

Draft Methods Report

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Framework for determining research gaps during systematic review: Evaluation

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Statement of Funding and Purpose

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Preface

The Agency for Healthcare Research and Quality (AHRQ) conducts the Effective Health Care Program as part of its mission to organize knowledge and make it available to inform decisions about health care. As part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Congress directed AHRQ to conduct and support research on the comparative outcomes, clinical effectiveness, and appropriateness of pharmaceuticals, devices, and health care services to meet the needs of Medicare, Medicaid, and the State Children's Health Insurance Program (SCHIP).

AHRQ has an established network of Evidence-based Practice Centers (EPCs) that produce Evidence Reports/Technology Assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care. The EPCs now lend their expertise to the Effective Health Care Program by conducting Comparative Effectiveness Reviews (CERs) of medications, devices, and other relevant interventions, including strategies for how these items and services can best be organized, managed, and delivered.

Systematic reviews are the building blocks underlying evidence-based practice; they focus attention on the strength and limits of evidence from research studies about the effectiveness and safety of a clinical intervention. In the context of developing recommendations for practice, systematic reviews are useful because they define the strengths and limits of the evidence, clarifying whether assertions about the value of the intervention are based on strong evidence from clinical studies. For more information about systematic reviews, see

<http://effectivehealthcare.ahrq.gov/reference/purpose.cfm>

AHRQ expects that CERs will be helpful to health plans, providers, purchasers, government programs, and the health care system as a whole. In addition, AHRQ is committed to presenting information in different formats so that consumers who make decisions about their own and their family's health can benefit from the evidence.

As part of a new effort in 2010, the Agency for Healthcare Research and Quality (AHRQ) has supported EPCs to work with various stakeholders, including patients, to further develop and prioritize the future research needed by decisionmakers. The Future Research Needs products are intended to inform and support researchers and those who fund research to ultimately enhance the body of comparative effectiveness evidence so that it is useful for decisionmakers.

Transparency and stakeholder input are essential to the Effective Health Care Program. Please visit the Web site (www.effectivehealthcare.ahrq.gov) to see draft research questions and reports or to join an e-mail list to learn about new program products and opportunities for input.

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The investigators deeply appreciate the considerable support, commitment, and contributions of the EPC team staff at <NAME>. We express our gratitude to the following individuals for their contributions to this project: <NAME>

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Structured Abstract

Background: Research gaps prevent systematic reviewers from making conclusions and, ultimately, limit our ability to make informed health care decisions. While there are well-defined methods for conducting a systematic review, there has been no explicit process for the identification of research gaps from systematic reviews. In a prior project we developed a framework to facilitate the systematic identification and characterization of research gaps from systematic reviews. This framework uses elements of PICOS (Population, Intervention, Comparison, Outcomes) to describe the gaps and categorizes the reasons for the gaps as (A) insufficient or imprecise information, (B) biased information, (C) inconsistent or unknown consistency results, (D) not the right information.

Objective: To further develop and evaluate a framework for the identification and characterization of research gaps from systematic reviews.

Methods: We applied the framework to 50 systematic reviews. Evidence-based Practice Centers (EPCs) also applied the framework either during a systematic review or during a future research needs project (FRN). EPCs provided feedback on the framework using an evaluation form.

Results: Our application of the framework to 50 systematic reviews identified about 600 unique research gaps. Key themes emerging from this task included the need to clarify instructions for dealing with multiple comparisons (lumping versus splitting) and added guidance for applying the framework retrospectively. We received evaluation forms from seven EPCs. EPCs applied the framework in 8 projects, five of which were FRNs. Key themes emerging from the evaluation forms included those we identified during our application of the framework, plus further clarification of the purpose of the framework, and the relationship of the framework to the assessment of the strength of evidence.

Conclusions: Our team evaluated a revised framework, worksheet and instructions. A final version is provided that incorporates revisions based on use of the framework across additional systematic reviews, including application by other EPCs. Future research would be helpful to test application during a systematic review as well as to evaluate the value of using the framework, for review authors and users of the reviews.

