Literacy and Health Outcomes

Volume I. Final Evidence Report

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Preface

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. This report on literacy and health outcomes was requested by the American Medical Association and funded by AHRQ. 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.

To bring the broadest range of experts into the development of evidence reports and health technology assessments, AHRQ encourages the EPCs to form partnerships and enter into collaborations with other medical and research organizations. The EPCs work with these partner organizations to ensure that the evidence reports and technology assessments they produce will become building blocks for health care quality improvement projects throughout the Nation. The reports undergo peer review prior to their release.

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.

We welcome written comments on this evidence report. They may be sent to: Director, Center for Outcomes and Evidence, Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850.

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Structured Abstract

Context: More than 90 million adults in the United States have poor literacy, which would cause them to have trouble finding pieces of information or numbers in a lengthy text, integrating multiple pieces of information in a document, or finding two or more numbers in a chart and performing a calculation. Those with poorer reading skills are believed to have greater difficulty navigating the health care system and to be at risk of experiencing poorer health outcomes.

Objectives: Research has examined the effect of low literacy on a wide variety of health outcomes, but we are unaware of any published systematic reviews that have analyzed these relationships or examined interventions to mitigate the health effects of low literacy. To evaluate the existing research, we performed a systematic review to address two four-part key questions based on questions initially posed by the American Medical Association and the Agency for Healthcare Research and Quality and put into final form in cooperation with our Technical Expert Advisory Group. The questions are as follows:

- **Key Question 1:** Are 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 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?

Data Sources: We searched a variety of data sources for studies published between 1980 and 2003, including MEDLINE, the Cumulative Index to Nursing and Allied Health (CINAHL), the Cochrane Library, the Educational Resources Information Center (ERIC) or Public Affairs Information Service (PAIS), and the Industrial and Labor Relations Review (ILRR) database. In MEDLINE, our primary database, we had to rely on key word searches because no MeSH headings specifically identify literacy-related articles. Similarly, the terms "literacy" or "health literacy" were searched in different databases with the choice based on the scope of the database. We also sought additional articles through Web-based bibliographies and experts.

Study Selection: For Key Question (KQ) 1, we included observational studies that reported original data, measured literacy with any valid instrument, and evaluated one or more health outcomes. We included studies that measured change in knowledge; we excluded studies that measured only readability or satisfaction with educational materials or that used Cloze-method questions as the only outcome. For KQ 2, we included uncontrolled before-and-after studies and nonrandomized and randomized controlled trials. Intervention studies either measured literacy or were conducted in populations that were known to have a high proportion of patients with low literacy. We excluded studies in which the primary language of the participant was not the same as that of the health care provider and studies conducted in developing countries.

Data Extraction: One investigator extracted information from each article directly into evidence tables. A second investigator checked these entries by re-extraction of the information. Disagreements were resolved by consensus of the two extractors. Both data extractors independently completed an 11-item quality scale for each article; scores were averaged to give a final measure of article quality.

Data Synthesis: We identified 3,015 unique abstracts from our literature searches. We excluded 2,330 that clearly did not meet our inclusion criteria after abstract review. Of the 684 remaining articles subjected to full review, 611 were rejected and 73 retained. Of those retained, 44 articles addressed KQ 1 and 29 articles addressed KQ 2.

Studies examining the relationship between low literacy and adverse health outcomes generally found that patients with low literacy had poorer health outcomes, including knowledge, intermediate disease markers, measures of morbidity, general health status, and use of health resources. Most studies were cross-sectional in design, and many failed to adequately address confounding and the use of multiple comparisons in their analyses. For KQ 2, most interventions led to improved outcomes, particularly for outcomes of understanding or knowledge. Fewer studies examined the effect of interventions for patients with low health literacy on morbidity and mortality. Most did not measure reading ability directly among participants in the studies.

Based on our 11-item quality scale, we found that the average quality of the individual articles addressing KQs 1a and 1b was good to fair. The quality of the one article addressing KQ 2a was good; the average quality of the articles addressing KQ 2b was fair. We did not find literature that discussed the portion of the key questions addressing costs or disparities, so an average grade is not available.

We also graded the strength of the evidence for this body of literature on a scale from I (strongest design) to IV (no published literature). We concluded that the literature addressing KQ 1a and 1b should receive a grade of II; it generally includes studies of strong design, but some uncertainty remains because of concerns about generalizability, bias, research design flaws, and adequate sample size. The literature addressing KQ 1c and 1d was rated III since the evidence is from a limited number of studies of weaker design and studies with strong designs have not been done. The literature addressing KQ 2a and 2b also received a grade of III, while the literature addressing KQ 2c and 2d received a grade of IV, indicating that there was no published literature.

Conclusions: Low literacy is associated with several adverse health outcomes, including low health knowledge, increased incidence of chronic illness, poorer intermediate disease markers, and less than optimal use of preventive health services. Interventions to mitigate the effects of low literacy have been studied, and some have shown promise for improving patient health and receipt of health care services. Future research, using more rigorous methods, is required to better define these relationships and to guide development of new interventions.

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Chapter 1. Introduction

Burden of the Problem

The National Literacy Act of 1991 defined literacy as "an individual's ability to read, write, and speak in English and compute and solve problems at levels of proficiency necessary to function on the job and in society, to achieve one's goals, and to develop one's knowledge and potential."[1] Low literacy is common in the United States. In 1993, the National Adult Literacy Study (NALS) reported that 40 million adult Americans scored on the lowest of five levels (level 1) and another 50 million scored at level 2.[2] Individuals are categorized in these two lowest levels if they have trouble finding pieces of information or numbers in a lengthy text, integrating multiple pieces of information in a document, or finding two or more numbers in a chart and performing a calculation.[2] Economists and educators have estimated that meeting the requirements of an ever-increasing percentage of jobs and the demands of day-to-day life, such as processing insurance forms and obtaining credit, requires skill above levels 1 and 2 on the NALS.[3]

Low literacy may also impair an individual's ability to function in the health care environment, which has increasingly relied on complex written information to guide medical care and improve health. Historically, the average reading level of patient materials related to health care has been 11th to 14th grade, but the average person's reading level is much lower.[4] Additionally, even patients who read at the college level have been found to prefer medical information written at the 7th grade level.[4]

Substantial research has documented the strong relationship between years of formal education and health outcomes.[5] In the 1990s, evidence emerged about the prevalence of low literacy among patients in the health care setting and its association with adverse health outcomes. For example, at two public hospitals in Atlanta and Los Angeles, 35 percent of English-speaking patients had inadequate literacy skills to function in the health care setting, based on the Test of Functional Health Literacy in Adults (TOFHLA).[6] In addition, 20 percent to 30 percent of patients incorrectly answered how many pills of a prescription should be taken, and similar proportions did not know how to read when their next appointment was scheduled.[6] In a national managed care program for Medicare enrollees, 34 percent of English-speaking patients had inadequate or marginal literacy based on the Short-TOFHLA (S-TOFHLA).[7] As a result of these and other reports, the nation has become more aware of the prevalence of low literacy and its effect on the health of the population.

Although one's literacy level is related to one's educational status, the correlation between years of education and literacy is not particularly strong. An individual's reading grade level is often found to be several grades below the last year of school completed.[4] Additionally, because of the emphasis in the United States on completing high school, 12 years of education represents a very large distribution of literacy levels. The ability to complete 12 years of education may draw on several factors in addition to the ability to read, including social support, community resources, motivation, and family expectations.

The impact of an individual's literacy level may go beyond his or her ability to understand written or even spoken instructions. It is one of several factors that may insidiously affect patient-physician communication dynamics and inadvertently lead to substandard medical care.

Note: Appendixes and Evidence Tables cited in this report are provided electronically at http://www/ahrq.gov/clinic/epcindex.htm.

Some studies suggest that patient-physician communication may be part of the pathway from low literacy to worse health.[8] In February 1999, the American Medical Association (AMA) Council on Scientific Affairs published a report on health literacy and recommended the allocation of federal and private funds for research in this area.[9]

Literacy and Health Literacy

An important step in examining the relationship between literacy and health outcomes is to clarify what literacy means and how it has been measured. In the English language, literacy has taken on several different meanings. In its most common usage, literacy refers to an individual's ability to read and write.[10] It is also sometimes used to describe a person's facility with or knowledge about a particular topic. For example, we often see phrases such as "science literacy," "computer literacy," and "sports literacy." These terms generally refer to a person's ability to function in a particular context that requires some background knowledge.

In this same way, "health literacy" has been defined as a constellation of skills that constitute the ability to perform basic reading and numerical tasks that are required to function in the health care environment.[9] Patients with adequate health literacy can read, understand, and act on health care information.[9] Some authors have used an expanded definition of health literacy that includes a working knowledge of disease processes, self-efficacy, and motivation for political action regarding health issues.[11] These definitions have value, but when evaluating the relationship between health literacy and health outcomes, one must consider what has actually been measured. To date, instruments used to measure literacy in the health care setting have focused on the ability to read and, in some cases, to use numbers.

Instruments commonly used to measure health literacy (Table 1) include the Wide Range Achievement Test (WRAT) reading subtest,[12] the Rapid Estimate of Adult Literacy in Medicine (REALM),[13] and the TOFHLA.[6] The WRAT and REALM are word recognition tests that assess whether a person can correctly pronounce a series of words listed in order of increasing difficulty. Both instruments have been validated as instruments of reading ability; they are highly correlated with one another (Table 2) and other traditional reading assessments in the educational literature.[13] The main difference between the REALM and WRAT is that the REALM uses words commonly seen in the health care setting. Although this choice adds face validity to the instrument for use in health care settings, the reported correlation between REALM and WRAT ($r = 0.88$) suggests that the information provided by the two instruments is not very different.

The TOFHLA takes a different approach and assesses literacy by using a modified Cloze method. In this approach, subjects read passages in which every fifth to seventh word has been deleted and insert the correct word from a choice of four words.[6] The TOFHLA also has subjects respond to prompts, such as pill bottle instructions and appointment slips, thus measuring patients' ability to use basic numerical information (numeracy) in a health context. The structure of this instrument, therefore, facilitates assessment of both reading comprehension and numerical comprehension (rather than just word recognition). During the development and validation of the TOFHLA, the authors found that the quantitative or "numeracy" subtest was highly correlated with the reading comprehension subtest ($r = 0.79$). The TOFHLA is also highly correlated with the REALM ($r = 0.84$) and the WRAT ($r = 0.74$).

Because the TOFHLA takes more than 20 minutes to administer, the developers created a short version (S-TOFHLA). This shortened version originally used two reading comprehension passages and four quantitative questions. The S-TOFHLA strongly correlates with the TOFHLA ($r = 0.96$). Perhaps more important, the reading comprehension section of the S-TOFHLA, without the quantitative questions, correlates almost as strongly ($r = 0.92$), leading the investigators to drop the quantitative questions and use only the two reading passages.

Although the TOFHLA is labeled as an instrument to measure health literacy, its style and structure, together with validation data, suggest that it is a measure of reading ability similar to the REALM and WRAT. As an example, individuals who read at the high school level but know nothing about diabetes are much more likely to score higher on the TOFHLA, REALM, and WRAT than people who read at the grade school level but know a good deal about their own diabetes and how to perform effective self-care. To date, no current instrument adequately assesses the more global concept of health literacy.

Although basic numeracy skills are commonly required to function in the health care setting, whether measuring them provides additional information beyond the reading assessment is not clear. As previously discussed, the TOFHLA includes several quantitative questions to measure how patients use basic numerical information. However, although the scores on the quantitative section are highly correlated with the reading comprehension section, they have not been independently validated.

A less common approach to measuring numeracy evaluated how people deal with information about probability, as would be needed to evaluate the risks and benefits of different treatment options.[14] Although the results of these studies have demonstrated that people have trouble with probability concepts, the scores on such assessments have not been studied in relation to health outcomes and are therefore excluded from this analysis.

Because of the ambiguity in the meaning of health literacy and the fact that instruments used in outcomes studies focus on ability to read, we use the term "reading ability" to describe the variable measured as the exposure in this body of literature. Most researchers and educators would agree that reading ability is a critical component of literacy and health literacy, even though it may not reflect other important factors such as speaking, writing, or problem solving, as discussed in the National Literacy Act, or ability to act on health information, as discussed in the AMA definition of health literacy. Researchers and advocates will continue to ponder and debate what "health literacy" should mean, but as yet, its measurement as a single variable eludes us. Therefore, this report focuses on the relationship between reading ability and health-related outcomes, including interventions that may strengthen that relationship.

Literacy and Vulnerable Populations

Although a significant proportion of the general population has low literacy, certain groups have an even higher prevalence. The NALS demonstrated a higher prevalence of poor literacy skills among the elderly.[2] This association has proven consistent with other studies of literacy in health care settings. However, because all the studies have been cross-sectional, we cannot differentiate between a cohort effect and a decline in individual literacy as a person ages. Both factors likely play a role. Educational opportunity has increased over the years in this country, and part of the association between age and literacy may reflect this trend (i.e., cohort effect). Studies have also shown that lower literacy is associated with lower cognitive ability.[15] Because

cognitive decline occurs more commonly in older age groups, literacy may also decline (i.e., an age effect).

The NALS also reported strong relationships between literacy and race or ethnicity. Self-reported scores from white adults are about 25 to 80 points higher on a scale of 0 to 500 than scores for any of the other racial or ethnic groups evaluated. Differential access to education by disadvantaged members of nonwhite populations may, at least partially, explain this result. This finding raises the question of whether literacy acts as a mediator in racial or ethnic disparities in health. If literacy is related to health outcomes, different literacy levels among different groups could contribute to differential health outcomes.

Additionally, one could consider whether an interaction exists between literacy and race or ethnicity with respect to health outcomes. For instance, a person with low literacy from a minority racial or ethnic background may experience more of an effect of low literacy than an individual from a majority race because of cross-cultural differences in communication or racism.

The NALS reported disparities in literacy level according to other markers of vulnerability. For example, years of education had the strongest relationship to literacy skill. Those who completed fewer years of education were much more likely to score at a lower level on the NALS. Similarly, the number of years of education achieved by one's parents was correlated with one's score on the NALS, but this association was not found to be as strong as the subject's own education.

Other factors associated with differences in literacy skill include geographic location, sex, incarceration, and income. Subjects living in the West and Midwest scored slightly higher than those in the Northeast and South. Males scored slightly higher than females on the document and quantitative scales but similarly on the prose scale. Incarcerated individuals scored significantly lower than the general population, largely explained by education and other demographic factors. Lower literacy skill was also much more common among those classified as poor or near poor. An important and as yet unanswered question is whether literacy is a mediator of adverse outcomes or whether it is merely a marker for other associated factors, such as poverty, lack of access to care, or lack of health insurance, that actually lead to poorer health outcomes.

Analyzing the Relationship Between Reading Ability and Health Outcomes

Etiologic research focuses on understanding the relationship between exposures and outcomes of interest. In this report, we want to determine whether poor reading ability (the exposure) leads to worse health outcomes. However, confounders (other variables that are related to both reading ability and health outcomes) can influence (i.e., bias or hide) the relationship between reading ability and health outcomes.

For instance, poor reading ability is often associated with lack of health insurance, lower income levels, and age. Each of these variables is also associated with worse health outcomes. Therefore, upon finding a relationship between literacy and a health outcome, exploring whether that relationship is causal or is a result of confounding is important. To do this, many researchers use analytic methods to try to "adjust" or account for confounders when trying to observe the true relationship between reading ability and health outcomes. Because adjusting for

confounders is an imperfect science, clear reporting of the methods and measurements is important to understand the study result.

Readability

For written educational materials to be effective, the target audience must be able to read and understand them. In evaluating interventions, researchers must consider the readability of written materials. Several approaches have been developed to measure "readability." Readability assessments often use formulas such as the Fry,[16] the Flesch-Kincaid formula (Microsoft Word®), or others that take into account length of sentences and the number of syllables in the words.

Some authors have recently suggested more comprehensive methods for assessing suitability of educational materials that take into account an expanded view of readability, including use of common words, graphics, and cultural appropriateness.[17] All these methods offer some objective means for determining the suitability of health education materials.

Several authors have published analyses of health education materials in which they assessed readability. Almost universally, the readability level of the materials exceeded the reading level of the average user. One could assume that because the readability level of the materials exceeds the users' measured reading level, the materials will not be understood. However, because both assessment of readability and reading ability are imperfect, such studies are not adequate on their own and cannot inform the key questions of this report. Therefore, we limited this report to studies with health outcomes and did not include literature evaluating readability unless the effect on health outcomes was reported.

Production of This Evidence Report

Organization

Given that low literacy is presumed to affect health and well-being negatively, the Agency for Healthcare Research and Quality (AHRQ) commissioned an evidence report through its Evidence-Based Practice Program and assigned it to the RTI International–University of North Carolina Evidence-Based Practice Center (RTI-UNC EPC). This issue is of particular concern to AMA, which originally nominated the topic. Our systematic review consolidates and analyzes the body of literature that has been produced to date regarding the relationship between literacy and health outcomes and the evidence about interventions intended to improve the health of people with low literacy.

Chapter 2 describes our methodological approach, including the development of key questions and their analytic framework, our search strategies, and inclusion/exclusion criteria. In Chapter 3, we present the results of our literature search and synthesis. Chapter 4 further discusses the findings and offers our recommendations for future research. This is followed by references, a listing of excluded studies, and a copy of our quality rating form. Appendixes are provided electronically at http://www.ahrq.gov/clinic/epcindex.htm and provide a detailed description of our search strings (Appendix A), our quality rating form (Appendix B), detailed evidence tables (Appendix C), and acknowledgments (Appendix D).

