

Impact of a Post Emergency Department Intervention in Patients with Limited Health Literacy and Cardiovascular Disease

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Abbreviations Used

- **AAA** - Area Agencies on Aging
- **AHL** - Adequate Health Literacy
- **CAHPS** - Consumer Assessment of Healthcare Providers and Systems
- **CVD**- Cardiovascular Disease
- **DID** - Difference in Difference
- **ED** - Emergency Department
- **FFS** - Fee-for-Service
- **LHL** - Limited Health Literacy
- **PROMIS** - Patient Reported Outcomes Measurement Information System
- **REALM** - Rapid Assessment of Adult Literacy in Medicine

Mentor Approval

I have read this thesis and approve the contents.

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Abstract

Background:

Cardiovascular disease (CVD) while largely preventable, is the leading cause of death in the US. Seniors with limited health literacy (LHL) are at high risk of CVD. These vulnerable patients also make emergency department (ED) visits to address health crises. An ED intervention may help these patients get information they need to better manage their health.

Methods:

A randomized controlled trial of Medicare beneficiaries was conducted in two EDs. Patients were assigned to a post-ED coaching intervention or usual care. Health literacy, self-reported comorbidities, and informational support were recorded at baseline and 30 days after ED discharge. Changes in self-reported informational support were compared between intervention and usual-care groups.

Results:

Patients with LHL had significantly higher rates of hypertension and CVD compared to those with adequate health literacy. Usual care patients experienced a significant drop (-3.2, $p < 0.0001$) in informational support after ED discharge while the intervention group did not. A large decline in informational support in patients with LHL and hypertension was reduced by the intervention (intervention -4.004, $p < 0.0001$, usual care -1.844, $p = 0.034$).

Conclusion:

An ED-to-Home coaching program improves informational support in patients at high-risk of adverse outcomes from CVD.

Background Literature & Hypothesis

Introduction

Cardiovascular disease is the leading cause of death in the United States, killing one in four Americans.¹ Vulnerable populations including the elderly, minorities, the poor, and those with limited health literacy, shoulder a disproportionate burden of cardiovascular disease. In recent years, much research has been conducted in populations with healthcare disparities in an attempt to find ways to reduce them. Many vulnerable populations receive a substantial portion of their healthcare in the emergency department (ED) but few ED interventions to reduce

healthcare disparities have been proposed or tested. Here we present a study conducted in two vulnerable ED populations, those who are elderly and those with limited health literacy, and examine their association with cardiovascular disease. We also report the impact of an ED-to-Home transitional care coaching program aimed at improving quality of life, including self-reported informational support, in these vulnerable patients.

Health Literacy

Health literacy is defined “as the degree to which individuals have the capacity to obtain, process, and understand basic health information needed to make appropriate health decisions and services needed to prevent or treat illnesses.”² Limited health literacy (LHL) has been associated with lower educational achievement and cognitive ability,³ worse mental health,⁴ and an increased chance of experiencing a significant decline in physical functioning compared to patients with adequate health literacy (AHL).⁵ Patients with LHL visit the ED more often,⁶ are admitted more often,⁷ and return to the ED within 14 days more often than patients with AHL.⁶ They often have difficulty communicating with healthcare providers.⁸ Less active communication and problem-solving with providers leaves patients less able to understand and manage medications and other instructions given by a provider.^{9,10} Patients with LHL are also less likely to have a primary care physician, insurance for medications,¹¹ and to obtain preventive health services⁸ than those with AHL. As a result of these and other factors, patients with LHL are considered to have poor access to healthcare.^{8,11}

Health Literacy’s Relationship to Cardiovascular Disease

Patients with limited health literacy may experience difficulty understanding basic health information, which appears to cause patients to desire less involvement in healthcare problem-solving and decision-making processes.¹² Many risk factors for cardiovascular disease are modifiable but require active patient self-management and collaboration with a provider. For example, cardiovascular risks can be reduced with diet, exercise, and tobacco cessation.¹⁴ Control of existing health conditions such as hypertension, elevated lipid levels, and type 2 diabetes can also modify cardiovascular risks. Less engaged patients, such as those with limited health literacy, may find it difficult to adopt the healthy behaviors that reduce risk of cardiovascular disease or to understand the information provided by their doctor to manage existing cardiovascular risks.¹³

Both limited health literacy and cardiovascular disease are prevalent in the elderly. Cardiovascular disease affects 46 million Americans over the age of 60 years.¹⁴ In addition, the

lowest health literacy values of any age group are in individuals over the age of sixty,¹⁵ negatively impacting an already disadvantaged population. Elderly patients with limited health literacy are twice as likely to have an indicator of poor access to health care¹¹ and poorer overall health than individuals with adequate health literacy.¹⁶ Poor access to healthcare is also a risk factor for the development of cardiovascular disease.

As more elderly patients develop cardiovascular disease, hospitalizations and mortality rates related to the disease increase. Today, two-thirds of all cardiovascular disease-related deaths occur in patients aged 75 and older.¹⁴ Elderly patients with cardiovascular disease also make up a large component of the chronically ill patient population who visit the ED more often than others.⁶

Outcomes Important to ED Patients

Efforts to help patients manage their health and healthcare are unlikely to be effective if they don't align with patients' perspectives. Patient members of our research team, who are elderly, have cardiovascular disease, and have used the ED, indicate the most important outcome to them is improved quality of life. Patients with LHL and cardiovascular disease visit the ED when they feel that they have no other option and need to seek care.^{8,11,17} Since many forms of cardiovascular disease are manageable with lifestyle changes, medication adherence, and basic information, providing a transitional care coaching intervention to patients with LHL and cardiovascular disease after an ED visit could improve their overall quality of life and health outcomes. Despite its importance, no data was found on quality of life in ED patients. The National Institutes of Health Patient Reported Outcomes Measurement Information System (PROMISTM) are precise, reproducible measures of quality of life that have been validated in the general US population, including the elderly and chronically ill. PROMIS measures to assess quality of life in numerous domains are available. Based on input from patient members of our research team, we assessed the impact of the ED-to-Home coaching intervention on physical health (physical function), social health (informational support), and emotional health (anxiety).

