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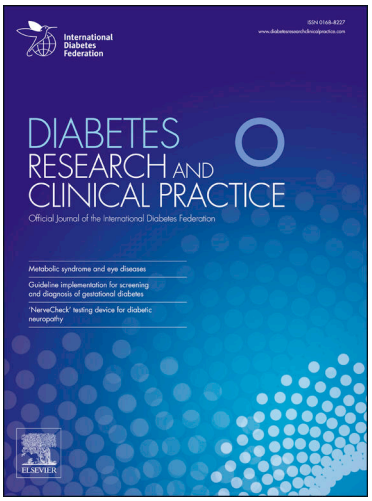

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Design and Psychometrics for New Measures of Health-Related Quality of Life in Adults with Type 1 Diabetes: Type 1 Diabetes and Life (T1DAL)

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Type 1 Diabetes Health-Related Quality of Life

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STRUCTURED ABSTRACT

Aims: To use a three-phase process to develop and validate new self-report measures of diabetes-specific health-related quality of life (HRQOL) for adults with type 1 diabetes. We report on four versions of the Type 1 Diabetes and Life (T1DAL) measure for people age 18-25, 26-45, 46-60, and over 60 years.

Methods: We first conducted qualitative interviews to guide measure creation, then piloted the draft measures. We evaluated psychometric properties at six T1D Exchange Clinic Network sites via completion of T1DAL and validated measures of related constructs. Participants completed the T1DAL again in 4-6 weeks. We used psychometric data to reduce each measure to 23-27 items in length. Finally, we obtained participant feedback on the final measures.

Results: The T1DAL-Adult measures demonstrated good internal consistency (α=0.85-0.88) and test-retest reliability (*r*=0.77-0.87). Significant correlations with measures of general quality of life, generic and diabetes-specific HRQOL, diabetes burden, self-management, and glycemic control demonstrated validity. Factor analyses yielded 4-5 subscales per measure. Participants were satisfied with the final measures and reported they took 5-10 minutes to complete.

Conclusions: The strong psychometric properties of the newly developed self-report T1DAL measures for adults with type 1 diabetes make them appropriate for use in clinical research and care.

Keywords: Patient-reported Outcomes, Quality of life, Psychosocial, Assessment

1. INTRODUCTION

Health-related quality of life (HRQOL) is a recognized patient-reported outcome defined as one's perception of their own well-being with respect to health status, physical functioning, health-related concerns, social and emotional functioning, and treatment satisfaction [1,2]. There is growing consensus about the importance of considering HRQOL and other patient-reported outcomes as key study outcomes in clinical trials [3], particularly in diabetes [4]. Clinically, the American Diabetes Association recommends routine screening and care aimed at improving psychosocial outcomes including HRQOL [5,6]. Thus, it is critical to use psychometrically sound instruments to assess diabetes-specific HRQOL.

Researchers conceptualize diabetes-specific HRQOL in various ways, and use many different measures to capture this construct (or specific aspects of the construct) [7]. Gaps in the availability of validated measures of diabetes-specific HRQOL for adults with type 1 diabetes and characteristics of existing measures limit their utility for research and clinical purposes [2,7-9]. Reviews of diabetes HRQOL measures [2,7-10] have identified common concerns with the conceptual, psychometric, and logistical aspects of existing measures. Conceptually, lack of clarity about what comprises diabetes-specific HRQOL has led to the widespread use of the term to represent many psychosocial or patient-reported outcome measures, even if they do not assess the construct of diabetes-specific HRQOL exactly or in full. For example, several that purport to assess HRQOL actually measure related constructs, such as diabetes distress, diabetes self-management behaviors/barriers, diet, health status, global well-being, and treatment satisfaction [7]. Fisher and colleagues [8] argue that researchers often select measures because others have used them previously, even if the measures do not assess HRQOL accurately or precisely. Using measures that assess patient-reported outcomes that are associated with but not equivalent to HRQOL

confounds HRQOL with other constructs (e.g., physical or emotional functioning, more general quality of life) and results in misleading research conclusions. Thus, it is recommended that researchers select well-designed and psychometrically sound measures that are contemporary, comprehensive, and disease-specific to most precisely measure HRQOL [7,9].

Reviews of existing HRQOL measures in diabetes [2,7-10] also identified problems with psychometrics and measure development. Commonly noted psychometric concerns include that reliability and/or validity data of HRQOL measures were often not reported, or indicated low reliability, validity, or range of scores. Construct validity concerns have been raised for measures that ask participants to rate their HRQOL with diabetes compared to a hypothetical life without diabetes, or that focus on physical symptoms or diabetes treatment burdens without assessing any positive experiences related to HRQOL. Moreover, during measure development, content was typically developed by professionals without adequate input from people with diabetes [1,11]. Many measures blend type 1 and type 2 diabetes, despite differences in disease presentation and treatment. Additionally, very few measures take a developmental approach or recognize potential differences in people's experiences with HRQOL at different periods of the lifespan [9], limiting the ability to track HRQOL over time or at different points in the lifespan. Total or composite scores are often reported, without factor analyses to identify subscales representing conceptually distinct aspects of HRQOL. Logistical concerns include measures that lack options to indicate when particular aspects of HRQOL are not applicable to the respondent and high response burden for measures that are very long or complicated to complete.

