TITLE PAGE

The Role of Individual and Organizational Health Literacy on Health Behaviors and Health Outcomes

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ABSTRACT (ACADEMIC)

Health literacy (HL) is defined as the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions. Low HL has been associated with poorer self-reported health status, inability to manage chronic conditions, and less use of preventive services. More research is needed to explore the relationship between HL and sugar-sweetened beverage (SSB) intake and physical activity (PA). Although numerous HL interventions are evident in the literature, those that test HL as a moderator of effectiveness are lacking. Additionally, it has been recognized that systems-level HL efforts are necessary to lessen the burden of individuals' low HL. This dissertation addresses these needs with three unique studies that took place within the rural, medically underserved southwest Virginia region.

Study 1 was a secondary analysis that examined the relationship and responsiveness of the Stanford Leisure-Time Activity Categorical Item (L-Cat) and adapted Godin Leisure-Time Exercise Questionnaire (GLTEQ) and determined if baseline HL status moderated intervention effects. There was high agreement L-Cat and adapted GLTEQ for classifying individuals as meeting PA recommendations. Baseline HL status did not moderate change in L-Cat or adapted GLTEQ measures.

Study 2 was a secondary analysis that determined if 6-month change in SSB intake predicted 6-month change in body mass index (BMI), weight, and quality of life (QOL), and determined if HL moderated these relationships. The regression models for weight and QOL were not significant. The BMI model was significant. Six-month change in SSB intake, experimental condition, and age were significant predictors for the BMI model. As hypothesized, HL did not moderate relationships in any models.

Study 3 details a multilevel mixed-methods needs assessment and collaboratively developed organizational HL improvement plan within the Virginia Department of Health (VDH). Staff responses revealed about half reported “doing well” across HL domains (written communication, oral communication, self-management and empowerment, supportive systems). However, needs were observed across all domains, with most improvement needed in written communication domain. There were significant correlations between clients’ HL status and their perceptions of VDHs HL practices, indicating potential areas of improvement within VDH.

ABSTRACT (GENERAL AUDIENCE)

Health literacy is defined as the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions. Low health literacy has been associated with poorer self-reported health status, inability to manage chronic conditions, and less use of preventive services. More research is needed to explore the relationship between health literacy and sugar-sweetened beverage intake and physical activity. Specifically, interventions that test the moderation of health literacy (i.e., how health literacy affects the strength of a relationship) are needed. Additionally, it has been recognized that systems-level health literacy efforts are necessary to lessen the burden of low health literacy. This dissertation addresses these needs within the rural, medically underserved southwest Virginia region.

Study 1 aimed to test the utility of two physical activity measures (Stanford Leisure-Time Activity Categorical Item and adapted Godin Leisure-Time Exercise Questionnaire) with a population of varying health literacy status with hopes of coming closer to identifying pragmatic standardized assessment of and detection of clinically meaningful change in physical activity behaviors, and to determine if health literacy moderated this change. Study 2 expanded upon existing research that has determined that a decrease in sugar-sweetened beverage intake can result in a decrease in weight and body mass index (BMI), and improvement in quality of life (QOL) by aiming to determine if six-month change in SSB intake predicted six-month change in BMI, weight, and QOL and if health literacy moderated these relationships. Study 3 responds to national and state-wide initiatives by detailing the first use of the AHRQ Toolkit within a public health setting, Virginia Department of Health, to conduct a needs assessment and organizational health literacy improvement plan.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

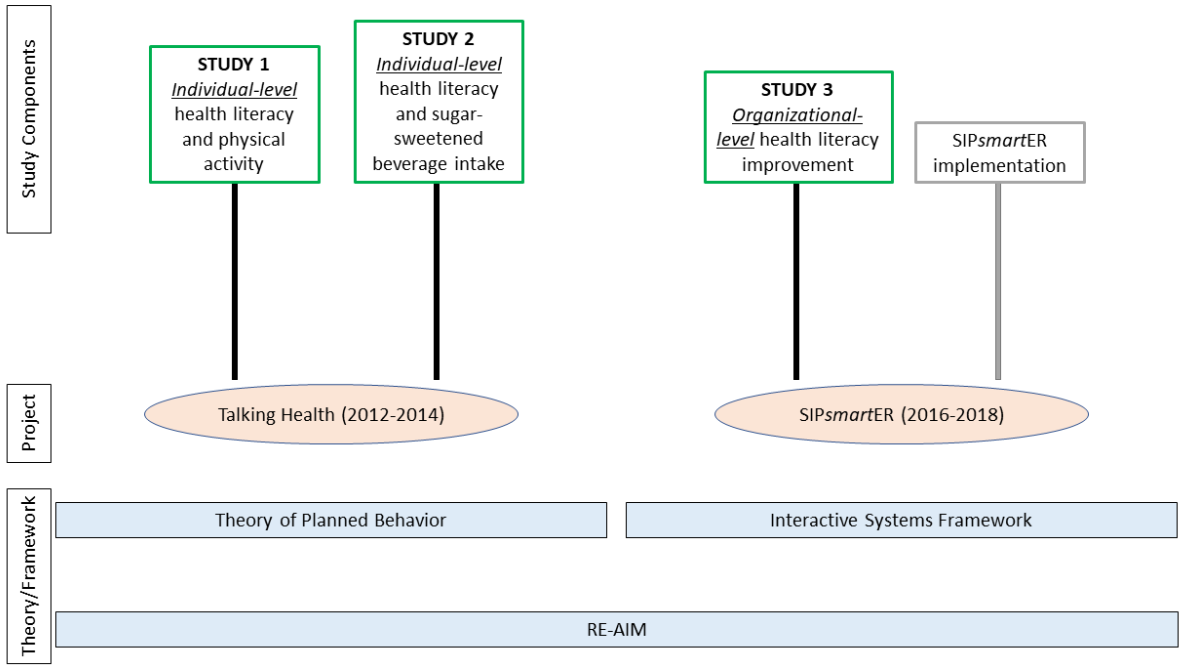
LIST OF ABBREVIATIONS

Abbreviation	Meaning
AHRQ	Agency for Healthcare Research & Quality
BMI	Body mass index
CCI	Clear Communication Index
GLTEQ	Godin Leisure-Time Exercise Questionnaire
HL	Health literacy
ISF	Interactive Systems Framework
L-Cat	Stanford Leisure-Time Activity Categorical Item
MVPA	Moderate-vigorous physical activity
OHL	Organizational health literacy
PA	Physical activity
QOL	Quality of life
RE-AIM	Reach, Effectiveness, Adoption, Implementation, and Maintenance Framework
SSB	Sugar-sweetened beverages
TPB	Theory of Planned Behaviors
VDH	Virginia Department of Health

CHAPTER 1: LITERATURE REVIEW

Background of and Context for Dissertation Studies

The purpose of this background section is to provide context for this dissertation. The core component of this dissertation is health literacy, and how this impacts health outcomes. As will be thoroughly described in this literature review, the studies in this dissertation focus on both individual-level and organizational-level health literacy. As illustrated in the figure below, the three studies that make up this dissertation originate from two separate research projects, Talking Heath and SIP*smart*ER. These projects are described in detail below, along with a brief introduction of the three dissertation studies in relation to each respective project. The theoretical and conceptual frameworks of these projects include the Theory of Planned Behavior (TPB), the Interactive Systems Framework (ISF), and the reach, effectiveness, adoption, implementation, and maintenance (RE-AIM) framework. The TPB, ISF, and RE-AIM framework are detailed after the description of Talking Health and SIP*smart*ER.



Research Projects

Talking Health (2012-2014)

The Talking Health trial took place between 2012-2014. Within the trial, participants were randomized to one of two intervention arms, SIP*smart*ER or MoveMore. The primary aim of the trial was to determine the effectiveness of SIP*smart*ER at decreasing sugar-sweetened beverage intake when compared to a matched-contact control group, MoveMore. The secondary aims were to explore causal pathways between Theory of Planned Behavior constructs and sugar-sweetened beverage consumption, and to determine reach (representativeness, adoption (feasibility), implementation (degree of fidelity, cost), and maintenance. The intervention component, SIP*smart*ER, was a six-month intervention aimed to decrease sugar-sweetened beverage intake that included three group classes, one live teach-back call, and 11 interactive voice response calls. It was framed by concepts from the Theory of Planned Behavior and health literacy concepts, including media literacy and numeracy. MoveMore was identical in structure, but differed in content as it focused on encouraging participants to be more physically active.[1] Talking Health was conducted across eight counties in southwest Virginia classified as medically-underserved, and included 301 participants (average income $23,173; 32%<HS education; 32.9% low health literate). Mixed effects (fixed and random effects) linear regression that accounted for intervention cohort and controlled for relevant demographics variables showed that SIP*smart*ER participants statistically significantly decreased sugar-sweetened beverage intake by 236±46 kilocalories per day during the six-month intervention period when compared to participants in a matched-contact control group, MoveMore, who decreased by 54±19 kilocalories per day. Results also showed that baseline health literacy status did not moderate any outcomes, including sugar-sweetened beverage intake and physical activity behavior. Additionally, health literacy status did not influence retention rates or program completion rates.[2]

Studies 1 and 2 of this dissertation are secondary analyses from the Talking Health trial. The primary goal of these studies is to determine if and how health literacy impacts health behaviors at the individual level. Study 1 focuses on the relationship between individual-level health literacy and physical activity. Study 2 examines the relationship between individual-level health literacy and sugar-sweetened beverage intake.

SIP*smart*ER *(2016-2018)*

The Talking Health trial showed that the SIP*smart*ER intervention was effective at decreasing sugar-sweetened beverage intake. Therefore, the next step was to translate this clinical effectiveness into typical practice settings, namely one particular public health system. The SIP*smart*ER trial, currently ongoing, began in 2016 as a partnership between four Virginia Department of Health districts and respective medical directors and researchers from Virginia Tech and University of Virginia. The primary aim of the work was to develop, establish feasibility, and determine the possible utility of an implementation strategy for SIP*smart*ER, which will reflect system-level needs, barriers, and resources specific to SIP*smart*ER, and also to simultaneously build general capacity related to organizational health literacy. The secondary aims were to determine the adoption and implementation process at the organizational level and to determine individual-level reach and effectiveness of SIP*smart*ER within the Virginia Department of Health. While implementation is on-going, preliminary results show high fidelity to lesson plans among VDH staff. For the organizational improvement component, staff (n=252) and client (n=187) needs assessment were conducted, a five-hour kick-off event was completed in May 2016, quarterly newsletter series launched in October 2016, and four in-person workshops on the Clear Communication Index (a research-based tool developed by the Centers

for Disease Control and Prevention used to develop, assess, and evaluate written public health materials) were held between October 2017 and March 2018.

Dissertation study 3 is based on the ongoing SIP*smart*ER trial. This study focuses on the organizational health literacy capacity building; the SIP*smart*ER implementation strategy and individual-level reach and effectiveness outcomes are beyond the scope of this dissertation. Thus, the purpose of Study 3 is to describe the process of addressing general capacity related to organizational health literacy.

Theoretical and Conceptual Frameworks

Theory of Planned Behavior

In response to a need for theory-based approaches when studying the relationships between health literacy and health outcomes, the Talking Health trial used the Theory of Planned behavior (TPB) to understand the determinants of sugar-sweetened beverage intake and physical activity behaviors.[1,2] The TPB has continually demonstrated the ability to predict and explain a wide variety of health behaviors.[3,4] The TPB links beliefs and behavior, and includes three constructs (i.e., attitudes, subjective norms, and perceived behavioral control) that influence behavioral intentions. In turn, behavioral intention and perceived behavior control determine an individual's behavior. Specifically, *attitudes* refers to personal evaluations of the beliefs about outcomes or performing a behavior (e.g., building positive attitudes about drinking less sugary drinks), *subjective norms* refers to personal evaluation of the approval of important individuals and motivation to comply with their approval (e.g., recognition that family members are trying to decrease sugar-sweetened beverage intake and desire to join their efforts), *perceived behavioral control* refers to the perceived power to act on facilitators or overcome barriers to enacting a behavior (e.g., confidence related to the skill to distinguish between sugary and non-sugary

drinks), and *behavioral intention* refers to the plan to change or engage in a behavior (e.g., stating in personal action plan the goal of reducing sugar-sweetened beverage intake by 10 ounces and overcoming relevant barriers with stated strategies).[5]

Interactive Systems Framework

Few healthcare organizations have documented use of an organizational or systems-based framework to guide organizational health literacy improvement efforts.[6-13] The work within Study 3 of this dissertation is framed by the Interactive Systems Framework (ISF).[14,15] The ISF includes both general capacity building and innovation-specific capacity building systems to advance the dissemination and implementation process. It consists of three systems: 1) the synthesis and translation system functions to condense information about interventions in preparation for use in the field, 2) the support system exists to simply support staff as they deliver an intervention, and 3) the delivery system refers to the actual implementation of interventions in the field.[15] While this work incorporates each of these three systems, it primarily focuses on the support system. This dissertation focuses on the general capacity building, namely the improvement of organizational health literacy capacity among four VDH districts. A detailed discussion of innovation specific capacity building (i.e., implementation of SIP*smart*ER) is again beyond the scope of this dissertation. In terms of capacity, dissemination and implementation efforts are most successful when strategies targeting both general and specific capacity are focused on. It is important not to bypass the foundational capabilities of an organization when targeting project-specific innovation.[15] The ISF was intentionally developed to intentionally draw upon the perspectives of various stakeholders.[15] In doing so, this ensures interaction of each of the three systems in order to improve implementation efforts

RE-AIM

While not explicitly a focus of this dissertation, it is important to provide background on the reach, effectiveness, adoption, implementation, and maintenance (RE-AIM) framework, used to frame both the Talking Health and SIP*smart*ER trials. The RE-AIM planning and evaluation framework emphasizes both internal and external validity, making it appropriate to use for both effectiveness research (e.g., Talking Health trial) and implementation research (e.g., SIP*smart*ER).[16] It is often used to lay the groundwork for potential translation of research into practice. In doing so, the RE-AIM framework This framework seeks facilitate the development, implementation, and evaluation of interventions with 5 key dimensions in mind: the ability to *reach* the intended target population, facilitate an *effective* intervention, urge *adoption* by key staff or organizations, and *implement* and *maintain* an intervention with consistency and longevity in a cost-efficient manner.[16] The framework emphasizes the importance of including each of these 5 dimensions when evaluating a program in order to conserve resources and improve public health efforts to improve health outcomes. However, each of these 5 dimensions are not always properly identified or operationalized as evidenced by recent systematic reviews.[17,18] Regardless of its widespread use and recognition of utility, a low number of interventions actually map out ways to improve reach, adoption, implementation, and maintenance outcomes.[18]

Introduction to the Literature Review

This literature review describes health literacy, consequences of low health literacy and health disparities particularly in the context of sugar-sweetened beverages and physical activity, and health literacy within the context of the healthcare system. The importance of pragmatic physical activity measurement among individuals of varying health literacy status is explored. Additionally, the importance of determining if amount of change in sugar-sweetened beverage

intake predicts changes in variables such as weight, BMI, and quality of life is emphasized, and the potential of health literacy as a moderator of this relationship is discussed. The transition of individual- to organizational-level health literacy is thoroughly described to provide context for the importance of improving capacity for organizational health literacy. One key part of such improvement efforts is measurement, and existing measures and tools used to assess and intervene upon organizational health literacy are described, along with commonly used measures of health literacy at the individual level.

Health Literacy and Health Disparities

Health literacy is defined as the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.[19] Over 36% of American adults are affected by low health literacy across all demographics. Elderly adults, minority populations, disabled individuals, those of low economic status, and with less than high school education are more likely to be low health literate.[20,21] Nearly half of the adult population lack sufficient health literacy skills to enable them to understand and properly act on health information and the demands of the healthcare system.[22] Additionally, only 12% of U.S. adults have high enough health literacy to perform complex health behaviors related to personal care or care of others.[21] Low health literacy has been associated with poorer self-reported health status, lack of ability to engage in self-care or manage chronic conditions, and less use of preventive services such as immunizations and screening. With low health literacy, individuals are more likely to improperly use medications and misinterpret prescription labels or related health messages.[23] Individuals with low health literacy are at higher risk for experiencing higher systolic blood pressure, poor glycemic control, higher rates of hospitalization and longer stays, insufficient knowledge of post-discharge treatment plan, and being less prepared to manage chronic disease(s).[24] Additionally, low health literate

individuals typically have higher emergency room costs and annual healthcare costs when compared to those with higher health literacy.[25,26] One estimate shows limited health literacy costs the United States between $50 and $73 billion per year.[26]

These findings are a result of the "health literacy epidemic", and for almost two decades research has centered on understanding the mechanisms behind health literacy.[27] Health literacy is a multidimensional concept, and in a systematic review of health literacy definitions and models, Sørensen and colleagues define 12 health literacy conceptual models.[28] The forerunner, a model described by Nutbeam, classifies health literacy as containing three typologies, functional health literacy (i.e., basic reading and writing skills needed to complete day to day functions),[29] interactive health literacy (i.e., advanced cognitive and literacy skills and social skills used to be active participants in day to day life), and critical health literacy (i.e., advanced cognitive and literacy skills and social skills used to critically analyze information to employ control over day to day events).[30] Sørensen and colleagues detail the 11 other conceptual models that built upon Nutbeam's by adding dimensions such as medial literacy, cultural literacy, civic literacy, and science literacy.[28]

There is a clear association between health literacy and health outcomes.[23]However, what has yet to be well-defined is why this association exists. Existing frameworks put forth by Paasche-Orlow and Wolf and by von Wagner and colleagues suggest that health literacy status impacts individuals' knowledge, health behaviors, and self-efficacy which accordingly influences health outcomes.[31,32] Over the past decade, the number of health literacy-focused interventions has increased both in quantity and quality,[23,33] under the premise that incorporating health literacy strategies will lessen the effects of low health literacy and ensure interventions are appropriate.[34] Systematic reviews have been conducted to determine the relationship between health literacy and health outcomes and to determine effective intervention strategies for various

health conditions such as diabetes,[35] cardiovascular disease,[36] cancer screening,[37] and overweight and obesity[38]. While results from each review were mixed, the consensus is that more research is needed to explore the relationship between health literacy and health outcomes, and intervention strategies that attempt to influence this relationship. Examples of intervention strategies include (but are not limited to) using teach-back or Ask Me 3 methods to confirm participant understanding, using/modifying appropriate written materials using principles of plain language and clear communication, emphasizing interpersonal interactions, using action-planning and self-monitoring, and providing content and delivery with language and cultural practices/beliefs in mind.

Health Literacy as a Moderator

Although health literacy interventions are of no shortage, published papers that incorporate statistical techniques to test health literacy as a moderating variable are lacking.[23,33] A moderator is a variable that influences the strength of a causal relationship.[39] For example, health literacy could be a moderator if an intervention worked differently for low versus high health literate individuals; that is, health literacy could be affecting the strength of intervention effectiveness. A mediator is a variable that lies on the causal pathway, and explains the relationship between the independent variable on the dependent variable.[39] For example, health literacy could be a mediator if an intervention changed health literacy status, and this resultant change influenced intervention outcomes; removing this mediation effect of health literacy may abolish the intervention effect as in this case, health literacy is on the causal pathway. In a systematic review of health literacy-related health promotion interventions, only 8 out of 25 interventions reported conducting a moderation analysis across different levels of health literacy. Findings from these interventions showed mixed results as to just how much health literacy status influenced the effectiveness of interventions.[33] In particular, the influence of health

literacy status on health behaviors and weight outcomes has not been thoroughly explored.[23,33,40] In sum, there is a gap in the literature related to how individual-level health literacy status may moderate changes in health behaviors and outcomes, including physical activity and weight. It is important to know if interventions have similar effects for individuals of low and high health literacy, particularly in health disparate populations.

Often mentioned and associated with health literacy, health disparities are differences in health that occur by particular categories, namely gender, race or ethnicity, income and education, disability, living in a rural locality, or sexual orientation.[41] Health disparities are not straightforward, but rather complex, as they result from a multitude of factors such as socioeconomic, environmental, psychosocial, structural, and healthcare-related.[42] These factors are closely tied to determinants of health, which can influence individuals' ability to take action towards good health and availability of choices or opportunities one has (e.g., early childhood development, educational attainment, access to food, access to healthcare services, social support).[43] Both low health literacy and health disparities predispose individuals to risk, specifically as it relates to healthcare; such individuals are more likely to have poorer healthcare quality, outcomes, and access to proper care. Some have touted health literacy as a health disparity in itself, meaning that health literacy has been found to be associated with many defined health disparities, such as minority racial and ethnic groups and poor educational attainment.[21,44,45] Others have relied on the fact that it may be possible to alter health literacy status, which would ease the burden of particular health disparities.[46,47] However, the relationship between health literacy and health disparities remains ambiguous.[48]

Health Behaviors of Interest

Studies 1 and 2 of this dissertation focus on sugar-sweetened beverage intake and physical activity behavior among a population of varying health literacy status. This section provides background on these two behaviors.

Sugar-Sweetened Beverage Intake

Sugar-sweetened beverages are any non-alcoholic liquid sweetened with any variety of added sugar, such as regular soda, energy drinks, fruit drinks, sports drinks, sweetened water, and coffee and tea with sugar added. As a new addition from previous editions, the latest 2015-2020 Dietary Guidelines for Americans recommends that daily intake of added sugars not exceed 10% of total calories.[49] However, almost half (49%) of adults nationwide reported drinking one sugar-sweetened beverage daily.[50] Overconsumption of sugar-sweetened beverages has been shown to lead to overweight and obesity, type 2 diabetes mellitus, cardiovascular disease, dental caries and tooth decay, and kidney disease.[51-55] The national obesity crisis cannot be ignored; around 36% (about 84 million) adults were classified as obese (body mass index of $\geq$30kg/m^2) between 2011-2014, predisposing them to higher risk for aforementioned chronic diseases.[56]

Adults that reside in rural areas are more likely to consume higher amounts of sugar-sweetened beverages, and are more likely to also be frequent consumers of fast-food meals, have low fruit and vegetable intake, and identify as food insecure.[57] Additionally, national data from NHANES and the Behavioral Risk Factor Surveillance System survey showed that daily sugar-sweetened beverage intake was higher among individuals with lower socioeconomic status.[58,59] Additionally, adults that identify as low health literate consume greater amounts of sugar-sweetened beverages when compared to higher health literate counterparts.[60,61]

Physical Activity Behavior

The recommendation put forth by the Physical Activity Guidelines for Americans, published by the United States Department of Health and Human Services, is that adults participate in at least five days of at least thirty minutes of moderate-to-vigorous cardiovascular activity, and at least two days of muscle strengthening activities per week.[62,63] However, according to an early release of data from the 2015 National Health Interview Survey, less than half (49%) meet cardiovascular recommendations, while less than a quarter (21%) reach the standard for muscle strengthening activities.[64] Including both cardiovascular and strengthening activities are important, and one cannot replace the other. Unfortunately, 2015 data show that 79% of adults did not meet recommendations for both forms of physical activity.[65]

Individuals who engage in physical activity on a regular basis can prevent various chronic diseases such as cardiovascular disease, type 2 diabetes mellitus, metabolic syndrome, obesity, and certain cancers.[66] According to the CDC, chronic diseases are the leading cause of death and disability in the United States. Additionally, such diseases are the most prevalent (half of all American adults have at least one chronic condition), most expensive, but most preventable health problems.[67] Those with poor health are more likely to have lower levels of PA-related self-efficacy, motivation, and intention, and in turn health literacy status may also influence PA behaviors.[32,68]

Health Behavior Measurement

Sugar-Sweetened Beverage Intake

Sugar-sweetened beverages are the primary source of added sugar in the diet of U.S. adults, measurement of beverage intake habits is necessary when intervening to improve health.[69,70]and The BEVQ-15 is a brief dietary assessment tool that consists of 15 items that assess habitual intake of beverages in terms of frequency and amount of consumption. Contrary to lengthier and limited measures such as food intake records and 24-hour recalls, this food

frequency questionnaire takes about 2 minutes to deliver and can be quickly scored which supports delivery of immediate feedback regarding beverage. The BEVQ-15 has been found valid and reliable in adults of varying health literacy status in both interviewer -administrated form and computer audio assisted platform.[71-73]

Physical Activity Behavior

Practical measures are needed for the standardized assessment and detection of clinically meaningful change in physical activity in a population with varying health literacy status.[62,74] Current physical activity self-report measures work well at distinguishing between individuals who meet or do not meet physical activity recommendations. According to systematic reviews of existing measures and their measurement properties, however, such measures fail to systematically define activity levels beyond this dichotomy, especially when it comes to classifying levels of physical activity in inactive populations well below the recommendation.[75-77] The Stanford Leisure-Time Activity Categorical Item (L-Cat), a brief single-item measure of leisure-time PA that has been validated against an objective measure of PA (i.e., Omron dual-axial pedometers) shown to be valid, reliable, and able to detect changes in PA over time[78] and the Godin Leisure Time Exercise Questionnaire (GLTEQ), a four-item measure that was developed to assess the frequency (i.e., number of times per week) of three intensities of leisure-time PA over a typical seven-day time period[79,80] demonstrate potential to overcome barriers exhibited by commonly used physical activity self-report measures to reduce participant and researcher burden, and enhance responsiveness.[78,79] It is important to determine the utility of these measures with both low and high health literate individuals.

