

Literacy and Health Outcomes

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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[®], PsycINFO[®], 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.

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.

Contents

- Chapter 1. Introduction..... 3
 - Burden of the Problem..... 3
 - Literacy and Health Literacy 4
 - Literacy and Vulnerable Populations 5
 - Analyzing the Relationship Between Reading Ability and Health Outcomes 6
 - Readability 7
 - Production of This Evidence Report..... 7
 - Organization 7
 - Technical Expert Advisory Group 8
 - Uses of This Report 8
- Chapter 2. Methods..... 11
 - Key Questions and Analytic Framework..... 11
 - Literature Review Methods 12
 - Inclusion and Exclusion Criteria 12
 - Literature Search and Retrieval Process 13
 - Literature Synthesis 14
 - Development of Evidence Tables and Data Abstraction Process..... 14
 - Quality and Strength of Evidence Evaluation 15
 - Peer Review Process 16
- Chapter 3. Results 21
 - Results of Literature Search..... 21
 - Key Question 1: Relationship of Literacy to Various Outcomes and Disparities 21
 - Literature Search and Included Studies 21
 - Use of Health Care Services 22
 - Health Outcomes 24
 - Costs of Health Care 30
 - Disparities in Health Outcomes or Health Care Service Use 30
 - Summary..... 30
 - Key Question 2: Interventions for People With Low Literacy..... 31
 - Literature Search and Included Studies 31
 - Use of Health Care Services 32
 - Health Outcomes 32
 - Costs of Health Care 34
 - Disparities in Health Outcomes or Health Care Service Use 35
 - Summary..... 35
- Chapter 4. Discussion..... 59
 - Overview..... 59
 - Principal Findings..... 59
 - Limitations of This Review and the Literature 61
 - Deficiencies in This Body of Literature 61
 - Analyzing the Relationship Between Reading Ability and Health Outcomes 62
 - Limitations to Our Review Procedures..... 63
 - Future Research 63

Conclusion.....	65
References and Included Studies	67
Listing of Excluded Studies	73
Quality Rating Form.....	105

List of Tables and Figures

Table 1.	Instruments commonly used to assess the relationship between literacy and health ..9
Table 2.	Correlations between common health literacy assessment tools10
Table 3.	Health literacy literature searches: inclusion and exclusion criteria19
Table 4.	Health literacy search strategy, yield, and final count of articles20
Table 5.	Summary of studies of relationship between health services, outcomes, costs, or disparities and literacy (KQ1).....37
Table 6.	Summary of studies of interventions to improve health-related outcomes in low literacy populations (KQ2)45
Table 7.	Measurement tools and criteria used to measure literacy in KQ 1 articles51
Table 8.	Studies of knowledge or comprehension of health service use (KQ 1a)53
Table 9.	Studies of knowledge or comprehension of health outcomes (KQ 1b)54
Table 10.	Studies of the relationship between literacy and depression (KQ1b).....55
Table 11.	Studies of the relationship between literacy and global health status (KQ1b).....56
Table 12.	Measurement tools and criteria used to measure literacy in KQ 2 articles57
Figure 1.	Analytic framework18
Figure 2.	Cumulative number of articles addressing KQ 1 and KQ 2 by year of publication36

**Appendixes and Evidence Tables are provided electronically at
<http://www.ahrq.gov/clinic/epcindex.htm>**

Summary

Introduction

Literacy can be defined 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 Literacy sometimes describes a person’s facility with or knowledge about a particular topic (e.g., “computer literacy”). In that context, “health literacy” is a constellation of skills that constitute the ability to perform basic reading and numerical tasks for functioning in the health care environment and acting on health care information.² Some authors include in this definition a working knowledge of disease processes, self-efficacy, and motivation for political action regarding health issues.³

Instruments for measuring literacy in the health care setting have focused on the ability to read and, in some cases, to use numbers. Commonly used are the Wide Range Achievement Test (WRAT) reading subtest,⁴ the Rapid Estimate of Adult Literacy in Medicine (REALM),⁵ and the Test of Functional Health Literacy in Adults (TOFHLA).⁶ The WRAT and REALM are word recognition tests validated as instruments of reading ability; they are highly correlated with one another and with other traditional reading assessments.⁵ The TOFHLA assesses literacy by a modified Cloze method: 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). A short version (S-TOFHLA) involves only two reading comprehension sections. All of these instruments are highly correlated with one another.

Low literacy is common in the United States; a decade ago, 40 million adult Americans scored on the lowest of five levels (level 1) of the National Adult Literacy Survey (NALS); another 50 million scored at level 2.⁷ These levels correspond to having 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.⁷ Meeting the requirements of an ever-increasing percentage of jobs and the many demands of day-to-day life requires skill above these NALS levels.⁸

Low literacy may impair functioning in the health care environment, affect patient-physician communication dynamics, and inadvertently lead to substandard medical care.^{2,9} It is associated with poor understanding of written or spoken medical advice, adverse health outcomes, and negative effects on the health of the population.^{6,10}

Certain groups have an especially high prevalence of low literacy. They include people who completed fewer years of education, persons of certain racial or ethnic groups, the elderly,⁷ and persons with lower cognitive ability.¹¹ Other factors associated with lower literacy include living in the South or Northeast (rather than the West and Midwest), female sex, incarceration, and income status classified as poor or near poor.

Given that low literacy may affect health and well-being negatively, the Agency for Healthcare Research and Quality (AHRQ) commissioned an evidence report from the RTI International–University of North Carolina Evidence-based Practice Center (RTI-UNC EPC). Literacy and health are of particular concern to the American Medical Association (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

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

outcomes and the evidence about interventions intended to improve the health of people with low literacy.

Methods

We examined two key questions in this review.

- 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?

Our inclusion/exclusion criteria limited studies to those with outcomes related to health and health services, studies published from 1980 on, and studies conducted in developed countries (United States, Canada, the United Kingdom, Australia, New Zealand, and Europe). Study participants included individuals of all ages.

We searched several databases, using terms such as “literacy” and “health literacy” and, in some cases, “numeracy” and the name or accepted acronym for standardized tests of literacy related to health outcomes (e.g., WRAT, REALM, and TOFHLA). For MEDLINE[®], our primary database, we had to rely on key word searches because no MeSH[®] headings specifically identify literacy-related articles. Other databases included the Cumulative Index to Nursing and Allied Health (CINAHL[®]), the Cochrane Library, the Educational Resources Information Center (ERIC), the Public Affairs Information Service (PAIS), and the Industrial and Labor Relations Review (ILRR). We reviewed Web-based bibliographies and sought inputs from our Technical Expert Advisory Group (TEAG) and external peer reviewers for articles that we may have missed.

Beginning with a yield of 3,015 articles, we retained 684 from a review of titles and abstracts. Following complete review of full articles, we determined that 73 articles were relevant to address our key questions and met our inclusion/exclusion criteria.

We graded the quality of individual articles using an approach based on domains and elements appropriate for intervention and observational studies:¹² study population, intervention, comparability of subjects, literacy measurement, maintenance of comparable groups, outcome measurement, statistical analysis, and appropriate control of confounding; we also noted funding source (but did not include that information in any numeric score). We also rated the strength of overall evidence, for the two key questions separately, in three domains: quality of the research; quantity of studies, including number of studies and adequacy of the sample size; and consistency of findings.^{12,13}

Results

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

We identified 44 articles addressing relationships between literacy and use of health care services, health outcomes, costs of health care, and disparities according to race, ethnicity, culture, or age. Study designs, data analysis, and presentation varied widely. The number of participants enrolled ranged from 34 to 3,260. Literacy was most often measured with the REALM (13 studies), TOFHLA or S-TOFHLA (11), or WRAT (6). Literacy levels used to compare study participants varied widely among studies. Most studies reported the unadjusted (bivariate) relationship between literacy and the outcome of interest; 28 adjusted for at least one covariate, chiefly age and education. The quality of articles reviewed for these key questions was fair to good. The overall strength of evidence ranged from II (studies of strong design but remaining uncertainty because of inconsistencies or concern about generalizability, bias, research design flaws, or adequate sample size, or consistent evidence from studies of weaker design) to III (the number of studies was too limited to rate the strength of the literature).

1a. Health Care Services. Six studies measured the relationship between literacy levels and knowledge of the use of health care services: mammography,¹⁴ cervical cancer screening,¹⁵ childhood health maintenance procedures and parental understanding of child diagnosis and medication,¹⁶ emergency department discharge instructions,¹⁷ “Heart Health Knowledge,”¹⁸ and informed consent.¹⁹ All but one¹⁶ demonstrated a statistically significant association between higher literacy level and knowledge of matters relating to use of these health services.

In two studies that prospectively evaluated the risk of hospitalization according to literacy status, inadequate literacy (relative to adequate literacy) was significantly associated with increased risk of hospitalization.^{20,21} In adjusted analyses, however, another study found no significant relationship between literacy and number of self-reported health care visits among subjects recruited from emergency rooms and walk-in clinics.²²

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 screening, and immunizations).^{23,24} In adjusted analyses, 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.²³ Adjusted analyses of cervical and breast cancer screening rates indicated that women with inadequate literacy had significantly greater odds of never having had a Pap smear or no mammogram in the past 2 years.²⁴ An adjusted analysis showed that patients with inadequate literacy had significantly higher odds of not having had either an influenza or a pneumococcal immunization compared to patients with adequate literacy.²⁴

1b. Health Outcomes. Ten studies used knowledge either as one of several outcomes or as the only outcome in regard to several behaviors or conditions: smoking,²⁵ contraception,²⁶ human immunodeficiency virus (HIV),²⁷⁻³⁰ hypertension,³¹ diabetes,³¹ asthma,³² and postoperative care.^{33,34} In general, these studies found a positive, significant relationship between literacy level and participants’ knowledge of these health issues.

Three studies evaluated the relationship between literacy and smoking.^{25,35,36} In adjusted analyses, the largest study (n = 3,019) found a significant relationship between low literacy and various measures of smoking among adolescent boys and girls.³⁶ Low reading ability was significantly associated (unadjusted analyses) with smoking among adults waiting for child-

related services in private and public clinics.³⁵ However, unadjusted rates of smoking among 600 pregnant women did not differ by literacy status.²⁵

Two unadjusted cross-sectional studies found a positive, significant relationship between higher literacy and likelihood of breast-feeding.^{35,37} Another study determined, in adjusted analyses, that patients with higher literacy had significantly better metered dose inhaler techniques than those of lower literacy.³²

The odds of having misused alcohol were significantly higher among boys but not girls with lower literacy levels.³⁶ Two other studies dealt with child behaviors. In adjusted analyses, youth from low-income neighborhoods who were more than two grades behind expected reading level (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.³⁸ Reading ability was an independent predictor of teacher-reported problem behavior, even after adjustment for early problem behavior and family adversity, and was lower at higher levels of family adversity.³⁹

Four studies evaluated the relationship between literacy and adherence to medical regimens or clinical trial protocols;⁴⁰⁻⁴³ two found no significant relationship.^{42,43} Regarding medication adherence, lower literacy was significantly associated with a greater odds of self-reported poor adherence among patients taking antiretrovirals for HIV infection.⁴¹ A more rigorous study, however, found no relationship.⁴³

Three studies assessed the relationship between literacy and diabetes outcomes.^{31,44,45} Two found statistically significant associations: first, parents' scores on the National Adult Reading Test (NART) were correlated with glycemic control among their children;⁴⁴ second, in adjusted analyses, lower S-TOFHLA scores were related to worse glycosylated hemoglobin (HbA1c) levels and reports of retinopathy and cerebrovascular disease.⁹ Neither of two studies identified an independent relationship between literacy and presence or control of hypertension.^{31,46}

One research group reported on the relationship between literacy and control of HIV infection in three cross-sectional studies (about 60 percent of patients participated in all three studies).^{27,29,47} Unadjusted analyses produced mixed results: better reading was associated with greater odds of undetectable viral load in two studies^{27,29} (but not in a third⁴⁷) and also greater odds of having a CD4 count greater than 300.²⁷

Five studies evaluating the relationship between literacy and self-reported depression yielded mixed results.^{18,47-50} Four found statistically significant associations between lower literacy and higher rates of depression in various patient populations: persons in a cardiovascular dietary education program,¹⁸ mothers,⁴⁹ HIV-infected patients,⁴⁷ and persons with rheumatoid arthritis.⁵⁰ Adjusted analyses in the fifth, and largest, study, however, did not show a significant relationship between literacy and depression among Medicare managed care patients.⁴⁸ Another study found no significant relationship between literacy and "emotional balance" among patients receiving informed consent for a bone marrow transplant.⁵¹

Literacy was not associated with functional status among patients with rheumatoid arthritis,⁵⁰ presence of migraine headaches among children,⁵² or presentation with late-stage prostate cancer (in adjusted analyses).⁵³

Four cross-sectional studies evaluated the relationship between literacy and a global health status measure.^{10,22,54,55} Two found a significant association between lower literacy and worse health status in adjusted analyses of adult patients,^{22,54} and one found a similar association in unadjusted analyses of elderly patients.¹⁰

1c. Costs of Health Care. The one study of low literacy and health care costs reported no relationship between literacy and overall or component charges for Medicaid services among patients enrolled largely because of pregnancy rather than medical need or medical indigence.⁵⁶

1d. Disparities in Health Outcomes or Health Care Service Use. One study directly examined the role of literacy as a mediator of disparities in health outcomes or health care service use.⁵³ In unadjusted analyses of data from a cross-sectional study of men with prostate cancer, black patients were significantly more likely than white patients to present with late-stage cancer; after adjusting for literacy, the researchers reported a smaller odds ratio that was no longer statistically significant.

Key Question 2: Interventions for People with Low Literacy

In all, 29 articles described interventions to mitigate the effects of low literacy on health outcomes, using randomized controlled trials, nonrandomized controlled trials, 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. Of these 29 studies, 19 measured the literacy of each participant: REALM (10 studies), WRAT (4), and various other instruments (5); criteria to define literacy level categories varied across studies. The remaining 10 studies involved populations known from previous research or clinical assessment to have a large proportion of people with poor literacy skills. We characterized the general quality of these articles as fair. The overall strength of evidence was either III or IV (no study addressed the question).

2a. Health Care Services. The only article addressing question 2a concerned preventive services. In a nonrandomized controlled trial, 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.⁵⁷

2b. Health Outcomes. Most studies addressing health outcomes focused on improvements in knowledge. 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.

In a controlled trial among patients at a sleep apnea clinic, participants with low literacy appeared to display higher knowledge with a videotape educational tool than with a brochure written at a readability level similar to the videotape’s script, but this conclusion is limited by methodological problems with multiple comparisons.⁵⁸ In another study, women of lower literacy understood illustrated materials about cervical cancer better than text materials.⁵⁹ In a randomized trial among cancer patients to examine the effect of an interactive videodisc to improve self-care of cancer fatigue symptoms, patients who received the intervention reported greater self-care ability, but this effect was not significantly related to the literacy level.⁶⁰ Another controlled trial compared a locally developed pamphlet about polio vaccine designed for patients with low literacy and a pamphlet from the Centers for Disease Control and Prevention that had also been designed for easy readability;⁵⁷ patients with lower literacy did not differ in their comprehension of the two pamphlets. Finally, a randomized trial of 1,100 patients compared the effectiveness of educational materials on colorectal cancer screening (videotape or easy-to-read brochure intended to be appropriate for people with low literacy) to usual care.⁶¹ Patients receiving either intervention had significantly greater improvements in knowledge scores after reviewing the educational materials than did the control group; both low- and high-

literacy groups that received either intervention showed significantly improved knowledge between the pre- and posttests, but rates of improvement in the two literacy groups did not differ significantly.

Several studies of the effect of interventions on health behaviors produced mixed results. 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; effects were greater among current smokers at entry than among ex-smokers.⁶² A community-based osteoarthritis intervention improved exercise behavior in a 6-week, before-and-after uncontrolled trial.⁶³ Medication adherence among patients 65 years and older improved over time when they were given verbal teaching about medication compliance; adding a color-coded medication schedule did not provide additional benefit.⁶⁴ Interventions addressing dietary behaviors produced small or no changes.⁶⁵⁻⁶⁸

Several studies used changes in biochemical or biometric markers to test the effect of their interventions. Participants in a specially designed workplace hypertension education and behavior change program had modest differences in blood pressure levels compared with those for nonparticipating controls.⁶⁹ Special cardiovascular nutrition or dietary interventions did not achieve significant differences in postprogram cholesterol levels for low-literacy patients.^{67,70} Finally, a randomized trial of a special educational intervention for patients with diabetes did not produce significant differences in HbA1c levels or weight loss.⁷¹

Few studies examined the effect of interventions on health outcomes that people can actually feel. An uncontrolled before-and-after trial found that an osteoarthritis education intervention could improve the functionality of people with osteoarthritis.⁶³ The only study to examine the effect of an intervention that included direct literacy-skill building demonstrated that a comprehensive family services center, compared with standard Head Start, could improve parental reading skill and reduce the prevalence of paternal depression.⁷²

2c. Costs of Health Care. No study assessed costs, charges, or reimbursements for these types of interventions.

2d. Disparities in Health Outcomes or Health Care Service Use. No study evaluated the effect of literacy-related interventions in narrowing disparities according to race, ethnicity, culture, or age.

Discussion

General Conclusions

Our review includes material different from that in previous reviews of literature of health literacy; in addition, it excludes important articles because they did not address our two key questions. Earlier reviews reached conclusions similar to ours about the general relationship between literacy and health;^{2,73} our rigorous approach should give readers confidence in the conclusion that low reading skill and poor health are clearly related. Conclusions about the effectiveness of interventions to mitigate the effects of low literacy remain less well supported at this time.

Future Research

Use of a wide variety of literacy measures and cutpoints for analysis and a wide range of outcomes made comparisons among studies difficult. Measurement techniques for low-literacy

populations warrant additional development and refinement. Of special importance are investigating whether and how literacy affects self-report of use of health care or health outcomes and designing questionnaires that are valid and consistent across literacy levels.

One limitation of the knowledge base to date is lack of appropriate specification for analytic models when variables being considered as potential confounders actually mediate the effect of reading ability on important health outcomes. Future research can build on previous work by examining more closely and rigorously the factors that mediate this relationship. For example, investigators could examine whether poor reading ability is really the cause of adverse health outcomes or whether it is a marker for, say, low socioeconomic status, poor self-efficacy, low trust in medical providers, or impaired access to care. Such information is crucial to designing and testing intervention studies.

Current research is heavily weighted toward studies with limited or no longitudinal component. The predominance of cross-sectional study designs for studies of literacy and health relationships makes it impossible to measure incident outcomes or assign cause and effect. Thus, 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.

Intervention studies have focused mostly on short-term knowledge outcomes rather than on more meaningful health outcomes. Future studies could link these short-term knowledge changes to important health outcomes.

Moreover, many interventions involve multiple components, but use of multimodal interventions inhibits understanding of which portions produced positive effects. Analysis that isolates the individual effect of the key components could help 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 are further important research avenues to foster understanding of how health system changes can positively affect literacy-related barriers.

Many interventional studies did not stratify outcomes by literacy level. Researchers should take this analytic step so that they can draw appropriate inferences about whether the intervention worked specifically among low-literacy individuals and helped to ameliorate differences in outcome according to literacy status. Studies could also determine whether measuring or stratifying outcomes by numeracy provides greater predictive ability for health outcomes than measuring and stratifying outcomes by literacy alone.

Investigators should compare interventions directed specifically at reducing literacy-related barriers with other means of improving health outcomes. Investigators in this field tend to focus on literacy as the variable of interest and, thus, often assume that improved written communication can improve health outcomes. Improving information delivery alone may, however, not mitigate the observed relationship between low literacy and poor health. Addressing self-efficacy, self-care, trust, or satisfaction may increase understanding of effective strategies for addressing poor health outcomes.

Provider-patient communication interventions that go beyond written materials may also prove to be a valuable avenue for future research. Investigations designed to teach physicians to use a “teach-back” method or other communication styles will aid understanding of whether and how they can improve outcomes.

Poor descriptions of interventions and lack of reporting how health outcomes were assessed, particularly whether questionnaires were presented in ways that would allow accurate responses

by participants with limited literacy, hampered synthesis of this literature. Another drawback to the current literature is lack of use (or at least incomplete reporting) of appropriate statistical measures (e.g., use of *P* values without measures of magnitude or confidence intervals), which made it difficult to determine if null findings represent true lack of effect or limitations in power. Thus, reporting of study interventions, statistics, and results should be improved.

Finally, both the concept of health literacy and its role in health care use and health outcomes need further evaluation. The current literature focuses on reading ability and health; taking a patient-centered approach that addresses challenges in navigating the health care system and providing self-care may enrich understanding of health literacy and ultimately how to measure and improve it.

Availability of the Full Report

The full evidence report from which this summary was taken was prepared for the Agency for Healthcare Research and Quality (AHRQ) by the RTI International–University of North Carolina Evidence-based Practice Center, under Contract No. 290-02-0016. It is expected to be available in February 2004. At that time, printed copies may be obtained free of charge from the AHRQ Publications Clearinghouse by calling 800-358-9295. Requesters should ask for Evidence Report/Technology Assessment No. 87, *Literacy and Health Outcomes*. In addition, Internet users will be able to access the report and this summary online through AHRQ's Web site at www.ahrq.gov.

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Evidence Report

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 imperfect. 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.

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.

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.

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.* 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 PSYCINFO, 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 Health¹⁸ 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.

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 684 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-

UCLA Medical Center in Los Angeles, CA.^{25,26} Study designs included cross-sectional (32), cohort (9), 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 (12 studies), the TOFHLA or S-TOFHLA (16 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 Hawthorne⁴⁵ (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. Hawthorne⁴⁵ 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 colleagues⁵³ 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 HIV⁴⁰ 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 arthritis⁵⁸ and HIV infection⁵⁶).

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 Rompa⁵⁶ 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 Rompa⁵⁶ 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 Skibbe⁶⁵ (South Africa) and Mulrow and colleagues⁶⁶ (United Kingdom) were not. Most studies were conducted in single sessions. Interventions to improve dietary behavior and a small group of other studies⁶⁶⁻⁷¹ 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 colleagues⁶⁹ 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 colleagues⁷³ 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 colleagues⁸⁹ 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 colleagues⁹⁰ 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%).

Wydra⁹³ 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 colleagues⁹¹ 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 colleagues⁹² 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 colleagues⁷² 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 colleagues⁷⁵ 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 colleagues⁷⁴ 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 colleagues⁷⁶ 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 colleagues⁷¹ 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 colleagues⁸⁸ 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 colleagues⁶⁷ 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 colleagues⁶⁹ reported that their community-based osteoarthritis intervention improved exercise behavior in a 6-week, before-and-after uncontrolled trial. Hussey⁸² 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 colleagues⁸⁵ 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 colleagues⁷⁹ 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 colleagues⁶⁶ 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 colleagues⁶⁹ 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 Daniels⁶⁸ 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.

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

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.

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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

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Notes: Reject #2

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Notes: Reject #2 or 3

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Notes: Reject #1

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Notes: Reject #1

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Notes: Reject #3

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Notes: Reject #2

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Notes: Reject #2

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Notes: Reject #3

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Notes: Reject #3

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Notes: Reject #7

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Notes: Reject #3

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Notes: Reject #3

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Notes: Reject #3

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Notes: Reject #3

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Notes: Reject #1

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Notes: Reject #3

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Notes: Reject #2

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Notes: Reject #1

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Notes: Reject #1

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Notes: Reject #1

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Notes: Reject #1

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Notes: Reject #4

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Notes: Reject #2

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Notes: Reject #2

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Notes: Reject #3

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Notes: Reject #2

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Notes: Reject #2

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Notes: Reject #3

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Notes: Reject #1

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Notes: Reject #1

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Notes: Reject #1

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Notes: Reject #3

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Notes: Reject #1

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Notes: Reject #1

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Notes: Reject #1

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Notes: Reject #1

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Notes: Reject #1

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Notes: Reject #1

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Notes: Reject #1

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Notes: Reject #1

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Notes: Reject #3

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Notes: Reject #3

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Notes: Reject #1

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Notes: Reject #1

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Notes: Reject #1

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Notes: Reject #3

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Notes: Reject #1

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Notes: Reject #3

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Notes: Reject #3

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Notes: Reject #1

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Notes: Reject #1

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Notes: Reject #2

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Notes: Reject #3

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Notes: Reject #3

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Notes: Reject #3

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Notes: Reject #1

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Notes: Reject #1

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Notes: Reject #1

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Notes: Reject #1

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Notes: Reject #1

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Notes: Reject #3

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Notes: Reject #3

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Notes: Reject #1

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Notes: Reject #1

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Notes: Reject #1

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Notes: Reject #3

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Notes: Reject #2, #3

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Notes: Reject #1

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Notes: Reject #1

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Notes: Reject #3

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Notes: Reject #2

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Notes: Reject #2

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Notes: Reject #1

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Notes: Reject #1

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Notes: Reject #1

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Notes: Reject #1

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Notes: Reject #1

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Notes: Reject #1

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Notes: Reject #3

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Notes: Reject #3

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Notes: Reject #1

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Notes: Reject #1

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Notes: Reject #1

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Notes: Reject #1

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Notes: Reject #1

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Notes: Reject #3

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Notes: Reject #3

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Notes: Reject #1

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Notes: Reject #3

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Notes: Reject #2

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Notes: Reject #3

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Notes: Reject #2

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Notes: Reject #2

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Notes: Reject #1

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Notes: Reject #3

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Notes: Reject #1

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Notes: Reject #3

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Notes: Reject # 3

Williams SA, Swanson MS. The effect of reading ability and response formats on patients' abilities to respond to a patient satisfaction scale. *J Cont Educat Nurs* 2001; 32(2):60-7.
Notes: Reject # 3

Wilson FL. Are patient information materials too difficult to read?. *Home Healthc Nurs* 2000; 18(2):107-15.
Notes: Reject #3

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Notes: Reject #3

Wilson FL. Measuring patients' ability to read and comprehend: a first step in patient education. *Nursingconnections*. 2000; 13(3):19-27.
Notes: Reject #1

Wilson FL. Research you can use. Are patient information materials too difficult to read? *Home Healthc Nurs* 2000; 18(2):107-15.
Notes: Reject #3

Wilson FL. The suitability of United States Pharmacopoeia Dispensary Information psychotropic drug leaflets for urban patients with limited reading skills. *Arch Psychiat Nurs* 1999; 13(4):204-11.
Notes: Reject #3

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Notes: Reject #3

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Notes: Reject #1

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Notes: Reject #3

Woloshin S, Schwartz LM, Moncur M, Gabriel S, Tosteson AN. Assessing values for health: numeracy matters. *Med Decision Making* 2001; 21(5):382-90.
Notes: Reject #3

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Notes: Reject #1

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Notes: Reject #1

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Notes: Reject #2

Yasenchak PA, Bridle MJ. A low-literacy skin care manual for spinal cord injury patients. *Patient Educ Counsel* 1993; 22(1):1-5.
Notes: Reject #2

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Notes: Reject #3

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Notes: Reject #2, #3

Ziegler J. How illiteracy drives up health costs. *Bus Health* 1998; 16(4):53-4, 57, 61.
Notes: Reject #1

Zimm A. The need to understand: addressing issues of low literacy and health. *On-Call* 1998; 1(4):20-3.
Notes: Reject #1

Zimmerman T, Shenenberger DW. Health literacy and diabetic control. *J Am Med Assoc* 2002; 288(21):2688.
Notes: Reject #1

Zion AB, Aiman J. Level of reading difficulty in the American College of Obstetricians and Gynecologists patient education pamphlets. *Obstetr Gynecol* 1989; 74(6):955-60.
Notes: Reject #3

Zung WW, Gianturco J. Further validation of the Ohio literacy test: correlation with the Wechsler adult intelligence scale and grade achieved in school. *J Clin Psychol* 1968; 24(2):197-8.
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:

Appendix A

Exact Search Strings

Appendix A. Exact Search Strings

Database: MEDLINE <1966 to October Week 1 2002>

Search Strategy:

-
- 1 literacy.mp. (1258)
 - 2 limit 1 to human (1143)

Database: MEDLINE <1966 to October Week 1 2002>

Search Strategy:

-
- 1 literacy.mp. (1258)
 - 2 limit 1 to human (1143)
 - 3 1 not 2 (115)

Ovid Technologies, Inc. Email Service

Search for: (1 or 2 or 3 or 4 or 5 or 6 or 7 or 8) not literacy.mp.

