# [2] Health and Medical Services

# (1) Health Care Insurance

# Health Care Insurance System

# Overview

# **Outline of Health Care Insurance System**

(As of April 2021)

				Number of							pril 2021)
			Insurer	subscribers		Insurance bene	fits		T	Financia	resources
	Sys	stem	(as of the end of March	(March 2020) Insured		Medical care benefits			Cash	Premium	State
			2020)	Families 1,000 persons	Co-payment	High-cost medical care benefit, Unitary high- cost medical/long-term care system	Hospital meal expenses	Hospital living expenses	benefits	rate	subsidy
Не	General employees	JHIA- managed Health Insurance	Japan Health Insurance Association	40,443 24,793 15,650		¥252.600 + (medical expenses – ¥842.000) x1%	(Co-payment for meal expenses)  · Households with residential tax Per meal ¥460  · Household exempted	(Co-payment for living expenses)  • General (I) (II) (III) Per meal ¥460 + Per day ¥370	• Sickness and injury allowance • Lump-sum birth allowance, etc	10.00% (national average)	16.4% of benefit expenses, etc.
Health Insurance	yees	Society -managed Health Insurance	Health Insurance Societies 1,388	28,837 [16,352 [12,485]		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	from residence tax Per meal first 90 days ¥210  Per meal after	exempted from residence tax Per meal \$\frac{\frac}\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac{\frac	Same as above (with additional benefits)	Different among health insurance associations	Fixed amount (subsidy from budget)
	un 3	ne insured der Article 3-2 of the Health urance Act	Japan Health Insurance Association	17 [ 12 [ 5		(Persons aged 70 or older but younger than 75) (average annual income:	90 days  ¥160  Lower income household exempted from residence tax Per meal	• Lower income household exempted from residence tax Per meal \$\text{\ti}\text{\texi{\text{\texi\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\texi{\text{\text{\texi}\text{\texit{\text{\text{\text{\texi{\texi{\texi{\texi{\texi{\texi{\texi	Sickness and injury allowance     Lump-sum birth allowance, etc.	Per day Class 1: ¥390 Class 11: ¥3,230	16.4% of benefit expenses, etc.
		men's Irance	Japan Health Insurance Association	117 58 59	After	(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	¥100	<ul> <li>Applicable to those aged 65 or older in long-term care beds</li> <li>For patients with</li> </ul>		9.60% (sickness insurance premium rate)	Fixed amount
Mutual		ional public mployees	20 mutual aid associations		reaching compulsory education age until age 70 30%	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)		intractable/rare diseases, etc. and thus in high need for inpatient	Same as	-	
Mutual aid associations		ocal public loyees, etc.	64 mutual aid associations	8,545 4,565 3,980	Before reaching compulsory education	¥15,000, outpatient (per person) ¥8,000 • Per-household standard amount 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		medical care, the amount of co-payment is the same as standard co- payment for	above (with additional benefits)	-	None
ons		vate school chers/staffs	1 Corporation		age 20%	benefits paid     Reduced payment for multiple high-cost medical care     For persons who have received high-cost care     three times within a twelve-month period, the		meal expenses		-	
		rmers, self-	Municipalities 1,716		70 or older but younger than 75 20% (30% for	maximum co-payment of the fourth time and up will be reduced to: (Persons younger than 70) (average annual income: over approximately 11.60 million yen)					41% of benefit expenses, etc.
	е	mployed, etc.	NHI associations 162		persons with more than a certain amount of income)	over approximately 11.00 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)					28.4~ 47.4% of benefit expenses, etc.
National Health Insurance (NHI)	per Er	Retired sons under mployees' Health nsurance	Municipalities 1,716	29,324  Municipalities 26,599  NHI associations 2,726		W44,000 (average annual income: under approximately 3.70 million yen) ¥44,000 (exempted from residence tax) ¥24,600  (Persons aged 70 or older but younger than 75) (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) ¥44,000 (average annual income: under approximately 3.70 million yen) ¥44,000 (average annual income: under approximately 3.70 million yen) ¥44,000 (average annual income: with a suffering from hemophilia or chronic renal failure requiring dialysis, etc.: ¥10,000 (patientyoungerthan 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 copayments 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-payments determined carefully according to their income and age.			•Lump-sum birth allowance, •Funeral expenses	Calculated for each household according to the benefits received and ability to pay Levy calculation formulas differ among insurers	None

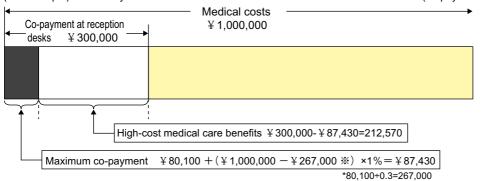
Medical care system for the elderly aged 75 and over	[Implementing bodies]  Wide area unions for medical care system for the elderly aged 175 and over	11. (30% person 18,032 more tt	s with nan a	(average annual income:	Same as above, except for Recipients of old-age Welfare Pensions Per meal ¥100	• Funeral expenses , etc.	amount of the per capita rate and income ratio of insured persons provided	• About10% of benefits, expenses, etc. are borne as insurance premiums (Breakdown of public funding) National: Prefectures Municipalities 4:1:1 In addition, about 40%
	47	amoui		*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) ¥44,000 (average annual income: under approximately 3.70 million yen) ¥44,000			of benefits, expenses, etc. are borne as insurance premiums	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 (0.50).

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

- O 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.
- O 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%)

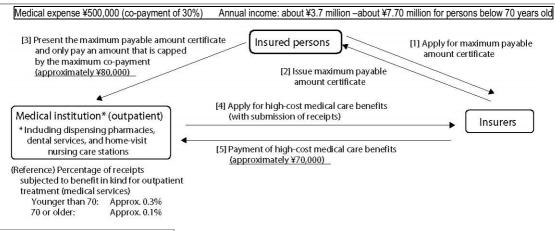


#### (Note) Per-household addition system

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

O 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.

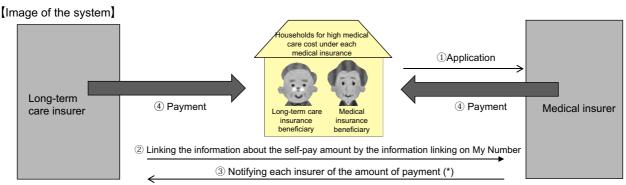


- Basic mechanism of benefit in kind
- [1] Insured persons, etc. apply to insurers, etc. for a maximum payable amount certificate to be issued. (Same treatment as with inpatient treatment)
- [2] Insurers issue insured persons with maximum payable amount certificates according to the income category of 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

- O 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 th 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 the 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".

