

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

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

Table 2. Correlations between common health literacy assessment tools

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

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

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

Category	Criteria
Study population	<p>All races, ethnicities, and cultural groups.</p> <p>Patients of all ages and caregivers whose primary language is the same as that of the health care provider and/or intervention.</p>
Study settings and geography	Studies conducted in the developed world, including North America, Australia, New Zealand, and Europe.
Time period	Published from 1980 to the present.
Publication criteria	<p>English only.</p> <p>Articles in print.</p> <p>Excluded were articles accepted for publication before appearance in the journal, articles in the so-called “gray literature,” and articles we could not obtain during the review period.</p>
Admissible evidence (study design and other criteria)	<p>Original research studies that provided sufficient detail regarding methods and results to enable use and adjustment of the data and results.</p> <p>Eligible study designs included</p> <ul style="list-style-type: none"> • before-and-after studies ; • controlled trials ; and • observational studies: prospective and retrospective cohort studies, case control studies; and cross-sectional studies . <p>Relevant outcomes must be able to be abstracted from data presented in the papers.</p> <p>Sample sizes must be appropriate for the study question addressed in the paper; single case reports or small case series (fewer than 10 subjects) were excluded.</p> <p>Other study exclusion criteria included studies</p> <ul style="list-style-type: none"> • of dyslexia and dementia; • with no original data; • with no health outcomes; • with an outcome limited to satisfaction or likeability of one intervention material compared to another; • that measured outcome only by a Cloze test of comprehension (but studies that used literacy measurements that included a Cloze test were retained); • focusing solely on the readability of materials; • that were nonintervention studies (KQ 1) and did not measure literacy in study participants; and • concerning the basic experimental science of reading ability (e.g., studies of brain function, including results from magnetic resonance imaging or electroencephalogram).

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

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

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

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

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

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

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

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

Study	Design	Health Measure	Literacy Measure	Results
Kalichman et al., 2000 ⁴⁰	Cross-sectional	HIV-infected patients' knowledge and understanding of their status and perceptions of treatment effects on transmission risks	Modified TOFHLA	Lower literacy was associated with not understanding CD4 counts or meaning of viral load. Lower literacy was associated with incorrect beliefs about HIV treatments and transmission risks.
Kalichman and Rompa, 2000 ³⁸	Cross-sectional	Health status awareness and understanding of HIV infection status, disease, and treatment-related knowledge	Modified TOFHLA	Lower literacy was associated with lack of knowledge and understanding of HIV-related health markers. Higher literacy group had higher knowledge of HIV disease and treatment than lower literacy group. Lower literacy group had more negative perceptions and experiences related to HIV-AIDS.
Kalichman et al., 2000 ³⁹	Cross-sectional	Reliability and validity of self-reported HIV-related health markers in HIV-infected adults	Modified TOFHLA	Lower literacy was more likely to have discrepant self-reported CD4 counts or viral loads.
Miller et al., 2003 ⁴¹	Prospective cohort	Dosing and compliance of HIV-infected individuals taking antiretroviral medication	S-TOFHLA	Lower medication knowledge was significantly associated with lower literacy.
Williams et al., 1998 ⁴²	Cross-sectional	Chronic disease and treatment among patients with diabetes or hypertension	TOFHLA	Patients with low literacy had less knowledge about diabetes and hypertension.
Williams et al., 1998 ⁴³	Cross-sectional	Knowledge about asthma	REALM	Knowledge increased with literacy.

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

Study	Design	Health Measure	Literacy Measure	Results
Wilson and McLemore, 1997 ³⁶	Cross-sectional	Patients hospitalized for knee or hip surgery “self-care” knowledge after education with written discharge instructions	REALM	The relationship between literacy and self-care knowledge after written education materials was not significant.
Health Behaviors and Adherence				
Arnold et al., 2001 ³⁴	Cross-sectional	Knowledge, attitude, and practices of tobacco use among pregnant women	REALM	No difference in the unadjusted rates of smoking according to literacy status.
Davis et al., 1999 ⁴⁷	Cross-sectional	Violent behavior in adolescents	Slosson Oral Reading Test	Youth who were more than two grades behind expected reading level were more likely than others to carry a weapon including a gun, take a weapon to school, miss school because it was unsafe, and be in a physical fight that required medical treatment.
Frack et al., 1997 ⁵²	Cross-sectional	Compliance with research protocols in a clinical trial	Cloze procedure	Patients who followed up as directed had a higher average literacy score than those who never followed up.
Fredrickson et al., 1995 ⁴⁴	Cross-sectional	Breast-feeding	WRAT	An association was found between low reading ability and never breast-feeding.
Fredrickson et al., 1995 ⁴⁴	Cross-sectional	Smoking	WRAT	An association between low reading ability and smoking.
Golin et al, 2002 ⁵⁰	Prospective cohort	Adherence among HIV-infected patients taking antiretrovirals	S-TOFHLA	No relationship between literacy and adherence was found.
Hawthorne, 1996 ⁴⁵	Cross-sectional	Tobacco use among 11 and 12 year olds	NR	A relationship between literacy and ever having used tobacco among boys but not among girls. The relationship between literacy and using tobacco in the past month was strong among both boys and girls.
Hawthorne, 1996 ⁴⁵	Cross-sectional	Alcohol use in adolescence	NR	Odds of having misused alcohol were higher among boys with lower literacy levels than among boys with higher literacy levels. No significant relationship emerged for girls by literacy level.