Citations: 1-200

Database: MEDLINE <1966 to October Week 3 2002>

Search Strategy:

-
- 1 WRAT.mp. (101)
 - 2 wide range achievement.mp. (152)
 - 3 Rapid estimate of adult.mp. (26)
 - 4 tofha.mp. (10)
 - 5 test of functional health.mp. (18)
 - 6 reading ability.mp. (458)
 - 7 reading skill.mp. (86)
 - 8 numeracy.mp. (41)
 - 9 (1 or 2 or 3 or 4 or 5 or 6 or 7 or 8) not literacy.mp. (701)
 - 10 from 9 keep 1-701 (701)

Database: CINAHL <1982 to October Week 4 2002>

Search Strategy:

-
- 1 literacy.mp. (918)

- 2 numeracy.mp. (17)
- 3 1 or 2 (932)
- 4 from 3 keep 1-932 (932)

PSYCINFO

Search History

#2 "health literacy"(45 records)

#1 "health literacy"(45 records)

The search: "health literacy" in the database(s) PsycINFO Weekly 2002/10 Week 5, PsycINFO Weekly 2002/10 Week 4, PsycINFO Weekly 2002/10 Week 3, PsycINFO Weekly 2002/10 Week 2, PsycINFO Weekly 2002/10 Week 1, PsycINFO 2002/08-2002/09, PsycINFO 2002/01-2002/07, PsycINFO 2001 Part B, PsycINFO 2001 Part A, PsycINFO 2000, PsycINFO 1999, PsycINFO 1998, PsycINFO 1996-1997, PsycINFO 1993-1995, PsycINFO 1990-1992, PsycINFO 1988-1989, PsycINFO 1985-1987, PsycINFO 1978-1984, PsycINFO 1967-1977, PsycINFO 1872-1966 returned 45 records

ERIC

Search History

#2 "health literacy"(25 records)

#1 "health literacy"(25 records)

The search: "health literacy" in the database(s) ERIC returned 25 records

AARP's AGELINE yielded 13 "health literacy" citations.

Search term: LITERACY [No restrictions]

The Cochrane Database of Systematic Reviews

Complete reviews (8 records selected)

PAIS

Search History

#2 health and literacy(49 records)

#1 health literacy(4 records)

The search: health and literacy in the database(s) PAIS International 1972-2002/12 returned 49 records

Appendix B
Quality Rating Form

Author, Year: _____ Reviewer _____

Short Title: _____

1. Study Population

- a. Adequate description of study population

- b. Study population appropriate for drawing relevant conclusions

- Good
- Fair
- Poor

- Good
- Fair
- Poor

Good	<input type="checkbox"/>
Fair	<input type="checkbox"/>
Poor	<input type="checkbox"/>

Comment: _____

2. Intervention (KQ2 Only)

Clearly described

- | | |
|------|--------------------------|
| Good | <input type="checkbox"/> |
| Fair | <input type="checkbox"/> |
| Poor | <input type="checkbox"/> |
| NA | <input type="checkbox"/> |

Comment: _____

3. Comparability of Subjects

Creation of comparable groups and appropriate randomization
Appropriate method of creating sample population

- | | |
|------|--------------------------|
| Good | <input type="checkbox"/> |
| Fair | <input type="checkbox"/> |
| Poor | <input type="checkbox"/> |

Comment: _____

4. Literacy Measurement

Use of valid, reliable and clearly defined method

- | | |
|------|--------------------------|
| Good | <input type="checkbox"/> |
| Fair | <input type="checkbox"/> |
| Poor | <input type="checkbox"/> |
| NA | <input type="checkbox"/> |

Comment: _____

5. Maintenance of Comparable Groups

Loss to follow-up and cross-over minimized

- | | |
|------|--------------------------|
| Good | <input type="checkbox"/> |
| Fair | <input type="checkbox"/> |
| Poor | <input type="checkbox"/> |

Comment: _____

6. Outcome Measurement

Method of outcome assessment clearly defined, standard, valid, reliable, and applied equally to groups (includes blinding)

- | | |
|------|--------------------------|
| Good | <input type="checkbox"/> |
| Fair | <input type="checkbox"/> |
| Poor | <input type="checkbox"/> |

Comment: _____

7. Statistical Analysis

Statistical tests appropriate and multiple comparisons addressed

- | | |
|------|--------------------------|
| Good | <input type="checkbox"/> |
| Fair | <input type="checkbox"/> |
| Poor | <input type="checkbox"/> |

Comment: _____

8. Appropriate Control of Confounding

Limitation, stratification or multivariate analysis or randomization

- | | |
|------|--------------------------|
| Good | <input type="checkbox"/> |
| Fair | <input type="checkbox"/> |
| Poor | <input type="checkbox"/> |

Comment: _____

9. Funding Source:

Appendix C

Evidence Tables

Appendix C. Evidence Tables

Because the evidence tables stand alone from the detailed explanation of methods and issues presented in the main evidence report, we recap here briefly the organization and content of the tables. Particularly relevant is the set of key questions we addressed, certain core items of information in the tables, and our quality grading scheme. We also provide an extensive glossary of every abbreviation, acronym, or other initialism used in the evidence tables, but insofar as possible we have attempted to spell out terms. For more detailed information, we refer readers to the full evidence report to be found at www.ahrq.gov.

Key Questions

The evidence tables in this appendix summarize all empirical articles discussed in Chapter 3 of our evidence report. We first present articles answering Key Question 1, followed by those answering Key Question 2; articles are then arranged alphabetically by author(s).

Our key questions and their paired subsets are as follows:

- **Key Question 1:** Are low 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?

Information in Evidence Tables

The tables contain information about the study citation (with references to these studies to be found at the end of the appendix), the study population and setting, the objectives of the research, the interventions, study outcomes (and literacy measures, where relevant), and the quality score (see below). When the investigators did analyses adjusting for covariates in multivariate models (such as sociodemographic or health characteristics of the study population), we have noted that

those analyses are adjusted and provided a listing of the covariates in question. Analyses relying on simpler bivariate relationships are noted as unadjusted.

Grading the Quality of Individual Studies

We rated the quality of each article based on the criteria in the quality rating form reproduced in Appendix B. We present these scores in the last column of each evidence table entry. The eight quality scores correspond to the first eight questions included on the quality rating form. Because we included both intervention and observational studies in our review, several quality rating form questions were relevant only to certain studies. In those cases, the quality rating for that item in the evidence table entry is “not applicable” (NA). We also collected information on the study’s funding source for the ninth (last) item on the quality rating form; however, that information (when available) was not included in a quantitative score and instead is presented separately in the last column of each evidence table entry.

The two study team members who abstracted the summary information concerning the article also independently rated the quality of each article. For each of the eight categories, articles were rated as “good,” “fair,” “poor,” or “NA.” We converted the good/fair/poor ratings into numeric values in which poor = 0, fair = 1, and good = 2. We excluded from our evaluation criteria for a particular study any items designated NA. Instances in which one rater provided a score for an item and the second said the item was NA were reconciled between the two raters. We did not reconcile any other ratings between the two abstractors.

Each of the eight quality scores we present in the evidence table represents a simple average of the scores provided by the two raters. The total score is then the average of each of these scores with each item weighed equally. 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 $= 1.5$.

Glossary of Abbreviations and Acronyms Used in Evidence Tables

Abbreviation/ Acronym	Definition
*	Calculated by evidence report authors
AA	African-American
ABLE	Adult Basic Learning Examination
ABMT	Autologous bone marrow transplant
AC	Asthma clinic
ADEPT	Adherence and Efficacy to Protease Inhibitor Therapy study
ADL	Activities of daily living
AFDC	Aid for Families with Dependent Children
AIDS	Acquired immune deficiency syndrome
BCT	Breast-conservation therapy
BMI	Body mass index
BSE	Breast self-exam
CARDES	Cardiovascular Dietary Education System
CBE	Clinical breast exam
CD	Compact disc
CD-ROM	Compact disc—read-only memory
CI	Confidence interval
COPD	Chronic obstructive pulmonary disease
CPAP	Continuous positive airway pressure
DBP	Diastolic blood pressure
DICCT	Deaconess Informed Consent Comprehension Test
dl	Deciliter
DM	Diabetes mellitus
DMHDS	Dunedin Multidisciplinary Health and Development Study
ED	Emergency department
EFNEP	Expanded Food and Nutrition Education Program
FSC	Family Service Center
GED	General equivalency degree
Grady	Grady Memorial Hospital, Atlanta, GA
HAART	Highly active antiretroviral therapy
Harbor	Harbor-UCLA Medical Center, Torrance, CA
HbA1c	Glycosylated hemoglobin
Hg	Mercury
HIV	Human immunodeficiency virus
HMO	Health maintenance organization
HTN	Hypertension
IADL	Instrumental activities of daily living
IDL	Instrument for the diagnosis of reading
IQ	Intelligence quotient
IUD	Intra-uterine device
kcal	Kilocalories
kg	Kilogram
KMS	Knowledge of Medication Subtest
LAE	Los Angeles English speaking (Harbor-UCLA Medical Center)
LAS	Los Angeles Spanish speaking (Harbor-UCLA Medical Center)
l	Liter
MDI	Metered dose inhaler
mg	Milligrams
MKS	Medication Knowledge Score
mm	Millimeters
mmol	Millimoles
MMSE	Mini-Mental State Examination
NA	Not applicable

Glossary of Abbreviations and Acronyms Used in Evidence Tables (continued)

Abbreviation/ Acronym	Definition
NART	National Adult Reading Test
NR	Not reported
NS	Not significant
OCP	Oral contraceptive pill
OR	Odds ratio
P	Probability
PACE	Pima County adult education program, Tucson, AZ
PAG	Pictorial anticipatory guidance
Pap test	Papanicolaou smear
PCKQ	Prostate Cancer Knowledge Questionnaire
PORT	Patient Outcomes Research Team
QLS	Questionnaire Literacy Screen
r	Correlation coefficient
RA	Research assistant
RCT	Randomized controlled trial
REALM	Rapid Estimate of Adult Literacy in Medicine
RR	Relative risk
RSPM	Raven Standard Progressive Matrices
SBP	Systolic blood pressure
SD	Standard deviation
SES	Socio-economic status
SF-36	Short Form 36
Sig	Significant
SIP	Sickness Impact Profile
SMOG	Readability formula
SNAP	Stanford Nutrition Action Program
SPMSQ	Short Portable Mental Status Questionnaire
STD	Sexually transmitted diseases
S-TOFHLA	Short Test of Functional Health Literacy in Adults
SWOG	Southwestern Oncology Group
TABE	Test of Adult Basic Education
TALS	Test of Applied Literacy Skills
TIPP	The Injury Prevention Program
TOFHLA	Test of Functional Health Literacy in Adults
UCLA	University of California, Los Angeles
US	United States
VA	Department of Veterans Affairs
WAIS-R	Wechsler Adult Intelligence Scale–Revised
WIC	Women, Infants, and Children
WRAT	Wide Range Achievement Test
WRAT3	Wide Range Achievement Test, 3rd edition
WRAT-R	Wide Range Achievement Test–Revised
yr(s)	Year(s)

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Evidence Table 1: Key Question 1

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
Citation: Andrasik et al., 1988 Design: Case-control Setting: NR Duration: One interview	To investigate differences between children with and without migraine headaches	Cases: Met definition for migraine headache as assessed by two study investigators, selected consecutively at project admission Controls: Recruited from friends of cases; could not have more than six headaches/yr or headaches that met definition for migraines, matched to cases by sex and age	64 (32 cases, 32 controls)	Age: 8 to 17 Sex: NR Race/Ethnicity: NR Income: NR Insurance Status: NR Other Characteristics: NR	NA

Evidence Table 1: Key Question 1 (continued)

Literacy Measurement	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
Measurement Tool: WRAT	WRAT scores did not differ between cases and controls	No multivariate analysis concerning literacy included	Total: 1.25 1) 0.5 2) NA 3) 1 4) 2 5) NA 6) 2 7) 1 8) 1
Literacy Levels : NR			Funding Source: National Institute of Neurological and Communicative Disorders and Stroke

Evidence Table 1: Key Question 1 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Arnold et al., 2001</p> <p>Design: Cross-sectional</p> <p>Knowledge, attitudes, and practices assessed through structured questionnaire</p> <p>Setting: Obstetrics clinics at Louisiana State University in Shreveport and E.A. Conway Hospital in Monroe, Louisiana</p> <p>Duration: September 1995 to April 1996</p>	<p>To assess reading level, tobacco knowledge, attitudes, and practices of pregnant women</p>	<p>Pregnant Adult or adolescent women AA or white</p>	<p>623 invited 23 refused 600 enrolled</p>	<p>Age: Mean: 23 Range: 12 to 45</p> <p>Sex: Female: 100%</p> <p>Race/Ethnicity: White: 51% AA: 49%</p> <p>Income: NR</p> <p>Insurance Status: % Medicaid/ uninsured among all clinic patients: Louisiana State University: 78% E.A. Conway: 95%</p> <p>Other Characteristics: Marital status: Married: White: 53% AA: 20% Not employed: White: 70% AA: 71%</p>	<p>Mean last grade completed among those > 18: 11th</p> <p>112 women not included in educational assessment because age 18 or younger</p>

Evidence Table 1: Key Question 1 (continued)

Literacy Measurement	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
Measurement Tool: REALM	Smoking rates (unadjusted): No sig difference according to literacy level: < 3rd: 15% 4th to 6th: 14% 7th to 8th: 18% > 9th: 25%	Reading level Age Race Marital status Number of pregnancies Living with a smoker Current smoking status	Total: 1.67 1) 2 2) NA 3) 1.5 4) 2 5) NA 6) 2 7) 1 8) 1.5
Literacy Levels: Mean reading level among those > 18 yrs: 7th to 8th < 7th grade reading level White: 9% AA: 28% 7th to 8th reading level White: 26% AA: 41% > 9th grade reading level White: 66% AA: 31%	Knowledge about effects of smoking (adjusted): Literacy sig predictor and negatively related to outcome		Funding Source: Louisiana Cancer and Lung Trust Fund
	Knowledge about effects of second hand smoke (adjusted): Literacy sig predictor ($P < 0.001$)		

Evidence Table 1: Key Question 1 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Baker et al., 2002</p> <p>Design: Prospective cohort</p> <p>Setting: Four Prudential managed care plans (Cleveland, Ohio; Houston, Texas; Tampa, Florida; Ft. Lauderdale-Miami, Florida (south Florida))</p> <p>Duration: 18 to 24 months</p>	<p>To explore the relationship between functional health literacy and the risk of hospital admission</p>	<p>Included: Medicare beneficiaries Age: = 65 3 months after enrollment in plan Language: English or Spanish</p> <p>Excluded: Dementia if missed one or more screening questions (not able to correctly identify year, month, state, year of birth, home address) If severe visual acuity impairment not correctable with eyeglasses</p>	<p>3,260</p> <p>7,471 contacted</p> <p>3390 refused</p> <p>737 ineligible</p> <p>84 did not complete TOFHLA (Response rate: 49%*)</p>	<p>Age: Adequate: 71.6 ± 5.6 Marginal: 74.1 ± 6.3 Inadequate: 75.6 ± 7.2</p> <p>Sex: Female: Adequate: 57.9% Marginal: 53.8% Inadequate: 57.8%</p> <p>Race/Ethnicity: Adequate: White: 84.0% AA: 6.6% English speaking Hispanic: 1.6% Spanish speaking Hispanic: 6.6%</p> <p>Marginal: White: 68.0% AA: 12.6% English speaking Hispanic: 2.5% Spanish speaking Hispanic: 16.4%</p> <p>Inadequate: White: 25.2% AA: 58.6% English speaking Hispanic: 2.3% Spanish speaking Hispanic: 13%</p> <p>Income (< \$15,000): Adequate: 36.6% Marginal: 56% Inadequate: 67.1%</p> <p>Other Characteristics: Number of chronic conditions (mean): Adequate: 1.9 Marginal: 2.1 Inadequate: 2.2</p>	<p>Yrs of School: Adequate: 0 to 8 yrs: 7.1% 9 to 11 yrs: 14.9% 12 yrs or GED: 38.3% > 12 yrs: 39.7%</p> <p>Marginal: 0 to 8 yrs: 24.2% 9 to 11 yrs: 25.6% 12 yrs or GED: 30.2% > 12 yrs: 20%</p> <p>Inadequate: 0 to 8 yrs: 40.9% 9 to 11 yrs: 24.3% 12 yrs or GED: 22.8% > 12 yrs: 12%</p>

Evidence Table 1: Key Question 1 (continued)

Literacy Measurement	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
Measurement Tool: S-TOFHLA, administered in English or Spanish	Time to first hospital admission (adjusted): Inadequate versus adequate literacy: RR = 1.29, 95% CI (1.07, 1.55)	Age Sex Race Education Income Smoking Alcohol use Chronic disease Self-reported physical health Self-reported mental health Literacy	Total: 1.8 1) 1.5 2) NA 3) 1.5 4) 2 5) 2 6) 2 7) 1.5 8) 2
Literacy Levels: Adequate: 64%* Marginal: 11%* Inadequate: 25%*	Marginal versus adequate literacy: RR = 1.21, 95% CI (0.97, 1.50) No sig difference by literacy level in models with interaction terms, for those with self-reported physical health 1 SD > mean Inadequate versus adequate literacy: RR = 1.60, 95% CI (1.24, 2.07) Marginal versus adequate literacy: RR = 1.42, 95% CI (1.02, 1.96)		Funding Source: Robert Wood Johnson Foundation
	Rates of hospitalization one or more times (unadjusted): Adequate literacy: 26.7% Marginal literacy: 33.9% Inadequate literacy: 34.9% Difference between the 3 groups: ($P < 0.001$)		
	Rehospitalization rate for those with one hospitalization (unadjusted): No sig difference by literacy level		

Evidence Table 1: Key Question 1 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Baker et al., 1998</p> <p>Design: Prospective cohort</p> <p>Setting: Urban public hospital (Grady Memorial), Atlanta, Georgia</p> <p>Duration: 2 yrs</p>	<p>To determine the association between patient literacy and hospitalization</p> <p>To compare role of literacy with education level</p>	<p>Included: Patients enrolled sequentially presenting to the ED or walk-in clinic with nonurgent problems between 9 a.m. and 5 p.m.</p> <p>Excluded: Age: < 18 Unintelligible speech Overt psychiatric illness Police custody English as a second language Too ill to participate Vision worse than 20/100</p>	<p>979 completed intake interview</p> <p>958 had records available</p>	<p>Age: Adequate: 36.2 Marginal: 43.7 Inadequate: 53.1 Mean: 40</p> <p>Sex: Female: 59%</p> <p>Race/Ethnicity: AA: 92%</p> <p>Income Markers: No phone: 39% No car: 76% Food assistance: 42%</p> <p>Insurance Status: Medicare or private: 24%* Medicaid: 20%* Uninsured: 56%</p> <p>Other Characteristics: Self-reported health: Good to excellent: 53% Fair: 32% Poor: 16% Hospitalized at least once during 2-year period: 21%</p>	<p>Yrs of School:</p> <p>Adequate: = 6: 1% 7 to 11: 22% 12: 50% > 12: 27%</p> <p>Marginal: = 6: 0% 7 to 11: 57% 12: 33% > 12: 11%</p> <p>Inadequate: = 6: 22% 7 to 11: 55% 12: 20% > 12: 3%</p>

Evidence Table 1: Key Question 1 (continued)

Literacy Measurement	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
Measurement Tool: TOFHLA, administered in English or Spanish	Risk of hospitalization one or more times in 2-year period (unadjusted): Adequate: 14.9% Marginal: 16.4% Inadequate: 31.5% Sig difference between three literacy levels ($P < 0.001$) Difference between marginal and adequate not sig	Age Sex Race Overall self-reported health Owns car Food assistance Owns telephone Insurance coverage Literacy	Total: 1.79 1) 2 2) NA 3) 2 4) 2 5) 1 6) 2 7) 1.5 8) 2
Literacy Levels: Adequate: 53% Marginal: 13% Inadequate: 35%	Risk of hospitalization one or more times in 2-year period (adjusted): Not controlling for education: Inadequate versus adequate literacy: OR = 1.69, 95% CI (1.13, 2.53) Marginal versus adequate literacy: Not sig Not controlling for health literacy: < 12 yrs versus > 12 yrs: Not sig 12 yrs versus > 12 yrs: Not sig		Funding Source: NR
	Risk of hospitalization among those hospitalized in the year prior to study entry (adjusted—controlling for literacy, age, receiving food assistance, and insurance): Inadequate versus adequate: OR = 3.15, 95% CI (1.45, 6.85) Marginal versus adequate: Not sig		

Evidence Table 1: Key Question 1 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Baker et al., 1997</p> <p>Design: Cross-sectional</p> <p>Setting: Emergency departments and walk-in clinics at public hospitals in Atlanta, Georgia (Grady Memorial) and Los Angeles County, California (Harbor-UCLA Medical Center in Torrance)</p> <p>Duration: One interview</p>	<p>To study the relationship between health literacy and self-reported health and use of health services</p>	<p>Included: Adults with nonurgent medical problems</p> <p>Excluded: Unintelligible speech Overt psychiatric illness Illness that precluded participation Visual acuity less than 20/100</p>	<p>Grady: 979, 77% of those approached</p> <p>LAE or LAS: 767</p> <p>84% of all those approached in Los Angeles</p>	<p>Age: Mean: Grady: 43.0 LAE: 38.0 LAS: 38.2</p> <p>Sex: Female: Grady: 58.8% LAE: 49.5% LAS: 64.5%</p> <p>Race/Ethnicity: Grady: White: 8% AA: 92% LAE: White: 29% AA: 47% Latino: 21% LAS: Latino: 100%</p> <p>Income Markers: Grady: Own car: 25% Own phone: 61% Food assistance: 42% LAE: Own car: 45% Own phone: 50% Food assistance: 36% LAS: Own car: 38% Own phone: 78% Food assistance: 26%</p> <p>Insurance Status: NR</p> <p>Other Characteristics: Grady: Poor health: 16% LAE: Poor health: 21% LAS: Poor health: 32%</p>	<p>Yrs of School: Grady: < 7: 8% 7 to 11: 38% 12: 38% > 12: 17%</p> <p>LAE: < 7: 2% 7 to 11: 26% 12: 43% > 12: 29%</p> <p>LAS: < 7: 55% 7 to 11: 27% 12: 8% > 12: 11%</p>

Evidence Table 1: Key Question 1 (continued)

Literacy Measurement	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
Measurement Tool: TOFHLA	Poor self-reported health versus not (unadjusted): Sig and greatest among those with inadequate literacy at all three sites ($P < 0.001$)	Age Sex Race Socioeconomic markers Income Literacy	Total: 1.83 1) 1.5 2) NA 3) 2 4) 2 5) NA 6) 1.5 7) 2 8) 2
Administered: English to English speakers Spanish to Spanish speakers Large print for those with poor vision	Poor self-reported health versus not (adjusted): Grady: Low versus adequate literacy: OR = 2.12, 95% CI (1.38, 3.24) Marginal versus adequate literacy: Not sig		Funding Source: NR
Literacy Levels: Grady: Adequate: 35% Marginal: 3% Inadequate: 52% LAE: Adequate: 78% Marginal: 9% Inadequate: 13% LAS: Adequate: 38% Marginal: 20% Inadequate: 42%	LAE: Low versus adequate literacy: OR = 2.19, 95% CI (1.34, 3.59) Marginal versus adequate literacy: OR = 1.80, 95% CI (1.06, 3.06) LAS: Low versus adequate literacy: OR = 1.72, 95% CI (1.20, 2.48) Marginal versus adequate literacy: Not sig		
	Poor self-reported health versus not (adjusted)—alternative specifications: Yrs of school completed used in analysis rather than literacy (< 7 yrs versus high school graduate); sig predictor for LAS group but not LAE or Grady Yrs of school not sig predictor after adjusting for literacy		
	Ambulatory care use (adjusted): Literacy not sig		

Evidence Table 1: Key Question 1 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Battersby et al., 1993</p> <p>Design: Case-control</p> <p>Setting: Two West London, inner-city general practices</p> <p>Duration: One interview</p>	<p>To test the association in patients with hypertension between cognitive functioning and literacy</p>	<p>Cases: Drawn from an up-to-date registry of hypertensive patients</p> <p>DBP = 100 mm Hg or SBP of = 180 mm Hg in preceding year or currently on drug treatment for hypertension</p> <p>Controls: Drawn from same registry and matched on age, sex, race, and health center but with DBP = 90 mm Hg, no record of antihypertensive treatment, DBP of = 100 mm Hg or SBP of = 180 mm Hg</p> <p>Excluded: Patients with stroke or transient ischaemic attack</p>	<p>90 cases</p> <p>90 controls</p>	<p>Age: Cases: 62.5 (9.2) Controls: 62.6 (9.2) Range: 40 to 70</p> <p>Sex: Female: 53%</p> <p>Race/Ethnicity: White: 87% Afro/Caribbean: 12%</p> <p>Income: NR</p> <p>Insurance Status: NR</p> <p>Other Characteristics: NR</p>	<p>Mean age when leaving school: Cases: 15.0 Controls: 14.6</p>

Evidence Table 1: Key Question 1 (continued)

Literacy Measurement	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
Measurement Tool: Schonell Graded Word Reading Test	Schonell scores did not differ appreciably between patients with and without HTN	No multivariate analysis concerning literacy included	Total: 1.58
Literacy Levels: Mean (SD) Cases: 78.4 (19.8) Controls: 81.3 (17.9)			1) 2 2) NA 3) 1.5 4) 2 5) NA 6) 2 7) 1 8) 1
			Funding Source: NR

Evidence Table 1: Key Question 1 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Bennett et al., 1998</p> <p>Design: Cross-sectional</p> <p>Setting: VA hospital in Chicago and university-based hospital in Shreveport, Louisiana</p> <p>Duration: One interview</p>	<p>To evaluate the association of poor literacy skills with higher rates of presentation of advanced stages of prostate cancer among low-income black and white men who receive care in equal-access medical systems</p>	<p>English speaking Waiting for appointment in prostate cancer clinic</p>	<p>212 (4% refusal rate)</p>	<p>Age: Mean: 70.8 (SD 7.9)</p> <p>Sex: Male: 100%</p> <p>Race/Ethnicity: White: 49%* Black: 51%*</p> <p>Income: NR</p> <p>Insurance Status: NR</p> <p>Other Characteristics: NR</p>	<p>NR</p>