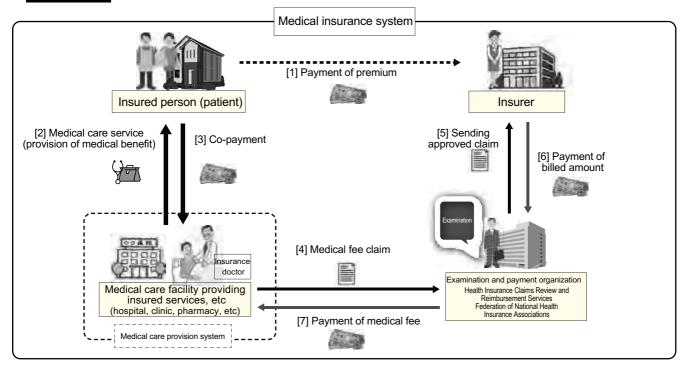


(\*) Calculating the total amount of annual self-payment amount from the information on self-payment amount obtained in (2), to calculate the amount of High Cost Total Medical Care payment amount. This calculated amount of payment is apportioned among the insurers according to the ratio of the self-payment 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 2020 Medical fees revision

### The FY 2020 Medical fee revision

# Medical fee revision

#### 1. Medical fees +0.55%

\*1 Of which, revised portion except for \* 2 +0.47% Revision rate of each fee Medical services +0.53% +0.53%

Dental services +0.59% Dispensations +0.16%

\*2 Of which, the special response to work style reforms of the employed doctors at emergency hospitals with utilizing consumption tax revenue + 0.08%

#### 2. Drug price

[1] Drug price ▲ 0.99%

\*2 Of which, Revisions to the actual prices, etc. ▲ 0.43%, Revisions to the recalculation of market expansion, etc. ▲ 0.01%

[2] Material price revision ▲ 0.02%

\* Of which, revision to the actual price, etc.

▲ 0.01%

# Responding to work style reform for the employed doctors

As the medical fee

Public expenses about 12.6 billion yen Public expenses about 14.3 billion yen

As the community medical care comprehensive securing fund

Regarding the response to work style reform for employed doctors, overtime work exceeding the upper limit will be resolved as soon as possible toward the application of the upper limit regulation for overtime work for doctors and the end of application of the provisional special level. In order to achieve above, the measures in medical fees and the measures of the Regional Medical Care Comprehensive Security Fund will be considered, in addition to the institutional measures to promote shortening of working hours by medical institutions.

# Basic Understanding of the FY2020 Medical fee revision

#### Basic recognition of the revision

- ▶ Realization of the social security system for all generations towards extending a healthy life and coming of a 100-year-old life society
- ▶ Realization of medical care accessible to patients and citizens
- ▶ Realization of a society where people can receive appropriate medical care with confidence regardless of where they live, and promotion of reforms in the working styles of doctors and others
- Securing the stability and sustainability of social security systems, and harmonization with the economy and finances

#### **Basic Perspectives and Specific Directions for Revision**

1 Reducing the burden on medical personnel and promoting reforms in the working styles of physicians, etc. [Priority Issues]

[Examples of Specific Directions]

- Evaluation of efforts to improve the working environment for doctors, etc., such as long working hours
- Evaluation of emergency medical care systems requiring urgent action from the perspective of securing regional medical care
- · Promotion of the use of ICT that contributes to the efficiency of operations

# 3 Differentiation and strengthening of medical functions, and promotion of cooperation and the Community-based Integrated Care System

[Examples of Specific Directions]

- · Evaluation of inpatient care based on medical functions and patients' conditions
- · Functional separation of outpatient care
- · Ensure high quality home medical care and home nursing care
- · Efforts to promote a Community-based Integrated Care System

# 2 Realization of high-quality medical care that is accessible, safe, and secure for patients and the public

[Examples of Specific Directions]

- · Evaluation of family doctors' functions
- Promotion of the provision of necessary information and consultation support for patients, efforts to prevent the progression of serious diseases and contribute to balancing medical treatment and work
- · Promotion of evaluation that also focuses on outcomes
- · Appropriate evaluation of areas that require prioritization
- 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
- Prioritization and optimization of necessary evaluations to promote a structural shift in pharmacies from physical to human services, and evaluation of in-hospital pharmacist services
- · Utilization of ICT in medical care

# 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 (Relisted)
- Functional differentiation of outpatient care and promotion of prevention of progression of serious diseases (Re-listed)
- Promotion of appropriate use of pharmaceuticals through collaborative efforts among physicians, in-house pharmacists, and pharmacy pharmacists

#### **Detailed Information**

#### Outline of the FY 2020 Medical fees revision

#### Outline of the FY 2020 Medical fee revision

# I Reducing the burden on medical personnel and promoting reforms in the working styles of physicians, etc.

- 1. Evaluation of emergency medical care systems requiring urgent action from the perspective of securing regional medical care
- 2 Evaluation of efforts to improve the working environment for doctors, etc., such as long working hours
- 3 Promotion of team medicine, etc. for task shifting or task sharing
- 4 Promotion of the use of ICT that contributes to the efficiency of operations
- II Differentiation and strengthening of medical functions, and promotion of cooperation and the Community-based Integrated Care System
- Evaluation of inpatient care based on medical functions and patients' conditions
- 2 Functional separation of outpatient care
- 3 Ensure high quality home medical care and home nursing care
- 4 Efforts to promote a Community-based Integrated Care System
- 5 Promotion of information sharing and cooperation among medical professionals and medical institutions

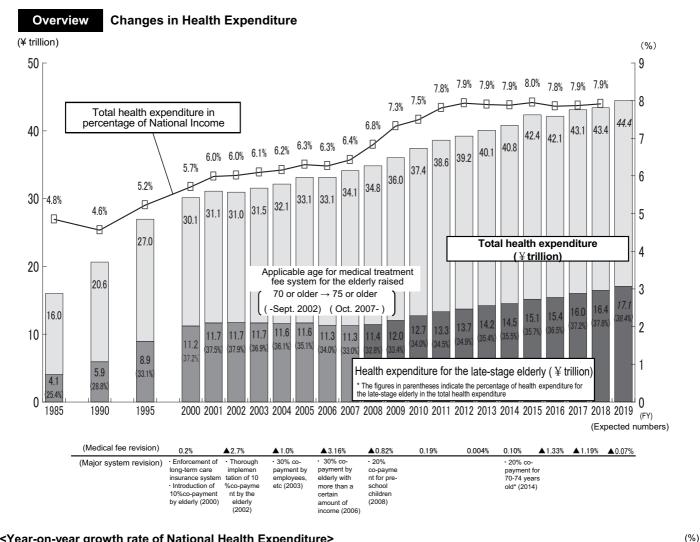
# I Realization of high-quality medical care that is accessible, safe, and secure for patients and the public

- 1.Evaluation of family doctors' functions
- 2 Promotion of information provision and consultation support necessary for patients
- 3 Enhancing multi-professional cooperation, including with local communities
- 4 Prevention of progression of diseases
- 5 Promotion of measures contributing to balancing medical treatment and work
- 6 Promotion of evaluation that also focuses on outcomes
- 7 Appropriate evaluation of areas that require prioritization
- 8 Appropriate evaluation and steady introduction of advanced medical technologies, including new technologies such as innovations in pharmaceuticals, medical equipment, and testing
- 9 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
- 10 Evaluation of pharmacies according to their family doctor functions in the community, prioritization and optimization of necessary evaluations to promote structural transformation of pharmacies from physical to human services, and evaluation of in-hospital pharmaceutical services
- 11 Utilization of ICT in medical care

# $\, \mathbb{N} \,$ $\,$ I mproving the stability and sustainability of the system through optimization and efficiency

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

# **Health Expenditure**



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

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	1985	1990	1995	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
Total health expenditure	6.1	4.5	4.5	<b>▲</b> 1.8	3.2	<b>▲</b> 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	2.4
Health expenditure for the late-stage elderly	12.7	6.6	9.3	<b>▲</b> 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	3.9
GDP	7.2	8.6	2.7	1.2	▲1.8	▲0.8	0.6	0.7	0.8	0.6	0.4	<b>▲</b> 4.0	▲3.4	1.5	▲1.1	0.1	2.6	2.2	2.8	0.7	2.0	0.1	_

(Note) 1. The national income and GDP are based on the national accounting announced by the Cabinet Office.

