

## The Relationship Between Literacy and Health Outcomes

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## Overview

- Literacy and health: background and systematic review
- Disease management as a strategy to improve outcomes for patients with low literacy

## Collaborators

### UNC

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## Funding Sources

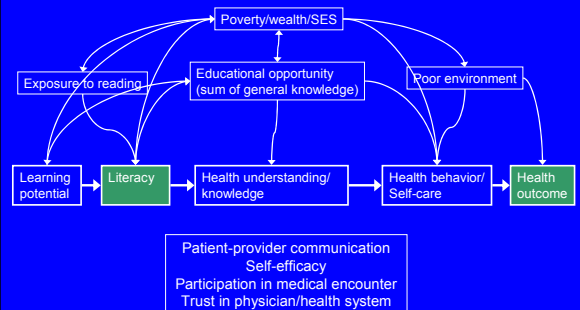
- RWJ Clinical Scholars Program
- UNC Program on Health Outcomes
- UNC Center for Research on Chronic Illness
- Pfizer Health Literacy Initiative
- Agency for Healthcare Research and Quality

## Literacy: United States

- Health care setting often requires advanced literacy skills
- National Adult Literacy Study 1992<sup>1</sup>
  - 40 million level 1
  - 50 million level 2
- National managed care program for Medicare enrollees: 34% inadequate or marginal literacy based on TOFHLA<sup>2</sup>
- Low literacy associated with adverse health outcomes

<sup>1</sup>Kirsch et al. 2002    <sup>2</sup>Gazmararian et al. JAMA 281: 445;1999.

## Conceptual Framework



## Systematic Review

- Key Question 1:  
Are literacy skills related to health outcomes?<sup>1</sup>
- Key Question 2:  
For individuals with low literacy skills, what are effective interventions to improve health outcomes?<sup>2</sup>

<sup>1</sup>DeWalt et al. under review

<sup>2</sup>Pignone et al. under review

## Literature Searching

- Used MEDLINE, CINAHL, PsychInfo, ERIC, and AGELINE
- In MEDLINE, lack of MeSH headings required keyword search: “literacy or numeracy” + “reading ability” + terms for main literacy measures
- Strategy in CINAHL was similar; other databases were searched using “health literacy”
- 92% of articles came from MEDLINE

## Study Eligibility Criteria

- Must measure a health outcome
- For KQ1 only, must measure literacy
- For KQ1, must be a cohort, case-control, or cross-sectional study (no descriptive studies)
- For KQ2, must be intervention trial with some health outcome comparison (before-after trial; randomized or nonrandomized controlled trial)
- For KQ2, literacy must be measured OR population studied must have had literacy measured previously

## Exclusions

- Studies conducted in developing countries
- Cross-sectional studies of association between literacy and cognitive impairment
- Studies measuring satisfaction only
- Studies in which literacy is the outcome rather than the exposure of interest
- Case reports or case series
- Studies with demographic outcomes only

## Results



## Search Results

- Identified 3015 articles in initial searches
- Excluded 2313 articles at abstract stage
- Examined 702 full articles
- Retained 74 articles:  
KQ1: 44; KQ2: 29
- Main reasons for rejection:
  - no original data: 48%
  - no health outcome: 34%
  - no literacy measure (KQ1 only): 10%

## Relationship between Literacy and Health Outcomes (KQ 1)

- Identified 44 articles that reported on 37 studies
- Most studies cross-sectional
- Wide range of health outcomes examined
- Most studies found that low literacy was associated with adverse health outcomes
- Quality fair-good

## Outcomes Associated with Literacy

### Health Outcomes/Health Services

- General health status
- Hospitalization
- Prostate cancer stage
- Depression
- Diabetes control
- HIV control
- Migraine
- Mammography
- Pap smear
- Pneumococcal immunization
- Influenza immunization
- STD screening

### Behaviors Only

- Substance abuse
- Breastfeeding
- Behavioral problems
- Adherence to medication
- Smoking

### Knowledge Only

- Birth control knowledge
- Cervical cancer screening
- Emergency department instructions
- Asthma knowledge
- Hypertension knowledge

## Outcomes Not Associated with Literacy

### Health Outcomes/Health Services

- Depression\*
- Hypertension
- Arthritis disability
- Visits to physicians
- Cost

