

area in Japan, we identified all hospitals in the study areas by examining hospital lists from the Japan Hospital Association, the largest authorized organization of hospitals in Japan, and the local resource information. Of 54 hospitals identified, we excluded 20 hospitals primarily treating psychiatric, rehabilitation, and geriatric noncancer patients. We approached the remaining 34 hospitals (11,033 beds), and a total of 23 hospitals (8964 beds, 81%) participated in this survey: three hospitals in Tsuruoka, seven hospitals in Kashiwa, eight hospitals in Hamamatsu, and five hospitals in Nagasaki.

### *Patients*

Inclusion criteria for patients in this study were 1) adult cancer patients with a primary tumor site in either the lung, esophagus, stomach, colon, rectum, pancreas, liver, biliary system, kidney, prostate, bladder, breast, ovary, or uterus; 2) presence of metastatic or recurrent cancer; 3) outpatient visits to the oncology or specialty division, such as respiratory medicine for lung cancer patients, between April and June 2008 (not the palliative care division only); and 4) informed of malignancy. We excluded malignancies of the brain, blood, central nervous system, neck, soft tissue, and other uncommon primary sites because of the infrequent prevalence and increased technical difficulties in patient recruitment. Only patients who had been informed of their diagnosis were recruited because we used the term “cancer” in the questionnaire. Exclusion criteria included 1) incapacity of the patient to complete the questionnaire (dementia, cognitive failure, or psychiatric illness); 2) severe emotional distress in the patient as determined by the principal treating physician; 3) poor physical condition leading to inability to complete the questionnaire; and 4) language difficulty or visual loss. Patients were recruited consecutively, with hospitals either sending each eligible patient a questionnaire by mail or delivering it directly by hand to the patient.

### *Measurements*

Data were collected on 1) pain intensity, 2) quality of life, 3) patient-perceived quality of palliative care, and 4) satisfaction.

*Pain Intensity.* Pain intensity was measured using the Japanese adaptation of the Brief Pain Inventory (BPI), with a score given for the pain at its worst (0–10), at its least (0–10), and a score for the average pain felt (0–10) in the previous 24 hours.<sup>18</sup> The reliability and validity of the BPI in Japanese populations has been established.<sup>18</sup> We did not collect the data about other variables (e.g., current pain) or pain medication because of patient burden and cost.

*Quality of Life.* Quality of life was measured using the Good Death Inventory (GDI) (short version).<sup>19,20</sup> The GDI was developed to specifically measure quality of life for Japanese patients with advanced cancer.<sup>19,20</sup> We used the GDI, not common tools such as the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire or the Functional Assessment of Cancer Therapy scale, because we intended to investigate broader areas of quality of life that Japanese patients regard as important, especially psycho-existential components beyond physical or functional areas. The full version of the GDI scale consists of 10 domains (three items for eight domains and two items for two domains) with a seven-point Likert-type scale from “1: strongly disagree” to “7: strongly agree:” physical and psychological comfort, living in a favorite place, maintaining hope and pleasure, having a good relationship with medical staff, not feeling a burden to others, having a good relationship with family, having independence, having environmental comfort, being respected as an individual, and a feeling of fulfillment at life’s completion. For this study, we adopted the shortened version, in which each domain had one item (i.e., a total of 10 domains with 10 items). The reliability and the validity of both versions have been established.<sup>19,20</sup> The total score of the GDI was calculated as the total score of 10 items, potential ranges of 7–70, with higher scores indicating respondents who felt they had greater quality of life. In addition, we investigated the full three items for the “physical and psychological comfort” domain to allow detailed investigation of this attribute.

*Patient-Perceived Quality of Palliative Care.* Patient-perceived quality of palliative care was measured using the Care Evaluation Scale (CES). The CES

is a well-validated and commonly used measurement tool in Japan to quantify the level of patient- or family-perceived need for improvements in palliative care.<sup>16,21,22</sup> The full version of the CES comprises eight subscales (three items for seven domains and two items for one domain), with a six-point Likert-type scale from “1: improvement is not necessary at all” to “6: highly necessary:” physical care provided by physicians, physical care provided by nurses, psycho-existential care, help with decision making, coordination/consistency of care, environment, availability, and cost. For this study purpose, we used the first five subscales (15 items), because the study aim focused on interpersonal areas, not social areas (i.e., environment, availability, and cost). The reliability of the validity of each subscale has been established.<sup>21,22</sup> Each subscale score was calculated as an average of the items belonging to the subscale, and the total score was calculated as an average of subscale scores. All scores are proportionally adjusted to range from 0 to 100, following the original studies,<sup>21,22</sup> and thus higher values indicate lower perception of necessity for improvement.

*Satisfaction and Demographic Data.* Satisfaction with medical care was measured using a single-item scale: “Are you satisfied with the medical care you currently receive?” As in a previous study,<sup>16</sup> patient responses were selected from a six-point Likert-type scale varying from “1: very dissatisfied” to “6: very satisfied.”

Background data obtained from patients included age, gender, living status, marital status, working status, levels of daily activity, and whether they were receiving radiotherapy or chemotherapy. To measure levels of daily activity, patients evaluated their own Eastern Cooperative Oncology Group performance status: 0 (no symptoms, able to carry on all activities without restrictions), 1 (mild symptoms but ambulatory and able to carry out work of a light or sedentary nature), 2 (ambulatory and capable of self-care for more than 50% of their waking hours), 3 (lying in a bed or sitting in a chair for more than 50% of their waking hours), and 4 (lying in a bed or sitting in a chair for the entire day).<sup>23</sup> The primary sites of medical care for patients were obtained from their medical charts.

### *Statistical Analyses*

As our primary aim was to understand the overall patient experience and no universal cut-off points exist, data distributions were analyzed for each item, not using the mean values or summary values. The difference among the regions of primary endpoints was not statistically significant, and we therefore report all the data.

For comparisons, pain intensity was classified into four groups following the previous systematic review: no pain, 0; mild, 1–4; moderate, 5–6; severe, 7 or more.<sup>6</sup> In addition, the proportion of the patients with pain of 5 or more was calculated as “substantial pain” to compare the results with other studies.<sup>7,8</sup>

Pain intensity, total score for the GDI, total score for the CES, and satisfaction were compared among groups of patients with different backgrounds and from different regions. Univariate analyses were performed using the Student’s *t*-test and using the analysis of variance with the Scheffé’s test, where appropriate. To explore the correlations among pain intensity, quality of life, quality of palliative care, and satisfaction, we calculated the Spearman’s correlation coefficients among these variables.

### *Results*

Of 1880 patients who met the inclusion criteria, 182 patients were excluded because of 1) incapacity of the patient to complete the questionnaire as a result of dementia, cognitive failure, or psychiatric illness ( $n = 87$ ), 2) severe emotional distress ( $n = 48$ ), 3) poor physical condition ( $n = 28$ ), 4) language difficulty or visual loss ( $n = 5$ ), and 5) unspecified reasons ( $n = 14$ ). During the study, 75 patients died, were admitted, or changed hospitals; and responsible physicians were unavailable for technical reasons for 30 patients. In addition, 100 patients refused to receive the questionnaire. Questionnaires were, therefore, sent to 1493 patients; five were returned because of an incorrect address. A total of 859 responses (58%) were obtained. Table 1 summarizes the patient backgrounds.

#### *Pain Intensity*

Approximately, 60% of patients reported some level of pain, with approximately 20%

Table 1  
Patient Characteristics (n = 859)

Characteristic	n	%
Gender (male, %)	471	55
Mean age (standard deviation [SD])	67 (11)	
Primary tumor sites		
Lung	221	26
Breast	148	17
Colon, rectum	131	15
Prostate	86	10
Stomach	75	8.7
Liver	39	4.5
Pancreas	30	3.5
Bladder	25	2.9
Uterus	24	2.8
Ovary	21	2.4
Esophagus	19	2.2
Bile duct	12	1.4
Kidney	11	1.3
Others	16	1.9
Living arrangement		
Not alone	784	91
Alone	66	7.7
Marital status		
Married	695	81
Divorced	100	12
Not married	49	5.7
Working		
Not working	657	77
Full time	120	14
Part time	65	7.6
Performance status		
0	243	28
1	371	43
2	181	21
3	37	4.3
4	14	1.6
Chemotherapy and/or radiotherapy		
Receiving	498	58
Not receiving	343	40

The percentages do not sum to 100% because of missing values.

reporting moderate to severe pain (Table 2). If the cut-off points are determined as 5, 17% of patients had a pain intensity of 5 or more for their worst pain in the previous 24 hours, and 11% of patients had this pain level as the average in the previous 24 hours.

