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Prioritization Criteria Methodology for Future Research Needs Proposals Within the Effective Health Care Program

PiCMe - Prioritization Criteria Methods

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Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of evidence reports and technology assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. The reports and assessments provide organizations with comprehensive, science-based information on common, costly medical conditions and new health care technologies and strategies. The EPCs systematically review the relevant scientific literature on topics assigned to them by AHRQ and conduct additional analyses when appropriate prior to developing their reports and assessments.

To improve the scientific rigor of these evidence reports, AHRQ supports empiric research by the EPCs to help understand or improve complex methodologic issues in systematic reviews. These methods research projects are intended to contribute to the research base in and be used to improve the science of systematic reviews. They are not intended to be guidance to the EPC program, although may be considered by EPCs along with other scientific research when determining EPC program methods guidance.

AHRQ expects that the EPC evidence reports and technology assessments will inform individual health plans, providers, and purchasers as well as the health care system as a whole by providing important information to help improve health care quality. The reports undergo peer review prior to their release as a final report.

We welcome comments on this Methods Research Project. They may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by e-mail to epc@ahrq.hhs.gov.

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Prioritization Criteria Methodology for Future Research Needs proposals Within the EHC Program

Structured Abstract

Background: The Agency for Healthcare Research and Quality through its Effective Health Care (EHC) Program partners with networks of researchers and clinical teams across North America, using input from stakeholders throughout the process of comparative effectiveness research, translation, dissemination, and implementation of research findings. The Evidence-based Practice Centers (EPCs) perform in depth reviews of existing evidence. An important part of these reviews is to not only synthesize the evidence, but also to identify the gaps in evidence that limited the ability to answer the systematic review questions. AHRQ supports EPCs to work with various stakeholders to further develop and prioritize the future research needed by decision-makers. AHRQ has commissioned a series of methods papers to inform this activity.

Objective: Clearly defined criteria are integral to the future research needs (FRN) prioritization process. The objective of this paper to propose preliminary criteria and a model worksheet that could be used by stakeholders when identifying, developing and prioritizing FRNs.

Methods/Approach: The EHC program topic selection criteria were used as a starting point. The experiences and reports of eight EPCs that conducted pilot projects for FRN prioritization were then utilized to refine the criteria. A draft proposal for FRN prioritization criteria and methodology was developed and circulated to the eight EPCs; feedback further informed the current draft.

Results: Research gaps identified from Comparative Effectiveness Reviews (CERs) automatically meet two of the five EHC Program criteria (Appropriateness and Importance) since the original CER topic was selected to be reviewed. The remaining three criteria (Desirability of new research/duplication, Feasibility, and Potential Value) are considered at different points when prioritizing Future Research Needs. EPCs should work with stakeholders to prioritize research gaps that are not or have not been addressed (desirability of new research/duplication) but are of high potential value. After identifying these high-priority research needs, the EPC will consider the feasibility and duplication when suggestion potential study designs.

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Background

Research prioritization is one of the key nodal points in the research cycle, i.e., research planning, research priority setting, strategies and implementation of research priorities, research utilization, research monitoring and evaluation (part of the research information system), and overall research management. In recognition of the resource, human, and financial costs of conducting research, the changing determinants and pattern of diseases or conditions and their effect on the population at large, and the evolving body of evidence, prioritization of future research needs must be responsive and dynamic and should be periodically reviewed and updated. Future Research Needs (FRN) prioritization takes place within the framework of the national health policies and national health research policies. For example, although federally funded research priorities in the United States are largely investigator initiated, [5] in making funding decisions, the National Institutes of Health (NIH) and other Federal agencies consider the impact of potential research in light of burden needs of society, existing scientific opportunities, the quality of individual research proposals, the experience of the applicant, and the ability to sustain research through adequate staffing and infrastructure.[5] The process of FRN prioritization should be well-documented for future reference, particularly where judgments and opinions are integral. All of the criteria used for FRN prioritization must be unequivocal and also independent of each other.

