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

PiCMeprioritization Criteria Methods
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PiCMe—Prioritization Criteria Methods

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None of the investigators have any affiliations or financial involvement that conflicts with the material presented in this report.

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.

An important part of evidence reports 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 identify and prioritize the future research that is needed by decisionmakers. This information is provided for researchers and funders of research in these Future Research Needs papers. These papers are made available for public comment and use and may be revised.

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 Future Research Needs document. 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 email to epc@ahrq.hhs.gov.

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Structured Abstract

Background. The Agency for Healthcare Research and Quality (AHRQ) 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 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 decisionmakers. 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 is to propose preliminary criteria and a model worksheet that EPCs and stakeholders could use 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 a series of iterations, leading to this document.

Results. The 18 EHC Program topic selection criteria were modified by the 8 EPCs as part of their FRN pilot projects. Criteria that did not apply to future research needs were dropped. Criteria that were already met by default, due to requirements for the selection of the topic for the comparative effectiveness reviews and systematic reviews, were set aside. The remaining criteria were separated into two domains: potential value and probability of success (feasibility, likelihood, capacity). The process for FRN projects was refined. The potential value criteria would be utilized for stakeholder prioritization of FRNs. The probability of success criteria would be applied after the priority FRNs underwent study design consideration by the EPC. EPCs could work with stakeholders to prioritize research gaps that are not or have not been addressed but are of high potential value. After identifying these high-priority research needs, the EPC will consider the feasibility and capacity criteria when developing potential study designs.
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Background

Research prioritization is one of the key nodal points in the research policy planning cycle, which encompasses 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 policy 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.

The process of making decisions about health-related priorities is complex and context-dependent and involves social processes. Therefore, priority-setting processes should be guided by ethical principles, including careful attention to conflicts of interest.\(^1,2\) Documentation of the process leading to a particular proposal being selected should be explicit and transparent.\(^1,3\) Other key principles for the priority-setting process include flexibility, adaptability to dynamic advances, and accountability.\(^1,3\)

Research 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,\(^4\) in making funding decisions, the National Institutes of Health 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.\(^4\) The prioritization process should be well documented for future reference, particularly where judgments and opinions are integral. All of the criteria used for research prioritization should be clear 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 decisionmakers, while 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 defined comparative effectiveness research and draft prioritization criteria for making research selections.\(^5\) 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.

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 comparative effectiveness research
  - 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 subpopulations
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. 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 selecting research topics within the EHC program, using 5 domains with 18 criteria. 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.

As one of the components of the EHC Program, the Evidence-based Practice Centers (EPCs) perform systematic reviews of existing evidence. Comparative effectiveness reviews (CER) and 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 topics. In most situations, there will be many more research gaps than can be reasonably narrowed in the near future, and many more future research needs proposals than can be reasonably undertaken. Therefore, prioritization of the proposals will be helpful, and it is desirable that the prioritization process be transparent and as consistent as possible among groups. Therefore, as part of an effort begun in 2010, AHRQ supported EPCs to work with various stakeholders to further develop and prioritize the future research needed by decisionmakers, including primary research and methods research. These future research needs (FRN) projects are intended to be used by researchers and funders of research to help improve the body of evidence as needed for decisionmakers. There was no previously established methodology for FRN projects, and the EPCs have been utilizing various methods for identifying and prioritizing evidence needs. One of the steps in this process is the definition of specific prioritization criteria, and in these pilot projects, EPCs and stakeholders used various implicit or explicit criteria.

The objective of this methods paper is to propose when, how, and which specific criteria can be explicitly considered when identifying the highest priority research needs.
Figure 1. Flowchart of future research needs process

1. Systematic review is published with EPC-determined evidence gaps
2. Orientation of stakeholders to CER question, FRN process, and prioritization criteria
3. Elaboration and consolidation of evidence gaps through iterative process with stakeholders
4. Transformation of evidence gaps into research questions using relevant framework
5. Ranking of research questions by stakeholders (potential value criteria) resulting in research needs
6. Addition of study design considerations and feasibility issues
7. Publication of future research needs document

Abbreviations: CER = comparative effectiveness review; EPC = Evidence-based Practice Center; FRN = future research needs
* May include identification of additional evidence gaps.
† Reduction through topic consolidation, preliminary prioritization, and consideration of ongoing research (duplication criteria).
‡ Evidence gaps that address specific methods issues would not use PICOTS framework
¥ May require iterative steps
Methods

We reviewed the prioritization criteria that the EPCs used in their pilot projects\textsuperscript{11} and the EHC program topic selection criteria.\textsuperscript{7} 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 prioritization criteria developed by the eight EPCs that conducted pilot FRN projects into the preexisting EHC topic selection criteria, acknowledging repetition and adding wording that enhanced the criteria description. After modification, the remaining criteria were divided into two prioritization steps as appropriate to the process of identifying FRNs and suggesting specific study designs. These criteria and steps were shared with EPCs that continue to conduct FRN projects and are reported below as suggested practices.
Prioritization

