

The history and role of Japan's public health care system

: Looking ahead to addressing aging

September 3

Boston Consulting Group Senior Advisor

Iwate Medical University Faculty of Medicine Visiting Professor

Former Policy Advisor, Cabinet Secretariat, Health and Medical Strategy Office

Former Director-General of the Medical Affairs Bureau of the Ministry of Health, Labour and Welfare

Toshihiko Takeda

The history and role of Japan's public health care system : Looking ahead to addressing aging

INTRODUCTION: CHARACTERISTICS OF JAPANESE MEDICAL CARE

JAPAN'S HEALTHCARE SYSTEM AND MEDICAL INSURANCE SYSTEM ARE UNIQUE WORLDWIDE

Japanese medical care

- Japanese "Universal Health Insurance" system
 (With "Health Insurance Card", anyone can go any madical institutions at any time)
- Medical Care Delivary System, mainly by private medical institutions
 ("Free Practice System": It is a sytem which allows any physician can establish a practice, provided that they submit a notification to the local government.)
- "Free Medical Specialty Advertising System"
 (It is a system which allows physicians to claim any specialty regardless of their field of expertise or years of experience.)
- Free Access

Management of medical care in Japan

- Introduced and raised patient copayments under free access
- Financial incentives to promote differentiation of functions under the "Medical Fee Schedule" (incentives)
- Promotion of local autonomy and introduntion of local medical plan to limit hospital beds
- Providing information for patients' selection
 (deregulation of advertising restrictions, prodiving information to the public)

The basics of Japan's healthcare policy

- Keep ensuring access to medical care <Top priority>

 (e.g., ensuring a stable supply of medicines)
- Improving the quality and efficiency of medical care (=pursuing optimal medical care)
- Emphasis on prevention
 (prevention of lifestyle-related diseases + prevention of "frailty")
- From medical care that "cures" to medical care that "cures and supports"
 (promoting and establishing community-based comprehensive care systems)

(Personally, I would also like to add, "From medicine to food" and "The three "life"s = as "life", as "livelihood", as "lifetime = emphasizing "IKIGAI" :sense of fulfillment in life.")

The basics of Japan's healthcare policy

Ensuring access to medical care
 (e.g., ensuring a stable supply of medicines)

- Stable supply of pharmaceuticals
- Countermeasures for uneven distribution of doctors

- Improving the quality and efficiency of medical care (=pursuing optimal medical care)
- Emphasis on prevention
 (prevention of lifestyle-related diseases + prevention of frailty)
- From medical care that "cures" to medical care that "cures and supports"
 (promoting and establishing community-based comprehensive care systems)

```
(Personally, I would also like to add, "From medicine to food" and "The three "life"s = as "life", as "livelihood", as "lifetime = emphasizing "IKIGAI" :sense of fulfillment in life.")
```

The basics of Japan's healthcare policy

- Ensuring access to medical care
 (e.g., ensuring a stable supply of medicines)
- Improving the quality and efficiency of medical care (=pursuing optimal medical care)
- Emphasis on prevention
 (prevention of lifestyle-related diseases + prevention of frailty)
 - From medical care that "cures" to medical care that "cures and supports" (promoting and establishing community-based comprehensive care systems)

(Personally, I would also like to add, "From medicine to food" and "The three "life"s = as "life", as "livelihood", as "lifetime = emphasizing "IKIGAI" :sense of fulfillment in life.")

- •The basic of "Medical Fee Schedule" is based on the new "Medical Fee Schedule" 1958.
- For in-patient care, DPC (Diagnosis Procedure Combination) was introduced in 2004.

The history and role of Japan's public health care system : Looking ahead to addressing aging

OVERVIEW OF JAPAN'S MEDICAL INSURANCE SYSTEM

LET'S TAKE A LOOK AT AN OVERVIEW OF JAPAN'S MEDICAL INSURANCE SYSTEM.

Overview of Medical Service Scheme in Japan

75 vears or older

10% copayment

Those with income equivalent to that of working people will bear 30% of the cost, and from October 1, 2022, those with income above a certain level other than working people will bear 20% of the cost.

•70 to 74 years old 20% copayment

Those with income equivalent to that of working people will bear 30% of the cost

 From compulsory education to age 69

30% copayment

 Yet to start compulsory education 20% copayment

Patient (insured)

Patient burden: 5.4 trillion ven

[Medical Service Providing Scheme]

(2) Receive service & pay copayment

> (3) Provide **Clinical service**

> > **Medical expenses** 46.7 trillion yen

Insurance premiums 23.4 trillion yen

(1) Insurance

contribution

(5) Reimbursement

85

Insurer

Hospital 8,122 1,481,183 beds Clinic 104,894 Dental clinics: Pharmacies:

*Figures are as of October 1, 2023 (Source: 2023 Medical Facility Static & Dynamic Survey)*Pharmacies are as of the end of March 2024 (Source: 2023 Health

75,780 beds 66,818

62,828

dministration Report)

Administrativ e bodies

[Medical insurance

system]

Public

fundina

(Principle schemes) (Number of enrollment) (Number of insurers)

-"National Health Insurance" 1.716

-Japan Health Insurance Association administered health insurance

-Association/union administered

health insurance -Mutual aid association Approx. 24 million

Claims

Approx. 39 million

1,383 Approx. 28 million

Approx. 10 million

Prefectural Municipal governments

Insurers

National

Supportive contribution

-Advanced Elderly Medical Service System 47 Approx. 19 million

Physician 343,275 **Dentist** 105,267 Pharmacist 323,690 Registered nurse 1.32 mil Public health nurse 0.67 mil

Midwife 0.42 mil

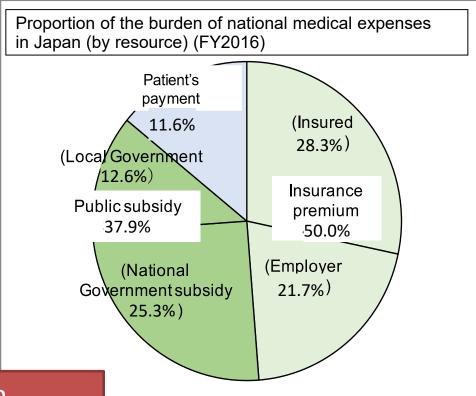
* Doctors, dentists, and pharmacists are as of December 31, 2022 (2022 Statistics on Doctors, Dentists, and Pharmacists).* Nurses, public health nurses, and midwives are based on the number of employed persons, compiled by the Nursing Division of the Medical Affairs Bureau, Ministry of Health, Labour and Welfare, based on the "2020 Medical Facility Dynamics Survey" and the "2020 Health Administration Report (Biennial Report)" of the Ministry of Health, Labour and Welfare.

Japanese "Universal Health Insurance" system

- O Our country has realized the world's highest level of life expectancy and healthcare standards through the Japanese "Universal Health Insurance" system.
- O It is necessary to ensure a safe and secure living of the citizens continuously by firmly maintaining the Japanese "Universal Health Insurance" with the current social insurance system.

Characteristics of Japanese "Universal Health Insurance" system

- 1. <u>Covering all citizens</u> by public medical insurance
- 2. Freedom of choice of medical institution (free access)
- 3. High-quality medical services with low costs
- 4. The social insurance system, <u>with large Government</u> subsidy to maintain the "Universal Health Insurance"



This is official explanation.
Sounds good... But is it sustainable?

[Outline of the Healthcare Insurance System]

Medical care system for the elderly aged 75 and over

- •Age 75 or over
- About 20 mil people
- 47 insurers (extended association)

Approx. 20 trillion yen

Age 75

System to address the imbalance in the payment of medical expenses for the under 75 (about 14.8 million people)

approx. 7 trillion yen (aforementioned)

Age 65.

"National Health Insurance"

Self-employed, farmer, retired,
•About 26.6 mil. people
•About 1.900 insurers

Approx. 9 trillion yen

Public-corporationrun Health Insurance

- Salaried employee of small or medium sized corporations
- About 39 mil. people
- 1 insurer

Approx. 7 trillion yen

Society-managed, employment-based

Health Insurance

- Salaried employee of Large Corporation
- -About 27.6 mil people
- About 1,400 insurers

Mutual aid association

- Civil officer
- About 9.6 mil.
 people
- •85 insurers

Approx. 6 trillion yen (total)

Population trends in Japan

O Japan's population has been declining in recent years. By 2070, the total population is expected to fall below 90 million, and the aging rate is expected to reach 39%. Actual Estimated in 2023 人口(万人) 14,000 126.15 mil in 2020 Productive age (15~ 64) population ratio 112.84 mil in 2040 12,000 36.03 mil 87 mil in 2070 Population of 39.28 mil 65 and above Productive age (15~64) 10,000 population ratio 52.1% 59.5% 33.67 mil 8,000 in 2020 Aging population 75.09 mil Population of ratio 28.6% 15~64 38.7% in 2020\ 6,000 Aging population (65 and above) ratio 62.13 mil 45.35 mil 4,000 Total fertility rate Total fertility rate 1.36 Population of 2,000 14 and below 1.33 in 2020 15.03 mil 11.42 mil 7.97 mil (年) 1950 1960 1970 1980 1990 2000 2010 2020 2030 2040 2050 2060 2070

(Source) Population figures up to 2020 are from the Ministry of Internal Affairs and Communications' "National Census," and total fertility rates are from the Ministry of Health, Labor and Welfare's "Population Dynamics Statistics." From 2025 onwards, figures are from the National Institute of Population and Social Security Research's "Future Population Estimates for Japan (Reiwa 5 Estimates)" (medium fertility (medium mortality) estimates).

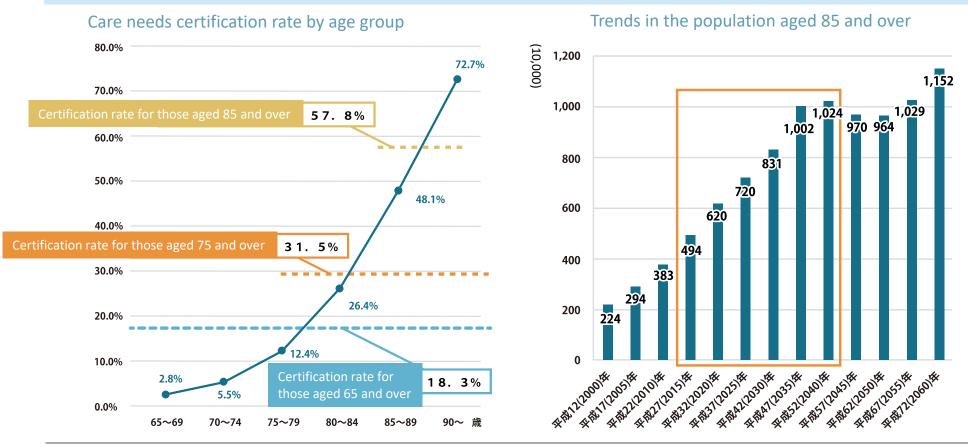
Japan's future estimated population (2023 estimate)

From a lecture by Miho Iwasawa, Director of the Population Trends Research Department at the National Institute of Population and Social Security Research (Social Insurance Weekly, August 21, 2023 issue)

- In terms of social security and healthcare, the year 2040 is significant.
- In that year, the number of deaths in Japan will peak at 1.67 million.
- In 2038, the number of births in Japan will fall below 700,000.
- The population aged 65 and over will peak in 2043.

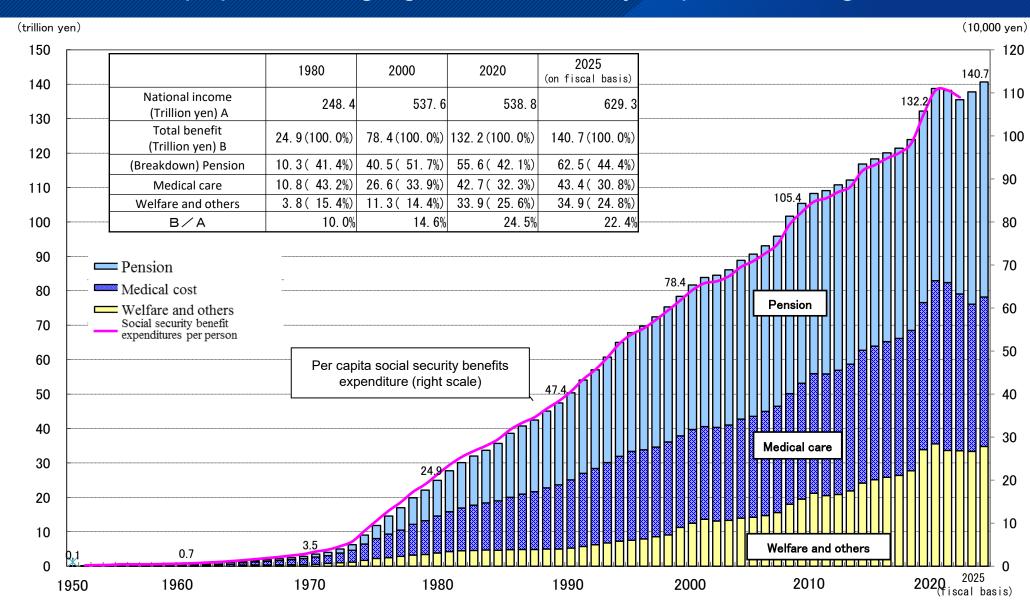
The need for integrated medical and nursing care will increase

The rate of people requiring nursing care increases with age, especially among those aged 85 and over. After 2025, the increase in the number of elderly people will slow down, but the population aged 85 and over is expected to continue to increase toward 2040, and the number of people requiring integrated medical and nursing care is expected to increase.



Source: Created based on the number of certified persons as of the end of September 2020 (Long-Term Care Insurance Business Status Report) and the population as of October 1, 2020 (Population Estimates by the Statistics Bureau, Ministry of Internal Affairs and Communications). Future projections are based on the National Institute of Population and Social Security Research's "Future Population Projections for Japan" (April 2017 estimates) using the medium birth rate (medium death rate) projection. Actual figures are based on the Ministry of Internal Affairs and Communications Statistics Bureau's "Census" (population adjusted to account for unknown nationality and age).

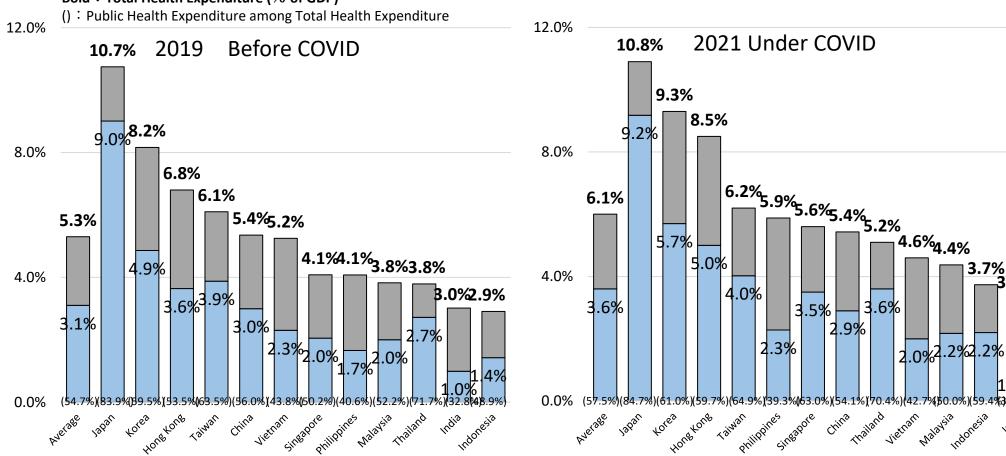
With population aging, social security expenditures grow



Source: Until fiscal 2023, data is from the National Institute of Population and Social Security Research's "Social Security Expenditure Statistics for Fiscal 2023"; for fiscal 2024–2025 (budget basis), data is from estimates by the Ministry of Health, Labour and Welfare.For fiscal 2025, gross domestic product is from "Economic Outlook and Basic Stance on Economic and Fiscal Management for Fiscal 2025 (Cabinet Decision on January 24, 2025)."(Note) The figures in the chart represent social security expenditure (trillion yen) for the fiscal years 1950, 1960, 1970, 1980, 1990, 2000, 2010, 2020, and 2025 (budget-based).

