VALIDATION OF THE U.S. ENGLISH VERSION OF THE PEDSQL 3.2 DIABETES MODULE

A Dissertation

by

ELENA MARIE MADELEINE DOSKEY

Submitted to the Office of Graduate and Professional Studies of
Texas A&M University
in partial fulfillment of the requirements for the degree of

DOCTOR OF PHILOSOPHY

Chair of Committee,	Cynthia A. Riccio
Co-Chair	William A. Rae
Committee Members,	Robert W. Heffer
	James W. Varni
	Myeongsun Yoon
Head of Department,	Shanna Hagan-Burke

August 2017

Major Subject: School Psychology

ABSTRACT

Assessing health-related quality of life (HRQOL) in children with chronic illnesses like diabetes is a growing area in pediatric psychology. Doing so across ethnic groups is important given the increased risk of diabetes to ethnic minority groups, particularly Hispanics. The psychometric properties of the self- and parent-proxy reports of the U.S. English version of the PedsQL 3.2 Diabetes Module (PedsQL 3.2 DM) were examined. Exploratory factor analyses supported a single-factor solution for the self- and parent-proxy reports, regardless of ethnicity. Moderate agreement was found between children's ratings of their diabetes-specific HRQOL and their caregivers' ratings of their children's diabetes-specific HRQOL for the total sample, regardless of ethnicity, and for Hispanics. Self- and parent-reported diabetes-specific HRQOL did not vary according to ethnicity (non-Hispanic or Hispanic). Poorer glycemic control was associated with poorer diabetes-specific HRQOL for the total sample, regardless of ethnicity. The strength of this relationship was not significantly different based on ethnicity (non-Hispanic or Hispanic). Insufficient sample sizes did not permit comparisons across type of diabetes or language of the measure. Future studies should examine the generalizability of these findings to children with type 2 diabetes and those who complete the PedsQL 3.2 DM in Spanish, especially given the rise in the incidence of children with type 2 diabetes and the continued growth of the Spanish-speaking population in the United States. The PedsQL 3.2 DM offers a brief way to examine diabetes-specific HRQOL in youth and provide tailored interventions to improve physical and mental health outcomes.

DEDICATION

To the students I taught at San Juan Diego Catholic High School in Austin, TX. Teaching you (but really learning from you) was the most transformative experience of my life. The majority of you were the first in your families to attend college, and your dedication and perseverance inspired me during these five years of my doctoral studies. I hope this body of work and the long days and hours it took to get this point may be an inspiration to you as you continue to wade through uncharted waters and emerge positively transformed by the journey.

"A quien mucho se le da, también se le pedirá mucho; a quien mucho se le confía, se le exigirá mucho más" –Lucas 12:48

ACKNOWLEDGEMENTS

"Receive, O Lord, all my liberty. Take my memory, my understanding, and my entire will. Whatsoever I have or possess, Thou hast bestowed upon me; I give it all back to Thee and surrender it wholly to be governed by Thy will. Give me love for Thee alone along with Thy grace, and with that, I am rich enough and ask for nothing more." –St. Ignatius of Loyola

Mom, thank you for being a model of faith, a voice of reason, and a wellspring of support. I love you more than I will ever be able to say.

Dad, I pray not a day goes by I do not honor you by honoring the dignity of the human mind and soul, especially when it seems most broken and lost. I am a better clinician and a better person because of you.

Albert, Alex, Nick, and all my friends, thanks for keeping me grounded and reminding me that I have an incredible life, due in large part to you.

Kayce and Mike Jones, you fed me countless meals, gave me a roof over my head during my trips to College Station, and sustained me with a beautiful friendship while I completed this dissertation. You made a time-intensive, demanding journey easier to navigate.

Dr. Rae, you took me on as your advisee on day 1 and gave me the latitude to tackle a demanding course load with advanced practica early on. Thank you for introducing me to Dr. Varni during my first year and for your unwavering confidence in my abilities. I promise to pay it forward in my career.

Dr. Riccio, you have the patience of Job. Who knows how many deadlines I would have missed, research questions I would not have considered, clinical concerns I would not have addressed, and other critical matters I would have overlooked had it not been for you. Your magnificent impact is immeasurable.

Dr. Varni, thank you for taking a chance on me during my first year and for your patience with me as the project ever-so-slowly gathered steam. Saying that your standards are high is an understatement. I hope I met them and maybe even raised them for students who will work with you in the future. Here is to the years of collaboration to come.

Dr. Heffer and Dr. Yoon, thank you for adding your expertise to my committee.

Vince Aguirre, I literally could not have completed this project without your hours of work with the data. Thank you for always bringing your cheerful disposition to our work and for answering my many questions. KTVC.

CONTRIBUTORS AND FUNDING SOURCES

Contributors

This work was supervised by a dissertation committee consisting of Cynthia A. Riccio, Ph.D. (chair), William A. Rae, Ph.D. (co-chair), and Myeongsun Yoon, Ph.D. of the College of Education and Human Development; Robert W. Heffer, Ph.D. of the College of Liberal Arts; and James W. Varni, Ph.D., Professor Emeritus of the College of Architecture.

The data analyzed for Chapter IV were provided by Dr. James W. Varni as part of the PedsQL 3.2 Diabetes Module Field Test Study. Data were collected by clinic staff at Ann and Robert H. Lurie Children's Hospital of Chicago, Chicago, IL; Children's Health Children's Medical Center Dallas, Dallas, TX; Cook Children's Medical Center, Ft Worth, TX; The Madison Clinic for Pediatric Diabetes at UCSF, San Francisco, CA; Mailman Center for Child Development, Miami, FL; Seattle Children's Research Institute, Seattle, WA; Stanford University School of Medicine, Stanford, CA; and University of Cincinnati Hospital Medical Center, Cincinnati, OH. Double-data entry and data reconciliation were completed by Vincent P. Aguirre, M.S., Morgan B. Drake, M.Ed., Marta Lynn Pardo, M.Ed., and the student. All other work conducted for the dissertation was completed by the student independently.

Funding Sources

Graduate study was supported by a fellowship from Texas A&M University and the Doctoral Training in School Psychology/Special Education: Focus on Children who

are English Language Learners (DTELL) grant. There are no outside funding contributions to acknowledge related to the research and compilation of this document.

NOMENCLATURE

QOL	Quality of life
HRQOL	Health-related quality of life
HbA1c	Hemoglobin A1c
PedsQL	The PedsQL: Measurement Model for the Pediatric Quality of Life Inventory
PedsQL 4.0 GCS	PedsQL 4.0 Generic Core Scales
PedsQL 3.0 DM	PedsQL 3.0 Diabetes Module
PedsQL 3.2 DM	PedsQL 3.2 Diabetes Module

TABLE OF CONTENTS

Page

LIST OF TABLES

CHAPTER I

INTRODUCTION

Quality of life (QOL) refers to an individual's perception of life within the numerous systems (e.g., individual, family, school, workplace, community, etc.) in which he or she lives and how that perception relates to his or her belief system, personal fulfillment, and goal attainment. More far-reaching than one's psychosocial adjustment, examining QOL involves taking a comprehensive look at the interaction of multiple factors that may combine to affect one's physical, social, emotional, mental, and spiritual well-being. Improving QOL by making adjustments to one or multiple of the systems in which an individual is involved can promote greater life satisfaction and can have positive carryover effects into other domains that were not initially targeted. A subset of QOL is health-related quality of life (HRQOL) that specifically involves an individual's health status and the impact of the systems in which the individual is involved on his or her health status. Systems that do not impact an individual's health status are not areas of focus in HRQOL. Physical and mental illness can have extensive implications beyond the reach of the symptoms that warrant a diagnosis in the first place, making examining HRQOL important to improving one's overall health status in order to target areas for improvement that may not have been considered in a clinician's initial treatment plan.

One illness that has been the focus of HRQOL research has been diabetes. The Centers for Disease Control and Prevention (CDC, 2014) estimated that approximately 208,000 individuals under the age of 20 had diabetes (either type 1 or type 2) in 2012.

Between 2001 and 2009, there were significant increases in the number of youth with both type 1 and type 2 diabetes across sexes, across ages, and in white, black, and Hispanic youth (Dabelea et al., 2014). Higher HbA1c values, a frequently used biological indicator of blood glucose levels/glycemic control/how well one's diabetes is being controlled, have been shown to be associated with lower levels of HRQOL, in children with type 1 diabetes (Frøisland et al., 2013; Ingerski, Laffel, Drotar, Repaske, & Hood, 2010; Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group [JDRF CGM Study Group], 2010; Kalyva, Malakonaki, Eiser, & Mamoulakis, 2011; Lawrence et al., 2012; Malik & Koot, 2009; Nansel et al., 2008; Naughton et al., 2008; Reid et al., 2013; Tahirović, Toromanović, Tahirović, Begić, & Varni, 2012; van Bussel et al., 2013; Varni et al., 2003; Varni et al., 2013). More specifically, poor levels of glycemic control in children with type 1 and 2 diabetes have been associated with struggles with coping with and managing the disease, depression, and anxiety, all dimensions that attempt to be captured and measured by HRQOL instruments (Hassan, Loar, Anderson, & Heptulla, 2006; Ingerski et al., 2010; Lawrence et al., 2012; Malik & Koot, 2009; Naughton et al., 2008; Varni et al., 2003). Children from ethnic minority backgrounds with type 1 or type 2 diabetes have been found to have significantly poorer rates of glycemic control when compared to their white peers (Petitti et al., 2009). Yet when children and adolescents can effectively manage their diabetes, they can also enjoy HRQOL levels similar to those of their peers without diabetes (Stahl et al., 2012).

As Dabelea et al. (2014) and Petitti et al. (2009) pointed out, diabetes and its ramifications are not limited to a specific ethnic demographic. This is particularly concerning for Hispanic youth. In 2013, nearly 25% of the children in the U.S. were Hispanic and by 2050, that proportion is expected to increase to more than one-third (Federal Interagency Forum on Child and Family Statistics, 2014). While most Hispanic children speak English well, over half of Hispanic children have a parent who does not speak English well (Murphey, Guzman, & Torres, 2014). Diabetes-related HRQOL has been investigated in English-speaking populations and other language groups, but there is a dearth of evidence regarding the reliability and validity of diabetes-specific HRQOL measures in Spanish, despite the risk factors associated with being Hispanic and having diabetes. Combined with the fact that fewer Hispanic children have health insurance than their black and white peers, the health implications grow in significance with the knowledge that Hispanics may not have access to the same level of care as their peers (Murphey et al., 2014). Casagrande and Cowie (2012) found that Hispanics' reduced access to health insurance relative to their counterparts from other ethnic groups also holds true in an adult population with diabetes. And even when children do have insurance, children and adolescents with diabetes on Medicaid/public insurance have been shown to have poorer HRQOL and increases in HbA1c levels (Hood et al., 2014; Jacobsen, Black, Li, Reynolds, & Lawrence, 2014; Naughton et al., 2008). Given the increase in the incidence of both type 1 and type 2 diabetes in youth of all ages and ethnicities, the relation between glycemic control and HRQOL, and the health care disparities among those from ethnic minorities and non-English-speaking backgrounds,

accurately assessing the areas of life affected by diabetes in children of various ethnic and language backgrounds is necessary to improve treatment outcomes in all areas.

The purpose of this study is to field test and thereby verify the reliability and validity of the U.S. English and U.S. Spanish versions of one such HRQOL instrument, the PedsQL 3.2 Diabetes Module (PedsQL 3.2 DM), in children and adolescents ages 2-18 with either type 1 or type 2 diabetes and their caregivers. The updated version of the PedsQL Diabetes Module and current focus of this project, the PedsQL 3.2 DM, is designed to capture aspects related to the HRQOL of individuals with diabetes across a large age range that includes adults and across a large range of time since diagnosis (Varni et al., 2013).

The following research questions will be addressed in this study.

1) Do the self-report and parent proxy-report of the U.S. English version of PedsQL 3.2 DM measure the five domains of diabetes-specific HRQOL in children with diabetes put forth by Varni et al. (2013)? Is the same factor structure present for type 1 and type 2 diabetes within each rater subgroup (self and parent proxy)? Is the same factor structure present for the U.S. English version and U.S. Spanish version within each rater subgroup (self and parent proxy)? Is the same factor structure present for non-Hispanic and Hispanic children within each rater subgroup (self and parent proxy)? It is hypothesized that a five-factor structure will not be supported, regardless of the rater (self or parent proxy), the type of diabetes (type 1 or type 2), the language of the measure (U.S. English or U.S. Spanish), or the ethnicity of

the children (non-Hispanic or Hispanic) and that a one-factor structure will be supported instead. Nansel et al.'s (2008) and Lawrence et al.'s (2012) analyses of the factor structure of the previous version of the PedsQL Diabetes Module support a one-factor structure.

2) Are children's overall ratings of their own diabetes-specific HRQOL in agreement with their caregiver's ratings of their children's HRQOL? Does the strength of this agreement change for children with type 1 or type 2 diabetes? Does the strength of this agreement change between the U.S. English version and the U.S. Spanish version? Does the strength of this agreement change between non-Hispanic and Hispanic children? It is hypothesized that children's overall ratings of their own diabetes-specific HRQOL and their caregivers' ratings of their children's diabetes-specific HRQOL will reflect moderate agreement, according to Landis and Koch's (1977) guidelines. It is hypothesized that the strength of the agreement will not be significantly different regardless of the type of diabetes, the language of the measure, or the ethnicity of the children. Abdul-Rasoul, AlOtaibi, AlMahdi, and AlKandari (2012) found moderate agreement (ICC = .51) when using ICCs to determine the level of agreement between the child and caregiver during the validation of the PedsQL 3.0 Diabetes Module (PedsQL 3.0 DM) in Arabic.

3) Is diabetes-specific HRQOL within each rater subgroup (self and parent proxy) significantly different based on the type of diabetes, the language of

the measure, or the ethnicity of the children? It is hypothesized that children with type 2 diabetes will have lower diabetes-specific HRQOL than children with type 1 diabetes, within each rater subgroup (self and parent proxy), similar to the findings of Naughton et al. (2008) and Varni et al. (2003). It is hypothesized that there will be no significant difference in the HRQOL of children who completed the U.S. English version of the measure and those who completed U.S. Spanish version of the measure, within each rater subgroup (self and parent proxy), as there is no current evidence to suggest otherwise. It is hypothesized that there will be no significant difference in the HRQOL of children who are Hispanic and those who are not Hispanic, within each rater subgroup (self and parent proxy), similar to the findings of Rhodes et al. (2012).

4) Is children's glycemic control, as measured by HbA1c levels, correlated with diabetes-specific HRQOL, as reported by both of the raters? Is the strength of this relation significantly different for children with type 1 vs. type 2 diabetes, within each rater subgroup (self and parent proxy)? Is the strength of this relation significantly different for those who completed the U.S. English version of the measure vs. those who completed the U.S. Spanish version of the measure, within each rater subgroup (self and parent proxy)? Is the strength of this relation significantly different for non-Hispanic children vs. Hispanic children, within each rater subgroup (self and parent proxy)? It is hypothesized that children's glycemic control, as measured by

HbA1c levels, will be significantly inversely correlated with diabetes-specific HRQOL, within each rater subgroup (self and parent proxy), regardless of the type of diabetes, the language of the measure, or the ethnicity of the children. That is to say, children with better glycemic control, as indicated by lower HbA1c levels, will have higher diabetes-specific HRQOL, within each rater subgroup (self and parent proxy), similar to the findings of Frøisland et al. (2013); Ingerski et al. (2010); JDRF CGM Study Group (2010); Kalyva et al. (2011); Lawrence et al. (2012); Malik & Koot, (2009); Nansel et al. (2008); Naughton et al. (2008); Reid et al., 2013; Tahirović et al. (2012); van Bussel et al. (2013); Varni et al. (2003); Varni et al. (2013). It is hypothesized that the strength of these relations will not differ based on the type of diabetes, the language of administration, or the ethnicity of the children, as the current evidence does not suggest otherwise.

Clinical Significance

Measuring and improving HRQOL in adults with chronic illness has been common practice and is becoming increasingly important in the fields of pediatrics and pediatric psychology (Varni, Burwinkle, & Lane, 2005). Although children and adolescents with diabetes fare much better physically than they did 50 years ago, the burden of care for children and families with regard to managing the disease has remained the same and increased in some instances (Fairchild, 2015). An illness such as diabetes has the potential to shape or alter a child's perception of his or her life by not only affecting the child's physical health but by also affecting other aspects of the

child's life such as psychological health, relationships, self-worth, and the ability to participate in activities that had been a normal part of that child's life. Being able to capture how HRQOL is affected in the presence of an illness allows psychologists and physicians to better understand the ramifications of that illness. Interventions can be implemented that not only treat the presenting illness but that also work to improve other aspects of life affected by the illness in a more cost-effective, tailored, and efficacious manner.

CHAPTER II

LITERATURE REVIEW

Health-related Quality of Life

Broadly speaking, QOL refers to "an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns" (World Health Organization, 1993, p. 2). HRQOL has been defined as dimensions of quality of life specifically related to an individual's health status, such as psychological adjustment and functional status, exclusive of the impact of the other systems in which the individual may be involved (Ferrans, Zerwic, Wilbur, & Larson, 2005; Wilson & Cleary, 1995). In a recent review of the literature involving the measurement of HRQOL, Bakas et al. (2012) found the three most referenced HRQOL theoretical models were those of Wilson and Cleary (1995), Ferrans et al. (2005), and the World Health Organization (2007).

Although these three models were most consistently used, in reviewing the literature related to HRQOL, Bakas et al. noted that there were a variety of similarly defined terms used when speaking about HRQOL, making comparisons of the concept of HRQOL across studies difficult. Bakas et al. also added that researchers may be defaulting to these three models simply because a better alternative does not currently exist. With that being said, Bakas et al. recommended that researchers and clinicians use Ferrans et al.'s (2005) model when measuring HRQOL and that disease-specific measures of HRQOL could be developed within this framework.

World Health Organization's 1993 recommendations

Prior to the development of its most recent QOL model, the World Health Organization (WHO) met in 1993 to determine how QOL should be assessed in children. The term HRQOL was not specifically discussed, but the proceedings of the meeting reflected the theme of physical wellness, the lack thereof, and the roles they play in one's QOL. The WHO did not develop a specific QOL measure as a result of this meeting but rather explored the various components that could be incorporated in a QOL measure. The WHO first decided that a QOL measure should be able to assess QOL in both healthy and sick children and should have a child-centered emphasis. The WHO went on to say that a person's QOL can be impacted by numerous interacting factors, from one's physical health to one's social standing to one's relationships, and that a QOL measurement tool "should explore a broad range of issues relating to a person's personal and social life and should concentrate on how these person's feel about themselves and their position in life" (p. 2).

At the time, the WHO organization voiced concerns that a child's self-report of his or her quality of life may be invalid and thus advocated for a caregiver proxy report in addition to the child self-report. The WHO added that a caregiver proxy report would also be helpful for those children who were too young to report on their QOL or who had cognitive deficits that prevented them from accurately reporting their QOL. They also noted that QOL may vary as children age, making age-specific measurements necessary. The WHO supported QOL measurements that could be used across cultures, that had "generic core and specific modules" (p. 3), and that took a strengths-based approach to

health rather than a deficits-based approach that only focused on the problems associated with one's health. Some of the domains that the WHO thought could be assessed by a QOL measure included "family/social relations, physical function, psychological (internal), physical appearance, psychosocial relations to social and material environment, and environment" (p. 4). As seen in these suggested domains, the WHO's conceptualization of QOL was broader in its scope and tapped into more areas beyond those immediately associated with an individual's health status. Notwithstanding the breadth, many of the suggestions regarding how QOL should be assessed have been incorporated into the battery of measures that are the subject of the present study.

