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Conflict of interest

None declared.

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Preferred place of care and place of death of the general public and cancer patients in Japan

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Abstract Dying at a favorite place is one of the important determinants for terminally ill cancer patients. The primary aim was to clarify (1) differences in preferred place of care and place of death among the general public across four areas across Japan and (2) preferred place of care and place of death among community-representative cancer patients. A cross-sectional mail survey was conducted on 8,000 randomly selected general population. We examined preferred place of care and place of death using two vignettes and obtained a total of 3,984 (50%) responses. For the pain scenario, approximately 50% of the general public throughout four areas chose home as their preferred place of care; and for the dependent-without-pain scenario, about 40% chose home as preferred place of care. In cancer patients, for both scenarios, approximately 40% chose home as the preferred place of care, and they were significantly less

likely to choose home. The most preferred combination of place of care and place of death was home hospice for both groups. Although there were statistically significant differences in preferred place of care and place of death among the four regions, the absolute difference was less than 8%. Independent determinants of choosing home as place of care included concern about family burden and being unable to adequately respond to sudden changes out of working hours. In conclusion, establishing more accessible home and hospice service is strongly required through arranging regional resources to reduce family burden, alleviating patient-perceived burdens, and improving 24-h support at home.

Keywords Preference · End-of-life · Home · Palliative care · Hospice

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Introduction

Dying at a preferred place is one of the most important determinants for terminally ill cancer patients in Japan and across the world [1, 2]. Understanding the preferred place of care and place of death is therefore the first step in ensuring adequate resources for patients [3–5], and multiple preference surveys in UK, USA, and other countries have been conducted to clarify the preferred place of care and place of death [6–8]. In these surveys, the general public and cancer patients generally chose home as the preferred place of care and place of death [6].

In Japan, a series of national surveys was conducted by the Ministry of Health, Labor, and Welfare in 2008 to reveal the preferred place of care and place of death [8]. Home was the preferred place of care in general, with 29% of respondents reporting that they wanted to receive care at home and be admitted to a hospice if necessary, and 23% preferring to receive care at home and be admitted to hospital if necessary. Another 11% chose home until death, while a considerable number of respondents reported that they want to be admitted to hospice earlier and stay until death (18%) or be admitted to hospital earlier and stay until death (10%). In summary, 63% of the general public chooses home as the place of care, and as place of death if physical and social conditions were acceptable if presented with terminal cancer. At the same time, this survey also demonstrated that less than 10% believed home death is achievable; the reasons listed included burden to family (80%), concerns about sudden changes in physical conditions (54%), cost (33%), unavailability of physicians visiting home (32%), unavailability of emergency hospital beds (32%), unavailability of nurses visiting home (19%), inadequate home environment (16%), lack of round-the-clock services (15%), and lack of family caregivers (15%). The absolute figures of each response did not change compared with the same surveys in 1998.

The findings provide useful insights about the preferred place of care and place of death of Japanese cancer patients, but existing studies have major limitations. First, there have been no surveys specifically targeted at cancer patients; thus, it is difficult to apply the results from the general population directly to cancer patients. Second, considerable differences may exist among various areas in Japan in medical resources, social resources, the delivery system of palliative care, and cultural backgrounds, rendering the findings from a national representative sample may not be always applicable to specific regions such as urban vs. rural areas [9, 10]. We thus believe that comparing the preferred place of care and place of death among different areas in Japan and clarifying the preferred place of care and place of death in cancer patients specifically are both of value.

In addition, although identifying predictors of preference about place of care and place of death is helpful for understanding how patients decide where they live at the end of their life, only a few studies have examined such determinants [6, 11–14]. In particular, it would be important to clarify the impact of concerns about home care on the preference of place of care and place of death because large surveys in Japan revealed that excessive apprehension significantly contributed to late referrals to specialized palliative care services [15], and few empirical studies have specifically addressed this topic [6, 11–14].

The primary aim of this study was to clarify (1) the differences in preferred place of care and place of death of the general public among different areas in Japan and (2) preferred place of care and place of death of cancer patients. Additional aims include clarifying concerns and values about home care of the general public and cancer patients and examining the effects of such concerns on preferred place of care and place of death.

Subjects and methods

We conducted a cross-sectional mail survey of the general public as part of a larger regional intervention trial, the Outreach Palliative Care Trial of Integrated Regional Model (OPTIM) study. This survey was performed at the initial phase of the OPTIM study, the details of which are reported elsewhere [16]. The institutional review board for the OPTIM study approved the ethical and scientific validity.

Study regions

This survey was conducted in four regions where the OPTIM study was employed. These areas were selected based on different palliative care system development across Japan: Tsuruoka (170,000 people, Yamagata prefecture), Kashiwa (670,000 people, Chiba prefecture), Hamamatsu (820,000 people, Shizuoka prefecture), and Nagasaki (450,000 people, Nagasaki prefecture). The systems in Kashiwa, Hamamatsu, and Nagasaki provide palliative care chiefly led by a national cancer center, a general hospital, and a general practitioner association, respectively, while the system of palliative care in Tsuruoka is not organized.

Although we had acknowledged that the study areas had been selected for the regional intervention study not for region-comparison studies about preferred place of death, we had determined that the use of this sample for this study was reasonable, because these four areas are typical as a representative from geographically and culturally different regions throughout Japan: Tsuruoka is typical rural area in North Japan, Kashiwa is a typical city around the capital region, Hamamatsu and Nagasaki are typical cities in

Central and West Japan, respectively. In addition, the most urban cities such as Tokyo and Osaka had been surveyed as one of the sample areas in the 2008 survey by the Ministry of Health, Labor, and Welfare [8].

Study subjects

For this survey, we initially identified 8,000 subjects in the general population by a stratified two-stage random sampling method of residents of the four areas. We selected 50 census tracts for each area and then selected 25 individuals, aged 40–79 years, within each census tract, thus identifying 2,000 individuals for each area. The census tracts usually cover 200 families to conduct national census surveys in Japan. We randomly sampled 50 census tracts in each prefecture and then sampled 25 individuals in each census tract according to the national census method in Japan. We mailed questionnaires to potential participants in June 2007 and sent a reminder postcard 2 weeks later.

