

Original article

Development of an instrument for patient-reported outcomes in Thai patients with type 2 diabetes mellitus (PRO-DM-Thai)

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Background: Effectiveness of self-care and treatment of diabetes mellitus depends upon patient awareness of their own health and disease outcomes. Physician decisions are improved by insight into patient perspectives.

Objective: To develop an instrument for patient-reported outcomes in Thai patients with type 2 diabetes mellitus (PRO-DM-Thai).

Methods: The study consisted of: (1) content development using a literature review and in-depth interviews of providers and patients, and validity testing using a content validity index (CVI); (2) construct validity and reliability testing by confirmatory factor and Cronbach's α analyses of data from a cross-sectional descriptive survey of 500 participants from May to June, 2011; and, (3) criterion-related validity from a cross-sectional analytical survey of 200 participants from September to November, 2011.

Results: PRO-DM-Thai passed all of the validity tests. The instrument comprises seven dimensions and 44 items, including physical function, symptoms, psychological well-being, self-care management, social well-being, global judgments of health, and satisfaction with care and flexibility of treatment. The CVI at the item-level (I-CVI) were between 0.83 to 1.00 and the scale-level average agreement (S-CVI/Ave) was 0.98. All dimension models had overall fit with empirical data, while the hypothesized model demonstrated a good fit ($\chi^2 = 5.23$; (df = 6), $P > 0.05$, AGFI = 0.986, RMSEA = 0.000). Cronbach's α for the total scale was 0.91 and for the subscales was 0.72–0.90. The total scores effectively discriminated groups of patients with different levels of disease control.

Conclusion: PRO-DM-Thai showed satisfactory levels of validity and reliability when applied to Thai diabetic patients.

Keywords: Instrument, patient-reported outcomes, reliability, type 2 diabetes, validity

Diabetes mellitus (DM) is a chronic disease and a major public health concern in Thailand as well as globally. Its complications, such as neuropathy, retinopathy, stroke, heart disease, and kidney disease lead to both individual and social problems [1]. A previous study revealed that the number of adults with DM (aged 20–79 years) worldwide was 285 million in 2010, but expected to increase to approximately 439 million by 2030; 69% of which would be in developing countries [2]. The number of suspected

cases in Thailand has increased dramatically. In 2009, the Thai National Health Examination Survey IV (NHES IV) showed a prevalence of diabetes in Thai people aged ≥ 15 years of 6.9%, or estimated at 3 million people, twice the NHES II prevalence in 1997 [3,4].

Only 68.8% of them were diagnosed, whereas 62.6% were treated, and only 28.5% of those treated had their fasting blood sugar levels under control [3]. Among Thais, type-2 DM accounts for the majority of DM (99%) [5].

The Diabetes Association of Thailand and the Endocrine Society of Thailand have set up the national guidelines for diabetes treatment, including medical treatment and patient self-management [6]. Patient

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health awareness, treatment compliance, and self-care are recognized as essential in controlling the disease and avoiding complications. Accordingly, the ability of patients to self-assess any disease status and treatment outcomes play important roles. To empower DM patients, instruments for patient-reported outcome have been developed in many developed countries [7-10]. Going beyond clinical indicators, they have been applied in clinical trials or clinical settings to gather information regarding the outcomes from the perspectives of patients, such as quality of life data.

The present study is aimed to develop and validate a questionnaire for patient-reported outcome that is applicable to Thai patients with type-2 DM (PRO-DM-Thai). We hope that this instrument will enable healthcare providers to understand DM patients and treatment outcomes better, while helping the patients to self-assess and improve their compliance and lifestyles.

Materials and methods

To develop an instrument for patient-reported outcome applicable for Thai patients with type 2 diabetes (PRO-DM-Thai), we deployed a three-step methodology consisting of: (1) content development; (2) confirmation of items and dimensions; and (3) instrument testing. The study was approved by the Institutional Review Board of the Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand, (IRB No. 057/53 on April 8, 2010 and April 9, 2011). All patients were provided detailed information and all provided signed written informed consent.

Step 1 Content development

Using qualitative designs, the first step of the study comprised literature review and in-depth interviews. Firstly, we conducted an extensive literature review, seeking to learn and clarify concepts of patient-reported outcomes measurements, and areas or dimensions of outcomes used in existing instruments from other countries. The sources of the information included PubMed, Science Direct, ProQuest, and Google, retrieved from 1990 to 2011. The following keywords and phrases were used: outcome measures in diabetes patients, instruments for measure diabetes outcomes, patient-reported outcomes, patient-reported outcomes for diabetic patients, and disease-specific measures of quality of life. Only published articles that matched the following criteria were selected: (1)

published in English with complete documentation; (2) related to the development of an instrument for patient-reported outcome and dimensions of outcomes, implementation or evaluation of the outcome measurement; or (3) a research article, report of reviewed articles and study reports that applied such instruments. The key findings were analyzed by tabulation to identify as many common areas of outcomes, as well as concrete examples of keywords and questions, as possible.

