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CANCER HEALTH LITERACY AND HOSPITALIZATION IN THE FIRST FIVE YEARS FOLLOWING A CANCER DIAGNOSIS

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CANCER HEALTH LITERACY AND HOSPITALIZATION IN THE FIRST FIVE YEARS
FOLLOWING A CANCER DIAGNOSIS

A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy at Virginia Commonwealth University.

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Abstract

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By Laura Anne Cartwright, Ph.D., M.P.H.

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BACKGROUND: The field of health literacy research has been focused recently on developing

more accurate measurement tools and understanding the relationship between health literacy and

health outcomes. Individuals with lower levels of health literacy have worse health outcomes,

including hospitalization rates, compared to those with adequate health literacy. This relationship

has yet to be examined in the cancer patient population, although significant relationships

between health literacy and cancer knowledge, screening behavior and quality of life have been

found. This study is the first to examine the relationship between health literacy and

hospitalization rates in a cancer patient population, and the first to examine the relationship

between health literacy and health outcomes using the recently developed Cancer Health

Literacy Tests (CHLT-30, CHLT-6).

METHOD: These secondary data analyses matched data collected during the larger Cancer Health Literacy Study (CHLS) to hospital data from electronic medical records. This study examined the data of 778 CHLS participants interviewed within the first five years of their cancer diagnosis. The outcomes of interest were the number of inpatient hospital admissions, the total number of days spent hospitalized, and the number of 30-day hospital readmissions. Multivariate multiple negative binomial regression modeling was done to identify predictors of the three hospitalization outcomes.

RESULTS: The CHLT-30 was found to significantly predict number of inpatient admissions when controlling for confounding variables, total days hospitalized, and number of readmissions. The CHLT-6 significantly predicted total days spent hospitalized when controlling for number of inpatient admissions, number of 30-day readmissions, treatment, race, stage, number of comorbidities, dying, and education level, with those with limited health literacy spending more days in the hospital as compared to those with adequate health literacy.

CONCLUSION: This study produced mixed results regarding the significance of health literacy in predicting hospitalization rates in a cancer patient population. However, this study provides evidence that health literacy may be a mediator in this relationship and further work should be done to test a full or partial mediation model.

Introduction

Health literacy, defined by the Institutes of Medicine (IOM) as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions", is the center of a relatively new but growing field of study (HHS, 2000 p. 32; Ratzan & Parker, 2000). Health literacy has been found to predict numerous health outcomes and the focus in the field recently has been on more precise measurement and expanding the understanding of what role health literacy plays in predicting health outcomes.

Research in the field of health literacy began with measures that focused exclusively on ability to read or pronounce words to determine health literacy level. As the definition and domains for health literacy were refined, it became clear that literacy is only one factor contributing to health literacy. In response to the inadequacy of currently used health literacy measures to measure the multiple domains of health literacy, the Cancer Health Literacy Test (CHLT-30) was developed and tested, resulting in a comprehensive and psychometrically valid measure of health literacy.

This study was designed to test the CHLT's ability to predict hospitalization rates in a cancer patient population. To date no study has examined this relationship in an exclusively cancer patient population. This is also the first study use the CHLT to assess the relationship between health literacy and health outcomes.

BACKGROUND

Health literacy has its early roots in biomedical studies examining patient comprehension and in adult literacy studies evaluating the appropriateness of printed patient education materials (Zarcadoolas, Pleasant, & Greer, 2005). As described by Ratzan (2001), the term "health literacy" was first used in 1974 in a paper titled, *Health Education as Social Policy,* calling for policy to support health education in schools (Ratzan, 2001; Simonds, 1974). Although research continued to examine the relationship between literacy and health, it was twenty-four years before a formal definition of health literacy was established.

Literacy and Health

Prior to the advent of health literacy as a separate construct, literacy had been identified as a strong predictor of disease and disease knowledge, self-care capacity, and health outcomes (Berkman et al., 2004; DeWalt, Berkman, Sheridan, Lohr, & Pignone, 2004). Since then, literacy and health literacy have sometimes been used interchangeably in the literature, making discussion of the literature both confusing and overlapping. However, there is overall agreement that literacy is an important component of health literacy and that individuals with limited literacy or those with limited health literacy have similar experiences in health and health settings (Baker, 2006).

The National Assessment of Adult Literacy (NAAL) was conducted in 1992, and then again in 2003, by the United States Department of Education to assess the prose, document, and

quantitative literacy of over 19,000 adults over the age of 16 (Kutner et al., 2007). This nationally representative study provided information about the prevalence and trends of literacy levels in the United States. The Department of Education formed the Committee on Performance Levels for Adult Literacy to develop cut off points for categorizing prose, document, and quantitative literacy scores. The categories of literacy levels developed by this committee were "below basic", "basic", "intermediate", and "proficient" (Dillow & White, 2007). Individuals with below basic literacy scores have only rudimentary literacy skills like signing one's name to a form. Those with basic literacy skills are able to successfully complete basic everyday literacy tasks (e.g. reading then following basic instructions in a pamphlet). Intermediate literacy indicates ability to complete moderately difficult literacy activities (e.g. searching for needed information in a dense document) and an individual with proficient literacy would be able to complete complicated and difficult literacy activities (e.g. synthesizing information from multiple sources to inform a decision).

In the most recent NAALS data available, collected in 2003, 30 million Americans were found to have below basic prose literacy, 27 million adults scored as below basic in document literacy, and 46 million scored as below basic in quantitative literacy (Kutner et al., 2007). Separate from those listed as below basic, the NAALs data also showed that seven million adults were nonliterate and unable to complete any basic literacy tasks.

Average prose, document and quantitative literacy scores were higher on average for White or Asian/Pacific Islander adults as compared to Black or Hispanic participants (Kutner et al., 2007). Adults 65 years or older had the lowest average prose, document, and quantitative literacy scores compared to all other age groups, although their average scores did increase from 1992-2003. As compared to 1992 data, the average 2003 prose literacy scores for the age groups

25-39 and 40-49 declined (Kutner et al., 2007). This study revealed that many Americans struggle with literacy skills on a daily basis.

More recent data regarding national literacy levels can be found in the Program for the International Assessment of Adult Competencies (PIAAC). This international survey was conducted in 2011 and 2012 by the Organization for Economic Co-operation and Development (Schleicher, 2008).The intention behind PIAAC was to assess how adult skills relate to education, economic and social outcomes. PIAAC defined literacy as the, "interest, attitude and ability of individuals to appropriately use socio-cultural tools, including digital technology and communication tools, to access, manage, integrate and evaluate information, construct new knowledge, and communicate with others in order to participate effectively in society" (Schleicher, 2008, p. 632).

In assessing prose literacy, the PIAAC categorizes scores into six ordinal categories, "Level 5", "Level 4", "Level 3", "Level 2", "Level 1" and "Below Level 1" (Rampey, Finnegan, & Goodman, 2016). Level 5 proficiency indicates an individual has the ability to "to be aware of subtle, rhetorical cues and to make high-level inferences or use specialized background knowledge" (Rampey, Finnegan, & Goodman, 2016, p. B-3). An individual with Below Level 1 proficiency has only a basic vocabulary and is "not required to understand the structure of sentences or paragraphs" (Rampey, Finnegan, & Goodman, 2016, p. B-3).

Numeracy was also assessed in the PIAAC, with six ordinal categories of numeracy proficiency levels, "Level 5", "Level 4", "Level 3", "Level 2", "Level 1" and "Below Level 1" (Rampey et al., 2016). At Below Level 1 an individual can perform very basic mathematical processes involving whole numbers (i.e. counting or sorting exercises). At Level 5 an individual

can, "understand complex representations and abstract and formal mathematical and statistical ideas, possibly embedded in complex texts" (Rampey, Finnegan, & Goodman, 2016, p. B-7).

The U.S. PIAAC National Supplement was conducted in 2013 and 2014 (Rampey et al., 2016). The survey was conducted with 8,670 noninstitutionalized adults. Literacy proficiency levels by age group from the 2013/14 supplement can be seen in Table 1, and numeracy proficiency levels by age group can be seen in Table 2. Level 4 and Level 5 were combined in reporting both literacy and numeracy results as is the convention for PIAAC data. This collapsing of categorizes is done because of the very small number of individuals who qualify as Level 5 (a maximum of 2% in the international level PIAAC data.).

Table 1. PIAAC Literacy Levels by Age Group

Age Group	Below Level 1	Level 1	Level 2	Level 3	Level 4 or 5
16 – 65	4%	13%	33%	36%	13%
66 - 74	8%	20%	39%	26%	7%

Table 2. PIAAC Numeracy Levels by Age Group

Age Group	Below Level 1	Level 1	Level 2	Level 3	Level 4 or 5
16 – 65	8%	19%	34%	29%	10%
66 - 74	15%	29%	33%	18%	6%

As Table 1 and Table 2 show, older Americans have higher percentages in the lower numeracy and literacy proficiency levels as compared to adults 16-65, reflecting a similar pattern found in the NAALs data.

Literacy and Health Outcomes

Studies examining the relationship between literacy and health outcomes have produced mixed results. In one systematic review of the literature, relationships between literacy and global health status and hospitalization rates were found, but the relationship between literacy and other specific health outcomes was not clearly defined (DeWalt et al., 2004). DeWalt et al. (2004) note that in studies examining the relationship between health outcomes and literacy, confounding variables were often not accounted for. Without studies clearly isolating the impact of literacy on various health outcomes, it is difficult to draw strong conclusions regarding this relationship. This review also found that studies reported no relationship between literacy and self-reported depression, the presence of migraines, adherence to clinical trial protocols or control of hypertension (DeWalt et al., 2004).

Research on the relationship between literacy and medication or treatment adherence also remains mixed. In a study examining the relationship between literacy and HIV medication adherence, Waite, Paasche-Orlow, Rintamaki, Davis and Wolf (2008) found that an individual with low literacy was over three times more likely to be non-adherent as compared to those with adequate literacy. In this study social stigma was identified as a mediator between literacy and medication adherence, with increased social stigma being associated with lower literacy levels and non-adherence. Gazmararian et al. (2006) found that the relationship between literacy and adherence became non-significant after controlling for confounding variables. Powers and Bosworth (2006) note that prospective studies using observations of patient behavior beyond self-report do not produce associations between adherence and literacy.

Although the relationship between literacy and medication adherence remains unclear, researchers are not yet ready to discount the potential relationship that may exist. For example,

Powers and Bosworth (2006) suggest that the nature of the chronic illness being examined, such as the amount of self-care required, and possibly the severity of a condition, may impact the relationship between adherence and literacy.

Literacy level is associated with knowledge of health services and health conditions, with higher literacy level being related to more knowledge (DeWalt et al., 2004; Macabasco-O'Connel et al., 2011). Macabasco-O'Connel et al. (2011) recruited symptomatic heart failure patients for a study to examine the relationship between literacy and heart failure-related quality of life, knowledge, self-efficacy and self-care. In this study low literacy was associated with lower heart failure-related quality of life. This relationship remained after adjusting for possible confounding variables. Lower literacy was also related to lower salt knowledge, poorer self-care behaviors and less self-efficacy.

There are very few recent studies examining literacy and health or health outcomes. This is likely due to the shift towards studying health literacy and the growth of health literacy as a research field. Studies examining the impact of literacy are becoming less common as the development of the construct of health literacy as well as the development and validation of additional measures of health literacy become available.

A Move to a Separate Construct of Health Literacy

In 1998 the World Health Organization (WHO) defined health literacy as "the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain good health" (Don Nutbeam, 1998, p. 357). To further differentiate health literacy from work being done examining the relationship between literacy and health, WHO stressed that health literacy, "means more

than being able to read pamphlets and successfully make appointments" and that it is "critical to empowerment" (Don Nutbeam, 1998, p. 357).

Following this international definition, the American Medical Association's (AMA) Ad Hoc Committee on health literacy (1999) defined health literacy broadly as, "the constellation of skills, including the ability to perform basic reading and numerical tasks required to function in the health care environment" (Parker et al., 1999, p. 553). However, by not recognizing self-care and medical decision-making that occurs outside traditional healthcare environments, this definition does not address the impact health literacy may have on daily life. The AMA's definition also does not contain sufficient detail on the domains of health literacy and required skills to be useful for research purposes. The members of the Ad Hoc Committee on health literacy called for further research on health literacy and programs to promote health literacy, as well as recommended that the US Department of Education include items to measure health literacy in their next nationwide evaluation of adult literacy levels in the United States (Parker et al., 1999).

The most frequently used definition of health literacy is the one adopted in 2000 by the Institute of Medicine (IOM) and used by the US Department of Health and Human Services in creating the health literacy related Healthy People (HHS, 2000; IOM, 2004). The IOM defines health literacy as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions" (HHS, 2000 p. 32; Ratzan & Parker, 2000). The IOM definition was expanded in 2010 to include communication as an important construct of health literacy when it was described in the Patient Protection and Affordable Care Act of 2010, Title V. (Somers & Mahadevan, 2010). The definition in the Patient Protection and Affordable Care Act of 2010, Title V reads, "the degree

to which an individual has the capacity to obtain, communicate, process, and understand health information and services in order to make appropriate health decisions" (Somers & Mahadevan, 2010, p. 7).

Although the IOM definition of health literacy is the accepted definition used in the literature, researchers have continued to develop their own definitions of health literacy. These definitions predominately focus on individual level skills or attributes and generally add to the domains outlined in the IOM definition. (Zarcadoolas et al., 2005)Zarcadoolas, Pleasant, and Greer (2005) define health literacy as "the wide range of skills, and competencies that people develop to seek out, comprehend, evaluate and use health information and concepts to make informed choices, reduce health risks and increase quality of life". (Kickbusch, Wait, & Maag, 2005)Kickbusch, Wait & Maag (2005) speak directly to context in their definition of health literacy, defining it as:

> The ability to make sound health decision(s) in the context of everyday life--at home, in the community, at the workplace, the healthcare system, the market place and the political arena. It is a critical empowerment strategy to increase people's control over their health, their ability to seek out information and their ability to take responsibility. (p. 8)

Recently, (Sorensen et al., 2012) conducted a systematic literature review to identify articles that contained definitions of health literacy. The researchers identified 17 unique definitions. Content analysis revealed that most definitions were composed of the following elements: skills or abilities, action, information, objectives, context and time. After analyzing each category the researchers wrote a new definition, thought to represent all 17 definitions:

> Health literacy is linked to literacy and entails people's knowledge, motivation and

competences to access, understand, appraise, and apply health information in order to make judgments and make decisions in everyday life concerning healthcare, disease prevention and health promotion to maintain or improve quality of life during the life course. (p. 3)

Although definitions of health literacy continue to be refined, how health literacy is conceptualized and used still varies widely. Health literacy has been described as both an asset to be improved through health education and communication initiatives (Don Nutbeam, 2000; Zarcadoolas, Pleasant, & Greer, 2003) and as an individual level risk factor for disease and poor health outcomes (D. Nutbeam, 2008). In a directed literature review examining health literacy research, Mackert, Champlin, Su and Guadango (2015) describe the field as becoming fragmented, with definitions and measurement of health literacy varying throughout the research.

Health Literacy Prevalence

Much like the occasional confusion between literacy and health literacy in the literature, there also are differences in the terms used to categorize levels of health literacy. Health literacy has been most frequently reported as "low" or "high", "inadequate", "marginal", or "adequate." One measure used in health literacy, the Rapid Estimate of Literacy in Medicine uses grade equivalents of 3rd grade and below, 4th – 6th grade, 7th – 8th grade, and 9th grade and beyond (Davis et al., 1993). The National Assessment of Adult Literacy (NAAL) classified individuals as having below basic, basic, intermediate, or proficient health literacy (Kutner, Greenburg, Jin, & Paulsen, 2006). Increasingly, the term "limited health literacy" is becoming the accepted term for low, inadequate, and less than a 9th grade reading level. For the purposes of this study the term "limited health literacy" will be used, unless different categories are specified in individual study findings.

Furthermore, the lack of consistent measurement makes determining the exact prevalence of limited health literacy difficult. On the NAAL, 53% of adults scored as having intermediate health literacy while 36% of adults scored at either basic or below basic health literacy levels (equivalent to limited health literacy) (Kutner et al., 2006). The health literacy data collected in the NAAL advanced the field of health literacy by demonstrating the pervasiveness of limited health literacy, and also showed that individuals at highest risk of disease are also at highest risk of having lower health literacy.

A pooled analysis of studies measuring health literacy estimates an overall prevalence of limited health literacy of 26% (Paasche-Orlow, Parker, Gazmararian, Nielsen-Bohlman, & Rudd, 2005). A later study recruiting 3,075 Medicare-eligible participants over the age of 70 found a limited health literacy prevalence of 24% (Sudore, Yaffe, et al., 2006). The authors of this study believe this may underestimate the rate of limited health literacy in the United States as only healthy and functioning older adults were considered eligible for the study, with those less functioning, and likely with lower health literacy, excluded from participating.

Adults over 65, who are the most likely to have chronic conditions that require self-care, have lower health literacy levels compared to adults under 65 years old (Kutner et al., 2006). African American adults also have lower average health literacy levels as compared to White adults (Gazmararian et al., 1999; Kutner et al., 2006; Schillinger et al., 2002). Although health literacy level is correlated with education level, 3% of adults with a bachelor's degree were classified as having below basic health literacy on the NAAL, indicating health literacy may be independent of education completed (Kutner et al., 2006). Other studies using a different measure of health literacy have found similar results (Matsuyama et al., 2011; P. N. Peterson et al., 2011). Overall, individuals with limited health literacy are more likely to be male, non-white,

older, and have less education as compared to those with adequate health literacy. (Cavanaugh et al., 2010; Paasche-Orlow et al., 2005; Sudore, Yaffe, et al., 2006).

Health Literacy and Health

Health literacy has been associated with a number of health outcomes, behaviors, and knowledge. Health literacy research routinely uses self-reported health status, hospitalization rates, treatment adherence, emergency department visits, or similar indicators of health as health outcomes when studying health literacy and health. Clinical health outcomes like high blood pressure, or disease progression are less common in health literacy literature as they narrow the focus of eligibility and make comparisons between groups difficult. For example, findings that suggest that health literacy has a positive relationship with severity of COPD symptoms are difficult to generalize to populations other than COPD patients. Hospitalization rates are frequently used as outcomes to reflect an individual's current health and these data are becoming more readily available with adoption of electronic medical records. A review of the literature shows that limited health literacy has been associated with increased emergency department visits, increased hospitalization, underutilization of preventative services and poor medication adherence (Baker, Parker, & Williams, 1998; Berkman et al., 2011).

Sudore et al. (Sudore, Mehta, et al., 2006), found that elderly individuals with limited health literacy were more likely to report lower self-rated health status and were more likely to report diagnoses of hypertension, diabetes mellitus and obesity. For participants with a confirmed diagnosis of type II diabetes, recruited from primary care and general internal medicine clinics, inadequate health literacy was an independent predictor of poor glycemic control and self-reported complications from diabetes (Schillinger et al., 2002). In another study

HIV-AIDS patients with limited health literacy had significantly lower self-reported health status (Kalichman & Rompa, 2000).