Interventions in Elderly Patients with LHL and Cardiovascular Disease

Transitional care interventions have been noted to be particularly effective in reducing hospital readmissions in chronically ill patients but no two transitional care interventions are the same.¹⁹ Programs typically provide a healthcare professional with the ability to spend substantial time working one-on-one with patients, which traditional office or hospital-based practices do not allow. That said, they are not a one-size-fits-all solution in terms of patient-centered outcomes. Reviews of the development and efficiency of transitional care

interventions reveal that one of the most important factors in developing an effective health-related intervention is health literacy.^{19,20}

A common transitional care program, the Coleman Care Transitions Intervention, has been effective at decreasing hospitalizations.^{21,22,23} The ED-to-Home transitional care coaching program is modeled on the Coleman model. The Coleman model is designed to empower patients and caregivers to schedule and attend a follow-up doctor's visit following a healthcare crisis, to recognize and respond to signs and symptoms of worsening disease, to reconcile medications, and create a dynamic patient-centered record to facilitate patient-provider communication.²¹

Many interventions are effective in patients with cardiovascular disease, although few have been tested in the ED setting.^{17,24,25,26,27,28} A study on the efficacy of a heart failure self-management program specifically for patients with LHL indicated that education on daily weight measurement, diuretic dose self-adjustment, and symptom recognition and response decreased patient hospitalizations and deaths.²⁵ No difference was found in the patient's quality of life, although patients were already stable in an outpatient setting.²⁵ Other studies report decreases in adverse clinical outcomes,²⁷ costs,²⁷ and cardiovascular disease risks for patients enrolled in a health behavior-related intervention.²⁹ Moreover, educational support interventions in patients with chronic heart failure increase medication adherence²⁸ and quality of life indicators^{17,26} and decrease return ED visits.²⁶

Within the scope of this study, cardiovascular disease is defined as self-reported angina, congestive heart failure, stroke, atrial fibrillation, or a heart attack/angina. LHL has already been linked with specific aspects of cardiovascular disease, such as less time to a heart attack or death, or the development of a specific form of cardiovascular disease, such as coronary heart disease.³⁰ Elevated blood pressure is also independently associated with LHL.³¹ LHL has also been associated with not only increased mortality rates,^{31,32,33,34,35} but also increased mortality rates in patients specifically hospitalized for coronary heart failure.^{32,34} Based on existing evidence, we hypothesized that rates of cardiovascular disease would be higher in ED patients with LHL compared to AHL. We further hypothesized that an ED-to-Home transitional care intervention with its one-on-one assistance to patients, would be as effective in individuals with cardiovascular disease and LHL as in those with AHL. In order to test our hypothesis, we tested the following aims:

1. To determine the prevalence of cardiovascular disease in older, chronically ill ED patients with LHL

2. To determine the extent to which a tailored, coaching ED-to-Home Intervention is differentially effective in modifying quality of life indicators in ED patients with cardiovascular disease and limited compared to adequate health literacy

Methods

Study Design

This study is a mixed-methods study, including quantitative and qualitative data from ED patients with LHL and cardiovascular disease. The study is based on a multi-site, randomized, controlled trial, “An Emergency Department-to-Home Intervention to Improve Quality of Life and Reduce Hospital Use.” Here, we examine the prevalence of LHL and cardiovascular disease in this cohort.

Study Population

ED patients who were Medicare Fee-For-Service (FFS) beneficiaries with at least one chronic medical illness comprised the study population. A total of 1,004 chronically ill adults were recruited at two study sites: UF Health Gainesville and UF Health Jacksonville. Patients were randomly assigned to the intervention and or usual care groups.

Study Setting

Study sites include the UF Health EDs at Gainesville and Jacksonville, FL. The UF Health Gainesville ED sees approximately 6,000 Medicare FFS recipients annually. Most (63%) are Caucasian and 34% are African-American.³⁶ UF Health Jacksonville ED sees approximately 5,000 Medicare FFS beneficiaries annually. Most (66%) are African-American and 32% are Caucasian.³⁶

Inclusion Criteria

Patients were eligible to participate if they were Medicare FFS beneficiaries, resided within the geographical area defined by specific zip codes (to enable home visits), had a working telephone (to allow for follow-up), and one or more chronic medical conditions including (but not limited to): hypertension, congestive heart failure, chronic obstructive pulmonary disease, coronary artery disease, depression, diabetes, stroke, pneumonia, osteoarthritis, rheumatologic disease, medical or surgical back conditions, hip fracture, peripheral vascular disease, cardiac arrhythmias, deep venous thrombosis, pulmonary embolism, liver disease, peptic ulcer disease or hemorrhage. Patients with a chronic condition unrelated to

cardiovascular disease were included in the study to allow for a comparison between the overall chronically-ill elderly population and the elderly population specifically chronically-ill with cardiovascular disease.

