

Validity and reliability of the Patient Assessment on Chronic Illness Care (PACIC) questionnaire among patients with type 2 diabetes mellitus in Malaysia: English version

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Abstract

Introduction: The Patient Assessment on Chronic Illness Care (PACIC) was developed to assess patients' perspectives on the alignment of primary care to the chronic care model. The Malay PACIC has been validated; however, Malaysia is a multicultural society, and English is spoken by many Malaysians and expatriates. We sought to validate the English version of the PACIC among patients with diabetes mellitus in Malaysia, as Malaysians may interpret a questionnaire that was originally developed for Americans in a different way.

Method: This study was conducted between November and December 2016 at two primary care clinics that offered integrated diabetes care at the time. These sites were selected to assess the discriminative validity of the PACIC. Site 1 is a Malaysian Ministry of Health-run primary care clinic while site 2 is a university-run hospital-based primary care clinic. Only site 1 annually monitors patient performance and encourages them to achieve their HbA1c targets using a standard checklist. Patients with diabetes mellitus who understood English were recruited. Participants were asked to fill out the PACIC at baseline and two weeks later.

Results: A total of 200 out of the 212 invited agreed to participate (response rate=94.3%). Confirmatory factor analysis confirmed the 5-factor structure of the PACIC. The overall PACIC score and the score in two of the five domains were significantly higher at site 1 than at site 2. The overall Cronbach's alpha was 0.924. At test-retest, intra-class correlation coefficient values ranged from 0.641 to 0.882.

Conclusion: The English version of the PACIC was found to be a valid and reliable instrument to assess the quality of care among patients with diabetes mellitus in Malaysia.

Introduction

Chronic non-communicable diseases, such as diabetes mellitus (DM), hypercholesterolemia, and hypertension, collectively constitute the global leading cause of death; they were responsible for 38 million (68%) deaths worldwide in 2012.¹ According to the 2015 Malaysia National Health Morbidity Survey (NHMS-5), the prevalence of DM among adults ≥ 18 years was 17.5%,² marking a clear increase from 11.6% in 2006³ and 15.2% in 2011.⁴

In Malaysia, a large majority (79.3%) of DM patients receive treatment from government providers.² However, only 24% of patients have their DM adequately controlled.^{5,6} Consequently, the majority of DM patients suffer from microvascular complications (75%), macrovascular complications (28.9%), and severe late complications, including cataract (27.2%), microalbuminuria (7%), neuropathy

(45.9%), leg amputation (3.8%), and angina pectoris (18.4%).⁵ Despite efforts by the Malaysian Ministry of Health to improve diabetic care and glycemic control, the prevalence of diabetes-related complications in Malaysia has held steady.⁶ This may be because none of these efforts have empowered patients or enabled self-management, whereby patients are responsible for day-to-day decisions about and activities to control their illness. There is a dire need to transform the current health care system in Malaysia by adopting a new health care model that emphasizes and enhances self-management.

The Chronic Care Model (CCM) aims to optimize outcomes for patients with a chronic illness. This model requires an engaged and competent patient to partner with the healthcare system in order to receive the most effective care.⁷ The CCM consists of six elements to improve chronic-illness management: health care organization, clinical information system,

delivery system design, decision support, self-management support, and community resources.⁷ The model encompasses evidence-based medicine and patient-centered care (PCC; defined as “providing care that is respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions”).⁸ PCC has been proven to improve patient outcomes and health care quality as well as reduce patient burden. The CCM has successfully changed healthcare practices for chronic conditions and has increased the success of managing DM patients. Integrated care requires patients with DM to perform self-blood glucose monitoring and enact lifestyle changes.⁷

