Health Literacy Interventions and Outcomes: an Updated Systematic Review

Stacey Sheridan, MD, MPH
RTI International–University of North Carolina Evidence-based Practice Center
Acknowledgements

Research Team:
• Nancy Berkman, PhD
• Katrina Donahue, MD, MPH
• David Halpern, MD, MPH
• Anthony Viera, MD, MPH
• Karen Crotty, Ph.D., M.P.H.
• Audrey Holland, M.P.H

• Michelle Brasure, Ph.D.
• Kathleen N. Lohr, Ph.D.
• Elizabeth Harden, M.P.H.
• Elisabeth Tant, B.A.
• Ina Wallace, Ph.D.
• Meera Viswanathan, Ph.D

Funding Source: AHRQ
• In 2004, AHRQ released the results of a systematic evidence review on literacy and health outcomes.

• This report showed:
  – Low health literacy is related to poorer health outcomes.
  – Health literacy interventions “show promise for improving patient health and receipt of healthcare services.”
Background

• Several national organizations have promoted health literacy as a research priority

• The research community has responded with new work

• To synthesize new work, AHRQ commissioned an update to its 2004 systematic evidence review
Questions Addressed

• Key Question 1: Are health 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 health 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?
Overview of Methods

- **Search Strategy:** MEDLINE® (2003-March 2009), CINAHL, PsychINFO, ERIC, the Cochrane Library

- **Inclusion of articles:** 2 independent reviewers reviewed titles/abstracts/articles

- **Quality rating of studies:** 2 independent reviewers, with focus on selection bias, measurement bias, confounding, power

- **Grading of overall literature:** research team, with focus on risk of bias, consistency, directness, precision
Specific Quality Rating Criteria For Articles

• Selection bias?
  – Method for Randomization?
  – Allocation Concealed?
  – Creation of Comparable Study Groups?
  – Maintenance of Comparable Study Groups?
  – Intent to Treat Analysis?

• Measurement bias?
  – Valid and Reliable Health Literacy Measure?
  – Valid and Reliable Outcome Measure?
  – Outcome Measures Equally Applied?
  – Blinding of Patients, Providers, and Outcome Assessors?

• Confounding?
  – Appropriate control of confounding?

• Power
  – Adequate sample size?
Results for Key Question 2: Effect of Interventions*

*Original Search only; does not include update search through May 2010
Included Studies

- 33 fair/good quality studies were included in the review*:
  - 19 RCTs, 2 cRCTs, 12 quasi-experimental studies
  - 14 used one specific low literacy strategy/19 used a mixture of strategies in their intervention
  - 13 stratified results by health literacy level

* 7 poor quality studies were excluded from analysis
Effects of Interventions Using Single Design Strategies

Grouped results into the following categories:

- Alternative document design (n=2)
- Alternative numerical presentation (n=1)
- Additive and alternative pictorial representation (n=6)
- Alternative media (n=1)
- Alternative readability and document design (n=4)
- Physician notification of literacy status (n=1)
Effects of Interventions Using Single Design Strategies

• In aggregate, strength of evidence was low.

• Several interventions improved comprehension in 1 or a few studies:
  – presenting only essential information (i.e. hospital death rates without other distracting information)
  – presenting essential information first (i.e. hospital death rates before consumer satisfaction)
  – presenting quality information with the higher number indicating better quality (i.e. “nurses per patient” rather than “patients per nurse”)
  – presenting information in pictograms in grouped rather than random format
Effects of Interventions Using Multiple Design Features

• Moderate strength of evidence that some interventions change health care service use

  – Intensive self-management and adherence interventions (n=4) reduced ED visits and hospitalizations

  – Educational interventions or cues for screening (n=2) increased colorectal and prostate cancer screening*

*benefits of increased prostate screening are unclear
Effects of Interventions Using Multiple Design Features

- Moderate strength of evidence that some interventions change some health outcomes
  - Self-management interventions (n=3) increased self-management behavior
    - in only study with stratified analysis effect greater in high literacy group
  - Intensive disease (not self) management programs (n=5) reduced disease prevalence and severity
Effects of Interventions Using Multiple Design Features

• Low strength of evidence for the effect of interventions on:
  – Knowledge (n=9)
  – Self-efficacy (n=9)
  – Adherence (n=4)
  – Quality of life (n =4)