Based on identified key information from the literature, we then formulated in-depth interview guidelines, and interviewed two groups of informants selected from the diabetic clinic of a university-level, tertiary-care medical center—namely healthcare providers, patients and their relatives. The providers group included 3 men and 6 women; three physicians, two nurses, two pharmacists, and two nutritionists with work experience in diabetic patient care ranging from 5 to 25 years. The consumers group included 14 participants, including 6 men and 8 women, 12 patients and 2 relatives. The mean age of the latter group was 61.36 years, ranging from 49 to 70 years. Ten of them lived with their families, while one lived alone. Half of the group had a university education, whereas 6 participants had a high-school, vocational-school education or diploma, and one had primary school education. The aim was to explore their experience in taking care of DM patients, the outcomes of care they were concerned with, and the outcomes they expected the DM patients to be aware of.

The patient group including the 14 patients with DM and their relatives were randomly selected from the clinic. The 12 patients, 6 men and 6 women, were recruited using the following selection criteria: (1) having been diagnosed with type 2 diabetes by a physician and having more than a one-year history of treatment at the diabetic clinic; (2) being 20 years old or over; and, (3) willing to participate and being able to communicate with the researcher by themselves. The sample, therefore, consisted of 12 patients with 2 to 20 years (mean 11.1 years) of experience with DM. About two-thirds of them received only oral medication, while 2 patients were treated with both insulin and oral hypoglycemic drugs. The group was equally distributed in terms of experiencing DM complications or having no experience at all. Two relatives of the patients were also selected to provide perspectives of care givers with the following criteria: (1) being a close relative who is also a caregiver of a diabetic patient;

(2) 20 years old or over; and (3) being able to understand the questions and willing to give answers.

All interviews were conducted voluntarily, and interviewees were asked for permission for tape-recorded conversations. The recorded information was reviewed and rechecked for content related to possible issues or areas of patient outcome that they could recognize by themselves and report, such as the symptoms of uncontrolled blood sugar levels and complications. Contents from earlier interviews were used to improve subsequent interviews to expand issue coverage, to verify patterns, and to clarify unclear issues. Gathered information from the literature review, the interviews with healthcare providers, and the interviews with patients and their relatives were analyzed and triangulated for a priori content validation. Content analysis, domain analysis [11], and a framework approach [12] were conducted by reading data to retrieve content (and their meanings), and separating and grouping of the contents to identify patterns. The patterns were subsequently linked to reveal relations, or core issues, of patient-reported outcomes, which could be suitable in the context of Thai diabetic patients. Moreover, the outputs were triangulated [13, 14] using information from different sources before arrived at a preliminary framework and domains of patient-reported outcomes.

The first version of PRO-DM-Thai questionnaire was drafted. It was then sent to a group of selected experts for two rounds of assessment of face validity and sampling validity—eleven experts for the first round and six experts for the second round. The experts included physicians, nurses, psychologists, lecturers of endocrinology and metabolism, and a linguist. They rated the questionnaire contents in three areas on 4-point scales: representativeness or relevance, clarity, and comprehensiveness. For example, on the relevance scale, the choices include 4 = the most relevant; 3 = relevant or has to be adjusted; 2 = less relevant or cannot use if not adjusted; and 1 = not relevant [15]. The experts were also asked to make comments on the language and wording issues [16].

The expert assessments, were then proven and used to calculate the content validity index (CVI)—the proportion of experts who judged an item as content valid. CVI were both at the item level CVI (I-CVI) and the scale level CVI (S-CVI) [15, 16]. Values of CVI scores are between 0 and 1. Questions with I-CVI below acceptable level (I-CVI ≥ 0.80) were removed to improve and overall reviewed with

S-CVI (average agreement) to an acceptable level (S-CVI/average ≥ 0.90). Questions were adjusted based on the first-round feedback, and sent for a second round for the final quantitative analysis on content validity including both face validity and sampling validity.

After the content validity test, the second draft of the questionnaire was tested by 15 diabetic patients randomized by queue card numbers at the same diabetic clinic for language comprehension and face validity. The findings were used to improve the third draft of the questionnaire for the construct validity test.