Wilson and Cleary's model

Rather than simply describing areas related to HRQOL, Wilson and Cleary (1995) sought to define a causal, more linear relation between these areas. Though they did acknowledge that the relation among the areas they defined is not always linear, they still attempted to conceptualize HRQOL as the result of a series of causal relations, moving from the micro level of the cell to the macro level, and involving the interaction between the individual and various systems. Biological and physiological factors impact HRQOL at the most basic level in Wilson and Cleary's model. Changes in these areas are frequently measured (e.g., blood pressure, cholesterol, lung functioning, etc.) as assessments of one's health status and affect HRQOL at the most basic level within an individual - the cell level.

Biological and physiological factors are then related to the manifestation or lack thereof of symptoms in an individual, the next domain in Wilson and Cleary's model.

Wilson and Cleary define a symptom as the "perception of an abnormal physical, emotional, or cognitive state" (p. 61). Symptoms of an illness affect an individual's HRQOL beyond the cell level and more at the level of the individual as a whole. Although Wilson and Cleary try to establish a causal link between the levels of their model, they acknowledge that research is inconsistent regarding the relation between biological and physiological factors and the reporting of physical and/or psychological symptoms. At this level of their model, Wilson and Cleary also note that environmental variables and nonphysical components of the individual also impact the reporting of symptoms, their relation to the presence of biological and physiological factors, and their impact on HRQOL.

Functional status, an individual's ability to complete certain tasks, follows symptom status in Wilson and Cleary's model. An individual's symptom status is thought to cause changes in an individual's functional status, such that with increasing symptomatology, an individual's functional status would decrease, given no additional supports within that person's environment and no additional motivation within the individual. Wilson and Cleary note this direct relation between symptom status and functional status may be mitigated if a person is motivated to continue to function as normal and/or has other people and/or community resources to help maintain normal levels of functioning. Changes in functional status affect the individual beyond the person-level and more on the level of the individual's ability to live up to his/her potential within the environment. Wilson and Cleary theorize that symptom status would mediate the relation between the biological and physiological factors and

functional status. In turn, measuring changes in biological and physiological variables, symptomatology, and functional status are key to understanding an individual's overall HRQOL, as they are distinct but related aspects of HRQOL that can all impact an individual's health status.

General health perceptions follow functional status in Wilson and Cleary's model. General health perceptions represent the combination of biological and physiological factors, symptom status, and functional status in addition to mental health status. Unlike the previous three levels within the model, general health perceptions are measured subjectively. Wilson and Cleary add that psychological and social supports within an individual's environment in addition to the individual's value system will also impact an individual's general health perceptions but not directly as with the three previous levels of the model. The final level of Wilson and Cleary's model is overall quality of life. The definition of overall quality of life within their model closely resembles the definition provided by the WHO in 1993 and recognizes the impact of other non-health-related factors.

Overall, Wilson and Cleary believe that HRQOL must be understood as the causal relation among the five aforementioned variables. Understanding how each level of their model directly affects the subsequent levels will help clinicians involved in various aspects of individuals' healthcare better tailor interventions at one or multiple levels of the model to improve HRQOL. Consequently, assessments of HRQOL should strive to measure all five of the areas described and the magnitude of their effect on an individual's overall HRQOL.

Ferrans, Zerwic, Wilbur, and Larson's model

One of the criticisms of Wilson and Cleary's (1995) model was that the individual and environmental factors that potentially affect the impact of the five variables within their linear model were poorly defined. Ferrans et al. (2005) preserved the five areas defined by Wilson and Cleary and also cited examples of what measures have been used to assess each of the five domains. Although Wilson and Cleary posited that individual and environmental factors did not influence the first level of the model, the biological/physiological variables, Ferrans et al. modified Wilson and Cleary's model to suggest that individual and environmental factors impact all five levels associated with HRQOL. With this addition, they also eliminated the unique effect of non-health related factors on overall quality of life in Wilson and Cleary's model. By clarifying the influence of the individual and environmental factors on the five dimensions of the model, Ferrans et al. felt this component was superfluous.

Ferrans et al. defined individual factors as those "demographic, developmental, psychological, and biological factors that influence health outcomes" (p. 337). Demographic factors include an individual's sex, age, and ethnicity, for instance, that may put that individual at higher risk for certain illnesses. Developmental factors capture an individual's behaviors characteristic of a certain stage of development or developmental status. For example, adolescents engage in risky behaviors, elevating their chances of acquiring certain illnesses. Psychological factors include an individual's motivation, emotional response patterns, and the individual's beliefs and attitudes toward illness. An example of biological factors includes family history of

certain illnesses. Environmental factors with the Ferrans et al. are comprised of social and physical factors. Social factors include the interpersonal interactions with groups like family and friends that affect an individual's health status. Physical factors include aspects of settings like the home, the neighborhood, and the work environment that can affect an individual's health status.

World Health Organization's 2007 model

In 2007, the WHO published the *World Health Organization International Classification of Functioning, Disability, and Health (WHO ICF)* as an update to their previous health status models (as cited in Bakas et al., 2012). Although the WHO ICF is divided into two parts, the first part dealing with disabilities and related functioning and the second part dealing with broader contextual factors that can impact health, it is a model that can be applied beyond HRQOL. The WHO ICF can also be used to describe health not only at the individual level, but also at the societal and cultural level. In contrast, the models proposed by Wilson and Cleary (1995) and Ferrans et al. (2005) have greater utility describing HRQOL at the individual level.

Health-related quality of life in children

Until recently, assessing HRQOL has been an effective practice mostly used in adult populations. But like adults, children also experience effects of illness beyond the physical symptoms for which they are being treated. Thus, HRQOL research is an area of great import and interest in the child and adolescent population in order to influence legislation at the policy level, structure treatment guidelines for a specific illness, and improve individual child outcomes (Matza, Swensen, Flood, Secnik, & Leidy, 2004).

Nearly half of physicians who received results of a patient's HRQOL inventory used the results to change therapy and almost all of the physicians who used the inventories found them helpful and precise (Rubenstein et al., 1989). HRQOL measures also represent a shorter alternative to longer measures of a patient's functioning that can be more quickly completed in the context of a physician's office, while offering additional insight into how a patient's functioning is directly related to his or her illness (Nelson, Landgraf, Hays, Wasson, & Kirk, 1990). In adults, measuring HRQOL has been shown to facilitate communication between the physician and patient and allow topics related to the patient's illness to be discussed that otherwise would not have been introduced by the physician (Varni et al., 2005). Varni, Burwinkle, and Lane (2005) have argued that using HRQOL measures in pediatric practice can help children and parents communicate their areas of need related to multiple aspects of life affected by the child's illness. Similar to what has been shown in HRQOL research with adults, assessing for HRQOL in children can help discover comorbid psychological and functional difficulties. This extensive and comprehensive reach of clinical assessment and care is a distinctive feature and advantage of measuring HRQOL as opposed to only capturing physiological indicators of disease status and changing treatment accordingly (Varni et al., 2005).

Measuring health-related quality of life in children

When assessing HRQOL in children, it is important that the measures are short, valid, and reliable; easy-to-use and easy-to-score; and able to capture significant changes in child outcomes (Varni et al., 2005). Matza et al. (2004) added that HRQOL measures for children and adolescents should be able to capture their levels of functioning in the

various systems in which they operate (e.g., family, school, peer, etc.). In line with the WHO's (1993) recommendations, Matza et al. (2004) and Varni et al. (2005) advocate for the use of a general, non-disease-specific HRQOL measure used in conjunction with a disease-specific module. The general HRQOL measure allows for HRQOL comparisons between healthy and sick children in addition to comparisons among children and adolescents with different illnesses. The disease-specific measure offers information about how aspects of the specific illness in question affects the child and may better capture clinical changes specific to that illness. Both Matza et al. (2004) and Varni et al. (2005) conclude that the research is mixed regarding the accuracy of a self-report of HRQOL as opposed to a parent proxy-report of HRQOL, suggesting that capturing both when possible may be the most comprehensive choice when determining treatment conceptualization and changes.

Using the existing theoretical models and recommendations for how HRQOL should be measured in children, a variety of measures have been developed that have been shown to measure varying aspects of HRQOL. Kenzik, Tuli, Revicki, Shenkman, and Huang (2014) compared the non- disease-specific parent-proxy versions of the CHIP (Starfield et al., 1995), the KIDSCREEN-52 (Ravens-Sieberer et al., 2005), the KINDL (Ravens-Sieberer & Bullinger, 1998), and the PedsQL (Varni, Seid, & Rode, 1999). The PedsQL was the shortest and the KIDSCREEN-52 was the longest. The KINDL and CHIP included questions outside of the domains of physical, emotional, social, and school functioning, related to financial stability, levels of independence and self-sufficiency, including levels of resiliency, and avoidance behaviors. After administering

all of the measures to nearly 900 caregivers over the phone, Kenzik et al. found that the KIDSCREEN-52 had the best structural validity (e.g., the stated domains measured what they purported to measure) and the PedsQL had the worst structural validity. Despite this finding, Kenzik et al. used the PedsQL as its standard of comparison when determining which measures had the best convergent validity. The KIDSCREEN-52 was shown to have the best convergent validity, followed by the KINDL and the CHIP. Finally, the PedsQL was found to do the best job detecting differences in levels of HRQOL between healthy children and sick children. Kenzik et al. acknowledged that their comparisons only involved the parent-proxy versions of the scales and that administering the measures in the same order for each participant may have affected their findings. Overall, Kenzik et al. echoed findings by de Wit, Delemarre-van de Waal, Pouwer, Gemke, and Snoek (2007) that various HRQOL measures have their own merits, with no measure rising above the rest, suggesting that clinicians should choose a HRQOL measure based on the needs and characteristics of their specific patient populations while still striving on an international level to standardize the terminology used when describing HRQOL.

Diabetes

One illness that has shown not only to have a physical effect on those living with it, but also psychological, functional, and HRQOL effects is diabetes. Diabetes is a disease marked by above-normal levels of glucose in the body where the body either does not produce insulin properly or does not use insulin properly to break down and absorb the glucose consumed (CDC, 2015). When glucose enters the body, it attaches

itself to hemoglobin, a protein in red blood cells that aids in the transport of oxygen throughout the body. With more glucose in the blood, glucose attaches to hemoglobin at higher rates, resulting in higher blood glucose/ blood sugar levels (American Diabetes Association, 2014). The A1C test, also referred to as the hemoglobin A1c, HbA1c, or glycohemoglobin test is the standard measure used to determine how well an individual is managing his or her diabetes (U.S. Department of Health and Human Services, 2014). In essence, HbA1c levels represent the average blood glucose levels in the body from the previous 3 months. When HbA1c levels are high, an individual is said to have poorer control of his or her diabetes or poorer glycemic control. Currently, individuals with HbA1c levels below 5.7% are said not to have diabetes; individuals with HbA1c levels between 5.7 and 6.4% are said to have prediabetes and are at risk of developing type 2 diabetes; and individuals with HbA1c levels of 6.5% and higher are said to have diabetes (U.S. Department of Health and Human Services, 2014).

Type 1 diabetes occurs when the cells responsible for producing insulin in the pancreas are destroyed, thus making it necessary for individuals with type 1 diabetes to take insulin to appropriately control their glucose levels. Approximately five percent of those with diabetes have type 1 diabetes. Ninety to ninety-five percent of people with diabetes have type 2 diabetes. Type 2 diabetes is primarily characterized by other bodily systems like muscles, fat tissue, and the liver not incorporating insulin properly. Because of the resistance that develops, the cells in the pancreas that produce insulin often begin not to work properly (CDC, 2014). Type 2 diabetes often can be treated with improved diet, exercise, and monitoring of glucose, but type 1 diabetes requires

life-long insulin intake (CDC, 2015). Physical complications associated with both types of diabetes include loss of vision, kidney failure, amputation, heart disease, high blood pressure, high cholesterol, and stroke. Additionally, in 2010, diabetes was the seventh most common cause of death in the U.S., though this may be an underestimation. Diabetes was listed anywhere on the death certificate for only 35 to 40% of those with diabetes who died and was listed as the primary cause of death for only 10 to 15% of those with diabetes who died, suggesting possible instances of underreporting of cause of death and of having a diagnosis of diabetes (CDC, 2014)

Diabetes in children

Type 1 diabetes is most often diagnosed in children (CDC, 2014). Notwithstanding the higher incidence of type 1 diabetes in children as opposed to type 2 diabetes, between 2001 and 2009, there was a 21% increase in children with type 1 diabetes and a 30% increase in children with type 2 diabetes. It is unclear if identification of children with diabetes has improved, resulting in the aforementioned increases, or if the incidence of diabetes has increased (Wooton & Melchior, 2017). These increases were significant across sexes, across ages, and among whites, blacks, and Hispanics (Dabelea et al., 2014). Based on estimates from 2009, of the youth under the age of 20 with type 1 diabetes, 71.50% were non-Hispanic white, 14.32% were Hispanic, 12.51% were non-Hispanic black, 1.49% were Asian/Pacific Islander, and 0.18% were American Indian/Alaskan Native (Pettitt et al., 2014). Within the period between 2008 and 2009, more children from minority backgrounds between the ages of 10-19 were diagnosed with type 2 diabetes than their white counterparts (CDC, 2014).

Based on estimates from 2009, of the youth under the age of 20 with type 2 diabetes, 36.65% were Hispanic, 35.30% were non-Hispanic black, 21.54% were non-Hispanic white, 3.84% were Asian/Pacific Islander, and 2.67% were American Indian/Alaskan Native (Pettitt et al., 2014).

Ethnic differences in outcomes among children with type 1 diabetes remained even after controlling for socioeconomic status. Willi et al. (2015) found that white children were more likely to use an insulin pump than their black and Hispanic counterparts and that black children were more likely to have higher HbA1c levels, more incidences of diabetic ketoacidosis, and more instances of severe hypoglycemia than their white and Hispanic counterparts. White and Hispanic youth in the sample did not differ with regard to HbA1c levels, severe hyperglycemia, or incidences of diabetic ketoacidosis, when controlling for socioeconomic status (Willi et al., 2015).

Not only are physical complications present in adults with diabetes, but they are also present in youth with diabetes. Kidney disease, retinopathy, and peripheral neuropathy were frequently present in youth diagnosed with both type 1 and type 2 diabetes but were significantly greater in youth with type 2 diabetes, even after accounting for difference in HbA1c levels, body mass indexes (BMIs), and mean arterial blood pressures (Dabelea et al., 2017). Being overweight or obese is common among youth with type 2 diabetes (80-90%), regardless of ethnicity, and also occurs in 35-50% of the youth with type 1 diabetes, regardless of ethnicity. While not all children who are obese have type 1 or type 2 diabetes, elevated BMIs and obesity in children and adolescents have been found to predict the development of type 2 diabetes and coronary

heart disease (Prendergast & Gidding, 2014; Tirosh et al., 2011). Obesity in and of itself, however, is not the only reason children develop type 2 diabetes (Wooton & Melchior, 2017). Onge, Miller, Motycka, & DeBerry (2015) found that, in some obese children, the pancreas releases insulin at a slower rate. In others, a different mechanism is at play:

> Target fat cells in the abdomen secrete chemicals that result in an inflammatory response. This inflammatory response contributes to increased fat in the liver, which is a risk factor for insulin resistance. This is a major precursor to the development of [type 2 diabetes] and [cardiovascular disease]. (as cited in Wooton & Melchior, 2017, p. 223)

Risk factors for cardiovascular disease such as high blood pressure, dyslipidemia, "elevated apolipoprotein B (apoB) levels, and small, dense LDL particles" are also prevalent in youth with diabetes (Hamman et al., 2014, p. 3338). Risk factors for developing type 2 diabetes in youth that cut across ethnicities include being female (1.5 times more likely to develop type 2 diabetes) and having a first-degree relative with type 2 diabetes (more than half of youth with type 2 diabetes have a first-degree relative with type 2 diabetes) (Prendergast & Gidding, 2014).

In addition to the physical complications associated with diabetes, children with diabetes are also at risk for cognitive and psychological complications. Schwartz, Wasserman, Powell, and Axelrad (2014) reviewed previous research regarding the cognitive effects associated with type 1 diabetes in children and found that poor glycemic control has been associated with deficits in information processing and

lowered cognitive ability. Psychologically, children and adolescents with diabetes are more likely to be depressed than peers without diabetes (Grey, Whittemore, & Tamborlane, 2002; Reynolds & Helgeson, 2011). Adolescents with type 1 diabetes with poorer glycemic control also have been shown to have higher levels of depression and anxiety (Hassan et al., 2006; Herzer & Hood, 2010).

Recognizing the psychological needs of children with diabetes, the International Society for Pediatric and Adolescent Diabetes (ISPAD) recommended that these children be served by a multidisciplinary team that includes a mental health professional to address psychological and behavioral health needs via regular assessment and intervention (de Wit, Pulgaron, Pattino-Fernandez, & Delamater, 2014). Despite this recommendation, de Wit, Pulgaron, Pattino-Fernandez, and Delamater (2014) found that a mental health professional is a part of the interdisciplinary team charged with caring for children with diabetes in only about 50% of the 155 clinics across the world that were sampled. Although this finding does not necessarily suggest that the psychological needs of children with diabetes are not being met, the lack of a mental health professional directly involved in the care of children with diabetes can limit the psychological supports available to these children and families.

Highlighting the added value of psychological services for children with diabetes, findings by Bitsko et al. (2013) demonstrate that psychological interventions are associated with improved glycemic control. Adolescents with type 1 diabetes referred for and who engaged in psychotherapy showed improved HbA1c levels after a year when compared to those referred for and who did not engage in psychotherapy.

After a year, the treatment group who engaged in psychotherapy showed comparable HbA1c levels to those in the control group who were not referred for psychotherapy. While both the group of adolescents who were referred for but did not engage in psychotherapy and the group of adolescents who were not referred for psychotherapy showed increases in their HbA1c levels over the year, the referred but not-treated group showed a significantly higher increase in their HbA1c levels than the control group. These results support the International Society for Pediatric and Adolescent Diabetes (ISPAD) recommendations (de Wit et al., 2014) and suggest that, unchecked, psychological distress in children with diabetes can result in poorer glycemic control, which has been documented to have been associated with a host of other complications.

Diabetes in Hispanics

According to the 2010 U.S. Census, 16.6% of the U.S. population (50.5 million people) identified as Hispanic or Latino, as defined as "a person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin regardless of race" (Ennis, Ríos-Vargas, & Albert, 2011, p. 2). Almost 13% of Hispanics over the age of 20 had diabetes between 2010 and 2012 as compared to the almost 8% of non-Hispanic whites (CDC, 2014). Other estimates suggest that the percentage of Hispanic adults with diabetes is closer to 17% (Schneiderman et al., 2014). Schneiderman et al. (2014) found that there was disparity, however, in the prevalence of diabetes among the various Hispanic ethnic groups in the U.S. Just over 10% of South American adults were estimated to have diabetes while just over 18% of Mexican adults were estimated to have diabetes. Regardless of ethnic group within the Hispanic population, having

diabetes was significantly related to older age, lower income, fewer years of education, and more years living in the U.S. Schneiderman et al. also found that only roughly 50% of Hispanic adults with diabetes were adequately educated about their diabetes and demonstrated sufficient glycemic control.