Two diabetes-specific HRQOL measures have been recently developed that overcome some of the limitations of previous diabetes-specific HRQOL measures. The Dawn Impact of Diabetes Profile (DIDP) is a brief measure assessing the perceptions of adults (age 18-75) with type 1 or

type 2 diabetes about how much diabetes has impacted their quality of life, with strong psychometric properties [12]. The DIDP includes one item for each of six or seven dimensions of HRQOL: physical health, financial issues, relationships, leisure activities, work or education, emotional well-being, and dietary flexibility (optional). The DIDP addresses both positive and negative impacts of diabetes, and was designed so that a companion version for family members of people with diabetes could be developed. The ViDa1is a 34-item measure of T1D-specific HRQOL with strong psychometrics [13]. There are four subscales derived from factor analysis: interference in everyday life, self-care, well-being, and disease-related worries. The ViDal was validated on people with T1D age 14-71 years of age. Both the DIDP and ViDal are valuable additions to the field of diabetes-specific HRQOL assessment. However, the DIDP is not specific to the experiences of people with T1D and is quite brief, making it well-positioned as an HRQOL screener but potentially limited in its ability to provide a breadth of clinically useful HRQOL information. Neither measure was designed to be developmentally tailored to reflect the unique HRQOL issues of distinct life stages (e.g., young adulthood, older adulthood), which may limit their precision.

Although there are measures that assess aspects of diabetes-specific HRQOL for adults with type 1 diabetes, the limitations of existing measures indicate a need for new measures that add options for HRQOL assessment. Ideally, new HRQOL measures should be brief, clinically relevant, psychometrically sound, and developmentally appropriate, and should precisely assess T1D-specific HRQOL rather than a related construct. Ultimately, clinicians and researchers need to be able to select a well-validated diabetes-specific HRQOL measure that best suits their needs [8,10]. Thus, as part of a larger study, which aimed to design and validate a new set of measures of diabetes-specific HRQOL for both people with type 1 diabetes across the lifespan and their

family members, we report *here on* the creation and evaluation of psychometric properties (validity, reliability, factor structure) of new diabetes-specific HRQOL measures for adults with type 1 diabetes. We previously published psychometric data for "Type 1 Diabetes and Life" (T1DAL) measures for children (age 8-11) and adolescents (age 12-17) [14], and for parents of youth and partners of adults with T1D [15]. In this paper, we report on the creation of T1DAL measures for adults in four age-bands: Young Adult (age 18-25), Adult-1 (age 26-45), Adult-2 (age 46-60), and Older Adult (age >60). We selected the age-bands based on developmental stages [16,17]. It was hypothesized that each T1DAL adult measure would be psychometrically valid (i.e., demonstrate construct and criterion validity) and reliable (i.e., demonstrate internal consistency and test-retest reliability). An exploratory aim was to identify subscales for each measure using factor analysis.

2. SUBJECTS, MATERIALS, AND METHODS

2.1 Study Design

To create and validate the new T1DAL measures, we followed multi-step measure development guidelines [18,19]. The aim of Phase 1 was to draft, pilot, and revise the measures based on prior instruments, literature, and qualitative data from adults with type 1 diabetes and their partners. The aim of Phase 2 was to test the measures' psychometrics and factor structure and reduce the measures' length. The aim of Phase 3 was to collect user feedback about the measures and make final changes to the number and content of items. Each phase received appropriate institutional review board approval. Participants received small monetary incentives for participation. Figure 1 illustrates the phases of the study, the number of participants in each phase, and the number of items on each version of the measure in each phase.

2.2 Recruitment

Inclusion criteria for all phases were age ≥18 years, type 1 diabetes duration of ≥12 months, fluent in written/spoken English, and able to provide informed consent. Exclusion criteria included significant comorbid medical, cognitive, or mental health conditions that could interfere with ability to participate. In all phases, study staff conducted informed consent processes including introduction of the study to potential participants and evaluation of understanding prior to obtaining written consent. Table 1 summarizes participants' demographic and clinical characteristics for each phase.

Phase 1

Participants were recruited from diabetes clinics at Indiana University School of Medicine. Research staff identified potentially eligible participants based on review of diabetes clinic schedules. Study staff sent informational letters to potentially eligible people and followed up by telephone, then conducted informed consent procedures in person at either a medical appointment or separate appointment. To enroll a sample of an adequate size for qualitative research, which would allow us to include people with a range of experiences and reach thematic saturation, we had recruitment targets of 6-10 participants per age-band (i.e., 24-40 total for the adult age-bands) [20]. We mailed letters to 233 potentially eligible adults. Study staff contacted 38 people who met eligibility criteria, and 28 (74%) consented and completed the interview. Once the recruitment targets were met, we did not continue to contact others who received letters.

After developing first drafts of the T1DAL measures for each age range, staff recruited 11 new adult participants (2-3 per age-band) to pilot and provide feedback about these newly drafted measures. This sample size is in the recommended range for pre-testing items on a newly developed measure [18,20].

