Functional Health Literacy, Chemotherapy Decisions, and Outcomes Among a Colorectal Cancer Cohort

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Background: Functional health literacy is essential for the self-management of chronic diseases and preventive health behaviors. Patients with cancer who have a low level of health literacy may be at greater risk for poor care and poor outcomes.

Methods: We assessed health literacy using the Short Test of Functional Health Literacy in Adults in 347 participants with colorectal cancer who were nested within a prospective observational study of system, health care provider, and participant characteristics influencing cancer outcomes.

Results: Having adequate health literacy increased the likelihood that participants with stage 3/4 disease received chemotherapy (odds ratio, 3.29; 95% confidence interval, 1.23–8.80) but had no effect on cancer stage at diagnosis or vital status at last observation during postenrollment follow-up. No difference was seen in health literacy status regarding participant beliefs and preferences about chemotherapy among those with stage 3/4 disease, nor in participant roles in deciding whether to receive chemotherapy.

Conclusions: Patients with lower levels of health literacy were less likely to receive chemotherapy compared with participants with higher levels of health literacy. Therefore, clear communication related to key health care decisions may lead to fewer disparities due to a patient’s level of health literacy.

Introduction

Functional health literacy, including the ability to read and understand medication labels, educational materials, hospital directional signs, and appointment slips, is essential for the self-management of chronic diseases and preventive health behaviors. However, individuals with the greatest health care needs may have the least ability to read and comprehend information needed to successfully function as patients. Inadequate health literacy could decrease the likelihood that these individuals at high risk will have beneficial health outcomes.

Having inadequate or marginal functional health literacy places patients at increased risk for medication nonadherence, hospital admission, poor health status, and worse clinical outcomes than their counterparts with higher levels of health literacy. A lower level of health literacy has also been associated with lower patient information seeking. Patients with poor reading ability may have issues accessing the health care system, understanding recommended treatments, and following the instructions of health care professionals. The American Medical Association has recognized that limited patient literacy impedes diagnosis and treatment, so it has adopted policies to increase the recognition of — and effect change in — functional health literacy.

In particular, health literacy levels may influence cancer outcomes. New patients may receive large amounts of unfamiliar technical information about their diagnosis. Oftentimes, health care professionals invite patients to participate in choosing among complicated treatment options. Adhering to chosen treatments can be a Byzantine process of understanding and complying with surgery, radiation therapy, multiple and varying chemotherapy regimes, and follow-up visits involving several health care professionals.

To evaluate the role of health literacy in decisions related to cancer treatment and to estimate the impact of health literacy on patient outcomes, we assessed health literacy in a set of patients with colorectal cancer (CRC) enrolled in a cohort study of health care processes. CRC has one of the largest disease burdens of any form of cancer, with approximately 140,000 new cases and 50,000 deaths in 2014 in the United States, making it a good test case of the effects of health literacy on cancer outcomes. We hypothe-
ized that greater levels of health literacy would be associated with early-stage disease, increased patient participation in treatment decisions, receipt of more appropriate treatment, and improved rates of survival.

**Methods**

**Study Population**

Participants were enrolled in the Cancer Care Outcomes Research and Surveillance Consortium (CanCORS), a prospective, population-based, multisite observational study of participants with lung and colorectal cancers that has been previously described. The population was diverse with respect to race, socioeconomic status, and geography. The purpose of the study was to assess the impact of system, care provider, and patient factors on cancer outcomes. Participants were at least 21 years of age at the time of CRC diagnosis and were enrolled within 3 months of diagnosis during 2003 to 2006. The study collected participant surveys, surrogate surveys for participants who were deceased or too ill to participate, and medical records data.

Abstractors at each site collected information on tumor characteristics and cancer treatments received. Participant and, when necessary, surrogate surveys were completed using computer-assisted telephone interviews. Surveys included items about demographic and socioeconomic factors (age, insurance coverage, income), communication with health care professionals, and beliefs and preferences regarding cancer treatments. The surveys have been previously described.

CanCORS included patients with colorectal and lung cancers who were enrolled by 7 groups of investigators. North Carolina recruited 990 patients with CRC, and it was the only site to administer health literacy assessments.

