BMJ Open

Validity and reliability of the Japanese version of the Patient Centered Assessment Method and its user guide: a cross-sectional study

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2020-037282
Article Type:	Original research
Date Submitted by the Author:	27-Jan-2020
Complete List of Authors:	Mutai, Rieko; Jikei University School of Medicine, Division of Clinical Epidemiology, Research Center for Medical Sciences; Jikei University School of Nursing, Adult nursing Sugiyama, Yoshifumi; Jikei University School of Medicine, Division of Clinical Epidemiology, Research Center for Medical Sciences Yoshida, Shuhei; Hiroshima University, Department of Community-Based Medical System; Jikei University School of Medicine, Division of Clinical Epidemiology, Research Center for Medical Sciences Horiguchi, Ryoko; Jikei University School of Medicine, Division of Clinical Epidemiology, Research Center for Medical Sciences Watanabe, Takamasa; Kita-adachi Seikyo Clinic, family medicine; Jikei University School of Medicine, Division of Clinical Epidemiology, Research Center for Medical Sciences Kaneko, Makoto; Hamamatsu University School of Medicine, Department of Family and Community Medicine; Jikei University School of Medicine, Division of Clinical Epidemiology, Research Center for Medical Sciences Tominaga, Tomokazu; Koganei Family Clinic; Jikei University School of Medicine, Division of Clinical Epidemiology, Research Center for Medical Sciences Hayashi, Daichi; State University of New York at Stony Brook, Department of Radiology, Stony Brook Medicine Matsushima, Masato; Jikei University School of Medicine, Division of Clinical Epidemiology, Research Center for Medical Sciences
Keywords:	PRIMARY CARE, EPIDEMIOLOGY, GENERAL MEDICINE (see Internal Medicine)

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

Validity and reliability of the Japanese version of the Patient Centered Assessment Method and its user guide: a cross-sectional study

Rieko Mutai[1, 2], Yoshifumi Sugiyama[1], Shuhei Yoshida[1, 3, 4, 5], Ryoko Horiguchi[1], Takamasa Watanabe[1, 3, 4], Makoto Kaneko[1, 3, 6, 7], Tomokazu Tominaga[1, 3, 6, 8], Daichi Hayashi[9], Masato Matsushima[1]

[1] Division of Clinical Epidemiology, Research Center for Medical Sciences, The Jikei University School of Medicine, Tokyo, Japan

[2] Department of Adult Nursing, The Jikei University School of Nursing, Chofu, Japan

[3] Centre for Family Medicine Development, Japanese Health and Welfare Co-operative Federation, Tokyo, Japan

[4] Kitaadachi-seikyo Clinic, Japanese Health and Welfare Co-operative Federation, Tokyo, Japan

[5] Department of Community-Based Medical System, Graduate School of Biomedical and Health Sciences, Hiroshima University, Hiroshima, Japan

[6] Musashikoganei Clinic, Japanese Health and Welfare Co-operative Federation, Koganei, Japan

[7] Department of Family and Community Medicine, Hamamatsu University School of Medicine, Hamamatsu, Japan

[8] Koganei Family Clinic, Koganei, Japan

[9] Department of Radiology, Stony Brook Medicine, Stony Brook, New York, USA

Corresponding author: Masato Matsushima

Division of Clinical Epidemiology, Research Center for Medical Sciences

The Jikei University School of Medicine

3-25-8 Nishi-Shimbashi, Minato-ku, Tokyo 105-8461, Japan

Tel: +81-3-3433-1111 (ext. 2398); Email: masato@jikei.ac.jp

Word count: 2968

ABSTRACT

Objectives The primary objective of this study was to develop the Japanese version of the Patient Centered Assessment Method (PCAM) and its user guide. The secondary objective was to examine the validity and reliability in the primary care setting.

Design Cross-sectional study.

Setting Three family physician teaching clinics located in urban residential areas in Tokyo, Japan.

Participants Patients who were aged 20 years or older, and who had an appointment with physicians at the three participating clinics.

Main outcome measures Patient complexity measured by PCAM and complexity/burden level measured by a Visual Analog Scale (VAS).

Results Although confirmatory factor analysis revealed that the indices did not meet the criteria of good fit, exploratory factor analysis revealed a new two-factor structure of "Social interaction" and "Personal well-being." Cronbach's alpha of PCAM was 0.86. Spearman's rank correlation coefficients between PCAM scores and VAS scores were 0.51 for complexity ($p<0.001$) and 0.41 for burden ($p<0.001$). There were 42 patients (14.3% of total patients) with PCAM scores greater than its mean of 16.5 but with complexity VAS scores less than its mean of 20.8.

Conclusions The Japanese version of PCAM and its user guide were developed through cognitive debriefing. PCAM is a valid and reliable tool to assess patient complexity in the primary care settings in Japan. Additionally, although the correlation between total PCAM scores and complexity/burden as assessed by VAS was moderate, PCAM can more precisely identify patient complexity than skilled physician's intuition.

Keywords

patient complexity, the Patient Centered Assessment Method, translation, cultural adaptation, validity, reliability

Strengths and limitations of this study

- This is the first study to develop the Japanese version of PCAM and its user guide by a standard translation process and to examine its validity and reliability in the primary care setting.
- The Japanese version of PCAM allows healthcare providers to address biopsychosocial problems without language barriers.
- Only three clinics in urban areas of Tokyo were included in the study settings, which could have limited the generalizability of our findings.
- PCAM scores might have been over or underestimated because inter-rater variability of PCAM scores was not evaluated.

INTRODUCTION

Social and economic conditions are associated with human health and have been termed social determinants of health (SDH).[1] Developed countries are now increasingly facing many obstacles caused by changes in the population pyramid, declining birthrates, and aging populations.[2] These demographic shifts are leading to a growing number of people with diverse and complex backgrounds, such as multimorbidity,[3-5] neuropsychiatric diseases including dementia[6,7] and depression,[8-10] less involvement in social networks,[11,12] and living alone.[13] Therefore, the role of primary care providers in addressing these patients' biopsychosocial complexities is becoming more important.

INTERMED[14-16] is an instrument that was developed to assess patient complexity in secondary care settings and the validity and reliability of the Japanese version has been verified.[17] Based on INTERMED, the Minnesota Complexity Assessment Method (MCAM)[18] was developed for use in the primary care settings, which led to an advanced version of MCAM, called the Minnesota Edinburgh Complexity Assessment Method (MECAM),[19] for the assessment of patients' biopsychosocial needs.

The Patient Centered Assessment Method (PCAM)[20] is an improved version of MECAM that can be applied to long-term conditions such as chronic obstructive pulmonary disease, diabetes mellitus, and coronary heart disease. In previous studies, we assessed and confirmed the validity and reliability of the original version of PCAM in the initial phase of the secondary care setting in Japan and identified a correlation between total PCAM scores and length of hospital stay[21]/degree of burden on medical staff.[22]

PCAM allows medical providers to assess patients' needs from biopsychosocial perspectives and to make referrals to a broader range of services.[20] However, we do not have a tool to evaluate patient complexity in the Japanese language for those who are not proficient in English. The development of a Japanese version of PCAM would urge more healthcare professionals to consider various biopsychosocial perspectives. The primary objective of this

study was to develop a Japanese version of PCAM and its user guide. The secondary objective was to examine the validity and reliability in the primary care setting in Japan.

METHODS

This study consisted of two phases. In the first phase, the Japanese version of PCAM and its user guide were developed. In the second phase, the validity and reliability of the Japanese version of PCAM were evaluated in the primary care setting.

First phase: Development of the Japanese version of PCAM and its user guide

PCAM and its user guide were translated into and culturally adapted to Japanese with the original author's permission in accordance with the guidelines of the World Health Organization and International Society Pharmacoeconomics and Outcomes Research Task Force for Translation.[23,24] First, the primary investigator (RM), who was a native speaker of Japanese, translated the original PCAM and its user guide into Japanese, and four researchers (RM, MM, SY, HW) discussed cultural adaptation to Japanese and completed the provisional versions. Next, a bilingual medical doctor (DH), who was not familiar with the original PCAM and its user guide, back-translated the provisional versions into English. Then, discrepancies between the original and back-translated English version were reviewed and revised by the original authors and three of the authors of this study (RM, MM, SY). Finally, we completed the prototype versions. During cognitive debriefing on the prototype versions, five Japanese physicians were interviewed to assess the interpretation and clarity of each item. These physicians were recruited from primary care clinics in Tokyo, Japan by means of snowball sampling considering age, sex, and years of experience.

Second phase: Evaluation of validity and reliability

Study design and setting

This was a cross-sectional study reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement.[25] This study was conducted at three family physician teaching clinics located in urban residential areas in Tokyo, Japan that were responsible for primary care with group practice: Kitaadachi-seikyo Clinic, Seikyo-ukima Clinic, and Musashikoganei Clinic affiliated with Japanese Health and Welfare Co-operative Federation.

Subjects

Patients who were aged 20 years or older, and who had an appointment with physicians at the three participating clinics were consecutively included. Exclusion criteria were visitors for a general check-up, patients who had difficulty communicating in Japanese, patients who were too sick to complete the questionnaire, or patients who declined to participate in this study.

Data collection

Data were collected by five physicians: two at Kitaadachi-seikyo Clinic, one at Seikyo-ukima Clinic, and two at Musashikoganei Clinic, Japanese Health and Welfare Co-operative Federation. The period for data collection was between January 5th, 2018 and July 25th, 2018 in consideration of the physicians' and the principal investigator's schedule: five days at Kitaadachi-seikyo Clinic, 15 days at Seikyo-ukima Clinic, and 12 days at Musashikoganei Clinic. In advance of the data collection, the principal investigator explained the Japanese version of the PCAM to the five physicians using the user guide to standardize the criteria of evaluation. Before a consultation, patients were asked to complete a self-administered questionnaire on demographic characteristics; furthermore, physicians evaluated the degree of complexity and burden using a Visual Analog Scale (VAS).[26] During or after a consultation, physicians used the Japanese version of the PCAM user guide and completed a PCAM form.

Outcome Measures

PCAM

PCAM consists of twelve items across four categories: "Health and well-being" (four items: "Physical health needs," "Physical health impacting mental well-being," "Lifestyle impacting mental well-being," and "Other mental well-being"), "Social environment" (four items: "Home environment," "Daily activities," "Social network," and "Financial resources"), "Health literacy and communication" (two items: "Health literacy" and "Engagement in discussion"), and "Service coordination" (two items: "Other services" and "Service coordination"). Each item is scored from 1 to 4 points, with total scores ranging from 12 to 48 points. The higher the score, the more complex the patient.

Complexity/burden level measured by VAS

In order to prevent physicians from confusing complexity with burden, these two were separately assessed. The VAS consisted of a 10-cm long horizontal line with a starting point of "not complex" or "no burden" (0 point) and an ending point of "the most complex" or "the heaviest burden" (100 points), respectively. A person without knowledge of the patients' information measured the length on the VAS.

Patient characteristics

Demographic characteristics including sex, age, marital status, household composition, household size, home ownership, years of residence, employment status, and educational background were obtained from a self-administered questionnaire, whereas main diseases, Charlson Comorbidity Index (CCI),[27,28] and copayment (the proportion of individual payment of medical expense depending on age and income) were obtained from medical records.

Sample size calculation

The recommended subjects-to-variables ratio is from 3:1 to 20:1 when conducting exploratory factor analysis.[29] Because a larger sample size has been reported to provide more precise results in factor analysis, the ratio of 20:1 was employed in this study. Therefore, because PCAM includes 12 items, the sample size was determined to be 300 in consideration of at most 60 participants having missing values.

Statistical analysis

Confirmatory factor analysis was conducted to assess construct validity, assuming a two-factor model of medicine- and patient-oriented complexity, which was derived from our previous study.[21] The model fit was judged to be good if the comparative fit index (CFI) was ≥0.90, standardized root mean residual (SRMR) was ≤0.08, and root mean squared error of approximation (RMSEA) was ≤0.08.[30]

When the model fit was insufficient, exploratory factor analysis with the iterated principal factor method and promax rotation was performed. Eigenvalues ≥1, with supplemental scree plot, and factor loading ≥0.4 were adopted to determine the number of common factors and items included.

Internal consistency was considered adequate if Cronbach's alpha was between 0.70 and 0.95.[31]

Spearman's rank correlation coefficient between total PCAM scores and complexity/burden as measured by VAS examined how closely the scale correlated with the physicians' general impressions.[32]

All statistical analyses were performed using STATA/SE version 14.0.[33,34] P-values <0.05 were considered statistically significant.

Ethical considerations

The research protocol for the first phase was approved by the Ethics Committee of The

Jikei University School of Medicine (ethics number: 28-365 [8608]). The research protocol for the second phase was approved by the Ethics Committee of The Jikei University School of Medicine (ethics number: 29-229 [8845]) and Tokyo Hokuto Health Co-operative (ethics number: 89). The principal investigator (RM), who was not associated with any of the three family physician teaching clinics, fully explained the content of this study to all subjects; they then provided written informed consent to participate.

Patient and public involvement

This study was conducted without patient involvement.

RESULTS

Cognitive debriefing

Cognitive debriefing was conducted by one female and four male physicians with a mean age of 36.4 years, ranging from 33 to 40. The mean years of experience as a primary care physician was 12.6 years, ranging from 10 to 17.

Although Item 3 of the PCAM asked, "Are there any problems with your client's lifestyle behaviors that are impacting on physical or mental well-being?", the category title in its user guide was "Lifestyle impacting mental well-being" without any specific mention of physical well-being. The phrase "physical well-being" was therefore added to resolve this discrepancy. Finally the Japanese version of PCAM (online supplementary file A) and its user guide (online supplementary file B) were developed.

Evaluation of validity and reliability

Of the 298 patients, 100 were recruited at Kitaadachi-seikyo Clinic, 101 at Seikyo-ukima Clinic, and 97 at Musashikoganei Clinic. Physicians missed out the entire PCAM in four patients and part of it in one patient, which lead to a total of 293 patients included in the final analysis.

Patient characteristics and main diseases are shown in Table 1 and Table 2.

Table 1. Patient characteristics

Age, mean (SD), years	72.4 (11.4)
Women, n (%)	164 (56.0)
Married, n (%)	178 (60.8)
Household composition, n (%)	
Single	70 (23.9)
Married couple	92 (31.4)
Other	131 (44.7)
Living arrangements, n (%)	
Living alone	70 (23.9)
Cohabiting	223 (76.1)
Home ownership, n (%)	
Owned	177 (60.4)
Rented	116 (39.6)
Years of residence, mean (SD), years	28.4 (17.4)
Employment status, n (%)	
Full-time employment	45 (15.4)
Part-time employment	28 (9.6)
Unemployment/Homemaker	166/36 (56.7/12.3)
Other	18 (6.1)
Academic background, n (%)	
Junior high school	85 (29.0)
High school	107 (36.5)
Junior college/Vocational school	51 (17.4)
University	44 (15.0)
Graduate school	6 (2.0)
Insurance copayment, n (%)	
0%	27 (9.2)
10%	134 (45.7)
20%	32 (10.9)

30%	100 (34.1)
CCI, mean (SD)	0.88 (1.4)

SD, standard deviation; CCI, Charlson Comorbidity Index.

Table 2. Main diseases diagnosed among patients

Classification of main diseases, n (%)	
Infectious and parasitic diseases	1 (0.3)
Neoplasms	11 (3.8)
Diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism	4 (1.4)
Endocrine, nutritional and metabolic diseases	
Total	73 (24.9)
Diabetes mellitus	49
Dyslipidemia	18
Mental and behavioral disorders	
Total	15 (5.1)
Vascular and unspecified dementia	10
Sleep-wake disorders	4 (1.4)
Diseases of the nervous system	8 (2.7)
Diseases of the circulatory system	
Total	137 (46.8)
Hypertension	111
Heart failure	20
Diseases of the respiratory system	
Total	11 (3.8)
COPD	6
Asthma	4
Diseases of the digestive system	
Total	12 (4.1)
GERD	6
IBS	1
Diseases of the skin and subcutaneous tissue	4 (1.4)
Diseases of the musculoskeletal system and connective tissue	

Total	10 (3.4)
Osteoporosis	7
Diseases of the genitourinary system	2 (0.7)
Injury, poisoning and certain other consequences of external causes	1 (0.3)
Total	293 (100)

COPD, chronic obstructive pulmonary disease; GERD, gasoesophagial reflux disease; IBS, irritable bowel syndrome.

The mean (standard deviation, SD) PCAM score was 16.5 (5.1) and the median (25th percentile–75th percentile) score was 15 (13-18). As shown in figure 1, the distribution of total PCAM scores was skewed to the right with a floor effect.

Confirmatory and exploratory factor analysis

Confirmatory factor analysis revealed the following indices for model fit: CFI=0.761, SRMR=0.104, and RMSEA=0.160.

Because the indices did not meet the criteria of good fit, exploratory factor analysis was performed and it revealed a new two-factor model. The items "Social network," "Health literacy," "Engagement in discussion," "Other services," and "Service coordination," which focus mainly on connection with healthcare service providers, contributed to the first factor, termed "Social interaction." The items "Physical health needs," "Physical health impacting mental well-being," "Other mental well-being concerns," "Home environment," and "Daily activities," which focus mainly on physical and psychological well-being, contributed to the second factor, termed "Personal well-being." However, the two items "Lifestyle impacting mental well-being" and "Financial resources" were not included due to a factor loading less than 0.4 (Table 3).

Table 3. Exploratory factor analysis of the Japanese version of the Patient Centered Assessment Method (PCAM)

	First factor	Second factor
Health and well-being		
Physical health needs	0.066	0.533
Physical health impacting mental well-being	–0.060	0.709
Lifestyle impacting mental well-being	0.186	0.109
Other mental well-being concerns	–0.112	0.754
Social environment		
Home environment	0.350	0.471
Daily activities	–0.068	0.719
Social network	0.439	0.329
Financial resources	0.266	0.354
Health literacy and communication		
Health literacy	0.824	–0.069
Engagement in discussion	0.894	–0.264
Service coordination		
Other services	0.598	0.328
Service coordination	0.618	0.306

Cronbach's alpha of PCAM was 0.86, and that of the two factors, "Social interaction" and "Personal well-being", were 0.85 and 0.79, respectively.

The correlation between PCAM and VAS (complexity and burden) is shown in figure 2. Spearman's rank correlation coefficients between PCAM scores and VAS were 0.51 for complexity ($p<0.001$) and 0.41 for burden ($p<0.001$). There were 42 patients (14.3% of total patients) with PCAM scores more than the mean score of 16.5 but with complexity scores less than the mean score of 20.8. Moreover, Spearman's rank correlation coefficient between complexity and burden was 0.77.

DISCUSSION

In this study, the Japanese version of PCAM and its user guide were developed through the process of translation, back-translation, and cognitive debriefing. Then, the validity and

reliability of the Japanese version of PCAM were assessed through exploratory factor analysis, which revealed the two new factors of "Social interaction" and "Personal well-being," although confirmatory factor analysis showed the model fit to be poor. Cronbach's alpha of PCAM, "Social interaction," and "Personal well-being" were all high. Additionally, the total score of PCAM was moderately correlated with complexity and burden as assessed by VAS.

The reason why confirmatory factor analysis showed the model fit to be poor was presumably due to differences between clinical settings. Our previous study was conducted in the initial phase in a secondary care setting and the participants were patients who were hospitalized in an acute hospital,[21] although this study was in the primary care setting. Exploratory factor analysis in the present study identified two new factors of PCAM, "Social interaction" and "Personal well-being." Of particular importance was the result that "Social interaction" was extracted separately from "Personal well-being", which was mainly related to physical and psychological well-being. This is because poor or insufficient social interaction has reportedly the same influence on mortality as smoking, and a greater influence on mortality than several risk factors such as obesity and physical inactivity.[35] As the biological plausibility of the impacts of social factors on health has been proved,[36] the association between SDH and mortality is now drawing more attention. In fact, the impact of social prescribing has been demonstrated to improve social conditions.[37,38] PCAM has been reported to promote referral to non-medical services addressing a wide variety of patient problems including social needs.[19] In addition to the importance of social factors, considering PCAM also assesses patients from biopsychological perspectives, it is consistent and reasonable that factors related to both social and biopsychological issues were extracted.

However, two items, "Lifestyle impacting mental well-being" and "Financial resources", had insufficient factor loading less than 0.4 and were not included in the two factors. The exclusion of the former item presumably resulted from the fact that 60 percent of all patients had lifestyle diseases such as diabetes mellitus, dyslipidemia, and hypertension, which were generally

well-controlled at the participating clinics; therefore, the impact of a patient's lifestyle on these diseases might have been underestimated. Additionally, severely alcoholic patients and drug abusers were possibly referred to specialized facilities, which could also have resulted in underestimation of this item. The exclusion of the latter item presumably resulted from the fact that copayment of medical expenses is at most 30% under the Japanese universal health insurance coverage system and 0% under the welfare system;[39,40] hence, few patients were likely troubled with financial problems due to healthcare. Moreover, previous research revealed that financial topics are taboo and inappropriate for discussion with healthcare providers;[41] therefore, this question might not have been answered accurately. In the Japanese version of PCAM, these items were not intentionally excluded in consideration of the fact that the overall Cronbach's alpha was 0.86, which indicates a high internal consistency without exclusion of these items. The fact that lifestyle-related and economic problems negatively influence physical and psychological conditions is established[42,43]; therefore, exclusion of these items requires caution and prudence, and further research is necessary.

This study showed a different two-factor structure from that of our previous study. To begin with, the mean score (standard deviation) of the CCI of the present study was 0.9 (1.4), which was lower than that of 2.0 (2.2) in our previous study[21] with higher biomedical complexity. Additionally, the mean (SD) age of patients in our previous study, 77.4 (11.9) years, was higher than that of the current study. Age-related disease such as dementia, depression, delirium[44-46] apparently lead to high psychological complexity. In terms of the factors extracted, for instance, "Medicine-oriented complexity" in the previous study included both items "Physical health needs" and "Other services/Service coordination", while "Personal well-being" in this study did not include "Other services/Service coordination". When patients' physical health needs are increasing, other inadequate services and service coordination will likely be revealed, which could result in increased hospitalization in the secondary care setting. In cases where patients are hospitalized due to acute and not severe diseases such as a mild bacterial

pneumonia, even in the secondary care setting, they usually do not need other services and service coordination. Therefore, both items "Physical health needs" and "Other services/Service coordination" were included in the same factor in the secondary care setting. In contrast, in the primary care setting, other such inadequate services and service coordination remains unrevealed because patients' physical health needs are less and, therefore, "Other services/Service coordination" was not included. These complicated and inter-related reasons could cause the difference in the two-factor structure of PCAM.

This study also showed a floor effect in the distribution of PCAM scores, whereas our previous study did not. The large number of patients, in fact, had low patient complexity; however, physicians might not be able to distinguish detailed factors related to subtle patient complexity due to limited consultation time.