### Quality of Life

For the items of the GDI (Table 3), more than 70% of the patients “agreed” or “strongly

agreed” with living in a favorite place (74%), having a good relationship with medical staff (77%), having independence (77%), having environmental comfort (71%), and being respected as an individual (73%). More than half but less than 60% of patients “agreed” or “strongly agreed” with “free from physical distress” (58%), free from emotional distress (52%), maintaining hope and pleasure (53%), and feeling of fulfillment at life’s completion (51%). Furthermore, approximately 50% of the patients “slightly agreed,” “agreed,” or “strongly agreed” with the statement “I feel a burden to others.”

### Quality of Palliative Care and Satisfaction

Approximately, 20% of patients reported that improvement is “necessary,” “substantially necessary,” or “highly necessary” in all five subscales: physical care by physicians, physical care by nurses, psycho-existential care, help with decision making, and coordination/consistency of care (Table 4).

Satisfaction levels were strongly dissatisfied in 1.0% (n = 9), dissatisfied in 2.2% (n = 19), slightly dissatisfied in 9.5% (n = 82), slightly satisfied in 27% (n = 229), satisfied in 49% (n = 417), and strongly satisfied in 10% (n = 88).

### Comparisons Among Patients With Different Backgrounds and From Different Regions

Analysis of patient background data showed working status was significantly associated with intensity of pain, and total score from the GDI (Table 5). Patient-reported performance status was significantly associated with pain intensity, total score for the GDI, total score for the CES, and satisfaction levels. Intergroup difference existed in performance status 0 vs. 1–4, 1 vs. 2–4 (pain intensity); 0 vs. 1–4, 1 vs. 2–4, 2 vs. 3, 4 (GDI); 0 vs. 2, 3 (CES); and 0 vs. 1, 2, 4 (satisfaction). There were no statistically significant differences in these outcomes among the regions (Table 5).

Table 2  
Pain Intensity Measured by the BPI

BPI Item	No Pain	Mild (1–4)	Moderate (5–6)	Severe (7–10)
Worst pain	43% (n = 373)	36% (n = 312)	8.5% (n = 73)	7.7% (n = 66)
Average pain	43% (n = 371)	42% (n = 363)	7.5% (n = 64)	2.7% (n = 23)
Least pain	51% (n = 435)	40% (n = 347)	2.9% (n = 25)	1.4% (n = 12)

The percentages do not sum to 100% because of missing values.

Table 3  
Quality of Life Measured by the GDI

Items in the GDI	Strongly Agree	Agree	Slightly Agree	Unsure	Slightly Disagree	Disagree	Strongly Disagree
<i>Physical and psychological comfort</i>							
Free from pain	25% (n = 216)	43% (n = 370)	12% (n = 104)	6.2% (n = 53)	4.4% (n = 38)	3.4% (n = 26)	2.2% (n = 19)
Free from physical distress	18% (n = 158)	40% (n = 346)	16% (n = 139)	8.6% (n = 74)	5.6% (n = 48)	4.4% (n = 38)	2.6% (n = 22)
Free from emotional distress	17% (n = 145)	35% (n = 301)	20% (n = 172)	11% (n = 91)	6.8% (n = 58)	4.9% (n = 42)	1.7% (n = 15)
<i>Living in a favorite place</i>							
Able to stay at favorite place	29% (n = 251)	45% (n = 384)	9.4% (n = 81)	6.3% (n = 54)	2.0% (n = 17)	2.2% (n = 19)	1.2% (n = 10)
<i>Maintaining hope and pleasure</i>							
Have some pleasure in daily life	19% (n = 162)	34% (n = 291)	16% (n = 139)	11% (n = 92)	5.7% (n = 49)	5.5% (n = 47)	2.7% (n = 23)
<i>Good relationship with medical staff</i>							
Trust the physician	37% (n = 316)	40% (n = 347)	11% (n = 93)	4.3% (n = 37)	2.1% (n = 18)	0.8% (n = 7)	1.3% (n = 11)
<i>Not being a burden to others</i>							
Feeling a burden to others	11% (n = 97)	19% (n = 159)	24% (n = 202)	9.1% (n = 78)	8.4% (n = 72)	13% (n = 115)	9.7% (n = 83)
<i>Good relationship with family</i>							
Spend enough time with family	28% (n = 241)	38% (n = 328)	13% (n = 109)	8.7% (n = 75)	3.6% (n = 31)	2.6% (n = 22)	1.6% (n = 14)
<i>Independence</i>							
Independent in daily activities	39% (n = 336)	38% (n = 327)	9.4% (n = 81)	3.5% (n = 30)	2.3% (n = 20)	1.7% (n = 15)	2.3% (n = 20)
<i>Environmental comfort</i>							
Live in calm circumstances	30% (n = 253)	41% (n = 349)	14% (n = 122)	5.9% (n = 51)	1.9% (n = 16)	1.6% (n = 14)	2.1% (n = 18)
<i>Being respected as an individual</i>							
Being valued as a person	29% (n = 245)	44% (n = 379)	12% (n = 103)	7.1% (n = 61)	1.2% (n = 10)	1.0% (n = 9)	1.5% (n = 13)
<i>Life completion</i>							
Feels that his or her life is fulfilling	21% (n = 177)	30% (n = 260)	17% (n = 147)	15% (n = 129)	6.6% (n = 57)	3.3% (n = 28)	2.4% (n = 21)

The percentages do not sum to 100% because of missing values.  
Domain names in italics.

Table 4  
Patient-Reported Quality of Palliative Care as Measured by the CES

Items in the CES	Improvement Is:					
	Not Necessary	Rarely Necessary	Somewhat Necessary	Necessary	Considerably Necessary	Highly Necessary
<i>Physical care by physicians</i>						
Tried to relieve physical discomfort	17% (n = 149)	38% (n = 325)	17% (n = 149)	16% (n = 135)	5.7% (n = 49)	1.6% (n = 14)
Dealt promptly with symptoms	19% (n = 164)	36% (n = 308)	17% (n = 144)	16% (n = 133)	5.2% (n = 45)	2.4% (n = 21)
Had adequate knowledge and skills	21% (n = 182)	34% (n = 290)	15% (n = 126)	15% (n = 131)	5.4% (n = 46)	2.7% (n = 23)
<i>Physical care by nurses</i>						
Responded promptly to needs	18% (n = 151)	35% (n = 296)	20% (n = 174)	14% (n = 122)	4.2% (n = 36)	1.5% (n = 13)
Had adequate knowledge and skills	14% (n = 122)	35% (n = 297)	23% (n = 193)	14% (n = 123)	4.4% (n = 38)	1.2% (n = 10)
Helped the patient to enjoy daily life	16% (n = 134)	35% (n = 297)	21% (n = 185)	16% (n = 134)	3.4% (n = 29)	0.9% (n = 8)
<i>Psycho-existential care</i>						
Helping to relieve concerns	17% (n = 148)	35% (n = 302)	22% (n = 185)	15% (n = 126)	4.7% (n = 40)	0.6% (n = 5)
Appropriate when depressed	16% (n = 134)	37% (n = 316)	21% (n = 182)	14% (n = 116)	5.1% (n = 44)	1.0% (n = 9)
Tried to keep the patient hopeful	18% (n = 158)	36% (n = 306)	20% (n = 168)	14% (n = 116)	5.5% (n = 47)	1.0% (n = 9)
<i>Help with decision making</i>						
Sufficient explanation about the current condition	23% (n = 197)	30% (n = 257)	20% (n = 175)	13% (n = 109)	7.1% (n = 61)	3.3% (n = 28)
Sufficient explanation about the expected outcome	15% (n = 130)	33% (n = 284)	25% (n = 211)	12% (n = 104)	7.2% (n = 62)	2.3% (n = 20)
Patient could participate in the selection of treatment	21% (n = 178)	35% (n = 296)	19% (n = 164)	13% (n = 113)	4.3% (n = 37)	2.1% (n = 18)
<i>Coordination/consistency of care</i>						
Cooperation among staff members	17% (n = 148)	36% (n = 305)	18% (n = 153)	15% (n = 125)	4.7% (n = 40)	1.6% (n = 14)
Same doctors and nurses provided care	23% (n = 201)	33% (n = 281)	15% (n = 131)	16% (n = 136)	4.1% (n = 35)	1.7% (n = 15)
Planned with consideration for the previous course of the disease	20% (n = 171)	33% (n = 287)	18% (n = 155)	12% (n = 104)	4.5% (n = 39)	1.6% (n = 14)

The percentages do not sum to 100% because of missing values.  
Domain names in italics.