The study population was a random sample of 347 participants from the North Carolina–based CanCORS study. The sample was stratified by self-reported years of education with oversampling of lower strata to achieve similar-sized strata of adequate vs inadequate or marginal health literacy, ultimately with the goal of enhancing power for planned analyses. We used the following sampling fractions for the respective ranges of years of education: 0 to 8 years (100%), 9 to 11 years (100%), 12 years (70%), and more than 12 years (40%).

The sample included all cancer stages. The Institutional Review Board at the University of North Carolina at Chapel Hill approved the protocol. All participants provided informed consent.

**Measure of Health Literacy**

Functional health literacy was assessed using the Short Test of Functional Health Literacy in Adults (S-TOFHLA). A trained interviewer visited participant homes to administer the assessment in person. The assessment tested reading comprehension using 36 questions in response to 2 prose passages.

Across the entire sample, 4 different interviewers were used, but 1 interviewer alone administered the assessment for any given participant. All interviewers were trained in how to administer the S-TOFHLA. The interviewer read a scripted introduction and instructions to the participant, and then remained silent while the participant completed the questionnaire. Participants were given up to 7 minutes to complete the questionnaire, but they were not told beforehand that the assessment would be timed.

Scores were categorized as inadequate (0–16 correct), marginal (17–22 correct), or adequate (23–36 correct). For analysis, we combined marginal and inadequate scores into 1 category.

**Chemotherapy Decisions**

As part of the surveys, participants in CanCORS answered questions about whether they received adjuvant chemotherapy, how the chemotherapy decision was made, and their beliefs and preferences regarding chemotherapy. Chemotherapy is generally recommended for patients with colon cancer diagnosed with stage 3 or 4 disease. We examined responses about chemotherapy decisions among participants with CRC in whom health literacy was assessed and who were diagnosed with either stage 3 or 4 disease. Survey responses of “Do not know,” “Declined to answer,” “Not applicable,” or were missing were considered noninformative. Noninformative responses were excluded when conducting Fisher exact tests to compare survey responses by level of health literacy.

**Outcomes**

CanCORS tumors were staged according to the TNM classification system. We considered stage 1/2 to be early-stage disease and stage 3/4 to be late-stage disease.

Participants were followed for survival after baseline data collection. Vital status for all participants was verified using the Social Security Death Index on May 4, 2010, providing at least 42 months of follow-up observation time for each person. We defined participant survival as dichotomous vital status (alive or dead) at last observation.

**Statistical Analysis**

Among participants in the literacy sample with any stage of cancer (N = 347), we calculated overall and health literacy–stratified descriptive statistics for demographic and socioeconomic characteristics. Chi-square tests of association were conducted to examine differences in participant characteristics.
by level of health literacy. We performed logistic regression analyses to estimate associations between health literacy and (1) whether participants received chemotherapy (for stage 3/4 disease), (2) cancer stage at diagnosis (for all participants), and (3) all-cause mortality at last observation after baseline (for all participants). Across all stages, we estimated the marginal effect of health literacy on survival as well as its conditional effect on demographic and socioeconomic covariates.

Among 130 participants with stage 3/4 disease in the health literacy sample, we calculated overall and health literacy–stratified descriptive statistics for responses to survey questions about their beliefs and preferences regarding chemotherapy, communication with health care professionals about chemotherapy, and their role in making the decision whether to receive chemotherapy. We used Fisher exact tests to evaluate whether survey responses differed by participant health literacy level.

For all tests of association, \( P \) values less than .05 were considered statistically significant. Analyses were performed at the University of North Carolina at Chapel Hill, which was the CanCORS site for all participants included in this study. We used CanCORS core data (version 1.16), medical record data (version 1.12), and participant survey data (version 1.12). All analyses were performed using SAS version 9.3 for Windows (SAS Institute, Cary, North Carolina).