Comparative effectiveness research is the conduct and synthesis of systematic research comparing different interventions and strategies to prevent, diagnose, treat and monitor health conditions. The purpose of this research is to inform patients, providers, and decision-makers, responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances. The Federal Coordinating Council (FCC) for Comparative Effectiveness Research (CER) defined CER and draft prioritization criteria for making research selections.[9] The definition and criteria were a guide to the Federal use of the funding appropriated for comparative effectiveness research in FY 2009 and FY 2010 in the American Recovery and Reinvestment Act (ARRA).

The FCC established:

Threshold Minimal Criteria (i.e., must meet these to be considered) for the Prioritization Criteria for Comparative Effectiveness Research:

- Included within statutory limits of Recovery Act and FCC definition of CER.
- Responsiveness to expressed needs and preferences of patients, clinicians, and other stakeholders, including community engagement in research.
- Feasibility of research topic (including time necessary for research).

Prioritization Criteria:

- Potential Impact (based on prevalence of condition, burden of disease, variability in outcomes, and costs of care).
- Potential to evaluate comparative effectiveness in diverse populations and patient sub-populations.
- Uncertainty within the clinical and public health communities regarding management decisions.
- Addresses need or gap unlikely to be addressed through other funding mechanisms.
- Potential for multiplicative effect (e.g., lays foundation for future CER or generates additional investment outside government).

The process of making decisions about health-related priorities is complex, context-dependent, and involves social processes. Therefore, priority-setting processes should be guided by ethical principles, including careful attention to conflicts of interest.[3,7] Documentation of the process leading to a particular proposal being selected should be explicit and transparent[3,8] Other key principles for priority-setting process include flexibility, adaptability to dynamic advances, and accountability.[3,8]

The Agency for Healthcare Research and Quality (AHRQ) through its Effective Health Care (EHC) Program funds individual researchers, research centers, and academic organizations to conduct effectiveness and comparative effectiveness research for clinicians, consumers, and policymakers.[1] AHRQ is the lead Federal agency charged with improving the quality, safety, efficiency, and effectiveness of health care for all Americans. The EHC program has carefully considered the range of principles and criteria and established a process for prioritizing research questions within the EHC program, using 5 criteria with 18 elements.[6] The EHC Program partners with networks of researchers and clinical teams across North America, using input from stakeholders throughout the process of comparative effectiveness research, translation, dissemination, and implementation of research findings.[1]

As one of the components of the EHC Program, the Evidence-based Practice Centers (EPCs) perform in depth reviews of existing evidence.[2] Comparative effectiveness reviews (CER), systematic reviews (SR) are intended to review and present the relevant evidence to inform real-world health care decisions for patients, providers, and policymakers. Beyond synthesizing the evidence, CERs identify gaps in evidence that may have limited the ability to answer the research questions.[3] As part of a new effort begun in 2010, AHRQ supported EPCs to work with various stakeholders to further develop and prioritize the future research needed by decision-makers.[10, 11] These Future Research Needs (FRN) projects are intended to be used by researchers and funders of research to help improve the body of CER evidence that would be useful for decisionmakers. As FRN projects are new, there is not previously established methodology, and the EPCs have been piloting various methods for identifying and prioritizing evidence needs.[4] In these pilot projects, EPCs and stakeholders used various implicit or explicit criteria.

The objective of this methods paper is to outline steps for when, how, and which specific criteria can be explicitly considered when identifying the highest-priority research needs.

Methods

We reviewed the prioritization criteria that the EPCs used in their pilot projects[4] and the EHC program Topic Selection criteria.[6] We modified the EHC Topic Selection criteria by adjusting for the differences between planning a systematic review of existing evidence and proposing future research to address gaps in the existing evidence. We mapped the new prioritization elements developed by the eight EPCs into the pre-existing EHC Topic Selection criteria. After modification, the remaining criteria were divided into two prioritization steps as appropriate to the process of identify future research needs and suggesting specific study designs. These criteria and steps were shared with EPCs who continue to pilot additional Future Research Needs projects and are reported below as suggested practices.