A study of adult inpatient cardiac patients found that limited health literacy was associated with patient's understanding of their medication regime (Marvanova et al., 2011). Patients with limited health literacy were less accurate in describing their preadmission medication's purpose, strength, dosage and dosage frequency as compared to cardiac patients with adequate health literacy.

One of the few studies to examine how health literacy could impact chronic illness management outcomes over time focused on a patient population with moderate to severe asthma (Apter et al., 2013). In this study health literacy was found to be positively associated with treatment adherence, operationalized as electronically monitored inhaled corticosteroid use, asthma control and asthma related quality of life. This prospective study found no associations between health literacy level and emergency department visits or hospitalizations among the asthma patient participants.

Sayah, Majumdar, Williams, Robertson and Johnson (F. Al Sayah, S. R. Majumdar, B. Williams, S. Robertson, & J. A. Johnson, 2013b) conducted a systematic review to better understand the relationship between health literacy and health outcomes in diabetes. This review found mixed or no evidence that health literacy was associated with a variety of commonly studied health outcomes in diabetes. (Al Sayah et al., 2013b) noted in this systematic review that the instruments used for measuring health literacy and the categorizations of health literacy levels varied across studies. Studies were also found to be inconsistent in how they accounted for potential confounding variables. These methodological concerns were the potential explanations

offered by Sayah et al. to explain the mixed findings and varying quality of research done examining health literacy and diabetes related health outcomes.

Low health literacy was found to be associated with elevated blood pressure in a cross-sectional study interviewing a cohort of hospitalized patients (McNaughton et al., 2014). Patients presenting with a condition known to elevate blood pressure, like alcohol withdrawal, were excluded from participation. This finding remained significant after controlling for age, sex, race, insurance status, comorbidities and being prescribed blood pressure medication.

When compared to those with adequate health literacy, individuals with limited health literacy also tend to underutilize preventive screening and practices. Functioning elderly adults with limited health literacy are less likely to have received a flu (Bennett, Chen, Soroui, & White, 2009; Scott, Gazmararian, Williams, & Baker, 2002; Sudore, Mehta, et al., 2006) or pneumococcal immunization (Scott et al., 2002). (Bennett et al., 2009) also found that patients with limited health literacy were less likely to receive mammograms or dental checkups as compared to those with adequate health literacy. Scott et al. (Scott et al., 2002) reported that women on Medicare with limited health literacy were 70% more likely to have never received a Pap smear.

A study of pregnant women with pregestational diabetes showed that women with limited health literacy were more likely to have unplanned pregnancies, receive prenatal care later in their pregnancy and were less likely to have taken folic acid before pregnancy or during the first trimester (Endres, Sharp, Haney, & Dooley, 2004). Sudore, Mehta et al. (Sudore, Mehta, et al., 2006) found that elderly participants with limited health literacy were less likely to have an established primary care provider. This finding is in contrast to a 1997 study that found no relationship between health literacy and established sources of care, however the 1997 study did

not focus on the elderly and had an average age of 43, making comparisons difficult (Baker, Parker, Williams, Clark, & Nurss, 1997). A more recent study done with patients presenting in the emergency room found no difference in self-report of having a primary care provider by health literacy level (Schumacher et al., 2013). Schumacher et al.(Schumacher et al., 2013) did find however, a significant difference between self-reported ability to see ones primary care provider in a timely fashion. This finding suggests that although those with limited health literacy may report having a primary care provider, they may have a harder time getting appointments and receiving care with this provider.

In a study of patients over the age of 18 years old presenting to an Emergency Care Center or Walk-In Clinic, participants with inadequate health literacy were twice as likely as those with adequate health literacy to be hospitalized at least once (Baker et al., 1998). After adjusting the model for self-reported health, socioeconomic status and demographic variables this relationship remained significant but decreased to 69% more likely to be hospitalized.

For patients with chronic obstructive pulmonary disease (COPD), lower health literacy is associated with poorer health outcomes including an increase in hospital and emergency department usage (Omachi, Sarkar, Yelin, Blanc, & Katz, 2013). After controlling for socioeconomic status, COPD patients with lower health literacy were more likely to have severe symptoms and to be hospitalized or go to the emergency department for COPD-related symptoms.

A secondary data analyses of discharge and health literacy data for patients admitted to the general medicine unit of Boston Medical Center found that limited health literacy was a risk factor for being rehospitalized within 30 days of an admission (Mitchell, Sadikova, Jack, & Paasche-Orlow, 2012). This study found that as compared to those with adequate health literacy,

patients with inadequate health literacy were 1.76 times more likely to be hospitalized or utilize the emergency department within 30 days of being discharged from the hospital. This relationship remained significant but decreased when controlling for potentially confounding variables, with patients with inadequate health literacy being 1.46 times more likely to have a 30-day readmission as compared to those with adequate health literacy.

Wu and colleagues (Wu et al., 2013) conducted a multisite prospective study with a cohort of patients with heart failure to examine the relationship between health literacy and all-cause hospitalizations. Wu et al. (2013) found that individuals with low health literacy levels had slightly higher annual rates of hospitalizations (0.79/person-year) when compared to those with adequate health literacy (0.70/person-year). When controlling for confounding demographic and clinical variables, those with low health literacy still had higher rates of hospitalization with an adjusted incidence rate ratio of 1.31, as compared to heart failure patients with adequate health literacy.

A study of 3,260 Medicare enrollees was conducted to examine the relationship between health literacy and mortality among the elderly (Baker et al., 2007). After adjusting for age, participants with inadequate health literacy were 70% more likely to die during the follow-up period as compared to participants with adequate health literacy. This relationship persisted even after adjusting for self-reported physical and mental health, chronic conditions and daily living limitations, although it decreased to being 52% more likely to die. Another study, conducted with end stage kidney disease patients, found similar results with limited health literacy being associated with a 54% increase in mortality risk after adjusting for gender, race and diabetes diagnosis (Cavanaugh et al., 2010).

In a study of functioning adults over the age of 70, those with limited health literacy had twice the risk of death when compared to those with adequate health literacy. Limited health literacy was not associated with a particular cause of death (Sudore, Yaffe, et al., 2006).

Several studies have found a relationship between health literacy and health knowledge. Higher levels of health literacy are associated with higher levels of disease specific knowledge for hypertension and diabetes (Williams, Baker, Parker, & Nurss, 1998) and HIV-AIDS (Kalichman & Rompa, 2000).

In a study of Medicare enrollees with a chronic illness (asthma, diabetes, congestive heart failure and/or hypertension), having limited health literacy was a significant predictor of an individual's knowledge about his or her chronic illness (Gazmararian, Williams, Peel, & Baker, 2003). This relationship existed even when adjusting for time since diagnosis, age of individual and attendance at a chronic illness educational course.

A study using the nationally representative 2003 National Assessment of Adult Literacy (NAAL) data found that, after controlling for demographic factors, health literacy mediates the relationship between race/ethnicity and health status as well as the relationship between education level and health status in this population of older adults (Bennett et al., 2009). This article further supports the idea that addressing deficits in health literacy may result in not only improved individual health outcomes, but also have an impact in narrowing the health disparity gaps that exist for certain race/ethnic groups.

Another study using the NAAL data found that health-related print literacy significantly mediates the black/white difference in self-reported health status and mediates the relationship between race and receiving vaccinations, mammograms, and dental care (Schillinger et al., 2002).

Health Literacy and Cancer

Health literacy is especially important within the context of cancer care. Cancer can be a complicated disease and patients frequently report feeling overwhelmed with the amount of information presented to them about their disease, treatment options, and prognosis (Cartwright, Dumenci, Siminoff, & Matsuyama, 2014; Matsuyama, Kuhn, Molisani, & Wilson-Genderson, 2013). Without adequate health literacy, cancer patients may struggle to understand this new information and may struggle to identify resources to help them during this time. Cancer patients need the knowledge and skills required to assess their symptoms for signs of an emergency, follow nutritional guidelines provided by their physicians and recognize what activities may put them at risk of infection or further illness. The need for adequate health literacy during a cancer diagnosis is problematic given that 60% of cancer diagnoses occur for adults over the age 65 (Cohen, 2007), who are already at a high risk of limited health literacy (Kutner et al., 2006).

Although the health literacy demands for cancer patients appear obvious, limited research has been done to explore the impact health literacy level has on cancer patients (Koay, Schofield, & Jefford, 2012). Research in this area has primarily focused on using health literacy to predict cancer-screening behaviors (Bennett et al., 2009; Pagán et al., 2012; Scott et al., 2002; White, Chen, & Atchison, 2008), to assess the relationship between health literacy and cancer and cancer treatment knowledge (Davis et al., 2001; Miller, Brownlee, McCoy, & Pignone, 2007; N. B. Peterson, Dwyer, Mulvaney, Dietrich, & Rothman, 2007; P. N. Peterson et al., 2011; Wilson et al., 2010), and in studies examining communication and decision-making (Amalraj, Starkweather, Nguyen, & Naeim, 2009; Friedman, Corwin, Dominick, & Rose, 2009; Kim et al., 2001; Seo, Goodman, Politi, Blanchard, & Kaphingst, 2016; Smith, Dixon, Trevena, Nutbeam, & McCaffery, 2009; Sparks & Nussbaum, 2008).

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Research on health literacy and cancer screening has focused on mammograms as a screening tool of breast cancer, the use of Papanicolaou (Pap) tests to screen for cervical cancer, and various modalities of screening for colorectal cancer (CRC) such as colonoscopy or use of a fecal occult blood test (FOBT) (Bennett et al., 2009; Ojinnaka et al., 2015; Pagán et al., 2012; Scott et al., 2002; White et al., 2008). Studies have found that limited health literacy is associated with a decreased likelihood of receiving a mammogram (Bennett et al., 2009; White et al., 2008). In CRC research, evidence shows that individuals with limited literacy are likely to have less knowledge about CRC or CRC screening (Davis et al., 2001; Miller et al., 2007; N. B. Peterson et al., 2007). Although the relationship between CRC knowledge and health literacy has been shown, several studies have reported no relationship between health literacy level and participation in CRC screening (Carmen E Guerra, Dominguez, & Shea, 2005; Miller et al., 2007; N. B. Peterson et al., 2007). Ojinnaka et al. (2015) found that individuals with adequate health literacy were more likely to have received a CRC as compared to those having inadequate health literacy. Although health literacy was associated with past screening behavior, Ojinnaka and colleagues (2015) found no association between health literacy and adherence to recommended CRC guidelines.

Similar findings for health literacy and Pap test knowledge were found, with limited health literacy being associated with less knowledge of the purpose of a Pap smear (Lindau et al., 2002). A relationship between health literacy and receiving a pap smear was demonstrated, with limited health literacy being negatively correlated with receipt of a Pap smear (Scott et al., 2002).

Although research examining the relationship between health literacy and cancer screening knowledge or behavior can be important in informing interventions and in assisting in cancer prevention, it doesn't tell us much about the health literacy levels of cancer patients.

Cancer prevention studies that examine screening largely recruit patients from family medicine or internal medicine clinics with no history of cancer. There is limited health literacy research conducted with cancer patients and focusing on health outcomes (Koay et al., 2012). Studies conducted with cancer patients tend to focus the relationship between health literacy and cancer knowledge or assessing the prevalence of health literacy of cancer patients (Gansler et al., 2005; Koay et al., 2013; Martinez-Donate et al., 2013; Smith et al., 2013; Treloar et al., 2013).

Of the few studies focusing on measureable health related outcomes in the cancer patient population, two have examined health related quality of life (Hahn et al., 2007; Song et al., 2012). Hahn et al. (Hahn et al., 2007) found that health literacy was not an independent risk factor for health related quality of life as measured by the Functional Assessment of Cancer Therapy General (FACT-G) or the Short Form-36 Health Survey (SF-36). Conversely, Song and colleagues (Song et al., 2012) found that limited health literacy was associated with poorer mental health well-being even after controlling for demographic variables and illness related factors, like types of treatment received, diagnosed comorbidities and cancer type. In bivariate analyses limited health literacy was associated with physical well-being, but this relationship became non-significant in analyses accounting for demographic variables.

Currently no published studies report findings on the relationship between health literacy and hospitalization rates in the cancer patient population. It is surprising that hospitalization, an outcome with established relationships with health literacy, has not been studied in the cancer patient or survivor population (Baker et al., 2002; Baker et al., 1998).

Framework

This study conceptualized health literacy using "The Causal Pathways of Health Literacy" model (see Figure 1) developed by health literacy scholars Paasche-Orlow and Wolf

(Paasche-Orlow & Wolf, 2007). This model was developed to explain findings in health literacy research. The focus of the model is on the pathways through which health literacy impacts health outcomes. The developers acknowledge that many additional factors may exist in addition to the direct pathways of the model and that socioeconomic variables are associated with both health literacy and health outcomes. As such, these variables may affect the association between health literacy and health outcomes. The Causal Pathways of Health Literacy Model reflects this by indicating that these variables influence health literacy level, but the model does not illustrate potential direct effects of sociodemographic variables on possible mechanisms of impact or health outcomes.

To develop the model, the authors used the National Institutes of Health definition of health literacy: "the degree to which individuals have the capacity to obtain, process and understand basic health information and services needed to make appropriate health decisions" (Paasche-Orlow & Wolf, 2007, p. S20). This model stresses the importance of an individual's skills as well as the complexity of the problems they are facing when evaluating health literacy (Paasche-Orlow & Wolf, 2007). This recognition of context and complexity of tasks lead to the inclusion of factors beyond the individual level of the patient. This can be seen in the model (see Figure 1) as each construct contains both an individual-level factor and exogenous system factors.
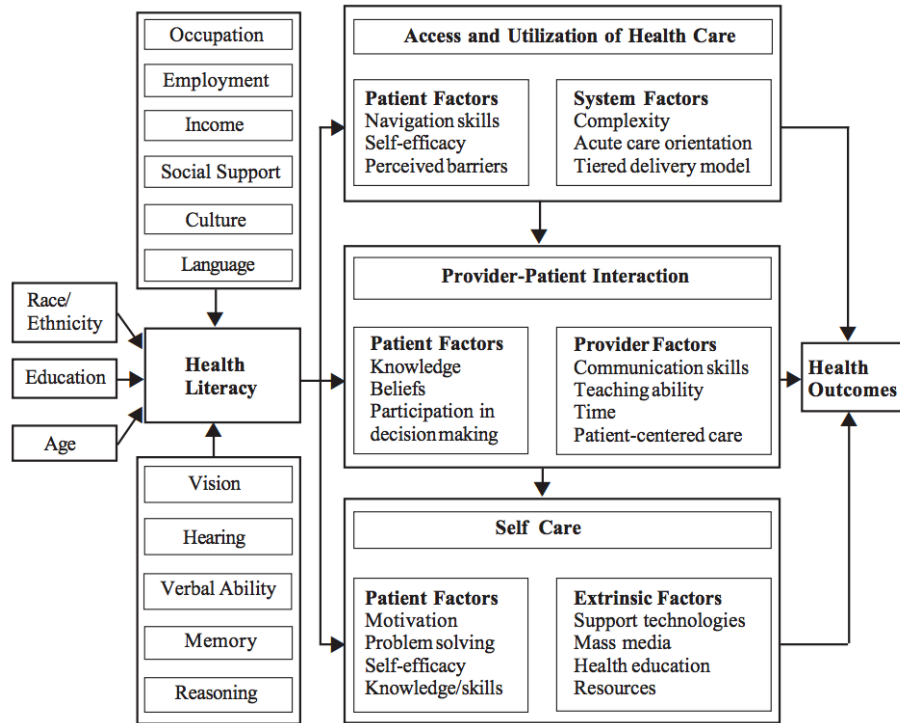
Figure 1. Causal pathways between limited health literacy and health outcomes.

Reprinted from "The causal pathways linking health literacy to health outcomes," by

M.K. Paasche-Orlow & M.S. Wolf, 2007, *American Journal of Health Behavior,*

31(Supplement 1)

In mapping the causal pathways between health literacy and health outcomes identified in

the literature, Paasche-Orlow and Wolf (2007) suggest that the major areas impacted by health

literacy levels are access and utilization of health care, patient-provider relationships, and self-

care. These major areas of impact then influence health outcomes.

Access and Utilization of Health Care

Paasche-Orlow and Wolf (2007) suggest that access and utilization of health care are

affected by a patient's navigation skills, self-efficacy in seeking care and perceived barriers, such

as shame or limited knowledge of the benefits of care. These concepts were added to the model

to reflect the literature that shows that patients with limited health literacy are more likely to

have a distrust of healthcare providers and report a lower satisfaction with care (Kalichman &

Rompa, 2000; C. A. Mancuso & Rincon, 2006). The complexity of a healthcare system, both the

physical buildings and the complexity surrounding financing and health insurance, will also

impact an individual's access and utilization of health care and are represented in the model. In

the model, Access and Utilization of Health Care reflect the perceptions and skills of an

individual and characteristics of a provider and of the health care facility, it does not describe

simply attendance of appointments.

Patient-provider Relationships

In this model, patient-provider interaction is another area of impact that provides a causal

pathway between health literacy and health outcomes (Paasche-Orlow & Wolf, 2007). The

literature shows that patients with low health literacy are more likely to have less knowledge or

incorrect beliefs regarding their disease and are less likely to actively engage in decision-making

as compared to those with adequate health literacy (Kalichman & Rompa, 2000; Williams et al.,

1998). The other half of provider-patient interaction is the characteristics of the provider. A

provider's communication and teaching skills, as well as time allowance for discussions with

patients, affects the quality of the provider-patient interaction (Brown & Bylund, 2008; Epstein

et al., 2005). Paasche-Orlow and Wolf (2007) include a patient-centered approach in the model

as it has become a new standard of care practice for providers. The patient-centered approach

recommends treating all patients as if they have potentially limited health literacy. However, as

Paasche-Orlow and Wolf (2007) note there is currently no evidence that this universal precaution

approach leads to better health outcomes for those with limited health literacy.

Self-Care

The final area of impact included in the model is self-care (Paasche-Orlow & Wolf,

2007). At the patient level the model includes the ability to problem solve, self-efficacy for

performing self-care, knowledge of how to perform self-care tasks and the motivation to

consistently and appropriately complete self-care tasks. The extrinsic factors included in the

model that impact self-care include mass media attention, health education and resources

surrounding the health concern or self-care activity. Support technologies designed to assist

patients in interpreting health information and making decisions regarding self-care also

influence an individual's ability to perform self-care activities.

Paasche-Orlow and Wolf designed this component-cause model to be parsimonious by

focusing on the pathways through access and utilization of health care, provider-patient

interaction, and self-care that health literacy impacts health outcomes. This model conceptualizes

health literacy as a single concept and does not break down health literacy into further

measurable domains. The model also views health literacy as a trait concept, characteristic to an

individual.

