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TRANSLATION, VALIDATION AND PSYCHOMETRIC EVALUATION OF PROBLEM AREAS IN DIABETES QUESTIONNAIRE: THE URDU VERSION

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Abstract:

Objective: The study aims to translate and examine the psychometric properties of the Urdu version of Problem Areas in Diabetes (PAID) questionnaire among Type 2 diabetic patients (T2DM) in Quetta, Pakistan.

Method: A standard ''forward–backward'' procedure of translation was used to translate the English version of PAID into Urdu (official language of Pakistan). The translated version was then validated on a convenience sample of 120 T2DM patients attending a public hospital in Quetta, Pakistan. Test-retest was carried out in order to evaluate the stability of test over time using Intraclass Correlation Coefficient. Reliability of questionnaire was tested using Cronbach alpha coefficient. Collected data were analysed for their consistency and validity using KMO confirmatory factor analysis.

Results: Adopting the recommended scoring method, PAID score was 36.25 indicating moderate diabetes-related issues in our study respondents. The instrument demonstrated good internal consistency (Cronbach's alpha = 0.838). The test–retest reliability value was 0.820. The Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy for the factor analysis was 0.834, an index of which Kaiser described as "meritorious" for factorial analyses. Factor analysis extracted 2 factors with cumulative explained variance of 40%. The oblique rotation of items showed strong loading (> 0.60) for all of the study items. The Structure and Pattern Matrix showed that item all questions were clearly factorized into construct confirming our finding not to exclude any item in the original questionnaire.

Conclusion: Results from this translation and validation study conclude that the Urdu version of the PAID is a reliable and valid measure of problem faced by T2DM patients and therefore a valid tool for the advancement of person-centered healthcare.

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*Please cite this article in press as Fahad Saleem et al, **Translation, Validation and Psychometric Evaluation of Problem Areas in Diabetes Questionnaire: The Urdu Version**, Indo Am. J. P. Sci, 2017; 4(05).*

INTRODUCTION:

Since its most primitive depiction, Type II Diabetes Mellitus (T2DM) is a well known unceasing and frequent situation[1]. Even though, the past decades reported an improved competence of T2DM diagnosis and management, the disease silhouette changed at an disquieting rate around the globe[2]. It is now known that cardiovascular diseases, stroke, cancer, continual respiratory ailments and DM carry almost fifty percent of the global disease encumber and 60% of all mortalities are accounted to T2DM [3].

T2DM is a serious apprehension with an increasing pervasiveness [4]. T2DM refers to an assemblage of muddles differentiated by unrelenting hyperglycemia that results from imperfection of insulin. T2DM is one of the 3 types and consists of majority of diabetics. In the past decade, almost 200 million of world' population were diabetic[5]. Additionally, massive increase in the incidence of T2DM was reported [6]. Additionally, one million deaths were also reported because of T2DM [7]. Population augmentation, elderly, dietetic revolutionization and obesity were the major factors towards amplified frequency of T2DM [8]. It was also predicted that this number will be increased to seventy percent and the occurrence will be increased [7].

Inline to the statistics, the prevalence of T2DM were more prominent in South Asia when compared with the globe [9]. One of the reasons is that common population is poor and have less entrée to healthcare services. Therefore, majority of the T2DM patients are identified tardily hence resulting diabetes-related complications [10]. Within this context, management of T2DM plays an important role in disease control. It is known that T2DM patients go through huge pressure while dealing with their disease. However, in the literature, there is no validated tool available in the Pakistani settings to assess the problems faced by T2DM patients. Therefore, this research is aimed to physcometrically analyze the 'problem area in diabetes questionnaire' (PAIDS) in Urdu (official language of Pakistan) for the use in Pakistani population [11]. The PAID scale is a straightforward, one page survey tool which is already been in practice for the last decade. PAID has high satisfactoriness and technical legality which is evident by a number of journal publications and c research abstracts. The

PAID measures diabetes-related expressive anguish and associates it measures of interrelated notions

like depression, social support, health beliefs, and life style. Additionally, the tool has proven to be responsive to changes over time following educational and therapeutic interventions.

