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The Relationship Between Health Literacy and Self-Management

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THE RELATIONSHIP BETWEEN HEALTH LITERACY AND SELF-MANAGEMENT

by

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THE RELATIONSHIP BETWEEN HEALTH LITERACY

AND SELF-MANAGEMENT

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Health literacy is an evolving concept, impacting all areas of health care. There is a need for improved understanding of the concept and its relationship with self-management especially in the United States (US) where health literacy has been limited to functional health literacy consisting of basic reading and writing. Health literacy is defined as the "ability to obtain, understand, and apply health information for healthcare decisions" (Nielsen, 2004, p. 32) and has been expanded into three sub-concepts of functional, communicative, and critical health literacy. The purpose of this dissertation is to explore and better understand the relationship between health literacy and self-management using a health literacy tool modified and evaluated in the US. The specific aims in this study were 1) to evaluate the validity and reliability of the Functional, Communicative, and Critical Health Literacy (FCCHL) tool in a Midwestern, socioeconomically vulnerable or unstable adult population, 2) to determine the efficacy of the FCCHL compared to the Newest Vital Sign (NVS) or Short Form of the Test of Functional Health Literacy in Adults (s-TOFHLA) in relation to self-management, and 3) to determine the relationship between the FCCHL components of functional, communicative and critical health literacy and the self-management components of patient activation, self-regulation, and self-efficacy. The study included a cross-sectional, convenience sample from both urban and rural US locations including a rural health clinic, an urban Federally Qualified Health Center (FQHC), and an urban workplace clinic supporting under-insured employees. A total of 276 participants were recruited for a fully powered study. The FCCHL tool was evaluated using construct, criterion, and

concurrent validity, internal consistency and external reliability. The tool was found to be valid and reliable when tested in this population. Additionally, it was determined by correlations that the FCCHL tool measured more than functional health literacy and was different than educational levels suggesting that more than literacy was measured. The relationship between the FCCHL and self-management showed statistically significant and higher correlations for all three self-management components as compared to the relationship between the NVS to self-management and s-TOFHLA to self-management. The relationship between the components of the FCCHL tool and self-management components were all moderately, positively correlated. Additionally, the multiple linear regression showed statistically significant relationships between FCCHL tool components with patient activation, self-efficacy, and self-regulation when adjusting for various demographic variables. These results support the use of the FCCHL tool to measure all three sub-concepts of health literacy and supports the positive relationship between health literacy and self-management. These findings support the use of the FCCHL tool to help determine a patient's total health literacy. Future studies should include the language and cultural adaptation of this tool to assess limited English proficient communities, describing the relationship of health literacy with health outcomes, testing FCCHL tool with a self-management intervention, and interventions determined by health literacy as measured by the FCCHL tool.

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CHAPTER I: INTRODUCTION

Background

Prior to 2000, the definition of health literacy closely resembled generalized literacy or health communication and was largely based on basic reading and numeracy ability (Baker, 2006). In 2000, Nutbeam published seminal work in which he significantly advanced the concept of health literacy. He expanded the definition beyond functional literacy to include the capacity to communicate and problem solve regarding one's health. He argued that the concept of health literacy needed to be expanded in response to the increasing complexity of the healthcare system, challenges of chronic care management, and the increasing dependence on patients to manage their healthcare (Nutbeam, 2008).

Then in 2004, the Institute of Medicine (IOM) released a report titled "Health Literacy: A Prescription to End Confusion." The aims of the report were to develop a comprehensive definition of *health literacy* and to address problems associated with limited health literacy, especially as they relate to health care utilization and poor outcomes. The IOM defined health literacy as "the ability to obtain, understand, and apply health information to make health decisions" and is now commonly used in the United State (US) (Kindig, Panzer, & Nielsen-Bohlman, 2004, p. 4).

The paradigm of health literacy is still changing (Sørenson et al., 2012), however, Nutbeam's proposal of adding communication and critical thinking is becoming the international standard. The three sub-concepts in Nutbeam's definition are now labeled functional, communicative, and critical health literacy. Communicative and critical health literacy are particularly important because each may be modified and may positively influence health self-management, even in the absence of functional health literacy (Wang et al., 2016). The individual concepts relate to knowledge, understanding, application, and problem solving as

well as the ability to read and write. Below are the definitions from Nutbeam's landmark publication (Nutbeam, 2000, p. 265-266).

> **Functional Health Literacy.** Sufficient basic skills in reading and writing to be able to function effectively in everyday situations.
>
> **Communicative Health Literacy.** More advanced cognitive and literacy skills which, together with social skills, can be used to actively participate in everyday activities, to extract information and derive meaning from different forms of communication, and to apply new information to changing circumstances.
>
> **Critical Health Literacy.** More advanced cognitive skills which, together with social skills, can be applied to critically analyze information, and to use this information to exert greater control over life events and situations.

Advancement in the study of health literacy has been hindered by the numerous definitions and an exhaustive list of tools attempting to capture this dynamic concept (Duell et al., 2015; Sørenson et al., 2012; Pleasant et al., 2015). In addition, many of the tools measure different aspects of health literacy. The standard measures of health literacy used in the US are the Newest Vital Sign (NVS) and the Test of Functional Health Literacy in Adults (TOFHLA). Both are measurements of functional health literacy (Duell, Wright, Renzaho, & Bhattacharya, 2015), i.e. they are focused exclusively on literacy, numeracy, and readability (Duell et al., 2015). Although easy to measure, a problem with using functional health literacy as the primary indicator of health literacy is that the factor it is measuring, i.e. literacy, is difficult to modify. As a result, interventions to address low health literacy generally reflect lower reading level or use of visual cues. As noted earlier, it is also clear that functional health literacy does not reflect the complexity of a patient's ability to interact within the health care system (Wang et al., 2016).

In spite of the IOM report and Nutbeam's work, there has been little progress in the US to incorporate the evolving concept of health literacy in practice or research. Currently, research in the United States primarily focuses on functional health literacy (Duell et al., 2015). That being said, research has clearly demonstrated that low functional health literacy is associated with poor health outcomes, poor quality of life, and high health care costs. Additionally, it is well established that low functional health literacy leads to increased use of emergency medicine, hospitalizations, chronic condition exacerbation, and decreased use of preventive care (Batterham et al, 2015; Hawkins, Kantayya, & Sharkey-Asner, 2015; Haun et al., 2015; Poureslami, et al, 2016; Sørenson et al., 2012). Low health functional literacy also negatively impacts patient engagement and their capacity to manage the complexities of chronic health problems (Batterham et al, 2015). Given the established relationship between functional health literacy and health outcomes, it is important to explore the impact that communicative and critical health literacy might have on health behaviors, outcomes, and costs, especially as they are impacted by successful self-management.

Self-Management

Chronic diseases are costly and burdensome to individuals, families, and society. Multiple chronic diseases increase the burden of disability and excessive cost significantly impacting the US health care system. It is estimated that by 2030, chronic disease management will cost more than $42 trillion in healthcare costs in the US (Allegrante, Wells, & Peterson, 2019). Self-management in the most basic form is defined as the "management of or by oneself; the taking of responsibility for one's own behavior and well-being" (Merriam-Webster Dictionary). Self-management is comprised of three separate tasks: management of disease, role, and emotion (Lorig & Holman, 2003). The skills required for successful self-management

include problem solving, decision making, resource utilization, patient-provider partnership, action planning, and self-tailoring (Lorig & Holman, 2003).

Self-management skills are essential to improve health outcomes, prevent disease, and maintain control of chronic disease. Self-management behavior is complex, and studies focused on strategies designed to optimize patient self-management continue to evolve. The ability to manage health is complicated by challenges such as multiple chronic comorbidities, the diminished functional capacity associated with longevity, and the complexities of the healthcare system. Self-management has long been a phenomenon of interest in nursing. Recently, a group of nursing researchers with expertise in self-management has recommended that three discrete measures be used to quantify patients' self-management activities: patient activation, self-efficacy, and self-regulation (Moore et al., 2015; Lorig et al., 2003).

Health literacy, measured as functional health literacy, is assumed to be foundational to successful self-management. Health literacy as measured by communicative and critical health literacy is also foundational (Batterham et al., 2015; Heijmans et al., 2015; & van der Vaart et al., 2012) and is considered a modifiable risk factor (Wang et al., 2016). It is essential that future research incorporate all three sub-concepts of health literacy, especially in relation to self-management strategies (Batterham et al., 2015; Heijimans et al. 2015; van der Vaart et al., 2012; Ishikawa et al., 2008; Wang et al., 2016).

Health Literacy and Self-Management

Linking self-management and health literacy is believed to improve adherence to treatment and medications, health behaviors, develop problem solving skills and techniques to reduce exacerbations, and improve knowledge about the disease process and self-management (Bailey et al., 2013; Federman et al., 2014; Lai et al., 2013; Poureslami et al., 2016). Health literacy is known to have a positive effect on knowledge, understanding, self-efficacy, and social

support, which are all positively associated with improved self-management (Fransen et al., 2012).

There is a small body of research that suggests a significant and direct, positive association between health literacy as defined by all three sub-concepts and self-management (Fransen et al., 2012; van der Heide et al., 2014; van der Vaart et al., 2012). However, there is limited or conflicting data that limits the association that can be made between health literacy and self-management. The complexity may be due to the variety and everchanging health literacy definitions and the complexity of health literacy as a concept. Further studies are needed to explore and improve the understanding of the relationship between health literacy as measured by all three sub-concepts and self-management (Wang et al., 2016; Heijmans et al., 2015).

Health Literacy Measurements

There are over 100 health literacy tools available. As previously stated, the current standards of measuring health literacy in the US include using either the TOFHLA or the NVS (Duell et al., 2015), both of which exclusively measure functional health literacy. However, internationally tools were developed to measure all three types of health literacy. The Functional, Communicative, and Critical Health Literacy tool (FCCHL), includes all three types of health literacy (Duell et al., 2015; Ishikawa, Takeuchi, & Yano, 2008; van der Vaart et al., 2012). The FCCHL tool was developed in Japan by Ishikawa et al. in 2008. It was modified and further developed by van der Vaart et al. in the Netherlands in 2012. This tool provides a comprehensive yet efficient measure of functional, communicative, and critical health literacy. The FCCHL tool is available in many languages, including Japanese, Dutch, English, Korean, and Chinese. The tool has only recently been studied in the US but has not been modified or culturally adapted for its use with communities living in the US (Luo et al., 2018).

Health Literacy Relationship with Self-Management

As previously mentioned, the relationship between functional health literacy and self-management in the United States is well-studied. The degree to which communicative and critical health literacy further impact self-management is less known. Without a way to adequately and pragmatically measure all three types of health literacy in the US, there is limited data to support health literacy as a means of improving self-management.

Recently, research has recognized total health literacy as a modifiable psychosocial factor that contributes to self-management behavior for chronic health conditions (Wang et al., 2016). Further clarifying the relationship between self-management and the components of health literacy can better inform strategies to improve patient self-management. The first step in building the understanding of self-management and health literacy is to introduce a pragmatic health literacy tool to measure all three components.

Significance

In the US, it is estimated that half of all adults have one or more chronic condition that accounts for 86% of the nation's $2.7 trillion annual healthcare expenditures (CDC, 2017). Improvements in healthcare have resulted in higher rates of people living longer, increasing the risk of chronic diseases. Patients must master the ability to manage symptoms and disability, monitor physical indicators, manage complex medication regimens, maintain proper levels of nutrition, diet, and exercise, adjust to psychological and social demands, and engage in productive interactions with healthcare providers (Hayes et al., 2016). Mastering these complex skills is considered self-management. Individual self-management focuses on both the maintenance of wellness and the management of chronic conditions and includes having the necessary skills, knowledge, and resources (Hayes et al., 2016; Lorig & Holman, 2003). Self-management supports individual medical management, life roles, and managing emergencies

that arise from chronic problems (Lorig et al., 2001). The time, money, and effort spent on self-management strategies are increasing, but reimbursement, time allocation, and resources appropriate for this care delivery are not fully supportive (Hayes et al., 2016). The US health care system is impacted significantly; it is estimated that by 2030 chronic disease management will cost more than $42 trillion in healthcare costs (Partnerships, 2018). The advancement of treatment and lifestyles that support longevity with chronic conditions requires increased ability to self-manage, therefore requiring improved strategies and implementation.

The proposed research has the potential to provide new data and early evidence on the relationship between total health literacy and self-management. The relationship will be the first step to modifying current health practices in the US through better evaluation of health literacy. This will result in the development of improved interventions, strategies for improved self-management, and the potential for millions of dollars saved. Additionally, changing how total health literacy is measured will impact policy in both hospitals and community settings and will possibly improve procedures and management of interactions among the system, provider, and patient.

Focusing on the socioeconomically vulnerable or unstable will add insight to the population most influenced by social determinants of health and complexities of the health care system. The Center for Disease Control defines vulnerable populations by three categories of demographics, health status, and socioeconomic factors (CDC, 2018). Specifically, socioeconomic factors include education level and poverty status. The definition of socioeconomic vulnerable populations included in this category are the low level of education and poverty as defined by the national poverty line. Those who are unstable waver between economic stability and instability and have lower education levels (CDC, 2018). Additionally, the target population has expected deficiencies with literacy based on education and poverty status.

This assumption allows differentiation between health literacy and education based on testing a variety of education and poverty levels.

Purpose and Aims

The purpose of this dissertation is three-fold: (1) evaluate the psychometric properties of the FCCHL tool in the US, (2) determine the relationship between health literacy, as measured by the FCCHL tool, and self-management, and (3) compare the efficacy of the FCCHL tool with that of the current US health literacy measurements.

The specific aims used to design this study are:

Aim 1: to evaluate the validity and reliability of the FCCHL tool in a Midwestern socioeconomically vulnerable or unstable adult population

Aim 2: to determine the relationship between the FCCHL components of functional, communicative, and critical health literacy and the self-management components of patient activation, self-regulation, and self-efficacy

Aim 3: to determine the efficacy of the FCCHL as compared to the NVS or TOFHLA in relation to self-management

Overview

This dissertation will explore and lead to better understanding of the relationship between health literacy and self-management using the FCCHL tool to measure health literacy that modified and evaluated in the US. The health literacy tool that expands beyond measuring just functional health literacy may provide insight to improving self-management strategies, especially for those who are socioeconomically vulnerable or unstable.

This dissertation has been prepared using the three-manuscript format as approved by the advisory committee. Chapter 2 provides an extensive review of the literature and a current state of the science of the relationship between health literacy as defined by Nutbeam and self-

management. The manuscript is titled "The Relationship Between Health Literacy and Self-Management: An Integrative Review." The original submission to *Patient Education and Counseling* was rejected and resubmission is intended for the journal *Medicine and Social Science.* The discussion from this manuscript reflects the foundation for the methodological design of the dissertation study.

Chapter 3 will provide psychometric evaluation of the FCCHL tool including validity and reliability in an adult Midwestern socioeconomically vulnerable or unstable population. The manuscript is titled "The Psychometric Testing of the Functional, Communicative, and Critical Health Literacy Tool" and will be submitted to *Patient Education and Counseling.* This manuscript provides the evidence for psychometric acceptability of the FCCHL tool and provides the results for Aim 1.

Chapter 4 presents the details of the relationships between health literacy and self-management as identified by Aim 2. Additionally, Chapter 4 provides results of the FCCHL tool as evaluated against current tools used in the US to determine the benefit of use for the relationship of self-management as identified by Aim 3. This includes evidence of the relationship between health literacy and self-management and supports the use of the FCCHL tool in the US population. The manuscript is titled "The Relationship Between Self-Management and Health Literacy as Measured by the FCCHL Tool" to be submitted to *Medicine and Social Science.* Finally, Chapter 5 provides an in-depth discussion on the conclusion of the study, including implications for research and practice.

Chapter II: Manuscript 1

Medicine and Social Science (to be submitted)

The Relationship Between Health Literacy and Self-Management: An Integrative Review

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Introduction

It is estimated that half of all adults in the United States (US), 117 million people, have one or more chronic condition that account for 86% of the nation's $2.7 trillion annual healthcare expenditures (CDC, 2017). Soon, the increase in the elderly population will further add to the number of patients with chronic conditions (Hayes et al., 2016). Improvements in healthcare have resulted in higher rates of people living with chronic diseases. Higher rates of chronic condition management increase expectations for both patients and providers. Time, money, and effort spent on self-management strategies are increasing. However, reimbursement, time allocation, and resources appropriate for this care delivery are not fully supported (Grady & Gough, 2014).