EHC Topic Selection Criteria

The EHC Program has 5 domains with 18 criteria for the selection of topics for SRs/CERs.\textsuperscript{1,5} The five overarching domains are (Table 1): Appropriateness (three criteria), Importance (seven criteria), Duplication (one criterion), Feasibility (one criterion), and Potential Value (six criteria).\textsuperscript{1}
<table>
<thead>
<tr>
<th>Appropriateness</th>
<th></th>
</tr>
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<tbody>
<tr>
<td>1 Represents a health care drug, intervention, device, or technology available</td>
<td></td>
</tr>
<tr>
<td>(or soon to be available) in the United States.</td>
<td></td>
</tr>
<tr>
<td>2 Relevant to enrollees in programs specified in Section 1013 of the Medicare</td>
<td></td>
</tr>
<tr>
<td>Modernization Act of 2003 (Medicare, Medicaid, Children's Health Insurance</td>
<td></td>
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<tr>
<td>Program [CHIP], other Federal health care programs).</td>
<td></td>
</tr>
<tr>
<td>3 Represents one of the priority health conditions designated by the</td>
<td></td>
</tr>
<tr>
<td>Department of Health and Human Services.</td>
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<tr>
<td>Importance</td>
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</tr>
<tr>
<td>1 Represents a significant disease burden affecting a large proportion of</td>
<td></td>
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<tr>
<td>the population or a priority population (e.g., children, elderly adults,</td>
<td></td>
</tr>
<tr>
<td>low-income, rural/inner city, minorities, or other individuals with</td>
<td></td>
</tr>
<tr>
<td>special health care or access issues).</td>
<td></td>
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<tr>
<td>2 Is of high public interest, affecting health care decision making,</td>
<td></td>
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<tr>
<td>outcomes, or costs for a large proportion of the U.S. population or for a</td>
<td></td>
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<tr>
<td>priority population in particular.</td>
<td></td>
</tr>
<tr>
<td>3 Was nominated/strongly supported by one or more stakeholder groups.</td>
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<tr>
<td>Desirability of new research / duplication</td>
<td></td>
</tr>
<tr>
<td>1 Potential for redundancy (i.e., whether a proposed topic is already</td>
<td></td>
</tr>
<tr>
<td>covered by an available or soon-to-be available high-quality systematic</td>
<td></td>
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<tr>
<td>review by AHRQ or others).</td>
<td></td>
</tr>
<tr>
<td>Feasibility</td>
<td></td>
</tr>
<tr>
<td>1 Adequacy (type and volume) of research for conducting a systematic review.</td>
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<tr>
<td>New availability evidence (particularly for updates or new technologies.</td>
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<tr>
<td>2 Potential for significant health impact:</td>
<td></td>
</tr>
<tr>
<td>To improve health outcomes.</td>
<td></td>
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<tr>
<td>To reduce significant variation in clinical practices known to be related to</td>
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<tr>
<td>quality of care.</td>
<td></td>
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<tr>
<td>To reduce unnecessary burden on those with health care problems.</td>
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<tr>
<td>3 Potential for change:</td>
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<tr>
<td>Proposed topic exists within a clinical, consumer, or policymaking context</td>
<td></td>
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<tr>
<td>that is amenable to evidence-based change.</td>
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<tr>
<td>A product from the EHC program could be an appropriate vehicle for change.</td>
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<tr>
<td>4 Potential risk from inaction:</td>
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<tr>
<td>Unintended harms from lack of prioritization of a nominated topic.</td>
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<tr>
<td>5 Addresses inequities, vulnerable populations (including issues for patient</td>
<td></td>
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<tr>
<td>subgroups).</td>
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<tr>
<td>6 Addresses a topic that has clear implications for resolving important</td>
<td></td>
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<tr>
<td>dilemmas in health and health care decisions made by one or more stakeholder</td>
<td></td>
</tr>
<tr>
<td>groups.</td>
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</table>

Abbreviations: 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 six criteria listed in Table 2. As a result, one does not necessarily need to revisit all of these criteria again when prioritizing FRNs. Of the aforementioned topic selection criteria, the three criteria of Appropriateness and the first three criteria of Importance are the default criteria; for clarity, these criteria could potentially be listed in a footnote with the FRN prioritization (Table 2).

### Table 2. Default criteria—always met prior to future research needs proposals*

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Represents a health care drug, intervention, device, or technology available (or soon to be available) in the United States.</td>
<td></td>
</tr>
<tr>
<td>Relevant to enrollees in programs specified in Section 1013 of the Medicare Modernization Act of 2003 (Medicare, Medicaid, Children’s Health Insurance Program [CHIP], other Federal health care programs).</td>
<td></td>
</tr>
<tr>
<td>Represents one of the priority health conditions designated by the U.S. Department of Health and Human Services.</td>
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<tr>
<td>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).</td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>Was nominated/strongly supported by one or more stakeholder groups.</td>
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</tbody>
</table>

*Appropriateness and Importance criteria included by default, in consideration 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 and do not have to be rechecked for FRN prioritization.

