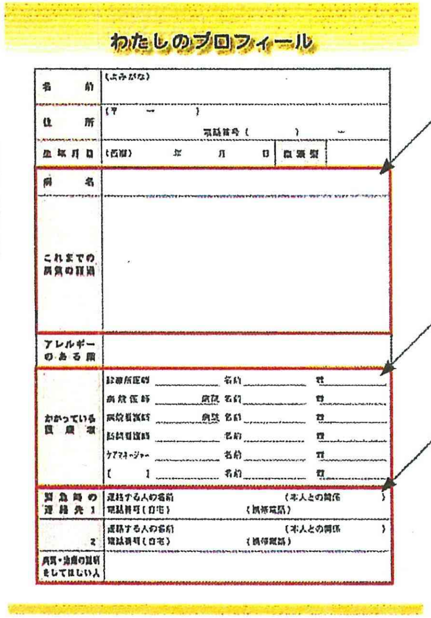
2.「わたしのカルテ」 HP「わたしのカルテ」

- 「わたしのカルテ」は，自分の医療情報（病歴など）や療養上の希望などを患者自身が記載し，持ち歩くノートである。
- 目的
  - ○患者に関わる医療機関が情報を共有し，複数の医療機関を受診することで，起こりやすくなるケアのフラグメンテーション（断片化）を防ぐ。
  - ○患者が伝えたいことを書き込むことにより，医療者に何度も同じことを説明する手間を省く。
- 使用方法
  - ○患者が複数の医療機関を受診する場合に用い，情報を共有する。
- 内容

1)「わたしのプロフィール」



わたしのプロフィール

名前	（よみがな）		
住所	（〒　－　） 電話番号（　）　－		
生年月日	（西暦）　年　月　日	血液型	
病名			
これまでの病気の経過			
アレルギーのある薬			
かかっている医療者	診療所医師 ＿＿＿ 名前 ＿＿＿ ☎ ＿＿＿ 病院医師 ＿＿＿病院 名前 ＿＿＿ ☎ ＿＿＿ 病院看護師 ＿＿＿病院 名前 ＿＿＿ ☎ ＿＿＿ 訪問看護師 ＿＿＿ 名前 ＿＿＿ ☎ ＿＿＿ ケアマネージャー ＿＿＿ 名前 ＿＿＿ ☎ ＿＿＿ ［　］ ＿＿＿ 名前 ＿＿＿ ☎ ＿＿＿		
緊急時の連絡先 1	連絡する人の名前　（本人との関係　） 電話番号（自宅）　（携帯電話）		
2	連絡する人の名前　（本人との関係　） 電話番号（自宅）　（携帯電話）		
病気・治療の説明をしてほしい人			

