

# VALIDATION AND PSYCHOMETRIC EVALUATION OF A PATIENT-REPORTED ASSESSMENT OF DISEASE BURDEN: EVIDENCE FROM A SAMPLE OF ADULTS WITH DIABETES, DEPRESSION, AND RHEUMATOID ARTHRITIS

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## BACKGROUND

- The Disease Burden Scale (DBS) assesses the impact of specific health conditions on key elements of a patient's life.
- This instrument is derived from the Diabetes Burden Scale (Kaplan, 2010; Greenfield et al., 1994), and currently includes four (4) items assessing the burden of an individual's condition on their overall health, social activities, lifestyle and finances (Figure 1).
- Each item is scored on a six-point scale and the items are summed to yield a raw score between 4 and 24, which is transformed for a total score ranging from 0 to 100 with higher scores indicating lower disease burden (Kaplan, 2010).
- While validation evidence has been published on the parent instrument (Kaplan, 2010), validation of the shortened version has not yet been completed.
- We evaluated the psychometric properties of the DBS and tested equivalence between paper and web-based administration modes in an observational study.

## Figure 1: Disease Burden Scale

Overall, how much of a burden is your \_\_\_\_\_ on you and your family in each of the following areas? \_\_\_\_\_

(Circle one number on each line)

	VERY LARGE Burden	LARGE Burden	Feel NEUTRAL	SMALL Burden	VERY SMALL Burden	NOT a Burden At All
a. Our overall health	1	2	3	4	5	6
b. Our social activities	1	2	3	4	5	6
c. Our lifestyle	1	2	3	4	5	6
d. Our finances in general	1	2	3	4	5	6

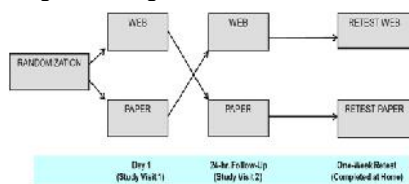
Notes:  
1. The instrument is designed to be administered with the blank space in the instruction line replaced with the name of the target health condition. In the current study, references to "depression," "diabetes," or "rheumatoid arthritis" were used for administration to each of the three groups of participants.  
2. When scored, higher DBS scores are indicative of lower levels of disease burden.

## METHODS

### Study Design

- The DBS and other questionnaire measures were administered to a large convenience sample of adults with chronic illnesses in a non-interventional study (outside of the clinical trial setting).
- This observational data collection effort used a randomized crossover design to assess equivalence between paper and electronic formats of the DBS.
- This study employed a web-based general population recruitment strategy in eight (8) U.S. cities. Individuals responding to study advertisements were screened via telephone for eligibility.
- Individuals between the ages of 18 and 70, who self-reported a diagnosis and treatment of depression, rheumatoid arthritis (RA), or type 2 diabetes (T2D); who were able to speak, read, and write in English, and were available to attend both data collection sessions for their location were eligible for participation.
- Recruitment quotas were used to generate subgroups of participants within each of the three (3) targeted health conditions.
- After providing informed consent, participants were randomized to complete the DBS on either paper or computerized format at their first study visit. The alternate format was completed at the second study visit (24 hours later) and the one-week retest was completed from home (Figure 2).

Figure 2: Diagram of Data Collection



### Measures

- Disease Burden Scale (DBS), paper and web versions
- WHOQOL-Bref and SF-36v2 (MCS and PCS subscales)
- Self-reported demographic and health variables

### Statistical Analyses

- Participant demographic and health variables were characterized with descriptive statistics.
- The intraclass correlation coefficient (ICC) was calculated to assess the one-week reproducibility of the DBS.
- Measurement equivalence is a function of the comparability of the psychometric properties of the data obtained via the original paper and adapted web administration mode. Equivalence of the paper and web-based DBS scores were assessed in this study by calculating the ICC between scores from the two modes, with values of 0.70 or greater considered indicative of equivalence (Nunnally & Bernstein, 1994).
- Cronbach's alpha was calculated to assess the internal consistency of the DBS.
- Convergent validity was assessed by examining the association between the DBS and 4 subscale scores (Physical, Psychological, Social Relationships, and Environment) of the WHOQOL-Bref.
- "Known groups" validity was assessed by examining discriminability between hypothesized groups with analysis of variance (ANOVA) models. Groups were defined by trichotomous groupings of the PCS and MCS scores from the SF-36v2.
- All analyses were conducted using SPSS.

