

Evidence-based Practice Center Systematic Review Protocol

Project Title: *Health Literacy Interventions and Outcomes: An Update of the Literacy and Health Outcomes Systematic Review of the Literature*

Background and Objectives for the Systematic Review

Background

Health literacy, as defined by the Institute of Medicine (IOM) in 2004, is “the degree to which individuals can obtain, process, and understand the basic health information and services they need to make appropriate health decisions.” This capacity includes the ability to interpret documents, read and write prose (print literacy), use quantitative information (numeracy), and speak and listen effectively (oral literacy) in a health care setting.

In 2003, the US Department of Education conducted a survey entitled “National Assessment of Adult Literacy” (NAAL). The most comprehensive examination of adult literacy to date, the NAAL surveyed more than 19,000 adults aged 16 and older. The assessment included items intended to directly measure health literacy. More than one-third of respondents (36%) scored in the lowest two categories (“basic” and “below basic”), suggesting that approximately 80 million adults in the United States have limited health literacy.¹ These people may have difficulty with even simple tasks like reading and understanding the instructions on a prescription bottle or filling out an insurance form. Low health literacy skills are more common in certain subgroups, including minorities, the elderly, Medicaid recipients, and people who have not completed high school.

In the past decade, researchers have demonstrated that low health literacy can have far-reaching consequences for an individual’s health. In our 2003 systematic evidence review, limited health literacy was associated with less knowledge of health care services and outcomes and adverse outcomes including increased disease prevalence and severity, lower utilization of screening and preventive services, and higher hospitalization rates.^{2,3} More recently, low health literacy has been linked to higher mortality in older adults.⁴ In our prior review, we also found some evidence that interventions may reduce the adverse effects associated with low health literacy.

Given the clear association between low health literacy and poor health outcomes, and the potential to reduce these outcomes with novel interventions, several national organizations have promoted health literacy as a research priority. With such attention from the American Medical Association (AMA), the IOM, National Institutes of Health (NIH), and Healthy People 2010, the research community has responded with new work in this field.

To synthesize the increasing volume of literature on health literacy, the Agency for Healthcare Research and Quality (AHRQ) has commissioned the RTI International–University of North Carolina Evidence-Based Practice Center (RTI–UNC EPC) to update its 2003

systematic literature review examining the effects of health literacy on health outcomes and interventions to improve those outcomes.

Objectives and Topic Nominator/Partner Information

AHRQ has requested an update to the 2004 systematic review *Literacy and Health Outcomes*. The original report and the report update were nominated by the AMA. The report will be based on a comprehensive and systematic review of the scientific literature, including extensive peer review of the draft report.

The RTI-UNC EPC was selected to conduct the original systematic review and update and develop the resulting reports. Experts from fields related to health literacy have been asked to serve as members of the Technical Expert Panel (TEP) and include experts in primary care, health education, clear language materials development, and health literacy measurement, research, and interventions. TEP input will help guide the systematic review of the literature.

The systematic review, published in 2004, analyzed the relationship between literacy and health outcomes and examined interventions that mitigate the health effects of low literacy. This update of the 2004 systematic review will be conducted to review additional literature to further our understanding of the relationship between health literacy (including not only print literacy, as was the focus of the earlier report, but also oral literacy and numeracy) and health outcomes and to understand what interventions are effective in mitigating the effect of low health literacy on health outcomes.

The Key Questions

Exhibit 2-1 provides two key questions (KQs) that will be used to guide the systematic review. Each question has 4 parts. One search will be conducted for each of the key questions. Parts c and d are derivative of the other key questions and will not have a separate literature search.

Exhibit 2-1. Key Questions for the Health Literacy Systematic Review

Key Question 1: Are health literacy skills related to

- a) Use of health care services?
- b) Health outcomes?
- c) Costs of health care?
- d) Disparities in health outcomes or health care service use according to race, ethnicity, culture, or age?

Key Question 2: For individuals with low health literacy skills, what are effective interventions to

- a) Improve use of health care services?
- b) Improve health outcomes?
- c) Affect the costs of health care?
- d) Improve health outcomes and/or health care service use among different racial, ethnic, cultural, or age groups?