When the focus narrows to the percentage of children who are Hispanic in the U.S., the numbers increase. Not only has the number of Hispanic youth in the U.S. grown, but the number of Hispanic youth in the U.S. with both type 1 and type 2 diabetes has also increased. Youth with diabetes from traditional minority ethnic groups, including Hispanics, have been shown to have significantly higher rates of the presence of risk factors for cardiovascular disease (e.g., high blood pressure, high cholesterol) than their white peers (Rodriguez et al., 2006). Youth with type 1 diabetes from ethnic minority groups were found to be at higher risk for the aforementioned complications of high blood pressure, dyslipidemia, "elevated apolipoprotein B (apoB) levels, and small, dense LDL particles" (Hamman et al., 2014, p. 3338). Rosenbaum et al. (2013) found that, after controlling for the amount of body fat, Hispanic middle-schoolers had higher levels of total cholesterol, one of the known risk factors for type 2 diabetes, compared to peers from other ethnic groups. Obesity, another known risk factor for type 2 diabetes, is also higher in Hispanic youth (21.2%) than in non-Hispanic white youth (14.0%) (Ogden, Carroll, Kit, & Flegal, 2012).

Not only have Hispanic youth have been shown to have significantly more risk factors for type 2 diabetes than their non-Hispanic peers, some findings also suggest that Hispanic youth exhibit poorer glycemic control than their non-Hispanic counterparts. In

a balanced sample of children and adolescents from a private diabetes clinic, Gallegos-Macias, Macias, Kaufman, Skipper, and Kalishman (2003) found that the Hispanics had poorer glycemic control than the non-Hispanics. Petitti et al. (2009) replicated these findings in a much larger nationwide sample when they found that children and adolescents from various ethnic minority groups had significantly poorer glycemic control than their white counterparts, regardless of type of diabetes. In addition to demonstrating poorer glycemic control, Hispanic youth have been found to have higher levels of diabetes-related conflict with their mothers and lower levels of parental acceptance of their diabetes than their Caucasian peers (Main et al., 2014).

Jacobsen, Black, Li, Reynolds, and Lawrence (2014) also investigated the relation between glycemic control and race/ethnicity among children and adolescents with type 1 and type 2 diabetes. Jacobsen et al. found that non-Hispanic white children and adolescents with type 1 diabetes were significantly more likely to have seen an endocrinologist for their diabetes care; non-Hispanic white children and adolescents with type 1 or type 2 diabetes also lived in significantly more affluent neighborhoods than their Hispanic and black peers with type 1 or type 2 diabetes. Additionally, results suggest that Hispanic children and adolescents with type 1 diabetes were over one-and-a-half times more likely to have poor glycemic control at a one-year follow-up when compared to their non-Hispanic white peers. When it came to type 2 diabetes, black children and adolescents were significantly more likely to have poor glycemic control at a one-year follow-up when compared to their non-Hispanic white and Hispanic peers. Given the growth in the number of youth across all ethnic groups with diabetes and the

myriad of physical, cognitive, and psychological effects associated with having diabetes, examining HRQOL in children and adolescents with diabetes merits further investigation to tailor clinical care and improve treatment outcomes in all of these and other areas.

Health-related Quality of Life in Children with Diabetes

In addition to the research that has been conducted regarding the physical, cognitive, and psychological effects in children with diabetes, a substantial body of research exists regarding the broader concept of HRQOL in children with diabetes from various nationalities. The relation between higher levels of HbA1c and thus, poorer glycemic control, and poorer HRQOL in children and adolescents with type 1 diabetes has been well documented (Frøisland et al., 2013; Ingerski et al., 2010; JDRF CGM Study Group, 2010; Kalyva et al., 2011; Lawrence et al., 2012; Malik & Koot, 2009; Nansel et al., 2008; Naughton et al., 2008; Reid et al., 2013; Tahirović et al., 2012; van Bussel et al., 2013; Varni et al., 2003; Varni et al., 2013). In addition to this finding, children with diabetes and their families have been shown to have reduced functioning in many of the domains that contribute to one's HRQOL. As expected, Malik and Koot (2009) found that poorer glycemic control as indicated by higher HbA1c levels was significantly related to poorer HRQOL in a sample of adolescents from the Netherlands with type 1 diabetes. Yet even after accounting for protective factors such as social support and positive levels of self-worth, stress related to having diabetes completely mediated the relation between HbA1c levels and HRQOL. These findings support the

idea that factors in addition to the biological and physiological ones contribute to children's HRQOL, particularly those with diabetes.

Frøisland et al. (2013) replicated Malik and Koot's (2009) findings, showing that higher HbA1c levels were associated with poorer HRQOL in children and adolescents with type 1 diabetes from Norway. Frøisland et al. also found that females and those who had diabetic ketoacidosis also demonstrated poorer HRQOL. Of note is that Frøisland et al. found that there were no differences in HRQOL in those children who received their insulin via an insulin pump when compared to those children who received insulin via injections, suggesting that the method of insulin delivery may not contribute to differences in HRQOL in children with diabetes.

HbA1c levels are not the only biological indicators of diabetes health status significantly associated with HRQOL in children and adolescents with diabetes. Using a sample of children and adolescents from diabetes summer camps in Hungary, Lukács, Varga, Kiss-Tóth, Soós, and Barkai (2014) looked at the relation between cardiorespiratory fitness levels and HRQOL and diabetes management in children and adolescents with type 1 diabetes. Lukács et al. found that children and adolescents with higher oxygen uptake, a sign of better cardiorespiratory fitness, had significantly better HRQOL and better glycemic control as evidenced by lower HbA1c levels. These results suggest that biological indicators other than HbA1c levels may be used to possibly predict HRQOL in children and adolescents with diabetes and that improvements in cardiorespiratory fitness may improve HRQOL in children and adolescents with diabetes, although more research in this area is needed to confirm these hypotheses.

Not only does diabetes-stress affect the child with diabetes, but it can also have an effect on the child's family. When comparing the families of children with and without type 1 diabetes in Portugal, Moreira, Frontini, Bullinger, and Canavarro (2014) found that children from less cohesive, more distressed families were found to have lower levels of HRQOL. Parents of children with type 1 diabetes reported feeling significantly more stressed and anxious regarding their role as parents than the parents of children without diabetes. Results also suggest that children with parents who fear their children will become hypoglycemic often end up with higher HbA1c levels, indicative of poorer glycemic control, and lower parent-reported levels of HRQOL (Johnson, Cooper, Davis, & Jones, 2013; as cited in Shepard, Vajda, Nyer, Clarke, & Gonder-Frederick, 2014). These findings lend credence to the previously described models suggesting that HRQOL can be affected by environmental variables like the systems in which in a child lives.

Van Bussel et al.'s (2013) findings from another sample of children with type 1 diabetes from the Netherlands also support the relation between HbA1c and HRQOL. Results also indicated that children with type 1 diabetes with lower HRQOL in the psychosocial domain demonstrated significantly more negative coping mechanisms when confronted with stress, such as trying to ignore the presence of diabetes, expressing negative emotional reactions toward having a diabetes, and wishing that they did not have the disease . Conversely, van Bussel et al. also found that those children in the sample with type 1 diabetes who accepted their health-status and the accompanying stress had significantly higher HRQOL. Results also suggest that children who fear

becoming hypoglycemic report lower levels of HRQOL and experience higher HbA1c levels, indicative of poorer glycemic control (Johnson et al., 2013). Combined with Malik and Koot's (2009) work, van Bussel et al.'s and Johnson et al.'s findings demonstrate the importance of assessing for HRQOL in children with diabetes, revealing the potential for targeted psychosocial interventions for children with diabetes struggling in that domain.

Although most of the HRQOL research in children with diabetes has been conducted with children with type 1 diabetes, some investigators have explored HRQOL in children and adolescents with type 2 diabetes. Initial findings suggest children with type 2 diabetes have poorer HRQOL than their peers without diabetes and their peers with type 1 diabetes but that poorer glycemic control has not been associated with poorer HRQOL in children with type 2 diabetes (Naughton et al., 2008; Varni et al., 2003). Rhodes et al. (2012) investigated HRQOL in adolescents with type 2 diabetes, prediabetes, and insulin resistance. Results indicated that there were no difference in HRQOL based on diagnosis and that adolescents endorsed lower overall levels of HRQOL compared to their guardians. The guardians characterized their children's physical functioning as significantly worse than their children did, and children and guardians rated their psychological functioning equally. Greater body mass index and higher levels of family conflict were significantly associated with poorer self-reported quality of life. When controlling for body mass index, Rhodes et al. found that black adolescents reported significantly lower levels of HRQOL than their white, Hispanic, and other ethnic counterparts. These findings help to substantiate those findings of Willi

et al. (2015) that suggest that black children with type 1 have poorer disease management than their non-black peers. Rhodes et al. also found that Hispanic parents perceived a significantly higher level of burden of care related to managing their children's diabetes compared to their non-Hispanic counterparts, despite their findings that suggested that Hispanic adolescents do not have significantly poorer HRQOL or disease management than their non-Hispanic peers.

Hood et al. (2014) also examined HRQOL and depression in a sample of adolescents with type 1 and type 2 diabetes at multiple time points over a period of five years. Glycemic control decreased for both those with type 1 and those with type 2 diabetes across the five years. At baseline and across the five years at the 1-year, 2-year, and 5-year time points, adolescents with type 2 diabetes had significantly more depressive symptoms and poorer diabetes-related HRQOL than their peers with type 1 diabetes. Results suggest that for those with type 1 diabetes, being younger, having had diabetes for longer, being black, and decreasing diabetes-related HRQOL over time predicted poor glycemic control at the 5-year time point. For those with type 2 diabetes, having had diabetes longer, being black or Hispanic, decreasing diabetes-related HRQOL over time, and increasing overall, non-diabetes-specific HRQOL predicted poor glycemic control at the 5-year time point. In a sample of Chinese youth with type 1 diabetes, Guo et al. (2015) found that elevations in depressive symptoms were associated with poorer HRQOL.

The PedsQL: Measurement Model for the Pediatric Quality of Life Inventory

As seen, accurately and reliably measuring HRQOL in children with diabetes can reveal significant areas of need and have the potential to alter the course of a child's treatment to promote the best outcomes. One of the most common system of measurements used to measure HRQOL is The PedsQL: Measurement Model for the Pediatric Quality of Life Inventory (PedsQL) (Varni, Seid, & Rode, 1999). The PedsQL measurements can be used to assess HRQOL in healthy children, adolescents, and young adults and those with acute and chronic illness. In line with the WHO's (1993, 2007) recommendations and Wilson and Cleary's (1995) and Ferrans et al. (2005) HRQOL models, the PedsQL assessments consist of age-appropriate generic core scales and age-appropriate disease-specific modules, with self-reports and parent proxy-reports for both.

PedsQL 4.0 Generic Core Scales

The PedsQL 4.0 Generic Core Scales (PedsQL 4.0 GCS) (Varni, Seid, & Kurtin, 2001) is the most recent version of the generic core scales in the PedsQL system of measurements. It is a 23-item non disease-specific assessment that measures HRQOL in the areas of physical functioning (8 items), emotional functioning (5 items), school functioning (5 items), and social functioning (5 items). The PedsQL 4.0 GCS yields six scores: a scale score that reflects responses on all items; a physical health summary score that reflects responses on the items related to physical functioning; a psychosocial health summary score that reflects responses on the items related to emotional, school, and social functioning; an emotional functioning score that reflects responses on the items related to emotional functioning; a school functioning score that reflects responses on

the items related to school functioning; and a social functioning score that reflects responses on the items relation to social functioning. In the original analysis by Varni et al. (2001), the items related to school functioning loaded onto two different factors: one related to cognitive functioning at school (school) and one related to absences due to illness (miss school) (Newman, Limbers, & Varni, 2010). The scale scores ($\alpha = 0.88$, $\alpha = 0.90$), physical health summary scores ($\alpha = 0.80$, $\alpha = 0.88$), psychosocial health summary scores ($\alpha = 0.83$, $\alpha = 0.86$), emotional functioning scores ($\alpha = 0.73$, $\alpha = 0.77$), school functioning scores ($\alpha = 0.68$, $\alpha = 0.76$), and social functioning scores ($\alpha = 0.71$, $\alpha = 0.75$) for the self-report and parent-proxy report, respectively, mostly reflected acceptable levels of internal consistency, following Nunnally and Bernstein's (1994) recommendation that scales should have Cronbach alpha values ≥ 0.70 to be deemed internally consistent and to be used for group comparison (Varni et al., 2001). While the scores in these areas were determined to be internally consistent for use with group comparisons, the scale score was found to be the most useful outcome score to be used on the individual-level, given the alpha values near 0.90 (Nunnally & Bernstein, 1994).

Children as young as 5 years old have also been found to reliably report their HRQOL using the PedsQL 4.0 GCS (scale score $\alpha = 0.86$, physical health summary score $\alpha = 0.72$, and psychosocial health summary score $\alpha = 0.82$) (Varni, Limbers, & Burwinkle, 2007a). Varni, Seid, and Kurtin (2001) and Varni, Limbers, and Burwinkle (2007a) also found the measure to discriminate between healthy and ill children. In various factor analyses conducted with the PedsQL 4.0 GCS, a five-factor model (physical, emotional, social, school, and miss school) has been supported in the parent-

proxy report and in the self-report across health condition groups, age groups, gender, socioeconomic status groups, language groups (English and Spanish), and mode of administration (in-person, mail, or telephone survey) (Limbers, Newman, & Varni, 2008a, 2008b, 2008c; Newman et al., 2010; Varni, Limbers, & Newman, 2008; Varni, Limbers, & Newman, 2009; Varni et al., 2001). The PedsQL 4.0 GCS have also been found to have acceptable rates of reliability and validity when administered electronically via the Internet (Varni, Limbers, Burwinkle, Bryant, & Wilson, 2008). Low to good agreement has been found between children's ratings of their HRQOL and their caregivers' ratings of their children's HRQOL as measured by intraclass correlation coefficients (ICCs) with the total scores on the PedsQL 4.0 GCS in samples of children with a variety of illnesses (Buck, Clarke, Powell, Tiffin, & Drewett, 2012; Cremeens, Eiser, & Blades, 2006; Hartman et al., 2014; Kunz, Hommel, & Greenley, 2010; Varni, Limbers, & Burwinkle, 2007a).

In a sample with type 1 diabetes, Varni et al. (2003) again found respective self-reported and parent-proxy reported scale scores ($\alpha = 0.88$, $\alpha = 0.89$), physical health summary scores ($\alpha = 0.76$, $\alpha = 0.82$), psychosocial health summary scores ($\alpha = 0.84$, $\alpha = 0.85$), emotional functioning scores ($\alpha = 0.73$, $\alpha = 0.77$), school functioning scores ($\alpha = 0.71$, $\alpha = 0.73$), and social functioning scores ($\alpha = 0.73$, $\alpha = 0.79$) to reflect acceptable levels of internal consistency. The PedsQL 4.0 GCS has been translated into multiple languages and in studies with children and adolescents with diabetes, has demonstrated to have acceptable rates of internal consistency for use with group comparisons. Table 1 summarizes the internal consistency statistics for the selected studies. While the PedsQL

4.0 GCS has been translated and statistically validated in languages other than the ones listed, the results in Table 1 are included for their germaneness to the present study.

Table 1
Cronbach Alpha Values for the PedsQL 4.0 GCS across Languages Other than English in Studies with Children and Adolescents with Diabetes

Scale	Arabic	Greek	Persian	Swedish
Self-report				
Scale Score	0.85	0.87	0.87	0.88
Physical Score	0.79	---	0.77	0.75
Psychosocial Score	0.79	---	0.82	---
Emotional Score	0.81	---	0.71	0.72
School Score	0.79	---	0.73	0.63
Social Score	0.74	---	0.73	0.77
Parent-proxy Report				
Scale Score	0.82	---	0.83	0.91
Physical Score	0.76	---	0.73	0.83
Psychosocial Score	0.82	---	0.79	---
Emotional Score	0.80	---	0.73	0.83
School Score	0.79	---	0.72	0.82
Social Score	0.84	---	0.71	0.77

Note. --- were inserted when the authors did not provide the listed Cronbach alpha value. Authors for the listed studies are: Arabic (Abdul-Rasoul, AlOtaibi, AlMahdi, & AlKandari, 2012); Greek (Kalyva et al., 2011); Persian (Jafari, Forouzandeh, Bagheri, Karamizadeh, & Shalileh, 2011); and Swedish (Sand, Kljajić, Schaller, & Forsander, 2012).

PedsQL 3.0 Diabetes Module

Not only does the PedsQL have generic core scales, but it also has disease-specific modules to better assess HRQOL in children and adolescents given the characteristics and trajectory of their specific condition. One such instrument within the PedsQL Measurement Model, the PedsQL Diabetes Module, has been widely used to gather information related to the health-related quality of life aspects most closely associated with diabetes (de Wit et al., 2007; Hilliard et al., 2013; Malik & Koot, 2009). The PedsQL 3.2 Diabetes Module (PedsQL 3.2 DM), the focus of this study, is an update from the previous version, the PedsQL 3.0 Diabetes Module (PedsQL 3.0 DM) (Varni et al., 2003). The PedsQL 3.0 DM is a 28-item measurement that measures

HRQOL in children and adolescents with diabetes in the areas of diabetes symptoms (11 items), treatment barriers (4 items), treatment adherence (7 items), worry (3 items), and communication (3 items). Despite these purported domains, a factor analysis by Nansel et al. (2008) revealed that items on neither the self-report nor the parent-proxy report loaded distinctly on the theorized five factors in a sample of children and caregivers with type 1 diabetes. There was some evidence to suggest the possibility of a two-factor model related to medical and behavior concerns, but this model was not consistent across the self- and parent-proxy reports. Instead, all of the items except for 2 on both the self-report and parent-proxy report loaded onto one factor, suggesting that a total HRQOL diabetes-specific score may be most meaningful in research and clinical settings. When comparing the Cronbach alpha values across the total scores and purported scale scores, the values for the total score on both the self-report and parent-proxy report were the highest ($\alpha = 0.87$, $\alpha = 0.87$), respectively, approaching an acceptable level of internal consistency for use with group comparisons and on an individual-level according to Nunnally & Bernstein's (1994) recommendations. Additionally, the relation between child-reported and parent-reported diabetes-specific HRQOL was statistically significant at the $p < .01$ level but moderate at best (0.43), highlighting the importance of having both children and their caregivers report HRQOL.

Lawrence et al. (2012) conducted a principal component analysis on the PedsQL 3.0 DM self-report and, similar to Nansel et al. (2008), did not find support for a five cluster model. The proposed five-factor model only explained a little over 40% of the variance; 11 clusters were needed to explain 60% of the variance and 18 clusters were

needed to explain 80% of the variance. As in Nansel et al.'s study, the Cronbach alpha values for the PedsQL 3.0 DM total scores across age groups were the highest, ranging from 0.80 to 0.89, indicating an acceptable level of internal consistency for use with group comparisons. Not only has the PedsQL 3.0 DM total score shown evidence of internal consistency on the English version of the measure, but it has also performed similarly on versions of the PedsQL 3.0 DM in other languages. Cronbach alpha values on the Arabic (self-report $\alpha = 0.82$, parent proxy-report $\alpha = 0.81$), Greek (self-report $\alpha = 0.81$), and Swedish (self-report $\alpha = 0.90$, parent proxy-report $\alpha = 0.91$) versions of the PedsQL were to be acceptable (Abdul Rasouel et al., 2012; Kalyva et al., 2011; Sand, Kljajić, Schaller, & Forsander, 2012). Despite lack of support for a five factor model based on the five areas of the PedsQL 3.0 DM, poor glycemic control has been found to be positively related to poor diabetes-specific HRQOL as indicated by the total score on the PedsQL 3.0 DM (Ingeski et al., 2010; Kalyva et al., 2011; Lawrence et al., 2012; Lukács et al., 2014; Reid et al., 2013; Tahirović et al., 2012). Results have also shown that poor diabetes-specific HRQOL as measured on the PedsQL 3.0 DM is correlated with higher levels of depression (Ingerski et al., 2010; Lawrence et al., 2012; Nansel et al., 2008)

When determining if children and caregivers rate children's diabetes-specific HRQOL using the PedsQL 3.0 DM similarly, results are mixed. Abdul-Rasoul, AlOtaibi, AlMahdi, and AlKandari (2012), Nansel et al. (2008), and Sundberg, Sand, and Forsander (2014) found no significant differences between the self-report and parent-proxy report total scores. Other findings revealed that parents rated their

children's diabetes-specific HRQOL significantly lower than their children (Kalyva et al., 2011; Jönsson, Lundqvist, Tiberg, & Hallström, 2015; Reid et al., 2013). Still other findings have suggested that parents rate their children's diabetes-specific HRQOL higher than their children (Yi-Frazier et al., 2016). Yi-Frazier et al. (2016) also found that larger discrepancies between children's and parents' ratings of HRQOL were associated with poorer glycemic control, but that these discrepancies were smaller among those with type 1 diabetes and larger among ethnic minority youth. Overall, when the total score on the PedsQL 3.0 DM is used, substantiated conclusions about diabetes-specific HRQOL can be made. Using the PedsQL 3.0 DM to assess diabetes-specific HRQOL has been shown to be effective in research in determining clinical correlates related to diabetes treatment outcomes and possible treatment modifications.