Health Literacy and the Healthcare System

Like health literacy itself, the healthcare system is complex. The healthcare system requires individuals to go through multiple cognitive and social processes, many of which are demanding beyond comprehension.[22] Most of the time, health information is harder to comprehend than other types of information.[81] Most Americans, nine out of ten adults, have a difficult time using health information that is available in healthcare facilities, retail outlets, in the media, and within the community.[82] Health literacy reflects the dynamic interplay between individual knowledge and skills and the demands of the healthcare system.[83] That is, demographic, socioeconomic, and existing health factors influence health literacy status, which in turn likely influences healthcare access and utilization, the relationship between patient and healthcare practitioner, and quality of self-care.[31] These interactions can play a role in determining health status and outcomes.[22] Even so, adults who are not readily classified as low health literate by a healthcare provider still have potential to demonstrate poor understanding of and adherence to healthcare information, as health literacy can be situational.[28,84]

The Transition of Health Literacy

Initiatives to raise awareness of and improve health literacy strongly complement a current cultural transition of the healthcare system. The culture of healthcare in America is undergoing an evolution from being hierarchical, autonomous, and expert-centered to being a collaborative, team-based, patient-centered entity.[85] This transition is of utmost importance when considering the increase in diversity and unique demands that the United States will continue to see in the upcoming years.[85] At the turn of the 21st century, health literacy was pinpointed as a national priority area by the Institute of Medicine's (now National Academy of Medicine) *A Prescription to End Confusion*.[22] As thoroughly explored by Dr. Rima Rudd in the *Surgeon*

General's Workshop on Improving Health Literacy in 2006, health literacy requires a two-sided approach. To adequately assess and intervene upon health literacy, one must acknowledge the demand sides (i.e., what the healthcare system requires) and the skill side (i.e., the individual capacities to respond to such demands of a system). Thus, Dr. Rudd determined that actions taken by the healthcare system to decrease the demands on individuals, and initiatives taken to determine individuals' skills are areas for improvement.[86] Furthermore, the Joint Commission played a role in proposing relevant standards in 2010, synonymous with their mission of providing high quality, safe care. These standards underscore the importance of effective communication, cultural competence, and patient-centered care.[87]

Health literacy improvement was further emphasized by policy and legislation just over a decade ago. The importance of incorporating health literacy strategies was first highlighted by the National Health Literacy Act of 2007 and the Plain Language Act of 2009. Over the almost past decade, it has been recognized that rather than solely focusing on the individual, systems-level efforts are needed to alleviate burden individuals face.[14] Further encouraged by requirements set forth in Patient Protection and Affordable Care Act and Plain Writing Act of 2010 (PPACA), organizations were urged to help their clients easily find and clearly comprehend health information.[88,89] As the foundation of the PPACA, the Institute for Healthcare Improvement's Triple Aim defines three arenas in which U.S. healthcare delivery can be enhanced. The goals of the Triple Aim are to reduce cost of care, improve health outcomes of populations, and improve patient experiences.[90] As these recommendations to enhance care were carried forth by the U.S. Department of Health and Human Service's *National Action Plan to Improve Health Literacy* in 2010,[22,82] system-level efforts to improve health literate care began to surface,[91,92] and the term organizational health literacy was coined.

Organizational Health Literacy

Organizational health literacy refers to the implementation and monitoring of organizational policies, practices, and structures that support patients in understanding health information, navigating the healthcare system, and managing their health.[14] Closely tied to quality improvement efforts, healthcare systems can take steps to decrease complexity to become more accessible to limited health literate populations.[93] Healthcare systems that embody organizational attributes (e.g., positive interaction with front desk staff) and emphasize patient engagement may have greater influence on patient health behaviors and outcomes, regardless of health literacy status.[94] Healthcare professionals that are aware of and enact health literacy strategies have been shown to improve patient outcomes and self-care ability, in addition to increasing self-efficacy and understanding. To sustain a health-literate healthcare environment, training and educating health professionals in all disciplines on the use of health literacy best practices is highly recommended.[95,96] However, Schillinger and Keller caution against summarizing organizational health literacy as simply improving the communication and interactions between patient and provider. Instead, organizational health literacy improvement includes multiple elements, ranging beyond the improvement of healthcare providers and patients to include strategic and leadership commitment, inclusion of health literacy in policy, patient-centered healthcare infrastructure, and overall higher level of expertise among the workforce to deal with population of varying health literacy status.[97] To make this tangible for healthcare organizations, the Institute of Medicine Health Literacy Roundtable defined 10 Attributes of Health Literate Organizations (10 Attributes). The 10 Attributes represent characteristics organizations embody that enable their clients and patients to better navigate, understand, and use information and services to properly manage their health, and serve as a benchmark of success to those intervening to improve.[14] Much of existing organizational health

literacy work has focused on the assessment and training of healthcare professionals according to key tenants from the 10 Attributes.

While comprehensive reviews of those who have explored organizational health literacy improvement are lacking, certain facilitators and barriers to success have emerged from the literature.[91,92,98] Key approaches to successful organizational health literacy improvement were tied to using more comprehensive, systems-based, or organizational approaches rather than isolated health literacy improvement strategies.[6-13] Additionally, ongoing support and promotion of improvement efforts by senior leadership was particularly important.[9,99-105] Organizations who utilized pragmatic tools or interventions were also more likely to experience success improving organizational health literacy capacity. Tools that were adaptable to organizations' needs, and low-intensity interventions that were implemented in small, steady increments helped to facilitate change.[7,8,11,106,107] Riffenburgh and colleagues summarize this well: "use of adaptable resources is helpful, but there are tools that need to be developed within an organization because they should be context-specific for politics and structure of a specific organization."[101] A common barrier identified was the large amount of organizational commitment required, low system capacity for change, and limited or no leadership support, which made it difficult for organizations to take steps to become health literate organizations.[11,108-110] Likely a result of healthcare delivery systems not supporting organizational change, studies reported lack of perceived importance, desire to change, and buy-in among all staff, especially clinicians and physicians.[103,111-114] Finally, many existing organizational health literacy improvement resources are geared towards the primary care setting, and a few studies reflect on the difficulty providing training that would be suitable for a variety of different types and disciplines of healthcare professionals.[109,115,116]

Health Literacy Measurement

Individual-Level Measurement

Until recently, measurement of health literacy has centered on individual-level health literacy, but organizational-level measures have begun to emerge over the past decade. Individual-level health literacy measurement tools aim to identify those who are at risk for low health literacy. Such tools are often used by researchers to both document the health literacy status of study participants and be able to control for health literacy status statistically. Additionally, healthcare professionals use these tools to determine the understanding, comprehension, and related abilities or needs of their patients. It is helpful for both researchers and healthcare professionals to have valid, reliable, and brief tools that accurately assess health literacy status. The Health Literacy Tool Shed is a repository of over 100 evidence-based and research-tested measures of individual-level health literacy, funded by the National Institute of Health's National Library of Medicine.[117] Use of over 35 reliable and valid tools have been documented in the literature.[118] Three of the most commonly used measures are the Test of Functional Health Literacy for Adults (TOFHLA), Newest Vital Sign (NVS), Rapid Estimate of Adult Literacy in Medicine (REALM).[29,119,120] The TOFHLA was originally 50-items, but has since been shorted to 40.[29,121] However, it is difficult for a single measure to fully capture health literacy. The majority of health literacy measurement tools have focused on assessing functional health literacy within a clinical setting, as healthcare providers often overestimate health literacy status of their patients and clients.[122,123] However, universal testing can be cumbersome, and has been known to unintentionally stigmatize individuals of low health literacy status.[122] Thus, the trend is shifting away from relying on measures of individual health literacy, and more towards implementing a universal precautions approach when interacting with clients (i.e., treating each client as if they may be at risk of not understanding health information).[124]

Organizational-Level Measurement

With this in mind, organizational health literacy measurement tools began to emerge. These tools seek to gather information from patients, healthcare professionals, and/or leadership to establish need and develop and implement meaningful improvement plans. These system-level efforts require thorough measurement throughout this process, and measures should be based upon what the field has learned thus far and emphasize performance-based measures across multiple levels. Around 68 existing organizational health literacy measurement tools have been thoroughly reviewed by Kripalani and colleagues. Of these, 29 (43%) tools assessed ≥1 of the 10 Attributes, while just 12 (18%) tools addressed ≥5 of the 10 Attributes.[98] Standardized and optimal measures for particular settings and contexts have yet to be defined. Additionally, many measurement tools are contained within toolkits and frameworks developed both nationally and internationally to help healthcare organizations increase the capacity for health literate care. A number of these cover almost all 10 Attributes, including the Agency for Healthcare Research and Quality Health Literacy Universal Precautions Toolkit (AHRQ Toolkit)[124] and Pharmacy Health Literacy Assessment Tool,[125] the American Medical Association's Communication Climate Assessment Toolkit,[126] Rudd and Anderson's Health Literacy Environment of Hospitals and Health Centers,[127] the Joint Commission's Advancing Effective Communication, Cultural Competence, and Patient- and Family-Centered Care: A Roadmap for Hospitals,[87] Other notable resources include Unity Point Health's "Building Health-Literate Organizations: A Guidebook to Achieving Organizational Change"[128], Minnesota's Health Literacy Toolkit[129], and the Centers for Disease Control and Prevention resources[130].

One of the most cited resource used to frame organizational health literacy improvement efforts in the U.S. is the AHRQ Toolkit.[12,13,99,107,110-112,131-146] This Toolkit is one of few that

address each of the 10 Attributes.[14,98] It has proven effective in multiple primary care practices, utility has been observed in other settings as well (e.g., community-based clinics, pharmacies, and health insurance domains).[147,148] The AHRQ Toolkit is a compilation of 21 evidence-based tools, that adhere to the universal precautions approach (i.e., treating all individuals as if they are unable to understand health information), used to assist healthcare organizations in promoting health literate practices.[124] Tools and resources provided are framed by four domains of health literacy (i.e., spoken communication, written communication, self-management and empowerment, and supportive systems).[98] The AHRQ Toolkit was initially developed for primary care settings, but was created to be adapted to fit the needs of other systems.

In a review of health literacy assessment tools, it is concluded that in order to establish a meaningful framework and measurement tools, community members or stakeholders should be involved in the research process from beginning.[149] Although intervening at the systems-level is necessary, the true measure of effectiveness is not the self-perception of providers to employ health literacy strategies, nor is it the external auditor's opinion of the readability of available patient education materials. The true measure of effectiveness, the driver of sustainability and resources, and motivation at all levels is the individual patients' health outcomes. However, certain limitations could make this difficult to achieve such as the transitory nature of the healthcare system and the resource- and labor-intensive efforts needed to capture meaningful change in patient outcomes. Ideally, organizational health literacy measurement tools should aim to assess all involved parties (e.g., patients, clinicians, staff, administrative leadership, organizational staff, and families) and should strive to include objective measures rather than solely inquiring on the perception of how a healthcare system is performing. Quantitative measures that include ratio-level items rather than relying on dichotomous outcomes should be

emphasized, and qualitative items should accompany this data to expand on the "how" and "why" organizational health literacy practices are the way they are.[98]

Health Literacy and Health Disparities: The Study Population

In addition to the nation-wide call for health literacy action at the systems-level, the Virginia Department of Health has recently set forth complementary objectives. Virginia has not engaged in an organizational health literacy improvement effort to date, but health-literacy specific strategies are included in the 2016 statewide "Virginia's Plan for Well-Being". The Plan details a series of targets aimed to improve access to healthcare for all residents and for health to establish an environment supportive of health promotion. The three overarching goals of the Virginia's Plan for Well-Being mirror the Institute for Healthcare Improvement's Triple Aim: to improve healthcare quality, improve the health of populations, and reduce per capita cost of healthcare. The plan includes specific and measurable goals and details strategies to reach these goals, two of which directly address health literate care: "to develop patient-centered health communications that have a positive impact on heath, healthcare, and health equity" and "to increase the number of providers, lay health advisors, and volunteers trained in health literacy to provide one-on-one education in medical, community, worksite, and household settings".[150]

In addition to the previously described nationwide disparities related to health literacy and behaviors such as sugar-sweetened beverage intake and physical activity, the need in Virginia is evident. Each of the three studies in this dissertation take place in rural, Appalachian southwest Virginia, an area classified as medically underserved, and also an area of considerable health disparities which predispose residents to physical activity and dietary inequalities.[151-154] The mean annual income in Virginia is $62,745, while the mean of the study counties was $39,922 (range $32,092 - $46,024).[152] Six out of eight (i.e., Lee, Pulaski, Washington, Grayson, Wise, and Wythe) counties had a higher percentage of individuals stating poor or fair health,

with Lee and Wythe county almost doubling the percentage of individuals who cited poor quality of life for this reason.[152] Across each of the eight counties, individuals are less likely to be insured, there is a higher ratio of population to primary care physician, and higher incidence of preventable hospital stays.[152] Only 65% of the target population has adequate access to one or more places to safely engage in physical activity (Virginia state average=of 81%), and consequently, 28% of the population is considered physically inactive (Virginia state average=22%).[152] Adults that reside within Appalachian southwest Virginia consume $\geq$3 times the national average amount of sugar-sweetened beverage consumption.[155] It is important to reiterate that low health literate adults consume more sugar-sweetened beverages, since the specific population of focus is of varying health literacy status, likely affected by low health literacy.[60,61] Initial findings from the Talking Health study, the parent trial of Study 2 and 3, show that SIP*smart*ER, a theory-based intervention developed with health literacy strategies was effective at decreasing sugar-sweetened beverage intake.[2] Existing literature shows that decreases in added sugar intake, and decreases in sugar-sweetened beverage intake significantly reduced body weight.[156,157] The relationship between sugar-sweetened beverage intake and body mass index is not as straightforward. A systematic review and meta-analysis of similarly intentioned randomized controlled trials revealed that sugar-sweetened beverage consumption did not have an overall effect on BMI, although overweight participants did experience a non-statistically significant decrease in BMI.[158] Other randomized controlled trials have shown slight decrease in BMI as a result of intervention to reduce sugar-sweetened beverage intake.[2,158] Also, Malik and colleagues state that for each daily serving of sugar-sweetened beverage consumed, adults would experience an incremental increase in BMI over a period of a year.[51]

Justification for Dissertation Studies

There is a clear need to lessen the burden of low health literacy. The three studies within this dissertation address this need in three ways by demonstrating an organizational health literacy improvement effort, assessing physical activity measures for utility within a low health literate population, and examining the relationship between change in sugar-sweetened beverage intake and change in weight and quality of life outcomes and exploring if and how findings differ by health literacy. Study 1 aims to test the utility of two physical activity measures with a population of varying health literacy status with hopes of coming closer to identifying pragmatic standardized assessment of and detection of clinically meaningful change in physical activity behaviors. Study 2 expands upon existing research that has determined that a decrease in sugar-sweetened beverage intake can result in a decrease in weight and BMI, and improvement in quality of life. What has yet to be explored is the relationship between levels change of sugar-sweetened beverage intake and levels of change outcomes (i.e., weight, BMI, and quality of life); determining if those that show greater improvements in intake are more likely to experience more weight loss, and if these relationships vary among participants of varying health literacy status could contribute new insight to this body of literature. Study 3 responds to national and state-wide initiatives by conducting a mixed-methods needs assessment and subsequently forming an organizational health literacy improvement plan. This study also contributes to the literature base by providing detail of the first use of the AHRQ Toolkit within a public health setting.

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CHAPTER 2: MANUSCRIPT 1 "THE RELATIONSHIP BETWEEN THE STANFORD LEISURE-TIME ACTIVITY CATEGORICAL ITEM AND THE GODIN LEISURE-TIME EXERCISE QUESTIONNAIRE AMONG RURAL INTERVENTION PARTICIPANTS OF VARYING HEALTH LITERACY STATUS"

Kružliakova N, Estabrooks P, You W, Hedrick V, Porter K, Kiernan M, Zoellner J. The relationship between the Stanford Leisure Time Exercise Questionnaire and the Godin Leisure-Time Exercise Questionnaire among rural intervention participants of varying health literacy status. (In Press, The Journal of Physical Activity and Health, accepted October 2017)

Abstract

Background: A pragmatic, self-reported physical activity measure is needed for individuals of varying health literacy status.

Methods: This study is a secondary analysis of a 6-month behavioral intervention for rural Appalachian adults developed using health literacy strategies. We examined the relationship and responsiveness of the Stanford **L**eisure-Time Activity **Cat**egorical Item (L-Cat) and adapted Godin Leisure-Time Exercise Questionnaire (GLTEQ) and determined if baseline health literacy status moderates intervention effects.

Results: Of 301 enrolled participants, 289 completed the L-Cat at baseline and 212 at six-months. Approximately 33% were low health literate and 43% reported annual income of ≤ $14,999. There was high agreement (84.1%) between the L-Cat and adapted GLTEQ for classifying individuals as meeting physical activity recommendations, with little difference by health literacy level (low literacy 80.4%, high literacy 85.9%). The primary source of incongruent classification was the adapted GLTEQ classified almost 20% of individuals as meeting recommendations whereas the L-Cat classified them as not meeting recommendations. There were differences in responsiveness between measures, but baseline health literacy status did not moderate change in any L-Cat or adapted GLTEQ measures.

Conclusion: Implications and recommendations for using the L-Cat 2.3 and GLTEQ among individuals of varying health literacy status are discussed.

Introduction

Regular physical activity (PA) has been shown to prevent or delay onset of multiple chronic diseases such as cardiovascular disease, type 2 diabetes mellitus, metabolic syndrome, obesity, and specific types of cancers.[62] United States PA guidelines recommend that adults engage in at least five days of thirty minutes or more of moderate-to-vigorous cardiovascular activity and at least two days of muscle strengthening activities per week.[58,59] Too few U.S. adults meet PA recommendations; approximately 49% of adults meet recommendations for aerobic activity, and only 21% meet strengthening activity recommendations.[60] Less active adults are more likely to have poor overall health status, increased risk of preventable chronic disease, and decreased functional capacity.[59]

Individuals with poor health status are more likely to have lower levels of PA-related self-efficacy, motivation, and intention.[64] Health literacy status may also influence PA behaviors.[65] Health literacy can be defined as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions".[157] Those with low or limited health literacy are more likely to experience poor health outcomes and be less able to properly self-manage their health or engage in preventive behaviors.[23] Health literacy-sensitive interventions have shown to effectively increase health promoting behaviors in adults.[31,158] While several prior studies have explored the relationship between health literacy and PA behaviors, most are cross-sectional and many do not use a validated measure of PA.[40,159-165] Of the studies that assessed PA using a validated PA recall questionnaire[159-161,163,164,166,167], the majority used lengthier (i.e., >10 items) and complex (i.e., assesses frequency and duration of several activities) measures such as the 7-day Physical Activity Recall Interview (7-day PAR).[166]

Pragmatic measures are needed for standardized assessment and detection of clinically meaningful change in PA in populations of varying health literacy status.[58,71] Existing self-report measures are successful at distinguishing between individuals who do or do not meet PA recommendations but come up short when attempting to systematically define activity levels beyond this dichotomy, especially inactive populations.[72-74] Further, such measures can be difficult to interpret and some lack responsiveness (i.e., the ability of an instrument to detect change over time in the construct measured).[168] The Stanford Leisure-Time Activity Categorical Item (L-Cat) and the Godin Leisure Time Exercise Questionnaire (GLTEQ) demonstrate potential to overcome barriers exhibited by commonly used PA self-report measures to reduce participant and researcher burden, and enhance responsiveness. The L-Cat is a brief single-item measure of leisure-time PA that has been validated against an objective measure of PA (i.e., Omron dual-axial pedometers) shown to be valid, reliable, and able to detect changes in PA over time.[75] There is potential utility of the L-Cat in a low health literate population as the instrument was developed to be easily comprehended with each category accompanied by unambiguous examples of relevant activities. The GLTEQ is a four-item measure that was developed to assess the frequency (i.e., number of times per week) of three intensities of leisure-time PA over a typical seven-day time period.[76] This instrument has been validated against accelerometers[77,169], VO_2 max (i.e., maximal oxygen consumption), and percentage body fat[170,171]. The L-Cat and GLTEQ have proven useful in adults who fall below the PA recommendations, but neither has been used among individuals of varying health literacy status.[75,77,172]

Objectives

Data for this manuscript are from the Talking Health trial, a randomized controlled trial in which participants were randomized into a PA behavioral intervention (i.e., MoveMore) or a sugar-sweetened beverage behavioral (SSB) intervention (i.e., SIP*smart*ER).[1] Focused on health

literacy, the overall goal of this secondary data analysis is to 1) explore the relationship between the L-Cat and adapted GLTEQ overall and by health literacy status, 2) examine the responsiveness (i.e., ability to capture six-month change in PA behaviors) of the L-Cat and adapted GLTEQ, and 3) determine if baseline health literacy status moderates intervention effects on L-Cat and GLTEQ measures. We hypothesize that 1) there will be high agreement among L-Cat and GLTEQ for meeting PA recommendations, 2) both the L-Cat and adapted GLTEQ would demonstrate responsiveness, and 3) agreement and six-month change according to the L-Cat and GLTEQ will not be moderated by baseline health literacy status (i.e., PA behaviors according to the L-Cat and adapted GLTEQ will not significantly vary between low and high health literate groups). The significance of this work, however, lies in the potential that our hypotheses are not met resulting in the need to refine or develop measures for participants with varying levels of health literacy

Methods

Study Design

Talking Health is a type 1 effectiveness-implementation hybrid randomized controlled trial that took place between March 2012 and November 2015. This trial was developed using the RE-AIM planning and evaluation framework,[16] the Theory of Planned Behavior,[5] and health literacy strategies.[2] The RE-AIM planning and evaluation framework was chosen to lay the groundwork for potential translation of research into practice.[1] Briefly, this framework seeks facilitate the development and evaluation of interventions across 5 constructs: ability to reach the intended target population, facilitate an effective intervention, urge adoption by key staff or organizations, implement and maintain an intervention with consistency and longevity in a cost-efficient manner.[16] In this context, intervention messages were framed according to the constructs of the Theory of Planned Behavior and health literacy strategies to positively

influence health behaviors. The TPB has been shown to predict and explain health behaviors, and surmises that behavior is determined by both behavioral intention (i.e., an individual's intent to perform a behavior) and perceived behavioral control (i.e., an individual's perception of control over performing a behavior).[5] Additionally, chosen health literacy strategies (i.e., clear communication, teach-back method, media literacy, numeracy) emphasize a culturally sensitive intervention and increase the likelihood of behavior change.[1] Participants were randomized into one of two matched-contact six-month behavioral interventions, MoveMore or SIP*smart*ER. The structure of both conditions consisted of three small-group classes, one live teach-back call, and eleven automated Interactive Voice Response calls. A detailed description of intervention structure, content, methods, and outcomes can be found elsewhere.[1,2]

MoveMore. MoveMore focused on improving PA behaviors and emphasized the importance of achieving 150 minutes of moderate-intensity aerobic activity and doing muscle-strengthening activities on 2 or more days per week.[1] MoveMore was adapted from an effective group-based PA program developed using group dynamics principles.[173,174] Class content included PA promotion, specifically education about benefits of meeting PA recommendation, risks of inadequate PA, and strengthening activity instruction. The live teach-back call incorporated a guided review of key concepts from first class along with self-monitoring support and guidance.[175] The automated IVR calls reinforced class content, facilitated goal-setting and continual self-monitoring, and served as accountability reminders.[176] Participants also received a resistance band to encourage strengthening activities and a "Walk Indoors!" DVD, an at home structured exercise program inclusive of aerobic and strengthening activities developed for a limited resource population.[177] In brief, MoveMore was effective at increasing reported L-Cat category and GLTEQ weekly moderate-to-vigorous physical activity (MVPA) and strengthening

exercise.[2] However, relationships among L-Cat category and GLTEQ or moderation of changes by health literacy status have not been explored.

