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HEALTH LITERACY AND QUALITY OF LIFE IN PATIENTS WITH EPILEPSY

by

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SOCIOLOGY

ABSTRACT

This exploratory study examined the impact of health literacy on quality of life (QoL) in persons with epilepsy (PWE). From the perspectives of cultural health capital and social disability theory, it was hypothesized that greater levels of health literacy would be associated with higher quality of life scores. The sample included patients with treatment-resistant epilepsy (TRE) enrolled in the University of Alabama at Birmingham Cannabidiol Program. Analyses included Pearson correlations, chi square, t-tests, and a nested linear regression model (alpha=0.1). The sample was composed of adult respondents (aged 19-63; n=79) and was 92% white with a mean age of 33; 44% of patients were in Special Education until age 21 and 29% report a total annual family income of less than $25,000. Significant bivariate relationships were found between health literacy and quality of life (p=.004), age (p=.0001), educational level (p<.0001), but negatively associated with income (p=.063). QoL was positively impacted by age (p=.095) and negatively associated with mood state (p=.059), and adverse effects (p=.096). The nested model showed health literacy has a significant positive effect on QoL where a 1% increase in health literacy is associated with a 6.61 point increase in QoL (p=.004) and this trend continued through each addition of independent factors and control variables. This is one of the first studies investigating the role of health literacy on QoL for persons with TRE. The results suggest that health literacy has a crucial role in QoL, perhaps functioning as a tool through which health care participation is expanded.

Further research is needed with larger, more diverse, and longitudinal sample to accurately model the development of health literacy and its impact on QoL for persons with TRE.

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LIST OF ABBREVIATIONS

AED	Anti-Epileptic Drug
AEP	Adverse Effects Profile
CBC	Complete Blood Count
CBD	Cannabidiol
CHC	Cultural Health Capital
POMS	Profile of Mood States
PWE	Persons with Epilepsy
QOL	Quality of Life
QOLIE-89	Quality of Life in Epilepsy 89
SES	Socioeconomic Status
TMD	Total Mood Disturbance
TRE	Treatment-Resistant Epilepsy
VEEG	Video-electroencephalography

INTRODUCTION

Over the past twenty years, health literacy and its influence on health outcomes has been paid increasingly more attention (Berkman et al. 2011, Nutbeam 2008, Paasche-Orlow et al. 2005). It has been proposed that globalization and the relative abundance of health-promoting technology could serve as a mechanism for increased self-mastery and improved patient engagement. However, the rise in internet-based health information sources has not contributed to a decrease in healthcare disparities. Instead, gaps in access and varying levels of comprehensibility of health information have resulted in unequal benefits for individual self-care (Leenen et al. 2016). Low levels of health literacy are consistently associated with more hospitalizations, less preventative healthcare, poorer medical adherence, and among elderly persons, poorer health status and higher mortality (Berkman et al. 2011).

Most health literacy research has focused on clinical outcomes and the ways health literacy shapes patient involvement in medical care. The research examining the impact of health literacy on quality of life is growing, but remains sparse when investigating people with a neurological disorder. Bautista (2009) conducted the first study establishing a link between health literacy and quality of life (QoL) in people with epilepsy (PWE). Bautisa findings provided a foundation from which to consider diverse interpretations of the fundamental question, “How does heath literacy impact quality of life for people with epilepsy?” This study focuses on patients with treatment-resistant epilepsy (TRE) and how conceptions of disability help explain both wide variation in health literacy as well as its influence on QoL.

Epilepsy

Epilepsy is one of the United States' most common neurological disorders (after migraine, stroke, and Alzheimer's disease) (Hirtz et al. 2007). About 3.4 million people in the U.S. have active epilepsy (defined as individuals who have a physician diagnosed seizure disorder or epilepsy and are currently taking an anti-epileptic drug (AED), have had 1+ seizures in the last year, or both (Zack 2017). This does not include acute asymptomatic seizures from head trauma, febrile seizures, or neonatal seizures (Hirtz et al 2007). Epilepsy is spectrum disorder in that not every person with epilepsy suffers from the same level of impairment nor the same type of seizure activity. In simple terms, an epileptic seizure is a sudden surge of electrical activity in the brain which can range from unnoticeable to completely incapacitating. Seizures are classified under three main categories: generalized, focal, and epileptic spasms (Stafstrom and Carmant 2015). These are then further subtyped by characteristics: absence, generalized tonic-clonic, myoclonic, and atonic; PWE can experience one or any number combinations of the categories.

Around a third of PWE have seizures that are not controlled by medicine; this is known as treatment-resistant epilepsy (TRE). Mortality is higher for PWE across all causes including cardiovascular diseases, malignant neoplasms, suicide (most often when psychiatric comorbidities are present), accidents, particularly drowning which is 15-19 times more likely for PWE; the life expectancy for PWE is 10 years less than the general population (Laxer et al. 2014, van Ool et al. 2016). The population with TRE is a vulnerable one in and need of further investigation to understand the complex ways social factors impact these patients' health outcomes and behaviors including and beyond clinical interactions.

Disparities in Care

There is ample literature linking socioeconomic status and health outcomes (Phelan, Link and Tehranifar 2010). This is particularly important for PWE as the incidence and prevalence of epilepsy is associated with socioeconomic deprivation (Szaflarski 2014) and, compared to individuals with other chronic conditions, PWE have report lower levels of physical and mental health (Kobau, Cui and Zack 2017). Research shows that compared to people with no history of epilepsy, PWE are less likely to have private health insurance, less likely to be employed, more likely to be insured under Medicaid, and more likely to be disabled. Further studies reveal that PWE have less education, lower household incomes, report transportation as a barrier to healthcare, and have less medication adherence (Elliott et al. 2009, Szaflarski et al. 2017, Thurman et al. 2016). These significant barriers to equitable health care require further research to assess the needs for intervention to close the gaps due to social inequalities.

THEORETICAL FRAMEWORK

This study draws upon fundamental cause theory, social disability, and cultural health capital theories and was informed by current health literacy and QoL literature. In medical sociology, the Fundamental Cause literature has described the multiple avenues through which socioeconomic status (SES) is associated with health outcomes (Phelan, Link and Tehranifar 2010) and has been used to explain how PWE often have a lower socioeconomic status and are not able to access the flexible material resources necessary for adaptive maneuvering through health care settings (Bautista and Wludyka 2007, Begley et al. 2009). Social disability theory offers the removal of barriers as a solution to gaps in care, but is an incomplete response for people with treatment-resistant epilepsy. Cultural health capital offers an alternative explanation for how PWE, regardless of SES and diagnosis, develop skills (i.e. health literacy) that positively impact QoL.

Health Literacy

Health literacy has evolved in its definition and application. Formerly a measure of the "degree to which individuals have the *capacity* to obtain, process, and understand basic health information and services needed to make appropriate health decisions" (Kutner et al. 2006, Nutbeam 2008). Contemporary definitions discard the term "capacity" as overly individualist and a reductionist disregard for broader social factors, and in its place use "can" in an effort to distinguish between intelligence (capacity) and health literacy as an ability (Berkman, Davis and McCormack 2010). Modifying the language to be reflective of abilities versus innate characteristics highlights the levels of power constraining an individual’s health choices. More specific to this study, health literacy is a discrete form of literacy in which an individual can readily interpret prose and apply that skill to understand medical, pharmaceutical, and self-management information (including consent forms, inserts, directions, etc.) (Berkman, Davis and McCormack 2010, Chinn 2011).

Unequal levels of health literacy contribute to health care disparities (the differences in the quality of health care that are not due to access-related factors or clinical needs, preferences, or appropriateness of intervention) by denying full health benefits to portions of the population (Hasnain-Wynia and Wolf 2010, Kickbusch 2001). Individuals with low levels of health literacy have not only less information about their disease, but have less information about practical/instrumental self-management care (Paasche-Orlow and Wolf 2007); low levels of health literacy are associated with poor health outcomes: more hospitalizations, more use of emergency care, less medical compliance, poor ability to understand labels and health messages, and higher all-cause mortality (Berkman et al. 2011, Peterson et al. 2011).

Health literacy is, at its core, an issue of communication. An issue which can function as a mediator between social class and health (Kivits 2009). Clinical setting communication styles are indicative of cultural health capital: patterns of behaviors, attitudes, and interactions that are valued and leveraged by both patients and providers in a health care setting (Dubbin, Chang and Shim 2013). From this stance, previous research supports low levels of cultural health capital impacting health literacy in two ways. First, most health care professionals are not aware of their patients' low levels of health literacy (Kickbusch 2001). This could be a result of cultural factors, communication styles/interview techniques, or simply the imposed time constraints of clinical interactions. Second, most patients report being too embarrassed to admit to their healthcare providers that they do not fully understand their instructions; patients with low levels of functional health literacy report shame and may not confide in family, caregivers, or clinicians about their struggles (Parikh et al. 1996). This disconnect could be associated with a less activated, more passive patient-physician interaction resulting in miscommunication (Paasche-Orlow and Wolf 2007). It is perhaps due to these cultural health capital inequalities that researchers have found that women of lower SES are less likely to use interpersonal sources for health care due to limited social networks (Jensen et al. 2010) and are more apt to adopt a passive approach to health care information absorption; incorporating things heard via television rather than actively seeking aid from people (medical and non-medical) or health-oriented literature (Bell 2014).

Health literacy and its impact on the quality of life for PWE is an important avenue for research. PWE are a historically marginalized and heavily stigmatized population; the literature describes the impact of stigma on health outcomes for PWE (Jacoby, Snape and Baker 2005). It is possible stigma could interfere with transparent clinical communication. Higher perceived epilepsy-related stigma and poor communication with clinicians are associated with lower AED adherence- which is critical to seizure control (Chesaniuk et al. 2014, Szaflarski 2014). There is evidence that PWE do not fully understand their condition nor the variation associated with individual cases. Many patients and their caregivers do not know how to name and explain their seizure type, recall what AEDs are taken, or how to reduce seizure frequency (Mameniskiene, Sakalauskaite-Juodeikiene and Budrys 2015). Bautista (2009) reported a relationship between improved QoL and greater health literacy, but no evidence linking health literacy to clinical outcomes. The sample was composed of majority urban, indigent, out-patient population with an annual household income <$10k. Further studies are needed to determine the effect of health literacy on QoL for PWE in more diverse populations.

