

Health Literacy Interventions and Outcomes: An Updated Systematic Review

Executive Summary

Introduction

Health literacy is “the degree to which individuals can obtain, process, and understand the basic health information and services they need to make appropriate health decisions.” It represents a constellation of skills necessary for people to function effectively in the health care environment and act appropriately on health care information. These skills include the ability to interpret documents, read and write prose (print literacy), use quantitative information (numeracy), and speak and listen effectively (oral literacy).

Low health literacy is a significant problem in the United States. In 2003, approximately 80 million adults in the United States (36 percent) had limited health literacy. Rates of limited health literacy in certain population subgroups were higher. For instance, rates were higher among the elderly, minorities, individuals who have not completed high school, adults who spoke a language other than English before starting school, and people living in poverty. Highlighting the health impact of low health literacy, a 2004 systematic evidence review found a relationship between low health literacy and poor health outcomes. Specifically, health literacy (measured by reading skills) was associated with health-related knowledge and comprehension, hospitalization rates, global health measures, and some chronic diseases.

Evidence-based Practice Program

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of evidence reports and technology assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. The reports and assessments provide organizations with comprehensive, science-based information on common, costly medical conditions and new health care technologies. The EPCs systematically review the relevant scientific literature on topics assigned to them by AHRQ and conduct additional analyses when appropriate prior to developing their reports and assessments.

AHRQ expects that the EPC evidence reports and technology assessments will inform individual health plans, providers, and purchasers as well as the health care system as a whole by providing important information to help improve health care quality.

The full report and this summary are available at www.ahrq.gov/clinic/epcix.htm.



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Evidence-Based
Practice

Given the burden of low health literacy and the potential to reduce poor outcomes using novel interventions to address it, several national organizations have called for action. In 2010, the U.S. Department of Health and Human Services (HHS) released a National Action Plan to Improve Health Literacy. Additionally, in recent years, several national organizations and agencies, including the Institute of Medicine, American Medical Association, National Institutes of Health, and HHS (in Healthy People 2010), have promoted health literacy as a research priority.

Researchers responded to these calls with new and more sophisticated work. Thus, to synthesize the increasing volume of literature on health literacy, the Agency for Healthcare Research and Quality (AHRQ) commissioned the RTI International–University of North Carolina Evidence-based Practice Center (EPC) to update its 2004 systematic review examining the effects of literacy on health outcomes and interventions to improve those outcomes. In this updated report, we focus on the same Key Questions as the original report:

Key Question 1. Outcomes: Are health literacy skills related to (a) use of health care services, (b) health outcomes, (c) costs of health care, and (d) disparities in health outcomes or health care service use?

Key Question 2. Interventions: 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 care, and (d) improve health care service use and/or health outcomes among different racial, ethnic, cultural, or age groups?

In contrast to our earlier report, we concentrate on “health literacy” rather than “literacy” for several reasons. First, we aimed to be consistent with recent conceptualizations of health literacy skills that separately examine print literacy, numeracy, and oral literacy. Second, an increasing number of newer measures are framed in specific health contexts and assess condition-related skills. Finally, measures of health literacy, print literacy (including prose and document literacy), and numeracy are highly correlated in national samples.

Although we believe our focus on health literacy appropriately represents the directions of research and policy in this field, we acknowledge that the literature contributing to this field does not organize itself neatly within our health literacy framework. For instance, several measures of health

literacy assess a combination of print literacy and numeracy skills, making distinctions between print literacy and numeracy difficult. Furthermore, the quantitative skills components of some measures have been extracted and used independently as measures of numeracy. To simplify this report, we separate health literacy (including any studies that presume to measure literacy or health literacy) from those that solely measure numeracy or oral literacy.

Methods

Changes From Our Prior Review

Our overall goals in this update were to evaluate whether newer literature was appropriate for answering our Key Questions and to determine whether earlier conclusions changed. Following discussions with our Technical Expert Panel, we modified the original methods as follows:

- We broadened our definition of health literacy to be consistent with the Ratzan and Parker (2000) definition used by Healthy People 2010 and the Institute of Medicine. Thus, our inclusion criteria included studies that measured numeracy and oral skills of participants.
- We required that studies directly measured the health literacy of the study population and did not assign health literacy level via self-report or similarity to other populations.
- To evaluate individual study quality, we incorporated advances in the methods of conducting systematic reviews.
- We included studies conducted in developing countries as long as they used an objective measure of literacy or health literacy in their participants.
- We reviewed knowledge as an outcome only for numeracy and intervention studies because evidence in the earlier review clearly concluded that greater literacy skills and higher health-related knowledge levels are positively related.
- If articles about intervention studies were missing information about intervention content, we queried the investigators to allow richer interpretation about what interventions may be effective in mitigating the effects of low health literacy.

