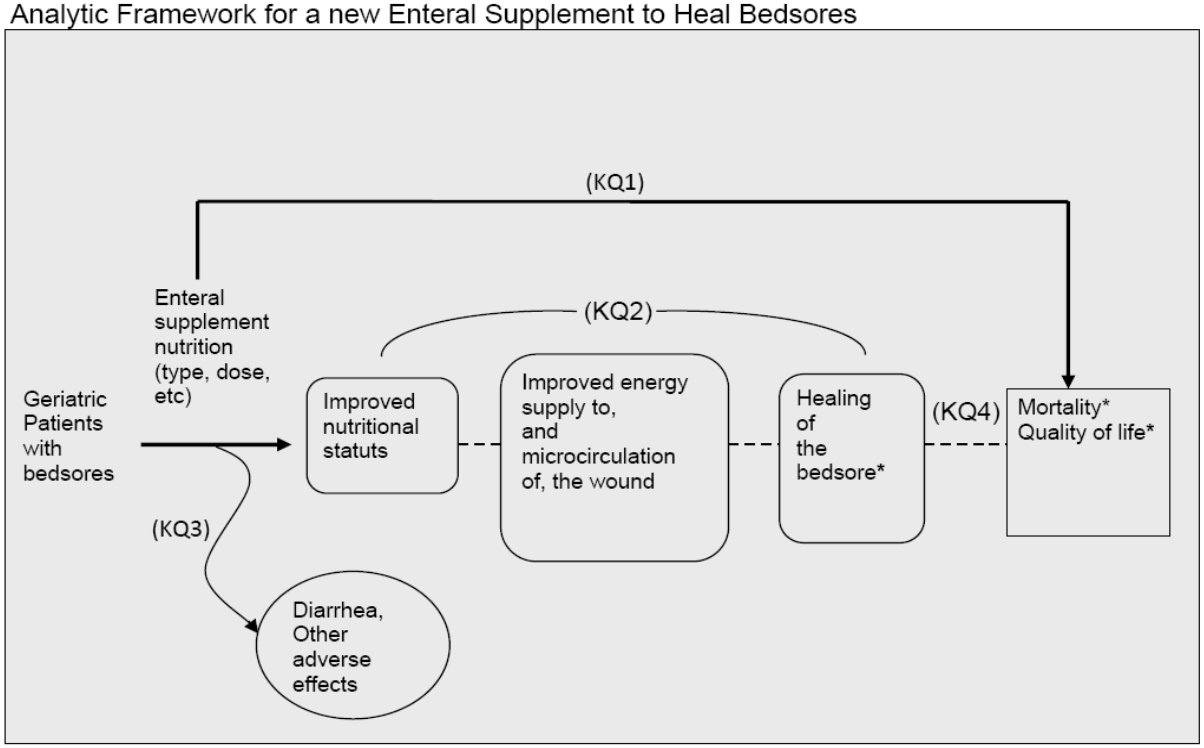
- Clarify assumptions about benefits from health care interventions, including long-term effects on quality of life, illness, and mortality.
- Be explicit about the reasoning behind clinical theories that link intermediate outcomes to outcomes of interest to patients, clinicians, and other health care 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 Key Question 1 of the analytic framework below). Input from key informants will assist with identifying and clarifying the important intermediate and long-term outcomes and the key questions that relate to those outcomes.

The key questions in the following analytic framework include:

> Key Question 1 (KQ1): Does enteral supplementation improve mortality and quality of life?
> Key Question 2 (KQ2): Does enteral supplementation improve wound healing?
> Key Question 3 (KQ3): How frequent and severe are side effects such as diarrhea?
> Key Question 4 (KQ4): Is wound healing associated with improved survival and quality of life?

Analytic Framework for a new Enteral Supplement to Heal Bedsores



More Information

For more information about comparative effectiveness reviews or the Effective Health Care Program, please visit the web site at http://effectivehealthcare.ahrq.gov/.

A useful glossary of terms used in comparative effectiveness research is available on the EHC Program's Web site. Please go to http://effectivehealthcare.ahrq.gov/tools.cfm?tooltype=glossary to access the glossary.

Appendix F
Conflict of Interest Policy

Key Informants

Key Informants are the end-users of research, including patients and caregivers, practicing clinicians, relevant professional and consumer organizations, purchasers of health care, and others with experience in making health care decisions. Within the EPC program, the Key Informant role is to provide input into identifying the Key Questions for research that will inform health care decisions. The EPC solicits input from Key Informants when developing questions for systematic review or when identifying high priority research gaps and needed new research. Key Informants are not involved in analyzing the evidence or writing the report and have not reviewed the report, except as given the opportunity to do so through the peer or public review mechanism.

Key Informants must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their role as end-users, individuals are invited to serve as Key Informants and those who present with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential conflicts of interest identified.

Technical Experts

Technical Experts comprise a multi-disciplinary group of clinical, content, and methodologic experts who provide input in defining populations, interventions, comparisons, or outcomes as well as identifying particular studies or databases to search. They are selected to provide broad expertise and perspectives specific to the topic under development. Divergent and conflicted opinions are common and perceived as healthy scientific discourse that results in a thoughtful, relevant systematic review. Therefore study questions, design and/or methodological approaches do not necessarily represent the views of individual technical and content experts. Technical Experts provide information to the EPC to identify literature search strategies and recommend approaches to specific issues as requested by the EPC. Technical Experts do not do analysis of any kind nor contribute to the writing of the report and have not reviewed the report, except as given the opportunity to do so through the public review mechanism

Technical Experts must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals are invited to serve as Technical Experts and those who present with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential conflicts of interest identified.

Peer Reviewers

Peer reviewers are invited to provide written comments on the draft report based on their clinical, content, or methodologic expertise. Peer review comments on the preliminary

draft of the report are considered by the EPC in preparation of the final draft of the report. Peer reviewers do not participate in writing or editing of the final report or other products. The synthesis of the scientific literature presented in the final report does not necessarily represent the views of individual reviewers. The dispositions of the peer review comments are documented and will, for CERs and Technical briefs, be published three months after the publication of the Evidence report.

Potential Reviewers must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Invited Peer Reviewers may not have any financial conflict of interest greater than $10,000. Peer reviewers who disclose potential business or professional conflicts of interest may submit comments on draft reports through the public comment mechanism.