### Behaviors Only

- Smoking\*
- Adherence to medication\*

### Knowledge Only

- Parental knowledge of child health care

\* - mixed findings

## Interventions to Improve Health Outcomes in Persons with Low Literacy (KQ 2)

- 29 studies examined the effect of interventions designed to mitigate the adverse impact of literacy on health outcomes
- Mixture of randomized trials and single group, uncontrolled experiments with pre- and post-intervention measurements for a range of health outcomes
- Few studies examined the interaction between literacy and the intervention
- Quality poor-fair

## Intervention Studies: Positive Findings

### Health Outcomes/Health Services

- Blood pressure
- Pneumococcal immunization rates
- Mammography rates
- Arthritis knowledge, behavior, and function
- Reduced depression

### Behaviors Only

- Self-care ability
- Dietary behavior
- Quitting smoking during pregnancy
- Breast exam accuracy

### Knowledge Only

- Sleep apnea knowledge
- Colon cancer screening knowledge
- Polio immunization knowledge
- Cervical cancer screening knowledge

## Intervention Studies: Negative Findings

### Health Outcomes/Health Services

- Cholesterol and blood pressure levels
- Colorectal cancer screening rates

### Behaviors Only

- Dietary outcomes\*

### Knowledge Only

- Comprehension of educational materials\*
- Comprehension of informed consent
- Recall of information about injury prevention

\* - mixed findings

## Exemplary Intervention Studies

- 5 controlled trials that measured literacy and stratified outcomes by literacy status
- Outcomes assessed: sleep apnea knowledge, cervical cancer knowledge, reported self-care ability, comprehension (polio vaccine), colon cancer knowledge/interest
- No studies reporting actual health outcomes

## Summary

- Low literacy (reading ability) is associated with a wide range of adverse health outcomes
- Unclear if low literacy is a causal factor in adverse health outcomes and/or a marker for other factors
- Probably mediated by more than just knowledge/understanding of health information
- Interventions to make health care materials easier to understand have had mostly positive effects on knowledge in populations with low literacy

## Areas for future research

- Need more high-quality studies of interventions that measure literacy and health outcomes and stratify results by literacy level
- Need more elucidation of pathways between literacy and health outcomes
- Need more work to understand the importance of literacy for understanding health disparities

## Chronic Disease Management



## Disease Management May Reduce Literacy-related Barriers

- Careful design of educational strategies may improve self-care, particularly for low literacy patients
- Disease management programs have not examined the role of literacy in the effectiveness of the interventions

## Disease Management Components

- Multidisciplinary teams
- Defined follow-up procedures
- Systems approach
- Patient education for self-care

## Heart Failure (HF) Epidemiology

- 4.8 million people in US have HF
- Leading cause of hospitalization among elderly
- Of those hospitalized, 25% to 50% are readmitted within 3-6 months
- Half of HF admissions are preventable
- Good self-care required for effective management

## Disease Management for Heart Failure

- Hospitalization rate decreased  
RR 0.77 [0.68,0.86]
- 7 of 8 studies reported cost savings
- No difference for mortality  
RR = 0.94 [0.75,1.19]
- No information on role of educational level or literacy

McAlister et al. Am J Med 110(5): 378, 2001.

## Research Question

Can a heart failure disease management intervention, targeted toward outpatients with low literacy, improve quality of life and reduce hospitalizations?

## Intervention

- 1-hour individualized education session
- Education booklet < 6th grade level
- Digital bathroom scale
- Scheduled follow-up phone calls
- Easy access to our team

## Development of Educational Materials

- Distilled to essential information
- Collaborated with medical illustrator
- Focus group feedback
- Cognitive interviews
- Revised materials



## Congestive Heart Failure

With congestive heart failure, the heart cannot pump the blood well. As a result, blood doesn't flow well.

Fluid leaks out of your blood vessels and backs up in the lungs and the legs.



Salt makes it harder for your body to get rid of fluid. You should avoid salt.

Fluid in lungs



Fluid in legs

## How Bad Is Your Congestive Heart Failure?

The chart below tells you how bad your heart failure is. Using it, you can tell how bad you can do.

