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Ⅴ. 研究成果の刊行物・別刷

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Usefulness of five-item and three-item Mental Health Inventories to screen for depressive symptoms in the general population of Japan

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Abstract

Background: The five-question Mental Health Inventory (MHI-5) is a brief questionnaire that can be used to screen for depressive symptoms. Removing the 2 anxiety-related items from the MHI-5 yields the MHI-3. We assessed the performance of the Japanese versions of the MHI-5 and MHI-3 in detecting depressive symptoms in the general population of Japan.

Methods: From the population of Japan, 4500 people 16 years old or older were selected by stratified-random sampling. The Medical Outcomes Study 36-Item Short Form Health Survey (SF-36, which includes the MHI-5) and the Zung Self-rating Depression Scale (ZSDS) were included in a self-administered questionnaire. ZSDS scores of 48 and above were taken to indicate the presence of moderate or severe depressive symptoms, and scores of 56 and above were taken to indicate the presence of severe depressive symptoms. We computed the correlation coefficient between the ZSDS score and the scores on the MHI-5 and MHI-3. We also computed the sensitivity, specificity, and area under the receiver operating characteristic (ROC) curve.

Results: Of the 3107 subjects (69% of the 4500 initially selected), 14.0% had moderate or severe depressive symptoms, and 2.0% had severe depressive symptoms as measured with the ZSDS. The correlations of ZSDS scores with MHI-5 scores and with MHI-3 scores were similar: -0.63 and -0.61, respectively. These correlation coefficients were almost the same whether or not the data were stratified by age and sex. For detecting severe depressive symptoms with the MHI-5, the area under the ROC curve was 0.942 (95%CI: 0.919 – 0.965); for the MHI-3, it was 0.933 (95%CI: 0.904 – 0.962).

Conclusion: The MHI-5 and MHI-3 scores were correlated with the ZSDS score, and can be used to identify people with depressive symptoms in the general population of Japan.

Background

Depression disorders are a major health problem in Japan. Depressive mood is associated with suicide in middle-aged workers [1], and the number of suicides has increased as economic conditions have worsened since 1998 [2]. Nonetheless, there are few studies of the

prevalence of depression or of depressive symptoms in communities in Japan [3,4].

To assist in detecting depression or depressive symptoms, many screening questionnaires have been developed. Some of these have 20 to 30 items, take only a few minutes to complete, use the number of symptoms as the score, and have good performance to detect depressive state. Instruments that are even shorter but nonetheless have good performance to detect depressive state have also been developed [5-7]. One such questionnaire is the five-item version of the Mental Health Inventory (MHI-5) [6,7]. The MHI-5 is used as the "Mental Health" domain of the Medical Outcomes Study 36-Item Short Form Health Survey (SF-36). The SF-36 has been translated into Japanese [8], and the Japanese version has been validated for use in the general population of Japan [9], but the performance of the MHI-5 has not been evaluated in detail. In addition, two of the items in the MHI-5 are almost identical to two items in a scale developed to measure anxiety [10]. We hypothesized that removing those two anxiety-related items would result in a scale (the MHI-3) that performs as well as the MHI-5 in detecting symptoms of depression.

In this study, we compared the Japanese version of the MHI-5 and MHI-3 to the 20-item Zung Self-rating Depression Scale (ZSDS) [11], and assessed the performance of the Japanese versions of the MHI-5 and MHI-3 in detecting depressive symptoms among the general population.

Methods

Setting and participants

We used data that had been collected previously for a study of the validity of the Japanese version of the SF-36, and calculated national norm scores of all subscales of the SF-36 [8,9]. Details of the nationwide survey have been described previously [9]. Briefly, a total of 4500 people 16 years old or older were selected from the entire population of Japan by stratified-random sampling in 1995. A self-administered questionnaire was mailed, and the subjects were visited to collect the questionnaires. The SF-36, the ZSDS [11] (described below), and questions about demographic characteristics were included in the questionnaire.

The ZSDS consists of 10 positively worded items and 10 negatively worded items asking about symptoms of depression. Several studies have established the ZSDS as a reliable and valid instrument for measuring depressive symptoms [12-14]. The ZSDS scores were used to define four categories of the severity of depression: within normal range or no significant psychopathology (below 40 points); presence of minimal to mild depression (40–47 points); moderate to marked depression (48–55 points); presence of severe to extreme depression (56 points and above). These score ranges result from the studies of Zung [15] and Barrett et al [16]. The ZSDS has been translated into Japanese and studies of the validity of the Japanese version have been published [17]. Because the ZSDS is not a clinical diagnostic tool, subjects with high scores are said to have depressive symptoms rather than "depression."

Like the rest of the SF-36, the MHI-5 was administered as a paper-and-pencil questionnaire. The instrument contains the following questions: 'How much of the time during the last month have you: (i) been a very nervous person?; (ii) felt downhearted and blue?; (iii) felt calm and peaceful?; (iv) felt so down in the dumps that nothing could cheer you up?; and (v) been a happy person?' For each question the subjects were asked to choose one of the following responses: all of the time (1 point), most of the time (2 points), a good bit of the time (3 points), some of the time (4 points), a little of the time (5 points), or none of the time (6 points). Because items (iii) and (v) ask about positive feelings, their scoring was reversed. The score for the MHI-5 was computed by summing the scores of each question item and then transforming the raw scores to a 0–100-point scale [18].

Items (i) and (iii) are almost identical to 2 items in the Zung Self-rating Anxiety Scale [10]. To make a scale that is even shorter than the MHI-5 and is focused on depression we removed those two anxiety-related items. Thus, the MHI-3 comprised only (ii), (iv), and (v) above. Possible scores on the MHI-3 ranged from 3 to 18 points.