PedsQL 3.2 Diabetes Module

For children and adolescents with diabetes, the PedsQL 3.2 Diabetes Module (PedsQL 3.2 DM) (Varni et al., 2013), the focus of this study, is intended to measure HRQOL in children, adolescents, and adults with type 1 or type 2 diabetes at various stages of the disease with varying times since diagnosis. The PedsQL 3.2 DM marks a departure from the PedsQL 3.0 DM in that it is intended to capture HRQOL symptoms in both children and adults with diabetes and in those with newly diagnosed diabetes rather than only for those who have had the illness for at least a year. In line with recommendations from the Food and Drug Administration (FDA), Varni et al. (2013) conducted focus groups of participants with type 1 diabetes between 8 and 45 years old and a group of guardians of participants between 8 and 18 years old. Overall, there were

31 participants with type 1 diabetes and 14 guardians interviewed, and three age groups were defined: 8 – 12, 12 – 18, and 18 – 45. Eighteen year-olds still in high school were included in the 12 – 18 group.

During the interviews, open-ended questions were asked regarding areas of concern related to diabetes management and other HRQOL symptoms associated with diabetes. During the interviews, participants of all ages voiced concerns about feeling different due to demands of managing their illness in addition to worrying about short-term complications associated with having diabetes. Of note, only adult participants worried about long-term complications of diabetes. Participants also reported a variety of physical symptoms associated with their diabetes.

Not only were participants asked open-ended about living with diabetes, but they were also to review existing items and items planned for inclusion on the newest version of the PedsQL Diabetes Module. In the PedsQL 3.0 DM, the five scales were diabetes symptoms, treatment barriers, treatment adherence, worry, and communication (Varni et al., 2003). The five-scale organization was preserved in the PedsQL 3.2 DM but the naming of the scales changed slightly for the PedsQL 3.2 DM, to: about my diabetes, treatment I, treatment II, worry, and communication. The "about my diabetes" scale still targets diabetes symptoms, the "treatment I" scale deals with general diabetes care questions common to most people with diabetes, and the "treatment 2" scale deals with more individualized diabetes care questions. Table 2 summarizes the changes made from the PedsQL 3.0 DM to the PedsQL 3.2 DM. Other changes not listed in the table include minor wording changes that clarified the meaning of some items, removal of

antiquated terms, and changes in the wording of items to better suit the age and cognitive level of the respondent (e.g., self vs. parent, child vs. teenager). Finally, participants concluded that a recall period on the measure of 1 month was too long of a time period to accurately recall concerns in the described areas; thus, the recall period was shortened to 7 days, a change that also aligned with FDA recommendations.

Table 2
Updates on the PedsQL 3.2 DM

Scale	# of items on PedsQL 3.0 DM	# of items on PedsQL 3.2 DM	Summary of Major Changes
Diabetes symptoms → About my diabetes	11	15	Added items related to vomiting, high-blood sugar, dizziness, and weakness
Treatment barriers → Treatment I	4	5	Pain associated with pricking finger or giving insulin shot separated into two items; "Embarrassed about having diabetes" moved to communication scale; added item related to embarrassment about diabetes treatment
Treatment adherence → Treatment II	7	6	Removed item related to wearing a medical identification bracelet
Worry	3	3	Removed item related to concern about medical treatment working; removed item about long-term complications from child version; added item about concern about having high blood-sugar
Communication	3	4	Added item "embarrassed about having diabetes" from communication scale
Total	28	33	

Note. The scale name listed to the left of the arrow is the name of the scale from the PedsQL 3.0 DM. The scale name listed to the right of the arrow is the name of the scale from the PedsQL 3.2 DM. The self-reports and parent proxy-reports of the PedsQL 3.2 DM for children ages 2-4 and children ages 5-7 have 32 items, instead of 33, with one fewer item on the worry scale.

The Present Study

Given the update to the PedsQL Diabetes Module, the psychometric properties of the PedsQL 3.2 DM must be demonstrated to ensure that the scores obtained on the

PedsQL 3.2 DM can be used for group comparisons and on the individual treatment level. Not only should the psychometric properties of the PedsQL 3.2 DM be supported with individuals with type 1 diabetes, the disease of the participants involved in the initial content validity investigation by Varni et al. (2013), it should also be determined if the psychometric properties of the PedsQL 3.2 DM hold when assessing the HRQOL of individuals with type 2 diabetes, given the rise in individuals with type 2 diabetes with unique health implications. Additionally, with the increase in the incidence of diabetes across all ethnic groups combined with the continued growth of the Hispanic and Spanish-speaking population in the U.S., an investigation into whether the psychometric properties of the PedsQL 3.2 DM are also robust when the measure is used with Hispanics and when the U.S. Spanish version of the measure is used is warranted.

CHAPTER III

METHODS

Participants

Three-hundred sixty three child-caregiver dyads were recruited from eight tertiary care children's hospitals in the United States. Children who did not have a type 1 or type 2 diabetes mellitus primary diabetes diagnosis were excluded from the study. Children and/or caregivers whose dominant language was a language other than English or Spanish were excluded from the study. Children under the age of 8 who spoke Spanish and/or had a caregiver who spoke Spanish were excluded from the study, as the PedsQL 3.2 Diabetes Module (PedsQL 3.2 DM) has not been linguistically validated in Spanish for children under the age of eight. Written informed consent was obtained from the caregiver and children who were 18 years-old; verbal assent was obtained and documented from all other children below the age of 18. The institutional review boards at the participating institutions approved the study. Of the 363 child-caregiver dyads that were recruited, data from 33 of them were excluded from analysis. Their HbA1c values reported in the medical chart review were obtained more than 3 months prior to the dyads completing the PedsQL assessments, suggesting that those Hba1c values were not representative of how well the children were managing their diabetes at that time. Data from participants ages 2-7 were also excluded (n=14) because these versions of the measure contained one fewer item and could confound the results of the factor analyses that were completed. Participant characteristics of the remaining 316 child-caregiver dyads are shown in Table 3.

Table 3
Participant Characteristics

	n	%	Mean ± SD
Age (years)			
Total (range 8-18)	316	---	13.70 ± 2.70
Child (range 8-12)	122	38.60	10.90 ± 1.48
Teen (range 13-18)	194	61.40	15.47 ± 1.57
Sex			
Male	153	48.4	---
Female	162	51.3	---
Ethnicity			
White/non-Hispanic	172	54.80	---
Black/non-Hispanic	59	18.70	---
Hispanic/Latino	54	17.10	---
Asian/Pacific Islander	8	2.50	---
Other	21	6.60	---
Diabetes diagnosis			
Type 1 diabetes	303	96.10	---
Type 2 diabetes	13	3.90	---
BMI	---	---	22.84 ± 7.67
BMI %ile	---	---	67.31 ± 26.28
HbA1c	---	---	8.53 ± 1.92
Language of form			
English	315	99.70	---
Spanish	1	0.30	---

Note. Missing values for total sample include: sex, 1 case subject (0.30%); ethnicity, 2 case subjects (0.60%); BMI %ile, 27 (8.5%)

Measures

PedsQL 3.2 Diabetes Module

Both the child and his/her caregiver completed the PedsQL 3.2 Diabetes Module (PedsQL 3.2 DM) (Varni et al., 2013), a diabetes-specific assessment that measures diabetes-related HRQOL across 32 items (ages 2-7) or 33 items (ages 8 and older). Items on the PedsQL 3.2 DM are divided into five areas: About my Diabetes, Treatment I, Treatment II, Worry, and Communication. It consists of parallel self-report and parent proxy-report forms for children ages 5-18, with specific forms for children ages 5-7, ages 8-12, and ages 13-18. Only a parent proxy-report form is used to assess diabetes-specific HRQOL in children ages 2-4. The versions of the forms assess functioning in

the same areas using nearly identical items, with the wording of the items only changing to reflect age-appropriate language and the point-of-view of the rater.

When completing the PedsQL 3.2 DM, children and caregivers rate the child's diabetes-specific HRQOL on nearly identical items that ask how much of a problem diabetes-related symptoms and concerns have been for the child and how hard diabetes-specific care tasks have been for the child in the past 7 days. Children and caregivers respond using a Likert-type response scale (on the self-report forms for children 8-18 and on the parent proxy-report forms children 2-18, 0 = never a problem/hard, 1 = almost never a problem/hard, 2 = sometimes a problem/hard, 3 = often a problem/hard, and 4 = almost always a problem/hard). This Likert-type response scale is consistent with that used on the PedsQL 4.0 GCS and with the other PedsQL disease-specific modules and has been shown to be effective for use with pediatric patients and their caregivers (Varni & Limbers, 2009; Varni et al., 2010).

Items on the PedsQL 3.2 DM are reverse-scored and linearly transformed (0 = 100, 1 = 75, 2 = 50, 3 = 25, and 4 = 0) so that higher scores are indicative of higher HRQOL and fewer problems. The total score and five scale scores are obtained by adding all of the item-scores and dividing the sum by the number of items answered in the measure or scale. If the child or caregiver did not respond to over 50% of the items, then the respective score is not calculated. This method of scoring in consistent with other versions of the PedsQL and other HRQOL measures (Varni & Limbers, 2009). Reliability estimates for the PedsQL 3.0 DM can be found in the previous chapter of this manuscript.

The self-report and parent proxy-reports of the U.S. Spanish version of the PedsQL 3.2 DM have been linguistically validated for children ages 8-18 according to a three-step process put forth by Acquadro, Conway, Giroudet, & Mear and the Mapi Research Institute (as cited in Newman et al., 2010). In the forward translation step, two local translators separately translate the original measure into the target language and then reconcile any differences in their translations to create one product. Then in the backward translation step, that product in the target language is translated back into the original language by another local translator who has no knowledge of the original document. Finally, in the patient testing step, the translated measure is administered to a sample from the target population to determine if the concepts are equivalent across the languages and if the directions, items, and responses are able to be easily understood.

PedsQL 4.0 Generic Core Scales

Both the child and his/her caregiver completed the PedsQL 4.0 Generic Core Scales (PedsQL 4.0 GCS) (Varni et al., 2001), a non-disease-specific assessment that measures HRQOL across 23 items in the areas of physical functioning, emotional functioning, school functioning, and social functioning. It consists of parallel self-report and parent proxy-report forms for children ages 5-18, with specific forms for children ages 5-7, ages 8-12, and ages 13-18. Only a parent proxy-report form is used to assess HRQOL in children ages 2-4. The versions of the forms assess functioning in the same areas using nearly identical items, with the wording of the items only changing to reflect age-appropriate language and the point-of-view of the rater.

When completing the PedsQL 4.0 GCS, children and caregivers rate the child's non-disease-specific (generic) HRQOL on nearly identical items that ask how much of a problem the child has had in the four described areas in the past seven days. Children and caregivers respond using a Likert-type response scale (on the self-report forms for children 8-18 and on the parent proxy-report forms children 2-18, 0 = never a problem, 1 = almost never a problem, 2 = sometimes a problem, 3 = often a problem, and 4 = almost always a problem). This Likert-type response scale is consistent with that used on the other PedsQL disease-specific modules and has been shown to be effective for use with pediatric patients and their caregivers (Varni & Limbers, 2009; Varni et al., 2010). Reliability estimates can be found in the previous chapter of this manuscript.

Items on the PedsQL 4.0 GCS are reverse-scored and linearly transformed (0 = 100, 1 = 75, 2 = 50, 3 = 25, and 4 = 0) so that higher scores are indicative of higher HRQOL and fewer problems. The six possible scores previously described are obtained by adding all of the item-scores and dividing the sum by the number of items answered in the measure or specific scale(s) of interest. If the child or caregiver did not respond to over 50% of the items, then the respective score is not calculated. This method of scoring in consistent with other versions of the PedsQL and other HRQOL measures (Varni & Limbers, 2009).

The self-report and parent proxy-reports of the U.S. Spanish version of the PedsQL 4.0 GCS have been linguistically validated for children ages 8-18 according to a previously described 3-step process put forth by Acquadro, Conway, Giroudet, & Mear and the Mapi Research Institute (as cited in Newman et al., 2010).

PedsQL Family Information Form

Caregivers completed an edited version of the PedsQL Family Information Form (Varni et al., 2001) in the appropriate language. The PedsQL Family Information Form gathers demographic information about the child; the child's family structure; the caregivers' employment status, education history, and diabetes history; and additional information about the child's diabetes history.

Medical Chart Review

A member of the staff at the tertiary care hospital completed a medical chart review (see Appendix) that gathers information related to the child's diabetes history and current biological markers related to the child's diabetes functioning from the visit during which the child and caregiver completed the PedsQL assessments. Information gathered includes the child's primary diabetes diagnosis and secondary medical diagnoses; the child's current HbA1c and BMI levels; whether the child uses an insulin pump and/or continuous glucose monitoring; and information about the child's previous hospitalizations due to complications from his/her diabetes. The form was created with input from James Varni, PhD, the developer of the PedsQL, and various endocrinologists.

Procedure

A research assistant approached caregivers of patients from the clinic to determine if they and their respective children would like to participate in the study. If consent was obtained, the caregiver first completed the Family Information Form, then the PedsQL 3.2 DM, and then the PedsQL 4.0 GCS. The child completed the PedsQL

3.2 DM and then the PedsQL 4.0 GCS. If a child or caregiver had questions while completing the measures, he or she could ask the research assistant. The research assistant or other IRB-approved member of the clinic staff completed the Medical Chart Review after the visit was complete. The Family Information Form, PedsQL 3.2 DM, PedsQL 4.0 GCS, and Medical Chart Review were mailed or sent electronically to Texas A&M University for input (double-entry and reconciliation) and analysis. Data were encrypted for safe storage. The data did not have information that could be linked to the participants' protected health information. The forms were stored in a locked filing cabinet.

CHAPTER IV

RESULTS

All analyses were conducted using SPSS, Version 24.0. Parallel analyses (Horn, 1965) and Velicer's minimum average partial (MAP) tests (Velicer, 1976) were conducted using syntax developed by O'Connor (2000). Additional analyses that were proposed for each research question within each rater subgroup (self and parent-proxy) according to type of diabetes (type 1 or type 2) or language of the measure (U.S. English or U.S. Spanish) were not conducted due to an insufficient number of participants in the type 2 diabetes and U.S. Spanish groups.

Missing Item Responses

The percentage of missing items responses for self- and the parent-proxy reports of the PedsQL 4.0 GCS were .36% and .42%, respectively. The percentage of missing items for the self- and parent-proxy reports of the PedsQL 3.2 DM were .49% and .52%, respectively.

Means, Standard Deviations, and Internal Consistency Reliability Estimates

Means and SDs of the PedsQL 4.0 GCS and the PedsQL 3.2 DM and internal consistency reliability estimates using Cronbach's alpha (Cronbach, 1951) are presented in Table 4. All of the scales exceeded the reliability threshold of $\alpha \geq 0.70$ that is needed to be deemed internally consistent and to be used for group comparison (Nunnally & Bernstein, 1994; Varni et al., 2001). While the scores in all areas were determined to be internally consistent for use with group comparisons, the total scale scores on the PedsQL 4.0 GCS and the PedsQL 3.2 DM were found to be the most useful outcome

scores to be used on the individual-level, given the alpha values near 0.90 (Nunnally & Bernstein, 1994).

Table 4
Means, Standard Deviations, and Internal Consistency Reliability Estimates for the PedsQL 4.0 GCS and the PedsQL 3.2 DM

Scales	Number of items	*n*	Mean ± SD	α
PedsQL 4.0 GCS				
Self-Report				
Total score	23	314	83.55 ± 12.59	0.88
Physical health	8	314	88.43 ± 12.64	0.76
Psychosocial health	15	314	80.93 ± 14.40	0.84
Emotional functioning	5	313	78.58 ± 19.22	0.74
Social functioning	5	314	90.46 ± 13.35	0.75
School functioning	5	313	73.92 ± 18.79	0.71
Parent-Proxy Report				
Total score	23	311	83.13 ± 14.22	0.92
Physical health	8	311	86.28 ± 17.20	0.87
Psychosocial health	15	311	81.40 ± 15.43	0.90
Emotional functioning	5	311	78.55 ± 19.96	0.84
Social functioning	5	311	90.31 ± 14.81	0.81
School functioning	5	309	75.45 ± 20.19	0.82
PedsQL 3.2 DM				
Self-Report				
Total score	33	315	76.91 ± 10.66	0.89
Parent-Proxy Report				
Total score	33	311	77.26 ± 10.93	0.90

Research Question 1

To determine if the five domains of diabetes-specific HRQOL in children with diabetes put forth by Varni et al. (2013) were present in the PedsQL 3.2 DM, exploratory factor analyses using the principal axis factor method with promax rotation (Yong & Pearce, 2013), testing a five-factor solution, a two-factor, and a one-factor solution, were conducted based on the a priori factor structure and Nansel et al.'s (2008) and Lawrence et al.'s (2012) findings. Parallel analysis (Horn, 1965) and Velicer's minimum average partial (MAP) test (Velicer, 1976) were also conducted to determine how many factors should be retained (Zwick & Velicer, 1986), apart from those suggested based on the a

prior factor structure and Nansel et al's (2008) and Lawrence et al.'s (2012) findings with the PedsQL 3.0 DM. Courtney (2013) describes parallel analysis.

> The PA method is implemented by generating a large number of data matrices from random data. Each matrix is generated in parallel with the real data meaning that matrices with the same number of cases and variables are created. Factors are retained in the real data as long as they are greater than the mean eigenvalue generated from the random data matrices. (p.4)

Velicer's MAP test retains components that represent systematic variance rather than residual or error variance (Courtney, 2013). Parallel analysis and Velicer's MAP test have been found to perform well in suggesting the number of factors to be retained and in many circles are preferred to the eigenvalue-greater-than-one rule (K1) which frequently overestimates the amount of factors and Cattell's Scree test which is susceptible to subjective interpretation (Courtney, 2013). Separate analyses were conducted for the self-report and parent proxy-report. Within each rater subgroup (self and parent proxy), separate analyses also were conducted according to the ethnicity of the children (non-Hispanic or Hispanic). Items with a factor loading value of .30 or higher were considered to load on a factor (Nansel et al., 2008; Tabachnick & Fidell, 2013). A summary of the communality values, the amount of variance in a variable the factors can reproduce, for the variables were reported (Thompson, 2004). Each factor must have had a minimum of three items (Costello & Osborne, 2005; Velicer & Fava, 1998).