Questionnaire

To enable comparisons with previous findings using a national sample, we decided to use the same questionnaire used by the Ministry of Health, Labor, and Welfare [8]. This questionnaire surveyed the respondents about preferred place of care and place of death using two brief scenarios. The first scenario described a terminally ill cancer patient with pain and given a prognosis of 6 months or less (the pain scenario), while the other scenario described a terminally ill cancer patient without pain, but dependent on others in their daily activities (without pain and dependent scenario). Choices with simplified combination definitions were: (1) home until death (home–home); (2) receive care at home, and admitted to hospice if necessary (home–hospice); (3) receive care at home, and admitted to hospital if necessary (home–hospital); (4) admitted to hospice earlier and stay until death (hospice–hospice); (5) admitted to nursing home and stay until death (nursing home–nursing home); (6)

admitted to hospital and stay until death (hospital–hospital); or (7) receive aggressive treatment at cancer center (cancer center–cancer center) [17]. Hospice meant in this study was palliative care units or inpatient hospice, and home-based hospice was regarded as home.

To clarify concerns about home care, we asked the respondents to rate the levels of agreement on the five point Likert-type scale from 1 (disagree) to 5 (strongly agree) for five items: concern of being unable to achieve adequate pain relief, unable to adequately respond to sudden changes in out-of-hours care, family physician visiting home is unavailable, family burden is heavy, and home care is too expensive. In addition, to explore respondent values about home care, we also asked the respondents to select one of three choices that best suited their chosen scale value to describe living and dying at home: (1) “dying at home is the best, if family respite and expert advice are available”; (2) “dying at home is undesirable despite any health care systems, due to perceived heavy burden to family”; and (3) “unsure”.

To establish the respondent background, we asked the respondents to report age, gender, length of stay in that region, and presence or absence of family members with cancer. To identify cancer patients, we asked the respondents to report whether they suffered from any of a list of 15 specific diseases including cancer.

Statistical analyses

Data distributions were calculated separately for the general public from each region and for cancer patients. Comparisons were performed using the chi-square test.

To explore the predictors of choosing home as preferred place of care, we compared the subject backgrounds and concern items about home care between those who chose home as place of care (i.e., home–home, home–hospice, home–hospital) and those who chose a place other than home (i.e., hospice–hospice, nursing home–nursing home, hospital–hospital, cancer center–cancer center) for each scenario. We then performed a multivariate logistic regression

Table 1 Subject backgrounds

	General public				Cancer patients
	Tsuruoka	Kashiwa	Hamamatsu	Nagasaki	
<i>N</i>	994	1106	947	937	189
Gender (male)	44% (<i>n</i> =442)	46% (<i>n</i> =507)	46% (<i>n</i> =439)	39% (<i>n</i> =370)	52% (<i>n</i> =99)
Age (year)	61±11	59±10	59±10	60±11	64±9.6
Length of stay in the region (>5 years)	90% (<i>n</i> =896)	95% (<i>n</i> =1054)	93% (<i>n</i> =876)	91% (<i>n</i> =855)	99% (<i>n</i> =187)
Experience that one of the family members had cancer	54% (<i>n</i> =536)	54% (<i>n</i> =592)	49% (<i>n</i> =465)	58% (<i>n</i> =540)	60% (<i>n</i> =113)

Total of some items do not add to 100% due to missing data

analysis of the dependent variable of choosing home as preferred place of care using all variables identified by univariate analyses as statistically significant ($P < 0.05$).

Results

Of the 8,000 questionnaires sent out to the general population in the four regions, we obtained a total of 3,984 (50%) responses, distributed as follows: 994 (50%, Tsuruoka), 1,106 (55%, Kashiwa), 947 (47%, Hamamatsu), and 937 (47%, Nagasaki). Of these, 189 responses were classified as “cancer patients”. Table 1 summarizes the demographic variables of all the respondents.

There were statistically significant differences in preferred place of care and place of death for the general public across regions for both scenarios ($P < 0.001$). In general, however, these differences were small (Table 2), with the absolute difference in percentages for each item among the regions less than 8%.

For the with-pain scenario, approximately 30% of all respondents chose home–hospice, while about half chose home as preferred place of care. For the dependent-without-pain scenario, approximately 20% of the respondents across regions chose one of home–hospice, hospice–hospice, or nursing home–nursing home, while approximately 40% chose home as preferred place of care.

For both scenarios, approximately 40% of the cancer patients chose home as preferred place of care, and 20–25% chose home–hospice as the preferred place of care–place of death (Table 3). There was a statistically significant difference in preferred place of care and place of death between cancer patients and the general public ($P < 0.001$ for both scenarios): lower percentages of home–home choice (e.g., 4.2% of cancer patients vs. 9.7% of general public for the with-pain scenario, and higher percentages of hospital–hospital choice (e.g., 20% of cancer patients vs. 8.0% of general public for the with-pain scenario).

Regarding concerns about home care, approximately 80% of both the general public and cancer patients agreed or strongly agreed that family burden is heavy, and approximately 70% agreed or strongly agreed that they were unable to adequately respond to sudden changes in out-of-hours care (Table 4). In addition, more than half of respondents agreed or strongly agreed that family physician visiting their home was unavailable and home care was too expensive, while approximately 40% agreed or strongly agreed that they were unable to achieve adequate pain relief at home.

In addition, the scale values ascribed to home care were split among the responses. Approximately 40% of respondents believed that dying at home is the best option if family respite and expert advice is available, while a similar number believed that dying at home is undesirable despite any

Table 2 Preferred place of care and place of death among the general public

Place of care	Place of death	With pain				Dependent without pain			
		Tsuruoka (n=994)	Kashiwa (n=1106)	Hamamatsu (n=947)	Nagasaki (n=937)	Tsuruoka (n=994)	Kashiwa (n=1106)	Hamamatsu (n=947)	Nagasaki (n=937)
Home	Home	11% (n=110)	11% (n=118)	9.3% (n=88)	7.4% (n=69)	6.6% (n=66)	5.2% (n=58)	5.4% (n=51)	4.7% (n=44)
	Hospice, if necessary	25% (n=244)	31% (n=346)	30% (n=286)	29% (n=273)	19% (n=186)	23% (n=249)	22% (n=212)	22% (n=202)
	Hospital, if necessary	13% (n=128)	8.7% (n=96)	12% (n=109)	11% (n=102)	11% (n=112)	7.9% (n=87)	10% (n=95)	9.4% (n=88)
Hospice	Hospice	12% (n=116)	18% (n=200)	17% (n=160)	17% (n=162)	17% (n=168)	24% (n=261)	24% (n=226)	23% (n=218)
Hospital	Hospital	12% (n=119)	5.3% (n=59)	7.5% (n=71)	7.6% (n=71)	13% (n=132)	6.9% (n=76)	7.5% (n=71)	9.0% (n=84)
Nursing home	Nursing home	14% (n=141)	11% (n=122)	10% (n=95)	10% (n=95)	23% (n=224)	21% (n=235)	17% (n=165)	17% (n=159)
Cancer centers	Cancer centers	9.5% (n=94)	11% (n=122)	6.8% (n=64)	9.2% (n=86)	6.7% (n=67)	9.0% (n=100)	5.7% (n=54)	6.3% (n=59)

