medical treatment for cancer in participating hospitals between March 1 and April 30, 2008 (preintervention), and between Nov 1 and Dec 31, 2010 (postintervention). We consecutively sampled bereaved families of patients who died between April 1, 2007, and March 31, 2008 (preintervention), and between April 1, 2010, and March 31, 2011 (postintervention), and questionnaires were sent in October, 2008 (preintervention), and October, 2011 (postintervention). Physicians and nurses were sampled in February, 2008 (preintervention), and January, 2011 (postintervention). Interviews with participating clinical staff were done from Jan 6, to March 31, 2011.

Interventions

Interventions were designed on the basis of a literature review, preliminary surveys, and discussion among the researchers and with health-care professionals in the study regions to resolve the identified major barriers to region-based palliative care.[18,19]

Four types of interventions were implemented—ie, those to improve the knowledge of, and skills in, palliative care (eg, dissemination of manuals and assessment instruments, interactive workshops), increase the availability of specialised palliative care services (eg, establishment of a new community palliative care team, outreach educational visits), coordinate community palliative care resources (eg, regional palliative care centres, whole-region interdisciplinary conferences, patient-held records, discharge-planning systems), and provide appropriate information about palliative care to the general public, patients, and families (panel 1).

To deliver the intervention, each region identified a team of local leaders, including a physician, a nurse, and a medical social worker who had already been working as a clinical specialist in the region, that was responsible for implementation. These leaders received a 2 day workshop from the research team before the interventions. To monitor and help with implentation of interventions, meetings between local leaders and the research group were held 25 times throughout the study, and a certified community nurse visited each region and followed up by telephone and email consistently.

We designed interventions so that structural or financial changes would not be needed in the health-care system, and aimed to optimise health-care resources within a region. With reference to the UK Medical Research Council recommendation[15] about complex interventions, we closely monitored the intensity of interventions, described the narrative intervention process in detail, and investigated the levels of exposure to interventions in the postintervention survey.

Procedures

Our study had four primary endpoints—namely, the proportion of patients with cancer who died at home, coverage of specialist services (ie, the ratio of patients who received specialised palliative care services to all patients who died of cancer), and patient-reported and family-reported qualities of palliative care on the care evaluation scale.[20,21] We obtained the proportion of patients who died at home from the national government registry. As reference data, the mean home-death rate of all patients with cancer in Japan was obtained. The number of patients who received specialised palliative care services was defined as the total number of patients listed by each specialised palliative care service. Duplicate counting was permitted (ie, if patients used more than one specialised palliative care service, they were counted each time). We used the total score of three subscales (physical care provided by physicians, physical care provided by nurses, and psychoexistential care, each of which had three items) of the care evaluation scale as a single scale. Each item was scored on a 6-point Likert-type scale (1=improvement is very necessary; 6=improvement is not necessary at all); high values suggest that patients perceive little need for improvement.

Secondary endpoints were care burden, length of hospital admission, quality of life, difficulty of delivering palliative care, and knowledge of palliative care. We measured care burden on the basis of the care burden section of the caregiving consequences inventory,[22] which comprises four items about physical, emotional, practical, and economic burden scored from 1 ("strongly disagree") to 7 ("strongly agree"); high values suggest a high perceived care burden. Bereaved family members reported the length of inpatient hospital admission of "2 weeks or longer" in the last month of life. Quality of life of patients, as judged by both patients and bereaved

Panel 1: Interventions to improve regional palliative care

Interventions introduced comprised four components. To improve the knowledge and skills of palliative care providers, pocket-size manuals of palliative care (a book and videos) and 13 assessment instruments (12 educational pamphlets for patients and families for each symptom, such as pain, and one comprehensive assessment instrument) were disseminated via printed materials and a web site, and used in educational workshops. To increase the availability of specialised palliative care services for community patients, each region established a community palliative care team through optimisiation of resources; the team provided outreach educational visits for community institutions. To coordinate community palliative care resources, each region established a regional palliative care centre and held a multidisciplinary conference to develop collaborative relationships between health-care workers in the region. Use of patient-held records to maintain continuity of care and introduction of a discharge planning system was encouraged. To provide information about palliative care, hand-sized leaflets, note-sized leaflets, posters, and DVDs were disseminated. Public libraries provided a set of 100 books about palliative care, and workshops were held for the general public.

families (as a proxy for terminally ill patients), was measured with the good death inventory.[23,24] Each item was scored from 1 ("strongly disagree") to 7 ("strongly agree"); high values suggest a high perceived quality of life. Additionally, we asked bereaved family members about whether they believed that patients had died in their preferred place.[23]