SIPsmartER. SIP*smart*ER focused on reducing SSB to eight fluid ounces or less per day.[178] In brief, SIP*smart*ER was effective at decreasing SSB consumption, improving overall diet quality, and improving BMI.[179] In this secondary data analysis of the Talking Health trial, SIP*smart*ER provides comparison condition data.

Study Setting

This study took place in an eight-county region in rural, Appalachian southwest Virginia. This area is classified as medically underserved and has considerable socioeconomic inequalities which predisposes residents to PA disparities.[149,150] Within this eight-county region, data from the Robert Wood Johnson Foundation's County Health Rankings indicates only 65% of the target population have adequate access to one or more places to safely engage in PA compared to a state average of 81%. In addition, 28% of the adult population is considered physically inactive (i.e., report no leisure-time physical activity), which exceeds the state average of 22%.[150]

Participants

Eligible participants were English-speaking adults who were at least 18 years old and who had consistent telephone access, no self-reported contraindications to engaging in PA, and an average self-reported SSB intake of ≥200 kilocalories per day. As described in detail elsewhere, both active and passive recruitment methods were employed.[180] In total, 1056 individuals were screened and 620 were eligible. Of these, 301 participants were enrolled with 146 randomized into MoveMore and 155 into SIP*smart*ER. PA instruments were completed by

289 participants at baseline and 212 participants at six-months (105 MoveMore, 107 SIP*smart*ER).

The study protocol was approved by the Virginia Tech Institutional Review Board. Participants completed written informed consent prior to beginning the study and received compensation in the form of gift cards for participating in pre- and post-data assessments ($25 and $50, respectively).

Measures

When participants were screened for eligibility, demographic information (i.e., sex, age, race, ethnicity, employment status, income, educational attainment, and number of children per household) was obtained. All other variables were measured at baseline and six-month data assessments. Health literacy was assessed by the interviewer-administered Newest Vital Sign, a validated six-item questionnaire of health literacy status used to identify individuals at risk for low health literacy based on comprehension of a nutrition facts label.[117] Health literacy level was scored categorically according to standardized protocol (i.e., low health literate= 0-3 answers correct, high health literate= 4-6 answers correct).[117] Anthropometric assessments included height and weight collected using standardized protocol and BMI scores were calculated.

For the PA measures, a computer-audio assisted platform was used to assess L-Cat (version 2.3) and an adapted GLTEQ was interviewer-administered.[24,41] Table 2.1 details format, content and scoring of these instruments. The L-Cat is a one-item questionnaire that estimates time spent engaging in leisure-time physical activity over the past month by self-categorization into one of six categories, ranging from inactive to very active. Categories list examples of activities according to frequency, duration, and intensity.[75] Participants who report categories 4-6 are classified into meeting recommendations. Given the audio assisted platform for this study, a

slight adaptation was made to the validated second version of L-Cat; language was changed from first to second person. Also, the language "leisure time" was changed to "free time" to support the literacy barriers of the population.

The original GLTEQ is a four-item measure. The first three questions ask about frequency (i.e., number of days per week) of leisure-time mild, moderate, strenuous activities over the past week, with example activities included for each intensity. The weekly frequencies are scored using a simple equation: (9 × strenuous) + (5 × moderate) + (3 × mild). The fourth question includes one sub-question about how often engagement in exercise caused an individual to work up a sweat, in which respondents can choose never/rarely, sometimes, or often. Although not scored, this response can be used to gauge individuals' perceived effort. [76,77] Reflective of research that employs the GLTEQ, an adapted version of the GLTEQ was used to assess duration (i.e., minutes per bout) in addition to frequency of activities.[181] The adapted instrument added an assessment of strengthening activities in addition to the three intensities of cardiovascular activities. The adapted GLTEQ was scored by computing average weekly minutes of MVPA, strengthening activities, and total PA. This scoring protocol allowed for assessment of achievement of PA recommendations; participants who reported ≥150 minutes of MVPA per week were classified as meeting recommendations.[59] "Recall of PA behaviors over a longer, non-defined period of time (e.g., typical week, typical month) is more complex than recall of behavior over the past week[182]; this difficulty is likely exacerbated in the low health literate population.[183] A recent review reports that psychometric quality of past week versus typical week recall methods hardly vary.[184] Thus, as a final adaptation, language was altered (i.e., reference period was changed from "past week" to "typical week") to decrease participant recall burden[185]; recalling past week's activities could be less complex due to recency of behaviors.[186]

Analysis

Data were entered into SPSS software, Version 24.0 (International Business Machines Corporation, Pittsburgh, PA). Descriptive statistics were used to summarize demographics, health literacy, L-Cat and GLTEQ measures. Using validated scoring procedures, the L-Cat and GLTEQ were treated both continuously and categorically (i.e., meet versus does not meet PA recommendations). For the L-Cat, scores of 4, 5, and 6 were combined to ensure sufficient sample size for comparison, resulting in four categories. Cross-tabs were used to explore the percent agreement between the L-Cat and GLTEQ for meeting versus not meeting physical recommendations. One-way ANOVAs were conducted to describe the cross-sectional relationships between L-Cat and GLTEQ. Cross-tabs and ANOVA analyses were conducted on participants with available data; sample sizes vary somewhat due to missing data. A multi-level mixed effects generalized linear model was conducted using Stata 13.0 (StataCorp LP, College Station, TX) to determine six-month changes in PA between the MoveMore and SIP*smart*ER conditions (i.e., main time effect) and to detect health literacy moderation effects on the L-Cat, original GLTEQ, and adapted GLTEQ. To promote consistency with the primary outcomes paper, mixed-effects models controlled for sex, age, race, ethnicity, educational attainment, employment/disability status, income, health literacy level, number of children, smoking status, and BMI. In addition, models used intention-to-treat with baseline observation carried forward imputations.[2,187,188]

Results

Demographics

Of the 301 participants enrolled in Talking Health, the 289 who completed L-Cat at baseline are included in this study. Mean age was 40.1 (±13.5) years, 77% were female, 90% were Caucasian, 1% identified as Hispanic/Latino, 49% were employed full- or part-time, 17%

were unable to work/on disability, mean annual household income was $21,981 (±16,443), 31% completed high school or less, and 57% of the sample was obese (mean BMI of 33.0 (±9.1) kg/m^2). Approximately 33% of participants were classified as low health literate. There were no significant differences in demographics between experimental conditions. A complete demographic table is published elsewhere.[2] Participants from this 8-county region were representative in terms of age, race, ethnicity, and educational attainment using United States Census data as comparison. Differences were observed in sex (i.e., males were underrepresented) and median annual income (i.e., participants' median income was <50% of United States Census median income).[180]

Percentage Agreement between L-Cat and GLTEQ at Baseline and Six-Month

Table 2.2 shows the percent agreement, at baseline, between the L-Cat and GLTEQ average weekly minutes MVPA when participants are dichotomously categorized in meeting/not meeting recommendations categories. Comparison of L-Cat and GLTEQ MVPA minutes per week revealed approximately 84.1% of participants were classified into matching categories (i.e., 80.6% of both do not meet recommendations, 3.5% of both meet recommendations) and 15.9% had incongruent classification at baseline. When examining participants by health literacy status, high agreement[189]is observed in both low health literate (80.4% classified consistently) and high health literate (85.9% classified consistently) groups. Similar percentage agreement is observed at six-months (data not shown), with 79.7% of participants classified into matching categories and high observed agreement in both low health literate (77.8% classified consistently) and high health literate (80.7% classified consistently) groups.[189]

Baseline Cross-sectional Relationship Between L-Cat and GLTEQ

Figure 2.1a depicts the distribution of GLTEQ MVPA minutes per week by L-Cat category and by health literacy status. As reported L-Cat category increases, minutes reported on GLTEQ also increases. Within L-Cat categories, the number of reported MVPA minutes per week is not significantly different between low health literate and high health literate participants with the exception of L-Cat category three (i.e., moderate activity about three times a week for about 15-20 minutes each time, or moderately difficult chores once a week for about 45-60 minutes, or team sports such as softball, basketball, or soccer once a week for about 45-60 minutes). In category 3, low health literate participants report an average of 54 minutes MVPA compared to high health literate report of 104 minutes ($F=6.5$, $p=0.02$).

Figure 2.1b describes the distribution of GLTEQ total PA minutes per week by L-Cat category and by health literacy status. Related to Figure 2.1a which examines MVPA, a similar trend is reflected and a significant difference in health literacy status is only observed in L-Cat category three. Low health literate participants report an average of 135 minutes total PA compared to high health literate report of 226 minutes ($F=14.3$, $p\leq0.01$).

Categorical Six-Month Change in L-Cat by Condition and Health Literacy Status

Among participants in the MoveMore group, Figure 2.2a shows categorical changes in the L-Cat from baseline to six-months. The majority of MoveMore participants (49%) report the same L-Cat category at both time points, yet 26% increase by one category and 18% increase by two categories. Examining the categorical change by low and high health literate groups reveals a relatively consistent pattern compared with the overall group.

Figure 2.2b details six-month categorical change in L-Cat among the SIP*smart*ER group. The majority of SIP*smart*ER participants (58%) report the same category at baseline and six-months. When compared to the MoveMore participants, a smaller proportion of participants

increase one (15%) and two (7%) categories. Consistent with the MoveMore group, the categorical change by health literacy status among SIP*smart*ER participants reveals a pattern relatively consistent with that of the overall group.

Six-Month Change in L-Cat and GLTEQ by Condition and Health Literacy Status

Table 2.3 displays adjusted baseline to 6-month changes for MoveMore and SIP*smart*ER participants, as well as relative differences between conditions and moderation by health literacy status. As illustrated, there were significant 0-6 months difference between conditions for the L-Cat (coefficient= -0.3, 95% CI= -0.5, -0.1), GLTEQ MVPA times per week (coefficient= -0.8, 95% CI= -1.7, -0.0), and GLTEQ strength minutes per week (coefficient= -19.8, 95% CI= -32.2, -7.5). Each of these significant findings were in the direction hypothesized. For example, MoveMore participants reported a 0.4 increase in L-Cat category after the six-month intervention, compared to a 0.1 category increase observed in the SIP*smart*ER condition. There were no significant 0-6 month differences between conditions for GLTEQ MVPA minutes per week, GLTEQ total PA times per week, or GLTEQ total PA minutes per week, yet significant time effects are observed in the MoveMore condition for improvements in the GLTEQ MVPA minutes per week (coefficient= 14.9, 95% CI= 5.8, 24.1), GLTEQ total PA times per week (coefficient= 1.2, 95% CI= 0.4, 1.9), and GLTEQ total PA minutes per week (coefficient= 30.4, 95% CI= 22.3, 38.5).

Health literacy status did not moderate change in PA for any of the six variables (i.e., L-Cat, GLTEQ MVPA times per week, GLTEQ MVPA minutes per week, GLTEQ total PA times per week, GLTEQ total PA minutes per week, GLTEQ strength minutes per week) (all $p>0.05$) (Table 2.3).

Discussion

To our knowledge, our study is the first to use the L-Cat and adapted GLTEQ in a community-based population among individuals of varying health literacy status and is the first randomized controlled trial to examine the relationship between health literacy status and PA using these two self-report measures. As such, our findings make several important contributions to the literature. First, we observed high agreement[189] (approximately 80%) between the L-Cat and GLTEQ in classifying individuals who meet/do not meet PA recommendations, and this agreement was relatively consistent among low and high health literate individuals. Second, within each increasing L-Cat category, reported minutes of the GLTEQ also increased; yet L-Cat category three reveals statistically significant differences among low and high health literate participants and deserves further exploration. Third, compared to SIP*smart*ER participants, a greater proportion of MoveMore participants showed improvements in L-Cat categories, demonstrating responsiveness of the L-Cat. Fourth, we observed significant between condition effects for L-Cat but not for the GLTEQ MVPA and total PA minutes per week. This was unexpected and future studies using an additional objective measure of PA are needed. Finally, health literacy status did not moderate changes in any indicator of PA, implying that the MoveMore intervention was robust in achieving similar six-month changes across measures in participants of varying health literacy status. Overall, this study provides preliminary evidence of the practicality of the L-Cat and the GLTEQ in an intervention study targeting participants with varying health literacy status and provides direction for future studies.

While there is no shortage of self-reported PA questionnaires, existing tools that attempt to capture intensity, frequency, duration, and type of PA have resulted in complex instruments that tend to suffer from a floor effect particularly when used in sedentary populations. This is even more important to consider when contemplating use of tools in populations with varying

health literacy status. There has been little focus on how health literacy status influences self-reported PA measures in low health literate populations. Given the demonstrated high agreement[189] in classification among the L-Cat and GLTEQ for meeting or not meeting recommendations among low and high health literate individuals in this study, it is important to recognize the 20% incongruent classification that was observed (i.e., the GLTEQ classified more participants as meeting recommendations than the L-Cat). Arguably, choosing a single category on the L-CAT may be less cognitively complex for participants than estimating the number of times per week, number of days per week, and minutes per day across four different exercise intensities or types, such as in the adapted GLTEQ.[183] Comparison of reported GLTEQ MVPA using the original and adapted GLTEQ demonstrates that the adapted tool (which measures frequency and duration) yields larger confidence intervals and did not reflect six-month change between conditions, in contrast to the original GLTEQ (which measures frequency only). The addition of duration (i.e., minutes per week) to the adapted GLTEQ boasts the benefit of potential increased sensitivity and can be useful when quantitative assessment of PA in terms of frequency and duration is desired but increases variance which ultimately impacted six-month change scores. However, the L-Cat may be an appealing instrument for researchers working in low health literate populations and when brief measurement is demanded.

The statistically significant difference in low and high health literate participants in L-Cat category three, but not for the other categories, is interesting and deserves further attention. Relative to the other L-Cat categories, category three appears more cognitively complex than the others. This category is longer and includes more activities and time ranges. For example, there are three distinct statements and each with associated times per week, minutes, and intensities. The other categories are shorter, and provide more simplistic, less descriptive statements. Yet contrary to assumptions, low health literate participants reported minutes that more closely

aligned with category three. Using cognitive interviews to examine potential differences between how individuals of varying health literacy status interpret and respond to this category could be extremely useful in further refining this category.[190] On the contrary, given that both are self-report measures, it is also feasible to postulate that this significant difference is more related to the cognitive complexity with the adapted GLTEQ. With the adapted GLTEQ, participants are asked to quantify their past week's activity in terms of number of days and minutes they were active. Depending on the respondent, this could be more challenging than selecting among the L-Cat's six categories. Regardless, the use of cognitive interviews is warranted to gauge perception of individuals' comprehension of L-Cat, explore potential differences by health literacy status, and determine if adaptations could be made to further refine the instrument and reduce any instance of measurement error.[183]

Our study largely supports the original validation study of the L-Cat by Kiernan and colleagues, who validated the L-Cat against an objective measure of PA and found that the L-Cat demonstrated responsiveness, and also exhibited concurrent criterion validity.[75] Based on the behavioral intervention strategies aimed at increasing MVPA and strengthening activities among MoveMore participants, and the lack of PA behavioral strategies in the SIP*smart*ER intervention[1], we hypothesized between group effects for all the physical activity indicators we evaluated. While the changes in L-Cat, GLTEQ MVPA times per week, and GLTEQ strength minutes per week are consistent with our hypothesis, the non-significant changes in GLTEQ MVPA minutes per week, GLTEQ total PA times per week, and GLTEQ total PA minutes per week are not. Understanding the responsiveness of PA self-reported questionnaires is important, yet this is rarely reported in the literature.[73,74] However, our findings indicate that the L-Cat and GLTEQ were similarly responsive among low and high literate participants, which makes an important contribution to the literature.

Likewise, our intervention research on a hard-to-access Appalachian study population and our focus on relationships between health literacy and physical activity addresses notable gaps in the literature. Approximately 80% of our study population were not meeting PA recommendations at baseline, which is substantially higher than national estimates.[60] Even with a 6-month theory-based and evidence-informed behavioral intervention, relatively few participants shifted from the do not meet into meet recommendations categorization for PA. Rather, the shift was observed within the lower L-Cat scores of 1, 2, and 3. Indeed, when examining the categorical classification, almost twice as many MoveMore participants increased L-Cat category compared to SIP*smart*ER. Although there was a modest increase in percentage of participants meeting the PA recommendations, the increase observed is still meaningful as even modest improvements in activity level can result in decreased risk for chronic disease.[191,192] Additionally, this categorical change did not vary by health literacy status. These are important findings; the PA behaviors of individuals with low health literacy need to be considered, as this subset of the population is less likely to engage in self-care behaviors such as PA.[23] Since the most meaningful health benefits result from moving from a state of inactivity to engaging in light activity,[193] a tool that is designed to categorize and detect shift in PA at the lower end of the activity spectrum is needed.[194-196] The L-Cat shows potential to fill this void.

Limitations

It is important to recognize a few limitations. First, no objective measure of PA was utilized to measure change in PA behaviors. Second, relationships between L-Cat and GLTEQ rely on comparison of monthly to weekly estimates of PA and both measures capture time spent engaging in leisure time physical activity and may underestimate participants' active time in occupational, domestic, or transportation related tasks. Third, while conducted in a high need,

medically underserved area, findings may not be generalizable to other populations. Fourth, MoveMore was the matched contact comparison group for SIP*smart*ER, meaning health behavior of focus was PA in lieu of sugar-sweetened beverages but program contact and structure mirrored that of SIP*smart*ER.[1] Thus, relative differences between conditions should be interpreted with caution due to the lack of a true control group. Although SIP*smart*ER participants were educated on sugar-sweetened beverage reduction and not PA behaviors, a health intervention of any kind has potential to influence health behaviors.[197] Additionally, since MoveMore participants were educated on PA, they may have been more knowledgeable about reporting their PA behaviors at the 6-month follow up in contrast to their ability to report at baseline. Finally, this secondary analysis was not explicitly powered to detect health literacy moderation effects;[2] therefore, the null moderation effects should be interpreted with caution. More studies utilizing L-Cat in a population of varying health literacy status and activity levels are warranted to further justify the utility and generalizability of this instrument.

Conclusion

Importantly, this exploratory study reveals several opportunities for future research, including the use of objective PA measures (e.g., accelerometers) to compare differences in self-reported PA measures by health literacy status; cognitive interviews to further explore refinement of L-Cat category three as well as differences in L-Cat and adapted GLTEQ interpretations among low and high health literacy participants; and the need for behavioral interventions sufficiently powered to detect health literacy moderation effects on PA outcomes. Despite limitations, the L-Cat and adapted GLTEQ are useful measures for cross-sectional and longitudinal assessment of self-report PA behaviors in rural, health-disparate communities found to be robust across health literacy levels. Each instrument has unique strengths and the L-Cat 2.3

is a viable option when brief, pragmatic measures of self-reported PA are needed for individuals of varying health literacy.

Tables and Figures

Table 2.1: Format, content, ad scoring methods of the Stanford-Leisure Time Activity Categorical Item (L-Cat) and the Godin-Leisure Time Exercise Questionnaire (GLTEQ)

	Stanford Leisure-Time Activity Categorical Item (L-Cat) Version 2.3	**Adapted Godin Leisure-Time Exercise Questionnaire (GLTEQ)**
Format	**Self-administered**	**Interviewer-administered**
Content	**During the past <u>month</u>, which statement best describes the kinds of physical activity you usually did during your FREE TIME (or time spent other than working at a job)? Please read all six statements before selecting <u>one</u>.** 1. You did not do much physical activity. You mostly did things like watching television, reading, playing cards, or playing computer games. Only occasionally, <u>no more than once or twice a month</u>, did you do anything more active such as going for a walk or playing tennis. 2. <u>Once or twice a week</u>, you did <u>light activities</u> such as getting outdoors on the weekends for an easy walk or stroll. Or once or twice a week, you did chores around the house such as sweeping floors or vacuuming. 3. <u>About three times a week</u>, you did <u>moderate activities</u> such as brisk walking, swimming, or riding a bike <u>for about 15-20 minutes each time</u>. Or about once a week, you did moderately difficult chores such as raking or mowing the lawn for about 45-60 minutes. Or about once a week, you played sports such as softball, basketball, or soccer for about 45-60 minutes. 4. <u>Almost daily, that is five or more times a week</u>, you did <u>moderate activities</u> such as brisk walking, swimming, or riding a bike <u>for 30 minutes or more each time</u>. Or about once a week, you did moderately difficult chores or played sports for 2 hours or more. 5. <u>About three times a week</u>, you did <u>vigorous activities</u> such as running or riding hard on a bike <u>for 30 minutes or more each time</u>. 6. <u>Almost daily, that is five or more times a week</u>, you did <u>vigorous activities</u> such as running or riding hard on a bike <u>for 30 minutes or more each time</u>.	**The next set of questions will ask you about the time you spend being physically active in the last 7 days. I will ask you about strenuous, moderate, mild, and strength training exercises. Notes that the main differences between the three categories is the intensity of the exercise. For example, please designate a type of exercise as either strenuous or moderate and not both. Only count exercise that was done during your free time. Do not count exercise that is a part of your job or housework.** 1. Considering the past week (7 days)[a], how many times on the average do you do the following kinds of exercise for more than 15 minutes during your free time? a) Strenuous exercise (heart beats rapidly) *(e.g., running, jogging, hockey, football, soccer, squash, basketball, cross country skiing, judo, roller skating, vigorous swimming, vigorous long distance bicycling)* _____ [Record times per week] _____ [Record minutes per time][b] b) Moderate exercise (not exhausting) *(e.g., fast walking, baseball, tennis, easy bicycling, volleyball, badminton, easy swimming, alpine skiing, popular and folk dancing)* _____ [Record times per week] _____ [Record minutes per time][b] c) Mild exercise (minimal effort) *(e.g., yoga, archery, fishing from river bank, bowling, golf, easy walking)* _____ [Record times per week] _____ [Record minutes per time][b] d) Strength exercise[c] *(e.g., weight lifting)* _____ [Record times per week] _____ [Record minutes per time] 2. Considering the past week (7 days), during your leisure time, how often do you engage in any regular activity long enough to work up a sweat (heart beats rapidly)? (Circle response)[a] OFTEN SOMETIMES NEVER/RARELY
Scoring method	**1) Categorical choice** *Did not meet recommendation* — Categories 1, 2, 3 *Met recommendation* — Categories 4, 5, 6	**1) Minutes per week[d]** *Did not meet recommendation* — Participants who reported <150 minutes of moderate and/or vigorous physical activity *Met recommendation* — Participants who reported ≥ 150 minutes of moderate and/or vigorous physical activity

[a] Original: "typical week" instead of "past week"
[b] Original: Minutes per time not collected
[c] Original: Did not include strength exercise
[d] Original: Recommended scoring calculation is Weekly leisure activity score = (9 × Strenuous) + (5 × Moderate) + (3 × Light)

Table 2.2: Proportion of participants who are classified as meeting recommendations (rec.) per L-Cat and GLTEQ MVPA minutes per week, **baseline**

		GLTEQ (MVPA minutes per week)	
Overall (n=289)[a]		*Does not meet rec. n (%)*	*Meets rec. n (%)*
L-Cat Category	*Does not meet rec. n (%)*	233 (80.6%)	40 (13.8%)
	Meets rec. n (%)	6 (2.1%)	10 (3.5%)

