Evidence-based Practice Center
Technical Brief Protocol

The protocol will be posted for informational purposes only, and public input will be sought only for the draft report.

Project Title:

Amendment Date(s) if applicable:

(Amendments Details–see Section VII)

I. Background and Objectives for the Technical Brief

Provide a description of the clinical problem that the new medical technology or healthcare intervention[1] is meant to address and a discussion of current medical practice as it relates to the clinical problem. This section should demonstrate what need the new technology/intervention has arisen to fill.

II. Guiding Questions

*Questions 1-4 below **shall be adapted** for each Technical Brief topic. The EPC shall provide a rationale for their included questions. When appropriate, additional sub-questions may be included and non-applicable sub-questions omitted. The purpose of defining these questions at this stage in the research is to make sure that as many as possible of the questions that should be asked are identified and asked, but it is not intended as a straightjacket or a pair of blinders. It is expected that the sub-questions may continue to evolve slightly over the course of the research as the researchers gain a deeper understanding of the topic.*

1. *Describe the Technology/Intervention:* What are the different types or modalities of the intervention that have been proposed or used in clinical practice? What are the potential advantages and disadvantages of these respective therapies compared to current practice? What are the potential safety issues and harms? Are there other features of this technology/intervention that need to be considered?
2. *Describe the Context in which the Technology/Intervention Is Used:* What is the current FDA status of the technology/intervention? What additional equipment or resources are needed along with the technology/intervention? How widely used is this intervention? What kinds of training, certification, and staffing are required? What modifications are in development? Are there other issues that need to be considered in regards to this technology/intervention?

[1] For the purposes of a Technical Brief, medical technology is defined as "medications, procedures, medical and assistive devices and technologies, diagnostic tests, behavioral change, and delivery system strategies" (FCC, 2009).

3. *Describe the Current Evidence of the Technology/Intervention:* What published and unpublished studies have reported on the use and safety of this intervention? Provide a state of the current research for the following information on available studies:
    a. Indication/patient inclusion criteria
    b. Type of intervention (if applicable)
    c. Study design/size
    d. Comparator used in comparative studies
    e. Concurrent/prior treatments
    f. Length of follow up
    g. Outcomes measured
    h. Adverse events/harms/safety issues reported
4. *Identify the Important Issues raised by the Technology/Intervention:* Discuss the implications of the current level of diffusion and/or further diffusion of this technology/intervention, given the current state of the evidence. In addition to the basic questions of efficacy and safety raised above, this shall include, but is not limited to, ethical, privacy, equity, cost, and/or economic efficiency considerations that impact diffusion of the technology/intervention , decision-making and/or conceptual thinking around the technology/intervention . What are the key decisional uncertainties? What are possible areas of future research?

III. Methods

The Technical Brief protocol shall integrate discussions with Key Informants, a search of the grey literature, and a search of published literature. The EPC shall discuss their strategy for integrating these research techniques into a single, cohesive review process. In particular, the EPC shall discuss how each of these techniques will be used to inform their response to the guiding questions above.

In general, responses to Questions 1 & 2 above rely on information from published narrative reviews, information in the grey literature, and Key Informant discussions; responses to Question 3 are usually based on peer-reviewed, published literature; and responses to Question #4 shall be based comparing what is thought to be important about the topic (KQ1&2) with what has actually been studied (KQ3).

1. Data Collection: The EPC shall also discuss separately its strategy for each of the following research processes:

A. Discussions with Key Informants

Describe a strategy for identifying and incorporating relevant Key Informants into the research process that ensures balance and efficiency. A list of these

individuals shall be attached to the project protocol for internal AHRQ use but will not be posted. This list should include both subject experts and end users of the technology/intervention, such as patients and caregivers, practicing clinicians, medical directors, P&T or similar committees, relevant professional and consumer organizations, purchasers of healthcare, and others with experience in making healthcare decisions relevant to the topic. Please note that patients or patient advocates should be included even if the technology/intervention is very new and patients are unlikely to have had experience with it. In this case, the role of patients is to identify what features would be important to them from the proposed new technology/intervention and what their concerns would be. The EPC shall adhere to all OMB requirements. In particular, OMB clearance shall be obtained for testing and/or focus group activities in which more than nine (9) individuals are asked the same questions.

