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第3次対がん総合戦略研究事業

緩和ケアプログラムによる地域介入研究

平成23～24年度 総合研究報告書

研究代表者 江口 研二

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「緩和ケアプログラムによる地域介入研究」
Outreach Palliative care Trial of Integrated regional Model (OPTIM)

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I. 総合研究報告

緩和ケアプログラムによる地域介入に関する研究

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研究要旨

目的は地域への緩和ケア体系的介入によるがん患者の Quality of Life 向上について前後比較研究を行った厚生労働科学研究費補助金第3次対がん総合戦略研究事業（以下厚労科研3次がん戦略研究）「緩和ケアプログラムによる地域介入研究（以下 OPTIM 研究）」のプロセス・アウトカム研究である。がん対策基本法に定められた緩和ケアの推進を全国に普及整備する際に資する成果物、介入過程を作成し、OPTIM 研究の複合的緩和ケアプログラムの有効性を評価するとともに、緩和ケアの向上に役立つマテリアル・運営プロセスを集約した。今年度は介入後調査（緩和ケアサービスの利用数、死亡場所、遺族調査）、プロセス研究（介入地域でのインタビュー調査、地域緩和ケアの課題と解決策）を解析し、アウトカム研究としての総括を行ない、地域の緩和ケアの実施担当者や行政関係者などにとっても有用な「OPTIM Report」を発行した。

A. 研究目的

本研究は、厚労科研3次がん戦略研究「OPTIM 研究」に対するプロセス・アウトカム研究である（表1）。OPTIM 研究は地域における体系的な介入によるがん患者の Quality of Life の向上を前後比較研究によって評価する研究である。さらにはがん対策基本法に定められた緩和ケアの推進を全国に普及整備する際に資する成果物、

表1

<p>Mixed-methods study</p> <ul style="list-style-type: none">●全国の4地域を対象とした前後比較研究+プロセス研究●MRCガイダンスに沿ったデザイン Craig P, Medical Research Council Guidance. Developing and evaluating complex interventions: the new Medical Research Council guidance. <i>BMJ</i> 2008;337:a1655.●複合介入 (complex intervention) ①医療者への教育、②専門家のアクセス、③ネットワーク構築、④啓発●プロセス研究 ①記述、②地域の医療福祉従事者100名を対象としたインタビュー、③課題と解決策の系統的整理 <p>Protocol paper: Morita T. <i>BMC Palliat Care</i> 2012;11:2 Position paper: Yamagishi A. <i>Am J Hosp Palliat Care</i> 2008;25:412</p>

介入過程を作成する。本研究により複合的緩和ケアプログラムの有効性を評価するとともに、緩和ケアの向上に役立つマテリアル・プロセスを集約して提示する。

2007年～2009年までの期間に、地域介入研究の前後比較研究のうち、前調査、介入、後調査の一部（患者調査、医療者調査）、プロセス研究の一部（地域の介入の記述）を終了した。本研究では、残りの後調査（緩和ケアサービスの利用数、死亡場所、遺族調査）、プロセス研究（介入地域でのインタビュー調査、地域緩和ケアの課題と解決策）を終了させ、アウトカム研究としての総括を行う。総括の上で、研究期間中に集積したすべての研究成果を1冊にまとめた「OPTIM Report」を発行する。このレポートは、地域の緩和ケアの実施者や行政にとって有用な内容となることが期待される。

B. 研究方法

1 新規のデータの取得

2011年度に新規に取得したデータとして、全国の4地域における2010年度のがん患者の死亡場所を人口動態統

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I. 総合研究報告書

計の目的外使用利用から取得した。2010年度の緩和ケア利用者数をすべての地域の専門緩和ケアサービス29施設から患者一覧表を取得した。4地域の57施設のがん患者の遺族2474名を対象として緩和ケアの質の評価などに関する質問紙調査を行った。

2 2010年度に取得したデータの解析

2010年度までに取得したデータとして、4地域の25施設に通院中のがん患者2087名（介入前）、2247名（介入後）を対象とした質問紙調査のデータベース；医師974名（介入前）、766名（介入後）のデータベース；看護師2726名（介入前）、2473名（介入後）のデータベースのクリーニングを行い、データを固定し、解析を行った。また、地域で生じたことのプロセスを研究するために100名のインタビュー調査を行い、質的に分析した。