Prioritization

EHC Topic Selection Criteria

The EHC Program currently has five criteria with 18 elements for the selection of topics for SRs/CERs.[3,9] These are categorized into five overarching constructs (Table 1): Appropriateness (3 elements), Importance (7 elements), Duplication (1 element), Feasibility (1 element), and Potential Impact (6 elements).[1]

Table 1: Effective Health Care Program topic selection criteria[6]

Appropriateness	1	Represents a health care drug, intervention, device, or technology available (or soon to be available) in the United States.
	2	Relevant to enrollees in programs specified in Section 1013 of the Medicare Modernization Act of 2003 (Medicare, Medicaid, State Children's Health Insurance Program [SCHIP], other Federal health care programs)
	3	Represents one of the priority health conditions designated by the Department of Health and Human Services
Importance	1	Represents a *significant disease burden* affecting a large proportion of the population or a priority population (e.g., children, elderly adults, low-income, rural/inner city, minorities, or other individuals with special health care or access issues).
	2	Is of *high public interest*, affecting health care decision making, 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 decision makers.
	5	Incorporates issues around both *clinical benefits and potential clinical harms.*
	6	Represents *important variation* in clinical care or controversy in what constitutes appropriate clinical care.
	7	Represents *high costs* due to common use, high unit costs, or high associated costs to consumers, patients, health care systems, or payers.
Desirability of new research / duplication	1	*Potential for redundancy* (i.e., whether a proposed topic is already covered by an available or soon-to-be available high-quality systematic review by AHRQ or others)
Feasibility	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)

Table 1: Effective Health Care Program topic selection criteria[6] (continued)

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 of care.
		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*:
		Proposed topic exists within a clinical, consumer, or policymaking context that is amenable to evidence-based change.
		A product from the EHC program could be an appropriate vehicle for change.
	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.

AHRQ=Agency for Healthcare Research and Quality; EHC=Effective Health Care

FRNs, by definition, derive from existing CERs and those CERs, in order to be conducted under the EHC Program, should have already fulfilled the selection criteria listed in Table 2. As a result, one does not necessarily need to revisit these criteria again when prioritizing FRNs.[9] Of the aforementioned five topic selection criteria, The two criteria of Appropriateness and Importance could potentially be set aside as a footnote for FRN prioritization.

Table 2. Default criteria—always met prior to FRN proposals

Appropriateness and Importance factors included in consideration by virtue of the fact that Future Research recommendations are made in the context of an EHC Systematic Review or Comparative Effectiveness Review, and all commissioned topics have met these criteria prior to selection for SR/CER
Represents a health care drug, intervention, device, or technology available (or soon to be available) in the United States.
Relevant to enrollees in programs specified in Section 1013 of the Medicare Modernization Act of 2003 (Medicare, Medicaid, State Children's Health Insurance Program [SCHIP], other Federal health care programs)
Represents one of the priority health conditions designated by the U.S. Department of Health and Human Services
Represents a significant disease burden affecting a large proportion of the population or a priority population (e.g., children, elderly adults, low-income, rural/inner city, minorities, or other individuals with special health care or access issues).
Is of high public interest, affecting health care decision making, outcomes, or costs for a large proportion of the U.S. population or for a priority population in particular.
Was nominated/strongly supported by one or more stakeholder groups.

