

表1 緩和ケアに関する普及啓発

	実施		計画	
	県	%	県	%
現状と課題について把握している（全国レベル）	16	35.6	0	0.0
現状と課題について把握している（都道府県レベル）	43	95.6	0	0.0
取り組むべき対策について述べている（全国レベル）	0	0.0	0	0.0
取り組むべき対策について述べている（都道府県レベル）	44	97.8	0	0.0
医療関係者への研修等の普及啓発を実施している	3	6.7	43	95.6
緩和ケアに関する関係諸機関への啓発を実施している	1	2.2	6	13.3
都道府県民への普及啓発を実施している（講演会・ちらし・インターネット等）	1	2.2	17	37.8

表2 緩和ケアの推進

	実施		計画	
	県	%	県	%
初期段階からの緩和ケア				
治療の初期段階からの緩和ケアを提供する緩和ケアチームの設置を推進している	3	6.7	42	93.3
施設緩和ケアの推進				
都道府県内の緩和ケア病棟を有する施設数を把握している	36	80.0	0	0.0
都道府県内の緩和ケア病床数を把握している	27	60.0	0	0.0
都道府県内の緩和ケア病棟で死亡した患者数を把握している	1	2.2	0	0.0
都道府県内の緩和ケア病棟で死亡した患者の全がん死亡者における割合を把握している（*1）	1	2.2	0	0.0
都道府県内の施設基準を満たさない施設における緩和ケア対応病床数を把握している（*2）	1	2.2	0	0.0
全がん死亡者における緩和ケア普及目標値を設定している（*1に対応）	1	2.2	0	0.0
全がん死亡者における緩和ケア病床数の目標値を設定している（*2に対応）	1	2.2	1	2.2
緩和ケアチームを持つ病院を把握している（例、加算届出施設数）	21	46.7	0	0.0
専門的な緩和ケアを行う医療機関を明示している	18	40.0	0	0.0

表3 緩和ケアに従事する人材の育成

	実施		計画	
	県	%	県	%
身体症状の苦痛緩和に携わる専門的知識及び技能を有する医師（専任）数を把握している（例、がん診療連携拠点病院を中心に）	9	20.0	0	0.0
精神症状の苦痛緩和に携わる専門的知識及び技能を有する医師数を把握している（例、がん診療連携拠点病院を中心に）	2	4.4	0	0.0
緩和に携わる専門的知識及び技能を有する常勤の看護師（専従）数を把握している（例、がん診療連携拠点病院を中心に）	15	33.3	0	0.0
緩和ケアに関する基本的知識・技術習得のための研修を実施している（がん治療に携わる医療従事者を対象）	2	4.4	44	97.8
患者の生き方や意思を尊重した医療提供を図るためのインフォームドコンセントや緩和ケアにかんする研修等を行っている（がん治療に携わる医療従事者を対象）	0	0.0	5	11.1
がん診療連携拠点病院を中核とした緩和ケアに関する研修体制を整備している（医療従事者や保健・医療・福祉の専門職を対象）	2	4.4	17	37.8
地域医療機関に対する専門的な相談対応や情報提供を実施している（がん診療連携拠点病院の地域緩和ケア支援部門等において）	1	2.2	13	28.9
職種や技術等に応じた段階的な研修会を開催している（医師会、看護協会、薬剤師会、がん診療連携拠点病院等による）	1	2.2	36	80.0

表4 在宅医療の実施

	実施		計画	
	県	%	県	%
高齢者の単独世帯数など、在宅医療の潜在的ニーズを把握している	5	11.1	0	0.0
都道府県内における在宅死の割合を把握している	27	60.0	0	0.0
都道府県内において、今後の在宅もしくは老人ホームにおける推計死亡者数を把握している	1	2.2	0	0.0
都道府県内で在宅での看取りの目標値を設定している	3	6.7	0	0.0
都道府県内で在宅での看取りが可能な在宅療養支援診療所数を把握している	5	11.1	0	0.0
都道府県内で在宅での看取りが可能な在宅療養支援診療所の充足率を試算している	0	0.0	0	0.0
都道府県内の訪問看護ステーション数を把握している	21	46.7	0	0.0
都道府県内の麻薬取扱薬局数を把握している	5	11.1	0	0.0

表5 在宅緩和ケアの推進

	実施		計画	
	県	%	県	%
在宅緩和ケアを担う医療機関等の現状把握を実施している	16	35.6	2	4.4
在宅緩和ケア推進のための普及・啓発活動を実施している	6	13.3	35	77.8
在宅緩和ケア実施のための地域の連携体制について把握している	3	6.7	36	80.0

表6 地域連携

	実施		計画	
	県	%	県	%
地域における緩和ケア支援部門を設置し、活動状況を把握している	26	57.8	14	31.1
地域の関係機関で構成される緩和ケア連絡協議会等のネットワークを構築し、活動状況を把握している	18	40.0	12	26.7
地域連携パスの導入を計画している（主に5大がん）	0	0.0	39	86.7
緩和ケアの地域連携パスの導入を計画している	0	0.0	12	26.7
地域連携パスを実施し、評価している	1	2.2	0	0.0
地域連携パスについて普及啓発を推進している	0	0.0	22	48.9

Ⅲ. 研究成果の刊行に関する一覧表・別刷

発表者氏名	論文タイトル名	発表誌名	巻号	ページ	出版年
Imai H, Kuroi K, Ohsumi S, Ono M, Shimozuma K.	Economic evaluation of the prevention and treatment of breast cancer-present status and open issues	Breast Cancer	14	81-87	2007
Imai H, Fujii Y, Fukuda Y, Nakao H, Yahata Y	Health-related quality of life and beneficiaries of long-term care insurance in Japan	Health Policy	85	349-355	2008
Fukuda Y, Nakamura K, Takano T, Nakao H, Imai H	Socioeconomic status and cancer screening in Japanese men: large inequality in middle-aged and urban residents	Environmental Health and Preventive Medicine	11	90-96	2007
Fukuda Y, Nakamura K, Takano T	Higher mortality in areas of lower socioeconomic position measured by a single index of deprivation in Japan	Public Health	121	163-73	2007
Fukuda Y, Nakao H, Yahata Y, Imai H.	Are health inequalities increasing? Trends of 1955 to 2000	BioScience Trends	1	38-42.	2007
Fukuda Y, Nakao H, Imai H.	Different income information as an indicator for socioeconomic inequality in health among Japanese adults	Journal of Epidemiology	17	93-99.	2007
Fukuda Y, Nakaya T, Nakao H, Yahata Y, Imai H.	Multilevel analysis of solar radiation and cancer mortality using ecological data in Japan	BioScience Trend	2	235-240	2008
Fukuda Y, Nakao H, Imai H.	In-depth descriptive analysis of trends in prevalence of long-term care in Japan	Geriatrics & Gerontology International	8	166-171	2008
福田吉治, 今井博久	日本における「健康格差」研究の現状	保健医療科学	56(2)	56-62.	2007
福田吉治	公衆衛生分野における政府統計の利活用と個人情報保護	学術の動向	12(12)	30-35.	2007

