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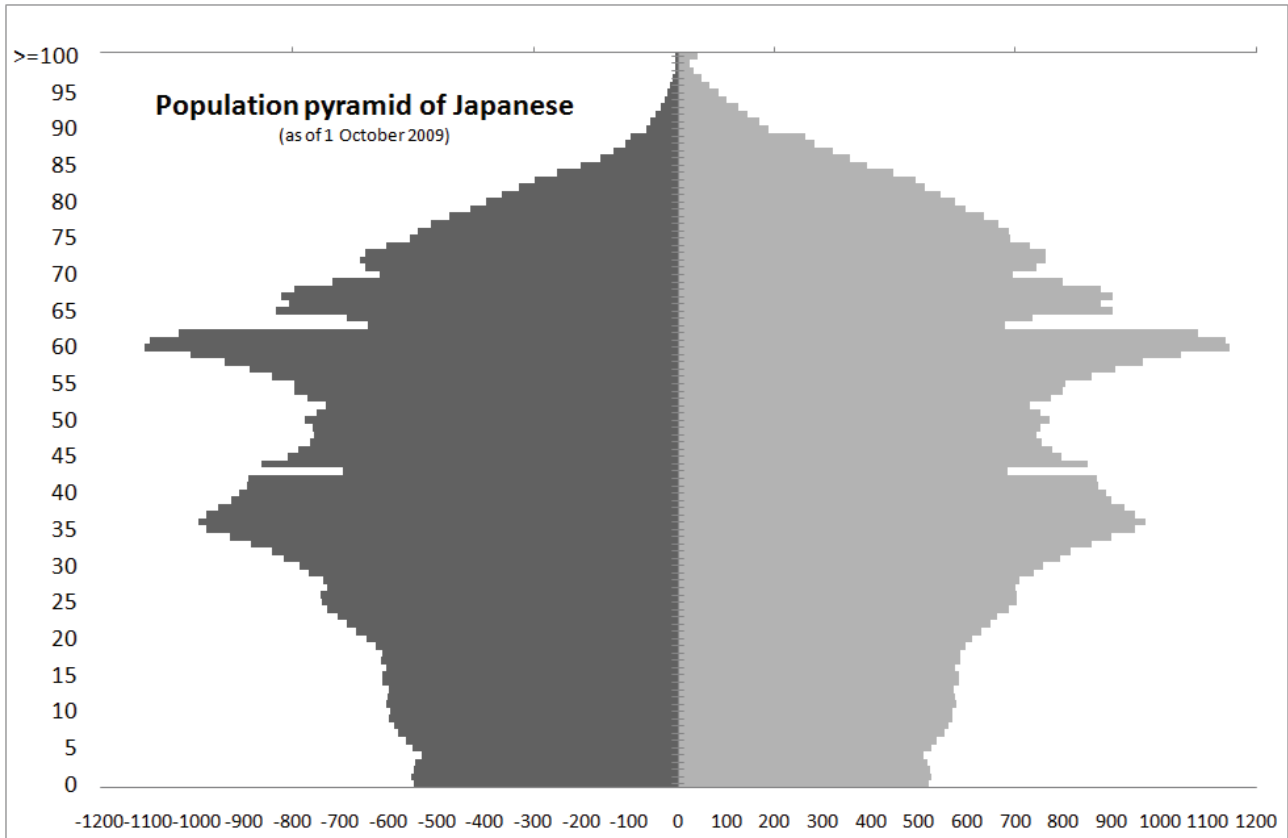
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Overview

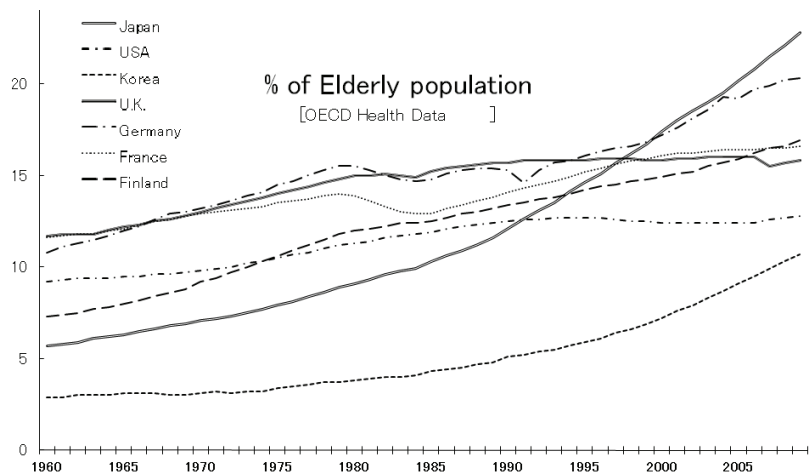
1. Demographic Trend of Japan

According to the estimate as of 1st October 2009, Japan's population is estimated to be approximately 127 million or approximately 1.9% of the world population (6.67 billion). As of 2007, Japan ranks as the 10th country in terms of population but is soon expected to slip out of top 10 due to stagnant population growth. Approximately 1.7% (2.2 million) of the population is foreign residents (also 1.13 million Japanese citizens are living abroad).



The year 2005 marked a mile stone in Japan's population history: it showed the first natural decrease in population. The number of deaths in the year (1,083,796) surpassed the number of births (1,062,530) for the first time, or 21,266 natural decrease of the population. According to the future population forecast, Japan has reached its peak population one year earlier than originally expected (2006) and will decline thereafter. In 2100, the population will shrink to 64 million, roughly the half of the present population (level of 1930).

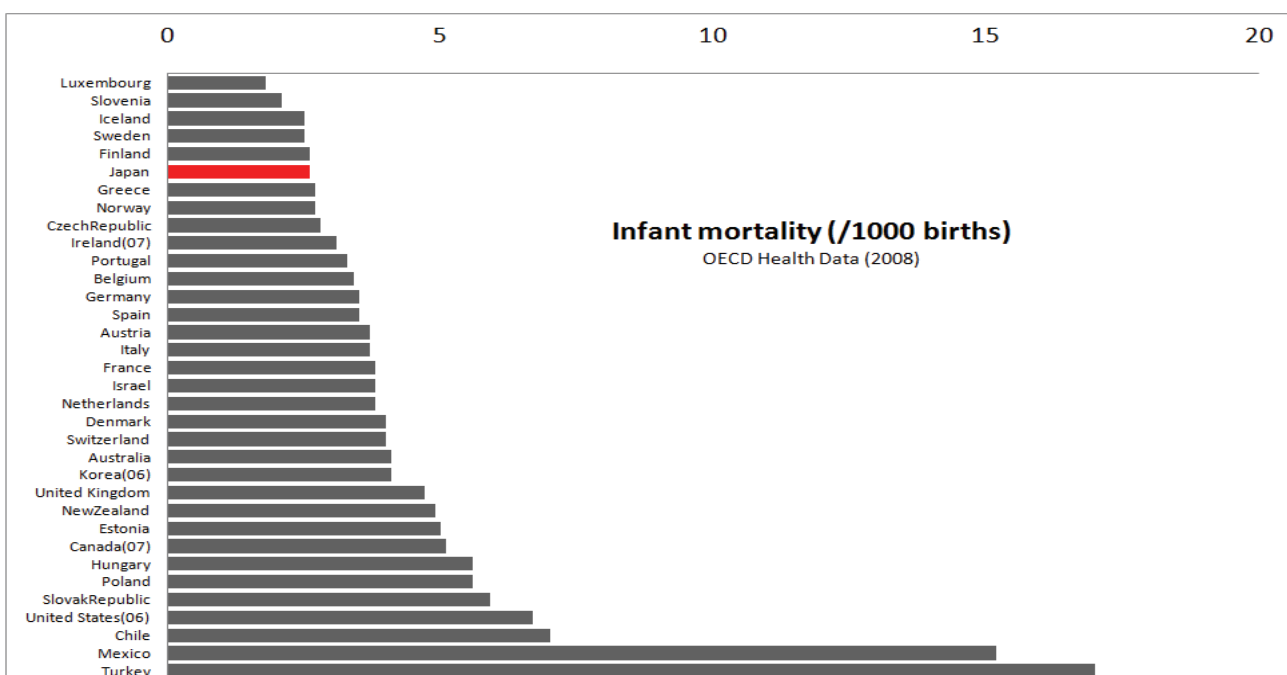
Due to the sharp decline of birth rate, Japan's population pyramid does not appear a



pyramid any longer; rather it appears as a “mush room”. As the two protrusions indicate, Japan has seen baby booms twice: one shortly after the Second World War (1947-50) and second in early 1970s. Japan will face an unprecedented aging society when the first baby boomers (now over 60 years old) retire.

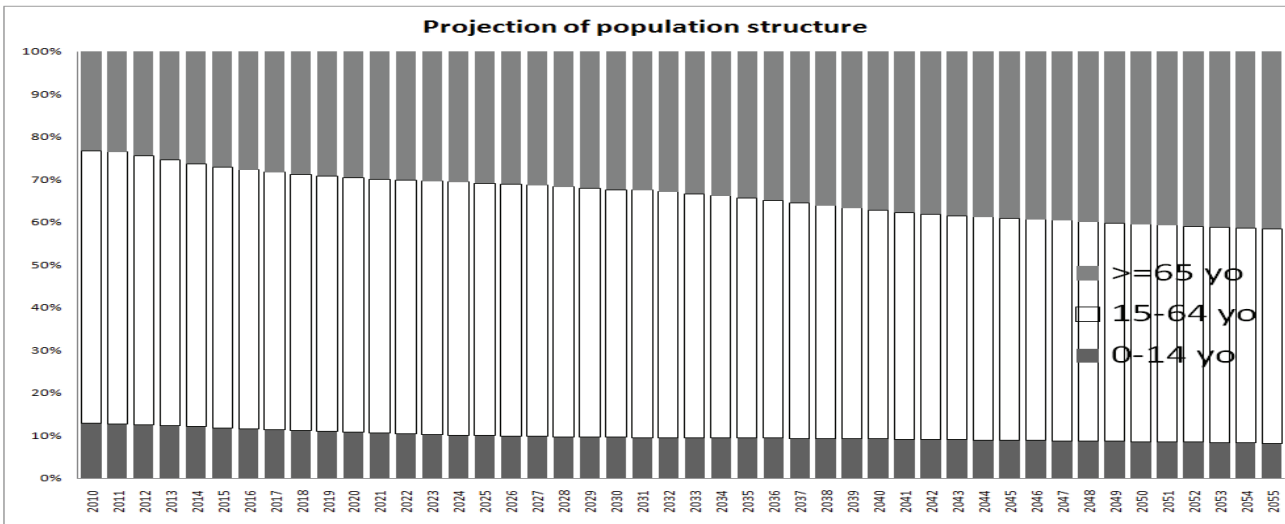
The stagnant population growth can be explained by sharp drop of birth rate. The crude fertility rate hit the record low of 1.25 in 2005. Japan is one the countries with the lowest crude fertility in the world following Italy (1.26) and Korea (1.17).

On the other hand, mortality has consistently improved over the years. The improvement has been most prominent in infant mortality. Japan now boasts the world’s lowest infant mortality with only 2.6 out of 1000 newborns die within the first year (2008). This figure was less than half of that of the U.S. (6.7 in 2006).

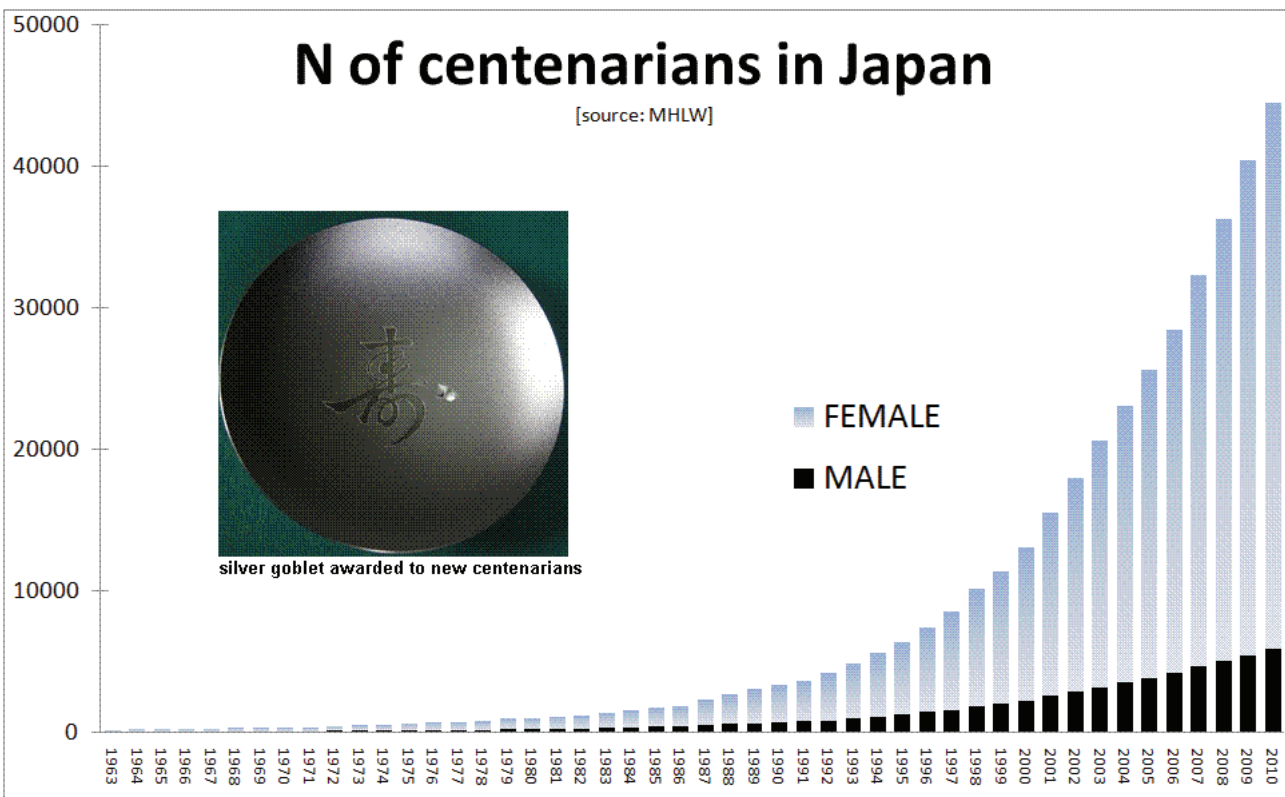


Improvement of mortality has prolonged life span to one of the longest in the world: 78.53 years for male and 85.49 years for female (2005 life table). Here again the year 2005 marked a turnaround: the life span shrank slight from previous year possibly due to the influenza epidemic.

Prolonged life span coupled with declining birth rate will inevitably make the entire population structure aging. According to the estimate, the percent of the elderly population, now 23%, will reach the peak of 40% in 2040.



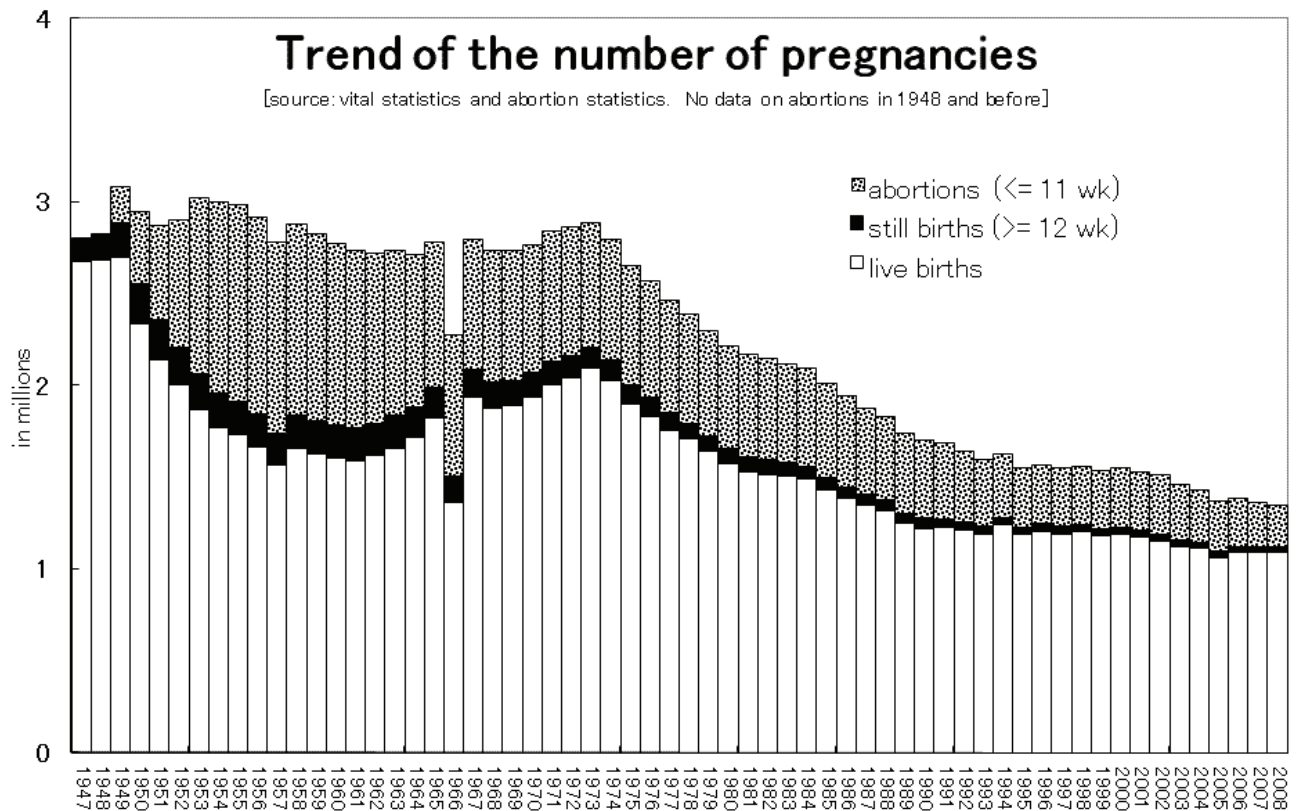
Reflecting the world longest life span, Japan also boasts one of the largest number of concentrations of centenarians. According to the estimate by MHLW, there are 44,449 centenarians nationwide as of 15 September 2010, of whom 86.8% are women. The elderly who reaches 100 years old will be celebrated with presents (silver goblet) from the Prime Minister pursuant to the Elderly Welfare Act since 1963. In 1963, the number of awardees was 153, but the number has increased to 44,449, or 290 fold increase. In 2009, due to financial crunch, the government had to reduce the size of goblets from 11.5cm to 9cm.



2. Birth Rate

The number of live births in 2009 was 1.07 million or 8.5 per 1000 population. A caution about the vital statistics is that the figure does not include foreign nationals. In fact, the

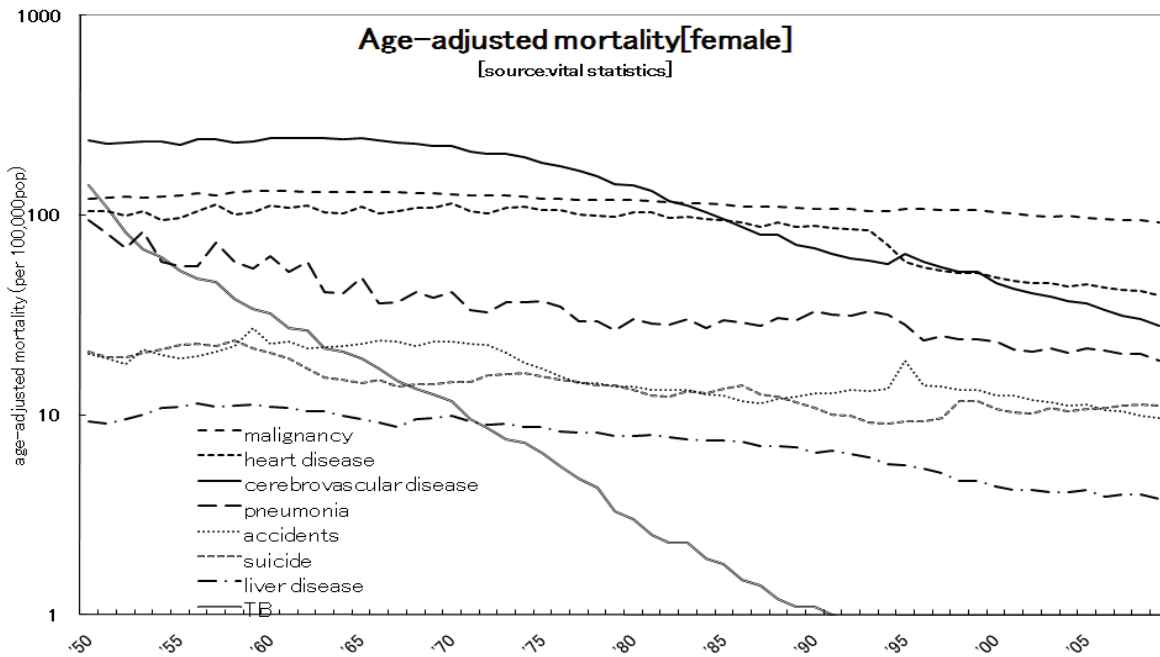
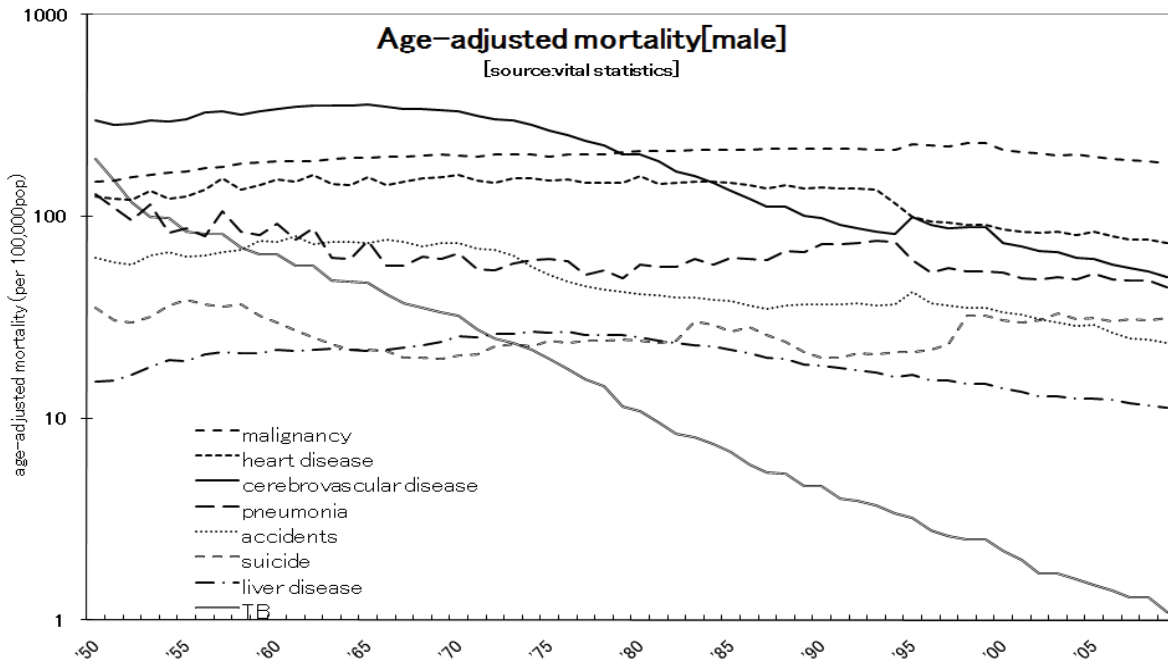
million. The then government was worried about the rapid population growth and eased the regulation of abortions in 1952. Consequently the number of abortions increased and decreased the number of birth to a bottom of 1.57 million in 1957. This policy change left a deep “gap” between two peaks of baby boomers.



3. Mortality

Crude mortality rate of Japan in 2009 was 9.1 per thousand. Crude mortality rate has been on a gradual increase since 1982 when the figure was 6.0 reflecting the aging of population.

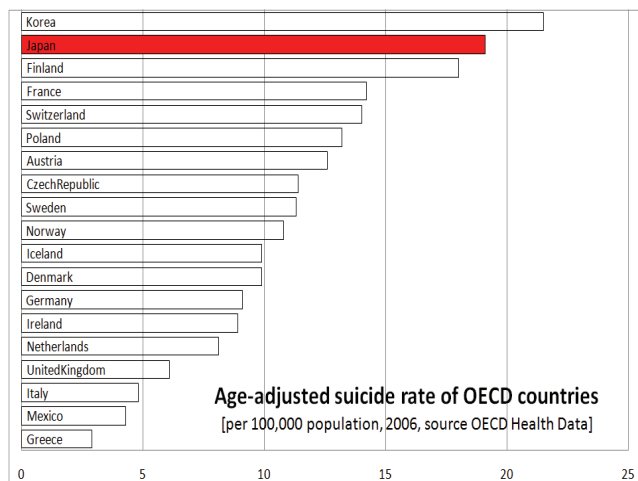
However, when the rate is age-adjusted, the mortality has consistently declined to the lowest of the developed countries. The decline was brought about first by the sharp decline of tuberculosis in the post war era and second by the sharp decline of cerebrovascular diseases.



(1) Suicide

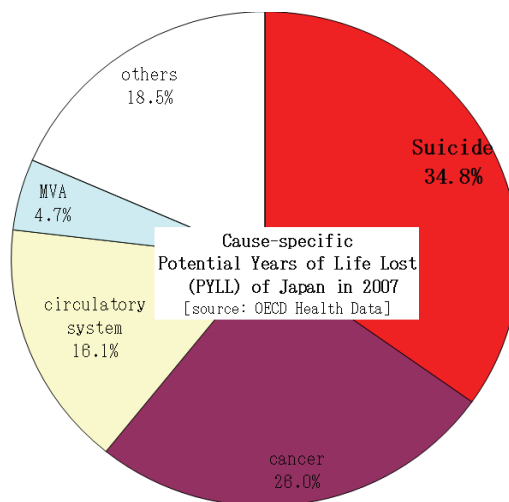
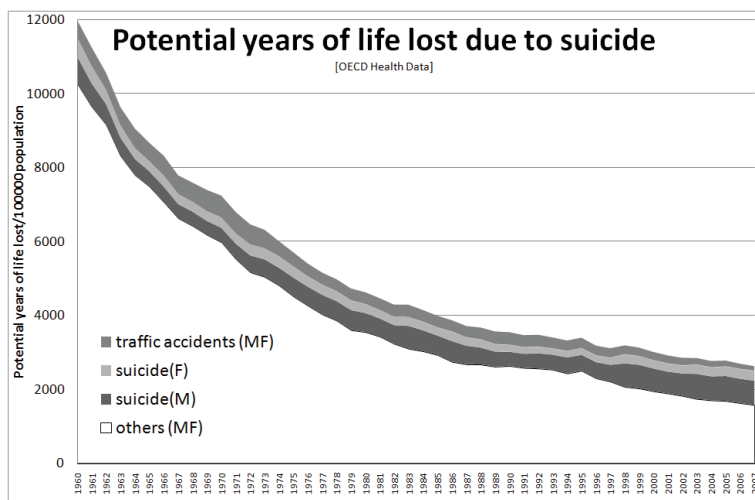
While Japan enjoys the world-longest life span, suicide is alarmingly becoming a public health threat. Japan has the highest suicide rate among industrialized countries.

A total of 32,845 people or 24 per 100,000 populations end their lives by themselves in 2009. Japan's long economic plight no doubt must have played a role in almost 50% increase of



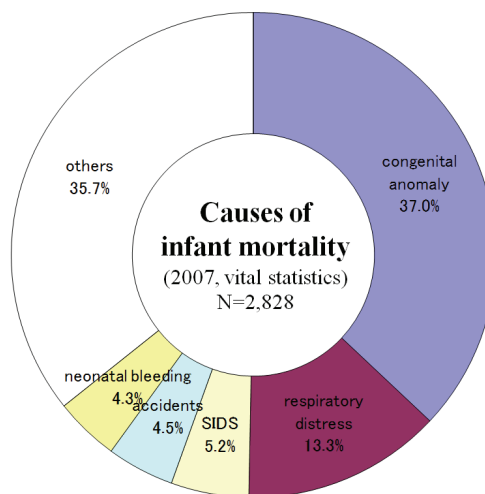
suicides since 1990 when Japan had “seen better days” (annual suicide then was around 20,000).

A sharp increase of suicide is a serious public health threat because suicide consumes as much as 34.8% of potential years of life lost (PYLL) in 2007. As the above graph shows, the absolute size of PYLL attributable to suicide has continued to occupy a sizable share in the cause-specific PYLL, while the share of other causes has declined dramatically in their size. In terms of PYLL, no public health measures will match the effect of suicide prevention.



(2) Infant mortality

Japan’s infant mortality, a sensitive indicator of national health condition, was 2.6 per thousand live births in 2009, one of the lowest in the world. This great achievement did not come at ease. Until as late as 1960s, Japan’s infant mortality was considerably higher than that of the U.S. or U.K. It has been achieved through concerted efforts in effective maternal and child health activities. Congenital anomaly accounts for 37% of infant mortality and constitutes by far the largest cause of death. Since congenital anomaly is hard to prevent in public health perspectives, preventing SIDS or accidents will be a next challenge in the field of maternal and child health.

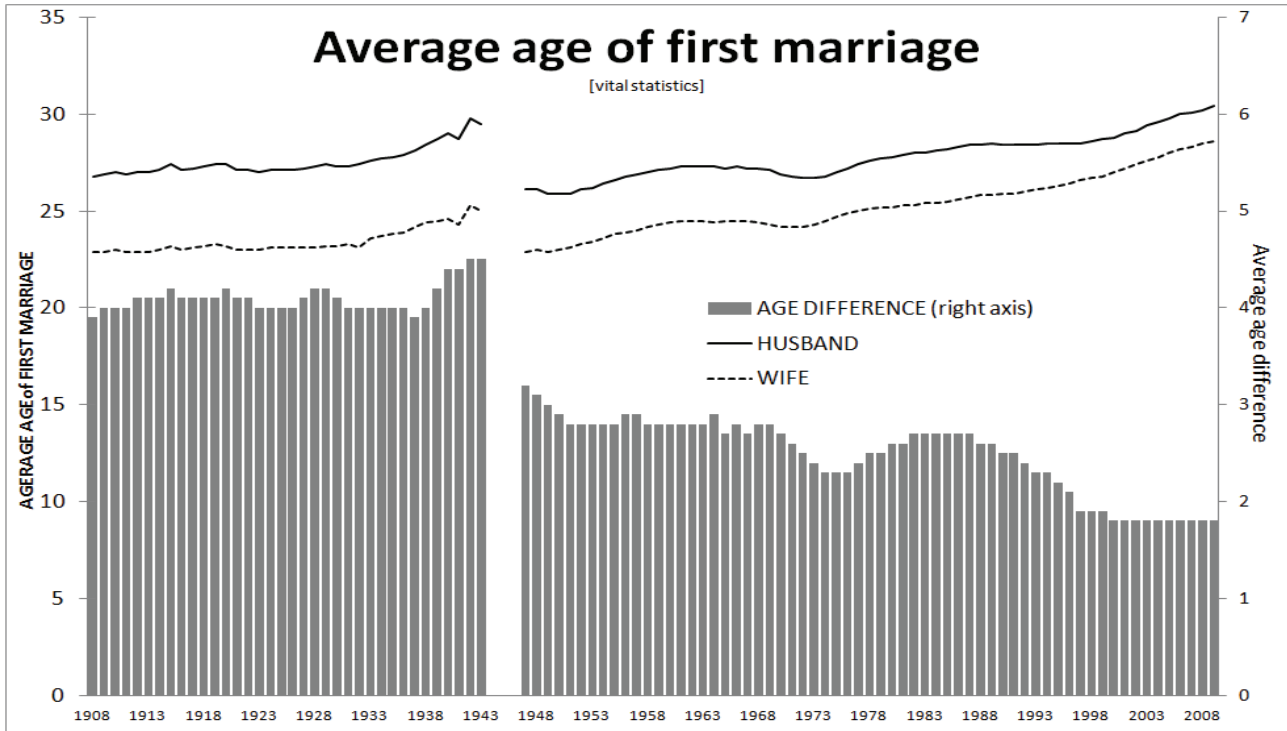


4. Marriage and divorce

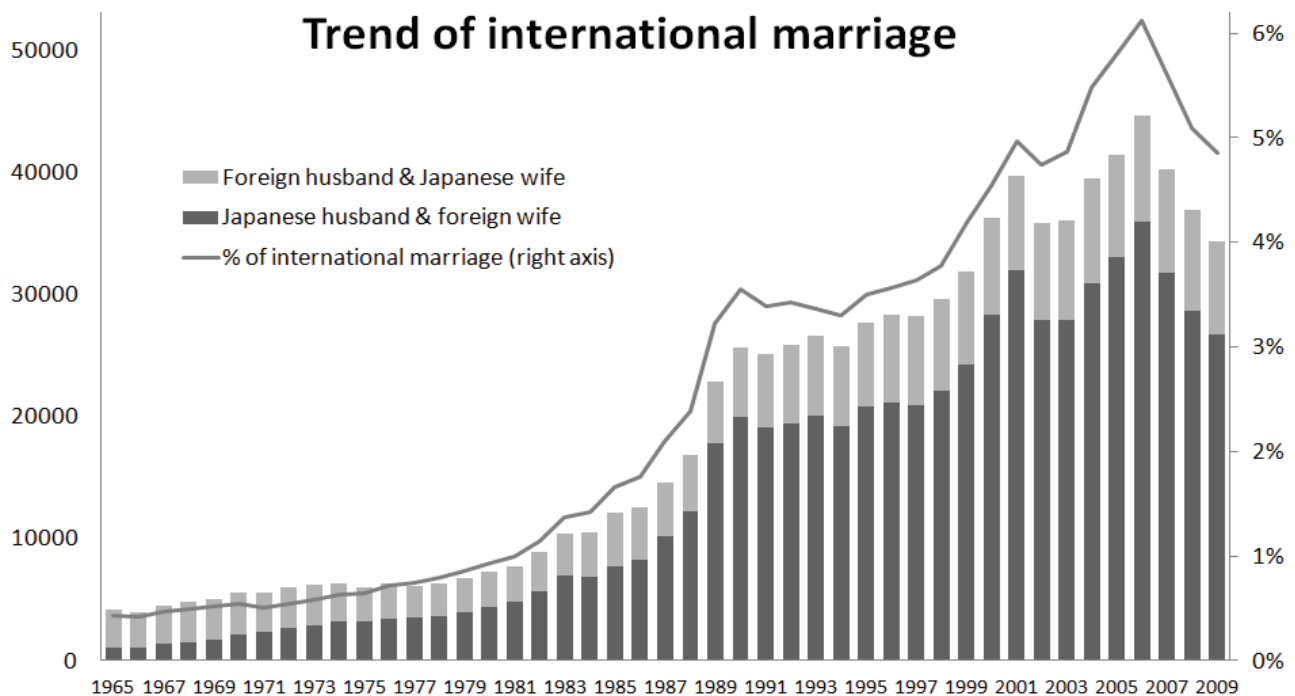
The number of marriage was 707,824 couples in 2009 or 5.6 per thousand population. The figure used to be over one million when the post-war baby boomers were in marital age in early 1970s. The number of divorce was 253,408 in 2009 or 2.01 per thousand population, considerably lower than the US (3.6 in 2005) or Russia (4.83 in 2007).

The average age of first marriage shows an interesting trend. The average age increase

in the pre-war period, declined dramatically in the post-war era and has increased since then (except slight decline in the 1970s when baby boomers got married). The average age of men reached 30 in 2006 and now 30.4 for men and 28.6 for women in 2009. The difference of age between men and women also shows an interesting trend: the difference has narrowed except the 1970s and is stabilized at around 1.8 years currently.



The number of international marriage is increasing and reached 6% of all marriages in 2008. Particularly, couples of Japanese men and foreign wives have increased dramatically.



5. Administrative structure of Public Health

(1) Brief history

The first legislation on health care system, *I-sei*, was enacted in 1874. This legislation included a wide area ranging from administrative structure of public health to pharmaceutical affairs and medical education. At that time the most urgent purpose of public health was infectious disease control. To make effective enforcement of control measures, the public health administration was incorporated into police apparatus. In 1875, the Bureau of Public Health was established in the Ministry of Internal Affairs, which had all-powerful authority over police, education and ideology. In 1937, the first Public Health Center Act was implemented and Ministry of Health & Welfare (MHW) was spun off from the Ministry of Internal Affairs in 1938.

Those dates signify the dark side of public health development of Japan: both public health centers and MHW were not established by the demand from the people, rather they were initiated as part of efforts for the war which had just started in China.

In the post-war era, the Public Health Center Act was amended in 1947 to include not only personal services but also regulatory function over pharmaceutical affairs, food sanitation and environmental health. The law was further amended in 1994 to change its name to the Regional Health Act to incorporate Municipal Health Centers (MHCs). In response to the massive health hazard such as the subway saline terrorism and the Great Osaka-Kobe earthquake, the new directive was set to make PHCs as main bastions for massive health hazard control.

(2) Organization and staffing

Public health activities are provided predominantly by local governments under supervision of Ministry of Health, Labor and Welfare (MHLW. MHW was merged with Ministry of Labor in 2001). The front line of public health activities is public health centers (PHCs), which number 510 as of April 2009. There used to be 848 PHCs as of March 1994, when the Regional Health Act was enacted. The act was intended to delegate much of the personal services provided by PHCs to MHCs and the ensuing radical restructuring process reduced the number to 510.

On the other hand, the number of MHCs has increased to 2,726 as of October 2008. The distinction between PHCs and MHCs may be confusing and warrant some further explanation. Both are the same in that both are part of local governmental bodies but PHCs are endowed with law enforcement power while MHCs are not.

For example, when a mass food poisoning breaks out, it is PHC that assumes the responsibility to investigate the cause and take necessary action against the restaurants. Also all health care facilities such as hospitals, clinics and pharmacies are subject to periodic audit by PHC.

What is confusing about the two is that both provide personal services. PHC and MHC share their responsibility by assigning more specialized and focused clients to PHC and more general clients to MHC. For example, all doctors who diagnose tuberculosis are

required to report to PHC and the patient records will be put into files maintained by PHC and the TB patients will be kept under surveillance by public health nurses (PHNs) of PHC. On the other hand, MHC provides more general and community oriented services such as well-baby clinic, immunization or mass health screening.

	Public Health Center (PHC)	Municipal Health Center (MHC)
personal services	specialized or focused (psychiatric, TB, intractable diseases, infectious disease such as HIV)	more general and community oriented (well baby clinic, immunization, health screening, disabled elderly)
Law enforcement	supervision and audit of health care facilities, restaurants	none
Organizational structure (N)	prefecture(380), major cities(130) totaling 510	cities, towns, villages (2,726)
Director	Must be MD with certain qualification*)	no requirement
Staff	all kinds of health professionals	predominantly public health nurses and dieticians

*) *The director of PHC has been, by law, required to be a MD, although the work is more administrative than clinical. The call for deregulation proposed that such requirement should be abolished, to which public health doctors strongly opposed. In April 2004, the requirement was partially loosened to allow non MDs to be directors of PHC when certain conditions are met. One must have health-related qualifications and have certain practical experience, and completed the one-year course of NIPH. Local governments may appoint non MDs who fulfill the above requirements when they cannot secure MDs to fill the directorship of PHCs.*

6. Training and research of public health

For the sake of providing recurrent training for professional staff working for PHCs and MHCs, MHLW maintains National Institute of Public Health (NIPH). NIPH expanded its size and scope after merging with National Institute of Hospital Management in April 2002 and consolidated in a new campus in Wako city in the suburb of Tokyo [new symbol and photo of the new building is shown]. The new NIPH provides a variety of professional training and research activities in the field of not only public health but also hospital management and social welfare.



NIPH is WHO-certified and started a new CPHP (Certified Public Health Professionals) course comparable to schools of public health in 2004. The new course consists of six subspecialties: Health & welfare administration, Community health and welfare, Environmental health, Biostatistics, Hospital administration and International health.

