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*Grand Design 2007**Attaining the Best Public Healthcare for All Generations in Japan— Chapter 2*

A Healthcare Delivery System that Meets the Needs of the People

JMAJ 50(5): 355–366, 2007

1. The Healthcare Environment in Japan

(1) A rapidly aging population

Japan's population has begun to decline.¹ On the one hand, the population over 75 years old reached 11.64 million by 2005, and is expected to nearly double to 22.66 million by 2030 (Fig. 2-1-1).² Nineteen point seven percent of the population will be over 75 years old by 2030, about the same as the percentage of the population over 65 years old (20.2%) in 2005 (Table 2-1-1).

This is not just an increase in the share of the elderly in the population. One must also consider that there are tremendous changes in the situation of elderly households. Seven point five percent of people over 75 years old lived alone in 1980, but this figure increased to 17.0% by 2005. Furthermore, in 2005, 16.3% of people over 75 lived as a household with their spouse. In other words, by 2005, nearly one-third (33.2%)³ of people over 75 lived either alone or with their elderly spouse (Fig. 2-1-2).

This kind of family environment that “old-old” people are living in today means that there is a significant danger associated with current policies emphasizing in-home care, and that there will be a continued need for the infrastructure provided in medical care facilities.

(2) Changes in the number of hospital beds

The number of hospital beds has been declining from the peak of 1.949 million in 1990 (Fig. 2-1-3).

Between 1990 and 2005, the number of short-stay beds declined by 489,000 (31.9%),⁴ from 1.536 million to 1.047 million. After FY2005,* the number of short-stay beds stabilized. One of the main reasons that the number of short-stay beds is no longer falling is that some long-stay beds were redesignated as short-stay beds after the government announced in 2005 that they would restructure the long-stay bed system.

After April 2006, the number of long-stay beds declined sharply from 381,000 in April 2006 to 369,000 in December 2006 (Fig. 2-1-4).

2. Estimated Future Number of Hospital Beds Required

(1) Number of acute-care (short-stay) hospital beds required

The rate of inpatient admissions per short-stay hospital bed has declined over the past few years (Fig. 2-2-1). One reason may be that in the past, since there was little progress toward functional specialization in hospital beds, patients now occupying long-stay beds were admitted to short-stay beds, and there is some improvement in shortening in the average length of stay. Particular for hospitals, the average length of stay has shortened by more than 1 day in the past 2 and 1-half years (Fig. 2-2-2).

Both trends—reduction in the total number of acute-care hospital beds and shortening of the average length of stay—are likely to continue in the future.

1 According to the “Population Estimate” of the Ministry of Internal Affairs and Communications (MIC) (J), Japan's population in June 2006 was 127.75 million, in July 2006 127.74 million, and by August 2006 127.72 million. Subsequently, the projections were revised based on the “2005 Population Census” to 127.74 million in June 2006 and 127.76 million in July 2006.

2 Japan National Institute of Population and Social Security Research, “Population Estimate for Japan” (estimated in December 2006). (J)

3 Due to rounding, the numbers do not match those in Fig. 2-1-2.

4 The numbers in the table do not add up to the numbers used in the text due to rounding.

The titles of Japanese materials listed in the footnotes are translated by JMA and indicated as (J) unless they have an English version.

* The fiscal year in Japan starts at the beginning of April and ends at the end of next March.

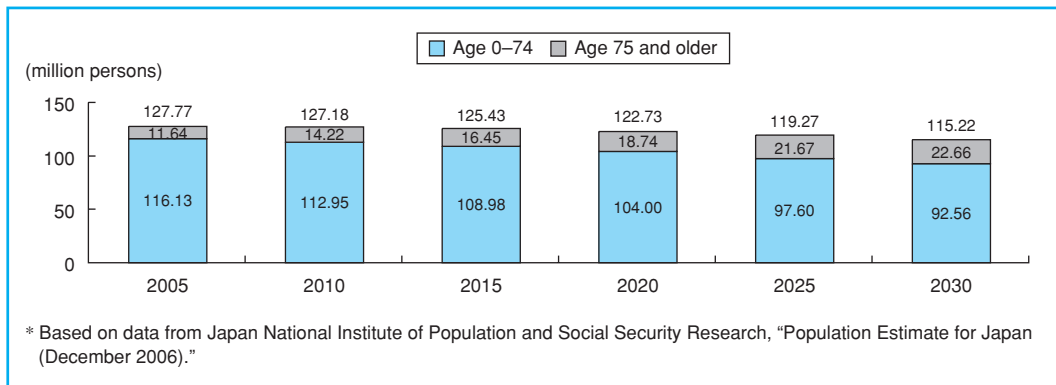


Fig. 2-1-1 Japan population estimates

Table 2-1-1 Estimated share of older persons in population

	2005	2010	2015	2020	2025	2030
Share of population aged 65 and older	20.2%	23.1%	26.9%	29.2%	30.5%	31.8%
(Restated) Share of population aged 75 and older	9.1%	11.2%	13.1%	15.3%	18.2%	19.7%

* Based on data from Japan National Institute of Population and Social Security Research, "Population Estimate for Japan (December 2006)."

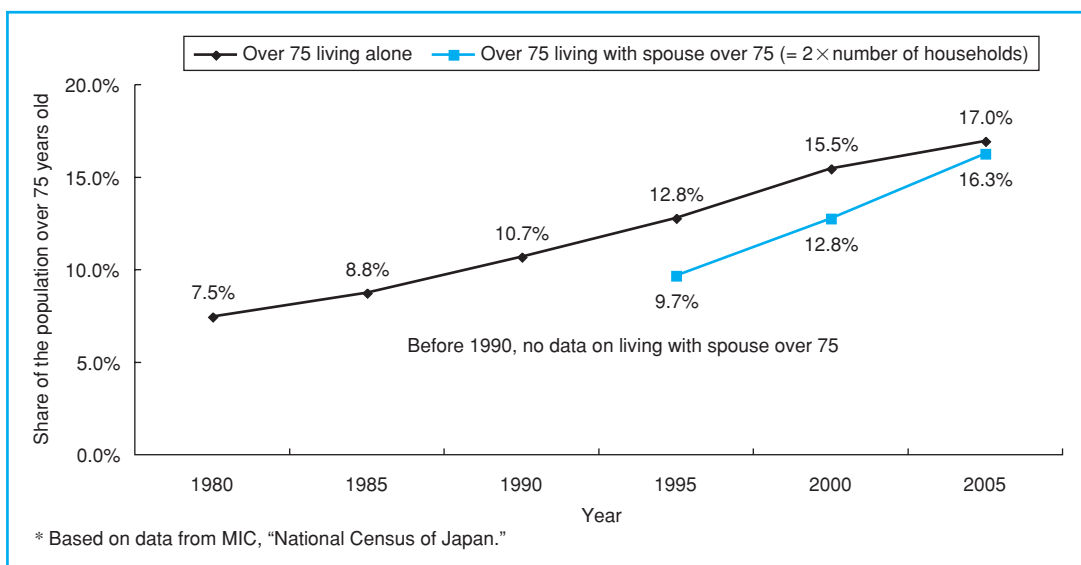


Fig. 2-1-2 Households with only people older than 75 years old—Living alone or with spouse over 75

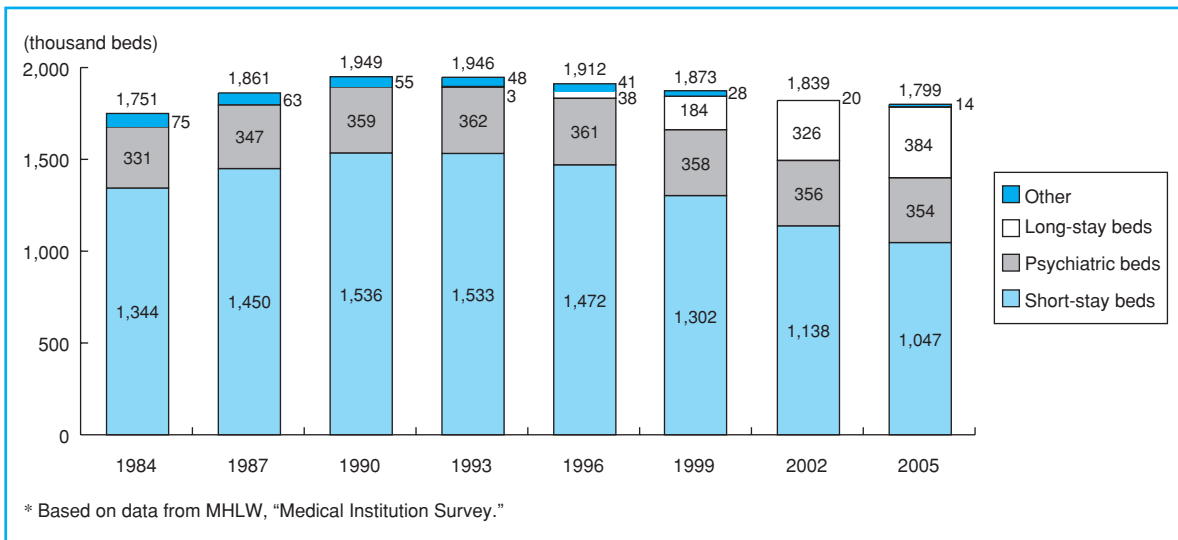


Fig. 2-1-3 Trends in number of hospital beds

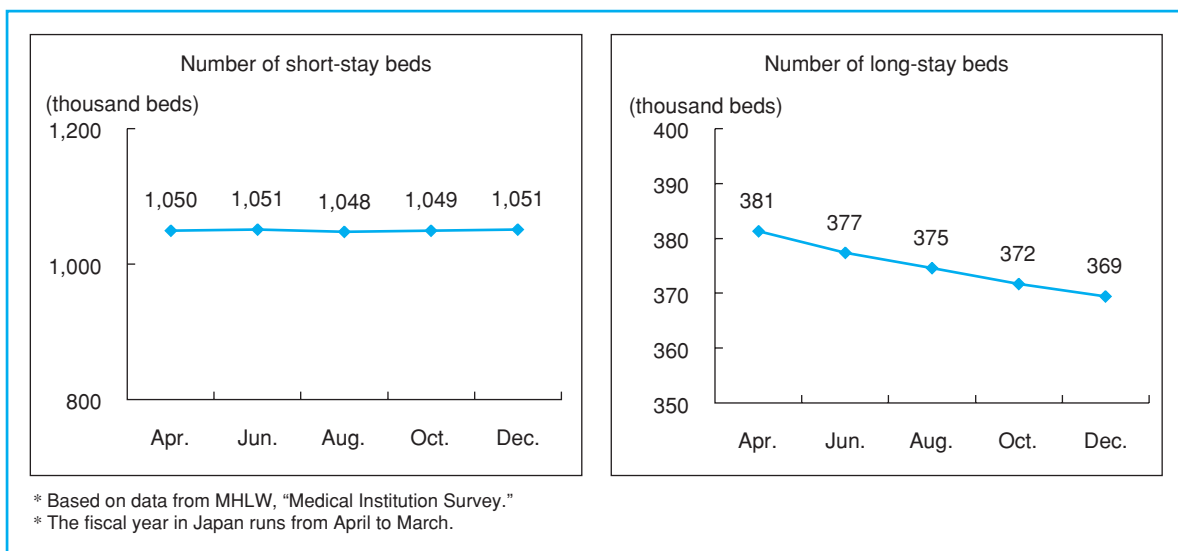


Fig. 2-1-4 Trends in short-stay beds and long-stay beds in FY2006

For the average length of stay, the Ministry of Health, Labor and Welfare (MHLW) has promoted a healthcare system reform⁵ designed to reduce by 50% the gap between the national average length of stay (20.2 days) and average length of stay in Nagano Prefecture (17.5 days),

the shortest of any prefecture.⁶ Subsequently, the national average length of stay did fall from 20.2 days to 19.8 days, a 2% contraction in 1 year.⁷

Let us assume that the rate of reduction remains 2% per year. In this case, the national average length of stay by 2011 will be reduced to

5 Ministry of Health, Labor and Welfare (MHLW), "Draft Proposal for Medical Care System Reform," October 2005. (J)

6 Figures from MHLW, "Report on Hospitals, 2004." (J) Data for 2005 reported that the shortest average length of stay was in Shizuoka Prefecture (17.4 days) followed by Nagano Prefecture (17.5 days).

7 In the preceding years, from 2003 to 2004, the average length of stay was reduced by 2.4% from 20.7 days to 20.2 days.

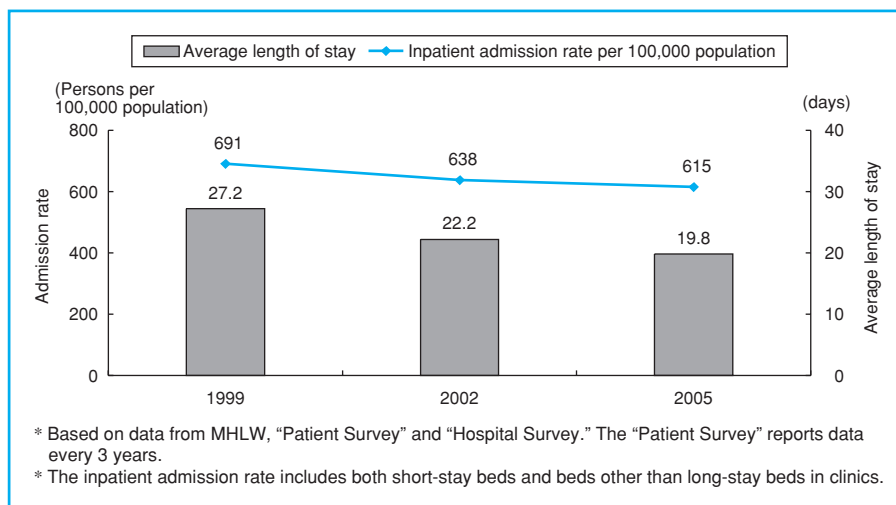


Fig. 2-2-1 Admission rate for short-stay beds and average length of stay

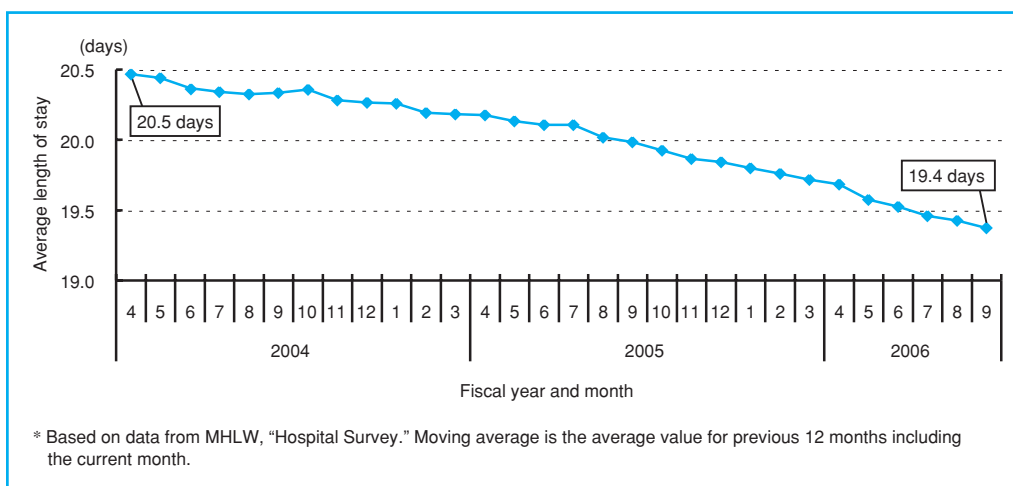


Fig. 2-2-2 Recent trends in average length of stay in short-stay beds (moving average)

17.5 days (the 2004 level for Nagano Prefecture). The inpatient admission rate, which strongly affects the average length of stay, will also have to decrease by 2% per year, and afterwards can be assumed to remain constant. Next, the number of patients can be estimated by multiplying the future population estimates by the inpatient admission rate. Moreover, since there is no systematic way to estimate the rate of hospital admission and discharge rates for acute-care hospital beds, the number of required acute-care hospital beds can be projected by assuming an 80% utilization rate.

Assumptions for estimating the required number of acute-care (short-stay) hospital beds

- Estimated inpatient admission rate: decrease by 2% per year through FY2011, thereafter no change
- Estimated number of inpatients = future population × admission rate
- Estimated number of beds required = estimated number of inpatients ÷ 0.8 (utilization rate of 80%)

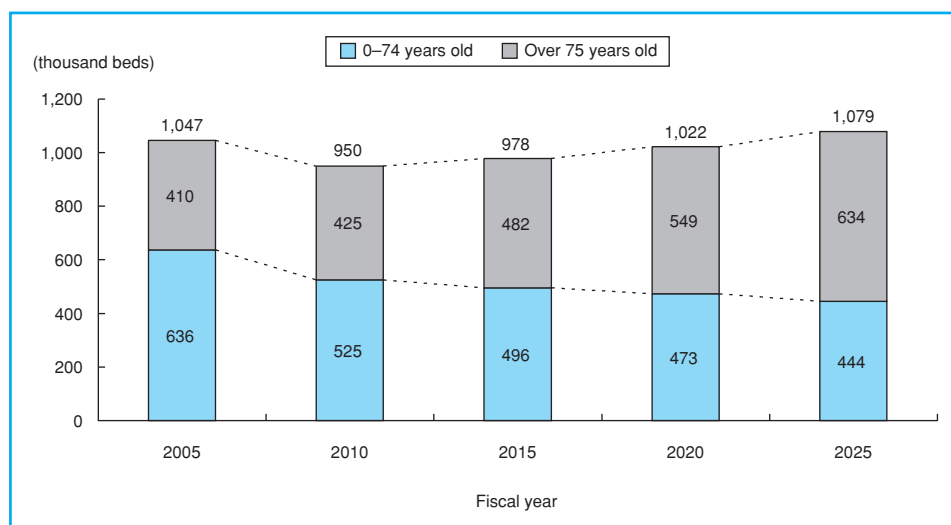


Fig. 2-2-3 Rough estimate of number of acute-care (short-stay) beds needed

Table 2-2-1 Need for acute-care (short-stay) beds (rough estimate)

		2005	2010	2015	2020	2025	Notes
Population (1,000)	0-74 years old	116,122	122,954	108,978	103,998	97,603	
	75 years old and older	11,646	14,222	16,452	18,737	21,667	
Inpatient administration rate (people per 100,000 population)	0-74 years old	411	372	364	364	364	Assume it will fall by 2% per year until 2011
	75 years old and older	2,644	2,390	2,342	2,342	2,342	
Patients (1,000)	0-74 years old	477	420	397	379	355	Population × inpatient admission rate
	75 years old and older	308	340	385	439	507	
	Subtotal	785	760	782	818	863	
Utilization rate		—	80.0%	80.0%	80.0%	80.0%	
Number of beds necessary*1 (1,000 beds)	0-74 years old	636	525	496	473	444	
	75 years old and older	410	425	482	549	634	
	Subtotal	1,047	950	978	1,022	1,079	

*1 Number of hospital bed in 2005 is actual number. Age group breakdown is standardized by number of patients by age group in Patient Survey.

* Based on data from MHLW, "Patient Survey," National Institute for Population and Social Security Research "Population Survey for Japan (December 2006)." 2005 population data is from MIC, "2005 National Census of Japan."

Based on the assumptions listed above, the estimated number of acute-care (short-stay) hospital beds required will be 978,000 in FY2015, 1.079 million in FY2025 (Fig. 2-2-3, Table 2-2-1). These numbers assume that the average length of stay will fall and then stabilize at a certain

level, but since the share of the population over 75 years old is rising, and this age group has a higher hospital admission rate, the number of acute-care (short-stay) hospital beds will likely be higher than the present amount.

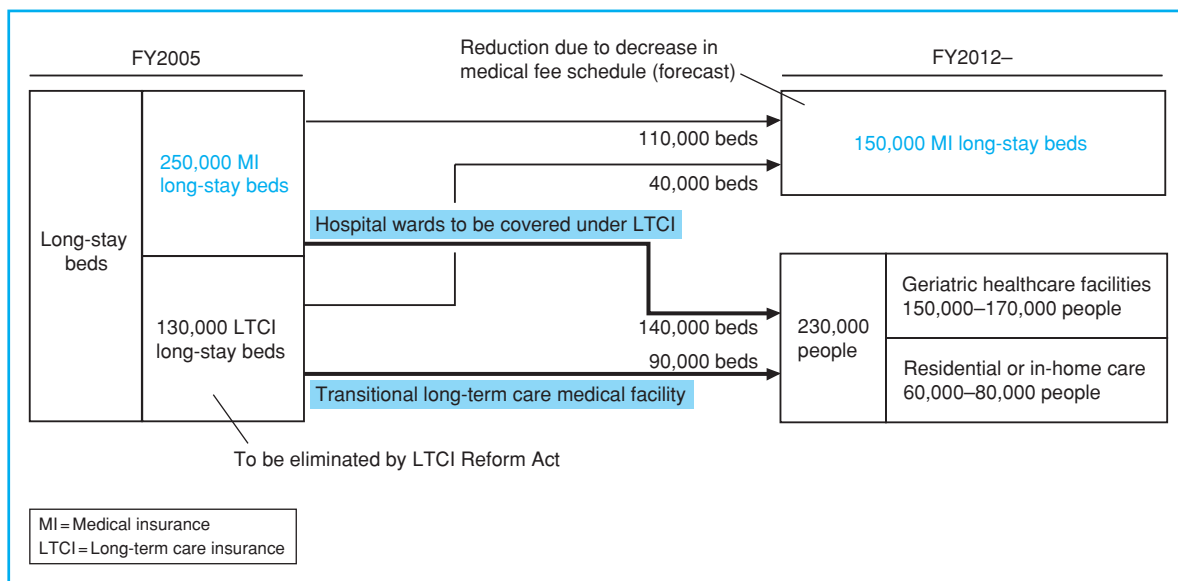


Fig. 2-2-4 Scenarios for restructuring long-stay beds (MHLW proposal)

(2) Number of chronic-care hospital beds required (currently designated as long-stay beds)

1) Plans for restructuring of long-stay beds (MHLW proposal)

Regarding the old old, the Ministry of Health, Labor and Welfare (MHLW) has stated that they have seen “increasingly longer periods of medical care, infection with multiple diseases (particularly chronic conditions).”⁸ Meanwhile, though, the infrastructure that supports care for the old old, the long-stay beds, continues to be reduced (Fig. 2-2-4).

In the healthcare reform of 2006, Japan’s national government eliminated the designation of “Long-Term Care Medical Facility for the Elderly,” and set a goal of reducing the total number of long-stay beds covered by medical insurance (MI long-stay beds) by 40%. Even patients already admitted to hospitals could be transferred to long-term care facilities or home-based care if they had low levels of medical need. These types of patients have been admitted through a process known as “social hospital-

ization,” which means hospitalization for non-medical reasons. In other words, even the national government acknowledges the continued need for 60% of MI long-stay beds.

The next section estimates the number of long-stay beds required based on actual patient conditions.

2) Actual patient conditions in long-stay beds

Patient conditions in long-stay beds covered by medical insurance (MI)

Based on a JMA survey,⁹ the relative composition of inpatients in long-stay beds covered by medical insurance (MI long-stay beds) is 42.1% in Medical Care Type 1, 45.2% in Medical Care Type 2, and 12.7% in Medical Care Type 3 (Table 2-2-2). Among the patients in Type 1, 30.9% have no prospect of discharge due to unstable medical condition, and of these patients, 68.4% require medical management or ongoing treatment. From this data we can estimate the number of patients requiring hospitalization in MI long-stay beds as 21.1% of those requiring Type 1 care ($0.309 \times 0.684 \times 100 (\%)$). This represents 8.9% ($0.421 \times 0.211 \times 100 (\%)$) of all inpatients. Similar calcula-

8 “Medical care for old-old people (rough draft for discussion)—how shall we think about medical care appropriate for the special physical and mental requirements of old-old people?” Presentation materials for the 6th session of the Social Security Advisory Council, Special Subcommittee on Medical Care for the Old Old, February 2007. Online at <http://www.mhlw.go.jp/shingi/2007/02/dl/s0205-8a.pdf> (J)

9 JMA, “Report on the Urgent Survey on Long-stay Beds” October 2006 (survey conducted July 2006). (J)

Table 2-2-2 Condition of patients in long-stay beds (2006)

1. Condition of patients in MI long-stay beds	100.0%
(1) Need MI long-stay bed (①+②+③)	66.8%
① Medical Care Type 1 Needing MI long-stay bed (⑦×⑧×⑨)	8.9%
② Medical Care Type 2	45.2%
③ Medical Care Type 3	12.7%
(2) Could be discharged to in-home care (under certain conditions) (④×⑤×⑥)	9.3%
④ Medical Care Type 1	42.1%
⑤ Stable condition, could be discharged (% of ④)	63.4%
⑥ Not living alone and not alone during day (% of ⑤)	35.0%
(3) Need long-term care facility	23.9%
⑦ Medical Care Type 1	42.1%
⑧ Unstable condition, discharge not possible (% of ⑧)	30.9%
⑨ Needs medical monitoring and treatment (% of ⑨)	68.4%

* JMA Report on the Urgent Survey on Long-Stay Beds, October 2006.

2. Condition of patients in LTCI long-stay beds	100.0%
(1) Need MI long-stay bed	38.7%
Medical Care Type 2 or 3	38.7%
(2) Could be discharged to in-home care (under certain conditions) (⑩×⑪×⑫)	10.8%
⑩ Medical Care Type 1	61.3%
⑪ Stable condition, could be discharged (% of ⑩)	66.4%
⑫ Not living alone and not alone during day (% of ⑪)	26.6%
(3) Need long-term care facilities	50.5%

* JMARI, Fukuoka Prefecture Medical Center, et al., "Report on Urgent Survey on Long-Stay Beds," JMARI Working Paper No.132, August 2006.

tions for inpatients undergoing Type 2 and Type 3 care results in an estimate that 66.8% of inpatients will require hospitalization in MI long-stay beds.

At the same time, the number of patients eligible to be transferred to in-home care can be estimated by taking the number of inpatients currently undergoing Type 1 care in MI long-stay beds (42.1%) who are medically eligible for discharge (63.4%) who do not live either alone or in a household composed only of elderly persons with no other family members present during the day (35%). Nine point three percent of all inpatients in MI long-stay beds would be eligible to be transferred to in-home care ($0.421 \times 0.634 \times$

0.350×100 (%)).

All other inpatients in MI long-stay beds who do not fill the conditions listed above may not have the highest degree of medical need, but would not be easily transferred to in-home care. Twenty-three point nine percent of all inpatients in MI long-stay beds would therefore have to be transferred to new long-term care facilities for the elderly.

Patient conditions in long-stay beds covered by long-term care insurance (LTCI)

We estimated the following based on surveys from JMARI and others.¹⁰

10 Yumiko Maeda, Kazutoshi Sato, Yuichi Hara, Fukuoka Prefecture Medical Center Research Institute for Health, Welfare and Medical Care, and the Fukuoka Prefecture Medical Association, "Report on Urgent Survey on long-stay beds" JMARI Working Paper No.132 p.5., August 2006 (data from June 2006 report for Fukuoka Prefecture). (J)

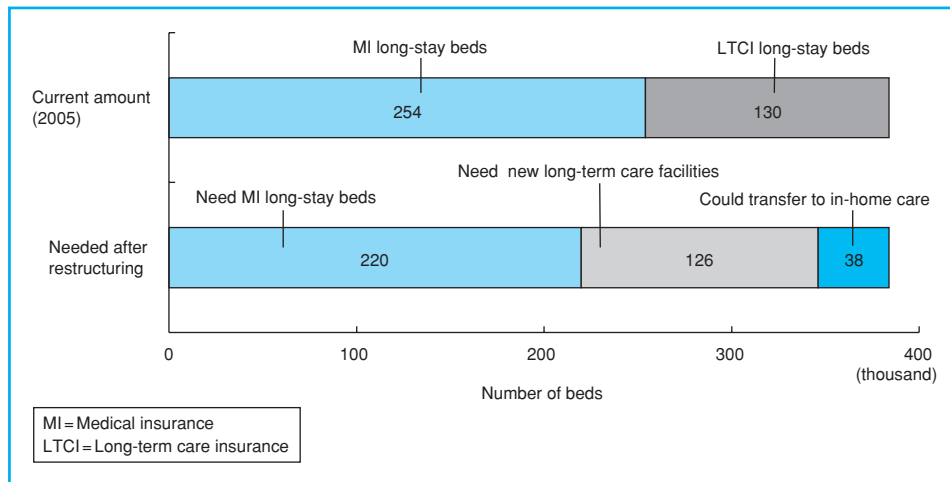


Fig. 2-2-5 Need for long-stay beds based on patient condition (2005)

Table 2-2-3 Need for long-stay beds considering patient condition (2005)

(1,000 beds or 1,000 people)

		Need for MI long-stay beds	Need for new long-term care facilities	Could transfer to in-home care ("social hospitalization")	Total
MI long-stay beds	Share	66.8%	23.9%	9.3%	100.0%
	Number of beds or persons	169.7	60.6	23.7	254.0
LTCI long-stay beds	Share	38.7%	50.5%	10.8%	100.0%
	Number of beds or persons	50.3	65.6	14.1	129.9
Total		219.9	126.2	37.8	383.9

* Hospital bed data from 2005. Patient condition from JMA survey in 2006.