Self-management focuses on both the maintenance of wellness and the management of chronic conditions and includes having skills, knowledge, and resources (Grady & Gough, 2014). Self-management supports patient medical management, life roles, and managing emergencies that arise from chronic problems (Lorig et al., 2001). Research identifies three components to effective self-management: self-efficacy, self-regulation, and patient activation (Moore et al., 2016). Studies regarding self-management are most valuable when all three components are included, because each variable represents different and important elements of the self-management process (Moore et al., 2016).

In this integrative review, self-management is defined by Lorig and Holman as taking control of one's own health through medical management, role management, and emotional management (Lorig & Holman, 2003). Self-efficacy is defined by Bandura as personal judgment of one's capability to organize and to execute a plan of action for a goal (Bandura, 1977). Patient activation is closely related to self-efficacy and defined as one's judgement of his/her ability to perform a set of self-management activities that includes skill building and execution (Hibbard

et al., 2004). Finally, self-regulation is defined as the ability to obtain health promotion by goal-directed attitudes and behaviors, such as self-monitoring health behaviors and seeking social support (Yeom et al., 2011).

Recently, there has been a recommendation from the National Institute of Nursing Research to use common data elements when measuring self-management (Lee, Lee, & Moon, 2016). This recommendation supports the notion that common data elements will leverage research and support generalizability across populations. The recommended common data elements for use in self-management studies include patient activation, self-regulation and self-efficacy. The recommended common data element measurements include the Patient Activation Measure (Hibbard et al., 2004), the Index of Self-Regulation (Yeom et al., 2011), and Self-efficacy for Managing Chronic Disease (Lorig et al., 2001).

Health literacy is foundational to successful self-management (Lorig et al., 2001; Batterham et al., 2016; Sørensen et al., 2012). The Institute of Medicine (IOM) defines health literacy (HL) as "the ability to obtain, understand, and apply health information to make informed health decisions" (Nielsen-Bohlman, Panzer, & Kindig, 2004, pg. 20). This definition is used in the US but is generally measured as functional HL. Functional HL is defined as the basic literacy skills, such as numeracy and literacy, that are established over time and are sensitive to culture and education level (Nutbeam, 2008). Standard tools used to measure functional HL focus on literacy, numeracy, and readability (Sørensen et al., 2012). The relationship between functional HL and self-management is well-established. Low functional HL is associated with poor health outcomes, low quality of life, and higher health care costs (Sørensen et al., 2012; Haun et al., 2015). However, because functional HL is primarily a reflection of a person's basic literacy, i.e. the ability to read and write, it is not an easily modifiable characteristic and does not reflect the complexity that informs the ability to self-manage health (Duell et al., 2015).

The conceptual understanding of HL has expanded to include three components based on the work by Nutbeam (2008). In addition to functional HL, communicative HL and critical HL are now recognized as components of HL (Batterham et al., 2016). Communicative HL is advanced communication and social skills needed to find health information, discuss the information with others, and associate new information with specific situations (Nutbeam, 2008; Heijmans et al., 2015). Critical health literacy is the advanced personal and social skills which translate into the application of health information to knowledge, skills, and improved interactions including decision making and empowerment (Nutbeam, 2008). The expanded definition of total HL fits well with the IOM definition. The definition is more encompassing than reading and writing and infers a higher level of understanding and application of knowledge, which is addressed by both the communicative and critical components of HL (Nutbeam, 2008). Additionally, the ability to modify characteristics is an important consideration when developing interventions designed to address HL with a goal of improving health outcomes. As noted previously, both communicative and critical HL are considered highly modifiable, while functional HL is not (Nutbeam, 2008).

Given the established relationship between functional HL and self-management, it is important to understand the impact the additional components of HL have on self-management. This integrative review aligns with the recommendations presented by Pleasant et al. (2015), specifically the need to further study HL. This includes analyzing measures of HL that evaluate the theory of total HL and producing studies that further demonstrate the relationship between HL with other concepts, in this case, self-management. The purpose of this integrative review is to analyze studies that explore the relationship between each of the three components of HL and self-management.

Method

Search Procedures and Study Selection

An integrative search was performed using the CINAHL, MEDLINE via PubMed, Embase, and Cochrane databases. Keywords used for the HL search included *health literacy, health information, health knowledge,* and *health education.* Self-management and the core component keywords included *self-care, self-management, self-efficacy, self-esteem, self-concept, self-regulation, self-control, patient participation, patient engagement, patient involvement, patient empowerment,* and *patient activation.* This resulted in 2,599 articles selected for initial review after the deletion of duplicates. The article titles and abstracts were reviewed, and articles were selected based on the inclusion and exclusion criteria as presented in Figure 1 and described in the following section.

Inclusion and Exclusion Criteria

Inclusion criteria for this integrative review included peer-reviewed, full text articles. The publication dates included January 2000 to February 2019. This timeframe was selected because articles prior to this date will not include the expanded definition of HL (Nutbeam 2000). Adults aged 19 and older were included and the articles had to contain or review relationships between the three types of HL and self-management, or self-management common data elements, including self-regulation, self-efficacy, and patient activation.

Exclusion criteria included any articles that were not full text (e.g. abstracts, posters, presentations, dissertations, opinion papers, or press releases). Articles were excluded if the articles were not published in English. Finally, the article was excluded if it did not report statistical relationships between HL and self-management or self-management concepts.

Results

Ten articles were selected for final review. Table 1 provides an overview of the articles and a brief summary of their individual characteristics. Table 2 provides information about the characteristics of the study, statistical relationships between HL and self-management concepts found in the studies, and conclusions and limitations about each of the articles. The tools that were used to measure HL are listed in both tables, and the tools formed to measure self-management are listed in in Table 2. The last three columns in Table 2 indicate which of the three components of self-management are used in relation to health literacy. The ten articles will be discussed in detail to compliment and expand upon the information provided in the tables.

Health Literacy Measures

The most commonly used tool to measure HL was the Functional, Communicative, and Critical HL (FCCHL) (Heijamns et al., 2015; Ishikawa et al., 2009; Lai et al., 2013; Lee et al., 2016; Matsuoka et al., 2016; Matsuoka et al., 2016; Van der Heide et al., 2015; Wang et al., 2016). The FCCHL tool was developed in Japan by Ishikawa et al. in 2008 and was designed to measure all three types of HL. The original tool was in Japanese and has since been translated into various languages, including Dutch, Swedish, English, and Chinese. No articles were found about the tool being used in the US. The FCCHL tool has established validity and reliability (α = 0.84, 0.77, 0.65 respectively for internal consistency). It is a 14-item tool that separates the three distinguishable HL types and provides an overall HL level (Ishikawa, Takeuchi, & Yano, 2008).

The countries that utilize the FCCHL tool include the Netherlands (Heijamns et al., 2015; van der Heide et al., 2015), China (Lai et al., 2013), Taiwan (Lee et al., 2016; Wang et al., 2016), Korea (Lee et al., 2016), and Japan (Ishikawa et al., 2009; Matsuoka et al., 2016; Matsuoka et al. 2016). The tool is available in Dutch (Heijamns et al., 2015; van der Heide et al., 2015), English

(Heijmans et al., 2015; Lai et al., 2013), Korean (Lee et al., 2016), and Japanese (Ishikawa et al., 2009; Matsuoka et al., 2016; Matsuoka et al. 2016). In this review, the FCCHL tool has been used in two settings: clinics for multiple chronic conditions (Heijamns et al., 2015; van der Heide et al., 2015), and diabetes clinics Ishikawa et al. 2009; Lai et al., 2013; Lee et al., 2016; Matsouka et al., 2016; Matsouka et al., 2016; Wang et al., 2016). The limitations of this tool were similar in all studies and included generic limitations, such as cross-sectional design limitations and possibly not measuring those who are completely illiterate and unable to complete the measure. Also, several researchers had to make small changes to the tool to address acculturation for the intended population. The change included the adjustment of words used during translation or in specific settings to clearly indicate each question's meaning (Lai et al., 2013; Lee et al., 2016).

The second comprehensive HL tool used was the 34-item Chinese HL Scale (Leung, Cheung & Chi, 2014). The measure has four specific dimensions which align with the IOM definition of HL. The dimensions include remembering, understanding, applying, and analyzing. The dimensions measure the ability of an individual to remember diabetic words, information, drug information, and various forms. It also measures the ability of an individual to make decisions about scenarios, analyze relevance of information, and determine if decisions are appropriate in different situations related to diabetic care. The internal consistency was reported with Cronbach's alpha of 0.884 and test-retest reliability of $r=0.898$, $p<0.001$. This tool was created in China and specific to the Chinese culture.

All articles referenced in this integrative review use the FCCHL tool except one. Additional tools were reviewed but did not meet the standards of the inclusion criteria, and therefore were not included in this integrative review. The Health Literacy Measurement Scale tool was considered for review as it measures all three types of HL. However, this tool was excluded from the review because it did not correlate the three types of health literacy with the

self-management components. The primary HL tool used in the US, the Newest Vital Sign, was not included in this integrative review, as it does not clearly measure all three types of HL, and it can be argued that it only focuses on functional HL (Duel et al., 2015).

Health Literacy and Self-Management

The earliest article found was published in 2008 and utilized all three types of HL described by Ishikawa et al. (2009). This cross-sectional study was completed in Japan on a diabetic, outpatient population. The study included 134 participants. The average age of the sample was 65, and 56% of the sample was male. The questionnaires measured HL with the FCCHL tool. Participants also completed the Patient's Perceived Participation measure, a tool that measures self-efficacy. The Patients Perceived Participation measure is a five-item tool that surveys the patient's perception of their physical conditions and symptoms, worries and concerns, preferences for treatment, and asks if they were given the opportunity to ask the questions they wanted. The measure was classified as self-efficacy because of the close relationship between the questions in this measure and the definition, particularly the personal judgment of capability to organize and complete goals. Multiple linear regression was used to evaluate the relationship between the two concepts. The FCCHL tool was divided into subcategories and each was correlated with the Patients Perceived Participation measure. The relationship was not significant; thus, HL was not determined to be related to self-efficacy using the PPP as a measure of self-efficacy.

Lai et al. studied a diabetic population who used an outpatient clinic for chronic care management in China. The study consisted of 63 participants. The average participant age was 57.7, and 38% of the population were male. The tools used in this cross-sectional study include the English version of the FCCHL tool and the Chinese version of the Summary of Diabetes Self-Care Activities (SDSCA). The SDSCA was categorized as self-regulation because it measures the

self-care activities needed to maintain diabetes. The authors evaluated the relationship between HL and self-regulation using Spearman's rho and multiple linear regression. The bivariate and multiple linear regression produced significant positive relationships between communicative and critical HL, but not with functional HL. The R^2, between communicative and critical HL and self-regulation was 0.227 and 0.178 respectively. The multiple linear regression results were congruent with the bivariate analysis with communicative and critical HL and showed a positive and significant relationship to self-regulation, but an insignificant relationship between functional HL. The beta coefficient for communicative HL is 7.344 and the beta coefficient for critical literacy is 6.340. The main limitation for the study that English is a requirement for completing the questionnaires whereas English is not the primary language for the participants.

Another study from China was reported by Leung et al. in 2014. The study was conducted in a diabetic outpatient clinic with a sample of 137 participants who were all over 65 years of age, with equal distribution of gender. Three different components were studied, including HL, self-regulation, and self-efficacy. HL was measured utilizing the 34-item Chinese HL Scale for Diabetes. Self-regulation was measured using a scale developed by the researchers regarding diabetes self-care. The tool included items related to daily tasks and self-care activities required for diabetic maintenance. Self-efficacy was measured using two custom questions that validated participant's perceived capacity to communicate with the health care provider. Both Spearman's rho correlation and structural equation modeling were used to assess the relationship between HL and self-regulation and HL and self-efficacy. It was found that HL had a weak but positive relationship with self-efficacy. Structural equation modeling resulted in a 0.228 and Spearman's rho of 0.240, with only 5% of the variance accounted for. In both

statistical models, HL was not significantly related to self-regulation. The major limitation to this study was the use of custom measurement tools for both self-efficacy and self-regulation.

Heijmans et al. published a cross-sectional study in 2015. The study was completed with a Dutch population including patients who utilized a chronic disease clinician in the Netherlands (Heijamns et al., 2015). The average age was 62 and 55% of the population was female. The three concepts measured include HL, self-regulation, and self-efficacy. HL was measured by the Dutch version of the FCCHL tool. Self-regulation was measured using the Partners in Health scale, and self-efficacy was measured using Perceived Efficacy in Patient-Doctor Interactions scale. Both scales are established measures of self-regulation and self-efficacy in the Dutch population, with Cronbach's alpha of 0.85 and 0.95 respectively. Multiple linear regression was used to measure the relationship between each concept, and results showed a relationship that was statistically significant. The R_{adj}^2 of 0.06 for the total health literacy in the relationship with self-regulation. The authors also determined the variance was low because of the impact functional HL has on the total HL, but failed to separate the three types of HL to determine individual variance on each type of HL on the two self-management variables.

Van der Heide et al., also from the Netherlands, reported on a cross-sectional study completed by 1,508 participants who utilized general practice for their chronic care management. Multiple chronic conditions were included in this study, and the age range was 45-74 years of age. 58% of the participants were female. HL was measured using the FCCHL tool, and self-efficacy and self-regulation was measured using the subscales of the Perceived Control Over Care scale. Spearman's rho correlation and multiple linear regression analysis were used to describe the relationships between the concepts. All of the correlations were positive and significant. Based on the multiple linear regression, the relationships between the three types of HL and self-regulation and self-efficacy were moderate in size and positive. Between 25% and

28% of the variance between both self-efficacy and self-regulation were accounted for when correlated with each of the three types of HL. The strongest correlation was between communicative HL and self-efficacy R_{adj}^2= 0.28 and between communicative HL and self-regulation R_{adj}^2=0.27. Using the full multiple linear regression model and after adjusting for functional and communicative HL, critical HL was not significantly associated with self-regulation or self-efficacy.

Lee et al. studied the relationship between the three types of HL and self-management measured by self-efficacy and self-regulation in a patient sample in South Korea. Based in a diabetes clinic, 459 participants completed questionnaires in this cross-sectional study. The majority of patients were 50-69 years of age and primarily female. The three concepts measured were HL, self-regulation, and self-efficacy. Health literacy was measured by the HL Scale, which is the Korean version of the FCCHL tool. Self-regulation was measured using the Summary of Diabetes Self-Care Activities. Finally, self-efficacy was measured using the Diabetes Management Self-Efficacy scale. The self-regulation and self-efficacy scales were specifically designed for diabetes, whereas the HL scale was more generic to chronic conditions and measured all three types of HL. The structural equation modeling results demonstrated a positive and significant relationship between total HL with both self-regulation and self-efficacy. The reported R^2 was 0.61 for total health literacy and self-regulation and 0.2 for total health literacy and self-efficacy. The authors concluded that HL measured by the HL Scale was directly and positively related to both self-efficacy and self-regulation.

Lee et al. studied the relationship between total HL, self-efficacy, self-regulation, and patient activation in the diabetic population in Taiwan. Two hundred and ninety-five participants were studied; the mean age was 58.2, and 57% of the participants were male. The FCCHL tool was used to measure HL but was never delineated into the individual concepts. The

three other variables include self-regulation measured by Diabetes Self-Care scale, self-efficacy measured by the Self-Efficacy for Diabetes Management scale, and patient activation measured by the Diabetes Empowerment Process scale. This is the only study found for this review to measure all three variables of self-management and all three types of HL. The authors used structural equation modeling and Spearman's rho correlation for the statistical analysis. Total HL was significantly correlated to all three self-management variables. The R^2 for total health literacy was reported as 0.43 and 0.51 for self-regulation and self-efficacy, respectively. Patient perceived empowerment, as measured by the Diabetes Empowerment Process, was used to measure patient activation and accounted for 30% of the variance when correlated with HL. Functional HL was separated from communicative and critical HL and accounted for only 7% of the variance in HL. The authors' separated functional HL from communicative and critical HL and recommends focusing on communicative and critical HL when trying to impact self-efficacy and self-regulation.

Matsuoka and his colleagues (2016) studied a population of 227 heart failure patients who used a cardiovascular medicine clinic in Japan. The mean age was 67.7, and 63% of the participants in this study were males. HL was measured using a heart failure specific version of the FCCHL tool, the Heart Failure-Specific HL Scale. Self-regulation was measured using the European Heart Failure Self-Care Behavior Scale. Both univariate and multiple linear regression were used to measure the association between the two concepts. Functional HL was not significantly correlated with self-regulation and was taken out in the multivariate equation. The adjusted R^2 value from the multiple linear regression model, after adjusting for functional HL, for communicative and critical HL and self-efficacy was 0.23. There is a strong positive and significant correlation between critical HL and self-regulation, with a beta coefficient of 0.154 for critical HL specifically after adjusting for demographics and functional HL.