（倫理面への配慮）

OTIM 研究計画は、がん対策のための戦略研究倫理委員会での審議、承認に加えて、地域参加施設倫理委員会の審査・承認を受けた。また、本研究のデータ解析・成果公表にあたっては、個人情報保護を遵守した。

C. 研究成果

I アウトカム研究

1 自宅死亡率

4地域での自宅死亡率は全国平均と比較して有意に増加した（図1）

2 緩和ケア利用数

4地域のがん患者死亡数に対する緩和ケアサービスの利用患者の比は0.31から0.50に増加した（図2）。

3 通院中の患者による緩和ケアの質評価

Care Evaluation Scale による患者による緩和ケアの質評価は前後で有意に改善したが変化量は小さかった（Effect size, 0.14；図3）。

4 医師・看護師の困難感

医師、看護師の緩和ケアに関する困難感は前後で改善した（Effect size, 0.52, 0.59；図4）。知識も改善した。

5 終末期がん患者の遺族による緩和ケアの質評価

介入前調査1348名、介入後調査1212名から回答を得た。解析では、Care Evaluation Scale による遺族による緩和ケアの質評価は前後で有意に改善した（Effect size, 0.24）。「体の苦痛が少なく過ごせた」「望んだ場所で過ごせた」と回答したものが増加した。自宅死亡では「望んだ場所で過ごせた」と回答したものがほとんどを占め、かつ、家族の介護負担は増加しなかった。

II プロセス研究の成果

プロセス研究として、1）各地域で実施された介入内容詳細の記述、2）各地域の多職種連携カンファレンス内容・フィールドノートから課題・解決策を質的分類し系統的に整理、3）地域リンクスタッフ100名のインタビュー調査から「なぜ、どのような変化が生じたのか」を質的に分析、の3要素を中心にまとめた。注目すべき成果として、地域緩和ケアプログラムがもたらした変化として医療福祉従事者が認識していたのは、【つながり