The Causal Pathways Model of Health Literacy is a conceptual model in which the three

areas of impact, Access and Utilization of Health Care, Provider-Patient Interaction, and Self-

Care are identified as mediators between health literacy and health outcomes (See Figure 2). A

variable is considered to mediate a relationship between independent and dependent variables

when: (a) it demonstrates significant relationships with both the independent and dependent

variable, and (b) controlling for the mediating variable changes the relationship between the

independent and dependent variable (Baron & Kenny, 1986). Using Figure 2 as an example, the

areas of impact are mediating the relationship between health literacy and health outcomes if b

and c are significant, and if a* changes as a result of controlling for the areas of impact. For

example if there is a statistically significant relationship between health literacy and self-care, a

statistically significant relationship between self-care and a health outcome, and the relationship between health literacy and a health outcome changes when self-care is controlled for, then self-care is said to be a mediating variable between health literacy and that health outcome.
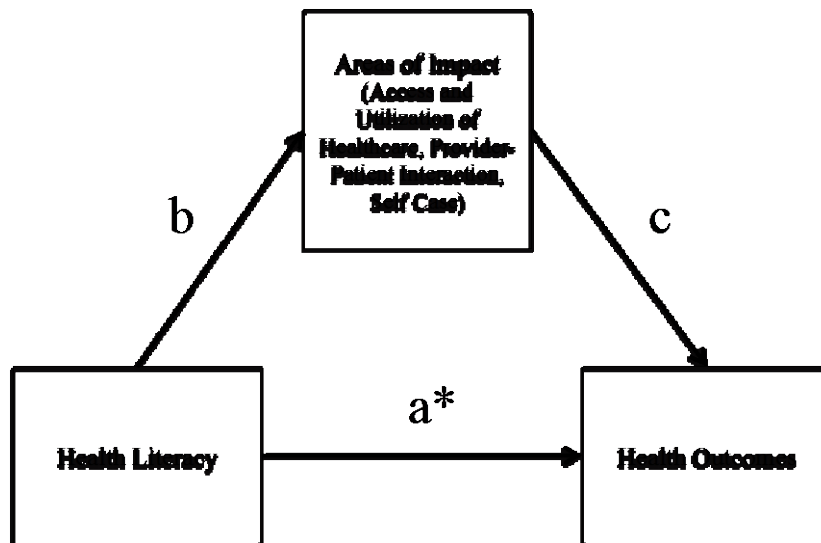
Figure 2. Illustration of the Causal Pathways Model of Health Literacy with areas of impact as mediators

In order to test a fully mediated model like the Causal Pathways Model of Health Literacy, one starts by making sure that the relationship between the independent variable and dependent variable is significant. For this model that would mean testing the relationship between health literacy and health outcomes, as illustrated in Figure 3. If this relationship is significant then one can expand the model by evaluating potential mediating variables.
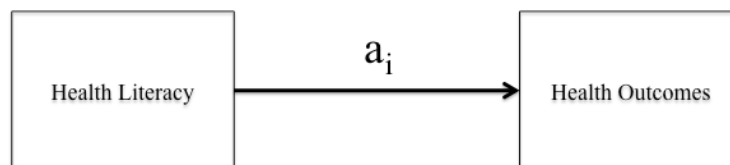
Figure 3. Direct effect of health literacy on health outcomes in a cancer patient population

The mediators identified by Paasche-Orlow and Wolf (2007) in the Causal Pathways Model of Health Literacy are based on a broad search of the literature. Figure 2 shows the

relationship between health literacy, health outcomes and mediators identified by Paasche-Orlow and Wolf (2007).

To date, no research has been conducted to measure the direct relationship between health literacy and health outcomes in a cancer patient population, visualized as in Figure 3. Before the mediating variables suggested by this model can be studied, the direct effects of health literacy on health outcomes in the cancer patient population need to be measured.

To ameliorate the gap in knowledge, this study examined the direct effects of health literacy on one of the commonly used health outcomes in health literacy research, hospitalization. Hospitalization is operationalized as, a count of inpatient hospitalizations, the total number of days an individual spends hospitalized, and the count of readmissions that occur within 30 days of a prior inpatient admission (see Figure 4). Evaluating these direct effects, represented as a_1, a_2, and a_3, allows further work to be done to examine the individual contributions of the mediating variables proposed by the model. Access and Utilization of Health Care, Provider-Patient Interaction, and Self-Care likely all impact hospitalization rates, but without the existence of a direct effect between health literacy and hospitalization, they cannot be evaluated. These mediating variables are outside the scope of this project, and the focus was on the direct effects.
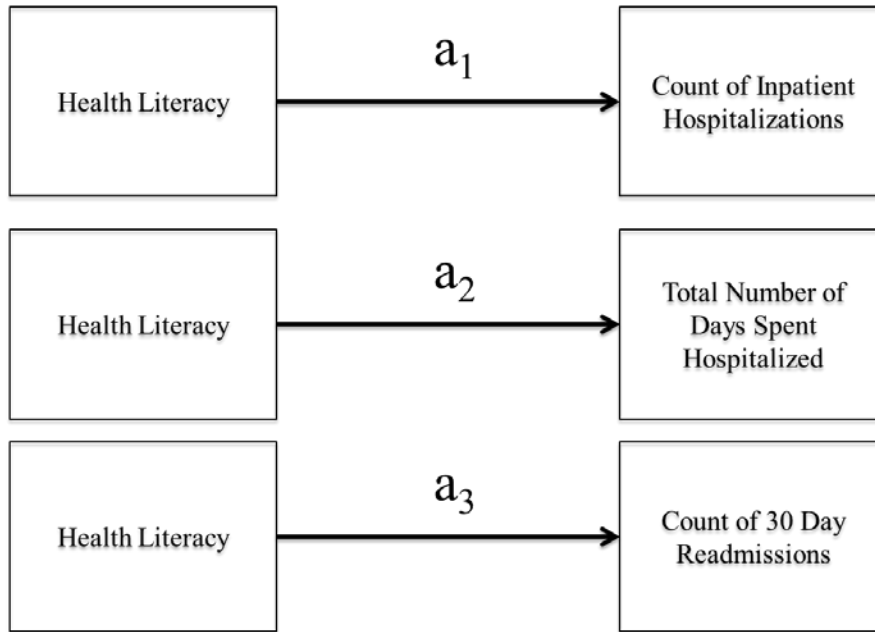
Figure 4. Direct effect of health literacy on health outcomes in a cancer patient population

This dissertation is the first examination of the direct effects of health literacy on health outcomes in a cancer patient population. In order to isolate the relationship of health literacy on health outcomes, potentially confounding variable were controlled for during analyses.

Measurement of Health Literacy

Research has shown that self-reported education level may be a poor indicator of health literacy (Buchbinder, Hall, & Youd, 2006; Kutner et al., 2006; Matsuyama et al., 2011). Buchbinder, Hall and Youd (2006) found that using education as an indicator of health literacy would misclassify 10% of the participants in their study. Researchers have also advised against simply asking patients about their health literacy deficits, as patients may feel embarrassed or ashamed to discuss any limitations (Baker et al., 1996; Parikh, Parker, Nurss, Baker, & Williams, 1996) and patients are often poor estimators of their health literacy levels (Ferguson, Lowman, & DeWalt, 2011). Accurate measures of health literacy are needed to produce reliable evidence about health literacy and its relationship with health.

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Measures of health literacy can vary in the domains of health literacy they measure, the categories of health literacy levels they produce, and the manner in which they are executed. A 2014 systematic literature review identified 51 unique measures of health literacy, measuring a variety of different domains of health literacy (Haun, Valerio, McCormack, Sørensen, & Paasche-Orlow, 2014). The primary measures of health literacy used in the literature are listed and described in Table 3. The majority of current measures focus heavily, if not solely, on measuring the literacy abilities of an individual. Although an important domain, reading ability does not provide an accurate and complete measure of the domains of an individual's health literacy level (Dumenci et al., 2013; Dumenci et al., 2014).

The most commonly used measures of health literacy are the Rapid Estimate of Adult Literacy in Medicine (REALM) (Davis et al., 1993), the Test of Health Literacy in Adults (TOFHLA) (Parker, Baker, & Williams, 1995) and the Short Test of Health Literacy in Adults (S-TOFHLA), a version of the TOFHLA that requires less administration time but remains reliable (Baker, Williams, Parker, Gazmararian, & Nurss, 1999). These three measures are described in detail below. Other commonly used measures of health literacy are shown in Table 3.

Table 3. Commonly Used Measure of Health Literacy

Measure Name	Description	Scoring	Correlation with literacy or health literacy measures	Citation
Rapid Estimate of Adult Literacy in Medicine (REALM)	Word recognition and pronunciation test using 66 health related words. Each correctly pronounced word is counted to give a final health literacy score. Scores are used to estimate reading level by grade.	Poor (0-44); Marginal (45-60); Adequate (61-66)	WRAT-R3: r = 0.64	(Davis et al., 1993)
Test of Health Literacy in Adults (TOFHLA)	This pen and paper test uses the cloze method to remove words from health related passages. Participants are asked to select the missing word. The second portion of the test involves answering numeracy items. The test is timed for both the numeracy and reading comprehension portion. Raw scores are converted to health literacy categorizations.	Inadequate (0-50); Marginal (60-74); Adequate (75-100)	WRAT-R3: r = 0.74; REALM: r = 0.84;	(Parker et al., 1995)
Short Test of Health Literacy in Adults (S-TOFHLA)	This is a modified version of the TOFHLA The test is timed for both the numeracy and reading comprehension portion. Scores are weighted to produce a total score out of 100.	Inadequate (0–53); Marginal (54–66); Adequate (67–100);	REALM: r = 0.80	(Baker et al., 1999)
Newest Vital Signs (NVS)	This health literacy measure uses a nutritional label as a prompt for answering the 6 items. Scores are calculated by summing the number of correct answers. Scores are then used to indicate the likelihood of low literacy.	Limited Literacy Likely (0-1); Limited Literacy Possible (2-3); Adequate (4);	REALM: r = 0.41; S-TOFHLA: r = 0.61	(Weiss et al., 2005)
Literacy Assessment for Diabetes (LAD)	Word recognition test modeled after the REALM and composed of 60 words common in diabetes patient education materials. Each correctly pronounced word is counted to give a final health literacy score. Scores are used to estimate reading level by grade.	Fourth grade and below (0-20); Fifth-Ninth grade (21-40); Ninth grade and above (41-60);	REALM r = 0.90 ; WRAT-R3 r = 0.81	(Nath, Sylvester, Yasek, & Gunel, 2001)

Medical Achievement Reading Test (MART)	This test was modeled after the WRAT and is composed of 42 common medical words and a list of 15 letters of the alphabet printed in small print on glossy paper to replicate prescription labels. Participants are asked to read the words aloud. Those who were unable to read the words were asked to read the list of 15 letters. Raw scores are converted to grade-level equivalency by using the chart from the WRAT-3	Grade level	WRAT-R3 r = 0.97	(Hanson-Divers, 1997)
Wide Range Achievement Test-Revised 3 (WRAT-3)	This word recognition test measures spelling and arithmetic abilities in addition to reading ability. Primarily used as a literacy measure, but frequently used in validity studies of new health literacy measures.	A norm table is used to convert raw scores to reading level categorization	PIAT-R r = 0.62-0.91	(Jastak & Wilinson, 1993)
Rapid Estimate of Adult Literacy in Dentistry (REALD)	This word recognition test models the REALM but replaces the words in REALM with ones commonly used in dentistry and contains only 30 words.	Score ranges from 0-30 with 0 being the lowest level of literacy and 30 being the highest level of literacy	REALM r = 0.86; TOFHLA r = 0.64	(Lee, Rozier, Lee, Bender, & Ruiz, 2007)
Health Literacy Skills Instrument (HLSI)	A computer administered 25-item measure of health literacy. Items represent the subscales prose, document, quantitative, oral and internet information seeking skills.	Below Basic Literacy (<70); Basic literacy (70–81); Proficient literacy (score>=82);	S-TOFHLA r = 0.80; REALM r = 0.80	(McCormack et al., 2010)
Health Literacy Skills Instrument Short Form (HLSI-SF)	This is a short form version of the HLSI and has only 10 items. Scores are presented as percentage of items correctly answered	Percentage of items correct	S-TOFHLA r = 0.36; HLSI r = .90	(Bann, McCormack, Berkman, & Squiers, 2012)
NAAL Health Literacy Scale	This test uses health related materials as prompts for open ended items. This test is not publically available.	Below Basic (0-184); Basic (185-225); Intermediate (226-309); Proficient (310-500);	Not reported	(Kutner et al., 2007)

Cancer Message Literacy Test- Listening (CMLT- Listening)	This test, using video clips as prompts, measures an individual's comprehension of spoken information. The test is self-administered on a touch screen computer.	Sum score of total correct items	REALM r = .46;	(Mazor et al., 2012)
Cancer Message Literacy Test- Reading (CMLT- Reading)	This test, using passages on cancer prevention and screening, measures an individual's comprehension of written information. The test is self-administered on a touch screen computer.	Sum score of total correct items	REALM r = .38;	(Mazor et al., 2012)
Health LiTT	This computer-based assessment is made up of 82 multiple-choice items. Items can be read to the participant by the computer.	Sum score of total correct items	Not reported	(Hahn, Choi, Griffith, Yost, & Baker, 2011)
Health Activities Literacy Scale (HALS)	This scale is linked to the NALS database. This measure uses 191 items from the NALS data set that are health focused. Scores range from 0-500 and are categorized by level of health literacy, with Level 1 being the lowest level of health literacy and 5 being the highest.	Level 1 (0-225); Level 2 (226-275); Level 3 (276-325); Level 4 (326-375); Level 5 (376-500);	S-TOFHLA r = 0.47	(Rudd, Kirsch, & Yamamoto, 2004)

Commonly Used Health Literacy Measures

The REALM was developed with the intention of measuring the grade associated reading levels of adults and is a unidimensional measure assessing only word pronunciation (Davis et al., 1993). Participants are asked to read 66 health-related words aloud, beginning with the easiest ("fat", "flu") through the most difficult ("osteoporosis","impetigo"). The test administrator scores whether the word is pronounced correctly or not. The total score is calculated by summing the number of correctly pronounced words. The scoring categories are $0 – 18$, $< 3^{rd}$ grade reading level; 19-44, 4th-6th grade reading level; 45-60, 7th -8th grade reading level; 61-66, high school reading level. Likely due to its ease of administration and scoring and the short examination time, roughly two minutes, researchers began using the REALM to approximate health literacy. A total score of less than 60 is considered to demonstrate limited health literacy. The REALM has a high test-retest reliability of 0.97 and correlates with the Wide Range Achievement Test-Revised (WRAT-R), a word recognition test also producing grade level reading ability estimates, $r = 0.63$ (Davis et al., 1993). A short version of the REALM, the REALM-R was developed in 2002 and is made up of only eight words (Bass, Wilson, & Griffith, 2003). The REALM-R is used less commonly in research and was designed to be used in busy primary care clinics to assess health literacy level of patients. If a participant receives a score of less than seven he or she is considered at high risk of having limited health literacy. The REALM-R has good reliability with a Cronbach's alpha of 0.91 and was significantly correlated with the REALM (r =0.72) and the WRAT-R (r = 0.78).

The TOFHLA was designed to directly measure health literacy (Parker et al., 1995). The TOFHLA tests prose literacy, reading comprehension and numeracy ability. Prose literacy and reading comprehension are assessed by having participants read passages with words missing,

using a modified Cloze method. The test is timed and participants are asked to select the correct missing word from three answer options. The TOFHLA assesses numeracy by asking participants questions about a series of prompts (e.g., pill bottles with prescription labels, appointment cards).

The TOFHLA score is calculated such that the numeracy portion represents 50% of the score although there are only 17 numeracy items and 50 reading comprehension items. The score is calculated by multiplying the numeracy score by 2.941 and adding it to the number of correctly answered reading comprehension items. Items left blank are scored as incorrect. The scores of the TOFHLA range from 0-100. The authors categorized the health literacy levels as inadequate (0-53), marginal (54-66) and adequate (67-100). The TOFHLA significantly correlates with the WRAT-R ($r = 0.74$) and the REALM ($r = 0.84$). The TOFHLA also has high reliability with Cronbach's alpha of 0.98.

The S-TOFHLA is composed of a subset of items from the TOFHLA (Baker et al., 1999). The S-TOFHLA uses only four of the numeracy items and 36 of the reading comprehension items. This cuts the administration time of the TOFHLA from 22 minutes to only 12 minutes for the S-TOFHLA. S-TOFHLA scores are weighted to produce scores ranging from 0-100 to match the TOFHLA and the resultant health literacy categories are the same. The S-TOFHLA has strong internal reliability with a Cronbach's alpha of 0.98 (Baker et al., 1999). The S-TOFHLA also significantly correlates with the TOFHLA ($r = 0.91$) and the REALM ($r = 0.80$).

Health Literacy Measurement Issues

There are a number of issues related to content, administration, and classification that lessen the psychometric strength of these health literacy measures.

First, the REALM, TOFHLA, and the S-TOFHLA require basic reading skills to be administered. If an individual is unable to read, he or she will be unable to even attempt, much less complete, the tests. As designed, the tests score individuals who cannot read as having zero health literacy skills. While reading ability is important, a deficit in reading skills does not necessarily mean that an individual lacks health literacy skills (Dumenci, Matsuyama, Kuhn, Perera, & Siminoff, 2013).

Recently more work has been done to integrate technology into measurement of health literacy (Dumenci et al., in press; Hahn et al., 2011; Mazor et al., 2012; McCormack et al., 2010). Using computer programs to read items to test takers allows for the measurement of other domains, like numeracy or health knowledge, without requiring reading ability. The use of computer programs may also help alleviate some of the embarrassment or shame patients with limited health literacy may experience during testing (Parikh et al., 1996; Wolf et al., 2007) by allowing them to take the test privately and independently.

A second measurement issue is related to the REALM. While administration of the REALM is straightforward, scoring relies on an administrator's determination of "correct" pronunciation, leaving the REALM open to bias. Measuring health literacy was not the intended use of the REALM. It was designed as a literacy measure and several other measures, like the Literacy Assessment for Diabetes (LAD) (Nath et al., 2001) and the Medical Achievement Reading Test (MART) (J. M. Mancuso, 2009),were also designed to measure reading literacy levels, but are currently used to make claims about health literacy levels. Misuse of these measures can result in misclassification of health literacy levels and could lead to inaccurate conclusions about an individual's ability to function in the health care setting (Dumenci et al., 2013).