[a] 84.1% agreement

		GLTEQ (MVPA minutes per week)	
Low Health Literate (n=97)[b]		*Does not meet rec. n (%)*	*Meets rec. n (%)*
L-Cat Category	*Does not meet rec. n (%)*	74 (76.3%)	15 (15.5%)
	Meets rec. n (%)	4 (4.1%)	4 (4.1%)

[b] 80.4% agreement

		GLTEQ (MVPA minutes per week)	
High Health Literate (n=192)[c]		*Does not meet rec. n (%)*	*Meets rec. n (%)*
L-Cat Category	*Does not meet rec. n (%)*	159 (82.8%)	25 (13.0%)
	Meets rec. n (%)	2 (1.0%)	6 (3.1%)

[c] 85.9% agreement

Table 2.3: Self-reported outcomes at baseline & post-program by treatment condition & health literacy status (n=289); LHL=low health literate, HHL= high health literate

Variable		**MoveMore**			**SIP*smart*ER**			**Relative effect between conditions** [c]	**Moderation effect**[c]
		Baseline [b]	**6 Month** [b]	**Adjusted change baseline to 6-month**[c]	**Baseline** [b]	**6 month** [a]	**Adjusted change baseline to 6-month**[c]		
L-Cat[a]	*All*	1.6 (1.1)	2.3 (1.1)	0.4 (0.3, 0.5)***	1.5 (0.9)	1.6 (1.0)	0.1 (-0.1, 0.4)	-0.3 (-0.5, -0.1)*****	n/a
	LHL	1.9 (1.4)	2.4 (1.1)	0.4 (0.1, 0.8)*	1.4 (0.8)	1.7 (1.0)	0.2 (-0.0, 0.5)	-0.2 (-0.5, -0.1)	-0.1 (-0.6, 0.3)
	HHL	1.5 (0.9)	2.2 (1.1)	0.4 (0.2, 0.6)***	1.6 (0.9)	1.6 (0.9)	0.0 (-0.2, 0.3)	-0.3 (-0.7, -0.0)*	
***-Original Tool-* GLTEQ MVPA (times/wk)**	*All*	1.7 (2.9)	3.4 (3.4)	1.0 (0.3, 1.7)**	1.7 (2.5)	1.8 (2.3)	0.2 (-0.3, 0.7)	-0.8 (-1.7, -0.0)*	n/a
	LHL	2.3 (3.7)	3.7 (3.9)	1.3 (-0.5, 3.2)	1.4 (2.4)	1.7 (2.3)	0.3 (-0.4, 1.0)	-1.0 (-3.0, 1.0)	0.2 (-0.2, 2.5)
	HHL	1.5 (2.5)	3.2 (3.1)	0.9 (0.4, 1.4)***	1.8 (2.6)	1.8 (2.3)	0.1 (-0.5, 0.7)	-0.8 (-1.7, 0.1)	
***-Adapted Tool-* GLTEQ MVPA (average mins/wk)**	*All*	39.1 (50.6)	54.0 (51.4)	14.9 (5.8, 24.1)******	39.8 (50.3)	43.1 (50.5)	3.3 (-11.7, 18.3)	-11.7 (-28.1, 4.8)	n/a
	LHL	39.5 (51.8)	55.1 (52.5)	18.5 (-4.4, 41.5)	37.1 (49.1)	42.8 (49.8)	5.7 (-14.5, 25.9)	-12.8 (-38.1, 12.6)	1.2 (-30.8, 33.2)
	HHL	38.9 (50.3)	53.6 (51.2)	13.5 (5.1, 21.9)**	41.4 (51.1)	43.2 (51.2)	1.9 (-14.0, 17.8)	-11.6 (-32.5, 9.3)	
***-Original Tool-* GLTEQ Total PA (times/wk)**	*All*	3.4 (4.1)	5.2 (4.0)	1.2 (0.4, 1.9)**	3.5 (4.1)	4.0 (3.7)	0.6 (0.1, 1.1)*	-0.6 (-1.4, 0.2)	n/a
	LHL	4.0 (4.9)	5.6 (4.3)	1.7 (0.3, 3.2)*	2.9 (3.9)	3.6 (3.5)	0.9 (0.2, 1.6)*	-0.9 (-2.4, 0.7)	0.4 (-1.9, 2.8)
	HHL	3.2 (3.7)	5.0 (3.9)	0.9 (0.0, 1.8)*	3.8 (4.2)	4.2 (3.9)	0.5 (-0.4, 1.3)	-0.5 (-1.7, 0.8)	
***-Adapted Tool-* GLTEQ Total PA (average mins/wk)**	*All*	97.7 (93.6)	128.0 (94.8)	30.4 (22.3, 38.5)***	99.5 (96.1)	106.9 (94.6)	7.4 (-11.4, 26.1)	-23.0 (-37.5, -8.6)	n/a
	LHL	104.4 (97.8)	128.8 (91.3)	26.5 (-0.2, 53.3)	98.0 (99.9)	104.6 (93.8)	6.6 (-11.0, 24.3)	-19.9 (-48.4, 8.7)	-4.3 (-52.9, 44.3)
	HHL	94.9 (92.2)	127.7 (96.6)	32.0 (21.0, 42.9)***	100.4 (94.4)	108.1 (95.5)	7.8 (-20.0, 35.6)	-24.2 (-50.6, 2.2)	

-Adapted Tool- **GLTEQ Strength (average mins/wk)**	*All*	6.9 (28.1)	24.1 (55.6)	17.2 (6.7, 27.6)**	13.4 (59.7)	10.7 (35.9)	-2.7 (-8.6, 3.2)	-19.8 (-32.2, -7.5)****	n/a
	LHL	12.4 (35.9)	42.0 (89.8)	29.4 (4.7, 54.0)*	28.3 (91.3)	17.7 (46.5)	-10.6 (-26.5, 5.4)	-39.9 (-71.9, -7.9)*	29.5 (-1.3, 60.4)
	HHL	4.7 (24.1)	16.8 (30.5)	12.2 (6.4, 18.0)***	4.8 (26.2)	6.7 (27.7)	1.8 (-0.5, 4.1)	-10.4 (-17.5, -3.2)**	

Statistical significance indicated by asterisks: *$p \leq 0.05$, **$p \leq 0.01$, ***$p \leq 0.001$.
L-Cat= Stanford Leisure-Time Activity Categorical Item, GLTEQ= Godin Leisure Time Exercise Questionnaire, PA= Physical Activity
[a] L-Cat: 1= low activity, 6 = high activity
[b] Means & Standard Deviations not adjusted for covariates
[c] Intention-to-treat baseline observation carried forward imputations were used in analyses. Models controlled for baseline covariates: sex, age, race, ethnicity, educational attainment, employment/disability status, income, health literacy level, number of children, smoking status, and BMI. The 95 % confidence intervals are adjusted to be cohort robust.

Figure 2.1a: Baseline GLTEQ moderate-to-vigorous (MVPA) minutes per week Cat by L-Cat category and by health literacy status

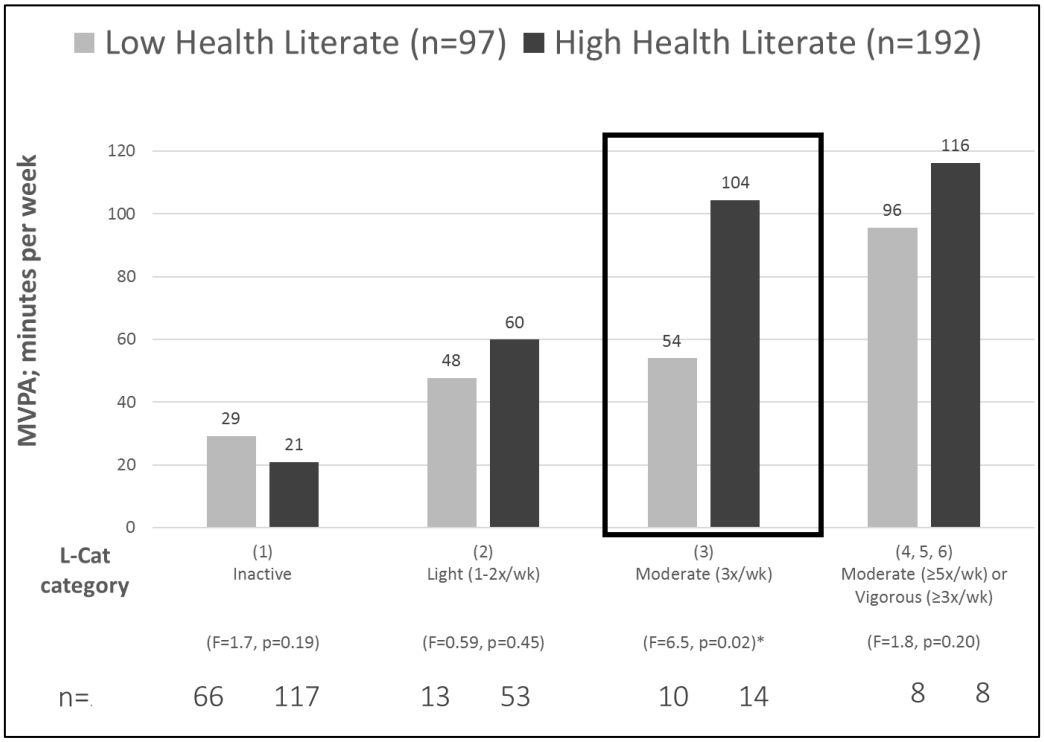


Figure 2.1b: Baseline GLTEQ total physical activity minutes per week by L-Cat by L-Cat category and by health literacy status

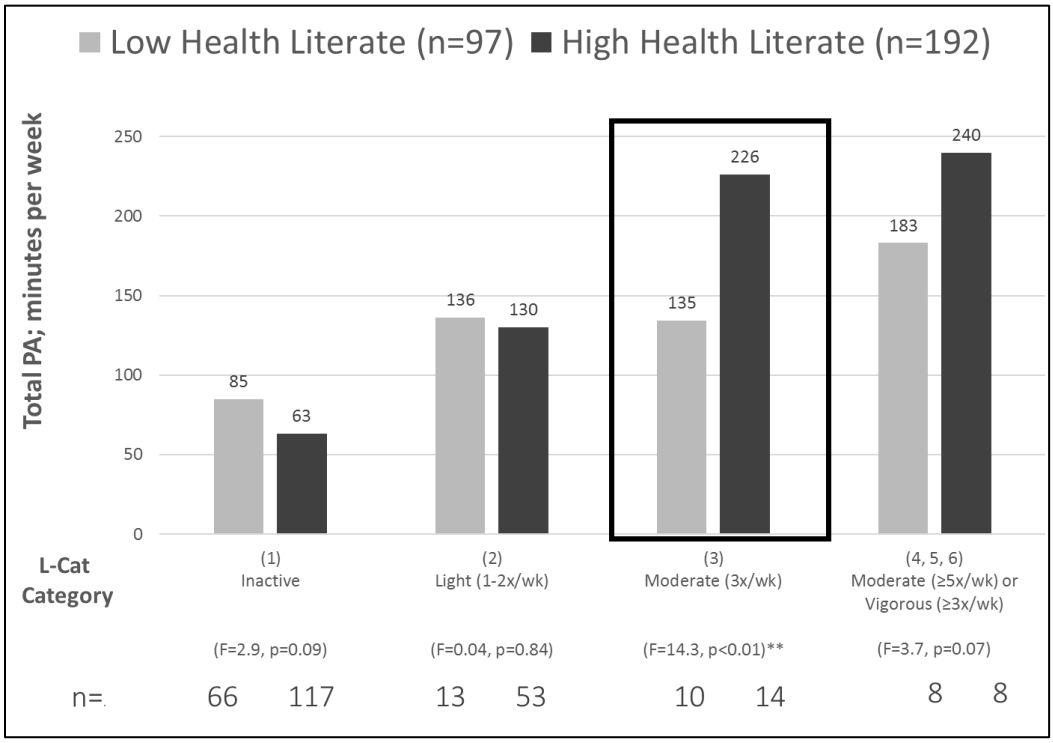


Figure 2.2a: **MoveMore**; Six-month change in L-Cat by health literacy status

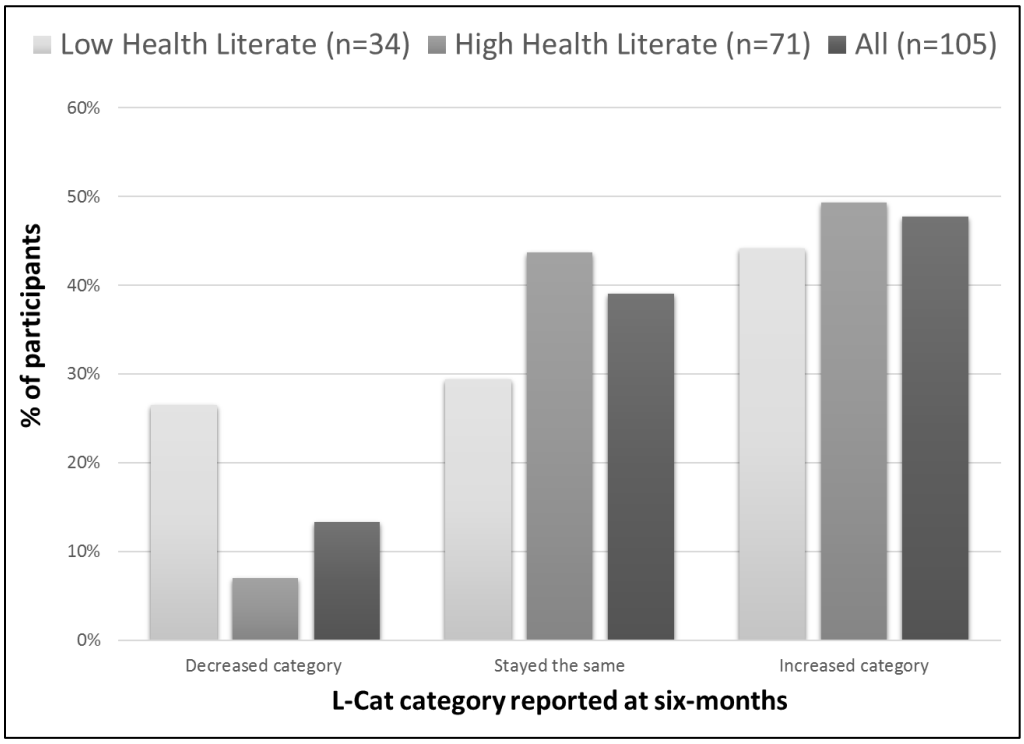
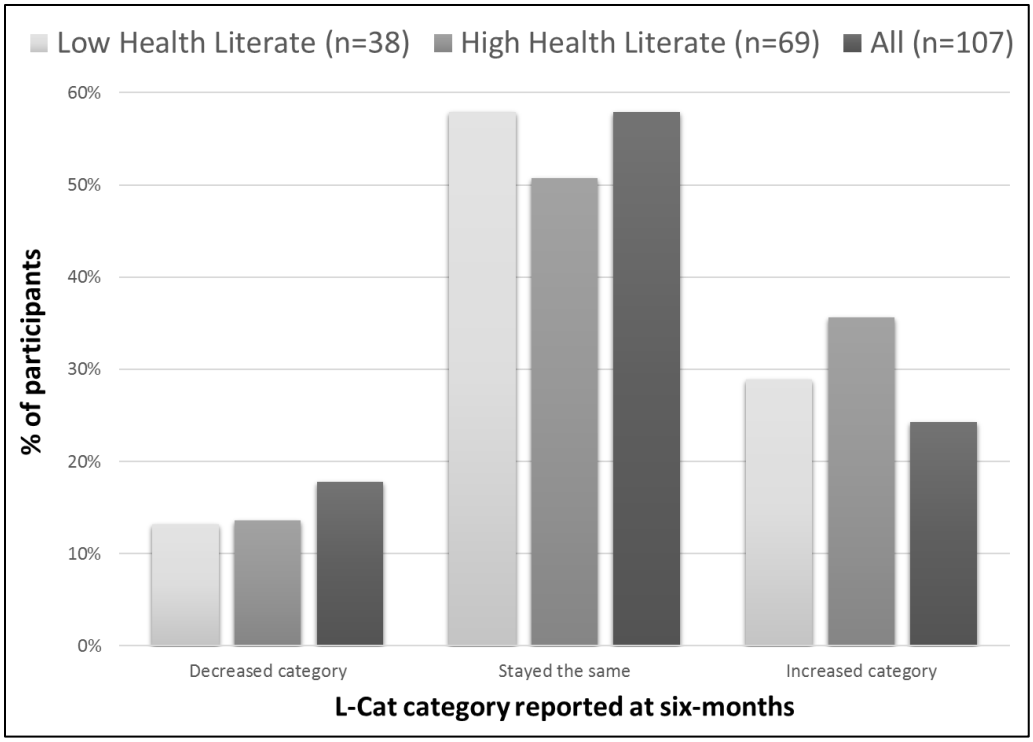


Figure 2.2b: **SIP*smart*ER**; Six-month change in L-Cat by health literacy status



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CHAPTER 3: MANUSCRIPT 2 "THE IMPACT OF CHANGE IN SUGAR-SWEETENED BEVERAGE INTAKE AND MODERATION OF HEALTH LITERACY ON CHANGES IN WEIGHT, BMI, AND QUALITY OF LIFE DURING A SIX-MONTH BEHAVIORAL INTERVENTION"

Abstract

Introduction: Reduction in sugar-sweetened beverage (SSB) intake has been associated with decreased BMI, weight, and increased quality of life (QOL). However, few studies consider how SSB change over time influences change in anthropometric and QOL outcomes, and fewer yet consider how health literacy (HL) status moderates outcomes.

Methods: This study is a secondary analysis of a 6-month behavioral intervention for rural Appalachian adults developed using HL strategies. The purpose was to examine if six-month change in SSB intake predicts six-month change in body mass index (BMI), weight, and QOL while controlling for baseline PA and total energy intake, condition, and demographic variables, and determine if baseline HL moderated these relationships.

Results: Of 301 participants enrolled, 296 were included in this study. Approximately 33% were low health literate and 57% of participants were obese. The regression models for weight and QOL were not significant. The BMI model was significant. Six-month change in SSB intake, experimental condition, and age were significant predictors for the BMI model. As expected, the interaction between change in SSB intake and HL status did not predict change in any of the three models.

Conclusion: Future studies should further investigate the relationship between change in SSB intake and change in outcomes (e.g., weight status). Furthermore, future work should continue to explore HL as a moderator of these relationships.

Introduction

Overconsumption of sugar-sweetened beverages (SSB) can lead to a multitude of health consequences, such as overweight and obesity, type 2 diabetes mellitus, cardiovascular disease, dental caries and tooth decay, and kidney disease.[1-5] SSB are defined as any non-alcoholic liquid sweetened with added sugar, such as regular soda, energy drinks, fruit drinks, sports drinks, sweetened water, and coffee and tea with sugar added. In the most recent edition of the Dietary Guidelines for Americans (2015-2020), recommendations state that daily intake of added sugars should not exceed 10% of total calories.[6] In the United States, around half (49%) of adults drink at least one SSB daily.[7] Adults that live in rural areas, particularly socioeconomically disadvantaged individuals, have been shown to consume higher amounts of SSB.[8-11] This disparity is particularly evident in Appalachian southwest Virginia as adults have been shown to consume $\geq$3 times the amount of SSB when compared to national averages.[12]

Interventions that include behavior change and/or nutrition education components have demonstrated effectiveness in reducing individual-level SSB consumption.[13,14] Additionally, long term health benefits, such as lower weight gain, can result from replacing SSB with zero- or low-calorie beverage alternatives.[15] It is commonly accepted that for each daily serving of SSB consumed, an incremental increase in body mass index (BMI) and weight would result.[1] However, a systematic review and meta-analysis of randomized controlled trials revealed that reducing SSB consumption did not have a statistically significant effect on BMI, although six studies within this review found that adding SSB to individuals' diets resulted in dose-dependent increase in BMI.[13] Furthermore, quality of life (QOL) has long been recognized as a benchmark to improving population health, and is commonly used to assess effects of treatments and behavioral interventions.[16] There is conflicting evidence on the association between health

literacy status and QOL, but consensus that QOL is a key indicator of health in the context of behavior change, such as weight loss.[17-19]

Higher consumption of SSB has also been shown to be influenced by an individual's health literacy status. [20,21] Health literacy is the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.[22] Low health literacy has also been associated with poorer self-reported health status as well as lack of ability to engage in self-care or manage chronic conditions.[23] The number of health literacy-focused studies has increased both in quantity and quality over the past decade.[23,24] However, evaluating if health literacy status moderates outcomes, such as SSB intake, has been insufficiently explored.[23,25] In a systematic review of health literacy-related health promotion interventions, only 8 out of 25 interventions reported conducting a moderation analysis across different levels of health literacy. Findings from these interventions showed mixed results as to the degree to which health literacy status influenced intervention effectiveness.[25] When working with populations of varying health literacy status, it is vital to determine if interventions have similar effects for individuals of low and high health literacy.

This study aims to address these gaps in the literature. This is a secondary data analysis from the Talking Health trial, a randomized controlled trial guided by the Theory of Planned Behavior and health literacy strategies. The intervention group, SIP*smart*ER, was found to be effective at reducing participants' consumption of SSB as compared to a matched-contact control participants, MoveMore.[26,27] The intervention group, SIP*smart*ER, showed significant decreases in weight and BMI, and a significant increase in quality of life (QOL) when compared to MoveMore. Despite these encouraging findings, the relationships between changes in SSB and

changes in outcomes (i.e., BMI, weight, and QOL) have not yet been explored. Likewise, health literacy as a moderator of these relationships has yet to be investigated, although the Talking Health trial found that health literacy did not moderate SSB reduction.

Thus, the first objective of this study is to determine if 6-month change in SSB intake is a significant predictor of 6-month change in BMI, weight, and QOL, while controlling for baseline physical activity, baseline total energy intake, condition (i.e., SIP*smart*ER or MoveMore), and relevant demographic variables. The second objective is to determine if health literacy moderates the relationship between change in SSB and BMI, weight, and QOL. It is hypothesized that 6-month change in SSB intake will be a statistically significant predictor of 6-month change in BMI, weight, and QOL, after controlling for aforementioned variables. It is also hypothesized that health literacy will not moderate these relationships, as SIP*smart*ER was developed using health literacy strategies and delivered using the universal precautions approach.[26,28]

Methods

Study design

This is a secondary data analysis from the Talking Health trial, a 6-month randomized controlled trial aimed to decrease SSB intake of rural adults. This behavioral intervention was developed using health literacy strategies and the Theory of Planned Behavior,[29] and participants were randomized into one of two matched-contact intervention groups, SIP*smart*ER or MoveMore. Both groups completed three small-group classes, one live teach-back call, and 11 automated Interactive Voice Response calls. The primary objective of the SIP*smart*ER group was to reduce SSB intake down to 8 fluid ounces per day or less, while the focus of the MoveMore group was to attain 150 weekly minutes of moderate-vigorous cardiovascular activity

and engage in muscle-strengthening activities on 2 or more days per week. A detailed description of intervention structure, content, methods, and outcomes can be found elsewhere.[26,27]

Participants

This study took place in an eight-county region in rural, Appalachian southwest Virginia. This area is classified as medically underserved and has considerable socioeconomic inequalities which predisposes residents to health disparities.[30-33] Eligible participants were English-speaking adults who were at least 18 years old and who had consistent telephone access, no self-reported contraindications to engaging in PA, and an average self-reported SSB intake of ≥200 kilocalories per day. As described in detail elsewhere, both active and passive recruitment methods were used.[26] In total, 1056 individuals were screened and 620 were eligible. Of these, 301 participants were enrolled and randomized into one of two conditions, with 155 randomized into SIP*smart*ER and 146 to MoveMore.

The study protocol was approved by the Virginia Tech Institutional Review Board. Participants completed written informed consent prior to beginning the study and received compensation in the form of gift cards for participating in pre- and post-data assessments ($25 and $50, respectively).