Physician-reported and nurse-reported difficulty of delivering palliative care were measured with the palliative care difficulty scale,[25] which consists of five subscales (communication in multidisciplinary teams, community coordination, expert support, alleviation of symptoms, and communication with patients and families) that assess the frequency of problems in daily practice with a Likert-type scale scored from 1 ("never") to 5 ("very much"); high values suggest a high perceived difficulty. We measured physician-reported and nurse-reported knowledge about palliative care with the palliative care knowledge test.[26] Responses were scored as correct or incorrect; high test scores suggest a high level of knowledge about palliative care.

Qualitative assessment

In addition to the surveys, all health-care professionals who had roles in the implementation of the interventions underwent semistructured face-to-face interviews with two trained research nurses in the late stages of, or after, the interventions—specifically between Jan 6 and March 31, 2011. Questions focused on the perceived changes and experiences during the study and perceived reasons for the changes. All interviews were audiotaped, transcribed verbatim, and subjected to thematic analysis on the basis of the grounded theory tradition.[27,28] Two nurse researchers (distinct from the research nurses who did the interviews) used a consistent comparison method to independently code interviews for major themes. Coding frameworks and assignments were discussed under the supervision of an experienced palliative care specialist (TM). Discussions between researchers resulted in full agreement about the codes and themes that emerged.

Statistical analysis

We used logistic regression to compare changes in home death rates and ratios of patients who received specialised palliative care services before and after the interventions. The significance of interventions was assessed by time interaction terms (ie, time trend). For comparison with the national reference data for home deaths, we did repeated measures analysis with robust variances (ie, a generalised estimating equation approach) to account for the longitudinal nature of the data. Scores on the care evaluation scale, caregiving consequences inventory, palliative care difficulty scale, and palliative care knowledge test before and after the interventions were compared with the Student's t-test. We calculated Hedges' g to estimate effect size.[29] For duration of hospital admission, we used the χ^2 test for trend. For interpretation, we deemed effect sizes of 0·2 small, 0·5 moderate, and 0·8 large.[30] We did regressional analyses for all primary endpoints to adjust for participants' background characteristics, such as age, sex, and region.

To adjust for difference in the proportions of places of death of the patients sampled, the weighted means of death location according to census data of four regions

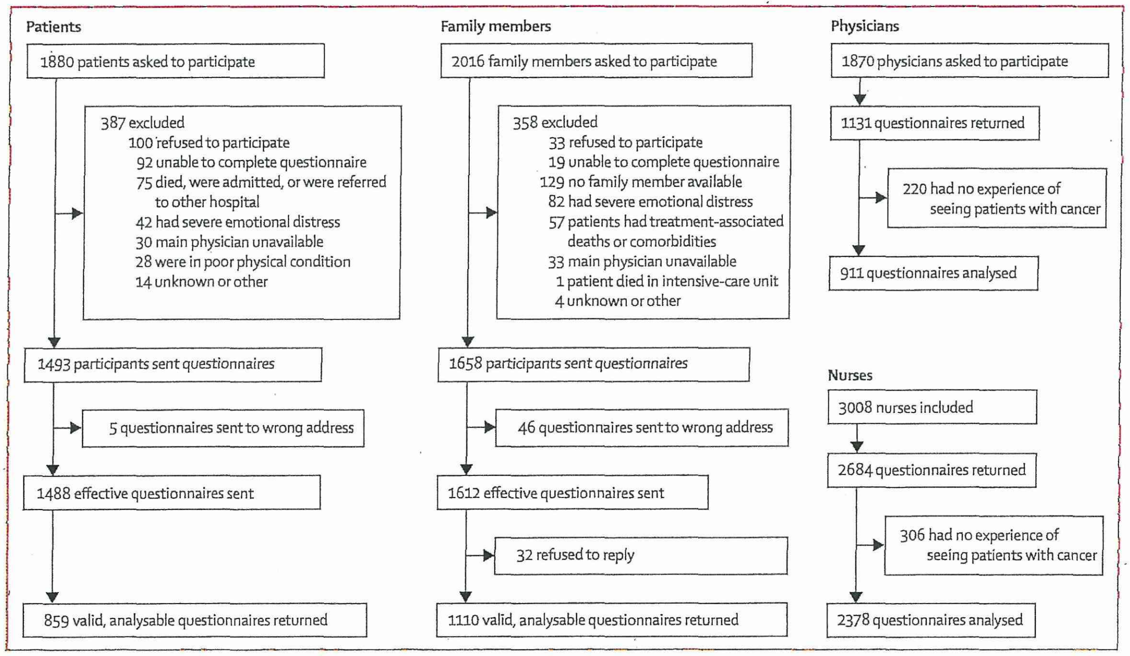

Figure 1: Recruitment of patients, bereaved family members, physicians, and nurses before intervention programme

