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## Evaluating Item Bias and Equitability of the Pediatric Quality of Life Inventory- Diabetes Module 5 Item Version Amongst Income and Racially Diverse Youth Living with Type 1 Diabetes

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EVALUATING ITEM BIAS AND EQUITABILITY OF THE PEDIATRIC QUALITY  
OF LIFE INVENTORY-DIABETES MODULE 5 ITEM VERSION AMONGST  
INCOME AND RACIALLY DIVERSE YOUTH WITH TYPE 1 DIABETES.

by

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A Thesis

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## Abstract

Type 1 Diabetes (T1D) is one of the most common chronic diseases among children in the United States, affecting around 244,000 children and adolescents. In 2014–2015 around 18,200 youth were diagnosed with T1D. T1D requires youth to participate in complex and burdensome health behaviors that can affect health-related quality of life (HRQoL). Measures such as the Pediatric Quality of Life Inventory- Diabetes Module Version 3.2 (PedsQL-DM) are used to determine how T1D has influenced youth and caregivers' daily lives. Recently, a 5-item version of the Pediatric Quality of Life Inventory- Diabetes Module (PedsQL-DMSF5) was developed; however, it is presently unclear if this measure is meaningfully free of bias across varying sociodemographic-illness durations. As such, this study aims to explore the measurement invariance of the PedsQL-DMSF5 across racialized categories (Black/ African American and White), genders, HbA1c, illness duration, and income. Youth with T1D (N= 181, 49% female, 51% male, 56 % African American, age M= 14.6, SD= 1.7, Hba1c M= 10.32, SD= 2.48, Median income = \$30,000 for 152 of the participants) and their caregivers completed the full PedsQL-DM. Youth also completed Diabetes Stress Questionnaire, and their HbA1c and illness duration were obtained through medical record review. Confirmatory Factor Analyses (CFAs) and correlations were conducted in Mplus. Youth and caregiver's report of the youth's T1D-HRQoL provided an excellent fit (RMSEA =.068, 90% CI: .039-.096; CFI=.957, SRMR=.053), acceptable reliability (youth/caregiver omega = .80/.68), and preliminary evidence of validity showed significant correlations of the PedsQL-DMSF5 Y/CG totals with the full 33 item PedsQL:  $r=.85/.84$ , Diabetes Stress:  $r=-.60/-.32.$ , and HbA1c:  $r=.26/-.35$ . There was a significant but small caregiver-youth concordance ( $r=.26$ ).

Youth and Caregiver PedsQL-DM SF5 scores were also found to be invariant at the scalar level across HbA1c, illness duration, gender, and median income, and partially invariant at the scalar level for race once item1 was removed. In families with youth living with type-1 diabetes, the PedsQL- DM SFs show promise to be a psychometrically robust, measure of T1D HRQoL that may be meaningfully free of bias across some sociodemographic and illness-specific categories. Caregiver-youth concordance highlights the importance of obtaining both youth and caregiver perspectives. Further validation suggests that the PedsQL-DM SFs may be a useful, brief, and equitable measure of Health-Related Quality of Life for youth with T1D and their families.

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## **Introduction**

Type 1 Diabetes is a common autoimmune disease among youth under the age of 20 that destroys the pancreas' ability to produce insulin (Lawrence et al., 2021). From 2001 to 2017 the prevalence of youth with Type 1 Diabetes (T1D) increased from 1.48 per 1,000 to 2.15 per 1,000 with an incidence rate of 0.217 per 1,000 (Lawrence et al., 2021). In 2014–2015 around 18,200 youth were diagnosed with T1D (American Diabetes Association, 2022). The SEARCH for Diabetes in Youth study reported that in 13 years (2002 to 2015), there was a 40% increase in risk for T1D incidence amongst non-Hispanic Black/African American children than non-Hispanic White children (Lipman et al., 2021; Petitti et al., 2013). The American Diabetes Association (2018) indicates that the estimated total economic cost of diagnosed diabetes in 2017 was \$327 billion, a 26% increase from the previous estimation in 2012 of \$245 billion (American Diabetes Association, 2018). Low-income/ economically marginalized (LIEM) youth and families are more at risk for poorer health outcomes, with income and self-management activities being a predictor of lower HRQoL (Rechenberg et al., 2014).

## **Diabetes Management and Care**

Managing T1D requires youth and their families to participate in complex health behaviors (monitoring glucose, adhering to a treatment plan, taking insulin, monitoring diet) that can be burdensome financially, emotionally, and physically, and that can affect their health-related quality of life (HRQoL), which is the well-being related to health, physical abilities, social-emotional functioning, and satisfaction with health care (van Duikerken, Snoek, & de Wit, 2020; Varni et al., 2018; Hillard et al., 2020). A multidisciplinary team (endocrinologists, diabetes health educators, dieticians, possibly a psychologist, nurse practitioners, etc) trained to work with youth and their families with Diabetes is essential for the management of T1D. There are a few

main activities that go into managing T1D: diabetes health education, nutrition therapy, physical activity, possibly psychotherapy, and glycemic control monitoring. Through health education, youth and their family will learn self-care skills (how to use equipment, check blood sugar, etc) (American Diabetes Association, 2020).

Individualized nutritional therapy is set in place to help with monitoring carbohydrate intake. Comprehensive nutrition education is provided once a dietitian nutritionist assesses caloric and nutrient intake in relation to weight status and cardiovascular disease risk factors, which helps determine macronutrient choices (American Diabetes Association, 2020). Factors such as family eating habits, allergies/ food sensitivities, religious or cultural norms, finances, physical activity, the patient and family's abilities in numeracy, and much more must be considered when developing the individualized nutrition plan. Around 60 minutes of moderate to intensive aerobic physical activity is recommended daily for youth with T1D, in addition to muscle and bone strengthening activities for at least 3 days per week (American Diabetes Association, 2020). Exercise could cause a short period of hyperglycemia followed by hypoglycemia; thus, education is provided about glycemia patterns before and after physical activity (American Diabetes Association, 2020). During diagnosis and throughout the follow-up appointments youth and their families could be referred to a psychologist/ mental health professional to assess for psychosocial challenges/ barriers to care and family stresses that could impact diabetes management. It is recommended that the psychologist/ mental health professional assess for food security, communication with the treatment team, adherence to the regimen, financial barriers, housing stability, health literacy, family functioning, social/community supports, and social/emotional development (American Diabetes Association, 2020). There are several assessments that can capture some of this information such as the

PedsQL-DM, Psychosocial Assessment Tool (PAT), Diabetes Family Conflict Scale (DFCS), Diabetes Stress Questionnaire (DSQ), and Behavior Assessment System for Children (BASC) just name a few. Appointments with their treatment team are ongoing processes to assess if changes need to be made in their regimen.