Exclusion Criteria

Patients without a working telephone and those residing outside the defined geographical area were excluded. Patients were also excluded if they had a current diagnosis of psychosis, were undergoing active cancer treatment, had dementia without a live-in caregiver, were on hospice care, resided in a skilled nursing or assisted living facility, or were organ transplant patients. These patients were already receiving social- and medical- support services or the critical nature of their illnesses could not be addressed by our program.

Randomization

After obtaining informed consent, participants were randomly assigned with equal probability to either the ED-to-home intervention (intervention) or usual-care groups. All participants received the same written and verbal discharge instruction from their treating physician and nurse. The intervention group received information on scheduling a home visit with a community-based, Area Agency on Aging healthcare coach.

Intervention Group

Participants in the intervention group received the coaching program from the Area Agency on Aging. Area Agencies on Aging (AAA) are community-based organizations that link chronically-ill patients with the support services needed to manage a current health crisis and to prevent future ones. Social support options usually offered to patients include case management support, caregiver support, transportation, disease management support, Medicare support, personal care support, and nutritional support.

A trained AAA healthcare coach (one for the Gainesville site and one for the Jacksonville site) conducted a home visit and at least three follow-up phone calls with these ED patients. The AAA coach was formally trained and used Coleman's care transitions intervention^{21,22,23} to assist patients:

1. Schedule and attend a follow-up doctor's visit
2. Recognize and respond to signs and symptoms of worsening disease
3. Review, understand, and address concerns about their current medications

4. Maintain a patient-centered health record to facilitate patient-provider communication

The home visit took place within 48 hours after ED discharge, based on patient preference. The patient advocate is trained and able to work with patients of all health literacy levels during multiple sessions and through assessment of the patient's understanding.

Usual-Care Group

The typical ED has high patient volumes and acuity, frequent provider interruptions and multiple patient hand-offs.²⁷ Patients in the usual care group received written and verbal discharge instructions from their ED providers.

Sample Size Determination

The primary outcome measures for this study are quality of life and preventable hospital-based care (return ED visits, hospital admissions). Our sample size determination was based on anticipated reduction in hospital-based care. Based on pilot data from the Jacksonville AAA, a power analysis was conducted to determine the sample size needed to detect a 30% reduction in preventable hospital-based care (ED visits and hospital admissions) in the intervention compared to the usual-care group. Three-hundred participants in both the intervention and usual-care groups (600 total) are required to detect a 32% (31 to ~21%) reduction in composite repeat ED visits and hospital admissions using Medicare claims data with a power of 80% and alpha of 0.05 at each site (Table 1).

Table 1: Sample Size		
	UF Health Gainesville	UF Health Jacksonville
Intervention	300	300
Usual-care	300	300

Data Sources and Collection

Quantitative data sources included electronic health record information, a baseline in-person survey, and a telephone follow-up survey.

Quantitative Data Sources

Baseline in-person Survey

At study entry, all participants were asked to complete a baseline, in-person survey conducted by a trained research associate. The baseline survey included measures of global health status such as patient comorbidities and satisfaction with overall care. Items to assess physical health (physical function), social health (informational support), and emotional health (anxiety) were obtained from PROMIS™ measures. Development of the PROMIS™ measures was funded by the NIH Roadmap for Medical Research Initiative to establish precise and efficient measures of patient-reported symptoms, functioning, and quality of life that are appropriate for patients with a wide variety of chronic medical illnesses.³⁷ Global health status was assessed with one question obtained from the PROMIS™ Global Health Scale. Satisfaction with care was assessed by a patient rating of their provider and overall healthcare using the Consumer Assessment of Healthcare Providers and Systems (CAHPS).³⁸ The CAHPS has been rigorously tested for reliability and validity.^{39,40}

The baseline survey recorded the participants' sociodemographic, socioeconomic, and health status characteristics using modified information from the 2011 Medicare Current Beneficiaries Survey. Patients who enrolled in the study were asked about their chronic medical conditions. Data from the electronic health record was also used to record chronic medical conditions and the nurse-assigned ED triage severity score.

Health literacy was assessed with the 66-item Rapid Estimate of Adult Literacy in Medicine (REALM).^{41,42} The REALM relies on word recognition and pronunciation from patient education materials and can be administered and scored in 3 minutes or less.

The REALM was selected because of its validation in diverse populations (racial/ethnic groups)⁴³ and older adults⁴⁴ as well as its brevity, a critical factor given the time-sensitive ED environment. Categories include adequate (≥ 61 words pronounced correctly; grade level ≥ 9) or limited health literacy (< 61 words pronounced correctly; grade level 0 – 8).⁴⁵

Telephone follow-up Survey:

All participants were contacted by the University of Florida Survey Research Center (UFSRC) within 31 – 60 days of ED or hospital discharge to participate in a telephone follow-up survey. The information in the baseline in-person interview and

telephone follow-up surveys was used to compare intervention and usual care group quality of life at the initial ED visit to responses 31 days later.

Qualitative Data Source

Twenty participants from each study site were selected for in-depth qualitative interviews. These patients were given the option to participate in the interview by UF investigators. Those who participated were compensated with a \$50 gift card. Interviewees were tape recorded only after informed consent was obtained. All identifying information was removed from the transcribed interviews. Investigators asked each participant about what led to their ED visit and what happened afterwards. Some patients who presented with cardiovascular disease were asked about their opinions in regards to how they developed the disease. Participants described their understanding in managing cardiovascular disease risk factors. All interview transcripts were evaluated for references to cardiovascular disease.