• Insufficient evidence on:
  – Behavioral intent
  – Health-related skills
  – Cost
  – Disparities
Effects of Interventions Using Multiple Design Features

- Common components of effective interventions:
  - High intensity
  - Theory basis
  - Pilot testing
  - Emphasis on skill building
  - Delivery by a health professional
Effects of Interventions Using Multiple Design Features

- Intermediate outcomes changing in studies that changed distal outcomes:
  - Knowledge
  - Self Efficacy
  - Behavior
Emerging opportunities for future health literacy interventions: A systematic literature review and application of the RE-AIM framework

Jamie Zoellner, PhD, RD
Paul Estabrooks, PhD
Kacie Allen, PhD student
Monica Motley, PhD student

Virginia Tech
Department of Human Nutrition, Foods & Exercise
Rationale for Review

• No review of health literacy literature has systematically addressed or reported on issues related to external validity

• Few behavioral intervention trials report on critical generalizability indicators (Glasgow et al., 2004; White et al., 2008; Akers et al. 2010)

• Public health impact
Background
RE-AIM Framework

- **R**each
- **E**ffectiveness/ **E**fficacy
- **A**doption
- **I**mplementation
- **M**aintenance

www.re-aim.org
Aims of Systematic Review

1. To determine the degree to which health literacy intervention studies reported on **internal and external validity** indicators that could inform **research to practice translation**

2. To identify **methodological gaps** related to the research design, evaluation, and reporting
Overview of Methods

• Search strategy

• Inclusion/exclusion criteria, n=27 articles
  – Randomized controlled trial (n=17)
  – Quasi experimental (n=10)

• Data abstraction
  – Operational definitions of RE-AIM dimensions (Estabrooks et al., 2003; White et al., 2008)

• Quality of reporting summarized using counts and percents
### Results: Overall (n=27)

<table>
<thead>
<tr>
<th>RE-AIM dimension</th>
<th>Number of scored components</th>
<th>Proportion reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reach</td>
<td>5</td>
<td>68%</td>
</tr>
<tr>
<td>Efficacy/Effectiveness</td>
<td>4</td>
<td>56%</td>
</tr>
<tr>
<td>Adoption</td>
<td>6</td>
<td>36%</td>
</tr>
<tr>
<td>Implementation</td>
<td>3</td>
<td>28%</td>
</tr>
<tr>
<td>Maintenance</td>
<td>3</td>
<td>6%</td>
</tr>
</tbody>
</table>

Across 21 scored components
- Range: 4-12
- Mean (SD): 8.6 (1.6)

<table>
<thead>
<tr>
<th>Quality of Reporting</th>
<th>Number of studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Good (15-20)</td>
<td>0</td>
</tr>
<tr>
<td>Fair (8-14)</td>
<td>20</td>
</tr>
<tr>
<td>Poor (0-7)</td>
<td>7</td>
</tr>
</tbody>
</table>
## Results: Reach

<table>
<thead>
<tr>
<th>Method to identify target population</th>
<th>93%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inclusion criteria</td>
<td>96%</td>
</tr>
<tr>
<td>Exclusion criteria</td>
<td>74%</td>
</tr>
<tr>
<td>Sample size and participation rate</td>
<td>44%</td>
</tr>
<tr>
<td>Characteristics of non-participants</td>
<td>30%</td>
</tr>
</tbody>
</table>

**Proportion reporting**

| Reach                                      | 68% |

**Good examples (all Reach components):**

### Results: Efficacy/Effectiveness

<table>
<thead>
<tr>
<th>Component</th>
<th>Proportion Reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Efficacy/effectiveness</td>
<td>56%</td>
</tr>
<tr>
<td>Measures/results for at least one follow-up</td>
<td>100%</td>
</tr>
<tr>
<td>Percent attrition</td>
<td>78%</td>
</tr>
<tr>
<td>Intent-to-treat analysis</td>
<td>22%</td>
</tr>
<tr>
<td>Quality of life</td>
<td>22%</td>
</tr>
</tbody>
</table>