福田吉治、助友裕子、片野田耕太、中尾裕之、八幡裕一郎、祖父江友孝、今井博久。	都道府県がん対策推進計画における死亡統計の利活用：地域診断は年齢調整死亡率を用いて適切に行われているか？	保健医療科学		(印刷中)	2009
--	--	--------	--	-------	------

資 料

- ・ 今井博久, がん対策の均てん化に向けて 米国 CCCP の交際ワークショップから, 週刊医学界新聞, 2779号, 2008年4月……………129
- ・ がん対策の立案・実施・評価に関する国際ワークショップ：パートナーシップによる包括的アプローチ (2007年1月18日) 会議録……………130

Review Article

Economic Evaluation of the Prevention and Treatment of Breast Cancer- Present Status and Open Issues

Hirohisa Imai^{*1}, Katsumasa Kuroi^{**2}, Shozo Ohsumi^{**3}, Michikazu Ono^{**4}, and Kojiro Shimozuma^{**5}

^{*1}Department of Epidemiology, National Institute of Public Health ^{**2}Division of Surgery, Breast Oncology, Nyuwakai Oikawa Hospital, ^{**3}Department of Breast Oncology, National Hospital Organization Shikoku Cancer Center, ^{**4}Department of Health Science and Social Welfare, School of Human Sciences Waseda University, ^{**5}Department of Healthcare and Social Services, Faculty of Service Industries, University of Marketing and Distribution Sciences, Japan.

Background: More effective methods of preventing and treating breast cancer are being sought by clinicians every day, and new drugs and interventions for overcoming this cancer are being energetically evaluated. At present, there are wide treatment options and many different objectives for breast cancer. These circumstances led us to seek information about the relative costs of the different medical options for the prevention and treatment of breast cancer and to try to ascertain whether one course of action is more efficient than other courses. Economic evaluation of healthcare is indispensable for selection of the best alternatives among medical interventions which are becoming more diverse day after day. The total medical expenditure continues to rise each year and some sort of evaluation from an objective and external viewpoint is required to provide the information with which to suppress this rise.

Methods: This paper surveys the three major reports published on this topic to date, for the purpose of demonstrating the importance and necessity of performing an economic analysis of the treatment and prevention of breast cancer. The three reports to be surveyed pertain to: (1) cost-effectiveness analysis of adjuvant chemotherapy for patients with lymph node negative breast cancer, (2) cost utility analysis of first-line hormonal therapy in advanced breast cancer, namely comparison of two aromatase inhibitors to tamoxifen, and (3) cost-effectiveness analysis of tamoxifen in the prevention of breast cancer. In addition, this paper discusses the advantages, limitations and perspective for the future of the economic evaluation of healthcare for breast cancer.

Results: (1) The authors concluded that if the average risk of all women of undergoing recurrence after this therapy is assumed to be 4% per year, adjuvant chemotherapy is definitely of benefit for node-negative, estrogen receptor-negative breast cancer patients. They additionally stated that this benefit decreases markedly if the changes in long-term survival are less than those in disease-free survival. In this connection, they pointed out that the benefit is considerably smaller among postmenopausal 60-year-old women. (2) The incremental cost per quality-adjusted progression-free life year (QAPFY) for letrozole and anastrozole, relative to tamoxifen, was Can \$12,500-19,600, which was lower than the criterion level (US \$50,000). On the basis of this result, the authors concluded that these two drugs are economically acceptable. Furthermore, when efficacy and cost effectiveness were analyzed together, it was concluded that letrozole is in fact preferable to anastrozole. (3) The model analysis of tamoxifen's cost effectiveness among women at increased risk for breast cancer yielded the following results. In the base-case analysis, involving the calculation of the costs and benefits of 5-year tamoxifen administration, the incremental cost effectiveness of tamoxifen was \$41,372 per life-year gained for women age 35 to 49 years, whereas for women age 50 to 59 years and 60 to 69 years, these values were \$68,349 and \$74,981, respectively. For women who had undergone hysterectomy and thus had no risk of the onset of endometrial cancer, the incremental cost effectiveness of tamoxifen was \$46,060 per life-year gained.

Conclusion: Medico-economic evaluation of breast cancer is very significant and valuable and is expected to stimulate efficient utilization of healthcare resources. It can provide important information to physicians, patients, insurers, pharmaceutical and other industries, healthcare policy planners, and others.

Breast Cancer 14:81-87, 2007.

Key words: Breast cancer, Economic evaluation, Cost-effectiveness analysis, Cost-utility analysis

Breast cancer is one of the leading causes of death in all developed countries, and expenditures connected with its treatment have been increasing year after year, until they now represent a large percentage of all medical expenditures in each nation^{1,2}. More effective methods of preventing and treating breast cancer are being sought by clinicians every day, and new drugs and interventions for overcoming this cancer are being energetically evaluated. At present, there are wide treatment options and many different objectives for breast cancer^{3,4}. These circumstances led us to seek information about the relative costs of the different medical options for the prevention and treatment of breast cancer and to try to ascertain whether one course of action is more efficient than other courses. Economic evaluation of healthcare is indispensable for selection of the best alternatives among medical interventions which are becoming more diverse day after day. The total medical expenditure continues to rise each year and some sort of evaluation from an objective and external viewpoint is required to provide the information with which to suppress this rise.

What constitutes the economic evaluation of healthcare? What purposes does such an evaluation serve? The economic evaluation of healthcare has two major purposes. One is to determine the cost of obtaining a given unit of health outcome. The cost per health outcome, e.g., the cost of caring for one low-birth-weight infant or the cost of the antihypertensive drugs to prolong the survival period by one year, is a piece of information needed not only by the financial officers of hospitals and pharmaceutical companies but also by governmental medical care policy planners. The other purpose is to conduct comparison of different courses of medical intervention, in addition to a separate analysis of each course of intervention. Healthcare resources are limited, and comparing the results of economic evaluations of different medical interventions will yield vital information about the most effective and efficient methods of allocating healthcare resources⁵.

Reprint requests to Hirohisa Imai, Department of Epidemiology, National Institute of Public Health, 2-3-6 Minami, Wako-shi, Saitama-ken, 351-0197, Japan.
E-mail: imaihiro@niph.go.jp

Abbreviations:

QAPFY, Quality-adjusted progression-free life year; QOL, Quality of life; CER, Cost effectiveness ratio; QALY, Quality-adjusted life year; CMF, Cyclophosphamide methotrexate fluorouracil; RCT, Randomized clinical trial; BCPT, Breast cancer prevention trial

The prevention and treatment of breast cancer may be a good model of the application of economic evaluation, because we need cost-effective alternatives for dealing with this disease. In the economic evaluation of healthcare, we have to evaluate health outcomes in connection with the costs of a given health outcome⁶. Cost-effectiveness analysis is a representative technique used for this evaluation. When health-related quality of life (health-related QOL) is deemed to be a health outcome, the economic evaluation of healthcare is called "cost-utility analysis." This paper will survey the three major reports published on this topic to date, for the purpose of demonstrating the importance and necessity of performing an economic analysis of the treatment and prevention of breast cancer. The three reports to be surveyed pertain to: (1) cost-effectiveness analysis of adjuvant chemotherapy for patients with lymph node negative breast cancer⁷, (2) cost-utility analysis of tamoxifen and 2 third-generation selective aromatase inhibitors⁸, and (3) cost-effectiveness analysis of prophylactic tamoxifen therapy for women at elevated risk for breast cancer⁹. In addition, this paper will discuss the advantages, limitations and perspective for the future of the economic evaluation of healthcare for breast cancer (Table 1).