Technical Expert Advisory Group

We identified technical experts in the field of health literacy to provide assistance throughout the project. The Technical Expert Advisory Group (TEAG) (see Appendix D) was expected to contribute to AHRQ's broader goals of (1) creating and maintaining science partnerships as well as public-private partnerships and (2) meeting the needs of an array of potential customers and users of its products. Thus, the TEAG was both an additional resource and a sounding board during the project. The TEAG included eight members: five technical/clinical experts; two members whose expertise and mission concern the interests and perspectives of patients and consumers; and one potential user of the final evidence report, an AMA representative.

To ensure robust, scientifically relevant work, the TEAG was called on to provide reactions to work in progress and advice on substantive issues or possibly overlooked areas of research. TEAG members participated in conference calls and discussions through e-mail to

- refine the analytic framework and key questions at the beginning of the project;
- discuss the preliminary assessment of the literature, including inclusion/exclusion criteria; and
- provide input on the information and categories included in evidence tables.

Because of their extensive knowledge of the literature on health literacy, including numerous articles authored by TEAG members themselves, and their active involvement in professional societies and as practitioners in the field, we also asked TEAG members to participate in the external peer review of the draft report.

Uses of This Report

This evidence report addresses the key questions outlined in Chapter 2 through systematic review of published literature. Our preliminary data already were made available to the Institute of Medicine (IOM) for its study on health literacy. We anticipate that the report will be of value to AMA for its various efforts to inform and educate physicians, including the *Roadmap for Clinical Practice* initiative. This report can inform practitioners about the current state of evidence and provide an assessment of the quality of studies that aim to improve health for people with low literacy. Researchers can obtain a concise analysis of the current state of knowledge in this field and will be poised to pursue further investigations that are needed to improve health for low-literacy populations. Health educators can also use this report to guide future interventions to improve health communication. Finally, policymakers can use this report to inform new strategies and the allocation of resources toward future research and initiatives that are likely to be successful.

Table 1. Instruments commonly used to assess the relationship between literacy and health

Instrument	Description of Test	Method of Assessment	Type of Score	Health Focus
Wide Range Achievement Test (WRAT) (www.addwarehouse.com)	Offers two equivalent alternate test forms, to be used individually or in combination for comprehensive test results. Can be used for persons aged 5 to 75 years. Standard scores and percentiles compare individual performance with that of others of the same age. Length about 10 minutes.	Word recognition and pronunciation	1. Continuous score 2. Grade level	No
Rapid Estimate of Adult Literacy in Medicine (REALM)	Designed to be used in public health and primary care settings to identify patients with low reading levels. Provides reading estimates for patients who read below a ninth grade level. Length about 1 to 2 minutes.	Word recognition and pronunciation	1. Continuous score 2. Grade level	Yes
Test of Functional Health Literacy in Adults (TOFHLA) (Center for Health Care Strategies, Tools to Evaluate Patient Education Materials Fact Sheet, www.chcs.org)	Used to measure functional health literacy—both numeracy and reading comprehension—using health-related materials. Available in Spanish and English. Length about 20 to 25 minutes. Also available in a short form (S-TOFHLA) that only uses two reading comprehension passages (about 5 to 10 minutes).	Prompts and Cloze method	1. Continuous score 2. Three categories determined by developer as inadequate (individuals will often be unable to read and interpret health texts), marginal (individuals will often have difficulty reading and interpreting health texts), and adequate (individuals will be able to read and interpret most health texts).	Yes

Table 2. Correlations between common health literacy assessment tools

Assessment Tools*	WRAT	REALM	TOFHLA
WRAT	1		
REALM	0.88 ($P < 0.001$)	1	
TOFHLA	0.74 ($P < 0.001$)	0.84 ($P < 0.001$)	1

*WRAT, Wide Range Achievement Test; REALM, Rapid Estimate of Adult Literacy in Medicine; TOFHLA, Test of Functional Health Literacy in Adults.

Chapter 2. Methods

In this chapter, we document the procedures that the RTI-UNC EPC used to develop this comprehensive evidence report on health literacy. To set the framework for the review, we first present the key questions and their underlying analytic framework. We then describe our strategy for identifying articles relevant to our key questions, our inclusion/exclusion criteria, and the process we used to abstract relevant information from the eligible articles and generate our evidence tables. We also discuss our criteria for grading the quality of individual articles and the strength of the evidence as a whole. Last, we explain the peer review process.

Key Questions and Analytic Framework

Based on the growing appreciation of the relationship between literacy and health, the complexity that can be involved in obtaining medical care, and health outcomes, we pose two key questions in this report, both of which have four parts. The AMA and AHRQ initially offered these questions, and we put them into final form with input from the TEAG:

- **Key Question 1**: Are 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 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?

In the analytic framework for these key questions (Figure 1), the exposure of interest (the characteristic that is the focus of the study) is the literacy level of an individual. The literacy level may be related to the effectiveness of interventions to improve the use of health care services or the actual health of the patient. Literacy may affect the cost of health care by interacting with the level and/or effectiveness of health care services used and the cost of interventions. Patient characteristics including race, ethnicity, sex, and age and cross-cultural communication barriers may confound these relationships. Provider characteristics may influence the relationships as well. This analytic framework is merely a lattice for understanding our approach to this issue. The relationship between literacy and health-related outcomes may, in reality, have many subtle aspects that cannot be adequately represented on such a figure.

Note: Appendixes and Evidence Tables cited in this report are provided electronically at http://www/ahrq.gov/clinic/epcindex.htm.

For Key Questions (KQ) 1a or 2a, we considered any process of care as a health service, including clinic and hospital visits and use of preventive health care and screening. For KQ 1b or 2b, the phrase "health outcomes" can take various meanings. We included knowledge and comprehension as either a health service or a health outcome, depending on context. Knowledge and comprehension and other categories of health outcomes are described below:

- *Knowledge and comprehension.* Because level of literacy constitutes the exposure of interest in the analytic framework, one may consider health knowledge as a proximal outcome. However, because much of the research on literacy and health has focused on understanding health information, not to consider these as a health outcome would eliminate a substantial portion of research. A common assumption is that knowledge improves health outcomes, but this relationship has not been proven definitively and most likely depends on the type of knowledge.
- *Biochemical or biometric health outcomes.* Although patients often cannot directly feel them, 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, and diabetes control.
- *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.

For KQ 1c measuring the cost of health care, we included any study that measured the monetary cost of health care services. For KQ 2c, we also included 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 looked for studies that reported the interaction between literacy and race, ethnicity, culture, or age with respect to health outcomes.

Literature Review Methods

Inclusion and Exclusion Criteria

Based on the final key questions specified above, we generated a list of inclusion and exclusion criteria (Table 3). We limited studies to those with outcomes related to health and health services. To ensure that the literature reviewed was relevant to current practice in the United States, we decided in agreement with our TEAG to restrict our searches to more current literature (1980 publication to the present, May 2003) and to studies conducted in developed countries, including the United States, Canada, the United Kingdom, Australia, New Zealand, and Europe. Therefore, we excluded the body of population-based studies concerning the role of poor literacy on public health outcomes in the developing world. Study participants included individuals of all ages and caregivers concerned with the outcomes of children.

As described in Table 3, we excluded studies for several reasons, including lack of a health-related outcome or results limited to the readability of materials. We also excluded studies that focused on literacy as an outcome rather than an exposure, as is seen in studies of physician office-based programs designed to improve children's literacy. We also excluded studies that used cognitive impairment or dementia as an outcome of interest because we would not be able to determine whether literacy was causing or being affected by the condition. Studies measuring only subjects' ability to interpret numerical information, without a clear health outcome, were excluded as well.

Literature Search and Retrieval Process

Databases and Search Terms. To identify the relevant literature for our review, we searched a variety of databases and employed different search strategies depending on the database (Table 4). In MEDLINE, our primary database, we had to rely on key word searches because no MeSH headings specifically identify literacy-related articles. Similarly, the terms "literacy" or "health literacy" were searched in different databases with the choice based on the scope of the database. For example, in health and biomedical databases such as MEDLINE, the Cumulative Index to Nursing and Allied Health (CINAHL), and the Cochrane Library, we searched on "literacy" because the health orientation was expected in those databases. In databases such as the Educational Resources Information Center (ERIC) or Public Affairs Information Service (PAIS), which include articles concerning a variety of literacy issues, we used "health literacy" to narrow the search to articles of interest. We also searched the Industrial and Labor Relations Review (ILRR) database to determine if any employer health literacy initiatives were discussed in the labor relations literature.

In addition, the searches in MEDLINE and CINAHL included the term "numeracy." In MEDLINE only, we searched for additional articles using the name or accepted acronym for standardized tests of literacy related to health outcomes including WRAT (Wide Range Achievement Test), REALM (Rapid Estimate of Adult Literacy in Medicine), and TOFHLA (Test of Functional Health Literacy in Adults). We reviewed the Web-based bibliographies produced by the Department of Society, Human Development, and Health of the Harvard School of Public Health[18]and the National Library of Medicine's bibliography concerning Health Literacy from their Current Bibliographies in Medicine series.[19] Finally, we also asked the TEAG and our external peer reviewers for titles of articles that we may have missed.

Table 4 presents the yield and results from our search. We conducted our initial search in late 2002 and updated it in May 2003. Beginning with a yield of 3,015 articles, we retained 73 articles that we determined were relevant to address our key questions and met our inclusion/exclusion criteria.

Article Selection Process. Once we had identified articles through the electronic database search, review articles, and bibliographies, we examined abstracts of articles to determine whether studies did, in fact, meet our criteria. One reviewer performed an initial evaluation of the abstracts for inclusion or exclusion. If one abstractor concluded that the article should be included in the review, it was retained in the analysis. Abstracts initially excluded from the study by one reviewer received a second review. The group included three physician health services researchers—Michael Pignone, MD, MPH (Scientific Director), Darren DeWalt, MD

(Co-Investigator), and Stacey Sheridan, MD, MPH (Co-Investigator)—and one health policy and health services researcher—Nancy Berkman, PhD, MLIR (Study Director).

Approximately 700 articles required review of the full article because of missing or uninformative abstracts. For the full article review, one reviewer read each article and decided whether it met our inclusion criteria. Those articles the reviewer determined did not meet our eligibility criteria, as presented in Table 3, were assigned a reason for exclusion. A second reviewer re-reviewed all initially excluded articles, and the decision to include any once-excluded articles was made as a group by the four senior staff members of the project. A list of articles excluded at full article review is provided at the end of this report, along with the reason for their exclusion.

Literature Synthesis

Development of Evidence Tables and Data Abstraction Process

The four senior staff members for this systematic review jointly developed the evidence tables. We created two sets of evidence tables, one for KQ 1 and one for KQ 2. They were designed to provide sufficient information to enable readers to understand the study and to determine quality; we gave particular emphasis to essential information on our key questions. The format of the tables, which was based on successful designs used for prior systematic reviews, varied slightly by key questions; the tables for KQ 2 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 three of the senior staff members had prior experience conducting evidence-based systematic reviews for AHRQ. This decision meant that we bypassed the use of data abstraction forms. Following this approach created efficiencies in production and did not result in any major changes in the type of information included in the evidence tables as the project progressed.

The abstractors trained themselves on entering data into the tables by abstracting several articles and then reconvening as a group to discuss the utility of the table design. This process was repeated through several iterations until they decided that the tables included the appropriate categories for gathering the information contained in the articles. The design was then reviewed by the TEAG through a teleconference.

The first reviewer (Dr. Pignone, Dr. DeWalt, or Dr. Sheridan) initially entered data from an article into the evidence table, and the second reviewer (Dr. Berkman) also reviewed the article and edited all initial table entries for accuracy, completeness, and consistency. All disagreements concerning the information reported in the evidence tables were reconciled by the two abstractors. The full research team met regularly throughout the period of article abstraction and discussed global issues related to the data abstraction process.

The final evidence tables are presented in their entirety in Appendix C. Entries for both tables are listed alphabetically. A list of abbreviations used in the tables appears at the beginning of the appendix.

Quality and Strength of Evidence Evaluation

Rating the Quality of Individual Articles. The RTI-UNC EPC's approach to assessing the quality of individual articles was developed based on the domains and elements recommended in the evidence report by West and colleagues, *Systems to Rate the Strength of Scientific Evidence.*[20] We developed one form for reviewing all studies, which is presented at the end of this report and in Appendix B. However, because we included both intervention and observational studies in our review, several questions were relevant only to certain studies. In cases in which the item was not relevant, the quality rating was "not applicable" (NA). The categories reviewed included the following:

1. *Study population* (whether it was adequately described and appropriate for drawing relevant conclusions). Both concerns were combined to form one score.
2. *Intervention* (whether it was clearly described). This category was only relevant and answered in relation to KQ 2. For KQ 1, the response was "NA."
3. *Comparability of subjects*. This item judged the quality of the methods used for creating the sample population, including the sampling strategy, the inclusion/exclusion criteria, and the approach to randomization or allocation. It also concerned the comparability of experimental and comparison groups.
4. *Literacy measurement* (whether the instrument used was valid, reliable, and clearly defined). This measure was important for our studies because it determined how the investigators evaluated the literacy of participants. For KQ 2, interventions in populations previously characterized by literacy measurement were included, but if participants' literacy was not directly evaluated, we graded the study as "poor" for this item.
5. *Maintenance of comparable groups.* This item captured the integrity of the samples among those studies that were conducted at more than one point in time. If the study included only one contact with participants, the grade was "NA."
6. *Outcome measurement* (whether the outcome was clearly defined and whether the method of assessment was reliable). This item also rated (in studies where it was appropriate) whether the study included blinding of participants or outcome assessors.
7. *Statistical analysis*. This factor included whether the tests used were conducted in an appropriate manner and whether the effect of multiple comparisons was taken into account.
8. *Appropriate control of confounding.* This item rated the study's use of multivariate statistical techniques and/or participant restriction, stratification, or randomization to control for confounding.
9. *Funding source.* Studies were recorded as being funded by government or private foundation or by private corporate sponsorship or as not stating their funding source.

The two article abstractors independently rated each article on each of the first eight categories as "good," "fair," or "poor." We then created a composite rating in which we gave

each item equal weight. Specifically, we converted ratings for each item into numeric values in which 0 = poor, 1 = fair, and 2 = good. We averaged the ratings of the two evaluators for each item. The total score was the average of all these scores. Because one or more items may be rated as "NA" and excluded as evaluation criteria for a particular study, the number of ratings being averaged varied across studies. We included in this final rating only those items that had been rated individually (i.e., given scores of good, fair, or poor); we excluded items judged "NA." The only items reconciled between the two abstractors were those in which one rater provided a score for the item and the second said the item was not applicable. Corresponding to our individual item ratings, we concluded that, overall, an article should be considered poor with a rating of < 1.0, fair with a rating of ≥ 1.0 and < 1.5, and good with a rating of ≥ 1.5.

We did not integrate our evaluation of funding source into the numeric quality score for each article because of a lack of comparability between the scores. Many articles did not list their funding source (24 in total), and it was not clear what the relative score should be for a study that provided no information. Therefore, we reported these data separately and descriptively only. We include overall article ratings, individual item ratings, and funding source in the evidence table entry for each article.

Grading the Strength of Available Evidence. We developed a scheme for grading the quality or strength of our body of evidence as a whole. Using the West et al.[20] report that compared various schemes for grading bodies of evidence, we based our evaluation on criteria developed by Greer et al.[21] that we deemed most applicable to the study designs included in our literature. That system included three domains: quality of the research, quantity of studies (including number of studies and adequacy of the sample size), and consistency of findings. Grades were developed by consensus of the four senior staff members.

We graded the body of literature applicable to each of the four components of the two key questions separately. The possible grades in our scheme are as follows:

I. The evidence is from studies of strong design; results are both clinically important and consistent with minor exceptions at most; results are free from serious doubts about generalizability, bias, or flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

II. The evidence is from studies of strong design, but some uncertainty remains because of inconsistencies or concern about generalizability, bias, research design flaws, or adequate sample size. Alternatively, the evidence is consistent but derives from studies of weaker design.

III. The evidence is from a limited number of studies of weaker design. Studies with strong design either have not been done or are inconclusive.