Several instruments have been developed and validated to assess PCC.⁹ Among them is the Patient Assessment of Chronic Illness Care (PACIC), which was selected due to its use by previous studies to assess patients’ perspectives on the alignment of primary care to the CCM⁹ and patient self-empowerment.¹⁰ Additionally, the instrument has good psychometric properties. In Malaysia, the Malay PACIC has been validated;¹¹ the aim of this study is to validate the English version of the PACIC for DM patients, as Malaysia is a multicultural society, and English is an important secondary language spoken by many Malaysians and expatriates. This re-validation is important because the standard English version of the PACIC, which was originally developed in the United States, may not necessarily be interpreted the same way in Malaysia on account of the cultural differences between the two countries.¹²

Methods

This validation study was conducted between November and December 2016 at two sites. Site 1 is a Malaysian Ministry of Health-run primary care clinic. It is serviced by one family medicine specialist, two medical officers (defined as those who have completed their housemanship, but have no specialist training), one diabetes educator, and one pharmacist. The infrastructure and staffing at site 1 are fairly limited; there are only three consultation rooms. Nevertheless, it provides integrated care for >1500 DM patients annually. The site-1 team delivers all elements of integrated care at one location except for diabetes retinopathy screening, which is done at a nearby clinic. Site 1 uses just one manual form to document all diabetes care; all team members have access to this record in order to ensure continuity of care. As with other public

health centers under the Ministry of Health, this clinic provides data for the National Diabetic Registry and is subject to regular audits. The diabetic team at site 1 annually monitors patient performance and encourages them to achieve their HbA1c targets using a standard checklist in order to achieve the care target set by the Ministry of Health.

Site 2 is a university-run primary care clinic in a teaching hospital under the Ministry of Education. It is serviced by 19 family medicine specialists, 35 family medicine trainees (currently undergoing their 4-year training to qualify as a family medicine specialist), and two medical officers. Site 2 has 32 consultation rooms. All DM patients have access to allied healthcare services (such as a diabetes nurse educator, a pharmacist, and a dietitian) and onsite diabetes retinopathy screening. Nevertheless, diabetes care in site 2 is delivered fragmentally, as all these services are located in different locations throughout the hospital. Providers split their time between patients in the primary care, endocrine, and geriatric clinics, among others; they may not always be well versed in the principles of primary care medicine. Site 2 uses electronic medical records, which likely aids continuity of care. However, access to these records may be limited to certain team members, which would limit its usefulness. Additionally, diabetes care is not regularly audited because there is no diabetes registry.

These sites were selected so we could assess the discriminative validity of the PACIC. We hypothesized that site 1 would have a higher PACIC score than site 2 because it monitors patients’ clinical outcomes and encourages them to achieve their HbA1c target at every consultation.

Participants

Participants were English-speaking DM patients who had been followed-up on for at least six months in the clinic. Patients with cognitive impairment or those who were too ill to participate were excluded.

Sample size

The sample size required to perform factor analysis was based on the number of items in the questionnaire multiplied by 10.¹³ Since the PACIC has 20 items, the minimum number of participants required was 200 (20*10).

Instruments used

Baseline demographic questionnaire

This instrument was used to collect the baseline demographic data of participants (age; gender; level of academic attainment; duration of diabetes; co-morbidities; diabetic medication).

The Patient Assessment of Chronic Illness Care (PACIC)

The PACIC consists of 20 items in five domains: patient activation (3 items), delivery system settings (3 items), goal setting/tailoring (5 items), problem solving/contextual (4 items), and follow up/ co-ordination (5 items). Each item was rated on a 5-point Likert scale from 1 (almost never) to 5 (almost always). Permission was obtained for its use through email on June 16th, 2016. Each domain is scored by the number of items within that domain. The overall PACIC score is calculated by summing the scores of all 20 items. A high PACIC score indicates that the care received was integrated and congruent with the CCM. A low PACIC score indicates that steps can be taken to improve health care services by improving the integration of delivered care.

Face and content validity

Face and content validity of the PACIC was determined by an expert panel consisting of two family medicine specialists, an academic experienced in instrument validation, and a family medicine trainee. The PACIC was then piloted in five adults with DM. Participants were invited to verbally express whether the items were easy to understand—no problems were reported. Hence, no changes were made.