METHODS:

Study participants, settings and inclusion criteria

A cross-sectional, observational study design was adopted to conduct this study. The study was conducted at Sandamen Provisional Hospital (SPH) Quetta, Pakistan. SPH is a tertiary teaching hospital and bears the major health burden of the city. Patients aging 18 years and above with a confirmed diagnosis of Diabetes Mellitus Type 2, using diabetic medications (OHA, Insulin or both) for the last six months and literate (speaking, reading and writing) with the national language of Pakistan (Urdu), were enrolled in the study. Those that had serious mental impairments, immigrants from other countries (i.e. Afghanistan, Iran, etc.) and pregnant women were excluded.

Sampling criterion

For translation and validation studies, 60 patients were initially enrolled for the study as this number was anticipated as likely to provide results of accurate validity and reliability (Institute for Health and Care Research, 2010). The number was doubled to increase the reliability of the study outcomes. Hence, a convenience sample of 120 T2DM patients visiting the outpatient department was approached from February 2017 until April 2017.

The translated version of the PAID scale was administered by face-to-face interviews. Socio-demographic and disease-related data were abstracted from the patient's medical records. All interviews were conducted by a pre-trained pharmacist (principal author). At the end of the study, 120 patients were found eligible and included in the analysis with a response rate of 100%. From the current cohort of patients, 30 were randomly selected for a two week reliability test-retest analysis.

Translation of the questionnaire

A structured information sheet, consisting of 2 sections was used for data collection. The first section focused on socio-demographic data and the second section consisted of the 20-itemed PAID scale. Translation of the questionnaires was performed according to the guidelines proposed for translation studies by International Society of

Pharmacoeconomics and Outcome Research [12]. Forward translation of the original questionnaires from English to Urdu was undertaken by 2 independent qualified linguistic translators (native speakers of Urdu and adept in English). However, the translators were blinded from each other to produce a translation of the original questionnaire into the target language. The translated versions were compared with the original versions by healthcare researchers. Reverse translation from Urdu to English was carried out by another independent translator. Continuous discussion sessions were held between the translator and researchers. Inconsistencies were resolved in a consensus meeting and a final version was approved. The translated questionnaire was then piloted with 25 T2DM patients. Their comments on the questionnaires were also taken into consideration which were later discussed and streamlined by the research team. The respondents took 15 minutes (on average) to complete the questionnaire. Responses of the pilot phase were not included in the final study results. At the same time, face and content validity of the questionnaire was determined by the research supervisors. The finalized Urdu version was made available for the reliability and validity study.

Data analysis
Data entry and analysis was performed using SPSS version 21. The statistical significance was set at $P < 0.05$ (two-tailed). Demographic data was presented in numbers and percentages. Internal consistency was assessed using Cronbach's Alpha reliability analysis. For reliability test using

Cronbach's alpha, alpha coefficient ≥ 0.70 was applied [13]. The stability of the construct measures was established by test-retest at an interval of 2 week by the same subjects using Intraclass Correlation Coefficient [ICC] [14]. The ICC model used was the One Way Random effects model, single measures [23]. Confirmatory Factor Analysis (CFA) was used to identify items that most adequately measure the true construct using principal axis factoring extraction while oblique rotation with Kaiser normalization onto 2 predetermined factors was performed to assess the construct validity of the questionnaire [15].

Ethical approval and informed consent
The study was approved by Institutional Review Board of Faculty of Pharmacy & Health Sciences, University of Balochistan, Quetta. Patients who agreed to participate were explained the nature and objectives of the study. Written consent was obtained for both test and re-test data collection. The patients were assured about the confidentiality of their responses and their right to withdraw from the study with no penalty or effects on their treatment.