Outcomes of Interest

The logic model in Figure A details outcomes that we included in our review as well as other conceptually important variables. It draws on several models of health literacy proposed by researchers in the field and on an integrated model of behavioral theory called the Integrative Theory. We applied this model to determine whether studies considered for inclusion had relevant health outcomes and to guide our presentation of included articles. It is not, however, a definitive guide to the relationship among variables because researchers have not explicitly tested many of these relationships yet. Furthermore, it does not specify the directionality of a good outcome; for some outcomes, increases represent the good outcome (e.g., adherence, most screening tests) and for others, decreases represent the good outcome (e.g., hospitalizations, mortality). We did not examine outcomes related to attitudes because of the belief that attitudes result from knowledge, which, as mentioned above, is not examined in the current report. Further, we did not examine outcomes related to social norms or patient-provider relationships (e.g., shared decisionmaking) because we thought that these variables likely affected the direction or strength of the relationship between behavioral intent and health outcomes, rather than laying on the causal pathway. Clearly, however, empiric work is needed to test these assertions prior to future reviews.

Literature Search and Retrieval Process

We searched MEDLINE®, the Cumulative Index to Nursing and Allied Health Literature, the Cochrane Library, PsycINFO, and the Educational Resources Information Center. For health literacy, we searched from 2003 to May 25, 2010. For numeracy, we searched from 1966 to May 25, 2010. We conducted keyword searches because no Medical Subject Headings terms specifically identify health-literacy-related articles. The terms health literacy, numeracy, and literacy, and terms or phrases related to instruments known to measure health literacy and numeracy, were the focus of the search. We excluded editorials, letters to the editor, case reports, and non-English language studies. We also manually searched reference lists of pertinent review articles and editorials for additional studies.

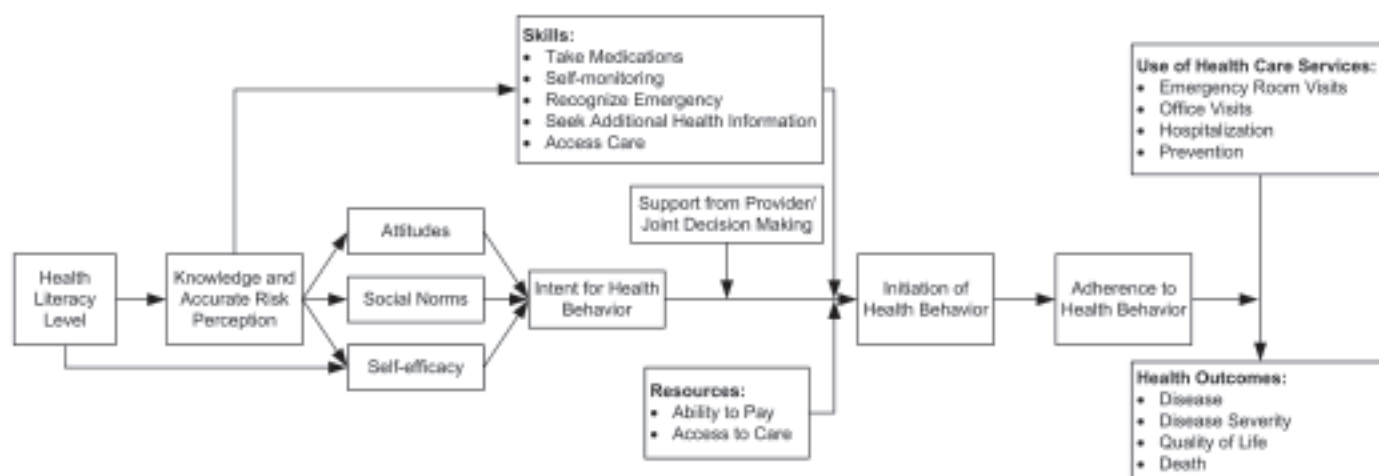
Article Review and Data Abstraction

We used standard EPC methods for dual review of abstracts and full text of articles to determine article inclusion. After determining article inclusion, one reviewer entered data about studies into evidence tables and a second, senior reviewer checked information for accuracy and completeness.