Representative Reports on Economic Evaluation of Breast Cancer

Cost-Effectiveness Analysis of Adjuvant Chemotherapy for Patients with Lymph Node Negative Breast Cancer

This paper, by Hillner and Smith in the United States, may well mark the start of the medico-economic studies of breast cancer that have been made over the past 15 years⁷. The data contained in this paper have been frequently cited since 1991 by other investigators in their medico-economic studies of breast cancer. This study may be one of the most excellent economic studies of breast cancer in the past 15 years. The study aimed at evaluating the efficacy of adjuvant chemotherapy for lymph node negative breast cancer at different levels of risk of recurrence and conducting a cost-effectiveness analysis of this therapy. The study was carried out after a clinical alert issued in 1988 by the American National Cancer Institute, which stated that "Chemotherapy can have a meaningful impact on the natural history of node-negative breast cancer patients."¹⁰. This

Table 1. Summary of Representative Reports on Economic Evaluation of Breast Cancer

authors	patients	methods	Regimens	CER or CUR/(unit)	Conclusion	conflict level
Hillner BE, <i>et al.</i> (1991)	ER: Stage I or IIa N, 45y.o. 60y.o. N, 45y.o. 60y.o.	<ul style="list-style-type: none"> Markov model. The analysis evaluated different scenarios of the benefit of therapy: improved disease-free survival for five years, with a lesser effect on overall survival (base line); a lifelong benefit from chemotherapy; and a benefit in disease-free survival with no change in overall survival by year 10. Charges in 1989 at the Medical College of Virginia and estimates from Medicare data. 	CMF CMF CMF CMF	\$15,400/QALY (5 years of benefit) \$18,800/QALY (5 years of benefit) \$5,100/QALY (lifelong benefit) \$7,400/QALY (lifelong benefit)	Chemotherapy substantially increases the quality-adjusted life expectancy of an average woman at a cost comparable to that of other widely accepted therapies. This benefit decreases markedly if the changes in long-term survival are less than in disease-free survival. Given the uncertain duration, the benefit may be too small for many women to choose chemotherapy.	2b
Dranitsaris G, <i>et al.</i> (2003)	Postmenopausal, ER+, PR+, first-line	<ul style="list-style-type: none"> Decision model Clinical data were obtained from a meta-analysis of modern (i.e., post-1990) randomized trials. Total hospital resource consumption was collected from the charts of 87 patients with advanced disease who had failed tamoxifen therapy. Quality of life data were got using Time Trade-Off technique, but utility of tamoxifen was not estimated. 	letrozole and anastrozole vs. tamoxifen (control)	letrozole: incremental Can \$12,500/QAPFY. anastrozole: incremental Can \$19,600/QAPFY	Letrozole and anastrozole are both economically acceptable alternatives to tamoxifen in the first-line treatment setting. However, given the available clinical data and the findings of the current study, letrozole would be the preferred choice.	2b
Noe LL, <i>et al.</i> (1999)	Age-groups (35-49, 50-59, 60-69, 35-69y.o.) defined cohorts of women who were at high-risk for developing breast cancer.	<ul style="list-style-type: none"> BCPT results, Markov model Cost estimates were obtained from the published literature. Only direct medical care costs of treating observed events were included. 	tamoxifen	35-49 y.o. incremental \$41,372/LYG 50-59 y.o. incremental \$68,349/LYG 60-69 y.o. incremental \$74,981/LYG all ages incremental \$46,060/LYG	The use of tamoxifen in high-risk women to prevent breast cancer in high-risk women may be cost effective, particularly in the 35-to-49 year-old age group and in those of any age who have had a hysterectomy.	3a

ER: estrogen receptor

CMF: cyclophosphamide, methotrexate, fluorouracil

CER: cost-effectiveness ratio

CUR: cost-utility ratio

QALY: quality-adjusted life years

QAPFY: quality-adjusted progress-free years

LYG: life years gained

conflict: +, supported by a pharmaceutical company

level: evidence level, from Oxford Centre for Evidence-Based Medicine Level of Evidence (<http://cebm.net/>)

alert was widely interpreted as a recommendation for adjuvant chemotherapy for such patients¹¹. However, if this advice were faithfully followed, adjuvant chemotherapy would be given to many women who statistically would not have experienced a recurrence. For this reason, there has been much controversy on the value of this recommendation. According to the reports published to date, the efficacy of adjuvant chemotherapy can be affirmed if evaluated from the viewpoint of whether or not the disease-free survival period of node-negative breast cancer patients is prolonged, but the extent of prolongation is not very great. It was not clear whether or not the therapy had much effect in prolonging the patients' overall survival. It was also reported that, although there was little probability that the patients would die from the adjuvant chemotherapy, most patients had adverse reactions to the therapy and the estimated total cost of this chemotherapy amounted to as much as \$338 million. These were serious considerations, and so the results of this study involving the cost-effectiveness analysis (by Hillner and Smith) had great importance.

The authors of this paper created a model containing such variables as risk of recurrence, efficacy of adjuvant therapy, duration of the benefit derived from adjuvant therapy, and quality of life (QOL). They calculated the expected survival period adjusted for QOL to analyze the cost-effectiveness of chemotherapy in the cohort of premenopausal 45-year-old women with node-negative breast cancer and the cohort of postmenopausal 60-year-old women with node-negative breast cancer. They thus developed a decision analysis model involving these two cohorts. For this model, the Markov process was used when calculating the cumulative outcome value for the cohort receiving adjuvant chemotherapy and the cohort without adjuvant chemotherapy. The analysis was conducted on the basis of the evaluation of various scenarios in which the patients enjoyed the benefits of the therapy. Specifically, it analyzed whether or not the therapy improved the disease-free survival for five years (the disease-free five-year survival rate?), whether or not it improved the life-long benefit expected from chemotherapy in general, and whether or not it improved the benefit related to disease-free survival while causing no change in overall survival by year 10.

The study revealed that for both the cohort of premenopausal 45-year-old women and the cohort

of postmenopausal 60-year-old women, adjuvant chemotherapy given to node-negative breast cancer patients resulted in excellent results in terms of lifelong benefit and benefit of disease free survival for 5 years. The cost effectiveness ratio (CER) reflected these excellent results, showing a \$15,000/quality-adjusted life year (QALY) for a 5-year benefit in the 45-year-old woman group, \$18,800/QALY for a 5-year benefit in the 60-year old woman group, \$5,100/QALY for lifelong benefit in the 45-year-old woman group and \$7,400/QALY for lifelong benefit in the 60-year-old woman group. The drug used for this chemotherapy was probably CMF in most cases. However, since the report does not explicitly refer to the drug used, and because some other chemotherapeutic agents were noted in some source data, care is needed when interpreting the results of this study.