RESULTS:
Demographic characteristics of study respondents
The demographic and respondents' characteristics are shown in Table 1. Males dominated the cohort with 65 (54.2%) of all respondents belonged to the age group of >47 years. Majority of them were married and 83 (69.2%) had urban residencies. 79 (65.8%) were on oral hypoglycaemic agents and 28 (23.3%) had family history of T2DM.

Table 1: Demographic characteristics of study respondents

Characteristics	Frequency	Percentage
Age group		
28-37	13	10.8
38-47	42	35.0
> 47	65	54.2
Gender		
Male	73	60.8
Female	47	39.2
Income*		
None	35	29.2
Pk. Rs. 20000	6	5.0
Pk. Rs. 20000-40000	25	20.8
> Pk. Rs 40000	54	45.0
Education		
Uneducated	31	25.8
Primary	8	6.7
Secondary	13	10.8
Intermediate	31	25.8
Graduate / postgraduate	37	30.8
Marital status		
Married	117	97.5
Unmarried	3	2.5
Ethnicity		
Pathan	57	47.5
Baloch	26	21.7
Punjabi	22	18.3
Sindhi	1	0.8
Other	14	11.7
Resident		
Urban	83	69.2
Rural	37	30.8
Occupation		
Unemployed	34	28.3
Government employee	27	50.8
Private employee / business	7	56.7
Diabetes duration		
1-5 years	57	47.5
6-10 years	37	30.8
> 10 years	26	21.7
Treatment regimen		
OHA	79	65.8
Insulin	13	10.8
Both	28	23.3
Family history of Diabetes Mellitus Type 2		
Yes	28	23.3
No	92	76.7

*Pk Rs = Pakistan rupees

The responses to PAID scale are reported in Table 2. As per criteria reported by the developers, the mean score was 36.25 indicating moderate diabetes-related issues in our study respondents.

Table 2: Responses to the questionnaire

Items in questionnaire	NP* (f, %)	MP* (f, %)	MDP* (f, %)	SSP* (f, %)	SP* (f, %)
Not having clear and concrete goals for your diabetes care	4 (3.3)	40 (33.3)	48 (40.0)	16 (13.3)	12 (10.0)
Feeling discouraged with your diabetes treatment plan	5 (4.2)	13 (10.8)	60 (50.0)	35 (29.2)	7 (5.8)
Feeling scared when you think about living with diabetes	1 (0.8)	18 (15.0)	39 (32.5)	43 (35.8)	19 (15.8)
Uncomfortable social situations related to your diabetes care	1 (0.8)	17 (14.2)	55 (45.8)	20 (16.7)	27 (22.5)
Feelings of deprivation regarding food and meals?	3 (2.5)	19 (15.8)	34 (28.3)	34 (28.3)	30 (25.0)
Feeling depressed when you think about living with diabetes	2 (1.7)	16 (13.3)	59 (49.2)	33 (27.5)	10 (8.3)
Not knowing if your mood or feelings are related to your diabetes?	7 (5.8)	30 (25.0)	54 (45.0)	24 (20.0)	5 (4.2)
Feeling overwhelmed by your diabetes?	4 (3.3)	17 (14.2)	51 (42.5)	35 (29.2)	13 (10.8)
Worrying about low blood sugar reactions	0 (0)	17 (14.2)	44 (36.7)	38 (31.7)	21 (17.5)
Feeling angry when you think about living with diabetes?	0 (0)	19 (15.8)	54 (45.)	33 (27.5)	14 (11.7)
Feeling constantly concerned about food and eating	11 (9.2)	32 (26.7)	29 (24.2)	27 (22.5)	21 (17.5)
Worrying about the future and the possibility of serious complications?	3 (2.5)	8 (6.7)	51 (42.5)	31 (25.8)	27 (22.5)
Feelings of guilt or anxiety when you get off track with your diabetes management?	4 (3.3)	22 (18.3)	38 (31.7)	49 (40.8)	7 (5.8)
Not "accepting" your diabetes?	3 (2.5)	22 (18.3)	58 (48.3)	35 (29.2)	2 (1.7)
Feeling unsatisfied with your diabetes physician?	3 (2.5)	27 (22.5)	47 (39.2)	32 (26.7)	11 (9.2)
Feeling that diabetes is taking up too much of your mental and physical energy every day?	9 (7.5)	29 (24.2)	53 (44.2)	24 (20.0)	5 (4.3)
Feeling alone with your diabetes?	3 (2.5)	23 (19.2)	39 (32.5)	36 (30.0)	19 (15.8)
Feeling that your friends and family are not supportive of your diabetes management efforts	3 (2.5)	23 (19.2)	55 (45.8)	30 (25.0)	9 (7.5)
Coping with complications of diabetes	2 (1.7)	16 (13.3)	48 (40.0)	32 (26.7)	22 (18.3)
Feeling "burned out" by the constant effort needed to manage diabetes?	2 (1.7)	18 (15.0)	43 (35.8)	30 (25.0)	27 (22.5)