Table 5  
Comparisons of Patient Backgrounds and Patient-Reported Pain Intensity, Quality of Life, Quality of Palliative Care, and Satisfaction

Patient Backgrounds	Pain Intensity (Worst Pain in Previous 24 hours)		GDI		CES		Satisfaction	
	Mean ± SD	P	Mean ± SD	P	Mean ± SD	P	Mean ± SD	P
Gender								
Male (n = 471)	1.8 ± 2.4	0.35	55 ± 9.5	0.84	68 ± 21	0.27	4.6 ± .97	0.48
Female (n = 374)	2.0 ± 2.5		55 ± 9.2		70 ± 20		4.5 ± .95	
Age								
Patient 75 years or older (n = 246)	2.0 ± 2.5	0.48	54 ± 10	0.18	69 ± 21	0.76	4.7 ± .90	0.004
Patient <75 years (n = 601)	1.8 ± 2.5		55 ± 9.0		69 ± 20		4.5 ± .98	
Primary tumor site								
Lung (n = 221)	1.9 ± 2.6	0.47	54 ± 9.5	0.79	69 ± 21	1.00	4.5 ± .9	0.93
Breast (n = 148)	1.9 ± 2.4		56 ± 9.1		69 ± 19		4.6 ± .9	
Colon, rectum (n = 131)	1.6 ± 2.3		55 ± 9.0		69 ± 21		4.6 ± 1.0	
Stomach (n = 75)	2.1 ± 2.7		55 ± 9.2		69 ± 20		4.5 ± 1.0	
Liver, pancreas, bile duct (n = 81)	2.1 ± 2.7		54 ± 8.3		69 ± 23		4.5 ± 1.1	
Prostate (n = 86)	1.4 ± 2.0		56 ± 11		68 ± 21		4.5 ± .9	
Urogenital (n = 81)	2.0 ± 2.6		54 ± 8.9		70 ± 21		4.4 ± 1.0	
Living								
Not alone (n = 784)	1.9 ± 2.5	0.80	55 ± 9.2	0.20	69 ± 20	0.029	4.5 ± .95	0.77
Alone (n = 66)	1.9 ± 2.6		53 ± 9.5		63 ± 23		4.5 ± 1.0	
Marriage status								
Married (n = 695)	1.8 ± 2.5	0.35	55 ± 9.3	0.24	70 ± 20	0.23	4.5 ± .95	0.15
Divorced (n = 100)	2.0 ± 2.4		53 ± 10		66 ± 23		4.6 ± .89	
Not married (n = 49)	2.3 ± 2.7		55 ± 8.0		67 ± 22		4.3 ± 1.2	
Working								
Not working (n = 657)	2.0 ± 2.6	0.001	54 ± 9.7	0.002	69 ± 21	0.74	4.5 ± .98	0.67
Full time (n = 120)	1.4 ± 2.1		57 ± 8.0		70 ± 19		4.5 ± .85	
Part time (n = 65)	1.1 ± 1.9		57 ± 7.7		67 ± 19		4.4 ± 1.0	
Performance status								
0 (n = 243)	0.48 ± 1.2	<0.001	60 ± 7.8	<0.001	74 ± 19	<0.001	4.7 ± .89	<0.001
1 (n = 371)	2.0 ± 2.3		55 ± 8.5		69 ± 20		4.5 ± .98	
2 (n = 181)	2.8 ± 2.8		51 ± 9.0		65 ± 21		4.5 ± .92	
3 (n = 37)	3.9 ± 3.3		44 ± 10		61 ± 20		4.3 ± 1.0	
4 (n = 14)	4.8 ± 3.4		43 ± 6.6		56 ± 27		3.8 ± 1.3	
Chemotherapy and/or radiotherapy								
Receiving (n = 498)	1.9 ± 2.4	0.38	55 ± 9.0	0.43	69 ± 20	0.52	4.5 ± .93	0.83
Not receiving (n = 343)	1.8 ± 2.5		55 ± 9.8		68 ± 21		4.5 ± 1.0	
Region								
Tsuruoka (n = 84)	1.6 ± 2.3	0.080	55 ± 8.6	0.27	66 ± 21	0.21	4.5 ± .91	0.41
Kashiwa (n = 147)	1.5 ± 2.4		56 ± 8.2		71 ± 19		4.6 ± .97	
Hamamatsu (n = 320)	2.0 ± 2.4		55 ± 10		70 ± 20		4.5 ± .87	
Nagasaki (n = 275)	2.1 ± 2.7		54 ± 9.3		66 ± 22		4.5 ± 1.0	

### Correlations Among Patient-Reported Pain Intensity, Quality of Life, Quality of Palliative Care, and Satisfaction

There were significant but mild to moderate correlations among the pain intensity, total score for the GDI, total score for the CES, and satisfaction levels (all  $P < 0.001$ , Fig. 1), except for the relatively high correlation between the total score for the CES and satisfaction levels. The correlation coefficients between satisfaction and

subscales of the CES were physical care by physicians ( $\rho = 0.63$ ), physical care by nurses ( $\rho = 0.59$ ), psycho-existential care ( $\rho = 0.63$ ), help with decision making ( $\rho = 0.66$ ), and coordination/consistency of care ( $\rho = 0.62$ ).

### Discussion

This was a region-based, multicenter survey comprehensively evaluating pain intensity,

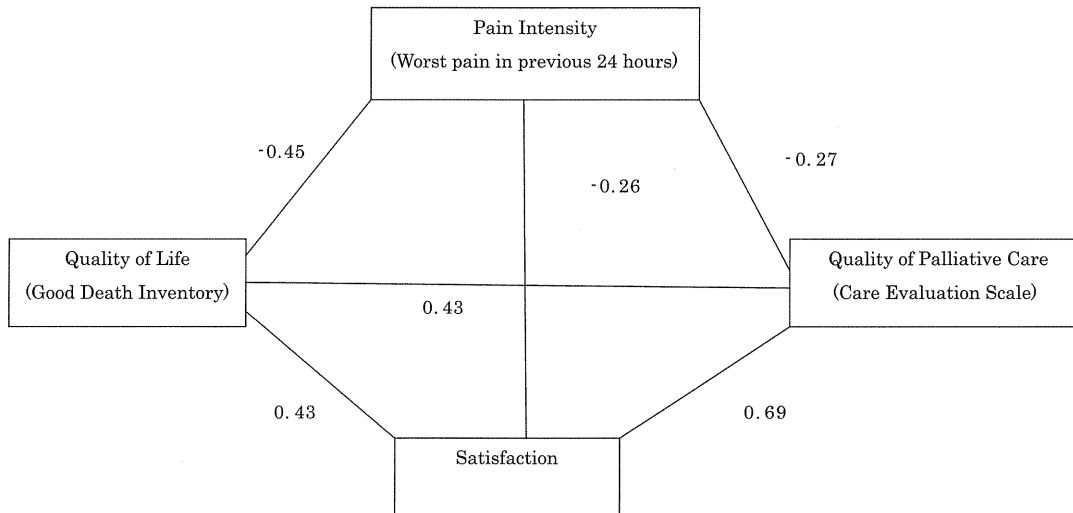


Fig. 1. Correlations among patient-reported pain intensity, quality of life, quality of palliative care, and satisfaction.

quality of life, quality of palliative care, and satisfaction as reported by outpatients with metastatic or recurrent cancer. In addition, this was the first nationwide multicenter survey about the pain experience of cancer patients in Japan. Significant but modest correlations among these variables indicated that they are overlapped but different concepts, and measuring them at the same time could be useful for understanding patients' overall experience. The strengths of this study include the relatively large number of patient responses analyzed, the high participating institution rates in each study region (which included 81% of the relevant inpatient beds), and the use of well-validated measurement tools of quality of life and quality of palliative care specifically developed for Japanese patients with advanced cancer. These measures enabled us to capture the broader areas of patient quality of life beyond symptom burden and functional status, especially psycho-existential components, and patient-perceived quality of care.

Approximately 60% of the patients in this study had some level of pain, which is similar to figures of 59%–74% reported in comparable Western populations.<sup>6</sup> Approximately 20% of the population in this study had moderate to severe pain, with corresponding Western figures varying between 20% and 49%.<sup>6</sup> Likewise, the population in this study with "substantial" pain, defined as pain intensity of 5 or more, was approximately 20%, compared with 20%

in a survey from The Netherlands.<sup>8</sup> These findings confirm that at least 20% of advanced cancer patients in outpatient settings experience moderate to severe pain, and pain management is still one of the most important areas for outpatient cancer care.