As previously stated, youth with T1D should be treated with insulin regimens, insulin could be used through multiple daily injections or continuous subcutaneous insulin infusion (American Diabetes Association, 2020). These activities are set in place to help maintain a Hemoglobin A1c of around 7% or less, which is a key marker of physiological adaptation to T1D (Whittemore et al., 2010). An HbA1c at 7% or less is crucial for decreasing the risk of microvascular complications (nephropathy, neuropathy, and retinopathy) and macrovascular complications (coronary artery disease, stroke, and premature mortality) (Chawla et al., 2016). Unfortunately, there is clear evidence of inequitable health outcomes based on socioeconomic status (SES) and racial/ethnic identities could present challenges to properly managing one's disease (Borschuk & Everhart, 2015; Dhaliwal et al., 2022).

### **Conceptual Model of Childhood Adaptation to T1D**

Whittemore and colleagues (2010) developed the Childhood Adaptation Model to Chronic Illness: Diabetes Mellitus to identify multiple factors that affect children's adaption to T1D (Whittemore et al., 2010). The model suggests three broad constructs influencing the level of adaptation (HbA1c and HRQoL): individual and family characteristics, psychosocial responses, and individual and family responses (Whittemore et al., 2010). When referring to individual and family characteristics these are aspects such as duration of diabetes, gender, socioeconomic status, race/ethnicity, treatment modality, pubertal development, and family environment (Whittemore et al., 2010). Psychosocial responses include factors such as



depressive symptoms (specifically avoidance) and anxiety that could lead to depression, behavioral disorders, and or eating disorders directly affecting HbA1c and HRQoL (Whittemore et al., 2010). A common coping strategy adolescents use is avoidance (which is a depressive symptom), which negatively impacts self-management, glycemic health, and HRQoL (Whittemore et al., 2010). This model focuses on the less severe psychosocial responses (i.e., stress, anxiety, and increased depressive symptoms) specific to T1D management. Individual and family responses represent factors such as family functioning, coping and self-efficacy, and self-management (Whittemore et al., 2010). Family functioning is an important aspect when it comes to managing a chronic illness such as T1D, specifically among adolescents' family conflict regarding diabetes management correlates to higher glycemic levels (Whittemore et al., 2010; Whittemore et al., 2004; Lewin et al., 2005). Family functioning is important for youth and their families to manage a chronic illness such as T1D. Among adolescents' family conflict regarding diabetes management correlates with higher HbA1c and lower HRQoL (Whittemore et al., 2010). It is suggested that coping skills, self-efficacy, family functioning, social competence, and self-management could possibly positively influence psychosocial responses and adaptation, with a reciprocal influence on individual and family responses. In the Childhood Adaptation to T1D Model adaptation is the degree a child and their family responds physically and mentally to diabetes-related stressors (Whittemore et al., 2010).

For the current study, we examined five prominent variables: race/ethnicity, illness duration, gender, socioeconomic status, and HbA1c management effect on youth's adaptation (glycemic control and HRQoL) to T1D (Petitti et al., 2009; Whittemore et al., 2010). In this model individual and family characteristics directly affect adaptation (Whittemore et al., 2010). The American Diabetes Association standards of medical care in Diabetes for children and

adolescents emphasized the need for culturally sensitive and developmentally appropriate tailored diabetes care plans (American Diabetes Association, 2020). For example, taking into consideration families' religious or dietary practices. Further, cultural differences and norms can contribute to the level of involvement in the management of T1D amongst ethnic/racial minority families (Whittemore et al., 2010). Literature has found that Black/ African American and Hispanic youth are made vulnerable to higher HbA1c values compared to white youth with T1D (Delamater et al., 1999; Keenan, et al., 2022; Whittemore et al., 2010).

Individual and family characteristics also account for race/ethnicity, socioeconomic status, illness duration, and gender. There are several factors that have been found to predict HbA1c as well as HRQoL such as identifying as a racial/ethnic minority, longer illness durations (greater than or equal to 2 years), household incomes less than \$25,000, having non-private insurance, lower parental education, older age, and non-two-parent households (Berlin et al., 2019; Petitti et al., 2009). In addition, LIEM youth and families are more at risk for worse health outcomes with some specific predictors such as parents' education status and self-management activities predicting HbA1c, and income and self-management activities predicting HRQoL (Rechenberg et al., 2014). Adaption to a chronic illness such as T1D could be experienced differently amongst ethnic/racial minority communities (Whittemore et al., 2010; Delamater et al., 1999; Keenan, et al., 2022; Berlin et al., 2019; Petitti et al., 2009). We have the PedsQL-DMSF5 measure, but we are not sure if it is reliable and valid for assessing HRQoL amongst ethnic/ racial minority samples with varying illness durations, socioeconomic statuses, genders, and metabolic controls.

### **Importance of Short-Form Screeners**

Due to various factors, psychosocial screenings are not provided/ accessible to all youth

and families. Psychosocial screening is broadly recommended and may be helpful to promote equity in T1D and collect information that could improve HRQoL

(AmericanDiabetesAssociation, 2017; Delamater, de Wit, McDarby, Malik, & Acerini, 2014; Hilliard et al., 2018; Young-Hyman et al., 2016). Questionnaires with many items can be time-consuming and burdensome not only for the families but for the multiple specialists that need time to meet with the families. Healthcare professionals have restricted time when meeting with families which can cause inefficiency within the healthcare setting (Finkelman et al., 2016).

