

## Original Research

# Creation and validation of a semi-quantitative instrument to assess the confidence of pharmacists in medication consultation for patients with depression: The pharmacists' confidence scale about medication consultation for depressive patients (PCMCD)

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Received (first version): 17-Jul-2019

Accepted: 20-Oct-2019

Published online: 4-Dec-2019

### Abstract

**Objectives:** To develop a semi-quantitative instrument to assess pharmacists' confidence in medication counseling for patients with depression, The Pharmacists' Confidence scale about Medication Consultation for Depressive patients (PCMCD), and investigated its validity.

**Methods:** Following discussions with practicing pharmacists, we developed a 12-item questionnaire to assess pharmacists' confidence in medication counseling for patients with depression. We launched web-based cross-sectional survey during November and December 2018 to 77 pharmacists employed at drug chain stores in Kansai area. Factor analysis was performed to evaluate the configuration concept validity. The least-squares method was used for factor extraction, and the resulting factors were subjected to direct oblimin rotation, with a factor loading cut-off of 0.4. To assess internal consistency, Cronbach's alpha values were calculated for each of the extracted factors (subscales). A multiple regression analysis was performed using simultaneous forced entry, with the scores obtained for each subscale as dependent variables and responder attributes as independent variables in order to investigate the factors associated with each subscale.

**Results:** During the factor analysis procedure, four questions were excluded by the cut-off rule. Eventually, a model with three subscales was identified, with a cumulative sum of squared loadings being 61.9%. The subscales were termed "relationship building," "comprehension of condition," and "information provision" based on the nature of the questions relevant for each of them. The Cronbach's alpha values for these subscales were 0.92, 0.73, and 0.72, respectively. The average inter-item correlation was 0.378. In addition, multiple regression analysis revealed that there were significant correlations between pharmacist career and both relationship building and information provision.

**Conclusions:** The PCMCD model demonstrated a satisfactory construct validity and internal consistency. This model will provide an excellent tool for assessing pharmacists' confidence in depression care.

### Keywords

Depression; Depressive Disorder; Pharmacists; Self Concept; Referral and Consultation; Counseling; Factor Analysis, Statistical; Surveys and Questionnaires; Validation Studies as Topic

## INTRODUCTION

According to 2017 health statistics published by the Japanese Government, the number of patients with depression and other mood disorders reached a national high of 1.276 million.<sup>1</sup> Pharmacotherapy plays an important part of depression therapies. However, antidepressant drugs cause nausea, somnolence, and other side effects, which often result in poor adherence as patients autonomously withdraw from medication.<sup>2,3</sup> Poor medication adherence compromises their work efficiency and quality of life (QOL).<sup>4,5</sup> For these reasons, pharmacists who interact with patients receiving antidepressants have an important role in depression care.

Interventions by pharmacists include patient education, emotional support, advice on adherence issues, monitoring of adverse events, and reference to psychiatrists.<sup>6,7</sup> Many randomized controlled trials showed that pharmacist intervention improves medication adherence.<sup>8-18</sup> Although the majority of pharmacists take a positive attitude towards their role in depression care, their practice may not span the full range of pharmaceutical care services for clients with depression.<sup>19</sup> A Japanese survey of practicing pharmacists reported that 64.0% acknowledged "difficulty relating to patients with mental illnesses".<sup>20</sup> Given an increasing academic and professional interest in improving pharmacists' skills to deal with patients with depression and other mental problems, we needed a psychometric instrument to evaluate the confidence and attitudes of pharmacists towards patients with depression.

