

Public Health
of
Japan
2023

Japan Public Health Association

Preface

Dr. Etsuji Okamoto of the National Institute of Public Health personally drafted this document as an English-language publication to concisely explain Japanese public health in an exhibit booth at the Annual Meeting of the American Public Health Association held in 2001. It is updated annually and published under the title *Public Health of Japan*, this being the 13th edition. This document seems to be the sole English-language pamphlet that describes current public health in Japan, and because of its excellent contents, the Japan Public Health Association has decided to print and issue it.

The contents of this document are as follows: Chapter 1, on demography, including 1. population pyramid, 2. birth rate, etc.; Chapter 2, on health status, including 1. health status and utilization of health services, 2. health promotion campaigns, 3. health promotion act and national health & nutrition survey, etc.; Chapter 3, on disease-specific measures, including 1. cardiovascular diseases, 2. cancer, 3. metabolic syndrome, etc.; Chapter 4, on specialty-specific measures, including 1. maternal and child health, 2. reproductive health and policy, 3. mental health, etc.; Chapter 5, on medical care, including 1. general view of Japan's health policy and planning, 2. health planning, etc.; Chapter 6, on health economics, including 1. health insurance, 2. health care system for the old-old, etc.; Chapter 7, on pharmaceutical affairs, including 1. pharmacies and separation of prescription dispensing, 2. pharmaceutical reimbursement and price setting, 3. clinical trials, etc.; Chapter 8, on environmental health, including 1. air pollution, 2. water pollution, etc.; Chapter 9, on industrial health, including 1. historical background, 2. administrative structure of occupational safety and health, etc.; Chapter 10, on social security and welfare, including 1. social security and financing, 2. welfare for the indigent, 3. maternal and child welfare, etc.; Chapter 11, on long-term care, including 1. administrative structure, 2. beneficiaries, 3. financing, etc.

The document also touches on the fields of social insurance and welfare, and its structure now incorporates new public health thinking, the new trend in public health in which there is collaboration between public health, healthcare, and welfare, that has often been described in recent years.

It is hoped that this document will be widely used both within Japan and abroad.

Dr. Yukio Matsutani, M.D., M.S.H.
President, Japan Public Health Association

Dr. Etsuji Okamoto curriculum vitae

1957 Born in Osaka
1983 graduated from Kinki University Medical School (MD)
1985 graduated from Osaka University Law School (L.L.B)
1986 completed internship at US Naval Hospital at Yokosuka, Japan
1988 graduated from UCLA School of Public Health (MPH)
1988-91 Postdoctoral fellow, Osaka University Medical School, Department of Public Health
1992-2001 Assistant professor, Kinki University Medical School, Department of Public Health
2001-2002 Division Head of Health Service Research, Department of Technology Assessment, National Institute of Public Health (NIPH)
2003-2011 Division Head of Health Service Management, Department of Management Sciences, NIPH
2011-2016 Senior Researcher, Department of Health & Welfare Service Research, NIPH
2016-present Professor, The University of Fukuchiyama.

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Overview

1. History of Japan's Public Health

(1) Pre-war Era:

Japan underwent a profound transformation with the abolition of feudal rule by the Tokugawa clan (Shogunate) and the restoration of imperialism ruled by the emperor in 1868, now recognized as the "Meiji Restoration." Following this, Japan embarked on a challenging journey to modernize its governmental structure to align with Western countries. In 1873, the Health Affairs Bureau was established as part of the Ministry of Education, later transitioning to the Ministry of Internal Affairs. The bureau enacted the Medical Affairs Act (isei) in 1874, which governed the medical care system, excluding medical education.

(2) Greater Japan Private Practitioners' Public Health Association (GJPPPHA):

However, effective public health administration required collaboration with private practitioners. Around 1881, a growing demand emerged to establish an organization representing private practitioners, leading to the formation of the "Greater Japan Private Practitioners' Public Health Association (GJPPPHA)" on May 27, 1883, in Tokyo. The association's charter articulated a two-fold mission: to study methodologies enhancing people's health and to cooperate with governmental efforts for public health. Many leaders of the association concurrently held positions in the health affairs bureau, with core members appointed from various specialties, including public health, personal hygiene, school health, prison health, military medicine, mental health, medicine, pharmacy, chemistry, child health, epidemiology, statistics, law, economics, civil engineering, industrial health, meteorology, and veterinary medicine.

The association's journals served as a valuable information source for health professionals. Initially titled "The Journal of GJPPPHA," it began in May 1873 and continued until the 40th volume in 1922. It was then renamed "Public Health" in 1923, with a shift to a monthly publication to better educate the general public. The membership grew from an initial 2,260 to 222,248 in 1911.

●Smallpox Vaccine Production:

In 1888, the GJPPPHA took on the government-assigned responsibility of producing smallpox vaccines, as it was the only infectious disease for which a vaccine was available at the time. The government initially established a production factory for smallpox vaccines as a monopoly but had to discontinue it due to budget deficits. Subsequently, the GJPPPHA assumed the responsibility for commercially sustainable production and supply of the vaccine, generating profits from its sale.

●Research Institute of Infectious Diseases:

One of the association's significant achievements was the establishment of a research institute specializing in infectious diseases. Driven by the renown of Dr. Shibasaburo Kitasato and supported by luminaries in Japan's public health, including Dr. Tai Hasegawa, Dr. Sensai Nagayo, Dr. Shinpei Goto, and Yukichi Fukuzawa, the GJPPPHA institute opened in November 1892. However, it was later transferred to the government as a national institute under the Ministry of Internal Affairs in April 1899.

- Training program for public health staff

The GJPPPHA also established a training program in 1895 to provide public health professional training to public health staff of local governments (except medical doctors). The training program was provided twice a year in Tokyo. Memorial Library of Sensai Nagayo Dr. Sensai Nagayo is well-known as the first bureau chief of health affairs of Meiji government. The GJPPPHA administered the Memorial Library of Sensai Nagayo since 1901. The library holding was approximately 3000 in 1912 but unfortunately was lost due to the Great Tokyo earthquake in 1923. The GJPPPHA also lost its head office, which was constructed in 1911, in the devastation of the earthquake.

(3) Incorporation to Japan Health Association (JHA)

The GJPPPHA was incorporated as a foundation on 26th December 1931 and was renamed "Japan Health Association (JHA)". The membership as of November 1933 was: honorable members 3, lifetime members 414, regular members 1820. The publication of the journal "Public Health" had to be discontinued after December 1943 because of the war. The head office of JHA survived the war but its activities were not resumed until 1950. Around that time, the Ministry of Health officer in charge of public health centers became also responsible for JHA.

(4) Association of Public Health Officers (APHO)

Apart from GHPPPHA, the Association of Public Health Officers (APHO) was organized on 11th June 1925. The membership included public health officers of prefectural governments and its mission was to enhance solidarity and professional skills of members (public health departments at that time were part of the local police departments). APHO published its professional journal which continued until the 21st volume in 1946. It had the membership of 1300 in 1936 and its activities were strengthened particularly after the Ministry of Health & Welfare was established in 1938.

2. Japan Public Health Association (JPHA)

(1) The reform of Japan's education system and public health

Japan's education system was radically reformed under the occupation by GHQ (the General Head Quarter). Japan's medical education was a two-tier system in the pre-war period: doctors were educated either at universities or vocational

schools. However, under the guidance of GHQ, the medical education was unified into universities of six-year education. Vocational schools of medicine were required to convert into universities starting in 1948 and the conversion was completed in 1952. The new curriculum of universities were started in 1949 and the new medical education emphasized public health. Most Japanese medical schools had a department of hygiene but an additional department of public health was added to emphasize public health in both professional training as well as medical research. Also, the National Institute of Public Health (NIPH) started to provide post-graduate public health training to health professionals starting in 1949. The new post-graduate public health training was a one-year course for medical doctors and later another one-year course was added for public health nurses. Also additional six-month post-graduate training for pharmacists and veterinary doctors were soon to be started.

(2) Distinction between hygiene and public health

Dr. Sensai Nagayo who took office as the first bureau chief of health of the then Ministry of Internal Affairs in 1875 used the term “*Eisei* (protecting life)” as a translation of “hygiene”. He also used the term “*Koshu-Eisei* (protecting people’s life)” which literally means “public health”, but it was not until the influx of American-style public health in the post-war era when the term “Koshu-Eisei” became widely used among health professionals.

As for academic societies, the Japan Joint Society of Hygiene was established after separating from other related fields of microbiology and parasitology in 1929 and was renamed to Japan Society of Hygiene in 1949. The inaugural issue of Japanese Journal of Hygiene was published in August 1946 and was continued till now after the name change of the society in 1949. Dr. Takeo Tamiya (former president of JPHA) described the distinction between hygiene and public health as follows:” Additional department of public health might face ambiguity to differentiate itself from the existing department of hygiene. Judging from the curriculum there seems to be much overlap between the two departments but drawing a clear distinction between them would be a great challenge. Still, there is enough reason to have two departments sharing their roles. Public health developed as opposed to “personal health”, but public health has increasingly shifted toward personal health to be successful. All public health fields including school health, maternal and child health, nutrition, tuberculosis, sexually transmitted disease, occupational diseases are closely related to personal health. Clinical medicine has historically been oriented toward diagnosis and treatment of diseases. However, they need to consider social and environmental factors in medical education to better prepare students for effective cooperation with public health activities. New departments of public health are expected to emphasize clinical medicine, personal health, statistics social science and administration

with theoretical and experimental foundation which is a traditional academic field practiced by the existing departments of hygiene. Distinction and relationship between public health and hygiene would be no less different from those among clinical and basic departments of medical education”.

(3) Establishment of Japanese Society of Public Health (JSPH)

Although, the entire Japan including its 70-year achievement in the field of public health was devastated by the defeat of the war, the recovery and reform of Japan’s public health owes much to the assistance and guidance of GHQ, particularly colonel Crawford F. Sams, head of the public health division of GHQ. On the 22nd August 1945, only one month after the end of the war, GHQ issued a mandate (Supreme Command for Allied Powers Instruction Note, SCAPIN 48) mandating Japanese government to act immediately on the following public health measures.

- 1) survey the prevalence of diseases, current status on doctors and other public health professionals, hospitals and other health facilities as well as medical materials, appropriateness of public health legislations,

- 2) weekly reports on surveillance of infectious diseases and take any measures as necessary,

- 3) recovery of water supply, sewage, waste disposal sites, resumption of medical care facilities, supply of medical materials, quarantine at ports, production of vaccines and blood products, prevention of sexually transmitted diseases and development of health statistics.

The SCAPIN48 served as a starting point from which Japan’s public health of the post-war period evolved. Soon after, GHQ issued another mandate (SCAPIN945) on the restructuring of public health administration on 11th May 1946 instructing Japanese government to establish bureaus in charge of public health, medical care, preventive medicine and social welfare as well as health and welfare departments in local governments. In response, the Ministry of Health & Welfare restructured its organization by establishing the Bureau of Public Health (three departments of statistics, preventive medicine and nutrition), the Bureau of Medical Care (five departments of medical affairs, pharmaceutical affairs, pharmaceutical production, hospital administration, long-term care) and the Bureau of Preventive Medicine (three departments of prevention, disease control and quarantine).



GHQ further mandated the strengthening of public health centers (PHCs) on 7th April 1947 and a radical structuring of PHCs followed. PHCs had existed since the pre-war period but their functions were not much different from general clinics. The newly restructured PHCs were held responsible for administering all health-related laws in their jurisdictions. Health-related laws covered vastly wide areas such as public health nurses, maternal and child health, health statistics, laboratory, dental hygiene, nutrition, food sanitation, health education, quarantine, sexually transmitted disease, tuberculosis.

Dr. Minoru Katsumata, then chief of the Bureau of Public Health recalled that Captain Sams had believed in the science-based health policy and insisted on having medical doctors in charge of the newly created three bureaus (Crawford F. Sams. *Medic*).

After seven years of occupation, Japan regained its independence on 28th April 1952 pursuant to the San Francisco Peace Treaty. During the seven years of occupation under GHQ, a series of health-related laws were enacted including the TB Prevention Law, Mental Health Law. Also, Japan gained a membership to WHO in May 1951.

(4) Unification of three organizations

After recovery of the main office building of JHA located in Chiyoda-ku, Tokyo in around 1950, unification of three organizations (JHA, APHO and JSPH) was proposed. The unification was achieved by merging JSPH and APHO into JHA which was already incorporated and JHA as a corporation changed its name to Japan Public Health Association (JPHA) on 30th January 1951.

Another challenge was how to unify professional journals published by individual organizations. JHA had its own official journal titled “Public Health” but its publication was temporarily discontinued due to war. On the other hand, a private publisher which would later become *Igaku-Shoin* started publishing a bi-monthly journal titled “Journal of Public Health” since October 1946 under the auspices of JSPH (cf. column). After deliberation, JHA authorized Igaku-Shoin to succeed the “Public Health” and the publisher changed the title from “Journal of Public Health” to a simpler “Public Health” beginning from its 8th volume in July 1950. The renamed journal “Public Health” became an official journal of JPHA starting from its 4th issue of the 8th volume in November 1950.

[column] History of Japan’s public health related professional journals

● Greater Japan Private Practitioners’ Public Health Association (GJPPPHA)

Monthly journal “Journal of Greater Japan Private Practitioners’ Public Health Association”: The 1st issue of the 1st volume [May 1883]→the 12th issue of the 40th volume [December 1922] (total: 460 issues). The journal was renamed “Public Health” on the 1st issue of the 41st volume and was continued to the 61st volume in December 1943.

● Association of Public Health Officers (APHO)

Monthly journal “Journal of the Association of Public Health Officers”: The 1st issue of the

1st volume [September 1925]→the 2nd issue of the 18th volume [December 1942]. Publication cycles were reduced to two issues in the 19th volume (1943), seven issues in the 20th volume (1944), none in 1945 and two issues in the 21st volume (1946). The publication was discontinued since then.

● Japanese Society of Public Health (JSPH)

Monthly journal “Journal of Public Health”: The 1st issue of the 1st volume [October 1946, one volume per half year] published by Igaku-Shoin. Renamed “Public Health” from the 1st issue of the 8th volume in July 1950→became the official journal of JPHA from the 4th issue of the 8th volume in November 1950.

(5) Publications of JPHA

● Infectious Disease Report:

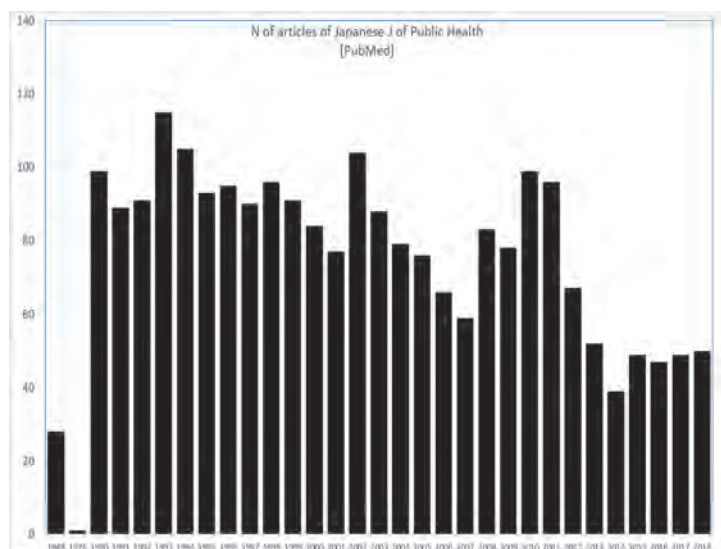
The inception of the "Infectious Disease Report" by JPHA dates back to June 10, 1953. Editorial contributions were undertaken by the infectious disease division of MHW, while JPHA handled the publication responsibilities. As the prevalence of infectious diseases waned in the country, the report underwent a transformation in April 1971, adopting the name "Public Health Information (Koshu Eisei Joho)." This nomenclature persists to the present day. Over the years, editorial duties were outsourced to various entities, including Shin-Kikaku publisher in 1990, Life publisher in 2006, and presently, to Social Insurance publisher.

● Japanese Journal of Public Health (JJPH) Journal:

The inaugural issue of the Japanese Journal of Public Health (JJPH, Nihon Koshu Eisei Zasshi) was introduced in March 1954, marking the commencement of its ongoing publication. JJPH, primarily a peer-reviewed academic journal in Japanese, experienced a notable shift in its 51st volume in 2004. During this milestone, an inaugural issue exclusively featuring articles in English was published, with a plan to release one English-exclusive issue each November. Indexed in PubMed, JJPH boasts a collection of 2,335 articles, accessible in full text through JSTAGE (www.jstage.jst.go.jp).

● Public Health of Japan (PHJ):

JPHA, affiliated with the World Federation of Public Health Associations (WFPHA), annually publishes a report providing a comprehensive overview of Japan's public health. The inaugural release occurred in 2001, coinciding with JPHA's participation in the 129th annual meeting of the American Public Health Association (APHA) in Atlanta, GA. Despite the unfortunate cancellation of JPHA's exhibition at the APHA annual meeting due to the 9/11



incident, the organization maintained a presence at subsequent meetings from the 130th (Philadelphia, PA) to the 139th (Washington DC). Notably, the 139th annual meeting saw JPHA hosting a special session on the "East-Japan Earthquake and the atomic disaster in Fukushima." Although participation in APHA annual meetings ceased afterward, JPHA continues to publish PHJ as a valuable reference for Japan's public health.

(6) Professional qualification of public health professionals

- Public Health Specialists

Since November 2009, JSPH established an accreditation system for certifying "Public Health Specialists" among its members. As of December 2018, a total of 934 JSPH members have received accreditation.

- Board Certified Physician for Public Health and Social Medicine

In December 2016, 14 professional organizations associated with public health and social medicine jointly established the professional organization "Japan Board of Public Health and Social Medicine (JBPHSM)" with the primary objective of certifying physicians with expertise in public health and social medicine.

organizations constituting JBPHSM

The Japanese Society for Hygiene (*)
Japan Society for Occupational Health (*)
Japanese Society of Public Health (*)
Japan Epidemiological Association (*)
Japan Society for Healthcare Administration (*)
Japan Association for Medical Informatics (*)
Japan Association for Disaster Medicine (*)
Japanese Society for Occupational Medicine and Traumatology (*)
Japanese Association of Public Health Center Directors
Association of Heads of Prefectural Departments of Health
Japan Association of Prefectural and Municipal Public Health Institutes
The Japanese Association of Directors of Departments of Hygiene & Public Health at Medical Schools
Japan Medical Association
The Japanese Medical Science Federation
*8 core associations (a doctor must be a member to be certified)
observer) Ministry of Health, Labor & Welfare, National Institute of Public Health

3. Current administrative structure of Japan's public health

Public health activities primarily fall under the jurisdiction of local governments, overseen by the Ministry of Health, Labor, and Welfare (MHLW), formed as a result of the merger between the Ministry of Health and the Ministry of Labor in 2001. Public health centers (PHCs) serve as the front line for these activities, and as of April 2023, there were 468 PHCs in operation across the country. This number is a significant decrease from the 848 PHCs that existed in March 1994, a reduction attributed to the enactment of the Regional Health Act, which transferred much of the personal services provided by PHCs to Municipal Health Centers (MHCs).

In contrast, the number of MHCs has increased to 2,419 as of April 2023. The distinction between PHCs and MHCs can be perplexing and may necessitate further

explanation. Although both are integral parts of local governmental bodies, PHCs are vested with law enforcement powers, whereas MHCs are not. Illustratively, in the event of a widespread foodborne illness, it is the responsibility of the PHCs to investigate the cause and take necessary actions against the responsible establishments. Furthermore, all healthcare facilities such as hospitals, clinics, and pharmacies are subject to periodic audits conducted by PHCs.

The confusion between the two entities arises from their shared responsibility in providing personal services. PHCs and MHCs manage their responsibilities by assigning more specialized and focused clients to PHCs and more general clients to MHCs. For instance, all doctors diagnosing tuberculosis are obliged to report to PHCs, which maintain the patients' records and keep TB patients under surveillance, overseen by public health nurses (PHNs) at the PHCs. On the other hand, MHCs offer broader community-oriented services, such as well-baby clinics, immunization, and mass health screenings.

	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 (352), major cities (93) Tokyo wards (23) totaling 468	cities, towns, villages (2,419)
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.*

4. Training and research of public health

To ensure that professional staff at Public Health Centers (PHCs) and Municipal Health Centers (MHCs) receive ongoing training, the Ministry of Health, Labor, and Welfare (MHLW) oversees the National Institute of Public Health (NIPH). In April 2002, NIPH expanded significantly after merging with the National Institute of Hospital Management and relocated to a new campus in Wako city, a suburb of Tokyo, signifying a new era captured by its new symbol and building photo. This revitalized NIPH offers a wide array of professional training and research programs, not only in public health but also in hospital management and social

welfare.

Moreover, NIPH collaborates with the Japan International Cooperation Agency (JICA) and the Western Pacific Regional Office of the World Health Organization (WHO WPRO) to provide training to international professionals, further enhancing its global impact and engagement. Other research institutes under MHLW include: Institute of Population and Social Security (IPSS, www.ipss.go.jp), National Institute of Infectious Diseases (NIID, www.niid.go.jp), National Institute of Health Sciences (NIHS, www.nihs.go.jp).



5. International Cooperation and Contribution

Japan plays a significant role in advancing global public health. Its contribution to the World Health Organization (WHO) in 2022 amounted to 9% (\$41 million, the 3rd largest). Aside from these designated contributions, Japan voluntarily allocates 76 million dollars to aid tropical disease prevention, primary healthcare, children's vaccination programs, emergency medical assistance, and research related to chemical exposure and its impact on health.

Due to the limitations placed on military activities by its peaceful constitution, Japan holds potential for greater involvement in terms of personnel within the public health field, as the current 43 Japanese staff members (as of May 2022) fall below the ideal number, which is estimated to be between 94 and 128, commensurate with the country's financial contribution. The introduction of the new international health course at NIPH is anticipated to bolster Japan's role in global cooperation, thus serving the common purpose.

In addition to its contributions to WHO, Japan fosters bilateral and multilateral cooperation through agencies such as the Japan International Cooperation Agency (JICA) and various non-governmental organizations (NGOs). The country provides economic assistance through multiple channels, including Overseas Development Assistance (ODA), Other Official Flows (OOF), and Private Flows (PF). In the fiscal year 2021, Japan's budget for ODA amounted to 17.6 billion

USD, encompassing both grants and loans. Much of the ODA related to public health is donated in the form of grants, supporting endeavors such as the construction of hospitals and the provision of medical equipment.

In terms of technological assistance, Japan engages in initiatives such as inviting technicians to Japan for training and dispatching Japanese experts to provide support in recipient countries.

6. Global Health Diplomacy and Universal Health Coverage

During the 5th Tokyo International Conference on African Development (TICAD) in June 2013, "Japan's Strategy on Global Health Diplomacy" was unveiled in Yokohama. This strategy underscored the call for universal health coverage (UHC) and embodied Japan's resolute commitment to achieving this objective. In a significant milestone, Prime Minister Abe authored an article, "Japan's Strategy for Global Health Diplomacy: Why It Matters", which was featured in *Lancet* in September 2013—an unprecedented instance of a Japanese Prime Minister contributing to an international medical journal.

Subsequently, UHC emerged as a pivotal agenda in the post-2015 Millennium Development Goals (MDGs), leading to the establishment of an international health collaboration division within the Ministry of Foreign Affairs in September 2013 to enforce this critical initiative. WHO resolution adopted in 2005 defines UHC as "*providing essential health services to everyone at affordable costs*". Achieving UHC necessitates not only ensuring physical access through the provision of healthcare personnel and facilities but also securing financial access to prevent individuals from forgoing care due to economic constraints and avert impoverishment from catastrophic medical expenditures.

To address financial access, a mandatory health insurance system akin to Japan's longstanding model, maintained for over half a century, is envisioned to serve as a proven framework.

Japan's Strategy on Global Health Diplomacy

June 2013, Government of Japan

<http://www.mofa.go.jp/mofaj/files/000005946.pdf>

1. Vision

Japan prioritizes global health in its foreign policy. By fully mobilizing its knowledge and expertise, Japan contributes to realizing a world where every person can receive basic healthcare service.

Japan promotes universal health coverage, while accelerating its efforts towards the achievement of the Millennium Development Goals (MDGs). Japan contributes to the solution of global health challenges and better health in the world through global collaboration and effective bilateral assistance as well as by utilizing its technology.

2. Background

Japan is in a unique position to make contributions in global health.

(1) Japan has achieved a society where people enjoy good health and longevity of life. Japan has maintained universal health care for more than 50 years. Japan has comparative advantage in the treatment and prevention of non-communicable diseases (NCDs).

(2) Japan paved the way toward the establishment of the Global Fund; introduced health

as G8 agenda; and has been contributing to the achievement of the MDGs, including its announcement of the Global Health Policy 2011-2015.

(3) Health is indispensable to achieve human security.

3. Global Context

(1) Health-related MDGs are lagging behind, particularly in Sub-Saharan Africa. We need to continue our efforts on maternal and newborn health, nutrition, infectious diseases and health system strengthening.

(2) There are emerging global health challenges such as non-communicable diseases (NCDs) and ageing which are not covered by the MDGs.

(3) As the year 2015 approaches, we need to establish an effective post-2015 development agenda.



Call for Universal Health Coverage

4. Actions

(1) Mainstream Universal Health Coverage (UHC)

- Lead the efforts to include the concept of UHC in the post-2015 development agenda.
- Position UHC as an exemplary effort to realize human security
- Effectively advance UHC through close coordination with relevant international organizations and other partners
- Capitalize on high-level events such as TICAD V and ASEAN-Japan Commemorative Summit Meeting (December 2013)

□ Share Japan's expertise with the international society on achieving UHC

(2) Effectively Implement Bilateral Assistance towards the realization of UHC

- Strengthen coordination among loan, grant and technical assistance
- Strengthen strategic assistance based on national program
- Strengthen assistance by improving the Japanese ODA Loan scheme (Newly applying preferential terms and conditions to Health and Medical Care and Services)
- Contribute by utilizing technologies of Japan

(3) Collaborate with Global Partners (Strategic Partnership)

- Promote global public private partnerships, e.g.,
 - Polio eradication in cooperation with the Gates Foundation
 - Establishment of GHIT-Fund to develop new health technologies
- Further strengthen strategic coordination between bilateral and multilateral assistance, working with the World Health Organization (WHO), the World Bank, the Global Fund and other organizations.

□ Collaborate with regional and global initiatives as well as other donors

(4) Strengthen Human Resources for Global Health

- Improve skills of global health specialists of Japan to develop and implement health-related policies, programs and projects
- Collaborate with special agencies and their specialists of Japan (such as medical institutions, universities, local governments, and industries)
- Contribute to international organizations in terms of human resources

Japan hosted the G-7 Summit meeting in Ise-Shima in May 2016, which issued the “G7 Ise-Shima Vision for Global Health” [<http://www.mofa.go.jp/files/000160273.pdf>].

Japan reconfirmed its continued commitment at the UHC Forum held in Tokyo in December 2017. As part of technical assistance to enhance UHC, JICA and NIPH collaborate to provide two-week intensive UHC training course inviting technical officers from countries pursuing UHC since 2013.

WHO has a research center in Kobe, the WHO KOBE Center (WKC), which was established in 1996. Starting in 2016, the center has set the promotion of UHC as its main research theme.

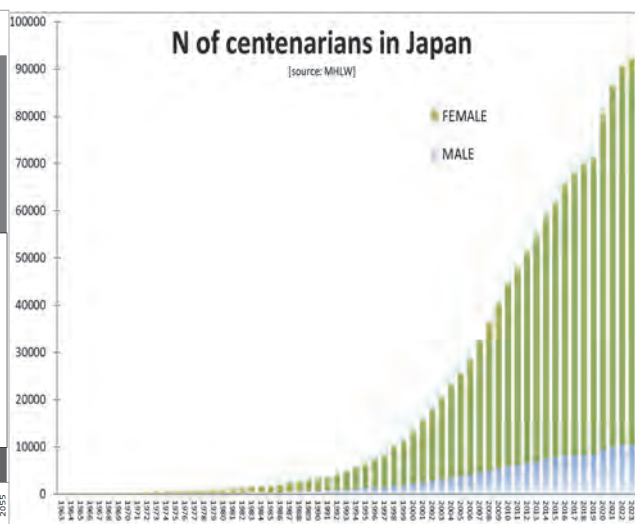
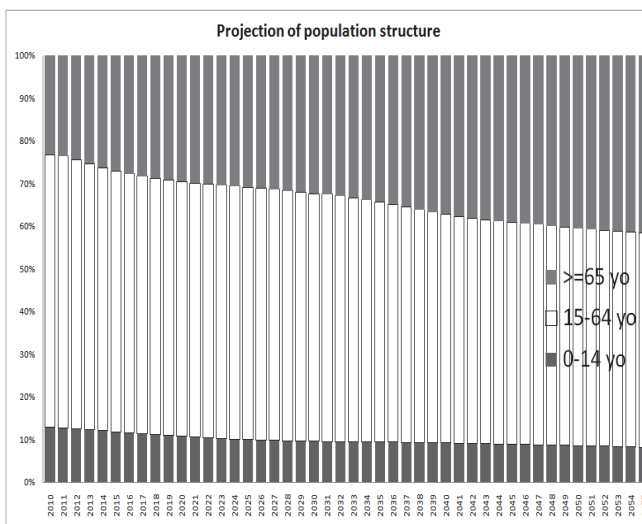
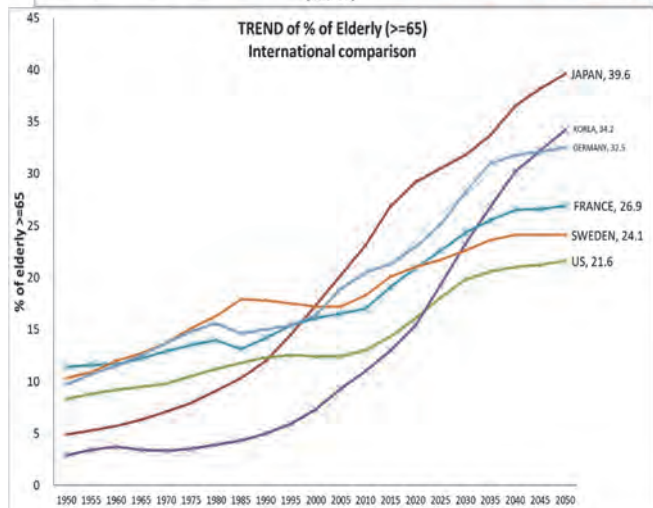
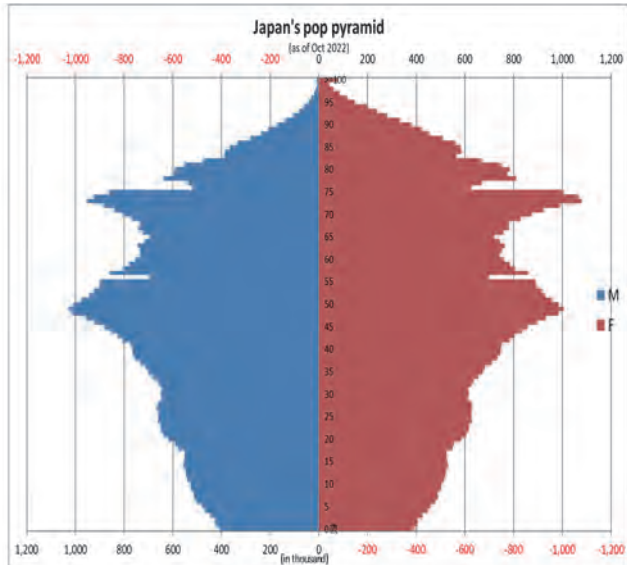
Chapter 1. Demography

1. Population pyramid

As of October 1, 2022, Japan's population is estimated to be around 125 million, including foreigners, accounting for approximately 1.8% of the global population of 7 billion. In 2020, Japan ranked as the 11th most populous country, yet is anticipated to drop out of the top 10 due to a stagnant population growth. Approximately 2.3% (2.9 million) of the total population are foreign residents, while 1.3 million Japanese citizens reside abroad.

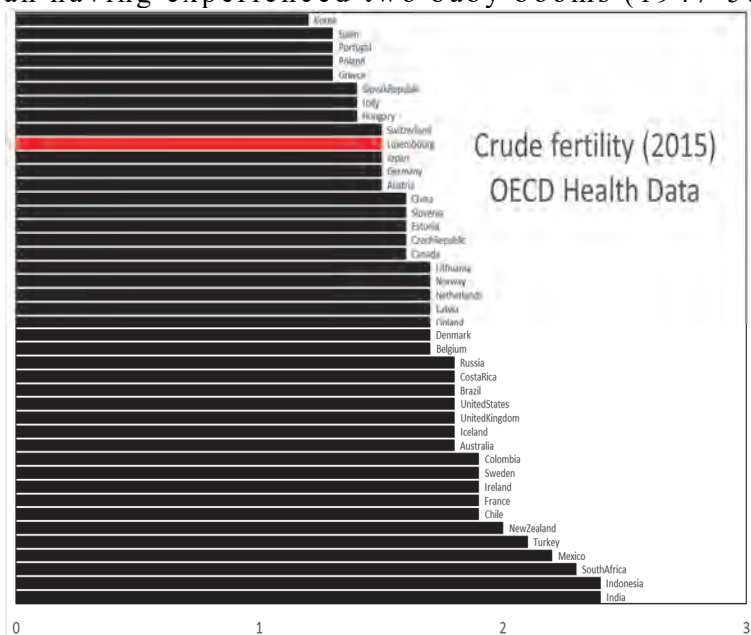
Notably, 2005 marked a significant milestone in Japan's demographic history, as it witnessed the first natural decrease in population. With the number of deaths (1,083,796) surpassing the number of births (1,062,530) by 21,266, it indicated a turning point in population dynamics. Contrary to initial projections, Japan

hit its population peak in 2006, and subsequent forecasts suggest a decline. By 2100, the population is expected to shrink to 64 million, roughly half of its current level (compared to the 1930 population count).



The population pyramid no longer resembles its iconic form due to a sharp decline in the birth rate, with Japan having experienced two baby booms (1947-50 and early 1970s). The aging society in Japan will coincide with the retirement of the first wave of post-war baby boomers, now over 65 years old.

The stagnant population growth can be attributed to the sharp drop in the birth rate, with Japan registering a crude fertility rate reaching a record low of 1.26 in 2005. Japan has one of the lowest crude fertility rates globally, following Italy (1.26) and Korea (1.0).



Although Japan's fertility rate slightly improved to 1.45 in 2015, it remains amongst the lowest in the world, despite efforts to boost birth rate.

Conversely, mortality rates have consistently improved over the years, particularly in infant mortality, with Japan now boasting the world's lowest infant mortality. The enduring advancements in mortality have contributed to an extended average lifespan, with Japan having one of the longest life expectancies in the world: 81.47 years for males and 87.57 years for females (2021 life table). Prolonged life expectancy coupled with a declining birth rate will inevitably result in an aging population structure, with the elderly projected to account for 40% of the population by 2040, marking a peak from the current 29%.

Reflecting its status as the country with the world's longest lifespan, Japan also hosts one of the largest populations of centenarians. According to estimates by the Ministry of Health, Labor, and Welfare, there are 92,139 centenarians in Japan as of September 15, 2023, with 89% being women. In accordance with the Elderly Welfare Act since 1963, individuals reaching 100 years old are celebrated with a silver goblet from the Prime Minister. The number of awardees has risen from 153 in 1963 to 47,107 in 2023. In 2009, due to financial constraints, the government reduced the size of the goblets from 11.5cm to 9cm, and in 2016, the silver goblet was substituted with amalgam.

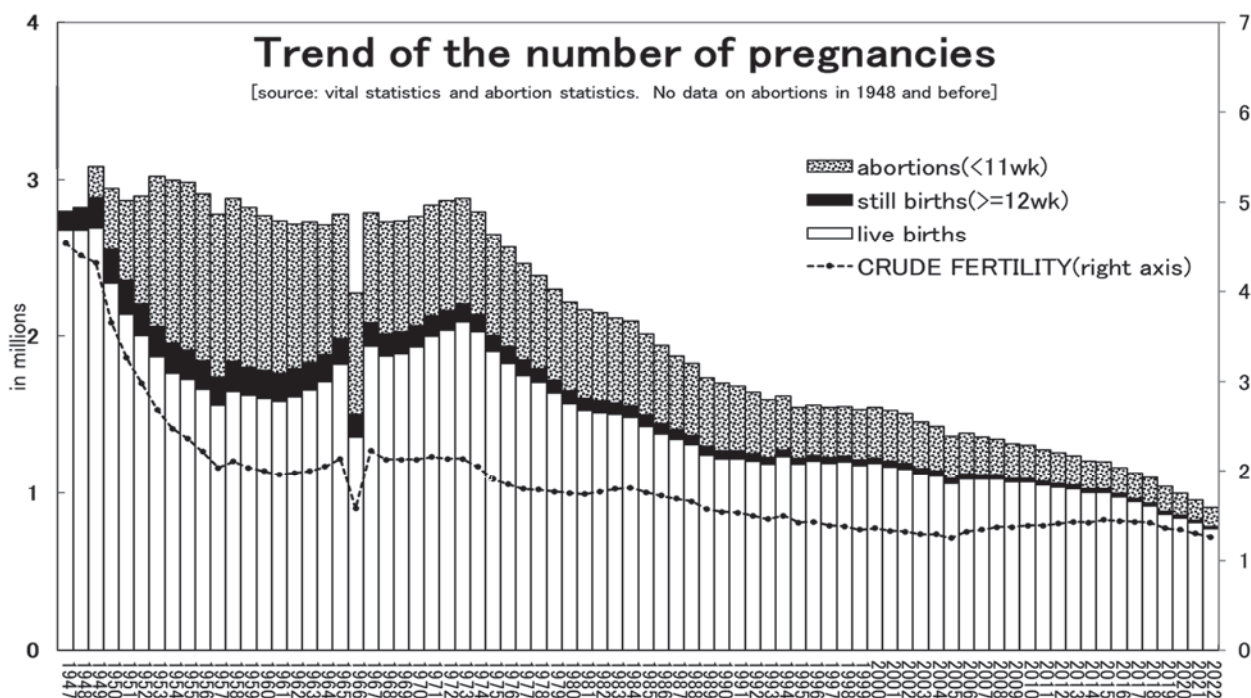
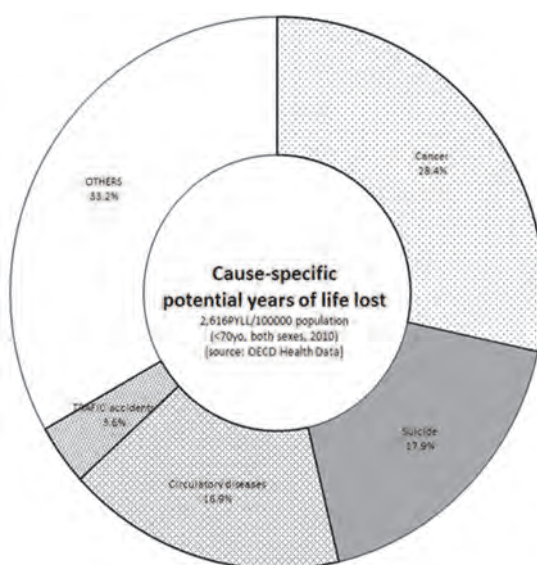
2. Birth Rate

In 2022, the number of live births in Japan was 770,747, equating to 6.3 births per 1000 population, for Japanese nationals only. It's important to note that the total number of live births, inclusive of foreign nationals, was actually 799,728,

with approximately 3.6% of newborns being foreigners.

The aging of Japan's population can be attributed not only to increased life expectancy but also to a significant decline in the birth rate. While Japan once boasted a high fertility rate, the annual live births during the first baby boom from 1947 to 1949 numbered around 2.6 million, leading to a crude fertility rate of 4. However, this rate has steadily declined to 1.26 in 2022, significantly below the replacement level. The trend of declining fertility is prevalent globally, and according to the latest data from the OECD, Japan's fertility rates are indeed low, though not the lowest among countries.

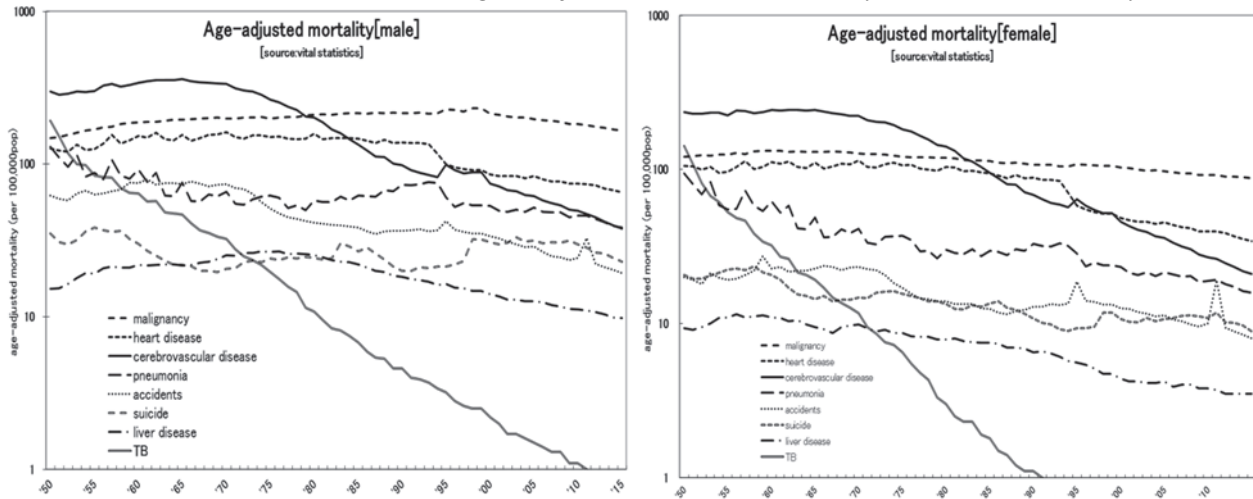
An intriguing aspect of the birth trend is Japan's liberal policy regarding abortions. The number of pregnancies remained stable in the postwar era until 1973. The decline in births during the 1950s and 60s was in most part due to the artificial abortions of pregnancies. In 1947, when Japan was grappling with post-war food shortages, the birth rate was 2.7 million. In response to concerns about rapid population growth, government regulations on abortions were relaxed in 1952, leading to a surge in abortion rates and a decline in live births to a low of 1.57 million in 1957 (excluding Okinawa prefecture). This policy shift created a substantial gap between the two peaks of baby booms.



3. Mortality

Crude mortality rate of Japan in 2022 was 12.9 per thousand. Crude mortality rate has been on a gradual increase since 1982 when the figure was 6.0 reflecting the aging of population.

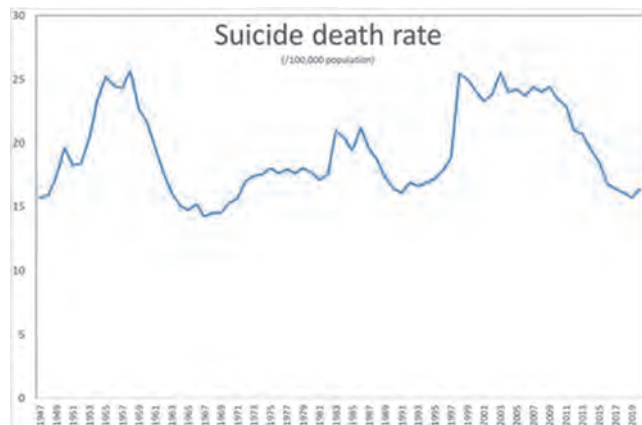
However, when the rate is age-adjusted, the mortality has consistently declined



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.