Evidence Table 1: Key Question 1 (continued)

Literacy Measurement	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
<p>Measurement Tool: REALM</p> <p>Literacy Levels: Percent < 6th grade by: Race: White: 8.7% Black: 52.3%</p> <p>Age: < 65: 35.4% 65 to 74: 25.8% > 74: 35.8%</p>	<p>Presence of stage D metastatic disease at presentation (unadjusted): Literacy level = 6th grade: 54.6% Literacy level > 6th grade: 37.7% Difference: ($P < 0.03$)</p> <p>Presence of stage D metastatic disease at presentation (adjusted): Literacy level = 6th grade versus > 6th grade: OR = 1.6, 95% CI (0.8, 3.4) ($P = NS$)</p>	<p>City where care received Age Race Literacy</p>	<p>Total: 1.92</p> <p>1) 2 2) NA 3) 2 4) 2 5) NA 6) 2 7) 1.5 8) 2</p> <p>Funding Source: VA</p> <p>Agency for Healthcare Policy Research and Quality</p>

Evidence Table 1: Key Question 1 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Conlin and Schumann, 2002</p> <p>Design: Cross-sectional</p> <p>Setting: Large teaching hospital, post-coronary bypass recovery ward</p> <p>Duration: One interview</p>	<p>To determine if patients recovering from open heart surgery were able to read and understand written discharge instructions</p> <p>To analyze the level of difficulty of standard discharge instructions and consent forms for open heart surgery</p>	<p>Included: Nonrandom, convenience purposive sample Recovering from open-heart surgery Selected by cardiac rehabilitation nurse No significant visual and/or acuity insufficiency</p> <p>Excluded: Those in severe discomfort or having complications from their recent surgery</p>	<p>34 selected</p> <p>4 refused</p> <p>30 tested</p>	<p>Age: Mean: 62.4 (SD 9.6) Range: 40 to 79</p> <p>Sex: Female: 20%</p> <p>Race/Ethnicity: NR</p> <p>Income: NR</p> <p>Insurance Status: NR</p> <p>Other Characteristics: NR</p>	<p>Number of Patients: 8th grade: 3%* 10th grade: 3%* 11th grade: 3%* 12th grade: 43%* 13th grade: 47%*</p>

Evidence Table 1: Key Question 1 (continued)

Literacy Measurement	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
Measurement Tool: REALM Literacy Levels: = 3rd grade: 3%* 7th to 8th grade: 17%* High school: 80%*	Correlation between REALM score and a cumulative score on a five-question knowledge test Patient given knowledge test on post-operative care instructions given in English during hospitalization Pearson r coefficient = 0.67, level of statistical significance not given Comparable correlation with education achievement: r = 0.13	No multivariate analysis concerning literacy included	Total: 0.83 1) 1 2) NA 3) 1 4) 2 5) NA 6) 1 7) 0 8) 0 Funding Source: NR

Evidence Table 1: Key Question 1 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Davis, Arnold, et al., 1996</p> <p>Design: Cross-sectional</p> <p>30-item structured face-to-face interview</p> <p>Setting: Ambulatory care clinic and eye clinic at Louisiana State University, Shreveport</p> <p>Duration: Summer 1994</p>	<p>To study the relationship of reading ability to the knowledge and attitudes that low-income women have regarding screening mammography</p>	<p>Age: = 40 No mammogram in last year Waiting in outpatient clinics</p>	<p>595 invited 35 refused 115 ineligible as had mammo-grams in last year 445 participated 417 used in literacy estimates</p>	<p>Age: Mean: 56 Range: 40 to 92</p> <p>Sex: Female: 100%</p> <p>Race/Ethnicity: White: 30% AA: 69% Other: 1%</p> <p>Income: < \$10,000: 83% \$10,000 to \$20,000: 14% > \$20,000: 3%</p> <p>Insurance Status: NR</p> <p>Other Characteristics: NR</p>	<p>Average last grade completed: 10th</p> <p>Highest grade completed: = 6th: 16% 7th to 8th: 15% 9th to 11th: 27% High school graduate rate: 42%</p>

Evidence Table 1: Key Question 1 (continued)

Literacy Measurement	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
<p>Measurement Tool: REALM</p> <p>Literacy Levels: Mean = 40 (4th to 6th) 0 to 3rd grade: 25% 4th to 6th grade: 22% 7th to 8th grade: 30% > 9th grade: 24%</p>	<p>Knowledge about mammograms: Raw REALM score positively correlated with knowledge about why women get mammograms: $r = 0.22$ ($P < 0.0001$) but not sig related to when to have the first mammogram or how often to have a mammogram</p> <p>Unadjusted REALM positively correlated with knowledge index composed of three factual questions: $r = 0.17$ ($P = 0.0008$); adjusted relationship also sig</p> <p>Attitudes: Lower reading level (unadjusted) sig associated with more concern about mammograms being harmful or painful or troublesome ($P < 0.05$); not statistically sig after adjustment</p> <p>Influence: Association between literacy and influence of physician not sig; literacy level inversely associated with influence from friends/relatives (unadjusted) ($P < 0.05$)</p>	<p>Age Education Income level Literacy</p>	<p>Total: 1.50</p> <p>1) 1.5 2) NA 3) 1 4) 2 5) NA 6) 1.5 7) 2 8) 1</p> <p>Funding Source: National Cancer Institute</p> <p>Cancer Center for Excellence and Research, Treatment and Education at Louisiana State University</p>

Evidence Table 1: Key Question 1 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Davis et al., 1999</p> <p>Design: Cross-sectional</p> <p>Setting: Summer track and field program for youths in low-income neighborhoods in Shreveport, Louisiana</p> <p>Duration: One interview</p>	<p>To investigate the relationship between lower literacy and violent behavior in adolescents</p>	<p>Participants in summer program who were entering grades 6 to 12 (data collected over 3 yrs of programs, 1994 to 1996)</p> <p>Recruited from nine predominately low-income neighborhoods</p>	386	<p>Age: Range: 11 to 18 11 to 12: 42% 13 to 14: 40% 15 to 16: 15% 17 to 18: 4%</p> <p>Sex: Female: 34%</p> <p>Race/Ethnicity: AA: 86%</p> <p>Income: NR</p> <p>Insurance Status: NR</p> <p>Other Characteristics: History of suspension from school: 35%</p>	<p>Old for grade: 25% Middle school: 64% High school: 36%</p>

Evidence Table 1: Key Question 1 (continued)

Literacy Measurement	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
Measurement Tool: Slosson Oral Reading Test-Revised	Association between low reading ability and violent behaviors, as measured by Youth Risk Behavior Survey (adjusted): Weapon carrying past 30 days: OR = 1.9, 95% CI (1.1, 3.5) Gun carrying past 30 days: OR = 2.6, 95% CI (1.1, 6.2) Weapon carrying at school past 30 days: OR = 2.1, 95% CI (0.9, 4.5) Missed school because felt unsafe: OR = 2.3, 95% CI (1.3, 4.3) In physical fight and required treatment past 1 year: OR = 3.1, 95% CI (1.6, 6.1) Had property damage at school in past 12 months (<i>P</i> = NS) In physical fight in past 12 months (<i>P</i> = NS)	Age Race Sex Low reading measured as reading = two grades below grade level	Total: 1.75 1) 1.5 2) NA 3) 1.5 4) 2 5) NA 6) 2 7) 1.5 8) 2 Funding Source: NR

Evidence Table 1: Key Question 1 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Fisch et al., 1998</p> <p>Design: Cross-sectional</p> <p>Setting: Outpatient informed consent visit prior to ABMT at Indiana University Hospital, Indianapolis</p> <p>Duration: Enrolled December 1994 to March 1996</p>	<p>To describe the information preferences, reading ability, and emotional balance (affect) of adult patients at the time of outpatient informed consent</p>	<p>Any patient admitted for ABMT</p> <p>Patients coming to the clinic to provide informed consent on the days the study research nurse was available</p>	<p>108 patients had ABMT</p> <p>1 refused to have reading assessment</p> <p>77 came at a time the research assistant was unavailable</p> <p>30 enrolled</p>	<p>Age: Mean: 42.7 (SD 10.5) Range: 18 to 64</p> <p>Sex: Female: 63%</p> <p>Race/Ethnicity: White: 94% AA: 3% Other: 3%</p> <p>Income: NR</p> <p>Insurance Status: NR</p> <p>Other Characteristics: Self-reported reading ability: Excellent: 30% Good: 53% Fair: 17%</p> <p>Diagnosis: Breast cancer: 46% Lymphoma: 27%</p>	<p>< 12th grade: 7%</p> <p>12th grade: 33%</p> <p>Post high school vocational: 17%</p> <p>College graduate: 26%</p> <p>Post-graduate studies: 17%</p>

Evidence Table 1: Key Question 1 (continued)

Literacy Measurement	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
Measurement Tool: WRAT3 Literacy Levels: Mean: 113.7 ± 7.39 (described as high-average range)	Relationship between changes on the Derogatis Affects Balance Scale (an objective mood scale) and reading ability before and after informed consent (unadjusted): No sig relationship found between the patterns of changes in affect and WRAT scores	No multivariate analysis concerning literacy included	Total: 1.25 1) 1 2) NA 3) 1 4) 2 5) NA 6) 1.5 7) 2 8) 0 Funding Source: Walther Cancer Institute

Evidence Table 1: Key Question 1 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Fortenberry et al., 2001</p> <p>Design: Cross-sectional</p> <p>Setting: Four of seven research sites (Denver, Colorado; Indianapolis, Indiana; Central Harlem, New York City, New York; Birmingham, Alabama) involved in the Gonorrhea Community Action Project</p> <p>Duration: One interview</p>	<p>To assess the relationship between health literacy and receipt of a screening test for gonorrhea in the past year</p>	<p>Respondents recruited from clinics, community-based organizations, and street intercept</p>	<p>Initial sample: 1,035</p> <p>722 used in analysis</p> <p>(Response rate: NR)</p>	<p>Age: Mean: 26.34 Range: 12 to 55</p> <p>Sex: Female: 59%*</p> <p>Race/Ethnicity: NR</p> <p>Income: NR</p> <p>Insurance Status: Source of payment for health care: Insurance: 59% Self-pay: 27% Free care: 5%</p> <p>Other Characteristics: Clinic site recruitment: 64% Gonorrhea test in past year: 54% Self-suspected gonorrhea: 28% Self-efficacy for health care seeking: Mean 5.64 on 7-point Likert scale from "very unsure of ability to go for check-up" to "very sure of ability to go for check-up" Self-reported health: Good/excellent: 74%</p>	<p>Mean education (n = 930): 11.8 yrs</p>

Evidence Table 1: Key Question 1 (continued)

Literacy Measurement	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
<p>Measurement Tool: REALM</p> <p>Literacy Levels: (n = 909) Dichotomized: 9th grade or higher: 65%</p>	<p>Gonorrhea test in the last year (adjusted) (n = 722): For the average respondent, those with > 9th grade literacy, compared to those with lower literacy, associated with a 10% increase in the probability of having a gonorrhea test in the past year: OR = 1.37, 95% CI (1.02, 1.93)</p> <p>Perceived risk for gonorrhea (unadjusted): REALM score negatively related so that the lower the literacy, the greater the perceived risk (P < 0.0001)</p>	<p>Suspected infection Self-check for STDs Self-efficacy for health care Self-rated health Insurance Clinic recruitment site Age REALM > 9th grade</p>	<p>Total: 1.33</p> <p>1) 1 2) NA 3) 1 4) 1.5 5) NA 6) 1.5 7) 1.5 8) 1.5</p> <p>Funding Source: Centers for Disease Control and Prevention</p> <p>National Institute of Mental Health</p>

Evidence Table 1: Key Question 1 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Frack et al., 1997</p> <p>Design: Cross-sectional</p> <p>Setting: English as a second language classes in three adult education centers in the San Diego area during the period of February to August 1994</p> <p>Duration: Initial interview, 3- and 6-month followup assessments</p>	<p>To investigate compliance with measurement protocols among Latino subjects participating in a cardiovascular disease prevention intervention targeting low-English literate adults</p> <p>Three groups created: (1) those who complied on time with the study's followup physical measurement protocols (on-time compliers), (2) those who complied late (late compliers), and (3) those who did not comply (noncompliers)</p>	<p>Attending English as a second language classes in three adult education centers in San Diego</p>	<p>338 (Represents ~54% of total number that heard recruitment presentation)</p>	<p>Age: Mean: 28.1 (SD 9.4)</p> <p>Sex: Female: About 50%</p> <p>Race/Ethnicity: Latino: 100%</p> <p>Income: On-time compliers: 1.96 (1.24) Late compliers: 2.26 (1.24) Noncompliers: 1.77 (0.98)</p> <p>Income Categories: 1 = < \$700 2 = (\$700 to \$1,099) 3 = (\$1,100 to \$1,499)</p> <p>Insurance Status: NR</p> <p>Other Characteristics: Employed: 53% Living in US < 3 yrs: 33%</p>	<p>= 9 yrs: 48%</p>

Evidence Table 1: Key Question 1 (continued)

Literacy Measurement	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
<p>Measurement Tool: Cloze procedure measured Spanish-language literacy</p> <p>Literacy Levels (mean): On-time compliers: 65.7 Late compliers: 64.9 Noncompliers: 60.0</p>	<p>Factors associated with level of compliance with research protocols (unadjusted): Spanish literacy (mean): On-time group literacy sig higher than noncomplier group ($P < 0.05$)</p>	<p>No multivariate analysis concerning literacy included</p>	<p>Total: 1.17</p> <p>1) 0.5 2) NA 3) 1 4) 1.5 5) NA 6) 1.5 7) 2 8) 0.5</p> <p>Funding Source: National Heart, Lung, and Blood Institute</p>

Evidence Table 1: Key Question 1 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Fredrickson et al., 1995</p> <p>Design: Cross-sectional</p> <p>Setting: Twelve pediatric, prenatal, or immunization clinics in Kansas: 2 private, 2 university, 2 indigent, and 6 Wichita-Sedgwich County health clinics</p> <p>Duration: Receiving care during June to July 1994</p> <p>One interview</p>	<p>To describe the epidemiology of parent reading abilities at 12 representative midwestern clinics</p> <p>To determine whether low literacy was associated with adverse health behaviors</p>	<p>Any parent or adult caretaker waiting for child-related services</p> <p>English or Spanish speaking</p>	<p>646 enrolled</p> <p>Less than 4% of those eligible declined</p>	<p>Age: Mean: 27.8 Range: 13 to 63</p> <p>Sex: Female: 92%</p> <p>Race/Ethnicity: White: 59%</p> <p>Income: NR</p> <p>Insurance Status: Insurance: 76%</p> <p>Other Characteristics: NR</p>	<p>Mean yrs of school: 12.1</p>

Evidence Table 1: Key Question 1 (continued)

Literacy Measurement	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
<p>Measurement Tool: WRAT</p> <p>Literacy Levels: Mean grade: 8.7 < 9th grade: 45% < 6th grade: 22% < 4th grade: 13% 10% were Spanish speaking and scored lower on the WRAT 41% of English speakers scored less than 9th grade</p>	<p>Rates of smoking, never breast-feeding, and lack of private health insurance sig associated with low reading ability ($P < 0.05$)</p> <p>No association with obesity found</p>	<p>No multivariate analysis concerning literacy included</p>	<p>Total: 0.92</p> <p>1) 1.5 2) NA 3) 1 4) 2 5) NA 6) 0.5 7) 0.5 8) 0</p> <p>Funding Source: NR</p>

Evidence Table 1: Key Question 1 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Gazmararian et al., 2000</p> <p>Design: Cross-sectional</p> <p>Setting: Four Prudential managed care plans (Cleveland, Ohio; Houston, Texas; Tampa, Florida; Ft. Lauderdale-Miami, Florida)</p> <p>Duration: One interview</p>	<p>To determine whether older adults with inadequate health literacy were more likely to report depressive symptoms and whether health literacy was an independent predictor of depression symptomatology</p>	<p>Included: Age: = 65 3 months after enrollment in plan Medicare beneficiaries living in the community Language: English or Spanish</p> <p>Excluded: Dementia: If missed one or more screening questions (not able to correctly identify year, month, state, year of birth, home address) Visual acuity: Excluded if severe impairment "Severe" category of the MMSE missing five or more responses on depression scale</p>	<p>3,171</p> <p>7,471 contacted</p> <p>3,247 refused</p> <p>737 not eligible</p> <p>143 no show</p> <p>84 incomplete surveys</p> <p>68 severe dementia</p> <p>21 incomplete data on depression scale</p> <p>(Response rate: 49%)</p>	<p>Age: 65 to 74: 64% Range: = 65</p> <p>Sex: Female: 57%</p> <p>Race/Ethnicity: White: 76%</p> <p>Income: = \$10,000: 34%</p> <p>Insurance Status: Medicare: 100%</p> <p>Other Characteristics: Social support: Married: 54.9% Tangible or social support: None or little of the time: 20.1% Some of the time: 19.3% Most of the time: 18.5% All of the time: 42.1%</p> <p>Exercise: = 4 times/week: 43.2% 3 times/week: 15.1% 1 to 2 times/week: 15.1% < 1 time/week: 26.6%</p> <p>Health conditions: 0: 10.9% 1: 21.6% 2: 23.8% 3 to 4: 31.5% = 5: 12.2%</p> <p>ADL limited: 4.3% IADL limited: 30% Self-rated health: Good/excellent: 73.2% Depressed: 13%</p>	<p>At least a high school education: 64%</p>

Evidence Table 1: Key Question 1 (continued)

Literacy Measurement	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
<p>Measurement Tool: S-TOFHLA</p> <p>Literacy Levels: Adequate: 65.6% Marginal: 11.3% Inadequate: 23.1%</p>	<p>Depression: Measured by global depression scale Score ranges from 0 to 15 where 0 to 4 = not depressed, 5 to 9 = mild depression, 10 to 15 = moderate to severe depression</p> <p>Outcome: Depressed (mild-severe to not depressed) (adjusted)</p> <p>Literacy: Inadequate versus adequate literacy: OR = 1.2, 95% CI (0.9, 1.7) Marginal versus adequate literacy: OR = - 0.5, 95% CI (0.3, 0.8)</p> <p>Education: No sig difference between > high school and lesser educational attainment categories</p>	<p>Sex Age BMI Drinking Chronic conditions Marital status Tangible support Exercise Education Annual income ADL limitations General health Literacy</p>	<p>Total: 1.67 1) 2 2) NA 3) 1 4) 2 5) NA 6) 1.5 7) 1.5 8) 2</p> <p>Funding Source: Partially supported by Robert Wood Johnson Foundation</p>

Evidence Table 1: Key Question 1 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Gazmararian, Baker, et al., 1999</p> <p>Design: Cross-sectional</p> <p>Setting: Four Prudential managed care plans (Cleveland, Ohio; Houston, Texas; Tampa, Florida; Ft. Lauderdale-Miami, Florida (south Florida))</p> <p>Duration: One interview</p>	<p>To determine the prevalence of low functional health literacy among community-dwelling Medicare enrollees in a national managed care organization</p>	<p>Included: Age: = 65 3 months enrollment in plan Language: English or Spanish Medicare beneficiaries</p> <p>Excluded: Dementia if missed one or more screening questions (not able to correctly identify year, month, state, year of birth, home address) Visual acuity if severe impairment not correctable with eyeglasses</p>	<p>3,260</p> <p>7,471 contacted</p> <p>3,247 refused</p> <p>737 ineligible</p> <p>3,487 agreed to participate</p> <p>143 no show</p> <p>84 incomplete surveys</p> <p>(Response rate: 51%*)</p>	<p>Age: 65 to 69: 37% 70 to 74: 27.3% 75 to 79: 19.3% 80 to 85: 11% > 85: 5.4%</p> <p>Sex: Female: 57.4%</p> <p>Race/Ethnicity: White: 76% Black: 11.8% English speaking Hispanic: 2% Spanish speaking Hispanic: 9.2% Other: 1%</p> <p>Income: < \$10,000: 18.2% \$10,000 to \$14,999: 21.6%</p> <p>Insurance Status: Medicare: 100%</p> <p>Other Characteristics: Occupation during longest period of time in adult life: Primary white collar: 21.3% Secondary white collar: 27.1% Primary blue collar: 12.2% Secondary blue collar: 31.6% At least one or more chronic condition: 66.5% Number of medications: None: 20% 1 to 2 per day: 36.5% = 3 per day: 43.5% Self-reported health; Good/excellent: 72.8%</p>	<p>Grade school or less: 17.3% Some high school: 18.4% High school: 33.6% More than high school: 30.7%</p>

Evidence Table 1: Key Question 1 (continued)

Literacy Measurement	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
<p>Measurement Tool: S-TOFHLA, administered in English or Spanish</p> <p>Literacy Levels: English: Adequate: 66.1% Marginal: 10.4% Inadequate: 23.5% Spanish: Adequate: 46.1% Marginal: 19.7% Inadequate: 34.2%</p>	<p>Inadequate or marginal health literacy versus adequate (adjusted): Mild to moderate cognitive impairment versus none: OR = 5.24, 95% CI (4.21, 6.53)</p> <p>Percentage with inadequate or marginal health literacy versus adequate (unadjusted): Sig more likely to be in fair/poor health versus excellent/good ($P < 0.001$) Sig more likely to have one or more chronic conditions ($P < 0.05$) Not sig related to number of medications (per day)</p>	<p>Study location Race/language Sex Age Education completed Occupation Cognitive impairment</p>	<p>Total: 1.67 1) 2 2) NA 3) 1 4) 2 5) NA 6) 2 7) 1.5 8) 1.5</p> <p>Funding Source: NR</p>

Evidence Table 1: Key Question 1 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Gazmararian, Parker, et al., 1999</p> <p>Design: Cross-sectional</p> <p>Setting: TennCare (Medicaid) members of Prudential HealthCare Community Plan (managed care) in Memphis, Tennessee</p> <p>Duration: One interview</p>	<p>To examine the relationship between reading ability and family planning knowledge and practices among Medicaid managed care enrollees</p>	<p>Age: 18 to 45</p> <p>Sex: Women enrolled in Prudential HealthCare Community Plan as of March 1, 1996</p>	<p>406</p> <p>2,917 age eligible</p> <p>1,136 located</p> <p>204 refused to participate</p> <p>216 not eligible</p> <p>95 additional not eligible</p> <p>Age: < 18</p> <p>(Response rate: 49%*)</p>	<p>Age: 19 to 24: 35%* 25 to 29: 21%* = 30: 43%*</p> <p>Sex: Female: 100%</p> <p>Race/Ethnicity: White: 23%* Black: 73%* Other: 3%*</p> <p>Income: < 100% poverty level: 50%</p> <p>Insurance Status: Medicaid: 100%</p> <p>Other Characteristics: Employed: 57%</p>	<p>< high school: 11%*</p> <p>High school: 40%*</p> <p>> high school: 49%*</p>

Evidence Table 1: Key Question 1 (continued)

Literacy Measurement	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
<p>Measurement Tool: S-TOFHLA to measure health literacy</p> <p>Passage from Medicaid Rights and Responsibility form written at 10th grade level</p> <p>Literacy Levels: Those who answered less than 80% of reading skills questions correctly identified as having low reading skills</p>	<p>Wanted to know more about birth control (adjusted): OR = 2.30, 95% CI (1.12, 4.73) higher among low versus good reading skills women</p> <p>Incorrect knowledge of time of month most likely to get pregnant (adjusted): OR = 4.54, 95% CI (2.18, 9.48) higher among low versus good reading skills women</p> <p>Proportion of women ever using various types of birth control who have low literacy (unadjusted): IUD 17.9%, douching 13.9%, rhythm 13.7%, sponge 8.5%, condom 8.4%, foam 8.1%, withdrawal 6.6%, OCP 8.1%, levonorgestrel 13.3%, Medroxyprogesterone 10.1%</p> <p>Pregnancy intendedness and current use of contraception: Did not vary by reading level (unadjusted)</p> <p>Women who did not know when they were more likely to become pregnant during their monthly cycle (unadjusted): 18.5% had low reading versus 4.9% of those who did know ($P = 0.001$)</p>	<p>Age</p> <p>Race</p> <p>Marital status</p> <p>Reading skill</p>	<p>Total: 1.33</p> <p>1) 2</p> <p>2) NA</p> <p>3) 1</p> <p>4) 1.5</p> <p>5) NA</p> <p>6) 1</p> <p>7) 1.5</p> <p>8) 1</p> <p>Funding Source: Partially supported by Robert Wood Johnson Foundation</p>

Evidence Table 1: Key Question 1 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Golin et al., 2002</p> <p>Design: Prospective cohort</p> <p>Setting: Public hospital-affiliated HIV clinic between February 1998 and April 1999</p> <p>Duration: 48 weeks</p>	<p>To assess predictors of long-term adherence to combination antiretroviral therapy using an accurate, objective adherence measure</p>	<p>Enrolled in the ADEPT study HIV infected Newly initiating a protease inhibitor or non-nucleoside reverse transcriptase inhibitor Spoke English or Spanish Adherence data available for at least two 4-week periods</p>	<p>140 enrolled in study</p> <p>60% of those eligible</p> <p>117 had = two 4-week periods for adherence measurement and so available for analysis</p>	<p>Age: Mean: 38 Range: 23 to 67</p> <p>Sex: Female: 20%</p> <p>Race/Ethnicity: AA: 27% White: 16% Hispanic: 47% Other: 10%</p> <p>Income: = \$10,000: 63%</p> <p>Insurance Status: NR</p> <p>Other Characteristics: Working: 30% Duration of diagnosis: Mean: 24 months Range: 1 to 120 months CD4 count nadir: 149 Range: 0 to 1,130 Intravenous drug use as source of HIV: 17% Currently in drug study: 40% Antiretroviral doses/day: Mean: 13.4 Range: 0 to 34</p>	<p>< high school graduate: 35%</p> <p>High school graduate: 48%</p> <p>College graduate: 17%</p>

Evidence Table 1: Key Question 1 (continued)

Literacy Measurement	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
Measurement Tool: S-TOFHLA administered in English or Spanish	Adherence to complex antiretroviral therapy (unadjusted): Literacy: $r = -0.01$ ($P = 0.88$)	Ethnicity Education Income Alcohol use Current active drug use	Total: 1.79 1) 2 2) NA 3) 1.5 4) 2
Literacy Levels: Mean: 30 Range on a 36-point scale: (10 to 36)	Adherence to a protease inhibitor or non-nucleoside reverse transcriptase inhibitor (adjusted): High school graduate versus less education, positive relationship ($P = 0.05$)	Dose frequency Number of reminders	5) 1 6) 2 7) 2 8) 2 Funding Source: National Institutes of Health

Evidence Table 1: Key Question 1 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Gordon et al., 2002</p> <p>Design: Cross-sectional</p> <p>Setting: Tertiary referral clinic for rheumatic diseases in Glasgow, Scotland</p> <p>Duration: One question-naire</p>	<p>To determine the prevalence of illiteracy in a cohort of rheumatoid arthritis patients and the impact of illiteracy on disease severity and function</p>	<p>All patients attending four consecutive clinics for rheumatoid arthritis patients</p>	<p>127 approached</p> <p>4 refused</p> <p>123 participated</p>	<p>Age: Median: 56 Range: 19 to 77</p> <p>Sex: Female: 79%*</p> <p>Race/Ethnicity: White: 98%*</p> <p>Income: Carstairs deprivation index: Group 6 or 7: 43% (most deprived) Group 1, 2, or 3: 24% (most affluent)</p> <p>Insurance Status: National Health Service</p> <p>Other Characteristics: NR</p>	<p>NR</p>

