

# [2] Health and Medical Services

## (1) Health Care Insurance

### Health Care Insurance System

#### Overview

#### Outline of Health Care Insurance System

(As of April 2022)

System	Insurer (as of the end of March 2021)	Number of subscribers (March 2021) Insured Families 1,000 persons	Insurance benefits				Financial resources		
			Medical care benefits				Cash benefits	Premium rate	State subsidy
			Co-payment	High-cost medical care benefit, Unitary high-cost medical/long-term care system	Hospital meal expenses	Hospital living expenses			
Health Insurance General employees	JHIA-managed Health Insurance	40,296 [24,877 15,419]	<p>(High-cost medical care benefit system)</p> <ul style="list-style-type: none"> <li>Maximum co-payment (Persons younger than 70)</li> <li>(average annual income: over approximately 11.60 million yen)</li> <li>¥252,600 + (medical expenses – ¥842,000) x 1% (average annual income: between about 7.70 million yen and about 11.60 million yen)</li> <li>¥167,400 + (medical expenses – ¥558,000) x 1% (average annual income: between about 3.70 million yen and about 7.70 million yen)</li> <li>¥80,100 + (medical expenses – ¥267,000) x 1% (average annual income: under approximately 3.70 million yen) ¥57,600 (exempted from residence tax) ¥35,400</li> </ul> <p>(Persons aged 70 or older but younger than 75)</p> <p>(average annual income: over approximately 11.60 million yen)</p> <ul style="list-style-type: none"> <li>¥252,600 + (medical expenses – ¥842,000) x 1% (average annual income: between about 7.70 million yen and about 11.60 million yen)</li> <li>¥167,400 + (medical expenses – ¥558,000) x 1% (average annual income: between about 3.70 million yen and about 7.70 million yen)</li> <li>¥80,100 + (medical expenses – ¥267,000) x 1% (average annual income: under approximately 3.70 million yen) ¥57,600 (exempted from residence tax) ¥35,400</li> </ul> <p>(Persons aged 70 or older but younger than 75)</p> <p>(average annual income: over approximately 11.60 million yen)</p> <ul style="list-style-type: none"> <li>¥252,600 + (medical expenses – ¥842,000) x 1% (average annual income: between about 7.70 million yen and about 11.60 million yen)</li> <li>¥167,400 + (medical expenses – ¥558,000) x 1% (average annual income: between about 3.70 million yen and about 7.70 million yen)</li> <li>¥80,100 + (medical expenses – ¥267,000) x 1% (average annual income: under approximately 3.70 million yen) ¥57,600 (exempted from residence tax) ¥35,400</li> </ul> <p>(Especially household with lower income among household exempted from residence tax)</p> <ul style="list-style-type: none"> <li>¥15,000, outpatient (per person) ¥8,000</li> </ul> <ul style="list-style-type: none"> <li>Per-household standard amount</li> <li>If more than one person younger than 70 pay ¥21,000 or more in a single month, per-household standard amount is added to the benefits paid</li> <li>Reduced payment for multiple high-cost medical care</li> <li>For persons who have received high-cost care three times within a twelve-month period, the maximum co-payment of the fourth time and up will be reduced to: (Persons younger than 70)</li> <li>(average annual income: over approximately 11.60 million yen)</li> <li>¥140,100 (average annual income: between about 7.70 million yen and about 11.60 million yen)</li> <li>¥93,000 (average annual income: between about 3.70 million yen and about 7.70 million yen)</li> <li>¥44,400 (average annual income: under approximately 3.70 million yen) ¥44,400 (exempted from residence tax) ¥24,600</li> </ul> <p>(Persons aged 70 or older but younger than 75)</p> <p>(average annual income: over approximately 11.60 million yen)</p> <ul style="list-style-type: none"> <li>¥140,100 (average annual income: between about 7.70 million yen and about 11.60 million yen)</li> <li>¥93,000 (average annual income: between about 3.70 million yen and about 7.70 million yen)</li> <li>¥44,400 (average annual income: under approximately 3.70 million yen) ¥44,400 (average annual income: under approximately 3.70 million yen)</li> </ul>	<ul style="list-style-type: none"> <li>(Co-payment for meal expenses)</li> <li>Households with residential tax Per meal ¥460</li> <li>Household exempted from residence tax Per meal first 90 days ¥210</li> <li>Per meal after 90 days ¥160</li> <li>Lower income household exempted from residence tax Per meal ¥130</li> <li>Per day ¥370</li> <li>Applicable to those aged 65 or older in long-term care beds</li> <li>For patients with intractable/rare diseases, etc. and thus in high need for inpatient medical care, the amount of co-payment is the same as standard co-payment for meal expenses</li> </ul>	<ul style="list-style-type: none"> <li>(Co-payment for living expenses)</li> <li>Households with residential tax Per meal ¥460</li> <li>Household exempted from residence tax Per meal ¥210</li> <li>Per day ¥370</li> <li>Lower income household exempted from residence tax Per meal ¥130</li> <li>Per day ¥370</li> </ul>	<ul style="list-style-type: none"> <li>Sickness and injury allowance</li> <li>Lump-sum birth allowance, etc.</li> </ul>	<ul style="list-style-type: none"> <li>10.00% (national average)</li> </ul>	<ul style="list-style-type: none"> <li>16.4% of benefit expenses, etc.</li> </ul>	
	Society-managed Health Insurance	Health Insurance Societies 1,388		28,680 [16,418 12,262]	Same as above (with additional benefits)	Different among health insurance associations	Fixed amount (subsidy from budget)		
	The insured under Article 3-2 of the Health Insurance Act	Japan Health Insurance Association		16 [11 5]	Same as above	Per day Class 1: ¥390 Class 11: ¥3,230	16.4% of benefit expenses, etc.		
Seamen's Insurance	Japan Health Insurance Association	116 [58 58]	Same as above	9.70% (sickness insurance premium rate)	Fixed amount				
Mutual aid associations	National public employees	20 mutual aid associations	<p>After reaching compulsory education age until age 70 30%</p> <p>Before reaching compulsory education age 20%</p>	<ul style="list-style-type: none"> <li>For patients with intractable/rare diseases, etc. and thus in high need for inpatient medical care, the amount of co-payment is the same as standard co-payment for meal expenses</li> </ul>	<ul style="list-style-type: none"> <li>Same as above (with additional benefits)</li> </ul>	None			
	Local public employees, etc.	64 mutual aid associations					8,545 [4,565 3,980]		
	Private school teachers/staffs	1 Corporation							
National Health Insurance (NHI)	Farmers, self-	Municipalities 1,716	<p>70 or older but younger than 75 20% (30% for persons with more than a certain amount of income)</p>	<ul style="list-style-type: none"> <li>Same as above (with additional benefits)</li> </ul>	<ul style="list-style-type: none"> <li>41% of benefit expenses, etc.</li> <li>28.4~47.4% of benefit expenses, etc.</li> </ul>	None			
		NHI associations 161							
	Retired						28,904 Municipalities 26,193 NHI associations		

persons under Employees' Health Insurance	Municipalities 1,716	2,711		under approximately 3.70 million yen) ¥44,400 •Reduced payment for persons receiving high-cost medical care for a long period Maximum co-payment for patients suffering from hemophilia or chronic renal failure requiring dialysis, etc.: ¥10,000 (patient younger than 70 with over average annual income of 7.70 million yen, receiving dialysis: ¥20,000 (Unitary high cost medical/long-term care benefit system) Reduced payment for persons whose total co-payments of health care and long-term care insurances for a year (every year from August to July of the next year) is extremely high. Maximum co-payment is determined carefully according to their income and age.				formulas differ among insurers	
Medical care system for the elderly aged 75 and over	[Implementing bodies]  Wide area unions for medical care system for the elderly aged 75 and over  47	18,060	10% (30% for persons with more than a certain amount of income)	(average annual income: over approximately 11.60 million yen) ¥252,600 + (medical expenses – ¥842,000) x1% (average annual income: between about 7.70 million yen and about 11.60 million yen) ¥167,400 + (medical expenses – ¥558,000) x1% (average annual income: between about 3.70 million yen and about 7.70 million yen) ¥80,100 + (medical expenses – ¥267,000) x 1% (average annual income: under approximately 3.70 million yen) ¥57,600 outpatient (per person) ¥18,000(¥144,000/year) (Household exempted from residence tax) ¥24,600, outpatient (per person) ¥8,000 (Especially household with lower income among household exempted from residence tax) ¥15,000, outpatient (per person) ¥8,000 • Reduced payment for multiple high-cost medical care (average annual income: over approximately 11.60 million yen) ¥140,100 (average annual income: between about 7.70 million yen and about 11.60 million yen) ¥93,000 (average annual income: between about 3.70 million yen and about 7.70 million yen) ¥44,400 (average annual income: under approximately 3.70 million yen) ¥44,400	Same as above	Same as above, except for • Recipients of old-age Welfare Pensions Per meal ¥100	• Funeral expenses, etc.	Calculated using the amount of the per capita rate and income ratio of insured persons provided by wide area unions  About 10% of benefits, expenses, etc. are borne as insurance premiums	• About 10% of benefits, expenses, etc. are borne as insurance premiums (Breakdown of public funding) National : Prefectures Municipalities 4 : 1 : 1  In addition, about 40% of the benefits will be borne by the working generation as support for the latter-stage elderly.

- (Note) 1. Insured persons of medical care system for the elderly aged 75 and over include those aged 75 or older or 65-75 certified as having a specific disability by a wide area union.  
 2. Persons with a certain amount of income include those with a taxable income of ¥1.45 million (monthly income of ¥280,000 or more) or persons whose total amount of gross income, etc. after deducting the basic amount of insured persons belonging to the 70-74 age group households is ¥2.10 million or more. However, those in households of two or more elderly with a taxable income of less than ¥5.20 million, and those of a elderly single-person household with a taxable income of 3.83 million and those with a total old income not more than ¥2.10 million are excluded. Lower income households exempted from residence tax is considered to be those with a pension income of ¥800,000 or less, etc.  
 3. Fixed-rate national subsidy for National Health Insurance shall be at the same level as that for the Japan Health Insurance Association-managed Health Insurance for those exempt from application of Health Insurance and those newly subscribed to the National Health Insurance on and after September 1, 1997.  
 4. The sums in the breakdown may not equal the total due to rounding.  
 5. The premium rate of Seamen's Insurance is the rate after the deduction resulting from the measure to reduce the burden of insurance premiums for insured persons (0.40%).

### Detailed Information 1 Outline of High-Cost Medical Care Benefit System

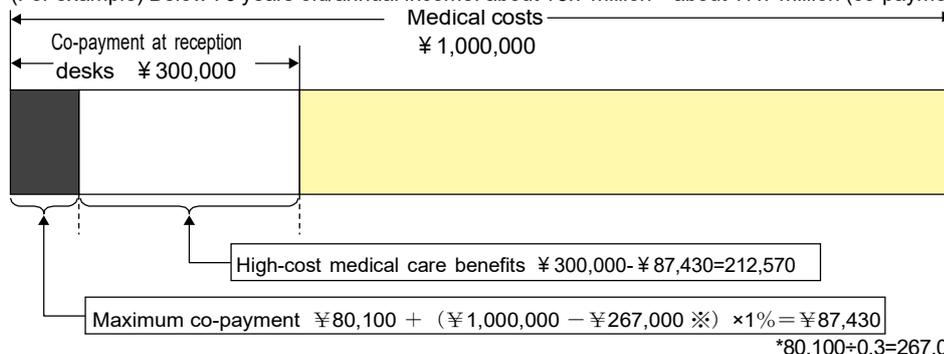
□The high-cost medical care benefit system is for use in avoiding co-payments made for medical costs becoming too expensive for family budgets. Under this system, households pay co-payments for medical costs at the reception desks of medical institutions but then get reimbursed by insurers for any amount exceeding the monthly maximum amount.

(\*1) In case of hospitalization, a benefit in kind system has been introduced in which the monthly payment at the reception desks of medical institutions is limited to the maximum co-payment.

(\*2) In case of outpatient treatment, a benefit in kind system was introduced in April 2012 for use when the monthly payment exceeds the maximum co-payment at the same medical institution.

□The maximum co-payment is set up according to insured persons' income.

(For example) Below 70 years old/annual income: about ¥3.7 million—about ¥7.7 million (co-payment of 30%)



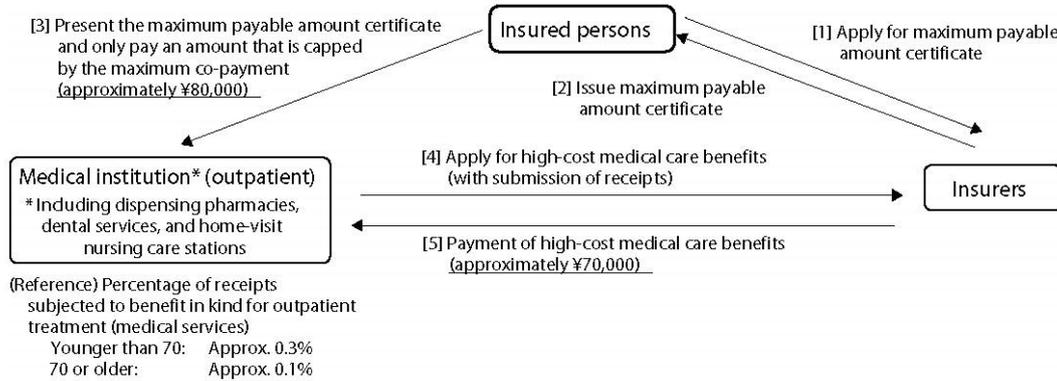
(Note) Per-household addition system

Even when partial co-payment does not exceed the maximum co-payment in the same medical institution, partial co-payments (those under 70 is ¥21,000) during the same month at multiple medical institutions can be added up. If the added-up sum exceeds the maximum, the high cost medical care system is applied.

## Detailed Information 2 Response to Benefit in Kind for Outpatient Treatment

□ A method (benefit in kind) of reducing the burden of patients paying high drug costs will be introduced for outpatient treatment in addition to conventional hospital treatment (enforced in April 2012). The method involves that when a patient receives outpatient treatment at the same medical institution and their monthly co-payment exceeds the maximum co-payment the insurer then makes the payment to the medical institution rather than the patient applying for the high-cost medical care benefits and receiving the benefits later, thus ensuring that the patient is only required to pay an amount which is capped at the maximum co-payment.

Medical expense ¥500,000 (co-payment of 30%) Annual income: about ¥3.7 million –about ¥7.70 million for persons below 70 years old



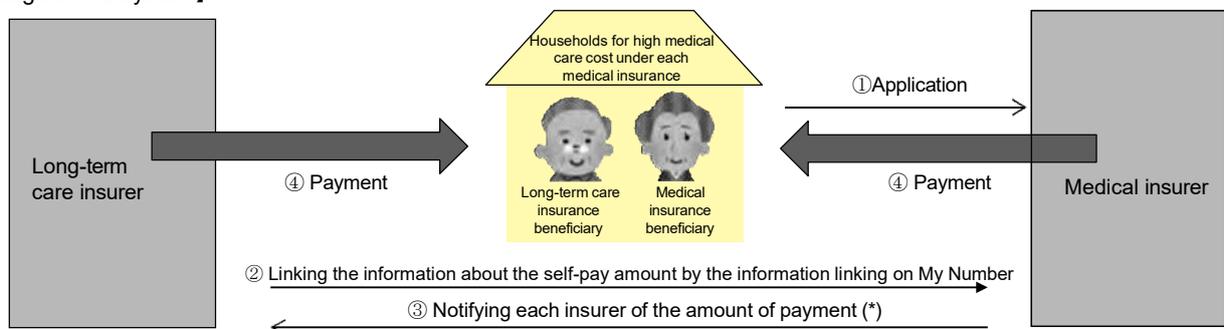
### Basic mechanism of benefit in kind

- [1] Insured persons, etc. apply to insurers, etc. for a maximum payable amount certificate to be issued. (Same treatment as with inpatient treatment)
- [2] Insurers issue insured persons with maximum payable amount certificates according to the income category of their household. (On an individual basis)
- [3] Insured persons present the maximum payable amount certificates at the counters of medical institutions. Medical institutions calculate the amount of the co-payment of insured persons, etc. on an individual basis and do not collect the amount exceeding the maximum co-payment, etc.  
\* Co-payment for the 1% addition must be made even if the maximum co-payment has been exceeded.
- [4] Medical institutions will require from insurers the amount of high-cost medical benefits in addition to receipts.

## Detailed Information 3 Outline of High Cost Long Term Care Total Medical Care Cost System

- The High Cost Long Term Care Total Medical Care Cost System is where the upper limit amount for the total of medical and long-term care self-payment costs in addition to the upper limit amounts of the self-payment costs respective for the medical costs and long-term care costs one year (August 1st to July 31st of the following year) is set and these two insurance programs jointly cover the costs exceeded such upper limit to mitigate the self-payment costs of the insured.
- ① Payment requirement: If the sum of self-payment of medical insurance and nursing care insurance exceeds the limit set for each income category in a household with medical insurance, an amount exceeding the limit is paid from the total amount.
  - ② Limit amount: Set according to the income and age of the insured
  - ③ Cost burden: Both of medical and long-term care insurers share the total burden according to the ratio of each self-payment amount.
- \*In long-term care, the same system is called the "High Cost Total Medical Care (Prevention) Service Cost".

### 【Image of the system】

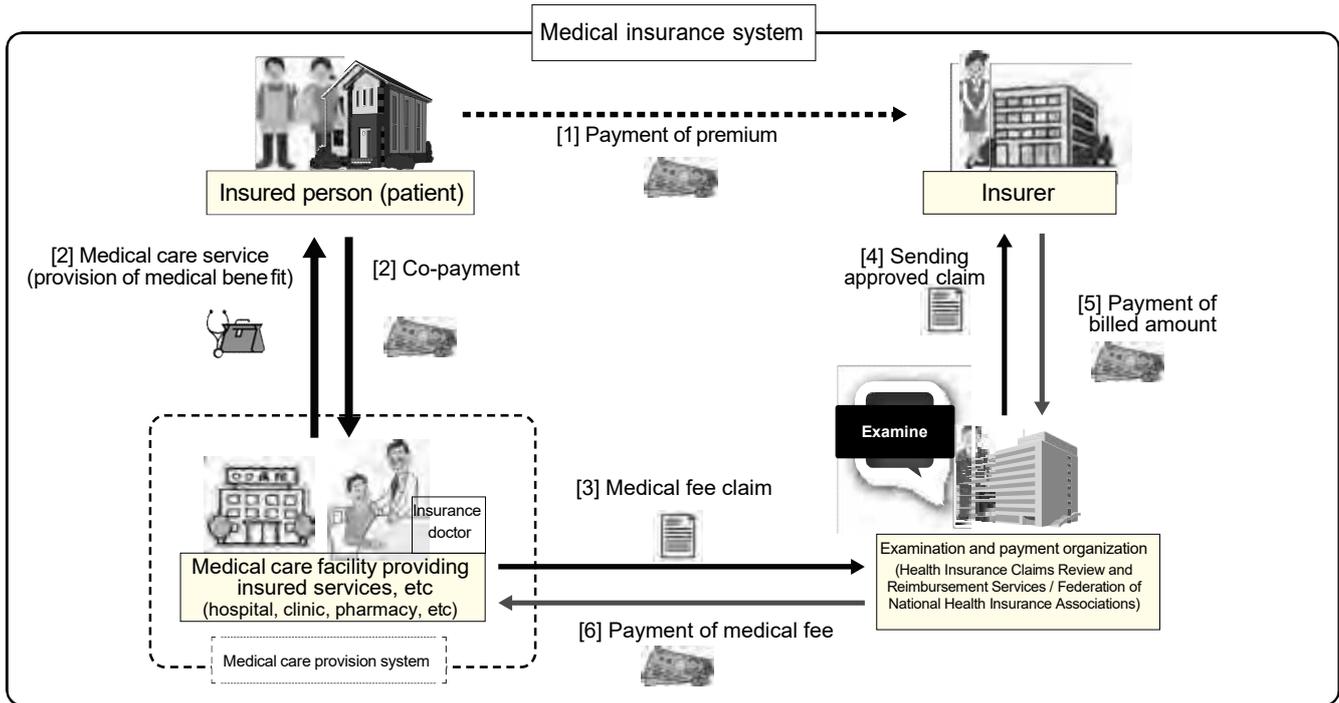


(\*) Calculating the total amount of annual self-payment amount from the information on self-payment amount obtained in (2), to calculate the amount of High Cost Total Medical Care payment amount. This calculated amount of payment is apportioned among the insurers according to the ratio of the self-payment amount, and the amount to be paid by each insurer is notified.

# Insured Medical Treatment System

## Overview

## Conceptual Chart of Insured Medical Treatment



Medical fees are classified into three types: medical, dental, and dispensing fees.

The medical fee is calculated by adding stipulated numbers of points for the individual medical activities provided (so-called "fee-for-service system"). The unit price for one point is ¥10. For a typhlitis hospitalization case, for example, the first visit fee, the hospitalization fee multiplied by the length of stay (days), the typhlitis surgery fee, the test fee and the drug fee are added to one another and medical care facility providing insured services will receive the total amount less the patient's co-payment from the examination and payment organization.

## Detailed Information Outline of the FY 2022 Medical fees revision

### The FY 2022 Medical fee revision

#### Medical fee revision

#### 1. Medical fees +0.43%

*1 Of which, revised portion except for * 2-5	+0.23%
Revision rate of each fee	
Medical services	+0.26%
Dental services	+0.29%
Dispensations	+0.08%

\*2 Of which, the special response to wage raises for medical personnel + 0.20%

\*3 Of which, improvement in efficiency by introducing and promoting a prescription refill system. ▲0.10% (Allow patients with stable conditions to use prescriptions for a certain period of time to obtain drugs without going to a medical institution under a proper coordination between physicians and pharmacists)

\*4 Of which, a special response to insurance coverage for fertility treatment +0.20%

\*5 Of which, arrival of the deadline for the implementation of measures for additional medical fees (for medical services) designed to protect children from infections ▲0.10%

Additional medical fees for dental services and dispensations are to be used for necessary measures including infection control.

#### 2. Drug price

[1] Drug price ▲ 1.35%

\*1 Of which, revision to the actual prices, etc. ▲ 1.44%

\*2 Of which, special response to insurance coverage for fertility treatment +0.09%

[2] Material price revision ▲ 0.02%

In addition to the items above, the Ministry will promote reform of the following items based on discussions in the Central Social Insurance Medical Council to deal with issues revealed by the pandemic from the perspective of providing high-quality medical services in an efficient manner.

- Optimization of evaluation of inpatient care including basic hospitalization fees for the patient-to-nurse ratio of 7:1 based on medical functions and patient' conditions for separating and enhancing medical functions as well as promoting cooperation
- Further promotion of a lump-sum payment system through revision of calculation methods based on the DPC (diagnosis procedure combination) for standardizing health care services and the length of hospital stay
- Revision of measures for medical fees concerning reform of doctors' work styles
- Revision of measures for medical fees concerning family doctors' functions in order to separate and coordinate functions of outpatient care
- Revision of a dispensing system of generic drugs based on cost-effectiveness
- Optimization of evaluation of pharmacy chains based on revenues and operational efficiency
- Optimization of prescription of fomentations from the perspective of optimizing pharmacy benefits through revision of insurance coverage for drugs on the government-set price list such as over-the- counter medications

## Basic Understanding of the FY2022 Medical fee revision

### Basic recognition of the revision

- ▶ Response to health care challenges such as the establishment of a health care system capable of dealing with emerging infectious diseases
- ▶ Extension of healthy life expectancy and promotion of a social security system for all generations in preparation for the era of 100- year life
- ▶ Making health care accessible for patients and citizens and providing safe and high-quality health care services
- ▶ Maintaining stability and sustainability of the social security system and striking the balance of the social security system with the economy and public finance

Important point of view: the revision contributes to creating a virtuous cycle of growth and distribution and enables people to live a stable life while boosting functions of the social security system and maintaining the sustainability of the system.

### Basic Perspectives and Specific Directions for Revision

#### 1 Establishing an efficient, effective and high-quality health care system capable of dealing with COVID-19 and other diseases [Priority Issues]

[Examples of Specific Directions]

- Response to COVID -19
- Efforts to establish a health care system capable of dealing with emerging infectious diseases and a review of medical plans
- Evaluation of inpatient care based on medical functions and patients' conditions
- Functional separation of outpatient care
- Evaluation of functions of family doctors, family dentists and pharmacists
- Ensure high-quality in-home care and home-visit care services
- Efforts to promote community-based integrated care systems

#### 3 Providing high-quality medical care services that are accessible and safe for patients and the public

[Examples of Specific Directions]

- Evaluation of systems to ensure patients' access to safe medical care and ensuring stable supply of pharmaceuticals
- Utilization of ICT and digital transformation in medical care
- Promotion of evaluation that also focuses on outcomes
- Appropriate evaluation of areas that require priority measures from the perspective of ensuring people's safety and security
- Promotion of prevention of progression of oral diseases, enhancement of responses to the decline in oral functions, and promotion of dental care with consideration for quality of life
- Appropriate evaluation of community pharmacies based on their functions as family pharmacies, promotion of a shift in pharmacists' role from focusing on dispensing drugs to focusing on inter-personal services, and evaluation of in-hospital pharmacist services

#### 2 Promotion of work - style reform for doctors, etc. and other measures to provide safe and high-quality health care services [Priority Issues]

[Examples of Specific Directions]

- Promotion of initiatives to adopt a management system for improving labor management and working conditions in medical institutions
- Improvement in working conditions and promotion of task sharing, task shifting and team medicine
- Promotion of the use of ICT that contributes to the efficiency of operations and evaluation of efforts to improve a severe work environment including long working hours
- Establishment of emergency medical care systems requiring an urgent action from the perspective of maintaining regional medical care
- Discussion on necessary measures concerning a pay increase for front-line health care workers and promotion of initiatives to reduce burdens on those workers based on the cabinet decision in November 2021

#### 4 Improving the stability and sustainability of the system through optimization and efficiency

[Examples of Specific Directions]

- Promotion of the use of generic drugs and follow-on biologics
- Utilization of cost-effectiveness evaluation system
- Appropriate evaluation based on prevailing market prices, etc.
- Evaluation of inpatient care according to medical functions and patients' conditions (Re-listed)
- Functional separation of outpatient care and promotion of prevention of progression of serious diseases (Re-listed)
- Promotion of efforts to prevent the progression of serious diseases
- Promotion of appropriate use of pharmaceuticals through collaborative efforts among physicians, in-house pharmacists, and pharmacy pharmacists
- Promotion of evaluation of pharmacies based on efficiency, etc.

## Outline of the FY 2022 Medical fee revision

### I Establishing an efficient, effective and high-quality health care system capable of dealing with COVID-19 and other diseases

1. Establishment of health care systems capable of dealing with COVID-19 and other diseases
2. Appropriate evaluation based on necessity of inpatient care for persons in the acute stage
3. Promotion of integrated payment through revision of calculation methods based on the DPC (diagnosis procedure combination) system
4. Appropriate revision for separation and coordination of functions in outpatient care based on measures for medical fees concerning family doctors' functions
5. Introduction of a refill prescription system based on doctors' prescription

### II Promoting work-style reform for doctors, etc. to provide safe, secure and high-quality medical care

- 1 Promoting reform of doctors' work styles
- 2 Pay increase for frontline medical personnel (Enforcement in October)
- 3 Reducing the burden on frontline medical personnel

### III Providing high-quality medical care that is accessible and safe for patients and the public

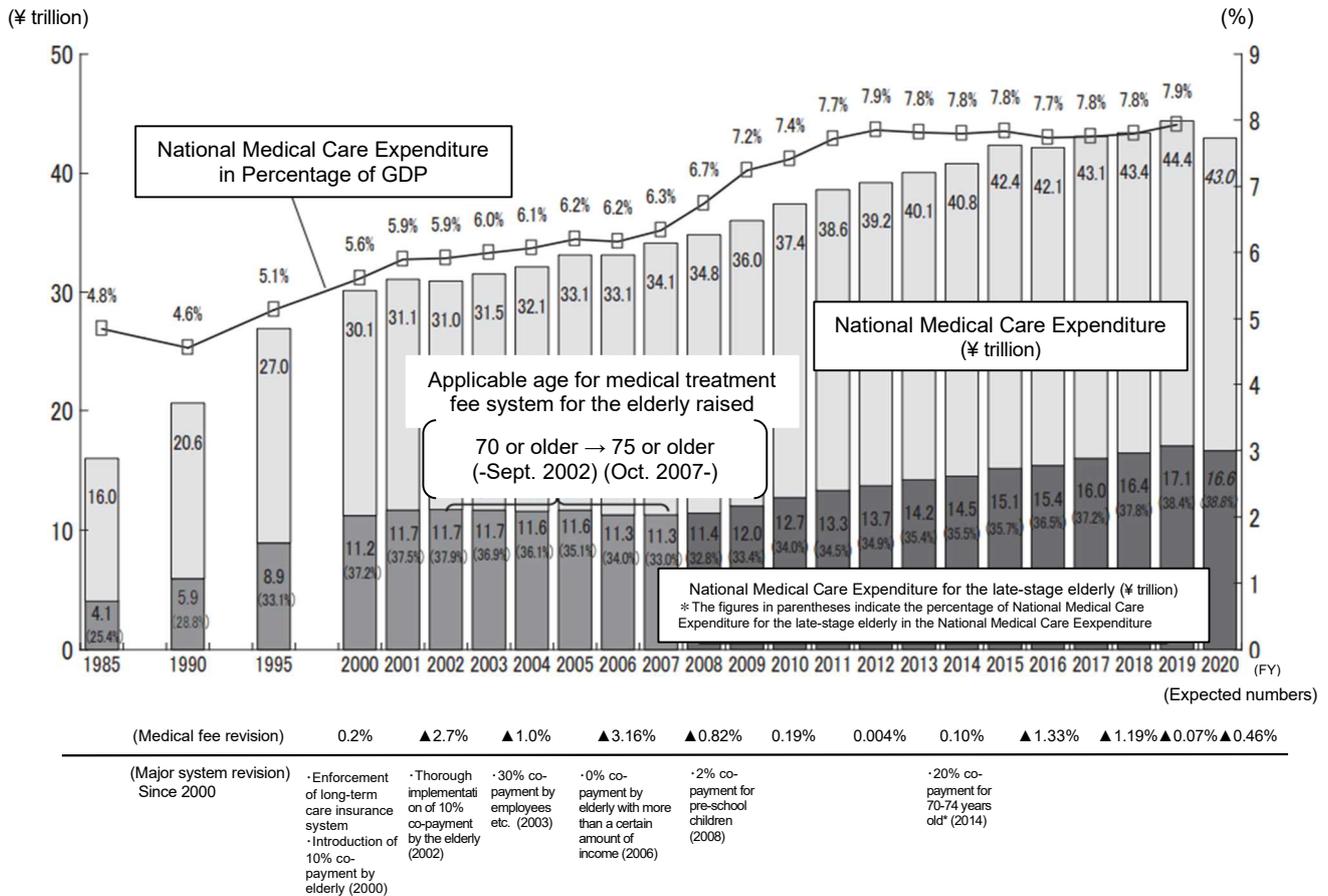
- 1 Promotion of telemedicine
- 2 New evaluation system concerning the use of patients' information through an online identity authorization system
- 3 Appropriate medical evaluation to ensure that women can receive safe and effective fertility treatment
- 4 Promotion of prevention of hospital acquired infections during dental outpatient care
- 5 Appropriate evaluation of medical skills such as surgeries

### IV Boosting stability and sustainability through improvement in efficiency and optimization

- 1 Promotion of the use of generic drugs
- 2 Promotion of evaluation of pharmacies according to efficiency, etc.
- 3 Optimization of prescription of fomentations from the perspective of the optimization of pharmacy benefits.

# Health Expenditure

## Overview



## <Year-on-year growth rate of National Medical Care Expenditure>

	1985	1990	1995	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
National Medical Care Expenditure	6.1	4.5	4.5	▲1.8	3.2	▲0.5	1.9	1.8	3.2	▲0.0	3.0	2.0	3.4	3.9	3.1	1.6	2.2	1.9	3.8	▲0.5	2.2	0.8	2.3	▲3.2
National Medical Care Expenditure for the late-stage elderly	12.7	6.6	9.3	▲5.1	4.1	0.6	▲0.7	▲0.7	0.6	▲3.3	0.1	1.2	5.2	5.9	4.5	3.0	3.6	2.1	4.4	1.6	4.2	2.5	3.8	▲2.4
GDP	7.2	8.6	2.6	1.4	▲1.9	▲0.7	0.5	0.6	0.8	0.6	0.2	▲4.1	▲3.6	1.5	▲1.0	▲0.1	2.7	2.1	3.3	0.8	2.0	0.2	0.5	—

- (Note) 1. GDP are based on the national accounting announced by the Cabinet Office.  
 2. National medical expenses (and those for advanced elderly. The same applies hereinafter) in FY2020 are estimates including the actual performance. The expenses for FY2020 are estimated by multiplying the national medical expenses for FY2019 by the rate of increase in approximate medical expenses in FY2020 (figures written in italics in the table above).  
 \*The budget freezing measure for co-payment ratios of persons aged 70 to 74 was lifted (10%→20%). 20% is applied to persons who reached 70 years of age in April 2014 or after and the ratio of 10% is left unchanged for persons who reached 70 years of age in March 2014 or before.

**Detailed Data 1** Health Expenditure of OECD Countries (2021)

Country	Total medical care expenditure		Per capita medical care expenditure (\$)		Remarks
		Rank		Rank	
United States	16.8	1	10,949	1	
Switzerland	11.7	2	6,518	4	
Germany	11.3	3	7,138	2	
France	11.1	4	5,278	12	
Japan	11.0	5	4,962	15	
Sweden	10.9	6	5,552	7	
Canada	10.8	7	5,370	11	
Belgium	10.7	8	5,458	9	
Norway	10.5	9	6,745	3	
Austria	10.4	10	5,705	6	
Netherlands	10.2	11	5,739	5	
United Kingdom	10.2	12	4,500	18	
Denmark	10.0	13	5,478	8	
Portugal	9.5	14	3,347	24	
Australia	9.4	15	4,919	14	
Chile	9.3	16	2,292	30	
Finland	9.2	17	4,559	16	
Spain	9.1	18	3,600	21	
New Zealand	9.1	19	4,212	19	

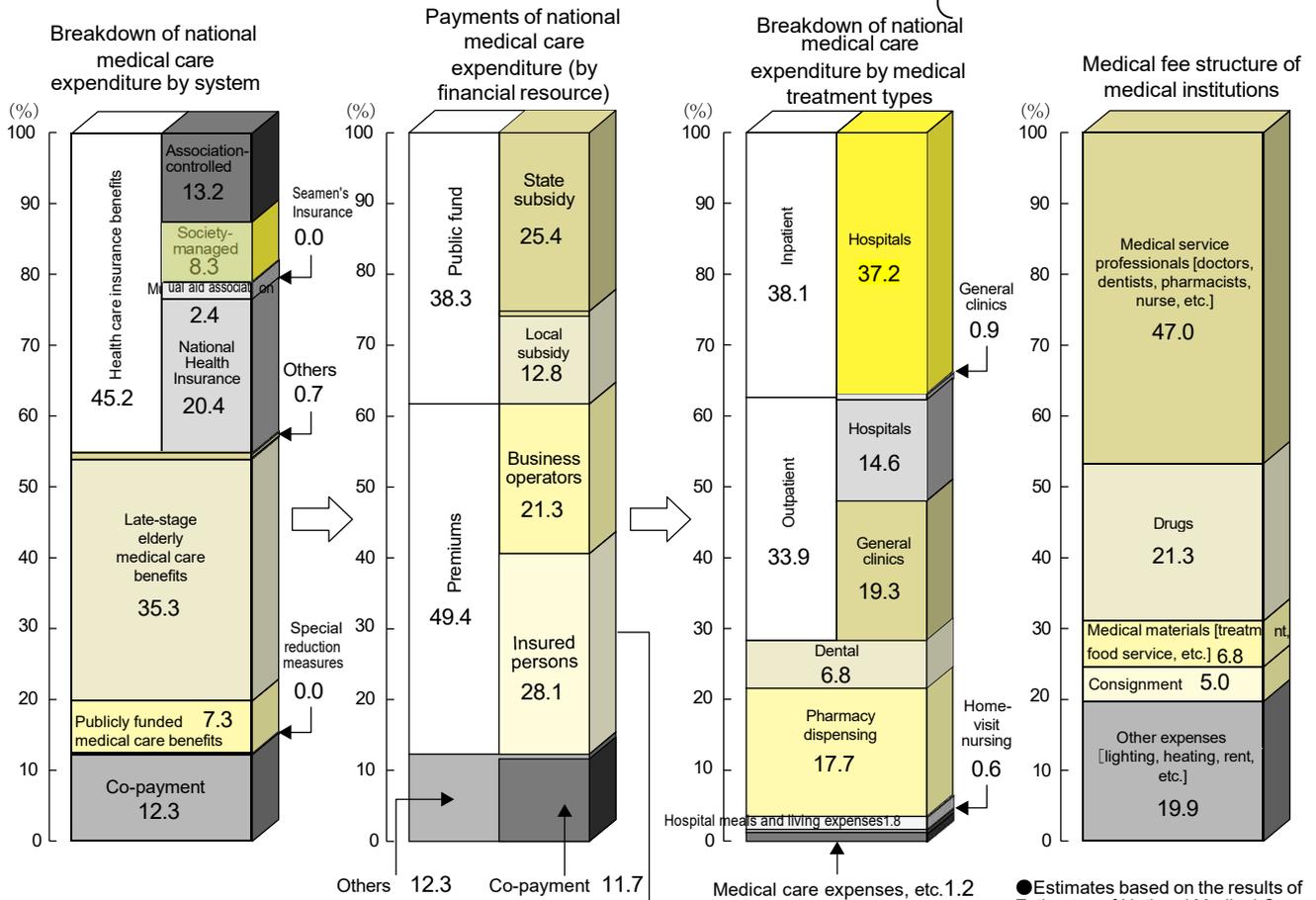
Country	Total medical care expenditure		Per capita medical care expenditure (\$)		Remarks
		Rank		Rank	
Italy	8.7	20	3,653	20	
Iceland	8.6	21	4,541	17	
Slovenia	8.5	22	3,304	25	
Korea	8.2	23	3,406	23	
Greece	7.8	24	2,319	29	
Czech Republic	7.8	25	3,418	22	
Colombia	7.7	26	1,276	36	
Israel	7.5	27	2,903	26	
Costa Rica	7.3	28	1,600	35	
Lithuania	7.0	29	2,727	27	
Slovakia	7.0	30	2,189	32	
Estonia	6.7	31	2,507	28	
Ireland	6.7	32	5,083	13	
Latvia	6.6	33	2,039	34	
Poland	6.5	34	2,289	31	
Hungary	6.4	35	2,170	33	
Mexico	5.4	36	1,133	38	
Luxemburg	5.4	37	5,415	10	
Turkey	4.3		1,267	37	
OECD average	8.8		4,087		

Source: "OECD HEALTH DATA 2021"

(Note) 1. The rank in this table indicates the rank among OECD member countries.