Statistical methods

First, we computed the correlation coefficient (Pearson's) between the ZSDS scores and the scores on the MHI-5 and the MHI-3. We computed the sensitivity, specificity, and area under the receiver operating characteristic (ROC) curve. Analysis of ROC curves has been described in detail and ROC analysis is used extensively in health-related diagnostics [19,20]. ROC analysis can be used to study the performance of diagnostic or screening tests across a wide range of sensitivities and specificities. For example, it can be used to compute the sensitivity (the true-positive rate) and specificity (the true-negative rate) for any specified test score. The area under the ROC curve (AUC) is an index of the amount of information the test provides over its entire scoring range [21,22]. In general, an AUC can range from 0.5, which indicates a test with no information, to 1.0, which indicates a perfect test. The "gold standard" criteria for diagnosing depression are considered to be those of the Diagnostic and Statistical Manual of Mental Disorders (DSM) [7]. In this study, because we could not interview all subjects, we used, instead, scores on the ZSDS. For each of the three categories of the severity of depressive states (ZSDS scores of 40 or higher), we

Table 1: MHI-5 scores by demographic categories

	N (%) 3107 (100)	Score of the MHI-5 Mean (SD)
Sex		
Male	1573 (51)	73.31 (18.63)
Female	1534 (49)	72.32 (19.55)
Age (years)		
<30	619 (20)	70.17 (18.47)
30 – 39	506 (16)	72.50 (17.47)
40 – 49	665 (21)	72.38 (20.28)
50 – 59	617 (20)	74.22 (18.60)
60 – 69	479 (15)	75.21 (19.11)
≥70	221 (7)	73.23 (21.09)
Annual household income (million yen)		
<3	385 (12)	69.37 (20.83)
3 – 4.9	670 (22)	71.87 (19.08)
5 – 6.9	685 (22)	72.62 (19.38)
7 – 9.9	648 (21)	73.72 (18.27)
10 – 11.9	228 (7)	74.57 (18.78)
≥12	266 (9)	76.63 (16.72)
Missing values	225 (7)	73.30 (19.4)
Schooling		
Junior high school	613 (20)	72.64 (19.88)
High school	1426 (46)	72.97 (18.88)
Junior college, college, or higher	1028 (33)	72.84 (18.85)
Missing values	40 (1)	69.95 (20.88)
Marital status		
Single	622 (20)	70.04 (18.89)
Married	2227 (72)	73.74 (18.8)
Separated	28 (1)	75.43 (16.86)
Divorced	65 (2)	68.66 (20.91)
Widowed	152 (5)	72.18 (22.27)
Missing values	13 (0)	70.00 (19.71)
Occupational status		
Full time worker	1610 (52)	73.05 (18.25)
Part time worker	299 (10)	74.27 (17.96)
Retired	164 (5)	72.51 (22.74)
Unemployed	171 (6)	69.34 (21.95)
Homemaker	533 (17)	73.06 (19.71)
Student	226 (7)	73.36 (18.77)
Other	83 (3)	68.48 (21.49)
Missing values	21 (1)	70.86 (16.64)

computed the AUC of each of the five items, the MHI-5, and the MHI-3. To define the cut-off points, we first considered each of the actually measured MHI-5 scores as a possible cut-off point. For each score, we took the sum of the sensitivity and the specificity. The score with the highest sum was used as the cut-off point. One cut-off point was determined for each of the three levels of severity defined by ZSDS scores (mild, moderate, and severe).

Results

The nationwide survey targeted 4500 people, and 3395 (male: 1704; female: 1691) responded to the questionnaire (75% response rate). Of these 3395 individuals, 3107 (male: 1573; female: 1534) completed all of the items on the ZSDS. The mean score on the MHI-5 was 72.8 (SD = 19.1). The mean scores on the MHI-5 for respondents of different demographic categories are shown in Table 1. These mean scores ranged from 68.5 to 76.6. Almost 23% of the respondents had ZSDS scores indicating mild depressive symptoms, 12% had scores indicating moderate depressive symptoms, and 2% had scores indicating severe depressive symptoms.

The correlations of ZSDS scores with MHI-5 scores and with MHI-3 scores were similar: -0.63 and -0.61, respectively. These correlation coefficients were almost

Table 2: Correlations of ZSDS scores with MHI-5 and MHI-3 scores, by demographic category

	MHI-5	MHI-3
All	-0.634	-0.614
Sex		
Male	-0.634	-0.610
Female	-0.635	-0.618
Age (years)		
<30	-0.653	-0.643
30 – 39	-0.686	-0.685
40 – 49	-0.619	-0.591
50 – 59	-0.576	-0.549
60 – 69	-0.635	-0.608
≥70	-0.698	-0.671
Annual household income (million yen)		
<3	-0.666	-0.638
3 – 4.9	-0.612	-0.596
5 – 6.9	-0.642	-0.642
7 – 9.9	-0.637	-0.602
10 – 11.9	-0.654	-0.642
≥12	-0.562	-0.554
Missing values	-0.613	-0.551
Schooling		
Junior high school	-0.612	-0.579
High school	-0.637	-0.617
Junior college, college, or higher	-0.651	-0.636
Missing values	.	.
Marital status		
Single	-0.661	-0.638
Married	-0.624	-0.602
Separated	.	.
Divorced	.	.
Widowed	-0.658	-0.642
Missing values	.	.
Occupational status		
Full time worker	-0.618	-0.601
Part time worker	-0.533	-0.509
Retired	-0.741	-0.711
Unemployed	-0.714	-0.692
Homemaker	-0.646	-0.636
Student	-0.680	-0.646
Other	.	.
Missing values	.	.

the same whether or not the data were stratified by age and sex (Table 2).