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Introduction

Evidence reports produced by Evidence-based Practice Centers (EPCs) have always included a future research section. However, in contrast to the explicit and transparent steps taken in the completion of a systematic review, there has not been a systematic process for the development of the future research sections.

In a prior methods project, our EPC set out to identify and pilot test a framework for the identification of research gaps.^{1,2} We searched the literature, conducted an audit of EPC evidence reports, and sought information from other organizations involved with evidence synthesis. Despite these efforts, we identified little detail or consistency in the frameworks used to determine research gaps within systematic reviews. In general, we found no widespread use or endorsement of a specific formal process or framework for identifying research gaps using systematic reviews.

We developed a framework to systematically identify research gaps from systematic reviews. This framework provided for the classification of where the current evidence falls short and why the evidence falls short. The framework included two elements: (i) the characterization the gaps and (ii) the identification and classification of the reason(s) for the research gap.

The PICOS structure (Population, Intervention, Comparison, Outcome and Setting) was used in this framework to describe questions or parts of questions inadequately addressed by the evidence synthesized in the systematic review. The issue of timing, sometimes included as PICOTS, was considered separately for Intervention, Comparison, and Outcome. The PICOS elements were chosen as this was the only sort of framework we had identified in an audit of existing methods for the identification of gaps used by EPCs and other related organizations (i.e., health technology assessment organizations). We also chose to use this structure as it is one familiar to EPCs, and others, in developing questions.

We felt it was not only important to identify research gaps but to determine how the evidence falls short, in order to maximally inform researchers, policy makers, and funders on the types of questions that need to be addressed and the types of studies needed to address these questions. Thus, the second element of the framework was the classification of the reasons for the existence of a research gap. For each research gap, the reason(s) that most preclude conclusions from being made in the systematic review is chosen by the review team completing the framework. To leverage work already being completed by review teams, we mapped the reasons for research gaps to concepts from commonly used evidence grading systems. Briefly, these categories of reasons, explained in detail in the prior JHU EPC report¹, are:

- A. Insufficient or imprecise information
- B. Biased information
- C. Inconsistent or unknown consistency results
- D. Not the right information

The framework facilitates a systematic approach to identifying research gap and the reasons for those gaps. The identification of where the evidence falls short and how the evidence falls short is essential to the development of important research questions and in providing guidance in how to address these questions. A comprehensive and explicit consideration of the existing evidence is necessary to identify unanswered and answerable questions and for the design of studies most likely to answer these questions.

As part of the previous methods product, we developed a worksheet and instructions to facilitate the use of the framework when completing a systematic review (See Appendix A). Preliminary evaluation of the framework, and worksheet, was completed by applying the framework to two completed EPC evidence reports. The framework was further refined through peer review. In this current project, we extend our work on this research gaps framework.

Our objective in this project was to complete two types of further evaluation (i) application of the framework across a larger sample of systematic reviews in different topic areas, and (ii) implementation of the framework by EPCs. These two objectives were used to evaluate the framework and instructions for usability and to evaluate the application of the framework by others, outside of our EPC, including as part of the process of completing an EPC report. Our overall goal was to produce a revised framework and instructions that could be used by EPCs to explicitly identify research gaps from systematic reviews.

Methods

We completed four steps as outlined below.

1.) Review and revise framework and develop detailed instructions

The framework and instructions were reviewed by team members, some of whom were not involved in the initial project. The framework and instructions were modified based on discussion.

2.) Test framework and instructions through application to existing systematic reviews

We tested the application of the revised framework and instructions with a sample of 50 systematic reviews of randomized controlled trials of clinical topics.

We applied the framework to all eligible EPC reports from 2009 to 2011. (Reports from 2007 to 2008 were included in the audit conducted in our prior report). We searched the AHRQ website for reports posted from January 1, 2009 to December 12, 2011 (<http://www.effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports>). We retrieved reports for consideration by selecting the heading "Search for Guides, Reviews, and Reports"; selecting, under Report Types, "Research Reviews" and then selecting, under Project Status, "Final".