**Detailed Data 2** Structure of National Medical Care Expenditure (FY 2019)

National medical care expenditure ¥44,389.5 billion  
Per capita medical care expenditure ¥351,800



● Insured persons' burden includes National Health Insurance premiums

● Estimates based on the results of Estimates of National Medical Care Expenditure FY2019 and Survey on Economic Conditions in Health Care (2019), etc.

Detailed Data 3

Changes in National Medical Care Expenditure and Percentage Distribution

Year	National medical care expenditure	General medical fees									Dental medical fees	Pharmacy dispensing medical fees 2)	Hospital meals and living expenses 3)	Medical treatment fees at health service facilities for the elderly 4)	Home-visit nursing medical fees
		Hospitals		General clinics		Inpatient medical fees		Outpatient medical fees		General clinics					
Estimated amount (¥100 million)															
1962	6,132	5,372	2,948	2,424	2,344	2,072	272	3,028	875	2,153	759	...	...	...	...
1965	11,224	10,082	5,499	4,583	4,104	3,635	469	5,978	1,864	4,113	1,143	...	...	...	...
1970	24,962	22,513	12,121	10,392	8,799	7,801	998	13,714	4,320	9,394	2,448	...	...	...	...
1975	64,779	59,102	32,996	26,106	25,427	22,640	2,787	33,675	10,356	23,319	5,677	...	...	...	...
1980	119,805	105,349	62,970	42,379	48,341	43,334	5,007	57,008	19,636	37,372	12,807	1,649	...	...	...
1985	160,159	140,287	92,091	48,195	70,833	65,054	5,778	69,454	27,037	42,417	16,778	3,094	...	...	...
1990	206,074	179,764	123,256	56,507	85,553	80,470	5,082	94,211	42,786	51,425	20,354	5,290	...	666	...
1995	269,577	218,683	148,543	70,140	99,229	94,545	4,684	119,454	53,997	65,456	23,837	12,662	10,801	3,385	210
2000	301,418	237,960	161,670	76,290	113,019	108,642	4,376	124,941	53,028	71,913	25,569	27,605	10,003	...	282
2001	310,998	242,494	164,536	77,958	115,219	110,841	4,378	127,275	53,695	73,580	26,041	32,140	9,999	...	324
2002	309,507	238,160	162,569	75,591	115,537	111,180	4,357	122,623	51,389	71,234	25,875	35,297	9,835	...	339
2003	315,375	240,931	164,077	76,854	117,231	112,942	4,289	123,700	51,135	72,565	25,375	38,907	9,815	...	348
2004	321,111	243,627	164,764	78,863	118,464	114,047	4,417	125,163	50,717	74,446	25,377	41,935	9,780	...	392
2005	331,289	249,677	167,955	81,722	121,178	116,624	4,555	128,499	51,331	77,167	25,766	45,608	9,807	...	431
2006	331,276	250,468	168,943	81,525	122,543	117,885	4,658	127,925	51,058	76,867	25,039	47,061	8,229	...	479
2007	341,360	256,418	173,102	83,316	126,132	121,349	4,782	130,287	51,753	78,534	24,996	51,222	8,206	...	518
Percentage distribution (%)															
1962	100.0	87.6	48.1	39.5	38.2	33.8	4.4	49.4	14.3	35.1	12.4	...	...	...	...
1965	100.0	89.8	49.0	40.8	36.6	32.4	4.2	53.3	16.6	36.6	10.2	...	...	...	...
1970	100.0	90.2	48.6	41.6	35.2	31.3	4.0	54.9	17.3	37.6	9.8	...	...	...	...
1975	100.0	91.2	50.9	40.3	39.3	34.9	4.3	52.0	16.0	36.0	8.8	...	...	...	...
1980	100.0	87.9	52.6	35.4	40.3	36.2	4.2	47.6	16.4	31.2	10.7	1.4	...	...	...
1985	100.0	87.6	57.5	30.1	44.2	40.6	3.6	43.4	16.9	26.5	10.5	1.9	...	...	...
1990	100.0	87.2	59.8	27.4	41.5	39.0	2.5	45.7	20.8	25.0	9.9	2.6	...	0.3	...
1995	100.0	81.1	55.1	26.0	36.8	35.1	1.7	44.3	20.0	24.3	8.8	4.7	4.0	1.3	0.1
2000	100.0	78.9	53.6	25.3	37.5	36.0	1.5	41.5	17.6	23.9	8.5	9.2	3.3	...	0.1
2001	100.0	78.0	52.9	25.1	37.0	35.6	1.4	40.9	17.3	23.7	8.4	10.3	3.2	...	0.1
2002	100.0	76.9	52.5	24.4	37.3	35.9	1.4	39.6	16.6	23.0	8.4	11.4	3.2	...	0.1
2003	100.0	76.4	52.0	24.4	37.2	35.8	1.4	39.2	16.2	23.0	8.0	12.3	3.1	...	0.1
2004	100.0	75.9	51.3	24.6	36.9	35.5	1.4	39.0	15.8	23.2	7.9	13.1	3.0	...	0.1
2005	100.0	75.4	50.7	24.7	36.6	35.2	1.4	38.8	15.5	23.3	7.8	13.8	3.0	...	0.1
2006	100.0	75.6	51.0	24.6	37.0	35.6	1.4	38.6	15.4	23.2	7.6	14.2	2.5	...	0.1
2007	100.0	75.1	50.7	24.4	36.9	35.5	1.4	38.2	15.2	23.0	7.3	15.0	2.4	...	0.2

Year	National medical care expenditure	Medical fees of medical treatment 5)	General medical fees				Outpatient medical fees				Dental medical fees	Pharmacy dispensing medical fees 2)	Hospital meals and living expenses 3)	Home-visit nursing medical fees	Medical care expenses, etc. 5)
			Hospitals		General clinics		Hospitals		General clinics						
Estimated amount (¥100 million)															
2008	348,084	254,452	172,298	82,154	128,205	123,685	4,520	126,247	48,613	77,634	25,777	53,955	8,152	605	5,143
2009	360,067	262,041	178,848	83,193	132,559	128,266	4,293	129,482	50,582	78,900	25,587	58,228	8,161	665	5,384
2010	374,202	272,228	188,276	83,953	140,908	136,416	4,492	131,320	51,860	79,460	26,020	61,412	8,297	740	5,505
2011	385,850	278,129	192,816	85,314	143,754	139,394	4,359	134,376	53,421	80,954	26,757	66,288	8,231	808	5,637
2012	392,117	283,198	197,677	85,521	147,566	143,243	4,323	135,632	54,434	81,197	27,132	67,105	8,130	956	5,597
2013	400,610	287,447	201,417	86,030	149,667	145,523	4,144	137,780	55,894	81,886	27,368	71,118	8,082	1,086	5,509
2014	408,071	292,506	205,438	87,067	152,641	148,483	4,158	139,865	56,956	82,909	27,900	72,846	8,021	1,256	5,543
2015	423,644	300,461	211,860	88,601	155,752	151,772	3,980	144,709	60,088	84,622	28,294	79,831	8,014	1,485	5,558
2016	421,381	301,853	214,666	87,187	157,933	154,077	3,856	143,920	60,589	83,332	28,574	75,867	7,917	1,742	5,427
2017	430,710	308,335	219,675	88,660	162,116	158,228	3,888	146,219	61,447	84,772	29,003	78,108	7,954	2,023	5,287
2018	433,949	313,251	224,435	88,816	165,535	161,705	3,831	147,716	62,730	84,986	29,579	75,687	7,917	2,355	5,158
2019	443,895	319,583	230,236	89,347	168,992	165,209	3,783	150,591	65,027	85,564	30,150	78,411	7,901	2,727	5,124
Percentage distribution (%)															
2008	100.0	73.1	49.5	23.6	36.8	35.5	1.3	36.3	14.0	22.3	7.4	15.5	2.3	0.2	1.5
2009	100.0	72.8	49.7	23.1	36.8	35.6	1.2	36.0	14.0	21.9	7.1	16.2	2.3	0.2	1.5
2010	100.0	72.7	50.3	22.4	37.7	36.5	1.2	35.1	13.9	21.2	7.0	16.4	2.2	0.2	1.5
2011	100.0	72.1	50.0	22.1	37.3	36.1	1.1	34.8	13.8	21.0	6.9	17.2	2.1	0.2	1.5
2012	100.0	72.2	50.4	21.8	37.6	36.5	1.1	34.6	13.9	20.7	6.9	17.1	2.1	0.2	1.4
2013	100.0	71.8	50.3	21.5	37.4	36.3	1.0	34.4	14.0	20.4	6.8	17.8	2.0	0.3	1.4
2014	100.0	71.7	50.3	21.3	37.4	36.4	1.0	34.3	14.0	20.3	6.8	17.9	2.0	0.3	1.4
2015	100.0	70.9	50.0	20.9	36.8	35.8	0.9	34.2	14.2	20.0	6.7	18.8	1.9	0.4	1.3
2016	100.0	71.6	50.9	20.7	37.5	36.6	0.9	34.2	14.4	19.8	6.8	18.0	1.9	0.4	1.3
2017	100.0	71.6	51.0	20.6	37.6	36.7	0.9	33.9	14.3	19.7	6.7	18.1	1.8	0.5	1.2
2018	100.0	72.2	51.7	20.5	38.1	37.3	0.9	34.0	14.5	19.6	6.8	17.4	1.8	0.5	1.2
2019	100.0	72.0	51.9	20.1	38.1	37.2	0.9	33.9	14.6	19.3	6.8	17.7	1.8	0.6	1.2

Source: "Estimates of National Medical Care Expenditure", Health Statistics Office to the Director-General for Statistics, Information System Management and Industrial Relations, MHLW

(Note)

1. With the launch of long-term care insurance system in April 2000, some of the expenses that were subjected to national medical care expenditure were transferred to long-term care insurance fees and are no longer included in national medical care expenditure on and after FY 2000.
2. Pharmacy dispensing was included in outpatient medical fees until they were newly classified as a separate item in FY1977.
3. Figures until FY2005 indicate "hospital meal expenses" (total amount of hospital meal expenses and standard co-payment) and figures since FY2006 indicate the total amount of hospital meal expenses, standard co-payment for meal expenses, hospital living expenses, and standard co-payment for living expenses.
4. Medical treatment fees at health service facilities for the elderly are not included in national medical care expenditure on and after FY 2000 because these fees are those who are certified for long-term care need.
5. "Medical fees of medical treatment" and "medical care expenses, etc." were included in "general medical fees" until they were newly classified as a separate item in FY 2008.

## Detailed Data 4

## Changes in national medical care expenditure for the Elderly in the Later Stage of Life

	FY	Total	Medical fees			Dispensing	Hospital meals and living	Home-visit nursing	Medical treatment etc.	Health service facilities for the elderly	
			Inpatient	Outpatient	Dental						
Actual amount (¥100 million)	FY 1983	33,185	31,966	17,785	13,405	776	640	.	.	579	.
	FY 1984	36,098	34,645	19,725	14,025	895	689	.	.	764	.
	FY 1985	40,673	38,986	22,519	15,433	1,034	785	.	.	902	.
	FY 1986	44,377	42,445	24,343	16,924	1,178	902	.	.	1,030	.
	FY 1987	48,309	46,104	26,247	18,605	1,252	1,037	.	.	1,168	.
	FY 1988	51,593	49,138	27,798	19,975	1,365	1,133	.	.	1,296	26
	FY 1989	55,578	52,573	29,400	21,743	1,430	1,312	.	.	1,441	253
	FY 1990	59,269	55,669	30,724	23,315	1,630	1,457	.	.	1,523	619
	FY 1991	64,095	59,804	32,325	25,705	1,773	1,689	.	.	1,633	970
	FY 1992	69,372	64,307	35,009	27,249	2,049	1,992	.	5	1,626	1,442
	FY 1993	74,511	68,530	36,766	29,536	2,228	2,529	.	29	1,535	1,888
	FY 1994	81,596	72,501	38,235	31,790	2,476	3,133	1,855	86	1,439	2,582
	FY 1995	89,152	75,910	38,883	34,319	2,708	3,909	4,678	174	1,224	3,259
	FY 1996	97,232	82,181	42,314	36,789	3,078	4,620	4,816	323	1,094	4,198
	FY 1997	102,786	85,475	44,205	37,965	3,305	5,606	4,869	479	1,073	5,285
	FY 1998	108,932	88,881	46,787	38,584	3,511	6,900	4,967	657	1,101	6,426
	FY 1999	118,040	94,653	49,558	41,181	3,915	8,809	5,115	858	1,169	7,436
	FY 2000	111,997	94,640	48,568	41,871	4,200	10,569	4,612	235	1,271	670
	FY 2001	116,560	97,954	50,296	43,243	4,416	12,462	4,677	191	1,277	-2
	FY 2002	117,300	97,155	51,198	41,434	4,522	13,913	4,689	192	1,352	-1
FY 2003	116,524	95,653	51,828	39,609	4,216	14,711	4,645	174	1,342	-1	
FY 2004	115,764	94,429	52,048	38,371	4,010	15,143	4,654	190	1,348	-0	
FY 2005	116,444	94,441	52,867	37,726	3,848	15,777	4,679	205	1,342	-0	
FY 2006	112,594	91,492	51,822	36,129	3,540	15,579	3,970	225	1,329	-0	
FY 2007	112,753	91,048	52,167	35,524	3,357	16,245	3,877	239	1,345	-	
FY 2008	114,146	91,558	53,009	35,029	3,520	17,035	3,850	264	1,439	-0	
FY 2009	120,108	95,672	55,594	36,381	3,698	18,717	3,914	289	1,517	.	
FY 2010	127,213	101,630	59,994	37,654	3,981	19,631	4,015	318	1,620	.	
FY 2011	132,991	105,409	62,170	38,980	4,260	21,489	4,029	341	1,725	.	
FY 2012	137,044	108,751	64,094	40,139	4,518	22,111	4,012	404	1,767	.	
FY 2013	141,912	111,837	65,599	41,484	4,753	23,798	1,028	461	1,788	.	
FY 2014	144,927	114,063	67,121	41,978	4,963	24,488	4,024	529	1,823	.	
FY 2015	151,323	118,083	69,219	43,643	5,221	26,698	4,063	616	1,862	.	
FY 2016	153,806	121,143	71,393	44,259	5,491	26,017	4,058	723	1,865	.	
FY 2017	160,229	126,372	74,905	45,695	5,772	26,996	4,155	839	1,867	.	
FY 2018	164,246	130,712	77,685	46,921	6,106	26,490	4,207	983	1,854	.	
FY 2019	170,562	135,733	80,577	48,692	6,464	27,527	4,257	1,150	1,895	.	

(Note) 1. Terms are defined as follows.

- Medical fees: Expenses paid for medical care services received at insurance medical care facilities. (excluding insurance pharmacies, etc.). (Benefit in kind)
- Dispensing: Refers to the expenses paid when receiving medicine at an insurance-covered pharmacy (Benefit in kind)
- Hospital Meals and living: Meal and living expenses during hospitalization. (Benefit in kind)
- Home-visit nursing: Expenses paid for home-visit nursing care services by the specified service providers. (Benefit in kind)
- Medical treatment, etc.: Expenses paid for prosthetic devices or treatment by Judo therapists in accordance with Articles 77 and 83 of the Act on Assurance of Medical Care for Elderly People. (Benefit in cash)
- Health services facilities for the elderly: Expenses paid for facility treatment at health service facilities for the elderly. (Benefit in kind) (Not applicable after March 2000)
- Expenses include co-payment, standard co-payment for meal/living expenses, and basic fees of home-visit nursing.

2. The figures up to March 2008 are for those subjected to medical services that are provided in the Health and Medical Services Act for the Aged.

3. The figures for FY2008 include delayed requests for health expenditure for the elderly from April 2008 to February 2009.

4. The figures for FY2011 do not include the Great East Japan Earthquake related health expenditure, etc. (¥4.5 billion of the total of estimated payment requests and health expenditure of unknown insurers).

5. The figures for FY2016 do not include the medical expenses related to the 2016 Kumamoto Earthquake (¥50 million of the total estimated payment requests and health expenditure of unknown insurers).

6. The figures for FY2018 do not include the health expenditure, etc. related to the damage of Typhoon No. 7 and Heavy Rain Event of August 2018 associated with the rain front, the 2018 Hokkaido Eastern Ibari Earthquake and Typhoon No. 21 (¥0.4 billion of the total of estimated payment requests and health expenditure of unknown insurers).

7. The figures for FY 2019 do not include the health expenditure, etc. related to the damage of Typhoon No. 15 and No.20 (¥0.2 billion of the total of estimated payment requests and health expenditure of unknown insurers).

Source "Annual report on the medical-care system for the latter-stage elderly", Health Insurance Bureau, MHLW

## Financial Status of Health Insurance System

### Overview

### Finance Status of the Health Insurance System (FY 2019 Settled Account)

(Unit: ¥100 million)

		Government-managed Health Insurance/ JHIA-managed Health Insurance	Society-managed Health Insurance	National Health Insurance (municipalities)	Seamen's Insurance	Medical care system for the elderly aged 75 and over
Operating revenue	Premium (tax) revenue	95,939	84,437	23,888	312	12,949
	National treasury contribution	12,113	27	31,080	29	51,060
	Prefectural contribution	—	—	10,486	—	15,319
	Municipal contribution	—	—	6,271	—	13,449
	Grants for late-stage elderly	—	—	—	—	64,932
	Grants for early-stage elderly	—	1	34,988	—	—
	Retirement grants	—	—	37	—	—
	Others	607	1,172	126,043	1	288
Total		108,659	83,637	232,792	343	157,998
HIV	Insurance benefit expenses	63,668	41,178	87,353	204	157,447
	Late-stage elderly support coverage	20,999	19,773	15,886	71	—
	Levies for early-stage elderly	15,246	14,550	64	29	—
	Contributions for retirees	2	18	—	0	—
	Others	3,383	5,619	129,011	7	868
Total		103,298	81,139	232,314	311	158,314
Balance of ordinary revenue and expenditure		5,361	2,498	479	32	-317

		Government-managed Health Insurance/ JHIA-managed Health Insurance	Society-managed Health Insurance
Non-operating revenue	Deferred repayment of state subsidy	-	-
	Non-operating subsidy for benefits, etc.	-	654
	Adjustment premium revenue	-	1,207
	Subsidies to financial adjustment programs	-	1,233
	Transfer from reserves, etc. and surplus carried forward	-	3,090
	Others	38	132
	Total	38	6,313
Non-operating expenditure	Contribution to financial adjustment programs	-	1,201
	Others	-	140
	Total	-	1,340
Balance of non-operating revenue and expenditure		38	4,973 (1,883)
Balance of total revenue and expenditure		5,399	7,471 (4,382)
Reserve fund, etc.		33,920	54,788

- (Note)
- The above figures indicate medical service revenue and expenditure.
  - The operating revenue of the National Health Insurance (operated by municipalities) is the total amount of special account of the municipalities or prefectures. The current account includes an extra-legal transfer from the Municipal General Account for use in covering the settlement of accounts. The amounts of the national subsidy, etc. for National Health Insurance (operated by municipalities) and the late-stage medical care system for the elderly were adjusted in the following fiscal year.
  - The figures in parentheses for the Society-managed Health Insurance indicate the net balance between non-operating revenue and expenditure and the balance between total revenue and expenditure, but exclude transfers from reserves, etc. and surpluses carried forward).
  - Reserve fund, etc. indicates reserves for the Japan Health Insurance Association-managed Health Insurance. It includes reserves, a reserve fund (¥5,117.5 billion), and assets such as land and buildings, etc. for the Society-managed Health Insurance.
  - In the non-operating revenue of the Japan Health Insurance Association-managed Health Insurance, operation account surplus at the end of FY2018 was added to FY2019 settlement of accounts.
  - The balance of total revenue and expenditure for the Japan Health Insurance Association-managed Health Insurance and Society-managed Health Insurance indicates the sum of the balance of operating revenue and expenditure and the balance of non-operating revenue and expenditure.
  - The figures may not equal the total, or balance of accounts may vary due to rounding.

Source: Health Insurance Bureau, MHLW

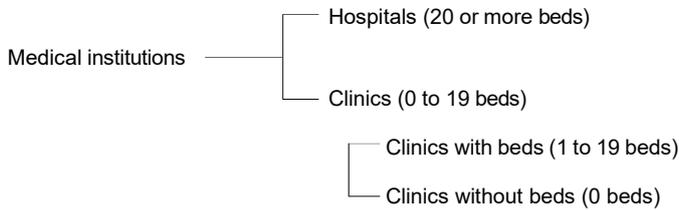
# Types of Medical Institutions

## Overview

## Types of Medical Institutions

### 1. Hospitals, Clinics

The Medical Care Act restricts the sites of medical practice to hospitals and clinics. Hospitals and clinics are classified as follows: hospitals are medical institutions with 20 or more beds and clinics are those with no beds or 19 or less beds.



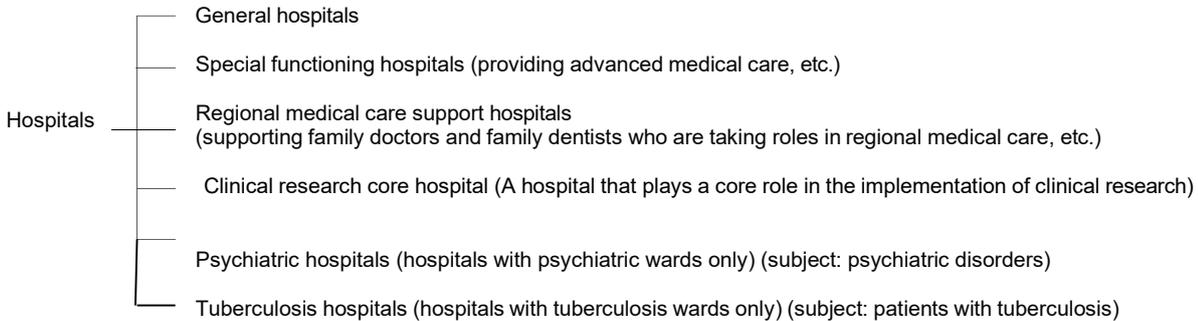
Hospitals are required to provide truly scientific and appropriate treatment to injured or sick people and are expected to have substantial facilities.

There is no strict regulation on facilities for clinics with 19 or less beds compared to hospitals.

### 2. Types of Hospitals

The Medical Care Act provides requirements (staff deployment standards, facility standards, responsibilities of managers, etc.) that are different from general hospitals for hospitals with special functions (special functioning hospitals, regional medical care support hospitals, clinical research core hospital) and accepts hospitals that satisfy requirements to use the name.

In addition, separate staff deployment standards and facility standards are provided for some beds in consideration of differences in subjects of patients (patients with psychiatric disorders or tuberculosis).



## Detailed Information 1 Outline of Special Functioning Hospitals

### Purpose

As part of efforts to systematize medical facility functions, the Minister of Health, Labour and Welfare approves individual hospitals having capabilities of providing advanced medical care, development of advanced medical technologies, and conducting advanced medical care training.

### Roles

- Provide advanced medical care
- Develop/evaluate advanced medical technologies
- Conduct advanced medical care training

### Requirements for Approval

- Having capabilities of providing, developing, evaluating, and conduct training of advanced medical care
- Providing medical care to patients who are referred to by other hospitals or clinics (maintaining the incoming referral rate of at least 50% and the outgoing referral rate of at least 40%)
- Number of beds .... Must have 400 or more beds.
- Staff deployment
  - Doctors ..... Twice as many as ordinary hospitals, etc. In addition, half the number of doctors specified by the staff More than half of the doctor's placement criteria must be from any of the 15 specialists.
  - Pharmacists ..... The minimum standard is 1/30 of the number of patients. (That for ordinary hospitals is 1/70 of the number of patients)
  - Nurses, etc. .... The minimum standard is 1/2 of the number of patients. (That for ordinary hospitals is 1/3 of the number of patients)
  - Deployment of at least one registered dietitian.
- Facilities ..... Must have intensive care units, sterile rooms, and drug information management rooms.
- Improvement of medical safety management system
  - Placement of staff responsible for medical safety management
  - Placement of full-time doctors, pharmacists and nurses in the medical safety management department
  - Mandatory reporting of all death cases, etc.
  - Establishment of a department to decide the suitability of medical provision using high-difficulty new medical technology and unapproved new medicines
  - External audit by the Audit Committee
- Professing 16 specified clinical areas in principle.
- Having at least 70 papers written in English published annually in refereed journals, etc.
- Regarding specific function hospitals corresponding to specific areas such as cancer, separate approval requirements are set for the advocacy of clinical department, introduction rate, reverse introduction rate, etc.

\* The number of approved hospitals (as of April 1,2022)..... 87

## Detailed Information 2 Regional Medical Care Support Hospital System

### Purpose

Given the viewpoint that it is desirable to provide medical care to patients in their neighborhood area, a specific function hospital was founded subject to the 1997 revision of the Medical Care Act, as a hospital capable of supporting family doctors and dentists in charge of regional medical care, through medical care provision for referral patients and joint utilization of medical devices, etc., as well as a hospital ensuring regional medical care. The approval of the foundation is given by the concerned prefectural governor individually.

### Roles

- Provide medical care to patients on referral (including the reverse case in which patients are referred to family doctors)
- Implement shared use of medical devices
- Provide emergency medical care
- Conduct training for regional medical professionals

### Requirements for Approval

- Principal entity of foundation: Government, prefecture, municipality, social medical corporation, medical corporation, etc., in principle.
- Providing medical care mainly to referred patients (meeting one of the following)
  - [1] Incoming referred rate of at least 80%
  - [2] Incoming referred rate of at least 65% and outgoing referred rate of at least 40%
  - [3] Incoming referred rate of at least 50% and outgoing referred rate of at least 70%
- Having the ability to provide emergency medical care
- Securing a system to enable doctors, etc. in regions to use buildings, facilities, and devices, etc.
- Holding trainings for those engaged in regional medical care.
- Having at least 200 hospital beds in principle and facilities appropriate for being regional medical care support hospitals, etc.

\* The number of approved hospitals (as of August 2021) ..... 666 Hospitals

### Purpose

As part of efforts to systematize medical facility functions, the Minister of Health, Labour and Welfare approves individual hospitals having capabilities of playing a core role in the implementation of clinical research.

### Roles

- Design a plan for a specified clinical research and conduct it
- Play a leading role in the implementation of a specified clinical research in case where it is conducted in cooperation with another hospital or clinic
- Provide another hospital or clinic with consultations on the implementation of specified clinical researches and necessary information, advice or another type of assistance
- Provide trainings on specified clinical researches

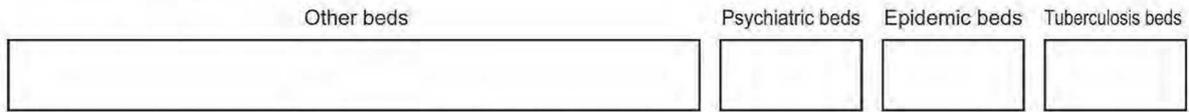
### Requirements of Approval

- Number of specified clinical researches conducted (in the past three years)
  - Number of specified clinical researches conducted by its own.....8 or more clinical trials led by doctors or 4 or more clinical trials led by doctors and 40 or more specified clinical researches
  - Number of specified clinical researches conducted jointly with different facilities.....2 or more clinical trials led by doctors or 20 or more specified clinical researches
- Number of papers on specified clinical researches (in the past three years)..... 45 cases or more
- Number of cases where assistance was provided for specified clinical researches conducted by other medical institutions (in the past year) .....15 cases or more
- Training on high-quality clinical researches
  - Number of workshops held for persons who conduct specified clinical researches (in the past year)..... 6 times or more
  - Number of workshops held for persons who support specified clinical researches (in the past year)..... 6 times or more
  - Number of workshops held for members of Certified Review Board (in the past year)..... 3 times or more
- Having 10 or more specified clinical departments
- Number of hospital beds: Having at least 400 hospital beds
- Staff deployment
  - Doctors and dentists: 5 persons or more
  - Pharmacists: 5 persons or more
  - Nurses: 10 persons or more
  - Clinical research coordinators, etc.: 24 persons or more
  - Data managers: 3 persons or more
  - Biological statisticians: 2 persons or more
  - Persons who have experience in working in pharmaceutical affairs approval examination bodies: 1 person or more
- Facilities: Must have clinical research facilities with equipment to ensure accuracy of researches and intensive care units
- The requirements for approval concerning the number of new specified clinical researches conducted and the number of person specified clinical researches are separately set for clinical research core hospitals that deal with specific areas.

\* The number of approved hospitals (as of April 1, 2022)..... 14 Hospitals

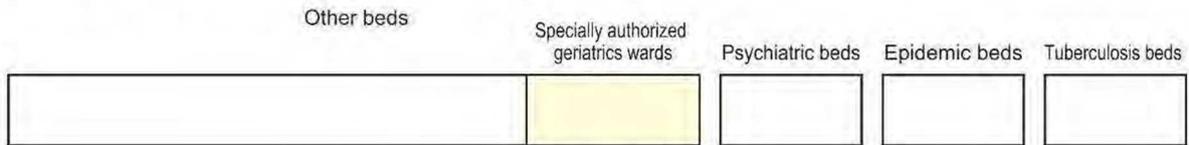
**Detailed Information 4** Revision of Bed Classification

[At the beginning (from 1948)]



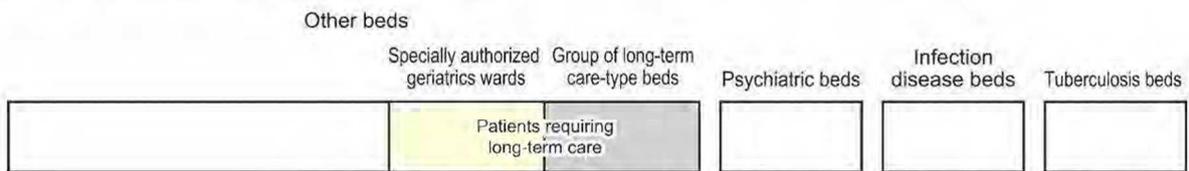
- Progress of aging
- Changes in disease structure

[Introduction of specially authorized geriatrics wards (1983)]



- In order to cope with the progress in aging and changes in disease structure, it was necessary to create facilities to provide medical care not only for elderly but for "patients requiring long-term care" in general.

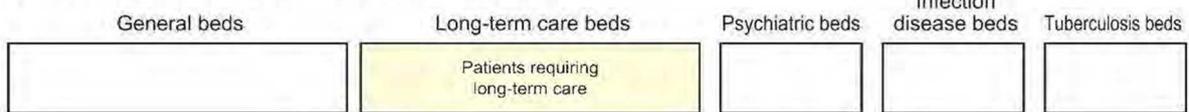
[Creation of long-term care-type bed group system (1992)]



- The number of patients requiring long-term care increased due to changes in disease structure caused by the rapid progress in the birth rate decline and aging. Although various systems have been created, including long-term care-type bed group system, patients with various symptoms are still intermingled.

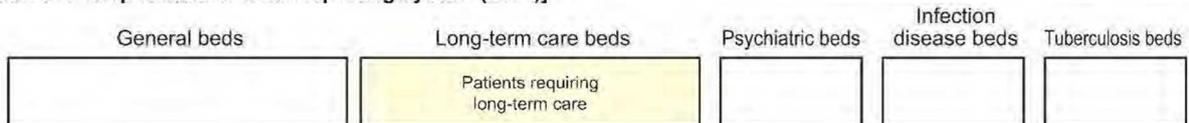
[Creation of general beds and long-term care beds (2000)]

Provide medical care that is suitable for patients' symptoms



- In order to promote division/cooperation of medical functions, identifying and analyzing information on medical functions implemented by the respective medical institutions in regions is important.

[Creation of a hospital bed function reporting system (2014)]



A system for selecting one of highly acute phase, acute phase, recovery phase, and chronic phase functions and reporting the function of general hospital beds and long-term care beds in each hospital ward was created.

## Trends with Medical Institutions

### Overview

### Changes in Number of Medical Institutions (Hospitals and Clinics)

Year	Hospitals	National (regrouped)	Public (regrouped)	Others (regrouped)	General clinics	Dental clinics
1877	159	12	112	35		
1882	626	(330)		296		
1892	576	(198)		378		
1897	624	3	156	465		
1902	746	4	151	591		
1907	807	5	101	691		
1926	3,429	(1,680)		1,749		
1930	3,716	(1,683)		2,033		
1935	4,625	(1,814)		2,811	35,772	18,066
1940	4,732	(1,647)		3,085	36,416	20,290
1945	645	(297)		348	6,607	3,660
1950	3,408	383	572	2,453	43,827	21,380
1955	5,119	425	1,337	3,357	51,349	24,773
1960	6,094	452	1,442	4,200	59,008	27,020
1965	7,047	448	1,466	5,133	64,524	28,602
1970	7,974	444	1,388	6,142	68,997	29,911
1975	8,294	439	1,366	6,489	73,114	32,565
1980	9,055	453	1,369	7,233	77,611	38,834
1985	9,608	411	1,369	7,828	78,927	45,540
1990	10,096	399	1,371	8,326	80,852	52,216
1995	9,606	388	1,372	7,846	87,069	58,407
1996	9,490	387	1,368	7,735	87,909	59,357
1997	9,413	380	1,369	7,664	89,292	60,579
1998	9,333	375	1,369	7,589	90,556	61,651
1999	9,286	370	1,368	7,548	91,500	62,484
2000	9,266	359	1,373	7,534	92,824	63,361
2001	9,239	349	1,375	7,515	94,019	64,297
2002	9,187	336	1,377	7,474	94,819	65,073
2003	9,122	323	1,382	7,417	96,050	65,828
2004	9,077	304	1,377	7,396	97,051	66,557
2005	9,026	294	1,362	7,370	97,442	66,732
2006	8,943	292	1,351	7,300	98,609	67,392
2007	8,862	291	1,325	7,246	99,532	67,798
2008	8,794	276	1,320	7,198	99,083	67,779
2009	8,739	275	1,296	7,168	99,635	68,097
2010	8,670	274	1,278	7,118	99,824	68,384
2011	8,605	274	1,258	7,073	99,547	68,156
2012	8,565	274	1,252	7,039	100,152	68,474
2013	8,540	273	1,242	7,025	100,528	68,701
2014	8,493	329	1,231	6,933	100,461	68,592
2015	8,480	329	1,227	6,924	100,995	68,737
2016	8,442	327	1,213	6,902	101,529	68,940
2017	8,412	327	1,211	6,874	101,471	68,609
2018	8,372	324	1,207	6,841	102,105	68,613
2019	8,300	322	1,202	6,776	102,616	68,500
2020	8,238	321	1,199	6,718	102,612	67,874

Source: 1875-1937: "Annual Report of Public Health", Ministry of Internal Affairs

1938-1952: "Annual Report of Public Health", Ministry of Health and Welfare

From 1953 on: "Survey of Medical Institutions", Health Statistics Office to the Director-General for Statistics, Information System Management and Industrial Relations, MHLW

(Note) The figures in parentheses indicate the total number of public sector medical institutions.

### Detailed Data 1

### Changes in Number of Hospitals by Establishing Organization and Number of Beds

	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Total	8,862	8,794	8,739	8,670	8,605	8,565	8,540	8,493	8,480	8,442	8,412	8,372	8,300	8,238
National	291	276	275	274	274	274	273	329	329	327	327	324	322	321
Public medical institutions	1,325	1,320	1,296	1,278	1,258	1,252	1,242	1,231	1,227	1,213	1,211	1,207	1,202	1,199
Social insurance organizations	123	122	122	121	121	118	115	57	55	53	52	52	51	49
Medical corporations	5,702	5,728	5,726	5,719	5,712	5,709	5,722	5,721	5,737	5,754	5,766	5,764	5,720	5,687
Private	533	476	448	409	373	348	320	289	266	240	210	187	174	156
Others	888	872	872	869	867	864	868	866	866	855	846	838	831	826
20-99 beds	3,391	3,339	3,296	3,232	3,182	3,147	3,134	3,092	3,069	3,039	3,007	2,977	2,945	2,970
100-299 beds	3,875	3,876	3,875	3,882	3,877	3,882	3,873	3,873	3,888	3,890	3,905	3,906	3,892	3,828
300-499 beds	1,123	1,111	1,106	1,096	1,090	1,087	1,083	1,091	1,098	1,095	1,089	1,081	1,062	1,046
500+ beds	473	468	462	460	456	449	450	437	425	418	411	408	401	394

Source: "Survey of Medical Institutions", Health Statistics Office to the Director-General for Statistics, Information System Management and Industrial Relations, MHLW

## Detailed Data 2

### Changes in Number of Hospitals by Hospital Type

	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Total	8,862	8,794	8,739	8,670	8,605	8,565	8,540	8,493	8,480	8,442	8,412	8,372	8,300	8,238
Psychiatric hospitals	1,076	1,079	1,083	1,082	1,076	1,071	1,066	1,067	1,064	1,062	1,059	1,058	1,054	1,059
Tuberculosis sanatorium	1	1	1	1	1	1	-	-	-	-	-	-	-	-
General hospitals	7,785	7,714	7,655	7,587	7,528	7,493	7,474	7,426	7,416	7,380	7,353	7,314	7,246	7,179

Source: "Survey of Medical Institutions", Health Statistics Office to the Director-General for Statistics, Information System Management and Industrial Relations, MHLW

## Detailed Data 3

### Changes in Number of Beds by Bed Type and Number of Beds per Hospital

	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Total	1,620,173	1,609,403	1,601,476	1,593,354	1,583,073	1,578,254	1,573,772	1,568,261	1,565,968	1,561,005	1,554,879	1,546,554	1,529,215	1,507,526
Psychiatric beds	351,188	349,321	348,121	346,715	344,047	342,194	339,780	338,174	336,282	334,258	331,700	329,692	326,666	324,481
Infectious disease beds	1,809	1,785	1,757	1,788	1,793	1,798	1,815	1,778	1,814	1,841	1,876	1,882	1,888	1,904
Tuberculosis beds	10,542	9,502	8,924	8,244	7,681	7,208	6,602	5,949	5,496	5,347	5,210	4,762	4,370	4,107
Long-term care beds	343,400	339,358	336,273	332,986	330,167	328,888	328,195	328,144	328,406	328,161	325,228	319,506	308,444	289,114
General beds	913,234	909,437	906,401	903,621	899,385	898,166	897,380	894,216	893,970	891,398	890,865	890,712	887,847	887,920
Number of beds per hospital	182.8	183.0	183.3	183.8	184.0	184.3	184.3	184.7	184.7	184.9	184.8	184.7	184.2	183.0

Source: "Survey of Medical Institutions", Health Statistics Office to the Director-General for Statistics, Information System Management and Industrial Relations, MHLW

## Detailed Data 4

### Changes in Rate of Bed Use and Average Length of Stay by Bed Type

	Rate of bed use												
	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Total	81.7	81.6	82.3	81.9	81.5	81.0	80.3	80.1	80.1	80.4	80.5	80.5	77.0
Psychiatric beds	90.0	89.9	89.6	89.1	88.7	88.1	87.3	86.5	86.2	86.1	86.1	85.9	84.8
Infectious disease beds	2.4	2.8	2.8	2.5	2.4	3.0	3.2	3.1	3.2	3.3	3.6	3.8	114.7
Tuberculosis beds	38.0	37.1	36.5	36.6	34.7	34.3	34.7	35.4	34.5	33.6	33.3	33.2	31.5
Long-term care beds	90.6	91.2	91.7	91.2	90.6	89.9	89.4	88.8	88.2	88.0	87.7	87.3	85.7
General beds	75.9	75.4	76.6	76.2	76.0	75.5	74.8	75.0	75.2	75.9	76.2	76.5	71.3
Long-term care beds for nursing care	94.2	94.5	94.9	94.6	93.9	93.1	92.9	92.1	91.4	90.9	91.3	90.7	88.1

	Average length of stay												
	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Total	33.8	33.2	32.5	32.0	31.2	30.6	29.9	29.1	28.5	28.2	27.8	27.3	28.3
Psychiatric beds	312.9	307.4	301.0	298.1	291.9	284.7	281.2	274.7	269.9	267.7	265.8	265.8	277.0
Infectious disease beds	10.2	6.8	10.1	10.0	8.5	9.6	8.9	8.2	7.8	8.0	8.3	8.5	9.8
Tuberculosis beds	74.2	72.5	71.5	71.0	70.7	68.8	66.7	67.3	66.3	66.5	65.6	64.6	57.2
Long-term care beds	176.6	179.5	176.4	175.1	171.8	168.3	164.6	158.2	152.2	146.3	141.5	135.9	135.5
General beds	18.8	18.5	18.2	17.9	17.5	17.2	16.8	16.5	16.2	16.2	16.1	16.0	16.5
Long-term care beds for nursing care	292.3	298.8	300.2	311.2	307.0	308.6	315.5	315.8	314.9	308.9	311.9	301.4	287.7

Source: "Hospital Report", Health Statistics Office to the Director-General for Statistics, Information System Management and Industrial Relations, MHLW

(Note) 1. The figures for March 2011 only include only the reported number of patients for 11 institutions (one in Kesen medical district, one in Miyako medical district of Iwate Prefecture, two in Ishinomaki medical district and two in Kesenuma medical district of Miyagi Prefecture, and five in Soso medical district of Fukushima Prefecture) due to the effect of the Great East Japan Earthquake.