With ZSDS scores as the basis for classifying depressive symptoms, ROC analysis allowed us to evaluate the performance of the MHI-5 and the MHI-3. The AUC values are shown in Table 3, and other performance characteristics are shown in Table 4. We also evaluated the performance of each of the MHI-5 question items individually (Table 3). For the individual items, the range of "cut-off scores" was determined by the range of each question's response options: from "none of the time" to "all of the time." The best-performing item for detecting severe depressive symptoms was the one asking about the frequency of "feeling downhearted and blue". That item had a sensitivity of 0.88 and a specificity of 0.77 (based on a score of 4 points or less). The AUC of the MHI-3 was only slightly lower than that of the MHI-5 (Figure 1).

Using the MHI-5, the prevalence of severe depressive symptoms (cut-off: 52 points) was 17%, that of moderate or severe depressive symptoms (cut-off: 60 points) was 28%, and that of mild, moderate, or severe depressive symptoms (cut-off: 68 points) was 40%.

Table 3: ROC analysis of individual MHI-5 items, the whole MHI-5, and the MHI-3, by severity of depressive symptoms

Items and scales	Severity of depressive symptom (range of ZSDS scores)					
	Mild, moderate, or severe (40 through 80)		Either moderate or severe (48 through 80)		Severe (56 through 80)	
	AUC	(95% CI)	AUC	(95% CI)	AUC	(95% CI)
(i) Nervous person	0.696	(0.677–0.716)	0.707	(0.680–0.734)	0.826	(0.774–0.879)
(ii) Down in the dumps	0.713	(0.694–0.733)	0.741	(0.714–0.769)	0.862	(0.813–0.910)
(iii) Calm and peaceful	0.745	(0.726–0.764)	0.755	(0.728–0.782)	0.845	(0.797–0.892)
(iv) Downhearted and blue	0.739	(0.720–0.758)	0.748	(0.721–0.776)	0.898	(0.855–0.941)
(v) Happy person	0.747	(0.729–0.765)	0.738	(0.711–0.765)	0.858	(0.811–0.905)
MHI-5*	0.810	(0.793–0.826)	0.819	(0.795–0.843)	0.942	(0.919–0.965)
MHI-3†	0.800	(0.783–0.817)	0.803	(0.779–0.828)	0.933	(0.904–0.962)

Values shown are areas under the ROC curves (AUC), and their 95% CIs, for three levels of depressive symptoms as measured by ZSDS scores. *The MHI-5 includes all 5 items. †The MHI-3 includes only items ii, iv, and v.

Table 4: Performance of the MHI-5 and MHI-3 for detecting depressive symptoms

	Mild, moderate, or severe depressive symptoms (ZSDS scores of 40 or higher)		Moderate or severe depressive symptoms (ZSDS scores of 48 or higher)		Severe depressive symptoms (ZSDS scores of 56 or higher)	
Prevalence	37%		14%		2%	
Instrument	MHI-5	MHI-3	MHI-5	MHI-3	MHI-5	MHI-3
(cut-off score)	(68)	(14)	(60)	(13)	(52)	(11)
Sensitivity	71.5%	76.4%	74.7%	77.1%	91.8%	90.0%
Specificity	79.1%	71.1%	80.0%	71.8%	84.6%	84.2%
Positive predictive value	66.7%	60.8%	37.1%	30.8%	10.8%	10.4%
Negative predictive value	82.5%	83.7%	95.1%	95.1%	99.8%	99.8%

Discussion

These data show that the MHI-5 and MHI-3 scores were each correlated with the ZSDS score and had good screening accordance with the ZSDS in the general population of Japan. We also found that the MHI-3 performs almost as well as the MHI-5. The best-performing single item was the one asking about "feeling downhearted and blue," which was also the case in the US [6]. The usefulness of the MHI-5 is consistent with results of a study done in the US [6]. Each scale and each item performed best as a detector of severe depressive symptoms, but each also contributed some information even for detecting moderate and mild depressive symptoms (Table 3). Both scales performed better than did any item alone.

Because prevalence affects positive predictive value, the latter was lowest for severe depressive symptoms and was highest for mild, moderate, and severe depressive symptoms (Table 4). For all levels of symptom severity, the positive predictive values of the MHI-3 were similar to those of the MHI-5, and for severe depressive symptoms they were nearly identical (10.8% and 10.4%) (Table 4).

A previous study showed that the prevalence of mood disorders (major depression, bipolar disorders, and dysthymia) as measured using the DSM criteria in Japanese people 20 years old and older was 3.1% [4]. On the other hand, 37% of the sample in the present study had mild, moderate, or severe depressive symptoms as measured using the ZSDS. People in whom depression is diagnosed using the DSM criteria are probably only a small number of those who report at least some depressive symptoms. In a previous study that also used the ZSDS, the prevalence of mild depressive symptoms among Japanese male workers was 45% [23], which is similar to that in our study.

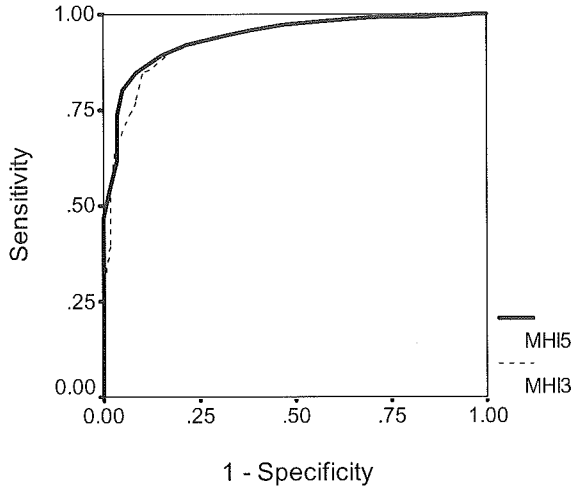

Figure 1
ROC curves of the MHI-5 and MHI-3 for detecting severe depressive symptoms (ZSDS above 55).