Among inpatients in long-stay beds covered by long-term care insurance (LTCI long-stay beds), 61.3% require Medical Care Type 1.¹¹ The remaining patients were classified as either Type 2 or Type 3. Patients requiring Type 2 or 3 care were currently in LTCI long-stay beds, but since they had a high need for medical care, they can be viewed as patients requiring MI long-stay beds.

Of these in Medical Care Type 1 (61.3%), those in stable condition (66.4%) who do not live alone (26.6%) would be able to transfer to in-home care. This is a total of 10.8% ($0.613 \times 0.664 \times 0.266 \times 100$ (%)) of all inpatients in LTCI long-stay beds (Table 2-2-2).

All other inpatients would require continuing medical care in LTCI long-stay beds. We estimate that 50.5% of inpatients currently in this type of beds would fit in this category.

As of 2005 there were 384,000 long-stay beds, of which 254,000 were MI long-stay beds and 130,000 beds were covered by LTCI. We estimate the number of beds required based on patient condition data as shown above (Fig. 2-2-5, Table 2-2-3).

- 220,000 MI long-stay beds required
- 126,000 beds should be transferred to new long-term care facilities (for example, an enhanced type of geriatric health services facilities)

¹¹ There is no necessary connection between Medical Care Type and LTCI long-stay beds, but in the survey, the number of patients per Medical Care Type was reported for LTCI long-stay beds as well.

Table 2-2-4 Inpatient admission rate for long-stay beds by type of insurance coverage (2005)

	Number of inpatients (1,000)		Population (1,000)	Inpatient admission rate (number of inpatients per 100,000 population)	
	Medical insurance	Long-term care insurance		Medical insurance	Long-term care insurance
0-74 years old	69.5	17.2	116,122	59.9	14.8
75 and older	164.7	96.1	11,646	1,414.2	825.2
Total	234.2	113.3	127,768	183.3	88.7

* Based on data from MHLW, "Patient Survey 2005."

* The overall inpatient admission rate itself is published in the Patient Survey, but here the separation between 0-74 years old and 75 and older is recalculated from the number of inpatients and the population.

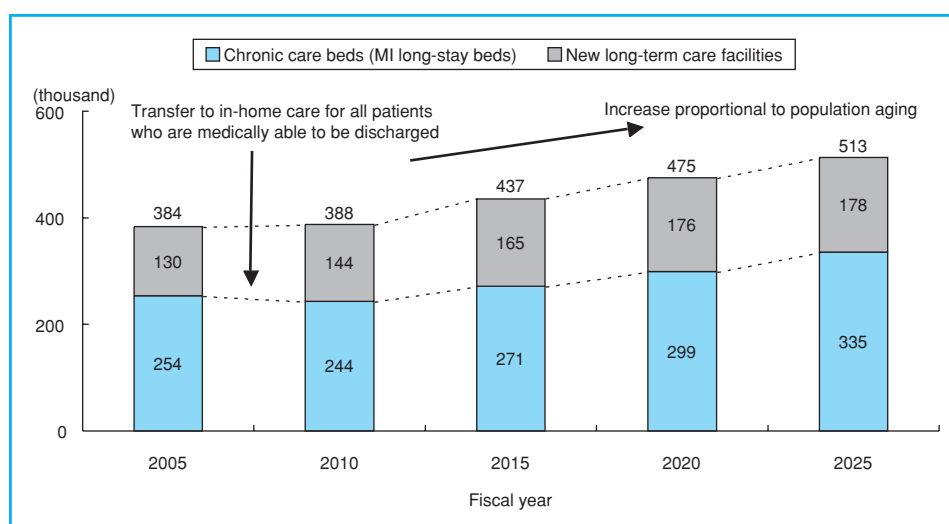


Fig. 2-2-6 Number of long-stay beds needed (rough estimate)

- 38,000 beds can be reduced due to patients transferred to in-home care

3) Estimated number of long-stay beds required

Assuming no change in the ratio of patients by Medical Care Type, the need for beds and facilities will increase as the share of the elderly in the population rises. Next the future need for chronic care inpatient facilities will be estimated.

According to the "Patient Survey" by MHLW in 2005, for every 100,000 people over 75 years old, 1,414.2 people were in MI long-stay beds, and 825.2 people in LTCI long-stay beds (Table 2-2-4). Based on the current patient conditions

(and the corresponding need for long-stay beds), for all ages, 66.8% of patients in MI long-stay beds and 38.7% of patients in LTCI long-stay beds will require continued care in MI long-stay beds (see Table 2-2-2). Accordingly, the number of inpatients per 100,000 population for people over 75 years old will be 944.8 in MI long-stay beds ($= 1,414.2 \times 66.8\%$),¹² and 319.3 in LTCI long-stay beds ($= 825.2 \times 38.7\%$). We can then determine the future number of patients needing long-stay beds by multiplying the future population estimates by the inpatient admission rate. The number of long-stay beds required is then obtained by dividing the estimated future num-

¹² Due to rounding, the numbers in the text do not add up to the same numbers in the table.

Table 2-2-5 Need for long-stay beds (rough estimate)

1. Number of chronic-care beds needed (currently MI long-stay beds)—Rough estimate

(1) Of those currently in MI long-stay beds, number who need continuing care in MI long-stay beds

		FY2005	FY2010	FY2015	FY2020	FY2025	Notes
Population (1,000)	0–74 years old	116,122	112,954	108,978	103,998	97,603	
	75 years old and older	11,646	14,222	16,452	18,737	21,667	
Inpatient admission rate (people per 100,000 population)	0–74 years old	59.9	40.0	40.0	40.0	40.0	Assumes it will fall no lower than 66.8%
	75 years old and older	1,414.2	944.8	944.8	944.8	944.8	
Patients (1,000)	0–74 years old	69.5	45.2	43.6	41.6	39.0	Population × inpatient admission rate
	75 years old and older	164.7	134.4	155.4	177.0	204.7	
Subtotal		234.2	179.5	199.0	218.6	243.7	
Utilization rate		—	95.0%	95.0%	95.0%	95.0%	
Number of beds necessary*1 (1,000 beds)	0–74 years old	75.4	47.5	45.9	43.8	41.1	
	75 years old and older	178.6	141.4	163.6	186.3	215.5	
Total ①		254.0	189.0	209.5	230.1	256.6	

(2) Need transfer from LTCI long-stay beds to MI long-stay beds

		FY2005	FY2010	FY2015	FY2020	FY2025	Notes
Population (1,000)	0–74 years old	116,122	112,954	108,978	103,998	97,603	
	75 years old and older	11,646	14,222	16,452	18,737	21,667	
Inpatient admission rate (people per 100,000 population)	0–74 years old	14.8	5.7	5.7	5.7	5.7	Assumes it will fall no lower than 38.7%
	75 years old and older	825.2	319.3	319.3	319.3	319.3	
Patients (1,000)	0–74 years old	17.2	6.5	6.2	6.0	5.6	Population × inpatient admission rate
	75 years old and older	96.1	45.4	52.5	59.8	69.2	
Subtotal		113.3	51.9	58.8	65.8	74.8	
Utilization rate		—	95.0%	95.0%	95.0%	95.0%	
Number of Beds Necessary*1 (1,000 beds)	0–74 years old	19.7	6.8	6.6	6.3	5.9	
	75 years old and older	110.2	47.8	55.3	63.0	72.8	
Total ②		129.9	54.6	61.9	69.3	78.7	

		FY2005	FY2010	FY2015	FY2020	FY2025	Notes
Total number of hospital beds needed ①+②		383.9	243.6	271.4	299.4	335.3	

2. Need care in new long-term care facility

		FY2005	FY2010	FY2015	FY2020	FY2025	Notes
Population aged 65 and older (1,000)		25,769	29,412	33,781	35,899	36,354	
Long-term care facilities (1,000 beds or people)		126.2	144.0	165.4	175.8	178.0	Compared to share of population aged 65 and older

↓
Corresponds to Number of People Needing New Long-term Care Facility in Table 2-2-3

*1 Number of hospital bed in 2005 is actual number. Age group breakdown is standardized by number of patients by age group in Patient Survey.

* Estimated based on data from MHLW, "Patient Survey," National Institute for Population and Social Security Research "Population Survey for Japan (December 2006)." 2005 population data is from MIC, "2005 National Census of Japan." Due to rounding, subtotals and final results will not match in some cases.

* MI long-stay beds = long-stay beds covered by medical insurance, LTCI long-stay beds = long-stay beds covered by long-term care insurance

ber of patients by the utilization rate of 95%.

Assumptions for estimating the required number of MI long-stay beds

- Estimated inpatient admission rate for people requiring continued hospitalization in MI long-stay beds
= current admission rate for MI long-stay beds \times 66.8%
- Estimated inpatient admission rate for people requiring transfer from LTCI long-stay beds to MI long-stay beds
= current admission rate for LTCI long-stay beds \times 38.7%
- Estimated number of long-stay beds required
= future population \times inpatient admission rate \div 0.95 (utilization rate of 95%)

If the system of LTCI long-stay beds is eliminated, based on FY2005 data there will be an additional 126,000 beds required (see Fig. 2-2-5). The future projected for MI long-stay beds needed is estimated based on the share of the population over 65 years old.

The estimates are based on the Medical Care Type composition from 2006 and assume no future changes in that composition. Any such changes could affect the estimates.

Based on the estimates, the minimum need for chronic-care hospital beds (the current system of MI long-stay beds) will be 244,000 in FY2010 (Fig. 2-2-6, Table 2-2-5). From the perspective of patient conditions, the figure of 150,000 MI long-stay beds that MHLW projects by FY2012 will be grossly insufficient. Moreover, by FY2015, we estimate that 271,000 chronic-care beds will be necessary, even more than the 254,000 beds available in FY2005.

The current system of LTCI long-stay beds will need to be reorganized into new types of long-term care facilities, such as enhanced geriatric health services facilities. We estimate that this will affect 165,000 beds (people) in FY2015, and 178,000 by FY2025.

Overall, there are 384,000 long-stay beds in FY2005, but by FY2015 we estimate that a total of 437,000 people will require MI long-stay beds or new long-term care facilities. The need will rise

to 513,000 beds by FY2025.

Until now, LTCI long-stay beds have been provided by medical facilities. Even among patients able to be discharged from MI long-stay beds to in-home care, there are many who need to continue rehabilitative treatment or have a serious cognitive illness.¹³ Therefore, in the future there will need to be new facilities or additional functional capacity in existing facilities to assure continuity of medical care like that previously provided by the long-stay hospital beds.

MHLW is preparing a policy to encourage in-home care for the elderly. But they have yet to develop plans for a community care infrastructure and services to support in-home healthcare, raising serious doubts about whether the elderly will be able to transfer to in-home care. The tendency of the current policy is to induce greater use of in-home care in order to reduce overall healthcare spending. We would like to show that this tendency should not lead to a policy that promotes discharge to in-home care at the expense of proper healthcare.

As we stated in Chapter 1 Section 1, “Healthcare desired by the public,” the Japanese people strongly want the elderly to be able to use inpatient and residential care facilities. Although it may be possible to reduce costs at least for government spending, this is either contrary to the needs of the people or at least greatly increases the psychological and economic burden on the people. Cautious discussion is necessary in order to ensure that there is no simplistic push to promote in-home care.

Summary—Rough estimate of total number of hospital beds

Here a rough estimate of the total number of hospital beds is provided using the estimates of short-stay beds and long-stay beds shown above. The number of inpatient psychiatric beds and other types of beds (for tuberculosis and infectious diseases) has tended to fall until now, but the number can be expected to stabilize in the future. As a result, the total number of hospital beds is estimated to be 1.561 million by FY2010. As the average length of stay is expected to

¹³ JMA, “Report on the Urgent Survey on Long-stay Beds” October 2006 (survey conducted July 2006). (J) Thirty point nine percent of patients in Medical Care Type 1 were in an unstable medical condition and could not be discharged. Of these patients, 16.3% required ongoing inpatient rehabilitation, and 12.3% had a serious cognitive illness.

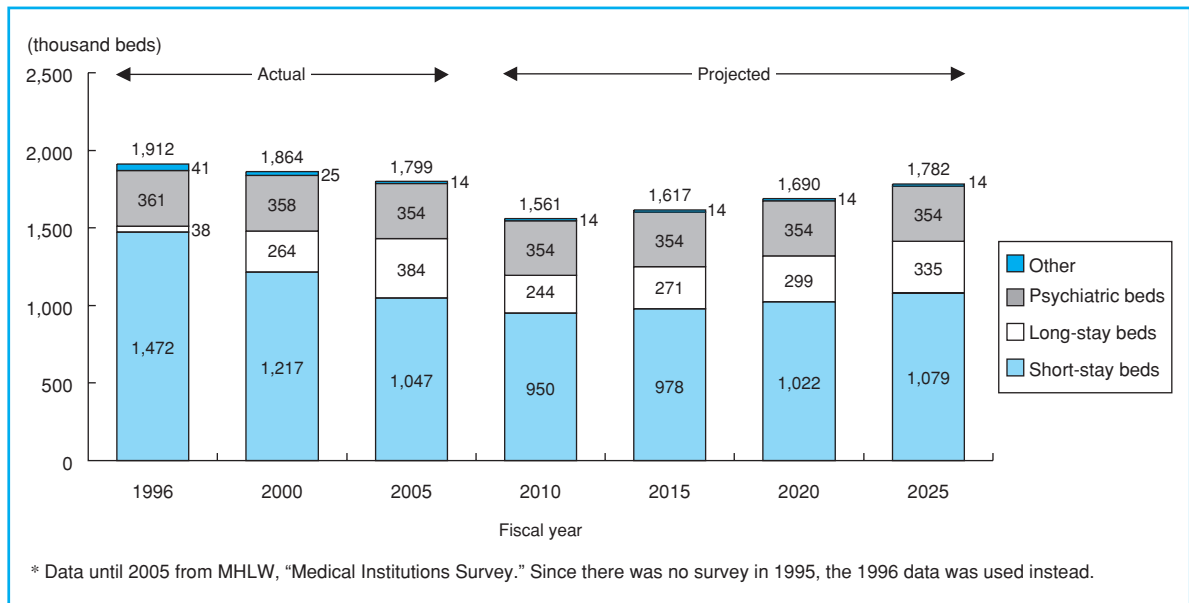


Fig. 2-2-7 Total number of hospital beds (rough estimate)

decrease between FY2005 and FY2010, the total of hospital beds is likely to decrease. After FY2010, however, the number of beds will rise with the increasing share in the population of the "old old" who have a higher rate of inpatient hospital admission. We estimate that by FY2015

1.617 million hospital beds will be needed, rising to 1.782 million by FY2025. Therefore, the current level of hospital beds should be basically maintained, since there is no reason to promote the elimination of hospital beds (Fig. 2-2-7).

Grand Design 2007

Attaining the Best Public Healthcare for All Generations in Japan— Chapter 3

Financial Aspects of the Health Insurance System

JMAJ 50(5): 367–388, 2007

1. Estimate of Future Healthcare and Long-Term Care Expenditure

(1) Current national health expenditure

Japan's national health expenditure in FY2004 was 32.1 trillion yen (US\$267.5 billion), an increase of 600 billion yen (US\$5 billion) from the previous year. National health expenditure had increased by over 1 trillion yen (US\$8.3 billion) per year in the past, but due to the introduction in FY2000 of the public Long-Term Care Insurance (LTCI) system, the entire increase from FY2001 (31.1 trillion yen or US\$259.2 billion) to FY2004 (32.1 trillion yen or US\$267.5 billion) was kept below 1 trillion yen (US\$8.3 billion) (Fig. 3-1-1).

Looking at per-capita national health expenditure by age groups shows that for the elderly, spending fell sharply just after introduction of LTCI, and since then has not increased by much at all. Similarly, for people aged 45 to 64 years old, per-capita health expenditure is virtually unchanged except for a slight increase. Per-capita spending for people aged 0 to 14 years, and 15 to 44 years increased by over 5% per year until 2000, but the increase from FY2003 to FY2004 was 0.4% for people 0 to 14 years old and 1.2% for people 15 to 44 years old (Fig. 3-1-2).

Cost containment policy for healthcare has also had an impact; in recent years, the per-capita health expenditure has almost stopped growing, and increases in national health expenditure have also been reduced to a very slow rate.

(2) Estimates of future health expenditure

1) Method

The JMA Grand Design has previously estimated future health expenditure by multiplying the expected number of patients by the per-capita daily unit costs. Increases in the number of patients and the daily unit costs on which the estimate is based were projected based on past trends. As we are now undergoing systemic reform, future estimates based on past trends in unit costs are going to be less reliable. Therefore, this chapter develops estimates of future increases in expenditure based on current increases in daily per-capita health expenditure, instead of the cumulative method based on past trends in daily unit costs and the number of patients.

Future estimates are calculated based on the most recent data in October 2006 by extending the increase trend excluding years with reductions in the medical fee schedule.¹ The steps in our analysis are presented below.

- Health insurance expenditure
= estimated rate of increase in per-capita health insurance expenditure (projecting current rates of increase into the future) × future population estimate
- Estimated national health expenditure based on current trends
= health insurance expenditure + social assistance
- Ideal level of health expenditure
= Estimated national health expenditure

¹ In the past few years, the number of short-stay beds has decreased, and the number of long-stay beds has increased. However, as in Chapter 2, we argue that the hospitalization rate in short-stay beds will not fall below a certain level, and that it is appropriate to increase the number of long-stay beds covered by medical insurance given the increase in the rate of population aging. Therefore, there may be a concern that the future rate of increase in per-capita healthcare spending will be higher than the current increases due to the expected increase in the number of hospital beds. Since one of the main reasons for the decrease in the number of hospital beds was the reduction in the official medical fee schedule, this issue can be handled by calculating the rate of increase by excluding years with cuts in the medical fee schedule. By creating a separate fee schedule for the "old old," we will also consider that increases in healthcare costs for the "old old" will become moderate.

The titles of Japanese materials listed in the footnotes are translated by JMA and indicated as (J) unless they have an English version. Yen/dollar exchange rate: 1 US dollar = 120 yen.

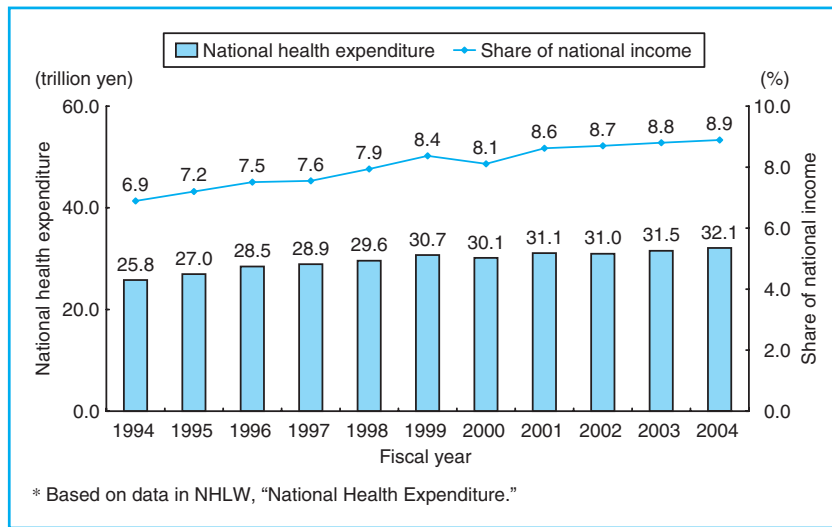


Fig. 3-1-1 Trends in national health expenditure

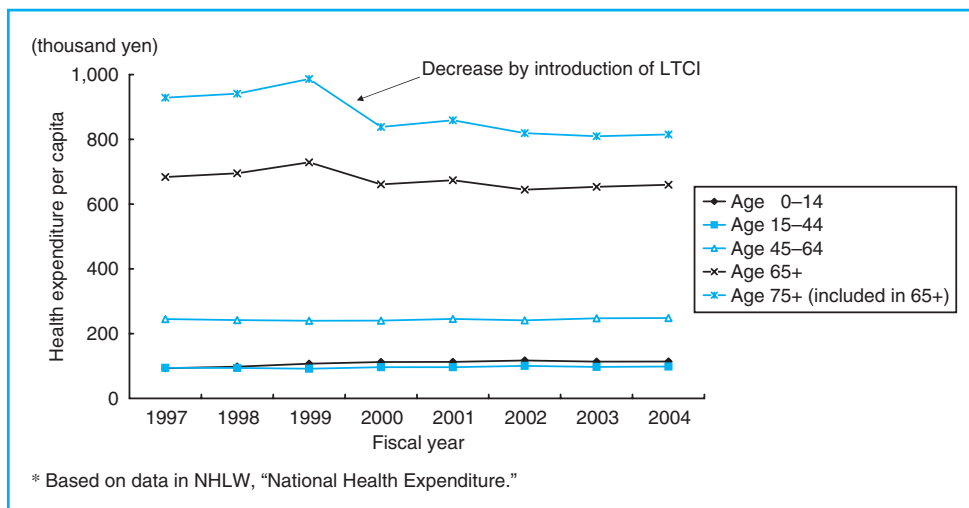


Fig. 3-1-2 Trends in per-capita national health expenditure

based on current trends + costs for improving safety and security

2) Detailed composition of ideal health expenditure

① Estimated health expenditure based on current trends

Rate of increase in per-capita health insurance expenditure

We use the Ministry of Health, Labor and Welfare

(MHLW), "Medical Information Analysis System (MEDIAS)."²

The minimum age for recipients of geriatric healthcare services was raised to 70 in September 2002, and was then raised by one year each of the following years until in October 2006 the age was set at 75. As a result, the annual increase in per-capita geriatric health insurance expenditure was much higher, and the trend value could not be used. In this analysis, the rate of increase for the

2 <http://www.mhlw.go.jp/topics/medias/month/index.html>

Table 3-1-1 Rate of increase in per-capita health insurance expenditure

	FY2002	FY2003	FY2004	FY2005	Average FY03–05	FY2006
Regular (under 70 years old)	-1.2%	0.4%	0.9%	1.5%	0.9%	-0.9%
Old (over 70 years old)	-3.6%	0.8%	0.2%	2.1%	1.0%	-1.2%
Geriatric healthcare system (included above)	-3.2%	3.4%	3.2%	5.1%	3.9%	1.6%

* Based on data in MHLW, "Current Trends in Health Expenditure, October 2006."

* Actual data from April–October 2006.

Old: Insured persons over 70 years old.

Geriatric Healthcare System: Until September 2002, persons over 70 years old. From October 2002 the age of eligibility was raised each year by 1 year, therefore the rate of increase in per-capita expenditure is high. After October 2006 the age of eligibility was 75 years and older.

Since the Geriatric Healthcare System was changing during this period, it is not possible to determine trends in the rate of increase.

Table 3-1-2 Estimate of per-capita health insurance expenditure

		FY2006	FY2010	FY2015	FY2020	FY2025
Per-capita health insurance expenditure (thousand yen)* ¹	Regular	168.8	175.2	183.6	192.3	201.5
	Old old	817.2	852.0	897.6	945.6	996.2
Population (million)* ³	Regular (age 0–74)	113.9	113.0	109.0	104.0	97.6
	Old old (age over 75)* ²	13.6	14.2	16.5	18.7	21.7
Health insurance expenditure (trillion yen)	Regular (age 0–74)	19.2	19.8	20.2	20.2	19.7
	Old old (age over 75)	11.1	12.1	14.8	17.7	21.6
	Total	30.3	31.9	34.8	37.7	41.3

*¹ Calculated from annualized increases from April–October 2006. Figures for the old old use data from the Geriatric Healthcare System which since October 2006 provides benefits for people over 75 years old.

*² The column for the population over 75 old in FY2006 is derived by reverse calculation from the number of beneficiaries in MEDIAS data for the Geriatric Healthcare System 2006.

*³ Population after FY2010 is from National Institute of Population Studies and Social Security Research, "Population Estimates for Japan, December 2006."

"old" population over 70 years old reported by the MEDIAS system is used as a proxy for the rate of increase in health insurance expenditure for the "old old" over 75 years old.³

In addition, we omit data from FY2002 and FY2006 where the fee schedule reduced skill-based fees. From FY2003 to FY2005, the per-capita health insurance expenditure increased by 0.9% for the non-elderly population, and 1.0%

for the "old old"⁴ (Table 3-1-1).

Per-capita health insurance expenditure

If we calculate based on the results from April to October 2006, the per-capita health insurance expenditure for the non-elderly population is 168,800 yen (US\$1,407), and 817,200 yen (US\$6,810) for the old old.⁵

Per-capita health insurance expenditure in

3 We look forward to reconfirming these estimates when the process of reforming the Geriatric Health Services Law. In April 2008 this law will be revised and the "Law Securing Healthcare for the Elderly" will take effect.

4 In April 2006, the JMA published estimates of health expenditure based on MEDIAS data. At the time, the rate of increase in per-capita health insurance expenditure was estimated to be 1.2% for insured persons, 1.7% in the Municipal managed health insurance system, and 1.3% for older persons.

5 The MEDIAS system publishes per-capita health insurance expenditure data separately for inpatients and outpatients. The number of patients overall and the number of older patients were found by dividing total inpatient health insurance expenditure by per-capita inpatient health insurance expenditure. Then, the per-capita health insurance expenditure was obtained by dividing the total health insurance expenditure by each population.

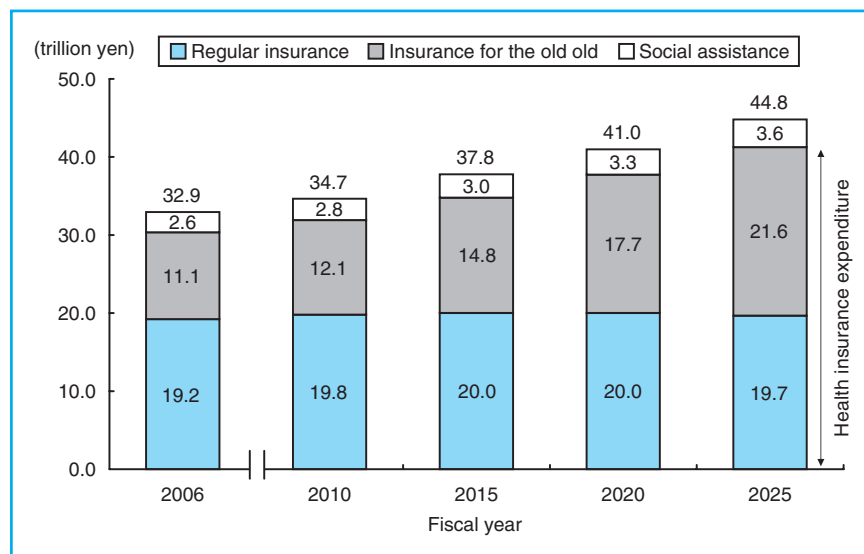


Fig. 3-1-3 Estimated future required health expenditure based on projection of current trends in health expenditure (March 2007 estimates)

the future is estimated by extending the trend of the increase in per-capita health insurance expenditure (0.9% overall, 1.0% for the old old.) (Table 3-1-1). We estimate per-capita non-elderly health insurance expenditure to be 183,600 yen (US\$1,530) and 897,600 yen (US\$7,480) for the old old in FY2015 (Table 3-1-2).

Health insurance expenditure

We then multiply the per-capita health insurance expenditure by the population estimate of the National Institute of Demographic and Social Security Research. As a result, health insurance expenditure in FY2015 is estimated to be 20 trillion yen (US\$166.7 billion) for the non-elderly population, and 14.8 trillion yen (US\$123.3 billion) for the old old, for a total of 34.8 trillion yen (US\$290 billion) (Table 3-1-2).

Social assistance

National health expenditure includes several components in addition to health insurance expenditure, including self-payment, workplace accident insurance, and several public spending systems such as payments for the welfare of the mentally disabled, mental health payments, and

social assistance payments under the Livelihood Protection Law. These components will be referred to as “social assistance.”

Just over half of social assistance are health-care services paid for as social assistance. These costs will continue to increase at the same rate that they are now. Since these payments under the social assistance system can be seen as supplemental welfare benefits, for this estimate we consider that the costs will be the same share of national health expenditure in the future as well. In FY2004⁶ social assistance accounted for 7.9% of national health expenditure.

