

Validity and reliability of the Japanese version of the CARE Measure in a general medicine outpatient setting

Muneyoshi Aomatsu^{a,*}, Hinako Abe^b, Keiko Abe^a, Hiroki Yasui^a,
Tomio Suzuki^c, Juichi Sato^c, Nobutaro Ban^c and Stewert W Mercer^d

^aDepartment of Education for Community-Oriented Medicine, Graduate School of Medicine, ^bSchool of Medicine and ^cDepartment of General Medicine, Graduate School of Medicine, Nagoya University, 65 Turumai-cho, Showa-ku, Nagoya, Japan and ^dGeneral Practice and Primary Care, Institute of Health and Wellbeing, University of Glasgow, Glasgow, G12 9LX, UK.

*Correspondence to Muneyoshi Aomatsu, Department of Education for Community-Oriented Medicine, Nagoya University Graduate School of Medicine, 65 Turumai-cho, Showa-ku, Nagoya, Japan; E-mail: maomatsu@med.nagoya-u.ac.jp

Received 18 February 2013; Revised 1 August 2013; Accepted 25 August 2013.

Background. Empathy is an important attribute in medicine, influencing both the process and outcome of consultations. However, there are no validated tools available in Japan to gather patient feedback on physicians' empathy. The Consultation and Relational Empathy (CARE) Measure developed in the UK is widely used internationally.

Objectives. To investigate the psychometric properties of a Japanese version of the CARE Measure.

Method. Following two cycles of translation and back translation, the Japanese CARE Measure was completed by 317 patients in a primary medical care clinic in Japan. Tests of internal reliability and validity included Cronbach's alpha, item-total correlations and factor analysis. Predicted associations between CARE Measure score and other variables were assessed by Spearman's rho.

Results. Low numbers of missing values (8.2–9.8%) and 'not applicable' responses (0–1.3%) suggested high acceptability and face validity of the Japanese CARE Measure. Internal reliability was high (Cronbach's alpha 0.984) and was reduced by the removal of any of 10 items. High corrected item-total correlations (0.897–0.946) suggested homogeneity. Factor analysis showed a single solution with high item loadings (0.917–0.957). Construct validity was supported by a significant relationship (Spearman's rho 0.74, $P < 0.001$) with overall satisfaction with the consultation.

Conclusion. The Japanese CARE Measure appears to be valid and reliable in a primary medical care setting. Further work is required to determine its ability to discriminate between doctors.

Keyword. Consultation, doctor–patient relationship, physician competency, primary care, quality of care.

Introduction

The consultation between doctor and patient remains the core activity of medical practice and physicians thus need to have good interpersonal communication skills.¹ Empathy is regarded as an important attribute in medicine and it enhances communication between patients and health care professionals.² Empathy influences not only patients' trust in physicians but also patients' disclosure of their concerns,³ adherence to therapy⁴ and symptom reduction.⁵ Physician empathy has been shown to improve certain outcomes⁶ and is a pre-requisite in enabling patients to feel more confident in the self-management of their conditions.⁷

Tools to measure physician empathy from patients' perspective are thus important so that feedback can be given and improvements made.⁸ The Consultation and Relational Empathy (CARE) Measure was developed

as a measure to evaluate empathy in the clinical encounter from the patient's perspective in the UK.^{9,10} This original version of the CARE Measure has been used to evaluate the therapeutic effect of empathy on physical symptom relief⁵ and for work-based assessment in the postgraduate training of GPs in the UK.¹¹ It has been used for many years in GP appraisal in the UK and has recently been accredited for use in revalidation of GPs by the General Medical Council. Currently, the CARE Measure has been translated and fully validated in German¹² and Chinese¹³ and is being widely used internationally.

