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-

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

UCLA Medical Center in Los Angeles, CA.[25,26] Study designs included cross-sectional (32), cohort (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 Hawthorne[45] (n = 3,019), was to identify predictors of early adolescent drug use, including smoking, among students in Australia. The study categorized students into low, middle, or high levels of literacy (the literacy assessment instrument and category divisions were unstated) and looked at the relationship between literacy and whether a student self-reported ever using tobacco or using tobacco in the past month. An adjusted analysis revealed a significant relationship between literacy (low literacy vs. high literacy) (OR 1.7; 95% CI 1.1, 2.7) and ever having used tobacco among boys but no significant relationship among girls. By contrast, the relationship between literacy and using tobacco in the past month was stronger than "ever used" and significant among both boys and girls.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Costs of Health Care

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

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

Disparities in Health Outcomes or Health Care Service Use

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

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

Summary

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

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

Key Question 2: Interventions for People With Low Literacy

Literature Search and Included Studies

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

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

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

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

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

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

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

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

Use of Health Care Services

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

Health Outcomes

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

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

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

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

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

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

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

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

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

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

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

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

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

Costs of Health Care

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

Disparities in Health Outcomes or Health Care Service Use

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

Summary

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

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