Total of some items do not add to 100% due to missing data

Table 3 Comparison of preferred place of care and place of death between cancer patients ($n=188$) and the general public

Place of care	Place of death	With pain		Dependent without pain	
		Cancer patients ($n=189$)	General public ($n=3984$)	Cancer patients ($n=189$)	General public ($n=3984$)
Home	Home	4.2% ($n=8$)	9.7% ($n=385$)	2.1% ($n=4$)	5.5% ($n=219$)
	Hospice, if necessary	25% ($n=48$)	29% ($n=1149$)	20% ($n=38$)	21% ($n=849$)
	Hospital, if necessary	12% ($n=23$)	11% ($n=435$)	14% ($n=26$)	9.6% ($n=382$)
Hospice	Hospice	13% ($n=24$)	16% ($n=638$)	21% ($n=39$)	22% ($n=873$)
Hospital	Hospital	20% ($n=37$)	8.0% ($n=320$)	16% ($n=31$)	9.1% ($n=363$)
Nursing home	Nursing home	12% ($n=22$)	11% ($n=453$)	15% ($n=28$)	20% ($n=783$)
Cancer centers	Cancer centers	7.9% ($n=15$)	9.2% ($n=366$)	6.3% ($n=12$)	7.0% ($n=280$)

Total of some items do not add to 100% due to missing data

health care systems due to the perceived heavy burden to family (Table 4).

The respondents who chose home as place of care in with-pain scenario were significantly more likely to be younger, and significantly less likely to have concern of being unable to achieve pain relief, of being unable to adequately respond to sudden changes in out-of-hours, that family burden is heavy, and that home care is too expensive (Table 5). Independent determinants of choosing home as place of care were: age, concern of being unable to adequately respond to sudden changes in out-of-hours, and concern family burden is heavy.

The respondents who chose home as the place of care when presented with the dependent-without-pain scenario were significantly more likely to be male and significantly less likely to be concerned about being unable to adequately respond to sudden changes in out-of-hours care and a heavy family burden (Table 5). Independent determinants of choosing home as place of care with the dependent-without-pain scenario were male, concern of being unable

to adequately respond to sudden changes in out-of-hours care, and concern about family burden.

Discussion

This is the first survey, to our knowledge, that compares preferred place of care and place of death of the general public among multiple areas in Japan and that addresses preferred place of care and place of death in cancer patients. One of the most important findings was of minimum difference in preferred place of care and place of death of the general public among all respondents and across all regions surveyed in this study. Indeed, the data in this study were similar to those from the national sample surveyed by the Ministry of Health, Labor, and Welfare [8]. One difference was our finding that regional demographic characteristics such as availability of beds, hospital provision, and differences between rural and urban areas are significant determinants of actual place of death [9], although this is not

Table 4 Concerns and values about home care of general public and cancer patients

	Total ($n=3,984$)	General public				Cancer patients ($n=189$)
		Tsuruoka ($n=994$)	Kashiwa ($n=1,106$)	Hamamatsu ($n=947$)	Nagasaki ($n=937$)	
Concerns						
Unable to achieve adequate pain relief	38% ($n=1,502$)	40% ($n=402$)	37% ($n=413$)	39% ($n=373$)	34% ($n=314$)	40% ($n=68$)
Unable to adequately respond to sudden changes out-of-hours	69% ($n=2,761$)	67% ($n=665$)	73% ($n=804$)	72% ($n=684$)	65% ($n=608$)	68% ($n=129$)
Family physician visiting home is unavailable	55% ($n=2,201$)	49% ($n=485$)	66% ($n=727$)	57% ($n=539$)	48% ($n=450$)	57% ($n=107$)
Family burden is heavy	81% ($n=3,241$)	80% ($n=791$)	83% ($n=916$)	84% ($n=793$)	79% ($n=741$)	79% ($n=149$)
Too expensive	52% ($n=2,058$)	50% ($n=495$)	51% ($n=563$)	51% ($n=487$)	55% ($n=513$)	52% ($n=99$)
Values						
Dying at home is the best, if family respite and expert advice available	39% ($n=1,535$)	47% ($n=391$)	46% ($n=458$)	45% ($n=368$)	41% ($n=318$)	37% ($n=63$)
Dying at home is undesirable despite any health care systems, due to perceived heavy burden to family	31% ($n=1,227$)	36% ($n=300$)	34% ($n=331$)	35% ($n=290$)	39% ($n=306$)	46% ($n=78$)
Unsure	16% ($n=657$)	17% ($n=140$)	20% ($n=198$)	20% ($n=165$)	20% ($n=154$)	17% ($n=28$)

Data are percentages of the responses of “agree” or “strongly agree” for each item

age, male, better physical health, family physician visiting home available, and the concept of a good death [6, 7, 11–14]. The findings of this study is also generally consistent with previous studies from Western countries, and confirmed that many among the general public and patient population have similar concerns about home care and that this significantly contributes to the expressed preference [11–14].

Family burden in this context includes patient-perceived burden and actual family burden in caregiving. Multiple studies indicate that patient-perceived burden is one of the most serious stressors in terminally ill cancer patients, even if family members do not report actual caregiving burden [21, 22]. Other studies confirmed that perceived burden is a major component in a cancer patient's decision regarding home care [23, 24]. On the other hand, family may experience actual burden from caregiving at home regardless of the levels of patient-perceived burden, especially in caring patients with low functional status [25, 26]. In addition, meta-analyses identified inadequate information including emergency measures and out-of-hour support as unmet needs of informal caregivers [27, 28], and that educational intervention alone achieves minimum beneficial effects on the concerns of family burden and being unable to adequately respond to sudden changes out-of-hours. These findings suggested that clinicians should alleviate such concerns through ongoing continual support in how to address problems at home, arranging regional resources to reduce actual family burden, and the provision of psychological support for patient-perceived burden [27–30].