National health expenditure

We estimate national health expenditure by adding health insurance expenditure to the social assistance (Fig. 3-1-3). In FY2015, non-elderly health expenditure will be 20 trillion yen (US\$166.7 billion), health expenditure for the old old will be 14.8 trillion yen (US\$123.3 billion), and social assistance will be 3 trillion yen (US\$125 billion), for a total of 37.8 trillion yen (US\$315 billion), rising to 44.8 trillion yen (US\$373.3 billion) by FY2025.

⁶ MEDIAS data until October 2006 has been made publicly available, but the most recent data for national health expenditure is for fiscal year 2004. Since it is not possible to determine the total national health expenditure without data for social assistance and others, data for 2004 is used.

Table 3-1-3 Estimated cost of employing personnel to ensure medical safety

1. Cost of the medical safety promotion system (per 100 medical personnel)

Job type	Person responsible for promotion of medical safety	Medical safety promotion committee member
Number of personnel	1	10 (committee members only)
Extent of duties for medical safety	100%	Additional task
Type of costs	<ul style="list-style-type: none"> • Salary and legally-mandated benefits • Study and training 	<ul style="list-style-type: none"> • Overtime pay • Study and training
Calculation of costs	<ul style="list-style-type: none"> • Salary and legally-mandated benefits: 8 million yen × 1 person = 8 million yen • Study and training (2 × per year) 100,000 yen × 2 times = 200,000 yen Total 8.2 million yen 	<ul style="list-style-type: none"> • Overtime pay (committee members only) 3,000 yen × 2 hours × 10 people × 1 time × 12 months = 720,000 yen • Study and training (2 × per year for all employees) 20,000 yen × 100 people × 2 times = 4 million yen Total 4.72 million yen
① Subtotal	12.92 million yen	

2. Costs of additional time (per 100 employees)

Job type	Regular employee
Number of personnel	Increase of 5% in staff = $0.05 \times 100 = 5$ people
Extent of duties for medical safety	Regular employees: physicians and nurses, etc.
Type of costs	<ul style="list-style-type: none"> • Salary and legally-mandated benefits
Calculation of costs	<ul style="list-style-type: none"> • Salary and legally-mandated benefits: 6 million yen × 5 people = 30 million yen Total 30 million yen
② Subtotal	30 million yen

3. Total cost (national)

Totals of ① and ② above	Conversion into health expenditure
42.92 million yen per 100 employees = 429,000 yen per employee	$429,000 \text{ yen} \times 2.632 \text{ million employees}^{*1} = 1.13 \text{ trillion yen}$

*1 MHLW 2005 Static and Dynamic Survey of Healthcare Organizations, "The Condition of Hospitals, 2005."

② Costs to improve medical safety and healthcare security

Medical safety personnel

In December 2003, the Japan Medical Association, the Japan Dental Association, and the Japan Pharmacists' Association proposed increases in the medical fee schedule to cover the cost of three measures vital for improving the quality of healthcare: (1) securing medical safety (particu-

larly the additional personnel required for the recommended system infrastructure), (2) medical materials and supplies not currently eligible for reimbursement by health insurance and (3) disposal of hazardous medical waste, particularly infectious waste matter. Unfortunately, none of these recommendations has yet been implemented.

In particular, increased public awareness and the rising standards of medical technology have

Table 3-1-4 Economic assumptions

(all in nominal terms)		FY2006	FY2007	FY2008	FY2009	FY2010	FY2011	FY2012–
Rate of price increase (goods)	Average (Case A)	0.5%	1.1%	1.6%	1.9%	2.1%	2.2%	1.0%
	Low (Case B)	0.5%	1.1%	1.5%	1.8%	1.9%	1.8%	1.0%
Rate of wage increase	Average (Case A)	2.0%	2.7%	3.1%	3.4%	3.2%	3.2%	2.1%
	Low (Case B)	2.0%	2.1%	2.3%	2.5%	2.2%	2.2%	1.8%
Investment yield	Average (Case A)	1.9%	2.6%	3.1%	3.5%	3.9%	4.1%	3.2%
	Low (Case B)	1.9%	2.5%	3.0%	3.5%	3.8%	3.9%	3.1%
Rate of increase in national income	Average (Case A)	2.0%	2.5%	2.9%	3.1%	3.1%	3.2%	1.6%
	Low (Case B)	2.0%	1.9%	2.1%	2.2%	2.1%	2.2%	1.3%

* Source: MHLW, "Forecast of Social Security Benefits and Burdens, May 2006."

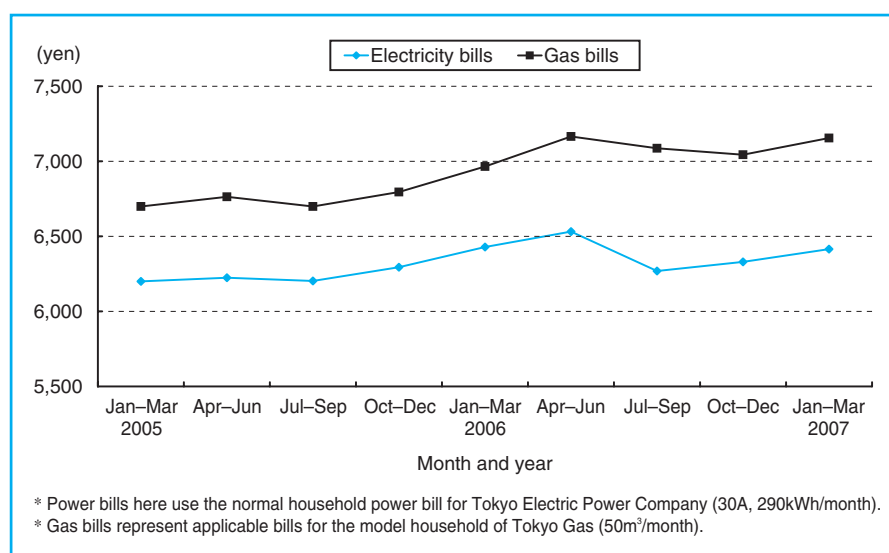


Fig. 3-1-4 Trends in monthly utility bills for electricity and gas

increased the personnel costs to assure health-care safety, and new supplemental fees have become necessary expenditures.

We propose that for every 100 people employed in medical institutions, there should be 1 person whose primary duty is to assure medical safety, and 10 persons be assigned secondary duties as members of a safety review committee. There will be additional overtime costs for regular employees. This scenario would require an additional 42.92 million yen (US\$357,700) in costs for every 100 medical employees, or 429,000 yen (US\$3,575) per employee (Table 3-1-3).

There are 2.632 million people⁷ employed in

medical institutions in Japan, so we calculate that an additional 1.13 trillion yen (US\$9.4 billion) per year (429,000 yen or US\$3,575 × 2.632 million employees) will be required. This is 3.5% of national health expenditure for 2004 (32.1 trillion yen or US\$267.5 billion). Therefore, for future years, we project that an additional 3.5% per year will be required for health expenditure.

Quality assurance for medical staff

Japan's medical fee schedule system is said to cover a wide variety of costs but none in much depth. Recent reforms, however, have made it difficult to secure adequate wages. If we are to

7 MHLW, "2005 Medical Facilities Static and Dynamic Survey, Overview of Hospital Report," November 2006. (J)

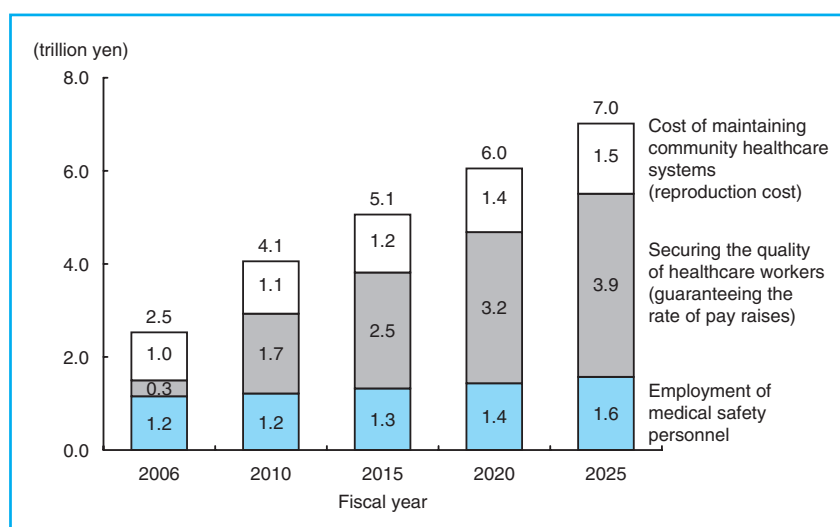


Fig. 3-1-5 Minimum additional costs necessary to improve medical safety and security (March 2007 estimates)

avoid reducing healthcare quality, it is essential to retain excellent employees. For this purpose we must be able to ensure that wage increases are the same as in other sectors. Table 3-1-4 presents wage increases based on the “average” scenario for wage increases shown in the “Outlook for Costs and Benefits in Social Security” by MHLW.⁸

Furthermore, the share of salaries in medical institution spending is 52.3% in hospitals, and 46.1% in clinics.⁹ If we take data for 2006 and multiply half of the amount of health expenditure by the rate of increase in wages, we then can project the future wage rates as shown in Table 3-1-4.

Costs of community healthcare network infrastructure

In “lifeline” utilities such as electricity and gas, fees for services can change to reflect changes in the price of fuel. As a result, there are short-term

increases in the price for electricity and gas (Fig. 3-1-4).

Moreover, a component of utility fees includes the cost of production and capital reinvestment.¹⁰ Remuneration for the cost of production of public goods,¹¹ known as the “fair rate of return,” is an essential concept for continued safe delivery of vital services. Actual examples of contemporary lifeline utilities show that the fair rate of return on business assets is about 3%.¹² Business assets consist of fixed assets (land, buildings, machines, etc.) operating capital, and deferred assets, but is primarily fixed assets. In other words, for lifeline utilities, the costs of reinvestment in fixed assets are included in the fee structure.

For medical institutions, in order to secure and maintain community healthcare networks, it is also essential to recover reproduction costs.¹³ In the case of hospitals, since fixed assets are about the same value as revenue from healthcare

8 There is some doubt about whether wages will increase by this amount. MHLW projections in 2004 forecast wage increases of 2.0% in 2006, 2.3% in 2007, and 2.7% in 2008. Yet in the “Preliminary Estimate of the Impact of Demographic Change on the Pension System” in February 2007 (J), the estimate for wages was reduced by 0.0% in 2006, and increased to 2.5% for 2007 and to 3.0% for 2008, and to 4.1% by 2011.

9 Data from Central Social Insurance Healthcare Association, “The 15th Situation Survey of Healthcare Economics (implemented June 2006).” (J) Data is used only for medical corporations, since data on facilities owned by individual physicians do not include owner compensation in salary expense statistics.

10 Office of the Prime Minister of Japan, “Current conditions and issues in the structural reform of fees for public services,” (J) Supplemental materials for the Report of the Discussion Group on Basic Issues of the Special Subcommittee of the Policy Committee on Price Stability, June 2002. Online (in Japanese) at <http://www5.cao.go.jp/seikatsu/2002/0625butsuan/kihonken01.html>

11 Source same as note 37 above. <http://www5.cao.go.jp/seikatsu/2002/0625butsuan/kihonken01.html>

12 Yumiko Maeda, “Comparing Trends in Power and Gas Prices to the Medical Fee Schedule,” JMARI Research Essay No. 50, April 2006. (J)

13 Because the medical fee schedule does not include the cost of capital reinvestment, it is said to encompass broad but shallow costs. Since it has been reformed as much as an order of magnitude, it is difficult to confirm this perception.

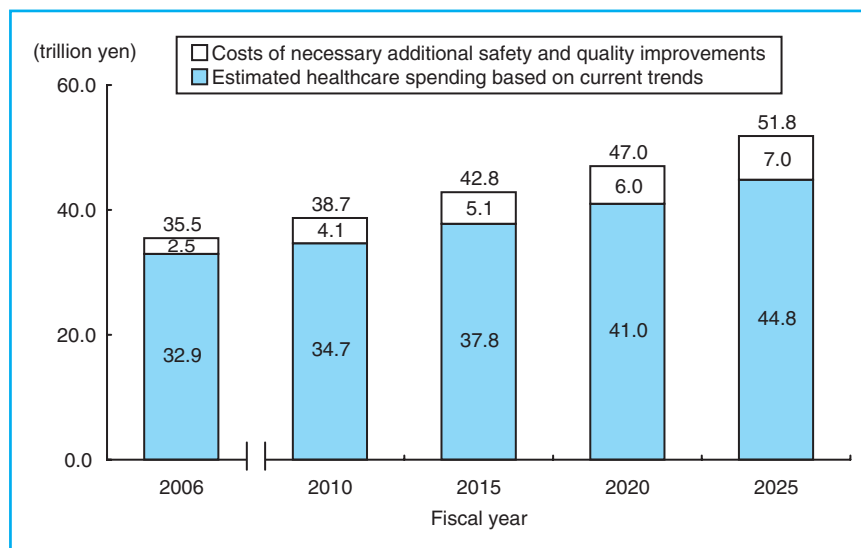


Fig. 3-1-6 Estimate of future required health expenditure (March 2007 estimates)

services (about equal to health expenditures),¹⁴ we calculate that an additional 3% should be added to healthcare spending (after adjusting for increased costs of medical safety personnel and wage increases).

The cumulative result of the components above show that by FY2015, an additional 5.1 trillion yen (US\$42.5 billion) will be needed to assure healthcare safety and security, an increase of 13.4% over the current health expenditure of 37.8 trillion yen (US\$315 billion),¹⁵ as shown in Fig. 3-1-5.

3) Conclusions regarding the ideal level of healthcare spending

We estimate that the ideal level of healthcare spending in FY2015 will be 42.8 trillion yen (US\$356.7 billion), increasing to 51.8 trillion yen (US\$431.7 billion) in FY2025 (Fig. 3-1-6).

The “ideal level” of healthcare spending here is the sum of projections based on current trends in healthcare spending and the costs that should be increased in order to provide safe and secure healthcare. Costs to improve safety and security include the costs of adding medical safety personnel, ensuring adequate wage increases, and necessary capital reinvestment. To these must

be added costs for emergency medical services, perinatal care, pediatric services, maintaining and improving community healthcare networks, as well as the costs of caring for an aging society. In the future, we would also like to expand our analysis to include importance and priority of each element.

(3) Future projections of Long-Term Care (LTC) expenditure

Japan’s Long-Term Care Insurance (LTCI) system has two types of beneficiaries: Type 1, over 65 years old, and Type 2, between 40 and 64 years old. Data by beneficiary type has only been made publicly available until 2004. Therefore, this estimate will be based on a proxy for per-capita LTC expenditure for people 65 and older, by dividing all the LTC expenditure by the population over 65 years old.

Rate of increase in per-capita LTC expenditure for people 65 and older

Between the introduction of the LTCI system in FY2000 and FY2004, there were continually large increases in per-capita LTC expenditure for people over 65 years old (Table 3-1-5). But in the past 2 years, because of a reduction in the official

14 Average costs for all hospitals calculated from Central Social Insurance Healthcare Association “The 15th Situation Survey of Healthcare Economics (implemented June 2006).” (J) Income from healthcare operations was 28.3 million yen (US\$236,000), and fixed asset was 28.4 million yen (US\$237,000). For clinics, fixed asset was not covered by the survey.

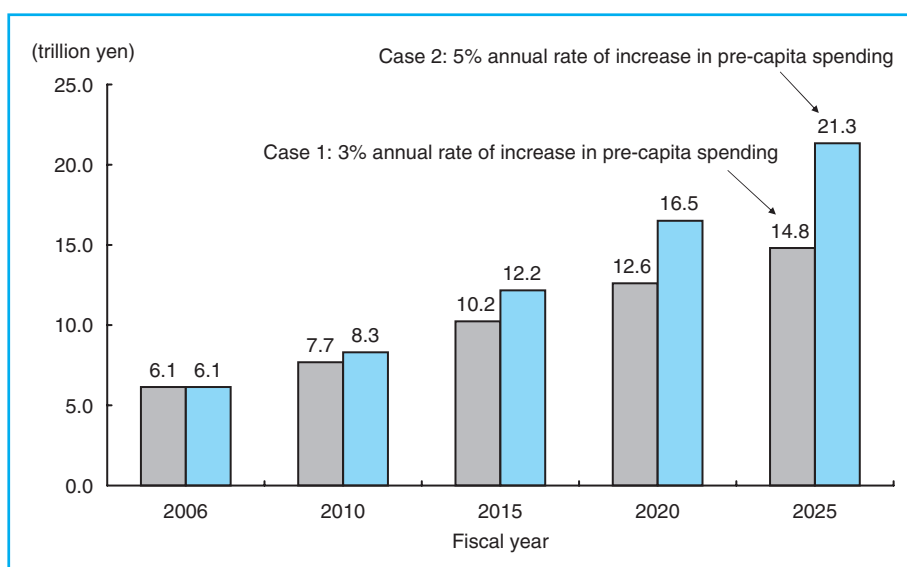
15 Due to rounding, data from the text may not match data in the figures.

Table 3-1-5 Trends in long-term care expenditure

	FY2000	FY2001	FY2002	FY2003	FY2004	FY2005	FY2006
Long-term care expenditure (billion yen)	3,627	4,592	5,193	5,689	6,203	6,296	6,141
Rate of increase	—	26.6%	13.1%	9.6%	9.0%	—	—
Long-term care expenditure per person older than 65 (thousand yen)	164.6	200.8	219.8	234.0	249.3	244.3	232.3
Rate of increase	—	22.0%	9.4%	6.5%	6.5%	—	—

* Data from FY2000–FY2004 are from MHLW, “Report on Long-Term Care Program.” Data from FY2005 and 2006 are based on expenditure data (not benefits) from the MHLW, “Survey of Long-Term Care Benefit, Reporting Periods May 2006–October 2006.”

* For fiscal year 2006, figures used are annualized from October 2006 survey data and include long-term care prevention.

**Fig. 3-1-7 Estimate of future long-term care expenditure (March 2007 estimates)**

LTC fee schedule, the rate of increase has been reached a plateau. In this estimate, we provide projections for future scenarios for increases of 3% and of 5%.

Per-capita LTC expenditure for people 65 and older

We use the most recent LTC expenditure from the May to October 2006 Survey (for the period April to September) and annualize the rate of increase (Table 3-1-5). In FY2006, the per-capita LTC cost for people 65 and older was 232,300 yen (US\$1,936).

LTC expenditure

Future projections of per-capita LTC expenditure for people 65 and older are obtained by multiplying the rate of increase in per-capita LTC expenditure by the population over 65 years old.

As a result, we estimate that by FY2015, national LTC expenditure will be 10.2 trillion yen (US\$85 billion) if the annual rate of increase in per-capita spending is 3% and 12.2 trillion yen (US\$101.7 billion) if the annual rate of increase is 5% (Fig. 3-1-7, Table 3-1-6).

However, MHLW's adjusted budget for LTC expenditure in FY2004 was 6.3 trillion yen

Table 3-1-6 Estimate of future long-term care expenditure

Case 1: 3% annual rate of increase in per-capita spending

	2006	2010	2015	2020	2025
Per-capita long-term care expenditure for people over 65 years old (thousand yen)	232.3	261.4	303.0	351.3	407.3
Population over 65 years old (million people)	26.4	29.4	33.8	35.9	36.4
Long-term care expenditure (trillion yen)	6.1	7.7	10.2	12.6	14.8

Case 2: 5% annual rate of increase in per-capita spending

	2006	2010	2015	2020	2025
Per-capita long-term care expenditure for people over 65 years old (thousand yen)	232.3	282.3	360.3	459.8	586.9
Population over 65 years old (million people)	26.4	29.4	33.8	35.9	36.4
Long-term care expenditure (trillion yen)	6.1	8.3	12.2	16.5	21.3

* Future population estimates are from National Institute of Population and Social Security Research, "Estimates of Japan's Future Population," December 2006.

(US\$52.5 billion), and the budget for FY2005 was 6.8 trillion yen (US\$56.7 billion), and in FY2006 MHLW proposed 7.1 trillion yen (US\$59.2 billion) in LTC expenditure (all figures include the effect of the reduction in the official LTC fee schedule).¹⁶ Yet the actual spending of 6.2 trillion yen (US\$51.7 billion) in FY2004 and 6.3 trillion yen (US\$52.5 billion) in FY2005 were lower than the official budget plans. One must assume that MHLW projections of future LTC expenditures as well as health expenditures are likely to be on the high side.

2. The Public Health Insurance System

(1) The scope of the public health insurance system

After the establishment of the universal health insurance system in 1961, share of co-payment in national health expenditure decreased substantially until reaching 10.5% in 1982¹⁷ (Fig. 3-2-1). Subsequently, however, co-payments increased,

reaching 15.3% by FY2004. The healthcare system reform currently underway focuses increasingly on raising patient co-payments.

The share of health expenditure paid for by people entirely out-of-pocket is very small. From FY1996 to FY2003 it stayed at 1.3%, declining slightly to 1.2% in FY2004. MHLW considers that the increase in health expenditure is highly affected by a natural tendency to increase due to factors such as advances in medical treatment.¹⁸ Even if that is true, since the share of spending paid entirely out-of-pocket is very low and stable, most of the costs of advances in medical treatment are absorbed within the boundaries of the public health insurance system.

Not reducing the scope of coverage is one of the basic principles of public health insurance. We will continue to maintain and even expand the boundaries of public health insurance. We consider healthcare with a high social value provided to all to be "universal healthcare." This should be the scope of the public health

16 MHLW, "Overview of LTCI System Reform Pamphlet: Reform in LTCI Law and LTC Fee Schedule," March 2006. Online in Japanese at <http://www.mhlw.go.jp/topics/kaigo/topics/0603/index.html>.

17 After the end of the 1960s, local governments in all prefectures began to subsidize free medical care for the elderly, and in 1973, the reform of the Old Age Welfare Law created a national system of government expenditure replacing individual co-payments. In 1983 the Old Age Health Care System was created in which co-payments were re-introduced, thereby increasing the share of patient burden in overall health expenditure.

18 In fiscal year 2004, national health expenditure increased by 1.8%. MHLW stated that costs related to the aging society were 1.5%, for the population increase 0.1%, and that the natural rate of increase due to technological advances, etc. was 1.2%. MHLW reduced the medical fee schedule by 1.0% overall.

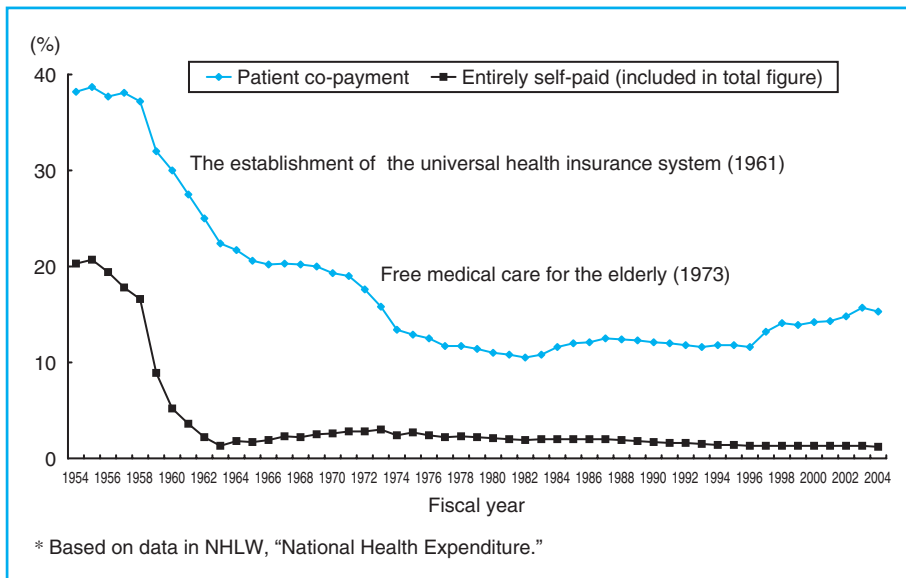


Fig. 3-2-1 Trends in share of patient co-payment in national health expenditure

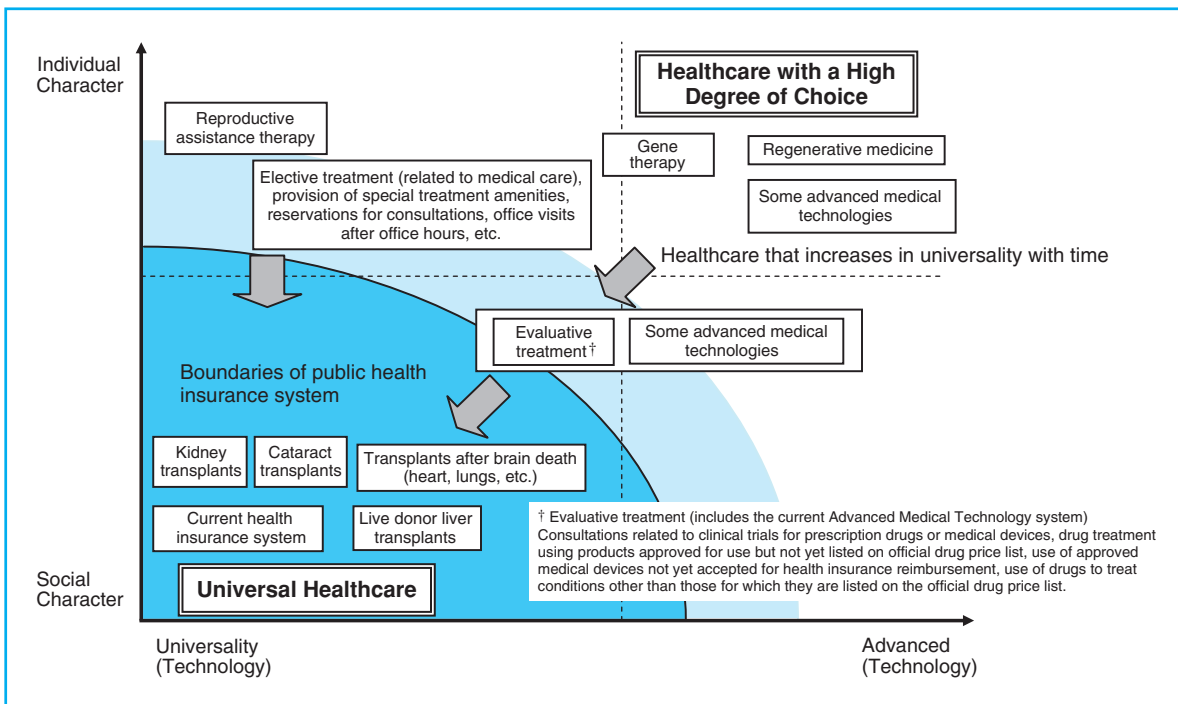


Fig. 3-2-2 The Boundaries of public health insurance

insurance system (Fig. 3-2-2). Some advanced medical treatments, such as gene-based therapies, organ transplants, and reproductive treatment (referred to here as “advanced medical treat-

ments”) now have taken on increasing societal and universal value, and should be smoothly absorbed into the public health insurance system, in order to provide highly comprehensive public

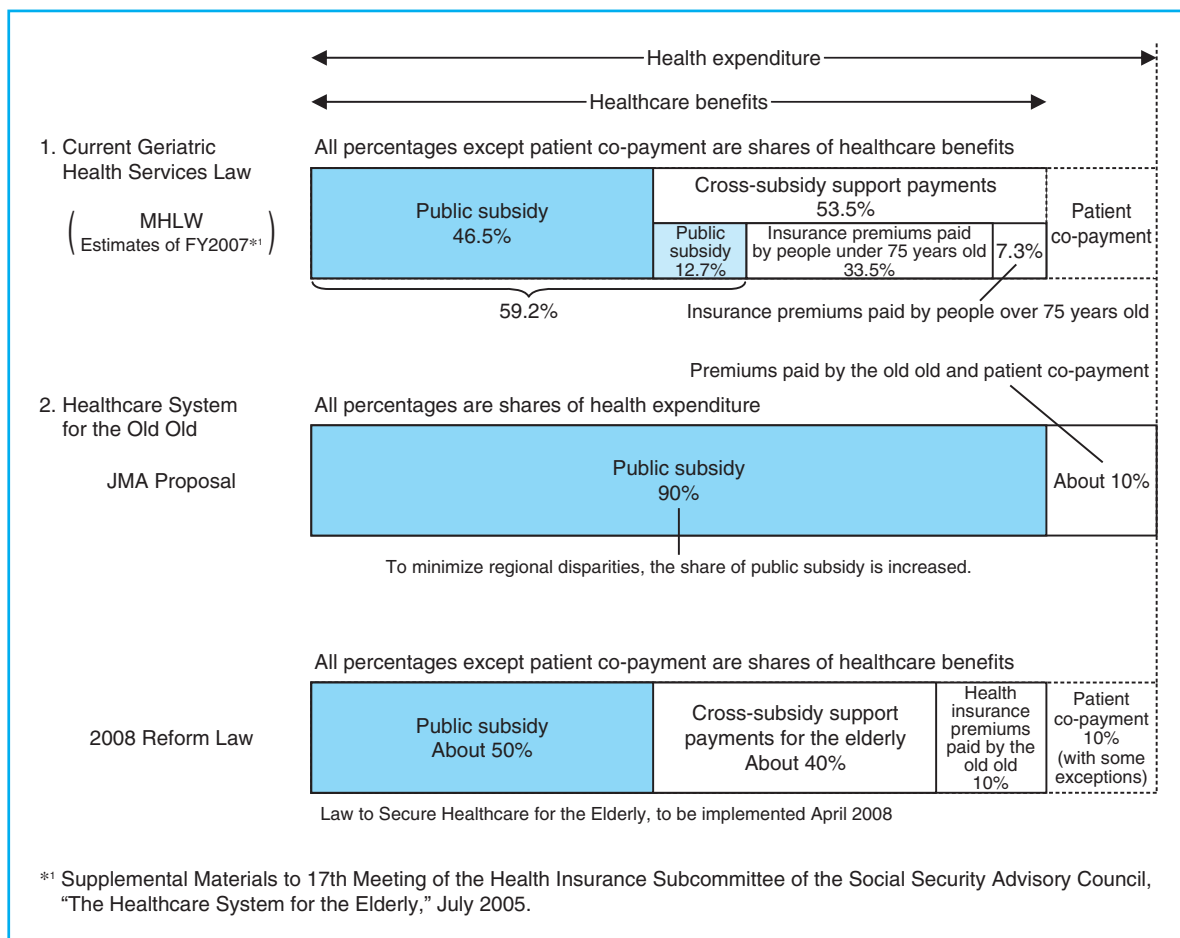


Fig. 3-2-3 Comparison of fiscal resources for Healthcare System for the Old Old

Table 3-2-1 Comparison of Healthcare System for the Old Old

	JMA Proposal	2008 Reform Law to secure healthcare for the elderly April 2008
Beneficiaries	People aged 75 years and older	People aged 75 years and older
Insurer	Prefectures	Prefecture-level insurance associations to which all municipal governments belong
Fiscal resources	Share of health expenditure • 90% public subsidy • 10% from insurance premiums paid by old old and patient co-payment	Share of benefits (expenditure minus patient co-payments) • 50% public subsidy • About 40% cross-subsidy system of support payments for the old old from other health insurance programs • 10% insurance premiums paid by the old old

health insurance. At the same time, some kinds of medical treatments are more of an elective nature (particularly the provision of luxury accommodations, appointment of consultation,

and consultations after office hours), and we do not propose that they be covered by public health insurance.