The correlation between total PCAM scores and complexity/burden as assessed by the VAS was found to be moderate. Although complexity and burden were separately assessed to prevent physicians from confusing these two variables, Spearman's rank correlation coefficient between complexity and burden was high. This indicates that physicians do not regard complexity as an objective index, but rather handle it as subjective feeling, or burden. Furthermore, patients that physicians regarded as being not complex were found to have somewhat high PCAM scores, even though physicians working at family physician teaching clinics are generally well trained to see patients from biopsychosocial perspectives. Accordingly, PCAM can more objectively and precisely identify patient complexity than skilled physician's intuition.

There are some limitations in this study. First, only three clinics in urban areas in Tokyo were included as study settings, which could have limited the generalizability of our findings. Second, inter-rater variability of PCAM scores was not evaluated. Patients were not assessed by two physicians because they usually visited the same primary care physician. Moreover, some of the clinics had only one physician on service at a time. As a result, PCAM scores might have been over- or under-estimated. However, a Japanese version of PCAM is necessary for healthcare

providers to address biopsychosocial problems without language barriers, which outweighs the above study limitations.

CONCLUSION

The Japanese version of PCAM and its user guide were developed through cognitive debriefing. PCAM was found to be a valid and reliable tool to assess patient complexity in the primary care setting in Japan. Additionally, although the correlation between total PCAM scores and complexity/burden as assessed by the VAS was moderate, PCAM can more precisely identify patient complexity than skilled physician's intuition.

Acknowledgements

The authors are grateful to the members of the Division of Clinical Epidemiology, Research Center for Medical Sciences, The Jikei University School of Medicine for their kind advice on this study. The authors also thank Dr. Yusuke Shigeshima for collecting the data and Mr. Yuta Yamauchi for processing the data.

Contributors

RM designed the study; collected, analyzed, and interpreted the data; and prepared and reviewed the manuscript. YS analyzed and interpreted the data; and prepared and reviewed the manuscript. MM designed the study; analyzed and interpreted the data; and prepared and reviewed the manuscript. SY designed the study; collected and interpreted the data; and reviewed the manuscript. RH designed the study; analyzed and interpreted the data; and reviewed the manuscript. MK, TW, and TT designed the study; collected the data; and reviewed the manuscript. DH back-translated PCAM and its user guide and reviewed the manuscript.

Funding

This study was supported by The Jikei University Research Fund for Graduate Students.

Disclaimer

The sponsor of this study had no role in the study design; the data collection, analysis, and interpretation; the manuscript preparation and reviewing; or the decision to submit the manuscript.

Competing interests

MM received lecture fees and lecture travel fees from the Centre for Family Medicine Development of Japanese Health and Welfare Co-operative Federation. MM is an adviser of the Centre for Family Medicine Development practice-based research network. MM is a program director of the Jikei Clinical Research Program for Primary-care. YS, SY, MK, TW, and TT are former trainees of the Jikei Clinical Research Program for Primary-care. TW currently is and SY, MK, and TT used to be family physicians at the Centre for Family Medicine Development of Japanese Health and Welfare Co-operative Federation. RM, RH, DH have nothing to disclose.

Data sharing statement

No additional data are available.

References

1 World Health Organization, Regional Office for Europe. Social determinants of health: the solid facts - second edition. 2003. https://apps.who.int/iris/bitstream/handle/10665/326568/9289013710eng.pdf?sequence=1&isAllowed=y (accessed 12 Oct 2019).

2 United Nations, Department of Economic and Social Affairs, Population Division. World Population prospects 2019: Highlights. https://population.un.org/wpp/Publications/Files/WPP2019_Highlights.pdf (accessed 13 Oct

2019).

3 Salisbury C, Johnson L, Purdy S, et al. Epidemiology and impact of multimorbidity in primary care: a retrospective cohort study. *Br J Gen Pract* 2011;61(582):e12–e21.

4 France EF, Wyke S, Gunn JM, et al. Multimorbidity in primary care: a systematic review of prospective cohort studies. *Br J Gen Pract* 2012;62(597):e297–e307.

5 Mitsutake S, Ishizaki T, Teramoto C, et al. Patterns of co-occurrence of chronic disease among older adults in Tokyo, Japan. *Prev Chronic Dis* 2019;16:E11.

6 Prince M, Bryce R, Albanese E, et al. The global prevalence of dementia: a systematic review and metaanalysis. *Alzheimers Dement* 2013;9(1):63–75.e2.

7 Ohara T, Hata J, Yoshida D, et al. Trends in dementia prevalence, incidence, and survival rate in a Japanese community. *Neurology* 2017;88(20):1925–32.

8 Read JR, Sharpe L, Modini M, et al. Multimorbidity and depression: A systematic review and meta-analysis. *J Affect Disord* 2017;221:36–46.

9 Alexopoulos GS. Depression in the elderly. *Lancet* 2005;365(9475):1961–70.

10 Mitchell PB, Harvey SB. Depression and the older medical patient--when and how to intervene. *Maturitas* 2014;79(2):153–9.

11 Domènech-Abella J, Lara E, Rubio-Valera M, et al. Loneliness and depression in the elderly: the role of social network. *Soc Psychiatry Psychiatr Epidemiol* 2017;52(4):381–90.

12 Steptoe A, Shankar A, Demakakos P, at al. Social isolation, loneliness, and all-cause mortality in older men and women. *Proc Natl Acad Sci U S A* 2013;110(15):5797–801.

13. Ministry of Health, Labour and Welfare. Comprehensive Survey of Living Conditions 2018. https://www.mhlw.go.jp/toukei/saikin/hw/k-tyosa/k-tyosa18/dl/02.pdf (accessed 27 Oct 2019).

14 Huyse FJ, Lyons JS, Stiefel FC, et al. "INTERMED": a method to assess health service needs. I. Development and reliability. *Gen Hosp Psychiatry* 1999;21:39–48.

15 Stiefel FC, de Jonge P, Huyse FJ, et al. "INTERMED": a method to assess health service needs. II. Results on its validity and clinical use. *Gen Hosp Psychiatry* 1999;21:49–56.

16 de Jonge P, Huyse FJ, Stiefel FC, et al. INTERMED: a clinical instrument for biopsychosocial assessment. *Psychosomatics* 2001;42:106–9.

17 Kishi Y, Matsuki M, Mizushima H, et al. The INTERMED Japanese version: inter-rater reliability and internal consistency. *J Psychosom Res* 2010;69:583–6.

18 Peek CJ, Baird MA, Coleman E. Primary care for patient complexity: not only disease. *Fam Syst Health* 2009;27:287–302.

19 Maxwell M, Hibberd C, Pratt R, et al. Development and initial validation of the Minnesota Edinburgh Complexity Assessment Method (MECAM) for use within the Keep Well Health Check. 2011. http://www.healthscotland.com/uploads/documents/18448-DevelopmentOfMinnesotaEdinburghComplexityMethod.pdf (accessed 10 Oct).

20 Pratt R, Hibberd C, Cameron I, et al. The patient centered Assessment Method (PCAM): integrating the social dimensions of health into primary care. *J Comorb* 2015;5;110–9.

21 Yoshida S, Matsushima M, Wakabayashi H, et al. Validity and reliability of the Patient Centred Assessment Method for patient complexity and relationship with hospital length of stay: a prospective cohort study. *BMJ Open* 2017;7:e016175.

22 Yoshida S, Matsushima M, Wakabayashi H, et al. Correlation of patient complexity with the burden for health-related professions, and differences in the burden between the professions at a Japanese regional hospital: a prospective cohort study. *BMJ Open* 2019;9:e025176.

23 Wild D, Grove A, Martin M, et al. Principles of good practice for the translation and cultural adaptation process for patient-reported outcomes (PRO) Measures: report of the ISPOR Task Force for Translation and Cultural Adaptation. *Value Health* 2005;8(2):94–104.

24 World Health Organization. Process of translation and adaptation of instruments. https://www.who.int/substance_abuse/research_tools/translation/en/ (accessed 18 Oct 2019).

25 von Elm E, Altman DG, Egger M, et al. Strengthening the reporting of observational studies in epidemiology (STROBE) statement: guidelines for reporting observational studies. *BMJ* 2007;335:806–8.

26 Miller, MD, Ferris DG. Measurement of subjective phenomena in primary care research: the visual analogue scale. *Fam Pract Res J* 1993;13(1):15–24.

27 Charlson ME, Pompei P, Ales KL, et al. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *J Chronic Dis* 1987;40:373–83.

28 Charlson ME, Charlson RE, Peterson JC, et al. The Charlson comorbidity index is adapted to predict costs of chronic disease in primary care patients. *J Clin Epidemiol* 2008;61:1234–40.

29 MacCallum RC, Widaman KF, Zhang S, et al. Sample size in factor analysis. *Psychol Methods* 1999;4:84–99.

30 Hooper D, Coughlan J, Mullen M. Structural equation modelling: guidelines for determining model fit structural equation modelling: guidelines for determining model fit. 2008;6(1):53–60.

31 Bland JM, Altman DG. Cronbach's alpha. *BMJ* 1997;314:572.

32 Dancey C, Reidy J. Statistics without maths for psychology: seventh edition. UK: Pearson Education Limited 2017;181–90.

33 StataCorp. Stata Statistical Software: Release 14. College Station, TX, 2015.

34 StataCorp. Stata 14 Base Reference Manual. College Station, TX: Stata Press, 2015.

35 Holt-Lunstad J, Smith TB, Layton JB. Social relationships and mortality risk: a meta-analytic review. *PLoS Med* 2010;7:e1000316.

36 Braveman P, Gottlieb L. The social determinants of health: it's time to consider the causes of the causes. *Public Health Rep* 2014;129(2):19–31.

37 Moffatt S, Steer M, Lawson S, et al. Link worker social prescribing to improve health and well-being for people with long-term conditions: qualitative study of service user perceptions. *BMJ Open* 2017;16;7:e015203.

38 Elston J, Gradinger F, Asthana S, et al. Does a social prescribing 'holistic' link-worker for older people with complex, multimorbidity improve well-being and frailty and reduce health and social care use and costs? A 12-month before-and-after evaluation. *Prim Health Care Res*

Dev 2019;20:e135.

39 Ministry of Health, Labour and Welfare. Overview of Medical Service Regime in Japan. https://www.mhlw.go.jp/bunya/iryouhoken/iryouhoken01/dl/01_eng.pdf (accessed 22 Oct 2019).

40 Ikegami N, Yoo BK, Hashimoto H, et al. Japanese universal health coverage: evolution, achievements, and challenges. *Lancet* 2011;378:1106–15.

41 Maxwell M, Hibberd C, Aitchison P, et al. The patient centred assessment method for improving nurse-led biopsychosocial assessment of patients with long-term conditions: a feasibility RCT. *Health Services and Delivery Research* 2018;6(4).

42 Danaei G, Ding EL, Mozaffarian D, et al. The preventable causes of death in the United States: comparative risk assessment of dietary, lifestyle, and metabolic risk factors. *PLoS Med* 2009;6(4):e1000058.

43 Marmot M, Bell R. Fair society, healthy lives. *Public Health* 2012;126(1):S4–S10.

44 Fong TG, Davis D, Growdon ME, et al. The interface between delirium and dementia in elderly adults. *Lancet Neurol* 2015;14(8):823–32.

45 LoGiudice D, Watson R. Dementia in older people: an update. *Intern Med J* 2014;44(11):1066–73.

46 Downing LJ, Caprio TV, Lyness JM. Geriatric psychiatry review: differential diagnosis and treatment of the 3 D's - delirium, dementia, and depression. *Curr Psychiatry Rep* 2013;15(6):365.

Figure 1. Distribution of total scores of PCAM. PCAM, Patient Centered Assessment Method.

Figure 2. Correlation between PCAM scores and complexity/burden level measured by VAS.

PCAM, Patient Centered Assessment Method; VAS, Visual Analog Scale.

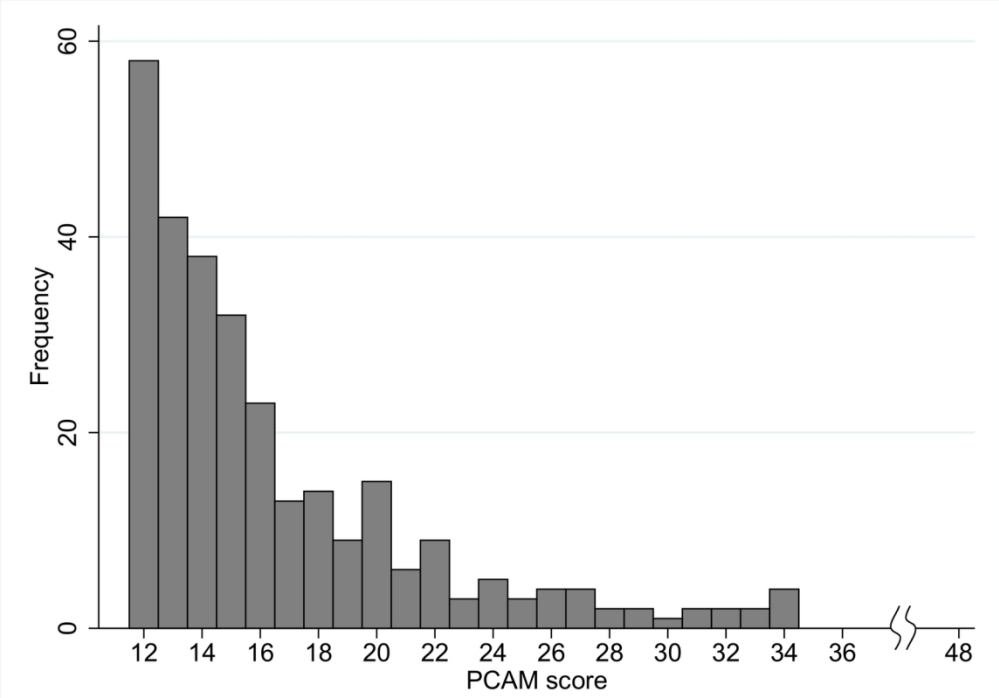


Figure 1. Distribution of total scores of PCAM. PCAM, Patient Centered Assessment Method.

139x101mm (300 x 300 DPI)

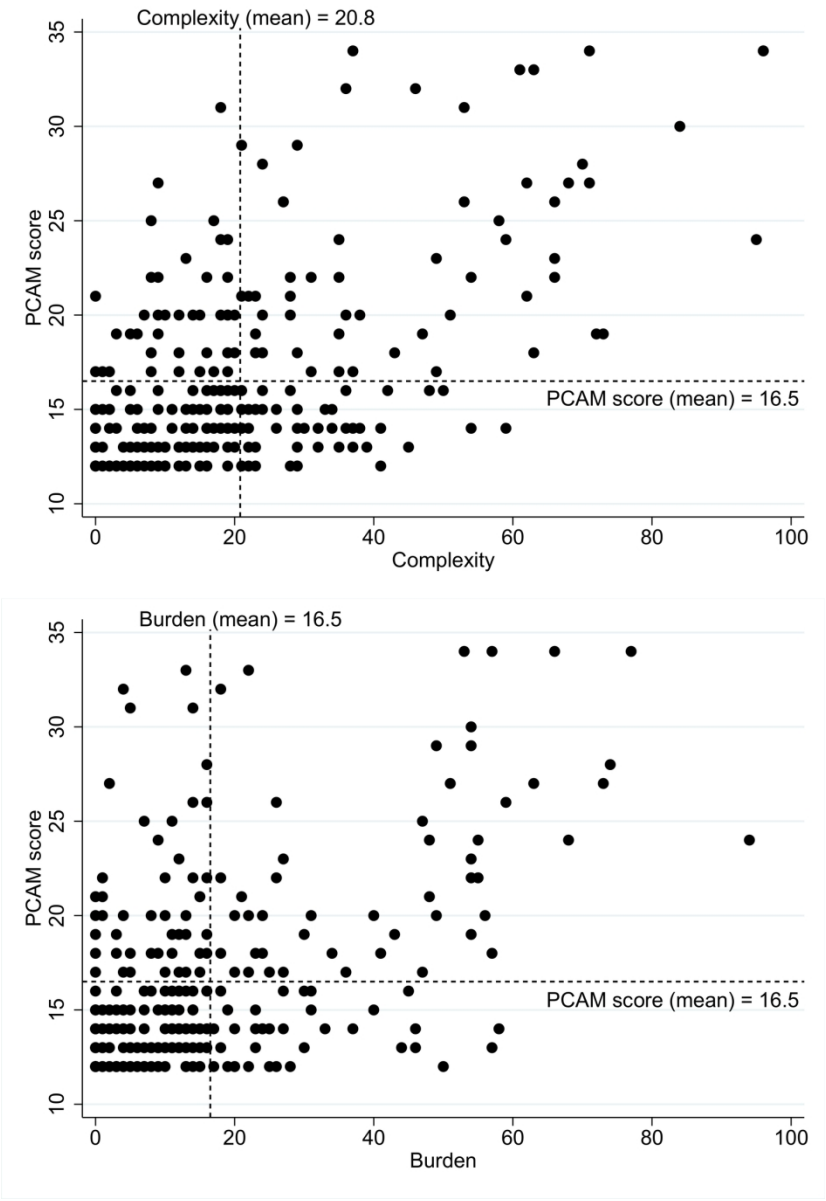


Figure 2. Correlation between PCAM scores and complexity/burden level measured by VAS. PCAM, Patient Centered Assessment Method; VAS, Visual Analog Scale.

139x203mm (300 x 300 DPI)

Supplementary File A

日本語版 Patient Centered Assessment Method (PCAM)

ID _____ 年 月 日

医師/看護師：

実施上の注意点：この評価シートをガイドとして使用し、あなたが各質問に答えやすいように、面談の間にあなた自身の言葉で患者に質問してください。この患者に関連した複雑性のレベルを反映させるように各項目で選択肢一つに丸をつけてください。面談の間か、もしくはその後に完成させてください。

身体の健康と心の安寧

1	患者の**身体の健康についてどのようなニーズ**があるかを考えた場合、更に**精査**が必要と思われる不確かな症状や問題（危険因子）があるか？		
不確かな問題は見出されない、あるいは問題はすでに吟味されている	軽度の漠然とした身体的症状あるいは問題がある；しかし日常生活に影響を及ぼさないか、患者の心配事ではない	日常生活に影響を及ぼす中等度から重度の症状あるいは問題がある	日常生活に重大な影響を及ぼす重度の症状あるいは問題がある
2	患者の**身体の健康**が**心の安寧**に影響しているか？		
懸念される問題は見出されない	心の安寧に軽度の影響を与えている（例：“うんざりする感じ”、“楽しみが減っている”）	心の安寧に中等度から重度の影響を与えており、日常生活の楽しみを妨げている	心の安寧に重度の影響を与えており、日常生活を妨げている
3	**身体の健康**や**心の安寧**に影響するような**生活習慣**（アルコール、薬、食事、運動）に伴う問題があるか?		
懸念される問題は見出されない	身体の健康や心の安寧に悪い影響を与える可能性がある軽度の問題を認める	身体の健康や心の安寧に中等度から重度の影響を与えており、日常生活の楽しみを妨げている	身体の健康や心の安寧に重度の影響を与えており、他者にも影響する可能性がある
4	患者の**心の安寧**について他に**何らかの懸念される問題**があるか? その深刻さや患者に与える影響をどのくらいと評価するか?		
懸念される問題は見出されない	軽度な問題ー日常機能を妨げない	中等度から重度の問題があり日常機能を妨げている	ほとんどの日常機能を妨げる重度の問題がある

社会的環境

1	**安全性、安定性**の点（家庭内暴力、安全でない家、隣人の嫌がらせを含む）から**居住環境**をどのように評価するか?		
一貫して安全で、支援的、安定している状態で、問題は見受けられない	安全で、安定しているがやや一貫性に欠ける	安全/安定しているか疑問がある	安全でなく、安定もしていない
2	**日常の活動**は患者の（心の）安寧にどう影響を与えているか？（現在失業中か予想される失業、仕事、介護、その他を含む）		
問題は見いだされないか、あるいは恩恵があると感じている	ある程度ありきたりの不満があるが、気がかりではない	時々、気分の落ち込みやストレスの一因となっている	心の安寧に重度の悪影響を与えている

3	**社会ネットワーク**（家族、仕事、友人）についてどのように評価するか?		
社会ネットワークに十分に参加している	社会ネットワークに不足なく参加している	ある程度、社会的に孤立し、参加が制限されている	孤独で社会的に孤立し、ほとんど参加していない
4	**金銭面**（すべての必要な医療ケアを受ける余裕があることを含む）についてはどう評価するか？		
金銭的に安定し、十分な収入があり、問題は見いだされない	金銭的に安定しているが、収入にいくつかの問題がある	金銭的に不安定で、収入にいくつかの問題がある	金銭的に不安定で、収入は極わずかしかなく、問題に直面している

健康リテラシーとコミュニケーション

1	自分の健康・安寧（症状、徴候、危険因子）と健康管理に必要なことを、患者は**今**、どの程度よく**理解しているか**?		
合理的によく理解していて、すでに健康管理をしているか、あるいはより良い管理をすることをいとわない	合理的によく理解しているがしかし、現時点ではアドバイスを受け入れられないと感じている	より良い管理を可能にするような理解を少ししかしていない	健康管理をするための重要なことについて理解していない
2	患者はどのくらいヘルスケアの話し合いに**参加する**ことができるか？（言語の壁、聴覚欠如、失語症、アルコールや薬物問題、学習困難、集中力）		
妨げがなく、率直なコミュニケーションで、障壁は見出されない	わずかな障壁があるものの、不足のないコミュニケーションである	中等度の障壁があり、コミュニケーション上のいくらかの困難がある	重度な障壁を伴うコミュニケーション上の深刻な困難がある

サービスコーディネーション

1	患者を支援するために必要な**他のサービス**はあるか?		
現時点では他のケア/サービスは必要としていない	他のケア/サービスはすでに受けており、不足はない	ケア/サービスを受けているが、十分ではない	ケア/サービスを受けておらず、受ける必要がある
2	現在、患者に関わっているサービスは**良く調整されている**か？（あなたが今薦めている他のサービスとの調整も含む）		
すべての必要なケア/サービスがすで受けており、良好に調整されている	必要なケア/サービスがすでに受けており、不足なく調整がなされている	必要なケア/サービスはすでに受けているが、いくらかの調整に妨げがある	必要なケア/サービスが欠如していて、（かつ/あるいは）調整が断片的である

通常のケア	経過観察	プラン作成	すぐに実施

どんな行動が必要か？	誰に協力を求めるべきか？	行動のための妨げは何か？	どんな行動をとるか？
備考：			

Supplementary File B

日本語版 Patient Centered Assessment Method(PCAM)
評価実施のためのユーザーガイド

＜身体の健康と心の安寧＞

項目１：身体の健康についてのニーズ

１.	患者の身体の健康についてどのようなニーズがあるかを考えた場合、更に精査が必要と思われる不確かな症状や問題（危険因子）があるか？		
不確かな問題は見出されない、あるいは問題はすでに吟味されている	軽度の漠然とした身体的症状あるいは問題がある；　しかし日常生活に影響を及ぼさないか、患者の心配事ではない	日常生活に影響を及ぼす中等度から重度の症状あるいは問題がある	日常生活に重大な影響を及ぼす重度の症状あるいは問題がある