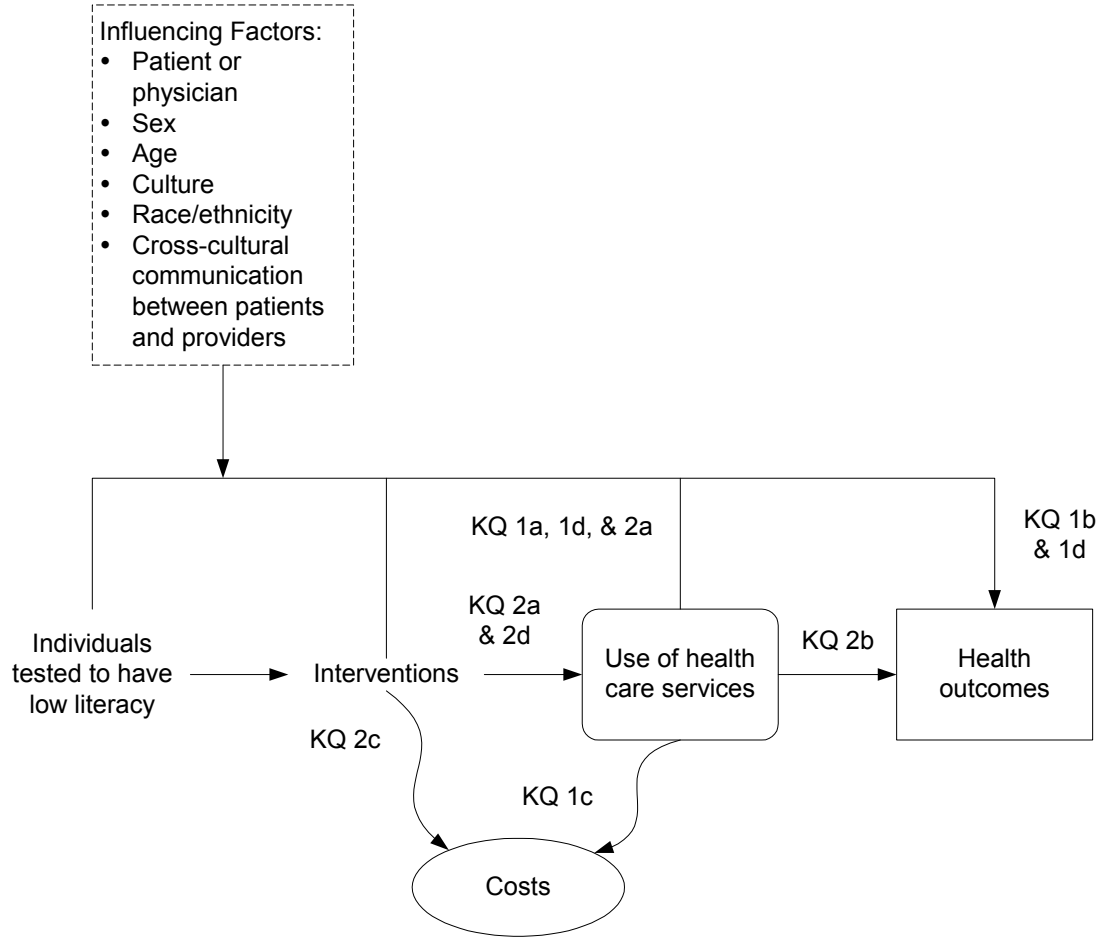
IV. No published literature.

Peer Review Process

Among the more important activities involved in producing a credible evidence report is conducting an unbiased and broadly based review of the draft report. External reviewers are

clinicians, researchers, representatives of professional societies, and potential users of the report, including TEAG members (see Appendix D). We asked peer reviewers to provide comments on the content, structure, and format of the evidence report and to complete a peer review checklist. We revised the report, as appropriate, based on comments from peer reviewers.

Figure 1. Analytic framework



Key Questions:

KQ 1: Are 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?

KQ 2: For individuals with low 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?

Table 3. Health literacy literature searches: Inclusion and exclusion criteria

Category	Criteria
Study population	All races, ethnicities, and cultural groups. Patients of all ages and caregivers whose primary language is the same as that of the health care provider and/or intervention.
Study settings and geography	Studies conducted in the developed world, including North America, Australia, New Zealand, and Europe.
Time period	Published from 1980 to the present.
Publication criteria	English only. Articles in print. 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.
Admissible evidence (study design and other criteria)	Original research studies that provided sufficient detail regarding methods and results to enable use and adjustment of the data and results. Eligible study designs included • before-and-after studies; • controlled trials; and • observational studies: prospective and retrospective cohort studies, case control studies; and cross-sectional studies. Relevant outcomes must be able to be abstracted from data presented in the papers. 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. Other study exclusion criteria included studies • of dyslexia and dementia; • with no original data; • with no health outcomes; • with an outcome limited to satisfaction or likeability of one intervention material compared to another; • that measured outcome only by a Cloze test of comprehension (but studies that used literacy measurements that included a Cloze test were retained); • focusing solely on the readability of materials; • that were nonintervention studies (KQ 1) and did not measure literacy in study participants; and • concerning the basic experimental science of reading ability (e.g., studies of brain function, including results from magnetic resonance imaging or electroencephalogram).

Table 4. Health literacy search strategy, yield, and final count of articles

Database and Search Strategy*	Total References Identified	Unduplicated References	Articles Excluded at Abstract Review Phase	Articles Retained for Full Review	Articles Rejected After Full Review	Articles Included
MEDLINE Key word search: literacy, numeracy, WRAT, Wide Range achievement, rapid estimate of adult, TOFHLA, test of functional health, reading ability, reading skill	2,065	2,065	1,599	466	399	67
CINAHL Literacy, numeracy	932	633	446	187	183	4
PSYCINFO Health literacy	45	20	13	7	6	1
ERIC Health literacy	25	23	8	14	14	0
AGELINE Health literacy	13	9	4	5	5	0
Cochrane Library Literacy	8	0	0	0	0	0
PAIS Health literacy	49	0	0	0	0	0
ILRR Health literacy	0	0	0	0	0	0
NLM Current Bibliographies in Medicine-Health Literacy	479	177	177	0	0	0
Harvard School of Public Health-Department of Health Literacy Studies	241	83	83	0	0	0
Expert Additions	11	5	0	5	4	1
Totals	3,868	3,015	2,330	684	611	73

*WRAT, Wide Range Achievement Test; TOFHLA, Test of Functional Health Literacy in Adults; CINAHL, Cumulative Index to Nursing and Allied Health; ERIC, Educational Resources Information Center; PAIS, Public Affairs Information Service; ILRR, Industrial and Labor Relations Review; NLM, National Library of Medicine.

Chapter 3. Results

This chapter presents the results of our literature search and our findings for both key questions, which were illustrated in Figure 1 and discussed in Chapter 2. KQ 1 asked if literacy skills are related to (a) use of health care services, (b) health outcomes, (c) costs, and (d) disparities in outcomes or utilization according to race, ethnicity, culture, or age. KQ 2 asked, for people with low literacy skills, whether effective interventions exist to (a) improve use of services, (b) improve health outcomes, (c) affect health care costs, and (d) improve outcomes or service use among various population groups defined by race, ethnicity, cultural background, or age.

We report our results in the two main sections of this chapter, reporting first on specific details about the yields of the literature searches and characteristics of the studies and then on the four main subquestions of interest for each key question. Summary tables presenting selected information on each study are contained at the end of this chapter for KQ 1 (Table 5) and KQ 2 (Table 6). Additional tables presenting findings grouped by selected outcomes appear at the end of this chapter. Detailed evidence tables appear in Appendix C.

Results of Literature Search

The literature search yielded 3,868 articles (3,015 unduplicated) (Table 4). Of these, we excluded 2,330 articles after reviewing the abstracts and pulled 684 articles for complete review. In addition to the database search, we solicited articles from Web-based bibliographies, the TEAG, and other experts in the field of health literacy; these sources provided 265 articles (within the total 3,015), of which 25 were not identified in our database searches and warranted full article review. Across all 682 articles retained for full article review, we included in our evidence report 67 articles found in MEDLINE, 5 articles from other databases, and 1 article suggested by our TEAG or other experts, totaling 73 articles in all. Of these, 44 address KQ 1 and 29 address KQ 2.

Key Question 1: Relationship of Literacy to Various Outcomes and Disparities

Literature Search and Included Studies

We identified 44 articles describing results that address the relationship between literacy and use of health care services, health outcomes, and costs of health care, as well as results limited to specific racial, ethnic, cultural, or age groups. Figure 2 shows the accumulation of studies by year for KQ 1 and 2. We found that the accumulated number of studies began to increase substantially around 1995, implying an increase in research projects beginning several years earlier. Of the total, 4 articles concern various study results from a cohort of patients enrolled in a Prudential Medicare Managed Care program.[7,22-24] Two articles present results based on data from a cohort of patients receiving services at Grady Hospital in Atlanta, Georgia, and Harbor-

Note: Appendixes and Evidence Tables cited in this report are provided electronically at http://www/ahrq.gov/clinic/epcindex.htm.

UCLA Medical Center in Los Angeles, CA.[25,26] Study designs included cross-sectional (32), cohort (8), case-control (2), and retrospective case series (1).

Disadvantages of a cross-sectional study design include the inability to measure incident outcomes and to assign cause and effect. However, when cross-sectional studies measure literacy, we can often safely assume that the same level of literacy predated the health outcome. This assumption, although obviously not true in children, may also not necessarily apply to elderly adults, in whom literacy levels may change over time. Additionally, medical illness may affect literacy more profoundly in these groups than in nonelderly adults.

Data analysis and presentation varied widely across the studies. Most studies reported the unadjusted (bivariate) relationship between literacy and the health-related outcome of interest. Twenty-eight of the 44 articles discussed the relationship between literacy and the health-related outcome after adjusting for at least one covariate. The most common covariate included in models was age, followed by education (13 articles). Most studies descriptively presented information on the participants' age, ethnicity, and education levels; about half included information on participants' income level. Less than half of the models adjusted for race or ethnicity; even less common were adjustments for income, insurance status, and health status. Sixteen studies included descriptive information about the participants' insurance status, but only 4 included insurance in a multivariate analysis.

The number of participants enrolled ranged from 34 to 3,260. In studies with relatively few participants, point estimates of the relationship between literacy and the outcome had large confidence intervals. Because of a lack of statistical power in these circumstances, relationships between literacy and outcomes may remain unrecognized. We present 95 percent confidence intervals when available or calculable rather than simple statements about statistical significance so the reader can observe where this may have been a concern.

Table 7 groups KQ 1 studies based on the literacy measurement tool used in the analysis and, further, the levels used to separate study participants. We found that literacy was most often measured with the REALM (13 studies), the TOFHLA or S-TOFHLA (11 studies), or the WRAT (6 studies). Within these groups, the literacy levels used to compare study participants varied widely among studies.

Use of Health Care Services

KQ 1a concerned the relationship between low literacy skills and the use of health care services (Evidence Table 1). Studies in this review focused on the association between literacy and knowledge of health care services, the risk of hospitalization, physician visits, and screening and prevention.

Knowledge of Health Care Services. Six studies measured the relationship between literacy levels and knowledge of the use of health care services (Table 8).[27-32] They measured knowledge or comprehension of mammography,[27] cervical cancer screening,[28] informed consent,[29] childhood health maintenance procedures and parental understanding of child diagnosis and medication,[30] emergency department discharge instructions,[31] and "Heart Health Knowledge."[32] With the exception of the Moon et al.[30] study, all these investigations demonstrated a statistically significant association between higher literacy level and knowledge of matters relating to use of these health services.

Hospitalization. Two studies prospectively evaluated the risk of hospitalization according to literacy status.[24,26] In both, adjusted (multivariate) analyses showed that a lower literacy level was significantly associated with increased risk of hospitalization. In a study done in a public hospital, Baker et al.[26] compared the effects of literacy and education on the odds of being hospitalized over a 1-year period. The odds of hospitalization were 1.69 higher (95% confidence interval [CI] 1.13, 2.53) for patients with inadequate literacy than for patients with adequate literacy on the TOFHLA, after adjusting for age, sex, race, health status, receiving financial assistance, and health insurance but not education. No significant differences were found between patients with marginal literacy and those with adequate literacy. Adjusted models controlling for years of education instead of literacy yielded no significant differences in risk of hospitalization.

In a second study among patients aged 65 and older enrolled in Medicare managed care plans, the odds of being hospitalized were 1.29 times higher (95% CI 1.07, 1.55) for patients with inadequate literacy than for patients with adequate literacy after adjusting for age, sex, race/ethnicity, language, income, and educational status.[24] People with marginal or adequate literacy did not differ significantly in the odds of being hospitalized.

Physician Visits. The one study examining the relationship between literacy and number of health care visits used self-reported visit data. Baker et al.[25] asked 2,659 patients about their number of physician visits in the past 3 months, presence of regular source of care, and whether they had received needed medical care during the past 3 months. After adjusting for confounders (age, health status, and economic indicators, which were proxies for income), they found no significant relationship between literacy status measured by the TOFHLA and self-reported access to physician visits. However, these subjects had been recruited from emergency rooms and walk-in clinics and may represent only the population that has accessed the health care system in those ways. We cannot assume that the lack of relationship between literacy and physician visits generalizes to the population as a whole, which would include those who have not needed medical care in the recent past and those seen in private physician offices.

Screening and Prevention. Two studies dealt with the relationship between literacy levels and three measures of health promotion and disease prevention interventions (screening for sexually transmitted diseases, cancer, and immunizations).[23,33]

Sexually Transmitted Disease Screening. Fortenberry et al.[33] found a positive relationship between literacy and screening for gonorrhea. Patients were selected from clinical and nonclinical sites in four cities around the country. Literacy assessments were incomplete for many of the patients; thus, to control for potential selection bias, the researchers estimated a two-stage model. Controlling for incomplete data and several patient characteristics, including insurance status and suspected infection, a reading level at or above the ninth grade was associated with a 10 percent increase in the probability of having a gonorrhea test in the past year.

Cancer Screening. Scott et al.[23] evaluated cancer screening rates by measuring the percentage of women who had never had a Pap smear or had not had a mammogram in the past 2 years. Participants in the study were 65 years of age and older and new enrollees in a Medicare managed care health plan. Adjusted (multivariate) analyses controlling for age, race, education, and income produced mixed results. Compared with patients with adequate literacy, patients with inadequate literacy had greater odds of never having had a Pap smear (odds ratio [OR] 1.7; 95% CI 1.0, 3.1) and greater odds of not having had a mammogram in the past 2 years (OR 1.5;

95% CI 1.0, 2.2). However, women who had marginal literacy (between inadequate and adequate) had even greater odds of never having had a Pap smear than women with adequate literacy (OR 2.4; 95% CI 1.2, 4.7) or inadequate literacy. In contrast, their odds of never having had a mammogram were no different than the odds of women with adequate literacy.

Immunization. The study of cancer screening also evaluated the relationship between literacy and adult immunization.[23] The authors evaluated the odds of patients having received selected preventive health services. In an adjusted analysis controlling for age, sex, race, education, and income, patients with inadequate literacy had 1.4 (95% CI 1.1, 1.9) times the odds of not having had an influenza immunization and 1.3 (95% CI 1.1, 1.7) times the odds of not having had a pneumococcal immunization compared with patients with adequate literacy. Those with marginal and adequate literacy did not differ significantly in these measures.

Health Outcomes

KQ 1b concerns the relationship between low literacy and health outcomes (Evidence Table 1). The articles reviewed include those concerning knowledge or comprehension as an outcome in and of itself, health behavior and adherence, and measures of disease prevalence, incidence, or morbidity.

Knowledge or Comprehension as an Outcome. Ten studies used knowledge either as one of several outcomes or as the only outcome (Table 9). These studies measured knowledge about smoking,[34] postoperative care,[35,36] contraception,[37] human immunodeficiency virus (HIV),[38-41] hypertension,[42] diabetes,[42] and asthma.[43] In general, these studies found a positive, significant relationship between literacy level and participants' knowledge of these health issues. All but 3 adjusted for covariates. The only study that did not demonstrate a statistically significant higher knowledge score with higher literacy level included a bivariate (unadjusted) analysis concerning knowledge about self-care after discharge following orthopedic surgery.[36]

Health Behaviors and Adherence. Studies concerned with literacy levels and health behaviors of various sorts centered on smoking, alcohol use, breast-feeding, asthma, problematic behaviors among children, and general ideas of adherence to health care regimens and recommendations.

Smoking. Three studies evaluated the relationship between literacy and smoking.[34,44,45] The objective of the largest study, by Hawthorne[45] (n = 3,019), was to identify predictors of early adolescent drug use, including smoking, among students in Australia. The study categorized students into low, middle, or high levels of literacy (the literacy assessment instrument and category divisions were unstated) and looked at the relationship between literacy and whether a student self-reported ever using tobacco or using tobacco in the past month. An adjusted analysis revealed a significant relationship between literacy (low literacy vs. high literacy) (OR 1.7; 95% CI 1.1, 2.7) and ever having used tobacco among boys but no significant relationship among girls. By contrast, the relationship between literacy and using tobacco in the past month was stronger than "ever used" and significant among both boys and girls.

Fredrickson et al.[44] selected adults waiting for child-related services in private and public clinics in Wichita, Kansas. They reported a significant ($P < 0.05$) unadjusted association between low reading ability (measure unspecified) and smoking, but they did not specify the magnitude of the association or adjust for confounders. Arnold et al.[34] also evaluated the

relationship between literacy and smoking practices among 600 pregnant women. They found no difference in the unadjusted rates of smoking according to literacy status.

Alcohol use in Adolescence. Hawthorne[45] evaluated the relationship between literacy level in adolescents and alcohol use. Although the odds of ever having used alcohol were not different according to literacy status, the odds of having misused alcohol were higher among boys with lower literacy levels than among boys with higher literacy levels (OR 2.6; 95% CI 1.4, 4.8). No significant relationship emerged for girls by literacy level (OR 2.1; 95% CI 0.8, 5.5).

Breast-feeding. Two unadjusted cross-sectional studies evaluated the relationship between literacy and breast-feeding,[44,46] and both found a positive significant relationship. Kaufman et al.[46] studied 61 new mothers in Albuquerque, New Mexico, and reported that those with literacy levels at or above ninth grade were more likely to breast-feed for at least 2 months than mothers with literacy at the seventh or eighth grade level (54% vs. 23%, $P = 0.018$). Fredrickson et al.[44] conducted a much larger study (646 mothers) and found a significant association ($P < 0.05$) between low reading ability (not specified) and never breast-feeding.