Quality of life reported by the patients was generally high in this survey, particularly living in a favorite place, having a good relationship with medical staff, having independence, having environmental comfort, and being respected as an individual. These findings reflect that the ambulatory patients that were being undertreated had relatively good performance status. Conversely, patients reported relatively lower quality-of-life scores in three domains: 1) physical distress other than pain, 2) emotional distress, and 3) existential components such as maintaining hope, feeling of life completion, and feeling a burden to others. These findings are consistent with previous study findings in which frequent concerns for outpatient cancer patients included physical distress other than pain (i.e., fatigue and gastrointestinal symptoms such as appetite loss, nausea, and taste changes); psychological distress (i.e., anxiety, fear, and depression); and existential components (i.e., uncertainty, fears about their cancer spreading, concerns about their future, the unpredictability of their existence, their dependence on others, and feeling a burden to others).<sup>10–14</sup> This study and others thus provide strong support for the urgent need for research to develop

appropriate assessment tools and effective interventions to palliate physical distress other than pain (e.g., fatigue, appetite loss), emotional distress including depression, and existential suffering specifically targeted to maintaining hope, life completion, and alleviating patient-perceived burden to others.<sup>24–26</sup>

Of special note was the very high prevalence (approximately 50%) of Japanese outpatients with advanced cancer who perceived themselves to be a burden to others. This was despite the fact that more than 90% of the patients were independent in their daily lives. This is in line with a large survey performed in Japan on terminally ill cancer patients that also indicated that one of the most common facets of existential suffering was perceived burden to others, and that this was not always associated with objective evidence of any impairment in the patients' activities.<sup>27</sup> Several studies from Western countries also have revealed that being a burden to others is one of the biggest concerns for cancer outpatients.<sup>13,14</sup> Recent studies on Japanese patients have identified potentially useful care strategies to palliate patient perception of being a burden, including practical, cognitive, and emotional approaches.<sup>27,28</sup> Further studies should be encouraged to explore better interventions for relieving patient-perceived burden to others in physically independent outpatients with advanced cancer.

Regarding the patient-perceived quality of care, 20% of patients in this study reported there was some need for improvements in all five subscales assessing the quality of palliative care; however, less than 5% of patients rated the need as "highly necessary." This is similar to the findings of another study using the same questionnaire for bereaved family members of cancer patients who died in certified palliative care units; in that study, less than 5% of respondents reported that improvements in palliative care were "highly necessary." In contrast, the percentage of respondents who reported that "no improvement was necessary" ranged from 23% to 38% in the palliative care unit survey vs. 20% or less in this survey.<sup>16</sup> This suggests that outpatients in the present study evaluated the quality of the palliative care they received as generally acceptable (i.e., not completely satisfied), and some improvement was desired in all areas, including physical care by physicians, physical care by nurses, psycho-

existential care, help with decision making, and coordination/consistency of care.

Performance status was the strongest predictor of patient-reported severe pain intensity, poor quality of life, low quality of care, and low satisfaction. This suggests that disease progression causes the development of multiple symptoms and a variety of needs. As the full assessment of the palliative care needs of all patients is not practical in many outpatient settings because of the limited availability of time and resources, an easily applicable screening tool for outpatients targeted to those with considerable decreases in performance status could identify patients who should be candidates for intensive palliative care interventions.<sup>9,29</sup> Feasible and effective strategies to identify the outpatients with lower performance status and unmet needs should be tested.

Of note, there was no statistically significant difference in pain intensity, quality of life, quality of palliative care, and satisfaction among the different regions with different palliative care systems. Potential interpretations include 1) presence or type of palliative care system had no influence on overall patient experience at a regional level, 2) measurement instruments have inadequate sensitivity (e.g., the CES is influenced by the patient-perceived quality of general care, not only quality of palliative care), and 3) many of the patients surveyed in this study were in generally good condition and may not require specialized palliative care. The effects of the palliative care system on patient outcomes should be investigated in further well-designed studies.

This study had several limitations. First, the response rate was moderate at 58%, and no analysis comparing respondents with nonrespondents was possible because of a lack of patient consent for using nonrespondent data. We cannot conclude, therefore, that response bias might make either over- or underestimation of the results possible. Second, we used a mail survey for this study instead of face-to-face or telephone interviews because of cost reasons, and the possibility that a different approach might obtain different results cannot be denied. One study performed in a similar setting in The Netherlands, however, demonstrated no statistically significant difference in the prevalence of pain when comparing data



collected using either an interview or a mail survey.<sup>8</sup> Therefore, we believe the method of questionnaire distribution was unlikely to alter the overall conclusions. Third, although the patients in this study came from a variety of locations and hospitals within the regions studied (more than 80% of inpatient beds are covered in each area), not all hospitals participated in the survey, particularly small hospitals. We believe, however, the number of patients receiving cancer treatment in such hospitals is small, and this bias does not influence the conclusions. Finally, as we did not obtain the data about medical treatments the patients actually received, we cannot conclude the appropriateness of care they received.

In conclusion, at least 20% of outpatients with metastatic or recurrent cancer experience moderate to severe pain, physical symptoms other than pain, emotional distress, and existential suffering such as maintaining hope, life completion, and feeling a burden to others; and reported that improvement in the quality of palliative care is necessary in multiple areas. Palliative care for Japanese outpatients with recurrent or metastatic cancer should be further improved.

### *Disclosures and Acknowledgments*

This study was funded by the Third Term Comprehensive Control Research for Cancer Health and Labor Sciences Research Grants in Japan. The authors have no other financial disclosures or conflicts of interest.

### *References*

1. World Health Organization. National cancer control programmes. Policies and managerial guidelines, 2nd ed. Geneva: World Health Organization, 2001.
2. Bakitas M, Lyons KD, Hegel MT, et al. Effects of a palliative care intervention on clinical outcomes in patients with advanced cancer. *JAMA* 2009;302:741–749.
3. Follwell M, Burman D, Le LW, et al. Phase 2 study of an outpatient palliative care intervention in patients with metastatic cancer. *J Clin Oncol* 2009;27:206–213.
4. Rabow MW, Dibble SL, Pantilat SZ, McPhee SJ. The comprehensive care team. A controlled trial

of outpatient palliative medicine consultation. *Arch Intern Med* 2004;164:83–91.

5. von Plessen C, Aslaksen A. Improving the quality of palliative care for ambulatory patients with lung cancer. *BMJ* 2005;330:1309–1313.

6. van den Beuken-van Everdingen MH, de Rijke JM, Kessels AG, et al. Prevalence of pain in patients with cancer: a systematic review of the past 40 years. *Ann Oncol* 2007;18:1437–1449.

7. Cleeland CS, Gonin R, Hatfield AK, et al. Pain and its treatment in outpatients with metastatic cancer. *N Engl J Med* 1994;330:592–596.

8. Schuit KW, Sleijfer DT, Meijler WJ, et al. Symptoms and functional status of patients with disseminated cancer visiting outpatient departments. *J Pain Symptom Manage* 1998;16:290–297.

9. Yamagishi A, Morita T, Miyashita M, Kimura F. Symptom prevalence and longitudinal follow-up in cancer outpatients receiving chemotherapy. *J Pain Symptom Manage* 2009;37:823–830.

10. Armes J, Crowe M, Colbourne L, et al. Patients' supportive care needs beyond the end of cancer treatment: a prospective, longitudinal survey. *J Clin Oncol* 2008;27:6172–6179.

11. Lidstone V, Butters E, Seed PT, et al. Symptoms and concerns amongst cancer outpatients: identifying the need for specialist palliative care. *Palliat Med* 2003;17:585–595.

12. Tishelman C, Lövgren M, Broberger E, Hamberg K, Sprangers MAG. Are the most distressing concerns of patients with inoperable lung cancer adequately assessed? A mixed-methods analysis. *J Clin Oncol* 2010;28:1942–1949.

13. Dudgeon DJ, Raubertas RF, Doerner K, et al. When does palliative care begin? A needs assessment of cancer patients with recurrent disease. *J Palliat Care* 1995;11:5–9.

14. Osse BH, Vernooij-Dassen MJFJ, Schadé E, Grol RPTM. The problems experienced by patients with cancer and their needs for palliative care. *Support Care Cancer* 2005;13:722–732.

15. Barbera L, Seow H, Howell D, et al. Symptom burden and performance status in a population-based cohort of ambulatory cancer patients. *Cancer* 2010;116:5767–5776.

16. Miyashita M, Morita T, Hirai K. Evaluation of end-of-life cancer care from the perspective of bereaved family members: the Japanese experience. *J Clin Oncol* 2008;26:3845–3852.

17. Yamagishi A, Morita T, Miyashita M, et al. Palliative care in Japan: current status and a nationwide challenge to improve palliative care by the Cancer Control Act and the Outreach Palliative Care Trial of Integrated Regional Model (OPTIM) study. *Am J Hosp Palliat Care* 2008;25:412–418.