Health Expenditure(% of GDP), 2019, 2021

Bold: Total Health Expenditure (% of GDP)

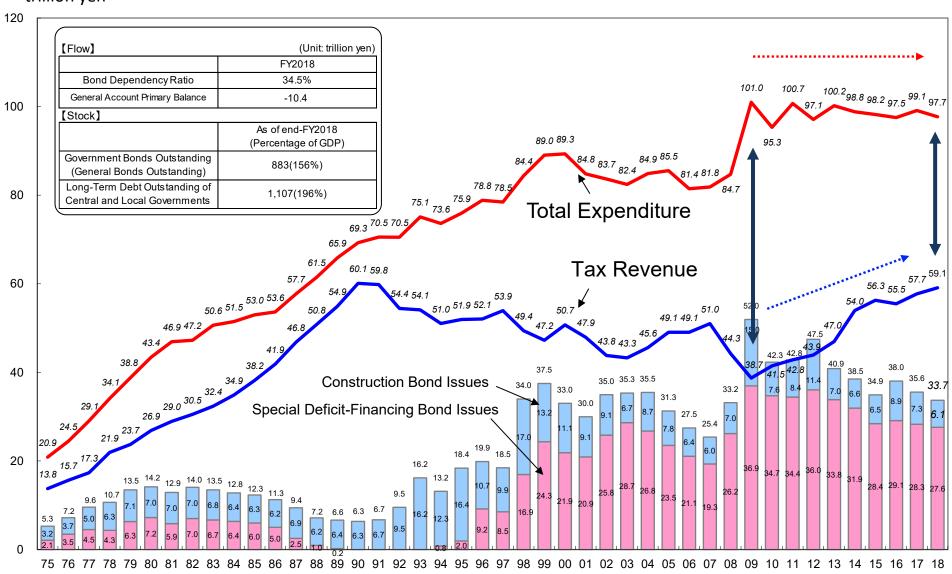


Source: WHO Global Health Expenditure Database, Health Facts of Hong Kong 2021,2022 Taiwan Ministry of Health and Welfare database https://www.dh.gov.hk/english/statistics_hs/files/2021.pdf https://www.dh.gov.hk/english/statistics_hs/files/2022.pdf https://www.mohw.gov.tw/lp-130-2.html

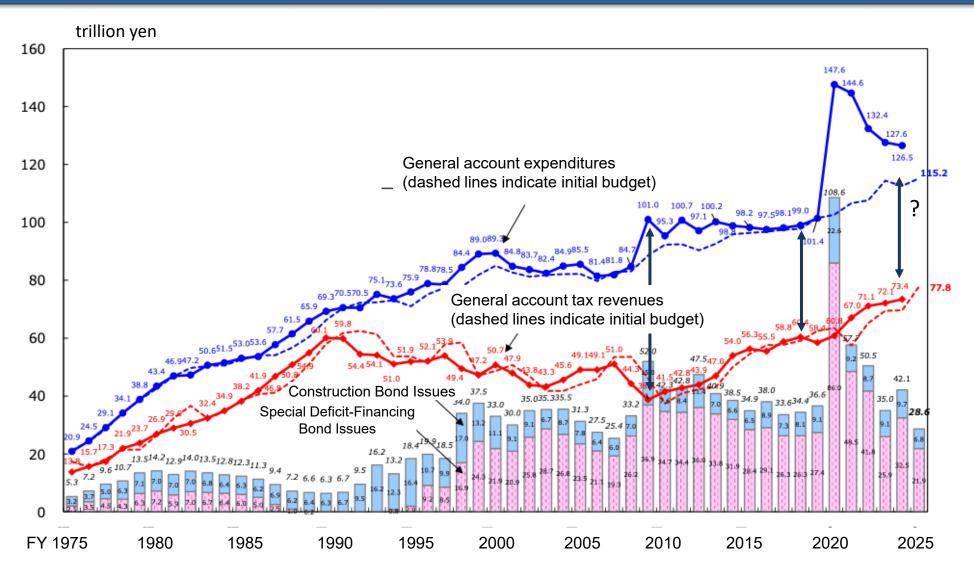
(public ratio vs total)

[Reference] Trends in general account tax revenue, total expenditure, and bond issuance



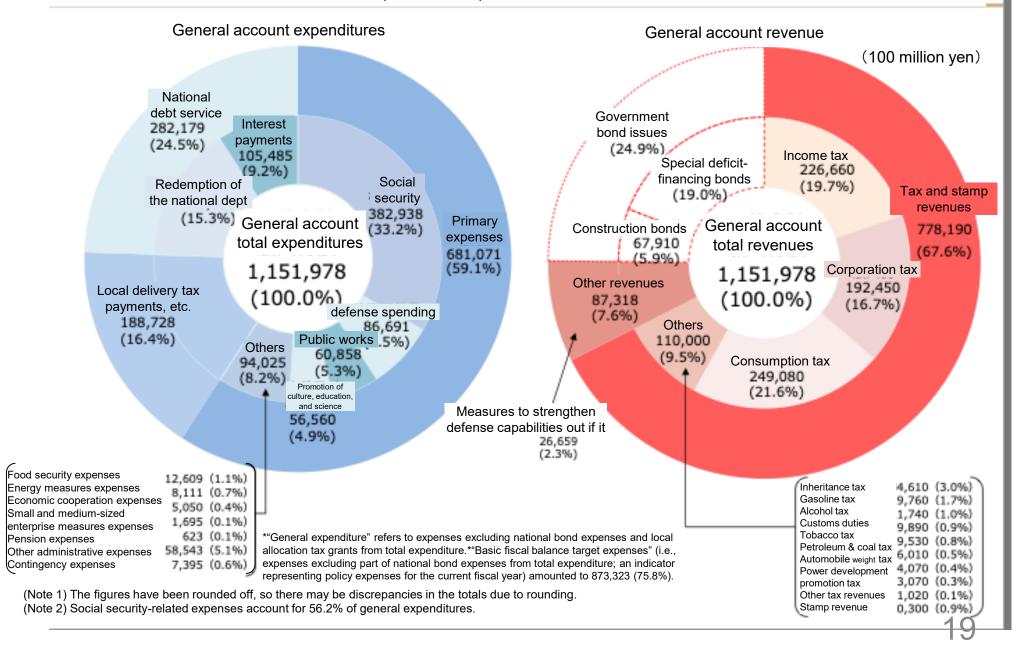


[Reference] Trends in general account tax revenue, total expenditure, and bond issuance

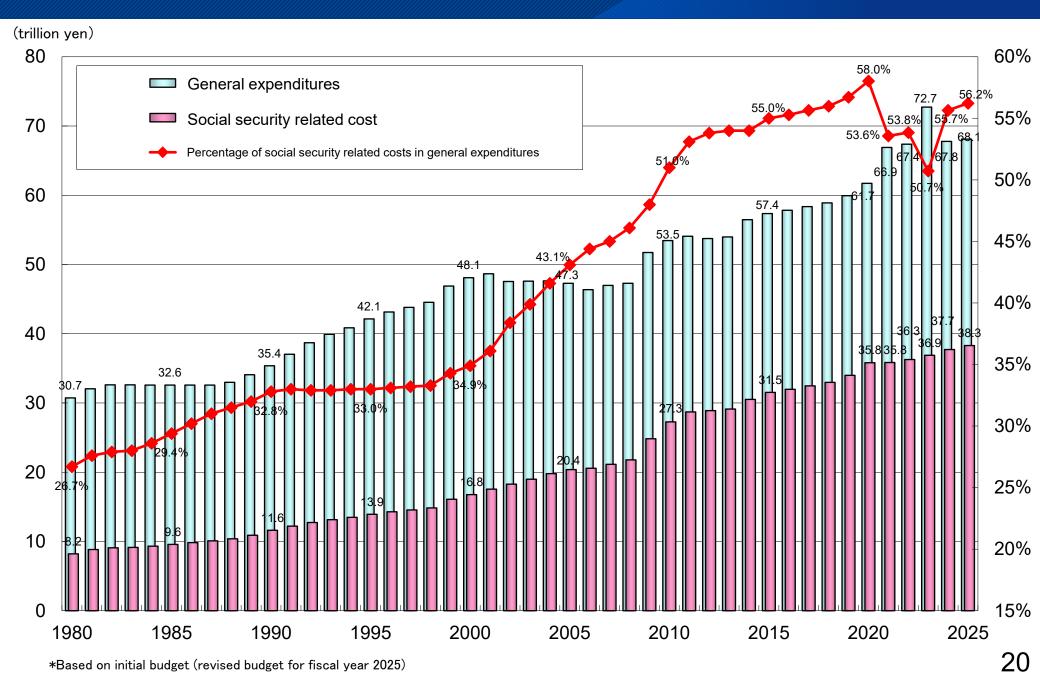


(Note 1) Until fiscal year 2023, figures are based on final accounts; for fiscal year 2024, figures are based on the revised budget; and for fiscal year 2025, figures are based on the budget revised by the House of Representatives and then the House of Councillors. The dotted line indicates the initial budget.(Note 2) The amount of public bonds issued includes temporary special public bonds issued in fiscal year 2000 to secure funds for activities to restore peace in the Gulf region, tax reduction special public bonds issued in fiscal years 2004 to 2006 to compensate for the decrease in tax revenue due to tax reductions implemented in advance of the increase in the consumption tax rate from 3% to 5%, fiscal year 2011: bonds issued to secure funds for measures to recover from the Great East Japan Earthquake; fiscal years 2012 and 2013: bonds issued to secure funds to achieve a 50% national government contribution to basic pensions.

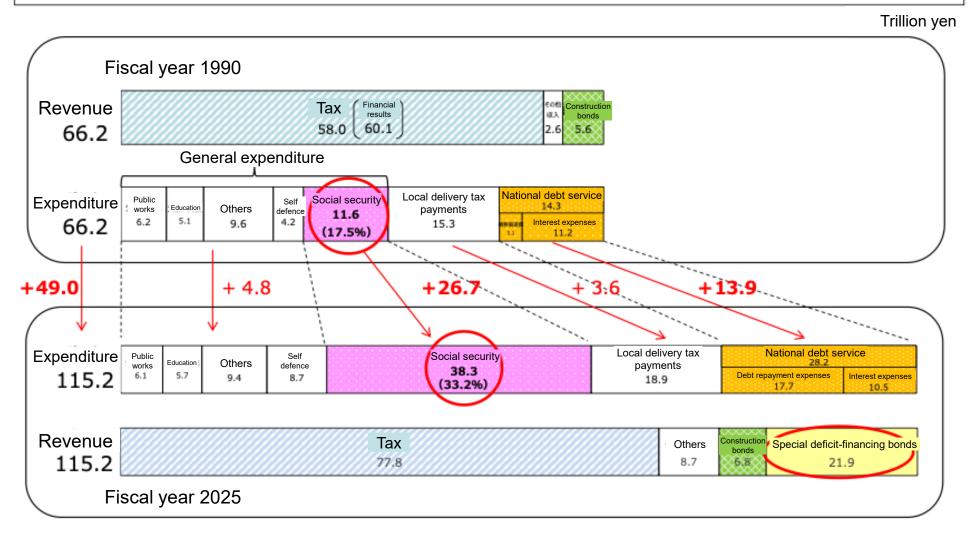
[Reference] FY 2025 General Account Budget (after revisions by the House of Representatives and House of Councillors) Composition of Expenditures and Revenues



Trends in general expenditure and social security-related expenditure



Compared to the initial budget for fiscal 1990, which was able to break away from issuing special bonds, the budget for fiscal 1995 shows a significant increase in social security-related expenses, which are being covered by special bonds.



Consumer tax rate was raised to 8%, from 5%, and will be 10% next year, both to finance preparation for new demands until 2025, and to have sound budget.

- Incrementally raise the consumption tax rate (national and local) to 8% in April 2014 and to 10% in October 2019
- Expand the allocation of consumption tax revenues to the four costs of social security (pensions, medical care, long-term care, and childcare) from the current three of elderly costs (basic pension, elderly medical care, and long-term care)
- Clarify the use of consumption tax revenues (use consumption tax revenues to finance social security)
- Pass on the entire consumption tax revenues to the people and do not use it to enlarge the government

Approx.

Enhanced social security

Approx. 2.7 trillion yen more

Stable social security:
Protecting the current social security
system

Approx. 10.8 trillion yen more

- O 50% of pensions are funded by the national treasury
 (incl. costs for ensuring that 50% of the basic pension is funded by the national treasury in FY2012 and FY2013)
- O Reduce the burden passed on to future generations
- Current social security expenditures involving increases due to aging (natural increase) and failure to secure stable financial resources
- O Increase in social security expenditures due to the consumption tax increase

Approx. 0.8 trillion yen

Approx. 2.9

Approx. 7.0

trillion yen

 Increase in pensions and medical service fees along with price increases Approx. 0.7 trillion yen

O Children and child-raising support

- Resolution of the problem of the children on waiting lists quantitative expansion of childcare and after-school ;hildren's clubs), etc.

Up to little under 1.6 trillion yen

O Enhancement of medical/long-term care

- Intensive input of medical care resources into the highly acute phase (expanded inpatient medical care), enhancement of home medical/long-term care (from hospitals/institutions to communities and homes), etc.

Up to approx. 0.6 trillion yen

Up to approx.

1.4 trillion yen

of the above (redundant)

O Improvement of the pension system

- Provide additional benefits to elderly people with a low income and disabled people, shorten the period of eligibility to receive benefits, etc.
- Expansion of measures to deal with poverty and income inequality (measures for low-income earners, etc.)

Reduction of social insurance contributions for low-income earners, total accumulation system, etc.

Approx.