Advanced medical treatments are currently

entirely paid for out-of-pocket, and until they can be completely covered by public health insurance, policies are necessary to reduce the burden on patients and healthcare facilities.

(2) Healthcare System for the Old Old

1) Basic principles and fiscal resources

In the Law Securing Healthcare for the Elderly which will be implemented in April 2008 (referred to here as the “2008 Reform Law”), the following points have been decided concerning the healthcare system for the “old old.”

- The system will apply to people aged 75 years and older
- The entity administering the insurance system will be a prefecture-wide league of all cities, towns and villages
- Each prefecture will be allowed to set its own fee schedule services (Special Administrative Fee Schedule)¹⁹
- Fiscal resources for insurance benefits (excluding patient co-payments) are 50% government spending, 40% insurance premiums from younger persons for the support of the old old, and 10% from insurance premiums by the old old themselves.

Of these points, since the younger population is going to decrease, half of the rate of decrease is going to have to be made up for by greater insurance premiums by the old old, while at the same time there is going to be a lower premium rate for the support payments for the old old. In other words, the 2008 Reform Law has already built in future increases of the burden for the old old themselves.

The JMA considers the 2008 Reform Law to be just a starting point. In the next section, we discuss the ideal type of healthcare system for the old old (Fig. 3-2-3, Table 3-2-1).

Basic Scheme of the Healthcare System for the Old Old (JMA Proposal)

1. Purpose

Japanese citizens should not have to suffer as a result of inequality. We pledge that they should be able to obtain equal healthcare

and be able to grow old enjoying peace of mind.

2. Coverage

People 75 years and older (the “old old”)

3. Insurers

Prefectural governments

4. Principles

Since they are at a high risk of contracting diseases, the principle of insurance does not work well, and insurance premiums and co-payments are a very high burden on the old old. Accordingly, the government should support them based on the principle of “security,” so that they do not have to live with the anxiety of income disparity.

5. Fiscal resources

Based on the principle of “security,” benefits should be as high as possible, and government spending should be the primary fiscal resource: 90% of the costs of health expenditure. The national government should provide the funds, so that disparities in regional fiscal resources do not occur. The 2008 Reform Law starts off by having government spending cover 50% of healthcare benefit expenditure. This should be increased step by step. Furthermore, the support payments for the old old (currently cross-subsidy payments for geriatric healthcare) should be abolished. Insurance premiums and co-payments should cover no more than a total of 10% of health expenditure. Part of the health insurance premium should be based on income, and some policy should be established to eliminate gross regional disparities. Co-payments, however, should be standardized, rather than income-based, and should be gradually reduced in the future.

6. Fee schedule

Outpatient fees will be fee-for-service, and inpatient fees will be in principle fee-for-service. Some chronic conditions can optionally be paid for by prospective payment. In all cases, the fee system should have a flexible approach, so that it does not become a one-size-fits-all payment approach.

¹⁹ In the Law to Secure Healthcare for the Elderly, Paragraph 14 (Special Administrative Fee Schedule) allows the Minister of Health, Labour and Welfare (abbreviated) to permit prefecture-level governments to establish different fee schedules, based on the conditions in the region if there is a need to reduce healthcare costs in the region, so long as this permission is fair from the standpoint of fairly providing adequate healthcare.

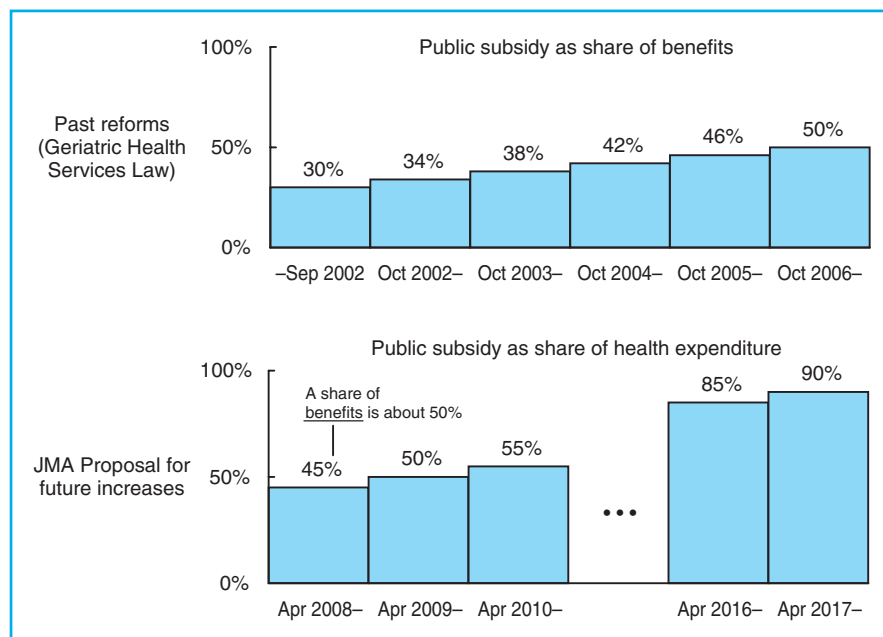


Fig. 3-2-4 Healthcare System for the Old Old—Proposal to increase the share of public subsidy

Separate fee schedules for each prefecture will not be permitted, since a “special administrative fee schedule” for each prefecture would only exacerbate regional disparities.

In April 2008, government spending for healthcare benefits in the new Healthcare System for the Old Old will begin at approximately 50% (about 45% of health expenditure).²⁰ Although this is one of the points already decided, that does not mean that it cannot change.

In the previous Geriatric Healthcare Reform Law, it turned out that the share of government spending was actually increased.²¹ We should learn from this precedent, and to mitigate the impact of sudden change, we propose increasing the share of government spending in a series of steps as shown in Fig. 3-2-4. From FY2009, if we increase the share of government spending by 5% per year, we will reach a total of 90% of health expenditure by FY2017. Furthermore, in

the 2008 Reform Law, the share of government spending was divided between the national government, prefectural governments, and local governments on a 4:1:1 ratio. In the future, in order to prevent regional disparities, we propose that the national government provide all of the government funds for the system.

2) Basic thoughts on end-of-life care

In the “End-of-life Care Guidelines (rough draft)”²² published by MHLW in September 2006, the intentions of the patient were given central importance. Then, in the “Healthcare for the Old Old (rough draft for discussion),”²³ on the issue of what kind of treatment to follow, patient choice was also very important. The principle of respect for the patient is quite noble. But there are many situations where it is very difficult for elderly patients to make decisions. There is the danger of isolating and cornering patients by going too far in demanding a decision from them in a time of vulnerability. We believe

20 Since no public subsidy will be given to the old old with incomes at the same level as those in the working-age population, the actual share for public subsidy will be lower than 50%.

21 The share of government spending in health benefit expenditure for geriatric healthcare was 30% in September 2002, but after that it increased by 4% per year, reaching 50% by October 2006.

22 <http://www.mhlw.go.jp/public/bosyuu/iken/dl/p0915-2a.pdf>

23 <http://www.mhlw.go.jp/shingi/2007/02/dl/s0205-8a.pdf>

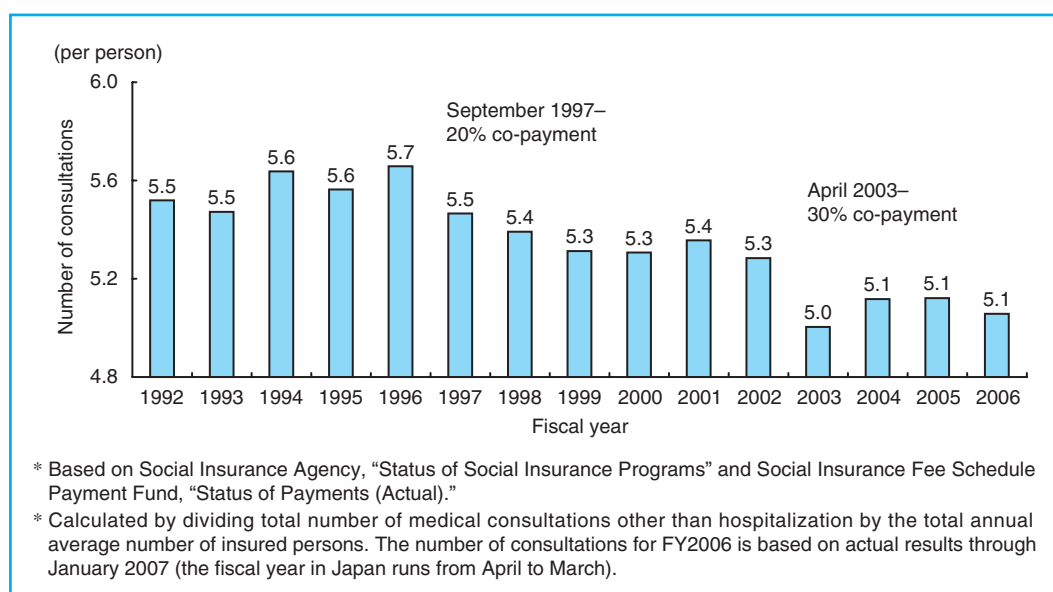


Fig. 3-2-5 Trends in the number of medical consultations per employee in Government-managed health insurance

that it is the duty of healthcare providers to find out what is best together with patients and their families.

Furthermore, there are many cases in which it is actually very difficult for people to pass away at home or in their own community due to their family situation or other complications. Accordingly, it is necessary to support a broader concept of "home," and through building an infrastructure in hospital wards and other facilities, to provide a broader range of options for family members to stay by the side of patients at the end of life.

Basic Principles of End-of-life Care

1. Respect for the intentions of the patient and the patient's family
2. Never withholding the best medical care based on the ethics of medical care providers
3. Providing multiple ways to stay with end-of-life patients until the very end

(3) The regular health insurance system

The share of co-payments for company employees in the regular health insurance system was increased in 1997 from 10% to 20%, and in 2003 to 30%. The per-capita number of outpatient visits per employee (excluding family members) had previously remained stable at 5.5 visits per

year. But in September 1997, after the increase in co-payment from 10% to 20%, the per-capita figure fell below 5.5. Subsequently, the number never rose again, and fell again to 5.0 after the co-payment was increased in April 2003 to 30%, and since then has increased only slightly to 5.1.

In this way, the increase in co-payments in the regular health insurance system constrained medical consultations, and once constrained they never recovered (Fig. 3-2-5). It would be a major problem if it became more difficult for patients insured by the regular health insurance system to obtain necessary healthcare. The effect on constraining medical consultations should be further examined. The JMA proposes returning the co-payment rate from 30% back to 20% for employees in the ordinary health insurance system.

(4) Fiscal resources for the public health insurance system

1) Benefits (comparison in FY2015)

Healthcare benefit expenditure under the JMA Proposal

The JMA proposes that 90% of health expenditures for the old old be paid for by government spending, and the remaining 10% through insurance premiums and co-payments by the old old themselves. As for the balance between

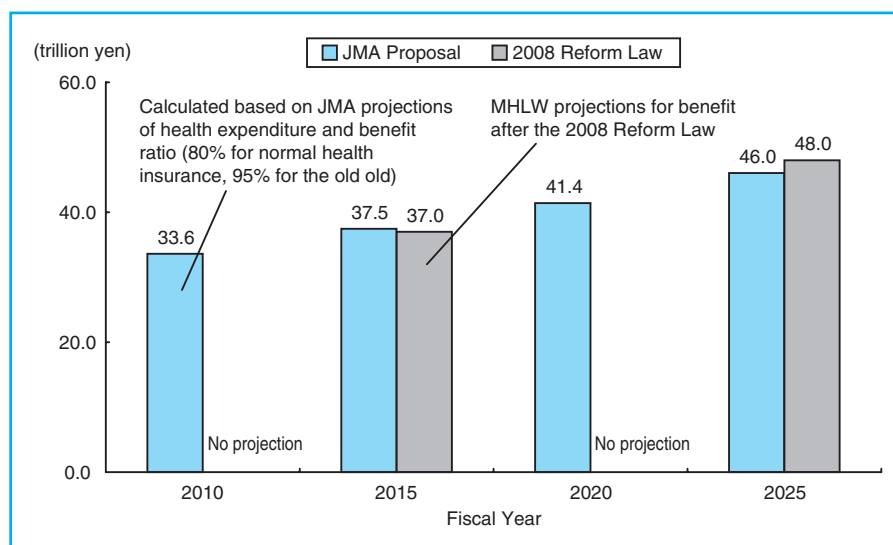


Fig. 3-2-6 Estimates of required healthcare benefits

Table 3-2-2 Healthcare benefits (rough estimates)

Healthcare spending (required)	(trillion yen)				
	FY2006	FY2010	FY2015	FY2020	FY2025
Regular	20.7	22.1	22.7	23.0	22.7
Old old	12.0	13.5	16.7	20.3	25.0
Subtotal	32.7	35.6	39.4	43.3	47.7
Social assistance	2.8	3.1	3.4	3.7	4.1
Total healthcare spending	35.5	38.7	42.8	47.0	51.8

* Amounts for regular and old old derived from projections based on extension of current trends in health insurance expenditure

Benefits ratio 80% for regular, 95% for old old
Assumes 100% benefits for social assistance

Healthcare benefits	(trillion yen)				
	FY2006	FY2010	FY2015	FY2020	FY2025
Regular		17.7	18.1	18.4	18.2
Old old		12.9	15.9	19.3	23.7
Health insurance share		30.5	34.1	37.7	41.9
Social assistance		3.1	3.4	3.7	4.1
Total healthcare benefits		33.6	37.5	41.4	46.0

Source: MHLW January 2006 Estimate

Healthcare benefits	(trillion yen)				
	FY2006	FY2010	FY2015	FY2020	FY2025
Total healthcare benefits	—	—	37.0	—	48.0

co-payments and insurance premiums, a final decision should be reached after subsequent discussions, but as a start we propose that 5% of health expenditure be covered by insurance premiums and 5% by co-payments. As a result,

the healthcare benefit expenditure will be 95% of health expenditure.

In the regular health insurance system, in principle healthcare benefit expenditure is 70% of health expenditure, but our proposal will raise

Table 3-2-3 Comparison of healthcare spending and benefits forecast for FY2015

(trillion yen)

	Healthcare spending	Healthcare benefits	Note
Regular insurance	22.7	18.1	80% benefits for regular insurance
Insurance for the old old	16.7	15.9	95% benefits for insurance for the old old
JMA Proposal			Assumes 100% benefits for social assistance (This amount includes an amount of care paid for entirely out of pocket, since it is unclear how care paid for entirely out of pocket is treated in the MHLW projected health expenditure.)
Social assistance	3.4	3.4	
Total	42.8	37.5	
2008 Reform Law*1			Total minus social assistance minus insurance for the old old
Regular insurance	24.5	19.1	
Insurance for the old old	16	14.4	90% benefits*2
Social assistance	3.5	3.5	Calculated at same share as in JMA Proposal
Total	44	37	MHLW data given as whole numbers only

*1 Data from MHLW, "Future Projections of National Health Expenditure, Benefits from Medical Insurance, and Geriatric Health Benefits (Based on Healthcare System Reform, January 2006)." Gray shaded areas are data directly quoted from MHLW report. Other data is estimated.

*2 Old old people who have incomes the same level as working-age people receive 70% benefits, but since there is also a system of subsidized premiums for old old people with low incomes, an average of 90% benefits is used here. MHLW also uses that same estimate on page 14 of the "Concerning the summary of the proposed for Partial Amendment of the Health Insurance Law," January 2006.

that to 80%.

Based on these assumptions, we calculate that by FY2015 healthcare benefit expenditure will be 37.5 trillion yen (US\$312.5 billion), and 46.0 trillion yen (US\$383.3 billion) in FY2025 (Fig. 3-2-6, Table 3-2-2).

Healthcare benefit expenditure under the 2008 Reform Law

MHLW projected that after the Law to Secure Healthcare for the Elderly implemented in April 2008 (hereafter referred to as the 2008 Reform Law), healthcare benefit expenditure would be 37 trillion yen (US\$308.3 billion) in FY2015, and 48 trillion yen (US\$400 billion) in FY2025.²⁴ In FY2015, the estimated amount for the JMA Proposal is about the same, while by FY2025 the estimated amount for the JMA Proposal is lower.

2) Government spending (comparison in FY2015)

Here we exclude social assistance and calculate a rough estimate of the total amount of govern-

ment spending required for the regular health insurance system (Municipal Managed Health Insurance and Employee's, Health Insurance) and the Healthcare System for the Old Old.

Government spending under the JMA Proposal

As stated in Chapter 3 Section 2, The Public Health Insurance System, 90% of the health expenditure for the old old should be provided for by government spending. In return, there should be no government spending at all in the regular health insurance system. Government spending should only be used to pay for the old old. By FY2015 we estimate that 15.1 trillion yen (US\$125.8 billion) will be required.

Government spending under the 2008 Reform Law

MHLW projects that 37 trillion yen (US\$308.3 billion) will be required for healthcare benefit expenditure by FY2015. Let us assume that the social assistance will be about 3.5 trillion yen (US\$29.2 billion). This means that 33.5 trillion

²⁴ MHLW, "Future Projections of National Health Expenditure, Benefits from Medical Insurance, and Geriatric Health Benefits (Based on Healthcare System Reform, January 2006)," Materials from First Session of the Discussion Group on Future Outlook for Healthcare Spending.

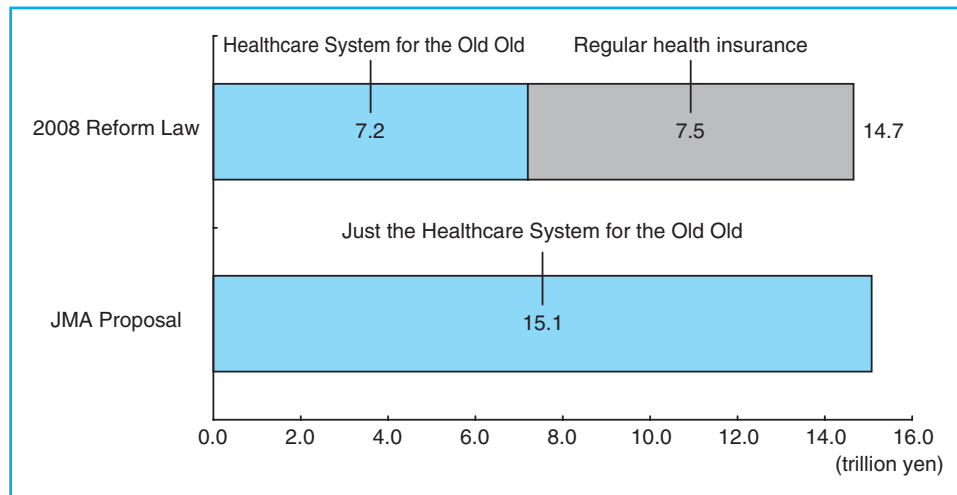


Fig. 3-2-7 Comparison of total public subsidy, fiscal year 2015

Table 3-2-4 Total amount of public subsidy, fiscal year 2015 (rough estimate)

JMA Proposal (public subsidy investment targeting only the old old) (trillion yen)			
System	Healthcare <u>spending</u>	Public subsidy	The share of public subsidy
Insurance for the old old	16.7	15.1	90% of healthcare spending

2008 Reform Law (trillion yen)			
System	Healthcare <u>benefits</u>	Public subsidy	The share of public subsidy
Regular health insurance	19.1	7.5	0.3 × (Benefits from regular insurance + support payments for old old)* ¹
Insurance for the old old	14.4	7.2	50% of healthcare benefits
Total	33.5	14.7	

*¹ Estimated as about 30% based on FY2006 budget.
 * Excluding social assistance.
 * Due to rounding, totals may not reflect the sum of each individual amount.

yen (US\$279.2 billion) will be required for health insurance benefit expenditure. Table 3-2-3 breaks down these figures for the old old and for all other persons.

Government spending actually amounts to a little under 60% of benefits in the Municipal Managed Health Insurance (MHI) system.²⁵ In the Government-Managed Health Insurance

(GHI) system government spending is just 13%. Cross-subsidy from these systems in the form of support payments for the old old consists of 50% for MHI and 16.4% for GHI (These figures exclude government spending for the administrative expenses of health insurance provided through mutual aid associations and corporate managed health insurance). We assume that gov-

25 According to the Ministers of Internal Affairs and Communication, Finance, and Health, Labor and Welfare Agreement on "Strengthening the Fiscal Basis for the Municipal Managed Health Insurance System" (J) from December 18, 2005, in the budget for fiscal year 2006 there will be 7.54 trillion yen (US\$62.8 billion) in health insurance benefits, of which 3.18 trillion yen (US\$26.5 billion) (42%) are financed by health insurance premiums, and 4.26 trillion yen (US\$35.5 billion) (56%) are covered through government spending, while all other sources contribute about 100 billion yen (US\$0.8 billion) (1%).

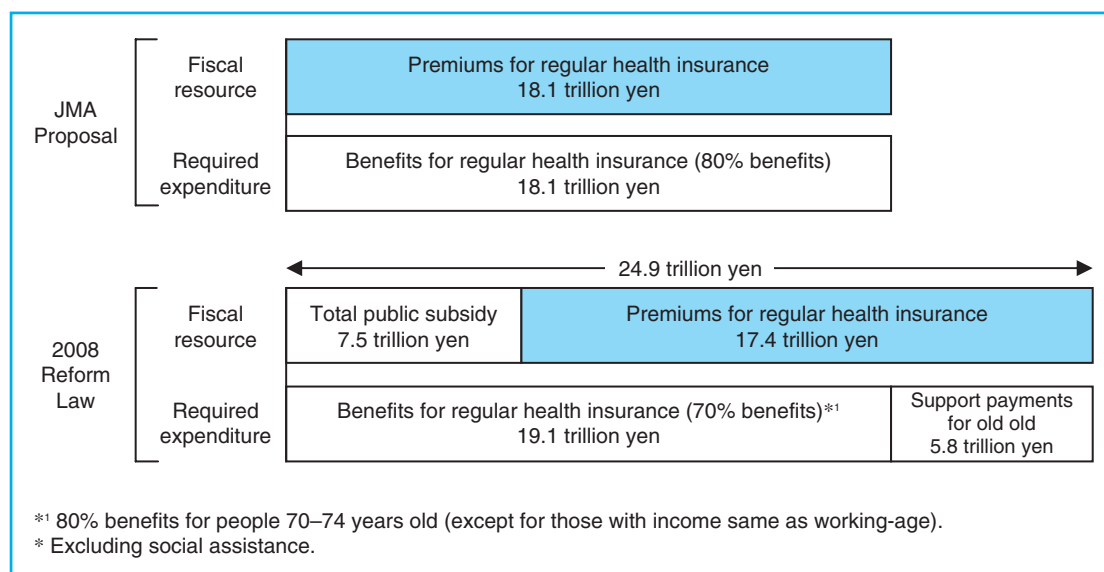


Fig. 3-2-8 Fiscal resources for regular health insurance fiscal year 2015 (rough estimate)

ernment spending will be about 30% of benefits and the support payments for the old old.

For the old old, the 2008 Reform Law has determined that 50% of healthcare benefits will be provided by government spending.

Therefore, we calculate that by FY2015, total government spending for healthcare will be 14.7 trillion yen (US\$122.5 billion) under the 2008 Reform Law, compared to 15.1 trillion yen (US\$125.8 billion) for the old old under the JMA Proposal (Fig. 3-2-7, Table 3-2-4).

3) Insurance premiums for regular health insurance (comparison in FY2015)

Insurance premiums under the JMA Proposal

The JMA proposes that government spending should cover 90% of health expenditures for the old old, and that no government spending be used in the regular health insurance system. Also, co-payments should be 20% in the regular health insurance system.

By FY2015, health expenditure in the regular health insurance system is estimated to be 22.7 trillion yen (US\$189.2 billion), and health insurance benefits are estimated to be 18.1 trillion yen (US\$150.8 billion) (Table 3-2-3). These benefits are to be paid entirely by insurance premiums.

Insurance premiums under the 2008 Reform Law

By FY2015, healthcare spending is estimated to be 24.5 trillion yen (US\$204.2 billion), and healthcare benefits 19.1 trillion yen (US\$159.2 billion) (Table 3-2-3). In addition, the regular health insurance system must also make payments to support healthcare for the old old (5.8 trillion yen or US\$48.3 billion, or 40% of the health benefits for the old old). Adding these two figures together, 24.9 trillion yen (US\$207.5 billion) will be required.²⁶

For fiscal resources, government spending is forecast to cover 30% (7.5 trillion yen or US\$62.5 billion) of benefits for regular health insurance and the support payments for healthcare for the old old. Insurance premiums will then be 17.4 trillion yen (US\$145 billion) (= 19.1 trillion yen or US\$159.2 billion + 5.8 trillion yen or US\$48.3 billion – 7.5 trillion yen or US\$62.5 billion) (Fig. 3-2-8).

Health insurance premiums in the JMA Proposal (18.1 trillion yen or US\$150.8 billion) would be slightly higher than those under the 2008 Reform Law (17.4 trillion yen or US\$145 billion). Next we discuss the best way to deal with the difference between the two amounts.

First, we will make the health insurance

²⁶ Due to rounding, totals may differ from the calculations on the original numbers. This applies to all subsequent numbers.

Table 3-2-5 Fairness effect of health insurance premiums (estimated from actual 2004 data)

	Health insurance premium (permillage) ‰	Health insurance premium revenue (trillion yen)		Fiscal effect (trillion yen)
		Fiscal year 2004	If premium rate was set same as government-managed health insurance premium	
		Actual		
Government-managed health insurance (GHI)	82.00	6.0	6.0	—
Corporate managed health insurance	74.84	5.8	6.4	0.6
National government employee mutual aid association	63.44	0.5	0.6	0.1
Local government employee mutual aid association	73.27	1.3	1.4	0.1
Private school employee mutual aid association	66.00	0.2	0.2	0.0
Total	—	13.7	14.6	0.9

* Source
 Social Insurance Agency, "Overview of FY2004 Single-Year Account Settlement for Government-Managed Health Insurance."
 National Federation of Health Insurance Societies, "Overview of FY2004 Health Insurance Society Account Settlement Forecasts."
 Ministry of Finance, Budget Bureau, "FY2004 Annual Statistical Report for National Government Officials Mutual Aid Associations."
 Council of Local Government Officials Mutual Aid Associations, "FY2004 Annual Report for Local Government Officials Mutual Aid Associations."
 The Promotion and Mutual Aid Association for Private Schools in Japan, "FY2004 Statistical Report on Private School Mutual Aid Associations."