PICOTS were used to define each key question as follows:

- KQ1
 - **Population:** Individuals and caregivers of all races and ethnicities
 - **Intervention:** Outcomes studies and so no applicable
 - **Comparison:** Studies compare outcomes among individuals with different levels of low health literacy and numeracy skills
 - **Outcomes:** Any health outcome with the exception of knowledge in those with low literacy (but not numeracy) because the prior relationship was considered well-established through the earlier review
 - **Time:** Articles are included that were published from 2003 forward for literacy and no time specification for numeracy. Studies may be cross-sectional or may follow individuals over varying lengths of time.
 - **Setting:** No exclusions. Individuals may be followed who are patients in the health care system or may be interviewed as part of a community-based study.
- KQ2
 - **Population:** Individuals and caregivers of all races and ethnicities with low health literacy

- **Intervention:** All interventions intended to improve the use of health care services or health outcomes in low literacy or numeracy individuals; this includes, but is not limited to, interventions addressing patient/provider communication and barriers to health care, self-efficacy, or behavior change.
- **Comparison:** Any comparator designated by the investigators, although a comparator is not necessary as long as pre-post intervention measures have been made.
- **Outcomes:** Any health related outcome associated with literacy and/or numeracy skills.
- **Time:** Articles are included that were published from 2003 forward for literacy and no time specification for numeracy. Studies may be cross-sectional or may follow individuals over varying lengths of time.
- **Setting:** No exclusions. Individuals may be followed who are patients in the health care system or may be interviewed as part of a community-based study.

Analytic Framework

Exhibit 3-1 gives an overview of the analytic framework for our key questions. Exhibit 3-2 outlines a more detailed logic model explicating outcomes to be included in our review and their conceptual relationship to each other. This more detailed model will be used to determine whether articles considered for inclusion have relevant health outcomes. It will also guide our analysis of included articles.

For KQ 1a or 2a, we will consider any process of care as a health service, including clinic and hospital visits, hospitalizations, and use of preventive health care and screening services.

For KQ 1b and 2b, we use the term ‘health outcomes’ broadly to encompass both intermediate and more distal outcomes.