The authors concluded that if the average risk of all women of undergoing recurrence after this therapy is assumed to be 4% per year, adjuvant chemotherapy is definitely of benefit for node-negative, estrogen receptor-negative breast cancer patients. They additionally stated that this benefit decreases markedly if the changes in long-term survival are less than those in disease-free survival. In this connection, they pointed out that the benefit is considerably smaller among postmenopausal 60-year-old women, and that opting to use this therapy for women in this group should be based on a careful comparison of the cost-to-benefit ratio of adjuvant chemotherapy.

Cost Utility Analysis of First-Line Hormonal Therapy in Advanced Breast Cancer: Comparison of Two Aromatase Inhibitors to Tamoxifen

This study, by Dranitsaris *et al.* in Canada, is based on an intensive effort to make a comprehensive evaluation of new drugs available for the treatment of breast cancer⁶. It involved not only the evaluation of responses and progression-free survival but also utility analysis, demonstrating how new anti-cancer agents used for the treatment of breast cancer should be evaluated. Tamoxifen has been serving as the standard first-line hormonal agent for women with advanced hormone-sensitive breast cancer. In recent years, however, a randomized clinical trial (RCT) comparing the conventional standard therapy using tamoxifen with a new regimen using third-generation selective aromatase inhibitors (anastrozole

and letrozole) demonstrated that the latter two drugs are at least comparable to tamoxifen in terms of efficacy^{12,13}. In view of these results from the RCT, we may say that anastrozole and letrozole should be considered viable alternatives to tamoxifen as first-line hormonal agents. In many countries however, and as a practical matter, the price of anastrozole and letrozole is higher than that of tamoxifen. For this reason, Dranitsaris *et al.* attempted to examine whether anastrozole and letrozole would have a better economic value, as compared with that of tamoxifen, when all clinical and economic factors were analyzed numerically. In addition, they undertook a cost-utility analysis to investigate whether treatment with anastrozole or letrozole would provide economically more attractive alternatives to tamoxifen therapy, in terms of the requirements of a publicly funded healthcare system.

In terms of methodology, this study can be viewed as an extremely sophisticated analysis. The decision model adopted for this study was developed and used to simulate and compare the outcome of ordinary treatment regimens. Clinical data for this study were derived from meta-analyses of RCTs conducted after 1990. The data pertaining to consumption of hospital resources were collected from the charts of 87 patients with advanced disease for whom tamoxifen therapy had failed. From these data, costs and benefits were calculated and linked together, to yield the incremental cost per quality-adjusted progression-free year (incremental cost/QAPFY).

The incremental cost per QAPFY for letrozole and anastrozole, relative to tamoxifen, was Can \$12,500-19,600, which was lower than the criterion level (US \$50,000). On the basis of this result, the authors concluded that these two drugs are economically acceptable. Furthermore, when efficacy and cost effectiveness were analyzed together, it was concluded that letrozole is in fact preferable to anastrozole.

Some limitations of this study are that it did not directly compare data on letrozole with data on anastrozole, that it did not take into account second-line hormonal therapy for non-responding patients, and that the analysis did not cover the costs of controlling drug-related reactions such as thromboembolic events.

Cost-Effectiveness Analysis of Tamoxifen in the Prevention of Breast Cancer

If it is possible to completely prevent breast cancer, it is obvious that prophylactic interventional steps should be taken. However, the effectiveness of prophylactic intervention in breast cancer has not been fully demonstrated. Furthermore, prophylactic intervention involves the risk for adverse reactions and entails considerable expense. When deciding on the implementation of prophylactic intervention, the relationship between benefit and cost, i.e., the results of an economic evaluation, is the most important factor. However, the economic evaluation of prophylactic intervention against breast cancer is usually not simple^{14,15}. Precise measurement and evaluation of possible future health hazards and the cost of intervention to prevent such hazards is only possible either through interventional studies (which take a long time and huge amounts of money) or through the analysis of models, which involves the creation of theoretical frameworks based on hypotheses derived from the results of existing studies. Here, we will review a paper published by Noe *et al.* who adopted the latter approach (model analysis)⁹.

Tamoxifen is often given as a prophylactic intervention against breast cancer. Several trials on this kind of intervention have been made, but there are problems with the age distributions of the subjects, the sample sizes and the study designs. None of these studies has demonstrated that the intervention was effective in terms of modifying the incidence of breast cancer. Following these unsatisfactory results, British researchers attempted to evaluate its cost effectiveness in the prevention of breast cancer among women at increased risk of developing the disease. The model analysis, conducted during this study, used data on the risks and benefits of tamoxifen, collected in the Breast Cancer Prevention Trial (BCPT). The analysis was based on the assumption that high-risk women could be divided into three groups: (1) women aged over 60, (2) women between 35 and 59 years of age who have a history of lobular carcinoma *in situ*, and (3) women age 35 to 59 years with a breast cancer risk at least as great as that of women 60 years of age. The high-risk women received either 10 mg of tamoxifen twice daily or no therapy to prevent breast cancer. It was assumed that the prophylactic effect of tamoxifen would be exerted immediately after the start of this therapy and would remain throughout the

dosing period. The decision model was used to estimate the incremental cost effectiveness of tamoxifen compared with no intervention, as preventive therapy for the age-group defined cohorts of women who had a high risk of developing breast cancer.

The model analysis of tamoxifen's cost effectiveness among women at increased risk for breast cancer yielded the following results. In the base-case analysis, involving the calculation of the costs and benefits of 5-year tamoxifen administration, the incremental cost effectiveness of tamoxifen was \$41,372 per life-year gained for women aged 35 to 49 years, whereas for women aged 50 to 59 years and 60 to 69 years, these values were \$68,349 and \$74,981, respectively. In the analysis of sensitivity, the benefit expected from 10-year prophylactic use of tamoxifen in these three cohorts was found to be \$20,806, \$36,421 and \$41,621, respectively. The factors found to be most sensitive were discount rates, breast cancer mortality rates and medical costs. For women who had undergone hysterectomy and thus had no risk of the onset of endometrial cancer, the incremental cost effectiveness of tamoxifen was \$46,060 per life-year gained.

Because model analysis involves calculations based on diverse assumptions, the results tend to be fragile in nature. Bearing this in mind, the authors of this paper conducted sensitivity analyses in an attempt to obtain more accurate results. Furthermore, taking into account possible adverse reactions to prophylactic interventions with tamoxifen, they affirmed the presence of evidence for the view that tamoxifen is associated with an increased risk of endometrial cancer. However, they also pointed out that the strategy of prophylactic intervention with tamoxifen among high-risk women may still be cost-effective. They added that this strategy would be particularly cost-effective in women in the 35-49 age group as well as among women of any age who had undergone hysterectomy.

Discussion

Medico-economic evaluation of breast cancer is very significant and valuable and is expected to stimulate efficient utilization of healthcare resources. It can provide important information to physicians, patients, insurers, pharmaceutical and other industries, healthcare policy planners, and oth-

ers. However, most of the economic evaluations of breast cancer conducted so far have utilized indirect data instead of direct data and have involved model analysis based on scenarios and assumptions. Clinical data with a satisfactorily high quality and volume concerning patients' QOL are difficult to obtain for use in economic evaluations. Many medico-economic studies have therefore relied on BCPT as a common source of data¹⁶. Thus, medico-economic evaluations have been conducted on a weak and unstable base, involving the danger of errors in all the evaluations in the same direction, if there has been some error in the common source of data. To avoid this and to achieve more solid analyses, databases for utilization by this kind of evaluation are greatly desired.