Like the REALM, the TOFHLA (Parker et al., 1995) and S-TOFHLA (Baker et al., 1999) also have a problematic administration. By virtue of being timed tests they suffer from item order effects. An item order effect occurs when the serial position of an item impacts the likelihood an individual will answer it correctly or incorrectly (Schwarz, Strack, & Mai, 1991). With timed tests it is more likely that the items at the end of the test will be answered incorrectly than those at the beginning of the test due to participants running out of time, not due to a difference in ability. The structure of the S-TOFHLA also does not allow for item independence as items are often contained within the same sentence in addition to being contained within the same passage. Failing to have item independence violates an assumption of item-response theory and potentially introduces error into the measurement of health literacy level (McDonald, 1999). Furthermore, multiple props, in addition to the pen and paper reading comprehension test, are required for administration, making the measures difficult to implement in the clinic.

These three measures' varied use of different categories of health literacy level makes comparing findings across studies difficult. The REALM grade reading level scores are generally converted such that those with fourth grade and below are considered to have inadequate health literacy, fifth to ninth grade are estimated as marginal health literacy, and above ninth grade is considered adequate literacy. This allows for comparisons of S-TOFHLA and REALM scores, but this is not the scoring system the REALM was developed to produce (Davis et al., 1993). Some researchers have also considered REALM scores below the ninth grade reading level as "below adequate" and above ninth grade reading level as "adequate reading level". This is problematic as it is not used consistently and is a cut point chosen for convenience, not based on psychometric properties of the REALM as a test.

As described previously, some past studies have indicated that a linear relationship may exist between health literacy and health outcomes, however the TOFHLA and the S-TOFHLA scores are overwhelmingly reported as categorical scoring (Wolf, Feinglass, Thompson, & Baker, 2010). By using cut-off scores to produce these categories of health literacy one loses the ability to assess differences between or within individuals identified as having adequate, marginal or inadequate health literacy. Despite being designed to produce three categories of health literacy level, studies frequently combine the marginal and inadequate levels to a new category, "limited" (DeWalt et al., 2004). Creating a dichotomous health literacy score from S-TOFHLA scores not only goes against the purpose of the measure, it further complicates comparisons of findings across studies.

The current measures of health literacy are inadequate based on their reliance on reading ability, varying issues with scoring and administration methods and questionable content coverage. Drawing any conclusion about outcomes based on inaccurate measures is difficult as it is possible that individuals are being miscategorized.

Cancer Health Literacy Study (CHLS)

A new measure of health literacy, The Cancer Health Literacy Test (CHLT), was developed with the intention of addressing the above measurement issues and providing a psychometrically sound measure of health literacy relevant to cancer (Dumenci et al., 2014). The CHLT is administered on a touchscreen laptop and the computer reads the items and answer options to participants. Although there are some items specifically designed to identify reading ability (an important, but not the only, skill in the health care environment), this auditory support and the simple interface allow all participants to make their best guess for the majority of the items, regardless of literacy ability.

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Development of the CHLT began with thorough qualitative work (Dumenci et al., 2014). A Delphi panel of experts (Okoli & Pawlowski, 2004) was convened to discuss and finalize the domains and definition of health literacy. The panel was conducted online and experts included physicians, health literacy experts, medical librarians, and adult educators. Following the input from the Delphi panel, focus groups of individuals with a history of cancer were conducted. Findings from these groups guided the development of 112 items that ensured broad content coverage of health literacy.

The 112 items were then cognitively tested with 25 patients with a history of cancer. Cognitive interviews focus on participants' understanding of what items are asking, the information they use to answer the items and how they choose the answer to an item (Beatty & Willis, 2007; Fowler Jr & Cosenza, 2009). During the cognitive interviews participants were asked to verbalize their thought process to identify any items that were confusing or misleading. Based on the results of the cognitive testing, the measure was reduced to 76 items (Dumenci et al., 2014). These 76 items were tested with 1,306 patients with a history of cancer. Of the 1,306 participants, 98 took the test again after 2-weeks and another 60 were retested after 6-months.

Testing of the 76 items resulted in reducing the number of items to 30, after poorly performing items were removed (Dumenci et al., 2014). Poorly performing items were identified through exploratory factor analysis (Mulaik, 2009), content coverage analysis (Lord, Novick, & Birnbaum, 1968), gender or ethnicity differences of responses and percentage of correct responses (Dumenci et al., 2014). The remaining items represent the domains of prose literacy, numeracy, navigation, and knowledge. This version of the CHLT, here forward referred to as the CHLT-30, demonstrated excellent content coverage and produced a continuous health literacy score ranging from 1-30, with a lower score indicating lower health literacy of a patient. This

continuous score allows researchers to identify any change in the health literacy score over time as well as allowing for differentiation on the lower end of the scale.

The one-factor model approach using the chi-square test, root mean square error of approximations (RMSEA), comparative fit index (CFI), and Tucker-Lewis index (TLI) using Hu-Bentler criteria (Hu & Bentler, 1999) were used to evaluate model fit (Dumenci et al., 2014). The CHLT-30 data supported a unidimensional representation of the latent variable cancer health literacy ($\chi^2_{(405)} = 542.57$, $P < .001$; RMSEA $= .016$; CFI $= .990$; TLI $= .989$). Items were relatively easy to answer allowing the CHLT-30 to identify differences towards the lower end of the cancer health literacy score continuum.

The CHLT-30 is reliable, with Cronbach's alpha of .88, a 2-week test-retest reliability of .90 and a 6-month test-retest reliability of .92. The CHLT-30 is significantly correlated with both the REALM (r $= .68$) and the S-TOFHLA (r $= .88$). The CHLT-30 was assessed, using multi-group confirmatory factor analysis, for any potential bias among gender or racial groups. No bias was identified although black patients' mean score was lower as compared to whites (p< .0001). No difference in scores between gender was identified (p=.247).

Following analysis of a two-parameter logistic Item Response Theory model (Embretson & Reise, 2000) of the CHLT-30 data, six items identified as the best at discriminating between health literacy levels were used to created a shortened version of the CHLT-30, here forward referred to as the CHLT-6 (Dumenci et al., 2014). The CHLT-6 data were best represented using a two-class solution (Pearson $\chi^2_{(50)} = 84.76$; p $= .002$; LR $\chi^2_{(50)} = 82.22$; $P = .003$). The CHLT-6 data indicated the presence of two subgroups of patients. One group, referred to as "adequate cancer health literacy", consisted of 82% of the participants in the study. The second group, referred to as "limited cancer health literacy", represented 18% of participants. Those in the

limited cancer health literacy group answered items correctly at a nearly chance rate (range: .49 - .67) while those in the adequate cancer health literacy group were much more likely to correctly answer items (range: .96 - .99).

The CHLT-6 categorizes individuals with precision and accuracy (Dumenci et al., 2014). An individual classified as belonging to the adequate health literacy group has a 95% chance of having adequate health literacy and an individual classified to the limited health literacy group has a 96% chance of having limited health literacy.

Rigorous psychometric testing demonstrates that the CHLT-30 and CHLT-6 are valid, reliable, and unbiased measures of cancer health literacy (Dumenci et al., 2014). Due to this and the tests' improved content coverage as compared to the most commonly used health literacy measures, the CHLT-30 and CHLT-6 was used to assess cancer health literacy in this dissertation.

Given the rigorous psychometric testing that prove that CHLT-30 and CHLT-6 are valid, reliable, and unbiased measures of cancer health literacy, these measures are ideal for testing the relationship between health literacy and cancer health outcomes. This dissertation research examined the ability of the CHLT to predict hospitalization in cancer patients. By determining whether health literacy, as measured by the CHLT, is associated with or predicts hospitalization there is the potential to impact how the CHLT is used in research or as a clinical diagnostic tool. This study is unique in that it draws from a sample of exclusively cancer patients to examine the relationship between health literacy and hospitalization.

The outcomes chosen for this study were selected based on past health literacy research as well as their importance in the cancer care context. Past research has shown that lower health literacy is associated with increased hospitalization rates, although this relationship has not been

examined specifically in the cancer patient population (Bailey et al., 2015; Baker et al., 1998; Berkman et al., 2011; Koay et al., 2012; Mitchell et al., 2012). Given the importance of health literacy in cancer care (Koay et al., 2012) it seems likely the relationships between health literacy level and hospitalization will be replicated in the cancer patient population as well. Furthermore, replicating the findings previously established in the literature for other medical conditions and diseases will strengthen the validity of the CHLT-30 and CHLT-6 as measures of cancer health literacy.

Aims and Hypotheses

Aim 1. Test the relationship between CHLT-30 and CHLT-6 scores and count of inpatient hospital admissions in the first 5 years following a cancer diagnosis.

H_1: Lower CHLT-30 scores will predict a higher count of inpatient hospital admissions.

H_2: Lower CHLT-30 scores will predict a higher count of inpatient hospital admissions when controlling for potential confounding variables.

H_3: Those classified as having limited health literacy by the CHLT-6 will have a higher count of inpatient hospital admissions as compared to those classified as having adequate health literacy.

H_4: Those classified as having limited health literacy by the CHLT-6 will have a higher count of inpatient hospital admissions as compared to those classified as having adequate health literacy when controlling for potential confounding variables.

Aim 2. Test the relationship between CHLT-30 and CHLT-6 and the total number of days spent hospitalized in the first 5 years following a cancer diagnosis.

H_1: Lower CHLT-30 scores will predict a higher number of the total number of days spent hospitalized.

H$_2$: Lower CHLT-30 scores will predict a higher number of the total number of days spent hospitalized when controlling for potential confounding variables.

H$_3$: Those classified as having limited health literacy by the CHLT-6 will have a higher number of total number of days spent hospitalized as compared to those classified as adequate health literacy.

H$_4$: Those classified as having limited health literacy by the CHLT-6 will have a higher number of total number of days spent hospitalized as compared to those classified as adequate health literacy when controlling for potential confounding variables.

Aim 3. Test the relationship between CHLT-30 and CHLT-6 and hospital 30 day readmission in the first 5 years following a cancer diagnosis.

H$_1$: Lower CHLT-30 scores will predict a higher number of 30 day readmissions.

H$_2$: Lower CHLT-30 scores will predict a higher number of 30 day readmissions when controlling for potential confounding variables.

H$_3$: Those classified as having limited health literacy by the CHLT-6 will have a higher number of 30 day readmissions as compared to those classified as having adequate health literacy.

H$_4$: Those classified as having limited health literacy by the CHLT-6 will have a higher number of 30 day readmissions as compared to those classified as having adequate health literacy when controlling for potential confounding variables.

Methodology

Datasets

To accomplish the aims of this dissertation, data were combined from pre-existing databases, described below. Given that medical record numbers (MRNs) are unique identifiers for individuals, datasets were linked through deterministic matching using MRNs. In deterministic matching the fields must match exactly to link the datasets.

Cancer Health Literacy Study (CHLS) Database

The CHLS database is comprised of 1,306 cancer patients who took part in the Cancer Health Literacy Study from April 2011 to April of 2013 (Dumenci et. al, 2014). As described previously, the CHLS was an NIH R01 study (Dumenci, PI) that developed and tested the CHLT. Included in the CHLS database are socio-demographic items, patient reported cancer type, date of diagnosis, and stage, responses to each CHLT item and CHLT scores. In addition, study participants agreed to have medical outcome information about them collected after completing the in-person interview. This study expanded on the findings of the CHLS by examining the CHLT's ability to predict hospitalization.

Massey Data Analysis System (MDAS)

The MDAS is a data repository maintained by the Analytic Services Office at Virginia Commonwealth University that integrates data from 12 different internal and external data sources. The goal of the MDAS is to provide data specific to cancer patients seen at Massey

Cancer Center. The relevant databases integrated within the MDAS for this project included the 1) Virginia Commonwealth University Hospital System Cancer Registry (VCUHSR); 2) the Virginia Commonwealth University Hospital System (VCUHS) hospital, physician and pharmacy billing claims data; 3) the VCUHS electronic medical records; and 4) the Social Security Death Index (SSDI). VCUHS hospital, physician and pharmacy billing data are updated weekly and data from the VCUHSCR and SSDI are integrated monthly.

Virginia Commonwealth University Hospital System Cancer Registry (VCUHSCR)

The VCUHSCR is a population-based database to which hospitals, clinics and pathology labs have been required to report new diagnoses of cancer since 1990. The VCUHSCR contains diagnostic information including type and location of cancer, the size of tumor(s), the spread of disease and the date of diagnosis. The VCUHSCR also contains information regarding the dates and types of treatment an individual received for his/her cancer, as well as demographic information, including age, sex, race, ethnicity, occupation and address.

Virginia Commonwealth University Hospital System (VCUHS) Hospital, Physician and Pharmacy Billing Claims Data and VCUHS Electronic Medical Records (VCUHS EMR)

VCUHS and Massey Cancer Center maintain electronic patient medical records and hospital system insurance record and billing databases. These databases include patient scheduling and appointment records, admission and discharge information, treatments and tests administered, charges billed, amounts received, and International Classification of Diseases version 9 (ICD-9) diagnosis and procedure codes.

Social Security Death Index (SSDI)

The Social Security Death Index (SSDI) is a national-level database containing death records for individuals with a Social Security Number since 1936. Data stored in the SSDI includes name, date of birth, date or partial date of death, social security number, and the zip code of the individual's last known residence.

Dataset Building for Analyses

The dataset used in this study was built by combining information from the previously described data sources. Deterministic matching of MRNs was used to link CHLS participants to available external datasets. The inclusion criteria and variables calculated are described below.

Inclusion Criteria

The CHLS database contains a heterogeneous sample of participants with a history of cancer. The first self-reported diagnosis date in the CHLS database was December 1963 and the newest was January of 2013. Participants were at varying points in their own cancer care journey. Some participants were dealing with a new diagnosis, some were in remission, some were managing a recurrence of cancer, and some were dealing with a new incidence in addition to a history of cancer. Given that the focus of this dissertation was to examine the relationship between health literacy and hospitalization rates, inclusion criteria were developed to create a more homogenous dataset in relation to likelihood of hospitalization. Participants eligible for inclusion in the final dataset of this study were CHLS participants with complete data for their medical record number (MRN) and CHLT-30 score, interviewed within the first five years of their first cancer diagnosis, and seen at least once at VCUHS. The MRN was used to link the CHLS dataset with the MDAS databases. By narrowing the inclusion criteria to the first five years of an individual's first diagnosis, individuals were identified during a time they were at a higher risk of hospitalization. Examining participants' first diagnoses removed the impact a

previous diagnosis of cancer could have on cancer health literacy level. For example, if an individual was diagnosed with breast cancer in 2010 and lung cancer in 2011, the diagnosis of interest would be the 2010 breast cancer diagnosis. Of the N=1,306 CHLS participants, 59.6% (n=778) were interviewed within the timeframe of interest, had complete data for their MRN and CHLT-30 score, and had a history of being a patient of VCUHS.

Variables in Study Dataset

Cancer Diagnosis, Diagnosis Date, and Staging

In the original self-reported CHLS, participants were only asked for staging information regarding their most recent cancer diagnosis, so stage information was not available for participants' past diagnoses. When the stage information in the CHLS database for participants' most recent diagnoses was examined, a third of participants reported not knowing the stage of their cancer and 3% of participants had a cancer type categorized as "Other or Unknown Diagnosis." In the CHLS research study, participants were only asked for the month and year of their diagnoses.

Given the potentially significant amount of missing information regarding staging and date of diagnosis, the cancer registry database was considered the primary source for information regarding participant diagnosis, date of diagnosis, and stage at diagnosis. If the participant did not have a cancer diagnosis, date of diagnosis or stage at diagnosis reported in the cancer registry data, then the self-report data was used. Fifty-eight participants did not have cancer data in the cancer registry database. This subset of n=58 had a range of 1-200 outpatient encounters at VCUHS and a range of 1-4 inpatient VCUHS encounters. For the n=58 participants without cancer registry information, self-report data existed in the CHLS database and was compared to the hospital billing dataset. The hospital billing dataset confirmed the self-reported diagnosis and

diagnosis date for n=52 participants. The remaining eight participants had conflicting reported

diagnosis dates when the self-report CHLS data and the hospital billing data were compared. To

determine final eligibility the VCUHS EMR was reviewed and all eight were found to be

ineligible for inclusion in these analyses due to participating in the CHLS more than five years

after their first cancer diagnosis. For the n=52 cases where the CHLS data was used for diagnosis

date, a default date of the 15th was used (i.e. if the CHLS variable for diagnosis date read March

2009, the new variable for diagnosis date would read 3/15/2009). This was done because cut off

dates for analyses were calculated using the diagnosis date.

A large portion of participants, 18.34%, did not have a cancer traditionally staged as

stage I – stage IV. Only true missing staging information was coded as a missing value.

Individuals with staging information listed as "in situ" are represented as having stage 0 cancer.

The final count for first cancer diagnosis and staging for that diagnosis is seen in Table 4.

Table 4. First Cancer Diagnosis and Stage

Diagnosis	Frequency (%)
Colon/Rectal/Anal	56 (7.2)
Gastrointestinal	34 (4.37)
Breast	76 (9.77)
Lung	90 (11.57)
Hematologic	224 (28.79)
Head and Neck	90 (11.57)
Skin	19 (2.44)
Endocrine	10 (1.29)
Genitourinary	81 (10.41)
Gynecologic	76 (9.77)
Other or Unknown	22 (2.83)

Stage	Frequency (%)
0	9 (1.16)
1	136 (17.48)
2	152 (19.54)
3	157 (20.18)
4	147 (18.89)
Not Applicable	135 (18.34)
Missing or Unknown	42 (5.40)

A small group of n=34 individuals were diagnosed with a new incidence of cancer in the time period of analyses so a flag variable was created. This flag variable indicated whether a participant received more than one new cancer diagnosis during the time period of analysis. Using the example described previously, if an individual was diagnosed with breast cancer in 2010 and lung cancer in 2011, their first cancer diagnosis would be Breast and the indicator variable a new incidence of cancer would equal one.

Mortality

The SSDI was the primary data source for patient mortality information. As 12-13% of deaths are omitted in the SSDI (Buchanich, Dolan, Marsh, & Madrigano, 2005), mortality information was also pulled from the VCUHSCR and VCUHS EMR databases to help identify any potentially missing data. The flag variable, Deceased_5, was created to indicate if a

participant died within the time period of data analyses. Individuals who died after the time period of analyses are not represented in this flag variable. A total of n=150 (19.28%) participants died during the time period of five years after their cancer diagnosis.

Time Period of Data Collection

The variable Time Period was calculated to determine the number of years of data available for analysis for each participant. Given that CHLS participants were interviewed at varying times in relation to their cancer diagnosis and treatment, the start date for analyses was chosen as the diagnosis date of a participant's first diagnosis of cancer. The end date of data collection was either five years from the diagnosis date, the date of death, or the date the data were pulled from the Massey Data Warehouse (June 13, 2014), which ever date was earliest. The variable Time Period was calculated by taking the difference between the end and start dates for data collection in years. Time Period ranged from 0.311 to 5.00 years, with a mean of 3.62 years, median of 3.78 and a mode of 5.00 years.