Exhibit 3-1. Analytic Framework for the Health Literacy Systematic Review

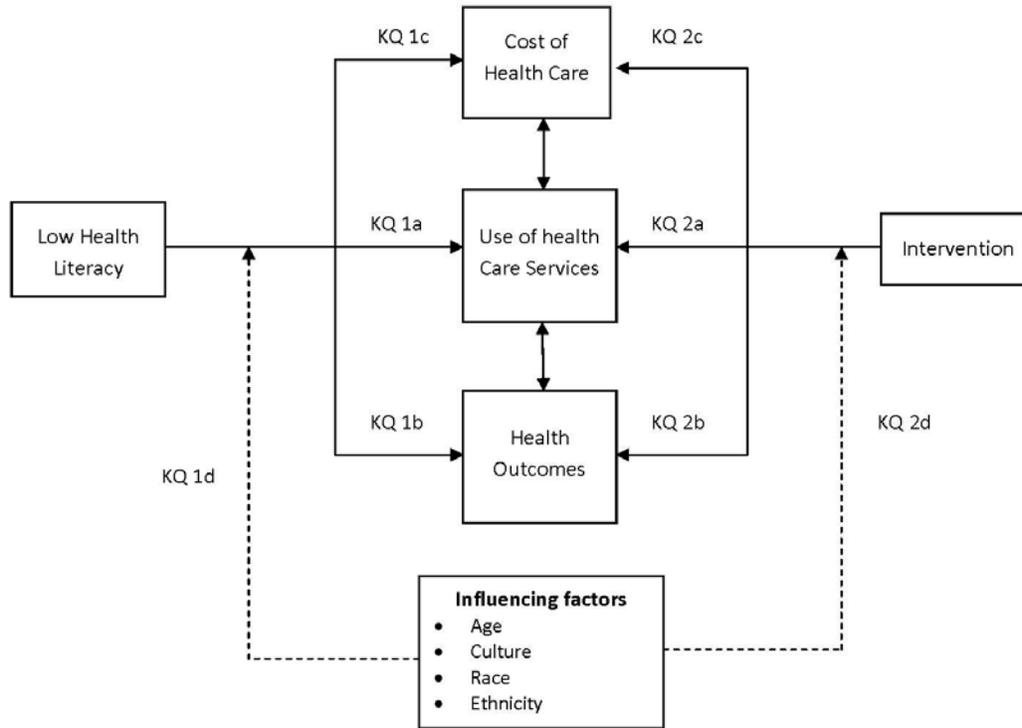
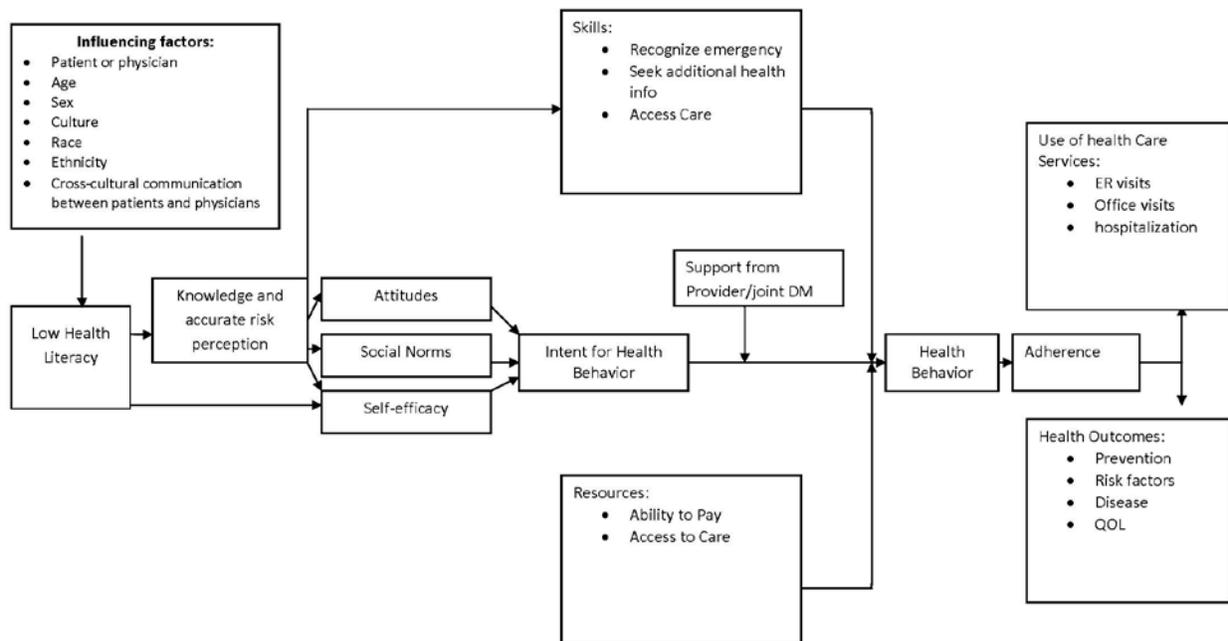


Exhibit 3-2. Logic Model for the Health Literacy Systematic review



- *Knowledge.* We consider knowledge as a final outcome only in relation to intervention studies (KQ2) because evidence in the earlier review clearly concluded that there is a positive relationship between greater health literacy skills and higher knowledge levels (KQ1).
- *Self-efficacy:* Self-efficacy, a person’s confidence in their ability to carry out a health behavior, is an important intermediate outcome in many behavioral theoretical models and is a predictor of behavioral intent. Several researchers have hypothesized a link between self-efficacy and literacy.
- *Behavioral Intent:* Behavioral intent is a person’s stated likelihood of starting a behavior and is an important intermediate step in the causal pathway between low health literacy and health outcomes.
- *Skills and Behavior:* The relationship between health literacy and intermediate and distal outcomes depends on a person’s health skills and behavior. Skills include a person’s ability to recognize an emergency, seek additional health information and access health care. Behaviors include taking medication, changing one’s lifestyle, or monitoring one’s health.

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- *Adherence*: Adherence is the ability to stick with a health behavior and is important predictor of health outcomes.
- *Biochemical or biometric health outcomes*. Biochemical or biometric measures such as blood pressure or glycosylated hemoglobin (HbA1c) can be important intermediate markers of more tangible health outcomes.
- *Measures of disease incidence, prevalence, morbidity, and mortality*. This category includes such outcomes as stage of cancer presentation, arthritis disease severity, diabetes control, and death rates. These are the ultimate outcomes the health care community is trying to affect.
- *General health status*. This outcome includes general measures of health status, usually assessed by self-report questionnaires that have been shown to predict health outcomes.
- *Use of health care services*. Health care services include clinic, hospital, and emergency room visits, and receipt of tests such as mammography and colonoscopy.