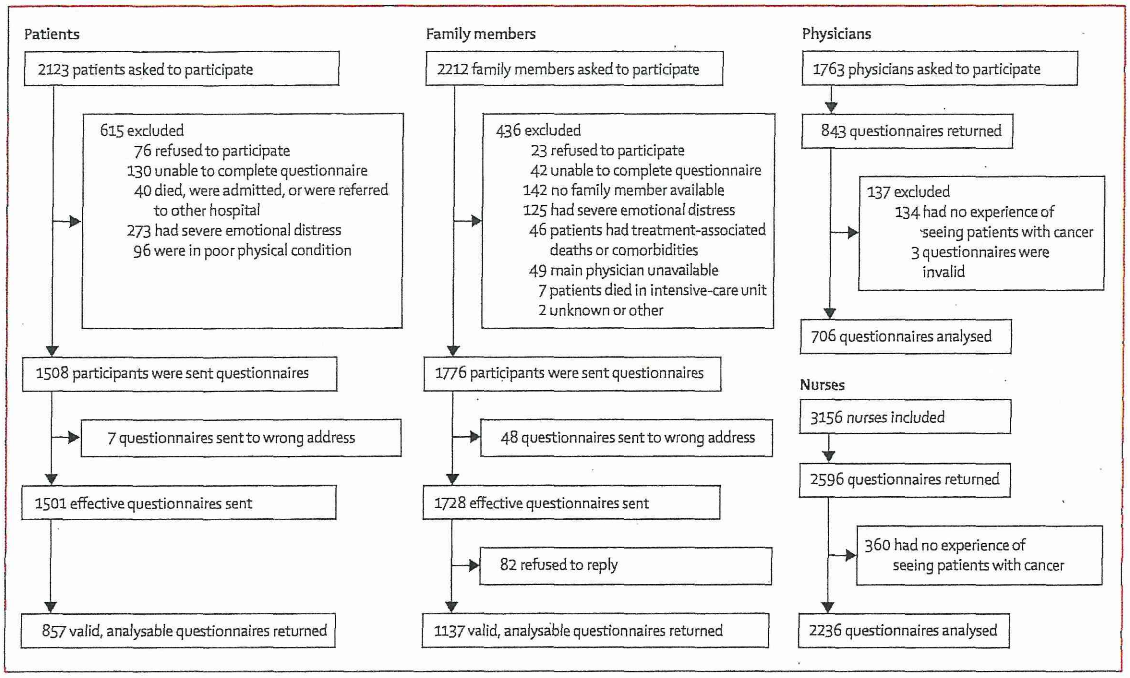

Figure 2: Recruitment of patients, bereaved family members, physicians, and nurses after intervention programme

were used for bereaved family outcomes. We did not calculate inter-reliability statistics for the results of qualitative interviews with health-care professionals. We calculated sample sizes for four primary endpoints. We used SAS (version 9.3) for all analyses. We deemed two-sided p values of 0·0125 or less to be significant (we used the Bonferroni correction for multiple comparisons). This trial is registered with UMIN Clinical Trial Registry, Japan (UMIN000001274).

Role of the funding source

The funding source had no role in study design; data collection, analysis, or interpretation; or the writing of the report. The corresponding author had full access to all data and final responsibility for the decision to submit for publication.

Results

859 patients, 1110 bereaved family members, 911 physicians, and 2378 nurses were analysed in the preintervention survey, and 857 patients, 1137 bereaved family members, 706 physicians, and 2236 nurses in the postintervention survey (figures 1, 2). Characteristics of patients are summarised in the appendix. Qualitative interviews, lasting a mean of 135 min (SD 39), were completed with 101 of 103 health-care professionals, resulting in 101 transcriptions (roughly 40 000 words each). 23 of 34 hospitals in the study regions agreed to participate (8964 of 11 033 [81·2%] beds).