Procedure

Participants were recruited through convenient sampling. All DM patients were screened for eligibility at the triage counter. Patients who fulfilled the inclusion criteria were informed of the voluntary study's purpose through the patient-information sheet. From those who agreed, written informed consent was obtained. Participants were then asked to fill in the baseline demographic form and the PACIC. Two weeks later, the PACIC was mailed to all participants. They were asked to mail the completed questionnaire back using the prepaid stamped envelope. If a reply was not received within a week, a reminder was sent.

Ethics approval was obtained prior to the study from the University Malaya Medical Centre Medical Ethics Committee (approval number: 20167-2615).

Data analyses

All analyses were performed using the Statistical Package for Social Sciences version 23.0 (Chicago, Illinois). Confirmatory factor analysis was done using Analysis of Moment Structure version 24.0 (Chicago, Illinois). Normality was assessed with the Kolmogorov–Smirnov test. Since normality could not be assumed, non-parametric tests were used. Continuous data was presented as median and interquartile range while categorical variables were presented as frequency and percentage.

Validity

Confirmatory factor analysis (CFA) was used to test whether our data fit the original 5-factor model. Various standard fit indices were used: normed chi-square, comparative fit index (CFI), and root mean square error of approximation (RMSEA).

The criteria of a good model of fit were as follows: normed chi-square < 3, CFI > 0.90, and RMSEA < 0.08. Each item should have a factor loading of > 0.4. Average variance (AVE) was calculated as the sum of the squared standardized factor loading divided by the number of items while the composite reliability (CR) was computed as a function of factor loading and error variance.¹⁴ CR and AVE values of more than 0.6 and 0.5, respectively, indicate good construct reliability.¹⁴

The Mann–Whitney U test was used to assess the discriminative validity of the PACIC by comparing the score between the two sites.

Reliability

The internal consistency of the PACIC was assessed using Cronbach's alpha. A Cronbach's alpha value of > 0.90 is said to be highly reliable with excellent internal consistency; 0.70–0.90 suggests that the scale has adequate internal consistency; < 0.70 indicates inadequate internal consistency.¹⁵ Corrected item-total correlation was used to determine the items that did not fit well in the questionnaire. Item-total correlation values must be > 0.20 to be considered acceptable. The effect of removing a single item on the Cronbach's alpha was also determined.¹⁵

Test-retest reliability was assessed using the intra-class correlation coefficient (ICC) to examine the strength of agreement between the repeated measures: >0.75 indicates excellent inter-rater agreement; 0.60–0.74 shows good agreement; 0.40–0.59 indicates fair to moderate agreement; <0.4 means poor agreement. Correlation was assessed using Spearman's rho correlation: <0.2 is poor; 0.21–0.40 is fair; 0.41–0.60 is good; 0.61–0.80 is very good; 0.81–1.0 is excellent.¹⁶

Results

A total of 200 out of the 212 invited agreed to participate (response rate=94.3%). Patients at site 2 were, relative to those at site 1, more likely to have a background in tertiary education and, on average, had a longer duration of DM (Table 1).