Step 2 Confirmation of items and dimensions

The next step was to test the construct validity of the instrument. To ensure distribution among patients with different levels of disease control, a stratified sampling was applied based on the blood-glucose control [6, 17]. In May and June 2011, we randomly selected a total of 500 participants, and divided them into two groups (250 per group): the well-controlled group with fasting plasma glucose (FPG) ≤ 126 mg/dl and glycated hemoglobin (HbA1c) $\leq 7.0\%$, and the uncontrolled group with FPG > 126 mg/dl and HbA1c $> 7.0\%$. To work with the questionnaire with 44 questions, the sample size was calculated to satisfy the number required for factor analysis (ten samples by one question) [18, 19].

The inclusion criteria include the following:

- 1) Type 2 diabetes patients aged ≥ 20 years old who had been receiving care from the Diabetic Outpatient Clinic at the university hospital for at least 1 year and showed up for follow-up visits.
- 2) Patients were informed about the survey, and were willing to participate in the study.
- 3) Patients who could communicate well with the researchers. In case of problems with reading, the researcher would read the questions to them, and let the patient select the answers.

Patients who have at least one of the following criteria were excluded:

- 1) Patients who were unable to understand or give information.
- 2) Patients who could not communicate in Thai.
- 3) Patients who were pregnant, because it is difficult to differentiate between outcomes affected by type 2 diabetes and pregnancy.

The collected data were analyzed by first-order confirmatory factor analysis (CFA) to examine the patterns of inter-relationships between several constructs [20]. To test construct validity of the questionnaire, each hypothesized dimension in the questionnaire was tested separately, including (physical function (PF), symptoms (Sym), psychological well-being (Psycho), self-care management (SM), social well-being (Soc), global judgments of health (GlobH), and satisfaction with care and flexibility of treatment (Satis). Then, the overall model of PRO-DM-Thai was tested to ensure a good fit.

Applying the same dataset, the questionnaire was tested for reliability by calculating Cronbach's coefficient (α) for internal consistency of both the entire scale and each of the subscales by dimension. The criterion for minimum performance was set at 0.70 or greater, a generally accepted standard [18]. After the contents of each item in each dimension were confirmed by CFA, and passed the reliability check, they were then used to develop the final draft of the questionnaire.

Finally, in this step we completed the operational definitions of the tool that is The Patient-Reported Outcomes Instrument for Thai Patients with Type 2 Diabetes Mellitus given abbreviated name PRO-DM-Thai. The questionnaire was used as a self-assessment instrument for diabetic patients to evaluate the outcomes of their diabetic care in two main areas: (1) the outcomes in terms of health, and (2) the outcomes directly related to the process of care.

Step 3 Instrument testing

The final draft was tested for concurrent criterion-related validity, to see whether or not the instrument could discriminate between patients with different levels of disease control. Applying similar inclusion and exclusion criteria as in the step-2 survey, 200 patients with DM were randomly selected at the clinic during the period of September to November, 2011. Instrument testing was conducted by either self-administration, or by face-to-face interview with the questionnaire.

In addition, at the same hospital visit, all patients received an assessment by a physician and were classified based on the assessment into three groups with different levels of disease control as follows:

Group 1: Well controlled, when the patient's glucose level is close to normal with HbA1c 7.0% and no complications.

Group 2: Fairly controlled, when the patient's symptoms of hyperglycemia or hypoglycemia have a HbA1c >7.0% to 10.9% and have mild complications.

Group 3: Poorly controlled, when the patient has several complications with HbA1c \geq 11.0%, with symptoms of hyperglycemia or hypoglycemia caused by acute complications such as diabetic ketoacidosis (DKA), hyperosmolar, severe hypoglycemia or infection.

Differences in the patient scores from the instrument between the three groups were then analyzed by Spearman's rank correlation, Kruskal–Wallis tests, and discriminant analysis to test the following hypotheses: (1) the scores gained from PRO-DM-Thai in each group of patients with different levels of disease control and the results from clinical diagnosis by a physician to assess the correlation; (2) the mean scores gained from PRO-DM-Thai in each group of patients with different levels of disease control having significant differences, (3) from (1) and (2), if the scores gained from the PRO-DM-Thai in each group of patients evaluated by a physician have significant differences so that the differences that occur in any dimension.