2. The figures for April 2016 include the number of patients except for one institution in Kumamoto prefecture (Aso medical area) which didn't submit the report due to the impact of the 2016 Kumamoto earthquake.

3. The figures for July and August 2018 include the number of patients except for one institution in Hiroshima Prefecture (Osan Medical Area) which didn't submit the report due to the impact of the heavy rain in July 2018.

4. The figures for June and July 2020 include only the reported number of patients for 1 institution (Kuma medical district) due to the impact of the heavy rain in July 2020.

5. The number of hospital patients represents the number of patients who are hospitalized at 12:00 a.m. each day regardless the number of beds permitted by law for each bed type. Therefore, the number of hospital patients in infectious disease beds include patients who use general beds under emergency conditions. Consequently, the bed utilization rate may exceed 100%.

## Overview of National Hansen's Disease Sanatoriums and National Hospital Organization, etc.

### Overview

Overview of National Hansen's Disease Sanatoriums and National Hospital Organization, etc.

#### [National Hansen's Disease Sanatoriums]

- 1,001 persons are admitted in 13 National Hansen's Disease Sanatoriums nationwide (as of May 1, 2021).
- National Hansen's Disease Sanatoriums provide mainly Hansen's disease aftereffects and medical care and health care related to lifestyle diseases for those as a result of aging.

(Reference) Number of facilities

Classification	Number of facilities	Number of persons admitted
National Hansen's Disease Sanatoriums	13	1,001

Classification	Number of facilities	Students quota (persons)
Training schools for nurses (National Hansen's Disease Sanatoriums)	2	80

#### [National Hospital Organization]

- National Hospital Organization is an independent administrative agency established and based on the "Act on the National Hospital Organization, Independent Administrative Agency" (Act No. 191 of 2002).
- National Hospital Organization utilizes nationwide hospital networks and provides examination, treatment, clinical study, education, and training in an integrated manner for medical care requiring risk management and active contribution by the government, medical care in the area of safety net that is not always implemented by other establishing entities, and medical care for 5 diseases and 5 businesses with regional needs taken into consideration.

(Reference) Number of hospitals (as of October 1, 2021)

Institutions	Number of hospitals	Number of beds
National Hospital Organization	140	52,699

#### [National Research Center for Advanced and Specialized Medical Care]

- National Research Centers for Advanced and Specialized Medical Care compose of 6 research-type national research and development agency established by shifting from National Centers for Advanced and Specialized Medical Care to non-public officer type independent administrative agencies under the "Act on National Research and Development Agency to Carry Out Research on Advanced Specialized Medical Services" (Act No. 93 of 2008)
- National Research Centers for Advanced and Specialized Medical Care conduct comprehensive and unitary surveys, research and development of technology as well as providing medical treatment associated with such diseases and training for specialized medical professionals on diseases with a great impact on people's health such as cancer, cerebral apoplexy, and cardiac diseases

(Reference) Number of hospitals (as of April 1, 2022)

Institutions	Specialized diseases, etc.	Number of hospitals	Number of beds
National Cancer Center	Cancer and other malignant neoplasm	2	1,003
National Cerebral and Cardiovascular Center	Cardiovascular diseases, cardiac diseases, cerebral apoplexy, hypertension	1	550
National Center of Neurology and Psychiatry	Mental diseases, neurological diseases, muscular diseases, mental retardation and other developmental disorders	1	486
National Center for Global Health and Medicine	Infection diseases and other diseases, International medical cooperation for developing countries.	2	1,166
National Center for Child Health and Development	Child health and development (pediatric care, maternity, paternal medicine, etc.)	1	490
National Center for Geriatrics and Gerontology	Geriatrics and gerontology (senile dementia, osteoporosis, etc.)	1	383

(Reference) Number of facilities (as of April 1, 2022)

Classification	Number of facilities	Students quota (persons)
National College of Nursing (National Center for Global Health and Medicine)	1	400

#### [Japan Community Healthcare Organization]

- Japan Community Healthcare Organization is an independent administrative agency established and based on "Act on the Japan Community Healthcare Organization, Independent Administrative Agency" (Act No. 71 of 2005).
- Japan Community Healthcare Organization has a wide variety of medical functions from emergency to rehabilitation. Also, one of the main traits of Japan Community Healthcare Organization is that about half of the hospitals under Japan Community Healthcare Organization have long-term care health facilities for the elderly. Through utilization of such facilities and collaboration with regional medical personnel, as an organization having nationwide facilities, it provides a wide variety of services seamlessly ranging from emergency to recovery rehabilitation to care for health and deals with securing regional medical and comprehensive care services. It especially specializes in 5 diseases, 5 businesses and rehabilitation, house care, etc. which are necessary in medicine and care in regional communities.

(Reference) Number of facilities (as of February 1, 2022)

Classification	Number of facilities	Number of beds
Hospital	57	15,249

Classification	Number of facilities	[Admission capacity]
Long-term care health facilities	26	2,472

Classification	Number of facilities	[Student capacity]
Nursing School	5	645

## Medical Professionals

### Overview Number of Physicians, etc.

The number of Physicians and dentists are increasing every year. As of December 31, 2020, there are 323,700 Physicians and 104,118 dentists.

#### Number of Medical Professionals

• Physicians	323,700 persons
• Dentists	104,118 persons
• Pharmacists	250,585 persons

Source: "Statistics of Physicians, Dentists and Pharmacists 2020", Health Statistics Office to the Director-General for Statistics, Information System Management and Industrial Relations, MHLW

\* Doctors and dentists are employees in medical facilities. Pharmacists are employees in pharmacies or medical facilities.

• Public health nurses	64,819 persons
• Midwives	40,632 persons
• Nurses	1,272,024 persons
• Assistant nurses	305,820 persons

Source: Health Policy Bureau, MHLW (2019)

• Physical therapists (PT)	100,964.5 persons
• Occupational therapists (OT)	51,055.7 persons
• Orthotists	10,130.1 persons
• Speech language hearing therapists	17,905.4 persons
• Orthotists	127.6 persons
• Clinical radiologic technologists	55,624.3 persons
• Medical technicians	67,752.0 persons
• Clinical engineers	30,408.9 persons

Source: "Survey of Medical Institutions and Hospital Report 2020", Health Statistics Office to the Director-General for Statistics, Information System Management and Industrial Relations, MHLW

\* Full-time equivalent numbers

• Dental hygienists	142,760 persons
• Dental technicians	34,826 persons
• Massage and shiatsu practitioners	118,103 persons
• Acupuncturists	126,798 persons
• Moxibustion practitioners	124,956 persons
• Judo therapists	75,786 persons

Source: "Report on Public Health Administration and Services 2020", Administrative Report Statistics Office to the Director-General for Statistics, Information System Management and Industrial Relations, MHLW

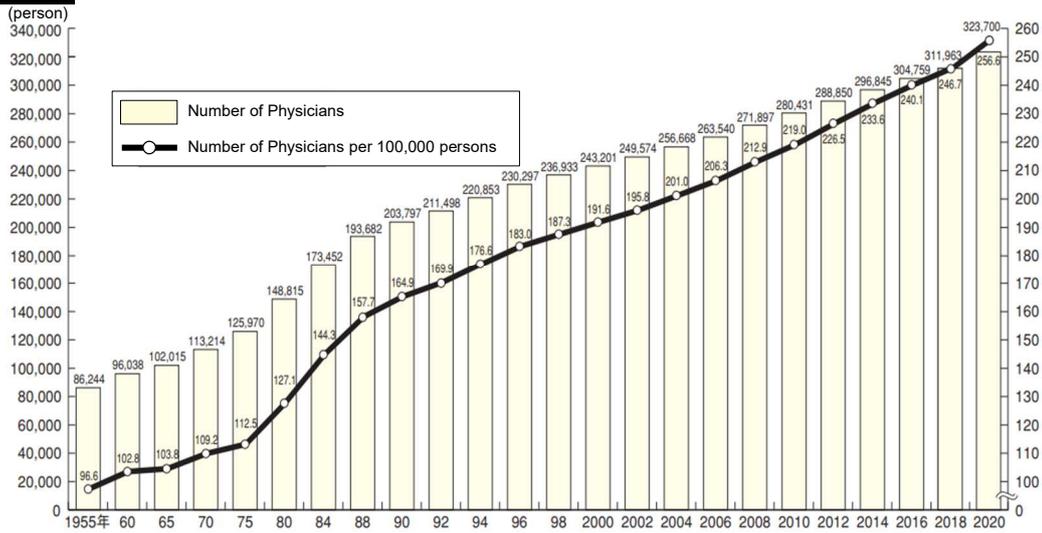
• Emergency life-saving technicians	66,899 persons
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Source: Health Policy Bureau, MHLW (as of March 31, 2022)

\* Number of registered licensees

**Detailed Data 1**

**Changes in Number of Physicians**

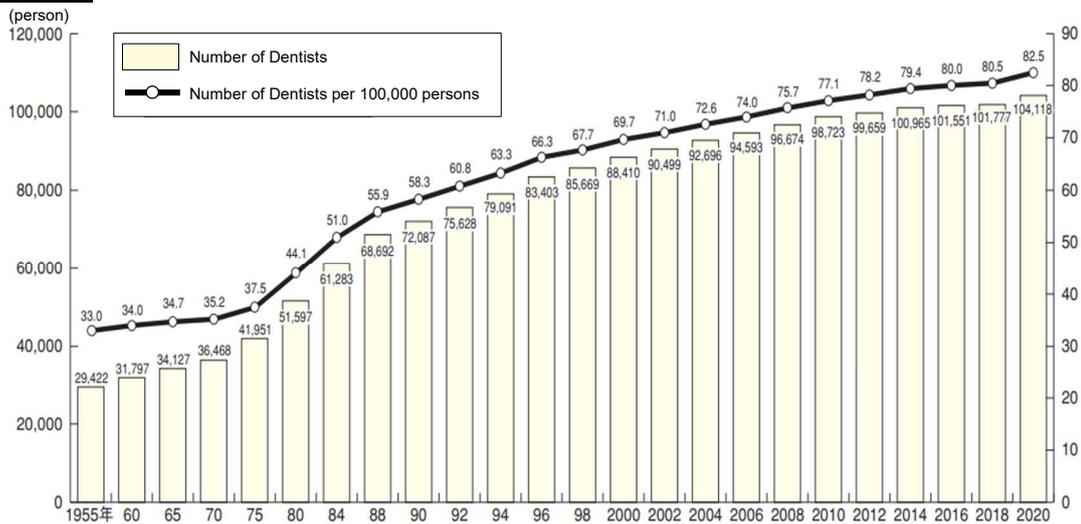


Source: "Statistics of Physicians, Dentists and Pharmacists", Health Statistics Office to the Director-General for Statistics, Information System Management and Industrial Relations, MHLW

\* Medical facility employees

**Detailed Data 2**

**Changes in Number of Dentists**

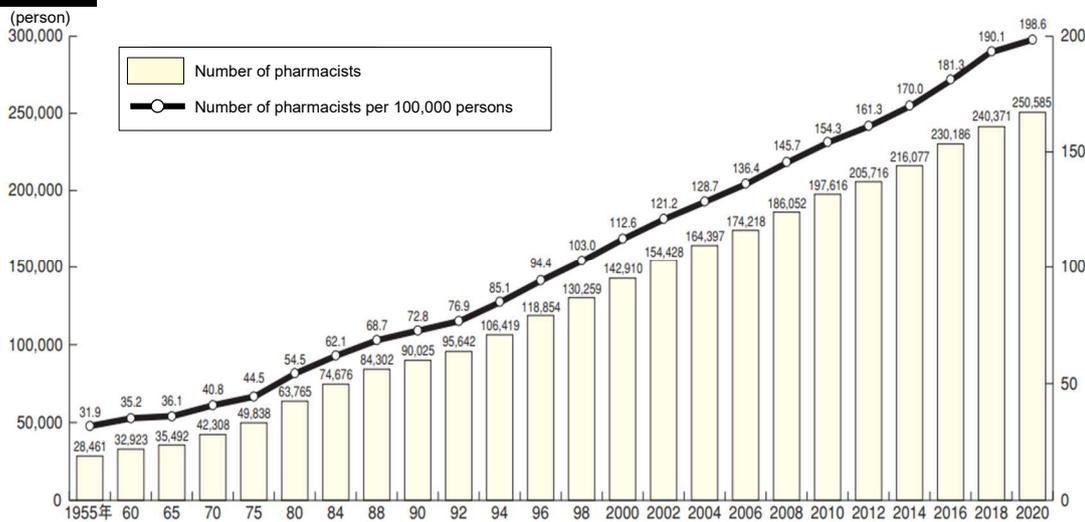


Source: "Statistics of Physicians, Dentists and Pharmacists", Health Statistics Office to the Director-General for Statistics, Information System Management and Industrial Relations, MHLW

\* Medical facility employees

**Detailed Data 3**

**Changes in Number of Pharmacists**

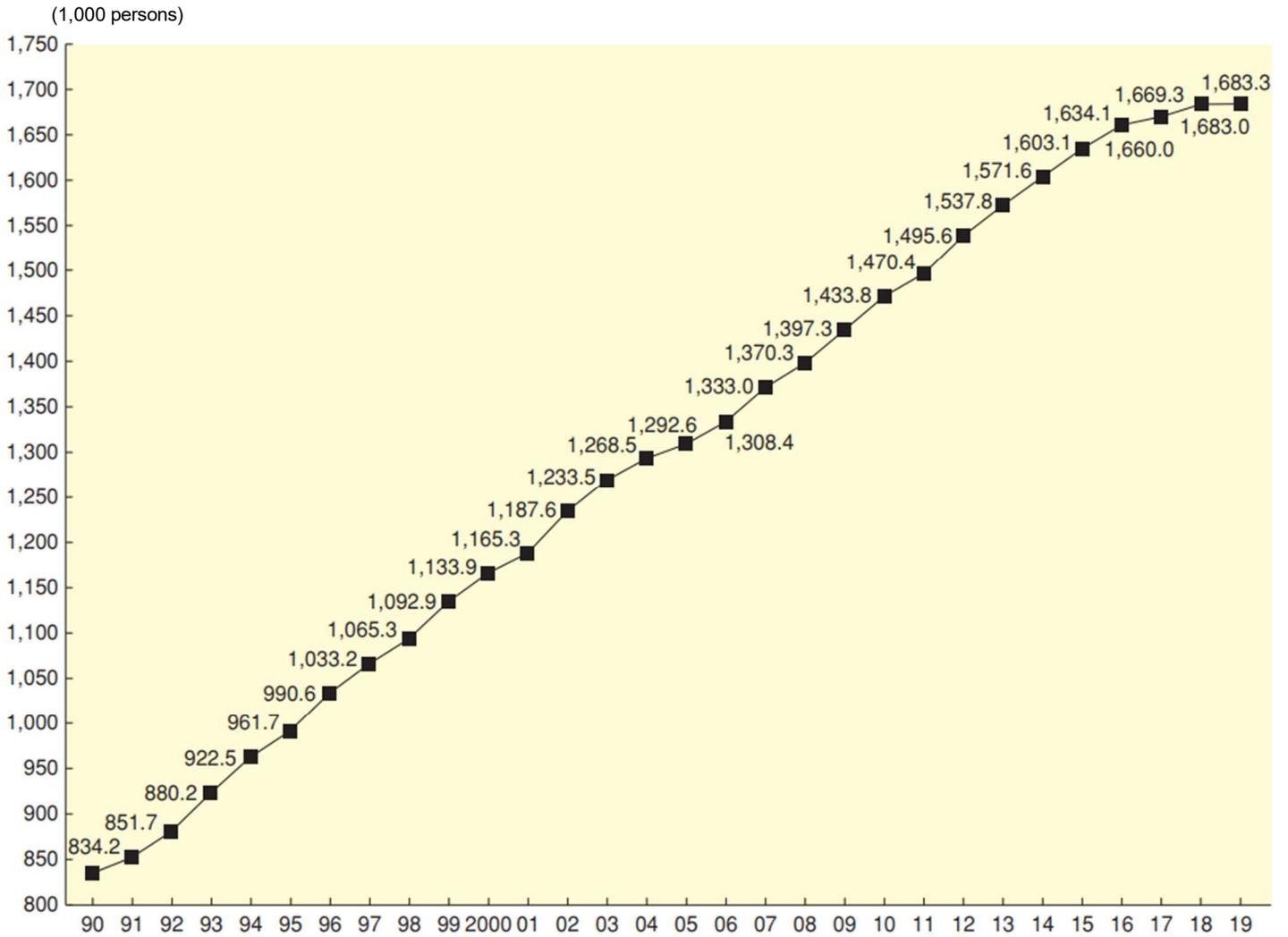


Source: "Statistics of Physicians, Dentists and Pharmacists", Health Statistics Office to the Director-General for Statistics, Information System Management and Industrial Relations, MHLW

\* Pharmacy or Medical facility employees

Detailed Data 4

Changes in Number of Nursing personnel



Source: Health Policy Bureau, MHLW

## Conforming Rate to the Statutory Number of Doctors and Nurses Designated in the Medical Care Act and Sufficiency Status (Results of FY2019 On-Site Inspection)

### Detailed Data 1 Regional Conforming Rates

(Unit: %)

Classification \ Region	Nationwide	Hokkaido Tohoku	Kanto	Hokuriku Koshinetsu	Tokai	Kinki	Chugoku	Shikoku	Kyushu
Doctors	97.3	93.0	98.1	96.7	98.8	99.2	97.1	96.9	97.6
Nurses	99.3	99.6	98.5	99.5	99.3	99.1	100.0	99.8	99.7

### Detailed Data 2 Nationwide Achievement Status

	Hospitals with insufficient number of doctors	Hospitals with sufficient number of doctors	Total
Hospitals with sufficient number of nurses	7,461 (96.3)	204 (2.6)	7,665 (99.0)
Hospitals with insufficient number of nurses	72 (0.9)	9 (0.1)	81 (1.0)
Total	7,553 (97.3)	213 (2.7)	7,746 (100.0)

(Note) The figures represent the number of hospitals (excluding dental hospitals) and the figures in parentheses represent the percentage.

(Explanation of terms)

- Numerical standards: The statutory number of doctors, nurses and associate nurses to be placed in a hospital is prescribed by the Medical Care Act.
- Conforming rate: "Percentage of hospitals satisfying the designated number of doctors/nurses" in "hospitals for which on-site investigation are conducted".
- Sufficient/insufficient: Of hospitals for which on-site investigation are conducted, those satisfying the numerical standards are counted as "sufficient" and those not satisfying the numerical standards are counted as "insufficient".

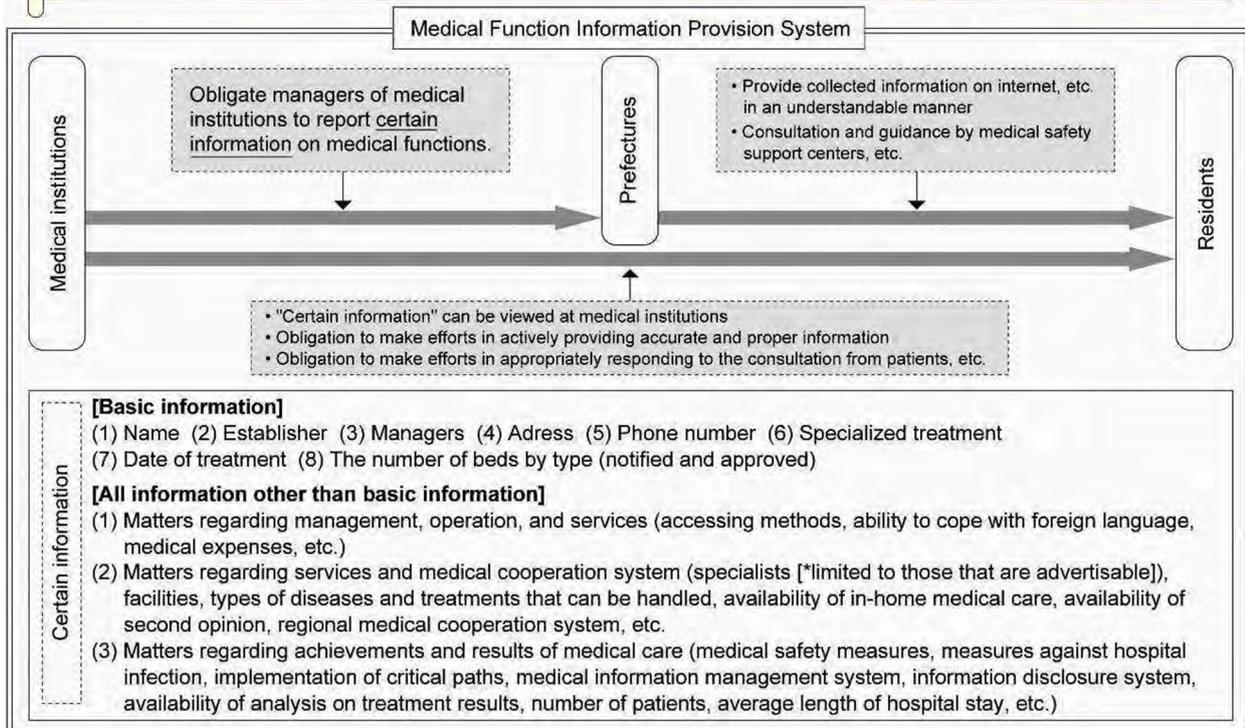
# Provision of Medical Function Information

## Overview

## Creation of Medical Function Information Provision System

Enforced April 1, 2007

Create a system to obligate medical institutions to report certain information on medical functions to prefectures and prefectures to collect the information and provide it to the public in an understandable manner (a similar system is created with pharmacies)



## Provision of documented explanation at the time hospitalization (Medical Care Act) (revised in 2006)

Legally establish in the Medical Care Act that managers of hospitals and clinics formulate, issue, and explain treatment plans at the beginning/end of hospitalization.

### [Overview of the revised system]

#### Obligation to provide treatment plans at the beginning of hospitalization

- Managers of medical institutions are obliged to prepare, issue, and appropriately explain treatment plans describing treatments to be provided to patients during hospitalization.
- In so doing, managers are obliged to make efforts in reflecting knowledge of medical professionals of hospitals/clinics and facilitate organic cooperation with them.

(Items to be described in the treatment plan)

- ◆ Name, date of birth, and gender of the patient
- ◆ Name of a doctor or dentist who is in charge of providing treatment to the patient
- ◆ Specify disease or injury that caused hospitalization and main symptoms
- ◆ Plans for providing examinations, surgeries, medications, and other treatments during hospitalization
- ◆ Other items designated by the Ordinances of the Ministry of Health, Labour and Welfare

#### Obligation to make efforts in providing recuperation plans at the end of hospitalization

- Managers of medical institutions are obliged to make efforts in preparing, issuing, and appropriately explaining recuperation plans describing matters regarding required health care, medical care, and welfare services after discharge.
- In so doing, managers are obliged to make efforts in cooperating with health care, medical care, and welfare service providers.

- [Effects]** • Improved information provision to patients • Improved informed consent • Promotion of team medical care
- Enhanced cooperation with other medical institutions (so-called adjustment function for leaving hospital)
  - Promotion of evidence-based medicine (EBM), etc.

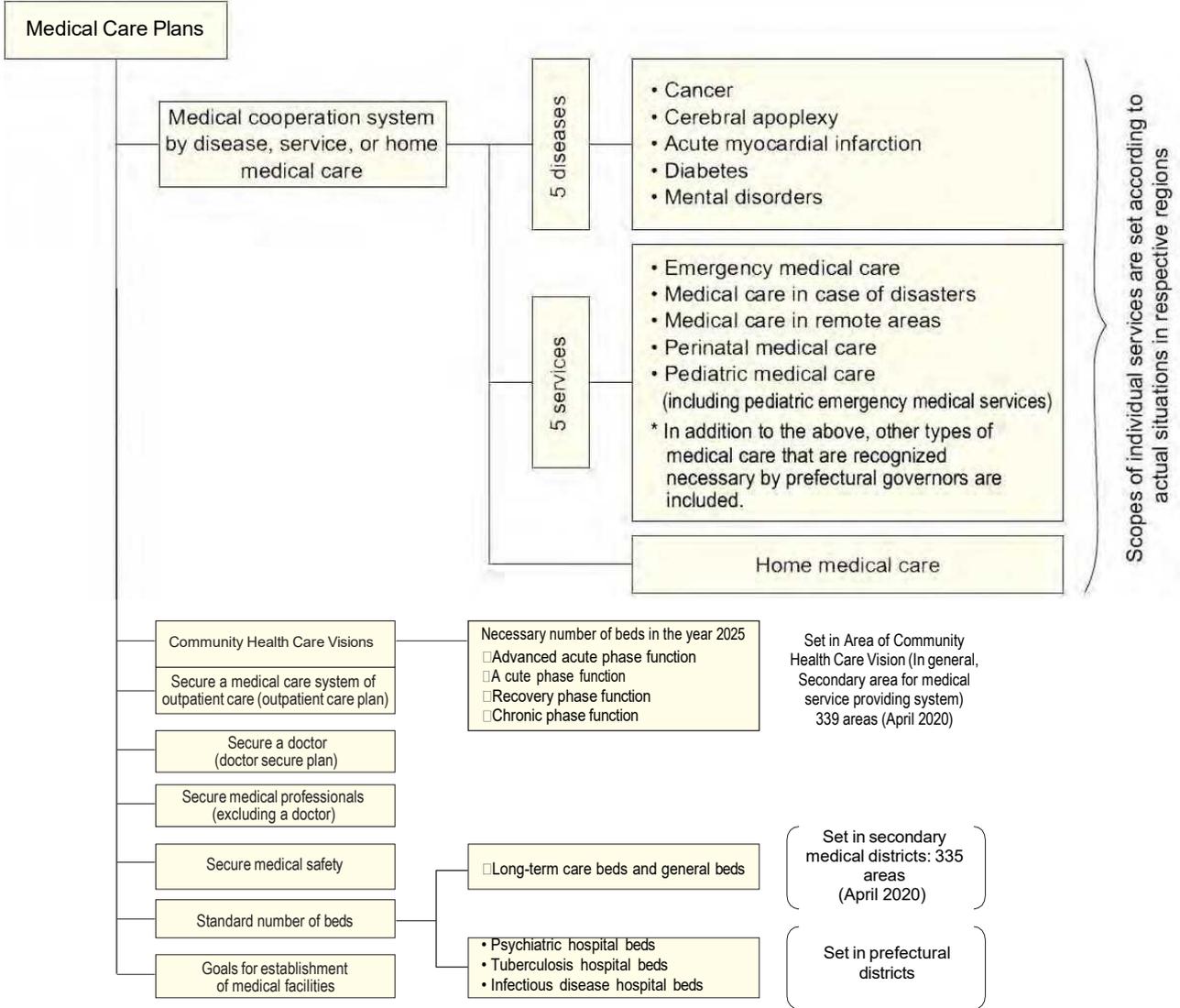
# Medical Care Plan

## Overview Overview of Medical Care Plan

### 1. Purpose

Establish a system for providing high quality and appropriate medical care efficiently by realizing continued medical care in communities through promoting a division of roles and cooperation of medical functions.

### 2. Contents



### 3. Status of standard number of beds and number of existing beds

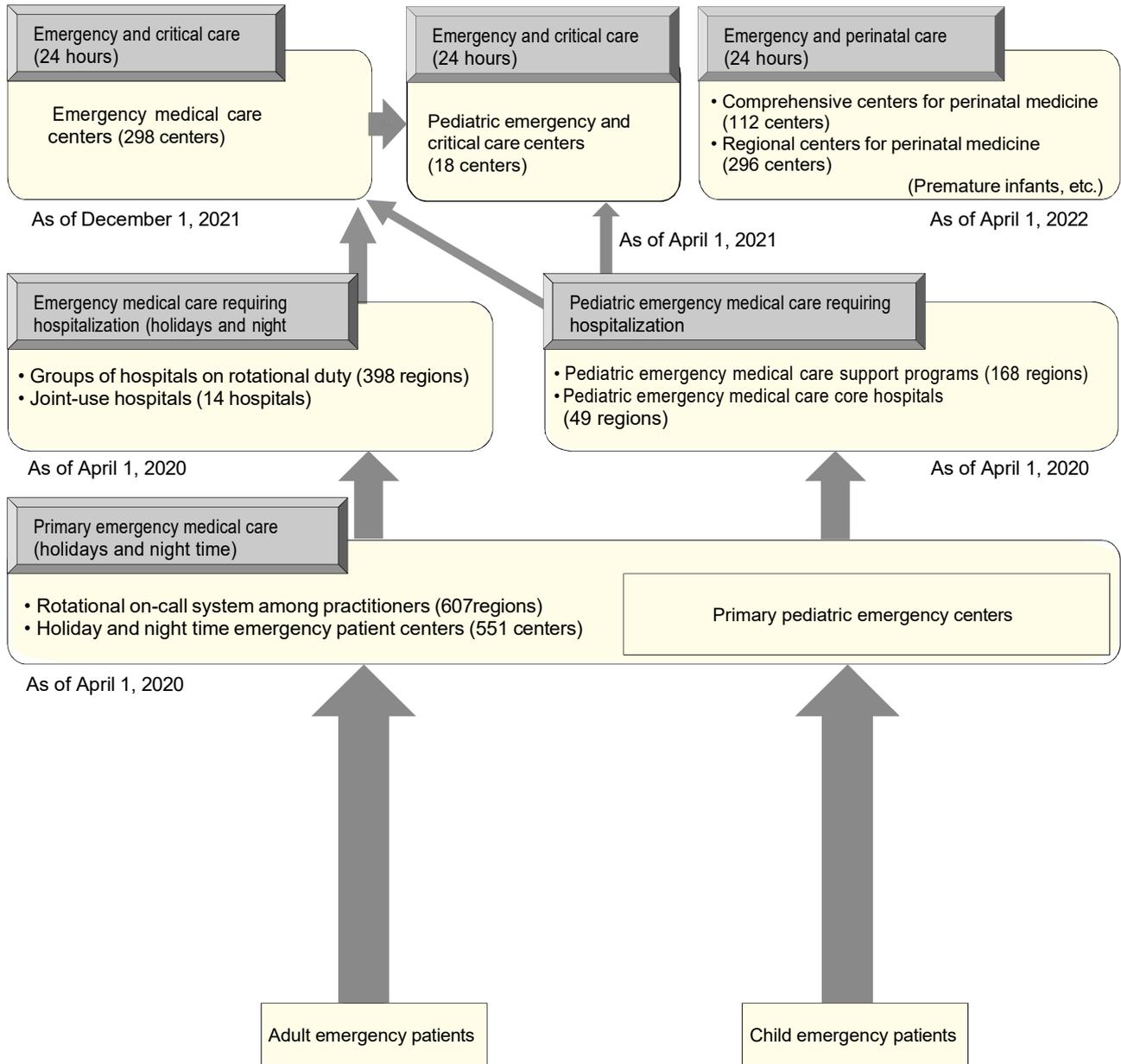
(As of April 2018)

Classification	Standard number of beds	Number of existing beds
Long-term care beds and general beds	1,017,066	1,228,598
Psychiatric hospital beds	282,104	330,405
Tuberculosis hospital beds	2,950	4,854
Infectious disease hospital beds	1,941	1,987

# Emergency Medical Service System

## Overview

## Structural Chart of Emergency Medical Service

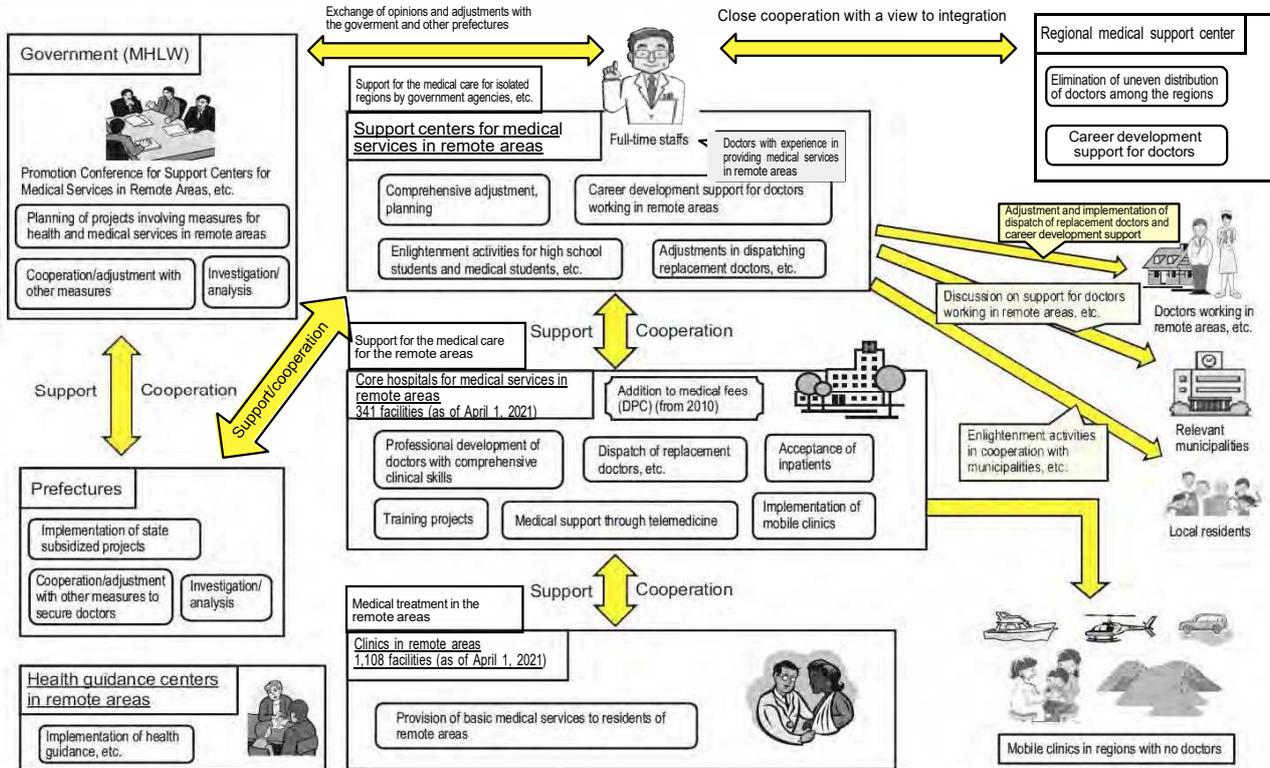


# Medical Services in Remote Areas

## Overview

### Structural Chart of Measures for Health and Medical Services in Remote Area

Establish an effective, efficient, and sustainable system that can provide medical services in remote areas mainly via prefectural support centers for medical services in remote areas in cooperation with governments, doctors working in remote areas, facilities and institutions engaged in medical services in remote areas, and residents of remote areas, and through studying advanced cases in other prefectures.



## Current Status of Measures for Health and Medical Services in Remote Areas

### 1. Efforts to build the medical system in remote areas

The medical system in remote areas, which has been taken measures in the remote area health care plan until 2017, shall be formulated integrally with the medical plan from 2018, and the medical system in remote areas shall be enhanced while further coordinating with other projects.

Year of investigation (once every 5 years)	Regions with no doctors	Subject population (10,000 persons)
1973	2,088	77
1984	1,276	32
1999	914	20
2004	787	16.5
2009	705	13.6
2014	637	12.4
2019	590	12.7

\* Regions with no doctors Regions with no medical institutions in which population of 50 or more people live within a radius of approximately 4 km from the major location of the region and it is not easy to use a medical institution.