**Good examples (all Efficacy/effectiveness components):**
Results: Adoption

<table>
<thead>
<tr>
<th>Adoption</th>
<th>Proportion reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description of intervention location</td>
<td>100%</td>
</tr>
<tr>
<td>Level of expertise of the delivery agent</td>
<td>72%</td>
</tr>
<tr>
<td>Inclusion/exclusion criteria of delivery agents or setting</td>
<td>18%</td>
</tr>
<tr>
<td>Description of staff who delivered the intervention</td>
<td>12%</td>
</tr>
<tr>
<td>Adoption rate of delivery agent or setting</td>
<td>8%</td>
</tr>
<tr>
<td>Method to identify delivery agent</td>
<td>4%</td>
</tr>
</tbody>
</table>

Good examples (4 of 6 components):

Results: Implementation

<table>
<thead>
<tr>
<th></th>
<th>Proportion reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implementation</td>
<td>28%</td>
</tr>
<tr>
<td>Intervention duration and frequency</td>
<td>63%</td>
</tr>
<tr>
<td>Extent protocol delivered as intended</td>
<td>15%</td>
</tr>
<tr>
<td>Measures of cost implementation</td>
<td>7%</td>
</tr>
</tbody>
</table>

Good examples (duration/frequency & extent delivered):

Good examples (cost):
## Results: Maintenance

<table>
<thead>
<tr>
<th>Maintenance</th>
<th>Proportion reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maintenance</td>
<td>6%</td>
</tr>
<tr>
<td>Outcome assessed ≥6 months following completion of intervention</td>
<td>11%</td>
</tr>
<tr>
<td>Program still in place</td>
<td>7%</td>
</tr>
<tr>
<td>Measures of cost maintenance</td>
<td>0%</td>
</tr>
</tbody>
</table>

**Good examples (individual outcomes ≥6 months):**

- Dewalt, et al. *BMC Health Services Research.* 2006;6(30)
Other Issues and Take Home Points

• Moderating and mediating effects of health literacy on outcomes

• Both internal AND external validity indicators inform research to practice translation

• Diversity of settings

• Reaching the target population

• Theoretical frameworks

• Limitations of review
For Questions
Observed Limitations in this Literature

• Methodological
  – Lack of comparison group
  – Measurement of multiple outcomes with insufficient attention to power for each
  – Failure to perform adequately controlled subgroup analyses by health literacy group
Observed Limitations in this Literature

• Conceptual:
  – Failure to perform subgroup analyses
  – Testing combined interventions with inability to determine effectiveness of individual components
  – Failure to report design features that would allow future content analyses
Logic Model

Skills:
- Take Medications
- Self-monitoring
- Recognize Emergency
- Seek Additional Health Information
- Access Care

Use of Health Care Services
- Emergency Room Visits
- Office Visits
- Hospitalization
- Prevention

Health Outcomes:
- Disease
- Disease Severity
- Quality of Life
- Death

Healthy Literacy Level

Knowledge and Accurate Risk Perception

Social Norms

Intent for Health Behavior

Support from Provider/ Joint Decision Making

Initiation of Health Behavior

Adherence to Health Behavior

Resources:
- Ability to Pay
- Access to Care

Attitudes

Self-efficacy
<table>
<thead>
<tr>
<th>Admissible evidence (study design and other criteria)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eligible study designs included</td>
</tr>
<tr>
<td>• before-and-after studies;</td>
</tr>
<tr>
<td>• controlled trials; and</td>
</tr>
<tr>
<td>• observational studies: prospective and retrospective cohort studies, case control studies; and cross-sectional studies.</td>
</tr>
<tr>
<td>Relevant outcomes must be able to be abstracted from data presented in the papers.</td>
</tr>
<tr>
<td>Sample sizes must be appropriate for the study question addressed in the paper; single case reports or small case series (fewer than 10 subjects) were excluded.</td>
</tr>
<tr>
<td>Other study exclusion criteria included studies</td>
</tr>
<tr>
<td>• of dyslexia and dementia.</td>
</tr>
<tr>
<td>• of normal reading development in children.</td>
</tr>
<tr>
<td>• with no health outcomes or no use of health care services.</td>
</tr>
<tr>
<td>• with an outcome limited to satisfaction or likeability of one intervention material compared to another, or attitudes, perceived social norms, or patient-physician interaction measures.</td>
</tr>
<tr>
<td>• solely about the readability of materials, but not about the relationship between health literacy and outcomes when readability is the focus of the intervention.</td>
</tr>
<tr>
<td>• in which health literacy, numeracy, or oral health literacy are not directly measured in the population by an objective measure or linked to outcomes at an individual level.</td>
</tr>
<tr>
<td>• in which the outcome is limited to dementia or cognitive impairment.</td>
</tr>
<tr>
<td>• in which health literacy is the exposure (KQ 1) and the only study outcome is knowledge.</td>
</tr>
<tr>
<td>• of the basic experimental science of reading ability (e.g., studies of brain function, including results from magnetic resonance imaging or electroencephalogram) or basic educational achievement.</td>
</tr>
<tr>
<td>• solely or chiefly for validation of an instrument.</td>
</tr>
<tr>
<td>• in which the intervention was not designed to address low health literacy or numeracy.</td>
</tr>
</tbody>
</table>
Titles and abstracts identified through searches: n = 2883