Simply examining the ratio of the sample size to the number of variables/items or setting a minimum sample size as a way to ensure that one obtains reliable factor analysis findings has been deemed insufficient. Although a larger sample size improves the stability of the factors and reduces error, the interaction among the sample size, the number of variables/items, the number of factors, and the communalities of the variables can still result in the extraction of accurate factors, even when the sample size is small (e.g., *N*=50) (MacCallum, Widaman, Zhang, & Hong, 1999; Velicer & Fava, 1998). Given the that some of the described factor analyses involved small sample sizes, examining the results of these factor analyses in the context of the sample size, the number of variables/items (33), the number of factors (5, 2, 1), and the communalities of the variables was necessary to draw conclusions about the reliability and accuracy of the results.

A principal axis factor analysis with a promax rotation extracting five factors did not result in all of the variables loading on the a priori scales for either the self- or parent-proxy reports. Table 5 summarizes the factor structures for the self- and parent-proxy reports. On the self-report, all items from the Worry scale loaded onto an individual factor with no other items, with item Wr3 also cross-loading onto another factor. For the parent-proxy report, items on the About My Diabetes scale loaded onto two factors, with item Ds8 not loading onto any factor and items Ds4 and Ds9 cross-loading onto two factors. Items from the Treatment I and Treatment II scales loaded onto two factors but not the a priori factors involving the Treatment I and Treatment II. All items from the Worry scale formed an individual factor with no other items. All

items from the Communication scale in addition to two items from the Treatment I scale loaded onto one factor.

The extracted five-factor structure on the self-report accounted for 42.07% of the total variance: factor 1 accounted for 25.68% of the total variance, factor 2 accounted for 6.45% of the total variance, factor 3 accounted for 3.85% of the total variance, factor 4 accounted for 3.23% of the total variance, and factor 5 accounted for 2.86% of the total variance. The extracted five-factor structure on the parent-proxy report accounted for 44.45% of the total variance: factor 1 accounted for 25.34% of the total variance, factor 2 accounted for 7.28% of the total variance, factor 3 accounted for 4.63% of the total variance, factor 4 accounted for 4.01% of the total variance, and factor 5 accounted for 3.20% of the total variance. Despite 63.64% and 60.61% of the communalities being low (<0.50) on the self- and parent-proxy reports, respectively, the presence of few factors, and few variables loading on these factors, the large sample size over 300 would suggest an accurate factor extraction, notwithstanding the discrepancy between item loadings on the self- and parent-proxy reports.

Table 5
Factor Structure of the PedsQL 3.2 DM, Five-factor Solution

	Self-report (*n*=314)					Parent-proxy report (*n*=309)				
Item	1	2	3	4	5	1	2	3	4	5
Ds1. Feel hungry		0.43							0.64	
Ds2. Feel thirsty	0.41	0.36		-0.36					0.88	
Ds3. Have to go to the bathroom too often	0.50								0.76	
Ds4. Have stomachaches	0.48					0.41			0.35	
Ds5. Have headaches	0.55					0.41				
Ds6. Feel the need to throw up	0.46					0.43				
Ds7. Go “low’	0.36					0.46				
Ds8. Go “high”										

Table 5 Continued

	Self-report (*n*=314)					Parent-proxy report (*n*=309)				
Item	1	2	3	4	5	1	2	3	4	5
Ds9. Feel tired	0.50					0.36			0.32	
Ds10. Get shaky	0.82	-0.30				0.79				
Ds11. Get sweaty	0.52					0.69				
Ds12. Feel dizzy	0.74					0.91				
Ds13. Feel weak	0.66					0.73				
Ds14. Have trouble sleeping										
Ds15. Get cranky or grumpy	0.51					0.36				
Tx1. Hurts to get finger pricked			0.72				0.41			
Tx2. Hurts to get insulin shots			0.72				0.39			
Tx3. Embarrassed about diabetes treatment				0.73				0.65		
Tx4. Argue with parents about diabetes care				0.33				0.37		
Tx5. Hard to do everything to care for diabetes		0.55					0.49			
Txx1. Hard to take blood glucose tests			0.46				0.71			
Txx2. Hard to take insulin shots			0.67				0.69			
Txx3. Hard to play or do sports		0.37					0.38			
Txx4. Hard to keep track of carbs		0.40					0.66			
Txx5. Hard to carry a fast-acting carb		0.47					0.74			
Txx6. Hard to snack when go "low"							0.46			
Wr1. Worry about going "low"					0.83					0.68
Wr2. Worry about going "high"					0.65					0.71
Wr3. Worry about long-term complications		0.45			0.47					0.59
Cm1. Hard to tell doctors and nurses how feel		0.65						0.65		
Cm2. Hard to ask doctors and nurses questions		0.76						0.69		
Cm3. Hard to explain illness to others		0.40		0.51				0.79		
Cm4. Embarrassed about having diabetes				0.75				0.82		

Note. Ds = About my diabetes scale, Tx = Treatment I scale, Txx = Treatment II scale, Wr = Worry scale, and Cm = Communication scale. Variables with factor loadings less than 0.30 were not included in the table.

A principal axis factor analysis extracting a single factor resulted in all of the variables loading on the single factor for both the self- and parent-proxy reports. Table 6 summarizes the single- and two-factor structures for the self- and parent-proxy reports.

The single-factor structure on the self-report accounted for 25.22% of the total variance and the single-factor on the parent-proxy report accounted for 24.73% of the total variance. A principal axis factor analysis with a promax rotation extracting two factors resulted in almost all of the variables loading on two factors. On the self-report, all items from the About My Diabetes scale except for item Ds7 loaded onto one factor in addition to item Wr2. The rest of the items loaded onto the second factor; item Ds7 did not load onto either factor. For the parent-proxy report, items on the About My Diabetes scale loaded onto one factor, while all of the remaining items loaded onto the second factor.

The extracted two-factor structure on the self-report accounted for 31.48% of the total variance: factor 1 accounted for 25.40% of the total variance and factor 2 accounted for 6.08% of the total variance. The extracted two-factor structure on the parent-proxy report accounted for 31.89% of the total variance: factor 1 accounted for 24.95% of the total variance and factor 2 accounted for 6.94% of the total variance. Despite 93.94% of the communalities being low (<0.50) on both the self- and parent-proxy reports, the presence of few factors, an overdetermination of variables loading on these factors, and the sample size over 300 would suggest an accurate factor extraction, notwithstanding the discrepancy between item loadings on the self- and parent-proxy reports. Given the support for a single-factor structure across the self- and parent-proxy reports, the total score on the PedsQL 3.2 DM was used as needed in the subsequent analyses.

Table 6
Factor Structure of the PedsQL 3.2 DM, Single- and Two-factor Solution

	Self-report	Parent-proxy report	Self-report		Parent-proxy report	
Item	Single factor	Single factor	Factor 1	Factor 2	Factor 1	Factor 2
Ds1. Feel hungry	0.39	0.54	0.46		0.47	
Ds2. Feel thirsty	0.43	0.59	0.72		0.57	
Ds3. Have to go to the bathroom too often	0.54	0.59	0.73		0.59	
Ds4. Have stomachaches	0.54	0.54	0.60		0.68	
Ds5. Have headaches	0.53	0..50	0.59		0.57	
Ds6. Feel the need to throw up	0.60	0.39	0.50		0.62	
Ds7. Go “low’	0.31	0.35			0.33	
Ds8. Go “high”	0.41	0.45	0.40		0.42	
Ds9. Feel tired	0.69	0.67	0.65		0.59	
Ds10. Get shaky	0.49	0.50	0.61		0.63	
Ds11. Get sweaty	0.54	0.57	0.64		0.74	
Ds12. Feel dizzy	0.53	0.61	0.61		0.76	
Ds13. Feel weak	0.57	0.61	0.60		0.77	
Ds14. Have trouble sleeping	0.53	0.51	0.34		0.40	
Ds15. Get cranky or grumpy	0.55	0.58	0.52		0.51	
Tx1. Hurts to get finger pricked	0.38	0.40		0.47		0.46
Tx2. Hurts to get insulin shots	0.37	0.32		0.61		0.46
Tx3. Embarrassed about diabetes treatment	0.41	0.47		0.75		0.55
Tx4. Argue with parents about diabetes care	0.48	0.48		0.41		0.43
Tx5. Hard to do everything to care for diabetes	0.68	0.47		0.61		0.52
Txx1. Hard to take blood glucose tests	0.43	0.47		0.55		0.64
Txx2. Hard to take insulin shots	0.47	0.46		0.64		0.67
Txx3. Hard to play or do sports	0.38	0.51		0.31		0.54
Txx4. Hard to keep track of carbs	0.52	0.41		0.38		0.53
Txx5. Hard to carry a fast-acting carb	0.56	0.39		0.46		0.58
Txx6. Hard to snack when go “low”	0.39	0.38		0.33		0.41
Wr1. Worry about going “low”	0.38	0.41		0.31		0.36
Wr2. Worry about going “high”	0.50	0.48	0.32			0.36
Wr3. Worry about long-term complications	0.55	0.41		0.39		0.35
Cm1. Hard to tell doctors and nurses how feel	0.61	0.57		0.47		0.53
Cm2. Hard to ask doctors and nurses questions	0.57	0.56		0.37		0.55
Cm3. Hard to explain illness to others	0.50	0.50		0.55		0.51
Cm4. Embarrassed about having diabetes	0.49	0.49		0.76		0.63

Note. Variables with factor loadings less than 0.30 were not included in the table.

When comparing the eigenvalues of the actual data to eigenvalues in the 50th percentile of the random data in parallel analysis, 11 factors were recommended for extraction from the self-report and 14 factors were recommended for extraction from the parent-proxy report. When comparing the eigenvalues of the actual data to eigenvalues in the 95th percentile of the random data in parallel analysis, 9 factors were recommended for extraction from the self-report and 11 factors were recommended for extraction from the parent-proxy report. According to Velicer's minimum average partial (MAP) test with the self-report, 2 factors should be extracted; according to the MAP test with the parent-proxy report, 5 factors should be extracted. Given the lack of agreement between the recommended number of factors for extraction suggested by the a priori factor structure, previous findings, and the results of the parallel analyses and Velicer's MAP tests, additional principal axis factor analyses were not conducted.

Based on the findings that all of the items loaded onto a single factor and that nearly all of the items loaded onto two distinct factors with no cross-loadings for both the self- and parent-proxy reports, principal axis factor analyses with promax rotations, testing a one- and two-factor solution, were repeated with the self- and parent-proxy reports for children of non-Hispanic and Hispanic descent. Table 7 summarizes the single- and two-factor structures for the self- and parent-proxy reports of non-Hispanics. A principal axis factor analysis extracting a single factor resulted in all of the variables except for item Ds7 loading on the single factor for the self-report. All of the variables except for item Tx2 loaded on the single factor for the parent-proxy report. The single-

factor structure on the self-report accounted for 24.73% of the total variance and the single-factor on the parent-proxy report accounted for 25.45% of the total variance.

A principal axis factor analysis with a promax rotation extracting two factors resulted in almost all of the variables loading on two factors. On the self-report, all items from the About My Diabetes scale except for items Ds7 and Ds14 loaded onto one factor in addition to item Wr2. The rest of the items loaded onto the second factor; items Ds7, Ds14, and Txx3 did not load onto either factor. For the parent-proxy report, items on the About My Diabetes scale loaded onto one factor, while all of the remaining items loaded onto the second factor.

The extracted two-factor structure on the self-report accounted for 31.13% of the total variance: factor 1 accounted for 24.91% of the total variance and factor 2 accounted for 6.21% of the total variance. The extracted two-factor structure on the parent-proxy report accounted for 32.47% of the total variance: factor 1 accounted for 25.66% of the total variance and factor 2 accounted for 6.80% of the total variance. More than 90% of the communality values were low (<0.50) on the self- and parent-proxy reports in both the single- and two-factor solutions (self- single-factor: 96.97%; parent-proxy single-factor: 100%; self- two-factor: 93.94%; parent-proxy two-factor: 93.94%). Despite the low communality values, the overdetermination of variables per factor and the large sample size over 250 would suggest a stable factor extraction for the two-factor solution, notwithstanding the discrepancy between item loadings on the self- and parent-proxy reports.

Table 7
Factor Structure of the PedsQL 3.2 DM for non-Hispanics, Single- and Two-factor Solution

	Self-report (*n*=258)	Parent-proxy report (*n*=254)	Self-report		Parent-proxy report	
Item	Single factor	Single factor	Factor 1	Factor 2	Factor 1	Factor 2
Ds1. Feel hungry	0.40	0.53	0.44		0.49	
Ds2. Feel thirsty	0.45	0.59	0.72		0.61	
Ds3. Have to go to the bathroom too often	0.56	0.59	0.73		0.61	
Ds4. Have stomachaches	0.53	0.57	0.61		0.74	
Ds5. Have headaches	0.49	0.48	0.60		0.58	
Ds6. Feel the need to throw up	0.57	0.43	0.47		0.65	
Ds7. Go “low’		0.32			0.31	
Ds8. Go “high”	0.38	0.43	0.40		0.44	
Ds9. Feel tired	0.70	0.66	0.64		0.63	
Ds10. Get shaky	0.49	0.56	0.61		0.63	
Ds11. Get sweaty	0.55	0.57	0.63		0.71	
Ds12. Feel dizzy	0.49	0.64	0.59		0.74	
Ds13. Feel weak	0.55	0.64	0.60		0.77	
Ds14. Have trouble sleeping	0.52	0.50			0.37	
Ds15. Get cranky or grumpy	0.57	0.59	0.60		0.55	
Tx1. Hurts to get finger pricked	0.36	0.38		0.44		0.50
Tx2. Hurts to get insulin shots	0.33			0.61		0.49
Tx3. Embarrassed about diabetes treatment	0.38	0.52		0.70		0.62
Tx4. Argue with parents about diabetes care	0.44	0.51		0.34		0.37
Tx5. Hard to do everything to care for diabetes	0.68	0.47		0.64		0.47
Txx1. Hard to take blood glucose tests	0.47	0.48		0.59		0.63
Txx2. Hard to take insulin shots	0.48	0.45		0.64		0.69
Txx3. Hard to play or do sports	0.37	0.51				0.51
Txx4. Hard to keep track of carbs	0.51	0.40		0.42		0.49
Txx5. Hard to carry a fast-acting carb	0.53	0.37		0.50		0.61
Txx6. Hard to snack when go “low”	0.39	0.35		0.35		0.43
Wr1. Worry about going “low”	0.37	0.43		0.32		0.43
Wr2. Worry about going “high”	0.52	0.48	0.32			0.40
Wr3. Worry about long-term complications	0.58	0.43		0.45		0.36
Cm1. Hard to tell doctors and nurses how feel	0.63	0.60		0.52		0.51
Cm2. Hard to ask doctors and nurses questions	0.59	0.57		0.44		0.50
Cm3. Hard to explain illness to others	0.43	0.52		0.50		0.44
Cm4. Embarrassed about having diabetes	0.48	0.51		0.71		0.60

Note. Variables with factor loadings less than 0.30 were not included in the table.

Table 8 summarizes the single- and two-factor structures for the self- and parent-proxy reports of Hispanics. A principal axis factor analysis extracting a single factor resulted in all of the variables except for item Txx1 loading on the single factor for the self-report. All of the variables except for items Ds6, Ds10, and Tx3 loaded on the single factor for the parent-proxy report. The single-factor structure on the self-report accounted for 29.06% of the total variance and the single-factor on the parent-proxy report accounted for 22.70% of the total variance.

A principal axis factor analysis with a promax rotation extracting two factors resulted in all of the variables loading on two factors. Some cross-loadings were observed and variables did not load consistently across the self- and parent-proxy reports. The extracted two-factor structure on the self-report accounted for 37.05% of the total variance: factor 1 accounted for 29.28% of the total variance and factor 2 accounted for 7.77% of the total variance. The extracted two-factor structure on the parent-proxy report accounted for 33.62% of the total variance: factor 1 accounted for 22.99% of the total variance and factor 2 accounted for 10.63% of the total variance. More than 75% of the communality values were low (<0.50) on the self- and parent-proxy reports in both the single- and two-factor solutions (self- single-factor: 93.94%; parent-proxy single-factor: 96.97%; self- two-factor: 78.79%; parent-proxy two-factor: 87.88%). The low communality values, small sample size, and lack of consistency of the single- and two-factor solutions across the self- and parent-proxy reports suggest that the extracted factor structures are not stable, despite the overdetermination of variables per factor.

Table 8
Factor Structure of the PedsQL 3.2 DM for Hispanics, Single- and Two-factor Solution

	Self-report (*n*=54)	Parent-proxy report (*n*=53)	Self-report		Parent-proxy report	
Item	Single factor	Single factor	Factor 1	Factor 2	Factor 1	Factor 2
Ds1. Feel hungry	0.34	0.55	0.61		0.53	
Ds2. Feel thirsty	0.39	0.58	0.62		0.67	
Ds3. Have to go to the bathroom too often	0.40	0.63	0.74	-0.31	0.75	
Ds4. Have stomachaches	0.56	0.34	0.55		0.37	
Ds5. Have headaches	0.71	0.61	0.55		0.60	
Ds6. Feel the need to throw up	0.67		0.61		0.35	
Ds7. Go “low’	0.55	0.45	0.66		0.40	
Ds8. Go “high”	0.50	0.52	0.31		0.47	
Ds9. Feel tired	0.63	0.77	0.64		0.54	0.39
Ds10. Get shaky	0.52		0.55		0.52	-0.40
Ds11. Get sweaty	0.55	0.58	0.75		0.86	
Ds12. Feel dizzy	0.65	0.43	0.67		0.69	
Ds13. Feel weak	0.62	0.43	0.61		0.72	
Ds14. Have trouble sleeping	0.50	0.59	0.41		0.57	
Ds15. Get cranky or grumpy	0.48	0.51		0.42	0.34	
Tx1. Hurts to get finger pricked	0.50	0.47		0.52	0.33	
Tx2. Hurts to get insulin shots	0.57	0.44		0.64		0.39
Tx3. Embarrassed about diabetes treatment	0.49			0.87		0.32
Tx4. Argue with parents about diabetes care	0.68	0.32		0.71		0.58
Tx5. Hard to do everything to care for diabetes	0.67	0.53		0.49		0.66
Txx1. Hard to take blood glucose tests		0.37		0.39		0.57
Txx2. Hard to take insulin shots	0.37	0.49		0.63		0.58
Txx3. Hard to play or do sports	0.54	0.52		0.52		0.58
Txx4. Hard to keep track of carbs	0.52	0.44	0.40			0.64
Txx5. Hard to carry a fast-acting carb	0.66	0.52	0.47			0.35
Txx6. Hard to snack when go “low”	0.39	0.51	0.34		0.35	
Wr1. Worry about going “low”	0.51	0.33	0.44		0.39	
Wr2. Worry about going “high”	0.38	0.55	0.35		0.50	
Wr3. Worry about long-term complications	0.49	0.34	0.32			
Cm1. Hard to tell doctors and nurses how feel	0.61	0.50	0.31	0.39		0.50
Cm2. Hard to ask doctors and nurses questions	0.47	0.55	0.35			0.60
Cm3. Hard to explain illness to others	0.72	0.38		0.75		0.66
Cm4. Embarrassed about having diabetes	0.48	0.35		0.91		0.76

Note. Variables with factor loadings less than 0.30 were not included in the table.