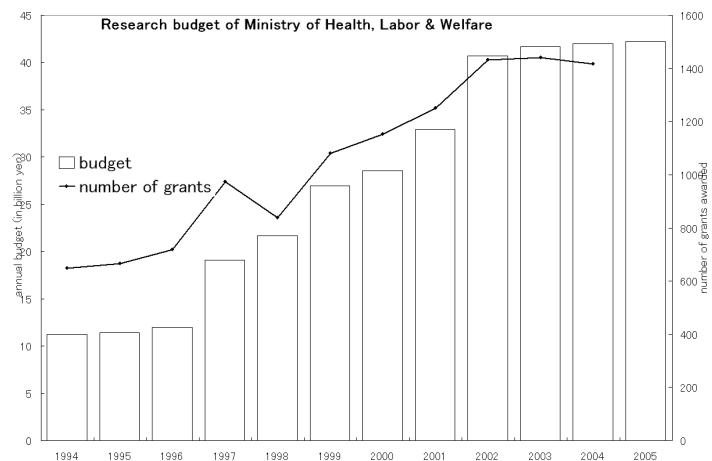
Particularly, the International health course accepts international students as well as

Japanese students and all courses will be taught in English. Being a governmental institute, no tuition is required and availability of low-cost dormitory will prove to be advantageous. NIPH also provides e-learning courses in twelve fields to provide practical training to public health professionals. NIPH also maintains a members-only website of “Health Crisis Management”.

7. Financing of Public Health related research

MHLW funds research grants in the field of public health. The budget of health and labor related research grant has more than tripled from 1996 to 2002 (12 to 40.7 billion yen) reflecting a strong interest of the government in life science and genome research. In 2005, an average of 28.7 million yen (\$26,000) was awarded to 1,454 projects involving more than 20,000 researchers.

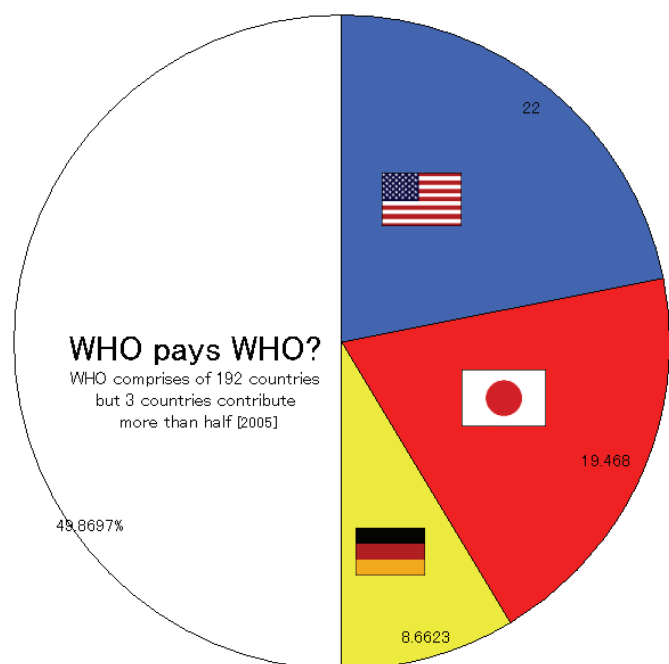
Such research is likely to involve privacy issues. To facilitate research activities in public health field while protecting privacy of human subjects, MHLW enacted a guideline for epidemiological research, which took effect in July 2002.



8. International Cooperation and Contribution

Japan is contributing a lot to the enhancement of public health in the world. Since 2000, approximately 20% of WHO budget is contributed by Japan, second only to the U.S., which contributes 22%. In addition to assigned contribution, Japan is voluntarily contributing 10.4 million dollars for the purpose of tropical disease prevention, primary health care, children vaccination program, emergency medical aid and research for chemical exposure on health.

Being restricted in military power by its peaceful constitution, Japan is expected to play a larger role in terms of manpower in the field of public health (only 38 Japanese staff out of 4,268 staff (including 1,681 experts) of WHO as of Sept 2005). The newly created international health course in



NIPH is expected to boost Japan's role in the worldwide cooperation to achieve the common cause.

Dr. Nakajima, the first Japanese who serve the director general of an international organization under UN, retired in July 1998 after serving 10 years of two terms. During his tenure, Japan helped establish a WHO research center in Kobe (WHO Kobe Center) in 1996 to further study on urbanization and health. Currently Dr. Omi is serving as Director General of the Western Pacific Regional Office of WHO.

Apart from contribution to WHO, Japan promotes bilateral and multilateral cooperation through JICA (Japan International Cooperation Agency) and other various NGOs.

Economic assistance through bilateral relationship is divided into three categories, ODA (Overseas Development Assistance), OOF (Other Official Flows) and PF (Private Flows). Japan's annual budget for ODA in FY 2009 is 672 billion yen (approximately 7 billion dollars), which is further subdivided into 1) gift and 2) loans. Many of public health related ODA is given as gift such as construction of hospitals and medical equipments. In FY 2008, 123 programs were provided as gift economic assistance in public health.

Technological assistance consists of inviting technicians to Japan for training and sending Japanese experts to the receiving countries. As of FY 2004, 65 projects were going on as shown below in the order of inception.

9. OECD Health Care Quality Indicator Project (OECD HCQI)

Another important field in international cooperation is with OECD (Organization of Economic Cooperation and Development). Although OECD is not primarily intended for public health, it is an important venue for developed countries to share and exchange experience and findings to solve the common problems in public health and social security.

In May 2004, the first health minister meeting was held in Paris. OECD has repeatedly held the ministerial meeting on social security but the meeting of health ministers was the first of its kind. There it was agreed to develop a common indicator to objectively measure the quality of health care of individual countries. The Health Care Quality Indicator (HCQI) is being collected and analyzed by experts from many member countries. Japan is going to contribute indicators to enable objective comparison of its level of quality in the world ranking.

In March 2006, the first 17 indicators were published and the project is moving into the second phase with more proposed indices in five major fields: cardiovascular diseases, diabetes, mental health, primary care and patient safety.

Chapter 1. Health Status

1. Health Status and Utilization of Health Services

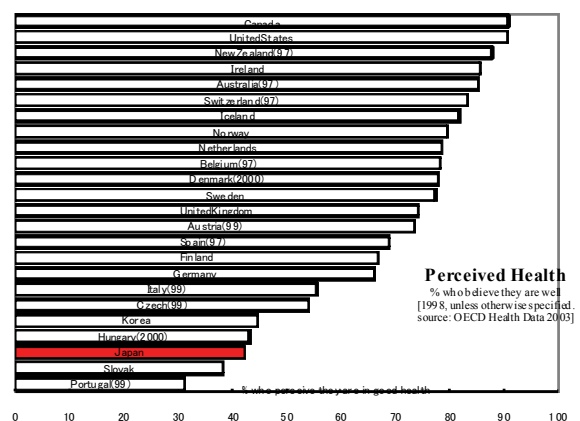
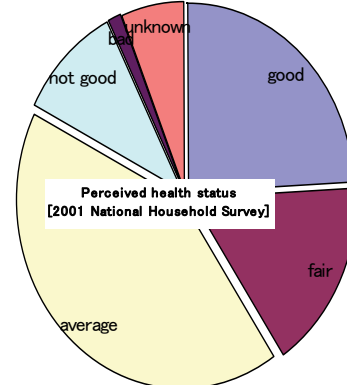
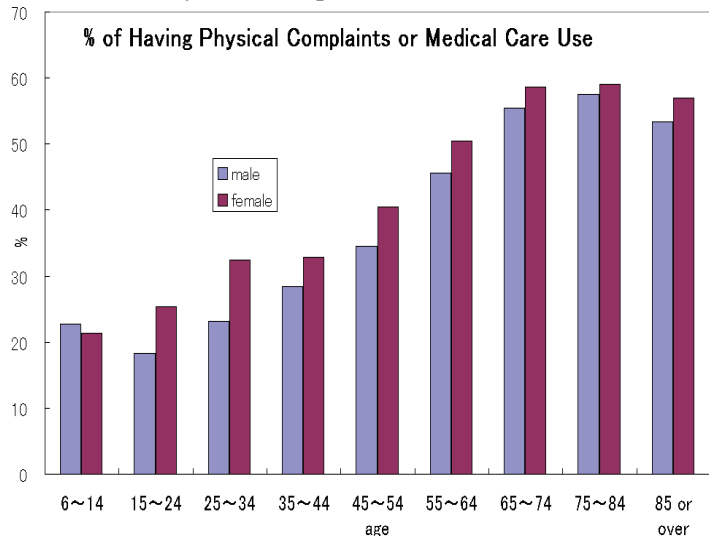
To grasp the health status and utilization of health services, the government conducts regular survey on the nation. One is a questionnaire survey on households [National Household Survey (NHS)] and the other is a survey on hospitals and clinics [Patient Survey].

According to the NHS conducted in June 2004, 32.3% of the population has at least one physical complaint. The percent of those who express at least one physical complaints increases with age in both sexes. The figure is a slight increase from 3 years ago (30.5% in 1998 survey), which may reflect the aging of the population.

NHS also surveys the perceived health status of the population. Asked how they perceive their health status, 40.6% of the population aged 6 years or over answered that their health is good or fair while 11.5% answered “not good” or “bad”.

International comparison of perceived health status reveals somewhat interesting findings. The OECD Health Data compares the percent of those who perceive their health status “good” as shown in the following graph. In the comparison year of 1998, 44.5% of the Japanese perceived their health as either “good” or “fair” almost on a par with the figure of Koreans. On the other hand, the U.S. and Canada had a far higher figure of nearly 90%. One might be cautioned in interpreting these findings because such subjective perception may involve methodology of survey and cultural attitudes.

Utilization of medical care is estimated by Patient Survey conducted every three years.

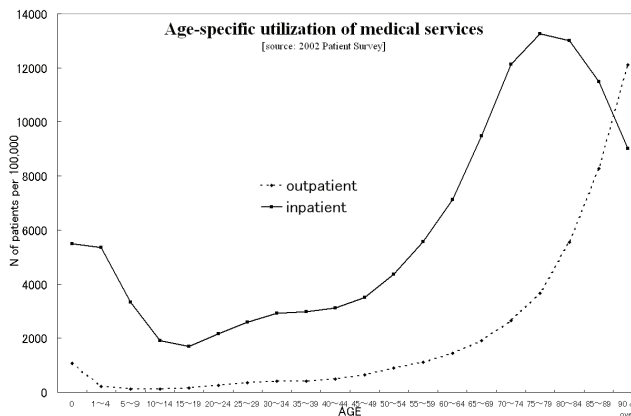


Patient Survey is a nation-wide sampling survey on inpatients and outpatients of hospitals and clinics and is conducted on one day in middle of October every three years, the latest of which was conducted in October 2002.

As of the survey date, 1.2% of the population is hospitalized and 5.4% of the population visited outpatient clinics. Age and sex-specific utilization expressed as the estimated number of patients per 100,000 populations is displayed in the graph.

The number of inpatient exceeds that of outpatient in the age groups of 90 or over in both sexes.

One should be cautioned that the estimated number of patients given in Patient Survey is a one-day sampling survey and underestimate the number of outpatients who regularly visit hospitals or clinics. The survey includes the interval of regular



outpatient visits, and then the number of patients who are under constant medical treatment can be estimated by multiplying the number of patients on the survey day with the average interval, plus the number of inpatients. According to the estimates, Hypertension is by far the most common disease with an estimated number of patients under medical treatment is seven million. Over than 6% of the entire population is under medical treatment with hypertension.

2. Health promotion campaigns

After achieving the life span of 80 years in and around 1978, the focuses of public health activities gradually shifted from infectious diseases to chronic noncommunicable diseases. Those diseases were “aging related disease” or “adult diseases” or what was later to be called as “lifestyle related diseases”. To combat these diseases, intervention into personal lifestyle is more important than medical care, and therefore it will inevitably involve national campaign to appeal to the general public.

As a result, a series of public health campaigns have been employed. Looking back, it turned out to be a history of a variety of national campaigns with mixed results.

(1) 1st wave: National Movement for Health Promotion (1978)

The 1st National Movement for Health Promotion was launched in 1978. One of the major measures taken in the 1st was establishing the Municipal Health Centers (MHC) in every municipality as the facility for health promotional activities in addition to the existing Public Health Centers (PHC).

However, it is noteworthy to mention that this first wave might have committed a mistake: relocation of public health nurses (PHNs) from the National Health Insurance section to MHCs. Before 1978, many municipal governments, which serve as insurers of their NHI programs, employed PHNs for health promotion and preventive medical activities

for the insured. Since not all residents are the insured of the NHI (enrollment is approximately 40% of the residents), the clients of PHNs were limited to those insured by the municipal governments.

To cater to all the eligible residents, PHNs were relocated to MHCs. Because of this change, the long tradition of PHNs working as part of health insurance operation was lost. For example, PHNs of the NHI bureau were allowed to investigate the health insurance claims to capture the medical care utilization of the patients they manage. After most PHNs were relocated to MHCs, they lost access to health insurance claims to use them for their public health activities.

This reform is now increasingly viewed as a policy mistake and the government is now promoting cooperation between NHI section and MHCs in a municipal government.

(2) 2nd wave: Active 80 Health Plan (1988)

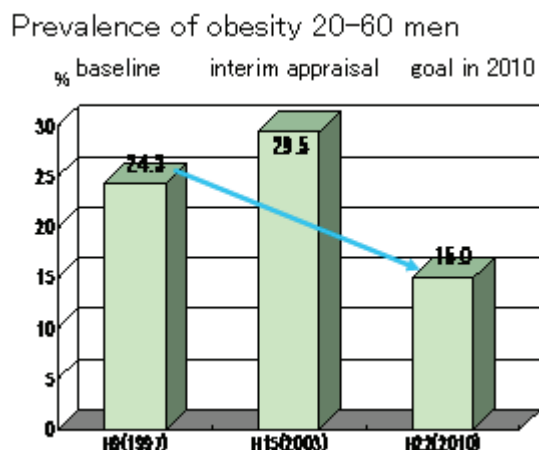
The 2nd wave was dubbed "Active 80 Health Plan" after its purposes to cater to the prolonged life span of 80 years. In it, an emphasis was placed in physical activities and to promote physical fitness, qualification of "Health Trainers" was initiated in 1988. Health Trainers possess knowledge of both medical and physical science to make prescription for recommended physical activities tailored to individual conditions and medical needs. Also, fitness clubs satisfying certain requirements such as having a certain number of qualified Health Trainers were given special designation by government. Although such designation will not entitle them to health insurance benefit, the membership fee for patients with chronic diseases such as hypertension, diabetes and hyperlipidemia will enjoy tax-exempt status if their physical activities regimen is prescribed by attending doctors and supervised by qualified Health Trainers.

Such promotion, coupled with economic booms at that time, spurred mushrooming of fitness clubs and stimulated the growth of health and fitness industry. However, this campaign did not have explicit goals to be achieved and no appraisal was made to quantify its achievement. At least, not many authorities believe that the campaign has made drastic results.

(3) 3rd wave: Healthy Japan 21 (2000-2010)

The 3rd wave of national health promotion movement, the Healthy Japan 21 (HJ21) is currently being actively promoted. The covered period is between the year 2000 and 2010 with defined set of goals. In this campaign, emphasis is placed in the prolongation of "healthy life span" which means the life span without disability. This emphasis reflects resentment over a considerable number of elderly with disability in the face of the world longest life span.

The HJ21 campaign set the explicit goals



against which its achievement is appraised. It set as many as 70 goals in nine fields (nutrition/diet, physical activities, mental health, tobacco, alcohol, dental health, diabetes, cardiovascular disease and cancer). The HJ21 initiative set itemized goals to be achieved by 2010 and requires an interim appraisal in 2005. The interim appraisal was disclosed in September 2005 with some disappointing results. Not many goals showed improvement since the baseline but showed even worsening. Overall, the outcome of the campaign was far from being satisfactory.

In the field of nutrition/diet, prevalence of obesity has increased particularly in men in 30s and 60s. Salt intake and rate of energy intake from fat has declined somewhat, but the proposed goal of eating vegetable >350gr/day has not been achieved at all. In the field of physical activities, the goal of 9200 steps for men and 8300 steps for women was set but the result was rather declining. In the field of tobacco, smoking rate of men has declined but the rate of women did not show any sign of decline. In the field of diabetes, the number of possible diabetics is estimated to be 16.2 million and shows no sign of decline. The rate of continued treatment for diabetes did not show any improvement. In the field of cardiovascular diseases, risk factors such as hypertension and diabetes did not improve at all. In the field of cancer, cancer screening rate did not increase and severe geographic maldistribution still remains.

Overall, one must become pessimistic about the prospect of achieving 70 goals by 2010 and these disappointing results constitute a backdrop of the radical and philosophical turnabout in the health care reform plan in 2006.

(4) Health Frontier Strategy (2005-2015)

Health Frontier Strategy (HFS) may be confusing because some of its goals and time frame overlap with the HJ21 campaign. After the enactment of the Long-term Care Insurance, the insurance benefit disbursement has increased leading to the financial crunch. Since the increase was predominantly in “light” level of disability, the need for “prevention” of disability was highlighted.

HFS does share the same goal with HJ21 in that both aim to prolong healthy life span (life span without disability), however HFS has dual goals: one for prevention of lifestyle-related diseases and another for prevention of disability. Also, HFS proposes more simple and explicit quantifiable goals to be achieved by 2015 as follows:

- Prevention of lifestyle-related diseases

- increase 5 year survival of all cancers by 20%
- decrease cardiovascular disease mortality by 25%
- decrease cerebrovascular disease mortality by 25%
- decrease incidence of diabetes by 20%

- Reduction of disability

- prevent worsening of the disabled elderly in borderline and level1 to level2 by 10%
- prevent becoming disabled (borderline and level1) by 20%

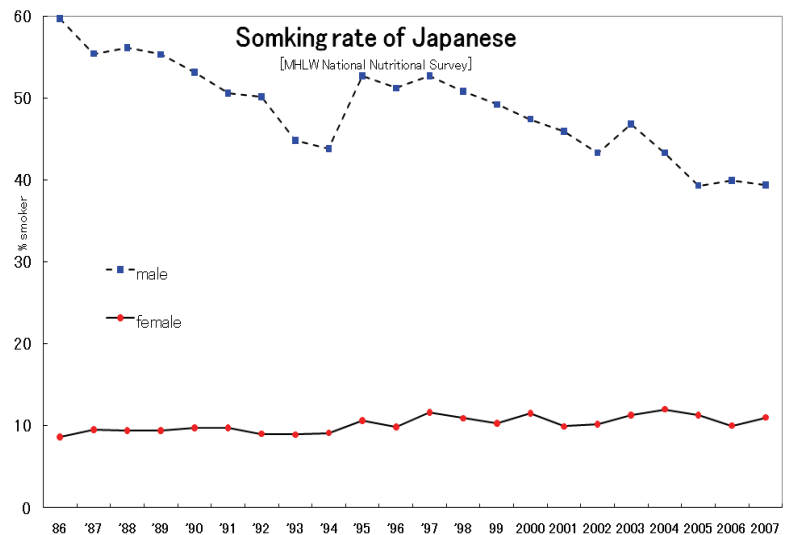
HFS also serves as a backdrop for the health care reform proposed in 2006 with its proposed goal of reducing the number of patients of metabolic syndrome by 25% by 2015.

3. Health Promotion Act and National Health and Nutrition Survey

As the legal basis of promoting the HJ21, a new law named Health Promotion Act was enacted in 2003. This law is intended to promote healthy lifestyle, mandatory segregation of smoking are and coordinate health screening conducted by different providers under different schemes. So far, for example, employers are required to provide health screenings to workers under the Industrial Safety and Hygiene Act, and schools provide health screenings to pupils under the School Health Act, and each health insurers provide health screening to the insured with little coordination with each other. The new law makes the formats of health screening records uniform to assure consistent record keeping in every individual.

The law also stipulates the National Health and Nutritional Survey (NHNS). NHNS is an equivalent of the U.S. NHANES and is a national sampling survey on nutrition intake and health status. NHNS was originally the National Nutrition Survey (NNS) conducted pursuant to the Nutrition Improvement Act since the postwar era. NNS was expanded to include blood exams and health related items. It took on more importance because it provides evidence to evaluate the outcome of a series of health policy campaigns.

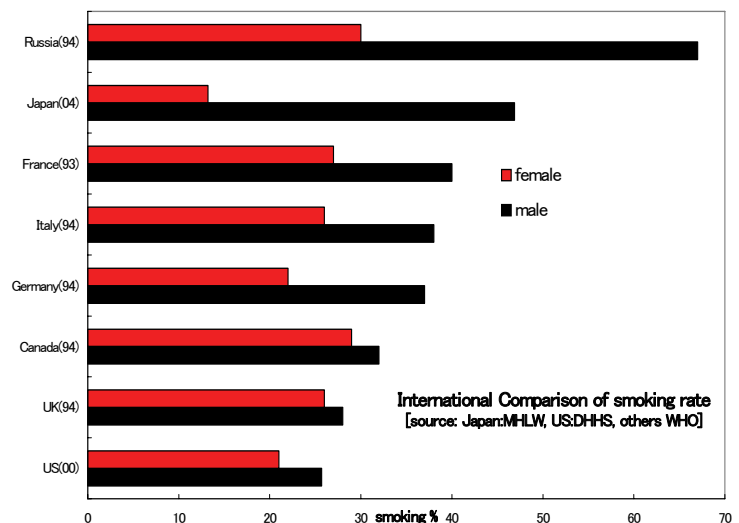
The new NHNS was started in November 2003 and will be conducted every year. The results of the 2007 survey were recently published. It was conducted on the randomly sampled 3,586 households from whom 8,119 people responded to the lifestyle questionnaire, 8,000 people underwent physical exams and 4,018 people provided blood samples.



4. Health Related Problems

(1) Tobacco Control

According to the NHNS in 2007, the smoking rate in Japan was 39.4% for male and 11% for female. Although the smoking rate for male has steadily been declining, it is still higher than most developed countries. The smoking rate for female is lower than most developed countries and is somewhat stable overall, but the smoking rate among young women in the 20s and 30s is increasing



alarmingly.

More alarming is the recent increase of the smoking rate among school children. According to the survey on junior and senior high school students conducted by government in 2000, the rate of "smoking in the last one month" increased in all grades: 36.9% of male and 16.2% of female students in 12th grade replied yes to the question. Moreover, 25, 9% of male and 8.2% of female 12th grade students say they smoke every day.

Despite health risk involving smoking, the government used to be not so enthusiastic about tobacco control mainly because the tobacco industry was the monopolistic government enterprise and hence a valuable source of tax revenue. Only after the government enterprise was privatized to the present JT, the government started to tackle the problem wholeheartedly.

The action plan for tobacco control was initiated in 1995. In cooperation to the plan, the tobacco industry voluntarily withheld nighttime operation of vending machines in 1997 and refrained from TV ads in 1998.

The plan called for separation of smoking and nonsmoking space as part of the anti smoking efforts. The separation is enforced according to the types of facilities and is mandatory for health facilities and public facilities.

The Health Promotion Act enacted in 2003 also endorsed the prevention of passive smoking by way of separated smoking. The WHO convention in May 2003 adopted the Tobacco Control Framework Convention, which Japan ratified in June 2004 and joined the other 40 ratifying countries.

(2) Alcohol Problems

According to the NHNS in 2006, the percent of drinking three times or more per week was estimated to be 50% for men and 13.8% for women.

According to the Patient Survey, a nationwide sampling survey on hospitals and clinics conducted in every three years, the number of alcoholism patients under medical treatment increased from 14,720 in 1968 to 19,100 in 2005 (alcoholic psychosis 2,400 plus alcohol dependency 16,700). Although the figures may appear small in comparison to the estimated number of heavy drinkers (2.4 million), the majority of alcoholism patients are considered to be under treatment for alcohol related conditions such as liver diseases.

Japan does have the "Prohibition against Drinking for Minors Act", but its effectiveness is seriously hampered by ubiquitous vending machines of alcohol. In 1993, the governmental Public Health Committee urged the total ban of vending machines and limiting the alcohol sales to over-the-counter.

Chapter 2. Lifestyle-related Diseases and Metabolic syndrome

1. A paradigm of "lifestyle-related diseases"

Chronic diseases such as cancer, cardiovascular diseases were once referred to as "aging related diseases" because the incidence increases with aging. However a new paradigm of "lifestyle-related diseases" was proposed by a report by the Public Health Committee in 1996 to emphasize primary prevention over secondary prevention. The rationale for creating the new paradigm of "lifestyle-related diseases" in place for "aging related diseases" is that the latter may give a false impression that such diseases are inevitable with aging and a sense of resignation that they are not preventable and can only be countered with early detection at best. The idea of lifestyle-related diseases emphasizes that they are preventable by appropriate modification of lifestyles.

2. Current status of major lifestyle related diseases

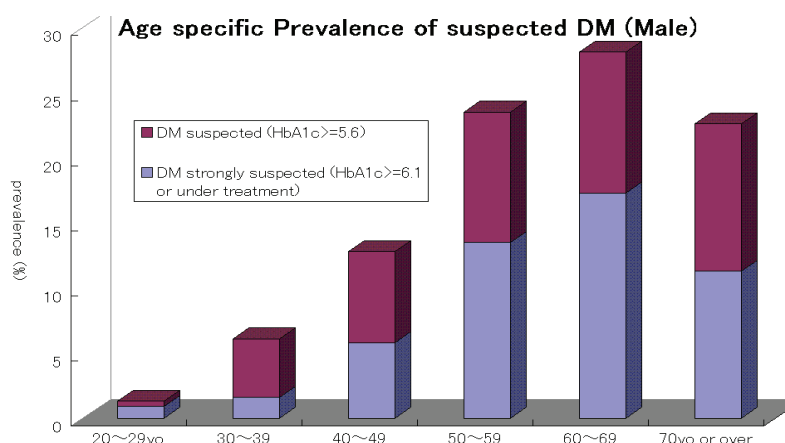
(1) Diabetes

Majority of diabetic patients in Japan are of type II or NIIDM, which is heavily dependent on lifestyle. Although its rank in the immediate cause of death is only the 10th in vital statistics, it also contributes to other major causes of death such as cardiovascular diseases or cerebrovascular diseases as major risk factors. Diabetes also contributes to various forms of disability such as renal failure and blindness.

Diabetic nephropathy accounted for about 43.4% of newly initiated dialysis patients (2007) and the number is increasing still. Also, as many as 2,300 people lose vision due to diabetic retinopathy making it the largest cause of blindness.

For the first time in November 1997, a nation-wide survey on prevalence of diabetes was conducted as part of the National Nutritional Survey. According to the survey result applied to the national population, the number of suspected cases of diabetes defined as "HbA1C 6.1% or over plus patients already under medical treatment" is estimated to be 6.9 million and the number of potential cases defined as "HbA1C 5.6% or over" is estimated to be 6.8 million (total population is 125 million).

The survey was repeated five years later in November 2002. Applying the same criteria with 5 years ago, the number of suspected cases increased to 7.4 million and potential cases 8.8 million chiefly due to population aging. The latest 2007 NHNS estimates the figure of suspected cases to be



8.9 million, potential cases 13.2 million respectively.

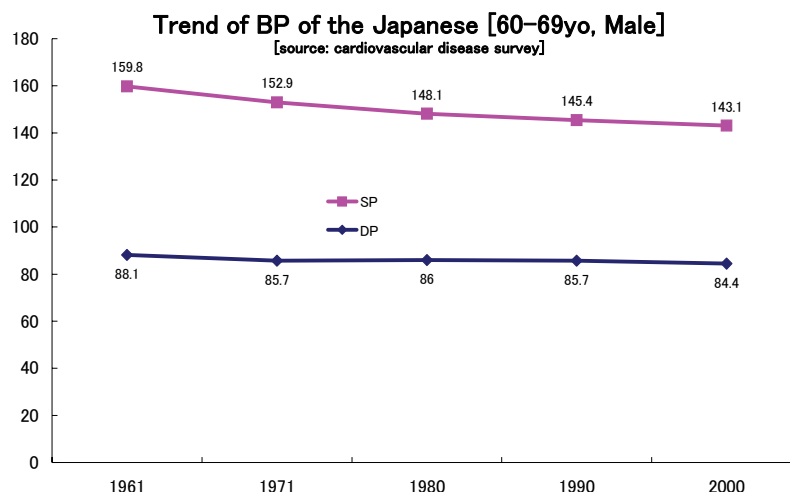
(2) Hypertension

According to the result of the 5th National Survey on Cardiovascular Diseases conducted in 2000, the prevalence of hypertension has increased slightly in the total number except men aged 60 years or over and women over 40. On the other hand the percent of people with hypertension who are currently under medical treatment has increased possibly due to the effective mass-screening program rigorously conducted for a last decade.

Japan used to have a high prevalence of cerebral apoplexy until as late as 1970s. The health indices concerning apoplexies as measured by mortality and prevalence have since then improved dramatically thanks to the great effort to control high blood pressure.

A series of nation-wide sampling surveys to elucidate the secular trend of blood pressure of the Japanese have been conducted at 10 years interval for 5 times 1961-2000. Each time BP was measured on subjects aged 30 years or older randomly sampled from the entire population. Tracing the long-term trend of BP bears witness to the yield of public health activities.

The average systolic pressure (SP) of men aged 60 to 69 was nearly 160 mmHg, but it has consistently declined to 143 in 2000. What is noteworthy about BP is that diastolic pressure (DP), which has not declined as drastically as SP. In other words, the difference or pulse pressure (PP) has shrunk. More



recently, PP is increasingly considered to reflect atherosclerosis or elasticity of blood vessel, then this trend may suggest that the BP of male Japanese has declined while suppressing atherosclerosis.

(3) Hyperlipidemia

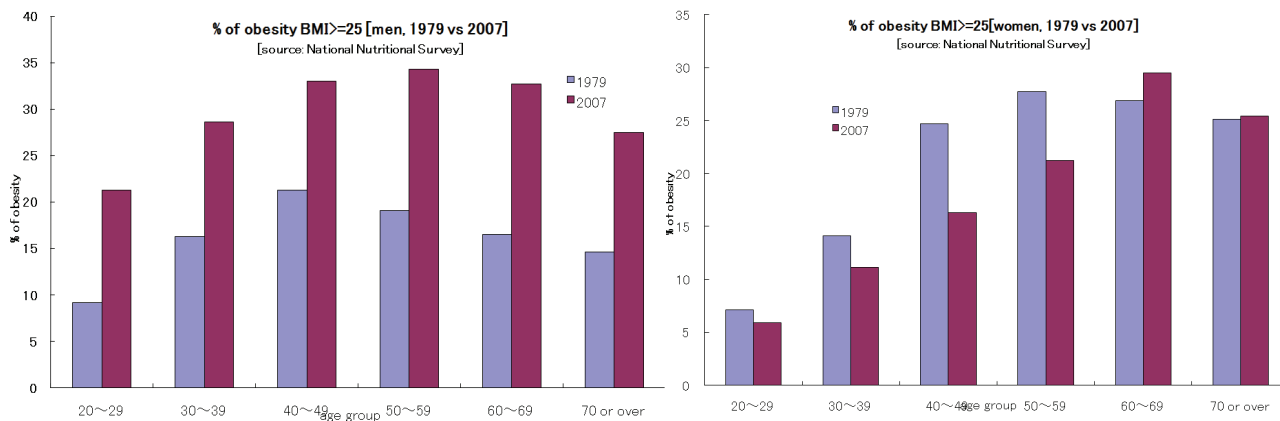
According to the Patient Survey conducted in October 1996, the number of patients under treatment for hyperlipidemia per age group is peaked in the age group of 70 to 74 at around 280 patients per 100,000. This figure severely underestimates the actual number of hyperlipidemia patients. Cautions should be taken because the survey is a cross sectional covering only three days and the number reflects only patients with hyperlipidemia as their primary diagnoses. Majority of hyperlipidemia patients are receiving treatment for the disease as secondary to other primary diagnoses.

(4) Obesity

Japan Obesity Association defines the obesity as BMI ≥ 25 . According to this definition, the NHNS conducted in November 2007 revealed that half men and 21.4% of

women aged 15 years old or over were obese. For men in their 40s, almost one out of three are obese.

When compared with 30 years ago, there is a marked increase of obesity among men in all age groups but not in women. Since the prevalence of obesity will increase in the later stage of life, obesity should be considered as a major public health concern in combating lifestyle related diseases.



(5) Cerebrovascular diseases

Cerebrovascular diseases used to occupy the most common cause of death until 1980. However it is now ranked in the 3rd place thanks to a sharp decline of the mortality especially due to a dramatic decline of cerebral bleeding because of better blood pressure control. Ironically enough, the improved survival of cerebral vascular diseases increased the number of surviving patients under treatment and the subsequent disabled people. Primary prevention of cerebral vascular diseases and tertiary prevention from disability such as acute phase rehabilitation remains a major challenge for Japan's public health.

(6) Heart diseases

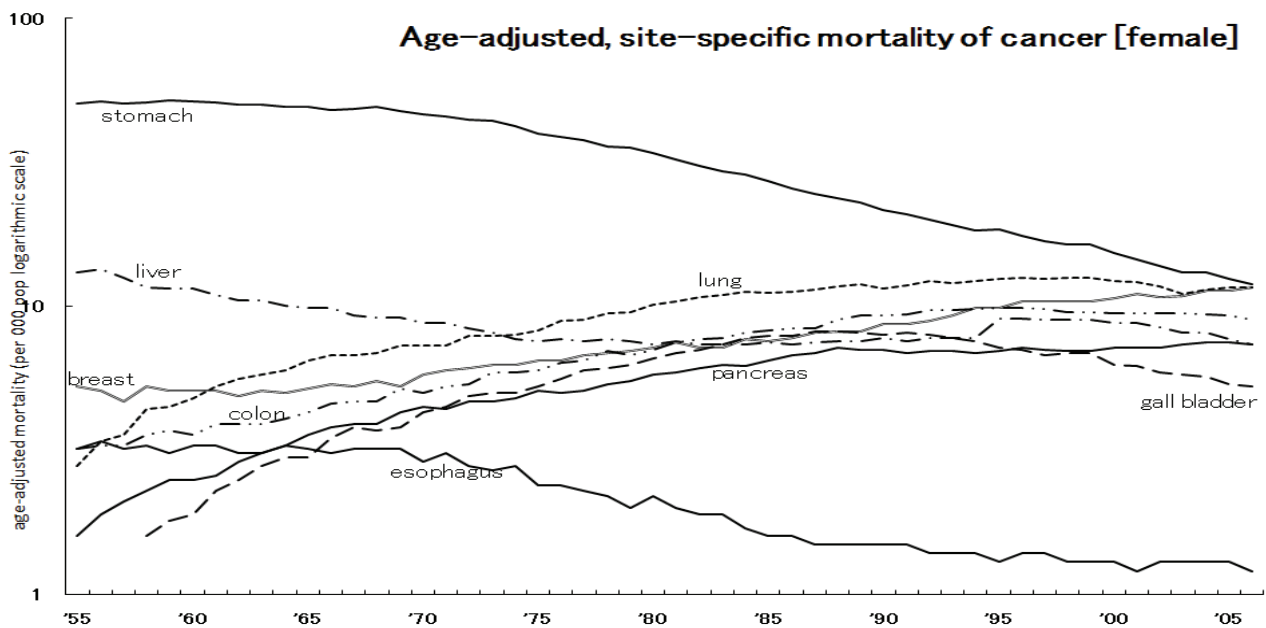
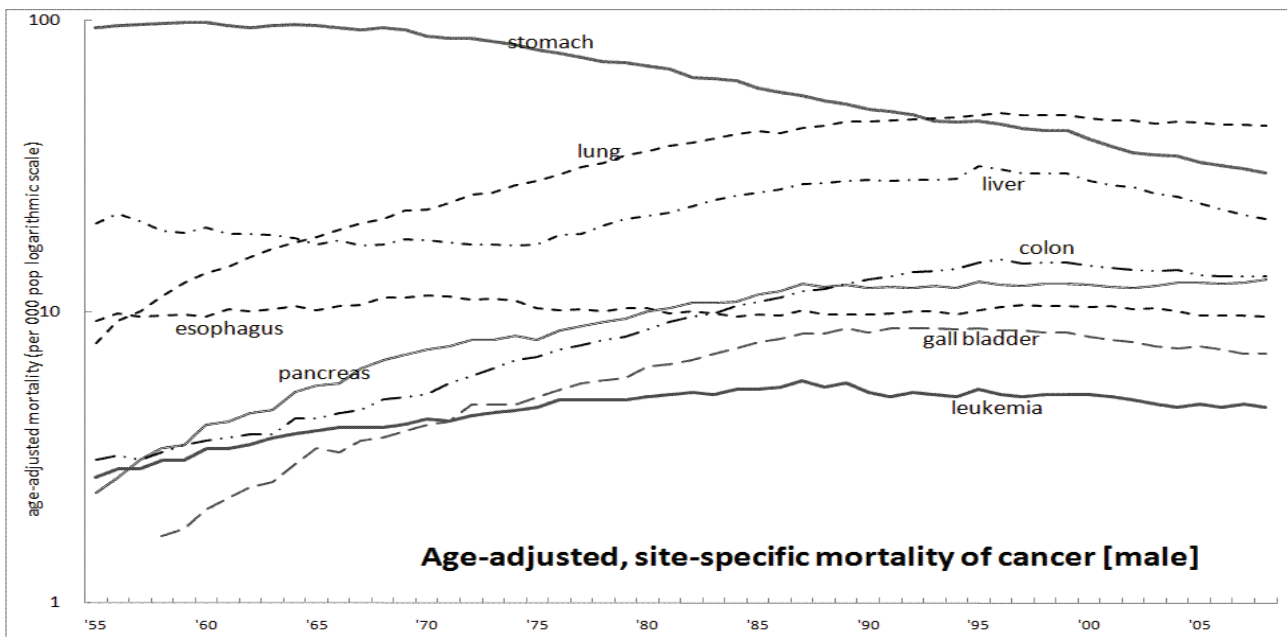
Japan used to have a high prevalence of rheumatic heart diseases but ischemic heart diseases are increasing even as the age-adjusted cause of death since 1993. Currently heart diseases are ranked as the second leading cause of death after cancer. As the incidence of ischemic heart diseases increases, some questions were raised as to the unsatisfactory rescue rate in the acute phase of onset. In addition to primary prevention, improvement of rescue and survival of acute phase should be emphasized.

(7) Cancer

Cancer has been the leading cause of death since 1981. Age-adjusted mortality shows a slight but gradual increase for male, while a slight decrease is observed for female. Site-specific cancer mortality shows that while mortality of stomach and uterine cancer are declining, lung and colon cancer mortality are on the rise suggesting effects of lifestyle changes.

Incidence of cancer cannot be known from vital statistics especially when the survival of cancer improves. According to some cancer registry such as the one being conducted in Osaka suggests that stomach cancer is still by far the commonest cancer for men and second

for women. However stomach cancer slipped from the top of the mortality for men thanks to improved survival. For women, stomach cancer is still the largest killer.



3. Metabolic syndrome: a waist size story

The concept of lifestyle-related diseases was further evolved to “metabolic syndrome” in 2005, when Japanese College of Internal Medicine adopted the uniform diagnostic criteria of “metabolic syndrome” in their 102th general assembly on 8th April of the year. The pathophysiology of the syndrome focuses on “visceral fat (fat deposition in abdominal cavity, as opposed to subcutaneous fat)”. Unhealthy lifestyle will lead to visceral fat deposition, which excretes adipocytokine causing various lifestyle-related diseases. However, Japan’s diagnostic criteria later stirred debates because some criteria such as waist circumference of 85cm for men and 90 cm for women were different from the race-specific criteria adopted by the International Diabetes Federation (IDF) at their

meeting in Berlin only six days later (14th April 2005). Japan's criteria of waist circumference were set to correspond to the visceral fat deposition of 100 square cm measured with CT. However, the IDF later adopted the criteria for Japanese of 90cm for men and 80cm for women in line with other Asians in 2007.

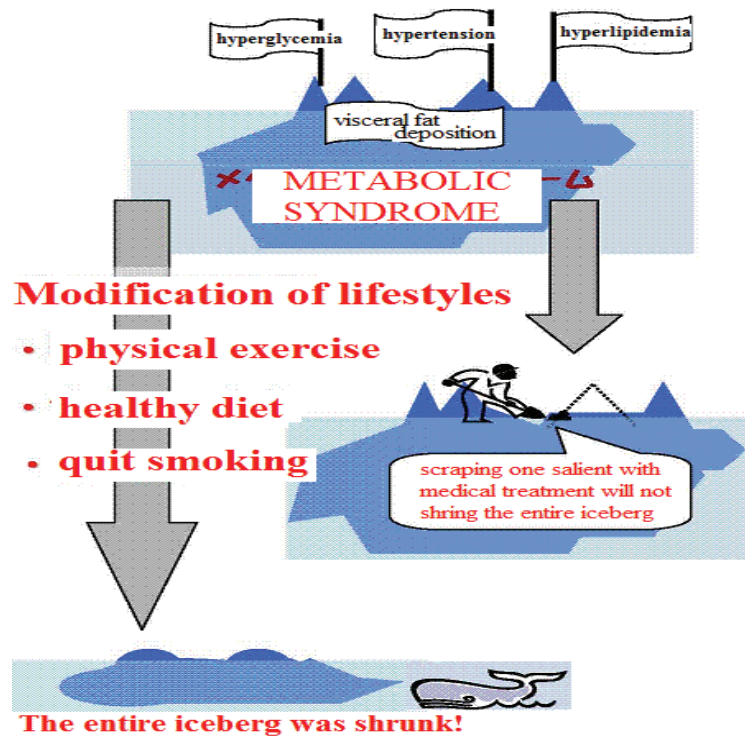
The new Japanese criteria of metabolic syndrome, nonetheless, attracted the interest of the MHLW, which was dismayed at the unsatisfactory outcome of the HJ21 (the % of obesity in 20-60 males was

24.3% at the baseline and was targeted to <15% by 2010. However, the interim evaluation showed a worsened result: 29.0%). The MHLW jumped over the new concept of metabolic syndrome to be used as a rationale for health promotional activities.