### 2. Status of Establishment

- (1) Prefectural office to support medical services in remote areas (subject to assistance for operational expenses)  
Scheduled to be established/operated in 40 prefectures as of April 1, 2021
- (2) Core hospitals for medical services in remote areas (subject to assistance of operational expenses, facility establishment expenses, and equipment installment expenses)  
341 hospitals are designated as of April 1, 2021
- (3) Clinics for medical services in remote areas (subject to assistance of operational expenses, facility establishment expenses, and equipment installment expenses)  
1,108 clinics (including National Health Insurance direct managed clinics) are established as of April 1, 2021

# Medical Safety Measures

## Overview

## Medical Safety Measures

[Basic idea] Implement respective measures with great respect being paid to the viewpoint of medical safety and quality improvement taking into consideration report of the study group on medical safety measures (June 2005).

### <Key Suggestions>

### <Measures>

#### [Improved medical quality and safety]

- Systematization of establishment of certain safety management system in clinics with no beds, dental clinics, maternity clinics, and pharmacies ([1]preparation of safety management guideline manual, [2] implementation of training on medical safety, and [3] internal report of accidents, etc.)
- Improved measures against hospital infection in medical institutions ([1] preparation of guidelines/manuals for preventing hospital infection, [2] implementation of training on hospital infection, [3] internal report on situation of infection, and [4] establishment of committee on hospital infection (only in hospitals and clinics with beds))
- Security of drug/medical device safety ([1] clarification of responsibilities regarding safety use, [2] establishment of work processes regarding safety use, and [3] regular maintenance check on medical devices)
- Improved quality of medical professionals
- Obligation for administratively punished medical professionals to take re-education training



- Enhancement of medical safety management system (revision of law in 2006, etc.)
- Obligation of establishment of hospital infection control system (revision of Ministry Ordinance in 2006)
- Obligation of placement of responsible persons regarding safety use of drugs/medical devices, etc. (revision of Ministry Ordinance in 2006)
- Work guidelines for medical safety managers and guidelines for formulating training programs (March 2007)
- Obligation for punished medical professionals to take re-education training (revision of law in 2006, etc.)

#### [Thorough implementation of preventive measures against recurrence through investigation/analysis of causes of medical accident cases, etc.]

- Thorough implementation of preventive measures against recurrence through investigation/analysis of causes of accident cases
- Discussion on reporting system of medical related deaths, investigation system of cause of medical related deaths, and out-of-court dispute resolution system in medical areas



- Promotion of projects to collect information on medical accidents, etc. (from FY2004)
- Provision of "medical safety information" (from FY2005-FY2014)
- Model projects for investigation/analysis of deaths related to medical practices (from FY2005)
- Training projects for developing human resources to engage in coordination/mediation of medical disputes (FY2006)
- Discussion on investigation of causes and prevention of recurrences of deaths caused by medical accidents, etc. (from April 2007 to December)
- Japan Obstetric Compensation System for Cerebral Palsy (from January 2009)
- Liaison Conference of Alternative Medical Dispute Resolution Organizations (from March 2010)
- Discussion on utilization of autopsy imaging for determination of cause of death (from September 2010 to July 2011)
- Discussion on ideal no-fault compensation system that will contribute to the improvement of medical care quality (from August 2011 to June 2013)
- Enforcement of investigation system for medical accidents (October 2015~)

#### [Promotion of information sharing with patients and the public and independent participation from patients and the public]

- Promotion of information sharing with patients and the public and independent participation from patients and the public
- Systematization of medical safety support centers



- Promotion of Patient Safety Action (PSA) (from FY2001)
- Obligation for medical institutions, etc. to make efforts in providing appropriate consultations to patients (revision of law in 2006)
- Systematization of medical safety support centers (revision of law in 2006, etc.)
- Work guidelines for medical communication promoters and guidelines for formulating their training programs (January 2013)

#### [Roles of the government and local governments on medical safety]

- Clarification of responsibilities of the government, prefectures, and medical institutions and roles of patients and the public, etc.
- Establishment of laws and regulations, promotion of research, and provision of financial support, etc.



- Clarification of responsibilities of the government, local governments, and medical institutions (revision of law in 2006)
- Promotion of comprehensive support projects of medical safety support centers (from FY2003)
- Research for promoting medical safety management system (scientific research of health, labour and welfare)
- Guidelines for safety management in Intensive Care Unit (ICU) (March 2007)
- Model projects for making perinatal medical institutions open hospitals (FY2005-FY2007)

# Improved Quality of Doctors

## Overview

## History of Clinical Training System

- 1948 1-Year internship system after graduation started (1-year program necessary to be qualified for National Examination)
- 1968 Creation of clinical training system (effort obligation of more than 2 years after obtaining medical license)



### [Issues of the conventional system]

1. Training was voluntary
2. Training programs were not clearly defined
3. Mainly focused on straight training for specialized doctors
4. Remarkably large disparities existed among institutions
5. Insufficient guidance system
6. Insufficient evaluation of training achievements
7. Unstable status/work conditions " part-time jobs
8. Heavy concentration of interns in large hospitals in urban areas

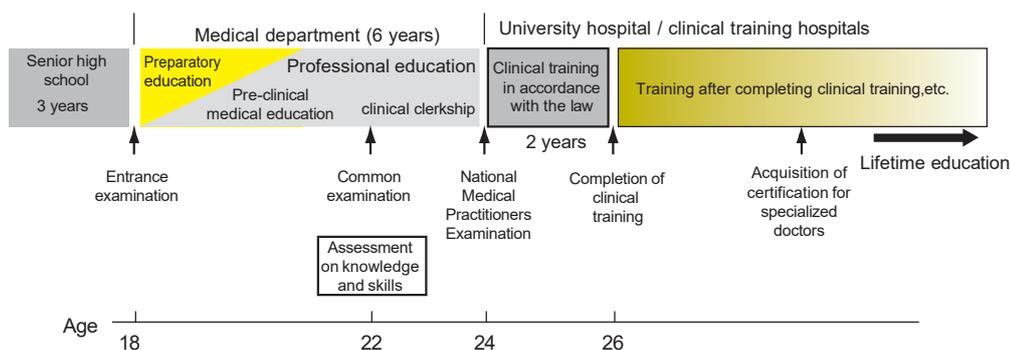
- 2000 Revision of the Medical Practitioners Act and the Medical Care Act (obligating clinical training)
- 2004 Enforcement of the new system
- 2010 Revision of the system
- 2015 Revision of the system
- 2020 Revision of the system

## Overview of Clinical Training System

### 1. Medical Education and Clinical Training

- Article 16-2 of the Medical Practitioners Act

Doctors to engage in clinical practice must take clinical training in hospitals attached to universities with medical training courses or hospitals designated by the Minister of Health, Labour and Welfare for no less than 2 years.



### 2. Basic Ideas of Clinical Training

(Ministerial Ordinance on clinical training provided in paragraph 1, Article 16-2 of the Medical Practitioners Act)

Clinical training must offer doctors the opportunity to cultivate the appropriate bedside manner and acquire basic diagnosis and treatment abilities while recognizing the social role to be fulfilled by medicine and medical services regardless of their future specialty so that they can provide appropriate treatment for injuries and diseases that frequently occur.

### 3. Status of Clinical Training

The number of enrollments of clinical trainees and the percentages of enrollments of clinical trainees in 6 prefectures with large cities (Tokyo, Kanagawa, Aichi, Kyoto, Osaka and Fukuoka) and other prefectures

Fiscal year	Number of enrollments	6 prefectures	Other prefectures
FY2003	8,166	51.3%	48.7%
FY2004	7,372	47.8%	52.2%
FY2009	7,644	48.6%	51.4%
FY2010	7,506	47.8%	52.2%
FY2013	7,674	45.5%	54.5%
FY2015	8,244	43.6%	56.4%
FY2016	8,622	42.6%	57.4%
FY2018	8,996	41.7%	58.3%
FY2019	8,986	41.7%	58.3%
FY2020	9,279	41.3%	58.7%

\* A new clinical training system was launched in FY 2004.

## Outline of 2015 System Reform

### (1) Appropriate core clinical training hospitals

- Appropriate core clinical training hospitals are clearly defined as those having an environment capable of training for most of the achievement goals and having overall management of, and responsibility for, interns and training programs.

### (2) Appropriate clinical training hospital groups

- Groups consist of those capable of forming various abilities related to frequently occurring diseases, etc.
- The geographical coverage of a hospital group is basically within the same prefecture and secondary medical district.

### (3) Cases required for core clinical training hospitals

- Newly applied hospitals with the annual number of inpatients being less than 3,000, but 2,700 or more that are deemed capable of providing high-quality training, are assessed through on-site evaluation for the time being.

### (4) Career development support

- Smooth interruption/resumption of clinical training according to various career paths, including pregnancy, childbirth, research, and study abroad, etc.

### (5) Revision of recruitment quota setting

- Reduction of the percentage of recruitment quotas for internship applicants (from approx. 1.23 times (FY2013) to 1.2 times for the time being (FY2015) and 1.1 times towards the next revision)
- Partial revision of the calculation formula for the upper limits of prefectures (the aging rate and the number of doctors per unit population are newly considered)
- The actual results of dispatching doctors of university hospitals, etc. is considered when setting a recruitment quota for each hospital.

### (6) Responses to regional limits and strengthening of roles of prefectures

- Limits are included to enable a prefecture to adjust the quota for each hospital within the upper limit of the prefecture with consideration given to regional limits and the actual results of dispatching doctors, etc.
- Necessary reviews will be made within 5 years after the enforcement of this revised system.

## Outline of 2020 System Reform

### (1) Comprehensive Doctor training before and after graduation

- Set up outcomes, measures and evaluation applicable for medical education model core curriculum.

### (2) Outcomes, measures and evaluation

- As outcomes, set up 'basic value as a doctor (professionalism)', 'capabilities, abilities' and 'basic diagnosis task' and 'ensure basic medical examination for admission, out-patient, emergencies and regional medicines'.
- As measures, make surgery, pediatrics, gynecology and obstetrics and psychiatry compulsory in addition to internal medicine, emergency, regional medicine and add that it includes the training for out-patients.
- Standardize the evaluation considering the continuity with model core curriculum.

### (3) The modality of clinical training hospital

- Make three-stage evaluation to four-stage for visiting survey of core hospitals which may have challenges and delete the designation from hospitals which do not show any improvement.
- Make the training for those who are in charge of program compulsory.
- Recommend strongly the third party evaluation.

### (4) Stable assurance of regional medical

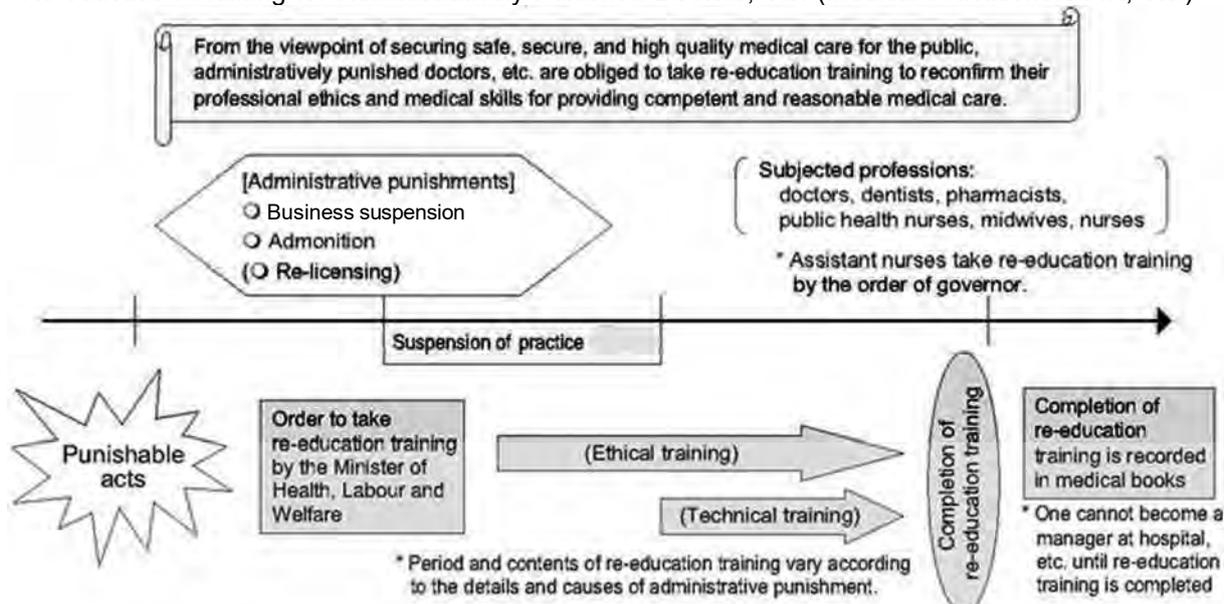
- Compress the recruiting ration up to 1.05 times and limit the maximum for calculating recruiting number of admission quota of medical department.
- As for the part of regional positions, etc., recruit differently from general matching.
- For setting up the designation and application number of clinical training hospital, prefectural governments will hear from regional medical measures committees, first.

### (5) Responses to diminishing international competitiveness on basic researches

- Set up courses for capacity building and training for basic doctors in university hospitals which are basic clinical training hospitals. Separate applicants from general applications and separate selection from the general matching.

\*Conduct required reviews within five years after the enforcement of this system review.

## Re-education Training for Administratively Punished Doctors, etc. (Medical Practitioners Act, etc.)



# Medical Corporation System

## Outline of Medical Corporation System

### 1. Purpose of the system

- Corporate bodies based on the Medical Care Act. The system was created by the 1950 revision of the Medical Care Act.
- Enabling administrative bodies of medical care service programs to become corporate bodies without losing the non-profit status of medical practices.

[Around the time of the system establishment]  
Reducing the difficulties of administering medical institutions by private persons  
(aiming to make fund collection easier)



Granting continuity of administration of medical institutions  
□ Securing stability of regional medical care

### 2. Establishment

- Associations or foundations based on the Medical Care Act.
  - Prefectural approval  
(An organization opening a medical institute in more than 2 prefectures shall obtain approval from a governor at its main address.)
- (Number of corporations)
- Medical corporations 56,303 (as of March 31, 2021)  
Of which 55,931 are associations (17,848 without contribution and 38,083 with contribution) and 372 are foundations.
    - \* Medical corporation without contribution
      - Medical corporation for which the ownership of residual assets in the event of dissolution is stipulated to be the government, local governments, or other medical corporations without contribution, etc. and exclude individuals (investors).
      - The revised Medical Care Act of 2006 limits newly established medical corporations to be those without contribution. The existing medical corporations, however, shall voluntarily transfer while applying the previous provisions.
  - Social medical corporations 333 (as of April 1, 2021)



### 3. Operation

- A medical corporation may carry out operations associated with the health/hygiene and social welfare in addition to medical practice (operation of hospitals, clinics, long-term care health facilities)
- Medical corporations certified as social medical corporations may engage in profit-making practices for the purpose of appropriating the profits to the administration of hospitals, etc.
- Dividend of surplus is not allowed.
  - \* Social medical corporations
    - Established by the 2006 revision of the Medical Care Act as medical corporations with high public interest that take roles of providing emergency medical care and medical services in remote areas while utilizing high vitality of the private sector.
    - Must meet the requirements such that family corporation members are excluded from being officers, etc. and limiting the ownership of residual assets, in the event of dissolution, to the government and local governments, etc.
    - Exempt from corporation tax on medical and health practices. Exempt from fixed assets tax on hospitals/clinics that engage in practices for securing emergency medical care, etc.

### (3) Health Promotion/Disease Measures

#### Health Centers, etc.

##### Overview

##### Activities of Health Centers

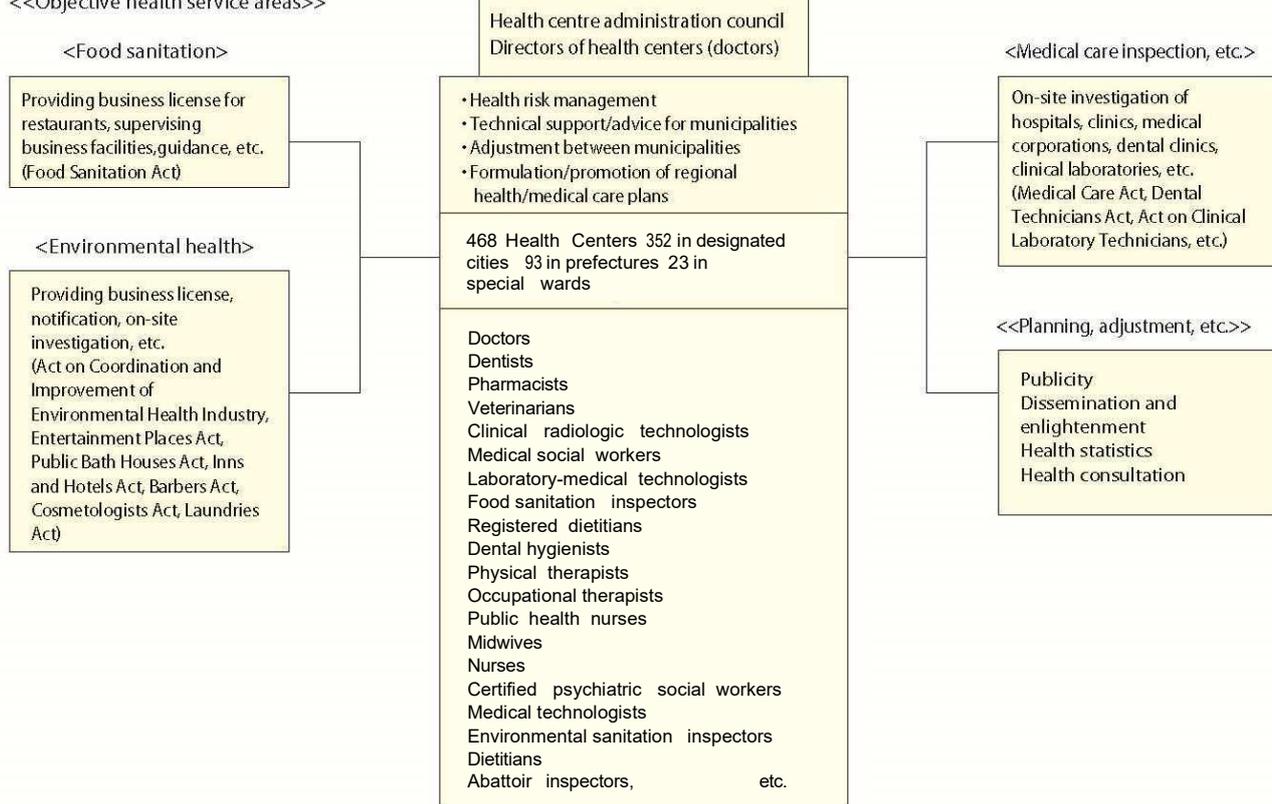
Health centers are front-line comprehensive public health administrative institutions that offer both personal and objective health services. Personal health services include broad-based services, services requiring specialized technologies, and services requiring team work of various health care professionals. In addition, health centers provide required technical assistance for health services provided by municipalities.

Health centers are established in 352 locations in 47 prefectures, 93 locations in 87 designated cities, and 23 locations in 23 special wards under the Community Health Act (As of April 1, 2022).

##### <<Personal health service areas>>



##### <<Objective health service areas>>



\* In addition to the activities above, health centers provide licenses for opening pharmacies (Pharmaceuticals and Medical Devices Act), take custody of dogs to prevent the spread of rabies (Rabies Prevention Act), and accept applications for opening massage clinics, etc. (Act on Practitioners of Massage, Finger Pressure, Acupuncture and Moxa-cauterization, etc.).

### Changes in Number of Health Centers

FY	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Total number of health centers	518	517	510	494	495	495	494	490	486	480	481	469	472	469	470	468
Prefectures	394	389	380	374	373	372	370	365	364	364	363	360	359	355	354	352
Cities	101	105	107	97	99	100	101	102	99	93	95	86	90	91	93	93
Special wards	23	23	23	23	23	23	23	23	23	23	23	23	23	23	23	23

Source: Health Service Bureau, MHLW

(Note) The number of clinics is as of April 1 of each year.

#### Detailed Data 1

#### Number of Full-time Medical Personnel at Health Centers by Occupation

Occupation	Number of personnel
	Person
Doctors	740
Dentists	81
Pharmacists	3,097
Veterinarians	2,269
Public health nurses	9,278
Midwives	68
Nurses	168
Assistant nurses	2
Radiology technicians, etc.	411
Medical technologists, etc.	653
Registered dietitians	1,313
Dietitians	48
Dental hygienists	307
Physical/occupational therapists	67
Others	12,170
<Included in the upper column>	
Medical social workers	21
Mental health welfare counselors	986
Nutrition counselors	1,035
<b>Total</b>	<b>30,727</b>

Source: "Report on Regional Public Health Services and Health Promotion Services", Administrative Report Statistics Office to the Director-General for Statistics and Information System Management and Industrial Relations, MHLW  
(Modified by Health Service Bureau) (as of the end of FY2020)

#### Detailed Data 2

#### Changes in Number of Public Health Nurses

(Unit: person)

	FY2009	FY2010	FY2011	FY2012	FY2013	FY2014	FY2015	FY2016	FY2017	FY2018	FY2019	FY2020
Municipalities	14,613	14,179	15,015	14,753	14,920	14,850	14,935	15,035	15,227	15,193	15,194	15,338
Designated cities / special wards	6,094	6,081	6,280	6,256	6,564	6,586	6,829	6,928	7,107	7,512	8,030	8,230
Subtotal	20,707	20,260	21,295	21,009	21,484	21,436	21,764	21,963	22,334	22,705	23,224	23,568
Prefectures	3,737	3,640	3,689	3,659	3,603	3,607	3,613	3,661	3,659	3,637	3,688	3,730
<b>Total</b>	<b>24,444</b>	<b>23,900</b>	<b>24,984</b>	<b>24,668</b>	<b>25,087</b>	<b>25,043</b>	<b>25,377</b>	<b>25,624</b>	<b>25,993</b>	<b>26,342</b>	<b>26,912</b>	<b>27,298</b>

Source: Report on Regional Public Health Services and Health Promotion Services, MHLW

FY2008 onward: "Report on Regional Public Health Services and Health Promotion Services", Administrative Report Statistics Office to the Director-General for Statistics, Information System Management and Industrial Relations, MHLW

(Note) The figures for FY2010 do not include some municipalities in Iwate Prefecture (Kamaishi City, Otsuchi Town, Miyako City, and Rikuzentakata City), clinics and municipalities in Miyagi Prefecture apart from Sendai City, and some municipalities in Fukushima Prefecture (Minamisoma City, Naraha Town, Tomioka Town, Kawauchi Village, Okuma Town, Futaba Town, Iitate Town, and Aizuwakamatsu City) due to the effect of the Great East Japan Earthquake.

# Health Promotion Measures

## Overview

## History of National Health Promotion Measures

<p>1st National Health Promotion Measures (FY 1978-1988)</p>	<p>(Basic concept)</p> <ol style="list-style-type: none"> <li>Lifetime health promotion             <ul style="list-style-type: none"> <li>Promotion of primary prevention of geriatric diseases</li> </ul> </li> <li>Promotion of health promotion measures through three major elements (diet, exercises, and rest) (special focus on diet)</li> </ol>	<p>(Outline of measures)</p> <ol style="list-style-type: none"> <li>Lifetime health promotion             <ul style="list-style-type: none"> <li>Establishment of health checkups and a complete health guidance system from infants and small children through to the elderly</li> </ul> </li> <li>Establishment of health promotion bases             <ul style="list-style-type: none"> <li>Establishment of health promotion centers, municipal health centers, etc.</li> <li>Securing sufficient human resources, including public health nurses and dietitians</li> </ul> </li> <li>Dissemination and enlightenment of health promotion             <ul style="list-style-type: none"> <li>Establishment of municipal health promotion councils</li> <li>Promoting the use of recommended dietary allowances</li> <li>Nutritional content labelling for processed food</li> <li>Conducting studies on health promotion, etc.</li> </ul> </li> </ol> <p>etc.</p>	<p>(Guidelines, etc.)</p> <ul style="list-style-type: none"> <li>Dietary guidelines for health promotion (1985)</li> <li>Report on nutritional content labelling for processed food (1986)</li> <li>Announcement of a weight scale diagram and table (1986)</li> <li>Report on smoking and health (1987)</li> </ul>
<p>2nd National Health Promotion Measures (FY 1988-1999) (Active 80 Health Plan)</p>	<p>(Basic concept)</p> <ol style="list-style-type: none"> <li>Lifetime health promotion</li> <li>Promotion of health promotion measures with the focus on exercise habits as they are lagging behind the other two of the three elements (diet, exercise, and rest)</li> </ol>	<p>(Outline of measures)</p> <ol style="list-style-type: none"> <li>Lifetime health promotion             <ul style="list-style-type: none"> <li>Enhanced health checkup and guidance system from infants and small children through to the elderly</li> </ul> </li> <li>Establishment of health promotion bases             <ul style="list-style-type: none"> <li>Establishment of health science centers, municipal health centers, health promotion facilities, etc.</li> <li>Securing sufficient manpower such as health fitness instructors, registered dietitians, and public health nurses</li> </ul> </li> <li>Dissemination and enlightenment of health promotion             <ul style="list-style-type: none"> <li>Promoting the use of and revising recommended dietary allowances</li> <li>Promoting recommended exercise allowance</li> <li>Promoting the system to approve health promotion facilities</li> <li>Action plan for tobacco control</li> <li>Promoting a system of nutrition information labelling for meals eaten outside home</li> <li>Promoting cities with health oriented cultures and health resorts</li> <li>Conducting studies on health promotion, etc.</li> </ul> </li> </ol>	<p>(Guidelines, etc.)</p> <ul style="list-style-type: none"> <li>Dietary guidelines for health promotion (by individual characteristics: 1990)</li> <li>Guidelines for nutrition information labeling for meals eaten outside home (1990)</li> <li>Report on smoking and health (revised) (1993)</li> <li>Exercise and Physical Activity Guidelines for Health Promotion (1993)</li> <li>Promoting guidelines on rest for health promotion (1994)</li> <li>Committee report on action plan for tobacco control (1995)</li> <li>Committee report on designated smoking areas in public spaces (1996)</li> <li>Physical activity guidelines by age (1997)</li> </ul>
<p>3rd National Health Promotion Measures (FY2000-2012) (National Health Promotion Movement in the 21st Century (Health Japan 21))</p>	<p>(Basic concept)</p> <ol style="list-style-type: none"> <li>Lifetime health promotion             <ul style="list-style-type: none"> <li>Focusing on primary prevention, extension of healthy life expectancy, and enhanced quality of life</li> </ul> </li> <li>Setting specific targets to serve as an indicator for national health/medical standards and promotion of health promotion measures based on assessments</li> <li>Creation of social environments to support individuals' health promotion</li> </ol>	<p>(Outline of measures)</p> <ol style="list-style-type: none"> <li>National health promotion campaign             <ul style="list-style-type: none"> <li>Dissemination and enlightenment of effective programs and tools with regular revision</li> <li>Dissemination and enlightenment of the acquisition of good exercise habits and improved dietary habits with a focus on metabolic syndrome</li> </ul> </li> <li>Implementation of effective medical examinations and health guidance             <ul style="list-style-type: none"> <li>Steady implementation of health checkups and health guidance with a focus on metabolic syndrome for insured persons/dependents aged 40 or older by Health Care Insurers (from FY2008)</li> </ul> </li> <li>Cooperation with industry             <ul style="list-style-type: none"> <li>Further cooperation in voluntary measures of industries</li> </ul> </li> <li>Human resource development (improving the quality of medical professionals)             <ul style="list-style-type: none"> <li>Improved training for human resource development in cooperation between the government, prefectures, relevant medical organizations, and medical insurance organizations</li> </ul> </li> <li>Development of evidence-based measures             <ul style="list-style-type: none"> <li>Revision of data identification methods to enable outcome assessments</li> </ul> </li> </ol> <p>etc.</p>	<p>(Guidelines, etc.)</p> <ul style="list-style-type: none"> <li>Dietary guidelines (2000)</li> <li>Committee report on relevance to designated smoking areas (2002)</li> <li>Sleep guidelines for health promotion (2003)</li> <li>Guidelines on implementation of health checkups (2004)</li> <li>Dietary Reference Intakes for Japanese (2005 edition) (2004)</li> <li>Guidelines for well-balanced diet (2005)</li> <li>Manual for smoking cessation support (2006)</li> <li>Exercise and Physical Activity Reference for Health Promotion 2006 (exercise guide 2006) (2006)</li> <li>Exercise guidelines for health promotion 2006 (Exercise Guide 2006) (2006)</li> <li>Dietary Reference Intakes for Japanese (2010 edition) (2009)</li> </ul>
<p>4th National Health Promotion Measures (from FY 2013) (The second term of National Health Promotion Movement in the 21st Century (Health Japan 21 (the second term)))</p>	<p>[Basic Concept]</p> <ol style="list-style-type: none"> <li>Extension of healthy life expectancy and reduction of health disparities</li> <li>Lifetime health promotion [prevention of onset and progression of lifestyle-related diseases, maintenance and improvement of functions necessary, establishment of social environment]</li> <li>Improvement of lifestyle and social environment</li> <li>Setting specific targets to serve as an indicator for national health/medical standards and promotion of health promotion measures based on assessments.</li> </ol>	<p>[Outline of measures]</p> <ol style="list-style-type: none"> <li>Focusing on extension of healthy life expectancy and reduction of health disparity             <ul style="list-style-type: none"> <li>Comprehensive promotion for lifestyle diseases and promotion of efforts supporting areas such as medical and long-term care.</li> </ul> </li> <li>Prevention of onset and progression of lifestyle diseases (Prevention of NCD (Non-Communicable Diseases))             <ul style="list-style-type: none"> <li>Promotion measures focused on primary prevention of cancer, cardiovascular disease, diabetes and COPD in addition to prevention of progression.</li> </ul> </li> <li>Maintenance and improvement of necessary functions for healthy social life.             <ul style="list-style-type: none"> <li>Promotion of mental health programs for mind, and health of the next generation and the elderly.</li> </ul> </li> <li>Development of social environment for supporting and protecting health.             <ul style="list-style-type: none"> <li>Providing information on the activities of companies working voluntarily on promoting health and evaluating these activities.</li> </ul> </li> <li>Improvement of lifestyle and social environment relating to nutrition, dietary habits, physical activity/exercise, rest, alcohol, smoking, dental and oral health, etc.             <ul style="list-style-type: none"> <li>Promoting formulation and review of standards and guidelines relating to all areas of lifestyle habits, dissemination of correct awareness, and establishment of cooperation with private companies and organization.</li> </ul> </li> </ol>	<p>[Guidelines, etc.]</p> <ul style="list-style-type: none"> <li>2013 Physical activities for healthy life (2013)</li> <li>Active Guideline—Physical activities for healthy life (2013)</li> <li>Manual for supporting non-smoking (2nd edition) (2013)</li> <li>2014 Sleeping guideline for healthy life (2014)</li> <li>Dietary Reference Intakes for Japanese (2020 edition) (2020)</li> <li>A report on effects of smoking on health by a study group (FY2016)</li> <li>Smoking Cessation Supporting Manual (Second Edition) (Supplemental Revision) (2018)</li> </ul>

## Outline of the Health Promotion Act

### Chapter 1. General Provisions

#### (1) Purpose

Provide basic matters regarding comprehensive promotion of people's health and make the effort to improve public health through implementation of measures for health promotion.

#### (2) Responsibilities

1. People: Improved interest and understanding of the importance of healthy lifestyle habits in being aware of one's own health status and make the effort to stay healthy throughout life.
2. The government and local governments: Make efforts to disseminate the appropriate knowledge on health promotion, collect/organize/analyze/make available information, promote researches, develop and improve the quality of human resources, and provide the required technical support.
3. Health promotion service providers (insurers, business operators, municipalities, schools, etc.): Make an active effort to promote health promotion programs for people including health consultations.

#### (3) Cooperation between the government, local governments, health promotion service providers, and other related entities.

### Chapter 2. Basic Policies (legally establish "Health Japan 21")

#### (1) Basic policies

Basic policies for comprehensive promotion of people's health are formulated by the Minister of Health, Labour and Welfare.

1. Basic direction with promoting people's health
2. Matters regarding goals in promoting people's health
3. Basic matters regarding formulation of health promotion plans of prefectures and municipalities
4. Basic matters regarding national health and nutrition surveys in Japan and other surveillance and researches
5. Basic matters regarding cooperation between health promotion service providers
6. Matters regarding dissemination of the appropriate knowledge on dietary habits, exercise, rest, smoking, alcohol drinking, dental health, and other lifestyle habits
7. Other important matters regarding promotion of people's health

#### (2) Formulation of health promotion plans for prefectures and municipalities (plans for health promotion measure to the people)

#### (3) Guidelines on implementation of health checkups

Guidelines on implementation of health checkups by health promotion service providers, notification of the results, a health handbook being issued, and other measures are formulated by the Minister of Health, Labour and Welfare in supporting people's lifelong self management of health.

## Outline of Results of National Health and Nutrition Survey 2019

### National Health and Nutrition Survey

- Objective:** Amassing basic information for comprehensive promotion of national health in accordance with the Health Promotion (Act No.103 of 2002)
- Subjects:** Household in 300 unit areas randomly selected from unit areas established in comprehensive Survey of Living Conditions 2019 (approximately 4,465 households) ,and members of households aged 1 or older
- Survey items:** [Survey on physical condition] Height, weight, abdominal circumference, blood pressure, blood tests, number of steps taken when walking, interview (medication status, exercise)  
[Survey on nutritional intake] Food intake, nutrient intake, etc., dietary situation (skipping meals, eating out, etc.)  
[Survey on lifestyle] General lifestyle encompassing dietary habits, physical activities, exercise, rest (sleep), alcohol usage, smoking, dental health, etc.

### Key points of the results of the survey

The proportion of those who are not improve eating and excise habits is one fourth of the population.

- The proportion of those who are interested in but not improving eating habits is highest, 24.6% in men and 25.0% in women.
- The proportion of those who are interested in but not improving exercise habits is highest, 23.9% in men and 26.3% in women.
- By the willing of improvement, the proportion of those who responded 'no time because they are busy at work (housework, rearing kids, etc.)' as a reason for preventing from barriers to healthy eating habits and barriers to regular exercise habits is the highest.

The situation of smoking and passive smoking is under improving

- The proportion of those who are smoking regularly is 16.7%, 27.1% in men and 7.6% in women which has significantly decreased within these 10 years.
- The proportion of participants who were exposed to passive smoking are 29.6% in restaurants and 27.1% in streets and recreation halls which has significantly decreased since 2003.

There is a regional gap on the preparation for emergency stocks of food.

- The proportion of those households who prepared for emergency stocks of food for preparing for disasters is 53.8%. By regional blocks, the highest block is Kanto I block (\*1), 72.3% and lowest block is South Kyushu block (\*2), 33.1%. (\*1 Saitama, Chiba, Tokyo, Kanagawa, \*2 Kumamoto, Miyazaki, Kagoshima and Okinawa)
- Among households who are storing emergency stocks of food, the proportion of households which store emergency stocks of food for at least three days was 69.9%.

## Detailed Data 1

## Status of formulating health promotion plans in regional governments nationwide

[Status of formulating health promotion plans in prefectures]

Already formulated in every prefecture (at the end of March 2004)

[Status of formulating health promotion plans in municipalities and special wards]

	Total	Formulated	Plan to formulate in FY 2020	Plan to formulate in FY 2021	Plan to formulate in FY 2022	No plan
Health center-designated cities	87	87	0	0	0	0
Special wards in Tokyo	23	23	0	0	0	0
Other municipalities	1,632	1,540	6	10	51	25

(As of January 1, 2021)

[Status of formulating health promotion plans in municipalities by prefectures]

Prefecture	No. of municipalities	Formulated	Formulation rate	FY 2020	FY 2021	FY 2022 or later	No plan
Hokkaido	175	138	78.9%	0	0	34	3
Aomori	38	38	100.0%	0	0	0	0
Iwate	32	32	100.0%	0	0	0	0
Miyagi	34	34	100.0%	0	0	0	0
Akita	24	24	100.0%	0	0	0	0
Yamagata	34	33	97.1%	1	0	0	0
Fukushima	56	49	87.5%	1	2	3	1
Ibaraki	43	43	100.0%	0	0	0	0
Tochigi	24	24	100.0%	0	0	0	0
Gunma	33	33	100.0%	0	0	0	0
Saitama	59	57	96.6%	1	1	0	0
Chiba	51	51	100.0%	0	0	0	0
Tokyo	37	30	81.1%	0	2	0	5
Kanagawa	27	26	96.3%	0	0	0	1
Niigata	29	29	100.0%	0	0	0	0
Toyama	14	14	100.0%	0	0	0	0
Ishikawa	18	18	100.0%	0	0	0	0
Fukui	16	16	100.0%	0	0	0	0
Yamanashi	26	26	100.0%	0	0	0	0
Nagano	76	69	90.8%	0	2	5	0
Gifu	41	41	100.0%	0	0	0	0
Shizuoka	33	33	100.0%	0	0	0	0
Aichi	49	49	100.0%	0	0	0	0
Mie	28	27	96.4%	0	1	0	0
Shiga	18	18	100.0%	0	0	0	0
Kyoto	25	19	76.0%	0	0	2	4
Osaka	34	31	91.2%	0	0	0	3
Hyogo	36	36	100.0%	0	0	0	0
Nara	38	38	100.0%	0	0	0	0
Wakayama	29	25	86.2%	0	0	1	3
Tottori	18	18	100.0%	0	0	0	0
Shimane	18	18	100.0%	0	0	0	0
Okayama	25	25	100.0%	0	0	0	0
Hiroshima	20	20	100.0%	0	0	0	0
Yamaguchi	18	18	100.0%	0	0	0	0
Tokushima	24	23	95.8%	1	0	0	0
Kagawa	16	16	100.0%	0	0	0	0
Ehime	19	18	94.7%	1	0	0	0
Kochi	33	33	100.0%	0	0	0	0
Fukuoka	57	53	93.0%	1	2	1	0
Saga	20	18	90.0%	0	0	1	1
Nagasaki	19	19	100.0%	0	0	0	0
Kumamoto	44	40	90.9%	0	0	2	2
Oita	17	17	100.0%	0	0	0	0
Miyazaki	25	24	96.0%	0	0	0	1
Kagoshima	42	42	100.0%	0	0	0	0
Okinawa	40	37	92.5%	0	0	2	1
	1,632	1,540	94.4%	6	10	51	25

(Note) Excluding health center-designated cities and special wards.