To illustrate how the Time Period variable was calculated, Figure 5 shows information for four hypothetical participants. In Figure 5, "Dx" represents the date of diagnosis, "X" represents the date of death, and the vertical dotted line represents the date the data were pulled from the previously described data sources, June 13, 2014. The rectangles in Figure 5 represent the Time Period of data analysis for each participant. The values for these dates, the date used as the end date to calculate Time Period, and the calculated value for Time Period can be seen in Table 5.

In examining participant 1, the earliest date when comparing five years from the diagnosis date, the date of death, and the date the data were pulled from the Massey Data Warehouse (June 13, 2014), was the date five years after diagnosis, 2/15/2013. Given it is the

earliest of the three possible end dates, it was used in calculating Time Period. For all

participants the start date was the date of diagnosis. Time period was calculated for participant 1

as, 2/15/2013 – 2/15/2008 = 5 years.

For participant 2 the earliest possible end date is the date of death, 9/28/2011. The Time

Period was therefore calculated by subtracting the end date from the diagnosis date, giving

9/28/2011 – 11/24/2009 = 1.84 years.

Figure 5. Calculating Time Period
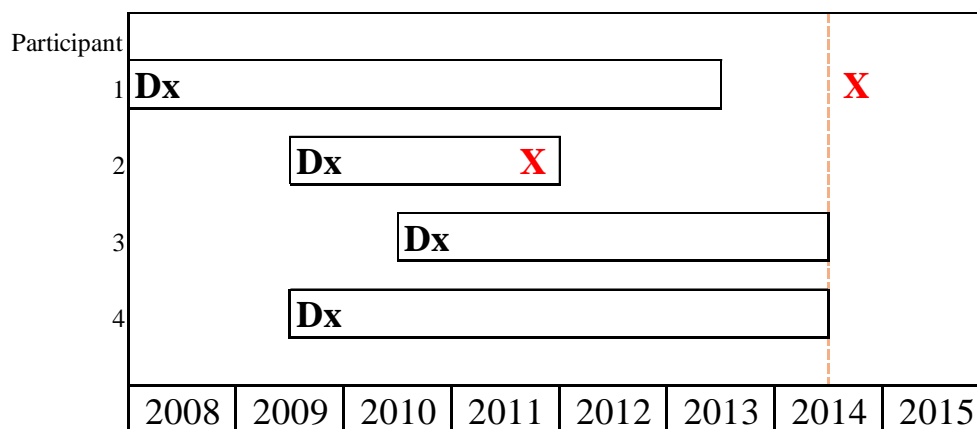
Table 5. Calculating Time Period Example

Participant	Date of Diagnosis	Date of Death	Date 5 Years After Diagnosis	End Date Used to Calculate Time Period	Time Period
1	2/15/2008	11/27/2014	2/15/2013	2/15/2013	5 years
2	11/24/2009	9/28/2011	11/24/2014	9/28/2011	1.84 years
3	7/11/2010	-	7/11/2015	7/13/2014	3.92 years
4	5/15/2009	-	5/15/2014	7/13/2014	5 years

Treatment Variables

Indicator variables for the most common cancer treatment types were created and drawn

from the CHLS self-report database, the VCUHS cancer registry, and the VCUHS EMR.

Indicator variables were given the value of one if the individual received treatment during the time period of data analyses. For the variable "surgery", only surgeries intended for treating the patient's cancer were included in analyses.

ICD-9 procedure codes, 41.0, 41.01, 41.02, 41.03, 41.04, 41.05, 41.06, 41.07, 41.08, 41.09, were used to identify those who received a BMT during the time period of data analysis. Counts for cancer treatments received are described in Table 6. The variables in Table 6 are not mutually exclusive, so an individual who received chemotherapy and radiation therapy would be represented in both the variable "Chemotherapy" and the variable "Radiation Therapy."

Table 6. Treatment Received

Treatment Received	Frequency (%)
Chemotherapy	497 (63.88)
Radiation Therapy	330 (42.42)
Surgery	315 (40.49)
Bone Marrow Transplant	26 (3.34)

Socio-Demographic Variables

Demographic variables including race/ethnicity, sex, education level, insurance type, and age at CHLS interview were obtained from the CHLS database. Counts for the self-reported demographics are listed in Table 7.

Table 7. Demographic Variables in the Final Dataset

Variable	Frequency (%)
Education	
Less than a High School Diploma	115 (14.8)
GED	24 (3.09)
High School Diploma	136 (17.5)
Some College	158 (20.33)
Associates/Technical Degree	84 (10.81)
Bachelor Degree	160 (20.59)
Beyond a Bachelors	100 (12.87)
Insurance	
Private	342 (44.02)
Public (Medicare/Medicaid/Hospital Assistance)	409 (52.64)
Uninsured	26 (3.35)
Race	
Black	300 (38.61)
White	471 (60.62)
Multi-racial or Other	6 (0.77)
Sex	
Female	386 (49.61)
Male	392 (50.39)
Age at CHLS Interview	
Range	19-89
Mean (Standard Deviation)	57.04 (11.90)

Travel Time to Massey Cancer Center

Travel time from the participant's home to the Massey Cancer Center was approximated using participant's zip code at the time of CHLS interview and the zip code for Massey Cancer Center. Travel time was calculated using a macro in SAS® software and Google Maps. As only hospitalizations that occurred at VCUHS were available for analyses, this variable was designed to help address concerns regarding potentially missing hospitalizations. Table 8 shows output for the calculated travel time in minutes.

Table 8. Travel to Massey Cancer Center

Driving Time in Minutes	
Range	6.00 – 299.00
Mean (SD)	35.34 (30.42)

Comorbidities

A commonly used and validated comorbidity measure, the Charlson Comorbidity index (CCI), was calculated for each participant by reviewing ICD-9 codes associated with inpatient or outpatient visits occurring within the data analysis time period. The CCI was originally developed to predict short term mortality of patients participating in longitudinal clinical trials, although its predictive ability was shown to continue when examining 10-year survival (Charlson, Pompei, Ales, & MacKenzie, 1987). Charlson and colleagues (1987) wanted a measure that could represent an individual's risk of mortality, based on comorbidities, at the onset of a clinical trial. Using medical record and mortality information, Charlson et al. (1987) identified 17 diagnoses that best predicted mortality. The count of comorbidities did significantly predict mortality. In order to account for the varying prognostic impact of individual diseases, Charlson et al. created a weighted scoring system. This weighted index score was informed by the relative risk of mortality for each disease. The weights ranged from 1 to 6, with a higher weight indicating higher likelihood of death and the final score was determined by summing the weighted values for each disease.

CCI scores and number of comorbidities tend to be low in research studies. In a study to develop an ICD-9 and ICD-10 coding system to calculate CCI, Quan et al. (2005) found that of 56,585 patients with inpatient discharge data, 63.8% had zero comorbidities at admission. A

study involving trauma patients similarly found very low comorbidity counts, with 66.8% of participants having zero comorbidities (Gabbe, Magtengaard, Hannaford, & Cameron, 2005).

The CCI scores used for these analyses were calculated using the ICD-9 codes developed by Quan et al. (2005) as outlined below in Table 9. The CCI score was calculated by summing the weighted scores for each comorbidity excluding cancer. Given that all participants have a diagnosis of cancer, it is not included in the count of comorbidities or the weighted CCI score, a practice commonly done when using the CCI to study specific diseases (Quan et al., 2011). The weighted score for metastatic cancer was included in the CCI score. Metastatic cancer shows a significant change in the disease and mortality. Staging information described previously reflects only the stage at diagnosis and does not reflect if the disease metastasizes.   The participants' comorbidity counts and weighted CCI score are reported in Table 10.

Weighted Score	Diagnosis	ICD-9 Codes	Frequency (%)
Table 9. Charlson Comorbidity Coding and Frequency			
1	Myocardial Infarction	410.x , 412.x	35 (4.50)
1	Congestive Heart Failure	398.91, 402.01, 402.11, 402.91, 404.01, 404.03, 404.11, 404.13, 404.91, 404.93, 425.4, 425.5, 425.6, 425.7, 425.8, 425.9, 428.x	75 (9.65)
1	Peripheral Vascular Disease	093.0, 437.3, 440.x, 441.x, 443.1, 443.2, 443.3, 443.4, 443.5, 443.6, 443.7, 443.8, 443.9, 471.x, 557.1, 557.9, V43.4	43 (5.53)
1	Cerebrovascular Disease	362.34, 430.x, 431.x, 432.x, 433.x, 434.x, 435.x, 436.x , 437.x, 438.x	44 (5.66)
1	Dementia	290.x, 294.1, 331.2	1 (0.13)
1	Chronic Pulmonary Disease	416.8, 416.9, 490.x, 491.x, 492.x, 493.x, 494.x , 495.x, 496.x, 497.x, 498.x, 499.x, 500.x, 501.x, 502.x, 503.x, 504.x, 505.x, 506.4, 508.1, 508.8	184 (23.68)
1	Rheumatic Disease	446.5, 710.0, 710.1, 710.2, 710.3, 710.4, 714.0, 714.1, 714.2, 714.8, 725.x	28 (3.60)
1	Peptic Ulcer Disease	531.x, 532.x, 533.x, 534.x	22 (2.83)
1	Mild Liver Disease	070.22, 070.23, 070.32, 070.33, 070.44, 070.54, 070.6, 070.9, 570.x, 571.x, 573.3, 573.4, 573.8, 573.9, V42.7	59 (7.50)
1	Diabetes without complications	250.0, 250.1, 250.2, 250.3, 250.8, 250.9	167 (21.49)
2	Diabetes with complications	250.4, 250.5, 250.6, 250.7	30 (3.86)
2	Paraplegia or Hemiplegia	334.1, 342.x, 343.x, 344.0, 344.1, 344.2, 344.3, 344.4, 344.5, 344.6, 344.9	18 (2.32)
2	Renal Disease	403.01, 403.11, 403.91, 404.02, 404.03, 404.12, 404.13, 404.92, 404.93, 582.x, 583.0, 583.1, 583.2, 583.3, 583.4, 583.5, 583.6, 583.7, 585.x, 586.x, 588.0, V42.0, V45.1, V56.x	70 (9.01)
3	Moderate or Severe Liver Disease	456.0, 456.1, 456.2, 572.2, 572.3, 572.4, 572.5, 572.6, 572.7, 572.8	11 (1.42)
6	Metastatic Carcinoma	196.x, 197.x, 198.x, 199.x	263 (33.85)
6	AIDS/HIV	042.x, 043.x, 044.x	26 (3.35)

Table 10. Comorbidities

Total Number of Comorbidities	Frequency (%)
0	267 (34.36)
1	212 (27.28)
2	152 (19.56)
3	85 (10.94)
4	28 (3.6)
5	16 (2.06)
6	10 (1.29)
7	4 (0.51)
8	2 (0.26)
9	1 (0.13)
Mean	1.38
Median	1.00
Mode	0

Weighted CCI Score	Frequency (%)
0	267 (34.36)
1	93 (11.97)
2	54 (6.95)
3	37 (4.76)
4	23 (2.96)
5	7 (0.9)
6	115 (14.8)
7	80 (10.3)
8	37 (4.76)
9	28 (3.6)
10	14 (1.8)
11	6 (0.77)
12	4 (0.51)
13	3 (0.39)
14	5 (0.64)
15	3 (0.39)
16	1 (0.13)
Mean	3.42
Median	2
Mode	0

Cancer Health Literacy Test Score

This study examined the relationship between the CHLT-30 and the CHLT-6 and count

of inpatient hospital admissions, total number of days spent hospitalized, and count of 30 day

readmissions. The numerical score of the CHLT-30 and the categorical score, limited or

adequate health literacy, of the CHLT-6 were both taken from the CHLT database. Table 11

shows the values for the CHLT measures of study participants.

Table 11. Cancer Health Literacy Test Scores

CHLT-6	Frequency (%)
Limited Health Literacy	142 (18.25)
Adequate Health Literacy	636 (81.75)
CHLT-30	
Range	6.00 – 30.00
Mean	23.67
Median	25.00
Mode	29.00

Outcome Variables

All outcome data were calculated using data from MDAS and are listed in Table 12. The

three outcome variables are the number of inpatient hospital admissions, the total number of days

spent hospitalized, and the total number of times an individual is readmitted to the hospital

within 30 days of being discharged from an inpatient admission. All outcomes variables were

calculated using all-cause admissions within the time period of data analysis.

Table 12. Hospitalization Outcome Variables

Number of Inpatient Hospital Admissions	
Range	**0 - 18**
Mean (SD)	**2.06 (2.70)**
Median	**1.00**
Total Days Hospitalized	
Range	**0 – 171**
Mean (SD)	**12.03 (20.50)**
Median	**4.00**
Number of 30 Day Readmissions	
Range	**0 – 13**
Mean (SD)	**0.66 (1.91)**
Median	**0**

Analysis

        Outcome variables are in the form of number of inpatient hospital admissions, number of

days total spent hospitalized, and number of 30-day readmissions within the time period of

analysis. This type of data is also referred to as count data. As expected, normal distributions of

the outcome variables of interest were not found. Instead, the data were positively skewed with

many cases where the outcome variables had a value of zero. Figure 6, Figure 7, and Figure 8

below show the distributions of the outcome variables referred to as Number of Inpatient

Hospital Admissions, Number of Days Spent Hospitalized, and Number of 30-Day

Readmissions. Given this, multivariate Poisson and negative binomial regression were

considered for model testing. Multivariate modeling involves including more than one outcome

variable in the model (Van Belle, Fisher, Heagerty, & Lumley, 2004). The advantage to

multivariate analysis is that all model parameters are simultaneously estimated, producing

greater power. Multivariable multiple regressions are models that have more than one outcome

and more than one predictor in the model at once. Dataset building was done using SAS[®]

software, Version 9.4, and the multivariate multiple regressions were done using MPlus

software, Version 7.4 (Muthén & Muthén, 2010). An alpha value of $\alpha \leq 0.05$ was used to