この項目では、健康診断の際に行われた身体的な検査の結果として見出だされた危険因子（血圧、血糖値）を含めてください。さらに、患者が自発的に挙げた問題、また、自身に影響を及ぼしている健康問題があるか尋ねてください。患者はすでにケアを受けているかもしれませんが、症状が変化していたり、持続して日常生活に影響を与えているかもしれません。

尋ねたらよいと思われる質問項目サンプル：

・現時点でのあなたの健康状態について述べてください。

・身体の健康についてはいかがでしょうか。

・もし、診療所以外（非医療機関）で PCAM による評価が行われている場合、あなたは医者にかかる必要が最近ありましたか？それは何のためですか？

項目２：身体の健康が心の安寧に与える影響

２.	患者の身体の健康が心の安寧に影響しているか？		
懸念される問題は見出されない	心の安寧に軽度の影響を与えている（例：“うんざりする感じ”、“楽しみが減っている”）	心の安寧に中等度から重度の影響を与えており、日常生活の楽しみを妨げている	心の安寧に重度の影響を与えており、日常生活を妨げている

ここでは、項目１で挙げられた問題や、生活習慣上の問題による身体の症状を考慮することになるでしょう。

尋ねたらよいと思われる質問項目サンプル：

・私たちがあなたの身体の症状や状態について話し合っている時、どのように感じますか？

・X という状態は現時点であなたにどのように影響していますか？
・あなたの心の状態はいかがですか？
・あなたはストレスを感じたり、うんざりする感じが少しでもありますか？

項目３：ライフスタイルが身体の健康と心の安寧に与える影響

３.	身体の健康や心の安寧に影響するような生活習慣（アルコール、薬、食事、運動）に伴う問題があるか？		
懸念される問題は見出されない	身体の健康や心の安寧に悪い影響を与える可能性がある軽度の問題を認める	身体の健康や心の安寧に中等度から重度の影響を与えており、日常生活の楽しみを妨げている	身体の健康や心の安寧に重度の影響を与えており、他者にも影響する可能性がある

この項目では、アルコール、薬物使用、食事、運動のような生活習慣による影響と、それらが身体と心の健康の両方にどのように影響を及ぼしているかを考慮しましょう。

尋ねたらよいと思われる質問項目サンプル：
・あなたはアルコールや薬物使用について、何か気になることがありますか？
・健康を維持するためにあなたがしていることはどんなことですか？運動？食事？

項目４：その他の心の安寧の問題

４.	患者の心の安寧について他に何らかの懸念される問題があるか？　その深刻さや患者に与える影響をどのくらいと評価するか？		
懸念される問題は見出されない	軽度な問題－日常機能を妨げない	中等度から重度の問題があり日常機能を妨げている	ほとんどの日常機能を妨げる重度の問題がある

ここでは、上記で考慮されたこと以外の心の安寧について考慮しましょう。ここでは統合失調症等のような厳しい状況に加えて、不安、うつ、自尊心、死別、虐待、人間関係、雇用問題が含まれるかもしれません。あなたは時間制限のある面談中に“パンドラの箱を開ける”ことを心配するかもしれません。このことは経験、訓練、サービスプランニングによってしばしば軽減することができます。（例：さらに案件を話し合うために、再度患者に来てもらえるようにすること）

時々、患者は希死念慮を表出するかもしれません。リスク評価を訓練することがこの問題に対処するのに役立つでしょう。こういう思いを訴える患者は、めったに差し迫った危険な状態であることはないでしょう。そして、会話がその危険を軽減することに役立つかもしれません。

尋ねたらよいと思われる質問項目サンプル：
・生活において、あなたの健康に影響を及ぼしているかもしれない、他のことはありませんか？
・個人的な人間関係が失われたり、変化したりしましたか？

・あなたは生活をどのくらいうまく管理できていると感じますか？

＜社会的環境＞

項目１：居住環境

１.	安全性、安定性の点（家庭内暴力、安全でない家、隣人の嫌がらせを含む）から居住環境をどのように評価するか？		
一貫して安全で、支援的、安定している状態で、問題は見受けられない	安全で、安定しているがやや一貫性に欠ける	安全/安定しているか疑問がある	安全でなく、安定もしていない

この質問項目では（患者と）話し合うには困難でやりがいがある領域になりますが、経験上、このツールを試しに使用した看護師は非常に有益であると見出しています。心の安寧についての話し合いを通して、問題が浮かび上がってくるかもしれません。患者が言ったことをそのまま受け売りで環境を評価することはできませんが、ここでは報告したことを記録することになるでしょう。この時点で、危険にさらされている患者はこの問題について打ち明けることはできないかもしれません。しかし、患者と普段通りに自然な態度で話し始めると、いずれ打ち明けてくれるかもしれません。

尋ねたらよいと思われる質問項目サンプル：

・お家ではいかがですか？

・お家やご近所は安全だと感じていますか？

・あなたは自分の住んでいるところについて満足と感じていますか？なぜそう感じますか？/感じないのはなぜですか？

項目２：日常の活動

２.	日常の活動は患者の（心の）安寧にどう影響を与えているか？（現在失業中か予想される失業、仕事、介護、その他を含む）		
問題は見いだされないか、あるいは恩恵があると感じている	ある程度ありきたりの不満があるが、気がかりではない	時々、気分の落ち込みやストレスの一因となっている	心の安寧に重度の悪影響を与えている

仕事のストレス、失業、責任のある介護はすべて安寧を貧しくする可能性があります。

尋ねたらよいと思われる質問項目サンプル：

・現在、日常の活動をいつも通りに送れていますか？それはなぜ？/なぜできないのですか？

・（もし、雇用されているなら）毎日仕事に行くことを楽しんでいますか？または仕事によってストレスが生じていますか？

・日常生活や（心の）安寧に影響を与えるような責任を抱えていますか？

項目３：社会ネットワーク

３.	社会ネットワーク（家族、仕事、友人）についてどのように評価するか？		
社会ネットワークに十分に参加している	社会ネットワークに不足なく参加している	ある程度、社会的に孤立し、参加が制限されている	孤独で社会的に孤立し、ほとんど参加していない

適切な社会ネットワークはうつ、不安、自殺を予防できます。

尋ねたらよいと思われる質問項目サンプル：

・もしあなたが問題や気分の落ち込みを感じたら、だれに話せますか？

・あなたは友達や家族から良く支えられていると感じますか？なぜそう感じますか？/感じないのはなぜですか？

・他にどのような支えが必要ですか？

項目４：金銭的な収入

４.	金銭面（すべての必要な医療ケアを受ける余裕があることを含む）についてはどう評価するか？		
金銭的に安定し、十分な収入があり、問題は見いだされない	金銭的に安定しているが、収入にいくつかの問題がある	金銭的に不安定で、収入にいくつかの問題がある	金銭的に不安定で、収入は極わずかしかなく、問題に直面している

借金や金銭面についての心配は心の安寧にとって、重大な危険因子となります。初めはこのことを話すのは難しい話題になり得ますが、現在の経済状況や増大する収入格差という文脈のなかで、“多くの人々は今、職を失うことや、収入の範囲内でやっていけるかを心配していますが、あなたはどうですか？”というように質問を一般化して始めることが有用かもしれません。

追加して尋ねたらよいと思われる質問項目サンプル：

・あなたは金銭的にゆとりがあると感じていますか？

・あなたは健康管理に関連した費用を支払えると感じていますか？

＜健康リテラシーとコミュニケーション＞

項目１：健康リテラシー

１.	自分の健康・安寧（症状、徴候、危険因子）と健康管理に必要なことを、患者は今、どの程度よく理解しているか？		
合理的によく理解していて、すでに健康管理をしているか、あるいはより良い管理をすることをいとわない。	合理的によく理解しているがしかし、現時点ではアドバイスを受け入れられないと感じている	より良い管理を可能にするような理解を少ししかしていない。	健康管理をするための重要なことについて理解していない

この項目は援助を受ける際の障害を明らかにすることを意図しています。これを文書化しておくと、今後のコンサルテーションに対しての情報提供や、さらに患者と話し合う機会を持つための理由として役に立つかもしれません。患者は健康の一つの側面は理解していますが、他の側面は理解していないかもしれません（例えば、喫煙量を減らす必要性は理解しているかもしれませんが、自宅での怒りが健康問題だとは理解していないかもしれません）。ここでのあなたの記録は全体像を反映しているべきです。もし患者に前向きに進み始めるための理解が十分にあれば、緑か黄色につけるとよいでしょう。

尋ねたらよいと思われる質問項目サンプル：
・あなたは医療者にまだ質問があると感じていますか？他に知りたいことは何でしょうか？
・あなたは健康、診断、問題について必要な情報をすべて持っていると感じますか？
・あなたの生活を、医療者が提案したように変えるという準備ができていると感じていますか？（食事、運動、健康管理）

項目２：話し合いへの参加

２.	患者はどのくらいヘルスケアの話し合いに参加することができるか？（言語の壁、聴覚欠如、失語症、アルコールや薬物問題、学習困難、集中力）		
妨げがなく、率直なコミュニケーションで、障壁は見出されない	わずかな障壁があるものの、不足のないコミュニケーションである	中等度の障壁があり、ミュニケーション上のいくらかの困難がある	重度な障壁を伴うコミュニケーション上の深刻な困難がある

上記のように、この項目では必要とされる治療よりも、話し合いに参加するための障壁を強調することを意図しています。このことは、患者にもう一度戻ってきてもらって、通訳者のような援助を提供できたり、学習困難者を援助するための資源を紹介できるかもしれません。

尋ねたらよいと思われる質問項目サンプル：
・医療者はあなたが理解しやすい方法で彼らの考えをあなたに説明をしますか？
・どうしたら医療者により理解してもらいやすくなりますか？

＜サービスコーディネーション＞

項目１：その他のサービス

１.	患者を支援するために必要な他のサービスはあるか？		
現時点では他のケア/サービスは必要としていない	他のケア/サービスはすでに受けており、不足はない	ケア/サービスを受けているが、十分ではない	ケア/サービスを受けておらず、受ける必要がある

この項目は、あなたが薦める（他のサービスへの）紹介と、あなたの薦めに対して従うことへの患者の関心と意思を評価するために使ってください。たくさんの紹介があるかもしれません。その中のいくつかは患者は受け入れたいと思っているでしょうし、その他は、現時点では解決しようとしていないか

もしれません。この紹介というものは、行動の必要性についてのあなたの意見を反映しているものです。実際に行われた紹介はあなたの意見と患者の希望を反映しています。患者は現時点ではこの紹介は適切でないと判断するかもしれません。

尋ねたらよいと思われる質問項目サンプル：

・あなたは医療者やケアに関わっているその他の人々から、現時点で必要なすべてのケアを受けていると感じていますか？

・あなたは私が提案した薦めについてどのくらい満足していますか？

・あなたが経過を見たい、解決したい最重要課題のように感じているものは何でしょう？

項目２：サービスコーディネーション

２.	現在、患者に関わっているサービスは良く調整されているか？（あなたが今薦めている他のサービスとの調整も含む）		
すべての必要なケア/サービスをすでに受けており、良好に調整されている	必要なケア/サービスをすでに受けており、不足なく調整がなされている	必要なケア/サービスはすでに受けているが、調整にいくらかの妨げがある	必要なケア/サービスが欠如していて、（かつ/あるいは）調整が断片的である

この項目は、すべてのケアとサービス（あなたが評価する前にすでに受けていることも含めて）がどの程度うまく調整できているかを示すために使用してください。もし、サービスとケアが断片的で、患者が利用することが難しい場合は、例え患者がやると決めて、良く参加していても、やり遂げることができないかもしれません。

尋ねたらよいと思われる質問項目サンプル：

・あなたが利用しているすべてのサービスはどのくらいうまく組み立てられたものですか？

・あなたが利用しているサービスは簡単にアクセスすることができて、あなたが利用できる時に提供されていますか？

・サービスやケアを受ける準備や、そこにアクセスすることが困難で、それら（サービスやケア）を受けられないことがありますか？

このセクションは、あなたが薦めている行動、誰に紹介するか、妨げになるもの、そして、患者が何をしたいかという意思表示を要約するために使いましょう。

どんな行動が必要か？	誰に協力を求めるべきか？	行動のための妨げは何か？	どんな行動をとるか？
備考：			

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1,3
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	5
Objectives	3	State specific objectives, including any prespecified hypotheses	5,6
Methods			
Study design	4	Present key elements of study design early in the paper	3,7
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6,7
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	6,7
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	7,8
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	6,7
Bias	9	Describe any efforts to address potential sources of bias	6,
Study size	10	Explain how the study size was arrived at	6,8,9
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	8
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	9
		(*b*) Describe any methods used to examine subgroups and interactions	n/a
		(*c*) Explain how missing data were addressed	10
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	n/a
		(*e*) Describe any sensitivity analyses	n/a
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	10
		(b) Give reasons for non-participation at each stage	10
		(c) Consider use of a flow diagram	n/a
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	10-12
		(b) Indicate number of participants with missing data for each variable of interest	n/a
Outcome data	15*	Report numbers of outcome events or summary measures	13,14
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	n/a
		(*b*) Report category boundaries when continuous variables were categorized	n/a
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	n/a
Discussion			
Key results	18	Summarise key results with reference to study objectives	14
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	17
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	14-17
Generalisability	21	Discuss the generalisability (external validity) of the study results	17
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	18

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Development and validation of a Japanese version of the Patient Centered Assessment Method and its user guide: a cross-sectional study

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2020-037282.R1
Article Type:	Original research
Date Submitted by the Author:	11-Aug-2020
Complete List of Authors:	Mutai, Rieko; Jikei University School of Medicine, Division of Clinical Epidemiology, Research Center for Medical Sciences; Jikei University School of Nursing, Adult nursing Sugiyama, Yoshifumi; Jikei University School of Medicine, Division of Clinical Epidemiology, Research Center for Medical Sciences Yoshida, Shuhei; Hiroshima University, Department of Community-Based Medical System; Jikei University School of Medicine, Division of Clinical Epidemiology, Research Center for Medical Sciences Horiguchi, Ryoko; Jikei University School of Medicine, Division of Clinical Epidemiology, Research Center for Medical Sciences Watanabe, Takamasa; Kita-adachi Seikyo Clinic, family medicine; Jikei University School of Medicine, Division of Clinical Epidemiology, Research Center for Medical Sciences Kaneko, Makoto; Hamamatsu University School of Medicine, Department of Family and Community Medicine; Jikei University School of Medicine, Division of Clinical Epidemiology, Research Center for Medical Sciences Tominaga, Tomokazu; Koganei Family Clinic; Jikei University School of Medicine, Division of Clinical Epidemiology, Research Center for Medical Sciences Hayashi, Daichi; State University of New York at Stony Brook, Department of Radiology, Stony Brook Medicine Matsushima, Masato; Jikei University School of Medicine, Division of Clinical Epidemiology, Research Center for Medical Sciences
Primary Subject Heading:	General practice / Family practice
Secondary Subject Heading:	General practice / Family practice, Epidemiology
Keywords:	PRIMARY CARE, EPIDEMIOLOGY, GENERAL MEDICINE (see Internal Medicine)

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

Development and validation of a Japanese version of the Patient Centered Assessment Method and its user guide: a cross-sectional study

Rieko Mutai[1, 2], Yoshifumi Sugiyama[1], Shuhei Yoshida[1, 3, 4, 5], Ryoko Horiguchi[1], Takamasa Watanabe[1, 3, 4], Makoto Kaneko[1, 3, 6, 7], Tomokazu Tominaga[1, 3, 6, 8], Daichi Hayashi[9], Masato Matsushima[1]

[1] Division of Clinical Epidemiology, Research Center for Medical Sciences, The Jikei University School of Medicine, Tokyo, Japan

[2] Department of Adult Nursing, The Jikei University School of Nursing, Chofu, Japan

[3] Centre for Family Medicine Development, Japanese Health and Welfare Co-operative Federation, Tokyo, Japan

[4] Kitaadachi-seikyo Clinic, Japanese Health and Welfare Co-operative Federation, Tokyo, Japan

[5] Department of Community-Based Medical System, Graduate School of Biomedical and Health Sciences, Hiroshima University, Hiroshima, Japan

[6] Musashikoganei Clinic, Japanese Health and Welfare Co-operative Federation, Koganei, Japan

[7] Department of Family and Community Medicine, Hamamatsu University School of Medicine, Hamamatsu, Japan

[8] Koganei Family Clinic, Koganei, Japan

[9] Department of Radiology, Stony Brook Medicine, Stony Brook, New York, USA

Corresponding author: Masato Matsushima

Division of Clinical Epidemiology, Research Center for Medical Sciences

The Jikei University School of Medicine

3-25-8 Nishi-Shimbashi, Minato-ku, Tokyo 105-8461, Japan

Tel: +81-3-3433-1111 (ext. 2398); Email: masato@jikei.ac.jp

1

2 **Word count:** 3949

3

ABSTRACT

Objectives The primary objective of this study was to develop the Japanese version of the Patient Centered Assessment Method (PCAM) and its user guide. The secondary objective was to examine the validity and reliability in the primary care setting.

Design Cross-sectional study.

Setting Three family physician teaching clinics located in urban residential areas in Tokyo, Japan.

Participants Patients who were aged 20 years or older, and who had an appointment with physicians at the three participating clinics.

Main outcome measures Patient complexity measured by PCAM and complexity/burden level measured by a Visual Analog Scale (VAS).

Results Although confirmatory factor analysis using a model described in a previous study revealed that the indices did not meet the criteria for good fit, exploratory factor analysis revealed a new three-factor structure of "Personal well-being," "Social interaction," and "Needs for care/service." Cronbach's alpha of PCAM was 0.86. Spearman's rank correlation coefficients between PCAM scores and VAS scores were 0.51 for complexity ($p<0.001$) and 0.41 for burden ($p<0.001$). There were 42 patients (14.3% of total patients) with PCAM scores greater than its mean of 16.5 but with complexity VAS scores less than its mean of 20.8.

Conclusions The Japanese version of PCAM and its user guide were developed through Japanese translation and cultural adaptation by cognitive debriefing. PCAM is a valid and reliable tool to assess patient complexity in the primary care settings in Japan. Additionally, although the correlation between total PCAM scores and complexity/burden as assessed by VAS was moderate, PCAM can more precisely identify patient complexity than skilled physician's intuition.

Keywords

patient complexity, the Patient Centered Assessment Method, translation, cultural adaptation, validity, reliability

Strengths and limitations of this study

- This is the first study to develop a Japanese version of the Patient Centered Assessment Method.
- In addition to the scale itself, we also developed a Japanese user guide through forward translation, back translation, and cognitive debriefing for cultural adaptation.
- We evaluated the structural validity by confirmatory factor analysis using a model that had been determined by exploratory factor analysis.
- The criterion validity was somewhat limited because we substituted visual analog scales for the external criteria.
- Generalizability may be limited given that only three clinics in urban areas participated .

INTRODUCTION

Social and economic conditions are associated with human health and have been termed social determinants of health (SDH).[1] Developed countries are now increasingly facing many obstacles caused by changes in the population pyramid, declining birthrates, and aging populations.[2] These demographic shifts are leading to a growing number of people with diverse and complex backgrounds, such as multimorbidity,[3-5] neuropsychiatric diseases including dementia[6,7] and depression,[8-10] less involvement in social networks,[11,12] and living alone.[13] Therefore, the role of primary care providers in addressing these patients' biopsychosocial complexities is becoming more important.

INTERMED[14-16] is an instrument that was developed to assess patient complexity in secondary care settings and the validity and reliability of the Japanese version has been verified.[17] Based on INTERMED, the Minnesota Complexity Assessment Method (MCAM)[18] was developed for use in the primary care settings, which led to an advanced version of MCAM, called the Minnesota Edinburgh Complexity Assessment Method (MECAM),[19] for the assessment of patients' biopsychosocial needs.

The Patient Centered Assessment Method (PCAM)[20] is an improved version of MECAM that can be applied to long-term conditions such as chronic obstructive pulmonary disease, diabetes mellitus, and coronary heart disease. The PCAM, a practical tool for identifying and assessing biopsychosocial problems, enables healthcare professionals to prioritize patients' needs in accordance with their severity and level of urgency.[20] The PCAM comprises four categories: "Health and well-being," "Social environment," "Health literacy and communication," and "Service coordination."[21] In previous studies, we assessed and confirmed the validity and reliability of the original version of PCAM in the initial phase of the secondary care setting in Japan and identified a correlation between total PCAM scores and length of hospital stay[22]/degree of burden on medical staff.[23]

As stated above, the PCAM allows medical providers to assess patients' needs from

biopsychosocial perspectives and to make referrals to a broader range of services.[20] In Japan, assessing patient complexity and acting on that basis has recently drawn considerable attention. One example is social prescribing, which has the potential to improve patients' health outcomes by linking them to appropriate services.[24] Additionally, the PCAM promotes sharing of information, which enables seamless interventions by physicians, nurses and other health care professionals. For example, in Japan, establishment of a care delivery system by multidisciplinary collaboration is encouraged, the aim being to facilitate provision of comprehensive and continuous care to patients and their families.[25] The PCAM is an indispensable tool for interprofessional information sharing. However, until now no Japanese equivalent for identifying and evaluating patient complexity has been available. A Japanese version of PCAM would be useful for healthcare professionals who are not proficient in English in that it would encourage and empower them to consider various biopsychosocial perspectives. The primary objective of this study was to develop a Japanese version of PCAM and its user guide. The secondary objective was to examine the validity and reliability in the primary care setting in Japan.

METHODS

This study consisted of two phases. In the first phase, the Japanese version of PCAM and its user guide were developed. In the second phase, the validity and reliability of the Japanese version of PCAM were evaluated in the primary care setting. In this study, we examined structural and criterion validity and internal consistency as reliability.

First phase: Development of the Japanese version of PCAM and its user guide

PCAM and its user guide were translated into and culturally adapted to Japanese with the original author's permission in accordance with the guidelines of the World Health Organization and International Society Pharmacoeconomics and Outcomes Research Task Force for Translation.[26,27] First, the primary investigator (RM), who was a native speaker of Japanese,

translated the original PCAM and its user guide into Japanese, and four researchers (RM, MM, SY, HW) discussed cultural adaptation to Japanese and completed the provisional versions. Next, a bilingual medical doctor (DH), who was not familiar with the original PCAM and its user guide, back-translated the provisional versions into English. Then, discrepancies between the original and back-translated English version were reviewed and revised by the original authors and three of the authors of this study (RM, MM, SY). Thus, we completed the prototype versions. Next, cognitive debriefing on the prototype versions was conducted in a small group to check alternative wording and to confirm the understandability, interpretation, and cultural relevance of the translation. Five Japanese physicians were recruited from primary care clinics in Tokyo, Japan by means of snowball sampling considering age, sex, and years of experience, and were interviewed to check and confirm each of the points described above.

Second phase: Evaluation of validity and reliability

Study design and setting

This was a cross-sectional study reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement.[28] This study was conducted at three family physician teaching clinics located in urban residential areas in Tokyo, Japan that were responsible for primary care with group practice: Kitaadachi-seikyo Clinic, Seikyo-ukima Clinic, and Musashikoganei Clinic affiliated with Japanese Health and Welfare Co-operative Federation.

Patient Participants

Patients who were aged 20 years or older, and who had an appointment with physicians at the three participating clinics were consecutively included. Exclusion criteria were patients for a general check-up, patients who had difficulty communicating in Japanese, patients who were too sick to complete the questionnaire, or patients who declined to participate in this study.