## Detailed Data 2 Number of Patients and Deaths Related to Lifestyle Diseases

	Estimated number of patients receiving medical treatment (1,000 persons)	Number of deaths (Person)	Death rate (Per 100,000 persons)
Malignant neoplasms	1,782	381,497	310.7
Diabetes mellitus	3,289	14,348	11.7
Hypertensive diseases	9,937	10,219	8.3
Heart diseases (excluding hypertensive)	1,732	214,623	174.8
Cerebrovascular diseases	1,115	104,588	85.2

Source:

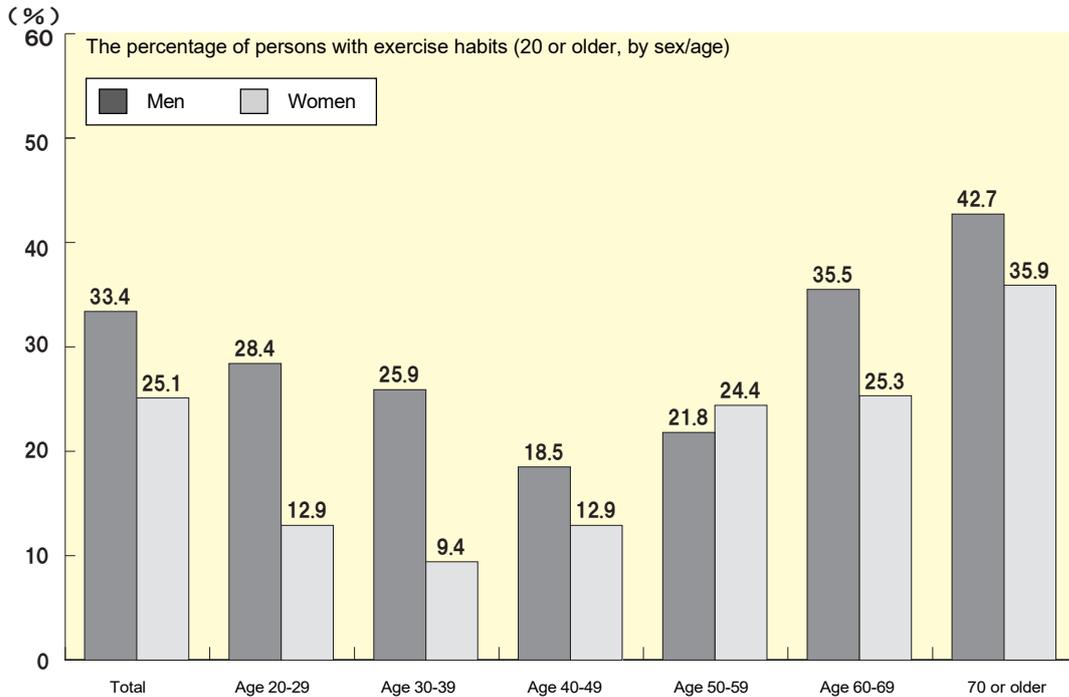
<The estimated number of patients receiving medical treatment> "Patient Survey 2017", Health Statistics Office to the Director-General for Statistics, Information System Management and Industrial Relations, MHLW  
 <Number of deaths, Death rate> "Vital Statistics", Vital, Health and Social Statistics Office to the Director-General for Statistics, Information System Management and Industrial Relations, MHLW (2021 preliminary data)

## Detailed Data 3 Prevalence related to Diabetes

Age	Males (survey samples: 1,013)		Females (survey samples: 1,399)	
	Strongly suspected of having diabetes	With possibilities of having diabetes	Strongly suspected of having diabetes	With possibilities of having diabetes
20-29	0.0%	1.8%	0.0%	2.2%
30-39	1.6%	1.6%	2.6%	1.8%
40-49	6.1%	6.1%	2.8%	4.7%
50-59	17.8%	11.8%	5.9%	13.1%
60-69	25.3%	14.9%	10.7%	18.3%
70 or older	26.4%	16.2%	19.6%	16.5%

Source: "National Health and Nutrition Survey 2019", Health Service Bureau, MHLW

**Detailed Data 4** Status of Exercise Habits



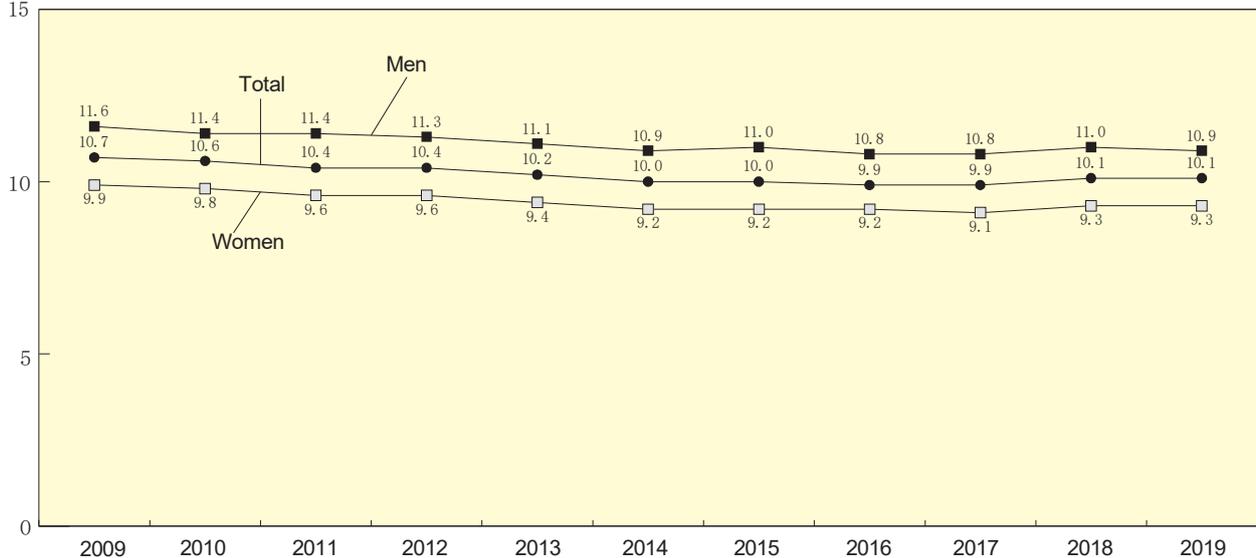
Source: "National Health and Nutrition Survey 2019", Health Service Bureau, MHLW  
 (Note) Persons with exercise habits: Those who have been continuing daily exercise of 30 minutes or longer at least 2 days a week for at least a year.

**Detailed Data 5** Average of salt intake (Aged 20 or Older, by Sex/Age)

(g / day)

	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
Men	11.6	11.4	11.4	11.3	11.1	10.9	11.0	10.8	10.8	11.0	10.9
Women	9.9	9.8	9.6	9.6	9.4	9.2	9.2	9.2	9.1	9.3	9.3
Total	10.7	10.6	10.4	10.4	10.2	10.0	10.0	9.9	9.9	10.1	10.1

(g / day)



"National Health and Nutrition Survey", Health Service Bureau, MHLW

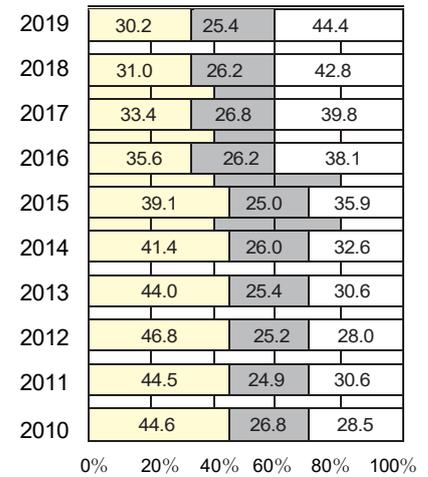
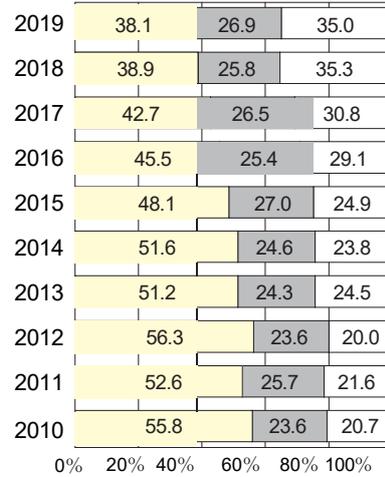
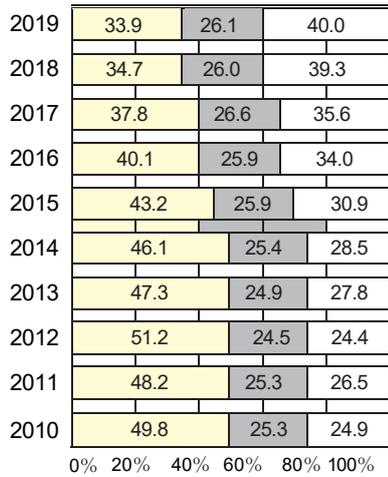
**Detailed Data 6**

**Secular Trend in Distribution of Fat Energy Ratio (Aged 20 or Older)**

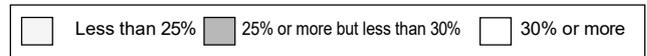
**Total**

**Men**

**Women**



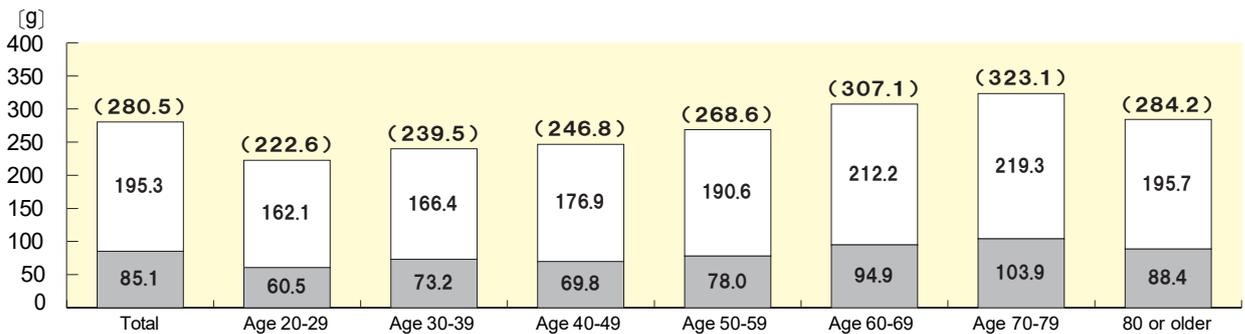
Source: "National Health and Nutrition Survey", Health Service Bureau, MHLW  
(Note) Fat energy ratio: Percentage of energy intake from fat



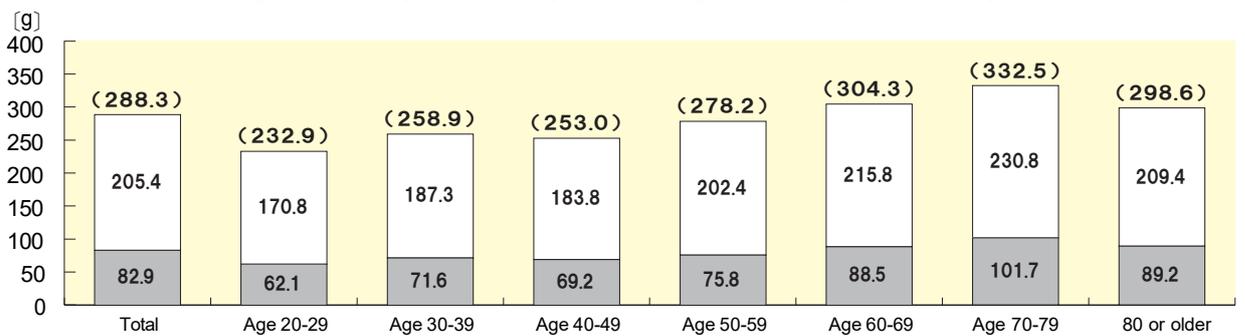
**Detailed Data 7**

**Average Intake of Vegetables, etc. (Aged 20 or Older, by Sex/Age)**

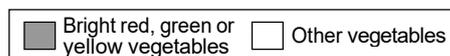
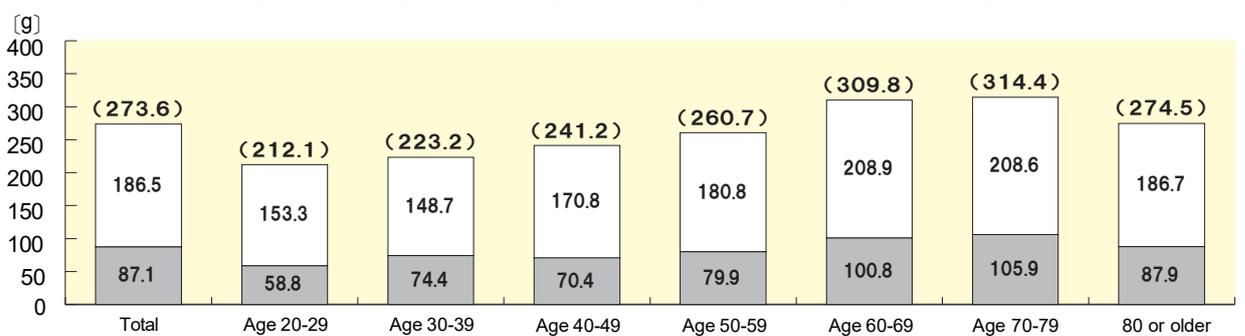
**Total**



**Men**



**Women**

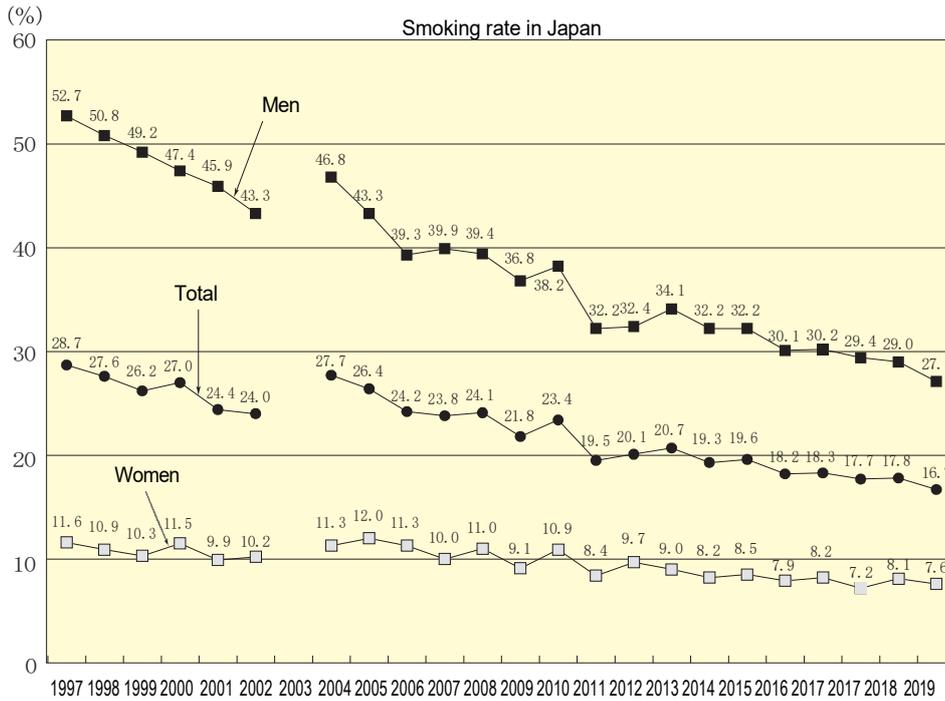


Source: "National Health and Nutrition Survey 2019", Health Service Bureau, MHLW

(Note) The figures in parentheses indicate the total intake of "bright red, green or yellow vegetables" and "other vegetables"

**Detailed Data 8**

**Smoking Rate in Japan**



Smoking rates in other countries (%)

Country	Men	Women
Japan	27.1	7.6
Germany	22.3	15.3
France	27.5	20.7
Netherlands	17.7	13.1
Italy	22.7	14.9
United Kingdom	17.7	13.8
Canada	12.0	8.7
United States	11.7	10.0
Australia	12.4	10.0
Sweden	10.1	10.6

Source: OECD Health Statics 2021

Source: "National Nutrition Survey" up to 2002 and "National Health and Nutrition Survey" from 2003 onward

(Note) Definition of smoking and survey methods differ between the National Nutrition Survey and the National Health and Nutrition Survey hence figures cannot simply be compared.

# Cardiovascular Measures

## Overview

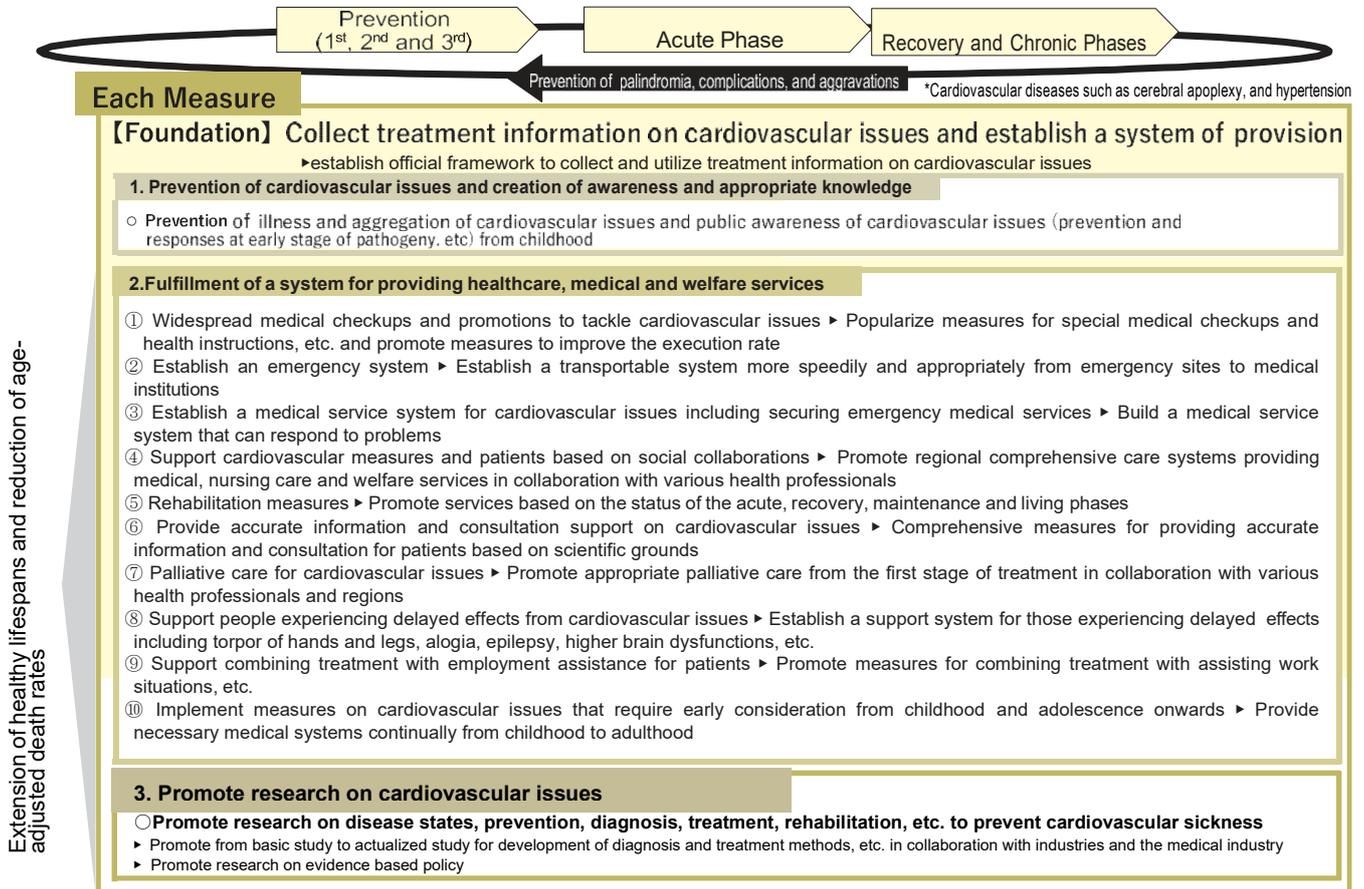
## The Basic Plan for Promoting Cardiovascular Measures

### Overall target

**Promote cardiovascular measures comprehensively** and widely from prevention, medical to welfare services targeting an over three-year **extension of healthy lifespans and a reduction of the age-adjusted death rate** by 2040 through taking the following measures: **1. Create awareness of cardiovascular prevention and accurate knowledge 2. Improve systems for health, medical, and welfare services 3. Promote research on cardiovascular issues**

For 3 years: 2020-2022

< Characters and measures of cardiovascular measures >



### Comprehensive cardiovascular measures

Strengthen collaboration and cooperation among relevant persons and design a prefectural plan and then evaluate and review basic plans

## Overview

### Basic Act on measures for treating cardiovascular diseases such as cerebral apoplexy and hypertension to extend life expectancy

Promulgation date: 14th Dec. 2018, Enforcement date: 1st Dec. 2019

#### Purpose

Based on the current situation where cardiovascular diseases such as cerebral apoplexy, hypertension, etc. are major causes of death of citizens, take measures for the prevention, etc. of cardiovascular diseases, extend the life expectancy of citizens, and reduce the burden on healthcare.

#### Overview

##### I Basic policy

- Deepen citizens' understanding and interest in the importance of preventing cardiovascular issues and implement swift and appropriate responses for patients with suspected cardiovascular issues
- Provide continuous and comprehensive services for healthcare, medical (including rehabilitation), and welfare services for cardiovascular patients irrespective of where they live
- Promote research on cardiovascular issues, provide outcomes of researches, etc. of technical improvement, develop goods utilizing those outcomes and provide them

##### II Legal measures

- The government will take legal, financial, and other actions required to implement cardiovascular measures

##### III Formation of a basic plan, etc. for the promotion of cardiovascular measures

- The government will establish a promotion committee for cardiovascular measures and set up a basic plan for the promotion of cardiovascular measures. And after at least every six years, it shall be reviewed. The prefectural governments will establish a prefectural promotion committee for cardiovascular measures and set up a prefectural basic plan for the promotion of cardiovascular measures. And after at least every six years, it shall also be reviewed.

##### IV Basic implementation

- 1) Promote the prevention of cardiovascular issues 2) Establish systems for the transport and admittance of patients with suspected cardiovascular issues 3) Improve medical institutions 4) Maintain and improve the quality of life of patients with cardiovascular issues 5) Establish collaborative systems among related institutions that provide health, medical, and welfare services 6) Foster those working in health, medical, and welfare services 7) Establish the collection and provision of information systems 8) Promote research, etc.

# Dental Health Promotion

## Overview

## 8020 (Eighty-Twenty) Campaign

### [History of 8020 (Eighty-Twenty) Campaign]

1989	A Study Group on the Dental Health Policy for Adults made public its interim report in which the "8020 (Eighty-Twenty) Campaign" calling for the retention of 20 or more teeth even at age 80 was proposed.
1991	"Promotion of 8020 Campaign" was set to be the major objective for the Dental Hygiene Week (June 4-10).
1992	"8020 Campaign promotion measure projects" were launched for dissemination and enlightenment of the 8020 Campaign (until 1996).
1993	8020 Campaign promotion support projects were launched for smooth implementation of 8020 Campaign promotion measure projects (until 1997).
1997	Municipal dental health promotion projects (menu projects) were launched.
2000	Prefecture-led "8020 Campaign promotion special projects" were launched.
2006	The results of the "Survey of Dental Diseases (2005)" were published to reveal that the percentage of persons achieving 8020 reached over 20% for the first time since the survey started.
2011	The "Dental Health Promotion Act" was approved.
2012	The "Basic Matters Related to the Promotion of Dental and Oral Health" was announced by the Minister in accordance with the "Dental Health Promotion Act". The "Health Japan 21 (second term)", which provides efforts for further advancing 8020 activities, was announced by the Minister. The results of the "Survey of Dental Diseases (2011)" were published to reveal that the percentage of persons achieving the 8020 goal exceeded 40%.
2013	The title of "Dental Hygiene Week" was changed to "Dental and Oral Health Week" and the priority objective "advancement of dental and oral health that supports the power to live – new development of 8020 Campaign throughout life –"
2017	The results of the "Survey of Dental Diseases in 2016 (Overview)" were published. Those who achieved the campaign's goal exceeded 50%.
2018	The interim evaluation of "Basic Matters Related to the Promotion of Dental and Oral Health" was compiled.

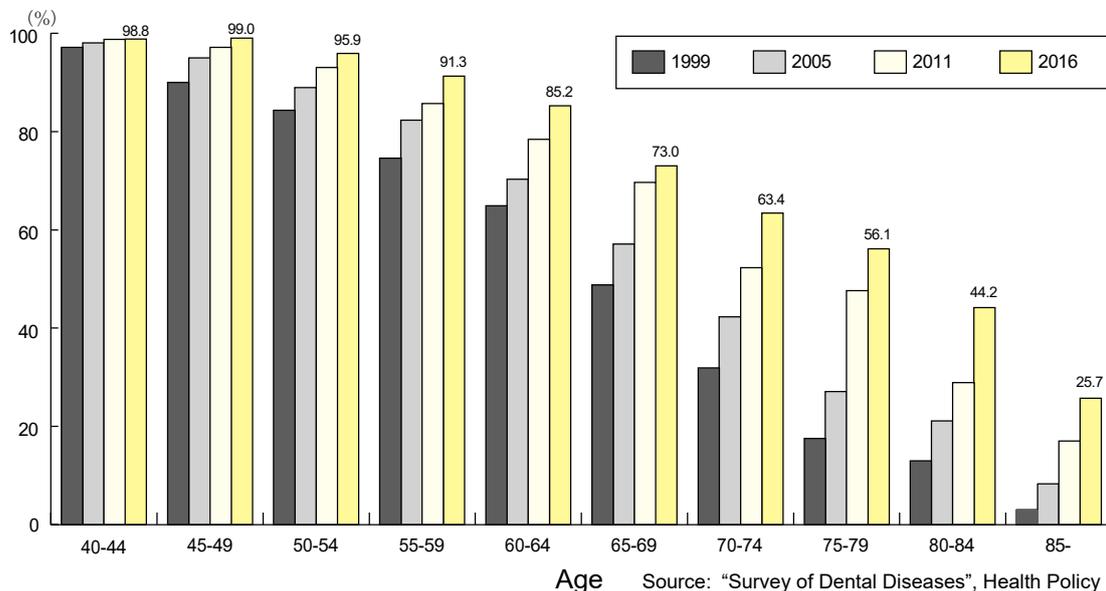
### [8020 Campaign and the "Basic Matters Related to the Promotion of Dental and Oral Health", "Health Japan 21 (second term)"]

The "Basic Matters Related to the Promotion of Dental and Oral Health" and "Health Japan 21 (second term)", announced in July 2012, mutually harmonized and provided further advancement of the "8020 Campaign". Both aim to raise the percentage of those retaining 20 or more teeth at age 80, setting the goal to reach 60% in FY 2022. Continued efforts are important to promote dental and oral health through lifelong dental health measures (8020 Campaign).

## Detailed Data

### Changes in Percentage of Persons Having 20 or More Teeth by Age Group

Year \ Age	40-44	45-49	50-54	55-59	60-64	65-69	70-74	75-79	80-85	85+
1999	97.1%	90.0%	84.3%	74.6%	64.9%	48.8%	31.9%	17.5%	13.0%	4.5%
2005	98.0	95.0	88.9	82.3	70.3	57.1	42.4	27.1	21.1	8.3
2011	98.7	97.1	93.0	85.7	78.4	69.6	52.3	47.6	28.9	17.0
2016	98.8	99.0	95.9	91.3	85.2	73.0	63.4	56.1	44.2	25.7

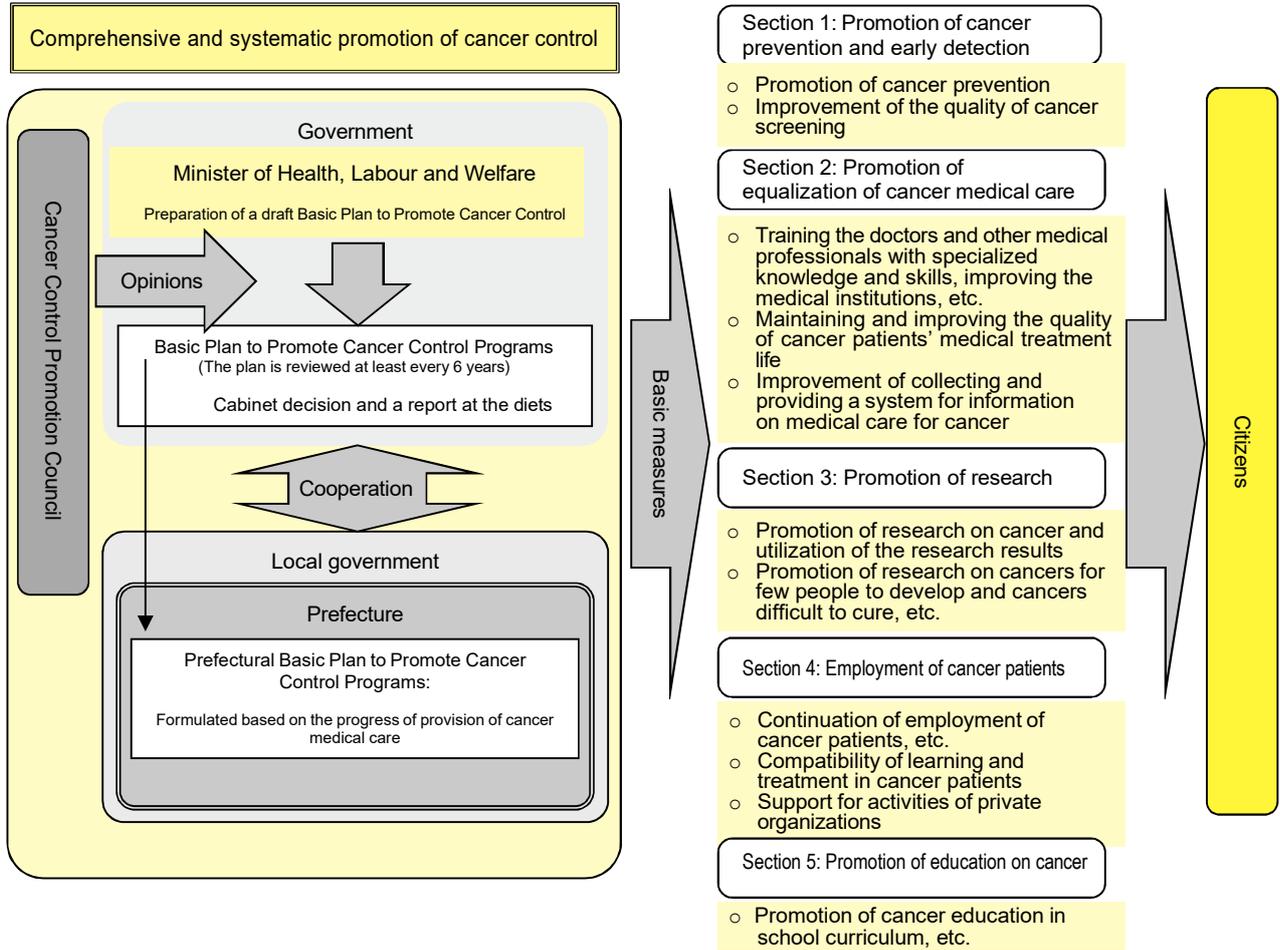


Age Source: "Survey of Dental Diseases", Health Policy Bureau, MHLW

# Cancer Control Measures

## Overview

Cancer control Act (Act No. 98 of 2006, enforced in April 2007, revised and enforced in December 2016)



## The 3rd-term Basic Plan to Promote Cancer Control Programs (Cabinet decision on March 9, 2018) \* (Outline)

### 1. Overall goal

"People, including cancer patients, learn and overcome cancer."

- ① Improvement of cancer prevention and screening based on scientific evidence ② Realization of patient-oriented cancer medicine  
③ Establishment of a society where patients can live peacefully while maintaining dignity

### 2. Measures of each section

#### 1. Cancer prevention

- (1) Primary cancer prevention
- (2) Early detection and screening of cancer (Secondary prevention)

#### 2. Improvement of cancer care

- (1) Cancer genome medicine
- (2) Surgery, radiation therapy, drug therapy, and immunotherapy for cancer.
- (3) Team medicine
- (4) Cancer rehabilitation
- (5) Supportive therapy
- (6) Rare and refractory cancers (Measures according to cancer characteristics)
- (7) Childhood cancers and cancers of AYA (\*) generation and the elderly (\*) Adolescent and Young Adult
- (8) Pathological diagnosis
- (9) Cancer registration
- (10) Efforts towards early development and approval of pharmaceuticals and medical equipment

#### 3. Coexistence with cancer

- (1) Palliative care after cancer diagnosis
- (2) Consultation support and information provision
- (3) Cancer measures and cancer patient support based on social cooperation
- (4) Social problems, including employment statuses of cancer patients
- (5) Cancer measures according to life stages

#### 4. Improvement of infrastructure to support the above

- (1) Cancer research
- (2) Human resource development
- (3) Cancer education and awareness

### 3. Comprehensive and systematic promotion of cancer measures

- |  |  |
|--|--|
| <ol style="list-style-type: none"> <li>1. Further cooperation among persons concerned</li> <li>2. Planning by prefectural governments</li> <li>3. Efforts of the people, including cancer patients</li> <li>4. Cooperation with patient organizations</li> </ol> | <ol style="list-style-type: none"> <li>5. Necessary financial measures and efficient and prioritized budgets</li> <li>6. Comprehension of goal achievements</li> <li>7. Review of basic plans</li> </ol> |
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## Outline of Cancer Registry Promotion Act

Cancer registration (Collection of information on cancer treatment by the national cancer registration or in-hospital cancer registration)

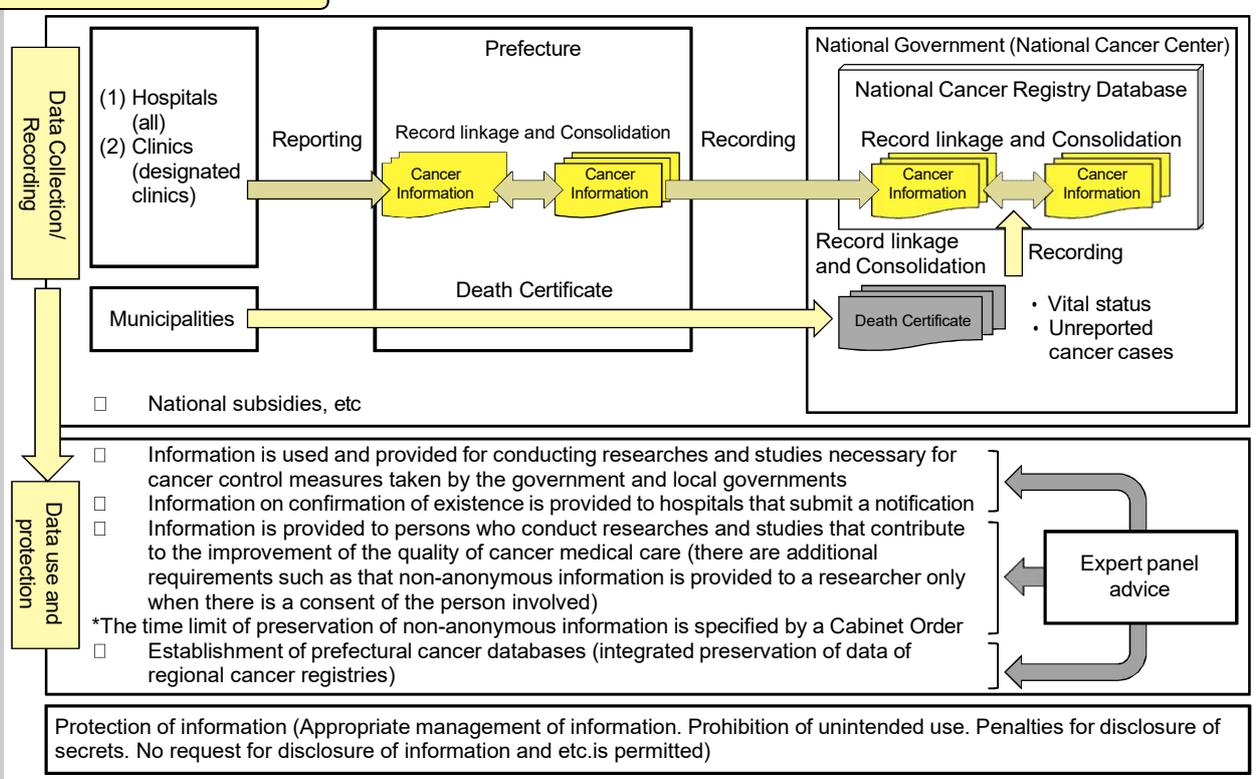
- National cancer registry: The government records and save information on cancer incidence, treatment and outcomes in Japan in a database.
- Hospital-based cancer registry: Hospitals record and preserve detailed information on cancer incidence, treatment and outcomes for the purpose of accurately keeping track of the status of cancer medical care.

➔ The measures for improvement of the quality of cancer medical care (improvement of the quality of cancer medical care and cancer screening and promotion of cancer prevention) and for enhanced provision of information on cancers, cancer medical care and their prevention to citizens and other cancer control measures are implemented based on scientific knowledge.

### Basic principles

- The national cancer registry grasps the status of cancers, treatment and outcomes as accurately as possible by means of broad information collection;
- The Hospital-based cancer registry aims to collect necessary information without fail through the national cancer registry and to disseminate and enhance such information;
- The Act aims to collect detailed information on cancer treatment with the aim of enhancing cancer control measures;
- It aims to utilize cancer registries information for researches and studies on cancers including those conducted by the private sector and to use their results for the benefit of society; and
- It aims to strictly protect individual information stored in cancer registries

### National Cancer Registry



Promotion of the hospital-based cancer registry (Promotion of the hospital-based cancer registry and system improvement for collection of information on cancer treatment)

Human resource development (Provision of necessary trainings for securing human resources who engage in administrative affairs of the national cancer registry or hospital-based cancer registry)

### Utilization of cancer registries information

- Government and prefectures⇒ Enhancement of cancer control measures, provision of information to medical institutions, disclosure of statistics and consultation services for patients
- Medical institutions⇒Provision of appropriate information to patients, analysis and evaluation of cancer medical care, improvement of the quality of cancer medical care
- Researchers who receive cancer registries information⇒Contribution to the improvement of the quality of cancer medical care

**Detailed Data**    **Statistics on Cancer**

Item	Current status	Source
Number of deaths	<p><u>Total of 381,497 persons (26.5% of all causes of death)</u>            [222,465 males (30.1% of all causes of death)]            [159,032 females (22.7% of all causes of death)]            → <u>"1 in every 3 Japanese die of cancer"</u></p>	Vital Statistics of Japan (2021 preliminary data)
Incidence rate	<p><u>980,856 persons (Not including carcinoma in situ)</u>            [558,874 males]</p> <p>Sites often affected: ① prostate, ② stomach, ③ large intestine, ④ lung, ⑤ liver</p> <p>[421,964 females]            Sites often affected: ① breast, ② large intestine, ③ lung, ④ stomach, ⑤ uterus</p>	National Cancer Registration patients' number and incidence rate Report 2018 (2018)
Lifetime risk	<p><u>Male: 65.0%, Female: 50.2%</u>            → <u>"1 in every 2 persons will contract cancer in Japan"</u></p>	Estimates by Center for Cancer Control and Information Services, National Cancer Center (2018)
Patients and persons receiving treatment	<p><u>The estimated number of patients receiving medical treatment is 1,782,000</u></p> <ul style="list-style-type: none"> <li>•The estimated number of inpatients on the dates of survey is 126,100</li> <li>•The estimated number of outpatients on the dates of survey is 183,600</li> </ul>	Patient Survey (2017)
Medical care expenditure for cancer	<p><u>¥4,153.4 billion</u>            * 13.0% of all medical care expenditures for general practice</p>	Estimates of National Medical Care Expenditure (FY 2019)

# Measures against allergic diseases

## Overview

Basic Act on Allergic Diseases Measures (enacted on December 25, 2015)

Diseases subject to this Act: Bronchial asthma, atopic dermatitis, allergic rhinitis, allergic conjunctivitis, pollinosis, food allergy

\*Although the Act provides that any disease other than the six diseases mentioned above may be specified by a Cabinet Order where necessary, there is no plan at this moment to add any disease.

