Topic Refinement Content Guidance Document

Note: Topic Refinement Document is not for public distribution.

Introduction

This document describes the three stages of refining the topic of an evidence product and outlines what Evidence-based Practice Centers (EPCs) need to deliver to AHRQ at each stage. EPCs create the topic refinement document sequentially in three parts and submit each part separately to AHRQ on completion.

- Part 1 records activities and decisions from topic refinement to Key Informant input.
- Part 2 documents activities and decisions from Key Informant engagement to public posting.
- Part 3 describes the elements for public posting on the Effective Health Care website for public comment.

This guidance pertains to both public nominations of topics (which are vetted through a topic nomination and selection procedure) and nominations from various partners or other federal agencies. For further details about submission, please see the *EPC Procedure Guide*.

Successful topic refinement will:

- Yield clear statements of the **decisional dilemmas to be addressed**, and the **intended use** (purpose) **and audience** for the subsequent evidence report.
- Ground the report efforts in finding and synthesizing **evidence to assist decisionmaking.**

To support these ends, this guidance aims to:

- Clarify that **EPCs have latitude** in discussing ways to focus the scope and Key Questions with partners and AHRQ throughout the topic refinement process.
- Underscore that **EPCs should exercise their judgment** concerning the breadth and depth of the proposed scope.

For each of the three products (Parts 1, 2, and 3), please place the following information on the first page of each section. While submission date may change for each product, the other elements (with the possible exception of the AHRQ TOO) will stay the same.

Date:

Topic:

EPC:

AHRQ Task Order Officer:

Partner:

Part 1: Summary of the Decisional Dilemmas and Preliminary Scope Development (Key Questions, PICOTS, and Analytic Framework)

Main Steps

EPCs should complete and submit Part 1 to AHRQ before their Key Informant (KI) discussions. Portions of this section, which is regarded as preliminary, will inform KI discussions and provide context for KIs.

Part 1 asks EPCs to briefly describe the decisional dilemmas the evidence product will address along with the intended audience and purpose. While the EPC's understanding of the dilemmas and purpose may evolve through this process, EPC authors will need to document this evolution. Part 1 also asks EPCs to document the development of three central elements: preliminary key questions (KQs); the populations, interventions, comparators, outcomes, timing, and settings (PICOTS); and the analytic framework (AF).

The decisional context, KQs, PICOTS, and AF outline the initial proposed scope of the topic. The preliminary literature scan can inform discussion about relevant interventions, comparators, outcomes, and other feasibility considerations.

Preliminary Background (Decisional Dilemmas)

EPCs should briefly describe the decisional dilemmas that the evidence product is meant to address. Topical experts, a preliminary literature search, materials from the Topic Brief (for nominations through the public process), and topic development recommendations (if relevant) will inform this description. The topic nomination can provide a starting point. A thorough understanding of the decisional context and the intended audience of the report will focus the evidence report on questions important to clinical practice or policy decisionmaking and will ensure an appropriate, but feasible, scope. This brief description should set the context for the KI discussion of the topic.

To complete Part 1, EPCs will need to conduct a targeted literature scan on the current state of the literature (see preliminary literature scan, below, for details). EPCs will work with KIs and the Partner to focus on essential questions and the interventions, comparators, and outcomes most directly applicable to the defined decisional dilemmas. EPCs can refine the exact literature search and sources further after discussions with the Technical Experts during the review portion of the project.

Elements of this preliminary background include:

- Intended audience and perspective of the proposed review, and intended uses of the evidence from the report (e.g., for clinical practice guidelines, for coverage decisions, to inform research priorities, or for benefit design).
- A description of the decisional dilemmas, such as
    - Controversy or uncertainty about a topic
    - Evidence needed to support decisionmaking
    - Other important issues of context or practice.
- Population(s)