2016 of the 5147 (39·2%) patients surveyed who died of cancer in the study regions in the preintervention period died at participating institutions, and 2212 of 5546 (39·9%) patients surveyed during the post-intervention period died at participating institutions.

	n
To improve knowledge of, and skills in, palliative care	
Manuals disseminated	24 353
Assessment instruments disseminated	174 891
Participants of interactive workshops	22 189
To increase the availability of community-specialised palliative care services	
Patients referred to a community palliative care team	429
Outreach educational visits	38
To coordinate community palliative care resources	
Consultations at regional palliative care centres	6775
Participants in whole-region interdisciplinary conferences	5902
Patient-held records disseminated	13 574
Hospitals introducing a discharge-planning system	23*
To provide appropriate information about palliative care	
Leaflets, posters, and DVDs disseminated	202 340
Participants in public workshops	10 226

Data are n, and are from four study regions (Hamamatsu, Kashiwa, Nagasaki, and Tsuruoka) between April 1, 2008, and March 31, 2011. *Of 27 hospitals.

Table 1: Number of interventions delivered to improve palliative care

See **Online** for appendix

Table 1 summarises the coverage of interventions during the study. 355 of 706 (50·3%) physicians and 994 of 2236 (44·5%) nurses participated at least once in an interactive workshop or a whole-region interdisciplinary conference, or both, and 517 of 706 (73·2%) physicians and 1512 of 2236 (67·6%) nurses used or acknowledged the manual or assessment instruments, or both.

In 2007, four palliative care units, ten hospital or community palliative care teams, five outpatient palliative care services, and no home palliative care teams were available. In 2010, after the interventions, five palliative care units, 11 hospital or community palliative care teams, 11 outpatient palliative care services, and two home palliative care teams were available. All services were maintained after the study.

The proportion of patients that died at home was significantly higher after than before the interventions (p<0·0001; table 2), and this increase was significantly greater than that noted in the national reference data (p<0·0001; figure 3). The ratio of patients who received palliative care services to patients who died of cancer (p<0·0001), and patient-reported (adjusted p=0·0027) and family-reported (p<0·0001) qualities of palliative care increased significantly from before the interventions to after the interventions.

In the postintervention surveys, of 581 patients who died at home, 311 family members were identified and sent questionnaires, and 221 returned completed questionnaires. 194 (87·78%) of the responding family members agreed or strongly agreed that the patient had died in his or her preferred place, and an additional nine (4·07%) slightly agreed. Furthermore, the care burden did not change significantly during the study period (for either all families or families of patients who died at home; table 2). Significantly fewer patients spent more than 2 weeks of the last month of their lives in hospital

	Before interventions	After interventions	Effect size	p	Adjusted p
Primary endpoints					
Home deaths	348/5147 (6·76%)	581/5546 (10·48%)	..	<0·0001	..
Ratios of patients who received specialised palliative care services to patients who died from cancer*	0·31	0·50	..	<0·0001	..
Quality of palliative care†					
Patient-reported	4·43 (1·08)	4·57 (0·97)	0·14	0·0055	0·0027
Family-reported	4·31 (1·12)	4·56 (1·08)	0·23	<0·0001	<0·0001
Secondary endpoints					
Care burden‡					
Total	3·97 (1·50)	4·03 (1·50)	0·04	0·3546	..
Families of patients who died at home	3·76 (1·57)	3·87 (1·54)	0·07	0·5874	..
2 weeks or more in hospital in the last month of life	744/1039 (71·61%)	677/1061 (63·81%)	..	<0·0001	..
Quality of life§					
Patient-reported	5·45 (0·98)	5·52 (0·92)	0·08	0·1024	0·1680
Family-reported	4·41 (0·97)	4·63 (0·96)	0·22	<0·0001	<0·0001
Physician-reported difficulty¶					
Total	2·69 (0·80)	2·28 (0·75)	0·52	<0·0001	<0·0001
Communication in multidisciplinary teams	2·47 (1·05)	2·10 (0·97)	0·37	<0·0001	<0·0001
Community coordination	2·96 (1·15)	2·25 (1·08)	0·63	<0·0001	<0·0001
Expert support	2·40 (1·25)	1·83 (1·06)	0·49	<0·0001	<0·0001
Alleviation of symptoms	2·94 (0·98)	2·76 (0·98)	0·18	<0·0001	<0·0001
Communication with patients	2·66 (0·94)	2·45 (0·92)	0·22	<0·0001	<0·0001
Physician-reported knowledge‖	72·00 (22·86)	78·46 (20·35)	0·30	<0·0001	<0·0001
Nurse-reported difficulty¶					
Total	3·15 (0·75)	2·72 (0·73)	0·59	<0·0001	<0·0001
Communication in multidisciplinary teams	3·09 (1·03)	2·65 (1·05)	0·42	<0·0001	<0·0001
Community coordination	3·03 (1·16)	2·37 (1·05)	0·60	<0·0001	<0·0001
Expert support	2·90 (1·30)	2·19 (1·14)	0·58	<0·0001	<0·0001
Alleviation of symptoms	3·49 (0·84)	3·28 (0·88)	0·24	<0·0001	<0·0001
Communication with patients	3·25 (0.91)	3·07 (0·97)	0·19	<0·0001	<0·0001
Nurse-reported knowledge‖	50·72 (20·16)	60·43 (21·89)	0·46	<0·0001	<0·0001