Measures

When participants were screened for eligibility, demographic information (i.e., sex, age, race, ethnicity, employment status, income, educational attainment, and number of children per household) was obtained. All other variables were measured at both baseline and 6-month data assessments. Anthropometric assessments included height and weight collected using

standardized protocol (using digital Tanita scale (Model: 310GS) and research-grade stadiometer), and BMI scores were calculated. Health literacy was assessed by the interviewer-administered Newest Vital Sign, a validated six-item questionnaire of health literacy status used to identify individuals at risk for low health literacy based on comprehension of a nutrition facts label.[34] SSB consumption data was gathered from the computer-audio assisted BEVQ-15.[35] All SSB consumption data included in this study come from this computer-audio assisted BEVQ-15. Dietary data was collected using three 24-hour recalls (one completed in person, two completed over the phone) and analyzed in Nutrition Data System for Research nutritional analysis software (NDS-R 2011, University of Minnesota). To assess physical activity, participants completed a computer-audio assisted Stanford Leisure-Time Exercise Questionnaire Version 2.3 (L-Cat). Participants also completed the interviewer-administered adapted Godin Leisure Time Exercise Questionnaire (GLTEQ).[36-38] The GLTEQ moderate-vigorous physical activity (MVPA) was the control variable included in the regression models. QOL was assessed using four questions that captured physical, mental, and overall health by asking participants how many unhealthy days they experienced over the last 30 days.[39]

Statistical analysis

Data were entered into SPSS software, Version 24.0 (International Business Machines Corporation, Pittsburgh, PA). Descriptive statistics were run to summarize demographic data. Pearson's correlations were run to measure the association between the dependent and independent variables for each model. Hierarchical multiple linear regression was used to determine if 6-month change in SSB intake could predict 6-month change in weight, BMI, and QOL while controlling for baseline GLTEQ MVPA, baseline total energy intake, condition, and

demographic variables (i.e., age, sex, educational attainment, mean annual income, work status, disability status, number of children, and baseline health literacy status).[40] Categorical variables were dummy coded, including sex, educational attainment, work status, disability status, number of children, and condition. Categorical variables sex, educational attainment, mean, work status, disability status, number of children were dummy coded. Within each of these models, moderation analysis was conducted by including the interaction term "baseline health literacy status by 6-month change in SSB".[41] Models used intention-to-treat with baseline observation carried forward imputations (i.e., for participants who did not complete the 6-month assessment, a zero change was presumed, and baseline values were substituted in place).[27,42,43]

Prior to analysis, six assumptions for hierarchical linear regression were assessed for each of the three models. First and second assumptions were met based on the study design; 1) the dependent variable was continuous, and 2) there were two or more continuous or categorical independent variables. The third assumption relates to independence of observations; independence of residuals was observed with Durbin-Watson statistics of 1.984, 1.971, and 1.872, respectively, for the weight, BMI and QOL models. The fourth assumption relates to the linear relationship between the dependent variable and each individual independent variable, and the dependent variable and independent variables as a whole; for all three models, linearity was established between the dependent variable and collective independent variables. The fifth assumption relates to data having equal error variances (i.e., homoscedasticity); homoscedasticity was observed when assessing visual inspection of a plot of studentized residuals versus unstandardized predicted values. The sixth assumption is that data do not show multicollinearity; there were no strong correlations between any of the independent variables and

based on assessment of Tolerance (all >0.1) and VIF values (all <10), no problem with collinearity detected.

The dependent variable was entered as 6-month change in BMI (Model 1), weight (Model 2) and QOL (Model 3). Each model included two Steps, Step 1 with all independent variables, and Step 2 with all independent variables and the addition of the interaction term (baseline health literacy status by 6-month change in SSB intake). For each of the three models, Step 1 included age, sex, educational attainment, mean annual income, work status, disability status, number of children, condition (i.e., SIP*smart*ER or MoveMore), baseline health literacy status, baseline GLTEQ MVPA, baseline total energy intake, and 6-month change in SSB intake. In Step 2, the interaction term baseline health literacy status by 6-month change in SSB intake was entered. If baseline health literacy by change in SSB, the interaction term, was statistically significant, moderation was assumed.[40]

Results

Of the 301 participants enrolled, five women who were pregnant at either/both baseline or 6-month assessments were excluded, and 296 participants were included in these analyses. Table 3.1 describes demographic characteristics. Mean age was 42.1±13.4 years, 81% were female, 93% were Caucasian, 31% completed high school or less, mean annual household income was $21,981±16,443, with 43% having an income of <14,999, and 21.5% of participants were overweight while 57% were obese (mean BMI of 33.0±9.1 kg/m^2). Approximately 33% of participants were classified as low health literate. There were no significant differences in demographics between experimental conditions.[27] As described in detail elsewhere, participants from this southwest Virginia region were representative in terms of age, race, ethnicity, and

educational attainment using United States (U.S.) Census data as comparison.[27] Differences were observed in sex (i.e., males were underrepresented) and median annual income (i.e., participants' median income was <50% of US Census median income).[44] Also depicted in Table 3.1, 6-month change in SSB intake ranged from -2157 to 738 kilocalories, with an average of -141±327 kilocalories. That is, participants decreased SSB intake by 141 kilocalories on average. Average 6-month change in BMI was -0.5±1.3 kg/m^2, weight was -0.19±3.3 kg, and QOL (# unhealthy days reported over past month) was -0.7±8.0 days. It was expected that BMI, weight, and QOL would decrease during the 6-month intervention period. Further, those who made larger decreases in SSB intake (i.e., larger negative values) were hypothesized to have larger decreases in BMI, weight, and QOL (i.e., larger negative values).

Correlation matrices were included to depict the associations between the dependent and each independent variable, and between independent variables in isolation (Table 3.2) prior to presenting the results of the hierarchical regression analyses. A significant negative correlation was observed between 6-month change in QOL and 6-month change in SSB (r=-0.17, p=0.002). That is, as 6-month change in SSB increased, 6-month change in QOL (i.e., number of unhealthy days per month) decreased, contrary to the positive directional relationship that was hypothesized. A significant positive correlation was found between 6-month change in QOL and baseline health literacy status (r=0.12, p=0.017). Of note, 6-month change in BMI and baseline health literacy status trended towards significance (r=-0.10, p=0.051). However, it is important to note these associations were weakly correlated, with all coefficients less than 0.2.

Hierarchical linear regression results are presented in Table 3.3a-c. Independent variables of interest are presented (i.e., 6-month change in SSB intake, baseline health literacy status,

condition (i.e., SIP*smart*ER or MoveMore), and the interaction term (baseline health literacy status by 6-month change in SSB intake). Covariates were presented only if significant.

Body Mass Index (BMI)

As illustrated in Table 3.3a, the BMI model was significant (R^2=0.08, F=1.89, p=0.03). While the 6-month change in SSB intake did not statistically significantly predict change in BMI (β=-0.12, p=0.28), baseline health literacy status (β=-0.15, p=0.04) and condition (β=-0.15, p=0.02) were significant predictors. For example, for every one standard deviation increase in baseline health literacy status, BMI 6-month change score decreases by 0.15 standard deviations. When condition equaled 1 (SIP*smart*ER), 6-month change in BMI decreased by 0.15 standard deviations as compared to 0 (MoveMore), holding other independent variables constant. Age was the only significant demographic covariate. For every one standard deviation increase in age, 6-month change in BMI decreases by 0.18 standard deviations (β=-0.18, p=0.008). There was not a statistically significant moderator effect of health literacy; the addition of the interaction term explained an additional 0.4% variance, and the interaction term was not a statistically significant predictor (β=0.12, p=0.27).

Weight

The regression model predicting 6-month change in weight was not significant (R^2=0.06, F=1.47, p=0.13) (Table 3.3b). Likewise, neither 6-month change in SSB intake (β=-0.11, p=0.31) nor baseline health literacy status were significant predictors (β=-0.11, p=0.11) in the weight change model. However, condition showed a strong trend towards being a significant predictor (β=-0.12, p=0.051). When condition equaled 1 (SIP*smart*ER), 6-month change in

weight decreased by 0.12 standard deviations as compared to 0 (MoveMore), holding other independent variables constant. Again, age was the only significant demographic covariate (β=-0.18, p=0.008). There was not a statistically significant moderator effect of health literacy; the addition of the interaction term explained an additional 0.2% variance, and the interaction term was not a statistically significant predictor (β=0.08, p=0.47).

Quality of Life (QOL)

The regression model predicting 6-month change in QOL was also not significant (R^2=0.06, F=1.49, p=0.12) (Table 3.3c). Six-month change in SSB intake significantly contributed to the prediction; for every one standard deviation increase in 6-month change in SSB intake, 6-month change in QOL (number of unhealthy days) decreased by 0.26 standard deviations (β=-0.26, p=0.02), which was not expected. Neither baseline health literacy status (β=-0.11, p=0.12) or condition (β=-0.10, p=0.12) were significant predictors. There were no significant demographic covariates. There was not a statistically significant moderator effect of health literacy; the addition of the interaction term explained an additional 0.1% variance, and the interaction term was not a statistically significant predictor (β=0.07, p=0.52).

Discussion

While existing randomized controlled trials have examined the effects of SSB consumption on body weight, this study is one of the first to investigate if 6-month change in SSB intake significantly predicts 6-month change in BMI, weight, and QOL. The change in the behavioral target of focus (i.e., SSB intake) did not predict change in BMI or weight but did impact change in QOL although the directionality of this relationship contradicted what was

hypothesized. That is, reported SSB decrease corresponded with increased number of unhealthy days reported in the QOL measure. This study is also the first to examine if the interaction between health literacy and change in SSB intake moderates change in anthropometric (i.e., BMI, weight) and QOL outcomes. These findings reiterate the importance of integrating health literacy strategies when developing and delivering behavioral interventions to reduce SSB intake, and the need to further investigate patterns of change in SSB intake and health literacy as a moderator.

The direction of the significant relationship between 6-month change in SSB intake and 6-month change in QOL was not as hypothesized. It was expected that an increase in SSB intake over the 6-month intervention period would result in increased number of unhealthy days, not the contrary. Of the three models, this dependent variable is the sole subjective, self-reported variable. Additionally, it is arguably the most subject to factors external to the model, the error term. Future studies investigating how change in health behavior impacts change in QOL should consider the influence of other potential covariates (e.g., chronic disease status, mental health, environmental factors, social support).

As expected, the interaction between change in SSB intake and health literacy status did not predict change in any of the three models. That is, the observed relationships between the dependent and independent variables are similar across every level of baseline health literacy status. Baseline health literacy status alone significantly influenced change participants' change in BMI. The directionality of this relationship was as hypothesized; as health literacy status increases, change in BMI decreases.

Increased SSB intake has been associated with lower health literacy status.[20,21] Additionally, observational studies report conflicting information regarding health literacy and

QOL; two cross-sectional analyses reveals no association,[17,19] while another shows a strong correlation[18]. The findings from this study correspond with the former, as health literacy status was not found to be associated with QOL. Nonetheless, the consequences of health literacy (i.e., poor health status, inability to manage chronic conditions or engage in self-care)[23] suggest that low health literate individuals may have difficulty losing weight and maintaining QOL.[45,46] However, behavioral interventions that are designed to be suitable for populations of varying health literacy status can help diminish this disparity.[47] The parent trial of this study was developed using health literacy strategies and based on the Theory of Planned Behavior[29], and was delivered using the universal precautions approach[28] to ensure the impact of health literacy status was minimal (i.e., interventions would have similar effects for both low and high health literate participants).[26] When testing behavioral outcomes such as change in BMI, weight, and QOL, it is not expected that the majority of variance be predicted by a proposed statistical model.[48] Behavioral change, such as weight loss, is impacted by a variety of factors, many of which are unable to be monitored or controlled for statistically. Behavior change, such as reducing intake of SSB, is complex and can be influenced by behavioral intention, attitude, self-efficacy, skills, norms and self-standards, social and environmental constraints, and emotional factors.[49] However, it is valuable to pursue analyses such as these to gain insight of how predictive certain modifiable behaviors (i.e., SSB intake) are of outcomes such as weight status and general well-being.

Additionally, condition and age were significant predictors for the BMI and weight models. Positive beta coefficients indicate that SIP*smart*ER participants were more likely than MoveMore participants to experience slight decreases in BMI and weight. Although the two arms of the effectiveness trial, SIP*smart*ER and MoveMore, were matched in structure and

periods of contact, their content was different which could have influenced slight variations in patterns of change in BMI, weight, and QOL. However, this finding should be carefully interpreted, as 6-month change in SSB did not significantly predict change in either BMI or weight and considering the beta coefficients for the effect of condition were weak. For age, participants who were older experienced greater decreases in BMI and weight. This confirms trends in existing research, a negative relationship (i.e., as age decreased, BMI and weight increased) as younger adults are more likely to experience greater BMI increases.[50] However, this relationship may be dependent on weight status[50], and including baseline weight and BMI in future analyses could shed light on this trend.

More longitudinal health literacy interventions are needed to fully capture predictors of change in outcomes such as BMI, weight, and QOL. Future work should aim to describe the relationship between behavior change (e.g., change in SSB intake), health literacy, intervention components, and outcomes (e.g., weight status).[51] Future analyses should consider the unit of SSB intake used, as this likely impacts the relationship, or at least the ease of interpretation between change in SSB intake and weight outcomes.[52] Mullie and colleagues expressed change in SSB intake in 40 kilocalorie units in their regression models, while Stern and colleagues interpreted SSB intake in terms of weekly servings and categorizing this variable in three categories (i.e., decrease, no change, or increase in SSB intake).[52,53] Findings and interpretation could be enhanced by looking at SSB intake in 8- or 16-ounce increments rather than 1-kilocalorie units as utilized in this study. Another important consideration is experimental condition. This study revealed significant condition effects, which suggests that exploratory analyses should also be conducted to examine conditions separately. Finally, the findings of this study underscore the importance that health literacy be looked at as a moderator, rather than

relying on cross-sectional observations associating health literacy with behavioral outcomes. Future research should explore how individual-level health behavior theory and health literacy strategies used in behavioral interventions influence patterns of change in anthropometric and wellness outcomes such as BMI, weight, and QOL. This is particularly important in health disparate areas, such as Appalachia, where adults tend to consume higher amounts of SSB.[8-12]

Finally, it is important to recognize that regression models significantly predicted change in BMI but did not significantly predict change in weight. This finding is a bit perplexing and deserves further exploration. Though the statistical significance of the models varies, overall, both models explain a relatively small amount of variance in BMI (8.0%, $p<0.05$) and weight (6.4%, $p>0.05$) models. To build upon this study, next steps would be examining the effect of condition closer, and rather than solely controlling for condition effects within regression models, splitting the model by condition should be considered. Also, change in BMI and weight were minimal among all participants, and interpretation of small change could have influenced the model.

Limitations

The study population was largely representative of the medically-underserved Appalachian region of rural southwest Virginia, but findings may not be generalizable to other populations (i.e., participants were mostly female, and had annual income less than U.S. average). Since SIP*smart*ER participants were educated on measurement and intake of SSB, they may have been more knowledgeable about reporting their SSB behaviors at the 6-month follow up in contrast to their ability to report at baseline. The remaining limitations resulted as a function of the data utilized. Since the regression models depended on both the correlations between the dependent and independent variables and the correlations between independent

variables, it is likely to suspect that statistically significant associations will arise as it is difficult to isolate predictors when considering the complexities of behavioral change.[48,49] This study used the last observation carried forward method, a form of intention to treat (ITT) analysis.[42,43] In behavioral interventions, nonresponse and noncompliance (e.g., not attending follow-up data collection resulting in missing data) is a reality. For this study specifically, key variables were change scores, which rely on outcome data from both baseline and 6-month assessments. Using ITT, noncompliance can be overcome by providing an unbiased estimate of missing outcome data and thus intervention effectiveness, in addition to preserving sample size and randomization. However, using ITT analysis may in fact underestimate treatment effects, since missing outcome data are estimated instead of detailing true responses.[42,43] In this study, using ITT was chosen as it provides the more conservative estimate, but this approach likely dilutes potential model effects. Future studies could consider multiple imputation or maximum likelihood estimation approaches to lessen this dilution effect.[43] Additionally, this analysis would benefit from the use of robust standard errors to correct standard errors in the instance models were misspecified.[54-56] Finally, this secondary analysis was not powered to detect health literacy moderation effects, thus the moderation analysis findings should be cautiously interpreted.

Conclusion

Change in SSB intake did not predict change in BMI or weight, but did impact change in QOL, although in the opposite direction as expected. Future studies should consider using an interpretable unit of SSB intake when looking at the change in SSB behavior and change in outcomes such as BMI, weight, and QOL. As SIP*smart*ER was developed using health literacy strategies and delivered using the universal precautions approach, health literacy did not

moderate this relationship in any model as expected. Future work aiming to reduce SSB intake, particularly those among limited health literacy populations should aim to include longitudinal health literacy interventions and consider incorporating statistical techniques to test health literacy moderation. Additionally, such studies should continue to explore how individual-level health behavior theory and health literacy strategies used in behavioral interventions influence patterns of change in anthropometric and wellness outcomes.

Tables and Figures

TABLE 3.1: Sample demographics and other key outcome variables

	Baseline	**Six-Month**
Characteristics	*n(%)*	*n(%)*
Age (Mean ± SD)	42 ±13.4	
18-24 years	37 (13)	
25-44 years	134 (45)	-
45-64 years	118 (40)	
≥65 years	7(2)	
Sex		
Male	56 (19)	-
Female	240 (81)	
Race		
Caucasian	275 (93)	
African American	13 (4)	-
More than one race	7 (2.5)	
Other	1 (0.5)	
Ethnicity		
Hispanic/Latino	3 (1)	
Education level		
≤High school	93 (31)	-
Some college or greater	203 (69)	
Annual household income (Mean ± SD)	23,370 ±17,196	
≤14,999	126 (43)	
15,000-34,999	94 (32)	-
35,000-54,999	39 (13)	
≥55,000	37 (12)	
Work status		
Employed full or part time	144 (49)	-
Unable to work/on disability	51 (17	
Number of children		
At least 1 child	149 (50)	-
No children in household	147 (50)	
Condition		
*SIP*smart*ER*	151 (51)	
MoveMore	145 (49)	
Health literacy status		
High likelihood/Possibility of limited HL (NVS 0-3)	97 (33)	-
Adequate HL (NVS 4-6)	199 (67)	
Body Mass Index (Mean ± SD)	33 ± 9.12	
Underweight (≤18.4)	5 (2)	
Normal (18.5-24.9)	59 (20)	
Overweight (25.0-29.9)	64 (22)	
Obese (≥30)	168 (57)	
Weight (kg) (Mean ± SD)	90.6 ± 25.4	
Quality of life (# unhealthy days per month) (Mean ± SD)	7.8 ± 8.4	
Total energy intake (kcals)[a] (Mean + SD)	1878.13 ± 907.33	1577.66 ± 629.58

Moderate-vigorous physical activity[b] (mins/wk) (Mean ± SD)	69.44 ± 127.41	105.12 ± 190.80
SSB intake (kcals) (Mean ± SD)	436.83 ± 338.78	247.56 ± 298.29
6-month change in SSB intake (kcals) (Mean ± SD; range)	-140.84 ± 327.33 (-2156.78 - 737.94)	
6-month change in BMI (kg/m^2) (Mean ± SD; range)	-0.5 ± 1.34 (-8.20 - 6.70)	
6-month change in Weight (kg) (Mean + SD; range)	-0.19 ± 3.30 (-21.40 - 13.40)	
6-month change in QOL (# unhealthy days/month) (Mean + SD; range)	-0.67 ± 8.03 (-30.0 - 28.0)	

[a] from average of three 24-hour recalls [b] from Godin Leisure-Time Exercise Questionnaire

TABLE 3.2: Correlation matrix of key variables for three regression models (n=296)

	6-month change in BMI (kg/m^2)	**6-month change in Weight (kg)**	**6-month change in QOL (# unhealthy days/month)**	**6-month change in SSB (kcals)**	**Baseline health literacy status**
6-month change in BMI (kg/m^2)	1	-	-	-	-
6-month change in Weight (kg)	-	1	-	-	-
6-month change in QOL (# unhealthy days/month)	-	-	1	-	-
6-month change in SSB (kcals)	0.01	-0.02	-0.17**	1	
Baseline health literacy status (0=low, 6=high)	-0.10	-0.06	0.12*	-0.001	1

* $p \leq 0.05$ ** $p \leq 0.01$ *** $p \leq 0.001$

Table 3.3a-c: Hierarchical regression analyses of predictors of 6-month change in (a) body mass index (BMI), (b) weight, and (c) quality of life (QOL) (n=296)

3a		**6-month change in BMI (kg/m^2)**	
	Step/Predictor	*Step 1*	*Step 2*
β	6-month change in SSB (kcals)	-0.02	-0.12
	Baseline health literacy status	-0.17*	-0.15*
	Condition (1=*SIP*smart*ER*, 0=MoveMore)	-0.15*	-0.15*
	Age	-0.17**	-0.18**
	Interaction term: 6-month change in SSB (kcals) x Baseline health literacy status	-	0.12
R^2		0.076	0.080
ΔR^2		-	0.004
F		1.94*	1.89*

3b		**6-month change in Weight (kg)**	
	Step/Predictor	*Step 1*	*Step 2*
β	6-month change in SSB (kcals)	-0.05	-0.11
	Baseline health literacy status	-0.13	-0.11
	Condition (1=*SIP*smart*ER*, 0=MoveMore)	-0.12*	-0.12
	Age	-0.17**	-0.18**
	Interaction term: 6-month change in SSB (kcals) x Baseline health literacy status	-	0.08
R^2		0.062	0.064
ΔR^2		-	0.002
F		1.56	1.47

3c		**6-month change in QOL (# unhealthy days)**	
	Step/Predictor	*Step 1*	*Step 2*
β	6-month change in SSB (kcals)	-0.20***	-0.26*
	Baseline health literacy status	0.10	0.11
	Condition (1=*SIP*smart*ER*, 0=MoveMore)	-0.10	-0.10
	Age	0.05	0.04
	Interaction term: 6-month change in SSB (kcals) x Baseline health literacy status	-	0.07
R^2		0.063	0.064
ΔR^2		-	0.001
F		1.59	1.49

- kcals= kilocalories; SSB= sugar-sweetened beverages; BMI= body mass index; QOL=quality of life
- Model controls for age, education, income, sex, work status, disability status, number of children, baseline health literacy status, baseline total energy intake, baseline Godin-Leisure Time Exercise Questionnaire Moderate-Vigorous Physical Activity
- NOTE: only control variables that significantly contributed to the models are illustrated
- β = standardized regression coefficient
- * $p \leq 0.05$ **$p \leq 0.01$ ***$p \leq 0.001$

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CHAPTER 4: MANUSCRIPT 3 "USE OF THE AHRQ HEALTH LITERACY UNIVERSAL PRECAUTIONS TOOLKIT IN A PUBLIC HEALTH SETTING: A NEEDS ASSESSMENT TO INFORM ORGANIZATIONAL HEALTH LITERACY CAPACITY"

Abstract

Introduction: Documented efforts to address organizational health literacy within a public health setting are lacking. To address this opportunity, a collaborative health literacy (HL) improvement team was formed between researchers and four southwest Virginia Department of Health (VDH) districts serving federally designated medically underserved counties.

Methods: This mixed-methods needs assessment is guided by the Agency for Healthcare Research and Quality (AHRQ) HL Toolkit. VDH staff completed a 37-item survey adapted from the toolkit and based on four domains of organizational HL. VDH customers completed a validated 3-item individual-level HL screening measure (1=lowest HL, 14=highest HL) and 7 questions on 4-point scale (1=never, 4=always) pertaining to personal perceptions of VDH services. Findings were used to develop a HL improvement plan, which consisted of e-newsletters and in-person workshops on the Clear Communication Index.

Results: Among 252 VDH staff (88% female, average age 49±12 years, 51% ≥ bachelor's degree) about 50% reported "doing well" across each HL domain; however, a subset reported "needs improvement" or "not doing" across written communication (31%), self-management and empowerment (24%), oral communication (19%), and supportive systems (16%) domains. Staff responses during roundtable discussion support and expand upon these quantitative findings. Among 185 VDH customers (82% female, average age 33±14, 40% ≤ high school education), perceptions of staffs' HL practices were high, ranging from 3.07 to 3.64 on a four-point scale. Customer HL status was significantly correlated ($p<0.05$-0.01) with comprehension of forms ($r=0.50$) and written materials ($r=0.48$), explanation of services ($r=0.26$), following instructions ($r=0.15$), and reference to personal history ($r=0.16$).