Disability

Contemporary disability perspectives differ widely depending on whether one is approaching from a theoretical, public health, or activist stance. The social model of disability posits that disability is the social consequence of impairment and that removal of barriers (physical and social) would lead to full societal participation by people with disabilities. Critics of this position say it does not attend that some people with disabilities have impairments that absolutely impact their everyday lives above and outside the world's social and physical barriers. Many sociologists approach disability studies from a foundation of deviance and/or stigma research. While this has historically been a relevant way to understand how people with disabilities are set away and apart from the nondisabled population, it diminishes the impact of medicalization on disability and its part in restricting acceptable human variation. Foucault's post-modern and post-structural interpretation of disability describes the compartmentalization of persons with disability and their objectification as a means of making governable the exercise of power and its creation of knowledge; that power is not something that is given or taken back, but is exercised and exists only in action through productive constraints (Tremain 2015).

Thus, cultural health capital constructs and confers the knowledge of these constraints through patient/clinician interaction and the development of health literacy allows the meaningful exercise of the power derived therein.

For PWE, disability is a complex phenomenon. Intellectual disability is conceptualized as the significant impairment of intellectual functioning: low IQ scores, limited conceptual/cognitive ability, and diminished social and practical skills (van Blarikom et al.). There are a variety of factors that impact intellectual disability in PWE: anti-epileptic drug (AED) side effects, and/or other social factors; further, it may by state-dependent or permanent (Cornaggia and Gobbi 2001). Researchers have struggled to identify the exact incidence of intellectual disability among PWE. Current figures estimate 16.1-50% of people with controlled seizures and 35-75% of those with treatment-resistant epilepsy are on the spectrum of intellectual disability (Arshad et al. 2011, Branford, Bhaumik and Duncan 1998, van Blarikom et al. 2006).

Physical disability is composed of diverse components that arise from the interaction of an individual's body and the features of one's social environment. The spectrum of disability includes limitations on individual physical functioning: mobility, stamina, visual or aural abilities, and so on. Epilepsy has historically been associated with physical disability. Much of the epilepsy literature has focused on the physical and emotional burden of the disease, and its resulting disability that it has on PWE and their families (De Boer, Mula and Sander 2008, Leonardi and Ustun 2002). From the cultural health capital, social disability, and Foucauldian perspectives, we can consider that disability associated with epilepsy is rather a disadvantage that can be moderated through access to means of power. Specific to this study, I examined health literacy and its effect upon quality of life.

Quality of Life

Health-related quality of life (QoL) is a matrix of important, valued dimensions of life that influence health, but not are considered health measures. These include self-reports of social, emotional, and physical health. QoL is crucial because diagnostic or clinical indicators may be helpful for clinicians, but do not usually address what is important to a patient (e.g., well-being, functionality, etc.). Further, QoL is essential for deciphering why patients with the same or similar clinical indicators exhibit different QoL outcomes (Guyatt, Feeny and Patrick 1993).

There are two instrumental approaches to measuring QoL. The first is the use of a generic measure that inventories aspects of an individual's life and aggregates them for an overall score. The second approach is to use a disease-specific instrument which has been designed to pick up on components of an individual's experience that are emblematic to the diagnosis and which research has established a tie. For people with epilepsy, the use of the Quality of Life in Epilepsy (QOLIE-89) was developed as an epilepsy-specific, targeted measure that is sensitive to the unique experience of living with epilepsy (Devinsky et al. 1995).

Research studying the QoL among PWE has reported higher levels of anxiety and depression, poor sleep, low self-esteem, lower levels of emotional and social functioning, and lower levels of employment (Charyton et al. 2009, Jacoby et al. 2015, Love et al. 2016, Meador et al. 2015). QoL for PWE is associated with age, duration of epilepsy, mood states, adverse effects, and seizure control (Szaflarski and Szaflarski 2003, Szaflarski et al. 2006). Living with epilepsy often means more care needed and higher medical costs (Mengoni et al. 2016, Taylor et al. 2011). The experience of living with epilepsy often results in a complete overhaul of one's biographical narrative. Kilinç (2017) identified three themes influencing quality of life for patients with adult epilepsy: *fear of seizures*- the unpredictable nature of seizures imbued the lives of PWE with anxiety; *the ripple effect*- the impact of epilepsy on life beyond the experience of seizures: driver's license loss, employment loss, housing loss; *re-evaluating the future*- the plans one had for one's future must be reconsidered after diagnosis. For PWE, QoL is also associated with intellectual and/physical disabilities through environmental factors (Bowley and Kerr 2000, van Blarikom et al. 2006).

Cultural Health Capital

With Bourdieu's notion of cultural capital (Bourdieu 1984, Bourdieu 1989, Bourdieu 2011) as its foundation, cultural health capital (CHC) provides a framework to understand how broad social inequalities are manifested in patient-clinician interactions (Shim 2010). Defined as the constellation of skills, attitudes, behaviors, attributes, and interaction styles adopted, utilized, and leveraged by both patients and providers, cultural health capital posits that this skill set is socially derived and contributes to the hierarchal power differential that impacts health outcomes (Shim 2010). Cultural health capital differs from Bourdieu's cultural capital in that it is a context-specific set of resources allowing for more effective healthcare interaction (e.g. instrumental approach to self-management, biomedical verbal competency, information seeking behavior). Unlike concepts of socioeconomic status and power conferral, CHC does not assume the leveraging of resources to be a purposeful action by patients exercising agency. Rather, the development of CHC is through repeated health-related practices and clinician interactions where the reciprocal interplay of choice and constraint become embodied by and embedded in an individual's habitus (Bourdieu 1984, Shim 2010). The development of adequate health literacy can be considered an achievement of the transactional nature of CHC in two ways: first, patients who interact with clinicians using accepted medical terminology establish themselves as informed and facilitate communication; second, healthcare providers may interpret the leveraging of such skills as a sign of a patient's adherence to ideal standards of patient compliance, and result in material benefits in care (Shim 2010). This study seeks to investigate a third possible outcome where the benefits gained from CHC result in nonmaterial benefits. Specifically, CHC in the form of health literacy positively impacts health-related quality of life. Thus, the focal research question of this study is "what is the relationship between health literacy and quality of life for PWE and does it exist independent of the factors already established by research?" Previous studies have shown that QoL for PWE is influenced by age, mood states, and medication adverse effects; these factors were included in analysis to better uncover the association between health literacy and QoL.

Considering the past theory and research, I hypothesized:

H1: Higher health literacy is associated with improved quality of life in PWE.

H2: Greater health literacy is associated with enhanced quality of life for PWE independent of mood states, adverse effects, and sociodemographic and economic factors.

METHODS

Study Design and Data

The study design was cross-sectional and included patients with treatment-resistant epilepsy enrolled in the University of Alabama at Birmingham Cannabidiol Program between 4/1/2015 and 7/18/2018. Each patient was referred to the study by their neurologist; inclusion was conditioned upon committee review of the physician-submitted application packet including a medical history, a VEEG (video-electroencephalogram) confirming the epilepsy diagnosis, laboratory tests (complete blood count (CBC), metabolic panel, and urinalysis), previous and current AED list, and a calendar documenting seizure activity.

The sample composed of adult respondents (aged 19-74; n=79) were interviewed using standardized questionnaires administered by a trained interviewer at the patient's first visit (Appendix A). The interview is composed of 27 structured items adapted from previously validated health survey measures. The initial interview included items assessing the patient's sociodemographic background, SES, self-reported health, and other social and psychosocial components.

Measures

Dependent Variables

Quality of life was measured using the Quality of Life in Epilepsy (QOLIE-89), a comprehensive instrument developed to gauge health-related QoL in PWE (Devinsky et al. 1995) (Appendix B-1). An overall QoL score based on 17 subscales with 4 underlying dimensions was used as the dependent variable. Higher scores on the QOLIE-89 indicate better health-related quality of life.

Main Independent Variable

Health literacy was assessed with three questions: 1) “How often does patient have someone help him/her read hospital materials?” 2) “How often does patient have problems learning about his/her medical condition?” with patient response choices: never, occasionally, sometimes, often, always. Both variables were reverse coded 0 “Always” to 4 “Never” and treated as continuous for bivariate analysis due to sample size. 3) “How confident is patient filling out forms by him/herself?” with respondent choices: not at all, a little bit, somewhat, quite a bit, extremely; responses coded 0 “not at all” to 4 “extremely” (Table 1). The three items were used to create a summative composite scale (Cronbach’s α=0.9) with possible values 0-12; where a higher score is indicative of a higher level of health literacy. Due to the positive skew of the distribution (Appendix C), the variable was transformed by natural logarithm.

Independent Factors

Sociodemographic factors included total family income, financial strain, education, mood state, adverse effects, race, and gender. Total family income was measured with the question "Can you tell me which category on this card best represents your total combined family income in the last 12 months?" Respondents chose from 21 possible response categories ranging from "$8000" to "$200,000+". For this study, the variable was categorized into terciles: Low: "$8000-$24,999", Middle: "$25,000-$79,999", and High: "$80,000-$200,00+" with the low tercile used as reference category.