<sup>2.</sup> National medical expenses (and those for advanced elderly. The same applies hereinafter) in FY2019 are estimates including the actual performance. The expenses for FY2019 are estimated by multiplying the national medical expenses for FY2018 by the rate of increase in approximate medical expenses in FY2019 (figures written in italics in the table above).

<sup>\*</sup>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.

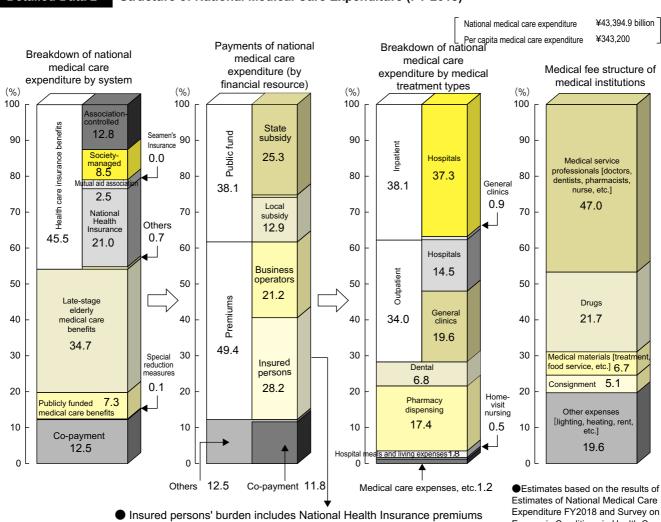
#### **Detailed Data 1 National Medical Care Expenditure of OECD Countries (2019)**

Country	Total medica		Per capita m care expend (\$)	14	Remarks	Country	Total medicare expendin GDP (%)	liture	Per capita m care expend (\$)		Remarks
	in GDP (%)	Rank	(Ψ)	Rank			III GDF (%)	Rank	(Ψ)	Rank	
United States	17.0	1	11,071.7	1		Iceland	8.8	20	4,811.4	16	
Switzerland	12.1	2	7,732.4	2		Italy	8.7	21	3,649.2	20	
Germany	11.7	3	6,645.8	4		Slovenia	8.3	22	3,224.0	25	
France	11.2	4	5,375.7	12		Korea	8.0	23	3,384.2	23	
Japan	11.1	5	4,822.8	15		Greece	7.8	24	2,383.6	29	
Sweden	10.9	6	5,782.3	6		Czech Republic	7.8	25	3,426.0	22	
Canada	10.8	7	5,418.4	11		Israel	7.5	26	2,932.5	26	
Norway	10.5	8	6,646.7	3		Colombia	7.3	27	1,212.6	36	
Austria	10.4	9	5,851.8	5		Slovakia	6.9	28	2,353.6	30	
Belgium	10.3	10	5,428.0	10		Ireland	6.8	29	5,275.5	13	
United Kingdom	10.3	11	4,653.1	17		Lietuva	6.8	30	2,638.1	27	
Denmark	10.0	12	5,567.9	8		Estonia	6.8	31	2,578.8	28	
Netherlands	10.0	13	5,765.1	7		Hungary	6.4	32	2,222.4	32	
Portugal	9.6	14	3,378.6	24		Poland	6.3	33	2,292.1	31	
Australia	9.3	15	5,787.4	14		Latvia	6.3	34	1,972.6	34	
New Zealand	9.3	16	4,204.0	19		Mexico	5.5	35	1,153.6	37	
Chile	9.1	17	2,159.4	33		Luxembourg	5.4	36	5,558.3	9	
Finland	9.1	18	4,578.4	18		Turkey	4.4	37	1,139.5	35	
Spain	9.0	19	3,616.5	21		OECD average	8.8		4,224.1		

Source: "OECD HEALTH DATA 2020"

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

#### **Detailed Data 2** Structure of National Medical Care Expenditure (FY 2018)



Economic Conditions in Health Care (2018), etc.

#### **Detailed Data 3**

# **Changes in National Medical Care Expenditure and Percentage Distribution**

	National	General									Dental	Pharmacy	Hospital	Medical	Home-visit
.,	medical care	medical	Hospitals	General	Impatient medical	Hospitals	General	Outpatient medical	Hospitals	General	medical	dispensing	mealand	treatment fees athealth	nursing
Year	expenditure	fees		clinics	fees		clinics	fees		clinics	fees	medical fees	living expenses	service facilities forthælderly	medical fees
												2)	3)	4)	
		Ī	i i	Ī	Ī	l .	l .	,	l00 million)	i i		i	i	i	l.
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 2002	310,998 309,507	242,494 238,160	164,536 162,569	77,958 75,591	115,219 115,537	110,841 111,180	4,378 4,357	127,275 122,623	53,695 51,389	73,580 71,234	26,041 25,875	32,140 35,297	9,999 9,835	:	324 339
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 2007	331,276 341,360	250,468 256,418	168,943 173,102	81,525 83,316	122,543 126,132	117,885 121,349	4,658 4,782	127,925 130,287	51,058 51,753	76,867 78,534	25,039 24,996	47,061 51,222	8,229 8,206	:	479 518
2007	341,300	200,410	170,102	00,010	120,102	121,040		ige distribu		70,004	24,550	01,222	0,200	ļi	1 310
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				
1973	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 2001	100.0 100.0	78.9 78.0	53.6 52.9	25.3 25.1	37.5 37.0	36.0 35.6	1.5 1.4	41.5 40.9	17.6 17.3	23.9 23.7	8.5 8.4	9.2 10.3	3.3 3.2	:	0.1 0.1
2002	100.0	76.9	52.5	24.4 24.4	37.3	35.9	1.4	39.6 39.2	16.6	23.0	8.4	11.4	3.2 3.1	•	0.1 0.1
2003 2004	100.0 100.0	76.4 75.9	52.0 51.3	24.4	37.2 36.9	35.8 35.5	1.4 1.4	39.2	16.2 15.8	23.0 23.2	8.0 7.9	12.3 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
2005	100.0	75.4 75.6	51.0	24.7	37.0	35.2	1.4	38.6	15.5	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
	National	Medical									Dental	Pharmacy	Hospital	Home-visit	Medical
Year	medical care	fees of medical	Hospitals	General	Impatient medical	Hospitals	General	Outpatient medical	Hospitals	General	medical fees	dispensing medical	meals and living	nursing medical	care expenses,
	expenditure	treatment 5)		clinics	fees		clinics	fees		clinics		fees 2)	expenses 3)	fees	etc. 5)
		,					Estimated	amount (¥1	00 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 2010	360,067 374,202	262,041 272,228	178,848 188,276	83,193 83,953	132,559 140,908	128,266 136,416	4,293 4,492	129,482 131,320	50,582 51,860	78,900 79,460	25,587 26,020	58,228 61,412	8,161 8,297	665 740	5,384 5,505
2010	385,850	272,226	192,816	85,314	140,906	139,394	4,492	131,320	53,421	80,954	26,020	66,288	8,231	808	5,637
2012	392,117	283,198	197,677	85,521	147,566	143,243	4,323	135,632 137,780	54,434	81,197	27,132	67,105	8,130	956	5,597
2013 2014	400,610 408,071	287,447 292,506	201,417 205,438	86,030 87,067	149,667 152,641	145,523 148,483	4,144 4,158	139,865	55,894 56,956	81,886 82,909	27,368 27,900	71,118 72,846	8,082 8,021	1,086 1,256	5,509 5,543
2015 2016	423,644 421,381	300,461 301,853	211,860 214,666	88,601 87,187	155,752 157,933	151,772 154,077	3,980 3,856	144,709 143,920	60,088 60,589	84,622 83,332	28,294 28,574	79,831 75,867	8,014 7,917	1,485 1,742	5,558 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 Percent	147,716 age distrib	62,730 ution (%)	84,986	29,579	75,687	7,917	2,355	5,158
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 2010	100.0 100.0	72.8 72.7	49.7 50.3	23.1 22.4	36.8 37.7	35.6 36.5	1.2 1.2	36.0 35.1	14.0 13.9	21.9 21.2	7.1 7.0	16.2 16.4	2.3 2.2	0.2 0.2	1.5 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	100.0 100.0	72.2 71.8	50.4 50.3	21.8 21.5	37.6 37.4	36.5 36.3	1.1 1.0	34.6 34.4	13.9 14.0	20.7 20.4	6.9 6.8	17.1 17.8	2.1 2.0	0.2 0.3	1.4 1.4
2013		11.0					1.0	34.4	14.0	20.4	6.8	17.8	2.0	0.3	1.4
2013 2014	100.0	71.7	50.3	21.3	37.4	36.4									
2014 2015	100.0 100.0	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
	100.0														