Shorter forms save time, which will allow for the inclusion of more questionnaires from various healthcare professionals to inform clinical care while minimizing families' burden (Keenan et al., 2022). The PedsQL-DM is one of the most internationally valid self-reported measures to assess youth and their family's opinions on their HRQoL (Varni et al., 2018). This assessment is multidimensional, taking into consideration disease-specific factors of that patient's life. There are 33 items consistent on five scales: eleven on diabetes symptoms, four on treatment barriers, seven on treatment adherence, three on worry, and three on communication (Varni et al., 2003).

A large number of items (i.e., 33) may present challenges when multiple and/or rapid assessments are needed, which led to the preliminary development and validation of 5, 10, and 15-item short-form versions of the PedsQL-DM (PedsQL-DMSF; Berlin et al., 2020). The PedsQL-DMSF appears to be psychometrically robust measures of diabetes-specific HRQoL in youth with T1D. Despite the potential benefits, short-form assessments can be more susceptible to having low internal consistency, low full-form correlations, not fitting for different groups of individuals, and clinically limiting the amount of content assessed (Semenkovich et al., 2021). The present study focused on the PedsQL-DMSF5; it is presently unclear if this measure is meaningfully free of bias across youth and families from different races, socioeconomic statuses,

varying illness durations, and metabolic controls. As previously noted, racial and ethnic minorities, as well as LIEM youth endure a disproportionate burden of diabetes and related complications affecting one's HRQoL (Ogunwole & Golden, 2021; Whittemore et al., 2010; Berlin et al., 2019; Petitti et al., 2009; Rechenberg et al., 2014). Thus, leading to the selection of five variables for this study: racialized categories (Black/African American and White), genders, median HbA1c, illness duration, and income. The Childhood Adaptability to T1D Model indicates these five variables being direct predictors of HRQoL.

### **Study Aims**

The aims of the present study are to examine: 1) the overall fit of the PedsQL-DMSF5 2) the measurement invariance of the PedsQL-DMSF5 across race, gender, HbA1c, illness duration, and income, 3) the validity of PedsQL-DMSF5 with youth PedsQL-DM (33 items), caregiver PedsQL-DMSF5, diabetes stress, and HbA1c, and 4) caregiver-youth concordance of PedsQL-DMSF5. It was hypothesized that the PedsQL-DMSF5 would have an overall good fit, measurement invariance across variables at a scalar level, show evidence of validity, and a significant but small caregiver-youth concordance/ association.

## **Methods**

### **Participants and Procedures**

Data were collected from youth (ages 12 to 18 years) with T1D and their caregivers who were recruited for the Predicting Resiliency in Youth with Type 1 Diabetes (PRYDE) study. Both youth and caregivers completed questionnaires regarding socio-demographics, diabetes self-management, psychosocial functioning, and diabetes family conflict (Semenkovich et al., 2021). Before collecting data, the study was approved through the Institutional Review Board (IRB) at Le Bonheur Children's Hospital and the University of Memphis both located in

Memphis, Tennessee. Inclusion criteria were, participants had to be 12–18 years old, speak English, and had T1D for 6 months or more (Semenkovich et al., 2021). Inclusion criteria for caregivers were that they are the legal guardian/ caregiver of a child ages 12-18 years old with T1D and speak English. Youths with a severe developmental disability, pregnant, had cystic fibrosis-related diabetes and/or maturity-onset diabetes of the young, and/or legal guardians who were unable to provide consent were ineligible to participate. Participants and their caregivers that met eligibility criteria were consented and assented in the endocrinology clinic at Le Bonheur Children’s Hospital. Access to youths’ medical records supported the extraction of health-related outcomes (HbA1c). Out of the 220 families that were approached for PRYDE, 195 consented and out of those youth and caregiver dyads 181 completed consent and baseline measures. Refer to Table 1 for sample characteristics and descriptive statistics for all variables. The participants identified as Black/Female (28%), Black/Male (28%) white/Female (21%), and White/Male (23%). The average age was 14.6 (SD= 1.7) average Hba1c was 10.32 (SD= 2.48), and the median income of \$30,000 for 152 participants.

## **Materials and Measures**

### ***Demographics and Diabetes-Related Outcomes***

Age, gender, race/ethnicity, and illness duration were reported by youth and caregiver dyads. Data collection began in 2013 and gender reporting options given to youth were sex-based terms “Male” and “Female”. Currently, we follow inclusive guidelines about distinguishing gender identity and gender expression from sex. Caregivers reported household income and marital status. The youth’s HbA1c was obtained from participants' medical records. Youth and caregivers completed full versions of the PedsQL-DM and other measures (Rybak et al., 2017).

### ***Health-Related Quality of Life***

The Pediatric Quality of Life- Diabetes Module 3.2 (PedsQL-DM) was used to assess diabetes quality of life amongst children and adolescents ages 12-18 years old and their caregivers. The PedsQL-DM is a child self-report and caregiver-proxied self-report measure with 33 items consisting of five domains (diabetes symptoms, treatment barriers, treatment adherence, worry, and communication) evaluating youth and their caregivers' perception of problems related to their diabetes (Varni et al., 2003). The 5-item version was developed after a series of analytical procedures administered on the 15 and 10-item versions. The lowest 10 items in factor loading were dropped for each subscale to create 5 item version. Confirmatory Factor Analyses were used to evaluate the proposed factor structures of a 5, 10, and 15-item version of the PedsQL-DM Short Form (PedsQL-DMSF). Results indicated that the 5, 10, and 15-item short forms were all found to have excellent factor structure and goodness of fit, adequate internal consistencies (youth: .75 to .89, parent: .60 to .91), and high latent correlations with the full scale 33 item version ( $r = .85$  to  $.99$ ).

The 5-item version consists of the following questions: It is hard for me to do everything I need to do to care for my diabetes (treatment barriers), I feel weak (diabetes symptoms), how hard it is to keep up with carbohydrates (treatment adherence), I worry about long-term complications from diabetes (worry), and It is hard for me to tell the doctors and nurses how I feel (communication). Items are scored using a 4-point scale (0: if it is never a problem, 1: if it is almost never a problem, 2: if it is sometimes a problem, 3: if it is often a problem, 4: if it is almost always a problem). After the scores are summed on a scale of 0-100, higher scores indicate a greater quality of life.