### SWELLING

Check how swollen

OK - Swelling in arms or legs

Bad - Swelling in knee areas



Call the UNC Clinic 919-843-6480

### WALKING

Check how you walk

OK - Shortness of breath with no pressure of breath

Bad - Short of breath of rest



Call the UNC Clinic 919-843-6480

### SLEEPING

Check how you sleep

OK - Needing 2 pillows or more to avoid shortness of breath

Bad - Have to sleep upright to avoid shortness of breath



Call the UNC Clinic 919-843-6480

If you weigh	How many fluid pills?	Number of Fluid Pills		
		1	2	3
178	UNC Clinic 919-843-6480	Swelling	Weight	Number of Fluid Pills
177	2	<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe	<input type="radio"/> Morning <input type="radio"/> Afternoon <input type="radio"/> Evening	1 1
176	2	<input checked="" type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe	<input type="radio"/> Morning <input type="radio"/> Afternoon <input type="radio"/> Evening	1 1
175	2	<input checked="" type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe	<input type="radio"/> Morning <input type="radio"/> Afternoon <input type="radio"/> Evening	1 1
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173	1	<input checked="" type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe	<input type="radio"/> Morning <input type="radio"/> Afternoon <input type="radio"/> Evening	2 2
172	1	<input checked="" type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe	<input type="radio"/> Morning <input type="radio"/> Afternoon <input type="radio"/> Evening	1 1
171	1	<input checked="" type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe	<input type="radio"/> Morning <input type="radio"/> Afternoon <input type="radio"/> Evening	1 1
170	1	<input checked="" type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe	<input type="radio"/> Morning <input type="radio"/> Afternoon <input type="radio"/> Evening	1 1
169	1	<input checked="" type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe	<input type="radio"/> Morning <input type="radio"/> Afternoon <input type="radio"/> Evening	1 1
168	1	<input checked="" type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe	<input type="radio"/> Morning <input type="radio"/> Afternoon <input type="radio"/> Evening	1 1
167	1	<input checked="" type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe	<input type="radio"/> Morning <input type="radio"/> Afternoon <input type="radio"/> Evening	1 1
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165	1	<input checked="" type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe	<input type="radio"/> Morning <input type="radio"/> Afternoon <input type="radio"/> Evening	1 1
164	1	<input checked="" type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe	<input type="radio"/> Morning <input type="radio"/> Afternoon <input type="radio"/> Evening	1 1
163	0	<input checked="" type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe	<input type="radio"/> Morning <input type="radio"/> Afternoon <input type="radio"/> Evening	1 1
162	919-843-6480	<input checked="" type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe	<input type="radio"/> Morning <input type="radio"/> Afternoon <input type="radio"/> Evening	1 1

## Randomized Controlled Trial



## Design of RCT

- Disease management versus usual care
- Follow patients for one year
- Outcomes assessed at 6 and 12 months
- Setting: Academic General Medicine Clinic
- Included patients with low and high literacy for a pre-specified sub-group analysis

## Eligibility

- Age 35-80 years
- Clinical diagnosis of HF with New York Heart Association class II-IV symptoms
- Exclusions included severe co-morbid illness, including oxygen dependent COPD, renal failure, or awaiting heart transplant

## Enrollment

- Screened for patients taking furosemide
- Referrals from cardiologists
- Collected baseline data
- Randomized with concealed allocation

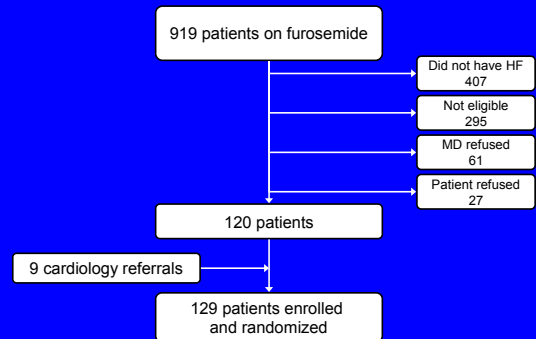
## Outcome Measures Assessed at 6 and 12 Months

- Primary Outcomes
  - HF-quality of life (Minnesota Living with Heart Failure Questionnaire)
  - Hospitalization or death
- Secondary Outcomes
  - HF knowledge
  - HF specific self-efficacy
  - HF self-care behavior

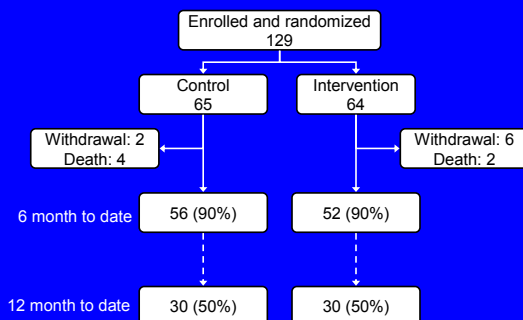
## Analysis

- Quality of life scores at 6 months
  - Linear regression
  - Adjustment for baseline differences in covariates
- Hospitalization or death
  - Negative binomial regression
  - Adjustment for baseline differences in covariates
- Pre-specified subgroup analysis of low literacy patients based on Test of Functional Health Literacy in Adults (TOFHLA)