In addition to its performance as shown in the present ROC analysis, an advantage of the MHI-5 may be the fact that it is part of the SF-36. The reason is that the possibility of a Hawthorne-type effect (i.e. an effect on study participants that results from their knowing that they are being studied) can be an obstacle to screening for depressive state. Specifically, the subjects' responses on a mental-health screening instrument may be affected by their knowledge that they are subjects in a study of mental health. Embedding the mental-health screening instrument in a more general survey, as the MHI-5 is embedded in the SF-36, could help minimize any such effect.

While the results of this study may be useful for public-health purposes, surveys done in primary-care settings could provide information that is more directly applicable to clinical work. Also, it should be kept in mind that ZSDS scores alone cannot be used to diagnose clinical depression. Studies using psychiatrist-diagnosed depression in addition to ZSDS scores would provide further information about the utility of the Japanese version of the MHI-5.

Another limitation is that the data set was obtained from a 1995 survey. Further studies are needed to confirm the performance of the MHI-5 and MHI-3 using data obtained in recent years.

In conclusion, the MHI-5 and MHI-3 scores were correlated with the ZSDS score, and can be used to identify people with depressive symptoms in the general population of Japan.

List of abbreviations

AUC: area under the ROC curve; MHI-5: the five-item version of the Mental Health Inventory; MHI-3: those 3 of the MHI-5 questions that were thought to be most directly related to depression; ROC: receiver operating characteristic; SF-36: the Medical Outcomes Study 36-Item Short Form Health Survey; ZSDS: the Zung Self-rating Depression Scale.

Authors' contributions

SY: analysis of the data, interpretation of results, manuscript writing; SF: initiation and study design, supervision, collection of data; JG: supervision, interpretation of results, manuscript writing.

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ORIGINAL ARTICLE

Patterns of care for COPD by Japanese physicians

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Objective: COPD treatment guidelines are available worldwide, yet it is not known how widely they are followed. This study evaluated the clinical care of COPD patients in Japan as compared to guideline recommendations.

Methods: A sample of general and specialist physicians was selected from private outpatient clinics and public hospitals in Japan. Physicians were provided two clinical vignettes (COPD and asthma) and asked to make a diagnosis. They were next asked to define diagnostic tests and treatment recommendations specifically for a COPD patient. Responses were compared to recommendations from current COPD guidelines.

Results: For the COPD unknown vignette, 6.2% of physicians diagnosed COPD while 54% diagnosed chronic bronchitis or emphysema. For COPD diagnosis, 81.9% of physicians recommended a CXR, 49.1% spirometry, and 17.7% a computed tomography scan. The most frequently recommended medication for a newly diagnosed COPD patient was theophylline (37.2%) followed by expectorants (32.1%) and inhaled anticholinergics (25.9%). Inhaled beta-agonists were recommended by fewer than 20% of all physicians.

Conclusion: Care for COPD patients by selected Japanese physicians diverges from published practice guidelines. COPD is an infrequently used diagnostic label; diagnostic evaluation is characterized by a high use of computed tomography scans, particularly by specialists; and bronchodilator use was low.

Key words: COPD, clinical practice guidelines, clinical vignettes, Japan, quality of care.

INTRODUCTION

Over the last decade there has been an increasing awareness that patterns of clinical care do not consistently match accepted evidence-based practices as recommended in the scientific literature.[1,2] As a result, medical societies and organizations have issued hundreds of clinical guidelines based upon the belief that dissemination of state-of-the-art knowledge will raise standards and improve the quality of medical care.

COPD represents an important medical condition with both a substantial burden of illness and economic impact.[3,4] Several widely published guidelines, such as those of the World Health Organization's Global Initiative for (Chronic) Obstructive Lung Disease (GOLD), outline appropriate diagnostic and therapeutic interventions for patients with COPD.[5–9] Outside a few countries, however, little is known about clinical practice or adherence to COPD practice guidelines.

While guidelines play a role in improving quality of care, the challenge in most countries has been to effectively translate practice guidelines into patient management. Implementation of guidelines demands a program design that accesses physician

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knowledge, skills and economic incentives and then aligns these with tools that can change practice, optimize health, and lower costs.

Current published evidence, while limited in scope and amount, suggests that clinical practice for COPD deviates from accepted guidelines and exhibits worrisome variations across regions.[10,11] Little objective information, however, exists on the practice patterns for the care of COPD patients across countries.[12] The Japanese Respiratory Society (JRS) first issued practice guidelines in 1999,[5] with the expectation that guidelines would stimulate concerns over practice variation and eventually lead to more effective use of diagnostic tests and treatments. Here, the results from a large survey of Japanese physicians caring for patients with COPD is reported. The results were compared with the JRS guidelines, particularly identifying where practices varied from recommended diagnostic evaluation and treatment.

METHODS

Sample

A sample of 350 Japanese physicians from six of Japan's eight regions was contacted. Both private practitioners, who typically work in outpatient practices, and publicly salaried physicians, who are typically hospital-based, were identified from professional association rosters and from lists of physicians known to provide care to respiratory patients. Physicians were classified as Primary Care (PCs), hospital-based internists (internists), or hospital-based respiratory specialists (specialists). Sampling was further stratified by the size of the community so that the physician sample reflected the population distribution among large cities (population >500 000), medium cities (100 000–500 000), small cities (10 000–100 000), and rural areas (<10 000).