### **Diabetes Stress Questionnaire**

The 65-item Diabetes Stress Questionnaire (DSQ) youth self-report measure assesses stressors that are specific to diabetes amongst older children and adolescents (9 to 20 years old) (Delamater et al., 2012). The DSQ evaluates diabetes-specific stressors based on a total score and eight subscales: Diabetes-Worry (“Feeling like there’s too much to do to keep my diabetes in good control”) Averse Interpersonal Effects(“Feeling that nobody really understands what it's like to have diabetes”), Peer Stress (“Having to take an insulin shot when I am with friends”), Parental Stress (“My parents reminding or nagging me about testing my blood or urine”), Self-Care Regimen (“Having to do my diabetes care while I'm away from home”), Diet (“Not being able to snack when I want”), Hyperglycemia (“Being in the hospital for ketoacidosis”), and Hypoglycemia (“Getting symptoms of low blood sugar like shakiness, sweating, hunger or headache”). Items were rated according to the degree of stress on a 4-point Likert scale (0 = not at all; 1 = a little; 2 = pretty much; 3 = very much). Evidence has shown that the DSQ has excellent internal consistency ( $\alpha = 0.97$ ), and criterion validity evidence (Kamody et al., 2014). In addition, the DSQ-65 and DSQ-24 have been found to be invariant across glycemic health, genders, race, grade level, illness duration, and annual income categories (Kamody et al., 2014; Klages et al., 2019).

## **Analytical Plan**

### ***Model Fit***

The present study aimed to assess the overall fit of the PedsQL-DMSF5 and the MI of the 5-item 1-factor model of the PedsQL-DMSF works amongst individuals with different racialized categories, genders, HbA1c, illness duration, and incomes (Figure 1). The analysis was conducted with the youth and caregiver groups to determine the fit of the PedsQL-DMSF5; both youth and caregivers completed full versions of the PedsQL. Invariance analyses using

multigroup Confirmatory Factor Analyses (CFAs) proceed from configural to metric, to scalar invariance as recommended with ordinal indicators (Bowen & Masa, 2015). The grouping variables were race (Black/ African American and White), gender (Female or Male), median income, illness duration, and HbA1cHbA1c. Analyses were conducted through Mplus 8.5.

A variety of indices were evaluated to determine model fit: chi-square, comparative fit index (CFI), Root mean square error of approximation (RMSEA), and Standardized Root Mean Square Residual (SRMR) (Kline, 2015). In the chi-square test, which assesses the difference between the observed sample and the expected population values, we were seeking to have a non-significant p-value and a small chi-square value (Kline, 2015). The CFI compares the fit of the model that was developed with the fit of the null model which assumes no covariance among variables. The CFI ranges from 0-1, values  $>.90$  is a recommendation for marginally adequate fit and a value of 0.95 or above indicates excellent fit (Hu & Bentler, 1999). The RMSEA is a measure of fit that estimates the difference between the population model and the hypothesized model population covariance matrix per degree of freedom (Chen, 2007; Boateng et al., 2018; Cook et al., 2009). An RMSEA value less than or equal to .05 indicate good fit, values between .05 and .08 indicate adequate model fit, and values greater than or equal to .1 indicate poor fit (Browne & Cudeck, 1993). A confidence interval (CI) measures the degree of certainty with the RMSEA as the estimate, on a 90% confidence level. The SRMR measures the average absolute value difference of the model implied against the observed correlations correlation (Chen, 2007; Boateng et al., 2018). The SRMR with a value less than 0.08 is a good fit and values less than .1 are considered adequate (Hu & Bentler, 1999).

### ***Measurement Invariance***

Measurement invariance analysis builds upon the previous level (configural, metric, and



scalar). The configural level determines if the factor structure (item clustering) is equivalent across groups. The metric level determines if factor loadings are equal across groups. The scalar level determines if indicator thresholds/intercepts (and factor loadings) are equal across groups. Each factor model was compared against each other (e.g., metric against configural, scalar against configural, and scalar against metric) to ensure the assessments were rigorous. As each level is built upon the invariant from the previous is constrained (factor loadings are made equivalent across groups, while still allowing the item intercepts to vary freely, etc.) (Bialosiewicz et al., 2013; Lee, 2018). Configural invariance is the baseline model, that determines pattern invariance. During this stage, we evaluated if the same item measured the construct across different multigroup models (Bialosiewicz et al., 2013). Once configural invariance was supported, we moved on to metric invariance. The metric level invariance of the relationship of the factor loadings was evaluated across each group and once achieved, allowed for comparisons using factor correlations/covariances.

Obtaining (metric) invariance of the factor loadings indicates that the construct has the same meaning across each group, suggesting it has the same relationship amongst the groups (Bialosiewicz et al., 2013). During this level, the metric model and the configural model were compared with a scaled chi-square difference test. While the decrement in model fit can be tested across models using the scaled chi-square difference test, the field has shifted from a focus on absolute fit in terms of  $\chi^2$  to a focus on alternative fit indices because  $\chi^2$  is overly sensitive to small, unimportant deviations from a “perfect” model in large samples (Chen, 2007; Cheung & Rensvold, 2002; French & Finch, 2006; Meade, Johnson & Braddy, 2008). As such Cheung and Rensvold’s (2002) criterion of a  $> 0.01$  decrease in CFI for nested MI models. Non-significant difference or CFI change  $< .01$  in the models indicated that the factor loadings are invariant, and

testing will continue to the scalar level.

Scalar invariance builds upon metric invariance by requiring that the scales intercepts (or thresholds with categorical data) be equal across groups. Item intercepts are the predicted item value (or “item proportions”/thresholds) when the latent variable equals zero. The scalar model is compared with the metric model, if there is no significant difference ( $CFI < .01$ ) the measure meets the criteria for scalar invariance, permitting comparisons using factor correlations/covariances and factor means. When non-invariance occurs, this suggests measurement bias and or that additional factors such as cultural norms or development differences affect participants' responses (Bialosiewicz et al., 2013).