①病名や病状を記入し，異なる医療機関で情報を共有する

②かかっている医療者を記入する

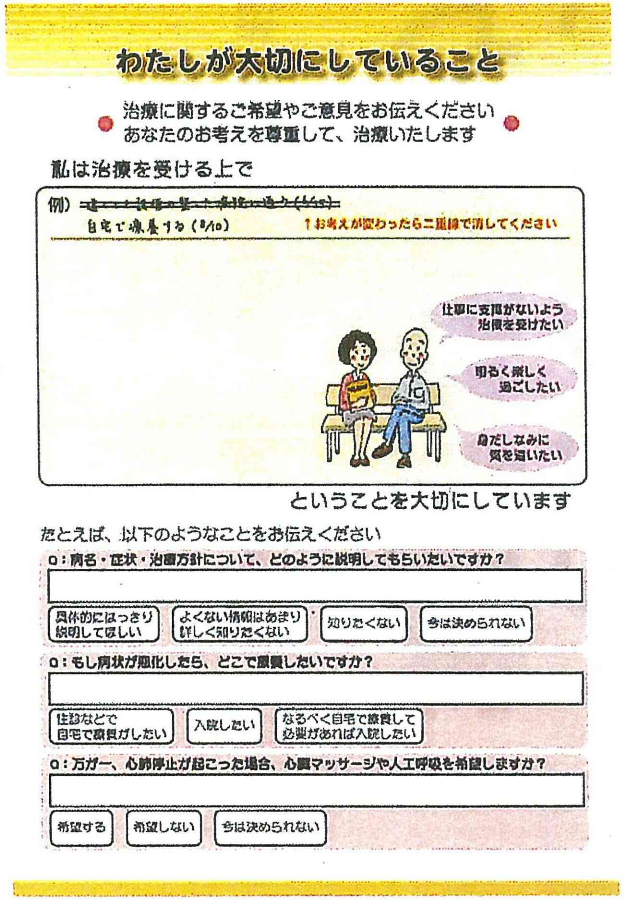
③主に連絡を受ける家族，連絡先を記入する

2)「わたしの療養記録」「わたしのファイル」

○療養記録，緊急時の対応，画像検査，血液検査を保存し，情報を共有する。

3)「わたしが大切にしていること」

○患者が大切にしたいと考えていること，病状説明の希望，療養場所の希望，心肺蘇生についての希望を記入し，情報を共有する。



わたしが大切にしていること

● 治療に関するご希望やご意見をお伝えください
あなたのお考えを尊重して、治療いたします ●

私は治療を受ける上で

例） ~~[illegible]~~
自宅で療養する（8/10）　↑お考えが変わったら二重線で消してください

ということを大切にしています

たとえば、以下のようなことをお伝えください

Q：病名・症状・治療方針について、どのように説明してもらいたいですか？

□ 具体的にはっきり説明してほしい　□ よくない情報はあまり詳しく知りたくない　□ 知りたくない　□ 今は決められない

Q：もし病状が悪化したら、どこで療養したいですか？

□ 往診などで自宅で療養がしたい　□ 入院したい　□ なるべく自宅で療養して必要があれば入院したい

Q：万が一、心肺停止が起こった場合、心臓マッサージや人工呼吸を希望しますか？

□ 希望する　□ 希望しない　□ 今は決められない

スリー

3 ステップ 実践緩和ケア

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Patient-perceived usefulness and practical obstacles of patient-held records for cancer patients in Japan: OPTIM study

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Abstract

Background: Although the use of a patient-held record (PHR) for cancer patients has been introduced in many settings, little is known about the role of the PHR in palliative care settings and use in Asian cultures.

Aim: This study investigated the patient-perceived usefulness and practical obstacles of using the PHR specifically designed for palliative care patients.

Design: This study adopted a qualitative design based on semi-structured interviews and content analysis.

Setting/participants: Fifty cancer patients were recruited from two regions in Japan. They used the PHR for more than three months, and then were asked to participate in a face-to-face interview.

Results: The content analysis revealed the following patient-perceived usefulness of the PHR: (1) increase in patient–staff communication; (2) increase in patient–family communication; (3) increase in patient–patient communication; (4) increase in understanding of medical conditions and treatments; and (5) facilitating end-of-life care discussion. The practical obstacles to using the PHR were also indicated: (1) the lack of adequate instruction about the role of the PHR; (2) undervaluing the role of the PHR and sharing information by medical professionals; (3) patients' unwillingness to participate in decision making; (4) concerns about privacy; (5) burdensome nature of self-reporting; and (6) patients' preference for their own ways of recording.

Conclusions: The PHR can be helpful in facilitating communication, understanding medical conditions and treatments, and facilitating end-of-life care discussion; however, for wide-spread implementation, resolving the obstacles related to both patients and health-care professionals is required.

Keywords

Advance care planning, community-based distribution, information sharing, palliative care, patient-held records

Introduction

Hospital care has become increasingly specialized and subdivided, and patients with chronic diseases tend to visit multiple health-care institutions.[1,2] These circumstances can result in the fragmentation of care and, thus, patients may face unnecessary hospital visits, repeated examinations, or unorganized treatments.[2,3] Although one fundamental way to resolve this situation is to make patient health records readily available to all health-care professional regardless of their

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location,[4] sharing patient information with other facilities is practically very difficult, because almost all institutions usually have a self-determined system of patient health records.