indicate significance for all analyses.
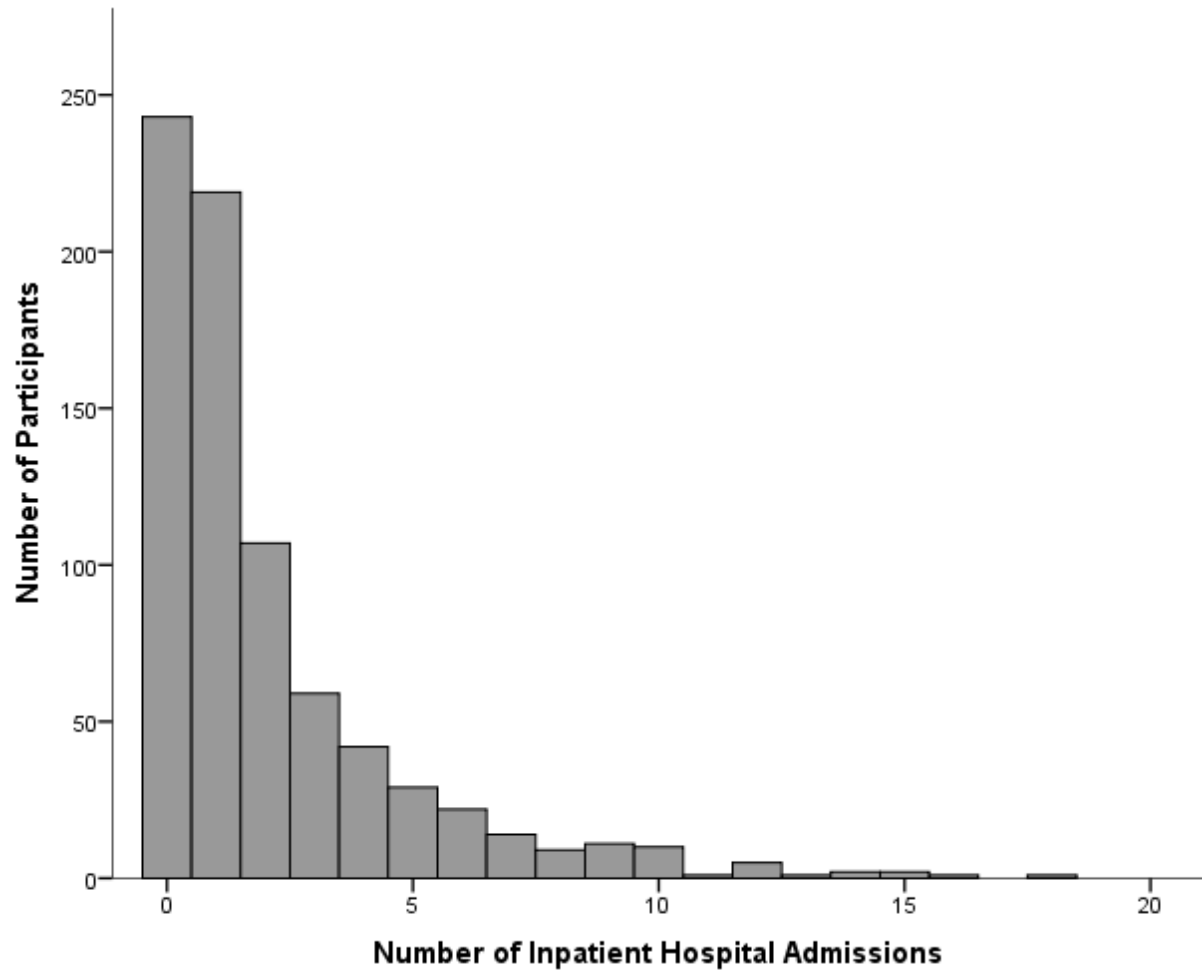
Figure 6. Histogram of Number of Inpatient Hospital Admissions
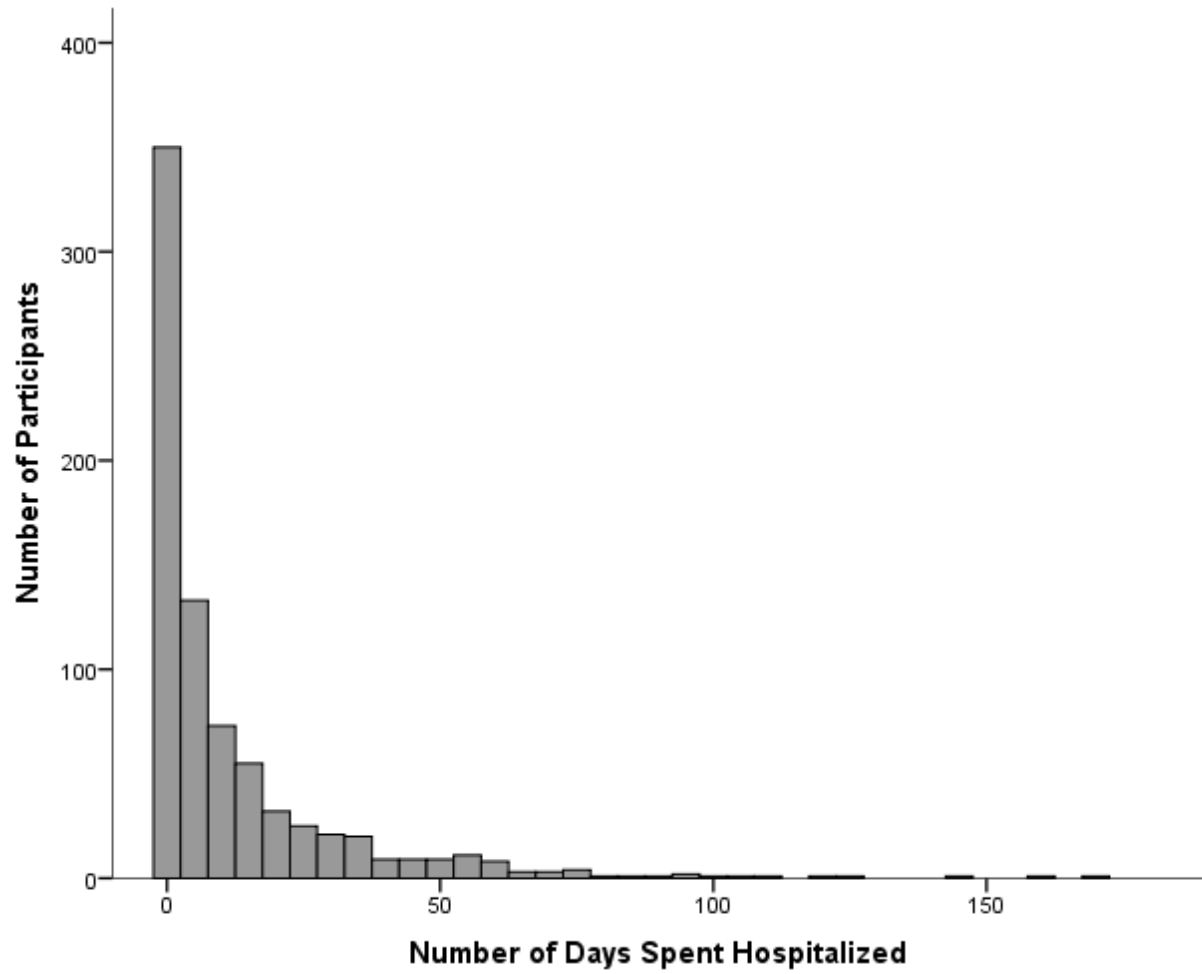
Figure 7. Histogram of Total Number of Days Spent Hospitalized
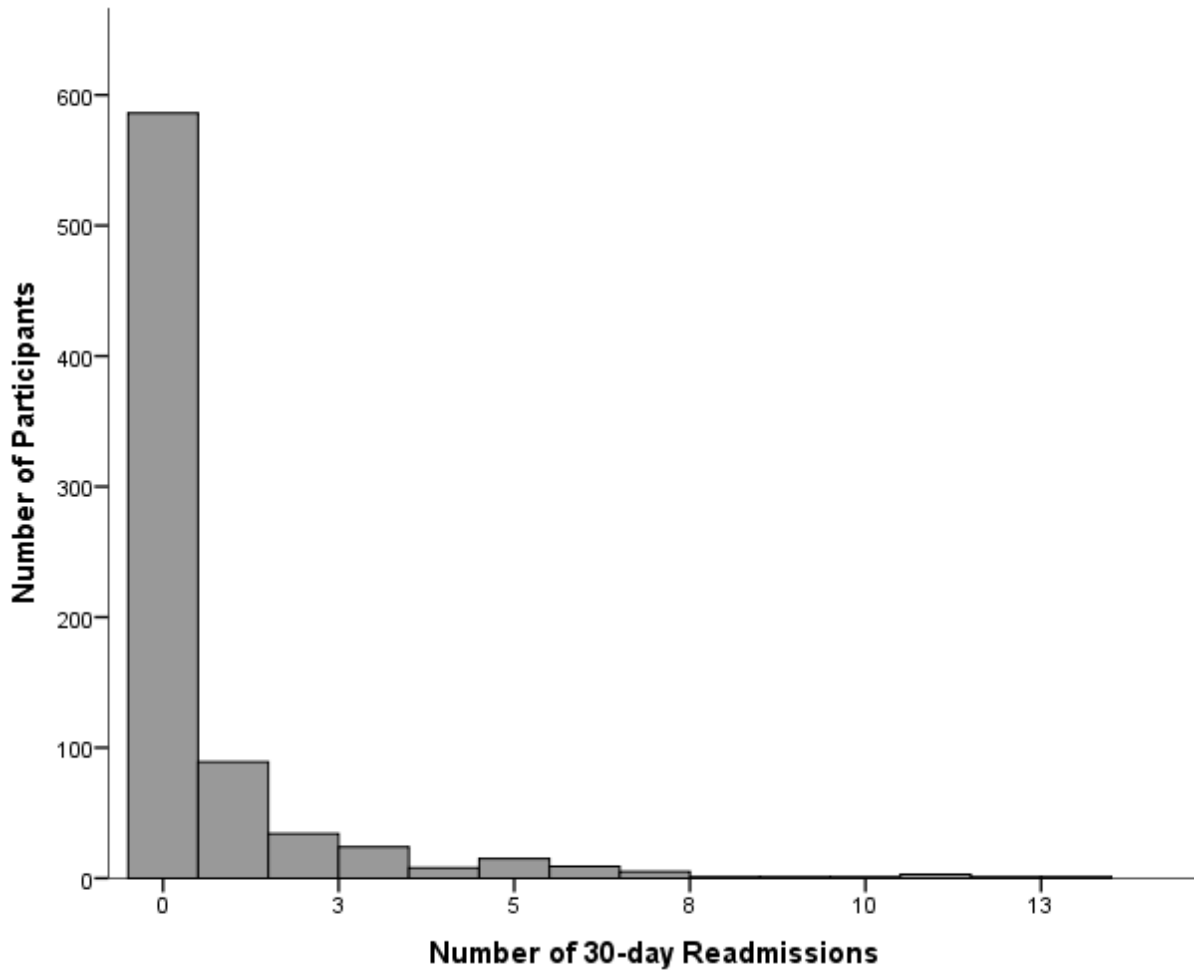
Figure 8. Histogram of Number of 30-Day Readmissions

Poisson regression is the generalized linear model most commonly used when working with count data that do not satisfy the statistical assumptions of linear regression (Vittinghoff, Glidden, Shiboski, & McCulloch, 2010). Poisson regression uses maximum likelihood, based on the Poisson distribution, to estimate regression parameters (Pagano, Gauvreau, & Pagano, 2000). The Poisson distribution assumes (a) the probability of a single event in an interval is proportional to the duration of the interval; (b) in an interval an infinite number of occurrences of the event are possible; and (c) events are independent within identical intervals and between

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consecutive intervals. The Poisson distribution contains only nonnegative integers, making it especially useful when working with count data (Gardner, Mulvey, & Shaw, 1995).

The assumptions that must be met to use the Poisson regression appropriately include (a) the log of the outcome variable has a linear relationship with the predictor variables; (b) observations are independent; and (c) the mean is equal to the variance (Gardner et al., 1995). This important final assumption and was tested during analysis by calculating the dispersion parameter, ϕ. The relationship of the dispersion parameter to the variance is given by the equation,

$$Var(y_i|x_i) = \phi\mu(y_i|x_i).$$

Given the Poisson regression assumption of equidispersion, that the variance and mean values are equal, we know that when $\phi \neq 1$ the assumption fails and the Poisson regression is not the appropriate method for model testing (Gardner et al., 1995). When the data distribution is truly a Poisson distribution, the dispersion parameter should be equal to the Pearson's chi-square value divided by the difference between the number of observations and parameters given by the equation,

$$\phi = \frac{\chi_p^2}{n-p}.$$

This equidispersion assumption was not met and overdispersion was found, defined as $\phi > 1$. Table 13 provides the mean and variances for the three outcome variables of interest. These data showed evidence of potential overdispersion.

Table 13. Mean and Variance of Outcome Variables		
Outcome Variable	**Mean**	**Variance**
Number of inpatient admissions	12.044	420.274
Total days spent hospitalized	2.057	7.286
Number of 30-day Readmissions	0.656	2.702

Given the overdispersion of the data, a negative binomial distribution was used for model testing. Negative binomial regression is considered a generalized Poisson regression and similarly models the log of the outcome variables of interest and uses maximum likelihood in estimating parameters (Lawless, 1987; Ridout, Hinde, & DemeAtrio, 2001). Negative binomial regression produces estimates of the regression coefficient, β, on the log scale. To interpret the values produced for the regression coefficients, one can produce the incident rate ratio (IRR) as,

$$IRR = e^{\beta}.$$

In negative binomial regression IRR can be interpreted as the rate of change expected in the count outcome y, given a one unit increase in the predictor x.

Negative binomial modeling provides a way to model heterogeneity in the data (Pedan, 2001). Negative binomial regression is a flexible nonlinear method with the same assumptions as the Poisson regression, except it has no assumption requiring the mean to equal the variance. While the Poisson model requires equidispersion, the negative binomial distribution gives the variance as a quadratic function of the mean and k, a dispersion factor estimated from the model (Vittinghoff et al., 2010). This relationship is given as,

$$Var(Y) = \mu + k\mu^2.$$

In situations where the dispersion factor, k, is found to equal zero, then equidispersion is found, and the negative binomial distribution functions the same as the Poisson distribution.

Variables Included in Model Building

In building the multivariate multiple negative binomial regression, the goal was to find a parsimonious model of the relationship between health literacy, as measured by the CHLT-30 or the CHLT-6, and hospitalization when controlling for potential confounding covariates. Covariates included in model building were selected based on past research regarding their

potential relationship to health literacy, as well as their potential ability to predict hospitalization. The counts for categorical variables and means for continuous variables included in model building are listed in Table 14.

High School Diploma Flag Variable.

The variable education is a categorical variable with seven levels. To account for education in the model, a flag variable indicating if an individual had a high school diploma was created and included in model building.

Race Variable.

Less than 1% of participants self-identified as a race other than non-Hispanic White or non-Hispanic Black. Given this, a new race indicator variable was created to indicate if a participant was non-Hispanic White or non-Hispanic Minority.

Stage IV Flag Variable.

Stage of cancer was thought to potentially have a relationship between both health literacy and hospitalization. Given that stage of cancer is an indicator of disease progression, it follows that an individual with a higher stage of cancer could potentially have a higher likelihood of hospitalization. Past research has shown those with limited health literacy are less likely to receive timely cancer screening procedures, potentially leading their cancers to be diagnosed at later stages (Bennett et al., 2009; Ojinnaka et al., 2015; Pagán et al., 2012; Scott et al., 2002; White et al., 2008),.

As described previously, 18.34% of individuals who participated in the CHLS had a cancer not traditionally staged as stage 0-IV. Treating the stage variable as a categorical variable to represent these data would introduce significant complexity to the multivariate models, as it would require the creation of six indicator variables, one for each stage level (0, I, II, III, IV, and

Not Staged); thus, by using stage as a categorical variable it is equivalent to adding six binary variables to the model. Treating the 18.34% as missing values is also undesirable as it would result in a significant decrease in sample size. Given this, the decision was made to create an indicator variable to indicate individuals with stage IV disease.

Chemotherapy, BMT, Deceased.

The variables indicating if a participant received chemotherapy, a bone marrow transplant, or died during the time period of analysis were included in model building. All three of these variables have the potential to be associated with increased hospitalization.

Comorbidity Count.

To ease interpretation of findings, the count of comorbidities was favored and included in model building, as it is expected that greater number of comorbidities will influence the hospitalization outcomes in this study.

Travel Time in Minutes.

As described previously, the travel time variable was included in model building to try and account for systematic bias that may exist due to potentially missing cases of hospitalizations at outside hospitals.

Log Time Period.

To account for the variation in time period of available data, the time period in years was included in model building. Given that negative binomial regression models the log of the outcome, the time period variable was calculated by taking the log of the variable Time Period, described previously. Using, log(Time Period) as the variable to represent time put the time period on the same scale (log-based scale) as the outcomes.

Table 14. Predictors Included in Final Model Building

Predictor	Frequency (%)
Stage IV	147 (18.9)
High School Diploma	638 (82.0)
Non-Hispanic White	471 (60.5)
Chemotherapy	497 (63.9)
BMT	26 (3.3)
Deceased	150 (19.3)

Predictor	Mean (SD)
Number of Comorbidities	1.4 (1.5)
Travel Time in Minutes	35.3 (30.4)
Log of Time Period	1.2 (0.5)

Results

Multivariate multiple regressions were run to examine the relationship between health literacy and the health outcomes of interest – the number of inpatient hospitalizations, total number of days hospitalized, and number of 30-day readmissions. Model building was done separately for the health literacy measure CHLT-30 and CHLT-6. The first model, M1, includes only the CHLT-30 or CHLT-6 and the three outcomes of interest. The second model, M2, includes the CHLT-30 or CHLT-6, the above described covariates, and the three outcomes of interest. The model parameters and their significance in M2 inform the structure of the final model M3. In M3 the CHLT-30 or -6 are regressed only on variables that produced significant results in M2. Graphical representation of models M1, M2, and M3 can be seen in Figure 9. The model building process and model outcomes are described below.
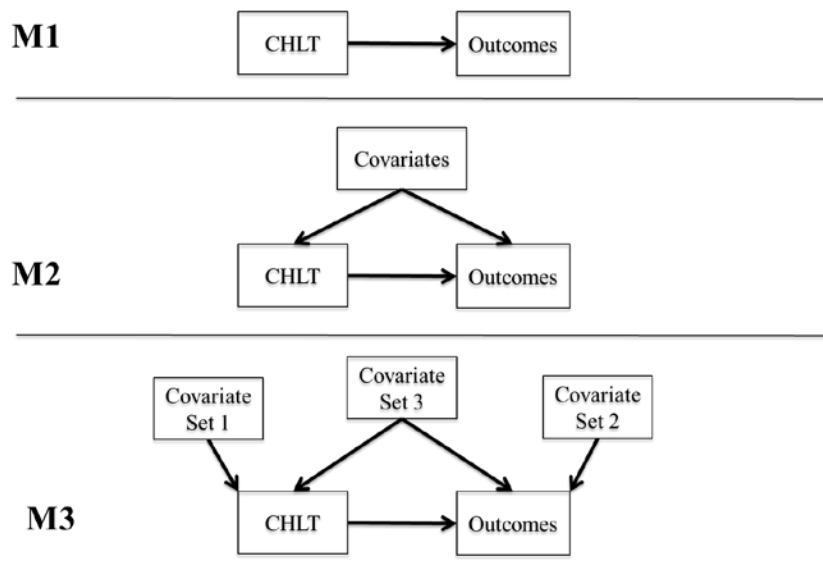
Figure 9. Iterations of Multivariate Model Building

Evidence of overdispersion was found for each iteration of model building (M1-M3) for both the CHLT-30 and the CHLT-6. The estimates of the dispersion parameter ϕ are listed for each outcome in each model in Table 15 for all models. The p-value for all calculations of the dispersion parameter were less than 0.0001, providing evidence that the negative binomial regression better represents the data than Poisson regression.

Table 15. Dispersion Parameter Estimates for Multivariate Models

Model	Outcome	CHLT-30		CHLT-6	
		Dispersion Parameter, ϕ	p-value	Dispersion Parameter, ϕ	p-value
M1	Number of Admissions	1.038	<0.0001	2.058	<0.0001
M1	Days Hospitalized	2.996	<0.0001	2.872	<0.0001
M1	Number of Readmissions	5.234	<0.0001	5.251	<0.0001
M2	Number of Admissions	1.061	<0.0001	2.058	<0.0001
M2	Days Hospitalized	2.234	<0.0001	2.872	<0.0001
M2	Number of Readmissions	3.581	<0.0001	5.251	<0.0001
M3	Number of Admissions	1.071	<0.0001	1.087	<0.0001
M3	Days Hospitalized	2.251	<0.0001	2.281	<0.0001
M3	Number of Readmissions	3.681	<0.0001	3.682	<0.0001

Multivariate Model Building with CHLT-30

Multivariate Model 1 (M1)

The results of model 1 can be seen in Table 16 below. M1 models CHLT-30 as a predictor of all three outcomes simultaneously. In M1 CHLT-30 produces a statistically significant relationship with number of inpatient hospital admissions (β=-0.055, p=0.006) and total number of days spent hospitalized (β=-0.022, p=0.019). The relationship between CHLT-30 and number of 30-day readmissions did not reach the level of significance (β=-0.018, p=0.227).

For the outcome, number of inpatient hospitalizations, the regression coefficient β= -0.055, indicating that the change in log count for inpatient hospital admissions is expected to decrease by 0.055 for every one unit increase in CHLT-30 score. Exponentiating this regression

coefficient for the CHLT-30 score gives an incidence rate ratio of 0.95, meaning a 5% reduction in the expected number of inpatient hospital admissions is expected for a one unit increase in CHLT-30 score.

For total number of days spent hospitalized, the regression coefficient β= -0.022, indicates that the change in log count for inpatient hospital admissions is expected to decrease by 0.022 for every one unit increase in CHLT-30 score. Exponentiating this regression coefficient for CHLT-30 score gives an incidence rate ratio of 0.98, meaning a 2% reduction in the expected number of inpatient hospital admissions is expected for a one unit increase in CHLT-30 score.

Table 16. M1 CHLT-30 Multivariate Model Outcomes

Outcome Variable	Predictor Variable	β	p-value
Number of Admissions	CHLT-30	-0.055	0.006
Days Hospitalized	CHLT-30	-0.022	0.019
Number of Readmissions	CHLT-30	-0.018	0.227

Multivariate Model 2 (M2)

Covariates were added to M2 as potential predictors of CHLT-30 score and all three outcome variables. As in M1, CHLT-30 serves as a predictor of the three health outcome variables of interest, but it now also serves as an outcome for the covariates. The model estimates for M2 can be seen below in Table 17.

Table 17. M2 CHLT-30 Multivariate Model Outcomes

Predictors	Number of Admissions		Days Hospitalized		Number of Readmissions		CHLT-30	
	β	p-value	β	p-value	β	p-value	β	p-value
CHLT-30	-0.027	0.088	-0.013	0.304	0.011	0.587	-	-
Stage 4	-0.019	0.924	-0.383	0.015	-0.036	0.885	0.022	0.95
High School Diploma	-0.223	0.246	-0.192	0.198	-0.18	0.478	5.207	<0.0001
Race	0.251	0.097	0.296	0.041	0.15	0.475	5.379	<0.0001
Chemotherapy	0.853	<0.0001	1.051	<0.0001	1.392	<0.0001	-0.372	0.207
BMT	1.525	<0.0001	1.514	<0.0001	1.018	<0.0001	0.125	0.891
Deceased	0.54	0.002	0.566	0.004	0.125	0.631	0.176	0.684
Comorbidity Count	0.349	<0.0001	0.299	<0.0001	0.294	<0.0001	-0.313	0.002
Log of Time Period	-0.111	0.489	-0.135	0.379	-0.368	0.08	-0.022	0.95
Travel Time	0.001	0.733	0.002	0.197	-0.002	0.535	-0.003	0.595

With the addition of covariates to the multivariate model, CHLT-30 is no longer a significant predictor of the number of inpatient hospital admissions (β=-0.027, p=0.088) or total number of days spent hospitalized (β=-0.013, p=0.304). As found in M1, CHLT-30 also did not predict the number of 30-day readmissions (β=0.011, p=0.587).