Of the remaining three EHC topic selection criteria (Desirability of New Research/Duplication, Feasibility, and Potential Value), 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). Therefore, when prioritizing future research needs, the process may be completed sequentially; first working with stakeholders to consider potential value and desirability, and then considering study design and feasibility as the subsequent step.

### Prioritization of Future Research Needs

After identifying the research gaps from a CER/SR, the EPC will work with stakeholders to identify the research that would fill those gaps, and then prioritize the research areas that are the most important. The EPC will identify and actively engage the important partners with a stake in conducting, funding, or using future research. Gathering meaningful input requires a careful selection of representatives as well as establishing a fair process for considering their input. This is often a multistep 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. Discussing future research needs for the clinical management of a condition will often require specification of the PICO elements (People/Population/Subpopulation/Patients with the condition, Intervention [Exposure, Test], Comparators, and Outcomes, Figure 1, bullet 4). 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. The proposed primary and secondary outcome measures, including surrogate measures and process measures should be itemized (O). Some of the research needs may be methodologic, and the PICO model will not apply. Methods research needs could be prioritized separately from content research needs.

The EPC will engage the stakeholders to consider which of these future research topic areas have the highest potential value (Figure 1, bullet 5). In order to inform the ranking process, we propose six potential value criteria (Table 3). The components of potential value criteria 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. EPCs have found that it often required at least two rounds of interaction with stakeholders to achieve prioritization of specific 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 3), the EPC will conduct a targeted scan of ongoing research. In the first phase of interaction with stakeholders, the lists of research needs are refined, with greater specificity and a preliminary round of prioritization may occur. In the second phase of interaction with stakeholders, final prioritization of the future research needs will be completed.

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 (Figure 1, bullet 6).
### Table 3. PiCMe potential value criteria

<table>
<thead>
<tr>
<th>PiCMe Criteria: EHC Criteria, Modified for Future Research, Supplemented With Additional Criteria</th>
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<tbody>
<tr>
<td><strong>Potential value criteria (for significant health impact): addressing evidence gap (knowledge, translation, implementation)</strong></td>
</tr>
<tr>
<td><strong>V1</strong></td>
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<tr>
<td><strong>V2</strong></td>
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<td><strong>V3</strong></td>
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<tr>
<td><strong>V4</strong></td>
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<tr>
<td><strong>V5</strong></td>
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**Abbreviations:** EHC = Effective Health Care; PiCMe = Prioritization Criteria Methods

Discussing the potential value of a future research need will sometimes be supported by specification of the PICOTS elements, and by presentation of the current strength of evidence (SoE) for the specific outcome of the PICOTS, based upon the current best evidence summarized in the CER/SR. The current strength of evidence could be used as a factor in the potential value prioritization; if the current SoE is low, higher value might be associated with new knowledge than if the current SoE is moderate. The PICO may be important in a situation where there is high SoE for one population group, but low or insufficient for another group; the PICO specificity would clarify that the prioritization was for the future research need for that specific population.

Different techniques may be used to support the stakeholder prioritization, using the criteria. One approach is to use multivoting or other ranking technique to shorten the initial list of FRNs, and then using a numeric scoring of each criterion for each FRN proposal to arrive at a prioritized rank order. Another approach is to use a numeric scoring of each criterion for each FRN proposal as an initial step, and then shorten the list to the high-scoring group, followed by a voting or multi-voting technique to arrive at a prioritized rank order. Likert scale numeric selection for each criterion for each FRN proposal could also be used, as an alternative to multivoting. 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 choosing not to apply a weighted value to each criterion effectively means a de facto equal value of one for each criterion. Stakeholders may assign a numeric value (weight) to each of the six criteria, so that this value may be multiplied by the prioritization assessment to provide a balance of criteria that reflects the relative values. If
stakeholders do not explicitly assign a weight to each criteria, or there is not agreement among stakeholders, the EPC may ask the stakeholders to be explicit about which criteria was most important when they selected their top priority research needs, and document this.

The approaches described here may be adapted based on decisions by the EPC and the stakeholders; including but not restricted to the criteria themselves; the techniques for applying the criteria, and the weight or value of each criterion. More practical testing is likely to be informative.

Criteria for Considering Study Designs

Beyond identifying future research needs of high importance to decisionmakers, it is also important to work with stakeholders to understand the feasibility of conducting new research that can answer the question being asked. It is important to engage a broad range of researchers experienced in various methodology types to identify what studies could possibly be conducted to help answer the question. The studies needed to answer many questions may not be feasible due to issues such as study design, capacity, ethical issues, duration, or rarity of disease.

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
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 describes a methodology for prioritizing the FRN recommendations. The proposed methodology used the foundation of existing EHC topic selection criteria and adapted them to be fit for purpose for the stakeholders with an interest in identifying prioritizing future research needs. This paper particularly focuses on the Potential Value criteria used when working with stakeholders to prioritize the FRN proposals derived from a CER/SR.
References