図1 自宅死亡率



図2 緩和ケア利用数

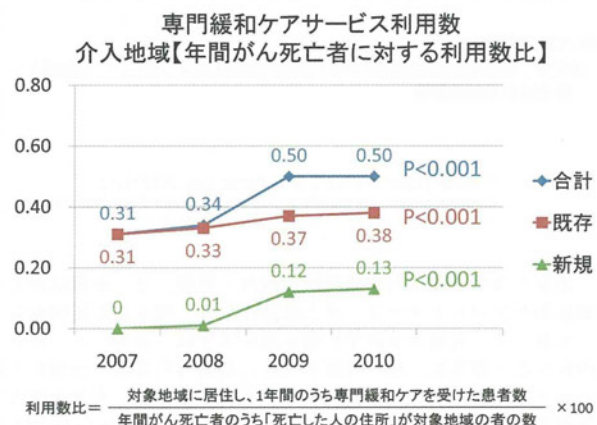


図3 通院中の患者による緩和ケアの質評価

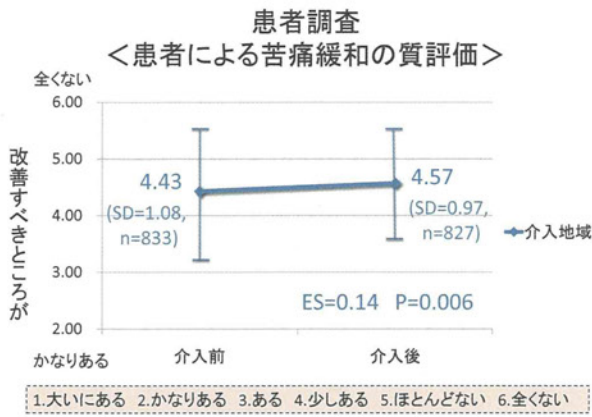


図4 医師・看護師の困難感

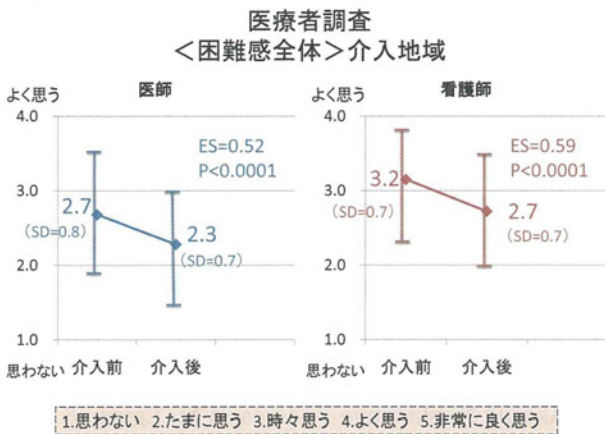
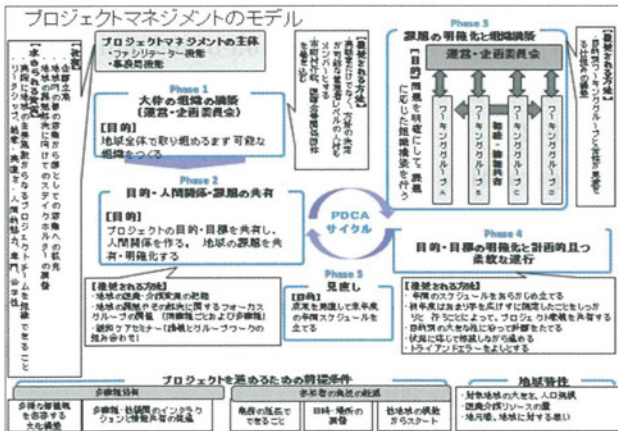
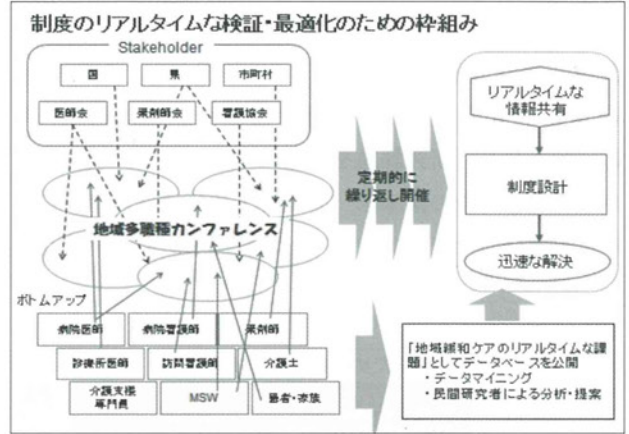


表2



ができネットワークが広がった】、【在宅医療が進んだ】、【緩和ケアの知識・技術、認識、実践が向上した】であった。これらは、アウトカム研究成果からも検証された(表2)。地域緩和ケアプログラムは、多職種が出会う機会を得ることによって、地域内の医療福祉従事者のコミュニケーション・連携を改善し、地域緩和ケアのアウトカムを向上させる可能性が示唆された。【つながりがで

表3



きネットワークが広がった】と臨床アウトカムとの関連について、また【在宅医療が進む】、【緩和ケアの知識・技術、認識、実践が向上する】ことについて、概念的枠組みを構築しえた(表3)。

D. 考察

地域緩和ケアプログラムは、緩和ケアに関する知識の提供、ネットワークの構築、専門家からの支援を強めることによって、1) 医師・看護師の困難感を改善し、2) 自宅死亡など患者の希望する場所での療養を増加させ、3) 患者からみた緩和ケアの質や quality of life を改善する可能性が示唆された。

すべての調査が終了したことで、プログラムのどの部分がどのような影響をもたらしたかについてインタビュー調査を含めた詳細な分析が可能となった。

E. 結論

OPTIM 研究は、過去のがん緩和ケアに関する地域介入の世界各国からの報告と比べてもそのサンプルサイズの規模は最大の研究である。設定したエンドポイントについて、介入の妥当性が検証された。プロセス研究の成果について下記のようにまとめることができた。地域緩和ケアプログラムは、緩和ケアの知識・技術の向上、専門家からの支援、特にコミュニケーションと連携の改善を通じて既存の資源を最大利用 (optimize) することと在宅の視点を持つことによって、地域緩和ケアのアウトカムを向上させる可能性が示唆された。このプログラムのうちエッセンスのみを抽出したもの (OPTIMize

strategy) はどのような制度・体制下でも利用可能で、制度や医療資源の再構築を行わずに実施可能であるため全国で行う価値がある(表4)。並行して、OPTIMIZE strategyで解消できない課題、新しい課題に迅速に対応・最適化し、研究課題を明確にするために、現場レベルと管理レベルの臨床家・研究者・政策決定者がいろいろな組み合わせでリアルタイムに状況を共有し最適化で