Phase 2

Participants were recruited from six diabetes centers within the T1D Exchange Clinic Network (investigators and staff at each site listed in Appendix 4). Sites were selected based on clinic size, geographic diversity, and history of successful engagement in multisite research of this nature. All age-bands were recruited from adult sites in Colorado, Michigan, and New York. Because young adults receive diabetes care in either pediatric or adult healthcare settings [21], participants age 18-25 were also recruited from pediatric sites in California, Colorado, and Tennessee. Research staff at each site reviewed schedules to identify potentially eligible participants from the clinic. All clinic patients were potentially eligible for this study; while staff prioritized recruiting participants, who were previously enrolled in the T1D Exchange Clinic Registry to facilitate access to existing demographic data, enrollment in the current study was not limited to prior registry participation. Sites sent informational letters and/or met potential participants at clinic visits to introduce the study and conduct informed consent procedures. Given the goal for the measures to ultimately be 20-30 items in length, our recruitment targets were 200-300 participants per age-band [18]. In total, 962 people enrolled: Age 18-25, n=252; Age 26-45, n=274; Age 46-60, n=250; Age >60, n=164.

Phase 3

The investigators recruited a new sample through Twitter, to conduct a final review of the measures. The recruitment target was 2-3 new participants per age-band (i.e., 8-12 across the adult age-bands); this small sample was adequate for the purpose of obtaining a last opportunity for feedback from people who were unfamiliar with the measures [20]. Interested people contacted the study team by direct message, email, or telephone. Staff followed-up by telephone to describe

the study, determine eligibility, and obtain informed consent. Nine people who contacted the study team were eligible and participated.

2.3 Procedures

Phase 1

Based on literature review and clinical observations, the investigators created a list of HRQOL topics to potentially assess in the measures. Staff used semi-structured scripts to conduct individual interviews and/or small focus groups about these topics (excerpts from scripts in Appendix 1). Interview questions asked participants to discuss several aspects of living with type 1 diabetes (e.g., interpersonal interactions, food and activity, thoughts and feelings related to type 1 diabetes, financial issues) and any other topics they felt were important. Staff were trained to ask open-ended questions and use prompts/probes to clarify responses. The interviews were audio-recorded and professionally transcribed. Participants also reported on their demographics, and staff conducted medical chart reviews to extract clinical data (e.g., date of diagnosis, most recent HbA1c).

Following thematic qualitative analysis of the interview transcripts, the study team then drafted the T1DAL measures with items written to capture themes based on the qualitative interviews, diabetes literature, and clinical experience. The structure and format were based on the MY-Q measure of HRQOL [22]. Behavioral and medical expert collaborators on the study team reviewed the measures and gave feedback. A new sample of participants piloted the measures, and staff conducted structured cognitive debriefing [23] (Appendix 2) to obtain feedback about: items/words that were confusing, difficult or uncomfortable to answer, repetitive, or unimportant, how hard or easy it was to answer each item, their interpretation of specific words/phrases, and suggestions for clarification/improvement. We also sought participant comments about their

feelings about completing this questionnaire in clinic and any other topics related to living with type 1 diabetes that they felt should be included. Interviews were audio-recorded and professionally transcribed, and interviewers summarized the feedback. The investigators then modified item wording and removed problematic items based on this feedback.

Phase 2

Participation included completing questionnaires on two occasions on a secure web-based portal, either at the clinic visit or at home via emailed link. Paper questionnaires were available upon request. At enrollment, participants completed the age-appropriate T1DAL measure and validated measures of related constructs to evaluate construct validity at baseline (outlined below). At follow-up (4-6 weeks later), participants completed the T1DAL measure only to examine test-retest reliability. Participants also granted study staff access to clinical and demographic data from medical charts and the Clinic Registry Study.

Phase 3

A new sample of nine participants completed the age-appropriate measure (PDF sent via email) and timed themselves while answering the measure. Staff then completed a cognitive interview by telephone using a similar script as in Phase 1 to obtain participant input about the measure's clarity, appropriateness, and repetitiveness. Interviews were audio-recorded and professionally transcribed, and interviewers summarized the participant comments. Study team members also reviewed and commented. The primary investigators finalized the measures based on participant and expert feedback.

2.3 Measures

2.3.a. T1DAL Measure

The number of items on each original version of the T1DAL in the validation study was 52 (age 18-25), 54 (age 26-45), 48 (age 46-60), and 49 (age >60). Instructions directed respondents to answer each item on a 5-point Likert scale ('Completely Disagree' to 'Completely Agree') based on their experience in the past 4 weeks. Items were presented in conceptual categories, such as "Diabetes at Work" and "Diabetes and How I Feel" and included an option to indicate items that were not applicable. Positively-worded items were scored 0=0, 1=25, 2=50, 3=75, or 4=100 and negatively-worded items were reverse-scored. Subscale and total scores were calculated by computing the mean and multiplying by 25 to convert to the 0-100 scale. Higher scores indicated better HRQOL. To avoid over-interpreting individual items, scores were not calculated if >10% of items were missing (>1 missing item for subscale score, >3 missing items for total score).

2.3.b. Construct Validity Measures

To assess general quality of life, the Satisfaction with Life Scale (SWLS) [24] prompted participants to rate their agreement with five judgements about their life from 1 ('Strongly Disagree') to 7 ('Strongly Agree'). The α range across age-bands in this sample was 0.90-0.93.