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

Study	Design	Health Measure	Literacy Measure	Results
Kalichman et al., 1999 ⁴⁹	Cross-sectional	Adherence to treatment for HIV and AIDS	Modified TOFHLA	Lower literacy was associated with greater odds of poor adherence.
Kaufman et al., 2001 ⁴⁶	Cross-sectional	Breast-feeding	REALM	Women with literacy levels at or above 9th grade were more likely to breast-feed for at least 2 months than mothers with literacy at the 7th or 8th grade level.
Li et al., 2000 ⁵¹	Retrospective case study	Adherence to breast conservation therapy in women with early-stage breast cancer	REALM	Literacy did not predict adherence to radiation, chemotherapy, or clinical appointments.
Stanton et al., 1990 ⁴⁸	Prospective cohort	Problem behavior in children	Burt Word Reading Test	Reading ability was an independent predictor of teacher-reported problem behavior.
Williams et al., 1998 ⁴³	Cross-sectional	Correct use of metered dose inhaler by patients with asthma	REALM	Patients with higher literacy had better metered dose inhaler technique.
Biochemical and Biometric Health Outcomes				
Battersby et al., 1993 ⁵⁵	Case-control	Diagnosis of hypertension	Schonell Graded Word Reading Test	No difference in reading ability between patients with or without hypertension was found.
Kalichman and Rompa, 2000 ⁵⁶	Cross-sectional	HIV infection	Modified TOFHLA	No significant association between reading comprehension and undetectable viral load.
Kalichman et al., 2000 ⁴⁰	Cross-sectional	HIV infection, optimism, and perceptions of care	Modified TOFHLA	Patients with better reading comprehension had greater odds of having an undetectable viral load than those with worse reading comprehension. No significant association between reading comprehension and undetectable viral load was found. Patients with lower literacy tended to be more optimistic about their future living with HIV.
Kalichman and Rompa, 2000 ³⁸	Cross-sectional	HIV infection, optimism, and perceptions of care	Modified TOFHLA	Better readers had greater odds of having an undetectable viral load than worse readers. Worse readers had greater odds of having a CD4 count less than 300 than did better readers. Patients with lower literacy had more distrust of providers and were less likely to believe that treatment helps.
Ross et al., 2001 ⁵³	Cross-sectional	Glycemic control in children with type 1 diabetes	WRAT3, children; NART, mothers	No significant correlation between literacy in children aged 5 to 17 and glycemic control. Parent's literacy was correlated with the child's glycemic control.

