Appendix A. EPC Topic Refinement Document

**Topic Refinement Content Guidance Document (Version 4 - 9/6/12)**

***Note: Topic Refinement Document is not for posting or public distribution.***

**This documents the stages of topic refinement. Each section is completed sequentially and submitted separately to AHRQ when completed. For further details about submission, please see the EPC Procedure Guide.**

* **Part 1 is a record of activities and decisions from the beginning of topic refinement to the point just before Key Informant input.**
* **Part 2 includes the elements for public posting. This will be posted on the EHC website for four weeks for public comment.**
* **Part 3 documents activities and decisions from key informant engagement to up to public posting.**
* **Part 4 documents decisions in response to public posting.**

**Part 1: Summary of Topic Development and Development of the Preliminary Scope (KQ, PICOTS and Analytic Framework)**

*Part 1 is completed and submitted to AHRQ prior to Key Informant discussions.*

*This documents scope changes and topic refinement activities (local expert input and preliminary literature scan) prior to key informant input. The preliminary key questions (KQ), PICOTS (Population, Intervention, Comparator, Outcomes, Timing, Setting) and analytic framework (AF) are developed from the initial KQ and PICOTS with local expert input, Topic Triage considerations, and the preliminary literature scan.*

*Portions of this document are frequently used to inform key informant discussions. The background and historical detail about the topic nomination can provide context for the key informants; the KQ, PICOTS and AF outline the proposed scope of the topic; and the preliminary literature scan can inform discussion about relevant interventions, comparators, and outcomes, and other feasibility considerations.*

**Summary of Topic Development**

|  |  |
| --- | --- |
|  | Fill in boxes with information from the Topic Triage Cover Sheet |
| Topic Name: |  |
| Topic Number: |  |
| Topic Triage Review Date: |  |
| Topic Investigator(s): |  |
| Nominator: |  |

Initial Key Questions from the Topic Triage Cover Sheet

Question 1

Question 2

Etc. with KQs

Initial PICO (Population, Intervention, Comparator, Outcome) from the Topic Triage Cover Sheet

|  |  |
| --- | --- |
| P: |  |
| I: |  |
| C: |  |
| O: |  |
| Narrative: |  |

Considerations from Topic Triage Discussion

*Summarize recommendations from the Topic Triage, such as scoping considerations and individuals to include as key informants. This information can be located in the Topic Triage Cover Sheet under “Summary of Discussion and Next Steps.”*

**Development of the Preliminary Key Questions, Analytic Framework and PICOTS**

Preliminary Key Questions

*The Preliminary Key Questions are developed with input from local experts and with the Topic Triage recommendations in mind, and serve as the starting point for Key Informant (KI) discussions. These Preliminary Key Questions on the proposed topic should reflect important decisional dilemmas in health care for stakeholders. With this in mind, the Key Questions must clearly define the logic and scope of the topic. For further discussion of Key Questions, consult the Methods Guide and the EPC Training Modules.*

Question 1:

1. Sub-Question 1
2. Sub-Question 1

Question 2:

1. Sub-Question 2
2. Sub-Question 2

Etc. with Questions

Preliminary Analytic Framework

*The Preliminary Analytic Framework provides a visual representation of the clinical logic and preliminary PICOTS (patients, interventions, comparators, harms, intermediate outcomes, and final health outcomes). The Preliminary Analytic Framework should be linked to the Preliminary Key Questions. For further details about analytic frameworks please see the Methods Guide and Training Modules.*

*(associations depicted with dashed line)*

Appendix Figure A1. Preliminary analytic framework for [insert title].