Survey

Practice patterns were evaluated using a structured interview that consisted of two parts. In the first part, two unknown case scenarios or clinical vignettes were completed by physicians. The second part was a structured person-to-person interview conducted by professionally trained interviewers asking questions about attitudes, diagnosis and treatment of COPD. The vignettes were produced by physicians who were knowledgeable in respiratory medicine. The vignettes were based on fictional patients with clinical symptoms and findings consistent with moderate to severe COPD (see Appendix 1). After reading the scenario, physicians were asked to make a diagnosis. For the structured interview, physicians were asked explicitly about diagnostic tests and treatments for a patient known to have COPD.

To avoid biasing physicians' answers to the survey, the unknown vignette was given first with no introduction or reference to COPD or any respiratory conditions. To further avoid bias, vignette responses were open-ended; the structured interview initially asked open-ended questions followed later by closed-ended questions.

Comparison to guidelines

Responses to the structured interview were contrasted with the 1999 JRS guidelines for the following items: defining COPD, ordering diagnostic tests, and specifying appropriate pharmacological management. The JRS guidelines vary from the GOLD guidelines (those in place at the time of this survey) in several important ways (see Appendix 2 for a comparison of key features between JRS and GOLD guidelines). The key variations are that in the JRS guidelines, COPD is defined as a disease producing a ventilatory disorder caused by chronic bronchitis and/or pulmonary emphysema; spirometry is used to define the severity of obstruction but not required to make the diagnosis; CXR and computed tomography (CT) scans are reported to be helpful for diagnosing emphysema; and inhaled anticholinergic agents, either alone or in combination with inhaled beta-agonists, are recommended as first line pharmacological therapy.

Although physicians were also asked about diagnostics and prescription treatment for the undiagnosed case, the comparison to guidelines analysis was performed only for the structured interview responses. This was done to avoid confounding effects of diagnosis with prescribing behaviour. (In the vignette, physician responses to diagnostics and treatments would be conditioned on their response to their diagnosis.)

Statistical analyses

Two sample tests of proportions were used to calculate the statistical significance of difference in responses between any two groups of physicians. Analysis was performed with Microsoft Excel (Microsoft, Bellevue, WA, USA) and STATA (Release 7.0, StataCorp., College Station, TX, USA).

RESULTS

Physician characteristics

Of the 350 contacted physicians (representing 0.14% of physicians in Japan), 226 agreed to participate. The final sample consisted of 150 PCs, 51 internists, and 25 specialists. A total of 20% of physicians in each category were from rural areas. For the hospital-based sample, 34% of physicians practised in small hospitals (100–199 beds); 47% worked in medium-sized hospitals (200–499 beds); and 18% practised in large hospitals (500+ beds). The three physician groups had comparable total patient loads and gender mix. Specialists saw more patients with chronic respiratory problems (60% of their total patients) compared with internists and PCs (12 and

8%, respectively). These differences between specialists and internists/PCs were statistically significant ($P < 0.001$).

Case scenario responses

The diagnostic accuracy for the COPD vignette is presented in Table 1. Separate columns are provided for each of the three physician categories and a fourth column lists the mean response rate by category. Physicians were allowed to list more than one likely diagnosis so the sums may be greater than 100%.

Interpretation of the physicians' diagnostic performance on the unknown vignette was dependent on terminology. Only 6.2% of diagnoses carried the exact term COPD. This low rate was consistent across all three physician types. However, inclusion of the terms COPD, chronic bronchitis or emphysema increased the percentage of physicians making the correct diagnosis to 48.0% of specialists, 74.5% of internists, and 59.3% of PCs. A diagnosis *not* including the terms COPD, chronic bronchitis or emphysema was used by 8.0% of specialists, 2.0% of internists (8% vs 2%, $P > 0.20$), and 16.6% of PCs. The difference between hospital-based physicians and PCs was significant ($P < 0.01$).

When asked if making the diagnosis of COPD was difficult, responses varied by physician type. A total of 46% of PCs felt making the diagnosis was difficult, due primarily to a lack of spirometry. One-third of internists felt the diagnosis was difficult, predominantly due to difficulty distinguishing COPD from other conditions. Only 6% of internists cited lack of spirometry as a reason for this difficulty. Only 16% of specialists felt the diagnosis was difficult, most commonly reporting that it was because the standards for diagnosis were inadequate. None of the specialists cited lack of spirometry.

Structured interview for chronic obstructive pulmonary disease diagnosis

Tables 2 and 3 present results from the structured interview. Responses represent the primary diagnostic tests and treatments that physicians typically would order or prescribe for a COPD patient. A CXR was the preferred diagnostic test across all physician types (81.9%). Spirometry was utilized in nearly half of the cases (49.1%), but more so by hospital-based physicians (88% of specialists, 63% of internists). Nearly 20% of all physicians used CT scans in their diagnostic evaluation with more than half of the specialists using CT scans as the primary test for COPD diagnosis.

Table 3 contains physicians' treatment recommendations for a COPD patient at the time of initial diagnosis and in chronic management. The majority of physicians agreed that COPD is difficult to treat (56% of specialists; 82% of internists; 73% of PCs). Overall, physicians prescribed theophylline and expectorants for approximately one-third of cases, despite the fact that these agents are only recommended by the JRS when patients are unable to use inhaled agents. Anticholinergics, which are recommended as the first-line pharmacological therapy, were the third most commonly prescribed agents. Specialists (84%) used anticholinergics far more than internists or PCs. Antibiotics were commonly used (20.1% of physicians for chronic COPD and 16.4% for newly diagnosed COPD). Use of inhaled beta-agonists was limited (<20%) across all physician types.