We also applied the framework to a random sample of Cochrane systematic reviews from 2009 to 2011. We searched The Cochrane Database of Systematic Reviews for reviews published from January 1, 2009 to December 12, 2011. The search was completed by selecting the date range 2009-2011, all issues, and restricting to 'reviews'.

Search results for the EPC reports and Cochrane reviews were screened serially by two team members using title and abstract to identify systematic reviews that:

- were published or completed within the time range of interest
- represented final or complete reviews
- addressed a clinical topic
- addressed questions about effectiveness or comparative effectiveness of therapies
- included randomized controlled trials

All eligible EPC reports were included. All Cochrane reviews were entered with a corresponding auto-generated reference number into a spreadsheet for random selection. Randomly selected Cochrane reviews were then screened using criteria and process described above. We selected the number of Cochrane reviews that, when added to the included EPC reports, would equal a combined total of 50 systematic reviews.

Two independent trained team members applied the framework to the 50 systematic reviews. To track progress, and maintain the results, the framework worksheet was translated to forms on DistillerSR (EvidencePartners, Ottawa, ON, Canada) and full-text articles of all eligible systematic reviews were uploaded. Pilot testing of the revised framework (from step #1) was conducted in October and November 2011. A training session on the use of the framework as translated into online forms was held December 9, 2011. Pilot testing of the system in DistillerSR was completed at the end of December 2011, with abstraction starting December 22,

2011. Abstraction was completed by April 1, 2011. Reviewers were asked to track and share any issues encountered in applying the framework. A comparison of the information abstracted by each reviewer was also completed to highlight any discrepancies that might indicate issues to address in the framework or instructions. A third team member reviewed all abstractions and brought forward to the team any apparent discrepancies or issues in the characterization of gaps or the reasons for gaps. These were discussed and common themes identified, for which responses were determined (i.e., revisions to framework or instructions).

3.) Evaluate implementation of framework

We issued multiple invitations for EPCs to apply the framework to identify gap in one or more of one of their projects. For instance, an invitation was issued during presentations at both the spring and fall 2011 EPC Directors' meetings, as well as via email (January 2012). An evaluation form was developed (Appendix B) to solicit structured feedback from the EPCs. There was no restriction on the type of review or future research needs project (FRN), in terms of question(s) or study design, that the EPC could consider using in applying the framework. (FRNs engage various stakeholders to develop and prioritize future research needs identified from EPC evidence reviews.) EPCs were asked to submit a completed evaluation form after use of the framework and were not asked to submit completed framework worksheets.

4.) Revise and finalize framework and instructions

Based on results of the evaluations, our team revised the framework and instructions.

Peer Review and Public Commentary

A draft of the report will be reviewed by AHRQ representatives and peer reviewers, and will be posted for public view and comment. Comments received will be reviewed and a report of comments and their disposition will be prepared and submitted with a revised report.

Results

1.) Review and revise framework and develop detailed instructions

The team reviewed and discussed the original framework and instructions. Revisions were made iteratively and based on consensus. The initial revised framework and instructions are provided in Appendix C. The primary revision of the framework was the addition of sub-categories for the reasons for the gap. The team felt that further granularity within the categories of reasons for gaps would make completion of the framework more straightforward for review teams, and would ease translation of research gaps to specific research questions, with guidance for studies needed to address those questions.

Definitions for each sub-code were added to the instructions.

The specific reasons for gaps are listed in the footnote of the worksheet and described below:

A. Insufficient or imprecise information

Information is insufficient or imprecise if data are sparse and thus uninformative and/or confidence intervals are wide and thus can include conflicting results or conclusions.

A1 – This reason should be selected if no studies are identified.

A2 – This reason should be selected if a limited number of studies are identified.

A3 – This reason should be selected if the sample sizes or event rates in the available studies are too small to allow conclusions.

A4 – This reason should be selected if the estimate of the effect (such as achieved from a meta-analysis) is imprecise. That is, if the width of the confidence interval is such that the conclusion could be for benefit or harm.

B. Information at risk of bias

The aggregate risk of bias is contingent upon the risk of bias of the individual studies.

