U.S. Preventive Services Task Force Procedures for Evidence-based Practice Centers

1. Topic Refinement

Background Information

Once a topic is prioritized by the Task Force for a new or updated recommendation, the scope of the topic and approach to the review must be defined to guide the researchers undertaking the systematic review process.

A topic team is appointed for each prioritized topic before topic scoping begins and consists of Task Force leads (including one of the Task Force chairs), at least one AHRQ Medical Officer, and the review team from an Evidence-based Practice Center (EPC). Based on expertise and interest, several Task Force members volunteer to serve as leads for each topic. An AHRQ Medical Officer is assigned to oversee the topic, and may be joined by the Task Force Scientific Director and/or Associate Scientific Director in overseeing that topic. A lead investigator is assigned by the EPC to lead the evidence review team.

Two integrated products are produced during topic refinement: a work plan and a research plan. Both of these documents are revised and finalized through discussions with the Task Force leads and the AHRQ Medical Officer in an ongoing process that includes public comment. Based on the template described below, a work plan that captures the history, previous Task Force recommendations, and proposed approach to the topic is drafted by the EPC review team. The purpose of the work plan is to establish the review perspective for the upcoming review.

During work plan development, the EPC review team considers the scope of the evidence needed for the Task Force to make its recommendation. For reviews undertaken to update existing Task Force recommendations, this process is based on:

1. Examination of the previous Task Force recommendation(s), including populations and clinical preventive services addressed, to determine their fit with current questions about the clinical preventive service.
2. Examination of the previous Task Force evidence review process for the topic and the review findings in order to identify established evidence, important review limitations, and evidence gaps.
3. Determination of current contextual information (e.g., changes in understanding of the nature of the disease process, or changes in diagnosis, therapeutics, or practice; controversy over any of these elements).

In order to facilitate the consistent development of the review approach across topics, the Task Force has developed a template to guide the development of the final work plan (see https://www.uspreventiveservicestaskforce.org/Page/Name/procedure-manual).

This template can be considered generally analogous to a protocol, such as those developed for an AHRQ Effective Health Care Program review or a Cochrane Review. It is also an articulation of the rationale for the scope decisions made in framing the topic.

The systematic review work plan development process includes identification of important sources of potential heterogeneity of screening or treatment effect and related subpopulations for each topic. The EPC review team summarizes the following information about subpopulations from literature searches that are routinely conducted during work plan development:

- How other guideline groups have recently handled subpopulation considerations for the topic
- How any recent, well-conducted systematic reviews have handled subpopulation considerations for the topic
- Data on incidence/prevalence, complications/morbidity, and mortality for the condition of interest by age, sex, race/ethnicity, and important topic-specific clinical characteristics

The above information is used to develop questions for key informant interviews. The EPC review team will consult 2-4 key informants who are clinical and content experts to help determine what is known about sources of heterogeneity of screening or treatment effect and potential subpopulation differences for the topic. Information obtained from literature searches and key informant interviews will guide decisions of whether and how the EPC review team will incorporate relevant subpopulations into the analytic framework, key questions, and inclusion/exclusion criteria.

To further specify the situation that is the object of its concern, the Task Force has adopted the Institute of Medicine's definition of primary care:

Primary care is the provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community. This definition acknowledges the importance of the patient clinician relationship as facilitated and augmented by teams and integrated delivery systems.

The Task Force considers interventions that are delivered in primary care settings or are judged to be feasible for delivery in or referable from primary care. To be feasible in primary care, the intervention could target patients seeking care in primary care settings, and the skills to deliver the intervention are or could be present in clinicians and/or related staff in the primary care setting, or the intervention could generally be ordered/initiated by a primary care clinician.

Task Force recommendations address primary or secondary preventive services. Primary preventive measures in a clinical setting are those provided to individuals to prevent the onset of a targeted condition (for example, aspirin for prevention of colorectal cancer), whereas secondary preventive measures identify and treat asymptomatic persons who have already developed risk factors or preclinical disease but in whom the condition has not become clinically apparent (for example, screening for diabetes or colon cancer). Preventive measures that are part of the treatment and management of persons with clinical disease are usually considered tertiary prevention and are outside the scope of the Task Force.

Based on the full draft work plan, a draft research plan that contains the analytic framework, key questions, and inclusion/exclusion criteria is created for public comment. After approval by the Task Force leads, this document is posted on the Task Force website for four weeks to allow public comment. All results from the comment period are provided verbatim to the topic team, and the EPC review team summarizes major themes and makes suggested revisions based on these comments.

The topic team discusses any major suggestions for revisions, the EPC review team incorporates final revisions into the research plan and work plan, and the Task Force leads approve these final products. For new topics, the work plan may be peer-reviewed and presented to the entire Task Force at one of its regular meetings. Development of a work plan generally takes from 6-9 months, including public comment.

Additional information on topic refinement for the USPSTF and a template for the workplan can be found at: https://www.uspreventiveservicestaskforce.org/Page/Name/procedure-manual .