Results

Step 1 Content development

Based on the literature review, the a priori content validation results for patient-outcomes for diabetic patients varied, but could be grouped into 9 dimensions [7, 21, 22]. These were: (1) physical function, (2) symptoms, (3) global judgments for health, (4) psychological well-being, (5) social well-being, (6) cognitive functioning, (7) role activities, (8) personal constructs, and (9) satisfaction with care and flexibility of treatment, which were the preliminary groups used as a guideline for in-depth interviews. The content analysis after the review and the interviews based on domain analysis method [11] and framework approach method [12] resulted in a reduction of the number of dimensions from 9 to 7. There were three original patient-outcome areas that were dropped. Firstly, there were concerns from the expert interviews on the validity of the "cognitive functioning" because patients with impairment in this area might not be able to self-report themselves correctly, especially the elderly, and suggested that this dimension be reserved for provider judgment [21]. Furthermore, certain related concepts in this area were integrated in the other dimensions, which might lead to better interpretation of patient outcomes, including self-management, psychological

well-being (e.g., concentration), and social well-being (e.g., ability to communicate). Similarly, the “role activities” dimension was omitted because related items were better covered by the “social well-being” dimension [23, 24]. Finally, the “personal construct” dimension was combined into the “psychological well-being” dimension because the interview information indicated the idea of spirituality and life satisfaction seemed to appeal more in a Buddhist society, particularly in the population age group common to DM, than satisfaction with bodily appearance as in the Western society [25, 26]. The self-management dimension was added as a new domain. They assessed whether or not the patient behaviors reflect their knowledge of the disease and self-efficacies were consistent with what had been raised by the systematic review of the effectiveness of self-management for people with diabetes and recommendations of the Task Force on Community Preventive Services [27] and other research reports [28-30]. Outcomes of care, both by the providers and self-care, were areas of outcomes that were usually not included in instruments focusing only on the quality of life [31, 32]. The first draft questionnaire consisted of 43 items in 7 dimensions. The linkage of contents and meanings on patient-reported outcomes by the core dimensions are shown in **Table 1**.

The first round of review was done by a group of 11 experts for relevancy to patient-reported outcomes and phrasing of diabetic care in a Thai context. The experts suggested suitable rephrases for improvements of some items. Seven items had to be rewritten to improve their semantic meanings; 16 items were further revised for general Thai patients with type 2 diabetes mellitus to improve their clarity; 10 items were dropped, and 17 new items were added. The later revision was improved and reevaluated by 6 experts. The results of this second round of review suggested the need for minor revisions of 5 items in a total of 50. The second draft was examined by 15 type-2 DM patients. They indicated that some words or phrases were too difficult to understand; some questions were too long, and suggested wording for revisions. The results from this session led to the third draft of the questionnaire, which consisted of 44 items for confirming construct validity testing by confirmatory factor analysis. Finally, after the third round of evaluation including both face validity and sampling validity, the experts approved the item clarity and content validity, also passed acceptability by providers, patients and their relatives. The CVI of the

third draft for relevant items at the I-CVI were between 0.83 and 1.00 and at the S-CVI/ave. was 0.96, as shown in **Table 1**.

Step 2 Confirmation of items and dimensions

The questionnaire was tested for construct validity by the sample of 500 patients with type 2 diabetes. Their characteristics are summarized in **Table 2**. The data were analyzed by confirmatory factor analysis. The measurement model described relationships between the observed variables and the underlying constructs they are designed to measure or the unobserved variables. There were eight measurement models in the present study: physical function (PF model), symptoms (Sym model), psychological well-being (Psycho model), self-care management (SM model), social well-being (Soc model), global judgments of health (GlobH model), satisfaction with care and flexibility of treatment (Satis model), and patient-reported outcomes (PRO-DM-Thai model). The modification index was used to adjust the model fit. The summary of goodness of fit of each dimension and the overall measurement model are shown in **Table 3**. Chi-square tests had lower values from the initial models and reached nonsignificant levels and the ratio of χ^2 to the degrees of freedom (relative chi-square) was less than 3 (less than 2 = model good fit, less than 3 = model fit), that indicating a difference between the estimated and observed covariance matrices. Both goodness-of-fit index (GFI) and adjusted goodness-of-fit index (AGFI) values were close to 1.00 (more than 0.95 = model good fit, more than 0.90 = model fit), and the root mean square error of approximation (RMSEA) values were less than 0.05 (less than 0.05 = model good fit, between 0.05 and 0.08 = model fit) [20]. All indices of measurement models were acceptable. As a result, the final draft of the questionnaire was concluded to comprise seven dimensions of patient outcomes, and 44 items.

Reliability testing

The questionnaire’s reliability was satisfactorily high as the Cronbach’s α for the total scale was 0.91. The coefficient for the subscales were as follows: 0.82 for physical function subscale, 0.90 for symptoms subscale, 0.72 for psychological well-being subscale, 0.85 for self-care management subscale, 0.76 for social well-being subscale, 0.90 for global judgments of health subscale, 0.84 for satisfaction with care and flexibility of treatment subscale, as shown in **Table 3**.