Data collection

Data were collected by five physicians: two at Kitaadachi-seikyo Clinic, one at Seikyo-ukima Clinic, and two at Musashikoganei Clinic, Japanese Health and Welfare Co-operative Federation. The period for data collection was between January 5th, 2018 and July 25th, 2018 in consideration of the physicians' and the principal investigator's schedule: five days at Kitaadachi-seikyo Clinic, 15 days at Seikyo-ukima Clinic, and 12 days at Musashikoganei Clinic. In advance of the data collection, the principal investigator explained the Japanese version of the PCAM to the five physicians using the user guide to standardize the criteria of evaluation. Patients were asked to complete a self-administered questionnaire on demographic characteristics while waiting for a consultation at the clinic; furthermore, physicians evaluated the degree of complexity and burden using a Visual Analog Scale (VAS).[29] During or after a consultation, physicians used the Japanese version of the PCAM user guide and completed a PCAM form.

Outcome Measures

PCAM

PCAM consists of twelve items across four categories[21]: "Health and well-being" (four items: "Physical health needs," "Physical health impacting mental well-being," "Lifestyle impacting mental well-being," and "Other mental well-being"), "Social environment" (four items: "Home environment," "Daily activities," "Social network," and "Financial resources"), "Health literacy and communication" (two items: "Health literacy" and "Engagement in discussion"), and "Service coordination" (two items: "Other services" and "Service coordination"). Each item is scored from 1 to 4 points, with total scores ranging from 12 to 48 points. The higher the score, the more complex the patient.

Complexity/burden level measured by VAS

Physicians possibly misperceive the psychological "burden" of caring for a patient with complex needs as intuitive patient "complexity." Therefore, patient complexity and psychological burden were measured separately, enabling the physicians to be aware of the difference between them and to evaluate them precisely. Measurements were performed by using a VAS. The VAS for "complexity" comprised a 10-cm-long horizontal line with a starting point of "not complex" (0 point) and an ending point of "the most complex" (100 points). The VAS for "burden" similarly comprised a 10-cm-long horizontal line with a starting point of "no burden" (0 point) and an ending point of "the heaviest burden" (100 points). A person who was blinded to the patients' information measured the length marked on the VASs.

There are currently no external criteria for examining criterion validity for which the validity and reliability have been established in the primary care setting. Therefore, a VAS, which is a practical tool, was substituted for external criteria.

Patient characteristics

Demographic characteristics including sex, age, marital status, household composition, household size, home ownership, years of residence, employment status, and educational background were obtained from a self-administered questionnaire, whereas main diseases, Charlson Comorbidity Index (CCI),[30,31] and copayment (the proportion of individual payment of medical expense depending on age and income) were obtained from medical records. Physicians chose one main disease from all of a patient's diseases for that patient's regular clinical visits.

Sample size calculation

The recommended subjects-to-variables ratio is from 3:1 to 20:1 when conducting exploratory factor analysis.[32] Because a larger sample size has been reported to provide more precise results in factor analysis, the ratio of 20:1 was employed in this study. Therefore, because

PCAM includes 12 items, the sample size was determined to be 300 in consideration of at most 60 participants having missing values.

Statistical analysis

Confirmatory factor analysis with the robust maximum likelihood estimation was conducted to assess structural validity, assuming a two-factor model of medicine- and patient-oriented complexity, which was derived from our previous study.[21] The model fit was judged to be good if the comparative fit index (CFI) was ≥0.90, standardized root mean residual (SRMR) was ≤0.08, and root mean squared error of approximation (RMSEA) was ≤0.08.[33]

When the model fit was insufficient, exploratory factor analysis with the robust maximum likelihood estimation and CF-Equamax rotation was performed. Parallel analysis was conducted to determine the number of common factors and factor loading ≥0.4 was adopted to determine which items to include. Then, confirmatory factor analysis was performed again using a model that had been determined by exploratory factor analysis.

Internal consistency was considered adequate if Cronbach's alpha was between 0.70 and 0.95.[34]

Spearman's rank correlation coefficient between total PCAM scores and complexity/burden as measured by VAS examined criterion validity and how closely the scale correlated with the physicians' general impressions.[35]

All statistical analyses were performed using STATA/SE version 14.0[36,37] and Mplus version 8.4.[38,39] P-values <0.05 were considered statistically significant.

Ethical considerations

The research protocol for the first phase was approved by the Ethics Committee of The Jikei University School of Medicine (ethics number: 28-365 [8608]). The research protocol for the second phase was approved by the Ethics Committee of The Jikei University School of

Medicine (ethics number: 29-229 [8845]) and Tokyo Hokuto Health Co-operative (ethics number: 89). The principal investigator (RM), who was not associated with any of the three family physician teaching clinics, fully explained the content of this study to all subjects; they then provided written informed consent to participate.

Patient and public involvement

This study was conducted without patient or the public involvement: they had no role in the study design; the data analysis, and interpretation; the manuscript preparation and reviewing; or the decision to submit the manuscript.

RESULTS

Japanese translation and cultural adaptation by cognitive debriefing

After the Japanese forward and backward translation process, cultural adaptation was conducted by interviewing one female and four male physicians between April 27th and May 18th, 2017. These five physicians' median (interquartile range, IQR) age and years of experiences as a primary care physician were 37 (34–38) and 12 (10–14) years, respectively. The median interview time (IQR) was 51 (17–55) minutes. The physicians pointed out 34 parts that required improvement; modification of these parts was subsequently discussed by the researchers. For example, the wording of the sample questions to patients in the user guide was changed from a literary to a colloquial style to make them easier to understand. Terms with the same pronunciation but different Chinese characters with different meanings were changed to avoid confusion. Twelve of the 34 modified parts were back-translated to minimize possible loss of the original meaning caused by the modification. Three were back-translated into exactly the same as the original English text; four in the PCAM and five in the user guide were confirmed and accepted by the original authors. Finally, the Japanese version of PCAM (online supplementary file A) and its user guide (online supplementary file B) were developed.

Evaluation of validity and reliability

A total of 298 eligible patients were recruited: 100 at Kitaadachi-seikyo Clinic, 101 at Seikyo-ukima Clinic, and 97 at Musashikoganei Clinic. Physicians missed out the entire PCAM in four patients and part of it in one patient, which led to a total of 293 patients included in the final analysis. Patient characteristics and main diseases are shown in Table 1 and Table 2.

Table 1. Patient characteristics

Age, mean (SD), years	72.4 (11.4)
Women, n (%)	164 (56.0)
Married, n (%)	178 (60.8)
Household composition, n (%)	
Single	70 (23.9)
Married couple	92 (31.4)
Other	131 (44.7)
Living arrangements, n (%)	
Living alone	70 (23.9)
Cohabiting	223 (76.1)
Home ownership, n (%)	
Owned	177 (60.4)
Rented	116 (39.6)
Years of residence, mean (SD), years	28.4 (17.4)
Employment status, n (%)	
Full-time employment	45 (15.4)
Part-time employment	28 (9.6)
Unemployment/Homemaker	166/36 (56.7/12.3)
Other	18 (6.1)
Academic background, n (%)	
Junior high school	85 (29.0)
High school	107 (36.5)

Junior college/Vocational school	51 (17.4)
University	44 (15.0)
Graduate school	6 (2.0)
Insurance copayment, n (%)	
0%	27 (9.2)
10%	134 (45.7)
20%	32 (10.9)
30%	100 (34.1)
CCI, mean (SD)	0.88 (1.4)

SD, standard deviation; CCI, Charlson Comorbidity Index.

Table 2. Main diseases diagnosed among patients

Classification of main diseases, n (%)	
Infectious and parasitic diseases	1 (0.3)
Neoplasms	11 (3.8)
Diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism	4 (1.4)
Endocrine, nutritional and metabolic diseases	
Total	73 (24.9)
Diabetes mellitus	49
Dyslipidemia	18
Mental and behavioral disorders	
Total	15 (5.1)
Vascular and unspecified dementia	10
Sleep-wake disorders	4 (1.4)
Diseases of the nervous system	8 (2.7)
Diseases of the circulatory system	
Total	137 (46.8)
Hypertension	111
Heart failure	20
Diseases of the respiratory system	
Total	11 (3.8)
COPD	6

Asthma	4
Diseases of the digestive system	
Total	12 (4.1)
GERD	6
IBS	1
Diseases of the skin and subcutaneous tissue	4 (1.4)
Diseases of the musculoskeletal system and connective tissue	
Total	10 (3.4)
Osteoporosis	7
Diseases of the genitourinary system	2 (0.7)
Injury, poisoning and certain other consequences of external causes	1 (0.3)
Total	293 (100)

COPD, chronic obstructive pulmonary disease; GERD, gasoesophagial reflux disease; IBS, irritable bowel syndrome.

The mean (standard deviation, SD) PCAM score was 16.5 (5.1) and the median (IQR) score was 15 (13–18). As shown in Figure 1, the distribution of total PCAM scores was skewed to the right with a floor effect.

Confirmatory and exploratory factor analysis

Confirmatory factor analysis using the model described in our previous study revealed the following indices for model fit: CFI=0.663, SRMR=0.104, and RMSEA=0.134.

Because the indices did not meet the criteria of good fit, exploratory factor analysis was performed. Parallel analysis suggested a maximum of six common factors. However, because the four- to six-factor models included a common factor that comprised one item, a three-factor model was employed. The items “Physical health needs,” “Physical health impacting mental well-being,” “Other mental well-being concerns,” and “Daily activities,” which focus on physical and mental well-being, contributed to the first factor, termed “Personal well-being.” The items “Social network,” “Health literacy,” and “Engagement in discussion,” which focus mainly on interaction

with social networks and health care professionals, contributed to the second factor, termed "Social interaction." The items "Home environment," "Other services," and "Service coordination," which focus on patients' needs arising in the home environment and satisfied with social services, contributed to the third factor, termed "Needs for care/service."

However, the two items "Lifestyle impacting mental well-being" and "Financial resources" were not included due to a factor loading less than 0.4 (Table 3).

Confirmatory factor analysis using the three-factor model revealed the following indices for model fit: CFI=0.923, SRMR=0.075, and RMSEA=0.074. Thus, all three fit indices met the criteria.

Table 3. Exploratory factor analysis of the Japanese version of the Patient Centered Assessment Method (PCAM)

	First factor	Second factor	Third factor
Health and well-being			
Physical health needs	0.527	0.165	0.017
Physical health impacting mental well-being	0.622	0.009	0.114
Lifestyle impacting mental well-being	0.099	0.144	0.083
Other mental well-being concerns	0.667	–0.022	0.094
Social environment			
Home environment	0.327	0.111	0.433
Daily activities	0.659	0.010	0.084
Social network	0.369	0.426	0.094
Financial resources	0.307	0.120	0.236
Health literacy and communication			
Health literacy	0.063	0.862	0.015
Engagement in discussion	–0.141	0.806	0.099
Service coordination			
Other services	0.020	0.056	0.915
Service coordination	0.014	0.086	0.885

Cronbach's alpha of PCAM was 0.86, and that of the three factors: "Personal well-being," "Social interaction," and "Needs for care/service" were 0.77, 0.78 and 0.89, respectively.

The correlation between PCAM and VAS (complexity and burden) is shown in Figure 2. Spearman's rank correlation coefficients between PCAM scores and VAS were 0.51 for complexity ($p<0.001$) and 0.41 for burden ($p<0.001$). There were 42 patients (14.3% of total patients) with PCAM scores more than the mean score of 16.5 but with complexity scores less than the mean score of 20.8. Moreover, Spearman's rank correlation coefficient between complexity and burden was 0.77.

DISCUSSION

In this study, a Japanese version of the PCAM and its user guide were developed through a process of translation, back-translation, and cognitive debriefing. Then, the structural validity of the Japanese version of the PCAM was assessed through exploratory and confirmatory factor analysis, which revealed the three new factors of "Personal well-being," "Social interaction," and "Needs for care/service," although confirmatory factor analysis using the model described in our previous study showed the model fit to be poor. Cronbach's alpha of PCAM, "Personal well-being," "Social interaction," and "Needs for care/service" were all high. Additionally, the total PCAM score was moderately correlated with complexity and burden as assessed by VAS, indicating that criterion validity was established to some extent.

This study showed a three-factor structure that differed from that of our previous study, this difference presumably being attributable to differences between the clinical settings. Our previous study was conducted in the secondary care setting and the participants were inpatients of an acute hospital,[21] whereas the current study was in the primary care setting. For example, one difference was that the mean (SD) CCI score was 0.9 (1.4) in the present study, which was lower than that of 2.0 (2.2) in our previous study[21] with higher biomedical complexity. Furthermore, the mean (SD) age of patients in our previous study, 77.4 (11.9) years, was higher

than that of the current study. In terms of factor structure, patients with greater physical health-related needs are likely to have greater needs for care and services, which could result in hospitalization in the secondary care setting. Thus, the "Medicine-oriented" factor in the previous study includes both the item "Physical health needs" and items that are included in the "Needs for care/service" factor in the present study. Conversely, in the primary setting, such needs for care and services may not be identified because the patients have fewer physical health-related needs. Therefore, the item "Physical health needs" was not included in the same factor as items that are included in the "Needs for care/service" factor. Rather, the item "Physical health needs" was treated as a component of physical well-being and therefore included in the "Personal well-being" factor in the present study. Additionally, the "Patient-oriented" factor in the previous study includes the items "Physical health impacting mental well-being," "Other mental well-being," "Daily activities," "Social network," "Health literacy," and "Engagement in discussion," whereas these items were divided into two factors, "Personal well-being" and "Social interaction," in the present study. This is probably because primary care physicians take care of people in the community and focus more on assessing their patients from social perspectives. In contrast, social aspects of hospitalized patients are less important in the secondary setting, where social aspects are combined with biopsychological factors in the "Patient-oriented" factor in the previous study.

The extraction of "Social interaction" and "Needs for care/service" from "Personal well-being", which is mainly related to physical and psychological well-being, was of particular importance. "Social interaction" includes items regarding "Social network" and "Health literacy and communication." Health literacy is the cognitive and social ability to obtain, understand, assess, and use information that is essential for good health,[40] and consists of basic/functional, communicative/interactive, and critical literacy;[41] in particular, communicative/interactive literacy is necessary for active participation in social networks. Therefore, it was consistent and reasonable to extract issues related to both social network and health literacy/communication as a common factor. On the other hand, "Needs for care/service" includes items regarding "Home

environment" and "Service coordination." The PCAM evaluates "Home environment" in terms of safety and stability.[21] In Japan, the population is rapidly aging, causing many related problems. For example, older adults are obliged to take care of their old spouses. The numbers of households with a single older adult and solitary deaths are increasing.[42,43] These problems that are attributable to an unsafe or unstable home environment, which may be solvable with nursing care and social welfare interventions, are assumed to be strongly associated with "Service coordination."

However, two items, "Lifestyle impacting mental well-being" and "Financial resources", had insufficient factor loading less than 0.4 and were not included in the three factors. The exclusion of the former item presumably resulted from the fact that 60 percent of all patients had lifestyle diseases such as diabetes mellitus, dyslipidemia, and hypertension, which were generally well-controlled at the participating clinics; therefore, the impact of a patient's lifestyle on these diseases might have been underestimated. Additionally, severely alcoholic patients and drug abusers were possibly referred to specialized facilities, which could also have resulted in underestimation of this item. The exclusion of the latter item presumably resulted from the fact that copayment of medical expenses is at most 30% under the Japanese universal health insurance coverage system and 0% under the welfare system;[44,45] hence, few patients were likely troubled with financial problems due to healthcare. Moreover, previous research revealed that financial topics are taboo and inappropriate for discussion with healthcare providers;[46] therefore, this question might not have been answered accurately. In the Japanese version of PCAM, these items were not intentionally excluded in consideration of the fact that the overall Cronbach's alpha was 0.86, which indicates a high internal consistency without exclusion of these items. The fact that lifestyle-related and economic problems negatively influence physical and psychological conditions is established.[47,48] These two items should therefore not be excluded at this stage; further cautious and prudent research is required to determine how best to accurately score and include them.

This study also showed a floor effect in the distribution of PCAM scores, whereas our previous study did not. The large number of patients, in fact, had low patient complexity; however, physicians might not be able to distinguish detailed factors related to subtle patient complexity due to limited consultation time.

The correlation between total PCAM scores and complexity/burden as assessed by the VAS was found to be moderate. Although complexity and burden were separately assessed to prevent physicians from confusing these two variables, Spearman's rank correlation coefficient between complexity and burden was high. This indicates that physicians do not regard complexity as an objective index, but rather handle it as subjective feeling, or burden. Furthermore, patients that physicians regarded as being not complex were found to have somewhat high PCAM scores, even though physicians working at family physician teaching clinics are generally well trained to see patients from biopsychosocial perspectives. Accordingly, PCAM can more objectively and precisely identify patient complexity than skilled physician's intuition.

There are some limitations in this study. First, only three clinics in urban areas in Tokyo were included as study settings, which could have limited the generalizability of our findings. Second, inter-rater variability of PCAM scores was not evaluated. Patients were not assessed by two physicians because they usually visited the same primary care physician. We considered it would be unethical to force them to see an unfamiliar physician and undergo another PCAM assessment due to their temporal, economic, and psychological burden. Moreover, some of the clinics had only one physician on service at a time. As a result, PCAM scores might have been over- or under-estimated. However, a Japanese version of PCAM is necessary for healthcare providers to address biopsychosocial problems without language barriers, which outweighs the above study limitations.

CONCLUSION

The Japanese version of PCAM and its user guide were developed Japanese translation

and cultural adaptation by cognitive debriefing. PCAM was found to be a valid and reliable tool to assess patient complexity in the primary care setting in Japan. Additionally, although the correlation between total PCAM scores and complexity/burden as assessed by the VAS was moderate, PCAM can more precisely identify patient complexity than skilled physician's intuition.

Acknowledgements

The authors are grateful to the members of the Division of Clinical Epidemiology, Research Center for Medical Sciences, The Jikei University School of Medicine for their kind advice on this study. The authors also thank Dr. Yusuke Shigeshima for collecting the data and Mr. Yuta Yamauchi for processing the data.

Contributors

RM designed the study; collected, analyzed, and interpreted the data; and prepared and reviewed the manuscript. YS analyzed and interpreted the data; and prepared and reviewed the manuscript. MM designed the study; analyzed and interpreted the data; and prepared and reviewed the manuscript. SY designed the study; collected and interpreted the data; and reviewed the manuscript. RH designed the study; analyzed and interpreted the data; and reviewed the manuscript. MK, TW, and TT designed the study; collected the data; and reviewed the manuscript. DH back-translated PCAM and its user guide and reviewed the manuscript.

Funding

This study was supported by The Jikei University Research Fund for Graduate Students (grant number: N/A).

Disclaimer

The sponsor of this study had no role in the study design; the data collection, analysis, and

interpretation; the manuscript preparation and reviewing; or the decision to submit the manuscript.

Competing interests

MM received lecture fees and lecture travel fees from the Centre for Family Medicine Development of Japanese Health and Welfare Co-operative Federation. MM is an adviser of the Centre for Family Medicine Development practice-based research network. MM is a program director of the Jikei Clinical Research Program for Primary-care. YS, SY, MK, TW, and TT are former trainees of the Jikei Clinical Research Program for Primary-care. TW currently is and SY, MK, and TT used to be family physicians at the Centre for Family Medicine Development of Japanese Health and Welfare Co-operative Federation. RM, RH, DH have nothing to disclose.

Data sharing statement

No additional data are available.

References

1 World Health Organization, Regional Office for Europe. Social determinants of health: the solid facts - second edition. 2003. https://apps.who.int/iris/bitstream/handle/10665/326568/9289013710eng.pdf?sequence=1&isAllowed=y (accessed 12 Oct 2019).

2 United Nations, Department of Economic and Social Affairs, Population Division. World Population prospects 2019: Highlights. https://population.un.org/wpp/Publications/Files/WPP2019_Highlights.pdf (accessed 13 Oct 2019).

3 Salisbury C, Johnson L, Purdy S, et al. Epidemiology and impact of multimorbidity in primary care: a retrospective cohort study. *Br J Gen Pract* 2011;61(582):e12–e21.

4 France EF, Wyke S, Gunn JM, et al. Multimorbidity in primary care: a systematic review of

prospective cohort studies. *Br J Gen Pract* 2012;62(597):e297–e307.

5 Mitsutake S, Ishizaki T, Teramoto C, et al. Patterns of co-occurrence of chronic disease among older adults in Tokyo, Japan. *Prev Chronic Dis* 2019;16:E11.

6 Prince M, Bryce R, Albanese E, et al. The global prevalence of dementia: a systematic review and metaanalysis. *Alzheimers Dement* 2013;9(1):63–75.e2.

7 Ohara T, Hata J, Yoshida D, et al. Trends in dementia prevalence, incidence, and survival rate in a Japanese community. *Neurology* 2017;88(20):1925–32.

8 Read JR, Sharpe L, Modini M, et al. Multimorbidity and depression: A systematic review and meta-analysis. *J Affect Disord* 2017;221:36–46.

9 Alexopoulos GS. Depression in the elderly. *Lancet* 2005;365(9475):1961–70.

10 Mitchell PB, Harvey SB. Depression and the older medical patient--when and how to intervene. *Maturitas* 2014;79(2):153–9.

11 Domènech-Abella J, Lara E, Rubio-Valera M, et al. Loneliness and depression in the elderly: the role of social network. *Soc Psychiatry Psychiatr Epidemiol* 2017;52(4):381–90.

12 Steptoe A, Shankar A, Demakakos P, at al. Social isolation, loneliness, and all-cause mortality in older men and women. *Proc Natl Acad Sci U S A* 2013;110(15):5797–801.

13. Ministry of Health, Labour and Welfare. Comprehensive Survey of Living Conditions 2018. https://www.mhlw.go.jp/toukei/saikin/hw/k-tyosa/k-tyosa18/dl/02.pdf (accessed 27 Oct 2019).

14 Huyse FJ, Lyons JS, Stiefel FC, et al. “INTERMED”: a method to assess health service needs. I. Development and reliability. *Gen Hosp Psychiatry* 1999;21:39–48.

15 Stiefel FC, de Jonge P, Huyse FJ, et al. “INTERMED”: a method to assess health service needs. II. Results on its validity and clinical use. *Gen Hosp Psychiatry* 1999;21:49–56.

16 de Jonge P, Huyse FJ, Stiefel FC, et al. INTERMED: a clinical instrument for biopsychosocial assessment. *Psychosomatics* 2001;42:106–9.

17 Kishi Y, Matsuki M, Mizushima H, et al. The INTERMED Japanese version: inter-rater reliability and internal consistency. *J Psychosom Res* 2010;69:583–6.

18 Peek CJ, Baird MA, Coleman E. Primary care for patient complexity: not only disease. *Fam Syst Health* 2009;27:287–302.

19 Maxwell M, Hibberd C, Pratt R, et al. Development and initial validation of the Minnesota Edinburgh Complexity Assessment Method (MECAM) for use within the Keep Well Health Check. 2011. http://www.healthscotland.com/uploads/documents/18448-DevelopmentOfMinnesotaEdinburghComplexityMethod.pdf (accessed 10 Oct).