Another study by Matsuoka (2016) and colleagues looked at 191 participants in a clinic setting in Japan who were receiving care for any number of comorbidities. The mean age of these participants was 66.9, and 65% of the participants were male. HL was measured using the FCCHL tool and was tested for an association with a custom question about perception of motivation. The question about motivation was judged to be closely defined as patient activation and was used as a patient activation measure in this review. Statistically, total HL was related to patient activation using a t-test comparing mean scores. The study showed that functional HL was not significant but both communicative and critical HL were positive and significant. The t-test indicated that participants who reported higher patient activation also had higher communicative and critical HL scores.

The final article reviewed was a cross-sectional study conducted in Taiwan by Wang et al. (2016) where 395 diabetic patients in an outpatient clinic setting were examined. The age ranged from 20-80 years, and 55% were male. The three measured variables include HL, self-regulation, and patient activation. HL was measured using a Chinese version of the FCCHL tool. Self-regulation was measured using the Chinses Diabetes Self-Care scale, and patient activation was measured using the Chinese Diabetes Empowerment Process scale. Bivariate regression was used to analyze the relationships between HL and the self-management concepts at two time points: baseline and one-year. Functional HL was measured separately, and communicative and critical HL were combined into a single measure for analysis. At baseline, functional health literary and combined communicative and critical HL were both positively and significantly correlated to patient activation. The relationship for both was limited with R^2 at 1% for functional HL and 4% for communicative and critical HL in relation to patient activation. Self-regulation and total HL were not measured at baseline. One year later the testing was repeated and at that point, the correlation between both functional HL, combined communicative and

critical HL, and both self-regulation and patient activation were also positive, but weak, with the R^2 accounting for only 7% of variability explained. The authors concluded that patient activation and self-regulation were informed by combined communicative and critical HL, but not by functional HL.

In summary, self-management was measured in three ways: self-efficacy, patient activation, and self-regulation or self-care behaviors. Overall, five articles measured all three types of HL and self-efficacy (Heijmans et al., 2015; Ishikawa et al., 2009; Lee et al., 2016; van der Heide et al., 2015; Lee et al., 2016), three articles measured all three types of HL with patient activation (Lee et al., 2016; Matsuoka et al., 2016; Wang et al., 2016), and eight articles measured all three types of HL and self-regulation (Heijmans et al., 2015; Lai et al., 2013; Lee et al., 2016; Matsuoka et al., 2016; van der Heide et al., 2015; Wang et al., 2016; Lee et al., 2016; Leung et al., 2014). Four of the articles measured more than one component of self-management (Heijmans et al., 2015; Lee et al., 2016; van der Heide et al., 2015; Wang et al., 2016; Le et al., 2016). Only one article measured all three types of HL and all three components of self-management (Wang et al., 2016).

Study Characteristics

Reviewing the study characteristics allowed for contextual and generalizable information to be identified and studied. The articles had several different characteristics worth noting, including design type, population type and number, research setting, country of origin, and concept identification. The population type and number of participants varied, but were all chronically ill adults, and most were middle aged. Sample sizes ranged from 63 to 1,508 participants. The reviewed articles were from five different countries. The countries include the Netherlands, China, South Korea, Taiwan, and Japan. Each article included various tools available in specific languages. The variation of the tools used were not always available in the

primary language of the participants, causing limitations. The country of origin is important, as this will change both HL and self-management. The differences in each country that may influence HL or self-management include healthcare type, government type, economic factors, and standard of living. The country of origin also changes the definition and context of HL such as beliefs and culture.

Discussion and Conclusion

This integrative review has several key findings. First, it supports a positive association between communicative and critical HL and the three core components of self-management. However, this knowledge is not robust. A key weakness in these studies is that all types of both HL and self-management are seldom measured and compared in the same study. Second, none of the studies reviewed identified health outcomes related to either HL or self-management. The significance of this is that health outcomes cannot be assumed without research on the direct relationships between the concepts and actual health outcomes. This is complicated in the US, where virtually all HL research only measures functional HL, but these studies do establish a strong correlation between functional HL and health outcomes. The impact the expanded definition of HL has on actual health outcomes is unknown.

Self-management is foundational to successfully combating the costly, extensive, and complex issues associated with chronic disease management. HL appears to be a key concept that influences self-management behaviors and outcomes by supporting the obtainment, understanding, and application of health information (CDC, 2017; Batterham et al., 2016; Moore et al., 2016). A consistent measurement of the three types of HL and self-management has not been studied, thus there has not been enough statistical data to suggest a standard of measuring either concept. There is opportunity to utilize the three types of HL into the US and

explore the relationships between the three types of HL, self-management, and health outcomes in the US system.

Recommendations

The first recommendation based on this review is to utilize a tool that includes all three types of HL (Yeom et al., 2011). It is essential to understand the influence of each component of HL on health outcomes, especially given the fact that communicative and critical HL appear to be even stronger predicators of self-management and are more easily modifiable, while functional HL is typically limited by the individual's completed education level.

The second recommendation is to study HL in the context of both self-management and health outcomes to determine if HL is a pre-cursor to self-management or an independent factor influencing health outcomes. This conclusion supports the need for a better tool, such as the kind of tools found in other countries, that will measure all three types of HL in the US (Duell et al., 2015).

The FCCHL is used internationally in a wide variety of populations and among individuals with numerous disease processes. There is variability in the recruitment process, age range, race, education level, and socioeconomic status. This variability limits the generalizability of the FCCHL tool, which is necessary to combat the shortcomings of the current US tools. Duell et al. (2015) suggested using the Newest Vital Sign until a new, more encompassing tool is developed and validated in the US. Additionally, researchers indicate evidence to conclude both communicative and critical HL as measured by the FCCHL tool are modifiable risk factors (Wang et al., 2016).

The recommended common data element measurements for self-management includes the Patient Activation Measure (Hibbard et al., 2004), the Index of Self-Regulation (Yeom et al., 2011), and the Self-efficacy for Managing Chronic Disease (Lorig et al., 2001). These three scales

were not utilized in any of the studies reviewed; however, this did not limit the conclusions made by each study with regard to the three types of HL and self-management.

Strengths and Limitations

The use of an integrative review provides a comprehensive search of the existing literature about the relationship between HL and self-management. The articles included statistical information, but not all conclusions were appropriate based on the provided statistics. The studies in this review did have adequate sample sizes for power analysis but lacked consistency in terms of characteristics. Most of the studies excluded patients who were cognitively impaired or had limited language proficiency, which limits the true understanding of all three types of HL. Further studies can include caregivers to determine the effect of the three types of HL on patients who are cognitively impaired or have limited language proficiency. A limitation of this integrative review is the generalization of the various studies, as all were cross-sectional studies. All the studies were conducted internationally and therefore may not be applicable to the US population.

Conclusion

Studies of the relationship between the three types of HL and self-management are varied and small in number. However, what studies do exist consistently have a limited statistically significant and positive relationship between the two concepts. This integrative review documents the need for continued study of HL, particularly a comprehensive approach. There is a need to further investigate the relationship between the three types of HL and self-management. Further, the three types of HL need to be studied in the US and in additional settings such as minority population and low socioeconomic populations to broaden the field of research on chronic disease.

Practice Implications

The findings of this study support the need to further evaluate the relationship between HL and self-management with the goal of impacting health outcomes. Although the relationship was not consistently reported, most studies showed an association between HL and self-management, but the strength of the relationship has yet to be established. Despite the efforts to increase self-management, there are barriers and insufficient interventions. HL may be a barrier to self-management, and interventions to increase HL might assist the patient. HL is applicable in every healthcare setting, which increases the need to understand the concept and its relationship with self-management. The trend to use the FCCHL tool internationally due to its pragmatic qualities and measurement of all three types of health literacy supports the need to validate it in the US. The availability of a tool such as the FCCHL would allow the provider resources to more accurately understand the patient's total health literacy and modify their communication and delivery of care accordingly and therefore increase the likelihood of improving self-management abilities of the patient.

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Figure 1. Identification of relevant articles

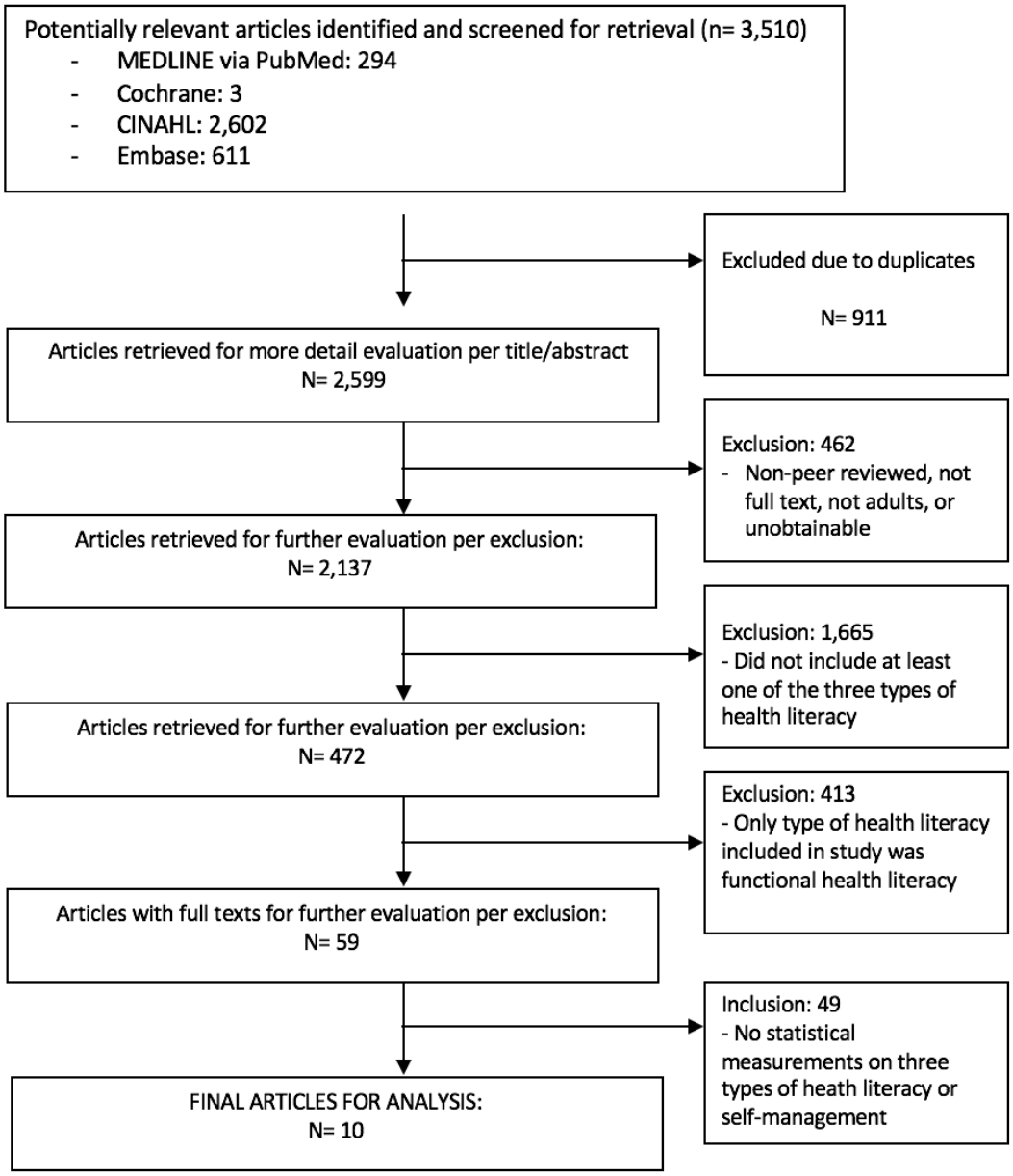

Table 1. Summary table.

Author, Year	Location	Correlations	HL Measure	SE Measure	PA Measure	SR Measure
Heijmans et al., 2015	Netherlands	HL w/ SR and SE	FCCHL – Dutch	Perceived Efficacy		Partners HC
Ishikawa et al., 2009	Japan	HL w/ SE	FCCHL – Japanese	Perceived Participation		
Lai et al., 2013	China	HL w/ SR	FCCHL			Self-Care DM
Lee et al., 2016	S. Korea	HL w/ SR and SE	FCCHL – Korean	DM SE Scale		Self-Care DM
Lee et al., 2016	Taiwan	HL w/ SR and SE	FCCHL	DM SE Scale	Empowerment	Self-Care DM
Leung et al., 2014	China	HL w/ SR	Chinese HL in DM			Capacity
Matsuoka et al., 2016	Japan	HL w/ PA	FCCHL		Motivation	
Matsuoka et al., 2016	Japan	HL w/ SR	FCCHL			EHFScBC
Van der Heide et al., 2015	Netherlands	HL w/ PA and SR	FCCHL	Organize Care		Self-Care
Wang et al., 2016	Taiwan	HL w/ SR and PA	FCCHL		Empowerment	Self-Care DM

FCCHL = Functional, Communicative, and Critical HL, SE = Self-efficacy, PA = Patient Activation, SR = Self-regulation, HL = HL, DM = diabetes, EHFScBC = European Heart Failure Self-Care Behavior Scale

Table 2. Full Evidence Table with Extended Information.

Article	Location Study Type	Sample	HL & SM Tools	Statistics Results	Conclusion Limitations	SE	PA	SR
Heijmans, et al. (2015)	Netherlands Cross-sectional	N =1,341 Disease = multiple chronic conditions Setting = clinic Age = mean 62 Sex= Male= 45%	HL: FCCHL-Dutch *Subscales:* Functional (FHL) Communicative (CoHL) Critical (CrHL) Overall (THL) SM: Partners in Health scale SE: Perceived Efficacy in Patient-Doctor Interactions	Statistics: multiple linear regression Results: FHL with SM = β=0.09 (p<.01) CoHL with SM = β=0.28 (p<0.001) CrHL with SM = β=0.10 (p<0.01) R_{adj}^2 = 0.20 (p<0.001) FHL with SE = β=0.11 (<.001) CoHL with SE= β=0.18 (<.001) CrHL with SE = β=0.09 (<.05) R_{adj}^2 = 0.13 (p<0.001)	Conclusion: one of two which looks at more than diabetic population, moderate evidence presented Limitations: evidence of relationship is significant but not strong enough variance	x		x
Ishikawa et al., (2009)	Japan Cross-sectional	N = 134 Disease = diabetes Setting = outpatient IM Age= mean 65 Sex= Male = 56%	Cross-sectional questionnaires HL: FCCHL – Japanese *Subscales:* Functional (FHL) Communicative (CoHL) Critical (CrHL) Overall (THL) SE: Patient's Perceived Participation Measure (PPPM)	Statistics: multiple linear regression Results: FHL with SE =β= -0.04 (p=0.934) CoHL with SE= β=1.63 (p=0.078) CrHL with SE = β= -0.42 (p=0.596) R^2 not given	Conclusions: Evidence shows no relationship between HL and SE Limitation: SE tool is a poor or limited tool that may not measure intended variable	x		

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Heijmans, et al. (2015)	Netherlands Cross-sectional	N =1,341 Disease = multiple chronic conditions Setting = clinic Age = mean 62 Sex= Male= 45%	HL: FCCHL-Dutch *Subscales:* Functional (FHL) Communicative (CoHL) Critical (CrHL) Overall (THL) SM: Partners in Health scale SE: Perceived Efficacy in Patient-Doctor Interactions	Statistics: multiple linear regression Results: FHL with SM = β=0.09 (p<.01) CoHL with SM = β=0.28 (p<0.001) CrHL with SM = β=0.10 (p<0.01) R_{adj}^2 = 0.20 (p<0.001) FHL with SE = β=0.11 (<.001) CoHL with SE= β=0.18 (<.001) CrHL with SE = β=0.09 (<.05) R_{adj}^2 = 0.13 (p<0.001)	Conclusion: one of two which looks at more than diabetic population, moderate evidence presented Limitations: evidence of relationship is significant but not strong enough variance	x		x
Ishikawa et al., (2009)	Japan Cross-sectional	N = 134 Disease = diabetes Setting = outpatient IM Age= mean 65 Sex= Male = 56%	Cross-sectional questionnaires HL: FCCHL – Japanese *Subscales:* Functional (FHL) Communicative (CoHL) Critical (CrHL) Overall (THL) SE: Patient's Perceived Participation Measure (PPPM)	Statistics: multiple linear regression Results: FHL with SE =β= -0.04 (p=0.934) CoHL with SE= β=1.63 (p=0.078) CrHL with SE = β= -0.42 (p=0.596) R^2 not given	Conclusions: Evidence shows no relationship between HL and SE Limitation: SE tool is a poor or limited tool that may not measure intended variable	x		