**Results**

Table 1 presents descriptive statistics among the 347 participants for whom health literacy was assessed. Despite our goal of a sample with approximately equal numbers with adequate

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Overall (N = 347)(^a)</th>
<th>Adequate Literacy (n = 242)(^a)</th>
<th>Marginal/Inadequate Literacy (n = 105)(^a)</th>
<th>( P ) value(^b)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>159 (47%)</td>
<td>101 (43%)</td>
<td>58 (57%)</td>
<td>.02</td>
</tr>
<tr>
<td>Female</td>
<td>178 (53%)</td>
<td>134 (57%)</td>
<td>44 (43%)</td>
<td></td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>264 (78%)</td>
<td>201 (86%)</td>
<td>63 (62%)</td>
<td>&lt; .0001</td>
</tr>
<tr>
<td>Nonwhite</td>
<td>73 (22%)</td>
<td>34 (14%)</td>
<td>39 (38%)</td>
<td></td>
</tr>
<tr>
<td>Age, years</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 65</td>
<td>160 (47%)</td>
<td>130 (55%)</td>
<td>30 (29%)</td>
<td>&lt; .0001</td>
</tr>
<tr>
<td>≥ 65</td>
<td>177 (53%)</td>
<td>105 (45%)</td>
<td>72 (71%)</td>
<td></td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Less than high school</td>
<td>72 (23%)</td>
<td>36 (16%)</td>
<td>36 (43%)</td>
<td>&lt; .0001</td>
</tr>
<tr>
<td>High school/GED</td>
<td>112 (36%)</td>
<td>80 (35%)</td>
<td>32 (39%)</td>
<td></td>
</tr>
<tr>
<td>Above high school</td>
<td>82 (26%)</td>
<td>76 (33%)</td>
<td>6 (7)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>44 (14%)</td>
<td>35 (15%)</td>
<td>9 (11)</td>
<td></td>
</tr>
<tr>
<td>Marital Status</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Currently married/living with partner</td>
<td>211 (63%)</td>
<td>158 (67%)</td>
<td>53 (52%)</td>
<td>.008</td>
</tr>
<tr>
<td>Widowed, divorced, separated, or never married</td>
<td>126 (37%)</td>
<td>77 (33%)</td>
<td>49 (48%)</td>
<td></td>
</tr>
<tr>
<td>Household Income ($), past year</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 20,000</td>
<td>75 (24%)</td>
<td>42 (19%)</td>
<td>33 (40%)</td>
<td>&lt; .0001</td>
</tr>
<tr>
<td>20,000–39,999</td>
<td>82 (27%)</td>
<td>56 (25%)</td>
<td>26 (31%)</td>
<td></td>
</tr>
<tr>
<td>40,000–59,999</td>
<td>52 (17%)</td>
<td>42 (19%)</td>
<td>10 (12)</td>
<td></td>
</tr>
<tr>
<td>≥ 60,000</td>
<td>78 (25%)</td>
<td>73 (32%)</td>
<td>5 (6)</td>
<td></td>
</tr>
<tr>
<td>Refused/do not know</td>
<td>22 (7%)</td>
<td>13 (6)</td>
<td>9 (11)</td>
<td></td>
</tr>
<tr>
<td>Cancer Stage</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1/2</td>
<td>187 (59%)</td>
<td>132 (60)</td>
<td>55 (57)</td>
<td>.7</td>
</tr>
<tr>
<td>3/4</td>
<td>130 (41%)</td>
<td>89 (40)</td>
<td>41 (43)</td>
<td></td>
</tr>
<tr>
<td>Received Chemotherapy</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>164 (53%)</td>
<td>129 (57)</td>
<td>35 (42)</td>
<td>.02</td>
</tr>
<tr>
<td>No</td>
<td>146 (47%)</td>
<td>98 (43)</td>
<td>48 (58)</td>
<td></td>
</tr>
<tr>
<td>Vital Status at Last Observation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alive</td>
<td>260 (77%)</td>
<td>187 (80)</td>
<td>73 (72)</td>
<td>.1</td>
</tr>
<tr>
<td>Dead</td>
<td>77 (23%)</td>
<td>48 (20)</td>
<td>29 (28)</td>
<td></td>
</tr>
</tbody>
</table>

\(^a\)Differences between numbers of patients for each column and number of patients for each characteristic are representative of missing data. Percentages are representative for nonmissing data for the characteristic.

\(^b\)\(P\) values were based on chi-square tests of each characteristic by levels of health literacy.

GED = general educational development.
and marginal/inadequate levels of health literacy, 105 (30%) were categorized as marginal/inadequate. Compared with those with an adequate level of health literacy, participants with marginal/inadequate health literacy were more frequently men, nonwhite, at least 65 years of age, not currently married or living with a partner, had not completed high school, and had annual household incomes below $40,000.