20 Pratt R, Hibberd C, Cameron I, et al. The Patient Centered Assessment Method (PCAM): integrating the social dimensions of health into primary care. *J Comorb* 2015;5;110–9.

21 Patient Centred Assessment Method (PCAM). https://med.umn.edu/sites/med.umn.edu/files/pcam_assessment_tool_2.0.pdf (accessed 28 July 2020).

22 Yoshida S, Matsushima M, Wakabayashi H, et al. Validity and reliability of the Patient Centred Assessment Method for patient complexity and relationship with hospital length of stay: a prospective cohort study. *BMJ Open* 2017;7:e016175.

23 Yoshida S, Matsushima M, Wakabayashi H, et al. Correlation of patient complexity with the burden for health-related professions, and differences in the burden between the professions at a Japanese regional hospital: a prospective cohort study. *BMJ Open* 2019;9:e025176.

24 Nishioka D, Kondo N. Addressing patients' social health risks at hospital: lessons from "social prescribing" activities. *Japanese journal of health economics & policy* 2018;30(1):5–18.

25 Ministry of Health, Labour and Welfare. Establishing the community-based integrated care system. https://www.mhlw.go.jp/english/policy/care-welfare/care-welfare-elderly/dl/establish_e.pdf (accessed 28 July 2020).

26 Wild D, Grove A, Martin M, et al. Principles of good practice for the translation and cultural adaptation process for patient-reported outcomes (PRO) Measures: report of the ISPOR Task Force for Translation and Cultural Adaptation. *Value Health* 2005;8(2):94–104.

27 World Health Organization. Process of translation and adaptation of instruments.

https://www.who.int/substance_abuse/research_tools/translation/en/ (accessed 18 Oct 2019).

28 von Elm E, Altman DG, Egger M, et al. Strengthening the reporting of observational studies in epidemiology (STROBE) statement: guidelines for reporting observational studies. *BMJ* 2007;335:806–8.

29 Miller, MD, Ferris DG. Measurement of subjective phenomena in primary care research: the visual analogue scale. *Fam Pract Res J* 1993;13(1):15–24.

30 Charlson ME, Pompei P, Ales KL, et al. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *J Chronic Dis* 1987;40:373–83.

31 Charlson ME, Charlson RE, Peterson JC, et al. The Charlson comorbidity index is adapted to predict costs of chronic disease in primary care patients. *J Clin Epidemiol* 2008;61:1234–40.

32 MacCallum RC, Widaman KF, Zhang S, et al. Sample size in factor analysis. *Psychol Methods* 1999;4:84–99.

33 Hooper D, Coughlan J, Mullen M. Structural equation modelling: guidelines for determining model fit structural equation modelling: guidelines for determining model fit. 2008;6(1):53–60.

34 Bland JM, Altman DG. Cronbach's alpha. *BMJ* 1997;314:572.

35 Dancey C, Reidy J. Statistics without maths for psychology: seventh edition. UK: Pearson Education Limited 2017;181–90.

36 StataCorp. Stata Statistical Software: Release 14. College Station, TX, 2015.

37 StataCorp. Stata 14 Base Reference Manual. College Station, TX: Stata Press, 2015.

38 Muthén & Muthén. Mplus Software version 8.4. Los Angeles, CA, 2017.

39 Muthén LK, Muthén BO. Mplus User's Guide: Eighth edition. Los Angeles, CA: Muthén & Muthén, 2017.

40 Nutbeam D. Health promotion glossary. *Health Promot Int* 1998;13(4):349–64.

41 Nutbeam D. Health literacy as a public health goal: a challenge for contemporary health education and communication strategies into the 21st century. *Health Promot Int*

2000;15(3):259–67.

42 Ministry of Health, Labour and Welfare. Comprehensive Survey of Living Conditions 2019. https://www.mhlw.go.jp/toukei/saikin/hw/k-tyosa/k-tyosa19/index.html (accessed 28 July 2020).

43 Medical Examiner's Office, Bureau of Social Welfare and Public Health, Tokyo Metropolitan Government. https://www.fukushihoken.metro.tokyo.lg.jp/kansatsu/kodokushitoukei/index.html

44 Ministry of Health, Labour and Welfare. Overview of Medical Service Regime in Japan. https://www.mhlw.go.jp/bunya/iryouhoken/iryouhoken01/dl/01_eng.pdf (accessed 22 Oct 2019).

45 Ikegami N, Yoo BK, Hashimoto H, et al. Japanese universal health coverage: evolution, achievements, and challenges. *Lancet* 2011;378:1106–15.

46 Maxwell M, Hibberd C, Aitchison P, et al. The patient centred assessment method for improving nurse-led biopsychosocial assessment of patients with long-term conditions: a feasibility RCT. *Health Services and Delivery Research* 2018;6(4).

47 Danaei G, Ding EL, Mozaffarian D, et al. The preventable causes of death in the United States: comparative risk assessment of dietary, lifestyle, and metabolic risk factors. *PLoS Med* 2009;6(4):e1000058.

48 Marmot M, Bell R. Fair society, healthy lives. *Public Health* 2012;126(1):S4–S10.

Figure 1. Distribution of total scores of PCAM. PCAM, Patient Centered Assessment Method.

Figure 2. Correlation between PCAM scores and complexity/burden level measured by VAS.

PCAM, Patient Centered Assessment Method; VAS, Visual Analog Scale.

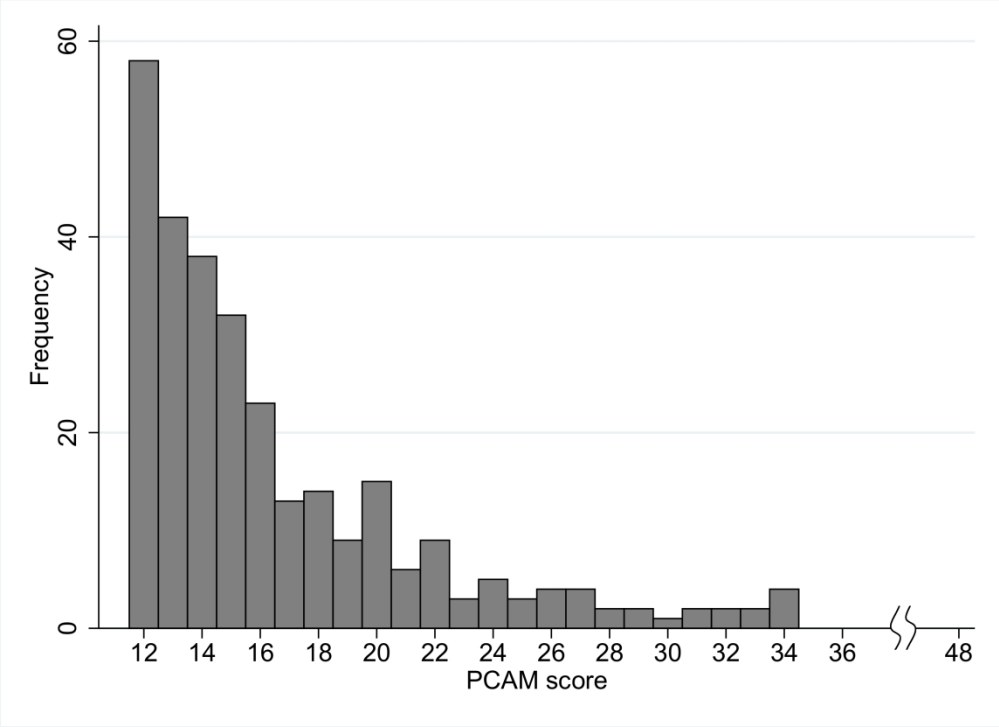
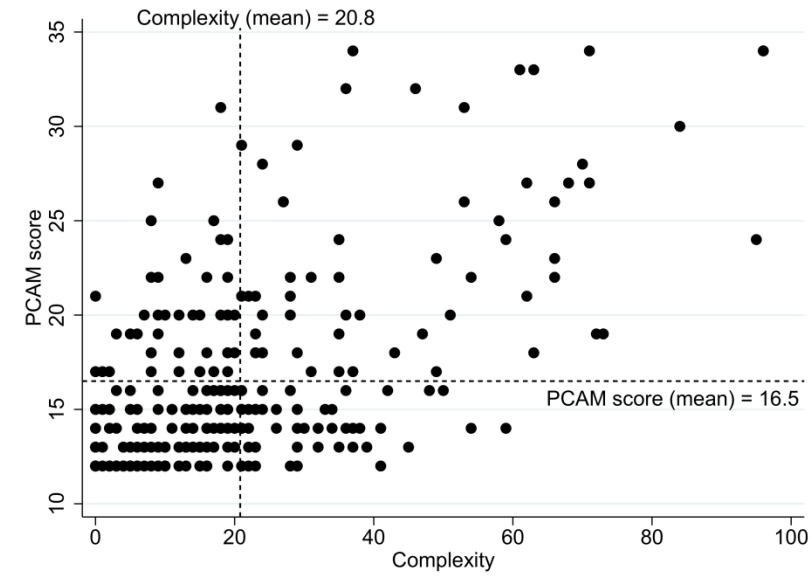


Figure 1. Distribution of total scores of PCAM. PCAM, Patient Centered Assessment Method.

139x101mm (600 x 600 DPI)



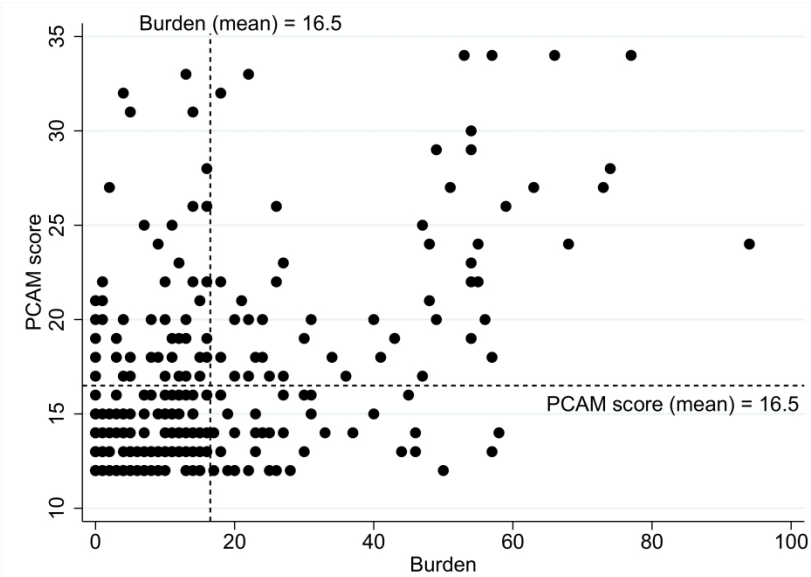


Figure 2. Correlation between PCAM scores and complexity/burden level measured by VAS. PCAM, Patient Centered Assessment Method; VAS, Visual Analog Scale.

139x203mm (600 x 600 DPI)

Supplementary File A

日本語版 Patient Centered Assessment Method (PCAM)

ID _____ 年 月 日

医師/看護師：

実施上の注意点：この評価シートをガイドとして使用し、あなたが各質問に答えやすいように、面談の間にあなた自身の言葉で患者に質問してください。この患者に関連した複雑性のレベルを反映させるように各項目で選択肢一つに丸をつけてください。面談の間か、もしくはその後に完成させてください。

身体の健康と心の安寧

1	患者の**身体の健康についてどのようなニーズ**があるかを考えた場合、更に**精査**が必要と思われる不確かな症状や問題（危険因子）があるか？		
不確かな問題は見出されない、あるいは問題はすでに吟味されている	軽度の漠然とした身体的症状あるいは問題がある；しかし日常生活に影響を及ぼさないか、患者の心配事ではない	日常生活に影響を及ぼす中等度から重度の症状あるいは問題がある	日常生活に重大な影響を及ぼす重度の症状あるいは問題がある
2	患者の**身体の健康**が**心の安寧**に影響しているか？		
懸念される問題は見出されない	心の安寧に軽度の影響を与えている（例：“うんざりする感じ”、“楽しみが減っている”）	心の安寧に中等度から重度の影響を与えており、日常生活の楽しみを妨げている	心の安寧に重度の影響を与えており、日常生活を妨げている
3	**身体の健康**や**心の安寧**に影響するような**生活習慣**（アルコール、薬、食事、運動）に伴う問題があるか?		
懸念される問題は見出されない	身体の健康や心の安寧に悪い影響を与える可能性がある軽度の問題を認める	身体の健康や心の安寧に中等度から重度の影響を与えており、日常生活の楽しみを妨げている	身体の健康や心の安寧に重度の影響を与えており、他者にも影響する可能性がある
4	患者の**心の安寧**について他に**何らかの懸念される問題**があるか? その深刻さや患者に与える影響をどのくらいと評価するか?		
懸念される問題は見出されない	軽度な問題ー日常機能を妨げない	中等度から重度の問題があり日常機能を妨げている	ほとんどの日常機能を妨げる重度の問題がある

社会的環境

1	**安全性、安定性**の点（家庭内暴力、安全でない家、隣人の嫌がらせを含む）から**居住環境**をどのように評価するか?		
一貫して安全で、支援的、安定している状態で、問題は見受けられない	安全で、安定しているがやや一貫性に欠ける	安全/安定しているか疑問がある	安全でなく、安定もしていない
2	**日常の活動**は患者の（心の）安寧にどう影響を与えているか？（現在失業中か予想される失業、仕事、介護、その他を含む）		
問題は見いだされないか、あるいは恩恵があると感じている	ある程度ありきたりの不満があるが、気がかりではない	時々、気分の落ち込みやストレスの一因となっている	心の安寧に重度の悪影響を与えている

3	**社会ネットワーク**（家族、仕事、友人）についてどのように評価するか?			
社会ネットワークに十分に参加している	社会ネットワークに不足なく参加している	ある程度、社会的に孤立し、参加が制限されている	孤独で社会的に孤立し、ほとんど参加していない	
4	**金銭面**（すべての必要な医療ケアを受ける余裕があることを含む）についてはどう評価するか？			
金銭的に安定し、十分な収入があり、問題は見いだされない	金銭的に安定しているが、収入にいくつかの問題がある	金銭的に不安定で、収入にいくつかの問題がある	金銭的に不安定で、収入は極わずかしかなく、問題に直面している	

健康リテラシーとコミュニケーション

1	自分の健康・安寧（症状、徴候、危険因子）と健康管理に必要なことを、患者は**今**、どの程度よく**理解しているか**?			
合理的によく理解していて、すでに健康管理をしているか、あるいはより良い管理をすることをいとわない	合理的によく理解しているがしかし、現時点ではアドバイスを受け入れられないと感じている	より良い管理を可能にするような理解を少ししかしていない	健康管理をするための重要なことについて理解していない	
2	患者はどのくらいヘルスケアの話し合いに**参加する**ことができるか？（言語の壁、聴覚欠如、失語症、アルコールや薬物問題、学習困難、集中力）			
妨げがなく、率直なコミュニケーションで、障壁は見出されない	わずかな障壁があるものの、不足のないコミュニケーションである	中等度の障壁があり、コミュニケーション上のいくらかの困難がある	重度な障壁を伴うコミュニケーション上の深刻な困難がある	

サービスコーディネーション

1	患者を支援するために必要な**他のサービス**はあるか?			
現時点では他のケア/サービスは必要としていない	他のケア/サービスはすでに受けており、不足はない	ケア/サービスを受けているが、十分ではない	ケア/サービスを受けておらず、受ける必要がある	
2	現在、患者に関わっているサービスは**良く調整されている**か？（あなたが今薦めている他のサービスとの調整も含む）			
すべての必要なケア/サービスがすで受けており、良好に調整されている	必要なケア/サービスがすでに受けており、不足なく調整がなされている	必要なケア/サービスはすでに受けているが、いくらかの調整に妨げがある	必要なケア/サービスが欠如していて、（かつ/あるいは）調整が断片的である	

通常のケア	経過観察	プラン作成	すぐに実施

どんな行動が必要か？	誰に協力を求めるべきか？	行動のための妨げは何か？	どんな行動をとるか？
備考：			

Supplementary File B

日本語版 Patient Centered Assessment Method(PCAM)
評価実施のためのユーザーガイド

＜身体の健康と心の安寧＞

項目１：身体の健康についてのニーズ

１.	患者の身体の健康についてどのようなニーズがあるかを考えた場合、更に精査が必要と思われる不確かな症状や問題（危険因子）があるか？		
不確かな問題は見出されない、あるいは問題はすでに吟味されている	軽度の漠然とした身体的症状あるいは問題がある；　しかし日常生活に影響を及ぼさないか、患者の心配事ではない	日常生活に影響を及ぼす中等度から重度の症状あるいは問題がある	日常生活に重大な影響を及ぼす重度の症状あるいは問題がある

この項目では、健康診断の際に行われた身体的な検査の結果として見出だされた危険因子（血圧、血糖値）を含めてください。さらに、患者が自発的に挙げた問題、また、自身に影響を及ぼしている健康問題があるか尋ねてください。患者はすでにケアを受けているかもしれませんが、症状が変化していたり、持続して日常生活に影響を与えているかもしれません。

尋ねたらよいと思われる質問項目サンプル：

・現時点でのあなたの健康状態について述べてください。

・身体の健康についてはいかがでしょうか。

・もし、診療所以外（非医療機関）で PCAM による評価が行われている場合、あなたは医者にかかる必要が最近ありましたか？それは何のためですか？

項目２：身体の健康が心の安寧に与える影響

２.	患者の身体の健康が心の安寧に影響しているか？		
懸念される問題は見出されない	心の安寧に軽度の影響を与えている（例：“うんざりする感じ”、“楽しみが減っている”）	心の安寧に中等度から重度の影響を与えており、日常生活の楽しみを妨げている	心の安寧に重度の影響を与えており、日常生活を妨げている

ここでは、項目１で挙げられた問題や、生活習慣上の問題による身体の症状を考慮することになるでしょう。

尋ねたらよいと思われる質問項目サンプル：

・私たちがあなたの身体の症状や状態について話し合っている時、どのように感じますか？

・Xという状態は現時点であなたにどのように影響していますか？
・あなたの心の状態はいかがですか？
・あなたはストレスを感じたり、うんざりする感じが少しでもありますか？

項目３：ライフスタイルが身体の健康と心の安寧に与える影響

３.	身体の健康や心の安寧に影響するような生活習慣（アルコール、薬、食事、運動）に伴う問題があるか？		
懸念される問題は見出されない	身体の健康や心の安寧に悪い影響を与える可能性がある軽度の問題を認める	身体の健康や心の安寧に中等度から重度の影響を与えており、日常生活の楽しみを妨げている	身体の健康や心の安寧に重度の影響を与えており、他者にも影響する可能性がある

この項目では、アルコール、薬物使用、食事、運動のような生活習慣による影響と、それらが身体と心の健康の両方にどのように影響を及ぼしているかを考慮しましょう。

尋ねたらよいと思われる質問項目サンプル：
・あなたはアルコールや薬物使用について、何か気になることがありますか？
・健康を維持するためにあなたがしていることはどんなことですか？運動？食事？

項目４：その他の心の安寧の問題

４.	患者の心の安寧について他に何らかの懸念される問題があるか？　その深刻さや患者に与える影響をどのくらいと評価するか？		
懸念される問題は見出されない	軽度な問題－日常機能を妨げない	中等度から重度の問題があり日常機能を妨げている	ほとんどの日常機能を妨げる重度の問題がある

ここでは、上記で考慮されたこと以外の心の安寧について考慮しましょう。ここでは統合失調症等のような厳しい状況に加えて、不安、うつ、自尊心、死別、虐待、人間関係、雇用問題が含まれるかもしれません。あなたは時間制限のある面談中に“パンドラの箱を開ける”ことを心配するかもしれません。このことは経験、訓練、サービスプランニングによってしばしば軽減することができます。（例：さらに案件を話し合うために、再度患者に来てもらえるようにすること）

時々、患者は希死念慮を表出するかもしれません。リスク評価を訓練することがこの問題に対処するのに役立つでしょう。こういう思いを訴える患者は、めったに差し迫った危険な状態であることはないでしょう。そして、会話がその危険を軽減することに役立つかもしれません。

尋ねたらよいと思われる質問項目サンプル：
・生活において、あなたの健康に影響を及ぼしているかもしれない、他のことはありませんか？
・個人的な人間関係が失われたり、変化したりしましたか？

・あなたは生活をどのくらいうまく管理できていると感じますか？

＜社会的環境＞

項目１：居住環境

１.	安全性、安定性の点（家庭内暴力、安全でない家、隣人の嫌がらせを含む）から居住環境をどのように評価するか？		
一貫して安全で、支援的、安定している状態で、問題は見受けられない	安全で、安定しているがやや一貫性に欠ける	安全/安定しているか疑問がある	安全でなく、安定もしていない

この質問項目では（患者と）話し合うには困難でやりがいがある領域になりますが、経験上、このツールを試しに使用した看護師は非常に有益であると見出しています。心の安寧についての話し合いを通して、問題が浮かび上がってくるかもしれません。患者が言ったことをそのまま受け売りで環境を評価することはできませんが、ここでは報告したことを記録することになるでしょう。この時点で、危険にさらされている患者はこの問題について打ち明けることはできないかもしれません。しかし、患者と普段通りに自然な態度で話し始めると、いずれ打ち明けてくれるかもしれません。

尋ねたらよいと思われる質問項目サンプル：

・お家ではいかがですか？

・お家やご近所は安全だと感じていますか？

・あなたは自分の住んでいるところについて満足と感じていますか？なぜそう感じますか？/感じないのはなぜですか？

項目２：日常の活動

２.	日常の活動は患者の（心の）安寧にどう影響を与えているか？（現在失業中か予想される失業、仕事、介護、その他を含む）		
問題は見いだされないか、あるいは恩恵があると感じている	ある程度ありきたりの不満があるが、気がかりではない	時々、気分の落ち込みやストレスの一因となっている	心の安寧に重度の悪影響を与えている

仕事のストレス、失業、責任のある介護はすべて安寧を貧しくする可能性があります。

尋ねたらよいと思われる質問項目サンプル：

・現在、日常の活動をいつも通りに送れていますか？それはなぜ？/なぜできないのですか？

・（もし、雇用されているなら）毎日仕事に行くことを楽しんでいますか？または仕事によってストレスが生じていますか？

・日常生活や（心の）安寧に影響を与えるような責任を抱えていますか？

項目３：社会ネットワーク

３.	社会ネットワーク（家族、仕事、友人）についてどのように評価するか？		
社会ネットワークに十分に参加している	社会ネットワークに不足なく参加している	ある程度、社会的に孤立し、参加が制限されている	孤独で社会的に孤立し、ほとんど参加していない

適切な社会ネットワークはうつ、不安、自殺を予防できます。

尋ねたらよいと思われる質問項目サンプル：

・もしあなたが問題や気分の落ち込みを感じたら、だれに話せますか？

・あなたは友達や家族から良く支えられていると感じますか？なぜそう感じますか？/感じないのはなぜですか？

・他にどのような支えが必要ですか？

項目４：金銭的な収入

４.	金銭面（すべての必要な医療ケアを受ける余裕があることを含む）についてはどう評価するか？		
金銭的に安定し、十分な収入があり、問題は見いだされない	金銭的に安定しているが、収入にいくつかの問題がある	金銭的に不安定で、収入にいくつかの問題がある	金銭的に不安定で、収入は極わずかしかなく、問題に直面している