18. Uki J, Mendoza T, Cleeland CS, Nakamura Y, Takeda F. A brief cancer pain assessment tool in

- Japanese: the utility of the Japanese Brief Pain Inventory—BPI-J. *J Pain Symptom Manage* 1998;16:364–373.
19. Miyashita M, Morita T, Sato K, et al. Good Death Inventory: a measure for evaluating good death from the bereaved family member's perspective. *J Pain Symptom Manage* 2008;35:486–498.
20. Miyashita M. Validation of the Good Death Inventory patient version 2008. Ministry of Health, Labor, and Welfare, 2008. Available from <http://mhlw-grants.niph.go.jp/niph/search/NIDD00.do>. Accessed June 4, 2010.
21. Morita T, Hirai K, Sakaguchi Y, et al. Measuring the quality of structure and process in end-of-life care from the bereaved family perspective. *J Pain Symptom Manage* 2004;27:492–501.
22. Miyashita M. Validation of the Care Evaluation Scale patient version 2008. Ministry of Health, Labor, and Welfare, 2008. Available from <http://mhlw-grants.niph.go.jp/niph/search/NIDD00.do>. Accessed June 4, 2010.
23. Oken MM, Creech RH, Tormey DC, et al. Toxicity and response criteria of the Eastern Cooperative Oncology Group. *Am J Clin Oncol* 1982;5:649–655.
24. Armes J, Chalder T, Addington-Hall J, Richardson A, Hotopf M. A randomized controlled trial to evaluate the effectiveness of a brief, behaviorally oriented intervention for cancer-related fatigue. *Cancer* 2007;110:1385–1395.
25. Lundholm K, Gunnebo L, Körner U, et al. Effects by daily long term provision of ghrelin to unselected weight-losing cancer patients: a randomized double-blind study. *Cancer* 2010;116:2044–2052.
26. Strong V, Waters R, Hibberd C, et al. Management of depression for people with cancer (SMaRT oncology 1): a randomised trial. *Lancet* 2008;372:40–48.
27. Akazawa T, Akechi T, Morita T, et al. Self-perceived burden in terminally ill cancer patients: a categorization of care strategies based on bereaved family members' perspectives. *J Pain Symptom Manage* 2010;40:224–234.
28. Ando M, Morita T, Akechi T, Okamoto T, Japanese Task Force for Spiritual Care. Efficacy of short-term life-review interviews on the spiritual well-being of terminally ill cancer patients. *J Pain Symptom Manage* 2010;39:993–1002.
29. Morita T, Fujimoto K, Namba M, et al. Screening for discomfort as the fifth vital sign using an electronic medical recording system: a feasibility study. *J Pain Symptom Manage* 2008;35:430–436.

*Original Article*

## A Scale for Measuring Feelings of Support and Security Regarding Cancer Care in a Region of Japan: A Potential New Endpoint of Cancer Care

Ayumi Igarashi, RN, PhD, Mitsunori Miyashita, RN, PhD, Tatsuya Morita, MD, Nobuya Akizuki, MD, PhD, Miki Akiyama, PhD, Yutaka Shirahige, MD, PhD, and Kenji Eguchi, MD, PhD

*Department of Gerontological Nursing (A.I.), Graduate School of Health Care Sciences, Tokyo Medical and Dental University, Tokyo; Department of Palliative Nursing (M.M.), Health Sciences, Graduate School of Tohoku University, Miyagi; Department of Palliative and Supportive Care (T.M.), Seirei Mikatahara General Hospital, Shizuoka; Psycho-Oncology Division (N.A.), Chiba Cancer Center, Chiba; Faculty of Policy Management (M.A.), Keio University, Kanagawa; Shirahige Clinic (Y.S.), Nagasaki; and Department of Internal Medicine and Medical Oncology (K.E.), Teikyo University School of Medicine, Tokyo, Japan*

---

### **Abstract**

**Context.** Having a sense of security about the availability of care is important for cancer patients and their families.

**Objectives.** To develop a scale for the general population to evaluate feelings of support and security regarding cancer care, and to identify factors associated with a sense of security.

**Methods.** A cross-sectional anonymous questionnaire was administered to 8000 subjects in four areas of Japan. Sense of security was measured using five statements and using a seven-point Likert scale: "If I get cancer 1) I would feel secure in receiving cancer treatment, 2) my pain would be well relieved, 3) medical staff will adequately respond to my concerns and pain, 4) I would feel secure as a variety of medical care services are available, and 5) I would feel secure in receiving care at home." We performed an exploratory factor analysis as well as uni- and multivariate analyses to examine factors associated with such a sense of security.

**Results.** The five items regarding sense of security were aggregated into one factor, and Cronbach's  $\alpha$  was 0.91. In the Yamagata area where palliative care services were not available, the sense of security was significantly lower than in the other three regions. Female gender ( $P=0.035$ ), older age ( $P<0.001$ ), and having cancer ( $P<0.001$ ) were significantly associated with a strong sense of security.

---

*Address correspondence to:* Ayumi Igarashi, RN, PhD, Department of Gerontological Nursing, Graduate School of Health Care Sciences, Tokyo Medical and

Dental University, 1-5-45 Yushima, Bunkyo-ku, Tokyo 113-8510, Japan. E-mail: igarashi.gh@tmd.ac.jp

*Accepted for publication:* April 12, 2011.

**Conclusion.** A new scale that evaluates sense of security with regard to cancer care was developed. Future studies should examine whether establishing a regional health care system that provides quality palliative care could improve the sense of security of the general population. *J Pain Symptom Manage* 2012;43:218–225. © 2012 U.S. Cancer Pain Relief Committee. Published by Elsevier Inc. All rights reserved.

#### Key Words

*Sense of security, palliative care, region, quality of care, general population*

### Introduction

Cancer is a serious disease affecting the lives of many people. In Japan, cancer affects half of the population (55% of males and 41% of females) throughout their lifetime<sup>1</sup> and is the cause of about 30% of all deaths.<sup>2</sup> It is essential that quality care is available for cancer patients. Outcomes of care for cancer patients have been measured using various indicators such as symptoms,<sup>3,4</sup> prognosis, quality of life,<sup>5,6</sup> quality of care,<sup>7,8</sup> patient satisfaction,<sup>9,10</sup> and family satisfaction;<sup>11</sup> however, there are no indicators that assess the overall availability of care, which could be used, for example, to compare regions.

Having a sense of security about the availability of high-quality care is very important for cancer patients and their families.<sup>12</sup> A sense of security should be evaluated from the perspective of the general population living in a region, in addition to cancer patients and their families. These perspectives reflect the quality of the regional system for providing health care services, and the awareness among the population of the services provided by the system. As part of quality assurance of regional cancer care, a sense of security among the general population is important.

Regarding the concept of a sense of security, Funk et al.<sup>12</sup> indicated that a feeling of security among family caregivers of cancer patients consisted of trust in competent professionals; timely access to needed care, services, and information; and a sense of their own identity and self-worth as caregivers and individuals. The domain of “access to care” encompasses a sense of feeling supported and the perceived access to care.<sup>12</sup> Milberg et al.<sup>13,14</sup> also suggested that having competent staff with a good attitude, access to care 24 hours a day, and being at home contributed to

a feeling of security among family caregivers. According to these proposed concepts, security is not only just trust in an individual health care professional but also a generalized sense of institutional trust in the health care system that makes people feel supported.<sup>12</sup> However, the concept of a sense of security has not been explicitly validated.

The aims of this study were 1) to develop a scale for the general population in regions of Japan that evaluates the sense of feelings of support and security regarding cancer care, and 2) to identify factors associated with a sense of security in those regions. This study is new in that the scale to assess the sense of security is measured from the perspective of the general population in a region and includes both trust in competent health care professionals and in the regional health care system, as proposed by Funk et al.<sup>12</sup>

### Methods

This study was conducted as a part of the Outreach Palliative Care Trial of Integrated Regional Model (OPTIM) study, launched by the Ministry of Health, Labor, and Welfare in Japan.<sup>15,16</sup> The OPTIM study is a regional intervention trial with the aim of establishing a regional palliative care model in four areas of Japan: a large urban area (Chiba: Kashiwa, Nagareyama, and Abiko City), a smaller urban area (Shizuoka: Hamamatsu City), and two rural areas (Nagasaki: Nagasaki City, and Yamagata: Tsuruoka and Mikawa City). In Chiba, Shizuoka, and Nagasaki, palliative care services are available; in Yamagata, such services are sparse.

We administered a cross-sectional anonymous questionnaire. In the questionnaire, we explained the aim of the study and regarded

the completion and returning of the questionnaire as consent to participate. The ethical and scientific validity of this study was confirmed by the institutional review board independently from the research project, which was organized by the Japan Cancer Society, the organization responsible for conducting the OPTIM study.

#### *Population and Procedures*

We identified 8000 subjects, 40–80 years of age, within the general population, using a stratified two-stage random sampling of residents in the four regions (2000 subjects in each area). We mailed questionnaires to potential participants in July 2007, and if the questionnaire was not returned, we sent a reminder postcard.