We should bear in mind that even when an economic evaluation has been carried out with utmost accuracy, there will be some limitations inherent in the information yielded from the evaluation. The information obtained gives nothing more than expenses per given unit or comparable values, i.e., it is information pertaining only to one aspect of the object. There are other types of social value (equality, justice, etc.) in addition to the one revealed by the evaluation. We should therefore consider medico-economic evaluation to be one of several sources of information available to us in the decision-making process. We should always be aware of both the advantages and limitations of this kind of evaluation.

In closing this paper, we would like to refer to the most crucial principle, which must be borne in mind by investigators attempting medico-economic evaluations. That is, the relationship between the investigator(s) and the sponsors providing the funds used for the analysis should be always made clear, and any financial relationships of the investigators to companies that manufacture or supply the drugs, methods of intervention and so on involved should be disclosed voluntarily. We would not say that medico-economic evaluation should be totally prohibited to investigators having a conflict of interest. However, we believe that investigators should always conduct research from a fair and neutral position.

References

- 1) Brown ML, Lipscomb J, Snyder C: The burden of illness of cancer: Economic cost and quality of life. *Annu Rev Public Health* 22:91-113, 2001.
- 2) WHO Statistics Information System. WHO Mortality

- Database. Table 1: Number of registered deaths. Released: January 2005. (http://www3.who.int/whosis/mort/table1.cfm?path=whosis,inds,mort,mort_table1&language=english)
- 3) Mina L, Sledge GW Jr: Twenty years of systemic therapy for breast cancer. *Oncology* (Williston Park) 20:25-32, 2006.
 - 4) Wright T, McGechan A: Breast cancer: new technologies for risk assessment and diagnosis. *Molecular Diagnosis* 7:49-55, 2003.
 - 5) Gold MR, Siegel JE, Russell LB, Weinstein MC edited: Cost-effectiveness in health and medicine. Oxford University Press, New York, 1996.
 - 6) M. F. Drummond, Mark J. Sculpher, George W. Torrance, Bernie J. O'Brien, Greg L. Stoddart. edited Methods for the Economic Evaluation of Health Care Programmes. Oxford University Press, 3rd 2005.
 - 7) Hillner BE, Smith TJ: Efficacy and cost effectiveness of adjuvant chemotherapy in women with node-negative breast cancer. A decision-analysis model. *N Engl J Med* 324:160-168, 1991.
 - 8) Dranitsaris G, Verma S, Trudeau M: Cost utility analysis of first-line hormonal therapy in advanced breast cancer: comparison of two aromatase inhibitors to tamoxifen. *Am J Clin Oncol* 26:289-296, 2003.
 - 9) Noe LL, Becker RV, 3rd, Gradishar WJ, Gore M, Trotter JP: The cost effectiveness of tamoxifen in the prevention of breast cancer. *Am J Manag Care* 5 (6 Suppl): S389-406, 1999.
 - 10) National Cancer Institute. Clinical alert. Bethesda, Md.: National Cancer Institute, May 16-18, 1988.
 - 11) Ingle JN: Assessing the risk of recurrence in breast cancer. *N Engl J Med* 322:329-331, 1990.
 - 12) Bonnetterre J, Thurlimann B, Robertson JF, Krzakowski M, Mauriac L, Koralewski P, Vergote I, Webster A, Steinberg M, von Euler M: Anastrozole versus tamoxifen as first-line therapy for advanced breast cancer in 668 postmenopausal women: results of the Tamoxifen or Arimidex Randomized Group Efficacy and Tolerability study. *J Clin Oncol* 18:3748-3757, 2000.
 - 13) Mouridsen H, Gershanovich M, Sun Y, Perez-Carrion R, Boni C, Monnier A, Apffelstaedt J, Smith R, Sleeboom HP, Janicke F, Pluzanska A, Dank M, Becquart D, Bapsy PP, Salminen E, Snyder R, Lassus M, Verbeek JA, Staffler B, Chaudri-Ross HA, Dugan M: Superior efficacy of letrozole versus tamoxifen as first-line therapy for postmenopausal women with advanced breast cancer: results of a phase III study of the International Letrozole Breast Cancer Group. *J Clin Oncol* May 19:2596-2606, 2001.
 - 14) Wait SH: Economic evaluation of endocrine therapy in the treatment of breast cancer. *Anticancer Drugs* 9:849-857, 1998.
 - 15) Butler JR: The economic potential of tamoxifen prophylaxis in breast cancer. *Pharmacoeconomics* 12:303-306, 1997.
 - 16) Fisher B, Costantino JP, Wickerham DL, Redmond CK, Kavanah M, Cronin WM, Vogel V, Robidoux A, Dimitrov N, Atkins J, Daly M, Wieand S, Tan-Chiu E, Ford L, Wolmark N: Tamoxifen for prevention of breast cancer: report of the National Surgical Adjuvant Breast and Bowel Project P-1 Study. *J Natl Cancer Inst* 90:1371-1388, 1998.



Health-related quality of life and beneficiaries of long-term care insurance in Japan

Hirohisa Imai^{a,*}, Yoshinori Fujii^b, Yoshiharu Fukuda^a,
Hiroyuki Nakao^a, Yuichiro Yahata^a

^a Department of Epidemiology, National Institute of Public Health, 2-3-6 Minami,
Wako, Saitama 351-0197, Japan

^b Faculty of Education and Culture, University of Miyazaki, Japan

Abstract

Objectives: A long-term care insurance (LTCI) system was introduced in 2000 in Japan. The clarification of information on the users and the ways in which services under this system have been utilized is essential for improving the system operation. This study was conducted for the purpose of clarifying what level of health-related quality of life (HRQOL) was achieved by individuals using the services under the LTCI system.

Methods: The subjects were inhabitants of two cities in the Kyushu district of Japan who were receiving daily home care services under the LTCI system. To analyze the relationships of the beneficiaries' HRQOL with their characteristics, the dependent variable was the EuroQol-5D (EQ-5D) scores adopted as an index of HRQOL, and the independent variables comprised the demographic features (gender, age, and living condition) of users receiving long-term care service as well as their opinions about fees for services, satisfaction with the services provided, and the degree of support/care required.

Results: The EQ-5D score was higher for females than for males and higher for the subjects living alone than for those displaying any other family composition. EQ-5D score decreased with an increase in the degree of support/care required. Multivariate analysis revealed that the degree of support/care required, gender and living condition were found to serve as variables that significantly contribute to utility.

Conclusions: Our analysis of the relationships between the characteristics of the LTCI beneficiaries and their HRQOL has yielded basic data that will be useful for improving the recently introduced LTCI system.

© 2007 Elsevier Ireland Ltd. All rights reserved.

Keywords: Long-term care; Quality of life; Aged; Insurance

1. Introduction

Japan implemented a new social insurance scheme for the frail and the elderly, namely, the long-term care insurance (LTCI) system, on 1 April 2000 [1]. Japan has the most rapidly aging population in the

* Corresponding author. Tel.: +81 48 458 6167;

fax: +81 48 469 2677.