The graphical explanation prepared by the MHLW in July 2005 illustrates the importance of lifestyle modification using a metaphor of iceberg. Various lifestyle-related diseases are tips of the iceberg whose main body is under water and invisible. Medical treatment aiming at each disease (a tip) will not be effective as long as the entire iceberg remains the same. To remedy lifestyle-related diseases, one must modify his/her unhealthy lifestyle to shrink the entire iceberg. Until early 1980s, lifestyle-related diseases (hypertension, hyperglycemia and hyperlipidemia) were considered as independent to each other although their progression tends to be concurrent. However, there has been a growing consensus among researchers that visceral fat deposition is a real culprit leading to the WHO's publication of the term "Metabolic syndrome". The pathophysiology of the syndrome has also been investigated and it is now widely believed that a certain adipocytokine (adiponectin, leptin, TNF- α , bisfatin) excreted from the visceral fat causes metabolic disorder leading to atherosclerosis.

Metabolic syndrome is equivalent to the disease entity of syndrome X, deadly quartet, insulin-resistance syndrome. However, its diagnostic criteria vary across different organizations: WHO (1999), NCEP-ATPIII(2005), IDF(2005) and Japan's criteria adopted jointly by eight related academic societies belonging to the Japan College of Internal Medicine. Some critics argue that metabolic syndrome should not be viewed as a well-defined disease entity in strict medical terminology which needs to be treated.

According to the criteria set forth by MHLW, metabolic syndrome is defined as a combination of visceral fat deposition PLUS one or more risk factors of hypertension



(SBP \geq 130mmHg or DBP \geq 85mmHg), hyperglycemia (FBS \geq 100mg/dl or HbA1c \geq 5.2%) and hyperlipidemia (triglyceride \geq 150mg/dl or HDL $<$ 40mg/dl). Visceral fat deposition is measured by waist circumference (\geq 85cm for men and \geq 90cm for women). Those with two or more risk factors will be subject to aggressive intervention and those with one risk factors will be subject to intermediate intervention. Those without visceral fat but with BMI \geq 25 may still be subject to intervention with loosened criteria than those with visceral fat deposition.

The term “metabolic syndrome” caught a lot of public attention making people nervously aware of their waist sizes. According to the 2004 NHNS, 23% of men are subject to aggressive intervention and 22.6% of them are to intermediate intervention. The figure for women is 8.9%, 7.8% respectively.

The metabolic syndrome took on importance as health policy agenda because the proposed health care reform 2008 emphasizes intervention by health insurers targeting metabolic syndrome. The government set the goal to reduce the number of patients by 25% between the starting year 2008 and the goal year 2015. To achieve the goal, all health insurers will be required to provide annual health checkups to beneficiaries aged 40-74 and keep individual health records in file as long as they remain insured.

The new program targeting metabolic syndrome started in April 2008. The MHLW set a goal that 70% of the target population (aged 40-74) receives health screening and 45% of those subject to intervention fulfill the six months intervention to be achieved by 2012. The achievement in the first year (2008) was 23.8% for municipal NHI programs.

Chapter 3. Health Protection

1. Maternal and Child Health

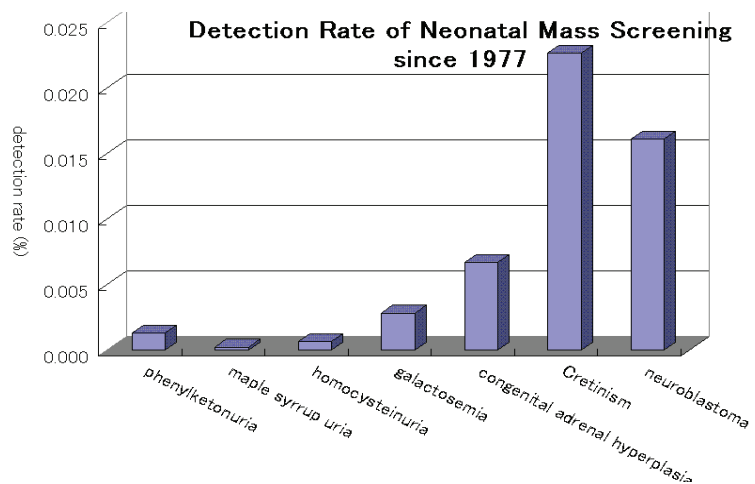
Japan's infant mortality used to be as high as 150-160 per thousand births until early 20th century but declined sharply to below 10 in 1975. Japan's current figure of 2.6 (2007) is one of the lowest even among developed countries. This may well be regarded as a triumph of Japan's post war maternal and child health (MCH) policy.

According to the MCH Act, pregnant mothers are required to report to the municipal governments and MCH notebooks will be issued. This entitles her to public funded free health guidance and preventive medical activities as well as a health record for the child through the course of pregnancy and after birth.

Health guidance and consultation by public health nurses may continue after birth especially when the new born babies are weighed 2500mg or less, in which case parents are required to report to the local public health centers to prompt them for quick action.

All newborn babies are entitled for public funded mass screening to detect congenital metabolic diseases such as phenylketonuria, and for the babies born to HB positive mothers, immunoglobulin and vaccination will be provided as part of health insurance benefit. In 1994, nearly 2,500 newborns received immunoglobulin and vaccination for HB out of 1.127 million newborns.

To detect preventable causes of intellectual impairments such as phenylketouria, mass screening program for neonates has been conducted since 1977. By 1998, 5,672 Cretinism, 2,330 neuroblastoma, 371 phenylketonuria have been detected to assure prompt treatment. However, questions were raised as to the effectiveness of mass screening for neuroblastoma and the program was discontinued in 2004. In a somewhat odd contrast, intrauterine diagnoses of Down syndrome and other detectable anomalies are not actively performed.



For very low birth weight babies who require intensive care after birth, health insurance coverage starts on the first day of their births as dependent family status of their parent's health insurance. The usually required 20-30% copayment will be waived by public funding for the babies whose birth weight below 2000g.

All babies are entitled to free well-baby checkups twice at the age of 1.5 years and 3 years, all of which are provided by municipal governments.

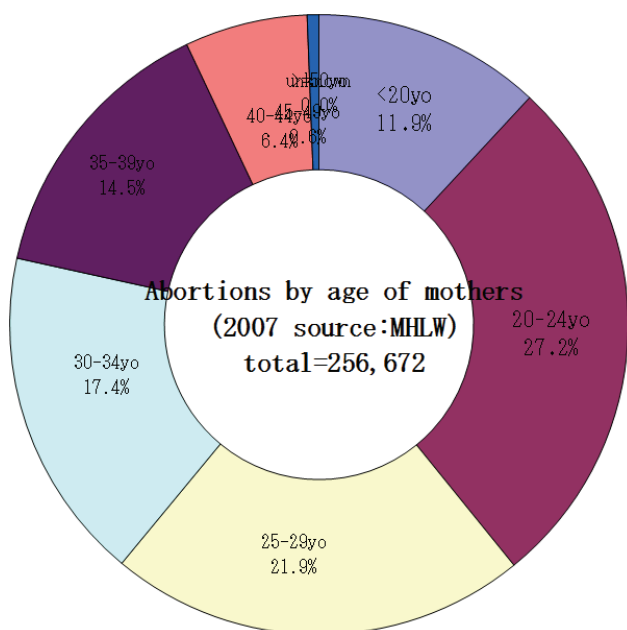
As for abortion, Japan is definitely a “pro-choice” country. The Maternity Protection Act (MPA) authorizes certified doctors to perform artificial abortion on women pregnant 21 weeks or less when the following conditions are met:

- 1) Pregnancy or delivery is likely to jeopardize the pregnant woman’s health in either physically or *economically* (italic author’s)
- 2) The woman got pregnant because of rape

Whether the requesting woman meets the above conditions is up to the certified doctors’ judgment. Doctors have to report the number of abortions performed pursuant to the MPA. If the aborted fetus is 13 weeks or older, it will be treated as still birth and doctors will have to issue certificates of still birth.

Japan’s Penal Codes penalize illegal abortions (The Penal Code section 212-216). Abortions performed pursuant to the MPA are exempted from such penalty.

The number of reported abortions in 2007 was 256,672, of which only 119 were because of rape. All others were performed for protection of maternal health either physically or economically. Majority of abortions are performed in early stage (11 weeks of gestation) of pregnancy, by which time no reporting of still births are required.



The number of abortions has declined to a quarter since 1955, when the number hit 1.17 million. The number of abortions of teenagers per age group 15-19 yo has steadily increased until 2001 perhaps because of younger sexual activities and non-use of oral contraceptive pills (OCP has not been approved until quite recently). The government made efforts to decrease unwanted pregnancies among teens. Currently approximately 7.8 per 1000 teenage (15-19yo) girls undergo abortions annually (2007), a sharp decline since 2001 when the figure was 13.

2. Mental Health

Japan’s mental health is notoriously characterized by its heavy reliance on hospitalization: the highest per capita psychiatric hospital beds in the world (355,269 beds in 2003 or 277.5 beds per 100,000 population, occupancy 92.9%), the average length of stay for psychiatric hospitals is 317.9 days in 2007, and the number of psychiatric patients in hospitals accounts for approximately 0.26 % of the entire population.

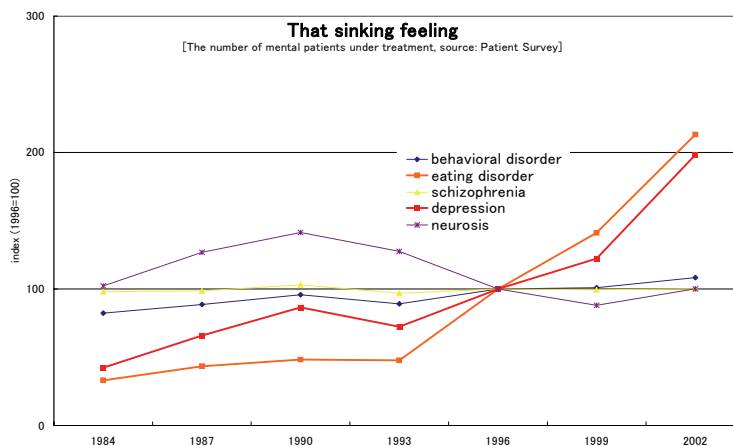
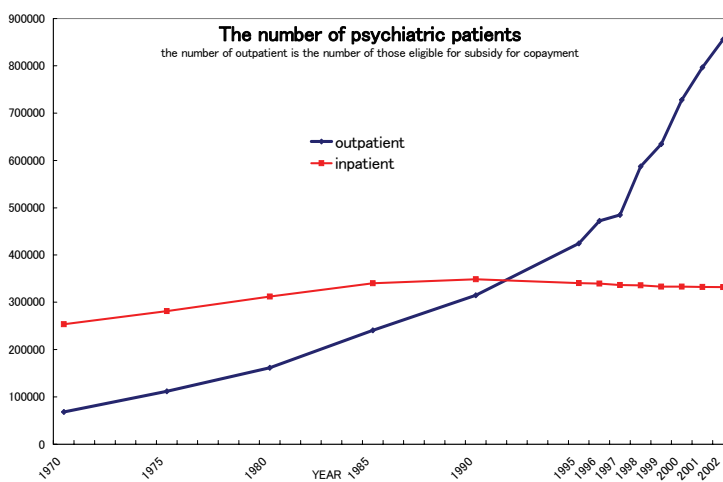
This “institutionalism” may be partially explained by a historical accident in late 60s in which then U.S. ambassador had been stabbed by a psychiatric patient (the Reischauer incident, 1964). This accident provoked a public outcry against the danger caused by

letting potentially dangerous psychiatric patients in community and called for construction of psychiatric hospital beds to segregate the psychiatric patients from the rest of the society. Then the generally perceived “safety” of Japan’s society might partially be made possible at the sacrifice of psychiatric patients’ right.

On the other hand, a series of scandals involving abuse in some psychiatric hospitals prompted arguments over potential violation of human rights of psychiatric patients. In 1987, the Mental Health Act was amended to assure more emphasis on human right protection of psychiatric patients by tightening the conditions of involuntary hospitalization.

Under the Mental Health Act, five forms of hospitalization are stipulated as involuntary hospitalization: detention hospitalization, emergency detention hospitalization, custodial hospitalization, immediate therapeutic hospitalization and observational hospitalization.

The most restrictive, detention hospitalization will be granted if the psychiatric patient presents “clear and present” danger to self and/or public as agreed by more than one qualified psychiatrist (to qualify, a doctor must have at least 5 years of clinical experience and 3 years of psychiatric practice fulfilling a certain training course and passing exams). Emergency detention hospitalization will be granted for up to 72 hours on the same condition with detention hospitalization with the diagnosis by only one qualified psychiatrist. Custodial hospitalization may be ordered by an attending psychiatrist if the legal custodians agreed without consent of the patient. Immediate therapeutic hospitalization may be ordered by an attending psychiatrist for prompt treatment of the disease. Observational hospitalization will be granted for temporary observation to allow time for the psychiatrist to make diagnoses.



Detention hospitalization accounted for 36.1% to total psychiatric hospitalization in 1965 but declined sharply ever since. Currently nearly 70% of psychiatric inpatients are voluntary and custodial hospitalization 27.5%. Detention hospitalization accounts for only 0.8%.

To encourage discharge from psychiatric hospitals and “normalization” of psychiatric

patients living in community, generous subsidy is awarded to the copayment for outpatient treatment. The number of psychiatric patients who are treated in outpatient has increased dramatically as shown. Broken down by diagnosis, depression and eating disorder have seen a sharp rise while the number of schizophrenia remained constant.

Regrettably, there have been sporadic criminal cases committed by psychiatric patients living in community. Pursuant to the Penal Code, crimes committed in unconsciousness are exempt from criminal prosecutions or may receive non-guilty verdict. A new law titled “Medical Care and Observation Act for Those who Commit Crimes under Unconsciousness” took effect in July 2003 to assure proper medical treatment and observation for those who are acquitted due to unconsciousness.

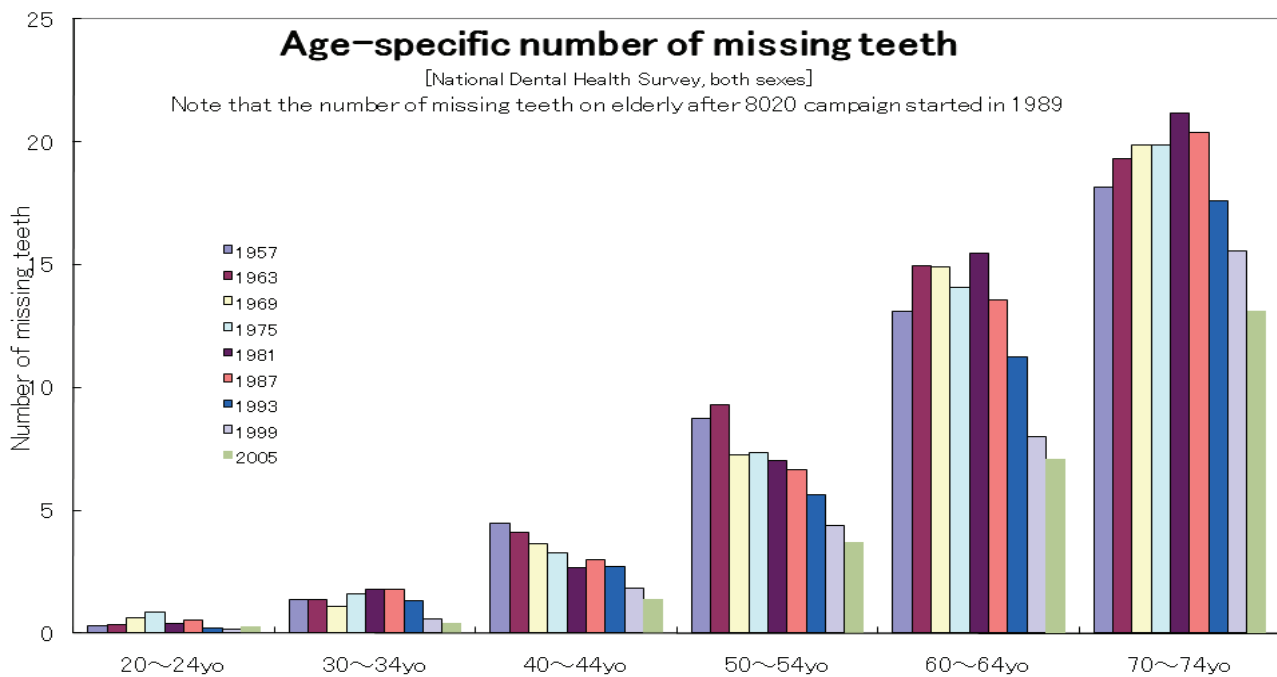
3. Oral Health

Japan’s oral health activities dates back to Taisho era (1912-25) when educational activities to emphasize oral hygiene started. In the post war era, oral health activities were provided by public health centers as part of MCH.

In 1989, the epoch-making “8020 campaign” was started, which signifies that “maintaining 20 teeth at the age of 80”. Since it was deployed as part of elderly health, it aimed at bed-ridden elderly who carry the risk of deteriorating teeth resulting in malnutrition.

MHLW conducts a nation-wide sampling survey on oral health every six years. The latest 2005 survey results show that 57.9% of men and 61.6% of women have at least one missing permanent teeth. For those with at least one missing teeth, the average number of missing teeth was 5.6 for men and 6.1 for women.

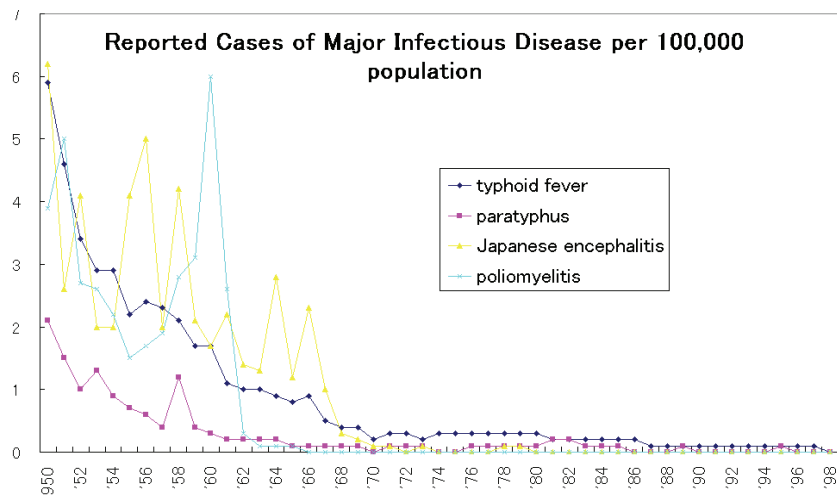
The following graph shows a historical trend of missing teeth since the first survey in 1957. Interestingly enough, while the number of missing teeth of younger generations has steadily declined, the number of missing teeth of elderly increased until 1987. The sharp decline afterward should have reflected the dramatic effect of “8020” campaign.



Overall, the oral health in Japan has improved dramatically particularly for the elderly. The goal set by the “8020 campaign” appears feasible.

4. Infectious Diseases

Japan used to be plagued with epidemics of infectious disease, which also claimed a high mortality. The number of reported cases of major traditional infectious disease has declined drastically since late 1960s, but so-called emerging and reemerging infectious diseases began to pose renewed public health threats.



In 1999, the new Infectious Diseases Control Act was enacted incorporating separate laws against STD, AIDS. Under the new law, infectious diseases are classified into four categories depending on their severity and societal risks.

(1) Hansen’s disease

Hansen’s disease is an infectious disease transmitted by *Mycobacterium Leprae* affecting skin and peripheral nerves. It was once considered as an incurable deadly disease but became curable by drugs (Diamino diphenyl sulfone, DDS and rifampicin). Since the infectiousness of the bacteria is not strong, the disease does not necessarily warrant isolation. However, Japan chose a forced isolation policy starting in 1907 and culminated

in the enactment of the Leprosy Prevention Act in 1953. Such forced isolation simply developed prejudice and suffering of the patients but the isolation continued until the abolishment of the Act in 1996. The patients filed a civil suit against the government claiming that they had been unduly isolated and their entire lives had been sacrificed. The court upheld the plaintiffs' claim in May 2001 and the government started a series of compensation as well as rehabilitation of the victims' honor. The forced isolation policy is now widely viewed as a smear in Japan's public health policy and a study group was organized to analyze the history in 2002 through 2004. In February 2006, another law was enacted to compensate the patients in the former Japan's colonies.

(2) Viral Hepatitis

Viral hepatitis is certainly one of major public health threats in modern Japan. There are estimated to be 1.1 to 1.4 million (more than 1% of population) carriers of hepatitis B (HBV) and 1.9 to 2.3 million (nearly 2% of population) hepatitis C (HCV) carriers. Hepatitis virus is a known cause of liver cancer. According to a survey, 76% of 30,000 liver cancer deaths in 1997 are attributed to HCV and 17% to HBV. More alarmingly, the number of liver cancer death per population has steadily increased from 14 per 100,000 in 1984 to 26.7 (36.4 for men, 17.6 for women) in 2008 and the increase is solely attributable to HCV.

One of the major transmission routes of HCV is iatrogenic. A considerable geographic variance of HCV prevalence might support this hypothesis: some hospitals and clinics used to provide IV treatment without much heed to sterilization and mass immunization programs were occasionally conducted without changing cylinders and needles in the past. Post transfusion hepatitis had been largely eradicated thanks to the introduction of HCV screening introduced in November 1989. Introduction of interferon to treatment of HBV and HCV to health insurance benefit in 1992 also contributed to effective treatment of carriers. To alleviate the financial burden of patients, patients' copayment for interferon treatment is capped at 10000 yen/month (50000 yen for patients with high income) for up to 72 weeks.

Long before the discovery of HCV in 1988, blood products of fibrinogen and Chrismacin (IX factor coagulant) were widely used in clinical settings. Fibrinogen was approved in 1964 and was used for massive bleeding in the course of delivery by OBGY doctors. Chrismacin was approved in 1972 for intracranial bleeding of newborns. Both products had warnings against iatrogenic viral infection.

Those, mostly women, who received fibrinogen and were infected HCV before 1988 sued the governments resulting in widely differed judgment on the responsibility of the government. The group of plaintiffs exerted an effective political campaign (one of the patient later became a congresswoman) and won the collective damage compensation. A special law for the compensation for the HCV patients/carriers who were infected through fibrinogen or Chrismacin took effect in January 2008. Those who claim that he or she has been infected HCV through blood products must first sue the government at a court and win

a final ruling or an arbitration to certify that their claims are legitimate, then the fixed sum of monetary damage (40 million yen for patients who developed cirrhosis or liver cancer, 20 million yen for patients of chronic hepatitis and 12 million yen for asymptomatic carriers) will be paid from PMDA (Pharmaceutical and Medical Device Agency). To help assist patients/carriers in obtaining old medical records, a long list of hospitals and clinics which prescribed fibrinogen/Chrimacin was published over the MHLW website. As of 1 July 2010, a total of 1,519 patients/carriers won the suits and are eligible for compensation (the claims must be made within five years or till January 2013).

Estimated number of HBV, HCV carriers and patients

HBV	< 6 years old in 1951-88 received mass vaccination (700000)	< 6 years old in 1951-88 NOT received mass vaccination (400000~700000)	HCV
	asymptomatic carrier (1-1.3 million)	vertical (mother->child) infection iatrogenic infection through blood intra-family infection sexual transmission	
symptomatic patients (70000)	infection through mass vaccination		infection through fibrinogen
			symptomatic patients (400000)

In order not to repeat the bitter history of iatrogenic infections through blood products, a series of measures were called for drug safety by an investigation committee in its final recommendation released on 28th April 2010. The recommended measures include: 1) increasing the number of technical staff of PMDA for drug safety by 100, 2) introduction of pharmacoepidemiology into pharmacists education and 3) strengthening neutrality and transparency of PMDA for drug evaluation process and 4) development of an effective data collection and analysis system such as health insurance claims database and data mining technique for post marketing surveillance. To study further about 4), investigative committees on “Development of health data base for drug safety” and “Effective use of electronic health records for safety” were organized, plus a research project on “Development of pharmacoepidemiological data base using health insurance claims (PI: Toshiharu Fujita)” was initiated.

(3) HIV/AIDS

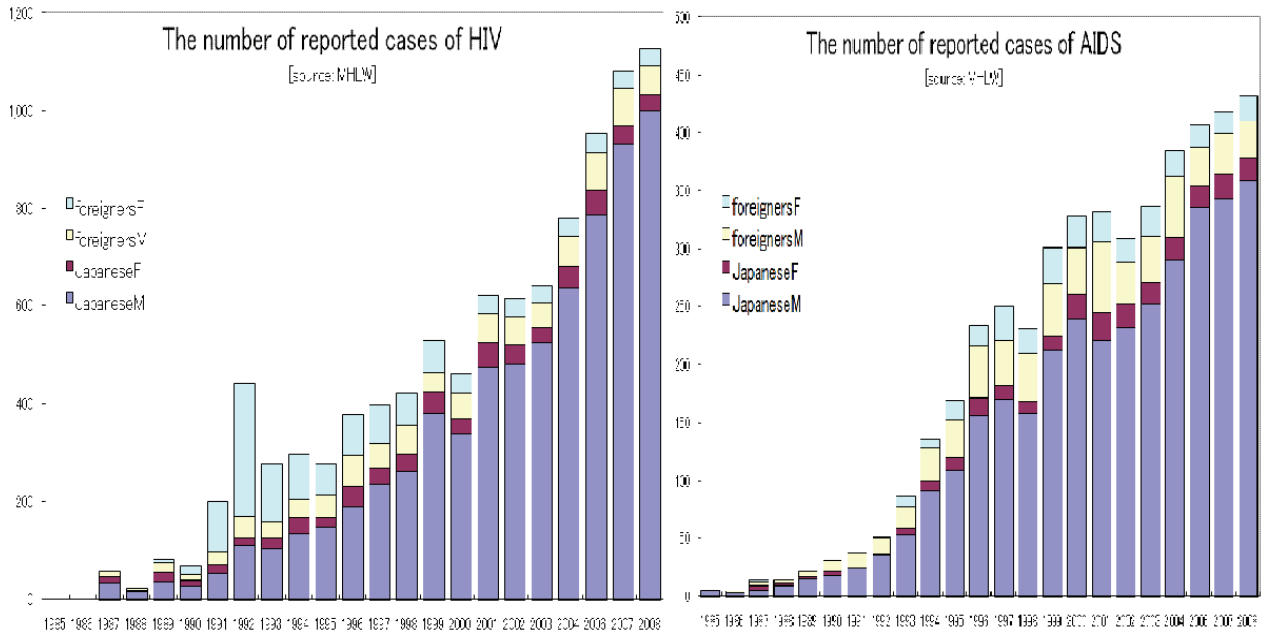
WHO/UNAIDS estimates that there are 33.2 million patients of HIV infection or AIDS worldwide at the end of 2007 with 2.5 million new cases in 2007 and cumulative death toll 2.1 million. The world figure of HIV/AIDS population is declining. Unfortunately this optimistic world phenomenon does not yet apply to Japan. The cumulated number of reported HIV positive cases in Japan was 10,552 and the number of AIDS patients was 4,899 as of March 2009 with cumulated death toll reached 1,506. Breakdown by transmission route is: homosexual contact 69.2%, heterosexual contact 19.5%, illicit IV drug use and longitudinal infection from mothers less than 0.5% respectively. However, the cases of

which transmission routes unknown account for nearly half of the foreign nationals and increasing even among Japanese.

AIDS epidemic in Japan can be summed up as following points:

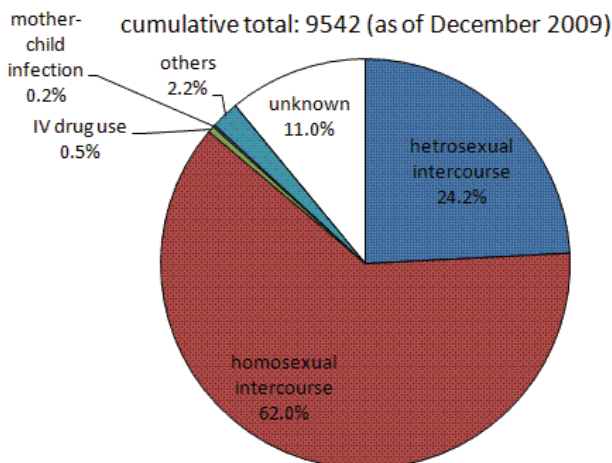
The number of reported cases of HIV is constantly growing among Japanese males with transmission routes of homo and heterosexual relationship.

The number of HIV and AIDS cases involving foreign nationals account for approximately 30% of reported cases in the order of Southeast Asia, Latin America.

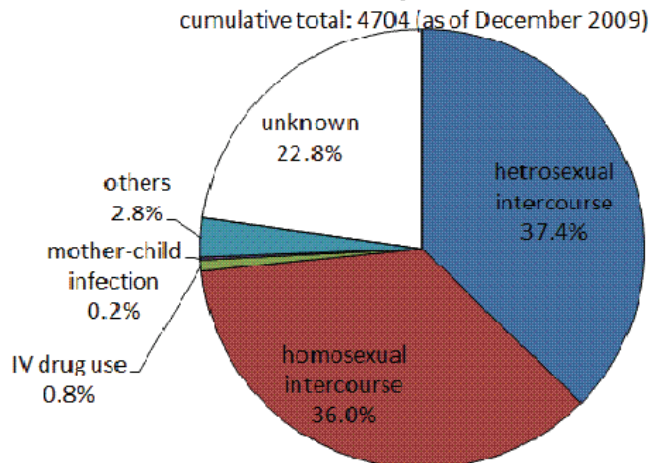


Majority of sexual transmission among Japanese took place inside the country for both HIV and AIDS with concentration in and around Tokyo area. However for homosexual intercourse, majority of transmission concentrates in Tokyo. As for geographical distribution, the number of reports from Kinki block (area around Osaka, Kyoto and Kobe) is alarmingly increasing. Routes of transmission differ between sexes. Homosexual intercourse constitutes a considerable portion of transmission while heterosexual intercourses are the most common routes for women.

Transmission routes of HIV infected men

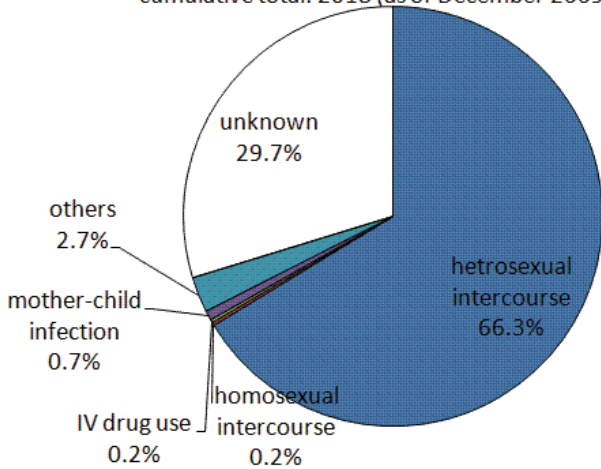


Transmission routes of AIDS developed men



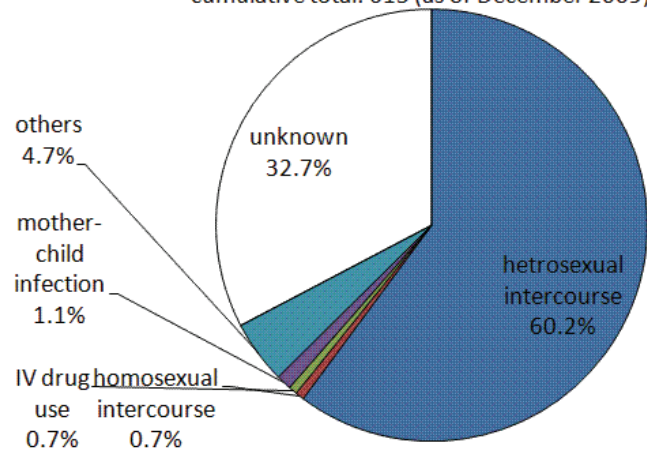
Transmission routes of HIV infected women

cumulative total: 2018 (as of December 2009)



Transmission routes of AIDS developed women

cumulative total: 615 (as of December 2009)



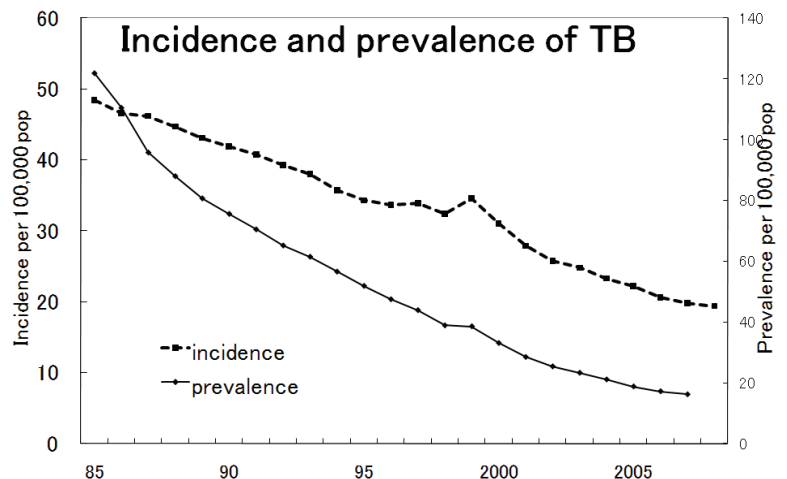
Although the severity of AIDS epidemic in Japan may be less than other countries in public health perspectives, it draws the regrettable past in which a nearly two thousand of hemophiliac patients had been infected iatrogenically through imported blood product. The dispute over the iatrogenic HIV infection culminated in 1996 when the then health minister officially apologized to the patients and the patients group and the government and pharmaceutical companies had settled according to the recommendation by court.

Also in the same year, criminal charges were brought against a leading doctor and a former Ministry of Health officer for professional negligence, but the district court acquitted the doctor in March 2000 ruling that the tragic iatrogenic HIV infection by blood product had not been foreseeable in and around 1985 and therefore the defendant could not be held professionally negligent.

(4) Tuberculosis

Japan is still suffering from a high tuberculosis (TB) mortality in comparison with major developed countries with 2,328 deaths in 2004 or 2 per 100,000 population. TB used to be the leading cause of death until as late as 1950 but has dropped to as low as the 25nd rank in 2001. In around 1950, the age specific mortality of TB was highest among young population: nearly 300 per 100,000 population in the 20s making the disease widely quoted in sad stories involving young men and women.

Under the TB Control Act, doctors who diagnosed TB patients are required to report to the nearest public health centers to prompt them to keep track of the patient. Public health centers have been serving as



the forefront for TB control and prevention. 25,311 new patients were reported in 2007. This translates into 19.8 per 100,000 population. The year 1997 was remarkable because the hitherto declining incidence rate turned upward for the first time in 43 years. Especially the number of active TB patients who are capable of infecting others was 11,318 in 2005.

Once reported, public health centers keep track of the patients until they are diagnosed as free of TB for three years. The cumulative number of patients kept track by public health centers was 62,244 as of December 2008, of whom 20,021 were active TB patients.

The long lasting trend of declining incidence and prevalence of TB showed a sign of resurgence in 1999 prompting MHLW to announce "TB Emergency Declaration". Because TB is concentrating in and around large cities, DOTS(Direct Observational Therapy of Streptomycin) had been actively pursued. The effort bore fruit and the number of patients currently under surveillance by PHC declined to 63,556 in 2007.

The TB Control Act require all babies aged 0 to 4 years old to be checked PPD skin test and receive immunization (BCG) for those who showed negative result (no immunity), all of which are publicly funded. If successful, BCG will develop immunity against TB evidenced by positive PPD test. This iatrogenically induced positive PPD test of Japanese citizens is sometimes puzzling to western doctors who naturally interpret the positive skin test as indication of TB infection. In Japan, mildly positive PPD skin test results are interpreted as evidence of immunity developed by BCG vaccination and is usually not interpreted as TB infection if other findings suggest otherwise.

Immunity endowed by BCG is not entirely everlasting nor does it provide full protection against TB as evidenced by sporadic outbreaks among young people. The PPD skin test will be repeated in elementary and junior high schools and BCG may be repeated for those students who failed to turn positive and hence no immunity.

In 1991, the Public Health Committee issued a recommendation with a targeted eradication of TB in the 2030s. In November 1992, the mass chest X-ray exams conducted on all school children in elementary and junior high schools were abolished to reduce unnecessary radioactive exposure, and those with strongly positive PPD skin test were asked to undergo thorough examination at hospitals or clinics. Before, school children of the 1st and 7th graders were examined with PPD skin test and were inoculated BCG booster shot but the practice was abolished in 2003. Babies were examined PPD skin test first and BCG was inoculated to those with negative result, but the preceding PPD skin test was abolished and all babies are recommended to be inoculated BCG by six months old.

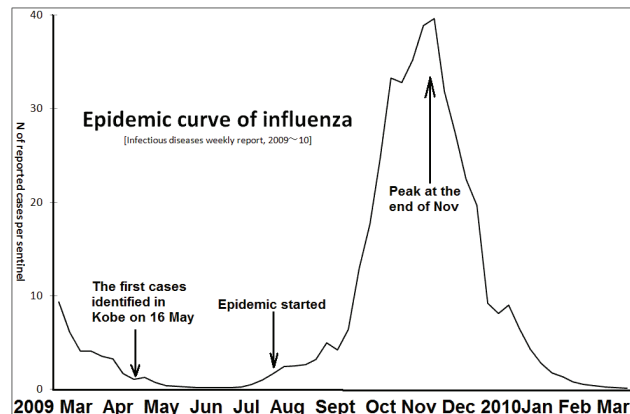
(5) Influenza

Seasonal influenza repeats epidemics every winter seasons. However, viral mutations develop novel influenza (H1N1) resulting in world pandemics. On 24th April 2009, WHO announced the novel influenza outbreaks in Mexico and raised the alert level to phase 4 on 28th April (later raised to phase 5 on 30th April). The MHLW immediately tightened quarantine following the pre-established protocol (called bay-side tactics to keep the

disease at bay). The first patients were identified among passengers from the US on 8th May, and apparently healthy contacts were immediately quarantined in a nearby hotel pursuant to the Infectious Disease Control Act.

Unfortunately, some infected people might have slipped through the quarantine and the first patients were identified in Kobe city on 16th May eventually spreading to all over the country. The index cases were not found despite active epidemiological surveys.

As it turned out, the virulence of the novel influenza was not so worth than



seasonal influenza and skepticism grew about the necessity and effectiveness of the bay-side tactics because the pre-established protocol was intended for deadly avian influenza (H5N1). MHLW defended by insisting that the bay-side tactics do not intend to block the epidemic altogether but delay and blunt the sharpness of the epidemic thus making time to prepare. After the epidemic subsided, MHLW set up a committee to retrospectively evaluate the appropriateness of the bay-side tactics. The final report, released on 10th June 2010, admitted the necessity of bay-side tactics but also emphasized the timing of discontinuation. It also pointed out that “bay-side” tactics may give a false impression among general public that it intends to block the disease completely and suggested changing the name of the measure.

(6) Infectious disease surveillance system

According to the Infectious Diseases Control Act, a surveillance system has been operational since 1981. It consists of two components: mandatory reporting for serious infectious diseases and voluntary reporting for less serious ones such as measles or influenza. For the latter, participating hospitals will report the number of diagnosed case on a weekly basis. The result is published over the web by the National Institute of Infectious Diseases (NIID) in English. (<http://idsc.nih.go.jp/kanja/index-e.html>). For example, epidemic of influenza is shown in a weekly report as the average number of new cases per “sentinel” (approximately 4700 nationwide).

(7) Mass vaccination program

Japan has achieved a great public health success in infectious disease control in the past, the most notable of which was the emergency import of polio live vaccine in 1961 when Asia had been hit by a large polio epidemic. Mass vaccination was also provided for school children for influenza in 1962 and became mandatory in 1977.