B1 – This reason should be selected if the study design(s) are inappropriate to address the question of interest (e.g., non-randomized studies for question where randomized studies are more appropriate).

B2 – This reason should be selected if there are major methodological limitations to the available studies leading to high risk of bias or limited internal validity.

C. Inconsistency or unknown consistency

Consistency is the degree to which results from included studies appear to be similar or in concordance.

C1 – This reason should be selected if only one study is identified. If there is only one available study, even if considered a large sample size, the consistency of results is unknown.

C2 – This reason should be selected if the results from available studies are inconsistent. Elements to consider include whether effect sizes vary widely, if the range of effect sizes is wide, limited or no overlap of confidence intervals, and, as appropriate, if statistical tests, such as I^2 , indicate heterogeneity.

D. Not the right information

There are a number of reasons why identified studies might not provide the right information to make conclusions about the review question.

D1 – This reason should be selected if the results from studies might not be applicable to the population of interest.

D2 – This reason should be selected if the duration of the interventions and/or comparisons is considered too short.

D3 – This reason should be selected if participants are not followed up for long enough duration in the included studies.

D4 – This reason should be selected if the optimal and/or most important outcomes are not assessed in the included studies. This reason also includes instances where only data on surrogate outcomes are available while data on more clinical and/or patient-important outcomes are needed.

D5 – This reason should be selected if the results from studies might not be applicable to the setting of interest. This would include cases where the interventions assessed in the studies are not applicable or available in setting of interest.

2.) Test framework and instructions through application to existing systematic reviews

There were 23 EPC reports published on the Effective Health Care Program website from January 1, 2009 to December 12, 2011. During screening, four were deemed ineligible due to the following reasons: “not an effectiveness review (n = 2) and “not a clinical topic” (n = 2).

There were 19 eligible EPC reports; therefore, 31 Cochrane reviews were randomly selected for initial consideration of eligibility criteria to bring the total sample of systematic reviews to 50. There were 6,967 records for January 1, 2009 to December 12, 2011 in the Cochrane Database of Systematic Reviews. Removing protocols, there were 4,269 records. After random sorting and selecting 31 reviews, 6 were determined to be ineligible due to the following reasons: “no RCTs included” (n = 3) and “not a clinical topic” (n = 3). After random selection of an additional 6 reviews, all 6 were deemed eligible.

There were 144 review questions included in the 50 systematic reviews. Of the 31 Cochrane reviews, 23 had one review question, 8 had two review questions (average 1.3 questions per review). This was quite different for the EPC reports; the smallest number of review questions was 4 and the highest was 7, with an average of 5.5 review questions per report. The estimated time taken for each reviewer to complete full gaps abstraction was about 7.5 hours for an EPC report and about 3 hours for a Cochrane review. Our four reviewers, two reviewers for each systematic review, took approximately 11 weeks total to complete gaps abstraction for the 50 systematic reviews.

The total number of gaps abstracted, counting those abstracted by each reviewer separately, was 1,830. The number of gaps per key question per reviewer ranged from 1 to 165. The average number of gaps abstracted by each reviewer per key question was 8.5 and 14.3 for the Cochrane reviews and EPC reports respectively. The overall mean number of gaps that each reviewer abstracted per key question was 12.7.

However, in reviewing the abstracted information we noted that one reviewer abstracted 165 gaps for one of the questions while the other reviewer abstracted 5 gaps for the same review question. This large discrepancy was due to the former abstractor listing each gap separately and the latter reviewer grouping interventions, comparators and outcomes together. After removing

this outlier value, the number of gaps per key question per reviewer ranged from 1 to 99. The average number of gaps abstracted by each reviewer per key question was 8.5 and 12.75 for the Cochrane reviews and EPC reports respectively. The overall mean number of gaps that each reviewer abstracted per key question was 11.6. Based on these averages, there were about 264 gaps identified from the Cochrane reviews (31 reviews x 8.5 gaps per review) and about 242 gaps identified from the EPC reviews (19 reviews x 12.75 gaps per review). We estimate that if full adjudication were completed there would be about 600 unique research gaps identified.