This study had several limitations. The response rate of 50% was not particularly high, and thus the findings are not easily applicable. We believe, however, that this is an acceptable limitation because other population-based surveys conducted by the Ministry of Health, Labor, and Welfare obtained similar results [8]. Furthermore, as we could not include some areas with local culture, e.g., Okinawa and islands areas, the results might be applied for these areas. We believe, however, the overall conclusion is less likely to change because major typical areas in Japan were surveyed in this study and the 2008 national surveys.

In conclusion, there was minimum difference in preferred place of care and place of death among the general public across four regions; cancer patients were less likely to report home as preferred place of care than the general public, and among the cancer patients at least 40% preferred home as the place of care and a considerable number preferred hospice. The major concerns significantly associated with preferred place of care were concern about family burden and being unable to adequately respond to sudden changes out-of-hours. Home care and hospice service in Japan needs to be more accessible and of good quality. In addition, clinicians should alleviate patient concerns about burden to their

family and being unable to adequately respond to sudden changes out-of-hours by ongoing continual support regarding home problems, arranging regional resources to reduce actual family burden, and providing psychological support for patient-perceived burden.

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STUDY PROTOCOL

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A region-based palliative care intervention trial using the mixed-method approach: Japan OPTIM study

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Abstract

Background: Disseminating palliative care is a critical task throughout the world. Several outcome studies explored the effects of regional palliative care programs on a variety of end-points, and some qualitative studies investigated the process of developing community palliative care networks. These studies provide important insights into the potential benefits of regional palliative care programs, but the clinical implications are still limited, because: 1) many interventions included fundamental changes in the structure of the health care system, and, thus, the results would not be applicable for many regions where structural changes are difficult or unfeasible; 2) patient-oriented outcomes were not measured or explored only in a small number of populations, and interpretation of the results from a patient's view is difficult; and 3) no studies adopted a mixed-method approach using both quantitative and qualitative methodologies to interpret the complex phenomenon from multidimensional perspectives.

Methods/designs: This is a mixed-method regional intervention trial, consisting of a pre-post outcome study and qualitative process studies. The primary aim of the pre-post outcome study is to evaluate the change in the number of home deaths, use of specialized palliative care services, patient-reported quality of palliative care, and family-reported quality of palliative care after regional palliative care intervention. The secondary aim is to explore the changes in a variety of outcomes, including patients' quality of life, pain intensity, family care burden, and physicians' and nurses' knowledge, difficulties, and self-perceived practice. Outcome measurements used in this study include the Care Evaluation Scale, Good Death Inventory, Brief pain Inventory, Caregiving Consequence Inventory, Sense of Security Scale, Palliative Care Knowledge test, Palliative Care Difficulties Scale, and Palliative Care Self-reported Practice Scale. Study populations are a nearly representative sample of advanced cancer patients, bereaved family members, physicians, and nurses in the region.

Qualitative process studies consist of 3 studies with each aim: 1) to describe the process in developing regional palliative care in each local context, 2) to understand how and why the regional palliative care program led to changes in the region and to propose a model for shaping regional palliative care, and 3) to systemically collect the barriers of palliative care at a regional level and potential resolutions. The study methodology is a case descriptive study, a grounded theory approach based on interviews, and a content analysis based on systemically collected data, respectively.

Discussion: This study is, to our knowledge, one of the most comprehensive evaluations of a region-based palliative care intervention program. This study has 3 unique aspects: 1) it measures a wide range of outcomes, including quality of care and quality of life measures specifically designed for palliative care populations, whether patients died where they actually preferred, the changes in physicians and nurses at a regional level; 2) adopts

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qualitative studies along with quantitative evaluations; and 3) the intervention is without a fundamental change in health care systems. A comprehensive understanding of the findings in this study will contribute to a deeper insight into how to develop community palliative care.

Trial Registration: UMIN Clinical Trials Registry (UMIN-CTR), Japan, UMIN000001274.

Background

Palliative care is an essential part of integrated cancer treatment [1]. Palliative care should be provided throughout an entire region, and several outcome studies have explored the effects of regional palliative care programs on places of death, the use of palliative care resources, patient-reported outcomes, family-reported outcomes, and cost [2-9]. In a cluster randomized controlled trial, a regional palliative care intervention, including developing a specialized inpatient palliative care service at an academic hospital, strengthening the cooperation between specialized palliative care and community health care services, developing clinical guidelines, and educational programs for community health care providers, contributed to an increase in the number of home deaths and higher levels of family satisfaction, but the patient-reported quality of life, measured by the EORTC-C30, was not significantly different [2-4]. A pioneer work as a regional palliative care model, the Edmonton program, observed that constructing a novel regional system, including a regional palliative care office to coordinate palliative care activities at specialist and community levels throughout the region, resulted in an increased number of home deaths and use of specialized palliative care services [5,6]. A recent palliative care quality improvement project in Ontario included developing and disseminating standard clinical tools for collaborative care planning and symptom assessment [7,8]. The audit study from this project demonstrated an increased documentation of symptoms and decreased use of emergency visits, while the symptom intensity and family satisfaction did not significantly improve. In addition, the Catalonia WHO demonstration project demonstrated an increase in the quantity and variety of specialized palliative care services and potential cost-saving effects [9]. More recently, the U.K. implemented the Gold Standards Framework, stressing communication and coordination in the community through developing a palliative care patient registry and regular meetings [10-13]. Qualitative studies suggest the most important benefit of the Gold Standards Framework is facilitating communication among health care professionals in the community, although the direct effects on patient and/or family outcomes were formally unmeasured. Multiple studies from Canada, the Netherlands, and Australia which investigated the process of developing community palliative care networks again revealed the perceived

importance of an increase in personal and formal contacts in health care professionals [14-16].

These studies provide important insights into the potential benefits of regional palliative care programs, but the clinical implications are still limited, because: 1) the interventions included a fundamental change in the structure of the health care system (Norway, Edmonton, Catalonia, and the U.K.), and, thus, the results would not be applicable for many regions where structural changes are difficult or unfeasible; 2) patient-oriented outcomes were not measured or explored only in a small number of populations, and interpretation of the results from a patient's view is difficult; and 3) no studies adopted the mixed-method approach using both quantitative and qualitative methodologies to interpret the complex phenomenon from multidimensional perspectives [17-20].

We believe, therefore, that a new study should include: 1) an intervention program available for many regions without fundamental changes to the health care system, 2) adequate patient-oriented outcomes, and 3) qualitative studies along with quantitative evaluation.

The aim of this presentation is to describe a study protocol of a region-based palliative care intervention trial using the mixed-method approach: the Outreach Palliative care Trial of Integrated Model (OPTIM study) from Japan.