Financial strain was assessed through 3 items: 1) "How would you describe the money situation in your household right now?" with response categories "comfortable with extra" "enough, but no extra" "have to cut back" or "cannot make ends meet." This variable was coded 0 "comfortable with extra" to 3 "cannot make ends meet" and was treated as continuous. 2) "In the past 12 months, how often has the following statement been true in your household '*the food we bought ran out and we didn't have money to get more."* with response options "Never true" "sometimes true" or "often true." This variable was dichotomized into "never true" as the reference category and the remaining values were combined into a "sometimes or often true" category. 3) "In the past 12 months, how often have you had problems covering the cost of your epilepsy medications?" Response categories included "never true" "sometimes true" and "often true." This variable was also dichotomized into "never true" as the reference category and the remaining values were combined into a "sometimes or often true" category

Education was measured by asking "What is the highest grade or year of school that you have completed?" The ten response categories ranging from "Completed grade 3 or

4” to “Completed graduate or professional degree” were condensed into 6 categories to simplify interpretation: “less than high school” “Special Education until 21” “graduated high school” “some college” “college degree” and “graduate or professional degree”. Race was treated as binary and coded 0 “white” 1 “black/African-American.” Gender was also treated as binary “female/male”.

A measure of overall self-reported health status was measured with the question “In general, would you say your health is excellent, very good, good, fair, or poor?” This variable was coded 0 “poor” to 4 “excellent” and treated as continuous for bivariate analysis. The interview schedule was structured in such a way that if a patient were nonverbal or otherwise unable to complete the interview, then a caregiver would answer as proxy. To measure this effect, a binary caregiver response versus patient response variable was created with patient response as the reference group.

Controls

Mood states were assessed using the Profile of Mood States (POMS), a widely-used instrument composed of 65 mood-related items in six dimensions: tension/anxiety, depression, anger/hostility, vigor/activity, fatigue, and confusion/bewilderment (McNair D 1992). The Total Mood Disturbance (TMD) value is a composite score used in this analysis and was calculated by summing respondent subscale scores and subtracting vigor/activity (Haythornthwaite) (Appendix B-2). Adverse effects were evaluated using The Adverse Events Profile; a 19-item inventory assessing medication side effects where higher scores indicate more severe medication adverse effects (Appendix B-3).

Analysis

Analyses were performed using Stata 15.1 software. Descriptive analysis included summarization of sociodemographic factors, health literacy scores, QOLIE-89 values, and controls (percentage distribution for categorical variables, and mean/median, standard deviation, and range for continuous variables), bivariate analyses—Pearson correlations for continuous/continuous and binary/continuous; cross-tabulations and Chi square tests for categorical/categorical variables), and a nested ordinary-least-squares (OLS) regression, with independent and control variables included in theoretically relevant blocks. The significance level of alpha = .10 was used based on limited sample size and exploratory nature of the study.

RESULTS

The sample was 54% female and 92% white. The mean age was 33. About 44% of the patients were in a Special Education program until 21 and the annual family income terciles were similarly divided (Table 1). Significant positive bivariate associations (Table 3) were found among health literacy and quality of life (*r*=.324, p=.004), age (*r* =.415, p=.0001), educational level (*r* =.449, p<.0001), food availability (r=.191, p=.092), and AED affordability (*r*= .191, p=.092), but negatively associated with income (*b*= -.21, p=.063). QoL was positively impacted by age (*r*=.19, p=.095) and negatively associated with mood state *(r*= -.189, p=.059), and adverse effects (*r*= -.214, p=.096). Positive associations were found between race and income (p=.07), food availability (p=.021) and AED affordability (p=.08), but race was negatively associated with reported money situation (p=.023).

To formally evaluate my hypotheses, I estimated a nested multivariate linear regression model of the effects of health literacy on QoL including all independent variables tested in bivariate analysis to account for potential spurious relationships. Table 3 shows the results of each model which support my hypotheses that health literacy positively impacts QoL and does so after the addition of independent variables and controls. Model 1 shows health literacy has a significant positive effect on QoL where a 1% increase in health literacy is associated with a 6.61 point increase in QoL (p=.004). The effect of health literacy on QoL continued to be positive and significant through the addition of age, race, and sex to Model 2 (*b*=6.89, p=.006); the inclusion of income and education values to Model 3 (*b*=7.57, p=.006); measures of financial strain in Model 4 (*b*=7.62, p=.007); self-rated health in Model 5 (*b*=7.47, p=.008); or when controlling for mood states and adverse effects in the final model (*b*=7.58, p=.006).

In my preliminary analyses, I controlled for caregiver-response, which resulted in a small reduction of the coefficient for health literacy (16% of the association between health literacy and QoL is accounted for by whether the respondent has a caretaker) and much larger standard errors resulting in loss of significance. However, the large increase in the standard errors suggests issues of multicollinearity. To examine this further, supplementary analyses included two additional nested multivariate linear regression models: the first included only patients who responded to the interview themselves; the second sample was comprised of caregiver-based response only (Appendix D 2-3).

Discussion

This study is an attempt to build on the limited research examining how, for PWE, QoL can be improved by better health literacy. Current disability research and advocacy promotes health literacy as a tool to provide access to disabled individuals- both physical access and long term assurance of competent, coordinated care (National Academy 2018). In this study, health literacy remained a statistically significant predictor of quality of life through each addition of independent factors, including the addition of adverse effects and total mood states and is especially interesting given the spectrum of disability represented by the sample. This seems to support the CHC, social disability, and contemporary advocacy perspectives that given access to appropriate resources, individuals can participate more fully in social interactions (i.e. clinical settings), thus improving QoL.

Previous research has noted health literacy as positively associated with income, education, and QoL, but negatively associated with advanced age and racial minority status (Mameniskiene, Sakalauskaite-Juodeikiene and Budrys 2015). Our bivariate findings (Table 3) support that higher education is a predictor of improved health literacy. This is somewhat intuitive as the development of health literacy is an educational process. Further, results are consistent with the original findings from Bautista that health literacy is positively associated with QoL. Inconsistent with previous research finding that older or elderly individuals have less knowledge of their disease, our results are that age is positive indicator of health literacy. This supports a CHC perspective wherein continuous interaction with a clinician results in greater health capital gains (i.e. health literacy). Age is also positively correlated with QoL and when interpreted in the context of its independent association with education, affordability of epilepsy medications, but negatively association with self-rated health, a possible explanation is that older individuals have more resources and have developed the self-management skills needed to enhance their quality of life.

In contrast to previous findings, a negative relationship was found between income and health literacy. While much research cites low socioeconomic status as an indicator of diminished health literacy, our findings were a positive relationship for the lowest tercile of income, but negative for the middle and highest levels. An explanation for this could be that the interview question aimed at determining annual income is to report “total family income” in the last year: including all sources of income from all individuals living in the household. Of the participants who are nonverbal and whose caregiver responded to the survey, many live at home with parents. Thus, it is possible that the highest levels of income are both a measure of higher family SES as well as reporting the more disabled patients. For the outcome variable, QoL, our results were consistent with previous QoL for PWE studies that found a negative correlation between QoL and adverse medication effects and mood state (Suurmeijer, Reuvekamp and Aldenkamp 2001, Szaflarski et al. 2006), but was most strongly associated with health literacy.

Many of the variables used in our models had a moderately strong bivariate relation with our main independent variable. After all independent and control variables were included through each conceptual step in our model, only health literacy remained statistically significant indicator of QoL which supports both our hypothesis that a relationship exists, and theoretical stance proposing that health literacy derived via clinical transaction serves as the bridge between disability and agency of care. When comparing the full model to the two supplementary analysis tables (Appendix D 2-3) it is possible to conclude that health literacy is a crucial contributor to QoL for PWE. For those who do not have a caregiver and who are active directors of their own care, the effect is stronger and more significant than for those who do not. However, the pattern is similar for both groups.

Limitations

Findings are not generalizable to the larger population of U.S. adults living with epilepsy. The sample is small (n=79) and composed of patients with TRE participating in the UAB CBD study and are therefore a specialized population. Further, participation in the study is restricted to the state of Alabama and this may introduce sociodemographic characteristics that are not reflected in the broader epilepsy population (e.g. sample is only 7.6% black or African-American despite the state of Alabama reporting a 26.4% black or African-American population). While the income terciles were evenly distributed, it should not be underestimated that nearly 30% of the sample has a total family income of less than $25,000 annually in a state with a median yearly income of nearly $45,000. However, this distribution is consistent with other studies conducted in the Deep South (Snodgrass et al. 2001). Previous analyses on this sample have not found a significant relationship between income and QoL for PWE (Szaflarski et al. 2017) and our results support those findings. All patients in the study have health insurance, which isn't the case for all epilepsy social research (Begley et al. 2009). Research examining the incidence and prevalence of epilepsy have found the rates to be highest for individuals under the age of 5 and over the age of 60 (Helmers et al. 2015). For our sample, there is no one under the age of 19 and only 6.35% of the sample is age 60 and above; thus, the sample may be further specialized.

A theoretical limitation is that health literacy is operationalized as a static concept within this study. Future research testing the theory of cultural health capital as an achievement of clinical interactions should consider health literacy a dynamic concept requiring measurement in a longitudinal setting.

Future Research Directions

More research is needed to determine if health literacy impacts QoL for larger, more diverse populations of PWE. Future directions of this study include comparisons across geocodes to investigate potential differences in rural versus urban environments and the respective impacts on QoL for PWE. Also, analysis of longitudinal data would allow a fuller examination of health literacy as an evolving and growing capacity borne of clinical interaction.

Implications for Practice

The clinical and institutional shift toward collaborative patient-centered care is made stronger and more efficient with a culture of health literacy and patient advocacy. Clinicians have the opportunity to grow patient knowledge and in turn provide optimal care by ensuring understanding, encouraging compliance and adherence, and promoting improved self-management. The promotion of which would reduce health care costs and improve QoL for PWE, particularly in rural or underserved areas where access to specialized care is not readily available.

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Table 1. Descriptive Statistics for the Epilepsy Sample (n=79)

Variable	Mean or Proportion	SD	Min	Max
Outcome Variable				
Quality of Life	48.87	19.59	2	85
Explanatory Variable	2.79	3.72	0	12
Health Literacy Index[a]				
Independent Variables				
Age	32.91	13.65	19	74
Race[b]	.076			
Sex[c]	.743			
Education	1.69	1.25	0	5
Income (annual)				
$8k- $24,999	29.11			
$25k-$79,999	37.97			
$80k-$200k+	32.91			
Self-Rated Health	2.06	1.11	0	4
Money Situation	2.05	.999	0	3
Food Availability[d]	.165			
AED Affordability[e]	.114			
Control Variables				
POMS	46.06	34.58	0	156
AEP	41.37	10.35	19	65

[a] Additive composite of health literacy measures

[b] 1 white, else 0.