A patient-held record (PHR) is a convenient tool to help patients organize their health information so that multiple medical professionals can share the information effectively.[5,6] In randomized clinical trials, cancer patients generally appreciated the use of the PHR as an organizer,[7] or as an aid for their understanding and decision making.[3] Although the global consensus is that patients should be more engaged in decision making regarding treatment,[8] in palliative care settings this can sometimes be a challenging process for both patients[9] and medical professionals.[10] Furthermore, while the choice of treatment is discussed in advance, and preferably transcribed in documented form, such as an advance directive,[11] few patients had actually discussed this.[12,13] Supporting aids for facilitating end-of-life care discussion are thus needed,[10,14] and the PHR may be one of the effective strategies. However, few studies have reported the potential role of the PHR in palliative care settings. In addition, to date, all studies on the PHR have come from America and European countries, and no empirical studies have been reported from Asian countries.

This study thus aimed to explore the patient-perceived usefulness and patient-perceived practical obstacles to using the PHR in palliative care settings involving Japanese cancer patients.

Subjects and methods

Design and participants

This was a part of a regional intervention study to improve the quality of palliative care at the community level (Outreach Palliative Care Trial of Integrated Regional Model (OPTIM) study).[15] The primary aim of the intervention was to standardize and improve the continuity of palliative care in the community, and the PHR was developed as a tool to improve the availability of patient information at the regional level and promote patient–staff communication.

To explore the potential patient-perceived usefulness of the PHR and practical obstacles to its use, a qualitative study using semi-structured interviews was conducted from January 2009 to January 2010. Adult cancer patients who used the PHR for at least three months in outpatient chemotherapy settings were interviewed. Patients with dementia or other cognitive impairments were excluded. The patients were recruited from two general hospitals: the Shonai General Hospital (Yamagata Prefecture) and the Seirei Mikatahara General Hospital (Shizuoka Prefecture) in Japan. The study was approved by the Institutional Review Boards of the participating hospitals.

Development of the PHR

Due to the lack of a standardized format for the PHR, we specifically designed it for cancer patients receiving palliative care through discussions among clinicians and researchers. A pilot test was conducted with 10 patients, and the PHR was revised and completed. The PHR is available at http://gankanwa.jp/tools/pro/pdf/karte2.pdf (in Japanese).

The PHR is an A4-sized nine-page paper-covered folder divided into the following sections: patient's personal profile, patient's medical history, list of health-care institutions where the patient has received treatment, contact numbers in an emergency, the name of the designated person to receive proxy consent, patient-reported diary, a pocket to hold important papers, emergency instructions for the patient and family, and preferences for end-of-life care.

The PHR has two palliative care-specific features. Firstly, it contains a section on emergency instructions from medical staff to patients and families (e.g. when the patient has pain, he/she will do …) to relieve concerns of patients and families of patients receiving palliative care. Secondly, it contains end-of-life care-related questions: patient preferences for informed consent, place of death, and a do-not-resuscitate (DNR) order.

Dissemination of the PHR

The PHR was firstly introduced to medical professionals at outpatient chemotherapy departments with a half-hour lecture of how to use it. Then, they were encouraged to use the PHR in the local area with their patients. The reason for selecting an outpatient chemotherapy setting as the study setting was that: (1) the patients have marked palliative care needs; (2) they often see multiple medical institutions (hospital outpatient, family physician, visiting nurse, palliative care specialist); and (3) they are likely to be very tolerant of this novel intervention. The instruction focused on the following: (1) sharing information is important to lessen the fragmentation of care; and (2) the managing of information by patients is useful to promote patient–staff communication, potentially leading to increased self-efficacy.

Interviews

The interview was semi-structured, audio-taped, and approximately 30–45 minutes long. All participants received the interview once at the hospital, and the interviewer was either a social worker (KK) or research nurse. The interview guide contained questions about the patient-perceived usefulness and practical obstacles of using the PHR in addition to the overall experience (e.g. How was the PHR useful for you? What was the practical barrier of the PHR for you? Did you answer the questions about end of life, and how did you feel?). The sample size was justified by recruiting participants until data saturation occurred.