Evidence Table 1: Key Question 1 (continued)

Literacy Measurement	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
<p>Measurement Tool: REALM</p> <p>Literacy Levels: = 9th grade: 85%* 7th to 8th grade: 12% 4th to 6th grade: 2%* < 3rd grade: 1%</p>	<p>Low literacy associated with anxiety and depression (unadjusted): Percent = 15 on hospital anxiety and depression scale: = 9th grade (literate group): 44% < 9th grade (illiterate group): 61% (<i>P</i> = 0.011)</p> <p>Health Assessment Questionnaire score (unadjusted): = 9th grade (literate group): 1.875 < 9th grade (illiterate group): 20 (<i>P</i> = 0.5)</p> <p>Extent of disability including antirheumatic drugs used or number of major joining arthroplastics: Association with literacy not sig (data not shown)</p>	<p>No multivariate analysis concerning literacy level included</p>	<p>Total: 1.33 1) 1.5 2) NA 3) 1 4) 2 5) NA 6) 2 7) 1 8) 0.5</p> <p>Funding Source: NR</p>

Evidence Table 1: Key Question 1 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Hawthorne, 1996</p> <p>Design: Cross-sectional</p> <p>Setting: Stratified sample of 6th year students (ages 11 and 12) from 86 schools in Melbourne, Australia</p> <p>Duration: One interview</p>	To identify key predictors of early adolescent social drug use	Students in selected schools	<p>3,019</p> <p>"99% participation rate"</p> <p>1,620 boys</p> <p>1,399 girls</p> <p>Re-analysis of existing data</p>	<p>Age: 11: 61% 12: 39%</p> <p>Sex: Female: 46%</p> <p>Race/Ethnicity: NR</p> <p>Income: NR</p> <p>Insurance Status: NR</p> <p>Other Characteristics: Birthplace: Australia: 83% Other: 17% Parental occupation: Professionals or managers: 39% Clerks, sales, service: 11% Tradespersons, laborers, cleaners: 35% Houseworker or unemployed: 15% Spoke a language other than English at home: 27% Parents born outside Australia: 49%</p>	NR

Evidence Table 1: Key Question 1 (continued)

Literacy Measurement	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
Measurement Tool: NR	Results presented as OR, 95% CI	Parents drink Parents smoke Parents' occupation Parents' birthplace Home language School SES rating Personal tobacco use (alcohol models) Personal alcohol use (tobacco models) Friends smoke Friends drink Age Personal birthplace Analgesic use Hours of drug education Drug knowledge Attitudes to others Attitudes to rewards Attitudes to health	Total: 1.42 1) 1 2) NA 3) 2 4) 0 5) NA 6) 1.5 7) 2 8) 2
Literacy Levels: Scale NR	Ever having used tobacco (adjusted): Literacy low versus high: Boys: OR = 1.7 (1.1, 2.7) Girls: OR = 1.1 (0.6, 2.0) Literacy middle versus high: Boys: OR = 1.3 (1.0, 1.7) Girls: OR = 1.1 (0.8, 1.3)		
Literacy analyzed in three categories: Low Middle High	Having used tobacco in the past month (adjusted): Literacy low versus high: Boys: OR = 4.2 (2.0, 8.9) Girls: OR = 4.4 (1.8, 10.7) Literacy middle versus high: Boys: OR = 1.7 (1.0, 2.9) Girls: OR = 2.0 (1.1, 3.8)		
	Ever having used alcohol (adjusted): Literacy low versus high: Boys: OR = 1.1 (0.6, 2.0) Girls: OR = 0.8 (0.3, 2.2) Literacy middle versus high: Boys: OR = 0.9 (0.7, 1.4) Girls: OR = 1.2 (0.7, 2.0)		
	Having used alcohol in the past month (adjusted): Literacy low versus high: Boys: OR = 1.9 (0.9, 3.8) Girls: OR = 1.2 (0.4, 3.4) Literacy middle versus high: Boys: OR = 0.9 (0.6, 1.4) Girls: OR = 0.9 (0.5, 1.7)		
	Having misused alcohol (adjusted): Literacy low versus high: Boys: OR = 2.6 (1.4, 4.8) Girls: OR = 2.1 (0.8, 5.5) Literacy middle versus high: Boys: OR = 1.6 (1.1, 2.4) Girls: OR = 1.2 (0.6, 2.2)		

Funding Source:
Victoria Health Promotion Foundation

Evidence Table 1: Key Question 1 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Kalichman, Benotsch, et al., 2000</p> <p>Design: Cross-sectional</p> <p>Setting: Recruited from AIDS service organizations, health care providers, social service agencies, community residences for people with HIV/AIDS, infectious disease clinics, fliers, word of mouth</p> <p>Atlanta, Georgia</p> <p>Duration: One interview</p>	<p>To test the hypothesis that poor health literacy is associated with less knowledge and understanding of one's own HIV-disease status and negative perceptions of provider communications</p> <p>To examine the relationship between health literacy and misperceptions about antiretroviral therapies</p>	<p>HIV positive Fluent in English</p>	294	<p>Age: Mean: 39.7 Range: 24 to 67</p> <p>Sex: Female: 22% Male: 78% Transgender: 0.5%</p> <p>Race/Ethnicity: White: 24% AA: 70% Other: 6%</p> <p>Income: < \$10,000/yr: 61%</p> <p>Insurance Status: NR</p> <p>Other Characteristics: NR</p>	<p>Mean: 13.0 yrs < 12 yrs: 21% 12 yrs: 32% > 12 yrs: 47%</p>

Evidence Table 1: Key Question 1 (continued)

Literacy Measurement	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
<p>Measurement Tool: TOFHLA reading comprehension section only</p> <p>Literacy Levels: "Lower health literacy": 18% "Higher health literacy": 82% Cut-off for higher health literacy at 80% correct on TOFHLA subtest Score: 0% to 20%: 2% 21% to 40%: 2% 41% to 60%: 3% 61% to 80%: 11% 81% to 90%: 23% 91% to 100%: 59%</p>	<p>Knowledge measures (adjusted): Does not know CD4 count: Lower versus higher literacy: OR = 1.9, 95% CI (0.9, 4.1) Understands meaning of CD4 count: Higher versus lower literacy: OR = 2.5, 95% CI (1.2, 5.4) Does not know viral load: Lower versus higher literacy: OR = 1.8, 95% CI (0.9, 3.5) Understands meaning of viral load: Higher versus lower literacy: OR = 3.4, 95% CI (1.3, 9.1)</p> <p>Optimism toward treatment (adjusted): Community upbeat about stopping AIDS: Lower versus higher literacy: OR = 2.4, 95% CI (1.1, 5.1) Believes there will be a cure for HIV in next few yrs: Lower versus higher literacy: OR = 3.1, 95% CI (1.5, 6.6)</p> <p>Perceived effects of treatment on transmission risks (adjusted): Taking drug cocktails makes it less likely to transmit HIV during sex: Lower versus higher literacy: OR = 3.0, 95% CI (1.4, 6.3) Safe to have unsafe sex if undetectable viral load: Lower versus higher literacy: OR = 5.8, 95% CI (2.2, 15.5) New AIDS treatment makes it easier to relax about unsafe sex: Lower versus higher literacy: OR = 6.0, 95% CI (2.6, 3.6)</p> <p>Health status and health behaviors (unadjusted): Undetectable viral load: Higher versus lower literacy: OR = 2.9, 95% CI (1.1, 8.1) At least one doctor visit per month: Lower versus higher literacy: OR = 2.3, 95% CI (1.2, 4.4)</p>	<p>Yrs of education</p>	<p>Total: 1.08 1) 1 2) NA 3) 1 4) 1.5 5) NA 6) 1.5 7) 1 8) 0.5</p> <p>Funding Source: National Institute of Mental Health</p>

Evidence Table 1: Key Question 1 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Kalichman et al., 1999</p> <p>Design: Cross-sectional</p> <p>Setting: Recruited from AIDS service organizations, health care providers, social service agencies, community residences for people with HIV/AIDS, infectious disease clinics, fliers, word of mouth</p> <p>Atlanta, Georgia</p> <p>Duration: One interview</p>	<p>To test the significance of health literacy relative to other predictors of adherence to treatment for HIV and AIDS</p> <p>Adherents (n = 148) compared to nonadherents (n = 36) (those who missed at least one dose of their antiretroviral medication in the past 2 days)</p>	HIV positive	<p>318</p> <p>184 on HAART and used for analysis (triple combination drug therapy)</p>	<p>Age: Nonadherent: Mean: 38.2 Adherent: Mean: 40.4</p> <p>Sex: Nonadherent male: 67% Adherent male: 78%</p> <p>Race/Ethnicity: Nonadherent: White: 17% AA: 75% Other: 8% Adherent: White: 45% AA: 49% Other: 6%</p> <p>Income: < \$10,000/yr Nonadherent: 66% Adherent: 62%</p> <p>Insurance Status: NR</p> <p>Other Characteristics: NR</p>	<p>Mean yrs (SD): Nonadherent: 12.2 (2.7) Adherent: 13.7 (2.3)</p>

Evidence Table 1: Key Question 1 (continued)

Literacy Measurement	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
<p>Measurement Tool: TOFHLA reading comprehension section only</p> <p>Literacy Levels: "Lower" literacy (those who scored below 85% correct): 16%</p>	<p>Adherence to combination antiretroviral therapies over a 2-day recall (adjusted): < 12 yrs education versus = 12 yrs: OR = 3.3, 95% CI (1.1, 10.7) (<i>P</i> < 0.05)</p> <p>Lower literacy versus higher literacy: OR = 3.9, 95% CI (1.1, 13.4) (<i>P</i> < 0.05)</p> <p>Barriers to adherence in past 30 days by literacy (lower versus higher) (unadjusted): Lower literacy more likely to report confusion (<i>P</i> < 0.01) Lower literacy more likely to report depression (<i>P</i> < 0.05) Lower literacy report wanting to cleanse their body (<i>P</i> < 0.05) No sig difference by literacy level in forget dose, did not have pills, too busy, too many pills, slept through dose, side effects</p>	<p>Age < 35 Ethnic minority Income < \$10,000 Education < 12 yrs Number of HIV symptoms Alcohol use Other drug use Social support Emotional distress Provider attitudes Lower literacy</p>	<p>Total: 1.50</p> <p>1) 1.5 2) NA 3) 1 4) 1.5 5) NA 6) 1.5 7) 1.5 8) 2</p> <p>Funding Source: National Institute of Mental Health Center for AIDS Intervention Research</p>

Evidence Table 1: Key Question 1 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Kalichman and Rompa, 2000a</p> <p>Design: Cross-sectional</p> <p>Setting: Recruited from AIDS service organizations, health care providers, social service agencies, community residences for people with HIV/AIDS, infectious disease clinics, fliers, word of mouth</p> <p>Atlanta, Georgia</p> <p>Duration: 1 day</p>	<p>To examine differences in emotional reactions to changes in health status between individuals living with HIV/AIDS who have lower versus higher health literacy skills</p>	<p>HIV positive Fluent English speaker</p>	294	<p>Age: Mean: 39.7 Range: 24 to 67</p> <p>Sex: Female: 22% Male: 78% Transgender: 0.5%</p> <p>Race/Ethnicity: White: 24% AA: 70% Other: 6%</p> <p>Income: < \$10,000/yr: 61%</p> <p>Insurance Status: NR</p> <p>Other Characteristics: Undetectable viral load Lower health literacy: 32% Higher health literacy: 38% (<i>P</i> = NS)</p>	<p>Mean: 13 yrs (SD 2.3) < 12 yrs: 21% 12 yrs: 32% > 12 yrs: 47%</p>

Evidence Table 1: Key Question 1 (continued)

Literacy Measurement	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
<p>Measurement Tool: TOFHLA reading comprehension section only</p> <p>Literacy Levels: "Lower health literacy": 26% "Higher health literacy": 74% Cut-off for higher health literacy: 85% correct on reading comprehension section of TOFHLA</p>	<p>Percent undetectable viral load (unadjusted): Lower health literacy: 32% Higher health literacy: 38% Difference: ($P = NS$)</p> <p>Emotional reactions to scenarios concerning increase in viral load among HIV-positive persons (unadjusted): Lower health literacy more likely than higher to be devastated ($P = 0.03$) Lower health literacy less likely than higher to be optimistic ($P = 0.01$) No sig difference in feeling afraid, depressed, hopeful, or relieved by literacy level</p> <p>Emotional reactions to scenarios concerning decrease in viral load (unadjusted): Lower health literacy more likely to be devastated ($P = 0.02$), afraid ($P = 0.03$), depressed ($P = 0.01$) Lower health literacy less likely to be hopeful ($P = 0.01$), optimistic ($P = 0.01$)</p> <p>Number of symptoms of affective depression (unadjusted): Greater in lower literacy versus higher group ($P < 0.01$)</p> <p>Level of social support (unadjusted): Less among lower literacy versus higher group ($P < 0.01$)</p>	<p>No multivariate analysis concerning literacy included</p>	<p>Total: 1.25 1) 1.5 2) NA 3) 1 4) 1.5 5) NA 6) 1.5 7) 1 8) 1</p> <p>Funding Source: National Institute of Mental Health Center for AIDS Intervention Research</p>

Evidence Table 1: Key Question 1 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Kalichman and Rompa, 2000b</p> <p>Design: Cross-sectional</p> <p>Setting: Recruited from AIDS service organizations, health care providers, social service agencies, community residences for people with HIV/AIDS, infectious disease clinics, fliers, word of mouth</p> <p>Atlanta, Georgia</p> <p>Duration: One interview</p>	<p>To test the hypothesis that poorer health literacy is associated with health status, awareness and understanding of one's HIV disease status, and HIV disease and treatment-related knowledge</p>	<p>HIV positive Fluent English speaker</p>	339	<p>Age: Mean: 42 Range: 22 to 69</p> <p>Sex: Female: 32%* Transgender: 1%</p> <p>Race/Ethnicity: White: 19%* AA: 78%* Other: 3%*</p> <p>Income: < \$20,000/yr: 85%*</p> <p>Insurance Status: NR</p> <p>Other Characteristics: Mean CD4 count: 314.6 cells/mm³ Mean log viral load: 3.2 copies/ml Undetectable viral load: 36%</p>	<p>Mean: 12.7 yrs < 12 yrs: 23% 12 yrs: 57% > 12 yrs: 20%</p>

Evidence Table 1: Key Question 1 (continued)

Literacy Measurement	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
<p>Measurement Tool: TOFHLA reading comprehension section only</p> <p>Literacy Levels: "Lower health literacy": 25% "Higher health literacy": 75% Cut-off for higher health literacy at 80% correct on TOFHLA subtest</p>	<p>All OR compare lower versus higher health literacy:</p> <p>Undetectable viral load (unadjusted): OR = 6.2, 95% CI (2.1, 18.5)</p> <p>Taking antiretrovirals (unadjusted): OR = 1.9, 95% CI (1.1, 3.2)</p> <p>< 300 CD4 cells/mm³ (unadjusted): OR = 2.3, 95% CI (1.1, 5.1)</p> <p>Hospitalized = three times (unadjusted): OR = 1.7, 95% CI (1.0, 3.0)</p> <p>Perceives health is good (unadjusted): OR = 0.5, 95% CI (0.2, 1.0)</p> <p>Knowledge and understanding of HIV-related health markers (adjusted): Does not know CD4 cell count: OR = 1.9, 95% CI (1.1, 3.5) Does not understand meaning of CD4 count: OR = 1.7, 95% CI (0.9, 3.3) Does not know viral load: OR = 2.3, 95% CI (1.3, 3.9) Does not understand meaning of viral load: OR = 2.2, 95% CI (1.1, 4.8)</p> <p>HIV disease and treatment knowledge test score (adjusted): Higher literacy group scored higher than lower ($P < 0.1$)</p> <p>Perceptions and experiences related to HIV/AIDS (adjusted): More negative among lower literacy group ($P < 0.05$)</p>	<p>Education</p>	<p>Total: 0.92</p> <p>1) 1 2) NA 3) 1 4) 1 5) NA 6) 1 7) 1 8) 0.5</p> <p>Funding Source: National Institute of Mental Health</p>

Evidence Table 1: Key Question 1 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Kalichman, Rompa, and Cage, 2000</p> <p>Design: Cross-sectional</p> <p>Setting: Recruited from AIDS service organizations, health care providers, social service agencies, community residences for people with HIV/AIDS, infectious disease clinics, fliers, word of mouth</p> <p>Atlanta, Georgia</p> <p>Duration: 1 month for 30 patients in sample</p> <p>One visit for rest of patients</p>	<p>To test the reliability and validity of self-reported CD4 lymphocyte counts and viral load in a community sample of HIV-infected men and women</p>	<p>HIV positive English speaker</p>	174	<p>Age: Mean: 40.5 Range: 23 to 58</p> <p>Sex: Female: 34% Male: 64% Transgender: 2%</p> <p>Race/Ethnicity: White: 16% AA: 77% Hispanic/Latino: 4% Other: 4%</p> <p>Income: < \$10,000/yr: 67%</p> <p>Insurance Status: NR</p> <p>Other Characteristics: Mean yrs aware of HIV status: 8.1 (SD 4.6)</p>	<p>Mean: 12.6 yrs (SD 2.3) < 12 yrs: 27%</p>

Evidence Table 1: Key Question 1 (continued)

Literacy Measurement	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
<p>Measurement Tool: TOFHLA reading comprehension section only</p> <p>Literacy Levels: Cut-off for higher health literacy: 85% correct on reading comprehension section of TOFHLA</p> <p>Compare percent correct on literacy test</p>	<p>Knew most recent CD4 count (unadjusted): Percent correct on literacy test: Knew: 86.7% Did not know: 77.8% Difference: ($P = 0.01$)</p> <p>Knew most recent viral load (unadjusted): Percent correct on literacy test: Knew: 89.5% Did not know: 77.4% Difference: ($P = 0.01$)</p> <p>Congruence between self-reported and chart-abstracted CD4 cell counts and viral loads (unadjusted): Percent correct on literacy test: Congruent: 92.2% Discrepant: 86.8% Difference: ($P = 0.03$)</p> <p>Discrepant self-reported CD4 counts or viral loads (adjusted): Lower versus higher literacy: OR = 3.7, 95% CI (1.1, 12.5)</p>	<p>Education Income Health literacy</p>	<p>Total: 1.08 1) 1 2) NA 3) 1 4) 1 5) NA 6) 1.5 7) 1 8) 1</p> <p>Funding Source: National Institute of Mental Health Center for AIDS Intervention Research</p>

Evidence Table 1: Key Question 1 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Kaufman et al., 2001</p> <p>Design: Cross-sectional</p> <p>Setting: Public health clinic, Albuquerque, New Mexico, including clinic and WIC office</p> <p>Duration: One interview</p>	<p>To examine the relationship between new mothers' literacy skills and their decision to breast-feed or bottle-feed their infants</p>	<p>New first-time mothers with infant between 2 and 12 months old</p> <p>English as first language</p> <p>Age: = 18</p> <p>Without vision deficits</p>	61 enrolled	<p>Age: 18 to 20: 49% 21 to 25: 28% 26 to 30: 16% 31 to 35: 7%</p> <p>Sex: Female: 100%</p> <p>Race/Ethnicity: White non-Hispanic: 41% Hispanic: 39% Other: 20%</p> <p>Income: < \$10,000/yr: 21% \$10,000 to \$20,000/yr: 38% \$21,000 to \$30,000/yr: 23%</p> <p>Insurance Status: NR</p> <p>Other Characteristics: NR</p>	NR

Evidence Table 1: Key Question 1 (continued)

Literacy Measurement	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
Measurement Tool: REALM Literacy Levels: = 9th: 64%* 7th to 8th: 36%*	Percent breast-feeding exclusively for at least 2 months (unadjusted): = 9th grade reading: 54% 7th to 8th grade reading: 23% Difference: ($P = 0.018$)	No multivariate analysis concerning literacy included	Total: 1.33 1) 1 2) NA 3) 1 4) 2 5) NA 6) 1.5 7) 2 8) 0.5 Funding Source: NR

Evidence Table 1: Key Question 1 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Li et al., 2000</p> <p>Design: Retrospective case study</p> <p>Setting: University surgical oncology service in a Shreveport, Louisiana, public hospital</p> <p>Duration: Median followup of 42 months</p>	<p>To determine the compliance with a standard BCT program in a predominantly indigent, minority population of patients with early breast cancer</p> <p>To compare the clinical outcomes of this group with those reported in clinical trials and to examine the socioeconomic factors that may have contributed to the rate of compliance</p> <p>Compliance defined as compliance with radiation therapy and clinical followup</p>	<p>Women with stage I or II breast cancer undergoing BCT from January 1990 to May 1995</p> <p>BCT defined as lumpectomy (partial mastectomy, segmentectomy, quadrantectomy) of the lesion with a microscopic tumor-free margin and complete level I and II axillary node dissection followed by radiation therapy</p>	<p>55</p> <p>Compliant: 20</p> <p>Non-compliant: 35</p>	<p>Mean Age: Compliant: 48 Noncompliant: 50</p> <p>Sex: Female: 100%</p> <p>Race/Ethnicity: Compliant group: White: 25% Black: 75% Noncompliant group: White: 40% Black: 60%</p> <p>Income: NR</p> <p>Insurance Status: Medicare: 18%* Commercial: 5%* Uninsured: 76%*</p> <p>Other Characteristics: NR</p>	<p>NR</p>

Evidence Table 1: Key Question 1 (continued)

Literacy Measurement	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
Measurement Tool: REALM	Only 36% of patients had full compliance	No multivariate analysis concerning literacy included	Total: 1.14
Literacy Levels:	Compliance with BCT (unadjusted):		1) 1
Compliant (n = 16):	64% did not complete some aspect of BCT program		2) NA
4th to 6th: 6%*	Lower literacy may be associated with lower compliance (data not shown)		3) 0.5
7th to 8th: 6%*			4) 2
> 9th: 88%*			5) 1
Noncompliant (n = 23):			6) 1.5
4th to 6th: 17%*			7) 1.5
7th to 8th: 17%*			8) 0.5
> 9th: 65%*			Funding Source: National Cancer Institute

Evidence Table 1: Key Question 1 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Lindau et al., 2002</p> <p>Design: Cross-sectional</p> <p>Setting: Women's health clinics at an academic medical center in Chicago, Illinois</p> <p>Duration: January to December 1999</p>	<p>To describe the relationship between health literacy, ethnicity, and cervical cancer screening practices</p> <p>To evaluate physician recognition of low literacy</p>	<p>Age: = 18 Language: English speaking Women only, clinic patients</p>	<p>601 approached</p> <p>584 eligible</p> <p>529 participated (91%)</p>	<p>Age: Mean: 27 Range: 18 to 54</p> <p>Sex: Female: 100%</p> <p>Race/Ethnicity: White: 14% AA: 58% Hispanic: 18%</p> <p>Income: NR</p> <p>Insurance Status: Medicaid: 72% Private insurance: 20% No insurance: 8%</p> <p>Other Characteristics: NR</p>	<p>1 to 6 yrs: 1% 7 to 8 yrs: 3% 9 to 12 yrs: 48% > 12 yrs: 47%</p>

Evidence Table 1: Key Question 1 (continued)

Literacy Measurement	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
<p>Measurement Tool: REALM</p> <p>Literacy Levels: Median score: 63 (score = 61 = high school level) 7th to 8th grade: 30% = 6th grade: 9%</p>	<p>Knowledgeable of purpose of Pap test (adjusted): Literacy > 9th grade versus = 9th grade: OR = 2.25, 95% CI (1.05, 4.80)</p> <p>Likelihood of seeking care in an emergency room or acute care facility (unadjusted): Below adequate literacy (less than high school) less likely than high school ($P < 0.001$)</p> <p>Likelihood of seeking care from a known provider (unadjusted): Below adequate literacy (less than high school) less likely than high school ($P < 0.001$)</p> <p>Physician perceptions of literacy (unadjusted): Estimations poorest among the lowest readers, overestimating the reading level 80% of the time Sensitivity of routine clinical encounter for detecting low literacy was poor (40.4%), many false-negative assessments</p>	<p>Education Employment Insurance Age Ethnicity Literacy</p>	<p>Total: 1.67</p> <p>1) 2 2) NA 3) 2 4) 2 5) NA 6) 2 7) 1 8) 1</p> <p>Funding Source: Northwestern Memorial Foundation</p>

Evidence Table 1: Key Question 1 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Miller et al., 2003</p> <p>Design: Prospective cohort</p> <p>Setting: Public hospital-affiliated HIV clinic between February 1998 and April 1999</p> <p>Duration: One interview</p> <p>Additional question on dosing at weeks 0, 8, 24, and 48</p>	<p>To investigate the association of knowledge of medication dosing with adherence among patients taking antiretroviral medication</p>	<p>HIV infected Enrolled in the ADEPT study, a new HAART regimen Spoke English or Spanish Attended = two ADEPT study visits during 48-week study</p>	<p>140 enrolled 128 had = two study visits and so available for the analyses</p>	<p>Age: Mean: 37 Range: 22 to 67</p> <p>Sex: Female: 20.3%</p> <p>Race/Ethnicity: White: 15.6% AA: 26.6% Hispanic: 46.9% Other/mixed: 10.9%</p> <p>Income: < \$10,000: 59.7%</p> <p>Insurance Status: NR</p> <p>Other Characteristics: Duration HIV infection: Mean: 13.3 ± 32.7 month Number of pills per day: 14.3 ± 5.7</p>	<p>< 12 yrs: 35.2% 12 to 15 yrs: 48.4% = 16 yrs: 16.4%</p>

Evidence Table 1: Key Question 1 (continued)

Literacy Measurement	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
Measurement Tool: S-TOFHLA, administered in English or Spanish Literacy Levels: Mean: 29.9 (SD 7.1) Range: 10 to 36	MKS at week 8 (unadjusted): Literacy: $r = 0.31$ ($P = 0.005$) Lower MKS prediction based on repeated measures at 0, 8, 24, and 48 weeks (adjusted): Associated with lower literacy ($P = 0.03$) For each 1-point increase in the 36-point literacy score, MKS increased by 0.5%	Income Education Age Clinical trial participation Language Social support Use of a device to complete knowledge survey Number of pills Literacy	Total: 1.71 1) 2 2) NA 3) 1.5 4) 2 5) 1 6) 1.5 7) 2 8) 2 Funding Source: National Institutes of Health

Evidence Table 1: Key Question 1 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Miller et al., 1996</p> <p>Design: Cross-sectional</p> <p>Setting: Ambulatory clinical trials of anti-infective agents</p> <p>Duration: One interview</p>	<p>To obtain basic descriptive statistical data for the DICCT</p> <p>To determine interscorer agreement of the scale</p> <p>To examine the DICCT's criterion validity</p> <p>To obtain participants' subjective ratings of the adequacy of clinical trials information</p>	<p>Entering one of four prospective, randomized, double-blind, multicenter, ambulatory trials of anti-infective agents</p> <p>Sequentially enrolled</p>	275	<p>Age: Mean: 36 (SD 12.8) Range: 18 to 78</p> <p>Sex: Female: 62%*</p> <p>Race/Ethnicity: NR</p> <p>Income: NR</p> <p>Insurance Status: NR</p> <p>Other Characteristics: NR</p>	<p>Mean: 14.4 yrs (SD 2.3)</p> <p>High school: 26%</p> <p>4-year college: 28%</p> <p>Range: 10 to 24 yrs (Data not available for 61 subjects)</p>