#### *Measurements*

We developed a questionnaire regarding the sense of security through discussions based on previous studies.<sup>12–14</sup> The questionnaire comprised five statements about the characteristics of health care professionals who provide adequate treatment and care (“competent professionals”) and adequate access to health care resources to feel supported (“timely access to needed care”), which are components indicated by Funk et al.<sup>12</sup> We did not include the “caregiver’s identity and self-worth<sup>12</sup>” in the questionnaire because the intended use of this scale in the OPTIM study was to measure the change in the level of competency of professionals and timely access to needed care as a result of the intervention for improving regional palliative care. The face validity of the questions was assessed based on full agreement of the authors.

The questionnaire statements were as follows: If I get cancer 1) I would feel secure in receiving cancer treatment, 2) my pain would be well relieved, 3) medical staff will adequately respond to my concerns and pain, 4) I would feel secure as a variety of medical care services are available, and 5) I would feel secure in receiving care at home. The translation from Japanese to English was done by a translation/back-translation procedure as follows: the questions were translated into English by a proficient translator; this translation was supervised by a bilingual person and modified. Subsequently, this prototype was translated

into Japanese by two researchers other than the authors. The back-translation was compared with the original Japanese questionnaire, and the authors approved it. We asked participants to rate their level of agreement with the statements on a seven-point Likert scale (1: strongly disagree, 2: disagree, 3: slightly disagree, 4: not sure, 5: slightly agree, 6: agree, and 7: strongly agree).

The demographic data, such as area where the respondent lived, age, gender, duration of residence in the region, current treatment of health problems, diagnosis of cancer (during or after treatment), family members’ experiences of cancer, and knowledge about palliative care also were included in the questionnaire.

#### *Statistical Analyses*

First, we conducted descriptive analyses of demographic data and responses concerning the sense of security regarding cancer care in the designated region.

*Scale Development.* To examine feasibility, we considered the rate of missing data for questions regarding sense of security. We then used exploratory factor analysis using the principal factor method for questions on sense of security; the factorial validity of the scale was examined. To assess the reliability of the scale, we calculated Cronbach’s  $\alpha$  coefficients.

The scale score was calculated by summing the points for the five items because the score was regarded as normally distributed. We set 25 points, which is the sum of five Number 5 ratings (“slightly agree”), or more as the cutoff on the sense of security scale to identify persons who felt secure.

*Related Factors.* To identify factors associated with a sense of security, univariate analyses were conducted using analysis of variance, the unpaired *t*-test, Pearson product-moment correlation coefficient, and Spearman rank correlation coefficient, where appropriate. Thereafter, the association of each hypothesized factor with the sense of security score was determined using multiple regression analysis.

Statistical analysis was performed using SAS Version 9.1 (SAS Institute, Inc., Cary, NC). The significance level was set at <0.05 (two-tailed).

**Results**

*Characteristics of Participants*

Of the 8000 questionnaires sent out, 26 were undeliverable and 3984 were returned. Among the respondents, 254 were excluded because of missing data for items regarding sense of security, and 3730 responses were analyzed (effective response rate: 46.8%). There was a significant difference in the response rate among the areas (Yamagata, 47%; Chiba, 53%; Shizuoka, 44%; and Nagasaki, 42%; Chi-squared test,  $P < 0.001$ ). Table 1 summarizes the characteristics of the respondents.

*Distribution of the Sense of Security in the Region*

Table 2 shows the distribution of responses regarding the sense of security. Although about 60% of the respondents (sum of "strongly agree," "agree," and "slightly agree") believed that they would be treated appropriately for cancer, less than half of the respondents believed that the treatment for pain and distress and the availability of health care services, including home care, would be sufficient.

*Feasibility*

The rate of missing values for the five items regarding the sense of security was 1.5%–3.5%.

*Exploratory Factor Analysis*

According to the results of the exploratory factor analysis, the five items regarding the sense of security were aggregated into one factor (Table 3). Cronbach's  $\alpha$  was 0.91.

Table 1  
Characteristics of Respondents ( $n = 3730$ )

Characteristic	n (%)
Area	
Yamagata	943 (25)
Chiba	1061 (28)
Shizuoka	877 (24)
Nagasaki	849 (23)
Gender	
Male	1648 (45)
Female	2012 (55)
Age (years), mean ( $\pm$ SD)	59.6 ( $\pm$ 10.5)
Duration of residence in the region	
Less than one year	42 (1)
One to five years	141 (4)
More than five years	3457 (95)
Treated for health problems	1959 (54)
Have cancer	177 (5)
Family members' experiences of cancer	2008 (55)
Awareness of palliative care	523 (15)

SD = standard deviation.  
Percentages for each item were calculated after excluding missing values.

*Related Factors*

*Univariate Analyses.* The association of each demographic factor with the sense of security score, which was calculated by summing the points of the five items, was examined using univariate analyses, and the results are shown in Table 4. The difference in the sense of security among the areas was significant ( $P < 0.001$ ). Other factors associated with a higher score for the sense of security were an older age ( $P < 0.001$ ), current treatment for a health problem ( $P < 0.001$ ), having cancer ( $P < 0.001$ ), and no family history of cancer ( $P = 0.005$ ). When examining correlations among variables, a family history of cancer was associated with gender (females had more

Table 2  
Distribution of Responses for Sense of Security Regarding Cancer Care ( $n = 3730$ )

If I get cancer:	Strongly	Disagree	Slightly	Not	Slightly	Agree	Strongly	Total
	Disagree (%)	(%)	Disagree (%)	Sure (%)	Agree (%)	(%)	Agree (%)	Agreement <sup>a</sup> (%)
(1) I would feel secure in receiving cancer treatment.	3	10	9	17	26	30	6	61
(2) My pain would be well relieved.	4	18	13	24	23	17	2	41
(3) Medical staff will adequately respond to my concerns and pain.	3	14	13	23	26	19	2	46
(4) I would feel secure as a variety of medical care services are available.	5	17	14	29	21	12	2	35
(5) I would feel secure in receiving care at home.	9	26	16	26	15	7	1	23

Percentages for each item were calculated after excluding missing values.  
<sup>a</sup>Sum of "slightly agree," "agree," and "strongly agree."

**Table 3**  
Exploratory Factor Analysis (n = 3587)

If I get cancer:	Factor 1	Communality
(1) I would feel secure in receiving cancer treatment.	0.82	0.67
(2) My pain would be well relieved.	0.88	0.77
(3) Medical staff will adequately respond to my concerns and pain.	0.91	0.83
(4) I would feel secure as a variety of medical care services are available.	0.90	0.82
(5) I would feel secure in receiving care at home.	0.77	0.59

Proportion of variance explained = 73.5%.

experiences of family cancer) and having a health problem was associated with age and having cancer ( $P < 0.001$ , respectively).

*Multiple Regression Analyses.* The results of multiple regression analyses are shown in Table 5.

**Table 4**  
Factors Related to Sense of Security According to Univariate Analyses (n = 3587)

Variable	Sense of Security Score	
	Mean (SD)	P-value
Area		
Yamagata	17.7 (7.1)	<0.001 <sup>a</sup>
Chiba	19.8 (6.3)	
Shizuoka	21.3 (6.2)	
Nagasaki	19.9 (6.6)	
Gender		
Male	20.0 (6.2)	0.571 <sup>b</sup>
Female	20.1 (6.3)	
Age	0.225 <sup>c</sup>	<0.001
Duration of residence in the region	-0.015 <sup>d</sup>	0.373
Treated for health problems		
Yes	20.6 (6.3)	<0.001 <sup>b</sup>
No	19.5 (6.2)	
Have cancer		
Yes	23.1 (5.7)	<0.001 <sup>b</sup>
No	19.9 (6.3)	
Family members' experiences of cancer		
Yes	19.5 (6.4)	0.005 <sup>b</sup>
No	20.1 (6.2)	
Awareness of palliative care		
Yes	20.1 (6.7)	0.666 <sup>b</sup>
No	20.0 (6.2)	

SD = standard deviation.

<sup>a</sup>Analysis of variance.

<sup>b</sup>t-test.

<sup>c</sup>Pearson product-moment correlation coefficient.

<sup>d</sup>Spearman rank correlation coefficient.

**Table 5**  
Factors Related to Sense of Security According to Multiple Regression Analyses (n = 3419)

Independent Variable	$\beta$	P-value
Area		
Yamagata	Reference	—
Chiba	0.143	<0.001
Shizuoka	0.242	<0.001
Nagasaki	0.140	<0.001
Gender		
Male	Reference	—
Female	0.035	0.035
Age	0.155	<0.001
Duration of residence in the region		
Less than one year	Reference	—
One to five years	0.023	0.436
More than five years	-0.004	0.898
Treated for health problems	0.015	0.389
Have cancer	0.090	<0.001
Family members' experiences of cancer	-0.028	0.096
Awareness of palliative care	-0.011	0.528

Determination coefficient:  $R^2 = 0.068$ .