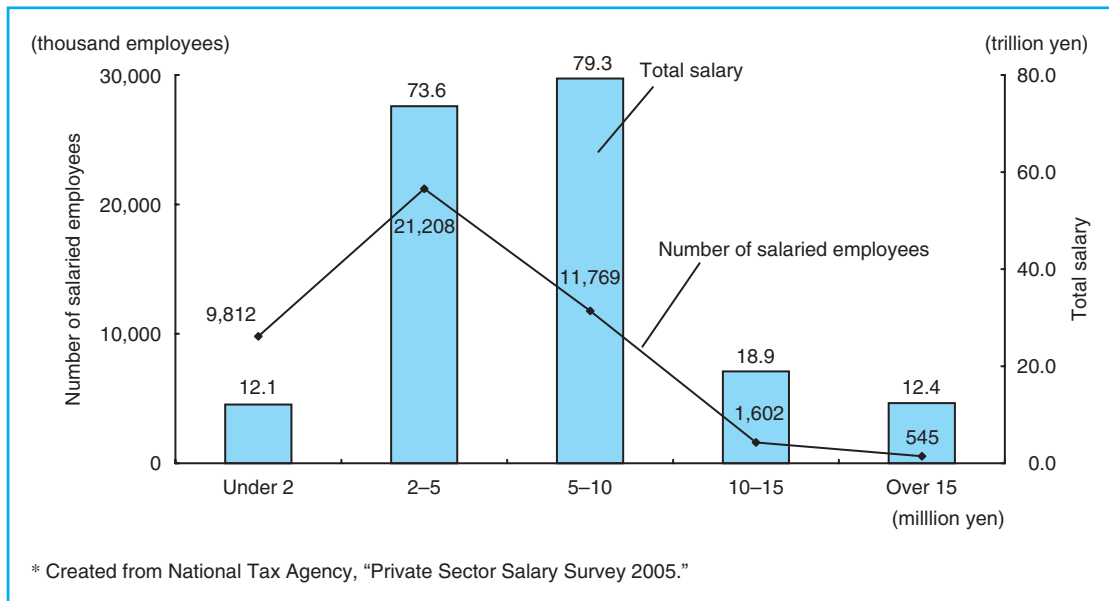


Fig. 3-2-9 Total salary by range and number of employees

premium rate more fair (Table 3-2-5). Currently, the premium rate in GHI is 82‰ of salary for all members, while the average premium rate in corporate managed health insurance is 74.84‰. In mutual aid associations, expenditures for healthcare and pensions are treated as a compre-

hensive benefit, and we have extracted figures relevant only for healthcare. Although it is not straightforward to compare two very different systems, if we raise corporate managed health insurance and mutual aid association insurance premiums to 82‰ of salary, an additional 900

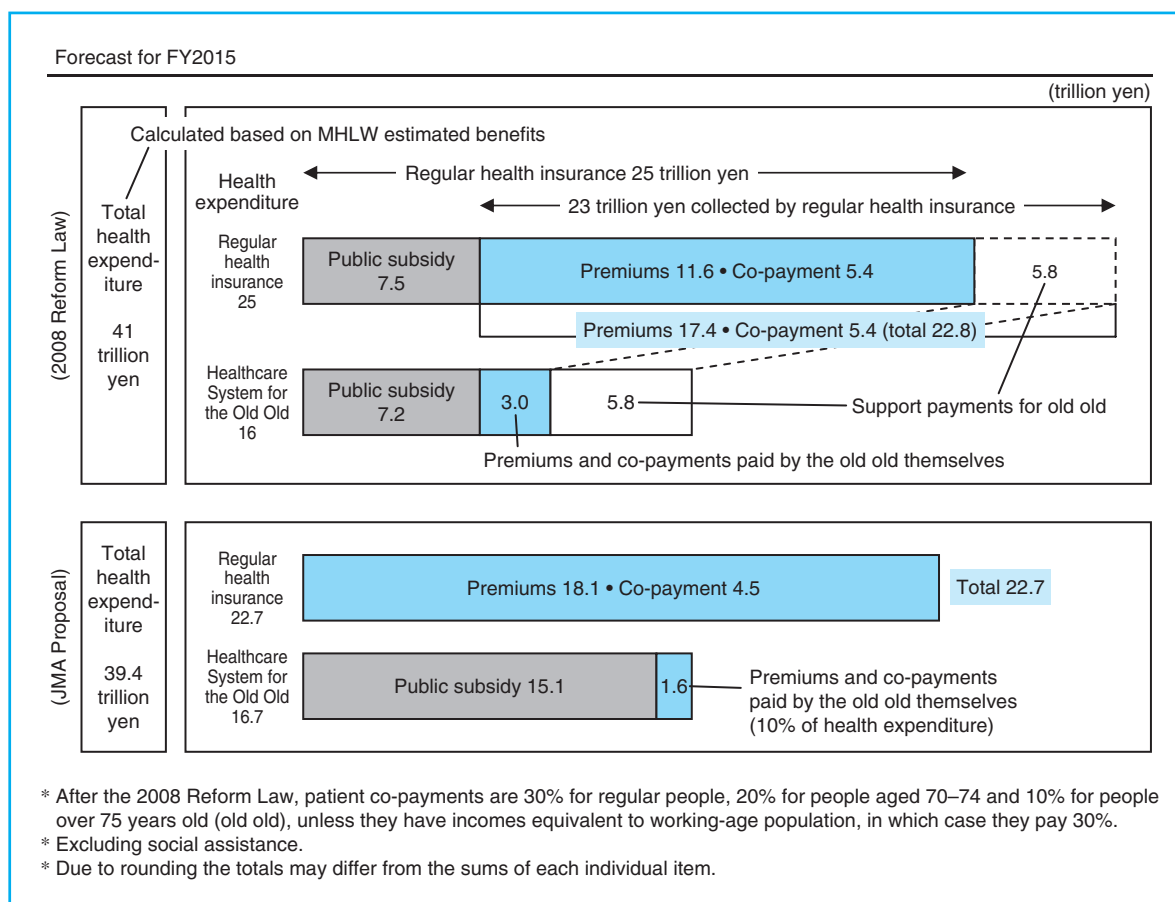


Fig. 3-2-10 Fiscal resources required for regular health insurance and Healthcare System for the Old Old (rough estimate)

billion yen (US\$7.5 billion) will be gained.

Second, we propose to eliminate the monthly cap on wages for calculating insurance premiums. The health insurance reform act of April 2007 set the insurance amount for all individuals with monthly income above 1.175 million yen (US\$9,792) (annual income above 14.1 million yen or US\$117,500) to be equal to the premium amount for individuals earning standard wage of 1.21 million yen (US\$10,083) (annual income of 14.52 million yen or US\$121,000). If we eliminate this monthly cap on wages for health insurance premiums, we can estimate the following effects on fiscal resources.

There are currently 545,000 people with annual incomes above 15 million yen (US\$125,000) (1.2% of Japan's 44.936 million salaried employees).

Their total annual income is 12.4 trillion yen (US\$103.3 billion) (6.3% of the 196.3 trillion yen or US\$1,635.8 billion in Japan's total salary) (Fig. 3-2-9).²⁷ These people have their health insurance premiums calculated on the basis of standard salary of 14.52 million yen (US\$121,000), so the salary actually subject to insurance premiums is 7.9 trillion yen (US\$65.8 billion) (= 14.52 million yen or US\$121,000 × 545,000 people). Since their actual salary is 12.4 trillion yen (US\$103.3 billion), there is a total of 4.5 trillion yen (US\$37.5 billion) in salary not subject to health insurance premiums.

If we calculate the insurance premium that would result from applying the GHI rate of 82% to the entire salary amount, there would be an addition 400 billion yen (US\$3.3 billion)

27 National Tax Agency, "Salary Survey 2005."

in insurance premiums. In other words, we can secure a maximum of an additional 400 billion yen (US\$3.3 billion) in insurance premiums if we lift the monthly cap on wages.

4) Summary of fiscal resources

Forecast for FY2015

Previously, fiscal resources under the Reform Law taking effect in 2008 were compared to the JMA Fiscal Resources Structure Proposal. The latter figures were calculated based on MHLW estimated health expenditures after the reforms take effect, which exceed JMA estimates. As a result, in the JMA Proposal we can reduce the co-payment for members in the regular health insurance system to 20%, and fund the Healthcare System for the Old Old almost entirely through government spending. The total amount of fiscal resources such as government spending and health insurance premiums would be just about the same as the total amount of

fiscal resources expected in the 2008 Reform Law. As a result, the JMA Proposal fits within reasonable limits (Fig. 3-2-10).

In a rapidly aging society with growing disparities, many people in Japan fear that income disparity will lead to a disparity in access to healthcare. People would like to have a society without disparities, in which few burdens are assigned based on individual characteristics, and in which help and mutual assistance are available.

It must also be noted that at present MHLW does not disclose figures for estimates of annual healthcare insurance benefit expenditures and the total amount of government spending by type of insurance system, so the analysis in this proposal is only a rough estimate. As soon as MHLW releases their estimates, we will provide a revised comparative analysis.

Glossary

■ **Health insurance benefits:**

Health insurance benefits are the benefits paid by public health insurance such as Government-Managed Health Insurance, Municipal Managed Health Insurance, and benefits for healthcare services for the elderly. Healthcare benefits = National health expenditure – patient’s co-payment

■ **Health insurance expenditure:**

Health insurance expenditure = Health insurance benefits + Patient’s co-payment

■ **Social assistance:**

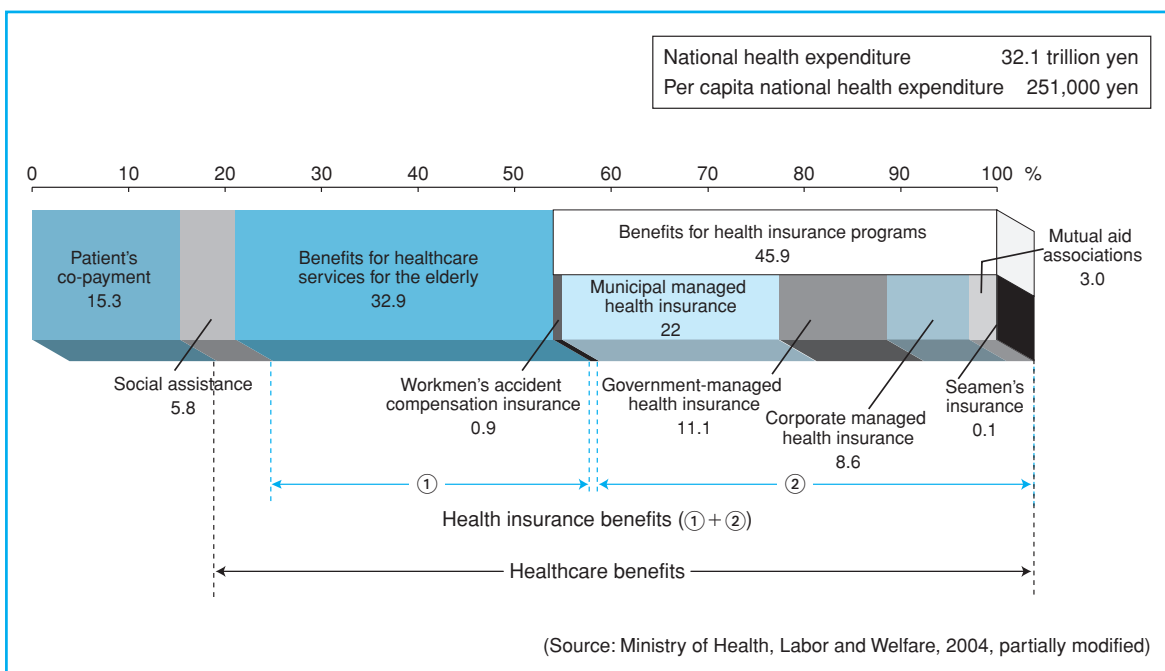
Social assistance is paid by public subsidy mainly under Livelihood Protection Law, and Mental Health and Mental Disability Welfare Law. Workplace accident health benefits and costs paid entirely out-of-pocket are also included in social assistance.

■ **National health expenditure:**

National health expenditure or health expenditure includes health insurance benefits, patient’s co-payment and social assistance. It does not include the costs of normal birth, costs of preventative care such as medical check-ups and immunizations, additional fees for private rooms and other amenities.

■ **Total health expenditure:**

Total health expenditure = National health expenditure + Long-term care service fees + Prevention and public health fees + Management costs



Cost sharing ratio of national health expenditure by payer

Professional Liability Insurance Program of the Japan Medical Association

JMAJ 50(5): 390–396, 2007

Katsuyuki KINOSHITA*¹

Introduction

The shortage of physicians has become a social issue in Japan in recent years, just as the incidence of medical errors has been on the rise. According to statistics on medical lawsuits (Fig. 1, source: Supreme Court website, “Disposition of medical lawsuits and average length of proceedings”), whereas 575 suits were newly filed in 1996, the number had reached 1,110 by 2004, a near doubling in only 10 years. The number of medical errors and medical disputes that do not reach court is estimated to be several times the number that do. It is also presumed to be growing. Against this background, the health care environment is undergoing four major changes.

- (1) With the recognition widely spread among the general public that “medical care is based on a contract between physicians and patients,” there is a growing tendency to blame physicians for medical outcomes contrary to the patient’s expectations and to seek compensation for damages from them.
- (2) Development of new technology and specialization in medicine may bring new risks. Progress of team-based medical care has involved more and more health professionals in medical areas, which is also likely to trigger to increase factors that may lead to medical errors.
- (3) Society is taking a harsh view on medical practice. Mass media increasingly picks up new perspectives of medicine including medical errors and informed consent, showing their interest more in patient-oriented health care.
- (4) In some medical institutions, specialties, and regions, the shortage of physicians, nurses,

and other health care workers is becoming a serious problem. Behind this fact lies a fact that these health professionals are forced to work under the harsh work conditions.

In these circumstances, the incidence of medical lawsuits is expected to continue to increase.

History of JMA Liability Insurance Program

The achievement of universal health insurance in 1961 heightened expectations of the public that a medical insurance card allows anyone in any place in Japan to ensure to receive quality health care, and thus guaranteed all levels of society with the opportunity to share impartially and equitably the benefits of health care. Along with this heightened awareness of their rights among the general public, expectations toward health care likewise increased, such that people expected not merely to receive health care but demanded for more satisfying medical care. This then led to an increasing incidence of malpractice disputes, including their development into litigation, arising from incidents in such urban areas as Tokyo, Yokohama, and Osaka.

In keeping with these changing times, medical associations in some urban areas reviewed the problems of how to handle the medical disputes. They formed within their medical associations a medical dispute settlement committee as a mutual-benefit mechanism to engage in dispute resolution for their members to support them in this area.

In June 1963, the JMA’s professional liability insurance program was authorized as a first trial in Japan. The contract coverage was 1 million yen

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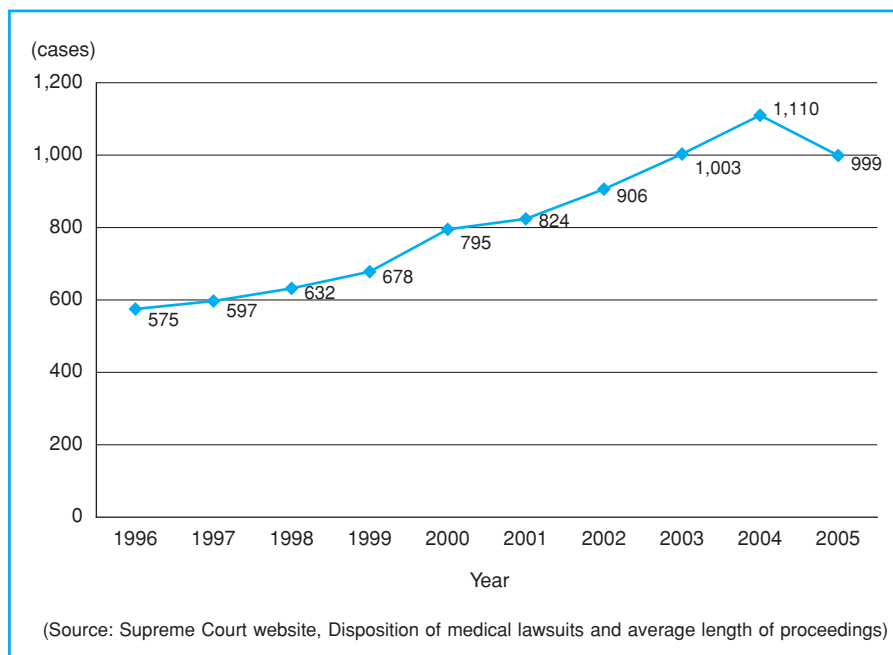


Fig. 1 Trends in the disposition of medical lawsuits

(US\$8,300)*² per incident and the maximum coverage per year was set at 3 million yen (US\$25,000). Together with the general spread of insurance, a dispute settlement committee was then established nationwide and came to play a role in the resolution of medical disputes.

Over the years, in the courts' view of civil liability, emphasis had been placed on the indemnification of the patients. Accordingly, there was a trend created to moderate certification level of physician negligence. And as such positions were adopted as "the definition of an abstract high standard of duty of care" and "the inference of negligence from the causal relationship between medical practice and errors." Thus, medical judgment and legal judgment came to deviate from each other, and in the theater of dispute itself, the attitude that medical rationale may be twisted if this serves to resolve a dispute has gained ground.

Court decisions in pollution cases and their resolution of traffic accident cases were then occasion for an accelerated trend towards large sums of compensation money for damages. The established ad hoc dispute resolution system became incapable of coping with it. This made it

imperative to fundamentally revisit the Japanese system of physicians' liability insurance.

In March 1972, the legal committee of the JMA compiled a "Report on the Legal Resolution of Medical Errors and Basic Theory" and offered three important recommendations:

First, "a high-value physicians' liability insurance program should be implemented nationwide having a rigorous investigatory mechanism that reflects rigorous medical judgment in jurisprudential judgments on the question of the existence of negligence when medical errors occur," i.e., requesting implementation of the present JMA professional liability insurance program.

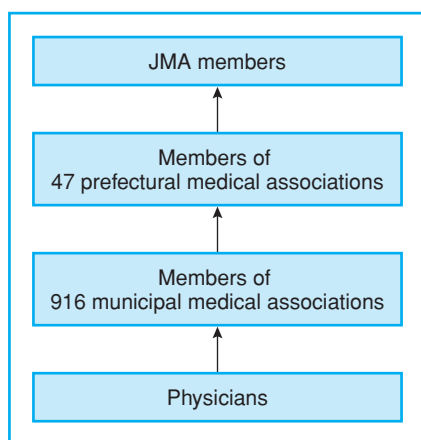
Second, "a national program of indemnification against serious damage occurring unavoidably where negligence on the part of a physician does not apply should be established," i.e., proposing the establishment of a non-fault compensation program.

Third, for "a dispute resolution mechanism should be established as state apparatus apart from the existing court system," i.e., proposing the establishment of a mechanism on the lines of alternative dispute resolution.

*2 Based on a yen-dollar exchange rate of 1 dollar = 120 yen.

Table 1 Outline of the JMA physicians' professional liability insurance

Insurant	Japan Medical Association
Insurance companies	Administered as a joint policy by the insurance companies below. The lead agent administers the contract and conducts dispute resolution. Tokio Marine & Nichido Fire Insurance Co., Ltd. (lead agent) Sompo Japan Insurance Inc. Mitsui Sumitomo Insurance Co., Ltd. Nipponkoa Insurance Co., Ltd.
Persons insured	JMA Class-A members
Coverage	Claims for compensation for corporal injury arising from medical practice where the claim exceeds 1 million yen.
Insurance payments & maximum indemnification	Insurance payments are for compensation paid and legal expenses. The maximum annual indemnification against compensation payments is 100 million yen per person insured.
Deductible	The deductible (self-pay burden) is 1 million yen per medical practice.
Term of policy	One year, as of July 1 of each year. Renewed annually, except in exceptional circumstances.
Premium	Premiums are paid by the JMA.
Dispute resolution	Working from decisions of the liability review board, the JMA and the insurance companies pursue dispute resolution in coordination with prefectural medical associations.

**Fig. 2 JMA-Local medical association relationship**

These proposals formed the basis for the inauguration, in July 1973, of the JMA physicians' professional liability insurance program. Major features of this program are that it is implemented as a social responsibility of the JMA, which is itself the insurant, and that all Class-A members are covered by it. A liability review board was also established as an even-handed, neutral body to render reasonable judgment on physician responsibility. Further, physicians'

liability insurance unique to the JMA emerged equipped with a system to support members in dispute resolution with high compensation amounts of up to 100 million yen (US\$833,000) annually (with 1 million yen deductible). Table 1 summarizes this program.

JMA Structure

As of December 1, 2006, the JMA had a membership of 164,110. This JMA membership comprises the members of the 47 prefectural medical associations, each such prefectural medical association being an independent corporate organization. Membership in local medical associations, both prefectural and municipal, is a requirement of membership in the JMA. (See Fig. 2.)

Member eligibility for liability insurance and subscription level

- (1) Members are divided broadly into three Classes, A, B and C. Out of these classes, Class-A members are automatically covered by the physicians' liability insurance. Class-A members further consist of three types; A1 members who are a founder or administrator, A2 members (B) who are an employed physician and A2 members (C) who are a

Table 2 Membership fees and insurance premiums

(FY2007)

	A1 members	A2 members (B)	A2 members (C)	B members	C members
Annual membership fee	¥130,000	¥83,000	¥40,000	¥28,000	¥6,000
(of which insurance premium)	¥70,000	¥55,000	¥34,000	n/a	n/a

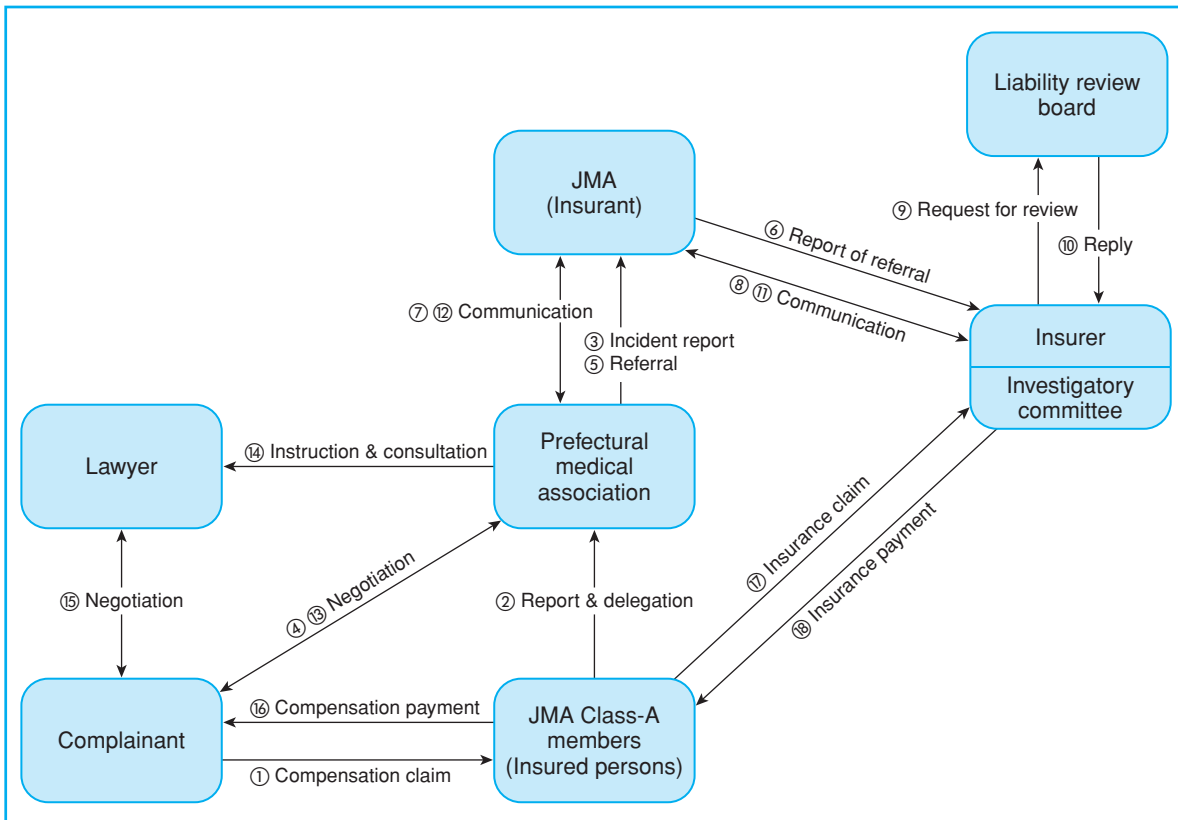


Fig. 3 Dispute resolution flowchart

resident under the Medical Practitioners Law. Class-B is for employed physicians and Class-C for residents. B and C members are not covered by the insurance.

- (2) The JMA is the insurant, and some 120,000 members, or c.75% of the membership, are covered by the insurance.

Insurers

The insurance is administered as a joint policy, for which the lead agent is Tokio Marine & Nichido Fire Insurance Co., Ltd., joined by Sompo Japan Insurance Inc., Mitsui Sumitomo Insurance Co., Ltd., and Nipponkoa Insurance Co., Ltd.

Table 2 outlines membership fees and insurance premiums.

Need for supplementary insurance

The JMA physicians’ liability insurance covered the liability of individual Class-A members, but payments for the liability of non-member physicians were cut, and there was a rush to establish an insurance program adequate for the needs of “A1 member administrator liability.” Additionally, recent years have seen an increase in the incidence of payments exceeding 100 million yen, and in September 2001, the JMA supplementary physicians’ liability insurance program

Table 3 Investigatory committee and liability review board

Investigatory committee: Formed by the insurers.
<ul style="list-style-type: none"> (1) Committee members selected by both insurers and the JMA. (2) Total committee membership is 26 persons. Breakdown: JMA appoints 17 physicians and 3 lawyers (formed as a JMA committee, with a 2-year term of service). Insurers appoint 3 insurer representatives and 3 lawyers. (3) Examines cases brought, requests reviews by the liability review board, and takes decisions on resolution policy going forward based on decisions of the review board.
Liability review board: Formed by the insurers.
<ul style="list-style-type: none"> (1) Composed of neutral members having no relationship with the JMA or the insurers. (2) Total board membership is 10 persons. Breakdown: 6 members with an academic and practical background in medical affairs and 4 persons with an academic and practical background in legal affairs, serving 2-year terms. (3) The board deliberates on whether liability exists, compensation amounts, and measures necessary to the pursuit of equitable and reasonable resolution.

was opened to “discretionary subscription” so as to make possible the payment of larger compensation amounts.

Currently, around 20% of Class-A members are subscribed.

JMA finances and the insurance program

All Class-A members are automatically subscribed to the JMA insurance program, and the JMA collects membership fees, including amounts corresponding to insurance premiums, and holds a contractual relationship directly with the insurance companies. The insurance companies have submitted the program and premium to the Financial Services Agency and obtained its approval, and the program is operated at the sole risk of the insurance companies, with no provision for partial extinguishment of membership fees for such reason as deterioration in the loss ratio. Therefore, the program is completely independent of JMA finances. However, the amount of the premium has been revised several times in the past in discussion between the two parties to the agreement.

Dispute Resolution Procedures (Fig. 3)

(1) Damages claims referred to prefectural medical associations

When a damages claim is filed against a person covered by the insurance by a complainant, the filing is reported to a prefectural medical asso-

ciation in accordance with the procedures for dispute resolution stipulated by the individual medical association and dispute resolution delegated accordingly (① and ② in Fig. 3).

(2) Subsequent resolution

1) Prefectural medical association sends incident report to the JMA

Of disputes referred to prefectural medical associations, those with compensation claims exceeding 1 million yen (including those expected to exceed that amount) are immediately reported to the JMA (③ in Fig. 3).

2) Referral to the JMA

When following insurance dispute resolution procedures, the prefectural medical association refers the case to the JMA, attaching the prescribed documentation (⑤ in Fig. 3). (This is normally done at the same time as the incident report.) Upon receiving the referral, the JMA contacts the insurance companies and requests an investigation, forwarding the referral documentation to the investigators (⑥ and ⑦ in Fig. 3).

N.B. Following referral and up until final resolution of the case, the prefectural medical association may continue to negotiate with the other party to the dispute (④ and ⑬ in Fig. 3).