Evidence Table 1: Key Question 1 (continued)

Literacy Measurement	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
<p>Measurement Tool: WRAT</p> <p>Literacy Levels: Mean: 116.9 ± 14.8 Range: 70 to 140 Mean is equivalent to reading level > 12th grade</p>	<p>DICCT score (unadjusted): Correlation with WRAT: r = 0.38, suggesting moderate correlation (P < 0.01)</p> <p>Correlation with WAIS-R vocabulary subtest: r = 0.44, suggesting moderate correlation (P = 0.01)</p>	<p>No multivariate analysis concerning literacy included</p>	<p>Total: 1.33</p> <p>1) 1 2) NA 3) 2 4) 2 5) NA 6) 1.5 7) 1 8) 0.5</p> <p>Funding Source: NR</p>

Evidence Table 1: Key Question 1 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Moon et al., 1998</p> <p>Design: Prospective cohort</p> <p>Setting: Five sites in metropolitan Washington, DC area: urban hospital-based ambulatory care center, urban HMO pediatric ambulatory care center, and three suburban practices</p> <p>January to May 1996</p> <p>Duration: Two interviews, second 48 to 96 hours after the first</p>	<p>To ascertain the impact of literacy level on parents' understanding of medical information and ability to follow therapy prescribed for their children</p>	<p>Included: Parents accompanying their children for acute care visits between January 30, 1996, and May 31, 1996</p> <p>Excluded: English not primary language Adult present not the primary caretaker for the child Not available for telephone followup Child being seen for well-child care</p>	<p>679 invited 17 excluded 29 refused 633 enrolled</p>	<p>Age: Mean: 32.4 Range: 13 to 78</p> <p>Sex: Female: 85.8%</p> <p>Race/Ethnicity: White: 32.2% AA: 65.7% Hispanic: 1.6%</p> <p>Income: NR</p> <p>Insurance Status: Commercial: 49.8% Medicaid: 42.7% Uninsured: 7.6%</p> <p>Other Characteristics: Hollingshead social status scale: Mean: 3.9 (corresponding to smaller business owners and skilled manual workers)</p>	<p>Mean: 13.43 yrs (SD 2.09) Range: 7 to 16 yrs</p>

Evidence Table 1: Key Question 1 (continued)

Literacy Measurement	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
Measurement Tool: REALM Literacy Levels: = 3rd: 1.9% 4th to 6th: 7.6% 7th to 8th: 34.7% = 9th: 55.8%	Parental knowledge of health maintenance procedures and child health measures: Up-to-date well-child visits: Unadjusted ($P = 0.009$) and adjusted ($P = \text{NS}$) correlation with REALM Knowledge of when the next well-child visit: Unadjusted: ($P = 0.026$) and adjusted ($P = \text{NS}$) correlation with REALM Up-to-date dental visits: Unadjusted ($P = 0.05$) and adjusted ($P = \text{NS}$) correlation with REALM Number of chronic medical problems: Unadjusted ($P = \text{NS}$) and adjusted ($P = \text{NS}$) correlation with REALM Number of hospitalizations: Unadjusted ($P = \text{NS}$) and adjusted ($P = \text{NS}$) correlation with REALM Parental perception of how sick child is: Unadjusted ($P = 0.0049$) and sig correlation with REALM in adjusted model (low-literate parents considered their children to be more sick) Parental understanding of medical information (adjusted): Diagnosis: Correlation with REALM ($P = \text{NS}$) Medication name/instructions: Correlation with REALM ($P = \text{NS}$) Medication purpose: Correlation with REALM ($P = \text{NS}$) Obtain medicine same day: Correlation with REALM ($P = \text{NS}$) Miss no doses: Correlation with REALM ($P = \text{NS}$)	Parental age Race Parental education REALM score	Total: 1.93 1) 2 2) NA 3) 2 4) 2 5) 1.5 6) 2 7) 2 8) 2 Funding Source: NR

Evidence Table 1: Key Question 1 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Ross et al., 2001</p> <p>Design: Cross-sectional</p> <p>Setting: Diabetes clinic at Royal Hospital for Sick Children in Edinburgh, Scotland</p> <p>Duration: One interview</p>	<p>To examine the relationship between mother's and child's intelligence and social class and glycemic control in children with type 1 diabetes</p>	<p>Included: Children attending the clinic and their mothers</p> <p>Excluded: Age: < 5 Children with special needs Families in which English was not the first language Duration of diabetes less than 1 yr One sibling if two affected in one family Children accompanied by their fathers</p>	<p>78 children and their mothers</p> <p>150 recruited</p> <p>102 eligible</p>	<p>Age: Median: 12 Range: 5 to 17</p> <p>Sex: Female: 51%</p> <p>Race/Ethnicity: NR</p> <p>Income: Social class: 1: 5% 2: 35% 3 (nonmanual): 16% 3 (manual): 17% 4: 1% 5: 26%</p> <p>Insurance Status: NR</p> <p>Other Characteristics: Mean duration of diabetes: 5 yrs Range: 1 to 13 yrs</p>	NR

Evidence Table 1: Key Question 1 (continued)

Literacy Measurement	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
Measurement Tool: Children: WRAT3 Mothers: NART	Glycemic control measured by averaging four values obtained over 1 yr	Age Sex Duration of diabetes Daily insulin dose WRAT RSPM NART Social class	Total: 1.58 1) 1.5 2) NA 3) 1.5 4) 2 5) NA 6) 2 7) 1 8) 1.5
Literacy Levels: Mean, standardized: Boys: 101.1 Girls: 106.9 Mean NART mothers: 20.2	Correlation between WRAT3 and glycemic control (unadjusted): $r = 0.21$ (raw score), $r = 0.10$ (standardized) ($P = \text{NS}$)		Funding Source: Novo Nordisk Pharmaceuticals Ltd.
	Correlation between maternal NART score and glycemic control (unadjusted): $r = 0.28$ ($P = 0.01$)		
	Glycemic control (adjusted): Sig predictors were child's age, NART		

Evidence Table 1: Key Question 1 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Schillinger et al., 2002</p> <p>Design: Cross-sectional</p> <p>Setting: Family practice and general internal medicine clinic at San Francisco General Hospital, a public hospital</p> <p>Duration: One interview, enrolled June to December 2000</p>	<p>To examine the association between health literacy and diabetes outcomes among patients with type 2 diabetes</p>	<p>Included: > 30 yrs old English or Spanish speaking Type 2 diabetes Database recorded visit with primary care physician in one of the clinics in last 12 months and at least one additional visit to the same physician within the prior 6 months</p> <p>Excluded: End-stage renal disease Psychotic disorder Dementia Blindness (corrected vision of 20/50 or worse excluded)</p>	<p>858 potentially eligible</p> <p>162 ineligible</p> <p>261 did not make visit during enrollment period</p> <p>36 refused</p> <p>17 too ill to participate</p> <p>413 completed questionnaire</p> <p>408 had HbA1C available in database</p>	<p>Age: Mean: 58.1 SD: 11.4</p> <p>Sex: Female: 58% Male: 42%</p> <p>Race/Ethnicity: White: 15% Black: 25% Latino: 42% Asian: 18%</p> <p>Income: < \$20,000/yr: 93%</p> <p>Insurance Status: Uninsured: 32% Medicare: 36% Medicaid: 23% Commercial: 9%</p> <p>Other Characteristics: Language: Spanish: 36% English: 64% Depression score: (possible range: 0 to 100): 38.5 (SD 22.5) Yrs with diabetes: Mean: 9.5 (SD 8.0) Received diabetes education: 78%</p>	<p>Some high school or less: 46% High school graduate or GED: 23% College graduate or some college: 28% Graduate degree: 3%</p>

Evidence Table 1: Key Question 1 (continued)

Literacy Measurement	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
<p>Measurement Tool: S-TOFHLA, English or Spanish version</p> <p>Literacy Levels: Adequate: 49% Marginal: 13% Inadequate: 38%</p>	<p>Relationship between literacy (measured as continuous S-TOFHLA score) and HbA1C (adjusted): For every 1-point increase on S-TOFHLA score, 0.02-point decrease in HbA1C ($P = 0.02$)</p> <p>Literacy and percentage with HbA1C < 7.2% (tight control) (adjusted): Inadequate: 20% Adequate: 33% OR = 0.57, 95% CI (0.32, 1.0) ($P = 0.05$)</p> <p>Literacy and percentage with HbA1C > 9.5% (poor control) (adjusted): Inadequate: 30% Adequate: 20% OR = 2.03, 95% CI (1.11, 3.73) ($P = 0.02$)</p> <p>Literacy and self-reported retinopathy (adjusted): Inadequate: 36% Adequate: 19% OR = 2.33, 95% CI (1.19, 4.57) ($P = 0.01$)</p> <p>Literacy and self-reported nephropathy (adjusted): OR = 1.71, 95% CI (0.75, 3.90) ($P = 0.20$)</p> <p>Literacy and self-reported lower extremity amputation (adjusted): OR = 2.48, 95% CI (0.74, 8.34) ($P = 0.14$)</p> <p>Literacy and self-reported cerebrovascular disease (adjusted): OR = 2.71, 95% CI (1.06, 6.97) ($P = 0.04$)</p> <p>Literacy and self-reported ischemic heart disease (adjusted): OR = 1.73, 95% CI (0.83, 3.60) ($P = 0.15$)</p>	<p>Age Sex Race Education Insurance Language Social support Depression Treatment regimen Yrs with diabetes Diabetes education S-TOFHLA score Accounted for clustering of patients within physicians Retinopathy and nephropathy models also controlled for hypertension and smoking, extremity amputation, cerebrovascular disease, and ischemic heart disease</p>	<p>Total: 2.0 1) 2 2) NA 3) 2 4) 2 5) NA 6) 2 7) 2 8) 2</p> <p>Funding Source: University of California, San Francisco Pfizer Pharmaceuticals Agency for Healthcare Research and Quality National Institutes of Health</p>

Evidence Table 1: Key Question 1 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Scott et al., 2002</p> <p>Design: Cross-sectional</p> <p>Setting: Four Prudential managed care plans (Cleveland, Ohio; Houston, Texas; Tampa, Florida; Ft. Lauderdale-Miami, Florida (south Florida))</p> <p>Data collection between fall and winter of 1996 to 1997</p> <p>Duration: One interview</p>	<p>To determine if persons with low functional health literacy among community-dwelling Medicare enrollees in a national managed care organization had lower reported levels of preventive care utilization</p>	<p>Included: Age: 65 to 79 3 months after enrollment in health plan Language: English or Spanish</p> <p>Excluded: Dementia: Missed one or more screening questions (not able to correctly identify year, month, state, year of birth, home address) Those with severe cognitive impairment as measured by the MMSE Visual acuity: Severe impairment not correctable with eyeglasses</p>	<p>2,722</p> <p>7,471 contacted</p> <p>3,247 refused</p> <p>737 ineligible</p> <p>143 did not come to interview</p> <p>3,487 agreed to participate</p> <p>538 older than 80</p> <p>84 did not complete S-TOFHLA</p>	<p>Age: Mean: 71</p> <p>Sex: Adequate: 58% Marginal: 52% Inadequate: 55%</p> <p>Race/Ethnicity: Adequate: White: 83% Black: 7% Hispanic: 8% Marginal: White: 63% Black: 14% Hispanic: 22% Inadequate: White: 50% Black: 29% Hispanic: 20%</p> <p>Income: < \$15,000/yr: Adequate: 32% Marginal: 50% Inadequate: 62%</p> <p>Insurance Status: Medicare: 100%</p> <p>Other Characteristics: Doctor visit in last 3 months: Adequate: 87% Marginal: 82% Inadequate: 86% Chronic health condition: Adequate: 64% Marginal: 68% Inadequate: 70% Limitation in IADL: Adequate: 22% Marginal: 33% Inadequate: 39%</p>	<p>Adequate: < high school: 22% High school: 39% > high school: 39%</p> <p>Marginal: < high school: 53% High school: 28% > high school: 20%</p> <p>Inadequate: < high school: 68% High school: 22% > high school: 10%</p>

Evidence Table 1: Key Question 1 (continued)

Literacy Measurement	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
<p>Measurement Tool: S-TOFHLA, administered in English or Spanish</p> <p>Literacy Levels: Adequate: 69% Marginal: 11% Inadequate: 20%</p>	<p>Odds of Having Received Preventive Care Services (adjusted):</p> <p>Literacy: Inadequate, marginal versus adequate</p> <p>Never had influenza vaccine: Inadequate: OR = 1.4, 95% CI (1.1, 1.9) Marginal: OR = 1.0, 95% CI (0.7, 1.4)</p> <p>Never had pneumococcal vaccine (multivariate model does not control for IADL): Inadequate: OR = 1.2, 95% CI (1.1, 1.7) Marginal: OR = 1.2, 95% CI (0.9, 1.7)</p> <p>No mammogram in past 2 yrs (multivariate model does not control for sex, chronic conditions, IADL): Inadequate: OR = 1.5, 95% CI (1.0, 2.2) Marginal: OR = 1.0, 95% CI (0.6, 1.5)</p> <p>Never had Pap smear (multivariate model does not control for sex, chronic conditions, IADL): Inadequate: OR = 1.7, 95% CI (1.0, 3.1) Marginal: OR = 2.4, 95% CI (1.2, 4.7)</p> <p>Differences in educational attainment not sig in any of these multivariate models</p>	<p>Study location</p> <p>Age</p> <p>Sex</p> <p>Race</p> <p>Education</p> <p>Income</p> <p>Any doctor visits (last 3 months)</p> <p>MMSE</p> <p>Chronic condition</p> <p>IADL limitation</p> <p>Literacy</p>	<p>Total: 1.92</p> <p>1) 2</p> <p>2) NA</p> <p>3) 2</p> <p>4) 2</p> <p>5) NA</p> <p>6) 1.5</p> <p>7) 2</p> <p>8) 2</p> <p>Funding Source: Robert Wood Johnson Foundation</p>

Evidence Table 1: Key Question 1 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Spandorfer et al., 1995</p> <p>Design: Prospective observational study</p> <p>Setting: Emergency department of hospital in a Philadelphia inner-city area with a high poverty rate</p> <p>Duration: April to October 1992</p>	<p>To assess patients' comprehension of their ED discharge instructions</p> <p>To determine if inner-city patients' literacy levels are adequate to comprehend written discharge instructions</p>	<p>Included: All patients discharged from the ED during 12 6-hour periods</p> <p>Excluded: Unwilling to participate Impaired visual acuity rendering them unable to read Unable to communicate in English and no translator Literacy of caretaker measured for children, mentally disabled, and non-English-speaking patients</p>	<p>228 eligible 5 refused 6 ineligible 217 included</p>	<p>Age: Mean: 36.0 (SD 16.6)</p> <p>Sex: Female: 51.6%</p> <p>Race/Ethnicity: White: 6.9% Black: 82% Hispanic: 8.8% Asian: 0.5%</p> <p>Income: NR</p> <p>Insurance Status: NR</p> <p>Other Characteristics: English as native language: 90.8% Patient identity: Patient: 91.7% Parent or guardian: 4.1% Caretaker: 0.5% Translator: 0.5%</p>	<p>Mean highest grade: 10.4 (SD 1.9)</p>

Evidence Table 1: Key Question 1 (continued)

Literacy Measurement	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
<p>Measurement Tool: WRAT</p> <p>Literacy Levels: Mean: 42.6 ± 14.8 (corresponds to a 6th grade reading level) = 4th grade: 40%</p>	<p>Comprehension of instructions scored on a scale from 1 to 5 (from no to excellent understanding) (adjusted): WRAT score positively related (<i>P</i> = 0.024) Mean comprehension score: 4.2 23% had no understanding of at least one component of the instructions Discharge instruction sheets: 11th grade based on Flesch and Gunning-Fogg indices; information also provided verbally by physician to some (unmeasured) extent</p>	<p>Education Age Sex Race Residence Primary language Level of physician training Sex of physician Medical versus surgical section of ED Time of discharge Literacy</p>	<p>Total: 1.75 1) 1.5 2) NA 3) 2 4) 2 5) NA 6) 1 7) 2 8) 2</p> <p>Funding Source: NR</p>

Evidence Table 1: Key Question 1 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Stanton et al., 1990</p> <p>Design: Prospective cohort</p> <p>Setting: Followup study of children born at Queen Mary Maternity Hospital, Dunedin, New Zealand</p> <p>Duration: Measured at birth, ages 3, 5, 7, 11, 13, and 15</p>	<p>To examine the relative value of measures of family adversity, reading, and IQ as predictors of problem behavior and hence their relevance to models of problem behavior</p>	<p>Born at Queen Mary Maternity Hospital, Dunedin, NZ between April 1, 1972 and March 31, 1973</p> <p>More detailed description of cohort elsewhere (Silva)</p> <p>Children enrolled in DMHDS</p>	<p>Original cohort: 1,139</p> <p>Age 3: 1,037 Age 5: 991 Age 7: 954 Age 9: 955 Age 11: 925 Age 13: 859 Age 15: 976</p> <p>For this study, 779 children had complete data and included in analysis</p>	<p>Age: Data used from various ages</p> <p>Sex: Female: 48% Male: 52%</p> <p>Race/Ethnicity: Predominantly European 3% Polynesian</p> <p>Income: NR</p> <p>Insurance Status: NR</p> <p>Other Characteristics: Family occupational background at child age 3: Unskilled: 22% Semiskilled: 55% Skilled: 23%</p>	<p>NA</p>

Evidence Table 1: Key Question 1 (continued)

Literacy Measurement	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
Measurement Tool: Burt Word Reading Test, 1974 Revision Literacy Levels: NR Used in regression analysis	Correlations between family adversity scores, IQ scores, and reading ability for boys and girls (all $P < 0.01$) (unadjusted): Reading ability/family adversity: Boys: $r = -0.26$ Girls: $r = -0.26$ Reading ability/preschool IQ: Boys: $r = 0.46$ Girls: $r = 0.54$ Reading ability/school-age IQ: Boys: $r = 0.63$ Girls: $r = 0.64$ Change in problem behavior during primary school yrs (adjusted): Reading ability sig prediction in model 1 (entered as variable 4) and model 2 (entered as variable 3)	Step-wise models: Model 1: Family adversity Early problem behavior School-age IQ Model 2: Family adversity Early problem behavior School-age IQ	Total: 1.42 1) 1 2) NA 3) NA 4) 2 5) 1.5 6) 1 7) 1.5 8) 1.5 Funding Source: Medical Research Council of New Zealand

Evidence Table 1: Key Question 1 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Sullivan et al., 1995</p> <p>Design: Cross-sectional</p> <p>Setting: General medicine practice at Regenstrief Health Center, Indianapolis, Indiana</p> <p>Duration: Completion of questionnaires at 6-month intervals over 3 yrs</p>	<p>To conduct a formal methodologic comparison of the response rates, item completion rates, and reliability of self-reported health status measures by three different methods of data collection</p>	<p>Type 2 diabetes mellitus Primary care physician enrolled in PORT study</p>	<p>983 eligible 697 agreed to participate (70.9%)</p>	<p>Age: QLS fail: Mean: 64.5 QLS pass: Mean: 58.5</p> <p>Sex: QLS fail: Female: 70.4% QLS pass: Female: 73.3%</p> <p>Race/Ethnicity: QLS fail: AA: 64.2% QLS pass: AA: 57.1%</p> <p>Income: < \$5,000: QLS fail: 65.5% QLS pass: 46.6%</p> <p>Insurance Status: NR</p> <p>Other Characteristics: Currently working: QLS fail: 8.0% QLS pass: 15.2% Fair or poor self-reported vision: QLS fail: 64.8% QLS pass: 46.4%</p>	<p>QLS fail: Mean: 8.0 yrs QLS pass: Mean: 10.9 yrs</p>

Evidence Table 1: Key Question 1 (continued)

Literacy Measurement	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
Measurement Tool: QLS Literacy Levels: Pass: 65% Fail: 35%	General health status (based on SF-36) (unadjusted): Mean scores on the eight dimensions of SF-36 were not sig different between patients who passed and failed the QLS, with the exception of physical function Patients who failed reported significantly poorer physical functioning: Mean: 33.5 versus 39.2 ($P < 0.05$)	No multivariate analysis concerning literacy included	Total: 1.50 1) 1.5 2) NA 3) 2 4) 1.5 5) NA 6) 1.5 7) 1.5 8) 1 Funding Source: Agency for Healthcare Policy and Research

Evidence Table 1: Key Question 1 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: TenHave et al., 1997</p> <p>Design: Cross-sectional</p> <p>Setting: Cholesterol screenings in local supermarkets; recruited for participation in CARDES</p> <p>Duration: Repeated interviews</p>	<p>To report on the development and use of an easy-to-administer literacy screening instrument and to determine the relationship of reading levels ascertained in this way to the sociodemographic and health profiles of nutrition program participants</p>	<p>Age: 40 to 70 Washington, DC, area</p>	<p>339 (Response rate NR; no information provided to calculate)</p>	<p>Age: 40 to 54: 41% 55 to 70: 59% Range: 40 to 70</p> <p>Sex: Female: 74%</p> <p>Race/Ethnicity: AA: 99%</p> <p>Income: < \$10,000: 38%</p> <p>Insurance Status: NR</p> <p>Other Characteristics: Occupation: Administrative/managerial: 12% Professionals/teachers/school personnel: 40% Technicians/clinicians: 8% Labor, maintenance, factory worker: 21% Service occupations, safety, security: 19%</p> <p>Hypertension: 50% Cholesterol > 200 mg/day: 86% History of heart attack: 6% History of hospitalization for heart condition: 12% Diabetes: 14%</p> <p>Leisure activity light/inactive: 79% Work activity light/inactive: 74%</p> <p>Rate Your Plate Knowledge: 20 to 33 (least knowledgeable): 9% 34 to 47 (somewhat knowledgeable): 55% 48 to 60 (very knowledgeable): 36%</p>	<p>< 8 yrs: 8% 8 to 11 yrs: 20% 12 yrs: 32% > 12 yrs: 38%</p>

Evidence Table 1: Key Question 1 (continued)

Literacy Measurement	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
<p>Measurement Tool: CARDES (developed for this study)</p> <p>Score 0 to 9: < 5th grade reading level 10 to 16: 5th to 8th grade reading level 17 to 20: > 8th grade reading level</p> <p>Similar to REALM and TABE</p> <p>Rank order correlation with REALM: Not given; with TABE: 0.73 (Cronbach's alpha 0.87)</p> <p>Literacy Levels (grade level): < 5th: 15% 5th to 8th: 33% > 8th: 52%</p>	<p>Health outcomes (adjusted) by CARDES literacy score:</p> <p>Heart Healthy Knowledge: 0 to 9: 28% 10 to 16: 31% 17 to 20: 42% (<i>P</i> = NR)</p> <p>Heart attack: 0 to 9: 14% 10 to 16: 4% 17 to 20: 3% (<i>P</i> = 0.012)</p> <p>Hospitalized for heart condition: 0 to 9: 24% 10 to 16: 12% 17 to 20: 7% (<i>P</i> = 0.003)</p> <p>Diabetes: 0 to 9: 20% 10 to 16: 20% 17 to 20: 10% (<i>P</i> = 0.053)</p> <p>Depression score, mean: 0 to 9: 4.58 10 to 16: 3.50 17 to 20: 2.56 (<i>P</i> = 0.0001)</p> <p>Information in alternate formats by CARDES literacy score (unadjusted):</p> <p>Used nutrition guide more than audio series: 0 to 16: 19% 17 to 20: 28% (<i>P</i> = 0.02)</p> <p>Used nutrition guide and audio series equally: 0 to 16: 27% 17 to 20: 28% (<i>P</i> = NR)</p> <p>Used audio series more than nutrition guide: 0 to 16: 54% 17 to 20: 28% (<i>P</i> = NR)</p>	<p>Age Sex Literacy</p>	<p>Total: 0.67</p> <p>1) 1 2) NA 3) 0 4) 1.5 5) NA 6) 0.5 7) 1 8) 0</p> <p>Funding Source: National Heart, Lung, and Blood Institute</p>

Evidence Table 1: Key Question 1 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Weiss et al., 1994</p> <p>Design: Retrospective cohort</p> <p>Setting: Members of a large Medicaid managed care plan in Tucson, Arizona</p> <p>Duration: 12 months</p>	<p>To determine the literacy skills of a population of Medicaid enrollees and if there was an association between their literacy skills and their health care costs</p>	<p>Included: Age: = 18 English or Spanish speaking Qualified for Medicaid because of AFDC eligibility, disability, or medical need/indigence Enrolled in the program for at least 1 yr prior to the start of the research</p> <p>Excluded: Those with medical conditions that might preclude an accurate assessment of reading skills (e.g., dementia, mental retardation, severe visual impairment) Those with congenital or hereditary disorders, including schizophrenia, which by themselves could affect medical costs independent of any possible relationship to literacy skills Patients who had been pregnant during the year of study to avoid confounding by charges of relating to pregnancy care</p>	<p>402 willing to participate (approximately 75% of potential subjects)</p> <p>(1) Computer generated random selection; (2) letter followed by phone call; (3) if no answer to repeated calls or unwilling to participate, an alternate subject selected at random</p>	<p>Age: Mean: 49.0 Range: 18 to 94</p> <p>Sex: Female: 78.4% Male: 21.6%</p> <p>Race/Ethnicity: White: 42.8% AA: 5.5% Hispanic: 45.8% Native American: 0.5% Asian: 0.5% Other: 3.7%</p> <p>Income: NR</p> <p>Insurance Status: Medicaid: 100%</p> <p>Other Characteristics: Marital status: Married: 20.2% Single: 35.8% Divorced: 32.6% Widowed: 11.2% Separated: 0.2% Employment status: Unemployed: 84.1% Working: 6.0% Not reported: 9.9% Self-assessment of health: Excellent: 5.5% Good: 35.3% Fair: 42.5% Poor: 16.7% Language of best skill: English: 80.1% Spanish: 19.9% Medicaid enrollment category: Disabled: 55.5% AFDC: 26.1% Needy/indigent: 18.4%</p>	<p>Mean: 9.7 yrs (SD 3.7) Range: 0 to 13 yrs</p>

Evidence Table 1: Key Question 1 (continued)

Literacy Measurement	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
<p>Measurement Tool: IDL</p> <p>Literacy Levels: Grade equivalent: 0: 8.7% 1: 4.7% 2: 5.1% 3: 5.6% 4: 4.2% 5: 5.2% 6: 13.7% 7: 14.2% = 8: 38.6%</p> <p>Mean reading levels: English speaking: 6.3 Spanish speaking: 3.1 (<i>P</i> = 0.018)</p>	<p>Medicaid charges: Entire cohort: Median: \$1,100 Range: \$0 to \$95,002 Mean: \$4,574</p> <p>Charges by grade level (median): 0: \$938 1: \$1,442 2: \$744 3: \$392 4: \$944 5: \$2,041 6: \$1,000 7: \$1,430 = 8: \$1,367</p> <p>Medicaid charges (adjusted): Relationship with literacy level: $R^2 = 0.0016$ (<i>P</i> = 0.43)</p> <p>Various components of medical charges (adjusted) including inpatient care, outpatient care, emergency care, home health care, physicians' fees, ancillary services such as laboratory, x-ray, pharmacy, durable medical equipment, short-term nursing home care: No sig relationship with literacy level</p>	<p>Not listed, although stated that they conducted multivariate analyses controlling for confounders</p>	<p>Total: 1.50 1) 1.5 2) NA 3) 1.5 4) 2 5) NA 6) 2 7) 1.5 8) 0.5</p> <p>Funding Source: Arizona Disease Control Research Commission (Arizona Department of Health and Human Services)</p>