借金や金銭面についての心配は心の安寧にとって、重大な危険因子となります。初めはこのことを話すのは難しい話題になり得ますが、現在の経済状況や増大する収入格差という文脈のなかで、“多くの人々は今、職を失うことや、収入の範囲内でやっていけるかを心配していますが、あなたはどうですか？”というように質問を一般化して始めることが有用かもしれません。

追加して尋ねたらよいと思われる質問項目サンプル：

・あなたは金銭的にゆとりがあると感じていますか？

・あなたは健康管理に関連した費用を支払えると感じていますか？

＜健康リテラシーとコミュニケーション＞

項目１：健康リテラシー

１.	自分の健康・安寧（症状、徴候、危険因子）と健康管理に必要なことを、患者は今、どの程度よく理解しているか？		
合理的によく理解していて、すでに健康管理をしているか、あるいはより良い管理をすることをいとわない。	合理的によく理解しているがしかし、現時点ではアドバイスを受け入れられないと感じている	より良い管理を可能にするような理解を少ししかしていない。	健康管理をするための重要なことについて理解していない

この項目は援助を受ける際の障害を明らかにすることを意図しています。これを文書化しておくと、今後のコンサルテーションに対しての情報提供や、さらに患者と話し合う機会を持つための理由として役に立つかもしれません。患者は健康の一つの側面は理解していますが、他の側面は理解していないかもしれません（例えば、喫煙量を減らす必要性は理解しているかもしれませんが、自宅での怒りが健康問題だとは理解していないかもしれません）。ここでのあなたの記録は全体像を反映しているべきです。もし患者に前向きに進み始めるための理解が十分にあれば、緑か黄色につけるとよいでしょう。

尋ねたらよいと思われる質問項目サンプル：
・あなたは医療者にまだ質問があると感じていますか？他に知りたいことは何でしょうか？
・あなたは健康、診断、問題について必要な情報をすべて持っていると感じますか？
・あなたの生活を、医療者が提案したように変えるという準備ができていると感じていますか？（食事、運動、健康管理）

項目２：話し合いへの参加

２.	患者はどのくらいヘルスケアの話し合いに参加することができるか？（言語の壁、聴覚欠如、失語症、アルコールや薬物問題、学習困難、集中力）		
妨げがなく、率直なコミュニケーションで、障壁は見出されない	わずかな障壁があるものの、不足のないコミュニケーションである	中等度の障壁があり、ミュニケーション上のいくらかの困難がある	重度な障壁を伴うコミュニケーション上の深刻な困難がある

上記のように、この項目では必要とされる治療よりも、話し合いに参加するための障壁を強調することを意図しています。このことは、患者にもう一度戻ってきてもらって、通訳者のような援助を提供できたり、学習困難者を援助するための資源を紹介できるかもしれません。

尋ねたらよいと思われる質問項目サンプル：
・医療者はあなたが理解しやすい方法で彼らの考えをあなたに説明をしますか？
・どうしたら医療者により理解してもらいやすくなりますか？

＜サービスコーディネーション＞

項目１：その他のサービス

１.	患者を支援するために必要な他のサービスはあるか？		
現時点では他のケア/サービスは必要としていない	他のケア/サービスはすでに受けており、不足はない	ケア/サービスを受けているが、十分ではない	ケア/サービスを受けておらず、受ける必要がある

この項目は、あなたが薦める（他のサービスへの）紹介と、あなたの薦めに対して従うことへの患者の関心と意思を評価するために使ってください。たくさんの紹介があるかもしれません。その中のいくつかは患者は受け入れたいと思っているでしょうし、その他は、現時点では解決しようとしていないか

もしれません。この紹介というものは、行動の必要性についてのあなたの意見を反映しているものです。実際に行われた紹介はあなたの意見と患者の希望を反映しています。患者は現時点ではこの紹介は適切でないと判断するかもしれません。

尋ねたらよいと思われる質問項目サンプル：

・あなたは医療者やケアに関わっているその他の人々から、現時点で必要なすべてのケアを受けていると感じていますか？

・あなたは私が提案した薦めについてどのくらい満足していますか？

・あなたが経過を見たい、解決したい最重要課題のように感じているものは何でしょう？

項目２：サービスコーディネーション

２.	現在、患者に関わっているサービスは良く調整されているか？（あなたが今薦めている他のサービスとの調整も含む）		
すべての必要なケア/サービスをすでに受けており、良好に調整されている	必要なケア/サービスをすでに受けており、不足なく調整がなされている	必要なケア/サービスはすでに受けているが、調整にいくらかの妨げがある	必要なケア/サービスが欠如していて、（かつ/あるいは）調整が断片的である

この項目は、すべてのケアとサービス（あなたが評価する前にすでに受けていることも含めて）がどの程度うまく調整できているかを示すために使用してください。もし、サービスとケアが断片的で、患者が利用することが難しい場合は、例え患者がやると決めて、良く参加していても、やり遂げることができないかもしれません。

尋ねたらよいと思われる質問項目サンプル：

・あなたが利用しているすべてのサービスはどのくらいうまく組み立てられたものですか？

・あなたが利用しているサービスは簡単にアクセスすることができて、あなたが利用できる時に提供されていますか？

・サービスやケアを受ける準備や、そこにアクセスすることが困難で、それら（サービスやケア）を受けられないことがありますか？

このセクションは、あなたが薦めている行動、誰に紹介するか、妨げになるもの、そして、患者が何をしたいかという意思表示を要約するために使いましょう。

どんな行動が必要か？	誰に協力を求めるべきか？	行動のための妨げは何か？	どんな行動をとるか？
備考：			

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1,3
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	5,6
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	3,6,7
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6-8
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	7
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8,9
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	6-8
Bias	9	Describe any efforts to address potential sources of bias	6,7
Study size	10	Explain how the study size was arrived at	9,10
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	10
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	10
		(*b*) Describe any methods used to examine subgroups and interactions	n/a
		(*c*) Explain how missing data were addressed	12
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	n/a
		(*e*) Describe any sensitivity analyses	n/a
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	11,12
		(b) Give reasons for non-participation at each stage	12
		(c) Consider use of a flow diagram	n/a
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	12-14
		(b) Indicate number of participants with missing data for each variable of interest	n/a
Outcome data	15*	Report numbers of outcome events or summary measures	14-16
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	n/a
		(*b*) Report category boundaries when continuous variables were categorized	n/a
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	n/a
Discussion			
Key results	18	Summarise key results with reference to study objectives	15-16
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	19
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	16-19
Generalisability	21	Discuss the generalisability (external validity) of the study results	19
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	20

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Development and validation of a Japanese version of the Patient Centered Assessment Method and its user guide: a cross-sectional study

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2020-037282.R2
Article Type:	Original research
Date Submitted by the Author:	08-Nov-2020
Complete List of Authors:	Mutai, Rieko; Jikei University School of Medicine, Division of Clinical Epidemiology, Research Center for Medical Sciences; Jikei University School of Nursing, Adult nursing Sugiyama, Yoshifumi; Jikei University School of Medicine, Division of Clinical Epidemiology, Research Center for Medical Sciences Yoshida, Shuhei; Hiroshima University, Department of Community-Based Medical System; Jikei University School of Medicine, Division of Clinical Epidemiology, Research Center for Medical Sciences Horiguchi, Ryoko; Jikei University School of Medicine, Division of Clinical Epidemiology, Research Center for Medical Sciences Watanabe, Takamasa; Kita-adachi Seikyo Clinic, family medicine; Jikei University School of Medicine, Division of Clinical Epidemiology, Research Center for Medical Sciences Kaneko, Makoto; Hamamatsu University School of Medicine, Department of Family and Community Medicine; Jikei University School of Medicine, Division of Clinical Epidemiology, Research Center for Medical Sciences Tominaga, Tomokazu; Koganei Family Clinic; Jikei University School of Medicine, Division of Clinical Epidemiology, Research Center for Medical Sciences Hayashi, Daichi; State University of New York at Stony Brook, Department of Radiology, Stony Brook Medicine Matsushima, Masato; Jikei University School of Medicine, Division of Clinical Epidemiology, Research Center for Medical Sciences
Primary Subject Heading:	General practice / Family practice
Secondary Subject Heading:	General practice / Family practice, Epidemiology
Keywords:	PRIMARY CARE, EPIDEMIOLOGY, GENERAL MEDICINE (see Internal Medicine)

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

Development and validation of a Japanese version of the Patient Centered Assessment Method and its user guide: a cross-sectional study

Rieko Mutai[1, 2], Yoshifumi Sugiyama[1], Shuhei Yoshida[1, 3, 4, 5], Ryoko Horiguchi[1], Takamasa Watanabe[1, 3, 4], Makoto Kaneko[1, 3, 6, 7], Tomokazu Tominaga[1, 3, 6, 8], Daichi Hayashi[9], Masato Matsushima[1]

[1] Division of Clinical Epidemiology, Research Center for Medical Sciences, The Jikei University School of Medicine, Tokyo, Japan

[2] Department of Adult Nursing, The Jikei University School of Nursing, Chofu, Japan

[3] Centre for Family Medicine Development, Japanese Health and Welfare Co-operative Federation, Tokyo, Japan

[4] Kitaadachi-seikyo Clinic, Japanese Health and Welfare Co-operative Federation, Tokyo, Japan

[5] Department of Community-Based Medical System, Graduate School of Biomedical and Health Sciences, Hiroshima University, Hiroshima, Japan

[6] Musashikoganei Clinic, Japanese Health and Welfare Co-operative Federation, Koganei, Japan

[7] Department of Family and Community Medicine, Hamamatsu University School of Medicine, Hamamatsu, Japan

[8] Koganei Family Clinic, Koganei, Japan

[9] Department of Radiology, Stony Brook Medicine, Stony Brook, New York, USA

Corresponding author: Masato Matsushima

Division of Clinical Epidemiology, Research Center for Medical Sciences

The Jikei University School of Medicine

3-25-8 Nishi-Shimbashi, Minato-ku, Tokyo 105-8461, Japan

Tel: +81-3-3433-1111 (ext. 2398); Email: masato@jikei.ac.jp

Word count: 3906

ABSTRACT

Objectives The primary objective of this study was to develop the Japanese version of the Patient Centered Assessment Method (PCAM) and its user guide. The secondary objective was to examine the validity and reliability in the primary care setting.

Design Cross-sectional study.

Setting Three family physician teaching clinics located in urban residential areas in Tokyo, Japan.

Participants Patients who were aged 20 years or older, and who had an appointment with physicians at the three participating clinics.

Main outcome measures Patient complexity measured by PCAM and complexity/burden level measured by a Visual Analog Scale (VAS).

Results Although confirmatory factor analysis using a model described in a previous study revealed that the indices did not meet the criteria for good fit, exploratory factor analysis revealed a new three-factor structure of "Personal well-being," "Social interaction," and "Needs for care/service." Cronbach's alpha of PCAM was 0.86. Spearman's rank correlation coefficients between PCAM scores and VAS scores were 0.51 for complexity ($p<0.001$) and 0.41 for burden ($p<0.001$). There were 42 patients (14.3% of total patients) with PCAM scores greater than its mean of 16.5 but with complexity VAS scores less than its mean of 20.8.

Conclusions The Japanese version of PCAM and its user guide were developed through Japanese translation and cultural adaptation by cognitive debriefing. PCAM is a valid and reliable tool to assess patient complexity in the primary care settings in Japan. Additionally, although the correlation between total PCAM scores and complexity/burden as assessed by VAS was moderate, PCAM can more precisely identify patient complexity than skilled physician's intuition.

Keywords

patient complexity, the Patient Centered Assessment Method, translation, cultural adaptation, validity, reliability

Strengths and limitations of this study

- This is the first study to develop a Japanese version of the Patient Centered Assessment Method.
- In addition to the scale itself, we also developed a Japanese user guide through forward translation, back translation, and cognitive debriefing for cultural adaptation.
- The criterion validity was somewhat limited because we substituted visual analog scales for the external criteria.
- Generalizability may be limited given that only three clinics in urban areas participated .

INTRODUCTION

Social and economic conditions are associated with human health and have been termed social determinants of health (SDH).[1] Developed countries are now increasingly facing many obstacles caused by changes in the population pyramid, declining birthrates, and aging populations.[2] These demographic shifts are leading to a growing number of people with diverse and complex backgrounds, such as multimorbidity,[3-5] neuropsychiatric diseases including dementia[6,7] and depression,[8-10] less involvement in social networks,[11,12] and living alone.[13] Therefore, the role of primary care providers in addressing these patients' biopsychosocial complexities is becoming more important.

INTERMED[14-16] is an instrument that was developed to assess patient complexity in secondary care settings and the validity and reliability of the Japanese version has been verified.[17] Based on INTERMED, the Minnesota Complexity Assessment Method (MCAM)[18] was developed for use in the primary care settings, which led to an advanced version of MCAM, called the Minnesota Edinburgh Complexity Assessment Method (MECAM),[19] for the assessment of patients' biopsychosocial needs.

The Patient Centered Assessment Method (PCAM)[20] is an improved version of MECAM that can be applied to long-term conditions such as chronic obstructive pulmonary disease, diabetes mellitus, and coronary heart disease. The PCAM, a practical tool for identifying and assessing biopsychosocial problems, enables healthcare professionals to prioritize patients' needs in accordance with their severity and level of urgency.[20] The PCAM comprises four categories: "Health and well-being," "Social environment," "Health literacy and communication," and "Service coordination."[21] In previous studies, we assessed and confirmed the validity and reliability of the original version of PCAM in the initial phase of the secondary care setting in Japan and identified a correlation between total PCAM scores and length of hospital stay[22]/degree of burden on medical staff.[23]

As stated above, the PCAM allows medical providers to assess patients' needs from

biopsychosocial perspectives and to make referrals to a broader range of services.[20] In Japan, assessing patient complexity and acting on that basis has recently drawn considerable attention. One example is social prescribing, which has the potential to improve patients' health outcomes by linking them to appropriate services.[24] Additionally, the PCAM promotes sharing of information, which enables seamless interventions by physicians, nurses and other health care professionals. For example, in Japan, establishment of a care delivery system by multidisciplinary collaboration is encouraged, the aim being to facilitate provision of comprehensive and continuous care to patients and their families.[25] The PCAM is an indispensable tool for interprofessional information sharing. However, until now no Japanese equivalent for identifying and evaluating patient complexity has been available. A Japanese version of PCAM would be useful for healthcare professionals who are not proficient in English in that it would encourage and empower them to consider various biopsychosocial perspectives. The primary objective of this study was to develop a Japanese version of PCAM and its user guide. The secondary objective was to examine the validity and reliability in the primary care setting in Japan.

METHODS

This study consisted of two phases. In the first phase, the Japanese version of PCAM and its user guide were developed. In the second phase, the validity and reliability of the Japanese version of PCAM were evaluated in the primary care setting. In this study, we examined structural and criterion validity and internal consistency as reliability.

First phase: Development of the Japanese version of PCAM and its user guide

PCAM and its user guide were translated into and culturally adapted to Japanese with the original author's permission in accordance with the guidelines of the World Health Organization and International Society Pharmacoeconomics and Outcomes Research Task Force for Translation.[26,27] First, the primary investigator (RM), who was a native speaker of Japanese,

translated the original PCAM and its user guide into Japanese, and four researchers (RM, MM, SY, HW) discussed cultural adaptation to Japanese and completed the provisional versions. Next, a bilingual medical doctor (DH), who was not familiar with the original PCAM and its user guide, back-translated the provisional versions into English. Then, discrepancies between the original and back-translated English version were reviewed and revised by the original authors and three of the authors of this study (RM, MM, SY). Thus, we completed the prototype versions. Next, cognitive debriefing on the prototype versions was conducted in a small group to check alternative wording and to confirm the understandability, interpretation, and cultural relevance of the translation. Five Japanese physicians were recruited from primary care clinics in Tokyo, Japan by means of snowball sampling considering age, sex, and years of experience, and were interviewed to check and confirm each of the points described above.

Second phase: Evaluation of validity and reliability

Study design and setting

This was a cross-sectional study reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement.[28] This study was conducted at three family physician teaching clinics located in urban residential areas in Tokyo, Japan that were responsible for primary care with group practice: Kitaadachi-seikyo Clinic, Seikyo-ukima Clinic, and Musashikoganei Clinic affiliated with Japanese Health and Welfare Co-operative Federation.

Patient Participants

Patients who were aged 20 years or older, and who had an appointment with physicians at the three participating clinics were consecutively included. Exclusion criteria were patients for a general check-up, patients who had difficulty communicating in Japanese, patients who were too sick to complete the questionnaire, or patients who declined to participate in this study.

Data collection

Data were collected by five physicians: two at Kitaadachi-seikyo Clinic, one at Seikyo-ukima Clinic, and two at Musashikoganei Clinic, Japanese Health and Welfare Co-operative Federation. The period for data collection was between January 5th, 2018 and July 25th, 2018 in consideration of the physicians' and the principal investigator's schedule: five days at Kitaadachi-seikyo Clinic, 15 days at Seikyo-ukima Clinic, and 12 days at Musashikoganei Clinic. In advance of the data collection, the principal investigator explained the Japanese version of the PCAM to the five physicians using the user guide to standardize the criteria of evaluation. Patients were asked to complete a self-administered questionnaire on demographic characteristics while waiting for a consultation at the clinic; furthermore, physicians evaluated the degree of complexity and burden using a Visual Analog Scale (VAS).[29] During or after a consultation, physicians used the Japanese version of the PCAM user guide and completed a PCAM form.

Outcome Measures

PCAM

PCAM consists of twelve items across four categories[21]: "Health and well-being" (four items: "Physical health needs," "Physical health impacting mental well-being," "Lifestyle impacting mental well-being," and "Other mental well-being"), "Social environment" (four items: "Home environment," "Daily activities," "Social network," and "Financial resources"), "Health literacy and communication" (two items: "Health literacy" and "Engagement in discussion"), and "Service coordination" (two items: "Other services" and "Service coordination"). Each item is scored from 1 to 4 points, with total scores ranging from 12 to 48 points. The higher the score, the more complex the patient.

Complexity/burden level measured by VAS

Physicians possibly misperceive the psychological "burden" of caring for a patient with complex needs as intuitive patient "complexity." Therefore, patient complexity and psychological burden were measured separately, enabling the physicians to be aware of the difference between them and to evaluate them precisely. Measurements were performed by using a VAS. The VAS for "complexity" comprised a 10-cm-long horizontal line with a starting point of "not complex" (0 point) and an ending point of "the most complex" (100 points). The VAS for "burden" similarly comprised a 10-cm-long horizontal line with a starting point of "no burden" (0 point) and an ending point of "the heaviest burden" (100 points). A person who was blinded to the patients' information measured the length marked on the VASs.

There are currently no external criteria for examining criterion validity for which the validity and reliability have been established in the primary care setting. Therefore, a VAS, which is a practical tool, was substituted for external criteria.

Patient characteristics

Demographic characteristics including sex, age, marital status, household composition, household size, home ownership, years of residence, employment status, and educational background were obtained from a self-administered questionnaire, whereas main diseases, Charlson Comorbidity Index (CCI),[30,31] and copayment (the proportion of individual payment of medical expense depending on age and income) were obtained from medical records. Physicians chose one main disease from all of a patient's diseases for that patient's regular clinical visits.

Sample size calculation

The recommended subjects-to-variables ratio is from 3:1 to 20:1 when conducting exploratory factor analysis.[32] Because a larger sample size has been reported to provide more precise results in factor analysis, the ratio of 20:1 was employed in this study. Therefore, because

PCAM includes 12 items, the sample size was determined to be 300 in consideration of at most 60 participants having missing values.

Statistical analysis

Confirmatory factor analysis with the robust maximum likelihood estimation was conducted to assess structural validity, assuming a two-factor model of medicine- and patient-oriented complexity, which was derived from our previous study.[21] The model fit was judged to be good if the comparative fit index (CFI) was ≥0.90, standardized root mean residual (SRMR) was ≤0.08, and root mean squared error of approximation (RMSEA) was ≤0.08.[33]

When the model fit was insufficient, exploratory factor analysis with the robust maximum likelihood estimation and CF-Equamax rotation was performed. Parallel analysis was conducted to determine the number of common factors and factor loading ≥0.4 was adopted to determine which items to include.

Internal consistency was considered adequate if Cronbach's alpha was between 0.70 and 0.95.[34]

Spearman's rank correlation coefficient between total PCAM scores and complexity/burden as measured by VAS examined criterion validity and how closely the scale correlated with the physicians' general impressions.[35]

All statistical analyses were performed using STATA/SE version 14.0[36,37] and Mplus version 8.4.[38,39] P-values <0.05 were considered statistically significant.

Ethical considerations

The research protocol for the first phase was approved by the Ethics Committee of The Jikei University School of Medicine (ethics number: 28-365 [8608]). The research protocol for the second phase was approved by the Ethics Committee of The Jikei University School of Medicine (ethics number: 29-229 [8845]) and Tokyo Hokuto Health Co-operative (ethics number:

89). The principal investigator (RM), who was not associated with any of the three family physician teaching clinics, fully explained the content of this study to all subjects; they then provided written informed consent to participate.

Patient and public involvement

This study was conducted without patient or the public involvement: they had no role in the study design; the data analysis, and interpretation; the manuscript preparation and reviewing; or the decision to submit the manuscript.

RESULTS

Japanese translation and cultural adaptation by cognitive debriefing

After the Japanese forward and backward translation process, cultural adaptation was conducted by interviewing one female and four male physicians between April 27th and May 18th, 2017. These five physicians' median (interquartile range, IQR) age and years of experiences as a primary care physician were 37 (34–38) and 12 (10–14) years, respectively. The median interview time (IQR) was 51 (17–55) minutes. The physicians pointed out 34 parts that required improvement; modification of these parts was subsequently discussed by the researchers. For example, the wording of the sample questions to patients in the user guide was changed from a literary to a colloquial style to make them easier to understand. Terms with the same pronunciation but different Chinese characters with different meanings were changed to avoid confusion. Twelve of the 34 modified parts were back-translated to minimize possible loss of the original meaning caused by the modification. Three were back-translated into exactly the same as the original English text; four in the PCAM and five in the user guide were confirmed and accepted by the original authors. Finally, the Japanese version of PCAM (online supplementary file A) and its user guide (online supplementary file B) were developed.

Evaluation of validity and reliability

A total of 298 eligible patients were recruited: 100 at Kitaadachi-seikyo Clinic, 101 at Seikyo-ukima Clinic, and 97 at Musashikoganei Clinic. Physicians missed out the entire PCAM in four patients and part of it in one patient, which led to a total of 293 patients included in the final analysis. Patient characteristics and main diseases are shown in Table 1 and Table 2.