*NP = not a problem, MP = Minor problem, MDP = Moderate problem, SSP = Somewhat serious problem, SP = Serious problem

As per scoring criteria offered by the developers, the mean score was 36.25 indicating moderate diabetes-related issues in our study respondents

The reliability of the questionnaire was established by testing both consistency and stability. The reliability of the constructs ranged from 0.819 – 0.852. Overall Cronbach's alpha value of 0.838 was reported at the test phase and was 0.820 (Retest) at two time points which has exceeded the pre-set value and illustrated very good reliability within the constructs. The Cronbach's alpha values for Test-Rest are illustrated in Table 3.

Table 3: Cronbach's Alpha values at two time points (N = 120 & N = 30)

Items in questionnaire	Scale Mean	Scale Variance	Total Correlation	Cronbach's Alpha
Not having clear and concrete goals for your diabetes care?	43.79	83.107	0.504	0.826
Feeling discouraged with your diabetes treatment plan	43.51	87.513	0.309	0.835
Feeling scared when you think about living with diabetes	43.22	83.163	0.526	0.825
Uncomfortable social situations related to your diabetes care	43.27	84.214	0.430	0.830
Feelings of deprivation regarding food and meals?	43.15	81.893	0.510	0.826
Feeling depressed when you think about living with diabetes	43.45	86.552	0.376	0.832
Not knowing if your mood or feelings are related to your diabetes?	43.81	89.097	0.193	0.840
Feeling overwhelmed by your diabetes?	43.43	83.389	0.515	0.826
Worrying about low blood sugar reactions	43.20	82.514	0.578	0.823
Feeling angry when you think about living with diabetes?	43.38	84.825	0.472	0.828
Feeling constantly concerned about food and eating	43.60	78.292	0.610	0.820
Worrying about the future and the possibility of serious complications?	43.13	80.671	0.654	0.819
Feelings of guilt or anxiety when you get off track with your diabetes management	43.45	94.132	0.940	0.852
Not "accepting" your diabetes?	43.63	88.402	0.284	0.836
Feeling unsatisfied with your diabetes physician	43.55	85.880	0.362	0.833
Feeling that diabetes is taking up too much of your mental and physical energy every day?	43.83	93.165	0.041	0.850
Feeling alone with your diabetes	43.35	85.003	0.374	0.833
Feeling that your friends and family are not supportive of your diabetes management efforts	43.57	85.659	0.406	0.831
Coping with complications of diabetes	43.26	80.580	0.657	0.819
Feeling "burned out" by the constant effort needed to manage diabetes?	43.21	80.586	0.614	0.821

The pooled alpha for all 20 items was 0.838 at week 1 and 0.820 at week 3. Values in columns are reported when item is deleted

Table 4: Reliability of Test-retest (N = 30) using Intraclass Correlation Coefficient (ICC)