Key Informants are important in Technical Briefs, because the technologies in questions are generally fairly new and relatively little written data may be available. Therefore Key Informants can contribute to an understanding of how the technology/intervention works, where it might fit into clinical care, and potential advantages or concerns. This does not mean that you need to report everything they say as if it were study data. The ideal role for Key Informants is to reveal questions and concerns that you might not have thought of otherwise. Where ever possible, try to verify what you learn from Key Informants through other means. If you have no other source, consider to what extent the information is likely to represent an opinion or objective data.

B. Grey Literature search.

Describe a strategy for searching the grey literature as well as the information that will be abstracted from these sources. Sources of information may include the internet, government websites, clinical trial databases, trade publications, and meeting abstracts. Examples of the type of information that may be obtained from these sources includes preliminary study findings, professional society consensus statements, and current coverage and/or payment policies. The SIPs may contribute to this part of the research, but should not be relied on; therefore an independent strategy needs to be developed.

C. Published Literature search.

Describe the proposed literature search strategy; plans to focus the literature review and databases to be searched, how hand searches may be done, review procedures, data to be abstracted, and assessment of evidence against the inclusion/exclusion criteria. The EPC should review the full text articles (not just the abstracts). If there is a clear and compelling reason to restrict part of the included literature to a review of the abstract only, this should be stated in the Protocol and discussed with the TOO. Also, include specific plans on updating the literature search concurrent with the peer review process. Describe your process for evaluating the appropriateness of incorporating any additional data

recommended during public and peer review or found during the updated literature search.

2. Data Organization and Presentation: The EPC shall discuss ways in which information will be summarized and presented in the technical brief.

A. Information Management

Describe methods for data abstraction from the published literature and how this data will be integrated with information from the grey literature and Key Informant interviews. Identify key characteristics that may be necessary to 1) respond to the guiding questions above and 2) develop a conceptual framework.

B. Data Presentation

Discuss how evidence will be summarized in a way that is logical and relevant to the issues that need to be addressed. It is expected that there may be considerable variation from topic to topic, so the focus should be on finding a presentation that best conveys the subject matter. If necessary, discuss planned graphical representations of an evidence map.

IV. References

V. Definition of Terms

If not applicable, simply make a note to that effect.

VI. Summary of Protocol Amendments

In the event of protocol amendments, the date of each amendment will be accompanied by a description of the change and the rationale.

(NOTE THE FOLLOWING PROTOCOL ELEMENTS ARE STANDARD SECTIONS TO BE ADDED TO ALL TECHNICAL BRIEF PROTOCOLS)

VII. Key Informants

Within the Technical Brief process, Key Informants serve as a resource to offer insight into the clinical context of the technology/intervention, how it works, how it is currently used or might be used, and which features may be important from a patient of policy standpoint. They may include clinical experts, patients, manufacturers, researchers, payers, or other perspectives, depending on the technology/intervention in question. Differing viewpoints are expected, and all statements are crosschecked against available literature and statements from other Key Informants. Information gained from Key Informant interviews is identified as such in the report. Key Informants 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

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 unique clinical or content expertise, 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.

VIII. 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 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.

IX. EPC Team Disclosures

EPC core team members must disclose any financial conflicts of interest greater than $1,000 and any other relevant business or professional conflicts of interest. Related financial conflicts of interest that cumulatively total greater than $1,000 will usually disqualify EPC core team investigators.

X. Role of the Funder

This project was funded under Contract No. xxx-xxx from the Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services. The Task Order Officer reviewed contract deliverables for adherence to contract requirements and quality. The authors of this report are responsible for its content. Statements in the report should not be construed as endorsement by the Agency for Healthcare Research and Quality or the U.S. Department of Health and Human Services.