Analysis

Content analysis was conducted, because the primary aim of this study was to collect and categorize the patients' experiences concerning the patient-perceived usefulness and practical obstacles to using the PHR. Records of the interviews were transcribed and anonymized. Firstly, two researchers independently identified terms that described the patients' experience regarding the use of the PHR, and then coded them to generate categories and themes from the perspective of similarities and differences. Discrepancy was resolved through discussions among the researchers, under the supervision of an experienced palliative care specialist (TM) and a certified community care nurse (AY). Secondly, two researchers (different from the above) independently determined whether each participant made remarks that belonged to any of the categories and, again, discrepancy was resolved through discussions. Finally, the generated categories were pooled into more abstract supra-categories according to the similarities and theoretical explanations based on the full agreement of the authors. Due to limited space, we report the sub-categories with numbers and some example quotations for several categories.

Results

During the study period, a total of 52 patients were recruited, one patient refused to participate, and one patient stopped using the PHR due to deterioration of their general condition. We thus finally obtained 50 participants: 29 were from Yamagata and 21 were from Shizuoka. The mean age was 66 years (SD = 12), and 70% (n = 35) were male. The primary tumor sites were the prostate (n = 19), stomach (n = 11), breast (n = 8), colon (n = 3), pancreas (n = 3), kidney or bladder (n = 2), lung (n = 1), esophagus (n = 1), bile duct (n = 1), and unknown (n = 1).

From 50 interviews, we obtained 190 meaningful units, and a total of 26 sub-categories and 11 categories with two themes emerged. Themes included: (1) the patient-perceived usefulness of the PHR and (2) the patient-perceived practical obstacles to using the PHR.

Patient-perceived usefulness of the PHR

The content analysis identified five benefits of using the PHR: (1) Increase in patient–staff communication; (2) increase in patient–family communication; (3) increase in patient–patient communication; (4) increase in understanding of medical conditions and treatments; and (5) facilitating end-of-life care discussion.

(1) Increase in patient–staff communication. The PHR was used as a tool to facilitate communication between patients and medical professionals. Some patients indicated that writing in their PHR made it easier to communicate compared to directly speaking to physicians (n = 4). The PHR was especially welcomed when the patients needed to discuss complicated or personal topics. Some patients stated that they could explain their conditions more accurately or express their wishes more easily (n = 10), so that relationships between patients and staff were more 'frank' (n = 4). They referred to their experience that physicians and nurses could understand what they felt by reading the PHR and offer appropriate treatments, and that they were relieved to know that staff understood their conditions (n = 5).

> I note my level of pain in it [PHR] and show it (to staff). It's good and easy to report my pain by writing on paper. (Patient 4: Male, 70, pancreas)

(2) Increase in patient–family communication. The PHR was used as a tool to help patients communicate with their family. Patients could share their records with their family (n = 7), so that their family could understand the patient's medical conditions more easily. Patients could also use the PHR to convey their decisions or feelings about their disease to family members (n = 3).

> I have my family, and I think it's good to show this [PHR] to young people in my family. I can describe my condition and ask for their cooperation, or have a talk. (Patient 2: Female, 68, colon)

(3) Increase in patient–patient communication. The PHR was used as a tool to help patients communicate with other patients. The PHR made patients feel 'connected with other patients' (n = 3), and opened a line of patient–patient communication (n = 3). They knew that a person who had the same-design PHR was a cancer patient, so they felt connected and started to communicate with each other.

> The woman sitting next to me said, 'Oh you have the same one [PHR] as me', and I said, 'Today, many people have the same one', and we started talking. We knew this is for cancer patients, but we didn't talk about the disease at first. We talked about hobbies, field work, and gardening. Well, I realize some people want to hide their disease, but, maybe, we both wanted someone to talk to. I felt a connection with her and she seems like a friend. In this sense, the PHR creates a connection with someone who I don't know at all, someone I can talk to. (Patient 16: Female, 66, breast)

(4) Increase in understanding of medical conditions and treatments. Many patients reported that the PHR helped them to understand their medical conditions and treatment. Patients could better understand the current state of their disease (n = 16) and the treatment they were receiving (n = 17). Some patients referred to their experience that looking back on the PHR gave them an opportunity to observe themselves, and they became more active in participating in their own treatment (n = 5).

(5) Facilitating end-of-life care discussion. The PHR was used as a tool to help patients think about end-of-life care. Some patients stated that they realized the importance of declaring their preference for informed consent, place of death, and DNR order, when they read the questions (n = 5); they could organize their feelings by writing notes in the PHR (n = 4).