[c] 1 male, else 0.

[d] 1 sometimes/often food runs out, else 0.

[e] 1 sometimes/often problems affording AEDs, else 0.

[f] 1 if caregiver were survey respondent, else patient response.

Table 2. Bivariate Associations among the Study Variables (n=79)

	QOLIE89	Age	Race	Sex	Income	Education	Money Situation	Food Availability	AED Affordability	Self-Rated Health	AEP	POMS
Health Literacy Index[a]	.324 (.004)	.415 (.0001)	.108	.081	-.21 (.063)	.449 (.0000)	-.136	.191 (.092)	.191 (.092)	-.114	.009	.055
QOLIE89	1.00	.19 (.09)	-.128	-.101	.056	.142	.185	-.031	.064	.127	-.189 (.096)	-.214 (.059)
Age			-.09	-.044	-.163	.381 (.0005)	-.113	.053	.331 (.003)	-.267 (.02)	-.137	-.087
Race[b]				.392^{f}	5.32^{f} (.07)	-.045	-.256^{f} (.023)	5.31^{f} (.021)	3.1^{f} (.08)	-.06	.241 (.034)	.235 (.038)
Sex[c]					.605^{f}	.001	-.21^{f} (.06)	1.37^{f}	4.86^{f} (.03)	-.109	.176	.047
Income						.051	35.47^{f} (.000)	18.25^{f} (.000)	8.32^{f} (.016)	.201 (.08)	-.01	.072
Education							.084	-.138	.119	-.142	-.047	.073
Money Situation								29.52^{f} (.000)	11.94^{f} (.008)	.401 (.0003)	.076	.04
Food Availability[d]									11.3^{f} (.001)	-.241 (.032)	.104	.169
AED Affordability[e]										-.201 (.08)	.173	.094
Self-Rated Health											-.014	.045
AEP												.461 (.0000)
POMS												1.00

Note: Pearson correlations with p-values are presented, excepted where noted otherwise. Significance values are noted in parentheses.

[a] Logged Additive composite of health literacy measures

[b] 1 white, else 0.

[c] 1 male, else 0

[d] 1 sometimes/often food runs out, else 0

[e] 1 sometimes/often problems affording AEDs

[f] Chi-square value

Table 3. Nested Linear Regression Model (n=79)

QOLIE89	Model 1 *b*	SE	Model 2 *b*	SE	Model 3 *b*	SE	Model 4 *b*	SE	Model 5 *b*	SE	Model 6 *b*	SE
Explanatory Variable												
Health Literacy Index[a]	6.61(.004)	2.20	6.89 (.006)	2.46	7.57 (.006)	2.68	7.62 (.007)	2.73	7.47 (.008)	2.74	7.58 (.006)	2.66
Independent Factors												
Age			0.04	.172	0.82	.181	0.05	.191	0.089	.194	-.03	.191
Race[b]			-11.3	8.05	-9.66	8.39	-9.32	8.56	-9.40	8.58	-4.04	8.63
Sex[c]			-4.52	4.23	-4.30	4.28	-3.94	4.48	-3.75	4.49	-2.90	4.42
Income					2.54	2.90	.144	3.50	0.405	3.51	1.15	3.46
Education					-.903	1.99	-1.20	2.03	-.961	2.05	-.599	2.01
Money Situation							4.68	2.92	3.75	3.08	5.04	3.08
Food Availability[d]							1.02	7.31	1.58	7.34	4.94	7.30
AED Affordability[e]							7.04	8.04	6.87	8.05	9.23	7.94
Self-Rated Health									2.07	2.17	2.03	2.13
Control Variables												
AEP											-.235	.240
POMS											-.116	.071
R^2	0.105		.146		.156		.194		.205		.272	
F for change in R^2	9.01 (.004)		1.20		0.43		1.09		0.91		3.01 (.056)	

Note: Significance levels are noted in parentheses.

[a] Logged additive composite of health literacy measures.

[b] 1 white, else 0.

[c] 1 male, else 0.

[d] 1 sometimes/often food runs out, else 0.

[e] 1 sometimes/often problems affording AED, else 0.

APPENDICES

UAB CBD Social Determinants of Health (SDH) Interview Schedule
Standardized Assessments
Health Literacy Transformation
Supplementary Regression Tables
Supplementary Regression Figures

APPENDIX A

UAB CBD Social Determinants of Health Interview Schedule

CBD Study

Social Determinants of Health (SDH)

INTERVIEW SCHEDULE A – ADULT (Initial)

(Participants ages 15 years or up)

Completed by: Study Participant/Patient

Study ID#: ___________ Date of Interview: ___________________

Note: For question items with 4 or more number of response categories, response categories will be printed on flashcards and handed-in to respondents to facilitate a response. See **[CARD #]** noted by the items below.

Note: Variable names are listed in square brackets [Variable].

Interviewer: Check, circle, or fill in responses, as needed. Use flash cards where required. Don't say variable names, only ask the question.

Sociodemographic/Background Information

[Age]

1. **How old are you as of today?**

   ____________ (age in years)

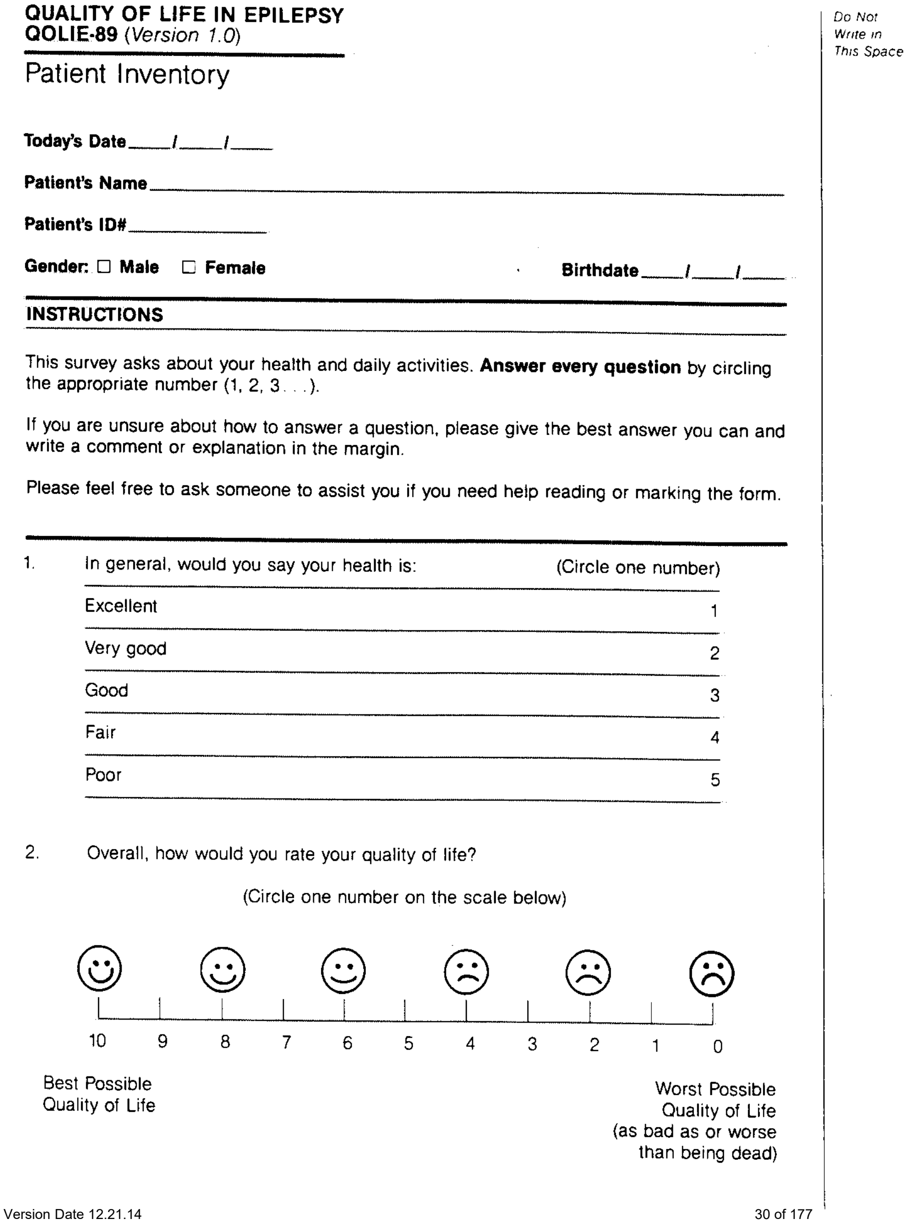
2. **What is your date of birth? Please give me the month, day and year.**

   Date of birth (day 1-31; month 1-12; year [4-digit]) __ __ / __ __ / __ __ __ __

APPENDIX B

Standardized Assessments

Assessment B-1: Quality of Life in Epilepsy 89 (QOLIE-89)



QUALITY OF LIFE IN EPILEPSY
QOLIE-89 (*Version 1.0*)

Patient Inventory

Do Not Write in This Space

Today's Date____/____/____

Patient's Name____

Patient's ID#____________

Gender: ☐ **Male** ☐ **Female** **Birthdate____/____/____**

INSTRUCTIONS

This survey asks about your health and daily activities. **Answer every question** by circling the appropriate number (1, 2, 3 . . .).

If you are unsure about how to answer a question, please give the best answer you can and write a comment or explanation in the margin.

Please feel free to ask someone to assist you if you need help reading or marking the form.