表4

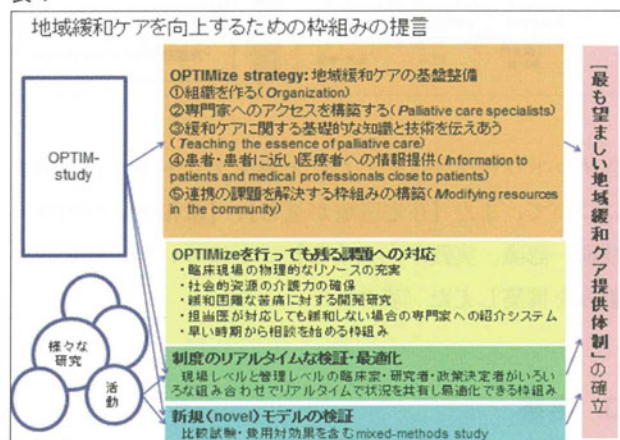


表5

地域緩和ケアプログラムを行っても残る課題と対策:まとめ	
バリア	方策
緩和ケアの評価 1) 対応しても苦痛が緩和しない 2) 診察や相談に十分な時間が無い	1) 担当医が対応して緩和しない場合の専門緩和ケアへの確実な対応 緩和困難な苦痛に対する開発研究 2) 臨床現場の物理的なリソースの充実
専門緩和ケアサービスの受診 1) 主治医から受診をすすめられない 2) 困ることがなかった・知らなかった	1) 担当医に患者の苦痛が具体的に簡単に伝わるシステム(目で見える問診票など) 2) 紹介すれば対応が可能な項目や紹介方法が明確に伝わるアナウンス
自宅死亡 1) 予想より早く進む病状 2) 不十分な苦痛緩和 3) 介護力の不足 4) 急変時・夜間の対応	1) 早い時期からの同意・相談を始める枠組み 2) 苦痛が悪化した場合緩和が得られる体制 3) 社会的資源の介護力の確保 4) 24時間体制の地域ごとの整備(グループ)
疼痛 1) 痛みの程度に応じて異なる理由	1) より専門的なケアへのアクセス

きる枠組みを作ることが必要である(表5)。効果的に緩和ケアのデリバリーを行う体制を明確にするために、組織の再構築をとまなう新規介入の効果について比較試験・費用対効果を含む mixed-methods studyで検証する必要がある。

F. 健康危険情報

本研究にあたって、被験者への健康被害の報告はない。

G. 研究発表

論文発表

1. Komura K, Yamagishi A, Akizuki N, Kawagoe S, Kato M, Shirahige Y, Eguchi K. Patient-perceived usefulness and practical obstacles of patient-held records for cancer patients in Japan: OPTIM study. *Palliative Medicine*. 27(2): 179-184, 2013
2. Yamagishi A, Morita T, Miyashita M, Yoshida S, Akizuki N, Shirahige Y, Akiyama M, Eguchi K. Preferred place of care and place of death of the general public and cancer patients in Japan. *Support Care Cancer*. 20(10): 2575-2582, 2012
3. Morita T, Miyashita M, Yamagishi A, Akizuki N, Kizawa Y, Shirahige Y, Akiyama M, Hirai K, Matoba M, Yamada M, Matsumoto T, Yamaguchi T, Eguchi K. A region-based palliative care intervention trial using the mixed-method approach: Japan OPTIM study. *BMC Palliat Care*. 2012 Jan 11; 11(1): 2. [Epub ahead of print]
4. Yamagishi A, Morita T, Miyashita M, Igarashi A, Akizuki N, Shirahige Y, Akiyama M, Eguchi K. Pain intensity, quality of palliative care, and satisfaction in outpatients with metastatic or recurrent cancer: a Japanese nation-wide region-based multicenter survey. *J Pain Symptom Manage*. 43(3): 503-514, 2012
5. Igarashi A, Miyashita M, Morita T, Akizuki N, Akiyama M, Shirahige Y, Eguchi K. A Scale for measuring feelings of support and security regarding cancer care in a region of Japan: A potential new endpoint of cancer care. *J Pain Symptom Manage* 43(2): 218-225, 2012
6. Yamagishi A, Morita T, Miyashita M, Ichikawa T, Akizuki N, Shirahige Y, Akiyama M, Eguchi K. Providing palliative care for cancer patients: The views and exposure of community general practitioners and district nurses in Japan. *J Pain Symptom Manage* 43(1): 59-67, 2012.
7. Hirai K, Kudo T, Akiyama M, Matoba M, Shiozaki M, Yamaki T, Yamagishi A, Miyashita M, Morita T, Eguchi K. Public awareness, knowledge of