In 2004, a mandatory 2-year postgraduate clinical training system was introduced across Japan that requires residents to be trained in clinical skills including empathy and communication skills, regardless of their future specialties.¹⁴ However, evaluation of the training is entrusted to each educational hospital by the

Ministry of Health, Labour and Welfare. To date, there is a lack of systematically applied evaluation tools with which to ensure that the training has been successful. Especially in evaluating empathy, the consideration of the patients' perspective is essential.⁸ However, there is no valid and reliable method to evaluate physicians' empathy from the patients' perspectives in Japan. In this study, we investigate the psychometric properties of a Japanese version of the CARE Measure, which could have utility in the postgraduate training and also more widely as Japan moves towards a more patient-centred care approach and a stronger primary-care-based health system.^{15–17}

Method

Translation and face validity of the CARE measure

The original CARE Measure has 10 items with response options of poor to excellent (scored 1–5) and a 'not applicable' option.⁹ The original English version of the CARE Measure was translated into Japanese by two native Japanese speakers who were both fluent in written and spoken English [a professor in the Department of General Medicine of Nagoya University (NB) and the lead researcher] and made the first draft of the Japanese version of the CARE Measure. The draft was back translated into English independently by two different bilingual native Japanese speakers who were not familiar with the original English CARE Measure. The lead researcher (MA) then made the second draft by the minor revision of the first draft according to advice from the original author of the CARE Measure (SWM).

The second draft of the Japanese CARE Measure was shown to 20 patients who were asked if the items in the measure were understandable. These 20 patients (aged from 26 to 72 years, 12 females and 8 males, with a range of medical conditions and educational levels) were recruited from the General Medicine outpatient clinic at Nagoya University Hospital and a private family medicine clinic (13 from Nagoya University Hospital and 7 from the family medicine clinic). Four out of the 20 patients were confused by one of the items (item 9: 'Helping you take control') because they wondered whether most patients would want to be given the initiative about their health management. Three patients considered that some items were similar (items 2 and 3; items 5, 6, 7 and 8; items 2, 3 and 5). However, all 20 patients could read the Japanese CARE Measure without assistance. All reported that they understood the language and the concepts of the 10 items within the measure. Therefore, a questionnaire, in which this second draft of the Japanese CARE Measure was included, was subsequently constructed in Japanese by the lead researcher (MA). Then, two male doctors of Department of General Medicine of Nagoya University, with more than 15 years of

experience, examined the full questionnaire with the translators and suggested only minor changes. The final version of the full questionnaire (the second draft of the Japanese CARE Measure and the second draft of the questionnaire about patients demographic and social information) was distributed to patients of the outpatient clinic of Department of General Medicine in Nagoya University Hospital. We chose the outpatient clinic of the university hospital because it provides a primary care facility run by qualified and experienced GPs. The certification of Family Practitioner in Japan only began in 2009. Residents complete a program of family practitioner at least 3 years after the completion of the mandatory 2-year training program. The current number of the certified Family practitioners is only 291 in 2012. Therefore, primary care is mainly provided by general physicians working in general medical outpatients (which function as primary care in that patients can consult directly without referral) or specialist physicians working privately (but without general practice training). In such situation, medical schools still assume education for the candidates for Japanese Family Practitioner, and experienced and trained family/general practitioners work as faculty members at Nagoya University Hospital. Thus, the setting we chose was as close as we could get to 'general practice' in Japan.

Content of the full questionnaire

The questionnaire collected information about whether a patient was seen by their usual doctor, how well the patient knew the doctor and how long the patient spent in the consultation. All these variables have previously been used in research into the CARE Measure in the UK¹⁸ and China.¹³ Overall satisfaction about the consultation and whether the patient would recommend the doctor to family or friends were assessed as single-question items.^{19,20} Additionally, satisfaction with consultation length was also collected as a variable, because a previous study emphasized the relation between consultation length and high-quality clinical care.¹⁹ Consultation time was reported by patients. Overall satisfaction with the consultation and satisfaction with the length of consultation were measured by a 4-point Likert-type scale. Whether the patients knew their doctor well and whether they would recommend the doctors to their family or friends were evaluated by a 5-point Likert-type scale as in previous studies.^{13,18}

The demographic and social information collected in the questionnaire included marital status, employment condition and educational level.