1. In general, would you say your health is: (Circle one number)

Excellent	1
Very good	2
Good	3
Fair	4
Poor	5

2. Overall, how would you rate your quality of life?

(Circle one number on the scale below)

10 9 8 7 6 5 4 3 2 1 0

Best Possible Quality of Life

Worst Possible Quality of Life (as bad as or worse than being dead)

Version Date 12.21.14

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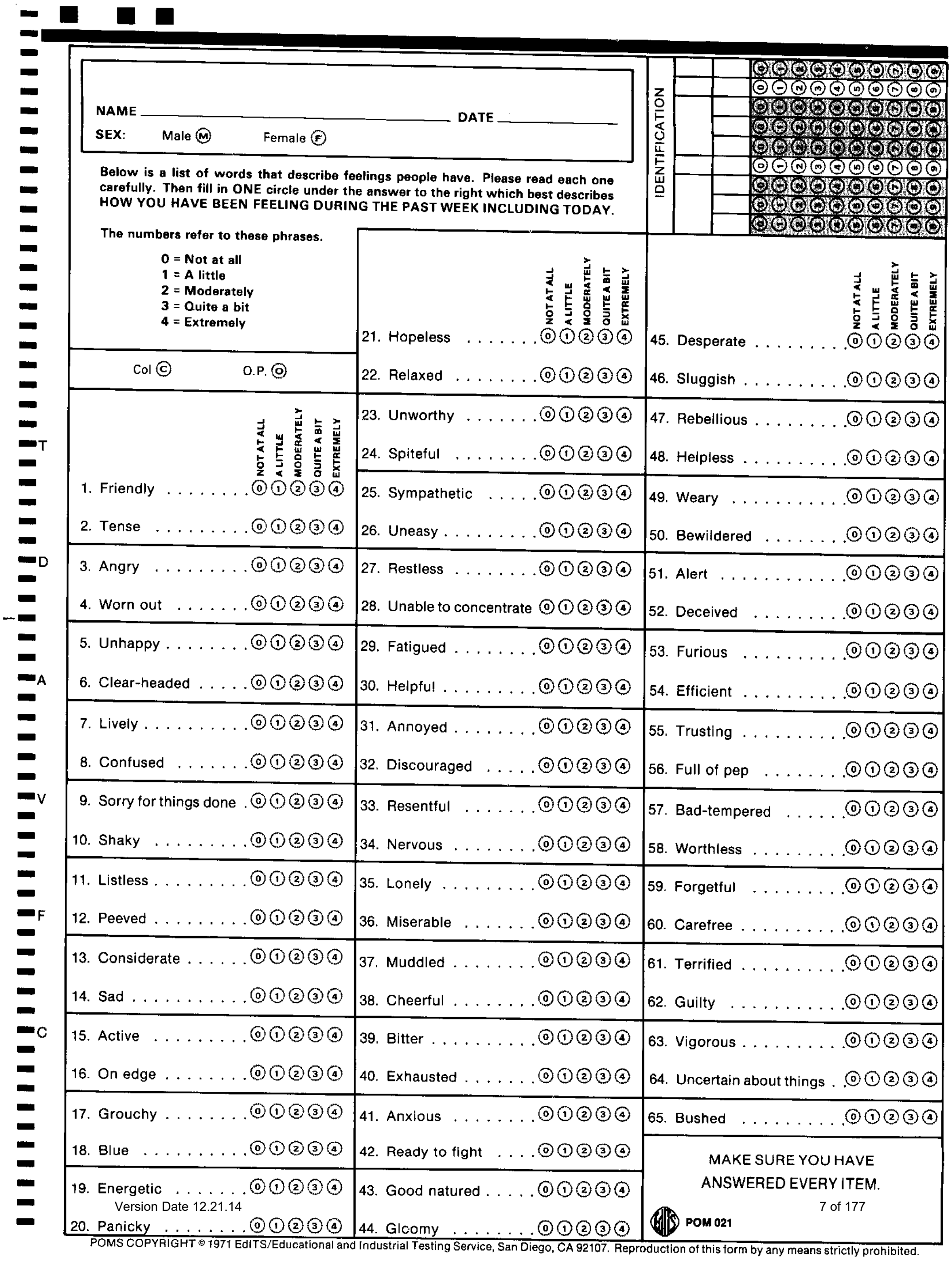
Assessment B-2: Profile of Mood States (POMS)



NAME ______________________ DATE __________

SEX: Male Ⓜ Female Ⓕ

IDENTIFICATION

⓪①②③④⑤⑥⑦⑧⑨
⓪①②③④⑤⑥⑦⑧⑨
⓪①②③④⑤⑥⑦⑧⑨
⓪①②③④⑤⑥⑦⑧⑨
⓪①②③④⑤⑥⑦⑧⑨
⓪①②③④⑤⑥⑦⑧⑨
⓪①②③④⑤⑥⑦⑧⑨
⓪①②③④⑤⑥⑦⑧⑨
⓪①②③④⑤⑥⑦⑧⑨

Below is a list of words that describe feelings people have. Please read each one carefully. Then fill in ONE circle under the answer to the right which best describes HOW YOU HAVE BEEN FEELING DURING THE PAST WEEK INCLUDING TODAY.

The numbers refer to these phrases.

0 = Not at all
1 = A little
2 = Moderately
3 = Quite a bit
4 = Extremely

Col Ⓒ O.P. ⓞ

	NOT AT ALL	A LITTLE	MODERATELY	QUITE A BIT	EXTREMELY
1. Friendly	⓪	①	②	③	④
2. Tense	⓪	①	②	③	④
3. Angry	⓪	①	②	③	④
4. Worn out	⓪	①	②	③	④
5. Unhappy	⓪	①	②	③	④
6. Clear-headed	⓪	①	②	③	④
7. Lively	⓪	①	②	③	④
8. Confused	⓪	①	②	③	④
9. Sorry for things done	⓪	①	②	③	④
10. Shaky	⓪	①	②	③	④
11. Listless	⓪	①	②	③	④
12. Peeved	⓪	①	②	③	④
13. Considerate	⓪	①	②	③	④
14. Sad	⓪	①	②	③	④
15. Active	⓪	①	②	③	④
16. On edge	⓪	①	②	③	④
17. Grouchy	⓪	①	②	③	④
18. Blue	⓪	①	②	③	④
19. Energetic	⓪	①	②	③	④
20. Panicky	⓪	①	②	③	④
21. Hopeless	⓪	①	②	③	④
22. Relaxed	⓪	①	②	③	④
23. Unworthy	⓪	①	②	③	④
24. Spiteful	⓪	①	②	③	④
25. Sympathetic	⓪	①	②	③	④
26. Uneasy	⓪	①	②	③	④
27. Restless	⓪	①	②	③	④
28. Unable to concentrate	⓪	①	②	③	④
29. Fatigued	⓪	①	②	③	④
30. Helpful	⓪	①	②	③	④
31. Annoyed	⓪	①	②	③	④
32. Discouraged	⓪	①	②	③	④
33. Resentful	⓪	①	②	③	④
34. Nervous	⓪	①	②	③	④
35. Lonely	⓪	①	②	③	④
36. Miserable	⓪	①	②	③	④
37. Muddled	⓪	①	②	③	④
38. Cheerful	⓪	①	②	③	④
39. Bitter	⓪	①	②	③	④
40. Exhausted	⓪	①	②	③	④
41. Anxious	⓪	①	②	③	④
42. Ready to fight	⓪	①	②	③	④
43. Good natured	⓪	①	②	③	④
44. Gloomy	⓪	①	②	③	④
45. Desperate	⓪	①	②	③	④
46. Sluggish	⓪	①	②	③	④
47. Rebellious	⓪	①	②	③	④
48. Helpless	⓪	①	②	③	④
49. Weary	⓪	①	②	③	④
50. Bewildered	⓪	①	②	③	④
51. Alert	⓪	①	②	③	④
52. Deceived	⓪	①	②	③	④
53. Furious	⓪	①	②	③	④
54. Efficient	⓪	①	②	③	④
55. Trusting	⓪	①	②	③	④
56. Full of pep	⓪	①	②	③	④
57. Bad-tempered	⓪	①	②	③	④
58. Worthless	⓪	①	②	③	④
59. Forgetful	⓪	①	②	③	④
60. Carefree	⓪	①	②	③	④
61. Terrified	⓪	①	②	③	④
62. Guilty	⓪	①	②	③	④
63. Vigorous	⓪	①	②	③	④
64. Uncertain about things	⓪	①	②	③	④
65. Bushed	⓪	①	②	③	④

Version Date 12.21.14

MAKE SURE YOU HAVE ANSWERED EVERY ITEM.

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POM 021

Assessment B-3: Adverse Effects Profile (AEP)

ID: __________ Visit:_______ Date: ___/___/_____

ADVERSE EVENTS PROFILE

During the past two weeks, have you had any of the problems or side-effects listed below?

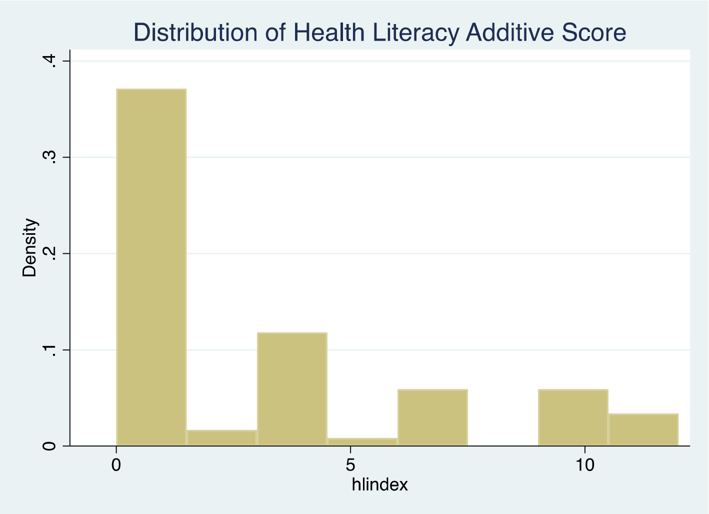
For each item, if it has always or often been a problem, circle 4; if it has sometimes been a problem, circle 3; and so on. Please be sure to answer every item.