To assess HRQOL, all participants completed the Pediatric Quality of Life Inventory (PedsQL[1]) Generic Core Scales Version 4.0 (generic HRQOL, 23 items), which has versions for adults aged 18-25 and over age 26 [25,26]. Participants between ages 18-45 also completed the Diabetes Module Version 3.2 (diabetes-specific HRQOL, 33 items) using the version validated for their age (there is no version for people over age 45) [25,27,28]. On each measure, they rated how much each item was a problem. In this sample, the α ranges were 0.92-0.94 (Generic) and 0.91-0.93 (Diabetes).

[1] Despite the PedsQL measures having the term Pediatric in the title, their validation samples have since been extended to include adults. In-text citations refer to the adult validation publications.

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Participants also completed the Short Form Health Survey, Version 2 (SF-12) [29], a 12-item assessment of physical functioning and symptoms, general health, and mental health symptoms. The α range in this sample was 0.33-0.45. We used the Mental Health Composite Score (MCS) in validity analyses, as it is most conceptually related to HRQOL.

To assess diabetes-related burdens, participants completed the Problem Areas in Diabetes scale (PAID) [30]. On this 20-item measure, respondents rate how much of a burden each item is (5-point scale: 'Not A Problem' to 'Serious Problem'). In this sample, the α range was 0.94-0.96.

2.3.c. Criterion Validity Measures

To assess adherence, participants completed the Self-Care Inventory-Revised [31], which assesses completion of diabetes management behaviors (5-point scale: 'Never Do It' to 'Always Do This As Recommended Without Fail'). The α range in this sample was 0.74-0.85. To assess glycemic control, the HbA1c value closest to the date of study participation was extracted from each participant's medical record.

2.4 Data Analysis

Phase 1

We conducted hybrid thematic analysis of the interview/focus group transcripts [32], following qualitative research methods guidelines [20,33] using NVIVO software (Version 11). Three behavioral scientists with expertise in diabetes and three research coordinators reviewed transcripts, identified common concepts, and created a codebook with operational definitions of these concepts for each code. As the team applied the codes to the transcripts, we discussed any additional concepts that we observed in the transcripts and added definitions to the codebook. This iterative process continued until there were no new codes identified. We double-coded 25% of transcripts and resolved any disagreements.

Phase 2

We conducted separate analyses by age-band. Table 1 presents the number of participants included in analyses (those with calculable T1DAL scores) in each age-band. First, we conducted exploratory factor analyses with all T1DAL items, using squared multiple correlations as prior communality estimates. Because there were no *a priori* hypothesized factors for each version of the newly developed T1DAL measures, exploratory factor analysis was more appropriate than confirmatory methods. We used maximum likelihood and promax (oblique) rotation to extract factors. We examined scree plots, proportion of variance explained, and clinical interpretability to decide on the number of meaningful factors for each age band. We inspected item properties to shorten each age-band's measure to 20-25 items, based on the following decision rules: no change in α if item dropped, ≥85% response rate, no ceiling or floor effect, and significant loading (≥0.30) on ≥1 factor. We also dropped items that assessed other constructs (e.g., self-management), were redundant, or received negative cognitive debriefing feedback. For any items loading on >1 factor, we considered each factor loading and conceptual fit. Each factor required ≥3 variables. In some cases, we retained individual items that did not load onto any factor but were deemed by the investigator team to be clinically meaningful and important to include on the measure. To evaluate reliability (internal consistency) we calculated Cronbach's α, and to evaluate validity and test-retest reliability, we calculated Pearson's correlations with other measures or across both timepoints.

Phase 3

No formal analyses were conducted for Phase 3 interview data, as the comments were brief and interpretable by visual review alone. Study team members reviewed the feedback from

participants and discussed whether any additional changes to the measures were indicated based on the feedback.

3. RESULTS

Phase 1

Qualitative analysis identified many themes related to diabetes-specific HRQOL, including feelings about diabetes, interpersonal relationships, and barriers to/facilitators of managing diabetes in everyday activities, reported elsewhere [34-36]. Feedback from participants during cognitive debriefing guided changes to the measures to increase clarity (e.g., cutting confusing items, adding instructions for clarification) and reduce redundancy between items.

Phase 2

For the Young Adult version (age 18-25), we included data from 252 participants in the factor analysis. The total score α was 0.92 (α with deleted variable, range = 0.92-0.92). We retained 27 items for the final T1DAL-Young Adult questionnaire, total score M=73.0±14.0, α=0.88 (α with deleted variable, range = 0.87-0.88), Fleisch-Kincaid=8.6. The final four factors were Emotional Experiences and Daily Activities (12 items), Handling Diabetes Well (4 items), Peer Relationships (5 items), and Healthcare Experiences (4 items). We retained two items that did not load on any factor, as they addressed a clinically important topic (family planning) that was not otherwise captured in the measure.