Table 2: Timeline for study for individual patients	
Event	Time-Table
Patient Recruitment: identified for possible study entry by UF physicians, nurses, and social workers and confirmed by trained research associates	Initial ED visit
Informed Consent: completed by research associates	Initial ED visit
Randomized: to intervention or usual-care groups	Initial ED visit
Base-line survey, in hospital survey	Initial ED visit
Health Literacy test: in hospital, through Rapid Estimate of Adult Health Literacy in Medicine (REALM)	Initial ED visit
Follow-up telephone survey: examines effectiveness of intervention and possible Health-Related Quality-of-Life	31 days after initial ED visit
In-Depth Interview: with 20 participants from each study site	31-60 days after initial ED visit

Table 3: Summary of data sources		
Treatment		
Variable	Data Source	
Exposure to Intervention or Usual Care Group	Randomization Sequence	
Potential Effect Modifiers		
Variable	Measure	Data Source
Health Literacy	REALM	Baseline, In-Person Survey
History of Cardiovascular Disease (defined as past history of heart attack, angina, congestive heart failure, stroke, or atrial fibrillation)	Chronic Medical Conditions from the Electronic Health Record	Baseline, In-Person Survey
At risk for Cardiovascular Disease (defined as past history of hypertension)	Chronic Medical Conditions from the Electronic Health Record	Baseline, In-Person Survey
Health-Related Quality of Life Outcome Variables		
Variable	Measure	Data Source
General Health Status	Global Health Survey	Baseline, In-Person Survey and Phone Follow-Up Survey
Physical Health: <i>Physical Function</i>	PROMIS™ Physical Function Survey	Baseline, In-Person Survey and Phone Follow-Up Survey
Social Health: <i>Informational Support</i>	PROMIS™ Informational Support Survey	Baseline, In-Person Survey and Phone Follow-Up Survey
Emotional Health: <i>Anxiety</i>	PROMIS™ Emotional Distress Survey	Baseline, In-Person Survey and Phone Follow-Up Survey
Patient-Level Covariates to Adjust for Randomization, Recruitment, or Retention Imbalance or Missing Data		
Variable	Measure	Data Source
Sociodemographic Characteristics	Race/Ethnicity, Age, Gender, Marital Status	Electronic Health Record and Baseline, In-Person Survey
Socioeconomic Characteristics	Employment, Insurance	Electronic Health Record and Baseline, In-Person Survey
Health Assessment: Chronic Medical Conditions	Type and number of other (not CVD related) chronic medical conditions	Electronic Health Record and Baseline, In-Person Survey
Triage Severity Score	Triage Severity Score	Electronic Health Record

Results

Patient Characteristics

1004 patients were enrolled in the study with ages varying from 60.044 to 99.882 years. The mean age was 72.174. Patient characteristics are reported in Table 4.

Table 4: Characteristics of all enrolled patients (N=1004)

		Frequency	Percent
Race	African American/Black	501	49.95
	Asian	4	0.40
	Native American or Alaskan Native	14	1.40
	Native Hawaiian or other Pacific Islander	1	0.10
	Other	20	1.99
	Caucasian	463	46.16
Hispanic Descent	Yes	32	3.20
	No	969	96.80
Supplementary Payer Status	Medicaid	457	45.52
	Private	219	21.81
	Other	246	25.50
Emergency Severity Score	1 - Immediate	15	1.53
	2 - Emergent	543	55.41
	3 - Urgent	366	37.35
	4 - Less Urgent	54	5.51
	5 - Non Urgent	2	0.20
Education	8th Grade or Less	124	12.41
	Some High School but did not graduate	230	23.02
	High school graduate or GED	302	30.23
	Some college or 2-year degree	214	21.42
	Four-year college degree graduate	68	6.81
	More than four-year college graduate	61	6.11
Employment	Retired	658	65.60
	Disabled	241	24.03
	Unemployed not looking for work	56	5.58
	Unemployed looking for work	10	1.00
	Employed part-time	24	2.39
	Employed full-time	14	1.40
Marital Status	Married	296	29.54
	Separated/Divorced	281	28.04
	Single/Never Married	130	12.97
	Widowed	295	29.44
Health Literacy	Adequate Health Literacy	413	50.12
	Limited Health Literacy	411	49.88
Self-Reported Hypertension	No Hypertension	179	17.83
	Hypertension	825	82.17
Self-Reported Cardiovascular Disease	No Cardiovascular Disease	205	20.42
	Cardiovascular Disease	799	79.58
Assigned Group	Usual-care	499	49.75
	Intervention	504	50.25

Patients lost to follow-up

Older patients, those with lower educational levels, LHL, more chronic conditions, and worse physical health status at baseline were less likely to complete the follow-up telephone survey. Women and patients who had Medicaid as a payer source were more likely to complete the follow-up telephone survey. Thirty percent of the usual care group and 27% of the intervention group did not complete the follow-up survey.

Health Literacy Level

Prevalence of LHL and AHL were roughly equal in the overall patient cohort (Table 4). Significant differences were identified among specific subgroups, which is explored below.

Specific Aim 1: Association of Limited Health Literacy and Prevalence of Cardiovascular Disease

Our first specific aim was to determine the association of LHL and prevalence of cardiovascular disease in older, chronically ill ED patients. In order to do this, we evaluated the responses of all chronically ill ED patients participating in the study. A total of 825 patients (82.17% of total) reported having hypertension and a total of 799 patients (79.58% of total) reported having a form of cardiovascular disease. Cardiovascular disease, for the purpose of this study, was defined as self-reported heart attack/angina, angina, congestive heart failure, stroke, and/or atrial fibrillation.