Specific EPC Procedures

Following the current procedures of the USPSTF, a complete topic refinement shall include the following activities

a. Submit Conflict of Interest Disclosure Forms and Confidentiality Forms

The EPC shall submit Confidentiality Forms from EPC team members and all other staff that work on USPSTF products. The forms can be found on the EPC SRC Secure Site: (https://epc-src.ahrq.gov/src/secureEHC/content.cfm?AREA=1&FLDR=6907)

The EPC shall follow the USPSTF Programs conflict of interest policy and shall use the USPSTF Program's disclosure form to report any conflicts of interest (**see Appendix I**). The disclosure forms shall be completed for each person contributing to the content of the report including EPC staff, consultants, subcontractors, expert reviewers and others. The disclosure forms shall be completed and forwarded to the USPSTF Coordinator, and Task Order Office (TOO) for review and approval prior to the initial Kick-off call. In the case of team members joining after the kick off, it is expected that their forms will precede them being introduced to AHRQ or the topic team of Task Force members. Disclosure forms shall be reviewed annually by the EPC Director/Program Manager if a project exceeds 12 months. Disclosure forms shall be resubmitted to the Coordinator/TOO when any major changes occur in activities of the team members related to the topic.

b. Develop Topic Work Plan

The EPC shall begin its own review of salient literature in order to refine the draft key questions and analytic framework, as well as clarifying and adding to sections on inclusion criteria and exclusion criteria. The developing document built in this process will be referred to as a 'topic work plan' and the format shall follow the template developed as part of EPC-II (see https://www.uspreventiveservicestaskforce.org/Page/Name/procedure-manual). Final approval of the work plan will come from the AHRQ MO/TOO following

agreement arrived at with the Task Force topic team, Scientific Directors, and the EPC staff. The main work of the evidence review performed by the EPC team will be directed by the detailed information in this topic work plan.

1) Request Kick-Off Calls

The EPC shall request a first call with the AHRQ Medical Officer (MO)/Task Order Officer (TOO) assigned to the topic to review the draft topic work plan. The EPC shall request a second "kick off" call with the MO/TOO and the USPSTF members assigned to the topic ("leads"). The EPC shall provide a draft of the topic work plan and other relevant materials for participants to review no later than 3 business days prior to the call with the MO/TOO and no later than 5 business days prior to the call with the Task Force leads. The EPC shall lead these discussions.

2) Summarize the Kick-Off Call and Revise Draft Topic Work Plan

The EPC shall summarize the initial kick off call and distribute minutes. In every case, the EPC shall summarize the second kick off call, distribute minutes from the call, and revise the work plan according to the MO/TOO.

3) The EPC may be asked to participate in additional calls with the MO/TOO and Task Force leads in order to finalize the draft topic work plan. The EPC should plan on at least one additional call.

c. Submit Draft Research Plan for Posting for Public Comment

1) For topic refinements for systematic evidence reviews, the EPC shall create a document based on the revised draft topic work plan referred to as a draft 'Research Plan' for posting for public comment. The elements in the draft Research Plan shall include: the analytic framework, key questions, contextual questions and a table of inclusion/exclusion criteria (referred to as Scientific Approach). The EPC will not be responsible for posting the draft Research Plan, developing instructions or questions for the Research Plan or for collecting or aggregating the public comments. The EPC shall provide alternate text for the analytic framework to meet 508 requirements according to HHS 508 regulations (http://www.hhs.gov/web/508). The Draft Research Plan shall be 508 compliant and ready for posting on the USPSTF website. The draft research plan shall be submitted to AHRQ no later than 2.5 weeks prior to the scheduled posting date.

d. Review Public/Peer Reviewer Comments on the Draft Research Plan, Revise and Finalize the Work Plan and Research Plan

1) For topic refinements for systematic evidence reviews, the EPC will be provided with a table of the comments received from the public on the draft Research Plan which will include all unedited comments. The EPC shall review the comments and provide a memo to the MO/TOO of key themes with proposed revisions to the Research Plan/Work Plan and a Research Plan with tracked changes

representing the proposed changes. The EPC shall use the copy-edited draft research plan when making track changes. Depending on the nature and number of public comments received, the EPC may request a conference call with the MO/TOO (with or without the USPSTF leads) to discuss the general tenor of the comments and review the plan for disposition of the comments, including how disparate comments will be handled. MO/TOO The EPC shall provide the revised research plan and other relevant materials for participants to review no fewer than 3 business days prior to each call. The EPC will lead these discussions.

The EPC shall draft a section for the final Research Plan that summarizes the changes that were made in response to the public comments received.

2) After the closing of the draft research plan public comments AHRQ will provide the EPC with a list of nomination's to be considered when finalizing the list of expert reviewers for the SER. The EPC shall provide suggestions to the MO/TOO as to which experts should be included in the final reviewer list.

e. Submit Final Topic Work Plan and Final Research Plan

1) For topic refinements for systematic evidence reviews, the EPC shall submit the final work plan and final research plan that incorporates comments to the MO/TOO. The Final Research Plan shall include a section, *Response to Public Comments*. The Final Work Plan shall include the list of nomination's to be considered when finalizing the list of expert reviewers for the SER. The Final Research Plan shall be 508 compliant and ready for posting on the USPSTF website. The final research plan shall be submitted to AHRQ no later than 4 weeks prior to the scheduled posting date.

3. Systematic Review Updates

Background Information

Reaffirmed topics are topics kept current by the Task Force because the topic is within the Task Force's scope and a Task Force priority, and because there is a compelling reason for the Task Force to make a recommendation. Topics that belong in this category are well established, evidence-based standards of practice in current primary care medical practice (e.g., screening for hypertension). While the Task Force would like these recommendations to remain active and current in its library of preventive services, it has determined that only a very high level of evidence would justify a change in the grade of the recommendation. Only recommendations with a current grade of A or D are considered for a focused review update. Therefore, the goal of the search for evidence in a focused review update is to find new and substantial evidence sufficient enough to change the recommendation.