For the Adult-1 version (age 26-45), we used data from 243 participants. The total score α was 0.91 (α with deleted variable, range = 0.90-0.91). We retained 27 items for the final T1DAL-Adult-1 questionnaire, total score M=63.0±12.8, α=0.85 (α with deleted variable, range = 0.83-0.85), Fleisch-Kincaid=8.6. The final five factors were Emotional Experiences and Daily

Activities (12 items), Peer Relationships (4 items), Family Relationships (3 items), Financial Considerations (3 items), and Healthcare Experiences (3 items). Similar to the Young Adult version, we retained two items about family planning that did not load on any factor.

For the Adult-2 version (age 46-60), we included data from 190 participants. The total score α was 0.90 (α with deleted variable, range = 0.90-0.90). We retained 25 items for the final T1DAL-Adult-2 questionnaire, total score M=62.0±15.1, α=0.87 (α with deleted variable, range = 0.85-0.87), Fleisch-Kincaid=7.8. The final five factors were Emotional Experiences and Daily Activities (7 items), Support from Others (4 items), Social Isolation (4 items), Financial Considerations (3 items), and Handling Diabetes Well (5 items). Similar to the Young Adult and Adult-1 versions, we retained two items that were clinically important (parenting one's own children, concerns regarding complications) but did not load on any factor.

For the Older Adult version (age >60), we included data from 160 participants. The total score α was 0.89 (α with deleted variable, range = 0.88-0.89). We retained 23 items for the final T1DAL-Older Adult questionnaire, total score M=61.7±15.5, α=0.86 (α with deleted variable, range = 0.84-0.86), Fleisch-Kincaid=8.5. The final four factors were Emotional Experiences and Social Isolation (12 items), Support from Others (3 items), Financial Considerations (3 items), and Handling Diabetes Well (5 items).

Table 1 presents the descriptive statistics for each validity measure. Tables 2 and 3 present the reliability and validity data for the total and subscale scores for each T1DAL measure. The total scores all demonstrated good internal consistency (α>0.80) and most subscales also demonstrated fair-good internal consistency (α>0.60). All T1DAL subscales and total scores had significant (p <0.0001) test-retest reliability correlations. All total scores and most subscale scores also demonstrated construct and criterion validity, with significant (at least p <0.05) correlations

with the validity measures in the expected directions. Appendix 3 provides example items for each measure. Appendix 4 provides example items that were deleted from each measure, with the reasons for deletion.

Phase 3

Participants reported that the measures were understandable, comfortable to answer, and relevant to their experiences with type 1 diabetes. They estimated the measures took less than 10 minutes to complete.

4. DISCUSSION

The self-report T1DAL measures, assessing age-appropriate diabetes-specific HRQOL in adults with type 1 diabetes, are psychometrically sound and appropriate for use in clinical care and research. Based on input gathered from adults with type 1 diabetes, the measures were developed and tested using rigorous qualitative and quantitative methods. This level of rigor in measure development and detailed psychometric data represents a significant advance beyond what has been reported for existing measures of HRQOL in adults with T1D. The T1DAL measures were designed to be brief, clinically relevant, and to capture real life experiences relevant to clinical trials and practice settings. The T1DAL total scores showed that adults in each age-band reported moderate diabetes-specific HRQOL, suggesting there is potential for HRQOL to improve with intervention [37,38].

Psychometric properties of the T1DAL measures were very strong. Each total score exhibited consistent validity and reliability. The significant associations with construct validity measures (i.e., other measures of quality of life and diabetes distress) demonstrate that the new T1DAL measures for adults provide accurate assessments of the patient-reported outcome

constructs that are part of HRQOL. The consistent associations between total scores and criterion validity measures (i.e., self-management behaviors and glycemic outcomes) further support the accuracy of the T1DAL measures in relation to key diabetes outcomes. The factors identified in factor analysis also had significant construct validity and test-retest reliability, supporting the psychometric properties of the subscales. The relatively low internal consistency of some subscales was due to small number of items per factor, which was intentional to reduce redundancy between items and maintain brevity. Mixed associations with the criterion validity measures suggest that a few subscales may not be directly related to self-management or glycemic outcomes, but this does not detract from their importance or contribution in relation to assessing and understanding overall HRQOL.

The rigorous multi-step development and validation process for the new T1DAL-Adult measures [18], and the comprehensive reporting of validity and reliability in these measures, address many of the gaps and concerns in existing HRQOL instruments [1,2,7-10]. Specifically, we followed guidelines for involving the target population in developing, piloting, and revising the measures, which has not been done consistently with previous HRQOL measures. Given concerns about the use of measures capturing other factors that are related but not precisely HRQOL, we made concerted efforts to ensure the T1DAL measures aligned with accepted, multi-faceted conceptualizations of HRQOL [7,9]. During the item generation and refinement process, and during the questionnaire-shortening step using validation data, we carefully selected items that assessed HRQOL specifically, rather than related constructs such as self-management or general quality of life. Additionally, we emphasized a well-rounded conceptualization of HRQOL, including both positive and negative aspects of living with type 1 diabetes. Finally, we reported detailed results regarding reliability, validity, and factor analyses, to provide comprehensive

psychometric properties about the new measures. Thus, the new T1DAL-Adult measures add a new option that is distinct from existing measures of HRQOL and add value in their theory-based conceptualization, stepwise development, rigorous validation, and detailed reporting of psychometric data.