Among participants with stage 3/4 disease having an adequate level of health literacy increased the odds of receiving chemotherapy compared with those with a marginal/inadequate level of health literacy (odds ratio [OR], 3.29; 95% confidence interval [CI], 1.23–8.80). However, across all stages, having an adequate level of health literacy did not increase the odds of presenting with early-stage compared with late-stage disease (OR, 1.11; 95% CI, 0.68–1.80).

For participants with stage 3/4 disease, Table 2 presents responses to survey questions about participant beliefs and preferences regarding chemotherapy, their roles in deciding whether to receive chemotherapy, and their communication with health care professionals about chemotherapy. Of the 130 participants with stage 3/4 disease, 89 (68%) had an adequate level of health literacy and 41 (32%) had inadequate/marginal levels of health literacy — percentages comparable with those for the sample across all stages. We found no statistically significant differences in participant responses by level of health literacy. Participants of all levels of health literacy thought that, after discussing chemotherapy with a health care professional, the treatment was likely to help them live longer (89% of those with an adequate level of health literacy and 100% of those with marginal/inadequate level of health literacy).

Although the differences were not statistically significant, participants with stage 3/4 disease and an adequate level of health literacy played...
Table 3. — Factors Associated With Death at Last Observation (n = 347)

<table>
<thead>
<tr>
<th>Variable*</th>
<th>Univariate</th>
<th>Multivariate*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OR 95% CI</td>
<td>OR 95% CI</td>
</tr>
<tr>
<td>Health literacy (inadequate/marginal vs adequate)</td>
<td>1.55 0.91–2.64</td>
<td>0.90 0.42–1.94</td>
</tr>
<tr>
<td>Sex (male vs female)</td>
<td>1.93 1.15–3.24</td>
<td>2.16 1.09–4.28</td>
</tr>
<tr>
<td>Race (nonwhite vs white)</td>
<td>1.50 0.84–2.70</td>
<td>1.45 0.66–3.19</td>
</tr>
<tr>
<td>Age (≥ 65 vs &lt; 65 years)</td>
<td>1.46 0.87–2.45</td>
<td>1.59 0.82–3.08</td>
</tr>
<tr>
<td>Education (less than high school vs completed high school/GED)</td>
<td>1.63 0.90–2.97</td>
<td>1.46 0.70–3.03</td>
</tr>
<tr>
<td>Marital status (not living with anyone vs married/living with a partner)</td>
<td>1.55 0.92–2.59</td>
<td>1.40 0.68–2.88</td>
</tr>
<tr>
<td>Household income (&lt; $40,000 vs ≥ $40,000)</td>
<td>1.46 0.82–2.59</td>
<td>1.23 0.57–2.67</td>
</tr>
<tr>
<td>Cancer stage (3/4 vs 1/2)</td>
<td>2.62 1.52–4.52</td>
<td>2.25 1.21–4.20</td>
</tr>
</tbody>
</table>

*For each variable (a vs b), a = index group and b = reference.
*Results from a model with all variables in the table simultaneously included as independent variables.

CI = confidence interval, OR = odds ratio.
GED = general educational development.

In the unadjusted regression of survival on health literacy, those with a marginal/inadequate level of health literacy had increased odds of being deceased at last observation compared with those with an adequate level of health literacy, but the effect was not statistically significant and disappeared when conditioned on cancer stage as well as demographic and socioeconomic covariates (Table 3). Male sex and stage 3/4 disease were associated with greater odds of being deceased at last observation, but no other notable effects were detected.

Discussion

Functional health literacy in patients with cancer may play a crucial role in successful treatment and outcomes. Importantly, health literacy is distinct from formal education. For example, one study found that 63% of patients with 9 to 11 years of education and 34% of patients who graduated from high school had a marginal/inadequate level of functional health literacy. Furthermore, low rates of adequate levels of functional health literacy are common, particularly among the elderly and those with less formal education. Among elderly patients (> 60 years of age) at urban public hospitals, one study found that 81% of English speakers and 83% of Spanish speakers had marginal/inadequate levels of functional health literacy. Functional health literacy is lower among older age groups even after adjusting for differences in mental status, frequency of reading the news, health status, and visual acuity. The physical health of participants with lower reading levels has been found to be poor compared with that of participants with higher reading levels even after adjusting for confounding sociodemographic variables. Individuals with an inadequate level of health literacy are also more likely to report depressive symptoms, explained in part by their worse health status.