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

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 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 health 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. Source: (Note)

#### **Detailed Data 4** Changes in Health Expenditure for the Elderly in the Later Stage of Life

	FY	Total	Medical				Dispensing	Hospital meals	Home-visit	Medical treatment	Health service
		Total	fees	Inpatient	Outpatient	Dental	Dispensing	and living	nursing	etc.	facilities for the elderly
	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
Actual amount (¥100 million)	FY 1995	89,152	75,910	38,883	34,319	2,708	3,909	4,678	174	1,224	3,259
.m	FY 1996	97,232	82,181	42,314	36,789	3,078	4,620	4,816	323	1,094	4,198
±10(	FY 1997	102,786	85,475	44,205	37,965	3,305	5,606	4,869	479	1,073	5,285
int (	FY 1998	108,932	88,881	46,787	38,584	3,511	6,900	4,967	657	1,101	6,426
mor	FY 1999	118,040	94,653	49,558	41,181	3,915	8,809	5,115	858	1,169	7,436
<u>a</u>	FY 2000	111,997	94,640	48,568	41,871	4,200	10,569	4,612	235	1,271	670
Actr	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	•

(Note) 1. Terms are defined as follows.

- a.Medical fees: Expenses paid for medical care services received at insurance medical care facilities. (excluding insurance pharmacies, etc.). (Benefit in kind)
- b.Dispensing: Refers to the expenses paid when receiving medicine at an insurance-covered pharmacy (Benefit in kind) c.Hospital Meals and living: Meal and living expenses during hospitalization. (Benefit in kind)
- d.Home-visit nursing: Expenses paid for home-visit nursing care services by the specified service providers. (Benefit in kind)

  e.Medical treatment, etc.: Expenses paid for home-visit nursing care services by the specified service providers. (Benefit in kind)

  e.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)
- f.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)
- g.Expenses include co-payment, standard co-payment for meal/living expenses, and basic fees of home-visit nursing

- 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.
   The figures for FY2008 include delayed requests for health expenditure for the elderly from April 2008 to February 2009.
   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 Iburi Earthquake and Typhoon No. 21 (¥0.4 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 2018 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
	Premium (tax) revenue	91,429	ìGĒH€	GĒG	HF€	FŒĤÍ
	National treasury contribution	11,850	Ğ	H€ĨĒFJ	GJ	IJÊHÍ
0	Prefectural contribution	_		F€ÎHÍJ		FI Ê FG
pera	Municipal contribution	_		îÊÍÍ		FHÊ€FH
Operating revenue	Grants for late-stage elderly	_				ÎŒÎÏH
even	Grants for early-stage elderly	_	G	HÎÊ€H		
le	Retirement grants	_		ÍJJ		
	Others	164	FÊ∃Ï	FGÎ ÊHÎ F	F	ĠF
	Total	103,443	ÌHÊĴ€Í	GHÍ ÉGH	H€	FÍ ŒĤÌ F
0	Insurance benefit expenses	60,016	l€ÊGÍ	îîâîî	G€€	FÍ FÊÎÎ
pera	Late-stage elderly support coverage	19,516	FÌ ÊGÌ	FÍΒ̈́I	ÎJ	
Operating expenditure	Levies for early-stage elderly	15,268	FÍ ŒUÎ	îì	HF	
expe	Contributions for retirees	208	<b>GFF</b>		F	
nditu	Others	2,505	ÍÊJI	FGJÉ Î J	Ϊ	ſď
ē	Total	97,513	Ì∰ÍI	G <b>HÉ</b> ÍÏ	H€Ï	FÍ ŒUF
	Balance of ordinary revenue and expenditure	5,930	HÊÉÍG	FÊÏÏ	Н	F€

		Government-managed Health Insurance/ JHIA-managed Health Insurance	Society-managed Health Insurance
	Deferred repayment of state subsidy	-	-
	Non-operating subsidy for benefits, etc.	-	658
Niama amanatina	Adjustment premium revenue	-	1,209
Non-operating	Subsidies to financial adjustment programs	-	1,120
revenue	Transfer from reserves, etc. and surplus carried forward	-	2,876
	Others	18	92
	Total	18	5,840
Non anaustina	Contribution to financial adjustment programs	-	1,203
Non-operating expenditure	Others	-	83
experialture	Total	-	1,287
Balance of non-	pperating revenue and expenditure	18	4,553 (1,676)
Balance of total	revenue and expenditure	5,948	7,604 (4,728)
Reserve fund, et	tc.	28,521	51,002

- (Note) 1. The above figures indicate medical service revenue and expenditure.
  - 2. 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 of ¥125.8 billion 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.
  - 3. 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).
  - 4. Contribution to health care services for the elderly is included in "others" of operating expenditure for each system.
  - 5. Reserve fund, etc. indicates reserves for the Japan Health Insurance Association-managed Health Insurance. It includes reserves, a reserve fund (¥4,733.6 billion), and assets such as land and buildings, etc. for the Society-managed Health Insurance.
  - 6. In the non-operating revenue of the Japan Health Insurance Association-managed Health Insurance, operation account surplus at the end of FY2015 was added to FY2016 settlement of accounts.
  - 7. 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.
  - 8. The figures may not equal the total, or balance of accounts may vary due to rounding.