The Depression Attitude Questionnaire (DAQ) is a well-known measure to examine health care professionals' attitude to depression.<sup>21</sup> Although this tool was originally developed in the UK for general practitioners, it was

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subsequently used with pharmacists and other professions.<sup>22-24</sup> The authors of the DAQ later developed a revised version (R-DAQ), and its validity has been demonstrated.<sup>25</sup> Scheerder *et al.* developed a set of nine questions that focused on the attitudes of pharmacists in regard to depression care.<sup>26</sup> Their questionnaire was used to evaluate the impact of depression training on community pharmacists' stigma toward people with depression.<sup>27</sup> In Japan, Tanaka *et al.* published and validated the Mental Illness and Disorder Understanding Scale (MIDUS).<sup>28,29</sup> Whereas the MIDUS was originally designed for clinicians, it was also valid for pharmacists.<sup>30</sup>

Despite these advances, there was no questionnaire that asks pharmacists to evaluate their confidence in their medication guidance for patients taking antidepressants. The DAQ has 24 questions and does not cover the level of confidence clinicians have in dealing with patients. The MIDUS questionnaire also was not designed for the purpose of measuring pharmacists' confidence when performing their duties. In fact, confidence and attitude are different social science concepts and should therefore be analyzed using different approaches.<sup>31</sup> Lindblom-Ylänne *et al.* defined confidence as "a recognition of one's own ability to achieve a specific goal under specific conditions".<sup>32</sup> Attitude, on the other hand, is not necessarily a recognition of one's own ability, and we believe that attitude may be clearly distinguished from confidence in this respect. In this study, we developed and evaluated the Pharmacists' Confidence Scale about Medication Consultation for Depressive Patients (PCMCD).

## METHODS

This study was performed with the approval of the Institutional Review Board of the Osaka University of Pharmaceutical Sciences. This study did not receive any investment funding.

This study was conducted from November 27, 2018 to December 30, 2018. This study was conducted in 161 pharmacists working at pharmacy chains who consented to participate in research on the effects of interventions initiated by drug store pharmacists for the purpose of improving adherence with currently planned antidepressant therapy (University Hospital Medical Information Network [UMIN] ID: 000037954). The inclusion criteria for this study were as follows: currently employed as a pharmacist; and has an understanding of the objectives of this study and is willing to respond. No particular exclusion criteria were defined.

### Study Population

Seventy-seven pharmacists employed at community drug chain stores in Kansai were recruited and underwent a web-based survey. At the beginning of the survey, participants read and understood the objectives of this study as well as the researchers' duty of confidentiality displayed on the web site. The software program was designed to show questions after they provided consent to participate.

## The Pharmacists' Confidence scale about Medication Consultation for Depressive patients (PCMCD)

The survey consisted of the 12-item PCMCD, and demographic attributes (gender, career as a pharmacist, pharmacy position, work style, number of patients to dispense antidepressants per week, and mental health prescription experience).

When constructing this questionnaire, we brainstormed with 2 drug store pharmacists who had at least 5 years of experience working at drug stores whose main business is handling prescriptions from doctors in the field of psychosomatic medicine, and prepared questions that take into account the "reality of the instructions given to depression patients by pharmacists about how to take their medications." When doing this, we referred to the Japan Pharmaceutical Association's "Guidelines for Working With High-Risk Drugs, v. 2.2".<sup>33</sup> A key guiding principle for the development process was to make the questions as easy-to-understand as possible. The prototype questionnaire was administered to two practicing pharmacists and three pharmacist students as a pilot run to check for ambiguities. Minor changes were made to correct typos and minimize possible differences among respondents in interpretation.

Responses were rated on a 5-point Likert scale of disagree (1), tend to disagree (2), neither agree nor disagree (3), tend to agree (4), agree (5). higher the score, the higher the level of the respondent's confidence in the item.