    - Description of the main populations of interest and of subpopulations, if appropriate
- Intervention(s) and Comparator(s)
    - Current treatments or standards of care, including relevant existing guidelines
    - Mechanism of action of the interventions
    - Availability in the United States; FDA approval status, if relevant
    - Interventions already established.
    - Interventions for which use(s), or uses compared with existing alternatives, may be uncertain.
    - Whether the issues concern effectiveness of specific interventions or classes of interventions.
    - For comparative effectiveness:
        - The proposed advantages and disadvantages of the interventions to be compared (e.g., cost, invasiveness, harms)
        - Specify the key comparisons.
    - For some complex interventions (e.g., care management, self-management) and organizational change interventions (e.g., PCMH) there should be an emphasis on defining the intervention.
- Outcomes
    - Outcomes of greatest importance for stakeholders, including patients. These are distinguished by final health outcomes, intermediate outcomes, and other outcomes (e.g., use of health care services) if appropriate. This should include both benefits and harms.
    - Outcomes with the current standard of care
- Settings
- Ongoing work in this topic area that could influence the timing of the review.
- Other factors (such as training, facility requirements, advocacy positions)

Preliminary Key Questions

Development of the preliminary KQs should follow logically and directly from the description of the decisional dilemmas and other information in the preliminary background. KQs that stray from the decisional context can increase the scope and decrease the utility of the subsequent systematic review.

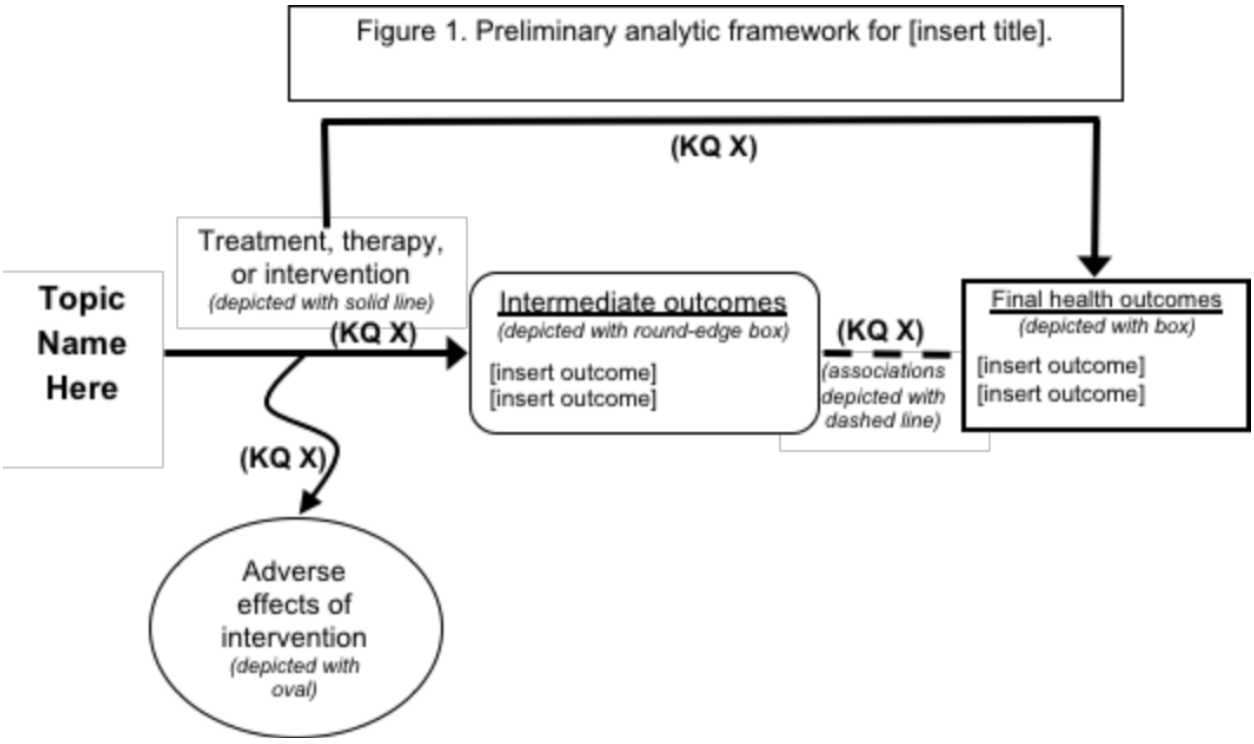
Key Question 1:
a. Subquestion 1.a
b. Subquestion 1.b
c. Etc.