Article	Location Study Type	Sample	HL & SM Tools	Statistics Results	Conclusion Limitations	SE	PA	SR
Lai, et al. (2013)	Singapore, China Cross-sectional	N = 63 Disease = Diabetes Setting = clinic Age = mean 57.7 Sex= male 38%	Cross-sectional questionnaires HL: FCCHL - English *Subscales:* Functional (FHL) Communicative (CoHL) Critical (CrHL) Overall (THL) SR: Summary of Diabetes Self-Care Activities	Statistics: Pearson's r for bivariate and multiple linear regression Results: *Bivariate relationships*: FHL with SR is r = 0.06 (p=.626) R^2=0.103 CoHL with SR is r =0.40 (p=.001) R^2=0.227 CrHL with SR is r =0.32 (p=.011) R^2=0.178 THL with SR is r =.35 (p=.005) R^2=0.123 *Multiple linear regression*: FHL with SR is β=-0.289 s.e.= 2.251 (p=0.898) R_{adj}^2 =0.103 CoHL with SR is β=7.344 s.e.= 2.520 (p=0.005) R_{adj}^2 = 0.227 CrHL with SR is β=6.340 s.e.= 2.871 (p=0.032) R_{adj}^2 = 0.178	Conclusions: Regression analysis shows positive association between communicative and critical HL and SR whereas no significant association with functional HL and SR Limitations: English was an inclusion criteria			x
Lee, et al. (2016)	South Korea Cross-sectional	N = 459 Disease = diabetes Setting = clinics Age = 20+ majority 50-69 Sex= M:183 F:276	HL: HLS (FCCHL similar) SR: Summary of diabetes Self-Care Activities SE: Diabetes Management Self-Efficacy Scale	Statistics: structural equation modeling Results: HL with SR = β=0.209 (p<0.01) R^2=0.61 HL with SE = β=0.450 (p<0.01) R^2=0.20	Conclusion: HL directly related to SR and SE. Limitations: tool may not be specific to other conditions and therefore not generalized to all chronic conditions	X		X

Article	Location Study Type	Sample	HL & SM Tools	Statistics Results	Conclusion Limitations	SE	PA	SR
Lee, et al. (2016)	Taiwan Cross-sectional	N = 295 Disease = diabetes Setting = clinic Age = mean 58.2 Sex= M:169 F: 126	HL: FCCHL SR: Diabetes self-care scale SE: Self-efficacy for Diabetes Management Scale PA: Diabetes empowerment process scale	Statistics: bivariate correlation and SEM Results: HL with SE = r=0.26 (p<.001) R^2=0.51 HL with SR = r=0.15 (p<.001) R^2=0.43 HL with PA = r=0.26 (p<.001) R^2=0.30	Conclusion: Supportive correlations for total HL and all three components of SM Limitations: HL not separated into three components and only reported as total HL	X	X	X
Leung, et al. (2014)	China Cross-sectional	N = 137 Disease = diabetes Setting = clinic Age = 65 through >85 Sex= F: 68 M: 69	HL: 34-item Chinese HL Scale for Diabetes SR: Likert 4 item self-care custom scale SE: 2 item custom scale	Statistics: structural equation modeling and Pearson's r Results: *SEM:* HL with SE= .228 (<.001) HL with SR = .078 (not significant) *Pearson's r:* HL with SE = r=0.240 (p<0.01) HL with SR = not related, insignificant	Conclusion: Statistics completed to show relationship with HL and SE Limitations: custom and untested scales/question to measure concepts cannot conclude measuring indicated concepts i.e. SR and SE	X		X

Article	Location Study Type	Sample	HL & SM Tools	Statistics Results	Conclusion Limitations	SE	PA	SR
Matsuoka, Kato, et al. (2016)	Japan Cross-sectional	N = 191 Disease = Comorbidity Setting = clinic Age = mean 66.9 Sex= M: 65%	HL: FCCHL - English *Subscales:* Functional (FHL) Communicative (CoHL) Critical (CrHL) Overall (THL) PA: motivation questions custom to this study	Statistics: T-tests for mean relationship Results: *Yes to motivation:* THL with PA = mean 34.45 SD= 4.82 (p<.01) FHL with PA = mean 12.2 SD= 2.57 (p=0.72) CoHL with PA = mean 12.65 SD= 2.22 (p<.01) CrHL with PA = mean 9.60 SD=2.59 (p<.01) No to motivation: THL with PA = mean 28.30 SD= 5.02 (p<.01) FHL with PA = mean 12.03 SD= 2.92 (p=0.72) CoHL with PA = mean 10.00 SD= 3.28 (p<.01) CrHL with PA = mean 6.27 SD=1.56 (p<.01)	Conclusion: Higher CoHL and CrHL scores reported higher motivation Limitations: mean scores reported but did not measure correlational values limiting study and PA questions were custom to this study limiting measurement of this concept		X	
Matsuoka, Tsuchihashi-Makaya, et al. (2016)	Japan Cross-sectional	N= 227 Disease= health failure Setting = cardiovascular medicine Age = mean 67.7 Sex = male 63%	HL: Heart Failure-Specific HL Scale (HF-HL) *Subscales:* Functional (FHL) Communicative (CoHL) Critical (CrHL) Overall (THL) SR: European Heart Failure Self-Care Behavior Scale (EHFScBS)	Statistics: univariate and multivariate multiple regression Results: *Univariate:* FHL with SR = B = -0.275 s.e. = 0.238 (p =0.249) CoHL with SR = B = -0.837 s.e.= 0.236 (p<0.01) CrHL with SR = B = -0.631 s.e.=0.229 (p<0.01) *Multivariate:* CoHL with SR = B = -0.069 s.e.=0.262 (p=0.337) CrHL with SR = B = -0.154 s.e.=0.242 (p=0.027) R^2= 0.264 and R_{adj}^2= 0.230	Conclusion: HL correlated with self-care behaviors. FHL not statistically significant Limitations: Reversal of tool therefore negative numbers are actually positive based on definition			X

Article	Location Study Type	Sample	HL & SM Tools	Statistics Results	Conclusion Limitations	SE	PA	SR
Van der Heide et al., (2015)	Netherlands Cross-sectional	N = 1,508 Disease= multiple chronic conditions Setting = GP Age=45-74 was 70% Sex= Female 58%	HL: FCCHL *Subscales:* Functional (FHL) Communicative (CoHL) Critical (CrHL) Overall (THL) SR: preform self-care SE: organize care	Statistics: multiple regression, linear regression modeling, and factor analysis Results: *Correlation via Pearson's r* (all p<.0001) FHL with SE = r = 0.33 R^2=0.1089 FHL with SR = r = 0.27 R^2= 0.07 CoHL with SE = r = 0.45 R^2= 0.2025 CoHL with SR = r = 0.35 R^2= 0.1225 CrHL with SE = r = 0.34 R^2= 0.1156 CrHL with SR = r = 0.27 R^2= 0.0729 *Multiple linear regression* (all p<0.05) FHL with SR = B = 0.17 R_{adj}^2= 0.25 CoHL with SR = B = 0.29 R_{adj}^2= 0.28 CrHL with SR = B = 0.17 R_{adj}^2= 0.26 FHL with SM = B = 0.12 R_{adj}^2= 0.25 CoHL with SM = B = 0.17 R_{adj}^2= 0.27 CrHL with SM = B = 0.11 R_{adj}^2= 0.26	Conclusion: HL related to patient's control over health care and specifically Communicative HL seems relevant as a possible determinant of the extent of which patients are able to exert control over care Limitations: Limitations of SR and SE scale as subsections of a full scale	X		X
Wang, et al. (2016)	Taiwan Cross-sectional	N = 395 Disease = diabetes Setting = outpt clinics Age = 20-80 Sex= M:216 F:179	HL: Chinese FCCHL *Subscales:* Functional HL= FHL Communicative and Critical HL = CCHL SM: Chinese Diabetes Self-Care Scale PA: Chinese Diabetes empowerment process scale	Statistics: bivariate regression Results: Baseline: FHL with PA = r=0.10 (<.05) R^2=0.01 CCHL with PA = r=0.20 (<.001) R^2=0.04 1-year later: FHL with PA = r=0.26 (<.001) R^2=0.068 FHL with SM = r=0.09 (not significant) CCHL with PA = r=0.18 (<.001) R^2=0.032 CCHL with SM = r=0.17 (<.001) R^2=0.029	Conclusion: weak, positive R^2 accounting for some of the variability Limitations: did not measure SM at baseline and did not separate communicative and critical concepts		X	X

CHAPTER III: Manuscript 2

Patient Education and Counseling, (to be submitted)

The Psychometric Testing of the Functional, Communicative, and Critical Health Literacy Tool

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Introduction

The definition of health literacy has transformed over time. Although there are many definitions, a patient's knowledge of health information, their communication skills, and their involvement in decision making are essential to capturing the essence of this social construct (Sorensen & Pleasant, 2017). The Institute of Medicine defines health literacy as "an individual's capacity to obtain, process and understand basic health information and services needed to make appropriate health decisions" (IOM, 2014).

Nutbeam has introduced a widely accepted theoretical model that delineates three separate and interconnected types of health literacy: functional, communicative, and critical (2000). Functional health literacy is based on having the basic skills of literacy and numeracy necessary to function in everyday situations. Communicative health literacy or interactive health literacy requires the cognitive and literacy skills to navigate different forms of communication that allow an individual to extract and derive meaning from information. Critical health literacy is a more advanced skill that combines social skills and critical analysis of information and uses this combination to exert control of life events and situations (Nutbeam, 2000). Despite Nutbeam and the IOM definition of health literacy, in the United States (US) health literacy has been measured almost exclusively as functional. For clarity, health literacy in this paper refers to total health literacy including all three sub-concepts of functional, communicative, and critical health literacy unless otherwise noted by indicating specifically which type of health literacy.

In the US, using functional measures of health literacy, low health literacy has been shown to be directly and indirectly associated with poor health outcomes, poorer quality of life, and higher rates for hospitalizations and emergency room visits (Hawkins, Kantayya, & Sharkey-Asner, 2010; Batterham, Hawkins, Collins, Buchbinder, & Osborne, 2016). Low functional health literacy limits the ability of patients to be actively engaged in their care, diminishing their ability

to self-regulate and to feel confident in managing their health (Batterham et al., 2016; Haun et al., 2015). CDC estimated that one in five Americans have inadequate health literacy to make necessary health care decisions and over 60% of Americans have low health literacy levels when measured using functional health literacy screening tools. Additionally, low functional health literacy is associated with higher heath care cost; some estimate that the cost associated with low functional health literacy at the national level is as much as $73 billion annually (Batterham et al., 2016; Haun et al. 2015; Hawkins et al., 2010). Even though it is clear that low functional health literacy has a significant negative impact on health, the only intervention available to address low functional health literacy is to lower the literacy level of health communication. Yet, both Nutbeam and the IOM would suggest that there are other factors, specifically communication and critical thinking, that are components of health literacy, are potentially modifiable, and may have a positive impact on health outcomes.

As previously shown, in the US, the traditional method of measuring health literacy is using objective measures focusing on functional health literacy. Complementary to objective measures are subjective measures that allow for self-assessment of health literacy levels. A self-assessment can provide insight into a patient's perceived ability to communicate and use health information (van der Vaart et al., 2012). However, there is little data on health literacy self-assessments or the relationship between self-assessment of a patient's ability to communicate and use health information and patient's health outcomes.

One self-assessment health literacy tool that incorporates and measures all three types of health literacy is the Functional, Communicative and Critical Health Literacy (FCCHL) tool (Ishikawa, 2008). The FCCHL is a 14-item tool first used in Japan with a diabetic population and demonstrates internal scale reliability for each of the three sub-scales (α = 0.84, 0.77, 0.65). van der Vaart and colleagues have since used this instrument in the Netherlands, and after

adaptation and translation to English and Dutch, the instrument demonstrates internal scale reliability with two separate studies. The first study reported α = 0.87, 0.87, 0.78 and the second study had α = 0.83, 0.94, and 0.80 for each of the subscales (van der Vaart et al., 2012). The results from the van der Vaart et al. studies demonstrate evidence of validity and reliability of the FCCHL and support its use in other populations. An adaptation of the FCCHL was completed and modification was made including adjustment to the needs of the US subjects, such as use of plain language and reducing the materials to an appropriate grade level. The FCCHL was culturally adapted to the US and a manuscript in currently under development. The current study will address an aim from a larger study as a necessary initial step in studying the relationship between the three types of health literacy and health outcomes. The purpose of the present study is to assess the validity and reliability of the US version of the FCCHL tool in a Midwestern socioeconomically vulnerable or unstable adult population.

Methods

This is a cross-sectional study measuring both validity and reliability in a vulnerable Midwestern adult population. Construct, concurrent, and criterion validity were calculated in relation to education level and two commonly used health literacy instruments. Additionally, internal and external reliability were calculated to evaluate the reliability of the FCCHL tool.

Subjects & Setting

A convenience sample was selected from an urban Federally Qualified Health Center (FQHC), a rural health clinic, and an urban workplace clinic supporting under-insured employees. Participation eligibility included being a patient at one of these clinics and having more than one chronic condition. Data collection was completed at the participant's respective clinic for convenience and accessibility. Subjects were asked to complete a demographic survey, FCCHL tool, Newest Vital Sign (NVS), and short-Test of Functional Health Literacy in Adults (s-TOFHLA).

Additional surveys were collected for the purpose of the larger study and were not included for the current study.

Procedure

Study data was collected and managed using Research Electronic Data Capture (REDCap) an electronic data capture tool hosted at University of Nebraska Medical Center. REDCap is a secure, web-based application designed to support data capture for research studies, providing 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources. Subjects were able to request a paper copy of the survey, and those who identified as illiterate were given assistance with the surveys.

Recruitment was done via flyers and referrals. Referrals were made by clinicians. The referred participants were contact for enrollment and consent was competed. In total, 276 subjects were recruited, provided informed consent, and completed the required testing. All subjects were asked to complete the FCCHL tool a second time after two weeks for test-retest purposes; subjects could return to the clinic or complete the tool via email. In total, 38 subjects retested an average of 2.9 weeks with the range of 2 to 4.6 weeks after the initial completion of the survey. The retest subjects were recruited by self-selection.

Instruments

The questionnaires included demographic information, FCCHL, NVS, and s-TOFHLA. The demographic information included age, gender, zip code, education level, marital status, ethnicity, race, employment status and job type, and household income. The FCCHL tool was previously translated to English but the English version had not been acculturated in the US. Therefore, the FCCHL was modified in the present study to include appropriate verbiage to

ensure understanding for English speakers in the United States. The English versions of the NVS and the s-TOFHLA were administered in accordance with the instructions provided by the respective tools. The NVS and s-TOFHLA were included in the study as they are the current standard for assessing health literacy in the US and, therefore, provided criterion validity. The NVS is a six-question objective measurement using a food label to test literacy and numeracy skills. The s-TOFHLA is a 34-item objective tool where words are missing from health-related passages and participants are instructed to choose the best word, from a list of four, to complete the sentences.

Scoring for the FCCHL tool, NVS, and S-TOFHLA was completed per instrument instructions and scores were recorded to represent low to high health literacy. FCCHL tool results range from 1-4 with 1 denoting high health literacy and 4 low health literacy. NVS is composed of six questions with 1 point given for each correct answer. Total points are added for a range of 0-6. Level one is denoted by 0-1 and suggests likelihood of limited literacy, level two is 2-3 points and indicates possibility of limited health literacy, and level three is 4-6 correct answers represents almost always adequate health literacy (Hubbard, 2011). The s-TOFHLA was scored per instructions (Baker, 1999). Correct answers were added for a maximum score of 36. Level one is inadequate functional health literacy with a score of 0-16 described as the inability to read and interpret health text. Level two is marginal functional health literacy with a score of 17-22 representing difficulty reading and interpreting health text. Level three is adequate functional health literacy score 23-36 interpreted as a participant's ability to read and interpret most health test (Baker, 1999).