Methods and Design

Overview and aims

This is a regional intervention trial, consisting of a pre-post outcome study and qualitative process studies. Initially, this study was designed as a cluster randomized controlled trial, but we have decided to adopt a mixed-method design because: 1) intervention itself should be applied to all populations over the country and a clear distinction between intervention and control groups is difficult [20], 2) a concealment problem is likely to occur [2-4], and 3) the most important mission at a national level is not to clarify if one specific intervention actually changes outcomes, but to obtain comprehensive insights into how to disseminate palliative care throughout the country [17,18].

The primary aim of the pre-post outcome study is to evaluate the change in the number of home deaths, use of specialized palliative care services, patient-reported quality of palliative care, and family-reported quality of

palliative care after the regional palliative care program. The secondary aims are to explore the changes in a variety of outcomes, including the distribution of locations of death; patient- and/or family-reported quality of life, whether patients died where they actually preferred, time spent at home, satisfaction, pain, care burden; knowledge, belief, and concerns about palliative care; and knowledge, difficulties, and self-reported practice about palliative care of physicians and nurses. Qualitative process studies are performed to obtain a deep insight into how and why the regional palliative care program does or does not work.

Data for the pre-post outcome study were collected in 2007-2008 as pre-intervention data and in 2010-2011 as post-intervention data. Data for qualitative studies were collected throughout the study periods.

Ethical and scientific validity was confirmed by the institutional review board of this study and all participating institutions.

Setting

To explore the potential influence of the variations in the existing health care system, we have decided to conduct this trial in 4 regions with different palliative care systems across Japan: Tsuruoka (170,000 population, Yamagata Prefecture), Kashiwa (670,000 population, Chiba Prefecture), Hamamatsu (820,000 population, Shizuoka Prefecture), and Nagasaki (450,000 population, Nagasaki Prefecture). Kashiwa and Hamamatsu have specialized hospital palliative care teams in a cancer center and general hospitals, respectively; Nagasaki has a coordinated palliative care system for home patients in addition to hospital palliative care teams; and Tsuruoka has no formal specialized palliative care service at the beginning of the study.

Interventions

Designing interventions

Interventions were designed on the basis of literature review, preliminary survey, and discussion among the researchers and clinical practitioners from the study regions [21-33].

To construct a conceptual framework, we initially reviewed the existing domestic and international literature available to identify barriers to provide quality palliative care [21-23], and performed a preliminary survey of 8,000 general public and 8,000 medical health care providers in the 4 regions before planning the interventions [24]. The task force then drafted the intervention protocol with close collaborative with representative health care providers from the 4 regions, and has finalized intervention protocol. The intervention protocol describes the minimum requirements for this study to allow it to meet the specific situations of regions [19,20].

To deliver the intervention, each region is asked to establish a "regional palliative care center" with several local leaders, who receive a start-up 2-day workshop from the study team before intervention with continuous follow-up. Local leaders include physicians, nurses, and medical social workers who have already been working as a clinical specialist in the region. Furthermore, local leaders foster link-staffs at each regional level. To facilitate interventions, meetings among local leaders are planned to be held about 25 times during this study period; a certified community nurse visits each region and followed up by telephone and e-mail as a facilitator; and interactive conferences among link-staffs from the 4 regions are held 3 times.

The interventions include 4 areas: 1) to improve the knowledge and skills of palliative care providers, 2) to increase the availability of specialized palliative care services for community patients, 3) to coordinate community palliative care resources, and 4) to provide appropriate information about palliative care to the general public, patients, and families. We designed all interventions not to require a fundamental change in the health care system, that is, to optimize the resources within the region.

To investigate the actual implementation, we regularly monitor the intensity of interventions by telephone and visiting the intervention area [18]. In addition, in the surveys, we investigate the levels of exposure to each intervention (e.g., whether they used or noticed materials, or they participated in workshops).

Specific interventions

To improve the knowledge and skills of palliative care providers, we have prepared a pocket-size manual of palliative care (a book and videos) and 13 assessment tools (12 educational pamphlets for patients and families for each symptom, such as pain; and 1 comprehensive assessment tool). These are provided with printed materials and a web site. The local leaders are asked to disseminate these materials and hold an interactive workshop to educate them on how to use these materials [25-28].

To increase the availability of specialized palliative care services for community patients, each region is asked to establish a community palliative care team through optimizing the existing resources, because, at the time of the study, such community palliative care teams are not available in Japan. In addition, the community palliative care team provides outreach educational visits for community intuitions [29].

To coordinate community palliative care resources, each region is asked to establish a "regional palliative care center". The regional palliative care center is then asked to hold a multidisciplinary conference to develop collaborative relationships among health care workers in the region, and share and resolve problems [10,14-16].

In addition, local leaders facilitate the use of patient-held-records to maintain continuity of care [30], and facilitate the introduction of a discharge planning system for all hospitals in the region [31].

To provide appropriate information about palliative care, we have prepared a hand-sized leaflet, note-sized leaflets, posters, and DVDs about palliative care, and ask local leaders to put them in public and health care institutions [32,33]. In addition, local leaders ask public libraries to provide a “book set” (a set of 100 books about palliative care), and provide workshops for the general public. Target themes identified as barriers include the misconception about cancer pain and opioids, palliative care, and death at home [33].

Measurements

Questionnaires are sent to patients, bereaved family members, physicians, and nurses recruited consecutively following the inclusion criteria by mail. We intend to obtain the sample as a nearly representative sample of each region as much as possible.

Subjects

Patients Due to the lack of an established method to identify all cancer patients living in a specific area in Japan, we identify all hospitals in the study areas with reference to hospital lists from the Japan Hospital Association, the largest authorized organization of hospitals in Japan, and the local resource information. In the pre-intervention survey, we obtained the participation of a total of 23 of 34 hospitals treating cancer patients (8,964 beds of 11,033 beds, 81%).

Inclusion criteria are: 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 department or each specialty division, such as respiratory medicine for lung cancer patients (not palliative care division only), and 4) informed of malignancy. We have determined to exclude malignancy of the brain, blood, central nervous system, neck, soft tissue, and other uncommon primary sites, due to the infrequent prevalence and increased technical difficulties in patient recruitment. We have decided to examine only patients who were informed of malignancy, because we use the term “cancer” in the questionnaire. Exclusion criteria include: 1) inability of the patient to complete the questionnaire (dementia, cognitive failure, psychiatric illness, language difficulty, or visual loss), 2) severe emotional distress of the patient as determined by the principal treating physicians, and 3) poor physical condition unable to complete the questionnaire.