Question 2:
a. Subquestion 2.a
b. Subquestion 2.b
c. Etc.

Continue as above through all KQs.

Preliminary Analytic Framework

The preliminary Analytic Framework (illustrated below as Figure 1) provides a visual representation of the clinical logic and preliminary PICOTS (adjusted to include harms and to break outcomes into intermediate and final health outcomes). The preliminary AF should be linked to the preliminary KQs. For further details about analytic frameworks, please see the *AHRQ Methods Guide*.



Preliminary PICOTS

The PICOTS (population, interventions, comparators, outcomes, timing, and setting) provide further detail about both the KQs and the AF. The EPC team may choose to organize the sections of the PICOTS by key question for greater clarity. Elements of the preliminary PICOTS should be consistent with the preliminary Analytic Framework, and should be all-inclusive, even if information from the preliminary KQs must be repeated.

Population(s)

- The description will likely will include definitions or descriptions of population(s) named in KQs (e.g., "We define adolescents to include those 13 to 19 years of age.")
- Specify by KQ if relevant.

Interventions

- For medications, insert class of drug with a sub-list (or table) of preparations by generic/chemical names. Specify if drugs will be considered individually or by class
- For devices, list type of device with relevant key features or characteristics.

- Include information on the FDA status, indications, and relevant warnings for drugs or devices to be included in the systematic review. This information may be included as an appendix.
- Specify co-interventions, if applicable
- Specify by KQ if relevant

Comparators

- Be specific about comparisons for questions of comparative effectiveness. Focus on comparisons of greatest interest.
- Placebo or active control; usual care; wait list
- Define "usual care" if possible
- Specify by KQ if relevant

Outcomes

- Specify by KQ if relevant

Intermediate outcomes

1. Intermediate outcome 1
2. Intermediate outcome 2, etc.

Final health or patient-centered outcomes

1. Final health or patient-centered outcome 1
2. Final health or patient-centered outcome 2, etc.

Adverse effects of intervention(s)

1. Adverse effect 1
2. Adverse effect 2, etc.

Timing

- Duration of follow-up

Settings

- Setting (e.g., primary care, specialty care, inpatient hospital)

Preliminary Literature Scan

Initial topic refinement requires a targeted literature scan on the current state of the literature; this includes guidelines, outcomes studied, and the existing scope of literature. EPCs should *not* synthesize this information. The literature scan should give a general sense of the body of evidence, greater detail about the topic, and the relative volume of literature.

This preliminary scan can inform KI discussions; promote examination of potential debates and uncertainties related to the topic; guide refinement of the key questions; assist in identifying relevant interventions, comparators, and outcomes; and guide considerations in focusing or modifying proposed scope. The literature scan can also identify any additions to the literature since topic development.

EPCs will work with KIs and Partner to focus key questions and narrow the interventions, comparators, and outcomes to those most directly applicable to the decisional dilemmas in question. EPCs should ensure that a revised scope will still serve the Partner's main intended purpose (such as a guideline development or policy decision).

If particular KQs or portions of the topic scope have only limited evidence, EPCs should identify the problem as an evidence gap. Limited evidence does not necessarily preclude inclusion of the issue in the review, and this decision should rest on the importance of the issue.

If the preliminary literature scan finds only a limited body of evidence for the *entire* review or identifies a recently published relevant systematic review, a new systematic review may not be warranted. In these cases EPCs, with KI and Partner input, should consider whether a different aspect of the decisional context could be explored with refocused key questions. If a new review appears not to be feasible or duplicates an existing review, after discussion with AHRQ the EPC Program may decide either to desist with the systematic review or to develop a different EPC product, such as a Technical Brief. In these cases, the EPC will present this updated information to the EPC Program topic prioritization group.