E-mail address: imaihiro@niph.go.jp (H. Imai).

world and will soon have the highest percentages of the elderly and the very old in its population [2,3]. Also, with the demographic trends toward fewer children and an aging population, attitudes toward supporting elderly parents and aged relatives are changing markedly; thus, the traditional system of informal caregiving by family members is said to be in crisis [4]. Under these circumstances, a new public LTCI system was introduced. The new insurance system is aimed at the "socialization" of care through mandatory social insurance [2]. Everyone aged 40 and older pays premiums, and everyone aged 65 and older is basically eligible for benefits based strictly on physical and mental disabilities. After application of care requirements, a care manager assigned to a particular case conducts an assessment of the client's physical disability during a home visit using an approximately 82-item questionnaire developed by the Ministry of Health, Labour and Welfare. The assessment forms are processed using a computer program that classifies applicants according to the degrees of support/care required. The municipal certification committee renders a final judgment of the degree based on the computer-generated classification and the opinion of the client's primary care physician. Eligibility status is classified into one of the following six levels after an assessment of the physical and cognitive functions of the individuals: Support Level, which is for individuals who are generally capable of conducting basic daily activities, but require some assistance; and five Care Levels, which are Care Level I (for individuals requiring partial care) to Care Level V (for those whose ability to conduct daily activities is almost impossible without extensive assistance) [5].

The number of benefits an individual receives from LTCI varies with eligibility status, increasing with the amount of support or care required. Benefits under this system are provided in the form of services, with money being paid to service providers directly. In principle, the beneficiaries can receive services under LTCI either at home or in appropriate facilities. Individuals eligible for the Support Level can only receive services at home. In the beginning, the system described in this outline was not a complete program, and various problems in the system have been noted since its implementation. The ability to clearly identify these problems and improve the sys-

tem requires accurate information on users of LTCI, what they think about the system, and the condition of their health. The government officials in charge of the system have stated their intention to closely monitor the implementation of this new system and conduct reviews every 3–5 years [6,7]. To date, few numerical analyses of service utilization under this insurance system have been performed. The clarification of basic information on users of this system and ways in which services under this system have been utilized is necessary.

Various attempts have been made to perform quantitative analyses of health-related quality of life (HRQOL), with the goal of evaluating the quality of health-related services provided [8–10]. Of the scales used for HRQOL assessment, those allowing calculations of the health utility (degree of contribution to health) of various factors are called "preference-based measures". EuroQol-5D (EQ-5D) is one such tool [11]. With this, all possible health states are arranged in a five-dimensional grid, and each dimension is rated by respondents on a three-level scale from 1 (no problem) to 3 (unable or extreme problem). The health status of an individual is assessed using this five-dimensional method and expressed numerically by "utility," which is the value of a particular health state, usually expressed on a scale from 1, perfect health, to 0, a state equivalent to death [12,13]. The utility is useful not only for the calculation of quality-adjusted life years (QALY) and other indicators, but also for cost-effectiveness analysis in health service research.

This study was conducted for the purpose of clarifying what level of HRQOL was achieved by individuals using the services under the LTCI system. To analyze the relationships of the beneficiaries' HRQOL with their characteristics, the dependent variable was the EQ-5D scores adopted as an index of HRQOL, and the independent variables comprised the demographic features (gender, age, and living condition) of users receiving long-term care service as well as their opinions about fees for services, satisfaction with the services provided, and the degree of support/care required. In this manner, we presented the level of the beneficiaries' HRQOL and the status of the utilization of the care services provided under this recently introduced LTCI system.

2. Methods

2.1. Subjects

This study was performed in Miyazaki City and Nobeoka City, both in Miyazaki Prefecture in the Kyushu district of Japan. Miyazaki City has a population of 305,270, and 16.9% of the population are elderly (≥ 65 years old) [14]. Nobeoka City has a population of 126,305, and 21.3% of the population are elderly [14]. The inhabitants of these two cities who have been receiving daily home care services under LTCI represented the pool from which subjects were drawn for this study. In Miyazaki City, 2000 individuals were selected by stratified randomization (depending on the degree of support or care required) from among 3567 individuals receiving home care services. Well-trained interviewers met with the 2000 subjects in their homes and conducted an original-questionnaire survey in January 2002. In Nobeoka City, all 1962 individuals receiving home care services were enrolled as subjects in this study, and were queried using the same original questionnaire that was used for the Miyazaki City subjects. The questionnaire was mailed to the subjects in August 2002. The subjects themselves filled out the questionnaire. For both surveys, if the subjects were unable to fill out the questionnaire by themselves, their family members filled it out for them. For both surveys, if the target subject was unable to fill out the questionnaire by himself, a close relative of the person was asked to fill out the form. This was not only the case for the survey conducted by mail. Informed consent was obtained in writing from all of the subjects. This study was approved in advance by the Institutional Review Board of Miyazaki Medical College.

2.2. Surveyed items

A questionnaire prepared by the authors was used for this study. The questionnaire included questions regarding basic demographic features, opinions about the fees for services, satisfaction with the services provided, and EQ-5D-related questions. Gender, age and the degree of support required were not asked in the questionnaire. They are from the data provided by the government. Living condition was rated by assigning the subjects to one of four categories (i.e., living alone, elderly couple living alone, living with children, and

others). Opinions about fees for services were rated on a 4-point scale: expensive, reasonable, cheap, and others. The degree of satisfaction with services provided was also rated on a 4-point scale: satisfied, moderately satisfied, unsatisfied, and others.

2.3. Analysis

The EQ-5D score was rendered as a utility value from 1 (perfectly healthy) to 0 (dead) using a conversion table developed for the Japanese population [8]. We analyzed the relationships of the EQ-5D score with the characteristics of beneficiaries. Student's *t*-test and analysis of variance were used to estimate the relationships of EQ-5D score with demographic features, opinions about fees for services, satisfaction with services provided, and the degree of support/care required. Significant differences between categories were evaluated using the Tukey–Kramer post hoc test. Stepwise linear regression analysis was used to develop the most parsimonious model from among all the factors. All statistical analyses were performed using JMP statistical software (ver. 3.25) and SPSS (ver. 10.0.5J, SPSS Japan, Tokyo, Japan).

3. Results

Responses were collected from 2659 subjects, comprising 1644 of the subjects in Miyazaki City (response rate: 82.2%) and 1015 of the subjects in Nobeoka City (response rate: 51.7%). By excluding subjects for whom complete data were unavailable, data for 2411 subjects (710 men, 1701 women) were analyzed. Table 1 shows the percentages of female and male subjects assigned to each category on the basis of answers to the five items: (1) age, (2) living condition, (3) opinions about fees for services, (4) satisfaction with services provided, and (5) the degree of support/care required.