For KQ 1c measuring the cost of health care, we will include any study that measured the monetary cost of health care services. For KQ 2c, we will also include studies measuring the cost of the intervention. Finally, to address KQ 1d and 2d, concerning disparities in health outcomes and use of health care services, we will look for studies that report on the *mediation* of the relationship between race, ethnicity, culture, or age and health outcomes (or the effectiveness of interventions) by health literacy. We will also include studies that report on variables, such as race, ethnicity, culture or age, examined as *moderators* of the relationship between literacy and health outcomes.

Solid lines show the relationship between low health literacy and outcomes (KQ1), while dotted lines show the effect of interventions on low health literacy (KQ2).

Methods

A. Criteria for Inclusion/Exclusion of Studies in the Review

Exhibit 4-1 presents the inclusion/exclusion criteria we will use during abstract and full text review.

Exhibit 4-1. Inclusion/Exclusion Criteria for the Systematic Review

Category	Criteria
Study population	<p>All races, ethnicities, and cultural groups.</p> <p>Patients of all ages and caregivers whose primary language is the same as that of the health care provider and/or intervention.</p>
Time period	<p>Published from 2003 to the present: Print literacy studies meeting other inclusion criteria, excluded from the earlier review and meet other inclusion criteria.</p> <p>Published from 1980 to the present: Health literacy studies (including oral literacy and numeracy), excluded from the earlier review and meet other inclusion criteria.</p>
Publication criteria	<p>English only.</p> <p>Articles in print.</p> <p>Excluded were articles accepted for publication before appearance in the journal, articles in the so-called “gray literature,” and articles we could not obtain during the review period.</p>
Admissible evidence (study design and other criteria)	<p>Original research studies that provided sufficient detail regarding methods and results to enable use and adjustment of the data and results.</p> <p>Eligible study designs included</p> <ul style="list-style-type: none"> ▪ before-and-after studies; ▪ controlled trials; and ▪ observational studies: prospective and retrospective cohort studies, case control studies; and cross-sectional studies. <p>Relevant outcomes must be able to be abstracted from data presented in the papers.</p> <p>Sample sizes must be appropriate for the study question addressed in the paper; single case reports or small case series (fewer than 10 subjects) were excluded.</p> <p>Other study exclusion criteria included studies</p> <ul style="list-style-type: none"> ▪ of dyslexia and dementia; ▪ with no original data; ▪ with no health outcomes or no use of health care services ; ▪ with an outcome limited to satisfaction or likeability of one intervention material compared to another; ▪ focusing solely on the readability of materials; ▪ where health literacy is not directly measured in the population ▪ that are outcome studies (KQ1) and the only study outcome is knowledge; ▪ concern the basic experimental science of reading ability (e.g., studies of brain function, including results from magnetic resonance imaging or electroencephalogram) or basic educational achievement.

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B. Searching for the Evidence: Literature Search Strategies for Identification of Relevant Studies to Answer the Key Questions

We will systematically search, review, and analyze the scientific evidence for each key question. The steps that we will take to accomplish the literature review are described below.

To identify the relevant literature for our review, we began with a focused MEDLINE search using a variety of terms, limited to English and human-only studies. We conducted key word searches since no MeSH headings specifically identify health literacy-related articles. The terms “health literacy,” “numeracy,” “literacy [tw]” and instruments known to measure health literacy were the focus of the search. We limited the “health literacy” and “literacy [tw]” searches to 2003 forward to be confident that we do not miss studies between the first review and this update and to not unnecessarily overlap with the literature reviewed earlier.

We also searched other databases (Cumulative Index to Nursing and Allied Health (CINAHL), the Cochrane Library, PSYCINFO, and the Educational Resources Information Center (ERIC)) which include articles concerning a variety of literacy issues. We used “health literacy” to narrow the search to articles of interest. Results from initial database searches are presented in Exhibit 4-2.