Asthma. Williams et al.[43] studied the relationship between literacy and correct metered dose inhaler (MDI) technique in a cross-sectional study of 469 patients. Patients with higher literacy had better MDI technique based on measuring the number of steps performed correctly after adjusting for education and whether the patient had a regular source of care (difference in number of correct steps out of six steps = 1.3 steps; 95% CI 0.9, 1.7).

Problem Behavior in Children. One cross-sectional study of 386 adolescents from low-income neighborhoods evaluated the relationship between literacy and behavior;[47] another cohort study of 779 children born in one hospital in New Zealand evaluated the relationship between reading ability and "problem behaviors" in younger children.[48] After controlling for age, race, and sex, youth who were more than two grades behind expected reading level based on the Slosson Oral Reading Test were more likely than others to carry a weapon including a gun, take a weapon to school, miss school because it was unsafe, and be in a physical fight that required medical treatment.[47] Stanton et al.[48] found that reading ability was an independent predictor of teacher-reported problem behavior, even after adjustment for early problem behavior and family adversity. They also demonstrated that reading ability was lower at higher levels of family adversity.

Adherence. Four studies evaluated the relationship between literacy and adherence;[49-52] three found no significant relationship. Two studies measured adherence among patients taking antiretrovirals for HIV infection using quite different study designs. Golin et al.[50] measured adherence over 48 weeks using electronic bottle caps, pill counts, and self-reports among 117 patients in a university HIV clinic using a prospective cohort design. In an unadjusted analysis, they did not find a relationship between literacy and adherence ($r = -0.01$, $P = 0.88$). By contrast, Kalichman et al.[49] studied 184 patients in an HIV clinic using a cross-sectional study design. After adjusting for race, income, social support, and education, they found that lower literacy was associated with a greater odds of poor adherence (OR 3.9; 95% CI 1.1, 13.4), defined as recall of missing any dose during the previous 48 hours. The more rigorous prospective longitudinal design used by Golin et al. included objective quantification of adherence, while the cross-sectional study by Kalichman et al. relied on patient recall of adherence.

Li et al.[51] evaluated adherence to breast conservation therapy among a small sample of 55 low-income women with early-stage breast cancer. In an unadjusted analysis, literacy did not

significantly predict adherence to radiation, chemotherapy, or clinical appointments; overall, only 36 percent of patients had full adherence.

Frack et al.[52] evaluated several factors associated with compliance with research protocols among Latino participants in a clinical trial. Spanish literacy was measured using the Cloze procedure. (Every fifth to seventh word was deleted from a text, and the subject was asked to fill in the missing words. A literacy score was then assigned based on the percentage correct). The patients who followed up as directed had a higher average literacy score than those who never followed up ($P < 0.05$ for the unadjusted difference).

Biochemical and Biometric Health Outcomes. Eight studies targeted questions about the relationship between literacy and health outcomes measured with clinical laboratory tests for diabetes, hypertension, and HIV infection.

Diabetes. Three studies assessed the relationship between literacy and diabetes outcomes.[42,53,54] Ross and colleagues[53] evaluated glycemic control, measured by glycosylated hemoglobin (HbA1c), in children with type 1 diabetes mellitus and its relationship to the child's and the parent's literacy using a cross-sectional design. They found no significant unadjusted correlation between WRAT scores for children aged 5 to 17 and glycemic control (r = 0.1). However, the parent's score on the National Adult Reading Test (NART) was correlated with the child's glycemic control (r = 0.28; $P = 0.01$) and, in a model adjusted for age and sex of the child, duration of diabetes, daily insulin dose, child literacy score, and social class, the NART score continued to be a significant predictor.

Both Williams et al.[42] and Schillinger et al.[54] evaluated the relationship between patient literacy and HbA1c in adults with type 2 diabetes mellitus using a cross-sectional study design. The Williams et al. study was designed primarily to look at diabetes-related knowledge. HbA1c values were available for only 55 patients (48% of the sample). Average HbA1c levels were higher (representing worse glycemic control) among those with inadequate literacy than among those with adequate literacy on the TOFHLA, but the unadjusted difference was not statistically significant (8.3% vs. 7.5%, $P = 0.16$).

The main aim of the Schillinger et al.[54] study was to measure the relationship between literacy and glycemic control among 408 patients from a public hospital internal medicine or family practice clinic. Patients with lower literacy appeared to have worse glycemic control. Among patients with inadequate literacy on the S-TOFHLA (n = 156), 20 percent had "tight" glycemic control (HbA1c < 7.2), compared with 33 percent of those with adequate literacy (n = 198) (adjusted OR 0.57; $P = 0.05$). After controlling for age, race/ethnicity, sex, education, language, insurance, depressive symptoms, social support, receipt of diabetes education, treatment regimen, and years with diabetes, the HbA1c level was found to be inversely related to the S-TOFHLA score (the HbA1c increased by 2 percent for every 1 point decrease in the S-TOFHLA score).

Schillinger et al.[54] also evaluated the relationship between literacy and self-reported diabetes complications. In adjusted models, patients with inadequate literacy were more likely than those with adequate literacy to report retinopathy (OR 2.33; 95% CI 1.2, 4.6) and cerebrovascular disease (OR 2.71; 95% CI 1.1, 7.0). Lower extremity amputation (OR 2.48; 95% CI 0.74, 8.3), nephropathy (OR 1.71; 95% CI 0.75, 3.9), and ischemic heart disease (OR 1.73; 95% CI 0.83, 3.6), were more common among patients with inadequate literacy, but differences were not statistically significant. This may be related to the sample size and the rarity of these events.

Hypertension. Two studies[42,55] evaluated the relationship between literacy and hypertension, but neither identified an independent relationship between literacy and presence or control of hypertension. Williams et al.[42] performed a cross-sectional study in two public hospitals among patients diagnosed with hypertension. In a bivariate comparison, they found that patients with inadequate literacy, measured by the TOFHLA, had higher systolic blood pressures than those with adequate literacy (155 mm Hg vs. 147 mm Hg, $P = 0.04$, n = 408). However, after adjusting for age, the difference was no longer significant.

Battersby et al.[55] performed a case-control study to compare literacy of patients with a diagnosis of hypertension to age-, race-, and sex-matched controls without hypertension (n = 180). They did not find a statistically significant difference in reading ability between patients with or without hypertension (Schonell Graded Word Reading Test: cases 78.4, controls 81.3).

HIV Infection. The relationship between literacy and control of HIV infection has been reported in three cross-sectional studies.[38,40,56] All studies were conducted by the same research group and enrolled patients from an HIV-positive population in Atlanta, Georgia. Each study was conducted independently, but about 60 percent of the patients participated in all three studies (S. Kalichman, personal communication, May 2003). Each study measured literacy using a modified TOFHLA and dichotomized literacy into high and low levels (an approach that differs from the recommended cut-offs of inadequate, marginal, and adequate literacy). In these studies, the cut-off between lower and higher literacy was set at getting 85 percent correct on the reading comprehension section of the TOFHLA, which is well into the adequate literacy level using the standard TOFHLA categories; hence, some patients categorized as low literacy in these studies would be categorized as adequate on the conventional TOFHLA. None of these studies adjusted for potential confounders in their analyses; as a whole, they found mixed results.

One study found that patients with better reading comprehension had 2.9 (95% CI 1.1, 8.1) times the odds of having an undetectable viral load than those with worse reading comprehension.[40] Another study showed that better readers had 6.2 (95% CI 2.1, 18.5) times the odds of having an undetectable viral load than worse readers.[38] In addition, worse readers had 2.3 (95% CI 1.1, 5.1) times the odds of having a CD4 count less than 300 than did better readers. The third study found no significant association between reading comprehension and undetectable viral load.[56] Given these conflicting results, drawing definite conclusions regarding HIV infection markers and reading comprehension is difficult.

Kalichman et al.[38,40] also measured the associations between literacy and optimism and perceptions of care. After controlling for education, the research team found that patients with lower literacy tended to be more optimistic about their future living with HIV[40] but had more distrust of providers and were less likely to believe that treatment helps.[38]

Measures of Disease Prevalence, Incidence, or Morbidity. Several studies examined the association between literacy and a variety of disease-specific measures relating to depression, asthma, cancer, and migraine.

Depression or Other Emotional Conditions. Five studies evaluating the relationship between literacy and depression yielded mixed results (Table 10).[22,32,56-58] All of these studies used self-report questionnaires to measure depression; two evaluated depression in the context of specific chronic diseases (rheumatoid arthritis[58] and HIV infection[56]).

The largest study, a cross-sectional evaluation of Medicare managed care patients conducted by Gazmararian et al.,[22] assessed depression using the well-validated Geriatric Depression Scale (GDS). The authors approached 6,734 patients; 3,171 participated, in a response rate of about 47

percent. This study found an unadjusted OR of being depressed of 2.7 (95% CI 2.2, 3.4) for those people with inadequate literacy compared to those with adequate literacy assessed by the S-TOFHLA. However, after adjusting for demographic, social support, health behavior, and health status factors, the adjusted OR of 1.2 (95% CI 0.9, 1.7) was no longer statistically significant. Although the authors concluded that a significant relationship between literacy and depression could not be observed, the limited response rate may have introduced bias. For example, if people with low literacy who are depressed were more likely to refuse to participate in the study, then differences between the groups would be harder to detect.

TenHave et al.[32] evaluated depression scores among subjects recruited for participation in a cardiovascular dietary education program and, as a part of the work, also evaluated a screening instrument to assess literacy. They measured depression (Beck Depression Inventory Short Form) and literacy (Cardiovascular Dietary Education System [CARDES] scale, a tool developed during this study) in 339 patients. Lower scores on the literacy assessment were statistically significantly associated with higher scores on the depression assessment after adjusting for age, suggesting a greater propensity for depression among those with lower literacy ($P = 0.0001$).

Zaslow et al.[57] evaluated depression and literacy among mothers and the relationship between maternal literacy and their children's depression and antisocial behavior. Risk of depression was higher among mothers who had lower literacy skills in an unadjusted analysis (estimated relative risk [RR] 1.60; 95% CI 1.21, 2.12). No relationship was detected between maternal literacy and depression or antisocial behavior among their children ($P > 0.10$).

Kalichman and Rompa[56] compared scores on the Center for Epidemiologic Studies Depression (CES-D) scale with scores on the TOFHLA in a group of patients infected with HIV. The total scores on the depression scales did not differ by literacy status. They found that scores on some CES-D questions or subscales were higher (representing more depression) for participants with lower literacy.

Gordon et al.[58] administered the Hospital Anxiety and Depression (HAD) scale to 123 consecutive patients with rheumatoid arthritis: literacy was assessed by the REALM. The percentage of patients with a score of 15 or above on the HAD scale (meaning more anxiety and depression) was greater among those who read below the ninth grade level than among those who read at or above the ninth grade level (61% vs. 44%, $P = 0.011$), but they did not adjust for confounders.

Of these five studies, four found statistically significant associations between lower literacy and higher rates of depression. However, the largest study failed to show this relationship. The discrepancy in results among these studies may be related to study design and analysis. For instance, because each study used different literacy assessments, the cut-off between high and low literacy was different between studies. Additionally, the populations were quite different. The Gazmararian et al.[22] study included only patients over age 65 who did not necessarily have a coexistent chronic condition. TenHave et al.[32] enrolled community-dwelling people who were 40 to 70 years of age. Gordon et al.[58] enrolled only patients with rheumatoid arthritis, Kalichman and Rompa[56] enrolled only patients with HIV infection, and Zaslow et al.[57] enrolled mothers receiving Aid for Families with Dependent Children (AFDC). Because of the substantial differences in patient populations, reaching any general conclusions about this relationship is problematic.

Differences between studies in adjustments for covariates also complicate interpretation of these data. Gazmararian et al.[22] did not find a significant relationship after adjusting for age and health status. TenHave et al.[32] adjusted for age but not health status and found a significant relationship. In unadjusted analyses, Kalichman and Rompa,[56] Zaslow et al.,[57] and Gordon et al.[58] found significant relationships for most of their depression-related outcome measures.

One other study evaluated the relationship between literacy and "emotional balance" after receiving informed consent for a bone marrow transplant.[59] This study measured reading ability using the WRAT and the Derogatis Affects Balance Scale to measure changes in affect after patients had given informed consent. The researchers found "no significant relationship between the patterns of affects changes and WRAT scores."[59(p 74)]

Arthritis and Functional Status. One cross-sectional study of 123 consecutive patients with rheumatoid arthritis evaluated functional status and literacy.[58] Functional status was measured using the Health Activities Questionnaire (HAQ). In a bivariate relationship, HAQ scores did not differ according to literacy dichotomized at the ninth grade level on the REALM.

Migraine. One case-control study evaluated the relationship between literacy (measured by the WRAT) among 32 children with migraine headaches and 32 control children without migraine headaches, all between 8 and 17 years of age.[60] In unadjusted analyses, the authors did not find a significant difference in literacy scores between the two groups.

Prostate Cancer. One cross-sectional study evaluated the relationship between literacy and stage of presentation of prostate cancer.[61] Bennett et al. dichotomized literacy at the sixth grade level using the REALM and found, in an unadjusted analysis, that men with lower literacy (n = 66) were more likely to present with late-stage prostate cancer than those with higher literacy (n = 146) (55% vs. 38%, $P = 0.022$). After adjusting for race, age, and location of care, the investigators found that the relationship between literacy and stage of presentation was smaller and no longer statistically significant (OR 1.6; 95% CI 0.8, 3.4).

Global Health Status Measures. Four cross-sectional studies evaluated the relationship between literacy and a global health status measure (Table 11).[7,25,62,63] Three teams found an association between lower literacy and worse health status. Weiss et al.[62] assessed global health status using the Sickness Impact Profile (SIP) in a group of relatively young participants (mean age 29 years). Literacy was dichotomized at the fourth grade reading level on the Test of Adult Basic Education (TABE) and Mott Basic Language Skills Program. After adjusting for age, sex, ethnicity, marital status, insurance status, occupation, and income, the investigators determined that people with lower literacy scored worse than those with higher literacy on the overall SIP (10.4% vs. 6.0%, $P = 0.02$) and on both the physical and psychosocial subcomponents of the SIP. Baker et al.[25] asked 2,659 patients at two public hospitals to report their overall health status. Both English- and Spanish-speaking patients participated; literacy was assessed in the preferred language. After controlling for age, sex, race, and socioeconomic indicators, they found that patients with inadequate literacy had about twice the odds of reporting poor health as patients with adequate literacy. Finally, Gazmararian et al.[7] asked 3,260 patients who were 65 years of age and older and enrolled in a Medicare managed care health plan to report their overall health status. In their bivariate comparison, patients with inadequate literacy were significantly more likely to self-report fair or poor health than patients with adequate literacy (43% vs. 20%, $P < 0.001$).

By contrast, Sullivan et al.[63] measured general health status among patients with type 2 diabetes using the Medical Outcomes Study Short Form 36 (SF-36). Literacy was assessed using

the Questionnaire Literacy Screen (QLS), which was being developed at the time of the study. In an unadjusted analysis, they found no difference in scores on the SF-36 according to whether the subject "passed" or "failed" the QLS.

Costs of Health Care

To answer KQ 1c, we searched for studies examining the relationship between low literacy and the costs of health care. The one study we found that examined this relationship contacted Medicaid patients by telephone or letter and enrolled 402 (75% participation rate).[64] Most patients in this study enrolled in Medicaid because of pregnancy rather than medical need or medical indigence (MNMI) (B. Weiss, personal communication, September 2003). The researchers measured literacy using the Instrument for the Diagnosis of Reading (IDL) and gathered charges from Medicaid records. They found no relationship between literacy and Medicaid charges ($r^2 = 0.0016$, $P = 0.43$). Weiss et al.[64] also evaluated several components of charges, such as inpatient care, outpatient care, and emergency care, but did not identify any relationship between literacy and component charges.

A subsequent unpublished statistical analysis including only nonpregnant patients (n = 74) found that the 18 patients with a reading level at or below third grade had higher mean Medicaid charges than the 56 who read above the third grade level ($10,688 vs. $2,891; $P = 0.025$) (B. Weiss, personal communication, September 2003). Because the reanalysis is preliminary and exploratory, further research is needed to support this finding.

Disparities in Health Outcomes or Health Care Service Use

KQ 1d concerns the relationship between low literacy skills and health outcomes or health care service use by race, ethnicity, culture, or age. Only one study directly examined the role of literacy as a mediator of disparities in health outcomes or health care service use. In a cross-sectional study of men with prostate cancer, Bennett et al.[61] evaluated the proportion who presented with late-stage prostate cancer according to literacy level and race. In a bivariate analysis, black patients were significantly more likely than white patients to present with late-stage cancer (unadjusted 49.5% vs. 35.9%, $P = 0.045$ [calculated OR 1.74]). After adjusting for literacy, age, and location of care, the odds ratio was smaller and no longer statistically significant (OR 1.4; 95% CI 0.7, 2.7). The authors suggest that literacy may be mediating some of the racial difference in stage of presentation for prostate cancer.