Actions taken for sustainable health care

"National Health Insurance"

- Abolish free care for the Aged in 1983
- 10% copayment in 1984
- 20% copayment in 1997
- Introducing new "Long-term care insurance" in 2000
- 30% copayment in 2003
- Introducing new "Medical Care System for the Elderly aged 75 and Over " in 2008

Health Care Delivery System

1990's

 Increase Long-term Care Services (New Insurance in 2000)

2000's

 Specialization of Hospital Functions to strengthen both acute care and rehabilitation

2010's

 Restructuring Health Care Delivery System, to "<u>Integrated</u> <u>Community-based Care</u> <u>System</u>"

Actions taken for sustainable health care

Cost Containment Actions

- Prevention
 - Oblige health Insurer to offer health checks to insured.
- Generic drug use
 - First target : 30% of all drugs
 - Current target: 80% of offpatent drug use
- Oblige Local Government to make a cost containment plan
 - target medical care cost
 - target health check rate

(Continued)

- Drug Price Revision and Reform of calculation method
- Appropriate use of superexpensive drugs
- Prevention of aggravation in patients, especially with diabetic patients
- Correction of Poly-pharmacy

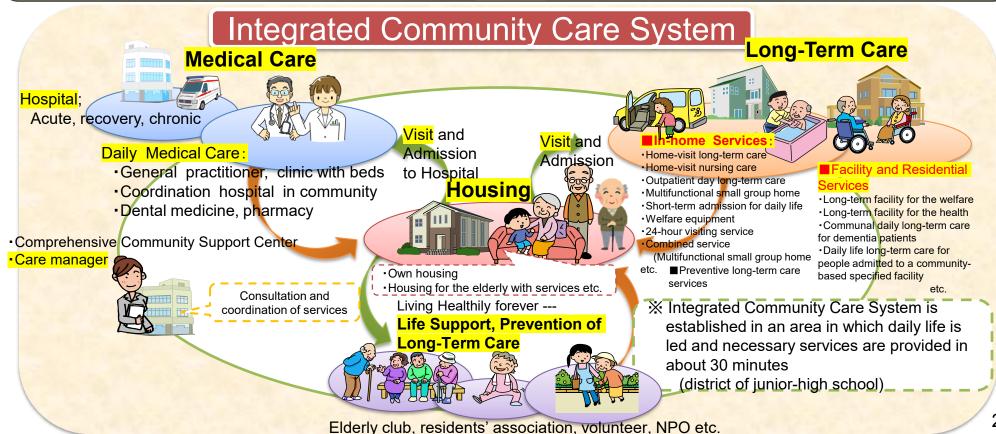
Establishment of Integrated Community Care System

Establishment of the system in which <u>medical care, long-term care</u>, <u>prevention, housing and life support are</u> <u>comprehensively maintained</u> will be realized in order to lead lives in long-lived area until the end of lives even if in a condition to be taken care of intensively.

It is estimated that the number of the elderly with dementia will increase, therefore it is important to establish integrated community care system to support the lives of the elderly with dementia in communities.

There are large differences in the conditions of the advancement of population aging. In urban areas, population over 75 years old will rapidly increase while total population is stable. In rural areas, population over 75 years old will moderately increase while total population will decrease.

It is necessary that <u>insurers (municipalities) and prefectures should create integrated community care system in</u> <u>accordance with the characteristics of the communities</u> which is based on the autonomy and independence of the communities.



Hospitals to community-based care

The Director's Office at Yubari City Hospital



Yubari Municipal Hospital

- Once a prestigious general hospital
- Located in the city center (near Yubari Station)
- Became financially unsustainable due to Yubari's population decline(116,000 → under 10,000)
- Securing doctors also became difficult
- •Converted into a bed-equipped clinic following the city's financial collapse

171 beds hospital → 19 beds clinic

Small-scale Multi-functional Nursing facility



Mimosa House

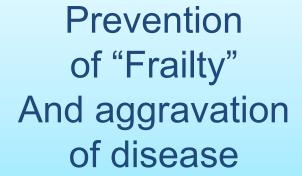
(Small-scale multifunctional nursing facility)

- Converted from a private residence in Yotsuya
- 1st and 2nd floors: Small-scale multifunctional facility; 3rd floor: Residence
- 1st floor: Multifunctional room; 2nd floor: Beds
- Located in the heart of a residential district

Registered capacity: 25 residents, 15 day-care users, 5 overnight stays

Longer healthy life

Health check and health promotion
Among young generation



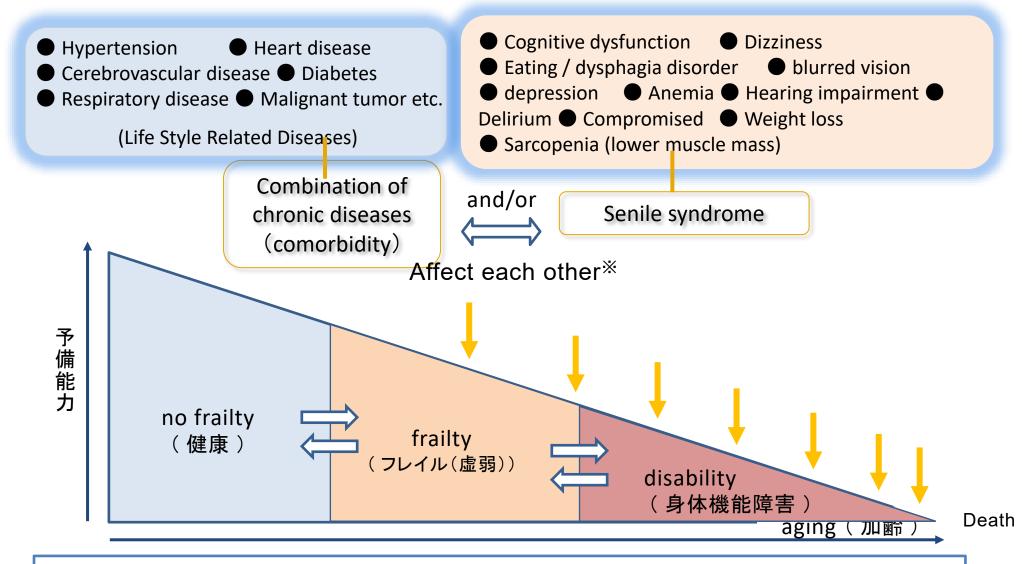




Collaboration with companies Incentive to health care insurers

Prevention of Frailty Collaboration with local community

Concept of Frailty



As for "frailty", since the academic definition has not yet been confirmed, this report says, "With the age, mental and physical vitality (motor function, cognitive function, etc.) declines, and multiple chronic diseases such as coexistence It is defined as a state image in which lifestyle functions are impaired, emotional and mental impairment has emerged, but on the other hand, it is possible to maintain and improve living functions through appropriate intervention and support

28

The history and role of Japan's public health care system : Looking ahead to addressing aging

CHARACTERISTICS OF JAPANESE MEDICAL INSURANCE

1: INSURERS, 2: MEDICAL FEES, 3: INSURANCE-COVERED MEDICAL INSTITUTIONS, 4: BENEFIT IN KIND

The history and role of Japan's public health care system : Looking ahead to addressing aging

JAPANESE MEDICAL INSURANCE 1: INSURERS

THERE ARE MANY MEDICAL INSURANCE INSURERS IN JAPAN

About "insurers" (overview)

- A distinctive feature of Japan's medical insurance is the large number of insurers.
- Because they have completely different historical backgrounds, they are divided into several groups: the employee insurance group and the community health group.
- Employee insurance is further divided into insurers that belong to the public servant group, insurers that belong to the large company group, and insurers that mainly focus on small and medium-sized enterprises.
- In the health insurance reforms that have taken place since 2000, national insurers have been shifted to prefecture-level management, and municipal insurers have been reorganized to prefecture-level management.
- This is based on the idea that medical insurance insurers need to be of an appropriate size.

Comparison of Insurers

payments, etc. for the advanced elderly

¥125.3 billion

(Full state funding)

16.4% of benefits, etc.

¥1.1344 trillion

(Full state funding)

Burden of public expenditure

Amount of burden of public

expenditure (*5)

(Based on FY2024 budget)

insurance premium

reduction, etc.

¥4.1353 trillion

(State: ¥2.9819 trillion)

	NHI by municipalities	Japan Health Insurance Association	Health insurance societies	Mutual aid associations	Medical Care System for the Advanced Elderly
Number of insurers (As of the end of March 2023)	1,716	1	1,388	85	47
Number of subscribers (As of the end of March 2023)	24.13 million people (16.36 million households)	39.44 million people Insured persons: 24.8 million Dependents of insured persons: 14.64 million	28.20 million people Insured persons: 16.55 million Dependents of insured persons: 11.65 million	9.82 million people Insured persons: 5.74 million Dependents of insured persons: 4.09 million	19.13 million people
Average age of subscribers (As the end of September 2022)	54.2 years old	38.9 years old	35.9 years old	33.1 years old	82.8 years old
Percentage of those aged between 65 and 74 (FY2022)	44.6%	8.2%	3.5%	2.4%	1.4%
Medical costs per subscriber (FY2022)	¥406,000	¥204,000	¥184,000	¥185,000	¥956,000
Average income per subscriber (*2) (FY2022)	¥960,000 Per household ¥1.43 million	¥1.75 million Per household ¥2.79 million	¥2.45 million Per household ¥4.18 million	¥2.46 million Per household ¥4.30 million	¥930,000
Average insurance premium per subscriber (FY2022) (*4) <employer's contribution="" included=""></employer's>	¥91,000 Per household	¥125,000 <¥251,000> Per insured person ¥200,000 <¥399,000>	¥139,000 <¥304,000> Per insured person ¥237,000 <¥519,000>	¥144,000 <¥287,000> Per insured person ¥253,000 <¥505,000>	¥79,000
Insurance premium contribution rate	9.5%	7.2%	5.7%	5.8%	8.6%
Burden of public expenditure	50% of benefits +	16.4% of henefits, etc.	Subsidies for insurers with	n heavy burden of support	About 50% of benefits,

32

etc. + insurance premium

reduction, etc.

¥9.3232 trillion

(State: ¥5.9227 trillion)

The history and role of Japan's public health care system : Looking ahead to addressing aging

JAPANESE MEDICAL INSURANCE 2: "MEDICAL FEES"

THERE ARE MANY MEDICAL INSURANCE INSURERS IN JAPAN

About "Medical Fee Schedule" (Overview)

- A distinctive feature of Japan's medical insurance system is that the government determines the point system for "Medical Fees".
- Hospitals and clinics use the same point system, which basically assigns
 points to the medical treatment provided by doctors.
- Primarily fee-for-service. Some hospitals are paid a lump-sum fee, but some aspects of fee-for-service remain.
- There is also the option of "cash payment," which is called "medical expenses payment".
- It is revised every two years, but there is no mechanism for automatically adjusting it based on prices or wages.

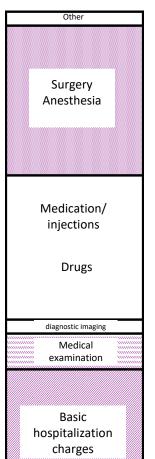
Overview of "Medical Fee System"

(1) "Medical Fee System"

- O Compensation received by insurance medical institutions and insurance pharmacies as compensation for insured medical services
- O Applied uniformly to all insurance medical institutions and insurance pharmacies (uniform nationwide)
- O Determined by the Minister of Health, Labour and Welfare based on discussions at the Central Social Insurance Medical Council (*Chuikyo*) (Notification by the Minister of Health, Labour and Welfare)
- (2) Functions of "medical fee system" (including score tables and related operating rules)
 - (1) Establish <u>prices</u> for individual medical services (characteristic as a <u>price list</u>)
 - * Technologies and services evaluated by quantifying them as points (¥10 per point).
 - (2) Establish the scope and content of insured medical services (characteristic as a list of items)
 - * Medical act not listed in the score table is not accepted as an insured medical treatment.
 - O Evaluation of technologies and services (about 5,000 items)
 - O Evaluation of prices of materials (about 17,000 items for pharmaceuticals, the prices of which are determined by the drug price standard)
- (3) Main role and impact of "medical fee system"
 - (1) Regulates remuneration for each medical service → Affects the quality and quantity of medical services
 - (2) Regulates medical business income of insurance medical institutions → Affects the management of insurance medical institutions
 - (3) Allocates medical expenses (medical resources) → Affects the <u>establishment of the medical care</u> <u>delivery system</u>
 - (4) Determines national medical care expenditure in conjunction with the amount of services provided → Affects the <u>national budget (finances)</u>

Example of "Medical Fee System"

- (Example) A patient was hospitalized for acute appendicitis for four days.
 - The patient had an appendix removal surgery on the day of admission and started eating a period evening after the surgery.



OBasic Hospitalization Charges

7,416 points

(Breakdown) Charges for Hospitalization in the Acute Stage(6) 1.404 points × 4 Additional charges within 14 days 450 points × 4

OAdditional Charges for Basic Hospitalization, etc. (for four days)

1,350 points

(Breakdown) Additional charges 2 for comprehensive inpatient care (per day) 200 points $\times 4$ Additional charges 2 for inpatient care at a clinical-training hospital (first day of 20 points hospital admission)

> Additional charges 2 for medical record management (first day of hospital admission) 30 points

> Additional charges for implementation of medical safety measures (first day of hospital admission) 85 points

Additional charges 2 for the arrangement of clerks who assist physicians with administrative work[clerk: physician=50:1] (First day of hospital admission)

415 points

6.740

O Surgery Surgery to Remove the Appendix

points

O Anesthesia 1.000

points

(Breakdown) Spinal anesthesia 850 points Anesthesia supervision fees (II) 150 points

Total 16.506

points

(Hospital dietary expenses (I) 670 yen per meal × 8 meals 5,360 yen) (Standard co-payment for dietary treatment (Households paying residential tax)

490 yen per meal × 8 meals 3,920 yen)

The charges are calculated based on a serious of expenses including those for ensuring basic medical management exercised upon hospital admission, maintaining nurse staffing levels and providing an appropriate environment for medical treatment.

(Basic Hospitalization

Charges)

These charges include such costs as simple tests and treatment procedures and vary depending on types of hospital wards, nursing staffing and the average length of hospital stay,

XIn addition to the range of other basic hospitalization charges, the basic hospitalization charges for medical wards for the care of patients include costs for medical examinations. medication, injections and simple treatments.

(Additional Points to **Basic Hospitalization** Charges, etc.)

Additional points are calculated per day or per hospitalization according to the functions of a medical institution such as staffing, special medical treatments, etc.

JAPANESE MEDICAL INSURANCE 3: "INSURANCE-COVERED MEDICAL INSTITUTIONS"

MUST BE HANDLED BY "INSURANCE-COVERED MEDICAL INSTITUTIONS"

About "Insurance-Covered Medical Institutions" (overview)

- In Japan, medical treatment covered by insurance is handled by "Insurance-Covered Medical Institutions." Medical institutions become "Insurance-Covered Medical Institutions" after receiving insurance designation.
- "Insurance-Covered Medical Institutions" must comply with the standards for handling medical insurance. These are called the "Regulations for the Provision of Madical Care" (Ministry of Health, Labour and Welfare Ordinance).
- If a medical institution commits fraud, such as filing fictitious claims in order to increase the number of insurance claims, its designation as an insurance medical institution may be revoked.
- Most medical institutions in Japan are designated as covered by insurance, but in recent years, the number of medical institutions (clinics) that only handle non-covered medical treatments (such as cosmetic medical treatments) has been increasing.

Overview of Medical Service Scheme in Japan

75 vears or older

10% copayment

Those with income equivalent to that of working people will bear 30% of the cost, and from October 1, 2022, those with income above a certain level other than working people will bear 20% of the cost.