Include the following in this section of Part 1:

- The databases searched
- Types of interventions, comparators, and outcomes studied
- Types of intervention and comparator combinations studied
- Identified areas of controversy or uncertainty

Assuming the original review proceeds more or less as planned at this stage, EPCs will further refine the exact literature search and sources after discussions with members of the Technical Expert Panel during the review portion of the project.

Summary of Input from Public Comments on KQ and PICOTS (if they were posted pre-award)

If KQ/PICOTS were posted before award of the task order, provide a high-level summary of public comments noting any themes and controversies. Include the number of commenters, and perspectives if relevant.

Summary of Input from Topic Experts

Topic experts provide input on current practice, available interventions, decisional dilemmas, and potentially many other aspects of the subject of the systematic review. Often these individuals provide clinical context and insight into the “real-world” situations of stakeholders. EPCs should provide a high-level summary of the input from these experts.

Changes from Initial KQs/PICOTS to Preliminary KQs/PICOTS

Changes to the initial KQs and PICOTS (from topic development) may be informed by public comment input, partner input, topic expert input, the preliminary literature scan, or recommendations from the topic prioritization group. Use a table like the sample Table 1 below to document issues or controversies, changes made or rejected, and the rationale.

Table 1. Changes to Key Questions and PICOTS				
Original Element	**Source**	**Comment**	**Decision and Changes**	**Rationale (Implications for Evidence Report)**
Intervention: nurse case management	Topical expert	Definition of nurse case management is too narrow	Broadened intervention to include case managers with training other than nursing. New definition: Case management, defined as the assignment of a single person, alone or in conjunction with a team, to coordinate all aspects of a patient's care	This will allow for a more thorough review of case management for adults with medical illness and complex care needs, while making it possible to compare different types of case management including that conducted by nurses. This broadens the relevance of the review to a larger audience.
KQ 1: In adults with medical illness and complex care needs, does case management improve patient outcomes?	Topical expert, literature scan	Complex care needs seem overly broad and vague	No change	We agree that this is a broad population and have purposely kept the definition of "complex care needs" broad. From the literature scan, the studies appear to be heterogeneous with regard to the populations and interventions. Given this heterogeneity, we believe that keeping the definition broad in this respect will prevent an overly narrow review that misses important approaches to case management. Our preliminary literature scan identified 26 RCTs/CCTs between 2006 and 2009 (after the Stanford-UCSF report) that **may be** applicable to the topic. This scan was not restricted to adults or medical illness.

Considerations for Key Informants (KIs)

This section of Part 1 outlines specific questions and issues to focus and structure the discussion with KIs. KIs may advise EPCs about the preliminary Key Questions, PICOTS, Analytic Framework, and other areas crucial to decisionmaking. They may also provide insight into issues that have been inadequately captured by the preliminary literature search and from topic expert input.

The Partner will help EPCs to understand the decisional context and dilemmas in the topic area and to focus the scope of the review accordingly. KI input will provide additional context about these matters. KIs can also identify the interventions and outcomes critical to decisionmaking. Finally, they can identify current standards of care and inform EPC teams about important comparators.

EPCs will solicit input from a KI panel. This small group should include the perspectives of patients and consumers, practicing clinicians, representatives of professional and consumer organizations, purchasers of health care, and others who will use the findings from the report to make health care decisions for themselves or others. This panel is distinct from the Technical Expert Panel (TEP); the TEP informs the scientific processes of the evidence review. Individuals may serve on both KI and TEP panels.