While not examining differences between groups, 10 studies were primarily focused on particular race/ethnicity groups or seniors: in 2 studies, 90 percent or more of participants were white;[58,59] in 3 studies, 90 percent or more of participants were black;[26,32,57] in 1 study, all participants were Hispanic;[52] and in 4 studies, all participants were 60 years of age and older.[7,22-24]

Summary

Based on the published data identified by our systematic review, literacy level has been found to be related to knowledge and comprehension, hospitalization, global measures of health, and some chronic diseases. In many cases, however, the evidence is mixed and depends on the

analytic methods used by the original investigators. For example, although literacy may be related to health outcomes in bivariate associations, when covariates such as education or socioeconomic status are controlled for, the relationship often becomes less strong and statistically nonsignificant. Furthermore, most of the data came from cross-sectional studies that were unable to measure changes in incident outcomes over time.

Key Question 2: Interventions for People With Low Literacy

Literature Search and Included Studies

Number and Type of Studies. We identified 29 articles describing interventions to mitigate the effects of low literacy on health outcomes. Table 6 summarizes these studies, which are reported in greater detail in Evidence Table 2. Most intervention studies were published within the past 10 years, reflecting the relative novelty of this line of research.

Included studies were generally of three types: randomized controlled trials, nonrandomized controlled trials (in which assignment to intervention or control groups was done by the day or the week or some other nonrandom process), and uncontrolled, single-group "before-and-after" studies. The number of participants enrolled ranged from 28 to 1,744; most studies had between 100 and 500 participants. Nearly all intervention studies were conducted in the United States; only the studies by Hugo and Skibbe[65] (South Africa) and Mulrow and colleagues[66] (United Kingdom) were not. Most studies were conducted in single sessions. Interventions to improve dietary behavior and a small group of other studies[66-71] followed participants longitudinally to assess changes in outcomes after an intervention.

As shown in Table 12, 19 of 29 intervention studies measured the literacy of each participant. Of these, 10 used the REALM, 4 used the WRAT, and 5 used a variety of other instruments; no intervention study used the TOFHLA. The criteria used to define literacy level categories varied across studies. The remaining 10 studies did not measure literacy directly but, rather, were conducted among populations known from previous assessments to have a large proportion of people with poor literacy skills. In addition to literacy, most studies reported participants' mean age, ethnicity, and mean education levels. Information on participants' income level and health insurance status was available for fewer studies.

Types of Interventions. The included studies tested a wide range of interventions for improving health outcomes in patients with poor literacy. Most interventions attempted to make health information more available to patients with limited literacy. Interventions designed to improve information delivery were often compared against standard information delivery or materials known to be more difficult to read. Some studies compared standard written information against specially designed pictographs, booklets, videotapes, or CD-ROMs designed for low-literacy audiences; others compared written information of different readability levels.

Bill-Harvey and colleagues[69] tested an intervention for osteoarthritis that was delivered by trained community leaders. Some studies, such as the one by Mulrow and colleagues,[66] used a multiple group design to test different combinations of a multimodal intervention. Most interventions were delivered at one session, although several studies, particularly those directed to dietary change, used multiple sessions.

Overall, these studies often had important limitations in design. They included (1) common use of uncontrolled before-and-after design; (2) failure to measure literacy or analyze results by literacy level; (3) failure to account for multiple comparisons in the analysis; and (4) inability to isolate the impact of overcoming literacy barriers compared with other co-interventions.

Types of Outcomes. Included studies measured the following outcomes of interest: knowledge and comprehension, health behaviors (e.g., smoking rates, dietary patterns, self-care), biochemical or other intermediate markers (e.g., cholesterol levels, weight, HbA1c, blood pressure), use of health services (pneumococcal vaccination rates, mammography rates), and disease-related functional status. Knowledge outcomes were most commonly used. Few studies directly measured health outcomes that participants could feel and report on directly, such as depression or measures of functional status.

Most included studies only compared outcomes from the intervention and the control groups, or evaluated a change in outcome if the study was a before-and-after design.[65,67-88] However, five studies stratified the analysis to examine the effect of the intervention according to literacy status.[89-93] This type of analysis is necessary to directly measure how the intervention performs for individuals with differing literacy levels.

Use of Health Care Services

KQ 2a concerns the impact of interventions to improve the use of health care services among individuals with low literacy skills. The only article in this category concerned preventive services. In a nonrandomized controlled trial, Davis and colleagues[73] found that an intervention consisting of a 12-minute video, coaching tool, verbal recommendation, and brochure significantly improved mammography utilization at 6 months (but not 24 months), compared with the verbal recommendation and brochure alone.

Health Outcomes

Knowledge and Comprehension. Improvement in knowledge was the most common outcome examined in the studies included for KQ 2. In most cases, participant knowledge improved after receiving the intervention. In five studies, investigators measured patient literacy and stratified the effect of the intervention by literacy status.[89-93]

In a controlled trial among patients at a sleep apnea clinic, Murphy and colleagues[89] used an 11-item questionnaire to compare the effect of a videotape educational tool against the effect of a brochure written at a readability level similar to the videotape's script. Participants with low literacy displayed higher knowledge with the video than with the brochure for 2 of the 11 questions (one about the types of sleep apnea, the other about treatment options for obstructive sleep apnea); for patients with higher literacy, the only percentage that was significantly higher among those who saw the video than among those who read the brochure was for those who correctly answered a question about the cause of sleep apnea.

Michielutte and colleagues[90] compared the effect of a brochure with illustrations on cervical cancer with the effect of a brochure using only text in a randomized trial. Patients with lower literacy on the WRAT (score < 46) understood the illustrated materials better than the text materials (61% vs. 35% of women, $P = 0.007$). For patients with higher literacy, no significant difference was detected (70% vs. 72%).

Wydra[93] performed a randomized trial among cancer patients to examine the effect of an interactive videodisc to improve self-care of cancer fatigue symptoms against no intervention. Patients who received the intervention reported greater self-care ability, but this effect was not significantly related to the literacy level of the patient ($P = 0.31$).

In another controlled trial, Davis and colleagues[91] compared a locally developed pamphlet about the polio vaccine designed for patients with low literacy and a pamphlet from the Centers for Disease Control and Prevention (CDC) that had also been designed for easy readability. Comprehension did not differ between the two pamphlets among patients with lower literacy (third grade reading level or less); among all other higher literacy groups, the locally developed pamphlet was associated with increased comprehension.

In a randomized trial of 1,100 patients at the Milwaukee County Hospital primary care clinic, Meade and colleagues[92] examined the effectiveness of educational materials on colorectal cancer that were intended to be appropriate for people with low literacy. Participants were assigned to one of two interventions (a videotape or an easy-to-read brochure) or to a usual care control group. Patients receiving either intervention had significantly greater improvements in knowledge scores after reviewing the educational materials than did the control group (26% for the video, 23% for the brochure, 3% for controls). Both low- and high-literacy groups, stratified at less than seventh grade or seventh grade and higher based on their WRAT scores, who received either intervention showed significantly improved knowledge between the pre- and posttests. However, the rates of improvement in the two literacy groups were not significantly different.

A number of other studies found that their low-literacy interventions improved everyone's knowledge or improved knowledge for all but those in the lowest category of literacy. Coleman and colleagues[72] found that knowledge of and confidence in performing breast self-examination increased among African-American women regardless of whether they used educational materials with drawings or photographs. Davis and colleagues[75] found a preference for more simplified language among candidates to participate in a research project who were asked to sign consent forms, but there was no difference in comprehension of the study associated with the literacy level of the forms. However, in another trial, Davis and colleagues[74] reported better comprehension for all but persons with the lowest literacy level when a simplified brochure with graphics was used to instruct parents about polio vaccine.

Eaton and colleagues[76] reported that more simplified drug education materials increased patient knowledge but that being more literate was equally important in accounting for drug knowledge. Kim and colleagues,[84] using a CD-ROM to educate men about prostate cancer treatments, found participants' levels of knowledge about treatment to be quite variable and directly associated with literacy level. Powell and colleagues[71] tested the use of information sheets with drawings to educate parents on injury prevention and found that the drawings made no difference in their recall of specific information after several weeks. In a test of prototype package insert information for emergency contraceptive pills, Raymond and colleagues[88] found that, although most women could understand enough information for the safe and effective use of the pills, less literate women typically understood less than the desired amount of information.

Health Behaviors. Several studies addressed the effect of interventions on health behaviors. The behaviors included smoking, dietary patterns, exercise or physical activity, or medication adherence. Outcomes were mixed.

Lillington and colleagues[67] found that pregnant smokers and ex-smokers who received a specially designed intervention with materials written at the third grade reading level were more likely to achieve abstinence during pregnancy and 6 weeks postpartum than those who received standard materials. The magnitude of the effect was greater among those who were current smokers at entry than for ex-smokers (ORs for abstinence at 9 months gestation, 1.7 and 1.06, respectively; ORs for abstinence at 6 weeks postpartum, 2.17 and 1.28, respectively). Bill-Harvey and colleagues[69] reported that their community-based osteoarthritis intervention improved exercise behavior in a 6-week, before-and-after uncontrolled trial. Hussey[82] found that medication adherence among patients 65 years and older improved over time when they were given verbal teaching concerning medication compliance; adding a color-coded medication schedule did not provide additional benefit, however. Interventions addressing dietary behaviors produced small or no changes.[78,79,81,89]

Biochemical or Biometric Markers. Several studies used changes in biochemical or biometric markers to test the effect of their interventions. Fouad et al.[70] found modest differences in blood pressure (net change 2.1 mm Hg) among participants in a specially designed workplace hypertension education and behavior change program when they were compared with nonparticipating controls. Kumanyika and colleagues[85] found no significant difference in postprogram cholesterol levels among African-Americans who were assigned to a special cardiovascular nutrition program compared with their preprogram levels; net differences in blood pressure were 3.2 mm Hg among women and 1.7 mm Hg among men, but neither of these results was statistically significant. Hartman and colleagues[79] also found no significant difference in cholesterol levels with a dietary intervention aimed at people of low literacy. Finally, in a randomized trial in London, Mulrow and colleagues[66] tested the effect of a special educational intervention for patients with diabetes. HbA1c did not differ between groups at either 7- or 11-month followup; weight loss improved moderately with the intervention at 7 months, but the difference did not persist at the 11-month followup.

Measures of Disease Prevalence, Incidence, or Morbidity. Few studies examined the effect of interventions on health outcomes that people can actually feel. The uncontrolled before-and-after trial by Bill-Harvey and colleagues[69] found that an osteoarthritis education intervention could improve the functionality of people with osteoarthritis. In the only study to examine the effect of an intervention that included direct literacy-skill building, Poresky and Daniels[68] found that a comprehensive family services center, compared with a standard Head Start program, could improve parental reading skill and reduce the prevalence of paternal depression.

Global Health Status. We identified no study of a literacy intervention that used a self-reported instrument to measure health-related quality of life or health status.

Costs of Health Care

KQ 2c concerns the impact of interventions to affect the cost of care among individuals with low literacy skills. We found no study assessing costs, charges, or reimbursements for these types of interventions in this population.

Disparities in Health Outcomes or Health Care Service Use

KQ 2d concerns the impact of interventions to improve health care utilization or outcomes among different racial, ethnic, cultural, or age groups. Although no studies compared differences between groups, some interventions were targeted toward particular populations defined by race, including three in which 90 percent or more were black,[83,85,86] and one (in South Africa) in which all participants were identified as "coloured."[65] Regarding ethnicity, one study involved only Hispanic participants.[77] Finally, four studies only enrolled participants who were 60 years of age and older.[80,82,84,87] None of these investigations, however, examined the interaction between literacy level and race, ethnicity, or culture in light of the intervention.

Summary

Studies of interventions designed to reduce the impact of low health literacy on health outcomes have increased over the past 10 years. Available data from multiple studies generally suggest that these types of interventions can increase knowledge and comprehension; limited evidence also suggests that they can improve functional outcomes and reduce morbidity.

Nonetheless, further work in this area will be needed to determine if this effect is robust. Little information is available to determine whether interventions can consistently improve health behaviors, biochemical markers, or specific and global health markers. Many of the studies that produced no statistically or clinically significant differences examined outcomes that are difficult to change, such as dietary behavior.

Figure 2. Cumulative number of articles addressing KQ 1 and KQ 2 by year of publication

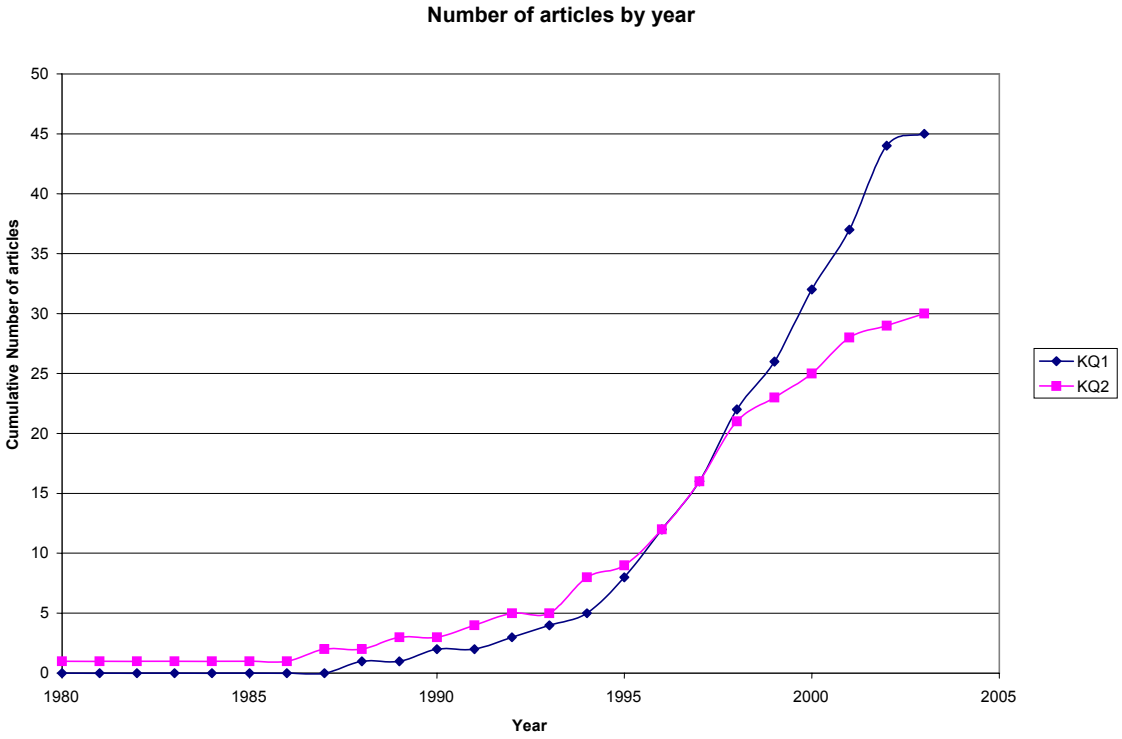


Table 5. Summary of studies of relationship between health services, outcomes, costs, or disparities and literacy (KQ 1)

Study	Design	Health Measure	Literacy Measure	Results
Use of Health Care Services				
Knowledge of Health Care Services				
Davis et al., 1996[27]	Cross-sectional	Knowledge and attitudes regarding mammography screening	REALM	Higher literacy level was associated with reasons why women get mammograms.
Lindau et al., 2002[28]	Cross-sectional	Cervical cancer screening practices	REALM	Higher literacy was associated with being more knowledgeable of the purpose of Pap test.
Miller et al., 1996 [29]	Cross-sectional	Adequacy of clinical trials information (informed consent)	WRAT	Higher literacy level was moderately correlated with understanding informed consent.
Moon et al., 1998[30]	Prospective cohort	Understanding of medical information and ability to follow therapy prescribed for child	REALM	Parents with low literacy were more likely to perceive their child as being sicker than higher literacy parents.
Spandorfer et al., 1995[31]	Prospective observational cohort	Emergency department discharge instructions	WRAT	Higher literacy level was associated with comprehension of instructions.
TenHave et al., 1997[32]	Cross-sectional	Heart health knowledge	CARDES	Higher literacy level was associated with greater knowledge of matters relating to use of these health services.
Risk of Hospitalization				
Baker et al., 2002[24]	Prospective cohort	Hospitalization	S-TOFHLA	Patients with inadequate literacy were more likely than patients with adequate literacy to be hospitalized.
Baker et al., 1998[26]	Prospective cohort	Hospitalization	TOFHLA	Patients with inadequate literacy were more likely than patients with adequate literacy to be hospitalized.
Physician Visits				
Baker et al., 1997[25]	Cross-sectional	Self-reported health and use of health services	TOFHLA	There was no association between literacy status and self-reported access to physician visits after adjusting for age, health status, and economic indicators.

Table 5. Summary of studies of relationship between health services, outcomes, costs, or disparities and literacy (KQ 1) (continued)

Study	Design	Health Measure	Literacy Measure	Results
Screening and Prevention				
Fortenbury et al., 2001[33]	Cross-sectional	Receipt of a screening for gonorrhea in the past year	REALM	Higher literacy was associated with an increase in the probability of having a gonorrhea test in the past year.
Scott et al., 2002[23]	Cross-sectional	New Medicare enrollees in a national managed care organization preventive care utilization	S-TOFHLA	Patients with inadequate literacy were more likely to have never had a Pap smear or a mammogram in the past 2 years. Women with marginal literacy were more likely to have never had a Pap smear than women with adequate literacy. Patients with inadequate literacy were less likely to have had either an influenza or pneumococcal immunization.
Health Outcomes				
Knowledge or Comprehension of Outcomes				
Arnold et al., 2001[34]	Cross-sectional	Knowledge, attitudes, and practice of tobacco use among pregnant women	REALM	Literacy was a predictor for knowledge of effects of smoking and secondhand smoke.
Conlin and Schumann, 2002[35]	Cross-sectional	Analysis of standard discharge instructions and forms for open heart surgery after recovery from open heart surgery	REALM	Literacy level was correlated with understanding standard discharge instructions and forms.
Gazmararian et al., 1999[37]	Cross-sectional	Family planning knowledge and practices among Medicaid managed care enrollees	S-TOFHLA	Women wanting to know more about birth control were more likely to have low reading skills. Incorrect knowledge of "time of month most likely to get pregnant" was higher among women with low reading skills.