Patients with LHL were found to have a statistically significant 4% higher chance of having both hypertension and cardiovascular disease than their AHL counterparts (Table 5).

Racial Disparities

The majority of the patients enrolled in this study described their race as either Caucasian or African-American. Those who described their race as African-American were found to have higher rates of cardiovascular disease or hypertension and were more likely to have LHL than their Caucasian counterparts. They were found to have a statistically significant increase, (7%) in prevalence of cardiovascular disease or hypertension, a recognized risk factor for other forms of cardiovascular disease, than their Caucasian counterparts (Table 6). African-American patients were found to have markedly different rates of LHL and AHL compared to Caucasian patients. Caucasian patients were found to have higher rates 73% of Caucasian patients had AHL, while 73% of African-American patients had LHL (Table 5).

Table 5: Prevalence of Health Literacy				
		Limited HL (n,%)	Adequate HL (n,%)	p-value
	Entire Cohort (n=1004)	411 (50%)	413 (50%)	
Comorbidity	Hypertension	378 (52%)	344 (48%)	0.0002
	Cardiovascular Disease	388 (52%)	364 (48%)	0.0014
Race	Caucasian	105 (27%)	288 (73%)	<0.0001
	African-American	288 (73%)	105 (27%)	

Table 6: Prevalence of Self-Reported Cardiovascular Disease by Race			
	Cardiovascular Disease or Hypertension (n,%)	No Cardiovascular Disease or Hypertension (n,%)	p-value
Caucasian	403 (87%)	60 (13%)	0.0024
African-American	473 (94%)	28 (5%)	

Health-Related Quality of Life Changes

The PROMIS™ Global Health Scale was administered in the baseline, in-person survey at the index ED visit and again during the follow-up telephone survey. The PROMIS instruments were used to measure self-reported physical functioning, anxiety, and informational support; higher scores for each category indicate more of the measured domain. For example, higher scores on the informational support domain indicate more informational support, while higher scores for anxiety indicate more emotional distress. The follow-up score for each category was subtracted from the baseline score to determine the impact of both time and the ED-to-Home Intervention on each aspect of a patient’s health (Table 7). Positive values reflect an increase in that aspect of a patient’s health and negative values reflect a decrease. The healthcare coach did not provide medical care or mental health counseling to patients. Instead the coach attempted to inform patients about their diseases and discuss strategies patients could employ to better manage their own health. Quality of life social health changes were examined here.

Patients' physical functioning and emotional health differences between the intervention and usual care groups utilized a different approach and were explored later (Table 11).

In order to account for potential differential attrition and loss to follow-up bias, propensity scores were constructed. This method assigns more weight to patients most like those who were lost to follow-up.

Health-Related Quality of Life Changes in Patient's Social Health

Overall Changes

Patient's social health was evaluated by self-reported informational support. Increases in a patient's informational support could lead to better disease outcomes as they understand more about their disease risk-factors, red-flags, and when and how to seek support.

Based on one-on-one coaching and extended patient interactions, we hypothesized that patients with LHL would benefit as much from the intervention as those with AHL. When looking at the overall patient population, those in the usual care group had a large and statistically significant drop in informational support. Those in the intervention group had an insignificant decline in informational support (Table 7). Based on planned subgroup analysis, a more obvious trend takes shape. All differences are reported here, but only those in bold were found to be statistically significant.

Race

We compared the differences in self-reported quality of life in patients who are Caucasian to those who are African-American. Most notably, African-American patients were found to have more than twice the decline in informational support after the ED visit than their Caucasian counterparts. The healthcare coach intervention was found to reduce the drop in informational support that African-American participants perceived by more than half (Table 7). There were no statistically significant differences in Caucasian patients' informational support from baseline to follow-up in either the intervention or usual care groups.

Health Literacy

Patients in the usual care group with LHL were found to have a 73% higher decline in informational support than those with AHL. It is possible the larger drop in informational support experienced by patients with LHL reflects the difficulties patients experience after leaving the fast-paced environment of the ED. The ED-to-Home transitional care coaching intervention was

found to reduce the decline in informational support experienced by those with LHL by approximately half.

Hypertension

Patients with self-reported hypertension assigned to the ED-to-Home transitional care coaching intervention had a 60% smaller drop in informational support than those in the usual care group.

Cardiovascular Disease

Among the usual care group, patients with self-reported cardiovascular disease had a 46% smaller decline in informational support than those with hypertension. Those with cardiovascular disease assigned to the intervention group had an insignificant decline in informational support. These results suggest the ED-to-Home intervention may not be particularly effective in patients who already have cardiovascular disease.