Fig. 1 shows what level of EQ-5D score was achieved by users of the service who were classified according to the various characteristics. The EQ-5D score was significantly higher for females than for males. Among the beneficiaries <90 years old, the EQ-5D score was unaffected by age. The EQ-5D score was higher for subjects living alone than for subjects with other living conditions. The EQ-5D score of the indi-

Table 1
Proportion (%) in characteristics of beneficiaries receiving daily home care services under long-term care insurance

Characteristic	Total (N=2411)	Female (N=1701)	Male (N=710)
Age			
<65	3.3	2.6	4.9
65–69	6.3	4.9	9.6
70–74	13.1	10.9	18.6
75–79	18.7	18.8	18.7
80–84	24.1	24.5	23.4
85–89	20.9	23.1	15.8
90–	13.3	15.0	9.0
NA	0.2	0.2	0.0
Family composition			
Living alone	27.8	32.3	17.0
Elderly couple alone	22.4	14.6	41.1
Living with children	37.4	39.6	32.1
Others	11.7	12.8	9.0
NA	0.7	0.8	0.7
Opinion about fee for services			
Expensive	20.4	19.5	22.7
Reasonable	56.5	56.3	56.9
Cheap	6.1	6.9	4.4
Others	5.7	6.1	4.6
NA	11.2	11.2	11.4
Satisfaction with services			
Satisfied	42.4	43.2	40.6
Moderately satisfied	39.6	40.5	37.5
Unsatisfied	3.1	2.9	3.5
Others	7.7	6.8	9.9
NA	7.2	6.6	8.6
Degree of support/care			
Support	23.8	27.9	14.1
I	33.2	35.0	28.9
II	18.4	16.3	23.4
III	9.6	7.6	14.5
IV	6.3	5.6	8.0
V	5.6	4.8	7.6
NA	3.0	2.8	3.5

NA = not available.

individuals who used the services and who felt that the services were inexpensive was high. The EQ-5D score was significantly lower for unsatisfied subjects than for subjects satisfied or moderately satisfied with the services. The EQ-5D score decreased with an increase in the degree of support/care required, and the decrease in the score was particularly marked as the degree of support/care required increased from Care Level III to Care Level IV. There were significant differences between the degrees of support/care required. The range of this

parameter was wide for the subjects at Care Level IV. Table 2 shows the results of multivariate analysis. The degree of support/care required, gender and living condition were found to serve as variables that significantly contribute to utility.

4. Discussion

Developed countries around the globe currently face many difficulties in implementing and operating health policies related to long-term care, owing to the progressive aging of the population and financial constraints [3,15,16]. When evaluating whether LTCI is functioning well, the need to improve or review the current system should be considered on the basis of data from practical studies (reflecting the real situations of beneficiaries), instead of attaching primary importance to opinions of experts or data from the analysis of abstract models [17]. In this study, we analyzed the relationships of utility using EQ-5D with the characteristics and other variables of individuals utilizing care services at home under the LTCI system. This enabled researchers to collect basic data that will prove useful for finding ways to improve the operation of the LTCI system that has recently been introduced in Japan.

When the scores of males and females were compared utilizing rough EQ-5D values, the scores of females were higher than those of the males; when the EQ-5D scores were adjusted for the degree of support/care required and living condition, the scores of the males were higher than those of the females. This is because males show higher HRQOL scores even with the same degree of support/care required. In the multivariate analysis adjusted for gender and the degree of support/care, the EQ-5D score was higher for the subjects living alone than for those living with a spouse. This may be interpreted as indicating that individuals too sick to live alone have already been accommodated in care facilities and that individuals who live alone and receive care services at home are often in relatively good health, resulting in a higher utility for subjects living alone.

HRQOL refers to the overall health-related quality of life, which is indicated as a utility value (a score of EQ-5D) in this study. Meanwhile, the degree of support/care required is a classification determined upon evaluation of 82 items focusing on the degree of lim-

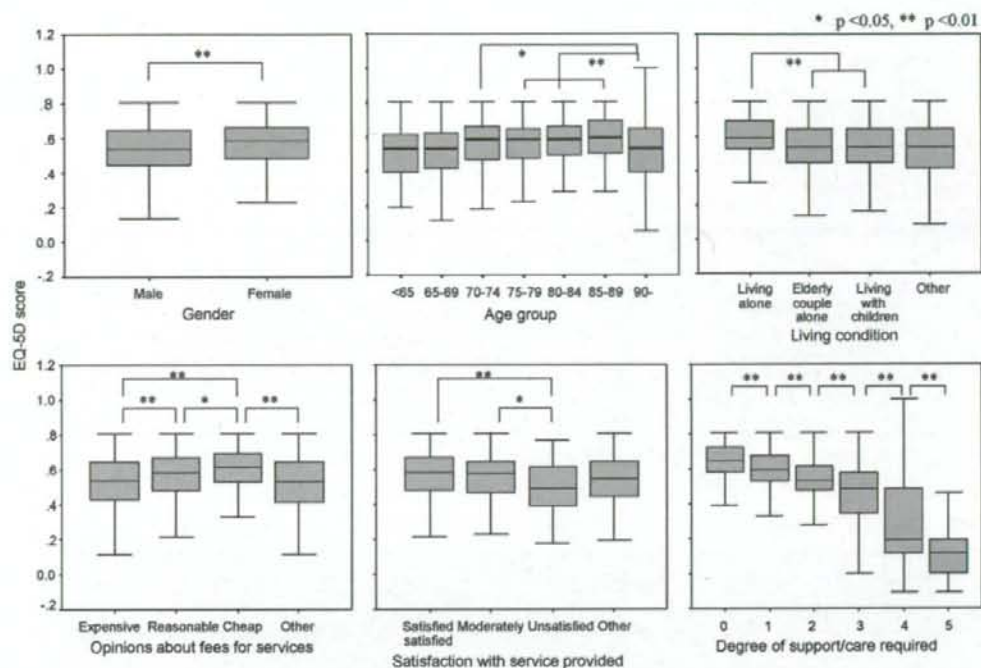


Fig. 1. Box and whisker plots of EQ-5D score achieved by users of the service who were classified according to the various characteristics: (1) gender, (2) age group, (3) living condition, (4) opinion about fees for services, (5) satisfaction with service provided, and (6) degree of support/care required. Median EQ-5D scores are indicated by horizontal bars. The vertical bars indicate the range, and the horizontal boundaries of the boxes represent the first and third quartiles.

itation of daily physical exertion. Thus, basically, the concepts of HRQOL and the degree of support/care required are different although both have overlapping contents. For example, EQ-5D includes psychological items such as "I'm anxious or depressed"; however, the degree of support/care required does not include items that measure psychological conditions. The degree of support/care required was found to be the factor exerting the greatest influence on EQ-5D score. As the degree of support/care required increased, the utility indicated by the score decreased. This decrease was not linear, but followed a sharp downward curve as the degree of support/care required increased from Care Level III to Care Level V. The range of the scores was considerably wider for subjects in Care Levels III and IV than for those in the other care levels. In a study of individuals requiring support or care con-

ducted by Honma and Katoh [18] using functional independence measure (FIM), which is one of the methods for the objective evaluation of activities of daily living (ADL), the FIM score was found to decrease sharply as the degree of support/care required increased from Care Level III to Care Level V. If such findings concerning decreases in ADL as evaluated using FIM are combined with the present results, which revealed a decrease in utility as determined by self-evaluation, utility or ADL begins to decrease markedly as the degree of support/care required increases beyond Care Level III. This finding suggests that the current criteria for classifying the degree of support/care required are not appropriate. Considering that the range of EQ-5D scores was relatively wide at Care Levels \geq III, the degrees of care above Care Level III may be broken down into more detailed classifica-