•70 to 74 years old 20% copayment

Those with income equivalent to that of working people will bear 30% of the cost

 From compulsory education to age 69

30% copayment

 Yet to start compulsory education 20% copayment

Patient (insured)

Patient burden: 5.4 trillion ven

[Medical Service Providing Scheme]

(2) Receive service & pay copayment

> (3) Provide **Clinical service**

> > **Medical expenses** 46.7 trillion yen

Insurance premiums 23.4 trillion yen

(5) Reimbursement

Insurer

Claims

Hospital 8,122 1,481,183 beds Clinic 104,894 75,780 beds 66,818 Dental clinics: 62,828 Pharmacies:

*Figures are as of October 1, 2023 (Source: 2023 Medical Facility Static & Dynamic Survey)*Pharmacies are as of the end of March 2024 (Source: 2023 Health

dministration Report)

Administrativ e bodies

National

Prefectural

Municipal

[Medical insurance

system]

Public

fundina

(Principle schemes)

(1) Insurance

contribution

(Number of enrollment) (Number of insurers)

-"National Health Insurance"

1.716 Approx. 24 million

-Japan Health Insurance Association administered health insurance

Approx. 39 million

-Association/union administered health insurance

1,383

Approx. 28 million

-Mutual aid association

85

Approx. 10 million

Insurers

governments

Supportive contribution

-Advanced Elderly Medical Service System 47 Approx. 19 million

Physician 343,275 **Dentist** 105,267 Pharmacist 323,690 Registered nurse 1.32 mil Public health nurse 0.67 mil Midwife 0.42 mil

* Doctors, dentists, and pharmacists are as of December 31, 2022 (2022 Statistics on Doctors, Dentists, and Pharmacists).* Nurses, public health nurses, and midwives are based on the number of employed persons, compiled by the Nursing Division of the Medical Affairs Bureau, Ministry of Health, Labour and Welfare, based on the "2020 Medical Facility Dynamics Survey" and the "2020 Health Administration Report (Biennial Report)" of the Ministry of Health, Labour and Welfare.

JAPANESE MEDICAL INSURANCE 4: BENEFITS IN KIND

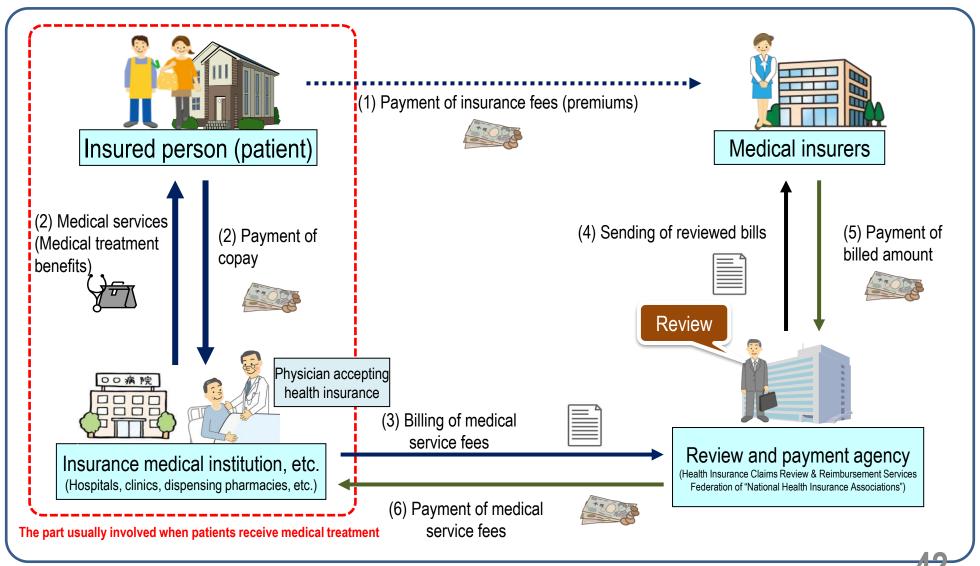
MOST MEDICAL CARE IS PROVIDED AS "BENEFITS IN KIND".

Overview of "Benefits in Kind"

- Japan's medical insurance benefits include both cash and "benefits in kind", but most are provided as "benefits in kind".
- When a patient presents their "health insurance card" to a medical institution, the
 medical institution must provide medical care to the patient. The costs will be charged
 to the insurer, and a certain amount will be charged to the patient.
- If a patient does not have an "health insurance card", they can pay the medical expenses first and then claim the costs to their insurer later.
- Medical care provided as "benefits in kind" must be provided in accordance with insurance standards. Medical treatments other than those approved by the insurance are prohibited. Combining insured and uninsured medical care is illegal. However, there are exceptions approved by the government (such as "Advanced Medical Treatments").

Flow of healthcare services provided under health insurance

The overall flow of healthcare services provided under health insurance is shown in the flowchart below.



HISTORY AND HISTORICAL BACKGROUND OF MEDICAL INSURANCE IN JAPAN

1: INSURERS, 2: "MEDICAL FEES", 3: "INSURANCE-COVERED MEDICAL INSTITUTIONS", 4: BENEFIT IN KIND

HISTORICAL BACKGROUND 1: INSURERS

THERE ARE MANY MEDICAL INSURANCE INSURERS IN JAPAN

Historical background of insurers and revision process (overview)

- Japan's health insurance system has developed gradually
- It started from the perspective of protecting workers.
- It expanded to civil servants.
- Meanwhile, self-employed people and agricultural workers were voluntarily introduced into insurance systems in rural areas.
- In 1961, all cities, all municipalities in Japan were required to implement medical insurance that covered all residents except employees.
- The process was implemented gradually law will be implemented over three years, and insurer-operated hospitals were established in various areas in response to complaints that people in rural areas have insurance but no medical care.
- It developed by recognizing existing insurance and filling in the gaps.

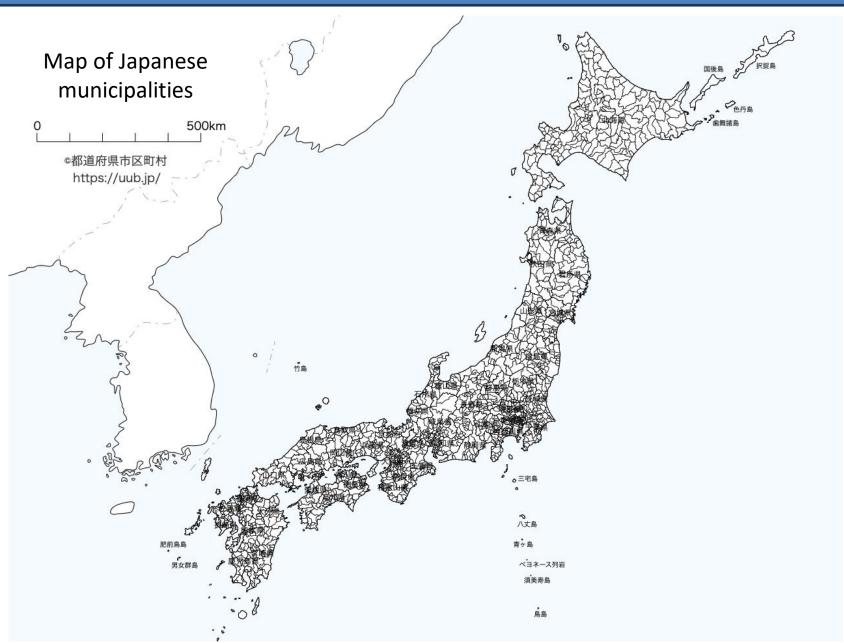
Historical background of insurers and the process of reform (reorganization of insurers)

- Since the introduction of "Universal Health Insurance", medical expenses have increased rapidly.
- A fiscal adjustment mechanism was introduced.
- Furthermore, the appropriate size of insurers was discussed from the perspective of strengthening insurer functions.
- As a result, the direction of insurer restructuring at the prefectural level was decided.
- The government-managed health insurance system, which was previously a single system nationwide, was shifted to fiscal management by 47 prefectures (legal amendment in 2006, implemented in 2008).
- Municipality-based (approximately 1,700) "National Health Insurance" was shifted to a prefecture-based system (47) (legal amendment in 2015, implemented in 2018).

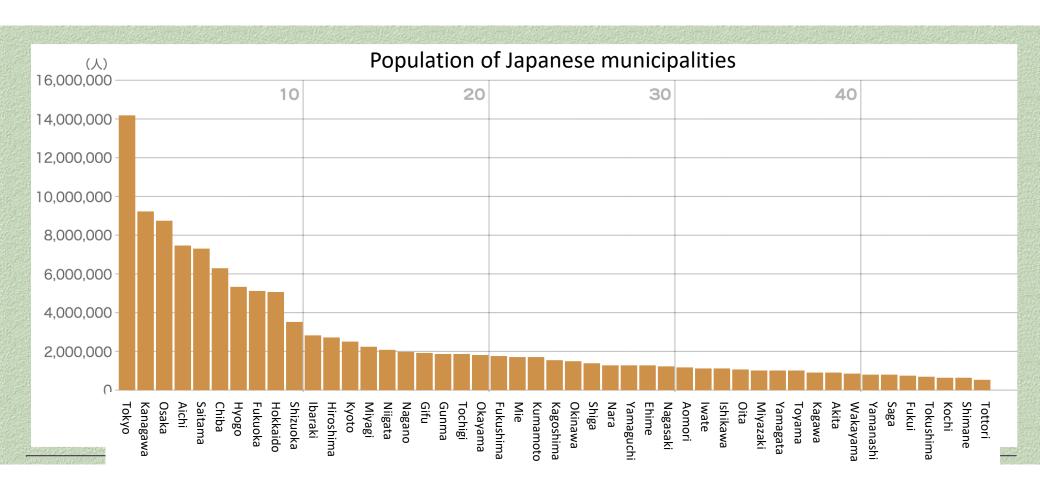
Japan's 47 Prefectures



Japan's 1,700 Cities, Towns, and Villages



Japan's 47 Prefectures' Population



Background to the privatization of government-managed health insurance and the establishment of prefecture-based systems

[Aims of privatizing government-managed health insurance and integrating it into prefectures]

- Strengthening the insurer function = Making it easier for public corporations independent from the national government to carry out health programs and respond to employers in accordance with local conditions, and strengthening disease prevention and health promotion programs
- Streamlining of administration: Abolishing health insurance directly managed by the government, allowing the government to focus on policy formulation and system supervision
- Financial transparency and clarification of responsibility: In the event of a deficit, the society which operates the system will bear the responsibility and will independently decide on insurance rates.
- The insurance premium rates were set by prefectures (starting in FY 2010). This will reflect the level of medical expenses in each region and encourage the insurer to exercise its functions.

The background to the prefectural-level allocation of "National Health Insurance" finances

[Aim of transferring the financial management of "National Health Insurance" to prefectures]

<Challenges>

- Many of the members are elderly or low-income earners, and medical costs are high, resulting in chronically unstable finances.
- Small municipalities have weak insurer functions (health services and financial management).

<Measures>

- Transferring responsibility for financial management to prefectures (medical benefit expenses for municipalities will be consolidated and managed by prefectures).
- Calculation of standard insurance premium rates for each municipality
- Wide-scale implementation of "medical cost optimization plans" and health programs

Item	Transition to the "Japan Health Insurance Association" (2008)	"National Health Insurance" financial management Shifted to Prefectures (2018)
Implementation date	October 1 , 2008	April 1 , 2018
Target system	Government-managed health insurance (employees of small and medium-sized enterprises)	"National Health Insurance" (municipal "National Health Insurance")
Management body before reform	Ministry of Health, Labour and Welfare (the government was the direct insurer)	Municipality: city, town, village (insurer)
Management body after reform	"Japan Health Insurance Association" (public corporation, commonly known as "Kyosai Kenpo")	Prefectures (responsible for financial management) + municipalities (qualification management and premium collection)
Main reforms	 Abolish the system in which the national government directly acts as an insurer Transition to independent management by public corporations Strengthen insurer functions (health programs, insurance premium rate setting) Introduction of prefecture-based insurance premium rates from FY 2010 	 Centralizing financial management to prefectures Prefectures setting standard insurance premium rates Promoting wide-area optimization of medical expenses and health programs Correcting disparities in insurance premiums between municipalities
Main background of the reform	 Government-run insurance provider lack strong insurer's functions Expanding fiscal deficit and increasing burden on the national treasury Trend toward reduction in direct government operations due to progress in administrative reform 	 Chronic financial difficulties due to aging and declining income levels Weak insurer functions in small municipalities Widening regional disparities in medical expenses and insurance premiums
the aim	 Strengthening the insurer's functions (emphasis on autonomy and strengthening of regional responsee) Streamlining the administration Clarifying financial responsibility 	Stabilizing the financial base (risk diversification)Correcting disparities between municipalitiesWide-area rationalization of medical expenses
Post-implementation characteristics	- Japan's largest employee insurer with approximately30 million subscribers- Premium rates vary by prefecture	-Prefectures manage the overall finances, while municipalities focus on collection and qualification workStandard insurance rates and actual insurance rates tend to be closer.

HISTORICAL BACKGROUND AND HISTORY 2: "MEDICAL FEES"

MEDICAL FEES ARE PAID BASED ON THE "MEDICAL FEE SCHEDULE"

Regarding "Medical Fees" (1)

- The first "Medical Fees" was the total contract system
- Prefectural Medical Associations were contracted to cover the total amount, and this was then distributed in each prefecture based on medical treatment performance (points were used at this time).
- The total volume of medical treatment varied from prefecture to prefecture, and the growth rate was also different, so this system showed a singns of stagnation.
- A system was introduced in which points will be determined by the government, Medical Associations, and insurers.

Regarding "Medical Fees" (2)

- The basis of payment was besed on a fee-for-service model, which combines products (medicines) and services (physicians' technical fees). Modernizing this system was a challenge.
- Transition to a new "Medical fee schedule" (1958)
- The goal was to separate products and services, to base "Medical Fees" on costs, and to move from fee-for-service to lump-sum payment. However, conflict intensified between hospital groups that welcomed the move and Medical Associations that opposed it.
- The system came to consist of two types of fee schedules: the new "Medical Fee Schedule", and the traditional "fee-for-service schedule" carried over from the past. These were referred to as Table A and Table B.

Regarding "Medical Fees" (3)

- In light of the abuse of the fee-for-service system during the era of free medical care for the elderly, a decision was made to establish a new compensation system, and a "Geriatric Medical Fee Schedule" for patients aged 70 and over was formulated (in 1983, the same year I joined the former Ministry of Health and Welfare, now the Ministry of Health, Labour and Welfare).
- Furthermore, without the co-payment, medical institutions could charge as much as they wanted and patients could visit as many times as they wanted, so free medical care was abolished at the same time.
- Ideally, patients should be required to pay a fixed rate, but at this point,
 they were only required to pay a low fixed amount.