Research Question 2

To determine if children's overall ratings of their own diabetes-specific HRQOL is correlated to their caregiver's ratings of their children's HRQOL, intraclass correlation coefficients (ICCs) were calculated for all participants. Then, additional ICCs were calculated within each rater subgroup (self and parent proxy), according to ethnicity of the children (non-Hispanic or Hispanic). A two-way mixed effects model was used and ICCs reflecting absolute agreement of a single measurement were obtained (McGraw & Wong, 1996; Varni, Limbers, & Burwinkle, 2007b). The total score on the PedsQL 3.2 DM was used as the measure of diabetes-specific HRQOL and to compute the ICCs; scale scores were not be included in these analyses. Landis and Koch's (1977) guidelines for interpreting kappa statistics, guidelines that have also been used to interpret ICCs, that ICCs ≤ .40 = poor to fair agreement; ICCs of .41 to .60 = moderate agreement; ICCs of .60 to .80 = substantial agreement; and ICCs of .81 to 1.00 = almost perfect agreement, were used.

Moderate agreement was found between children's ratings of their own diabetes-specific HRQOL and their caregivers' ratings of their children's HRQOL as measured by the total scores on the PedsQL 3.2DM, with an ICC of 0.44, 95% CI [0.35, 0.53]. Moderate agreement was found between non-Hispanic children's ratings of their own diabetes-specific HRQOL and their caregivers' ratings of their children's HRQOL as measured by the total scores on the PedsQL 3.2DM, with an ICC of 0.43, 95% CI [0.32, 0.52]. Moderate agreement was found between Hispanic children's ratings of their own diabetes-specific HRQOL and their caregivers' ratings of their children's HRQOL as

measured by the total scores on the PedsQL 3.2DM, with an ICC of 0.52, 95% CI [0.30, 0.69].

Research Question 3

To determine if diabetes-specific HRQOL is significantly different based on ethnicity of the children (non-Hispanic or Hispanic), independent samples *t* tests were conducted within each rater subgroup (self and parent proxy). The total score on the PedsQL 3.2 DM was used as the measure of diabetes-specific HRQOL; scale scores were not included in these analyses.

Levene's test for equality of variances was found to be violated for the independent samples *t* test with the self-report ($F = 5.59$, $p = .02$) so degrees of freedom were adjusted from 311 to 69. Results from an independent samples *t* test indicated that non-Hispanic children ($M = 77.20$, $SD = 10.26$, $n = 259$) reported similar HRQOL as Hispanic children ($M = 75.70$, $SD = 12.5$, $n = 54$), $t(69) = 5.59$, $p = 0.41$, two-tailed. Results from an independent samples *t* test indicated that caregivers of non-Hispanic children ($M = 76.85$, $SD = 10.90$, $n = 256$) rated their children's HRQOL similarly to caregivers of Hispanic children ($M = 79.63$, $SD = 10.86$, $n = 53$), $t(307) = 0.18$, $p = 0.09$, two-tailed.

Research Question 4

To determine if children's glycemic control, as measured by HbA1c levels, is correlated with diabetes-specific HRQOL as reported by both of the raters, Pearson product moment correlations (*r*) were computed for both the self-report and parent proxy-report, regardless of the ethnicity of the children. Additional Pearson product

moment correlations (*r*) comparing HRQOL and glycemic control were then conducted within each rater subgroup (self and parent proxy), taking into account the ethnicity of the children (non-Hispanic or Hispanic). The total score on the PedsQL 3.2 DM was used as the measure of diabetes-specific HRQOL; scale scores were not included in these analyses. Effect sizes (r^2), statistical significance ($\alpha = .05$), and confidence intervals (95%) were reported. Fisher's *r-to-z* transformations were computed to test for potential differences in correlations within each rater subgroup (self and parent proxy), based on the ethnicity of the children (non-Hispanic or Hispanic).

Children's glycemic control, as measured by HbA1c levels, was significantly inversely correlated with self-reported diabetes-specific HRQOL ($r(313) = -0.18$, $r^2 = 0.03$, $p < 0.05$, 95% CI [-0.28, -0.07]) and was significantly inversely correlated with parent-reported diabetes-specific HRQOL ($r(309) = -0.11$, $r^2 = 0.01$, $p < 0.05$, 95% CI [-0.22, 0.00]), regardless of the ethnicity of the children. In other words, as HbA1c levels increased (glycemic control deteriorated), self-reported and parent-reported HRQOL decreased. For non-Hispanic children, children's glycemic control, as measured by HbA1c levels, was significantly inversely correlated with self-reported diabetes-specific HRQOL ($r(257) = -0.17$, $r^2 = 0.03$, $p < .05$, 95% CI [-0.28, -0.05]) and was not significantly correlated with parent-reported diabetes-specific HRQOL ($r(254) = -0.10$, $r^2 = 0.01$, $p = 0.11$, 95% CI [-0.22, 0.02]). For Hispanic children, children's glycemic control, as measured by HbA1c levels, was not significantly correlated with self-reported diabetes-specific HRQOL ($r(52) = -0.25$, $r^2 = 0.03$, $p = 0.07$, 95% CI [-0.49, 0.01]) and was not significantly correlated with parent-reported diabetes-specific HRQOL ($r(51) =$

-0.12, r^2 = 0.38, p = 0.02, 95% CI [-0.38, 0.16]). There was no significant difference between correlations of HbA1c levels and self-reported diabetes-specific HRQOL of non-Hispanic and Hispanic children (z = 0.55, p = 0.58). There was no significant difference between correlations of HbA1c levels and parent-reported diabetes-specific HRQOL of non-Hispanic and Hispanic children (z = 0.13, p = 0.90).

CHAPTER V

SUMMARY

This study explored the psychometric properties of the PedsQL 3.2 DM as a measure of diabetes-specific HRQOL in addition to whether children's overall ratings of their own diabetes-specific HRQOL are in agreement with their caregiver's ratings of their children's HRQOL. This study also examined if diabetes-specific HRQOL is different based on the ethnicity of the children and if children's glycemic control is related to diabetes-specific HRQOL.

Research Question 1

As hypothesized, the self-report and parent-proxy reports of the U.S. English version of the PedsQL 3.2 DM did not measure the five domains of diabetes-specific HRQOL in children with diabetes put forth by Varni et al. (2013), regardless of the rater (self or parent proxy). When five factors were extracted via principal axis factor analysis, multiple cross-loadings occurred within the self-report and the factor extraction between the self- and parent-proxy reports were incongruent, suggesting that the extracted factor structures are not stable and should not be accepted. An analysis of the correlation matrix for the self-report revealed that items Ds7 (I go low), Ds8 (I go high), Txx3 (It is hard for me to exercise or do sports), and Txx6 (It is hard for me to snack when I go low) were weakly related to the majority of the other items within the measure ($r < 0.30$ with all items except two for items Ds7, Ds8, and Txx3; $r < 0.30$ with all items except one for item Txx6). The correlation matrix for the parent-proxy report revealed that item Txx6 was weakly related to the majority of the other items within the measure

($r < 0.30$ with all items except one). The elimination of item Txx6 may improve the stability of the factor structure, but it is unlikely to improve it to such a degree that the resulting five-factor structures capture the five domains put forth by Varni et al. (2013) and that the resulting five-factor structures are the same across the self- and parent-proxy reports.

As hypothesized, a single-factor solution was supported, regardless of the rater (self or parent proxy). Nansel et al. (2008) and Lawrence et al. (2012) found support for a single-factor structure with the previous version of the PedsQL DM, the PedsQL DM 3.0. Given the support for a single-factor structure, the use of the total score on the PedsQL 3.2 DM is appropriate. Estimates of internal consistency reliability of the total score for the self- and parent-proxy reports exceeded the reliability threshold of $\alpha \geq 0.70$ that is needed to be deemed internally consistent and to be used for group comparison and approached or matched the reliability threshold of $\alpha \geq 0.90$ that is needed to be deemed internally consistent and to be used on the individual-level (Nunnally & Bernstein, 1994; Varni et al., 2001).

Similar to Nansel et al.'s (2008) findings, a two-factor solution showed promise for both the self- and parent-proxy reports. On the self-report, all items loaded onto two factors except for item Ds7. All of the items within the a priori About My Diabetes scale in addition to item Wr2 (I worry about going high) loaded onto one factor while the remaining items loaded onto another. The division of items onto factors on the parent-proxy report was clearer: all of the items within the a priori About My Diabetes scales loaded onto one factor and the remaining items loaded onto another. Based on a

comparison with the two-factor structures obtained by Nansel at al. (2008) on the self- and parent-proxy reports, the current two-factor structures that were obtained are more uniform across raters and more closely delineate the distinctions between diabetes-specific symptoms and all other aspects of diabetes management. Despite this improvement, neither of the obtained two-factor solutions should be adopted given the inconsistencies across raters. Findings instead support the use of a single-factor solution.

Parallel analyses and Velicer's minimum average partial (MAP) tests were conducted to estimate how many factors should be extracted from the self- and parent-proxy reports. Estimates ranged from 2 to 14 factors, depending on the type analysis. According to the MAP test with the self-report, 2 factors should have been extracted; according to the MAP test with the parent-proxy report, 5 factors should have been extracted. Based on the two-factor solution for the self-report and the five-factor solution for parent-proxy report, the results of the MAP tests seem to fit with the extracted factor structures. On the self-report, all of the items except for one (item Ds7) loaded onto two factors with no cross-loadings. On the parent-proxy report, all of the items except one (item Ds8) mapped onto five factors, with only two items cross-loading. The About My Diabetes items split into two factors; the Treatment I and Treatment II items all loaded onto one factor except items Tx3 (I am embarrassed by my diabetes treatment) and Tx4 (My parents and I argue about my diabetes care), which loaded onto a factor with the Communication scale items; and the fifth factor included the three items from the Worry scale. It may be that the a priori domains are more

salient for parents than for children in terms of thinking about diabetes symptom-presentation and management, resulting in a closer approximation of the a priori domains on the parent-proxy report than on the self-report.

Inadequate sample size did not permit for exploratory factor analyses to be conducted for those children with type 1 and type 2 diabetes or for those who completed the U.S. English version or U.S. Spanish version within each rater subgroup (self and parent proxy). Additional principal axis factor analyses were not conducted based on the estimations of factors-to-be-extracted via parallel analyses. Extracting a minimum of 9 factors carries no clinical and practical significance given the content of the items within the PedsQL 3.2 DM.

Given the varied estimates produced by the parallel analyses and the Velicer's MAP tests and the incongruence between the five-factor solutions of the self- and parent-proxy reports, only repeat principal axis factor analyses extracting single- and two-factor solutions were conducted for non-Hispanics and Hispanics within each rater subgroup (self and parent proxy). The single-factor solutions for the self- and parent-proxy reports obtained regardless of the ethnicity of the participants was not replicated when separate single-factor solutions were extracted for non-Hispanics and Hispanics. The two-factor solution for the self-report obtained regardless of the ethnicity of the participants was not replicated when separate two-factor solutions were extracted for non-Hispanics and Hispanics. The two-factor solution for the parent-proxy report obtained regardless of the ethnicity of the participants was replicated when a two-factor solution was extracted for non-Hispanics but not for Hispanics. For both the self- and

parent-proxy reports with Hispanics, the two-factor solutions showed factor loadings that were more discrepant from those produced with the entire sample than did the two-factor solutions generated with the self- and parent-proxy reports with non-Hispanics.

These additional analyses within each rater subgroup for non-Hispanics and Hispanics were conducted for exploratory purposes, at best, and were statistically inappropriate, at worst. Best statistical practice suggests that a comparison of the stability of factor structures between groups should be analyzed via confirmatory factor analysis and not multiple exploratory factor analyses. Therefore, the aforementioned results of the exploratory analyses for non-Hispanics and Hispanics within each rater subgroup (self and parent proxy) should be interpreted with extreme caution. If more data are collected from Hispanic participants, the increase in sample size combined with an improvement in the communality values may improve the stability of the factor structure across non-Hispanics and Hispanics. Once it is decided that a certain factor-structure will be used, moving forward, comparisons of the factor structures across groups such as diabetes diagnosis, language of the measure, ethnicity of the participants, etc. should be completed with confirmatory factor analysis.

Research Question 2

As hypothesized, children's overall ratings of their own diabetes-specific HRQOL and their caregivers' ratings of their children's diabetes-specific HRQOL reflected moderate agreement, according to Landis and Koch's (1977) guidelines. Due to inadequate sample size, it is unknown if the strength of this agreement changed for children with type 1 or type 2 diabetes or if the strength of this agreement changed for

the U.S. English version and the U.S. Spanish version. Also as hypothesized, the strength of the agreement was not significantly different depending on the ethnicity of the children. All of the children and caregivers within the total sample, all non-Hispanic children and caregivers, and all Hispanic children and caregivers demonstrated moderate agreement regarding their ratings of the children's HRQOL. These findings replicate those found by Abdul-Rasoul et al. (2012) with the PedsQL 3.0 DM in Arabic.

Moderate agreement between children's and caregivers' ratings of children's diabetes-specific HRQOL support Matza et al.'s (2004) and Varni et al.'s recommendation (2005) that capturing both children's and caregivers' perceptions of children's HRQOL when possible may be the most comprehensive choice when determining treatment conceptualization and changes. Yi-Frazier et al. (2016) also advocated for gathering both self- and parent-proxy reports but noted that, when ratings are significantly different, using the self-report may ensure that more concerns are addressed, as she and her colleagues found that youth reported lower ratings of diabetes-specific HRQOL compared to their caregivers. Discrepant ratings between child and caregiver may yield clinically meaningful information, particularly in light of lab results (i.e., HbA1c levels) that shed light on diabetes management. Opportunities for problem-solving and reeducation are ample when HRQOL ratings are disparate and when ratings do not match the necessary level of concern that should be warranted based on the biological markers of disease management. Given the moderate agreement between raters, capturing the perspective of only one rater may attenuate the breadth and depth of the concerns related to HRQOL and thus, possible areas for intervention.

Research Question 3

As hypothesized, diabetes-specific HRQOL within each rater subgroup (self and parent proxy) did not significantly vary based on the ethnicity of the children (non-Hispanic or Hispanic). These findings replicate those of Rhodes et al. (2012). Additional comparisons were not made with the other ethnicities represented in the sample. If sample size permits, an examination of the differences in HRQOL in children with diabetes based on ethnicity (White/non-Hispanic; Black/non-Hispanic; Hispanic/Latino; and Asian/Pacific Islander) would be worthwhile, given previous findings suggesting that children with diabetes of Black/non-Hispanic descent have poorer HRQOL (Hood et al., 2014; Rhodes et al., 2012; Willi et al., 2015). Inadequate sample size did not permit for comparisons of diabetes-specific HRQOL for those children with type 1 and type 2 diabetes or for those who completed the U.S. English version or U.S. Spanish version within each rater subgroup (self and parent proxy).

Research Question 4

As hypothesized, children's glycemic control, as measured by HbA1c levels, was significantly inversely correlated with diabetes-specific HRQOL, as reported by both of the raters, regardless of ethnicity. Children with better glycemic control, as indicated by lower HbA1c levels, had higher diabetes-specific HRQOL, within each rater subgroup (self and parent proxy), similar to the findings of Frøisland et al. (2013); Ingerski et al. (2010) JDRF CGM Study Group (2010); Kalyva et al. (2011); Lawrence et al. (2012); Malik and Koot, (2009); Nansel et al. (2008); Naughton et al. (2008); Reid et al., 2013; Tahirović et al. (2012); van Bussel et al. (2013); Varni et al. (2003); Varni et al. (2013).

When this relation was analyzed separately among non-Hispanics and Hispanics, the significance of the relation was only retained among non-Hispanics completing the self-report. Despite this finding, a comparison of the strength of the relations between glycemic control and diabetes-specific HRQOL between non-Hispanics and Hispanics revealed non-significant differences. Inadequate sample size did not allow for it to be determined if the strength of this relation was significantly different for children with type 1 or type 2 diabetes or for those who completed the U.S. English version of the measure or those who completed the U.S. Spanish version of the measure, within each rater subgroup (self and parent proxy). The lack of significant difference of the strength of the relation between non-Hispanics and Hispanics adds to the existing literature base related to glycemic control and diabetes-specific HRQOL, as previous researchers have not examined differences in the strength of this relation based on ethnicity. If a stratified sample could be obtained among the participants based on ethnicity, further analyses could be conducted to determine if the strength of this relation is significantly different among ethnic groups beyond just the non-Hispanic and Hispanic distinction.

Implications, Limitations, and Future Directions

Despite improvement in diabetes management over the past half century, managing all aspects of the illness remains a demanding, time-consuming, physically-, emotionally-, and socially-taxing process. Teasing apart which aspects of a child's diabetes management (the presence of symptoms, treatment demands, worry about the illness, and communication with providers) most prominently contribute to a child's diabetes-specific quality of life could not be determined in this investigation. However,

while the two-factor solutions were not completely supported, an analysis of the variance explained by the factors suggest that the majority of the variance is explained by the items related to the presence of diabetes symptoms. The additional items add to the variance explained and may be of clinical import on the individual level but the additional domains purportedly captured by the PedsQL 3.2 DM contribute less to HRQOL than do the actual diabetes-symptoms.

In line with the WHO's (1993), Matza et al.'s (2004), and Varni et al.'s (2005) recommendations, the use of a general, non-disease-specific HRQOL measure should be used in conjunction with a disease-specific module in order to allow for both inter-illness and intra-illness comparisons. An analysis of the results of the PedsQL 4.0 GCS in relation to the PedsQL 3.2 DM was not the focus of this study, as this study's focus was primarily on the psychometric properties of the PedsQL 3.2 DM. Future studies comparing the relationship between glycemic control and HRQOL as measured by the total score and the scales of the PedsQL 4.0 GCS, which have been validated in numerous studies and have been shown to be related to glycemic control (Varni et al., 2003), may shed more light regarding the HRQOL of children with diabetes in multiple domains that the PedsQL 3.2 DM is not sensitive enough to measure. Internal consistency reliability estimates suggest that the potential exists for results on the PedsQL 3.2 DM to be used to compare quality of life across groups (e.g., type 1 diabetes and type 2 diabetes).

With the push for more integrated care in pediatric settings and evidence of the treatment and cost benefits of integrating behavioral medicine and traditional medical

care (Asarnow, Rozenman, Wiblin, & Zeltzer, 2015; Blount et al., 2007; Katon et al., 2006; Yarbro & Mehlenbeck, 2016), psychology as a discipline is in a position to uniquely contribute to the changing face of the delivery of health-care services. With specific regard to treating children with diabetes, as previously mentioned, the International Society for Pediatric and Adolescent Diabetes (ISPAD) also recommended integrating behavioral health services and traditional medical care (de Wit et al., 2014). A measure like the PedsQL 3.2 DM allows behavioral health professionals to quickly assess for concerns and subsequently, to engage in brief, tailored intervention based on the patient's needs or to advocate for more intensive mental-health interventions. Given the present evidence of the relation between poor glycemic control and poor quality of life and additional evidence that poor diabetes-specific HRQOL has, in part, predicted poor future glycemic control (Hood et al., 2014), improving quality of life may directly play a role in improving the course of a child's diabetes.

As mentioned previously, the inadequate sample size of those with type 2 diabetes prevented several hypotheses from being tested and thus prevented the current findings being generalized to this subgroup. Of the sample included for the current analyses, no intentional effort was made to specifically recruit children with type 2 diabetes. Convenience sampling was conducted from the tertiary care children's hospitals; given that the overwhelming majority of children with diabetes have type 1 diabetes, it is not surprising that that the overwhelming majority of children included in the sample have a primary diagnosis of type 1 diabetes. The homogeneity of the sample regarding primary diabetes diagnosis limits the generalizability of the results. Deliberate

recruitment and inclusion of children with type 2 diabetes and their caregivers in the sample is needed to extend the current findings to those children with type 2 diabetes. With the previously discussed findings that some with type 2 diabetes have poorer HRQOL than those with type 1 diabetes (Naughton et al., 2008; Varni et al., 2003), replicating (or not replicating) these initial findings with a substantial sample with type 2 diabetes can help medical teams determine if those with type 2 diabetes warrant specific treatment modifications and interventions. Ensuring, first, that the single-factor structure holds for those with type 2 diabetes is essential, as the focus groups used to create the PedsQL 3.2 DM revision all had type 1 diabetes (Varni et al., 2013).