Data collection for validation and reliability of CARE Measure

The data collection using the full questionnaire was carried out in the outpatient clinic of General Medicine in the university hospital. Doctors and nurses in charge of the clinic agreed to the study. Consent was also

obtained from each doctor whose patients were to be recruited into the study. Although six or seven doctors were in the clinic everyday, for logistical reasons, patients of one doctor were invited to participate each day. When a doctor considered that asking the participation of patient could affect their condition (e.g. anxiety disorder) or patients could not answer appropriately because of their disease (e.g. dementia), those patients were excluded. The other patients were invited consecutively. At the end of consultations, each doctor asked the patient to answer the questionnaire in the reception area of the outpatient clinic. If patients went to the reception, the questionnaire was explained and distributed to them, either by reception staff or the second author (HA). The data were collected from July to December of 2011.

The questionnaire was distributed by the second author (HA), and three clerks and a nurse of the clinic, who were given a detailed manual and explanation about the distribution, helped in data collection. Patients completed the questionnaire after the consultation, in the waiting area. Although patients were encouraged to answer the questionnaire in the hospital, some patients preferred to answer it after leaving the hospital. Therefore, such patients completed the questionnaire at their home and posted it back. Written and verbal information was given to each patient including that the questionnaire was anonymous, responses would be treated in strictest confidence and that no information that they gave would be seen by any of the doctor or other clinic staff. The questionnaire was self-completed whenever possible but the helpers who distributed the questionnaire could provide assistance when required and this was recorded on the questionnaire.

Data analysis: reliability and validity

All statistical analysis was performed using SPSS 19. In this study, we have examined certain aspects of reliability and validity of the Japanese CARE measure, utilizing approaches that were employed in the initial validation of the original (English) and Chinese version of the measure.^{9,10,13} The acceptability and face validity of the Japanese-CARE Measure were assessed by the number of 'not applicable' scores for each of the 10 items (i.e. when patients ticked a 'not applicable' box). If patients did not answer an item by leaving it blank, then, we coded as 'missing'. Internal reliability was assessed by Cronbach's alpha and whether removal any of the 10 items weakened the Cronbach's alpha. Homogeneity was examined by corrected item-total correlations. Construct validity was examined by comparison of CARE Measure scores with overall patients' satisfaction about the consultations, since on both theoretical and empirical grounds perceived empathy (CARE Measure score) would be expected significantly and positively related to the satisfaction scores.^{21,22} Correlation between the CARE Measure

score and the overall patients' satisfaction was examined by Spearman's rho, because both variables were not normally distributed.

Exploratory factor analysis was performed to test the internal structure of the CARE Measure and to determine if the items within the measure formed a distinct construct. Factor analysis is a method to examine correlation among several items in a questionnaire. When the items measure same construct, the result of factor analysis shows those items as one factor.²³ The analysis was done by entering the 10 Japanese CARE Measure items and the factor loading of each item was examined (principal component analysis, with Varimax rotation and Kaiser normalization, SPSS).

The association between demographic, socio-economic and consultation factors (time, continuity, satisfaction for consultation length) and the Japanese CARE Measure scores were also examined by Spearman's rho.

Data analysis: scoring the CARE Measure

In analyzing the total score of the Japanese CARE measure, we included only questionnaires that had no missing values or not applicable responses. Summing up scores of each item, we calculated the total scores of each included questionnaire with a range from 10 to 50 and looked at the relationship between the CARE measure and other variables as outlined above.

Results

A total of 473 patients consulted the nine doctors during study period. Of these, 317 (67%) were asked to complete the questionnaire. Of these, 311 (98%) at least partially completed the questionnaire. Only eight patients (2.6%) needed help to answer the questionnaire and this was because of visual impairment. Overall, 272 patients (86% of those approached) answered all items in the questionnaire including the CARE Measure, characteristics of the consultation and socio-demographic information.

Patient characteristics

The mean age [with standard deviation (SD)] of participating patients was 57.12 ± 15.89 years, almost two-thirds were female, more than 50% were married and there was a range of educational levels (Table 1).