Having a high school diploma significantly predicts health literacy level as measured by the CHLT-30 (β= 5.207, p<0.0001). Individuals with a high school diploma are expected to have a CHLT-30 score 82.5% higher than those without a high school diploma. Compared to non-Hispanic minorities, non-Hispanic White participants had significantly higher CHLT-30 scores (β=5.379, p<0.0001). The final covariate with a significant relationship with CHLT-30 was the number of comorbidities (β=-0.313, p=0.002). The incidence rate ratio for the number of comorbidity and CHLT-30 is 0.73, meaning a 27% reduction in CHLT-30 score is expected for each additional comorbidity diagnosis.

As seen in Table 17 the variables indicating receipt of chemotherapy (β=0.853, p<0.0001) and bone marrow transplant (β=1.525, p<0.0001), dying during the time period (β=0.54, p=0.002), and number of comorbidities (β=0.349, p<0.0001) all significantly predict number of inpatient hospital admissions. Similar relationships are seen between the outcome variable total number of days hospitalized, and chemotherapy (β=1.392, p<0.0001), bone marrow transplant (β=1.514, p<0.0001), dying during the time period (β=0.566, p=0.004), and number of comorbidities (β=0.299, p<0.0001). Unique to the outcome total number of days hospitalized is the significance of the flag variable indicating a stage IV cancer (β=-0.383, p=0.015) and race (β=0.296, p=0.041). Individuals with stage IV cancer had a 31.8% reduction in the number of days hospitalized, and non-Hispanic white participants had a 34.4% increase in number of days hospitalized as compared to non-Hispanic minority participants. The number of 30-day readmissions was significantly predicted by chemotherapy (β=1.392, p<0.0001), bone marrow transplant (β=1.018, p<0.0001) and the number of comorbidities (0.294, p<0.0001).

The variable travel time in minutes was non-significant for the number of inpatient hospitalization (β=0.001, p=0.733), total number of days hospitalized (β=0.002, p=0.197) and the number of 30-day readmissions (β=-0.002, p=0.535). This finding indicates that proximity to VCUHS and Massey Cancer Center does not impact the outcomes of interest. The log of time period was also non-significant for the number of inpatient hospitalization (β=-0.111, p=0.489), total number of days hospitalized (β=-0.135, p=0.379) and the number of 30-day readmissions (β=-0.368, p=0.080).

Multivariate Model 3 (M3)

The parameter estimates calculated for M2 informed the structure of M3. As Figure 9 above indicates, significant covariates were grouped into three subsets and regressed onto the appropriate outcomes. Nonsignificant covariates identified in M2 were not included in M3.

Covariate subset 1 includes all variables that were significant only for the CHLT-30. The covariates in covariate subset 1 are the indicator variable for having a high school diploma. Covariate subset 2 includes variables that were significant only for the hospitalization outcomes and did not reach significance for CHLT-30. The variables in covariate subset 2 are bone marrow transplant, chemotherapy, deceased, and the indicator variable for stage IV. Covariate subset 3 includes variables that were significant predictors of both the CHLT-30 score and the hospitalization outcomes. The variables in covariate subset 3 were the number of comorbidities and race. The estimated model parameters for the final model, M3, can be seen in Table 18.

In the final multivariate multiple negative binomial model with CHLT-30, the direct relationship between CHLT-30 and number of inpatient hospital admissions (β=-0.035, p=0.020) was statistically significant. For every one point increase in CHLT-30 score, participants experienced a 3.4% reduction in number of inpatient hospital admissions, when controlling for covariates and the two other outcomes. Direct effects between CHLT-30 and total number of days hospitalized (β=-0.018, p=0.137), and number of 30-day readmissions (β=0.008, p=0.662) did not reach significance.

As also seen in M2, the covariates race (β=5.349, p<0.0001), having a high school diploma (β=5.238, p<0.0001) and number of comorbidities (β=-0.312, p=0.002) significantly predict CHLT-30 score. As compared to non-Hispanic participants, and holding race and number of comorbidities constant, non-Hispanic white participants have an incident rate ratio of 210.4, meaning they are expected to have a CHLT-30 score 110.4% higher on average. When holding

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race and number of comorbidities constant, participants with a high school diploma are expected to have a CHLT-30 score 88.3% higher on average than those with less than a high school diploma. For each additional comorbidity an individual has, CHLT-30 score is expected to decrease by an average of 26.8% when holding race and high school diploma status constant.

In M3, number of inpatient hospitalization admissions is significantly predicted by receiving chemotherapy ($\beta = 0.858$, $p<0.0001$), receiving a bone marrow transplant ($\beta= 1.493$, $p<0.0001$), dying in the time period ($\beta=0.602$, $p=0.003$), and number of comorbidities ($\beta= 0.356$, $p<0.0001$). Total number of days spent hospitalized is significantly predicted by receiving chemotherapy ($\beta = 1.052$, $p<0.0001$), receiving a bone marrow transplant ($\beta= 1.496$, $p<0.0001$), having a stage 4 cancer ($\beta= -0.384$, $p=0.012$), number of comorbidities ($\beta= 0.300$, $p<0.0001$), and race ($\beta= 0.293$, $p=0.045$). The number of 30-day readmissions is significantly predicted by receiving chemotherapy ($\beta = 1.444$, $p<0.0001$), receiving a bone marrow transplant ($\beta= 0.941$, $p=0.002$), and number of comorbidities ($\beta= 0.292$, $p<0.0001$).

Table 18. M3 CHLT-30 Multivariate Model Outcomes

| | Outcomes | | | | | | | |
| | Number of Admissions | | Days Hospitalized | | Number of Readmissions | | CHLT-30 | |
Predictors	β	p-value	β	p-value	β	p-value	β	p-value
CHLT-30	-0.035	0.020	-0.018	0.137	0.008	0.662	-	-
Chemotherapy	0.858	<0.0001	1.052	<0.0001	1.444	<0.0001	-	-
Stage 4	-0.027	0.891	-0.384	0.012	-0.031	0.900	-	-
BMT	1.493	<0.0001	1.496	<0.0001	0.941	0.002	-	-
Deceased	0.602	0.003	0.649	<0.0001	0.391	0.063	-	-
Number of Comorbidities	0.356	<0.0001	0.300	<0.0001	0.292	<0.0001	-0.312	0.002
Race	0.258	0.114	0.293	0.045	0.081	0.721	5.349	<0.0001
High School Diploma	-	-	-	-	-	-	5.238	<0.0001

Multivariate Model Building with CHLT-6

Multivariate multiple negative binomial regression was conducted using the CHLT-6 in the same manner as CHLT-30, described previously.

Multivariate Model 1 (M1)

The results of multivariate model 1 for CHLT-6 can be seen in Table 19 below. In M1 CHLT-6 produces a statistically significant relationship with number of inpatient hospital admissions (β= -0.289, p=0.018). Exponentiating the regression coefficient for CHLT-6 and count of inpatient hospitalization gives an incidence rate ratio of 0.749. When compared to individuals with limited health literacy, participants with adequate health literacy have an average 25% reduction in number of inpatient hospital admissions.

The relationship between CHLT-6 and total number of days spent hospitalized (β= -0.254, p=0.366) and number of 30-day readmissions did not reach the level of significance (β= -0.185, p=0.373).

Table 19. M1 CHLT-6 Multivariate Model Outcomes

Outcome Variable	Predictor Variable	β	p-value
Number Admissions	CHLT-6	-0.289	0.018
Days Hospitalized	CHLT-6	-0.254	0.366
Number Readmissions	CHLT-6	-0.185	0.373

Multivariate Model 2 (M2)

Covariates were added to M2 as possible predictors of CHLT-6 score and all three outcome variables. As in M1, CHLT-6 enters the model as a possible predictor of the three health outcome variables of interest, but it now also serves as an outcome for the covariates. The model estimates for M2 can be seen below in Table 20.

Table 20. M2 CHLT-6 Multivariate Model Outcomes

	Outcomes									
	Number of Admissions		Days Hospitalized		Number of Readmissions		CHLT-6			
Predictors	Beta	p-value	Beta	p-value	Beta	p-value	Beta	p-value	Odds Ratio	95% CI
CHLT-6	-0.184	0.43	-0.257	0.061	-0.128	0.549	-	-	-	-
Stage 4	-0.024	0.907	-0.387	0.014	-0.035	0.889	-0.208	0.485	0.812	(0.452, 1.457)
High School Diploma	-0.307	0.124	-0.171	0.226	-0.07	0.769	1.893	<0.0001	6.642	(4.071, 10.838)
Race	0.142	0.316	0.281	0.041	0.0242	0.227	2.209	<0.0001	9.103	(5.543, 14.950)
Chemotherapy	0.868	<0.0001	1.059	<0.0001	1.385	<0.0001	-0.076	0.747	0.926	(0.583, 1.473)
BMT	1.515	<0.0001	1.517	<0.0001	1.006	<0.0001	-0.021	0.973	0.979	(0.293, 3.279)
Deceased	0.536	0.003	0.547	0.005	0.121	0.645	-0.159	0.661	0.853	(0.418, 1.739)
Comorbidity Count	0.36	<0.0001	0.303	<0.0001	0.292	<0.0001	0.057	0.423	1.059	(0.920, 1.218)
Log of Time Period	-0.117	0.468	-0.137	0.374	-0.376	0.076	0.013	0.963	1.014	(0.577, 1.781)
Travel Time	0.001	0.631	0.002	0.192	0.002	0.459	0.001	0.877	1.001	(0.003, 1.008)

As was seen in the models with CHLT-30, the addition of covariates to the multivariate model results in CHLT-6 no longer significantly predicting number of inpatient hospital admissions (β= -0.184, p= 0.43). As found in M1, CHLT-6 also did not predict total number of days spent hospitalized (β= -0.257, p= 0.061) or number of 30-day readmissions (β= -0.128, p= 0.549).

Having a high school diploma significantly predicts health literacy level as measured by the CHLT-6 (β=1.893, p<0.0001). The variable high school diploma has an odds ratio of 6.462 (4.071, 10.838), indicating that individuals with a high school diploma are nearly six and half times as likely to have adequate health literacy as compared to those without a high school diploma. Race was also a significant predictor of health literacy (β=2.209, p<0.0001) with an odds ratio of 9.103 (5.543, 14.950), with non-Hispanic White participants being over nine times as likely to have adequate health literacy.

As seen in Table 20 the variables indicating receipt of chemotherapy (β=0.868, p<0.0001) and bone marrow transplant (β=1.515, p<0.0001), dying during the time period (β=0.536, p=0.003), and number of comorbidities (β=0.36, p<0.0001) all significantly predict number of inpatient hospital admissions. Similar relationships are seen between the outcome variable total number of days hospitalized, and chemotherapy (β=1.059, p<0.0001), bone marrow transplant (β=1.517, p<0.0001), dying during the time period β=0.547, p=0.005), and number of comorbidities (β=0.303, p<0.0001). Unique to the outcome total number of days hospitalized is the significance of the flag variable indicating a stage IV cancer (β=-0.387, p=0.014) and race (β=0.281, p=0.041). Having a stage IV cancer predicts a 32.1% reduction in days spent hospitalized as compared to those having a lower stage or not staged cancer, and non-Hispanic white participants spent 32.4% increase in the number of days spent hospitalized.

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Number of 30-day readmissions was significantly predicted by chemotherapy (β=1.385, p<0.0001), bone marrow transplant (β=1.006, p<0.0001) and number of comorbidities (β=0.292, p<0.0001).

The variable travel time in minutes was non-significant for number of inpatient hospitalization (β=0.001, p=0.0.631), total number of days hospitalized (β=0.002, p=0.192) and number of 30-day readmissions (β=0.002, p=0.459). The log of time period was also non-significant number of inpatient hospitalization (β=-0.117, p=0.468), total number of days hospitalized (β==0.137, p=0.192) and number of 30-day readmissions (β=-0.376, p=0.076).

Multivariate Model 3 (M3)

The parameter estimates calculated for M2 informed the structure of M3. Significant covariates identified in M2 were grouped into three subsets and regressed onto the appropriate outcomes, as seen for M3 in Figure 9. Nonsignificant covariates identified in M2 were not included in M3.

Covariate subset 1 includes all variables that were significant only for the CHLT-6. The only covariate in covariate subset 1 is the race variable. Covariate subset 2 includes variables that are significant only for the hospitalization outcomes and did not reach significance for CHLT-6. The variables in covariate subset 2 are bone marrow transplant, chemotherapy, deceased, and the indicator variable for stage IV. Covariate subset 3 includes variables that were significant predictors of both the CHLT-6 score and the hospitalization outcomes. The variables in covariate subset 3 are the number of comorbidities and race. The estimated model parameters for the final model for CHLT-6, M3, can be seen in Table 21.

Table 21. M3 CHLT-6 Multivariate Model Outcomes

| Predictors | Number Admissions | | Days Hospitalized | | Readmissions | | CHLT-6 | | | |
	Beta	p-value	Beta	p-value	Beta	p-value	Beta	p-value	Odds Ratio	95% CI
CHLT-6	-0.273	0.215	-0.296	0.033	-0.096	0.668	-	-	-	-
Chemotherapy	0.876	<0.0001	1.062	<0.0001	1.441	<0.0001	-	-	-	-
Stage 4	-0.040	0.847	-0.388	0.011	-0.023	0.927	-	-	-	-
BMT	1.464	<0.0001	1.497	<0.0001	0.94	0.002	-	-	-	-
Deceased	0.589	0.004	0.627	<0.0001	0.398	0.058	-	-	-	-
Number of Comorbidities	0.377	<0.0001	0.305	<0.0001	0.286	<0.0001	-	-	-	-
Race	0.107	0.470	0.258	0.050	0.175	0.40	2.164	<0.0001	8.702	(5.346, 14.166)
High School Diploma	-	-	-	-	-	-	1.846	<0.0001	6.337	(3.952, 10.163)

In the final multivariate multiple negative binomial model with CHLT-6, the direct relationship between CHLT-6 and total number of days spent hospitalized became significant (β=-0.296, p=0.033) and produces an incident rate ratio of 0.744. This significant relationship means that when compared to individuals with limited health literacy, participants with adequate health literacy have 25.6% fewer days spent hospitalized on average. Number of inpatient hospital admissions (β=-0.273, p=0.0215) and number of 30-day readmissions (β=-0.096, p=0.668) regressed on to CHLT-6 did not reach significance.

Race (β=2.164, p<0.0001) significantly predicts CHLT-6 and produces an odds ratio of 8.702 (5.346, 14.166). Having a high school diploma (β=1.846, p<0.0001) also significantly predicts CHLT-6, with those having a high school diploma being over six times as likely to have adequate health literacy as compared to those who do not have a high school diploma (OR=6.337).

Number of inpatient hospitalization admissions is significantly predicted by receiving chemotherapy (β = 0.866, p<0.0001), receiving a bone marrow transplant (β= 1.464, p<0.0001), dying in the time period (β=0.589, p=0.004), and number of comorbidities (β= 0.377, p<0.0001). Total number of days spent hospitalized is significantly predicted by receiving chemotherapy (β = 1.062, p<0.0001), receiving a bone marrow transplant (β= 1.497, p<0.0001), having a stage 4 cancer (β= -0.388, p=0.011), dying during the time period (β=0.627, p<0.0001), race (β=0.258, p=0.05), and number of comorbidities (β= 0.305, p<0.0001). The number of 30-day readmissions is significantly predicted by receiving chemotherapy (β = 1.441, p<0.0001), receiving a bone marrow transplant (β= 0.940, p=0.002), and number of comorbidities (β= 0.286, p<0.0001).

<center>**Discussion**</center>

In designing this study it was believed that given how often cancer patients are hospitalized and the complicated nature of cancer and cancer treatment, health literacy would play an important role in hospitalization rates. The results of this study are mixed in supporting this idea.

CHLT-30's Ability to Predict Outcomes

Health literacy as measured by the CHLT-30, which produces a continuous score ranging from 0-30, was significant in predicting count of inpatient hospital admissions and days spent hospitalized when it was the only predictive variable in the model (M1). When covariates were introduced to the model in model building step M2, the continuous health literacy score was no longer a significant predictor of hospitalization outcomes. However, in the final iteration of model building, M3, CHLT-30 was a significant predictor of number of inpatient admissions. Total number of days spent hospitalized, and number of 30-day readmissions remained non-significant in M3.

The significant relationship between CHLT-30 and number of inpatient admissions existed in the expected direction, with higher health literacy predicting fewer inpatient admissions. This finding has been previously found in populations of heart failure patients (Wu et al., 2013), patients presenting to the emergency department (Baker et al., 1998) and patients with a diagnosis of COPD (Omachi et al., 2013). Each of these previous studies measured or categorized health literacy differently. Baker et al. (1998) and Wu et al. (2013) both used the STOFHLA to measure health literacy, but while Baker and colleagues (1998) used all three

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categories of health literacy, inadequate, marginal, and adequate, that the STOFHLA produces, Wu et al. (2013) collapsed the categories inadequate and marginal into a new category called "low health literacy" and compared this new category to the "adequate health literacy" group during analyses. Omachi et al. (2013) used health literacy score produced using three Likert scale items, which produced a continuous health literacy score.

Covariates in CHLT-30 Model's Ability to Predict Outcomes

The final model for the CHLT-30 (M3) shows that receiving chemotherapy or a bone marrow transplant and number of comorbidities significantly predicts the number of inpatient hospital admissions, total number of days spent hospitalized, and number of 30-day readmissions. These relationships exist in the expected direction, with receipt of chemotherapy or bone marrow transplant treatments or higher numbers of comorbidities predicting higher hospitalization rates across all three outcomes.

Unique to the number of days hospitalized, is the significance of having a stage IV cancer and race. Having a stage IV cancer predicts 31.9% fewer days spent in the hospital as compared to those with a cancer not stage IV, when controlling for having a high school diploma, race, health literacy score, receiving chemotherapy or bone marrow transplant, dying, number of comorbidities, and number of inpatient hospitalizations and 30-day readmissions. Having a stage IV cancer did not significantly predict the number of inpatient hospitalizations or count of 30-day readmissions. This is a surprising finding as stage of cancer indicates the spread and severity of the disease, so it was presumed that a higher stage would predict more days in the hospital. A potential explanation could be that individuals diagnosed with an end stage cancer receive less aggressive treatment in hopes of preserving quality of life, but there is no way to account for that in these analyses. For example, although this study controls for receipt of chemotherapy

treatment, no data were collected regarding the toxicity of the chemotherapy drugs used or the intent of treatment (curative versus palliative).