The rationale behind the mass vaccination for school children was to strengthen herd immunity to control influenza epidemic. The effect of such mass vaccination is vividly illustrated by Thomas A. Reichert et al as below. The excess death of elderly was suppressed when mass vaccination on school children was under way. However the

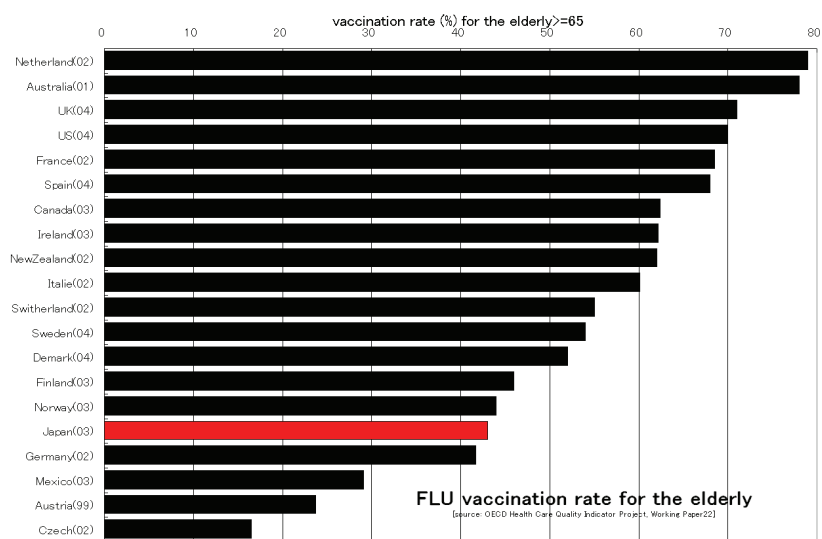
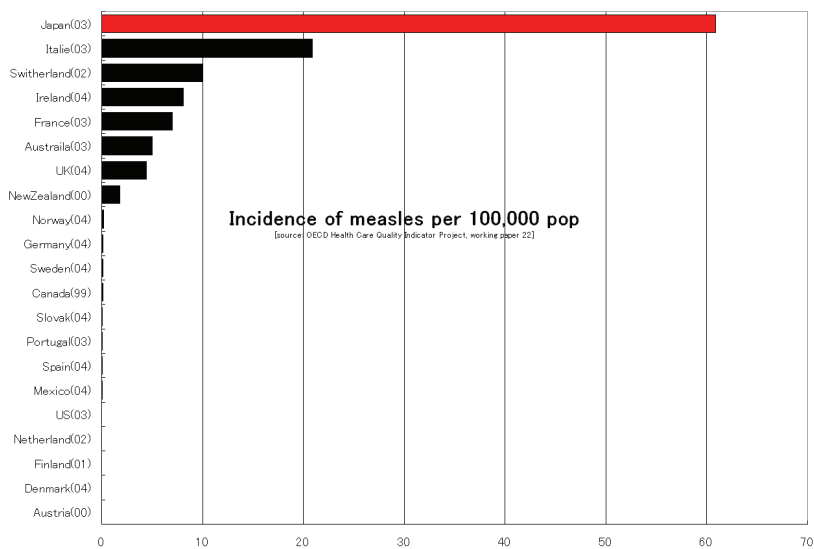
mandatory vaccination was eased in 1985 and discontinued in 1994 in response to the public outcry against adverse effects.

Possibly due to reduced herd immunity, Japan has seen a large resurgence of influenza in 1998-99 seasons resulting in estimated 20,000 deaths most of whom were the elderly. In 2001, the Act was amended again to encourage FLU vaccination to the elderly on a voluntary basis. FLU vaccination rate for the elderly came to be viewed as a quality indicator of an entire country and was included in the OECD Health Care Quality Indicator (March 2006, OECD HCQI Project working paper 22). Japan's rate was 43% in 2003 and is ranked low in the "world quality ranking".

For vaccine-preventable infectious diseases, Japan has higher incidence of measles

than most developed countries despite well-developed vaccination program. The reason is probably its timing: Japan's officially endorsed vaccination is for one year or older, by which age most children contract the disease. Given the world lowest infant mortality, the delayed measles vaccination does not seem to jeopardize children's health.

The outline of Japan's mass vaccination program is below. As for measles, mumps and rubella, a combined vaccine (MMR) was introduced in 1989 but was plagued with aseptic meningitis due to its mumps component and was discontinued in May 1993. Currently mumps vaccination is not provided.



Japan's current mass vaccination program

target diseases (vaccine)		stage	eligible age	recommended vaccinating age	number of occulation
Diphtheria, Pertussis, Tetanus	absorbed DPT combined vaccine	1st	3-90 months	3-12 months	3
		1st booster	at least 6 months after the 1st	12-18 months after	1
		2nd	11,12 years(DT toxoid)	12 years	1
	DT toxoid	1st	3-90 months	3-12 months	2(precipitate) 3(liquid)
		1st booster	at least 6 months after	12-18 months after	1
		2nd	11,12 years	12 years	1
Polio			3-90 months	3-18 months	2
measles, rubella	dry attenuated live component vaccine	1st	12-24 months		1
		2nd	5-6 years		1
Japanese encephalitis		1st	6-90 months	3 years	2
		1st booster	at least 1 year after the 1st	4 years	1
		2nd	9-13 years	9 years	1
tuberculosis	BCG		by 6 months		1
influenza (voluntary)		1)65 years or over 2)60-64 years old with high risk		by middle of December before the epidemic	once every year

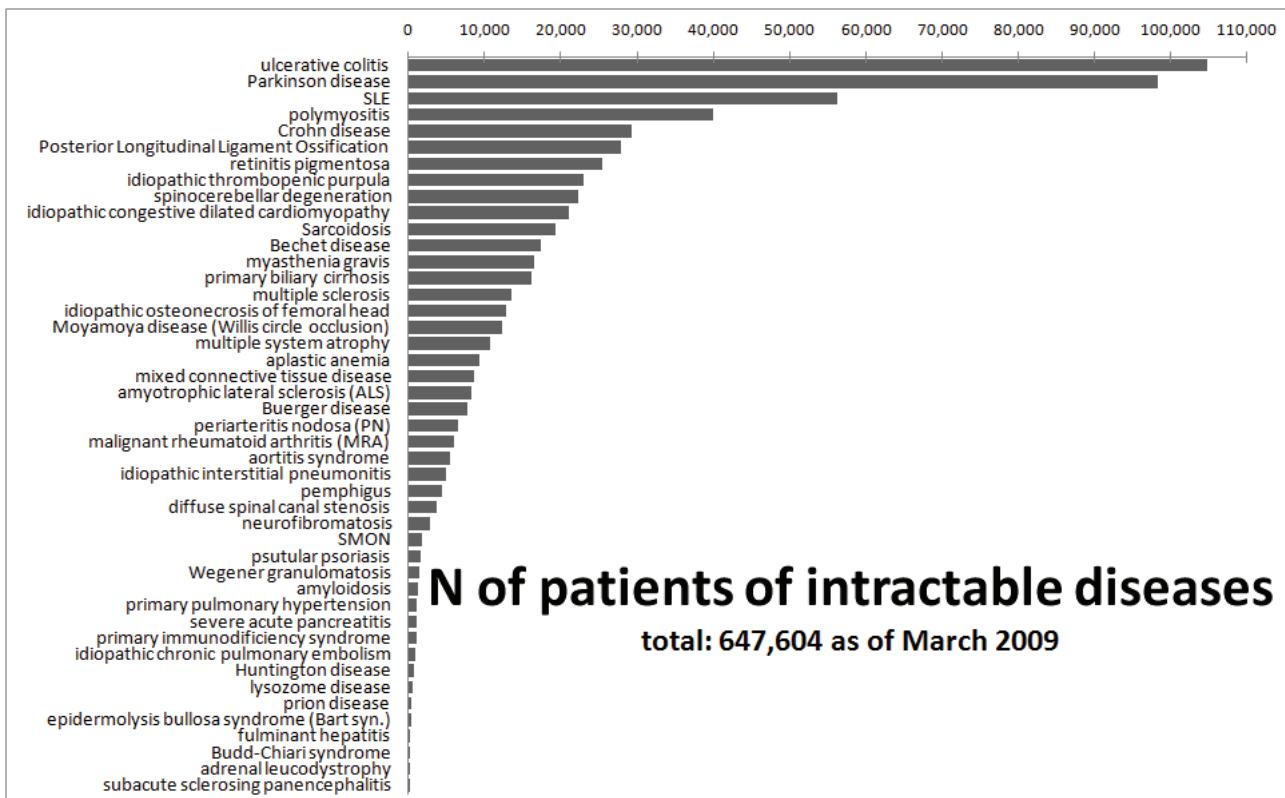
(8) Quarantine

MHLW has 110 quarantine offices in 81 ports and 29 airports. They quarantined over 30 million visitors by air (173,598 airplanes) and over 2 million visitors by sea (70,866 ships) as well as imported food, animals and plants. The most imminent threat for quarantine is that of avian influenza (H5N1). There have been sporadic outbreaks of avian FLU in poultry factories including a case in Kyoto in 2004. The limitation of quarantine is that they are unable to quarantine migrating birds.

5. Research and Subsidies for Diseases of Scientific Interest

Japan has disease specific research and public subsidies programs for certain diseases. These diseases are called "diseases of scientific interest" and 130 diseases are listed as of 2009. Programs aimed at these diseases consist of two pillars: research grants and public subsidies for patients.

Public subsidies for patients will effectively waive the copayment of 20 to 30% of health care cost under the national health insurance system for the treatment related with the diseases on the condition that the patients cooperate with the research programs. This program is a corner stone for the epidemiological survey for such diseases. The latest figure of the number of patients eligible for the subsidy is listed below.



6. Public Assistance for A-Bomb Victims

In recognition of the uniqueness of the A-bomb exposure in Hiroshima and Nagasaki in August 1945, the A-bomb victims are entitled to special public assistance not available for other war casualties. A-bomb victims include those who were exposed intrauterine at the time of bomb blast and those who entered into the bombed area within two weeks. The number of listed victims has declined somewhat due to aging and now 259,556 as of March 2006.

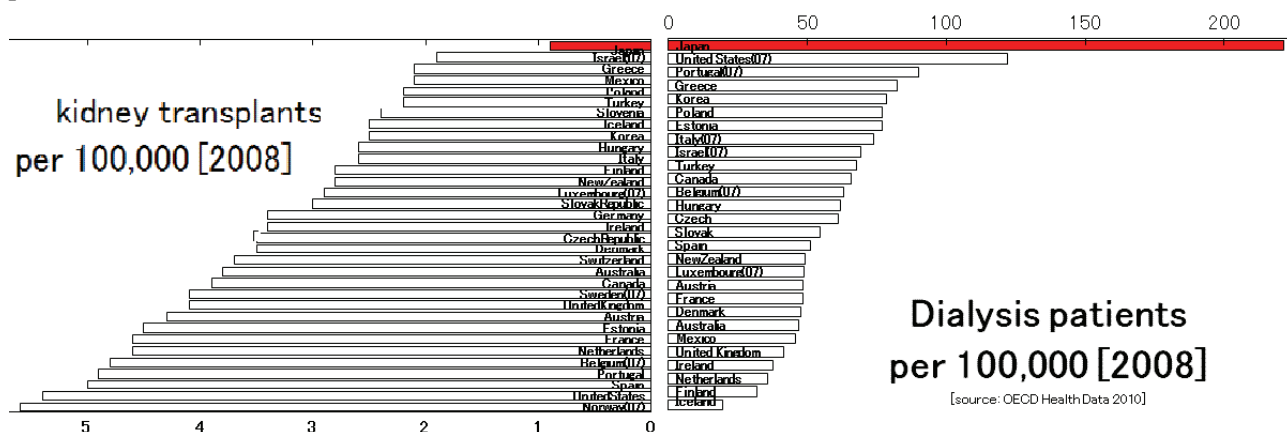
The benefit includes public subsidies to waive copayment for health insurance, and cash benefit in the amount of 33,900 yen (approximately 300 dollars) per month for those with chronic diseases not necessarily related to A bomb exposure such as cardiovascular diseases (approximately 80% of those eligible are receiving this cash benefit).

As for research activities to study the long-term effect of radiation exposure, a research institute was established under cooperation between Japan and the U.S. in 1975 and its findings are contributing much to the development of radiation exposure standards and protection.

7. Renal Failure

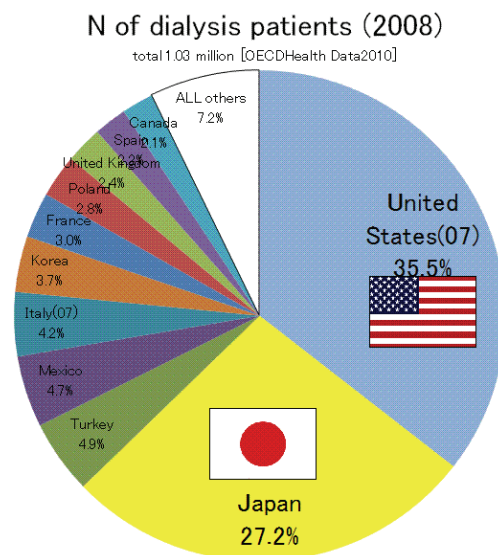
Japan has 110,360 dialysis units and 282,622 dialysis patients at the end of 2008 or one out of 451.8 people and approximately one fifth of the world dialysis patients. This reflects a small number of kidney transplantation (only 1,224 in 2007, of which cadaver transplantation was only 163) and the generous coverage of health insurance system (for renal dialysis the patients' copayment is capped at 10,000 yen (approximately 100 dollars)

per month.

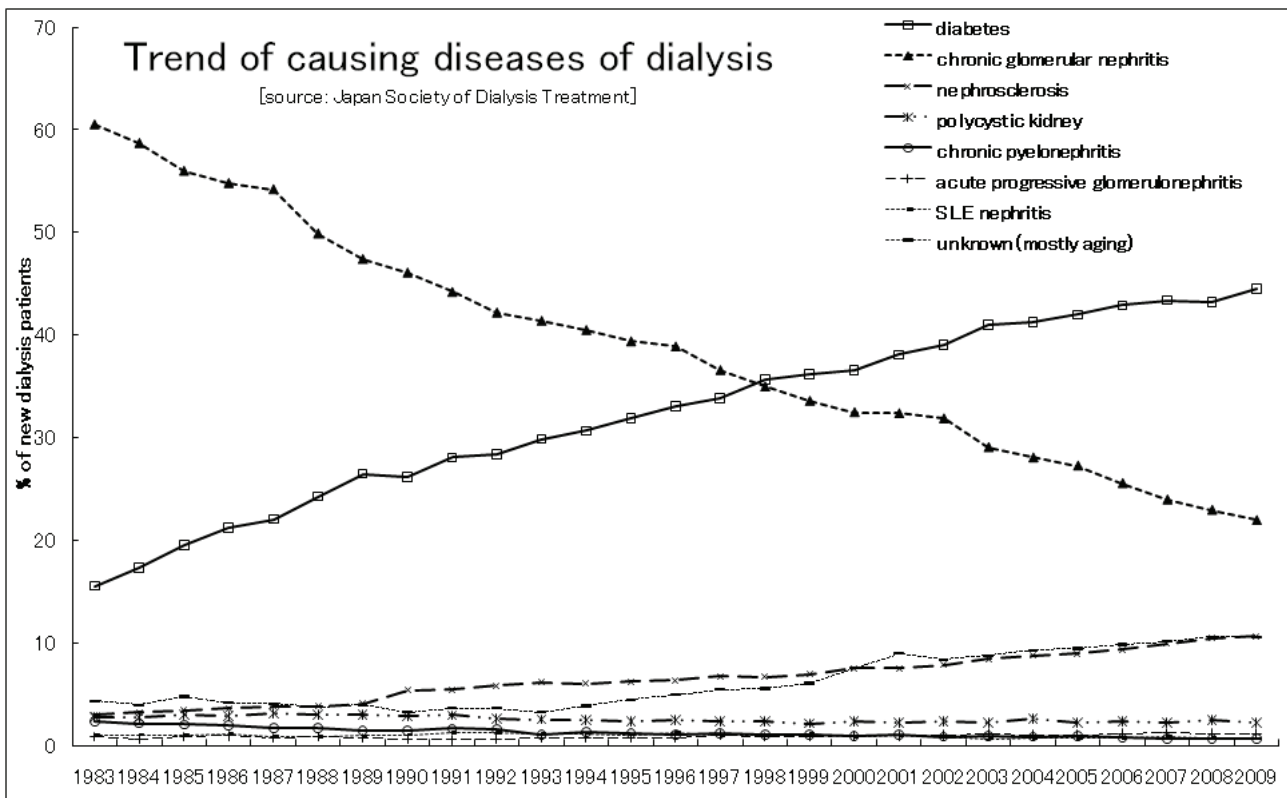


Renal failure used to be considered fatal until December 1962, when dialysis was included in health insurance benefit. Still, health insurance subjected the patients to 20 to 30% copayment, which would accumulate to a considerable sum for long-term treatment such as dialysis. In October 1972, public subsidy was introduced to help ease the financial burden of dialysis patients and in October 1984, the Health Insurance Act was amended to cap the monthly copayment for long-term treatment such as dialysis and hemophiliacs to 10,000 yen (the copayment was raised to 20,000 yen per month now).

The above graphs illustrate clearly Japan's peculiar position in OECD countries: it is ranked top in terms of the number of dialysis and bottom in terms of kidney transplants per population. Dialysis (costing five million yen annually) costs approximately 1.4 trillion yen or 4% of total health

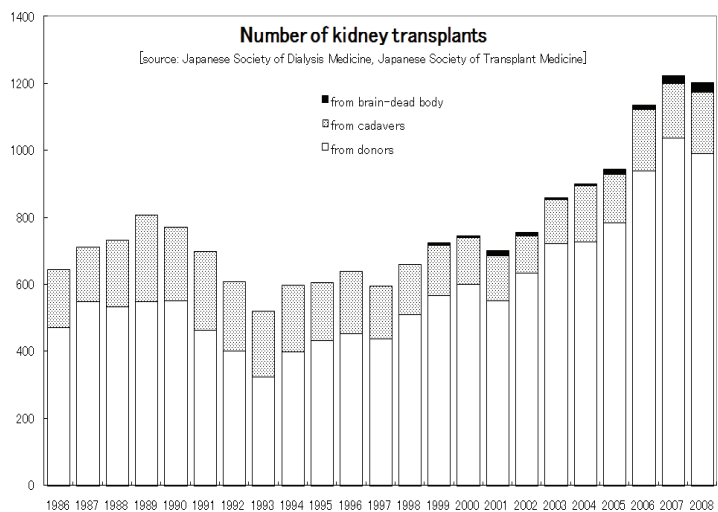


care expenditure of Japan. More alarmingly the increasing trend does not show signs of leveling off. There are over one million dialysis patients in OECD countries in 2008, of which Japan accounts for 27.2%, next only to the U.S.. The increase is mainly attributable to diabetic nephropathy as shown in the graph below suggesting an urgent need for controlling diabetic complications.



8. Organ Transplantation

Kidney transplantation was included in health insurance benefit in 1978, but cadaver transplantation was not available in the absence of the law that authorizes removal of organs from corpses. The Cornea and Kidney Transplantation Act was enacted in 1980 to authorize removal of cornea and kidney from corpses on certain conditions, but the dissemination of cadaver transplantation was still hampered by prohibition of organ removal from brain dead bodies.



Surgeons had to wait until the heart beat completely stops before they could remove the donated organs, which compromised the success rate of transplantation, although cadaver transplantation was somewhat enhanced by establishing the organ sharing information network in 1983. Also, removal of other organs such as heart, lungs and livers were not yet permitted.

Some frustrated patients resorted to traveling abroad to receive transplantations provoking public outcry in some countries and commercial organ transactions in other countries. Even corneal transplantations rely as much as 40% of corneas on import from

abroad.

In October 1997, the long awaited Organ Transplantation Act was enacted to authorize removal of donated organs from brain dead bodies. As a peculiar twist of legal reasoning, the law authorizes brain death only for those who expressed their wish to donate organs of their choice and consent to acknowledge brain death as their time of death. Moreover the declaration of brain death may only be made after following a strict guideline set forth in the law. Also the law prohibits buying and selling of organs for commercial purposes.

There have been criticisms that Japan's legal requirements of diagnosis of brain death and organ donation. For example, children under 16 years old are not capable of giving consent. Because of this, transplants were not available for pediatric patients necessitating pediatric patients to travel abroad for transplantations. The Organ Transplantation Act was amended in 2009. Effective in January 2010, donors were allowed to express their preference to donate their organs to their relatives, and in the absence of written consent of the deceased, relatives are allowed to give consent on their behalf. The new act is hoped to loosen the requirements thereby facilitate organ transplants.

In February 1999, the first organ transplant of heart, liver, kidney and cornea removed from a brain dead body was performed under the new law. The number of patients on the waiting list as of January 2010 was, 12,009 for kidney, 157 for heart, 285 for liver, 143 for lungs and 2,681 for eyes.

As for bone marrow transplant, the bone marrow bank, a database of HLA typing of potential bone marrow donors, was established in December 1991 and maintains a database of over 357,378 potential donors as of March 2009. The bank could match the cumulative number of 11,587 patients who underwent bone marrow transplants by March 2010.

Chapter 4. Medical Care

1. General View of Japan's Health Policy and Planning

Japan's medical care is characterized by ready access, free choice of providers and equality of treatment opportunities. These characteristics owe much to its ubiquitous health insurance system that covers the entire population. Through the health insurance system, the price of every medical procedures as well as pharmaceutical price are under strict government control. Japan's great success in achieving one of the highest health standard in the world is no doubt the fruit of these strengths.

However these seemingly satisfactory achievements of Japan's medical care have not been without problems. Lack of quality assurance mechanism, amenity of hospital wards and patients' right such as access to their medical records have been increasingly brought under criticism in recent years particularly after a series of serious malpractice cases had been exposed.

2. Health Planning

Japan's health policy used to be that of *laissez faire* until 1985, when the Medical Service Act was amended for the first time in the postwar period to require prefectural governments to set up the regional health planning by which the prefectural governments can control the growth of hospital beds in the area with excess bed capacity. This was a bitter reflection over the traditional *laissez faire* policy that had resulted in a serious geographic maldistribution of medical care facilities and personnel. It was also part of cost control measures against spiraling health care cost.

As of March 2006, the country is divided into 365 regions that controls the number of acute general hospital beds (psychiatric beds and TB beds are controlled at prefectural level, which numbers 47). Of these, 217 regions have excessive hospital beds than the objectively assessed number of necessary beds and henceforth are subject to restrictions on new hospital beds construction.

As the history suggests, Japan's regional health planning developed as beds-control measures. In the structural reform in 2008, the revised Medical Service Act incorporated critical path and quality indicators into the regional health planning in the field of four diseases (diabetes, cancer, stroke and heart diseases) and five categories of care (emergency medicine, rural health, disaster health, pediatrics and obstetric care).

The revision of the Medical Service Act was part of the "Structural Reform of Health Care 2008" and the new regional health planning will be implemented as part of the "Health Care Cost Containment Plan (HCCCP)", a five year plan set up by each prefecture. For the development of health planning, an effective information technology such as electronic health record (EHR) will be necessary. A national database of health insurance claims will also provide an infrastructure for such purposes.

3. Health Manpower

Japan's health care is staffed with 286,699 doctors (224.5 per 100,000 population), 99,426 dentists (77.9), 267,751 pharmacists (209.7) and 1.25 million nurses (99.1) as of the end of 2008.

Medical education in Japan is six years course enrolling high school graduates. There are 80 medical schools including a Defense Medical College. The post graduate training has been poorly developed in Japan. Beginning in April 2003, the 2 year post graduate training became mandatory and a matching program to recruit new medical graduates and clinical training hospitals was developed.

All health professionals are under guidance of MHLW, which licenses them. In case of misconducts, the MHLW minister is authorized to discipline them with temporary suspension of their license or revocation. In case of medical malpractices, such sanctions were imposed only in the cases which constitute criminal prosecution. However, in reply to the growing outcry, MHLW took such a disciplinary action against doctor who committed serious malpractices in 2004.

Another problem was that doctors who were sanctioned with temporary suspension of licenses were allowed to practice simply after the suspension terminated without any compensation or contribution. There has been a growing demand that some form of reeducation should be required before the suspended doctors are allowed to return to the practice. As part of the structural reform, the Doctors' Act was amended in 2006 to require the suspended doctors to receive certain reeducation including ethics.

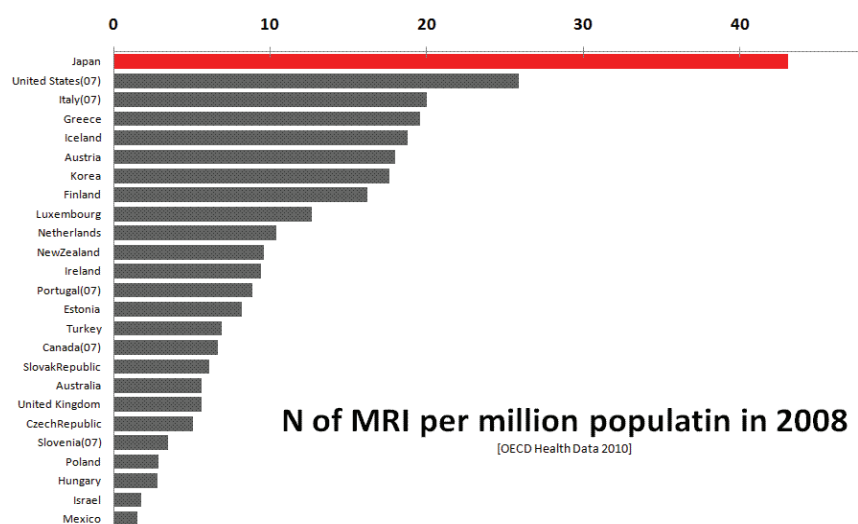
4. Hospitals and Clinics

The Medical Service Act delineates the medical care facilities as hospitals and clinics. Hospitals are further classified into acute general hospitals, psychiatric hospitals and tuberculosis hospitals and clinics are classified into medical clinics and dental clinics depending on the case mix

of the patients they treat.

It is noteworthy that a considerable number of medical clinics (12,399 as of October 2007) own inpatient beds up to 19. These clinics with beds effectively functioning as small sized hospital and their inpatient beds constitute approximately

155,143 beds out of 1.78 million beds (approximately 8.7%).

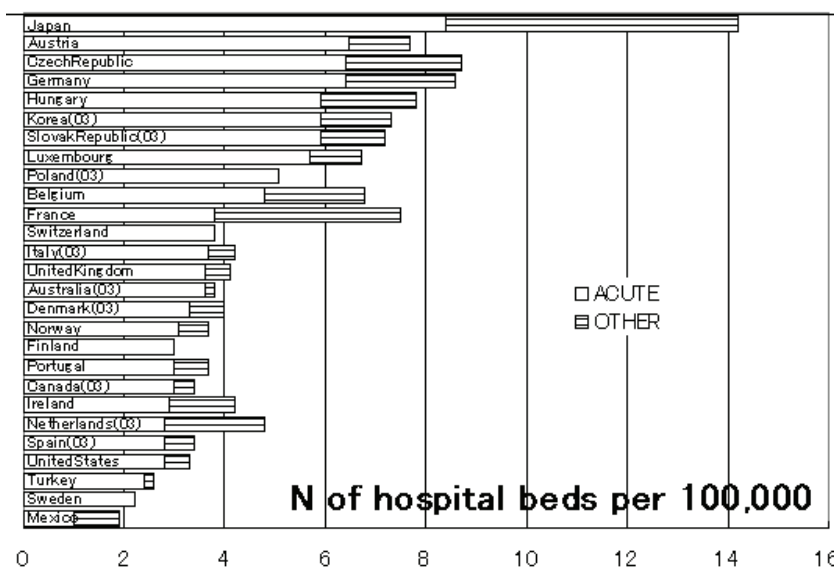


The total number of inpatient beds in Japan as of October 2007 was approximately 1.78 million including 351,188 psychiatric beds. Acute general beds of hospitals are approximately 1.36 million or just above 1% of the total population. These figures suggest that Japan has larger number of inpatient beds per population than most countries in the world by every means. Still, the number has somewhat declined from the peak of 1.95 million beds in 1990 thanks chiefly to the hospital beds control by the regional health planning enforced by the Medical Service Act.

As of October 2008, there were 8,794 hospitals of all categories, over 10% decline since its peak of 10,096 in 1990 reflecting mergers and acquisitions in recent years.

There were 99,532 medical clinics, of which 12,399 were clinics with 19 or less inpatient beds and the rest were clinics without beds. The number of clinics with beds has been constantly declining while the number of clinics without beds has steadily increased.

The ownership of hospitals and clinics in Japan is predominantly in private sector. However since the average size of national and public hospitals tend to be larger, public sector accounts for approximately 46% in terms of hospital beds. Ownership of private sector is either sole proprietorship or medical corporations (MC). MCs are special professional corporations incorporated pursuant to the Medical Service Act.

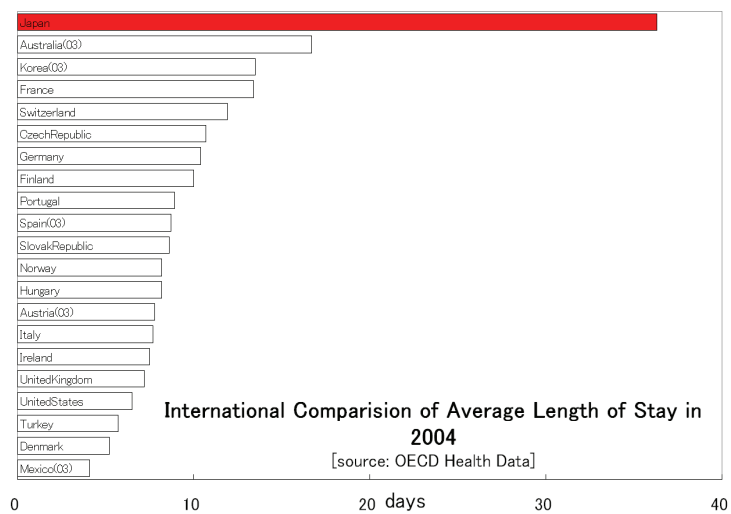


MCs are similar to for-profit corporations in that they are established by direct investment from private shareholders but differ from for-profit corporations in that they are prohibited from disbursing profit to shareholders as a form of dividends. However the corporate asset of MCs is nonetheless the shareholders' property and they are entitled to claim refund at its market value anytime. MCs are also subject to more regulations and supervision by the regulatory authority as to their business and operations than ordinary for-profit corporations.

In general, for-profit corporations are prohibited from owning and operating hospitals and clinics based on the so-called "not-for-profit" principle presumably dictated by the Medical Service Act. This "not-for-profit" principle was somewhat eased in the field of home care in the Long-Term Care Insurance system but is strictly adhered in the field of medical care and institutional LTC despite strong call for deregulation mainly from industry side.

Japanese hospitals are in general well equipped: two out of three hospitals including psychiatric and tuberculosis hospitals have whole body CT scan. The percent of hospitals that own high-tech medical equipment is: NMR-CT (MRI) 23%, angiography 27% and UGI fiber scopes 72% (Health Care Facilities Survey as of October 1999). This dissemination of high-tech equipment may be beneficial to patients but may not be favorable in health economics viewpoint. Disseminating these high-tech equipment in a cost-effective manner while securing easy access to patients will be difficult but important health policy issues.

Japan's inpatient care is characterized by prolonged length of stay: 36.3 days for all hospital beds (including psychiatric beds) in 2004, longer than any other OECD countries. The ALOS has steadily been declining due to increasing number of nursing homes of the LTC insurance: the latest figure is 20.2 days for acute general beds and 338 days for psychiatric beds.



Increasing attention is being focused on geriatric long-term hospital beds, which number approximately 383,911 as of 2005.

As part of the 2006 structural reform, the government announced a plan to reduce the geriatric long-term beds to 150,000 by 2012 with an aim to reduce the already long ALOS. To understand the situation, one must understand the peculiar status of geriatric long-term beds.

Since the inception of the LTCI in 2000, the geriatric long-term beds were separated into two types: one paid from health insurance and another type paid from the LTCI. Ironically enough, the case mix of the patients occupying these beds does not differ much and simply they cost far more than the same patients institutionalized in nursing homes and skilled nursing facilities.

The reduction is expected to be achieved through restructuring the hospital beds into nursing homes or skilled nursing facilities.

5. National Hospitals and National Centers

By far the largest hospital chain in Japan was, ironically, MHLW itself. Succeeding military hospitals and tuberculosis sanatoriums in the prewar period, the chain consisted of 239 hospitals and sanatoriums scattered nationwide in 1986. The financial conditions of these hospitals were such that the government had to pump in exorbitant sum of subsidies.

In 1984, the Committee for Administrative Reform called for consolidation and privatization of national hospitals. In 1987, the Special Act for Reforming National Hospitals was enacted and many hospitals were either abolished or privatized. Eventually

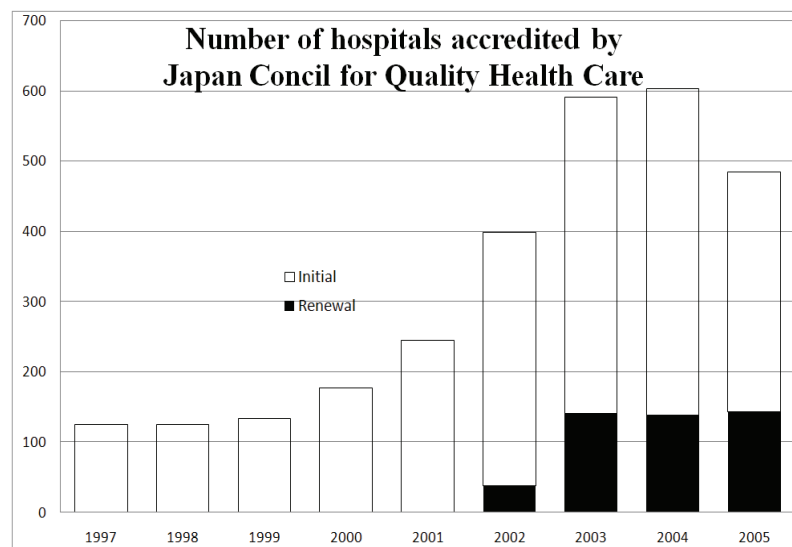
the remaining 146 hospitals were separated from the government as a newly formed NGO called “National Hospital Organization (NHO)” in April 2004. The new NHO consists of 146 hospitals with approximately 60,000 beds and 47,423 employees including approximately 5,000 doctors (The chain also includes 13 sanatoriums for Hansen diseases). The new hospital chain will focus on “policy-oriented health care” in 19 fields such as AIDS, disaster medicine and international collaboration in health. It is also expected to serve as a coordination center for clinical research such as clinical trials and clinical indicators.

National centers were established as flag ships of national hospitals with specific purposes. Currently there are six national centers including the National Cancer Institute (Tokyo, 1962), the National Cardiovascular Center (Osaka, 1977), the National Mental & Neurological Institute, the International Medical Center (Tokyo, 1993), the National Pediatrics Center (Tokyo, 2002) and the National Longevity Center (Aichi, 2004). They will also be separated as independent administrative corporations in April 2010.

6. Accreditation Program of Hospitals

There has been no formal accreditation program to evaluate and certify hospitals and clinics in Japan until 1997, when Japan Council for Quality Health Care (JCQHC) started its official accreditation program.

Accreditation is voluntary and hospitals that would like to undergo accreditation must apply and pay the accreditation fee (1.2-2.7 million yen or approximately 10 to 20 thousand US\$ including five year period). As of March 2007, 2333 hospitals were accredited as satisfying the standards set by the organization (30% of 8978 hospitals nationwide).



Unlike the US JCAHO, whose accreditation is a precondition for participation in Medicare/Medicaid, Japan’s JCQHC accreditation is voluntary and has no legal grounds and the number of hospitals seeking accreditation appears to have peaked out as shown in the graph. As an incentive for getting accreditation, the accredited items are exempt from restrictions of advertisement and accredited hospitals are allowed to advertise the items to the public.

7. Patient safety and medical malpractice

Safety in medical care is increasingly drawing public attention almost in parallel with patients’ awareness of their right. Japan has long been considered as non-litigious society

but an alarming increase of the number of medical malpractice related litigations filed every year suggests a rapidly occurring transformation of both societal atmosphere and patients' attitude. MHLW has long taken a "hands-off" stance about medical malpractice and negligence on the basis that they are basically civil disputes, which should be settled among concerned parties. However a series of serious accidents disclosed at major medical centers have prompted the government to intervene as a precautionary measure.

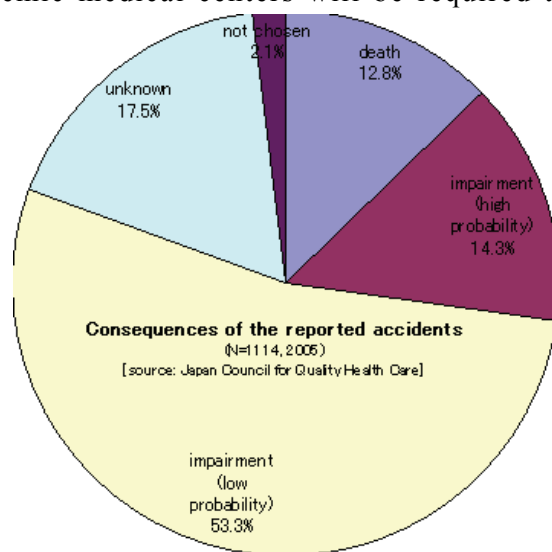
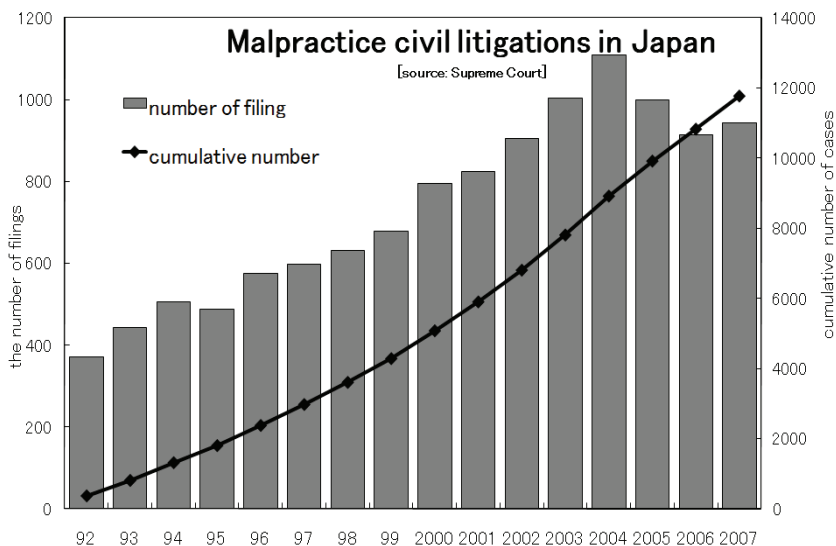
(1) Reporting system of medical errors/adverse events

Effective in October 2002, the Medical Service Act was revised to require that all hospitals as well as clinics with inpatient beds to take necessary precautionary measures including a guideline to secure safety, reporting system from

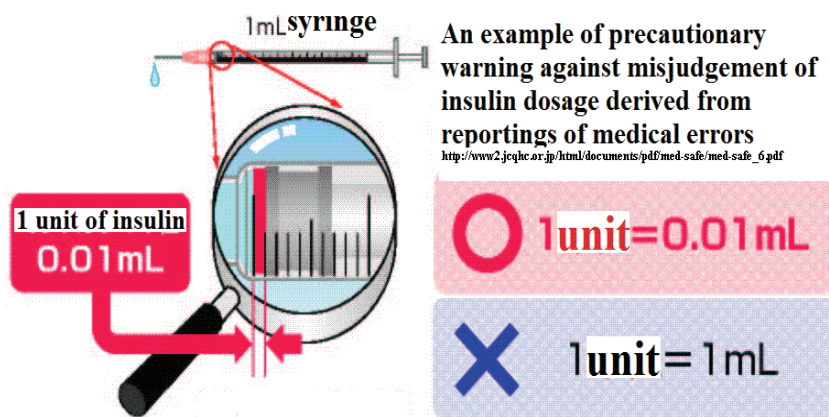
employees about any potentially dangerous "near miss" cases in daily operation and training and monitoring about safety. Particularly, academic medical centers will be required to appoint a full-time "risk manager" both for prevention of accidents and taking appropriate actions in case any claims are brought up patients.

