Appendix A
Exact Search Strings

Appendix A. Exact Search Strings

Database: MEDLINE <1966 to October Week 1 2002>
Search Strategy:
---
1 literacy.mp. (1258)
2 limit 1 to human (1143)

Database: MEDLINE <1966 to October Week 1 2002>
Search Strategy:
---
1 literacy.mp. (1258)
2 limit 1 to human (1143)
3 1 not 2 (115)

Ovid Technologies, Inc. Email Service

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

Citations: 1-200

Database: MEDLINE <1966 to October Week 3 2002>
Search Strategy:
---
1 WRAT.mp. (101)
2 wide range achievement.mp. (152)
3 Rapid estimate of adult.mp. (26)
4 tofhla.mp. (10)
5 test of functional health.mp. (18)
6 reading ability.mp. (458)
7 reading skill.mp. (86)
8 numeracy.mp. (41)
9 (1 or 2 or 3 or 4 or 5 or 6 or 7 or 8) not literacy.mp. (701)
10 from 9 keep 1-701 (701)

Database: CINAHL <1982 to October Week 4 2002>
Search Strategy:
---
1 literacy.mp. (918)

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

PSYCINFO
Search History
#2 "health literacy"(45 records)
#1 "health literacy"(45 records)

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

ERIC
Search History
#2 "health literacy"(25 records)
#1 "health literacy"(25 records)

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

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

Search term: LITERACY [No restrictions]
The Cochrane Database of Systematic Reviews
Complete reviews (8 records selected)

PAIS

Search History
#2 health and literacy(49 records)
#1 health literacy(4 records)

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

Appendix B
Quality Rating Form

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

Short Title:_____

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

   Good ☐ Fair ☐ Poor ☐

Comment: _____

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

   Good ☐ Fair ☐ Poor ☐ NA ☐

Comment:_____

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

   Good ☐ Fair ☐ Poor ☐

Comment: _____

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

   Good ☐ Fair ☐ Poor ☐ NA ☐

Comment: _____

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

   Good ☐ Fair ☐ Poor ☐

Comment: _____

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

   Good ☐ Fair ☐ Poor ☐

Comment:

_____

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

   Good ☐ Fair ☐ Poor ☐

Comment: _____

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

   Good ☐ Fair ☐ Poor ☐

Comment: _____

9. **Funding Source:**

Appendix C
Evidence Tables

Appendix C. Evidence Tables

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

Key Questions

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

Our key questions and their paired subsets are as follows:

- **Key Question 1**: Are low literacy skills related to:

  a. Use of health care services?
  b. Health outcomes?
  c. Costs of health care?
  d. Disparities in health outcomes or health care service use according to race, ethnicity, culture, or age?

- **Key Question 2:** For individuals with low literacy skills, what are effective interventions to:

  a. Improve use of health care services?
  b. Improve health outcomes?
  c. Affect the costs of health care?
  d. Improve health outcomes and/or health care service use among different racial, ethnic, cultural, or age groups?

Information in Evidence Tables

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

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

Grading the Quality of Individual Studies

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

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

Each of the eight quality scores we present in the evidence table represents a simple average of the scores provided by the two raters. The total score is then the average of each of these scores with each item weighed equally. Corresponding to our individual item ratings, we concluded that, overall, an article should be considered poor with a rating of < 1.0, fair with a rating of $= 1.0$ and < 1.5, and good with a rating of $= 1.5$.

Glossary of Abbreviations and Acronyms Used in Evidence Tables

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

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

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

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Evidence Table 1: Key Question 1

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

Literacy Measurement	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
Measurement Tool: Slosson Oral Reading Test-Revised **Literacy Levels:** Reading level two or more grade levels behind (referred to as low reading level): 43%	**Association between low reading ability and violent behaviors, as measured by Youth Risk Behavior Survey (adjusted):** Weapon carrying past 30 days: OR = 1.9, 95% CI (1.1, 3.5) Gun carrying past 30 days: OR = 2.6, 95% CI (1.1, 6.2) Weapon carrying at school past 30 days: OR = 2.1, 95% CI (0.9, 4.5) Missed school because felt unsafe: OR = 2.3, 95% CI (1.3, 4.3) In physical fight and required treatment past 1 year: OR = 3.1, 95% CI (1.6, 6.1) Had property damage at school in past 12 months (*P* = NS) In physical fight in past 12 months (*P* = NS)	Age Race Sex Low reading measured as reading = two grades below grade level	**Total:** 1.75 1) 1.5 2) NA 3) 1.5 4) 2 5) NA 6) 2 7) 1.5 8) 2 **Funding Source:** NR

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 1: Key Question 1 (continued)

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

Evidence Table 2: Key Question 2

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

Literacy Measurement	Intervention	Main Outcomes and Results	Covariates Used in Multivariate Analysis	Quality Score
Measurement Tool: None **Literacy Levels:** NR	Group 1: Monthly videotape lessons with printed handouts, viewed during 30-minute session, conducted in groups of 3 to 5; materials written at the 4th to 6th grade level, met monthly for 6 months Group 2: Same as Group 1 but without videotapes, and first session was 1 hour in length Group 3: Same initial first session as Group 2, but no further intervention All given test to assess knowledge outcomes in month 7, repeated at month 11	**Change in HbA_1 from baseline to month 7 (unadjusted):** Group 1: Median increase of 0.2% Group 2: Median increase of 0.4% Group 3: Median decrease of 0.3% No statistical differences within or between groups Findings at 11 months similar **Change in weight at 7 months (unadjusted):** Group 1: 1.0 kg weight loss Group 2: 0.1 kg weight loss Group 3: No change Difference: ($P < 0.05$) No sig difference at 11 months Knowledge score was not sig affected by the interventions **Weight or HbA_1 % change (adjusted):** No sig difference found	Age Sex Race Education Duration of diabetes Compliance beliefs	**Total:** 1.25 1) 1 2) 2 3) 1.5 4) 0 5) 1 6) 2 7) 1.5 8) 1 **Funding Source:** Pfizer Pharmaceuticals

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

Evidence Table 2: Key Question 2 (continued)

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

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Appendix D
Acknowledgments

Appendix D. Acknowledgments

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Technical Expert Advisory Group

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