Some patients also wanted someone to know their future decisions ($n = 5$); they wanted to leave messages to their family or clinical staff so they could understand their ideas in case something happened to them.

> I leave messages for my family (in the PHR). My family may think I want to stay at home, but our children have their own families so we [my husband and I] don't want to bother them. We write that if our children don't have enough money, we want not to stay at home. We can organize our ideas through writing. (Patient 26: Female, 73, breast)

> In my case, I write it myself. My husband knows about my disease very well, and my kids also know, but I don't tell them my (wishes) in certain cases. I'm not willing to say some things, but, in case something happens to me, I think this [PHR] is useful to express my wishes. (Patient 28: Female, 73, stomach)

Patient-perceived practical obstacles to using the PHR

Content analysis identified six patient-perceived obstacles: (1) the lack of adequate instruction about the role of the PHR; (2) undervaluing the role of the PHR and sharing information by medical professionals; (3) patients' unwillingness to participate in decision making; (4) concerns about privacy; (5) burdensome nature of self-reporting; and (6) patients' preference for their own ways of recording.

(1) The lack of adequate instruction about the role of the PHR. Patients often did not understand the role of the PHR properly ($n = 13$), and they stated that they were not sure why they should use the PHR even if they received instructions several times.

(2) Undervaluing the role of the PHR and sharing information by medical professionals. Many patients referred to their experience that some medical professionals did not understand the value of using the PHR to share information with staff in other facilities ($n = 12$). They experienced that not all medical professionals participating in their treatments responded adequately when the patients showed the PHR, so patients could not recognize its value.

> I take notes, but my doctor doesn't read them. I file papers by myself. If he reads my writing, and checks my pain and medicine, or sees me at any time, then I think it would have been encouraged. (Patient 11: Female, 44, breast)

(3) Patients' unwillingness to participate in decision making. Many patients did not actually want to be involved in decision making: they stated that they wanted to 'leave the decisions to their doctor' ($n = 25$). In addition, some patients did not want to think about the future ($n = 7$), and they reported that it was too early to think about end-of-life-related questions.

> There are many treatments, chemotherapy, and so on, but I don't think about my disease deeply, often because it will change my life. There is a variety of treatments, radiation, and other things, but I leave it to my doctor. (Patient 39: Male, 70, prostate)

> When I have this [PHR], I don't feel anything. But, when I read it, I am shocked. The questions (about advance directives) made me feel like, 'Well, do I need to answer this now?' Well, does this apply to me? I think these are important at the end, but for me now? I thought, 'I have some more time left.' So, I didn't answer. (Patient 22: Female; 46, stomach)

(4) Concerns about privacy. Some patients did not use the PHR because of privacy issues. They did not want anyone to know that they have cancer, so they wanted to avoid being seen using the PHR ($n = 5$). In addition, some patients did not want to share their 'personal' information with others ($n = 10$), and hesitated to show their notes in the PHR to someone because they wrote their 'honest feelings'. Some patients referred to the risk of losing private information ($n = 2$).

(5) Burdensome nature of self-reporting. Some patients simply stated that they did not like taking notes due to viewing it as burdensome or unnecessary ($n = 15$), especially when their conditions were stable. These patients sometimes stopped using the PHR because they had 'nothing special' to write in it. In addition, a patient maintained that he had no energy left to record notes in the PHR, and some patients did not like carrying the PHR because it was too big ($n = 4$).

> It's bothersome for me every week now. I have used the same medicine every week. My symptoms don't change a lot, so the same situation continues. It's bothersome to take the same notes every time. If anything changes, it's fine, but there are only little changes, so it's a bit bothersome. (Patient 27: Female, 45, breast)

(6) Patients' preference for their own ways of recording. Some patients have a preferred way of recording the course of their treatment. They already have their own notebooks ($n = 4$), or simply prefer talking ($n = 1$).

Discussion

This is the first study to investigate the patient-perceived usefulness and practical obstacles to using the PHR in an Asian population, and also one of the few studies about the PHR specially designed for palliative care settings. The findings are generally consistent with those from Western countries, but several unique aspects emerged.