Although the general process of conducting the focused review update shall be similar to that of conducting a systematic evidence review, the size of the update is estimated to be smaller that of a regular systematic evidence review and will vary according to the scope of questions identified for updating. In the case where there is an addition of new contextual questions or comparisons, the EPC will follow the methods and procedures defined for systematic reviews in the EPC Procedures Guide and USPSTF Procedures Guide. The EPC shall document any changes to the report protocol. The EPC shall provide an updated report that summarizes the updated evidence and what it adds to the original review.

4. Systematic Evidence Reviews

Background Information

The Task Force has determined that using systematic reviews is the best method for organizing and evaluating the existing scientific evidence relevant to questions about a clinical preventive service. In order to answer the relevant questions about a clinical preventive service, the EPC review team usually undertakes a series of related systematic reviews to answer each of the questions in the analytic framework.

Additional information on conducting systematic evidence reviews for the USPSTF can be found at: https://www.uspreventiveservicestaskforce.org/Page/Name/procedure-manual .

For behavioral counseling topics which previously received an "A" or "B" grade recommendation from the USPSTF when a recommendation was last issued, the Contractor shall complete a table highlighting exemplar behavioral interventions identified in the updated review to assist with providing further implementation details. Please refer to **Appendix II**I for specific steps.

Specific EPC Procedures

Following the current procedures of the USPSTF, a complete systematic evidence review for the USPSTF shall include the following activities:

a. Literature Search, Review, and Development of Data Collection Forms

In drafting evidence reviews, the EPC shall follow the standard methodological procedures of the USPSTF (see USPSTF Procedure Manual at https://www.uspreventiveservicestaskforce.org/Page/Name/procedure-manual). The EPC shall systematically search, abstract, review, and analyze the scientific evidence for each question and the variance, if any, of the evidence according to age, gender, race/ethnicity and any other important subgroups. Specifically, following the final work plan, the EPC shall:

1) Provide important background information including the epidemiology of the risk factors, disease, and complications from the disease by important subgroups age, sex, and race/ethnicity (at a minimum) and information about current practice;
2) Develop appropriate data collection forms;
3) Systematically search Medline, Cochrane, NICE and other appropriate databases containing literature relevant to the questions to be addressed

4) Review abstracts against inclusion/exclusion criteria to determine potential eligibility for inclusion in evidence syntheses;
5) Retrieve and review full articles on potentially eligible studies;
6) Extract key data from each eligible study and enter abstracted data into electronic database;
7) During the data abstraction phase of the systematic evidence review, the EPC will collect information to complete the Behavioral Intervention Implementation table for 2-3 exemplar interventions. Please refer to **Appendix III** for specific steps;
8) Maintain file of excluded studies with reasons for exclusion; reasons for exclusion shall be recorded at the full-article screening stage;
9) Review each eligible study to assess quality according to a three-point scale (good, fair, poor) developed by the USPSTF (see the USPSTF Procedure Manual at https://www.uspreventiveservicestaskforce.org/Page/Name/procedure-manual); quality assessment of individual studies may use methods in addition to the USPSTF procedures, if newer methods for quality assessment are available or if study designs are not fully addressed by USPSTF methods. All assessments should result in quality ratings of good, fair, poor. All methods for quality assessment should be fully described in the draft systematic evidence review.
10) Use appropriate procedures and monitoring to reduce bias, enhance consistency and to check accuracy of study reviews (e.g., abstraction by at least two reviewers, etc.)

Participate in Call with Medical Officer/Task Order Officer to Discuss Progress of Literature Review

The EPC shall participate in a call with the MO/TOO and USPSTF leads to discuss interim results from the literature review and also provide the following to the MO for review: 1.Abstraction forms; 2.Draft methods section of their report, if drafted (at a minimum their section on study selection) and 3.Flow diagram of included articles. The MO/TOO will facilitate scheduling the call. The EPC shall lead this discussion and shall prepare summary materials for this call and submit them to the MO/TOO. The EPC should plan for at least one call with the USPSTF topic leads to present interim results.

b. Synthesize Literature and Conduct Analyses

Following the final work plan, the EPC shall:

1) Prepare evidence tables and summary of estimates of important patient health outcomes associated with each preventive service, including a summary of overall benefits and harms associated with each potential intervention;
2) For behavioral counseling topics which previously received an “A” or “B” grade recommendation from the USPSTF when a recommendation was last issued, the Contractor shall complete a table highlighting exemplar behavioral interventions identified in the updated review to assist with providing further implementation details. Please refer to **Appendix III** for specific steps;

3) Incorporate the results from the previous systematic evidence review if available and if studies from previous review meet current inclusion criteria;
4) Perform meta-analyses;
5) Rate the body of evidence for each key question according to predetermined criteria (see the USPSTF Procedure Manual at www.uspreventiveservicestaskforce.org https://www.uspreventiveservicestaskforce.org/Page/Name/procedure-manual) for EPC assessment at the key question level;
6) Identify priorities for future research.