## RESULTS

### Participant Characteristics

- 230 participants enrolled and completed the baseline assessment, and 228 (99%) completed the retest.
- Participant demographic characteristics are presented in Table 1.
  - The mean age of participants was 44.3 years; 51.3% were female, and 58.3% were White.
  - 33.9% of participants were married or living with a partner, 39.1% had never been married.
  - 42.2% of participants were employed either part- or full-time; 35.2% were unemployed at the time of the study.
- Health Characteristics of participants are presented in Table 2.

Table 1: Demographic Characteristics

PARTICIPANT CHARACTERISTIC (N=230)	Mean (SD, range)	
Age	44.3 (13.5, 18-75)	
Education (highest grade completed)	Mean (SD, range)	14.7 (2.4, 8-20)
Gender		
N (%) Male	112 (48.7%)	
N (%) Female	118 (51.3%)	
Ethnicity		
N (%) Not Hispanic	190 (82.6%)	
N (%) Mexican American/Mexican	15 (6.5%)	
N (%) Other Hispanic or Latino	15 (6.5%)	
N (%) Both Mexican and other Hispanic	2 (0.9%)	
N (%) Missing	8 (3.5%)	
Race		
N (%) American Indian or Alaskan Native	3 (1.3%)	
N (%) Asian	8 (3.5%)	
N (%) Black/African American	50 (21.7%)	
N (%) Hispanic or Latino	21 (9.1%)	
N (%) Native Hawaiian or other Pacific Islander	...	
N (%) White	134 (58.3%)	
N (%) Other	18 (8.1%)	
Marital Status		
N (%) Married	54 (23.5%)	
N (%) Widowed	4 (1.7%)	
N (%) Separated	11 (4.8%)	
N (%) Divorced	36 (15.6%)	
N (%) Never married	90 (39.1%)	
N (%) Living with partner	24 (10.4%)	
N (%) Other	8 (3.5%)	
N (%) Missing	1 (0.4%)	
Employment		
N (%) Full time	51 (22.2%)	
N (%) Part time	46 (20.0%)	
N (%) Homemaker	4 (1.7%)	
N (%) Student	14 (6.1%)	
N (%) Retired	20 (8.7%)	
N (%) Not employed	81 (35.2%)	
N (%) Other	14 (6.1%)	
Household Income		
N (%) UNDER \$5,000	12 (5.2%)	
N (%) \$5,000-11,999	27 (11.7%)	
N (%) \$12,000-19,999	27 (11.7%)	
N (%) \$20,000-29,999	12 (5.2%)	
N (%) \$30,000-39,999	17 (7.4%)	
N (%) \$40,000-49,999	17 (7.4%)	
N (%) \$50,000-74,999	30 (13.0%)	
N (%) \$75,000-99,999	22 (9.6%)	
N (%) \$100,000 AND OVER	19 (8.3%)	
N (%) Missing	18 (7.8%)	
Living Situation		
N (%) Living alone	74 (32.2%)	
N (%) Living with spouse/partner only	40 (17.4%)	
N (%) Living with spouse/partner and children	35 (15.2%)	
N (%) Living with other relatives	31 (13.5%)	
N (%) Living with other(s) (not related)	36 (15.7%)	
N (%) Other	14 (6.1%)	

Table 2: Health Characteristics

PARTICIPANT CHARACTERISTIC (N=230)	Mean (SD, range)	
Qualifying Target Health Condition		
N (%) Depression	101 (43.9%)	
N (%) Type 2 Diabetes	76 (33.0%)	
N (%) RA	53 (23.0%)	
General Health		
N (%) Excellent	15 (6.5%)	
N (%) Very Good	56 (24.3%)	
N (%) Good	99 (43.0%)	
N (%) Fair	51 (22.2%)	
N (%) Poor	9 (3.9%)	
Number of Days Physical Health Not Good in Last 30 Days	Mean (SD, range)	7.2 (9.3, 0-30)
Number of Days Spent Sick in Bed in Last 30 Days	Mean (SD, range)	3.4 (5.4, 0-27)
Number of Days Mental Health Not Good in Last 30 Days	Mean (SD, range)	9.6 (10.0, 0-30)
Number of Medical Professional Visits in Last 3 Months	Mean (SD, range)	3.4 (3.9, 0-30)
Number of Daily Medications	Mean (SD, range)	3.7 (3.0, 0-17)
SF-36 (PCS)	Mean (SD, range)	44.3 (12.3, 13.0-71.0)
SF-36 (MCS)	Mean (SD, range)	35.2 (15.8, 2.6-71.5)