The Physicians' Act mandate that the doctor shall report to police when the patient dies of unexpected causes, but there is no mandatory reporting of incidences that fall short of death. In 2004, the Medical Service Act was again revised to require a certain designated hospitals (including all university medical centers. There are 273 hospitals in 2006) reporting of any medical accidents to the JCQHC effective in October 2004.

The reporting is performed with strict **confidentiality**: for example, only the day of the week and time zone is reported. The purpose of reporting is for prevention of such errors or accidents, not for punishing the responsible persons. In 2005, 1,114 accidents were reported, of which 143 cases had resulted in patients' death. In 2006, the data were 1,296 accidents of which 152 were fatal.

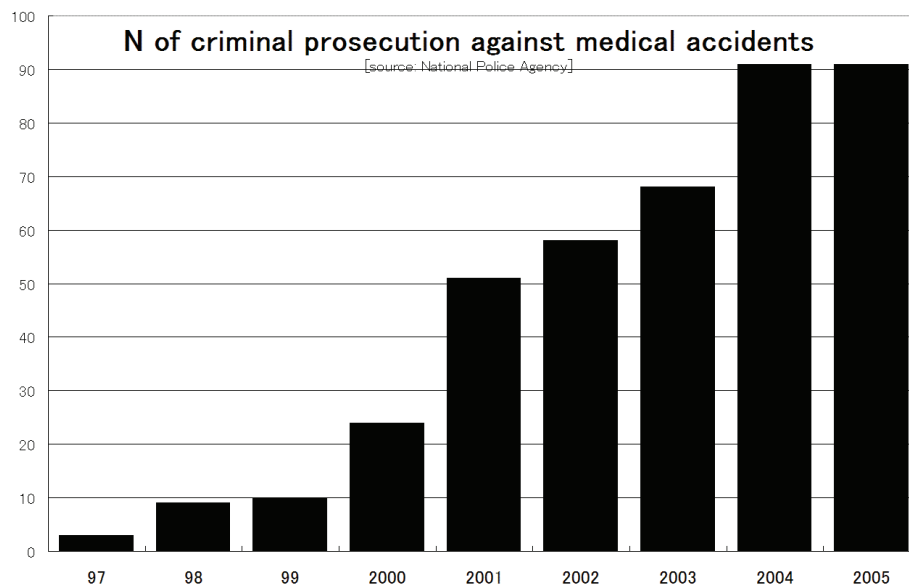


JCQHC publishes the analysis of the reported cases every quarter. The following is an example of precautionary warning derived from reporting that inexperienced nurses misjudged the dosage of insulin through confusion of unit and ml. The warning is expressed in a visual and impressive manner and posted over the website.



(2) Controversy over criminal prosecution

Japan’s penal code includes “accidental death or injuries resulting from professional negligence (the Penal Code, section 211). This criminal charge is unique to Japan because not many other countries have the same incrimination. This charge is applied when anybody causes death or brings bodily harm to others for failure to pay due attention required for professional activities. Here, professional activities refer to any activities which need



license or qualification, the most typical of which is car driving. Drivers who killed or injured somebody else while driving a car for failure to pay due attention will be charged for this crime and doctors and any health professionals are no exception.

However, medical malpractices have seldom been prosecuted as criminal cases mainly due to the lack of prompt alerts to the police. Such good old days were radically altered in and around 1999, when a serious medical error in which surgeons had operated on a wrong patient at a prestigious university hospital and alerted the entire society. Since then, the number of criminal charges brought against doctors for medical accidents or errors resulting in death or bodily harm of patients increased radically as shown in the above graph.

The alarming increase of criminal prosecutions culminated in early 2006, when a OBGY doctor was arrested after he had performed a C-section on a pregnant woman with rare and difficult obstetrical complications (*placenta praevia AND accreta*) who had eventually died of excessive bleeding. Police charged him with “accidental death resulting from

professional negligence” for not taking required attention such as transferring her to the tertiary hospitals. The incident came to be called “Ono hospital incident” after the name of the hospital in Fukushima prefecture and provoked a nationwide debate.

Medical community including OBGY association defended him that the patient’s condition had been rare and difficult ones and that he should not be held responsible simply for not being able to rescue her. The impact of the incidence was such that the number of medical graduates who sought OBGY had declined due to discouragement.

On 20th August 2008, the district court ruled that the doctor was not guilty. This incident not only provoked debate but also sent a strong caution to the police and prosecutors that they should be rather cautious in pursuing criminal charges against medical accidents.

(3) The proposed Medical Accidents Investigation Committee

Medical community resents police involvement on medical accidents but the section 21 of the Physicians’ Act require doctors to report to police within 24 hours when patients die of “unnatural causes”. The Supreme Court ruling in April 2004 held that deaths due to medical accidents are also unnatural causes and failure to report to police would constitute the violation of the section 21.

After the ruling, there has been a growing outcry among medical communities calling for revision of the Physicians’ Act to preclude police involvement. MHLW proposed a bill “Medical Accidents Investigation Committee (MAIC) Act” in 2007. The bill intends to set up MAIC and require medical providers to report any medical accidents. If a provider report to MAIC, their obligation to report to police would be waived thereby effectively precluding initial involvement by police.

However the medical communities once again disliked the clause that “MAIC may notify the police if they found that the accidents are caused by gross negligence”. In April 2008, the third draft was published and an endless debate is still going on.

Chapter 5. Health Economics

Japan’s Health Insurance Act was enacted in 1922 but it did not take effect until 1927 due mainly to the large earthquake hitting Tokyo area in September 1923. The enactment was motivated by German social insurance model created by Bismarck and was intended to cover industrial workers. Non-employed population such as farmers and fishermen were left uninsured. In 1938, the National Health Insurance (NHI) Act was enacted and non-employed population was insured through mutual aid associations.

It is noteworthy that the NHI act was enacted in 1938 simultaneously with the notorious National Mobilization Act. This historical fact suggests the dark side of the NHI system, which was intended as part of the war efforts (Sino-Japanese war broke out in July 1937 and the war procrastinated eventually leading to the WWII).

In the postwar era, the NHI act was revised to expand the coverage for the entire nation. It was 1961 when the national coverage was achieved.

1. Health Insurance

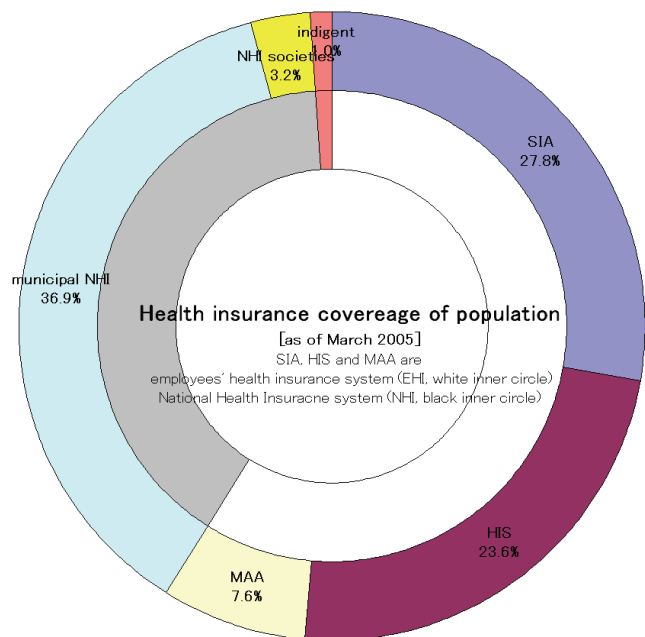
The health insurance system not only finances the health care but also serves as a “*defacto*” policy implementation tool to enable the government to macro-manage the behavior of hospitals and clinics in the entire nation through the uniform fee schedule.

Although the health insurance system covers the entire population, it is by no means a single unified system. Instead, it is a fragmented system consisting of different insurers covering different segments of the population.

The system consists of two major pillars: The employees’ health insurance (EHI) that covers employed working population and their dependent family members and The National Health Insurance (NHI) that covers non-employed population. The EHI is further divided into Health Insurance

Societies (HIS) that are established in major corporations and Japan Health Insurance Association (JHIA) that covers employees and medium to small sized corporations. For civil servants, Mutual Aid Association (MAA) provides coverage equivalent to HISs. The NHI is further divided into municipal governments and NHI societies that are established by some occupational association such as doctors, dentists, lawyers and self-employed construction workers.

Currently the ratio between EHI and NHI is 3:2. The rest 1% are indigent people who



are covered by the means-tested welfare system.

The distribution of enrollment to different insurance system is heavily affected by economic situation. When the job market is bad, there is a migration from EHI to NHI. Due to the long-lasting economic slump, the number of HIS has shrunk from over 1800 to 1502 (as of March 2008) while the enrollment of NHI is increasing. Nearly two million people migrated from EHI to NHI during one year ended in May 2002. With no improvement in the job market in sight for the foreseeable future, the migration toward NHI will continue.

Starting in April 2008, the elderly 75 years old or over (plus those aged 65-74 with certain disability) were separated from health insurance system and were enrolled to the newly established Health Care System for the Old-old (HCSO) operated on a prefectural level. Unfortunately, the new HCSO turned out to be so unpopular among the elderly and the new Democratic administration promised that the HCSO would be abolished by 2012.

(1) Premium

Since Japan's health insurance is social insurance, premium is metered to one's income. In case of the EHI, the premium rate is simply a certain % of monthly salary plus bonus (the number of dependent family members does not matter) with a cap (620,000 yen or approximately \$5000 for monthly salary and 2 million yen or 17 thousand dollars for annual bonuses). The rate of JHIA (the largest insurer) is 8.2% plus 1.23% for the LTCI for beneficiaries over 40 years old. Employers are required to contribute at least half of the premium for their employees. The rates of HISs vary between 4 and 10%.

Premium schedule of municipal NHI varies considerably. It consists of three parts: annual basic premium per household, annual per capita premium for each beneficiary and income-related part subject to the annual per household cap of 530000 yen (approximately \$5000).

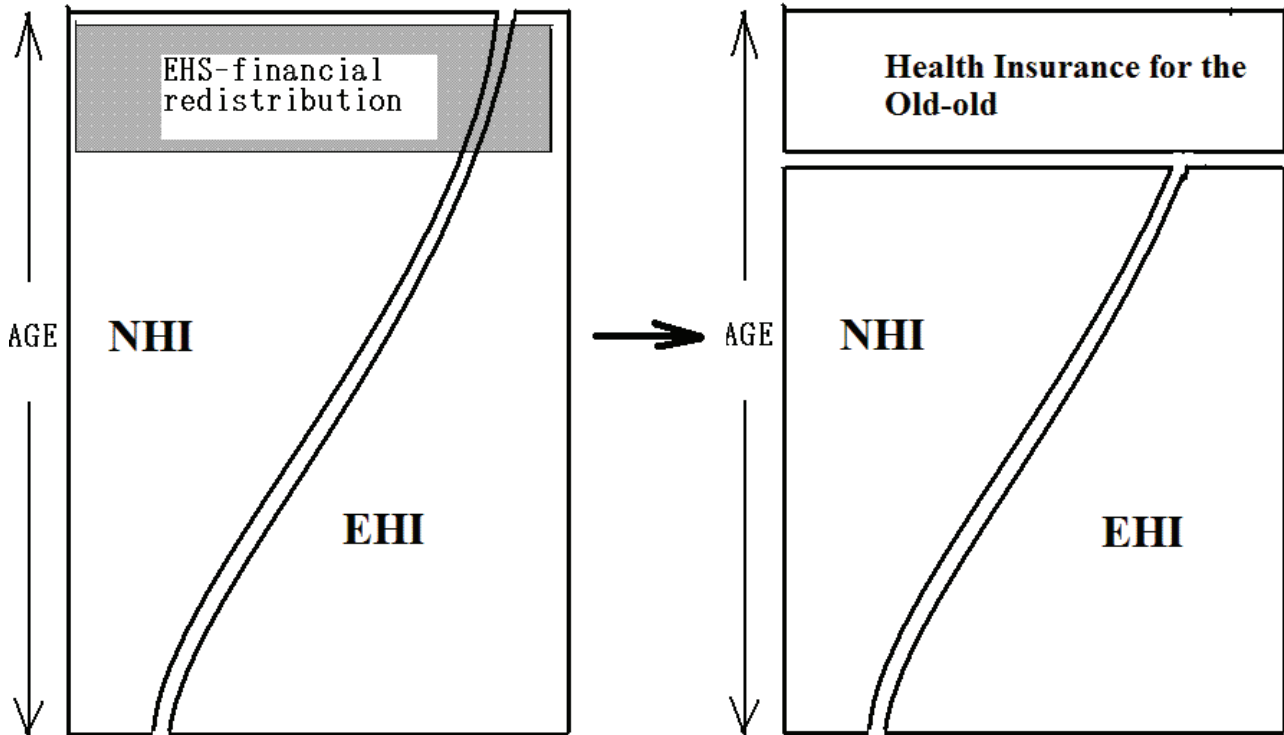
(2) Governmental subsidy

For some insurers, premium contribution is supplemented by the governmental subsidies. Subsidies are most for municipal NHI, in which the 43% of benefit disbursement is subsidized. For JHIA, 13% of the benefit disbursement is subsidized. HISs covering large corporations receives not subsidies.

2. Health Care System for the Old-old

In 2008, the health insurance system was radically restructured. The elderly population aged 75 years or older was separated and covered by the newly created the Health Care System for the Old-old (HCSO).

Establishment of the Health Insurance for the Old-old in 2008



(1) Brief history of the elderly health care system

Since Japan's population has been ageing considerably, the health care system had inevitably to cope with financing problem. The Elderly Welfare Act was implemented in 1963. It was later revised to subsidize the copayment of health insurance to guarantee easy access to health care starting in 1973.

However the elimination of copayment drastically inflated the health care cost for the elderly and financially distressed the NHI system run by municipal governments because of uneven distribution of elderly enrollment among different insurance systems. There was a strong call for total unification of fragmented health insurance system for better risk sharing of the elderly health care cost, but such solutions were not likely to come by because of strong opposition from industry side.

As an alternative, the Elderly Health Act was implemented to introduce a financial redistribution mechanism among different health insurance systems to equalize the disparity of elderly enrollment, which took effect in 1983. After the implementation of the EHS, health care cost for the elderly 70 years old or over was financed in a somewhat different manner than ordinary population. While the elderly population are also enrolled to health insurance system and pay the same premium with the younger population, their health care cost are paid by municipal governments where the elderly resides.

All the health insurers contribute to a newly created financial pool managed by a public corporation and the amount of contribution of individual insurers are calculated to adjust the disparity of the elderly enrollment, i.e., the insurers with less than national average elderly enrollment will have to contribute more than they are otherwise responsible, while the insurers with higher than national average elderly enrollment will contribute less than

they are otherwise responsible.

It is still noteworthy that although the EHS ameliorate the financial plight of the municipal NHI system, it eventually proved to be only a patchwork remedy without a total unification of health insurance system leading to the radical reform in the field of long term care as a form of the LTCI system which effectively unifies the insurers to municipal governments.

(2) Policy debate over the reform

When Japan turned the new century, it has radically restructured the bureaucratic system of the government. The leadership of the prime minister was vastly strengthened enabling the strong initiative by the PM Koizumi who took power in April 2001. The newly created Advisory Committee on Economics and Financing advocated streamlining health care system including the EHS.

Through the policy debates that ensued, policy options were actively debated but eventually the Congress enacted the reform law which would change the EHS Act into the "Elderly Health Care Security Act (EHCSA)" in June 2006. The EHCSA separates the elderly 75 years or older (old-old) from the rest of the population as an independent health insurance system.

(3) Organizational and financing structure

What distinguishes the HCSO from the previous EHS (as well as the LTCI) is that the HCSO is administered by the organizations established in each 47 prefectures. Therefore premium schedules also differ from prefecture to prefecture. Since majority of the old-old elderly are pensioners, premium will be withheld from pension payment. Actually, the largest aim of creating a new independent system was to make the ever-growing pension fund as yet another source of health care financing.

However the premium from the entire old-old population (approximately 10% of the population) constitutes only 10% of the revenue. About half of the revenue is from tax and 40% is from contributions from all health insurers of younger population.

(4) Fee schedule and benefit structure

The fee schedule does not essentially differ from the ordinary health insurance. However, some modifications are made. One example is the family doctor fee for the old-old. This is intended to be a forerunner of capitation and gate keeper model.

(5) The doomed fate of the new system

As it turned out, the newly created HCSO was doomed. As soon as new health insurance cards were delivered to the old-old elderly, criticism and dissatisfaction arose. The old-old elderly was deeply dismayed at the name in the first place. It was named the Health Care System for the Old-old according to an academic definition of the elderly 75 years or over chiefly to differentiate it from another financial redistribution system for the elderly aged 65-74 (Young-old). However, when lay people ignorant of such academic definitions felt disgusted when they received new insurance cards in April 2008 because they misinterpreted the name of the new system as something like "Latter-stage Elderly Healthcare System" implying that the recipients were near-end of their lives. The

unpopularity of the new system was so overwhelming to the point that the then prime minister Fukuda had to change the name to the "Longevity Healthcare System". The then minister of health, Yoichi Masuzoe, laments that the unpopular new system was responsible for the loss of many health-related congress persons in the general election in 2009 in his memoir "The war chronicle of the Ministry of Health, Labour & Welfare". The new Democratic administration vowed to abolish it by the end of 2012 and the discussion on the new system started again.

3. Fee schedule and Reimbursement system

The benefit of Japan's health insurance system is comprehensive and uniform: one can safely assume that all medical services including dental care and outpatient medication are covered to all nation regardless of the insurance system.

The reimbursement is basically fee-for-service and the government sets the national uniform fee schedule as well as the price list of all drugs covered by insurance (unfortunately Viagra is not covered). There is no capitation payment like British NHS nor manage-care arrangement as seen in the U.S..

The fee schedule is revised every two years through the negotiation between the government and the provider sides (Japan Medical Association etc). The fee schedule revision is important in health policy making because not only it changes the price but also it implements certain health policy. For example, the government may be able to encourage doctors over the country to provide more house calls through economic incentives by raising the price for house calls.

The year 2008 coincided with the fee schedule revision year and charges of typical cases are presented below.

Charges for typical cases (yen, \$1=105yen)

[source: documents presented by MHLW to explain the fee schedule revision. March 2008]

[case1] 57yo diabetes, visit outpatient clinics once a month, direct dispensing		[case2] 78yo hypertension, visiting outpatient clinic twice a month, on	
lifestyle-related disease management fee 12800		evaluation & management fee for old-old 6000	
follow-up visit 600		follow-up visit 720X2	
others 520		others 520	
TOTAL 13920		prescription fee 680X2	
(patient copayment 30%) 4180		TOTAL 9300	
		(patient copayment 10%) 930	
		pharmacy	
[case3] 29 yo acute appendicitis, emergency surgery and hospital stay 4		pharmacist management fee 400X2	
hospital charge (4 days) 17280X4		add-on for generic dispensing 40X2	
others 8130		compliance management 350X2	
surgery (appendectomy) 62100		information on generic 100	
anesthesia 10500		dispensing fee 650X2	
TOTAL 149850		drug charge 420X2	
(patient copayment 30%) 44960		TOTAL 3820	
		(patient copayment 10%) 930	

Reimbursement is not 100%. Patients are required to pay a certain specified copayment whenever they receive treatment. The copayment is 30% (10-20% for elderly over 75) with monthly cap, beyond which the overpayment will be refunded by insurers upon request.

4. Claims processing and computerization

Hospitals and clinics submit claims for direct reimbursement to the insurers. Practically, insurers do not handle the claims, instead they maintain clearinghouses for claims processing. All hospitals and clinics will submit all the claims to the clearing houses established in each of 47 prefectural level. Clearinghouses are authorized to audit the claims to verify the content of the claims, after then the reimbursement will be paid to each hospital or clinic. Claims are submitted in every calendar month. The total number of such claims is well over one billion per year (!).

In 2001, the IT Strategy Act was enacted under the Mori administration proclaiming that Japan would be the world most advanced IT technology country by 2005. Subsequently the MHLW published its first “Health Care Information Grand Design” in December 2001 and set the goal of computerization of insurance claims of hospitals more than 50% by the end of FY2004 and more than 70% by the end of FY 2006. Moreover, the revision of the Health Insurance Act in 2002 included a provision requiring the government to “develop a system to collect, analyze, evaluate and disseminate data on health care and health care cost (the supplementary provisions Sec.2, 6(2))”. Unfortunately, despite this Grand Design and a new provision, the computerization of claims did not advance as scheduled. In 2005, it became apparent that health care field was most underdeveloped in terms of IT.

This time, the IT Strategic HQ of the cabinet took an initiative and set a time limit of 2011 for the full computerization of claims expressed in a document titled “The Platform for the Health Care Reform” published on 1 December 2005. It also stated that “efforts shall be made to analyze the online claims information”. The subsequent “The New Strategy for IT Reform” published by the IT Strategic HQ in January 2006, for the first time, proposed establishing a “national database of health insurance claims” to be used for epidemiological research. This landmark decision was much influenced by the Korean development of the data warehouse by their Health Insurance Review Agency (HIRA).

In response to the New Strategy for IT Reform, MHLW compiled the 2nd Grand Design in March 2007, an action plan for the next five years. It reconfirmed the stated goal of full computerization of insurance claims by the end of FY 2010 (March 2011) and set a schedule for the “national database of health insurance claims”. The system shall be constructed by the end of FY 2008 (March 2009) and start collection of computerized claims data in 2009 and will start publication of the results of analysis in 2011. The “committee for utilization of health insurance claims for betterment of the quality of health care” was launched in July 2007 and will compile the final report by the end of the year.

Computerization of claims is rapidly developing. According to the latest figure released by Social Insurance Payment Fund (SIPF), the percent of claims submitted electronically

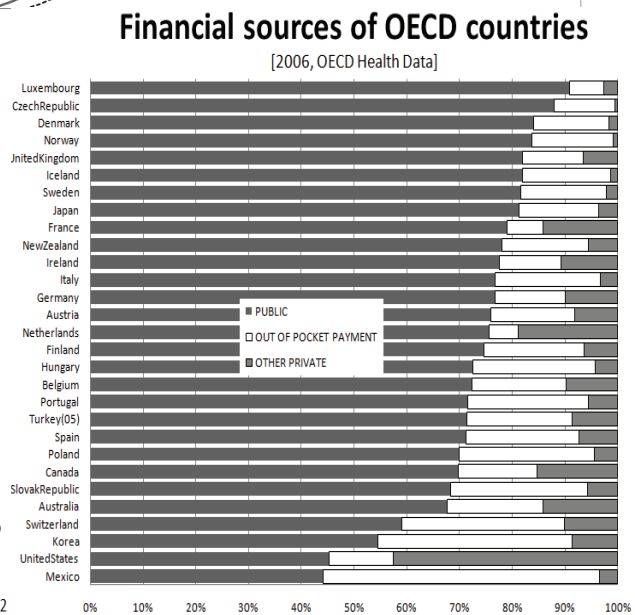
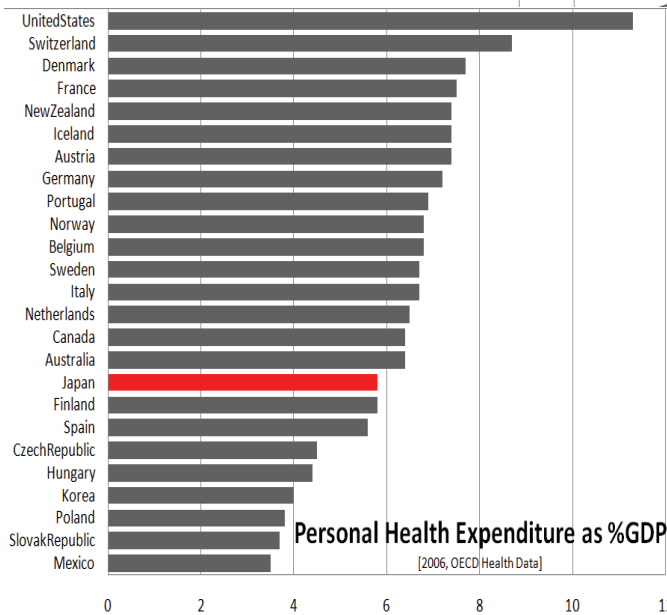
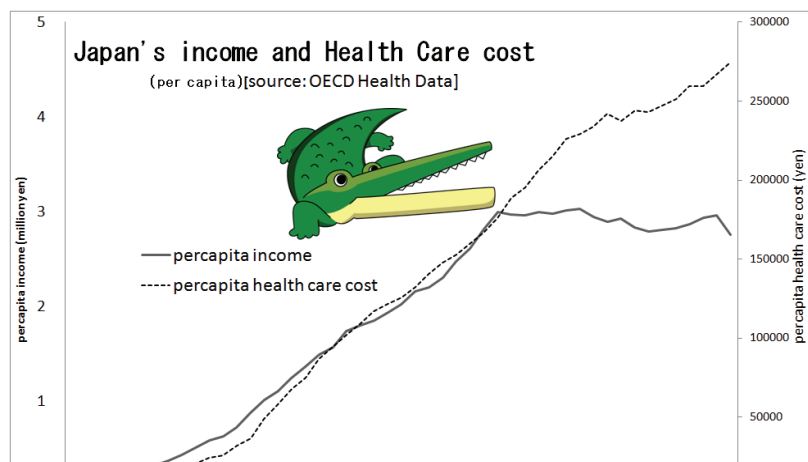
reached 99.5% for hospitals, 89.5% for clinics and 99.9% for pharmacies) in August 2010. For hospitals and pharmacies, computerization was almost achieved.

Once Japan's claims are computerized, they are expected to be a powerful tool for not only health economics research but also epidemiological research. Pursuant to the section 16 of the EHCSA, the MHLW is authorized to collect all data of health insurance claims as well as health checkup and guidance data from insurers. Based on this provision, the national database was established in April 2008 (health insurance claims data were collected since April 2009). The rule for use of the data for research purposes will be promulgated as a ministerial decree and the data use is expected to start early 2011.

5. National Health Care Expenditure

The government estimates the total disbursement of health care cost paid to hospitals, clinics and other related health care providers such as pharmacies and independent visiting nursing stations, which is called the National Health Care Expenditure (NHCE).

The estimated total of NHCE



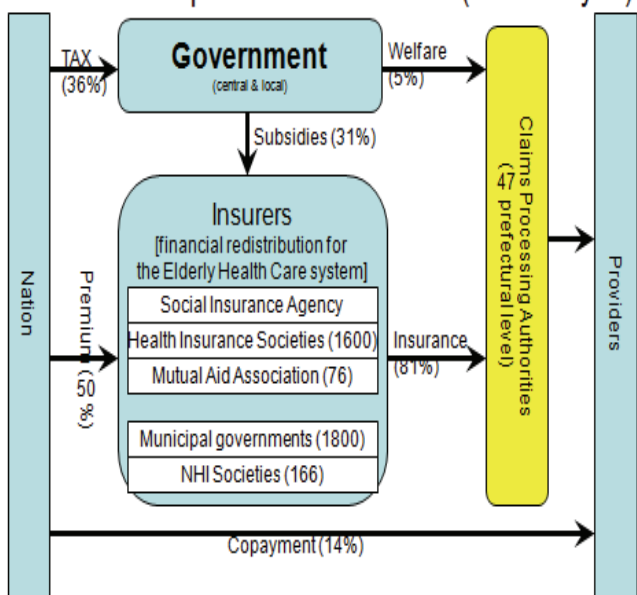
in FY2008 was 34.1 trillion yen or approximately 350 billion dollars or 260,000 yen (2,600 dollars) per capita, which constitutes 9% of Japan's National Income (NI, 374.8 trillion yen in 2007) or 6.5% of Gross Domestic Product (GDP, 500 trillion yen).

Although this figure may seem reasonable particularly in comparison with the U.S., one should be reminded that the scope of NHCE is much more narrowly defined than the national health expenditure of the U.S.. Japan's NHCE is strictly limited to the cost paid

by public financing system to health care providers and does not include private payment such as glasses and contact lens, OTC drugs, add-on payment for amenity. According to the estimate made by the Institute of Health Economics and Policy (IHEP), the NHCE is underestimated by at least 10% from the more broadly defined health care expenditure of other countries.

The government has set a policy goal of controlling the growth of NHCE in parallel to the growth of the National Income (NI) so as not to strain the household. The percent of the NHCE per NI was 6% in 1990, when the bubble economy raised the national income, but has increased steadily since then to 9% in 2007.

Flow chart of Japan's Health Care Cost (32 trillion yen)



coupled with the rapidly aging population, the burden of health care cost will inevitably continue to grow in the foreseeable future.

As for the financial source, the NHCE is broken down to insurance premium 49.2%, general tax revenue 36.7% and patients' out-of-pocket 14.1%. The share of patients' out-of-pocket is growing due to the increased copayment of the health insurance system. As measured by %GDP, Japan ranks low of the middle of OECD countries with regard to personal health expenditure.

6. The Structural Reform 2008

In April 2001, the Koizumi administration took power and a “neo-conservative” reform plan was adopted. There are two important “brains” behind the Koizumi reform: the Council on Economic and Fiscal Policy (CEFP) (<http://www.keizai-shimon.go.jp/english/index.html>) and the Council on Deregulation and Privatization (CDP). Members of the “brains” are dominated by economists and business leaders excluding medical societies. Therefore, the debate over the reform is the battle between the neo-conservative reformers (CEFP, CDP) vs. opponents (Japan Medical Association).

The stance of MHLW fluctuated in between. Shortly after Koizumi took power, the CEFP issued the first policy statement “The basic fiscal policy and socioeconomic structural reform” dubbed “*Honebuto Houshin* (audacious policy)” in June 2001. The statement included two radical proposals: health care rationalization program and global budget on elderly health care cost. The CDP proposed a variety of deregulation measures such as allowing for-profit companies to own and manage hospitals, direct negotiation and contact between providers and insurers (Japanese manage-care) and on-line processing of health insurance claims.

Their proposals were welcomed by Ministry of Economics & Industry and Ministry of

Finance but were, imaginably, unpopular among medical communities and MHLW also appeared reluctant, although it did issue a working plan to realize the *Honebuto Houshin* in September 2001. In fact, not much of the proposals were realized as of 2005. In 2002, as a political compromise of revising the health insurance laws to increase patients' copayment, the revision included a mandate that a structural reform plan should be completed in two years. The mandates also included a recommendation that the government set up an information system to keep track of health care cost, quality and utilization, which has not been realized yet.

The general election in September 2005 turned out to be the fanfare of the Koizumi administration. The overwhelming victory of the ruling party (excluding the renegades who had opposed privatization of the postal services) brought with it the boost for what became called the "structural reform of the health care system". The reform plan, which passed the Congress in June 2006, involves radical measures which few would have anticipated.

In 2008, the following agenda took effect:

- Establishment of the new independent EHCSA covering the elderly aged 75 or over. The new insurer will be cooperatives of municipal governments in prefectural level.
- Consolidating health insurers at prefectural level. The Social Insurance Agency which has been managing the governmental health insurance will be separated into 47 prefectural levels as independent organization. As a precursor, a committee involving all health insurers is already established in every prefecture.
- Introduction of primary prevention programs against metabolic syndrome. All health insurers will be required to provide annual health checkups as well as post screening health guidance to all beneficiaries including dependent family members.
- Development of IT. These include the full electronic transfer of insurance claims on provider side, and record keeping of individualized records of health checkups between age 40 thru 74 years old. Also computerized insurance claims will be actively used to facilitate the disease management.
- Reduction of geriatric LTC hospital beds through development of "community path" to enhance effective coordination among various care providers encouraging early discharge.

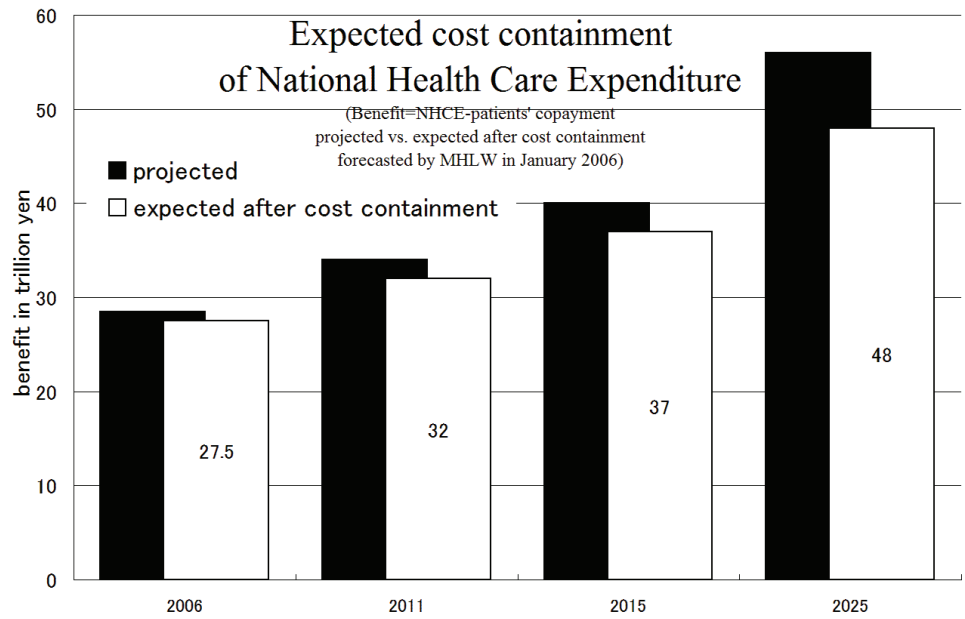
The prevention program against metabolic syndromes and reduction of geriatric long-term care hospital beds are two pillars of the newly created "Health Care Cost Containment Plan (HCCCP)" developed by each prefectures. In early 2006, MHLW produced a forecast of NHCE in the long future. According to the forecast, the benefit (=NHCE-patients' copayment, 85% of NHCE) was projected to be 34 trillion yen in 2011, the last year of the five year plan. MHLW hoped that the benefit will be reduced to 32 trillion yen through prevention of metabolic syndromes and reduction of geriatric LTC hospital beds. It would eventually amount to 8 trillion yen savings in 2025.

The forecast turned out to be doomed from the very beginning. MHLW officially acknowledged that no cost saving would be anticipated from primary prevention program in its public announcement.

Prefectures did presented the prospect of health care cost by reduction of geriatric

LTC hospital beds. Unfortunately, the reduction only added up to 0.7 trillion yen in 2011. This was a far cry from the expected reduction of 2 trillion yen benefit (or 2.35 trillion yen of NHCE).

This gloomy aspects painfully remind everyone the difficulty of cost containment of health care.



Chapter 6. Pharmaceutical Affairs

As part of the tradition of oriental medicine, poor separation of prescription and dispensing of drugs have long characterized Japan's medical care, in which doctors directly dispense drugs to the patients. This tradition has been considerably modified thanks to the government efforts through economic incentives by way of manipulating the uniform fee schedule.

Japan's pharmaceutical regulation, on the other hand, has sometimes been smeared by iatrogenic disasters involving pharmaceutical adverse effects (ADR), the recent cases of which involve Sorivudine scandals in 1993 and iatrogenic HIV infection through imported blood products in the 1980s.

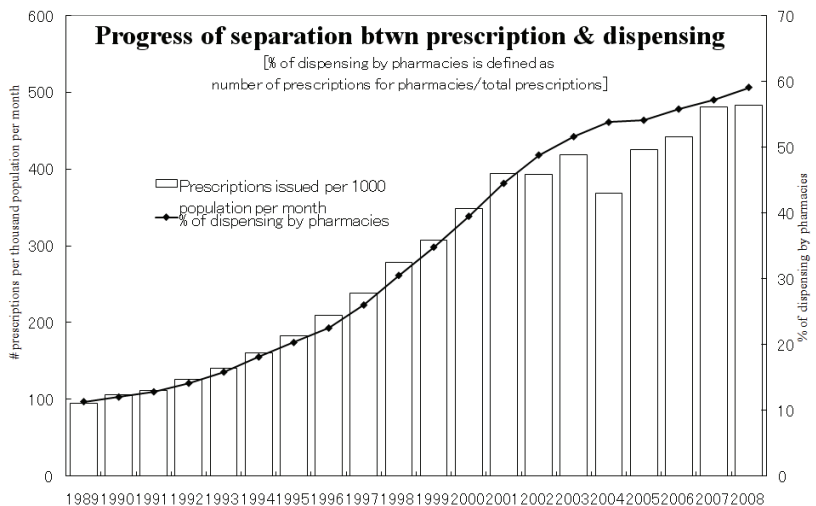
1. Pharmacies and Separation of Prescription and Dispensing

Traditionally Japanese doctors commonly dispense drugs directly to patients. This is welcomed by both doctors and patients because doctors can raise profit through markups between whole sale prices and reimbursement prices set by the government and patients can save time for receiving all necessary care at a time.

This non-separation prescription and dispensing may explain the high share of pharmaceuticals in the NHCE. The government and pharmacist association have long endeavored to enhance the separation by rewarding higher prescription fee to doctors who choose issuing prescriptions rather than directly dispensing since middle of 1970s.

However initial efforts to enhance separation between prescription and dispensing were hampered by physicians' conflicts of interest. Many doctors and hospitals established their affiliated pharmacies in their neighborhood and pocketed both higher prescription fee and pharmaceutical markups. To encourage "pure" independence of pharmacies, "carrots and sticks" measures have been taken: penalizing doctors who develop collusive arrangement with pharmacies and rewarding pharmacies that have fewer ties with particular hospitals or doctors.

From the health insurance policy, the official reimbursement price has been repeatedly reduced to discourage doctors from direct dispensing by reducing the pharmaceutical markups. Also, generic substitution has been promoted by way of listing the drug with generic names rather than brand names in the official reimbursement list for the products whose patents had



expired. For inpatient care, all inclusive per diem reimbursement system is increasingly suppressing the share of pharmaceutical cost in the inpatient health care cost.

According to Japan Pharmacists Association, 59.1% of outpatient prescriptions are dispensed by pharmacies in 2008 (the rest are dispensed by prescribing doctors directly bringing some pharmaceutical markups to doctors). The separation rate varies considerably from prefecture to prefecture ranging from 27.3% to 77.3%. Ideally, each patient should have an attending pharmacy which checks against potential duplicate dispensing. However some pharmacies depend on hospitals or clinics located nearby and it is still common to see patients get dispensed from multiple pharmacies affiliated with hospitals and clinics making the advantage of separation of dispensing hard to achieve.

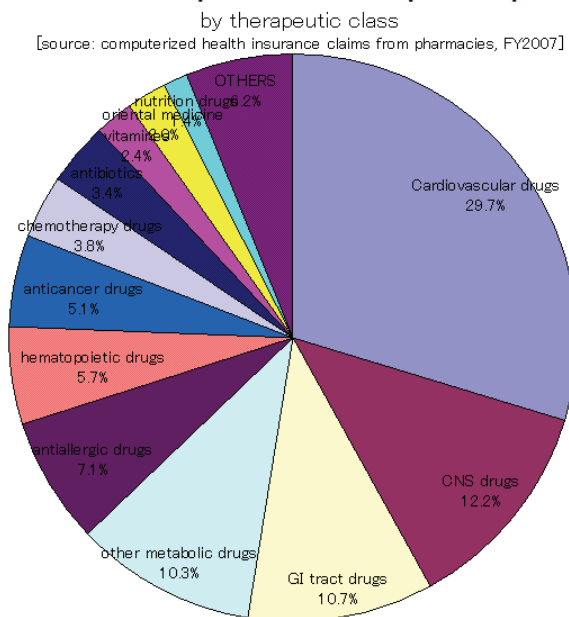
Pharmacies advanced well in computerization of health insurance claims: 99.7% of pharmaceutical claims are submitted electronically in August 2009. Since computerized claims contain detailed pharmaceutical data including therapeutic classes, the computerization enables detailed analysis of claims data. In March 2008, MHLW started to provide monthly data from pharmaceutical claims submitted electronically. The system is called Pharmaceutical MEDIAS available over the MHLW website [<http://www.mhlw.go.jp/topics/medias/month/index.html>].

Since Pharmaceutical MEDIAS is a population survey on administrative data, not a sampling survey like Social Insurance Claims Survey conducted in every June, it can analyze drug-specific utilization data. The following is a result of pharmaceutical expenditure broken down by therapeutic class.

As part of cost control efforts, prescription only drugs are increasingly switched to OTC, the recent example of which includes H2 blocker. Further, deregulation to allow retail stores to sell nonprescription drugs is being discussed.

Since 2006, the Pharmacists Act was revised and only the graduates of six-year pharmaceutical schools became eligible for the national licensing examination.

Pharmaceutical expenditure of prescription drugs



2. Pharmaceutical Reimbursement and Price Setting

The government sets prices of all drugs reimbursed by the health insurance system. The list of reimbursable drugs includes nearly 14,000 items for both oral, IV and ointment. To calculate the price, the government is authorized by the Pharmaceutical Affairs Act to conduct a market survey every year.