Together with the validated T1DAL measures for children and adolescents [14], the adult T1DAL measures can be used to assess diabetes-specific HRQOL across the lifespan. The investigators created and evaluated each age-band's measure separately to generate developmentally specific items and subscales. We began with qualitative data from adults with type 1 diabetes in each age-band to ensure the final measures represented the specific HRQOL-related experiences of each life stage [9]. Using the same scoring approach for each measure allows users to not only compare scores within each age-band, but to assess HRQOL longitudinally as people move though different age-bands.

4.1 Limitations and Considerations.

Limitations of this research should be considered. As with all research, participant characteristics may limit the generalizability of the results. Because we did not obtain consent from people who declined to participate, we were unable to determine whether or in what ways the enrolled sample was biased. Additionally, we did not collect data on complications, which may be related to HRQOL, so it is not possible to determine how similar this sample is to the population in this regard. We conducted the Phase 1 qualitative interviews that informed the T1DAL assessments at an academic medical center in an urban area in the Midwestern United States. The characteristics and experiences of patients at this center may differ from people in other locations. Across the different study phases, samples were largely non-Hispanic White (especially in the older age-bands) and some had relatively high use of insulin pumps. However, the sample's

recruitment of participants from across the U.S. in the validation phase and the consistency of the results across age-bands and with previous research reduce these concerns. Additionally, psychometric validity patterns of the T1DAL-Adult measures (Young Adult, Adult-1, Adult-2, and Older Adults) were similar to the psychometric results previously published for the T1DAL-Child and Adolescent versions, which had more racial/ethnic diversity [14], further reducing concerns about this limitation. Future research examining the psychometrics and functionality of the measures for racially/ethnically and socio-economically diverse people with diabetes is critical.

The construct validity should be considered in relation to the measures used for comparisons. We selected the PedsQL measure for diabetes-specific HRQOL, largely to ensure consistency in methods used across the lifespan. While the PedsQL measures were originally developed for youth and later validated in adults [26-28], limitations include having published psychometrics only up to age 45 for the Diabetes Module. Using a different measure designed specifically for older adults may have generated different results. For general HRQOL, PedsQL Generic Core Scales psychometric data are published up to age 25 (although there is a version available for people age 26 and older [25]). To address this, we supplemented with the Mental Health Composite of the SF-12, another measure of HRQOL. The construct validity results with the SF-12 measure should also be considered with caution given its low α, however its inclusion is supported both by its established psychometric strength and the overall consistent pattern of T1DAL correlations with the SF-12 and other construct validity measures. These challenges with the construct validity measures we used for HRQOL further underline the gaps in existing measures of this important construct. They also highlight the need for a new, well-constructed and well-validated measure of HRQOL with developmentally appropriate versions across the lifespan.

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One gap in constructs assessed in T1DAL is the use of diabetes devices and technologies in relation to HRQOL. As these technologies are advancing rapidly, we elected not to include content that could quickly become outdated. Other relevant measures (e.g., Diabetes Technology Questionnaire for continuous glucose monitoring [39]; INSPIRE measures for automated insulin delivery [40]) were designed specifically to address issues related to about diabetes technologies and may be used with the T1DAL measures. Additionally, conducting sensitivity analyses were beyond the scope of this study, so we cannot comment on how scores change in relation to shifts in clinical outcomes or care. Future research evaluating the T1DAL measures' sensitivity to change and feasibility in practice settings will help inform the utility and implementation of the measures in clinical care and clinical trials.

4.2 Conclusion

The newly developed T1DAL measures for adults with type 1 diabetes comprise a rigorously constructed and tested set of questionnaires that address many concerns of previous HRQOL assessment. The brevity and clinical relevance of the T1DAL measures for adults make them suitable for use to assess diabetes-specific HRQOL, a key patient-reported outcome, in clinical practice and research. An important addition compared to other measures is the inclusion of both negative and positive aspects of living with diabetes, which provides a fuller assessment of this broad construct. Together with versions for children and adolescents with type 1 diabetes [14], T1DAL offers a new option for HRQOL measurement across the lifespan, and the developmentally tailored content with consistent scoring across age-bands permits longitudinal measurement. With our rigorous methodological approaches that adhere to guidelines for measure development and validation [18], as well as our strong psychometric data, the T1DAL-Adult

measures represent an important advance in the field that fills the gaps left by previous research, and can be used to improve patient care and clinical research.

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Marisa Hilliard is the guarantor and is responsible for the contents of this article. To access or use the T1DAL measures, please contact Dr. Hilliard at marisa.hilliard@bcm.edu.

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Figure 1. Flowchart of measure development and validation phases.