Full text articles excluded: n = 633

288 Studies that do not measure literacy or health literacy
157 Studies with no original data
151 Studies with no health outcomes (i.e., descriptive only or have outcomes like likability, satisfaction)
15 Studies answering KQ1 where literacy is measured (not numeracy) and the only study outcome is knowledge.
6 Studies examining normal reading development in children
5 Ecological data only
3 Studies in which the outcome is limited to dementia or cognitive impairment.
2 Systematic Evidence Review only
2 Studies about dyslexia
2 Intervention studies that do not address low health literacy
1 Studies published in abstract form only
1 Unable to obtain the article

Full text articles retrieved: n = 780

Articles included in this review n = 147

Poor quality n = 35

Good and fair quality includes by key question (KQ):

KQ1 Total = 81 articles (68 studies)
KQ1a = 23
KQ1b = 58
KQ1c = 2
KQ1d = 6
KQ1 Numeracy = 13

KQ2 Total = 33 articles (31 studies)
KQ2a = 7
KQ2b = 32
KQ2c = 1
KQ2d = 0

Some articles were included for more than one KQ
Results for Key Question 1: Impact of Health Literacy on Outcomes*

*Original Search only; does not include update search through May 2010
Included Studies

- 96 studies (162 articles) met inclusion criteria for KQ1
  - 11 good quality
  - 57 fair quality
  - 28 poor quality (not considered further)

- Of 68 fair/good quality studies (94 articles),
  - Most cross-sectional, 15 cohorts
  - 81 articles examined health literacy, 13 numeracy, 0 oral literacy
Impact of Health Literacy on Outcomes

• **High strength of evidence for***:
  – Higher mortality among seniors (n=2)

• **Moderate strength of evidence for**:
  – Poorer ability to interpret labels and health messages (n=3)
  – Greater probability of depression (n=8)
  – Lower quality of life among seniors (n=4)
  – Lower receipt of influenza vaccine (n=4)
  – Greater emergency care use (n=8)
  – Increased hospitalizations (n=5)

*Knowledge outcome excluded b/c clearly related in 2004 review*
Impact of Health Literacy on Outcomes

• Low Strength of Evidence for:
  – Preventive Screening
  – Access to Care
  – Self-efficacy
  – Behavior (healthy lifestyle, smoking, ETOH, sexual)
  – Adherence
  – Skill (taking meds)
  – Disease Prevalence/Severity (asthma, HTN, DM, Prostate Ca control, global health)
  – Quality of Life, non-seniors
  – Costs
Health Literacy as a Mediator

- Multiple studies (n=5) suggest that HL is a mediator between race and health outcomes
Impact of Numeracy on Outcomes

• Strength of Evidence low for:
  – Accuracy of risk perception (n=5)
  – Knowledge (n=4)
  – Skill in taking medicine (n=2)
  – Skill in interpreting health information (n=2)
  – Disease prevalence and severity (n=3)

• Strength of Evidence insufficient for:
  – Self-efficacy
  – Behavior
  – Cost
  – Disparities
Observed Limitations of Literature

• Methodological:
  
  – Small sample sizes with lack of power to detect differences among literacy subgroups
  
  – Wide variation in potential confounding variables included in multivariate analyses
    • Potential under and over-controlling
Observed Limitations of Literature

• Conceptual:
  
  – Lack of studies looking at mediators of the relationship between health literacy and health outcomes
  
  – Lack of studies looking at health disparities and cost
  
  – Lack of studies looking at numeracy, oral literacy, or a broader set of health literacy skills.