3) Investigation and review (Table 3)

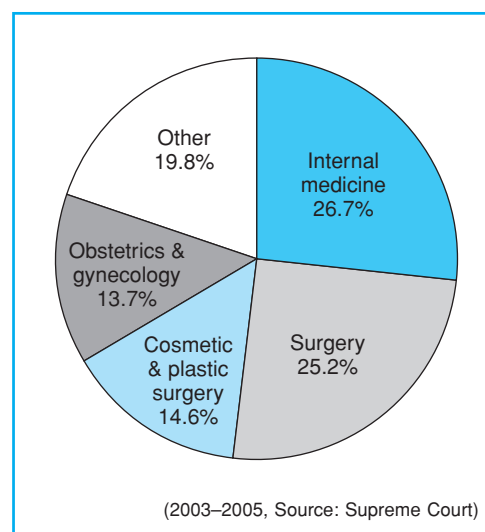
Following an investigation by the investigatory committee, the insurance companies, while maintaining close contact with the JMA, request a review by the liability review board (⑧ and ⑨

Table 4-1 New medical litigation brought and average length of proceedings

	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005
New cases	575	597	632	678	795	824	906	1,003	1,110	999
Avg length of proceedings (months)	37.0	36.3	35.1	34.5	35.6	32.6	30.9	27.7	27.3	26.9

Table 4-2 Cases filed, by clinical specialty

	2003	2004	2005
Internal medicine	254	280	265
Pediatrics	22	30	29
Psychiatry	40	43	33
Dermatology	22	20	8
Surgery	239	253	260
Cosmetic surgery	143		97
Plastic surgery	152		43
Urology	17	28	23
Obstetrics & gynecology	138	151	119
Ophthalmology	30	30	30
Otolaryngology	24	26	28
Anesthesiology	9	16	7
Other	28	26	23


Fig. 4 Proportions of cases filed, by clinical specialty

in Fig. 3).

N.B. Where the engagement of a lawyer or other such measures are required, these are performed in consultation with the JMA (and prefectural medical association).

4) Review and subsequent resolution

The review board conducts an even-handed review as to liability, the amount of any compensation, and related matters. When the review board has replied, the investigatory committee makes a decision on a negotiation policy in accordance with the board's reply and notifies the JMA of its decision. The JMA relays this information to the prefectural medical association and requests its cooperation (⑩, ⑪, and ⑫ in Fig. 3).

(3) Final resolution

1) In reaching a final conclusion in accordance with the notification provided by the investigatory committee and forwarded by the JMA,

the prefectural medical association seeks negotiation and resolution after first obtaining the agreement of members with a resolution proposal that respects the positions of members (⑬, ⑭, ⑮, and ⑯ in Fig. 3).

- 2) The prefectural medical association then informs the insurance companies, through the JMA, of settlements reached out of court, a statement of legal costs, and related matters.
- 3) Upon finalizing the amount of the insurance claim paid in the investigatory committee, the insurance companies make this payment directly to the member (⑰ and ⑱ in Fig. 3).

Statistical Data on Medical Litigation from the Supreme Court

The number of new cases filed annually has exceeded 1,000 since 2003, about double the number 10 years ago. The time required to hear a dispute has shortened by some 10 months from

10 years ago, and in these past few years, cases have been concluded in just over 2 years. Medical litigation, too, is accelerating (Table 4-1). Internal medicine, surgery, cosmetic and plastic surgery, and obstetrics and gynecology account for 80% of the total (Table 4-2). Figure 4 is a pie chart of the leading clinical specialties given in that table.

Future Directions

This framework has now endured 35 years, but we have in the past revised it in keeping with member and secular requirements and also instituted new supplementary insurance (at discretionary

subscription). It will continue to be important to build relationships of trust between physicians and patients through the appropriate settlement of medical disputes on the basis of close collaboration between the JMA and local medical associations and to improve on sound operation of the program so that members feel secure in providing health care.

Acknowledgements

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Medical Care as Social Common Capital

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When medical care is regarded as social common capital, every member of the society is entitled, as basic human rights, to receive the best available medical care that the society can provide, regardless of the economic, social, and regional circumstances, even though this does not necessarily imply that medical care is provided free of charge. The government is required to compose the overall plan that would result in the management of the medical care component of social common capital that is socially optimum. This plan consists of the regional distribution of various types of medical institutions and the schooling system to train physicians, nurses, technical experts, and other co-medical staff to meet the demand for medical care. The government is then required to devise institutional and financial arrangements under which the construction and maintenance of the necessary medical institutions are realized and the required number of medical professionals are trained without social or bureaucratic coercion. It should be emphasized that all medical institutions and schools basically are private and the management is supervised by qualified medical professionals.

The fees for medical care then are determined based on the principle of marginal social costs pricing, not through merely market mechanisms. It may be noted that, the smaller the capacity of the medical component of social common capital, the higher are the fees charged to various types of medical care services. Hence, in composing the overall plan for the medical care component of social common capital, we must explicitly take into account the relationships between the capacity of the medical care component of social common capital and the imputed prices of medical care services. The socially optimum plan for the medical care component of social common capital then is one in which the resulting system

of imputed prices of various types of medical care services leads to the allocation of scarce resources, privately appropriated or otherwise, and the accompanying distribution of real income that are socially optimum.

When, however, physicians provide medical care services to those whose health is impaired due to diseases or injuries, the very nature of medical care necessarily implies that the processes of diagnosis and curative treatment may occasionally involve the impairment, physical or mental, of patients, whereas the curative effects are not necessarily absolutely guaranteed. If an ordinary person were to perform his or her job this way, he or she would certainly be criminally prosecuted. Only qualified physicians and co-medical staff are immune from such prosecution, because in addition to being licensed to practice medical care and being trusted on a fiduciary basis with the management of the medical care component of social common capital, they must obey professional codes of conduct truthfully and to take care of patients with the best scientific knowledge and the highest available technical proficiency of the medical sciences today. For such presuppositions to be fulfilled, it is not only necessary for arrangements to be institutionalized so the provision of medical care and the conduct of each physician are properly monitored in terms of peer review or some other means, but it is also necessary that an overall system of incentive mechanisms, in terms of social esteem and a compensatory scheme, to be established whereby it becomes in physicians' own self-interest to obey professional codes of conduct truthfully and to seek the best scientific knowledge and the highest available technical proficiency available in medicine.

Under such utopian presuppositions, total expenditures for the construction and mainte-

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nance of the socially optimum medical care component of social common capital then exceed, generally by a large amount, the total fees paid by the patients under the principle of marginal social cost pricing. The resulting pattern of resource allocation and real income distribution, however, is optimum from the social point of

view. The magnitude of the deficits with respect to the management of the socially optimum medical care component of social common capital then may appropriately be regarded as an index to measure the relative importance of medical care from the social point of view.

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Current Status of Electronic Health Record Dissemination in Japan

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Hiroshi TANAKA *¹

Abstract

The present paper describes the history and current status of the spread of electronic health records (EHRs)^{*2} and factors that facilitate or suppress their use, as well as discussing issues that relate to the further spread and future prospects of EHRs in Japan. The use of EHRs began in the latter half of the 1990s, and spread steadily because of subsidies initiated in 2002 by the Ministry of Health, Labour and Welfare. Current adoption rates are similar in clinics and hospitals, with both showing average figures of 6–7%. In terms of the scale of facilities, more than 25% of large hospitals with 400 or more beds use EHRs, whereas the corresponding percentage is much lower among hospitals with less than 100 beds, indicating that the introduction of EHRs in small-scale hospitals is challenging. The use of EHRs is beneficial in that it allows the electronic storage of medical records, sharing of data among hospital staff members, and support for treatment planning by computerized critical path. The major problem involved in EHRs is the high cost of their introduction and maintenance. Issues to be solved for the future of EHRs include cost reduction, reimbursement for costs, and specialty-specific usage. In future, EHRs are expected to play a role as a basis for cooperation in providing successful regional health care.

Key words Electronic health records, Lifelong electronic health records, Healthcare information technology

Introduction

The use of electronic health records (EHRs), i.e., computerized clinical information, has long been a goal of healthcare information technology in Japan. Adoption of the EHR system was attempted by some pioneering hospitals in the 1990s, in recognition that the system was the next generation in hospital information technology, following the electronic order-entry system. It was not until 2000 that the EHRs became widespread.¹ Currently, the spread of EHR technology is not necessarily rapid, but it is steadily being extended throughout medical facilities in Japan, including clinics and small-scale hospitals.

Information technology in the healthcare field

has progressed rapidly on an international level in this century, and large-scale national policies for introducing healthcare information technology have been adopted in many Western countries. The main goal of advancing healthcare information technology is to construct a lifelong EHR system that would allow each person to obtain his or her healthcare information throughout life and to use the information for health management and the prevention of disease.

The introduction of EHRs provides various benefits to individual medical facilities. In addition, however, EHRs form a basis for the promotion of healthcare information technology and hospital-clinic cooperation, cooperation among various medical facilities for regional healthcare, and nationwide management of lifelong healthcare,

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*2 Computerized patient records which are used exclusively within the hospital are ordinarily called EMRs (Electronic Medical Records), whereas EHR usually refers to the patient healthcare information shared by multiinstitution to use for the lifelong health record of each people. But in this article, for the sake of simplicity, we uniformly use the word EHR for both cases.

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Table 1 Changes in healthcare IT promotion centering on EHRs

From the 1970s	Departmental systems, such as medical accounting systems.
From the 1980s	Development and dissemination of order-entry systems.
1990s	Development of EHRs through isolated trial systems.
1994	Inauguration of Electronic Medical Record Study Group at the Japan Association of Medical Informatics.
1995	Report on the model medical care project in EHR system development, a project supported by the Ministry of Health and Welfare.
From 1995	Development of the EHR-type hospital information system (Kameda, Kanazawa Medical University, Tsuyama Central Hospital).
1999	Notification issued by the chief of the Health and Welfare Policy Division, Ministry of Health, Labour and Welfare, concerning the development of the Grand Design toward Computerization in the Medical Field.
2000	Japan Medical Association guidelines for provision of clinical records.
2001	Grand Design toward Computerization in the Medical Field issued by the Ministry of Health, Labour and Welfare. Project of Medical Networking Promotion with Advanced Information Technology implemented by the Ministry of Economy, Trade and Industry.
2002–2003	Subsidy for EHR adoption as a project for Improvement of Medical Facilities Equipped with EHRs by the Ministry of Health, Labour and Welfare.
2003	Medical IT promotion set up as one of seven prioritized areas in e-Japan Strategy II.
2004	Promotion of the use of EHRs by e-Japan Priority Policy Program 2004.
2005	Medical IT task and reimbursement incentive in “IT Policy Package—2005” issued by IT Strategic Headquarters.
2006	IT Strategic Headquarters issued the following: prioritized healthcare IT promotion in the New IT Reform Strategy, use of the online medical receipt system within 5 years, lifelong use of health checkup data, dissemination of EHRs, and development of grand designs. In June, healthcare IT strategy was determined in the Priority Policy Program. The Japan Healthcare IT Initiative was established.

as mentioned above. The spread of EHRs is not only significant in the sharing of information within a medical facility, but also helps to extend healthcare information technology. In this regard, policies that provide economic incentives to accelerate the spread of the EHR system are needed. One of these is a program begun in April 2006 for the provision of additional remuneration for electronic records, which has caused slight but steady progress.

This paper, which describes the current status of EHR use in Japan, is based on the results of several surveys. In particular, factors facilitating and suppressing the spread of EHRs are discussed.

History of EHR Use in Japan

The status of healthcare information technology in Japan will be described briefly, with special reference to the development and dissemination of EHRs (Table 1).

(1) Prehistory: The term “electronic health records (EHRs)” was used as early as the 1980s,

with the recognition that they represented the future of electronic management of healthcare information. However, the main target at that time was computerization of medical records. Until the early 1990s, EHRs generally were used on a trial basis, on isolated computers or workstations, by instructors in medical schools or clinicians in the front line.

(2) Advent of EHR systems for hospitals: The late 1990s saw an advance in healthcare information technology. First, in 1995, an EHR system development project sponsored by the Ministry of Health and Welfare was carried out, and a model EHR was proposed. Previously, in 1994, an EHR research group was organized as part of the Japan Association of Medical Informatics. Along with these changes, computerized patient records and general hospital order-entry systems were combined in medium-scale or larger hospitals, resulting in the advent of third-generation general hospital information systems utilizing EHRs. Such electronic systems were developed and applied in several pioneering hospitals. How-

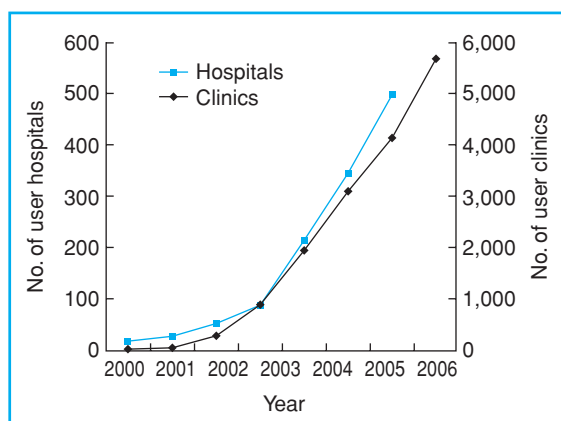


Fig. 1 Changes in adoption of EHRs in medical facilities (hospitals and clinics)

ever, the majority of medium and large hospitals gave the highest priority to the adoption of computerized order-entry systems. In 1999, statistics showed that less than 20 hospitals and about 50 clinics throughout the nation were using EHR systems.

(3) Increased spread of EHRs: In response to the trend pointing toward the promotion of EHRs, the Ministry of Health and Welfare in 2000 issued a directive that permitted the storage of medical data in electronic media as long as three criteria, authenticity, visual readability, and storage property, were ensured. Under these circumstances, the Grand Design toward Computerization in the Medical Field, which specified healthcare information technology programs planned up to 2006, was issued by the Ministry of Health, Labour and Welfare in December 2001, in coordination with the e-Japan strategy of the Japanese Government. Thus, the spread of EHRs became a national policy. In addition, the 2001 supplementary budget provided for a project of Medical Networking Promotion with Advanced Information Technology by the Ministry of Economy, Trade and Industry. Following the Grand Design, the Ministry of Health, Labour and Welfare implemented a project for the improvement of medical facilities equipped with EHRs (budgetary help for 249 medical facilities) in 2002 and 2003. Thereafter, EHRs came into much more widespread use.

Even after the end of subsidies in 2003, well over 100 medical facilities adopted EHRs in 2004 and 2005, resulting in steady, but hardly explosive, progress.

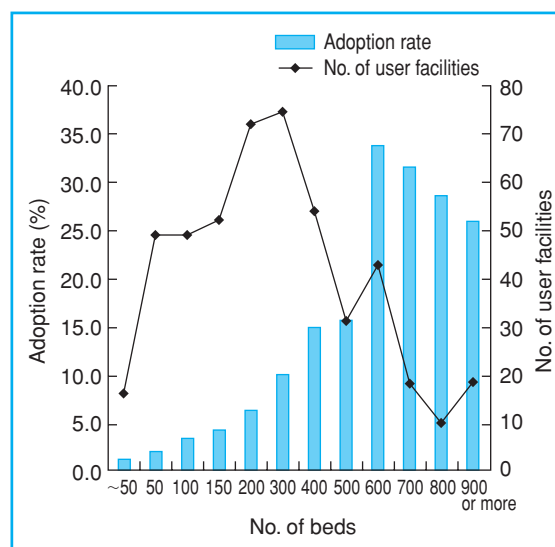


Fig. 2 Changes in adoption of EHRs in medical facilities in relation to the number of beds (hospitals and clinics, 2005)

Current Status of EHR Use

Characteristics of the current use of EHRs in Japan are described below.

Similar rates of spread in clinics and hospitals

The collection of 2006 statistical data from clinics and hospitals using EHRs is underway through the joint effort of the Japanese Association of Healthcare Information Systems (JAHIS) and ME Development Co., Ltd., with statistics obtained only from clinics that use EHRs. Therefore, 2005 statistics on hospitals using EHRs were used for analysis.² As Fig. 1 shows, about 10-fold more clinics are using EHRs; however, this is proportional to the existing 10-fold difference in the absolute numbers of clinics and hospitals as a whole. Therefore, since 2002, the relative increase in the rate of adoption of EHRs has been similar in clinics and hospitals.

Estimated rate of EHR adoption in hospitals with 400 beds or more (as of the end of 2006)

In relation to the number of beds, the rate of EHR adoption is less than 10% among small- to medium-scale hospitals with less than 200 beds,

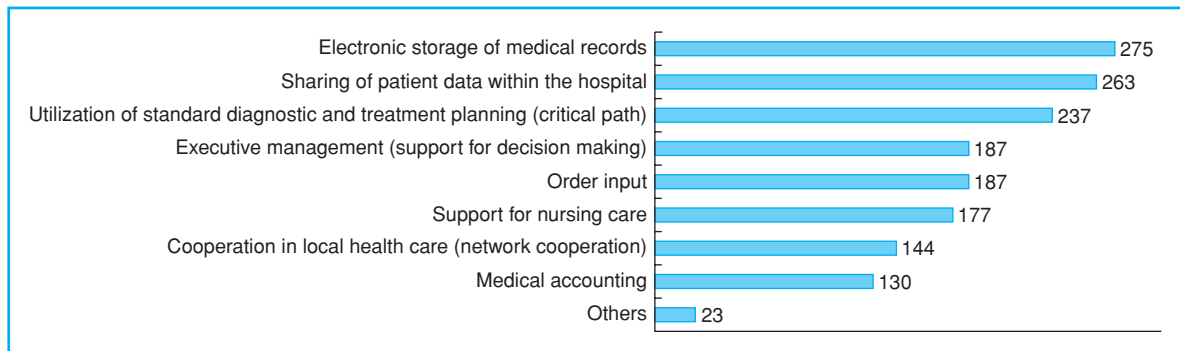


Fig. 3 Most highly anticipated features of EHRs

(Excerpt from the report of the results of the 2004 project for demonstrating the interoperability of medical information systems, sponsored by the Ministry of Economy, Trade and Industry, 2006)

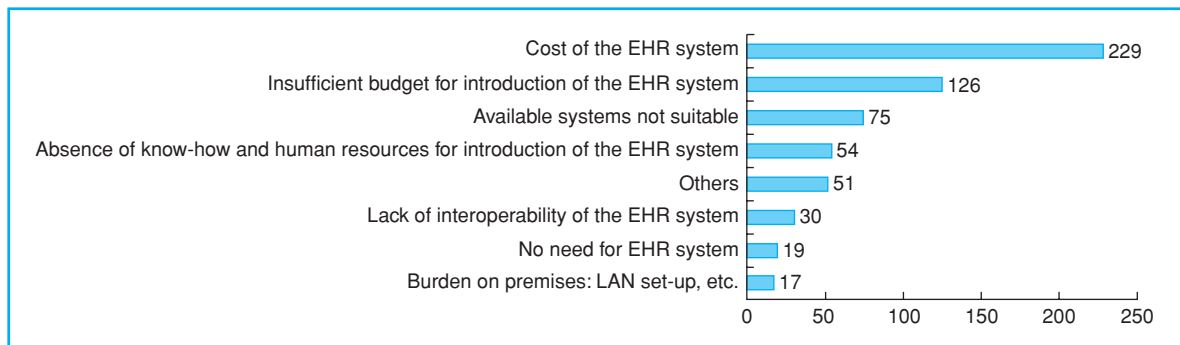


Fig. 4 Factors suppressing the spread of EHRs

(Excerpt from the report of the results of the 2004 project for demonstrating the interoperability of medical information systems, sponsored by the Ministry of Economy, Trade and Industry, 2006)

the predominant size category for hospitals in Japan. In contrast, among medium- to large-scale hospitals with 300 beds or more, the EHR adoption rate is more than 10% (Fig. 2), whereas the corresponding rate is about 30% among large-scale hospitals with 600 beds or more. The 2001 Grand Design set a goal of EHR adoption in more than 60% of hospitals with 400 beds or more. As of 2005, however, the rate was just 20.9% among such hospitals. Although 2006 statistics are not yet available, extrapolation of the increase from 2004 to 2005 indicates an estimated adoption rate of 25–27% for 2006. Therefore, the Grand Design seems to have achieved only about 50% of its goal.

EHR spread in relation to number of beds

Closer observation has revealed that about 70

hospitals each are using EHRs among medium-scale hospitals with less than 200, 300, or 400 beds. Although the percentage remains modest because the denominator is very large for hospitals of this size, EHRs are rapidly being adopted. However, both the actual number and the percentage of institutions using EHRs are very low for hospitals with less than 100 beds. It is apparent that promoting EHRs to such small hospitals is an important task for the future.

Factors Advancing and Retarding the Spread of EHRs

Although EHR use has been increasing steadily, it is clear that the goal of the Grand Design has not been reached. It is therefore important to ask what can be expected from EHRs and what

stands in the way of their wider use. The Medical Information System Development Center carried out a survey on this issue as part of the 2004 project for demonstrating the interoperability of medical information systems sponsored by the Ministry of Economy, Trade and Industry. In this survey, questionnaires were sent to 1,379 hospitals, and responses were obtained from 374 of them.³ Results of the survey showed that hospitals using EHRs included those with 100–500 beds, particularly those with 300 beds. Further details of distribution not mentioned here can be accessed in the project report, but the distribution profile is much the same as that shown in Fig. 2.

The most highly anticipated features of the EHR system, as indicated by the survey (Fig. 3), include electronic storage that provides various benefits for medical practice and hospital management, sharing of information, and critical path usage. In contrast, among the drawbacks of EHRs (Fig. 4), the high cost of current EHR systems was predominant.

The cost of the EHR system does not depend simply on the size of the hospital. The cost of introducing an EHR system per bed is not constant, but increases with the size of the hospital. Clinics and small hospitals usually adopt an EHR system designed specifically for internal medicine or limited specialties with very little customization, whereas large hospitals have a number of specialties including organ-specific surgical departments. They thus require a system that is different from those designed exclusively for internal medicine. The latter hospitals tend to require costly customization, resulting in increased overall costs.

Major factors needed to accelerate the use of EHRs include cost reduction, standardization of EHR systems, and improvement of the human interface, including the input environment.

Problems in the Current Spread of EHRs

What needs to be done to promote the widespread use of EHRs? Although ease of use of the EHR system is the main factor, the following factors also are important.

Additional reimbursement for computerized medical records: an incentive to introduce the EHR system

As mentioned previously, benefits of the use of

EHRs are not necessarily clear from the viewpoint of management. Hospital administrators are hesitant to introduce expensive EHR systems to their hospitals, since computerization of medical records is incurred as a necessary expenditure, similar to energy expenses. In this regard, the new item in national health insurance system, medical record computerization for reimbursement, which became effective as of April 2006, is promising. However, the amount of reimbursement seems to be too low to have any meaningful effect at this time. An adequate reimbursement incentive may be a boon to promoting the system. Therefore, substantial enhancement of the computerization incentive strategy is needed.

Cost reduction of the EHR system: toward increased introduction of standard EHRs

As indicated by the results of the aforementioned questionnaire survey, cost reduction of the EHR system is an important factor in its spread. The larger the hospital, the stronger the demand for system customization, thus increasing the cost of introduction. Although there are circumstances specific to individual hospitals, the introduction of standard EHRs should be encouraged, while discouraging excessive customization insofar as possible. Promotion, dissemination, and adoption of standard EHRs lead not only to reducing of the cost of EHR system introduction, but also to the facilitation of interinstitutional cooperation. For this purpose, it is necessary to provide incentives to hospitals that adopt the standard EHR style and are willing to share medical information among institutions in the regional community.

Dissemination of EHRs specific to specialties: reflecting practice process

The aforementioned standardization of EHRs refers to the basic structure of the EHR system. In actuality, the process of clinical practice differs among different specialties. Most current EHR systems are designed for the practice of internal medicine. Since surgical specialties are different from medical specialties in the process of diagnosis and treatment, current uniform EHR systems are unsuitable in various aspects. If variant EHR systems of the standard structure but applicable to different practice processes specific to different specialties were made available, computerization of medical records might be more acceptable to

medical professionals, resulting in more widespread use.

Linkage of information to hospital practice: toward logistics and prevention of malpractice

When EHR systems are used within closed wire networks, EHRs cannot play the primary role in informatization of practical hospital care. For instance, current EHR systems often do not register accurate information about the injection of a particular patient by a nurse. At present, barcodes are used for data input. The use of electronic tags that transmit ID information in the future would allow automatic identification of individual instruments and issue an alert if an error in the act of care were to occur. This means that one creates an information space that includes the interface between the information system and the surrounding practice environment, thereby achieving successful hospital logistics and prevention of malpractice. To this end, informational linkage to the surrounding practice environment by total computerization of the hospital utilizing ubiquitous communication technology is essential.

Clinical practice-support: beyond the level of simple computerization of paper medical records

Introduction of the EHR system will support medical professionals in improving clinical practice, for example, by facilitating integrative referral to clinical information. It is also desirable that the benefits of EHRs extend to the user clinician. Further, it is important that multiple benefits including not only clinical practice support, i.e., integrative referral to patient information, but also the following be offered to users: support for treatment planning by computerized critical path, provision of drug information (particularly information on drug interactions), various reminder

features for use in individual patients, and provision of guidelines for standard clinical practice in conjunction with the Internet. The EHR systems currently available in Japan offer poor support to clinical practice, remaining at the level of simple computerization of paper medical records. Thus, development of the full capabilities of clinical practice by computerization of clinical information has not been fully realized. If the primary value of EHRs to users can be achieved, however, EHR dissemination will be accelerated.

EHRs that Link the Institutional Milieu to the Regional Community: Toward the second generation

As mentioned in the Introduction, industrially advanced nations in Europe and North America have simultaneously undertaken large healthcare information technology projects in order to achieve national dissemination of lifelong EHRs. Although the use of EHRs in medical facilities has not reached the required level, it remains necessary to promote interinstitutional sharing of patients' clinical records through cooperation between hospitals and clinics as well as between hospitals; this stage refers to the second generation of EHRs.⁴ Such linkage of information with other facilities is an important basis for establishing regional healthcare information spheres, an essential step toward the realization of lifelong EHRs.

Future progress in healthcare information technology is likely to result in cooperation between medical facilities in regional healthcare, specifically to realize regional self-contained medical care by means of the critical path through cooperation with regional medical facilities, and may be integrated with lifelong health information, finally leading to a basis for the control and understanding of the health and medical care history of each individual.

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High Prevalence of Drug-induced Pneumonia in Japan

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Abstract

In recent years, drug-induced pneumonia has attracted increased attention in Japan, following adverse effects that were found to occur with the use of gefitinib and leflunomide. It was even determined that the same agent might produce different imaging patterns of lung injury, and fatal lung disorders have been associated with imaging patterns and pathologic findings of diffuse alveolar damage. Epidemiological research has revealed that drug-induced lung disease of any type is associated with the presence of common risk factors of occurrence and poor prognosis. For example, drug-induced lung disease is more likely to occur when there is preexisting interstitial pneumonia. International comparisons have suggested that drug-induced lung disease is more common in Japan than in many other countries. However, because the physicians who prescribe drugs have a different specialty from that of those who assess the side effects of the drugs, there have been barriers to research, and the detection of adverse events may be delayed. Gefitinib, a molecular targeting drug, has been found to be highly effective for lung cancer that presents particular gene mutations in EGFR tyrosine kinase, and it has been confirmed that this mutation is frequent among the Japanese population. In the globalized competition of drug development, elucidation of the race-specificity in drug-induced lung disease is as important a topic as the efficacy of drugs. It is necessary to ensure the safety of medical care by understanding the mechanisms of such lung injury.

Key words Drug-induced pneumonia, Acute lung injury, Gefitinib, Leflunomide, Genetic predisposition

Introduction

Since emergency safety information on lung injury related to gefitinib (Iressa[®]) was issued in October 2002, drug-induced pneumonia has attracted a great deal of attention in Japan. Currently in Japan, drug-induced lung disease is specified as a side effect of 1,232 drug products and a serious side effect of 1,185 drug products, and warnings about the possibility of such injury are attached to 50 drug products (as of April 2004, based on information on drugs and devices from the URL of the Pharmaceuticals and Medical Devices Agency). Drug-induced pneumonia is a form of lung injury. It is unclear as to why the number of new drugs that can cause lung injury is increasing rapidly at this time (Fig. 1).

This paper provides an overview of the current status of drug-induced pneumonia in Japan.

Recent Increases in Drug-induced Lung Disease

The recently developed molecular-targeting drugs have more definitive sites of action than those developed a decade ago. Although these drugs have potent therapeutic effects, they also are associated with increases in serious adverse effects.

Lung injury related to the molecular-targeting drug gefitinib was first reported in 2002 in Japan, and that related to the antirheumatic drug leflunomide, reported one year later, raised the issue of drug-induced lung injury and the overall safety of drugs in this country. Currently, a variety of

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drugs have the potential to induce lung injury (Table 1).¹ In addition, it has been indicated that the frequency of drug-induced lung injury is higher in Japan than in other countries.

In recent years, many drugs have been developed by non-Japanese pharmaceutical companies

and imported into Japan as medicinal products of established efficacy and safety.