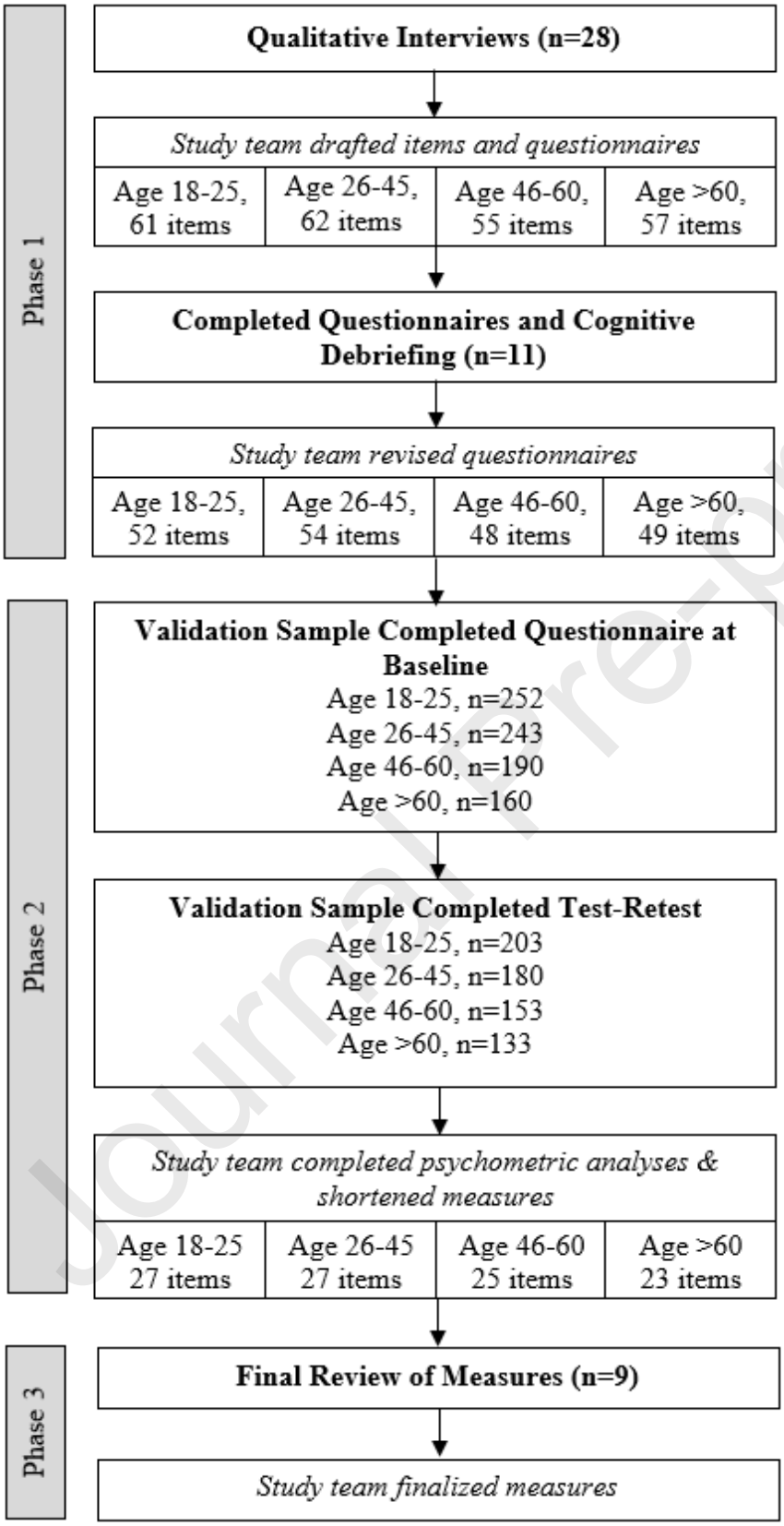

Table 1. Participant characteristics by study phase.

	Phase 1		Phase 2				Phase 3
Clinical and Demographic	Qualitative	Debriefing	18-25	26-45	46-60	>60	Debriefing
N°	28	11	252	243	190	160	9
Age, M±SD, years	42.8±15.9	39.8±17.1	21.4±2.3	35.1±6.1	53.8±4.1	67.5±5.3	43.2±19.3
Duration of T1D, M±SD, years			10.8±5.6	18.0±10.1	30.1±14.1	36.6±16.2	
Gender, % female	54%	64%	49%	54%	56%	48%	89%
Race/Ethnicity, % non-Hispanic White	93%	91%	69%	80%	93%	94%	100%
HbA1c, M±SD	7.9±1.2*	7.0±0.9	8.9±2.0	8.2±1.6	7.9±1.3	7.6±1.0	7.1±0.6
(NGSP, IFCC)	63±14*	53±10	74±21	66±18	63±14	60±11	54±7
Insulin regimen, % pump	61%	73%	43%	53%	73%	63%	89%
Validation Measures, M (SD)							
PedsQL Diabetes			65.2±14.2	63.4±11.5			
PedsQL Generic			79.9±15.6	74.0±15.9	74.6±14.6	71.3±17.0	
SF-12 – PCS			53.0±6.3	50.6±8.0	49.9±8.3	46.6±9.8	
SF-12 – MCS			44.1±11.1	41.9±10.3	46.7±9.1	47.4±8.8	
SWLS			23.9±6.8	23.5±7.2	24.4±7.3	24.4±7.6	
PAID			39.5±16.8	39.6±13.6	35.5±14.3	34.2±12.4	
SCI-R			3.4±0.6	3.3±0.6	3.6±0.5	3.8±0.5	

Notes: °n with calculable HRQOL scores *HbA1c values available for 27 participants in Phase 1: Qualitative. HbA1c = Hemoglobin A1c. PedsQL = Pediatric Quality of Life Inventory. SWLS = Satisfaction with Life Scale. PAID = Problem Areas in Diabetes scale.