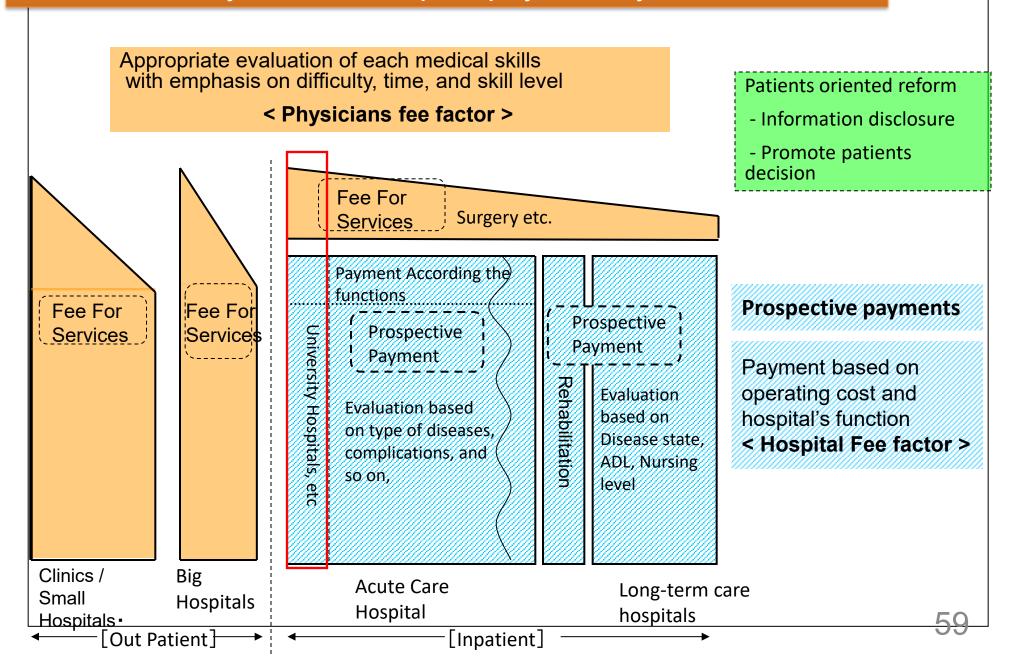
Regarding "Medical Fees" (4)

- In 2003, a new comprehensive "Medical Fee schedule" for hospitalization was introduced to some medical institutions. This is a system called DPC, which is modeled after the US DRG-PPS. It is a groundbreaking system in which the total fee is determined by diagnosis group, and a fixed daily fee is paid, with a higher fee during the early stages of hospitalization.
- This allowed hospitals to increase their daily fees by shortening hospital stays, and the government was able to curb the growth of medical expenses.
- I was in the department in charge when this system was introduced.
- For outpatient care, various comprehensive points have been considered,
 but it is difficult to say that they have been successful at this point.

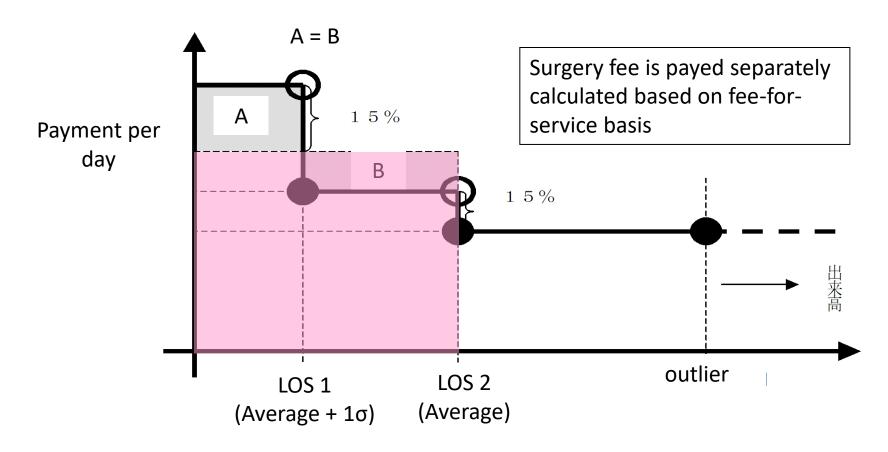
57

INTRODUCTION OF DPC

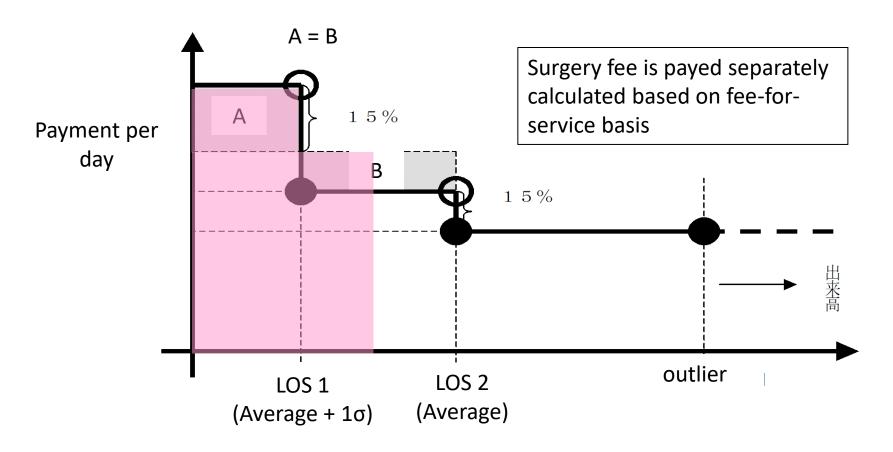
Reform of Physician & Hospital payment system in 2000's



Introducing "DPC" Diagnosis Procedure Combination



Increased Hospital incomes per day and Reduced Medical Expenditures



Example:

Restructuring two hospitals



Yamagata Prefectural Nihonkai Hospital Sakata City Hospital



Status of Yamagata Prefectural Nihonkai Hospital and Sakata City Hospital befor reorganization

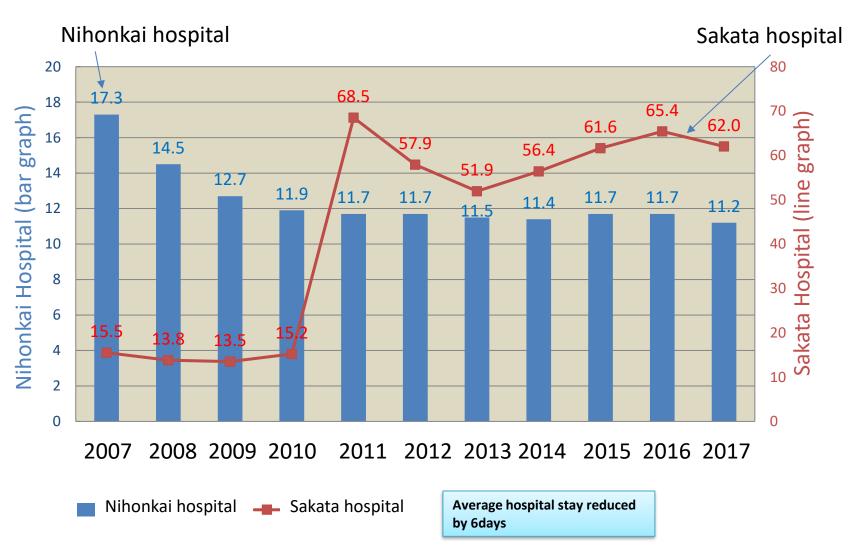
(As of 2005, at the Time of Reorganization Plan Formulation)

As of FY 2005

items	Nihonkai Hospital	Sakata Hospital
Opening Date of the Current Ward	June 1993	September 1969
Number of beds	528	400
Number of clinical departments	25	15
Daily Average Outpatients	954	868
Average Daily Inpatients	439	333
Bed Occupancy Rate	83.9	83.3
Medical Revenue per Patient (Outpatient)	JPY 8,328	JPY 7,393
Medical Revenue per Patient (Inpatient)	JPY 36,255	JPY 36,047
Net Profit or Loss	JPY('000) -170,306	JPY('000) 211,855
Deficit	√ JPY('000) —10,678,05 3	JPY('000) 0

The accumulated deficit of Sakata Municipal Hospital (¥1,367,366 thousand) was addressed in accordance with Article 15 of the Enforcement Ordinance of the Local Public Enterprise Act.

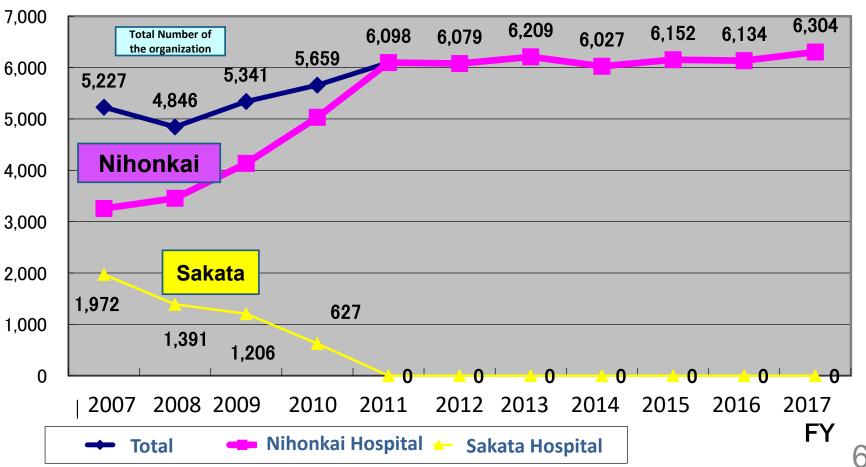
Change of the Length of Stay



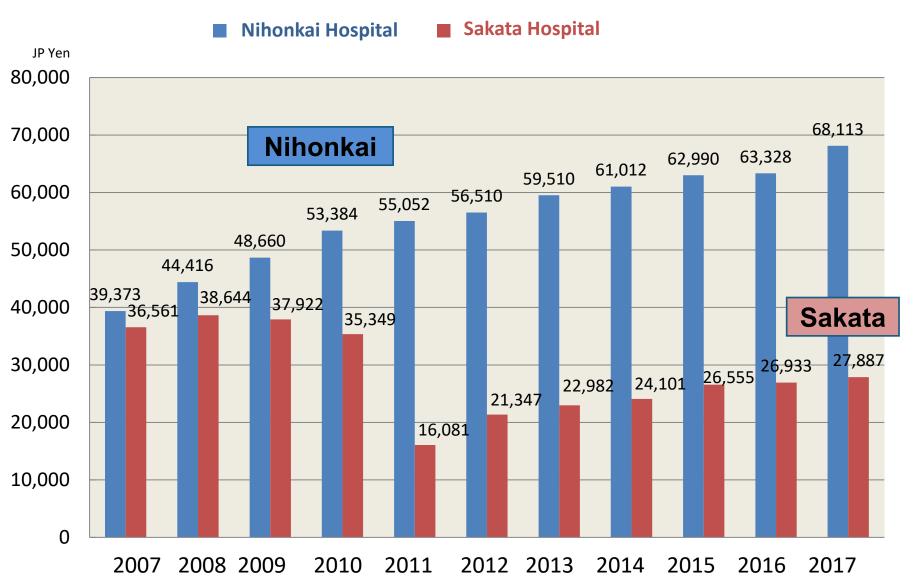
Number of Surgery

Up 1,077 / two hospital combined

Number of Surgery



Revenue / inpatient (per day)



What I thought about when introducing DPC

- Regardless of the diagnostic group, remuneration should be based on costs
 (more detailed classification than US DRGs was necessary = elimination of unintended incentives)
- It was necessary to realize an electronic score table. →(a table format was needed without changing the calculation logic)
- Coefficients should be used instead of scores. → (The weighting of the score setting should be clarified)
- The perspective of income security for the previous year should be taken into account. However, weighting should be possible based on severity assessment. → (Adjustment coefficients + DPC weighting)
- It was necessary to promote standardization of diagnostic names (It was essential for medical information technology)
- It was necessary to create a summary for each hospitalization. → (It was essential as medical data)
- Having the function of disclosing information was necessary. → (because this makes predictability of medical expenses, comparison with averages possible)
- It is necessray to double hospital unit prices and make true hospital management possible.

DRUG COST (SEPARATION OF MEDICAL AND PHARMACEUTICAL FUNCTIONS)

Criticism of drug price difference raised

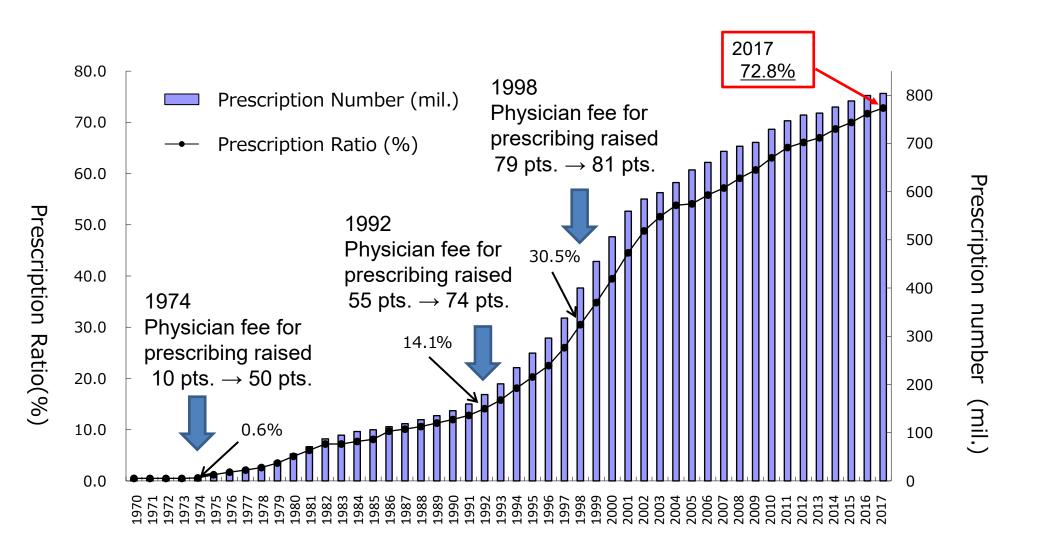
On Nov. 9, 1989, total amount estimate of medical institutions' drug price difference was reported on the front page of Japanese leading news paper.

It said, "Yakka-Sa", difference of actual purchasing price at medical institutions and their reimbursement price, which is officially determined as a Drug Tariff by the MHLW, totals 1 trillion and 300 billion yen.

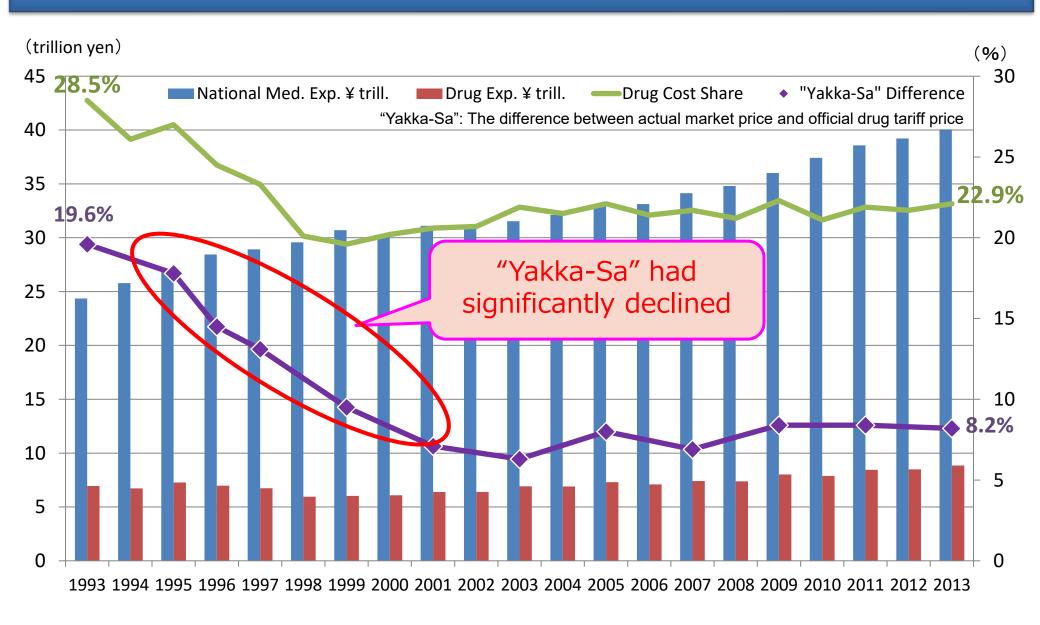
One of the reason that the difference existed and the difference goes to medical institutions' budget is Japanese historical structure of not separating dispensing from prescribing.