Table 7: Unweighted Changes in Social Health Scores in Patients from Baseline to Follow-Up		Social Health: <i>Informational Support</i> Follow-up - Baseline	
		Usual Care	Intervention
	Entire Cohort	-3.2 (n=351, p<0.0001)	-0.82 (n=364, p=0.1884)
Race	Caucasian (n=462)	-1.964 (n=192, p=0.048)	0.272 (n=170, p=0.9767)
	African-American (n=499)	-4.558 (n=159, p<0.0001)	-2.146 (n=179, p=0.0248)
Health Literacy	Adequate Health Literacy (n=411)	-2.25 (n=148, p=0.0261)	-0.087 (n=160, p=0.8586)
	Limited Health Literacy (n=590)	-3.889 (n=203, p=0.0001)	-1.394 (n=204, p=0.1116)
Comorbidity	Hypertension (n=823)	-3.106 (n=276, p<0.0001)	-1.252 (n=308, p=0.051)
	Cardiovascular Disease (n=554)	-1.679 (n=195, p=0.0411)	-0.626 (n=204, 0.2943)

Specific Aim 2: Quality of Life Changes by Health Literacy & Hypertension

Our second specific aim was to determine the extent to which a tailored, coaching ED-to-Home transitional care intervention differentially impacts quality of life in ED patients with

cardiovascular disease and limited compared to adequate health literacy. To do this, we evaluated the quality of life responses of all chronically ill ED participants in the study who self-reported hypertension. Responses were compared by health literacy level. Quality of life was also evaluated in those who self-reported hypertension. Hypertension was chosen as the indicator of cardiovascular disease because it is found more often in patients with LHL,³¹ is correlated with the development of further cardiovascular disease and is a modifiable risk factor for the development of adverse outcomes from cardiovascular disease such as stroke, heart attack and congestive heart failure.¹³ Health literacy levels may determine if patients understand the steps they need to take to avoid this development.²

Among patients with hypertension, those with AHL in both the usual care and intervention groups were found to have insignificant changes in informational support after leaving the ED. All patients with LHL experienced a significant decrease in informational support in the month following the ED visit; however, patients assigned to the coaching Intervention reported half of the decline in informational support as their usual care counterparts (Table 8).

Table 8: Mean Effect of the ED-to-Home Intervention by Health Literacy on Patients with Hypertension		Social Health: <i>Informational Support</i> Follow-up - Baseline	
		Usual Care	Intervention
Self-Reported Hypertension	Overall (n=823)	-3.106 (n=276, p<0.0001)	-1.252 (n=308, p=0.051)
	Adequate Health Literacy (n=328)	-1.793 (n=112, p=0.1689)	-0.483 (n=134, p=0.6198)
	Limited Health Literacy (n=492)	-4.004 (n=164, p<0.0001)	-1.844 (n=174, p=0.034)

Weighted Changes

Propensity score weighting was used to account for differences in between-group differences in patient characteristics at baseline as well as for non-random attrition. This approach assigned each patient a weight equal to the inverse probability of being assigned to the Intervention or Usual-Care group at baseline. A second weight was constructed to estimate the inverse probability of remaining in the study given baseline covariates. This allowed a greater weight to be given to patients most like those who did not respond and are therefore underrepresented in the sample. Significance was determined at the p<0.05 level and both unweighted and weighted models are presented. All quantitative analyses were conducted

using Stata v.13. The differences between patient characteristics of the unweighted and weighted propensity scores are shown in Table 9.

Additional analyses on changes in patient’s informational support were conducted using propensity scores (Table 10). A difference-in-difference (DID) analysis was conducted, clustered by site to account for unmeasured site-level factors. The analysis followed an intention-to-treat approach to avoid potential issues of noncompliance and missing data, common to randomized controlled trials. The DID is calculated by first finding the difference in baseline and follow-up quality of life scores in both the intervention and the usual care and calculating the mean of each. The difference in these mean-differences is then calculated to determine the effect the intervention has on a patient’s quality of life. For example, a positive DID value reflects an increase in patient’s informational support as a result of the intervention. DID scores are reported for informational support (Table 10) and for physical functioning and anxiety (Table 11).

The propensity scores resulted in less statistically significant differences between the intervention and usual care groups than many of the unweighted scores, although the direction of scores were similar. Patients who self-reported hypertension were found to benefit from the intervention in terms of their informational support (DID 1.68, p=0.044), while patients who had already developed cardiovascular disease did not have statistically significant changes in scores.

Table 9: Characteristics of participants by before and after propensity scoring (N=749)

	Unweighted				Weighted			
	Overall (N=749) %	Intervention (N=384) %	Usual-care (N=365) %	p-value	Overall (N=749) %	Intervention (N=384) %	Usual-care (N=365) %	p-value
Mean Age (SD)	72.1 (8.2)	72.9 (8.0)	72.2 (8.5)	0.64	72.4 (9.1)	72.2 (9.5)	72.6 (8.7)	0.55
Gender				0.95				0.91
Male	64	64	64		61	61	61	
Female	36	36	36		39	39	39	
Non-Caucasian				0.31				0.50
Yes	51	53	49		54	55	53	
No	49	47	51		46	45	47	
Emergency Severity Index^{1^}				0.88				0.53
High Acuity	42	43	42		43	44	42	
Less Urgent	58	57	58		57	56	58	

^{1^} Categorized as High Acuity (ESI=1, 2) or Less Urgent (ESI=3, 4, 5)

Table 9 (continued): Characteristics of participants by before and after propensity scoring (N=749)