SF-12 = Short Form Health Survey 12, Version 2; PCS = Physical Health Composite Score, MCS = Mental Health Composite Score. SCI-R = Self-Care Inventory Revised.

Table 2. T1DAL total and subscale scores and reliability estimates.

Age	Scale Name	M±SD	Internal Consistency (α°)	Test-retest (r)
18 -25	Total	61.7±15.0	0.88	0.82*
	Emotional Experiences & Daily Activities	45.6±20.5	0.86	0.81*
	Handling Diabetes Well	70.2±21.1	0.79	0.68*
	Peer Relationships	76.2±19.1	0.68	0.61*
	Healthcare Experiences	82.5±16.5	0.70	0.56*
26-45	Total	63.9±12.5	0.85	0.85*
	Emotional Experiences & Daily Activities	51.0±17.1	0.83	0.82*
	Family Relationships	82.5±20.4	0.57	0.71*
	Peer Relationships	81.7±17.5	0.63	0.71*
	Healthcare Experiences	86.5±18.9	0.83	0.49*
	Financial Considerations	46.1±27.5	0.60	0.76*
46-60	Total	61.4±15.3	0.87	0.87*
	Emotional Experiences & Daily Activities	42.8±21.8	0.79	0.71*
	Financial Considerations	58.0±26.1	0.69	0.74*
	Handling Diabetes Well	74.2±17.9	0.66	0.69*
	Support from Others	77.4±21.3	0.70	0.60*
	Social Isolation	56.4±24.2	0.70	0.74*
>60	Total	62.7±15.5	0.86	0.80*
	Emotional Experiences & Social Isolation	50.3±20.1	0.84	0.73*
	Handling Diabetes Well	77.4±17.7	0.68	0.67*
	Financial Considerations	65.2±27.3	0.68	0.79*
	Support from Others	81.0±18.7	0.48	0.45*

Note: °Standardized Cronbach's alpha *p<0.0001

Table 3. Validity estimates for T1DAL total and subscale scores.

Age	Scale	PedsQL Diabetes	PedsQL Generic	SWLS	PAID	SF-12 MCS	SCI-R	HbA1c
18-25	Total	0.71**	0.65**	0.50**	-0.70**	0.48**	0.43**	-0.23**
	Emotional Experiences & Daily Activities	0.73**	0.62**	0.42**	-0.70**	0.45**	0.35**	-0.17*
	Handling Diabetes Well	0.56**	0.53**	0.49**	-0.58**	0.44**	0.52**	-0.33**
	Peer Relationships	0.33**	0.29**	0.21**	-0.30**	0.19**	0.26**	-0.19*
	Healthcare Experiences	0.23**	0.28**	0.24**	-0.26**	0.24**	0.26**	0.01
26-45	Total	0.73**	0.67**	0.54**	-0.73**	0.59**	0.28**	-0.30**
	Emotional Experiences & Daily Activities	0.69**	0.63**	0.48**	-0.72**	0.56**	0.24**	-0.20*
	Family Relationships	0.46**	0.45**	0.38**	-0.42**	0.36**	0.20**	-0.30**
	Peer Relationships	0.33**	0.23**	0.27**	-0.27**	0.33**	0.15*	-0.15
	Healthcare Experiences	0.32**	0.28**	0.21**	-0.32**	0.15*	0.15*	-0.23**
	Financial Considerations	0.34**	0.35**	0.27**	-0.34**	0.27**	0.10	-0.06
46-60	Total		0.65**	0.52**	-0.73**	0.52**	0.19*	-0.35**
	Emotional Experiences & Daily Activities		0.53**	0.40**	-0.69**	0.48**	0.11	-0.20**
	Financial Considerations		0.39**	0.42**	-0.63**	0.42**	0.23*	-0.26**
	Handling Diabetes Well		0.40**	0.38**	-0.51**	0.44**	0.35**	-0.40**
	Support from Others		0.23**	0.25**	-0.29**	0.23**	0.09	-0.28**
	Social Isolation		0.50**	0.36**	-0.49**	0.41**	0.05	-0.21**
>60	Total		0.61**	0.57**	-0.75**	0.49**	0.19*	-0.21*
	Emotional Experiences & Social Isolation		0.62**	0.50**	-0.75**	0.47**	0.11	-0.18*
	Handling Diabetes Well		0.39**	0.42**	-0.63**	0.42**	0.23**	-0.26**
	Financial Considerations		0.24**	0.30**	-0.25**	0.20*	0.08	-0.08
	Support from Others		0.31**	0.37**	-0.28**	0.25**	0.23**	-0.05

Notes: *p<.05, **p<.01. PedsQL = Pediatric Quality of Life Inventory. SWLS = Satisfaction with Life Scale. PAID = Problem Areas in Diabetes scale. SF-12 MCS = Short Form Health Survey 12, Version 2, Mental Health Composite Score. SCI-R= Self-Care Inventory-Revised. HbA1c = Hemoglobin A1c.