### Statistical Analysis

The distribution of the scores for the questions in the 12 items of the PCMCD were investigated and the mean,

Variable	No. (%)
Gender (females)	57 (74.0)
Pharmacist career (years)	
<1	4 (5.2)
1-3	11 (14.3)
4-9	20 (26.0)
≥10	42 (54.5)
Pharmacy manager position	
Yes	34 (44.2)
No	43 (55.8)
Work style	
Full-time	60 (77.9)
Part-time	16 (20.8)
Other	1 (1.3)
Number of patients to dispense antidepressants per week	
≤1	20 (26.0)
2-5	18 (23.4)
6-10	8 (10.4)
11-20	7 (9.1)
21-30	2 (2.6)
31-40	3 (3.9)
41-50	3 (3.9)
51-60	1 (1.3)
≥61	9 (11.7)
Mental health prescription experience	
Current pharmacy in the vicinity of a mental health clinic	33 (42.9)
Former pharmacy in the vicinity of a mental health clinic	21 (27.3)
Worked at mental health clinic in the past	5 (6.5)
None of the above	25 (32.5)

standard deviation, skewness, and kurtosis of the scores in each item were calculated. In addition, the ceiling effect/floor effect was also assessed depending on whether or not the values obtained by adding the standard deviation to the mean or subtracting the standard deviation from the mean were within the range of possible values for the scores (5 to 1).

To evaluate construct validity, an exploratory factor analysis was conducted. The least-squares method was used for factor extraction, and the resulting factors were subjected to direct oblimin rotation, with a factor loading cut-off of 0.4. The Kaiser-Guttman rule was used to determine the number of factors; the maximum number of factors with eigenvalues of at least 1 was taken to be the number of constituent factors. A factor correlation matrix was created to explore the relationship between subscales. To assess internal consistency, Cronbach's alpha values were calculated for each of the PCMCD subscales.<sup>34</sup> In addition, in order to measure internal consistency reliability, the average inter-item correlation was calculated.

The PCMCD subscales were scored based on the mean points for the questions that related to them. These subscale scores were then analyzed for association with the demographic attributes. A multiple regression analysis was performed using simultaneous forced entry, and the strength of the correlations to respondent attributes was measured. All statistical tests were performed using the PASW® Statistics 18 (SPSS Inc., Chicago, IL) with a two-tailed significance level of 5%.

## RESULTS

The response rate was 47.8%. The demographic attributes of 77 respondents are summarized in Table 1. The study population included 57 women (74.0%). The majority of the respondents had 10 or more years of experience as pharmacists (54.5%). For the number of patients to dispense antidepressants per week, zero or one was the most common response (26.0%), followed by two to five (23.4%).

Table 2 summarizes the responses to the PCMCD questionnaire. Question No. 1 (instruction on drug use) had the highest mean (SD) score of 3.4 (0.85), whereas Question No. 6 (comprehension of patient condition) had the lowest mean (SD) score of 2.4 (0.81). No ceiling or floor effects were observed for any of the items. The average inter-item correlation was 0.378 (Online appendix 1).

The factor analysis identified a PCMCD model with three main factors (A, B, and C), as shown in Table 3. The Kaiser-Meyer-Olkin measure of sampling accuracy was 0.829. The significance probability of Bartlett's test of sphericity was less than 0.001. During the analytical procedure, Question Nos. 4, 5, 9, and 10 were eliminated by the cut-off rule. The cumulative sum of squared loadings was 61.9% (Online appendix 2). Because the maximum number of factors with eigenvalues greater than 1 was 3, the number of constituent factors was determined to be 3 (Appendix 3). The Cronbach's alpha values for Factors A, B, and C were 0.92, 0.73, and 0.72, respectively.

Because Factor A included Question No. 11 (establish a trust relationship with patients), this factor was labeled as "relationship building." Factor B was termed

Table 2. Response distribution to the Pharmacists' Confidence scale about Medication Consultation for Depressive patients (PCMCD) questionnaire