	Unweighted				Weighted			
	Overall (N=749)	Intervention (N=384)	Usual-care (N=365)	p- value	Overall (N=749)	Intervention (N=384)	Usual-care (N=365)	p- value
	%	%	%		%	%	%	
Medicaid	43	47	39	0.02	42	45	39	0.10
Private Insurance	26	26	25	0.86	22	23	21	0.51
Other Insurance	25	23	27	0.21	26	24	28	0.14
Education				0.77				
Less than HS	33	34	32		35	36	34	0.86
HS	29	28	29		30	30	31	
Some College or More	38	37	39		34	34	34	
Marital Status				0.53				0.70
Single/Never Married	11	12	10		13	14	12	
Separated/Divorced	29	29	28		27	27	26	
Married	32	30	35		30	28	32	
Widowed	28	28	27		30	31	29	
Health Literacy				0.16				0.18
Adequate Health Literacy	43	43	42		40	41	38	
Limited Health Literacy	41	43	40		43	44	42	
Missing	16	13	19		17	15	20	
Comorbidity count				0.84				0.97
0 to 2	17	17	17		17	17	17	
3 to 4	42	43	41		43	43	44	
5 or more	41	41	42		39	39	39	
Chronic Conditions								
Heart	41	41	41	0.95	42	42	42	0.92
Hypertension	86	88	85	0.26	87	88	85	0.24
Diabetes	43	43	43	0.99	43	44	43	0.90
Depression	20	19	22	0.42	19	18	19	0.62
COPD	35	35	35	0.96	34	34	34	1.00
Mean Quality of Life at Baseline (SD)								
Physical	38.5 (8.9)	38.5 (8.9)	38.4 (8.9)	0.84	38.9 (9.6)	38.9 (9.9)	38.9 (8.8)	0.97
Information	54.1 (10.3)	53.5 (10.3)	54.8 (11.1)	0.08	54.8 (11.0)	54.1 (11.6)	55.5 (10.3)	0.09
Anxiety	56.6 (10.0)	56.3 (9.8)	57.0 (10.1)	0.31	56.6 (10.2)	56.3 (10.5)	56.9 (10.1)	0.41

Table 10: Weighted Changes in Patient’s Social Health (Informational Support)			
		Difference in Difference (DID) (Intervention - Usual-care)	p-value
Overall	Unweighted	2.17	0.025
	Unweighted, Covariates	2.20	0.008
	Weighted	2.05	0.114
	Weighted, Covariates	2.05	0.117
Health Literacy	Adequate Health Literacy	2.19	0.050
	Limited Health Literacy	2.64	0.137
	Unknown Health Literacy	0.21	0.945
Comorbidity	Hypertension	1.68	0.044
	Cardiovascular Disease	1.05	0.243
Comorbidity Count	0 to 2	0.50	0.907
	3 to 4	2.70	0.039
	5 or more	2.05	0.264

Quality of Life Changes in Patient’s Physical and Emotional Health

Based on patient feedback, we also examined the impact of the intervention on patient’s physical function and anxiety/emotional distress (Tables 11 and 12). In order to most effectively report the results of the intervention on changes in either physical functioning or anxiety, the difference in difference scores for each patient subgroup were reported after the baseline to follow-up scores (Table 11) in Table 12. These difference in difference scores show the difference between the baseline and follow-up scores. Significant differences in either category (physical functioning or anxiety/emotional distress) would reflect a difference between the intervention and usual-care groups, instead of within either group (as with the baseline to follow-up scores). Therefore, the difference in difference calculation reveals whether the intervention made a significant difference in either category for patients.

Patients' self-reported physical function was lowest at the time of the ED visit and increased over the ensuing 30 days in both groups, as expected (Table 11). The difference in difference values (Table 12) revealed no significant differences in physical function in those assigned to the intervention compared to usual care groups.

Emotional health was evaluated in terms of anxiety, with higher values reflecting higher levels of emotional distress. The usual-care group did not have a significant difference in anxiety from baseline to follow-up, although those in the intervention group actually had an increase in anxiety at follow-up (1.396, $p=0.012$, Table 11). However, the difference in difference analysis showed no difference between the usual-care and intervention groups as a whole (Table 12). No statistically significant differences in emotional health were found between the intervention and usual-care groups, with the exception of patients with self-reported cardiovascular disease. These patients had a statistically significant positive difference in difference value, reflecting higher levels of anxiety for those in the health care coach intervention group (Table 12). The higher levels of anxiety in patients with cardiovascular disease could be attributed to patients in the intervention group understanding more, and worrying more, about the risks associated with cardiovascular disease from the health care coach. Additional questioning of participants would be required to confirm this hypothesis.

Table 11: Unweighted Changes in Physical and Emotional Health Scores in Patients from Baseline to Follow-Up	Physical Health: <i>Physical Functioning</i> Follow-up - Baseline		Emotional Health: <i>Anxiety</i> Follow-up - Baseline	
	Usual Care	Intervention	Usual Care	Intervention
Entire Cohort	1.149 (n=330, $p=0.0113$)	1.353 (n=353, $p=0.0004$)	0.158 (n=339, $p=0.158$)	1.396 (n=366. $p=0.012$)

Table 12: Unweighted Difference in Difference Scores in Physical and Emotional Health		Physical Health: <i>Physical Functioning</i>		Emotional Health: <i>Anxiety</i>	
		Difference in Difference (DID) (Intervention - Usual-care)	p-value	Difference in Difference (DID) (Intervention - Usual-care)	p-value
	Entire Cohort	0.43	0.541	1.35	0.067
Health Literacy	Adequate Health Literacy (n=411)	0.08	0.869	1.55	0.231
	Limited Health Literacy (n=590)	0.56	0.677	1.49	0.290
Comorbidity	Hypertension (n=823)	0.60	0.253	1.39	0.126
	Cardiovascular Disease (n=554)	0.68	0.352	1.79	0.022

Summary & Conclusions

Cardiovascular disease, which kills one in four Americans, can be largely prevented or controlled by managing specific risk factors, such as hypertension. Patients with limited health literacy lack the capacity to obtain, process, and understand basic health information needed to prevent or treat illnesses,² which may explain higher rates of hypertension and cardiovascular disease among patients enrolled in our study with LHL. Patients with LHL may need additional help to understand and manage their condition. As a result, we evaluated whether a post-ED intervention that aimed to provide the coaching support to patients that ED and hospital-based providers cannot, was differentially effective in patients with cardiovascular disease and limited compared to adequate health literacy.