Source: Health Insurance Bureau, MHLW

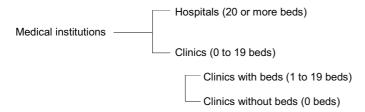
# **Types of Medical Institutions**

#### 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.



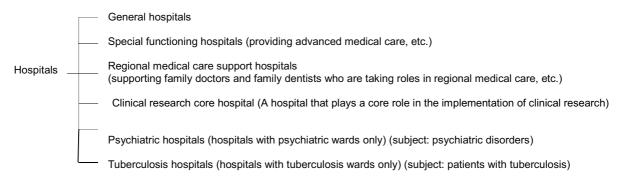
Hospitals are required to provide truly scientific and appropriate treatment to injured or sick people and are expected to have substantial facilities.

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

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

#### Requirements for Approval

- O Having capabilities of providing, developing, evaluating, and conduct training of advanced medical care
- O 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%)
- O Number of beds .... Must have 400 or more beds.
- O Staff deployment
  - 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.
- O Facilities ............. Must have intensive care units, sterile rooms, and drug information management rooms.
- O 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
- O Professing 16 specified clinical areas in principle.
- O Having at least 70 papers written in English published annually in refereed journals, etc.
- O 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.

# 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

- O Provide medical care to patients on referral (including the reverse case in which patients are referred to family doctors)
- O Implement shared use of medical devices
- O Provide emergency medical care
- O 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%
- O Having the ability to provide emergency medical care
- O Securing a system to enable doctors, etc. in regions to use buildings, facilities, and devices, etc.
- O Holding trainings for those engaged in regional medical care,
- O Having at least 200 hospital beds in principle and facilities appropriate for being regional medical care support hospitals, etc.

<sup>\*</sup> The numberofapproved hospitals (as of April 1,2021) ......87

<sup>\*</sup> The number of approved hospitals (as of September, 2020) ..... 652 Hospitals

#### **Detailed Information 3**

#### **Outline of Clinical Research Core Hospital System**

#### **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**

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

#### Requirements of Approval

ONumber 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
- ONumber of papers on specified clinical researches (in the past three years) .........45 cases or more
- ONumber of cases where assistance was provided for specified clinical researches conducted by other medical institutions (in the past year) ....15 cases or more
- OTraining 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

OHaving 10 or more specified clinical departments

ONumber of hospital beds: Having at least 400 hospital beds

OStaff 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
- OFacilities: Must have clinical research facilities with equipment to ensure accuracy of researches and intensive care units
- OThe requirements for approval concerning the number of new specified clinical researches conducted and the number of papers on specified clinical researches are separately set for clinical research core hospitals that deal with specific areas.

<sup>\*</sup> The number of approved hospitals (as of April 1, 2021) ...... 13 Hospitals

	Other beds		Psychiatric beds	Epidemic beds	Tuberculosis bed
	Progress of aging     Changes in diseas				
uction of specially authori	Zed geriatrics wards (19	Specially authorized geriatrics wards	Psychiatric beds	Epidemic beds	Tuberculosis be
on of long-term care-type	Other beds Specially autho	2)]		Infection	
	geriatrics wa	rds care-type beds	Psychiatric beds	disease beds	Tuberculosis be
		lents requiring			
		ig term eare			
on of general beds and lor	caused by the rapideen created, inclusion are still intermingle	ents requiring long-ter d progress in the birth ding long-term care-t d.	rate decline and ag	ing. Although vario	ous systems have
ion of general beds and lor Provide medical care that is	caused by the rapi been created, inclu are still intermingle ng-term care beds (2000	ents requiring long-ter d progress in the birth ding long-term care-t d.	rate decline and ag	ing. Although vario	ous systems have
	caused by the rapibeen created, incluare still intermingle ng-term care beds (2000 suitable for patients' sym	ents requiring long-ter d progress in the birth ding long-term care-t d.	rate decline and ag	ing. Although vario	ous systems have
Provide medical care that is	caused by the rapibeen created, incluare still intermingle ag-term care beds (2000 suitable for patients' sym  Long-te	ents requiring long-ter d progress in the birth iding long-term care-t d. )]]	rate decline and ag ype bed group syste	ing. Although varion, patients with varion with varions with varions and infection	ous systems ha arious symptom
Provide medical care that is General beds	caused by the rapibeen created, incluare still intermingle are still intermingle suitable for patients' sym  Long-te  Patien long  In order to promote information on medimportant.	ents requiring long-tent progress in the birth iding long-term care-t d.  )]  inptoms  irm care beds  ints requiring interm care  division/cooperation dical functions implements	Psychiatric beds of medical functions.	Infection disease beds identifying and ar	Tuberculosis be
Provide medical care that is	caused by the rapibeen created, incluare still intermingle are still intermingle suitable for patients' sym  Long-te  Patien long  In order to promote information on medimportant.  on reporting system (20)	ents requiring long-tent progress in the birth iding long-term care-t d.  )]  inptoms  irm care beds  ints requiring interm care  division/cooperation dical functions implements	Psychiatric beds of medical functions.	Infection disease beds identifying and ar	Tuberculosis be

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	Public	Others	General clinics	Dental clinics
	•	(regrouped)	(regrouped)	(regrouped)	Contrar cimiles	201101 0111100
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	7,108	99,824	68,384
2010	8,605	274	1,258	7,118	99,547	68,156
2012	8,565	274	1,252	7,073	100,152	68,474
2012	8,540	273			*	•
2013	8,493	329	1,242	7,025	100,528	68,701
2014	8,493 8,480	329 329	1,231	6,933	100,461	68,592
2016			1,227	6,924	100,995	68,737
2016	8,442	327 327	1,213	6,902	101,529	68,940
	8,412	-	1,211	6,874	101,471	68,609
2018 2019	8,372 8,300	324 322	1,207	6,841	102,105	68,613
2019		522	1,202	6,776	102,616	68,500

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 Policy 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
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
National	291	276	275	274	274	274	273	329	329	327	327	324	322
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
Social insurance organizations	123	122	122	121	121	118	115	57	55	53	52	52	51
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
Private	533	476	448	409	373	348	320	289	266	240	210	187	174
Others	888	872	872	869	867	864	868	866	866	855	846	838	831
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
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
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
500+ beds	473	468	462	460	456	449	450	437	425	418	411	408	401

## Detailed Data 2 Changes in Number of Hospitals by Hospital Type

	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
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
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
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

Source: "Survey of Medical Institutions", Health Statistics Office to to the Director-General for Statistics, Information Policy 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
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
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
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
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
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
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
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