(The Secure Site contains some additional guidance for stakeholder engagement: https://epc-src.ahrq.gov/src/secureEHC/content.cfm?AREA=1&FLDR=6790)

Potential issues to address include the following:

- Standard of care, to inform relevant comparators
    - What is the current perception or understanding of guidelines or standards of care?
    - How is usual care defined?
- Relevant interventions
    - What interventions or technologies are already established?
    - How widespread is the use of the interventions or technologies?
- Uncertainty, decisional dilemmas
    - What decisions are you trying to make?
    - Does clinical practice vary? If so, how and why? Is this variation a problem?
    - What interventions do you have questions about and why?
    - Is the uncertainty about benefits, harms, or other? Be specific about which outcomes would affect your decision to use the intervention?
    - Why might you be interested in this intervention or technology?
    - What would keep you from using it?
    - What are the comparisons of greatest interest?
    - Is it important to know *how well* an intervention works? Or just that it works? Or how it works compared to another existing intervention?
- Contextual issues
    - What other considerations might influence your decisions about care?
    - Should certain settings or populations be included, specifically studied, or excluded?
    - Are other considerations in decisionmaking important, such as insurance coverage, geography, or other patient and health care delivery factors?
    - Targeted questions regarding PICOTS or other elements of the proposed scope

EPCs may need to develop separate questions for stakeholders with different perspectives. Patients, consumers, and their advocates might require different questions than clinicians or health system representatives, for example. This section of Part 1 should present these (different) KQs in an easily readable format like that below.

Questions and issues for general Key Informants:

1. Question 1
2. Question 2, etc.

Questions and issues for patient or consumer Key Informants:

1. Question 1
2. Question 2, etc.

Questions and issues for clinical or systems Key Informants:

1. Question 1
2. Question 2, etc.

Part 2: Development of the Draft Scope

Both Parts 2 and 3 of the Topic Refinement Document are completed and submitted to AHRQ after KI input.

Do not include draft KQ, PICOTS, or AF here. These elements belong in Part 3 – KQ Posting Document, which is posted on AHRQ's Effective Health Care website for public comment

Summary of Key Informant Discussions

EPCs should provide a high-level summary of relevant points from the KI discussions. Specific details will be documented in call minutes or other materials and can be included in appendixes.

Elements to include:

- Composition of KI panel including details of relevant expertise and perspectives represented
- Details about any pertinent conflicts of interest (COI)
- Reference documents distributed to KIs. These documents should be uploaded to the secure site for reference.
- Description of methods used to engage KIs (e.g., email feedback, telephone calls, webinar)
- Clarification of elements of KQs, PICOTS, or AF
- Issues and controversies
- Areas of agreement among the panel
- Areas of disagreement among the panel
- Additional issues identified.

Example of high-level summary: *All key informants agreed with the rationale of limiting the scope to case management for medical illness, because the relevant interventions and outcomes are substantially different for mental illness. Similarly, they agreed with the rationale of limiting the topic to adults, because interventions and outcomes are different for children and adolescents. Some key informants noted that CERs of case management for mental illness and for children would also be valuable. However, they agreed that a review focusing on a more homogeneous population is more likely to provide useable information about the effective elements of case management.*

Although the key informants endorsed most elements of the preliminary PICOTS, KQ, and AF as being relevant and appropriately inclusive, several issues recurred and led to important revisions. The three notable revisions were the following: (1) expanding the scope to include all forms of case management for medical illness, not just nurse case management; (2) refining the definition of the population of interest from "high risk adult patients with chronic medical illnesses" to "adults with medical illness and complex care needs"; and (3) clarifying that case managers may work alone or with a team. These changes somewhat narrowed the scope of our description of the decisional dilemmas.

Updated Results of Preliminary Literature Scan

EPCs should update the preliminary literature scan to assess the volume of literature if KI input required revision of the KQs or the PICOTS.

Elements to include:

- Number of relevant studies and types of study design
- Proposed size of the systematic review based on estimated number of studies or abstracts
- Recent relevant systematic reviews (to assess for any duplication)
- Types of interventions, comparators, and outcomes studied (if any were added to or removed from the topic scope)
- Types of intervention and comparator combinations that have been studied (if any were added or removed from the topic scope)