Regarding the specific parameterization used for the measurement invariance analyses, items were declared ordinal, and weighted least squares estimation was used with the Theta parameterization, setting the metric of latent variables by fixing the factor loading of the first indicator to one. (Millsap, 2011). In the *configural models*, the remaining factor loadings, factor variances, and thresholds were free across groups, the residual variances were fixed at one in all groups, and factor means were fixed at zero in all groups. *The metric model* had factor loadings constrained to be equal across groups, residual variances fixed at one in one group and free in the other group, and factor means fixed at zero in one group and free in the other group. The first threshold of each item was held equal across groups. The second threshold of the item that was used to set the metric of the factor was held equal across groups. Factor variances were free across groups. *The scalar model* had factor loadings and thresholds constrained to be equal across groups, residual variances fixed at one in one group and free in the other groups, factor means fixed at zero in one group and free in the other groups, and factor variances were free across groups.

### ***Validity Evidence***

When metric invariance was achieved, correlations were conducted to determine evidence of convergent validity between youth PedsQL-DMSF5 with youth and caregiver full 33-item PedsQL-DM, caregiver PedsQL-DMSF5, HbA1c, and DSQ. Evidence of convergent validity suggests that tests that have the same or similar constructs should be highly correlated to one another (Chin & Yao, 2014). We also examined caregiver-youth concordance of the PedsQL-DMSF. It was expected that the PedsQL-DMSF5 will be positively associated with the youth and caregiver full 33-item PedsQL-DM, caregiver PedsQL-DMSF5, DSQ, and HbA1c. In addition, so a significant caregiver-youth concordance/association.

### **Results**

All models were analyzed, on the configural, scalar, and metric levels to determine which has the best model fit. Data were screened before analysis for outliers and missing data. We used the maximum likelihood and weighted least square mean and variance (WLSMV) as our estimators. Before MI was conducted, we assessed the overall fit of the PedsQL-DMSF5. The PedsQL-DMSF5 provided an excellent fit overall: Chi-square = 53.809 (df = 29, p = .0034), RMSEA (0.068, 90% C.I 0.039 - 0.096), SRMR (0.053), and CFI (0.957) (Table 2). Acceptable reliability was found amongst the youth ( $\omega = .80$ ) and caregivers ( $\omega = .68$ ) for the PedsQL-DMSF5. Measurement invariance analyses of the PedsQL-DMSF5 across the five variables: race (Black or African American and White), genders, median HbA1c, illness duration, and income were conducted.

As can be seen in Table 2, measurement invariance analyses indicated that the PedsQL-DMSF5 was found to be invariant on a scalar level for the five variables: HbA1c, illness duration, gender, median income, and race. Although invariance was found on a scalar level for race of all

the scaled chi-square difference tests (SCSDT), the ones for race had the smallest (yet non-significant) p-values (.10, .16, and .27). As such the adjustments were made and measurement invariance analyses were re-conducted for race. From our analysis of the results, it was determined that we had to free the intercepts of item 1 in communication (It is hard for me to tell the doctors and nurses how I feel) due to the loading of that variable amongst the group. Once we switched the item factor loading that was fixed to one to set the latent metric from item 1 in communication (It is hard for me to tell the doctors and nurses how I feel) to worry item 3 (I worry about long-term complications from diabetes), and a partial scalar model (freeing item 1 constraints) was explored (Table 2). This did not result in substantive differences (e.g., Metric against Configural:  $\Delta\text{CFI} = -0.003$ , SCSDT  $p = 0.064$ , Scalar against Metric, and Scalar against Metric:  $\Delta\text{CFI} = -0.010$   $p = 0.331$ ).

Refer to Table 3 for validity correlations between the youth 5-item version of PedsQL-DMSF with youth and parent full 33-item PedsQL-DM, parent 5-item version PedsQL-DMSF, DSQ, and HbA1c. The PedsQL-DMSF5 showed evidence of convergent validity indicating that there were significant correlations of the PedsQL-DMSF5 youth and caregivers totals with the full 33 items PedsQL ( $r = .85$ ,  $p < .000$ ) and Diabetes stress ( $r = .60$ ,  $p < .000$ ). HbA1c ( $r = 0.26$ ,  $p < .000$ ) and Caregiver-youth concordance ( $r = 0.26$ ,  $p < .000$ ) of PedsQL-DMSF5 were significant but weakly correlated.

## **Discussion**

The Childhood Adaptation to T1D Model suggested that race/ethnicity, illness duration, socioeconomic status, HbA1c management, and gender all directly (and indirectly) affect glycemic health and HRQoL, in addition to having a direct effect on psychosocial responses (depression symptoms and anxiety/stress) individual and family responses (coping, self-efficacy,

family functioning) (Whittemore et al., 2010). The current study aimed to examine: 1) the overall fit of the PedsQL-DMSF5 2) the measurement invariance of the PedsQL-DMSF5 across race, gender, HbA1c, illness duration, and income, 3) the validity of PedsQL-DMSF5 with youth PedsQL-DM (33 items), caregiver PedsQL-DMSF5, diabetes stress, and HbA1c, and 4) caregiver-youth concordance of PedsQL-DMSF5. It was hypothesized that the PedsQL-DMSF5 would have measurement invariance across variables, validity evidence, and a significant but small caregiver-youth concordance/ association. This study's results supported our hypothesis that the PedsQL-DMSF5 would have a good overall fit, MI at a scalar level across variables, show evidence of validity, and have a significant but low caregiver-youth concordance. In addition, evidence of validity was found amongst the youth 5-item version of the PedsQL-DMSF and the youth and parent full 33-item PedsQL-DM, parent 5-item version PedsQL-DMSF, the Diabetes Stress Questionnaire, and HbA1c. There was a small but significant caregiver-youth concordance of the PedsQL-DMSF5, highlighting the importance of obtaining youth and caregiver perspectives on HRQoL. This information can lead to further exploration into what exactly is causing the discord in their experiences and how the clinician can aid in bridging the gap.