Table 1. Patient characteristics

Age, mean (SD), years	72.4 (11.4)
Women, n (%)	164 (56.0)
Married, n (%)	178 (60.8)
Household composition, n (%)	
Single	70 (23.9)
Married couple	92 (31.4)
Other	131 (44.7)
Living arrangements, n (%)	
Living alone	70 (23.9)
Cohabiting	223 (76.1)
Home ownership, n (%)	
Owned	177 (60.4)
Rented	116 (39.6)
Years of residence, mean (SD), years	28.4 (17.4)
Employment status, n (%)	
Full-time employment	45 (15.4)
Part-time employment	28 (9.6)
Unemployment/Homemaker	166/36 (56.7/12.3)
Other	18 (6.1)
Academic background, n (%)	
Junior high school	85 (29.0)
High school	107 (36.5)
Junior college/Vocational school	51 (17.4)
University	44 (15.0)

Graduate school	6 (2.0)
Insurance copayment, n (%)	
0%	27 (9.2)
10%	134 (45.7)
20%	32 (10.9)
30%	100 (34.1)
CCI, mean (SD)	0.88 (1.4)

SD, standard deviation; CCI, Charlson Comorbidity Index.

Table 2. Main diseases diagnosed among patients

Classification of main diseases, n (%)	
Infectious and parasitic diseases	1 (0.3)
Neoplasms	11 (3.8)
Diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism	4 (1.4)
Endocrine, nutritional and metabolic diseases	
Total	73 (24.9)
Diabetes mellitus	49
Dyslipidemia	18
Mental and behavioral disorders	
Total	15 (5.1)
Vascular and unspecified dementia	10
Sleep-wake disorders	4 (1.4)
Diseases of the nervous system	8 (2.7)
Diseases of the circulatory system	
Total	137 (46.8)
Hypertension	111
Heart failure	20
Diseases of the respiratory system	
Total	11 (3.8)
COPD	6
Asthma	4
Diseases of the digestive system	

Total	12 (4.1)
GERD	6
IBS	1
Diseases of the skin and subcutaneous tissue	4 (1.4)
Diseases of the musculoskeletal system and connective tissue	
Total	10 (3.4)
Osteoporosis	7
Diseases of the genitourinary system	2 (0.7)
Injury, poisoning and certain other consequences of external causes	1 (0.3)
Total	293 (100)

COPD, chronic obstructive pulmonary disease; GERD, gasoesophagial reflux disease; IBS, irritable bowel syndrome.

The mean (standard deviation, SD) PCAM score was 16.5 (5.1) and the median (IQR) score was 15 (13–18). As shown in Figure 1, the distribution of total PCAM scores was skewed to the right with a floor effect.

Confirmatory and exploratory factor analysis

Confirmatory factor analysis using the model described in our previous study revealed the following indices for model fit: CFI=0.663, SRMR=0.104, and RMSEA=0.134.

Because the indices did not meet the criteria of good fit, exploratory factor analysis was performed. Parallel analysis suggested a maximum of six common factors. However, because the four- to six-factor models included a common factor that comprised one item, a three-factor model was employed. The items "Physical health needs," "Physical health impacting mental well-being," "Other mental well-being concerns," and "Daily activities," which focus on physical and mental well-being, contributed to the first factor, termed "Personal well-being." The items "Social network," "Health literacy," and "Engagement in discussion," which focus mainly on interaction with social networks and health care professionals, contributed to the second factor, termed

"Social interaction." The items "Home environment," "Other services," and "Service coordination," which focus on patients' needs arising in the home environment and satisfied with social services, contributed to the third factor, termed "Needs for care/service."

However, the two items "Lifestyle impacting mental well-being" and "Financial resources" were not included due to a factor loading less than 0.4 (Table 3).

Table 3. Exploratory factor analysis of the Japanese version of the Patient Centered Assessment Method (PCAM)

	First factor	Second factor	Third factor
Health and well-being			
Physical health needs	0.527	0.165	0.017
Physical health impacting mental well-being	0.622	0.009	0.114
Lifestyle impacting mental well-being	0.099	0.144	0.083
Other mental well-being concerns	0.667	–0.022	0.094
Social environment			
Home environment	0.327	0.111	0.433
Daily activities	0.659	0.010	0.084
Social network	0.369	0.426	0.094
Financial resources	0.307	0.120	0.236
Health literacy and communication			
Health literacy	0.063	0.862	0.015
Engagement in discussion	–0.141	0.806	0.099
Service coordination			
Other services	0.020	0.056	0.915
Service coordination	0.014	0.086	0.885

Cronbach's alpha of PCAM was 0.86, and that of the three factors: "Personal well-being," "Social interaction," and "Needs for care/service" were 0.77, 0.78 and 0.89, respectively.

The correlation between PCAM and VAS (complexity and burden) is shown in Figure 2. Spearman's rank correlation coefficients between PCAM scores and VAS were 0.51 for

complexity (p<0.001) and 0.41 for burden (p<0.001). There were 42 patients (14.3% of total patients) with PCAM scores more than the mean score of 16.5 but with complexity scores less than the mean score of 20.8. Moreover, Spearman's rank correlation coefficient between complexity and burden was 0.77.

DISCUSSION

In this study, a Japanese version of the PCAM and its user guide were developed through a process of translation, back-translation, and cognitive debriefing. Then, the structural validity of the Japanese version of the PCAM was assessed through exploratory factor analysis, which revealed the three new factors of "Personal well-being," "Social interaction," and "Needs for care/service," although confirmatory factor analysis using the model described in our previous study showed the model fit to be poor. Cronbach's alpha of PCAM, "Personal well-being," "Social interaction," and "Needs for care/service" were all high. Additionally, the total PCAM score was moderately correlated with complexity and burden as assessed by VAS, indicating that criterion validity was established to some extent.

This study showed a three-factor structure that differed from that of our previous study, this difference presumably being attributable to differences between the clinical settings. Our previous study was conducted in the secondary care setting and the participants were inpatients of an acute hospital,[21] whereas the current study was in the primary care setting. For example, one difference was that the mean (SD) CCI score was 0.9 (1.4) in the present study, which was lower than that of 2.0 (2.2) in our previous study[21] with higher biomedical complexity. Furthermore, the mean (SD) age of patients in our previous study, 77.4 (11.9) years, was higher than that of the current study. In terms of factor structure, patients with greater physical health-related needs are likely to have greater needs for care and services, which could result in hospitalization in the secondary care setting. Thus, the "Medicine-oriented" factor in the previous study includes both the item "Physical health needs" and items that are included in the "Needs

for care/service" factor in the present study. Conversely, in the primary setting, such needs for care and services may not be identified because the patients have fewer physical health-related needs. Therefore, the item "Physical health needs" was not included in the same factor as items that are included in the "Needs for care/service" factor. Rather, the item "Physical health needs" was treated as a component of physical well-being and therefore included in the "Personal well-being" factor in the present study. Additionally, the "Patient-oriented" factor in the previous study includes the items "Physical health impacting mental well-being," "Other mental well-being," "Daily activities," "Social network," "Health literacy," and "Engagement in discussion," whereas these items were divided into two factors, "Personal well-being" and "Social interaction," in the present study. This is probably because primary care physicians take care of people in the community and focus more on assessing their patients from social perspectives. In contrast, social aspects of hospitalized patients are less important in the secondary setting, where social aspects are combined with biopsychological factors in the "Patient-oriented" factor in the previous study.

The extraction of "Social interaction" and "Needs for care/service" from "Personal well-being", which is mainly related to physical and psychological well-being, was of particular importance. "Social interaction" includes items regarding "Social network" and "Health literacy and communication." Health literacy is the cognitive and social ability to obtain, understand, assess, and use information that is essential for good health,[40] and consists of basic/functional, communicative/interactive, and critical literacy;[41] in particular, communicative/interactive literacy is necessary for active participation in social networks. Therefore, it was consistent and reasonable to extract issues related to both social network and health literacy/communication as a common factor. On the other hand, "Needs for care/service" includes items regarding "Home environment" and "Service coordination." The PCAM evaluates "Home environment" in terms of safety and stability.[21] In Japan, the population is rapidly aging, causing many related problems. For example, older adults are obliged to take care of their old spouses. The numbers of households with a single older adult and solitary deaths are increasing.[42,43] These problems

that are attributable to an unsafe or unstable home environment, which may be solvable with nursing care and social welfare interventions, are assumed to be strongly associated with "Service coordination."

However, two items, "Lifestyle impacting mental well-being" and "Financial resources", had insufficient factor loading less than 0.4 and were not included in the three factors. The exclusion of the former item presumably resulted from the fact that 60 percent of all patients had lifestyle diseases such as diabetes mellitus, dyslipidemia, and hypertension, which were generally well-controlled at the participating clinics; therefore, the impact of a patient's lifestyle on these diseases might have been underestimated. Additionally, severely alcoholic patients and drug abusers were possibly referred to specialized facilities, which could also have resulted in underestimation of this item. The exclusion of the latter item presumably resulted from the fact that copayment of medical expenses is at most 30% under the Japanese universal health insurance coverage system and 0% under the welfare system;[44,45] hence, few patients were likely troubled with financial problems due to healthcare. Moreover, previous research revealed that financial topics are taboo and inappropriate for discussion with healthcare providers;[46] therefore, this question might not have been answered accurately. In the Japanese version of PCAM, these items were not intentionally excluded in consideration of the fact that the overall Cronbach's alpha was 0.86, which indicates a high internal consistency without exclusion of these items. The fact that lifestyle-related and economic problems negatively influence physical and psychological conditions is established.[47,48] These two items should therefore not be excluded at this stage; further cautious and prudent research is required to determine how best to accurately score and include them.

This study also showed a floor effect in the distribution of PCAM scores, whereas our previous study did not. The large number of patients, in fact, had low patient complexity; however, physicians might not be able to distinguish detailed factors related to subtle patient complexity due to limited consultation time.

The correlation between total PCAM scores and complexity/burden as assessed by the VAS was found to be moderate. Although complexity and burden were separately assessed to prevent physicians from confusing these two variables, Spearman's rank correlation coefficient between complexity and burden was high. This indicates that physicians do not regard complexity as an objective index, but rather handle it as subjective feeling, or burden. Furthermore, patients that physicians regarded as being not complex were found to have somewhat high PCAM scores, even though physicians working at family physician teaching clinics are generally well trained to see patients from biopsychosocial perspectives. Accordingly, PCAM can more objectively and precisely identify patient complexity than skilled physician's intuition.

There are some limitations in this study. First, only three clinics in urban areas in Tokyo were included as study settings, which could have limited the generalizability of our findings. Second, inter-rater variability of PCAM scores was not evaluated. Patients were not assessed by two physicians because they usually visited the same primary care physician. We considered it would be unethical to force them to see an unfamiliar physician and undergo another PCAM assessment due to their temporal, economic, and psychological burden. Moreover, some of the clinics had only one physician on service at a time. As a result, PCAM scores might have been over- or under-estimated. However, a Japanese version of PCAM is necessary for healthcare providers to address biopsychosocial problems without language barriers, which outweighs the above study limitations.

CONCLUSION

The Japanese version of PCAM and its user guide were developed Japanese translation and cultural adaptation by cognitive debriefing. PCAM was found to be a valid and reliable tool to assess patient complexity in the primary care setting in Japan. Additionally, although the correlation between total PCAM scores and complexity/burden as assessed by the VAS was moderate, PCAM can more precisely identify patient complexity than skilled physician's intuition.

Acknowledgements

The authors are grateful to the members of the Division of Clinical Epidemiology, Research Center for Medical Sciences, The Jikei University School of Medicine for their kind advice on this study. The authors also thank Dr. Yusuke Shigeshima for collecting the data and Mr. Yuta Yamauchi for processing the data.

Contributors

RM designed the study; collected, analyzed, and interpreted the data; and prepared and reviewed the manuscript. YS analyzed and interpreted the data; and prepared and reviewed the manuscript. MM designed the study; analyzed and interpreted the data; and prepared and reviewed the manuscript. SY designed the study; collected and interpreted the data; and reviewed the manuscript. RH designed the study; analyzed and interpreted the data; and reviewed the manuscript. MK, TW, and TT designed the study; collected the data; and reviewed the manuscript. DH back-translated PCAM and its user guide and reviewed the manuscript.

Funding

This study was supported by The Jikei University Research Fund for Graduate Students (grant number: N/A).

Disclaimer

The sponsor of this study had no role in the study design; the data collection, analysis, and interpretation; the manuscript preparation and reviewing; or the decision to submit the manuscript.

Competing interests

MM received lecture fees and lecture travel fees from the Centre for Family Medicine

Development of Japanese Health and Welfare Co-operative Federation. MM is an adviser of the Centre for Family Medicine Development practice-based research network. MM is a program director of the Jikei Clinical Research Program for Primary-care. YS, SY, MK, TW, and TT are former trainees of the Jikei Clinical Research Program for Primary-care. TW currently is and SY, MK, and TT used to be family physicians at the Centre for Family Medicine Development of Japanese Health and Welfare Co-operative Federation. RM, RH, DH have nothing to disclose.

Data sharing statement

No additional data are available.

References

1 World Health Organization, Regional Office for Europe. Social determinants of health: the solid facts - second edition. 2003. https://apps.who.int/iris/bitstream/handle/10665/326568/9289013710eng.pdf?sequence=1&isAllowed=y (accessed 12 Oct 2019).

2 United Nations, Department of Economic and Social Affairs, Population Division. World Population prospects 2019: Highlights. https://population.un.org/wpp/Publications/Files/WPP2019_Highlights.pdf (accessed 13 Oct 2019).

3 Salisbury C, Johnson L, Purdy S, et al. Epidemiology and impact of multimorbidity in primary care: a retrospective cohort study. *Br J Gen Pract* 2011;61(582):e12–e21.

4 France EF, Wyke S, Gunn JM, et al. Multimorbidity in primary care: a systematic review of prospective cohort studies. *Br J Gen Pract* 2012;62(597):e297–e307.

5 Mitsutake S, Ishizaki T, Teramoto C, et al. Patterns of co-occurrence of chronic disease among older adults in Tokyo, Japan. *Prev Chronic Dis* 2019;16:E11.

6 Prince M, Bryce R, Albanese E, et al. The global prevalence of dementia: a systematic review

and metaanalysis. *Alzheimers Dement* 2013;9(1):63–75.e2.

7 Ohara T, Hata J, Yoshida D, et al. Trends in dementia prevalence, incidence, and survival rate in a Japanese community. *Neurology* 2017;88(20):1925–32.

8 Read JR, Sharpe L, Modini M, et al. Multimorbidity and depression: A systematic review and meta-analysis. *J Affect Disord* 2017;221:36–46.

9 Alexopoulos GS. Depression in the elderly. *Lancet* 2005;365(9475):1961–70.

10 Mitchell PB, Harvey SB. Depression and the older medical patient--when and how to intervene. *Maturitas* 2014;79(2):153–9.

11 Domènech-Abella J, Lara E, Rubio-Valera M, et al. Loneliness and depression in the elderly: the role of social network. *Soc Psychiatry Psychiatr Epidemiol* 2017;52(4):381–90.

12 Steptoe A, Shankar A, Demakakos P, at al. Social isolation, loneliness, and all-cause mortality in older men and women. *Proc Natl Acad Sci U S A* 2013;110(15):5797–801.

13. Ministry of Health, Labour and Welfare. Comprehensive Survey of Living Conditions 2018. https://www.mhlw.go.jp/toukei/saikin/hw/k-tyosa/k-tyosa18/dl/02.pdf (accessed 27 Oct 2019).

14 Huyse FJ, Lyons JS, Stiefel FC, et al. "INTERMED": a method to assess health service needs. I. Development and reliability. *Gen Hosp Psychiatry* 1999;21:39–48.

15 Stiefel FC, de Jonge P, Huyse FJ, et al. "INTERMED": a method to assess health service needs. II. Results on its validity and clinical use. *Gen Hosp Psychiatry* 1999;21:49–56.

16 de Jonge P, Huyse FJ, Stiefel FC, et al. INTERMED: a clinical instrument for biopsychosocial assessment. *Psychosomatics* 2001;42:106–9.

17 Kishi Y, Matsuki M, Mizushima H, et al. The INTERMED Japanese version: inter-rater reliability and internal consistency. *J Psychosom Res* 2010;69:583–6.

18 Peek CJ, Baird MA, Coleman E. Primary care for patient complexity: not only disease. *Fam Syst Health* 2009;27:287–302.

19 Maxwell M, Hibberd C, Pratt R, et al. Development and initial validation of the Minnesota Edinburgh Complexity Assessment Method (MECAM) for use within the Keep Well Health

Check. 2011. http://www.healthscotland.com/uploads/documents/18448-DevelopmentOfMinnesotaEdinburghComplexityMethod.pdf (accessed 10 Oct).

20 Pratt R, Hibberd C, Cameron I, et al. The Patient Centered Assessment Method (PCAM): integrating the social dimensions of health into primary care. *J Comorb* 2015;5;110–9.

21 Patient Centred Assessment Method (PCAM). https://med.umn.edu/sites/med.umn.edu/files/pcam_assessment_tool_2.0.pdf (accessed 28 July 2020).

22 Yoshida S, Matsushima M, Wakabayashi H, et al. Validity and reliability of the Patient Centred Assessment Method for patient complexity and relationship with hospital length of stay: a prospective cohort study. *BMJ Open* 2017;7:e016175.

23 Yoshida S, Matsushima M, Wakabayashi H, et al. Correlation of patient complexity with the burden for health-related professions, and differences in the burden between the professions at a Japanese regional hospital: a prospective cohort study. *BMJ Open* 2019;9:e025176.

24 Nishioka D, Kondo N. Addressing patients' social health risks at hospital: lessons from "social prescribing" activities. *Japanese journal of health economics & policy* 2018;30(1):5–18.

25 Ministry of Health, Labour and Welfare. Establishing the community-based integrated care system. https://www.mhlw.go.jp/english/policy/care-welfare/care-welfare-elderly/dl/establish_e.pdf (accessed 28 July 2020).

26 Wild D, Grove A, Martin M, et al. Principles of good practice for the translation and cultural adaptation process for patient-reported outcomes (PRO) Measures: report of the ISPOR Task Force for Translation and Cultural Adaptation. *Value Health* 2005;8(2):94–104.

27 World Health Organization. Process of translation and adaptation of instruments. https://www.who.int/substance_abuse/research_tools/translation/en/ (accessed 18 Oct 2019).

28 von Elm E, Altman DG, Egger M, et al. Strengthening the reporting of observational studies in epidemiology (STROBE) statement: guidelines for reporting observational studies. *BMJ* 2007;335:806–8.

29 Miller, MD, Ferris DG. Measurement of subjective phenomena in primary care research: the visual analogue scale. *Fam Pract Res J* 1993;13(1):15–24.

30 Charlson ME, Pompei P, Ales KL, et al. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *J Chronic Dis* 1987;40:373–83.

31 Charlson ME, Charlson RE, Peterson JC, et al. The Charlson comorbidity index is adapted to predict costs of chronic disease in primary care patients. *J Clin Epidemiol* 2008;61:1234–40.

32 MacCallum RC, Widaman KF, Zhang S, et al. Sample size in factor analysis. *Psychol Methods* 1999;4:84–99.

33 Hooper D, Coughlan J, Mullen M. Structural equation modelling: guidelines for determining model fit structural equation modelling: guidelines for determining model fit. 2008;6(1):53–60.

34 Bland JM, Altman DG. Cronbach's alpha. *BMJ* 1997;314:572.

35 Dancey C, Reidy J. Statistics without maths for psychology: seventh edition. UK: Pearson Education Limited 2017;181–90.

36 StataCorp. Stata Statistical Software: Release 14. College Station, TX, 2015.

37 StataCorp. Stata 14 Base Reference Manual. College Station, TX: Stata Press, 2015.

38 Muthén & Muthén. Mplus Software version 8.4. Los Angeles, CA, 2017.

39 Muthén LK, Muthén BO. Mplus User's Guide: Eighth edition. Los Angeles, CA: Muthén & Muthén, 2017.

40 Nutbeam D. Health promotion glossary. *Health Promot Int* 1998;13(4):349–64.

41 Nutbeam D. Health literacy as a public health goal: a challenge for contemporary health education and communication strategies into the 21st century. *Health Promot Int* 2000;15(3):259–67.

42 Ministry of Health, Labour and Welfare. Comprehensive Survey of Living Conditions 2019. https://www.mhlw.go.jp/toukei/saikin/hw/k-tyosa/k-tyosa19/index.html (accessed 28 July 2020).

43 Medical Examiner's Office, Bureau of Social Welfare and Public Health, Tokyo Metropolitan Government. https://www.fukushihoken.metro.tokyo.lg.jp/kansatsu/kodokushitoukei/index.html

44 Ministry of Health, Labour and Welfare. Overview of Medical Service Regime in Japan. https://www.mhlw.go.jp/bunya/iryouhoken/iryouhoken01/dl/01_eng.pdf (accessed 22 Oct 2019).

45 Ikegami N, Yoo BK, Hashimoto H, et al. Japanese universal health coverage: evolution, achievements, and challenges. *Lancet* 2011;378:1106–15.

46 Maxwell M, Hibberd C, Aitchison P, et al. The patient centred assessment method for improving nurse-led biopsychosocial assessment of patients with long-term conditions: a feasibility RCT. *Health Services and Delivery Research* 2018;6(4).

47 Danaei G, Ding EL, Mozaffarian D, et al. The preventable causes of death in the United States: comparative risk assessment of dietary, lifestyle, and metabolic risk factors. *PLoS Med* 2009;6(4):e1000058.

48 Marmot M, Bell R. Fair society, healthy lives. *Public Health* 2012;126(1):S4–S10.

Figure 1. Distribution of total scores of PCAM. PCAM, Patient Centered Assessment Method.

Figure 2. Correlation between PCAM scores and complexity/burden level measured by VAS.

PCAM, Patient Centered Assessment Method; VAS, Visual Analog Scale.