This survey is conducted with close cooperation with wholesalers who submit their transaction records with health care providers. The official reimbursement price will set at the weighted average of the transaction price plus the reasonable margin that is usually set at 2%. For newly approved drugs, the price will be set by comparison with other drugs of the same therapeutic effect. For a limited number of innovative drugs, some bonus prices may be awarded on a case-by-case basis.

Because Japan imports pharmaceutical products heavily from the U.S., the transparency of price setting has occasionally become centers of the trade negotiations between two countries. In 2001, President Bush and PM Koizumi reached an accord named “The U.S.-Japan Economics Partnership for Growth”, in which both sides agreed on enhancing transparency of drug price setting through ensuring the American industries the access to the raw data on which the price setting was based as well as streamlining the new drug approval process.

The share of generic products of Japan is lower than most other developed countries. According to IMS, the share of generic products as measured by dosage in 2006 of major countries was: US(63%), UK(59%) and Germany (56%). Japan’s figure was only 16.9% according to Japan Generic Manufacturers Association (5.2% on monetary values). As part of health care cost containment measures, MHLW declared a policy to increase the share of generic products to 30% from present 16.9%. To encourage generic substitution, the practicing rules of doctors was revised in April 2008 and doctors were asked to check on their prescription when they do NOT permit generic substitutions (before doctors were asked to check when they DO permit so).

3. Clinical Trials

Pharmaceutical products, cosmetics and medical equipment are subject to regulation by the Pharmaceutical Affairs Act. The Act was amended in April 1993 to allow public subsidies for research and development of orphan drugs as well as accelerated review.

New drug applications will be subject to preliminary review by a special agency named “Pharmaceuticals and Medical Equipment Evaluation Center” and then final review by the Pharmaceutical Affairs Committee. Final decision is left to the discretion by the MHLW.

Regulations on clinical trials were tightened by the amendment of the Pharmaceutical Affairs Act in June 1996 in response to a series of misconducts exposed in the preceding years.

This led to “hollowing of clinical trials”. Tightened regulation coupled with low interest of doctors in clinical research discouraged doctors from clinical trials. Deregulation to accept foreign research data added to this trend: multinational pharmaceutical companies prefer to conduct clinical trials outside of Japan and later get a new drug approval by “importing” data to Japan. As a result, a considerable number of new drugs remain unavailable for Japanese patients even after they are approved somewhere else in the world. It is also feared that this “hollowing” of clinical trials will deprive Japan

of its scientific competency.

Furthermore, deregulation to allow foreign research data may not always appropriate because the same drug may affect differently among different races. One example is Omeprazole (proton pump inhibitor). Higher prevalence of poor metabolizer due to genetic type CYP 2C19 makes the drug more effective at lower dosage.

To revitalize clinical trials, the Pharmaceutical Affairs Act was revised to initiate “doctors-sponsoring” clinical trials, which took effect in July 2003. Until then, only pharmaceutical companies could apply clinical trials. Even if doctors wish that certain indications should be added to existing drugs, they are not authorized to conduct clinical trials by themselves (prescribing drugs to patients for unapproved indications is prohibited as off-label prescription). On the other hand, pharmaceutical companies are not interested in conducting expensive clinical trials without much commercial promise.

Another measure taken by government was to develop a large-scale network of clinical trials to enable participating hospitals and doctors to share resources such as data centers and IRBs. A supporting organization, Japan Clinical Research Assist Center (JCRAC) was established together with its data management center (DMC) in 2001. JCRAC is currently assisting seven clinical trials through data management, data analysis, IRB and training of Clinical Research Coordinators (CRC).

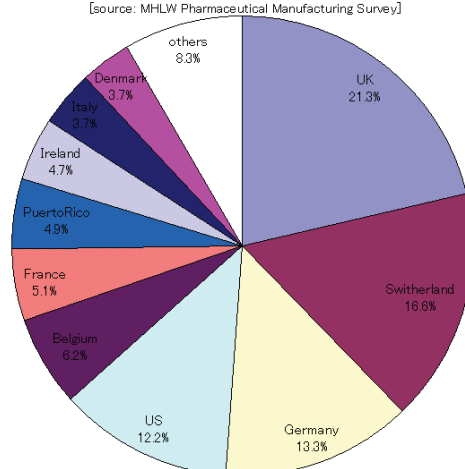
In April 2003, MHLW published a “3 year plan for vitalizing clinical trials” to facilitate clinical trials in medical school affiliated hospitals and reached an agreement with Japan Medical Association in promoting doctors-sponsoring clinical trials in community hospitals in August 2003.

4. Japan’s Pharmaceutical Industry

The output of Japan’s pharmaceutical industry was 6.4 trillion yen or approximately 60 billion dollars in 2006, of which only 133 billion yen or approximately 1.2 billion dollars was exported. Japan also imported 1.56 trillion yen or approximately 14 billion dollars worth pharmaceuticals from abroad in 2006. The output of Japan’s pharmaceutical industry has been quit stagnant for last ten years. This long stagnation has reduced Japan’s share in the world pharmaceutical market considerably. According to GlaxoSmithKline Annual Report 2000, Japan constitutes 14.9% of the world pharmaceutical marketplace (32 billion Euro in 215 billion Euro worldwide) in 2000 but Japan’s share declined to 11% in 2004 according to IMS Health. Of Japan pharmaceutical imports (1.56 trillion yen or approximately 14 billion dollars in 2006), top three countries namely UK, Switzerland and Germany constituted roughly half. What is noteworthy is that while Japan’s

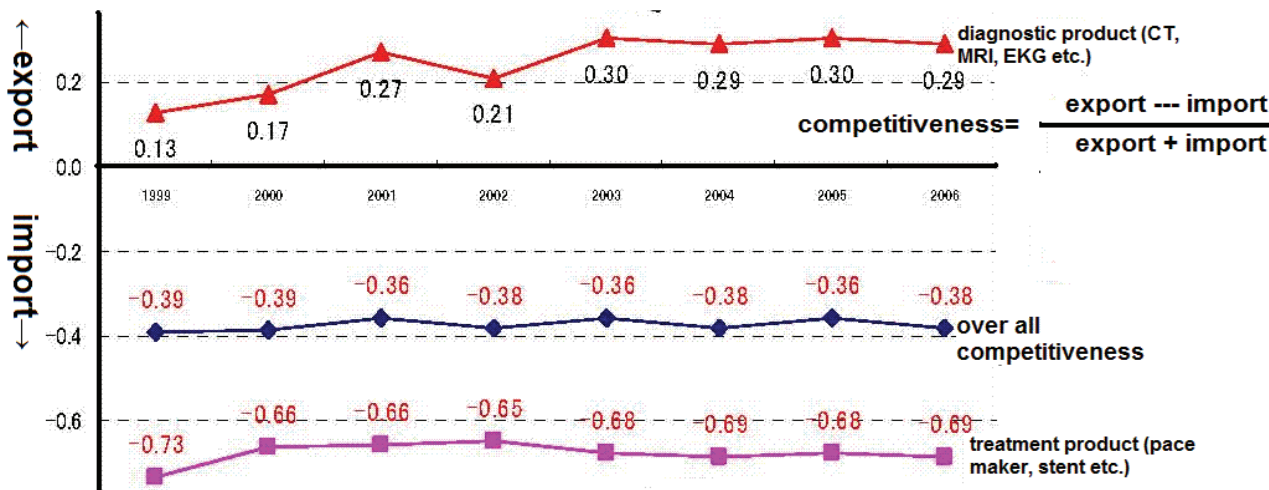
Countries of Japan’s pharmaceutical imports
(2006, total 1.56 trillion yen)

[source: MHLW Pharmaceutical Manufacturing Survey]



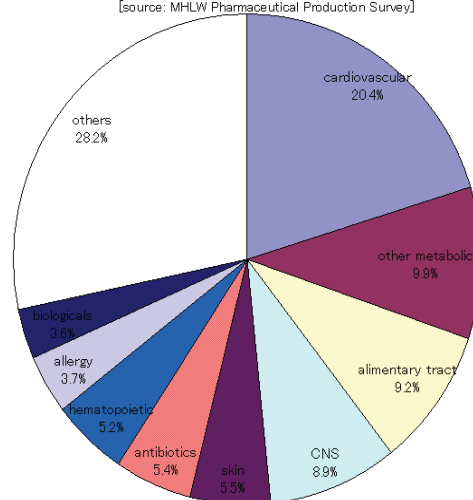
pharmaceutical production has been stagnant, the amount of pharmaceutical import has grown 58% in five years (2001-2006).

Pharmaceutical industry is one of the “weakest” industries of Japan as shown in the graph below (source: MHLW Pharmaceutical Industrial Production Survey) with constant negative trade imbalance. Although Japan is strong in diagnostic products such as CT, MRI, EKG, it is weak in treatment products such as pace makers and stent. Overall, it has a constant trade “deficit”.



The weakness of Japan’s pharmaceutical industry may be explained by its smaller size of the companies: Japan has 463 pharmaceutical companies whereas the U.S. has 483. Even the largest Japanese company (Takeda) is ranked 16th in the world ranking and all others are below 20th. This fragmented industry structure may be the result of non-competitive environment of Japan’s national health insurance system, in which government dictates drug prices and reimbursement is guaranteed. Unlike auto industry, Japanese pharmaceutical industry grew to be domestic-oriented industry. In the era of consolidation of the pharmaceutical industry, Japanese pharmaceutical companies face challenges to stay competitive in the world market.

Japan’s pharmaceutical production by therapeutic class (2005, total 6.4 trillion yen)
[source: MHLW Pharmaceutical Production Survey]

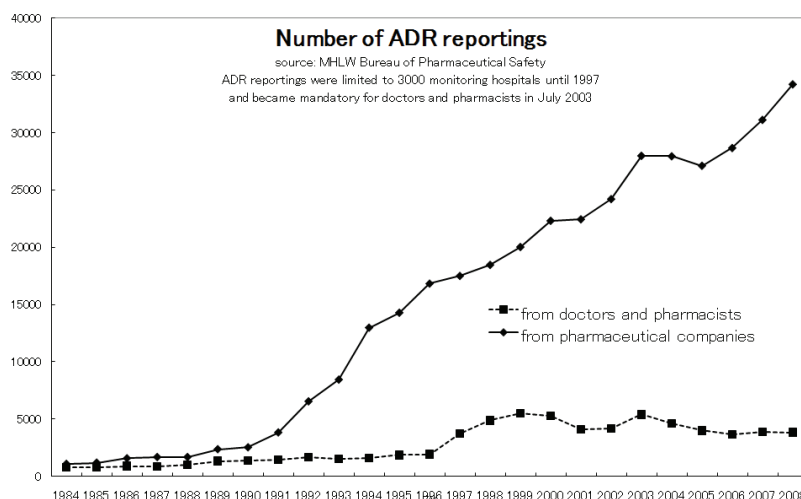


As for the pharmaceutical production broken down by therapeutic class, cardiovascular drugs were produced in the ex-factory value of one trillion yen or approximately 20.4% of the total Japan’s pharmaceutical output in 2005 (6.4 trillion yen) according to the Pharmaceutical Manufacturing Survey by MHLW.

5. Pharmaceutical Monitoring and Surveillance

The history of Japan's pharmaceutical affairs has been tainted by repeated tragedies concerning drug side effects and MHLW vowed to prevent it by establishing a monument of "No more drug tragedies" in front of its office building in 1998. Therefore pharmaceutical monitoring surveillance is of utmost importance. Adverse drug reactions (ADR) reporting has been mandatory for pharmaceutical companies but reporting from health care providers was initiated in 1967 in the wake of the WHO resolution in 1963. Monitors were expanded to include pharmacies in 1973 and the then MHW started periodic newsletter to inform health care providers of ADRs in 1974.

A new standard for PMS (Post Marketing Surveillance) for pharmaceutical companies was established in 1993. However it failed to prevent the Sorivudine tragedy, in which 16 patients had died within a month after the new drug had been put into market. Originally the ADR reporting was limited to certain

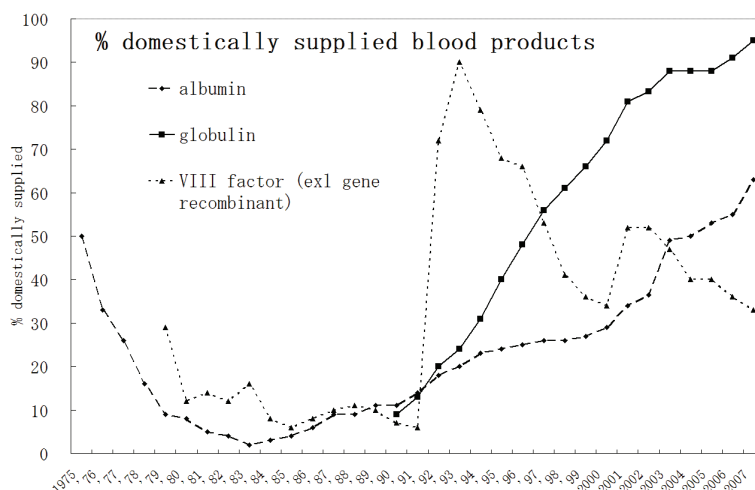


monitoring hospitals and the number of reporting has somewhat been stagnant until 1997, when ADR reporting was broadened to all doctors and pharmacists. Although the reporting was voluntary, the number of ADR reporting from doctors and pharmacists has increased. In July 2003, ADR reporting became mandatory for all doctors and pharmacists.

All reported cases are evaluated by a subcommittee of the Central Pharmaceutical Affairs Committee. MHLW periodically publishes "Pharmaceutical Safety Information" every other month and issues "Emergency Safety Information" in an ad hoc manner.

6. Blood Products

Japan's per capita consumption of blood products are higher than most developed countries. Basically all blood products consumed domestically should be supplied by donated blood. However the donated blood alone is not sufficient to fulfill the domestic demand and majority of the blood necessary for production of plasma fraction



products such as albumin and globulin is imported. As of 2008, 61% of albumin and 96% of globulin are supplied by domestic blood donation.

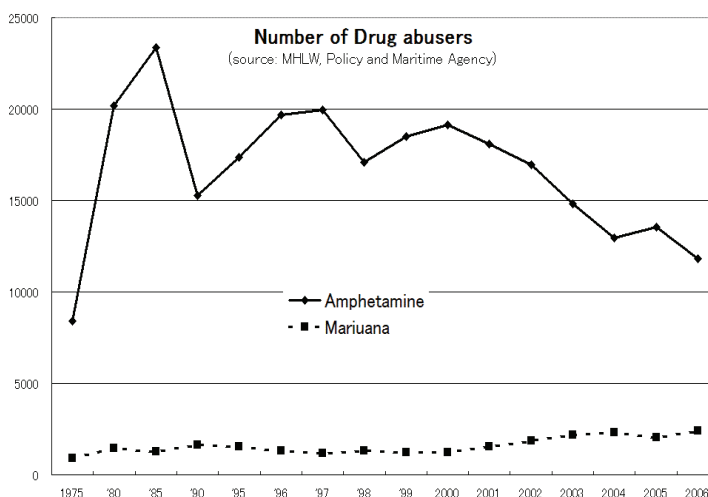
Japan has seen a sharp increase of blood products consumption in the late 1970s, boosted by huge pharmaceutical markups. This excessive use of blood products may be partially to blame for the spread of the iatrogenic HIV infection in the middle of 1980s. Controlling of excessive use of blood products has been attempted through practice guidelines and utilization reviews. Still, a large geographic variance is observed in the per capita use of fresh frozen plasma (FFP) and albumin product.

Much effort has been directed at controlling iatrogenic infection through blood products. After the outbreak of BSE in Europe, people who ever lived in any of 10 European countries for longer than 6 months after 1980 are banned from donating blood since 2001. Also, anybody who comes back from abroad became banned from blood donation for 3 weeks in the wake of WestNile outbreak in the U.S. since November 2002. Further, the Pharmaceutical Affairs Act was amended to require all health professionals to report infections suspected of transmitting through blood products as of July 2003.

7. Substance and drug abuse

Historically, Japan's drug abuse became a social problem in early post-war period. Around late 1940s, more than 50,000 people were arrested for amphetamine abuse. In 1950s, heroin addiction became a problem but successfully controlled by strict law enforcement. However, the 1980s saw the second wave of amphetamine abuse with more than 20,000 arrests.

Nowadays, newer types of abusive substance are circulated thanks to internet. In 2005, MDMA was added to the control drug list. Thanks to a strict law enforcement as well as campaign, the number of abusers shows a decline.



Chapter 7. Environmental Health

Ancient Japan was believed to be a country relatively free of environmental problems. Although, Edo, an ancient name of Tokyo, was a metropolis whose population exceeded one million at that time, foreign visitors then were marveled at the cleanness of the city. Actually outbreaks of infectious diseases such as plague or cholera were seldom seen in most cities at that time, although fires hazards were rampant due to the “wood and paper” structure of houses.

Japan sequestered itself from the rest of the world for as long as 260 years beginning in early 17th century till the middle of the 19th century, which might have protected the country from intrusion of any foreign-born infectious diseases, but well developed sewage system might also have been a contributing factor.

Japan threw away the antique feudalism and aggressively modernized the country with industrialization, and then a series of environmental problems emerged. The first law aimed at environmental protection was the Smoke Control Act in 1962. As a series of massive environmental disasters unfolded, the public concern on environmental issues inevitably intensified. In 1967, the Anti Pollution Act was enacted and by 1970, the Air Pollution Control Act, the Noise Control Act and the Environmental Pollution Victims Compensation Act were enacted. Symbolizing the government resolution to tackle the problem, the Environment Protection Agency was instituted in 1971. In 1993, the Environmental Protection Policy Act (EPPA) was enacted. It has three basic principles:

- Succession and reception of the benefit of environment
- Structuring a sustainable society which poses less burden on environment
- Promoting environmental protection through international cooperation

Pursuant to this law, the government sets criteria for environment and environmental assessment as necessary. The section 16 of the law requires environmental standards for air, water, soil and noise.

1. Air Pollution

For air pollutants, environmental standards are set for the following nine pollutants.

● Sulfur dioxide (SO₂)

Sulfur dioxide is generated by combustion of fossil fuel such as oil or coal, and causes harm on respiratory tracts and is believed to be a cause of acid rain. Current environmental standards hold that an hourly average of 0.1 ppm and daily average of 0.04 ppm.

● Carbon monoxide (CO)

Most of carbon monoxide (CO) in the ambient air is emitted by cars due to incomplete combustion. Current environmental standards are eight hours average of 20 ppm and daily average of 10 ppm.

● Suspended particular matter (SPM)

Suspended particular matter (SPM) refers to particular matters floating in the air whose diameter is 10 micrometer or less. Environmental standards for SPM are hourly average 0.2 mg/m^3 and daily average 0.1 mg/m^3 .

● Nitrogen dioxide (NO₂)

Nitrogen dioxide (NO_x) is emitted by combustion of fossil fuel mainly from factories and automobiles. With high concentration, NO_x damages respiratory tract and, on global level, is responsible for acid rain and photochemical smog. Its ambient concentration has been under constant monitoring.

● Photochemical oxidant

Oxidant is generated from NO_x through interaction with sunlight. It has irritable effect on mucosa and respiratory tract.

Above pollutants are “veterans” whose environmental standards were set in 1973. The following pollutants are “new comers” whose standards were newly introduced in 1997 and after. Worthy of note is Dioxin. With growing public concern on this substance, the special law “Anti Dioxin Measure Act” was enacted in 2000 and standards were set for both ambient air and food intake. A survey conducted in 2001 revealed that average daily intake of Dioxin by Japanese was found to be $1.63 \text{ pgTEQ/Kg/day}$.

(1) SORA (Study On Respiratory disease and Automobile exhaust)

Thanks to the aggressive efforts for air pollution control, the ambient air quality has improved considerably. Nonetheless, there are concerns that air pollution might have been simply “localized” to the roadside areas particularly in view of the increasing prevalence of asthma and respiratory symptoms among school children.

The Ministry of Environment launched a large-scale epidemiological survey on school children and infants living in the roadside of busy streets starting in 2005. The project is called “study on respiratory disease and automobile exhaust” and is acronymed as SORA, meaning sky in Japanese and consists of two parts: a cohort study on school children and a case-control study on infants.

Already approximately 16,000 school children were recruited for the cohort study and the baseline survey was completed in 2005. They will be followed up to the year 2009 to evaluate relationship among individual exposure to automobile exhaust (estimated by modeling), confounding factors such as domestic allergen as well as ambient air pollution levels and subsequent health effects.

As for the case-control study, volunteers were selected from 100,000 infants who received health checkups at the age of 1.5 (July 2006-March 2008) and 3 (February 2008-March 2010). Cases will be those who developed asthma in the intervals of health checkups and controls will be selected from those who did not.

(2) Environmental Health Surveillance System (EHSS)

EHSS is a national version of air pollution monitoring system started in 1996. Questionnaire is distributed to mothers of three-year old children as part of the three-year old health checkup. Area-specific health data are linked with geographical environmental

monitoring system to enable epidemiological study on environmental cause of human diseases. Six-years old children survey was added in 2004 and linked with those who responded to the survey at three years old. The first findings were published in December 2006 and reported the “incidence” of asthma and other onsets of respiratory symptoms for the first time (Only “prevalence” was available because of the cross-sectional nature of the EHSS).

Such cohort study was possible because the EHSS collects personal identifiable data such as name, date of birth and address and the survey is conducted in predetermined 44 areas. Of 52 thousand six-year old respondents in the 2004 survey, 23,110 respondents were matched with three-year old respondents in the 2000 and 2001 surveys allowing for estimation of “incidence” of asthma in three years period. The result was somewhat unexpected: incidence of asthma was higher in areas with higher SO₂ concentration. The finding illustrated the individual’s history of allergy is far more important factor in asthma onset than any environmental factors (Odds ratio of history of allergy was 2.13-2.14 while that of SO₂ was 0.46, both $p < 0.05$).

(3) Japan Environment & Children (Eco-Chil) Study

To identify the epidemiological relationship between child growth and chemical exposure during pregnancy and early childhood, the Ministry of Environment launched a large cohort study on children in 2010 called Japan Environment & Children (Eco-Chil) Study. The



working hypothesis is “exposure to chemical substance during pregnancy and early childhood might influence the incidence of congenital anomalies, mental retardation, allergy and immunity”. With ample funding from the ministry (3.1 billion yen), a total of 100,000 pregnant women will be recruited and babies will be followed-up until 13 years old collecting blood samples from mothers and babies as well as umbilical cord.

2. Drinking water supply

In 1787, 1.2 million residents out of 2 million residents in Edo (ancient name of Tokyo) were served with water supply. The Edo water supply was arguably the largest in the world, compared to 0.9 million in London and 0.8 million in Paris. This is partially the reason why Edo, one of the largest metropolises in the world then, was relatively free from outbreaks of water-borne diseases such as cholera, which haunted London at that time.

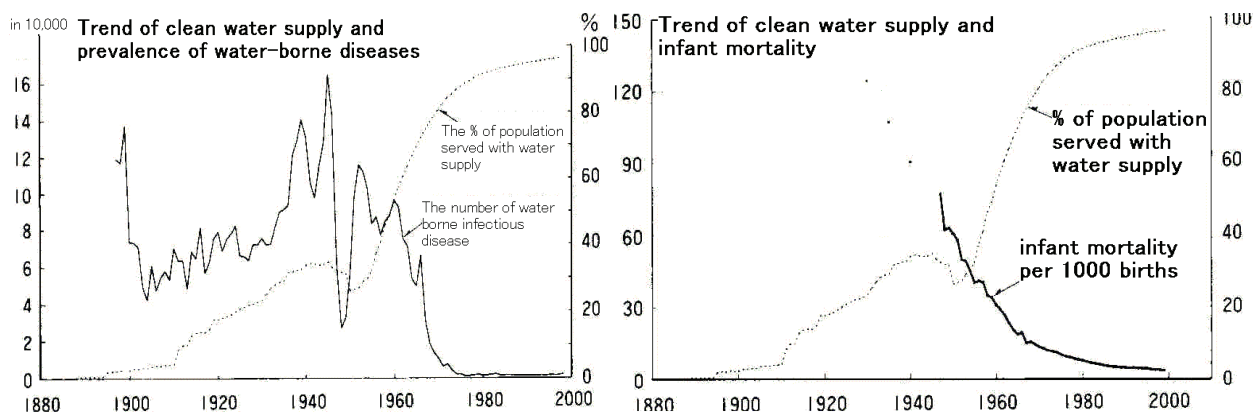
However, in national level, the % of population served with water supply remained 32.2% in 1955. The water supply was rapidly developed after that and 90% in 1980 and currently serves 97.4% of the total population in 2007.

The long-term trend suggests the health indices show marked improvement as the coverage of water supply exceeds 50% and the prevalence of water-borne disease reduces to minimal when the coverage is above 80%.

Although Japan has relatively heavy rain fall, most of Japan's rivers are short and flows like "cascade". Therefore Japan relies heavily on dams to store water. Approximately 71.4% of water comes from dammed pool.

The Drinking Water Supply Act assigns the responsibility of supplying clean water to municipal governments. Approximately 3,000 municipal governments operate approximately 11,000 water supply programs, the largest of which is Tokyo metropolitan government serving as many as 12 million residents.

A Jewish critic (Izaya Bendathan) once blamed Japanese for them to presume that "Water and safety is free" most vividly evidenced by an idiom "spending like water". Of course drinking water is not free. Monthly water bill for 20 cubic meters, an average household consumption, costs 3,083 yen (2001) ranging from as low as 700 yen to as high as 6,190 yen. Each municipal government operates its water supply business independently to make both ends meet. Some advocate "privatization" of water supply, but it is questionable for private enterprises to operate in areas where water is hard to come by.



3. Sewage system

In the middle age, as people lived in an increasingly crowded environment, lack of sewage system brought about epidemics of water-borne infectious diseases. When John Snow made a monumental work on cholera epidemics in 1855, the first sewage system was constructed in London. Other industrialized countries followed suite and, in 1884, Tokyo (Edo was renamed Tokyo after the Meiji Restoration in 1868) also had the first sewage system.

As of 2008, 72.7% of population is served with sewage system, but the rate is only 42.7% for small towns and villages whose population is less than 50,000. Japan's sewage system processes 14.2 billion cubic meters of sewage water and the 75 million tons of sludge constitute 19% of industrial waste. 74% of them are recycled as fertilizer or construction materials.

As for urine and feces disposal, 67.7% of the total population is served with sewage system and 23.4% is served with septic tanks. However 9.3% of population is still not served with proper disposal.

4. History of Pollution Related Diseases

In the course of rapid modernization and industrialization, Japan witnessed tragic cases of pollution related diseases, some of which are well-known to the world with a lingering distress of the victims. The following are some of them.

(1) Minamata disease

Minamata disease, immortalized by photographer Eugene Smith with his picture book “*Minamata*”, is arguably the world worst tragedy of organic mercury poisoning. It occurred in Minamata bay of Kyushu (see the map) early in the 1950s due to the bioaccumulation of organic (methyl) mercury emitted into the sea from a nearby chemical plant. Medically, minamata disease is Hunter-Russel syndrome characterized by neurological disturbance such as motor disturbance, central narrowing of visual field. However, it was only in 1968 when the government officially acknowledged the cause and effect of the disease. A series of civil suits followed since 1967 and the disease became an icon for the civil movement against the pollutions.

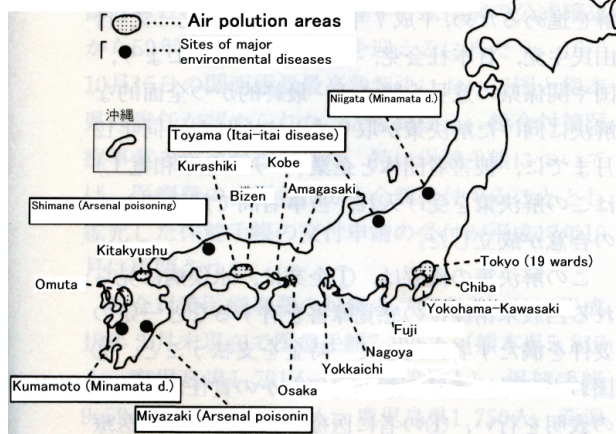
(2) Itai-itai disease

Itai-itai disease is chronic poisoning of cadmium first found along the Jintsu river in Toyama prefecture. It affected farmers who ate rice contaminated by cadmium emitted from a mine upstream. Medically it is osteomalacia caused by calcium draining from bone minerals due to impaired proximal renal tubules (detected by increased urinary secretion of beta2microglobulin). By the same token with osteoporosis, women are more susceptible to the disease than men. Because of weakened bone, victims suffered from multiple bone fractures complaining pain (*itai* means pain in Japanese).

(3) Chronic arsenic poisoning

Arsenic is a poison deadly enough to kill people in acute poisoning. Historically it has been notorious for its use in assassinations (victims include Napoleon!?) or crimes (Wakayama curry poison incident in 1998) and also killed many in industrial accidents (Morinaga arsenic milk tragedy in 1955 killed at least 130 babies affecting 12,344 according to a report by the government). However, only chronic poisoning is classified as a pollution-related disease. Clinically its symptoms are manifested in nasal cavity as a form of perforation or ulceration as well as multiple neuropathy.

Sites of air pollution and major environmental diseases



5. Environmental Pollution Victims Compensation System

One of the unique features of Japan’s environmental protection is its “Environmental Pollution Victims Compensation System (EPVCS)”. This is a collective out-of-court

arbitration between polluters and victims whose health had been compromised by the pollution. Under this system, victims do not have to resort to lengthy court procedures to win damages. The system was developed in a bitter lesson learned from lengthy court battles involving environmental diseases.

The EPVCS compensates two major pollution related diseases: respiratory diseases derived from air pollution and chronic intoxication by toxic substances. The respiratory diseases include chronic bronchitis, emphysema, asthma and the chronic intoxication includes some world-famous pollution disasters that took place in Japan in the past: Minamata disease (Organic mercury poisoning), Itai-itai disease (Cadmium poisoning) and chronic arsenic poisoning. To be eligible for compensation, a person must apply for diagnosis to determine if an applicant meets the diagnostic criteria (such as central narrowing of visual field for Minamata disease) but disputes arose in ambiguous cases which fail to present typical symptoms.

A total of 2,958 victims have been diagnosed as Minamata disease by EPVCS to date, of which 895 are still alive. As for the disputed cases, a political compromise was reached in 1995 that the government set up an additional measure to provide subsidies for medical care for the plaintiffs. A total of 12,374 patients became eligible for the additional measure by July 1996.

According to the Polluter Pay Principle (PPP), the EPVCS system is wholly financed by compensatory damage paid by polluters and the government pays only its administrative cost. As for air pollution, the compensatory damage is levied by the government from major air pollutants, namely automobiles and smoking factories in proportion to the amount of SO_x emitted from each polluter. For automobiles, the damage is levied from their car tax in proportion to the size of their engine. For factories, the damage is levied in proportion to the amount of smoke emission. As for chronic intoxication, the damage is levied from the responsible corporations.

6. Measures against the Global Warming issues

According to the 4th report by IPCC (International Panel for Climate Change) in 2007, the average temperature will rise by 1.1-6.4 centigrade by the end of the 21st century and the sea level will rise by 18-59 cm due to the global warming.

The Kyoto conference on the global warming (COP3) held in December 1997 was a landmark event in the field of global environmental protection. As a host country, Japan enacted the “Anti Global Warming Act” in October 1998 and expressed its determination to achieve the goal set by the Kyoto protocol. Still, the amount of “green house” effect gas emitted in Japan in 2005 was estimated to be 1.36 billion tons or 7.8% more than 1990 level, a far cry from the reduction of 6% targeted by the Kyoto protocol. To enforce the reduction, the government is looking to “environment tax” levied on emitted gas, to which the industry is vehemently opposing.

The IPCC report also predicts a dismal forecast: the global warming will be suppressed to

2-2.4 centigrade hike from 2000 to 2050 if the greenhouse effect gas emission is reduced by 50-85%. But that will also reduce the world GDP by as much as 5.5%.

7. Public Health in Environmental Disasters

Japan has been hit by environmental disasters that involved potential public health hazards. Here are some descriptions how public health dealt with those disasters.

(1) The Great Kobe Earthquake

At 5:46 AM on 17th January 1995, Kobe City was hit by an earthquake of magnitude 8, resulting in 5,488 casualties. According to the vital statistics, 5,175 (94.3%) died on the first day of the disaster, of whom 4,059 died of crashing, 488 died of burning, 256 died of injury.

The first few days were spent in chaotic conditions. Many casualties flooded the hospitals and clinics with very limited resources for treatment. The road was soon jammed with cars and vehicles making it impossible for fire engines and ambulances to pass. The fires broke out afterward ran rampant because fire fighters could not secure water supply. In a matter of hours, the entire city was a mass of debris and excavated bodies.

Kobe city government set up the disaster HQ one hour after the jolt. A few city officials who could manage to reach the office found themselves inundated with screaming requests from hospitals, many of which had been severely damaged and left without power and water supply. The initial efforts of Kobe health officers were aimed at securing lifelines to these facilities and transporting inpatients to hospitals in unaffected areas. Fortunately, as media reported the severity of the disaster, many offers for help came from all parts of the country as well as from abroad. More difficult task was how to bring the stuff to the needy area because most roads were too jammed to allow smooth traffic.

Shortly after the earthquake, temporary refuges were set up in a variety of locations such as schools, citizen halls and public facilities. Sanitation and public health soon became major concerns. Make shift toilets were set up at such refuges. Offensive odor filled the living spaces. Water in the swimming pool and leakage from pipe was stored and used for washing the human excrement. Public health centers distributed disinfectant to such toilets. Disinfectant for hand and finger distributed by public health centers were believed to be effective in keeping hygienic conditions of food.

It was rather fortunate that the disaster hit in the winter season in terms of preventing infectious diseases. Actually no complaints about pests were reported in most refuges.

Although a great number of victims were lost in the initial phase of the disaster, it may well be regarded as a triumph of public health activities in that it could prevent secondary casualties due to disease or unhygienic conditions, which almost always accompany such large scale disasters.

[reference: Osaka University Medical School Department of Public Health “Public Health Activities under the Great Earthquake[in Japanese]” June 1995]

(2) Outbreaks of Massive Pathogenic E.coli Food Poisoning

The year 1996 proved to be *annus horribilis* with massive outbreaks of pathogenic O157 E.coli food poisoning, in which 17,877 had developed symptoms and 12 deaths. However, by far the largest outbreak took place in Sakai city in July of that year.

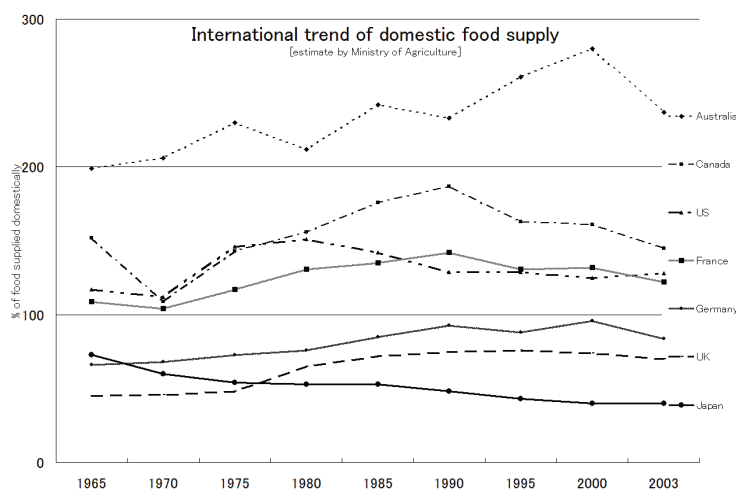
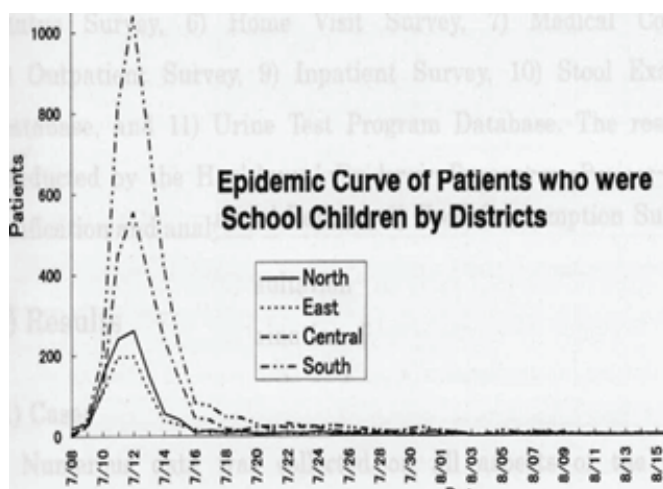
On Saturday, the 13th of July 1996, at about 10 am, Department of the Public Health of the Sakai City Office received a report from the Sakai City Hospital about 10 patients from local elementary schools whose chief complaints were diarrhea and bloody stool during the night of July 12.

Similar reports were received at the municipal public health centers from other medical institutions. Immediately, a massive food poisoning case was suspected and an investigation was started. On 13th, a total of 255 children from 33 local elementary schools received medical care for diarrhea or bloody stool. At 3 p.m., a task force was set up at the city office.

A rapidly growing number of school children started to complain of strong abdominal cramps, diarrhea and bloody stool. By 14th, over 2000 people were receiving medical care at many hospitals and clinics.

The case was later confirmed as E. coli O157:H7 infection. This strain of bacteria proved to be deadly because it secretes toxin called Bello toxin causing hemolytic-uremic syndrome (HUS).

From the onset of the outbreak, school lunch was the most suspected cause of poisoning. Thorough investigation eventually concluded that radish sprouts grown and harvested by a nearby producer were the most probable cause. [source: Sakai City "Report on the Outbreak of E.coli 157 Infection in Sakai City" December 1997, p.9]



8. Food Sanitation

Japan imports much of its food. According to the estimate by Ministry of Agriculture, 61% of food on caloric basis is imported. Japan's domestic food supply has consistently

declined and is now one of the lowest domestic supply rate even among developed countries.

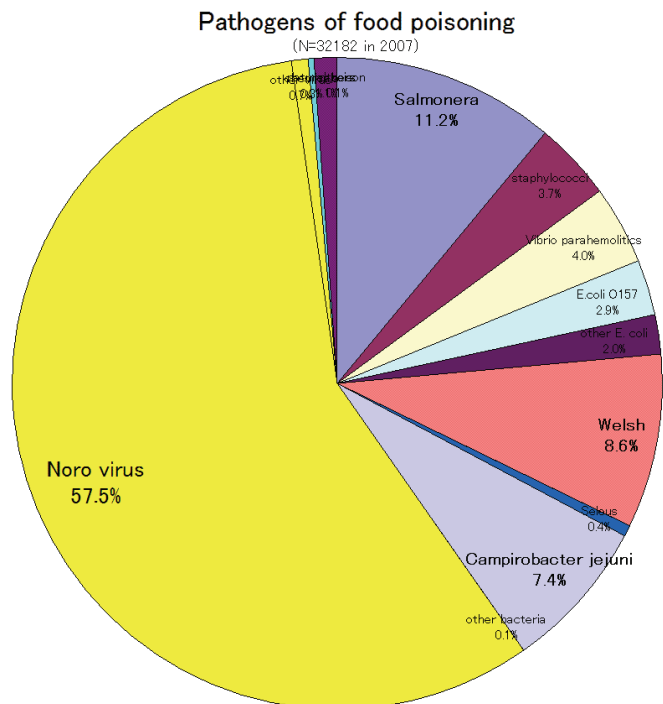
(1) BSE problem

The high reliance on foreign import makes Japan susceptible to food-related diseases. Outbreak of BSE (Bovine Spongiform Encephalopathy) in Europe in 2000 and a subsequent case reported in Japan in September 2001 sent an alarm to the government and the general public alike. After that, all cows were examined for BSE and approximately 8.18 million cows were examined by May 2008, from which 35 cows were found positive. Since August 2005, examinations were done for cows 21 months or older. Further, spinal cord, distal end of jejunum are mandated to be removed.

In response to the BSE threat, the Food Safety Act was enacted, which introduced a series of new approaches such as risk assessment, risk management and risk communication. Also the new act established the Food Safety Committee in the Cabinet Office, which takes charge of risk assessment of food safety.

(2) Food poisoning

Doctors who diagnose food poisoning are required to report to the nearest PHC and 30,000 to 40,000 cases are reported in average year. In 1996 when Japan was hit by O157, the number climbed to 46,179 but the number has been stabilized to 32,182 in 2007. The pathogens identified in reported cases (number of patients) in 2007 (N=32,182) are shown in the graph.