Questions	n (%)					Mean (SD)	skewness	kurtosis
	disagree	Tend to disagree	neither agree nor disagree	Tend to agree	agree			
1. I can appropriately instruct how to take antidepressants.	1 (1.3)	8 (10.4)	31 (40.3)	30 (39.0)	7 (9.1)	3.4 (0.85)	-0.21	0.02
2. I can provide information on side effects of antidepressants.	4 (5.2)	19 (24.7)	31 (40.3)	19 (24.7)	4 (5.2)	3.0 (0.96)	0	-0.34
3. I can tell what to do when a side effect develops.	3 (3.9)	25 (32.5)	28 (36.4)	18 (23.4)	3 (3.9)	2.9 (0.93)	0.19	-0.51
4. I can comprehend the patient's medication adherence status.	7 (9.1)	28 (36.4)	27 (35.1)	12 (15.6)	3 (3.9)	2.7 (0.98)	0.32	-0.24
5. I can provide guidance to patients with poor medication adherence.	12 (15.6)	29 (37.7)	30 (39.0)	6 (7.8)	0 (0)	2.4 (0.85)	-0.05	-0.62
6. I can comprehend the patient's medical condition.	10 (13.0)	34 (44.2)	29 (37.7)	3 (3.9)	1 (1.3)	2.4 (0.81)	0.3	0.52
7. I can perceive change in the patient's medical condition.	5 (6.5)	25 (32.5)	30 (39.0)	16 (20.8)	1 (1.3)	2.8 (0.90)	0.01	-0.51
8. I can comprehend the patient's comorbid illnesses.	11 (14.3)	25 (32.5)	29 (37.7)	12 (15.6)	0 (0)	2.5 (0.93)	-0.09	0.79
9. I can ease the patient's anxiety about medication.	3 (3.9)	17 (22.1)	40 (51.9)	14 (18.2)	3 (3.9)	3.0 (0.85)	0.08	0.35
10. I can understand the patient's background and value system.	7 (9.1)	33 (42.9)	23 (29.9)	12 (15.6)	2 (2.6)	2.6 (0.95)	0.42	-0.26
11. I can establish a trust relationship with the patient.	6 (7.8)	20 (26.0)	38 (49.4)	11 (14.3)	2 (2.6)	2.8 (0.88)	-0.02	0.17
12. I can maintain a good trust relationship with the patient.	4 (5.2)	14 (18.2)	41 (53.2)	16 (20.8)	2 (2.6)	3.0 (0.84)	-0.22	0.4

No.	Question	Factor loading			Cronbach's Alpha
		A	B	C	
11	I can establish a trust relationship with the patient.	0.954	0.005	0.112	0.92
12	I can maintain a good trust relationship with the patient.	0.767	0.09	0.15	
6	I can comprehend the patient's medical condition.	0.288	0.798	-0.171	0.73
7	I can perceive change in the patient's medical condition.	0.126	0.719	-0.001	
8	I can comprehend the patient's comorbid illnesses.	-0.17	0.559	0.145	0.72
3	I can tell what to do when a side effect develops.	0.055	0.125	0.771	
2	I can provide information on side effects of antidepressants.	0.028	0.039	0.68	
1	I can appropriately instruct how to take antidepressants.	0.054	-0.075	0.552	

Cumulative sum of squared loadings: 61.9%

“comprehension of condition,” as it included three questions that related to patients’ conditions. Factor C was termed “information provision” because it included three questions that related to communicating basic information to clients. Table 4 represents the final factor correlation matrix. The highest correlation coefficient was noted between Factor A and Factor C ( $r = 0.345$ ), followed by the correlations between Factor A and Factor B ( $r = 0.316$ ) and between Factor B and Factor C ( $r = 0.301$ ) in this order.

Table 5 summarizes the results of analysis on the association between the subscales and demographic attributes. None of the three subscales exhibited statistically significant differences between genders. The longer pharmacist career was associated with a non-significant increase in each of the three subscale scores. In addition, respondents who had someone close suffering from depression showed a non-significantly higher mean score for all the subscales than those who did not. Moreover, the number of patients to dispense antidepressants per week showed no significant association with any of the three subscales.