Insufficient or imprecise information (Gap Reason A) was the most frequent reason that prevented the original reviewers from reaching a conclusion on several research questions (Gap Reason A was used 1,716 times). Inconsistency or unknown consistency among studies (Gap Reason C) was the next common reason for the research gaps (selected 462 times). The reason ‘not the right information’ (Gap Reason D) was chosen 273 times. Biased information (Gap Reason B) was selected 227 times. There were 18 instances where reviewers thought that gaps existed due to another reason (the gap reason did not fit into Gap Reason code A, B, C, or D). Table 1 provides a breakdown by reason code. Note that multiple reasons could be selected for each gap, and these are total numbers across both reviewers’ abstractions.

Table 1: Reasons for gaps

Gap Reason	Number of Times Selected*
A – Insufficient or imprecise information	1,716
A-1 No studies	790
A-2 Limited number of studies	507
A-3 Small sample sizes	140
A-4 Imprecise estimate of effect	279
B – Biased information	227
B-1 Inappropriate study design	91
B-2 Major methodological limitations	136
C – Inconsistency	462
C-1 Consistency unknown	297
C-2 Inconsistent results	165
D – Not the right information	273
D-1 Results not applicable to population	51
D-2 Inadequate duration of intervention	21
D-3 Inadequate duration of follow-up	73
D-4 Most important outcomes not addressed	128
D-5 Results not applicable to setting	25
Other reason	18

* Includes selection by either reviewer; multiple reasons may be selected for a gap

Two trained team members independently applied the framework retrospectively to existing systematic reviews. A third team member reviewed all abstractions and brought forward to the team apparent discrepancies in the number and type of gaps, as well as the reasons for gaps, abstracted from the same review question. This iterative adjudication process identified a number of issues. The key themes, and our responses, are outlined in Table 2. Completing full adjudication was considered beyond the scope of this report, but is planned as future work.

Table 2: Key themes from adjudication process

Theme	Response
After the pilot test, it was apparent that some reviewers were reading through results and determining gaps based on their own interpretation.	Clarified with team the process for this project. Added discussion in instructions about differences and considerations in applying framework during systematic review compared to retrospectively applying framework to existing systematic review.
Some reviewers abstracted details about the population into the worksheet, even when those details were included in the original review question.	We added additional details to the instructions about the elements to be abstracted into PICOS columns of worksheet.
The same gaps were sometimes characterized as one and sometimes treated as separate gaps.	A discussion of the issue of ‘lumping versus splitting’ has been added to the instructions.
Reviewers put similar text in “Gap Text” or “Notes”.	Guidance for how to use these columns has been added to the instructions.

3.) Evaluate implementation of framework

After several reminders, 7 EPCs submitted 8 evaluations (one EPC submitted an evaluation form from two different project teams). Most evaluation forms were submitted in June with the last submitted July 7, 2012. Detailed results are provided in Appendix D.

Five (63%) used the framework during the completion of a future research needs project (FRN). The remainder applied the framework as part of a systematic review. Because there may be differences in how the framework works when applied retrospectively rather than during a systematic review, we have noted next to the feedback comments whether the framework was applied during a systematic review or as part of a FRN.

All 8 respondents indicated that they had previously identified gaps from systematic reviews. However, only one provided a description of methods that had been used by the EPC to identify gaps. The other respondents typically listed prior FRN topics rather than describe any methods that they had used for the identification of gaps.

Respondents noted a number of advantages to using the framework. The primary advantage noted was that use of the framework facilitated a structured and systematic approach. Respondents highlighted that this was in contrast to the somewhat ‘arbitrary’ process typically used, and that use of the framework may limit the potential influence of the particular priorities of the research team.

Each respondent provided feedback on the disadvantages and problems, as well as suggestions, for the framework and instructions. We have provided a detailed response to each comment in Appendix D. The common themes of issues raised were:

- Implementation of framework to reviews or questions with very limited evidence
- Implementation of framework to questions for which strength of evidence was not assessed
- Completing worksheet when there are gaps comprising multiple comparisons and/or outcomes

4.) Revise and finalize framework and instructions

We added or revised text, and included examples, to provide clarification or further guidance within the instructions. The final framework worksheet and instructions are provided in Appendix E.