c. Submit List of Suggested Expert Reviewers

At least five months prior to submission of the draft evidence report, the EPC shall identify 4-6 individuals to suggest as peer reviewers. This list shall include the expert nominations submitted by AHRQ at the draft research plan stage. When submitting the list to AHRQ, the EPC shall indicate which reviewers came in through the nominations process. The EPC shall submit the names and professional affiliations of the selected peer reviewers to the MO/TOO. The MO/TOO may also add names of individuals for peer reviewers, including other federal agencies before approving the final list develop appropriately balanced peer review panel. The EPC shall collect COI forms from the final list of approved peer reviewers, assess and identify any significant COIs and send for AHRQ review and feedback. AHRQ will provide feedback and the EPC shall invite approved peer reviewers.

d. Produce Draft Evidence Review (Report)

The EPC shall prepare a draft evidence report with tables and appendices that follows the template and the requirements of AHRQ's EPC Style Guidelines in preparing the final report and appendices. Questions about any part of the Style Guidelines should be directed to Joya Chowdhury (310-427-1309 or Joya.Chowdhury@ahrq.hhs.gov).

Draft evidence reports for peer review are expected to be complete and of the same quality as a final report so that the peer review process can function effectively. Peer Review Draft reports that are not complete and/or which do not follow AHRQ's format will be returned as incomplete.

The evidence report is to be concise and written in sufficient detail and clarity to be the primary document. It shall include a synopsis of the scientific evidence on each key question and subsets, and reference to the linkages in the analytic framework, as well as a summary of the quality of the evidence for each key question. The discussion shall be a synthesis of the results and include future research and conclusions sections. The evidence report also shall incorporate results from the previous systematic evidence review, if available.

Specifically, the draft report shall include:

Structured Abstract
Chapter 1. Introduction and Background (*with appropriate subheadings)*
Chapter 2. Methods
Chapter 3. Results
Key Question 1

Key Question 2
Key Question 3, etc.

Chapter 4. Discussion
Summary of Review Findings
Contextual Issues
Limitations
Emerging Issues/Next Steps
Relevance for priority populations, particularly racial/ethnic minorities and older adults
Future Research
Conclusions

Acknowledgments
References
Figures
Figure 1. Analytic Framework and Key Questions

Summary Tables
Table 1. Recommendations of Other Groups
Table 2. Summary of Evidence Table (see USPSTF procedure manual)
Table 3. KQ1 Evidence table (included studies)
Table 4. KQ 2 Evidence table (included studies)
Table 5. KQ 3 Evidence table (included studies)
Table 6. KQ 4 Evidence table (included studies)
Table 7. KQ 5 Evidence table (included studies)
Table 8. KQ 6 Evidence table (included studies)
Table 9. Behavioral Intervention exemplar table (using USPSTF Table attached at the end of this document)

Appendix A. Detailed Methods
Appendix A1. Search Strategies
Appendix A2. Inclusion and Exclusion Criteria
Appendix A3. Literature Flow Diagram
Appendix A4. List of Excluded Studies
Appendix A5. U.S. Preventive Services Task Force Quality Rating Criteria
Appendix A6. Expert Reviewers of the Draft Report

Appendix B. Evidence Tables and Quality Tables
Appendix B1. Data Abstraction of Studies
Appendix B2. Quality Ratings of Studies

Appendix C. Supplemental Materials

Other Appendices As Needed

e. Submit Draft Evidence Review for AHRQ and Task Force Review

The EPC shall submit the draft report to the MO/TOO; the MO/TOO will conduct a quick review prior to requesting the EPC to send it to peer reviewers. The MO/TOO will

approve the draft for peer review.

f. Submit Draft Evidence Review for Peer Review

The EPC shall send the report directly to reviewers electronically as a pdf file (a hard copy shall be submitted upon request). To be considered for the peer review task, the individuals must commit to reviewing the draft report and providing written comments within a very circumscribed time frame. The EPC shall use a watermark (preferable) or header that identifies the report as a draft. The EPC shall develop a reviewer form to capture their comments.

The EPC shall send the final draft evidence review and review form to AHRQ to disseminate to the TF partners. AHRQ will send the draft report and modified reviewer form to eight federal partners of the USPSTF (CDC, CMS, FDA, HRSA, IHS, NIH, SAMHSA, VA). AHRQ will collect the comments from federal partners and send an aggregated document to the EPC
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g. Update Literature Search

During the peer review time period, the EPC shall perform an updated literature search, using the same search strategy as originally done, to ensure that the search is current (i.e., less than 6 months when the final report is anticipated to be published). The EPC shall discuss the findings of the updated search with the MO/TOO assigned to the topic, particularly findings that may change the results of the systematic review (may be done at the same time as comments are reviewed in the subsequent task). The EPC shall incorporate the findings into the final report. Active literature surveillance is required for all topics throughout the lifespan of the review.

h. Review Peer Reviewer Comments and Provide Summary

The EPC shall review and analyze the comments received from the peer reviewers, Task Force leads, and federal partners and revise the draft report as appropriate.
In preparation of the Task Force meeting, the EPC shall provide a summary of the comments received and highlight significant comments to the MO/TOO and Contracting Officer, along with the revised evidence report.

The EPC shall also include the summary in the EPC presentation.