Exhibit 4-2. Results of Literature Search

Medline search for the terms “numeracy,” “health literacy,” and specific health literacy instruments by full name, by acronym, and with the term “literacy”:

#1	Search numeracy	173
#2	Search numeracy Limits: Humans, English	146
#3	Search “health literacy”	789
#4	Search “health literacy” Limits: Entrez Date from 2003, Humans, English	586
#5	Search #2 OR #4	716
#6	Search literacy	39075
#7	Search “rapid estimate of adult literacy” OR real*	215538
#8	Search #6 AND #7	920
#9	Search “test of functional health literacy” OR tofhl*	295
#10	Search #6 AND #9	295
#11	Search “Hebrew health literacy test” OR HHLT	6
#12	Search “medical achievement reading test” OR MART	1202
#13	Search #6 AND #12	23
#14	Search “newest vital signs” OR NVS	203
#15	Search #6 AND #14	6
#16	Search “short assessment of health literacy” OR SAHLSA	170
#17	Search #6 AND #16	170
#18	Search “wide range achievement test” OR WRAT	290
#19	Search #6 AND #18	77
#20	Search “nutritional literacy” OR “literacy assessment for diabetes” OR LAD OR SIL OR “single item numeracy screener” OR DAHL OR “demographic assessment” OR BEHKA OR “brief estimate” OR “diabetes numeracy” OR “medical data interpretation” OR “subjective numeracy” OR “numeracy test”	18220
#21	Search #6 AND #20	264
#22	Search #8 OR #10 OR #11 OR #13 OR #15 OR #17 OR #19 OR #21	1661
#23	Search #8 OR #10 OR #11 OR #13 OR #15 OR #17 OR #19 OR #21 Limits: Entrez Date from 2003, Humans, English	729
#24	Search #5 OR #23	1310
#25	Search #5 OR #23 Limits: Editorial, Letter, Case Reports	58
#26	Search #24 NOT #25	1252

MEDLINE search of instruments that measure health literacy, excluding acronyms, and not combined with the term “literacy”:

#1	Search “rapid estimate of adult literacy”	104
#2	Search “test of functional health literacy”	290
#3	Search “Hebrew health literacy test”	6
#4	Search “medical achievement reading test”	0
#5	Search medical achievements reading test”	68
#6	Search “newest vital signs”	1
#7	Search “short assessment of health literacy”	170
#8	Search “wide range achievement test”	219
#9	Search “literacy assessment for diabetes”	225
#10	Search “nutritional literacy”	3
#11	Search “single item numeracy screener”	0
#12	Search #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11	991
#13	Search #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 Limits: Entrez Date from 2003, Humans, English	473
#14	Search #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 Limits: Entrez Date from 2003, Humans, Editorial, Letter, Case Reports, English	5
#15	Search #13 NOT #14	468

Additional yield: 39 records

Medline search of the term “literacy [tw]”:

#1	Search literacy [tw]	5516
#2	Search literacy [tw] Limits: Entrez Date from 2003, Humans, English	2337
#3	Search literacy [tw] Limits: Editorial, Letter, Case Reports	243
#4	Search #2 NOT #3	2226

Additional yield: 1451 records

Searches of additional databases of the term “health literacy”:

CINAHL = 34

Cochrane = 61

PsycINFO = 65

ERIC = 34

Additional yield: 113

Our initial searches yielded 2,855 citations across databases. We reviewed our search strategy with the TEP and will supplement as needed according to any future recommendations. In addition, to attempt to avoid retrieval bias, we will manually search the reference lists of landmark studies and background articles on this topic to look for any relevant citations that might have been missed by electronic searches. We will also conduct an updated literature search before completing the final draft of the report. We do not anticipate incorporating gray literature in this search.

C. Data Abstraction and Data Management

We will review all titles and abstracts identified through searches against our inclusion/exclusion criteria. Each abstract will be independently reviewed by two members of the team. When differences arise between the reviewers, we will include studies for full-text review. For studies without adequate information to make the determination, we will again review the full text. All results will be tracked in an EndNote database.

We will retrieve the full text of all titles included during abstract review. Each full-text article will be independently reviewed by two members of the team for inclusion or exclusion based on the eligibility criteria described above. If both reviewers agree that a study does not meet the eligibility criteria, the study will be excluded. If the reviewers disagree, conflicts will be resolved by discussion and consensus or by consulting a third, independent party. As above, all results will be tracked in an EndNote database including, where applicable, the reason a study did not satisfy eligibility criteria so that we can later compile a listing of excluded articles and reasons for such exclusions.