Table 5. Summary of studies of relationship between health services, outcomes, costs, or disparities and literacy (KQ 1) (continued)

Study	Design	Health Measure	Literacy Measure	Results
Kalichman et al., 2000 [40]	Cross-sectional	HIV-infected patients' knowledge and understanding of their status and perceptions of treatment effects on transmission risks	TOFHLA, reading only	Lower literacy was associated with not understanding CD4 counts or meaning of viral load. Lower literacy was associated with incorrect beliefs about HIV treatments and transmission risks.
Kalichman and Rompa, 2000[38]	Cross-sectional	Health status awareness and understanding of HIV infection status, disease, and treatment-related knowledge	TOFHLA, reading only	Lower literacy was associated with lack of knowledge and understanding of HIV-related health markers. Higher literacy group had higher knowledge of HIV disease and treatment than lower literacy group. Lower literacy group had more negative perceptions and experiences related to HIV-AIDS.
Kalichman et al., 2000[39]	Cross-sectional	Reliability and validity of self-reported HIV-related health markers in HIV-infected adults	TOFHLA, reading only	Lower literacy was more likely to have discrepant self-reported CD4 counts or viral loads.
Miller et al., 2003[41]	Prospective cohort	Dosing and compliance of HIV-infected individuals taking antiretroviral medication	S-TOFHLA	Lower medication knowledge was significantly associated with lower literacy.
Williams et al., 1998[42]	Cross-sectional	Chronic disease and treatment among patients with diabetes or hypertension	TOFHLA	No significant association found between literacy and blood glucose control or blood pressure.
Williams et al., 1998[43]	Cross-sectional	Ability of asthma patients to use a metered dose inhaler	REALM	Knowledge increased with literacy.

Table 5. Summary of studies of relationship between health services, outcomes, costs, or disparities and literacy (KQ 1) (continued)

Study	Design	Health Measure	Literacy Measure	Results
Wilson and McLemore, 1997[36]	Cross-sectional	Patients hospitalized for knee or hip surgery "self-care" knowledge after education with written discharge instructions	REALM	The relationship between literacy and self-care knowledge after written education materials was not significant.
Health Behaviors and Adherence				
Hawthorne, 1996[45]	Cross-sectional	Tobacco use among 11 and 12 year olds	NR	A relationship between literacy and ever having used tobacco among boys but not among girls. The relationship between literacy and using tobacco in the past month was strong among both boys and girls.
Fredrickson et al., 1995[44]	Cross-sectional	Smoking	WRAT	An association between low reading ability and smoking.
Arnold et al., 2001[34]	Cross-sectional	Knowledge, attitude, and practices of tobacco use among pregnant women	REALM	No difference in the unadjusted rates of smoking according to literacy status.
Hawthorne, 1996[45]	Cross-sectional	Alcohol use in adolescence	NR	Odds of having misused alcohol were higher among boys with lower literacy levels than among boys with higher literacy levels. No significant relationship emerged for girls by literacy level.
Kaufman et al., 2001[46]	Cross-sectional	Breast-feeding	REALM	Women with literacy levels at or above 9th grade were more likely to breast-feed for at least 2 months than mothers with literacy at the 7th or 8th grade level.
Fredrickson et al., 1995[44]	Cross-sectional	Breast-feeding	WRAT	An association was found between low reading ability and never breast-feeding.

Table 5. Summary of studies of relationship between health services, outcomes, costs, or disparities and literacy (KQ 1) (continued)

Study	Design	Health Measure	Literacy Measure	Results
Williams et al., 1998[43]	Cross-sectional	Correct use of metered dose inhaler by patients with asthma	REALM	Patients with higher literacy had better metered dose inhaler technique.
Davis et al., 1999[47]	Cross-sectional	Violent behavior in adolescents	Slosson Oral Reading Test	Youth who were more than two grades behind expected reading level were more likely than others to carry a weapon including a gun, take a weapon to school, miss school because it was unsafe, and be in a physical fight that required medical treatment.
Stanton et al., 1990[48]	Prospective cohort	Problem behavior in children	Burt Word Reading Test	Reading ability was an independent predictor of teacher-reported problem behavior.
Golin et al, 2002[50]	Prospective cohort	Adherence among HIV-infected patients taking antiretrovirals	S-TOFHLA	No relationship between literacy and adherence was found.
Kalichman et al., 1999[49]	Cross-sectional	Adherence to treatment for HIV and AIDS	TOFHLA, reading only	Lower literacy was associated with greater odds of poor adherence.
Li et al., 2000 [51]	Retrospective case study	Adherence to breast conservation therapy in women with early-stage breast cancer	REALM	Literacy did not significantly predict adherence to radiation, chemotherapy, or clinical appointments.
Frack et al., 1997[52]	Cross-sectional	Compliance with research protocols in a clinical trial	Cloze procedure	Patients who followed up as directed had a higher average literacy score than those who never followed up.
Biochemical and Biometric Health Outcomes				
Ross et al., 2001[53]	Cross-sectional	Glycemic control in children with type 1 diabetes	WRAT3, children; NART, mothers	No significant correlation between literacy in children aged 5 to 17 and glycemic control. Parent's literacy was correlated with the child's glycemic control.

Table 5. Summary of studies of relationship between health services, outcomes, costs, or disparities and literacy (KQ 1) (continued)

Study	Design	Health Measure	Literacy Measure	Results
Williams et al., 1998[42]	Cross-sectional	Glycemic control in adults with type 2 diabetes	TOFHLA	Poorer glycemic control among those with inadequate literacy, but the unadjusted difference was not statistically significant.
Schillinger et al., 2002[54]	Cross-sectional	Glycemic control in adults with type 2 diabetes	S-TOFHLA	Patients with lower literacy had worse glycemic control. The glycemic level was found to be inversely related to literacy.
Williams et al., 1998[42]	Cross-sectional	Patients diagnosed with hypertension	TOFHLA	No independent relationship between literacy and presence or control of hypertension was found. Patients with inadequate literacy had higher systolic blood pressures than those with adequate literacy but was not significant when adjusted.
Battersby et al., 1993[55]	Case-control	Diagnosis of hypertension	Schonell Graded Word Reading Test	No difference in reading ability between patients with or without hypertension was found.
Kalichman and Rompa, 2000[56]	Cross-sectional	HIV infection	Modified TOFHLA	No significant association between reading comprehension and undetectable viral load.
Kalichman et al., 2000[40]	Cross-sectional	HIV infection, optimism, and perceptions of care	Modified TOFHLA	Patients with better reading comprehension had greater odds of having an undetectable viral load than those with worse reading comprehension. No significant association between reading comprehension and undetectable viral load was found. Patients with lower literacy tended to be more optimistic about their future living with HIV.
Kalichman and Rompa, 2000[38]	Cross-sectional	HIV infection, optimism, and perceptions of care	Modified TOFHLA	Better readers had greater odds of having an undetectable viral load than worse readers. Worse readers had greater odds of having a CD4 count less than 300 than did better readers. Patients with lower literacy had more distrust of providers and were less likely to believe that treatment helps.

Table 5. Summary of studies of relationship between health services, outcomes, costs, or disparities and literacy (KQ 1) (continued)

Study	Design	Health Measure	Literacy Measure	Results
Measures of Disease Prevalence, Incidence, or Morbidity				
Gazmararian et al., 2000[22]	Cross-sectional	Self-reports of depression in a Medicare population	S-TOFHLA	The odds of being depressed were greater for those people with inadequate literacy compared to those with adequate literacy. After adjusting for demographic, social support, health behavior, and health status factors, the correlation was no longer statistically significant. A significant relationship between literacy and depression could not be observed. No significant relationship was found after adjusting for age and health status.
TenHave et al., 1997[32]	Cross-sectional	Self-reports of depression in adults participating in a cardio-vascular dietary education program	CARDES	Lower scores on the literacy assessment were statistically significantly associated with higher scores on the depression assessment after adjusting for age, suggesting a greater propensity for depression among those with lower literacy.
Zaslow et al., 2001[57]	Cohort	Mothers' reports of child's depression and antisocial behavior	Test of Applied Literary Skills	Risk of depression was higher among mothers who had lower literacy skills. No relationship was detected between maternal literacy and depression or antisocial behavior among their children.
Kalichman and Rompa, 2000[56]	Cross-sectional	Self-reported depression in HIV-infected patients	TOFHLA	Total scores on the depression scales did not differ by literacy status. Some depression subscales were higher (representing more depression) for participants with lower literacy.
Gorden et al., 2002[58]	Cross-sectional	Self-report of depression in patients with rheumatoid arthritis	REALM	Patients with more anxiety and depression were greater among those who read below the 9th grade level than among those who read at or above the 9th grade level.
Fisch et al., 1998[59]	Cross-sectional	Emotional balance after receiving informed consent materials for a bone marrow transplant	WRAT	No significant relationship between the patterns of affects changes and literacy.
Gordon et al., 2002[58]	Cross-sectional	Arthritis and functional status of patients with rheumatoid arthritis	REALM	Health activity did not differ according to literacy dichotomized at the 9th grade level.

Table 5. Summary of studies of relationship between health services, outcomes, costs, or disparities and literacy (continued)

Study	Design	Health Measure	Literacy Measure	Results
Andrasik et al., 1988[60]	Case-control	Children with and without migraines	WRAT	No significant difference in literacy scores between the two groups was found.
Bennett et al., 1998[61]	Cross-sectional	Stage of presentation of prostate cancer	REALM	Men with lower literacy were more likely to present with late-stage prostate cancer than those with higher literacy. After adjusting for race, age, and location of care, the investigators found that the relationship between literacy and stage of presentation was smaller and no longer statistically significant.
Global Health Status Measures				
Weiss et al., 1992[62]	Cross-sectional	Health status	Tests of Adult Basic Education and Mott Basic Language Skills Program	People with lower literacy scored worse than those with higher literacy on both the physical and psychosocial subcomponents.
Baker et al., 1997[25]	Cross-sectional	Overall health status	TOFHLA	Patients with inadequate literacy had about twice the odds of reporting poor health than patients with adequate literacy.
Gazmararian, et al., 1999[7]	Cross-sectional	Medicare managed care health plan	S-TOFHLA	Patients with inadequate literacy were significantly more likely to self-report fair or poor health than patients with adequate literacy.
Sullivan et al., 1995[63]	Cross-sectional	General health status of patients with type 2 diabetes	QLS	No difference in scores on the SF-36 according to whether the subject "passed" or "failed" the QLS.
Cost of Health Care				
Weiss et al., 1994[64]	Retrospective cohort	Costs of health care in Medicaid patients	Instrument for the Diagnosis of Reading	No relationship between literacy and Medicaid charges.
Disparities in Health Outcomes or Use of Health Services				
Bennett et al., 1998[61]	Cross-sectional	Men who presented with late-stage prostate cancer	REALM	Black patients were significantly more likely than white patients to present with late-stage cancer. After adjusting for literacy, age, and location of care, the odds ratio was smaller and no longer statistically significant.

Table 5. Summary of studies of relationship between health services, outcomes, costs, or disparities and literacy (KQ 1) (continued)

Study	Design	Health Measure	Literacy Measure	Results
Gordon et al., 2002;[58] Fisch et al., 1998;[59] Hayes, 1998;[80] Baker et al., 1998;[26] TenHave et al., 1997; [32] Zaslow et al., 2001;[57] Williams et al., 1999[94] Frack et al., 1997; [52] Gazmararian et al., 1999;[7] Gazmararian et al., 2000; [22] Scott et al., 2002; [23] Baker, et al., 2002[24]				Study did not examine differences between groups. Low literacy was associated with anxiety and depression.

Note: REALM, Rapid Estimate of Adult Literacy in Medicine; WRAT, Wide Range Achievement Test; CARDES, Cardiovascular Education Dietary System; TOFHLA, Test of Functional Health Literacy in Adults; S-TOFHLA, Short-TOFHLA; NR, not reported.

Table 6. Summary of studies of interventions to improve health-related outcomes in low-literacy populations (KQ 2)

Study	Design	Intervention	Literacy Measure	Results
Use of Health Care Services				
Davis et al., 1998[73]	RCT (randomized at the level of appointment day and analyzed at person level)	Combinations of video, verbal recommendation, and brochure.	REALM	The full intervention with video improved mammography rate at 6 months but not at 24 months compared with a verbal recommendation alone or verbal recommendation with a brochure.
Outcomes: Knowledge and Comprehension				
Coleman et al., 2003[72]	Non-RCT	Educational materials on breast cancer self-examination for African-American women using versions with drawings or photographs.	None	Women using both versions had increased knowledge of breast cancer screening, confidence in breast self-examination, and performance scores when practicing with silicone models. However, women who had the photographic version had higher rates of finding lumps in the silicone breast models.
Davis et al., 1996[74]	Non-RCT	Specially prepared lower grade level parent educational pamphlet with instructional graphics about polio vaccine and standard pamphlet.	REALM	Comprehension was better and time needed to read was less for the lower grade level pamphlet than for the standard pamphlet for all but persons in the lowest literacy level.
Davis et al., 1998[91]	RCT	Two low-literacy pamphlets (6th grade level) for parents on polio vaccine, one with instructional graphics and one without.	REALM	Parents preferred the pamphlet with graphics over the one without and scored higher comprehension with it as well.
Davis et al., 1998[75]	Non-RCT	Special low-literacy consent form (7th grade level) and standard consent form (16th grade level) for participation in clinical cancer research studies.	REALM	Participants preferred the lower grade level version of the consent form. Participants with a lower literacy level more heavily preferred the lower grade level version. There was no difference, however, between the two forms in participant comprehension.
Eaton and Holloway, 1980[76]	RCT	Standard educational materials on warfarin (10th grade level) and simplified materials (5th grade level).	Adult Basic Learning Examination	Patient knowledge of warfarin was higher with higher literacy and with simplified materials.

Table 6. Summary of studies of interventions to improve health-related outcomes in low-literacy populations (KQ 2) (continued)

Study	Design	Intervention	Literacy Measure	Results
Kim et al., 2001[84]	Posttest only	A specially designed CD-ROM educational program given to men newly diagnosed with prostate cancer.	REALM	Knowledge of prostate cancer varied greatly, and greater knowledge was associated with higher literacy as measured by the REALM. Typically preferences for treatment made after using the CD-ROM but before conferring with the physician were quite different from the treatment actually received after conferring with the physician.
Meade et al., 1994[92]	RCT	Simply written brochure, a videotape (with similar contents) about colorectal cancer, and no educational intervention.	WRAT	Printed and videotaped materials were equally effective in increasing knowledge and recall of colon cancer information and more effective than no educational intervention. Similar results regardless of literacy level.
Michielutte et al., 1992[90]	RCT	Two cervical cancer information brochures: one used two-color illustrated, narrative text (SMOG grade level 8.4); the second used simple, bulleted text with no illustrations (SMOG grade level 7.7).	WRAT-R, (adapted for this study)	The two-color illustrated brochure with narrative text increased the comprehension level among low-literacy women as compared to the bulleted text with no illustrations. High-literacy women had similar comprehension regardless of brochure.
Murphy et al., 2000[89]	Non-RCT	A 13-minute sleep apnea video written at 12th grade level and a brochure written at the 12th grade level.	REALM	Video improved two areas of knowledge for low-level readers as compared to the brochure and only improved one area of knowledge among high-level readers.
Powell et al., 2000[71]	Non-RCT	Special low-literacy injury prevention information sheet (using drawings) and standard injury prevention sheet.	None	Most parents recall receiving printed information about injury prevention at a child's clinic visit when asked several weeks later; however, their recall of specific information on injury prevention was limited and no better in the group receiving the special information sheet with pictorials.
Raymond et al., 2002[88]	Posttest only	Prototype package insert for emergency contraceptive pills.	REALM	Most women participants were able to understand the key information for safe and effective use of the drug. However, less literate women were less likely to understand the information to meet most of the educational objectives of the insert than more literate women.

Table 6. Summary of studies of interventions to improve health-related outcomes in low-literacy populations (KQ 2) (continued)

Study	Design	Intervention	Literacy Measure	Results
Wydra, 2001[93]	RCT	An interactive videodisc designed to help cancer patients improve self-care of illness-related fatigue.	WRAT3	Patients who used the videodisc had greater improvement in self-care ability than those who did not use it, and they received more education and covered more content. They also reported less fatigue and making fewer changes in routine due to fatigue. Similar results regardless of literacy level.
Outcomes: Health Behaviors				
Bill-Harvey et al., 1989[69]	Separate sample pretest/posttest	Special 10-hour educational intervention (SMOG grade level 8) administered by community members designed for low-literacy patients with osteoarthritis.	None	The intervention group had increased knowledge, greater exercise behavior, and improved attitude.
Gans et al., 1998[78]	Pretest/ posttest	Special CD and picture food book developed for low-literacy persons to improve diet and reduce blood cholesterol.	None	Preliminary data indicate that persons exposed to the intervention achieved reductions in dietary fat intake in the 3 months after exposure to the intervention.
Hartman et al., 1997[79]	RCT	Diet/nutrition intervention designed for low-literacy patients to change low-fat eating pattern and standard nutrition education materials.	Adult Basic Learning Examination, Level II	The low-fat intervention was associated with improvements in eating behaviors related to substituting low-fat for high-fat foods and with overall low-fat eating behavior.
Howard-Pitney et al., 1997[81]	RCT (randomized at the classroom level and analyzed at individual level)	Special nutrition education program (six 90-minute sessions and 12-week maintenance sessions) focusing on lowering dietary fat intake and the usual nutrition education focusing on general nutrition in a low-literacy population (66% at 8th grade level or below).	WRAT	Intervention group showed greater improvement on nutrition knowledge, attitudes toward eating a low-fat diet, and self-efficacy for achieving a low-fat diet.