Non-Hispanic White participants had a 34% increase in expected total days spent hospitalized as compared to non-Hispanic minority participants when controlling for health literacy, having a high school diploma, treatment, stage, mortality, number of comorbidities, number of inpatient admissions and total number of 30-day readmissions. This finding may be reflecting racial disparities often found in healthcare. Past health disparities research has found differences by race in cancer treatment recommendations (Li, Malone, & Daling, 2003; Shavers & Brown, 2002) as well as types of cancer treatment patients chose, (Hurwitz et al., 2016; Ross et al., 2016) both of which could potentially contribute to length of stay in the hospital.

Past research has found differences by race for length of hospital stay, with non-white cancer patients' hospital stay durations significantly longer as compared to white cancer patients' (Parsons, Habermann, Stain, Vickers, & Al-Refaie, 2012; Ravi et al., 2015). This study found the opposite to be true, with non-Hispanic white patients having more days in the hospital. The heterogeneity of cancer diagnoses may explain why this finding differs from past research. In examining hospital length of stay post-cancer surgery, Parsons et al. (2012) included only patients diagnosed with thoracic, abdominal, or pelvic cancer. Ravi et al. (2015) included only solid tumor patients (esophageal, stomach, pancreatic, colon, renal, bladder, prostate, gynecologic, or lung cancer) receiving surgery for their cancer. In contrast this study included solid tumor cancer, hematological cancer, and skin cancer patients. Additionally, Rave et al. (2015) and Parsons et al. (2012) only examined the length of stay post-surgery, while this study included all cause hospitalizations for five years post diagnosis, which may explain the differences in findings.

There were 11 unique categories of cancer diagnosis identified in this study. Given how much undue complexity it would introduce into the study, cancer type was not included in modeling. However, the finding that race predicts hospitalization in a direction not found in the literature could potentially be further explained by the racial distribution across cancer diagnoses in this study. For example, 28.7% of participants in this study had a hematological cancer, and 69.1% of these hematologic patients were white. If patients with a hematological cancer have longer hospital lengths of stay, either due to severity of disease or treatment standards, cancer diagnosis could serve as a mediating variable in the relationship between race and days spent in the hospital. Future studies should examine this potential mediation by obtaining larger sample sizes across diagnoses to allow for comparisons.

Dying during the time period of analysis was a significant predictor of both number of inpatient admissions and total days spent hospitalized when controlling for covariates and other outcomes in the model. For patients who died during the time period of analyses, a 91.4% increase in total days spent hospitalized and 82.6% increase in the number of inpatient admissions is expected when compared to participants who do not die during the time period. This relationship reflects past research showing dramatic increases in hospital utilization of cancer patients at the end of life (Langton et al., 2014).

CHLT-30 score was significantly predicted by education, race and number of comorbidities. Individuals with a high school diploma had higher health literacy as compared to those without a high school diploma. Non-Hispanic White participants had higher scores as compared to non-Hispanic minority participants, and there was a negative relationship between number of comorbidities and health literacy, such that higher number of comorbidities predicted a lower health literacy score. These findings replicate past research showing a positive

relationship between education and health literacy (Dumenci et al., 2014; Carmen E. Guerra &

Shea, 2007; Kutner et al., 2006; Matsuyama et al., 2011; N. B. Peterson et al., 2007) and

minority participants being at a higher risk of having lower health literacy as compared to white

participants (Cavanaugh et al., 2010; Gazmararian et al., 1999; Kutner et al., 2006; Paasche-

Orlow et al., 2005; Schillinger et al., 2002; Sudore, Yaffe, et al., 2006). Past research has also

shown that an increased comorbidity score is associated with a lower health literacy level, but

this is the first study to examine this relationship using the CHLT-30 as the measure of health

literacy (Carmen E. Guerra & Shea, 2007; Gwynn et al., 2016).

CHLT-6's Ability to Predict Outcomes

Model 3 using the CHLT-6 demonstrated that health literacy was a significant predictor

of the number of total days spent hospitalized when controlling for treatment received, stage of

cancer, dying, number of comorbidities, race, education level, number of inpatient hospital

admissions, and number of 30-day readmissions. This study found that those with limited health

literacy were at a higher risk of spending more days in the hospital as compared to those with

adequate health literacy. This same model found that the CHLT-6 did not significantly predict

how many times an individual would be hospitalized, or how many 30-day readmissions they

would experience. According to this model individuals with limited health literacy spent a

greater number of days in the hospital regardless of the number of times they were admitted, as

compared to those with adequate health literacy.

The CHLT-6's ability to predict total number of days spent hospitalized is difficult to

contextualize. One would think that once hospitalized, individuals are being tended to by

healthcare professionals and health literacy could potentially have less impact on length of stay.

A possible explanation for this finding is that individuals with limited health literacy, although

not hospitalized more often than those with adequate health literacy, are admitted for more serious conditions or arrive more ill when they are hospitalized. Past research has found lower health literacy associated with poorer self-care (F. Al Sayah, S. Majumdar, B. Williams, S. Robertson, & J. Johnson, 2013a; Apter et al., 2013; Matsuoka et al., 2016; Mixon et al., 2014; Schillinger et al., 2002), less knowledge regarding disease (Gazmararian et al., 2003; P. N. Peterson et al., 2011) and medication regime (Marvanova et al., 2011). These findings could result in patients with limited health literacy presenting in a worse condition than those with adequate health literacy and this severity could then translate longer hospital stays.

Health literacy has also been shown to have a negative relationship with preventative care, such as receiving flu shot (Bennett et al., 2009; Scott et al., 2002; Sudore, Mehta, et al., 2006) or pneumococcal immunization (Scott et al., 2002). This lack of preventative care could allow opportunistic infections that are not directly cancer-related to impact the health of individuals with limited health literacy, leading to them having longer hospital stays as compared to those with adequate health literacy.

The finding that CHLT-6 predicts total number of days spent hospitalized is in contrast to the final model using CHLT-30 as the measure of health literacy, which found CHLT-30 predicted only number of inpatient admissions. These conflicting findings may be the result of the different scoring produced by the two measures. The CHLT-6 categorizes patients as having either limited or adequate health literacy, while the CHLT-30 produces a continuous score. The relationship between health literacy and number of inpatient admissions may only produce significant results when examining the entire continuum of health literacy scores, versus comparing just the two groups of health literacy levels. A similar explanation could also explain the significance for the CHLT-6 in predicting total days hospitalized. It may be that when

comparing the two groups a relationship can be seen, but this relationship is much weaker when using a continuous health literacy score.

Covariates in CHLT-6 Model's Ability to Predict Outcomes

As was seen with models using the CHLT-30, in models using CHLT-6 race and education had significant relationships with health literacy. Individuals with a high school diploma and being non-Hispanic white are more likely to have adequate health literacy. In contrast to CHLT-30 modeling however, number of comorbidities did not predict the CHLT-6 categorization of health literacy. This finding is important to researchers who may use the CHLT in the future. Although the CHLT-6 has a faster administration and provides a user friendly categorical score of "limited" or "adequate" health literacy, research looking at health literacy and health outcomes would be wise to use the CHLT-30 given its significant relationship to number of comorbidities.

As was the case in the CHLT-30 modeling, having a stage IV cancer resulted in significantly fewer days spent hospitalized. The explanation for this finding is likely the same as previously described above. Also as was the case with the CHLT-30 model M3, the final CHLT-6 model indicates that receiving chemotherapy or a bone marrow transplant and number of comorbidities significantly predict the number of inpatient hospital admissions, total number of days spent hospitalized, and number of 30-day readmissions. Receipt of chemotherapy and bone marrow treatments and higher numbers of comorbidities predicted higher hospitalization rates across all three outcomes.

The final CHLT-6 model shows that non-Hispanic white participants had a 29.4% increase in number of days spent hospitalized as compared to non-Hispanic minority participants. This parallels the significant relationship found between race and number of days

spent hospitalized in the final model iteration (M3) using CHLT-30. The potential explanation

for this finding is the same as described above.

Non-Significant Relationships Between CHLT and Outcomes

One explanation for the nonsignificant relationships between the CHLT-30 continuous

health literacy score and total number of inpatient admissions and 30-day readmissions, and the

CHLT-6 categorical health literacy level and the number of inpatient hospital admissions and 30-

day readmissions could lie in the time frame selected for these analyses. Cancer patients,

especially in the first 5 years following their diagnosis, are highly managed by care providers,

formal and informal, so health literacy may have less of an influence as compared to other

patient populations. Cancer is a life-threatening disease for which healthcare providers and

others mobilize a high level of support. Individuals with lower health literacy may be

accommodated by friends and family who are able to step in and help. In the CHLS study, for

participants who stated they brought a family member or friend to doctor appointments, 84.8%

reported that this individual was "Extremely Involved" or "Very Involved" in their day to day

care. As the health literacy level of these informal caregivers was not measured, future research

should investigate if the presence of caregivers and their health literacy levels have an impact on

hospitalization rates.

In the years following a cancer diagnosis patients are seen frequently by their oncologists.

Although the standards of care vary by cancer diagnosis and treatment modalities, in general

cancer patients are seen every three or four months for the first three years posttreatment, then

transition to annual follow-up appointments after the first three years (National Cancer Institute

[NCI], 2010). These frequent visits may involve scans, bloodwork and general health check-ups

that could not only aid individuals in managing their cancer, but may also serve to identify other

potential health problems. This level of care and follow up may be significantly different in the cancer patient population as compared to past research examining more heterogeneous populations.

Given the complexity of treatment plans and potential severity of disease, it is also possible that cancer patients are followed by oncology staff more closely than primary care patient populations studied in the past. Massey Cancer Center specifically is a safety-net hospital, designed to meet the needs of an underserved population. It is possible that although no formal health literacy training has been provided to the cancer center employees, the health professionals in that clinic have learned to recognize individuals who may struggle with health information or need additional resources and provide them with appropriate assistance.

Similarly, treatments for cancer are frequently not self-administered. Although there is significant self-care involved in taking medication to manage symptoms, the primary modalities of cancer treatment are administered in the clinic by trained professionals. Short of not showing up for chemotherapy, radiation, or surgical appointments, primary treatment is largely out of the patients' hands. This is in contrast to populations like COPD and heart failure patients, where treatment may be managed by the patient at home, and in which a significant relationship between health literacy and hospitalization has been found (Omachi et al., 2013; Wu et al., 2013).

A relationship between health literacy and hospitalization has been found for heterogeneous participant samples, including patients presenting at the emergency department (Baker et al., 1998), general medicine department (Mitchell et al., 2012) and Medicare enrollees (Baker et al., 2007). However, Apter et al. (2013) found no relationship between health literacy and hospitalization in a study of patients with moderate to severe asthma. This current study,

using CHLT-30 and CHLT-6, contributes to the mixed findings, indicating that health literacy may not predict hospitalization in the same way across different patient populations. As is frequently the situation in health literacy research, the variety of health literacy measures used (STOFHLA, TOFHLA, REALM, CHLT, and a 3-item questionnaire) also makes comparing the findings regarding hospitalization difficult.

This study did not replicate findings of Mitchell and colleagues (2012). Mitchell et al. (2012) found that individuals with inadequate health literacy, when controlling for potentially confounding variables, were 1.46 times more likely to have a hospital admission within 30 days of being discharged from the hospital. Important differences exist between the study conducted by Mitchell and colleagues (2012) and this study. Mitchell et al. (2012) approximated health literacy using the REALM, a measure not psychometrically designed to measure health literacy directly (Dumenci et al., 2014) and used a binary outcome, indicating if at least one 30-day readmission occurred. In contrast this study used a psychometrically validated measure of health literacy, and examined the number of 30-day readmissions.

Additional analyses were conducted to see if the findings from Mitchell et al. (2012) could be replicated. An indicator variable signifying ≥ 1 30-day readmission occurred was created and analyses were done for the CHLT-30 and CHLT-6 separately. The readmission indicator variable was regressed on CHLT-30 using logistic regression, and no significant relationship was found between the indicator variable and the CHLT-30 ($p=0.176$). A chi-square test was conducted to examine the relationship between the CHLT-6 and the indicator variable, and it also produced nonsignificant results ($p=0.229$). Even when adjusting the analyses, no significant relationship was found and the findings could not be replicated in this population

using the CHLT-30 or CHLT-6. This gives strength to the idea that perhaps the relationship between health literacy and hospitalization is different across different patient populations.

Given that health literacy as measured by the CHLT-30 was significant as the only predictor in the model for number of days hospitalized, then became non-significant when covariates were added to the model suggests that future work should investigate health literacy's potential role as a mediator between individual factors, in this study demographic, treatment, morbidity, stage, and numbers of comorbidities, and health outcomes. Although beyond the scope of this study, future work could test full or partial mediation models. A recent study used path analysis to evaluate health literacy's ability to mediate the relationship between various demographic variables and participants self-reported patient activation (Gwynn et al., 2016). Gwynn et. al (2016) found that health literacy fully-mediated racial disparities in self-reported patient activation. If health literacy were found to be a full or partial mediator, this could inform intervention or clinical practices to address health disparities, potentially narrowing the gap that exists for certain subpopulations.

Study Limitations

The data contained in the VCUHSCR and SSDI have the potential to be up to a year behind. However, as CHLS data collection was completed in April 2013, this delay in updating the databases should only produce minimal disruption to this study. Given the CHLS data was collected from April 2011 – April 2013, at the time the hospital databases were accessed, June 13, 2014, it was 14 months since the final participant was interviewed.

In the CHLS, participants with a lifetime history of a cancer diagnosis and who were healthy enough to participate were recruited, regardless of the current status of their cancer. Although this study used eligibility criteria to narrow focus to individuals interviewed within the

first five years of their first cancer diagnosis, it is possible that this sample of participants has an overrepresentation of patients who have responded well to treatment, had their disease transition into remission, or who had less severe disease. If this were the case this sample would be less likely to become hospitalized as compared to more ill individuals.

This secondary analyses was a retrospective examination of available data sources. The study was limited in that only the hospitalization data from VCUHS were available for analysis. No records of being hospitalized at other institutions were available for analyses. Future research using a prospective longitudinal design should be done to capture all instances of hospitalization at any hospital.

Study Strengths

This study benefited from the fact that the CHLS data contains a large sample of participants from the Massey Cancer Center. The participants in the CHLS were diverse in terms of race/ethnicity, socioeconomic status, and cancer diagnosis and stage. This diversity allows for greater generalizability of findings.

This study also fills a gap in the current health literacy literature. It is the first study to utilize a purely cancer patient population to examine the relationship between health literacy and hospitalization rates. Furthermore, it is the first study to use the CHLT-30 and CHLT-6, a psychometrically sound and valid instrument, in examining this relationship. A better understanding of this relationship can guide future research examining the relationship between health literacy and health outcomes.

Future Work

This study was the first to examine hospitalization and health literacy in a cancer patient population, and the first to examine hospitalization rates using the psychometrically sound

CHLT-30 and CHLT-6. Future work should focus on addressing some of the questions this study leaves unanswered through a different methodological approach, and by examining health literacy as a mediator between individual factors and health outcomes.

A prospective longitudinal study recruiting several cohorts of participants at various points in their cancer care journey could help identify what, if any, impact looking only at the first 5 years after a diagnosis had on these results. This methodology would allow for comparison of the cohort groups to examine how health literacy may be acting as a mediator between level of oncologic care and hospitalization. As was theorized above, it is possible when a patient is experiencing high levels of follow up and management by their oncology team, health literacy has little effect on their rates of hospitalization, but health literacy may become a more significant predictor of hospitalization rates when the level of follow-up care decreases.

This future study should also administer the CHLT-30 and CHLT-6 at multiple time points to examine if health literacy level changes over time. Currently no study has examined health literacy's ability to change over time. This is largely due to the field's beginnings of using measures that relied almost exclusively on reading ability. Given that health literacy was formerly measured using literacy measures, short of teaching participants to read, one would not expect heath literacy level change. The refinement of health literacy and its domains and the subsequent improvements in measurement allow for the testing of the assumption that health literacy does not change over time. One would expect that increases in exposure to cancer information, guidance from healthcare providers, and additional experiences as a cancer patient could result in an increase in health literacy level. Longitudinal studies demonstrating that health literacy level can change are needed to truly define health literacy as a modifiable variable.

A future study could also gather information directly from participants regarding when and where they are hospitalized, and then gather ICD-9 or medical record information from the utilized hospital systems. This methodology would guarantee no missed occurrences of hospitalization, and would allow participants to confirm all instances of hospitalization.

A future prospective longitudinal study should also collect data on reasons for hospitalization and explanations for continued hospital stay. Collecting these data in a future study would aid in explaining the finding that participants with limited health literacy, as measured by the CHLT-6, experienced more days hospitalized, when controlling for number of times hospitalized. Being able to examine why those with limited health literacy had longer hospital stays would help in beginning to address this disparity.

A future study with larger sample sizes by cancer diagnosis would allow for analyses between and within groups. Given that cancer treatment standards of care vary across diagnoses and stages, having larger sample sizes of each type of cancer could identify if there are significantly different rates of hospitalization by cancer diagnosis. In doing a large scale study like this, health literacy's direct effect could be examined by cancer diagnosis and compared across diagnoses.

Future analyses testing mediation using the CHLT-30 and CHLT-6 could help identify if health literacy serves as a mediator and a number of health outcomes. These findings would be important as interventions and patient education programs could assist those with limited literacy, potentially impacting health outcomes.

Summary

  Health literacy is a growing area of research, with a focus on improving measurement and identifying how health literacy impacts health outcomes. This study contributes to the field by examining health literacy's role in predicting hospitalization rates in a cancer patient population using a psychometrically valid measure. This study found that a continuous health literacy score, produced by the CHLT-30, had a negative relationship with number of inpatient hospital admissions and total days hospitalized in the first five years of an individual's first cancer diagnosis. This relationship dissipated when demographic, treatment and cancer stage variables were entered into the model for total days hospitalized, but persisted for number of inpatient hospital admissions. Given past research showing health literacy's ability to predict hospitalization in different patient populations, this study provides evidence that health literacy could be a mediator, with its impact on hospitalization varying depending on covariates, such as diagnosis or patient population.

  This study found that although individuals with limited health literacy have similar numbers of inpatient admissions and 30-day readmissions, as compared to those with adequate health literacy, they spent significantly more days in the hospital in the first five years post-diagnosis. This relationship was significant when controlling for demographic, treatment and

stage variables. The reasons for the longer lengths of stay are not currently understood, and future research should seek to further understand why in order to address this disparity.

This study has provided further evidence that a relationship between health literacy level and hospitalization rates exists, but that this relationship is not yet fully understood. The results of this study should inform future research to examine the structure of the relationship between health literacy and hospitalization, along with other health outcomes, through prospective longitudinal studies, and encourage further work be done specifically in the cancer patient population.

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