EPCs shall provide a full disposition after the Task Force meeting

i. Request Call/Webinar with Medical Officer/Task Order Officer and Task Force Leads to Discuss Draft Evidence Review

The EPC shall request up to 2 calls with the MO/TOO and Task Force leads to discuss the draft evidence report. This call should take place no earlier than one week after the distribution of the draft report. The TOO will designate an AHRQ Medical Officer for each topic as well as 3-4 Task Force members who will serve as leads on the topic. The MO will facilitate scheduling the call. The EPC shall set-up a webinar to present the draft slide presentation and facilitate the discussion. The EPC shall lead this discussion. The slides shall be sent to the MO/TOO no later than 3 business days before the call/webinar with the MO/TOO. Two calls are required in order to walk the Task Force leads through all the evidence and address all of their questions. The MO/TOO may invite and authorize any individuals necessary for the calls. The EPC may be asked to participate in additional calls based on the complexity of the evidence for presentation and the nature of the Task Force leads' questions.

j. Participate in Call with Medical Officer /Task Order Officer and Task Force Leads to Discuss Draft Recommendation Statement

The EPC shall participate in up to 2 with the MO/TOO and Task Force leads to discuss the draft recommendation statement. The MO/TOO may invite and authorize any individuals necessary for the calls. The EPC PI shall serve as a consultant to the MO/TOO on the available evidence during these calls. The MO/TOO will facilitate scheduling the call. The EPC will not lead this discussion and is not responsible for sending a summary of the call to all participants. However, the EPC shall prepare materials for these calls, as requested by the MO/TOO. At times, the Task Force members may request additional summary tables of the evidence or additional calculations in order to help them estimate the net benefits. Any requested materials shall be submitted in advance of the call.

k. Submit Draft Systematic Evidence Review for USPSTF Meeting Briefing Book

The EPC shall revise the draft report based on any feedback received from the MO/TOO. A final draft evidence review shall be submitted a minimum of 3 weeks prior to the scheduled USPSTF in-person meeting.

l. Give Presentation on Evidence at In-person USPSTF Meeting

The EPC shall revise the slides used during the call with the MO/TOO and Task Force leads based on their feedback. These slides will be used for the presentation during the in-person Task Force meeting. Final slides and any other materials shall be submitted to AHRQ no later than 1 week prior to the in-person Task Force meeting. .

The Principle Investigator of the research team shall present a summary of the evidence to the full USPSTF at one of its in-person meetings. The USPSTF meets three times a year in March, July and November in Rockville, MD.

m. Create Disposition Table of Peer Reviewers Comments

The EPC shall review and analyze the comments received from the peer reviewers, Task Force leads, and federal partners and revise the draft report as appropriate.

The EPC shall document the process for reviewing and analyzing all comments, including a detailed description of the disposition of substantive comments. The EPC shall submit one complete copy of each reviewer's comments to the MO/TOO and a report/disposition table of comments to the MO/TOO and Contracting Officer, along with the revised evidence report.

m. Submit Draft Evidence Review for Posting for Public Comment

Based on the discussion during the in-person Task Force meeting, the EPC and MO/TOO shall determine whether the draft evidence report submitted for the Briefing Book (Task k) needs to be revised before it is posted for public comment. The EPC will not be responsible for posting the draft Evidence Review, developing instructions or questions for the Evidence Review or for collecting or aggregating the public comments. The report shall be submitted electronically. Separate files shall be submitted for each section of the report (i.e., body of paper, appendices, figures, tables), along with one combined pdf file. The draft evidence review shall be 508 compliant and ready to be posted on the USPSTF website. The draft evidence review shall be submitted to AHRQ no later than 6 weeks prior to the scheduled posting date.

n. Review Public Comments on the Draft Evidence Review

The EPC will be provided with a table of the comments received from the public on the draft Evidence Review. The EPC shall review the comments and provide a memo to the TOO of key themes with proposed revisions to the evidence review.. If necessary, depending on the nature and number of public comments received, the EPC shall request a conference call with the MO/TOO (with or without the USPSTF topic team) to discuss the general tenor of the comments and any specific critical comments and review the plan for disposition of the comments, including how conflicting comments will be handled. The MO/TOO will facilitate scheduling the call. The EPC shall provide the revised evidence review and other relevant materials such as new evidence for participants to review 1 week prior to any call. The EPC shall lead these discussions.

o. Finalize Systematic Evidence Review (Report)

To finalize the report, the EPC shall make any changes necessary to address concerns raised during the in-person Task Force meeting and/or the public comment/peer review period. This may include additional review and analysis of the evidence. The EPC shall draft a section in the report, *Response to Public Comments* that summarizes the changes made to the final report in response to the public comments received. The final report shall be edited by the EPC to remove grammatical, typographical, numerical, and citation errors.

p. Submit Final Systematic Evidence Review (Report)

The EPC shall submit the final evidence report to the Task Order Officer and the Contracting Officer at AHRQ. The reports shall be submitted electronically. Separate files shall be submitted for each section of the report (i.e., body of paper, appendices, figures, tables), but also as one combined pdf file. The final report shall be 508 compliant and ready to be posted on the USPSTF website. The final report shall be submitted to AHRQ no later than 8 weeks prior to the scheduled posting date

Endnote or other reference manager software shall be used to compile reference lists and bibliography. Citations shall be "grabbed" electronically by the software from PubMed or another source to render them as accurate as possible. A final bibliography also shall be submitted electronically (if feasible given software versions) and on CD (only the MO/TOO needs to receive the bibliography on CD). Tables and charts must be delinked from underlying databases.