The Yamagata area showed a significantly smaller score for the sense of security compared with the other areas ( $P < 0.001$ ). Female gender ( $P = 0.035$ ), older age ( $P < 0.001$ ), and diagnosis of cancer ( $P < 0.001$ ) were associated with a high score for sense of security. The associations of these variables, other than the area and age, were not strong, and the determination coefficient was small (0.068).

## Discussion

In this study, we developed a scale to evaluate the general population in regions of Japan to assess their feelings of support and security regarding cancer care. The scale was constructed using one factor, and showed good face validity based on the full agreement of the authors, and factorial validity and internal consistency on factor analysis. The sense of security in the Yamagata area was poor compared with that in the other three areas. Being female, of an older age, and having cancer were associated with a strong sense of security. Additionally, more than half of the respondents felt uneasy (i.e., "strongly disagree," "disagree," "slightly disagree," and "not sure") about the availability of adequate treatment for pain and distress caused by cancer and of the types of health

care services available (e.g., home care). These responses suggest that many people were unsure about the adequacy of regional cancer care.

To our knowledge, this is the first study to evaluate the sense of security regarding cancer care from the perspective of the general population. In the Yamagata area, where specialized palliative care services were not available at the time of the survey, the sense of security was relatively poor. This result suggests that the scale could reflect the adequacy of the regional system for providing health care services, thus suggesting good known-group validity.

In the scale developed in this study, the sense of security of the general population comprised trust in health care professionals to adequately respond to patients' pain and distress from cancer, and feeling that various medical and care services are readily available, even at home.<sup>12</sup> To improve the sense of security in a region, it is important for the general population to feel supported; thus, health care professionals should be educated in cancer and palliative care, palliative and other care services should be available, and these services should be accessible to the general population. This new scale would be a useful endpoint for evaluating the comprehensive sense of security in the general population of a region. It also may be used as an indicator of the adequacy of health care services (including the competency of health care professionals and accessibility to care) provided in the region and awareness of the services among the general population.

Furthermore, the scale, although developed to target the general population, also could be used with cancer patients and their families. Whereas the questionnaire queried the general population about a hypothetical diagnosis of cancer, the surveys of cancer patients and their families using this instrument could collect more practical data on the sense of security based on care already received.

We also identified factors other than "area" that are associated with a sense of security, to be able to apply the OPTIM model effectively to other regions of Japan in the future. Older age, female gender, and a diagnosis of cancer were associated with a strong sense of security; having health problems and a family member's experience of cancer, which were associated with a sense of security on univariate but not

multivariate analysis, might be confounding factors of age and having cancer, and gender, respectively.

First, the results for age and gender were comparable to previous studies regarding patient satisfaction with health care, which indicated that older patients were more satisfied with their care than younger ones, but the association of gender and satisfaction differed.<sup>17-19</sup> Our results showing that older people had a strong sense of security are supported by the results of a previous study in which older individuals remembered an earlier less accessible health care system and so were less ready to criticize, and that they did not have high expectations.<sup>18</sup> Additionally, because many older persons lead a community-based life compared with younger ones, they may have easy access to regional health care; consequently they may feel more secure regarding its accessibility. For gender, a previous study put forward a reason why females may be more satisfied with the health care they have received than males; the level of communication with health care staff affected patient satisfaction, and females communicated more with staff than males.<sup>20</sup> In the present study, however, the scores for sense of security were almost equal between males and females, and the standardized partial regression coefficient of the multiple regression analysis was small. Further analyses regarding the influence of gender are needed.

Second, the subjects with cancer felt more secure regarding cancer care than those without cancer. This result suggests that, whereas a person without cancer may feel a vague anxiety about cancer and its care, once a person gets cancer and has experienced receiving care, he or she may feel secure because the level of individual treatment and care in Japan is of a relatively high quality. On the other hand, subjects with a family member who had cancer had a poor sense of security compared with those without such experience, although the difference was not significant on multivariate analysis. This situation might be a result of experiencing earlier cancer care in Japan, which was poor. Doctors did not tell patients they had cancer, and pain control was inadequate. Consequently, many patients died a painful death. The result may suggest that individuals who lost a family member (mostly parents) to cancer, in times past, saw their pain and distress; therefore, they have



the impression that cancer causes great distress and so a poor sense of security regarding cancer care. However, in Japan, palliative care teams became covered by National Medical Insurance in 2002, and the Cancer Control Act was established in 2007; as a result, palliative care has progressed so that more effective treatments are available.

Nonetheless, the association of each variable with a sense of security was not strong, and the determination coefficient was small. There should be factors associated with a sense of security other than those measured in this study. To identify effective strategies for improving the sense of security in the general population within a region, future studies should look at the association of more detailed characteristics of the respondents with the sense of security. For example, if persons with negative perceptions about palliative care (such as "a place where people only wait to die")<sup>21</sup> have a low sense of security, strategies that specifically educate about palliative care and improve the perceptions of such persons would be needed. Also, if persons who do not know of the availability of specialized palliative care services and other care resources (e.g., home care) in the region have a low sense of security, strategies that disseminate knowledge on the availability of services would be needed.

This study had several limitations. First, the content validity and test-retest reliability were not confirmed; further study is needed. Generally, the reliability of a scale should be verified using the test-retest method. However, Cronbach's  $\alpha$  (internal consistency) also can be used as an indicator of reliability; if Cronbach's  $\alpha$  is high, the coefficient of test-retest reliability also would be expected to be high.

Second, although we considered that the scale for the sense of security could be a measure of the adequacy of the system for providing health care services and the awareness among the population of the services, the construct validity has not been confirmed. Future studies should compare the sense of security with other indicators regarding the quality of the regional health care system, such as death at home, the number of patients receiving specialized palliative care, and evaluation of patients and the bereaved family, which were not measured during the study period but are measured now in the OPTIM study.<sup>15</sup>

Third, the response rate of the survey was not high, the difference in response rate among the areas was significant, and we could not clarify the characteristics of nonresponders; therefore, a response bias may exist. However, because the response rate of opinion surveys in the general population in Japan is generally about 50%,<sup>8,22-24</sup> the response rate of the study may be acceptable.

In conclusion, this study developed a new scale to evaluate feelings of support and security regarding cancer care in regions of Japan. This scale may be a useful endpoint for studies on the comprehensive sense of security, as well as adequacy of the system for providing health care services for cancer in a region, and awareness among the general population of the services. The OPTIM study is an intervention trial for improving these endpoints; we are awaiting the results of this intervention.

### *Disclosures and Acknowledgments*

This study was supported by a grant-in-aid for the Third Term Comprehensive Strategy for Cancer Control in Japan. The funder was not involved in the conduct of this study or its submission. The authors declare no conflicts of interest.

The authors would like to express special thanks to Meiko Kuriya, Kazuki Sato, and Yoko Hanada for their expert comments.

### *References*

1. Foundation for Promotion of Cancer Research. Cancer statistics in Japan. Tokyo, Japan: Foundation for Promotion of Cancer Research, 2009.
2. Statistics and Information Department, Ministers Secretariat, Ministry of Health, Labor, and Welfare. Vital statistics of Japan, 2009. [in Japanese]. Tokyo, Japan: Ministry of Health, Labor, and Welfare, 2010.
3. Okuyama T, Wang X, Akechi T, et al. Japanese version of the M. D. Anderson Symptom Inventory: a validation study. *J Pain Symptom Manage* 2003;26:1093-1104.
4. Miyashita M, Yasuda M, Baba R, et al. Inter-rater reliability of proxy simple symptom assessment scale between physician and nurse: a hospital-based palliative care team setting. *Eur J Cancer Care (Engl)* 2010;19:124-130.
5. Cella D, Tulsky D, Gray G, et al. The Functional Assessment of Cancer Therapy scale: development

and validation of the general measure. *J Clin Oncol* 1993;11:570–579.

6. Aaronson N, Ahmedzai S, Bergman B, et al. The European Organization for Research and Treatment of Cancer QLQ-C30: a quality-of-life instrument for use in international clinical trials in oncology. *J Natl Cancer Inst* 1993;85:365–376.

7. Morita T, Hirai K, Sakaguchi Y, et al. Measuring the quality of structure and process in end-of-life care from the bereaved family perspective. *J Pain Symptom Manage* 2004;27:492–501.

8. Miyashita M, Sanjo M, Morita T, Hirai K, Uchitomi Y. Good death in cancer care: a nationwide quantitative study. *Ann Oncol* 2007;18:1090–1097.

9. Lo C, Burman D, Hales S, et al. The FAMCARE-Patient scale: measuring satisfaction with care of outpatients with advanced cancer. *Eur J Cancer* 2009;45:3182–3188.

10. Brédart A, Sultan S, Regnault A. Patient satisfaction instruments for cancer clinical research or practice. *Expert Rev Pharmacoecon Outcomes Res* 2010;10:129–141.