### Basic principles

- (1) Improving living conditions by taking comprehensive measures.
- (2) Providing appropriate medical care for allergic diseases regardless of the location of residence.
- (3) Establishing a system by which appropriate information can be obtained and a support system to maintain and improve the quality of life.
- (4) Promoting researches on allergic diseases and disseminating, utilizing and evolving their achievements.

### Basic Guidelines for Promotion of Control Measures for Allergic Diseases

- The Minister of Health, Labour and Welfare shall formulate the Basic Guidelines for the purpose of comprehensively promoting measures against allergic diseases
- Basic matters concerning the promotion of measures against allergic diseases
- Matters concerning measures for raising awareness and disseminating knowledge about allergic diseases and for prevention thereof
- Matters concerning the securing of systems to provide medical care for allergic diseases
- Matters concerning researches and studies on allergic diseases
- Other important matters concerning the promotion of measures against allergic diseases

### Ministry of Health, Labour and Welfare

#### Allergic Disease Control Promotion Council

- The Council expresses its opinions when the Basic Guidelines for Measures against Allergic Diseases are formulated or changed
- Its members are appointed by the Minister of Health, Labour and Welfare

#### (Members)

- Patients and their representatives
- Persons who involve in medical care for allergic diseases
- Persons who have academic experience

\*Matters necessary for the organization and operation of the Council are provided for by a Cabinet Order

# Measures against Hepatitis

## Overview

## Basic Act on Hepatitis Measures

Basic Act on Hepatitis Measures (Act No.97 of 2009)

Comprehensive formulation/enforcement of measures against hepatitis

- To stipulate basic principles for measures against hepatitis;
- To clearly responsibilities of the government local government s, medical insures, citizens, and doctors, etc.;
- To formulate guidelines concerning promotion of measures against hepatitis, and
- To comprehensively promote measures against hepatitis by stipulating basic articles for them

### Basic measures

#### Promotion of prevention and early detection

- Prevention of hepatitis
- Quality improvement of hepatitis examinations, etc.

Research promotion

#### Promotion of equalization of medical services for hepatitis patients, etc.

- Training of doctors and other medical professionals to acquire the expertise
- Establishment and improvement of medical institutions
- Financial support for medical care expenses on hepatitis patients
- Securing opportunities for hepatitis care
- Establishment and improvement of system for collecting and proving information on hepatitis care, etc.

Measures must be taken with careful consideration given to the human rights of patients and elimination of discrimination against them

### Formulation of basic measures against hepatitis

#### The Council for Promotion of Hepatitis Measures

- Representatives of hepatitis patients, etc. Advice
- The medical profession engaged in hepatitis care
- Persons with relevant knowledge and experience

Relevant administrative organizations

Establish



Request for documents, etc.



Minister of Health, Labour and Welfare

Formulation

#### Basic measures against hepatitis

- Announcement
- Revises at least every 5 years
- Revise if necessary

#### Response to cirrhosis and liver cancer

- Creation of an environment for improved treatment level

- Support for patients with severe cirrhosis and liver cancer

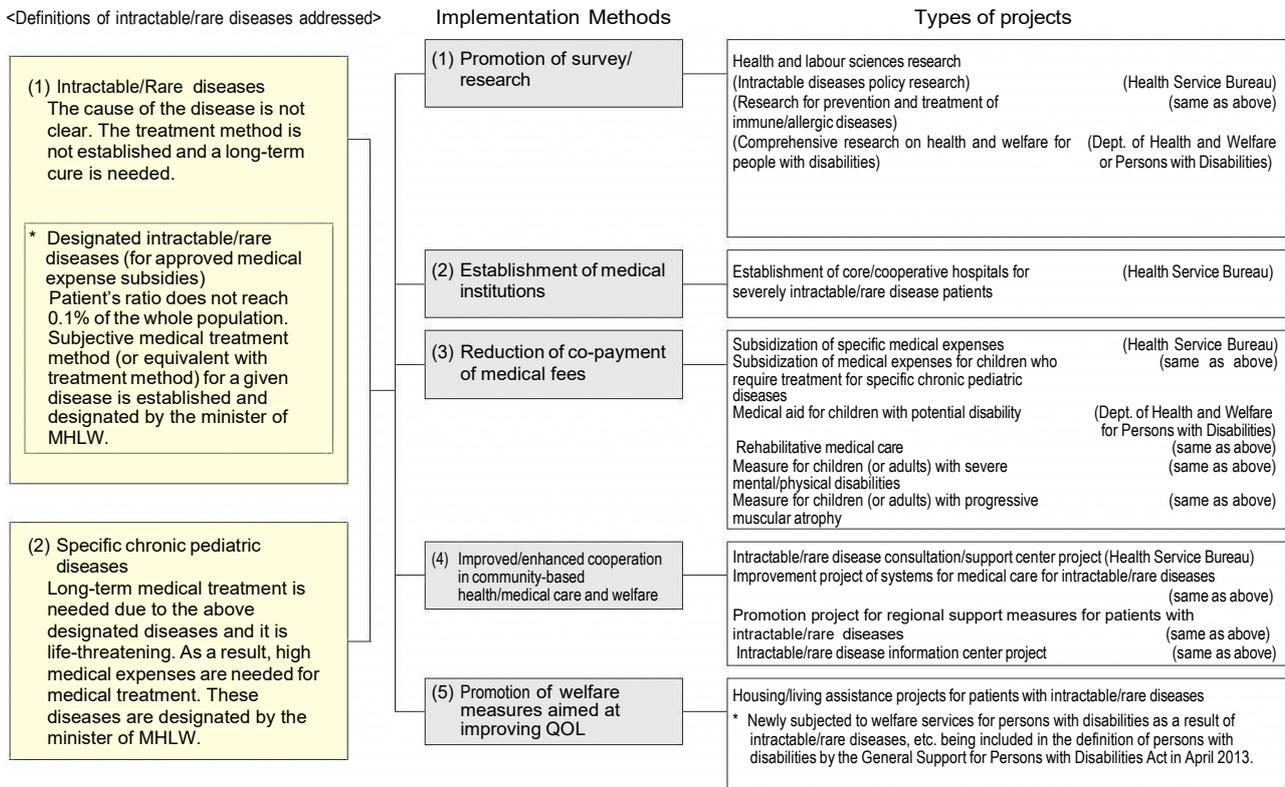
<p><b>1 The basic direction to take in promoting the prevention of hepatitis and hepatitis-related medical care</b></p> <ul style="list-style-type: none"> <li>○ Aiming to reduce the number of hepatitis B patients who develop liver cirrhosis or liver cancer by achieving a complete cure for hepatitis and setting a target for the reduction in such patients while using the prevalence of liver cancer as an indicator</li> </ul>	<p><b>6 Matters concerning surveys and research on hepatitis</b></p> <ul style="list-style-type: none"> <li>○ To evaluate and verify research achievements comprehensively, and promote hepatitis research as the basis for comprehensive promotion of measures against hepatitis so that the past achievements can be appropriately reflected on such measures</li> </ul>
<p><b>2 Matters concerning measures to take in preventing hepatitis</b></p> <ul style="list-style-type: none"> <li>○ Necessary to disseminate correct knowledge about hepatitis to prevent new infections</li> <li>○ To promote measures to prevent mother-to-child transmission of hepatitis B virus and continue promoting periodic hepatitis B vaccination and interferon-free treatment</li> </ul>	<p><b>7 Matters concerning promotion of research and development of medicine to use hepatitis-related medical care</b></p> <ul style="list-style-type: none"> <li>○ Necessary to proceed with research and development of hepatitis medicine-related new medicines, including medicines related to treatment of hepatitis B, cirrhosis and liver cancer and make a prompt review of clinical trials and research in light of recent trends concerning hepatitis medicine</li> </ul>
<p><b>3 Matters concerning improvement of a system to use implementing hepatitis examinations and their capabilities</b></p> <ul style="list-style-type: none"> <li>○ To inform all citizens that they need to receive hepatitis virus test at least once</li> <li>○ To continue to develop a system that allows for examination of the hepatitis virus tests with due consideration to the convenience of people who got tested and their privacy in the workplace.</li> <li>○ To make such efforts that a hepatitis virus test can be carried out together with a medical examination, while making the concerned parties understand, such as medical insurers and employers.</li> </ul>	<p><b>8 Matters concerning public awareness and dissemination of information concerning hepatitis is and matters concerning respect for the human rights of hepatitis patients, etc.</b></p> <ul style="list-style-type: none"> <li>○ Necessary to disseminate information and enlighten people to promote receipt of hepatitis virus tests, prevent new infections, discontinue unfair discrimination against hepatitis patients, protect their human rights, and create an environment where people can live a secure social life</li> </ul>
<p><b>4 Matters concerning securing of a system to use providing hepatitis-related medical care</b></p> <ul style="list-style-type: none"> <li>○ Necessary to further develop the regional hepatitis clinical care network so that all hepatitis patients can receive continuous and appropriate hepatitis medicine.</li> <li>○ To make further efforts for increase of hepatitis virus inspection and follow-up after the inspection</li> <li>○ Necessary to enlighten stakeholders such as business operators and get their understanding and cooperation so that the employees can receive medical treatment continuously while continuing to work</li> </ul>	<p><b>9 Other important matters concerning the promotion of hepatitis measures</b></p> <ul style="list-style-type: none"> <li>○ To strengthen and enhance support for hepatitis patients and their families, etc.</li> <li>○ To discuss strategies to push for a project to promote research on treatment of liver cancer and severe liver cirrhosis based on the implementation status of the project including how to inform the public about the effective use of the project</li> <li>○ To require the national government to urge the local governments to make a plan and set a target concerning measures against hepatitis after consultation with the stakeholders based on the actual circumstances in the community</li> <li>○ To request each citizen to confirm his/her own hepatitis virus infection, have proper knowledge about the possibility of infection, act appropriately to prevent new infection, acquire correct knowledge and make efforts for responding appropriately not to cause discrimination against hepatitis patients, etc.</li> </ul>
<p><b>5 Matters concerning prevention of hepatitis and human resource development for hepatitis medical care</b></p> <ul style="list-style-type: none"> <li>○ To develop human resources with knowledge about the prevention of hepatitis infection and those capable of helping people who have tested positive for hepatitis receive appropriate treatment, such as hepatitis medical coordinators and promote opportunities to make the best use of their skills and knowledge</li> </ul>	

# Intractable/Rare Disease Measures

## Overview Outline of Intractable/Rare Disease Measures

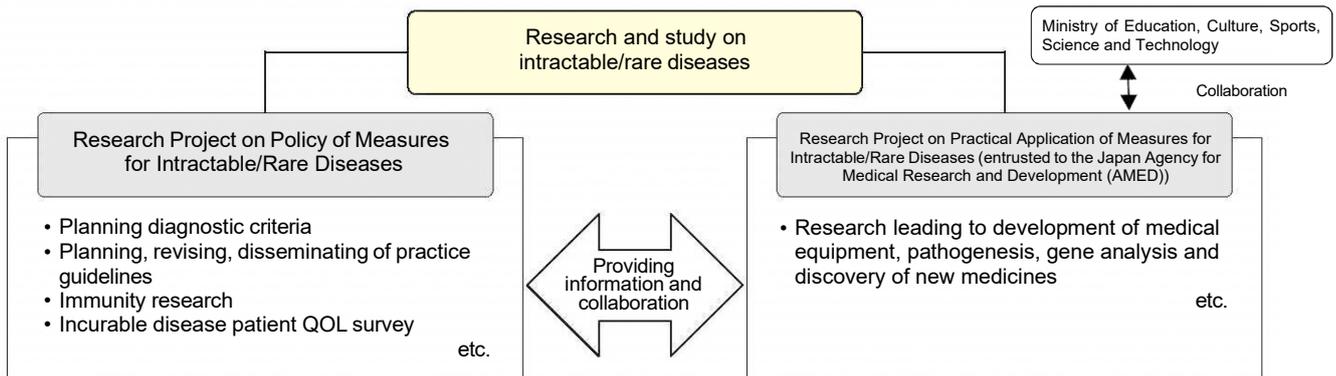
Various projects have been implemented based on Act on Medical Care and Social Supports for Patients with Intractable/Rare Diseases

<Definitions of intractable/rare diseases addressed>



## Intractable Diseases Policy Research Program

In order to comprehensively and strategically conduct researches on intractable/rare diseases, the project makes use of the nationwide database to specify epidemiology and pathogenesis, develop new cure methods and conduct researches with the use of regenerative medical techniques as well as promotes researches and studies integrated with the policies for intractable/rare diseases.



## Detailed Data Designated intractable/rare diseases

No.	Disease Name	No.	Disease Name	No.	Disease Name
1	Spinobulbar muscular atrophy	103	CFC syndrome	205	Fragile X syndrome related disease
2	Amyotrophic lateral sclerosis	104	Costello syndrome	206	Fragile X syndrome
3	Myelopathic muscular atrophy	105	ChARGE syndrome	207	Tmc/Art.: truncus arteriosus
4	Primary lateral sclerosis	106	Cryopyrin associated periodic fever syndrome	208	Corrected TGA
5	Progressive supranuclear palsy	107	Systemic-onset juvenile idiopathic arthritis	209	TGA
6	Parkinson's disease	108	TNF receptor associated periodic syndrome	210	Single ventricle
7	Corticobasal degeneration	109	Atypical hemolytic uremic syndrome	211	Hypoplastic left heart syndrome
8	Huntington disease	110	Blau syndrome	212	Tricuspid atresia
9	Neuroacanthocytosis	111	Congenital myopathy	213	Pulmonary atresia with intact ventricular septum
10	Charcot-Marie-Tooth disease	112	Marinesco – Sjogren's syndrome	214	Pulmonary atresia with ventricular septal defect
11	Myasthenia gravis	113	Muscular dystrophy	215	Tetralogy of Fallot
12	Congenital myasthenic syndrome	114	Non- dystrophic myotonia syndrome	216	Double outlet right ventricle (DORV)
13	Multiple sclerosis / Optic neuromyelitis	115	Hereditary periodic paralysis	217	Ebstein disease
14	Chronic inflammatory demyelinating polyradiculo neuropathy/Multifocal motor neuropathy	116	Atopic myelitis	218	Alport's syndrome
15	Inclusion body myositis	117	Syringomyelia	219	Galloway-Mowat syndrome
16	Crow-Fukase syndrome	118	Myelomeningocele	220	Rapidly progressive glomerulonephritis
17	Multiple-system atrophy	119	Isaacs syndrome	221	Anti-glomerular basement membrane disease
18	Spinocerebellar degeneration (except multiple-system atrophy)	120	Hereditary dystonia	222	Primary Nephrotic syndrome
19	Lysosomal storage disease	121	Nerve ferritin disease	223	Primary membranoproliferative glomerulonephritis
20	Adrenoleukodystrophy	122	Brain table hemosiderosis	224	Purpura nephritis
21	Mitochondrial diseases	123	Autosomal recessive leukoencephalopathy with baldness and degenerative spondylosis	225	Congenital nephrogenic diabetes insipidus
22	Moyamoya disease	124	Autosomal dominant cerebral artery disease with subcortical infarct and leukoencephalopathy	226	Interstitial cystitis
23	Prion disease	125	Autosomal dominant cerebral arteriopathy with subcortical infarction and leukoencephalopathy	227	Osler disease
24	Subacute sclerosing panencephalitis	126	Perry syndrome	228	Obliterating bronchiolitis
25	Progressive multifocal leukoencephalopathy	127	Frontotemporal lobar degeneration	229	Pulmonary proteinosis (autoimmunity/hereditary)
26	HTLV-1-associated myelopathy	128	Vickers staff brainstem encephalitis	230	Alveolar hypoventilation syndrome
27	Idiopathic basal ganglia calcification diseases	129	Epilepticus type (biphasic) acute encephalopathy	231	α1-antitrypsin deficiency
28	Systemic amyloidosis	130	Congenital insensitivity to pain with anhidrosis	232	Camey complex
29	Ulrich disease	131	Alexander disease	233	Wolfram syndrome
30	Distal muscular dystrophy	132	Congenital supranuclear palsy	234	Peroxisomal disease (excluding adrenoleukodystrophy)
31	Beth Rem myopathy	133	Moebius syndrome	235	Accessory thyroid hyperplasia disease
32	Autophagic vacuolar myopathy	134	Nervous system malformation/De Morsier syndrome	236	Pseudohypoparathyroidism
33	Schwarz Yanperu syndrome	135	Aicardi syndrome	237	Adrenocorticotrophic hormone insensitivity
34	Neurofibromatosis	136	Hemimegalencephaly	238	Vitamin D-resistant rickets/osteomalacia
35	Pemphigus	137	Focal cortical dysplasia	239	Vitamin D-dependent rickets/osteomalacia
36	Epidermolysis bullosa	138	Nerve cell migration disorder	240	Phenylketonuria
37	Pustular psoriasis (universal)	139	Congenital cerebral white matter aplasia	241	High tyrosinemia type 1
38	Stevens-Jonson syndrome	140	Dorabie syndrome	242	High tyrosinemia type 2
39	Toxic epidermal necrosis	141	Medial temporal lobe epilepsy with hippocampal sclerosis	243	High tyrosinemia type 3
40	Takayasu's disease	142	Myoclonic epilepsy absences	244	Maple syrup urine disease (MSUD)
41	Giant cell arthritis	143	Epilepsy with myoclonic cataplexy	245	Propionic acidemia
42	Polyarteritis nodosa	144	Lennox-Gastaut syndrome	246	Methylmalonic acidemia
43	Microscopic polyangiitis	145	West syndrome	247	Isovaleric acidemia
44	Multiple vasculitis granulomatous disease	146	Otawara syndrome	248	Glucose transporter 1 deficiency
45	Eosinophilic multiple vasculitis granulomatous disease	147	Early myoclonic encephalopathy	249	Glutaric acidemia type 1
46	Malignant rheumatoid arthritis	148	Infant epilepsy with migratory focus seizure	250	Glutaric acidemia type 2
47	Buerger's disease	149	One side convulsion, hemiplegia – epilepsy syndrome	251	Urea cycle disorders
48	Primary antiphospholipid antibody syndrome	150	Ring chromosome 20 syndrome	252	Lysinuric protein intolerance
49	Systemic lupus erythematosus	151	Rasmussen's encephalitis	253	Congenital malabsorption of folate
50	Dermatomyositis / polymyositis	152	PCDH19 related syndrome	254	Porphyria
51	Systemic scleroderma	153	Refractory frequent partial seizures in infancy/acute encephalitis	255	Multiple carboxylase deficiency
52	Mixed connective tissue disease	154	Epilepsy with continuous spikes and waves during slow sleep (CSWD)	256	Muscle type glycogen storage disease
53	Sjogren's syndrome	155	Landau-Kleffner syndrome	257	Glycogen storage disease
54	Adult-onset Still's disease	156	Rett syndrome	258	Galactose-1 – phosphate uridylyltransferase deficiency
55	Relapsing polychondritis	157	Sturge-Weber syndrome	259	Leucithin-cholesterol acyltransferase deficiency
56	Bechet's disease	158	Tuberous sclerosis	260	Sitosterolemia
57	Idiopathic dilated cardiomyopathy	159	Xeroderma	261	Tangier disease
58	Hypertrophic cardiomyopathy	160	Congenital ichthyosis	262	Primary hyperlipidemia
59	Constrictive cardiomyopathy	161	Familial benign chronic pemphigus	263	Cerebrotendinous xanthomatosis
60	Aplastic anaemia	162	Pemphigoid (including acquired epidermolysis bullosa)	264	Abeta-lipoproteinemia
61	Autoimmune hemolytic anemia	163	Idiopathic acquired systemic anhidrosis	265	Lipodystrophy
62	Paroxysmal nocturnal	164	Oculocutaneous albinism	266	Familial Mediterranean fever
63	Idiopathic thrombocytopenic purpura	165	Pachydermoperiostosis syndrome	267	Hyper-IgD syndrome
64	Thrombotic thrombocytopenic purpura	166	Pseudoxanthoma elasticum	268	Nakajo-nisumura syndrome
65	Primary immunodeficiency syndrome	167	Marfan syndrome	269	Purulent gonitis • pyoderma gangrenosum • hirsutism syndrome
66	IgA nephropathy	168	Ehlers-Danlos syndrome	270	Chronic nonbacterial osteomyelitis
67	Polycystic kidney	169	Menkes disease	271	Spondylarthritis ankylopoietica
68	Ossification of the ligamentum flavum	170	Okushitaru horn syndrome	272	Fibrodysplasia ossificans progressive
69	Ossification of the posterior longitudinal ligament	171	Wilson's disease	273	Congenital scoliosis with rib anomaly
70	Extensive spinal canal stenosis	172	Hypophosphatasia	274	Osteogenesis imperfecta
71	Idiopathic femoral head necrosis	173	VATER syndrome	275	Thanatophoric dysplasia
72	Pituitary ADH secretion disorders	174	Nasu-Hakola disease	276	Achondroplasia
73	Pituitary TSH secretion hyperthyroidism	175	Weaver's syndrome	277	Lymphangiomatosis/gorham's disease
74	Pituitary PRL secretion hyperthyroidism	176	Coffin-Lowry syndrome	278	Huge lymphatic malformation (cervicofacial lesion)
75	Cushing's disease	177	Arima syndrome	279	Huge venous malformation (neck oropharyngeal diffuse lesion)
76	Pituitary gonadotropin secretion hyperthyroidism	178	Mowat - Wilson syndrome	280	Huge arteriovenous malformation (cervicofacial or limb lesion)
77	Pituitary growth hormone secretion hyperthyroidism	179	Williams' syndrome	281	Klippel-Trenaunay-Weber syndrome
78	Anterior pituitary hypothyroidism	180	ATR-X syndrome	282	Congenital thropoietic anemia
79	Familial hypercholesterolemia (homozygus)	181	Crouzon syndrome	283	Acquired pure red cell aplasia
80	Thyroid hormone insensitivity syndrome	182	Apert syndrome	284	Diamond-blackfan anemia
81	Congenital adrenal cortex enzyme deficiency	183	Pheiffer syndrome	285	Fanconi anemia
82	Congenital adrenal hypoplasia	184	Anley-Bløker syndrome	286	Hereditary sideroblastic anemia
83	Addison's disease	185	Coffin Siris syndrome	287	Epstein-Barr virus
84	Sarcoidosis	186	Trothmund-Thomson syndrome	288	Autoimmune hemorrhaphilia XIII
85	Idiopathic interstitial pneumonia	187	Kabuki syndrome	289	CronWhite-Canada syndrome
86	Pulmonary arterial hypertension	188	Polysplenia syndrome	290	Chronic nonspecific multiple ulcers of the small intestine
87	Pulmonary venous obstruction/pulmonary capillary hemangiomatosis	189	Asplenia syndrome	291	Hirschsprung disease (entire colon type or small intestine type)
88	Chronic thromboembolic pulmonary hypertension	190	Branchio-oto-renal syndrome	292	Cloacal extrophy
89	Lymphangiomeleom yomatosis	191	Werner's syndrome	293	Persistent cloaca
90	Retinitis pigmentosa	192	Cockayne's syndrome	294	Congenital diaphragmatic hernia
91	Bad chian syndrome	193	Prader-Willi syndrome	295	Infant giant liver hemangioma
92	Idiopathic portal hypertension	194	Sotos' syndrome	296	Biliary atresia
93	Primary biliary cirrhosis	195	Noonan's syndrome	297	Alagille syndrome
94	Primary sclerosing cholangitis	196	Young Simpson's syndrome	298	Hereditary pancreatitis syndrome
95	Autoimmune hepatitis	197	1p36 deletion syndrome	299	Cystic fibrosis
96	Crohn's disease	198	4p syndrome	300	IgG4-related disease
97	Ulcerative colitis	199	Spy syndrome	301	Heredomacular dystrophy
98	Eosinophilic gastrointestinal disease	200	No. 14 chromosome father disomy syndrome	302	Leber's hereditary optic neuropathy
99	Chronic idiopathic pseudo-bowel obstruction	201	Angelman syndrome 303	303	Ascher syndrome
100	Huge bladder short and small colon intestinal peristalsis deficiency	202	Smith-Magenis syndrome	304	Juvenile-onset bilateral sensorineural hearing loss
101	Intestinal ganglion cells insignificant disease	203	22q11.2 deletion syndrome	305	Delayed endolympathic hydrops
102	Rubinstein - Teibi syndrome	204	Emanuel syndrome	306	eosinophilic sinusitis

## Detailed Data Designated intractable/rare diseases

No.	Disease Name
307	Canavan disease
308	Progressive leukoencephalopathy
309	Progressive myoclonic epilepsy
310	Congenital syndrome
311	Congenital tricuspid stenosis
312	Congenital mitral valve stenosis
313	Congenital pulmonary vein stenosis
314	Left pulmonary artery right pulmonary artery intillation
315	Nail Patella syndrome/LMX 1 B-related nephropathy
316	Carnitine circuit disorder
317	Triple enzyme deficiency
318	Citrin deficiency
319	Sepiapterin reductase (SR) deficiency
320	Congenital glycosylphosphatidylinositol (GPI) deficiency
321	Nonketotic hyperglycinemia
322	$\beta$ -ketothiolase deficiency
323	Aromatic L-amino acid decarboxylase deficiency
324	Methyl glutamic nuria
325	Hereditary autoinflammatory disease
326	Marble bone disease
327	Idiopathic thrombosis (limited to those due to hereditary thrombophilia)
328	Anomalous anterior segment formation
329	Anindia
330	Congenital tracheal stenosis / Congenital subglottic stenosis
331	Idiopathic multicentric Castleman disease
332	Gelatinous drop-like corneal dystrophy
333	Hutchinson — Gifford syndrome
334	Cerebral creatine deficiency syndromes
335	Nephronophthisis
336	Familial hypobetalipoproteinemia-1 (homozygote)
337	Homocystinuria
338	Progressive familial intrahepatic cholestasis

# Infectious Disease Measures

## Overview

Outline of the Act on Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases

(Approved on September 28, 1998 and enforced on April 1, 1999)

### Preventive administrative measures against outbreak and spread of infectious diseases

- Development and establishment of the surveillance system for infectious diseases
- Promotion of comprehensive nationwide and prefectural measures (in order to facilitate cooperation of related parties, basic guidelines to prevent infectious diseases are formulated and announced by the government, and the prevention plans by the prefectural governments)
- Formulation of guidelines to prevent specific infectious diseases, including influenza, sexually transmitted diseases, AIDS, tuberculosis, measles rubella and mosquito-borne infectious diseases (the government formulates and announces guidelines to investigate causes, prevent outbreak and spread, provide medical care services, promote research and development, and obtain international cooperation for the diseases that particularly require comprehensive preventive measures)

### Types of infectious diseases and medical care system

Type of infectious disease	Key measures	Medical care system	Medical fee payment
New infectious diseases	Hospitalization	Designated medical institutions for specific infectious disease (several in number nationwide designated by the government)	Publicly funded in full (no insurance applied)
Type 1 (Plague, Ebola hemorrhagic fever, South American hemorrhagic fever, etc.)		Designated medical institutions for Type 1 infectious disease [1 hospital in each prefecture designated by prefectural governors]	Medical insurance applied with public funds (for hospitalization)
Type 2 (Avian influenza (H5N1, H7N9), Tuberculosis, MERS, etc)		Designated medical institutions for Type 2 infectious disease [1 hospital in each secondary medical service area designated by prefectural governors]	
Type 3 (Cholera, Enterohemorrhagic Escherichia coli infection, etc.)	Work restriction in certain jobs	General medical institutions	Medical insurance applied (partial cost sharing)
Type 4 (Avian influenza (excluding H5N1, H7N9), Zika virus infection, etc.)	Sterilization and other objective measures	General medical institutions	Medical insurance applied (partial cost sharing)
Type 5 (Influenza (excluding avian influenza and novel influenza infection, etc.), AIDS, viral hepatitis (excluding hepatitis E and hepatitis A), etc.)	Identification of the situation with infection and information provision	General medical institutions	Medical insurance applied (partial cost sharing)
Novel influenza infection, etc.	Hospitalization	Designated medical institutions for specific/Type 1/Type 2 infectious disease	Medical insurance applied with public funds (for hospitalization)

\* Infectious diseases other than Type 1, 2, or 3 infectious diseases requiring emergency measures are designated as "designated infectious diseases" in Cabinet Order and are treated the same as Type 1, 2, and 3 infectious diseases for a limited period of 1 year in principle.

### Development of hospitalization procedures respecting patients' human rights

- Work restriction and hospitalization according to the type of infectious disease
- Introduction of a system to recommend hospitalization based on patients' decisions
- Hospitalization up to 72 hours by orders of prefectural governors (directors of health centers)
- Hospitalization for every 10 days (30 days for tuberculosis) with hearing opinions from the council for infectious disease examination established in health centers
- Reporting of complaints on conditions of hospitalization to prefectural governors
- Provision of special cases to make decisions within 5 days against the request for administrative appeal from the patients who are hospitalized for more than 30 days
- In the event of emergency, the government should be responsible for providing necessary guidance to prefectural governments on hospitalization of patients.

### Development of measures, including sufficient sterilization to prevent infectious diseases from spreading

- Sterilization to prevent Type 1, 2, 3, and 4 infectious diseases and pandemic influenza from spreading
- Restricting entry to buildings to prevent Type 1 infectious diseases from spreading
- In the event of emergency, the government should be responsible for providing necessary guidance to prefectural governments on sterilization and other measures.

#### Development of countermeasures against zoonoses



- Prohibition of the import of monkeys, masked palm civets, bats, African soft-furred rats, prairie dogs, etc.
- Establishment of the import quarantine system for monkeys from designated exporting countries
- Designation of 11 diseases, including Ebola hemorrhagic fever, etc., as subjects of notification obligation for veterinarians
- "Notification System for the Importation of Animals" to require importers of living mammals and birds, and carcasses of rodents and Lagomorpha to report necessary information to the Minister of Health, Labour and Welfare (quarantine station) along with a health certificate issued by government authorities of the exporting countries

#### Development of regulation on possession of pathogens, etc.



- Regulation through enforcement of standards of prohibition, permission, notification, and facilities according to the classification of Type 1, 2, 3, and 4 pathogens, etc.
- Establishment of standards on facilities according to the types of pathogens, etc.
- Development of regulations on prevention of infectious disease outbreaks, selection of persons in charge of handling pathogens, and obligation for the owners to notify the transportation of pathogens, etc.
- Supervision by the Minister of Health, Labour and Welfare on facilities handling pathogens, including on-site investigation of the facilities and orders of corrective measures for sterilization/transfer methods, etc.

#### Development of measures against novel influenza



- Implementation of measures, including hospitalization, etc. and enabling measures equivalent to those for Type 1 infectious diseases to be taken by Cabinet Order
- Request for persons possibly infected to report health status and abstain from going out
- Disclosure of information regarding outbreak and measures to be taken, etc.
- Report on progress from prefectural governors
- Enhancement of cooperation between prefectural governors and directors of Quarantine Stations

#### Prepare countermeasures in COVID-19



- Place COVID-19 as a 'new influenza, etc. infection' and enable to take measures for those infected
- Make compulsory on reporting health conditions for those who are expected to be infected
- Ensure viability on admission, accommodation treatment, home treatment and proactive epidemiological study
- Strengthen information collaboration among countries and local authorities
- Governmental or Prefectural request for collaboration from medical personnel (including medical institutes) and test institutes during emergencies
- Comprehensive arrangement by Prefectural Governors on admission, etc.

# Immunization

## Overview

## Diseases and Persons Subjected to Routine Vaccination

Diseases	Persons subjected to vaccination
Diphtheria	1. Those aged 3 months or older but younger than 90 months 2. Those aged 11 years or older but younger than 13 years
Pertussis	Those aged 3 months or older but younger than 90 months
Polio (acute myelitis)	Those aged 3 months or older but younger than 90 months
Measles	1. Those aged 12 months or older but younger than 24 months 2. Those aged 5 years or older but younger than 7 years who are in the period between 1 year before entering elementary school and the date of entering school
Rubella	1. Those aged 12 months or older but younger than 24 months 2. Those aged 5 years or older but younger than 7 years who are in the period between 1 year before entering elementary school and the date of entering school
Japanese encephalitis	1. Those aged 6 months or older but younger than 90 months 2. Those aged 9 years or older but younger than 13 years
Tetanus	1. Those aged 3 months or older but younger than 90 months 2. Those aged 11 years or older but younger than 13 years
Tuberculosis	Those younger than 1 year old
Hib infection (Haemophilus influenzae type B)	Those aged 2 months or older but younger than 60 months
Pneumococcal infectious disease (limited to one that is of infants)	Those aged 2 months or older but younger than 60 months
Varicella	Those aged 12 months or older but younger than 36 months
Hepatitis B	Those younger than 1 year old
Human papillomavirus infection	Females who are in the period between the first day of the fiscal year in which they turn 12 years old and the last day of the fiscal year in which they turn 16 years old
Rotavirus infection disease	1 titer: From 6 weeks to 24 weeks after birth 5 titer: From 6 weeks to 32 weeks after birth
Influenza	1. Those aged 65 years or older 2. Those aged 60 years or older but younger than 65 years suffering from cardiac, renal, or respiratory disorders, etc.
Pneumococcal infectious disease (limited to one that is of the elderly)	1. Those aged 65 years 2. Those aged 60 years or older but younger than 65 years suffering from cardiac, renal, or respiratory disorders, etc.

\* 1 Men born between April 2, 1962 and April 1, 1979 can receive routine rubella vaccinations until March 31, 2025.

\* 2 Persons born between April 2, 1995 and April 1, 2007 can receive routine Japanese encephalitis vaccinations before they reach the age of 20.

\* 3 Women born between April 2, 1997 and April 1, 2008 can receive routine HPV vaccinations until March 31, 2025.

## Detailed Data

## Benefits type and Amount of Relief System for Injury to Health with Vaccination

(As of April 1, 2022)

Routine and temporary vaccinations against category A diseases Temporary vaccination against category B diseases			Routine vaccination against category B diseases		
Benefit type	Qualification	Details and amount of benefit	Benefit type	Qualification	Details and amount of benefit
Subsidy for medical care expenses	Recipients of medical services due to illness caused by vaccination	Amount equivalent to co-payment calculated based on the case of health insurance	Subsidy for medical care expenses	Recipients of medical services due to illness caused by vaccination	Amount equivalent to co-payment calculated based on the case of health insurance
Medical allowance	Same as above	Inpatient: 8 days or more per month: (month) ¥36,900 Inpatient: less than 8 days per month: (month) ¥34,900 Outpatient: 3 days or more per month: (month) ¥36,900 Outpatient: less than 3 days per month: (month) ¥34,900 Inpatient and outpatient treatment within the same month: (month) ¥36,900	Medical allowance	Same as above	Inpatient: 8 days or more per month: (month) ¥36,900 Inpatient: less than 8 days per month: (month) ¥34,900 Outpatient: 3 days or more per month: (month) ¥36,900 Outpatient: less than 3 days per month: (month) ¥34,900 Inpatient and outpatient treatment within the same month: (month) ¥36,900
Pension for rearing children with disabilities	Fosterers of children younger than 18 with certain disabilities caused by vaccination	Class 1: (annual) ¥1,579,200 (additional amount for long-term care):(annual) ¥844,300 Class 2: (annual) ¥1,263,600 (additional amount for long-term care):(annual) ¥562,900	Disability Pension	Those aged 18 or older with certain disabilities caused by vaccination	Class 1: (annual) ¥2,804,400 Class 2: (annual) ¥2,244,000
Disability Pension	Those aged 18 or older with certain disabilities caused by vaccination	Class 1: (annual) ¥5,048,400 (additional amount for long-term care):(annual) ¥844,300 Class 2: (annual) ¥4,039,200 (additional amount for long-term care):(annual) ¥562,900 Class 3: (annual) ¥3,028,800	Survivors' Pension	The bereaved will be beneficiary in case the deceased who died from vaccination was the main wage earner of the family (Pension shall be paid up to 10 years)	(annual) ¥2,452,800
Lump-sum death benefit	The bereaved of the person who died of diseases caused by vaccination	¥44,200,000	Lump-sum benefit for survivors	The bereaved will be beneficiary in case the deceased who died from vaccination was not the main wage earner of the family	¥7,358,400
Funeral allowance	Hosts of funerals for those who died of diseases caused by vaccination	¥212,000	Funeral allowance	Hosts of funerals for those who died of illness caused by vaccination	¥212,000

\* The medical care covered by the benefits of the medical expenses and medical allowances for Category B disease shall be the medical care required when it is deemed necessary to be admitted to a hospital or clinic.

\* Deadline for claiming a health problem in category B diseases

(Note) 1. The term of claims for subsidy for medical care expenses and medical allowance shall be within 5 years after the payment of the expenses eligible for the benefits.

2. The deadline for claiming medical allowance shall be five years from the first day of the month following the month in which the medical treatment date for such claim belongs.

3. The term of claims for Survivors' Pension and lump-sum benefit for survivors shall be within 2 years from the death of the deceased who died from vaccination for the cases where the deceased was paid with subsidy for medical care expenses, medical allowance, or Disability Pension for his/her complications or disabilities while he/she was alive, or within 5 years from the death for other cases.