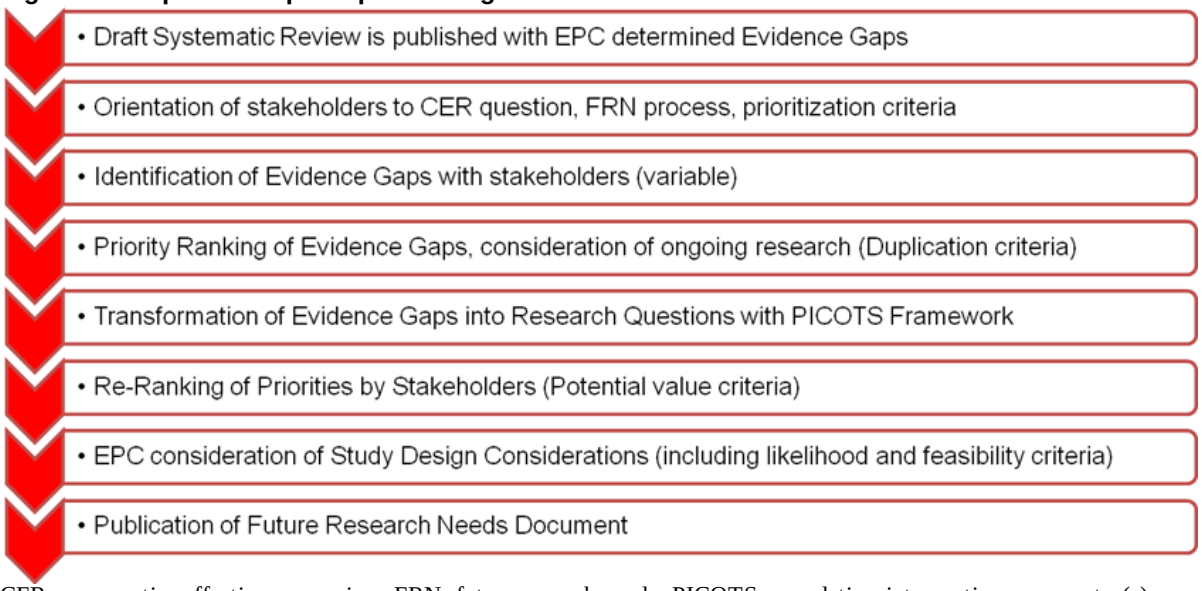
CER=comparative effectiveness review; FRN=future research needs; SR=systematic review

Of the remaining three EHC topic selection criteria, there is a natural division in the appropriate stage for application of criteria and expertise needed to apply the criteria. The criterion of Feasibility is appropriate only when considering a specific research design and best applied by persons with expertise in conducting primary research. On the contrary, stakeholders

who will be using the research to make decisions need to consider whether suggested research would be helpful (have Potential Value), especially in relation to ongoing or already conducted research (Desirability of new research/duplication).

We propose a sequential process for prioritizing research gaps into future research needs as described in Figure 1.

Figure 1. Proposed steps in prioritizing future research needs



CER=comparative effectiveness review; FRN=future research needs; PICOTS=population, intervention, comparator(s), outcomes, timing, setting

Stakeholder Prioritization

After identifying the research gaps from a CER/SR, the EPC works with stakeholders to prioritize these gaps to those research areas that are the most important. This is often a multi-step process. Initial engagement of stakeholders begins with orientation to the topic, goals, process, and expectations (Figure 1, bullet 2). EPCs have frequently, at this early stage, also solicited suggestions for research gaps from stakeholders (Figure 1, bullet 3). Frequently, the research areas that stakeholders suggest may not have been reviewed in the original CER/SR, although may be a relevant and worthwhile question for study.

EPCs have found that it requires at least two rounds of prioritization with stakeholders to get specific enough research questions. The first step may be to identify those areas of gaps that have been or will be covered by ongoing or existing research. In this step (Figure 1, bullet 4), the EPC will conduct a scan of ongoing research and perhaps a scan of the research on topics that were not covered in the original CER/SR and provide this information to stakeholders to which research gaps are of lower priority.

In the second step of stakeholder prioritization, the EPC will define greater specificity around the research gaps to help stakeholders in prioritizing which may yield the highest value. Discussing future research needs for a condition will often require specification of the PICO elements People/Population/Subpopulation/Patients with the condition, Intervention (Exposure, Test), Control, and Outcomes) (Figure 1, row 5). A description of the population or subpopulation (P) to be studied should be stated. The proposed intervention and proposed comparator(s) (if any) should be itemized (I,C); the comparator could be a placebo or a head to

head comparison with another active intervention, or a different type of study. The proposed primary and secondary outcome measures, including surrogate measures and process measures should be itemized (O). The EPC will then ask the stakeholders to consider which of these future research topic areas have the highest potential value (Figure 1, row 6).