As the graph vividly illustrates, Noro virus accounts for by far the largest share of pathogens. Actually Noro virus is a new comer: it first appeared in 1998 and increased since. Noro virus is likely to outbreak in winter through sea food like oyster.

(3) Safety of imported food

Japan used to ban import of rice chiefly for the purpose of protecting domestic farmers. It became part of the international trade conflict with the U.S. in the 1980s. The government excused that the restriction on food import was due to safety concerns. However, when rice became in severe shortage in 1993 due to bad climate, the government was forced to import rice from Thailand. Japan's food import has actually consistently increased and it has become the largest food importing country in the world in terms of monetary value. Consequently, Japan became vulnerable to the safety threats of imported food.

Concerns were particularly intensified about foods imported from China thanks to repeated cases of food contaminated with chemicals or pesticides. In January 2008, ten

people in Chiba and Hyogo prefectures who ate frozen dumpling imported from China got poisoned. Police later identified the cause as organic phosphate pesticide, methamidophos. The importer, JT Foods, voluntarily recalled the sold food. Police suspected a criminal act behind the contamination and requested Chinese authority for investigation. However, Chinese authority dismissed the claim and the cause is still at large.

Inspection on imported food is the responsibility of quarantine offices. Food inspectors located in 31 quarantine offices examine importing applications and conduct sampling and laboratory examinations pursuant to the Food Sanitation Act. Laboratory examinations are consolidated in two Imported Food Quarantine Laboratories in Yokohama and Kobe quarantine offices. Laboratory examinations were conducted on 10.7% of 1.86 million importing applications in 2006.

(4) HACCP

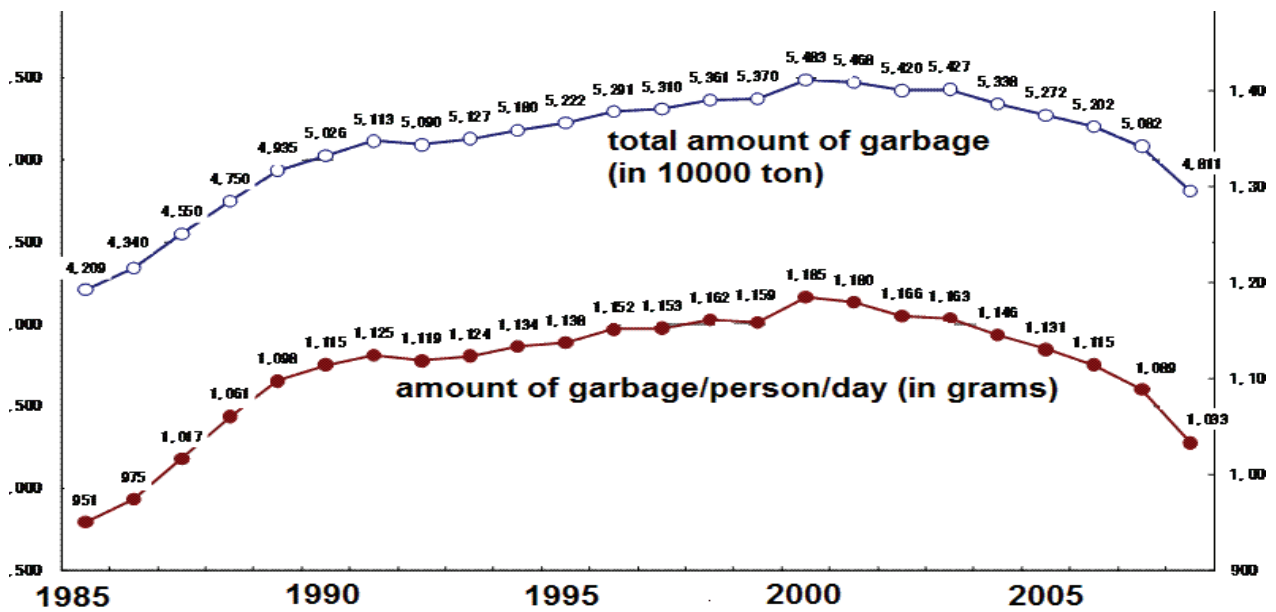
HACCP is an acronym of Hazard Analysis and Critical Control Point and was adopted in May 1996 for dairy product. A manufacturer of dairy product may obtain approval of MHLW if it manufactures the product based on HACCP.

9. Waste disposal

Since late 1960s through early 1970s, when the environment became a serious political agenda, waste disposal became a hot issue leading to an enactment of the Waste Disposal Act in 1970. The Act classifies waste into domestic waste and industrial waste and assign municipal governments in charge of domestic waste disposal. The disposal of industrial waste is the responsibility of businesses and the manifest system was introduced in 1997. In 2003, the Act was further amended to strength the penalty against illegal dumping and facilitate recycling.

(1) Domestic waste

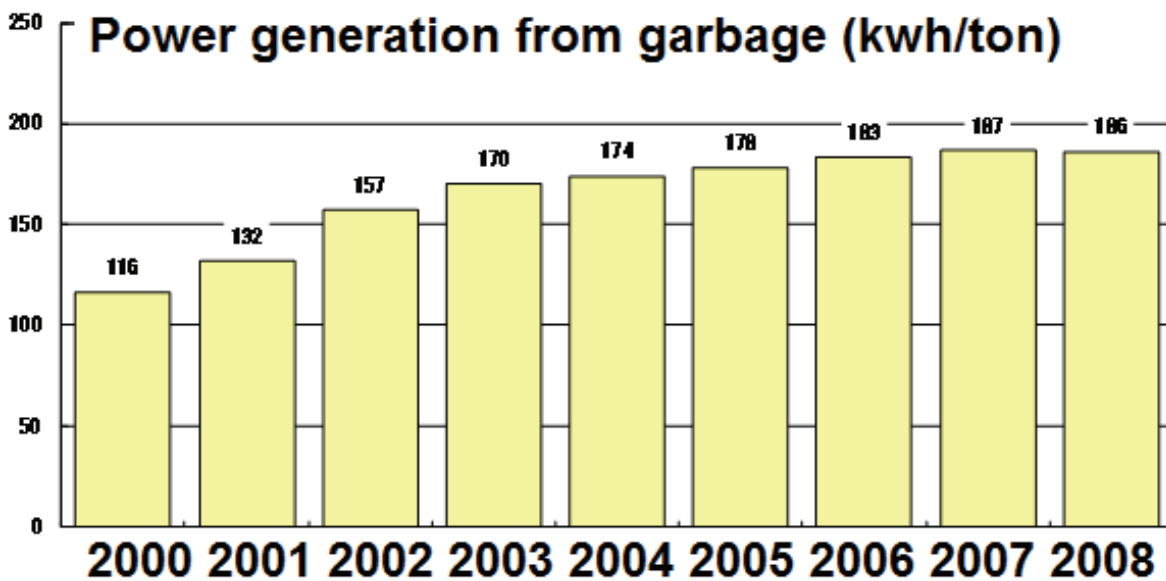
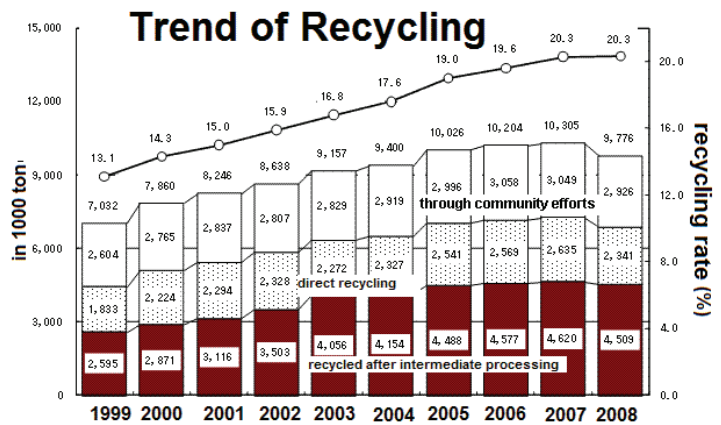
The amount of garbage (domestic waste) was estimated to be 48.1 million ton in 2008 (Survey on domestic waste disposal compiled by the Ministry of Environment). Of them, only 1.8% was directly dumped and 20.3% (9.8 million ton) was recycled (the rest was dumped after intermediate processing, e.g., incineration). Thanks to efforts for garbage reduction, selective collection and recycling, the amount of garbage (domestic waste) per capita per day has been declining since 2000 (from 1,185 gram in 2000 to 1,033 gram in 2008).



It is noteworthy that much of recycling is done by community efforts not by municipal governments. As much as 2.9 million tons garbage was recycled by community efforts in 2008, of which 92.7% was paper.

(2) Incineration sites

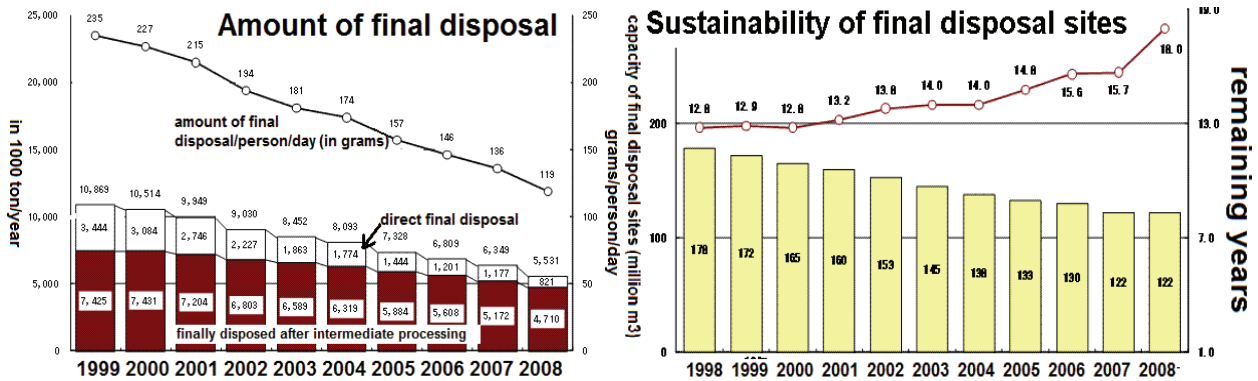
There are 1,269 incineration sites throughout the country with capacity of 0.19 million tons. Of which 300 sites have power plants as well generating 186 kwh per one ton of garbage showing a great improvement of efficiency from 2000 (116 kwh per ton). The total power generated was 6,935 gwh (giga watt hour) in 2008.



(3) Final disposal sites

Thanks to garbage reduction efforts, the amount finally disposed has constantly declined.

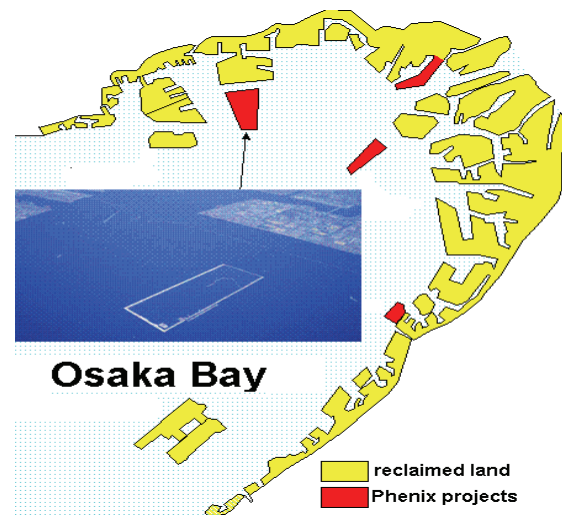
Although an average Japanese generate 1,033 grams of garbage every day, only 119 grams were finally dumped into disposal sites. Securing final disposal sites is a serious matter because the capacity of final disposal sites have been dwindling. Fortunately, the efforts to reduce garbage outperformed the dwindling capacity of final disposal sites and consequently the remaining years of final disposal sites have actually been prolonged.



Projects to secure the final disposal sites by reclaiming the sea surface were launched in 1982. The “Phoenix” project was launched in Osaka bay serving many cities in a wide area. The project constructed four artificial island and started to receive garbage in 1990. Already as large as 500 hectare artificial islands will be reclaimed.

(4) Recycling

Recycling of waste has been enforced by a series of legislations mandating recycling such as the “Package Recycling Act (1995)”, “Electric Appliance Recycling Act (1998)”, “Construction Material Recycling Act (2000)”, “Food Recycling Act (2000)” and “Automobile Recycling Act (2002)” achieving the final recycling rate of 20.3% in 2008. As many as 300 disposal facilities (23.2%) have power plants capable of generating 1.6 million kw. These efforts contributed to the prolongation of sustainability of final disposal sites (11.7 years in 1997 to 18 years in 2008) despite their declining capacity.



The Waste Disposal and Cleaning Act classifies domestic wastes and industrial wastes and assign the responsibility of collection and disposal of the former to municipal governments while the responsibility for the latter to each industrial generators. In 1997, the manifest system to keep track industrial wastes to ensure proper disposal was introduced, in which each waste generators are required to issue a manifest to the disposers.

Japan is generally viewed in the world as a successful country in achieving effective recycling of resources. To make it possible, the following recycling laws set goals to ensure recycling of resources.

Package recycling

Package and containers account for approximately of 56% of volume and 23% of weight of domestic wastes according to the survey conducted by then Ministry of Health & Welfare in 1995. In 1995, the Package and Container Recycling Act was enacted requiring households to put out their garbage in a separated manner to facilitate recycling.

Electric appliance recycling

The Electric Appliance Recycling Act in 1998 requires both consumers and manufacturers to recycle four types of appliances namely television, air conditioner, refrigerator and laundry machines.

Construction waste recycling

The Construction Waste Recycling Act in 2000 requires construction companies to separate construction wastes such as concrete, metal and timber on site to facilitate recycling at construction sites exceeding certain scales.

Food recycling

The Food Recycling Act in 2000 requires food manufacturers and processors to reuse uneaten food or wastes for fertilizer or compost.

Automobile recycling

The latest legislation, the Automobile Recycling Act in 2002 requires automobile manufacturers to recycle properly the used cars and prevent any illegal dumping.

Chapter 8. Industrial Health

1. Historical background

The origin of Japan's occupational safety and health can be traced back to the Factory Act in 1911 (became effective in 1916) with an intention to protect young or female workers from exhaustive and dangerous working conditions mostly in the then burgeoning textile industry. The scope of the act had been gradually expanded, but the all-encompassing act to protect workers of all industries was not enacted until the post war era. The Labor Standard Act was enacted in 1947.

In later years, the increasing number of work-related accidents, most prominent of which were large scaled gas explosions in mines, prompted a series of enactments of working condition safe guards.

Also, chronic work-related diseases such as pneumoconiosis among mine workers and Reynaud disease among forest workers using chain saws alerted industries the importance of preventive measures and health maintenance for the workers. In 1955, special acts for silicosis and traumatic spinal injuries were enacted to promote such measures.

In 1972, the Occupational Safety and Health Act (OSHA) was separated from the Labor Standard Act and established the industrial doctors as a medical specialty.

2. Administrative Structure of Occupational Safety and Health

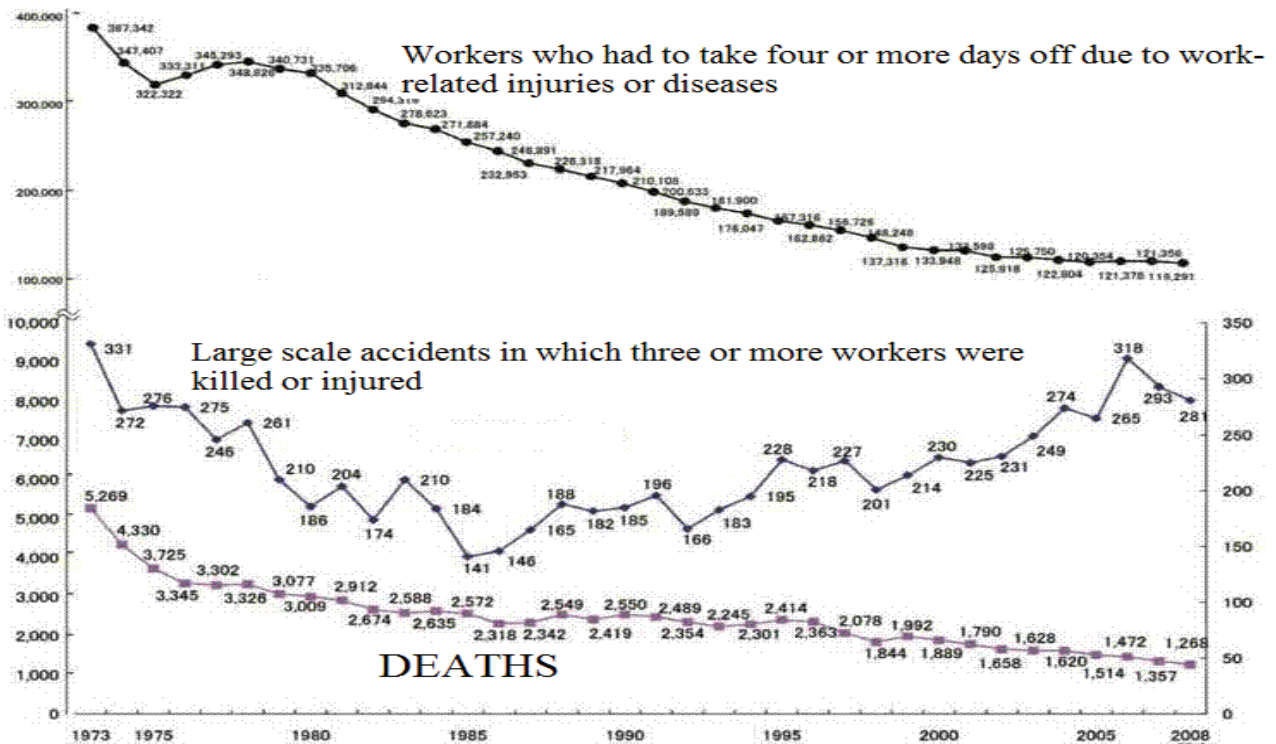
Under the OSHA, employers who employ 50 or more workers will be required to contract an industrial doctor. Also, employers who employ 1000 or more workers (including employers of certain industry who employ 500 or more workers) must employ an industrial doctor on a full time basis.

Industrial doctors are responsible for health maintenance of all workers and must conduct an on-site inspection of the working conditions to make sure the conditions are safe and healthy. Industrial doctors are charged with suggesting professional opinions to employers and managers with regard to safety and health maintenance of the workers although these opinions are not legally binding.

All employers, regardless of industries, are required to conduct health check-ups once a year. For workers working under special conditions, additional exams are included in the regular health check-ups.

3. Work-related Accidents

The number of victims of work-related accidents has been declining steadily since its peak in 1961, when the death toll was nearly 7000. The number of death caused by work-related accidents was 1,268 in the year 2008. The construction industry accounts for 34% of the death toll followed by the manufacturing industry (20.5%). However, when measured by incidence per working hours, the traffic industry has the highest incidence: 3.67 per million working hours (the numerator includes both death and injuries).



4. Workers' Compensation

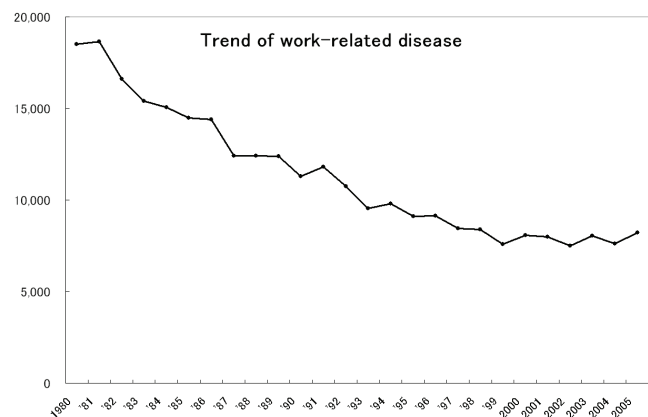
According to the Labor Standard Act, employers are held responsible for any financial damage caused by work-related accidents. To guarantee the financial liability, the MHLW operates the Workers' Compensation Insurance (WCI).

The WCI covers not only medical cost for treatment of diseases and injuries but also pay monetary damages to lost wages, disabilities and annuity for bereaved family members. Also the WCI covers not only injuries caused by accidents but also work-related diseases.

To have the WCI applied, one must apply to the local labor offices, a branch of MHLW and the determination of a disease as work-related is not always easy task. Sometimes disputes arise between the applying workers (or bereaved family members) and MHLW leading to litigations.

Premium is paid by exclusively by employers in proportion to the total wages.

The premium rate varies depending upon the risk of occupations, ranging from the lowest rate for office workers (0.45%) to the highest rate for "construction sites of dams, tunnels" (11.8%).



5. Karo-shi controversy

Some workers die or get disabled by cerebral vascular diseases and ischemic heart diseases. These deaths and disabilities may qualify for the WCI benefit if the underlying

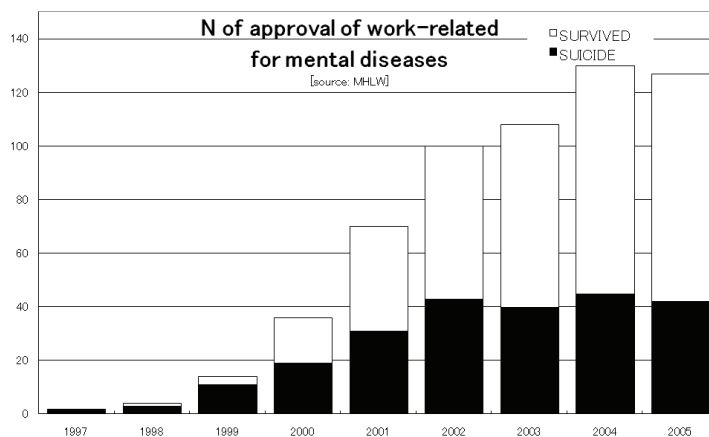
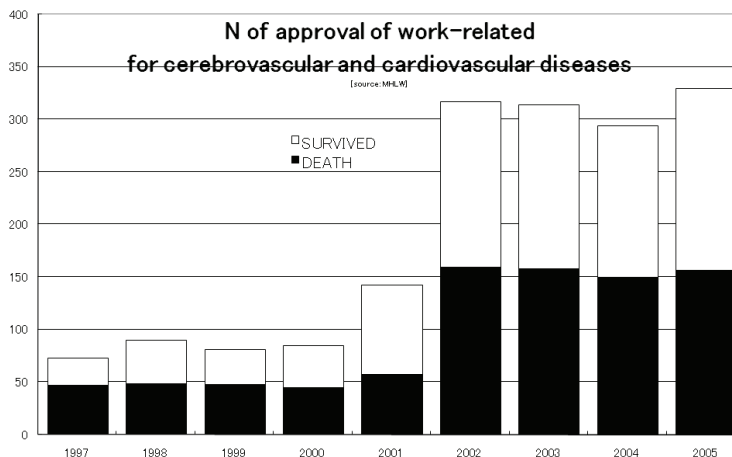
conditions were worsened by excessive working stresses. However, establishing the cause and effect relationships is often difficult. Although, the government does have its own arbitration process, disputes infrequently lead to litigations. Bereaved family members who attribute the death of their family to excessive working conditions and fatigue claim the causality by calling the death Karo-shi, or death due to excessive work in Japanese.

To facilitate the determination of causality and avoid disputes, the government presets some criteria for common work-related diseases, such as noise deafness, asbestosis and neck-shoulder disorders. For cerebral and ischemic heart diseases, the criteria were first introduced in 1987 and were later revised in 1995.

Also controversial are those related with cardiovascular diseases and psychiatric diseases. In September 1999, the criteria for determining work-related causality for psychiatric disorders were published.

In view of the importance of prevention of Karo-shi, the WCI act was amended to expand health check-ups to include secondary through examinations for workers who showed some abnormalities in regular health check-ups in 2000.

The effect of the introduction of the new criteria is dramatic. The number of approved cases jumped up shortly after the revision. Likewise, approval of mental diseases as work-related became also easier particularly for suicide cases.

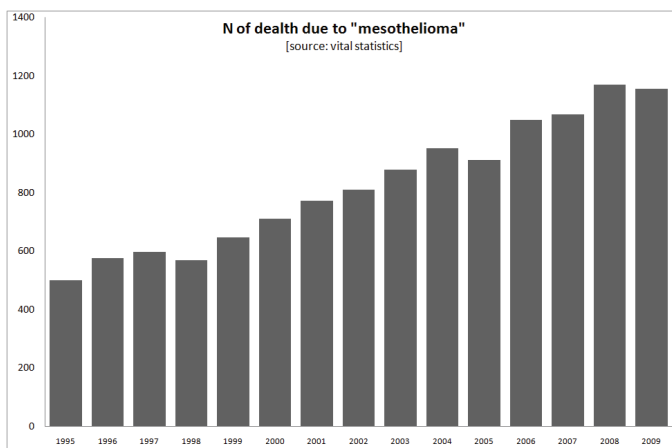


6. Asbestosis

Asbestos had been widely used for industrial purposes until it was banned in middle of the 1970s for its carcinogenicity. The carcinogenicity of asbestos has a long latent period (20-40 years) and its fatal effects emerged the world entered into this century.

In 2005 a big scandal broke out after an epidemiological survey revealed elevated incidence of mesothelioma, a type of lung cancer caused by inhalation of asbestos. The survey revealed that the asbestos emitted from some factories affected not only the exposed workers but also residents living in the neighborhood. Media reported increased deaths due to mesothelioma (lung cancer specifically caused by asbestos) around former factory sites handling asbestos. Boosted by media coverage, there was a surge of asbestos-related

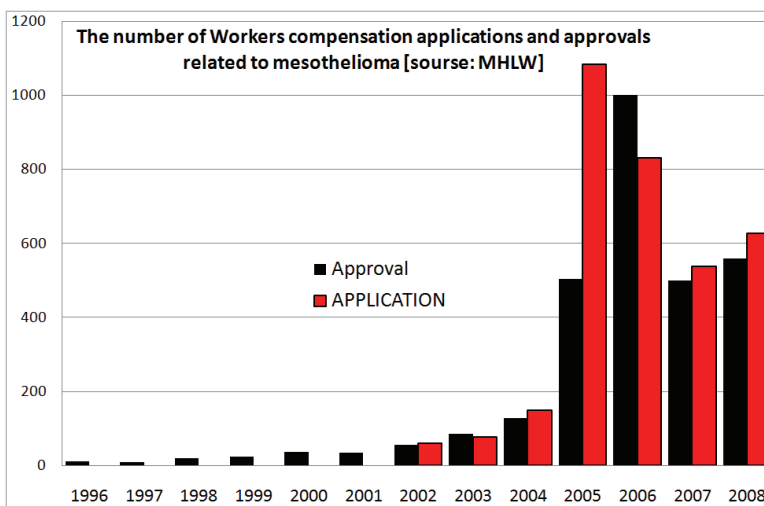
WCI application in 2006 (1006 mesothelioma patients were determined to be caused by asbestos). However, the WCI does not apply to the affected local residents. Large scale class litigations are under way against corporations which operated the responsible factories.



Asbestos had been regarded as a major industrial hazard and workers who developed asbestos-specific diseases such as mesothelioma and pneumoconiosis were entitled for compensation by the WCI. However, little was known that it also affect local residents living around the factory sites and they had no compensation.

In response to the public outcry, the government enacted the Act for Health Hazard by Asbestos in February 2006 entitling non-workers for monetary compensation. Compensation of victims is essentially the civil liability of responsible polluters. However, it is always difficult for victims and their survived family members to demonstrate the cause and effect relationship in the court. Because asbestos was in such a wide use, it is even impossible for them to know who is to be sued. Hence there was a need for enactment of a new collective compensation system.

The asbestos compensation system set up a monetary fund with the initial endowment of 38.8 billion yen and would be financed by compulsory contribution from all corporations. Corporations which used asbestos would be required to contribute more.



People who claim that they had developed mesothelioma or lung cancer due to asbestos may apply to the Environmental Preservation

and Revitalization Corporation (NGO affiliated with Ministry of Environment) for compensation. Since mesothelioma is considered to be specifically caused by asbestos, the applicants need only to demonstrate the accuracy of diagnosis with pathological evidence. The process is more complicated for applicants with non-specific lung cancer: they not only need to demonstrate the accuracy of diagnosis but also need to demonstrate the level of environmental exposure to asbestos.

According to the criteria set by the government in March 2006, the applicants must demonstrate that their exposure to asbestos had been equivalent to more than double the risk

of developing lung cancer than general population. This is tantamount to the exposure to 25 fibers/ml/year. Clinically, either 1) evidence of pneumoconiosis on chest X ray or CT, 2) amount of asbestos fibers or particles in lung exceeds a certain level (>5000 particles or >two million asbestos fibers in 1 gram of dry lung tissue or >five asbestos fibers in 1ml of alveolar lavage).

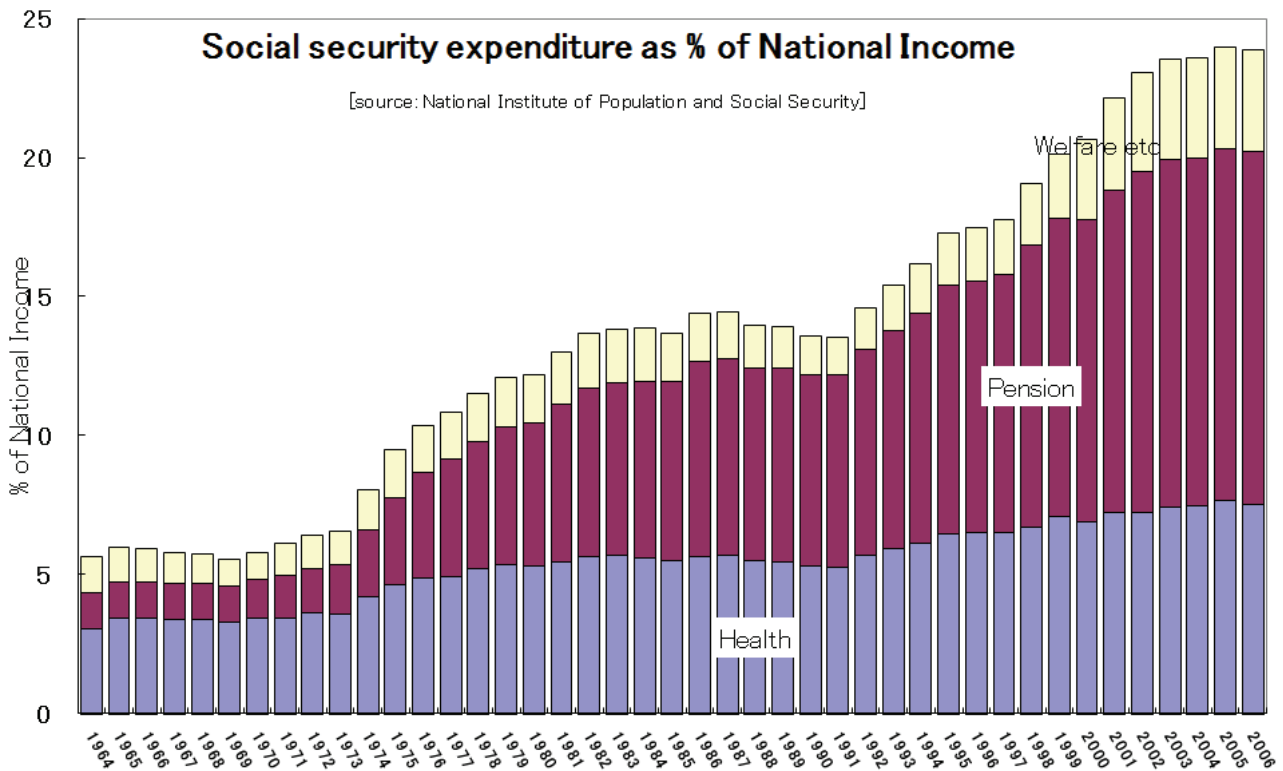
Chapter 9. Social Security and Welfare

1. Social Security and financing

The article 25 of the Constitution states that “All nationals shall have the fundamental human right to live healthy and cultural livelihood in the minimum” and the statement issued by the Social Security Committee in 1950 defines the social security as “economic assurance against potential causes of poverty either by way of insurance or public subsidy but for those who fall below poverty level, the public subsidy shall guarantee the minimum livelihood as declared in the Constitution”.

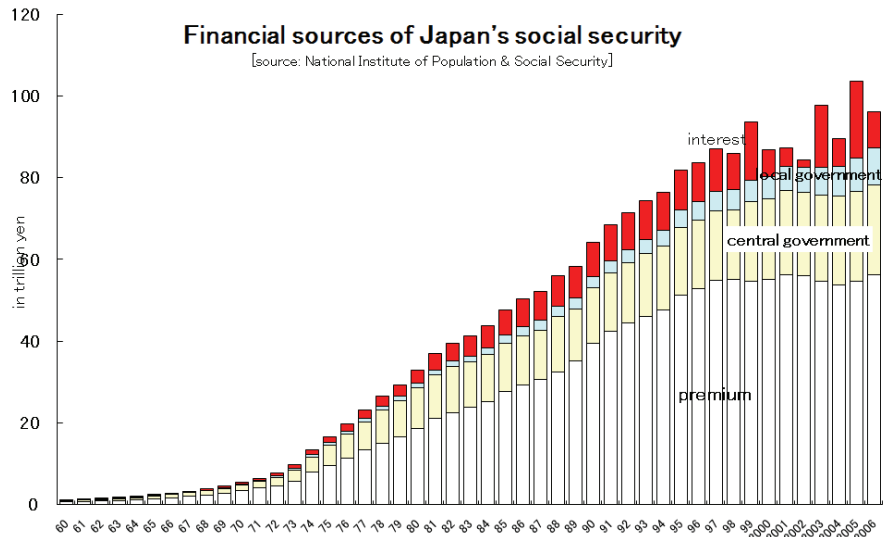
(1) Financing aspects of social security

Social security is undeniably the most important priority in Japan and is also very expensive. Its sheer economic size can easily be illustrated by the share in the national economy. The expenditure related to social security in 2006 was 89.1 trillion yen or about 23.87% of National Income (373 trillion yen). Forty years ago, in 1964, it was only 5%, meaning that social security used to be of far less concern for most people.



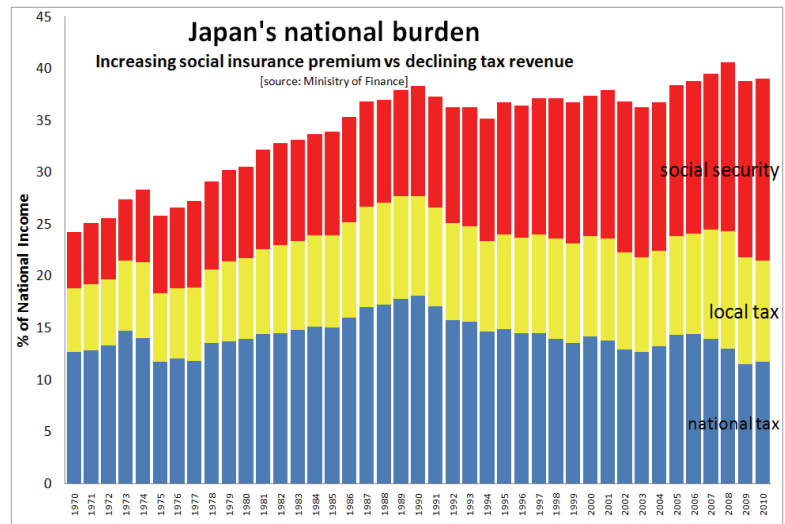
Social security relies its financial source largely to premium and government subsidy (tax). Japanese people pay social insurance premium of 56.2 trillion yen out of their 373 trillion yen annual income in 2006, more than the national tax (income tax, corporate tax and consumption tax, etc), 42 trillion yen. From both central and local government, social security receives 26.7 trillion yen subsidy.

Another important source of income is interest, derived from accumulated social security fund. Unfortunately, due to historically low interest rate, the interest income dwindled: it now brings in only 1.6 trillion yen or 4.8% of total social security revenue.



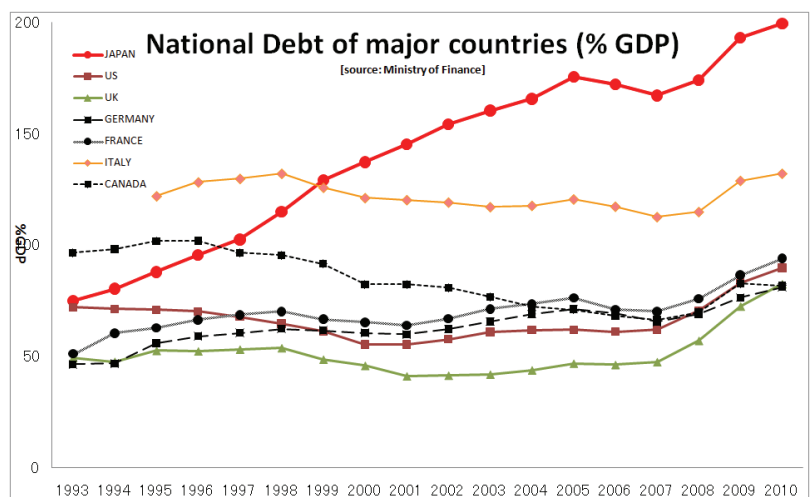
(2) National Burden

The % of social insurance premium plus tax in National Income is called “National Burden”, a measure of disposable income. For the first time, it exceeded 40% in 2007. However the composition of the burden has changed dramatically. Burden of social insurance premium has consistently increased while that of national tax has declined from 18% in 1990 to 13% in 2009.



The National Burden of Japan is still low in comparison with other developed countries despite her aging population: Japanese pay 14.6% of their income for social insurance premium and 23.8% for tax for both central and local governments, due largely to the very low tax rate (FY2008).

However these figures should be interpreted with caution. Japan has heavier debt than any other countries, for which the government will eventually have to pay back. Japan's loan spree started in around 1990, when Japan's “bubble” economy burst dragging the country into the deep and prolonged recession.

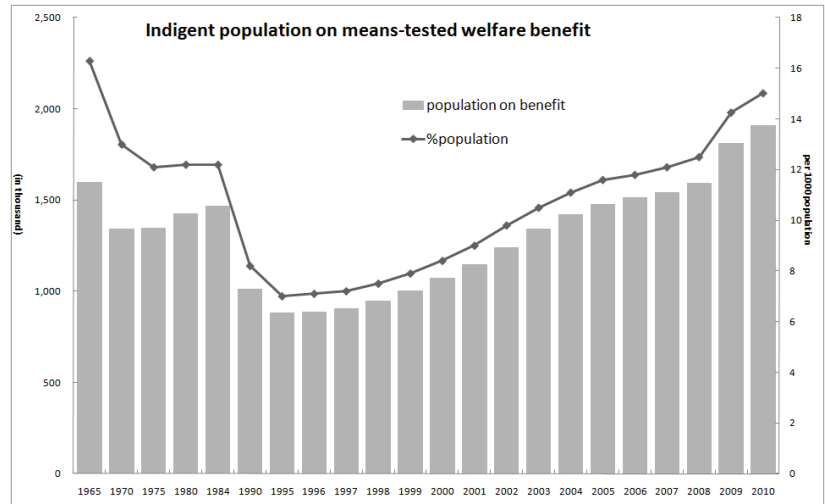


Japanese government responded to the declining tax revenue with loan as a form of governmental bonds. As a result, Japan quickly ran up to the top of “debt” countries. As of 2007, Japan’s debt reached 1.7 times the GDP. Such an accumulating debt burden may not be solved without a huge inflation.

2. Welfare for the Indigent

Poverty has always been at the center of social welfare. Under the Livelihood Protection Act, anybody who fell below the preset level of poverty will be entitled to the means-tested welfare benefits.

To administer the system, all cities have social welfare offices staffed by caseworkers. Anybody who wishes to receive the welfare benefit for the



indigent must apply and undergo means tests. There are eight kinds of benefits: living expenses, education, housing, long term care, delivery, occupational assistance, funeral and medical care.

The system is heavily affected by the economics of the country. In 1951, 2.42% of the total population was on the roster of the indigent. The percent has consistently declined to hit the record low of 0.7% in 1995. However, Japan’s long lasting economic slumps are casting dark shadows over the system: the percent of the roster is on the rise again. The figure in March 2010 was 1.5%.

(1) Livelihood assistance

After all available resources such as savings or financial support by relatives, livelihood assistance may be afforded after means-test. The benefit is rendered to fill the “gap” between the minimum living standards and available financial resources of the recipients.

The minimum living standards are minutely set by government. For example, a household of three (33 year old man and 29 year old woman and 4 year old child) living in Tokyo is supposed to need 162,170 yen (approximately \$1500) to assure minimal living standards. Households whose income below this standards are entitled to living assistance benefit to fill the gap.