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

# Detailed Data 4 Changes in Bed Utilization Rate and Average Length of Stay by Bed Type

		Bed utilization rate											
	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
Total	82.2	81.7	81.6	82.3	81.9	81.5	81.0	80.3	80.1	80.1	80.4	80.5	80.5
Psychiatric beds	90.2	90.0	89.9	89.6	89.1	88.7	88.1	87.3	86.5	86.2	86.1	86.1	85.9
Infectious disease beds	2.2	2.4	2.8	2.8	2.5	2.4	3.0	3.2	3.1	3.2	3.3	3.6	3.8
Tuberculosis beds	37.1	38.0	37.1	36.5	36.6	34.7	34.3	34.7	35.4	34.5	33.6	33.3	33.2
Long-term care beds	90.7	90.6	91.2	91.7	91.2	90.6	89.9	89.4	88.8	88.2	88.0	87.7	87.3
General beds	76.6	75.9	75.4	76.6	76.2	76.0	75.5	74.8	75.0	75.2	75.9	76.2	76.5
Long-term care beds for nursing care	93.9	94.2	94.5	94.9	94.6	93.9	93.1	92.9	92.1	91.4	90.9	91.3	90.7

		Average length of stay											
	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
Total	34.1	33.8	33.2	32.5	32.0	31.2	30.6	29.9	29.1	28.5	28.2	27.8	27.3
Psychiatric beds	317.9	312.9	307.4	301.0	298.1	291.9	284.7	281.2	274.7	269.9	267.7	265.8	265.8
Infectious disease beds	9.3	10.2	6.8	10.1	10.0	8.5	9.6	8.9	8.2	7.8	8.0	8.3	8.5
Tuberculosis beds	70	74.2	72.5	71.5	71.0	70.7	68.8	66.7	67.3	66.3	66.5	65.6	64.6
Long-term care beds	177.1	176.6	179.5	176.4	175.1	171.8	168.3	164.6	158.2	152.2	146.3	141.5	135.9
General beds	19	18.8	18.5	18.2	17.9	17.5	17.2	16.8	16.5	16.2	16.2	16.1	16.0
Long-term care beds for nursing care	284.2	292.3	298.8	300.2	311.2	307.0	308.6	315.5	315.8	314.9	308.9	311.9	301.4

Source: "Hospital Report", Health Statistics Office to the Director-General for Statistics, Information Policy 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 Kesennuma medical district of Miyagi Prefecture, and five in Soso medical district of Fukushima Prefecture) due to the effect of the Great East Japan Farthquake

<sup>2.</sup> 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.

<sup>3.</sup> 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.

### 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) 1,468 persons are admitted in 13 National Hansen's Disease Sanatoriums nationwide (as of May 1, 2020).
- (2) 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	1,090	

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

#### [National Hospital Organization]

- (1) 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).
- (2) 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, 2020)

Institutions	Number of hospitals	Number of beds
National Hospital Organization	143	53,029

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

- (1) 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)
- (2) 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, 2021)

(Reference) Number of nospitals (as of April 1, 20	(21)		
Institutions	Specialized diseases, etc.	Number of	Number
mondations	opedialized diseases, etc.	hospitals	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, 2021)

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

#### [Japan Community Health care Organization]

- (1) Japan Community Health care Organization is an independent administrative agency established and based on "Act on the Japan Community Health care Organization, Independent Administrative Agency" (Act No. 71 of 2005).
- (2) Japan Community Health care Organization has a wide variety of medical functions from emergency to rehabilitation. Also, one of the main traits of Japan Community Health care Organization is that about half of the hospitals under Japan Community Health care 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, 2021)

(Reference) Number of facilities (as of February 1, 2021)		
Classification	Number of facilities	Number of beds
Hospital	57	15,240
Classification	Number of facilities	[Admission capacity]
Long-term care health facilities	26	2,479
Classification	Number of facilities	[Student capacity]
Nursing School	6	685

# **Medical Professionals**

#### Overview

Number of Physicians, etc.

The number of Physicians and dentists are increasing every year. As of December 31, 2018, there are 311,963 Physicians and 101,777 dentists.

#### **Number of Medical Professionals**

Physicians
Dentists
Pharmacists
311,963 persons
101,777 persons
Pharmacists
240,371 persons

Source: "Statistics of Physicians, Dentists and Pharmacists 2018", Health Statistics Office to the Director-General for Statistics, Information Policy and Industrial Relations, MHLW

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

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

Source: Health Policy Bureau, MHLW (2019)

· Physical therapists (PT) 91,694.8 persons 47,852.0 persons · Occupational therapists (OT) Orthoptists 8,889.1 persons · Speech language hearing therapists 16,639.2 persons • Orthotists 105.3 persons · Clinical radiologic technologists 54,213.1 persons Medical technicians 66,866.0 persons 28,043.4 persons · Clinical engineers

Source: "Survey of Medical Institutions and Hospital Report 2017", Health Statistics Office to the Director-General for Statistics, Information Policy and Industrial Relations, MHLW

<sup>\*</sup> Full-time equivalent numbers

Dental hygienists	132,629 persons
Dental technicians	34,468 persons
<ul> <li>Massage and shiatsu practitioners</li> </ul>	118,916 persons
<ul> <li>Acupuncturists</li> </ul>	121,757 persons
<ul> <li>Moxibustion practitioners</li> </ul>	119,796 persons
Judo therapists	73,017 persons

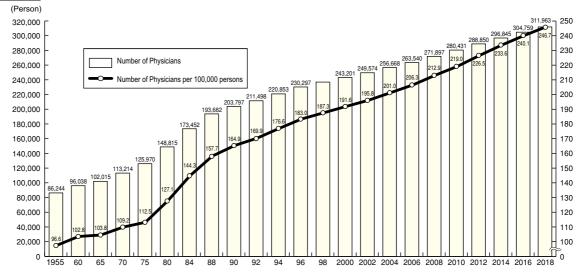
Source: "Report on Public Health Administration and Services 2018", Administrative Report Statistics Office to the Director-General for Statistics and Information Policy, MHLW

• Emergency life-saving technicians 61,771 persons

Source: Health Policy Bureau, MHLW (as of March 31, 2020)

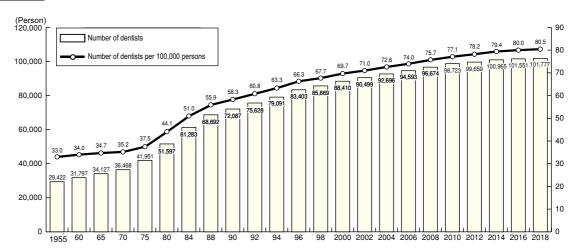
<sup>\*</sup> Number of registered licensees

# Detailed Data 1 Changes in Number of Physicians



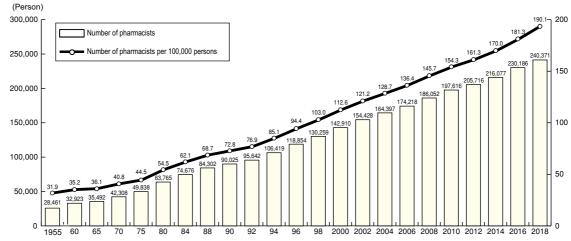
Source: "Statistics of Physicians, Dentists and Pharmacists", Health Statistics Office to the Director-General for Statistics, Information Policy and Industrial Relations, MHLW