We propose six potential value criteria with an optional seventh if the duplication criterion was not previously considered (Table 3). The components of potential value include the importance of the condition, the importance of the evidence gap between what we know and what we need to know (degree of uncertainty), and the known degree of inappropriate variability in the management of the condition or controversy about what constitutes appropriate clinical care. The evidence gap may involve knowledge, or knowledge translation, or implementation, or a combination. After completing the potential value prioritization process, the next step would be an effort to delineate study design and other parameters of the envisioned research.

Table 3. PiCMe potential value criteria

PiCMe Criteria: EHC Criteria, Modified for Future Research, Supplemented With Additional Criteria	
	Potential value criteria (for significant health impact): addressing evidence gap (knowledge, translation, implementation)
V1	Potential for significant health impact on the current and future health status of people with respect to burden of the disease and health outcomes: mortality, morbidity, and quality of life.
V2	Potential to reduce important inappropriate (or unexplained) variation in clinical practices known to relate to quality of care. Potential to resolve controversy or dilemmas in what constitutes appropriate health care. Potential to improve decision-making for patient or provider, by decreasing uncertainty.
V3	Potential for significant (nontrivial) economic impact related to the costs of health service: to reduce unnecessary or excessive costs; to reduce high costs due to high volume use; to reduce high costs due to high unit cost or aggregate cost. Costs may impact consumers, patients, health care systems, or payers.
V4	Potential risk from inaction: Unintended harms from lack of prioritization of proposed research; opportunity cost of inaction
V5	Addresses inequities, vulnerable, diverse populations (including issues for patient subgroups); potential to reduce health inequities
V6	Potential to allow assessment of ethical, legal, social issues pertaining to the condition
V7[a]	Potential for new knowledge (Research would not be redundant; Question not sufficiently researched, including completed and in-process research; Utility of available evidence limited by changes in practice, e.g., disease detection or evolution in technology)

[a]Optional if not done in previous step.
EHC=Effective Health Care; PiCMe= Prioritization Criteria Methods

Discussing the potential value of a PICO-specific future research need will often require knowledge of the current strength of evidence (SoE), based upon current best evidence summarized in a SR/CER. These components (PICO and current SoE) are incorporated with the potential value criteria in a sample worksheet for determining prioritization (Table 4). The purpose of such a worksheet is to help stakeholders focus their own implicit criteria in ranking the top research areas. Because different methods may be utilized the worksheet may be adapted as necessary, but it is used as a reminder that stakeholders should be able to identify which criteria they used to select their highest choice research areas. The sample worksheet may be particularly useful if EPCs choose to assign numeric values to prioritization criteria and to use a quantitative ranking for prioritization. Pilot experiences found that Likert scales did not sufficiently differentiate high priority needs, multi-voting was more useful to decrease the size of

the list. Regardless of the approach taken, it should be identified a priori in a project protocol and reported clearly and transparently in the final product.

It is not the intent of this paper to assert that each criterion is equal in value to each other criterion. For any given clinical topic, the relative value of the criteria may differ from another clinical topic. We suggest that if stakeholders do not explicitly weigh each criteria that EPCs ask stakeholders to be explicit about which criteria was most important when they selected their top priority research needs, and document as such.

Table 4. Potential value criteria prioritization worksheet

PiCMe Criteria: EHC Criteria, modified for future research, supplemented with additional criteria									
	Potential value criteria (for significant health impact): addressing evidence gap (knowledge, translation, implementation)	**Indicate proposed population/ subpopulation (P) in the thick-bordered cell below; for each row, make notation as applicable**	**Indicate proposed intervention/ comparator; PCRCT or head-to-head comparison or other (I,C) in the thick-bordered cell below; for each row, make notation as applicable**	**Indicate proposed primary outcome – benefits / harms, long-term, etc (O) in the thick-bordered cell below; for each row, make notation as applicable**	**Indicate current Strength of Evidence (SOE) in the thick-bordered cell below[¥]; for each row, make notation as applicable**	**Yes (enter value = 1)**	**No (enter value = 0) (also: use for NA)**	**Weight[a]**	**Row Total (multiply Yes column value X Weight column value)**
V1	Potential for significant health impact on the current and future health status of people with respect to burden of the disease and health outcomes: mortality, morbidity, and quality of life.							3	
V2	Potential to reduce important inappropriate (or unexplained) variation in clinical practices known to relate to quality of care. Potential to resolve controversy or dilemmas in what constitutes appropriate health care. Potential to improve decision-making for patient or provider, by decreasing uncertainty.							3	