Table 1: Demographic characteristics of participants

Variables	Total (n=200) n (%)	Site 1: Ministry of Health-run district primary care clinic (n=95) n (%)	Site 2: University- run hospital-based primary care clinic (n=105) n (%)	p-value#
Median age in years (IQR)	59 (52.0-66.0)	58 (52.0-67.0)	60 (50.5-64.5)	0.445
<i>Gender</i>				
Male	81 (40.5)	40 (42.1)	41 (39.5)	0.660
Female	119 (59.5)	55 (57.9)	64 (61.0)	
<i>Highest level of education</i>				
Primary (6 years of education)	20 (10.0)	20 (10.0)	6 (5.7)	0.010*
Secondary (12 years of education)	109 (54.5)	109 (54.5)	50 (47.6)	
Diploma/tertiary (≥13 years of education)	71 (35.5)	42 (21.0)	49 (46.7)	
Median duration of DM (years; IQR)	7.0 (4.0-11.0)	5.0 (3.0-9.0)	8.0 (5.0-13.0)	<0.001*
<i>Hypoglycemic agents prescribed</i>				
Biguanide (e.g., metformin)	176 (88.0)	83 (87.4)	93 (88.6)	
Sulfonylurea (e.g., gliclazide)	96 (48.0)	53 (55.8)	43 (41.0)	
Insulin	54 (27.0)	24 (25.3)	30 (28.6)	
Alpha-glucosidase inhibitor (e.g., acarbose)	22 (11.0)	8 (8.4)	14 (13.3)	
DPP-4 inhibitor (e.g., sitagliptin)	21 (10.5)	5 (5.3)	16 (15.2)	
<i>Number of patients followed-up on</i>				
By the dietician	119 (59.5)	46 (48.4)	73 (69.5)	
For fundoscopy	141 (70.5)	53 (55.8)	88 (83.8)	
By the diabetic nurse educator	138 (69.0)	80 (84.2)	58 (55.2)	

The Mann–Whitney U test was used for continuous variables while the chi-squared test was used for categorical variables.

* Statistically significant; DPP-4=dipeptidyl peptidase-4

Validity

CFA showed that the PACIC had five domains (Table 2); the normed chi-square was 2.284, the CFI was 0.89, and the RMSEA was 0.08. When all 20 items were loaded into the five constructs, all items had standardized loading factors of >0.40 (except for item 16), average variance extracted (AVE) values >0.50 (except for the delivery system domain and the follow-up/coordination domain), and composite reliability (CR) values >0.60.

Table 2: Confirmatory factor analysis of the Patient Assessment of Chronic Illness Care

Item no.	Domains (factor loadings)					Average variance extracted	Composite Reliability
	Patient activation	Delivery system design/ decision support	Goal setting/ tailoring	Problem solving/ contextual	Follow-up/ coordination		
1	0.812					0.551	0.871
2	0.771						
3	0.632						
4		0.652				0.371	0.639
5		0.577					
6		0.597					
7			0.824			0.666	0.804
8			0.762				
9			0.512				
10			0.516				
11			0.716				
12				0.704		0.591	0.852
13				0.767			
14				0.829			
15				0.769			
16					0.207	0.373	0.722
17					0.471		
18					0.609		
19					0.768		
20					0.800		

Normed chi-squared=2.284; comparative fit index (CFI)=0.89; root mean square error approximation (RMSEA)=0.08.

The overall PACIC score, as well as the score of two domains (goal setting/tailoring and follow-up/coordination), were significantly higher at site 1—a district primary care clinic that monitored patient outcomes—than at site 2, a hospital-based primary care clinic that did not monitor patient outcomes (Table 3).

Table 3: Discriminative validity of the Patient Assessment of Chronic Illness Care

Domain	Site 1: Ministry of Health-run primary care clinic (n=95)		Site 2: University-run hospital-based primary care clinic (n=105)		Mann-Whitney U test	
	Median	IQR	Median	IQR	z-score	p-value
Patient activation	11.00	11.00	10.00	10.00	-1.693	0.090
Delivery system design/ decision support	11.00	11.00	11.00	11.00	-1.87	0.061
Goal setting/tailoring	18.00	18.00	16.00	16.00	-3.635	<0.001*
Problem solving/contextual	14.00	14.00	14.00	14.00	-0.728	0.467
Follow-up/coordination	16.00	16.00	15.00	15.00	-2.825	0.004*
Overall PACIC score	70.00	70.00	67.00	67.00	-2.148	0.032*

The Reliability

The overall Cronbach's alpha for the PACIC was 0.924, with each domain ranging from 0.639 to 0.850 (Table 4). All corrected item-total correlation values were >0.20. The deletion of item 16, "contacted after a visit to see how things were going," increased the Cronbach's alpha from 0.700 to 0.744.