Bereaved family Due to the legal limitation of a mortality-follow back survey, we identify all hospitals in the study areas in the same way as the patient survey, and general practice clinics with experience of caring for terminally ill cancer patients with reference to the local resource information.

Inclusion criteria for this bereaved family survey are: 1) bereaved adult family members of an adult cancer patient who died in the institution or at home (one family member was selected for each patient), 2) a primary tumor site of either the lung, esophagus, stomach, colon, rectum, pancreas, liver, biliary system, kidney, prostate, bladder, breast, ovary, or uterus, 3) received medical treatments on at least 3 or more days by the institution, and 4) informed of malignancy. Exclusion criteria include: 1) incapacity to complete the questionnaire (dementia, cognitive failure, psychiatric illness, language difficulty, or visual loss), 2) severe emotional distress of the family as determined by the principal treating physicians, 3) treatment-associated death or death from commodity, 4) death in intensive care units, and 5) family member unavailable.

Physicians and nurses We identify hospitals treating cancer patients in the same way as the patient survey, all general practice clinics, and district nurse services.

Inclusion criteria for the physician and nurse survey are: 1) hospital physicians and nurses working at cancer-related branches for at least 3 years (internal medicine, surgery, respiratory medicine, gastro-enterology, urology, breast cancer, gynecology, hematology, radiation oncology, clinical and medical oncology, otolaryngology, and palliative medicine), 2) representative physicians of general practice clinics, and 3) all district nurses.

Outcome Measures (Table 1)

We have determined that this study adopt 4 primary end-points due to the complex nature of the intervention: 1) number of home deaths, 2) number of patients who received specialized palliative care services, 3) patient-reported quality of palliative care, and 4) bereaved family-reported quality of palliative care [20]. In addition, we adopt multiple end-points to interpret the results from multiple perspectives.

Location of death We record the number of cancer patients who died at home, hospitals, and nursing homes from the national government registry every year, and, further, the number of patients who died in palliative care units from each palliative care unit. As the reference data, we obtain the average rate of home death in Japan during this study period. The rationale of setting the number of home deaths as one of the primary end-points is that, while many patients want to die at home, home deaths actually occur at a rate of only 6.0% in Japan [24].

Table 1 Outcome measures

	Primary end-points	Secondary end-points
Location of death	Home death	Distribution of location of death (home, hospital, palliative care units, nursing home)
Use of specialized palliative care services Patients	Number of patients who received specialized palliative care services	Backgrounds of patients referred to specialized palliative care services
Patients		
Quality of palliative care	Total score of 3 subscales of "physical care provided by physicians", "physical care provided by nurses", "psycho-existential care) of the Care Evaluation Scale	Care Evaluation Scale -physical care provided by physicians -physical care provided by nurses -psycho-existential care -help with decision-making -coordination/consistency of care
Quality of life		Good Death Inventory -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 the family -having independence -having environmental comfort -being respected as an individual -a feeling of fulfillment at life's completion
Pain		Brief Pain Inventory
Satisfaction		Satisfaction scale
Knowledge, beliefs, and concerns		Knowledge of opioids, Beliefs about palliative care, Concerns about home care
Feelings of support and security about cancer care in the region Bereaved family members		Sense of Security Scale
Bereaved family members		
Quality of palliative care	Total score of 3 subscales of "physical care provided by physicians", "physical care provided by nurses", "psycho-existential care) of the Care Evaluation Scale	Care Evaluation Scale -same as patient, and, -help with decision making for family -family care
Quality of life of the patient (proxy)		Good Death Inventory (same as patient)
Satisfaction		Satisfaction scale
Knowledge, beliefs, and concerns		Knowledge of opioids, Beliefs about palliative care, Concerns about home care
Feelings of support and security about cancer care in the region		Sense of Security Scale
Care burden		Caregiving Consequence Inventory -Burden
Time spent at home		Time spent at home
Physicians and nurses		
		Palliative Care Knowledge Test -philosophy, pain, dyspnea, delirium, and gastrointestinal symptoms Palliative Care Difficulty Scale -expert support, alleviating symptoms, community coordination, communication in multidisciplinary teams, and communication with patients and families Palliative Care Self-reported practice Scale

Use of specialized palliative care services The rationale of setting the number of patients who received specialized palliative care services as one of the primary end-points is that multiple studies revealed the beneficial effects of specialized palliative care services on

patient outcomes [34,35], and, thus, we believe it is reasonable to assume that higher involvement in specialized palliative care services would result in the improvement in patient outcomes [36]. To calculate the number of patients who received specialized palliative care services,

we initially identify all specialized palliative care services, and ask each service to provide a complete patient list every year. The specialized palliative care service is defined as “specialized palliative care provided by palliative care specialists”, including: 1) palliative care unit, 2) hospital palliative care team, 3) community palliative care team, 4) outpatient palliative care clinic, and 4) home palliative care team.

The number of patients who received specialized palliative care services is defined as the total of number of patients listed in each specialized palliative care service, and, thus, if one patient received two types of specialized palliative care service, the number of uses of specialized palliative care services is two. Although we have acknowledged the non-duplicated counting is ideal, we gave up on this calculation because not all participating institutions allow providing patient data beyond the institutions due to privacy issues. The ratio of the number of patients who received specialized palliative care services to all cancer death was calculated.

In addition, to explore whether “early palliative care” is realized, the backgrounds of patients referred to specialized palliative care services, such as the performance status, status of disease-modifying treatment, and consultation aims, are obtained from the patient lists.

Quality of palliative care The quality of palliative care is measured by both patients and bereaved families using the Care Evaluation Scale, a well-validated and the most commonly used measurement tool to quantify the user-perceived quality of palliative care in Japan [35]. The psychometric properties are established in both patients and bereaved family members [37,38]. The full version of the Care Evaluation Scale consists of 8 subscales for patients and 10 subscales for families with a 6-point Likert-type scale from “1: improvement is not necessary at all” to “6: highly necessary”. One item example is “doctors dealt promptly with discomforting symptoms of the patient”. For this study, we have excluded 3 subscales, environment, cost, and availability, because the intervention does not intend to change these outcomes. For the primary end-points, we use 3 subscales (physical care provided by physicians, physical care provided by nurses, and psycho-existential care) as a single scale, because this directly measures the degree to which patients/family members evaluate medical professionals respond to patients’ physical and psychological distress. All subscales of the Care Evaluation Scale are used for the secondary end-points.