Example: *We conducted a preliminary assessment of the literature available for this review. Inclusion criteria limited studies to randomized controlled trials enrolling adults with a history of stone recurrence followed for a minimum of 1 year and published in English. Previous systematic reviews with similar inclusion criteria identified eight published studies for dietary therapy (up to date as of March 2008) and 24 published studies (up to date as of September of 2009). We conducted an update of these searches using MEDLINE. This identified nearly 100 trials published in 2008 and 2009 meeting the search parameters. A broad strategy was employed using the MeSH term urolithiasis and limiting results to (controlled clinical trial, randomized clinical trial, randomized controlled trial, systematic reviews, or meta-analysis). This preliminary screening suggests that at least two additional studies may be available to address dietary therapy key questions. However, one study included in the previous systematic review did not meet the longer follow-up time inclusion criteria of 1 year proposed in the current project. Therefore, a total of nine trials were identified to address dietary therapy key questions. Two additional studies were identified to address pharmacological therapy key questions for a total of 26 studies. More rigorous and comprehensive searching and screening will be conducted during the next phase of this project.*

Changes between Preliminary and Draft Background/KQ/PICOTS/AF

EPCs should document changes made between the preliminary and draft Background, KQ, PICOTS and AF. This material should include any outstanding issues and specify other needed input (such as Technical Expert Panel input, public commentary, or a formal literature search) and the rationale. These points should be documented in Table 2 or one like it.

Table 2. Changes to Background, Key Questions, PICOTSs, or Analytic Framework

Original Element	Source	Comment	Decision and Change	Rationale (Implications for Evidence Report)
Population: subgroups	KI	Defined subgroups of patients with complex illness	Decision deferred	Will await TEP input from the Technical Expert Panel to identify subgroups of interest.
Population: all patients	KI	Case management is really used for high risk patients	Limit population to adults with medical illness, and exclude those for whom case management is used primarily to manage mental illness	Limiting the scope to adults and medical illness is more relevant to stakeholders and is the population for which important decisional dilemmas exist.
Intended audience and/or decisional dilemma				Excluding children and mental health cases necessarily narrowed the intended audience, but the decision to broaden our scope to include more than nurse case management and case managers working alone or in teams expands the audience to health system managers whose systems currently practice or are considering this kind of medical case management.

Part 3: Key Question Posting Document for [*Insert Title*]

Background (Decisional Dilemmas, 2-5 pages)

EPCs should describe the decisional context or dilemmas about the condition(s), role of the intervention, relevant claims about comparative effectiveness and safety, and the targeted audience. This material should be taken from the "Preliminary Background," Part 1 of the Topic Refinement Document, but AHRQ expects EPCs to revise the background section here in response to KI input and elements of the targeted literature scan. EPCs can also revise the original background write-up to provide more specific and relevant context for the draft key questions, PICOTS, and analytic framework.