Conclusions: Findings reveal notable strengths and weaknesses in current health literacy practices from both staff and client perspectives, with the greatest need identified in the written communication domain. E-newsletter series and in-person workshops on CCI were executed and evaluated, laying the groundwork for additional HL improvement activities within VDH. Limitations specific to the public health setting and recommendations for future work are discussed.

Introduction

The health care system is complex; patients and their caretakers are required to navigate and interpret information received. This information includes communicating with health care practitioners, applying information learned to care of self or others, completing forms or giving consent, and reading and understanding written material such as medication instructions.[1] Consequently, health literacy was pinpointed as a national priority area at the turn of the 21st century, and over the past decade it has been recognized that systems-level efforts are necessary in order to alleviate the burden individuals face.[2,3] As such, the term organizational health literacy was coined and is defined as the extent to which health organizations and systems (and their staff) support individuals (i.e., patients, clients) as they seek, receive, and use information and services.[3] Current efforts to improve organizational health literacy target the provider- or staff-level initially, rather than the individual patient or client. However, changes and considerations made by providers and staff have potential to impact patient-level outcomes.

Individual-level health literacy is the degree to which people have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.[4] Low health literacy affects over 36% of adults in America, and has been consistently associated with poorer self-reported health status, less use of preventive services, and inability to engage in self-care or manage chronic conditions. [5,6] The concept of health literacy reflects the dynamic interplay between individual competencies and health care demands; individual health literacy is dependent on a person's existing knowledge and skills and how understandable and user-friendly health care systems and their staff present information and services.[7,8]

Public health encompasses multiple essential services ranging from health promotion to occupational health to environmental health and disaster preparedness. While the range of public

health services offered are extensive, organizational health literacy principles have broad application and should be incorporated within each area of work.[9] The challenge exists in addressing each of these areas by removing barriers to patient-centered healthcare and then increase the capacity for organizational health literate care.

The Agency for Healthcare Research and Quality's (AHRQ) Health Literacy Universal Precautions Toolkit (Toolkit) is a tool designed to support patients of various health literacy levels by reducing complexity within the healthcare system.[10] The Toolkit includes evidence-based guidance that healthcare systems can use to determine that appropriate practices are in place, and to determine areas of need. It consists of 21 evidence-based tools that adhere to the universal precautions approach (i.e., treating all individuals as if they are unable to understand health information). These tools each represent one or more of the four domains of health literacy: oral communication, written communication (e.g., Clear Communication Index, or CCI), self-management and empowerment, and supportive systems.[10] One available tool to address communication is the teach-back method, a way of checking if a patient understands and is able to state in their own words key things to know or do to manage their health.[10] Ways to improve written communication include assessing and designing easy to read materials, such as through use of the CCI, which is a tool used to develop, assess, and evaluate written public health materials.[10,11] For the self-management and empowerment domain, tools such as creating action plans and encouraging patients to ask questions are suggested.[10] Finally, for supportive systems, tools such as referring to appropriate resources in community and non-medical support are used.[10]

The Toolkit was initially developed for primary care settings but was created to be adapted to fit the needs of other systems. Utility has been observed in other settings as well (e.g.,

community-based clinics, pharmacies, and health insurance domains).[12,13] This Toolkit is one of few measures that address each of the Ten Attributes of Health Literate Organizations, illustrated by the Roundtable on Health Literacy in a paper commissioned by the National Academy of Medicine.[2,14] These ten attributes represent characteristics organizations embody that enable their clients to better navigate, understand, and use information and services to properly manage their health, and serve as a benchmark of success.[2]

Objectives

In order for health care organizations to improve health literate care, assessment of organizational health literacy characteristics must take place in order to identify areas for improvement and address change in health literacy practices.[2,14,15] With a long-term aim of building capacity for organizational health literacy and bolstering success of future public health initiatives, the objectives of this mixed-methods case study targeting four Virginia Department of Health (VDH) districts were 1) to perform a needs assessment using adapted AHRQ Toolkit instruments to identify perceptions in health literacy practices from both VDH staff and clients, and across the four domains of organizational health literacy and 2) to describe how the needs assessment findings were used to collaboratively develop and implement an organizational health literacy improvement plan within the VDH districts. The needs assessment consisted of quantitative data collected using a staff assessment tool and client assessment tool, and qualitative data collected from staff using open-ended questions during roundtable discussions. The improvement process included a professional development event to raise awareness, an e-newsletter series, and in-person workshops on the CCI.

Methods

Study Design and Setting

This case study describes a partnership between medical directors and public health staff from the VDH and an academic research team from the University of Virginia and Virginia Tech, and details a mixed-methods needs assessment and initial improvement process used to inform a subsequent organizational health literacy improvement plan. This work took place within four VDH districts (Lenowisco, Cumberland Plateau, Mount Rogers, and New River). A significant part of southwest Appalachian Virginia, these rural areas are prone to significant health disparities, lower educational and literacy levels, and socioeconomic disadvantages.[16-18] The Virginia Healthy Opportunity Index, part of the Virginia Health Equity Report, is a composite measure of the social determinants of health within each county. The counties that make up the four VDH districts score poorly on the Health Opportunity Index when compared to other areas in Virginia, meaning they have less opportunity comparatively.[19]

Figure 4.1 details the timeline and components of this organizational health literacy case study. The study protocol was approved by the Virginia Tech Institutional Review Board and both VDH staff and clients provided consent prior to participation.

Mixed-Methods Needs Assessment

1) Foundation of the Health Literacy Improvement Team

The partnership between the researchers and VDH medical directors and staff was born from shared desire to reduce such identified disparities by expanding evidence-based programming, particularly related to decreasing sugar-sweetened beverage intake, a prioritized health problem. To lay the groundwork for doing so, VDH stakeholders also expressed intention to build capacity

related to organizational health literacy. Thus, the role of this effort is to strengthen the organizational health literacy capacity to support the implementation of the SIP*smart*ER project, a health literacy intervention proven effective at reducing sugar-sweetened beverage consumption among adults in southwest Virginia.[20]

During planning meetings that took place prior to this study, the research team shared and described the AHRQ Toolkit as a method to assess and promote general organizational-level health literacy. To gather multiple perspectives, the research team engaged VDH organizational decision-makers (i.e., medical directors) and VDH staff (e.g., health educators, nurses). Initial meetings were framed by AHRQ Toolkit Tool 1 "Form a Team", with the focus being establishing a health literacy improvement team, discussing both personal and organizational hopes for collaboration, deciding upon the AHRQ Health Literacy Toolkit, and collaboratively adapting staff and client assessment tools. The original AHRQ Primary Care Health Literacy Assessment Tool was piloted with the three medical directors for relevance and acceptability. The research team reviewed responses and solicited feedback from the medical directors on how to improve this staff assessment tool. In the same manner, the client assessment tool was piloted with the health literacy improvement team and subsequently revised, as described below.

2) Staff and Client Assessment Measures

Existing, evidence-based AHRQ Toolkit instruments were modified to best capture the four domains of organizational health literacy (i.e., written communication, oral communication, self-management and empowerment, and supportive systems) in a public health setting. The adapted staff and client instruments were revised per feedback from VDH medical directors to generalize questions to staff who work outside of the clinical setting. This collaborative adaptation process

resulted in tools appropriate for the VDH population that adequately capture staff and client perceptions of health literacy practices within four VDH districts.

Staff

Based on feedback from the medical directors, the original 56-item AHRQ Primary Care Health Literacy Assessment Tool was adapted to be more suitable for this public health setting. Language was modified (e.g., "patient" was changed to "client"; "clinician" changed to "staff"; "medical attention" was changed to "services"), and less relevant questions were removed (i.e., questions that pertained to the environment rather than interpersonal interactions) leaving 37 retained items. In addition, demographic characteristics were self-reported. This survey was delivered through Training Finder Real-time Affiliate Integrated Network (TRAIN), Virginia's affiliate of the nation-wide web-based learning portal routinely utilized by VDH staff to complete online trainings and assessments. See Appendix A for the full instrument.

Staff perceptions of health literacy practices were assessed in April 2016, prior to the kick-off event, the initial professional development event. All staff were at least 18 years old, spoke English as their primary language, were required by their VDH medical director to complete the survey, and consented to sharing their responses for research purposes.

Client

Client perceptions of health literacy practices within each VDH district were assessed between July and September of 2016. All clients were at least 18 years of age, spoke English as their primary language, and had received service from VDH within the past year.

Clients completed a paper-based survey that included seven questions about their perceptions of care given by VDH staff member(s). Questions were adapted from the Health Literacy Responsiveness of Primary Care Practices screener and the AHRQ Health Literacy Patient

Interview Tool.[21,22] Three questions were included to assess subjective health literacy status.[23-25]Client responses were collected by VDH staff. Staff from each district were trained per protocol and screened VDH clients in multiple localities (e.g., clinics, work sites, reception areas, WIC office). See Appendix B for the full instrument.

3) Kick-Off Event Roundtable Discussion

A five-hour staff-wide training took place May 2016. The purpose of this kick-off event, framed by AHRQ Toolkit Tool 3 "Raise Awareness", was to raise awareness of the importance of health literacy and inform staff of implementing a universal precautions approach when interacting with clients (i.e., treating each client as if they may be at risk of not understanding health information).[21] The training was led by the Virginia Tech research team, and there were 279 attendees in total. At the end of this training, additional staff perceptions were gathered regarding practice and training related needs. The attendees were grouped and seated at tables (~8 staff per table) according to discipline, and led in roundtable discussion using a modified World Café approach, a method that stimulates collaborative dialogue around purposeful questions in a large group setting.[26] Staff were posed open-ended questions developed by the health literacy improvement team. Roundtable discussions were recorded on poster-size paper (one poster-size paper per question per table) and photographs of each table's poster-size papers were taken.

Improvement Process

1) Developing a Health Literacy Improvement Plan

Once the Toolkit was decided upon and initial needs assessment data collected, the team began constructing a plan based on guidelines in AHRQ Tool 2 "Create a Health Literacy

Improvement Plan". Meetings then shifted focus from assessment measures towards conducting improvement activities. The improvement plan consisted of a staff-wide professional development event to raise awareness of organizational health literacy improvement activities and plans for using needs assessment results to inform the delivery of e-newsletters and in-person trainings.

2) E-newsletters

The health literacy improvement team developed a quarterly email e-newsletter series entitled "Health Literate SWVA" (SWVA, southwest Virginia) using AHRQ Toolkit tools and other existing health literacy resources such as the Centers for Disease Control and Prevention, Health Resources and Services Administration, the National Library of Medicine, and relevant health communication and risk prevention literature. The email marketing service MailChimp was used to generate and mass-deliver e-newsletters to the work email addresses of VDH staff.[27] Launched in October 2016, the e-newsletters were framed around the four domains of health literacy and aimed to address relevant concerns brought forth by staff at the kick-off event. Each e-newsletter provided techniques staff could use to improve client experiences and outcomes and reinforced content from the kickoff event. To gauge usefulness of the e-newsletters, a survey link was embedded to encourage staff to share their thoughts on the content with the research team after viewing. Before releasing each e-newsletter, a final draft was sent to VDH stakeholders for comments and suggestions. Additionally, the email listserv was updated prior to each release to include new hires in ongoing improvement efforts. Figure 4.1 summarizes which components of the AHRQ Toolkit were included in each e-newsletter.

3) Clear Communication Workshop

Developed by a team of content experts from the Centers of Disease Control and Prevention, the CCI is a tool with four open-ended questions and 20 quantitative questions used to assess, develop, and evaluate a variety of public communication materials. It was developed to help users and distributors of such material comply with the Plain Language Act of 2010 and guidelines set forth in the National Action Plan to Improve Health Literacy.[11] As part of the health literacy improvement plan, an in-person staff development workshop based upon the CCI was conducted for each of the four VDH districts. To work with existing organizational structure and decrease staff burden, this workshop was held during an existing staff development day at a convenient location, unique to each district. The research team designed this 90-minute workshop to help VDH staff 1) recognize why, how, and by whom the CCI was developed, 2) understand core components of the CCI, and 3) use the CCI to assess and/or evaluate and/or design written materials with confidence, particularly materials they use in everyday practice. The first 30 minutes of the workshop were didactic, and the final hour was interactive (i.e., staff were split up by discipline and each group assessed written materials relevant to their discipline using the CCI). The intention of this workshop was to help staff be cognizant of issues to keep in mind when working with written materials and incorporate easy to implement strategies in their daily routines. The workshop was quantitatively and qualitatively evaluated using a paper-based survey at the completion of the workshop.

At the end of each workshop, staff completed surveys that consisted of 6 quantitative items and 5 qualitative items. Demographic characteristics were also assessed. This survey, developed by the research team, assessed the utility of the workshop as part of the overall organizational health literacy improvement plan and asked staff to report their thoughts on the

content, delivery, usefulness, and planned use of concepts in their daily practice as health care professionals. See Appendix C for the full instrument. As the workshops were held within each district individually, results are presented by each district as well.

Statistical Analysis

SPSS statistical analyses software version 24.0 (International Business Machines Corporation, Pittsburgh, PA) was used for all analyses unless otherwise indicated below. Descriptive statistics were used to summarize staff and client demographic characteristics.

Staff Needs Assessment

Descriptive statistics were used to summarize staff needs assessment survey responses. Reliability analysis (Cronbach alpha) was conducted to determine the internal consistency of the four subscales of the adapted AHRQ Tool used for staff needs assessment.

Client Needs Assessment

Descriptive statistics were used to summarize client needs assessment survey responses. Spearman's correlations were conducted to measure the association between client perceptions of health literacy practices and client self-reported health literacy status.

Kick-off Event Roundtable Discussion

Each table's posters for the four open-ended questions were photographed using a digital camera, and transcribed verbatim by an unbiased research assistant into a Microsoft Excel spreadsheet. Content analysis was used to categorize staff responses.[28] With guidance of the primary investigator, one research associate and one research assistant independently used an inductive approach to generate initial themes. They then met with another research associate to resolve discrepancies, develop final codes, and create a code book and definitions. Then, the

same research assistant along with another research assistant independently assigned meaning units from each table's responses into the appropriate code. If found to be overly specific, codes were collapsed when deemed necessary both during and after the coding process. Using Microsoft Excel, code counts were tabulated and totals for each code were summarized descriptively. Interrater reliability (percent agreement) was calculated,[29]and disagreements were discussed and resolved.[28] Efforts were made to triangulate quantitative and qualitative data from the staff needs assessment and roundtable discussion responses to cross-validate and strengthen findings.[30]

E-Newsletters

Using data from the MailChimp server, response rates for each newsletter were recorded and analyzed descriptively in Microsoft Excel. Specifically, the number and percentage of staff that opened each email newsletter and the number and percentage of staff that clicked on one or more hyperlinks embedded within a newsletter was tallied.

Clear Communications Workshop

Descriptive statistics were used to summarize staff survey responses for each workshop. Survey data was transcribed verbatim by an unbiased research assistant into a Microsoft Excel spreadsheet. Content analysis was used to analyze responses to qualitative questions. Using SPSS, code counts were tabulated and totals for each code were summarized descriptively.[28]

Results

Demographics

VDH staff that attended the kick-off event and completed the needs assessment (n=252) were 88% female, average age 49±12 years, 95% Caucasian, 51% ≥ bachelor's degree, and 55%

worked at VDH for >10 years. Of note, staff from various disciplines participated, including administrative (22%), environmental health (15%), epidemiology/emergency response (4%), health education (4%), nursing (34%), Woman, Infants, & Children (14%), and other reported positions (7%) (Table 4.1).

A total of 642 clients were screened, of which 185 indicated they had received service from VDH within the past year and were included in the analysis. VDH clients (n=185) were 82% female; average age 33±14 years, 91% Caucasian, 91% non-Hispanic, 40% ≤ HS education, and a reported subjective health literacy status average of 12.8 out of 14 (1=lower health literacy, 14=higher health literacy) (Table 4.1).

Staff Needs Assessment

The adapted tool demonstrated acceptable internal consistency; all four subscales had high levels (range =0.79-0.85). Across all four domains, staff perceptions of unit health literacy practices reflected between 42-58% responses categorized as "doing well". Between 15-25% of staff noted that practices "need improvement", and less than 10% of responses reflected that staff were "not doing" a particular practice. According to staffs' self-reported perceptions, the most improvement was needed in the written communication domain, followed by the self-management and empowerment domain, then oral communication domain, and needing the least improvement the supportive systems domain. Notably, between 11-15% of staff selected they were "not sure" about a particular item, and between 10-19% felt that the particular item was "not applicable for my role".

Average self-perception responses of individual health literacy practices ranged from the majority of staff reporting they "sometimes" engage in a particular practice to "always". Results

from the individual questions are summarized in Figures 4.2e-j. Overall, self-perception of individual health literacy practices mirrored that of the unit-based practices, with a majority of staff reporting that they engage in health literacy practice while room for improvement was evident.

Client Needs Assessment

Overall, clients' perceptions of staff's health literacy practices were high, ranging from 3.07 to 3.64 on a four-point scale (Table 4.2). For five of seven organizational health literacy practices, there was a statistically significant positive correlation with client's health literacy status (i.e., the higher the clients' health literacy status, the higher their perception of the staffs' health literacy practices). These correlations were strongest for written health literacy practices.

Kick-Off Event Roundtable Discussion

Responses from the roundtable discussions support and expand upon the findings from the quantitative staff needs assessment across all four domains of health literacy (Table 4.3). Across all four questions, interrater reliability between the two coders was high, with agreement ranging from 76.1%-80.2% (average 77.2%). Across 3 out of 4 questions (questions 1, 2b, and 3), communication emerged as the most commonly discussed theme, whereas the least common themes were knowledge and culture and supportive systems. In question 1, the oral communication theme included codes such as working to decrease language barriers (57% tables) and using plain language or simplifying a message (54% tables). In question 2b, the most frequently referenced codes within the communication solutions theme included simplifying procedures and materials (54%) and using updated written materials (46%). In question 3, the

communication training theme included codes related to oral communication strategies (49%0 and management of language barriers (46%). Contrarily, the supportive systems theme was the most commonly theme mentioned in question 2a, and the least frequently mentioned was the knowledge and culture theme. Within the supportive systems theme, staff most often responded with codes related to having limited time with clients (51%) and being understaffed or undertrained (32%).

Each of the four open-ended questions addresses the four domains of health literacy and are described below as such. For written communication, 54% of the tables reported that the written materials clients were exposed to were too complex. In response to this, staff voiced that they already take time to modify or explain such complex written material, whether it be an intake form or educational pamphlet (59%) and could work to simplify procedures and materials (54%) and further update written materials (46%).

About 41% of tables voiced that barriers related to oral communication are often due to language barriers and many already work to address this and other difficulties by working to decrease language barriers (73%), and by simplifying language and using health literacy strategies such as open-ended questions (51%) and teach-back (46%).

In terms of self-management and empowerment, responses showed that staff encountered barriers stemming from cultural challenges and trust issues, but staff reflected they work to build trust and reduce judgement (59%) and can further overcome this by emphasizing individualized interactions (46%) and receiving more training on cultural competence (51%).

While few staff reporting either not doing or needing improvement with health literacy practices related to supportive systems, many reported barriers such as having limited time with clients (51%) and being understaffed or not properly trained (32%). Staff reported that in the

past, this has been mediated by increasing access to patients by reducing distractions (46%) and providing relevant staff training (32%). Other strategies referenced that could mediate this include incorporating electronic solutions and technological improvements (49%) and collaboration between health professionals (38%).

E-newsletters

E-newsletters were sent and delivered to around 300 staff members during each release. This number varied due to hiring changes. The staff open rate was 83% (251/303), 74.9% (222/297), 70.7% (210/297), and 9.3% (30/321) for e-newsletters 1-4, respectively. Likewise, 8.9% (27/303), 6.2% (18/297), 2.7% (18/297), and 1.0% (4/321) clicked at least one link for e-newsletters 1-4, respectively.

Clear Communication Workshop

The New River (n=50), Lenowisco (n=49), and Cumberland Plateau (n=31) districts included staff from all disciplines (i.e., administrative, clinical, WIC, environmental health, population health, emergency preparedness, health education, and financial), while the Mount Rogers district included 40 staff from the clinical and WIC disciplines. Overall, the majority of attendees were female ($\geq$79%), and the time worked at VDH ranged from less than one year to over 50 years. On a five-point scale, one being strongly disagree and 5 being strongly agree, responses ranged from 3.48 to 4.38 with regards to the training's content, delivery, usability, and applicability to everyday practice. When asked what they liked about the workshop, staff most commonly mentioned that they liked the applicability of activities such as using own materials to learn the CCI, that they appreciated the dialogue about the importance of improving

communication, and that they enjoyed the interactive design of the workshop. The largest complaint was that more time was needed to complete the workshop, and some staff voiced a desire for tips on using the CCI with social media content and in conjunction with verbal communication strategies. When asked what new information or skills were learned during the workshop, staff most often mentioned they learned how to assess, evaluate, or improve communication materials and that their awareness was raised when considering the understandability of materials and clarity of interactions with clients. While a majority of staff mentioned ways, they would like to use information gleaned from this workshop (e.g., using the CCI to assess, redesign, or develop materials or making sure materials are read and explained to clients in a clear, understandable way), many identified barriers. Commonly cited barriers were being required to use certain forms or education materials, needing approval from upper management to change materials, and needing more time to assess or develop materials.

Discussion

With an overarching aim of building capacity for organizational health literacy, conducting organizational needs assessment is a necessary first step to becoming health literate health care organization.[2,14,15] This organizational health literacy needs assessment builds on established health literacy domains identified in the AHRQ Toolkit, commonly used by others to assess and intervene to improve organizational health literacy capacity. The adapted AHRQ Toolkit needs assessment instruments were successfully used to conduct a needs assessment and inform development of a subsequent health literacy improvement plan that aligns with identified training needs among four VDH districts. This study is the first to use the AHRQ Toolkit in a public health setting and contributes unique insight of our process. Areas of improvement were

noted from both staff and client perspectives, with the most need identified in written communication. In addition, health literacy status was significantly correlated with clients' perceptions of staff health literacy practices.

The original AHRQ Toolkit was created for the primary care setting but has been adapted for rheumatology and cardiology[31] and a similar toolkit was created for pharmacy settings[32]. This study is novel in that it represents the first use of the AHRQ Toolkit in a public health setting. Public health staff at VDH play a key role in preventing and controlling chronic disease and reducing health care disparities. There are many disciplines that make up VDH, including administrative, environmental health, epidemiology and emergency response, health education, nursing, and Woman, Infants, & Children (WIC). When developing the health literacy improvement plan, it was difficult to develop training content to be suitable for all disciplines. While this was a challenge, it strengthened our approach by broadening our horizons beyond training materials developed solely for primary care. This also kept us cognizant of ensuring our delivery of written and oral communication was something that would engage nurses and environmental health personnel alike. The adaptability of the AHRQ Toolkit allowed us to think outside of the box while still aligning with the Toolkit's purpose and structure, enabling us to apply AHRQ Toolkit tools and principles in a manner that would be accepted and beneficial to the health department as a key public health setting.

The staff needs assessment was strengthened by including perceptions of individual health literacy practices and health literacy practices of the staff members' respective unit. Individual perceptions of practice mirrored those of unit-based practices, and results designated the focus initial e-newsletter and professional development workshops. These results enabled us to prioritize these domains when developing the improvement plans.

It is important to assess whether clients are satisfied with care received in a health-related environment,[33] and particularly imperative to determine that healthcare organizations are accessible and suitable for patients.[2] The client needs assessment gives a snapshot of client perceptions of VDH staff practices. The finding that clients' perception of staff health literacy practices were correlated with client health literacy status has important implications. This is most evident in written communication domain, which closely aligns with findings from the staff assessment and reinforce importance of training on written communication practices and strategies. The knowledge that clients with lower self-reported health literacy status have lower perceptions of health literacy practices justifies why it is important to take steps to improve organizational health literacy within VDH. The value of patient perspective reinforces the importance of multilevel assessment when working to improve organizational health literacy capacity.