Table 1 Frequency of most likely diagnosis for the COPD case scenario

Diagnosis	Specialists	Internal medicine	Primary care	Total
Includes COPD, CB or E	92.0%	98.0%	83.4%	87.6
COPD	4.0	5.9	6.7	6.2
COPD w/chronic bronchitis or emphysema (C/CB/E)	4.0	0.0	1.3	1.3
Chronic bronchitis or emphysema	40.0†	68.6§	51.3	54.0
C/CB/E w/asthma	24.0	11.8	11.3	12.8
C/CB/E w/other	20.0	11.8	12.7	13.3
Does not include C, CB or E	8.0	2.0	16.6	12.4
Asthma	8.0¶	2.0¶	5.3††	4.9
Other‡‡	0.0‡	0.0§	11.3††	7.5

†Difference between specialists and internists is significant ($P < 0.05$).
‡Difference between specialists and primary care physicians (PCs) is significant ($P < 0.05$).
§Difference between internists and PCs is significant ($P < 0.05$).
¶Difference between specialists and internists is not significant ($P > 0.20$).
††Difference between specialist/internists and PCs is significant ($P < 0.01$).
‡‡Other includes lung cancer, pneumonia, heart failure, upper respiratory infection.
C, COPD (chronic obstructive pulmonary disease); CB, chronic bronchitis; E, emphysema.

Table 2 Primary diagnostic tests required for a COPD diagnosis

Test	Specialist	Internal medicine	Primary care	Total
CXR	60†‡	86	84	81.9
Spirometry	88†‡	63§	38	49.1
CT scan of chest	52†	29§	8	17.7
Arterial blood gas	16	28§	10	14.6
Pulse oximetry	4†	22§	9	11.3
Electrocardiogram	12	16	15	14.8
Peak flow measurement	16	14	7	9.5
Blood test	4	18	13	13.0
Breathing capacity	8	14	8	9.3

In these responses, physicians were allowed to report more than one test and so column totals are therefore more than 100%.

†Difference between specialists and internists is significant ($P < 0.05$).

‡Difference between specialists and primary care physicians (PCs) is significant ($P < 0.05$).

§Difference between internists and PCs is significant ($P < 0.05$).

CT, computed tomography.

Table 3 Recommended medications for COPD stages/events

Medication	Specialists	Internal medicine	Primary care	Total
Treatments for newly diagnosed COPD				
Antibiotics	8.0‡	3.9§	22.0	16.4
Anticholinergics—inhaled	84.0†‡	29.4§	15.0	25.9
Beta-2 agonists—inhaled	20.0‡	11.8	6.0	8.9
Beta-2 agonists—oral	20.0	9.8	18.0	16.4
Expectorants	8.0†‡	35.3	35.0	32.1
Steroid—inhaled	4.0	5.9	6.0	5.8
Steroid—injection	0.0	0.0	0.0	0.0
Steroid—oral	0.0	0.0	0.0	0.0
Theophyllines—oral	48.0‡	58.8§	28.0	37.2
Treatments for management of chronic COPD				
Antibiotics	8.0‡	17.6	23.0	20.1
Anticholinergics—inhaled	84.0†‡	25.5	19.0	27.7
Beta-2 agonists—inhaled	20.0‡	15.7§	5.0	9.1
Beta-2 agonists—oral	12.0	13.7	17.0	15.7
Expectorants	8.0†‡	41.2	33.0	32.1
Steroid—inhaled	24.0‡	15.7	9.0	12.2
Steroid—injection	0.0	0.0	0.0	0.0
Steroid—oral	0.0	0.0	0.0	0.0
Theophyllines—oral	48.0‡	49.0§	27.0	34.3

†Difference between specialists and internists is significant ($P < 0.05$).

‡Difference between specialists and primary care physicians (PCs) is significant ($P < 0.05$).

§Difference between internists and PCs is significant ($P < 0.05$).

COPD, chronic obstructive pulmonary disease.

DISCUSSION

This report describes practice patterns for COPD from a broad cross-section of providers in Japan. Overall, there is a wide variation of reported practices in Japan compared to the JRS guidelines. The lack of adherence to COPD guidelines seen in this study is similar to what has been demonstrated in other countries.[12–14] Some of the practice variation may reflect distinctive attributes of the Japanese health-care setting. Other deviations, however, more likely reflect the global challenge of implementing guidelines to effectively alter physician care practice.[13,14]

Overview of the Japanese health-care system

The Japanese health-care system is characterized by unique features that impact on practice patterns.

Understanding these features may be helpful in assessing the results of this investigation.

Japan has had universal coverage (i.e. the government sets all health-care prices, including physician fees, drug and hospital charges). There is only one single universal fee schedule and fees apply universally to all patients regardless of who provides care. Doctors and hospitals are paid on a fee-for-service basis. The fee schedule is complex, with approximately 3000 prices covering various procedures, each having detailed billing rules. A national claims survey regularly analyzes the volume of procedures that are performed. The government changes the fee schedule after each review, to control overall costs. Prices of new drugs and procedures are not set according to actual cost, but at the price of an existing comparable drug or procedure.

Medication costs are reimbursed on a fee-for-service basis. Doctors in private practice are allowed to dispense medications in their office. Patients, therefore, often visit the doctor for the sole purpose of filling a prescription. Physicians receive a dispensing fee for this service.

Hospitals are divided into two categories: larger hospitals, which are often affiliated with academic institutions, and smaller private facilities. Two-fifths of the hospitals are small (less than 100 beds) and are effectively extensions of clinics. These smaller hospitals are owned and managed by individual doctors. Specialists practice almost exclusively in large hospitals and tend to spend their entire professional lives working in the hospitals, which are affiliated with university clinical departments.

Accessibility to equipment used for diagnosing COPD varies. Spirometry is not readily available to all physicians. However, CT scanning equipment is frequently available even in smaller private hospitals and sometimes in physicians' offices.