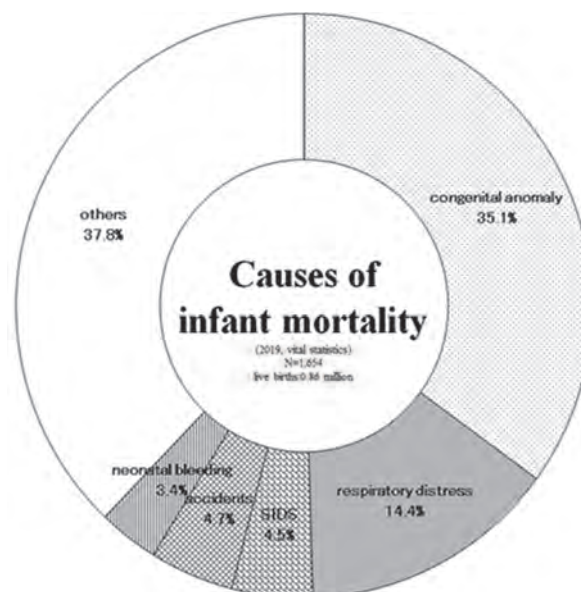
(1)Suicide

While Japan enjoys the world-longest life span, suicide is alarmingly becoming a public health threat. Japan is one of the highest suicide rate countries among industrialized countries. A total of 21,238 people or 17.4 per 100,000 populations end their lives by themselves in 2022. A sharp increase of suicide is a serious public health threat because suicide consumes as much as 17.9% of potential years of life lost (PYLL) in 2010. 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

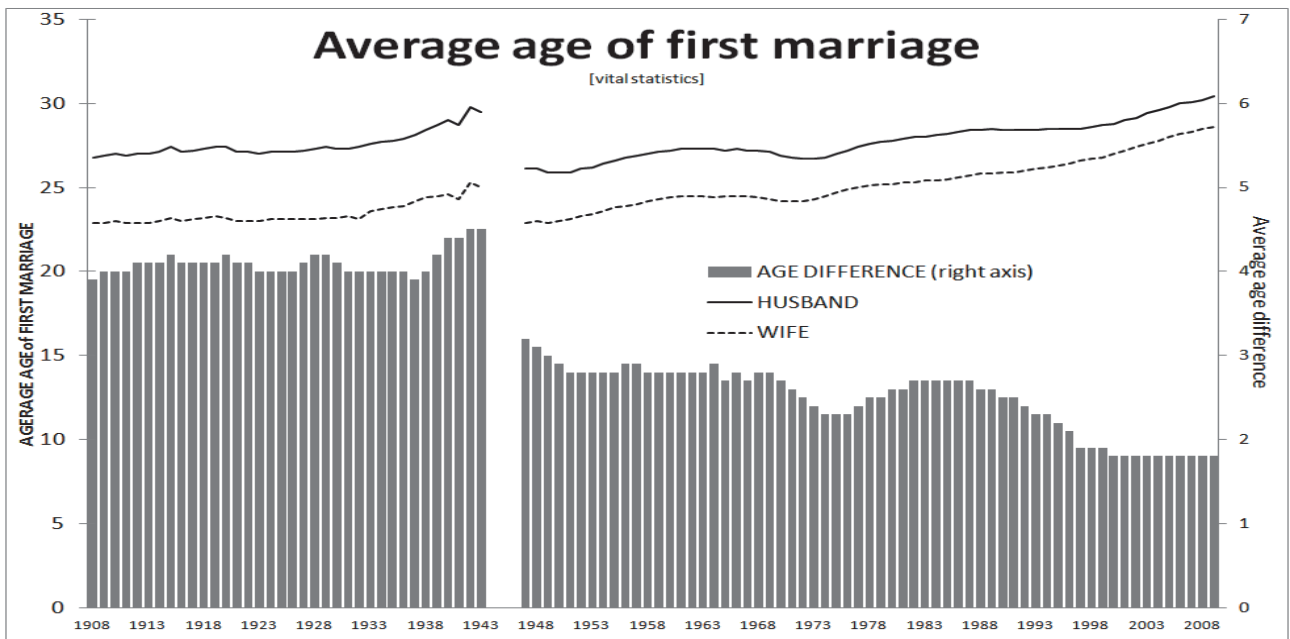
Japan's infant mortality, a sensitive indicator of national health condition, was 1.8 per thousand live births in 2022 (N=1,356), one of the lowest in the world. This great achievement did not come at ease. Until as late as 1960s, Japan's infant mortality was considerably higher than that of the U.S. or U.K. It has been achieved through concerted efforts in effective maternal and child health activities. Congenital anomaly accounts for 35.1% of infant mortality and constitutes by far the largest cause of death.



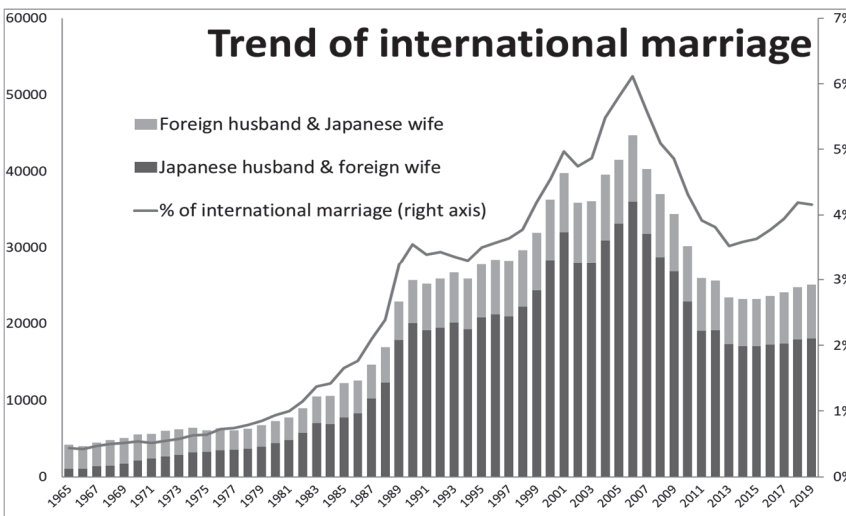
Sudden Infant Death Syndrome (SIDS) accounted for 10.4% of infant deaths in 1995 but the number of SIDS declined sharply to 3.3% in 2018. Whether this decline signifies a true decrease of cases or just an artifact by increased autopsies required by the guideline issued in 2005 remains unanswered.

4. Marriage and divorce

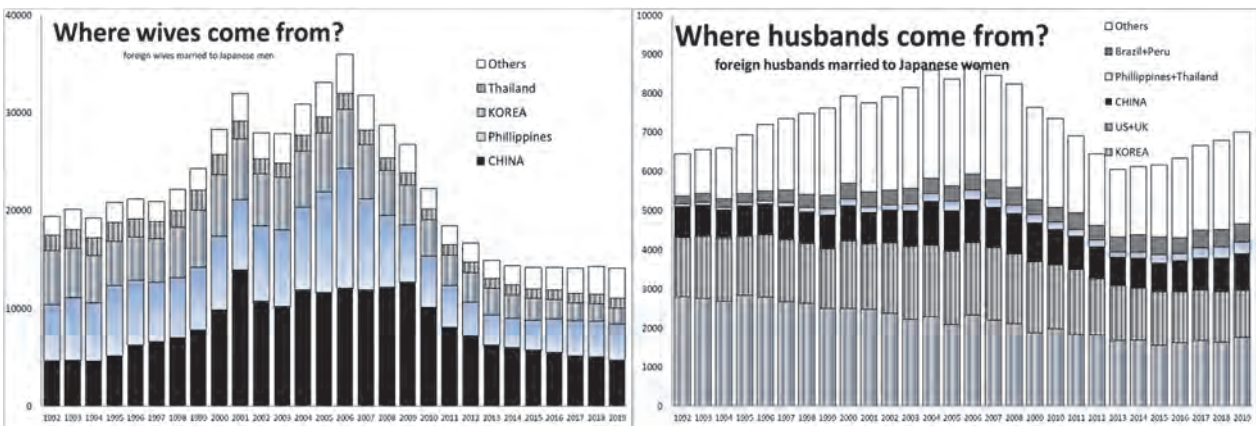
In 2022, the number of marriages in Japan stood at 504,878 couples, equating to 4.1 per thousand of the population. Notably, this figure contrasted sharply with the numbers seen during the early 1970s when post-war baby boomers were actively marrying, with marriage figures surpassing one million at that time. Additionally, the number of divorces in 2022 was reported to be 179,096, amounting to 1.47 per thousand of the population. This figure falls considerably lower than the divorce rates seen in the US (3.6 in 2005) and Russia (4.83 in 2007). A significant shift has occurred in the average age of first marriage over the years. The average age experienced an increase in the pre-war period, witnessed a notable decline in the post-war era, and has since been on the rise, with a slight dip in the 1970s coinciding with the marriage of baby boomers. By 2006, the average age of first marriage for men had reached 30, and now stands at 31.1 for men and 29.7 for women as of 2022. The discrepancy in age at the time of marriage also showcases an intriguing shift: the age difference has generally narrowed, except for the 1970s, and now stabilizes at approximately 1.6 years.



The number of international marriages is increasing and reached 6% of all marriages in 2006. Particularly, couples of Japanese men and foreign wives have increased dramatically. The number of international marriages declined since. The reason is unclear.



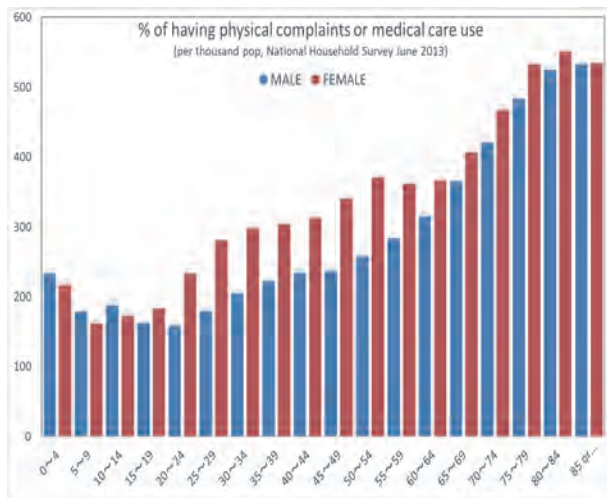
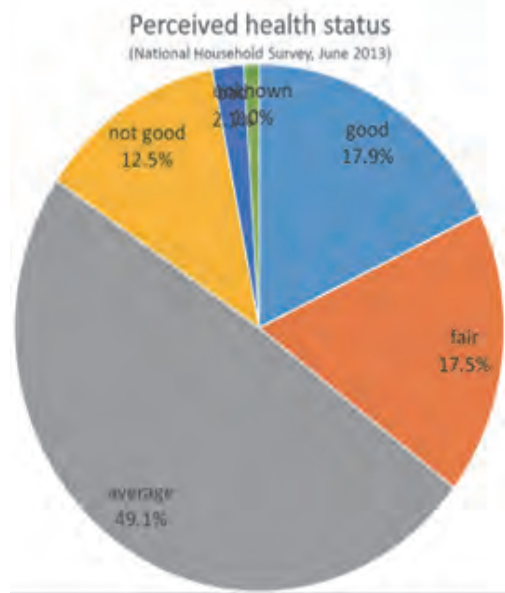
The breakdown of countries of Japanese husbands and wives are as shown below.



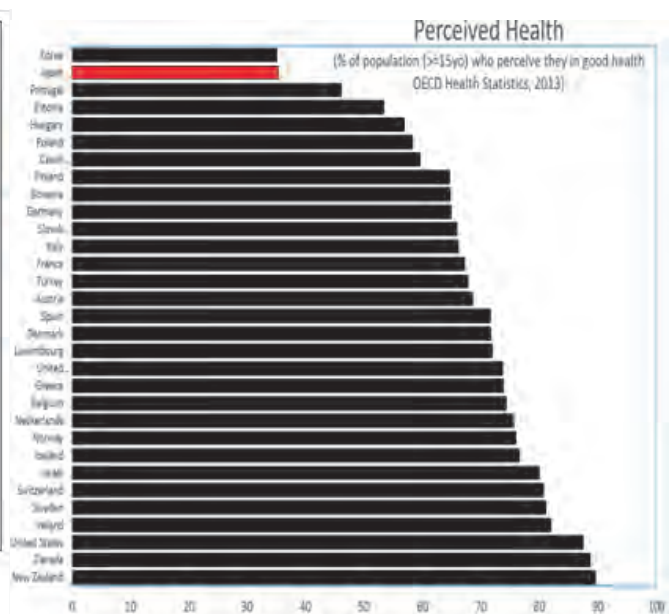
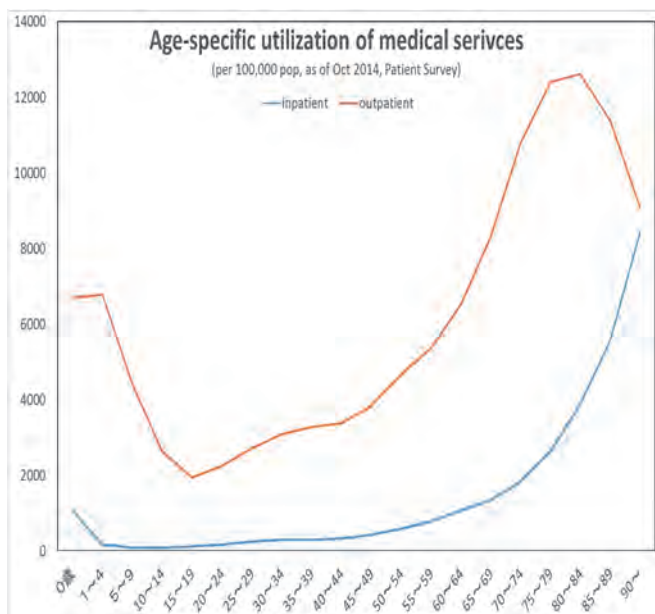
Chapter 2. Health Status

1. Health Status and Utilization of Health Services

The government utilizes regular nation-wide surveys to assess health status and healthcare service utilization. These surveys include the National Household Survey (NHS), a questionnaire-based survey on households, and the Patient Survey, conducted in hospitals and clinics. Findings from the NHS conducted in June 2013 revealed that 31.2% of the population reported at least one physical complaint, with this proportion rising with age in both sexes. The NHS also assesses the perceived health status of individuals, revealing that 35.4% of the population aged 15 years or older rated their health as "good" or "fair," while 14.6% reported their health as "not good" or "bad." An international comparison of perceived health status, presented in OECD Health Statistics, showed that in 2013, 35.4% of Japanese citizens perceived their health as



"good," with figures similar to those of Koreans. On the contrary, the U.S. and Canada showed a significantly higher percentage, nearing 90%. Interpretation of these findings should be approached with caution, as subjective perceptions may reflect survey methodologies and cultural attitudes.



The Patient Survey, conducted once every three years, provides an estimate of medical care utilization among hospital inpatients and outpatients. The most recent survey in October 2014 discovered that 1% of the population was hospitalized, while 5.7% visited outpatient clinics. Notably, the utilization of outpatient services declined remarkably among the elderly over age 80 due to increased inpatient utilization. It's essential to recognize the limitations of the Patient Survey, as it represents a one-day sampling that underestimates the number of regular outpatient visits to hospitals or clinics. This survey accounts for the interval of regular outpatient visits, enabling the estimation of patients under constant medical treatment by factoring in the average interval, alongside the number of inpatients. The study revealed that hypertension is the most common disease, with an estimated seven million patients undergoing medical treatment, representing over 6% of the entire population.

2. Health promotion campaigns

Following the attainment of an average life expectancy of around 80 years in 1978, public health initiatives gradually pivoted their focus from infectious diseases to chronic noncommunicable diseases, often referred to as "age-related diseases", "adult diseases", or later termed as "lifestyle-related diseases". Addressing these ailments prioritizes interventions in personal lifestyle, which underscores the significance of national campaigns to appeal to the general public. Consequently, a slew of public health campaigns have been initiated, culminating in a mixed history of varying national campaigns and their outcomes.

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

In 1978, the 1st National Movement for Health Promotion was initiated, marking the establishment of Municipal Health Centers (MHC) in every municipality to serve as facilities for health promotion activities alongside the existing Public

Health Centers (PHC).

However, it is crucial to highlight a potential oversight from this first wave, notably the relocation of public health nurses (PHNs) from the National Health Insurance section to MHCs. Prior to 1978, many municipal governments, serving as insurers for their National Health Insurance (NHI) programs, employed PHNs for health promotion and preventive medical activities specifically for the insured individuals. Given that only approximately 40% of residents were enrolled in NHI, the reach of the PHNs' services was limited to this insured population.

To address this limitation, PHNs were transferred to MHCs, resulting in the loss of their longstanding role within health insurance operations. For instance, PHNs previously embedded within the NHI bureau had the ability to analyze health insurance claims, providing insight into the medical care utilization of the patients under their care. Following their relocation to MHCs, they forfeited access to health insurance claims for use in their public health initiatives.

This reform is increasingly being acknowledged as a policy misstep, prompting the government to advocate for improved collaboration between the NHI section and MHCs within municipal governments.

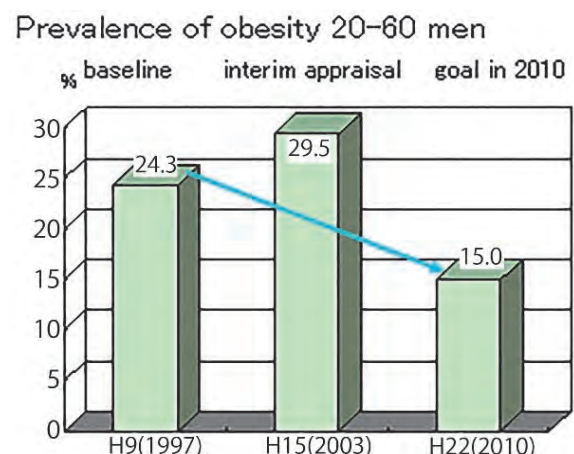
(2) 2nd wave: Active 80 Health Plan (1988)

The second wave, known as the "Active 80 Health Plan," was named for its focus on addressing the increased life expectancy of 80 years. This initiative placed a strong emphasis on physical activity and the promotion of physical fitness. To support this, the qualification of "Health Trainers" was introduced in 1988. Health Trainers are equipped with knowledge encompassing both medical and physical sciences, enabling them to devise tailored physical activity prescriptions tailored to individual needs and medical requirements. Furthermore, fitness clubs that meet specific criteria, including employing a designated number of qualified Health Trainers, were eligible for special government designations.

These designations did not entitle fitness clubs to healthcare benefits, but they did grant a tax-exempt status for membership fees for individuals with chronic diseases such as hypertension, diabetes, and hyperlipidemia, provided their physical activities regimen was prescribed by attending doctors and overseen by qualified Health Trainers.

The implementation of this initiative, alongside economic booms, led to a proliferation of fitness clubs and stimulated the growth of the health and fitness industry.

However, there was not a defined set of goals associated with this campaign, and



no formal assessment was conducted to measure its impact. Consequently, there are few authorities that believe the initiative yielded substantial results.

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

The Healthy Japan 21 (HJ21), marking the third wave of the national health promotion movement, spanned from 2000 to 2010 and was designed with specific objectives. Central to this campaign was the focus on extending the "healthy life span," denoting a life free from disability. This emphasis stemmed from concerns about a significant number of elderly individuals experiencing disabilities, despite having the world's longest life expectancy.

HJ21 outlined explicit goals across nine domains, including nutrition/diet, physical activities, mental health, tobacco, alcohol, dental health, diabetes, cardiovascular disease, and cancer. By 2010, the initiative aimed to achieve 70 specific goals. However, the 2011 interim assessment revealed a lackluster performance, with only 10 goals out of 59 being successfully accomplished. Notably, nine goals demonstrated a deteriorating trend, such as the number of walking and the prevalence of diabetes complications, painting an overall unsatisfactory picture of the campaign's outcomes.

Within the nutrition/diet sphere, there was a notable rise in obesity prevalence, especially among men in their 30s and 60s. While salt intake and fat-derived energy intake witnessed slight declines, the targeted goal of consuming more than 350 grams of vegetables per day remained unattained. In the realm of physical activities, the set goal of 9200 steps for men and 8300 steps for women experienced a decline rather than improvement. Tobacco-related statistics indicated a decrease in smoking rates among men but no corresponding decline among women.

Concerning diabetes, the estimated number of potential diabetics stood at 16.2 million, showing no signs of reduction, and the rate of sustained diabetes treatment exhibited no improvement. In the cardiovascular disease domain, risk factors such as hypertension and diabetes did not show any amelioration. Similarly, in cancer-related aspects, the screening rate did not increase, and a significant geographic maldistribution persisted.

(4) 4th wave: Healthy Japan 21 phase II (2013-2023)

The 2nd phase of HJ21 covers the period between 2013 and 2023 with the following objectives.

Current status and goals of the Healthy Japan 21 phase II

		Current status (2010)	goals (2022)
healthy lifespan	prolongation of healthy life span	M: 70.42y F: 73.62y	more prolongation than life span
	reduction of inter-prefectural inequality of healthy life span	M: 2.79y F: 2.95y	reduction of inter-prefectural inequality
cancer	reduction of age-adjusted cancer mortality (<75yo)		84.3 73.9
	increase of cancer screening rate	stomach: M36.6%, F28.3%	50%
		lung: M26.4%, F23.0%	
		colon: M28.1%, F23.9%	
		cervical c: F37.7%	
breast: F39.1%			
cardiovascular diseases	reduction of age-adjusted mortality of CVA (cerebrovascular) and IHD (ischemic heart diseases)	CVA: M49.5, F26.9 IHD: M36.9, F15.3	CVA: M41.6, F24.7 IHD: M31.8, F13.7
	reduction of systolic blood pressure	M: 138mmHg, F:133mmHg	M: 134mmHg, F:129mmHg
	reduction of lipidemia	% of TCho>240mg/dl: M13.8%, F22.2% % of LDL>160mg/dl: M8.3%, F11.7%	% of TCho>240mg/dl: M10%, F17% % of LDL>160mg/dl: M6.2%, F8.8%
	reduction of metabolic-related syndrome	14 million (2008)	25% reduction (2015)
	screening and health guidance rate for metabolic-related syndrome	screening rate:41.3% health guidance rate: 12.3%	screening rate:70% health guidance rate: 45%
DM	reduction of new dialysis patients due to DM nephropathy	16,247	15,000
	continuity of DM control	63.70%	75%
	% of DM patients with >8% HbA1c	1.20%	1%
	control of DM prevalence	8.9 million	10 million
COPD	increased awareness of COPD	25%	80%

(5) Health Frontier Strategy (2005-2015)

The Health Frontier Strategy (HFS) may cause confusion due to some overlapping goals and time frames with the HJ21 campaign. Following the implementation of Long-term Care Insurance, there has been an increase in insurance benefit disbursement, leading to a financial strain. This rise is primarily observed in the "light" level of disability, prompting a heightened emphasis on the "prevention" of disability.

While HFS shares a common goal with HJ21 in prolonging the healthy life span (life span without disability), it distinguishes itself with dual objectives: preventing lifestyle-related diseases and preventing disability. Moreover, HFS presents clear and straightforward quantifiable goals to be achieved by 2015:

- Prevention of lifestyle-related diseases:
 - Increase the 5-year survival rate of all cancers by 20%
 - Decrease cardiovascular disease mortality by 25%
 - Decrease cerebrovascular disease mortality by 25%
 - Decrease the incidence of diabetes by 20%
- Reduction of disability:
 - Prevent the worsening of disabled elderly individuals in borderline and level 1 to level 2 by 10%
 - Prevent the onset of disability (borderline and level 1) by 20%

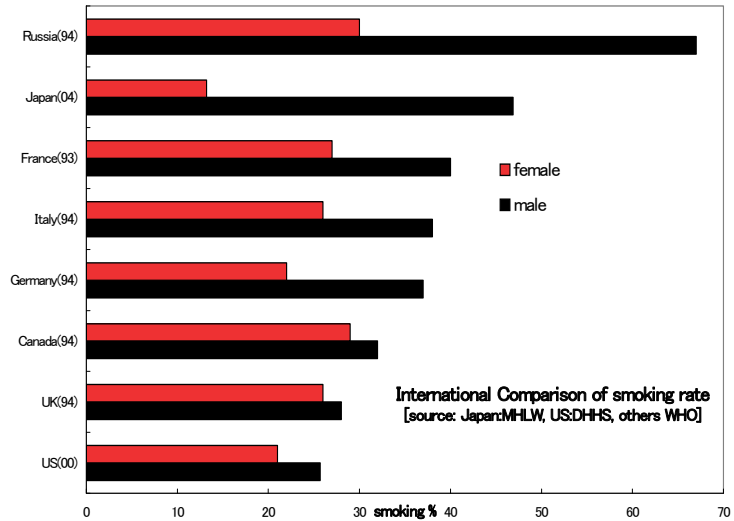
HFS also serves as the foundation for the health care reform proposed in 2006, aiming to reduce the number of patients with metabolic syndrome by 25% by 2015.

3. Health Promotion Act and National Health & Nutrition Survey

The introduction of the Health Promotion Act in 2003 served as the legal foundation for advancing the Healthy Japan 21 (HJ21). This legislation aimed to encourage a healthy lifestyle, enforce designated smoking areas, and coordinate health screenings conducted by various providers under different schemes. Prior

to this, disparate entities, such as employers and schools, independently administered health screenings with minimal coordination. The Health Promotion Act standardized the format of health screening records, ensuring consistent record-keeping practices.

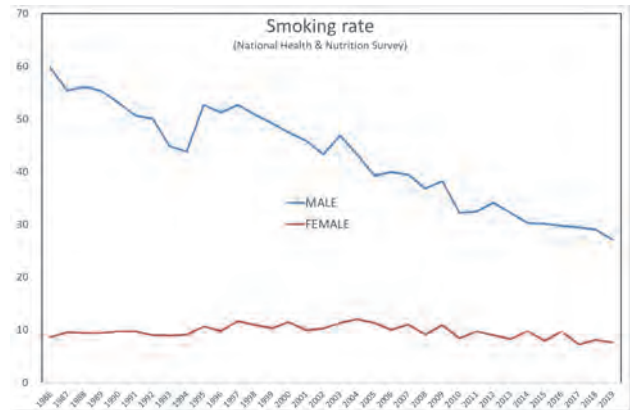
Furthermore, the Act stipulated the National Health and Nutritional Survey (NHNS), equivalent to the U.S. NHANES. Originally known as the National Nutrition Survey (NNS), NHNS has evolved from its postwar origins and expanded to encompass blood exams and other health-related assessments. The survey, conducted annually since November 2003, involves a randomly sampled 3,586 households, with 8,119 individuals responding to lifestyle questionnaires, 8,000 undergoing physical exams, and 4,018 providing blood samples.



4. Health Related Problems

(1) Tobacco

The NHNS of 2019 highlighted a smoking rate of 27.1% for males and 7.6% for females in Japan. Despite a gradual decline in male smoking rates, they remain higher than in most developed countries. Notably, the smoking rate among young women in their 20s and 30s is alarmingly increasing. Concerns also extend to school children, as evidenced by a 2000 government survey indicating rising smoking rates among students.



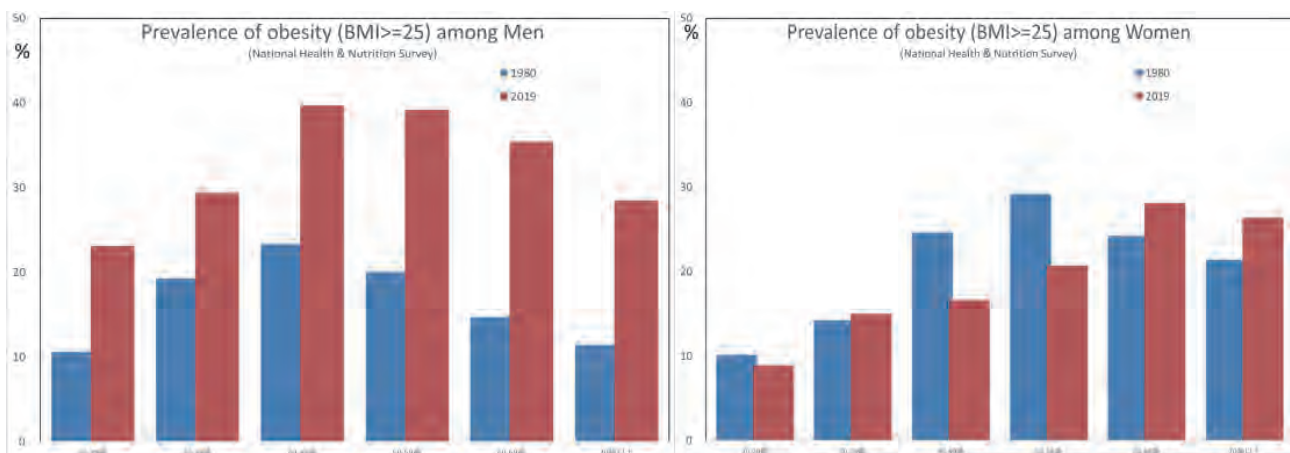
Initially, the government's commitment to tobacco control was tempered by the tobacco industry's status as a monopolistic government enterprise. Only after privatization did the government earnestly address the issue. The 1995 tobacco control action plan led to voluntary industry measures, such as restricting nighttime vending machine operations in 1997 and refraining from TV ads in 1998. The Health Promotion Act of 2003 endorsed passive smoking prevention through separated smoking areas, aligning with the WHO Tobacco Control Framework Convention ratified by Japan in June 2004.

(2) Alcohol

The NHNS in 2019 reported that approximately 34% of men and 8.8% of women drank three times or more per week. While the number of alcoholism patients under medical treatment has stabilized, alcohol-related conditions, particularly liver diseases, persist. Efforts to address alcohol-related problems include the "Prohibition against Drinking for Minors Act" and the "Framework Law against Health-related Problems of Alcohol" enacted in 2013. The latter promotes responsible drinking habits, supports addictive patients' groups, but falls short of a total ban on alcohol sales through vending machines.

(3) Obesity

As per the Japan Obesity Association's definition (BMI ≥ 25), the NHNS in November 2019 indicated obesity rates of 33.0% for men and 22.3% for women aged 15 and above. A significant increase in obesity among men in all age groups, especially those in their 40s, is observed when compared to three decades ago. Recognizing the potential impact on lifestyle-related diseases, addressing obesity emerges as a crucial public health concern.



Chapter 3. Disease-specific measures

1. Cardiovascular diseases

(1) Cerebrovascular diseases

Until 1980, cerebrovascular diseases were the predominant cause of death in Japan. Presently, they hold the third position, owing to a significant reduction in mortality, particularly due to a sharp decline in cerebral bleeding attributed to improved blood pressure control. Paradoxically, the enhanced survival rates for cerebrovascular diseases have led to an increase in patients living with the condition and subsequently, a rise in individuals with disabilities. Effectively preventing cerebrovascular diseases and implementing tertiary prevention measures, including acute-phase rehabilitation, pose significant challenges for Japan's public health.

(2) Heart diseases

Japan previously faced a high prevalence of rheumatic heart diseases; however, since 1993, ischemic heart diseases have been on the rise, currently ranking as the second leading cause of death after cancer. The increasing incidence of ischemic heart diseases has prompted questions about the unsatisfactory rescue rates during the acute onset phase. In addition to primary prevention, there is a pressing need to emphasize improvements in the rescue and survival rates during the acute phase.

2. Cancer

Since 1981, cancer has held the position of the leading cause of death in Japan. The increased incidence and improved survival rates resulting from advancements in cancer treatment have led to a higher prevalence of individuals living with cancer.

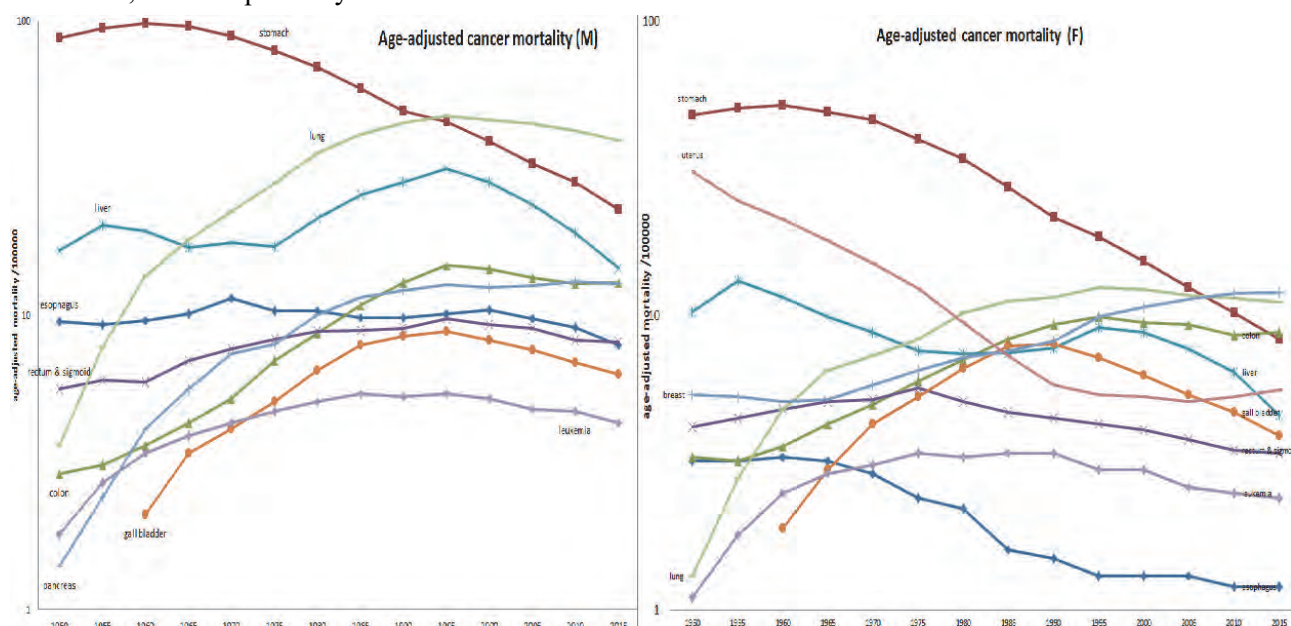
(1) Cancer registry

Until recently, Japan lacked a national cancer registry. Some prefectures, like Osaka and Miyagi, initiated voluntary cancer registries over half a century ago. However, reporting cancer cases was routinely conducted without patients' consent or any legal foundation, raising privacy concerns. Proposals for legislation faced opposition. The enactment of the Personal Data Protection Act in 2005, prohibiting reporting patient data without consent or legal basis, raised concerns about the sustainability of cancer registries. The Health Promotion Act of 2002 encouraged, but did not mandate, prefectures to establish cancer registries. The Great East-Japan earthquake and subsequent nuclear disaster in 2011 spurred concerns about cancer risks from radiation, leading to the enactment of the Cancer Registry Promotion Act in 2013. A nationwide cancer registry commenced in January 2016.

[http://www.jacr.info/publication/document/CRIJ_eng.pdf]

(2) Mortality

Age-adjusted mortality, measured at five-year intervals, reveals a recent downward trend in age-adjusted cancer mortality for men. Stomach cancer mortality has consistently declined since 1960, while lung and liver cancer peaked around 1995 and have been on a decline since. The sharp decline in liver cancer since 1995 reflects a unique cohort effect, with the male cohort born between 1926-35 being infected with the hepatitis C virus in the early 1950s during a period of amphetamine abuse. However, for women, the improvement in cancer survival is unsatisfactory. Uterine cancer's age-adjusted mortality, which declined until 1990, has shown a "resurgence" after 2005. This unexpected exacerbation might explain Japan's hasty introduction of HPV vaccination to school-age girls in 2013, subsequently curtailed due to vaccination side effects.



Future cancer incidence/mortality after the nuclear disaster

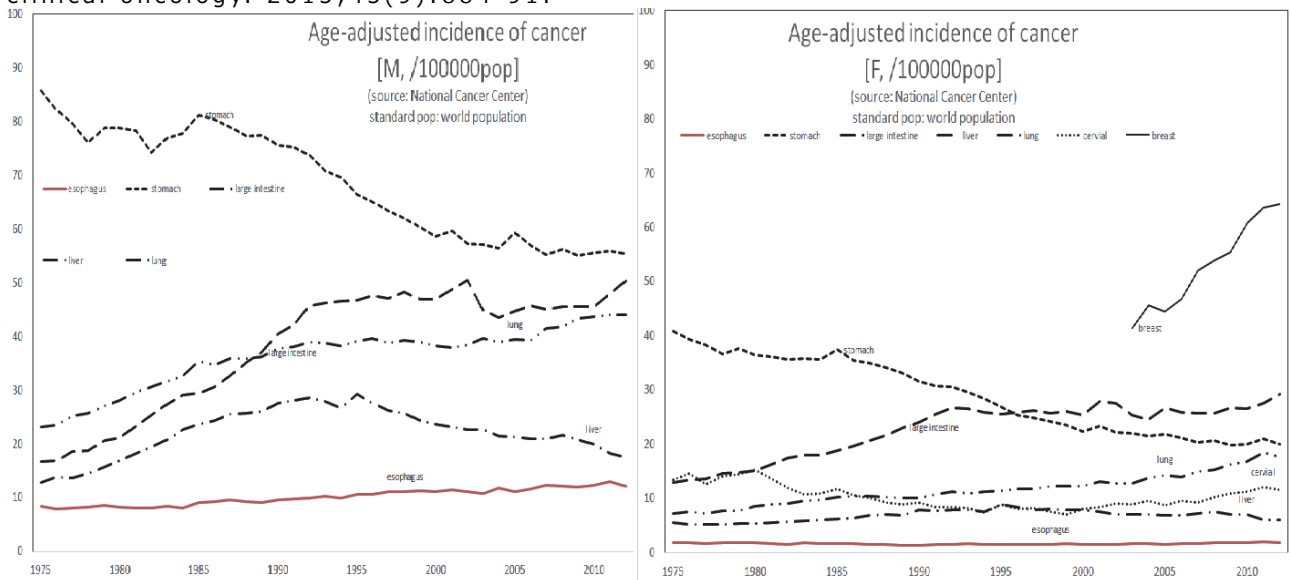
The East-Japan earthquake and the subsequent nuclear disaster at Fukushima on March 11th 2011 exposed many people to radiation hazard. People became concerned that radiation would increase future cancer incidence particularly among children. Experts reassure by saying that low-level radiation will not significantly increase cancer incidence. The government decided to expand the "Eco-Chil" study, a large cohort study following children to detect the relationship between the environment and health to cover all children in Fukushima prefecture with an aim to monitor future incidence of any cancer. The National Cancer Center revised the "Cancer Statistics" and updated a new future projection of cancer incidence and mortality. Comparing the cancer incidence in 2020 projected in the "Cancer Statistics 2004" and "Cancer Statistics 2012", the cancer incidence of all sites is likely to increase slightly: 525,000 new cases for men (projection in 2004 was 500,723) and 377,000 new cases for women (projection in 2004 was 337,396). However, the projection is mixed among different sites. Liver cancer is expected to decline: 27,600 new cases for men (projection in 2004 was 33,266) and 15,800 new cases for women (projection in 2004 was 17,571). However, the incidence of leukemia in 2020 is expected to increase: 6,300 new cases for men (projection in 2004 was 5,396) and 4,700 new cases for women (projection in 2004 was 4,583). Japan has ample experience of cancer epidemiology following up A-bomb victims, which showed increased incidence of leukemia. Will the findings from Hiroshima and Nagasaki hold for Fukushima? The answer will be known after a long-term follow-up of the victims. [Sobue T. Cancer Statistics 2012. Shinohara publisher, April 2012, p76-77]

(3) Incidence

Age-adjusted incidence of cancer is published by the National Cancer Center. The long-term trend as measured by using the world population as reference shows a different pattern among different sites. While the declining trend of stomach and lung is obvious, the recent sharp increase of breast cancer is remarkable.

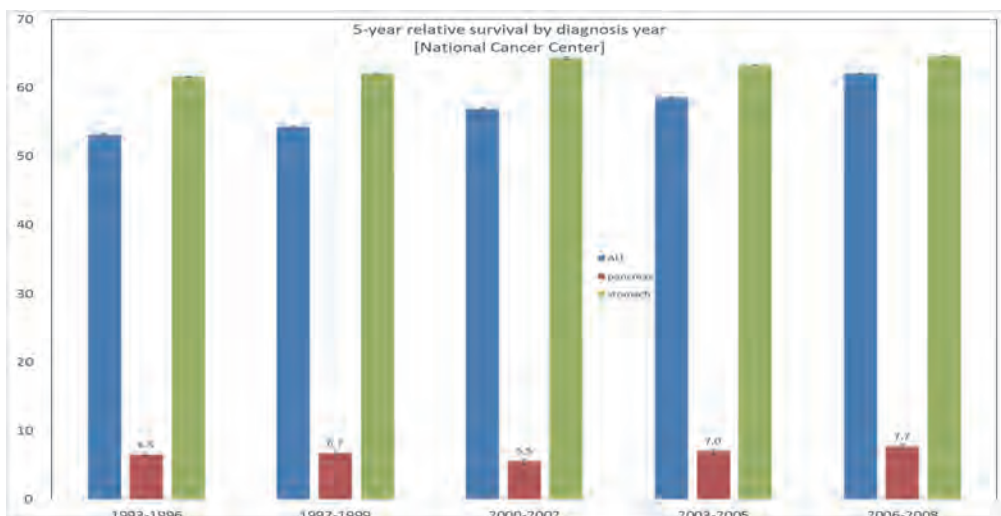
[http://ganjoho.jp/en/professional/statistics/table_download.html]

Hori M, Matsuda T, Shibata A, Katanoda K, Sobue T, Nishimoto H, et al. Cancer incidence and incidence rates in Japan in 2009: a study of 32 population-based cancer registries for the Monitoring of Cancer Incidence in Japan (MCIJ) project. Japanese journal of clinical oncology. 2015;45(9):884-91.



(4) Survival

The advent of enhanced cancer care has led to improvements in survival rates, particularly evident in the 5-year relative survival measurements. According to the National Cancer Center (NCC), the overall 5-year relative survival rate for both sexes and all cancers diagnosed in the period 2006-8 reached 62.1%. Despite these positive trends, certain cancers, such as pancreatic cancer, continue to exhibit lower survival rates, highlighting persistent challenges in specific cancer types.



(5) Screening

Municipal governments offer cancer screening to residents, either free of charge or with a minimal copayment. This screening targets stomach, colon, and lung cancers for residents aged 40 and older, while cervical and breast cancer screenings are provided for female residents aged 20 and older. It is important to note that the following table does not encompass screenings offered by other providers, such as worksites. In addition to providing screenings, municipal governments have been mandated since 2009 to conduct follow-ups on recipients suspected of cancer in the subsequent year. The detailed follow-up data obtained contributes valuable information for assessing the efficiency of cancer screening, including the detection rate.

Cancer screening conducted by municipal governments (FY2014)

	stomach	colon	lung	cervical	breast
target population (P)	75090560			54234198	
N of recipients (N) in FY2013	3729576	8294168	7430915	4448311	3064503
N suspected of cancer (S)	320178	648242	181281	86912	228925
N confirmed of cancer (C)	6019	20209	4525	2967	9558
N/P	4.97%	11.05%	9.90%	8.20%	5.65%
C/N	0.16%	0.24%	0.06%	0.07%	0.31%
S/N	8.58%	7.82%	2.44%	1.95%	7.47%
C/S	1.88%	3.12%	2.50%	3.41%	4.18%

(6) Prevention

In April 2013, the routine vaccination program introduced Human Papillomavirus (HPV) vaccination as a preventive measure against cervical cancer, specifically targeting school-age girls (typically in the 7th grade, around 13 years old). However, as the HPV vaccination was implemented on a larger scale, reports of side effects prompted the Ministry of Health, Labour and Welfare (MHLW) to suspend the "active promotion" of vaccination. It is essential to clarify that this suspension does not entail a complete halt to vaccination but rather a cessation of "active promotion." Consequently, vaccination rates experienced a significant decline. Subsequently, individuals affected by side effects initiated mass litigation against both the government and pharmaceutical companies. The resumption of "active promotion" remains uncertain at present.