Initially, we looked at the relationship between health literacy and the prevalence of cardiovascular disease. The patient cohort consisted of 1004 enrolled Medicare FFS enrollees across two study sites with varying health literacy levels and comorbidities. Each study site was part of an academic health center, one in an urban center and one in a college town and surrounding rural area. All patients completed a baseline ED survey that recorded health literacy and quality of life through the REALM and PROMIS measures, respectively. Data from the baseline surveys revealed 4% higher rates of both hypertension (a modifiable risk factor for

cardiovascular disease) and cardiovascular disease in patients with limited, compared to adequate health literacy.

In order to determine the effectiveness of the intervention, patients were randomized, with equal probability, to either the usual care or intervention group. Those in the intervention group were visited by a healthcare coach who also followed up with them via phone for 30 days. The healthcare coach from the AAA followed the Coleman Care Transitions Intervention protocol^{21,22,23} and assisted patients in scheduling a follow-up doctor's visit, recognizing and responding to signs and symptoms of worsening disease, reviewing and understanding their medications, and creating a patient-centered health record to facilitate patient-provider communication. The healthcare coach was able to spend more time with each patient than is typically available in the time-sensitive environment of the ED, which may have allowed them to address concerns that patients with LHL may not have been able to have addressed as easily as their AHL counterparts.

Our main quantitative variable for comparison consisted of changes in informational support a patient feels at follow-up versus baseline. We hypothesized that the intervention the coach provided would result in increased informational support at follow-up, yet we found a drop in informational support among all patient groups. It is possible the drop can be attributed to patients leaving the supportive environment of the ED after baseline. The ED is seen by patients as a place where medical professionals ensure they are going to be okay and can answer any questions they have. Therefore, patients may feel higher levels of informational support while in the ED than 30 days later when the follow-up phone call was completed. In the overall cohort, the usual care group had a statistically significant drop in informational support (-3.2, $p < 0.0001$), while the intervention group did not (-0.82, $p = 0.1184$). The ED may serve as the main source of health-related informational support for some vulnerable patients. Given the decline in informational support after the ED visit, it is possible that patients will continue to use the ED to fill gaps in needed information.

In order to determine the differential effectiveness of the intervention in patients with cardiovascular disease and limited health literacy, we compared changes in informational support by univariate (adequate vs. limited health literacy or presence of a comorbidity, hypertension or cardiovascular disease) and bivariate analysis (presence of hypertension and AHL vs presence of hypertension and LHL). Usual care patients with limited health literacy were found to have a larger drop in informational support than those with adequate health literacy. Overall, those in the intervention group did not have a statistically significant decline in

informational support at follow-up from baseline. The intervention was found to reduce the drop in informational support by more than half in patients with hypertension (usual-care, -3.106, $p < 0.0001$, vs. intervention, -1.252, $p = 0.051$). This same effect was seen to a smaller effect in patients with cardiovascular disease. This result suggests that in our diverse study population across two study sites, the ED-to-Home transitional care coaching intervention may be more effective at blunting the post-ED drop in informational support in patients who have hypertension and not a more developed form of cardiovascular disease. For example, the health care coach may be able to explain how to interpret a simple blood pressure value within certain ranges to a patient more easily than explain more complicated forms of cardiovascular disease. As a result, it is possible that patients with cardiovascular disease require more informational support than our intervention was able to provide.

In bivariate analysis, no significant differences were found between the usual-care and intervention groups in informational support among patients with hypertension and AHL. However, a significant difference was found between the intervention and usual-care groups in patients with hypertension and LHL. Patients with hypertension and LHL in the usual care group experienced one of the largest drops in informational support of any patient subgroup after leaving the ED (-4.004, $p < 0.0001$). The intervention group experienced only 46% of the drop in informational support, -1.844 ($p = 0.034$) seen in usual care participants. African-American patients also experienced a large drop in informational support (-4.558, $p < 0.0001$). These results build upon our univariate results and show that the ED-to-Home healthcare coach intervention is most effective in patients with both limited health literacy and hypertension.

In summary, this study found higher rates of hypertension and cardiovascular disease among patients with limited, as compared to adequate health literacy. We report that patients with hypertension and limited health literacy experience some of the largest drops in informational support after leaving the Emergency Department. We found that the ED-to-Home coaching program has a significant and positive impact on informational support in the days following the ED visit in these vulnerable and high-risk patients.

Potential Future Directions

The study was based on a multi-site, randomized, controlled trial, “An Emergency Department-to-Home Intervention to Improve Quality of Life and Reduce Hospital Use,” that

sought to determine the impact of the coaching on health service use and patient-reported quality of life. In our study, we saw the most benefit in specific patient subgroups, notably those with LHL and hypertension. Our study shows that the described transitional care coaching program might be most effective if tailored for specific patients at ED discharge.

The program might be more even more effective if specific information about hypertension and its relationship to cardiovascular disease is discussed with patients. Additions could include the importance of blood pressure control and maintaining a healthy lifestyle. Many of the patients who were lost to follow-up in this study had LHL. The coaching program might be more effective if new ways of allowing the coach to connect with these patients are developed.

In the future, examination of the impact the ED-to-Home transitional care coaching intervention will focus on health service use from Medicare claims.

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