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

Study	Design	Health Measure	Literacy Measure	Results
Schillinger et al., 2002 ⁵⁴	Cross-sectional	Glycemic control in adults with type 2 diabetes	S-TOFHLA	Patients with lower literacy had worse glycemic control. The glycemic level was found to be inversely related to literacy.
Williams et al., 1998 ⁴²	Cross-sectional	Glycemic control in adults with type 2 diabetes	TOFHLA	Knowledge of diabetes was lower for patients with a low literacy status. No differences were found in the control of diabetes according to literacy status.
Williams et al., 1998 ⁴²	Cross-sectional	Patients diagnosed with hypertension	TOFHLA	Knowledge of hypertension was lower for patients with low literacy status. No differences were found in the control of hypertension according to literacy status.
Measures of Disease Prevalence, Incidence, or Morbidity				
Andrasik et al., 1988 ⁶⁰	Case-control	Children with and without migraines	WRAT	No significant difference in literacy scores between the two groups was found.
Bennett et al., 1998 ⁶¹	Cross-sectional	Stage of presentation of prostate cancer	REALM	Men with lower literacy were more likely to present with late-stage prostate cancer than those with higher literacy. After adjusting for race, age, and location of care, the investigators found that the relationship between literacy and stage of presentation was smaller and no longer statistically significant.
Fisch et al., 1998 ⁵⁹	Cross-sectional	Emotional balance after receiving informed consent materials for a bone marrow transplant	WRAT	No significant relationship between the patterns of affects changes and literacy.
Gazmararian et al., 2000 ²²	Cross-sectional	Self-reports of depression in a Medicare population	S-TOFHLA	The odds of being depressed were greater for those people with inadequate literacy compared to those with adequate literacy. After adjusting for demographic, social support, health behavior, and health status factors, the correlation was no longer statistically significant. A significant relationship between literacy and depression could not be observed. No significant relationship was found after adjusting for age and health status.
Gordon et al., 2002 ⁵⁸	Cross-sectional	Arthritis and functional status of patients with rheumatoid arthritis	REALM	Health activity did not differ according to literacy dichotomized at the 9th grade level.
Gordon et al., 2002 ⁵⁸	Cross-sectional	Self-report of depression in patients with rheumatoid arthritis	REALM	Patients with more anxiety and depression were greater among those who read below the 9th grade level than among those who read at or above the 9th grade level.

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

Study	Design	Health Measure	Literacy Measure	Results
Kalichman and Rompa, 2000 ⁵⁶	Cross-sectional	Self-reported depression in HIV-infected patients	Modified TOFHLA	Total scores on the depression scales did not differ by literacy status. Some depression subscales were higher (representing more depression) for participants with lower literacy.
TenHave et al., 1997 ³²	Cross-sectional	Self-reports of depression in adults participating in a cardio-vascular dietary education program	CARDES	Lower scores on the literacy assessment were statistically significantly associated with higher scores on the depression assessment after adjusting for age, suggesting a greater propensity for depression among those with lower literacy.
Zaslow et al., 2001 ⁵⁷	Cohort	Mothers' reports of child's depression and antisocial behavior	Test of Applied Literary Skills	Risk of depression was higher among mothers who had lower literacy skills. No relationship was detected between maternal literacy and depression or antisocial behavior among their children.
Global Health Status Measures				
Baker et al., 1997 ²⁵	Cross-sectional	Overall health status	TOFHLA	Patients with inadequate literacy had about twice the odds of reporting poor health than patients with adequate literacy.
Gazmararian, et al., 1999 ⁷	Cross-sectional	Medicare managed care health plan	S-TOFHLA	Patients with inadequate literacy were significantly more likely to self-report fair or poor health than patients with adequate literacy.
Sullivan et al., 1995 ⁶³	Cross-sectional	General health status of patients with type 2 diabetes	QLS	No difference in scores on the SF-36 according to whether the subject "passed" or "failed" the QLS.
Weiss et al., 1992 ⁶²	Cross-sectional	Health status	Tests of Adult Basic Education and Mott Basic Language Skills Program	People with lower literacy scored worse than those with higher literacy on both the physical and psychosocial subcomponents.
Cost of Health Care				
Weiss et al., 1994 ⁶⁴	Retrospective cohort	Costs of health care in Medicaid patients	Instrument for the Diagnosis of Reading	No relationship between literacy and Medicaid charges.

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

Study	Design	Health Measure	Literacy Measure	Results
Disparities in Health Outcomes or Use of Health Services				
Bennett et al., 1998 ⁶¹	Cross-sectional	Men who presented with late-stage prostate cancer	REALM	Black patients were significantly more likely than white patients to present with late-stage cancer. After adjusting for literacy, age, and location of care, the odds ratio was smaller and no longer statistically significant.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Study	Population	Results
Weiss et al., 1992 ⁶²	Young English-speaking adult students in an adult education class	Lower literacy associated with poorer health status score (adjusted)
Baker et al., 1997 ²⁵	Middle-aged English- and Spanish-speaking patients of hospital walk-in clinics or emergency departments	Lower literacy associated with poorer health status rating (adjusted)
Sullivan et al., 1995 ⁶³	Middle-aged and elderly patients with type 2 diabetes	No difference in physical functioning and literacy
Gazmararian et al., 1999 ⁷	Elderly Spanish- and English-speaking Medicare beneficiaries without dementia	Lower literacy associated with poorer health status rating (unadjusted)

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

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

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

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

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

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