Items in questionnaire	Code	ICC*	95% Cl	*p*-value
Not having clear and concrete goals for your diabetes care?	ICC[1,1]	0.840	0.693-0.920	< 0.05
Feeling discouraged with your diabetes treatment plan	ICC[1,1]	0.899	0.798-0.950	< 0.05
Feeling scared when you think about living with diabetes	ICC[1,1]	0.829	0.674-0.914	< 0.05
Uncomfortable social situations related to your diabetes care	ICC[1,1]	0.918	0.836-0.960	< 0.05
Feelings of deprivation regarding food and meals?	ICC[1,1]	0.986	0.732-0.931	< 0.05
Feeling depressed when you think about living with diabetes	ICC[1,1]	0.879	0.764-0.941	< 0.05
Not knowing if your mood or feelings are related to your diabetes?	ICC[1,1]	0.858	0.726-0.930	< 0.05
Feeling overwhelmed by your diabetes?	ICC[1,1]	0.860	0.729-0.931	< 0.05
Worrying about low blood sugar reactions	ICC[1,1]	0.844	0.700-0.922	< 0.05
Feeling angry when you think about living with diabetes?	ICC[1,1]	0.900	0.802-0.951	< 0.05
Feeling constantly concerned about food and eating	ICC[1,1]	0.823	0.664-0.911	< 0.05
Worrying about the future and the possibility of serious complications?	ICC[1,1]	0.938	0.874-0.970	< 0.05
Feelings of guilt or anxiety when you get off track with your diabetes management	ICC[1,1]	0.712	0.481-0.851	< 0.05
Not "accepting" your diabetes?	ICC[1,1]	0.803	0.630-0.901	< 0.05
Feeling unsatisfied with your diabetes physician	ICC[1,1]	0.869	0.745-0.935	< 0.05
Feeling that diabetes is taking up too much of your mental and physical energy every day?	ICC[1,1]	0.851	0.712-0.926	< 0.05
Feeling alone with your diabetes	ICC[1,1]	0.844	0.700-0.922	< 0.05
Feeling that your friends and family are not supportive of your diabetes management efforts	ICC[1,1]	0.900	0.802-0.951	< 0.05
Coping with complications of diabetes	ICC[1,1]	0.823	0.664-0.911	< 0.05
Feeling "burned out" by the constant effort needed to manage diabetes?	ICC[1,1]	0.938	0.874-0.970	< 0.05

*ICC values using One Way Random effect model (Model 1), single measures, 95% Confidence Interval

Confirmatory Factor Analysis: Construct Validity:
The Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy for the factor analysis was 0.834, an index of which Kaiser described as "meritorious" for factorial analyses[16]. Barlett's Test of Sphericity reported a significant Chi-square value of 1160.142 with p < 0.05 leading us to reject null hypothesis and assist us to conclude that there were correlations in the data set which were appropriate for factor analysis.

Table 4 & 5 displays the extracted communalities and loadings into two factors for 20 items along with the ICC. Both pattern matrix and structure matrix were reported as a mean to double confirm the factors because of the possibilities that the values in the pattern matrix could be suppressed due to the relationships between factors 17. Factor analysis extracted 2 factors with cumulative explained variance of 40%. A factor loading of an absolute value of > 0.30 is considered important and will be retaine. Generally, the oblique rotation of items showed strong loading (> 0.60) for all of the study items. The Structure and Pattern Matrix showed that item all questions were clearly factorized into construct confirming our finding not to exclude any item in the original questionnaire.