Health care professionals must be sensitive to the level of functional health literacy of their patients when they provide information regarding treatment options and prognoses. Analyses of the readability of patient education materials, discharge instructions, and consent forms have found that these materials are typically written at too complex a level for many or most patients. Some evidence suggests that tailoring communications for adults with low literacy can be effective. However, patients with a variety of health literacy levels may have difficulty understanding health information; therefore, improving communication may help patients across all levels of health literacy.

To mitigate barriers to health literacy, health care professionals should take steps when meeting with patients to ensure that communication is clear and that patients understand what is being taught to them. One recommended strategy involves the health care professional asking the patient questions toward the end of a clinical encounter to assess whether the patient recalls and understands the information or instructions provided. For example, the health care professional might ask the patient about the name, dose, and frequency of a medication that was just prescribed. This approach, which is often called the “teach-back” method, provides health care professionals with an opportunity to confirm patient understanding and gives patients the opportunity to solidify
their understanding.

Previous studies of health literacy found that lower levels of literacy were correlated with being male, and having less formal education and income. The demographic and socioeconomic characteristics of our sample followed these patterns (see Table 1).

In evaluating our hypotheses, we found that an adequate level of health literacy increased the likelihood of receiving chemotherapy among patients with stage 3/4 disease, a finding that suggests greater levels of health literacy might help patients receive better care. However, we detected no other clear differences by level of health literacy in patient beliefs, preferences, or decision-making about chemotherapy. We did not find an association between level of health literacy and either cancer stage at diagnosis or vital status at last observation.

**Limitations**

Our study had several limitations. First, our small sample limited our power to detect differences by health literacy status. Second, the S-TOFHLA might not precisely capture the desired construct of health literacy. Instead, it could be better regarded as a test of reading comprehension in a health care context rather than as a test of the broader concept of health literacy. Specifically, the S-TOFHLA might not evaluate aspects of health literacy other than reading, such as oral health literacy, navigation, and culture. The limitations of the instrument as a measure of health literacy could attenuate its association with some health outcomes. A third potential limitation that might be more general to health literacy research is the challenge of including sufficiently large numbers of participants with marginal/inadequate levels of literacy to detect the effects of health literacy levels. As noted, our goal was a sample of approximately 50% marginal/inadequate health literacy, but our actual sample had 30% marginal/inadequate health literacy. We targeted patients for inclusion in the health literacy substudy using formal education as a proxy, and our results reinforced the conclusion of prior research that formal education and health literacy, while related, are distinct. Several previous studies of health literacy using the S-TOFHLA (not all on cancer) obtained samples with even lower percentages of marginal/inadequate levels of health literacy.

The lower-than-expected numbers of participants with marginal/inadequate levels of proficiency in studies of health literacy suggest that selection bias might influence which patients enter these studies. To be eligible for inclusion in our sample, participants had to enroll in CanCORS, complete a baseline survey, and be administered the S-TOFHLA. Patients who died before completing any of these steps could not have participated in the sample. For included patients, the mean number of days from cancer diagnosis to CanCORS enrollment and baseline survey was 150 days and from diagnosis to S-TOFHLA administration was 640 days.

It is possible that, if the level of health literacy was associated with rates of survival, then patients with CRC who died before enrolling in CanCORS, or before they could complete the baseline survey or the S-TOFHLA, might have had disproportionately low levels of health literacy. Poor health and difficulty completing surveys among those with low levels of health literacy might systematically limit these patients’ participation in studies of health literacy. Future studies of health literacy should be designed to account for this possibility.

**Conclusions**

In the context of previous research, patients with CRC could benefit from health care professionals’ sensitivity toward, and adjustment to, different levels of patient health literacy. In addition, health care professionals should consider that any of their patients might have difficulty understanding and making decisions about health care. Therefore, clear communication is likely to help both lower and higher health literacy patients.

Among patients with stage 3/4 disease, those with lower levels of health literacy were less likely to receive chemotherapy compared with patients with higher levels of health literacy. To provide high-quality, patient-centered care, health care professionals should consider strategies of clear communication and patient engagement, recognizing that health literacy might affect physician–patient interactions and choices in medical care.

**References**