Data Analysis

Data analysis was completed using the version 25 SPSS statistical software package. Construct validity was measured using confirmatory factor analysis (CFA). Concurrent validity

was measured using Spearman's rho correlations. Criterion validity was measured using contrasting groups, and ANOVA was used to determine any significant difference between the groups' scores. Internal reliability was measured using Cronbach's alpha coefficient. Finally, external reliability was measured using test-retest or intraclass correlation coefficient. A power analysis was conducted using G*Power 3.1.9.2 and it was determined that 269 participants were needed (Buchner, Erdfelder, & Faul, 1997). A total of 275 was collected to offset attrition and assure completion of data analysis.

Results

Subjects

Participant characteristics retrieved from the demographics instrument and health literacy as measured by the FCCHL, NVS, and s-TOFHLA are shown in Table 1. Education was delineated into four separate categories. Very low education included those who selected elementary or some high school but no diploma or GED. Low education included those with a high school diploma or GED. Middle education included some college but no degree and two-year degrees. Finally, high education included those with a four-year degree and over. A total of 276 participants were recruited by only 262 completed all of the tools. A total of eight participants skipped one or more of the 14 questions in the FCCHL tool and were excluded from the calculations. One participant was removed as they only completed half of the tools in the study. Three participants were removed as they skipped one or more of the NVS questions and two participants were removed as they skipped one or more of the s-TOFHLA items.

Internal Reliability

For internal consistency of the FCCHL, Cronbach's alpha >0.70 was set to be acceptable for this analysis. Cronbach's alpha was 0.84, 0.79, and 0.89 for functional, communicative, and critical health literacy subscales respectively. Total tool had a Cronbach's alpha of $\alpha = 0.87$.

External Reliability

External reliability was measured and completed via test-retest methodology. A total of 38 participants were retested on the FCCHL tool on an average of 2.9 weeks with a range of 2 to 4.6 weeks after initial testing. The intraclass correlation coefficient was calculated and the results can be seen in Table 2. The coefficient is preferred over 0.7 for good correlation, over 0.8 for optimal and over 0.9 for excellent correlation. Both functional and critical subscales scored above 0.7 but communicative and total scores were 0.61 and 0.67 respectively indicating fair but not good stability.

Construct Validity

Construct validity was measured using Confirmatory Factor Analysis (CFA). CFA showed good fit for a three-factor model of the three health literacy sub-scales and the summary can be seen in Table 3. Standardized factor loadings of the three subcategories were 0.29 functional and critical, 0.35 for functional and communicative and 0.68 for communicative and critical. The loading was appropriate and positive for each of the variables in the subcategories (Fig. 1 & 2). The pattern matrix is below in Table 4 with a Bartlett's value of 0.00 and Kaiser-Meyer-Olkin Test (KMO) of 0.860, displaying significance and loading appropriately as KMO over 0.50 is appropriate and showing clustering of the tools as they were designated.

Criterion Validity

Criterion validity was measured by comparing the mean scores of the sub-scales as well as overall health literacy using the FCCHL tool. The comparison was completed by four education groups including very low, low, middle, high. The results of comparison of means and differences of the FCCHL tool and education level compared to the NVS and s-TOFHLA can be seen in Table 5 and 6. Based on the results, criterion validity was met.

Concurrent Validity

Concurrent validity was measured using Spearman's rho with a reported matrix shown below in Table 7. Correlations were completed on the FCCHL three sub-scales and total health literacy with the NVS total score and level, s-TOFHLA total score and level, and education level. Results indicate that FCCHL's functional health literacy subscale, total health literacy, NVS results and level, s-TOFHLA results and level, and education were all significant correlated in varying degrees. Communicative health literacy was significant but with very low correlation and critical health literacy was not significantly correlated with any factors other than the other sub-scales and overall FCCHL tool.

Discussion and Conclusion

The need for improved understanding of health literacy is critical. Current models in the US provide objective measures specific for literacy and numeracy. A need for improved understanding of the advancing and widely accepted model by Nutbeam (2000) can be measured using the tool originally created by Ishikawa et al. 2008 and modified by van der Vaart et al, 2012. As mentioned, there are multiple tools that measure health literacy and it is important to measure all three concepts.

Reliability

The internal consistency and external reliability of the FCCHL were measured. Internal consistency was measured using Cronbach's alpha and resulted in values over 0.80 for all three sub-scales and the overall tool. This result is consistent with previous testing in other countries and shows good internal consistency.

The external reliability was tested using test-retest by way of intraclass correlation coefficient. Functional and critical health literacy scales were good as they were over 0.70 but communicative and total FCCHL scales were fair as they were approaching 0.70. The limitations

associated with the retesting include the limited number of participants who were retested. Overall, fair but acceptable stability was demonstrated for the FCCHL tool in this population.

Validity

The three types of validity measured include construct, criterion, and concurrent validity. The results from construct validity demonstrate good fit with statistical significance. The CFA model showed a few items loaded less including the first item of the functional sub-scale. The first item of the scale asks if reading a label is difficult due to size of font. This question does not fit the concept but is an important piece as accommodations can be made to reduce unnecessary disability. The overall CFA and pattern fit shows that each of the sub-scales have proper loading and grouping of items. This also shows that each sub-scale measures different concepts. This is important as the communicative and critical sub-scales were attempting to measure more than just functional health literacy.

Criterion validity was measured by comparing subscale and total means by education groups. There was a normal distribution of education levels and the literacy levels based on the functional health literacy tools showed that education and literacy were consistent. The results demonstrate that the objective measurements, NVS and s-TOFHLA, were able to align with the education levels and demonstrate literacy. The FCCHL, a self-assessment, reported an increase in ability to communicate suggesting an accommodation for lack of literacy. Groups did not differ for communicative and critical sub-scales. This is an important finding as literacy cannot be changed but communication and application of health information into decision making can be modified. This also demonstrates that the three sub-scales measure different concepts. Therefore, when compared across education groups, the tools testing literacy and numeracy were significantly different, and the communicative and critical health literacy subscales were not significantly different. These results support the need for a tool beyond education and

functional health literacy and need to include the communicative and critical health literacy subscales.

Concurrent validity was measured using Spearman's rho correlations. The low and absent correlation of the communicative and critical health literacy subscales with the other tools suggests that they are measuring different concepts. The correlations also suggest that the s-TOFHLA is closely correlated with education level. The NVS correlations also suggest that numeracy and not critical heath literacy is being measured. The low and absent correlation of the communicative and critical health literacy subscales with the other tools suggests that they are measuring different concepts. The correlations also suggest that the s-TOFHLA is closely correlated with education level. The NVS correlations also suggest that numeracy and not critical heath literacy is being measured.

The results demonstrated that the FCCHL tools is measuring three different concepts. The FCCHL total score is related to the NVS and s-TOFHLA but the subscales measure different concepts. This would be predicted as the FCCHL is predicated to look at the concepts of communication and critical thinking as well as functional ability. Overall, the FCCHL tool was seen to have good validity and reliability in the identified population.

The intention of this study was to add to the field of health literacy in the US. The population was specifically selected because the socioeconomically vulnerable or unstable are at increased risk for poor outcomes based on their socioeconomic status. The comparison of the tools provides sufficient evidence for the need for both objective and subjective measurements, expanding past basic literacy and numeracy skill assessment. The tools objectively measuring literacy and numeracy are sensitive but not specific. Most of the population, which is literate, can still have difficulties in navigating the healthcare system and making decisions related to their own health, but this will be missed when using the tools only addressing functional health

literacy. Work completed internationally has supported the FCCHL tool as measurement of all three subscales of health literacy (van der Vaart et al., 2012 & Heijimens et al., 2015). The subjects were equally distributed into educational categories creating an opportunity to evaluate the FCCHL tool in the very low, low, middle, and high education levels.

Limitations of this study include the generalizability of the results and limitations of testing validity and reliability. The population included in this study was limited to Midwestern urban and rural communities. Additionally, the population was primarily Caucasian and limited to English only. Finally, additional validity and reliability tests and rest-testing are recommended for further evaluation with other US populations.

The practical implications of this tool are based on the ease of use including the limited amount of time it takes to complete the tool and the tool can be completed independently without proctoring. The scoring of the FCCHL tool allows clinicians to address certain areas and focus interventions on the areas which are identified by the patient. Additionally, this tool provides a self-assessment on items beyond functional health literacy which can be closely associated with education level.

In conclusion, the advancement of the study of health literacy as a factor influencing health requires additional study and an expansion of the measures used. This study demonstrates the appropriateness of the FCCHL as a tool designed to measure health literacy broadly. With established psychometric properties, the tool can be used to explore both the relationship between the sub-concepts and health. Next steps include exploring the relationship of functional, communicative, and critical health literacy, as measured by the FCCHL tool, with self-management. Finally, future refining of the FCCHL tool and translation and acculturation into Spanish for a Midwestern Hispanic group would be useful for practice.

Note

Study data were collected and managed using REDCap electronic data capture tools hosted at University of Nebraska Medical Center (UNMC). REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies. REDCap at UNMC is supported by Research IT Office funded by Vice Chancellor for Research (VCR) and receives partial support from the Great Plains IDeA-CTR grant. This publication's contents are the sole responsibility of the authors and do not necessarily represent the official views of the VCR and NIH.

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Table 1

Participant characteristics and Health Literacy scores, n=262

Gender, n (%)	
Female	143 (54.6)
Male	119 (45.4)
Age, mean (S.D.)	51.1 (14.6)
Education, n (%)	
Very Low – below high school	31 (11.8)
Low – GED or diploma	85 (32.4)
Middle – some college to 2-year degree	89 (34)
High – 4-year degree and over	53 (20.2)
Unknown/None of the Above	4 (1.5)
Income, mean (S.D.)	6.2 (4.2)
Below Poverty Line	74 (28.2)
100%-200% Poverty Line	51 (19.5)
200%-400% Poverty Line	58 (22.1)
Over 400% Poverty Line	75 (28.6)
Functional HL, mean (S.D.)[a]	3.2 (0.6)
Communicative HL, mean (S.D.)[a]	3.0 (0.6)
Critical HL, mean (S.D.)[a]	3.0 (0.7)
Total HL, mean (S.D.)[a]	3.1 (0.5)
NVS Levels, mean (S.D.)[b]	2.2 (0.9)
NVS Level 1, n(%)	74 (28.2)
NVS Level 2, n(%)	62 (23.7)
NVS Level 3, n(%)	126 (48.1)
NVS Total, mean (S.D.)[c]	3.1 (2.1)
s-TOFHLA Levels, mean (S.D.)[b]	2.9 (0.4)
s-TOFHLA Level 1, n(%)	8 (3.1)
s-TOFHLA Level 2, n(%)	13 (5)
s-TOFHLA Level 3, n(%)	241 (92)
s-TOFHLA, mean (S.D.)[d]	32.3 (5.5)

a= Range 1-4, b=Range 1-3, c=Range 1-6, d=Range 1-36

HL = health literacy, NVS = Newest Vital Sign, s-TOFHLA = short Test of Functional Health Literacy in Adults

Table 2. Intraclass Correlational Coefficient of the FCCHL tool (n=38)

	Correlational Coefficient	CI	Significance
Functional	0.72	0.46, 0.86	0.000
Communicative	0.61	0.25, 0.8	0.003
Critical	0.70	0.4, 0.84	0.000
Total Score	0.67	0.33, 0.82	0.001

Figure 1. Standardized Confirmatory Factor Analysis

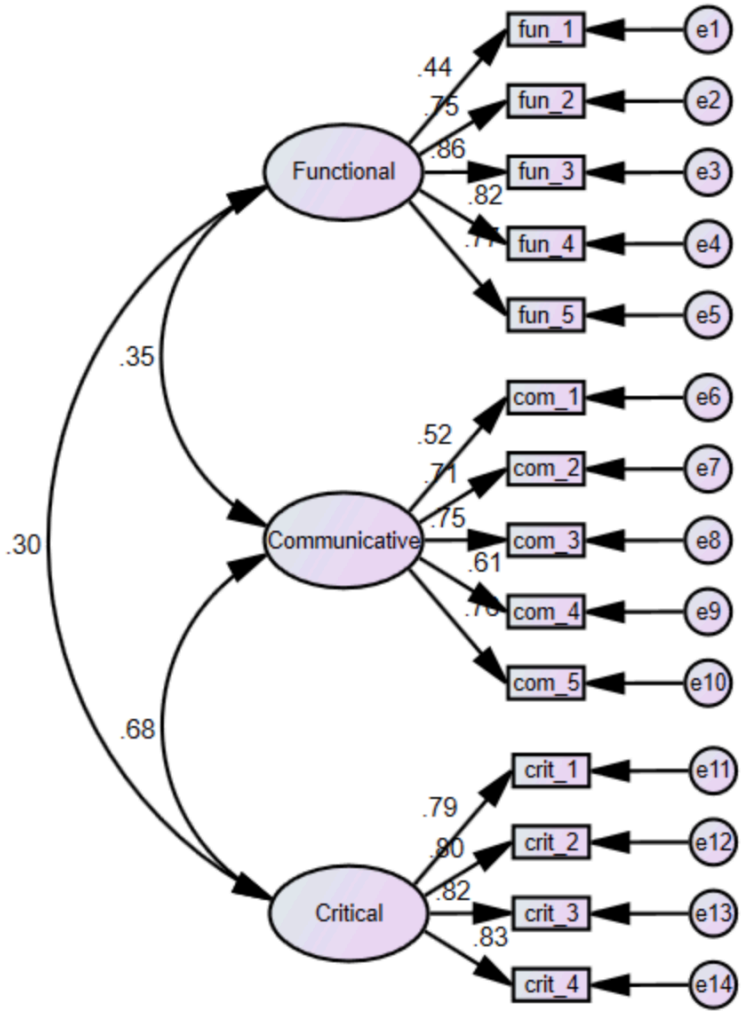

Figure 2. Unstandardized Confirmatory Factor Analysis

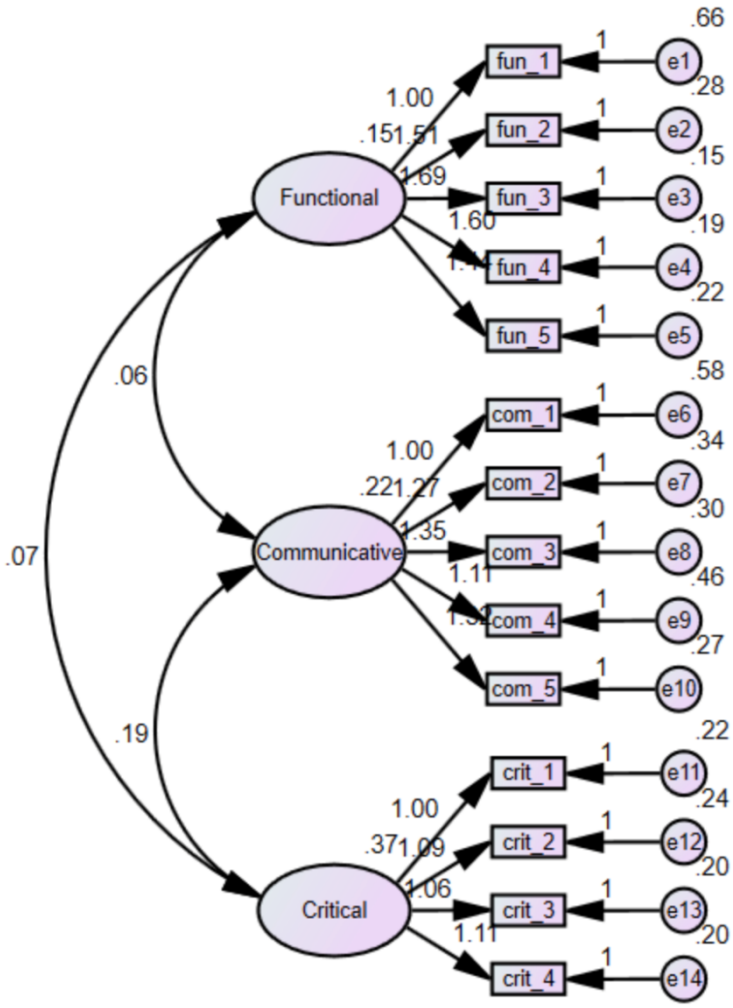

Table 3. Summary of fit indices for the 3-factor confirmatory factor analysis model

	SB x^2	df	RMSEA (90% CI)
Standardized	357.24	77	0.115 (0.103 – 0.127)

Table 4. Confirmatory Factor Analysis Pattern Matrix

Pattern Matrix[a]

	Component		
	1	2	3
fun_rev_1	-.035	.569	-.017
fun_rev_2	.066	.821	-.069
fun_rev_3	-.084	.904	.013
fun_rev_4	.012	.840	.059
fun_rev_5	.020	.813	.025
com_1	-.209	-.078	.858
com_2	.158	-.007	.729
com_3	.091	.270	.671
com_4	.217	.003	.537
com_5	.314	.075	.558
crit_1	.745	-.013	.180
crit_2	.866	-.028	-.006
crit_3	.911	.036	-.099
crit_4	.844	.002	.066

Extraction Method: Principal Component Analysis.
Rotation Method: Oblimin with Kaiser Normalization.

a. Rotation converged in 7 iterations.