Vaccination rate of HPV vaccination

		2013	2014
target population	1st	1,209,943	1,106,503
	2nd	1,124,428	971,328
	3rd	1,120,701	994,151
individual vaccination	1st	97,466	3,847
	2nd	66,199	4,129
	3rd	86,982	6,195
mass vaccination	1st	1,190	48
	2nd	369	43
	3rd	251	43
vaccination rate	1st	8.15%	0.35%
	2nd	5.92%	0.43%
	3rd	7.78%	0.63%

source: Administrative reports of community health activities

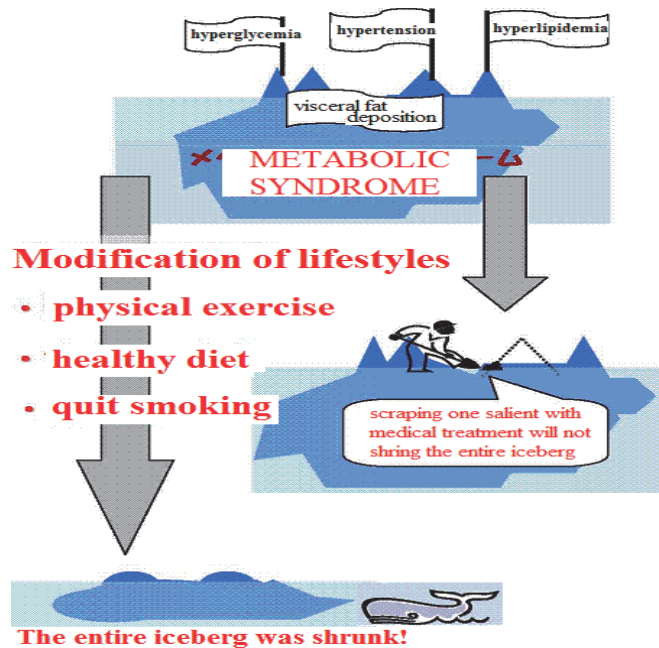
3. Metabolic syndrome

The concept of lifestyle-related diseases transformed into "metabolic syndrome"

in 2005 when the Japanese College of Internal Medicine adopted uniform diagnostic criteria during their 102nd general assembly on April 8th.

(1) Theory and background

The pathophysiology of metabolic syndrome focuses on "visceral fat" (abdominal cavity fat). Unhealthy lifestyles lead to visceral fat deposition, releasing adipocytokines that cause various lifestyle-related diseases. Debates arose over Japan's diagnostic criteria, especially regarding waist circumference, differing from race-specific criteria adopted by the International Diabetes Federation. Despite debates, Japan's metabolic syndrome criteria gained significance, capturing the attention of the Ministry of Health, Labour, and Welfare (MHLW). MHLW utilized the concept as a rationale for health promotion activities, emphasizing lifestyle modification as illustrated by an iceberg metaphor. The shift from viewing lifestyle-related diseases independently to recognizing visceral fat as a key culprit led to the WHO's publication of the term "metabolic syndrome."



(2) New initiative

Metabolic syndrome became a focal point in health policy following the 2008 health care reform, emphasizing health insurer interventions. The government aimed to reduce metabolic syndrome cases by 25% between 2008 and 2015. Health insurers provided annual checkups for those aged 40-74, introducing health guidance by professionals and establishing a National Database (NDB) for monitoring and evaluation. Despite challenges in matching health check and insurance claim records, the NDB accumulated substantial data since 2008:

- Not only providing health checkups (*tokutei-kenshin*), health insurers were required to provide "health guidance (*tokutei-hoken-shido*)" by professional nurses or nutritionists to help those with metabolic syndrome improve their unhealthy lifestyle.
- MHLW developed a national database (NDB) matching BOTH health check records and all health insurance claims whose personal ID is coded (anonymized) for the purpose of "monitoring and evaluation" of the economic effects of health checkups and guidance.
- The NDB may be used for research purposes under certain conditions.

(3) National database (NDB)

The NDB developed under the new initiative is arguably one of the largest patient database. It started to accumulate health checkups data from 2008 and health insurance claims data (claims submitted electronically only) from 2009. The results of health checkups and guidance is shown below: the recipient rate of

health checkups increased steadily from 34.6% to 43.4% in 7 years. However, the rate of metabolic syndrome (including those diagnosed as borderline) decreased by only 0.9% (26.8% to 25.9%).

[The data contained in the table below is slightly different from official administrative report. For example, the official target population in 2014 was 53.85 million because the indigent population under welfare is excluded from health checkups and guidance program (plus some other exclusions). Also, the decrease of prevalence of metabolic syndrome must be sex-age-adjusted. According to the official report, the recipient rate was 48.6% and the decrease of metabolic syndrome between 2008 and 2014 was 3.18% after sex-age-adjustment. Even with the official estimate, the goal of reducing the prevalence of metabolic syndrome by 25% between 2008 and 2015 is not likely to be achieved.]

Results of health checkups and guidance targeting metabolic syndrome (source: NDB)

	population (40-74yo)(P)	health checkup			health guidance					
		recipients (R)	R/P	healthy borderline (A)	metabolic syndrome(B)	(A+B) /R	target (A)+(B)-(D)	completed	completion rate	
2008	57,783,656	20,003,634	34.6%	14,647,408	2,483,568	2,872,658	26.8%	3,960,613	299,344	7.6%
2009	58,075,699	21,410,859	36.9%	15,707,696	2,633,129	3,070,034	26.6%	4,043,443	493,634	12.2%
2010	58,340,026	22,230,635	38.1%	16,360,102	2,664,459	3,206,074	26.4%	4,050,745	529,032	13.1%
2011	58,545,878	23,131,645	39.5%	16,944,436	2,803,332	3,383,877	26.7%	4,193,440	630,193	15.0%
2012	58,840,009	24,016,470	40.8%	17,746,687	2,841,857	3,427,926	26.1%	4,246,642	695,816	16.4%
2013	59,145,362	25,002,415	42.3%	18,451,924	2,966,483	3,584,008	26.2%	4,234,870	753,989	17.8%
2014	59,662,006	25,911,180	43.4%	19,193,435	3,036,019	3,681,726	25.9%	4,393,971	766,222	17.4%

(D) recipients who are already under treatment

However, its use for economic evaluation of health checkups and guidance is limited due to low matching rate (The Government Audit Office surveyed the matching rate and concluded that only 19% of health insurance claims were matched to health checkups records in FY2011. The matching rate varied considerably among different types of insurers: 50.4% for municipal NHI and 0% for Japan Health Insurance Association).

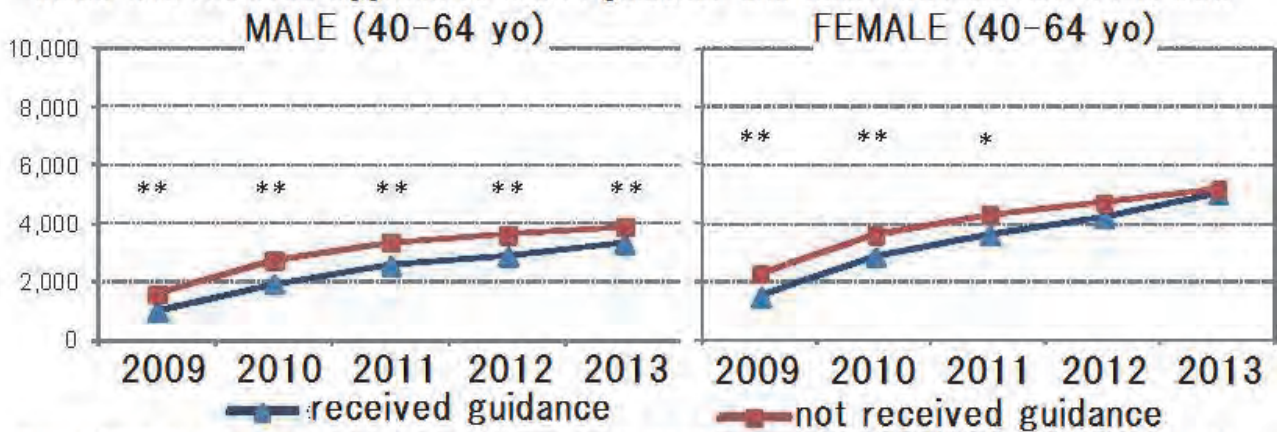
[http://www.jbaudit.go.jp/pr/kensa/result/27/pdf/270904_zenbun_01.pdf]

(4) Economic effects of health guidance

Despite the low matching rate of the NDB, the MHLW evaluated the economic impact of health guidance on outpatients' expenditure for metabolic syndrome-related issues. The evaluation, focusing on selected health insurers, showed that male recipients of health guidance experienced annual savings of approximately 6000 yen in metabolic syndrome-related outpatient expenses. The cost-saving effects persisted for five years, while female recipients exhibited two years of cost-saving effects.

[<http://www.mhlw.go.jp/file/05-Shingikai-12401000-Hokenkyoku-Soumuka/0000123428.pdf>]

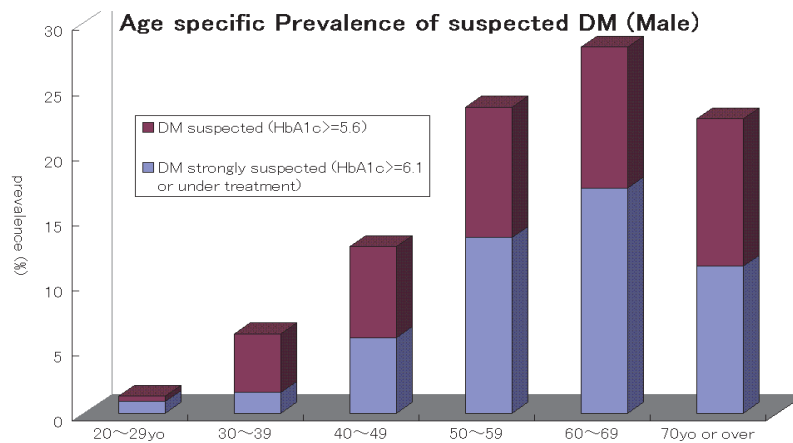
Comparison of metabolic syndrome-related annual outpatient expenditures between those who received aggressive health guidance and those who did not in FY2008



<http://www.mhlw.go.jp/file/05-Shingikai-12401000-Hokenkyoku-Soumuka/0000090331.pdf> [p131,2]

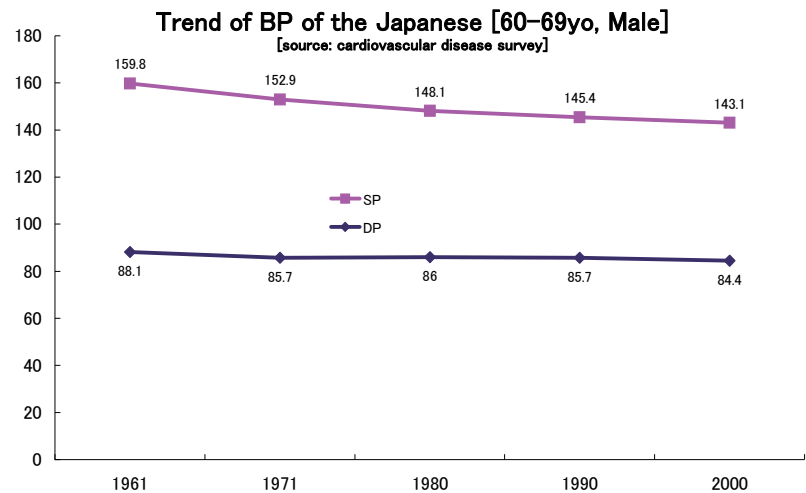
1) Diabetes

The majority of diabetic patients in Japan have type II diabetes (NIIDM), heavily influenced by lifestyle. Although ranking 10th in immediate causes of death, diabetes contributes significantly to major causes like cardiovascular and cerebrovascular diseases. Diabetic complications, including nephropathy and retinopathy, pose substantial health concerns.



2) Hypertension

The prevalence of hypertension slightly increased according to the 5th National Survey on Cardiovascular Diseases in 2000, except in men aged 60 or over and women over 40. Mass-screening programs contributed to increased treatment rates. Japan witnessed a notable decline in cerebral apoplexy due to effective high blood pressure control. Long-term surveys from 1961-2000 demonstrated a decline in average systolic pressure for men aged 60-69, indicating successful public health efforts.

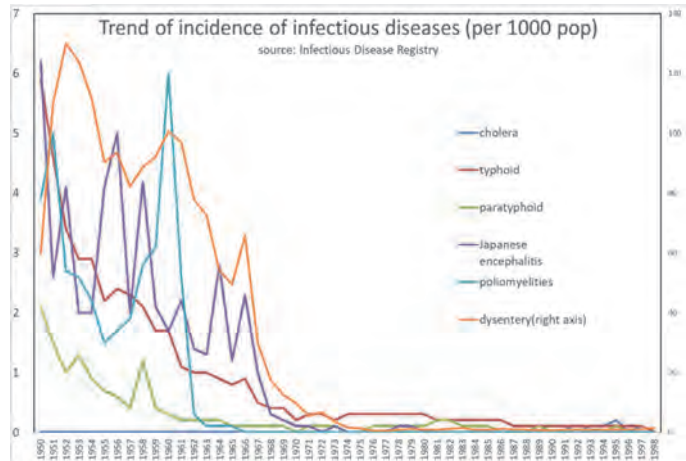


3) Hyperlipidemia

The Patient Survey in October 1996 revealed a peak in hyperlipidemia patients aged 70-74. However, caution is advised, as this cross-sectional survey covering only three days might underestimate the actual number, considering many hyperlipidemia patients receive treatment for it as a secondary condition.

4. Infectious Diseases

Historically, Japan grappled with infectious disease epidemics that inflicted considerable mortality. Although reported cases of traditional infectious diseases markedly decreased after the late 1960s, new challenges emerged with the rise of emerging and reemerging infectious diseases.



1) Infectious disease surveillance system

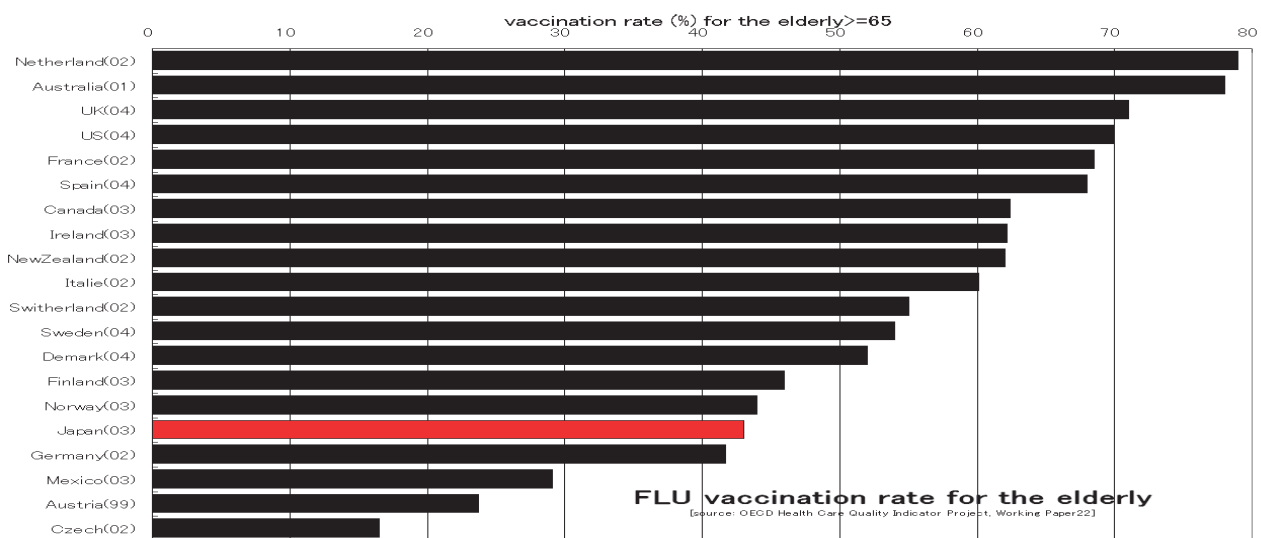
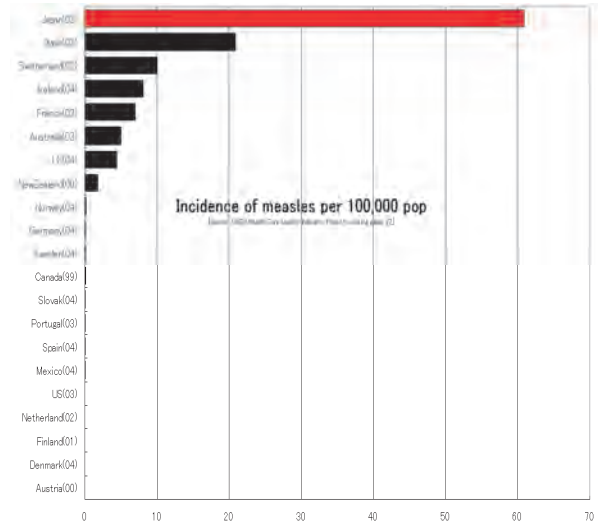
Aligned with the Infectious Diseases Control Act, Japan established a surveillance system in 1981, comprising mandatory reporting for severe infectious diseases and sentinel surveillance for less critical ones like measles or influenza. Participating hospitals provide weekly reports on diagnosed cases, available on the National Institute of Infectious Diseases (NIID) website. For example, influenza epidemics are detailed in terms of average new cases per "sentinel," totaling around 4,700 nationwide. For example, epidemic of influenza is shown in a weekly report as the average number of new cases per "sentinel" (approximately 4700 nationwide).

In response, the year 1999 witnessed the enactment of the Infectious Diseases Control Act, consolidating laws addressing sexually transmitted diseases (STD) and AIDS. The legislation categorized infectious diseases into four groups based on severity and societal risks. (<http://idsc.nih.go.jp/kanja/index-e.html>)

2) Mass vaccination program

Japan achieved significant success in infectious disease control, notably through the emergency import of polio live vaccine in 1961 and mandatory mass vaccination for school children against influenza starting in 1977. However, the easing of mandatory vaccination in 1985 and discontinuation in 1994 led to a resurgence of excess deaths due to influenza. Japan faced challenges, including a higher incidence of measles than in other developed countries, partially attributed to delayed vaccination.

The introduction of the Human Papilloma Virus (HPV) vaccination in 2013 faced setbacks, with reports of adverse events leading to a temporary halt. Despite safety concerns, the vaccination was resumed in 2022 after an extended hiatus.



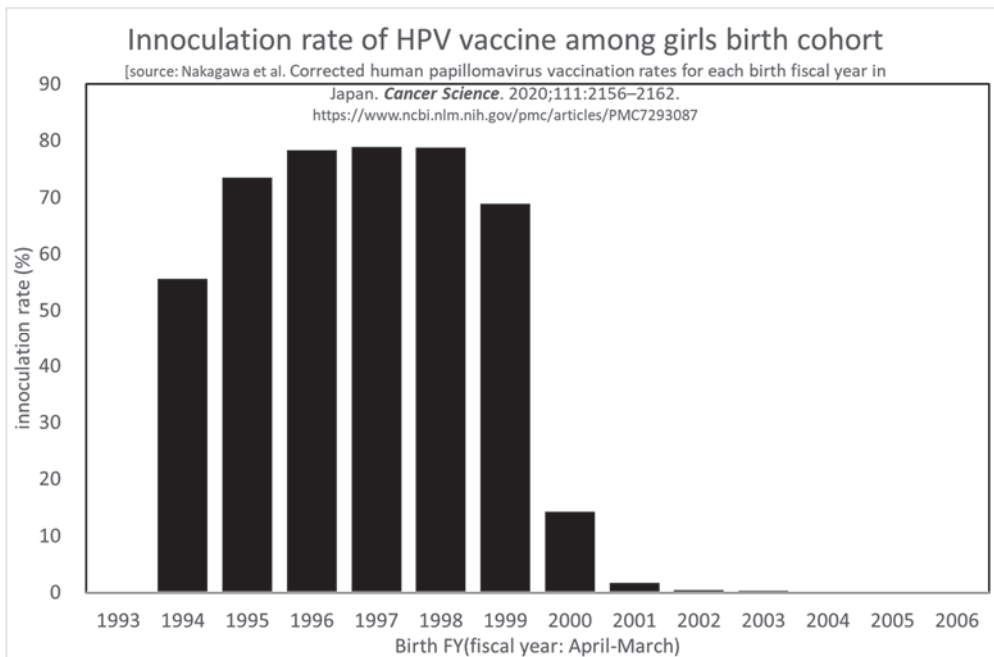
The outline of Japan's mass vaccination program is below.

Japan's current scheduled 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	3-12months	3
		1st booster	at least 6 months after the 1st	12-18 moths after	1
		2nd	11,12 years(DT toxoid)	12 years	1
	DT toxoid	1st	3-90 months	3-12months	2(precipitate) 3(liquid)
		1st booster	at least 6 months after	12-18 moths 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
Hib			2-60 months		
pneumococcal			2-60 months		
Human Papilloma Virus (HPV)			the 6th grade of elementary school to 1st grade of senior high school	1st grade of junior high school	3
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

In April 2013, a new vaccination was added to the scheduled mass vaccination program: Human Papilloma Virus (HPV) vaccination. However, as soon as the vaccine began to be inoculated to teen age girls, massive reports of adverse events such as complex regional pain syndrome (CRPS) poured in, leading to a “halt” of the program only a few months after the introduction. The irony was that the vaccine was NOT intended for infectious disease *per se* but for prevention of cervical cancer in the long term. If the purpose was for cancer prevention, it could be achieved through individualized voluntary vaccination, not through scheduled mass vaccination to control epidemics.

After a lengthy debate over the safety issues, the promotion of HPV vaccination for teen-aged girls was resumed in April 2022 after nine years' recess. Since the vaccination is provided to girls of 6th to 16th grade, a large gap developed among different birth cohorts. As shown in the graph, girls born 1995-99 had nearly 80% inoculation rate, whereas those born in FY 2000 or onward had negligible inoculation rate.



For girls born in the nine years' period of 1997-2006, who missed opportunities of vaccination, the “catch-up” vaccinations are provided during the three-years campaign period free of charge.

Real harm!?!---Statement by WHO Advisory Committee

The sudden “halt” of Japan’s scheduled mass vaccination of HPV vaccination attracted a global attention. WHO Global Advisory Committee on Vaccine Safety (GACVS) released a statement reaffirming its position in support of the safety of the HPV vaccines. In an unusual twist as an international organization, it pointed out Japan in a critical comment as follows:

“The circumstances in Japan, where the occurrence of chronic pain and other symptoms in some vaccine recipients has led to suspension of the proactive recommendation for routine use of vaccine in the national immunization program, warrants additional comment. Review of clinical data by the national expert committee led to a conclusion that symptoms were not related to the vaccine, but it has not been possible to reach consensus to resume HPV vaccination. As a result, young women are being left vulnerable to HPV-related cancers that otherwise could be prevented. As GACVS has noted previously, policy decisions based on weak evidence, leading to lack of use of safe and effective vaccines, can result in real harm” .

[http://www.who.int/vaccine_safety/committee/GACVS_HPVS_statement_17Dec2015.pdf]

3) Quarantine

The Ministry of Health, Labour and Welfare (MHLW) operates 110 quarantine offices across ports and airports. These offices handle over 30 million visitors by air and over 2 million by sea, along with imported goods. The primary concern is avian influenza (H5N1), given the inability to quarantine migrating birds.

4) Specific Infectious Diseases:

(1) Hansen's Disease:

Once considered incurable, Hansen's disease became treatable with drugs. However, Japan's forced isolation policy, enacted in 1907 and lasting until the abolishment of the Leprosy Prevention Act in 1996, resulted in prejudice and suffering for patients. A 2006 law sought to compensate patients, acknowledging the historical flaws in public health policy.

(2) Viral Hepatitis

Viral hepatitis poses a substantial threat in Japan, with millions of carriers. Hepatitis B (HBV) and Hepatitis C (HCV) contribute to liver cancer, with an alarming increase in liver cancer deaths. Iatrogenic transmission, especially through blood products, has been a significant factor. Japan enacted a special law in 2008 to compensate patients infected through blood products, emphasizing the need for enhanced drug safety measures to prevent future iatrogenic infections.

In conclusion, Japan's approach to infectious diseases reflects a dynamic interplay of historical challenges, evolving policies, and ongoing efforts to safeguard public health.

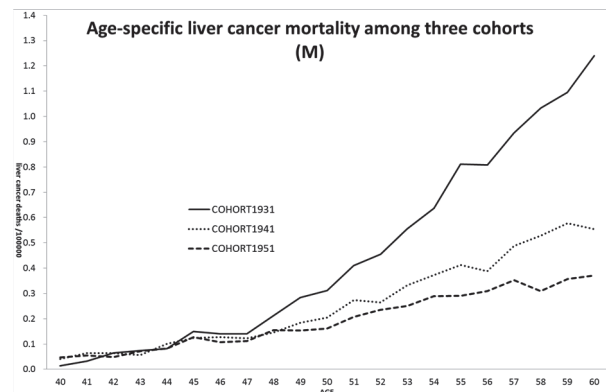
Estimated number of HBV, HCV carriers and patients

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		asymptomatic carrier (1.5-1.9 million)
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.

How HCV spread?

Japan and most Asian countries have high prevalence of HCV. This may be explained by Asian traditional medical practice: acupuncture. HCV can be infected iatrogenically through improperly sterilized needles. However, Japan's situation is peculiar in that a certain birth cohort, notably men born between 1926 and 1934 have higher prevalence than other generation. They have been called "Showa *hitoketa* (single digit age of Showa era)" generation because the era corresponds to the first nine years of Showa era. The age-specific liver cancer mortality showed no difference among three cohorts born in 1931, 41 and 51 until the age of 47. However, the liver cancer mortality of the cohort born in 1931

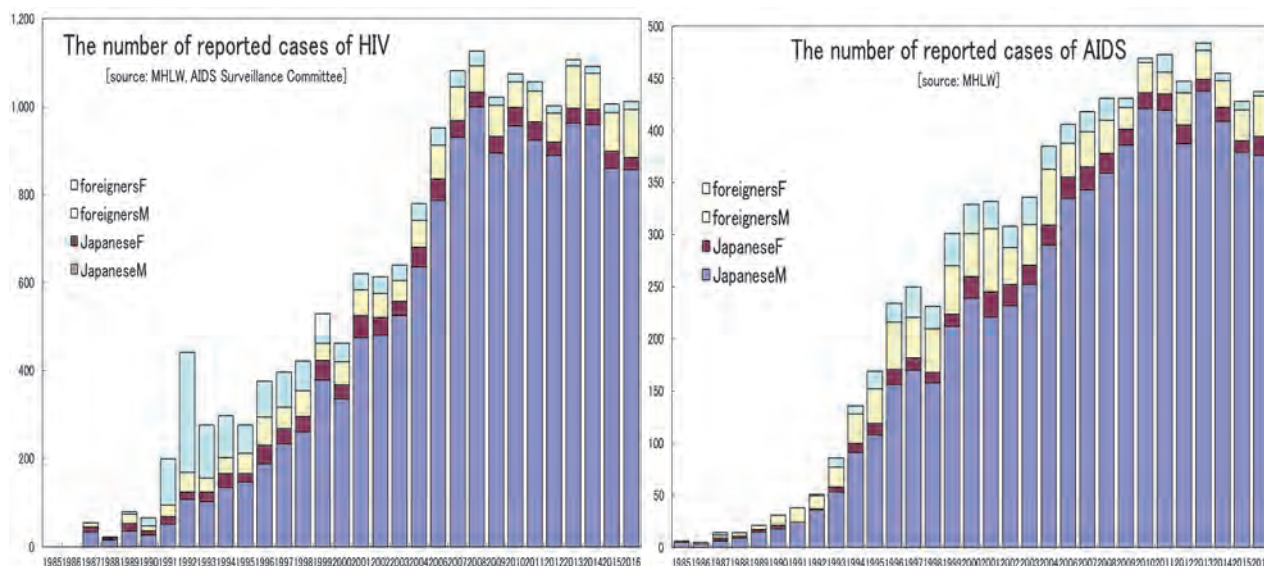


increased sharply afterward. One might wonder how this particular male cohort was infected with HCV. In early 1950s, when the “Showa hitoketa” men were in twenties, Japan was plagued with amphetamine abuse among youth (Amphetamine was officially banned in June 1951 but illicit use continued until middle of the 1950s). Unaware of the risk of infection, abusers shared unsterilized needles and syringes. Decades later, when they became middle-age, many died of liver cancer and cirrhosis.

Okamoto E. Cohort analysis of incidence/mortality of liver cancer in Japan through logistic curve fitting. *Asian Pac J Cancer Prev.*2013;14(10):5891-3

(3) HIV/AIDS

The global HIV/AIDS landscape, characterized by declining figures, unfortunately, contrasts with the situation in Japan. Despite the decreasing worldwide prevalence, Japan faces specific challenges, with reported HIV-positive cases reaching 23,231 and AIDS patients numbering 10,306 as of December 2021. Transmission routes vary, with homosexual contact comprising 61.2%, heterosexual contact 24.1%, and minimal cases from IV drug use or maternal transmission. Notably, the cases with unknown transmission routes, particularly among foreign nationals, constitute nearly half.

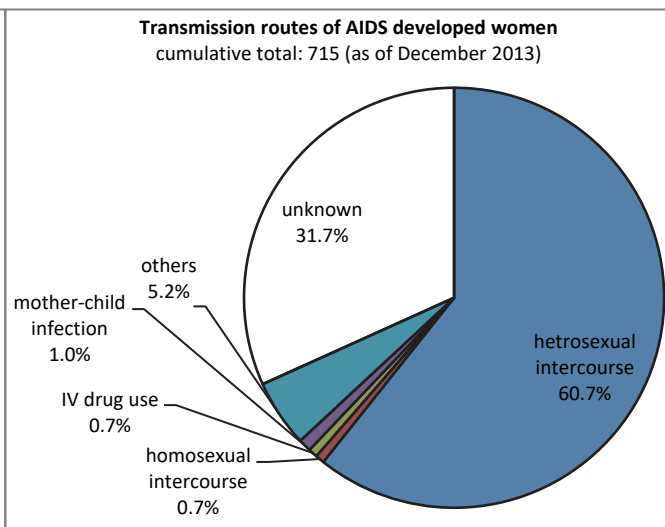
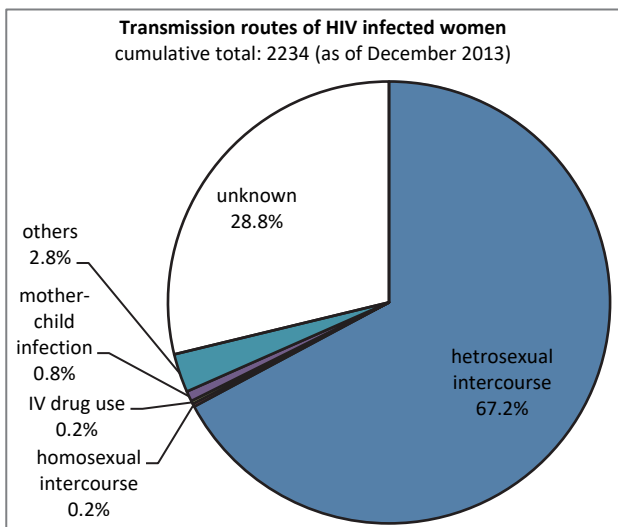
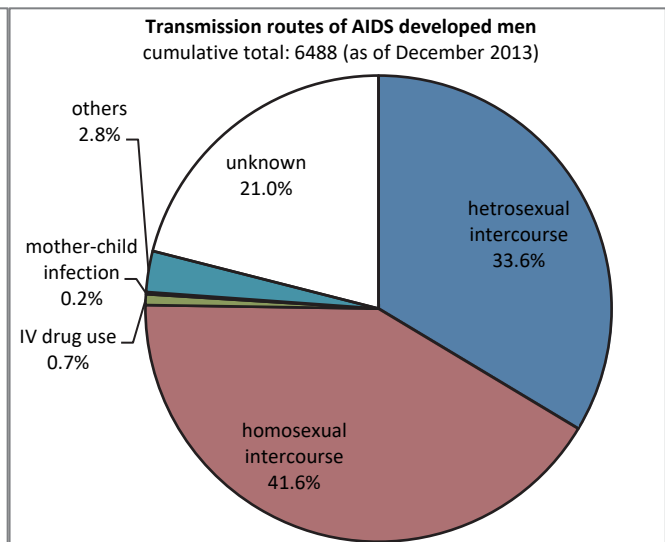
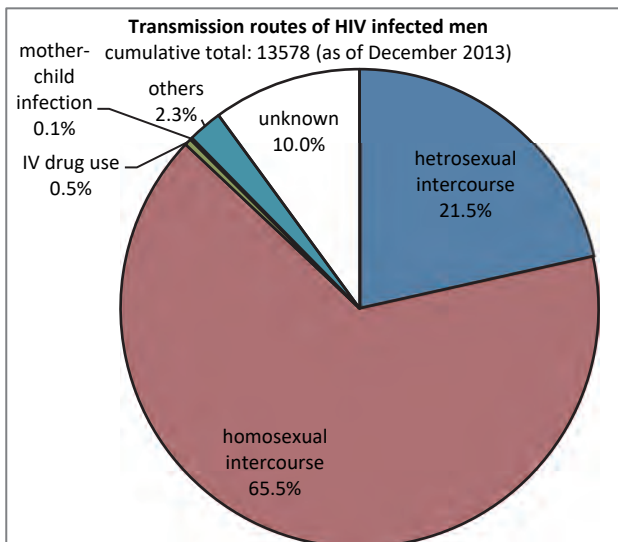


The AIDS epidemic in Japan unfolds through several key points:

A rising number of reported HIV cases among Japanese males, involving both homosexual and heterosexual relationships.

Foreign nationals contribute to approximately 30% of reported HIV and AIDS cases, primarily from Southeast Asia and Latin America.

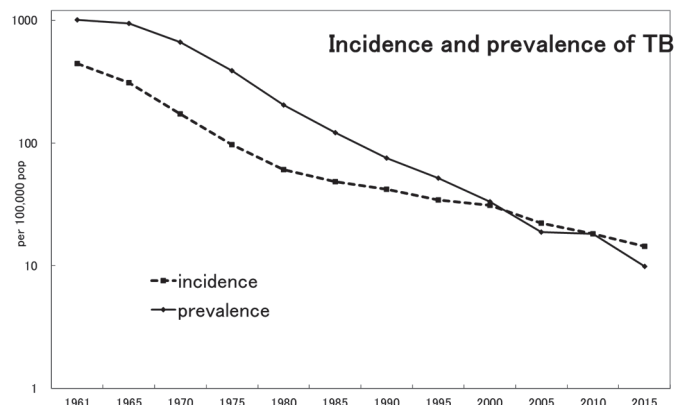
Geographically, the majority of sexual transmission cases among Japanese occur domestically, concentrated in and around the Tokyo area. Tokyo sees higher transmission rates for homosexual intercourse, while the Kinki block, encompassing Osaka, Kyoto, and Kobe, reports an alarming increase in overall cases. Transmission routes also differ by gender, with homosexual intercourse a significant factor for men and heterosexual intercourse more common for women.



While the severity of Japan's AIDS epidemic may be comparatively lower, it remains a reminder of past issues. The iatrogenic HIV infection of nearly two thousand hemophiliac patients through imported blood products led to a public health crisis. In 1996, the health minister formally apologized, and subsequent legal actions resulted in compensation. Criminal charges in 2000, however, resulted in an acquittal, citing unforeseeability of iatrogenic HIV infection around 1985.

(4) Tuberculosis

Japan grapples with a persistently high tuberculosis (TB) mortality rate, with 1,664 deaths in 2022, or 1.4 per 100,000 population. Despite TB dropping from a leading cause of death in 1950 to the 29th rank in 2015, the country still faces challenges. Under the TB Control Act, doctors must report TB diagnoses



to public health centers, which play a crucial role in control and prevention.

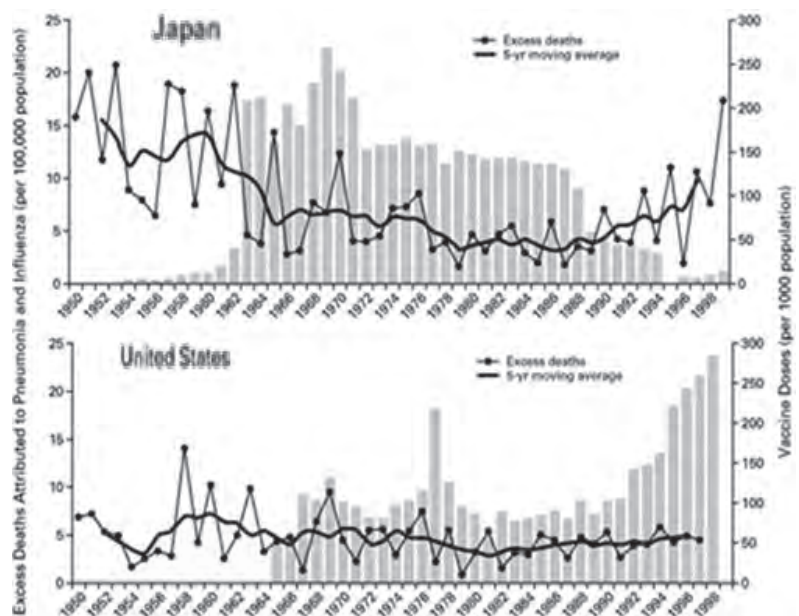
In 2021, 11,519 new TB patients were reported, translating to 9.2 per 100,000 population. Public health centers monitor patients for three years after the initial report, with 27,754 individuals tracked by the end of 2021, including 7,744 active TB patients. The declining trend faced a resurgence in 1999, leading to an official "TB Emergency Declaration." Efforts concentrated around large cities, with Direct Observational Therapy of Streptomycin (DOTS) successfully reducing patients under surveillance.

Japan's approach involves mandatory PPD skin tests and immunization (BCG) for babies aged 0 to 4, with publicly funded measures. However, the interpretation of a positive PPD test can be puzzling, as it may indicate BCG-induced immunity rather than TB infection. A recommendation in 1991 aimed for TB eradication by the 2030s, leading to adjustments in examination practices.

(5) Influenza

Seasonal influenza poses recurrent challenges, and novel strains can lead to global pandemics. Japan's response to the novel influenza (H1N1) outbreak in 2009 involved a rigorous quarantine approach, referred to as "bay-side tactics." While the initial concern was based on avian influenza (H5N1), the strategy faced criticism as the perceived virulence of the novel influenza did not align with the severity initially anticipated.

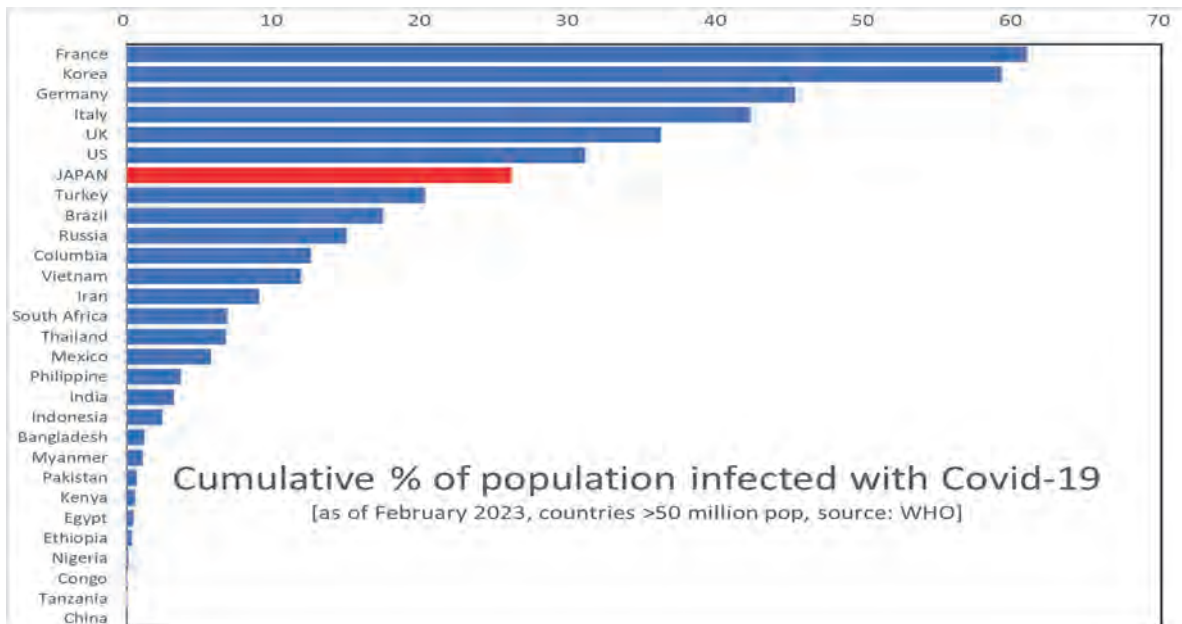
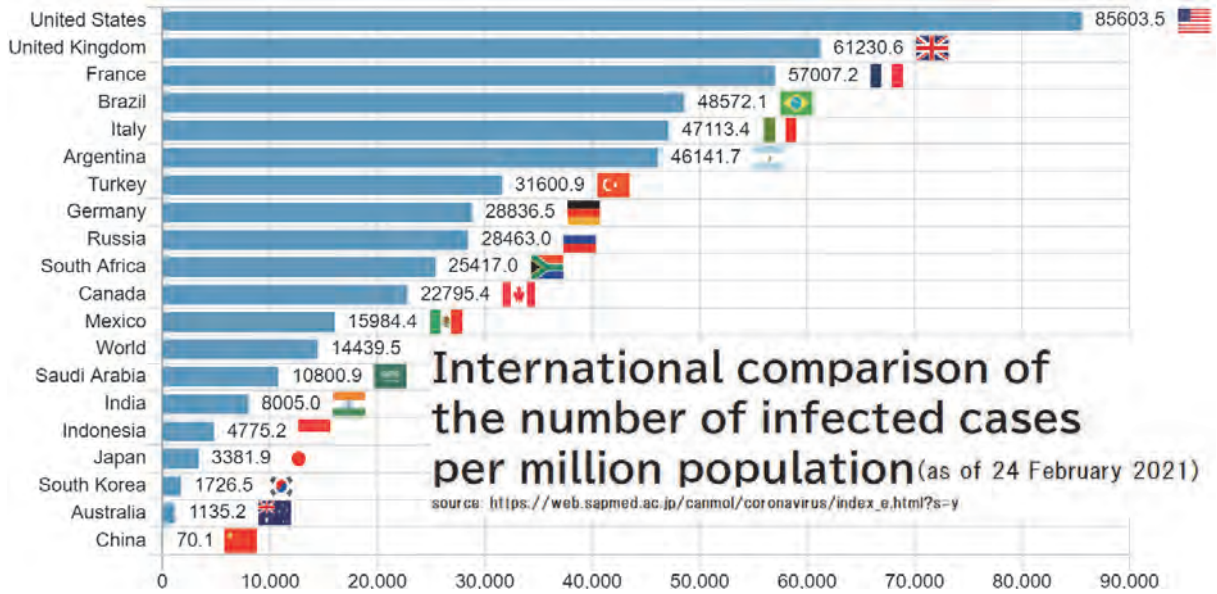
Despite skepticism, the bay-side tactics aimed at delaying and blunting the epidemic gained retrospective validation. A committee report in 2010 acknowledged the necessity but recommended reconsidering the nomenclature. This episode underscored the need for flexible strategies and clear communication during public health emergencies.



(6) COVID-19

1) Cumulative infections per population

The COVID-19 pandemic entered its fourth year, revealing Japan's initially underestimated infection rates. In the pandemic's early stages, Japan's low infection rates were attributed to a restrictive PCR testing policy related to the impending 2020 Summer Olympics. However, as of February 2023, cumulative infections per population reached approximately 33 million, challenging the myth of Japan's initial success.



2) Mass vaccination program

The mass vaccination program, initiated in April 2021, utilized mRNA vaccines and faced challenges with the emergence of the Omicron variant in 2022. By February 2023, over 80% of the population received the primary two-dose vaccination series, but bivalent booster vaccination rates remained at 23.7%.

Population coverage of Covid-19 vaccination

(as of February 2023, source:MHLW)

	ALL AGES	elderly (>=65yo)
1st	81.4%	92.7%
2nd	80.3%	92.4%
3rd	68.2%	91.1%
4th	46.2%	83.3%
5th	23.7%	65.5%

Bivalent booster vaccination by product is as follows.