## DISCUSSION

We developed a semiquantitative instrument to assess pharmacists’ confidence in medication consultation for patients with depression (PCMCD), and investigated its validity. The factor analysis of the PCMCD scale identified an acceptable model with three subscales: relationship building, comprehension of condition, and information provision. Although there are various understandings regarding the number of items that should be included in 1 factor, MacCallum *et al.* showed that in the case of high communality (0.6-0.8) with a questionnaire with a ratio of 10 questions to 3 factors, a convergent solution without Heywood cases is reliably obtained.<sup>34</sup> This can be said to demonstrate that in cases with high communality, there will be no problems even if there are around 3 items per factor. With factors that only affect 2 variables, the solutions are considered unstable and untrustworthy because problems with discrimination where commonality cannot be uniformly determined from the data arise.<sup>35</sup> However, we concluded that such factors should not be excluded when it is taken into consideration that 1) the

factor “relationship building” is thought to be one of the most important factors for measuring pharmacists’ confidence in dealing with depression patients, and 2) there are reports of studies in which analyses were conducted using commonly used questions that included factors that included only 2 variables.<sup>36</sup> The resulting cumulative sum of squared loadings (61.9%) showed that these subscales had sufficient construct validity. Furthermore, internal consistency of these subscales was supported by the Cronbach’s alpha values ( $>0.7$ ).<sup>37</sup> In addition, because the average inter-item correlation was 0.378, which was within the range of 0.2-0.4 recommended by Piedmont *et al.*, the PCMCD questions are reasonably homogeneous, and contain sufficiently unique variance so as to not be isomorphic with each other.<sup>38</sup> In addition to these psychometric properties, the PCMCD questionnaire was concise and quick to complete because it focused on patient-oriented practice of pharmacists.

As shown in Table 2, Question No. 1 (instruction on drug use) and Question No. 2 (information on side effects), which were grouped under the information provision subscale, had the highest mean scores (3.44, 3.00, respectively). However, given that providing information on drug use and side effects is one of the fundamental responsibilities of pharmacists, these scores may not be sufficiently high. We speculate that these results reflected the sense of difficulty that many pharmacists had in relating to patients with depression, as suggested by prior studies.<sup>19,20</sup> This sense of difficulty could have something to do with the fact that a certain proportion of patients with depression also have mild cognitive impairment and Alzheimer-type dementia, which may interfere with effective communication.<sup>39,40</sup>

The comprehension of condition subscale included Question No. 6 (comprehension of patient condition) and Question No. 8 (comprehension of comorbid illnesses), which had the lowest and third lowest mean scores (2.36 and 2.55), respectively. An elevated risk of depressive symptoms is associated with a variety of underlying diseases including cancer, metabolic disorders (e.g., diabetes mellitus and dyslipidemia), and cardiovascular diseases (e.g., hypertension and ischemic heart failure) in addition to cognitive dysfunctions, as mentioned above.<sup>39-42</sup>

	Factor A	Factor B	Factor C
Factor A: Relationship building	1	0.316	0.345
Factor B: Comprehension of condition		1	0.301
Factor C: Information provision			1

Table 5. Associations between the Pharmacists' Confidence scale about Medication Consultation for Depressive patients (PCMCD) subscales and demographic attributes

	Relationship building		Comprehension of condition		Information provision	
	r <sup>d</sup>	p	r <sup>d</sup>	p	r <sup>d</sup>	p
Gender <sup>a</sup>	0.099	0.485	-0.085	0.531	0.007	0.961
Pharmacist career (year)	0.312	0.044	0.071	0.628	0.376	0.016
Pharmacy manager position <sup>b</sup>	-0.015	0.912	-0.006	0.965	0.165	0.225
Someone close with depression	0.096	0.481	0.169	0.199	-0.072	0.597
Number of patients to dispense antidepressants per week	0.023	0.884	0.198	0.2	0.049	0.761
Current pharmacy in the vicinity of a mental health clinic <sup>c</sup>	0.073	0.665	-0.143	0.382	0.06	0.723
Former pharmacy in the vicinity of a mental health clinic <sup>c</sup>	-0.052	0.696	0.146	0.253	-0.078	0.553
Worked at mental clinic in the past <sup>c</sup>	0.038	0.783	0.039	0.772	0.076	0.585
R <sup>2</sup> value	0.208		0.264		0.207	

a: male=1, female=0; b: pharmacy manager=1, not pharmacy manager=0; c: Yes = 1, No = 0 d: standard partial regression coefficient