Consultation characteristics

The characteristics of the consultation are shown in Table 2. Only 18 patients (5.7%) saw a new doctor (whom they met for the first time). The mean estimated consultation length was 17 minutes (SD ± 14.3 minutes) with almost a half of consultations lasting >15 minutes. Almost three quarters of the patients were highly satisfied with the length of consultation. Although most of the patients consulted their usual doctor, only 25.9% of

TABLE 1 Patients' demographic characteristics

	<i>n</i> (%)
Age (years)	
39 or less	49 (15.5)
40–69	168 (53.0)
>69	82 (25.9)
Missing	18 (5.7)
Gender	
Male	107 (33.8)
Female	199 (62.8)
Missing	11 (3.5)
Marital status	
Single	72 (22.7)
Married	188 (59.3)
Separated	1 (0.3)
Divorced	12 (3.8)
Widowed	26 (8.2)
Missing	18 (5.7)
Educational level	
Junior high school	31 (9.8)
High school	99 (31.2)
Vocational college	37 (11.7)
Junior college	43 (13.6)
University	73 (23.0)
Graduate school	10 (3.2)
Others	4 (1.3)
Missing	20 (6.3)
Employment status	
Employed (full- or part-time, including self-employed)	133 (42.0)
Unemployed or looking for work	13 (4.1)
Retired from paid work	42 (13.2)
Unable to work due to long-term sickness or disability	22 (6.9)
Looking after your home/family	76 (24.0)
At School or in full-time education	4 (1.3)
Other	7 (2.2)
Missing	20 (6.3)

the patients felt they knew their doctors very well. Over 75% of the patients were very satisfied or completely satisfied with the consultation, and a similar proportion of the patients thought they could recommend their doctors to relatives.

Japanese CARE measure

All items in the CARE Measure had <10% missing values, ranging from 8.2% (item 1, 6) to 9.8% (item 10; Table 3). The rate of 'not applicable' response ranged from 0 (item 1–3, 5–8) to 1.3% (item 10; Table 3). There were no missing values and 'not applicable' responses among patients who completed the questionnaire with helpers. The distribution of the CARE Measure scores for each item is shown in Table 3. The scores were slightly positively skewed towards the higher end but there was not a marked ceiling effect. The mean total CARE Measure score was 38.41 (SD ± 8.60, *n* = 272). The range

of recorded scores was 16–50. There was no significant difference of total scores between respondents with helpers and without helpers ($t(270) = 1.470$, $P = 0.143$, mean difference = 5.21, 95% confident interval = -1.77 to 12.18).

In terms of the internal reliability of the CARE Measure, Cronbach's alpha was high at 0.984, which was reduced slightly by removal of any of the 10 items (Table 4). Corrected item-total correlations were similarly high for all items (Table 4). Factor analysis showed that the 10 items within the Japanese CARE Measure were measuring a single factor (eigenvalue > 1), and each item of the Japanese CARE Measure loaded highly on the factor (Table 5). Since only a single factor was extracted, Varimax rotation was not possible. The finding of the factor analysis indicates a robust internal structure of the Japanese CARE Measure.

In support of construct validity, the expected relationship between CARE Measure score and patient satisfaction was observed. The CARE Measure score was significantly correlated with overall satisfaction (Spearman's rho 0.74, $P < 0.001$). Whether the patient recommended the doctor to family or friends, satisfaction with the length of the consultation, how well the patient knew the doctor and the actual length of consultation all significantly correlated with the total CARE Measure score, with a Spearman's rho of 0.66 ($P < 0.01$), 0.57 ($P < 0.01$), 0.39 ($P < 0.01$) and 0.17 ($P < 0.01$), respectively. There were no significant relationships between the CARE Measure score and any of the demographic, socio-economical variables and whether the doctor was usual doctor or not (results not shown).

Discussion

In this study, we have reported the translation of the original CARE measure into Japanese and its preliminary validation in a general medicine clinic of a university hospital. The construct validity of the Japanese CARE Measure was supported by positive correlations with patients' overall satisfaction for their consultations and whether the patients recommend the doctors to their family or friend. These were similar findings to both the original English language version and the Chinese version of the CARE Measure.^{13,24} Based on work on the original and Chinese CARE Measure, we would expect a weak but significant positive association between CARE score and consultation length, satisfaction with the length and how well the patient knew the doctor, while little or no association with demographic or socio-economic factors.^{13,24,25} This was confirmed in the present study. The significant correlations between the Japanese CARE Measure and the patients' satisfaction with the consultations length and whether the patients knew the doctors well were also found in previous validation studies.^{13,24} Cronbach's alpha, item-total correlations and factor analysis confirmed the reliability