The threat of drug-induced lung injury has long been known. However, since serious side effects associated with high fatality are rare and not readily noticeable in comparison with the

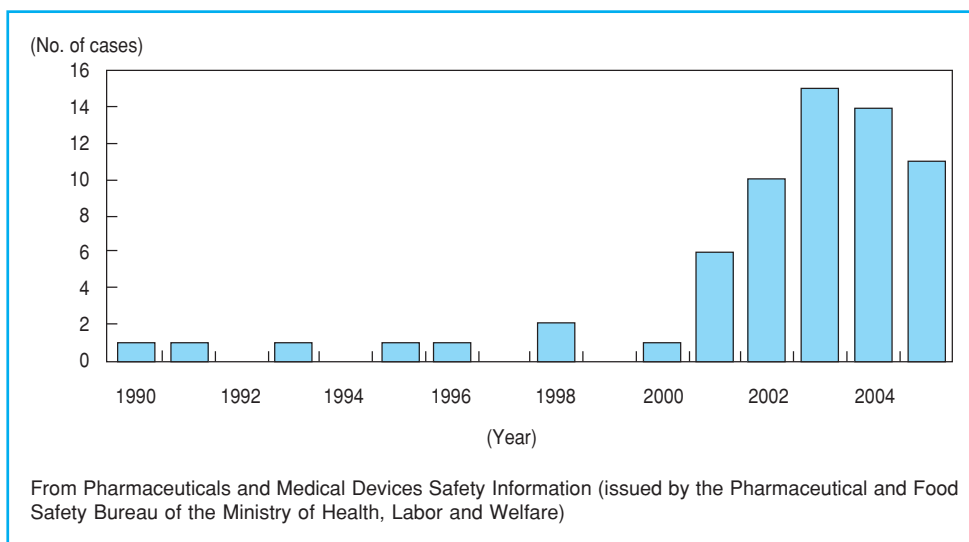


Fig. 1 Annual changes in number of reports of drug-induced lung disease
(Produced by Professors Keishi Kubo and Nobuoki Kohno. Provided by Prof. Kubo)

Table 1 Changes in reported causes and number of cases of drug-induced lung disease

	-1980	1981-1990	1991-
Anticancer drugs	225	66	40
Gold compounds	44	46	17
Antibiotics	9	54	49
Antituberculous drugs	1	7	9
Chinese indigenous medicines	0	3	78
Chinese indigenous medicines + IFN	0	0	22
IFN	0	3	31
Antirheumatic drugs	0	4	18
Antipyretic analgesics	0	10	30
Psychotropics	1	10	8
Antihypertensive drugs	2	3	2
Others	14	12	34
Total	296 cases	218 cases	338 cases

Whereas the causative agents of drug-induced lung disease were predominantly anticancer drugs in the past, a wide variety of drugs are now reported to induce such lung disease.

(Drug-induced lung disease, Kekkaku, 1999¹)

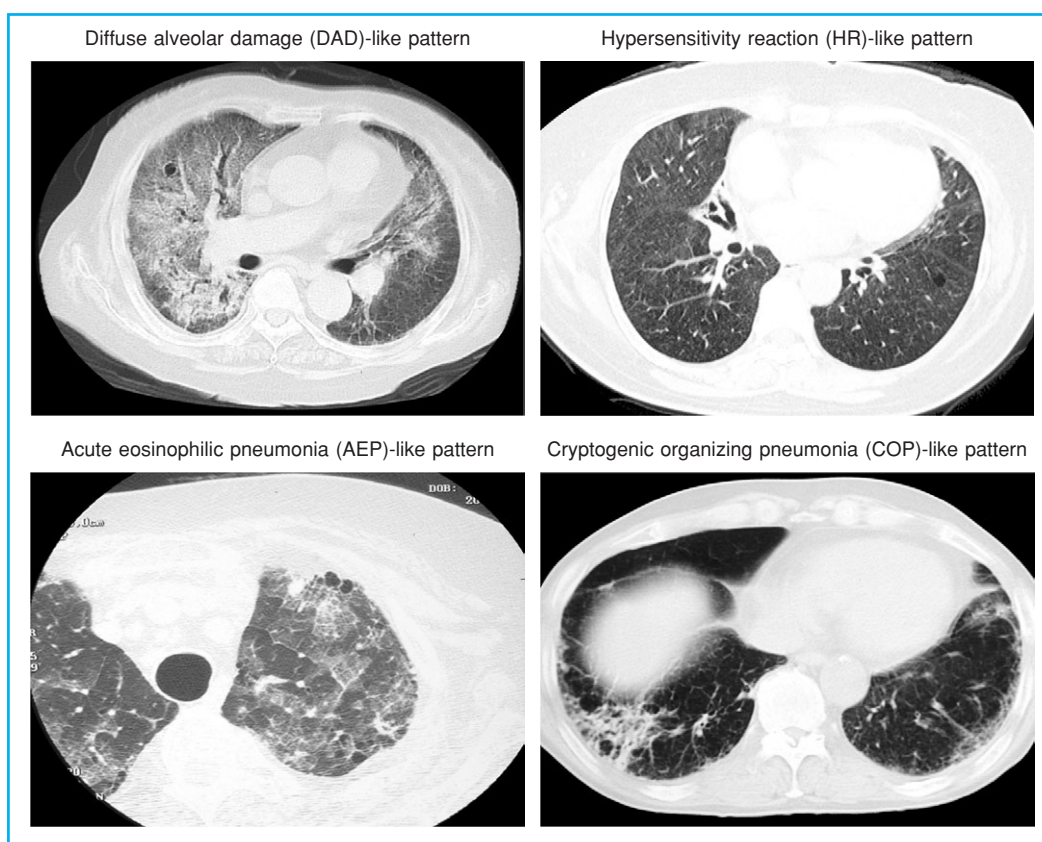
efficacy of the drugs, there is a risk of allowing the drug to enter the market without recognizing its adverse effects during the process of clinical trials.² In fact, the cases of acute lung injury caused by gefitinib in 2002 and by leflunomide in 2003 that attracted general attention in Japan were those that occurred after the drugs' introduction. Fatal drug-induced lung injury in particular was frequent among the Japanese, presenting a challenge that should be addressed as a high-priority issue today.

Most cases of drug-induced lung disease present imaging findings of interstitial pneumonia characterized by bilateral diffuse, extensive patchy, reticular, or ground-glass appearance, with a pattern of infiltration in some cases. Accompanying thickening of the interlobular septum and an intralobular reticular pattern often occur, presenting varying distributions of lesions. These lesions can be classified into at

least 4 patterns: (1) diffuse alveolar damage (DAD)-like pattern, (2) acute eosinophilic pneumonia (AEP)-like pattern, (3) hypersensitivity reaction (HR)-like pattern, and (4) organizing pneumonia (OP)-like pattern (Fig. 2).³ Fatal lung disorders have the DAD-like pattern in common, and the prognosis is poor regardless of the drug used. The characteristic features of drug-induced lung disease that should be noted here include: 1) the presence of imaging patterns associated with particular drugs; 2) poor prognosis for the DAD pattern regardless of which drug is used; 3) the likelihood that the DAD pattern will be limited to a particular category, namely, those with underlying interstitial pneumonia.

International Comparison in a Globalized Era

Is it true that Japanese people are especially



(Leflunomide-related lung injury in patients with rheumatoid arthritis: imaging features, *Modern Rheumatology*, 2005³)

Fig. 2 Four patterns of leflunomide-induced lung injury

prone to drug-induced lung disease?

Taking bleomycin as an example, the incidence of bleomycin-induced lung injury obtained through dividing the number of reported bleomycin-induced lung injury cases by an estimated number of patients who used this drug based on deliveries from warehouses (assuming the use of 200 mg per patient) is 0.66% in Japan and 0.01% worldwide, showing a distinct difference (in-house estimation).⁴ Similarly, the incidence of gefitinib-induced lung injury is 3.98% in Japan (case-control study, AstraZeneca), which is about 13-fold higher than the corresponding rate,

0.3%, in the USA (FDA Approval Letter).⁵ The incidence of leflunomide-induced lung injury in Japan was 1.81%, about 100-fold higher than the overseas rate of 0.017%⁶ (Table 2). The mortality rate from these drug-induced lung diseases was as high as 40%, with all deaths related to the DAD pattern.

On the other hand, cases of idiopathic pulmonary fibrosis (IPF) found in Japan have a high risk of acute exacerbations and often result in fatal outcome.⁷ However, acute exacerbations of IPF have not been well recognized in Western countries, showing a different clinical picture

Table 2 Comparison of the incidence rates of drug-induced lung disease in Japan and abroad

	Japan	Overseas
Gefitinib	3.98% (4,473 Japanese cases, AstraZeneca's cohort study)	0.3% (23,000 US cases, FDA Approval Letter)
Leflunomide	1.81% (3,867 Japanese cases)	0.017% (861,860 overseas cases)
Bleomycin	0.66% (3,772 Japanese cases)	0.01% (295,800 global cases)

The incidence rate is markedly higher in Japan than abroad for any of the causative agents.

Table 3 Risk factors of occurrence and prognostic factors of gefitinib-induced lung injury

	AstraZeneca expert meeting March 2003	WJTOG July 2003/June2004	AstraZeneca's special investigation August 2004
Method of analysis	Cases of onset (spontaneous report) n = 152	Retrospective, all cases n = 1,976	Prospective, all cases n = 3,322
Incidence of interstitial pneumonia	1.9%	3.8%	5.8%
Factors of occurrence		Male, Smoking history, Hypoxemia,* Idiopathic lung fibrosis**	Male, Smoking history, Interstitial lung disease History of chemotherapy
Prognostic factor	Male, Squamous cell carcinoma, Idiopathic lung fibrosis	Male,** PS2 or more, Early onset	Male, PS2 or more
Remarks	Relationship between imaging patterns and prognosis		No relation between the trough blood concentration and the incidence

* Added by the report in June 2004, ** Absent in the report in June 2004.

from Japan. It is noteworthy that among cases of dermatomyositis/polymyositis, fatal cases with less conspicuous myositis negative for Jo-1 [amyopathic dermatomyositis (ADM)] leading to DAD might be more frequent in East Asia.^{8,9,10} The difference in recognition of the clinical picture of the same disease between Japan and Western countries suggests the presence of ethnic differences in drug-induced lung disease between Japanese and Westerners.

Common Risk Factors of Lung Injury Found in Epidemiologic Research

Risk factors for the development of lung injury related to gefitinib include male sex, history of smoking, preexisting pulmonary fibrosis or interstitial lung disease, and history of chemotherapy,⁵ whereas such risk factors for leflunomide are

male sex, history of smoking, preexisting interstitial pulmonary lesions, age 65 years or older, and albumin levels of less than 3.0 g/dl.⁶ Thus, many risk factors exist in common.

In Japan, preexisting interstitial pneumonia/pulmonary fibrosis has been considered a risk factor for anticancer drug-induced lung injury, and patients with these conditions have been excluded from clinical trials. It has been reported that, for the use of gefitinib, preexisting interstitial pneumonia/pulmonary fibrosis is not only a prognostic factor after onset (expert meeting) but also a risk factor for developing lung injury (WJTOG survey, AstraZeneca special investigation) (Table 3). For the use of leflunomide, the incidence of lung injury in patients with and without preexisting interstitial pneumonia/pulmonary fibrosis was 10.2% and 1.2%, respectively, a 10-fold difference.

Table 4 Case-control study within a cohort (Nov. 2003–Feb. 2006)

Total registered cases: n=4,473 (goal n=6,000)

ILD: 155 cases (No. of cases assured by an independent evaluation committee: 122)

a: Crude cumulative incidence of ILD from a cohort analysis set

Initial registry cases	Iressa	Other chemotherapy	Total
Total	1,482	1,677	3,159
ILD number	59	35	94
Incidence % (95% CI)	3.98 (3.05–5.11)	2.09 (1.46–2.89)	2.98 (2.41–3.63)

b: Incidence of ILD adjusted for imbalance between different treatments

	Cumulative incidence (95% CI)
Gefitinib	4.5% (2.4–8.4%)
Other chemotherapy	1.9% (0.8–4.6%)

Cumulative incidence of ILD assuming that the whole cohort were treated by one of the two options.

c: Vital prognosis of patients after onset of ILD

	Death by ILD	Surviving from ILD
Gefitinib	31.6% (n=25)	68.4% (n=54)
Other chemotherapy	27.9% (n=12)	72.1% (n=31)
Total	30.3% (n=37)	69.7% (n=85)

Once ILD occurred, the fatality was about 30%, regardless of the drug used.

(Interstitial lung disease in Japanese lung cancer patients—A cohort and nested case-control study, *Am J Respir Crit Care Med*¹¹)

The results of a case-control study of gefitinib within a cohort of 4,473 patients were reported in September 2006. In this study, lung injury was found in about 4% of patients on gefitinib, in contrast to about 2% among patients on conventional chemotherapy (Table 4a). The 3-month cumulative incidence of interstitial lung disease (ILD) adjusted for imbalance between different treatments was estimated to be 4.5% for gefitinib therapy and 1.9% for other chemotherapy (Table 4b). However, once ILD occurred, the mortality rate was approximately 30% in any treatment group (Table 4c).¹¹ These results suggest that different factors were involved in the onset and prognosis of ILD.

We presume the existence in the Japanese population of a subgroup of individuals who are prone to fibrosis and susceptible to fatal lung

disorders. This group is considered especially vulnerable to pulmonary fibrosis, characterized by acute exacerbations of IPF, and also has a common genetic predisposition related to drug-induced lung disease.

Genetic Predisposition in the Japanese Population

It has been pointed out that the high frequency of gene mutations of EGFR tyrosine kinase in Japanese female patients with pulmonary adenocarcinoma is reflected in the difference in efficacy of gefitinib. Missense mutation (exons 18, 19) and deletion mutation (exon 21) of EGFR tyrosine kinase are found only in tumor cells. Gefitinib is highly effective for tumors showing the cell growth of EGF-EGFR dependency through

Table 5 Autophosphorylation sites of tyrosine kinase

	wild	Point L858R	Deletion L747-P753
Y845	–	+	–
Y992	–	+	+
Y1045	– +	– +	– +
Y1068	–	+	+
Y1173	– +	– +	– +

Phosphorylation in Y992 and Y1068 is constantly seen with both point mutation and deletion mutation. Gefitinib acts on tyrosine kinase to exerts therapeutic effects.

(Gefitinib-sensitizing EGFR mutations in lung cancer activate anti-apoptotic pathways, *Science*, 2004.¹² Activating mutations in the EGFR underlying responsiveness of NSCLC to gefitinib, *New Engl J Med*, 2004¹³)

Table 6 Analysis of the efficacy of gefitinib in Taiwanese patients

	Odds ratio	95% Confidence interval	P
Female gender	10.9	1.78–67.0	0.01
BAC	9.71	1.46–64.4	0.019

BAC: bronchiolo-alveolar carcinoma

Extraction factors of EGFR mutations by logistic regression analysis.

Female gender and a histologic type of bronchiolo-alveolar carcinoma showed a close correlation with the presence of EGFR mutations. The above results are similar to the results of analysis in Japanese patients.

(Female sex and bronchioloalveolar pathologic subtype predict EGFR mutations in non-small cell lung cancer, *Chest*, 2005¹⁴)

continuous autophosphorylation (Y992, Y1068) resulting from these mutations. The high response rate to gefitinib therapy among Asian patients has been attributed to these characteristic features (Table 5).^{12,13} The incidence of lung injury related to gefitinib therapy is markedly low as compared with the rate of its efficacy. However, it is inferred that gene hunting, an approach relatively easy to address, is useful for elucidating the mechanisms of the efficacy and adverse effects of molecular-targeting drugs. A study of 35 patients in Taiwan revealed EGFR gene mutations in 17 patients, with such mutations being more frequent among women than men [23% (4/17) in men vs. 72% (13/18) in women]. A logistic regression analysis also showed that female sex (odds ratio, 10.9) and bronchiolo-alveolar carcinoma (BAC) (odds ratio, 9.71) are important factors related to gene mutations (Table 6).¹⁴ However, most of these EGFR gene mutations are heterozygous, and it is unclear why such mutations are more frequent in females and in BAC.

On the other hand, drugs that inhibit pyrimidine biosynthetic enzymes of lymphocytes, such as leflunomide, require a multifaceted understanding that includes induction of infection. It

is also necessary to consider the pathogenesis of respiratory complications besides gene mutations. Investigation of common factors from a cross-sectional viewpoint is required to better elucidate fatal lung disorders.

Conclusion

The sensitivity of the Japanese population to drug-induced lung disease has attracted attention following the development of gefitinib- and leflunomide-related adverse effects. Since the incidence of drug-related adverse effects is not especially high, the efficacy of a drug and its side effects tend to be studied in different areas of specialization, causing inevitable difficulties in research. To ensure the use of safe drugs among Japanese patients in a globalized market for drug development, it is necessary to further clarify the situation of drug-induced lung disease in Japan, make it internationally recognized, and link it to the development of safe and effective treatments through sincere efforts by academic societies, commercial enterprises, and the government. We understand that we are at the starting line of such action.

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Measles Outbreak in Adolescents

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Key words Measles, Adolescent, Vaccination, WHO

In the spring and summer of 2007, the largest measles outbreak since 2001 spread across Japan, causing hundreds of universities to close. More than 50,000 university students were affected by campus closures. The outbreak started in the Tokyo area, spread to the Osaka area and then right across Japan. The outbreak affected Waseda University and Keio University, the oldest and most prestigious private universities in Japan. In addition to universities, many high schools were also closed. A notable characteristic of this outbreak was the high incidence in adolescents. Data from the Infectious Disease Surveillance Center¹ defined two peaks of measles patients. One peak was among infants less than 2-year-old who had not received the measles vaccination, and the other peak represented people in their teens and early twenties. Nearly two-thirds of these adolescent patients had not been vaccinated nor were aware of their immunization record, whereas the remaining patients had received the measles vaccine once.

Measles predominantly affects infants and children, so why did the 2007 measles outbreak hit adolescents? First, the vaccination rate was low in this age range. In 1989, a trivalent measles-rubella-mumps (MMR) vaccine was introduced to the Japanese vaccine program and administered to infants. The MMR vaccine caused an increased number of aseptic meningitis cases,² which was attributed to the Urabe-strain used to prepare the mumps vaccine. As a result, the MMR vaccine was withdrawn in 1993 and only a monovalent measles vaccine was administered thereafter. However, in the interim period, many parents did not vaccinate their children because of potential side effects, resulting in a low

vaccination rate in this age group. In addition, secondary vaccine failure may have occurred in the adolescents who received the vaccine but still contracted measles. The live, attenuated measles vaccine is very effective and gives 95–98% protective immunity in vaccinated individuals. Secondary vaccine failure results from waning immunity. Since measles is uncommon in Japan, people rarely encounter measles patients and are not naturally boosted. The loss of this natural boosting may increase secondary vaccine failure in adolescents, because immune memory lasts only for 10–15 years. On the other hand, adults older than 30 years were much more likely to have contracted measles naturally or were boosted by contacts with measles patients.

This measles outbreak shows that measles is still endemic in Japan, although its incidence has been gradually decreasing. The first measles outbreak was described in 994. During the Edo dynasty (1600–1867), measles outbreaks were frequent in Tokyo city, and measles was considered a life-determining disease (Fig. 1). Measles has been eradicated in the Americas and is being eliminated in Europe. On the other hand, Japan is notorious as a measles exporting country.³ The World Health Organization (WHO) defines three sequential phases for measles eradication: 1) measles control phase, 2) measles outbreak prevention phase, and 3) measles elimination phase.⁴ Japan is still in the measles control phase, in which a significant reduction in measles incidence and mortality is observed but measles is still endemic. In spite of the longest life expectancy and the lowest infant mortality in the world, Japan is struggling to eradicate measles. Political will is needed to eradicate measles from

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Fig. 1 Nishiki-e in 1886 describing how to treat measles

Three men are getting rid of measles, whose symptoms such as headache, thirst, delirium, and weight loss are personified. Courtesy of Naito Museum of Pharmaceutical Science and Industry.

countries, and it seems that Japan has lacked the political will, which is largely due to the Ministry of Health, Labour and Welfare of Japan.

In 2001, WHO and United Nations Children's Fund (UNICEF) released a joint statement on strategies to reduce measles mortality worldwide.⁵ In the statement, the following strategies were recommended to achieve and maintain interruption of indigenous measles transmission: 1) routine immunization with very high immunization coverage (i.e. >95%), 2) second opportunity for measles vaccination, 3) measles surveillance (i.e. investigation and laboratory testing of all suspected measles cases), 4) improved management of complicated cases. In Japan, measles immunization coverage used to be 80–90%. After the withdrawal of the MMR vaccine, the Ministry of Health, Labour and Welfare did not take effective action to control measles until 2006, and detrimentally changed the Preventive Vaccination Law in 1994. Under the altered law, measles vaccination is not mandatory but only recommended to infants in Japan. In contrast, the USA introduced the MMR vaccine in 1971 and a second dose of the vaccine in 1989. The USA achieved more than 95% measles vaccine coverage, mainly because an updated immunization record is required to enter schools and nurseries.

Since 1997, the annual incidence of measles has been less than one case per million in the USA.⁶ The few cases that have occurred were internationally imported or linked to imported cases. In a joint statement, the WHO and UNICEF set eradication goals for each large geographical area to achieve and maintain interruption of indigenous measles transmission: the Americas by 2000, the European Region by 2007, and the Eastern Mediterranean Region by 2010.⁵ Measles has been eradicated from the Americas and nearly eradicated from the European Region. How about Japan? Is any action being taken against measles?

In 2006, the Ministry of Health, Labour and Welfare of Japan introduced a divalent measles and rubella (MR) vaccine to routinely vaccinate 1-year-old infants. The ministry also introduced a second MR dose to all 5-year-old children as a preschool immunization. This dose regime is aimed at boosting immunity in order to avoid secondary vaccine failure. In addition, vaccine surveillance was reinforced. The measles incidence was measured by the number of patients diagnosed in a selected number of medical facilities. Recently, an increasing number of prefectural public health institutes has started investigating all measles cases, as recommended

by the WHO surveillance standard. Moreover, recent immunization coverage is reported to be over 95% among 2–4-year-old children.¹ Due to high immunization rates, 2–7-year-old children escaped the 2007 measles outbreak.¹ This measles outbreak is subsiding and its final size is expected to be smaller than that of 2001.

With all these efforts, the measles endemic should soon end and measles should be eradicated from Japan by 2012, the target eradication year set by the WHO for the West Pacific area. We also hope that Japan will no longer be blamed as a “measles-export-country.”

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Recent Activities of the Toyama Medical Association

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As of April 2006, a new executive director of the Toyama Medical Association, the author of this article, was chosen to replace Dr. Katahisa Shinokawa, the outgoing executive director of the Association. Although the new executive director will continue to carry out projects initiated by his predecessor, new ideas and strategies may be applied when necessary, particularly with regard to various situations including responses to measures and policies arising from the reform of the medical care system initiated in 2006. Therefore, the association can be expected to carry out a variety of new approaches and measures.

Similar to other parts of Japan, the population of Toyama Prefecture has been decreasing. After peaking at 1,126,679 in January 1998, the prefecture's population had declined to approximately 1,100,000 as of April 2006. This decrease has been a result of declining birthrates and an exodus of young people seeking higher education outside the prefecture. This represents a major problem for Toyama, one that is complicated by an increase in the population of elderly citizens, resulting in a ranking higher than most prefectures in Japan. The Toyama Medical Association had a total of 1,585 member doctors as of April 30, 2006, as follows: category A: founder or manager of a medical facility: 732; category B1: manager of a public medical facility: 40; category B2: doctors working for a public or private medical facility: 721; and category C: doctors not covered by any of the above: 92. A new compulsory clinical training system for doctors in Japan was begun in 2004. Fifty trainee doctors of the system's first generation underwent clinical training in this prefecture, and 15 of the 50 eventually moved to medical institu-



tions outside the prefecture. Difficulty in securing hospital doctors and shortages of doctors in various specialties are major issues in Toyama Prefecture, as they are in various other prefectures as well. The tasks facing the medical association, future challenges, and efforts at change are described below.

Reorganization of City and County Medical Associations

Recent years have seen unification and consolidation among counties, cities, and municipalities in Japan. Such changes in administrative districts have caused changes in medical care zones. In response to these changes, county and city medical associations, which are at the forefront of local health care, have sought consolidation, reorganization, or unification. In Toyama Prefecture, the vision is one of centering the role of medical associations on the secondary medical care zone. This vision has prompted the reorganization of county and city medical associations, which is currently underway.

Each of the four medical care zones in this

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prefecture has an established pediatric emergency system that is highly regarded by community residents. However, there are difficulties in maintaining and developing these systems, and a plan for structuring an intensified emergency center has been discussed. Although the realization of this plan would require extension beyond the borders of secondary medical care zones, the key to success of the plan is to form a stable community-oriented structure. This is an urgent task whose completion would provide residents of Toyama Prefecture with improved community-oriented medical care, without requiring them to wait for possible revision of the current medical program.

Improvements in End-of-Life Care

Investigation into seven suspected cases of euthanasia at Imizu City Hospital, the most recent of which occurred in October 2005 and led to exposure of the other six cases, has highlighted problems involved in end-of-life care in Japan, and various discussions regarding this issue are ongoing. It may not be appropriate, however, for a single prefectural medical association to formulate standards for end-of-life care. While requesting that the national government create guidelines, Toyama Prefecture also is working to establish an agreement pertaining to standard end-of-life care. The Toyama Medical Association is working on this task together with the Toyama Governmental Hospital Directors' Council.

To further the topic of end-of-life care, training programs for doctors hosted jointly with the prefectural government and a public forum for residents of Toyama Prefecture hosted by this medical association were planned in 2006. Member doctors are highly interested in this issue, because of the aforementioned suspected cases of euthanasia in the prefecture. In order to respond to the interest of members, this prefectural medical association intends to provide further opportunities for training and to continue its consideration of this issue in cooperation with the residents of the prefecture.

Community Medical Activities of Toyama Medical Association

The Toyama Medical Association has its own home health care and support system. The medi-

cal resources of all the doctors who are members of the association are compiled in a database that is available to the public on the Association's Web site. This database serves as an important tool in promoting home health care, and we are attempting to further improve the database. Our medical association also has been commissioned to carry out two projects: the Cancer Etiology Survey and the Stroke Registry of Toyama Prefecture. In particular, the latter project has successfully compiled a list of almost all patients with stroke throughout the prefecture. This highly esteemed project provides various suggestions as to measures for the prevention and management of stroke, and will be continued into the future.

In 2006, the Toyama City Medical Association began to incorporate examinations that gauge "forgetfulness" in the screening of dementia in health checkups of prefectural residents. We are focusing our attention on the results of this attempt, and intend to extend this approach to the entire prefecture.

The Toyama Medical Association also has an agreement with the Toyama prefectural government concerning the provision of medical care services during disasters. We intend to work on making this agreement more precise.

Scholarly Activities and Lifelong Learning

Medical services need to be patient-centered. Therefore, it is our duty to provide patients with safe, high-quality medical care. To this end, medical care providers are required to update their medical knowledge and skills on an ongoing basis. To promote this continuing education, the Toyama Medical Association offers lectures and workshops on a variety of timely topics. In particular, we offer enriched workshop programs in the field of industrial health, and we assist doctors who wish to acquire qualifications as industrial specialists. We intend to continue offering this support.

Participatory training programs have recently become available. In particular, advanced cardiac life-support training sessions are offered three times a year in cooperation with the Department of Emergency/Disaster Medicine, School of Medicine, Toyama University. This program has been popular, and applicants have exceeded the enrollment limit each time. In addition, the Toyama Medical Association holds annual meet-

ings and provides grants for research done by members on such occasions. Many members apply for the grant program, and grants are given to an average of 10 applicants each year.

Establishment of a Clinical Trial Support Center

A clinical trial support center was set up in our medical association in September 2004 to promote the implementation of clinical trials in medical institutions in the prefecture. With the

cooperation of member doctors, several contracts have been made between sponsors and medical institutions. We intend to further enhance the activity of the clinical trial support center in the future. We consider that participation in this project represents an enhancement of scientific education. Efforts will be made to obtain further cooperation among members in promoting participation.

It is our duty to improve the role of this medical association by continuing to work together with our members.

Physician Shortage in Ishikawa Prefecture

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Kunio KONDO*¹

Ishikawa prefecture is located central north of Japan stretching north to south. It is a medium-sized prefecture with a population of 1.17 million. About half of the population is concentrated around Kanazawa City.

The membership of the Ishikawa Prefectural Medical Association is 1,594.