Some main limitations of this study were that we had relatively a small sample size and we only had participants from two racialized categories. Also, we used structural equation modeling, which is based on classical test theory, when an item response theory (IRT) or a more flexible hybrid approach, such as Moderated Nonlinear Factor Analysis (Bauer, 2017) may be preferred. With an IRT approach, there are several comprised models that provide information for specific items and the scales they contain through the analysis of individual item responses (Langer et al., 2008). This approach has been used with health outcome scale development due to

the ability to identify how items perform across different subgroups (Langer et al., 2008; Hays et al., 2000). The IRT approach through CFA models using “covariates” (i.e., MIMIC variables) can allow for both categorical and continuous variables that might influence means/intercepts, and/or factor loadings (Bauer, 2017; Montoya & Jeon, 2020). Therefore, these approaches could be better suited when assessing HRQoL amongst different subgroups, allowing for the adaptability of the assessment based on that individual’s level of HRQoL.

While the a priori metrics for scalar invariance were met (e.g., non-significant chi-square difference test no CFI decrease  $>0.01$ ), a partially invariant scalar model without constraints on youth item 1 (It is hard for me to tell the doctors and nurses how I feel) was preferred. Partial invariance for this item could suggest that in the future using a different item from the communication subscale that is found to be more invariant could be beneficial. In addition, this could suggest that measurement bias and or that additional factors such as cultural norms or developmental differences affected the participant's responses to that item (Bialosiewicz et al., 2013). The mistrust within the healthcare system stemming for decades and generations could possibly affect how Black/African American youth internalize and respond to this item. In the Childhood Adaptation to T1D Model cultural differences and norms contribute to the self-management practices of children and their families, which is directly correlated to HRQoL and HbA1c (Whittemore et al., 2010). Further research could explore Black/ African American youth with T1D experiences with their healthcare professionals and how cultural norms/ values and/or discrimination affect their relationship with their healthcare team and quality of care. This study has important implications for clinical treatment and research on youth with T1D in marginalized communities. In addition, measures should be modified depending on the validity and reliability of the assessment amongst systematically oppressed populations, to improve their health equity

and quality of life (Keenan et al., 2022).

Systematically oppressed youth (African American/ Black, Latino, Asian/ Pacific Islander, and Navajo) are made vulnerable to higher HbA1c levels, less frequent self-management/treatment regimen consistent behaviors, and higher caregiver and youth stress (Borschuk & Everhart, 2015; Guo, Whittemore, & He, 2011). Social Determinants of Health (SDOH) arising from structural and or system-level rooted inequities are related to worsened diabetes prevalence, glycemic health, and diabetes-related deaths (Ogunwole & Golden, 2020). Literature on SDOH has found associations between social and environmental factors (i.e., neighborhood/ physical environment, food insecurity, limited resources/ supports, and healthcare quality) and additional barriers to care that can affect health outcomes (Hill-Briggs et al., 2020). Communities with insufficient quality, access, and timeliness of care, LIEM communities, children without health insurance, and children with unemployed parents had a higher prevalence of diabetic ketoacidosis when diagnosed as opposed to children who carry financial, vocational, and race-based generational privilege (Usher-Smith et al., 2011; Borschuk & Everhart, 2015).

Future research should examine SDOH factors to recognize the systemic impact of socioeconomic status, neighborhood/ physical environment, food environment, health care, and social context on culturally and ethnically diverse youth and their families with T1D. An additional point that warrants raising is the items on the PedsQL-DM is all reverse coded, which are items/experiences that are “negative” indicators of quality of life. The sole focus on problems and "deficits” when gathering and assessing child and caregiver experience with HRQoL is at odds with equity and strength-based approaches and more balanced alternatives are available (Hilliard et al., 2020; O’Reilly, 2021). Very few questionnaires focus on the positives/ strengths of a medical illness (Hilliard et al., 2017). Hilliard and colleagues (2020) conducted a study to

design and evaluate the psychometric properties of a set of developmentally tailored measures of diabetes specific HRQoL for youth with T1D, called “Type 1 Diabetes and Life” (T1DAL). T1DAL was modeled after the Mind Youth Questionnaire (MY-Q), this questionnaire is a validated measure for diabetes-specific HRQoL (Hilliard et al.,2020). After qualitative interviews from youth and caregiver dyads the research developed items to reflect the themes from the qualitative interviews and previous literature to ensure that T1DAL- adolescents and T1DAL-Children include both strengths and challenges specific to diabetes HRQoL (Hilliard et al.,2020). Results from this study indicated that T1DAL HRQoL measures demonstrated good internal consistency ( $\alpha= 0.84$  and  $0.89$ ) and test–retest reliability ( $r=0.78$  and  $0.80$ ) (Hilliard et al.,2020). There were significant correlations between T1DAL and measures of the general quality of life, PedsQL generic core scale, PedsQL-DM, diabetes burden, and diabetes strengths that demonstrated construct validity (Hilliard et al.,2020). In addition, correlations with measures of self-management and HbA1c demonstrated criterion validity (Hilliard et al.,2020).

Literature has indicated that psychosocial challenges affect HbA1c and a growing need for a strength-based diabetes-specific HRQoL measure (Hilliard et al., 2020). Assessments such as T1DALs give clinicians a more well-rounded view of HRQoL of youth and their families living with T1D that doesn’t just focus on the “negative” aspects of the disease. The Childhood Adaption to T1D Model’s construct on individual and family responses suggests that HRQoL is impacted by caregiver psychosocial factors and the family’s ability to adapt, support, and communicate (Whittemore et al., 2010). Highlighted how adolescents’ family conflict regarding diabetes management correlates to higher HbA1c and HRQoL (Whittemore et al., 2002; Whittemore et al., 2004; Lewin et al., 2005; Laffel et al., 2003). In the present study, 7.8% of participants had an HbA1c of 7% or less. Although HbA1c was found to be invariant and had



significant but low correlations with the youth PedsQL-DMSF more exploration should be done to determine barriers to care that the youth and their families are experiencing that are affecting their glycemic control. Our findings suggest that youth and caregivers' perspectives on HRQoL should be explored more. A family functioning scale and parent stress scale could also be included in that battery of measures that assess HRQoL amongst adolescents and their caregivers with T1D in addition to informing future studies around stress and family functioning amongst adolescents and young adults with T1D.