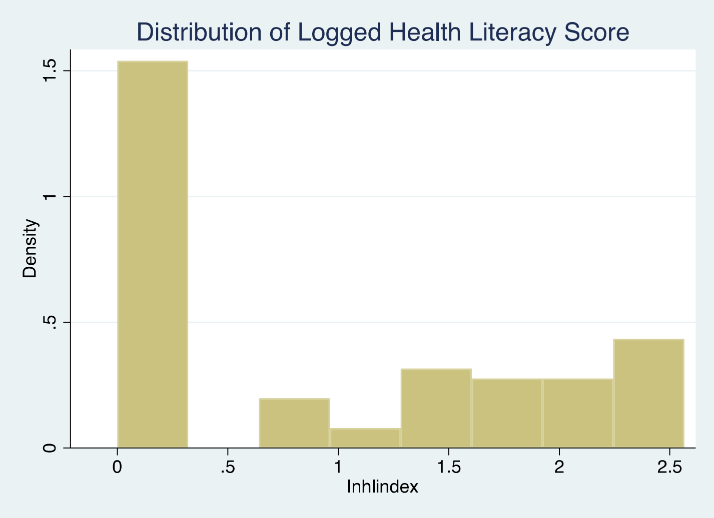
	Always or often a problem	Sometimes a problem	Rarely a problem	Never a problem
Unsteadiness	4	3	2	1
Tiredness	4	3	2	1
Restlessness	4	3	2	1
Feelings of aggression	4	3	2	1
Nervousness and/or agitation	4	3	2	1
Headache	4	3	2	1
Hair loss	4	3	2	1
Problems with skin, e.g. acne, rash	4	3	2	1
Double or blurred vision	4	3	2	1
Upset stomach	4	3	2	1
Difficulty in concentrating	4	3	2	1
Trouble with mouth or gums	4	3	2	1
Shaky hands	4	3	2	1
Weight gain	4	3	2	1
Dizziness	4	3	2	1
Sleepiness	4	3	2	1
Depression	4	3	2	1
Memory Problems	4	3	2	1
Disturbed sleep	4	3	2	1

APPENDIX C

Health Literacy Transformation

Supplementary graphs and statistical tests used when transforming the health literacy measures from a three-question categorical variable, to a logged additive composite. Single health literacy item linear regressions were performed to determine if a single measure were more important to the theoretical concept. Multiple t-tests were used to verify the Pearson correlations used in the expanded bivariate table.





A-C-3 Descriptive Statistics for Categorical Health Literacy Measures (n=79)

Variable	Mean (%)	SD	Min	Max
How often does patient have someone help them read hospital materials?	.823	1.33	0	4
Never	8.86			
Occasionally	5.06			
Sometimes	11.39			
Often	8.86			
Always	65.82			
How often does patient have problems learning about their medical condition?	1.10	1.43	0	4
Never	11.39			
Occasionally	8.86			
Sometimes	11.39			
Often	15.19			
Always	53.16			
How confident is patient filling out medical forms by themselves?	.873	1.29	0	4
Not at All	63.29			
A Little Bit	7.59			
Somewhat	12.66			
Quite a Bit	11.39			
Extremely	5.06			

A-C-4: Linear Regression: Reading Help

QOLIE89	b	SE	t	p	95% CI	
Reading Help[a]	5.77	2.01	2.86	.006	1.745071	9.79085
Age	.002	.194	0.01	.992	-.3849844	.388992
Race[b]	-4.16	8.62	-0.48	.631	-21.37779	13.05838
Sex[c]	-3.30	4.43	-0.75	.459	-12.14581	5.542573
Annual Family Income	1.19	3.45	0.34	.732	-5.709941	8.083948
Education	-1.27	2.11	-0.60	.550	-5.488003	2.947141
Money Situation	5.03	3.07	1.64	.106	-1.106342	11.16907
Food Availability[d]	6.35	7.22	0.88	.382	-8.055979	20.76063
AED Affordability[e]	12.2	8.10	1.51	.137	-3.968642	28.35847
Self-Rated Health	1.60	2.13	0.75	.456	-2.667676	5.871398
AEP	-.223	.240	-0.93	.357	-.7023125	.2564461
POMS	-.105	.071	-1.49	.141	-.2466244	.035699

[a] Patient needs help reading hospital materials
[b] 1 if white, else 0
[c] 1 male, else 0
[d] 1 sometimes/often food runs out, else 0
[e] 1 sometimes/often problems affording AEDs, else 0

A-C-5: Linear Regression: Forms Confidence

QOLIE89	b	SE	t	p	95% CI	
Forms Confidence[a]	4.96	1.99	2.49	.015	.9770542	8.94129
Age	.085	.190	0.45	.654	-.2934319	.4641406
Race[b]	-3.17	8.72	-0.36	.718	-20.574	14.24249
Sex[c]	-2.95	4.48	4.48	.513	-11.89718	6.00468
Annual Family Income	.622	3.49	0.18	.859	-6.340913	7.584004
Education	-.583	2.08	-0.28	.780	-4.734276	3.568387
Money Situation	4.48	3.13	1.43	.158	-1.775598	10.72857
Food Availability[d]	3.86	7.54	0.51	.610	-11.19319	18.91322
AED Affordability[e]	8.10	8.02	1.01	.316	-7.91556	24.11721
Self-Rated Health	2.18	2.15	1.01	.315	-2.116507	6.476912
AEP	-.198	.244	-0.81	.418	-.6844384	.2878985
POMS	-.110	.072	-1.54	.130	-.2529372	.0330439

[a] Patient's reported confidence filling out medical forms for themselves

[b] 1 if white, else 0

[c] 1 male, else 0

[d] 1 sometimes/often food runs out, else 0

[e] 1 sometimes/often problems affording AEDs, else 0

A-C-6: Linear Regression: Problems Reading

QOLIE89	b	SE	t	p	95% CI	
Problems Reading[a]	3.52	1.75	2.02	.048	.0344214	7.00502
Age	.081	.195	0.41	.680	-.3090383	.4707274
Race[b]	-3.90	8.90	-0.44	.662	-21.67173	13.86479
Sex[c]	-2.94	4.56	-0.64	.521	-12.05083	6.169412
Annual Family Income	.589	3.54	0.17	.869	-6.482218	4.410851
Education	.422	1.99	0.21	.833	-3.567024	4.410851
Money Situation	4.86	3.17	1.53	.130	-1.467565	11.18482
Food Availability[d]	6.36	7.48	0.85	.398	-8.571306	21.28674
AED Affordability[e]	9.63	8.22	1.17	.246	-6.793399	26.04355
Self-Rated Health	2.64	2.19	1.21	.232	-1.726172	7.005733
AEP	-.216	.247	-0.88	.385	-.7095186	.2770253
POMS	-.120	.073	-1.65	.104	-.2647298	.0253033

[a] Patient report of difficulty learning about medical condition(s) due to reading difficulties

[b] 1 if white, else 0

[c] 1 male, else 0

[d] 1 sometimes/often food runs out, else 0

[e] 1 sometimes/often problems affording AEDs, else 0

A-C-7: Results of t-test: Race

	Sex						95% CI for Mean Difference		
	White			Black/African-American					
	M	SD	n	M	SD	n		t	df
Health Literacy index	.842	.956	73	1.23	1.01	6	-1.20,.424	-0.95	77

* p < .05 **p <.01 ***p <.001

A-C-8: Results of t-test: Sex

	Sex						95% CI for Mean Difference		
	Female			Male					
	M	SD	n	M	SD	n		t	df
Health Literacy index	.942	.928	43	.787	.928	36	-.585, .278	-0.712	77

* p < .05 **p <.01 ***p <.001

A-C-9: Results of t-test: Food Availability

	Food Has Run Out						95% CI for Mean Difference		
	Never True			Sometimes/Often True					
	M	SD	n	M	SD	n		t	df
Health Literacy index	.791	.949	66	1.28	.941	13	-1.06,.082	-1.71*	77

* p < .05 **p <.01 ***p <.001

A-C-10: Results of t-test: AED Affordability

	Has Had Trouble Paying for AED						95% CI for Mean Difference		
	Never True			Sometimes/Often True					
	M	SD	n	M	SD	n		t	df
Health Literacy index	.806	.958	70	1.38	.849	9	-1.24,.095	-1.71*	77

* p < .05 **p <.01 ***p <.001

A-C-11: Results of t-test: Caregiver Proxy Respondent

	Respondent						95% CI for Mean Difference		
	Patient			Caregiver					
	M	SD	n	M	SD	n		t	df
Health Literacy index	1.60	.799	38	.201	.496	41	1.10, 1.69	9.39***	77

* p < .05 **p <.01 ***p <.001

APPENDIX D

Supplementary Regression Tables

Items were standardized after regression to examine their weights within the model. A-D-2 and A-D-3 are full nested linear regression models investigating the differences in patients who responded to their interviews themselves and those who had caregiver proxies respond.

A-D-1: Linear Regression Model with Standardized Coefficients (n=79)

	b	t	P>t	bStdX	bStdY	bStdXY	SDofX
Health Literacy	7.5802	2.847	0.006	7.271	0.387	0.371	0.959
Age	0.0280	0.146	0.884	0.382	0.001	0.020	13.652
Race	-4.0380	-0.468	0.641	-1.077	-0.206	-0.055	0.267
Sex	-2.8909	-0.654	0.515	-1.449	-0.148	-0.074	0.501
Income	1.1491	0.333	0.741	0.910	0.059	0.046	0.792
Education	-0.5991	-0.298	0.767	-0.751	-0.031	-0.038	1.254
Money Situation	5.0374	1.638	0.106	5.031	0.257	0.257	0.999
AED Affordability	9.2188	1.161	0.250	2.948	0.470	0.150	0.320
Food Availability	4.9367	0.676	0.501	1.842	0.252	0.094	0.373
Self-Rated Health	2.0303	0.955	0.343	2.260	0.104	0.115	1.113
AEP	-0.2347	-0.977	0.332	-2.428	-0.012	-0.124	10.346
POMS	-0.1162	-1.645	0.105	-4.017	-0.006	-0.205	34.580
constant	41.7393	3.094	0.003	.	.	.	.