## Tuberculosis Measures

### Overview Outline of Tuberculosis Prevention Measures

- A. Regular physical checkups (tuberculin test, X-ray test, etc.) ————— Elderly (over 65), (high school) students, employees working at school and hospitals, and facility residents
  
- B. Regular preventive vaccination (BCG) ————— Infants younger than 1 year old
  
- C. Patient management
  - Notification — At the time of diagnosis and admission/discharge from hospital.
  - Registration — Tuberculosis registration cards, identification of the current situation of patients
  - Medication advice — Home-visit, health education, etc.
  - Screening for proper disease management — Persons requiring follow-ups, patients who have suspended treatment, etc.
  
- D. Infection prevention
  - Contact health examination — Health examination to contact person with tuberculosis patients
  - Work restriction, etc. —
  - Admission recommendation — Work restrictions to tuberculosis patients  
— Admission recommendation to tuberculosis patients .
  - Hospitalization care —
  
- E. Medical care (public fund)
  - Hospital visit medical care — Medical care expenses for tuberculosis patients who have been given recommendation/order for hospitalization  
— Medical fees for hospital visit medical care for tuberculosis patients

### Detailed Data 1 Changes in Number of Newly Notified Tuberculosis Patients, Incidence, and Number of Deaths

Year	Number of newly notified patients	Incidence	Number of deaths	Death rate
	(Person)	(Per 100,000 persons)	(Person)	(Per 100,000 population)
1960	489,715	524.2	31,959	34.2
1965	304,556	309.9	22,366	22.8
1970	178,940	172.3	15,899	15.4
1975	108,088	96.6	10,567	9.5
1980	70,916	60.7	6,439	5.5
1985	58,567	48.4	4,692	3.9
1990	51,821	41.9	3,664	3.0
1995	43,078	34.3	3,178	2.6
1999	43,818	34.6	2,935	2.3
2000	39,384	31.0	2,656	2.1
2001	35,489	27.9	2,491	2.0
2002	32,828	25.8	2,317	1.8
2003	31,638	24.8	2,337	1.9
2004	29,736	23.3	2,330	1.8
2005	28,319	22.2	2,296	1.8
2006	26,384	20.6	2,269	1.8
2007	25,311	19.8	2,194	1.7
2008	24,760	19.4	2,220	1.8
2009	24,170	19.0	2,159	1.7
2010	23,261	18.2	2,129	1.7
2011	22,681	17.7	2,166	1.7
2012	21,283	16.7	2,110	1.7
2013	20,495	16.1	2,087	1.7
2014	19,615	15.4	2,100	1.7
2015	18,280	14.4	1,956	1.6
2016	17,625	13.9	1,893	1.5
2017	16,789	13.3	2,306	1.9
2018	15,590	12.3	2,204	1.8
2019	14,460	11.5	2,087	1.7
2020	12,739	10.1	1,909	1.5
2021	11,519	9.2	1,844	* 1.5

Source: <Number of newly registered patients / prevalence rate>

"Aggregate Result of the Annual Reports of Surveillance of Tuberculosis", Health Service Bureau, MHLW

<Number of deaths / Death rates>

"Vital Statistics", Vital, Health and Social Statistics Office to the Director-General for Statistics and Information System Management and Industrial Relations, MHLW

(Note) 1. The figures for 1998 and later do not include those of atypical mycobacteria positive.

2. The increase in the number of deaths and the mortality rate after 2017 includes the impact of revisions to the cause of death classification, etc.

3. The figures indicated by "\*" are preliminary data.

**Detailed Data 2****Tuberculosis Incidence by Prefecture (as of the end of 2020)**

	Prefecture or City	Incidence
Prefectures with the 5. lowest incidence	Miyagi	5.9
	Yamanashi	5.9
	Iwate	6.1
	Tottori	6.1
	Yamagata	6.6
Prefectures with the highest incidence	Osaka	15.8
	Tokushima	13.5
	Gifu	13.4
	Okinawa	12.7
	Nagasaki	12.4

**Detailed Data 3****International Comparison of Tuberculosis Incidence**

Country	Incidence
United States	3.0
Canada	5.5
Sweden	5.5
Australia	6.9
Netherlands	5.0
Denmark	5.0
France	8.7
United Kingdom	8.0
Japan	10.1

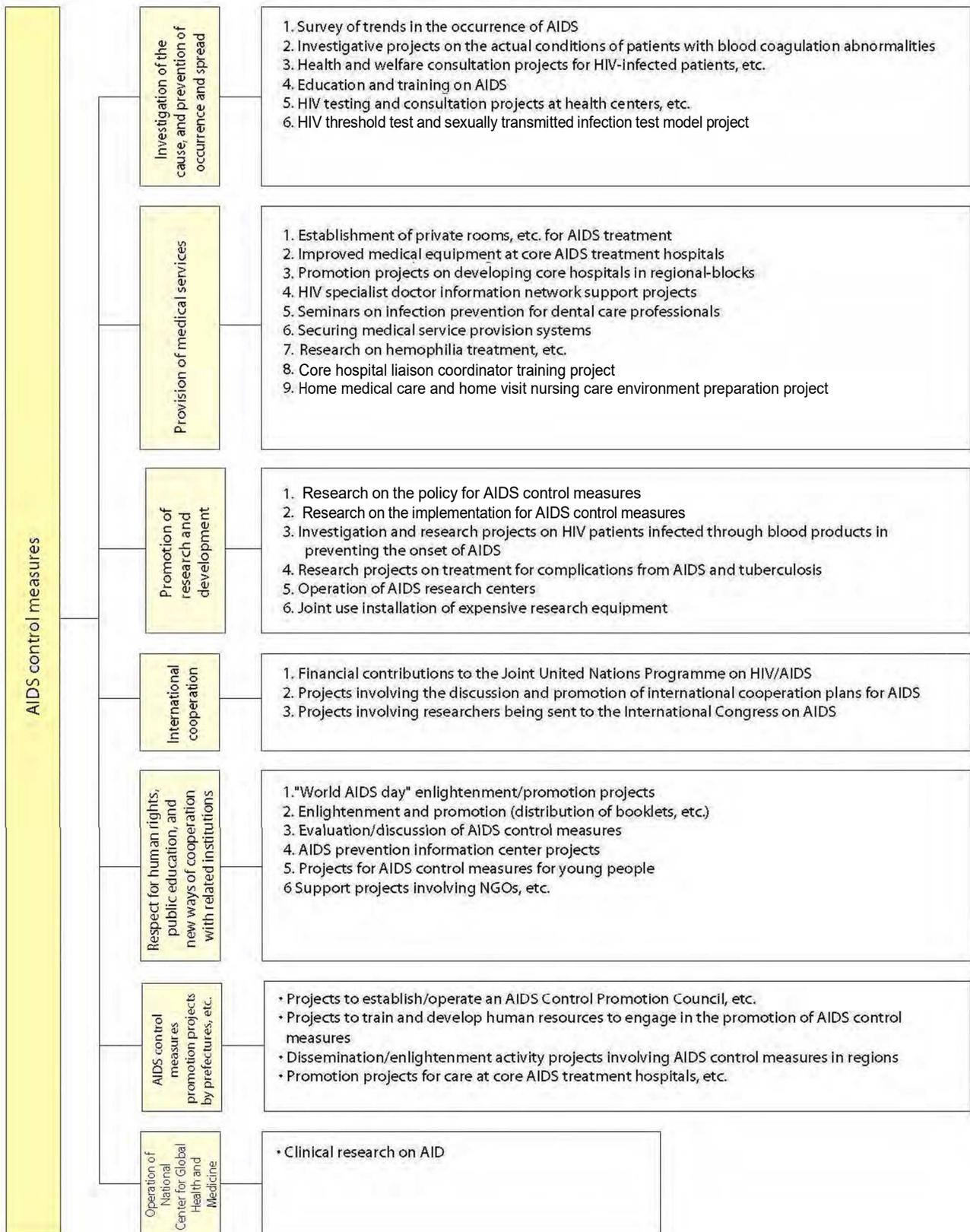
Source: WHO's global tuberculosis database

\*Data is referred to one at 2019 except Japan.

# AIDS Control Measures

## Overview

## Outline of AIDS Control Measures



## Detailed Data 1

## Changes in Number of HIV Carriers and AIDS Patients by Nationality and Gender

Category	Nationality	Gender	1985	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	Total	Total % of
HIV	Japan	Male	0	0	34	15	35	27	52	108	102	134	147	189	234	261	379	336	475	481	525	636	709	787	931	999	894	956	923	889	963	959	860	857	802	768	741	598	17,806	79.2
		Female	0	0	11	4	18	10	17	16	22	32	19	41	34	36	45	32	50	40	32	44	32	49	38	34	38	41	42	31	33	35	38	28	22	32	29	21	1,046	4.7
		Total	0	0	45	19	53	37	69	124	124	166	166	230	268	297	424	368	525	521	557	680	741	836	969	1,033	932	997	965	920	996	994	898	885	824	800	770	619	18,852	83.8
	Foreign national	Male	0	0	10	4	21	11	26	45	33	37	47	65	49	58	39	53	59	55	48	62	60	76	76	60	71	59	71	65	97	82	88	108	136	121	116	114	2,122	9.4
		Female	0	0	0	0	6	18	105	273	120	95	64	81	80	67	67	41	37	38	35	38	31	40	37	33	18	19	20	17	13	15	20	18	16	19	17	17	1,515	6.7
	Total		0	0	10	4	27	29	131	318	153	132	111	146	129	125	106	94	96	93	83	100	91	116	113	93	89	78	91	82	110	97	108	126	152	140	133	131	3,637	16.2
AIDS	Japan	Male	5	3	6	9	15	18	24	36	53	91	108	156	170	158	212	239	221	232	252	290	291	335	343	369	386	421	419	387	438	409	379	376	348	328	281	282	8,080	80.9
		Female	0	0	3	2	2	3	0	1	5	9	11	15	12	10	12	21	24	20	19	19	11	20	22	19	15	15	16	18	11	13	11	18	21	15	9	10	432	4.3
		Total	5	3	9	11	17	21	24	37	58	100	119	171	182	168	224	260	245	252	271	309	302	55	365	378	401	436	435	405	449	422	360	394	369	343	290	292	8,512	85.2
	Foreign national	Male	1	2	3	3	4	10	14	13	19	28	33	45	39	42	46	41	61	36	39	54	49	33	34	32	21	29	21	31	28	26	30	39	27	25	37	46	1,041	10.4
		Female	0	0	2	0	0	0	0	1	9	8	17	18	29	21	31	28	26	20	26	22	16	18	19	21	9	4	17	11	7	7	8	4	17	9	6	7	438	4.4
	Total		1	2	5	3	4	10	14	14	28	36	50	63	68	63	77	69	87	56	65	76	65	51	53	53	30	33	38	42	35	33	38	43	44	34	43	53	1,479	14.8
	Total		6	5	14	14	21	31	38	51	86	136	169	234	250	231	301	329	332	308	336	385	367	406	418	431	431	469	473	447	484	455	428	437	413	377	333	345	9,991	100.0

Source: "AIDS Surveillance Report 2020", National AIDS Surveillance Committee, MHLW

(Note) The figures do not include HIV carriers and AIDS patients who have been infected through blood-coagulation-factor preparations.

## Detailed Data 2

## Status of AIDS Patients in the World (as of the end of 2020, UNAIDS Report)

Region		Number of HIV infected patients (adults/children)	Number of newly infected HIV patients (adults/children)	Percentage of HIV-positive adults (%)	Number of persons died from AIDS (adults/children)
Asia Pacific	2020	5.80 million [4,300,000-7,000,000]	0.24 million [170,000-310,000]	0.2 [0.1-0.2]	0.13 million [87,000-200,000]
	2010	4.90 million [3,900,000-6,400,000]	0.32 million [240,000-450,000]	0.2 [0.2-0.3]	0.28 million [170,000-460,000]
East/South Africa	2020	20.60 million [16,800,000-24,400,000]	0.67 million [470,000-930,000]	6.5 [5.2-7.6]	0.31 million [220,000-470,000]
	2010	16.80 million [15,000,000-18,900,000]	1.20 million [940,000-1,400,000]	7.5 [6.5-8.5]	0.66 million [510,000-870,000]
Eastern Europe, Central Asia	2020	1.60 million [1,500,000-1,800,000]	0.14 million [120,000-160,000]	0.9 [0.8-1.0]	35,000 [28,000-43,000]
	2010	0.89 million [810,000-970,000]	0.10 million [94,000-110,000]	0.5 [0.5-0.5]	34,000 [25,000-41,000]
Latin America	2020	2.10 million [1,400,000-2,700,000]	0.10 million [66,000-150,000]	0.4 [0.3-0.6]	31,000 [20,000-46,000]
	2010	1.50 million [1,100,000-1,800,000]	0.10 million [78,000-130,000]	0.4 [0.3-0.5]	42,000 [29,000-58,000]
Caribbean Coast	2020	0.33 million [280,000-390,000]	13,000 [8,700-18,000]	1.1 [0.9-1.3]	6,000 [4,300-8,500]
	2010	0.30 million [250,000-390,000]	19,000 [14,000-31,000]	1.2 [1.0-1.7]	13,000 [9,300-22,000]
Middle East / North Africa	2020	0.23 million [190,000-310,000]	16,000 [12,000-28,000]	<0.1 [<0.1-0.1]	7,900 [6,000-13,000]
	2010	0.18 million [120,000-250,000]	16,000 [9,000-27,000]	<0.1 [<0.1-0.1]	8,800 [5,800-13,000]
Western/Central Africa	2020	4.70 million [3,900,000-5,800,000]	0.20 million [130,000-330,000]	1.3 [1.0-1.6]	0.15 million [100,000-210,000]
	2010	6.00 million [4,400,000-8,000,000]	0.41 million [240,000-620,000]	2.4 [1.7-3.2]	0.37 million [240,000-540,000]
Western Europe / Central Europe / North America	2020	2.20 million [1,900,000-2,600,000]	67,000 [53,000-81,000]	0.3 [0.2-0.3]	13,000 [9,200-17,000]
	2010	1.80 million [1,600,000-2,000,000]	75,000 [62,000-90,000]	0.3 [0.3-0.3]	21,000 [15,000-28,000]
Total	2020	37.70 million [30,200,000-45,100,000]	1.50 million [1,000,000-2,000,000]	0.7 [0.6-0.9]	0.68 million [480,000-1,000,000]
	2010	32.40 million [27,400,000-38,500,000]	2.20 million [1,700,000-2,900,000]	0.7 [0.6-0.9]	1.40 million [1,000,000-2,000,000]

\*Actual figures fall within the range of the figures in parentheses. The estimated numbers and ranges are calculated based on the best data available to date.

Source: UNAIDS 2021 estimates

## Pandemic Influenza Preparedness

### Overview

### Pandemic Influenza Preparedness

#### Pandemic Influenza

Pandemic influenza occurs when a new type of influenza virus, which has never spread among humans, gains a new ability for human-to-human transmission. In contrast to seasonal influenza, which can cause outbreak annually, humans have little or no immunity to pandemic influenza. This allows pandemic influenza an ability to efficiently transmit from one human to another, possibly resulting in global pandemic. In recent years, a highly pathogenic avian influenza A(H5N1) that can be transmitted from birds to humans has sporadically emerged, mainly in Asia, the Middle East, and Africa. In addition, the infection to humans of bird flu (H7N9) have been reported in China. If the virus mutates into a form that can spread among humans, it could have a significant impact on people's well-being, health, lives and the national economy. The government is therefore implementing the following pandemic preparedness and response measures.

(Assumptions made in the National Action Plan)

Number of patients consulting medical institutions	Approx. 13-25 million
Number of inpatients	Approx. 0.53-2 million
Number of deaths	Approx. 0.17 - 0.64 million

#### Major events

Dec. 2005	Formulation of the "National Action Plan for Pandemic Influenza" (Meeting of Relevant Ministries and Agencies on Countermeasures against Avian Influenza, etc.)
May 2008	Amendment of the Act on Infectious Disease Control and the Act on Quarantine (Legislative preparation by categorizing a new or re-emerging influenza as "pandemic influenza" to legally conduct hospitalization and quarantine at the ports of entry. In addition, influenza H5N1 transmitted from birds to humans was categorized as the infectious disease category 2 "avian influenza (H5N1)" in the Act on Infectious Diseases Control)
Feb. 2009	Amendment of the "National Action Plan for Pandemic Influenza" (Meeting of Relevant Ministries and Agencies on Countermeasures against Pandemic Influenza and New Infectious Diseases, Avian Influenza, etc.) followed by the amendment of the Act on Infectious Diseases Control
Apr. 2009	Emergence of Influenza A(H1N1)pdm09
Mar. 2011	The announcement was made in March that it is no longer recognized as "a new or reemerging influenza strain, or a designated infectious disease" as stipulated in the Act on Infectious Disease Control as of March 31, and measures were switched to those for seasonal influenza
July 2011	Amendment of the Act on Preventive Vaccinations (providing new temporary vaccinations framework based on the assumption of pandemic influenza that had the same level of high transmissibility as the influenza A(H1N1)pdm09 but not highly pathogenic)
Sep. 2011	Revision of the "National Action Plan for Pandemic Influenza" (Ministerial Meeting on Countermeasures against Pandemic Influenza) followed by the experiences of influenza A(H1N1)pdm09
Apr. 2012	Approval of the "Act on Special Measures for Pandemic Influenza and New Infectious Diseases Preparedness and Response" (Legal countermeasures when a pandemic influenza and new infectious disease emerged)
Jun. 2013	Formulation of the "National Action Plan for Pandemic Influenza" (Cabinet decision) Formulation of the "Guideline for Pandemic Influenza" (Meeting of Relevant Ministries and Agencies on Countermeasures against Pandemic Influenza and New Infectious Diseases, Avian Influenza, etc.)
Mar. 2016	Partial revision of the Guideline for Pandemic Influenza (Meeting of Relevant Ministries and Agencies on Countermeasures against Pandemic Influenza and New Infectious Diseases, Avian Influenza, etc.) in response to the review of the policies for stockpiles of antiviral drugs.
Sep. 2017	"National Action Plan for Countermeasures against New Influenza" (Cabinet decision) was partially amended and "Guideline for Pandemic Influenza" was partially revised, due to the changes in the stock amount of anti-influenza virus drugs, etc.
Mar. 2019	"Cell culture method vaccine actual production facility maintenance promotion project" completed.

#### Major budgetary projects

Capacity development of medical institutions against pandemic influenza	Arrange and secure necessary number of beds and medical resources at medical institutions designated by local governments to accept pandemic influenza patients
Dissemination of countermeasures against pandemic influenza	Public communications for individuals, families and workplaces. Information sharing with medical institutions through e-mail magazines
Stockpiles of antiviral drugs	Stockpile targeting approximately 45 million people, including national, prefectural, and distribution
Stockpiles of H5N1 pre-pandemic vaccine	Priority is given to stockpiling of vaccine stocks with a high "importance in crisis management". Store Equip H7N9 type London stock for about 10 million by the end of 2020
Promotion of technical development on Pandemic Influenza	Promotion of technical development by Cell culture method vaccine on Pandemic Influenza

# Organ Transplantation and Hematopoietic Stem Cell Transplantation

## Overview

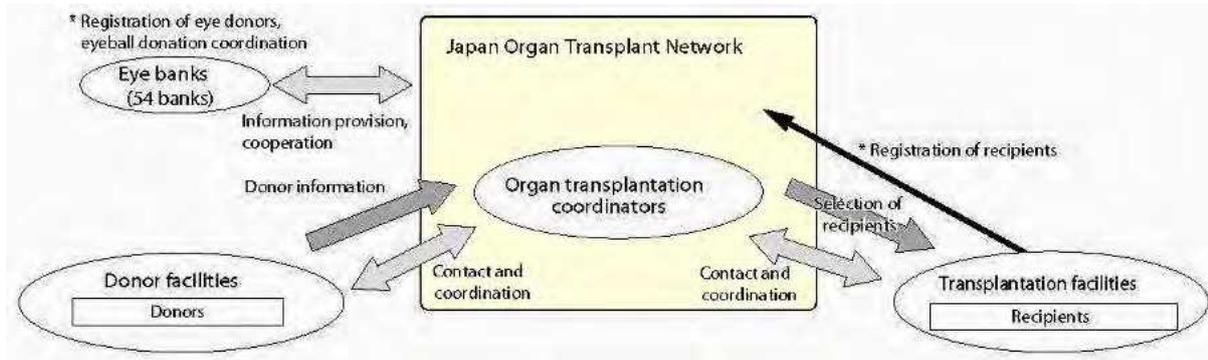
## Organ Transplantation System based on The Organ Transplant Law

[Organ Transplantation System]

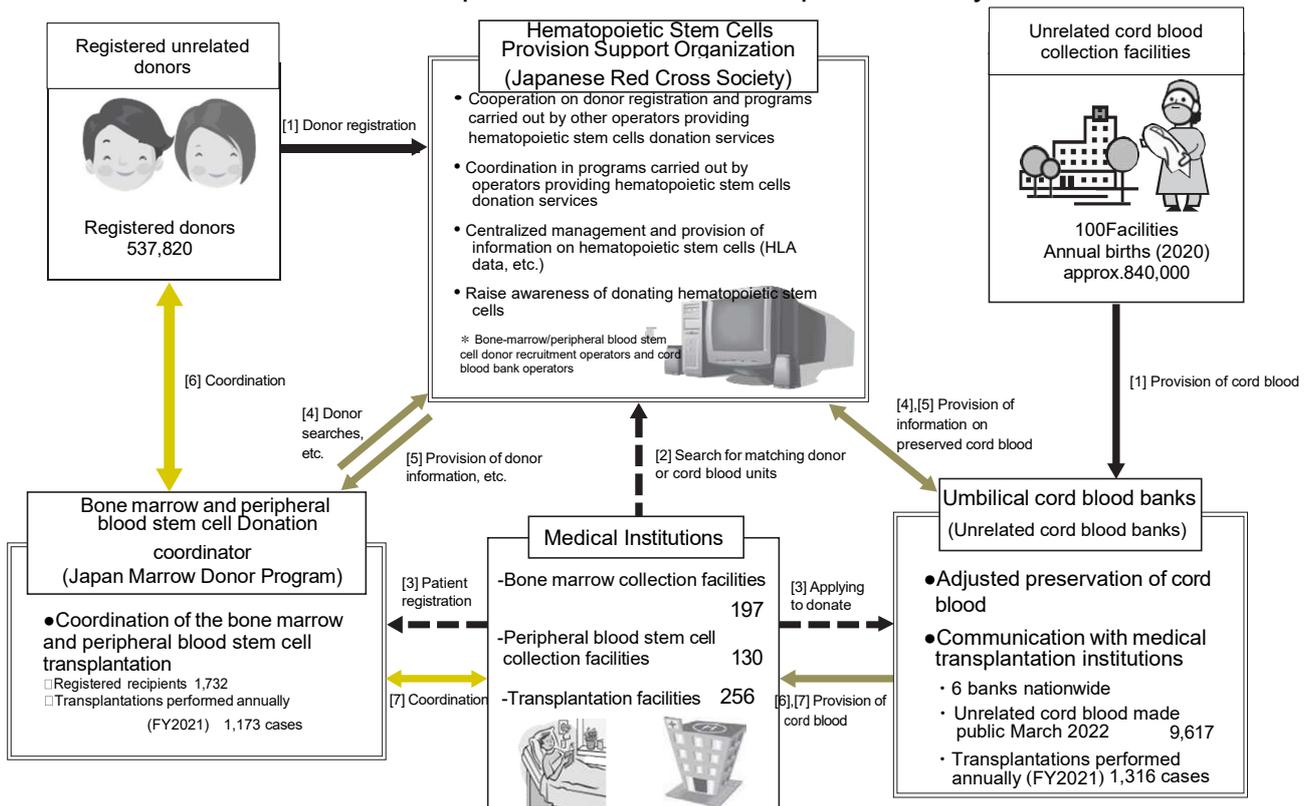
The traditional kidney transplantation system was reviewed and a new centralized nationwide kidney transplantation network established in FY1995. Enforcement of the "Act on Organ Transplantation" in October 1997 enabled multiple organ transplantations and the pertinent network.

At present fair and appropriate mediation of organ donations has been conducted mainly by the Japan Organ Transplant Network through recipients being selected using universal standards. With regard to the transplantation of eyeballs (corneas), mediation work, including enlightenment and promotion activities, is being carried out by eye banks at 54 locations nationwide.

Diagram of Organ Transplantation Network System



Unrelated Hematopoietic Stem Cell Transplantation System



As of the end of March 2022

## Detailed Data 1

## Accumulated Number of Organ Transplantations based on the Act on Organ Transplantation

	Number of donors		Number of transplantations performed		Registered transplant applicants
		Under brain death		Under brain death	
Heart	649 persons	649 persons	648 cases	648 cases	921 persons
Lung	556 persons	556 persons	684 cases	684 cases	493 persons
Liver	687 persons	687 persons	736 cases	736 cases	327 persons
Kidney	2,233 persons	751 persons	4,180 cases	1,473 cases	13,917 persons
Pancreas	476 persons	472 persons	472 cases	469 cases	192 persons
Small intestine	26 persons	26 persons	26 cases	26 cases	10 persons
Eyeball (cornea)	21,665 persons	338 persons	35,203 cases	638 cases	1,888 persons

Source: Japan Organ Transplant Network, Japan Eye Bank Association

- (Note) 1. The number of donors and the number of transplantations performed indicate the cumulative total from October 16, 1997 (the day of the enforcement of the Act on Organ Transplantation) to March 31, 2022. The number of registered transplant applicants is as of March 31, 2022.
2. There have been 821 persons of brain death tests conducted nationwide under the Act on Organ Transplantation since the enforcement of the law until March 31, 2022. In the seven cases, the donor was determined legally brain dead, but the organ was not removed for medical reasons. The case is therefore not included in the number of donors.
3. The number of pancreas and kidneys includes the number of pancreatic kidney simultaneous transplants (401 cases) and the number of registered pancreatic kidney simultaneous transplant applicants (154 persons).
4. The number of heart and lung cases includes the number of the heart lung simultaneous transplants (3 cases) and the number of registered heart lung simultaneous transplant applicants (4 persons).
5. The number of liver and kidney cases includes the number of cases of liver kidney simultaneous transplants (34 cases) and the number of registered liver kidney simultaneous transplant applicants (41 persons).
6. The number of liver and small intestine cases includes the number of registered liver small intestine simultaneous transplant applicant (1 person).

## Detailed Data 2

## Changes in Numbers of Hematopoietic Stem Cell Transplantations Performed

	Unrelated donors		Number of unrelated transplantations		
	Number of registered donors	Number of registered cord blood	Bone marrow	Peripheral blood stem cell	Cord blood
FY 1991	3,176	-	-	-	-
FY 1992	19,829	-	8	-	-
FY 1993	46,224	-	112	-	-
FY 1994	62,482	-	231	-	-
FY 1995	71,174	-	358	-	-
FY 1996	81,922	-	363	-	1
FY 1997	94,822	-	405	-	19
FY 1998	114,354	-	482	-	77
FY 1999	127,556	-	588	-	117
FY 2000	135,873	4,343	716	-	165
FY 2001	152,339	8,384	749	-	221
FY 2002	168,413	13,431	739	-	296
FY 2003	186,153	18,424	737	-	697
FY 2004	204,710	21,335	851	-	674
FY 2005	242,858	24,309	908	-	658
FY 2006	276,847	26,816	963	-	732
FY 2007	306,397	29,197	1,027	-	762
FY 2008	335,052	31,149	1,118	-	859
FY 2009	357,378	32,793	1,232	-	895
FY 2010	380,457	32,994	1,191	1	1,075
FY 2011	407,871	29,560	1,269	3	1,107
FY 2012	429,677	25,385	1,323	15	1,199
FY 2013	444,143	13,281	1,324	19	1,134
FY 2014	450,597	11,595	1,269	62	1,165
FY 2015	458,352	11,185	1,176	58	1,311
FY 2016	470,270	11,287	1,127	123	1,347
FY 2017	483,879	9,991	1,059	182	1,334
FY 2018	509,263	9,516	992	222	1,355
FY 2019	529,965	9,162	992	240	1,430
FY 2020	530,953	9,316	838	258	1,431
FY2021	537,820	9,617	869	304	1,316
Total	-	-	25,016	1,487	21,377

Source: Japan Marrow Donor Program, Japanese Red Cross Society

\* The figures for cord blood stem from FY1996 to FY1998 indicate the number of transplantations coordinated by cord blood banks before the establishment of the Japan Cord Blood Bank Network.

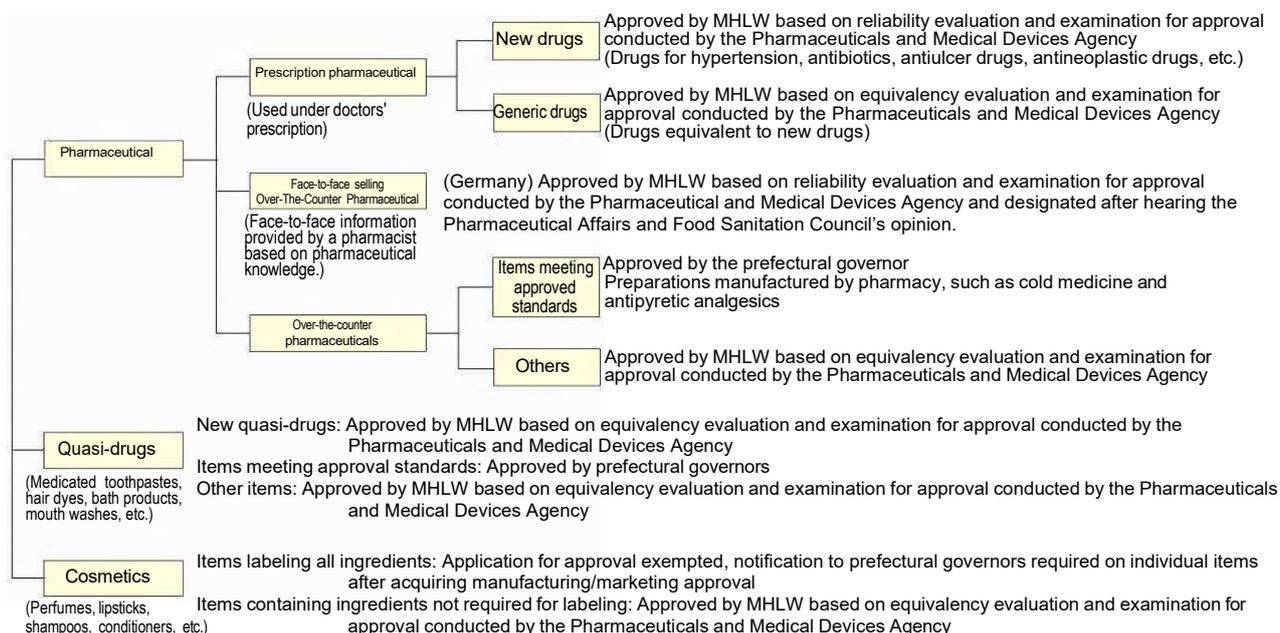
\* Number of donors is as of the end of the respective years.

## (4) Pharmaceuticals, etc.

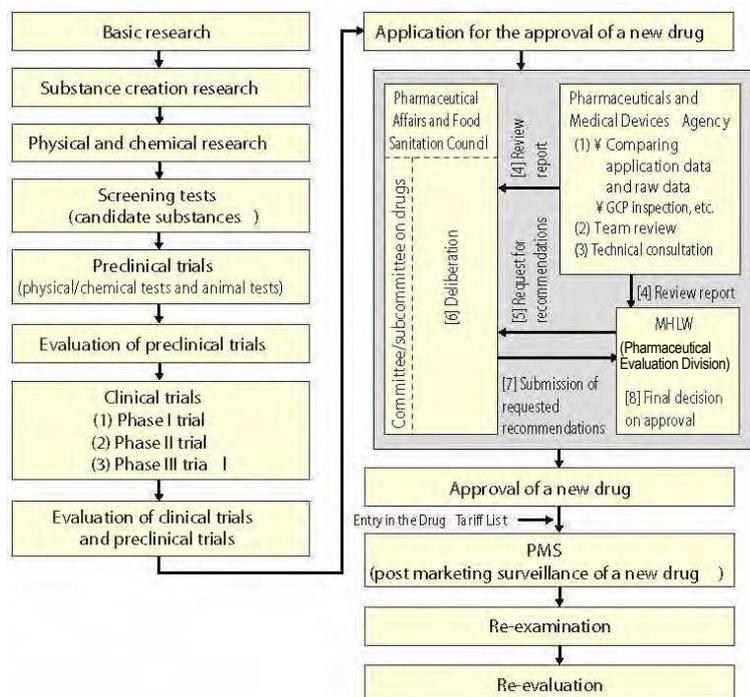
### Approval/Licensing System for Pharmaceuticals, Quasi-Drugs, and Cosmetics

#### Overview

#### Classification of Examinations for the Approval of Pharmaceuticals, etc.



#### Flow of Examination for the Approval of a New Pharmaceutical



#### [Examination for the approval of a new drug]

The quality, efficacy, and safety of a new drugs require an especially careful review. Therefore, a mechanism is in place in which the Pharmaceutical Affairs and Food Sanitation Council (an advisory organ to the Minister of Health, Labour and Welfare) composed of experts in the fields of medical science, pharmaceutical science, veterinary science, and statistical science deliberates on these subjects based on a number of data derived from basic and clinical studies. This mechanism also includes the decision-making process in which the Minister of Health, Labour and Welfare makes decisions on the approvals of new drug based on the results of the deliberations of the Council.

Good Laboratory Practices (GLP) for the implementation of animal testing (against toxicity) among non-clinical tests and Good Clinical Practices (GCP) for the implementation of clinical tests are set forth by ministerial ordinances. Each test is regulated by GLP and GCP to assure appropriate testing.

#### [License for marketing and manufacturing pharmaceuticals, etc.]

The approval and licensing system for pharmaceuticals, etc. was revised. Since April 2005, the system has been applied separately to a marketing authorization holder that ships products to markets and to a manufacturer of the products.

To obtain a license, a marketing authorization holder will be reviewed whether it complies with the standards on quality control procedures, as well as post-marketing safety control procedures. A manufacturer will be reviewed whether it complies with the standards on structure and facilities of manufacturing sites and on quality control procedures.

Prefectural governors issue the license for marketing and that for manufacturing, except for manufacturing of some pharmaceuticals that require sophisticated manufacturing technology.

(Note) The trials that are deemed necessary for application for the approval of a new drug can be roughly divided into two categories: predclinical (physical/chemical tests and animal tests) and clinical trials. Clinical trials are conducted on a phased basis from phase I trial (a small number of healthy volunteers), the phase II trial (a small number of patients), and the phase III trial (a large number of patients), as indicated in the chart above.

**Detailed Data 1** Number of Licenses for Marketing Authorization Holder of Drugs, etc.

(As of the end of 2021)

Category	Pharmaceuticals		Quasi-drugs	Cosmetics	Total	
	Class 1	Class 2				
Marketing	986	271	715	1,500	4,077	6,563

Source: Pharmaceutical Safety and Environmental Health Bureau, MHLW  
 (Note) Licenses are granted by prefectural governors (from April 1, 2005).

**Detailed Data 2** Number of Approvals for Manufacturing/Import/Marketing Drugs, etc. (2021)

		Prescription pharmaceuticals	Face-to-face selling / OTC pharmaceuticals	Quasi-drugs	Cosmetics
Manufacturing	Approval	476	381	1,746	0
Marketing	Approval with partial revision	2,099	247	167	0
Approval	Total	2,575	628	1,913	0

Source: Pharmaceutical safety and Environmental Health Bureau, MHLW  
 (Note) The figures exclude in vitro diagnostics.

**Detailed Data 3** Number of Approvals for Manufacturing Pharmaceuticals, etc.

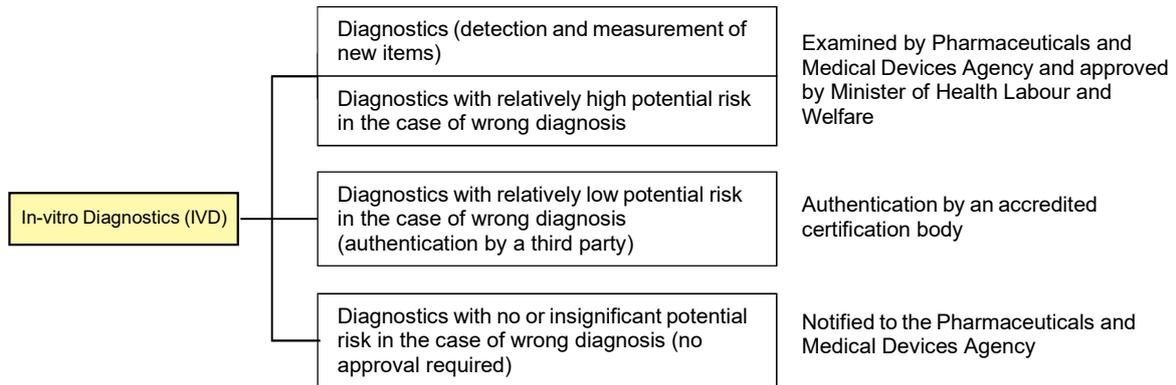
(As of the end of 2021)

Category	Pharmaceuticals	Quasi-drugs	Cosmetics	Total
Manufacturing	1,970	2,014	3,996	7,980

Source: Pharmaceutical safety and Environmental Health Bureau, MHLW  
 (Note) Licenses are granted by prefectural governors from April 1, 1995 (excluding some drugs).

# Review for the Approval of In-vitro Diagnostics (IVD)

## Overview Review for the Approval of IVD



## Detailed Data 1 Number of Licenses for Marketing IVD

(As of the end of 2021)

	IVD
Marketing	174

Source: Survey conducted by Pharmaceutical Safety and Environmental Health Bureau, MHLW  
 (Note) Licenses are granted by prefectural governors.