**Topic**

**Name**

**Here**

Intermediate outcomes   
*(depicted with round-edge box)*

* [insert outcome]
* [insert outcome]

Treatment, therapy,   
or intervention   
*(depicted with solid line)*

**(KQ X)**

**(KQ X)**

**(KQ X)**

**(KQ X)**

Final health outcomes   
*(depicted with box)*

* [insert outcome]
* [insert outcome]

Preliminary Background

*The Background section describes the condition(s), role of the intervention, relevant claims about comparative effectiveness and safety, and outlines the rationale for a systematic review on the topic. The background section will be a work in progress. This initial section developed for distribution to Key Informants should set the context for their discussion of the topic.*

*This will require a targeted literature scan by the EPC on the current state of the literature (see preliminary literature scan for specific details). If there is a large body of literature, the EPC will work with key informants to focus the questions on those most essential. The exact literature search and sources can be further refined after discussions with the Technical Experts during the review portion of the project.*

*Elements to include*

* *Population:*
  + *Nature and burden of condition*
  + *Description of subpopulations, if appropriate*
* *Intervention, Comparator*
  + *Current treatment or standard of care and/or existing guidelines*
  + *Mechanism of action*
  + *Availability in the United States; FDA approval status*
  + *Are there interventions for which there is uncertainty regarding use?*
  + *Proposed advantages and disadvantages of the intervention (cost, invasiveness, harms, etc)*
* *Outcomes*
  + *What are the outcomes with the current standard of care?*
  + *What are the outcomes of importance for stakeholders?*
  + *What outcomes are studied in the literature?*
* *Setting and context*
* *Rationale for an evidence review*
  + *Controversy or uncertainty about a topic*
  + *Literature is confusing or conflicting*
  + *Relevant literature not in one place*
  + *Clinical decisions are complicated*
* *Relevance of research question to clinical decision making or policymaking*
  + *Theoretical and potential benefits or harms of the intervention or technology*
  + *Weighing benefits and harms*
  + *Targeting specific populations*
  + *Applicability to general practice (how will the review help readers understand how this intervention or technology fits with what is currently available?)*
  + *Patient preferences*
  + *Cost, if relevant*
  + *Coverage*
* *Availability of scientific data to support the systematic review and analysis* 
  + *Studies*
  + *Systematic reviews*
* *Assessment of other ongoing work in this topic area.*
* *Other contextual factors (such as training, facility requirements, advocacy positions)*
* *Potential audiences of the proposed review. How will could this report be used (e.g., issues in guidelines, coverage decisions, or benefit design)?*

Preliminary PICOTS (patients, interventions, comparators, outcomes, timing, setting)

*The PICOTS provide further detail of the key questions and analytic framework. Elements of the preliminary PICOTS should be consistent with the Preliminary Analytic Framework, and the TR team may choose to organize the sections of the PICOTS by key questions for greater clarity*

Population(s)

* Insert, even if noted in KQs. The description will likely will include definitions or descriptions of population(s) named in KQs. e.g., “Adolescents” will include ages 13-19 years.
* *Specify by KQ if relevant.*

Interventions

* *Insert, even if noted in key questions or if just one intervention*
* *For medications, insert class of drug with a sublist of preparations by generic/chemical names.*
* *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

* *Placebo or active control; usual care; other intervention*
* *Define if possible “usual care”*
* *Specify by KQ if relevant*

Outcomes

* *Specify by KQ if relevant*

Intermediate outcomes

1. [Insert]

Final health or patient-centered outcomes

1. [Insert]

Adverse effects of intervention(s)

1. [Insert]

Timing

* *Duration of follow-up*

Setting

* *Setting (primary, specialty, in-patient)*

Preliminary Literature Scan

*Initial topic refinement requires a targeted literature scan on the current state of the literature (including guidelines, outcomes studied, scope of literature). This should not be synthesized. While the literature scan performed during topic development gives a general sense of the body of evidence, this search may be more specific, and provide greater detail about the topic and relative volume of literature. It can inform the Topic Refinement team about key areas to focus on in KI discussions, promote an informed discussion about potential debates and uncertainties related to the topic; guide formulation of the key questions; assist in identifying relevant interventions, comparators, and outcomes; and guide considerations in broadening or narrowing proposed scope. This can also identify additional literature and relevant SRs if a period of time has lapsed between the end of topic development and commencement of topic refinement activities.*

*If there is a large body of literature, the EPC will work with key informants to focus the questions on the outcomes, comparators and interventions that are most essential.*