N of inoculation of bivalent booster vaccination by product

		3rd	4th	5th
ALL AGES	total N of inoculation	2780372	22085488	29565346
	Pfizer(BA.1)	714155	6106666	1333224
	Pfizer(BA.4-5)	1796278	13412160	26959859
	Moderna(BA.1)	199060	2162281	779976
	Moderna(BA.4-5)	70879	404381	492287
elderly (>=65yo)	total N of inoculation	164996	2778605	23576584
	Pfizer(BA.1)	50225	1174233	1141088
	Pfizer(BA.4-5)	104450	1430826	21503850
	Moderna(BA.1)	8029	150070	618515
	Moderna(BA.4-5)	2292	23476	313131

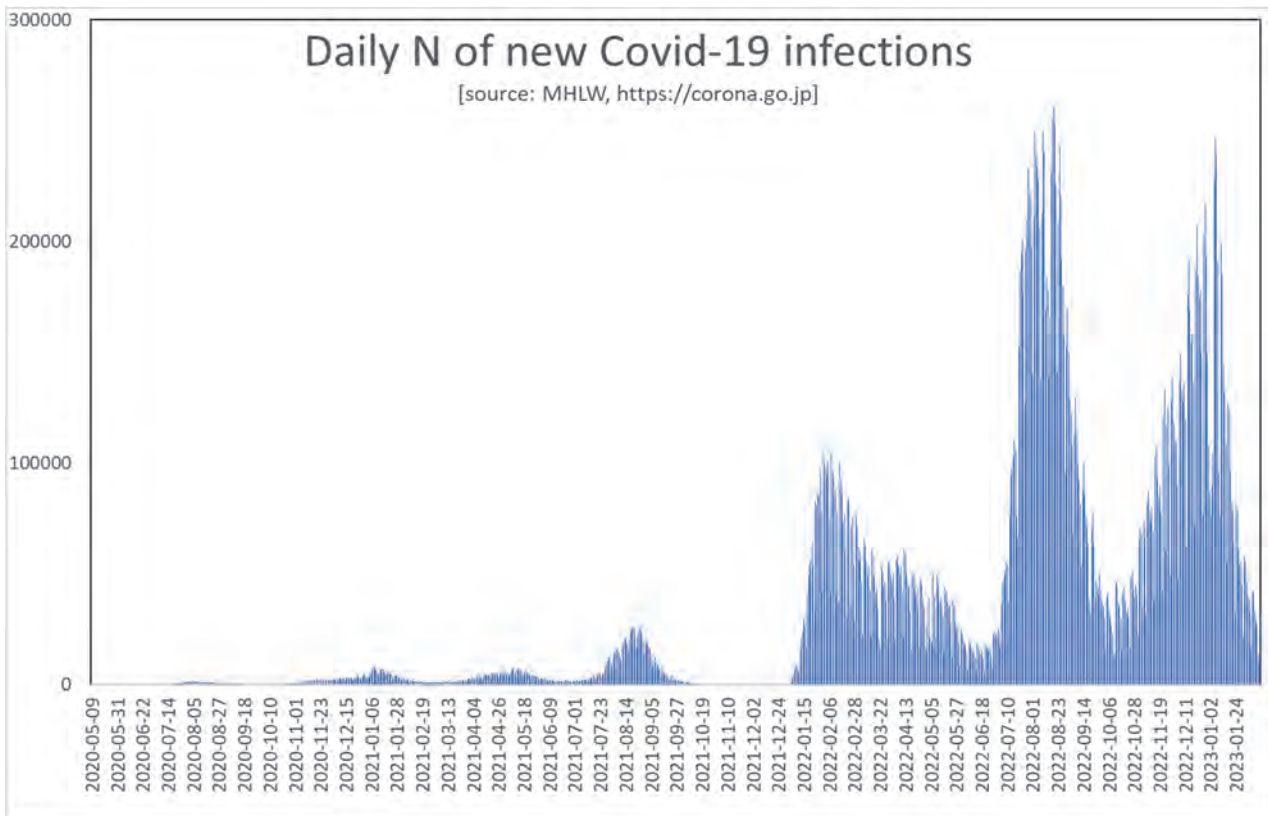
3)The state of emergency declarations

On 7th April 2020, the states of emergency were declared in seven major prefectures including Tokyo and Osaka, which was later expanded to the entire country on 16th April. Under the state of emergency, people were encouraged to stay-at-home and restaurants were ordered to close before dusk. The state of emergency was repeated four times as shown.

Periods of the state of emergency

1st : 2020/4/7~5/25
 2nd : 2021/1/8~3/21
 3rd : 2021/4/25~6/20
 4th : 2021/7/12~9/30

Japan has been haunted by seven waves of epidemic. As the graph below shows, the first four waves in 2021 appear to be negligible when compared with the following waves in 2022 particularly after the emergence of the Omicron variant. As of February 2023, the cumulative number of infections was approximately 33 million (26% of Japan's population) and the cumulative deaths was 71,686.



Stigma toward COVID-19 victims: Are the victims to blame?

Although Japan has relatively been spared of the scourge of the epidemic, victims of COVID-19 in Japan may face worse stigma than most countries. A psychology professor conducted an international survey to compare the people's attitude toward victims and found that Japanese are less sympathetic to the victims than other countries.

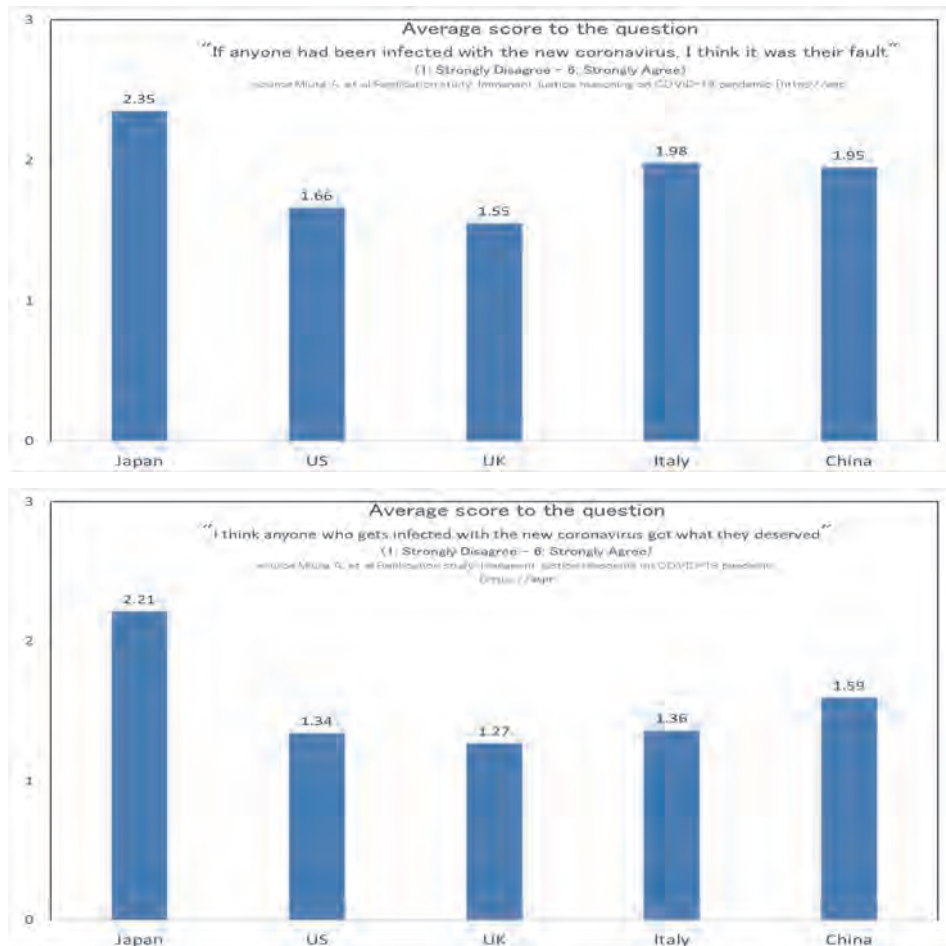
Prof. Miura, in collaboration with researchers in US, UK, Italy and China, surveyed the following questions to the general public in March-April 2020 asking them to grade their attitude (immanent justice reasoning, IJR) from strongly disagree (1) to strongly agree (6).

Q1: If anyone had been infected with the new coronavirus, I think it was their fault.

Q2: I think anyone who gets infected with the new coronavirus got what they deserved.

[Miura A, et al. Replication study: Immanent justice reasoning on COVID-19 pandemic <https://aspredicted.org/3bf3a.pdf>]

In both questions, Japan scored higher than four countries, signifying that Japanese are less sympathetic to the victims than people in four comparing countries. In fact, a considerable number of victims suffered not only from the disease but also stigma given by neighbors and social networking.



5. Intractable diseases

The term "intractable disease" holds a distinct administrative definition, encompassing conditions meeting specific criteria. It refers to diseases with unknown causes, lacking established therapies, and likely leading to chronic disabilities. Additionally, these ailments require long-term care, causing mental stress and imposing a substantial financial burden on households. Notably, malignant neoplasms are excluded from this classification.

The origins of intractable diseases trace back to the late 1960s when SMON (subacute myelo-optico-neuropathy), a chronic neurological disorder, emerged as an epidemic. Initially shrouded in mystery, SMON's cause was later identified as a side effect of the stomach drug chinofom. Despite the clarification, the initial lack of understanding subjected patients to social stigma. The SMON tragedy prompted governmental intervention, leading to the coinage of the term "intractable disease."

The special measure, initiated in 1972, initially targeted four diseases: SMON, SLE (systemic lupus erythematosus), myasthenia gravis, and Bechet disease. This initiative involved research grants and public subsidies, covering 30% of healthcare copayments for patients. Over time, the perception shifted, with many viewing it more as a social welfare program than a research effort. The continuous

demand to include more diseases in the category reflects the hope for increased subsidies.

As of 2021, the program encompasses 338 diseases, with 18 having no registered patients. The total registered patients reached 1,021,606 by March 2021, making it a substantial patient database for rare diseases. The data derived from intractable disease research is available at www.nanbyou.or.jp.

(1) Research and Subsidies for Diseases of Scientific Interest

Japan employs disease-specific research and public subsidy programs for diseases termed "diseases of scientific interest," totaling 130 as of 2009. These programs involve research grants and public subsidies for patients, aiming to waive 20-30% of healthcare copayments for eligible patients under the national health insurance system. The patient cooperation with research programs is crucial for these subsidies, facilitating epidemiological surveys. The enactment of "The Law for Health Care for Nanbyo Patients" in January 2015 expanded the target diseases from 56 to 110, with copayments reduced to 20% but with exclusions for some patients.

(2) Patient database

Japan benefits from a national clinical database for rare diseases due to the subsidy system covering intractable diseases. The Nanbyo Information Center (<http://www.nanbyou.or.jp/english/index.htm>) established this database in 2019, facilitating various research endeavors. Presently, 338 diseases are listed as intractable diseases in the database, with specific patient numbers available for each disease. The administrative report highlights distinct age-distribution patterns across different diseases.

Age-distribution of intractable diseases (top 10 diseases with most patients)

	Parkinson disease	Ulcerative colitis	SLE	Crohn disease	PLLO	scleroderma	spinocerebellar deg.	Myasthenia gravis	dermatomyositis	retinitis pigmentosa
total	142375	140574	64468	47633	36401	27647	27365	25416	24894	23979
00~09yo	-	5	2	3	-	-	1	14	4	3
10~19yo	4	1331	303	705	-	14	40	120	72	107
20~29yo	19	15204	4808	8661	25	193	351	583	418	325
30~39yo	137	22740	9079	10913	294	562	949	1305	1052	773
40~49yo	1214	31697	15119	12499	2043	1882	2184	2830	2907	1865
50~59yo	5347	28371	13354	8525	4881	4137	3447	4013	4799	3022
60~69yo	20776	20574	10699	3736	8041	7002	5783	5244	6365	4975
70~74yo	27444	9760	5400	1299	6746	5530	4830	3753	3997	4120
>=75yo	87434	10892	5704	1292	14371	8327	9780	7554	5280	8789

SLE: systemic lupus erythematosus, PLLO:posterior longitudinal ligament ossification

What is "Nanbyo"?

The research and subsidy program for diseases of scientific interest was started in 1972. It was prompted by a mysterious outbreak of "SMON (*Sub-acute myelo-optico-neuropathy*)" disease. The disease appeared as an unknown neurological disease around 1955 and developed into a nation-wide epidemic in around 1967-68. It took a long time before the disease was revealed to be a iatrogenic disease caused by chinofom, a digestive drug commonly used then. Many patients suffered from an unfounded speculation that it was contagious. A public outcry that the government should take measures to deal with such unknown diseases eventually led to an establishment of the research and subsidy program. Initially, four diseases were designated as *Nanbyo*

(intractable diseases in Japanese): SMON, Bechet, SLE and ulcerative colitis. The initial four diseases were expanded to 56 in 2013 and will further be expanded to 110 in 2015.

For the purpose of subsidy, nanbyo is defined as follows:

- 1) the number of patients is less than 0.1% of the population
- 2) causes unknown
- 3) effective treatments are not established
- 4) long-term burden on daily living
- 5) established diagnostic criteria

Intractable diseases and the number of patients (by descending order)

Parkinson's disease	142375	Buerger's disease	2259	Bad chiari syndrome	225
Ulcerative colitis	140574	Pustular psoriasis (universal)	2058	Stevens-Jonson syndrome	219
Systemic lupus erythematosus	64468	Primary immunodeficiency syndrome	1943	Crow-Fukase syndrome	215
Crohn's disease	47633	Giant cell arthritis	1716	TGA	211
Ossification of the posterior longitudinal ligament	36401	Spinobulbar muscular atrophy	1622	Pulmonary proteinosis (autoimmune)	204
Systemic scleroderma	27647	Mitochondrial diseases	1602	Double outlet right ventricle (DOR)	203
Spinocerebellar degeneration (except multiple sclerosis)	27365	Lysosomal storage disease	1529	Brain table hemosiderosis	202
Myasthenia gravis	25416	Idiopathic multicentric Castleman disease	1354	Heredomacular dystrophy	202
Dermatomyositis/polymyositis	24894	Frontotemporal lobar degeneration	1287	Alport's syndrome	195
Retinitis pigmentosa	23979	Autoimmune hemolytic anemia	1275	Cronkhite-Canada syndrome	189
Multiple sclerosis/Optic neuromyelitis	21437	Eosinophilic gastrointestinal disease	1144	Idiopathic thrombosis (limited to the lower extremities)	177
Idiopathic dilated cardiomyopathy	20387	Rapidly progressive glomerulonephritis	1084	Pituitary TSH secretion hyperthyroidism	175
Idiopathic femoral head necrosis	20003	Purpura nephritis	1045	Corrected TGA	172
Idiopathic thrombocytopenic purpura	18793	HTLV-1-associated myelopathy	1027	West syndrome	168
Anterior pituitary hypothyroidism	18653	Primary sclerosing cholangitis	1010	Prader-Willi syndrome	167
Primary biliary cholangitis	17993	Marfan syndrome	1003	Chronic idiopathic pseudo-bowel obstruction	165
Sjogren's syndrome	17628	Huntington disease	950	Ehlers-Danlos syndrome	165
Idiopathic interstitial pneumonia	17589	Paroxysmal nocturnal hemoglobinuria	927	Tricuspid atresia	161
Sarcoidosis	16138	Cushing's disease	926	Autosomal dominant cerebral arteriovenous malformation	156
Behcet's disease	15537	Myelopathic muscular atrophy	921	Autosomal dominant cerebral arteriovenous malformation	156
Moyamoya disease	13894	Lymphangioleiomyomatosis	885	Leber's hereditary optic neuropathy	134
Eosinophilic sinusitis	13404	Tuberous sclerosis	880	Primary lateral sclerosis	127
Progressive supranuclear palsy	12766	Congenital adrenal cortex enzyme deficiency	864	Alveolar hypoventilation syndrome	122
IgA nephropathy	12699	Interstitial cystitis	863	Idiopathic basal ganglia calcification	115
Primary Nephrotic syndrome	12018	Relapsing polychondritis	840	Ebstein disease	115
Polycystic kidney disease	11935	Acquired pure red cell aplasia	818	Aniridia	115
Multiple-system atrophy	11694	Osler disease	802	Werner's syndrome	114
Microscopic polyangiitis	10681	Primary antiphospholipid antibody syndrome	797	Osteogenesis imperfecta	113
Amyotrophic lateral sclerosis	10514	Charcot-Marie-Tooth disease	774	Isaacs syndrome	108
Mixed connective tissue disease	10182	Systemic-onset juvenile idiopathic arthritis	743	Pulmonary atresia with intact ventricular septum	105
Aplastic anaemia	8724	Wilson's disease	695	Pseudohypoparathyroidism	105
Autoimmune hepatitis	6962	Inclusion body myositis	690	Huge arteriovenous malformation	105
Ossification of the ligamentum flavum	6715	Syringomyelia	626	Hereditary dystonia	103
Extensive spinal canal stenosis	5845	Tetralogy of Fallot	597	Vickers staff brainstem encephalitis	103
Malignant rheumatoid arthritis	5281	Prion disease	481	Pseudoxanthoma elasticum	101
Eosinophilic multiple vasculitis granulomatous	5162	Familial Mediterranean fever	471	Pulmonary atresia with ventricular septal defect	95
Chronic inflammatory demyelinating polyradiculoneuropathy	5158	Idiopathic acquired systemic anhidrosis	433	Glycogen storage disease	92
Muscular dystrophy	5056	Autoimmune hemorrhaphilia XIII	423	Atypical hemolytic uremic syndrome	90
Corticobasal degeneration	4749	Biliary atresia	373	Myelomeningocele	87
Takayasu's disease	4730	Thrombotic thrombocytopenic purpura	361	Achondroplasia	85
Pituitary growth hormone secretion hyperthyroidism	4613	Familial hypercholesterolemia (homozygous)	352	Chronic nonspecific multiple ulcer	85
Chronic thromboembolic pulmonary hypertension	4608	Single ventricle	349	Urea cycle disorders	84
Hypertrophic cardiomyopathy	4481	Vitamin D-resistant rickets/osteomalacia	342	Rett syndrome	80
Pulmonary arterial hypertension	4230	Primary membranoproliferative glomerulonephritis	333	Xeroderma	80
Spondylarthritis ankylopoietica	4219	Addison's disease	329	Congenital ichthyosis	80
Neurofibromatosis	4218	Anti-glomerular basement membrane disease	319	Sturge-Weber syndrome	79
Adult-onset Still's disease	4148	Congenital myopathy	316	Chronic nonbacterial osteomyelitis	77
Pemphigoid (including acquired epidermolysis bullosa)	3965	Idiopathic portal hypertension	312	Asplenia syndrome	75
Systemic amyloidosis	3892	Epidermolysis bullosa	309	Cryopyrin associated periodic fever	74
Pituitary ADH secretion disorders	3641	Accessory thyroid hypergalia disease	307	Subacute sclerosing panencephalitis	72
Pemphigus	3515	Distal muscular dystrophy	295	22q11.2 deletion syndrome	71
Multiple vasculitis granulomatous disease	3196	Adrenoleukodystrophy	255	Focal cortical dysplasia	70
IgG4-related disease	3016	Phenylketonuria	248	Toxic epidermal necrosis	68
Polyarteritis nodosa	2347	Lennox-Gastaut syndrome	241	Medial temporal lobe epilepsy with amnesia	67
Pituitary PRL secretion hyperthyroidism	2260	Klippel-Trenaury-Weber syndrome	236	Constrictive cardiomyopathy	64

Familial benign chronic pemphigus	60	Blau syndrome	20	Arima syndrome	6
Progressive multifocal leukoencephalopathy	59	Non- dystrophic myotonia syndrome	20	Pheiffer syndrome	6
Hereditary periodic paralysis	59	Otawara syndrome	20	Branchio-oto-renal syndrome	6
Dorabe syndrome	55	Hypophosphatasia	20	No. 14 chromosome father disomy	6
Citrin deficiency	51	Ascher syndrome	19	Glutaric acidemia type	6
Congenital adrenal hypoplasia	49	VATER syndrome	18	Nakajo-nisimura syndrome	6
Epilepticus type (biphasic) acute encephalopat	48	Sitosterolemia	18	Marinesco - Sjogren ' s syndrome	5
Congenital nephrogenic diabetes insipidus	48	Charge syndrome	17	4psyndrome	5
Huge venouse malformation [neck oropharynge.	48	Pachydermoperiostosis syndrome	17	Fragile X syndrome related diseas	5
Nerve cell migration disorder	47	Crouzon syndrome	17	Vitamin D-dependent rickets/oste	5
Williams ' syndrome	46	Progressive leukoencephalopathy	17	Multiple carboxylase deficiency	5
Polysplenia syndrome	45	Beth Rem myopathy	16	Abeta-lipoproteinemia	5
Cerebrotendinous xanthomatosis	44	Aicardi syndrome	14	Thanatophoric dysplasia	5
Lymphangiomas/gorham ' s disease	44	Mowat - Wilson syndrome	14	Perry syndrome	4
Thyroid hormone insensitivity syndrome	43	Sotos ' syndrome	14	Nasu-Hakola disease	4
Alexander disease	43	α 1-antitrypsin deficiency	14	Coffin-Lowry syndrome	4
Refractory frequent partial seizures intussusce	41	Huge lymphatic malformation (cervicof	14	Coffin Siris syndrome	4
Porphyria	41	Cloacal exstrophy	14	Lecithin-cholesterol acyltransfera:	4
Persistent cloaca	41	Anomalous anterior segment formation	14	Myoclonic epilepsy absences	3
Atopic myelitis	40	Ring chromosome	13	Emanuel syndrome	3
Pituitary gonadotropin secretion hyperthyroidisr	39	Glucose transporter	13	Fragile X syndrome	3
Congenital insensitivity to pain with anhidrosis	39	Cystic fibrosis	13	Isovaleric adidemia	3
Noonan ' s syndrome	39	Carnitine circuit disorder	13	Glutaric acidemia type	3
Alagille syndrome	39	Congenital myasthenic syndrome	12	Triple enzyme deficiency	3
Rasmussen ' s encephalitis	37	Intestinal ganglion cells insignificant di	12	Aromatic L-amino acid decarboxyl	3
Hypoplastic left heart syndrome	37	PCDH19 related syndrome	12	Nerve ferritin disease	2
Juvenile-onset bilateral sensorineural hearing l	35	Maple syrup urine disease (MSUD)	12	Anley-Bixler syndrome	2
Neuroacanthocytosis	33	Propionic acidemia	12	Trothmund-Thomson syndrome	2
Progressive myoclonic epilepsy	33	Fanconi anemia	12	High tyrosinemia type	2
Congenital cerebral white matter asplasia	32	Hereditary sideroblastic anemia	12	Galactose-1 - phosphate uridyltra	2
Epilepsy with continuous spikes and waves dur	32	Epstein-Barr virus	12	Congenital tricuspid stenosis	2
Obliterating bronchiolitis	31	Hirschsprung disease (entire colon typ	12	Left pulmonary artery right pulmor	2
Primary hyperlipidemia	31	Moebius syndrome	11	Sepiapterin reductase (SR) deficie	2
Lipodystrophy	31	Nervous system malformation/De Mor:	11	Gelatinous drop-like corneal dystro	2
Delayed endolymphatic hydrops	31	Early myoclonic encephalopathy	11	Schwarz Yanperu syndrome	1
TNF receptor associated periodic syndrome	30	Kabuki syndrome	11	Huge bladder short and small colo	1
Tmc/Art.; truncus arteriosus	29	Adrenocorticotrophic hormone insensitiv	10	Menkes disease	1
Congenital tracheal stenosis/Congenital subgl	29	Rubinstein - Teibi syndrome	9	Okushipitaru horn syndrome	1
Congenital syndrome	28	Wolfram syndrome	9	5psyndrome	1
Angelman syndrome	27	Congenital thropoietic anemia	9	Smith-Magenis syndrome	1
Pulmonary venous obstruction/pulmonary capill	25	Hereditary autoinflammatory disease	9	High tyrosinemia type 3	1
Muscle type glycogen storage disease	25	Autophagic vacuolar myopathy	8	Hyper-IgD syndrome	1
Hereditary pancreatitis syndrome	25	Costello syndrome	8	Canavan disease	1
One side convulsions, hemiplegia - epilepsy sy	24	Congenital supranuclear pasly	8	Congenital pulmonary vein stenosi	1
Methylmalonic acidemia	24	ATR-X syndrome	8	Nonketotic hyperglycinemia	1
Chronic nonbacterial osteomyelitis	24	Apert syndrome	8	Weaver ' s syndrome	-
Congenital scoliosis with rib anomaly	24	1p36 deletion syndrome	8	Young Simpson ' s syndrome	-
Hemimegalencephaly	23	Tangier disease	8	Galloway-Mowat syndrome	-
Oculocutaneous ablinism	23	Purulent gonitis · pyoderma gangrenosu	8	Peroxisomal disease(excluding ad-	-
Fibrodysplasia ossificans progressive	23	Congenial diaphragmatic hernia	8	High tyrosinemia type	-
Diamond-blackfan anemia	23	Congenital mitral valve stenosis	8	Congenital malabsorption of falate-	-
Ulrich disease	22	Autosomal recessive leukoencephalop:	7	Infant giant liver hemangioma	-
Epilepsy with myoclonic cataplexy	21	Landau-Kleffner syndrome	7	Congenital glycosylphosphatidylin-	-
Infant epilepsy with migratory focus seizure	21	Cockayne ' s syndrome	7	β -ketothiolase deficiency	-
Camery complex	21	Nail Patera syndrome/LMX 1 B-relatec	7	Methyl glutamic nuria	-
Marble bone disease	21	CFC syndrome	6	Hutchinson-Gilford syndrome	-

Chapter 4. Specialty-specific measures

1. Maternal and Child Health

Japan's remarkable success in reducing infant mortality, from as high as 150-160 per thousand births in the early 20th century to the current figure of 1.8 (2022), stands as a testament to the effectiveness of its post-war Maternal and Child Health (MCH) policy.

(1) Prenatal care

Under the MCH Act, pregnant mothers report to municipal governments, receiving MCH notebooks for access to public-funded health guidance and preventive activities. Municipal health centers offer free MCH services, but prenatal care and deliveries are handled by private OBGY doctors or midwives. Charges for prenatal care aren't reimbursed by health insurance, yet a lump sum of 420,000 yen, or additional subsidies for prenatal checks, aids in easing financial burdens. Health guidance continues after birth, especially for babies weighing 2500g or less.

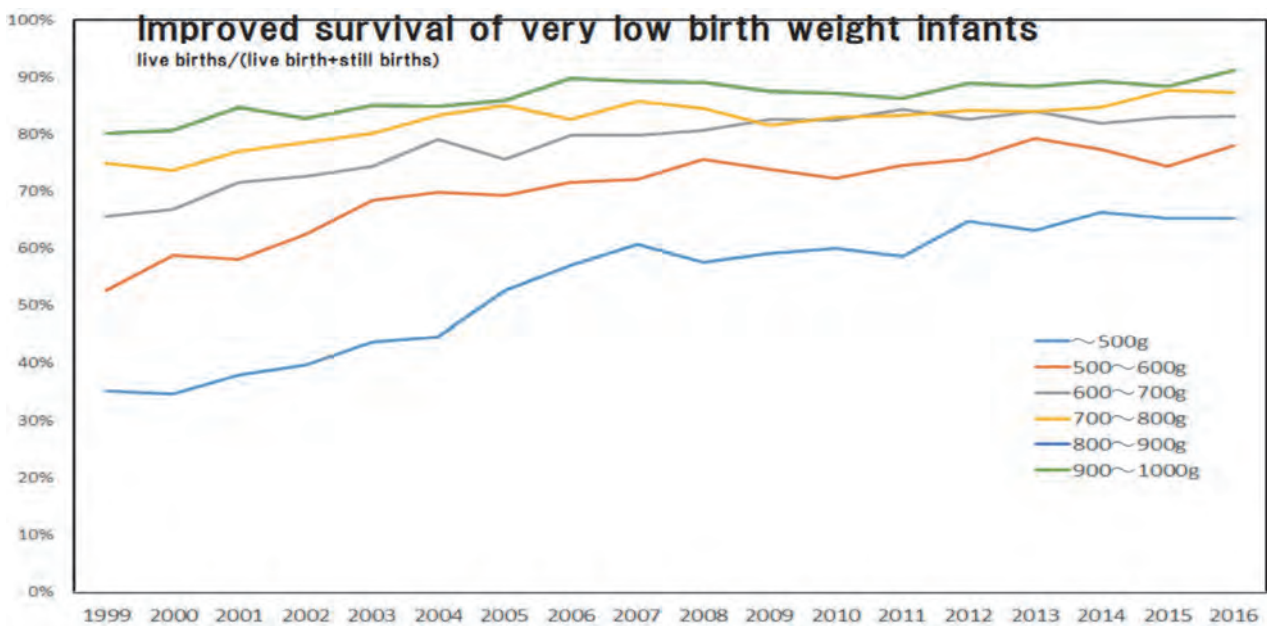
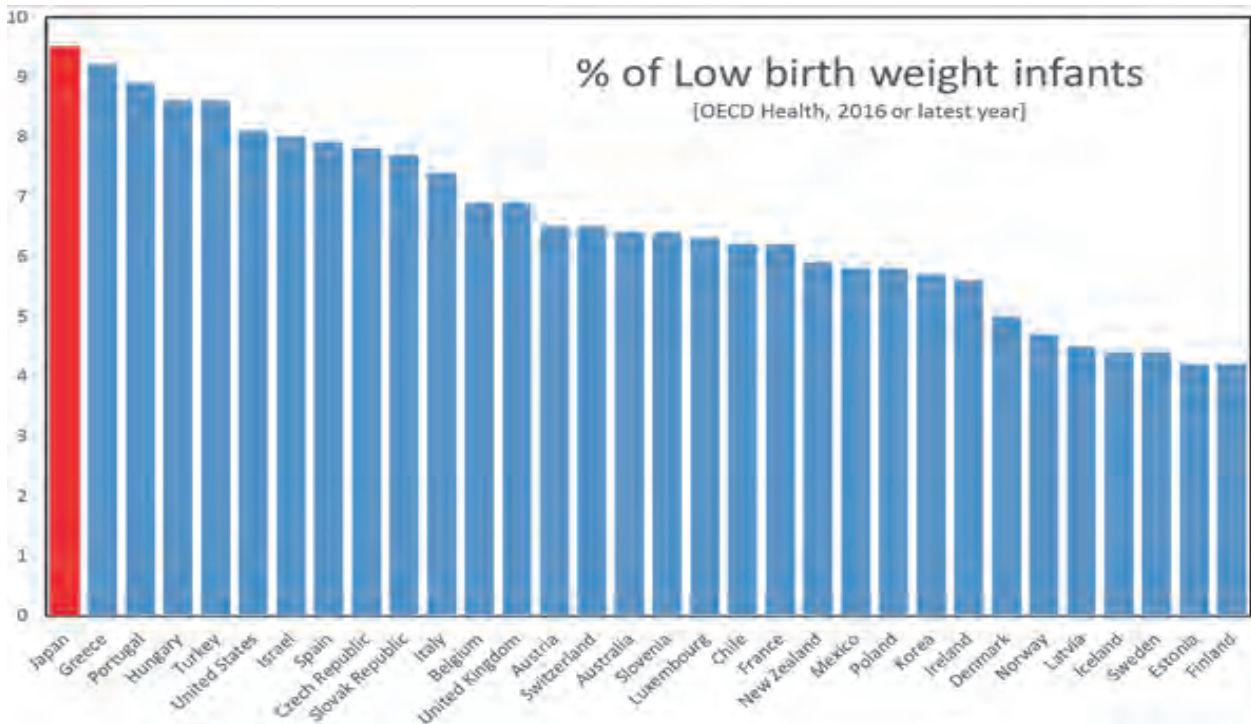
(2) Neonatal screening

All newborns undergo public-funded mass screening for congenital metabolic diseases, while babies born to HB-positive mothers receive immunoglobulin and vaccination. Despite administrative reports lacking statistics on HB-positive cases, the screening program has been pivotal. The mass screening program for neuroblastoma, discontinued in 2004, faced questions about its effectiveness.

To detect preventable causes of intellectual impairments such as phenylketouria, mass screening program for neonates has been conducted since 1977. By 2021, 19,467 Cretinism, 800 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.

(3) Low birth weight babies

Japan's high rate of low birth weight (LBW) babies, around 10%, reflects advanced neonatal care's success. Intensive care for very low birth weight babies is covered by health insurance, with a waiver for the usual 20-30% copayment for babies below 2000g.



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.

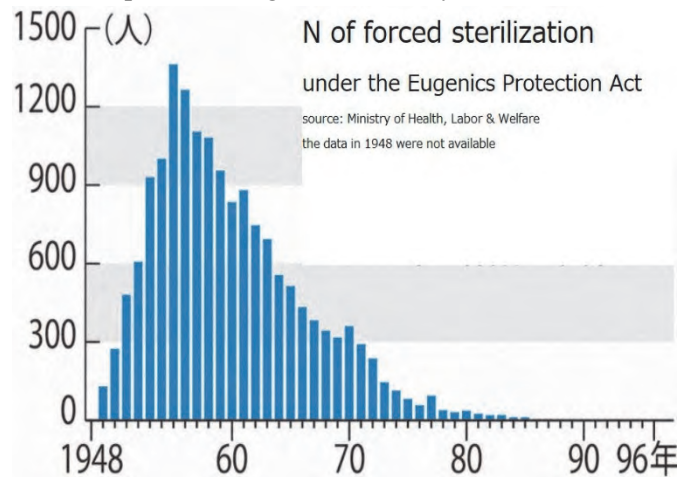
(4) Follow-up after birth

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

2. Reproductive Health and Policy

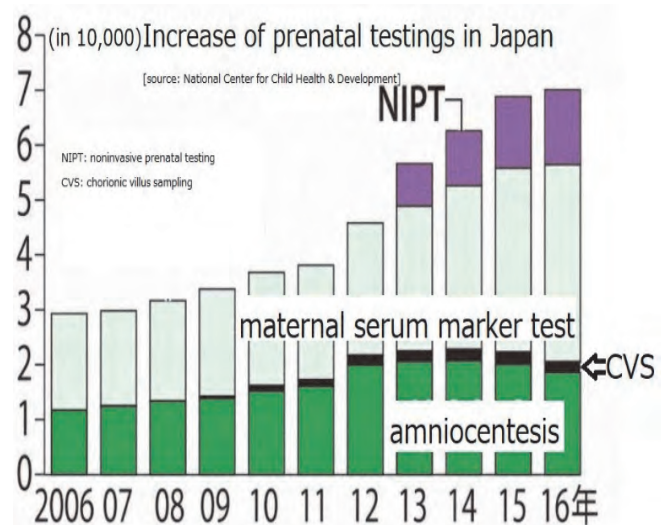
(1) History

Pre-war Japan encouraged childbearing, penalizing abortions through the Penal Code and supporting forced sterilization for people with disability under the National Eugenics Act. However, such population growth policy was drastically changed in the post-war era for fear of overpopulation. As part of population control measure, legalizing abortions and promoting voluntary sterilization pursuant to the Eugenics Protection Act. In 1996, the Eugenics Protection Act was revised to the Maternity Protection Act abolishing the forced sterilization clauses for people with disability. Afterward, forced sterilization became viewed as a dark side of Japan's population policy. A victim's lawsuit in 2018 and discussions on an official apology reveal ongoing repercussions.



(2) Prenatal screening

With an aging population, interest in prenatal screening grows. Amniocentesis, performed at mothers' request, lacks mandatory offering by OBGY doctors. Maternal serum marker testing, which measures certain substances such as AFP (alpha fetoprotein) to predict the probability of chromosomal aberrations, was introduced in 1990s. Alarmed by potential malpractice threats for failing to inform pregnant mothers of the option, the MHLW issued a guidance exempting OBGY doctors from mandatory offering.



The non-invasive prenatal testing (NIPT) introduced in 2013 faces restrictions, limiting eligibility to women aged 35 or over, with genetic counseling prerequisites. The “non-informing” principle was revised in 2021 by the revised recommendation by the committee, which states that “it is appropriate to inform pregnant women of the options of prenatal screening without persuasion”.

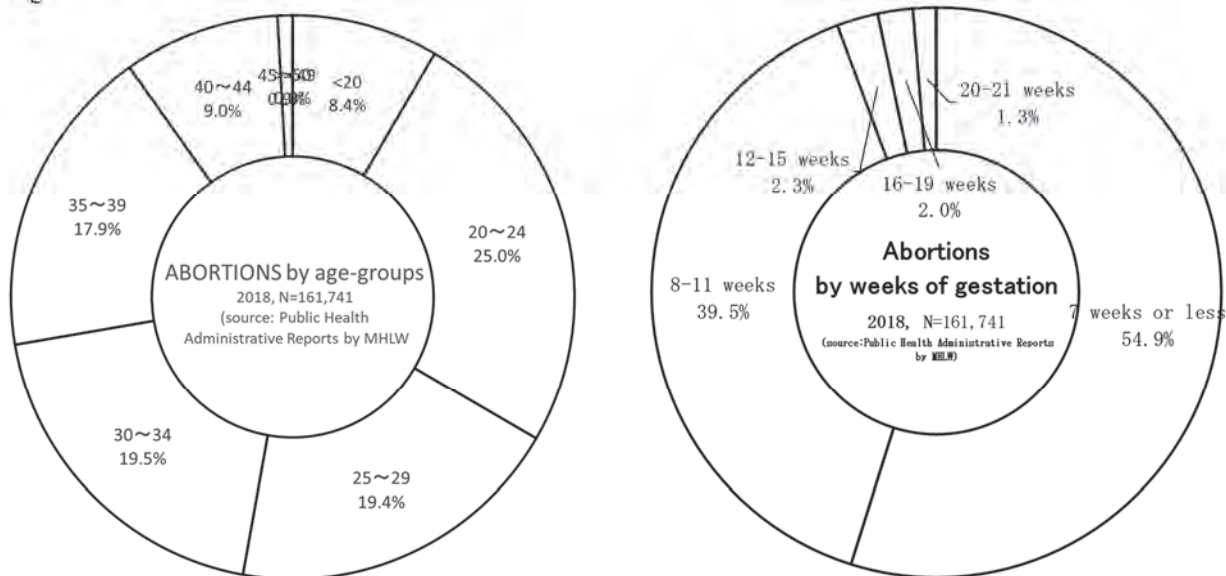
Results of NIPT (N=58150, April 2013~March 2018)

	trisomy21	trisomy18	trisomy13	total	
positive results (P)	617	327	93	1037	
positive rate	1.06%	0.56%	0.16%	1.78%	
confirmed {	true positive (TP)	547	238	52	837
	false positive (FP)	20	32	37	89
	non-confirmed	50	57	4	111
outcome					
aborted (AB)	515	173	41	729	
AB/(P-FP)	86.3%	58.6%	73.2%	76.9%	
intrauterine fetal death (IUFD)	52	101	13	166	

[source: http://www.nipt.jp/nipt_04.html]

(3) Abortions

Japan remains "pro-choice" with the Maternity Protection Act (MPA) allowing certified doctors to perform abortions up to 21 weeks for health or rape-related concerns. Penal Codes penalize illegal abortions, but those under the MPA are exempt. Reported abortions in 2021 numbered 126,174, mostly for maternal health protection. Teenage abortions declined sharply since 2001 due to government efforts and increased contraceptive use, marking a positive trend in unwanted pregnancies.



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 4.7 per 1000 teenage (15-19yo) girls undergo abortions annually (2018), a sharp decline since 2001 when the figure was 13.

Japan turns pro-life!?

Although Japan is a pro-choice country, controversies arose when an innovative new prenatal screening was approved in 2012. The controversial new technology was

the non-invasive prenatal genetic testing (NIPT) developed by a US venture Sequenom. The new technology named MaterniT21 can diagnose Down syndrome and other chromosomal aberrations in fetuses just by testing mother's blood. The new test is much safer than amniocentesis and more accurate. Some OBGY doctors expressed concerns that pregnant mothers who find their fetuses having congenital disorders may choose abortions. The OBGY society proposed a guideline to restrict the testing to a few hospitals with sufficient number of counselors. Mothers with positive results will be counseled to make informed choices. Japan's Maternity Protection Act prohibits abortions solely based on the malformations of fetuses. However, there was evidence that while the number of total abortions has declined consistently, the estimated number of abortions of fetuses diagnosed as having abnormalities by prenatal diagnoses did increase two fold after 2000 (shown below).

Estimated N of abortions due to congenital anomaly

	1990-99	2000-09
anencephalus	938	1180
hydrocephalus	123	173
fetal hyrops	507	1341
nuchal translucency	526	1077
Down syndrome	368	1122
others	2919	6813
total	5381	11706

Yokohama City Univ, International Congenital Malformation Monitoring Center
 source: Yomiuri Newspaper dated 22nd July 2011

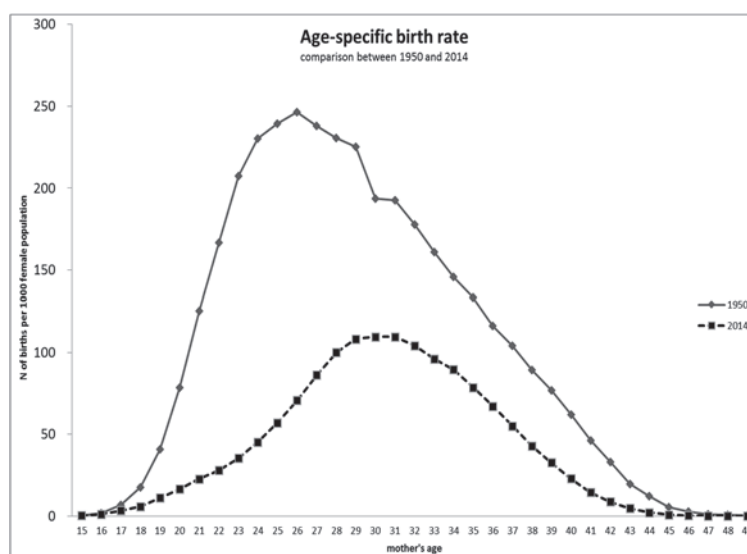
(4) Assisted reproductive treatment (ART)

Japan stands at the forefront of the assisted reproductive treatment (ART) landscape, witnessing the birth of 69,797 babies through ART in 2021, constituting 8% of total births, as reported by the Japan Obstetrics and Gynecology (OBGY) Society.

A growing number of couples grapple with infertility, primarily attributed to the advancing age of mothers. In 2020, the average maternal age reached 32 years, a significant five-year increase since 1973.

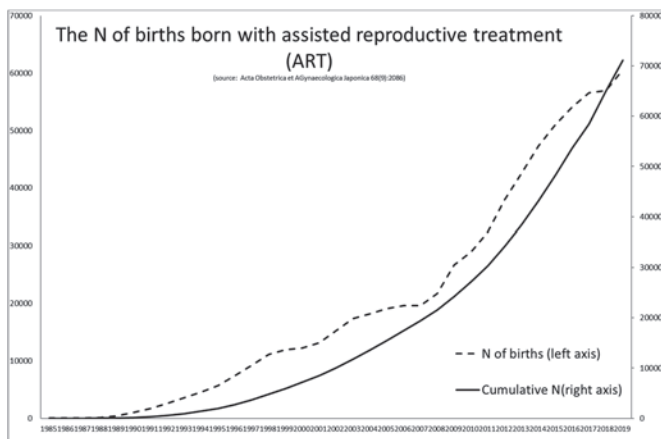
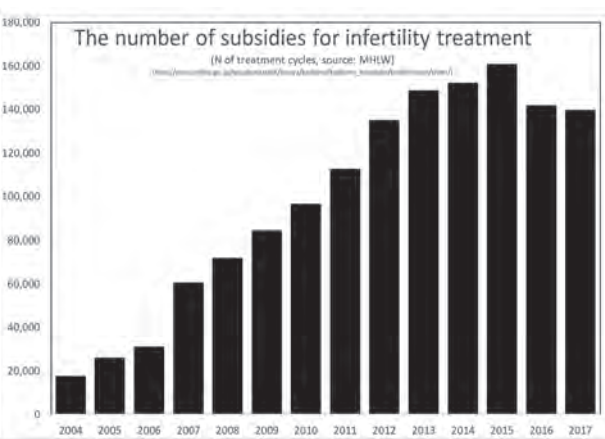
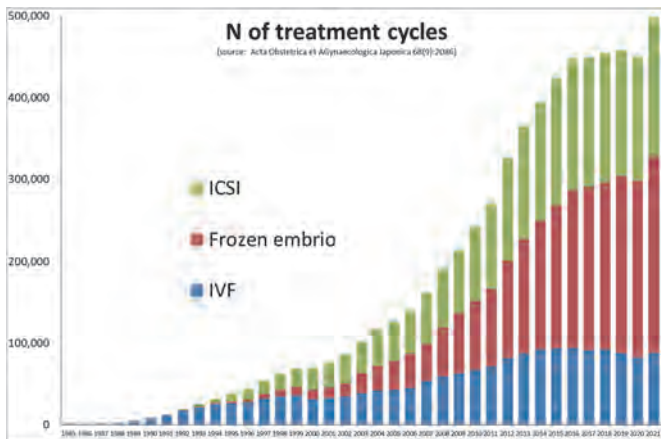
The government, recognizing the challenges faced by infertile couples, initiated financial assistance in 2004.