Table 1. Summary of content development of PRO-DM-Thai

Dimensions	Description	Questions items (abbreviations)	Item derivation			
			I-CVI	Reviews	Pt	Exp
Physical Function (PF)	Relating to physical ability and measuring physical functioning e.g., mobility, dexterity, range of movement, physical activity, activities of daily living	PF1 Self doing activities	1.00	✓ [7, 10, 21-23, 28, 33-38]	✓	✓
		PF2 Self doing activities of daily living	1.00			
		PF3 Self doing housework	0.83			
		PF4 Self walking more than 500 meter	0.83			
		PF5 Self use of public transport	1.00			
Symptoms (Sym)	Relating to diabetes-specific symptoms and diabetes-related symptoms e.g., hypoglycemia, hyperglycemia, neuropathy, nephropathy, retinopathy	Sym1 Hypoglycemic symptoms	1.00	✓ [7, 10, 21-24, 28, 33, 36-39]	✓	✓
		Sym2 Hyperglycemic symptoms	1.00			
		Sym3 Abnormal symptom at foot/feet	1.00			
		Sym4 Nephropathy-related symptoms	1.00			
		Sym5 Cardiovascular disease-related symptoms	1.00			
		Sym6 Have a blurred vision	1.00			
		Sym7 Have infected symptom in the body	1.00			
Psychological Well-being (Psycho)	Relating to psychological well-being especially disease-related e.g., anxiety, depression, coping, positive well-being and adjustment, life satisfaction, concentration	Psycho1 Feel depression and anxiety	1.00	✓ [7, 10, 21-24, 28, 33-40]	✓	✓
		Psycho2 Can find a way to relieve stress	1.00			
		Psycho3 Positive well-being and adjustment	1.00			
		Psycho4 Can live with life satisfaction	1.00			
		Psycho5 Concentrate on work or activities	0.83			
Self-care management (SM)	Relating to self-care behavior managing disease, able to follow recommendations, exercising, check-ups, monitoring, diet control, drug compliance	SM1 Able to look after yourself in time and accurate if hypoglycemia occur	1.00	✓ [7, 10, 21-24, 27-30, 33, 35-39]	✓	✓
		SM2 Able to look after yourself in time and accurate if hyperglycemia occur	1.00			
		SM3 Measure blood glucose level once a week	0.83			
		SM4 Weight control	1.00			
		SM5 Look after feet health	1.00			
		SM6 Sweet meal diet control	1.00			
		SM7 Carbohydrate diet control	1.00			
		SM8 High-fat diet control	1.00			
		SM9 Salty foods diet control	1.00			
		SM10 Avoid beverages contained alcohol	1.00			
		SM11 Drug compliance	1.00			
		SM12 Exercise at least 3–5 times a week	1.00			
Social well-being (Soc)	Relating to family and intimate relations, social contact, integration and social opportunities, leisure activities, and satisfaction, travelling	Soc1 Family relations	1.00	✓ [7, 10, 23, 24, 28, 33-39]	✓	✓
		Soc2 Friends and acquaintances relations	1.00			
		Soc3 Attend family activities	1.00			
		Soc4 Attend community events	1.00			
		Soc5 Give advice to each other with diabetes patients	1.00			
Global judgments of health (GlobH)	Relating to overall of general quality of life and the impact of diabetes on general quality of life e.g., current health ratings, diabetes controls life, general restrictions, diabetes restrictive, diabetes limits freedom	GlobH1 The hypoglycemia occur 3–4 times a week	1.00	✓ [7, 10, 21, 23, 24, 28, 33-40]	✓	✓
		GlobH2 Physical examination to detect complications of diabetes at least once a year	1.00			
		GlobH3 The HbA1c more than 9%	1.00			
		GlobH4 Have a complication that much affected on life	1.00			
		GlobH5 Cannot do something due to be careful about the level of blood glucose	1.00			
Satisfaction with care and flexibility of treatment (Satis)	Relating to satisfaction with care and treatment of patients and care teams, (information, time, and care), access to care	Satis1 Satisfied with information given by physicians and nurses	1.00	✓ [7, 10, 21-24, 28, 33-40]	✓	✓
		Satis2 Can apply the knowledge learned from doctors and nurses to control diabetes	1.00			
		Satis3 Satisfied with physician treatment	1.00			
		Satis4 Medical satisfaction	1.00			
		Satis5 Satisfied with the process of health care services	1.00			

Total 7 dimensions, 44 Items, Scale-content validity index average agreement: S-CVI/Ave = 0.96