Quality of life Quality of life is measured by both patients and bereaved families using the Good Death Inventory, a specific measure of the quality of life of Japanese patients with advanced cancer [39,40]. We have decided to use the Good Death Inventory, not common tools such as EORTC or FACT, because: 1) we

intend to investigate broader areas of quality of life Japanese palliative care populations regard as important, especially psycho-existential components [41,42], and 2) existing quality of life measures largely depend on patient functional levels and previous studies failed to detect potentially beneficial effects of intervention [4]. The full version of this scale consists of 10 domains with a 7-point Likert-type scale from “1: strongly disagree” to “7: strongly agree”. One item example is “I am free from physical distress”. The subscale “living in a favorite place” includes “(the patient) is able to stay at his/her favorite place”, and, thus, we can analyze not only the death location but also whether the death location was a preferred place of death of the patients [2].

Satisfaction Satisfaction of the patient and family with medical care is measured using a single item scale: “Are you satisfied with the medical care you currently receive?” with a 6-point Likert-type scale varying from “1: very dissatisfied” to “6: very satisfied”.

Pain intensity Pain intensity of the patients is measured using the Japanese version of the Brief Pain Inventory, with a score given for the pain at its worst (0-10), at its best (0-10) and a score for the average pain felt (0-10) over the previous 24 hours. The reliability and validity in Japanese populations has been established [43].

Knowledge, perceptions, and concerns about palliative care Knowledge, perceptions, and concerns about palliative care of the patients and families is measured using 10 items, similar to previous surveys [33], on a 5-point Likert-type scale from 1:strongly disagree to 5: strongly agree. Knowledge of opioids is examined using 2 items: “opioids can relieve most pain caused by cancer” and “opioids are addictive and/or shorten life”. Beliefs about palliative care are examined using 3 items: “palliative care relieves pain and distress”, “palliative care is provided along with chemotherapy and/or radiation therapy”, and “palliative care is only for terminally ill patients”. Concerns about homecare are examined based on 5 items: “pain can be alleviated as effectively through home-visit services as it can at the hospital”, “home - visit services cannot respond to sudden changes in a patient’s condition”, “it is hard to find home-visiting physicians”, and “being taken care of at home puts a burden on the family”.

Feelings of support and security regarding cancer care in the region Feelings of support and security regarding cancer care in the region are measured by patients and families using the newly developed Sense of Security Scale [44]. This is 5-item scale to assess feelings of support and security concerning cancer care in a region. One item example is “I would feel secure as a variety of medical care services are available in the region”.

Care burden Care burden is measured using the Caregiving Consequences Inventory [45]. The Caregiving

Consequences Inventory is developed to quantify caregiving consequences from a bereaved family member's perspective, and it consists of 4 positive domains and 1 burden domain. For this study, the burden domain is used.

Time spent at home Due to a lack of administrative data available to calculate time spent at home, we ask bereaved family members the time spent at home during the last 1 and 3 months.

Knowledge, difficulty, and self-perceived practice of palliative care of physicians and nurses Physician- and nurse-reported knowledge is measured using Palliative Care Knowledge Test [46]. This scale consists of 5 subscales, with correct, incorrect, and do not know responses.

Physician- and nurse-reported difficulty of palliative care is measured with the Palliative Care Difficulty Scale, a validated tool to quantify the levels of difficulty when health professionals provide palliative care [47]. This scale consists of 5 subscales with a 5-point Likert-type scale from 1: never to 5: very much. One item example is "it is difficult to get support from experts on alleviating symptoms".

Physician- and nurse-reported self-perceived practice is measured employing the Palliative Care Self-reported Practice Scale, a validated tool to quantify the levels of adherence to recommended practices in palliative care fields⁴⁷. This scale consists of 6 subscales with a 5-point Likert-type scale from 1: never to 5: very much. One item example is "I routinely inquire about the family's concerns in the dying phase".

Quality indicators As quality indicators as region-level palliative care, we collect 20 quality indicators from nation-level administrative database, such as opioids consumption, the number of home care service, the number of palliative care specialists, and the number of palliative care units.

Qualitative studies

Qualitative studies consisting of 3 studies.

Descriptive study

A descriptive study is performed to describe the process in developing regional palliative care in each local context. The study methodology is descriptive case studies, and this includes a variety of materials each region has made or arranged for local interventions.

Interview study

This study is performed to understand the process of how and why the regional palliative care program makes changes in the region. The ultimate purpose of this study is to propose a model for shaping regional palliative care. The research methodology is a grounded theory approach, and the data source is in-depth interviews with health care professionals.

Systematic collection of barriers and potential resolutions

This study is performed to systemically identify the barriers of palliative care at a regional level and potential resolutions. The research methodology is content analyses, and the data source is multiple focus-groups repeatedly conducted during the entire study period, field notes, and documents obtained.

Sample size calculations and analyses

As this study have 4 primary-end-points, i.e., the number of home deaths, use of specialized palliative care services, patient-reported quality of palliative care, and family-reported quality of palliative care, we have set alpha error of 0.0125 (two-sided) by the Bonferroni correction for multiple comparisons. All variables are compared between before and after the interventions using the Student t-test and Chi-square test, where appropriate.

Patient-reported quality of palliative care and family-reported quality of palliative care

To detect 0.2 effect size (one-fifth difference of standard deviation) for quality of palliative care (the Care Evaluation Scale) under statistical power of 0.8, 558 responses for each pre-intervention and post-intervention period is required for the analyses³⁵. We have thus determined that 1500 patients and bereaved family members should be surveyed at each time in consideration of the estimated response rate (40-60%) and missing values (10%) [35].

The number of home deaths and use of specialized palliative care services

We first assumed 6% and 8% as each pre-intervention value from the national data, respectively, and we expected to achieve 12% and 20% as meaningful increases after the intervention, respectively; and this lead to the calculated sample size of 506 and 186 at the each point, respectively. In practice, as we survey all cancer death in 4 regions (5000), the sample size is sufficient.

Discussion

This study is, to our knowledge, one of the most comprehensive evaluations of a region-based palliative care intervention program. This study has 3 major unique aspects.