Discussion

Key Findings

- We revised the framework to provide for more granular coding for the reason for the research gap.
- Each of the EPC respondents indicated that they had previously identified research gaps from systematic reviews. However, only one described methods used to identify gaps. This finding is in line with results from prior EPC project that EPCs and other systematic reviewers do not use formal methods or frameworks for identifying gaps from systematic reviews.
- Key themes emerged from our application of the framework to existing systematic reviews, and through the evaluation of the use of the framework by EPCs. Common themes included at what point the framework is applied (during a systematic review or retrospectively using an existing systematic review) and the level of detail needed when characterizing gaps (i.e., lumping versus splitting). We modified the instructions to address the challenges by providing suggestions for addressing the challenges, and highlighting areas that should be discussed by team members prior to the identification of research gaps using the framework.

Limitations

We chose to apply the framework to 50 systematic reviews to have a number that could be accomplished within our timeframe, yet a large enough number to include systematic reviews across a range of topics. We limited our application to systematic reviews of randomized controlled trials of clinical topics. We imposed this restriction to get a more homogenous set of systematic reviews; to be more certain that differences we saw during application of the framework were due to potential issues with the framework rather than distinct differences in the study design included or topic addressed by the systematic review (i.e., clinical versus other). Future testing of the framework, for different sort of questions, including reviews of other study designs and different sorts of questions, may lead to further revisions of the framework or instructions.

We chose to include Cochrane reviews, in a number to add to 50 when EPC reports included, as these reviews follow a clear and explicit method, and were likely to meet eligibility criteria (i.e., include RCTs and address clinical topic). This was seen as preferable to conducting a search and screen for eligible systematic reviews.

We were able to solicit feedback from 8 different EPC teams, however, only 3 of these applied the framework to an ongoing systematic review (and one of these applied the framework after completing of the results section). Further use during a systematic review may identify issues or challenges requiring additional revisions to the framework or instructions.

We did not ask EPCs to track the time it took them to apply the framework. We had discussed this in detail and ultimately felt that it was not a matter of simply completing the framework worksheet. The process, similar to grading strength of evidence, is inherently

iterative so it is not clear at what point one would start and stop the clock. Issues of how the use of the framework fits into a systematic review project, including considerations of any additional time needed, is an area for future research.

On a related note, we did not assess the best process for application of the framework. We feel that the same team process should be used as in completing the strength of evidence assessments. As with the strength of evidence assessments, there is judgment involved in identifying and characterizing gaps. This suggests a need for team orientation and pilot testing, followed by team discussions after the completion of the process.

While we asked EPCs to try using the framework as part of one of their projects we have limited information about how the EPCs applied the framework. To that end, we don't know if the EPCs applied the framework as an academic exercise (therefore providing information on usability) or if they integrated the completion of the framework with a current project (that might provide us with better idea of usefulness). Similarly, we do not know how, or if, EPCs used the results of applying the framework in their project(s).

Future Research

There are several outstanding questions or research that may further this work:

- Do the changes made to framework and instructions improve usability? As review teams use the framework there may be additional challenges identified. Further testing across different types of questions, and with reviews including different study designs, may be completed. A set of examples may be added to the instructions to illustrate common issues, such as how to use the framework to capture methodological gaps.
- What is the best process for using the framework? What is the most efficient and appropriate way to integrate this process into the conduct of systematic review or FRN? Is there an optimal time during a systematic review or FRN at which to complete the framework?
- In our previous report, we had proposed a format for presenting research gaps. Further research could assess the best way for team members to use and present the results of the application of the framework to, depending on their objectives:
 - (a) develop future research needs sections for systematic reviews, or
 - (b) solicit input from stakeholders in developing Future Research Needs documents.
- Similar to the assessment of strength of evidence, the identification of gaps and the reasons for gaps is based on interpretation and judgment. We outlined in the instructions some issues that should be discussed by a team before starting to identify research gaps. Included are the often arbitrary decisions about which reason(s) is most important in limiting ability to draw conclusions. Future research could determine if a decision system, like a hierarchy, could be established to aid these decisions. Such a ranking might be based on the extent of influence in limiting conclusions and/or the ability to ameliorate the reason(s) through future studies.
- The framework facilitates a more systematic approach to the identification of research gaps, but there is little research on how this information may be utilized and by whom, and whether gaps identified through the framework are more useful. Does using a formal method to identify gaps, such as the framework, provide value for the systematic review authors and for the users of the systematic review (or FRN)? A comparison to other