### Measurement Properties of the DBS

- Across all participants, the mean (SD) DBS scores were 44.8 26.6 (Paper) and 42.7 26.8 (Web).
- DBS scores were observed to vary significantly between health condition subgroups within both the paper (f=12.255; p<0.0001) and web (f=15.415; p<0.001) administrations:
  - Major depression: Mean( SD) of 36.1 26.3 Paper and 32.6 24.9 Web
  - RA: Mean( SD) of 46.7 24.2 Paper and 46.6 25.5 Web
  - T2DM: Mean( SD) of 55.0 24.8 Paper and 53.4 25.6 Web
- The score difference between Paper and Web was -1.99 (p=0.091).
- The ICC between Paper and Web was 0.876 [CI 0.840 to 0.905] (Table 3).
- Test-retest reproducibility was observed to be strong (ICC of 0.944 and 0.953 for paper and web, respectively; Table 3).
- The instrument was internally consistent in both paper and web format (alpha=0.899 and 0.920, respectively).

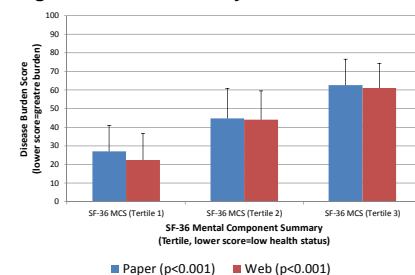
Table 3: DBS Equivalence and Reproducibility

Measurement Characteristic	N	Intraclass correlation coefficient	95% CI	
			Lower	Upper
Equivalence: DBS Paper to DBS Web	230	0.876	0.840	0.905
One-week test-retest: DBS Paper	125	0.944	0.920	0.961
One-week test-retest: DBS Web	105	0.953	0.931	0.968

### Known-groups Validity

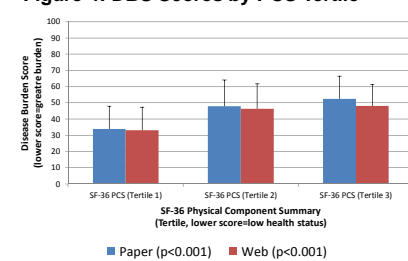
- The DBS significantly discriminated (p<0.001) between tertiles of the MCS (Figure 3) and PCS (Figure 4).

Figure 3: DBS Scores by MCS Tertile



- References:
- Kaplan S, Blimack J, Sorkin D, Ngo-Metzger Q, Greenfield S. (2010). Who can respond to treatment: Identifying patient characteristics related to heterogeneity of treatment effects? Medical Care. 48(6 Suppl 1), S9-S16.
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  - Nunnally JC, Bernstein IH. (1994) Psychometric Theory (3rd ed.). New York, NY: McGraw-Hill.
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Figure 4: DBS Scores by PCS Tertile



### Convergent Validity

- The DBS total score had significant correlations above the hypothesized r=0.30 with each of the evaluated subscales of the WHOQOL-Bref.
  - Physical Health : r=0.572 paper, 0.568 web
  - Psychological : r=0.646 paper, 0.649 web
  - Social Relationship: r=0.460 paper, 0.443 web
  - Environment: r=0.497 paper, 0.515 web

## LIMITATIONS

- The study utilized a convenience sample recruited from web-based advertisements. As such, the sample may differ in demographic and/or health characteristics from the overall US population.
- The self-reported nature of the data is potentially vulnerable to response bias.

## CONCLUSIONS

- In this randomized crossover validation study, the DBS was observed to have adequate measurement properties.
  - The measure was observed to have high one-week reproducibility and was found to be internally consistent.
  - Equivalence between paper and web-based administration mode was demonstrated.
  - The DBS was significantly related to all evaluated subscales of the WHOQOL-Bref.
  - The DBS successfully discriminated between appropriate known groups of the SF-36v2.
- This study provides evidence that the DBS is a valid and psychometrically sound brief measure of disease burden.