Quality Review

Two reviewers independently rated the quality of studies (good, fair, or poor) using criteria designed to detect selection bias, measurement bias, confounding, and inadequate power. Reviewers resolved all disagreements

Figure A. Logic model for analyzing studies of health literacy



about quality ratings by consensus. We did not consider further any studies that we rated poor quality.

Data Synthesis and Grading Strength of Evidence

We synthesized the data in our review qualitatively. We did not have a sufficient number of studies with similar outcomes or similar interventions to consider quantitative analysis (meta-analysis or statistical pooling) of data. Furthermore, we primarily discussed information from the current searches, providing only aggregate summaries of data from our 2004 review. As part of data synthesis, we paid particular attention to a few issues. First, we closely examined whether studies accounted for relevant confounding variables in their analyses. Because the goal of etiologic research focuses on understanding the relationship between exposures and outcomes of interest, it is important that confounders are controlled for to determine accurate estimates of effect. Second, we looked closely at studies that reported the relationship between both health literacy and numeracy and the same outcome. This allowed inferences about the relative strengths of the measures on outcomes. Third, for intervention studies, we looked at common features of successful interventions and at the impact of interventions on multiple related outcomes. This allowed inference about the effective components and mechanisms of health literacy interventions.

The investigative team jointly discussed and graded the overall body of literature and generated recommendations for future research. For grading strength of evidence, we used the AHRQ EPC program's approach: assigning grades of high, moderate, low, or insufficient to the evidence after considering the domains of risk of bias, consistency, directness, and precision. We resolved disagreements by consensus discussion.

Results

Search Results and Included Studies

Our searches of electronic databases and review articles produced 3,496 unduplicated records. Ultimately, for the two main questions, we included studies rated either good or fair quality: 81 studies (95 articles) addressed Key Question 1 and 42 studies (45 articles) addressed Key Question 2. Key Question 1 results are presented separately in relation to health literacy (86 articles) and numeracy (16 articles). Of these, we identify the 7 articles that address both health literacy and numeracy.

Key Question 1: Relationship of health literacy to various outcomes and disparities

Sixty-four articles pertaining to this part of Key Question 1 had cross-sectional designs; 22 were cohort studies. We categorized studies examining outcomes associated with differences in health literacy level into two main domains: use of health care services and health outcomes. Strength of evidence evaluations focused on the relationship between the lowest health literacy group and the highest. The evidence was sparse for evaluating differences between those with marginal health literacy (a middle category) and adequate health literacy (the highest category).

Use of Health Care Services – Health Literacy

Moderate evidence about health care service use showed that lower health literacy was associated with increased hospitalization (five studies), greater emergency care use (nine studies), lower use of mammography (four studies), and lower receipt of influenza vaccine (four studies). Evidence for all other analyses of health care service use was low or insufficient because of inconsistent findings or outcomes; this includes studies about colon screening, Papanicolaou (Pap) tests, testing for sexually transmitted infections, pneumococcal immunization, and access to care.

Health Outcomes – Health Literacy

Lower health literacy was associated with poorer outcomes in some of the health outcomes examined. A higher risk of mortality for seniors (two studies) was clearly associated with lower health literacy (high strength of evidence). Lower health literacy was associated with poorer ability to demonstrate taking medications appropriately (five studies), poorer ability to interpret labels and health messages (three studies), and poorer overall health status among seniors (five studies) (all of moderate strength of evidence). In these studies, the evidence consisted of all observational studies, generally with a medium risk of bias and results in a consistent direction.

The strength of evidence for the many other outcomes we examined—adherence, self-efficacy, smoking, alcohol use, healthy lifestyle, review of prescription information, HIV risks and sexual behaviors, chronic disease prevalence, HIV severity and symptoms, asthma severity and control, diabetes control and related symptoms, hypertension control, prostate cancer control, quality of life, and costs—was either low or insufficient. The literature consisted of only a small number of studies, poorly designed studies, and/or inconsistent results.