Data are n/N (%) or mean score (SD) unless otherwise specified. *N=1606 before the intervention and 2783 after the intervention. †Measured with the care evaluation scale, which ranges from 1 to 6 (high score suggests low perception of necessity for improvement). ‡Measured with the caregiving consequences inventory, which ranges from 1 to 7 (high score suggests low perceived care burden). §Measured with the good death inventory, which ranges from 1 to 7 (high score suggests a high perceived quality of life). ¶Measured with the palliative care difficulty scale, which ranges from 1 to 5 (high score suggests a high level of perceived difficulties). ‖Measured with the palliative care knowledge test, which ranges from 0 to 100 (high score suggests high level of accurate knowledge).

Table 2: **Summary of endpoints before and after programme of interventions**

after the interventions than before the interventions ($p<0·0001$; table 2).

Family-reported quality of life of terminally ill patients was significantly higher after than before the interventions (adjusted $p<0·0001$), whereas patient-reported quality of life did not significantly change ($p=0·1680$; table 2). Physician-reported and nurse-reported difficulties in delivering palliative care decreased significantly after the interventions ($p<0·0001$), with overall effect sizes of more than 0·5 (table 2). Physician-reported and nurse-reported knowledge increased significantly after the interventions (table 2). Greater improvements were noted in the subscales of community coordination, expert support, and communication in multidisciplinary teams (table 2).

Through analysis of the qualitative data, we identified seven themes, typical data for three of which are included in the appendix. The health-care professionals who had roles in the implementation of the interventions greatly emphasised improved communication and cooperation between regional health-care professionals (data not shown) and described various ways in which communication and cooperation improved daily palliative care practices—eg, many meetings were held at which specialists and responsible persons were more easily contactable than they had been previously. The main perceived reasons for changes were whole-region interdisciplinary conferences and informal interactions at various meetings (data not shown).

Implementing health-care professionals also perceived increased confidence in the system to care for patients with cancer at home (data not shown). Changes were identified both in hospitals and the community, and the implementing health-care professionals stated that these changes resulted in timely discharge to home or a longer stay at home, or both (data not shown). Perceived reasons for these changes included collaboration with various specialties, easier exchange of information, increased availability of specialists and inpatient resources, development of discharge-planning divisions, and improved hospital clinicians' knowledge about what care was provided at home and community clinicians' general improved knowledge (data not shown).

Discussion

Our study was one of the largest and most comprehensive mixed-methods studies to explore the effects of a region-wide programme of interventions to improve palliative care for patients with cancer (panel 2). We measured interpretable multidimensional outcomes from a large population (that was nearly representative of the regions involved), and introduced interventions that could be adopted in other regions. The qualitative study, furthermore, suggests a framework for how this change occurred, and this framework can guide researchers and policy makers designing interventions to improve region-based palliative care.

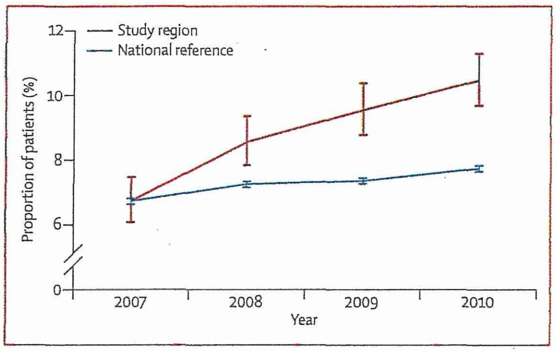

Figure 3: **Proportion of patients with cancer who died at home after the programme of interventions compared with national standards**

Bars are 95% CIs. In study regions, 348 of the 5147 (6·8%) total cancer deaths in 2007, 463 of the 5394 (8·6%) total cancer deaths in 2008, 507 of the 5302 (9·6%) total cancer deaths in 2009, and 581 of the 5546 (10·5%) total cancer deaths in 2010 were home deaths. In national reference data, 22 623 of the 336 468 (6·7%) total cancer deaths in 2007, 24 941 of the 342 963 (7·3%) total cancer deaths in 2008, 25 433 of the 344 105 (7·4%) total cancer deaths in 2009, and 27 508 of the 353 499 (7·8%) total cancer deaths in 2010 were home deaths.