I. 総合研究報告書

- availability, and readiness for cancer palliative care services : A population-based survey across four regions in Japan. *Journal of Palliative Medicine* ; 14 (8) : 918-922, 2011
8. Akiyama M, Takebayashi T, Morita T, Miyashita M, Hirai K, Matoba M, Akizuki N, Shirahige Y, Yamagishi A, Eguchi K. Knowledge, beliefs, and concerns about opioids, palliative care, and homecare of advanced cancer patients : a nationwide survey in Japan. *Support Care Cancer*. 20(5) : 923-931, 2011
 9. 山岸暁美, 赤澤輝和, 瀬尾利佳子, 末田千恵, 白髭豊, 木下寛也, 秋月伸哉, 鈴木聡, 加藤雅志, 江口研二. 地域の緩和ケアに関する望ましいリソースデータベースとは何か : 多地域・多職種の見聞交換会による評価 : 癌と化学療法 (in Press)
 10. 森田達也, 野末よし子, 花田芙蓉子, 宮下光令, 鈴木聡, 木下寛也, 白髭豊, 江口研二. 地域対象の緩和ケアプログラムによる医療福祉従事者の自覚する変化 : OPTIM-study. *Palliat Care Res*. 7(1) : 121-135, 2012
 11. 古村和恵, 山岸暁美, 赤澤輝和, 鈴木聡, 和泉典子, 的場元弘, 森田達也, 江口研二. 市民の緩和ケアに対するイメージの変化. *緩和ケア*22(1), 79-83, 2012
 12. 江口研二 日本におけるがん緩和ケアの現状と展望 *日中医学* 26 : 3-6, 2012
 13. 江口研二 解説ASCO provisional clinical opinion—the integration of palliative care into standard oncology care (J Clin Oncol 2012 ; 30 : 880-7) *腫瘍内科* 10(3) : 279-84, 2012
 14. 森田達也 井村千鶴 野末よし子 鈴木聡 渋谷美恵 木下寛也 原田久美子 白髭豊 平山美香 江口研二 地域緩和ケアプログラムに参加した医療福祉従事者が最も大きいと体験すること : OPTIM-study. *Palliative Care Research* 7(2) : 209-17, 2012
 15. 古村和恵, 宮下光令, 木澤義之, 川越正平, 秋月伸哉, 山岸暁美, 的場元弘, 鈴木聡, 木下寛也, 白髭豊, 森田達也, 江口研二. 進行がん患者と遺族のがん治療と緩和ケアに対する要望—821名の自由記載からの示唆—. *Palliative Care Research* ; 6(2) : 237-245, 2011

的場元弘, 森田達也, 江口研二. 市民公開講座を受講した前後の緩和ケアに対するイメージの変化 : OPTIM study. 第16回日本緩和医療学会学術大会、札幌、2011年7月