Potential moderators and mediators of the relationship between health literacy and health outcomes were also identified during our review. Two studies concluded that social support and health care system characteristics modify the magnitude and/or direction of the relationship between health literacy and adherence and health literacy and blood pressure control. Four studies concluded that knowledge, patient self-efficacy, and stigma might act as mediators or intermediaries in the causal pathway between health literacy and health outcomes and explain at least some of the negative impact of low health literacy on these health outcomes. In addition, one study suggested that health literacy may mediate the effect of education, income, and urbanicity on health outcomes.

Costs – Health Literacy

Evidence was insufficient to evaluate the relationship between differences in health literacy levels and costs. The two relevant studies examined different payment sources (Medicaid and Medicare) and different populations, and found inconsistent results.

Disparities in Outcomes – Health Literacy

In relation to disparities, health literacy appeared to mediate the effect of race on several health outcomes. These included conditions that keep a person from working, long-term illness, self-reported health status, receipt of an influenza vaccine, physical and mental health-related quality of life, self-reported health, prostate-specific antigen levels, nonadherence to HIV medications, and enrollment in health insurance. Health literacy also mediated differences by both race and gender in the misinterpretation of medication label instructions.

Key Question 1: Relationship of numeracy to various outcomes and disparities

In this update, we identified 16 studies examining the relationship between numeracy and health outcomes. Eleven were cross-sectional in design. Four studies were randomized controlled trials (RCTs) that analyzed their data in a cross-sectional manner for this analysis; one study used a prospective cohort design.

In general, the evidence pertaining to this Key Question was either low or insufficient given the small number of studies; these studies often had high risk of bias or, collectively, gave us mixed results.

Use of Health Care Services – Numeracy

Only one study addressed the relationship between numeracy and use of health care services (low strength of evidence). It reported no effect of numeracy on up-to-date screening for breast and colon cancer, but it appeared to be limited by inadequate power to detect a meaningful effect.

Health Outcomes – Numeracy

Relationships between numeracy level and accuracy of risk perception (five studies), knowledge (four studies), skills taking medication (six studies), and disease prevalence and severity (three studies) were mixed. The evidence for the relationship between numeracy and other health outcomes, such as self-efficacy or behavior, was insufficient to draw conclusions. No study addressed the costs associated with differences in numeracy level.

Disparities in Outcomes – Numeracy

Two studies examined whether numeracy level mediates health disparities. Numeracy appeared to mediate the relationship between race and levels of hemoglobin A1c and between gender and HIV medication management capacity.

Key Question 1: Comparison of the relationship of health literacy and numeracy to the same outcomes

Seven studies addressed the effects of both health literacy and numeracy on various outcomes. Of the seven, only four performed adjusted analyses on the same outcomes, thereby allowing assessment of whether these exposures affect health outcomes differently. All suggest that numeracy is more highly correlated with outcomes than health literacy. However, all must be interpreted with caution, because the proportion of individuals with low health literacy was small, raising the possibility of ceiling effects that could obscure effects in the literacy analyses.

Key Question 2: Interventions to improve low health literacy

In this update, we included 42 studies of good or fair quality addressing the effect of interventions designed to mitigate the effects of low health literacy; of these, 27 were RCTs, 2 were cluster randomized trials, and 13 were quasi-experimental studies. We focused our analyses on 2 separate sets of studies: 21 that used one specific strategy (single design features) to lessen the effects of low health literacy and 21 that used a mixture of strategies combined into a single intervention.

Interventions With Single Design Features

Of intervention studies testing single design features, two focused on alternative document design, three on alternative numerical presentation, eight on additive or alternative pictorial representations, four on alternative media, and seven on a combination of alternative readability and document design. Additionally, one intervention focused on the effects of physician notification about patients' literacy status on health outcomes. Effects were measured primarily in terms of comprehension.