Initially capped at a maximum of 150,000 yen, the support could be availed up to three times a year for a maximum of five years. In 2011, a revision expanded the allowance to "up to three times a year with a maximum of ten times," emphasizing the importance of concentrated trials while mothers are still in their youth.



In 2016, an age limit of 43 was set due to decreased pregnancy probabilities beyond this threshold, resulting in a decline in subsidies awarded.

Despite the prevalence of ART, it remained outside the coverage of health insurance schemes, with unregulated prices for procedures like in vitro fertilization (IVF) and intracytoplasmic sperm injection (ICSI). The considerable price variations posed a financial deterrent for young couples considering ART. However, in April 2022, as ART was incorporated into public health insurance benefits, with prices regulated by the national uniform fee schedule. Eligible couples, where women must be younger than 43 at the start of treatment, can access ART by paying a 30% copayment, with a financial cap in place. The inclusion in health insurance benefits may induce demand, presenting concerns given the existing shortage and geographical maldistribution of providers. The extent to which this inclusion will impact demand remains uncertain.



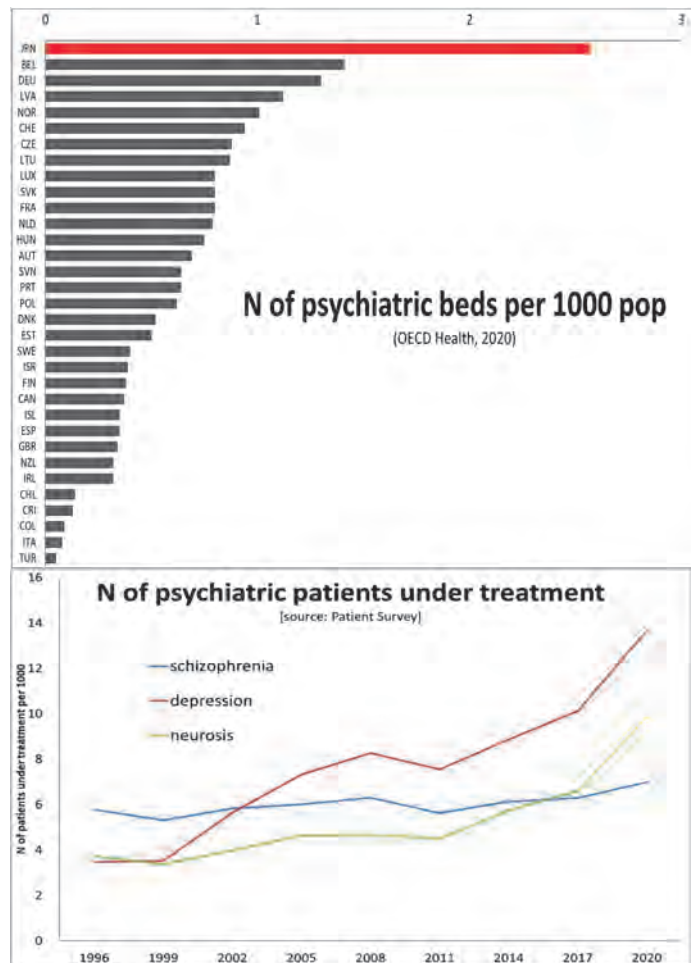
3. Mental Health

Japan's mental health system is characterized by a significant reliance on hospitalization, boasting the highest number of psychiatric hospital beds per capita globally, with 324,481 beds in 2020 (equivalent to 264 beds per 100,000 population), and an 84.8% occupancy rate. In 2020, the average duration of stay in psychiatric hospitals was 277.0 days, and psychiatric patients in hospitals constituted approximately 0.25% of the entire population.

This tendency towards "institutionalism" can be partially traced back to a historical incident in the late 60s known as the Reischauer incident in 1964, where the then U.S. ambassador was attacked by a psychiatric patient. This event sparked public concern about the potential danger posed by allowing mentally ill individuals into the community, leading to a push for the construction of psychiatric hospital beds to segregate such patients from the broader society. However, this perceived societal "safety" may have come at the expense of the rights of psychiatric patients.

Conversely, a series of scandals involving abuse within some psychiatric hospitals triggered discussions about potential human rights violations against psychiatric patients. In response, the Mental Health Act was amended in 1987 to place greater emphasis on protecting the human rights of psychiatric patients by tightening the conditions for involuntary hospitalization.

The Mental Health Act outlines five types of involuntary hospitalization: detention hospitalization, emergency detention hospitalization, custodial hospitalization, immediate therapeutic hospitalization, and observational hospitalization. Detention hospitalization, the most restrictive, is granted when a psychiatric patient poses a "clear and present" danger to themselves and/or the public, as agreed upon by more than one qualified psychiatrist. The prevalence of detention hospitalization has declined significantly since 1965, now accounting for only 0.8% of psychiatric hospitalizations, with voluntary and custodial hospitalizations making up the majority.

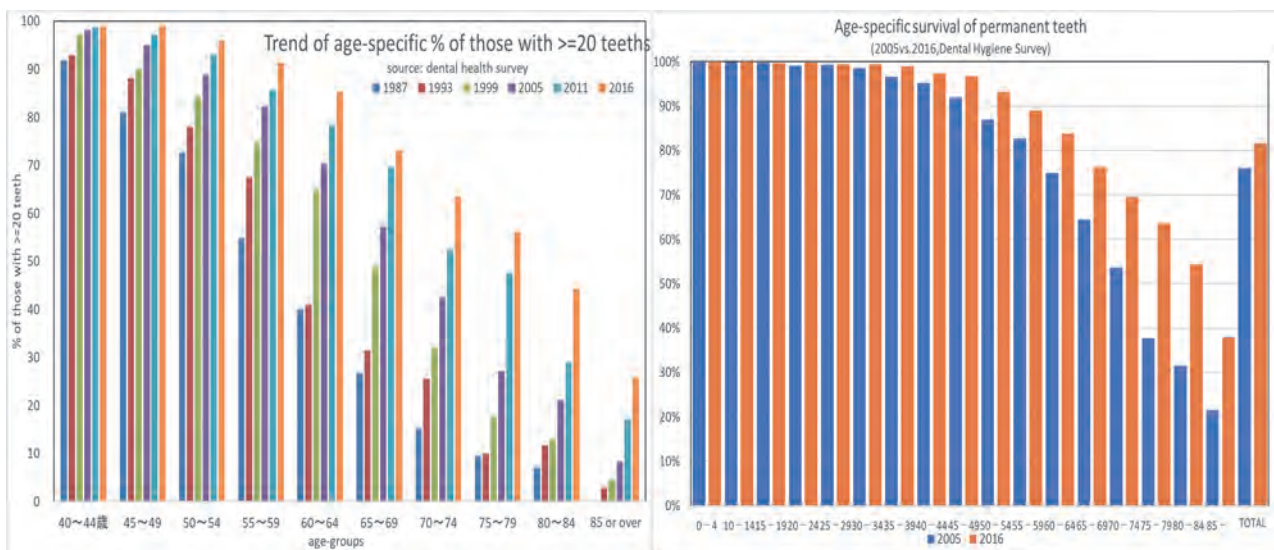


To promote the discharge of psychiatric patients from hospitals and encourage their integration into the community, substantial subsidies are provided to cover copayments for outpatient treatment. The number of psychiatric patients treated on an outpatient basis has surged, particularly for conditions like depression and eating disorders, while the number of schizophrenia cases has remained stable.

Unfortunately, there have been isolated criminal cases involving psychiatric patients living in the community. According to the Penal Code, crimes committed in an unconscious state are exempt from criminal prosecution or may result in a non-guilty verdict. In response, the "Medical Care and Observation Act for Those who Commit Crimes under Unconsciousness" was enacted in 2005 to ensure proper medical treatment and observation for individuals acquitted due to unconsciousness.

4. Oral Health

Japan's commitment to oral health traces back to the Taisho era (1912-25) when educational initiatives emphasizing oral hygiene were initiated. Post-war, public



health centers provided oral health activities as part of Maternal and Child Health (MCH), presuming that tooth cavities were primarily a concern for children. In 1928, a noteworthy campaign was launched designating June 4th as "oral health awareness day" due to its pronunciation, "mu-shi," resembling tooth cavities in Japanese.

The groundbreaking "8020 campaign" commenced in 1989, advocating for the preservation of at least 20 teeth at the age of 80. Initially focusing on elderly health to address the risk of deteriorating teeth leading to malnutrition, the campaign's jurisdiction expanded from the Elderly Health Act to the Health Promotion Act in 2008, encompassing the entire population.

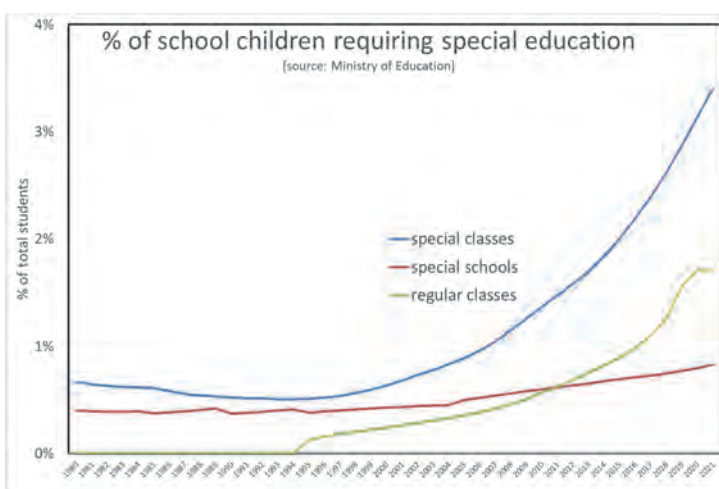
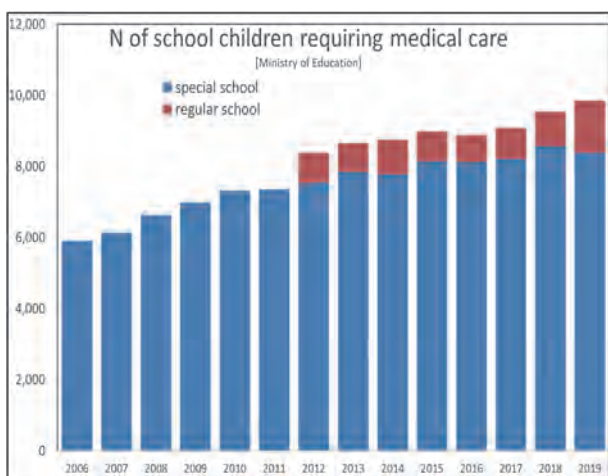
The Ministry of Health, Labour and Welfare (MHLW) has conducted a nationwide oral health survey every six years since 1957. Since the introduction of the "8020

campaign," the percentage of individuals with 20 or more teeth has steadily increased. In 2016, for the first time, over 50% of individuals aged 80 or above maintained 20 or more teeth, marking a substantial improvement in oral health, especially among the elderly. Over an eleven-year span (2005-2016), there was a remarkable increase in the survival of permanent teeth, with the most significant improvements observed among the elderly age groups. The survey also highlights tooth brushing practices, revealing that 18.3% brush once a day, 49.8% twice a day, and 27.3% brush three times or more.

5. School Health

Special education in Japan caters to physically and/or mentally handicapped children through special schools for severe cases, special classes in regular schools for moderate cases, and supplementary classes assisting mildly handicapped children. In 2021, out of the 9.7 million compulsory school-age children, 79,625 (0.82%) were studying at special schools (high severity), 326,458 (3.4%) received special education in special classes in regular schools, and 163,397 (1.7%) received special education in supplementary classes in regular schools. In total, 5.9% of school-age children are receiving special education.

Since around 1990, there has been a significant increase in the percentage of school-age children requiring special education, a trend that continues. Another concern in Japan's school health is children requiring medical care, such as those on respirators, tube feeding, and artificial hearts. This might be a consequence of improved neonatal care, saving children who might not have survived otherwise. Furthermore, a 2012 survey by the Ministry of Education estimated that approximately 6.5% of regular class children have learning disabilities (LD) or attention deficit hyperactivity disorder (ADHD).



6. A-Bomb Victims

Recognizing the unique circumstances of the A-bomb exposure in Hiroshima and Nagasaki in August 1945, special public assistance is extended to A-bomb

survivors, a privilege not afforded to other war casualties. This category includes individuals exposed in utero at the time of the bomb blast and those who entered the affected area within two weeks. The number of officially listed victims has decreased due to the aging population, from the peak of 372,179 in 1982 down to 118,935 as of March 2022.

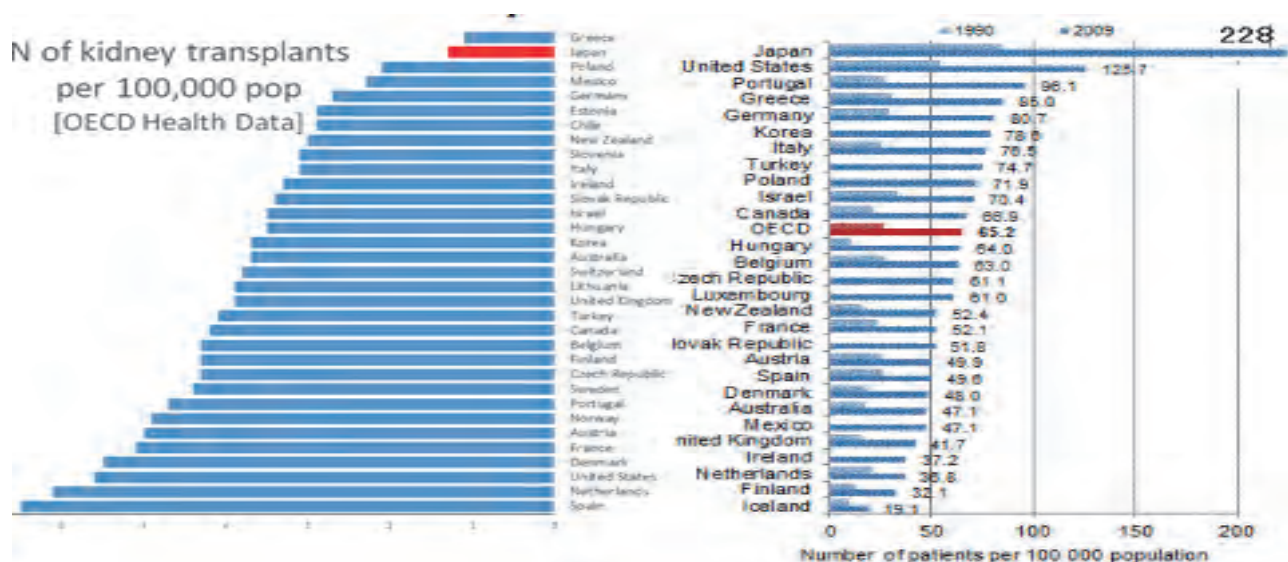
The benefits encompass public subsidies to eliminate copayments for health insurance and a cash benefit of 33,900 yen (approximately 300 dollars) per month for those with chronic diseases, not necessarily related to A-bomb exposure, such as cardiovascular diseases (approximately 80% of eligible recipients avail this cash benefit). In the realm of research activities aimed at studying the long-term effects of radiation exposure, a collaborative research institute was established by Japan and the U.S. in 1975, and its findings significantly contribute to the development of radiation exposure standards and protection.

7. Renal Failure

As of the end of 2021, Japan boasts 145,821 dialysis units catering to 349,700 patients, translating to one out of every 400 people and approximately one-fifth of the world's dialysis patients. This starkly contrasts with the relatively low number of kidney transplantations (only 1,648 in 2021, with cadaver transplants at 186), despite the extensive coverage provided by the health insurance system (capping patients' copayments for renal dialysis at 10,000 yen or approximately 100 dollars per month).

Renal failure, once deemed fatal until December 1967 when dialysis was incorporated into health insurance benefits, still subjected patients to a 20-30% copayment under health insurance, accumulating substantial costs for long-term treatments like dialysis. In October 1972, a public subsidy was introduced to alleviate the financial burden of dialysis patients, and in October 1984, the Health Insurance Act was amended to limit the monthly copayment for long-term treatments to 10,000 yen (recently raised to 20,000 yen per month).

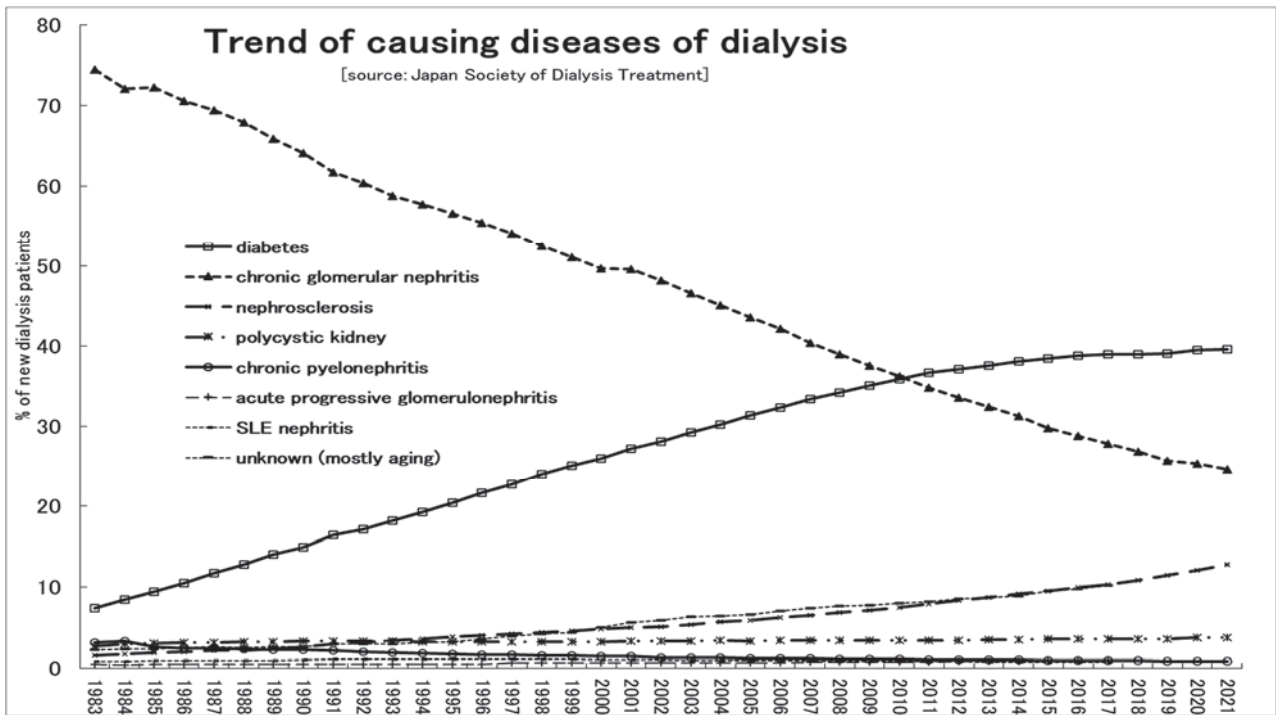
The graph illustrates Japan's unique standing among OECD countries: ranking highest in the number of dialysis cases per population and lowest in terms of kidney transplants. The annual cost of dialysis, approximately five million yen, constitutes about 4% of Japan's total healthcare expenditure. Moreover, this trend shows no signs of slowing, with Japan accounting for 27.2% of over one million dialysis patients in OECD countries as of 2008, largely attributed to diabetic nephropathy, emphasizing the urgent need to manage diabetic complications.



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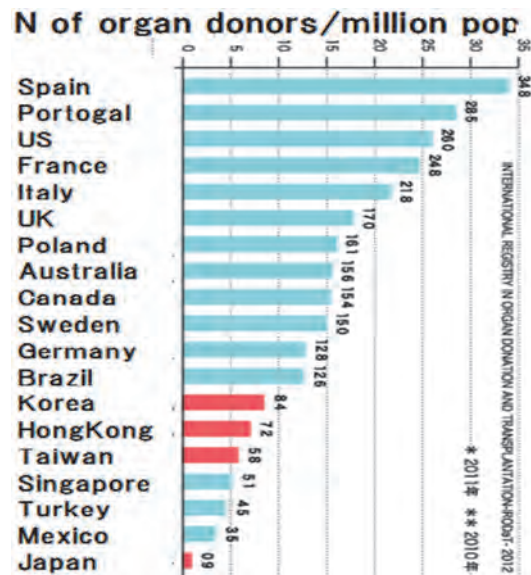
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8. Organ Transplantation

Organ transplants in Japan face significant inactivity primarily due to a shortage of organ donors, with Japan having the fewest organ donors globally. Additionally, the lack of enthusiasm among doctors and government reluctance contributes to this inactivity.

Although kidney transplants were included in health insurance benefits in 1978, cadaver transplantation faced hindrances due to the absence of legislation authorizing organ removal from corpses. The Cornea and Kidney Transplantation Act of 1980 allowed removal under certain conditions but was restricted by the prohibition of organ removal from brain-dead bodies. The Organ Transplantation Act of October 1997 authorized organ removal from brain-dead bodies, with strict guidelines and limitations, prohibiting the commercial buying and selling of organs. The first successful organ transplant under the new law took place in February 1999, marking a significant step forward.



The number of transplants by organs

(source: Japan Organ Transplant Network)

[<https://www.jotnw.or.jp/assets/docs/data/brain-death-data/analyze2018.pptx>]

	1995*	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	合計
heart	-	-	0	0	3	3	6	5	0	5	7	10	10	11	6	23	31	28	37	37	44	51	56	55	428
heart & lung	-	-	-	-	-	-	-	-	0	0	0	0	0	0	1	0	0	0	1	0	0	1	0	0	3
lung	-	-	-	0	0	3	6	4	2	4	5	6	9	14	9	25	37	33	40	41	45	49	56	58	446
liver	-	-	0	0	2	6	6	7	2	3	4	5	10	13	7	30	41	40	38	43	55	54	62	57	485
liver & kidney	-	-	-	-	-	-	-	-	-	-	-	0	0	0	0	0	0	1	1	2	2	3	7	3	19
pancreas	-	-	-	-	0	0	0	1	1	0	1	1	4	4	0	2	6	9	9	5	4	5	8	3	63
pancreas & kidney	-	-	-	-	0	1	6	2	1	5	5	8	8	6	7	23	29	18	24	24	32	33	35	31	298
kidney	118	183	159	149	158	145	145	122	135	168	155	189	179	204	182	186	182	174	130	101	133	141	156	148	3,742
small intestine	-	-	-	-	0	1	0	0	0	0	0	0	2	1	1	4	3	0	1	0	0	1	0	3	17
total	118	183	159	149	163	158	170	141	141	185	177	219	222	253	213	293	329	303	281	253	315	338	380	358	5,501

A country where one can choose one's time of death

Japan's Organ Transplant Law has made Japan a peculiar country where one can choose one's time of death. One can express one's choice in an organ donor card (below) among three options: 1) agree to donate organs after brain death, 2) agree to donate organs only after heart stops and 3) do not agree to donate organs, effectively awarding a person a choice of one's time of death in a death certificate.



〈 1. 2. 3. いずれかの番号を○で囲んでください。〉

- 私は、脳死後及び心臓が停止した死後のいずれでも、移植の為に臓器を提供します。
- 私は、心臓が停止した死後に限り、移植の為に臓器を提供します。
- 私は、臓器を提供しません。


〈 1 又は 2 を選んだ方で、提供したくない臓器があれば、×をつけてください。〉
【 心臓・肺・肝臓・腎臓・膵臓・小腸・眼球 】

〔特記欄： _____ 〕

署名年月日： _____ 年 _____ 月 _____ 日

本人署名(自筆)： _____

家族署名(自筆)： _____



There have been criticisms regarding Japan's legal requirements for diagnosing brain death and organ donation, especially in cases involving children under 16 years old who are deemed incapable of giving consent. Consequently, pediatric patients had to seek transplants abroad due to these legal restrictions.

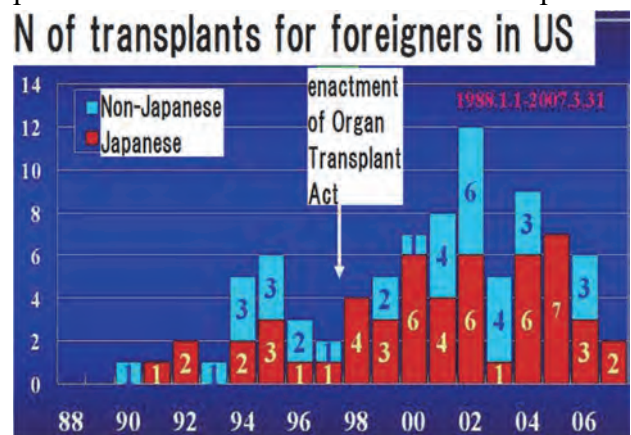
In an effort to address these issues, the Organ Transplantation Act was amended in 2009. The amendments, effective from January 2010, allowed donors to express their wish to donate organs to their relatives. In cases where there was no written consent from the deceased, relatives were permitted to give consent on their behalf, a provision that became effective in July 2010. These revisions aimed to relax legal constraints surrounding brain death, thereby facilitating organ transplants from brain-dead donors. Subsequently, the first pediatric donors aged between 10

and 15 were recorded in April 2012, and the first case involving a pediatric donor younger than six occurred. In 2022, the number of transplants from brain-dead donors included 69 heart, 83 lung, 128 kidney, 1 pancreas, 66 liver, and 3 small intestine transplants, according to the Japan Organ Transplant Network. However, these numbers fell significantly short of the patients on the waiting list, which, as of March 2022, consisted of 13,722 for kidneys, 917 for hearts, 285 for livers, 489 for lungs, and 1,888 for eyes (corneas). Regarding bone marrow transplants, a bone marrow bank, established in December 1991, maintains a database of approximately 540,000 potential donors as of March 2023. The bank has successfully matched 27,558 patients who underwent bone marrow transplants since January 1993.

Transplant tourism

Because of the paucity of donors, there is a strong interest and demand in transplant tourism. However, the Istanbul declaration in 2008 and WHO guidance in 2010 prohibited it declaring that "transplant tourism is permitted only when it does not jeopardize transplants for native patients". Further, the discontinuation of organ removals from executed bodies in China after 2015 narrowed the gate for Japanese patients. Currently, only the U.S. accept foreign patients with some limitations (5% rule). Majority of foreign transplant patients in U.S. are from Japan. The cost for such transplant tourism is gigantic: well over \$3 million.

Japanese government eventually approved that part of such transplant tourism be reimbursed by public health insurance in Dec 2017. This is remarkable in that Japan declared the non-compliance with the internationally agreed rules. There is a concern that Japan will face international criticism over "organ trafficking".



Transplant tourism has gained interest due to the shortage of donors. However, the Istanbul declaration in 2008 and WHO guidance in 2010 prohibited it, stating that "transplant tourism is permitted only when it does not jeopardize transplants for native patients." The discontinuation of organ removals from executed bodies in China after 2015 further limited options for Japanese patients. Currently, only the U.S. accepts foreign patients with some limitations (5% rule), with the majority of foreign transplant patients in the U.S. originating from Japan. The cost for such transplant tourism is exorbitant, well exceeding \$3 million.

Remarkably, in December 2017, the Japanese government approved reimbursement for part of transplant tourism expenses through public health insurance, signaling a departure from internationally agreed rules and raising concerns about potential international criticism over "organ trafficking."

Chapter 5. Medical Care

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

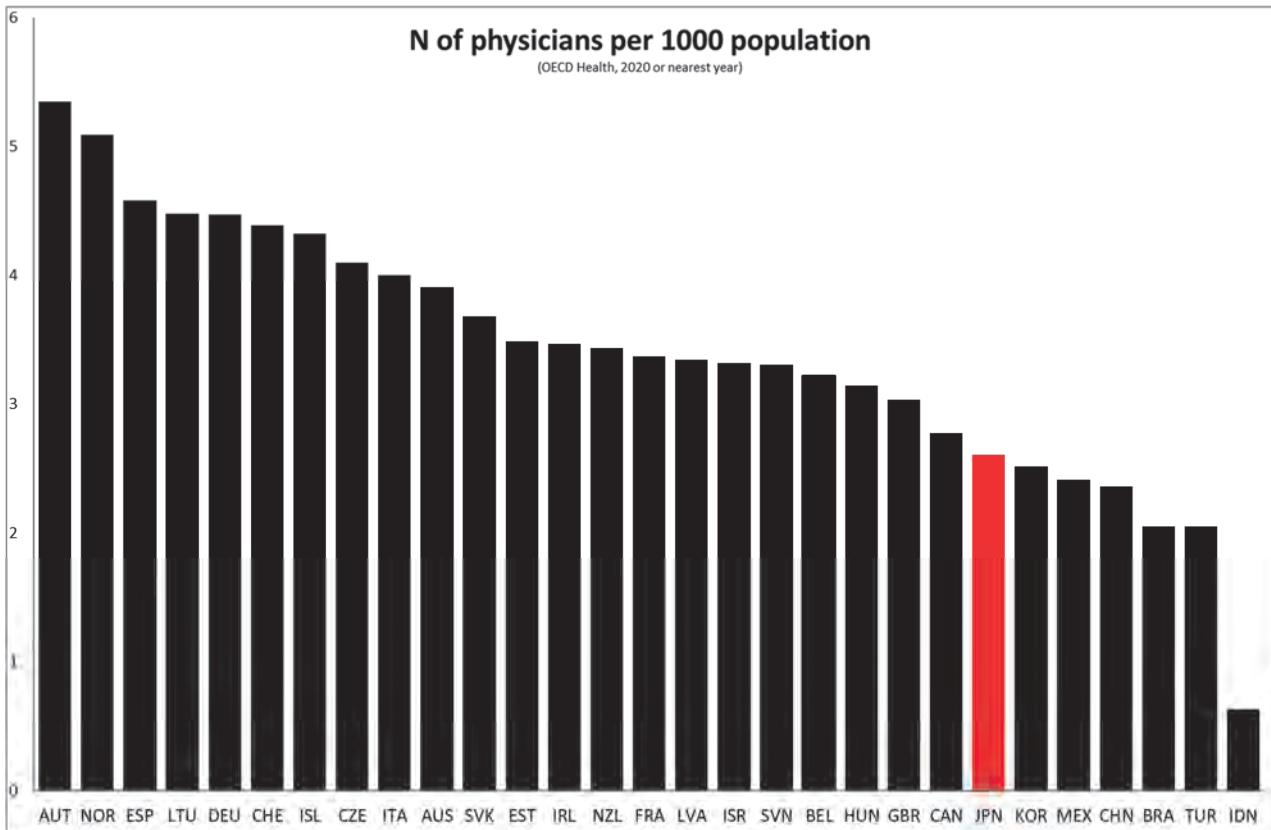
Japan's healthcare system is marked by accessible medical care, provider choice, and equal treatment opportunities, all thanks to its widespread health insurance system covering the entire population. The government strictly regulates the prices of medical procedures and pharmaceuticals through this system, contributing to Japan's remarkable success in achieving high health standards globally. However, recent criticisms have surfaced, focusing on issues such as a lack of quality assurance mechanisms, the condition of hospital wards, and patient rights, particularly following the exposure of serious malpractice cases.

2. Health Planning

Japan's health policy underwent a significant shift in 1985 when amendments to the Medical Service Act aimed to counter the historical laissez-faire approach. Prefectural governments were mandated to establish regional health planning to control the excessive growth of hospital beds, addressing geographic maldistribution and spiraling healthcare costs. Currently, the country is divided into 335 regions, controlling acute general hospital bed numbers. The 2008 structural reform incorporated critical path and quality indicators into regional health planning, focusing on specific diseases and care categories. This initiative aligns with the "Health Care Cost Containment Plan (HCCCP)," emphasizing the importance of information technology, including electronic health records.

3. Health Manpower

Japan's health workforce comprises 339,623 doctors, 107,443 dentists, 321,982 pharmacists, and 1.56 million nurses as of 2020. The country faces a growing demand to increase medical school enrollments, with efforts to enhance postgraduate training starting in 2003. Health professionals operate under the guidance of the Ministry of Health, Labor, and Welfare (MHLW), which issues licenses. Concerns about misconducts led to disciplinary actions, and in 2006, the Doctors' Act was amended to require reeducation for suspended doctors, including ethical training.



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 was not well developed. 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

Japan classifies medical care facilities into hospitals and clinics, further categorizing hospitals into acute general, psychiatric, and tuberculosis hospitals.

Notably, a considerable number of medical clinics function as small-sized hospitals, with approximately 5.4% of beds provided by clinics with up to 19 inpatient beds. Despite a decline in overall bed numbers since 1990, Japan still maintains a higher number of inpatient beds per population compared to many other countries. The ownership of hospitals and clinics is predominantly in the private sector, with public hospitals accounting for approximately 46%.

Trend of inpatient beds by category

	Total	hospitals							clinics	dental clinics	
		psychiatric beds	infectious disease beds	tuberculosis beds	leprosy beds	general acute care beds	geriatric beds	long-term care beds			
1975	1428482	1164098	278123	21042	129055	14020	721858	264085	299		
1978	1510702	1232779	294550	19616	99874	13076	805663	277685	238		
1981	1647818	1362161	314065	17094	77406	11636	941960	285351	306		
1984	1750768	1467050	331099	15042	60067	10729	974234	75879	283445	273	
1987	1860595	1582393	347196	13772	48938	9997	1052023	110467	277958	244	
1990	1949493	1676803	359087	12199	42210	9398	1105046	148863	272456	234	
1993	1946255	1680952	362436	11061	37043	8833	1077022	181734	2823	265083	220
1996	1911595	1664629	360896	9716	31179		1031671	193295	37872	246779	187
1999	1872518	1648217	358449	3321	24773		980150	114418	167106	224134	167
2002	1839376	1642593	355966	1854	17558		903823	23377	325701	196596	187
2005	1798637	1631473	354296	1799	11949		904199		359230	167000	164
2008	1756115	1609403	349321	1785	9502		909437		339358	146568	144
2011	1712539	1583073	344047	1793	7681		899385		330167	129366	100
2014	1680712	1568261	338174	1778	5949		894216		328144	112364	87
2017	1653303	1554879	331700	1876	5210		890865		325228	98355	69
2020	1593633	1507526	324481	1904	4107		887920		289114	86046	61

As of October 2020, there were 8,238 hospitals of all categories, over 10% decline since its peak of 10,096 in 1990 reflecting mergers and acquisitions in recent years. There were 102,612 medical clinics, of which 6,303 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.

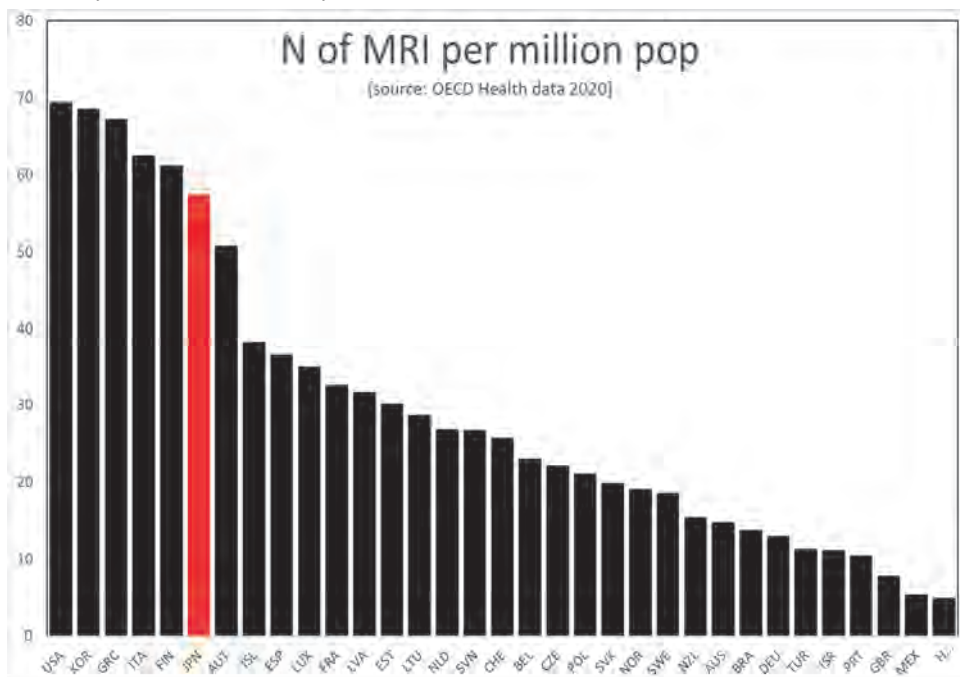
The ownership of hospitals and clinics in Japan is predominantly in private sector. However, since the average size of national and public hospitals tend to be larger, public sector accounts for approximately 46% in terms of hospital beds. Ownership of private sector is either sole proprietorship or 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)

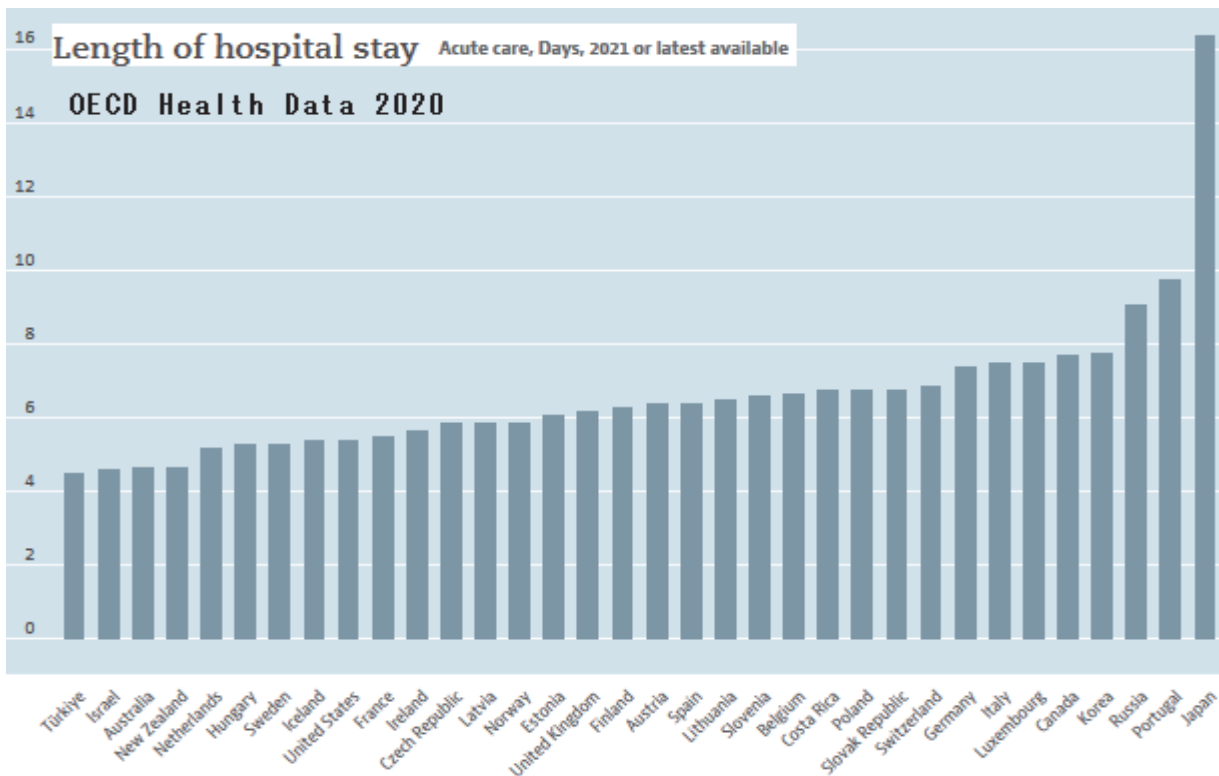


41.1%, angiography 20% and UGI fiber scopes 60% (Health Care Facilities Survey as of October 2011). This dissemination of high-tech equipment may be beneficial to patients but may not be favorable in health economics viewpoint. Disseminating such high-tech equipment in a cost-effective manner while securing easy access to patients will be difficult but important health policy issues.

Japan’s inpatient care is characterized by prolonged length of stay: 32.0 days for all hospital beds (including psychiatric beds) in 2013, 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 289,114 as of 2020. 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.



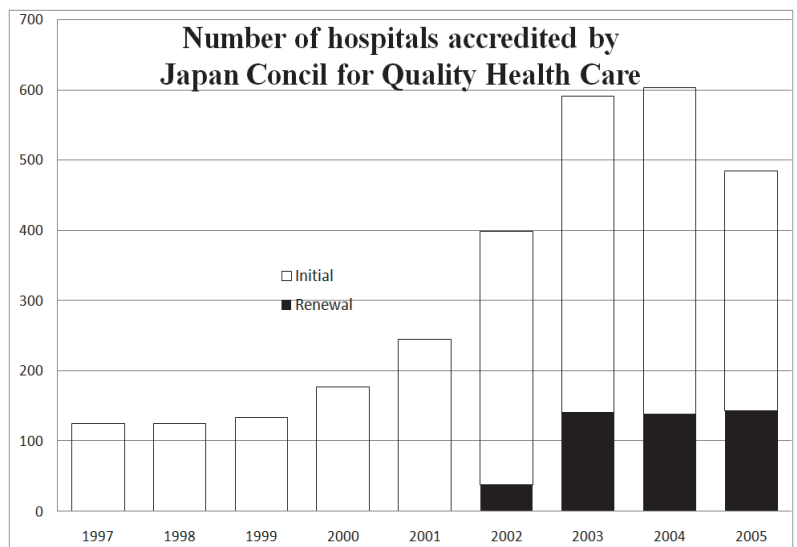
The reduction is expected to be achieved through restructuring the hospital beds into nursing homes or skilled nursing facilities.

5. National Hospitals and National Centers

The National Hospital Organization (NHO) emerged in 2004, separating from the government to focus on "policy-oriented health care" in various fields. Six national centers, established for specific purposes, were designated to become independent administrative corporations in 2010. The restructuring aimed to improve efficiency and financial conditions, with the NHO focusing on coordinating clinical research.

6. Accreditation Program of Hospitals

Japan initiated a formal accreditation program in 1997 through the Japan Council for Quality Health Care (JCQHC). While voluntary, accreditation exempts accredited items from advertisement restrictions. As of 2007, 30% of hospitals nationwide were accredited. Unlike the U.S., accreditation is not a precondition for participation in government



healthcare programs, but accredited hospitals enjoy advertising benefits.

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/incidents

Medical "incidents" are

defined as "near-miss" cases potentially leading to "accidents". According to the well-known *Heinrich's law*, one can reduce accidents by preventing incidents.

N of medical malpractice litigations and criminal prosecution [source: the Supreme court]

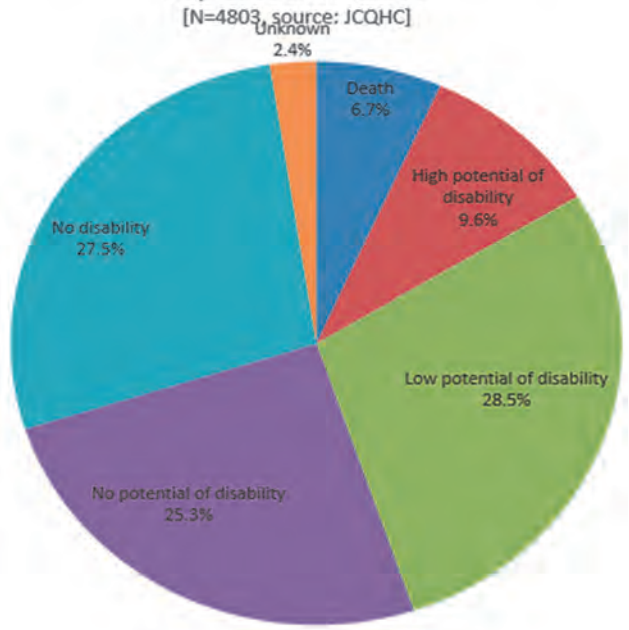
	N of new litigations	N settled	N pending	average time spent(in months)	criminal cases
1992	371	364	1257		
1993	442	347	1352		
1994	506	392	1466		
1995	488	426	1528	38.8	
1996	575	500	1603	37	
1997	597	527	1673	36.3	3
1998	632	582	1723	35.1	9
1999	678	569	1831	34.5	10
2000	795	691	1934	35.6	24
2001	824	722	2034	32.6	51
2002	906	870	2073	30.9	58
2003	1,003	1,036	2,035	27.7	68
2004	1,110	1,004	2,138	27.3	91
2005	999	1,062	2,075	26.9	91
2006	913	1,139	1,849	25.1	98
2007	944	1,027	1,766	23.6	92
2008	876	986	1,656	24	79
2009	732	952	1,436	25.2	81
2010	791	921	1,306	24.4	75
2011	771	801	1,276	25.1	64
2012	792	844	1,224	24.5	93
2013	802	804	1,222	23.3	81
2014	865	794	1,293	22.6	55
2015	832	787	1,338	22.8	43
2016	864	790	1,412	23.2	43
2017	828	780	1,460	24.4	50
2018	773	806	1,427	23.5	37
2019	828	853	1,402	25.2	33
2020	834	666	1,570	26.1	34

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 (incidents) 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 by patients.