Table 5. Compare groups Mean (S.D.)

Education Group (n)	Fun HL (4-1 high)	Com HL (4-1 high)	Crit HL (4-1 high)	Total HL (4-1 high)	NVS (1-6 high)	NVS Level (1-3 high)	s-TOFHLA (1-36 high)	s-TOFHLA Level (1-3 high)
1 (34)	2.23 (0.83)	2.12 (0.69)	2.15 (0.8)	2.18 (0.69)	1.97 (1.75)	1.69 (0.78)	24.53 (9.71)	2.42 (0.8)
2 (90)	1.86 (0.68)	2.10 (0.68)	2.08 (0.74)	2.01 (0.55)	2.16 (1.77)	1.82 (0.80)	31.38 (6.03)	2.88 (0.45)
3 (91)	1.69 (0.42)	1.94 (0.57)	2.02 (0.61)	1.87 (0.40)	3.77 (1.93)	2.46 (0.77)	33.69 (3.15)	2.98 (0.15)
4 (56)	1.58 (0.47)	1.85 (0.57)	2.02 (0.67)	1.80 (0.43)	4.34 (1.78)	4.34 (1.78)	34.52 (2.92)	2.96 (0.19)
5 (4)	1.9 (0.84)	1.70 (0.48)	1.38 (0.43)	1.68 (0.34)	1.75 (1.71)	1.75 (1.71)	29.75 (5)	3 (0.00)
TOTAL	1.8 (0.62)	1.99 (0.63)	2.04 (0.69)	1.94 (0.49)	3.11 (2.06)	3.11 (2.06)	31.91 (6.15)	2.88 (0.43)

Education Group: 1 = below high school, 2 = High school diploma or GED, 3 = some college or associates degree, 4 = bachelor's degree or higher, 5 = not reported

Table 6. ANOVA, Difference between groups by education

	F	Sig.
Functional	7.77	0.000
Communicative	2.23	0.07
Critical	1.26	0.29
Total HL	4.56	0.001
NVS	19.12	0.000
NVS Level	17.25	0.000
s-TOFHLA	22.25	0.000
s-TOFHLA Level	13.22	0.000

Table 2. Spearman's Rho Correlations													
Spearman's Rho	Age	Income	ED Level	Chronic Dis	Fun HL	Com HL	Crit HL	Total HL	s-TOFHLA	NVS	PAM	SECCC	ISR
Age	1	-.003	-.14*	.10	-.13*	-.09	-.005	-.08	-.22*	-.37**	-.15*	.05	-.02
Income	-.003	1	.26**	-.17**	.24**	.07	-.04	.05	.23**	.30**	.19**	.19*	.06
ED level	-.14*	.26**	1	-.13*	.11	.18**	.10	.23**	.44**	.39**	.21**	.17**	.08
Chronic Dis	.10	-.17*	-.13*	1	-.06	.01	-.06	-.06	-.15*	-.19**	-.08	-.21**	-.13*
Fun HL	-.13*	.11	.24**	-.06	1	.35**	.31**	.67**	.29**	.30**	.22**	.19**	.22**
Com HL	-.09	.07	.18**	.01	.35**	1	.56**	.81**	.18**	.20**	.40**	.29**	.26**
Crit HL	-.005	-.04	.10	-.06	.31**	.56*	1	.82**	.05	.06	.32**	.29**	.32**
Total HL	-.08	.05	.23**	-.06	.67**	.81**	.82**	1	.22**	.24**	.41**	.35**	.34**
s-TOHFLA	-.22**	.29**	.44**	-.15*	.29**	.18**	.05	.22**	1	.66**	.33**	.22**	.01
NVS	-.34**	.30**	.39**	-.19*	.30**	.20**	.06	.24**	.66**	1	.33**	.22**	.03
PAM	-.15*	.19**	.21**	-.08	.22**	.40**	.32**	.41**	.33**	.33**	1	.36**	.36**
SECC	.05	.19**	.17**	-.21**	.19**	.29**	.29*	.35**	.22**	.22**	.36**	1	.37**
ISR	-.02	.08	.06	-.13*	.22**	.26**	.32**	.34**	.01	.03	.36**	.37**	1

* p<0.5
** p<0.001

Chapter IV: Manuscript 3

Medicine and Social Science, (to be submitted)

The Relationship Between Self-Management and Health Literacy as Measured by the FCCHL Tool

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Introduction

Chronic diseases are costly and burdensome to individuals, families, and society. Having multiple chronic diseases increase the burden of disability to individuals and families. Chronic disease is defined as "having a condition that lasts one year or more and require on going medical attention or limits activities of daily living or both" (CDC, 2019). The impact of chronic conditions is estimated to affect six in ten adults with four in ten having two or more. Examples of chronic conditions include diabetes, cancer, hypertension, stroke, and are often onset by risk behaviors such as tobacco use, poor nutrition, and inactivity (CDC, 2019). Additionally, excessive costs for management disproportionally affect those with multiple chronic diseases disproportionally and especially those who are socioeconomically vulnerable (Allegrante, Wells, & Peterson, 2019). Chronic disease has a significant negative impact on the United States (US) health care system; it is estimated that by 2030 chronic disease management will cost more than $42 trillion in health care costs (Partnerships, 2018). The advancement of treatment and changes in lifestyles that support longevity for people with chronic conditions also require increased ability to self-manage. Self-management is comprised of three separate tasks: management of disease, role, and emotion (Lorig & Holman, 2003).

The skills required for successful self-management include problem solving, decision making, resource utilization, patient-provider partnership, action planning, and self-tailoring (Lorig & Holman, 2003). These skills are positively impacted by effective partnering between clinicians and patients. Health literacy is an important concept influencing the partnership as well as patients' ability to manage their chronic health problems. Nielsen-Bohlman, Panzer, and King (2004) define health literacy as the ability to obtain, understand, and use health information to make health care choices. Nutbeam (2008) expanded on his original definition to frame health literacy as an asset using his original concept of health literacy as three sub-

concepts: functional, communicative, and critical health literacy. Functional health literacy is comprised of the basic skills, such as reading and writing, which are needed to process health information. Communicative health literacy is more complex and consists of the social and communication skills needed to obtain and fully understand health information. Critical health literacy is the most complex skill and consists of the abilities to obtain, assess, and apply health information and make health care decisions (Nutbeam, 2000).

Knowledge, communication, and decision-making skills, the underlying themes of health literacy, are also the basis of self-management (Fransen, von Wagner, & Essink-Bot, 2012; Lai, Ishikawa, Kiuchi, Mooppil, & Griva, 2013). Low functional health literacy is linked to increased mortality, poor quality of life, improper use of health care services, decreased capacity for disease self-management, increased risk for medical errors, medication adherence and errors (Bailey, Ormasionwu, & Wolf, 2013), and increased health care costs (Lai et al., 2013). Linking self-management and overall health literacy can improve a patient's adherence to treatment and medications, their health behaviors, their ability to problem solve, and improve their basic understanding of the disease process (Bailey et al., 2013; Federman et al., 2014; Lai et al., 2013; Poureslami, Nimmon, Rootman, & Fitzgerald, 2016)

Although there is a clear relationship between functional health literacy and self-management, there are limited data that clearly support the association between all three components of health literacy and self-management, possibly because there is no widely accepted definition of self-management or consistency in the measures used. Nevertheless, studies indicate that health literacy influences the patient's knowledge and assessment of information, impacts adherence, self-efficacy, communication skills, and motivates patients to improve lifestyle behaviors. All of these are directly linked to self-management abilities (Fransen et al., 2012; Hejimans et al., 2015; Ishikawa et al., 2008; Wang et al., 2016). Further studies are

needed to improve our understanding of the association between health literacy and self-management, especially communicative and critical health literacy, both of which are modifiable psychosocial factors that can directly influence disease self-management (Wang et al., 2016). The purpose of this paper is to add to the body of knowledge exploring the relationship between the three types of health literacy and self-management. There are two aims to this study and are a part of a larger study. Aim 1 was to determine the relationship between the FCCHL components of functional, communicative, and critical health literacy and the self-management components of patient activation, self-regulation, and self-efficacy. Aim 2 was to determine the efficacy of the FCCHL as compared to the NVS or TOFHLA in relation to self-management

Methods

Sample & Setting

This study is a cross-sectional study of both urban and rural Midwestern adult populations. A convenience sample was selected from an urban Federally Qualified Health Center (FQHC), a rural community health center, and an urban clinic supporting employees of a business. The sample aimed to represent socioeconomically vulnerable or unstable populations based on the US poverty line, and to compare rural and urban participations with limited access to health care due to a variety of reasons. The inclusion criteria for participants were: having at least two chronic conditions in which they self-manage, being over the age of 19, English speaking, and being established patients at the clinic as defined by having at least one visit related to a chronic condition for management. Exclusion criteria included pregnancy, which temporarily complicates chronic condition management, and dementia or other cognitive limitations that could limit the ability for self-assessment surveys.

Those who met the inclusion and exclusion criteria were referred by the clinic staff or practitioner to participate in the study, recruitment was also done via flyers posted in the clinic. Those referred were recruited, consented, and enrolled upon meeting eligibility requirements in the clinic which they use. All recruitment, consent, and surveys were conducted in accordance with institutional IRB policies. Participants were asked to complete a series of surveys including a demographical instrument, three health literacy tools, and three common data elements of self-management. In total, 276 subjects were recruited, and 275 completed all the surveys.

Data Collection

Data collection was completed using the electronic data collection platform REDCap, which was downloaded onto an iPad. REDCap originated at Vanderbilt and is contracted through the Nebraska university system, providing a HIPPA-compliant and secure method of data capturing and management (Harris et al., 2009). Participants were able to request a paper copy of the survey, and those who identified as illiterate were given assistance with the surveys. Only a few participants chose paper version of the surveys, usually due to either lack of familiarity with a tablet or concern about data security due to mistrust of the internet. Most participants, despite age or socioeconomic status, were familiar with how to use a tablet and appeared comfortable completing the surveys via REDCap.

Measures

Health Literacy. The health literacy tools included the Functional, Communicative, and Critical Health Literacy (FCCHL) tool, the Newest Vital Sign (NVS), and the short version of the Test of Functional Health Literacy in Adults (s-TOFHLA). The NVS and s-TOFHLA were used as a comparison for establishing efficacy of the FCCHL tool when related to self-management. The tools were chosen as they represent the current standard of health literacy measurement in the US. The FCCHL tool contains three subscales and has 14 self-report style questions that can be

answered on a 4-point scale. The FCCHL tool was originally developed by Ishikawa et al. (2008) in Japanese and adapted by van der Vaart et al. (2012) in Dutch and English. Validity and reliability testing was completed in the US and a manuscript is currently under development. The FCCHL tool was both valid and reliable in the target population which was collected incongruence with data collection of this study.

The English version of the NVS was given in person, per instructions provided by Pfizer Inc. The English version of the s-TOFHLA was given and scored based on instructions provided with the tool. Scores for the FCCHL tool, NVS, and s-TOFHLA were recorded to represent low health literacy to high health literacy as calculated by each tool's instructions.

Self-Management. The common data tools for self-management were selected based on a study by Moore et al. (2015) that recommended three tools for three sub-concepts of self-management. The three tools include the Patient Activation Measure (PAM), the Index of Self-Regulation, and the Self-Efficacy for Chronic Conditions. The PAM was created by Hibbard et al. (2005) and is a 13-item, Likert-style scale that was administered and scored per the instructions. The results were divided into four stages of activation. Index of Self-Regulation is a 9-item, Likert-style scale measuring the level of self-regulation associated with management of activity (Yeom et al., 2011). The Self-Efficacy of Chronic Conditions was completed similarly to the other scales and was a 6-item, Likert-scale measuring self-efficacy associated with chronic conditions (Lorig et al, 2003). All three tools were administered and scored according to the instructions.

Data Analysis

Data analysis was completed using an appropriate statistical software package, SPSS. Sample size calculations were performed for each of the three aims using G*Power 3.1.9.2 (Buchner, Erdfelder, & Faul, 1997). The tool acculturation measurement indicates a correlational coefficient of 0.3 and 0.5, which are all medium effect sizes (Cohen, 1992). The study is a

correlational, normal bivariate model assuming a two-tailed test with an alpha =0.05 and has 80% power to detect an effect size of *r=.218* with a sample size of N=260. A total of 275 was collected to ensure completion of data.

Correlations were measured using Spearman's Rho. Multiple regression was performed to determine the effects of health literacy on the self-management after adjusting for demographic characteristics and chronic disease complexity. Chronic disease complexity was determined based on whether the participants indicated if they had one of five different types of chronic diseases. The five chronic diseases include asthma, hypertension, chronic obstruction pulmonary disease (COPD), diabetes (not specified), and depression. Three models were completed 1) demographics, 2) independent health literacy variables, and 3) all three health literacy tools run together.

Results

Participant Characteristics

Participant characteristics and health literacy as measured by the FCCHL, NVS, and s-TOFHLA, and self-management as measured by PAM, ISR, and SECC are shown in Table 1. Education was delineated into four separate categories. Very low education included those who selected elementary or some high school but no diploma or GED. Low education includes those with a high school diploma or GED. Middle education included some college but no degree and two-year degrees. Finally, high education included those with a four-year degree and over. The mean income level was $40,000 to $49,999. The number of chronic conditions relates to the five specific conditions diabetes, hypertension, depression, asthma, or COPD. Additional chronic diseases were listed freely but were not counted for this study. A total of 276 participants were recruited but only 262 completed all the tools. A total of eight participants skipped one or more of the 14 questions in the FCCHL tool and were excluded from the calculations. One participant

was removed as they only completed half of the tools in the study. Three participants were removed as they skipped one or more of the NVS questions and two participants were removed as they skipped one or more of the s-TOFHLA items.

Health literacy Tool Comparison

The FCCHL tool was compared to the NVS and s-TOFHLA by way of correlation and multiple regression. Spearman's rho was used to determine the correlations of each health literacy component compared to various demographic information and all three self-management components (see Table 2). It was found that the total FCCHL tool has a statistically significant relationship with all three components of self-management with correlations ranging from .34 to .41. The total FCCHL had a higher correlation to each of the self-management components than both the NVS and s-TOFHLA. FCCHL was the only tool that correlated with the Index of Self-Regulation with r=0.34, compared to r=0.03 and r=0.01 for NVS and s-TOFHLA respectively.

Health Literacy and Self-management

Spearman's rho correlation was completed with the patient characteristics, health literacy, and self-management (Table 2). Health literacy measured by NVS, s-TOFHLA and the functional health literacy component of the FCCHL tool were significantly correlated with education but the critical and communicative components with either had limited correlation or were not significantly correlated, respectively. The FCCHL tool had stronger correlates with patient activation and self-efficacy than the NVS and s-TOFHLA. Only the FCCHL tool was correlated to self-regulation. The three self-management tools were similarly correlated with each other.

Stepwise multiple linear regression was conducted to assess if the independent variables predict the dependent variable (see Tables 3-9). The adjusted R^2 shows higher for the

communicative, critical, and overall FCCHL tool and there is consistency with the values related to functional health literacy such as NVS and s-TOFHLA. The independent variable in Tables 3-8 for Model 1 includes age, gender, education, and number of chronic conditions. The next step, Model 2, included health literacy as the final as the final independent variable. The patient characteristics showed significance with gender related to patient activation and having one chronic condition related to self-regulation. Model 2 was completed for each of the self-management components and completed individually for the subcomponents of the FCCHL tool, the total FCCHL tool, NVS and s-TOFHLA tools. The final step, Model 3, included all of the demographic information and the three health literacy tools to compare the three tools. Patient activation showed that each of the health literacy tools were significantly correlated with the component when adjusting for the patient characteristics. In Model 3 for patient activation, adjusting for the patient characteristics and including all three health literacy tools, only the FCCHL tool was significantly correlated with patient activation with $p < .001$ for FCCHL, $p = .174$ for NVS, and $p = .452$ for s-TOFHLA (Table 5). The same significance was consistent for self-efficacy and self-regulation with the FCCHL tool was consistently significantly correlated with the three self-management components and the NVS and s-TOFHLA were not significantly correlated (Table 6 and 7).