Firstly, we found that the PHR was regarded as useful in facilitating communication and understanding at various levels; some patients using the PHR tended to talk to their physicians more easily and ask them more questions. This is consistent with previous studies which showed that if physicians or nurses accessed the summary records of their patients, they took a significantly longer time in consulting with their patients;[16] reading written information or taking notes clarifies what patients have heard from physicians, thereby decreasing their fear and uncertainty,[17,18] and the use of the PHR improves communication between patients and health-care professionals.[19] These findings indicate that the use of the PHR could overcome the difficulty of information sharing and facilitate patient–doctor communication for at least some patients.

Of interest is that some patients in this study reported that the PHR facilitated not only patient–doctor communication, but also patient–patient communication. This is a novel finding, and suggests using the PHR could improve the social network of patients through the visible message of 'comrades' for some patients.

Secondly, some practical obstacles against disseminating the PHR identified in this study are of importance. In this study, obstacles to disseminating the PHR are related to both medical professionals (inadequate instruction about the role of the PHR; undervaluing the role of the PHR and sharing information by medical professionals in the region), and patients (unwillingness to participate in decision making; concerns about privacy; burdensome nature of self-reporting; own ways of recording). These findings are very consistent with the results from Western countries that health-care professionals often do not acknowledge or welcome the use of the PHR;[16,19,20] patients felt discouraged by professionals' disinterest in the PHR,[7] and wide-spread acknowledgement of the PHR by health-care professionals at a regional level is of great importance to disseminate it.[19] Regarding patient barriers, previous studies similarly indicated the same-designed PHR could be a stigma for cancer patients;[21] patients already had duplicated other notebooks or evaluated the PHR as very burdensome.[7] That is, these findings confirm that implementation of the PHR throughout the region would require repeated instruction to patients at various levels throughout the region, maximum efforts to improve acknowledgement of the PHR of all medical professionals throughout the region, and careful consideration about patient privacy. Furthermore, some patients do not want to use the PHR because of unwillingness to participate in decision making and the burdensome nature of self-reporting and, thus, the wide-spread use of the PHR would require substantial long-term efforts anyway.

The third finding of this study is related to the role of the PHR specially designed for palliative care patients in facilitating end-of-life discussions. This PHR contains questions about a patient's preferences regarding informed consent, place of death, and DNR order, as an important topic to be addressed in this setting.[11] In this study, questions about end-of-life care preferences in the PHR helped some patients to think about their future and preferred end-of-life care, and many patients appreciated the importance. On the other hand, some patients reported that they were shocked when they received the PHR containing end-of-life questions, because they felt it was 'too early' to think about these questions. Although in-advance discussion is associated with a better psychological status of patients[22] and the PHR can be a starting point of in-advance discussion about end-of-life care, individualized assessment about the timing of handing the PHR and careful follow-up are required.

In addition, the findings of this study provided some important insights to disseminate the PHR for Asian populations. In this study, the majority of patients interviewed stated that they did not use the PHR, because they were unwilling to participate in decision making and wanted to leave important decision to their physicians. This is a similar finding to a UK observation that some patients regarded the PHR as an 'an unwelcome reminder' and felt more anxious.[7] There is a general tendency whereby Japanese patients are not willing to hear bad news or want to leave decision making to physicians.[23,24] These findings therefore mean that implementation of the PHR may be more difficult in some Asian populations, where sharing the decision-making process may not be entirely welcomed by all patients.

Another aspect of interest is that Japan already has a well-established system for disseminating a medical handbook for Maternal and Child Health. This handbook is a type of PHR for pregnant women, introduced in 1942. Now, the usage rate is nearly 100%,[25] and all pregnant women are asked to bring this handbook to their physicians or nurses before seeing them. This phenomenon suggests that, in Japanese culture, patients could be ready to accept the PHR if they receive adequate instruction and all medical professionals involved in patient care acknowledge the PHR. Nonetheless, as this study revealed the implementation difficulties in the previous studies, organizational changes in the health-care system so that all medical professionals involved in patient care appropriately acknowledge the role of the PHR is a key feature for its successful implementation.