Table 4. Potential value criteria prioritization worksheet (continued)

PiCMe Criteria: EHC Criteria, modified for future research, supplemented with additional criteria									
	Potential value criteria (for significant health impact): addressing evidence gap (knowledge, translation, implementation)	**Indicate proposed population/ subpopulation (P) in the thick-bordered cell below; for each row, make notation as applicable**	**Indicate proposed intervention/ comparator; PCRCT or head-to-head comparison or other (I,C) in the thick-bordered cell below; for each row, make notation as applicable**	**Indicate proposed primary outcome – benefits / harms, long-term, etc (O) in the thick-bordered cell below; for each row, make notation as applicable**	**Indicate current Strength of Evidence (SOE) in the thick-bordered cell below[¥]; for each row, make notation as applicable**	**Yes (enter value = 1)**	**No (enter value = 0) (also: use for NA)**	**Weight[a]**	**Row Total (multiply Yes column value X Weight column value)**
V3	Potential for significant (nontrivial) economic impact related to the costs of health service: to reduce unnecessary or excessive costs; to reduce high costs due to high volume use; to reduce high costs due to high unit cost or aggregate cost. Costs may impact consumers, patients, health care systems, or payers.							3	
V4	Potential risk from inaction: Unintended harms from lack of prioritization of proposed research; opportunity cost of inaction							1	
V5	Addresses inequities, vulnerable, diverse populations (including issues for patient subgroups); potential to reduce health inequities							1	
V6	Potential to allow assessment of ethical, legal, social issues pertaining to the condition							1	

Table 4. Potential value criteria prioritization worksheet (continued)

PiCMe Criteria: EHC Criteria, modified for future research, supplemented with additional criteria									
	Potential value criteria (for significant health impact): addressing evidence gap (knowledge, translation, implementation)	**Indicate proposed population/ subpopulation (P) in the thick-bordered cell below; for each row, make notation as applicable**	**Indicate proposed intervention/ comparator; PCRCT or head-to-head comparison or other (I,C) in the thick-bordered cell below; for each row, make notation as applicable**	**Indicate proposed primary outcome – benefits / harms, long-term, etc (O) in the thick-bordered cell below; for each row, make notation as applicable**	**Indicate current Strength of Evidence (SOE) in the thick-bordered cell below[¥]; for each row, make notation as applicable**	**Yes (enter value = 1)**	**No (enter value = 0) (also: use for NA)**	**Weight[a]**	**Row Total (multiply Yes column value X Weight column value)**
V7[b]	Potential for new knowledge (Research would not be redundant; Question not sufficiently researched, including completed and in-process research; Utility of available evidence limited by changes in practice, e.g., disease detection or evolution in technology)							3	
								15	

[a]Panel performing prioritization can set weights; the values in this table are examples only.
[b]Optional

Criteria for Considering Study Designs

Once the stakeholders have identified the questions that need to be answered to make decisions, the next step is to consider what study design is both feasible and likely to answer the questions in a valid manner. Another methods paper focuses on the steps for considering the study designs to address research needs.[12] In brief, this step incorporates consideration of the feasibility criteria (Figure 1, bullet 7) of the study design.

Conclusions

CERs identify important gaps in evidence; these can be used to inform future research needs. FRNs can be used by researchers and funders advance the knowledge base. Integral to this process is having explicit criteria for prioritizing the FRNs. This paper reviews the EHC Topic Selection criteria and describes where each of the five criteria (Appropriateness, Importance, Desirability of new research/duplication, Feasibility, and Potential Value) are considered when identifying the highest priority research needs from a CER. A topic which has been selected for a CER will inherently meet the Appropriateness and Importance criteria. This paper particularly focuses on the Potential Value and Desirability of new research/duplication criteria that are used when working with stakeholders to prioritize the research gaps of a CER. Another related EHC methods paper focuses on how EPCs consider the feasibility criteria when suggesting potential study designs.

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