Table 6. Summary of studies of interventions to improve health-related outcomes in low-literacy populations (KQ 2) (continued)

Study	Design	Intervention	Literacy Measure	Results
Hussey, 1994[82]	Non-RCT	Verbal teaching to elderly patients about medications with or without a color-coded medication schedule.	Comprehension Subtest of Gates-MacGinitie Reading Test	Knowledge in both groups of patients increased, but compliance to medication schedule improved more among those in the color-coded intervention group overall and especially among those who had initial low compliance.
Lillington et al., 1995[67]	RCT (randomized at clinic level but analyzed at individual level)	Pregnant smokers and ex-smokers received specially designed, culturally appropriate materials on smoking cessation written at 3rd grade level that included one-on-one counseling, a self-help guide, booster postcards, and an incentive contest, or just standard materials.	None	The special materials intervention was more effective than the standard materials in achieving higher quit rates during pregnancy among baseline smokers, and lower relapse rates 6 weeks postpartum among baseline ex-smokers.
Murphy et al., 1996[86]	Non-RCT	African-American adult basic education class participants at or below 6th grade reading level in a specially designed 8-hour intervention to improve dietary behaviors.	REALM	The intervention increased knowledge of food measurements and portion sizes.
Outcomes: Biochemical or Biometric Markers				
Fouad et al.,1997[70]	Non-RCT	Year-long worksite antihypertension educational intervention designed for low-literacy workers.	None	Intervention participants who were unskilled showed a drop in their systolic and diastolic blood pressures.
Kumanyika et al., 1999[85]	RCT	A cardiovascular nutrition education program for African-Americans with elevated cholesterol or high blood pressure (four monthly classes in addition to food pictures, video and audio recordings, and written nutrition guide with pictures given to both full intervention and self-help groups).	Specially designed scale	Total cholesterol and low density lipoprotein cholesterol decreased in both groups. Blood pressure (systolic and diastolic) improved for persons with initial elevated blood pressure in both groups.

Table 6. Summary of studies of interventions to improve health-related outcomes in low-literacy populations (KQ 2) (continued)

Study	Design	Intervention	Literacy Measure	Results
Mulrow et al., 1987[66]	RCT	Monthly educational sessions about diabetes knowledge (with or without videotapes) over 11 months versus a single session.	None	After 7 months, the intervention with the videotapes resulted in greater weight loss than the intervention without videotapes or the one-time education session. The weight loss was not sustained at the 11-month followup.
Outcomes: Disease-Related Functional Status				
Poresky and Daniels, 2001[68]	RCT	Comprehensive family services center versus a standard Head Start program.	Comprehensive Adult Student Assessment Scale	Overall family well-being increased in the comprehensive service center group—higher income, increased literacy, and decreased parents with high depression scores.
Costs				
None Identified	—	—	—	—
Disparities in Health Outcomes or Use of Health Services				
Fitzgibbon et al., 1996[77]	RCT	Twelve-week culture-specific dietary intervention for Hispanic families (mothers were attending literacy program).	None	Mothers in the intervention group reduced their percent fat and saturated fat intake. There was no change in the control group.
Hayes, 1998[80]	RCT	A "geragogy-based" intervention (large print, easy to read, organized for elderly) for medication instruction or usual approach to discharge from emergency departments.	REALM	The group of persons discharged and receiving the geragogy-based medication instruction had more knowledge of medications than those who got the standard discharge.
Hugo and Skibbe, 1991[65]	Posttest only	Low-literacy South African population's ability to identify content on breast-feeding from color or black and white images.	None	Most women expressed a preference for breast-feeding after exposure to the intervention. In addition, women were more able to understand the instructions conveyed in the color photographs than in the black and white one.
Jacobson et al., 1999[83]	RCT	A low-literacy one-page handout on pneumococcal vaccination and a one-page low-literacy handout on nutrition used in conjunction with a patient-physician dialogue.	None	Group receiving the pneumococcal handout had more discussions about it with their physician and were more likely to receive the immunization than group receiving handout on nutrition.

Table 6. Summary of studies of interventions to improve health-related outcomes in low-literacy populations (KQ 2) (continued)

Study	Design	Intervention	Literacy Measure	Results
Pepe and Chodzko-Zajko, 1997[87]	Single sample pre-test/posttest	A cholesterol education video delivered at 2 week followup visit for low-literacy seniors.	REALM	After viewing the video and 1 month later, participants had greater knowledge of cholesterol and cardiovascular disease. However, knowledge was associated with literacy as measured by the REALM.

Note: RCT, randomized controlled trials; REALM, Rapid Estimate of Adult Literacy in Medicine; WRAT, Wide Range Achievement Test; WRAT-R, WRAT-Revised; SMOG, a readability formula.

Table 7. Measurement tools and criteria used to measure literacy in KQ 1 articles

Study	Measurement Tool	Literacy Measurement Levels
Stanton et al., 1990[48]	Burt Word Reading Test, 1974 Revision	NR
TenHave et al., 1997[32]	CARDES (developed for this study)	< 5th grade 5th to 8th grade > 8th grade
Frack et al., 1997[52]	Cloze procedure measured Spanish-language literacy	Mean
Weiss et al., 1994[64]	Instrument for the Diagnosis of Reading (IDL)	Grade equivalent: 0 through ≥ 8th grade
Kalichman and Rompa, 2000[38]	Modified TOFHLA reading comprehension section	"Lower health literacy" "Higher health literacy" Cut-off for higher health literacy at 80% correct on TOFHLA subtest
Hawthorne, 1996[45]	NR	Low, middle, high
Sullivan et al., 1995[63]	Questionnaire Literacy Screen (QLS)	Pass: all answers correct Fail
Arnold et al., 2001[34] Conlin and Schumann, 2002[35] Davis et al., 1996[27] Gordon et al, 2002[58] Moon et al., 1998[30] Scott et al., 2002[23] Williams et al., 1998[43] Wilson and McLemore, 1997[36]	REALM	≤ 3rd grade 4th to 6th grade 7th to 8th grade ≥ 9th grade
Li et al., 2000[51]	REALM	4th to 6th grade 7th to 8th grade ≥ 9th grade
Bennett et al., 1998[61]	REALM	≤ 6th grade > 6th grade
Fortenberry et al., 2001[33] Kaufman et al., 2001[46] Lindau et al., 2002[28]	REALM	< 9th grade ≥ 9th grade or higher
Battersby et al., 1993[55]	Schonell Graded Word Reading Test	Mean
Schillinger et al., 2002[54]	S-TOFHLA, English or Spanish version	Inadequate Marginal Adequate
Davis et al., 1999[47]	Slosson Oral Reading Test, Revised	Reading level 2 or more grade levels behind (referred to as low reading level)

Table 7. Measurement tools and criteria used to measure literacy in KQ 1 articles (continued)

Study	Measurement Tool	Literacy Measurement Levels
Gazmararian et al., 1999[37]	S-TOFHLA	Low, good
Golin et al., 2002[50]	S-TOFHLA	36-point scale
Baker et al., 2002[24] Gazmararian et al., 1999[7] Gazmararian et al., 2000[22]	S-TOFHLA	Inadequate Marginal Adequate
Miller et al., 2003[41]	S-TOFHLA	Mean
Weiss et al., 1992[62]	Tests of Adult Basic Education and Mott Basic Language Skills Program	≤ 4th grade 5th to 6th grade 7th to 8th grade ≥ 9th grade
Zaslow et al., 2001[57]	Test of Applied Literacy Skills (TALS), developed by Educational Testing Service	5 levels Levels 1 to 2 considered low literacy
Baker et al., 1997[25] Baker et al., 1998[26] Williams et al., 1998[42]	TOFHLA	Adequate Marginal Inadequate
Kalichman et al., 1999[49] Kalichman et al., 2000[39] Kalichman and Rompa, 2000[56]	TOFHLA reading comprehension section only	Lower literacy: score below 85% correct Higher literacy: score 86% correct or higher
Kalichman et al., 2000[40]	TOFHLA reading comprehension section only	Lower literacy: score below 80% correct Higher literacy: score 80% correct or higher
Andrasik et al., 1988[60]	WRAT	NR
Fredrickson et al., 1995[44]	WRAT	< 4th grade 4th to 5th grade 6th to 7th grade 8th to 10th grade 11th to 12th grade 13+ grade
Fisch et al., 1998[59] Spandorfer et al., 1995[31]	WRAT	Mean
Ross et al., 2001[53]	WRAT3 (children) NART (mothers)	WRAT3: mean NART: mean
Miller et al., 1996[29]	WRAT reading subtest	Mean

Note: NA, not applicable; NR, not reported; TOFLA, Test of Functional Health Literacy in Adults; S-TOFHLA, Short TOFHLA; CARDES, Cardiovascular Dietary Education System; WRAT, Wide Range Achievement Test; WRAT3, Wide Range Achievement Test, 3rd edition; NART, National Adult Reading Test.

Table 8. Studies of knowledge or comprehension of health service use (KQ 1a)

Study	Population	Results
Davis et al., 1996[27]	Low-income women at an ambulatory clinic at Louisiana State University at Shreveport	Lower literacy correlated with lower knowledge about mammograms (adjusted)
Lindau et al., 2002[28]	Women in women's health clinics at an academic medical center in Chicago, predominantly Medicaid insurance	Higher literacy associated with more knowledge about cervical cancer screening (adjusted)
Miller et al., 1996[29]	Participants enrolling in anti-infective clinical trials	Moderate correlation between literacy and understanding of informed consent (unadjusted)
Moon et al., 1998[30]	Parents of children in urban and suburban pediatric practices in Washington, DC	No correlation between literacy and parental knowledge of health maintenance procedures or child health measures (adjusted)
Spandorfer et al., 1995[31]	Impoverished inner-city patients at an emergency department in Philadelphia	Reading ability was best predictor of knowledge of discharge instructions (adjusted)
TenHave et al., 1997[32]	Community members coming to a cholesterol screening at a local supermarket	Higher literacy associated with more "Heart Healthy Knowledge" (*P* value not reported) (unadjusted)

Table 9. Studies of knowledge or comprehension of health outcomes (KQ 1b)

Study	Population	Results
Arnold et al., 2001[34]	Predominantly Medicaid or uninsured pregnant women	Low literacy predicted lower knowledge about smoking effects (adjusted)
Conlin and Schumann, 2002[35]	Patients recovering from open heart surgery at a teaching hospital	Lower literacy correlated with lower score on knowledge test of discharge instructions (unadjusted)
Gazmararian et al., 1999[37]	Female Medicaid managed care enrollees in Memphis, Tennessee	Lower literacy associated with less knowledge of time most likely to get pregnant during menstrual cycle (adjusted)
Kalichman et al., 2000[40]	HIV-infected individuals living in Atlanta, Georgia	Higher literacy associated with higher likelihood of understanding the meaning of the CD4 count or viral load (adjusted)
Kalichman and Rompa, 2000[38]	HIV-infected individuals living in Atlanta, Georgia	Lower literacy associated with less understanding of meaning of CD4 counts and viral load; lower literacy associated with less knowledge of disease and treatment based on 14-item questionnaire (adjusted)
Kalichman et al., 2000[39]	HIV-infected individuals living in Atlanta, Georgia	Higher literacy associated with knowledge of CD4 counts and viral load (adjusted)
Miller et al., 2003[41]	HIV-infected patients in a public hospital affiliated clinic	Literacy associated with knowledge of antiretroviral medication (unadjusted)
Williams et al., 1998[42]	Patients with diabetes or hypertension attending a primary care clinic at a public hospital in Los Angeles or Atlanta	Higher literacy associated with more knowledge about hypertension and diabetes (adjusted)
Williams et al., 1998[43]	Adult asthma patients in the emergency department at Grady Memorial Hospital	Higher literacy associated with more asthma knowledge (adjusted)
Wilson and McLemore, 1997[36]	Patients hospitalized for knee or hip surgery	No correlation between literacy level and patients' level of knowledge about self-care after receiving written education materials (unadjusted)

Table 10. Studies of the relationship between literacy and depression (KQ 1b)

Study	Population	Results
Gazmararian et al., 2000[22]	Elderly persons without dementia in a Medicare health plan	Marginal literacy associated with lower rate of depression (adjusted)
TenHave et al., 1997[32]	Mostly black middle-aged and elderly persons attending a supermarket cholesterol screening	Lower literacy associated with higher depression scores (adjusted)
Kalichman and Rompa, 2000[56]	Mostly black middle-aged HIV-positive patients	Lower literacy associated with more symptoms of depression (unadjusted)
Gordon et al., 2002[58]	Mostly white middle-aged rheumatoid arthritis patients	Lower literacy associated with higher rate of depression (unadjusted)
Zaslow et al., 2001[57]	Black young adult mothers who qualified for Aid to Families with Dependent Children	Lower literacy associated with higher rate of depression (unadjusted)

Table 11. Studies of the relationship between literacy and global health status (KQ 1b)

Study	Population	Results
Weiss et al., 1992[62]	Young English-speaking adult students in an adult education class	Lower literacy associated with poorer health status score (adjusted)
Baker et al., 1997[25]	Middle-aged English- and Spanish-speaking patients of hospital walk-in clinics or emergency departments	Lower literacy associated with poorer health status rating (adjusted)
Sullivan et al., 1995[63]	Middle-aged and elderly patients with type 2 diabetes	Lower literacy associated with poorer physical functioning scores (unadjusted)
Gazmararian et al., 1999[7]	Elderly Spanish- and English-speaking Medicare beneficiaries without dementia	Lower literacy associated with poorer health status rating (unadjusted)

Table 12. Measurement tools and criteria used to measure literacy in KQ 2 articles

Study	Measurement Tool	Literacy Measurement Levels
Eaton and Holloway, 1980[76]	Adult Basic Learning Examination (ABLE)	NR
Hartman et al., 1997[79]	ABLE, Level II	≤ 8th grade 9th to 12th grade > 12th grade
Hussey, 1994[82]	Comprehension Subtest of the Gates-MacGinitie Reading Test	NR
Poresky and Daniels, 2001[68]	Comprehensive Adult Student Assessment Scale	Continuous measurement
Davis et al., 1998[73] Davis et al., 1998[75] Murphy et al., 2000[89] Hayes, 1998[80] Raymond et al., 2002[88]	REALM	≤ 3rd grade 4th to 6th grade 7th to 8th grade ≥ 9th grade
Kim et al., 2001[84] Davis et al., 1996[74]	REALM	≤ 3rd grade 4th to 6th grade 7th to 8th grade ≥ 9th grade Mean score
Davis et al., 1998[91]	REALM	Mean, median
Murphy et al., 1996[86]	REALM	Mean
Pepe and Chodzko-Zajko, 1997[87]	REALM	≥ 9th grade < 9th grade
Kumanyika et al., 1999[85]	Specially designed scale	≤ 8th grade > 8th grade
Howard-Pitney et al., 1997[81]	WRAT	≤ 8th grade > 8th grade
Meade et al., 1994[92]	WRAT	≥ 7th grade < 7th grade
Wydra, 2001[93]	WRAT3	≤ Average (≤ 109) > Average
Michielutte et al., 1992[90]	WRAT-R (adapted for this study)	Dichotomized into high and low literacy at the median score
Bill-Harvey et al., 1989[69] Coleman et al., 2003[72] Fitzgibbon et al., 1996[77] Fouad et al., 1997[70] Gans et al., 1998[78] Hugo and Skibbe, 1991[65] Jacobson et al., 1999[83] Lillington et al., 1995[67] Mulrow et al., 1987[66] Powell et al., 2000[71]	None	NA

Note: NA, not applicable; NR, not reported; REALM, Rapid Estimate of Adult Literacy in Medicine; WRAT, Wide Range Achievement Test; WRAT3, WRAT 3rd edition; WRAT-R, WRAT, Revised

Chapter 4. Discussion

Overview

During this systematic review, the RTI-UNC EPC identified a moderately large body of literature addressing the relationship between literacy and health outcomes. We focused on health service use, health outcomes, health care costs associated with low literacy, and disparities in these variables by race, ethnicity, cultural background, and age. Commonly examined outcomes included use of health care services, health knowledge, intermediate biochemical or biometric disease markers, measures of morbidity or disease prevalence, and self-rated global health status. We also examined a related body of work that assessed the impact of various interventions attempting to overcome or mitigate the effects of low literacy on these types of outcomes.

Our review systematically identified, organized, and critically analyzed both studies that examined the relationship between literacy and health and interventions designed to lessen the adverse health effects associated with low literacy. Although previous reviews on the topic of health literacy have identified relevant published literature through database searching and consultations with experts,[9,19] they have not attempted to answer specific research questions using a similarly rigorous systematic approach to article inclusion, evaluation, and reporting. Previous reviews also either did not report explicit eligibility criteria or did not perform a systematic quality rating process. In contrast, our review was expressly designed and conducted to answer two specific key questions agreed to among AHRQ, the EPC staff, and our TEAG; we then carried out a systematic process to reach that goal.