* Separating dispensing from prescribing is called "IYAKU BUNGYO" in Japan

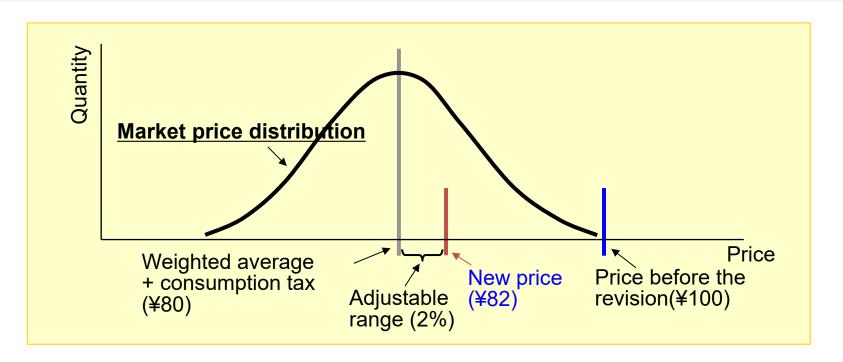
Historical trend in prescription rate compared with dispensing in DR's Office



Historical Trend of "Yakka-Sa" and Drug Cost in "National Health Insurance"



Current pricing method for listed drugs



The new drug price is the weighted average of the wholesaler's selling price to medical institutions and pharmacies (market price excluding tax), with consumption tax added as well as the span of the adjustable range (2% of drug price before the revision) for stabilizing drug distribution.

Change the course - - Why?

Japan Medical Association (JMA)
 Chairman Dr. Takemi kept saying;

"Physician's mission is not selling drugs."

- JMA has changed policy to new physician fee scheme that put emphasis on technical fee in 1973.
- Prescribing fee had been raised significantly in 1974.
 - (Giving incentives not dispensing drugs but writing prescriptions for patients)

Criticism of drug price difference: Media

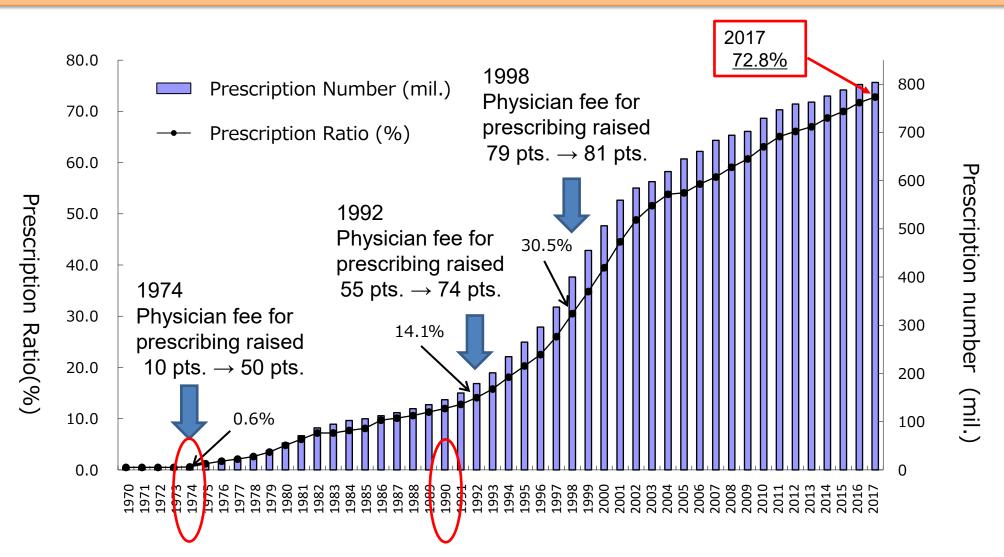
On Nov. 9, 1989, total amount estimate of medical institutions' drug price difference ("Yakka-sa") was reported on the front page of <u>Japanese leading newspaper</u>.

It said, "Yakka-Sa", difference between actual purchasing prices at medical institutions and their reimbursement prices, which is officially determined as a Drug Tariff by the MHLW, totals 1.3 trillion yen.

One of the reason that the difference exists and the difference goes to medical institutions' budget is the Japanese historical structure of not separating dispensing from prescribing.

^{*} Separating dispensing from prescribing is called <u>"IYAKU BUNGYO"</u> (医薬分業) in Japan

Historical trend in prescription rate Compared with dispensing in Dr's Office



Change the drug pricing scheme

- Reducing yakka-sa and paying for the innovation -

• Former rule: One price for all the same ingredients, with specific drug names. (統一限定収載方式)

Different companies and drugs are sold with different prices = large disparities

From 1978, each drug was <u>listed with its brand</u> name and its own price
 (銘柄別収載方式)

The price of each drug has become more reflective of the value of that drug. = more value-based rule

Criticism of drug price difference: Media (1)

"the Ministry has officially provided a specific figure for the total amount of the drug price difference. During the same year, the medical expenses paid to medical institutions by each health insurance and patients were about 5,160 billion yen, of which one-quarter of this was profit margins for medical institutions. The medical institution makes an insurance claim for the drug cost used by the patient at the standard price. In reality, however, most drugs are purchased at a discounted price, and the difference is exactly the same as making money for medical institutions."

Criticism of drug price difference: Media (2)

"the total gross profit for one year is calculated as 1,324.8 billion yen, and the average profit margin reaches 25.7%. According to the ministry's Health Insurance Bureau, if this is per capita, it is about 10,000 yen per year, and about 40,000 yen for a standard four-person household, which is the profit margin for medical institutions. If the entire profit is returned to the insured, the standard premium per household can be reduced by 3000 yen per month. The Ministry of Health and Welfare has reviewed the actual drug purchase price of medical institutions and revised the drug price standard once every two years in order to reduce the margin of drug price gains. The next revision is scheduled for next spring. "

Criticism of drug price difference: Media (3)

"The story of Toshiro Murase, Vice President of the Japan Medical **Association:** Social insurance is all controlled. On the other hand, pharmaceuticals brought into the market are subject to the competition principle as a trade in a free economic society. The Ministry of Health and Welfare approves the drug price after acknowledging that, and even if a margin arises, it is not bad. The Ministry of Health and Welfare itself has used drug price margins as a lever for low-cost policies, and the margins are actually used as a source of hospital management, such as salaries for medical institutions."

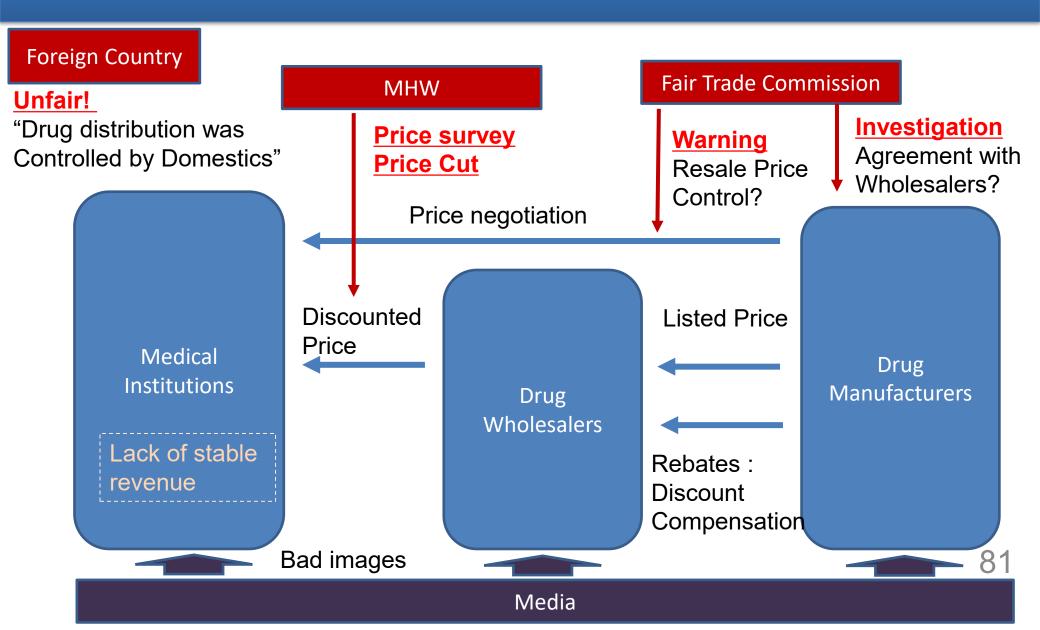
Background

Drug price revision were deep and frequent.

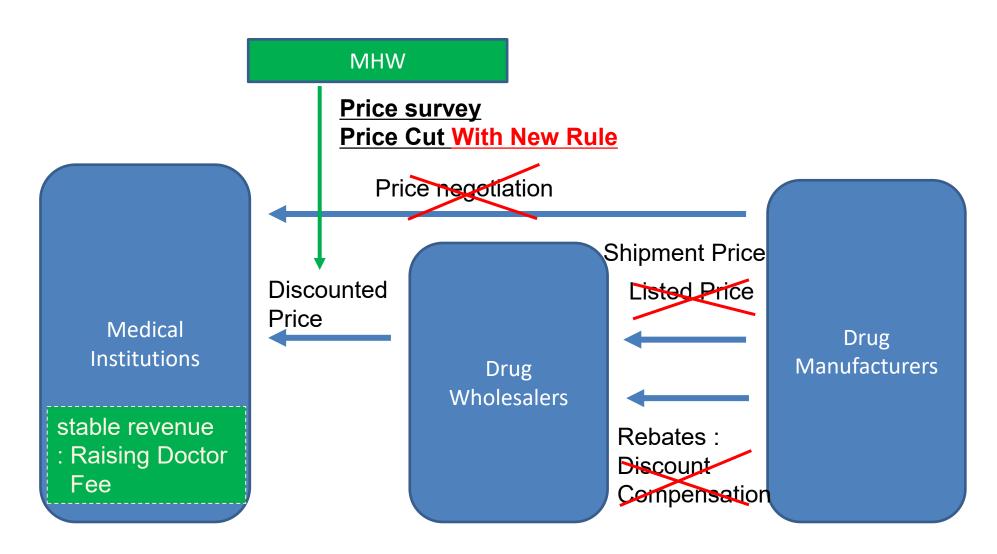
```
1981/6/1 - 18.6 % (biggest)
1983/1/1 - 4.9 %
1984/3/1 - 16.6 %
1985/3/1 - 6.0 %
1986/4/1 - 5.1 %
1988/4/1 - 10.2 %
```

Drug industry worried the continuous price reduction very much. Medical institutions' operation became unstable.

Situation: unsustainable



Change into Sustainable system?



R-Zone and its reduction

Year	R-Zone	Yakka-sa	Drug ratio	Drug price revisopn
1992	R=15			
1994	R=13	19.6%(1993)	26.1%	-6.6%
1996	R=11	17.8%(1995)	24.5%	-6.8%
1997	R=10、LLP8	14.5%(1996)	23.3%	-4.4%
1998	R=5、LLP2	13.1%(1997)	20.1%	-9.7%
2000	R=2	9.5%(1999)	20.2%	-7.0%

Note: LLP = Long-term Listed Products, R = Reasonable Zone

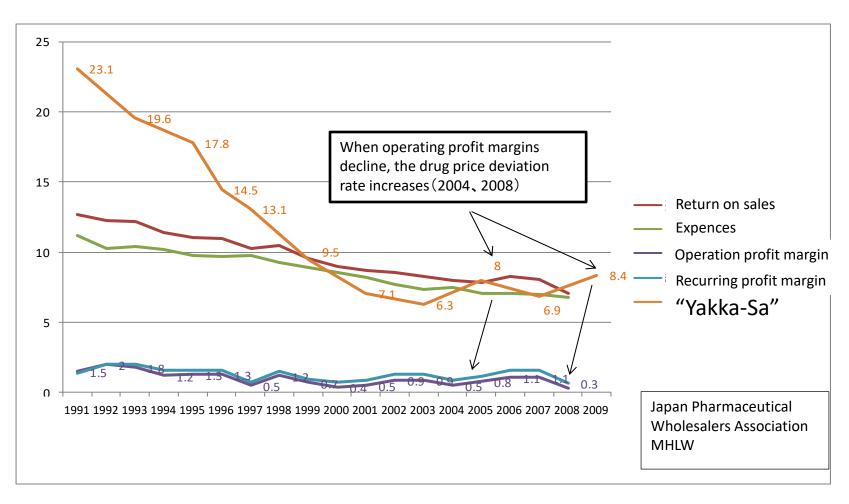
R-Zone (Reasonable zone)

- Ryukinkyo (Drug distribution system modernization committee) had put together a report on drug price reform in 1990.
- "Japan-U.S. Structural Impediments Initiative" was being discussed. Improvement in terms of transparency of transaction and fair trade was demanded from the U.S.
- Chuikyo (Central Social Insurance Medical Council) had put together a proposal to the Minister of MHLW on drug price reform in 1991.
- New rule for price revision was introduced, and new price should be based on average market price + R-zone.
- Reasonable zone had reduced step by step to the level that the industry didn't expected (Political Decision)

84

"Yakka-Sa" and Drug distributors profit change

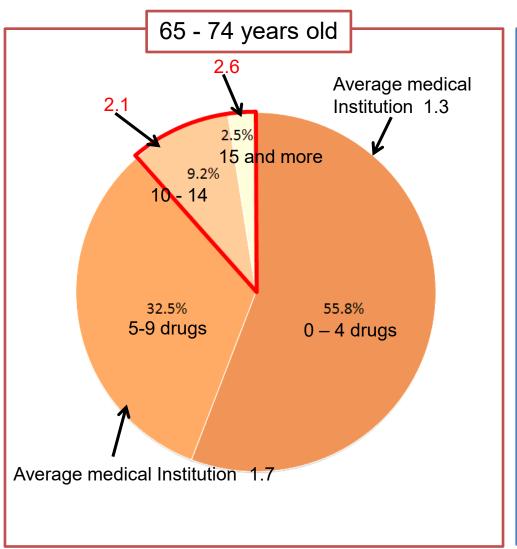
Profit rate of distributors had declined to 0.3%.

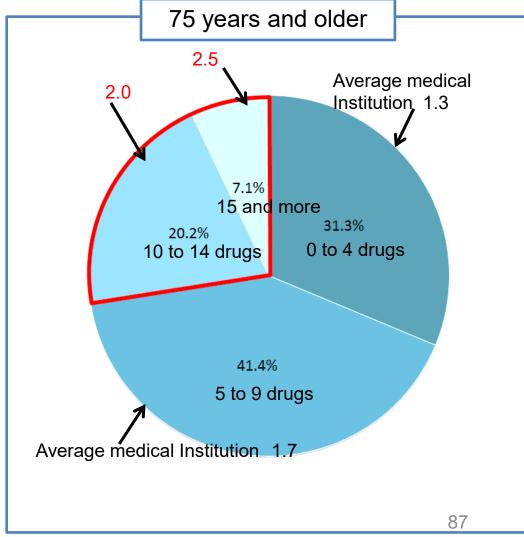


Drug Distribution Reform

- With new reform, drug wholesalers' profits getting low, having little or minus margin to offer big discounts to medical institutions.
- New drugs comes in, many of them sold with higher price, and innovative drugs had limited needs for discounts to appeal to physicians.