(2) Medical assistance

As for medical care, recipients of the Livelihood Protection Act are mostly exempt from compulsory NHI system and their medical bills will be paid from general tax as medical assistance. Diseases remain as the main cause of falling into poverty and as much as 80% of the recipients are receiving medical care. In financial terms, medical cost accounts for approximately 56% of the entire budget of the system.

Approximately 130,000 people (10.6% of those receiving medical assistance, 1.22 million) are hospitalized, of whom approximately 60,000 are psychiatric diseases. This accounts for approximately 17% of the total psychiatric beds (350,000) of Japan. Of the psychiatric inpatients on medical assistance, nearly half (47.8%) of them have been hospitalized longer than five years. This reflects the fact that majority of such prolonged hospitalization is schizophrenia.

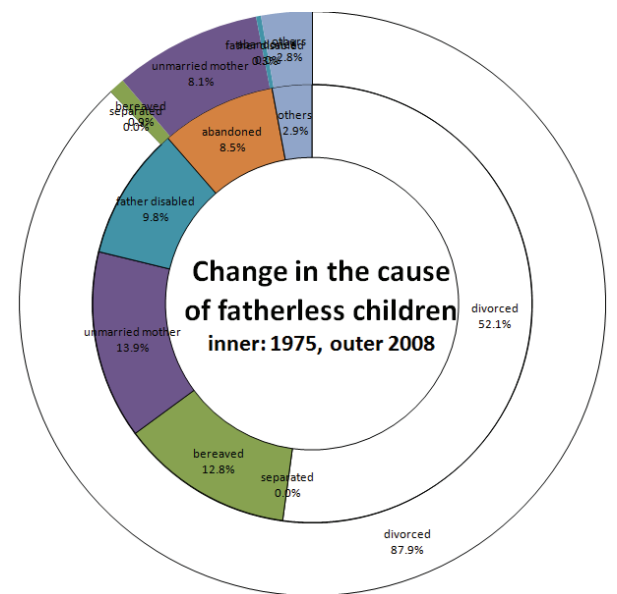
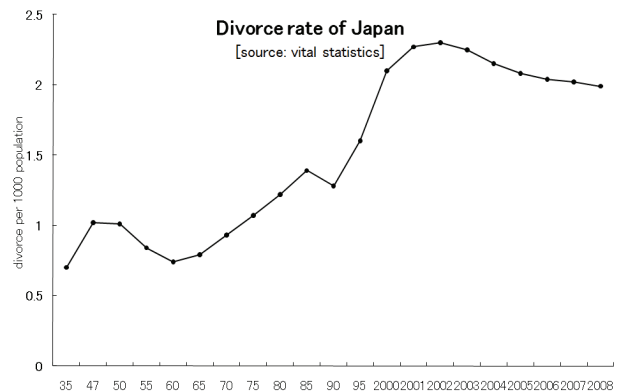
3. Maternal and Child Welfare

Social security for mother and children families is twofold: for those whose father died, survivors' benefit of the pension system will apply, but those who divorced with father will not qualify for the survivors' benefit. However, the recent sharp increase of divorce has brought the single mother and children households issue on top of the social problem list.

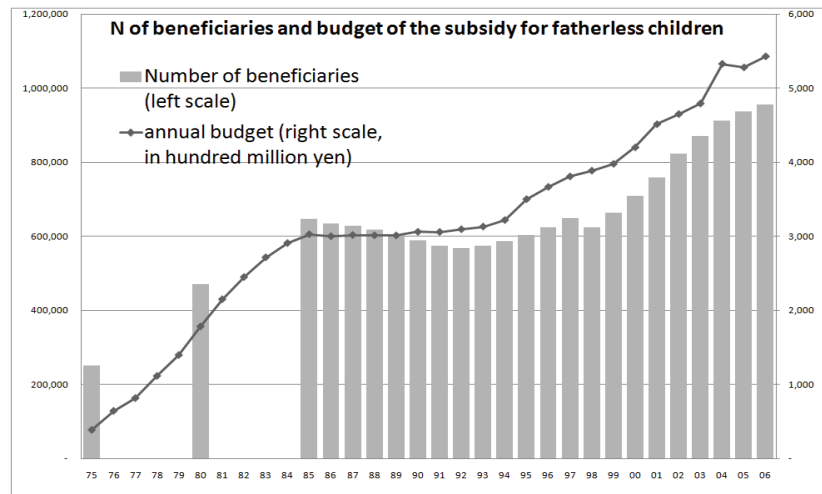
Japan's divorce was approximately 253,408 in 2009 or 2 per 1000 population. This figure is far smaller than the U.S. with 3.6 per 1000 divorce rate (2005). However, Japan's figure has more than doubled since the 1960s.

Divorced partners still owe legal liability to support the children, but their fulfillment of their obligation is not satisfactory. According to the Single Mother and Child Household Survey conducted in 2006, only 38.8% of the surveyed households had formal arrangements of alimony. The reasons of not having a formal arrangement of alimony were "the ex-partner had no will/ability to pay alimony (47%)", "do not like to be bother with the ex-partner (23.7%)" and "attempted to make an arrangement but in vain (9.5%)". Consequently only 19% of single mother & child households were currently receiving alimony and as much as 59.1% had never received it. Their average annual income is only three million yen.

To provide financial support, the government provides the "the Subsidy for Fatherless Children" to single mother and child households. Benefits are available not only to divorced families but also to unmarried mothers. The causes of fatherless children have changed dramatically since 1975.



Monthly benefit is 41,720 yen (\$420) for families with one child and 967,215 households are on the roster in March 2008, a 3.85 times increase since 1975. The government disbursement exceeds 500 billion yen and is increasing. The financing of the “Subsidy for Fatherless Children” is becoming a heavy financial burden for the government.



4. Welfare for the disabled

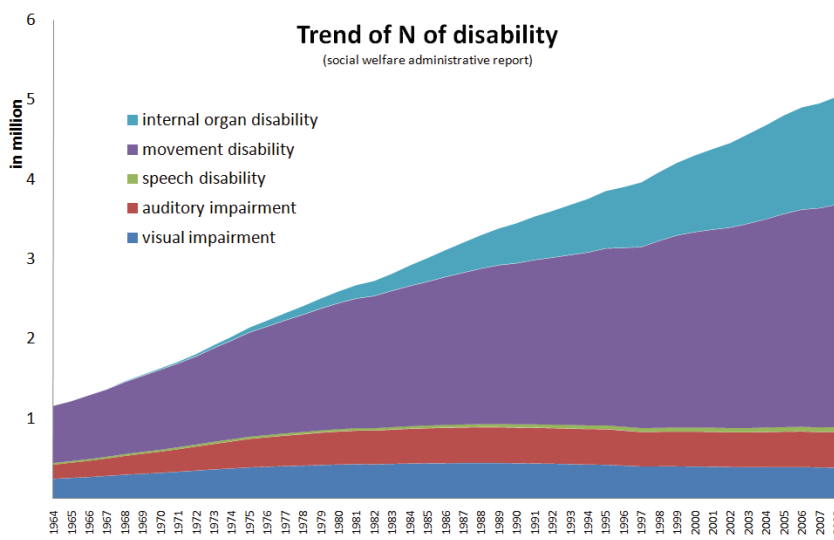
Disability is classified into physical disability, intellectual disability and psychiatric disability. Each disability had been addressed separately by different legislatures.

In April 2003, a new system of provision of welfare services for physical and intellectual disabilities was introduced. The new system introduced “*reimbursement (shien-hi)*” system in place of the *direct provision (sochi)* by municipal governments. Under the old direct provision system, the recipients had no freedom of choice of providers because the municipal governments would unilaterally determine and contract the providers. Under the reimbursement system, recipients are allowed to choose providers and providers “bill” to the payers (municipal governments) just like hospitals bill to the insurers. The introduction of the new system encouraged the use of services and boosted the number of recipients of domestic services increased by 1.6 fold in only 1.5 years between April 2003 and October 2004. Still, psychiatric patients were left out of the new system.

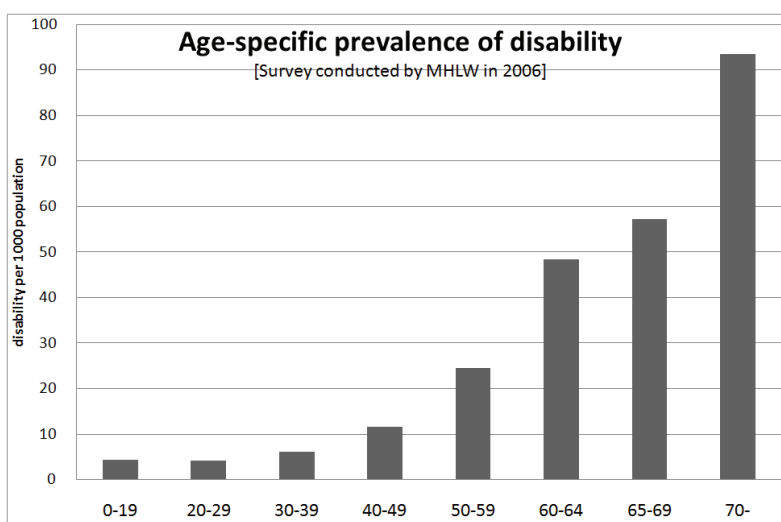
In April 2006, the new Independence of the Disabled Facilitating Act (IDFA) took effect and the social welfare systems for three disabilities were united. Since the Long-term Care Insurance (LTCI) does not cover young people with disability, the new IDFA intended to provide the long-term care equivalent to that of the LTCI to people with disability. So, mechanisms similar to the LTCI were introduced to the care for the disabled. The need assessment system is one example. To receive home help services or other long-term care related services, applicants must undergo assessment to objectively determine his or her level of care need using assessment tools containing 106 items. Municipal governments determine the level of care need (six levels) considering the professional opinion of attending doctors. Within the limit of the designated level, applicants are entitled to receive services they choose.

(1) Physical disability

The government surveys the number of people of physical disability every five years. According to the latest 2006 survey, there were estimated to be approximately 3.48 million (27.7 per thousand population) adults (>=18 yo) and 93,100 children (<18 yo) with physical disability.



The type of disability was extremities (50.5% for adult, 53.8% for children), internal organ (such as dialysis, HIV/AIDS) (30.7%, 22.2%), auditory/verbal impairment (9.8%, 18.6%) and visual impairment (8.9%, 5.3%). Reflecting a sharp increase of kidney failure, internal organ impairment is the fastest growing type of physical disability. Prevalence of disability increase with age. Nearly one out ten of the elderly over 70 have some disability.



(2) Intellectual disability

According to the governmental survey, there are estimated to be 547,300 (4.3 per thousand population) people with intellectual impairment as of 2005 (419,000 living in community and 128,300 were institutionalized), of whom 125,000 were children (<18 yo). For children with disability (including both physical and intellectual disability), special assistance schools/education is provided. According to the Ministry of Education, approximately 286,000 children were attending these schools/education in 2008. This means that 2.17% of educational age population are attending special assistance education. Increasingly, children with developmental disorders which has been overlooked so far attract special attention. To address such hitherto overlooked disorders as learning disability (LD), attention deficit and hyperactivity disorder (ADHD) and Asperger syndrome, a new law “Developmental Disorder Assistance Act” took effect in April 2005.

(3) Psychiatric disability

According to the Patient Survey, a sampling survey on hospitals and clinics every three

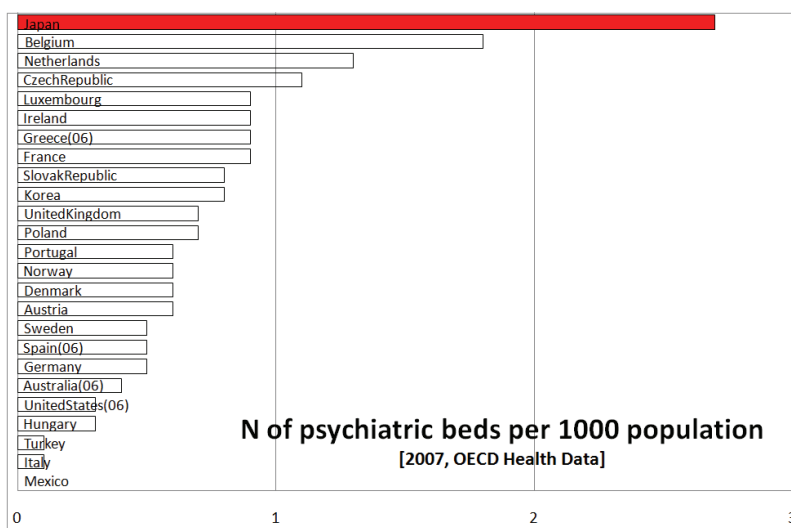
years, there were estimated to be approximately three million people under medical treatment with diagnoses of psychiatric diseases including 350,000 inpatients. Although many of the psychiatric patients are mild cases and will recover eventually, a considerable number of them are in chronic conditions to qualify as disability. Patients with longer than six months of psychiatric disorders may be eligible for the Mental Health & Welfare Act. The certificate (notebook) has three classes (mild, moderate and severe) and entitle the holders for benefits such as reduced copayment for ambulatory psychiatric care, deductibles of income tax and discounts of public utilities. A total of 404,883 people (3.2 per thousand population) are issued the certificates (mild 82,971, moderate 248,102 and severe 73,810).

Japan has notoriously many psychiatric hospital beds per population as shown in the graph of OECD Health Data. Approximately 60% of the 350,000 inpatients are schizophrenia. The governmental committee estimated that at least 70,000 out of 350,000 inpatients can be discharged if conditions are met and advocated that these patients should be discharged within ten years in September 2004. Unfortunately, the proposal did not realize yet.

(4) Financial support for the disabled

For children and minors (<20 yo) with any disability, the Special Disability Subsidy is paid to their parents or custodians. The monthly amount is 50,750 yen (\$500) for severe disability and 33,800 yen (\$338) for moderate disability

Adults (>=20) with disability are supported by disability benefit of National Pension (plus Employees' Pension for salaried workers). The annual amount of NP benefit is approximately one million yen (\$10,000) for severe disability and 800,000 yen (\$8,000) for moderate disability.



The number of physical disability has consistently increasing reflecting the population ageing. The number of internal organ impairment includes renal failure patients on dialysis and accounts for most of the recent increase of the number of people with disability.

5. Welfare for Homeless

Reflecting Japan's long economic recession, homelessness is increasingly becoming a top agenda for public health policy. For the first time, MHLW conducted a nationwide survey for homelessness in January 2003. The survey identified 25,296 homeless people nationwide, with the largest population in Osaka (7,757) followed by Tokyo (6,361).

Their average age is 55.9 years old and 48.9% are living in public parks. 64.7% of them are working, mostly of garbage collection.

6. Pension system

For a country with the world-highest aging, pension system is increasingly an important agenda in social security. One might start with looking back its brief history.

(1) History

In the pre-war period, military servicemen and civil servants were entitled to receive pension after retirement. After the defeat of the WWII, the military pension was suspended in February 1946 by order of GHQ and numerous former servicemen were left with no income. After Japan regained its independence, the military pension was revived in August 1953 and as many as two million former servicemen became eligible. Also, the War Victims Relief Act was implemented in April 1952 and civilian workers who had been mobilized for the war efforts were entitled to receive pension.

The insurance-type pension system for corporate workers was first established in 1942 as part of the war efforts. In the beginning, the retirement pension was started at the age of 55. By the revision in 1954, the eligible age was gradually raised to 60 (for men taking 16 years: 1957-73 and for women taking 12 years: 1987-99). For the non-employed population, National Pension was established in 1961 achieving the universal coverage of those over 20 years old for pension system. The starting age of National Pension has been 65 since its inception.

Given the population forecast that there would be 40% of the population over 65 years old, it was apparent that the starting age had to be raised to 65. But the proposal was met with strong opposition from both labor and business. In 1989, the bill was passed to raise the starting age by one in every three years from 1998 to 2010 (it was intended to see that the starting age of the post-war baby boomers would be raised to 65.). However, it was delayed by three years (i.e., 2001-2013) and the raising of the starting age was for the half of the pension. Another twelve years must be waited before achieving the starting age of 65 in the year 2025.

In 1985, a radical restructuring was done for the pension system fragmented between the self-employed and employees. National Pension was reformed to serve as a compulsory base pension for all people aged 20-59 and the governmental subsidies were concentrated into this scheme (no governmental subsidies for employees' pension or civil servants' Mutual Aid Associations). Also, housewives of employed workers had no compulsory pension system. If wives get divorce, they were left with no pension. After the reform of 1985, all housewives were enrolled to National Pension and their eligibility for pension were guaranteed (premium is paid by all employees and employers).

In 2003, pension became a most hotly debated political issue after it was disclosed that the premium contribution of National Pension had declined dramatically. Until 2002, premium collection for the National Pension was largely done by municipal governments,

but the job was delegated to the Social Insurance Agency (SIA). SIA, with its 312 branch offices nationwide was unable to match the effort of municipal governments (1,800 nationwide) and the premium collection rate quickly dropped to 62.8% from 70.9% in previous year, bringing the very existence of the pension system into question. The latest figure in 2009 was 60% (Premium can be paid within two years and the ultimate collection rate will be higher).

What was worse, some politicians (most notably Naoto Kan who later became prime minister) who blamed the cabinet members for failure to pay premium in certain periods, were themselves found to have delinquent periods. These exposes, coupled with a series of scandals such as leakage of personal information and bribery cases undermined the public trust in the SIA as well as the pension system itself.

Further, another scandal that as many as 50 million records were “missing” was exposed in 2006 by a congressman, Akira Nagatsuma who became famous as “Mr. Pension” and later became minister of MHLW himself. The problem was mainly because Japan had no unique social security number until January 1997. When unique numbers were issued to 101 million individuals in 1997, there were almost 300 million “records” stored in the SIA database. Of them, 250 million records were linked to 101 million individuals but approximately 50 million records were left unlinked. Due to the lack of unique number, missing or wrong personal data of names, date of birth resulted in many records unlinkable to unique numbers. The then minister of MHLW, Yoichi Masuzoe pledged linking all outstanding records. Special committees were set up to investigate the appeals made by individuals who felt that their records were inaccurate and make necessary corrections. Also, mail inquiries were sent to individuals to verify their records. Through these efforts, 14.6 million records were successfully linked to unique social security numbers as of June 2010. MHLW vowed to complete investigation by the end of 2013.

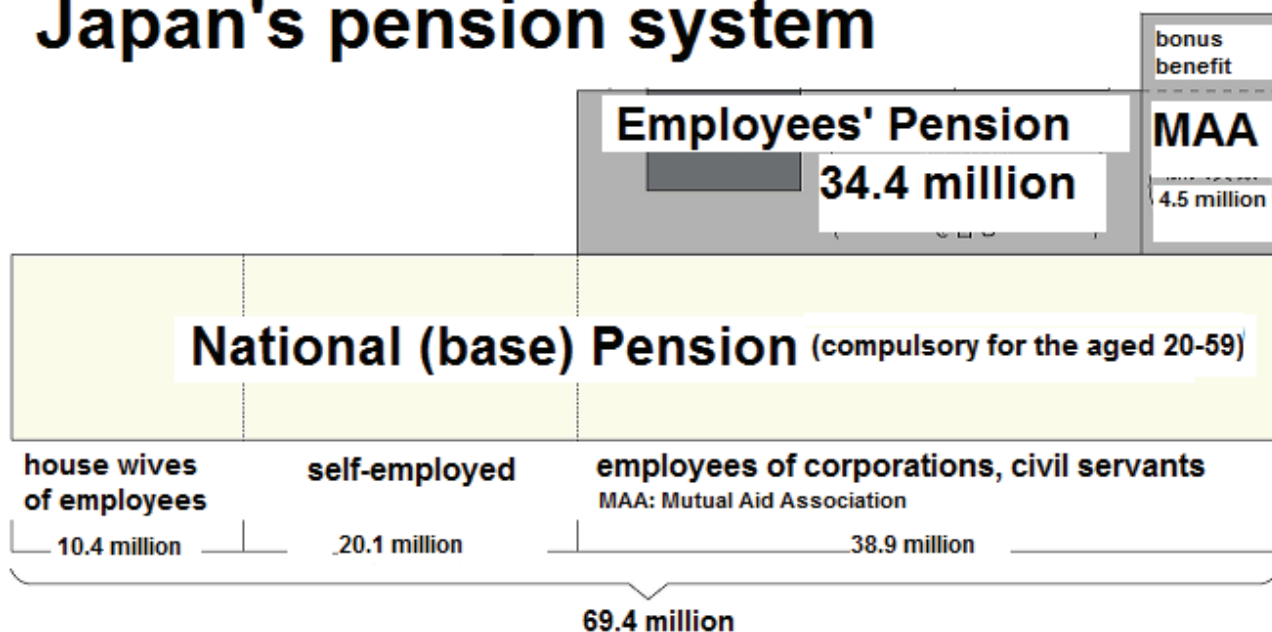
The government decided to recruit a civilian professional from private insurance companies as the director of SIA replacing a career bureaucrat of MHLW, with a hope that such experience professional of insurance business will be able to revive the plagued National Pension system. Eventually SIA was quasi-privatized in January 2010 to be Japan Pension Service (JPS). Also JPS launched a series of confiscation of private properties on those who willfully refuse to pay premium.

(2) Structure

Japan’s pension system consists of two pillars: NP and Employees’ Pension (EP), just like health insurance system consisting of National Health Insurance (NHI) and Employees’ Health Insurance (EHI) system, with the following two differences.

- Health insurance is operated by a variety of insurers while pension system is operated uniformly by JPS.
- Health insurance is pluralistic: each individual enroll to only one insures, i.e. salaried workers do not enroll to NHI. Pension system, on the other hand, NP enroll the entire population aged 20 to 59. Salaried workers enroll to both NP and EP dually.

Japan's pension system



(3) Eligibility and premium

NP has three categories of its enrollees.

- Category I: Non employed population aged 20-59, such as self-employed, students or jobless workers (20.1 million as of March 2009).
- Category II: Salaried workers who dually enroll to EP (38.9 million).
- Category III: Dependent spouses of salaried workers aged 20 to 59 (10.4 million).

Compulsory monthly premium for category I enrollees are a flat 15,100 yen. Premium for category II is 16% of monthly salary (most workers receive bonuses in addition to monthly salaries on average of 3 months worth, which also subject to the same premium rate). For category III, no additional premium is required (premium is paid by all salaried workers collectively).

Premium for category II is withheld from paychecks and therefore the collection rate is nearly 100%, as well as for category III. However, for category I, the monthly premium of 15,100 yen must be paid voluntarily and therefore end up in such a low collection rate of 60%.

(4) Benefits

Pension benefit is classified into three kinds. Here, only NP benefit is described, omitting EP benefits. Half of NP benefit is financed by governmental subsidy.

● survivors' benefit

Dependent family members such as spouses or children whose bread winners are deceased can receive survivors' benefit. NP survivors' with one child can receive monthly benefit of 86,300 yen. This benefit does not apply to divorced families, which may be eligible for Child Support Allowances discussed in the other section.

● disability benefit

Disability benefit of NP constitutes an important part of disabled people. Monthly benefit is 83,775 yen for severely disabled and 67,017 yen for moderately disabled.

Those who become disabled before age 20, i.e. disabled before they become eligible for NP, will be entitled for the benefit after they become even if they have no premium contribution (such benefit is financed by government subsidy). However for those unfortunate who become disabled while they are defaulting their premium contribution will have no benefit. Such “pension less” disabled people are one of the difficult policy debate.

- retirement benefit

By far the largest portion of NP benefit is retirement benefit. Benefit becomes available at the age of 65 for enrollees who paid premium 25 years (300 months) or longer. Monthly benefit is 67,017 yen for those who paid premium in full 40 years (age 20 thru 59) but will be reduced if the period for which premium has been paid less than 40 years. Given the average life span of 65 years old Japanese women is 23.64 years and 18.6 years for men, the future NP burden will inevitably grow, making many Japanese wonder if the system is really sustainable for the future.

As for EP, the retirement benefit becomes available at the age of 60 but the starting age will be raised gradually to 65 starting in FY2013. In that year the cohort born between April 1953 and March 1954 will reach 60, when the eligible age will be raised to 61. This means that the cohort born between April 1953 and March 1954 will have to wait until FY2014 to receive the retirement benefit. The eligible age will be raised by one year every three years, i.e., that the eligible age will be raised every two birth cohorts. The eligible age will be 62 for the cohorts born between April 1955 and March 1957, 63 for the cohorts born between April 1957 and March 1959, 64 for the cohorts born between April 1959 and March 1961. Eventually the cohorts born in April 1961 or after will have to wait until the age of 65 before they are eligible for any retirement benefit. The above time schedule will be waived for five years for women. For women, the cohort born in April 1966 or after will start receive retirement benefit at the age of 65. In view of Japan’s long life span, even the eligible age of 65 appears too young. The U.S., with its much lower elderly population than Japan will delay the eligible age from the present 65 to 67 by the year 2027.

Since the average annual income of the elderly households was only three million yen according to the National Household Survey in June 2007 and pension income accounted for 70%, securing income of the elderly over 60 will be important for happy retirement. Pursuant to the Elderly Employment Security Act, corporations are required to raise the retirement age to 65 gradually by the year 2013.

(5) 2004 revision of pension system

Actuarial basis of pension system is revised every 5 years reviewing the latest demographic trend and economic indices. The year 2004 was the year. After lengthy, and occasionally violent, parliamentary debates, the following decisions were made.

- Make both ends meet by the year 2100.
- Increase the premium, which had been frozen since 1996, to up to 16,900 yen for NP and 18.3% for EP gradually by 2017.

- Increase the government subsidy for NP from current 1/3 to 1/2 by 2009.

The ultimate goal of the 2004 revision is to secure the income of the retired elderly at 50% level of their income during working age.

7. International treaty of social security

Internationalization called for mutual coordination of pension contribution. When salaried workers are sent to another countries, in many times both employers and workers find themselves responsible for dual premium payment to both governments. This increases financial burden of corporations and without prospect of receiving retirement benefits. This is particularly true for Japan, which requires much longer period of enrollment than other countries: it requires at least 25 years of enrollment before he or she becomes eligible for receiving retirement pension.

International treaties are bilateral treaties between two countries and include the following provisions.

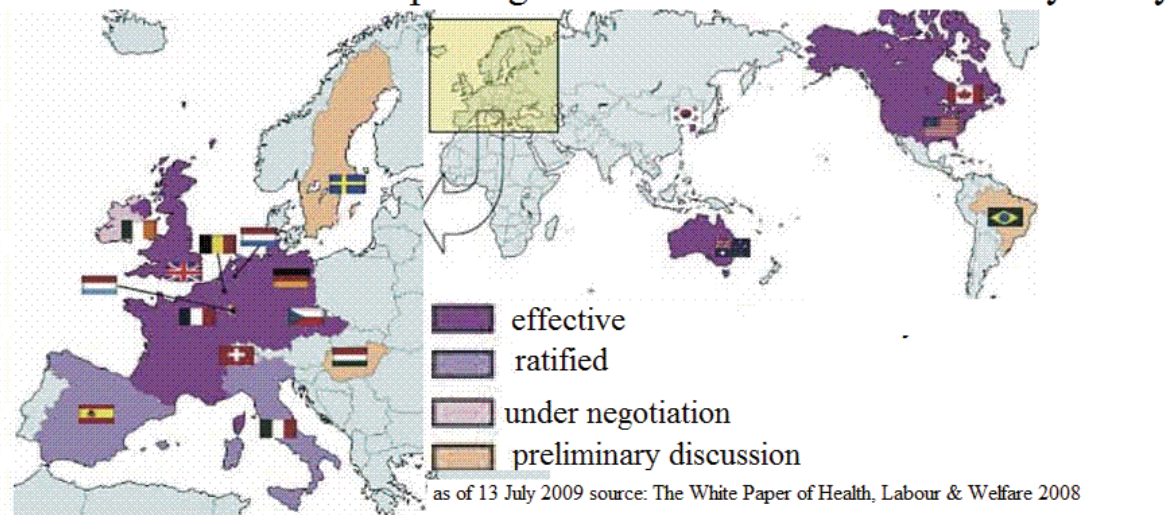
- 1) Exemption of pension enrollment for nationals who work in the host country for a short time to avoid duplicate premium contribution.
- 2) Tantalization of enrollment period for a person who has enrollment periods in more than one countries to determine his or her eligibility for retirement benefit.
- 3) In some cases, exemption from compulsory health insurance may also apply.

The first of such treaty was ratified with Germany in 2000, followed by UK in 2001. In 2004, Japan ratified the treaty with US and Korea. The negotiation is currently underway with Canada, France and Belgium.

The provisions of the treaty vary. The Japan-US treaty is most comprehensive including the above all three. The German treaty includes 1) and 2). The UK and Korean treaties include only 1).

The Japan-US treaty is worthy of particular comments not only because it affects the largest number of nationals (over 50,000 Japanese are employed in the U.S.) but also it includes a provision of health insurance. In a sense, Japan's long-held policy of requiring all residents in the country to enroll to its health insurance system was modified and allows Americans in Japan for a short time (<5 years) to be excluded from the health insurance programs.

Countries with which Japan signed international social security treaty



Chapter 10. Long-Term Care

In April 2000, the much-awaited Long-Term Care Insurance (LTCI) took effect. The new system will not only expand the long-term care services but also include some innovative aspects not seen in traditional health insurance system.

1. Administrative structure

In contrast to the health insurance system, which has a fragmented structure with different insurers covering different segments of population, the LTCI system has a uniform structure: it is administered by municipal governments (there are three categories of municipal governments, namely cities, towns and villages depending on the population size). Municipal governments insure all residents aged 40 years or older where he or she resides.

For example a 45-year-old male worker of Sony Corporation will be insured by SONY health insurance society for health insurance but will be insured by the municipal government where he resides for the LTCI. He will have to switch to different insurer for health insurance coverage if he switches the company but will continue to be insured by the same municipal government for the LTCI as long as he does not move somewhere else.

Because all beneficiaries are consolidated to municipal governments, it became possible for municipal governments to draw a long-range plan to cope with the LTC. All municipal governments are required by the LTCI law to develop a strategic plan with 5-year time frame to make a sound actuarial prospect.

Municipal governments also administer their own health insurance (NHI). However it is difficult for municipal governments to draw a long range plan because only a fragment of residents are insured by the municipal governments and the number of insured residents varies depending on the economic situation (for example, a huge lay off will deprive workers of health insurance coverage and they will migrate to the NHI system which are administered by municipal governments).

2. Beneficiaries

As mentioned earlier, the LTCI does not cover the entire population. The beneficiaries are limited to people aged 40 years or over, or roughly half the population. This reflects the purpose of the LTCI law, which clarifies that the law is intended for disability caused by aging.

Further the beneficiaries are divided into two categories: beneficiary I for elderly aged 65 or over and beneficiary II for people whose age is 40 to 64 years old.

The distinction between the two categories is the difference of premium collection as discussed below.

3. Financing

Although Japan's LTCI may be classified as social insurance, it is an amalgam of both

German and British models in terms of financing, i.e. half of the finance comes from tax and the half comes from premium contribution. Insurance premium is levied on all beneficiaries but the method of levying varies between the two categories of beneficiaries.

For the beneficiary I, most of whom are pensioners, the premium is withheld from their pension payment. For the beneficiary II, most of whom are working class, health insurers levy the premium by adding on the health insurance premium. There are a small number of beneficiary I who do not receive pension. They are required to pay voluntarily to the municipal government.

Since more than 1800 municipal governments administer the LTCI system, the premium level also varies from municipality to municipality. The average monthly premium is approximately 3000 yen and ranges from 1500 to 5000 yen. In each municipality, the premium is scaled to the beneficiaries' income with 3 times difference between the lowest and the highest income bracket.

4. Need Assessment

Unlike health insurance, the benefit of the LTCI will not automatically be granted just by showing the insurance card. To be eligible for the benefit, the beneficiary must apply to the municipal government for need assessment. Only after the person is assessed as disabled, he or she will be entitled to the benefit.

A beneficiary must apply to the municipal government and the municipal government dispatches a surveyor to the applicant. The surveyors must be qualified care managers and on-site survey will be conducted using the uniform assessment tool, which consists of 73 survey items to measure ADLs, IADLs and behaviors. The surveyors may record any particular findings to be considered for final assessment but they have no authority to make any judgment.

The recorded assessment tools will be evaluated by computer to give preliminary assessment [dismiss, borderline, level 1,2,3,4,5]. The municipal governments will also ask attending doctors who are designated in the application forms to submit their professional opinion.

The need assessment review committees [NARC] consisting of around five health and welfare professionals will review the surveyors' findings and doctors' professional opinion to decide whether the preliminary assessment should be altered.

What is important about the assessment process is that although NARCs have authority to make final assessment, they do not start their review from scratch. They decide WHETHER THE PRELIMINARY ASSESSMENT SHOULD BE ALTERED OR NOT by reviewing the surveyors' findings and doctors' opinion. In 80% of the cases, the preliminary assessment will be final.

The need assessment is valid only for the specified period, usually 6 months. Beneficiaries must apply for renewals to stay eligible for the benefit.

5. Benefit

Benefit of the LTCI system is divided into institutional care and home care. The home care is characterized by integration of medical and non-medical care within the same individually assessed budgetary cap.

Medical and non-medical services were not in a competitive relationship before the LTCI system was implemented: medical services were reimbursed by the Elderly Health Care system and non-medical services were financed by welfare system. However the LTCI system brought both sectors into a competitive relationship in which one's gain is another's loss, because they have to compete over the fixed "pie" of budgetary cap.

Medical	Non-medical
visiting nursing	home help
visiting rehabilitation	catering bathing
ambulatory rehabilitation[day care]	ambulatory service[day service]

The monetary terms of benefit is metered to the level of care need. The level of care need will determine the per diem cost for institutional care and the monthly budget cap for home care as shown below:

level of care need and benefit (yen)

	monthly cap for home care [visiting and ambulatory services]	per diem cost for institutional care [skilled nursing facilities]
borderline1	48700	not permitted
borderline2	104000	
level1	165800	7810
level2	194800	8300
level3	267500	8830
level4	306000	9370
level5	358300	9900

6. Need Assessment Tool

Objective evaluation of the individual's eligibility for benefit was a premeditated policy throughout the design of the LTCI system. This reflects a bitter reflection over some of the drawbacks of the health insurance system, most prominent of which is the "medically unjustifiable" prolonged hospitalization.

Because of chronic shortage of nursing home beds, many elderly who lack adequate care at home are institutionalized at geriatric hospitals without firm medical necessity. Although all health insurance claims are subject to rigorous review, such "medically unjustifiable" prolonged hospitalization is seldom denied payment chiefly because it is difficult to challenge the physicians' judgment without an objective evaluation tool.

The German LTCI also has an assessment tool but Japan's tool is far more complex and sophisticated. An evidence-based approach was adopted to develop the assessment tool: a radical departure from traditional negotiation oriented policymaking. A field survey was

conducted on a sample of residents of selected nursing homes to quantify the care need by means of one-minute time study and correlate it with ADL measurement. The methodology was in many ways similar to that of the U.S. with its development of MDS, RUGs.

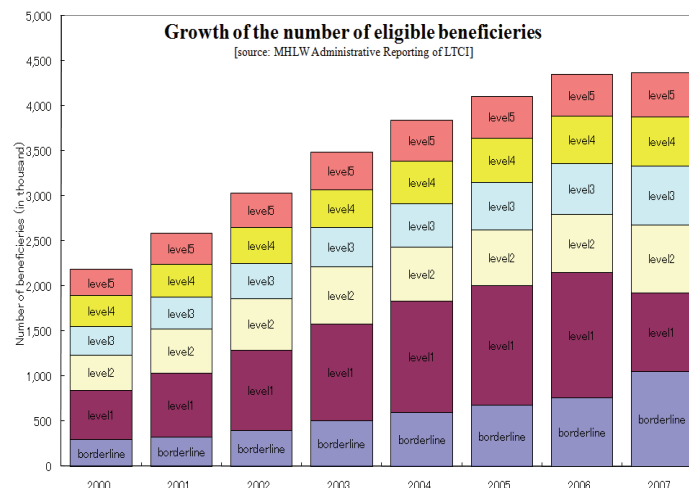
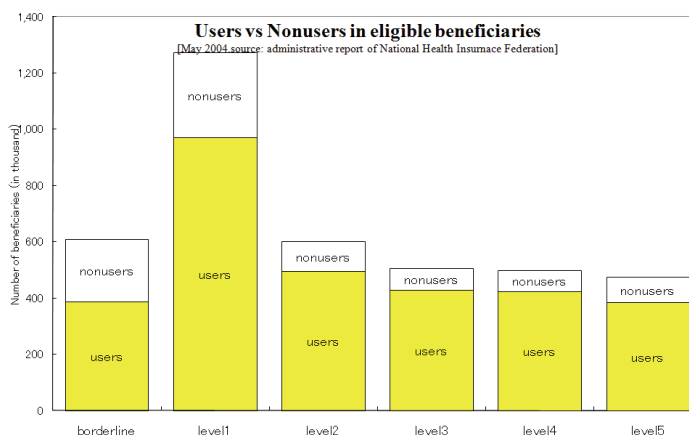
The product was the assessment tool consisting of 73 items that will predict the individual care need with certain accuracy. The tool is fully computerized to facilitate the assessment process and is now used nationwide to determine the eligibility for the benefit.

7. Care Management

Another key policy of Japan's LTCI is care management. Care management is a professional service to coordinate different services provided by different providers to accommodate geographically dispersed home settings within a limit of allocated budget.

The U.K. in its Community Care Act 1990 first implemented care management. This was part of the welfare reform promoted by Thatcher administration. Care management was expected to be important for Japan's LTCI system because the benefit includes not only non-medical services such as home help but also medical services such as visiting nursing services. This is a sharp difference from German LTCI, which provides purely non-medical services and therefore lacks official care management system.

To cater to the need for need assessment and care management, a considerable number of skilled experts were needed. A new professional called "care manager" was created and the first qualification exam was started in September 1998. Qualification will be given professionals who already possess health or welfare related licenses and have at least five years of clinical experience.



8. Experience in five years and Reform in 2006

As more and more beneficiaries become familiar with the new system, the number of beneficiaries who applied for need assessment and qualifies for the benefit also increased gradually. As of October 2006, approximately 4.4 million beneficiaries were assessed as

eligible for the benefit. This figure is approximately 17% of the total beneficiaries I (26 million). Trend and distribution of level of care need for last five years is shown in the graph below. The number of eligible beneficiaries increased at a faster rate than the increase of the elderly population. This does not mean that an increasing number of Japanese elderly are in need of care. The graph shows that the growth is more evident in lower level of care need. The share of borderline and level1 was 40% of the total eligible beneficiaries but almost 50% now, suggesting the so-called “wood work” effects: more people were prompted to apply for need assessment as they gain more knowledge of the system. Not all eligible beneficiaries actually utilize services. Approximately 76% of those eligible actually utilize services. Not surprisingly, beneficiaries in lower level of care need are less likely to actually use services as shown in the graph.

As the LTCI became more familiar in daily life and people became more willing to utilize the services, cases of fraud and abuse also increased. The much feared unfavorable effects of care managers serving as a sales representatives became increasingly evident. Care managers approach beneficiaries who have not been much interested in the LTCI and made their applications on behalf with a hope that an additional eligible beneficiary will bring in additional clients. Under improper care management, the level of care need of recipients is more likely to deteriorate than improve.

In view of these unfavorable consequences, the reform 2006 emphasized “preventive care” rather than just catering to the need of beneficiaries. Following is the major points of revision.

(1)Change of application process

To be eligible for benefit, beneficiaries must apply to municipal governments for need assessment. Originally the LTCI act authorized service providers to apply for the beneficiaries. Such was the main cause of the “wood work” effects. After April 2006, such authority will be severely restricted for service providers.

(2)Change of need assessment process

On-site survey for need assessment is primarily the responsibility of municipal governments. However, it has been common for municipal governments to contract service providers to send their care managers to the applicants’ home. After the revision, such relegation will be prohibited for initial assessment and discouraged for renewal assessment. Further, NARC will be authorized to change the level of care need to the newly created category “borderline2” for the beneficiaries assessed as level1 after evaluating the prospect of recovery or improvement.

(3)Community support center and preventive care management

Unlike British care management system where care managers are neutral agents employed by municipal governments, majority of Japan’s care managers are employees of service providers, and hence will inevitably serve as sales representatives of the providers. Japan’s reform 2006 was an atavism to the British model. For beneficiaries assessed as borderline (1 and 2), care management will be provided by newly created Community

Support Center (CSC) under direct contract with municipal governments. Such “preventive care management” intends to prevent the elderly at risk of disability from deteriorating further by improvement of nutrition and enhancement of exercise.

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