5. Decision Analysis Modeling

Background Information

The Task Force uses modeling to inform the recommendation process for certain topics. Models can be valuable tools to address the limitations of evidence from trials when trying to understand population level effects of interventions. Collaborative modeling is a coordinated effort between two or more teams independently developed models to examine the same question; it allows systematic exploration of differences between models and the effect of these differences on model findings. More specifics on USPSTF Modeling methods can be found in the USPSTF Procedure Manual:
https://www.uspreventiveservicestaskforce.org/Page/Name/procedure-manual

Specific EPC Procedures

The decision analysis shall be conducted in coordination and concurrently with the systematic evidence review for the topic. Following the current procedures of the USPSTF and Effective Healthcare program, complete collaborative decision analysis modeling for the USPSTF shall include the following activities:

a. Conducting the Modeling

The EPC shall participate in regular phone calls with AHRQ staff, TF and the Principal Investigator of the targeted systematic evidence review (SER) to discuss the scope and progress of the decision analysis modeling throughout the review of the topic, starting at the scoping and topic refinement stage. The EPC will use estimates from the systematic evidence review in the models to the extent possible. Generally the EPC will assemble model inputs, make any necessary changes to model structures, develop model output spreadsheets, calibrate and conduct analyses as appropriate.

AHRQ staff, TF and EPC will agree on questions to be addressed, common inputs, and common outputs to use in their separate models, based where possible on the systematic evidence review. The analyses will include those directed to the following types of questions/tasks, relevant to the application of a technology to a program of screening.

1. Operating Characteristics of the screening technology to be modeled (e.g. sensitivity) including possible adjustments to the characteristics of the technology from those observed in trials to those likely to be observed in the general medical community;
2. Various alternative strategies for the management of suspicious nodules, and the impact on the operating characteristics of the overall implementation of the screening technology and its sequale;
3. Age, sex, and periodicity of screens (including starting and stopping age; encompasses total number of screens), family history, racial/ethnic subgroups, risk of associated conditions and use of medications or other treatments, and the ability to generate risk scores for commonly used risk model, possibly including life expectancy as an alternative to age as the metric to end screening (to try to exclude those from screening who are not suitable candidates for surgery), occupational exposure
4. Generate risk factors as represented in various birth cohorts as representative of the U.S. population
5. Output metrics of interest including consideration of mortality reduction, person years of life gained, quality adjusted person year of life gained, false positives, overdiagnosis, and iatrogenic radiation induced cancers.
6. Impact of longer follow-up on mortality reduction and on cumulative harms of screening;
7. Other possible risk factors, e.g. smoking history and COPD that determines eligibility for screening, including the possible use of composite risk scores.
8. Perform appropriate sensitivity analysis
9. Compare results of the different models used in the collaborative effort as they pertain to the main issues addressed and discuss the results (if consistent); or if inconsistent (reasons for inconsistency are explained and are credible).

b. Develop Topic Work Plan based on Evidence Review Work Plan

In parallel with the evidence review work plan/ research plan, a work plan shall be developed for the decision analysis through discussions with the Task Force leads and the AHRQ Medical Officer. During work plan development, the decision analysis team considers the scope of the evidence needed for the Task Force to make its recommendation. The structure, template, and steps for the work plan are the same as the evidence review work plan process.

c. Submit List of Suggested Expert Reviewers

At least five months prior to submission of the draft evidence report, the EPC shall identify 4-6 individuals to suggest as peer reviewers. This list shall include the expert nominations submitted by AHRQ at the draft research plan stage. When submitting the list to AHRQ, the EPC shall indicate which reviewers came in through the nominations process. The EPC shall submit the names and professional affiliations of the selected peer reviewers to the MO/TOO. The MO/TOO may also add names of individuals for peer reviewers, including other federal agencies before approving the final list develop appropriately balanced peer review panel. The EPC

shall collect COI forms from the final list of approved peer reviewers, assess and identify any significant COIs and send for AHRQ review and feedback. AHRQ will provide feedback and the EPC shall invite approved peer reviewers.

c. Produce Draft Decision Analysis Report

The EPC shall prepare a draft decision analysis report which should present information from each of the models and put the comparative modeling findings in context for presentation to the US Preventive Services Task Force. The EPC shall refer to and include in the report the items listed in the "Collaborative Modeling Evaluation Checklist" which outlines how the USPSTF will evaluate the models; please refer to **Appendix IV**. Required components of draft and final reports are:

- Structured Abstract
- Introduction
- Methods
- Results (this section should be organized by key question)
- Discussion
- Conclusion
- References
- Summary tables
- Appendices

The text of the report is not to exceed 7000 words. There is no limit on the appendices. The EPC shall submit a report that follows the template and the requirements of AHRQ's EPC Style Guidelines in preparing the final report and appendices. Questions about any part of the Style Guidelines should be directed to Joya Chowdhury (301-427-1309 or Joya.Chowdhury@ahrq.hhs.gov).

Draft reports for peer review are expected to be complete and of the same quality as a final report so that the peer review process can function effectively. Peer Review Draft reports that are not complete and/or which do not follow AHRQ's format will be returned as incomplete.