I-CVI = Item-content validity index, Reviews = Literature review, Pt = Patients, Exp = Expert

Table 2. Characteristics of participants

Characteristics	Step2 (n = 500)	Step3 (n = 200)
Age (range 32–90 and 32–89) (years)	66.1 ± 10.8	67.2 ± 11.0
Duration of type 2 diabetes (years)	15.1 ± 8.4	15.8 ± 7.9
Sex (F/M) (%)	66.8/33.2	68.0/32.0
Marital Status (%)		
Single	12.6	13.5
Married	66.8	70.0
Widowed	20.6	16.5
Education level (%)		
Primary school or lower	41.2	46.0
Secondary school	21.6	23.0
University or higher	37.2	31.0
Occupation (%)		
Housework / not working	48.0	59.5
Currently employed by government or private sector	12.2	11.5
Privately owned business	10.4	10.0
Retirement	23.2	19.0
Other	6.2	–
Therapy (%)		
Diet control only	2.2	–
Oral medicines only	62.6	57.0
Insulin only	2.4	1.0
Insulin + oral medicines	32.8	42.0
Type of health insurance coverage (%)		
Universal coverage scheme or Social security scheme	10.4	10.0
Civil servant medical benefit scheme	62.4	59.0
Out-of-pocket expense	27.2	31.0
Living status (%)		
Living with family	87.4	86.5
Living with relative(s)	7.6	7.5
Living alone	5.0	6.0
Related complications (%)		
Not have complications/comorbidity	4.6	2.0
Have complications/comorbidity	95.4	98.0
Mean HbA1c (%)	7.4 ± 1.4	7.7 ± 1.7
Mean fasting plasma glucose (FPG) (mg/dl)	140.0 ± 51.1	146.4 ± 59.7

Table 3. Goodness-of-fit summary for each dimension and the overall measurement models (n = 500)

Measurement model	Index						Reliability coefficient
	χ^2	χ^2/df	P	GFI	AGFI	RMSEA	Cronbach's α
PF model	2.34	0.78	0.50	0.998	0.991	0.000	0.82
Sym model	14.68	1.47	0.14	0.992	0.977	0.031	0.90
Psycho model	1.70	0.56	0.64	0.999	0.993	0.000	0.72
SM model	42.07	1.27	0.13	0.986	0.967	0.023	0.85
Soc model	0.72	0.36	0.70	0.999	0.996	0.000	0.76
GlobH model	0.01	0.01	0.95	1.000	1.000	0.000	0.90
Satis model	0.72	0.24	0.87	0.999	0.997	0.000	0.84
PRO-DM-Thai model	5.23	0.87	0.51	0.997	0.986	0.000	0.91

χ^2 = Chi-square statistic, df = degrees of freedom, relative chi-square = χ^2/df , GFI = Goodness-of-fit index, AGFI = Adjusted goodness-of-fit index, CFI = RMSEA = Root mean square error of approximation

Step 3 Instrument testing

The final draft questionnaire of PRO-DM-Thai was tested for concurrent criterion-related validity with another group of patient samples of 200 participants. The sample characteristics are shown in **Table 2**. The findings indicate the total scores of the patient-reported outcomes by the PRO-DM-Thai are able to discriminate groups of patients with different levels of disease control (**Figure 1**). Detailed results of the

test, summarized in **Table 4**, demonstrated that the scores are significantly different between the well-controlled (W), the fairly-controlled (F), and the poorly-controlled (P) groups. As shown in **Table 4**, the dimensions having highest discriminating powers include the satisfaction with care and flexibility of treatment, global judgments for health, symptoms, and self-care management, respectively.

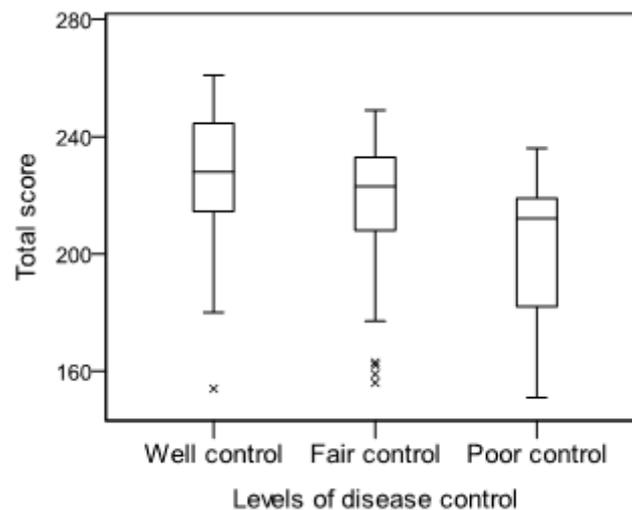


Figure 1. Boxplots of the PRO-DM-Thai total scores stratified to groups of patients with different levels of disease control assessed by physicians