Evidence Table 1: Key Question 1 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Weiss et al., 1992</p> <p>Design: Cross-sectional, participants selected randomly from within each class</p> <p>Setting: PACE program in Tucson, Arizona</p> <p>Duration: One interview</p>	<p>To determine whether a relation exists between literacy and health status among a group of US adults with poor literacy skills</p>	<p>Included: Student in PACE Reading skills between grade level 0 and 12.9 Spoke and understood English well enough to participate in study English spoken in the home when children Age: = 16</p> <p>Excluded: Mentally retarded Known learning disability</p>	<p>197 met eligibility requirements</p> <p>193 agreed to participate</p>	<p>Age: Mean: 28.5 (SD 10.6)</p> <p>Sex: Female: 61%</p> <p>Race/Ethnicity: White: 29.5% Black: 9.8% Hispanic: 53.4% Native American: 6.7% Other: 0.6%</p> <p>Income: Mean: \$7,610/yr (SD \$7,020/yr)</p> <p>Insurance Status: NR</p> <p>Other Characteristics: Language spoken in childhood home: English only: 71.0% English and Spanish: 26.9% Country of birth: US: 91.2% Mexico: 6.7%</p>	<p>Mean: Grade 9.9 (SD 1.96)</p>

Evidence Table 1: Key Question 1 (continued)

Literacy Measurement	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
<p>Measurement Tool: Tests of Adult Basic Education and Mott Basic Language Skills Program</p> <p>Literacy Levels: Mean grade: 7.17 (\pm 2.77) = 4th: 19% 5th to 6th: 20% 7th to 8th: 23%* = 9th: 37%*</p>	<p>Score on SIP (questionnaire) measuring health status; higher SIP score indicates poorer health (adjusted):</p> <p>Mean physical score: = 4th reading: 6.2 > 4th reading: 2.3 Difference: ($P = 0.002$)</p> <p>Mean psychosocial score: = 4th reading: 15.4 > 4th reading: 8.0 Difference: ($P = 0.02$)</p> <p>Mean overall (total): = 4th reading: 10.4 > 4th reading: 6.0 Difference: ($P = 0.02$)</p>	<p>Age Sex Ethnicity Marital status Insurance status Occupation Income Literacy</p>	<p>Total: 1.92</p> <p>1) 2 2) NA 3) 2 4) 2 5) NA 6) 2 7) 1.5 8) 2</p> <p>Funding Source: University of Arizona Foundation</p>

Evidence Table 1: Key Question 1 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Williams, Baker, Honig, et al., 1998</p> <p>Design: Cross-sectional</p> <p>Setting: Emergency department and asthma clinic at Grady Memorial Hospital, an urban public hospital in Atlanta, Georgia</p> <p>Duration: November 1995 to May 1996</p>	<p>To determine the relationship of literacy to asthma knowledge and ability to use an MDI among patients with asthma</p>	<p>Included: Treatment for asthma in the ED or AC Age: = 18 = 3-month history of asthma No prior diagnosis of COPD, emphysema, chronic bronchitis</p> <p>Excluded: Intoxication Overt psychiatric illness Lack of cooperation Native language other than English Too ill to participate Vision worse than 20/100 Prior enrollment in the study</p>	<p>Enrolled sequentially based in patients attending ED or AC at certain days and times</p> <p>ED: 398</p> <p>approached, 25 excluded, 57 refused, 48 failed to complete survey</p> <p>AC: 255 approached, 16 excluded, 12 refused, 10 failed to complete survey</p> <p>Total: 510 completed survey, 483 completed REALM, 469 completed MDI assessment, 483 included in analysis</p>	<p>Age: ED: Mean: 37.3 (SD 13.6) AC: Mean: 46.7 (SD 14.9)</p> <p>Sex: Female: ED: 59% AC: 81%</p> <p>Race/Ethnicity: ED: White: 5% Black: 95% AC: White: 11% Black: 89%</p> <p>Income: NR</p> <p>Insurance Status: ED: Insured: 38% AC: Insured: 54%</p> <p>Other Characteristics: Yrs of asthma: ED: = 1: 3% 2 to 5: 11% 6 to 10: 13% 11 to 20: 21% > 20: 52% AC: = 1: 8% 2 to 5: 23% 6 to 10: 14% 11 to 20: 17% > 20: 38%</p>	<p>ED: = 6 yrs: 3% 7 to 11: 29% 12: 40% > 12: 28%</p> <p>AC: = 6 yrs: 5% 7 to 11: 30% 12: 34% > 12: 30%</p>

Evidence Table 1: Key Question 1 (continued)

Literacy Measurement	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score																								
Measurement Tool: REALM Literacy Levels: = 3rd: 13% 4th to 6th: 27% 7th to 8th: 33% = 9th: 27%	Mean knowledge score (range 0 to 20) (unadjusted): = 9th literacy level: 15.1 = 3rd literacy level: 11.9 r = 0.36 Knowledge increased at each of the four literacy levels ($P < 0.01$) Asthma knowledge score (adjusted): Relationship with literacy level (= 9th grade comparison group): <table border="1"> <thead> <tr> <th>Literacy</th> <th>Coefficient</th> <th>P value</th> </tr> </thead> <tbody> <tr> <td>= 3rd</td> <td>-2.8</td> <td>< 0.001</td> </tr> <tr> <td>4th to 6th</td> <td>-1.5</td> <td>< 0.001</td> </tr> <tr> <td>7th to 8th</td> <td>-1.1</td> <td>< 0.001</td> </tr> </tbody> </table> <p>Difference in knowledge score between those reading at = 9th grade and those reading at = 3rd grade (adjusted): 2.7 points, 95% CI (1.9, 3.5)</p> <p>Metered dose inhaler skills (0 to 6 steps) (adjusted):</p> <table border="1"> <thead> <tr> <th>Literacy</th> <th>Coefficient</th> <th>P value</th> </tr> </thead> <tbody> <tr> <td>= 3rd</td> <td>-1.3</td> <td>< 0.001</td> </tr> <tr> <td>4th to 6th</td> <td>-0.7</td> <td>< 0.001</td> </tr> <tr> <td>7th to 8th</td> <td>-0.2</td> <td>0.13</td> </tr> </tbody> </table> <p>Difference in number of correct metered dose inhaler steps between patients reading at = 9th to those reading at = 3rd: 1.3 steps, 95% CI (0.9, 1.7)</p>	Literacy	Coefficient	P value	= 3rd	-2.8	< 0.001	4th to 6th	-1.5	< 0.001	7th to 8th	-1.1	< 0.001	Literacy	Coefficient	P value	= 3rd	-1.3	< 0.001	4th to 6th	-0.7	< 0.001	7th to 8th	-0.2	0.13	Yrs of schooling Self-perceived better understanding of asthma Reported regular source of care Age Duration of asthma Health status Insurance status Site of study entry Literacy	Total: 1.83 1) 2 2) NA 3) 1.5 4) 2 5) NA 6) 1.5 7) 2 8) 2 Funding Source: NR
Literacy	Coefficient	P value																									
= 3rd	-2.8	< 0.001																									
4th to 6th	-1.5	< 0.001																									
7th to 8th	-1.1	< 0.001																									
Literacy	Coefficient	P value																									
= 3rd	-1.3	< 0.001																									
4th to 6th	-0.7	< 0.001																									
7th to 8th	-0.2	0.13																									

Evidence Table 1: Key Question 1 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Williams, Baker, Parker, et al., 1998</p> <p>Design: Cross-sectional</p> <p>Setting: Grady Memorial Hospital, Atlanta, Georgia, and the Harbor-UCLA Medical Center general medicine clinic in Torrance, California (both are public hospitals)</p> <p>Duration: One interview</p>	<p>To examine the relationship between functional health literacy level and knowledge of their chronic disease and treatment among patients with hypertension or diabetes</p>	<p>Included: HTN or DM At least one medication Age: = 18 Not previously enrolled in any literacy studies No overt psychiatric illness Not in police custody Not too ill to participate No unintelligible speech No lack of cooperation Registered into the clinic and waiting to see a physician Vision equal to or better than 20/100</p> <p>Excluded: Grady only: English as second language</p>	<p>Harbor: 488 screened, 386 eligible, 364 completed interview</p> <p>Grady: 284 screened, 250 eligible, 216 completed interview</p>	<p>Mean Age: HTN (n = 402): Adequate: 53.4 Marginal: 57.7 Inadequate: 64.2 DM (n = 114): Adequate: 49.8 Marginal: 53.2 Inadequate: 57.5</p> <p>Sex: Female: HTN (n = 402): Adequate: 72% Marginal: 88% Inadequate: 69% DM (n = 114): Adequate: 67% Marginal: 69% Inadequate: 76%</p> <p>Race/Ethnicity: HTN (n = 402): Adequate: White: 17% Black: 64% Latino: 16% Marginal: White: 4% Black: 78% Latino: 18% Inadequate: White: 5% Black: 72% Latino: 22.5% DM (n = 114): Adequate: White: 33% Black: 37% Latino: 29% Marginal: White: 0% Black: 31% Latino: 69% Inadequate: White: 2% Black: 18% Latino: 80%</p>	<p>HTN (n=402): Adequate: = 6th: 2% 7th to 11th: 31% 12th: 37% Marginal: = 6th: 10% 7th to 11th: 56% 12th: 26% Inadequate: = 6th: 42% 7th to 11th: 40% 12th: 15% DM (n = 114): Adequate: = 6th: 2% 7th to 11th: 29% 12th: 37% Marginal: = 6th: 39% 7th to 11th: 39% 12th: 15% Inadequate: = 6th: 78% 7th to 11th: 16% 12th: 4%</p>

Evidence Table 1: Key Question 1 (continued)

Literacy Measurement	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
<p>Measurement Tool: TOFHLA</p> <p>Literacy Levels: HTN (n = 402): Adequate: 39% Marginal: 12% Inadequate: 49% DM (n = 114): Adequate: 45% Marginal: 11% Inadequate: 44%</p>	<p>HTN: Knowledge measured by 21 item test (unadjusted): Adequate: 16.5 ± 2.3 Marginal: 15.2 ± 2.2 Inadequate: 13.2 ± 3.1 Difference: (<i>P</i> < 0.001)</p> <p>Difference between inadequate and adequate literacy (adjusted): OR = 1.9, 95% CI (1.2, 2.6)</p> <p>DM: Knowledge measured by 10 item test (unadjusted): Adequate: 8.1 ± 1.6 Marginal: 7.1 ± 2.0 Inadequate: 5.8 ± 2.1 Difference: (<i>P</i> < 0.001)</p> <p>Diabetes knowledge = 5 answers correct versus > 5 answers correct (adjusted): OR = 4.5, relationship negative and sig</p> <p>No sig association found between literacy and blood glucose control or blood pressure</p>	<p>Age Yrs of school completed Duration of disease</p>	<p>Total: 1.92 1) 2 2) NA 3) 2 4) 2 5) NA 6) 1.5 7) 2 8) 2</p> <p>Funding Source: Robert Wood Johnson Foundation</p>

Evidence Table 1: Key Question 1 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Wilson and McLemore, 1997</p> <p>Design: Cross-sectional</p> <p>Setting: Patients hospitalized for orthopedic surgery on knee or hip</p> <p>Duration: One interview</p>	<p>To examine (a) the relationship between patients' own reports of the highest grade completed in school and their actual reading level and (b) the relationship between literacy and patients' level of knowledge about self-care after receiving education involving written discharge instructions</p>	<p>Orthopedic patient Age: = 18 English-speaking Physically and mentally able to participate in the study</p>	26	<p>Age: Mean: 66 Range: 29 to 82</p> <p>Sex: Female: 65.4%</p> <p>Race/Ethnicity: White: 46%* AA: 54%*</p> <p>Income: NR</p> <p>Insurance Status: NR</p> <p>Other Characteristics: Hip replacement: 34.6% Knee replacement: 65.4%</p>	<p>Completed junior high: 11.5% High school graduate: 46.2% Some college: 19.2% College graduate: 23.1% (Range: Junior high school or greater)</p>

Evidence Table 1: Key Question 1 (continued)

Literacy Measurement	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
Measurement Tool: REALM Literacy Levels: = 3rd: 0 4th to 6th: 4% 7th to 8th: 19% = 9th: 77%	Relationship between self-reported educational level and actual reading level (unadjusted): $r = -0.39$ ($P < 0.05$) As self-reported educational level increased, patient's actual ability to read decreased Relationship between literacy level and patients' level of knowledge about self-care after receiving written education materials as measured by questionnaire (unadjusted): ($P = NS$) Readability of discharge instructions (Fry readability formula): Total hip arthroplasty: 5th grade level Precautions for patients with arthroplasty joints: 8th grade level Total joint replacement instructions: College level Mean readability level for the three discharge instruction tools: 10th grade level	No multivariate analysis concerning literacy included	Total: 1.08 1) 0.5 2) NA 3) 1 4) 2 5) NA 6) 1 7) 1.5 8) 0.5 Funding Source: NR

Evidence Table 1: Key Question 1 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Zaslow et al., 2001</p> <p>Design: Cohort study</p> <p>Setting: Atlanta, Georgia (community based)</p> <p>Duration: 5 yrs</p>	<p>To determine the relationship between maternal depressive symptoms and low literacy on child developmental outcomes in a welfare population</p>	<p>Included: Mothers and their children if: The mother would otherwise qualify for AFDC The child was between 3 and 4 yrs of age at enrollment Members of AA families</p> <p>Excluded: Mothers with a severely ill or disabled child Family member with a chronic health condition</p>	<p>372 families completed Wave 1 data (83% of those invited)</p> <p>Final analysis limited to 351</p>	<p>Age: NR</p> <p>Sex: Female: 100% Children: NR</p> <p>Race/Ethnicity: AA: 100%</p> <p>Income: Any earnings in past year: 20%</p> <p>Insurance Status: Medicaid: 100%</p> <p>Other Characteristics: Mean maternal age at first birth: 21.5</p>	<p>High school graduate, GED, or greater: 66%</p>

Evidence Table 1: Key Question 1 (continued)

Literacy Measurement	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
Measurement Tool: TALS (document literacy scale)	Overall, 39% of participants were depressed 25% had low literacy and depression 28% had low literacy but no depression 33% did not have low literacy and no depression 14% did not have low literacy but also had depression	Maternal literacy Maternal depressive symptoms	Total: 1.86 1) 2 2) NA 3) 2 4) 2 5) 2 6) 2.5 7) 1.5 8) 1.5
Literacy Levels: Low literacy (Levels 1 to 2 on TALS): 53%	<p>Child's score on depressive/withdrawn subscale of the Behavior Problems Index (adjusted):</p> <p>Sig effect of interaction of maternal literacy and maternal depression ($P = 0.01$)</p> <p>"In the presence of lower maternal literacy, children of mothers with more depressive symptoms had more depressive/withdrawn behavior problems than children of mothers with fewer depressive symptoms" ($P = 0.001$)</p> <p>"However, in the presence of higher maternal literacy, depressive/withdrawn scores did not differ according to depressive symptom level" ($P = NS$)</p>		<p>Funding Source:</p> <p>Office of the Assistant Secretary for Planning and Evaluation</p> <p>Department of Health and Human Services</p>

Evidence Table 2: Key Question 2

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Bill-Harvey et al., 1989</p> <p>Design: Uncontrolled trial</p> <p>Setting: Senior centers and community centers within housing complexes for the elderly in Hartford, Connecticut</p> <p>Duration: 6 weeks</p>	To determine the effect of an osteoarthritis education program for low-literacy adults	NR	100 enrolled 76 completed (75%)	<p>Age: Mean: 73 Range: 54 to 89</p> <p>Sex: Female: 96%</p> <p>Race/Ethnicity: White: 34% Black: 66%</p> <p>Income: NR</p> <p>Insurance Status: NR</p> <p>Other Characteristics: NR</p>	Mean yrs of school: 8.8 Range: 0 to 15 = 9th grade: 58%

Evidence Table 2: Key Question 2 (continued)

Literacy Measurement	Intervention	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
Measurement Tool: None	Specially designed osteoarthritis educational program administered by "indigenous community leaders"	Change in knowledge pre/postverbal and picture tests Verbal knowledge change: Increase 9.5 percentage points ($P < 0.001$) Picture knowledge change: Increase 0.8 percentage points ($P < 0.001$)	No multivariate analysis concerning literacy included	Total: 0.69 1) 1 2) 1 3) 0 4) 0 5) 0 6) 1 7) 1.5 8) 1
Literacy Levels: NA				Funding Source: National Institutes of Health

Evidence Table 2: Key Question 2 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Coleman et al., 2003</p> <p>Design: Two-group non-randomized trial</p> <p>Setting: Women receiving care in health department clinics in Arkansas</p> <p>Duration: Pre- and posttest interviews</p>	<p>To develop and test low-literacy written materials for breast cancer prevention in AA women</p>	<p>Women only</p>	<p>Controls: 258</p> <p>Intervention patients: 116</p>	<p>Mean Age: Controls: 33.7 (14 to 69) Intervention: 41.2 (15 to 64)</p> <p>Sex: Female: 100%</p> <p>Race/Ethnicity: Controls:* White: 9% AA: 47% Hispanic: 13% Other: 1% Intervention:* White: 45% AA: 53% Hispanic: 3%</p> <p>Income: NR</p> <p>Insurance Status: NR</p> <p>Other Characteristics: NR</p>	<p>NR</p>

Evidence Table 2: Key Question 2 (continued)

Literacy Measurement	Intervention	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
Measurement Tool: None	Control: Received no intervention	Women who received the materials had greater knowledge and intention to follow CBE and BSE guidelines ($P < 0.001$)	No multivariate analysis concerning literacy included	Total: 0.71 1) 1 2) 2 3) 0 4) 0 5) NA 6) 1.5 7) 0.5 8) 0
Literacy Levels: NA	Intervention: Received two educational pamphlets: one with drawings, the other using photographs; written at third grade level	Women who received the materials were more accurate in performing BSE on a 0 to 19 scale: Mean 10.2 versus 4.3 ($P < 0.001$) Among AA women 40 and older, women who received materials were more accurate in performing BSE ($P = 0.001$)		Funding Source: National Cancer Institute

Evidence Table 2: Key Question 2 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Davis, Berkel, et al., 1998</p> <p>Design: RCT</p> <p>Setting: University Hospital, Shreveport, Louisiana</p> <p>Duration: Intervention and 6-month record/telephone followup</p>	<p>To study the effect of three approaches to increase mammography usage</p>	<p>Age: = 40 Ambulatory care or eye clinic patient No mammogram in the past year</p>	445	<p>Age: Mean: 56</p> <p>Sex: Female: 100%</p> <p>Race/Ethnicity: White: 30% AA: 69%</p> <p>Income: < \$20,000/yr: 97%</p> <p>Insurance Status: NR</p> <p>Other Characteristics: NR</p>	<p>50% < high school grad</p> <p>Intervention Group 1: Mean grade completed: 9.8 < 6th: 15% 7th to 8th: 11% 9th to 11th: 29% High school/college: 45%</p> <p>Intervention Group 2: Mean grade completed: 9.5 < 6th: 11% 7th to 8th: 22% 9th to 11th: 28% High school/college: 37%</p> <p>Intervention Group 3: Mean grade completed: 10.0 < 6th: 16% 7th to 8th: 12% 9th to 11th: 26% High school/college: 46%</p>

Evidence Table 2: Key Question 2 (continued)

Literacy Measurement	Intervention	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
<p>Measurement Tool: REALM</p> <p>Literacy Levels: Mean: 4th to 6th Intervention: Group 1: 0 to 3rd: 25% 4th to 6th: 21% 7th to 8th: 30% > 9th: 24% Group 2: 0 to 3rd: 29% 4th to 6th: 18% 7th to 8th: 30% > 9th: 23% Group 3: 0 to 3rd: 20% 4th to 6th: 26% 7th to 8th: 31% > 9th: 23%</p>	<p>Group 1: Personal recommendation for mammography</p> <p>Group 2: Same intervention as received by intervention group 1 and National Cancer Institute brochure on mammography designed for low-literacy women</p> <p>Group 3: Same intervention as received by intervention group 2 and custom 12-minute interactive motivational and educational intervention for small groups, including video based on focus groups held with low-income women and led by peer educator and cancer nurse</p>	<p>Mammography rate at 6 months (unadjusted): Group 1: 21% Group 2: 18% Group 3: 29% Difference: ($P = 0.05$)</p> <p>Mammography rate at 6 months (adjusted): Sig difference between the three intervention groups ($P = 0.03$)</p> <p>Mammography at 24 months (unadjusted): Group 1: 37% Group 2: 34% Group 3: 40% Difference: ($P = NS$)</p>	<p>Age Race Literacy Mammography Knowledge at baseline</p>	<p>Total: 1.63 1) 2 2) 1.5 3) 1.5 4) 2 5) 0.5 6) 1.5 7) 2 8) 2</p> <p>Funding Source: National Cancer Institute</p> <p>The Cancer Center for Excellence in Research, Treatment and Education, Louisiana State University Medical Center, Shreveport, Louisiana</p>

Evidence Table 2: Key Question 2 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Davis, Bocchini, et al., 1996</p> <p>Design: Nonrandomized controlled trial</p> <p>Setting: Three clinic sites in Shreveport: pediatric clinic at Louisiana State University, Caddo Parish Health Unit, and private pediatric office</p> <p>Duration: One interview</p>	<p>To determine whether a simple pamphlet concerning the polio vaccine prepared at a low reading level would be preferable to the available Centers for Disease Control and Prevention polio vaccine pamphlet</p>	<p>Parents, adults accompanying children, or adult patients seen in one of three pediatric clinics in July 1993</p>	<p>568 potential</p> <p>32 refused</p> <p>14 incomplete data</p> <p>522 final sample</p> <p>Group 1: 233</p> <p>Group 2: 289</p>	<p>Age: Mean: 29 Range: 13 to 70</p> <p>Sex: NR</p> <p>Race/Ethnicity: White: 39% Black: 60% Hispanic: 1%</p> <p>Income: NR</p> <p>Insurance Status: Privately insured: 28%</p> <p>Other Characteristics: Site: Private clinic: 19% Hospital clinic: 33% Public health clinic: 48%</p>	<p>Mean: 12.3 yrs Range: 2 to 20 yrs</p> <p>Non-high school graduates: 65%</p>

Evidence Table 2: Key Question 2 (continued)

Literacy Measurement	Intervention	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
Measurement Tool: REALM Literacy Levels: Mean: 54 (7th to 8th grade) Range: 1 to 66 (= 3rd grade to = high school) > 9th grade: 53% > 7th grade: 80%	Group 1: Centers for Disease Control and Prevention pamphlet (existing intervention); readability using Fog index 10th grade Group 2: Louisiana State University pamphlet (new intervention); readability using Fog index 6th grade Structured survey used to capture participant demographics, attitudes, and comprehension	Reading time-mean: Group 1: 13 min 47 sec Group 2: 4 min 20 sec Difference: ($P < 0.0001$) Comprehension score-mean: Group 1: 56% Group 2: 72% Difference: ($P < 0.0001$) Outcomes stratified by reading level: = 9th grade readers comprehension: Group 1: 67% Group 2: 83% Difference: ($P < 0.0001$) = 6th grade readers comprehension: Group 1: 37% Group 2: 51% Difference: ($P < 0.002$) = 3rd grade readers comprehension: Group 1: 29% Group 2: 45% Difference: ($P < 0.07$)	No multivariate analysis concerning literacy included	Total: 1.50 1) 1.5 2) 2 3) 0.5 4) 2 5) NA 6) 1.5 7) 1.5 8) 1.5 Funding Source: NR

Evidence Table 2: Key Question 2 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Davis, Fredrickson, et al., 1998</p> <p>Design: RCT, randomized by day of week in clinic</p> <p>Setting: Three clinic sites in Shreveport: pediatric clinic at Louisiana State University, Caddo Parish Health Unit, and private pediatric office</p> <p>June to July 1995</p> <p>Duration: One interview</p>	<p>To compare two polio vaccine pamphlets written on a 6th grade level for reading ability, comprehension, and preference</p>	<p>Parents or other adults accompanying children being seen for immunization in one of the clinics</p>	<p>646 potential 26 refused 10 incomplete data 610 included</p>	<p>Mean Age: Group 1: 28 Group 2: 29</p> <p>Sex: Group 1: Female: 92% Group 2: Female: 94%</p> <p>Race/Ethnicity: Group 1: White: 50% Black: 49% Group 2: White: 52% Black: 47%</p> <p>Income: NR</p> <p>Insurance Status: NR</p> <p>Other Characteristics: Group 1: Private clinic: 33% Hospital clinic: 28% Public health clinic: 39% Group 2: Private clinic: 33% Hospital clinic: 33% Public health clinic: 34%</p>	<p>Mean: 12.5 yrs = 9th: 97% = 10th: 86% 1+ yr college: 30%</p>

Evidence Table 2: Key Question 2 (continued)

Literacy Measurement	Intervention	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
Measurement Tool: REALM Literacy Levels: Mean: 7th to 8th grade = 9th grade: 69%	Group 1: Centers for Disease Control and Prevention improved pamphlet (existing intervention) Group 2: Louisiana State University pamphlet (new intervention) Readability using Fox index (6th grade) and Flesh Kincaid (4th grade) same for both interventions	Comprehension: All reading levels: Group 1: 60% Group 2: 65% Difference: ($P < 0.01$) By reading levels: Group 2 better than Group 1 for = 9th grade reading levels ($P < .001$) No sig difference between the two groups for < 9th grade levels ($P < .001$) Comprehension scores of those in lowest two reading levels, 0 to 3 and 4 to 6 not sig improved with Group 2 pamphlet	No multivariate analysis concerning literacy included	Total: 1.71 1) 2 2) 2 3) 1 4) 2 5) NA 6) 1.5 7) 2 8) 1.5 Funding Source: NR

Evidence Table 2: Key Question 2 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Davis, Holcombe, et al., 1998</p> <p>Design: Nonrandomized trial</p> <p>Setting: Private and university oncology clinics and a low-income housing complex</p> <p>Duration: One interview</p>	<p>To test if a simplified consent form developed at Louisiana State University Medical Center would improve the comprehension and attitude of participants compared to the standard SWOG consent form</p>	<p>Patients, friends, or family members at private and university oncology clinics</p> <p>Residents of low-income housing project</p>	183	<p>Age: Mean: 48 Range: 19 to 85</p> <p>Sex: Female: 76%</p> <p>Race/Ethnicity: White: 44% AA: 56%</p> <p>Income: NR</p> <p>Insurance Status: NR</p> <p>Other Characteristics: Cancer: 29%</p>	<p>Mean: 11.9 yrs</p>

Evidence Table 2: Key Question 2 (continued)