Implications of the study

The findings from this study demonstrate confusion in terminology with respect to the definition of COPD. Few physicians in this study used the term 'COPD', preferring to use the terms chronic bronchitis or emphysema. These results are consistent with those of a Canadian study of PCs in private practice.[15] Using a different COPD case scenario, only 16% of Canadian physicians listed COPD as the diagnosis. An unknown COPD vignette given to US physicians in another study revealed that just over half of physicians made the correct diagnosis.[7] These findings support the general observation that misdiagnosis may be especially common in COPD.[3] This may be compounded by a significant 'overlap' in diagnosis with other respiratory conditions, such as asthma, and likely contributes to misdiagnosis, inappropriate treatment and inadequate evaluation of these patients.[16,17]

Availability of tests, procedures or treatments listed in a guideline is another important factor in ensuring successful implementation of guidelines. Lack of access to spirometry was cited by more than one-quarter of physicians in this study, and appears to contribute to the finding that only half of all physicians used spirometry.[18] The under-utilization of spirometry certainly contributed to the observed under-diagnosis of COPD in this study. These findings regarding spirometry are consistent with patterns observed elsewhere. A 1998 US study, which examined health plan records, found that only 25%–45% of patients with COPD had a history of having their spirometry assessed. A similar pattern was found in a Canadian study.[10,15] In addition to access to diagnostic equipment, another possible contributing factor to the relatively low use of spirometry in Japan is the apparent lack of understanding of the central role of spirometry in the identification of obstructive lung disease.

The use of CT scans, which the JRS guidelines allow for the assessment of emphysema, provides a contrast to spirometry. In this survey, CT scans were recommended for COPD diagnosis by nearly 20% of the physicians, including half of the specialists. There may be several reasons for this. In Japan, three times the number of CT scans are performed as in the USA, and unlike other countries, CT scans are commonly performed in the office setting.[19] In addition to its availability, the reimbursement system in Japan potentially provides an incentive to use this procedure instead of spirometry.[18,20] CT scanning provides a reimbursement of 13 300 Yen (inclusive of the radiologists fee) compared to 3000 Yen for spirometry.[21] Another factor may be the clinical tradition that has relied on imaging instead of physical function. CT is considered by physicians to be particularly useful for screening for lung cancer.

Arguably, overcoming local barriers is one of the most important factors in the successful implementation of guidelines.[22–26] One important barrier is continued adherence to older standards of care in the face of new guidelines or scientific evidence. In this study, treatment for COPD did not match JRS guidelines. Even when provided with the diagnosis, only one-fourth of physicians recommended anticholinergics, a first-line agent according to the JRS and GOLD guidelines. The second-line agent, theophylline, and non-recommended expectorants were used by more physicians overall. These results are consistent with other reports in the literature.[11] A 1996 study on a representative sample of the US population showed that 25% of COPD patients still received theophylline, while only 5% received anticholinergics.[12] This was after the 1995 American Thoracic Society guidelines recommended anticholinergics, and after an important article in 1993 emphasized the role of anticholinergics in COPD management.[7,27] In Japan, cultural issues may play a role in physician practice patterns. Use of inhalers, for example, conflicts with cultural pressures to avoid public displays of disability.[28] This suggests that educational efforts are needed to overcome these barriers of patient preferences and perceptions.

Overall, hospital-based specialists performed similarly to internists with respect to making an appropriate diagnosis, but out-performed both internists and primary care physicians in recommending spirometry as a diagnostic technique, and in the use

of anticholinergics for treatment. The present study was unable to discern if this difference was due to differences in educational knowledge or differences related to the hospital versus private office practice setting. Primary care physicians, but not internists, indicated a lack of access to spirometry, which could partly explain some of the difference in diagnostic testing results. Awareness of current treatment guidelines is a likely reason for differences in drug recommendations.

This study has several limitations. First, these results are derived from self-reports of actual clinical practice. It is possible that the quality of clinical care may be overstated. A recent study, however, has shown that clinical vignettes are significantly better than chart abstraction at measuring actual clinical practice, and are acceptable as a method of measuring practice patterns.[29] Physicians assessed by the use of vignettes do not appear to overestimate actual practice: vignette scores are generally lower than scores observed in standardized patient visits. Second, the survey format allows physicians ample time to deliberate on their responses. In contrast, actual patient visits in Japan are very short and physicians have little time for deliberation. A third limitation is that the response rate was 65% from a convenience sample of physicians. Thus, it is possible that the responses are not totally representative of all practitioners in Japan. The results did not allow a comparison of the characteristics of physician practice types and the locations of participants and nonparticipants. It is possible that an inherent bias may have existed in regard to those physicians who were willing to participate in the study. Another limitation is the lack of rigorous validation of the clinical vignettes. However, pulmonary experts believed the clinical features clearly distinguished COPD as the primary diagnosis. Lastly, there were no direct questions asked about the impact of reimbursement programs and cultural issues on reported diagnostic and treatment patterns. Inferences made about factors contributing to divergence from guidelines are derived from knowledge concerning the unique aspects of the Japanese health-care system.

Improving the quality of medical care begins with an accurate assessment of physician practice. In this study, the diagnosis and care of COPD patients in Japan diverged from guidelines. In part, differences appear to be due to a lack of knowledge as evidenced by the responses to a known case of COPD. In a clinical setting, where the diagnosis is not known or not suspected, prior evaluation and treatment are likely to be worse. Care that falls short of adherence to accepted clinical guidelines cannot solely be attributed to a lack of physician ability or knowledge.[5,30] Other factors such as reimbursement incentives and cultural issues play a role. Future international evaluations would be helpful in highlighting the degree to which other countries diverge from published guidelines. Future studies also need to assess environmental factors and intervention strategies that will overcome local barriers that appear to inhibit the alignment of recommendations based on the scientific literature with clinical practice.