Table 4. Summary of statistical testing of PRO-DM-Thai to discriminate patients with difference levels of disease control assessed by physicians

Technique	Spearman's rank correlation (<i>r</i>)	Post hoc test and <i>P</i> of one-way ANOVA				Discriminant analysis Classified	Ranking
		W>F	F>P	W>P	<i>P</i>		
Overall	0.27**	✓*	✓*	✓*	0.001*	Yes	+++
Dimensions							
Physical Function	0.03	–	–	–	0.913	No	0
Symptoms	0.29**	✓*	–	*	<0.001**	Yes	++
Psychological Well-being	0.11	–	–	–	0.222	No	0
Self-care management	0.25**	✓*	✓*	✓*	0.002*	Yes	++
Social well-being	0.03	–	–	–	0.383	No	0
Global judgments of health	0.29**	✓*	–	✓*	<0.001**	Yes	+++
Satisfaction with care and flexibility of treatment	0.31**	✓*	✓*	✓*	<0.001**	Yes	+++

P* < 0.05, *P* < 0.001, “✓” = different, “–” = not different, W = well controlled, F = fairly controlled, P = poorly controlled, Yes = classified, No = not classified, +++ = results of testing have significant all 3 techniques, ++ = results of testing have significant 2 techniques, 0 = results of testing not significant all techniques

Discussion

Based on a three-step development approach consisting of the qualitative and quantitative parts to test all content validity, construct validity, and concurrent criterion-related validity, the newly developed PRO-DM-Thai questionnaire demonstrates good reliability and validity properties. The final version comprises seven dimensions and 44 items, as shown in **Table 1**. By comparison with the first draft based on evidence from the key literature [7, 21, 22], we originally defined nine dimensions including: (1) physical function, (2) symptoms, (3) global judgments for health, (4) psychological well-being, (5) social well-being, (6) cognitive functioning, (7) role activities, (8) personal constructs, and (9) satisfaction with care and flexibility of treatment. Only 6 out of the 9 dimensions, including physical functions, symptoms, global judgment for health, psychological well-being, social well-being, and satisfaction with care and flexibility of treatment, remained valid throughout the subsequent steps of the validation process in our study settings without major revisions. They indicated common areas of outcomes which could be perceived, self-assessed, and reported by Thai patients with DM, and patients with DM in developed countries.

The “physical function” primarily focused on activities of daily living. Although there might be some differences in details at the item level, such as ability to operate machinery (washing, dressing) and drive a car, mostly they were areas of patient and provider concerns as supported by consistency of evidence from the literature and the interviews. This area is a particular concern in the elderly group [25, 41]. Similarly, the “symptoms” dimension could be recognized by patients because they usually reported the information during physician visits. The “global judgment of health” also remained in the instrument because it reflected the health contentment, and patient assessment of impacts of DM on overall quality of life and daily living. The “social well-being” focused on relationships with family members and friends, as well as attendance in community events. Nevertheless, unlike the reviewed evidence, the satisfaction with sexual capability was dropped in subsequent validation processes. Thai patients, particularly the elderly, were found very reluctant to respond to questions in this area, which might compromise the validity of the assessment and willingness to use the tool. This issue might be reconsidered if the application of this instrument was on other young, sexually active

patients. In addition, the “psychological well-being” dimension was about feelings and emotional responses to the disease, such as anxiety, stress, focus, satisfaction in life. However, with respect to the interview, content validity testing and construct validity testing, the original outcome area of personal construct was integrated into this dimension. This dimension also included satisfaction with bodily appearance. By contrast, the “satisfaction with care and flexibility of treatment,” asked about patient’s contentment of health care given by physicians and nurses, including medicine [10, 42, 43]. Therefore, the core patient-reported outcomes dimensions of the instrument in diabetic care for the Thais were concluded to have 7 dimensions or domains, namely: (1) physical function, (2) symptoms, (3) psychological well-being, (4) self-care management, (5) social well-being, (6) global judgments for health, and (7) satisfaction with care and flexibility of treatment. If we would go into more details, the outcomes could be divided into two groups as follows: Group 1, the outcomes in terms of health, and Group 2, the outcomes directly related to the process of care. It should also be noted that the first group of outcomes could be, firstly direct health outcomes—such as physical function, symptoms, psychological well-being, and global judgments of health, or secondly outcomes that were consequently affected health statuses, or disease complications or resulted disabilities—such as social well-being, and global judgments of health. By contrast, the Group 2 outcomes have not been used as common in clinical trials, such as those of Fitzpatrick et al. and Garratt et al. [7, 21, 22].