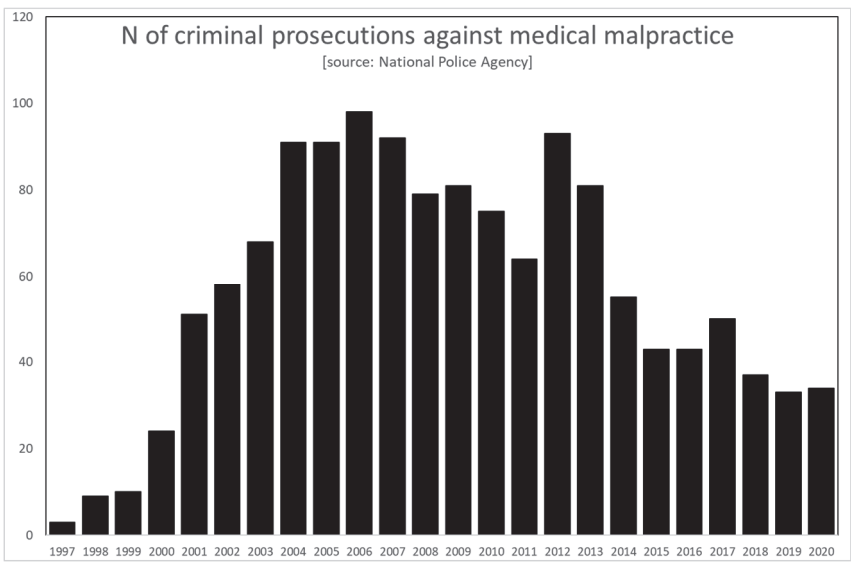
The Physicians’ Act mandate that the doctor shall report to police when the patient dies of unexpected causes, but there is no mandatory reporting of incidence that fall short of death. In 2004, the Medical Service Act was again revised to require a certain designated hospitals (including all university medical centers. A total of 857 hospitals as of 2021) reporting of any medical accidents to the JCQHC.

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 2020, a total of 4802 adverse events were reported, of which 330 cases (6.7%) had resulted in death [https://www.med-safe.jp/pdf/year_report_english_2020.pdf].

Severity of medical adverse events reported in 2020



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 [med-safe.jp]. A total of 179 reports on



medical safety are published in English as of 2021.

(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.

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) Medical Accidents Investigation & Support Center (MAISC)

Medical community resents police involvement on medical accidents but the section 21 of the Physicians' Act requires 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.

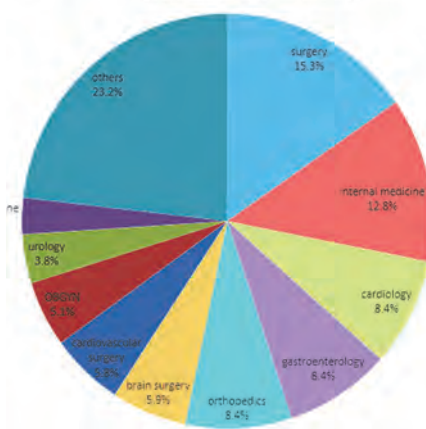
After the ruling, there has been a growing outcry among medical communities calling for revision of the Physicians’ Act to preclude police involvement. MHLW drafted a bill “Medical Accidents Investigation Committee (MAIC) Act” in 2007. The bill intends to set up MAIC and require medical providers to 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”. Eventually, the drafted bill was aborted.

The legacy revived in 2014 as “Medical Accidents Investigation and Support Center (MAISC)[<https://www.medsafe.or.jp>]”. MAISC was created through the revision of the Medical Service Act. Unlike MAIC, MAISC is a private organization designated by the MHLW and has no law enforcement authority. Pursuant to the Medical Service Act, administrators of hospitals and clinics are required to report to MAISC as medical accidents when unexpected deaths occurred. However, investigations are left to administrators’ responsibility. The point is that the initial judgment on whether the death is “unexpected” or not is the administrator’s discretion. The mission of MAISC is essentially investigative and not pursuing the faults or responsibility.

The MAISC started operation in October 2015 and during the 7.5 years of operation, the MAISC received a total of 2,548 accidents from providers. Providers are expected to conduct in-house investigations on the accidents and submit in-house investigative reports to MAISC. So far, a total of 2,222 in-house investigative reports were

specialty-specific share of reported medical accidents
[source: MAISC, 2015~22, N=2,548]



Activities of Medical Accidents Investigation & Support Center (MAISC)

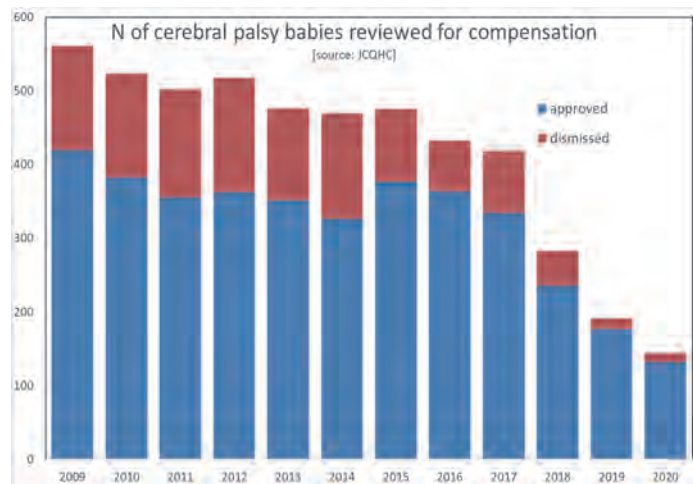
	N of consultations from patients or families	N of cases warned to providers by MAISC	N of accidents reported by providers	N of in-house investigative reports by providers	N of investigation requests to MAISC by providers	N of external investigative reports by MAISC
2015	597	—	81	7	0	0
2016	1,731	14	406	219	19	0
2017	1,933	21	370	321	39	2
2018	1,989	39	377	361	23	11
2019	2,054	25	373	364	33	21
2020	1,610	23	324	355	27	20
2021	1,685	14	317	311	33	40
2022	1,612	16	300	284	29	38
total	13211	152	2548	2222	203	132

submitted to MAISC by providers. Although MAISC has no law enforcement authority, it may conduct external investigations upon request from either providers or patients/families. So far, a total of 203 such requests were made to MAISC and a total of 132 external investigative reports were completed by MAISC.

When broken down by medical specialties, surgery has the largest share in the medical accidents reported to MAISC by providers (N=2,548).

(4) No-fault obstetrical compensation system for cerebral palsy (NOCSCP)

The no-fault obstetrical compensation system for cerebral palsy (NOCSCP) is a legal and collective compensation system quite unique to Japan. Like colleagues in many countries, doctors contract malpractice insurance to provide financial protection against civil litigations filed by patients against doctors. However, malpractice insurance can be applicable only when doctors are at fault and the plaintiffs must bear the burden of proof to win the compensation. Also, the civil litigations are stressful and time-consuming task for both plaintiffs and defendants. Among medical specialties, OBGY carries the highest risk of such malpractice litigations. The situations can be worse when cases involve cerebral palsy (CP) because the cause-effect relationship can be difficult to determine.



In 2009, MHLW established a collective, no-fault compensation system to help reduce the burden of both plaintiffs (patients) and defendants (doctors). MHLW authorizes JCQHC to collect premium (¥12000 or approximately \$100 per delivery) from all OBGY hospitals and clinics and pay monetary compensation if new born babies meet certain criteria. Currently, the criteria include 1) gestation of 28 weeks or longer, 2) babies are evaluated as severe levels of CP. If babies meet the criteria, a lump-sum payment of six million yen (approximately \$50000) will be paid followed by annual payment up to 1.2 million yen (approximately \$10000) for up to 20 years (maximum of 30 million yen). The number of babies awarded compensation has been around 300-400/year (the total number of birth was around one million).

The NOCSCP is a unique system only found in Japan. By collectively applying no-fault compensation system, both plaintiffs and defendant can be relieved from the litigious burden.

Growing public awareness of patient rights and an increase in medical malpractice litigations have prompted changes in Japan's approach to patient

safety. The reporting system for medical incidents was established in 2002, aiming to prevent accidents. Criminal charges for medical malpractices have increased, leading to debates and caution regarding their pursuit. The establishment of the Medical Accidents Investigation & Support Center (MAISC) in 2015 has allowed for in-depth investigations, and the no-fault obstetrical compensation system for cerebral palsy alleviates the burden on both patients and doctors involved in malpractice cases.

Chapter 6. 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

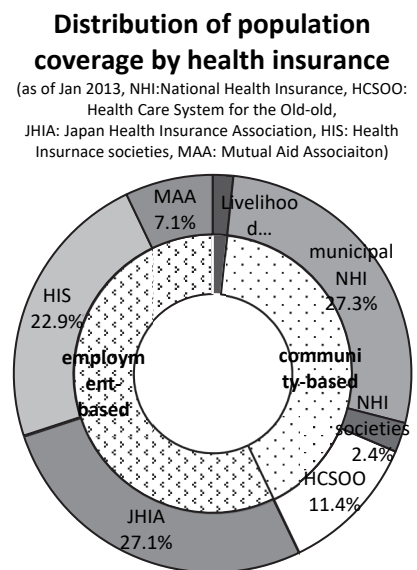
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(1) Premium

Premiums in Japan's health insurance are income-based. EHI premiums are a percentage of monthly salary, while JHIA rates include contributions to HCSO. Municipal NHI premiums vary and consist of fixed per-capita and income-related components.



Example of premium (annual, in 2015)

HCSO (Tokyo): 42200 yen + 8.98% of annual income
 NHI (Tokyo 23 wards): 43200 yen + 10% of annual income (including contributions to HCSO, 2.17% and premium for LTCI: 1.53%)

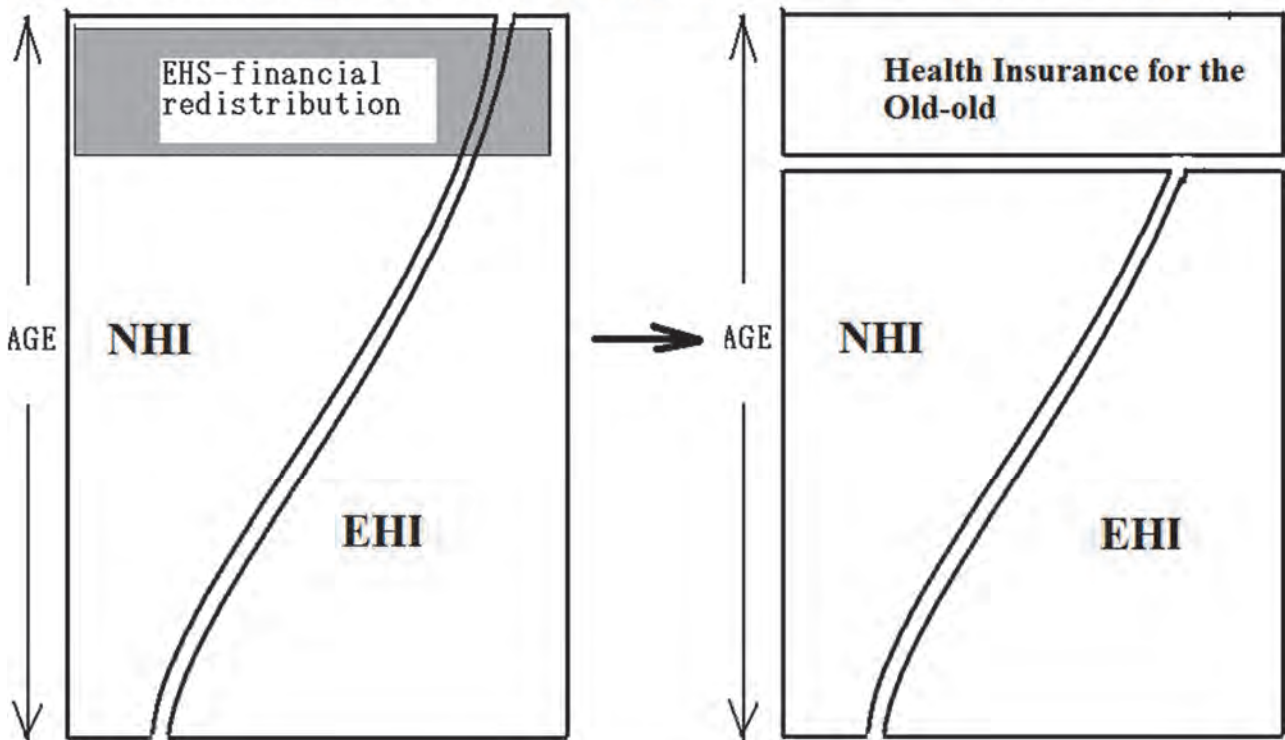
(2) Governmental subsidy

Some insurers receive governmental subsidies, with municipal NHI being the most subsidized at 43%. JHIA benefits from a 16.4% subsidy, while large corporations' HISs receive none. HCSO is heavily subsidized, with only 10% from premiums and the rest shared by the government, prefectures, municipalities, and working-age contributors.

2. Health Care System for the Old-old

In 2008, the HCSO was established, separating the elderly aged 75 or over into an independent system. The premium source includes pension payments, taxes, and contributions from health insurers. Despite rapid growth, the system faces challenges as the elderly population over 75 years old is expected to reach 22 million in 2025.

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 12% 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. The contribution to the HCSO is collected as an added-on to health insurance premium. In case of Japan Health Insurance Association (JHIA), which enrolls workers of small-medium sized corporations, the premium rate for HCSO contribution is 3.42% (shared half between employers and employees). Effectively, it is an additional income tax.

(4) Current status

Given Japan's rapidly aging population, the HCSO is growing rapidly. The enrollment was 11.4 million in 2008 when the system was established. The enrollment was 19.7 million in FY2023 including 249,838 disabled aged 65-74, most of whom are kidney failure patients on dialysis. The number of the elderly 75 years or older is expected to reach 22 million in FY2025, when all of the post-war baby boomers will be 75 years or older. By then, the working population is expected to dwindle and the burden of contribution to the HCSO is expected to be far heavier than today.

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..

Charges for typical cases (yen, \$1=100yen)

[case1] 57yo diabetes, visit outpatient clinics once a month, direct dispensing		[case2] 78yo hypertension, visiting outpatient clinic twice a month, on medication	
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%)	382

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. Charges of typical cases are presented below. 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).

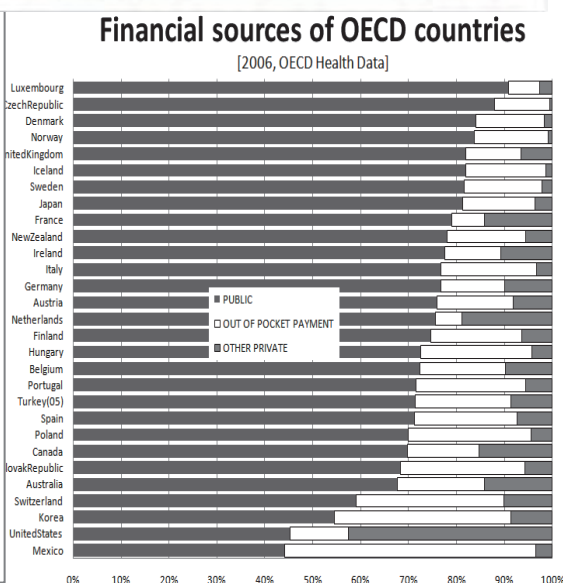
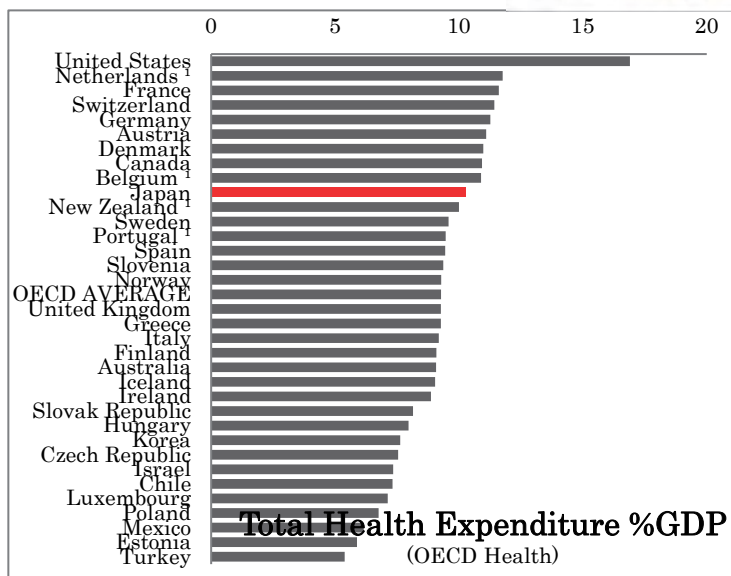
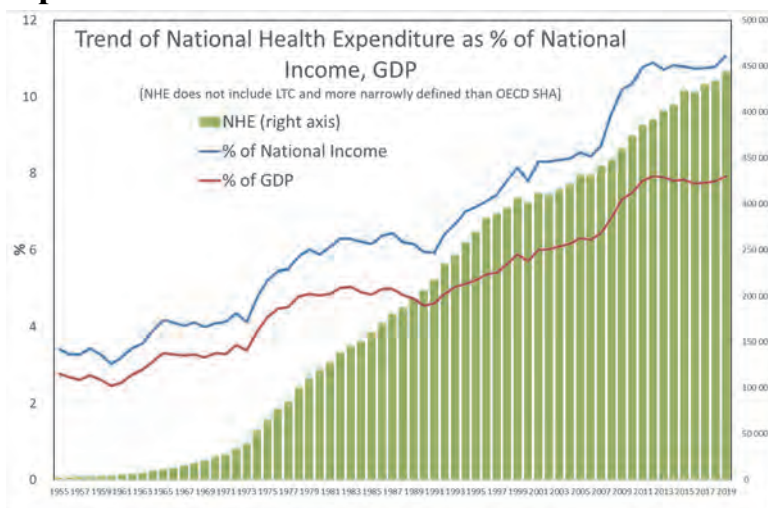
In response to the New Strategy for IT Reform, MHLW compiled the 2nd Grand Design in March 2007, an action plan for the next five years. It reconfirmed the stated goal of full computerization of insurance claims by the end of FY 2010

(March 2011) and set a schedule for the “national database of health insurance claims”.

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).

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).



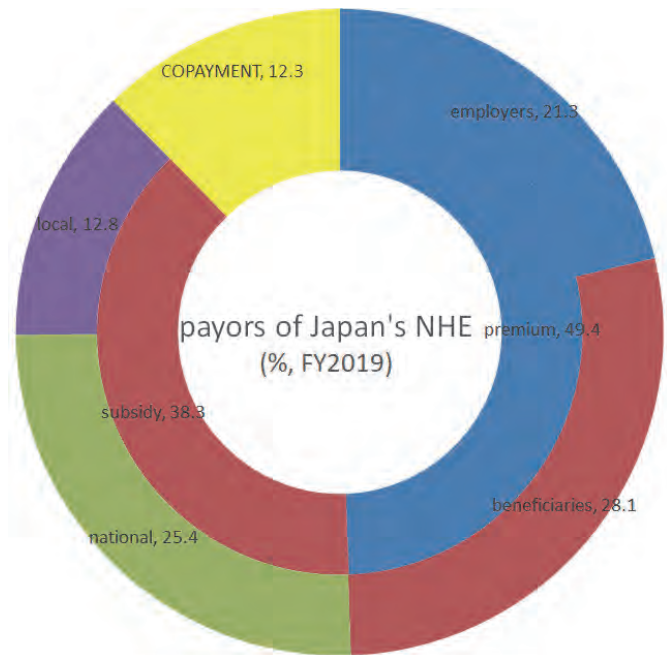
The estimated total of NHCE in FY2021 was 45 trillion yen or approximately 385 billion dollars or 333,000 yen (3,000 dollars) per capita, which constitutes 11.2% of Japan’s National Income (NI, 400 trillion yen in 2019) or 8% of Gross Domestic Product (GDP, 560 trillion yen). The share of NHCE in GDP has increasing gradually reflecting population aging and increase of high-cost medical technology.

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 11% in 2019. Given the long lasting economic slump 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 50%, subsidy from general account 38% and patients' out-of-pocket 12% (FY2021). 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.

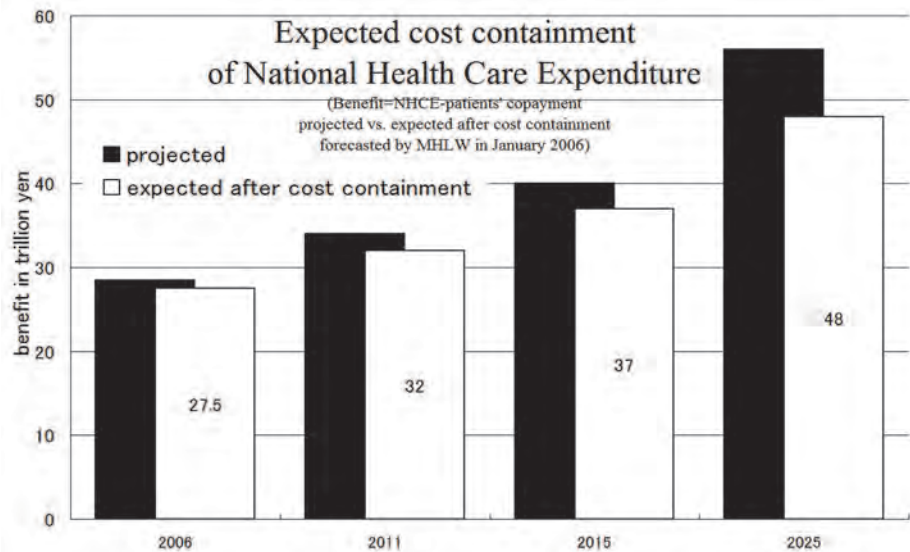
● Introduction of primary prevention programs against metabolic syndrome. All health insurers will be required to provide annual health checkups as well as post screening health guidance to all beneficiaries including dependent family members.

● 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.

Japan's Health Insurance Act, enacted in 1922, faced delays in taking effect until 1927, primarily due to the devastating Tokyo earthquake in September 1923. Inspired by the German social insurance model of Bismarck, it aimed to cover industrial workers initially, leaving non-employed populations, such as farmers

and fishermen, uninsured. In 1938, the National Health Insurance (NHI) Act was introduced, extending coverage to the non-employed through mutual aid associations.

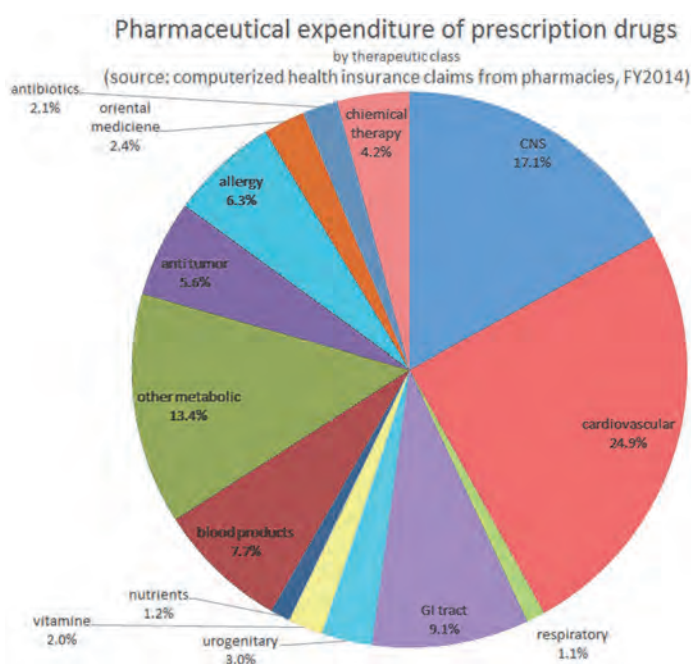
An interesting historical note is that the NHI Act of 1938 coincided with the infamous National Mobilization Act, revealing a darker side, indicating its role in wartime efforts during the Sino-Japanese war and eventually leading to World War II. Postwar, revisions expanded the NHI Act's coverage nationwide, achieving national coverage in 1961.

Chapter 7. 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.

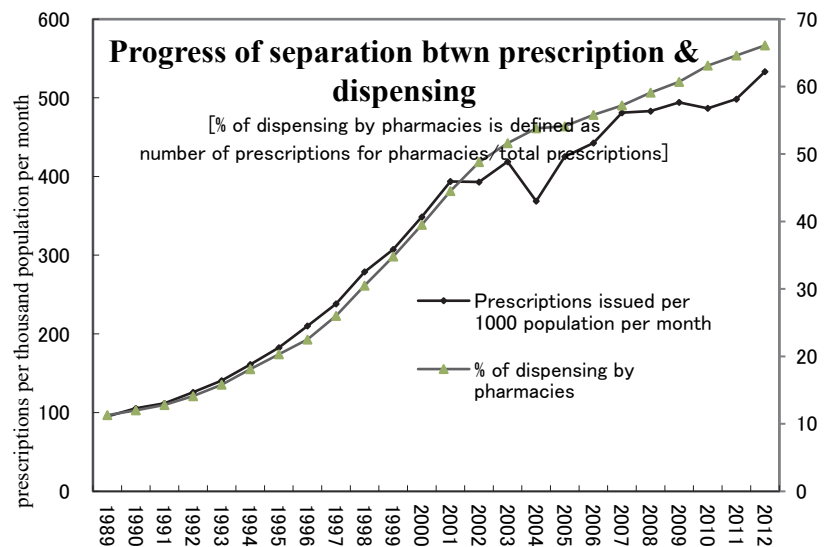
1. Pharmacies and Separation of Prescription and Dispensing

Traditionally, Japanese doctors have often directly dispensed drugs to patients, a practice prevalent in the country's medical care system. This approach has been favored by both doctors and patients, allowing physicians to increase profits through markups between wholesale and government-reimbursed prices. Additionally, patients benefit by receiving comprehensive care in a single visit, saving time. However, this non-separation of prescription and dispensing has contributed to the high pharmaceutical share in the NHCE. Efforts to enhance separation, initiated in the 1970s, faced challenges due to conflicts of interest. Many doctors established affiliated pharmacies, leading to the pocketing of higher prescription fees and pharmaceutical markups. Measures, including penalties for collusive arrangements and incentives for independent pharmacies, have been implemented to encourage a more distinct separation. Despite these efforts, challenges persist, with varying separation rates across prefectures and patients often obtaining medications from multiple pharmacies affiliated with hospitals.



2. Pharmaceutical Reimbursement and Price Setting

The Japanese government determines the prices of all drugs covered by health insurance, with nearly 15,000 items listed for oral, IV, and ointment use. The pricing process involves an annual market survey, conducted collaboratively with wholesalers, to establish the official reimbursement price. This price is set at the weighted average of transaction prices plus a reasonable margin (typically 2%). New drugs undergo pricing comparisons based on therapeutic effects, with some innovative drugs receiving bonus prices on a case-by-case basis. Economic evaluations, including cost-effectiveness analyses, are gaining attention in drug pricing decisions. Transparent pricing has occasionally been a focal point in trade negotiations, particularly concerning pharmaceutical imports from the U.S. Efforts are underway to increase the share of generic products, with policy changes and revised doctor practices to encourage generic substitution.

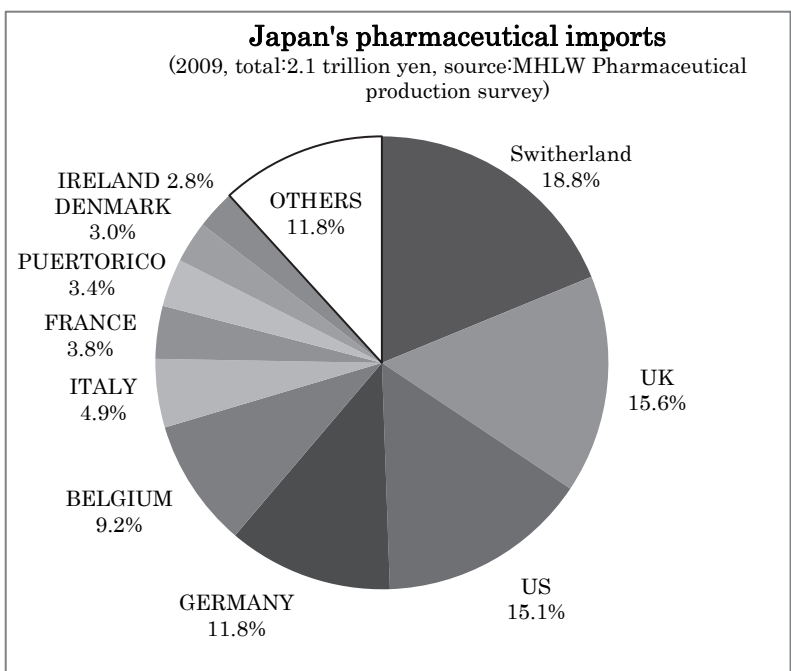
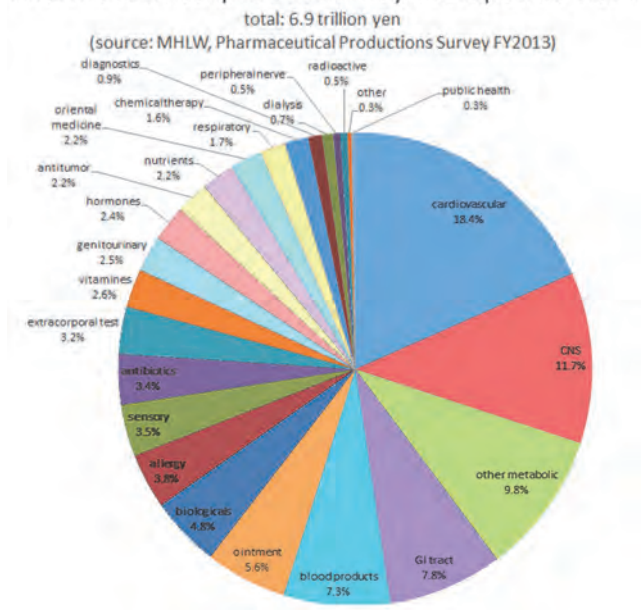


3. Clinical Trials

Regulations governing pharmaceuticals, cosmetics, and medical equipment in Japan fall under the Pharmaceutical Affairs Act, amended in 1993 to support research on orphan drugs and expedite reviews. Clinical trial regulations were tightened in 1996 due to prior misconducts, leading to a decline in trials and reliance on foreign research data. To revitalize clinical trials, amendments in 2003 allowed doctors to sponsor trials, previously limited to pharmaceutical companies. A network, Japan Clinical Research Assist Center (JCRAC), was established in 2001 to support trials across hospitals, fostering data sharing and collaborative resources. Challenges in clinical research and potential racial differences in drug responses have been considerations in deregulation efforts.

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

Pharmaceutical production by therapeutic class



(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.

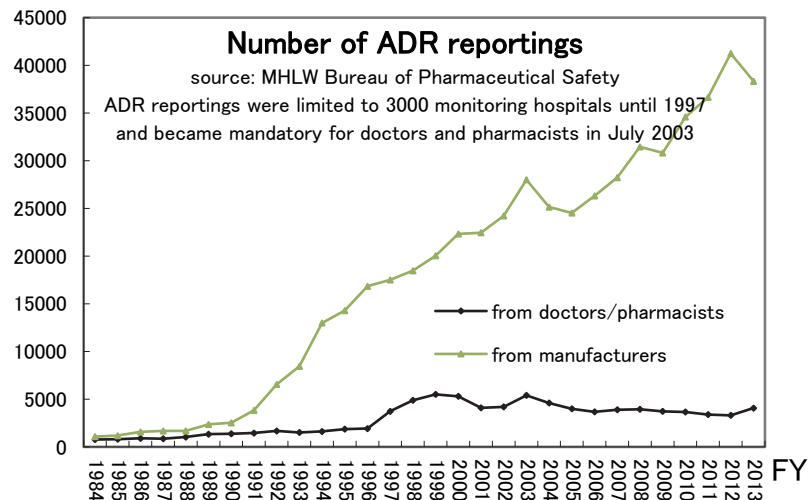
4. Japan’s Pharmaceutical Industry

Japan's pharmaceutical industry, with an output of 10 trillion yen in 2022, faces challenges due to stagnant growth over the past decade. Despite being one of the world's largest markets in 2000, Japan's share declined to 5% in 2021. In the field of pharmaceutical trade, Japan's trade balance was deficit: Japan's pharmaceutical import was 3.4 trillion yen while its export was 649 billion yen or only 6.5% of Japan's pharmaceutical output in 2022. As for medical devices, Japan's import was 2.9 trillion yen while the export was 1.1 trillion yen. The industry's weakness is attributed to smaller company sizes, with 463 pharmaceutical companies in Japan compared to 483 in the U.S. The national health insurance system, dictating drug prices and ensuring reimbursement, has led to a domestic-oriented industry. The industry has struggled to stay competitive globally amid consolidation trends. Cardiovascular drugs constitute a significant portion of Japan's pharmaceutical

output.

5. Pharmaceutical Monitoring and Surveillance

Japan's pharmaceutical history has been marked by tragedies related to drug side effects, prompting a commitment to prevention. Monitoring and surveillance involve mandatory adverse drug reaction (ADR) reporting from pharmaceutical companies, health care providers, and pharmacies. Despite efforts, the Sorivudine tragedy

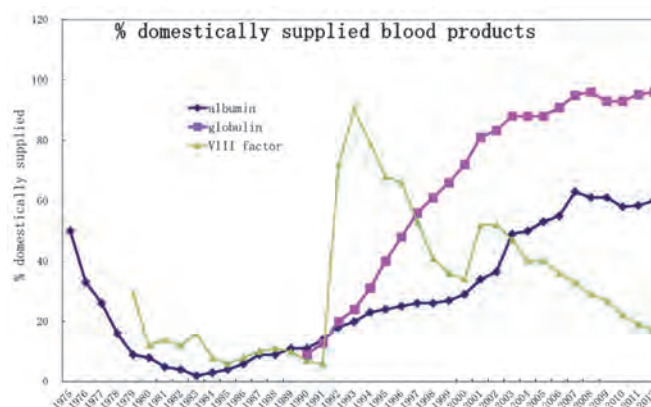


highlighted the limitations of the system. A shift to mandatory reporting from all doctors and pharmacists in 2003 aimed to improve the system's effectiveness. A subcommittee evaluates reported cases, and safety information is periodically published to inform the public and health care providers.

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 2011, 58.5% of albumin and 95.3% 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.

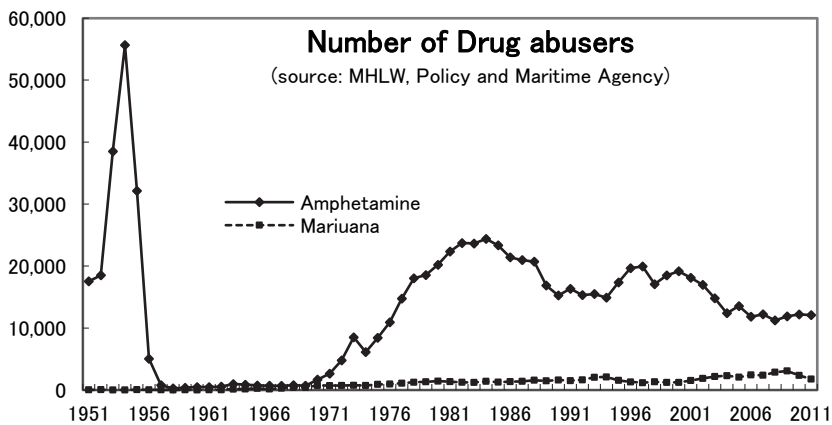


Much effort has been directed at controlling iatrogenic infection through blood products. After the outbreak of BSE in Europe, people who ever lived in any of

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

Japan's history of drug abuse, spanning amphetamines and heroin, saw waves in the post-war period, with strict law enforcement curbing the issues. In the 1980s, a second wave of amphetamine abuse emerged, but concerted efforts, including legal measures, have led to a decline in recent years. The internet has introduced new types of abusive substances, and legislative actions continue to adapt to emerging challenges.



8. Health & Medical Strategy

The Abe administration recognizes health and medical technology as a national strategy, enacting the "Health and Medical Strategy Promotion Act" in 2014. This strategy focuses on various areas, including new drug development, medical devices, regenerative technology, and international health diplomacy. The establishment of Japan Agency for Medical Research Development (AMED) in 2015 aims to coordinate research grants and support medical research. International collaboration initiatives, such as the Japan-ASEAN Health Initiative, demonstrate Japan's commitment to global health partnerships.

Chapter 8. Environmental Health

Ancient Japan was often perceived as a nation relatively untroubled by environmental issues. Despite Edo, an ancestral moniker for Tokyo, boasting a population exceeding one million, foreign visitors marveled at the city's cleanliness. Notably, outbreaks of infectious diseases like plague or cholera were infrequent in most cities during that era, although the prevalence of fire hazards was high due to the prevalent "wood and paper" construction of houses.

Japan isolated itself from the world for a remarkable 260 years, commencing in the early 17th century until the mid-19th century. This isolation might have shielded the country from foreign-born infectious diseases, but the well-developed sewage system could have also played a role.

The transformation from feudalism to industrialization marked Japan's aggressive modernization, leading to a surge in environmental challenges. The initial legislative response to environmental protection was the Smoke Control Act in 1962. Subsequent environmental disasters prompted increased public concern, culminating in the passage of the Anti Pollution Act in 1967. By 1970, additional legislation, including the Air Pollution Control Act, the Noise Control Act, and the Environmental Pollution Victims Compensation Act, had been enacted. Symbolizing the government's commitment, the Environment Protection Agency was established in 1971. In 1993, the Environmental Protection Policy Act (EPPA) was enacted, emphasizing principles such as the succession of environmental benefits, building a sustainable society with minimal environmental impact, and promoting environmental protection through international cooperation. Pursuant to this law, the government establishes criteria for environment and environmental assessments, particularly focusing on air, water, soil, and noise standards.

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 . New standards were set in 2009 for small SPM whose diameter less than 2.5 micrometers (PM_{2.5}) due to the concern on its health effects. A total of 700 monitoring posts are installed for monitoring. 16.1% of them failed to fulfill the standards in 2013. Concerns among people were raised thanks to the seriousness of air pollution in China and Japan also had to enact a contingency plan.

● 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 three parts: 1) a cohort study on school children, 2) case-control study on infants and 3) cross-sectional study on adults.

1) Approximately 16,000 school children were recruited for the cohort study and the baseline survey was completed in 2005. They were 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.

2) 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.

3) Questionnaire was distributed to 110,000 adults in nine cities to conduct a case-control study

for asthma and a cross-sectional survey for COPD.

However, the survey report was disclosed in 2011 and the findings were largely negative. No meaningful association was identified between air pollution and health effects. One might argue that Japan's air condition had improved enough to make its health effects undetectable. The results might have been otherwise if it had been conducted in Beijing!

(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". According to the Ministry of Environment, the incidence of congenital anomaly has increase alarmingly for last 25 years.

With ample funding from the ministry (3.1 billion yen), a total of 100,000 pregnant women recruited since 2011 and babies will be followed-up until 13 years old collecting blood samples from mothers and babies as well as umbilical cord.



Finally, a total of 103,106 mothers volunteered as of Jan 28th 2015.
[<http://www.env.go.jp/chemi/ceh/>]

Findings from Japan's Eco-Chil study

[<https://www.env.go.jp/chemi/ceh/results/publications.html>]

A total of 197 original articles are listed as findings from Eco-Chil study. The following is selected results from them.

● Paternal occupational exposure to chemicals and sex ratio of offspring

Lancet Planet Health. 2019 Dec;3(12):e529-e538.

The proportion of boys whose fathers were regularly occupationally exposed to insecticides was 0.445 (males, n=293; females, n=366; 95% CI 0.406–0.483), which was lower than the proportion of boys whose fathers were not exposed to insecticides. After adjusting for confounding factors, regular paternal occupational exposure to insecticides (adjusted relative risk 0.86, 95% CI 0.78–0.96) and medical disinfectants (0.95, 0.90–1.00) were significantly associated with lower sex ratios among their offspring compared with the offspring of fathers not exposed to these substances. A declining proportion of boys could potentially be due to fathers working in environments in which they are exposed to chemicals.

● Prenatal Exposure to Household Pesticides and Neonatal Weight and Length Growth

International J of Environmental Research and Public Health. 2020 Jun 26;17(12):4608.

Small but significant associations (i) between the use of fumigation insecticides and decreased birth weight, and (ii) between frequencies of exposure to pyrethroid pesticides, especially mosquito coils/mats, and suppression of neonatal length growth. Prenatal exposure to household pesticides, especially those containing pyrethroids, might adversely influence fetal and postnatal growth trajectories.

● Excessive mobile phone use during pregnancy and low birth weight

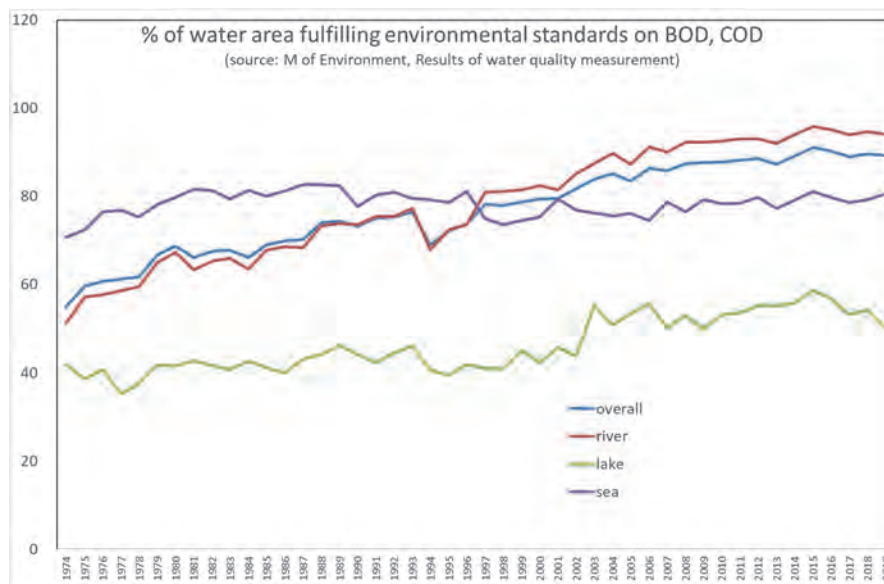
Environmental Health and Preventive Medicine 2017. 22:52

Pregnant women tend to excessively use mobile phones in Japan. The mean infant birth weight was lower in the excessive use group than in the ordinary use group, and the frequency of infant emergency transport was significantly higher in the excessive use group than in the ordinary use group. Excessive mobile phone use during pregnancy may be a risk factor for lower birth weight and a high rate of infant emergency transport.

2. Water pollution

Water pollution, as well as air pollution, used to be a serious public health threats in the era of rapid economic growth (1960-70s). Thanks to the great efforts for environmental protection, Japan's water condition had improved drastically.

To protect water quality, release of waste water into public water such as river, lake and sea is regulated by the Anti-water pollution Act, which sets standards of density of water pollutants. Excretion of dirty water above the standards into public water is prohibited and enforced by law. Also, the Ministry of Environment regularly monitor the quality of public water in terms of BOD, COD as well as dissolved oxygen (DO), suspended solids (SS) and E Coli. The graph below shows a steady improvement of water quality over the last 40 years.



3. Water sanitation

(1) 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 98.1% of the total population in 2019.