Introduction of the interventions increased the proportion of deaths occurring at home—a result consistent with the findings of a previous randomised study,[4] which did not, however, assess whether the increase in the rate of home deaths was associated with the patients' preferences or those of their families. A strength of our study was that most family members of patients who died at home confirmed that the patient wanted to die at home. Furthermore, we noted no evidence of increases in the care burden of families of patients who died at home. The absolute number of home deaths was, nonetheless, still low after the interventions, suggesting that some structural or financial changes are needed in the health-care system before a further increase in the proportion of home deaths will occur.

Significant improvements in patient-reported and family-reported qualities of care and family-reported quality of life were noted, but changes in patients' outcomes were generally small, probably because the high scores of outpatients in the preintervention survey caused ceiling effects and interventions were mainly targeted to patients with more advanced cancer.

Importantly, the intervention programme significantly decreased difficulties associated with delivering palliative care reported by physicians and nurses at a regional level, especially those related to communication, coordination, and expert support. This finding was strongly supported by the qualitative findings, which showed that communication and cooperation were particularly improved, suggesting that one of the most powerful perceived effects is improved communication between health-care professionals.[10–13]

An additional strength of the qualitative study was that many ways in which good communication and cooperation can positively affect daily practice and patients' outcomes were clearly described. The key

Panel 2: Research in context

Systematic review

We searched PubMed and palliative care journals (*Journal of Pain and Symptom Management, Palliative Medicine, Journal of Palliative Medicine,* and *Supportive Care in Cancer*) with the terms (("palliative care" [MeSH Terms] OR "palliative care"[All Fields]) OR "end-of-life" [All Fields]) AND ("region" [All Fields] OR "population-based" [All Fields] OR "community" [All Fields]) for articles published between Jan 1, 1990, and Jan 31, 2013. We identified four series of studies assessing regional palliative care programmes. The earliest work was about the development of a regional palliative care programme in Edmonton (AB, Canada).[7] Later, a cluster-randomised controlled trial[4,5] was done in Norway. We also identified quality-improvement projects with no control groups in Spain[6,9] and Ontario, Canada.[8] The results of these studies suggested that a programme of interventions has positive effects on some outcomes for regional palliative care delivery, including place of death. However, the comprehensive effects of such a programme on an entire region are poorly understood, because no studies have comprehensively assessed a representative sample of patients, bereaved family members, and health-care professionals throughout a region. Furthermore, no studies were based on a mixed-methods design to explore how these changes occurred.

Interpretation

Our study clarified the effects of a programme of regional palliative care interventions on a range of outcomes, including place of death, use of specialised palliative care services, patient-perceived and family-perceived quality of care, patients' quality of life, family care burden, and physician-perceived and nurse-perceived difficulties and knowledge. Although the programme of interventions had an overall benefit, the largest effect in both quantitative and qualitative studies was improved communication between health-care professionals. Our study adds important insights about the comprehensive effect of regional palliative care programmes and the crucial value of communication between health-care professionals to improve palliative care at a regional level.

interventions cited were whole-region interdisciplinary conferences and informal interactions at various types of meeting. These findings provide insight into why improved communication is important for high-quality palliative care at a regional level and strongly imply that easing communication between health-care professionals is essential for improvement of regional palliative care.

Our study had some substantial limitations, the most important of which was the absence of a control group (excepting people who died at home and were included in national data). Second, the outcomes measured with questionnaire surveys might have been affected by selection, response, and recall biases. Although we statistically adjusted for all noted differences in participants' backgrounds, the intervention effects might have been overestimated, especially in the samples of patients and bereaved families, because of an unexplained increase in excluded participants as a result of severe emotional distress and an increase in sampling from home settings. These methodological limitations can be overcome in future studies through use of, when feasible, data from complete patients' registries or a mortality follow-back survey, or both. Third, our data might not be a fully representative regional sample, although most hospital beds and roughly 40% of deceased patients were included. Fourth, we did not measure objective metrics of health-service use (eg, number of admissions). Fifth, patients who received medical care from an institution within 2 days or who were not informed of malignancy (and their families) did not have input. Finally, we excluded patients who did not have cancer.