H. 知的財産権の出願・登録状況 (予定を含む)

1. 特許取得

なし

2. 実用新案登録

なし

学会発表

1. 古村和恵, 山岸暁美, 赤澤輝和, 鈴木聡, 和泉典子,

Ⅱ. 研究成果の刊行に関する一覧表

Ⅱ. 研究成果

書籍（外国語）

著者氏名	論文タイトル名	書籍全体の 編集者名	書 籍 名	出版社名	出版地	出版年	ページ
なし							

書籍（日本語）

著者氏名	論文タイトル名	書籍全体の 編集者名	書 籍 名	出版社名	出版地	出版年	ページ
なし							

雑誌（外国語）

発表者氏名	論文タイトル名	発表誌名	巻号	ページ	出版年
Komura K, Yamagishi A, Akizuki N, Kawagoe S, Kato M, Morita T, Eguchi K	Patient-perceived usefulness and practical obstacles of patient-held records for cancer patients in Japan : OPTIM study	Palliative Medicine	27(2)	179-184	2013
Yamagishi A, Morita T, Miyashita M, Yoshida S, Akizuki N, Shirahige Y, Akiyama M, Eguchi K.	Preferred place of care and place of death of the general public and cancer patients in Japan.	Support Care Cancer	20(10)	2575-82	2012
Morita T, Miyashita M, Yamagishi A, Akizuki N, Kizawa Y, Shirahige Y, Akiyama M, Hirai K, Matoba M, Yamada M, M a t s u m o t o T, Yamaguchi T, Eguchi K.	A region-based palliative care intervention trial using the mixed-method approach : Japan OPTIM study.	BMC Palliat Care	11(1)	2	2012
Yamagishi A, Morita T, Miyashita M, Igarashi A, Akiyama M, Akizuki N, Shirahige Y, Eguchi K.	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.	J Pain Symptom Manage	43(3)	503-514	2012 3
Igarashi A, Miyashita M, Morita T, Akizuki N, Akiyama M, Shirahige Y, Eguchi K.	A Scale for Measuring Feelings of Support and Security Regarding Cancer Care in a Region of Japan : A Potential New Endpoint of Cancer Care	J Pain Symptom Manage	43(2)	218-225	2012 2
Yamagishi A, Morita T, Miyashita M, Ichikawa T, Akizuki N, Shirahige Y, Akiyama M, Eguchi K.	Providing palliative care for cancer patients : the views and exposure of community general practitioners and district nurses in Japan.	J Pain Symptom Manage	43(1)	59-67	2012 1
Kei Hirai, Tadashi Kudo, Miki Akiyama, Motohiro Matoba, Mariko Shiozaki, Teruko Yamaki, Akemi Yamagishi, Mitsunori Miyashita, Tatsuya Morita, Kenji Eguchi	Public Awareness, Knowledge of Availability, and Readiness for Cancer Palliative Care Services : A Population-Based Survey across Four Regions in Japan.	Journal of Palliative Medicine	14(8)	918-922	2011 8

Ⅱ. 研究成果

発表者氏名	論文タイトル名	発表誌名	巻号	ページ	出版年
Akiyama M, Takebayashi T, Morita T, Miyashita M, Hirai K, Matoba M, Akizuki N, Shirahige Y, Yamagishi A, Eguchi K.	Knowledge, beliefs, and concerns about opioids, palliative care, and homecare of advanced cancer patients : a nationwide survey in Japan	Supportive Care Cancer (E-Pub)	20(5)	923-931	2011 6

書籍（日本語）

発表者氏名	論文タイトル名	発表誌名	巻号	ページ	出版年
木下寛也、渡邊敏、小笠原鉄郎、橋本淳、松尾直樹、三宅智、森田達也	がん専門病院が地域緩和ケアの向上のために取り組んでいることと課題	癌と化学療法	39(10)	1527-32	2012
森田達也、宮下光令、井上芙蓉子、佐藤一樹、五十嵐歩、五十嵐美幸、山口拓洋、橋本修二	遺族調査に基づく自宅死亡を希望していると推定されるがん患者数	Palliative Care Research	7(2)	403-407	2012
森田達也、井村千鶴、野末よし子、鈴木聡、渋谷美恵、木下寛也、原田久美子、白髭豊、平山美香、江口研二	地域緩和ケアプログラムに参加した医療福祉従事者が最も大きいと体験すること：OPTIM-study	Palliative Care Research	7(2)	209-217	2012
森田達也、古村和恵、佐久間由美、井村千鶴、野末よし子、木下寛也、白髭豊、山岸暁美、鈴木聡	患者所持型情報共有ツール『わたしのカルテ』の評価：OPTIM-study	Palliative Care Research	7(2)	382-388	2012
森田達也、秋月伸哉、鈴木聡、木下寛也、白髭豊、宮下光令	異なる算出方法による地域での専門緩和ケアサービス利用数の比較	Palliative Care Research	7(2)	374-381	2012
山本亮、大谷弘行、松尾直樹、新城拓也、宇野さつき、廣瀬光、松原龍弘、瀧川千鶴子、前野宏、佐々木一義、茅根義和、池永昌之、森田達也	看取りの時期が近づいた患者の家族への説明に用いる『看取りのパフレット』の有用性：多施設研究	Palliative Care Research	7(2)	192-201	2012
白髭豊、野田剛稔、北條美能留、後藤慎一、富安志郎、出口雅浩、奥平定之、安中正和、平山美香、吉原律子、船本太栄子、五十嵐歩、宮下光令、森田達也	OPTIM プロジェクト前後での病院から在宅診療への移行率と病院医師・看護師の在宅の視点の変化	Palliative Care Research	7(2)	389-394	2012
和泉典子、秋山美紀、奥山慎一郎、難波幸井、柏倉貢、富樫清、渋谷美恵、鈴木聡	地域における多施設・多職種デスカンファレンス参加者の体験に関する探索的研究	Palliative Care Research	7(2)	354-362	2012