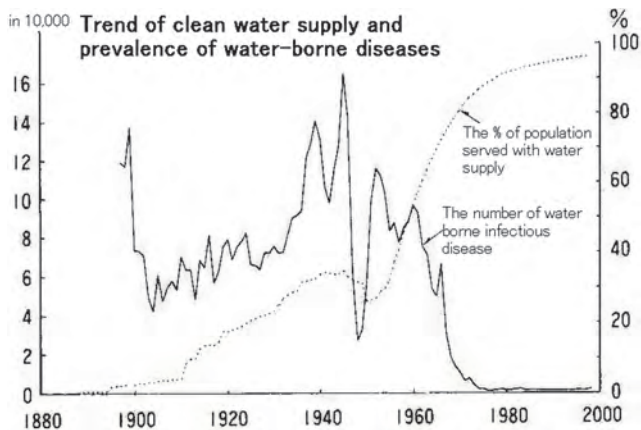
The long-term trend suggests the health indices show marked improvement as the coverage of water supply exceeds 50% and the prevalence of water-borne disease reduces to minimal when the coverage is above 80%.

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.



(2) 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 2019, 79.7% of population is served with sewage system, but the rate is only 52.5% 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.

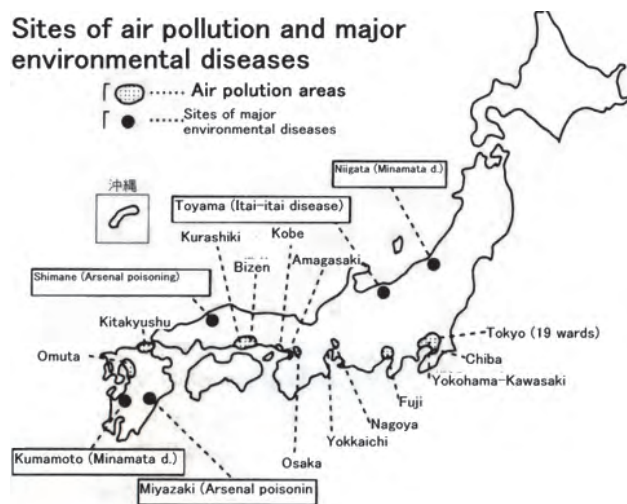
(1) Minamata disease

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.

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 5th report by IPCC (International Panel for Climate Change) in 2014, the average temperature will rise by 0.3-4.8 centigrade by the end of the 21st century and the sea level will rise by 26-82 cm due to the global warming above the 1986-2005 average depending upon the four scenarios).

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 “greenhouse” 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 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

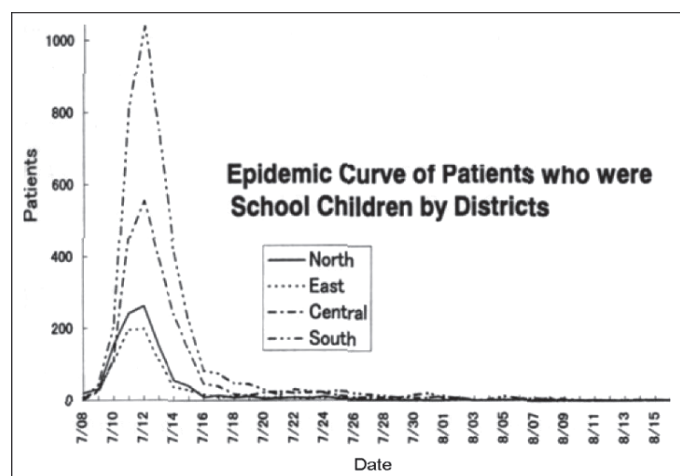
The massive outbreaks of pathogenic O157 E.coli food poisoning, in which 17,877 had developed symptoms and 12 deaths occurred in the summer of 1996. By far the largest outbreak took place in Sakai city in July of that year.

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).

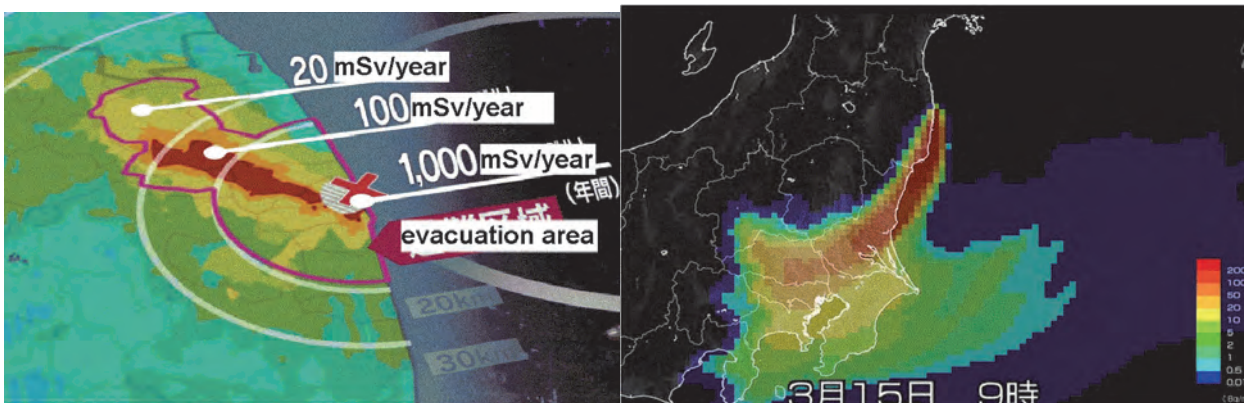
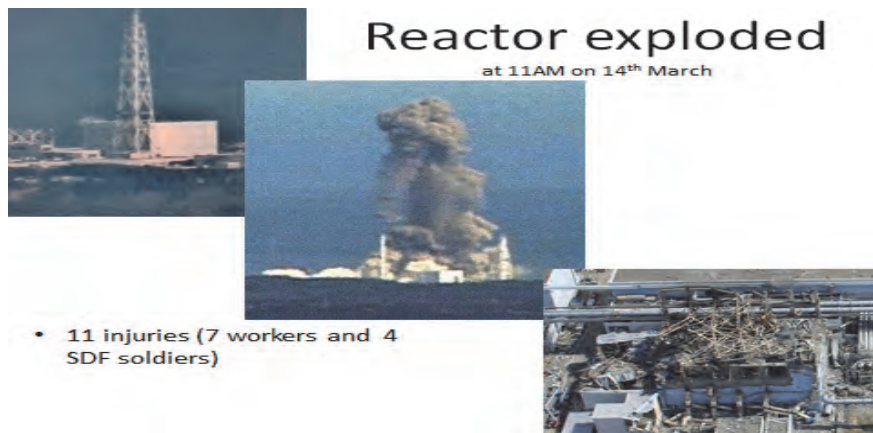


From the onset of the outbreak, school lunch was the most suspected cause of poisoning. Thorough investigation eventually concluded that radish sprouts grown and harvested by a nearby producer were the most probable cause.[source: Sakai City “Report on the Outbreak of E.coli 157 Infection in Sakai City”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

(3) East-Japan earthquake and Fukushima nuclear disaster

On March 11, 14:36 a magnitude 9.0 earthquake occurred in North East Japan. Almost 50 minutes later, a huge tsunami hit the northeast coast. When the 15 m high tsunami hit the Fukushima Daiichi Nuclear Plant, the reactors were flooded and lost the cooling function leading to the melt-down of the reactors. On 14

March, 11:01, A hydrogen explosion happened in the reactor. Residents within the 20 km of the plant evacuated.



High radioactive materials were released to the air. At first it spread to the northwest, but it was blown southward to the densely populated area around Tokyo.

By sheer coincidence, the evacuated area was part of the study site of “Eco-Chil” study and the disaster occurred shortly after the recruitment of pregnant mothers was started. Recruitment was halted after the disaster but the Ministry of Environment decided to expand the “Eco-Chil” study to the entire Fukushima prefecture (population: two million) and the recruitment of pregnant mothers was resumed on October 1st 2012. The press release reads, “The Eco-Chil study is a large cohort study involving 100,000 pairs of mother and child. It follows them until the child becomes 13 years old to analyze the relationship between environment and health. In Fukushima prefecture, the recruitment was started in 14 cities, towns and villages since January 2011. In recognition of the lingering concerns over the negative effects of radiation on health, the Eco-Chil study was expanded to the entire prefecture to monitor if any adverse health effects occur among Fukushima children”. The research protocol was revised to include “radiation effects” as environmental factors to be monitored. According to the press release, a total of 13,134 pregnant mothers had already volunteered as of 28th January 2015.

Another attempt to monitor the long-term health effects to the residents of the affected areas is Tohoku Medical Megabank (TMM), a project similar to the

deCODE biobank in Iceland. TMM recruits volunteers from the residents in Miyagi and Iwate prefectures for a genome cohort of 150,000 volunteers of three generations. It first recruits pregnant mothers at OBGY clinics and through them recruits their husbands as well as their fathers and mothers. The recruited participants will be followed up for ten years.

Is cancer increasing in Fukushima!? : controversies lingering on

After the nuclear disaster, Fukushima prefectural government started the “Fukushima Health Management Survey” to monitor the potential health effects from radiation exposure. One would be naturally alerted at the fact that thyroid cancer had increase after four years in Chernobyl. However, thanks to the high sensitivity of sophisticated ultrasound techniques, controversies evolved as to the interpretation of the observed cases even among experts. Some experts claim that “The thyroid cancers identified in this survey so far are unlikely to be due to radiation exposure, and are more likely to be the result of screening using highly sophisticated ultrasound techniques” [Suzuki S. Clinical Oncology 2016 Jan 25]. On the other hand, Tsuda claims that “An excess of thyroid cancer has been detected by ultrasound among children and adolescents in Fukushima Prefecture within 4 years of the release, and is unlikely to be explained by a screening surge.” [Tsuda T, et al. Epidemiology 2015 Oct 5] Since the development of cancer is a long-time process, it will need some more time before any definite conclusions are reached. Residents exposed to radiation will have no other choices than waiting with their fingers crossed.

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.

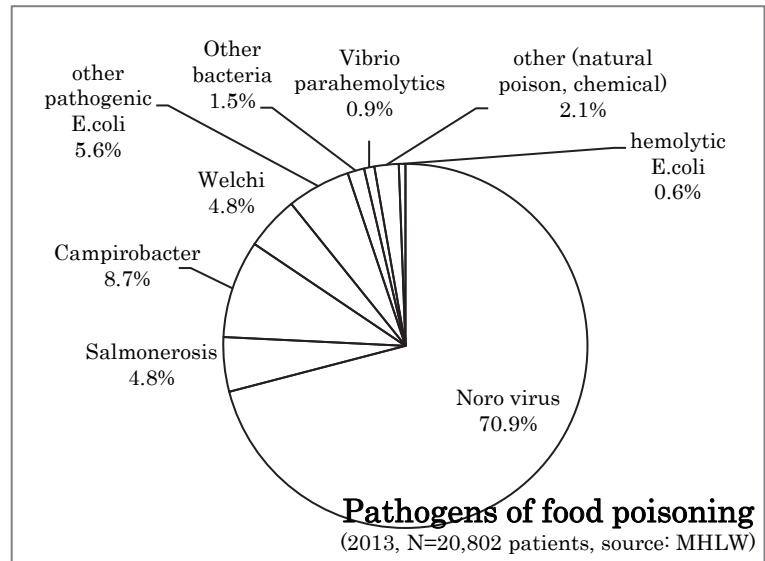
(1) BSE problem

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 2013 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.

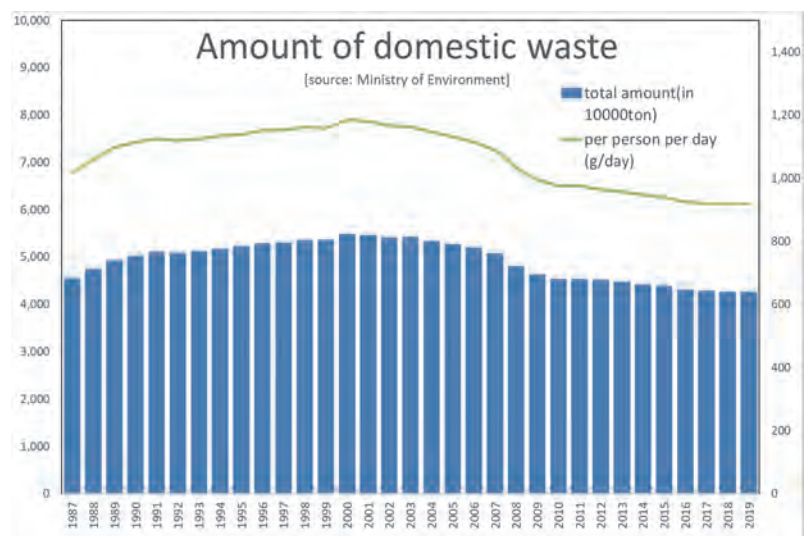
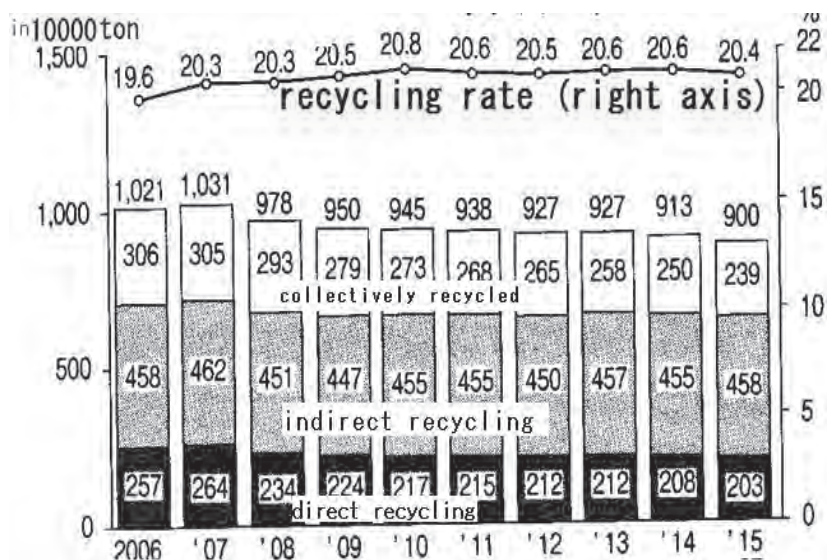
9. Waste disposal

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 facilitates recycling.

(1) Domestic waste

The amount of garbage (domestic waste) was estimated to be 42.74 million ton in 2019 (Survey on domestic waste disposal compiled by the Ministry of Environment). Of them, only 1.1% was directly dumped and 20.4% (9 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 918 gram in 2019).

It is noteworthy that much of recycling is done by community efforts not by municipal governments. As much as 2.4 million tons garbage was recycled by community efforts in 2015, of which 92.7% was paper.



(2) Incineration sites

There are 1,067 incineration sites throughout the country with capacity of 0.18 million tons. Of which 384 sites have power plants as well generating 193 kwh per one ton of garbage showing a great improvement of efficiency from 2000 (116 kwh per ton). The total power generated was 9,981 gwh (giga watt hour) in 2019.

(3) Final disposal sites

Thanks to garbage reduction efforts, the amount finally disposed has constantly declined. Although an average Japanese generate 918 grams of garbage every day, only 119 grams were finally dumped into disposal sites. Securing final

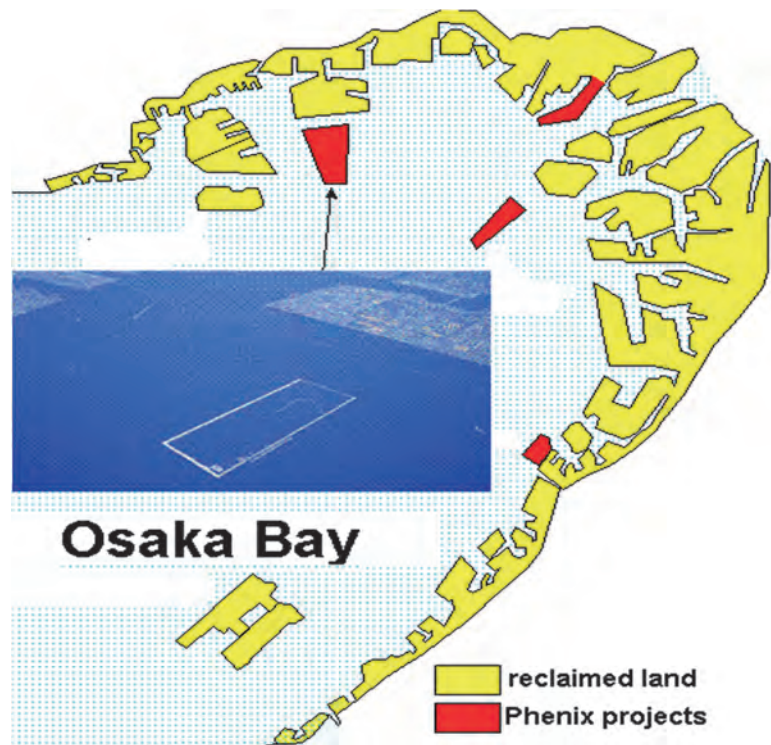
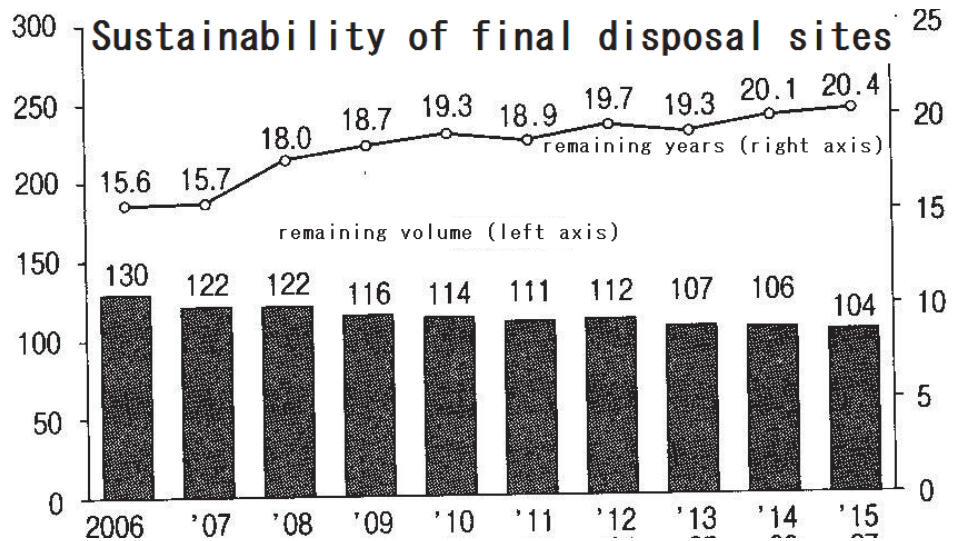
disposal sites is a serious matter because the capacity of final disposal sites have been dwindling. Fortunately, the efforts to reduce garbage outperformed the dwindling capacity of final disposal sites and consequently the remaining years of final disposal sites have actually been prolonged.

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 were 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 9. Industrial Health

1. Historical background

The foundation of Japan's occupational safety and health initiatives can be traced back to the Factory Act of 1911 (effective in 1916), primarily designed to safeguard young and female workers from hazardous conditions prevalent in the growing textile industry. Although the act's scope expanded gradually, a comprehensive measure covering workers across all industries emerged only after World War II with the enactment of the Labor Standard Act in 1947.

In subsequent years, a surge in work-related accidents, notably large-scale gas explosions in mines, led to the implementation of safety measures. The recognition of chronic work-related diseases like pneumoconiosis and Reynaud disease emphasized the importance of preventive measures. Special acts addressing silicosis and traumatic spinal injuries were introduced in 1955 to promote such measures. In 1972, the Occupational Safety and Health Act (OSHA) was established, separating from the Labor Standard Act and instituting industrial health doctors as a specialized medical role.

2. Administrative Structure of Occupational Safety and Health

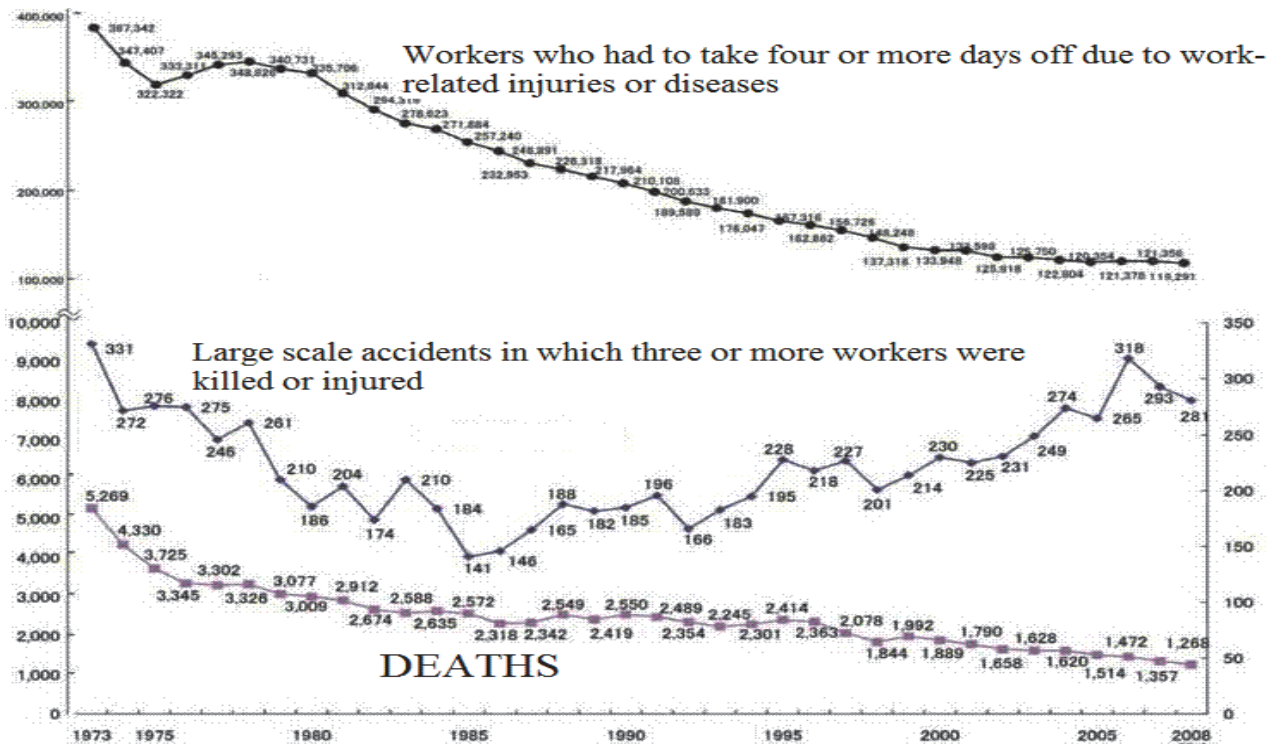
Under the OSHA, employers with 50 or more workers must engage occupational health physicians, and those with 1000 or more workers (or certain industries with 500 or more workers) must employ full-time occupational health physicians. These professionals are responsible for ensuring the health maintenance of workers and conducting on-site inspections to guarantee safe working conditions. Although their suggestions to employers are not legally binding, occupational health physicians play a crucial role in advising on safety and health maintenance.

All employers, irrespective of industry, are obligated to conduct annual health check-ups for their workers, with additional examinations included for those working under special conditions. To support small employers exempt from contracting occupational health physicians, the Japan Organization of Occupational Health and Safety (JOOHS) maintains Occupational Health Promotion Centers in each prefecture, alongside managing nationwide occupational hazards hospitals.

3. Work-related Accidents

Since its peak in 1961, the number of victims of work-related accidents has steadily declined. In 2011, there were 1,024 deaths (2,338 including earthquake-related accidents). The construction industry accounted for 34% of fatalities, followed by the manufacturing industry at 20.5%. However, when measured by

incidence per working hours, the traffic industry had the highest incidence, with 3.67 per million working hours, encompassing both deaths and injuries.



4. Workers' Compensation

Since its peak in 1961, the number of victims of work-related accidents has steadily declined. In 2011, there were 1,024 deaths (2,338 including earthquake-related accidents). The construction industry accounted for 34% of fatalities, followed by the manufacturing industry at 20.5%. However, when measured by incidence per working hours, the traffic industry had the highest incidence, with 3.67 per million working hours, encompassing both deaths and injuries.

Premium is paid 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%).

N of work-related diseases by causing factors

	pneumo cancer	other coniosis	chemical diseases	working exposure	oxygen environment	injuries	physical environ ment	pathogens	
2004	1	814	83	284	368	11	5370	513	165
2005	5	767	178	306	425	9	5829	459	248
2006	1	765	149	320	432	12	5962	487	241
2007	9	640	186	258	518	12	6252	552	257
2008	10	587	222	220	490	11	6625	502	207
2009	10	531	176	191	388	9	5721	328	137
2010	6	516	153	228	394	4	5819	865	126
2011	5	439	222	257	381	10	5654	651	160
2012	4	361	232	204	372	12	5688	684	186
2013	6	334	183	205	346	16	5253	785	182
2014	81	263	134	201	420	4	5445	1088	202
2015	76	251	131	247	419	9	5339	1159	201
2016	72	210	117	215	311	13	5574	1165	125
2017	81	191	126	222	378	5	5963	1317	105
2018	76	165	170	263	457	7	5937	2615	171
2019	53	164	165	220	457	5	6015	1947	113
2020	1	127	99	241	462	12	6533	2173	6291
2021	4	130	125	248	426	3	6731	1331	19494

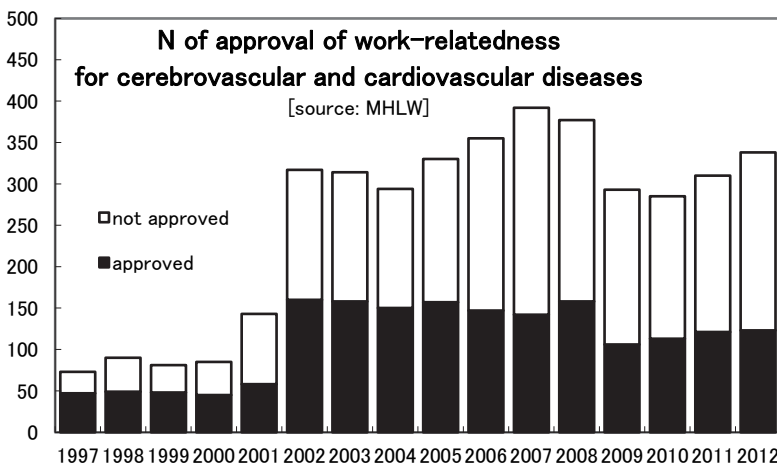
Work-related diseases include infectious diseases. During the pandemic of Covid-19, many workers got infected through their works. During the two years 2020-21, a total of 25,373 workers got infected with Covid-19, of whom 105 lost lives. When broken down by industry, health care workers bore the heaviest brunt: as many as 16,610 workers (approximately 66% of the work-related infections) got infected with 28 casualties. The 28 health care workers who sacrificed their lives in the fight against Covid-19 may well be regarded as “martyrdom”.

N of work-related Covid-19 infections & deaths by industry

	N of cases		N of death	
	2020	2021	2020	2021
other industries	187	922	5	10
other manufacturing industries	10	45		
printing and paper industries	8	55		
automobile industries	104	549	1	2
transportation	213	614	3	16
chemical industries	27	198		
cargo shipping	7	87		
metal manufacturing	5	238		2
construction	187	1153	2	10
commerce and financing	329	1545	4	11
food processing industries	66	841		2
cleaning industries	102	245	1	4
entertainment industries	90	511		1
textile industries	85	40		
steel industries	5	71		2
electricity, gas and plumbing	26	71		
agriculture and fishery	3	42		
health care industries	4578	12032	3	25
wood furniture production	3	40		
china manufacturing	6	33	1	
total	6041	19332	20	85

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.

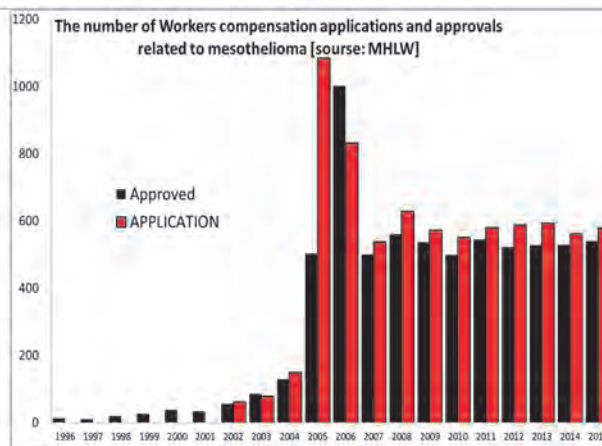
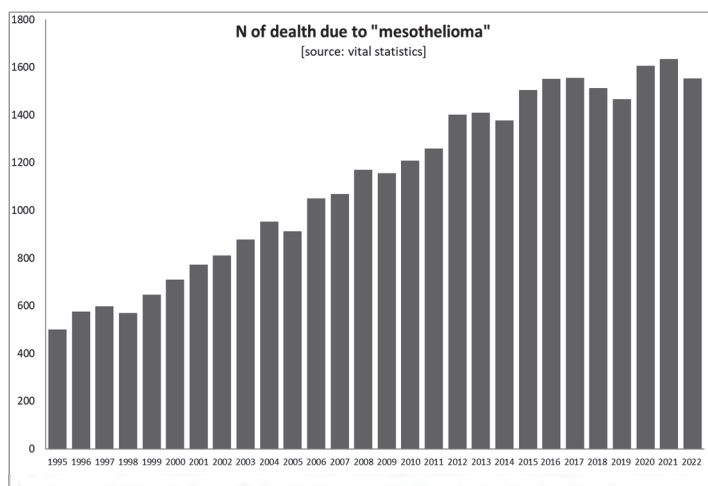
6. Asbestosis

Asbestos had been 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 affects 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

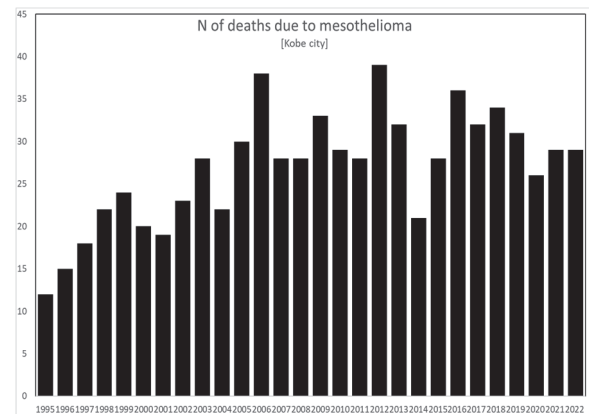


Corporation (NGO affiliated with Ministry of Environment) for compensation. Since mesothelioma is considered to be specifically caused by asbestos, the applicants need only to demonstrate the accuracy of diagnosis with pathological evidence. The process is more complicated for applicants with non-specific 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).

Is Kobe at risk?

The carcinogenic effect of asbestos is long-lasting. The number of deaths due to mesothelioma is increasing nation-wide reflecting the exposure to asbestos in the past. Kobe was hit by a large earthquake in 1995 and there is a growing concern that people might have been massively exposed to asbestos from demolished buildings after the quake. 30 years have passed since the quake and the number of deaths due to mesothelioma in Kobe did not increase conspicuously higher than the national trend so far. However, given the long latency period, it may be too premature to conclude that Kobe residents are spared from environmental exposure to asbestos.



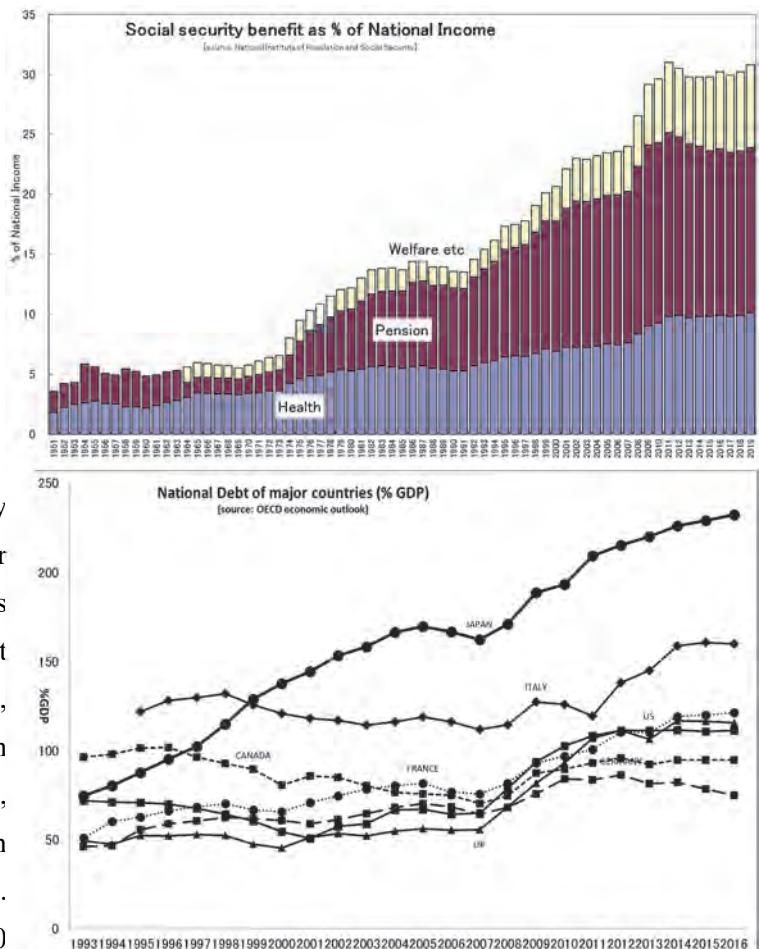
Chapter 10. Social Security and Welfare

1. Social Security and financing

Article 25 of the Constitution affirms the fundamental human right of all nationals to a healthy and culturally enriched livelihood. The 1950 statement by the Social Security Committee defines social security as economic assurance against potential poverty, either through insurance or public subsidy. For those falling below the poverty level, the public subsidy ensures a minimum livelihood, as declared in the Constitution.

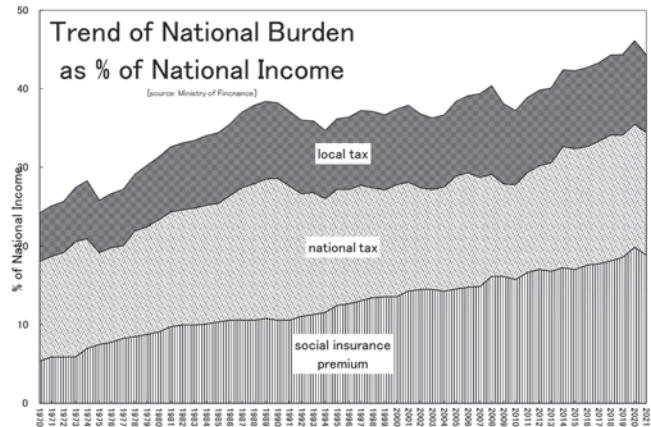
(1) Financing aspects of social security

Social security is a top priority in Japan, though it comes at a considerable cost. Its economic significance is evident in its share of the national economy. In FY2020, social security expenditures amounted to 136.4 trillion yen, approximately 23% of the GDP (540 trillion yen). This marks a significant increase from 1951 when it constituted only 3.5% of the economy. Financing for social security primarily comes from premiums and government subsidies (taxes). In 2022, Japanese citizens paid 64.8 trillion yen in social insurance premiums, surpassing the 54 trillion yen collected from national taxes. Social security also receives a 40 trillion yen subsidy from both central and local governments. Another source of income is the interest from the accumulated social security fund, generating 1.6 trillion yen or 4.8% of the total social security revenue due to historically low interest rates.



(2) National Burden

The percentage of social insurance premiums plus tax in National Income is referred to as the "National Burden," indicating disposable income. This burden exceeded 40% for the first time in 2012. While the burden of social insurance premiums has consistently increased, the share of national tax declined from 18.1% in 1990 to 11.7% in 2009. Japan's National Burden was 48.4%, with citizens paying 19% of their income for social insurance premiums and 29.4% for taxes (both central and local governments) as of FY2022. However, caution is advised in interpreting these figures due to Japan's heavy debt, reaching three times the GDP in 2022, potentially requiring significant inflation to address the accumulating burden.

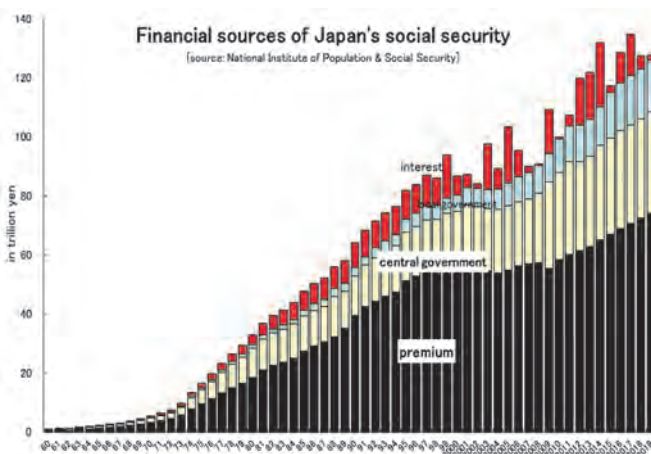
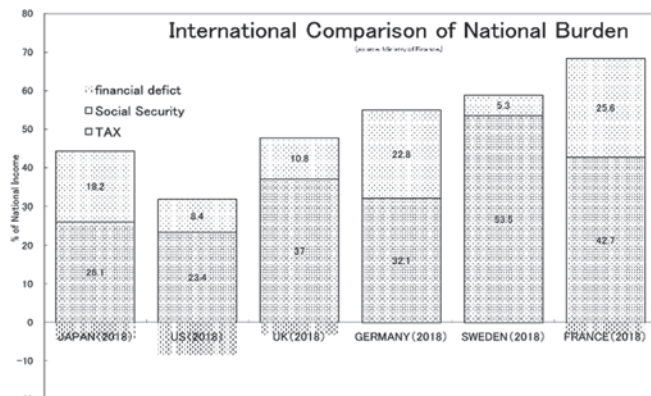


2. Welfare for the Indigent

Poverty has always been at the center of social welfare. Under the Livelihood Protection Act (LPA), 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 recipients. The percent has consistently declined to hit the record low of 0.7% in 1995 shortly after the “bubble economy” busted. 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 2015 was 1.7%.



(1) Livelihood assistance

After all available resources such as savings or financial support by relatives were exhausted, 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 LPA 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 50% of the entire budget of the system.

Approximately 118,000 people (10.6% of those receiving medical assistance, 1.76 million) are hospitalized, of whom approximately 50,000 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.

Nishinari ward, Osaka city: a showcase of poverty

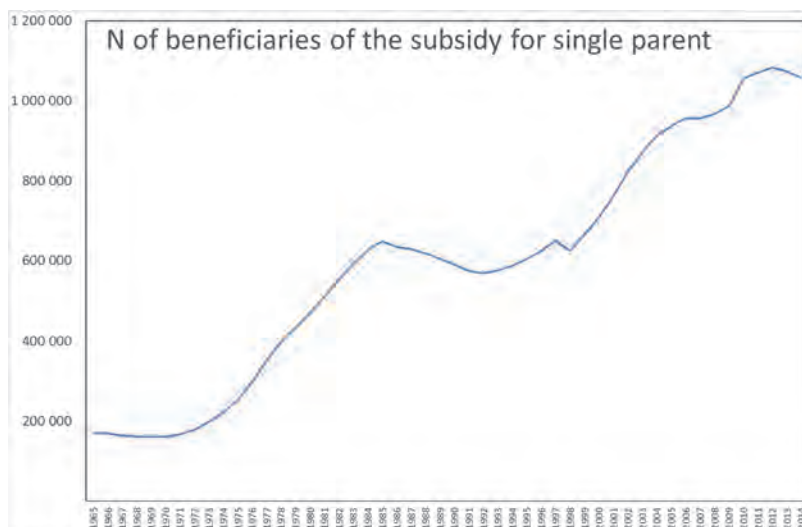
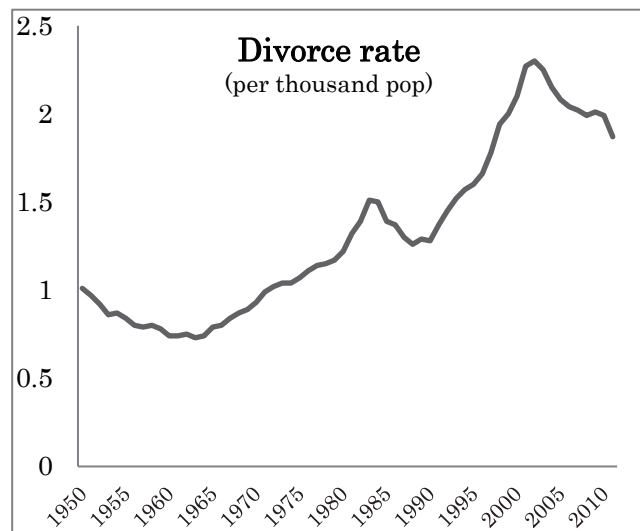
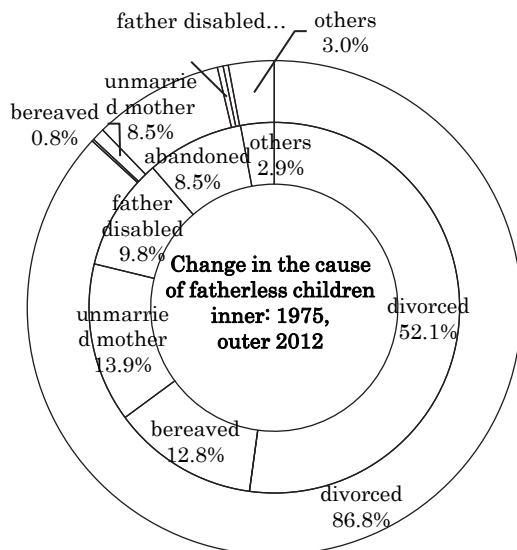
As shown above, the number of the recipients of the LPA is increasing year by year consuming a heavy burden on both the central and local government. Financing of LPA is shared by the central and local government by 3:1. In FY2012, the central government allocates 2.8 trillion yen (33 billion US\$) making the total budget for LPA at 3.7 trillion yen.

The situations are most serious in Osaka city, the second largest city (pop: 2.5 million) with one out of 17.6 residents are recipients of the LPA. Osaka city has 152,870 recipients in March 2012 accounting for 7.4% of the total number of recipients nationwide: 2.07 million. Osaka city consists of 24 wards and Nishinari ward has the highest concentration of the LPA recipients. Nishinari ward of Osaka city is notoriously bad socio-economic environment. One out of 4.3 Nishinari ward residents are recipients and it has the shortest life span: 77.6 years for men in 2005(national 78.79). Reflecting the high poverty rate, some hospitals/clinics attract unusually many LPA patients. Unlike many other countries, Japan’s LPA reimburses the same prices for medical services to hospitals and clinics at no copayment charged to patients. Because of the lack of copayment, doctors can charge to LPA without worrying about patients’ ability to pay (in contrast, ordinary patients insured by health insurance will have to pay 30% of the medical charges to providers). For example, the share of generic drugs is lower in LPA patients than ordinary patients (20.9% vs 23.0% according to the government). Speculation had that some patients seek unnecessary treatment or medications and some hospitals/clinics intentionally

collude to take advantage of those patients. The new city mayor, Toru Hashimoto, who was elected in October 2011 took a decisive action to control the medical assistance of LPA. A survey revealed numerous inappropriate treatment as well as some fraud and abuse cases. The city introduced a new local rule regulating hospitals and clinics located in Nishinari ward in July 2012. The counter-measures attempted in Nishinari ward provided a lesson motivating the national government to follow. Considering that LPA is misused to obtain psychotropic drugs such as sleeping the purpose of drug abuse, the MHLW developed a computer program to analyze electronic claims submitted by pharmacies to detect duplicate medication as well as potential fraud and abuse.

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 193,251 in 2020 or 2 per 1000 population. This figure is far smaller than the U.S. with 3.4 per 1000 divorce rate (2012). 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 was only three million yen.