As a policy implication, establishment of a structure to improve communication between health-care professionals is an extremely important element of regional palliative care programmes. We recommend the use of combined methods to understand the overall effects of region-wide multicomponent interventions.

Contributors

TM drafted the paper and had roles in data collection and study conception and design. MM and TY contributed to data analysis and interpretation and study conception and design. AY, NA, YS, and MA contributed to study conception and design, data collection, and critical revision of the article for important intellectual content. YK and KH contributed to study conception and design and critical revision of the article for important intellectual content. CI contributed to study conception and design and data analyses of the qualitative study. MK and KE contributed to study conception and design, critical revision of the article for important intellectual content, and organisation of the research team.

Conflicts of interest

We declare that we have no conflicts of interest.

Acknowledgments

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ORIGINAL ARTICLE

Exploring the perceived changes and the reasons why expected outcomes were not obtained in individual levels in a successful regional palliative care intervention trial: an analysis for interpretations

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Abstract

Context The Japan Outreach Palliative Care Trial of Integrated Model (OPTIM) study, a mixed-methods study to evaluate the effects of a comprehensive regional palliative care program, revealed that the program provided broad positive outcomes at the regional level: increased home death, palliative care use, patient- and family-reported qualities of care, and health care professionals' difficulties. Not all participants however obtained positive outcomes and thus exploring the reasons why expected outcomes were observed in individual levels could be of value.

Aims The primary aims were to explore why expected outcomes were not obtained in individual participants, and the perceived changes in daily practices of physicians and nurses were explored.

Subjects and methods Postintervention questionnaire survey on 857 patients, 1,137 bereaved family members, 706 physicians, and 2,236 nurses were analyzed.

Results The reasons for not achieving home deaths included unexpected rapid deterioration, caregivers unavailable, concerns about adequate responses to sudden changes, and physical symptoms uncontrolled, while lack of physician availability at home and lack of information from physicians were less frequently reported. The reasons for not receiving specialized palliative care services were the lack of recommendations from physicians and no information about

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palliative care services. The reason for evaluating the quality of palliative care as not high was that clinicians tried to relieve symptoms, but there were limited effects and insufficient time. Many physicians and nurses reported that they became more aware of palliative care, that the availability of palliative care specialists and knowledge about palliative care improved, and that they cooperated with other regional health care providers more easily.

Conclusion The OPTIM study seemed to succeed in optimizing physician availability at home, improves physician information about home care, achieved maximum efforts to relieve patient distress by clinicians, and increased communication among regional health care professionals. To achieve further better outcomes, multiple interventions to the health care system to be performed on the basis of a comprehensive regional palliative care program are proposed.

Keywords Palliative care · Community · Home death · Barrier · Quality of care

Introduction

Home deaths, the use of palliative care services, and quality of palliative care are among important outcomes in palliative care. To date, multiple intervention studies investigated whether a specific program actually leads to better outcomes in the location of death, use of palliative care services, and quality of life [1–7]. These outcome studies, however, when the intervention failed to demonstrate beneficial effects overall or for some individuals, did not explore the reasons why these outcomes were observed. Factors potentially contributing to the achievement of these outcomes were explored in survey studies, such as determinants of home death and barriers to referral to specialized palliative care services [8–12]. Exploratory analyses along with intervention studies are recently recommended to identify why the expected outcomes were or were not observed [13, 14].

More recently, the Japan Outreach Palliative Care Trial of Integrated Model (OPTIM) study revealed that a comprehensive regional palliative care program provided broad positive outcomes [15–17]. In this intervention study, a comprehensive regional palliative care program to optimize the existing resources achieved broad positive outcomes at the regional level: increased home death, palliative care use, patient- and family-reported qualities of care, and decreased health care professionals' difficulties. Obviously, not all participants obtained positive outcomes, and we believe that exploring the reasons why expected outcomes were not obtained in individual levels is of value to obtain insight for better interpretation of the results of the regional palliative care program.

The primary aim of this study was to explore the reasons why patients did not die at home, did not receive palliative care services, and did not evaluate the quality of palliative care as high for individual levels in a successful regional intervention study. Additional aim was to clarify the perceived changes in daily practices of physicians and nurses during the study periods.

Subjects and methods

This is an analysis of a region-based palliative care intervention trial: Japan OPTIM study [15–17]. In the postintervention questionnaire surveys, we asked the patients, bereaved family members, physicians, and nurses about the potential reasons why patients did not die at home, did not receive palliative care services, and did not evaluate the quality of palliative care as high, in addition to perceived changes in daily practices of physicians and nurses during the study periods. The study methodology was described in detail in the methodology paper [16]. Ethical and scientific validity was confirmed by the institutional review board of this study and of all participating hospitals.