Overall, the strength of evidence for specific design features in these interventions was low or insufficient. This is attributable, in large part, to differences in the types of interventions and, subsequently, in the mix of results. Looking closely within categories of design features, however, the following specific design features seemed to improve comprehension for low-health-literacy populations in one or a few studies: (1) presenting essential information by itself (i.e., information on hospital death rates without other distracting information, such as information on consumer satisfaction); (2) presenting essential information first (i.e., information on hospital death rates before information about consumer satisfaction); (3) presenting health plan quality information such that the higher number (rather than the lower number) indicates better quality; (4) using the same denominators to present baseline risk and treatment benefit; (5) adding icon arrays to numerical presentations of treatment benefit; and (6) adding video to verbal narratives. Additionally, in reexamining data from our 2004 review within these categories, we identified further evidence of potential benefit from using reduced reading level and/or illustrated narratives. In contrast, one study raised questions about whether certain design features, such as colored traffic symbols to denote death rates in hospitals of varying quality or symbols accompanying nonessential quality information, may actually worsen health choices among those with low health literacy.

Interventions With a Combination of Features

The strength of evidence for studies combining multiple strategies to mitigate the effects of low health literacy on either health care use or outcomes was more variable than it was for single-feature interventions.

Use of Health Care Services

Across all studies in this category, we found moderate strength of evidence that interventions included in the review changed health care service use. Specifically,

intensive self-management and adherence interventions appeared to be effective in reducing emergency room visits and hospitalizations. Additionally, educational interventions and/or cues for screening increased colorectal cancer and prostate cancer screening (although we note that the health benefits of additional prostate cancer screening are not clear).

Health Outcomes

We found evidence of moderate strength that some interventions changed health outcomes. For instance, intensive disease-management programs appeared to be effective at reducing disease prevalence/severity. Furthermore, self-management interventions increased self-management behavior; however, in the only study that stratified a subgroup analysis by health literacy level, improvements were sometimes greater for those who had adequate health literacy and at other times greater for those with inadequate health literacy in adjusted analyses. The effects of other interventions on other health outcomes, including knowledge, self-efficacy, health-related skills, adherence, quality of life, and costs were mixed; thus, the strength of evidence was insufficient.

Components of effective interventions were their high intensity, theory basis, pilot testing before full implementation, emphasis on skill building, and delivery of the intervention by a health professional. Interventions that changed distal outcomes (e.g., health care service use or health outcomes) appeared to work by affecting intermediate factors, such as increasing knowledge or self-efficacy, or by changing behavior.

Too few studies addressed the effects of health literacy interventions on the outcomes of behavioral intent, and disparities to draw any meaningful conclusions; the strength of evidence is insufficient.

Discussion

What This Update Adds to the 2004 Review

The results of this review expand our understanding of the relationship between health literacy and health outcomes in several ways. First, a majority of studies included in this review performed multivariate analysis, allowing us to make better estimates of the true effect of health literacy on health outcomes. Second, new studies have addressed the relationship between numeracy level and health outcomes. This allows a better understanding of what it means to be health literate. Third, we identified a limited body of

research that begins to identify variables that may be on a causal pathway between health literacy and health outcomes. These variables include knowledge, self-efficacy, and social stigma. Finally, new studies suggest that health literacy can be a mediator of racial disparities in health outcomes.

We also learned many new things about interventions to mitigate the effect of low health literacy. First, we identified several design features of interventions that were effective in one or a few studies (enumerated above); they all warrant further study in broader populations. Second, interventions focused on a broader range of outcomes, allowing us to make inferences about effect across outcomes. Preliminary examination of these studies suggests that effective interventions to mitigate the effects of low health literacy may work by increasing knowledge and self-efficacy or by changing behavior. Additionally, certain factors appear to be key in making the interventions effective with respect to distal outcomes (e.g., self-management, hospitalizations, mortality); these include high intensity, theory basis, pilot testing before full implementation, emphasis on skill building, and delivery of the intervention by a health professional (e.g., pharmacist, diabetes educator).

Limitations of the Literature

As with all systematic reviews, our results and conclusions depend on the quality of the published literature. Heterogeneity in outcomes, populations, study designs (or interventions), and measured outcomes was a problem for both Key Questions. This level of diversity in the knowledge base precluded us from pooling results statistically.