A-D-2: Nested Linear Regression Model with Caretaker (N=41)

QOLIE89	Model 1 *b*	SE	Model 2 *b*	SE	Model 3 *b*	SE	Model 4 *b*	SE	Model 5 *b*	SE	Model 6 *b*	SE
Explanatory Variable												
Health Literacy Index[a]	6.51	6.43	6.47	6.66	4.84	6.90	5.80	2.73	5.65	7.33	3.99	7.67
Independent Factors												
Age			.295	.407	.336	.413	.332	.429	.324	.437	.172	.479
Race[b]			-2.83	15.17	.173	16.2	-.746	16.98	-.247	17.4	3.61	18.2
Sex[c]			-1.92	6.72	-2.28	6.83	-2.93	7.06	-2.56	7.33	-1.09	7.64
Income					5.49	5.04	1.30	6.88	1.55	7.06	2.77	7.46
Education					3.43	5.61	1.33	6.11	1.48	6.24	2.37	6.42
Money Situation							5.56	5.53	5.86	5.75	6.59	5.95
Food Availability[d]							.141	16.9	-.454	17.4	-3.56	18.1
AED Affordability[e]							12.7	22.8	13.3	23.3	6.89	24.7
Self-Rated Health									-.933	3.87	-1.72	4.09
Control Variables												
AEP											-.391	.472
POMS											-.024	.143
R^2	0.026		.046		.095		.132		.134		.161	
F for change in R^2	1.02		.26		.93		.44		.06		.46	

Note: *p<.05 **p<.01 ***p<.001

[a] Logged additive composite of health literacy measures,

[b] 1 white, else 0.

[c] 1 male, else 0.

[d] 1 sometimes/often food runs out, else 0.

[e] 1 sometimes/often problems affording AEDs, else 0.

A-D-3: Nested Linear Regression Model without Caretaker (n=41)

QOLIE89	Model 1 *b*	SE	Model 2 *b*	SE	Model 3 *b*	SE	Model 4 *b*	SE	Model 5 *b*	SE	Model 6 *b*	SE
Explanatory Variable												
Health Literacy Index[a]	6.86 (.06)	3.59	8.53*	3.61	8.93*	3.78	9.37*	3.95	8.75*	3.99	7.20 (.06)	3.70
Independent Factors												
Age			-.068	.198	-.025	.208	-.101	.236	-.032	.245	-.081	.230
Race[b]			-17.7 (.07)	9.50	-18.5 (.07)	9.92	-19.9 (.09)	11.1	-18.3	11.1	-8.41	11.0
Sex[c]			-5.98	5.68	-6.50	5.88	-6.88	6.86	-3.70	7.46	-3.38	6.91
Income					.617	4.16	.407	4.17	1.04	4.94	1.83	4.54
Education					-1.86	2.24	-1.84	2.45	-.990	2.57	-1.09	2.41
Money Situation							1.96	3.98	1.38	4.01	3.30	3.76
Food Availability[d]							-.069	9.01	1.57	9.12	5.79	8.65
AED Affordability[e]							8.26	9.08	8.04	9.06	10.5	8.87
Self-Rated Health									3.63	3.31	3.03	3.03
Control Variables												
AEP											-.310	.313
POMS											-.163 (.08)	.088
R^2	0.064		.178		.702		.785		.296		.043	
F for change in R^2	3.66 (.06)		.26		.93		.44		.06		.46*	

Note: *p<.05 **p<.01 ***p<.001; values significant at p<.10 are noted in parentheses).

[a] Logged additive composite of health literacy measures

[b] 1 white, else 0.

[c] 1 male, else 0.

[d] 1 sometimes/often food runs out, else 0.

[e] 1 sometimes/often problems affording AEDs, else 0.

A-D-4: Linear Regression with Income as Continuous

QOLIE89	b	SE	t	p	95% CI	
Health Literacy Index[a]	7.54	2.79	2.70	.009	1.953854	13.11811
Age	.024	.189	0.13	.900	-.3548238	.4025857
Race[b]	-7.07	9.59	-0.74	.464	-26.25078	12.10164
Sex[c]	-3.24	4.42	-0.73	.467	-12.08008	5.604711
Annual Family Income	.271	.538	0.50	.616	-.8041215	1.346946
Education	-.509	2.08	-0.24	.808	-4.673691	3.655954
Money Situation	4.27	3.15	1.36	.180	-2.021598	10.57125
Food Availability[d]	4.15	7.39	0.56	.577	-10.62293	18.91442
AED Affordability[e]	6.85	8.12	0.84	.402	-9.382927	23.07876
Self-Rated Health	2.04	2.11	0.97	.337	-2.174651	6.254751
AEP	-.166	.245	-0.68	.500	-.6558497	.3235403
POMS	-.095	.071	-1.32	.190	-.2371241	.0480743

Note: Income is a 21-category variable: $8000-$200,000 total annual family income from all sources

[a] Logged additive composite of health literacy measures

[b] 1 if white, else 0

[c] 1 male, else 0

[d] 1 sometimes/often food runs out, else 0

[e] 1 sometimes/often problems affording AEDs, else 0

A-D-5: Linear Regression with Income Categorical

QOLIE89	b	SE	t	p	95% CI	
Health Literacy Index[a]	7.51	2.64	2.85	.006	2.240659	12.78242
Age	.046	.189	0.24	.809	-.3331307	.4252314
Race[b]	-4.61	8.56	-0.56	.591	-21.70529	12.47278
Sex[c]	-3.08	4.38	-0.70	.485	-11.82284	5.66915
Annual Family Income[d]						
$25,000-$79,999	8.60	6.08	1.41	.162	-3.541167	20.74827
$80,000-$200,000+	4.01	6.95	0.58	.565	-9.857602	17.88452
Education	-.305	2.00	-0.15	.880	-4.305955	3.69681
Money Situation	3.99	3.13	1.28	.206	-2.253263	10.24237
Food Availability[e]	5.96	7.27	0.82	.416	-8.558402	20.46931
AED Affordability[f]	8.51	7.88	1.08	.285	-7.240717	24.25241
Self-Rated Health	2.45	2.13	1.15	.253	-1.795077	6.696378
AEP	-.207	.239	-0.87	.389	-.684411	.2697882
POMS	-.103	.071	-1.45	.151	-.243516	.0384227

Note: *p<.05 **p<.01 ***p<.001

[a] Logged additive composite of health literacy measures

[b] 1 if white, else 0

[c] 1 male, else 0

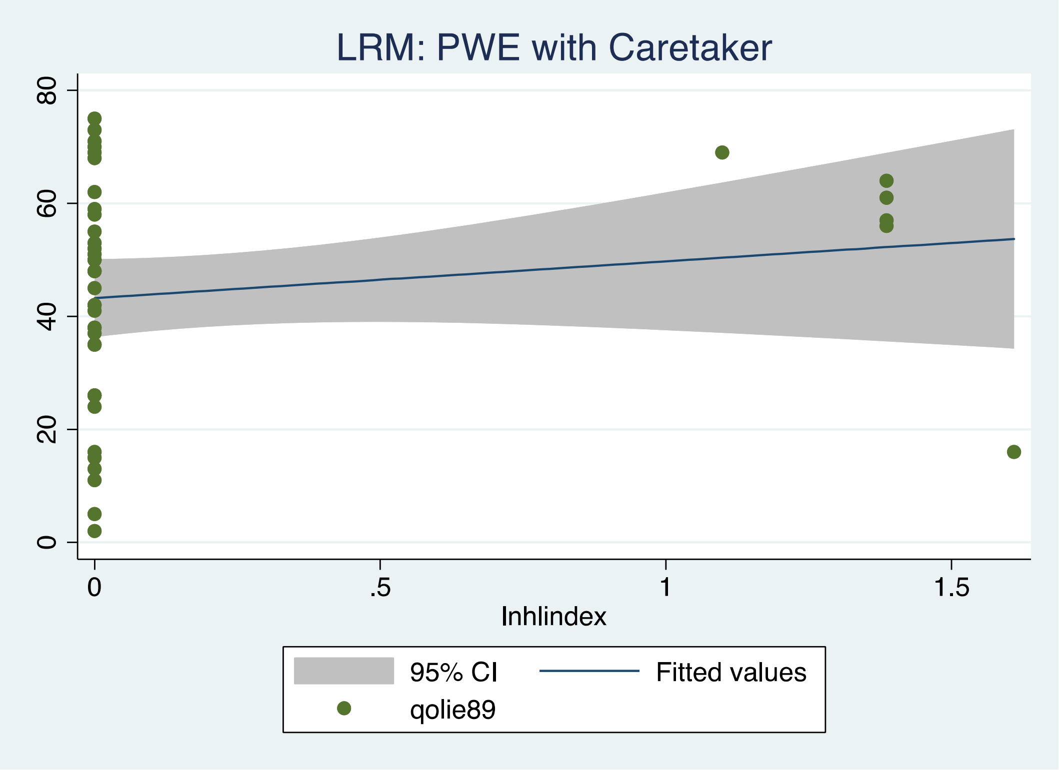
[d] Reference group $8,000-$24,999 annually