The draft decision analysis report is to be concise and written in sufficient detail and clarity to be the primary document.

d. Submit Draft Decision Analysis Report for AHRQ and Task Force Review

The EPC shall submit the draft report (complete with all items above) for peer review to the MO/TOO; the MO/TOO will conduct a quick review prior to requesting the EPC to send it to peer reviewers. The MO/TOO will approve the draft for peer review.

e. Submit Draft Decision Analysis Report for Peer Review

The EPC shall send the report directly to reviewers electronically as a pdf file (a hard copy shall be submitted upon request). To be considered for the peer review task, the individuals must commit to reviewing the draft report and providing written comments within a very circumscribed time frame. The EPC shall use a watermark (preferable) or header that identifies the report as a draft. The EPC shall develop a

reviewer form to capture their comments.

f. Based on New Evidence Update Input Parameters and Analysis

During the peer review time period, based on the updated literature search conducted by the systematic evidence review team, the modeling team shall discuss the findings of the updated search with the MO/TOO assigned to the topic, particularly findings that may require new runs from the decision analysis and change the results of the decision analysis and systematic evidence review (may be done at the same time as comments are reviewed in the subsequent task). The EPC shall conduct new runs as needed by the USPSTF and incorporate the findings into the final report.

g. Review Peer Reviewer Comments and Provide Summary

The EPC shall review and analyze the comments received from the peer reviewers, Task Force leads, and federal partners and revise the draft report as appropriate.

In preparation of the Task Force meeting, the EPC shall provide a summary of the comments received and highlight significant comments to the MO/TOO and Contracting Officer, along with the revised decision analysis report.

The EPC shall also include the summary in the EPC presentation.

EPCs shall provide a full disposition after the Task Force meeting

h. Request Call with Medical Officer/Task Order Officer and Task Force Leads to Discuss Draft Decision Analysis Report

The EPC shall request a call with the MO/TOO to discuss the draft decision analysis report. This call should take place no earlier than one week after the distribution of the draft report. The TOO will designate an AHRQ Medical Officer for each topic as well as 3-4 Task Force members who will serve as leads on the topic. The MO will facilitate scheduling the call. The EPC shall lead this discussion. A draft slide presentation to facilitate the discussion of the decision analysis results is required and shall be sent no later than 3 business days before the call with the MO/TOO. Two to three calls are required in order to walk the Task Force leads through all the evidence and results and address all of their questions. The MO/TOO may invite and authorize any individuals necessary for the calls. The EPC may be asked to participate in additional calls based on the complexity of the model and evidence for presentation and the nature of the Task Force leads' questions.

i. Participate in Call with Medical Officer /Task Order Officer and Task Force Leads to Discuss Draft Recommendation Statement

The EPC shall participate in up to 2 calls with the MO/TOO and Task Force leads to discuss the draft recommendation statement. The MO/TOO may invite and authorize any individuals necessary for the calls. The Model and SER PIs shall serve

as a consultant to the MO/TOO on the available decision analysis results during these calls. The MO/TOO will facilitate scheduling the call. The EPC will not lead this discussion and is not responsible for sending a summary of the call to all participants. However, the EPC shall prepare materials for these calls, as requested by the MO/TOO. At times, the Task Force members may request additional information or additional calculations in order to help them estimate the net benefits. Any requested materials shall be submitted in advance of the call.

The PI, SER PI, and other investigators if it is deemed necessary, will participate on up to ten conference calls with the USPSTF topic workgroup, the Medical Officer, and the SER PI to discuss the results, draft report, peer reviewer comments and draft presentation

j. Submit Draft Decision Analysis for USPSTF Meeting Briefing Book

The EPC shall revise the draft report based on any feedback received from the MO/TOO. A final draft decision analysis report shall be submitted a minimum of 3 weeks prior to the scheduled USPSTF in-person meeting.

k. Give Presentation on the Models at In-person USPSTF Meeting

The EPC shall give an on-site presentation of the methods, results and conclusions of the decision analysis at the USPSTF meeting agreed upon for the topic in Rockville, Maryland. The EPC shall revise the slides used during the call with the MO/TOO and Task Force leads based on their feedback. These slides will be used for the presentation during the in-person Task Force meeting. Final slides and any other materials shall be submitted to AHRQ no later than 1 week prior to the in-person Task Force meeting.

The SER and Model PIs shall present a summary of the evidence to the full USPSTF at one of its in-person meetings. The USPSTF meets three times a year in Spring, Summer and Fall/Winter in Rockville, MD.

l. Create Disposition Table of Peer Reviewers Comments

The EPC shall review and analyze the comments received from the peer reviewers, Task Force leads, and federal partners and revise the draft report as appropriate.

The EPC shall document the process for reviewing and analyzing all comments, including a detailed description of the disposition of substantive comments. The EPC shall submit one complete copy of each reviewer's comments to the MO/TOO and a report/disposition table of comments to the MO/TOO and Contracting Officer, along with the revised decision analysis report.

m . Submit Draft Decision Analysis Report for Posting for Public Comment

Based on the discussion during the in-person Task Force meeting, the EPC and MO/TOO shall determine whether the draft report submitted for the Briefing Book (Task j) needs to be revised before it is posted for public comment. The EPC will not

be responsible for posting the draft report, developing instructions or questions or for collecting or aggregating the public comments. The report shall be submitted electronically. Separate files shall be submitted for each section of the report (i.e., body of paper, appendices, figures, tables), along with one combined pdf file. The draft report shall be 508 compliant and ready to be posted on the USPSTF website. The draft report shall be submitted to AHRQ no later than 6 weeks prior to the scheduled posting date.