Draft Key Questions

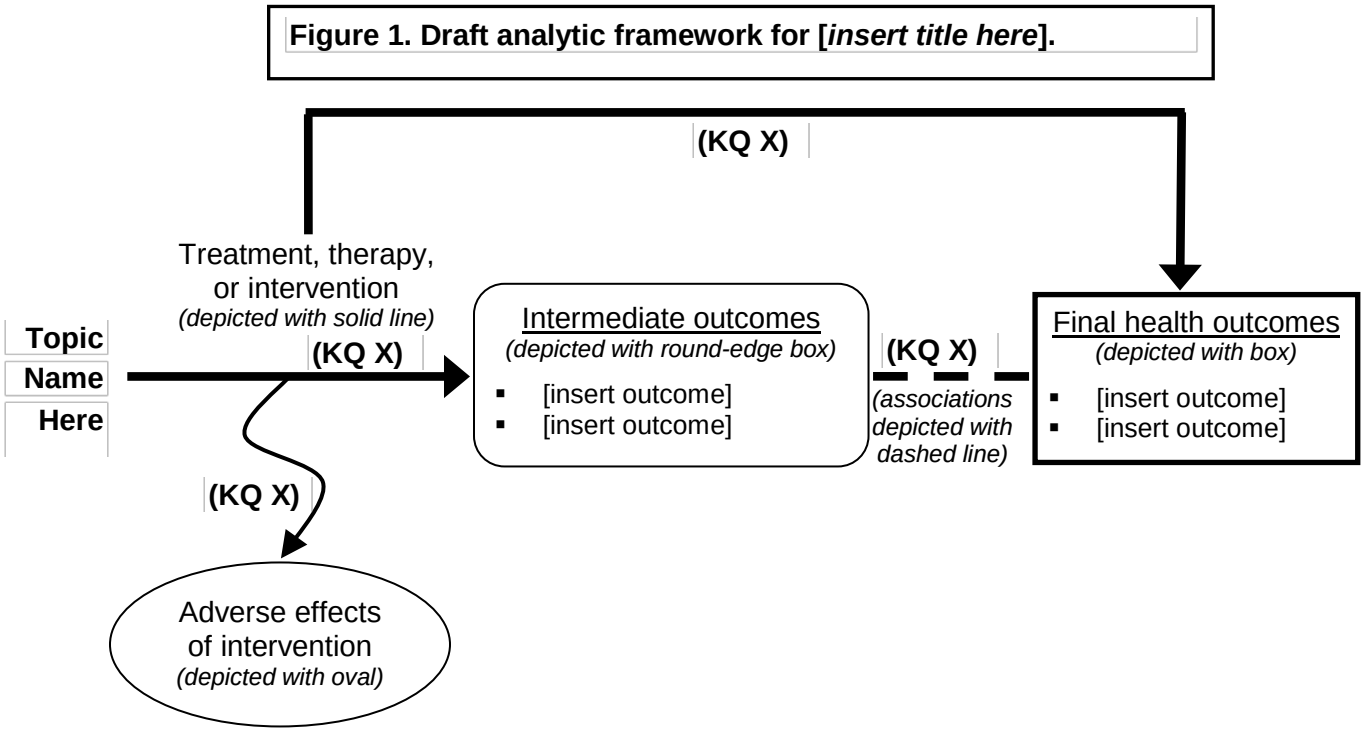
Question 1:
- Sub-Question 1.a
- Sub-Question 1.b, etc.

Question 2:
- Sub-Question 2.a
- Sub-Question 2.b, etc.

Continue as above through all KQs.

For updates of previous systematic reviews, specify whether the original key questions have changed and briefly discuss those changes.

Draft Analytic Framework



Include alternate text to the figure (for 508 compliance) in a separate file. For example:

Figure 1: This figure depicts the key questions within the context of the PICOTS described below. In general, the figure illustrates how [treatment 1] versus [treatment 2] may result in intermediate outcomes such as A, B, or C and/or final health outcomes such as X, Y, or Z. Also, adverse events may occur at any point after patients receive the treatment.

PICOTS

Population(s)

- The description will likely will include definitions or descriptions of population(s) named in KQs (e.g., "We define adolescents to include those 13 to 19 years of age.")
- Specify by KQ if relevant.

Interventions

- For medications, insert class of drug with a sub-list (or table) of preparations by generic/chemical names. Specify if drugs will be considered individually or by class
- For devices, list type of device with relevant key features or characteristics.

- Include information on the FDA status, indications, and relevant warnings for drugs or devices to be included in the systematic review. This information may be included as an appendix.
- Specify co-interventions, if applicable
- Specify by KQ if relevant

Comparators

- Be specific about comparisons for questions of comparative effectiveness. Focus on comparisons of greatest interest.
- Placebo or active control; usual care; wait list
- Define “usual care” if possible
- Specify by KQ if relevant

Outcomes

- Specify by KQ if relevant

Intermediate outcomes

1. Intermediate outcome 1
2. Intermediate outcome 2, etc.

Final health or patient-centered outcomes

1. Final health or patient-centered outcome 1
2. Final health or patient-centered outcome 2, etc.

Adverse effects of intervention(s)

1. Adverse effect 1
2. Adverse effect 2, etc.

Timing

- Duration of follow-up

Settings

- Setting (e.g., primary care, specialty care, inpatient hospital)

Definition of Terms

EPCs should provide a table of terms, acronyms, abbreviations, or initialisms defined in readily understandable, non-jargon, language.

References

[References for TR part 3]