*While limited evidence may be identified at this stage for particular KQ or portions of the topic scope, this does not necessarily preclude inclusion in the final review if it is an area that is of importance to decisionmakers and should be highlighted as an important gap in evidence. If there is a limited body of relevant literature identified for the overall proposed review or a recent relevant evidence review is identified, the EPC, with KI input, could consider whether the key questions could be focused differently or whether an evidence review on this topic would be possible or duplicative. After discussion with AHRQ, this may result in a decision not to proceed with the systematic review, or development of a different EPC product, such as a Technical Brief.*

*The exact literature search and sources will be further refined after discussions with the Technical Experts during the review portion of the project.*

*Elements to include*

* *The databases searched*
* *Relevant guidelines*
* *Any recent relevant systematic reviews (to assess for any duplication)*
* *Types of interventions, comparators, and outcomes studied*
* *Types of intervention and comparator combinations that have been studied*
* *Areas of controversy or uncertainty identified*

Summary of Topical Expert Input

*Topical experts provide input on current practice, available interventions, decisional dilemmas, etc. Often these individuals provide clinical context, and insight into the “real-world” situations of stakeholders. This should be a high-level summary of input from topical experts.*

**Table A1. Changes between initial KQ/PICOTS and preliminary KQ/PICOTS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Original Element** | **Source** | **Comment** | **Decision** | **Change** | **Rationale** |
| Intervention: nurse case management | Topical expert | Definition of nurse case manage-ment is too narrow | Broadened intervention to include case managers with training other than nursing | 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. |
| Population: all patients | Literature scan | Literature scan identified diverse populations and variability in tasks of case manage-ment | Limited population to adults with medical illness, and exclude those for whom case management is used primarily to manage mental illness | Adults with medical illness and complex care needs | Limiting the scope to adults and medical illness would focus on a more homogeneous population and is more likely to provide usable information about the effective elements of case management. |
| KQ 1: In adults with medical illness and complex care needs, does case management\* improve patient outcomes? | Topical expert, literature scan | Complex care needs seems overly broad and vague | No change | NA | 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. We anticipate considerable variation in the basis upon which studies consider care needs to be complex. 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 feasibility 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. Despite the diversity of the studies identified in this scan, this would seem to be an encouraging sign that the relevant body of literature is manageable for this review. |

*Changes to the initial KQ and PICOTS may be informed by topical expert input, preliminary literature scan, or Topic Triage recommendation. This table provides documentation of issues or controversies, changes that were or were not made, and the rationale.*

Considerations for Key Informants (KI)

*This section outlines specific questions and issues to focus and structure the discussion with KI. The KI panel may clarify elements of the Preliminary Key Questions, Analytic Framework, and PICOTS. They may also provide insight into issues that have been inadequately captured in the limited literature search and local expert input, or because specific issues require the perspective, experience, or technical knowledge of the KI panel. KI input should help the TR team to understand the questions that decision-makers struggle with (decisional dilemmas) to ensure the review addresses these issues. They may also identify relevant interventions and outcomes that are most important for decisionmaking, and identify current standards of care to inform the TR team about the most appropriate comparators to include in the evidence review.*

*Input will be solicited from a KI panel comprised of a small number of individuals. Relevant individuals may be patients and consumers, practicing clinicians, relevant professional and consumer organizations, purchasers of health care, and others who will use the findings from the report to make healthcare decisions for themselves or others. The KI panel should include perspectives of individuals who would make decisions with the findings of the report, as well as those who would be affected by these decisions. These informants are distinct from the Technical Expert Panel which is constituted to inform the scientific processes of the evidence review.*