At retest, 141 of the original 200 participants responded (response rate=70.5%); 59 participants were uncontactable (n=48) and 11 refused to answer the questionnaire again (n=11). Spearman rho correlation ranged from 0.597 to 0.858 while intra-class correlation coefficient values ranged from 0.641 to 0.882 (Table 4).

Table 4: Psychometric properties of the Patient Assessment of Chronic Illness Care

Domain	Item no.	Test (n=200)			Retest (n=141)	
		Cronbach alpha	Corrected item-total correlation	Cronbach alpha if item is deleted	Spearman rho correlation	Intraclass correlation coefficient
Patient activation	1	0.780	0.642	0.676	0.746	0.782
	2		0.663	0.657	0.737	0.762
	3		0.554	0.769	0.811	0.882
Delivery system design/ decision support	4	0.639	0.425	0.583	0.829	0.805
	5		0.491	0.490	0.597	0.660
	6		0.438	0.555	0.786	0.811
Goal setting/ tailoring	7	0.792	0.654	0.730	0.715	0.740
	8		0.622	0.741	0.629	0.641
	9		0.498	0.781	0.854	0.823
	10		0.515	0.776	0.851	0.829
Problem solving/ contextual	11	0.850	0.616	0.739	0.760	0.844
	12		0.640	0.830	0.795	0.805
	13		0.698	0.806	0.842	0.801
	14		0.751	0.782	0.743	0.847
Follow-up/ coordination	15	0.700	0.670	0.818	0.785	0.813
	16		0.225	0.744	0.801	0.785
	17		0.504	0.631	0.825	0.766
	18		0.445	0.656	0.838	0.827
	19		0.535	0.620	0.783	0.766
	20		0.606	0.585	0.858	0.773

Discussion

The PACIC was found to be a 5-factor model and a good model-of-fit with adequate psychometric properties. It was able to discriminate between two sites with different levels of integrated care for DM patients.

CFA confirmed that the English version of the PACIC was a 5-factor model, as per the original PACIC validation study.⁹ Some studies reported that the PACIC was a 1-factor,¹⁷ 2-factor,^{18,19} or a 3-factor model.^{11,20} The Malay PACIC found that their instrument was a 3-factor model

("patient healthcare interaction," "follow up/ coordination," and "delivery system design") after two items (10 and 16) were deleted.¹¹ "Goal setting" was not recognized as a domain but was integrated into a new domain ("patient health-health care interaction").¹¹ One possible explanation is that patients may have assessed their care differently as health care systems vary by site. The original PACIC validation also found that the five PACIC domains did not map perfectly to the CCM.⁹ Two of the CCM's components (delivery system design and decision support) merged to become a single domain in the PACIC, while the self-

management component of the CCM was further divided into three separate domains: patient activation, goal setting/tailoring, and problem-solving/contextual counseling.

The PACIC was able to discriminate the integrated care provided, thus confirming the discriminative validity of our instrument; this is in line with a previous study.¹⁹ Site 1 had a higher overall PACIC score because it monitored patients' clinical outcomes and provided a higher level of integrated care than did site 2. This may be because the diabetes care-delivery model at site 1 mirrored the CCM, as it encouraged self-management. Additionally, the advisory clinic panel in site 1 consisted of leaders from the local community, which collaborated with a non-communicable disease prevention community ("*Komuniti Sibat Pembina Negara*" [KOSPEN]),²¹ to enhance primary health care. The regular use and implementation of diabetes care audits using the National Diabetes Registry also enabled site 1 to closely monitor their DM patients (and easily trace those who default treatment) and ensure the delivery of coordinated care.