## Detailed Data 2 Number of Approvals for Marketing (2021)

	Medicines for in-vitro diagnosis
Approval	108
Approval with partial change	96
Total	204

Source: Survey conducted by Pharmaceutical Safety and Environmental Health Bureau, MHLW

## Detailed Data 3 Number of Registrations for Manufacturing IVD

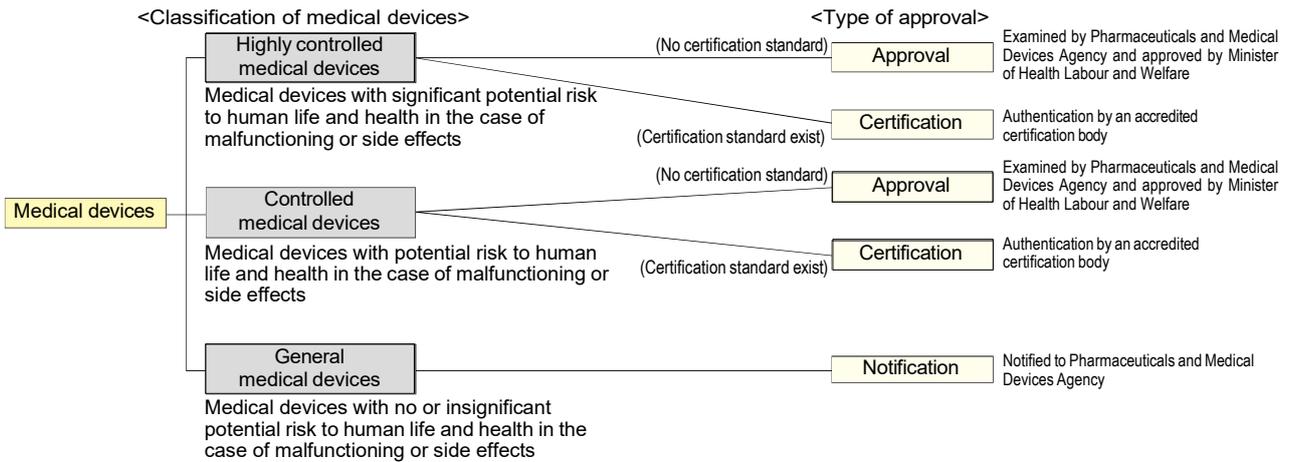
(as of the end of 2021)

	IVD
Manufacturing	220

Source: Pharmaceutical Safety and Environmental Health Bureau, MHLW  
 (Note) Licenses are granted by prefectural governors.

# Medical Device Approval/Licensing System

## Overview Review for the Approval of Medical Devices



## Detailed Data 1 Number of Licenses for Marketing Authorization Holder of Medical Devices

(As of the end of 2021)

Category	Class 1 medical devices	Class 2 medical devices	Class 3 medical devices	Total
Marketing	760	1,173	917	2,850

Source: Survey conducted by Pharmaceutical Safety and Environmental Health Bureau, MHLW  
(Note) Licenses are granted by prefectural governors (from April 1, 2005).

## Detailed Data 2 Number of Approvals for Marketing Medical Devices (2021)

		Medical devices
Marketing	Approval	482
	Approval with partial change	623
	Total	1,105

Source: Survey conducted by Pharmaceutical Safety and Environmental Health Bureau, MHLW

## Detailed Data 3 Number of Licenses and registrations for Manufacturing Medical Devices, etc.

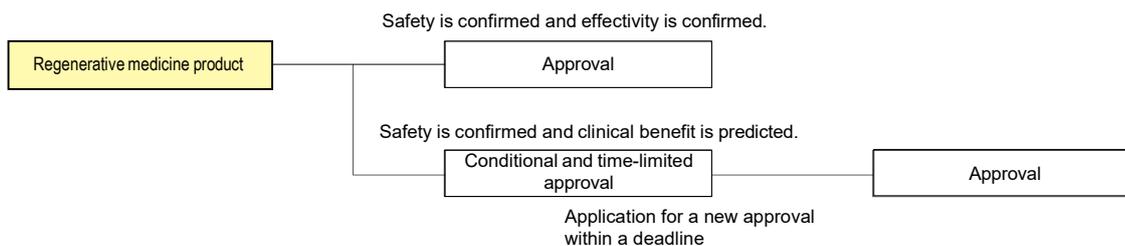
(As of the end of 2021)

		Medical devices
Manufacturing		4,478
Repairs		6,494

Source: Survey conducted by Pharmaceutical Safety and Environmental Health Bureau, MHLW  
(Note) Manufacturing licenses are granted by prefectural governors.  
Repairing licenses are granted by prefectural governors.

## Overview

### Review for the Approval of Regenerative medicine product



## Detailed Data 1

### Number of Licenses for Marketing Authorization Holder of Regenerative medicine Detailed Data 1 product (2021)

	Regenerative medicine product
Marketing	16

Source: Survey conducted by Pharmaceutical Safety and Environmental Health Bureau, MHLW  
 (Note) Licenses are granted by prefectural governors.

## Detailed Data 2

### Number of Approvals for Marketing Regenerative medicine product (2021)

	Regenerative medicine product
Approval	5
Approval with partial change regarding manufacture and sales	8
Total	13

Source: Survey conducted by Pharmaceutical Safety and Environmental Health Bureau, MHLW

## Detailed Data 3

### Number of Licenses for Manufacturing Regenerative medicine product

(As of the end of 2021)

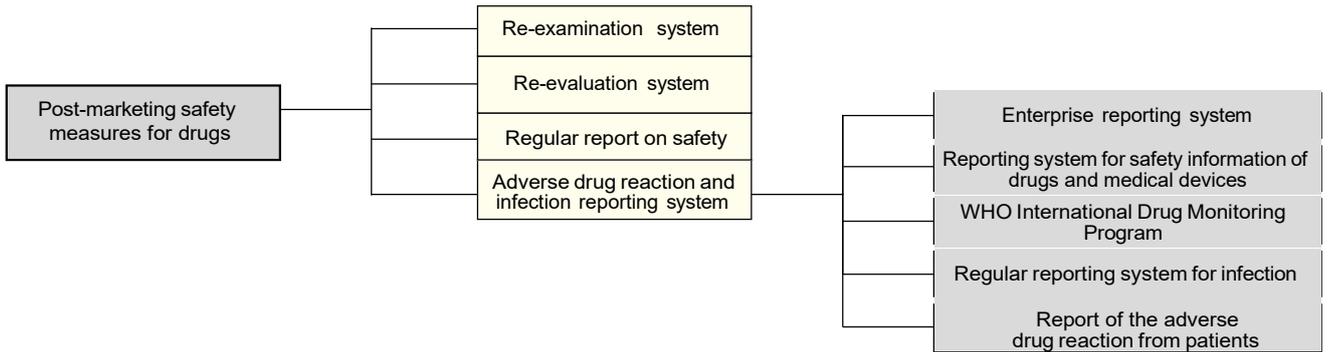
	Regenerative medicine product
Manufacturing	24

Source: Survey conducted by Pharmaceutical Safety and Environmental Health Bureau, MHLW.

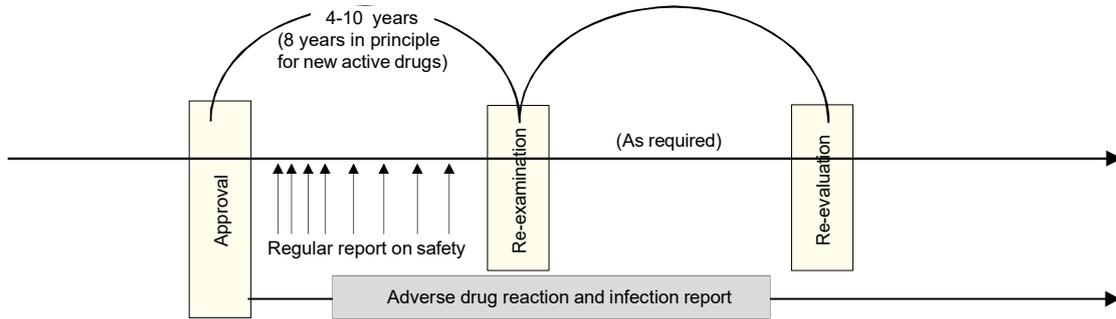
# Post-Marketing Safety Measures for Drugs/Medical Devices

## Overview

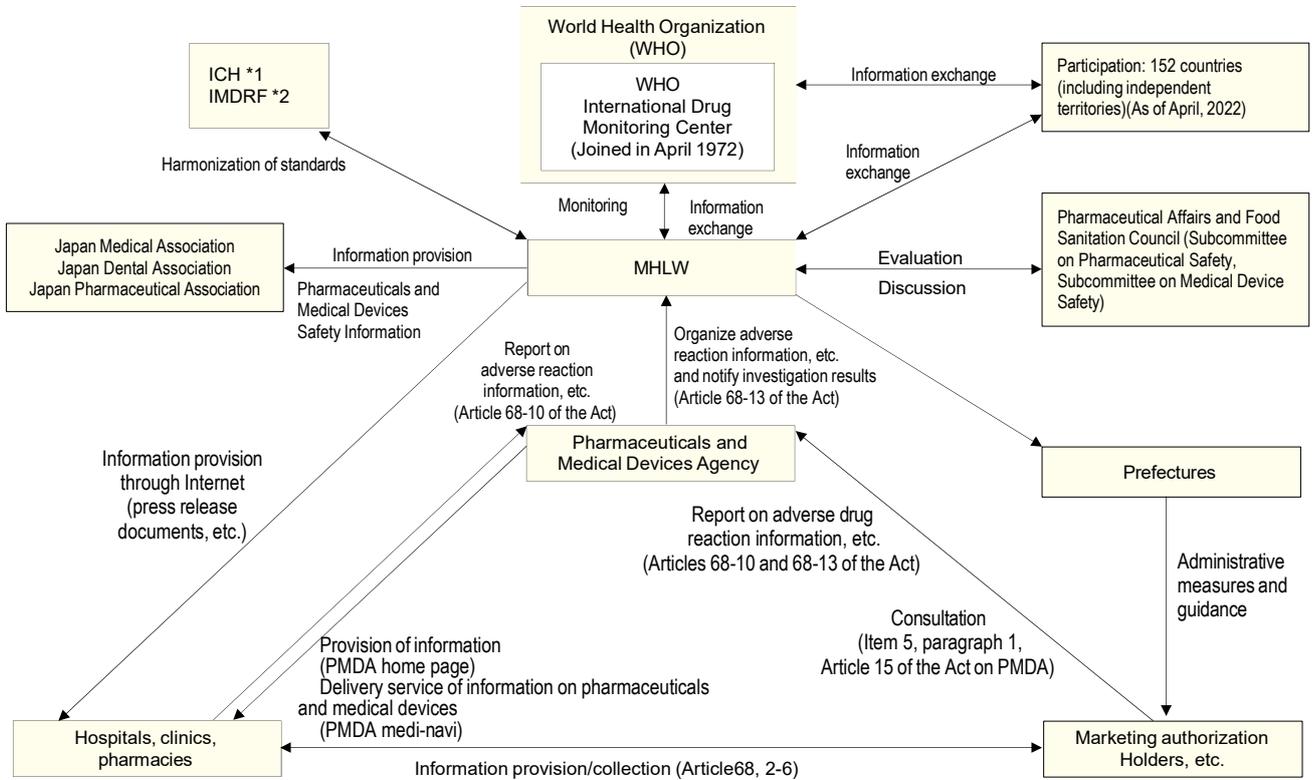
### Post-Marketing Safety Measures for Drugs



### Flow of Post-Marketing Surveillance and Re-examination/Re-evaluation of Drugs



### Outline of the Adverse Drug Reaction, etc. Reporting System



\*1: International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use  
 \*2: International Medical Device Regulators Forum

## Detailed Data 1 Results of Prescription Drug Re-examination

(As of the end of FY2021)

No. of reexamination results (no. of items)		
Drugs that can be approved for effectiveness	Drugs that are approved for effectiveness with partial revision of matters to be approved	Drugs that are not approved for effectiveness
4,338	142	0

\* In case that the same items are reexamined more than once, calculated figures are based on actual reexamination.

Source: Survey conducted by Pharmaceutical Safety and Environmental Health Bureau, MHLW

## Detailed Data 2 Results of Prescription Drug Re-evaluation

(As of the end of FY2021)

### (1) Phase 1 re-evaluation

	No. of finished ingredients or no. of subscriptions	No. of finished items
Total	1,819	19,612
Only one ingredient contained in medicine	1,159	18,169
Mixed ingredients for medicine	660	1,443

### (2) Phase 2 re-evaluation

	No. of finished ingredients or no. of subscriptions	No. of finished items
Total	131	1,860
Only one ingredient contained in medicine	108	1,668
Mixed ingredients for medicine	23	192

### (3) New reevaluation

	No. of ingredients	No. of finished items
Total	1,115	9,225
Re-evaluation for medicine effect	477	4,635
Re-evaluation of quality	638	4,590

Source: Survey conducted by Pharmaceutical Safety and Environmental Health Bureau, MHLW

- (Note) 1. Phase 1 re-evaluation (between November 1973 and September 1995): Ingredients approved before September 30, 1967)  
 2. Phase 2 re-evaluation: covers ingredients approved between January 1988 and March 1996 : covers ingredients approved between October 1, 1967 and March 31, 1980.  
 3. New re-evaluation (between December 1990 and March 2017): covers all the ingredients.

## Detailed Data 3 Changes in the Number of Reports on Adverse Drug Reaction, etc. in the Past 5 Years

(Unit: case)

FY	Reports from marketing authorization holders <sup>Note 1)</sup>					Reports on adverse drug reactions from medical professionals <sup>Note 3)</sup>
	Reports on adverse drug reactions <sup>Note 2)</sup>	Reports on infectious diseases <sup>Note 2)</sup>	Reports on research results	Reports on overseas measures	Regular reports on infectious diseases	
FY 2017	60,872	100	1,206	1,492	1,052	7,624
FY 2018	62,037	73	1,078	1,451	1,084	9,931
FY 2019	60,405	72	983	1,579	1,061	9,537
FY 2020	51,359	70	874	1,652	1,070	10,985
FY 2021	82,257	51	989	1,730	1,060	40,374

Note 1) Including a report once accepted but withdrawn later by the manufacturer/seller (such as one found to have not taken the medicine after reporting, etc.), and a report accepted as a non-target report (such as one for which the causal relation was denied due to additional information after the reporting).

Note 2) Reports on domestic cases.

Note 3) The figure consists of the number of adverse reaction reports based on the safety information reporting system and the number of post-vaccination side reaction reports.

Source: Survey conducted by Pharmaceutical Safety and Environmental Health Bureau, MHLW

## Detailed Data 4 Changes in the Number of Fault Reports on Combination Drugs<sup>(Note1)</sup> Medical Devices

FY	Fault cases of combination(domestic)	Fault cases of combination drugs (Overseas)
2017	1,120	2,951
2018	1,653	2,542
2019	1,395	2,634
2020	1,429	2,622
2021	1,480	2,929

Note 1) A medicinal combination product refers to a medicine that has been approved for sale as an integrated unit with mechanical device such as insulin pen injector. Subject to the enforcement of the Pharmaceuticals and Medical Devices Law on November 25, 2014, reporting was mandated from November 25, 2016 after the transitional measure period from November 25, 2014 to November 24, 2016.

Source: Survey conducted by Pharmaceutical Safety and Environmental Health Bureau, MHLW

**Detailed data 5****Reported number of adverse reactions, etc. of quasi-drugs/cosmetics** <sup>Note 1)</sup>

FY	Quasi-drugs (domestic)	Cosmetics (domestic)
FY 2017	119	97
FY 2018	103	83
FY 2019	119	80
FY 2020	97	58
FY 2021	78	63

Note 1) Reporting was made mandatory after the enforcement of the ministerial ordinance that revised part of the Ordinance for Enforcement of the Pharmaceutical Affairs Act and part of the ministerial ordinance concerning the standards for post-marketing safety management of the pharmaceuticals, quasi-drugs, cosmetics and medical equipment on April 1, 2014.

Source: Survey conducted by Pharmaceutical Safety and Environmental Health Bureau, MHLW

**Detailed Data 6****Changes in Number of Reports on Adverse Event Related to Medical Devices, etc. in the Past 5 Years**

FY	Reports from marketing authorization holders (Unit: case)					Reports on adverse drug reactions from medical professionals (Unit: case)
	Reports on adverse event <sup>Note 1)</sup>	Reports on infectious diseases <sup>Note 2)</sup>	Reports on research results	Reports on overseas measures	Regular reports on infectious diseases	
FY 2017	50,887	0	2,701	2,437	56	441
FY 2018	52,544	0	2,314	2,512	69	487
FY 2019	76,053	0	3,147	1,201	66	498
FY 2020	129,159	0	3,068	883	75	427
FY 2021	144,492	0	3,883	1,184	73	354

Note 1) Reports on adverse event include overseas cases.

Note 2) Reports on domestic cases.

Source: Survey conducted by Pharmaceutical Safety and Environmental Health Bureau, MHLW

**Detailed Data 7****Changes in Number of Reports on adverse events including drugs produced by utilizing regenerative medicine**

FY	Reports from manufacturers (Unit: case)					Reports on adverse drug reactions from medical professionals (unit: case)
	Reports on adverse event <sup>Note 1)</sup>	Reports on infectious diseases <sup>Note 2)</sup>	Research reports	Reports on overseas measures	Regular reports on infectious diseases	
FY 2017	110	0	0	0	34	0
FY 2018	163	0	0	0	0	34
FY 2019	1,145	0	1	2	62	0
FY 2020	1,951	0	1	6	74	6
FY 2021	2,390	0	2	7	100	5

Note 1) Reports on adverse event of drugs produced by utilizing regenerative medicine, etc. including overseas cases.

Note 2) Reports on domestic cases

Source: Survey conducted by Pharmaceutical Safety and Environmental Health Bureau, MHLW

# Relief Systems for Adverse Drug Reactions and Infections Acquired through Biological Products

## Overview

### [Relief System for Adverse Drug Reactions]

The purpose of this system is to provide various relief benefits and prompt relief to patients and their families, apart from civil liability, in relation to injury caused by adverse reactions despite the proper use of drugs.

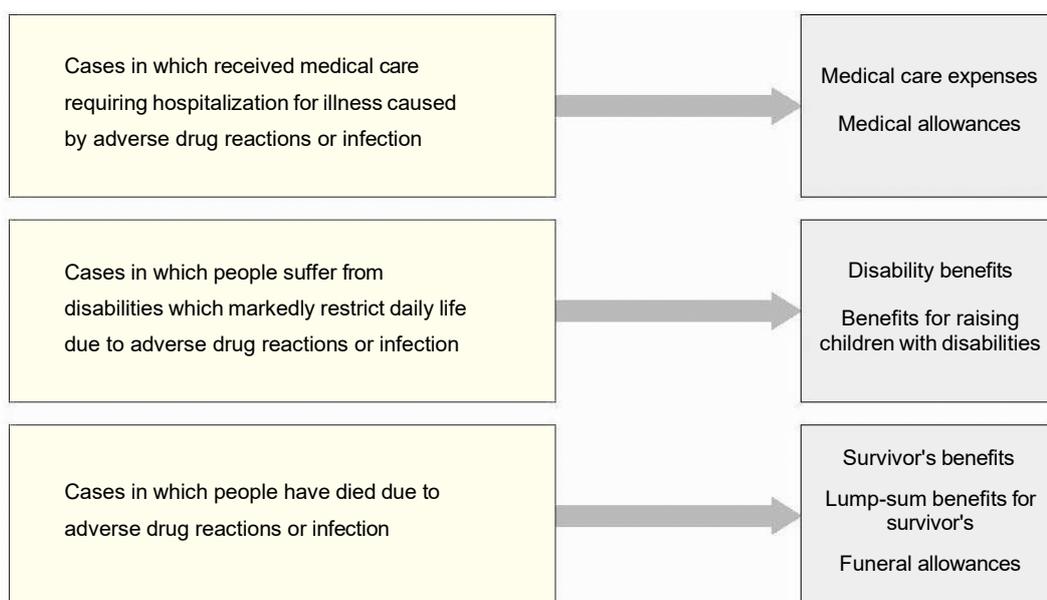
### [Relief System for Infections Acquired through Biological Products]

The purpose of this system is to provide various relief benefits and prompt relief to patients and their families, apart from civil liability, in relation to injury caused by infections despite the proper use of biological products.

### [Responsible organization]

Pharmaceuticals and Medical Devices Agency

### [Types of Relief Benefits]



### [Activities on the Relief for Caused Damages]

Since 1968, the Agency has been entrusted by the pharmaceutical enterprises and the government to pay health management allowances, etc. to patients who have been settled by SMON (subacute myelo-optico-neuropathy) of the lawsuit out of court.

### [Relief Program for AIDS patients, etc. caused by Blood Products]

A survey and research project has been conducted since FY 1993 for helping HIV carriers infected through the use of contaminated blood products to prevent them from developing symptoms. For the prevention of the onset of AIDS and for health management in daily life, the government provides health management expenses and in turn requests the carriers report their health status.

Since FY 1996, assistance on health management expenses has been provided for the health management of those who developed AIDS and accepted the court settlement.

## Detailed Data Changes in Status of Adverse Drug Reaction Relief Payments (as of the end of each FY)

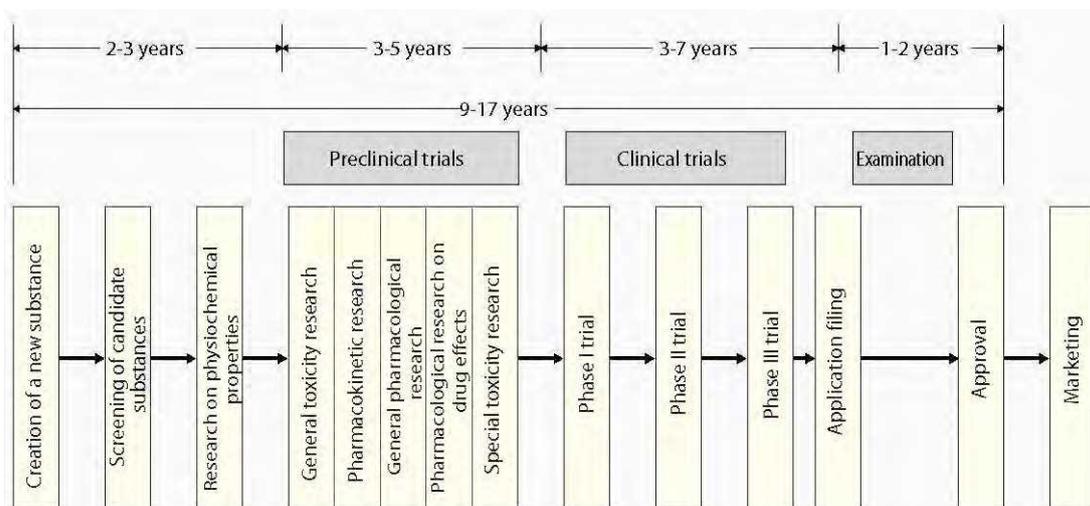
	FY1980- FY1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Amount (¥1,000)	8,705,179	935,148	1,022,185	1,055,985	1,204,243	1,262,647	1,587,567	1,582,956	1,696,525	1,798,706	1,783,783	1,867,190	2,058,389	1,920,771	1,959,184	2,113,286	2,086,902	2,267,542	2,351,545	2,353,225	2,461,090	2,420,942	2,375,568
Number of claims (case)	3,814	480	483	629	793	769	760	788	908	926	1,052	1,018	1,075	1,280	1,371	1,412	1,566	1,843	1,491	1,419	1,590	1,431	1,379
Number of payments (case)	2,965	343	352	352	465	513	836	676	718	782	861	897	959	997	1,007	1,204	1,279	1,340	1,305	1,263	1,285	1,342	1,213

Source: Pharmaceutical and Medical Devices Agency

## Research/Development of Drugs and Pharmaceutical Industry

### Overview Process and Period of New Drug Development

Developing a new drug is considered to take 9-17 years and require nearly ¥100 billion per product including the costs of abandoned cases.



### Detailed Data Breakdown of Marketing Authorization Holders of Drugs, etc. by Scale

Category	Number of enterprises		Drug sales (¥100 million)		Prescription drug sales (included) (¥100 million)	
		Percentage		Percentage		Percentage
Capital of less than ¥100 million	146	47.2%	4,450	3.2%	3,032	2.7%
¥100 million - 5 billion	105	33.9%	27,685	19.6%	21,786	19.0%
¥5 billion or more	58	18.8%	109,670	77.3%	89,901	78.4%
<b>Total</b>	<b>309</b>	<b>100.0%</b>	<b>141,804</b>	<b>100.0%</b>	<b>114,719</b>	<b>100.0%</b>

Source: "Survey of the Prescription Pharmaceuticals Industry of Japan (FY2020)", Health Policy Bureau, MHLW

(Note 1) Survey targets were enterprises marketing drugs with approval of marketing authorization under the Law on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical devices as of March 31, 2021, that were members of categorized organizations (15 organizations) of the Federation of Pharmaceutical Manufacturers' Association of Japan.

(Note 2) As for the numerical values in the table, it may not agree with the total due to the rounding of figures.

## Medical Devices

### Overview Production of Medical Devices, etc.

(Unit: ¥100 million, %)

Year	Production	Percent change from the previous year	Export	Import	Total domestic production
1979	5,669	23.1	—	—	—
1989	12,195	9.9	2,266	2,972	12,819
1999	15,075	-0.4	3,273	8,345	19,298
2005	15,724	2.5	4,739	10,120	20,695
2006	16,883	7.4	5,275	10,979	24,170
2007	16,845	-0.2	5,750	10,220	21,727
2008	16,924	0.5	5,592	10,907	22,001
2009	15,762	-6.9	4,752	10,750	21,829
2010	17,134	8.7	4,534	10,554	22,856
2011	18,085	5.5	4,809	10,584	23,525
2012	18,952	4.8	4,901	11,884	25,894
2013	19,055	0.5	5,305	13,008	26,722
2014	19,895	4.4	5,723	13,685	27,655
2015	19,456	-2.2	6,226	14,249	27,173
2016	19,146	-1.6	5,840	15,564	28,455
2017	19,904	4.0	6,190	16,492	29,314
2018	19,490	-2.1	6,676	16,204	28,672
2019	25,221	29.4	9,713	27,230	39,864
2020	24,263	-3.8	9,909	26,373	39,354

Source: "Annual Report on the Survey of Pharmaceutical Industry Productions, Health Policy Bureau, MHLW"

### Detailed Data Production by Medical Device Type

(Unit: ¥100 million, %)

Category	Production	Percentage	Category	Production	Percentage
1 Medical mirror	2,850	11.7	40 Medical knife	64	0.3
2 Cannulae/catheters of assorted tip configurations	2,746	11.3	41 Dental impression material	58	0.2
3 Visceral function substitute	2,545	10.5	42 Dental engine	55	0.2
4 Medical X-ray device and X-ray tube for medical X-ray device	2,103	8.7	43 Medical microtome	54	0.2
5 Blood test device	1,796	7.4	44 Medical cauterizer	52	0.2
6 Visceral function test device	1,333	5.5	45 Thermometer	44	0.2
7 Orthopedic goods	1,162	4.8	46 Diagnosis program	44	0.2
8 Physiotherapy device	1,109	4.6	47 Dental cutting machine	37	0.2
9 Dental metals	1,021	4.2	48 Medical washer	34	0.1
10 Vision corrective lens	806	3.3	49 Dental ground materials	33	0.1
11 Pump for drugs	737	3.0	50 Tampon for menstruation treatment	30	0.1
12 Vision tester	499	2.1	51 Medical inhalant	30	0.1
13 Needles and puncture needle	464	1.9	52 Incubator	29	0.1
14 Blood collecting or transfusion device	351	1.4	53 Dental calcium sulfate and calcium sulfates' goods	27	0.1
15 Others	347	1.4	54 Medical light	25	0.1
16 X - ray film	325	1.3	55 Plate materials	24	0.1
17 Medical gap-filling adhesive	294	1.2	56 Accessories designated due to the MHLW Act	21	0.1
18 Medical materials generator	265	1.1	57 Medical centrifugal separator	21	0.1
19 Blood pressure test or pulse wave velocity test device	190	0.8	58 Radiological material diagnosis device	21	0.1
20 Orthopedic instruments and apparatus (note)	185	0.8	59 Opening or stoma device	21	0.1
21 Syringe barrel	180	0.7	60 Dental materials for root canal filling	19	0.1
22 Dental unit	171	0.7	61 Perception test or physical function test device	19	0.1
23 Respiratory equipment	164	0.7	62 Eyeglasses for sight correction	17	0.1
24 Hearing aid	160	0.7	63 Visual acuity chart and color anomaly test table	17	0.1
25 Medical puncture device and rotating instrument (note)	145	0.6	64 Medical forceps	16	0.1
26 Dental hand piece	136	0.6	65 Medical rolled cotton	14	0.1
27 Tooth crown materials	131	0.5	66 Hearing test device	12	0.0
28 Condom	122	0.5	67 Protection kit from radiation hazard	11	0.0
29 Medical disinfection apparatus	113	0.5	68 Anesthesia apparatus and Rebreathing bags for anesthesia apparatus and gas canister	9	0.0
30 Operating table and treatment table	102	0.4	69 Dental casting apparatus	8	0.0
31 Vibrator	97	0.4	70 Medical elevator	8	0.0
32 Electrical therapy apparatus for household use	93	0.4	71 Pneumothorax and pneumoperitoneum apparatus	7	0.0
33 Electrosurgical unit	93	0.4	72 Medical pincette	7	0.0
34 Medical evacuator	86	0.4	73 Splint	7	0.0
35 Suture	85	0.3	74 Dental steamer and polymerization vessel	6	0.0
36 Urine test or stercus test device	78	0.3	75 Medical incubator	5	0.0
37 Ligation device and Suturing devices	77	0.3	76 Impression taking or maxillomandibular registration device	5	0.0
38 Magnetic therapy apparatus	72	0.3	77 Medical scissors	5	0.0
39 Acus or moxibustion device	72	0.3	78 Medical dilator	5	0.0

Category	Production	Percentage	Category	Production	Percentage
79 Medical sew	4	0.0	93 Medical snare	1	0.0
80 Medical uncal	4	0.0	94 Spatula	1	0.0
81 Dental wax	4	0.0	95 Medical chisel	1	0.0
82 Dental filling instruments	4	0.0	96 Contraceptive device	0	0.0
83 Surgical gloves and finger cot	3	0.0	97 Medical spoon	0	0.0
84 Dental filling instrument	3	0.0	98 Medical Water sterilizers	0	0.0
85 Hernia supporters (note)	3	0.0	99 Medical bougie	0	0.0
86 Medical treatment program	3	0.0	100 Medical hammer	0	0.0
87 Dental desiccator	3	0.0	101 Smallpox vaccination device	0	0.0
88 Stethoscope	2	0.0	102 Plexor	0	0.0
89 Biological fluid test device	2	0.0	103 Contact lenses (excluding for sight correction)	0	0.0
90 Dental probe	2	0.0	104 Medical raspatory	0	0.0
91 Dental broach	1	0.0	105 Finger pressure substitute	0	0.0
92 Medical lever	1	0.0	Total	24,263	100.0

Source: "Annual Report on the Survey of Pharmaceutical Industry Productions 2020", Health Policy Bureau, MHLW

## Pharmacies

### Overview

Separation of dispensing and prescribing functions is a system towards improving the quality of national medical care by dividing the roles of doctors and pharmacists based on their specialized field in that doctors will issue prescriptions to patients and the pharmacists of pharmacies then dispense according to those prescriptions.

[Advantages of separation of dispensing and prescribing functions]

- 1) As regular pharmacy pharmacists can continuously grasp the patient's medications, it makes possible to avoid the multiple medications and interactions caused by visiting multiple clinical departments, then the effectiveness and safety of drug therapy will improve.
- 2) Pharmacists, in cooperation with prescribing physicians and dentists, will explain effects, side effects, directions for use, etc. of drugs to patients (patient medication counseling) so that patients enable to improve their understanding on drugs and are expected to take dispensed drugs as directed leading to improved efficacy and safety of drug therapies.
- 3) Doctors and dentists can freely prescribe drugs necessary for patients regardless of their own stocked drugs.
- 4) Issuing prescriptions to patients allows them to learn about their own medications.
- 5) Reduction of outpatient dispensing work by hospital pharmacists allows them to engage in hospital activities for inpatients which they should essentially perform.

### Detailed Data Changes in Number of Pharmacies and Prescriptions

FY	Number of pharmacies	Number of prescriptions (10,000/year)	Number of prescriptions per 1,000 persons (per month)	Nationwide average rate of separation of dispensing and prescribing functions (%)
FY1989	36,670	13,542	95.2	11.3
FY1990	36,981	14,573	105.4	12.0
FY1991	36,979	15,957	111.7	12.8
FY1992	37,532	17,897	125.8	14.1
FY1993	38,077	20,149	140.6	15.8
FY1994	38,773	23,501	161.0	18.1
FY1995	39,433	26,508	182.5	20.3
FY1996	40,310	29,643	210.0	22.5
FY1997	42,412	33,782	238.1	26.0
FY1998	44,085	40,006	278.8	30.5
FY1999	45,171	45,537	307.3	34.8
FY2000	46,763	50,620	348.6	39.5
FY2001	48,252	55,960	393.7	44.5
FY2002	49,332	58,462	393.0	48.8
FY2003	49,956	59,812	418.8	51.6
FY2004	50,600	61,889	368.7	53.8
FY2005	51,233	64,508	425.2	54.1
FY2006	51,952	66,083	442.5	55.8
FY2007	52,539	68,375	481.0	57.2
FY2008	53,304	69,436	483.0	59.1
FY2009	53,642	70,222	494.1	60.7
FY2010	53,067 *	72,939	486.6	63.1
FY2011	54,780	74,689	498.3	65.1
FY2012	55,797	75,888	533.3	66.1
FY2013	57,071	76,303	510.2	67.0
FY2014	57,784	77,558	509.3	68.7
FY2015	58,326	78,818	513.1	70.0
FY2016	58,678	79,929	533.1	71.7
FY2017	59,138	80,386	529.8	72.8
FY2018	59,613	81,229	568.9	74.0
FY2019	60,171	81,803	547.6	74.9
FY2020	60,951	73,116	533.1	75.7

Source: The number of pharmacies as of December 31 of each year until 1996 and of the end of each fiscal year from 1997 on by the Pharmaceutical Safety and Environmental Health Bureau, MHLW. The number of prescriptions for 1,000 persons, and prescription receiving rate investigation by Japan Pharmaceutical Association.

(Note) How to calculate the rate of prescription receipt are as follows:

$$\text{Prescription receipt rate (\%)} = \frac{\text{Number of prescriptions to pharmacies}}{\text{Number of prescriptions issued to outpatients (total)}} \times 100$$

\* Miyagi Prefecture is not included due to the effect of the Great East Japan Earthquake.

# Blood Programme

## Overview

### [Blood Products]

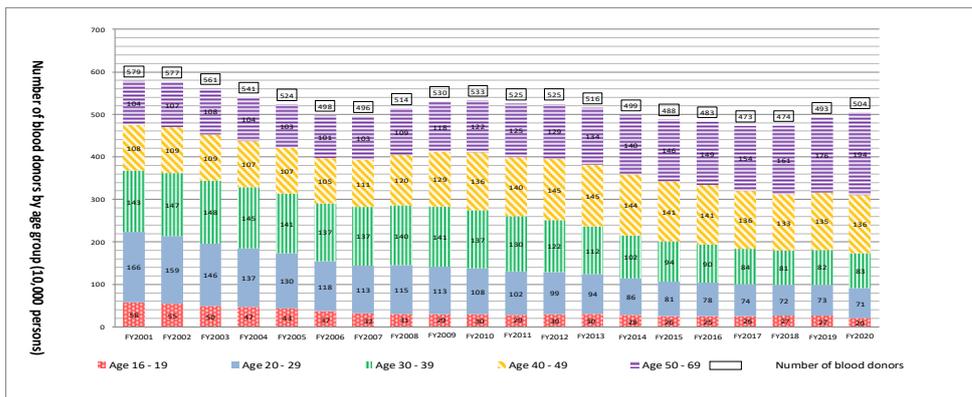
Blood products refer to all pharmaceutical products which are derived from human blood and are roughly classified into blood transfusion products and plasma derivatives. All of the blood transfusion products are supplied through blood donations in Japan. Regarding plasma derivatives, the domestic self-sufficiency has been achieved for blood coagulation factor products. On the other hand, for some albumin products and anti-HBs human immunoglobulin products, the products and raw materials are still imported from overseas. From the viewpoint of ethics and international fairness, efforts are being made to achieve domestic self-sufficiency for these plasma products.

Category	Type	Application
Blood transfusion products	Red blood cell products	Anemia due to hematopoietic organ diseases and chronic bleeding, etc.
	Plasma products	Liver damage, disseminated intravascular coagulation (DIC), thrombotic thrombocytopenic purpura (TTP), hemolytic-uremic syndrome (HUS), etc.
	Platelet products	Active bleeding, preoperative conditions of surgical operation, large volume blood transfusion, disseminated intravascular coagulation (DIC), blood disorders, etc.
Plasma derivatives	Albumin products	Hemorrhagic shock, nephrotic syndrome, hepatic cirrhosis accompanying intractable ascites, etc.
	Immunoglobulin products	Aglobulinemia or hypoglobulinemia, severe infection, chronic inflammatory demyelinating polyneuropathy(CIDP), Kawasaki disease, etc
	Blood coagulation factor products	Supplementing blood coagulation factor to patients with blood coagulation factor deficiency

### [Status of Blood Donation]

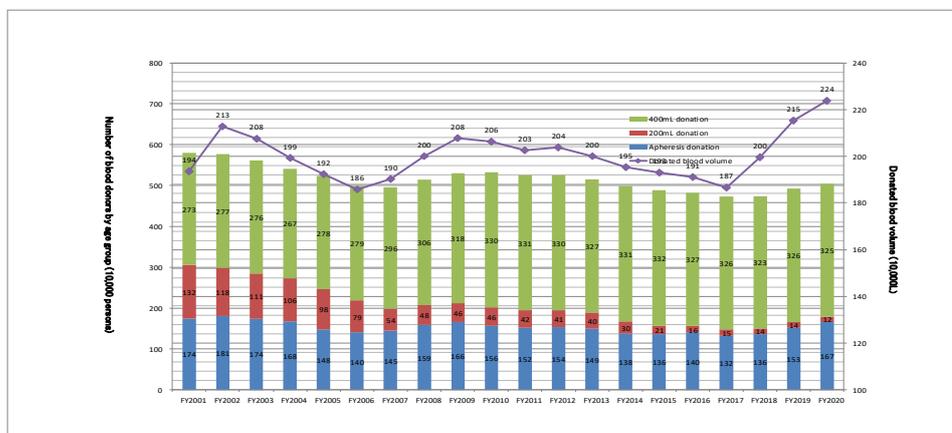
In recent years, due to an increase in the amount of blood donated per person, the required amount of blood can be secured with a smaller number of donors than before. On the other hand, looking at the number of blood donors by age group, the proportion of donors in their 10s, 20s and 30s in the total blood donors has decreased significantly compared with 10 years ago. It is important to encourage more young people to donate blood.

## Detailed Data 1 Change in Number of Blood Donors



Source: Survey by Japanese Red Cross Society, and created by Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labor and Welfare

## Detailed Data 2 Changes in Number of Blood Donors by Donation Type and Donated Blood Volume



※From 2018, the amount of blood donated by component blood donation is calculated based on the total volume at the manufacturing stage (including the amount of blood storage solution).

# (5) Health Risk Management System

## Health Risk Management System

### Overview

### MHLW Health Risk Management System Diagram