Overview of the OPTIM study [17]

This study was performed in four regions of Japan. We obtained preintervention data for outcomes before or in early phase of the intervention period and postintervention data after or later phase of the intervention periods. The intervention program was implemented from April 2008 to March 2011. The primary end points were home death, use of a palliative care service, and patient-reported and bereaved family-reported qualities of palliative care. Intervention is a comprehensive program covering four areas: (1) to improve the knowledge and skills of palliative care, (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 so they did not require a fundamental change in the health care system, that is, to optimize the existing health care resources within the region. After interventions, the percentage of home deaths increased from 6.8 to 10.5 %, and this increase was significantly greater than that in national data. Moreover, 88 % of the family members confirmed that patients who died at home had preferred home death, and the care burden showed no significant increase. The ratio of patients who received palliative care services increased significantly. The patient- and family-reported qualities of care were significantly better after intervention (effect size, 0.14 and 0.23). Physician-and nurse-reported difficulties, especially regarding communication and coordination, decreased significantly (effect size, 0.52 and 0.59). Accompanying qualitative analysis identified participant's greatly emphasized improved communication and cooperation among regional health care professionals.

Subjects

For this analysis, all data from 857 patients, 1,137 bereaved family members, 706 physicians, and 2,236 nurses from postintervention surveys were used. Patients bereaved family members, physicians, and nurses were sampled throughout the region as they were nearly representative sample.

Patients

Inclusion criteria were (1) adults with a metastatic or recurrent cancer of the lung, esophagus, stomach, colon, rectum, pancreas, liver, biliary system, kidney, prostate, bladder, breast, ovary, or uterus; (2) outpatient visits to the oncology or each specialty division; and (3) the patient had been informed of the malignancy. 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) unable to complete the questionnaire due to poor physical condition.

Bereaved families

Inclusion criteria for bereaved family members were (1) an adult family member of an adult patient with cancer who had died in a health care institution or at home (one family member listed as a principle caregiver on the medical record was selected for each patient); (2) the cancer was a primary tumor of the lung, esophagus, stomach, colon, rectum, pancreas, liver, biliary system, kidney, prostate, bladder, breast, ovary, or uterus; (3) the patient had received medical treatment from the institution on three or more days; and (4) the patient had been informed of the 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) unavailable family member. Families were surveyed 6 to 12 months after patient's death.

Physicians and nurses

Inclusion criteria were (1) hospital physicians and nurses working in cancer-related specialties, a representative physician of general practice clinics, or all district nurses; and 2) clinical experience of 3 years or longer. Subjects are excluded if they have treated no cancer patients during the most recent year.

Measurements

We generated question items on the basis of the existing literature [8–12], discussion among the authors, and interviews on 20 health care professionals. The questions focused on the potential reasons why expected outcomes were not obtained for each individual and perceived changes during the study periods. We prepared "the others" item with free comments for all questions because there might be other reasons we had assumed and to enable qualitative analyses further. To obtain the views from both physicians/nurses and patients/families, the questions in the physician questionnaire were designed as corresponding to those in the patient questionnaire, e.g., "asked the patients about their preferred place of death as much as possible" (in the physician/nurse questionnaire) vs. "no information from physicians" (in patient/family questionnaire). Pilot test was performed on 20 physicians and nurses; no formal reliability and validity testing was performed.

Reasons why patients did not die at home

We first asked bereaved family members who reported that patients did not die at their preferred place where the patient had wanted to die (home, palliative care unit, hospital, and others). We then asked family members who reported that patients had wanted to die at home but actually died at other places about the potential reasons, including (1) caregivers unavailable, (2) unexpected rapid deterioration, (3) physical symptoms uncontrolled, (4) home-visit physicians or nurses unavailable, (5) concerns about adequate responses to sudden changes, (6) belief that the patient would become better, and (7) no information from physicians. Family members were asked to choose all relevant items.

We also asked all physicians and nurses about the degree of agreement for each statement based on their clinical experience during the study period based on a 5-point Likert-type scale from disagree to agree (1) patients and/or families did not desire death at home even if recommended, (2) caregivers unavailable for patients who wanted to die at home, (3) unexpected rapid deterioration, (4) physical symptoms uncontrolled, (5) home-visit physicians or nurses unavailable, (6) tried to respond to patients' desire to stay