This study has several limitations. Firstly, as this study is based on the content analysis of interviews of 50 cancer patients, generalizations should be carefully discussed. Secondly, the potential influence of patient gender and cancer sites was not explored due to the small number of participants. Thirdly, as the participants used the PHR for only three months, the effect of the long-term usage of the PHR is unknown. Finally, this study only focused on the patient-perceived usefulness and obstacles to using the PHR, and future studies with other primary end-points will be needed.

In conclusion, the PHR can be helpful in facilitating communication, understanding medical conditions and treatments, and facilitating end-of-life discussion; however, for wide-spread implementation, resolving the obstacles related to both patients and health-care professionals is required.

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Conflict of interest

None declared.

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Effects of a programme of interventions on regional comprehensive palliative care for patients with cancer: a mixed-methods study

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Summary

Background Improvement of palliative care is an important public health issue, but knowledge about how to deliver palliative care throughout a region remains inadequate. We used surveys and in-depth interviews to assess changes in the quality of palliative care after regional interventions and to gain insights for improvement of palliative care at a regional level.

Methods In this mixed-methods study, a comprehensive programme of interventions for regional palliative care for patients with cancer was implemented from April 1, 2008, to March 31, 2011 in Tsuruoka, Kashiwa, Hamamatsu, and Nagasaki in Japan. Interventions included education, specialist support, and networking. We surveyed patients, bereaved family members, physicians, and nurses before and after the interventions were introduced. We also did qualitative interviews with health-care professionals after the interventions were introduced. Primary endpoints were numbers of home deaths, coverage of specialist services, and patient-reported and family-reported qualities of care. This trial is registered with UMIN Clinical Trial Registry, Japan (UMIN000001274).

Findings 859 patients, 1110 bereaved family members, 911 physicians, and 2378 nurses provided analysable preintervention surveys; 857 patients, 1137 bereaved family members, 706 physicians, and 2236 nurses provided analysable postintervention surveys. Proportions of home deaths increased significantly, from 348 of 5147 (6·76%) before the intervention programme to 581 of 5546 (10·48%) after the intervention programme (p<0·0001). Furthermore, 194 of 221 (87·78%) family members of patients who died at home answered that these patients had wanted to die at home. The ratio of patients who received palliative care services to all patients who died of cancer increased significantly (from 0·31 to 0·50; p<0·0001). The patient-reported (effect size 0·14; adjusted p 0·0027) and family-reported (0·23; <0·0001) qualities of care were significantly better after interventions than before interventions. Physician-reported and nurse-reported difficulties decreased significantly after the introduction of the interventions. Qualitative interviews showed improved communication and cooperation between health-care professionals because of greater opportunities for interactions at various levels.

Interpretation A regional programme of interventions could improve the quality of palliative care. Improvement of communication between health-care professionals is key to improvement of services.

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Introduction

Improvement of palliative care is an important health-care issue worldwide.[1] Several systematic reviews have shown the benefits of palliative care to patients and families.[2,3] Palliative care should thus be provided consistently throughout an entire region, and several studies have explored the effects of programmes of interventions in regional palliative care on place of death (ie, home death *vs* death in hospital, nursing home, or other location), use of palliative care services, patient-reported and family-reported outcomes, and health-care costs.[4–9] For example, a cluster-randomised controlled trial has shown that regional palliative care interventions helped to increase family satisfaction and the proportion of deaths occurring at home. However, whether such increases show patients' preferences, and how such changes occur, were not explored.[4–9]

In the past 10 years or so, the UK has implemented the Gold Standards Framework, which stresses communication and coordination in the community through development of a palliative care registry and regular meetings.[10] The results of a review[10] suggested that the most important perceived benefit of the Gold Standards Framework is enabling of communication between health-care professionals in the community—a finding consistent with those from studies in Australia,[11] Canada,[12] and the Netherlands.[13] These studies provide important insights into the potential benefits of regional palliative care programmes. However, clinical implications are few because the interventions often required structural or

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financial changes in the health-care system (and thus could not be applied when such changes were difficult or unfeasible), and multidimensional outcomes (especially patient-reported outcomes) were not measured or were explored in only some populations and provided few insights about the regional effects of the interventions. A mixed-methods approach has been proposed as a potentially useful strategy to examine the effects of complex interventions,[14,15] but, to the best of our knowledge, no large-scale mixed-methods studies of regional palliative care interventions have been done.