First, as an outcome study, this study measures a wide range of outcomes, enabling comprehensive understanding and interpretation of the results. Especially, this study is outstanding in terms of: 1) we can obtain patient and family views as a nearly representative sample of advanced cancer patients and bereaved family members in the region; 2) we measure quality of care and quality of life specifically designed for palliative care populations, not heavily depending on the functional

status; 3) we can know whether a patient actually died where they preferred, not only the location of death itself; and 4) we quantitatively measure the change in physicians' and nurses' knowledge, difficulties, and self-reported practice at regional levels, especially difficulties in communicating among local health care professionals. These efforts are all novel, and would provide useful insights to disseminate palliative care at regional levels as well as important information for designing future intervention studies in this area.

Second, this study adopts a qualitative process method. Rich description in each local context, understanding how the program works in shaping community palliative care through the grounded theory approach, and systematic collection of barriers and resolution will lead to obtaining deep insights into how quality community palliative care is developed. We will use the findings in two ways, namely as a practical guidance for clinicians and as an integrated information resource for policy makers.

Third, the intervention applied in this study is without a fundamental change in health care systems. This means the findings from this study would be applicable to all regions in Japan and probably in other countries, and clarify what is necessary for community palliative care as a basis. In other words, after completing this study, we can plan a randomized controlled trial using "novel" intervention requiring fundamental changes in the health care system.

The study analyses will be completed by the end of 2013, and a comprehensive understanding of the findings of this study will contribute to a deeper insight into how to develop community palliative care.

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Authors' contributions

TMO led the drafting of this paper and development of the protocol. MMI and TY co-designed the protocol from the view point of statistical specialists. AY and TMO co-designed qualitative process studies. NA, YK, MA, KH, MMA, MY, and YS co-designed the intervention protocol as specialists and/or local leaders. KE organized the study structure, funded all aspects of this study, and supervised all phases of this study. All authors read and approved the final draft.

Competing interests

The authors declare that they have no competing interests.

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Original Article

Pain Intensity, Quality of Life, Quality of Palliative Care, and Satisfaction in Outpatients With Metastatic or Recurrent Cancer: A Japanese, Nationwide, Region-Based, Multicenter Survey

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Abstract

Context. Increasing numbers of patients with advanced cancer are receiving anticancer and/or palliative treatment in outpatient settings, and palliative care for outpatients with advanced cancer is being recognized as one of the most important areas for comprehensive cancer treatment.

Objectives. The aim of this study was to evaluate pain intensity, quality of life, quality of palliative care, and satisfaction reported by outpatients with advanced cancer.

Methods. Questionnaires were sent to 1493 consecutive outpatients with metastatic or recurrent cancer from four regions in Japan; 859 responses were analyzed (58%). Questionnaires included the Brief Pain Inventory, Good Death Inventory, Care Evaluation Scale, and a six-point satisfaction scale.

Results. Approximately 20% of the patients reported moderate to severe pain. Whereas more than 70% agreed or strongly agreed with “good relationship with medical staff” and “being respected as an individual,” less than 60% agreed or strongly agreed with “free from physical distress,” “free from emotional distress,” “maintaining hope,” and “fulfillment at life’s completion”; 54% reported some agreement with “feel a burden to others.” About 20% reported that improvement is necessary in physical care by physicians, physical care by nurses, psycho-existential care, help with decision making, and coordination/consistency of care; 13% reported some levels of dissatisfaction.

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Conclusion. A considerable number of outpatients with metastatic or recurrent cancer experienced pain, physical symptoms, emotional distress, and existential suffering, and advocated improvements in palliative care across multiple areas. *J Pain Symptom Manage* 2012;43:503–514. © 2012 U.S. Cancer Pain Relief Committee. Published by Elsevier Inc. All rights reserved.

Key Words

Pain, quality of life, quality of care, satisfaction, outpatient, advanced cancer

Introduction

Palliative care is an essential part of integrated cancer treatment.¹ Increasing numbers of patients with advanced cancer are receiving anti-cancer and/or palliative treatment in outpatient settings,^{2–5} and palliative care for outpatients with advanced cancer is being recognized as one of the most important areas for comprehensive cancer treatment.^{6–15} Nonetheless, few studies investigating patient symptom burden have focused on outpatients with advanced cancer. For example, a recent review on pain prevalence in cancer patients identified 52 relevant studies.⁶ Of these, 22 studies specifically evaluated patients with advanced, metastatic or terminal illness, but only five specifically focused on outpatients. A recent research study from Ontario revealed that half of 45,118 ambulatory cancer patients experienced some level of pain or dyspnea.¹⁵ These studies revealed that many outpatients with cancer suffer from multiple physical and psychological symptoms.

Measuring not only symptom burden but quality of life and patient-reported quality of care can be of value for the comprehensive understanding patients' cancer experiences, and measuring these outcomes at a regional level would be useful for improving palliative care in particular areas. To our best knowledge, however, there are few region-based large surveys of outpatients with advanced cancer that identify symptom burden, quality of life, patient-perceived quality of care, and satisfaction with care.¹⁵ In addition, there have been no multicenter studies in Japan to assess the prevalence of pain as reported by cancer patients themselves, despite a large amount of empirical data from nationwide surveys of bereaved families.¹⁶

Thus, the primary aim of this region-based, multicenter study was to assess pain intensity, quality of life, quality of palliative care, and satisfaction with medical care in outpatients with

metastatic or recurrent cancer. Additional aims were 1) to explore the potential differences in pain intensity, quality of life, quality of palliative care, and satisfaction among regions, and 2) to explore the potential correlations among pain intensity, quality of life, quality of palliative care, and satisfaction.

Methods

A cross-sectional study was performed by sending questionnaires to consecutive outpatients with metastatic or recurrent cancer in four regions in Japan. This survey was part of the preintervention measurements collected for the regional intervention trial, the Outreach Palliative Care Trial of Integrated Regional Model (OPTIM) study, and the study's methodology is reported in detail elsewhere.¹⁷ The ethical and scientific validity of this study was confirmed by the institutional review board of the Japan Cancer Society, and by those of all participating hospitals.

Participating Hospitals

Four study regions were chosen for intervention studies to cover a variety of areas with different palliative care systems across Japan: Tsuruoka (population 170,000, Yamagata prefecture), Kashiwa (population 670,000, Chiba prefecture), Hamamatsu (population 820,000, Shizuoka prefecture), and Nagasaki (population 450,000, Nagasaki prefecture). Kashiwa and Hamamatsu have specialized hospital palliative care teams in a cancer center and general hospitals, respectively; Nagasaki has a coordinated palliative care system for home patients in addition to hospital palliative care teams; and Tsuruoka had no formal specialized palliative care service at the time of the survey.

Because of a lack of an established method to identify all cancer patients living in a specific