The Japanese medical system allows patients to select hospitals and pharmacies according to their preference, and this prevents community pharmacists from comprehending their clients' overall conditions of health. In a study of community pharmacists' involvement in mental illness care, Scheerder *et al.* mentioned "too little information about patients and their treatment" as a key perceived barrier to providing depression care.<sup>22</sup> The lack of sufficient information about the medical condition of their clients may prevent pharmacists in Japan from being confidently involved in depression care. Currently, the Japanese health care system is encouraging patients to bring their drug profile book to the pharmacy when they purchase prescription drugs, and its use contributes to preventing redundant prescriptions and possible drug interactions.<sup>43,44</sup> This and other tools may help community pharmacists gain information on the comorbid conditions of their clients and become actively involved in depression care.

There are several limitations to this study. The first is that the sample size might be too small. There has been much discussion to date about what is an appropriate sample size for performing a factor analysis. Evertit *et al.* have recommended 10 or more as the N:p ratio, where N is the number of samples and p is the number of variables.<sup>45</sup> According to this view, our study has an inadequate N:p ratio of 6.42. However, Gorsuch *et al.* assert that an N:p ratio of 5 or above is acceptable, and according to this view our study had an adequate sample size.<sup>46</sup> Furthermore, Barrett and Kline reported that comparison of the results of factor analyses of large-scale studies with N:p ratios of 20 and 30 and small-scale studies in subsamples extracted therefrom that had N:p ratios of 3 and 1.6 found that there was adequate reproducibility in the subsamples as well.<sup>47</sup> We believe that in light of these findings, it is not possible to say unequivocally that the sample size of this study was too small. Second, the study population was relatively biased with respect to several demographic attributes. For example, the majority of respondents had a 10-year or longer career, and were working or had worked at pharmacies in the vicinity of mental health clinics at the time of the survey. In addition, almost half of the respondents were in the management position. These characteristics of the study population warrant a further study that includes pharmacists with different demographic background. Third, although this questionnaire has been reviewed by native English speakers, the original was

prepared in Japanese, and the validity and reliability of this questionnaire therefore need to be verified in a study in pharmacists who are native English speakers. However, we think that the issues that are discussed in this questionnaire are common to pharmacists around the world, and that no major differences will arise between countries or regions. Fourth, test-retest reliability has not been addressed in this study.

Despite those limitations, this study was the first of its kind to evaluate the current status of confidence of Japanese community pharmacists in dealing with patients with depression.

## CONCLUSIONS

This study demonstrated the validity and reliability of the PCMCD model as an instrument to evaluate the confidence of pharmacists in interacting with patients with depression. The PCMCD model constituted of three subscales: relationship building, comprehension of condition, and information provision. Since this questionnaire focused on patient-oriented practice of pharmacists, it was concise and quick to complete. These features underscore the utility of the PCMCD questionnaire as a reliable and easy-to-administer tool for assessing the degree of pharmacists' confidence in their practice. It will also help evaluate the effects of educational programs for pharmacists.

## ACKNOWLEDGEMENT

The authors are indebted to the contributions of Mr. Y. Iwanaga, Mr. T. Okumura, and Ms. Y. Moriuchi of Apis Pharmacy Co., Ltd., Osaka, Japan, and many other pharmacists for the conduct of this survey. I am also grateful to Professor H. Sakurai for his advice about data analysis.

## CONFLICT OF INTEREST

The authors reported no conflicts of interest.

## FUNDING

We received no funding.

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