The Japanese medical system is characterised by free access, fully covered by national insurance, and has no system of primary-care physicians.[16,17] Patients can freely access all medical institutions, but the organisation of palliative care resources varies widely between regions. 7% of patients who die from cancer die at home, another 7% die in inpatient hospices or palliative care units, and the rest die in hospitals.[17] As in other countries, how to deliver palliative care throughout the region and how to increase the numbers of patients who die in their preferred location are important issues in Japan.

We did a mixed-methods study to assess changes in various outcomes in regional palliative care after the introduction of a programme of interventions and to explore how the changes occurred. Our ultimate purpose was to get insights into provision of high-quality palliative care at a regional level.

Methods

Study design and participants

The Japan Outreach Palliative Care Trial of Integrated Regional Model (OPTIM) study is a mixed-methods study of a regional palliative care intervention trial for patients with cancer[18,19] that was done in four regions of Japan—specifically, Tsuruoka (Yamagata Prefecture), Kashiwa (Chiba Prefecture), Hamamatsu (Shizuoka Prefecture), and Nagasaki (Nagasaki Prefecture). All cooperative hospitals, general practice clinics, district nurse services, and other health-care organisations in these regions participated into the study.

Methods have been previously described;[19] the rationale for the study design and each endpoint, psychometric properties, item examples of measurement instruments, interventions, sample size calculations, and details of statistical analyses are presented in an accessible short-form protocol. The ethical and scientific validity of this study was confirmed by the institutional review board of this study and the boards of all participating hospitals. Our study was done according to the ethical guidelines for Epidemiological Research by the Ministry of Health, Labor and Welfare, and written informed consent was not necessary.

For the **accessible short-form protocol** see http://gankanwa.umin.jp/optim_protocol.pdf

We surveyed participants, then introduced interventions to improve palliative care, and then surveyed participants again. Because of the absence of a registry system to identify all potential participants, we identified all hospitals, general practice clinics, and district nurse services in each area with reference to lists from the Japan Hospital Association and local information. Research coordinators at each institution identified and approached potential participants.

The aims of the surveys were to explore the perceived changes in quality of care and quality of life (patients and bereaved families) and the changes in perceived difficulties and knowledge (survey of doctors and nurses). Participants were administered identical questionnaires before and after the implementation of the programme of interventions.

We sent questionnaires by mail to all patients, bereaved family members, physicians, and nurses who met the inclusion criteria. We intended to obtain a sample that was as representative of each region as possible. Eligible patients were adults with metastatic or recurrent cancer of the lung, oesophagus, stomach, colon, rectum, pancreas, liver, biliary system, kidney, prostate, bladder, breast, ovary, or uterus, who had been informed of their malignancy and made outpatient visits to the oncology or relevant specialty department.

We identified bereaved family members in hospitals and at all general practice clinics with experience of caring for terminally ill patients with cancer. Inclusion criteria for bereaved family members were having an adult family member with cancer who had died in a health-care institution or at home (one family member listed as the main caregiver on the medical record was selected for each patient) who had had a primary tumour of the lung, oesophagus, stomach, colon, rectum, pancreas, liver, biliary system, kidney, prostate, bladder, breast, ovary, or uterus; received medical treatment from the institution on 3 days or more; and been informed of the malignancy. Bereaved family members of patients who died from treatment-associated complications or comorbidities or who died in intensive-care units were also excluded.

Physicians and nurses were recruited from hospitals, general practice clinics, and district nurse services. Hospital physicians and nurses working in cancer-related specialties, a representative physician of general practice clinics, and all district nurses with 3 years or more of clinical experience (ie, who had completed residency training) were eligible for inclusion. Health-care workers were excluded if they had not treated any cancer patients during the previous year.

We obtained preintervention data for outcomes before or in the early stage of the intervention period and postintervention data for outcomes after or in the late stage of the intervention period. The intervention programme was implemented from April 1, 2008, to March 31, 2011; these dates were prospectively defined. We got information about the location of death of patients with cancer from the national government registry and the number of patients who receive specialised palliative care services from each service for each year from 2007 to 2010. We consecutively recruited patients who were receiving