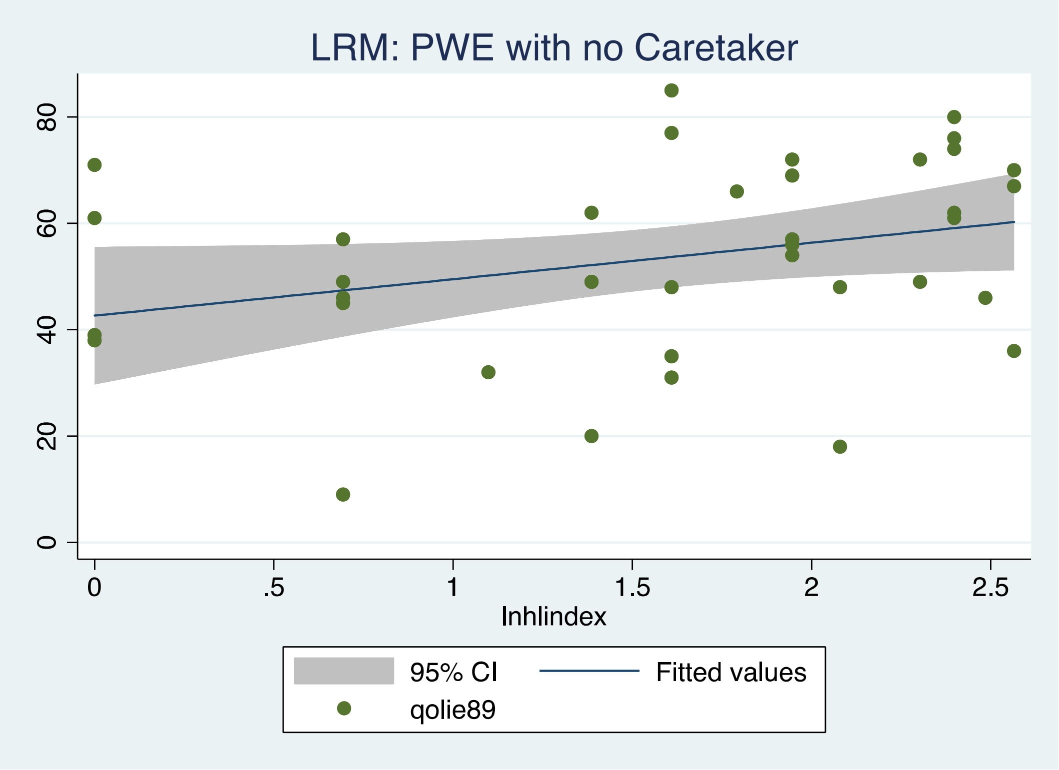
[e] 1 sometimes/often food runs out, else 0

[f] 1 sometimes/often problems affording AEDs, else 0

APPENDIX E

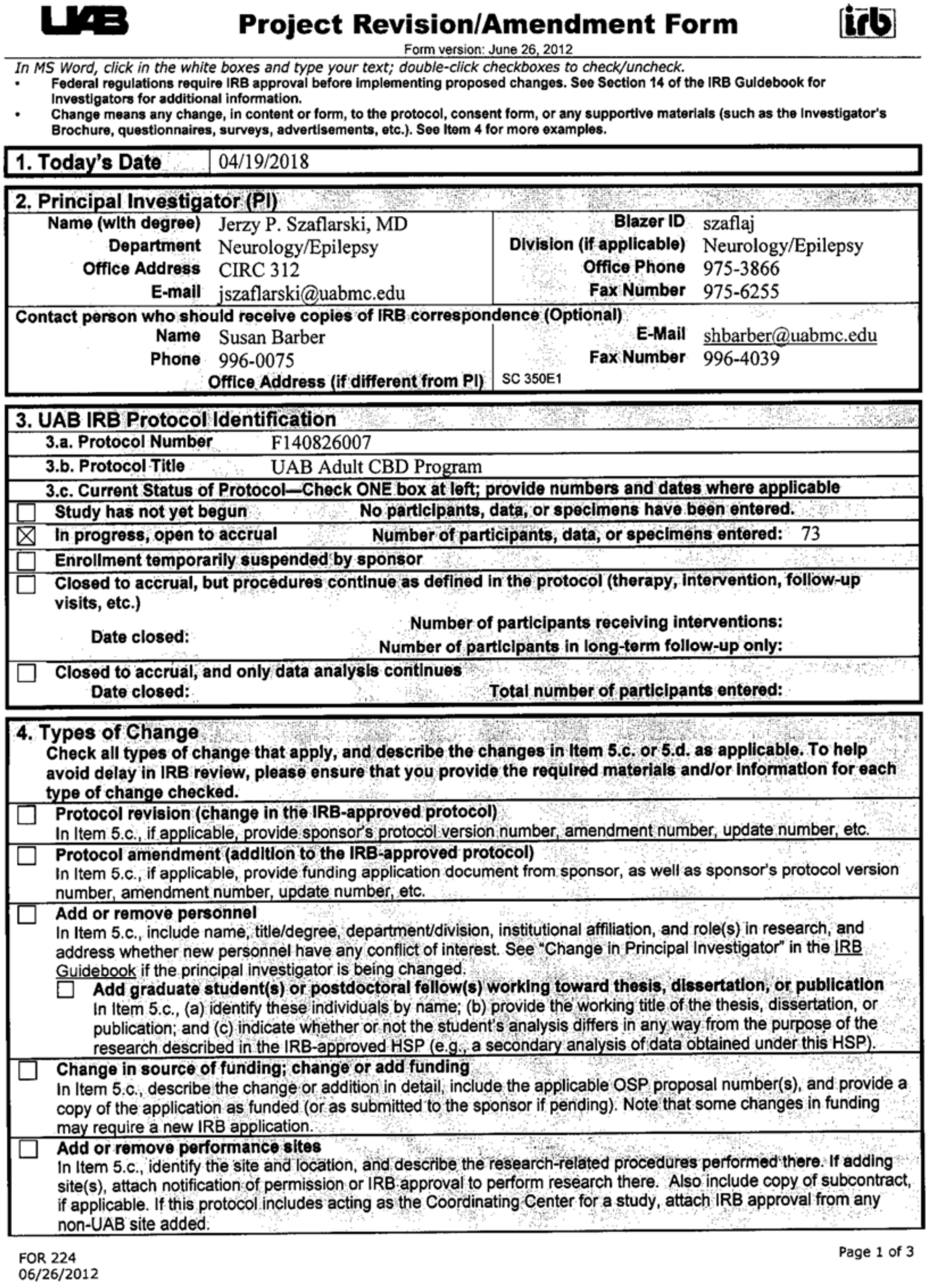
Supplementary Regression Figure


LRM: PWE with Caretaker
0
20
40
60
80
0
.5
1
1.5
lnhlindex
95% CI
Fitted values
qolie89


LRM: PWE with no Caretaker
0
20
40
60
80
0
.5
1
1.5
2
2.5
lnhlindex
95% CI
Fitted values
qolie89

APPENDIX F

IRB/PRA APPROVAL



UAB

Project Revision/Amendment Form

irb

Form version: June 26, 2012

In MS Word, click in the white boxes and type your text; double-click checkboxes to check/uncheck.

- **Federal regulations require IRB approval before implementing proposed changes. See Section 14 of the IRB Guidebook for Investigators for additional information.**
- **Change means any change, in content or form, to the protocol, consent form, or any supportive materials (such as the Investigator's Brochure, questionnaires, surveys, advertisements, etc.). See Item 4 for more examples.**

1. Today's Date	04/19/2018

2. Principal Investigator (PI)

Name (with degree)	Jerzy P. Szaflarski, MD	**Blazer ID**	szaflaj
Department	Neurology/Epilepsy	**Division (if applicable)**	Neurology/Epilepsy
Office Address	CIRC 312	**Office Phone**	975-3866
E-mail	jszaflarski@uabmc.edu	**Fax Number**	975-6255

Contact person who should receive copies of IRB correspondence (Optional)

Name	Susan Barber	**E-Mail**	shbarber@uabmc.edu
Phone	996-0075	**Fax Number**	996-4039
Office Address (if different from PI)	SC 350E1		

3. UAB IRB Protocol Identification

3.a. Protocol Number	F140826007
3.b. Protocol Title	UAB Adult CBD Program

3.c. Current Status of Protocol—Check ONE box at left; provide numbers and dates where applicable

☐ **Study has not yet begun** **No participants, data, or specimens have been entered.**

☒ **In progress, open to accrual** **Number of participants, data, or specimens entered:** 73

☐ **Enrollment temporarily suspended by sponsor**

☐ **Closed to accrual, but procedures continue as defined in the protocol (therapy, intervention, follow-up visits, etc.)**

Date closed: **Number of participants receiving interventions:**

Number of participants in long-term follow-up only:

☐ **Closed to accrual, and only data analysis continues**

Date closed: **Total number of participants entered:**

4. Types of Change

Check all types of change that apply, and describe the changes in Item 5.c. or 5.d. as applicable. To help avoid delay in IRB review, please ensure that you provide the required materials and/or information for each type of change checked.

☐ **Protocol revision (change in the IRB-approved protocol)**
In Item 5.c., if applicable, provide sponsor's protocol version number, amendment number, update number, etc.

☐ **Protocol amendment (addition to the IRB-approved protocol)**
In Item 5.c., if applicable, provide funding application document from sponsor, as well as sponsor's protocol version number, amendment number, update number, etc.

☐ **Add or remove personnel**
In Item 5.c., include name, title/degree, department/division, institutional affiliation, and role(s) in research, and address whether new personnel have any conflict of interest. See "Change in Principal Investigator" in the IRB Guidebook if the principal investigator is being changed.

- ☐ **Add graduate student(s) or postdoctoral fellow(s) working toward thesis, dissertation, or publication**
  In Item 5.c., (a) identify these individuals by name; (b) provide the working title of the thesis, dissertation, or publication; and (c) indicate whether or not the student's analysis differs in any way from the purpose of the research described in the IRB-approved HSP (e.g., a secondary analysis of data obtained under this HSP).

☐ **Change in source of funding; change or add funding**
In Item 5.c., describe the change or addition in detail, include the applicable OSP proposal number(s), and provide a copy of the application as funded (or as submitted to the sponsor if pending). Note that some changes in funding may require a new IRB application.

☐ **Add or remove performance sites**
In Item 5.c., identify the site and location, and describe the research-related procedures performed there. If adding site(s), attach notification of permission or IRB approval to perform research there. Also include copy of subcontract, if applicable. If this protocol includes acting as the Coordinating Center for a study, attach IRB approval from any non-UAB site added.