TABLE 2 Patients' responses about consultation characteristics

	<i>n</i> (%)	Mean ± SD
Number of consultation by today's doctor		
First	18 (5.7)	
Between 2 and 4	44 (13.9)	
>5	242 (76.3)	
Missing	13 (4.1)	
Preference to be seeing today's doctor as your usual doctor		
Yes	17 (5.8)	
No	1 (0.3)	
I have already been seen by today's doctor several times	292 (92.1)	
Missing	7 (2.2)	
Duration of consultation time		
≤5 minutes	39 (12.2)	
Between 6 and 10 minutes	94 (29.7)	
Between 11 and 15 minutes	69 (21.8)	
Between 16 and 20 minutes	35 (11.0)	
>20 minutes	62 (19.4)	
Missing	18 (5.7)	
Mean (SD) duration of consultation time in minutes		17.24 ± 14.34
How satisfied was the patient with the length of time with the doctor		
Not at all satisfied (1)	3 (0.9)	
Fairly satisfied (2)	65 (20.5)	
Very satisfied (3)	159 (50.2)	
Completely satisfied (4)	77 (24.3)	
Missing	13 (4.1)	
Mean (SD) satisfactory score with duration of consultation		3.02 ± 0.71
How well the patient knew the doctor		
Not at all (1)	31 (9.8)	
2	19 (6.0)	
3	81 (25.6)	
4	77 (24.3)	
Know very well (5)	82 (25.9)	
missing	27 (8.5)	
Mean (SD) familiarity score		3.55 ± 1.26
Would you recommend the doctor to your family or friend		
Definitely not (1)	0 (0)	
Probably not (2)	3 (0.9)	
Not sure (3)	46 (14.5)	
Probably yes (4)	148 (46.7)	
Definitely yes (5)	107 (33.8)	
Missing	13 (4.1)	
Mean (SD) recommendation score		4.18 ± 0.72
How satisfied was the patient with the consultation of the doctor		
Not at all satisfied (1)	2 (0.6)	
Fairly satisfied (2)	60 (18.9)	
Very satisfied (3)	142 (44.8)	
Completely satisfied (4)	94 (31.5)	
Missing	19 (6.0)	
Mean (SD) satisfactory score		3.10 ± 0.73

of the internal structure of the Japanese CARE Measure and these findings also accord with previous work on the original and Chinese versions of the measure.^{13,25} Therefore, these findings positively supported internal and external validity of the Japanese CARE Measure. A similar study implemented in Hong Kong¹³ used the patient enablement index (PEI)²⁶ for the examination of construct validity. However, we were unable to use the

PEI because it had not been translated in Japanese when this study was conducted, although it is now available.²⁷

The face validity and acceptability were examined by the number of missing value and 'not applicable'. In UK and Hong Kong, item 9 and 10 had higher numbers of 'not applicable' than other items,^{10,13} in addition item 4 also had higher 'not applicable' responses in Hong Kong.¹³ The Japanese CARE Measure showed a lower number