n. Review Public Comments on the Draft Decision Analysis Report

The EPC will be provided with a table of the comments received from the public on the draft report. The EPC shall review the comments and provide a memo to the MO/TOO of key themes with proposed revisions to the draft report. If necessary, depending on the nature and number of public comments received, the EPC shall request a conference call with the MO/TOO (with or without the USPSTF topic team) to discuss the general tenor of the comments and any specific critical comments and review the plan for disposition of the comments, including how conflicting comments will be handled. The MO/TOO will facilitate scheduling the call. The EPC shall provide the revised draft report and other relevant materials such as new evidence for participants to review 1 week prior to any call. The EPC shall lead these discussions.

o. Finalize Decision Analysis Report

To finalize the report, the EPC shall make any changes necessary to address concerns raised during the in-person Task Force meeting and/or the public comment/peer review period. This may include additional review and analysis of the evidence. The final report shall be edited by the EPC to remove grammatical, typographical, numerical, and citation errors.

p. Submit Final Decision Analysis Report

The EPC shall submit the final decision analysis report to the MO/TOO and the Contracting Officer at AHRQ. The reports shall be submitted electronically. The final report shall be submitted to AHRQ no later than 8 weeks prior to the scheduled posting date.

Separate files shall be submitted for each section of the report (i.e., body of paper, appendices, figures, tables), but also as one combined pdf file. The final report shall be 508 compliant and ready to be posted on the USPSTF website. Endnote or other reference manager software shall be used to compile reference lists and bibliography. Citations shall be "grabbed" electronically by the software from PubMed or another source to render them as accurate as possible. A final bibliography also shall be submitted electronically (if feasible given software versions) and on CD (only the MO/TOO needs to receive the bibliography on CD). Tables and charts must be delinked from underlying databases.

6. Manuscript

Manuscripts based on the evidence reports (articles summarizing evidence syntheses produced by the EPCs for each topic) and decision analysis reports are published in the

same peer-reviewed journals as the corresponding recommendations of the USPSTF. The USPSTF currently has publishing agreements with *Journal of American Medical Association.*

Following the current procedures of the U.S. Preventive Services Task Force, preparation of a manuscript shall include the following activities:

a. **Prepare Draft Manuscript for Submission to Peer-reviewed Journal**

The EPC shall prepare a draft manuscript based on the findings of the evidence review and decision analysis for publication in a peer-reviewed journal. The USPSTF currently has an agreement with *The Journal of American Medical Association* that gives the publisher first right of refusal to publish manuscripts from the USPSTF Program that pertain to adults or adolescents in accordance with their manuscript requirements. AHRQ will work directly with *JAMA* to coordinate publication of the report with the manuscript publication. The EPC is responsible for keeping the MO/TOO updated on the status of any and all journal publications.

The EPC shall submit the draft manuscript to the Task Order Officer for approval prior to submission. The manuscript shall be submitted electronically. The EPC shall aim to submit the approved manuscript to the publisher at the same time the draft evidence report is posted for public comment (approximately 3-6 months after the Task Force meeting).

b. Request Copyright Assertion

After receiving approval of the draft manuscript from the TOO, the EPC shall submit a request to the TOO for copyright assertion for the manuscript. The EPC shall incorporate the following language within the disclosure:

Funding/Support: This research was funded under contract number HHSA290201500007I, Task Order 2 from the Agency for Healthcare Research and Quality (AHRQ), US Department of Health and Human Services.

Role of the Funders/Sponsor: Investigators worked with USPSTF members and AHRQ staff to develop the scope, analytic framework, and key questions for this review. AHRQ had no role in study selection, quality assessment, or synthesis. AHRQ staff provided project oversight; reviewed the report to ensure that the analysis met methodological standards, and distributed the draft for peer review. Otherwise, AHRQ had no role in the conduct of the study; collection, management, analysis, and interpretation of the data; and preparation, review, or approval of the manuscript findings. The opinions expressed in this document are those of the authors and do not reflect the official position of AHRQ or the US Department of Health and Human Services.

Please see the EPC IDIQ contract for further information on Copyright Assertion.

c. Respond to Reviewer Comments

The EPC shall respond to reviewer comments made by the journal according to the timelines specified by the journal as well as any comments on the draft report or draft recommendation statement received from the public that may impact the manuscript. The EPC shall consult with the MO/TOO to discuss extensive or "unrealistic" comments, request adjustments to the timeline, etc. The EPC shall submit the revised manuscript to the journal, and at the same time, send a copy to the MO/TOO.

d. Review Galley and Page Proofs

The EPC shall review all proofs of the manuscript(s) necessary for publication. The EPC shall send any revisions to the journal and provide a copy to the MO/TOO.

7. Administration

The EPC will be asked to participate in regular calls with the MO/TOO to review the status of a topic, and to submit monthly status reports. With the final report, the EPC shall complete a short self-evaluation. The emphasis will be on using these evaluations for quality improvement. Where problems are identified, the EPC shall describe reasons for the problems and plans for future improvement.

Appendixes

I. USPSTF COI Policy and Form


USPSTF EPC Disclosure Policy_15 p


USPSTF EPC Disclosure_7 pages.pc

II. Behavioral Intervention Implementation Steps - Systematic Evidence Review


Behavioral Intervention Impleme


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III. Collaborative Modeling Evaluation Checklist


Collaborative Modeling Evaluation Cl