The limitations of the literature for Key Question 1 studies included:

- Lack of a priori specification and inconsistent approaches to creating health literacy and numeracy levels or thresholds in analyses, hampering comparisons between studies;
- Inconsistent choices of potential confounding variables in multivariate analyses;
- Small sample sizes, making it impossible for us to determine whether null findings represented a true lack of effect or simply limitations in statistical power;
- Studies in just one clinic or in other narrowly defined patient populations, rendering the applicability of findings to other settings or populations unknowable;
- Use of health literacy tools that continue to focus primarily on reading ability;

- The limited number of studies examining potential mediators of health literacy, such as self-efficacy, knowledge, or beliefs;
- Few studies examining the role of health literacy on health disparities; and
- No studies examining differences in outcomes related to oral literacy skills.

The limitations of the literature for Key Question 2 studies included:

- Lack of an adequate control or comparator group in many studies, limiting the ability to determine the true effect(s) of the intervention;
- Measurement of multiple outcomes with insufficient attention to ensure that each had been adequately powered to detect a difference;
- Testing interventions that combined various design features to mitigate the effect of low health literacy but offering no way to determine the effectiveness of individual components;
- Failure to perform adequately controlled subgroup analyses that would elucidate differential effects of interventions in low- and high-health-literacy populations; and
- Failure to report adequately the intervention design features that would allow future content analyses of effective interventions.

Future Research

The field of health literacy has clearly advanced since our 2004 review appeared. The progress has been both conceptual and empirical. Nonetheless, many opportunities remain for important future research. Such investigations will improve our understanding of the impact of health literacy on the use and outcomes of health care and will expand the knowledge base about the impact of interventions intended to improve health literacy. Our recommendations for future research involve both better methods and specific clinical or operational topics.

In examining the relationship between literacy and health outcomes, investigators should consider:

- Specifying a priori their cutpoints for distinguishing levels of health literacy and noting the relevance of those levels to (a) the outcomes and population being studied and (b) the body of similar work in the field;

- Using health literacy measurement tools that go beyond health-related literacy and numeracy to capture additional and potentially critical skills, particularly oral health literacy;
- Ensuring sufficient statistical power to detect differences among relevant health literacy levels;
- Controlling for an adequate set of potential confounders;
- Improving the applicability of results to broader populations and settings; and
- Further examining potential mediators and moderators of the relationship between health literacy and health outcomes.

In examining the impact of interventions to mitigate the effects of low health literacy, investigators should consider:

- Testing novel approaches to increase motivation; improved techniques for delivering written, oral, or numerical information; and “work-around” interventions such as patient advocates;
- Determining the effective components of already-tested interventions that employ a combination of features intended to lessen the effects of low health literacy. Although a combination of intervention features has repeatedly been shown to ensure the success of interventions, paring away ineffective features could save delivery time and result in more cost-effective delivery;
- Determining the cost-effectiveness of effective programs; and
- Determining the effect of practice and policy interventions. We found almost no studies that addressed such interventions.

Implications of This Report for Clinicians and Policymakers

We anticipate that this update will continue to raise awareness among clinicians and policymakers alike that low health literacy has a substantial impact on the use of health care services and health outcomes; it also hints at the role of health literacy in disparities in utilization or outcomes among groups defined by various sociodemographic characteristics. However, little remains known about the direct effect of lower health literacy on the costs of health

care. Addressing the burden of low health literacy that we have identified warrants the attention of many stakeholders.

We highlight effective interventions that could be implemented in clinical practice now. Intensive interventions related to medication adherence, self-management, and disease management delivered by clinical practitioners are of special interest.

Additionally, for policymakers, we underscore the critical need for research funding to test practice and policy interventions, particularly those that, to date, have gone largely untested. The recent HHS National Action Plan to Improve Health Literacy helps enumerate these and other critical actions for health care professionals and policymakers to take in addressing the multifaceted issues involving health literacy in this country.

Full Report

The executive summary is part of the following document: Berkman ND, Sheridan SL, Donahue KE, Halpern DJ, Viera A, Crotty K, Holland A, Brasure M, Lohr KN, Harden E, Tant E, Wallace I, Viswanathan M. Health Literacy Interventions and Outcomes: An Updated Systematic Review. Evidence Report/Technology Assessment No. 199. (Prepared by RTI International–University of North Carolina Evidence-based Practice Center under Contract No. 290-2007-10056-I.) AHRQ Publication No. 11-E006. Rockville, MD. Agency for Healthcare Research and Quality. March 2011. Available at: www.ahrq.gov/clinic/tp/lituptp.htm.

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