*Potential issues to address with key informants:*

* *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 you currently using?*
  + *How widespread is the use of the interventions or technologies?*
* *Uncertainty, decisional dilemma*
  + *Is there variability in clinical practice? Is this a problem?*
  + *Do the questions capture this adequately?*
  + *Outcomes (benefits and harms). What is your current understanding of outcomes with the current standard of care? (or if no current treatments are available, what is your understanding of the natural progression of disease?)*
  + *What are the potential advantages or disadvantages of one intervention or technology over others? (i.e. ease of use, access, cost, invasiveness, patient preference, use of other resources or tests)*
  + *Why might you be interested in this intervention or technology?*
  + *What would keep you from using it?*
  + *Is it important to know how well an intervention works? Or just that it works?*
  + *What benefits or harms (outcomes) would influence whether you would use or recommend this intervention or technology?*
  + *What outcomes are most important for you to make a decision? Which outcomes are less important?*
* *Contextual issues*
  + *Are there other considerations which influence decisions about care?*
  + *Are there certain settings or populations which should be included or specifically studied?*
  + *Are there other considerations in decisionmaking that are important, such as insurance coverage, geography, etc.?*
* *Targeted questions regarding PICOS or other elements of the proposed scope*

Questions and issues for Key Informants

|  |  |
| --- | --- |
| 1. |  |
| 2. |  |
| 3. |  |
| 4. |  |
| 5. |  |
| 6. |  |

Part 2: Key Question Posting Document for [*Insert Title*]

Draft Key Questions

Question 1

1. Sub-Question 1
2. Sub-Question 1

Question 2

1. Sub-Question 2
2. Sub-Question 2

Etc. with Questions

*For updates of reports specify if changes have been made to the original key questions and provide some discussion of the changes.*

Draft Analytic Framework

*(associations depicted with dashed line)*

Appendix Figure A2. Draft analytic framework for [*insert title here*].

Topic

Name

Here

Intermediate outcomes  
*(depicted with round-edge box)*

* [insert outcome]
* [insert outcome]

Treatment, therapy,   
or intervention   
*(depicted with solid line)*

(KQ X)

(KQ X)

(KQ X)

(KQ X)

Final health outcomes  
*(depicted with box)*

* [insert outcome]
* [insert outcome]

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

Appendix Figure A2: This figure depicts the key questions within the context of the PICOTS described in the previous section. In general, the figure illustrates how [treatment 1] versus [treatment 2] may result in intermediate outcomes such as A, B or C and/or long-term outcomes such as X, Y or Z. Also, adverse events may occur at any point after the treatment is received.

Background (2-5 pages)

*The purpose of the Background section is to describe the condition(s), role of the intervention, relevant claims about comparative effectiveness and safety, outline the rationale for a systematic review on the topic, and describe expected audience. Please see specific elements for inclusion in “Preliminary Background”, Part 1 of the Topic Refinement Document.*

*It is expected that the background section will be revised in response to key informant input and elements of the targeted literature scan. It may also be revised to provide more specific and relevant context for the draft key questions, PICOTS and analytic framework.*

Population(s)

* *Insert, even if noted in KQs. The description will likely include definitions or descriptions of population(s) named in KQs. e.g., “Adolescents” will include ages 13-19 years.*
* *Specify by KQ if relevant.*

Interventions

* *Insert, even if noted in key questions or if just one intervention so potential sources of Scientific Information Packets are apparent to the public.*
* *For medications, insert class of drug with a sublist of preparations by generic/chemical names.*
* *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**

* *Placebo or active control; usual care; other intervention.*
* *Define if possible “usual care.”*
* *Specify by KQ if relevant.*

Outcomes

* *Specify by KQ if relevant.*

Intermediate outcomes

1. [Insert]

Final health outcomes

1. [Insert]

Adverse effects of intervention(s)

1. [Insert]

Timing

* *Duration of follow-up*
* *Specify by KQ if relevant*

Setting

* *Setting (primary, specialty, in-patient)*
* *Specify by KQ if relevant*

Definition of Terms

References

Appendix A References

1. Kemper A, Coeytaux R, Sanders G, et al. Disease-Modifying Antirheumatic Drugs (DMARDs) in Children With Juvenile Idiopathic Arthritis (JIA). Comparative Effectiveness Review No. 28. (Prepared by the Duke Evidence-based Practice Center under Contract No. HHSA 290 2007 10066-I.) AHRQ Publication No. 11-EHC039-EF. Rockville, MD: Agency for Healthcare Research and Quality; September 2011. Available at: www.effectivehealthcare.ahrq.gov/reports/ final.cfm.