Not only was the sample size inadequate for those with type 2 diabetes, but the sample size was also inadequate for those who completed the U.S. Spanish version of the measure. Prior to the beginning of data collection, one of the tertiary care children's hospitals gave assurance it would be able to recruit participants who spoke or had a caregiver who spoke Spanish. During data collection, this site determined they had underestimated the linguistic and ethnic makeup of their patient population, not only reducing the number of Hispanics who were recruited but also virtually eliminating the number of participants who would be able to complete the U.S. Spanish versions of the PedsQL 3.2 DM. As previously discussed, over half of Hispanic children have a parent who does not speak English well (Murphey et al., 2014), highlighting the importance of ensuring that Spanish-speaking caregivers and their children with diabetes be included in future studies involving the PedsQL 3.2 DM to ensure that the U.S. Spanish version of

the PedsQL 3.2 DM adequately captures the needs and functioning of these children and families.

The proportion of Hispanics in the current sample was representative of the proportion of Hispanic children with diabetes in the population of children with diabetes, as estimated by Pettitt et al. (2014) in a sample of 7,695 youth with diabetes. While the current sample size of Hispanics allowed for appropriate statistical analyses to be conducted, increasing the number of Hispanic participants may help to strengthen the current findings as they relate specifically to Hispanics. It is possible that the number of Hispanics was slightly underrepresented given that those families who indicated "Other" as their ethnicity were not asked to delineate their ethnic makeup. Families who endorsed the "Other" distinction may have been part-Hispanic. While the argument can be made that inclusion of these participants in the analyses comparing non-Hispanics and Hispanics may have confounded the results, it is also not known if those who endorsed "Hispanic" are exclusively Hispanic or identify as Hispanic despite being multi-ethnic. Ensuring that the PedsQL 3.2 DM accurately captures the HRQOL of Hispanics is critical, especially in light of the increased risk for diabetes-related health problems in ethnic minority youth, including Hispanics.

Excluding participants whose HbA1c was collected beyond 3 months of completing the measures reduced the number of participants who were included in the current study. Once it was discovered during data collection that some sites were using HbA1c levels that did not reflect current glycemic control, site administrators were asked to obtain a current HbA1c level for subsequent participants. It could be argued

that information from these participants should have been included for the factor analyses of the PedsQL 3.2 DM self- and parent-proxy reports where these values were not needed but not for the analyses involving the relation of HbA1c levels and HRQOL. However, to preserve the uniformity of the sample across analyses, the decision was made to exclude the data from these participants across all analyses.

The data from the 2-7 year-olds who completed the study were also excluded from the current analyses, even though the original design included them as a portion of the projected sample. Given one of the primary aims of the study was to conduct exploratory factor analyses on the self- and parent-proxy reports of the PedsQL 3.2 DM, including versions of the measures that did not contain the same amount of items as the other measures seemed to undermine the core processes involved in exploratory factor analyses. SPSS would have eliminated these measures from the exploratory analyses regardless, because listwise deletions remove cases from analyses when pertinent variables from those cases have missing data. Similar to the situation involving the HbA1c data described above, some may have excluded the information from these participants for the factor analyses of the PedsQL 3.2 DM self- and parent-proxy reports but not for the analyses involving the relation of HbA1c levels and HRQOL. However, to preserve the uniformity of the sample across analyses, the decision was made to exclude the data from these participants across all analyses.

The difference between the self- and parent-proxy reports of the PedsQL 3.2 DM for ages 2-7 and ages 8-18 involves the elimination of item wr3 (worrying about long-term complications from diabetes) from the reports for ages 2-7. During the focus

groups conducted when creating the PedsQL 3.2 DM, it was found that only adults worried about the long-term complications from diabetes (Varni et al., 2013). Despite this finding, the item regarding long-term worry is included on the self- and parent-proxy reports for children ages 8-18 but is not included on the parent-proxy report for children ages 2-7. To ensure consistency among the versions of the modules, it may be beneficial ultimately to decide to eliminate this item entirely or only add it to the parent-proxy report for children of all ages.

Conclusion

As the incidence of diabetes increases across diabetes types and across ethnic groups, so too does the importance of measuring HRQOL in children with chronic illness like diabetes. Results from HRQOL measures like the PedsQL 3.2 DM can influence treatment decisions that affect numerous domains of life beyond just the physiological. The total score on the PedsQL 3.2 DM affords clinicians and researchers alike the opportunity the compare HRQOL in children with diabetes across ethnic groups within this population and to monitor treatment outcomes on an individual basis. Poor diabetes-specific HRQOL has been found to be associated with poor glycemic control, supporting the idea that disease management has implications beyond the physical manifestation of symptoms and that improvements in HRQOL could positively impact the course of a child's diabetes. As the number of Hispanics and Spanish-speakers with and without diabetes continues to grow in the United States, more research is needed to determine if the PedsQL 3.2 DM as it currently stands adequately captures the needs of this substantial subpopulation.

REFERENCES

Abdul-Rasoul, M., AlOtaibi, F., AlMahdi, M., & AlKandari, H. (2012). Reliability and validity of the Arabic version of the PedsQL 4.0 Generic Core Scales and PedsQL 3.0 Diabetes Module. *Journal of Diabetes Mellitus, 2*(3), 301-307. doi:10.4236/jdm.2012.23047

American Diabetes Association. (2014). *A1c and eAg*. Retrieved from http://www.diabetes.org/living-with-diabetes/treatment-and-care/blood-glucose-control/a1c/?loc=lwd-slabnav

Bakas, T., McLennon, S. M., Carpenter, J. S., Buelow, J. M., Otte, J. L., Hanna, K. M., … Welch, J. L. (2012). Systematic review of health-related quality of life models. *Health and Quality of Life Outcomes, 10*, 134. doi:10.1186/1477-7525-10-134

Bitsko, M. J., Bean, M. K., Bart, S., Foster, R. H., Thacker, L., & Francis, G. L. (2013). Psychological treatment improves hemoglobin A1c outcomes in adolescents with type 1 diabetes mellitus. *Journal of Clinical Psychology in Medical Settings, 20*(3), 333-342. doi:10.1007/s10880-012-9350-z

Blount, A., Schoenbaum, M., Kathol, R., Rollman, B. L., Thomas, M., O'Donohue, W., & Peek, C. (2007). The economics of behavioral health services in medical settings: A summary of the evidence. *Professional Psychology: Research and Practice, 38*(3), 290-297. doi:10.1037/0735-7028.38.3.290

Buck, D., Clarke, M., Powell, C., Tiffin, P., & Drewett, R. (2012). Use of the PedsQL in childhood intermittent exotropia: Estimates of feasibility, internal consistency

reliability and parent-child agreement. *Quality of Life Research, 21*(4), 727-736. doi:10.1007/s11136-011-9975-7

Casagrande, S. S., & Cowie, C. C. (2012). Health insurance coverage among people with and without diabetes in the U.S. adult population. *Diabetes Care, 35*(11), 2243–2249. doi:10.2337/dc12-0257

Centers for Disease Control and Prevention [CDC]. (2014). *National diabetes statistics report: Estimates of diabetes and its burden in the United States, 2014*. Atlanta, GA: U.S. Department of Health and Human Services. Retrieved from http://www.cdc.gov/diabetes/pubs/statsreport14/national-diabetes-report-web.pdf

Centers for Disease Control and Prevention [CDC]. (2015). *Basics about diabetes.* Retrieved from http://www.cdc.gov/diabetes/basics/diabetes.html

Costello, A., & Osborne, J. (2005). Best practices in exploratory factor analysis: Four recommendations for getting the most from your analysis. *Practical Assessment, Research & Evaluation, 10*(7), 1-9.

Courtney, M. G. R. (2013). Determining the number of factors to retain in EFA: Using the SPSS R-menu v2.0 to make more judicious estimations. *Practical Assessment, Research & Evaluation, 18*(8), 1-14.

Cremeens, J., Eiser, C., & Blades, M. (2006). Factors influencing agreement between child self-report and parent proxy-reports on the Pediatric Quality of Life Inventory™ 4.0 (PedsQL™) generic core scales. *Health and Quality of Life Outcomes, 4*. doi:10.1186/1477-7525-4-58

Cronbach, L. J. (1951). Coefficient alpha and the internal structure of tests. *Psychometrika, 16*(3), 297-334.

Dabelea, D., Mayer-Davis, E. J., Saydah, S., Imperatore, G., Linder, B., Divers, J., … Hamman, R.F. (2014). Prevalence of type 1 and type 2 diabetes among children and adolescents from 2001 to 2009. *Journal of the American Medical Association, 311*(17), 1778-1786. doi:10.1001/jama.2014.3201

Dabelea, D., Stafford, J. M., Mayer-Davis, E. J., D'Agostino, R. J., Dolan, L., Imperatore, G., … SEARCH for Diabetes in Youth Study Group. (2017). Association of type 1 diabetes vs type 2 diabetes diagnosed during childhood and adolescence with complications during teenage years and young adulthood. *JAMA, 317*(8), 825-835. doi:10.1001/jama.2017.0686

de Wit, M., Delemarre-van de Waal, H. A., Pouwer, F., Gemke, R. J., & Snoek, F. J. (2007). Monitoring health related quality of life in adolescents with diabetes: A review of measures. *Archives of Disease in Childhood, 92*(5), 434-439.

de Wit, M., Pulgaron, E. R., Pattino-Fernandez, A. M., & Delamater, A. M. (2014). Psychological support for children with diabetes: Are the guidelines being met? *Journal of Clinical Psychology in Medical Settings, 21*(2), 190-199. doi:10.1007/s10880-014-9395-2

Ennis, S. R., Ríos-Vargas, M., & Albert, N. G. (2011, May). *The Hispanic population: 2010*. (U.S. Census Brief No. C2010BR-04). Retrieved from http://www.census.gov/prod/cen2010/briefs/c2010br-04.pdf

Fairchild, J. (2015). Changes in management and outcomes for children and adolescents with type 1 diabetes over the last 50 years. *Journal of Paediatrics and Child Health, 51*(1), 122-125. doi:10.1111/jpc.12821

Federal Interagency Forum on Child and Family Statistics. (2014). *America's children: Key national indicators of well-being, 2014, Table POP3*. Retrieved from http://www.childstats.gov/americaschildren/tables/pop3.asp?popup=true

Ferrans, C. E., Zerwic, J. J., Wilbur, J. E., & Larson, J. L. (2005). Conceptual model of health-related quality of life. *Journal of Nursing Scholarship, 37*(4), 336-342. doi:10.1111/j.1547-5069.2005.00058.x

Frøisland, D. G., Graue, M., Markestad, T., Skrivarhaug, T., Wentzel-Larsen, T., & Dahl-Jørgensen, K. (2013). Health-related quality of life among Norwegian children and adolescents with type 1 diabetes on intensive insulin treatment: A population-based study. *Acta Paediatrica, 102*(9), 889-95. doi:10.1111/apa.12312

Gallegos-Macias, A. R., Macias, S. R., Kaufman, E., Skipper, B., & Kalishman, N. (2003). Relationship between glycemic control, ethnicity and socioeconomic status in Hispanic and white non-Hispanic youths with type 1 diabetes mellitus. *Pediatric Diabetes, 4*(1), 19-23.

Guo, J., Whittemore, R., Jeon, S., Grey, M., Zhou, Z., He, G., & Luo, Z. (2015). Diabetes self-management, depressive symptoms, metabolic control and satisfaction with quality of life over time in Chinese youth with type 1

diabetes. *Journal of Clinical Nursing, 24*(9/10), 1258-1268. doi:10.1111/jocn.12698

Grey, M., Whittemore, R., & Tamborlane, W. (2002). Depression in type 1 diabetes in children: Natural history and correlates. *Journal of Psychosomatic Research, 53*(4), 907-911. doi:10.1016/S0022-3999(02)00312-4

Hamman, R., Dabelea, D., Bell, R., D'Agostino, R., Dolan, L., Imperatore, G., … SEARCH for Diabetes in Youth Study Group. (2014). The SEARCH for diabetes in youth study: Rationale, findings, and future directions. *Diabetes Care, 37*(12), 3336-3344. doi:10.2337/dc14-0574

Hartman, E., Pawaskar, M., Williams, V., McLeod, L., Dubois, D., Benninga, M., & Joseph, A. (2014). Psychometric properties of PedsQL Generic Core Scales for children with functional constipation in The Netherlands. *Journal of Pediatric Gastroenterology and Nutrition*, *59*(6), 739-747. doi:10.1097/MPG.0000000000000527

Hassan, K., Loar, R., Anderson, B. J., & Heptulla, R. A. (2006). The role of socioeconomic status, depression, quality of life, and glycemic control in type 1 diabetes mellitus. *The Journal of Pediatrics, 149*(4), 526-531. doi:10.1016/j.jpeds.2006.05.039

Herzer, M., & Hood, K. K. (2010). Anxiety symptoms in adolescents with type 1 diabetes: Association with blood glucose monitoring and glycemic control. *Journal of Pediatric Psychology, 35*(4), 415–425. doi:10.1093/jpepsy/jsp063

Hilliard, M. E., Lawrence, J. M., Modi, A. C., Anderson, A., Crume, T., Dolan, L. M., … SEARCH for Diabetes in Youth Study Group. (2013). Identification of minimal clinically important difference scores of the Pediatric Quality of Life Inventory in children, adolescents, and young adults with type 1 and type 2 diabetes. *Diabetes Care, 36*(7), 1891–1897. doi:10.2337/dc12-1708

Hood, K. K., Beavers, D. P., Yi-Frazier, J., Bell, R., Dabelea, D., Mckeown, R. E., & Lawrence, J. M. (2014). Psychosocial burden and glycemic control during the first 6 years of diabetes: Results from the SEARCH for Diabetes in Youth study. *The Journal of Adolescent Health, 55*(4), 498-504. doi:10.1016/j.jadohealth.2014.03.011

Horn, J. L. (1965). A rationale and test for the number of factors in factor analysis. *Psychometrika, 30*(2), 179-185. doi: 10.1007/BF02289447

Ingerski, L. M., Laffel, L., Drotar, D., Repaske, D., & Hood, K. K. (2010). Correlates of glycemic control and quality of life outcomes in adolescents with type 1 diabetes. *Pediatric Diabetes, 11, 563*–571. doi:10.1111/j.1399-5448.2010.00645.x

Jacobsen, J. J., Black, M. H., Li, B. H., Reynolds, K., & Lawrence, J. M. (2014). Race/ethnicity and measures of glycaemia in the year after diagnosis among youth with type 1 and type 2 diabetes mellitus. *Journal of Diabetes and its Complications, 28*(3), 279-285. doi:10.1016/j.jdiacomp.2014.01.010

Jafari, P., Forouzandeh, E., Bagheri, Z., Karamizadeh, Z., & Shalileh, K. (2011). Health related quality of life of Iranian children with type 1 diabetes: Reliability and validity of the Persian version of the PedsQL Generic Core Scales and Diabetes

Module. *Health and Quality of Life Outcomes, 9*, 104. doi:10.1186/1477-7525-9-104

Johnson, S. R., Cooper, M. N., Davis, E. A., & Jones, T. W. (2013). Hypoglycaemia, fear of hypoglycaemia and quality of life in children with Type 1 diabetes and their parents. *Diabetic Medicine: A Journal of the British Diabetic Association, 30*(9), 1126-1131. doi:10.1111/dme.12247

Jönsson, L., Lundqvist, P., Tiberg, I., & Hallström, I. (2015). Type 1 diabetes - impact on children and parents at diagnosis and 1 year subsequent to the child's diagnosis. *Scandinavian Journal of Caring Sciences, 29*(1), 126-135. doi:10.1111/scs.12140

Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group [JDRF CGM Study Group]. (2010). Quality-of-life measures in children and adults with type 1 diabetes: Juvenile Diabetes Research Foundation continuous glucose monitoring randomized trial. *Diabetes Care, 33*(10), 2175-2177. doi:10.2337/dc10-0331

Kalyva, E., Malakonaki, E., Eiser, C., & Mamoulakis, D. (2011). Health-related quality of life (HRQoL) of children with type 1 diabetes mellitus (T1DM): Self and parental perceptions. *Pediatric Diabetes, 12*(1), 34–40. doi:10.1111/j.1399-5448.2010.00653.x

Katon, W., Unützer, J., Fan, M. Y., Williams, J. W., Jr., Schoenbaum, M., Lin, E. H. B., … Hunkeler, E. M. (2006). Cost-effectiveness and net benefit of enhanced

treatment of depression for older adults with diabetes and depression. *Diabetes Care, 29*(2), 265-270. doi:10.2337/diacare.29.02.06.dc05-1572

Kenzik, K. M., Tuli, S. Y., Revicki, D. A., Shenkman, E. A., & Huang, I. (2014). Comparison of 4 pediatric health-related quality-of-life instruments: A study on a Medicaid population. *Medical Decision Making, 34*(5), 590-602. doi:0.1177/0272989X14529846

Kunz, J., Hommel, K., & Greenley, R. (2010). Health-related quality of life of youth with inflammatory bowel disease: A comparison with published data using the pedsql 4.0 generic core scales. *Inflammatory Bowel Diseases, 16*(6), 939-946.

Landis, J. R., & Koch, G. G. (1977). The measurement of observer agreement for categorical data. *Biometrics, 33*(1), 159-174.