Literacy Measurement	Intervention	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
Measurement Tool: REALM Literacy Levels: REALM mean: 52 (average 7th to 8th grade level) < 45 on REALM (6th grade level or lower): 25%	Specially developed consent form with readability of 7th grade level on Fog index versus standard form with 16th grade level on Fog index	Patient comprehension measured on a 10-item scale (percent correct): Intervention form: 58%, 95% CI (48.6, 67.0); correct SWOG form: 56%, 95% CI (43.8, 66.8) (<i>P</i> = NS) Comprehension of both forms sig declined with lower reading level Intervention form preferred by those reading at below a 9th grade level	No multivariate analysis concerning literacy included	Total: 1.43 1) 1.5 2) 2 3) 1 4) 2 5) NA 6) 1.5 7) 1 8) 1 Funding Source: NR

Evidence Table 2: Key Question 2 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Eaton and Holloway, 1980</p> <p>Design: RCT</p> <p>Setting: Outpatient clinics at Minneapolis VA Medical Center, Minnesota</p> <p>Duration: One interview</p>	<p>To determine whether alteration of the readability level of patients concerning information on the drug warfarin would influence comprehension of the material</p> <p>To study the effect of alteration on attitudes of the study population toward drug information materials</p>	<p>Able to read English</p> <p>Able to see normal size type</p> <p>Not taking warfarin</p> <p>Outpatients at Minneapolis VA Medical Center</p>	108 patients	<p>Age: Mean: 48</p> <p>Sex: NR</p> <p>Race/Ethnicity: NR</p> <p>Income: NR</p> <p>Insurance Status: NR</p> <p>Other Characteristics: NR</p>	NR

Evidence Table 2: Key Question 2 (continued)

Literacy Measurement	Intervention	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
Measurement Tool: ABLE Literacy Levels: Not stated, just used in analysis	Group 1: Warfarin materials at grade 5 readability Group 2: Warfarin materials at grade 10 readability Readability computed with Raygon Readability Estimate Comprehension evaluated with 23-item true/false test written at 5th grade level Attitudes evaluated through multiple-choice test	Knowledge about warfarin according to literacy level and readability: Literacy level explained 24% of variance ($P < 0.001$) Readability explained 8% of variance ($P < 0.001$) Perception of clarity of materials: Depended on reading ability for Group 2 materials at 10th grade readability, not so for Group 1 with 5th grade materials	No multivariate analysis concerning literacy included	Total: 1.50 1) 1 2) 1.5 3) 1 4) 2 5) 1.5 6) 2 7) 2 8) 1 Funding Source: Partially supported by the VA

Evidence Table 2: Key Question 2 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Fitzgibbon et al., 1996</p> <p>Design: RCT, randomized at the level of the family</p> <p>Setting: Literacy training program in a largely Hispanic community of Chicago, Illinois</p> <p>Duration: 12 weeks</p>	<p>To compare the efficacy of a 12-week, family-based culture-specific dietary intervention with a no-treatment control to reduce cancer risk among low-literacy, low-income Hispanics</p>	<p>Included: At least one child aged 7 to 12 Mother and children willing to attend 12 weekly 1-hour classes and complete an assessment Ability to read English or Spanish not required for participation</p> <p>Excluded: Self-admitted alcoholics or consumed more than two alcoholic drinks per day</p>	<p>38 mothers 17 sons 31 daughters</p>	<p>Age: Mothers: Mean: 35 (SD 6.6) Children: Mean: 9 (SD 2.0)</p> <p>Sex: Female: 100%</p> <p>Race/Ethnicity: Hispanic: 100% Puerto Rican: 55% Mexican American: 29%</p> <p>Income: < \$5,000: 52.6% \$5,000 to \$11,999: 28.9% \$12,000 to \$15,999: 2.6% \$16,000 to \$24,999: 15.8%</p> <p>Insurance Status: NR</p> <p>Other Characteristics: Mothers: BMI: Mean: 28.7 (SD 5.4) SES: Mean: 16.3 (SD 7.5) Preferred language: English: 58%</p>	<p>Mothers: Mean: 9.1 yrs (SD 4.0)</p>

Evidence Table 2: Key Question 2 (continued)

Literacy Measurement	Intervention	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
Measurement Tool: None	Controls: Standard pamphlets on health behaviors and nutrition, with no accompanying classes	No sig differences in any measures between treatment and control groups, before and after interventions Mothers' measures include: Fat intake	Not listed, but multivariate analysis is mentioned	Total: 1.38 1) 1 2) 2 3) 2 4) 0 5) 2 6) 1.5 7) 1 8) 1.5
Literacy Levels: NR	Intervention: 12-week, culture-specific, cancer prevention curriculum that encouraged adoption of a low-fat, high-fiber diet; activity-based curriculum; accommodated both English and Spanish speakers; instruction took place at the literacy training site (familiar to all participants); incorporated ethnic foods; made foods appealing to children; lots of discussion in classes	Saturated fat intake Fiber intake Exercise Nutrition knowledge Children's measures include: Dietary intake Nutrition knowledge		Funding Source: American Cancer Society

Evidence Table 2: Key Question 2 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Fouad et al., 1997</p> <p>Design: Quasi-experimental; "cases" who completed program matched with nonparticipating controls</p> <p>Setting: Birmingham, Alabama</p> <p>Duration: 1 yr per participant</p>	<p>To test the effect of a specially designed hypertension education and behavior change program for low-literacy city employees of Birmingham, Alabama</p>	<p>City employees who were found to have elevated blood pressure (SBP > 140 or DBP > 90) on screening exams</p>	<p>600 employees offered participation</p> <p>130 enrolled</p> <p>81 completed program, data available for 77</p> <p>81 controls drawn from nonparticipants</p> <p>162 total</p>	<p>Age: < 45: 63%</p> <p>Sex: Female: 14%</p> <p>Race/Ethnicity: White: 36% Black: 63%</p> <p>Income: NR</p> <p>Insurance Status: NR</p> <p>Other Characteristics: NR</p>	<p>Grade school: Intervention: 15% Control: 17%</p> <p>High school: Intervention: 47% Control: 45%</p> <p>Trade school: Intervention: 23% Control: 24%</p> <p>College: Intervention: 10% Control: 13%</p>

Evidence Table 2: Key Question 2 (continued)

Literacy Measurement	Intervention	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
Measurement Tool: None Literacy Levels: NR	Specially designed educational program for workers in unskilled labor departments using color graphics, models, and games with culturally appropriate examples; weight and blood pressure assessed each visit; goal-setting; food examples; monetary incentives Intervention and control received newsletters, tip sheets, and posters	Change in SBP: Intervention: -4.5 mm Hg ($P = 0.03$) Control: -2.4 ($P = 0.19$) Difference: ($P = 0.42$) Change in DBP: Intervention: -2.7 mm Hg (0.06) Control: -1.0 mm Hg (0.40) Difference: ($P = 0.34$)	No multivariate analysis concerning literacy included	Total: 1.13 1) 1 2) 2 3) 1.5 4) 0 5) 1 6) 1.5 7) 1 8) 1 Funding Source: National Heart, Lung, and Blood Institute

Evidence Table 2: Key Question 2 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
Citation: Gans et al., 1998 Design: Uncontrolled trial Setting: NR Duration: 3 months	To test an intervention consisting of an audio CD and picture book designed to improve dietary patterns	NR	1,744	Age: NR Sex: NR Race/Ethnicity: Hispanic: 20% Income: NR Insurance Status: NR Other Characteristics: NR	NR

Evidence Table 2: Key Question 2 (continued)

Literacy Measurement	Intervention	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
Measurement Tool: None Literacy Levels: NA	Audio CD and picture book, extensively tested in focus groups and through pilot tests CD had 21 "tracks" (each 2.5 to 3.5 minutes) that the user could listen to	Dietary behavior as measured by the Food Habits Summary score: Mean change -0.17, at 3-month followup ($P < 0.001$)	No multivariate analysis concerning literacy included	Total: 0.8 1) 0 2) 2 3) NA 4) NA 5) NA 6) 1 7) 1 8) 0 Funding Source: National Heart, Lung, and Blood Institute

Evidence Table 2: Key Question 2 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Hartman et al., 1997</p> <p>Design: RCT, randomized at level of educator, not at level of participant</p> <p>Setting: EFNEP program in the Twin Cities Metropolitan area, Minnesota</p> <p>Duration: 8-week mean time from pretest to posttest</p>	<p>To determine the impact of an educational program on health attitudes, low-fat eating behaviors, dietary fat consumption, and total blood cholesterol levels in patients with low literacy skills</p>	<p>EFNEP participant English speaking</p>	<p>64% of those who provided baseline information completed the study</p> <p>Subjects completed: 130 intervention, 70 control</p>	<p>Age: Intervention: Mean: 31.1 (SD 0.9) Control: Mean: 27.3 (SD 0.9)</p> <p>Sex: Intervention: Female: 90% Control: Female: 97%</p> <p>Race/Ethnicity: Intervention: White: 64% AA: 22% Other: 12% Control: White: 36% AA: 51% Other: 11%</p> <p>Income: Intervention: < \$5,000: 23% \$5,000 to \$9,999: 37% \$10,000 to \$20,000: 9% \$20,000+: 31% Control: < \$5,000: 24% \$5,000 to \$9,999: 27% \$10,000 to \$20,000: 13% \$20,000+: 36%</p> <p>Insurance Status: NR</p> <p>Other Characteristics: Marital status: Intervention: Single: 55% Married: 24% Previously married: 21% Control: Single: 58% Married: 16% Previously married: 26%</p>	<p>Intervention: < high school degree: 54% High school diploma: 39% GED: 7%</p> <p>Control: < high school diploma: 50% High school diploma: 44% GED: 6%</p>

Evidence Table 2: Key Question 2 (continued)

Literacy Measurement	Intervention	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
Measurement Tool: ABLE, Level II Literacy Levels: Intervention: = grade 8: 67% Grades 9 to 12: 24% > grade 12: 9% Control: = grade 8: 73% Grades 9 to 12: 11% > grade 12: 16%	Intervention: "Help Yourself to Health," a low-fat nutrition education curriculum; provides simple, practical, and relevant nutrition information in a fun and entertaining format Control: "Eating Right is Basic 2" (usual EFNEP materials); focuses generally on food budgeting, food safety, and healthy eating	Attitude scale (adjusted), uses Model 1 covariates: Intervention: 0.21 Control: 0.22 Difference: -0.01, 95% CI (-0.01, 0.00) Eating Pattern Scale (adjusted), uses Model 2 covariates: Intervention: 0.54 Control: 0.57 Difference: -0.03, 95% CI (-0.01, -0.005) Dietary variables all use Model 3 covariates: Energy intake (adjusted): Intervention: 1,857 kcal Control: 1,683 kcal Difference: 174, 95% CI (-107, 455) Total fat intake (adjusted): Intervention: 33.1 kcal Control: 34.2 kcal Difference: -1.1, 95% CI (-4.3, 2.1) Saturated fat intake (% energy) (adjusted): Intervention: 11.7% Control: 12.6% Difference: -0.9, 95% CI (-2.5, 0.8) Cholesterol intake (mg/1,000 kcal) (adjusted): Intervention: 127.3 Control: 146.6 Difference: -19.3, 95% CI (-50.7, 12.1) Blood cholesterol level (mg/dl) (adjusted): Intervention: 182.6 Control: 179.1 Difference: 3.5, 95% CI (-7.1, 14.2)	Model 1: Children Marital status Physical activity Sex Initial scale value Volunteer status BMI Age Ethnicity Income Reading ability Model 2: Age BMI Children Ethnicity Income Marital status Reading ability Sex Initial scale value Volunteer status Model 3: Age BMI Children Ethnicity Marital status Reading ability Sex Initial value Time Volunteer status	Total: 1.19 1) 1.5 2) 1 3) 1 4) 2 5) 0.5 6) 1 7) 1 8) 1.5 Funding Source: National Institutes of Health

Evidence Table 2: Key Question 2 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
Citation: Hayes, 1998 Design: RCT, posttest only Setting: Emergency departments in rural midwestern areas Duration: Interview 48 to 72 hours after discharge	To compare the level of medication knowledge of elderly ED patients receiving instruction by one of two teaching methods: (1) Control: the usual preprinted discharge instructions (2) Intervention: geragogy schemaband instruction using individualized computer-generated discharge instructions	Age: = 60 Able to speak and read English Urgent or deferrable category at triage and deemed stable by the nurse Able to understand and sign consent form Discharged home from ED on at least one prescribed medication Able to use telephone Cognitively intact per the SPMSQ (less than two errors on adjusted scale)	63 entered study 3 excluded because could not be contacted for followup 60 used in analyses	Age: Mean: 75.6 Range: 60 to 98 Sex: Female: 63% Race/Ethnicity: White: 100% Income: NR Insurance Status: NR Other Characteristics: Mean SPMSQ: 9.84 out of 10	Mean: 11.25 yrs Range: 4 to 18 yrs < 9th grade: 23% Some college: 28%

Evidence Table 2: Key Question 2 (continued)

Literacy Measurement	Intervention	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
Measurement Tool: REALM Literacy Levels: Mean: 59.15 Range: 15 to 66 = 6th grade level: 23% 7th to 8th: 65% = 9th: 12%	Control: Preprinted instructions (usual) Intervention: Geragogy-based instructions (instruction designed for elderly adult learners) Telephone interview 48 to 72 hours after discharge	KMS (lower scores better) (unadjusted): Control: 52 Intervention: 47.6 Difference: 4.5, 95% CI (0.39, 8.51) (<i>P</i> = 0.016) KMS mean difference (adjusted): 4.30, 95% CI (0.51, 8.09) Only medication complexity and experimental group membership covariates were sig, literacy was not	Medication complexity Literacy Living arrangement Education Age Sex	Total: 1.63 1) 2 2) 2 3) 1 4) 2 5) 2 6) 1.5 7) 1 8) 1.5 Funding Source: Emergency Nurse's Foundation/ Sigma Theta Tau software contributed by Logicare Corporation

Evidence Table 2: Key Question 2 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Howard-Pitney et al., 1997</p> <p>Design: Randomized trial</p> <p>Setting: Vocational and general education classes in San Jose, California</p> <p>Duration: Approximately 5 months</p>	<p>To test the effect of a dietary intervention for low-literacy, low-income adults</p>	<p>Adults in vocational or basic education classes</p>	<p>351 participants from 24 classes randomized, 79% completed baseline and first followup measure</p> <p>183 in SNAP classes</p> <p>168 in general nutrition classes</p>	<p>Mean Age: Intervention: 31 Control: 31</p> <p>Sex: Female: Intervention: 86% Control: 82%</p> <p>Race/Ethnicity: Intervention: Asian: 10% Hispanic: 58% White: 20% Other: 12% Control: Asian: 13% Hispanic: 59% White: 15% Other: 12%</p> <p>Income: < \$10,000/yr: Intervention: 63% Control: 66%</p> <p>Insurance Status: NR</p> <p>Other Characteristics: NR</p>	<p>= 8th grade: Intervention: 6% Control: 4%</p> <p>9th to 11th grade: Intervention: 38% Control: 36%</p> <p>12th grade: Intervention: 34% Control: 36%</p> <p>= 12th grade: Intervention: 21% Control: 24%</p>

Evidence Table 2: Key Question 2 (continued)

Literacy Measurement	Intervention	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
Measurement Tool: WRAT Literacy Levels: Low literacy: 8th grade level or below: 66% Average grade level reading ability: 7.4 8th grade level or below: 66%	Six special nutrition education classes, each 90 minutes Intervention: Curriculum that focused primarily on lowering dietary fat intake (SNAP) Control: Existing general nutrition curriculum	Nutrition knowledge: Net change in % correct SNAP versus general nutrition classes: +7.7% ($P = 0.01$) Nutrition attitudes: Net change mean SNAP versus general nutrition classes: +0.2 ($P = 0.02$) Nutrition self-efficacy: Net change in mean SNAP versus general nutrition classes: +0.2 ($P = 0.04$)	No multivariate analysis concerning literacy included	Total: 1.69 1) 1.5 2) 2 3) 1.5 4) 2 5) 1.5 6) 2 7) 1.5 8) 1.5 Funding Source: National Heart, Lung, and Blood Institute

Evidence Table 2: Key Question 2 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Hugo and Skibbe, 1991</p> <p>Design: Experimental, before-and-after study</p> <p>Setting: Prenatal clinic in Tygerberg Hospital, South Africa</p> <p>Two successive occasions in 1989</p> <p>Duration: Two interviews</p>	<p>To determine the ability of illiterate female patients to interpret instructional illustrations on breast-feeding</p>	<p>Illiterate (not having passed standard 3 and not being able to read and to write simple sentences)</p> <p>Participant in prenatal clinic</p> <p>Age: 18 to 40</p> <p>Primagravida</p> <p>“Coloured” ethnic population group that attended antenatal clinics at Tygerberg Hospital</p>	<p>60 participated in first attendance</p> <p>47 completed the questionnaire at second visit</p>	<p>Age: Range: 18 to 40</p> <p>Sex: Female: 100%</p> <p>Race/Ethnicity: "Coloured": 100%</p> <p>Income: NR</p> <p>Insurance Status: NR</p> <p>Other Characteristics: NR</p>	<p>NR</p>

Evidence Table 2: Key Question 2 (continued)

Literacy Measurement	Intervention	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
<p>Measurement Tool: Illiteracy: not having passed standard 3 and not being able to read and to write simple sentences</p> <p>Literacy Levels: Ranged from total illiteracy to very limited reading ability</p>	<p>Three different graphic illustrations concerning breast- relative to bottle-feeding presented to each patient: (1) simplified black and white diagram, (2) detailed black-and-white illustration, (3) color illustration</p>	<p>Ability to identify the graphic (% of patients correctly identifying content): Simplified black and white: 9% (same 9% as in detailed) Detailed black and white: 9% (same 9% as in simplified) Color illustration: 66%</p>	<p>No multivariate analysis concerning literacy included</p>	<p>Total: 0.13 1) 0 2) 1 3) 0 4) 0 5) 0 6) 0 7) 0 8) 0</p> <p>Funding Source: NR</p>

Evidence Table 2: Key Question 2 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Hussey, 1994</p> <p>Design: Controlled trial, alternate assignment to groups, not randomized</p> <p>Setting: Geriatric outpatient clinic in a large county hospital in the southwestern United States</p> <p>Duration: 2 to 3 weeks</p>	<p>To evaluate the effectiveness of verbal teaching and of a color-coded chart that had been designed to tailor a medication regimen to the elderly person's daily schedule</p> <p>To measure the effects on both knowledge and compliance</p>	<p>Age: = 65 At least one chronic health problem Low SES or indigent Not blind or colorblind Patients of geriatric outpatient clinic</p>	<p>80 participated, convenience sample</p>	<p>Age: Mean: 75 (SD 5.4)</p> <p>Sex: Female: 70%</p> <p>Race/Ethnicity: Caucasian: 33% AA: 62% Hispanic: 5%</p> <p>Income: < \$10,552/yr: 100% of patients</p> <p>Insurance Status: NR</p> <p>Other Characteristics: Lived alone: 42.5% Lived with spouse: 33.8% Average number of diagnoses: 1.9 Average number of medications: 4.1 Average number of doses/day: 7.4</p>	<p>Mean: 8 yrs</p>

Evidence Table 2: Key Question 2 (continued)

Literacy Measurement	Intervention	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
Measurement Tool: Comprehension Subtest of the Gates-MacGinitie Reading Test Literacy Levels: Average estimated at 3rd to 4th grade reading level	Group 1: Verbal teaching about medications Group 2: Group 1 intervention + color-coded medication schedule	Knowledge gain (unadjusted): Group 1 and Group 2: Sig increase in knowledge among total population ($P < 0.001$) No sig difference between Group 1 and Group 2 Compliance Group 1 and Group 2: Sig increase in compliance after verbal teaching ($P = 0.007$) Comparing Group 1 to Group 2: Among patients with low compliance scores at baseline, Group 2 had more improvement than Group 1 No difference between the two groups with high compliance scores (data not provided)	No multivariate analysis concerning literacy included	Total: 1.44 1) 1.5 2) 2 3) 0.5 4) 2 5) 2 6) 1.5 7) 1 8) 1 Funding Source: NR

Evidence Table 2: Key Question 2 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Jacobson et al., 1999</p> <p>Design: RCT</p> <p>Setting: Ambulatory care clinic at Grady Memorial Hospital, Atlanta, Georgia</p> <p>Duration: One interview</p>	<p>To determine whether the use of a simple, low-literacy educational tool enhances patient-physician dialogue about pneumococcal vaccination and increases rates of immunization</p>	<p>Primary care visit Not yet immunized One of four indications: (1) age = 65, (2) diabetes, (3) heart failure, (4) other chronic medical problems Not blind No dementia English speaking Not previously vaccinated</p>	<p>922 eligible 487 had previous vaccination, 2 skipped triage area 433 enrolled Intention to treat analysis used</p>	<p>Age: Mean: 63 (SD 12.7)</p> <p>Sex: Female: 69.3%</p> <p>Race/Ethnicity: White: 6.5% AA: 92.6% Other: 0.9%</p> <p>Income: NR</p> <p>Insurance Status: Uninsured: 24.9% Government/private: 75.1%</p> <p>Other Characteristics: NR</p>	<p>= 8th grade: 37.0% 9th to 11th grade: 27.7% = high school: 35.3%</p>

Evidence Table 2: Key Question 2 (continued)

Literacy Measurement	Intervention	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
<p>Measurement Tool: None</p> <p>Literacy Levels: Previously measured in this population with TOFHLA</p> <p>Marginal or inadequate literacy > 80% in elderly population at this clinic</p>	<p>Group 1 (control): Low-literacy nutrition brochure</p> <p>Group 2 (intervention): Low-literacy pneumococcal vaccine brochure written at below 5th grade level as assessed by Flesh-Kincaid</p> <p>Outcomes assessed through brief questionnaire</p>	<p>Clinician discuss vaccine with patient (unadjusted): Group 1: 9.9% Group 2: 39.4% RR = 3.97, 95% CI (2.71, 5.83) (<i>P</i> < 0.001)</p> <p>Patient received vaccine (unadjusted): Group 1: 3.8% Group 2: 19.9% RR = 5.28, 95% CI (2.80, 9.93) (<i>P</i> < 0.001)</p> <p>Patient read brochure (unadjusted): No sig difference between Groups 1 and 2</p> <p>Patient showed brochure to physician (unadjusted): Group 1: 17.4% Group 2: 37.1% RR = 2.13, 95% CI (1.54, 2.94) (<i>P</i> < 0.001)</p> <p>Clinician recommended vaccine (unadjusted): Group 1: 6.1% Group 2: 27.1% RR = 4.43, 95% CI (2.67, 7.30) (<i>P</i> < 0.001)</p> <p>Group 2 sig more likely than Group 1 to receive vaccine or discuss it with their clinician (adjusted): (<i>P</i> < 0.001)</p>	<p>Race</p> <p>Sex</p> <p>Age</p> <p>Education</p> <p>Health status</p> <p>Insurance status</p> <p>Level of clinician training</p> <p>Vaccine indication</p>	<p>Total: 1.63</p> <p>1) 1.5</p> <p>2) 2</p> <p>3) 2</p> <p>4) 0</p> <p>5) 2</p> <p>6) 2</p> <p>7) 2</p> <p>8) 1.5</p> <p>Funding Source: National Vaccine Program, Centers for Disease Control and Prevention</p> <p>Georgia Emerging Infections Program</p> <p>Indigent Care Trust Funds from State of Georgia</p> <p>Office of Health Promotion and Disease Prevention at Grady Health Systems</p>

Evidence Table 2: Key Question 2 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Kim et al., 2001</p> <p>Design: One-group uncontrolled trial</p> <p>Setting: Urology clinics in two VA hospitals in Chicago, Illinois</p> <p>Duration: NR</p>	<p>To evaluate the knowledge, level of satisfaction, and treatment preferences of men newly diagnosed with prostate cancer after participation in a CD-ROM shared decision-making program and the relationship between prostate cancer knowledge and health literacy</p>	<p>New diagnosis of prostate cancer</p>	<p>31 recruited 30 completed (Response rate cannot be calculated)</p>	<p>Age: Age at time of diagnosis: 67 ± 9.5 yrs</p> <p>Sex: Male: 100%</p> <p>Race/Ethnicity: White: 50% AA: 43% Asian American: 7%</p> <p>Income: NR</p> <p>Insurance Status: NR</p> <p>Other Characteristics: Married: 63.3% Clinical stage cancer: A: 16.7% B: 70% C: 3.3% D: 10%</p>	<p>Less than high school: 23.3% High school graduate: 43.4% Advanced education: 33.3%</p>

Evidence Table 2: Key Question 2 (continued)

Literacy Measurement	Intervention	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
Measurement Tool: REALM Literacy Levels: Mean score (7th to 8th grade) 57.1 (SD ± 10.9) 4th to 6th grade: 10% 7th to 8th grade: 26.7% = 9th grade: 63.3%	Intervention: CD-ROM about prostate cancer; includes textual descriptions of stages of cancer and associated treatment options, illustrated by anatomical drawings Includes presentations by physicians, video clips showing patients receiving treatment, and video testimonials by prostate cancer patients and their families	Knowledge measured by PCKQ and educational attainment (unadjusted): Less than high school: PCKQ: 62.1% High school graduate: PCKQ: 74.1% Advanced education: PCKQ: 82.2% Difference: (<i>P</i> = NS) Correlation between PCKQ and REALM score (unadjusted): <i>r</i> = 0.65 Difference: (<i>P</i> = 0.0001) Satisfaction with information presented and likelihood of following treatment preferences not sig different by literacy or educational attainment (data not provided)	No multivariate analysis concerning literacy included	Total: 1.19 1) 1.5 2) 2 3) 0.5 4) 2 5) 1 6) 1 7) 1.5 8) 0 Funding Source: Schering Plough Inc. VA

Evidence Table 2: Key Question 2 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Kumanyika et al., 1999</p> <p>Design: RCT</p> <p>Setting: Community-based trial; participants recruited from supermarket screenings held in primarily AA neighborhoods in Washington, DC</p> <p>Duration: 1 yr</p>	<p>To evaluate the effect of a special cardiovascular nutrition education package designed for AAs based on CARDES</p>	<p>Included: Persons 40 to 70 yrs with a history of hypertension or an abnormal total cholesterol (= 5.2 mmol/l)</p> <p>Excluded: Possible renal disease, alcoholism, depression, or other psychiatric illness</p>	<p>435 persons screened at CARDES clinic</p> <p>388 eligible</p> <p>330 enrolled</p>	<p>Age: 40 to 54: 41% 55 to 70: 59%</p> <p>Sex: Female: 74%*</p> <p>Race/Ethnicity: AA: 100%</p> <p>Income: < \$15,000/yr: 52%</p> <p>Insurance Status: NR</p> <p>Other Characteristics: History of heart disease: Group 1: 15% Group 2: 7% History of diabetes: Group 1: 14% Group 2: 15%</p>	<p>Less than 12th grade: 24%</p>

Evidence Table 2: Key Question 2 (continued)