Multi-Medication situation of aged patients in Japan





Left-over drug at home

With prescription days get longer, more left-over drugs are frequently found at home by forgetting, reducing by own, and disappear of needs.











The history and role of Japan's public health care system : Looking ahead to addressing aging

HISTORICAL BACKGROUND AND HISTORY 3: "INSURANCE-COVERED MEDICAL INSTITUTIONS"

Regarding "Insurance-Covered Medical Institutions" (no major changes to the system)

- In Japan, medical treatment covered by insurance is handled by "Insurance-Covered Medical Institutions." Medical institutions become "Insurance-Covered Medical Institutions" after receiving designation by government.
- "Insurance-Covered Medical Institutions" must comply with the standards for handling medical insurance. These are called the "Regulations for the Provision of Madical Care" (Ministry of Health, Labour and Welfare Ordinance).
- If a medical institution commits fraud, such as filing fictitious claims in order to increase the number of insurance claims, its designation as an insurance medical institution may be revoked.
- (reposted the previous slides) There have been no major changes to this system.

The history and role of Japan's public health care system : Looking ahead to addressing aging

HISTORICAL BACKGROUND AND HISTORY 4: BENEFITS IN KIND

INCREASINGLY PATIENTS CAN CHOOSE AND PAY

Regarding "in-kind benefits" (system transition 1)

- Medical care provided as "benefits in kind" must be provided in accordance with insurance standards. Medical treatments other than those approved by the insurance are prohibited. Combining insured and uninsured medical care is illegal.
- (partially reposted the previous slide)
- Traditionally, the provision of special rooms has been permitted to be charged extra
 for the room difference (patient choice in the area of amenities), but the expansion of
 this practice was discussed.
- In 1984, a legal amendment was made allowing the combination of insured and uninsured medical treatment.
- The above measures were gradually expanded.

Regarding "in-kind benefits" (System transition 2)

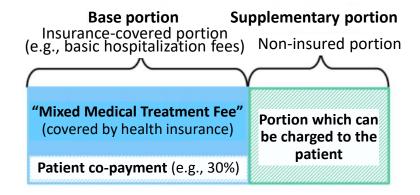
- In 1984, a legal amendment was made allowing the combination of insured and uninsured medical treatment.
- The above measures were gradually expanded.
- The most important mechanism today is the handling of "Advanced Medical Treatments".
- According to documents from the Ministry of Health, Labor and Welfare, the current situation is as follows:

Overview of the system

"Mixed Medical Treatment Fee System"

Introduced under the 2006 legal reform

Mechanism of "Mixed Medical Treatment Fee System"



* "Mixed Medical Treatment Fee System" clearly stipulates requirements when collecting fees from patients, including the obligation to display the charges.

OEvaluative Treatments

- "Advanced medical treatments"
- Medical services related to clinical trials of pharmaceuticals, medical devices, and regenerative medicine products
- Use of pharmaceuticals, medical devices, or regenerative medicine products after regulatory approval but before insurance coverage
- Off-label use of drugs listed in the drug price standards (where partial modifications of dosage, method, or indications have been approved for application)
- •Use of program-based medical devices (after first-stage regulatory approval, aiming for re-evaluation through a challenge application)

OPatient-requested treatments ODesignated Treatments

- Special care environment (private rooms with additional charges)
- Use of gold alloys in dental treatment
- Complete dentures with metal base
- Scheduled/appointment-based consultations
- Out-of-hours consultations
- Initial consultations at large hospitals
- Follow-up consultations at large hospitals
- Guidance and management for pediatric dental caries
- Hospitalization exceeding 180 days
- Medical procedures exceeding the permitted number of times
- Multifocal intraocular lenses used for lens reconstruction
- Program-controlled medical devices after the end of insurance coverage period
- Intermittently scanned continuous glucose monitoring devices
- Sperm freezing and thawing
- Long-term inpatient medical supplies

Overview of the system ("Advanced Medical Treatments")

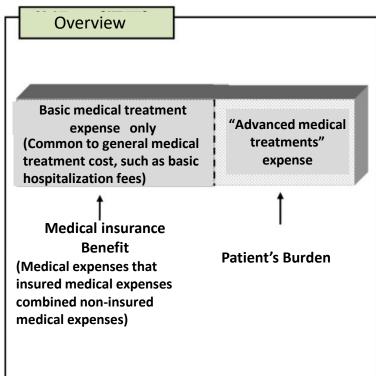
What is "Advanced Medical Treatments"

"Advanced Medical Treatments"

OA System that sets facility standards to ensure the safety and effectiveness of advanced medical technologies that are not yet covered by insurance. It allows for the combined use on insured and uninsured medical treatment, and evaluate them with a view to future introduction of insurance.

Olnsurance applies to basic medical expenses, such as basic hospitalization fees, which are common to general medical treatment, but "advanced medical treatments" expenses are borne by the patient.

OFor each medical technology to be recognized as "advanced medical treatments", it must undergo an examination for safety, effectiveness, etc.by the Council for "advanced medical treatments", and medical institutions that implement the "advanced medical treatments" must notify or obtain approval from the Minister of Health, Labor and Welfare.



Classification of target medical technology

.O"Advanced Medical Treatments" A

- 1. Medical technology that doesn't involve the use of unapproved drugs, medical devices, regenerative medicine products, or off-label use of unapproved drugs, medical devices, regenerative medicine products. (excluding item4)
- 2. The following medical technologies with minimal impact on the human body when implemented. (excluding item4)
- (1)Medical technology involving the use of unapproved in vitro diagnostics or off-label use of in vitro diagnostics.
- (2)Medical technology involving the use of unapproved diagnostic reagents or off-label use of diagnostic reagents.
- (3) Medical technology involving the use of unapproved medical devices or off-label use of medical devices for the purpose of testing.

O"Advanced Medical Treatments" B

- 3. Medical technology involving the use of unapproved drugs , medical devices, or regenerative medicine products, or off-label use of drugs, medical devices, or regenerative medical products. (excluding item2)
- 4.In the light of its safety, effectiveness of the medical technology, it is deemed to require particularly intensive observation and evaluation its implementation environment, effectiveness, etc.

Overview of the system ("Selected Medical Services")

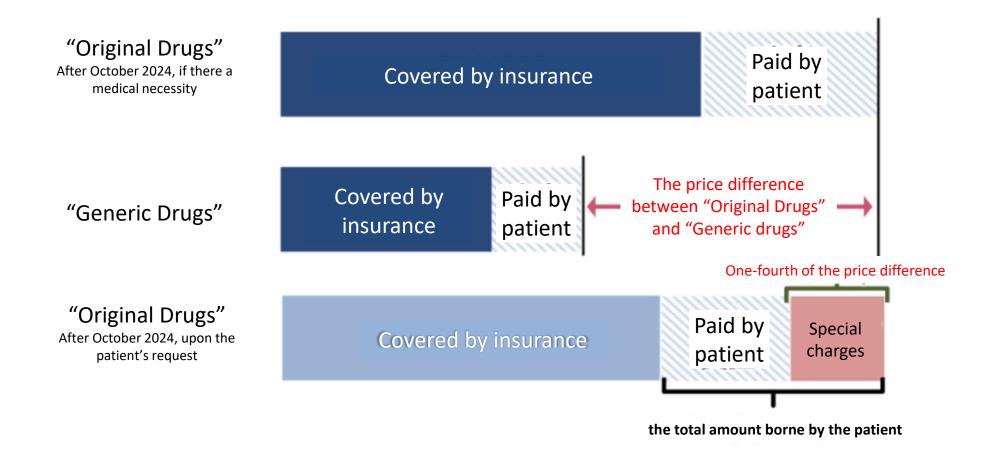
"Selected Medical Services"

"Selected Medical Services" refer to services under combined insured and non-insured medical treatment that are not intended for future inclusion in public health insurance. Patients may receive these services by paying special additional charges to combine non-insured treatment with insured treatment. There are the following types of "Selected Medical Services":

- Special care environment (private rooms with additional charges)
- Use of gold alloys in dental treatment
- Complete dentures with metal base
- Scheduled/appointment-based consultations
- Out-of-hours consultations
- Initial consultations at large hospitals
- Follow-up consultations at large hospitals
- Guidance and management for pediatric dental caries
- Hospitalization exceeding 180 days
- Medical procedures exceeding the permitted number of times
- Multifocal intraocular lenses used for lens reconstruction.
- Program-controlled medical devices after the end of insurance coverage period
- Intermittently scanned continuous glucose monitoring devices
- Sperm freezing and thawing
- Long-term inpatient medical supplies

Overview of the system (newly introduced measures of patient costs related to drug selection)

Exceptional billing calculation



The history and role of Japan's public health care system : Looking ahead to addressing aging

JAPAN'S MEDICAL INSURANCE SYSTEM: HOW TO DEAL WITH THE AGING POPULATION AND HOW TO UTILIZE PRIVATE INSURANCE

Use of private insurance (transition 1)

- Initially, the government and Medical Association were opposed to the use of private insurance, as it would allow for mixed (insured and uninsured) medical treatment.
- In private insurance, products that add fixed hospitalization benefits as riders became popular, but these have no relationship to insured medical treatment related to hospitalization.
- The Ministry of Health, Labour and Welfare was opposed to systems and insurance that weakened the effectiveness of co-payments, as the abolition of co-payments had led to abuse of the system.
- Subsequently, resistance to the use of private insurance gradually weakened, with the combination of insured and uninsured medical treatment becoming permitted.
- In Japan, almost all medical care is covered by medical insurance, and no alternative products are sold.

99

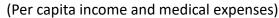
Use of private insurance (transition 2)

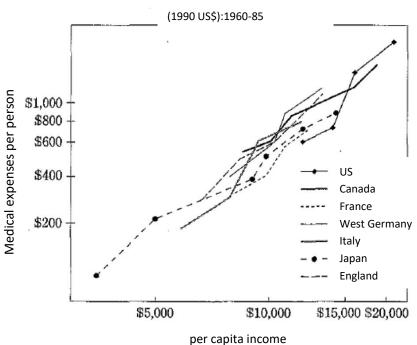
- Subsequently, it became possible to pay copayments by credit card and receive benefit equivalent to the copayments through private insurance.
- Meanwhile, cancer insurance has become widespread, and as a result, riders to cancer insurance that cover the costs of "Advanced Medical Treatments" designated by the government have become widespread.
- Discussions regarding the use of private insurance are still ongoing in various areas.
- However, it is limited to the costs associated with nationally insured medical treatment or the costs of non-insured medical treatment approved by the government, and is of a complementary nature.
- This is because Japan's public health care system has a "Universal Health Insurance" system that basically covers all necessary medical care.

Factors behind the overall increase in medical expenses: Relationship with income

According to international comparative research,

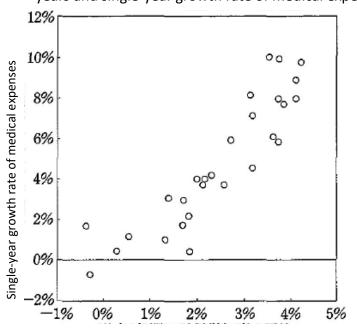
- -There is a positive correlation between per capita medical expenses and per capita income,
- -There is a positive correlation between the annual growth rate of medical expenses and the income growth rate over the past six years (not just for a single year). has been pointed out.





Source: Getzen (1995) 36.

Average annual income growth rate over the past six years and single-year growth rate of medical expenses



Average annual Income growth rate over the past six years

Source: Getzen (1995) 37.

Source: "Basio Theories and Issues in Health Economics" (edited by Nishimura Shuzo, Tanaka Shigeru, and Endo Hisao, Keiso Shobo, 2006) Chapter7 "International Comparison of Total Medical Expense Levels and Issues and Empirical Research on Determinants" (by Gonjo Zenichi)

23. Oct. 2008 National Social Security Conference Materials

As income increases, medical expenses also increase.

As income increases, the need for medical care expands.

Another example: Generally, as income rises, the proportion of food expenses in household expenses tends to decrease. (This is called the "Engel Coefficient".)

- As people become wealthier, their medical needs become more diverse.
- As income increases, people tend to invest more in their own health.

It could also be considered as above.



Greetings MESSAGE

Meeting overview CONCEPT

Report REPORT

MEMBER

Opinion solicitation OPINION

Symposium

promotion city. MODEL

Japan is becoming a healthadvanced nation.

New vision for 2035 now available

Developing a vision of Japan's health care policies for the year 2035

We are now accepting applications from municipalities to participate in New vision for 2035 now available! the Healthcare 2035 Promotion City initiative!



New vision for 2035 now available!

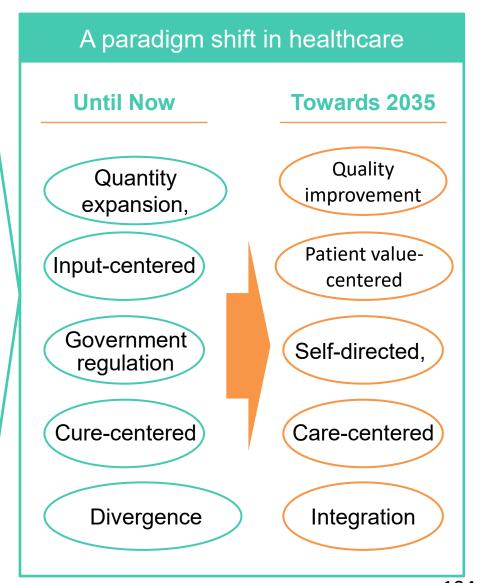
Japan Vision: Health Care 2035 Report

A paradigm shift is necessary to respond to the changes in society and the economy 20 years from now



Challenges and prospects for 2035

- Increasing healthcare needs, diversifying social environments and values, growing disparities, and advancing globalization.
- Rather than simply maintaining the current system by increasing burdens and reducing benefits, we need to share values and visions and restructure healthcare as a new "social system.
- "While maintaining the world's highest level of health, we must also contribute to Japan's economic growth and development through innovation in healthcare technologies and systems.
- We must also seriously address fiscal reconstruction and actively contribute to Japan's economy and finances.
- By overcoming the declining birthrate and aging society, Japan will further develop and lead the international community in the face of the aging population, thereby establishing itself as a nation with a long and healthy life expectancy.



2018 Nobel Prize in Medicine Awarded to 2 Cancer Immunotherapy Researchers



The Nobel Prize for Physiology and Medicine was awarded to James P. Allison, left, and Tasuku Honjo on Monday for their work on cancer research.

Jonathan Nackstrand/Agence France-Presse — Getty Images





In accordance with the approval conditions for this drug, we will conduct a usage results survey (investigating all cases) after manufacturing and marketing approval. and will take the necessary messures to ensure the appropriate treatment of thin drug.