Impact of the New Post-graduate Medical Training Program

The new postgraduate medical training program initiated in April 2004 brought significant change to community health care in Ishikawa prefecture. There are two medical colleges in this prefecture, Kanazawa University Faculty of Medicine and Kanazawa Medical University, which have sent doctors to the local areas of this prefecture. Previously, 70% of graduates began their training program at university hospitals and 30% at designated clinical training hospitals. With the launch of the new program, however, more medical residents took the program at clinical training hospitals than at university. This was something unexpected. Furthermore, many local medical residents in the matching system expressed a preference for urban training hospitals, and very few remained at the local medical university.

The number of medical residents in Ishikawa prefecture is also decreasing. From 97 in 2004 to 66 in 2005 and 53 in 2006, the rate of decline is higher than that in other prefectures of Japan. Criticisms related to the problems of the training curriculum and the quality of the preceptors have been observed, but there are also problems uniquely related to the traditional local environment which are difficult to solve. Although the number of medical residents allowed at the Central Prefec-



tural Hospital increased from 4 to 6, more should be permitted to take the program at this hospital to improve community health, given the recent situation where it is difficult to provide enough doctors for the local area from the two colleges. It is necessary to secure more medical residents by participation in joint seminars hosted by the designated clinical training hospitals.

Ishikawa prefecture may be broadly divided into four regions, northern Noto, central Noto, central Ishikawa and Kaga. The average number of doctors per 100,000 population in Japan is 201. It is 146 for northern Noto, 130 for central Noto, 344 for central Ishikawa and 130 for Kaga, showing that doctors are concentrated in central Ishikawa. Under these circumstances, drastic changes in community health care have been observed, especially in northern Noto.

The total number of doctors in northern Noto was 63 in 2003, the year prior to the establishment of the new training program. It declined to 55 in 2006. This resulted from the return of many of the doctors working in the local areas to the university hospitals due to the lack of medical office staff in those hospitals. Although there are

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four general hospitals in this area, there are currently chronic shortages of nurses and doctors, and a hospital there has closed one of its wards of 50 beds. Furthermore, a vicious cycle is being observed in this hospital as many hospital doctors in middle management who are under heavy workloads leave the hospital to open their own clinic to practice medicine.

Measures to Resolve the Problems

In this age of continuously declining birthrate and aging population, it is becoming difficult to be sure of receiving sufficient health care whenever you need it. The following measures are some of those being implemented to counter this problem in Ishikawa prefecture:

(1) A "Community Health Program" was established, financially supported by Ishikawa prefecture. A total of 20 million yen or about US\$ 166,660 has been budgeted for this 2 year project. Practical training is provided to establish a networking system of the community health resources in northern Noto. Visiting the four general hospitals in Noto in every half-year, we are gathering information to develop a system for the more effective use of limited health resources.

(2) Operation of a human resource agency for community health. This agency registers doctors who retire from medical practice and come back to their hometown from other areas and arrange for their reemployment in the clinics in remote areas of this prefecture. One doctor was successfully sent to a hospital in Noto in April 2006.

(3) Creation of a physician training program. This is a 4-year program for doctors completing their residency. The first year involves training at the Prefectural Central Hospital, the second and third years consist of working in a local-government hospital in northern Noto and the fourth year consists of training in a tertiary medical institution such as the National Cancer Center. However, there have been no applicants for this program. We are currently reviewing its contents.

(4) A major issue is to secure a sufficient number of pediatricians, obstetricians and gynecolo-

gists. There is a national shortage of doctors in these specialties. No medical college graduates entered the medical office of the college for pediatrics, obstetrics and gynecology in Ishikawa in 2006. Behind this fact is the demanding work involved in these specialty areas and the impact of the declining birthrate. As a counter measure, a medical scholarship award program was newly created. In this program, a scholarship of up to 2,400,000 yen will be provided to medical students in their fifth and sixth years and to graduate students who are seeking to become pediatricians, obstetricians or gynecologists. The scholarships are awarded for up to 2 years. If these 2 years are spent working as permanent physicians in pediatrics or in obstetrics and gynecology at a local-government hospital, repayment of the scholarship is waived. Even more important than solving the issues of harsh work conditions and financial burden, the biggest problem is that of how to produce medical residents who really want to become specialists in pediatrics, or obstetrics and gynecology.

(5) The Ishikawa Medical Association in 2006 set up a Women Doctor's Committee. The number of women doctors in this prefecture is 40,040 as of 2004, accounting for 16.4% of all doctors. The ratio of successful applicants of women doctors in the national medical examination to the total stands at 33.7% in 2005 and it is expected to reach 50% in the near future. Health care which fully takes into account the activities of women doctors is essential. In comparison with US and Europe, however, there is a steep decline in the number of women working in their thirties in Japan due to marriage, child-bearing and child-care, and the difficulties in balancing work and child-care. Consequently, this may be a large contributor to the shortage of doctors in the fields of pediatrics, obstetrics and gynecology which attract more women doctors than other fields. Improvement in the work environment for women doctors to allow them to safely continue to work, including care for sick children with diseases, night childcare and a retraining program for women doctors would be key elements of a solution to the shortage of physicians.

Academic Activities of the Yamanashi Medical Association

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Shigemi KUBOTA*¹

The academic activities of the Yamanashi Medical Association include the hosting of Yamanashi General Medical Conferences by the Yamanashi Medical Society, publication of the medical journal *Yamanashi Igaku*, studies of schistosomiasis japonica, maintaining a hepatocellular carcinoma registry, hosting the Japan Medical Association's continuing medical education (CME) programs, and delivering Medical Association lectures at Yamanashi University that are hosted by the CME Committee of our association. This paper presents an outline of these activities.

Yamanashi Medical Society

The Yamanashi Medical Society, which comprises 27 sectional groups, is run by board members recommended by the respective sectional groups and those recommended by the president of the Yamanashi Medical Association. The main activity of the society is to host the Yamanashi General Medical Conference every year.

The 32nd such conference was held at the Yamanashi Medical Association Hall on March 12, 2006. It included 94 presentations (78 oral presentations and 16 poster sessions), a report on the Registration of Liver Cancer in Yamanashi Prefecture, and a special lecture entitled "Recent Progress in Charged Particle Therapy for Malignant Tumors: Recent Progress" given by Hirohiko Tsujii, Head of the Charged Particle Therapy Research Center at the National Institute of Radiological Sciences.

In 2004, the conference included a lecture entitled "Measures Tailored to the Prevention of Lifestyle-Related Diseases" delivered by Zentaro



Yamagata, Professor of Yamanashi University, two research reports, and bestowment of a Scientific Encouragement Prize from the Yamanashi Medical Association.

The Yamanashi Medical Society publishes an annual academic journal, *Yamanashi Igaku*, which includes original articles, proceedings of the general medical conference and records of the CME programs of the Japan Medical Association, and after deliberations by the editorial board, also includes reports of ongoing projects, special lectures, and research papers presented at the general medical conference. The latest issue, vol.34, was published in October 2006.

Research Projects

A major research project of the Yamanashi Medical Association on liver diseases began with a questionnaire survey on the topic that was implemented on the basis of a proposal made at a meeting of the Yamanashi Medical Society in 1983 that some meaningful research be carried out to mark the 10th anniversary of the society. In 1985, a research executive committee (Chair:

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Fumiyoshi Iida) was set up in the Yamanashi Medical Society to carry out a 10-year follow-up study of registered patients with liver disease resulting from schistosomiasis japonica and those with non-schistosomiac liver disease, with particular attention being given to the possible development of hepatocellular carcinoma. An overview of the results of the follow-up study was reported in 1997. A total of 791 patients, comprising 484 with schistosomiasis japonica and 307 controls, were followed and the presence of schistosomiasis was found to cause no significant effect on the development of hepatocellular carcinoma as a whole or in relation to the presence or absence of HCV antibodies. A report of the above results was published by Iida et al. in *Yamanashi Igaku* (1997;25:1–10), the *Journal of the Japan Medical Association* (1998;120:99–104), and the *Bulletin of the World Health Organization* (1999;77:573–581).

Later, another survey, Hepatocellular Carcinoma in Yamanashi Prefecture: a Case-Control Study, carried out from December 1998 to November 2001 revealed that alcohol consumption, HBs antigen, HCV antibodies, and a history of blood transfusions were significant risk factors for hepatocellular carcinoma. In October 2002, we organized the Executive Committee for the Yamanashi Medical Association Hepatocellular Carcinoma Survey, chaired by Ryuichi Iida, and a registry of cases of primary liver cancer was initiated, with the aim of registering all corresponding cases in the prefecture. A total of 1,204 cases were registered in the first 3 years: 558 cases in fiscal 2003, 369 cases in fiscal 2004, and 227 cases in fiscal 2005. Of these patients, 682 are alive and 424 have died. It is expected that, in another 5 years, the registry will be able to cover all existing liver cancer patients in Yamanashi Prefecture. Academic consideration will be initiated at that time.

A governmental project to establish a regional cancer registry was recently initiated. Based on our experience, our advice would be that the securing of a venue and personnel is the minimum required to promote the project. It is important to establish a well-organized body that allows for continuous registration through procedures kept as simple as possible and does not rely only on the efforts of a few particular individuals.

Continuing Medical Education (CME)

Each year in September, the Japan Medical Association provides weekend CME programs. For example, in 2005, well-known speakers gave the following lectures:

- “Problems in recent reproductive medicine: including sexually transmitted diseases of youth,”
- “Issues surrounding the diagnosis and treatment of Alzheimer’s disease,”
- “Recent trends in doping: with a focus on the National Sports Festival,”
- “Frontiers in the treatment of rheumatism,” and
- “What is metabolic syndrome? Toward the prevention of type 2 diabetes mellitus.”

In 2006, learned authorities gave the following lectures:

- “New-type influenza,”
- “Exercise and sports for the elderly,”
- “Gastroenterological surgery: an update,”
- “Usefulness of PET in the diagnosis and treatment of cancer,” and
- “Advances in chemotherapy of digestive tract cancer.”

Subjects were chosen from among those that were of most interest to members, and the programs were highly successful.

The CME Committee of our association holds medical association lectures at Yamanashi University twice a year. The 36th program, in 2005, provided the following lectures under the heading “Current status of Yamanashi University Hospital: distinctive activities of five specialties of internal medicine”:

- First Department of Internal Medicine: “Recent topics for digestive tract internal medicine,”
- Second Department of Internal Medicine: “Recent leading-edge practice of cardiovascular medicine,”
- Neurology: “Support for the intractable disease ALS,”
- Hematology: “Diagnosis and treatment of hematopoietic tumors,” and
- Third Department of Internal Medicine: “Radical treatment of diabetes mellitus and its complications.”

The 37th program included the following:

- “Medical safety management: safety measures in a university hospital,”
- “Measures against infection: measures against hospital infections including medications in a

university hospital,”

- “Measures for emergency patients: response to emergency cases in a university hospital,” and
- “Hospital-hospital cooperation and hospital-clinic cooperation: efforts of a university hospital.”

This program provided up-to-date information on treatment as well as crisis management in a university hospital, providing an opportunity to consider preparedness for potential crises in clinics.

In 2005, the Japan Medical Association offered

278 CME lectures, and the filing return rate was 76.8%.

The above is a brief description of our activities. We should be aware that CME is a public mission imposed on physicians to provide patients with high-quality medical care, while enhancing our own professionalism. We intend to continue providing academic activities that will enhance learning in the medical sciences and to provide medical care of high quality while also valuing the fundamentals.

Liberal Practice, Not Outside Control*¹

JMAJ 50(5): 423–426, 2007

Jörg-Dietrich HOPPE*²

The freedom of the medical profession has been in jeopardy

Ladies and gentlemen, dear colleagues,

If I might be allowed to say so—dear representatives of the German Bundestag, dear Minister—the latest Healthcare Reform did not meet up to our expectations; rather, it exceeded even our worst fears.

As a result, tens of thousands of physicians demonstrated last year—they protested and went on strike. This Republic had never seen anything like that before.

But what causes people who really only live for their profession to suddenly take to the streets? It is the feeling that medical activity is subject to total outside control.

Never before has the freedom of the medical profession been so in jeopardy. But at the same time, dear colleagues, never before have we fought so fiercely for the freedom of the medical profession—and that is something we can be proud of.

We demonstrated a new degree of solidarity, embracing physicians from all fields.

We took a common stand for patient care that reflects the fundamental ethical convictions of our profession.

We made it clear that it is impossible to provide good medical services without reasonable working conditions and a sufficient degree of freedom.

Ladies and gentlemen, this law solves none of the key problems in the health sector.

The Act on the Strengthening of Competition in Statutory Health Insurance (GKV-WSG) is way off the main target of the Federal Government of creating a secure, long-term financial basis.

The financing of the new Health Fund—essentially through wage-based contributions paid by employers and employees—does not put a single extra euro into the system. The limited resources are merely redistributed.

The future fixing of the general contribution rate by the Federal Government is ultimately nothing other than a global budget that will be the subject of renegotiation within the ruling government each year.

Even now, the discussions in the Coalition regarding financing of the government allocations to the health insurance funds indicate that the fixing of the contributions will primarily be governed by budget policy considerations—and less by the necessity of providing need-oriented medical services.

Destruction of the liberal practice of medicine

What does “Act on the Strengthening of Competition in Statutory Health Insurance” actually mean? Does it really strengthen competition? Who is supposed to compete with whom? Who are the customers, what are the goods? I know that sounds banal, but it’s an honest analysis. Because I doubt that a patient-oriented health sector can work according to the laws of the market economy.

I have the impression, and I must say this very clearly, that the principles of the pure market economy have been introduced here, not those of the social market economy, for example. First, the physicians are service providers, then the patients are sickness providers, then there is sickness as a subject of business, then the physicians become agents in the medicine business and finally, ladies and gentlemen, we have assembly-line medicine

*¹ This is an English version of a speech originally made in German by Prof. Jörg-Dietrich Hoppe, the President of the German Medical Association and the German Medical Assembly, at the Opening of the 110th German Medical Assembly in Münster on 15 May 2007.

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for the sick—is that really a development we want to see?

Above all, I can see one principle behind this development: the denationalisation of provision for elementary requirements and the nationalisation of the procedures for providing medical services. That is the constant principle of all the so-called Healthcare Reforms of recent years.

Liberal practice, ladies and gentlemen—the independence of the physician in selecting a therapy, on which the patient was previously able to rely—this liberal practice is apparently a disruptive factor in a system of state-controlled health management.

“Streamlining of the market” in the hospital sector

Physicians are intended to practise rationing and work in competition with each other—that is all the strengthening of competition means for physicians and patients. And what does that mean explicitly? What does competition mean for the in-patient sector, for example?

The increasing privatisation in the hospital sector is unfortunately also being accompanied by a concentration process—or “streamlining of the market” in the hospital landscape, as the health economists put it.

The Rhenish-Westphalian Institute for Economic Research (RWI) calculated that roughly 10% of all hospitals will disappear from the market by the year 2010. The simple comment on the subject in the Institute’s 2006 Hospital Rating Report:

“Streamlining of the market improves system efficiency.”

It says that hospital closures will primarily be governed by business management criteria, not by the security of provision of medical services. Even the experts from the RWI state that gaps in provision could thus arise in principle.

Because of this increasing economisation, ever fewer hospitals are willing to employ physicians who have not yet acquired any specialist qualification. Given that there is already a shortage of physicians in certain disciplines—in general practice, for example—this is a frightening prospect with fatal consequences for the provision of medical services.

Smaller hospitals, particularly municipal hospitals, are hardly in a position to bear this burden. They can recommend themselves as takeover

candidates, at best. In that case, strengthening competition benefits only the big players in the hospital landscape—the small ones fall by the wayside, and the provision of basic in-patient care suffers a serious blow.

Is that what we want, is that what we really want?

True, the Ministers of Health of the Länder have said time and again that they intend to defend their responsibility for the structure of the hospital landscape. But just a look at the past gives more than enough reason to doubt their words.

But what will the people in structurally weak areas do then? The aged and the chronically ill already have difficulty finding a general practitioner. They are reliant on medical services being provided near to their home. These people would then have to travel even farther to the nearest hospital, and the waiting times would be longer still.

Waiting times, staff cutbacks and restrictions of the range of available services—that, ladies and gentlemen, is called structural rationing. No one knows whether they will be hit, and no one knows when they will be hit.

The special sacrifice was not even justified when the Reform materialised, and certainly not in times of an economic upswing. The public sector can expect 20 billion euros more in revenue this year alone, and even as much as 40 billion next year.

Medicine and economisation

In the outpatient sector, too, the ministerial bureaucrats have done their very best to push the responsibility for rationing onto the physicians. After all, the state would not like to be identified with the consequences of resource limitation. Consequently, the Federal Joint Committee—which is de jure still an instrument of self-administration, but de facto an executive agency—is now to play a key role in deciding on distribution of the scarce funds, and to regulate the quantity of services and also the content of services via quality control measures.

So, on what health policy blueprint is this law based? Let me summarise the key points once again:

- Establishment of a centrally planned economy for the health insurance funds,
- “Streamlining of the market” in the hospital

- sector, with implicit rationing,
- Establishment of a state-supervised rationing agency in the outpatient sector, and
 - Destruction of the liberal practice of medicine.

I am firmly convinced that the GKV-WSG is preparing the ground for “citizens insurance.” How else can we interpret the incorporation of elements of statutory health insurance in private health insurance, and of elements of private health insurance in statutory health insurance? The structures are being matched first, before the differences are ultimately eliminated completely.

I can tell you what that’s aiming at: a national insurance plan with standard contributions and standard medical services. But we don’t want that, and neither does the public.

Medicine is undoubtedly engaged in a conflict with economisation, and clandestine rationing is the tactical tool.

For steady provision of good medical services

The question is: how can good medical services for the entire population be guaranteed on a sustainable basis—despite demographic developments, despite the dire financial straits of the statutory health insurance system, and despite constant attempts to standardise medical treatment.

How much individuality of treatment will still be possible in the face of these trends towards industrialisation? The answer to this question will be decisively dependent on the extent to which we physicians are still able to practise our profession on an independent and self-determined basis in the future.

But good medical practice presupposes special confidence and trust. Patients quite rightly expect their physicians to give them individual treatment in keeping with the possibilities offered by modern medicine. However, it is becoming increasingly difficult to meet this rightful expectation.

The everyday medical world is characterised by poor working conditions, a lack of time and financial resources, and excessive bureaucracy. State-prescribed compulsory documentation takes time that is lost for the treatment of patients.

Politicians keep calling for more “narrative-based medicine,” and then they go and abuse junior physicians to feed the bureaucrats.

The provision of medical services is increas-

ingly being controlled by planning targets for patient care—be it in the form of Disease Management Programmes or Diagnosis-Related Groups—and most recently also by industrialisation trends in the hospital sector.

A kind of complete control of medical activity is the economic counterpart of what we have experienced as a culture of mistrust in the political sphere.

But the individual nature of the patient-physician relationship eludes state control and economic planning *sui generis*.

Things must stay that way, and not even the latest attempt at surreptitious surveillance must be allowed to change that.

Confidence is dependent on confidentiality

Ladies and gentlemen,

Confidence is dependent on confidentiality. Patients must be able to reveal their complaints to their physician without reserve. They must be able to rely unconditionally on everything they tell the physician being subject to medical confidentiality and remaining secret. Patient secrecy is one of the most important rights of patients. However, the bill on reforming telecommunications surveillance, and the plans relating to the retention of data for future use, fundamentally jeopardise the highly personal, confidential relationship between physician and patient.

The preservation of confidentiality must continue to have top priority. That equally applies in connection with introduction of the electronic health card. The technical solutions must be designed in such a way that the patient-physician relationship enjoys unrestricted protection and the data remain confidential, regardless of the legal situation.

The access of unauthorised persons to highly sensitive patient data must also be categorically ruled out in the future—otherwise, we face the threat of permanent surreptitious surveillance in this quarter, too.

Given the current orientation of the electronic health card project, it would appear to serve only administrative processes, such as e-prescriptions or simplification of administrative procedures at the health insurance funds.

Future of transplantation medicine

Another topic greatly influenced by confidence

in us physicians is that of organ donation. Ten years after adoption of the Transplantation Act, we intend to hold in-depth discussions of the future of transplantation medicine in Germany at this Medical Assembly.

Although organ donation meets with widespread approval in our society, we nevertheless face a major shortage of donated organs. 12,000 patients are waiting for an organ, hoping for a new life. But three people on the waiting list die every day.

The National Ethics Council has now called for a kind of objection-based solution for organ donation throughout Germany. This proposal is also supported by many physicians involved in transplantation medicine. We will discuss the subject openly and honestly in the next few days and also examine the possibilities of living donation in detail.

At the German Medical Assembly here in Münster, we will discuss our ideas regarding a health policy programme and illustrate options for a reform for a competitive, multiple-payer health insurance system.

Absolute priority on the provision of good medical services for sick people

After all, the road to a national insurance plan is not an absolute “must,” nor must it emerge as an inevitable matter of course!

What we need is not a political corset for off-the-peg medicine, but—at last—framework conditions for practising the medical profession under which the provision of good medical services for sick people has absolute priority.

Last year, we physicians made it quite clear that we are no longer willing to compensate for the under-financing of the statutory health insurance system by doing unpaid work. We therefore once again call on the government to keep its promise and at last abolish the budgets for the provision of medical services.

We are simply no longer capable of rendering high-quality medical services under the pressure of permanent budgeting and increasingly tough price competition.

We want to help our colleagues in the field, explicitly and continuously, quarter by quarter, by addressing the health policy topics they need to inform their patients.

A European Perspective on the Clinical Research Ethical Review Procedure

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Frank WELLS*¹

A major challenge that exists for each of the, now 27, member states in the European Union is how to adopt a Directive whilst still retaining all the national characteristics within the particular field that is to be covered by that Directive.^{*2} On the other hand, the adoption of a European Directive can provide a good opportunity to alter, or even abandon, national characteristics that have become outdated or are inappropriate or irrelevant.

One such Directive, known as the Clinical Trials Directive, was introduced in 2001 (20/2001/EC),¹ which required member states to adopt the principles of good clinical (research) practice where they had not already done so and, particularly, to establish research ethics committees. For some member states these had, in practice, been in operation for many years, but in others the ethical review procedure for clinical trials was vestigial and, for them, the implementation of this Directive presented a number of problems.

The European Forum for Good Clinical Practice (EFGCP) is a not-for-profit organisation, based in Brussels, which exists to promote, in its widest sense, and across the board, uniformly high standards for the conduct of clinical research. It is a confusing convention that, throughout the clinical research community, the word 'research' has been dropped from the phrase 'good clinical research practice', but that is what 'good clinical practice' (GCP) means, certainly in the context of this article.

One of the key features of the strategy of the European Forum for Good Clinical Practice (EFGCP) has always been to promote European values and principles in ethics across the EU mem-

ber states and in international research. The standards against which this should be achieved were, by general agreement, set out by the Declaration of Helsinki of the World Medical Association,² the International Conference on Harmonisation (ICH) process as it applied to good clinical practice (GCP)³ and, as far as Europe is concerned, were included within the Clinical Trials Directive.¹ All these important policy documents included reference to the structure and function of independent ethics committees established to provide the ethical review of all clinical trial protocols.

EFGCP operates through conferences, workshops and working parties and it was the EFGCP Ethics Working Party that felt that the advent of the Clinical Trials Directive presented a golden opportunity to ascertain exactly how this extremely important Directive, which was drafted to ensure that clinical trials throughout Europe were all conducted to the same high standard having been subjected to a proper ethical review, had in practice been interpreted in each of the 25 member states. We felt that reporting on the structure and function of research ethics committees in every member state was important, given that such a review had not been conducted previously by anyone else and that nobody seemed to know what was happening outside their own country in this regard.

We were particularly mindful that one of the functions of EFGCP is to observe the methods by which member states fulfil the various Directives of the European Commission that affect the conduct of clinical research to GCP standards. Thus it was in early 2005 that the EFGCP Ethics

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*2 A Directive is a form of European Legislative instrument which is binding as to the effect to be achieved but permits the Member State to choose the form and method of legislative implementation.

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Working Party recognised that the ethical review processes in the various member states varied widely and that, in the context of multi-national research, it was not easy to be sure that ethical review had been consistent across the whole of Europe. The Working Party even wondered whether the differences between operational policies in the various member states might interfere with the aims of the Directives. Furthermore, whereas a sponsor could be reasonably confident that it understood the ethical review process that operated in the member states in which it regularly conducted research, it was sometimes difficult to gain access to the ethical review process in other member states in which it might wish to conduct research in the future.

A subgroup of the EFGCP Ethics Working Party was established, specifically to ascertain in detail exactly what were the structures and functions of research ethics committees across the 25 member states of the EU. The nine members of the subgroup came from eight different member states, which made it easy for us to share the work that had to be done. In practice, we acknowledged that Luxembourg relied wholly on Belgian legislation in this regard, and, because much clinical research emanates from, or is conducted within, Switzerland and Norway, we took a pragmatic decision to add these two countries to our project.

The differences we discovered were widespread. For example, roughly half the member states specify that an application should be made to an ethics committee by the sponsor, whereas the other half specify that it should be made by the chief investigator. Another example revealed the different methods by which a single opinion is obtained for a multi-site application within any given member state: some countries designate which committee out of several, whereas others only have one committee for the whole country anyway. The most striking differences arose in the areas of training for members of research ethics committees and of quality assurance, assessment and accreditation of such committees.

We were particularly interested in the independence of research ethics committees (RECs). For some time there has been concern within the research ethics community that the equivalent

bodies to RECs in the USA are institutional review boards (IRBs) which, by definition, cannot be truly independent as they are based on specific, usually academic, institutions. In general, we found that RECs in Europe are constituted in such a way as to ensure that the independence of committees and of individual members is safeguarded, but there were some member states that clearly followed the institution-based model. However, where appropriate safeguards are in place, even institutional review boards can demonstrate that they operate independently; but such safeguards are not always there. It is therefore important that bodies such as the WMA and EFGCP strive to ensure that any committee conducting ethical reviews of research projects involving human subjects is truly independent in its constitution and in its decision-making processes.

EFGCP hopes that this report⁴ published in January 2007 will be of practical use to sponsors, investigators, regulators and those that have responsibility for setting research ethics committees up and subsequently approving them. The report could not have been produced without the invaluable help and co-operation provided by the many persons within the member states who have provided information that has been gathered together.

Finally, the development of the research ethical review process in Europe is inevitably in a state of flux. Recent entrants into the EU have clearly striven to achieve the requirements of the Directive and of its recent companion on GCP (2005/28/EC).⁵ New candidates for EU membership, notably Bulgaria and Romania, have yet to demonstrate their adoption of these Directives but no doubt they will. Even within well-established member states we found that the detail of how ethical review was actually being conducted was constantly changing. However, by referring to the relevant websites for the various countries, readers will be able to check for themselves the exact situation pertaining at any given time. The challenge of safeguarding research subjects is a highly responsible one for research ethics committees throughout the world. Our awareness of the importance of this challenge should go some way towards ensuring that the highest possible standards of clinical research practice are attained.

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My thoughts among the relics in Rome

Together with Mr. H Tsuruoka, international manager of JMA, I had an opportunity to visit the Italian Medical Association in Rome at the end of August, following a whole-day discussion on the revamping of the World Medical Journal (WMJ) at the office of the American Medical Association in Chicago. At the sophisticatedly designed office of the Italian Medical Association in central Rome, the association's Vice-President, Dr. Benato, and his colleagues welcomed us warmly. We had a fruitful discussion, exchanging views and information on recent healthcare issues in both countries. A PPT presentation by the Italian doctors provided ample information about the country's health system.

On entering the international section of the association, we were delighted to find a copy of the JMA Journal Issue No.1 of this year on the shelf and on the wall a Japanese-language anti-tobacco campaign poster which was printed in Japan as part of the JMA's advocacy efforts. Finding these items made us feel very much at home at the Italian Medical Association.

We learned that Italy has already introduced a universal health insurance system like Japan, a system whose results are characterized by a longer life expectancy and very low infant mortality rate. It was clear that our two associations share common issues for the present and future, even though there are several differences in the statuses and structures of the two systems, such as changes in disease structure and demographic composition with a growing aged population in the society and the challenge of introducing new tools into healthcare, such as a flying doctor program and other cutting edge technology, including IT.

Amongst the magnificent architecture that still remains scattered around Rome today is a monument to the lofty spirit and sound intelligence of mankind that has been preserved since the time of the Roman Empire. If we look back

on the history of medicine, there has been a universal and basic demand by people and societies for high-level medical treatment for individual patients and for general healthcare services which can be provided at a reasonable and appropriate cost. The efforts required to achieve this task may not be the same kind as those which created a new monument in stone, but it is nevertheless a challenge which should be undertaken with human wisdom.

I understand that the Italian Medical Association has been withdrawn from the WMA for a long time. I truly believe that the absence of the Italian Medical Association is a loss to the WMA as a large body representing physicians around the globe.

I sincerely hope that we will continue to further deepen the ties of friendship and mutual communication of health related ideas between our two associations. It is also our hope that the Italian Medical Association, which has such a rich history and solid achievements, will consider rejoining the WMA in the near future.

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Commemorative medal of the Italian Medical Association