## Enrollment Results



## Follow-up to Date



## Baseline Characteristics

Variable	Control (n=65)	Intervention (n=64)
Mean Age, years (SD)	62 (10)	63 (10)
African American, %	55%	56%
<b>Male, %</b>	<b>42%</b>	<b>58%</b>
Education, years	9.8 + 2.8	9.1 + 3.2
Income <15,000/yr, %	68%	69%
Medicaid, %	32%	36%
Medicare, %	73%	72%
Literacy Inadequate, %	40%	45%
<b>Hypertension, %</b>	<b>87%</b>	<b>73%</b>
<b>Diabetes, %</b>	<b>52%</b>	<b>61%</b>

## Baseline HF Characteristics

Variable	Control (n=65)	Intervention (n=64)
Time with HF, median years (interquartile range)	3 (1-9)	2.5 (1-8)
NYHA class, %		
II	47	53
III	51	40
<b>Systolic dysfunction, %</b>	<b>48</b>	<b>36</b>
Medications, %		
ACEI or ARB	69	75
<b>B-blocker</b>	<b>71</b>	<b>55</b>
<b>Digoxin</b>	<b>37</b>	<b>27</b>

## Baseline HF Measures

Variable	Control (n=65)	Intervention (n=64)
Knowledge, mean percent (SD)	57 (19)	56 (19)
Self-efficacy, mean score (SD)	22 (2.2)	22 (2.1)
Daily weight measurement, %	15	13
<b>HFQOL score, mean (SD) (range 0-105)</b>	<b>57 (21)</b>	<b>45 (21)</b>

## No Difference in HFQOL at 6 Months

Outcome	Control	Intervention	Difference (CI)	P value
Change in HFQOL score	-6	1	7 (-2, 15)	0.13
Adjusted* Model			2 (-6, 11)	0.58

\*Adjusted for baseline HFQOL, B-blocker use, systolic function, sex, diabetes, hypertension

## Distribution of Admissions

Count of admissions or death	Control (n=57)	Intervention (n=57)
0	30 (53%)	36 (63%)
1	13 (23%)	12 (21%)
2	6 (11%)	1 (2%)
3	1 (2%)	1 (2%)
4	2 (3.5%)	5 (9%)
5	2 (3.5%)	1 (2%)
6	2 (3.5%)	1 (2%)
7	0 (0%)	1 (2%)
8	1 (2%)	0 (0%)
Mean	1.16	0.96
Total	66	55

## No Difference in Incidence Rate for Hospital Admission or Death

Unadjusted Incidence Rate Ratio (IRR)  
0.83 [0.43, 1.61]

Adjusted IRR  
0.68 [0.36, 1.32]

\*Adjusted for baseline HFQOL, B-blocker use, ACEI or ARB use, and hypertension

## Improved HF Knowledge, Self-Efficacy, and Self-Care Behavior

6 Month Outcome	Control	Intervention	Difference (CI)	P value
Knowledge change	-2	10	12 (4, 19)	<0.01
Self-efficacy change	-0.5	1.3	2 (0.5, 3.1)	<0.01
Daily weight measurement, %	21	88	67 (53, 81)	<0.01



## Results for Patients with Low Literacy

53 patients found to have inadequate literacy based on the TOFHLA

(28 intervention, 25 control)

No difference in HFQOL

## Inadequate Literacy Lower Admission or Death Incidence Rate

Unadjusted Incidence Rate Ratio (IRR)  
0.80 [0.29, 2.25]

Adjusted\* IRR  
0.35 [0.13, 0.94]

\*Adjusted for baseline HFQOL, B-blocker use, ACEI or ARB use, and hypertension

## Preliminary Analysis Conclusions

- HF disease management improves knowledge and self-efficacy
- No change in HF QOL
- HF disease management may decrease the combined endpoint of hospitalization or death for patients with low literacy skills