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APPENDIX 1

English translation of the text for the chronic obstructive pulmonary disease case scenario

Mr F.Y. is a 65-year-old gentleman who complains of a bothersome, productive cough for the past 2 days. The productive cough has been present for at least the last 5 years, but it was mild and usually present only in the morning. However, it has now become worse. He also has severe shortness of breath. The patient has no history of allergy. He has a 20 pack-year history of smoking. Clinical examination of the patient reveals a patient with moderate to severe dyspnoea and marked tachycardia and tachypnoea. A wheeze is apparent and there are scattered rhonchi on auscultation. There are no other significant findings.

APPENDIX 2

Comparison of features of Global Initiative for (Chronic) Obstructive Lung Disease and Japanese Respiratory Society guidelines

Feature	GOLD guidelines[1†]	JRS guidelines[1]
Definition	COPD is characterized by airflow limitation that is not fully reversible. The definition does not use the terms chronic bronchitis or emphysema.	COPD is a condition characterized by airflow obstruction associated with chronic bronchitis or pulmonary emphysema.
Diagnostic tests	A diagnosis of COPD should be considered in an individual who presents with characteristic symptoms and a history of exposure to risk factors. The diagnosis should be confirmed by spirometry and the level of severity determined. Other tests should be undertaken in a patient with moderate to severe COPD: bronchodilator reversibility testing, inhaled glucocorticosteroid trial; CXR; arterial blood gas; alpha-1 antitrypsin deficiency screening.	CXR cannot diagnose chronic bronchitis, but 80% of emphysema cases have characteristic changes. Low attenuation CT scan reflects changes due to emphysema. Spirometry shows characteristic features of emphysema: obstructive ventilatory disorder, abnormal lung elasticity, decreased CO diffusion, abnormal arterial blood gases
Management of stable COPD	Smoking cessation to slow disease progression. Bronchodilators are central to symptom management. Choice between beta-2 agonists, anticholinergics and methylxanthines depends on availability of medications and patient response. Inhaled bronchodilators preferred over theophylline. Inhaled glucocorticosteroids for selected patients with spirometric responses to these agents or for patients with recurrent acute exacerbations requiring antibiotics and oral glucocorticosteroids. Mucolytics and regular use of antitussives not recommended. Influenza vaccine. Rehabilitation, long-term oxygen therapy in respiratory failure, and surgical treatment for selected patients.	Smoking control, improved nutrition, rehabilitation and appropriate oxygen therapy. Inhaled anticholinergic agents are first-line. If symptoms are not controlled, add inhaled beta-2 agonist. If symptoms not controlled, add oral theophylline. If symptoms not controlled, add corticosteroid. If there is heavy sputum, expectorant may be used. Influenza and pneumococcal vaccines.

[†]At the time of this study.
CT, computed tomography.

〈原　著〉

入院患者用患者満足度尺度の開発
－下位尺度と項目の再設定と再検証：HPSQ-25からHPSQ-13へ－

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Reappraisal and Sequential Development of the measures of patient satisfaction for hospitalized patients : From HPSQ-25 to HPSQ-13

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要　旨

平成14年にわれわれが作成した入院患者用患者満足度評価尺度であるHPSQ-25は，信頼性・妥当性に優れた評価尺度であったが，6つの下位尺度に関する因子構造分析の結果，因子をよりシンプルなものに変更する必要性があることが示唆されていた．今回，HPSQ-25の再構築と，より簡便な尺度への質問項目削減を試みた．関東地区の3医療施設における入院患者386名に対し再度HPSQ-25による患者満足度評価を行い，その後，一定のルールを用いて項目の削減を行った．その結果，前年度で問題とされていた4つの因子はすべて“スタッフと患者の間のコミュニケーション”という1つの概念に収束し，4つの因子における合計17の質問項目は6つの質問項目にまで収束させることが可能であった．その結果，新たに再構築された入院患者用患者満足度評価尺度は，13項目3下位尺度のより簡便なものとなった．新たな尺度の信頼性・妥当性の検証も行い，満足すべき結果を得ることができた．

Key words：患者満足度，アウトカム評価，入院患者

はじめに

近年，患者立脚型アウトカムとして，健康関連QOLや患者満足度を定量することで，医療の質を評価する動きが高まってきている[1) 2)]．健康関連QOLの定量と測定に関しては，世界的にも評価の目的別にコンセンサスが生まれつつあり，SF-36などの評価尺度は臨床や研究においても多く用いられている[3) 4)]．一方，患者満足度の定量は，その概念整理の難しさや，評価の目的によってその概念が一定しないなどの問題のために，評価のスタンダードとなるような尺度を開発することが難しい現状にある[5)]．そのため，病院への入院患者など，より焦点を絞った母集団に対して使用することを前提とした評価尺度の開発が望まれている[6)]．

平成14年，われわれは，病院における入院患者への医療サービスを測定するアウトカム指標としての患者満足度評価尺度であるHospital Patient Satisfaction Questionnaire-25（HPSQ-25）の開発を試み，その心理計量学的特性について検証を行った[7)]．HPSQ-25は，過去の文献や現場での質的データから評価項目のプールを作り，膨大なプールから，評価項目と患者満足の構成因子を探索することによって，6因子25項目の質問項目のセットにまとめあげたものであり，信頼性や妥当性においても一定の基準を満たすものであった．しかしながら，因子分析において，6因子中の，“人間的側面”，“コミュニケーション”，“情報伝達”，および“技術的評価”の下位尺度に，概念的な因子の広がり，因子間での明確な差異を認めることができなかった．これは，下位尺度の因子項目が無駄に多いことを意味しており，因子項目，質問項目の削減の必要性を示唆させる結果となった[7)]．

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