Product name

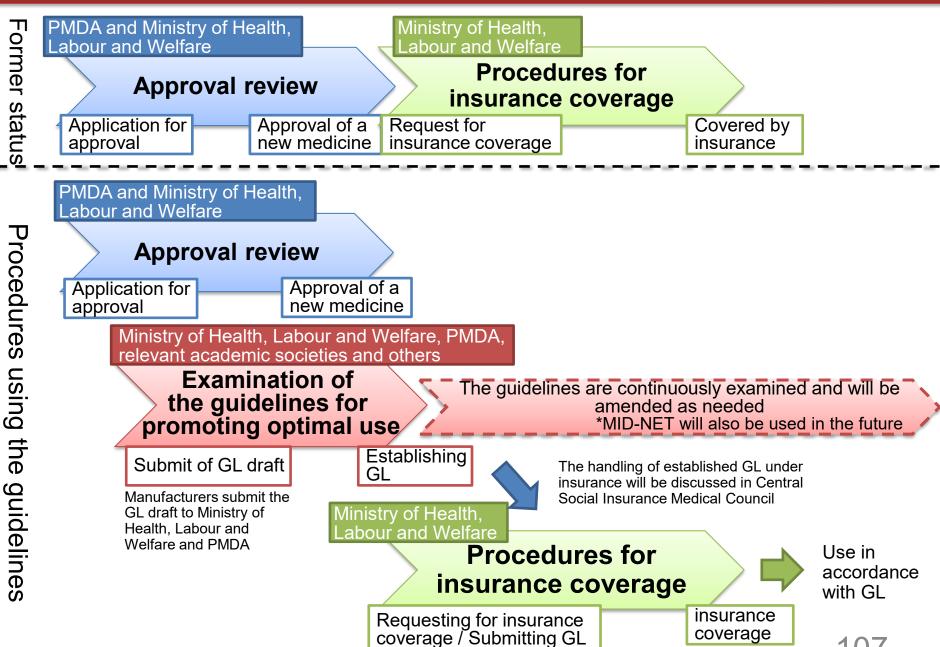
Generic name of the drug

Effects and Efficacy

Dr. Tasuku Honjo, **Novel Prize Winner**



Procedures from approval to insurance coverage



Special drug price revision for high-price drug

- The drug price for Opdivo was reduced by 50% as an emergency measure.
- It was ensured that the product is restricted to effective use in accordance with the guideline.

Approx. **Opdivo** Approx. 360,000 yen 730,000 yen At the time of approval in Jul. 2014, \triangle 50%(drug price) (←Drug price) the indication was Approx. 300,000 yen only rare disease of Approx. 200,000 yen malignant melanoma Approx. 140,000 yen Optimal use guideline Additional indications such as lung cancer were added and the

market was

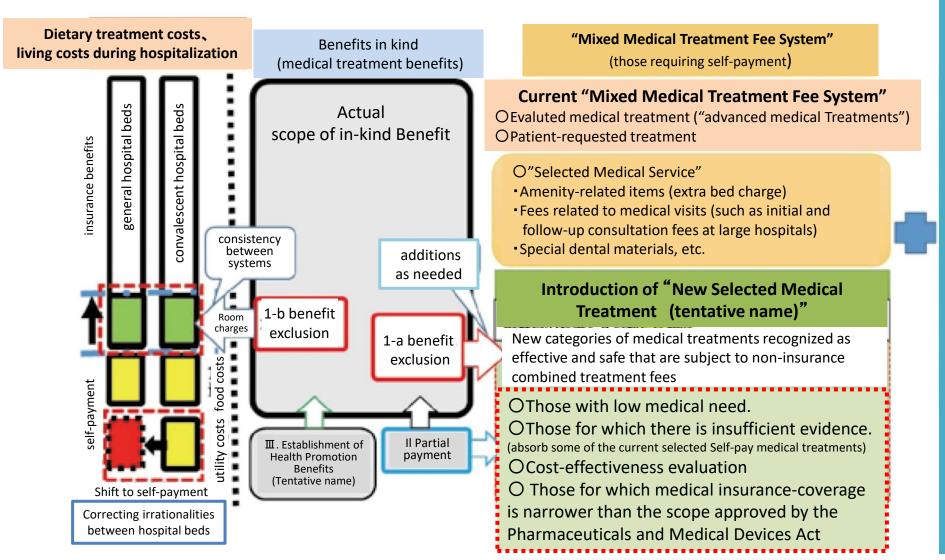
drastically expanded,

Study Group on Revision of the Scope of Public Health Insurance Benefits Report

[Report summary]

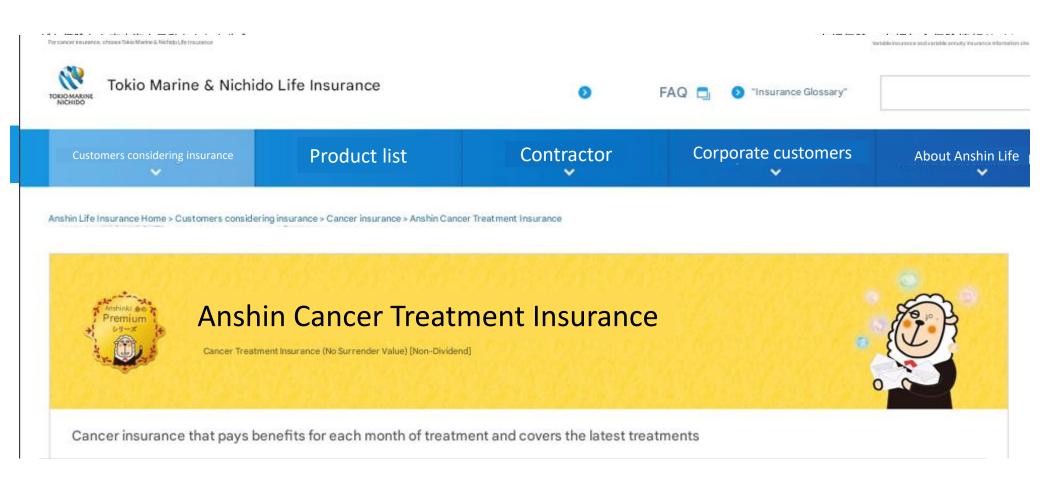
The public health insurance system faces a tough environment, with a declining population, a declining birthrate and aging population, an increasing burden on the working generation, and steady growth in medical expenses, making ensuring its sustainability a policy issue. Based on the philosophy of "necessary and appropriate medical care should be provided in kind," this study group aims to: 1) evaluate medically and scientifically evidenced and essential for the treatment of illness; 2) ensure the appropriateness of the system (correction of irrationalities) and consistency between systems from the perspective of patients and other stakeholders; and 3) evaluate the proactive efforts of citizens, insurers, and family doctors that contribute to extending healthy life expectancy. We examined the appropriateness and validity of the scope of benefits provided by the current public health insurance system from the following three perspectives. Furthermore, since removing certain medical technologies from the current scope of benefits would mean that even basic costs would have to be borne by the patient, we also reorganized and examined the system for combined uninsured medical care expenses, and proposed the creation of a new category called "New Selected Medical Care (tentative name)" that would allow for the payment of combined uninsured medical care expenses, in addition to the current "selected medical services" that is not intended to be covered by insurance, even for medical technologies that have been recognized as effective and safe. Furthermore, from the perspective of ensuring access to medical care for the public and patients, we also considered the use of private insurance and consideration for low-income earners. The overall picture of the research results is as follows.

Overall overview of the study group's recommendations

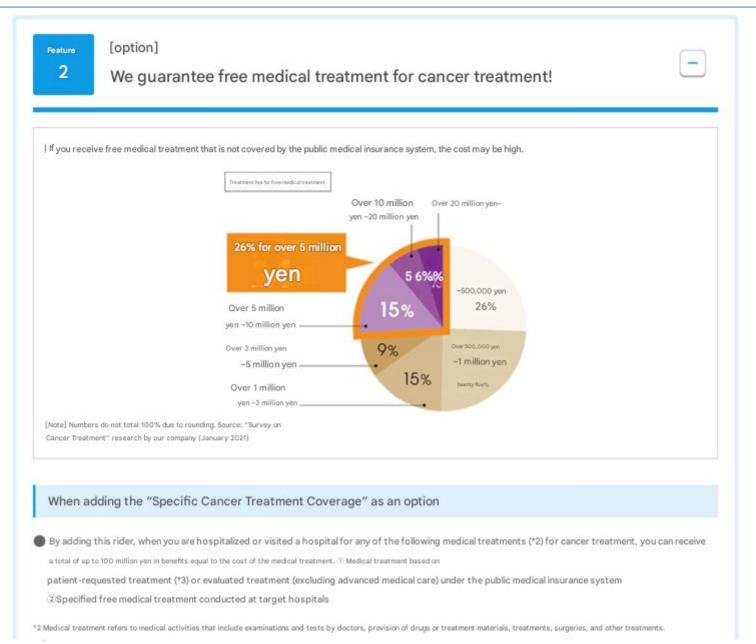


Source: Study Group

An example of private insurance for cancer treatment that complements National Medical Insurance



An example of private insurance for cancer treatment that complements National Medical Insurance



112

High-cost pharmaceuticals tend to be limited to specific patient groups.

Summary of the results of the drug pricing organization

	Calculation Similar effice method comparison me		· •		L Δυσυς† 1 2014			
			New drug		Reason for the absence of similar drugs			
spo	প্র Ingredient Name		Nivolumab (genetical recombination)			There are no other products already listed with the same efficacy and effects		
g Meth	Efficacy/effect		Unresectable malignant melanoma		as this	as this drug, and since the pharmacological effects, composition, and chemical structure are different, it has been determined that, overall, there		
ountin	Pharmacological action		PD-1/PD-1 ligand binding inhibition		and ch			
Appropriateness of Adopting Cost Accounting Methods	Composition and Chemical Structure Consists of 440 amino acid residues Two H chains (y4 chains) and 214 L chain (K chain) consisting of amino acid residues. It is a glycoprotein (molecular weight: approximately 145,000) consisting of two chains. The 221st amino acid residue of human PD-1 is replaced by Pro. Recombinant human IgG4 monoclonal antibody. It is a clonal antibody.			14 L chain (K acid residues. ular weight: onsisting of two cid residue of Pro.	is no drug that is most similar to this drug and is eligible for new drug pricing.			
	dosag	tration route, e form, and usage	' Ionce every three weeks					

High-cost pharmaceuticals tend to be limited to specific patient groups.

Summary of the results of the drug pricing organization

	• · · · · · · · · · · · · · · · · · · ·		acy comparison First calculation organization			January 12, 2017		
			New drug		Most Similar Medication			
Validity of Most Similar Drug Selection	Ingredi	ient Name	Pumprolizumab (genetical re	combination)	Nivolun	Nivolumab (genetical recombination)		
	Effica	cy/effect	Unresectable malignant mela PD-L1-positive unresectable, recurrent non-small cell lung	advanced or	Unresectable malignant melanoma Unresectable, advanced or recurrent non- small cell lung cancer Unresectable or metastatic renal cell carcinoma Relapsed or refractory classical Hodgkin lymphoma			
	Pharmacological action		PD-1/PD-1 ligand binding i	nhibition	Same as left			
	Composition and Chemical Structure		A recombinant human monoclonal antibody against human PD-1 (a glycoprotein consisting of two H chains (y1 chains) each consisting of 447 amino acid residues and two L chains (chains) each consisting of 218 amino acid residues (molecular weight: approximately 149,000)		Recombinant human IgG4 monoclonal antibody against human PD-1 (a glycoprotein produced in Chinese hamster ovary cells, consisting of two heavy chains of 440 amino acid residues and two light chains of 214 amino acid residues)			
	Administration route, dosage form, and usage		Injection, injectable medication, once every three weeks		Injection, injectable medication, twice every three weeks			

High-cost pharmaceuticals tend to be limited to specific patient groups.

(Continued from the previous page)

Key Points of Objections to the Initial Proposal by New Drug Listing Applicants	In the first-line treatment of non-small cell lung cancer, this drug has shown a significant extension of overall survival compared to standard chemotherapy. In addition, its use is recommended as the first choice in domestic and international clinical guidelines, and it is positioned as a standard treatment for the target disease, so it is eligible for a utility premium (II).				
	Second accounting organization	January 30, 2017			
Views on the Above Objections	against renal cell carcinom drug, and that there have				

Many high-priced drugs are not approved or covered in Japan -- From the National Cancer Center website

Home > About the National Cancer Center > Organization > "Advanced medical treatments" and Cost-Effectiveness Evaluation Office > Drugs that are not approved or are off-label use in Japan under the Pharmaceutical and Medical Device Act

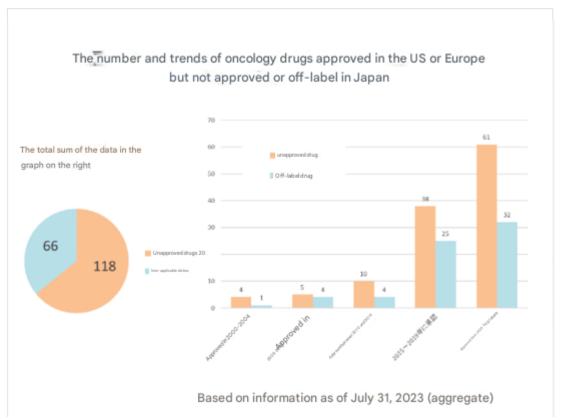
Drugs that are not approved or are off-label use in Japan under the Pharmaceutical and Medical Device Act



・シェアする



This list was created by the National Cancer Center's Office of "Advanced medical treatments" and Cost-Effectiveness Evaluation based on the "Unapproved Drug Database (links to external site)" published by the Pharmaceuticals and Medical Devices Agency (PMDA), with the addition of approval information from the United States and Europe.



"Advanced medical treatments" and Cost-Effectiveness **Evaluation Office**

- Medical expenses paid by
- patients themselves when using unapproved drugs (model case)
- About the "Advanced medical treatments" Evaluation Committee
- Regarding medicines that are not approved or are off-label for use in Japan under the Pharmaceutical and
- Medical Device Act

Not approved or covered cancer drug made public -- From the National Cancer Center website

List of Pharmaceuticals and Indications Not Approved or Off-Label Under the Pharmaceutical Affairs Law in Japan

No.	General name in Japanese	General name in English	Product name in Japan	Product name in U.S.	Company name	Development situation	Similar medicine in Japan	; Type of cancers	Efficiency
1	ドスタルリマブ	Dostarlimab-gxly	-	JEMPERL I	Glaxo	Not started yet		· Uterus	Recurrent or progressive endometrial cancer (in combination with chemotherapy)
2	タラゾパリブ	Talazoparib	-	TALZENN A	Pfizer	Under develop ment		Urology	HRR-mutated castration- resistant prostate cancer (in combination with enzalutamide)
3	グロフィタマブ	Glofitamab-gxbm	-	COLUMVI	CHUGAI	Under develop ment		Blood	Relapsed or refractory diffuse large B-cell lymphoma
4	ニボルマブ	Nivolumab	OPDIVO	OPDIVO	ONO YAKUHIN	Not started yet		Child	Unresectable or metastatic malignant melanoma <expanded 12="" aged="" and="" for="" indication="" older="" patients="" pediatric="" years=""></expanded>
									117

Approved by the Governm ent of Japan	Approved: by the Governm ent of U.S.	Date of approval by the U.S. FDA	Approval by the Europe FMA	Date of approval by the Europe FMA	Other information	2 grade or more in NCCN guidelines	Drug cost per month (1 cycle/28 days) yen	Remarks on drug cost calculation
Not ;approved yet	:Approved	July 2023	Not approved yet			0	¥1,778,257	
Not approved yet	Approved	June 2023	Not approved yet			0	¥2,101,688	
Not approved yet	Approved	June 2023	Approved	July 2023		0	¥3,270,075	
Out of cathegory	Approved	July 2017	Approved	May 2023		0	¥732,810	Calculated based on an average weight of 46 kg for a 13-year-old childCalculated using the dosage when combined with ipilimumab