Lawrence, J. M., Yi-Frazier, J. P., Black, M. H., Anderson, A., Hood, K., Imperatore, G., … SEARCH for Diabetes in Youth Study Group. (2012). Demographic and clinical correlates of diabetes-related quality of life among youth with type 1 diabetes. *The Journal of Pediatrics, 161*(2), 201-207. doi:10.1016/j.jpeds.2012.01.016

Limbers, C. A, Newman, D. A., & Varni, J. W. (2008a). Factorial invariance of child self-report across age subgroups: A confirmatory factor analysis of ages 5 to 16 years utilizing the PedsQL 4.0 Generic Core Scales. *Value in Health, 11*(4), 659-668. doi:10.1111/j.1524-4733.2007.00289.x

Limbers, C. A, Newman, D. A., & Varni, J. W. (2008b). Factorial invariance of child self-report across healthy and chronic health condition groups: A confirmatory

factor analysis utilizing the PedsQLl 4.0 Generic Core Scales. *Journal of Pediatric Psychology, 33*(6), 630–639. doi:10.1093/jpepsy/jsm131

Limbers, C. A, Newman, D. A., & Varni, J. W. (2008c). Factorial invariance of child self-report across socioeconomic status groups: A multigroup confirmatory factor analysis utilizing the PedsQL 4.0 Generic Core Scales. *Journal of Behavioral Medicine, 31*(5), 401-411. doi:10.1007/s10865-008-9166-3

Lukács, A., Varga, B., Kiss-Tóth, E., Soós, A., & Barkai, L. (2014). Factors influencing the diabetes-specific health-related quality of life in children and adolescents with type 1 diabetes mellitus. *Journal of Child Health Care, 18*(3), 253–260. doi:10.1177/1367493513486964

MacCallum, R. C., Widaman, K. F., Zhang, S., & Hong, S. (1999). Sample size in factor analysis. *Psychological Methods, 4*(1), 84-99. doi:10.1037/1082-989X.4.1.84

Main, A., Wiebe, D. J., Croom, A. R., Sardone, K., Godbey, E., Tucker, C., & White, P. C. (2014). Associations of parent–adolescent relationship quality with type 1 diabetes management and depressive symptoms in Latino and Caucasian youth. *Journal of Pediatric Psychology, 39*(10), 1104-1114. doi:10.1093/jpepsy/jsu062

Malik, J. A., & Koot, H. M. (2009). Explaining the adjustment of adolescents with type 1 diabetes: Role of diabetes-specific and psychosocial factors. *Diabetes Cares, 32*(5), 774-779. doi:10.2337/dc08-1306

Matza, L. S., Swensen, A. R., Flood, E. M., Secnik, K., Leidy, N. K. (2004). Assessment of health-related quality of life in children: A review of conceptual,

methodological, and regulatory issues. *Value in Health, 7*(1), 79-92. doi:10.1111/j.1524-4733.2004.71273.x

McGraw, K. O., & Wong, S. P. (1996). Forming inferences about some intraclass correlation coefficients. *Psychological Methods, 1*(1), 30-46. doi:10.1037/1082-989X.1.1.30

Moreira, H., Frontini, R., Bullinger, M., & Canavarro, M. C. (2014). Family cohesion and health-related quality of life of children with type 1 diabetes: The mediating role of parental adjustment. *Journal of Child and Family Studies, 33*(2), 347-359. doi:10.1007/s10826-013-9758-6

Murphey, D.., Guzman, L., & Torres, A. (2014). *America's Hispanic children: Gaining ground, looking forward.* (Publication No. 2014-38). Retrieved from http://www.childtrends.org/wp-content/uploads/2014/09/2014-38AmericaHispanicChildren.pdf

Nansel, T. R., Weisberg-Benchell, J., Wysocki, T., Laffel, L., Anderson, B., & Steering Committee of the Family Management of Diabetes Study. (2008). Quality of life in children with type 1 diabetes: A comparison of general and diabetes-specific measures and support for a unitary diabetes quality-of-life construct. *Diabetic Medicine, 25*(11), 1316-1323. doi:10.1111/j.1464-5491.2008.02574.x

Naughton, M. J., Ruggiero, A. M., Lawrence, J. M., Imperatore, G., Klingensmith, G. J., Waitzfelder, B., … SEARCH for Diabetes in Youth Study Group. (2008). Health-related quality of life of children and adolescents with type 1 or type 2

diabetes mellitus: SEARCH for Diabetes in Youth study. *Archives of Pediatrics and Adolescent Medicine, 162*(7), 649-657. doi:10.1001/archpedi.162.7.649

Nelson, E. C., Landgraf, J. M., Hays, R. D., Wasson, J. H., & Kirk, J. W. (1990). The functional status of patients: How can it be measured in physicians' offices? *Medical Care, 28*(12), 1111-1126.

Newman, D. A., Limbers, C. A., & Varni, J. W. (2010). Factorial invariance of child self-report across English and Spanish language groups in a Hispanic population utilizing the PedsQL 4.0 Generic Core Scales. *European Journal of Psychological Assessment, 26*(3), 194–202. doi:10.1027/1015-5759/a000026

Nunnally, J. C., & Bernstein, I. R. (1994). *Psychometric theory*. New York: McGraw-Hill.

O'Connor, B. P. (2000). SPSS and SAS programs for determining the number of components using parallel analysis and Velicer's MAP test. *Behavior Research Methods, Instrumentation, and Computers, 32*, 396-402.

Ogden, C. L., Carroll, M. D., Kit, B. K., & Flegal, K. M. (2012). Prevalence of obesity and trends in body mass index among US children and adolescents, 1999-2010. *The Journal of the American Medical Association, 307*(5), 483-90. doi:10.1001/jama.2012.40

Onge, E. S., Miller, S. A., Motycka, C., & DeBerry, A. (2015). A review of the treatment of type 2 diabetes in children. *The Journal of Pediatric Pharmacology and Therapeutics (JPPT), 20*(1), 4–16. doi:10.5863/1551-6776-20.1.4

Pettitt, D. J., Talton, J., Dabelea, D., Divers, J., Imperatore, G., Lawrence, J. M., … SEARCH for Diabetes in Youth Study Group. (2014). Prevalence of Diabetes in U.S. Youth in 2009: The SEARCH for Diabetes in Youth Study. *Diabetes Care, 37*(2), 402-408. doi:10.2337/dc13-1838

Petitti, D. B., Klingensmith, G. J., Bell, R. A., Andrews, J. S., Dabelea, D., Imperatore, G. G., … SEARCH for Diabetes in Youth Study Group. (2009). Glycemic control in youth with diabetes: The SEARCH for Diabetes in Youth Study. *The Journal of Pediatrics, 155*(5), 668-672.e1-3. doi:10.1016/j.jpeds.2009.05.025

Prendergast, C., & Gidding, S. (2014). Cardiovascular risk in children and adolescents with type 2 diabetes mellitus. *Current Diabetes Reports, 14*(2). doi:10.1007/s11892-013-0454-0

Ravens-Sieberer, U., & Bullinger, M. (1998). Assessing health-related quality of life in chronically ill children with the German KINDL: First psychometric and content analytical results. *Quality of Life Research, 7*(5), 399-407.

Ravens-Sieberer, U., Gosch, A., Rajmil, L., Erhart, M., Bruil, J., Duer, W., … Kidscreen Group E. (2005). KIDSCREEN-52 quality-of-life measure for children and adolescents. *Expert Review of Pharmaeconomics & Outcomes Research, 5*(3), 353-364. doi:10.1586/14737167.5.3.353

Reid, A. M., Balkhi, A. M., St. Amant, J., McNamara, J. H., Silverstein, J. H., Navia, L., & Geffken, G. (2013). Relations between quality of life, family factors, adherence, and glycemic control in pediatric patients with type 1 diabetes

mellitus. *Children's Health Care, 42*(4), 295-310. doi:10.1080/02739615.2013.842455

Reynolds, K. A., & Helgeson, V. S. (2011). Children with diabetes compared to peers: Depressed? Distressed? *Annals of Behavioral Medicine, 42,* 29-41. doi:10.1007/s12160-011-9262-4

Rhodes, E. T., Goran, M. I., Lieu, T. A., Lustig, R. H., Prosser, L. A., Songer, T. J., … Laffel, L. M. (2012). Health-related quality of life in adolescents with or at risk for type 2 diabetes mellitus. *The Journal of Pediatrics, 160*(6), 911-917. doi:10.1016/j.jpeds.2011.11.026

Rodriguez, B. L., Fujimoto, W. Y., Mayer-Davis, E. J., Imperatore, G., Williams, D. E., Bell, R. A., … Linder, B. (2006). Prevalence of cardiovascular disease risk factors in U.S. children and adolescents with diabetes: The SEARCH for Diabetes in Youth study. *Diabetes Care, 29*(8), 1891-1896. doi:10.2337/dc06-0310

Rosenbaum, M., Fennoy, I., Accacha, S., Altshuler, L., Carey, D., Holleran, S., … Levine, R. (2013). Racial/Ethnic differences in clinical and biochemical type 2 diabetes mellitus risk factors in children. *Obesity, 21*(10), 2081-2090. doi:10.1002/oby.20483

Rubenstein, L. V., Calkins, D. R., Young, R. T., Cleary, P. D., Fink, A., Kosecoff, J., … Brook, R. H. (1989). Improving patient function: A randomized trial of functional disability screening. *Annals of Internal Medicine, 111*(10), 836-842. doi:10.7326/0003-4819-111-10-836

Sand, P., Kljajić, M., Schaller, J., & Forsander, G. (2012). The reliability of the health related quality of life questionnaire PedsQL 3.0 Diabetes Module for Swedish children with type 1 diabetes. *Acta Paediatrica, 101*(8), e344-e349. doi:10.1111/j.1651-2227.2012.02706.x

Schneiderman, N., Llabre, M., Cowie, C. C., Barnhart, J., Carnethon, M., Gallo, L. C., … Aviles-Santa, M. L. (2014). Prevalence of diabetes among Hispanics/Latinos from diverse backgrounds: The Hispanic Community Health Study/Study of Latinos (HCHS/SOL). *Diabetes Care, 37*, 2233–2239. doi:10.2337/dc13-2939

Schwartz, D. D., Wasserman, R., Powell, P. W., & Axelrad, M. E. (2014). Neurocognitive outcomes in pediatric diabetes: A developmental perspective. *Current Diabetes Report*, *14*(10). doi:10.1007/s11892-014-0533-x

Shepard, J. A., Vajda, K., Nyer, M., Clarke, W., & Gonder-Frederick, L. (2014). Understanding the construct of fear of hypoglycemia in pediatric type 1 diabetes. *Journal of Pediatric Psychology*, *39*(10), 1115–1125. doi:10.1093/jpepsy/jsu068

Stahl, A., Straßburger, K., Lange, K., Bächle, C., Holl, R. W., Giani, G., & Rosenbauer, J. (2012). Health-related quality of life among German youths with early-onset and long-duration type 1 diabetes. *Diabetes Care, 35*(8), 1736-1742. doi:10.2337/dc11-2438

Starfield, B., Riley, A. W., Green, B. F., Ensminger, M. E., Ryan, S. A., Kelleher, K., … Vogel, K. (1995). The adolescent child health and illness profile: A population-based measure of health. *Medical Care, 33*(5), 553-566.

Sundberg, F., Sand, P., & Forsander, G. (2014). Health-related quality of life in preschool children with type 1 diabetes. *Diabetic Medicine, 32*(1), 116-119. doi:10.1111/dme.12557

Tabachnick, B. G., & Fidell, L. S. (6th Ed.) (2013). *Using multivariate statistics*. Boston: Pearson/Allyn & Bacon.

Tahirović, H., Toromanović, A., Tahirović, E., Begić, H., & Varni, J. W. (2012). Health-related quality of life and metabolic control in children with type 1 diabetes mellitus in Bosnia and Herzegovina. *Collegium Antropologicum, 36*(1), 117-121.

Thompson, B. (2004). Exploratory and confirmatory factor analysis: Understanding concepts and applications. Washington, DC: American Psychological Association.

Tirosh, A., Shai, I., Afek, A., Dubnov-Raz, G., Ayalon, N., Gordon, B., … Rudich, A. (2011). Adolescent BMI trajectory and risk of diabetes versus coronary disease. *The New England Journal of Medicine, 364*(14), 1315-25. doi:10.1056/NEJMoa1006992

U.S. Department of Health and Human Services, National Institute of Diabetes and Digestive and Kidney Diseases. (2014, March). *The A1C test and diabetes* (NIH Publication No. 14–7816). Retrieved from http://www.niddk.nih.gov/health-information/health-topics/diagnostic-tests/a1c-test-diabetes/Pages/index.aspx#15

van Bussel, A., Nieuwesteeg, A., Janssen, E., van Bakel, H., van den Bergh, B., Maas-van Schaaijk, N., … Hartman, E. (2013). Goal disturbance and coping in children with type I diabetes mellitus: Relationships with health-related quality of life and

A1c. *Canadian Journal of Diabetes, 37*(3), *169-74*. doi:10.1016/j.jcjd.2013.02.058

Varni, J. W., Burwinkle, T. M., Jacobs, J. R., Gottschalk, M., Kaufman, F., & Jones, K. L. (2003). The PedsQL in type 1 and type 2 diabetes: Reliability and validity of the Pediatric Quality of Life Inventory Generic Core Scales and Type 1 Diabetes Module. *Diabetes Care, 26*(3), 631-637.

Varni, J. W., Burwinkle, T. M., & Lane, M. M. (2005). Health-related quality of life measurement in pediatric clinical practice: An appraisal and precept for future research and application. *Health and Quality of Life Outcomes, 3*(34). doi:10.1186/1477-7525-3-34

Varni, J. W., Curtis, B. H., Abetz, L. N., Lasch, K. E., Piault, E. C., & Zeytoonjian, A. A. (2013). Content validity of the PedsQL 3.2 Diabetes Module in newly diagnosed patients with type 1 diabetes mellitus ages 8-45. *Quality of Life Research, 22*, 2169–2181. doi:10.1007/s11136-012-0339-8

Varni, J. W., & Limbers, C. A. (2009). The Pediatric Quality of Life Inventory: Measuring pediatric health-related quality of life from the perspective of children and their parents. *Pediatric Clinics of North America, 56*(4):843-63. doi:10.1016/j.pcl.2009.05.016

Varni, J. W., Limbers, C. A., & Burwinkle, T. M. (2007a). How young can children reliably and validly self-report their health-related quality of life?: An analysis of 8,591 children across age subgroups with the PedsQL 4.0 Generic Core Scales. *Health and Quality of Life Outcomes, 5*(1). doi:10.1186/1477-7525-5-1

Varni, J. W., Limbers, C. A., & Burwinkle, T. M. (2007b). Parent proxy-report of their children's health-related quality of life: An analysis of 13,878 parents' reliability and validity across age subgroups using the PedsQL 4.0 Generic Core Scales. *Health and Quality of Life Outcomes, 5*(2). doi:10.1186/1477-7525-5-2

Varni, J. W., Limbers, C. A., Burwinkle, T. M., Bryant, W. P., & Wilson, D. P. (2008). The ePedsQL in type 1 and type 2 diabetes: feasibility, reliability, and validity of the Pediatric Quality of Life Inventory Internet administration. *Diabetes Care, 31*(4), 672-677. doi:10.2337/dc07-2021

Varni, J. W., Limbers, C. A., & Newman, D. A. (2008). Factorial invariance of the PedsQL™ 4.0 Generic Core Scales child self-report across gender: A multigroup confirmatory factor analysis with 11,356 children ages 5 to 18. *Applied Research in Quality of Life*, *3*(2), 137-148. doi:10.1007/s11482-008-9051-9

Varni, J., Limbers, C., & Newman, D. (2009). Using factor analysis to confirm the validity of children's self-reported health-related quality of life across different modes of administration. *Clinical Trials*, *6*(2), 185-195. doi:10.1177/1740774509102309

Varni, J. W., Seid, M., & Kurtin, P. S. (2001). PedsQL 4.0: Reliability and validity of the Pediatric Quality of Life Inventory version 4.0 Generic Core Scales in healthy and patient populations. *Medical Care, 39*(8), 800-812.

Varni, J. W., Seid, M., & Rode, C. A. (1999). The PedsQL: Measurement Model for the Pediatric Quality of Life Inventory. *Medical Care, 37*(2), 126-139.

Varni, J. W., Stucky, B. D., Thissen, D., DeWitt, E. M., Irwin, D. E., Lai, J.-S., … DeWalt, D. A. (2010). PROMIS Pediatric Pain Interference Scale: An item response theory analysis of the Pediatric Pain item bank. *The Journal of Pain : Official Journal of the American Pain Society*, *11*(11), 1109–1119. doi:10.1016/j.jpain.2010.02.005

Velicer, W. F. (1976). Relation between factor score estimates, image scores, and principal component scores. *Educational & Psychological Measurement, 36*, 149-159.

Velicer, W. F., & Fava, J. L. (1998). Effects of variable and subject sampling on factor pattern recovery. *Psychological Methods, 3*(2), 231-251.

Willi, S. M., Miller, K. M., DiMeglio, L. A., Klingensmith, G. J., Simmons, J. H., Tamborlane, W. V., … Lipman, T. H. (2015). Racial-ethnic disparities in management and outcomes among children with type 1 diabetes. *Pediatrics, 135*(3), 424-434. doi:10.1542/peds.2014-1774

Wilson, I. B., & Cleary, P. D. (1995). Linking clinical variables with health-related quality of life: A conceptual model of patient outcomes. *The Journal of American Medical Association, 273,* 59-65.

Wooton, A. K., & Melchior, L. M. (2017). Obesity and type 2 diabetes in our youth: A recipe for cardiovascular disease. *The Journal for Nurse Practitioners*, *13*(3), 222-227. doi:10.1016/j.nurpra.2016.08.035

World Health Organization [WHO]. (1993). *Measurement of QOL in children.* Geneva, Switzerland: World Health Organization, Division of Mental Health.

Yarbro, J., & Mehlenbeck, R. (2016). Financial analysis of behavioral health services in a pediatric endocrinology clinic. *Journal of Pediatric Psychology*, *41*(8), 879-887. doi:10.1093/jpepsy/jsv109

Yi-Frazier, J. P., Hilliard, M. E., Fino, N. F., Naughton, M. J., Liese, A. D., Hockett, C. W., … Lawrence, J. M. (2016). Whose quality of life is it anyway? Discrepancies between youth and parent health-related quality of life ratings in type 1 and type 2 diabetes. *Quality of Life Research: An International Journal of Quality of Life Aspects of Treatment, Care & Rehabilitation*, *25*(5), 1113-1121. doi:10.1007/s11136-015-1158-5

Yong, A. G., & Pearce, S. (2013). A beginner's guide to factor analysis: Focusing on exploratory factor analysis. *Tutorials in Quantitative Methods for Psychology, 9*(2), 79-94.

Zwick, W. R., & Velicer, W. F. (1986). Comparison of five rules for determining the number of components to retain. *Psychological Bulletin, 99*(3), 432-442. doi:10.1037/0033-2909.99.3.432

APPENDIX

PEDSQL™ 3.2 DIABETES MODULE FIELD TEST

MEDICAL CHART REVIEW

Date: _____ / _____ / _____
MM DD YYYY

Data Collection Site:
_____

Participant's 4 Digit Study ID#: ☐☐☐☐

Primary Diabetes Diagnosis: *Please check one*

☐ Type 1 Diabetes Mellitus

☐ Type 2 Diabetes Mellitus

Secondary Diagnosis/Diagnoses: *Please check "Yes" or "No" for each secondary diagnosis*

☐ Yes	☐ No	Autoimmune Thyroid Disease (Circle one: Hypothyroidism/Hyperthyroidism)
☐ Yes	☐ No	Celiac Disease
☐ Yes	☐ No	Hypertension
☐ Yes	☐ No	Nephropathy
☐ Yes	☐ No	Dyslipidemia
☐ Yes	☐ No	ADHD
☐ Yes	☐ No	Asthma
☐ Yes	☐ No	Autism Spectrum Disorder
☐ Yes	☐ No	Intellectual Disability
☐ Yes	☐ No	Other: _____

Date of Diabetes Diagnosis: _____ / _____
(Month) (Year)

OR

Time Since Diagnosis: _____
(Years and months)

Does the patient currently use an insulin pump? *Please check one:*
□ Yes □ No

Does the patient currently use Continuous Glucose Monitoring (CGM)?
Please check one: □ Yes □ No

Most Recent Hemoglobin A1c Level (HbA_{1c}):

Value _____ % Normal range _____ %

Date: _____ / _____ / _____
MM DD YYYY

Most Recent BMI:

Value _____ Percentile _____ %

Date: _____ / _____ / _____
MM DD YYYY

In the past 6 months how many times was the patient seen in an Urgent Care Center, Emergency Department, and/or required hospitalization because of his/her diabetes?

Please circle one: 0 1 2 >3 Unknown

What was the problem (check all that apply)?

□ Ketones □ Diabetic ketoacidosis (DKA)

□ Hypoglycemia (low blood sugars) □ Seizure

□ Other: _____ □ Unknown

Since the patient was diagnosed with diabetes, how many times was the patient seen in an Urgent Care Center, Emergency Department, and/or required hospitalization because of his/her diabetes?

Please circle one: 0 1 2 >3 Unknown

What was the problem (check all that apply)?

□ Ketones □ Diabetic ketoacidosis (DKA)

□ Hypoglycemia (low blood sugars) □ Seizure

□ Other: _____ □ Unknown

Has the patient experienced diabetic ketoacidosis (DKA) since being diagnosed with diabetes (circle one)?

a. Yes (if yes, how many times?) ___ *b.* No *c.* Unknown