Table 2

Results of multivariate analysis for health utility of beneficiaries receiving daily home care services under long-term care insurance (coefficient of determination, $R^2 = 0.43$)

	Coefficient	95% CI	<i>p</i> -Value
Intercept	0.675	0.667, 0.684	
Gender			0.012
Male	0		
Female	-0.023	-0.031, -0.016	
Degree of support/care			<0.01
Support	0		
I	-0.061	-0.074, -0.049	
II	-0.123	-0.138, -0.108	
III	-0.222	-0.241, -0.203	
IV	-0.365	-0.387, -0.342	
V	-0.521	-0.545, -0.498	
Living condition			0.022
Living alone	0		
Elderly couple alone	-0.019	-0.032, -0.007	
Living with children	0.007	-0.004, 0.017	
Others	-0.014	-0.029, -0.002	

tions. After reviewing the current LTCI system, a more sophisticated classification of the degree of support/care appears warranted, so that the physical and mental statuses of beneficiaries will be reflected more accurately.

According to the figure of age and EQ-5D scores, although there was a significant difference in individuals older than 70 years of age, the differences in EQ-5D scores by age were not very large in general. This may be because the elderly who are in a physically serious condition are already in care facilities (the subjects in this study are beneficiaries at home). In the case of providing long-term care service to the elderly at home, age may not be a significant index; therefore, it may be necessary to use caution in classifying users according to their age when designing a system of long-term care service provision as a health policy. This study found that the HRQOL scores of the users classified into 4 and 5 in terms of the degree of support/care required were significantly low. It is necessary to clarify the degree of the contribution of the service currently provided to the improvement of their HRQOL. The results of this may provide a certain answer to the discussion between two major opinions, which are "the service should be increased due to the insufficiency of the current benefit and payment" and "the service should be reduced because provision does not contribute to the improvement of HRQOL."

A previous study showed that the perception of fees for services as "expensive" is associated with a low degree of satisfaction with the services provided [19]. In this study, a small percentage of the subjects (3.1%) were unsatisfied with the services provided, and their EQ-5D score was significantly lower than that of the subjects satisfied or moderately satisfied with the services. However, in the multivariate analysis, neither opinions about fees for services nor the degree of satisfaction with the services provided served as significant independent variables. In this study, which was designed as a cross-sectional study, whether subjects who said they were unsatisfied with services were actually unsatisfied with the services or simply answered this because they were in poor health (probably also accompanied by a low health-related quality of life) remains unclear. A more detailed study is needed to answer this question.

This study has several limitations. First, the method of collecting questionnaire responses differed between the two cities. The interviewers visited the care service users in one city to collect questionnaire responses; however, responses from care service users in another city were collected by mail. In spite of this, no significant differences were noted between these two groups of care service users in terms of male-to-female ratio or age distribution. No significant differences in EQ-5D score were observed between the two cities ($p = 0.35$).

when an ANOVA was conducted to adjust for gender, degree of support/care required, and living condition. Although the distribution of the degree of support/care required differed significantly between these two cities ($p < 0.01$), combining the data from these two cities using different methods of data collection does not seem to have significantly affected the analysis. Second, the results do not represent all of the recipients of the long-term care insurance service as this study only targets people receiving the service in their homes but does not include people who are at care facilities. The reason why we limited the target of this study was because its purpose was to clarify the characteristics that impact on the HRQOL of elderly individuals. To do so, it was necessary to separate those who were staying at home and who were staying at care facilities due to the differences in various conditions that might impact on their HRQOL (e.g., status of individual lives and living condition). Other studies are necessary to examine the HRQOL of the elderly staying at care facilities.

In conclusion, our analysis of the relationships between demographic characteristics and EQ-5D score for care service users at home under LTCI revealed that the degree of support/care required, gender and living condition are factors that significantly influence the operation of this insurance system. This study has yielded basic data that will be useful for improving the LTCI system recently introduced in Japan. Practical analyses should be continued to monitor the actual status of services under this system.

References

- [1] Matsuda S. The health and social system for the aged in Japan. *Aging-Clinical and Experimental Research* 2002;14(4):265–70.
- [2] Campbell JC, Ikegami N. Long-term care insurance comes to Japan. *Health Affairs (Millwood)* 2000;19(3):26–39.
- [3] Anderson GF, Hussey PS. Population aging: a comparison among industrialized countries. *Health Affairs (Millwood)* 2000;19(3):191–203.
- [4] Lai OK. Long-term care policy reform in Japan. *Journal of Aging & Society Policy* 2001;13(2–3):5–20.
- [5] Health and Welfare Statistics Association. Long-term care insurance. *Journal of Health and Welfare Statistics* 2000;47(9):238–43.
- [6] Health and Welfare Statistics Association. Long term care insurance. *Journal of Health and Welfare Statistics* 1999;46(9):236–9.
- [7] Sasaki M. Outline of long-term care insurance system in Japan [Article in Japanese]. *Nippon Naika Gakkai Zasshi* 2004;93(12):2579–86.
- [8] Ikeda S, Ikegami N. Preference-based measure (focus on EQ-5D). In: Ikegami N, Fukuhara N, Shimozuma K, Ikeda S, editors. *Handbook of QOL evaluation*. Tokyo: Igaku-Shoin; 2002. p. 45–9.
- [9] Kurimori S, Fukuda Y, Nakamura K, Watanabe M, Takano T. Calculation of prefectural disability-adjusted life expectancy (DALE) using long-term care prevalence and its socioeconomic correlates in Japan. *Health Policy* 2006;76(3):346–58.
- [10] Borowiak E, Kostka T. Predictors of quality of life in older people living at home and in institutions. *Aging-Clinical and Experimental Research* 2004;16(3):212–20.
- [11] Brooks R. EuroQol: the current state of play. *Health Policy* 1996;37(1):53–72.
- [12] Dolan P. Modeling valuations for EuroQol health states. *Medical Care* 1997;35(11):1095–108.
- [13] Tsuchiya A, Ikeda S, Ikegami N, Nishimura S, Sakai I, Fukuda T, et al. Estimating an EQ-5D population value set: the case of Japan. *Health Economics* 2002;11(4):341–53.
- [14] Society for the study of a municipality. *Survey of municipality*. Tokyo: Daiichihouki; 2002.
- [15] Ikegami N, Campbell JC. Japan's health care system: containing costs and attempting reform. *Health Affairs (Millwood)* 2004;23(3):26–36.
- [16] Frist WH. Health care in the 21st century. *New England Journal of Medicine* 2005;352(3):267–72.
- [17] Messinger-Rapport BJ. Evidence-based medicine: is it relevant to long-term care? *Journal of the American Medical Directors Association* 2004;5(5):328–32.
- [18] Honma S, Katoh E. Relationship between FIM and the officially recognized level of support/care required. *Journal of Japanese Association of Rehabilitation Nursing* 2001;13:186–8.
- [19] Miura K. Evaluation of certification of care needs in Japan's long-term care insurance and the determinants of degree of satisfaction with the certification. *Keio Igaku* 2002;79(1):17–26.