methods would answer questions such as whether use of the framework identifies more research gaps, whether gaps are characterized more completely, and whether gaps identified in this way provide a better basis for the development of research agendas.

As noted earlier, we also plan to complete full adjudication of the gaps, and reasons for gaps, abstracted during this project with a goal of quantitatively and qualitatively describing the characteristics of the gaps, and the relative proportions of research gaps that are due to different types limitations in the evidence. This will provide an evidential basis upon which to improve the design of future RCTs to better address comparative effectiveness questions.

Implications for Practice

The first question in determining whether and how to use the framework is the purpose of identifying gaps. This will determine the level of granularity needed for the characterization of the research gaps. The second question is related to the systematic review being used to identify gaps. For instance, if the team feels like “the entire systematic review is a gap” then it may not be worthwhile going through the process of using the framework. However, we do feel that even in that case the elements of the framework may help to ensure an explicit process.

We recognize that there are different structures for systematic review teams. We suggest that the framework be applied by the same team members, and process, as employed in completing the strength of evidence grading. We make this suggestion based on our findings that there are different challenges in applying the framework retrospectively, and to increase the potential for leveraging the work completed in assessing the strength of evidence.

If completing the identification of research gaps as part of a FRN or otherwise using framework in a retrospective manner with existing systematic reviews, we have some specific suggestions:

- Restrict abstraction of gaps and reason(s) for gaps to explicit statements made by the review authors. Do not review and interpret the specific results to identify gaps or reasons for gaps. Abstract the gaps and reasons for gaps that are specifically noted by the systematic reviewer authors.
- The team completing the abstraction retrospectively should meet to discuss and agree on sections to be reviewed (text, tables, etc.) as well as what to do if there are apparent discrepancies between sections of the systematic review.
- Inserting the section name and page number(s) (in Notes field of framework worksheet) used to identify a gap might be helpful for adjudication and review.

For an FRN, the gaps identified could be used by the team in developing the list of gaps to be presented to and considered by stakeholders. Depending on the number of gaps identified the team may choose to prioritize or categorize the gaps prior to presentation to stakeholders.

Whether being completed during a systematic review or applied retrospectively, the instructions (Appendix E) should be reviewed by all participating team members prior to use of the framework. To leverage the work of assessing strength of evidence, the relevant guidance on the grading system should also be reviewed. Pilot testing should be completed with, as in strength of evidence assessment training, meetings with the full team to calibrate judgments. As noted in the instructions, the research gap framework may be used in different formats (Word, Excel, Access, DistillerSR) depending on the process being employed by the review team.

Conclusions

In our prior project, we found that very few systematic reviewers used an explicit method to identify research gaps. We completed further evaluation and development of a framework to identify research gaps from systematic reviews. Our framework may be applied during the conduct of or using existing systematic reviews to facilitate an explicit process to characterize where the current evidence falls short and why or how the evidence falls short.

Reference list

1. Robinson KA, Saldanha IJ, Mckoy NA. Frameworks for determining research gaps during systematic reviews. Methods Future Research Needs Report No. 2 AHRQ Publication No. 11-EHC043-EF. Rockville, MD: Agency for Healthcare Research and Quality. June 2011. PMID: 21977524
2. Robinson KA, Saldanha IJ, Mckoy NA. Development of a framework to identify research gaps from systematic reviews. *Journal of Clinical Epidemiology* 2011 Dec;64(12):1325-30. PMID: 21937195