# **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 Policy and Industrial Relations, MHLW

# Detailed Data 3 Changes in Number of Pharmacists



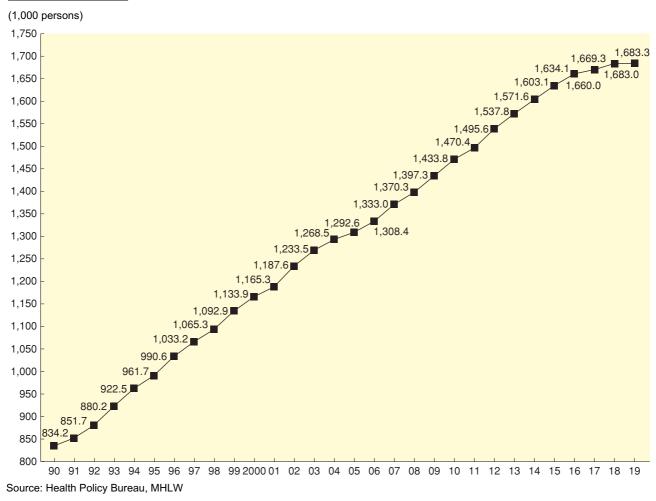
Source: "Statistics of Physicians, Dentists and Pharmacists", Health Statistics Office to the Director-General for Statistics, Information Policy and Industrial Relations, MHLW

<sup>\*</sup> Medical facility employees

<sup>\*</sup> Medical facility employees

<sup>\*</sup> Pharmacy or Medical facility employees

# Detailed Data 4 Changes in Number of Nursing personnel



# Conforming Rate to the Statutory Number of Doctors and Nurses Designated in the Medical Care Act and Sufficiency Status (Results of FY2018 On-Site Inspection)

# **Detailed Data 1** Regional Conforming Rates

(Unit: %)

									( - 1 1 1 1 7 7 )
Regio	Nationwide	Hokkaido Tohoku	Kanto	Hokuriku Koshinetsu	Tokai	Kinki	Chugoku	Shikoku	Kyushu
Doctors	97.0	92.7	98.6	96.2	98.8	99.3	96.3	95.1	97.2
Nurses	99.0	99.7	98.1	99.3	98.4	98.6	99.2	99.3	99.8

# 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	7,467 (95.7)	225 (2.9)	7,692 (98.6)
Hospitals with insufficient number of nurses	104 (1.3)	6 (0.1)	110 (1.4)
Total	7,571 (97.0)	231 (3.0)	7,802 (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".

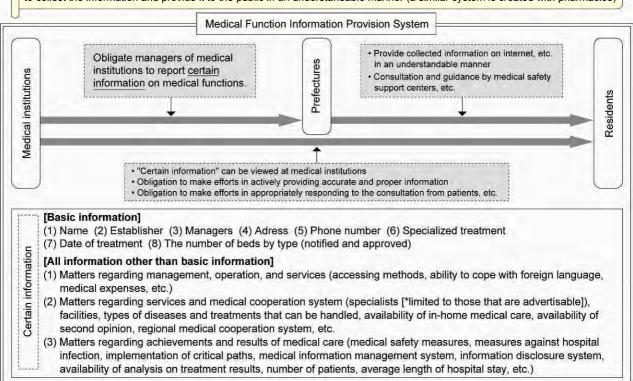
## **Provision of Medical Function Information**

#### **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 doting, 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**

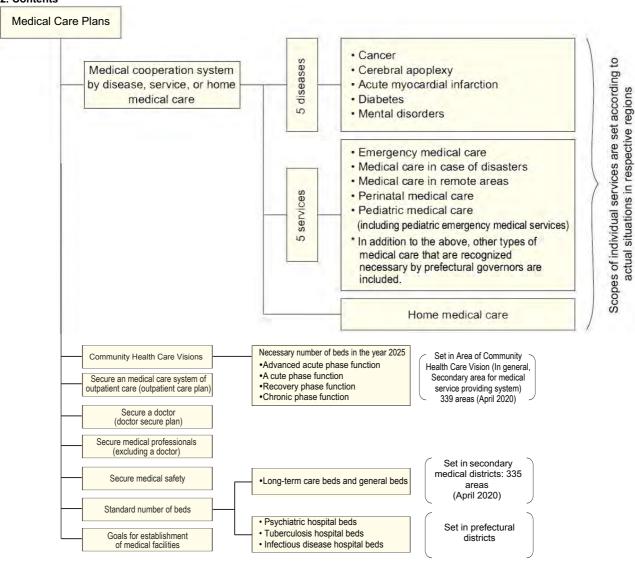
#### Overview

#### **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

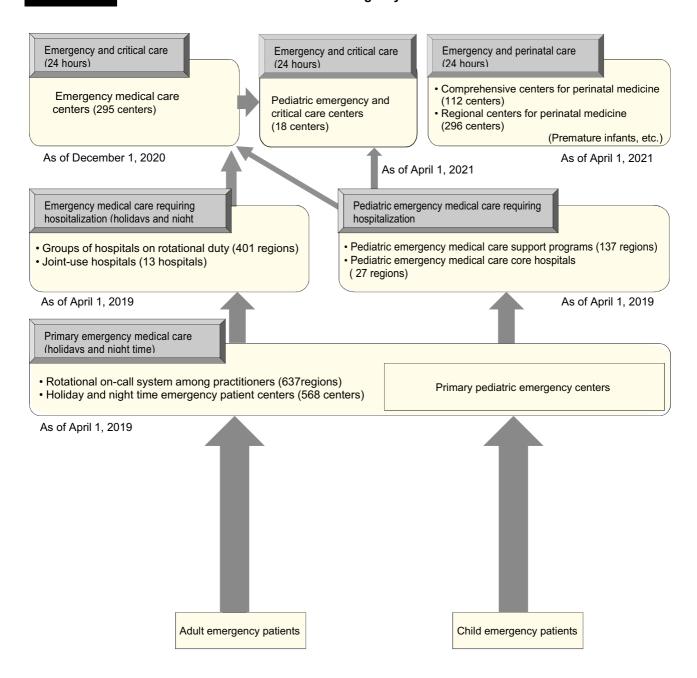
(As of April 2018)

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

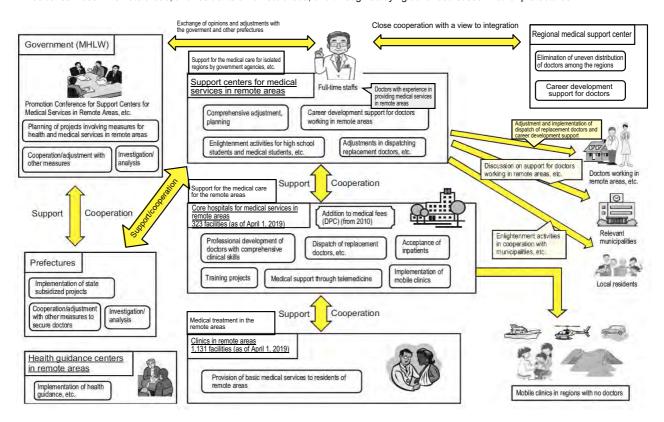


#### **Medical Services in Remote Areas**

#### 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

<sup>\*</sup> 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, 2019
- (2) Core hospitals for medical services in remote areas (subject to assistance of operational expenses, facility establishment expenses, and equipment installment expenses) 323 hospitals are designated as of April 1, 2019
- (3) Clinics for medical services in remote areas (subject to assistance of operational expenses, facility establishment expenses, and equipment installment expenses)
  - 1,131 clinics (including National Health Insurance direct managed clinics) are established as of April 1, 2019