TABLE 3 Distribution of Japanese CARE Measure scores

CARE measure item	Poor (%)	Fair (%)	Good (%)	Very good (%)	Excellent (%)	Does not apply	Missing	Mean score
1. Making you feel at ease (being friendly and warm towards you, treating you with respect; not cold or abrupt)	0 (0)	23 (7.3)	83 (26.2)	114 (36.0)	71 (22.4)	0 (0)	26 (8.2)	3.80±0.90
2. Letting you tell your 'story' (giving you time to fully describe your illness in your own words; not interrupting or diverting you)	0 (0)	22 (6.9)	80 (25.2)	118 (37.2)	70 (22.1)	0 (0)	27 (8.5)	3.81±0.89
3. Really listening (paying close attention to what you were saying; not looking at the notes or computer as you were talking)	0 (0)	23 (7.3)	72 (22.7)	119 (37.5)	75 (23.7)	0 (0)	28 (8.8)	3.85±0.90
4. Being interested in you as a whole person (asking/knowing relevant details about your life, your situation; not treating you as 'just a number')	0 (0)	22 (6.9)	81 (25.6)	106 (33.4)	78 (24.6)	1 (0.3)	29 (9.2)	3.84±0.91
5. Fully understanding your concerns (communicating that he/she had accurately understood your concerns; not overlooking or dismissing anything)	1 (0.3)	23 (7.3)	77 (24.3)	105 (33.1)	82 (25.9)	0 (0)	29 (9.1)	3.85±0.94
6. Showing care and compassion (seeming genuinely concerned, connecting with you on a human level; not being indifferent or 'detached')	2 (0.6)	22 (6.9)	80 (25.2)	108 (34.1)	79 (24.9)	0 (0)	26 (8.2)	3.82±0.94
7. Being positive (having a positive approach and a positive attitude; being honest but not negative about your problems)	1 (0.3)	16 (5.0)	75 (23.7)	115 (36.3)	81 (25.6)	0 (0)	29 (9.1)	3.90±0.89
8. Explaining things clearly (fully answering your questions, explaining clearly, giving you adequate information; not being vague)	1 (0.3)	21 (6.6)	69 (21.8)	116 (33.6)	83 (26.2)	0 (0)	27 (8.5)	3.89±0.91
9. Helping you to take control (exploring with you what you can do to improve your health yourself; encouraging rather than 'lecturing' you)	4 (1.3)	28 (8.8)	77 (24.3)	105 (33.1)	73 (23.0)	2 (0.6)	28 (8.8)	3.75±0.99
10. Making a plan of action with you (discussing the options, involving you in decisions as much as you want to be involved; not ignoring your views)	3 (0.9)	26 (8.2)	72 (22.7)	112 (35.3)	69 (21.8)	4 (1.3)	31 (9.8)	3.79±0.96

TABLE 4 Reliability and homogeneity of Japanese CARE Measure

	Scale mean if item deleted	Corrected item-total correlation	Cronbach's alpha if item deleted
1. Making you feel at ease	34.59	0.897	0.983
2. Letting you tell your 'story'	34.58	0.912	0.983
3. Really listening	34.54	0.925	0.982
4. Being interested in you as a whole person	34.56	0.924	0.982
5. Fully understanding your concerns	34.56	0.930	0.982
6. Showing care and compassion	34.57	0.946	0.982
7. Being positive	34.50	0.928	0.982
8. Explaining things clearly	34.50	0.926	0.982
9. Helping you to take control	34.65	0.915	0.983
10. Making a plan of action with you	34.61	0.904	0.983

TABLE 5 Internal structure of the Japanese CARE Measure: exploratory factor analysis

	Component (factor)
	Factor one
1. Making you feel at ease	0.917
2. Letting you tell your 'story'	0.929
3. Really listening	0.940
4. Being interested in you as a whole person	0.939
5. Fully understanding your concerns	0.944
6. Showing care and compassion	0.957
7. Being positive	0.942
8. Explaining things clearly	0.941
9. Helping you to take control	0.931
10. Making a plan of action with you	0.921

All items loaded onto a single factor and thus varimax rotation was not possible.

of 'not applicable' for all items than previous studies. On the other hand, the rate of missing value was higher in this study than the previous Chinese study. However, this might have simply resulted from the structure of questionnaire that asked about background information first and then the Japanese CARE measure second, and had a 'thank you' message at the end of the first section on socio-demographic information. Therefore, some participants may have misunderstood and thought they had finished answering at the end of the first section. Future versions of the questionnaire will thus be changed to avoid this. The low rate of responders who needed help indicated that most participants can self-complete the CARE Measure without problems.

In this study, 90.2% of the patients answered that they had met the doctors whom they consulted several times before, while 18.4% of patients answered that the doctors who treated them was usual doctor in Hong Kong.¹³ The number of the patients treated by their usual doctors was not reported in the UK study, but almost half of patients came to clinics because of long-standing problems. Thus, continuous relationships

between patients and physicians may affect the percentage of 'not applicable', and the effect should be examined in further research. On the other hand, it may be the extent to which the patient feels she knows the doctor that affects the CARE Measure score rather than simply seeing the same doctor at each visit, as in the three studies 'knowing the doctor well' was positively associated with perceptions of the doctors' empathy.