Consequently, the articles included in our report will differ from those found in previous reviews of literature from the same time period. Many important articles related to the field of health literacy were not included here because they did not address the specific key questions we sought to explore. Although previous reviews have reached similar conclusions about the general relationship between literacy and health,[9,95] our rigorous methodological approach to this topic should give readers confidence in the conclusions drawn from the data and related recommendations for improving future research.

Principal Findings

To provide some context for the strength of this knowledge base and the evidence from the research done to date, we applied a rigorous process for grading the quality of individual articles (described in detail in Chapter 2). These grades (averaged across two independent reviewers and based on evaluations on up to 13 domains relating largely to internal validity) can be found in the evidence and summary tables provided in this report and its appendixes. Articles were characterized as good (grade ≥ 1.5), fair (grade 1.0 to 1.49), or poor (grade < 1.0).

In all, we reviewed 44 studies about the linkages between literacy and health outcomes, broadly defined. Our average grade for the 13 articles measuring the relationship between literacy skills and health services outcomes (KQ 1a) was 1.49, or fair to good.[24,26-31,33,36,38,41,43,62] We graded two of these articles as poor. Of the 31 articles addressing the relationship between literacy skills and health outcomes (KQ 1b), our average quality grade was 1.47, or also fair to

Note: Appendixes and Evidence Tables cited in this report are provided electronically at http://www/ahrq.gov/clinic/epcindex.htm.

good.[7,8,22,23,25,32,34,35,37-39,42,44-53,55-63] We generally graded individual articles as fair or good and graded only 2 as poor. We did not find any *additional* articles that addressed only the relationship between literacy skills and the costs of health care (KQ 1c) or the relationship between literacy skills and disparities (KQ 1d); hence, there are no individual article quality grades associated with these subquestions.

Generally, most studies reported an association between lower literacy and adverse health outcomes or use of services. Most presented results as odds ratios, as is common with categorical outcomes. However, as the percentage of a group with a particular outcome becomes larger (as is seen in many of these studies), ORs may magnify the apparent effect size. In some cases, the size of the effect may appear larger with an OR than with a risk ratio. Despite this common limitation and those presented in relation to our quality grade for each article, our systematic review confirms that the currently available evidence suggests a relationship between low literacy skills and poor health.

Similarly, we calculated the average quality grade for the 29 articles reviewed to address effective interventions to improve health care service use among individuals with low literacy skills (KQ 2a) and those to improve health outcomes among this group (KQ 2b). The single article that addressed KQ 2a received a grade of 1.63, or good.[73] The remaining 28 articles addressed health outcomes corresponding to KQ 2b; the average grade was 1.27, or fair. Three articles were rated as poor.

Fewer studies have examined interventions designed to mitigate the effects of low literacy on health and health services outcomes than simply the association between literacy and health. We purposely created liberal eligibility criteria to allow identification of as many studies as possible that would address these questions, but the field of research in this area has not matured to the point that extensive information about interventions is available. In addition, many of the studies we identified tested interventions in such a way that we could not determine if they helped individuals with low literacy less, more, or equally than individuals with higher literacy.

Five studies used designs that have the greatest likelihood of determining whether the intervention could diminish the effects of low literacy or at least produce positive effects similar to those seen in participants with higher literacy.[27,90-93] These studies used randomized (or quasi-randomized) allocation, measured literacy in all participants, and stratified their results according to literacy level. Although they employed a strong research design, all were designed to examine only changes in knowledge. Their chief drawback is, then, that this is ultimately only an intermediate outcome that may or may not have a relationship with outcomes that influence people's actual health. Although our review uncovered numerous interventions that were found to improve knowledge or more distal health outcomes in mixed populations that included substantial numbers of people with low literacy, determining at this time whether certain types of interventions can actually reduce the literacy-associated disparities in health we noted in our first key question remains a challenge.

In addition to evaluating the quality of each individual article, we also evaluated the quality of the body of evidence available to address each of the subquestions within KQ 1 and 2 (Table 13). (See Chapter 2 for background information on our methodology for developing these grades.) Grades potentially ranged from a high of I for a body of literature with the strongest design to IV for those situations in which no study addressed the question. We found reasonably good evidence to address the relationship between literacy skills and health services outcomes (KQ 1a) and the relationship between literacy skills and health outcomes (KQ 1b) and

rated the evidence for both of these as II. Numerous studies have appropriately examined the relationship between literacy and health services utilization and health outcomes. The use of cross-sectional designs that do not adequately control for confounders, inconsistent measurement, and mixed findings in relation to some outcomes prevents our assignment of the highest grade. We found very few studies that addressed the relationship between literacy skills and costs (KQ 1c) or disparities (KQ 1d), and so this body of literature was rated as III. No study was considered strong enough to be conclusive.

We identified fewer studies that addressed KQ 2 than we did for KQ 1. Because only one study addressed KQ 2a concerning the relationship between literacy interventions and health services outcomes, we graded this body of evidence as III, indicating that the number of studies was too limited to grade the literature. A larger body of research concerned KQ 1b about the relationship between interventions to address low literacy and health outcomes. These studies were limited by testing interventions that did not contribute to our understanding of the specific effect of mitigating literacy barriers; the reasons were mainly failing to measure and perform stratified analyses by literacy level and concentrating on short-term knowledge rather than on more direct health outcomes. Because of these problems, we also evaluated this body of literature as III. Finally, we graded the body of research addressing KQ 2c (costs of interventions) and 2d (disparities in the effects of interventions) as IV because no studies dealt with these topics.

Limitations of This Review and the Literature

Deficiencies in This Body of Literature

Our systematic review should be interpreted in the context of several limitations. First, as with all systematic reviews, its findings depend on the quality of the published literature. The limitations in the strength of the available studies (see Chapter 3) include the following:

- use of a wide variety of literacy measures and cutpoints for analysis, making comparisons among studies difficult
- predominance of cross-sectional study designs for KQ 1, leading to inability to measure incident outcomes or assign cause and effect
- lack of outcome stratification by literacy level for interventions
- inconsistent and potentially inappropriate control for covariates
- lack of reporting of appropriate statistical measures (i.e., use of *P* values without measures of magnitude or confidence intervals), making it difficult to determine if null findings represent true lack of effect or limitations in power
- lack of reporting on methods for assessing health outcomes, particularly whether the questionnaires were presented in ways that would allow accurate responses by participants with limited literacy
- focus on knowledge rather than more meaningful health outcomes

- the wide range of outcomes assessed, complicating comparisons among studies
- poor descriptions of interventions
- use of multimodal interventions, making it difficult to know which portions produced positive effects

Second, the relative paucity of articles about the effects of literacy on health care costs and on racial, ethnic, or age-related disparities makes us unable to draw conclusions in these areas.

Analyzing the Relationship Between Reading Ability and Health Outcomes

An important concern relating to the research design modeling the relationship between reading ability and health is the analysis of confounding. Efforts to determine a causal relationship between reading ability and health outcomes often rely on analytic techniques to eliminate bias due to confounders (other variables related to both reading ability and health). If confounders are not appropriately included, a misestimation of the relationship between reading ability and health could result, leading to faulty conclusions and policy decisions. For instance, reading ability may be associated with a lack of health insurance or other sociodemographic variables that are known to be related to health outcomes. If these variables are not included in the analysis, the reported relationship between literacy and outcomes may be inaccurate.

Determining the appropriate specification for analytic models can be difficult because greater levels of adjustment do not always lead to better (unbiased) estimates. This is particularly true if the variables being considered as potential confounders actually mediate the effect of reading ability on the outcome; that is, a confounder actually lies in the causal pathway as a possible link between reading ability and the outcome in question.

Education serves as a good example of this phenomenon (as would health status or income). Difficulty in reading may cause people to complete fewer years of formal education, and completing fewer years of education may then be associated with worse health outcomes. In this case, the years of education completed mediate the effect of reading ability on the health outcome. Adjusting for years of education would lead us to underestimate the effect of reading ability; that is, it is a form of overadjustment. If reading ability truly causes fewer years of education, which in turn causes worse health, then attributing that effect to reading ability is acceptable and analysts need not adjust their data according to years of education. In practice, the links from literacy to education to health are not well understood, so we cannot make a definitive statement about whether or not to adjust for education. Therefore, individual authors need to carefully assess the role of potential confounders and clearly present the data included in their analyses.

A more rigorous approach, albeit much more time consuming and expensive, is to design an intervention to correct for the cause of the poor outcome. For instance, a randomized controlled trial to teach literacy skills would be the best method to demonstrate the role of literacy in health outcomes. If making educational materials easy to read mitigates the entire effect of having low reading ability, a randomized trial comparing an easy to read material with a more difficult to read material, and stratification of results by participants' reading abilities, would offer important insights into etiology.

Limitations to Our Review Procedures

In addition to the limitations of this overall body of literature and the particular challenges it poses, our review process also had some limitations. Because of time and resource constraints, we did not conduct dual, independent, blinded review of articles for inclusion or abstraction of information into evidence tables. Instead, one reviewer performed the initial review, and a second reviewer reviewed that input and recommended changes. Differences were reconciled between the two reviewers. Although this approach is ostensibly less rigorous than some in the evidence-based practice community might follow, we believe, on the basis of several years' experience at our EPC with this process, together with rigorous external peer review, that our approach produces as high-quality results as the more expensive and time-consuming dual blinded review. We did use dual review for grading the quality of individual articles, although using the same second reviewer for all articles precludes rigorous evaluation of systematic bias in these assessments.

Finally, the absence in MEDLINE of specific subject terms for literacy made systematic identification of articles measuring literacy and health outcomes difficult. The searches yielded a large number of off-topic titles and abstracts that we still needed to review. The National Library of Medicine could improve this problem by developing a MeSH heading for health literacy.

Future Research

Because currently available studies leave many important questions unanswered, additional research is needed to advance this field. Future research can build on the previous work to elucidate the relationship between literacy and health, such as examining more closely and rigorously the factors that mediate the relationship between literacy and important health outcomes.

For example, investigators could examine the question of whether poor reading ability is really the cause of adverse health outcomes or whether it is a marker for other problems, such as low socioeconomic status, poor self-efficacy, low trust in medical providers, or impaired access to care. Such information is also crucial to designing and testing future intervention studies.

Because investigators in this field tend to focus on literacy as the variable of interest in etiologic research, it is often assumed that improved written communication can improve health outcomes. However, research suggests that improving information delivery alone may not mitigate the observed relationship between low literacy and poor health. Addressing other important factors, such as self-efficacy, self-care, trust, or satisfaction, may increase our understanding of effective strategies for addressing poor health outcomes.

Current research is heavily weighted toward studies with limited or no longitudinal component. More prospective cohort studies that measure changes in outcomes and literacy over time will provide a greater understanding of the relationships among literacy, age, and health outcomes and the extent to which changes in health status actually affect literacy.

We also need further development of measurement techniques for low-literacy populations. Literacy may systematically affect the quality of data gathered by self-report questionnaires, perhaps even if they are administered verbally. This factor may be particularly important when using Likert-type scales.[96] Evaluation of questionnaire responses in light of other objective

measures may help to clarify whether literacy affects self-report and how to design questionnaires that are valid and consistent across literacy levels.

Studies could also determine whether measuring or stratifying outcomes by numeracy provides additional predictive ability for health outcomes than measuring and stratifying outcomes by literacy alone. Although the numeracy measure in the TOFHLA is highly correlated with the measure of reading comprehension, numeracy itself may be an important mediator of the differential health effects in populations with marginal health literacy and may be a target for intervention. Additionally, numeracy, measured through a different set of skills than those tested in the TOFHLA, may discriminate better for certain health outcomes. For example, the ability to grasp and use probabilities and ratios may better predict which patients will comprehend the benefits of screening and treatment and consider them in making choices about their health care than the ability to read and apply information from appointment slips and bottles.

Intervention studies are becoming more common, but they have focused mostly on short-term knowledge outcomes. Future studies could link these short-term knowledge changes to important health outcomes. Moreover, many interventions that we identified involve multiple components. Analysis that isolates the individual effect of the key components could significantly advance the field and help us determine "how much" intervention is enough to improve health. Documenting the importance of low patient literacy in chronic illness programs and understanding how to mitigate its effects would contribute greatly to the field. Analysis of these programs may also help us understand how health system changes can positively affect literacy-related barriers.

Interventions to allay the effects of low literacy should incorporate methods to better identify the extent to which interventions directed specifically at reducing literacy-related barriers improve the relationship between literacy and health outcomes compared with interventions that use other means to improve health outcomes. Data analysis of intervention studies should include results stratified by literacy level. Without such analysis, the reader cannot determine if the intervention worked specifically among low-literacy individuals and whether it helped to ameliorate differences in outcome according to literacy status.

Provider-patient communication interventions that go beyond written materials may also prove to be a valuable avenue for future research. Although we are not aware of any current studies that trained providers in a specific communication strategy and measured health outcomes according to patient literacy status, at least one study has tried to observe communication strategies and correlate them with outcomes.[8] Patients whose physician used the "teach-back" method appeared to have better control of their diabetes, independent of patient reading ability. However, intervention studies designed to teach physicians to use this or other communication styles are needed to help us understand whether they will actually improve outcomes.

The concept of health literacy needs further evaluation. As previously discussed, we do not know of a measurement of "health literacy" as a single variable. This report focuses on the relationship between reading ability and health, since that is what has been measured in the existing literature. The role of health literacy beyond reading ability (or scores on reading ability tests such as the REALM, TOFHLA, and WRAT) needs further investigation. A patient-centered approach designed to understand the challenges of navigating the health care system

and providing self-care may lead to an enriched understanding of health literacy and ultimately how to measure and improve it.

Conclusion

Our systematic review confirms that low literacy as measured by poor reading skills is associated with a range of adverse health outcomes. Rigorous, well-designed studies of interventions to mitigate the effects of low literacy are less common than research documenting the association between literacy and health. What is available, however, suggests that well-conceived interventions can at least improve the outcome of knowledge for participants with both higher and lower literacy levels. Future studies that improve on the methodological limitations of existing studies examining the relationship between literacy and health are warranted, as are more well-designed intervention studies that measure not only knowledge but also more distal outcomes, such as well-validated biomarkers, disease incidence or severity, and indices of health service utilization and access.

Table 13. Overall strength of the evidence for this body of literature

Key Question	Grade (I-IV Scale)*
1. Relationship between literacy and health	
1a. Health services	II
1b. Health outcomes	II
1c. Costs	III
1d. Disparities	III
2. Effect of interventions	
2a. Health services	III
2b. Health outcomes	III
2c. Costs	IV
2d. Disparities	IV

I. The evidence is from studies of strong design; results are both clinically important and consistent with minor exceptions at most; results are free from serious doubts about generalizability, bias, or flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.
II. The evidence is from studies of strong design, but some uncertainty remains because of inconsistencies or concern about generalizability, bias, research design flaws, or adequate sample size. Alternatively, the evidence is consistent but derives from studies of weaker design.
III. The evidence is from a limited number of studies of weaker design. Studies with strong design either have not been done or are inconclusive.
IV. No published literature.

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Listing of Excluded Studies

Key for Reasons for Exclusion

1. Studies with no original data
2. Nonintervention studies that do not measure literacy
3. Studies with no health outcomes
4. Studies examining normal reading development in children
5. Studies about dyslexia
6. Studies on the basic experimental science of reading ability (e.g., studies of brain function, MRI, EEG)
7. Studies performed in developing countries
8. Non-English language studies
9. Studies published in abstract form only
10. Case-report only
11. Ecological data only
12. Unable to obtain the article

Note: Appendixes and Evidence Tables cited in this report are provided electronically at http://www/ahrq.gov/clinic/epcindex.htm.

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Notes: Reject #3

Quality Rating Form

Author, Year:_____ _____ **Reviewer** _____

Short Title:_____

1. **Study Population**
   a. Adequate description of study population — Good ☐ Fair ☐ Poor ☐
   b. Study population appropriate for drawing relevant conclusions — Good ☐ Fair ☐ Poor ☐

   → Good ☐ Fair ☐ Poor ☐

Comment: _____

2. **Intervention (KQ2 Only)**
   Clearly described

   Good ☐ Fair ☐ Poor ☐ NA ☐

Comment:_____

3. **Comparability of Subjects**
   Creation of comparable groups and appropriate randomization
   Appropriate method of creating sample population

   Good ☐ Fair ☐ Poor ☐

Comment: _____

4. **Literacy Measurement**
   Use of valid, reliable and clearly defined method

   Good ☐ Fair ☐ Poor ☐ NA ☐

Comment: _____

5. **Maintenance of Comparable Groups**
   Loss to follow-up and cross-over minimized

   Good ☐ Fair ☐ Poor ☐

Comment: _____

6. **Outcome Measurement**
   Method of outcome assessment clearly defined, standard, valid, reliable, and applied equally to groups (includes blinding)

   Good ☐ Fair ☐ Poor ☐

Comment: _____

7. **Statistical Analysis**
   Statistical tests appropriate and multiple comparisons addressed

   Good ☐ Fair ☐ Poor ☐

Comment: _____

8. **Appropriate Control of Confounding**
   Limitation, stratification or multivariate analysis or randomization

   Good ☐ Fair ☐ Poor ☐

Comment: _____

9. **Funding Source:**