Even after adjusting for multiple comparisons, the FCCHL tool and its subcomponents more significantly associated with self-management than the other health literacy tools. The adjusted R^2 demonstrates a higher percentage of variation explained by the FCCHL on the various self-management components. The three subcomponents and the overall FCCHL tool were highly significant for all three self-management components. Finally, the NVS and s-TOFHLA were either barely significant or not significantly associated with the self-management components.

Discussion and Conclusion

The purpose of this paper is to add to the body of knowledge exploring the relationship between the three types of health literacy and self-management. The first aim of this study was to determine the relationship between the FCCHL components of functional, communicative, and critical health literacy and the self-management components of patient activation, self-regulation, and self-efficacy. Aim 2 was to determine the efficacy of the FCCHL as compared to the NVS or TOFHLA in relation to self-management was to describe the relationship between health literacy and self-management using a health literacy tool designed to measure all three components of health literacy compared to the relationship between self-management and functional health literacy. The results support the positive and highly significant relationship between health literacy when measured by the FCCHL tool and self-management components. Additionally, the results of this study provide evidence that the FCCHL tool is more highly associated with self-management components compared to the two other health literacy tools currently used in the US.

The univariate multiple linear regression provided results to support the use of the FCCHL tool when measuring health literacy and self-management, supporting a strong association between the FCCHL tool and self-management. Additionally, it shows the other two tools, commonly used in the US, have very limited or no association with the self-management components. These results support the use of the FCCHL tool in the US.

Limitations of this study include generalizability and that the instruments are self-report. The population included in this study was limited to Midwestern urban and rural communities. Additionally, the population was primarily Caucasian and limited to English only. Finally, the assessment of objective and subjective measurements requires additional validation and testing to ensure measurement of the target concept.

Practice Implications

The use of the FCCHL tool in practice will allow improved measurement of health literacy when working on self-management strategies with patients who have more than one chronic condition. The individual components of the FCCHL were all highly significantly associated with the individual self-management components. The individual components of the FCCHL tool measure a unique type of health literacy. It would be beneficial to the provider to know each level when preparing instructions, communicating, and sharing health information to be applied on an individual level. This tool provides an efficient and effective option to measure health literacy and provide directive feedback for immediate action and individualized care.

Conclusion

In conclusion, the study was able to provide results developing the relationship between health literacy and self-management. Additionally, the study showed the strength of the FCCHL tool when measuring health literacy and associated with the different components of self-management. Based on the results of this study, further exploration of the FCCHL tool in the US population is recommended. Future research focusing on the implementation of the FCCHL tool and relationship with health outcomes is needed. The FCCHL tool is a new way to understand health literacy. The expanded definition of health literacy is essential to impacting health through improved health literacy and self-management strategies.

Note

Study data were collected and managed using REDCap electronic data capture tools hosted at University of Nebraska Medical Center (UNMC). REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies. REDCap at UNMC is supported by Research IT Office funded by Vice Chancellor for Research (VCR) and receives partial support from the Great Plains IDeA-CTR grant. This

publication's contents are the sole responsibility of the authors and do not necessarily represent the official views of the VCR and NIH.

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Table 1. Participant Characteristics N = 262

Gender, n (%)	
Female	143 (54.6)
Male	119 (45.4)
Age, mean (S.D.)	51.1 (14.6)
Education, n (%)	
Very Low	34 (12.3)
Low	90 (32.6)
Middle	91 (33)
High	56 (20.3)
Unknown/None of the Above	4 (1.4)
Income, mean (S.D.)	6.2 (4.2)
Below Poverty Line	74 (28.2)
100%-200% Poverty Line	51 (19.5)
200%-400% Poverty Line	58 (22.1)
Over 400% Poverty Line	75 (28.6)
Total HL, mean (S.D.)[a]	3.1 (0.5)
NVS Level, mean (S.D.)[b]	2.2 (0.9)
NVS Level 1, n(%)	74 (28.2)
NVS Level 2, n(%)	62 (23.7)
NVS Level 3, n(%)	126 (48.1)
NVS Total, mean (S.D.)[c]	3.1 (2.1)
s-TOFHLA Level, mean (S.D.)[b]	2.9 (0.4)
s-TOFHLA Level 1, n(%)	8 (3.1)
s-TOFHLA Level 2, n(%)	13 (5)
s-TOFHLA Level 3, n(%)	241 (92)
s-TOFHLA, mean (S.D.)[d]	32.3 (5.5)
PAM Total, mean (S.D.)[e]	63.41 (2.4)
PAM Level, mean (S.D.)[a]	2.72 (1)
ISR Total Score, mean (S.D.)[c]	2.64 (0.9)
SECC Total Score, mean (S.D.)[f]	6.53 (2.4)

a= Range 1-4, b=Range 1-3, c=Range 1-6, d=Range 1-36, e= 1-100, f=1-9

Table 2. Spearman's Rho Correlations													
Spearman's Rho	Age	Income	ED Level	Chronic Dis	Fun HL	Com HL	Crit HL	Total HL	s-TOFHLA	NVS	PAM	SECCC	ISR
Age	1	-.003	-.14*	.10	-.13*	-.09	-.005	-.08	-.22*	-.37**	-.15*	.05	-.02
Income	-.003	1	.26**	-.17**	.24**	.07	-.04	.05	.23**	.30**	.19**	.19*	.06
ED level	-.14*	.26**	1	-.13*	.11	.18**	.10	.23**	.44**	.39**	.21**	.17**	.08
Chronic Dis	.10	-.17*	-.13*	1	-.06	.01	-.06	-.06	-.15*	-.19**	-.08	-.21**	-.13*
Fun HL	-.13*	.11	.24**	-.06	1	.35**	.31**	.67**	.29**	.30**	.22**	.19**	.22**
Com HL	-.09	.07	.18**	.01	.35**	1	.56**	.81**	.18**	.20**	.40**	.29**	.26**
Crit HL	-.005	-.04	.10	-.06	.31**	.56*	1	.82**	.05	.06	.32**	.29**	.32**
Total HL	-.08	.05	.23**	-.06	.67**	.81**	.82**	1	.22**	.24**	.41**	.35**	.34**
s-TOHFLA	-.22**	.29**	.44**	-.15*	.29**	.18**	.05	.22**	1	.66**	.33**	.22**	.01
NVS	-.34**	.30**	.39**	-.19*	.30**	.20**	.06	.24**	.66**	1	.33**	.22**	.03
PAM	-.15*	.19**	.21**	-.08	.22**	.40**	.32**	.41**	.33**	.33**	1	.36**	.36**
SECC	.05	.19**	.17**	-.21**	.19**	.29**	.29*	.35**	.22**	.22**	.36**	1	.37**
ISR	-.02	.08	.06	-.13*	.22**	.26**	.32**	.34**	.01	.03	.36**	.37**	1

* p<0.5
** p<0.001

Table 3. Multivariable Model of Patient Characteristics for Patient Activation, Self-efficacy, and Self-regulation outcomes										
		Patient Activation			Self-efficacy			Self-regulation		
		B	SE	p	B	SE	p	B	SE	p
Age		-.121	.076	.111	.011	.010	.277	<.000	.004	.970
Gender	Female	7.435	2.392	.002	.689	.313	.029	.104	.118	.380
Education (levels)	Under High School	-3.632	4.356	.405	-.381	.569	.504	-.030	.215	.504
	High School Diploma/ GED	-5.969	3.274	.070	-.736	.429	.087	-.108	.162	.504
	Some College, Associates	-6.208	3.135	.049	-.216	.410	.599	-.145	.155	.350
No. Chronic Cond	0	-.622	7.096	.930	1.694	.928	.069	.557	.351	.113
	1	6.849	6.976	.327	1.545	.911	.069	823	.345	.018
	2	.505	7.042	.943	.737	.920	.424	.391	.328	.263
	3	-4.218	7.385	.568	.669	.965	.489	.558	.407	.175
	4	2.894	8.239	.726	.398	1.076	.712	.554	.407	.175

Table 4. Multivariable Model of Patient Characteristics for HL outcomes																			
		Functional			Communicative			Critical			FCCHL			NVS			s-TOFHLA		
		B	SE	p	B	SE	p	B	SE	p	B	SE	p	B	SE	p	B	SE	p
Age		-.004	.003	.161	-.004	.003	.123	-.001	.003	.737	-.003	.002	.165	-.044	.007	.000	-.038	.022	.077
Gender	Female	.094	.079	.234	.105	.082	.202	.068	.092	.462	.087	.064	.170	.851	.222	.000	2.361	.680	.001
Education (levels)	Under High School	-.344	.319	.281	-.288	.331	.385	-.694	.371	.062	-.476	.257	.065	.691	.896	.441	-3.623	2.751	.189
	High School Diploma/ GED	.039	.306	.898	-.295	.318	.354	-.639	.356	.074	-.325	.347	.188	.698	.856	.416	2.332	2.639	.378
	Some College, Associates	.179	.305	.558	-.213	.317	.502	-.651	.355	.068	-.258	.246	.296	2.091	.853	.015	4.108	2.631	.120
No. Chronic Cond	0	.162	239	.499	.234	.249	.349	.362	.279	.195	.267	.193	.168	.388	.672	.564	2.031	2.067	.327
	1	.068	.235	.499	.488	.244	.047	.449	.273	.102	.350	.189	.066	.539	.658	.413	1.988	2.026	.328
	2	.068	.239	.771	.367	.247	.139	.313	.277	.259	.272	.192	.157	.115	.666	.413	2.858	2.052	.165
	3	.047	.248	.849	.256	.258	.323	.214	.289	.459	.194	.200	.333	-.062	.696	.929	2.193	2.145	.308
	4	.255	.271	.349	.633	.282	.026	.550	.316	.083	.492	.219	.025	.175	.760	.818	1.675	2.343	.475

Table 5. Multivariable regression models for Health Literacy in Relationship to Patient Activation								
	Model 2				Model 3			
	B	SE	p-value	Adj R^2	B	SE	p-value	Adj R^2
Functional	6.329	1.893	0.001	0.142				
Communicative	10.161	1.759	<.001	0.21				
Critical	9.139	1.519	<.001	0.218				
FCCHL	14.87	2.154	<.001	0.249	14.109	2.178	<.001	.255
NVS	1.76	0.649	0.007	0.129	.919	.674	.174	
s-TOFHLA	0.539	0.242	0.028	0.12	.188	.250	.452	

*Model 2 is individual testing of the health literacy components adjusted for patient characteristics of age, gender, education, and number of chronic conditions

** Model 3 is all three health literacy tools together adjusting for patient characteristics

Table 6. Multivariable regression models for Health Literacy in Relationship to self-efficacy								
	Model 2				Model 3			
	B	SE	p-value	Adj R^2	B	SE	p-value	Adj R^2
Functional	6.329	1.893	0.001	0.142				
Communicative	10.161	1.759	<.001	0.21				
Critical	9.139	1.519	<.001	0.218				
FCCHL	14.87	2.154	<.001	0.249	1.492	.090	<.001	.195
NVS	1.76	0.649	0.007	0.129	.071	.034	.037	
s-TOFHLA	0.539	0.242	0.028	0.12	.091	.090	.310	

*Model 2 is individual testing of the health literacy components adjusted for patient characteristics of age, gender, education, and number of chronic conditions

** Model 3 is all three health literacy tools together adjusting for patient characteristics

Table 7. Multivariable regression models for Health Literacy in Relationship to self-regulation								
	Model 2				Model 3			
	B	SE	p-value	Adj R^2	B	SE	p-value	Adj R^2
Functional	6.329	1.893	0.001	0.142				
Communicative	10.161	1.759	<.001	0.21				
Critical	9.139	1.519	<.001	0.218				
FCCHL	14.87	2.154	<.001	0.249	.576	.112	<.001	.117
NVS	1.76	0.649	0.007	0.129	-.061	.035	.078	
s-TOFHLA	0.539	0.242	0.028	0.12	.014	.013	.284	

*Model 2 is individual testing of the health literacy components adjusted for patient characteristics of age, gender, education, and number of chronic conditions

** Model 3 is all three health literacy tools together adjusting for patient characteristics

Chapter V: Conclusion and Discussion

Discussion

The purpose of this dissertation was to explore and better understand the relationship between health literacy and self-management using a health literacy tool modified and evaluated in the US. The specific aims in this study were: 1) to evaluate the validity and reliability of the Functional, Communicative, and Critical Health Literacy (FCCHL) tool in a Midwestern socioeconomically vulnerable or unstable adult population; 2) to determine the efficacy of the FCCHL compared to the Newest Vital Sign (NVS) or Short Form of the Test of Functional Health Literacy in Adults (s-TOFHLA) in relation to self-management; and 3) to determine the relationship between the three FCCHL components of functional, communicative, and critical health literacy and the self-management components of patient activation, self-regulation, and self-efficacy.

Major components of this dissertation included: an integrative review for health literacy and self-management; reliability and validity testing of a health literacy tool new to the US; and determining the relationship between the new health literacy tool and self-management. Chapter I provided an introduction describing the background, significance, and purpose of the dissertation. The problem of numerous definitions of health literacy was identified as a major gap in the literature. Another gap was the varying and often conflicting data regarding the relationship between health literacy and self-management.

Chapter II provided an integrative review of the relationship between health literacy and self-management. The purpose of the review was to analyze studies that explore the relationship between each of the three sub-concepts of health literacy and self-management. Studies were excluded if the study did not include measurement for all three types of health literacy: functional, communicative, and critical. Self-management was measured using the

common data elements of self-efficacy, self-regulation, and patient activation (Moore et al., 2015). Using the PRISMA method for integrative reviews, ten articles were used for the final review. Major outcomes of this paper included support for a limited and positive relationship between health literacy and self-management. The majority of studies reviewed used a version of the FCCHL tool when studying health literacy as functional, critical, and communicative but only one study was found to date used the FCCHL tool in the US. Finally, the relationship between health literacy and self-management was reviewed but no additional relationships between health literacy and health outcomes were reported. The results from this integrative review provided direction for the studies described in Chapters III and Chapter IV.

In Chapter III the results are provided for Aim 1: to evaluate the validity and reliability of the FCCHL tool in a Midwestern socioeconomically vulnerable or unstable adult population. The purpose of this study was to test the validity and reliability of the English version of the FCCHL tool in the United States. The study was conducted in three settings to ensure diversity of the population in terms of education and socioeconomic status. The intention was to find a population mix where literacy is an issue. The population was well dispersed between very low, low, middle, and high levels of educations and was also distributed evenly into the four categories of the national poverty level, <100%, 100%-200%, 200%-400%, and over 400%. Reliability was measured using internal consistency and external reliability measures. Validity was measured using construct, concurrent, and criterion validity. Comparisons were used using education levels and measured in relation to the current US standard tools of measuring health literacy. As described in Chapter III, the FCCHL tool was, overall, determine to be valid and reliable. It was clear that the FCCHL subscales measuring communicative and critical health literacy were measuring different constructs than the standard tools focused on functional health literacy. This supports the hypotheses that there are three separate components to

health literacy-functional, communicative, and critical--and that if measuring all three concepts is desired, the FCCHL would be the preferred tool

In Chapter IV the results for Aims 2 and 3 are described. The purpose of Aim 2 was to determine the relationship between the FCCHL components of functional, communicative, and critical health literacy and the self-management components of patient activation, self-regulation, and self-efficacy. The correlations between health literacy and self-management were resoundingly positive and significant. A stepwise multiple regression that adjusted for income, age, gender, and education resulted in the FCCHL being more correlated and appropriate for health literacy measurement than the NVS and the s-TOFHLA. Health literacy as measured by the FCCHL tool was positively and significantly correlated with all three self-management components. The other two health literacy tools were less correlated with self-efficacy and patient activation and were not significantly correlated with self-regulation. Aim 3 was to determine the efficacy of the FCCHL compared to the NVS or s-TOFHLA in relation to self-management. The results showed that the FCCHL tool was highly significantly associated with all three self-management components even when adjusting for the other two health literacy tools.

The results from this study show the importance of the FCCHL tool in relationship with self-management support strategies. The recommendations from this study include using the FCCHL tool in place of the NVS and s-TOFHLA when working on self-management support strategy. Chapter IV concludes that the FCCHL tool is valid and reliable and measures communicative and critical factors that are different from functional health AND are positively correlated with three key components of self-management support: patient activation, self-efficacy and self-regulation.