Although the present study showed that the PedsQL-DMSF5 had measurement invariance for most of the variables, the sample size is relatively small (N =181). While under some circumstances factor analyses with sample sizes ranging from about 35 to 60 participants are appropriate, it is important to note that larger sample sizes are preferable (Wolf, Harrington, Clark, & Miller, 2013). Replication of the present findings with larger samples across the country is also necessary to assess generalizability and invariance amongst the different demographic factors in different regions. Moreover, future studies across the country should assess invariance across other demographics such as race, language, culture, gender, HbA1c, and illness duration to determine if the PedsQL-DMSF5 is adequate in various subgroups. Given that cultural differences and norms contribute to the level of involvement in the management of T1D amongst ethnic/racial minority families (Whittemore et al., 2010). It is important to consider if the PedsQL-DM is perceived the same cross-culturally, considering cultural norms a difference. Currently, in the United States, the PedsQL-DM and generic core scale are only offered in English and Spanish, however, it has been translated to various other languages while still maintaining validity and reliability.

Studies have been conducted looking at translating the PedsQL (4.0) generic core scale

self and caregiver reports for youth ages 8-18years old, from English into various languages such as Arabic and Chinese (Arabiati et al., 2011; Sze et al., 2022). In both studies when the PedsQL generic core scale was adapted to their language of origin they found that the assessment was reliable and valid for both the child and caregiver self-report and had satisfactory psychometric properties (Arabiati et al., 2011; Sze et al., 2022). Multiple studies have been conducted to translate the PedsQL-DM English version to Brazilian Portuguese, Arabic, Italian, and Greek. All studies have been found to be reliable and valid assessments of the quality of life amongst children and their families within their communities, with Cronbach alpha coefficients above 0.7 and (Abul-Rasoul et al., 2012; d'Annunzio et al., 2014; Emmanouilidou et al., 2008; Garcia et al., 2018). These versions presented moderate to medium correlations between the total scores of children's self-report and caregiver self-report scales (Garcia et al., 2018). There was a reoccurring trend for all the translated versions of the PedsQL-DM in the domain's treatment barriers in the child and caregiver reports and treatment adherence in the caregiver's report presented coefficients below 0.70 (Garcia et al., 2018). This could suggest that these domains aren't easily adaptable to allow children and their families from various cultural backgrounds to express their barriers to care which can affect treatment adherence.

A cross-cultural measurement invariance of the PedsQL4.0 generic core scale was conducted to determine the MI among adolescents sampled from Bulgaria, Croatia, India, Indonesia, Nigeria, Serbia, and Turkey (Stevanovic et al., 2015). The study's participants were from different socioeconomic statuses, cultural, and religious backgrounds (Stevanovic et al., 2015). The results found that the PedsQL4.0 generic core scale did not have invariance when evaluated cross-culturally (Stevanovic et al., 2015). Researchers from this study also suggested that an IRT approach could be more beneficial to access MI for the PedsQL 4.0 generic core

scale (Stevanovic et al., 2015). Stevanovic and colleagues (2015) did indicate that even though MI wasn't supported cross-culturally it doesn't mean it shouldn't be used for within-country comparisons, studies have found support for the MI of the PedsQL 4.0 generic module across different cultural backgrounds within the same country (Newman et al., 2010). Although there have been studies indicating the reliability and validity of the PedsQL 4.0 generic core scale and the PedsQL-DM in various countries researchers should proceed with caution when making cross-cultural comparisons of overall HRQoL and Diabetes specific quality of life (Stevanovic et al., 2015).

### **Conclusion**

As we strive to provide culturally sensitive and developmentally appropriate individualized diabetes self-management treatment plans that improve the HRQoL these findings are important to propel those efforts. Findings from this study could suggest that the PedsQL-DMSFs may be a bias-free and equitable measure of HRQoL for youth with T1D and their families from various socio-demographics and with differing illness durations. Psychosocial measures such as the PedsQL-DM should be tailored to the current population you are working with to make it culturally normed. As previously noted, caregiver-youth concordance of the PedsQL-DMSF5 was significant but low. This highlights the importance of obtaining both youth and caregiver perspectives. The cumulation of brief, reliable, and valid assessments that focus on challenges/ stressors to care and diabetes-related strengths regarding health outcomes can allow clinicians to individualize treatment plans for the psychosocial needs of their patients. In addition, further research should be explored to improve different factors in the three constructs of the Child Adaption to T1D Model to continue improving HRQoL amongst ethnic minority children and their families. HRQoL assessments utilizing a strength based and IRT approach

could allow clinicians to tailor treatment plans to balance the challenges and strengths of youth and their families, ultimately improving HRQoL.

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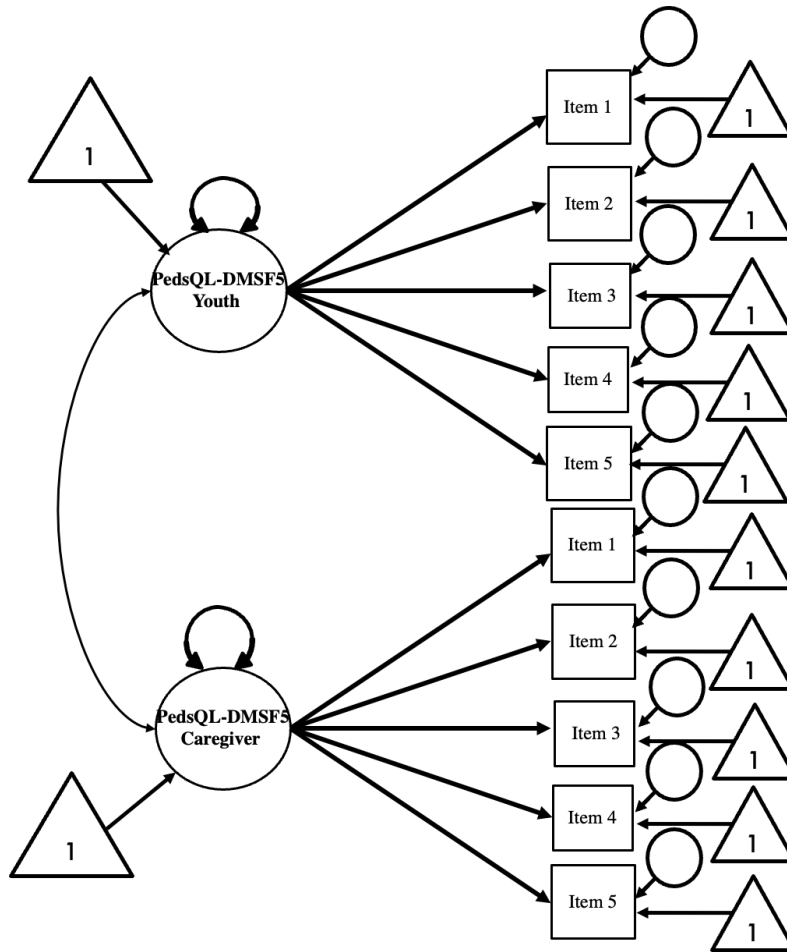
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**Figure 1**