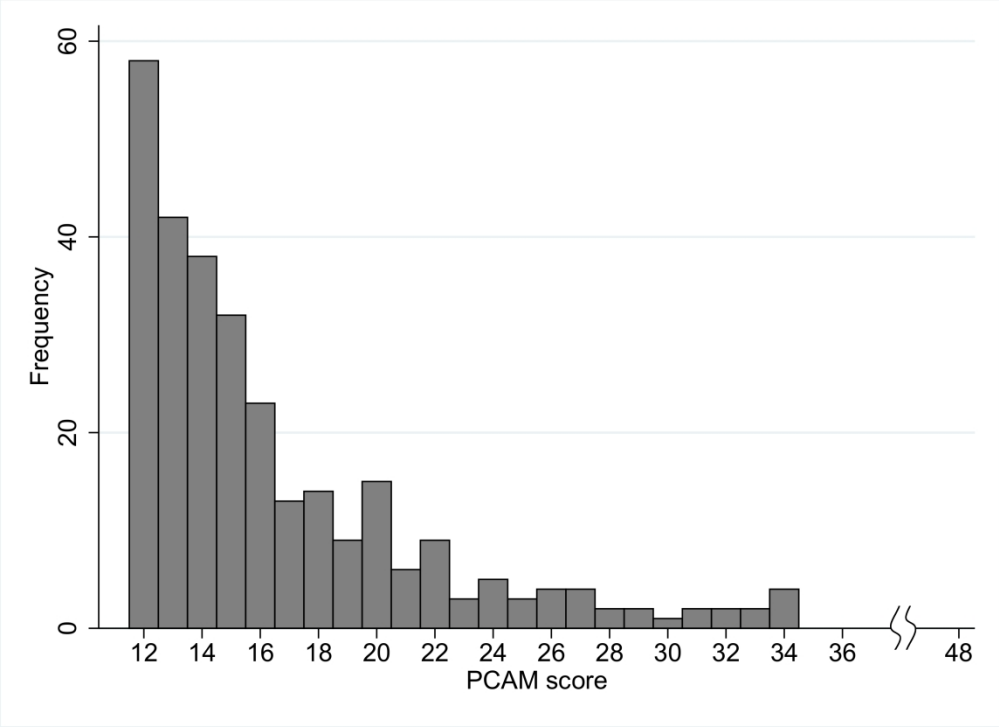
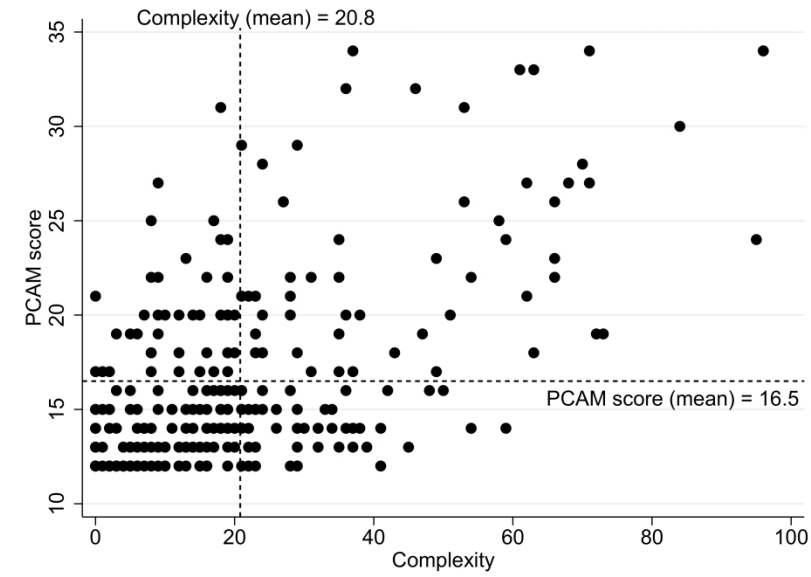


Figure 1. Distribution of total scores of PCAM. PCAM, Patient Centered Assessment Method.

139x101mm (600 x 600 DPI)



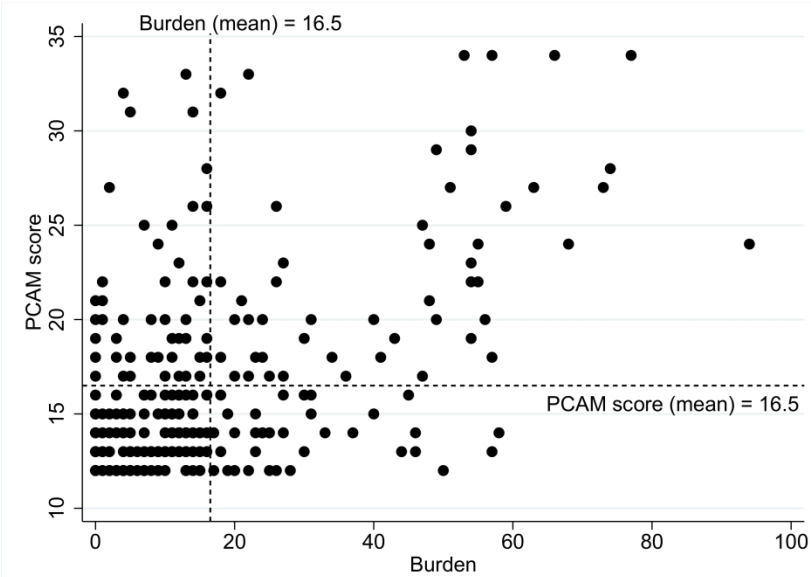


Figure 2. Correlation between PCAM scores and complexity/burden level measured by VAS. PCAM, Patient Centered Assessment Method; VAS, Visual Analog Scale.

139x203mm (600 x 600 DPI)

Supplementary File A

日本語版 Patient Centered Assessment Method (PCAM)

ID _____ 年 月 日

医師/看護師：

実施上の注意点：この評価シートをガイドとして使用し、あなたが各質問に答えやすいように、面談の間にあなた自身の言葉で患者に質問してください。この患者に関連した複雑性のレベルを反映させるように各項目で選択肢一つに丸をつけてください。面談の間か、もしくはその後に完成させてください。

身体の健康と心の安寧

1	患者の**身体の健康についてどのようなニーズ**があるかを考えた場合、更に**精査**が必要と思われる不確かな症状や問題（危険因子）があるか？		
不確かな問題は見出されない、あるいは問題はすでに吟味されている	軽度の漠然とした身体的症状あるいは問題がある；しかし日常生活に影響を及ぼさないか、患者の心配事ではない	日常生活に影響を及ぼす中等度から重度の症状あるいは問題がある	日常生活に重大な影響を及ぼす重度の症状あるいは問題がある
2	患者の**身体の健康**が**心の安寧**に影響しているか？		
懸念される問題は見出されない	心の安寧に軽度の影響を与えている（例：“うんざりする感じ”、“楽しみが減っている”）	心の安寧に中等度から重度の影響を与えており、日常生活の楽しみを妨げている	心の安寧に重度の影響を与えており、日常生活を妨げている
3	**身体の健康**や**心の安寧**に影響するような**生活習慣**（アルコール、薬、食事、運動）に伴う問題があるか?		
懸念される問題は見出されない	身体の健康や心の安寧に悪い影響を与える可能性がある軽度の問題を認める	身体の健康や心の安寧に中等度から重度の影響を与えており、日常生活の楽しみを妨げている	身体の健康や心の安寧に重度の影響を与えており、他者にも影響する可能性がある
4	患者の**心の安寧**について他に**何らかの懸念される問題**があるか? その深刻さや患者に与える影響をどのくらいと評価するか?		
懸念される問題は見出されない	軽度な問題ー日常機能を妨げない	中等度から重度の問題があり日常機能を妨げている	ほとんどの日常機能を妨げる重度の問題がある

社会的環境

1	**安全性、安定性**の点（家庭内暴力、安全でない家、隣人の嫌がらせを含む）から**居住環境**をどのように評価するか?		
一貫して安全で、支援的、安定している状態で、問題は見受けられない	安全で、安定しているがやや一貫性に欠ける	安全/安定しているか疑問がある	安全でなく、安定もしていない
2	**日常の活動**は患者の（心の）安寧にどう影響を与えているか？（現在失業中か予想される失業、仕事、介護、その他を含む）		
問題は見いだされないか、あるいは恩恵があると感じている	ある程度ありきたりの不満があるが、気がかりではない	時々、気分の落ち込みやストレスの一因となっている	心の安寧に重度の悪影響を与えている

3	**社会ネットワーク**（家族、仕事、友人）についてどのように評価するか?			
社会ネットワークに十分に参加している	社会ネットワークに不足なく参加している	ある程度、社会的に孤立し、参加が制限されている	孤独で社会的に孤立し、ほとんど参加していない	
4	**金銭面**（すべての必要な医療ケアを受ける余裕があることを含む）についてはどう評価するか？			
金銭的に安定し、十分な収入があり、問題は見いだされない	金銭的に安定しているが、収入にいくつかの問題がある	金銭的に不安定で、収入にいくつかの問題がある	金銭的に不安定で、収入は極わずかしかなく、問題に直面している	

健康リテラシーとコミュニケーション

1	自分の健康・安寧（症状、徴候、危険因子）と健康管理に必要なことを、患者は**今**、どの程度よく**理解しているか**?			
合理的によく理解していて、すでに健康管理をしているか、あるいはより良い管理をすることをいとわない	合理的によく理解しているがしかし、現時点ではアドバイスを受け入れられないと感じている	より良い管理を可能にするような理解を少ししかしていない	健康管理をするための重要なことについて理解していない	
2	患者はどのくらいヘルスケアの話し合いに**参加する**ことができるか？（言語の壁、聴覚欠如、失語症、アルコールや薬物問題、学習困難、集中力）			
妨げがなく、率直なコミュニケーションで、障壁は見出されない	わずかな障壁があるものの、不足のないコミュニケーションである	中等度の障壁があり、コミュニケーション上のいくらかの困難がある	重度な障壁を伴うコミュニケーション上の深刻な困難がある	

サービスコーディネーション

1	患者を支援するために必要な**他のサービス**はあるか?			
現時点では他のケア/サービスは必要としていない	他のケア/サービスはすでに受けており、不足はない	ケア/サービスを受けているが、十分ではない	ケア/サービスを受けておらず、受ける必要がある	
2	現在、患者に関わっているサービスは**良く調整されている**か？（あなたが今薦めている他のサービスとの調整も含む）			
すべての必要なケア/サービスがすで受けており、良好に調整されている	必要なケア/サービスがすでに受けており、不足なく調整がなされている	必要なケア/サービスはすでに受けているが、いくらかの調整に妨げがある	必要なケア/サービスが欠如していて、（かつ/あるいは）調整が断片的である	

通常のケア	経過観察	プラン作成	すぐに実施

どんな行動が必要か？	誰に協力を求めるべきか？	行動のための妨げは何か？	どんな行動をとるか？
備考：			

Supplementary File B

日本語版 Patient Centered Assessment Method(PCAM)
評価実施のためのユーザーガイド

＜身体の健康と心の安寧＞

項目１：身体の健康についてのニーズ

１.	患者の身体の健康についてどのようなニーズがあるかを考えた場合、更に精査が必要と思われる不確かな症状や問題（危険因子）があるか？		
不確かな問題は見出されない、あるいは問題はすでに吟味されている	軽度の漠然とした身体的症状あるいは問題がある；　しかし日常生活に影響を及ぼさないか、患者の心配事ではない	日常生活に影響を及ぼす中等度から重度の症状あるいは問題がある	日常生活に重大な影響を及ぼす重度の症状あるいは問題がある

この項目では、健康診断の際に行われた身体的な検査の結果として見出だされた危険因子（血圧、血糖値）を含めてください。さらに、患者が自発的に挙げた問題、また、自身に影響を及ぼしている健康問題があるか尋ねてください。患者はすでにケアを受けているかもしれませんが、症状が変化していたり、持続して日常生活に影響を与えているかもしれません。

尋ねたらよいと思われる質問項目サンプル：

・現時点でのあなたの健康状態について述べてください。

・身体の健康についてはいかがでしょうか。

・もし、診療所以外（非医療機関）で PCAM による評価が行われている場合、あなたは医者にかかる必要が最近ありましたか？それは何のためですか？

項目２：身体の健康が心の安寧に与える影響

２.	患者の身体の健康が心の安寧に影響しているか？		
懸念される問題は見出されない	心の安寧に軽度の影響を与えている（例：“うんざりする感じ”、“楽しみが減っている”）	心の安寧に中等度から重度の影響を与えており、日常生活の楽しみを妨げている	心の安寧に重度の影響を与えており、日常生活を妨げている

ここでは、項目１で挙げられた問題や、生活習慣上の問題による身体の症状を考慮することになるでしょう。

尋ねたらよいと思われる質問項目サンプル：

・私たちがあなたの身体の症状や状態について話し合っている時、どのように感じますか？

・Xという状態は現時点であなたにどのように影響していますか？
・あなたの心の状態はいかがですか？
・あなたはストレスを感じたり、うんざりする感じが少しでもありますか？

項目３：ライフスタイルが身体の健康と心の安寧に与える影響

３.	身体の健康や心の安寧に影響するような生活習慣（アルコール、薬、食事、運動）に伴う問題があるか？		
懸念される問題は見出されない	身体の健康や心の安寧に悪い影響を与える可能性がある軽度の問題を認める	身体の健康や心の安寧に中等度から重度の影響を与えており、日常生活の楽しみを妨げている	身体の健康や心の安寧に重度の影響を与えており、他者にも影響する可能性がある

この項目では、アルコール、薬物使用、食事、運動のような生活習慣による影響と、それらが身体と心の健康の両方にどのように影響を及ぼしているかを考慮しましょう。

尋ねたらよいと思われる質問項目サンプル：
・あなたはアルコールや薬物使用について、何か気になることがありますか？
・健康を維持するためにあなたがしていることはどんなことですか？運動？食事？

項目４：その他の心の安寧の問題

４.	患者の心の安寧について他に何らかの懸念される問題があるか？　その深刻さや患者に与える影響をどのくらいと評価するか？		
懸念される問題は見出されない	軽度な問題－日常機能を妨げない	中等度から重度の問題があり日常機能を妨げている	ほとんどの日常機能を妨げる重度の問題がある

ここでは、上記で考慮されたこと以外の心の安寧について考慮しましょう。ここでは統合失調症等のような厳しい状況に加えて、不安、うつ、自尊心、死別、虐待、人間関係、雇用問題が含まれるかもしれません。あなたは時間制限のある面談中に“パンドラの箱を開ける”ことを心配するかもしれません。このことは経験、訓練、サービスプランニングによってしばしば軽減することができます。（例：さらに案件を話し合うために、再度患者に来てもらえるようにすること）

時々、患者は希死念慮を表出するかもしれません。リスク評価を訓練することがこの問題に対処するのに役立つでしょう。こういう思いを訴える患者は、めったに差し迫った危険な状態であることはないでしょう。そして、会話がその危険を軽減することに役立つかもしれません。

尋ねたらよいと思われる質問項目サンプル：
・生活において、あなたの健康に影響を及ぼしているかもしれない、他のことはありませんか？
・個人的な人間関係が失われたり、変化したりしましたか？

・あなたは生活をどのくらいうまく管理できていると感じますか？

＜社会的環境＞

項目１：居住環境

１.	安全性、安定性の点（家庭内暴力、安全でない家、隣人の嫌がらせを含む）から居住環境をどのように評価するか？		
一貫して安全で、支援的、安定している状態で、問題は見受けられない	安全で、安定しているがやや一貫性に欠ける	安全/安定しているか疑問がある	安全でなく、安定もしていない

この質問項目では（患者と）話し合うには困難でやりがいがある領域になりますが、経験上、このツールを試しに使用した看護師は非常に有益であると見出しています。心の安寧についての話し合いを通して、問題が浮かび上がってくるかもしれません。患者が言ったことをそのまま受け売りで環境を評価することはできませんが、ここでは報告したことを記録することになるでしょう。この時点で、危険にさらされている患者はこの問題について打ち明けることはできないかもしれません。しかし、患者と普段通りに自然な態度で話し始めると、いずれ打ち明けてくれるかもしれません。

尋ねたらよいと思われる質問項目サンプル：

・お家ではいかがですか？

・お家やご近所は安全だと感じていますか？

・あなたは自分の住んでいるところについて満足と感じていますか？なぜそう感じますか？/感じないのはなぜですか？

項目２：日常の活動

２.	日常の活動は患者の（心の）安寧にどう影響を与えているか？（現在失業中か予想される失業、仕事、介護、その他を含む）		
問題は見いだされないか、あるいは恩恵があると感じている	ある程度ありきたりの不満があるが、気がかりではない	時々、気分の落ち込みやストレスの一因となっている	心の安寧に重度の悪影響を与えている

仕事のストレス、失業、責任のある介護はすべて安寧を貧しくする可能性があります。

尋ねたらよいと思われる質問項目サンプル：

・現在、日常の活動をいつも通りに送れていますか？それはなぜ？/なぜできないのですか？

・（もし、雇用されているなら）毎日仕事に行くことを楽しんでいますか？または仕事によってストレスが生じていますか？

・日常生活や（心の）安寧に影響を与えるような責任を抱えていますか？

項目３：社会ネットワーク

３.	社会ネットワーク（家族、仕事、友人）についてどのように評価するか？		
社会ネットワークに十分に参加している	社会ネットワークに不足なく参加している	ある程度、社会的に孤立し、参加が制限されている	孤独で社会的に孤立し、ほとんど参加していない

適切な社会ネットワークはうつ、不安、自殺を予防できます。

尋ねたらよいと思われる質問項目サンプル：

・もしあなたが問題や気分の落ち込みを感じたら、だれに話せますか？

・あなたは友達や家族から良く支えられていると感じますか？なぜそう感じますか？/感じないのはなぜですか？

・他にどのような支えが必要ですか？

項目４：金銭的な収入

４.	金銭面（すべての必要な医療ケアを受ける余裕があることを含む）についてはどう評価するか？		
金銭的に安定し、十分な収入があり、問題は見いだされない	金銭的に安定しているが、収入にいくつかの問題がある	金銭的に不安定で、収入にいくつかの問題がある	金銭的に不安定で、収入は極わずかしかなく、問題に直面している

借金や金銭面についての心配は心の安寧にとって、重大な危険因子となります。初めはこのことを話すのは難しい話題になり得ますが、現在の経済状況や増大する収入格差という文脈のなかで、“多くの人々は今、職を失うことや、収入の範囲内でやっていけるかを心配していますが、あなたはどうですか？”というように質問を一般化して始めることが有用かもしれません。

追加して尋ねたらよいと思われる質問項目サンプル：

・あなたは金銭的にゆとりがあると感じていますか？

・あなたは健康管理に関連した費用を支払えると感じていますか？

＜健康リテラシーとコミュニケーション＞

項目１：健康リテラシー

１.	自分の健康・安寧（症状、徴候、危険因子）と健康管理に必要なことを、患者は今、どの程度よく理解しているか？		
合理的によく理解していて、すでに健康管理をしているか、あるいはより良い管理をすることをいとわない。	合理的によく理解しているがしかし、現時点ではアドバイスを受け入れられないと感じている	より良い管理を可能にするような理解を少ししかしていない。	健康管理をするための重要なことについて理解していない

この項目は援助を受ける際の障害を明らかにすることを意図しています。これを文書化しておくと、今後のコンサルテーションに対しての情報提供や、さらに患者と話し合う機会を持つための理由として役に立つかもしれません。患者は健康の一つの側面は理解していますが、他の側面は理解していないかもしれません（例えば、喫煙量を減らす必要性は理解しているかもしれませんが、自宅での怒りが健康問題だとは理解していないかもしれません）。ここでのあなたの記録は全体像を反映しているべきです。もし患者に前向きに進み始めるための理解が十分にあれば、緑か黄色につけるとよいでしょう。

尋ねたらよいと思われる質問項目サンプル：
・あなたは医療者にまだ質問があると感じていますか？他に知りたいことは何でしょうか？
・あなたは健康、診断、問題について必要な情報をすべて持っていると感じますか？
・あなたの生活を、医療者が提案したように変えるという準備ができていると感じていますか？（食事、運動、健康管理）

項目２：話し合いへの参加

２.	患者はどのくらいヘルスケアの話し合いに参加することができるか？（言語の壁、聴覚欠如、失語症、アルコールや薬物問題、学習困難、集中力）		
妨げがなく、率直なコミュニケーションで、障壁は見出されない	わずかな障壁があるものの、不足のないコミュニケーションである	中等度の障壁があり、ミュニケーション上のいくらかの困難がある	重度な障壁を伴うコミュニケーション上の深刻な困難がある

上記のように、この項目では必要とされる治療よりも、話し合いに参加するための障壁を強調することを意図しています。このことは、患者にもう一度戻ってきてもらって、通訳者のような援助を提供できたり、学習困難者を援助するための資源を紹介できるかもしれません。

尋ねたらよいと思われる質問項目サンプル：
・医療者はあなたが理解しやすい方法で彼らの考えをあなたに説明をしますか？
・どうしたら医療者により理解してもらいやすくなりますか？

＜サービスコーディネーション＞

項目１：その他のサービス

１.	患者を支援するために必要な他のサービスはあるか？		
現時点では他のケア/サービスは必要としていない	他のケア/サービスはすでに受けており、不足はない	ケア/サービスを受けているが、十分ではない	ケア/サービスを受けておらず、受ける必要がある

この項目は、あなたが薦める（他のサービスへの）紹介と、あなたの薦めに対して従うことへの患者の関心と意思を評価するために使ってください。たくさんの紹介があるかもしれません。その中のいくつかは患者は受け入れたいと思っているでしょうし、その他は、現時点では解決しようとしていないか

もしれません。この紹介というものは、行動の必要性についてのあなたの意見を反映しているものです。実際に行われた紹介はあなたの意見と患者の希望を反映しています。患者は現時点ではこの紹介は適切でないと判断するかもしれません。

尋ねたらよいと思われる質問項目サンプル：

・あなたは医療者やケアに関わっているその他の人々から、現時点で必要なすべてのケアを受けていると感じていますか？

・あなたは私が提案した薦めについてどのくらい満足していますか？

・あなたが経過を見たい、解決したい最重要課題のように感じているものは何でしょう？

項目２：サービスコーディネーション

２.	現在、患者に関わっているサービスは良く調整されているか？（あなたが今薦めている他のサービスとの調整も含む）		
すべての必要なケア/サービスをすでに受けており、良好に調整されている	必要なケア/サービスをすでに受けており、不足なく調整がなされている	必要なケア/サービスはすでに受けているが、調整にいくらかの妨げがある	必要なケア/サービスが欠如していて、（かつ/あるいは）調整が断片的である

この項目は、すべてのケアとサービス（あなたが評価する前にすでに受けていることも含めて）がどの程度うまく調整できているかを示すために使用してください。もし、サービスとケアが断片的で、患者が利用することが難しい場合は、例え患者がやると決めて、良く参加していても、やり遂げることができないかもしれません。

尋ねたらよいと思われる質問項目サンプル：

・あなたが利用しているすべてのサービスはどのくらいうまく組み立てられたものですか？

・あなたが利用しているサービスは簡単にアクセスすることができて、あなたが利用できる時に提供されていますか？

・サービスやケアを受ける準備や、そこにアクセスすることが困難で、それら（サービスやケア）を受けられないことがありますか？

このセクションは、あなたが薦めている行動、誰に紹介するか、妨げになるもの、そして、患者が何をしたいかという意思表示を要約するために使いましょう。

どんな行動が必要か？	誰に協力を求めるべきか？	行動のための妨げは何か？	どんな行動をとるか？
備考：			

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1,3
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	5,6
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	3,6,7
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6-8
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	7
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8,9
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	6-8
Bias	9	Describe any efforts to address potential sources of bias	6,7
Study size	10	Explain how the study size was arrived at	9,10
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	10
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	10
		(*b*) Describe any methods used to examine subgroups and interactions	n/a
		(*c*) Explain how missing data were addressed	12
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	n/a
		(*e*) Describe any sensitivity analyses	n/a
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	11,12
		(b) Give reasons for non-participation at each stage	12
		(c) Consider use of a flow diagram	n/a
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	12-14
		(b) Indicate number of participants with missing data for each variable of interest	n/a
Outcome data	15*	Report numbers of outcome events or summary measures	14-16
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	n/a
		(*b*) Report category boundaries when continuous variables were categorized	n/a
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	n/a
Discussion			
Key results	18	Summarise key results with reference to study objectives	15-16
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	19
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	16-19
Generalisability	21	Discuss the generalisability (external validity) of the study results	19
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	20

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.