We found that delivery of in-person professional development workshops was best done in conjunction with existing staff development days to make best use of time and resources. To make the CCI workshop a relevant and usable experience for the staff, we solicited existing written materials and handouts most frequently used by staff, including those which they thought may have opportunity for improvements. This proved to be successful in helping us create a richer experience for the staff, as a majority of staff from all four districts voiced their appreciation of being able to apply their new knowledge of the CCI tool to their own materials that they were familiar with. Feedback received from the post-workshop evaluation showed that most staff found the workshop valuable and contributed skills and strategies they could use in the future to raise awareness of or improve written communication materials. Staff also reported

barriers that helped us further evaluate needs within each district, such as having little room to assess or adapt written materials because of upper-level management restrictions.

We were successful in accomplishing a staff and client needs assessment and developing an improvement plan based upon findings; however, there are a few notable challenges worth mentioning. We began the project with four medical directors, who each play an instrumental role in leadership and district-wide coordination of care. Two medical directors stepped down from their position, and one new medical director was appointed during this project, which caused us to continually emphasize partnership development and revisit our health literacy improvement plan. Another challenge was the lack of time VDH staff had to incorporate additional roles in excess of their job responsibilities. While many strategies suggested during the roundtable discussion are immediately feasible (e.g., using plain language, emphasizing individualized interactions with clients), others require time and resources and may be difficult to implement (e.g., assessing and improving written materials, providing training in communication and cultural competence). As a result, improvement efforts were largely driven by the research team and VDH medical directors, and engagement among staff during the planning process was limited. Ideally, "front line" staff (e.g., nurses, WIC specialists, environmental health personnel, health educators) should be involved in organizational health literacy improvement efforts, as these are the individuals who are carrying out day-to-day work and boast invaluable perspective.[10,34-37] However, oftentimes this is initiated by tireless efforts of health literacy change champions, informal advocates, or staff hired to solely address organizational health literacy improvement.[38] Additionally, a more comprehensive, integrated approach is warranted in order to help healthcare organizations embody characteristics of organizational health literacy (i.e., health literacy improvement should not exist in isolation).[39-44] A final challenge was

developing and successfully executing the improvement plan based on staff feedback primarily due to time and resource constraints.

Limitations

First, although it is ideal to collect a more comprehensive assessment of clients,[14] time and resources prevented us from being able to request perceptions beyond the seven-item measure. Second, the AHRQ Primary Care Health Literacy Assessment Tool included response categories "not sure" and "not applicable for role". It is worth exploring staff who are choosing these response categories. For example, it is possible that staff chose "not applicable for role" based on their perception that a certain practice does not apply to their discipline, when in fact the importance of this practice in terms of health literate care is greater than realized. Additionally, the "not sure" response could reflect lack of health literacy related training or unfamiliarity with health literacy practices such as teach-back or creating action plans.[39] Finally, the fourth e-newsletter reflected lower viewing and engagement rates. The first three newsletters were sent between 9 and 10 o'clock in the morning, while the fourth was sent between 1 and 2 o'clock in the afternoon. This difference in delivery time could have affected the viewing rates, for example if staff were less likely to check email after noon compared to in the morning. The fourth newsletter was also sent a week and a half before the Thanksgiving holiday, also a time when VDH heavily prioritizes flu season immunization and prevention.

Implications for Policy and Practice

A notable strength of this study is the utilization of multi-level quantitative assessment of heath literacy practice perceptions at both the staff and client levels, as an organizational needs assessment is best completed by surveying staff, clients, and the environment.[14] Future work

should aim to include objective environmental audits or staff and provider interactions. Additionally, this work would benefit from qualitative perceptions of practice at the client level. We plan to maintain partnerships with VDH and continue work within health literacy improvement teams based on the needs identified in our assessments. Our projected plan would include a continuation of the quarterly e-newsletter series, between one and two district-wide professional development events per year, and when appropriate, a reassessment of health literacy practice perceptions and needs to determine next steps of the improvement process. To build upon this needs assessment and researcher-driven improvement plan, the adoption and implementation of the AHRQ Toolkit by each individual district could be tested. Each district's approach to utilizing the toolkit is valuable, ranging from which tools were chosen to be used, and how implementing tools altered health literacy practices.[10,40,41]

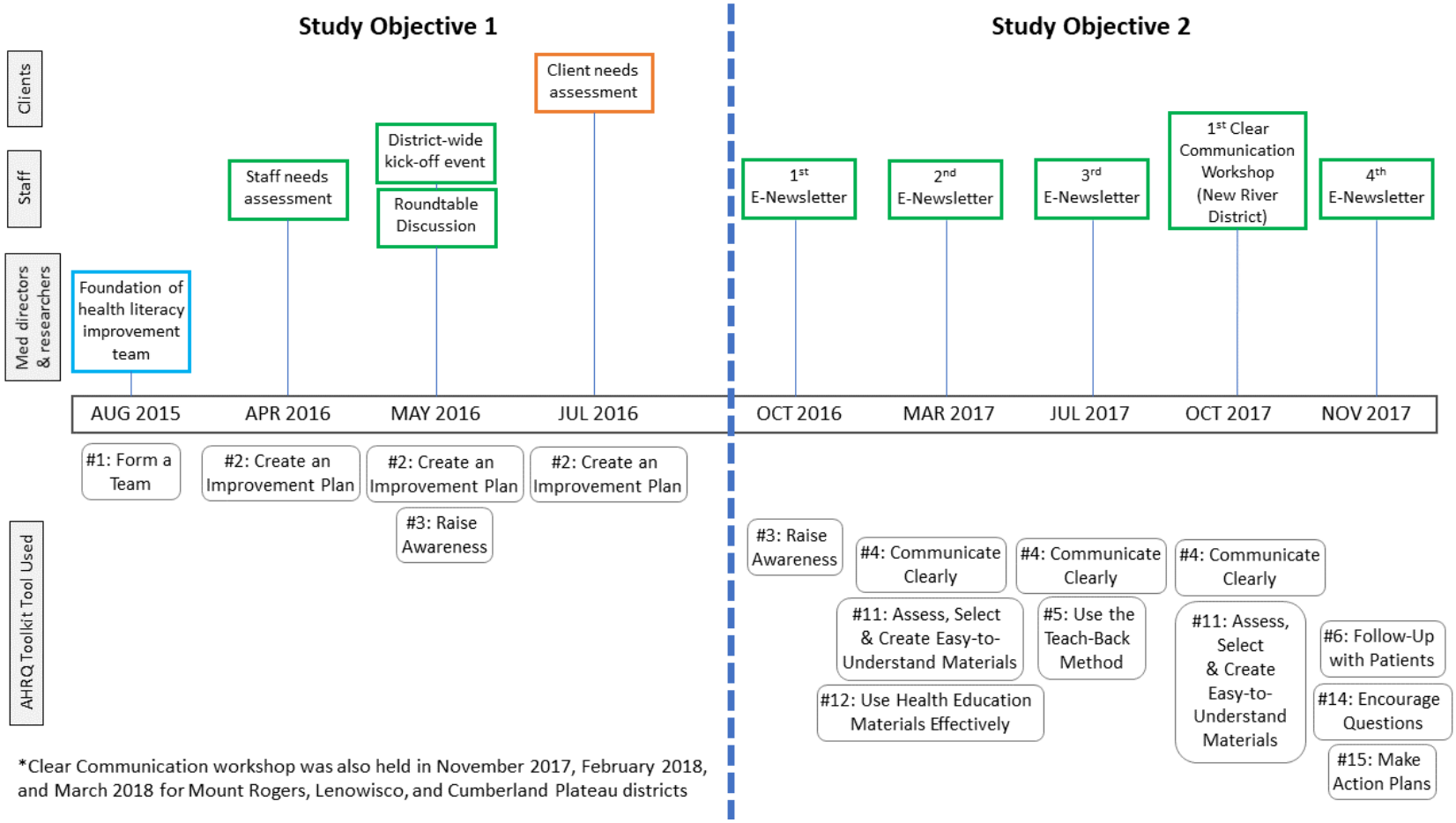
Conclusion

This study is the first to use the AHRQ Toolkit in a public health setting to conduct an organizational needs assessment and develop a health literacy improvement plan, which included e-newsletters and in-person workshops. Findings reveal notable strengths and weaknesses in current health literacy practices from both staff and client perspectives, with the greatest need identified in the written communication domain. In the future, it is recommended that objective environmental assessments are conducted, and that qualitative perspectives are gathered from both staff/provider and client/patient levels. Notably, health literacy status was significantly correlated with clients' perceptions of staff health literacy practices. Future improvement efforts should consider evaluating whether client or patient perceptions of practice are correlated with health literacy status. Although there is a trend towards adopting a universal precautions approach regardless of need, it is important to recognize a system's unique barriers to health

literacy and implement training. Future work should expand on this study and consider an AHRQ Toolkit adapted for a public health setting.

Tables and Figures

Figure 4.1: Timeline of events organized by study objective and level of participant involved



VDH=Virginia Department of Health; AHRQ=Agency for Healthcare Research & Quality; #=AHRQ Toolkit tool number

Table 4.1: Baseline demographics for staff and clients

STAFF (n=252)		CLIENTS (n=185)	
Characteristic	**n (%), unless otherwise noted**	**Characteristic**	**n (%), unless otherwise noted**
Sex		**Sex**	
Male	28 (11.6)	Male	32 (17.1)
Female	213 (88.4)	Female	153 (81.8)
Age (Years), M(SD)	49.0 (12.3)	**Age (Years), M(SD)**	33.4 (13.7)
18 - 24	3 (1.4)	17-24	57 (31.3)
25 - 44	75 (34.2)	25-44	90 (49.5)
45 - 64	128 (58.4)	45-64	27 (14.8)
≥ 65	13 (5.9)	≥65	8 (4.4)
Race		**Race**	
Caucasian	240 (95.2)	Caucasian	171 (91.4)
Other	2 (0.8)	Other	12 (6.5)
Educational Attainment		**Ethnicity**	
High school degree/GED	59 (23.4)	Hispanic/Latino	6 (3.2)
Associate's degree	65 (25.8)	Not Hispanic/Latino	171 (91.4)
Bachelor's degree	94 (37.3)	**Education Level**	
Graduate degree	34 (13.5)	≤ High school degree	74 (39.8)
VDH District		Some college	54 (29.0)
Cumberland Plateau	48 (19.0)	College degree	37 (19.9)
Lenowisco	54 (21.4)	Graduate degree	21 (11.3)
Mount Rogers	110 (43.7)	**Health Literacy Status, M (SD)**	
New River	40 (15.9)	1=lowest, 14=highest	12.8 (1.7)
Unit		**VDH District**	
Administrative	55 (21.8)	Cumberland Plateau	73 (39.0)
Environmental Health	38 (15.1)	Lenowisco	27 (14.4)
Epidemiology/emergency response	10 (4.0)	Mount Rogers	30 (16.0)
Health education	11 (4.4)	New River	57 (30.5)
Nursing	86 (34.1)		
WIC	35 (13.9)		
Other	17 (6.7)		
Years in Staff Position			
0 - 10	140 (56.0)		
11 - 20	41 (16.4)		
21 - 30	36 (14.4)		
31 - 40	19 (7.6)		
≥ 41	14 (5.6)		
Years at VDH			
0 - 10	112 (44.6)		
11 - 20	51 (20.3)		
21 - 30	52 (20.7)		
31 - 40	21 (8.4)		
≥ 41	15 (6.0)		

Figures 4.2a-j: (a-d) Self-perception of **unit** health literacy practices and (e-j) self-perception of **individual** health literacy practices, according to Agency for Healthcare Research & Quality's (AHRQ) four domains of health literacy (n=252)

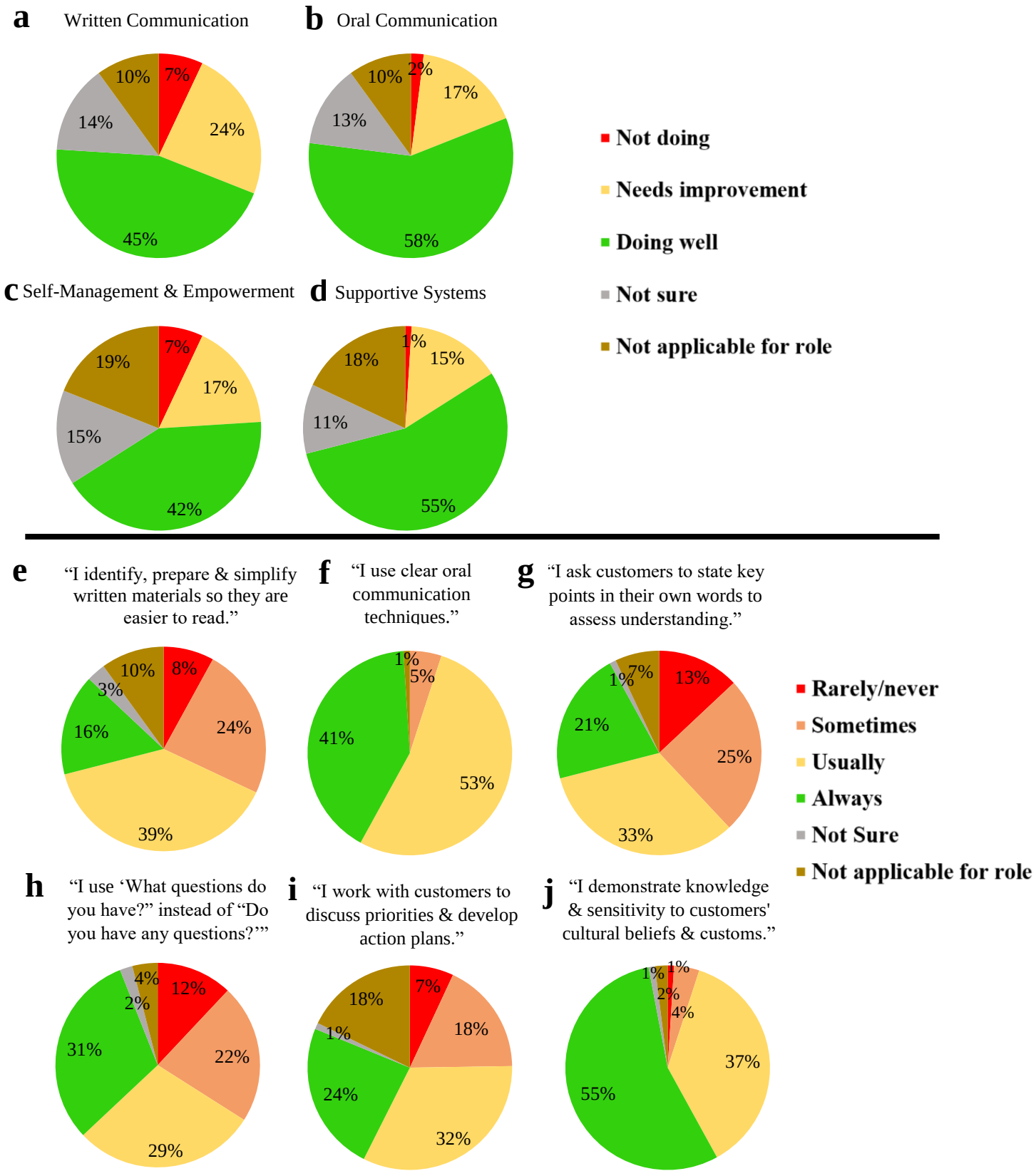


Table 4.2: Correlation between client health literacy score & client perception of Virginia Department of Health (VDH) services (n=185)

	***M (SD)*[a]**	***Spearman's r* (p value)**
VDH asks about following instructions	3.07 (1.00)	0.15 ***(0.04)***
VDH refers to personal history	3.25 (0.81)	0.16 ***(0.04)***
VDH forms easy to understand	3.43 (0.73)	0.50 ***(<0.01)***
VDH written materials easy to understand	3.52 (0.69)	0.48 ***(<0.01)***
VDH staff spends enough time w/client	3.54 (0.67)	0.13 *(0.08)*
VDH encourages questions	3.54 (0.72)	0.13 *(0.09)*
VDH explains services	3.64 (0.59)	0.26 ***(<0.01)***

[a] Scale of 1-4 with 1=never, 2=sometimes, 3=usually, 4=always
Self-reported health literacy status with 3=low health literacy, 14=high health literacy; M=12.8, SD=1.7

Table 4.3: VDH staff responses from kick-off event roundtable discussion. The 279 staff were grouped in 37 tables. **Broad Theme:** This number represents the total of tables that chose codes that fit within the identified theme. **Codes:** For each of the 4 questions, the common denominator is 37. Tables were included in code count if they included one or more responses that fit a code.

Question 1: *"Think about a typical low health literate client that is served by your unit. What are some specific practices that your unit could do to strengthen the VDH experience of a low health literacy client?"*		
Broad Theme	*Code (out of 37 tables)*	*Examples*
ORAL COMMUNICATION (n=77)	Decrease language barriers 57% (n=21)	"need to translate materials in different languages" "use interpreters or language line"
	Use plain language/Simplify message 54% (n=20)	"limit medical terminology or technical terms and speak in layman's terms" "make conversation with patient informative, short, and to the point"
	Ask [open-ended] questions 51% (n=19)	"ask clients 'what questions do you have' rather than 'do you have any questions to encourage feedback' " "ask open-ended questions to determine comprehension"
	Use teach-back 46% (n=17)	"use teach back technique to make sure you communicated effectively" "have clients repeat information back to assess understanding"
AWARENESS/CULTURAL COMPETENCE (n=64)	Offer assistance 68% (n=25)	"take the time to explain and educate about forms and procedures" "offer every client help reading and completing forms"

	Reduce judgement/Build trust/Demonstrate cultural competence 59% (n=22)	"be aware of cultural differences; place yourself in client's place and make them feel at ease" "create a welcoming non-judgmental environment"
	Awareness of signs of low health literacy /Don't assume understanding 46% (n=17)	"check for understanding and make adjustments" "be alert to physical and verbal cues that patient needs help with paperwork"
WRITTEN/AUDIOVISUAL COMMUNICATION (n=48)	Provide written or audiovisual materials for reference 70% (n=26)	"provide videos to explain environmental health processes and permits" "put brochures and posters in waiting areas, and use health education videos in waiting room"
	Modify/explain written material 59% (n=22)	"simplify language on printed forms, avoiding jargon and acronyms" "provide appropriate paperwork that is sensitive to literacy needs and explain purpose of each form"
SUPPORTIVE SYSTEMS (n=32)	Refer to proper services 32% (n=12)	"make sure patients are aware of other services they may qualify for" "empower clients by pointing them to resources outside of our agency"
	Hire more staff/Provide staff training 32% (n=12)	"need oral communication education" "need more employees to enable more time for appointments with each client"
	Increase access/Reduce distractions 22% (n=8)	"more client focused time versus paperwork time" "provide private area to discuss issues"

Question 2a: *"What are the challenges that you or your unit face to improve the VDH experiences of a low health literacy client?"*		
Broad Theme	*Code (out of 37 tables)*	*Examples*
SUPPORTIVE SYSTEMS BARRIERS (n=51)	Limited time with client 51% (n=19)	"having enough time to spend with client to explain everything" "too much required material to cover"
	Understaffed/undertrained staff 32% (n=12)	"staff pulled too many directions" "undertrained staff"
	Unreliable access/contact with clients 30% (n=11)	"getting in touch with clients for follow-up" "[lack of] transportation to clinic"
	Limited financial resources/Technology 24% (n=9)	"difficult to navigate VDH website to obtain handouts and information" "lack of funding"
COMMUNICATION BARRIERS (n=35)	Complex [written] materials for clients 54% (n=20)	"not having visual aids/handouts at appropriate literacy levels" "paperwork and educational materials is at higher reading level than clients ability"
	Language barriers 41% (n=15)	"patients with limited English skills" "not enough translators"
KNOWLEDGE & CULTURAL BARRIERS (n=23)	Cultural/trust barriers b/t staff & client 51% (n=19)	"perception that environmental health is the bad guy" "clients can't understand due to cultural differences"
	Client lack of awareness 11% (n=4)	"patients that are not aware of what health department actually does" "lack of awareness concerning own insurance benefits"

Question 2b: *"How can your unit work with the health literacy team to help address these challenges?"*		
Broad Theme	*Code (out of 37 tables)*	*Examples*
COMMUNICATION SOLUTIONS (n=60)	Simplified procedures and materials 54% (n=20)	"pick most important education needs" "simplify materials, make them have narrow focus"
	Use/update written material 46% (n=17)	"follow up verbal information with written information" "use simple literature; more pictures less words"
	Translators/language line 38% (n=14)	"need more interpretation services, phone services can be slow and ineffective" "need easier access to interpreter to help deliver message"
	Reliable access/contact with clients 24% (n=9)	"offer home visits and school-based clinics" "collect multiple ways to contact clients"
SUPPORTIVE SYSTEMS SOLUTIONS (n=56)	Electronic solutions & technology improvements 49% (n=18)	"use electronic medical records to reduce paperwork" "evaluate and simplify phone system so client can reach a person"
	More staff/Staff training 46% (n=17)	"cross train staff to fill in when short-staffed" "training in communication skills to address language barriers and education levels and cultural sensitivity"
	Collaboration between health professionals 38% (n=14)	"communicate between disciplines" "work in a team and ask for suggestions on how to better relate"

	Outreach/referral to proper services 19% (n=7)	"outreach to local dentists and mobile dental/medical unit" "use incentives to bring clients in"
KNOWLEDGE & CULTURAL SOLUTIONS (n=17)	Emphasis of individualized interactions/UPA 46% (n=17)	"don't assume knowledge and understanding" "earn trust, understand frustration, and take time to listen"
Question 3: *"What are the health literacy training needs for you and/or your unit to help fulfill our health literacy charge?"*		
Broad Theme	*Code* *(out of 37 tables)*	*Examples*
COMMUNICATION TRAINING (n=35)	Oral communication strategies 49% (n=18)	"need refreshers on teach-back and related skills" "need better ways for us to simplify our counseling"
	Management of language barriers 46% (n=17)	"training to better communicate w/ people who don't speak English" "training on how to use language line (interpreter phone line)"
	Use of/Simplification of written materials 41% (n=15)	"need to know how to simplify information for patients" "educate employees to evaluate reading level of educational materials"
KNOWLEDGE AND CULTURAL TRAINING (n=19)	Training on cultural competence 51% (n=19)	"more cultural sensitivity training due to diverse populations" "refresher course on recognizing low HL"
SUPPORTIVE SYSTEMS TRAINING (n=6)	Client education strategies 16% (n=6)	"need ways to encourage participation" "need different learning strategies for limited reading comprehension of clients"

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CHAPTER 5: GENERAL CONCLUSIONS

General Conclusions

Almost half of adults in the United States lack health literacy skills necessary to understand and utilize health information.[1] Unsurprisingly, low health literacy has been consistently linked to poorer health status.[2] Low health literate adults consume greater amounts of sugar-sweetened beverages (SSB) when compared to higher health literate counterparts.[3,4] Overconsumption of SSB has been associated with overweight and obesity, type 2 diabetes mellitus, cardiovascular disease, and other chronic conditions.[5-9] Health literacy status may also negatively influence physical activity (PA) behaviors,[10,11] significant when considering those who engage in regular PA can prevent various chronic diseases.[12] In addition to these disparities in health behaviors, healthcare organizations can work to decrease complexity and improve accessibility and understandability for limited health literate populations.[13] However, existing organizational health literacy improvement efforts have targeted the primary care setting. Minimal studies reflect on the difficulty providing training that would be appropriate for a multitude of disciplines of healthcare professionals.[14-16] There is an unmistakable need to minimize the burden of those with low health literacy. This dissertation addresses this need by focusing on health literacy at the individual and organizational levels. All three studies took place within rural southwest Virginia, an area classified as medically underserved.[17-20] This eight-county region is affected by considerable health disparities, many of which make it difficult to engage in PA and make appropriate dietary choices.[18]

Study 1 explored two self-report PA measures to determine their utility within low health literate populations. It also explored whether health literacy moderated intervention effects differently when PA was assessed with two different measures. Results enabled us to identify pragmatic standardized assessment tools with the ability to define clinically meaningful change

in PA behaviors. This study leaves us with a few notable opportunities for future research. First, including the use of objective PA measures (e.g., accelerometers) to compare differences in self-reported PA measures by health literacy status could further validate self-reported PA measures. Second, cognitive interviews could be conducted to delve within the intricacies of both the L-Cat and the adapted Godin Leisure-Time Exercise Questionnaire (GLTEQ). Obtaining input from both low and high health literacy individuals on the understandability of L-Cat category three, and the overall appropriateness and interpretation of the L-Cat and adapted GLTEQ would strengthen the ability of this tool to predict cross-sectional and longitudinal change in PA. Finally, findings reiterate the immense need for behavioral interventions that are sufficiently powered to detect health literacy moderation effects on PA outcomes and encourage future research to keep this in mind during study conception. This study concludes that the L-Cat and adapted GLTEQ each have unique strengths, but both are valuable measures for cross-sectional and longitudinal assessment of self-report PA behaviors in rural, health-disparate communities, and that such tools were found to be robust across health literacy levels.