11. Morita T, Chihara S, Kashiwagi T, Quality Audit Committee of the Japanese Association of Hospice and Palliative Care Units. A scale to measure satisfaction of bereaved family receiving inpatient palliative care. *Palliat Med* 2002;16:141–150.

12. Funk L, Allan D, Stajduhar K. Palliative family caregivers' accounts of health care experiences: the importance of "security". *Palliat Support Care* 2009;7:435–447.

13. Milberg A, Strang P. Met and unmet needs in hospital-based home care: qualitative evaluation through open-ended questions. *Palliat Med* 2000;14:533–534.

14. Milberg A, Strang P, Carlsson M, Börjesson S. Advanced palliative home care: next-of-kin's perspective. *J Palliat Med* 2003;6:749–756.

15. Yamagishi A, Morita T, Miyashita M, et al. Palliative care in Japan: current status and a nationwide

challenge to improve palliative care by the Cancer Control Act and the Outreach Palliative Care Trial of Integrated Regional Model (OPTIM) study. *Am J Hosp Palliat Care* 2008;25:412–418.

16. Eguchi K. Development of palliative medicine for cancer patients in Japan: from isolated voluntary effort to integrated multidisciplinary network. *Jpn J Clin Oncol* 2010;40:870–875.

17. Lewis J. Patient views on quality care in general practice: literature review. *Soc Sci Med* 1994;39:655–670.

18. Sitzia J, Wood N. Patient satisfaction: a review of issues and concepts. *Soc Sci Med* 1997;45:1829–1843.

19. Morita T, Chihara S, Kashiwagi T, Quality Audit Committee of the Japanese Association of Hospice and Palliative Care Units. Family satisfaction with inpatient palliative care in Japan. *Palliat Med* 2002;16:185–193.

20. Hall J, Roter D, Katz N. Meta-analysis of correlates of provider behavior in medical encounters. *Med Care* 1988;26:657–675.

21. Sanjo M, Miyashita M, Morita T, et al. Perceptions of specialized inpatient palliative care: a population-based survey in Japan. *J Pain Symptom Manage* 2008;35:275–282.

22. Miyata H, Tachimori H, Takahashi M, Saito T, Kai I. Disclosure of cancer diagnosis and prognosis: a survey of the general public's attitudes toward doctors and family holding discretionary powers. *BMC Med Ethics* 2004;5:E7.

23. Sanjo M, Miyashita M, Morita T, et al. Preferences regarding end-of-life cancer care and associations with good-death concepts: a population-based survey in Japan. *Ann Oncol* 2007;18:1539–1547.

24. Morita T, Miyashita M, Shibagaki M, et al. Knowledge and beliefs about end-of-life care and the effects of specialized palliative care: a population-based survey in Japan. *J Pain Symptom Manage* 2006;31:306–316.

*Original Article*

# Providing Palliative Care for Cancer Patients: The Views and Exposure of Community General Practitioners and District Nurses in Japan

Akemi Yamagishi, PhD, RN, Tatsuya Morita, MD, Mitsunori Miyashita, RN, PhD, Takayuki Ichikawa, MA, Nobuya Akizuki, MD, PhD, Yutaka Shirahige, MD, PhD, Miki Akiyama, PhD, and Kenji Eguchi, MD, PhD

*Department of Nursing (A.Y.), Seirei Christopher University, Hamamatsu, Shizuoka; Department of Palliative and Supportive Care, Palliative Care Team, and Seirei Hospice (T.M.), Seirei Mikatahara General Hospital, Hamamatsu, Shizuoka; Department of Palliative Nursing (M.M.), Health Sciences, Tohoku University Graduate School of Medicine, Sendai, Miyagi; Department of Adult Nursing/Palliative Care Nursing (T.I.), School of Health Sciences and Nursing, Graduate School of Medicine, The University of Tokyo, Tokyo; Psycho-Oncology Division (N.A.), Chiba Cancer Center, Chiba, Chiba; Shirahige Clinic (Y.S.), Nagasaki, Nagasaki; Faculty of Policy Management (M.A.), Keio University, Fujisawa; and Department of Internal Medicine (K.E.), Teikyo University School of Medicine, Tokyo, Japan*

**Abstract**

**Context.** The role of general practitioners (GPs) and district nurses (DNs) is increasingly important to achieve dying at home.

**Objectives.** The primary aim of this region-based representative study was to clarify 1) clinical exposure of GPs and DNs to cancer patients dying at home, 2) availability of symptom control procedures, 3) willingness to participate in out-of-hours cooperation and palliative care consultation services, and 4) reasons for hospital admission of terminally ill cancer patients.

**Methods.** Questionnaires were sent to 1106 GP clinics and 70 district nursing services in four areas across Japan.

**Results.** Two hundred thirty-five GPs and 56 district nursing services responded. In total, 53% of GPs reported that they saw no cancer patients dying at home per year, and 40% had one to 10 such patients. In contrast, 31% of district nursing services cared for more than 10 cancer patients dying at home per year, and 59% had one to 10 such patients. Oral opioids, subcutaneous opioids, and subcutaneous haloperidol were available in more than 90% of district nursing services, whereas 35% of GPs reported that oral opioids were unavailable and 50% reported that subcutaneous opioids or haloperidol were unavailable. Sixty-seven percent of GPs and 93% of district nursing services were willing to use palliative care consultation services. Frequent reasons for admission were family burden of

*Address correspondence to:* Akemi Yamagishi, PhD, RN, Department of Nursing, Seirei Christopher University, 3453 Mikatahara, Kita-ku, Hamamatsu, Shizuoka

433-8558, Japan. E-mail: ayamagishi-tky@umin.ac.jp

*Accepted for publication:* March 4, 2011.

caregiving, unexpected change in physical condition, uncontrolled physical symptoms, and delirium.

**Conclusion.** Japanese GPs have little experience in caring for cancer patients dying at home, whereas DNs have more experience. To achieve quality palliative care programs for cancer patients at the regional level, educating GPs about opioids and psychiatric medications, easily available palliative care consultation services, systems to support home care technology, and coordinated systems to alleviate family burden is of importance. *J Pain Symptom Manage* 2012;43:59–67. © 2012 U.S. Cancer Pain Relief Committee. Published by Elsevier Inc. All rights reserved.

### Key Words

Home, general practitioner, district nurse, palliative care, community

## Introduction

Dying at a preferred place is an important outcome for terminally ill cancer patients, and many patients prefer home as place of death across the world and in Japan.<sup>1,2</sup> Specialized home care services appear to be effective in improving the patient's quality of life and ability to stay at home,<sup>3,4</sup> but the rates of home death vary among countries. In Japan, only 6% of cancer deaths occurred at home in 2009.<sup>5,6</sup>

A number of significant determining factors for achieving a home death have been identified by multiple empirical studies. These include patient and caregiver preference, intensity of home care services, and level of family support, as well as disease characteristics, patient's functional status, availability of hospital beds, rural or urban environment, and historical trend.<sup>7–10</sup> These findings consistently stress the role of the community health care system in achieving home death, as well as the patient's and family's preference to stay at home.

Given the importance of community health services, the role of general practitioners (GPs) has become the focus of recent palliative care research.<sup>11–18</sup> In these studies, current availability, barriers, and promising effective regional systems have been investigated using surveys of GPs and district nurses (DNs). On the whole, many GPs are willing to participate in palliative care and, in reality, see a relatively small number of palliative care patients each year.<sup>11</sup> At the same time, they experience the barriers of unfamiliar palliative care skills, medical technology, time constraints (especially out-of-hours demands), lack of

community services to reduce the family burden of caregiving, and lack of coordination and communication among community health care workers.<sup>11</sup>

In Japan, palliative care is very strongly facilitated as a part of the government's cancer policy. Palliative care is increasingly seen as a part of comprehensive cancer treatment, and developing a regional model is urgently needed. Nonetheless, there have been very few large surveys about the availability of palliative care from community health care providers.<sup>19,20</sup> Only one nationwide survey involved over 50,000 GP clinics and investigated their clinical exposure to palliative care, general willingness to be involved in palliative care, and knowledge about palliative care. In that survey, 60% of GPs had no experience in caring for cancer patients dying at home and 82% had no experience in prescribing opioids during the year but 47% expressed a willingness to provide medical care for terminally ill cancer patients dying at home. Furthermore, less than 20% were confident about palliative care skills, and less than half had correct knowledge about opioids.

This survey provides a nationwide overview of palliative care from the point of view of GPs, but the perspective of other professionals, especially DNs, is lacking; there are no data about the availability of symptom control procedures and willingness to participate in specific programs; and no region-based representative survey exists. We believe that gathering the views of GPs and DNs working from the same region is another valuable method to help understand