Literacy Measurement	Intervention	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
Measurement Tool: Specially designed scale Literacy Levels: = 8th grade: Group 1: 47% Group 2: 49%	Group 1 (control): Received periodic brief counseling by nutritionist, food cards, and nutrition guide Group 2 (intervention): Received same as Group 1 and also received CARDES materials including audio program and a series of four monthly nutrition classes	Change in total cholesterol and systolic blood pressure at 12 months Total cholesterol (women): Group 1: -0.43 mmol/l Group 2: -0.41 mmol/l Difference: ($P = 0.8$) Total cholesterol (men): Group 1: -0.36 mmol/l Group 2: -0.50 mmol/l Difference: ($P = 0.4$) Systolic blood pressure (women): Group 1: -10.6 mm Hg Group 2: -7.4 mm Hg Difference: ($P = 0.2$) Systolic blood pressure (men): Group 1: -0.8 mm Hg Group 2: +0.9 mm Hg Difference: ($P = 0.5$)	No multivariate analysis concerning literacy included	Total: 1.63 1) 1.5 2) 2 3) 2 4) 0.5 5) 1.5 6) 2 7) 2 8) 1.5 Funding Source: National Institutes of Health

Evidence Table 2: Key Question 2 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Lillington et al., 1995</p> <p>Design: RCT with clinic randomization</p> <p>Setting: Four WIC sites in south and central Los Angeles</p> <p>October 1990 to December 1992</p> <p>Duration: 1.5 to 10.5 months</p>	<p>To develop and test culturally appropriate low-literacy smoking cessation intervention materials designed to increase quit rates and prevent relapse postpartum for low-income AA and Hispanic women</p>	<p>Included: WIC participant Age: > 18 Pregnant, any stage of gestation Current smoker or ex-smoker who quit in the past 12 months</p> <p>Excluded: Early delivery</p>	<p>768</p> <p>1,102 smokers and ex-smokers eligible</p> <p>18% (198) refused</p> <p>12% (132) ineligible</p> <p>(Response rate: 79%)</p> <p>555 at followup</p>	<p>Age: Mean: 26.8 Range: 18 to 43</p> <p>Sex: Female: 100%</p> <p>Race/Ethnicity: AA: 53% Hispanic: 42.6% White: 3.6% Other: 0.7%</p> <p>Income: NR</p> <p>Insurance Status: NR</p> <p>Other Characteristics: Gestation: 0 to 3 months: 13.9% 4 to 6 months: 50.1% 7 to 9 months: 36% Gravida: Multiparous: 86.5% Primiparous: 13.5% Smoking status: Current: 40.5% Ex: 59.5%</p>	NR

Evidence Table 2: Key Question 2 (continued)

Literacy Measurement	Intervention	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
Measurement Tool: NR Literacy Levels: Not measured and no report of previous measure	Intervention: 15-minute one-on-one sessions including (1) counseling providing information on risk of smoking or reinforcement to continue abstinence; (2) self-help guide of behavior change strategies: Time for Change (3 step approach to quitting with 12 behavior change activities to be completed; (3) reinforcement booster cards 1 month after study entry; (4) incentive contest: weekly drawing for baby items for all people who turned in behavior sheets Control: Usual care, including printed information about the risks of smoking during pregnancy and a group quit smoking message at their initial visit Third grade reading level in English and Spanish, but tool to assess not reported	Baseline smokers: Odds of quitting reported at 9 months gestation: OR = 1.75, 95% CI (1.19, 2.55) Odds of quitting reported at 6 weeks postpartum: OR = 2.17, 95% CI (1.21, 3.91) Ex-smokers: Odds of quitting reported at 9 months gestation: OR = 1.06, 95% CI (0.99, 1.13) Odds of quitting reported at 6 weeks postpartum: OR = 1.28, 95% CI (1.10, 1.49) Subgroup Analysis: Baseline AA smokers: Odds of quitting reported at 9 months gestation: OR = 1.93, 95% CI (1.23, 3.03) Odds of quitting reported at 6 weeks postpartum: OR = 3.13, 95% CI (1.48, 6.60) Baseline Hispanic smokers: Odds of quitting reported at 9 months gestation: OR = 1.33, 95% CI (0.58, 3.05) Odds of quitting reported at 6 weeks postpartum: OR = 1.20, 95% CI (0.33, 4.36)	No multivariate analysis concerning literacy included	Total: 1.00 1) 1.5 2) 1.5 3) 1 4) 0 5) 1 6) 1 7) 1 8) 1 Funding Source: State of California Tobacco Control Program National Cancer Institute

Evidence Table 2: Key Question 2 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Meade et al., 1994</p> <p>Design: RCT, randomized by permuted block method into one of three groups</p> <p>Setting: Primary care clinic at Milwaukee County Medical Complex, Wisconsin</p> <p>Duration: Pretest, 7.5-minute intervention, and posttest</p>	<p>To determine whether printed or videotaped information is more effective in enhancing colon cancer knowledge</p>	<p>Age: = 50 Able to speak and read English Absence of visual and hearing impairments Able to give free consent Eligibility for at least one colon cancer screening measure</p>	1,100	<p>Age: Mean: 60.6</p> <p>Sex: Female: 72%</p> <p>Race/Ethnicity: White: 44% Black: 54%</p> <p>Income: NR</p> <p>Insurance Status: NR</p> <p>Other Characteristics: NR</p>	<p>Median: 11 yrs</p>

Evidence Table 2: Key Question 2 (continued)

Literacy Measurement	Intervention	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
Measurement Tool: WRAT dichotomized: = 7th grade < 7th grade Literacy Levels: Median: 7th grade	Group 1 (control): No intervention Group 2: Booklet written at 5th to 6th grade reading level Group 3: Videotape content similar to booklet Pretest/posttest design 24 questions at 5th to 6th grade reading level	Knowledge improvement on a 24-question posttest, based on pretest scores: Group 1: 3% Group 2: 23% Group 3: 26% Groups 2 and 3 sig better than Group 1 ($P < 0.05$) No sig difference between Groups 2 and 3 Subgroup analysis by dichotomized literacy level (< 7th, = 7th) in Groups 2 and 3; no sig differences in score improvement according to literacy level	No multivariate analysis concerning literacy included	Total: 1.75 1) 1.5 2) 2 3) 2 4) 2 5) 1 6) 1 7) 2 8) 1.5 Funding Source: Wisconsin Department of Health and Social Services

Evidence Table 2: Key Question 2 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Michielutte et al., 1992</p> <p>Design: RCT</p> <p>Setting: One private family practice and three public health clinics: obstetrics/gynecology, family planning, and STDs</p> <p>Duration: One session</p>	<p>To test the effect of two cervical cancer and condyloma information brochures on comprehension of information, one with illustrations and one without</p>	<p>Included: Women = 18</p> <p>Excluded: Women who reported no ability to read or who reported "serious illnesses"</p>	<p>254 recruited</p> <p>217 final sample</p> <p>112 received illustrated brochure</p> <p>105 received non-illustrated version</p>	<p>Age: NR</p> <p>Sex: NR</p> <p>Race/Ethnicity: NR</p> <p>Income: NR</p> <p>Insurance Status: NR</p> <p>Other Characteristics: NR</p>	<p>NR</p>

Evidence Table 2: Key Question 2 (continued)

Literacy Measurement	Intervention	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
Measurement Tool: WRAT-R (adapted for this study)	Two different versions of a cervical cancer screening informational brochure	Comprehension scores: Total sample: Version 1: 65.2% Version 2: 53.3% Difference: ($P = 0.076$)	No multivariate analysis concerning literacy included	Total: 1.50 1) 0.5 2) 2 3) 2 4) 1.5 5) NA 6) 1.5 7) 1.5 8) 1.5
Literacy Levels: Range: 19 to 88	Version 1: Illustrated, narrative text (SMOG 8.4)	Low WRAT-R: Version 1: 61% Version 2: 35% Difference: ($P = 0.007$)		
Results dichotomized into high and low literacy at the median score: 46	Version 2: Simple bulleted text only (SMOG 7.7)	High WRAT-R: Version 1: 70% Version 2: 72% Difference: ($P = 0.814$)		Funding Source: NR

Evidence Table 2: Key Question 2 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Mulrow et al., 1987</p> <p>Design: RCT</p> <p>Setting: Diabetes clinic in Central London</p> <p>Duration: 11 months</p>	<p>To determine if an educational program (monthly sessions with or without video tapes) designed specifically for patients with diabetes and low literacy could improve glucose and weight control outcomes</p>	<p>Included: Patients with diabetes who were overweight (> 130% ideal body weight) and not taking insulin</p> <p>Excluded: Diabetes onset before age 29 History of diabetic ketoacidosis Age: > 70</p>	<p>Initial screening done by computer record</p> <p>290 patients invited</p> <p>150 responded</p> <p>120 enrolled</p> <p>68% completed</p>	<p>Age: Mean: 53</p> <p>Sex: Female: 55%</p> <p>Race/Ethnicity: West Indian: 49%</p> <p>Income: NR</p> <p>Insurance Status: NA</p> <p>Other Characteristics: Mean HbA: 10.2%</p>	<p>Mean yrs: Group 1: 9.0 Group 2: 9.0 Group 3: 9.7</p>

Evidence Table 2: Key Question 2 (continued)

Literacy Measurement	Intervention	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
Measurement Tool: None Literacy Levels: NR	Group 1: Monthly videotape lessons with printed handouts, viewed during 30-minute session, conducted in groups of 3 to 5; materials written at the 4th to 6th grade level, met monthly for 6 months Group 2: Same as Group 1 but without videotapes, and first session was 1 hour in length Group 3: Same initial first session as Group 2, but no further intervention All given test to assess knowledge outcomes in month 7, repeated at month 11	Change in HbA_{1c} from baseline to month 7 (unadjusted): Group 1: Median increase of 0.2% Group 2: Median increase of 0.4% Group 3: Median decrease of 0.3% No statistical differences within or between groups Findings at 11 months similar Change in weight at 7 months (unadjusted): Group 1: 1.0 kg weight loss Group 2: 0.1 kg weight loss Group 3: No change Difference: ($P < 0.05$) No sig difference at 11 months Knowledge score was not sig affected by the interventions Weight or HbA_{1c} % change (adjusted): No sig difference found	Age Sex Race Education Duration of diabetes Compliance beliefs	Total: 1.25 1) 1 2) 2 3) 1.5 4) 0 5) 1 6) 2 7) 1.5 8) 1 Funding Source: Pfizer Pharmaceuticals

Evidence Table 2: Key Question 2 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Murphy et al., 1996</p> <p>Design: Randomized trial, randomized by classroom</p> <p>Setting: Adult basic education reading classes at a welfare-to-work site in Shreveport, Louisiana</p> <p>Duration: 2 months</p>	<p>To design a nutrition curriculum that could be used in adult educational sites and to measure its efficacy toward increasing nutrition knowledge and changing dietary practices</p>	<p>Participant in the adult reading class Reading at or below 6th grade reading level</p>	28	<p>Age: Mean: 26</p> <p>Sex: Female: 86%</p> <p>Race/Ethnicity: Black: 100%</p> <p>Income: Welfare population</p> <p>Insurance Status: NR</p> <p>Other Characteristics: NR</p>	<p>Mean: 10.4 yrs</p>

Evidence Table 2: Key Question 2 (continued)

Literacy Measurement	Intervention	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
Measurement Tool: REALM Literacy Levels: Mean: 25.3 Range: 1 to 61 Intervention Group: Mean: 7.3 Range: 1 to 20 Control Group: Mean: 43.3 Range: 8 to 61 (Control group had a sig higher mean reading level)	Intervention: 8-hour, 8-day curriculum including lessons on the food groups, vitamins, portion sizes, reading of labels, meal planning, low-fat snack choices, and identification of the nutritive value of foods; included written materials, visual aids, and participatory exercises Controls: No intervention	Change in score on pre/posttests: Measuring portion size (unadjusted): Intervention group improved 0.4 points ($P < 0.05$) Controls improved 0.3 points ($P = NS$) Reading labels (unadjusted): Intervention improved 1.6 points ($P < 0.01$) Controls declined 0.3 points ($P = NS$) Consumption behaviors (self-report) (unadjusted): ($P = NS$)	No multivariate analysis concerning literacy included	Total: 1.56 1) 2 2) 2 3) 1.5 4) 2 5) 2 6) 1 7) 1.5 8) 0.5 Funding Source: NR

Evidence Table 2: Key Question 2 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Murphy et al., 2000</p> <p>Design: Nonrandomized controlled trial (patients assigned on alternating basis to read or watch video)</p> <p>Setting: Sleep clinic at Louisiana State University, Health Sciences Center</p> <p>Duration: Immediate postvideo measurement</p>	<p>To determine if an instructional videotape was more effective for increasing short-term knowledge about sleep apnea than a simplified brochure designed at the same literacy level</p>	<p>Included: Age: = 18 Primary caregiver answered if patient younger than age 18</p>	<p>195 eligible</p> <p>192 participated</p> <p>Of these, 20 were caregivers</p>	<p>Age: Mean: 45 Range: 18 to 72</p> <p>Sex: Female: 46%</p> <p>Race/Ethnicity: Black: 41% White: 58% Other: 1%</p> <p>Income: NR</p> <p>Insurance Status: NR</p> <p>Other Characteristics: Medical diagnosis: Sleep apnea: 82% Narcolepsy: 8% Other: 10%</p>	<p>Mean yrs of schooling: 12</p> <p>Range: 3rd grade to post-graduate</p>

Evidence Table 2: Key Question 2 (continued)

Literacy Measurement	Intervention	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
<p>Measurement Tool: REALM</p> <p>Literacy Levels: Mean: 53.2 (grade 7 to 8) Median: 63 (grade = 9) Score < grade 9: 40%</p> <p>Brochure (Control): Grade 0 to 3: 9% Grade 4 to 6: 11% Grade 7 to 8: 24% Grade = 9: 56%</p> <p>Video (Intervention): Grade 0 to 3: 13% Grade 4 to 6: 6% Grade 7 to 8: 18% Grade = 9: 64%</p>	<p>Intervention: 13-minute video presenting definition of sleep apnea, associated health problems, types of apnea, symptoms, testing, treatment, benefits of treatment; substantial instructional graphics, demonstrations, conversation</p> <p>Control: Brochure mimicking content of video</p> <p>Both written at 12th grade reading level according to Fog index</p>	<p>Knowledge on an 11-item questionnaire: Those with = 9th grade reading level answered 10/11 questions more accurately than those with reading level < 9th grade after reading the brochure (unadjusted)</p> <p>Those with reading ability < 9th grade performed significantly better on 2 questions when viewing video versus brochure (unadjusted): (1) type of sleep apnea that is caused when air passages blocked: 66% versus 43% ($P < 0.05$); (2) identify what CPAP does: 94% versus 78% ($P < 0.05$); no sig difference for other questions</p> <p>Outcomes concerning (1) type of sleep apnea that is caused when air passages blocked and (2) identification of CPAP; low-literacy group that viewed video more likely to obtain knowledge than low-literacy group that read brochure (adjusted)</p> <p>Those with reading ability = 9th grade performed better on 1 question when saw video rather than read brochure (unadjusted): (1) type of sleep apnea that is caused when air passages blocked: 100% versus 92% ($P < 0.05$)</p>	<p>Race Sex Clinic site</p>	<p>Total: 1.00 1) 1 2) 1.5 3) 0.5 4) 2 5) 0.5 6) 1 7) 1 8) 0.5</p> <p>Funding Source: Partially supported by Louisiana State University Health Sciences Center, Shreveport, Louisiana</p>

Evidence Table 2: Key Question 2 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Pepe and Chodzko-Zajko, 1997</p> <p>Design: Before-and-after study</p> <p>Setting: Clients of an urban health department in the Midwest</p> <p>Duration: 6 weeks</p>	<p>To examine the effect of a videotaped cholesterol education program designed for low-income, ethnically diverse, inner-city-dwelling older adults with a wide range of reading abilities</p>	<p>Low-income, ethnically diverse city dwellers Age: 60 to 80 Used the health department</p>	<p>From a potential pool of 200, clients were called by phone and invited to participate</p> <p>First 20 clients to accept were enrolled</p>	<p>Age: Mean: 69 Range: 61 to 78</p> <p>Sex: Female: 45%*</p> <p>Race/Ethnicity: White: 50%* AA: 30%* Other: 20%*</p> <p>Income: NR</p> <p>Insurance Status: NR</p> <p>Other Characteristics: None</p>	<p>Mean: 11.4 yrs</p>

Evidence Table 2: Key Question 2 (continued)

Literacy Measurement	Intervention	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
<p>Measurement Tool: REALM</p> <p>Literacy Levels: Mean: 63 Range: 55 to 66</p> <p>< 9th grade: 45% = 9th grade: 55%</p>	<p>Cholesterol information videotape delivered at 2-week followup visit</p> <p>Pretest/posttest design with post-test given 1 month following intervention</p>	<p>Change in mean cholesterol knowledge score from baseline to T2 (2 weeks) and to T3 (6 weeks): Baseline: 62% Two-week followup: 77% Six-week followup: 72% Difference over time: ($P < 0.05$)</p> <p>Pretest knowledge: = 9th grade reading level: 70% < 9th grade reading level: 57%</p> <p>Two-week test: = 9th grade reading level: 79% < 9th grade reading level: 63%</p> <p>Six-week followup: = 9th grade reading level: 75% < 9th grade reading level: 54%</p> <p>Correlation between reading ability and cholesterol knowledge: Baseline: $r = 0.43$ ($P < 0.05$) Two-week: $r = 0.48$ ($P < 0.05$) Six-week: $r = 0.66$ ($P < 0.05$)</p> <p>Change over time in cholesterol knowledge not different between reading groups, implying that different literacy level groups did not learn at a different rate due to the intervention</p>	<p>No multivariate analysis concerning literacy included</p>	<p>Total: 1.31</p> <p>1) 1.5 2) 2 3) 0.5 4) 2 5) 1 6) 2 7) 1.5 8) 0</p> <p>Funding Source: NR</p>

Evidence Table 2: Key Question 2 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Poresky and Daniels, 2001</p> <p>Design: RCT</p> <p>Setting: Head Start programs in rural northeastern Kansas</p> <p>Duration: 2 yrs</p>	<p>To evaluate the effects associated with the implementation of the FSC project for parents of children in Head Start</p> <p>Goals related to literacy, employability, and substance abuse</p>	<p>Parent/caretaker of a child in Head Start</p> <p>Group 1: Regular Head Start program</p> <p>Group 2: FSC enhanced Head Start program</p>	<p>Baseline: 80 families</p> <p>Year 1 followup: 71 families</p> <p>Year 2 followup: 60 families</p>	<p>Age: NR</p> <p>Sex: Female: 94%</p> <p>Race/Ethnicity: Euro-Americana: 66%* AA: 20%* Hispanic American: 5%* Native American: 4%* Asian American: 3%* Other: 3%*</p> <p>Income: = \$15,000/yr baseline: Group 1: 8% Group 2: 10% > \$15,000 Year 2: Group 1: 10% Group 2: 40%</p> <p>Insurance Status: NR</p> <p>Other Characteristics: NR</p>	<p>Group 1 (baseline): High school diploma: 48% GED: 30% Associate's degree: 3% Bachelor's degree: 3%</p> <p>Group 2 (baseline): High school diploma: 53% GED: 18% Associate's degree: 3% Bachelor's degree: 9%</p>

Evidence Table 2: Key Question 2 (continued)

Literacy Measurement	Intervention	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
Measurement Tool: Comprehensive Adult Student Assessment Scale	Group 1 (control): Regular Head Start program; details not given	Change in depression scores (Center for Epidemiological Studies-Depression scale): Change over time in percent depressed (unadjusted): Group 1: Baseline: 35% Time 1: 23% Time 2: 33% (<i>P</i> = NS) Group 2: Baseline: 48% Time 1: 39% Time 2: 23% (<i>P</i> = NS)	No multivariate analysis concerning literacy included	Total: 1.25 1) 1 2) 1.5 3) 1 4) 2 5) 1 6) 1.5 7) 1 8) 1
A score above 225 is considered to be high school proficiency	Group 2 (intervention): FSC enhanced Head Start program; FSC case managers developed and implemented formalized case plans for parents; worked with parents to develop a goal plan; met weekly with parents to assist them and assess progress; helped link parents with relevant community resources; goals to become employed, reach literacy goals, and reduce substance abuse	Change in reading ability (Comprehensive Adult Student Assessment scale): Group 1: Baseline: 250.52 Time 1: 251.13 Time 2: 250.83 (<i>P</i> = NS) Group 2: Baseline: 259.52 Time 1: 283.34 Time 2: 301.34 (<i>P</i> < 0.05)		Funding Source: NR
Literacy Levels: Group 1 (n = 23): Mean 250.52				
Group 2 (baseline) (n = 29): Mean 259.52				

Evidence Table 2: Key Question 2 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Powell et al., 2000</p> <p>Design: Nonrandomized controlled trial</p> <p>Intervention: Morning clinic parents</p> <p>Control: Afternoon clinic parents</p> <p>Setting: Pediatric clinic at Northwestern University Medical Center in Chicago, Illinois</p> <p>Duration: 14 to 28 days</p>	<p>To compare a PAG sheet requiring limited reading skills to a TIPP sheet for providing injury prevention to low-income urban families</p> <p>To evaluate caretaker recall of injury prevention information</p>	<p>Parents of children = 6 yrs who receive their primary medical care in the continuity clinic</p> <p>Telephone in the home</p> <p>Language: English</p>	<p>115 enrolled</p> <p>66 families participated</p> <p>(Response rate NR; calculation cannot be done)</p>	<p>Age: PAG: Child: Mean age 38 months Parent: 27 yrs</p> <p>TIPP: Child: 19 months Parent: 28 yrs</p> <p>Sex: NR</p> <p>Race/Ethnicity: Minority: PAG: 83% TIPP: 90%</p> <p>Income: Public aid: PAG: 80% TIPP: 85%</p> <p>Insurance Status: NR</p> <p>Other Characteristics: NR</p>	<p>NR</p>

Evidence Table 2: Key Question 2 (continued)

Literacy Measurement	Intervention	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
Measurement Tool: NR Literacy Levels: Not measured and no report of previous measure	Intervention: Verbal information and PAG sheet (four to six pictures of black or Hispanic child in injury situation); 7th grade reading level text Control: Verbal information and TIPP sheet; 9th grade reading level text Scale for assessment of readability not given Telephone recall survey 14 to 28 days following clinic visit; caller blinded to study group	Difference in recall of injury prevention information: Items recalled: PAG: 2.1 ± 1.5 TIPP: 1.6 ± 1.1 No sig differences recalled in items overall or in relation to fire/burns, falls, guns, or drowning	No multivariate analysis concerning literacy included	Total: 1.13 1) 1 2) 1.5 3) 1 4) 0 5) 0.5 6) 2 7) 2 8) 1 Funding Source: NR

Evidence Table 2: Key Question 2 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Raymond et al., 2002</p> <p>Design: Before-and-after study</p> <p>Setting: Malls and family planning clinics in or near eight large US cities (Denver, Los Angeles, Chicago, San Antonio, Philadelphia, Miami, Phoenix, Washington, DC)</p> <p>Duration: June to July 2001</p>	<p>To evaluate comprehension of a prototype over-the-counter package label for an emergency contraceptive pill product</p>	<p>Female Age: 12 to 50 Able to read English well enough to read an over-the-counter product label Without a health care or marketing background Without a history of participating in the study</p>	<p>663 interviewed 7 did not meet inclusion criteria 656 included in analysis</p>	<p>Age: Median: 21 Range: 12 to 50</p> <p>Sex: Female: 100%</p> <p>Race/Ethnicity: Race: White: 51.4% Black: 24.6% Other: 24.0%</p> <p>Ethnicity: Hispanic: 23.5%</p> <p>Income: \$0 to \$15,000: 11.6% \$15,001 to \$25,000: 12.8% \$25,001 to \$35,000: 20.6% \$35,001 to \$45,000: 22.6% > \$45,000: 32.4%</p> <p>Insurance Status: NR</p> <p>Other Characteristics: NR</p>	<p>= 8th grade: 4.6% 9th to 11th grade: 22.6% High school or GED: 30.4% Vocational/technical school: 2.8% Some college: 17.9% College or higher: 21.7%</p>

Evidence Table 2: Key Question 2 (continued)

Literacy Measurement	Intervention	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
Measurement Tool: REALM Literacy Levels: Among subgroups of subjects age 18 or older who had not completed college (n = 395) = 6th grade: 4.6% 7th to 8th grade: 30.8% = 9th grade: 64.6%	Prototype product label and insert for emergency contraceptive pill Contents of the intervention are displayed in the paper Patients given actual package and asked several questions about use of the product	Understanding of communication objectives: 121 comparisons within subgroups were performed, but data not shown "The only apparent pattern was that women of lower literacy were significantly less likely to understand almost all objectives than more literate women. However, 8 of the 11 objectives were each understood by more than 80% of women with low literacy."	No multivariate analysis concerning literacy included	Total: 1.13 1) 1.5 2) 2 3) 1 4) 2 5) 0 6) 1.5 7) 0.5 8) 0.5 Funding Source: Merck Fund, Women's Capital Corps

Evidence Table 2: Key Question 2 (continued)

Study Description	Research Objective	Eligibility Criteria	Total Sample Size	Demographic and Other Characteristics	Education
<p>Citation: Wydra, 2001</p> <p>Design: RCT</p> <p>Setting: Four comprehensive cancer centers (Lebanon, New Hampshire; Philadelphia, Pennsylvania; San Antonio, Texas; and Los Angeles, California)</p> <p>Duration: One session and one mail questionnaire</p>	<p>To determine the effect of an interactive videodisc program designed to improve self-care with respect to fatigue symptoms for patients with cancer</p>	<p>Included: Age: = 18 Receiving outpatient cancer treatment Provide written consent</p> <p>Excluded: Less than 5th grade reading level Brain or visual dysfunction</p>	<p>174</p> <p>86 intervention patients</p> <p>88 control patients</p> <p>159 observations used in analysis</p>	<p>Age: Intervention: 57.2 Control: 54.2</p> <p>Sex: Female: Intervention: 45% Control: 53%</p> <p>Race/Ethnicity: Intervention: White: 81% AA: 10% Latino: 8% Control: White: 81% AA: 9% Latino: 8% Missing: 2%</p> <p>Income: NR</p> <p>Insurance Status: NR</p> <p>Other Characteristics: Computer experience: Intervention: None: 10% Little: 36% Much: 53% Control: None: 11% Little: 35% Much: 51% Missing: 2%</p>	<p>NR</p>

Evidence Table 2: Key Question 2 (continued)

Literacy Measurement	Intervention	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
Measurement Tool: WRAT3 Literacy Levels: Intervention: = average: 66% > average: 34% Control: = average: 60% > average: 40% Note: Low literacy defined as deficient to average score (= 109)	Pre- and posttest measure of self-care ability, measured by multiple-choice test developed by the researchers Intervention: Interactive videodisc module Control: Conventional instruction (whatever was normally provided by the treatment facility)	Change in self-care ability (measured on study-specific scale): Intervention patients reported greater self-care ability after the intervention ($P < 0.0001$) Change in self-care ability not sig related to literacy level ($P = 0.31$) but sig related to education ($P = 0.01$)	Age Literacy level Computer experience Learning style Race Institution Education Sex	Total: 1.31 1) 1 2) 2 3) 0.5 4) 1.5 5) 0 6) 1.5 7) 2 8) 2 Funding Source: National Center for Nursing Research National Cancer Institute

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Appendix D

Acknowledgments

Appendix D. Acknowledgments

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Technical Expert Advisory Group

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