Behavioral interventions that include behavior change and/or nutrition education components have been effective in in reducing individual-level SSB consumption.[21-23] Study 2 expanded upon existing research findings from one such intervention that found that a SSB intervention leads to a reduced intake in SSB, decreased BMI and weight, and increased QOL.[23] Study 2 explores the relationship between change in SSB intake and change in BMI, weight, and QOL outcomes. While it would have been expected that the participants that showed the greatest reductions in SSB intake were more likely to decrease BMI or lose weight, results showed that 6-month change in SSB intake was not a significant predictor of change for BMI or weight. However, 6-month change in SSB intake did significantly impact change in QOL. Additionally,

this study tested whether health literacy moderated these relationships. As hypothesized, health literacy was not a significant moderator in any of the three models. This is not surprising, as the SIP*smart*ER intervention was developed using health literacy strategies and delivered using the universal precautions approach, and because of this both low and high health literate participants experienced similar intervention effects. Since change in SSB intake was not identified as a predictor of change, other variables are likely at play. More work needs to be done to determine which variables influence patterns of change in anthropometric and wellness outcomes. Additionally, forthcoming research that intends to reduce SSB intake among limited health literacy populations should aim to utilize longitudinal health literacy interventions to be better positioned to identify patterns of change. Future work should continue to consider health literacy status and explore the impact of developing interventions using individual-level health behavior theory and health literacy strategies used in behavioral interventions.

Health literacy interventions aimed to improve health behaviors are abundant, however, published papers that incorporate statistical techniques to test health literacy as a moderator are scant.[2,24] Studies 1 and 2 address this gap in the literature by exploring whether health literacy moderates intervention effects and outcomes. Future work should continue to fill this gap by considering incorporation of statistical techniques to test health literacy moderation.

Study 3 described a multilevel organizational health literacy needs assessment and resulting improvement efforts, including an e-newsletters series and in-person workshops on the Clear Communication Index. An all-encompassing aim of this study was to build capacity for organizational health literacy. To begin this process, this study accomplished the essential first step in building capacity, conducting an organizational needs assessment.[25-27] Notably, this study was the first to use the Agency for Healthcare Research and Quality (AHRQ) Toolkit in a public

health setting. Framed by the components of the AHRQ Toolkit, this study built upon the four established domains of health literacy (written communication, oral communication, self-management and empowerment, and supportive systems). From both staff and client perspectives, results revealed strengths and weaknesses in current health literacy practices, and the greatest need was observed within the written communication domain. To build upon this study and individualize improvement efforts, the adoption and implementation of the AHRQ Toolkit by individual districts could be tested. This would provide value by gathering perspective on each district's approach to utilizing the Toolkit. This could further advance the literature base by providing information on which tools were chosen to be used and why, and by describing how tool implementations altered health literacy practices.[28-30] To strengthen implementation, a "health literacy change champion" (i.e., a staff member dedicated to organizational health literacy efforts) from each district could focus on leading the charge of improvement activities and establishing a culture of change among all staff, which in turn would help increase buy-in.[30-32] Future work could build upon the established success of the AHRQ Toolkit and its first use within public health in Study 3, and contribute to a Toolkit adapted for a public health setting. In the future, it is also recommended that staff and client assessments be accompanied with objective environmental assessments and qualitative perceptions from clients (in addition to staff). Existing literature shows that needs assessment and improvement efforts should lie within a comprehensive systems-based approach, which underlines the importance of considering health literacy in the context of quality of care, healthcare cost savings, and patient safety and satisfaction.[30-34] Finally, a key finding of this study was that customers' health literacy status was significantly correlated with their perceptions of staff health literacy practices. This confirmed the importance of our work to improve organizational health literacy within VDH and laid the

groundwork for continuation of the health literacy improvement plan. Next steps include strengthening and solidifying the organizational health literacy improvement team and continuing to build on feedback received from staff and leadership throughout this initial improvement process. Future work should consider whether evaluating client/patient perceptions of practice are correlated with health literacy status; the patients' perspectives are meaningful and provide validation of the importance of multilevel assessment when working to improve organizational health literacy capacity.

In conclusion, this dissertation responds to the necessity to diminish the burden of low health literacy by focusing on health literacy at the individual and organizational levels. To successfully monitor change in behaviors such as PA, future work should aim to determine pragmatic measures appropriate for populations of varying health literacy status. Findings and recognized limitations from each of the three studies revealed benefits of incorporating qualitative analysis, whether to bolster instruments utilized or gather needed perspectives when conducting an organizational needs assessment. To expand on behavioral intervention effectiveness, future research should also strive to detail patterns and magnitude of change in behaviors in relation to health outcomes. This initial effort to improve organizational health literacy within the health department can be expanded upon, and adaptation of the AHRQ Toolkit for a public health setting should be considered. Behavioral interventions, especially those depicting longitudinal change, should test health literacy as a moderating variable. Given what is known about the effects of health literacy on health status, health behaviors, and ability to navigate the healthcare system, it is essential that future work investigate how health literacy moderates individual- and organizational-level health outcomes. This dissertation provides

evidence of the importance of health literacy when pursuing individual-level behavior change and when seeking to improve practices within healthcare organizations.

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Appendix A: Staff Needs Assessment Instrument

Provider Organizational Health Literacy Perceptions Survey

This survey is about the health literacy practices that happen within the Virginia Department of Health. Health literacy practices are all customer-centered care activities and protocols that involve making sure customers can understand and act on health-related information provided to them.

Choose one answer for each question unless directed otherwise. Please answer honestly; your individual responses will only be seen by the research team at Virginia Tech.

The first set of questions asks you about health literacy practices you may do during your job.

1. I know how to identify, prepare and simplify written materials so they are easier to read.

   ☐ Always ☐Usually ☐Sometimes ☐Rarely/Never ☐Not sure ☐Not applicable for my role

2. I use clear oral communication techniques (e.g., uses plain, everyday words, limit to 3-5 main points, and information is specific and concrete).

   ☐ Always ☐Usually ☐Sometimes ☐Rarely/Never ☐Not sure ☐Not applicable for my role

3. I have received awareness and sensitivity training about health literacy issues.

   ☐ Always ☐Usually ☐Sometimes ☐Rarely/Never ☐Not sure ☐Not applicable for my role

4. I ask customers to state key points in their own words (i.e., teach-back method) to assess understanding of care instructions.

   ☐ Always ☐Usually ☐Sometimes ☐Rarely/Never ☐Not sure ☐Not applicable for my role

5. I encourage customers to ask questions by using these words: “What questions do you have?” instead of “Do you have any questions?”

☐ Always ☐Usually ☐Sometimes ☐Rarely/Never ☐Not sure ☐Not applicable for my role

6. I work with customers to discuss priorities and develop action plans to promote changes in behaviors or practices.

   ☐ Always ☐Usually ☐Sometimes ☐Rarely/Never ☐Not sure ☐Not applicable for my role

7. I demonstrate knowledge and sensitivity to customers' cultural beliefs and customs.

   ☐ Always ☐Usually ☐Sometimes ☐Rarely/Never ☐Not sure ☐Not applicable for my role

This next set of questions asks you to rate how well *your unit* engages in different health literacy practices to help your customers better understand and be able to act on health-related information. When answering these questions, think about your unit, or the group in your health district that you regularly work with.

Written Communication Practices

8. All forms intended for customer use or data collection are concise, limit jargon, and are designed using standard techniques to make them easy to read.

   ☐ Doing Well ☐ Needs Improvement ☐ Not doing ☐ Not sure ☐ Not applicable

9. At least one staff member knows how to identify, prepare and simplify written materials so they are easier to read.

   ☐ Doing Well ☐ Needs Improvement ☐ Not doing ☐ Not sure ☐ Not applicable

10. Staff pilot test new written materials for appeal and comprehension with a few customers.

    ☐ Doing Well ☐ Needs Improvement ☐ Not doing ☐ Not sure ☐ Not applicable

11. Staff have reviewed all of our written materials to check how easy they are to read using a readability formula.

    ☐ Doing Well ☐ Needs Improvement ☐ Not doing ☐ Not sure ☐ Not applicable

12. Customer education materials are concise, limit jargon, and are designed using standard techniques to make them easy to read.

☐ Doing Well ☐ Needs Improvement ☐ Not doing ☐ Not sure ☐ Not applicable

13. Lab and test results letters are concise, limit jargon, and are designed using standard techniques to make them easy to read (e.g., avoid the use of “positive” or “negative” results).

    ☐ Doing Well ☐ Needs Improvement ☐ Not doing ☐ Not sure ☐ Not applicable

14. Appointment slips are clear and concise. They provide contact information for customers with questions and, when needed, include preparation instructions that are easy to understand.

    ☐ Doing Well ☐ Needs Improvement ☐ Not doing ☐ Not sure ☐ Not applicable

15. Staff assesses customer’s language preference.

    ☐ Doing Well ☐ Needs Improvement ☐ Not doing ☐ Not sure ☐ Not applicable

Oral Communication Practices

16. Staff uses clear oral communication techniques (e.g., uses plain, everyday words, limit to 3-5 main points, and information is specific and concrete)

    ☐ Doing Well ☐ Needs Improvement ☐ Not doing ☐ Not sure ☐ Not applicable

17. Staff does not use medical jargon when communicating with customers (e.g., not using words like anticoagulant, hypertension, NPO).

    ☐ Doing Well ☐ Needs Improvement ☐ Not doing ☐ Not sure ☐ Not applicable

18. Staff does not talk too fast when communicating with customers.

    ☐ Doing Well ☐ Needs Improvement ☐ Not doing ☐ Not sure ☐ Not applicable

19. Staff members have received awareness and sensitivity training about health literacy issues.

    ☐ Doing Well ☐ Needs Improvement ☐ Not doing ☐ Not sure ☐ Not applicable

20. All levels of practice staff have agreed to support changes to improve customer understanding.

    ☐ Doing Well ☐ Needs Improvement ☐ Not doing ☐ Not sure ☐ Not applicable

21. Staff offers everyone help regardless of appearance (e.g., filling out forms, giving directions).

☐ Doing Well ☐ Needs Improvement ☐ Not doing ☐ Not sure ☐ Not applicable

22. Staff members who have customer contact can identify behaviors that may indicate literacy problems.

☐ Doing Well ☐ Needs Improvement ☐ Not doing ☐ Not sure ☐ Not applicable

23. Staff uses audio/video materials and/or visual aids to promote better understanding and enhance communication with customers (e.g., food models for portion sizes, model of body part, and instructional videos).

☐ Doing Well ☐ Needs Improvement ☐ Not doing ☐ Not sure ☐ Not applicable

24. Staff talks with customers about any education materials they receive during the visit and emphasizes the important information.

☐ Doing Well ☐ Needs Improvement ☐ Not doing ☐ Not sure ☐ Not applicable

25. Staff asks customers to state key points in their own words (i.e., teach-back method) to assess understanding of care instructions.

☐ Doing Well ☐ Needs Improvement ☐ Not doing ☐ Not sure ☐ Not applicable

26. Staff encourages customers to ask questions by using these words: "What questions do you have?" *instead of* "Do you have any questions?"

☐ Doing Well ☐ Needs Improvement ☐ Not doing ☐ Not sure ☐ Not applicable

27. Staff uses trained interpreters or language services with customers who do not speak English well.

☐ Doing Well ☐ Needs Improvement ☐ Not doing ☐ Not sure ☐ Not applicable

28. When staff gives directions for finding the office, they refer to familiar landmarks and public transportation routes as needed.

☐ Doing Well ☐ Needs Improvement ☐ Not doing ☐ Not sure ☐ Not applicable

29. Our staff reviews medications with customers at least annually, and after any significant medical event to ensure concordance between customer and clinical recommendations.

☐ Doing Well ☐ Needs Improvement ☐ Not doing ☐ Not sure ☐ Not applicable

30. Our staff discusses different methods for taking medications correctly and offers customers assistance setting up a system (e.g., pill box, pill chart).

☐ Doing Well ☐ Needs Improvement ☐ Not doing ☐ Not sure ☐ Not applicable

Self-Management and Empowerment Practices

31. Staff creates an environment that encourages our customers to ask questions and get involved with their care.

☐ Doing Well ☐ Needs Improvement ☐ Not doing ☐ Not sure ☐ Not applicable

32. Staff encourages customers to write down questions while waiting for their appointment.

☐ Doing Well ☐ Needs Improvement ☐ Not doing ☐ Not sure ☐ Not applicable

33. Staff have clear roles and responsibilities about teaching customers' self-management skills (e.g., dietary advice, using a glucometer or inhaler).

☐ Doing Well ☐ Needs Improvement ☐ Not doing ☐ Not sure ☐ Not applicable

34. Our staff contacts our customers between office visits to ensure understanding or to follow up on plans made during the visit.

☐ Doing Well ☐ Needs Improvement ☐ Not doing ☐ Not sure ☐ Not applicable

35. Staff confirms (by mail or phone) customer follow through after a referral is made.

☐ Doing Well ☐ Needs Improvement ☐ Not doing ☐ Not sure ☐ Not applicable

36. Our unit requests feedback from customers.

☐ Doing Well ☐ Needs Improvement ☐ Not doing ☐ Not sure ☐ Not applicable

37. Staff work with customers to discuss priorities and develop action plans to promote changes in behaviors and practices.

☐ Doing Well ☐ Needs Improvement ☐ Not doing ☐ Not sure ☐ Not applicable

Supportive Systems

38. Staff asks customers if they need extra support and offers to work together with them.

☐ Doing Well ☐ Needs Improvement ☐ Not doing ☐ Not sure ☐ Not applicable

39. Staff assesses customer's non-medical barriers and takes initiative to address them and provide appropriate referrals or extra support as needed.

☐ Doing Well ☐ Needs Improvement ☐ Not doing ☐ Not sure ☐ Not applicable

40. Staff assists customers to find affordable medications and fill out applications as needed.

☐ Doing Well ☐ Needs Improvement ☐ Not doing ☐ Not sure ☐ Not applicable

41. Staff asks customers if they would like help understanding their bills or insurance forms.

☐ Doing Well ☐ Needs Improvement ☐ Not doing ☐ Not sure ☐ Not applicable

42. Staff maintains an updated list of community resources and refers customers as needed.

☐ Doing Well ☐ Needs Improvement ☐ Not doing ☐ Not sure ☐ Not applicable

43. Staff helps customers to access community-based programs (e.g., adult literacy, English for speakers of other languages, stop smoking, weight loss).

☐ Doing Well ☐ Needs Improvement ☐ Not doing ☐ Not sure ☐ Not applicable

44. Staff demonstrates knowledge and sensitivity to customers' cultural beliefs and customs.

☐ Doing Well ☐ Needs Improvement ☐ Not doing ☐ Not sure ☐ Not applicable

The last set of questions asks about you so we can learn about more about the people taking the survey.

45. Which unit do you work *most* closely with?

☐Administrative ☐Environmental Health ☐Epidemiology & Emergency Response
☐Health Education ☐Nursing ☐WIC ☐Other

46. Which health district do you work in *most often*?

☐ Cumberland Plateau ☐ Lenowisco ☐ Mt Rogers ☐ New River

47. What is your position title?

_____

48. How many years have you been in this position?

_____

49. How many years have you been working with VDH?

_____

50. What is your highest level of educational attainment?

☐ High School Diploma / GED ☐ Associate's degree ☐ Bachelor's degree ☐ Graduate degree

51. I have completed previous professional development about health literacy, including learning strategies to help those with low health literacy be better able to understand and act on health-related information.

☐Yes ☐No ☐Not Sure

If yes, can you please describe what this/these experiences?

_____
_____

52. Ensuring that customers understand the health-related information provided to them could strengthen the effect of services provided to by VDH

☐ Strongly Disagree ☐Disagree ☐Neither Disagree or Agree ☐ Agree ☐Strongly Agree

Please describe why you choose this answer.

_____
_____

53. What is your gender?

☐ Male ☐ Female ☐ Other ☐ Do not wish to answer

54. What year were you born? _____

55. Which of the following best describes you? *Choose all that apply*.

☐ White ☐ Black/African American ☐ Asian
☐ Native Hawaiian / Pacific Islander ☐ American Indian/Alaskan Native ☐ Other _____
☐ I do not wish to reply

Virginia Department of Health Customer Survey

Thank you for being willing to complete this survey. By filling out this survey, you agree to let Virginia Tech use the answers you provide to help the Virginia Department of Health and other health departments improve their services.

The answers you provide will be kept private; only the researchers will know how you replied. If you do not want to answer a question, you can skip it. If you have any questions about the survey, please ask the staff member who asked you to complete the survey or you can call Dr. Zoellner or Dr. Porter who are leading this project at 540.553.1768.

First, we would like to know what beverages you have drank in the past month.

1. During the past 30 days, how often did you drink regular soda or pop that contains sugar? *Do not include diet soda or diet pop.* Select only one and fill in number.

   ☐ ___ Times per day ☐ ___ Times per week ☐ ___ Times per month
   ☐ Never

2. During the past 30 days, how often did you drink sugar-sweetened fruit drinks (such as Kool-aid™ and lemonade), sweet tea, and sports or energy drinks (such as Gatorade™ and Red Bull™)? *Do not include 100% fruit juice, diet drinks, or artificially sweetened drinks*. Select only one and fill in number.

   ☐ ___ Times per day ☐ ___ Times per week ☐ ___ Times per month
   ☐ Never

These next 3 questions will help us understand the reading needs of people taking this survey. *Choose only one answer for each question.*

3. How certain are you that you could fill out medical forms by yourself?

   ☐ Extremely ☐ Quite a bit ☐ Somewhat ☐ A little bit ☐ Not at all

4. How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy?

☐ Never ☐ Sometimes ☐ Usually ☐ Always

5. How would you describe your ability to read?

☐ Excellent or very good ☐ Good☐ Okay ☐ Poor ☐ Terrible or very poor

Next, we would like to know how well staff at the Virginia Department of Health explain things to you and how well they listen to you.
Choose only one answer for each question.

6. Have you received services from the health department in the past 12 months, such as medical care, education, restaurant inspections or environmental services.

☐ No *Skip to question 14* ☐ Yes *Continue to question 7*

7. When you fill out health department forms, how often are they written in a way that is easy for you to read, understand, and complete?

☐ Never ☐ Sometimes ☐ Usually ☐ Always

8. When you receive written materials from the health department, how often are they easy for you to read and understand?

☐ Never ☐ Sometimes ☐ Usually ☐ Always

9. When you need information/services, how often do health department staff refer to important information about your history that you have previously given them?

☐ Never ☐ Sometimes ☐ Usually ☐ Always

10. When you need information/services, how often do health department staff spend enough time with you?

☐ Never ☐ Sometimes ☐ Usually ☐ Always

11. When you need information/services, how often do health department staff encourage you to ask questions?

☐ Never ☐ Sometimes ☐ Usually ☐ Always

12. When you need information/services, how often do health department staff explain things in a way that is easy to understand?

☐ Never ☐ Sometimes ☐ Usually ☐ Always

13. When you need information/services, how often do health department staff ask you to describe how you were going to follow instructions?

☐ Never ☐ Sometimes ☐ Usually ☐ Always

Last, we have some questions are about you so we can learn about the people taking this survey.

14. What is your gender? ☐ Male ☐ Female ☐ Prefer not to respond

15. What year were you born? _____

16. Which of the following best describes you? *Choose all that apply*.

☐ White ☐ American Indian/Alaskan Native

☐ Black or African American ☐ Native Hawaiian or Other Pacific Islander

☐ Asian ☐ Other _____ ☐ Prefer not to respond

17. Which of the following best describes you? *Choose one*.

☐ Hispanic ☐ Non-Hispanic ☐ Not sure

18. What is the highest grade of school that you completed? *Choose one*.

☐ Grades 0-8 ☐ Grades 9-11 ☐ High school

☐ Some college school ☐ College graduate ☐ Graduate

19. Would you like to learn more about SIP*smart*ER, a Virginia Department of Health program that helps decrease sugary drinks?

☐ No ☐ Yes; please provide your contact information below

20. May we contact you in the future to learn more about your views on Virginia Department of Health services?

☐ No ☐ Yes; please provide your contact information below

Name: _____

Mailing Address: _____

Home Phone Number: _____ Email Address _____

Cell Phone Number: _____ Cell Receives Text Messages: Yes ___ No ___

Appendix C: Clear Communication Workshop Survey Instrument

Organizational Health Literacy
Professional Development Workshop Follow-Up

Thank you for taking part in this professional development workshop. This short survey asks about your experience and how the workshop might impact your practice. We also ask questions about you so we can know more about the people taking the survey.

Please answer honestly. Your responses will only be seen by the research team at the University of Virginia.

General Impression of the Professional Development Workshop

1. I learned new information and skills during this professional development workshop.

   ☐ Strongly Disagree ☐ Disagree ☐ Neither Disagree or Agree ☐ Agree ☐ Strongly Agree

2. This professional development workshop provided useful information and skills for someone in my role.

   ☐ Strongly Disagree ☐ Disagree ☐ Neither Disagree or Agree ☐ Agree ☐ Strongly Agree

3. The content of this professional development workshop will help me be better at my job.

   ☐ Strongly Disagree ☐ Disagree ☐ Neither Disagree or Agree ☐ Agree ☐ Strongly Agree

4. The content of this professional development workshop could improve the level of service VDH provides to its customers.

   ☐ Strongly Disagree ☐ Disagree ☐ Neither Disagree or Agree ☐ Agree ☐ Strongly Agree

5. The professional development workshop was delivered in an engaging manner.

   ☐ Strongly Disagree ☐ Disagree ☐ Neither Disagree or Agree ☐ Agree ☐ Strongly Agree

6. What did you like most about this professional development workshop?

   _____

   _____

   _____

7. What could be improved about this workshop to make it better when delivered in the future?

_____

_____

_____

What I am Taking Away from the Workshop

8. How often do you think you will use the information or skills you learned in this workshop in your everyday professional practice in the future?

☐ Not sure ☐ Rarely/Never ☐ Sometimes ☐ Often ☐ (Almost) always

9. What new information or skills did you learn during this workshop?

_____

_____

_____

10. How you *plan* to use the information or skills from this workshop in your professional practice? If the information or skills in this workshop were not new to you, describe how you have used them in the past.

_____

_____

_____

11. Please describe what *resources or support from VDH* you might need to help you apply the information or skills from this workshop in your everyday professional practice.

_____

_____

_____

About Me

12. Which unit do you work most closely with? *Choose all that apply*.

☐ Administrative ☐ Clinical ☐ Environmental ☐ Financial ☐WIC

13. Which health district do you work in?

☐ Cumberland Gap ☐ LENOWISCO ☐ Mt Rogers ☐ New River Valley

14. How many years have you been working with VDH?

_____

15. What is your gender? ☐ Male ☐ Female

16. What year were you born? _____

17. Which of the following best describes you? *Choose all that apply*.

☐ White ☐ Black/African American ☐ Asian ☐ Do not wish to reply

☐ Native Hawaiian/Pacific Islander ☐ American Indian/Alaskan Native ☐ Other _____