Limitations

There are several limitations to this study. First, the population does not allow for generalizability of the FCCHL tool. The tool was meant for individuals who had chronic conditions in order to relate to self-management concepts. The use of the three sub-concepts of health literacy is not consistent with other studies completed in the US and therefore has limited relatability. The lack of tools measuring communicative and critical health literacy make it difficult to adequately measure concurrent validity. The varying definitions and lack of tools limits the comparisons between studies. Additionally, the FCCHL tool is different from the current US tools as it is a self-report measure. The difference between subjective and objective measurements does create some concern but the NVS and s-TOFHLA are highly associated with education whereas, the FCCHL is not. Finally, the gap of relating health literacy with health outcomes was not resolved by this study and requires future evaluation.

Implications

The primary implication from this study includes the use of the FCCHL tool in the tested population. The tool was previously modified, and the results described in this dissertation support the use of this tool in clinical practice. The FCCHL tool provides a quick self-assessment of the three types of health literacy. The three types of health literacy provide more dynamic information to the healthcare professional. Functional health literacy results from the FCCHL tool provided insight to the reading and visual disabilities of the individual. The communicative section provides information about communication ability and preference. The critical health literacy section provides the healthcare provider information about the application and understanding of information regarding health.

An additional implication is the advancement of the relationship between health literacy and self-management. The study shows a limited but positive relationship. Additional testing is

necessary to fully understand the relationship between health literacy and self-management. Improving the tools to better understand the concept will advance the science of health literacy and self-management. Without strong evaluation, changes are underexposed, and improvements are limited. The ability to accurately measure a concept aids in the development of an intervention. The results of this study show that the use of the FCCHL tool will assist in better understanding of total health literacy.

Future Studies

The studies in this dissertation provide evidence that communicative and critical health literacy are correlated and associated with the components of self-management. Future studies should focus on health education designed to positively impact self-management support and therefore health outcomes. There are two future studies based on the results of this study. First, translation into other languages is a priority. The tool must undergo translation and cultural adaptation for appropriately use in various populations. The first translation will be into Spanish and culturally adapted to the predominant Hispanic community based on the research site. The acculturation is necessary to ensure the desired outcomes from the tool. The inclusion of the Hispanic population is especially important in the Midwest due to the size and needs of the population.

Second, a future study would include testing the FCCHL tool with an intervention directed at changing specific self-management behaviors and components to see if the tool will show change overtime. An example of an intervention to test the FCCHL tool would be the Stanford self-management intervention which focuses on improving self-management behavior using concepts created by Dr. Lorig and her team. The results from this study support the continuation of developing health literacy as an asset and in relationship with self-management.

Conclusion

The impact of functional health literacy on the US population is well established. The addition of communicative and critical health literacy will add significance value to health literacy as a foundation to self-management strategies and therefore health outcomes. Health literacy is especially important for those who are vulnerable and specifically to those who are socioeconomically vulnerable. The complexity of healthcare is not only reliant on the ability to read but more dynamically, the ability to communicate, navigate, and implement the abundance of information available. The adaptation of the FCCHL tool may be a first step to a fuller understanding of the intense impact of health literacy on health.

Future research should focus on the integration and implementation of the FCCHL tool that will allow for a stronger understanding of the tool. The focus on communicative and critical health literacy will provide new insight to interactions and resources of clinicians. Modification of functional health literacy is unlikely, especially in the clinical setting. However, adaptations, interventions, and incorporation of communicative and critical health literacy may clarify the concept of health literacy and provide direction to this everchanging concept. Further examination of how health literacy relates to self-management and health outcomes is necessary. The focus of health literacy should include all three sub-concepts. The results of this study have supported and expanded conception of health literacy and demonstrate the need to incorporate communicative and critical health literacy, as well as functional, into healthcare and healthcare research.

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Appendix A

FUNCTIONAL, COMMUNICATIVE, AND CRITICAL HEALTH LITERACY TOOL

When you read materials for your health such as medication packages, instructions, or visit forms

		Always	Often	Sometimes	Never
1)	Is the print is too small to read even if with glasses/contacts?	○	○	○	○
2)	Are there words that you do not know or have never seen before?	○	○	○	○
3)	Is the information too hard to understand, or you have to ask for help to understand?	○	○	○	○
4)	Does the information take a long time to understand?	○	○	○	○
5)	Do you need help from someone else to understand?	○	○	○	○

When you are finding or using information for your health:

		Always	Often	Sometimes	Never
6)	Can you find information from different places (e.g. internet, health care workers, TV)	○	○	○	○
7)	Can you find the information you wanted?	○	○	○	○
8)	Is the information you are given or find understandable?	○	○	○	○
9)	Can you tell someone about your thoughts and concerns related to your health (i.e. doctor, nurse, pharmacist, family, friends)	○	○	○	○
10)	Can you use the information you are given or find in your daily life?	○	○	○	○

When you are given, finding, or using information for your health:

		Always	Often	Sometimes	Never
11)	Can you tell if the information is about you and your health?	○	○	○	○
12)	Can tell if the place you found the information is truthful or trustworthy?	○	○	○	○
13)	Can tell if the information is true or correct?	○	○	○	○
14)	Can you use the information to make health related choices?	○	○	○	○

Appendix B

NEWEST VITAL SIGN TOOL

	Check yes or no if they answered the question correctly or not **READ TO SUBJECT:** **This information is on the back of a container of a pint of ice cream.**	
1)	If you eat the entire container, how many calories will you eat?	◯ Yes ◯ No (Answer: 1,000)
2)	If you are allowed to eat 60 grams of carbohydrates as a snack, how much ice cream would you have?	◯ Yes ◯ No (1 cup, half container, 2 servings - need to say "How much would that be?")
3)	Your doctor advises you to reduce the amount of saturated fat in your diet. You usually have 42 g of saturated fat each day, which includes one serving of ice cream. If you stop eating ice cream, how many grams of saturated fat would you be consuming each day?	◯ Yes ◯ No (Answer: 33)
4)	If you usually eat 2,500 calories in a day, what percentage of your daily value of calories will you be eating if you eat one serving?	◯ Yes ◯ No (Answer: 10%)
	Read to Subject: **Pretend that you are allergic to the following substances: penicillin, peanuts, latex gloves, and bee stings.**	
5)	Is it safe for you to eat this ice cream?	◯ Yes ◯ No (Answer: No)

Appendix C

SHORT FORM – TEST OF FUNCTIONAL HEALTH LITERACY IN ADULTS TOOL

Here are some medical instructions that you or anybody might see or hear in the hospital. These instructions are in sentences that have some of the words missing. Where a word is missing, a blank line is drawn, and for possible words that could go in the blank, there are options to the right. I want you to figure out which of the four words should go in the blank, which word makes the sentence makes sense.

1)	Your doctor has sent you to have a _____ x-ray.	◯ stomach ◯ diabetes ◯ stitches ◯ germs
2)	You must have an _____ stomach when you come for _____	◯ asthma ◯ empty ◯ incest ◯ anemia (Selection for the First Blank)
3)	You must have an [stofhla_2] stomach when you come for _____ .	◯ is. ◯ am. ◯ if. ◯ it. (Select for the Second Blank)
4)	The x-ray will _____ from 1 to 3 _____ to do.	◯ take ◯ view ◯ talk ◯ look (Select for the First Blank)
5)	The x-ray will [stofhla_4] from 1 to 3 _____ to do.	◯ beds ◯ brains ◯ hours ◯ diets (Select for the Second Blank)
6)	For supper have only a _____ snack of fruit, _____ and jelly, with coffee or tea.	◯ little ◯ broth ◯ attack ◯ nausea (Select for the First Blank)
7)	For supper have only a [stofhla_6] snack of fruit, _____ and jelly, with coffee or tea.	◯ toes ◯ throat ◯ toast ◯ thigh (Select for the Second Blank)
8)	After _____, you must not _____ or drink.	◯ minute, ◯ midnight, ◯ during, ◯ before, (Select for the First Blank)

9)	After [stofhla_8], you must not _____ or drink	◯ easy ◯ ate ◯ drank ◯ eat (Select for the Second Blank)
10)	anything at _____ until after you have _____ the x-ray.	◯ ill ◯ all ◯ each ◯ any (Select for the First Blank)
11)	anything at [stofhla_10] until after you have _____ the x-ray.	◯ are ◯ has ◯ had ◯ was (Select for the Second Blank)
12)	Do not eat _____	◯ appointment ◯ walk-in ◯ breakfast ◯ clinic
13)	Do not _____, even _____	◯ drive ◯ drink ◯ dress ◯ dose (Select for the First Blank)
14)	Do not [stofhla_13], even _____.	◯ heart. ◯ breath. ◯ water. ◯ cancer. (Select for the Second Blank)
15)	If you have any _____, call the x-ray _____ at 616-4500.	◯ answers ◯ exercises ◯ tracts ◯ questions (Select for the First Blank)
16)	If you have any [stofhla_15], call the x-ray _____ at 616-4500.	◯ department ◯ sprain ◯ pharmacy ◯ toothache (Select for the Second Blank)
17)	I agree to give correct information to _____ if I can receive Medicaid.	◯ hair ◯ salt ◯ see ◯ ache
18)	I _____ to provide the county information to _____ any	◯ agree ◯ probe ◯ send ◯ gain (Select for the First Blank)

19) I [stofhla_18] to provide the county information to _____ any

- ◯ hide
- ◯ risk
- ◯ discharge
- ◯ prove

(Select for the Second Blank)

---

20) statements given in this _____ and hereby give permission to

- ◯ emphysema
- ◯ application
- ◯ gallbladder
- ◯ relationship

---

21) the ____ to get such proof. I _____ that for

- ◯ inflammation
- ◯ religion
- ◯ iron
- ◯ county

(Select for the First Blank)

---

22) the [stofhla_21] to get such proof. I _____ that for

- ◯ investigate
- ◯ entertain
- ◯ understand
- ◯ establish

(Select for the Second Blank)

---

23) Medicaid I must report any _____ in my circumstances

- ◯ changes
- ◯ hormones
- ◯ antacids
- ◯ charges

---

24) within _____ (10) days of becoming _____ of the change.

- ◯ three
- ◯ one
- ◯ five
- ◯ ten

(Select for the First Blank)

---

25) within [stofhla_24] (10) days of becoming _____ of the change.

- ◯ award
- ◯ aware
- ◯ away
- ◯ await

(Select for the Second Blank)

---

26) I understand _____ if I DO NOT like the _____ made on my

- ◯ thus
- ◯ this
- ◯ that
- ◯ than

(Select for the First Blank)

---

27) I understand [stofhla_26] if I DO NOT like the _____ made on my

- ◯ marital
- ◯ occupation
- ◯ adult
- ◯ decision

(Select for the Second Blank)

---

28) case, I have the _____ to a fair hearing. I can _____ a

- ◯ bright
- ◯ left
- ◯ wrong
- ◯ right

(Select for the First Blank)

29) case, I have the [stofhla_28] to a fair hearing. I can _____ a

- ◯ request
- ◯ refuse
- ◯ fail
- ◯ mend

(Select for the Second Blank)

---

30) hearing by writing or _____ the county where I applied.

- ◯ counting
- ◯ reading
- ◯ calling
- ◯ smelling

---

31) If you _____ TANF for any family _____, you will have to

- ◯ wash
- ◯ want
- ◯ cover
- ◯ tape

(Select for the First Blank)

---

32) If you [stofhla_31] TANF for any family _____, you will have to

- ◯ member
- ◯ history
- ◯ weight
- ◯ seatbelt

(Select for the Second Blank)

---

33) _____ a different application form. _____ , we will use

- ◯ relax
- ◯ break
- ◯ inhale
- ◯ sign

(Select for the First Blank)

---

34) [stofhla_33] a different application form. _____ , we will use

- ◯ Since
- ◯ Whether
- ◯ However
- ◯ Because

(Select for the Second Blank)

---

35) the _____ on this form to determine your _____.

- ◯ lung
- ◯ date
- ◯ meal
- ◯ pelvic

(Select for the First Blank)

---

36) the [stofhla_35] on this form to determine your _____.

- ◯ hypoglycemia
- ◯ eligibility
- ◯ osteoporosis
- ◯ schizoprenia

(Select for the Second Blank)

Appendix D

PATIENT ACTIVATION MEASURE

1)	When all is said and done, I am the person who is responsible for managing my health.	◯ Disagree Strongly ◯ Disagree ◯ Agree ◯ Agree Strongly ◯ N/A
2)	Taking an active role in my own health care is the most important factor in determining my health and ability to function.	◯ Disagree Strongly ◯ Disagree ◯ Agree ◯ Agree Strongly ◯ N/A
3)	I am confident that I can take actions that will help prevent or minimize some symptoms or problems associated with my health.	◯ Disagree Strongly ◯ Disagree ◯ Agree ◯ Agree Strongly ◯ N/A
4)	I know what each of my prescribed medications does.	◯ Disagree Strongly ◯ Disagree ◯ Agree ◯ Agree Strongly ◯ N/A
5)	I am confident that I can tell when I need to go get medical care and when I can handle a health problem myself.	◯ Disagree Strongly ◯ Disagree ◯ Agree ◯ Agree Strongly ◯ N/A
6)	I am confident I can tell a doctor concerns I have even when he or she does not ask.	◯ Disagree Strongly ◯ Disagree ◯ Agree ◯ Agree Strongly ◯ N/A
7)	I am confident that I can follow through on medical treatments I need to do at home.	◯ Disagree Strongly ◯ Disagree ◯ Agree ◯ Agree Strongly ◯ N/A
8)	I understand the nature and causes of my health problems.	◯ Disagree Strongly ◯ Disagree ◯ Agree ◯ Agree Strongly ◯ N/A

9)	I know the different medical treatment options available for my health condition.	◯ Disagree Strongly ◯ Disagree ◯ Agree ◯ Agree Strongly ◯ N/A
10)	I have been able to maintain the lifestyle changes for my health that I have made.	◯ Disagree Strongly ◯ Disagree ◯ Agree ◯ Agree Strongly ◯ N/A
11)	I know how to prevent further problems with my health.	◯ Disagree Strongly ◯ Disagree ◯ Agree ◯ Agree Strongly ◯ N/A
12)	I am confident I can figure out solutions when new situations or problems arise with my health.	◯ Disagree Strongly ◯ Disagree ◯ Agree ◯ Agree Strongly ◯ N/A
13)	I am confident I can maintain lifestyle changes, like diet and exercise, even during times of stress.	◯ Disagree Strongly ◯ Disagree ◯ Agree ◯ Agree Strongly ◯ N/A

Appendix E

SELF-EFFICACY OF CHRONIC CONDITIONS

We would like to know how confident you are in doing certain activities. For each of the following questions, please choose the number that corresponds to your confidence that you can do the tasks regularly at the present time.

1 = not confident at all to 10 = totally confident

1)	How confident are you that you can keep the fatigue caused by your disease from interfering with the things you want to do?	◯ 1, not at all confident ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7 ◯ 8 ◯ 9 ◯ 10, totally confident
2)	How confident are you that you can keep the physical discomfort or pain of your disease from interfering with the things you want to do?	◯ 1, not at all confident ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7 ◯ 8 ◯ 9 ◯ 10, totally confident
3)	How confident are you that you can keep the emotional distress caused by your disease from interfering with the things you want to do?	◯ 1, not at all confident ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7 ◯ 8 ◯ 9 ◯ 10, totally confident
4)	How confident are you that you can keep any other symptoms or health problems you have from interfering with the things you want to do?	◯ 1, not at all confident ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7 ◯ 8 ◯ 9 ◯ 10, totally confident
5)	How confident are you that you can do the differ ent tasks and activities needed to manage your health condition so as to reduce you need to see a doctor?	◯ 1, not at all confident ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7 ◯ 8 ◯ 9 ◯ 10, totally confident
6)	How confident are you that you can do things other than just taking medication to reduce how much your illness affects your everyday life?	◯ 1, not at all confident ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7 ◯ 8 ◯ 9 ◯ 10, totally confident

Appendix F

INDEX OF SELF-REGULATION TOOL

	Index of Self-Regulation					
		strongly disagree	disagree	neutral	agree	strongly agree
1)	I routinely think of the benefits of regular physical activity.	○	○	○	○	○
2)	I remind myself of the good that I am doing by staying physically active.	○	○	○	○	○
3)	I remind myself of the importance of physical activity.	○	○	○	○	○
4)	I keep track of the ways that I stay physically active.	○	○	○	○	○
5)	I watch for signs of progress as I stay physically active.	○	○	○	○	○
6)	I monitor myself to see if I am meeting my goals for physical activity.	○	○	○	○	○
7)	I have learned new habits that help me to participate in physical activity.	○	○	○	○	○
8)	I have learned new ways to stay physically active.	○	○	○	○	○
9)	I have learned to make changes in my physical activity that I can live with.	○	○	○	○	○