We will design evidence tables that identify study information including study design, methods, and results. Trained abstractors will extract the relevant data from each included article into preformatted tables. Data abstractions will be reviewed for accuracy by a senior member of the team. We will create two sets of evidence tables, one for KQ 1 and one for KQ 2. The format of the tables will vary slightly by key question; in particular, the tables for KQ 2 will include a column that describes the intervention.

For this work, the RTI-UNC EPC team decided to abstract data from included articles directly into evidence tables, in part because most staff members had prior experience conducting evidence-based systematic reviews for AHRQ. This decision means that we bypass the use of data abstraction forms. Following this approach will create efficiencies in production and will not result in any major changes in the type of information included in the evidence tables as the project progresses.

D. Assessment of Methodological Quality of Individual Studies

To assess the quality (internal validity) of studies, we will use predefined criteria based on those developed for the earlier review, by the US Preventive Services Task Force (ratings: good, fair, poor) and the National Health Service Centre for Reviews and Dissemination and methods expertise available through our own and other EPCs.² In general terms, a “good” study has the least bias and results are considered to be valid. A “fair” study is susceptible to some bias but probably not sufficient to invalidate its results. A “poor” rating indicates significant bias (e.g., stemming from serious errors in design or analysis) that may invalidate the study’s results. We will update the methodology used in our earlier study as necessary after reviewing recent criteria developed by the RAND EPC to evaluate bias in randomized controlled trials and recently developed criteria on the quality of observational studies developed by Nancy Berkman and Meera Viswanathan at the RTI-UNC EPC.

Two independent reviewers will assign quality ratings to each study. Disagreements will be resolved by discussion and consensus or by consulting a third, independent party.

E. Data Synthesis

We anticipate that the data found in the literature review will be synthesized qualitatively. We do not anticipate that we will have a sufficient number of studies with similar outcomes or similar interventions to improve health outcomes in a population of individuals with low health literacy to consider quantitative analysis (meta-analysis) of data from those studies.

F. Grading the Evidence for Each Key Question

We will rate the strength of evidence based on the standard methods of the EPCs, which use a revised version of the approach devised by the GRADE working group.⁵ Developed to grade the quality of evidence and the strength of recommendations, this approach incorporates the following elements: study design, study quality, consistency, directness, presence of imprecise or sparse data, high probability of publication bias, and magnitude of the effect. We use four grades: high, moderate, low, and insufficient.

References

An initial list of key authors and citations which met our inclusion criteria upon full article review appear in Appendix A. Some of these studies may be excluded upon more detailed dual review and additional articles are likely to be added when the literature review is updated.

Summary of Protocol Amendments

In the event of protocol amendments, the date of each amendment will be accompanied by a description of the change and the rationale.

NOTE: The following protocol elements are standard procedures for all protocols.

Review of Key Questions

Key questions submitted by partners are reviewed and refined as needed by the EPC and the TEP to ensure that the questions are specific and explicit about what information is being reviewed.

Technical Expert Panel

A TEP is selected to provide broad expertise and perspectives specific to the topic under development. Divergent and conflicted opinions are common and perceived as healthy scientific discourse that results in a thoughtful, relevant systematic review. Therefore, study questions, design, and/or methodological approaches do not necessarily represent the views of individual technical and content experts. The TEP provides information to the EPC to identify literature search strategies, reviews the draft report, and recommends approaches to specific issues as requested by the EPC. The TEP does not do analysis of any kind nor contribute to the writing of the report.

Peer Review

Approximately five experts in the field will be asked to peer review the draft report and provide comments. The peer reviewer may represent stakeholder groups such as professional or advocacy organizations with knowledge of the topic. Peer review comments on the preliminary draft of the report are considered by the EPC in preparation of the final draft of the report. The synthesis of the scientific literature presented in the final report does not necessarily represent the views of individual reviewers. The dispositions of the peer review comments are documented and will be published three months after the publication of the evidence report with the reviewer identification information removed.

It is our policy not to release the names of the peer reviewers or TEP panel members until the report is published so that they can maintain their objectivity during the review process.

References

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APPENDIX A: Preliminary List of Citations Meeting Our Inclusion Criteria

Key Question 1:

- Aggarwal A, Speckman JL, Paasche-Orlow MK, et al. The role of numeracy on cancer screening among urban women. *Am J Health Behav* 2007;31(Suppl 1):S57-68.
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