Site 2 patients were more likely to have a background in tertiary education than those at site 1. This may be because site 2 is an established hospital-based primary care clinic (>50 years) that is located next to a university, meaning it is populated by well-educated retired individuals. Site 2 also saw longer DM durations, likely because these patients tend to have more complications, and specialist referrals are easier at site 2 than at site 1.

The overall Cronbach's alpha of the PACIC was 0.924, which is similar to the findings of previous studies.^{10,18–20} This suggests that the PACIC has achieved adequate internal consistency. However, the "delivery setting" domain only had a Cronbach's alpha of 0.639. This may be due to item no. 4 ("Given a written list of things I should do to improve my health"). Ideally, doctors would provide patients with a written list to improve their health. Instead, however, doctors in site-2 generally advise patients verbally. The practice of contacting a patient after a visit is seldom practiced in Malaysia due to resource limitations (item no. 16: "Contacted after a visit to see how things were going"). However, deletion of item 16 only slightly increased the Cronbach's alpha from 0.700 to 0.744. This item was retained because a Cronbach's alpha value of ≥ 0.700 is adequate. It would be best to keep all the items in the questionnaire so that, when re-validating a questionnaire in another country,

results can be compared. Test-retest reliability is sufficient; Spearman rho values indicate good to excellent correlation while ICC values indicate good to excellent inter-rater agreement, showing that the PACIC has achieved stable reliability. Previous validation studies also found that the PACIC was a reliable instrument.⁹

Although no changes were made to the original English PACIC, it was important for the English PACIC to be re-validated in Malaysia to ensure that the interpretation of the questionnaire was similar to that of the original.¹² This was confirmed by the adequacy of its psychometric properties, which confirmed that the English PACIC can now be used in Malaysia to assess the quality and care provided by primary care physicians.

During the original development of the PACIC, the authors recruited 283 adults suffering from chronic illness to validate their instrument.⁹ The most common chronic illnesses among these participants were hypertension, arthritis, depression, diabetes, asthma, and pain.⁹ Diabetes is an archetypal chronic illness needing integrated care between patients and healthcare providers. Although we only recruited participants with diabetes, it is likely that most of them also have other chronic illnesses, such as hypertension and hyperlipidemia. Therefore, the results of our study may also be applicable to patients with other chronic conditions.

One limitation of this study is that we were unable to randomly recruit participants, as neither site had a registry of DM patients coming in for the day. Additionally, it was not possible to assess the convergent validity of the PACIC because there were no other validated instruments that assessed PCC when this study was conducted. A clear strength of our study is that the English PACIC underwent the process of validation, which provides evidence for the construct and discriminative validity of the English PACIC in Malaysia.

Conclusion

The English PACIC was deemed a 5-factor model and a good model of fit. It was found to be a valid and reliable instrument for patients to assess the quality and care provided by their primary care physicians based on the CCM. This instrument can be used to evaluate the care provided by various centers to better align them with CCM recommendations, ultimately improving the outcomes of DM patients.

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Abbreviations used

DM : Diabetes mellitus
 NHMS-5 : 2015 Malaysia National Health Morbidity Survey
 CCM : Chronic Care Model
 PCC : Patient-centered care

PACIC : Patient Assessment of Chronic Illness Care
 CFA : Confirmatory factor analysis
 CFI : Comparative fit index
 RMSEA : Root mean square error of approximation
 AVE : Average variance
 CR : Composite reliability
 ICC : Intra-class correlation coefficient
 KOSPEN : “Komuniti Sihat Pembina Negara”

Conflicts of interest

All authors declare that they have no conflict of interest.

How does this paper make a difference to general practice?

- The English Patient Assessment of Chronic Illness Care (PACIC) instrument was found to be a 5-factor model and a good model of fit.
- It was found to be a valid and reliable instrument, as it had adequate psychometric properties.
- It can now be used to assess the quality of care among patients with diabetes mellitus in Malaysia and to determine whether the care aligns with chronic care-model recommendations.

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