Table 5: Survey Items, Communalities and Rotated Factor Loading (n=130)

Survey Items	Factor Matrix[a]		Structure Matrix		Pattern Matrix[b]		Communalities
	Factor Loading		Factor Loading		Factor Loading		Extraction
Not having clear and concrete goals for your diabetes care?	.631	.111	.527	.537	.378	.394	.411
Feeling discouraged with your diabetes treatment plan	.644	-.071	.615	.421	.532	.220	.420
Feeling scared when you think about living with diabetes	.460	-.418	.592	.050	.669	-.203	.386
Uncomfortable social situations related to your diabetes care	.650	-.323	.725	.253	.734	-.024	.527
Feelings of deprivation regarding food and meals?	.685	-.492	.828	.163	.894	-.174	.711
Feeling depressed when you think about living with diabetes	.737	-.413	.842	.255	.869	-.073	.713
Not knowing if your mood or feelings are related to your diabetes?	.674	-.113	.660	.415	.587	.193	.467
Feeling overwhelmed by your diabetes?	.677	.246	.512	.662	.306	.547	.519
Worrying about low blood sugar reactions	.724	.101	.615	.598	.455	.426	.535
Feeling angry when you think about living with diabetes?	.721	.083	.620	.583	.467	.407	.526
Feeling constantly concerned about food and eating	.559	.713	.210	.895	-.149	.952	.820
Worrying about the future and the possibility of serious complications?	.660	.138	.542	.577	.379	.434	.455
Feelings of guilt or anxiety when you get off track with your diabetes management	.427	.505	.177	.656	-.083	.688	.437
Not "accepting" your diabetes?	.318	.046	.270	.264	.199	.189	.103
Feeling unsatisfied with your diabetes physician	.566	-.176	.588	.293	.557	.083	.351
Feeling that diabetes is taking up too much of your mental and physical energy every day?	.405	.432	.187	.591	-.041	.607	.351
Feeling alone with your diabetes	.566	-.176	.588	.293	.557	.083	.351
Feeling that your friends and family are not supportive of your diabetes management efforts	.677	.246	.512	.662	.306	.547	.519
Coping with complications of diabetes	.644	-.071	.615	.421	.532	.220	.420
Feeling "burned out" by the constant effort needed to manage diabetes?	.650	-.323	.725	.253	.734	-.024	.527

Note:
KMO=0.834, Barlett's Test of Sphericity, p<0.05
Extraction Method: Principal Axis Factoring.; Rotation Method: Oblimin with Kaiser Normalization.
a. 2 factors extracted. 9 iterations required, b. Rotation converged in 9 iterations.

DISCUSSION:

The KMO statistic is a measure of sampling adequacy, both overall and for each variable[16]. Values < 0.8 are considered as good and serve as an indication that factor analysis will be useful for the variables taken into the study. This usually occurs when most of the zero-order correlations are positive. KMO values less than 0.5 occur when most of the zero-order correlations are negative. KMO values less than 0.5 require remedial action, either by deleting the offending variables or by including other variables related to the offenders. Therefore, our dataset is highly suitable for CFA or "factorizable".

Confirmatory Factor Analysis (CFA) using principal axis factoring extraction method and oblique rotation method with Kaiser normalization onto 2 predetermined factors was performed to assess the construct validity of the questionnaire. The Shapiro-Wilk test which was applied to assess the distribution of data[18], suggested that the data set severely violated the assumption of normality, with all *p*-values less than 0.05, hence principal axis factoring extraction method was chosen for the CFA [19] (Costello & Osborne, 2005). Direct oblimin rotation with delta set at zero was chosen for naturalistic and psychological data whereby we believe the factors are somewhat correlated [20]. We restricted the extracted factors to two factors as there is suggestion of 5 to 10 participants per variable up to a total of 300 [21]. By using a ratio of (5:1 variable), the calculated sample size was 80 subjects. By considering a 20% of non-participation rate, a minimum sample of 96 subjects were needed. Hence, the 120 responses were sufficient to generate good factor solutions. Our analysis also indicated that no item needs to be carefully examined and rephrased in future translations into other languages. Overall, our analysis confirms that two factors are appropriate to account for the validity of the survey instrument in Urdu language.

CONCLUSION:

The translated version of PAID (Urdu) is a reliable and valid tool that can be used for future studies in both clinical and non clinical setups.

Declaration of interest

The authors have no relevant affiliations or financial involvement with any organization or entity with a financial **interest in or financial conflict with the subject matter or materials discussed in the manuscript.**

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