Ⅱ. 研究成果

発表者氏名	論文タイトル名	発表誌名	巻号	ページ	出版年
木澤義之、梅田恵、新城拓也、石ヶ森一枝、奥山慎一郎、木下寛也、白髭豊、井村千鶴、野末よし子、森田達也	地域で統一した緩和ケアマニュアル・パンフレット・評価シートの評価：OPTIM-study	Palliative Care Research	7(2)	172-184	2012
木下寛也、松本禎久、阿部恵子、宮下光令、森田達也	がん専門病院緩和ケア病棟の運営方針が地域の自宅がん死亡率に及ぼす影響	Palliative Care Research	7(2)	348-353	2012
森田達也	緩和ケア地域介入研究（OPTIM-study）が明らかにしたこと：明日への示唆	ベストナース	7月号	6-15	2012
山田博英、小田切拓也、津村明美、井村千鶴、宮下光令、森田達也	患者・遺族調査から作成した医療者向け冊子「がん患者さん・ご家族の声」	Palliative Care Research	7(1)	342-347	2012
森田達也、井村千鶴、野末よし子、鈴木聡、渋谷美恵、木下寛也、原田久美子、白髭豊、平山美香、江口研二	地域緩和ケアプログラムに参加した医療福祉従事者が地域連携のために同職種・他職種に勧めること	Palliative Care Research	7(1)	163-171	2012
森田達也、野末よし子、井村千鶴	地域緩和ケアにおける「顔の見える関係」とは何か？	Palliative Care Research	7(1)	323-333	2012
森田達也、野末よし子、宮下光令、小野宏志、藤島百合子、白髭豊、川越正平	在宅緩和ケアを担う診療所として在宅特化型診療所とドクターネットは相互に排他的か？	Palliative Care Research	7(1)	313-322	2012
前堀直美、水上有紀子、安達三郎、永江浩史、藤本亘史、森田達也	外来患者のがん疼痛に対する保険薬局薬剤師の電話モニタリング・受診前アセスメントの効果	ペインクリニック	33(6)	817-824	2012
井村千鶴、佐原千恵子、梨田えり子、濱田史子、工藤ゆかり、鈴木留美、前堀直美、齋藤広江、鳥山講子、森田達也	地域で行うデスカンファレンスの有用性と体験	緩和ケア	22(2)	189-194	2012
井村千鶴、鄭陽、白土明美、藤本亘史、佐々木一義、吉川陽子、鈴木留美、大岩早苗、井上聡、森田達也	患者・遺族調査の結果に基づいた緩和ケアセミナーの有用性	ペインクリニック	33(2)	241-250	2012 2
佐藤泉、小野宏志、細田修、青木茂、井村千鶴、佐藤文恵、前堀直美、小坂和宏、森田達也	在宅特化型診療所と連携する訪問看護ステーションの遺族評価	訪問看護と介護	17(2)	155-159	2012 2
森田達也、野末よし子、花田芙蓉子、宮下光令、鈴木聡、木下寛也、白髭豊、江口研二	地域対象の緩和ケアプログラムによる医療福祉従事者の自覚する変化：OPTIM-study	Palliative Care Research	7(1)	121-135	2012 2
古村和恵、山岸暁美、赤澤輝和、鈴木聡、和泉典子、的場元弘、森田達也、江口研二	市民の緩和ケアに対するイメージの変化	緩和ケア	22(1)	79-83	2012 1