A key strength of this study was the time and effort given to establishing an accurate and culturally meaningful translation of the English CARE measure into Japanese, which was an iterative process and not a simple matter of translation and back translation. A similarly lengthy and complex process was reported for the Chinese CARE Measure.¹³ The high response rate of those invited to take part (98%) with high completion rates (86%) was also a strength.

The study had several limitations. Firstly, it was conducted in only a single setting, and the lead author was both working in the clinic and carrying out the research, which may have influenced patients' responses or decision to take part. Secondly, because it was only a single setting, the feasibility of carrying out such research in other settings such as rural or private clinics was not tested. The setting used, though useful as it is a primary care clinic run by trained Family Physicians, may be atypical in terms of consultation length and continuity of care.²⁸ Thirdly, the selection of suitable patients was determined by the attending physician, which may have introduced bias and led to the exclusion of almost a third of patients attending those doctors within the time period of the study. Patients with specific diseases (e.g. anxiety, dementia) were excluded from the study, whereas previous studies have made an effort to be more inclusive.^{9,10,13} However, we were able to include divergent patients in terms of their demographic and socio-economic status. It is important to emphasize that this study aimed to examine the validity and reliability of the Japanese CARE Measure and as such did not require a representative sample of patients (either in terms of those attending the clinic or the Japanese population as a whole). If the Japanese CARE Measure were to be rolled out nationally, then further

large-scale data would need to be collected in order to establish normative values for benchmarking. Since only internal reliability was examined in this study, the inter-rater reliability of the CARE Measure should be also investigated in a further work to determine its ability to effectively discriminate between physicians, as has been demonstrated for the UK and Chinese versions.^{10,29}

Conclusion

The Japanese CARE Measure appears to be valid and reliable in a primary medical care setting. Further work is required to determine its ability to discriminate between doctors before its utility in evaluating doctors' interpersonal skills in a summative way can be established.

Declaration

Funding: Japan Society for the Promotion of Science KAKENHI (21590559).

Ethical approval: for the study was obtained from the ethical committee of Nagoya University (approval number 188056).

Conflict of interest: none.