The PRO-DM-Thai passed all validity tests—content, construct, and criterion-related validity. The content validity test combined both qualitative and quantitative techniques. Nevertheless, it was difficult to compare content validity indices with previous studies as most reviewed studies did not assess their content validity indices. The construct validity confirmed that the PRO-DM-Thai questionnaire comprised appropriate content in the context of the Thai patients with DM. All dimensions models demonstrated overall good fit with empirical data, as indicated by the hypothesized first-order CFA to test the multidimensionality of a theoretical construct [20]. All indices of this questionnaire were acceptable. Besides, scoring was not difficult to interpret. The ability to discriminate groups of patients with different levels of disease control using the total score was also satisfactory. It is noteworthy that, despite some

differences, the dimensions having most discriminating powers that include satisfaction with care and flexibility of treatment, global judgments of health, symptoms, and self-care management, respectively. The finding was supported by Heisler et al. [29], who assessed the well-being of the patient's ability to self-manage in diabetic care. They found that patients who have always self-assessed their diabetes management were associated with success in controlling blood glucose levels. As a result, our evidence was sufficient to demonstrate that the PRO-DM-Thai might be more suitable for cross-sectional, short-term evaluation. Further studies are needed for longitudinal assessments in which patients may be more exposed to long-term complications of DM because this is the first time such a patient-reported outcomes instrument has been developed and tested. The main objective of the first testing this kind of instrument is not to check for sensitivity, specificity, because the purpose of developing this tool is not for diagnosis. In step three of the study we proved criterion-related validity of the instrument, which can accurately differentiate patients by comparing with clinical judgment by a physician, when we found that the total scores of the patient-reported outcomes by the PRO-DM-Thai are able to discriminate groups of patients with different levels of diseases control. This was sufficient qualification for the first testing to accept validity at the time, and did not explore the subject of sensitivity to changes before, because this basic pattern of the process of developing tools was that we must prove the validity at the time before studying in terms of sensitivity to changes at the later state of development. It is similar to the development of other patient-reported outcome instruments [44, 45]. Therefore, one of the limitation of this study is the PRO-DM-Thai does not reflect the sensitivity to changes in disease condition and further study is needed to improve this limitation.

The PRO-DM-Thai questionnaire achieved a high level of internal consistency as measured by the Cronbach's α for the total scale at 0.91. Compared to the study of Srithongsuk [46], the Thai version of the Diabetes Quality of Life questionnaire had a Cronbach's α for the total scale of only 0.74. At a subscale level, we could compare the test of the PRO-DM-Thai ($n = 500$) with the original English version ($n = 262$) and the Thai-translated version ($n = 397$) of the Diabetes-39 or D-39 (the quality of life questionnaire for diabetic patients) in four similar

dimensions of outcomes from the study of Songraksa [47]. They had quite similar levels of Cronbach's coefficients. We believe that a better reliability performance may be a result the development of the PRO-DM-Thai in Thailand, rather than adapted from other settings [48].

In spite of the demonstrated strengths of this instrument, the PRO-DM-Thai should be used with caution. Certain limitations because of our validation methodologies and the characteristics of this version of the questionnaire should be noted. First, the study setting was limited to one university-level hospital in order to maximize its internal validity. The hospital is in an urban area, having rather good educational background or access to health information. Its generalizability should be further tested. Second, the instrument was designed and tested in patients with type-2 DM receiving ambulatory care. Applications of the PRO-DM-Thai in patients with type-1 DM needs more investigation. Moreover, we did not explore its use in inpatient care. Third, although the instrument indicates the 7 core dimensions of patient-reported outcomes in DM care, score standardization is necessary for wider use. It needs larger study population to build a more reliable database for comparison. On average it takes about 30 min to respond to the questionnaire. Therefore, reduction of the items into a shorter version may make this instrument more practical [44, 45, 49, 50].

Conclusion

As instruments for patient-reported outcomes have become more common in developed countries, they could also be useful in developing ones. Patient-reported outcomes for patients with type-2 DM in the Thai context might comprise 7 dimensions including physical function, symptoms, psychological well-being, self-care management, social well-being, global judgments for health, and satisfaction with care and flexibility of treatment. The PRO-DM-Thai questionnaire with 44 items has been proven a valid and reliable a tool for DM patients to assess the outcomes of their diabetic care. This instrument may help empower patients to monitor themselves, and assist physicians to gain more insight into the outcomes of treatment from the patients' perspectives.

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