Ⅱ. 研究成果

発表者氏名	論文タイトル名	発表誌名	巻号	ページ	出版年
山岸暁美、森田達也、古村和恵、末田千恵、白髭豊、木下寛也、秋月伸哉、鈴木聡、加藤雅志、江口研二	地域のがん緩和ケアの課題と解決策の抽出：OPTIM-studyによる複数地域・多職種による評価	がんと化学療法	38(11)	1889-95	2011 11
小野宏志、細田修、井村千鶴、青木茂、佐藤文恵、前堀直美、小坂和宏、佐藤泉、森田達也	地域の多職種で作成した調査票を用いた在宅死亡がん患者の遺族による多機関多職種の評価	緩和ケア	21(6)	655-663	2011 11
森田達也	緩和ケアの地域関連 OPTIM プロジェクト浜松地域リソースの「オプティマイズ=最大活用」と網目のようなネットワークが緩和ケア普及の鍵	Medical Partnering	56	1-5	2011 11
古村和恵、宮下光令、木澤義之、川越正平、秋月伸哉、山岸暁美、的場元弘、鈴木聡、木下寛也、白髭豊、森田達也、江口研二	進行がん患者と遺族のがん治療と緩和ケアに対する要望—821名の自由記述からの示唆—	Palliative Care Research	6(2)	237-245	2011 11
川越正平、廣岡佳代、白髭豊	電話インタビュー調査に基づく在宅医療診療連携システムの類型化(OPTIM方式)	日本医事新報	No.4565	87-92	2011 10
森田達也、井村千鶴、野末よし子、赤澤輝和、伊藤富士江	多施設との医療連携の現状：緩和ケア普及のための地域プロジェクト(OPTIM-study)浜松地域のあゆみと今後の課題	最新精神医学	16(5)	563-572	2011 9
井村千鶴、青木茂、細田修、小野宏志、佐藤泉、佐藤文恵、前堀直美、小坂和宏、森田達也	在宅死亡したがん患者の遺族による退院前カンファレンス・退院前訪問の評価	緩和ケア	21(5)	533-541	2011 9
鈴木留美、山口崇、藤本亘史、安藤江美、加藤亜沙代、森田達也	「生活のしやすさ質問票 第3版」を用いた外来化学療法患者の症状頻度・ニーズおよび専門サービス相談希望の調査	緩和ケア	21(5)	542-548	2011 9
末田千恵、山岸暁美、鈴木聡、木下寛也、鄭陽、白髭豊、木澤義之、森田達也	どのような緩和ケアセミナーが求められているのか：4,188名が評価した緩和ケアセミナーの有用性に影響する要因	ペインクリニック	32(8)	1215-22	2011 8
山岸暁美、赤澤輝和、瀬尾利佳子、末田千恵、古村和恵、森田達也	在宅緩和ケアに関する望ましいリソースデータベースとは何か—多地域多職種を対象とした質的研究	緩和ケア	21(4)	443-448	2011 7
森田達也	緩和ケア普及のための地域プロジェクト(OPTIM-study)の経過と今後の課題	ホスピス緩和ケア白書2011		24-36	2011 夏頃
清原恵美、井村千鶴、梨田えり子、福田かおり、森田達也、井上聡	地域における緩和ケア病棟の役割—緩和ケア病棟における地域の看護師を対象とした研修の評価—	死の臨床	34(1)	110-115	2011 6
井村千鶴、野末よし子、伊藤富士江、赤澤輝和、森田達也	病院と地域とで行う連携ノウハウ共有会とデスカンファレンスの参加者の体験	緩和ケア	21(3)	335-342	2011 5
森田達也	緩和ケア普及のための地域プロジェクト(OPTIM-study)の経過と今後の課題	大阪保険医雑誌	39(533)	10-17	2011 4

Ⅲ. 研究成果の刊行物・別刷

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 patients⁹ 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 patients²² 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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