*Conceptual model tested by confirmatory factor analyses (CFA) of the youth and Caregiver*

*Model Fit for the PedsQL-DMSF5 with Race, Illness Duration, HbA1c, Gender, and Income*



**Table 1***Participant characteristics*

Characteristics	Sample
<i>N</i>	181
Youth age (years), <i>M(SD)</i>	14.63, (1.71)
Youth Gender	
Female (%)	49 (27.1%)
African American/ Black (%)	28 (15.5%)
Non-Hispanic White (%)	21 (11.6%)
Male (%)	51 (28.8%)
African American/ Black (%)	28 (15.5%)
Non-Hispanic White (%)	23 (12.7%)
Youth Race	
African American/Black (%)	n = 56 (30.9%)
Non-Hispanic White (%)	n = 44 (24.3%)
Median Income ( <i>n</i> =152), <i>M(SD)</i>	\$35,970 (\$10,130)
20 <sup>th</sup> %	\$7,500
40 <sup>th</sup> %	\$19,000
Median	\$30,000
60 <sup>th</sup> %	\$30,000
80 <sup>th</sup> %	\$70,000
HbA1c mmol/mol, <i>M(SD)</i>	10.32, (2.48)
<i>HbA1c Categories n (%)</i>	
>7.0%	14 (7.8%)
7.1% - 7.4%	10 (5.6%)
7.5% -9.5%	58 (26.7%)
9.6% -13.9%	79 (43.9%)
>14%	29 (16.1%)
Illness duration, years	4.35 (3.50)
Caregiver sex	
Female (%)	84 (84%)
Male (%)	16 (16%)
Caregiver relation, biological (%)	90 (90%)

*Note:* Participant demographics for youth and caregivers for full sample. Data are mean (SD) unless otherwise stated.

**Table 2***Model fit and Invariance Testing of the Pediatric Quality of Life Inventory- Diabetes Module**Version 3.2 (PedsQL-DMSF)*

<b>Model</b>	<b># Free Para- meters</b>	<b>X<sup>2</sup></b>	<b>df</b>	<b>p</b>	<b>CFI</b>	<b>RMSEA (90% CI)</b>	<b>SRMR</b>
PedsQL-DMSF5	56	53.809	29	.003	0.957	.068 (.039 -.039)	.053
<b>Race</b>							
Configural	112	68.872	58	.155	0.981	.047 (0.000 -0.085)	.059
Metric	104	81.327	66	.097	0.973	.052(0.000 -0.086)	.062
Scalar	76	111.705	94	.103	0.968	.047(0.000 -0.077)	.067
Partial Scalar (Item 1)	81	103.247	89	.143	0.975	0.043 (0.000-.075)	.065
Metric against Configural		13.245	8	.104			
Scalar against Configural		44.375	36	.160			
Scalar against Metric		32.013	28	.274			
<b>Median Income</b>							
Configural	112	77.613	58	.044	0.962	.067(0.012- 0.103)	.066
Metric	104	86.909	66	.043	0.960	.065(0.012- 0.099)	.069
Scalar	76	114.094	94	.078	0.961	.053 (0.000 - 0.085)	.075
Metric against Configural	-	10.296	8	.245			
Scalar against Configural	-	39.18	36	.329			
Scalar against Metric	-	28.904	28	.417			
<b>Gender</b>							
Configural	112	88.451	58	.006	0.948	.076 (0.041-0.107)	.068
Metric	104	97.108	66	.008	0.946	.072 (0.038 - 0.102)	.070
Scalar	76	115.337	94	.067	0.963	.05 (0.000 - 0.079)	.073
Metric against Configural	-	9.966	8	.267			
Scalar against Configural	-	30.055	36	.747			
Scalar against Metric	-	19.748	28	.874			
<b>Illness Duration</b>							
Configural	110	107.558	58	<.001	0.911	.106(0.074 - 0.137)	.079
Metric	102	110.684	66	.001	0.920	.095 (0.063 - 0.125)	.080
Scalar	75	129.109	93	.008	0.935	.072 (0.038 - 0.100)	.082
Metric against Configural	-	4.38	8	.821			
Scalar against Configural	-	27.417	35	.816			
Scalar against Metric	-	22.378	27	.718			
<b>HbA1c</b>							
Configural	110	92.448	58	.003	0.940	.082(0.049 - 0.112)	.068
Metric	102	98.523	66	.006	0.944	.075(0.041 - 0.104)	.070
Scalar	75	128.159	93	.009	0.939	.065(0.034 - 0.092)	.074
Metric against Configural	-	8.241	8	.410			
Scalar against Configural	-	42.495	35	.180			
Scalar against Metric	-	34.828	27	.143			

**Table 3**

*Validity correlations between youth 5 item version of PedsQL-DMSF with full youth and parent 5 item version PedsQL-DMSF, HbA1c, and Diabetes Stress Questionnaire*

Variables	r PedsQL Youth 5 item	p
Youth-33 (33 item)	0.85	<0.001
Parent-5 (5 item) *	0.26	<0.001
Parent-33 (33 item)	0.32	<0.001
HbA1c	0.26	<0.001
Diabetes Stress (DSQ)	0.60	<0.001

Note: Variables were reversed coded for Pearson correlation coefficient (r) making them positive. Abbreviations: Youth-33, youth full 33 item version of PedsQL-DM, Parent-5, parent 5 item version of PedsQL-DM, Parent-33, parent full 33 item version of PedsQL-DM, and DSQ, Diabetes Stress Questionnaire (youth).

\*Caregiver-youth concordance