## Diabetes Disease Management

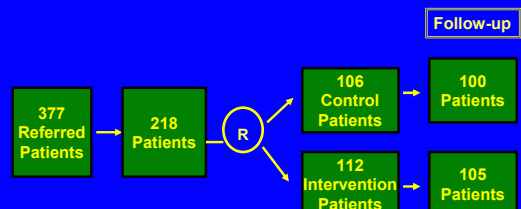
- Database
- Pharmacist-led
- Patient education
- Care coordination
- Phone follow-up
- Use of treatment and monitoring algorithms
- Integrated into primary care



## Evaluation

- Design
  - Randomized controlled trial of intensive disease management versus one-time session and usual care
  - One year duration
  - 6 & 12 month outcomes
- Setting: UNC general internal medicine practice
- Population : Poor glucose control (HbA1c $\geq$ 8%)

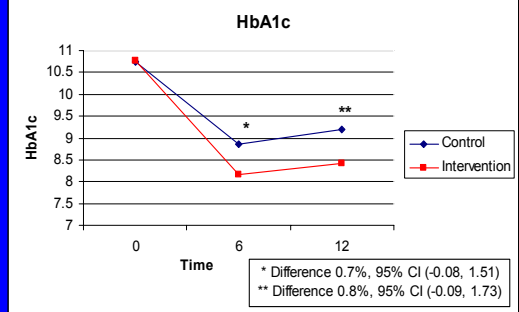
## Study Enrollment



## Outcome Measures

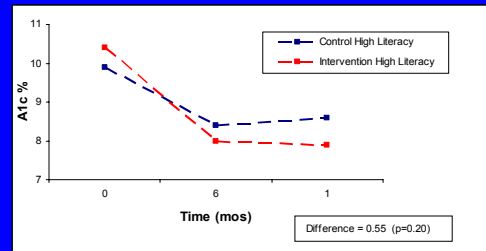
- Primary Measures (Collected at 0,6,12 months)
  - HbA1c
  - Blood pressure
  - Aspirin use
- Secondary Measures (Collected at 0,6,12 months)
  - Diabetes knowledge
  - Treatment satisfaction
  - Medical visits
  - Potential harms

## Improvement in HbA1c

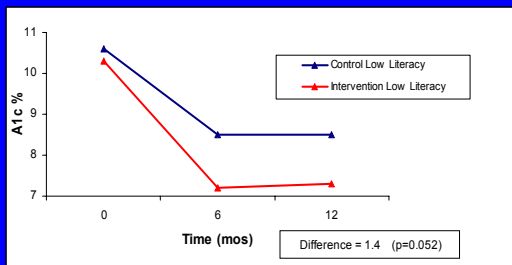


## Results According to Literacy Status

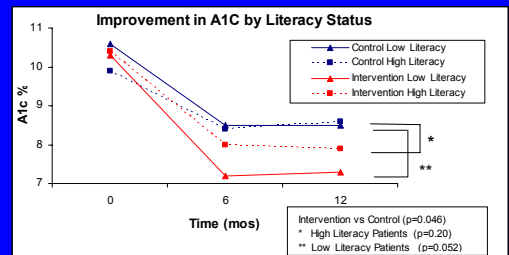
### Diabetes Control: Results for Patients with Literacy Above 6th Grade Level



### Diabetes Control: Results for Patients with Literacy at or Below 6th Grade Level



### Diabetes Control: Stratified by Literacy Status



## Limitations

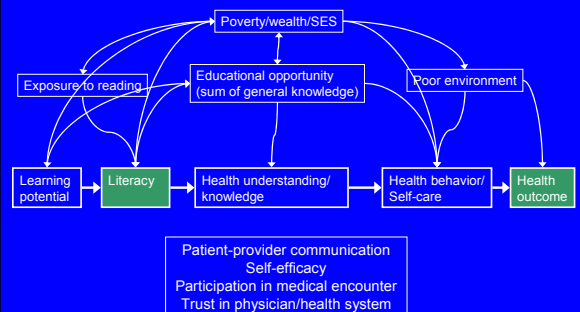
- Not blinded
- Quality of life instrument not designed for low literacy users
- Sample size small
- Outpatient recruitment
- Generalizability

## Lessons Learned

- Easy-to-read materials necessary but not sufficient
- Activated patient seems important
- Frequent reinforcement and encouragement necessary
- Measurement is challenging

## Understanding the Relationship Between Literacy and Health Outcomes

## Conceptual Framework



## Summary

- Systematic review
  - Literacy level is related to health outcomes
  - Unclear about the nature of the relationship
- Heart failure and diabetes disease management designed for low literacy patients as possible type of intervention
  - Addressing multiple factors appears to help