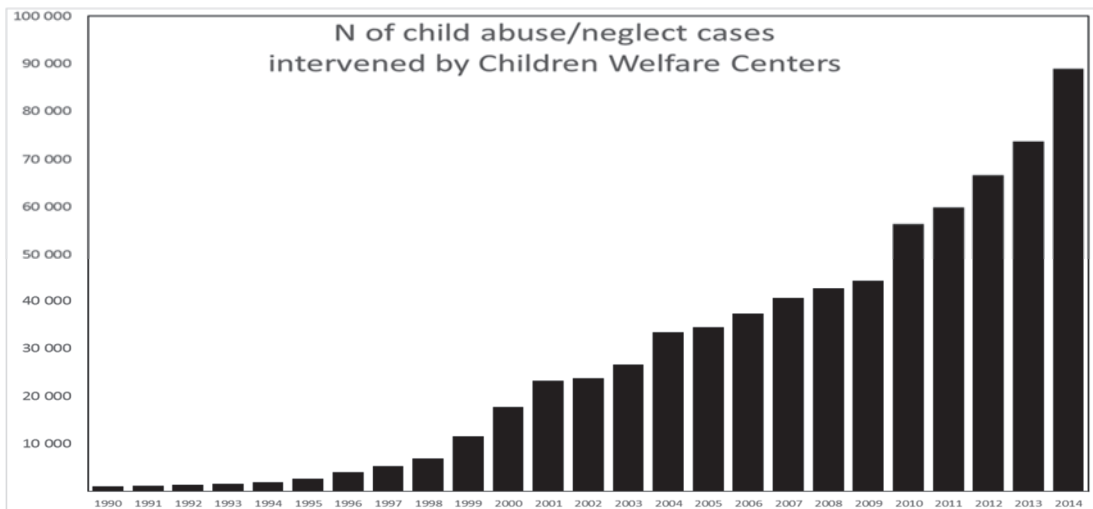
To provide financial support, the government provides the “the Subsidy for Fatherless Children” to single mother and child households. Benefits are available not only to divorced families but also to unmarried mothers. The causes of fatherless children have changed dramatically since 1975.

Monthly benefit is 41,720 yen (\$420) for families with one child and 900,673 households are on the roster in March 2019, nearly 4 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.

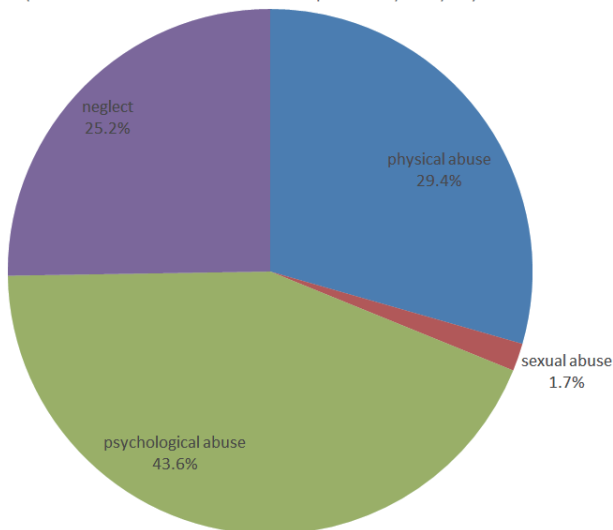
4. Child abuse and neglect

The Child Abuse Prevention Act was enacted in 2000, which defines child abuse and neglect as 1) physical abuse, 2) sexual abuse, 3) neglect and 4) psychological abuse. Pursuant to the act, anyone who finds children being abused are required to report the case to municipal governments, welfare offices or Child Welfare Centers (CWC). CWCs provide professional consultation on abuse, neglect, health and behaviors of children and are the forefronts to detect child abuse and take measures as necessary. CWCs are inundated by a sharp increase of reporting on child abuse.

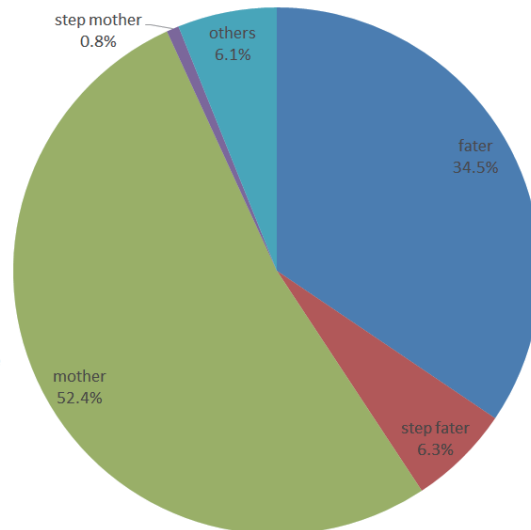
Children Custody Facilities are facilities providing shelters to children suffering from abuse, neglect and abandonment. There were 590 facilities nationwide with capacity of 33,852. According to the survey conducted by MHLW in February 2013, there were 27,549 children under custody, of whom 18% were due to abuse, 15% neglect. Children under custody show a higher prevalence of disability and the prevalence is increasing at an alarming rate. According to the survey conducted every five years, the prevalence of intellectual disability among children under custody increased from 3.4% (1998) to 6.9%(2003), 8.2%(2008) and 10.6%(2013).



Child abuse/neglect by categories
(source: Social Welfare Administrative Reports 2014, N=88,931)



Child abusers by categories
(source: Social Welfare Administrative Reports 2014, N=88,931)



5. Welfare for the disabled

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

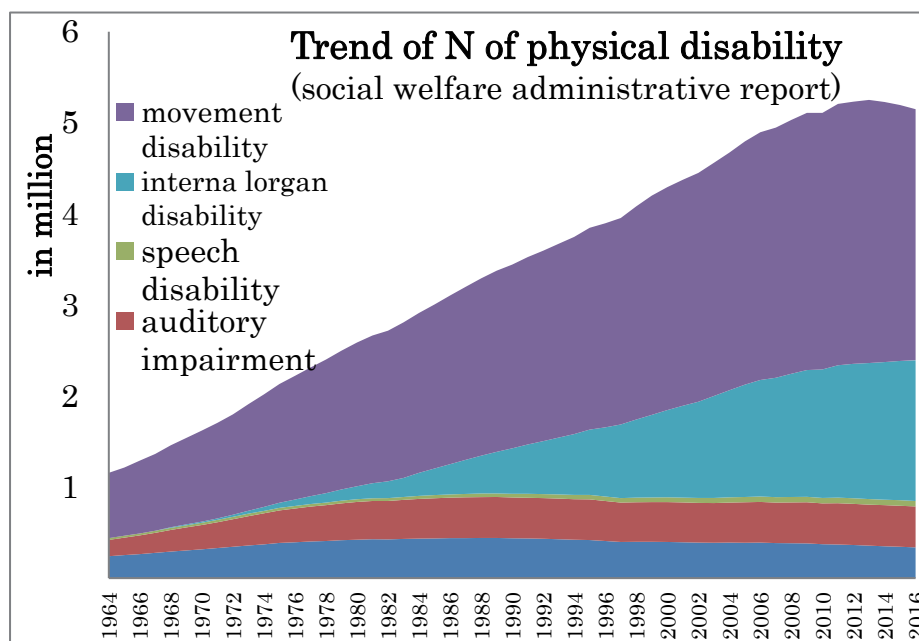
In April 2003, a new system of provision of welfare services for physical and intellectual disabilities was introduced. The new system introduced “*reimbursement (shien-hi)*” system in place of the *direct provision (sochi)* by municipal governments. Under the old direct provision system, the recipients 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 2016 survey, there were estimated to be approximately 4.3 million (33.7 per thousand population) adults (≥ 18 yo) and 72,700 children (< 18 yo) with physical disability. The type



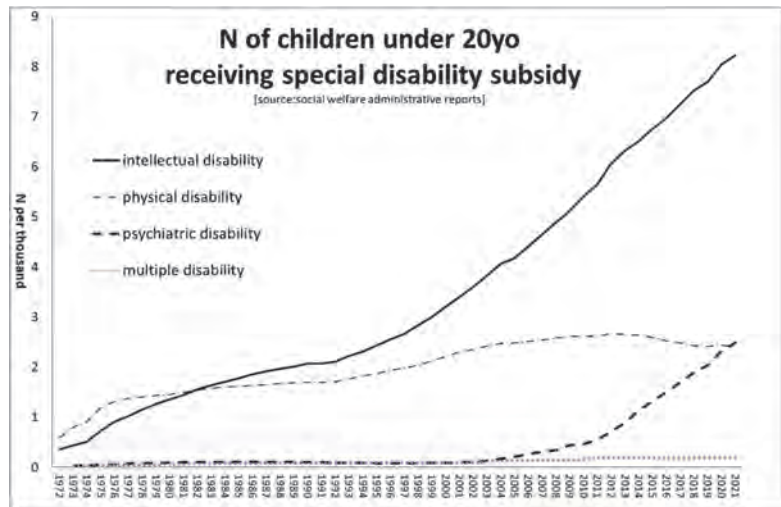
of disability was extremities (50.5% for adult, 53.8% for children), internal organ (such as dialysis, HIV/AIDS) (30.7%, 22.2%), auditory/verbal impairment (9.8%, 18.6%) and visual impairment (8.9%, 5.3%).

Reflecting a sharp increase of kidney failure, internal organ impairment is the fastest growing type of physical disability. Prevalence of disability increases with age. Nearly one out ten of the elderly over 70 have some disability.

(2) Intellectual disability

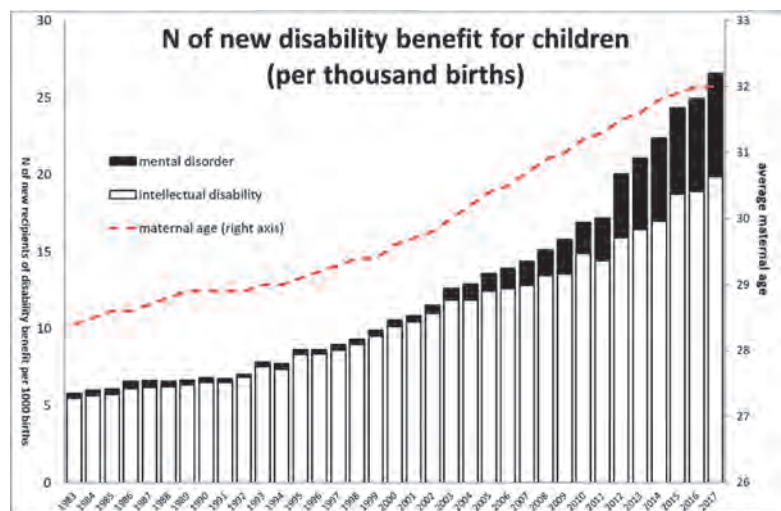
Intellectual disability is measured by IQ and is classified into light (IQ:70-51), medium (IQ:50-36), severe (IQ:35-21) and most severe (IQ \leq 20). According to the governmental survey as of December 2011, there were estimated to be 621,700 (4.9 per thousand) people with intellectual impairment (severe 241,800, mild 303,200), of whom 125,000 were children (< 18 yo). Prevalence of intellectual

disability among children aged 0-9 yo has increased steadily every survey: 2.8/1000 in 1995 survey, 3.6/1000 in 2000 survey, 4.9/1000 in 2005 survey and 5.4 in 2011 survey. The reason of this steady increase is not clear. Increase of Down syndrome because of higher maternal age might explain (average age of mothers increased by 2.8 years between 1995 and 2018:29.1(1995) and 32(2018)). In fact, the number of children (<=20yo) with intellectual disability receiving special disability subsidy has been increasing more than the number of physical disability.



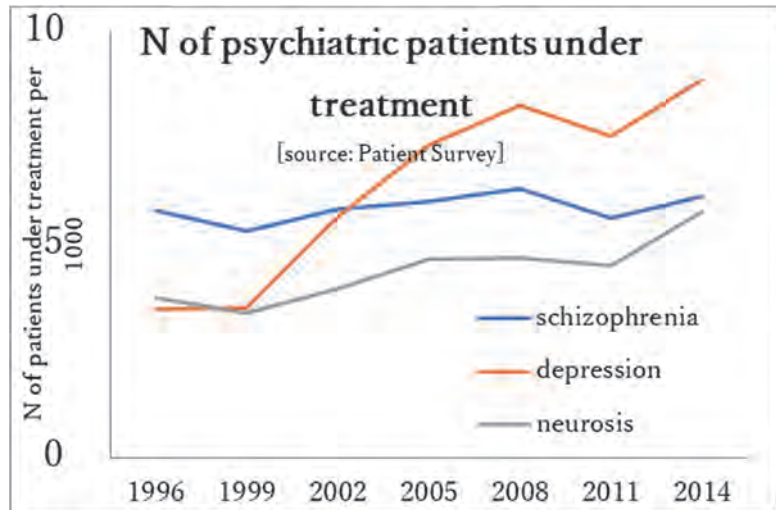
For children with disability (including both physical and intellectual disability), special assistance schools/education is provided. According to the Ministry of Education, approximately 3.58% of school-age children are attending special assistance education (cf. school health).

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.

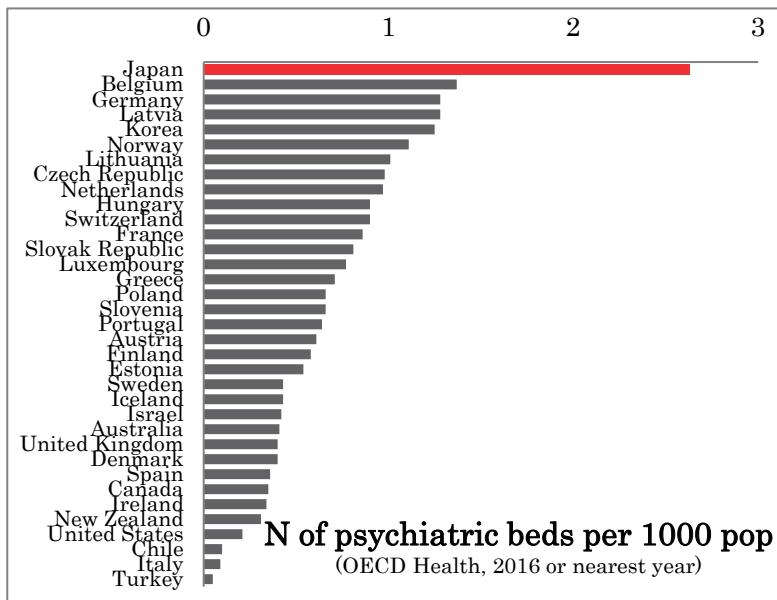


(3) Psychiatric disability

According to the Patient Survey, a sampling survey on hospitals and clinics every three years, there were estimated to be approximately four 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 entitles the holders for benefits such as reduced copayment for ambulatory psychiatric care, deductibles of income tax and discounts of public utilities. A total of 937,084 people (7.4 per thousand population) are issued the certificates (mild 258,190, moderate 560,857 and severe 118,037) in 2017.



Japan has notoriously many psychiatric hospital beds per population as shown in the graph of OECD Health Data. Approximately 60% of the 300,000 inpatients are schizophrenia. The governmental committee estimated that at least 70,000 out of 300,000 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.

There are two types of involuntary hospitalizations in addition to voluntary hospitalizations pursuant to the Mental Health & Welfare Act: 1) involuntary hospitalizations with family's consent and 2) forced hospitalizations to prevent harms on self or others. The second "forced hospitalization" may be executed by

the agreement of more than one qualified psychiatrists. Currently (as of June 2015), 54% of psychiatric inpatients (284,806) are voluntary, 44.8% are involuntary hospitalizations with family's consent and 0.5% (1,515 patients) are forced hospitalization to prevent harms on self or others.

Medical observation for suspects acquitted due to mental disorder

Japan's penal code acquits or reduces penalty for criminal defendants with mental disorder (the Penal Code, section 39). However, victims of crimes, naturally, feel frustrated to see the culprits acquitted just because of the disease. In 2005, a new law "Medical Observation for the Suspects Acquitted for Mental Disorder Act" took effect. The new law requires the acquitted suspects to receive appropriate mental care not to repeat the same crimes again. Such "medical observation" is requested by the prosecutors. On 12th August 2017, a female medical officer of MHLW was stabbed to death by her younger brother at home. The culprit was accused of murder but was acquitted on 7th December because of mental disorder. The prosecutor reportedly requested the medical observation pursuant to the law. The murdered officer was one of the main promoters of the "normalization" of the psychiatric patients to community life and her "martyr" were lamented by many.

[Sankei News. <https://www.sankei.com/affairs/news/171208/afr1712080011-n1.html>]

(4) Financial support for the disabled

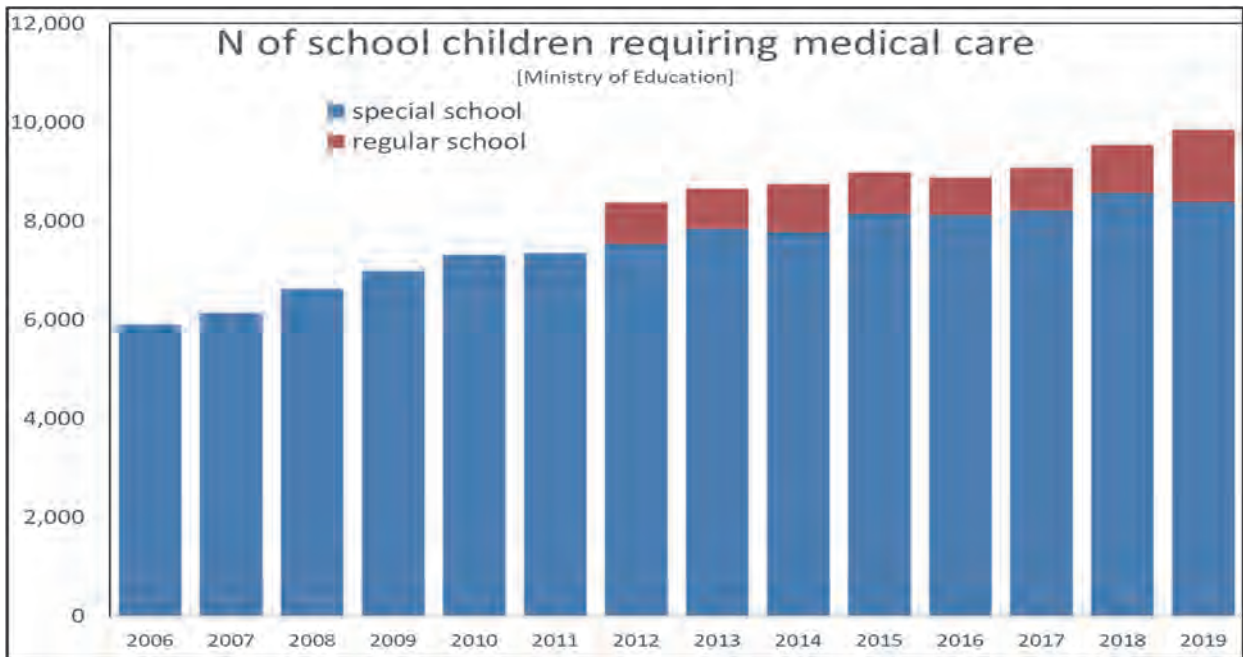
For children and minors (<20 yo) with any disability, the Special Disability Subsidy is paid to their parents or custodians. The monthly amount is 50,400 yen (\$504) for severe disability and 33,570 yen (\$336) for moderate disability.

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) Children with medical care need

Japan has one of the lowest infant mortality rates thanks to the well-developed neonatal care. However, despite efforts of doctors seeking "intact survival (surviving without any physical disability)", a growing number children survive with constant need for medical care such as respirator, tracheotomy and tube-feeding. According to the survey by the Ministry of Education, nearly 9,845 children with medical care are attending schools (8,392 are attending special schools and 1,453 are attending regular school as of May 2019). In response to the increasing demand for special medical care for the disabled children, the Act for children with medical care need was enacted in 2021 and Support Centers for Children with Medical Care Need are being established in every prefecture. A growing number of children with medical care need are enrolled to regular schools instead of special schools posing challenges to schools as well as school teachers.



6. 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.

7. 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.

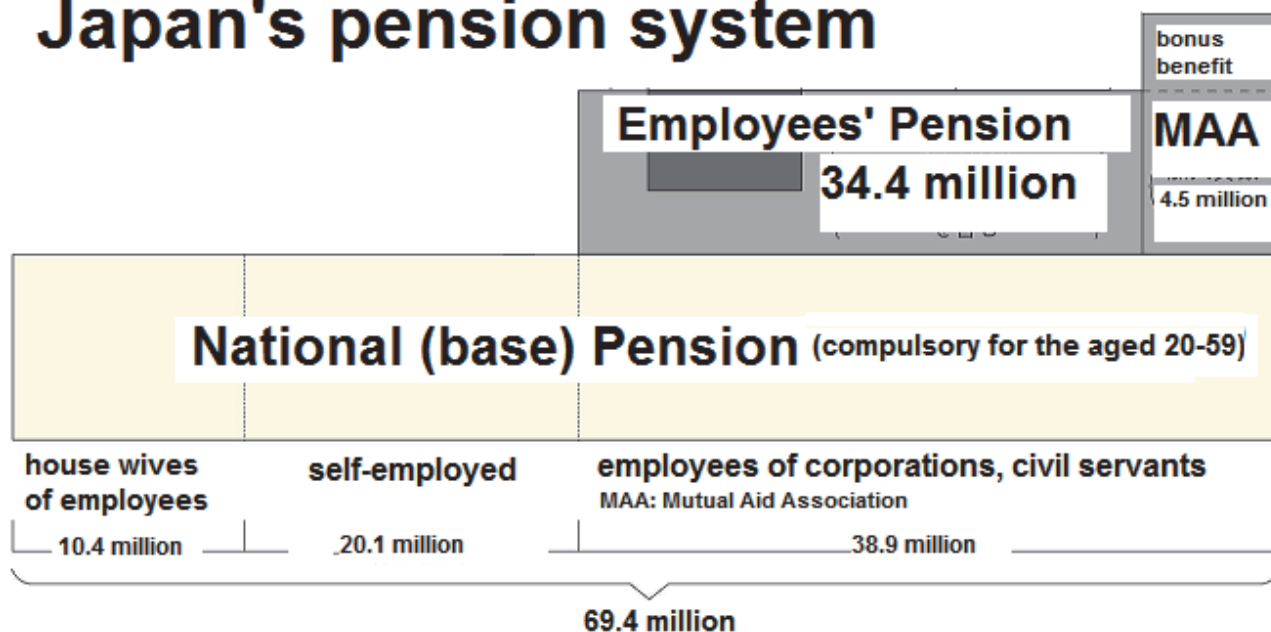
The government decided to recruit a civilian professional from private insurance companies as the director of SIA replacing a career bureaucrat of MHLW, with a hope that such experience professional of insurance business will be able to revive the plagued National Pension system. Eventually SIA was quasi-privatized 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 enrolls 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 10 years (120 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 24.4 years and 20 years for men (2017 lifetable), 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.

(6) Social security and taxation integral reform 2012

The Social security and taxation integral reform was enacted in August 2012. The main purpose of the bill was to raise the consumption tax rate from 5% to 8% in April 2014 and 10% in October 2015. The increased consumption tax will be used mainly for social security. The bill included 1) expansion of employees' pension system to part-time workers in October 2016, 2) shortening the minimum enrollment period for elderly pension from the current 25 years to 10 years in October 2015 and 3) unification of civil servants and private sector workers into one in October 2015.

8. 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.

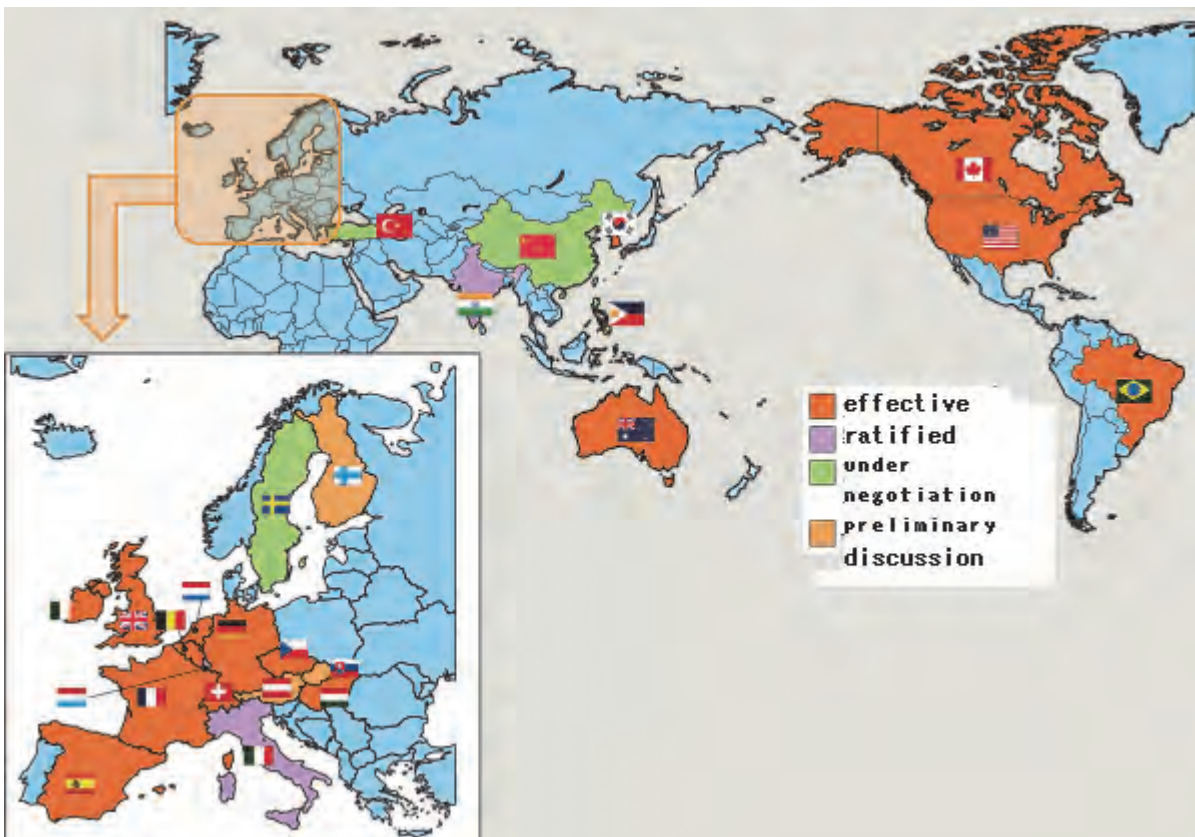
The first of such treaty was ratified with Germany in 2000, followed by UK in 2001. In 2004, Japan ratified the treaty with US and Korea.

The 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.

The treaty with China will also be important given the mutual closeness between the countries. A total of 140,931 Japanese are living in China and a total of 674,879 Chinese are living in Japan (2011). China started a new social insurance scheme in July 2011 and start to enroll foreign workers on 15th October 2011. In case of Shanghai with the largest Japanese population (approximately 70,000), the premium rate of pension is 22% for employer and 8% for employee, the rate of health insurance 12% for employer and 2% for employee. The overall rate is higher than Japan possibly because Chinese insurance is not subsidized by government. After lengthy negotiation, Japan and China reached an agreement on totalization of pension on 8th May 2018 (Japan-China treaty does not include health insurance) and took effect in September 2019.



Chapter 11. 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 out of the city.

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 1700 municipal governments administer the LTCI system, the premium level also varies from

municipality to municipality. The average monthly premium is approximately 6,000 yen and ranges from 3,000 to 8,000 yen. In each municipality, the premium is scaled to the beneficiaries' income with 3 times difference between the lowest and the highest income bracket.

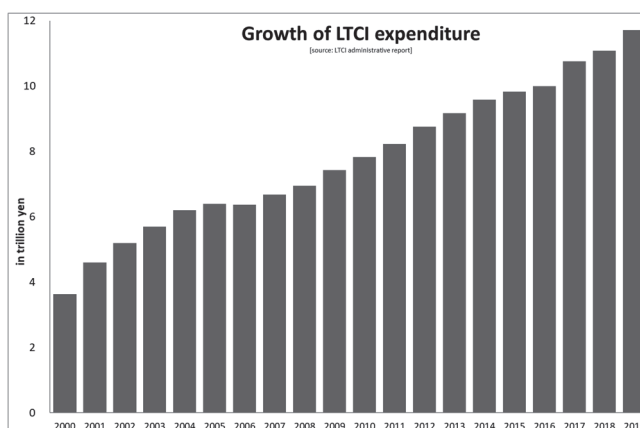
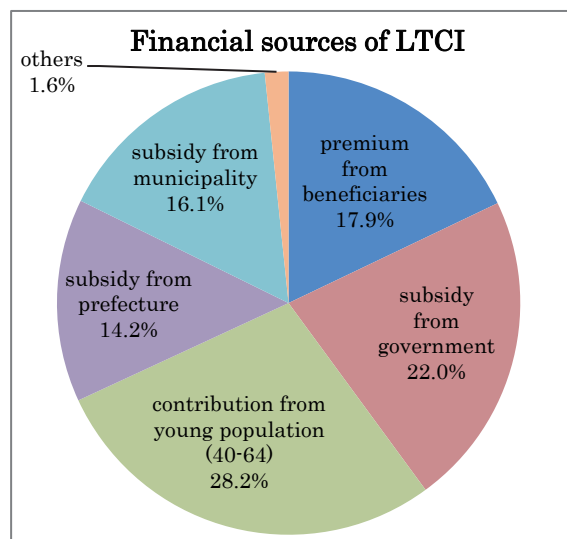
Expenditures of LTCI have grown considerably since its inception in 2000: from 3.6 trillion yen to 12 trillion yen in FY2019.

4. Care-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 final 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 visiting rehabilitation ambulatory rehabilitation[day care]	home help catering bathing ambulatory service[day service]

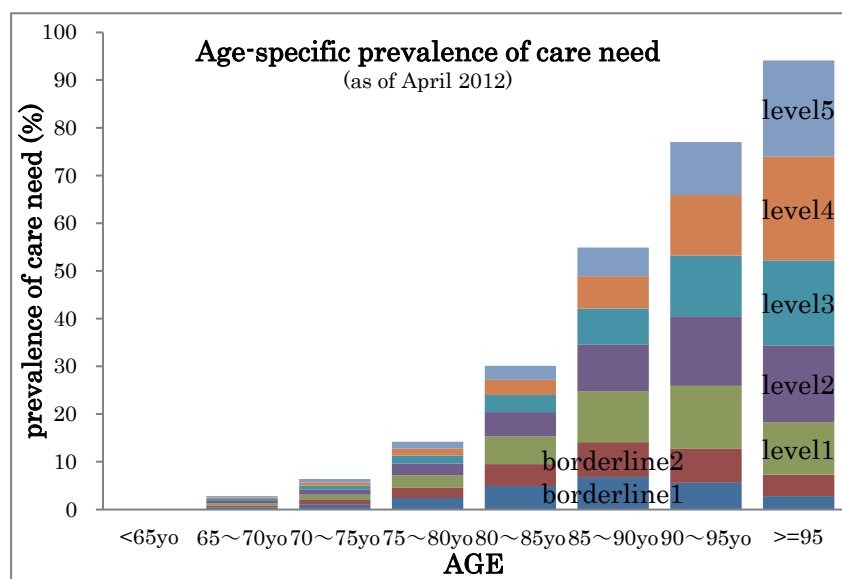
The monetary terms of benefit is metered to the level of care need, which reflects the estimated care time. The level of care need will determine the per diem cost for institutional care and the monthly limit for home care as shown.

Overall, 2.9% of beneficiaries receiving home services exceed the monthly limit. The % of those exceeding the limit are skewed to those in need of high care need.

	estimated care time (min)	monthly limit (yen)	actually spent (yen)	% spent	% of recipients exceeding limit
borderline1	25~32	48700	22900	46.1	0.7
borderline2	32~50	104000	41960	40.3	0.3
level1		165800	75800	45.7	2.1
level2	50~70	194800	104560	53.7	4.2
level3	70~90	267500	156700	58.6	4.5
level4	90~110	306000	190490	62.3	5.3
level5	110~	358300	233080	65.1	5.9
TOTAL					2.9

6. Care-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.

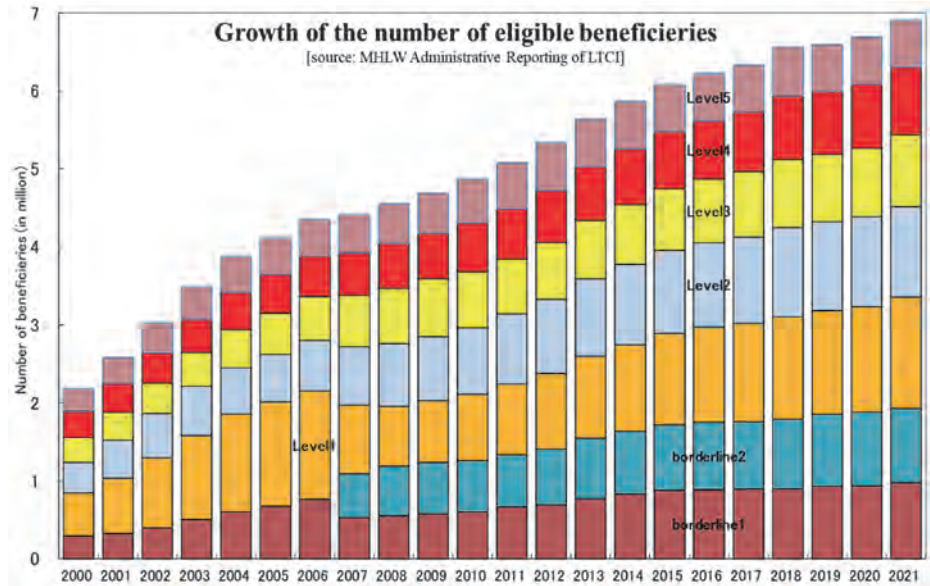


Because of chronic shortage of nursing home beds, many elderly who lack adequate care at home are institutionalized at geriatric hospitals without firm medical necessity. Although all health insurance claims are subject to rigorous review, such "medically unjustifiable" prolonged hospitalization is seldom 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

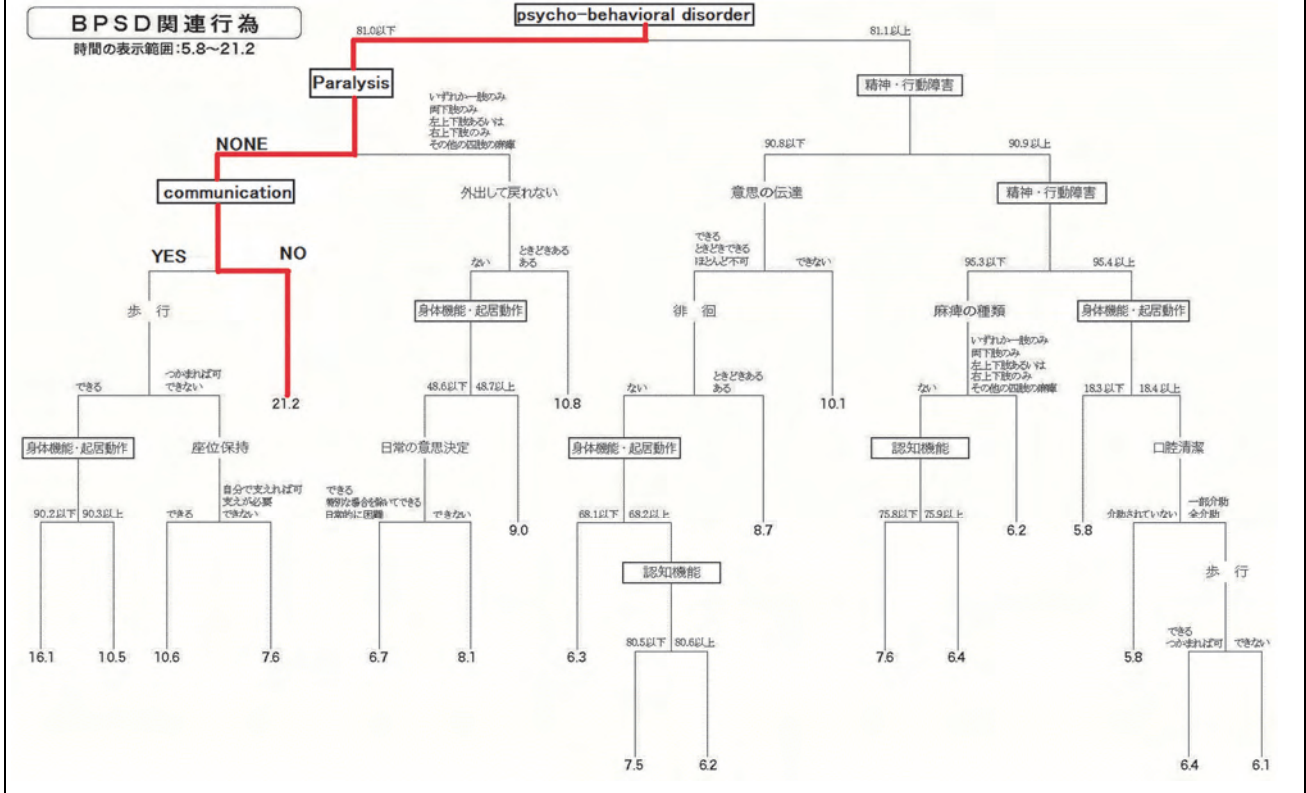
nursing homes to quantify the care need by means of one-minute time study and correlate it with ADL measurement. The methodology was in many ways similar to that of the U.S. with its development of MDS, RUGs.

The product was the assessment tool consisting of 74 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. The prevalence of care need is minimal in people younger than 65yo but increases with age. The elderly 95 years old or over will be assessed in need of care for as much as 95% of them. The number of beneficiaries assessed as in need of care increased dramatically from 2.18 million in 2000 to 6.69 million in 2020.



Tree model

The level of care need is assessed by applying the findings of on-site survey items to eight tree models (eating, excretion, movement, sanitation, indirect living assistance, BPSD, rehabilitation and medical care). Each tree model estimates care time and the level is decided by the sum of eight estimated care time. In case of BPSD (Behavioral and Psychological Symptoms of Dementia), first the applicant is assessed about psycho-behavioral disorder and is classified whether the assessment is below 81 or not. Next, does the applicant have paralysis? And, does the applicant have any communication problems? If the applicant's status was NO to both items, then the care time is estimated to be 21.2 minutes as shown below. It is interesting to know that, in the domain of BPSD, a person without paralysis or communication problems requires more care time than otherwise.

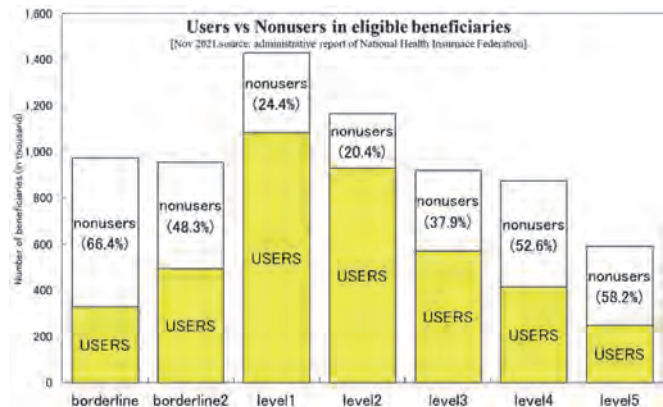


7. Care Management

A pivotal aspect of Japan's LTCI is care management, a professional service designed to coordinate diverse services from different providers to address the dispersed nature of home settings within allocated budgets. The U.K. introduced care management in its 1990 Community Care Act, aligning with Japan's LTCI, which covers both non-medical and medical services. This distinguishes it from Germany's LTCI, exclusively offering non-medical services and lacking an official care management system. To meet the demand for need assessment and care management, a new professional role, the "care manager," was established. The first qualification exam began in September 1998, requiring professionals with existing health or welfare-related licenses and a minimum of five years of clinical experience.

8. Reforms of LTCI

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 April 2020, approximately 6.69 million beneficiaries were assessed as eligible for the benefit. This figure is approximately 18.4% of the total beneficiaries I (36 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 51% 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.

(1) Reform in 2006

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.

(a) 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.

(b)Change of care-need assessment process

On-site survey for care-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.

(c)Integrated Community Care 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 Integrated Community Care Support Center (ICCS) 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.

Functions and staffing of ICCS

- Serves as a hub of networking for community care
- Human right protection and advocacy
- Integrated and continuous care management
- Preventive care management

ICCS is staffed with three categories of professionals: public health nurse, social workers and care managers. Ideally for every 3,000~6,000 elderly (>=65), at least one professional for each job category should be allocated.

(2)Reform in 2008

Following the "COMSN" scandal, anti-fraud and abuse measures were strengthened and requirement of compliance of providers were introduced. For example, on-site survey for care need assessment, which had been delegated to private providers, became required to be conducted by municipal government directly to ensure neutral and accurate assessment.

COMSN scandal

The COMSN corporation was the largest LTC provider. It had 2,081 branches (1,110 were home help providers), approximately 65,000 clients with the revenue of 63.9 billion yen. The company was known as the most grown company taking advantage of the new LTCI. However, Tokyo Metropolitan Government revealed fraudulent claims, serious violation of staff requirement and falsification in the application process in one of their branch (Contracts and supervision of providers of LTCI are in the jurisdiction of prefectural governments). When Tokyo Metropolitan Government attempted to cancel the LTCI contract of the branch, the company dodged the sanction by voluntarily closing the branch. Further, the same scandals were

revealed about branches of the COMSN corporation in other prefectures out of Tokyo. In June 2007, MHLW ordered all prefectures not to contract with providers of COMSN corporation. Again, the COMSN corporation tried to dodge the sanction by transferring all branches to another affiliated corporation. Eventually, the company was forced to withdraw from the LTC business due to public outcry. All branches of the company were eventually sold to local providers in respective prefecture. The scandal of the largest LTC business and the subsequent withdrawal surprised the society prompting the reform strengthening regulation and supervision on providers.

(3) Reform in 2011

The number of recipients and the total expenditure of the LTCI is increasing steadily. To protect the financial health of the LTCI, the reform in 2011 introduced a new initiative “integrated community care”. The integrated community care is defined as “medical care, long-term care, prevention, domestic services and housing are provided seamlessly and in an integrated manner”.

A particular emphasis is placed on “housing”. If houses are barrier-free and suitable for the disabled, then an elderly will be able to continue to live in their homes even if they become disabled. Housing condition is important for the finance of the LTCI because the disabled elderly who cannot live at home will have to be institutionalized. The institutional care such as nursing homes, geriatric hospitals are expensive and heavy burden for the LTCI. Also, many elderly possess substantial asset in the form of real estate or financial asset (60% of the personal financial asset of 1500 trillion yen is owned by the elderly over 60). If such affluent elderly choose to stay at home even after they become disabled, it will bring about substantial saving for the LTCI. The LTC facilities such as nursing homes, skilled nursing facilities and geriatric hospitals are financed exclusively by the LTCI except 10% copayment charged to recipients. On the other hand, the elderly dormitory and high-end senior housing are essentially real estate business and residents will pay the house rent out of their own pockets.

The high-end senior dormitory are like dormitories in that they provide personal care for bathing, toileting and eating. New residents have to pay “deposit” occasionally exceeding ten million yen at front in addition to monthly rent plus charges for care. They are based on the Elderly Welfare Act and increased sharply after the introduction of the LTCI in 2000. There are 15,134 high-end senior dormitories with 573,541 capacities in 2019.

Another type is “senior housing with care services” which is essentially similar to rental housing. It is based on the newly enacted “Elderly Housing Security Act” through collaboration between the Ministry of Land, Infrastructure and Transportation (MLIT), collaborating with MHLW. The number of senior housing increased sharply since it was introduced. There are 7,892 facilities with 267,7246 units in May 2021. MLIT targets 600,000 supply of senior housing with

care services.

If the supply of housing suitable for disabled elderly becomes sufficient, the elderly can continue to live in their original community if different types of care are provided in an integrated and seamless manner. Integrated care

Increase of senior housing with care services

	N of houses	N of units
2011	30	994
2012	2587	77599
2013	4105	130447
2014	5070	163160
2015	5885	191871
2020	7892	267246

will be coordinated by ICCSCs. Currently, a total of 5,221 ICCSCs are operational as of April 2020 (there are additional 1,781 branches and 333 subcenters). Their jurisdiction is expected to be equivalent to those of junior high schools. Since there are approximately 10,000 junior high schools (average population size:12,700), more ICCSCs will be necessary to achieve the goal. ICCSC will play a key role in implementing the integrated community care.

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Japan Public Health Association

1-29-8, Shinjuku, Shinjuku-ku, Tokyo, 160-0022 JAPAN

Tel: +81-3-3352-4281, Fax +81-3-3352-4605

<http://www.jpha.or.jp>

The entire content of this book is viewable on the above website

For inquiry about the content, mail to:

okamoto-etsuji@fukuchiyama.ac.jp