References

- Kurtz S, Silverman J, Draper J. *Teaching and Learning Communication Skills in Medicine*, 2nd ed. Oxford: Radcliffe Publishing, 2005.
- Coulehan JL, Platt FW, Egener B *et al*. 'Let me see if i have this right.': words that help build empathy. *Ann Intern Med* 2001; **135**: 221–7.
- Maguire P, Faulkner A, Booth K, Elliott C, Hillier V. Helping cancer patients disclose their concerns. *Eur J Cancer* 1996; **32A**: 78–81.
- Vermeire E, Hearnshaw H, Van Royen P, Denekens J. Patient adherence to treatment: three decades of research. A comprehensive review. *J Clin Pharm Ther* 2001; **26**: 331–42.
- Rakel D, Barrett B, Zhang Z *et al*. Perception of empathy in the therapeutic encounter: effects on the common cold. *Patient Educ Couns* 2011; **85**: 390–7.
- Hojat M, Louis DZ, Markham FW, Wender R, Rabinowitz C, Gonnella JS. Physicians' empathy and clinical outcomes for diabetic patients. *Acad Med* 2011; **86**: 359–64.
- Mercer SW, Jani BD, Maxwell M, Wong SY, Watt GC. Patient enablement requires physician empathy: a cross-sectional study of general practice consultations in areas of high and low socioeconomic deprivation in Scotland. *BMC Fam Pract* 2012; **13**: 6.
- Stepien KA, Baernstein A. Educating for empathy. A review. *J Gen Intern Med* 2006; **21**: 524–30.
- Mercer SW, Maxwell M, Heaney D, Watt GC. The consultation and relational empathy (CARE) measure: development and preliminary validation and reliability of an empathy-based consultation process measure. *Fam Pract* 2004; **21**: 699–705.
- Mercer SW, McConnachie A, Maxwell M, Heaney D, Watt GC. Relevance and practical use of the Consultation and Relational Empathy (CARE) Measure in general practice. *Fam Pract* 2005; **22**: 328–34.
- Murphy DJ, Bruce DA, Mercer SW, Eva KW. The reliability of workplace-based assessment in postgraduate medical education and training: a national evaluation in general practice in the United Kingdom. *Adv Health Sci Educ Theory Pract* 2009; **14**: 219–32.
- Neumann M, Wirtz M, Bollschweiler E *et al*. Determinants and patient-reported long-term outcomes of physician empathy in oncology: a structural equation modelling approach. *Patient Educ Couns* 2007; **69**: 63–75.
- Fung CS, Hua A, Tam L, Mercer SW. Reliability and validity of the Chinese version of the CARE Measure in a primary care setting in Hong Kong. *Fam Pract* 2009; **26**: 398–406.
- Kozu T. Medical education in Japan. *Acad Med* 2006; **81**: 1069–75.
- Ban N, Fetters MD. Education for health professionals in Japan—time to change. *Lancet* 2011; **378**: 1206–7.
- World Health Organization Regional Office for the Western Pacific, Ministry of Health, Labour and Welfare, Japan. *Health Service Delivery Profile: Japan 2012*. Manila: World Health Organization, Regional Office for Western Pacific Region, 2012.
- World Health Organization Western Pacific Region. Patient-centred health care: supportive health systems. In: *People-Centred Health Care: Technical Papers*. Manila: World Health Organization, Regional Office for the Western Pacific, 2008, pp. 51–60. http://www.wpro.who.int/health_services/people_at_the_centre_of_care/documents/PCITechPapers20Aug2008.pdf (accessed on 16 September 2013).
- Mercer SW, Watt GC. The inverse care law: clinical primary care encounters in deprived and affluent areas of Scotland. *Ann Fam Med* 2007; **5**: 503–10.
- Campbell SM, Hann M, Hacker J *et al*. Identifying predictors of high quality care in English general practice: observational study. *BMJ* 2001; **323**: 784–7.
- Ramsay J, Campbell JL, Schroter S, Green J, Roland M. The General Practice Assessment Survey (GPAS): tests of data quality and measurement properties. *Fam Pract* 2000; **17**: 372–9.
- Larson EB, Yao X. Clinical empathy as emotional labor in the patient-physician relationship. *JAMA* 2005; **293**: 1100–6.
- Zachariae R, Pedersen CG, Jensen AB, Ehrnrooth E, Rossen PB, von der Maase H. Association of perceived physician communication style with patient satisfaction, distress, cancer-related self-efficacy, and perceived control over the disease. *Br J Cancer* 2003; **88**: 658–65.
- Briggs SR, Cheek JM. The role of factor analysis in the development and evaluation of personality scales. *J Pers* 1986; **54**: 106–48.
- Mercer SW, Murphy DJ. Validity and reliability of the CARE measure in secondary care. *Clin Gov* 2008; **13**: 269–83.
- Mercer SW, Hatch DJ, Murray A, Murphy DJ, Eva KW. Capturing patients' views on communication with anaesthetists: the CARE measure. *Clin Gov* 2008; **13**: 128–37.
- Mercer SW, Howie JG. CQI-2—a new measure of holistic interpersonal care in primary care consultations. *Br J Gen Pract* 2006; **56**: 262–8.
- Kurosawa S, Matsushima M, Fujinuma Y *et al*. Two principal components, coping and independence, comprise patient enablement in Japan: cross sectional study in Tohoku area. *Tohoku J Exp Med* 2012; **227**: 97–104.
- Hashimoto H, Ikegami N, Shibuya K *et al*. Cost containment and quality of care in Japan: is there a trade-off? *Lancet* 2011; **378**: 1174–82.
- Mercer SW, Fung CS, Chan FW, Wong FY, Wong SY, Murphy D. The Chinese-version of the CARE measure reliably differentiates between doctors in primary care: a cross-sectional study in Hong Kong. *BMC Fam Pract* 2011; **12**: 43.