# **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>

#### [Improved medical quality and safety]

- O 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))
- O 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)
- O Improved quality of medical professionals
- Obligation for administratively punished medical professionals to take re-education training

# [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 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
- O Systematization of medical safety support centers

# [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.

#### <Measures>

- O Enhancement of medical safety management system (revision of law in 2006, etc.)
- O 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.)
- OPromotion of projects to collect information on medical accidents, etc. (from FY2004)
- O 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)
- O 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)
- O 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~)
- O 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)
- O 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**

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



#### [Issues of the conventional system]

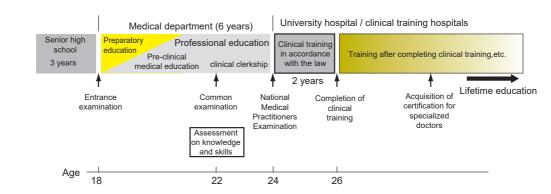
- 1. Training was voluntary
- 2. Training programs were not clearly defined
- 3. Mainly focused on straight training for specialized doctors
- 4. Remarkably large disparities existed among institutions
- Insufficient guidance system
- 6. Insufficient evaluation of training achievements
- 7. Unstable status/work conditions "part-time jobs
- 8. Heavy concentration of interns in large hospitals in urban areas
- O 2000 Revision of the Medical Practitioners Act and the Medical Care Act (obligating clinical training)
- O 2004 Enforcement of the new system
- O 2010 Revision of the system
- O 2015 Revision of the system
- O 2020 Revision of the system

### **Overview of Clinical Training System**

#### 1. Medical Education and Clinical Training

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

### 3. Status of Execution

医師国家試験合格

[1] Clinical resident training facilities (FY2019)

Clinical resident training hospitals (core type)	913
Clinical resident training hospitals (cooperative type)	1,488
University hospitals (core type equivalent)	124
University hospitals (cooperative type equivalent)	16

[3] Changes in enrollment status of interns (by 6 prefectures with large cities (Tokyo, Kanagawa, Aichi, Kyoto, and Osaka) and other prefectures)

Classification	6 prefectures	Other prefectures
Old system (FY2003)	51.3%	48.7%
1st year of new system (FY2004)	47.8%	52.2%
6th year of new system (FY2009)	48.6%	51.4%
7th year of new system (FY2010)	47.8%	52.2%
10th year of new system (FY2013)	45.5%	54.5%
11th year of new system (FY2014)	44.4%	55.6%
12th yeay of new system (FY2015)	43.6%	56.4%
13th yeay of new system (FY2016)	42.6%	57.4%
14th yeay of new system (FY2017)	41.8%	58.2%
15th yeay of new system (FY2018)	41.7%	58.3%
16th yeay of new system (FY2019)	41.7%	58.3%

[2] Changes in enrollment status of interns (by university hospitals and clinical training hospitals)

Classification	University	Clinical resident
	hospitals	training hospitals
Old system (FY2003)	72.5%	27.5%
1st year of new system (FY2004)	55.8%	44.2%
2nd year of new system (FY2005)	49.2%	50.8%
6th year of new system (FY2009)	46.8%	53.2%
7th year of new system (FY2010)	47.2%	52.8%
10th year of new system (FY2013)	42.9%	57.1%
11th year of new system (FY2014)	42.8%	57.2%
12th year of new system (FY2015)	41.7%	58.3%
13th year of new system (FY2016)	40.5%	59.5%
14th year of new system (FY2017)	40.4%	59.6%
15th year of new system (FY2018)	38.9%	61.1%
16th year of new system (FY2019)	38.1%	61.9%

#### **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.

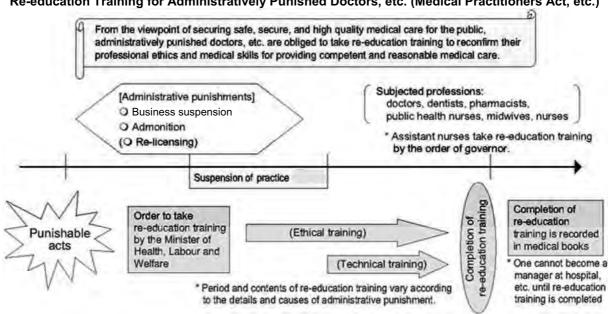
#### (4) Stable assurance of regional medical

- · 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

O Corporate bodies based on the Medical Care Act. The system was created by the 1950 revision of the Medical Care Act.

O Enabling administrative bodies of medical care sorries programs to become corporate bodies without leging the paper prof.

 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

O Associations or foundations based on the Medical Care Act.

O 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 55,674 (as of March 31, 2020)

Of which 55,304 are associations (16,583 without contribution and 38,721 with contribution) and 370 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 323 (as of April 1, 2020)

#### 3. Operation

- OA 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)
- OMedical 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.
- ODividend 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

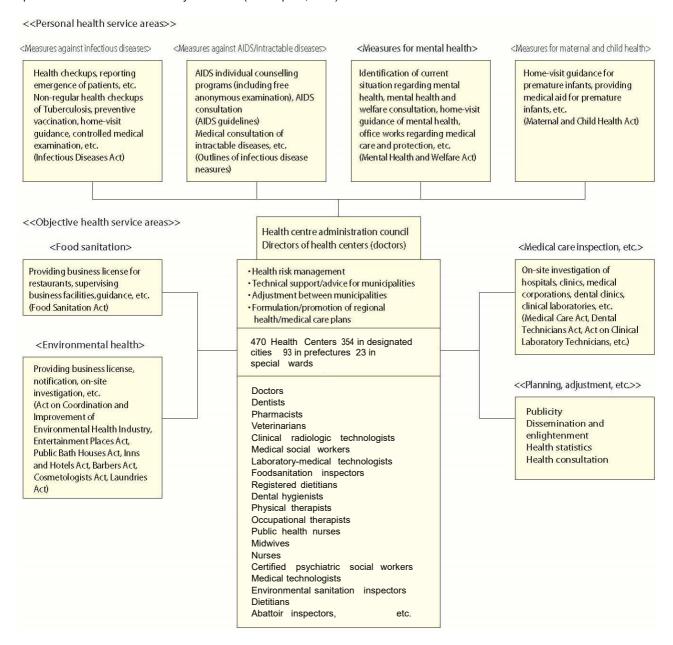
# Health Centers, etc.

#### **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 354 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, 2021).



\* 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
otal number of nealth centers	518	517	510	494	495	495	494	490	486	480	481	469	472	469	470
Prefectures	394	389	380	374	373	372	370	365	364	364	363	360	359	355	354
Cities	101	105	107	97	99	100	101	102	99	93	95	86	90	91	93
Special wards	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	738
Dentists	73
Pharmacists	2,998
Veterinarians	2,189
Public health nurses	8,516
Midwives	52
Nurses	123
Assistant nurses	4
Radiology technicians, etc.	425
Medical technologists, etc.	708
Registered dietitians	1,234
Dietitians	42
Dental hygienists	308
Physical/occupational therapists	83
Others	10,393
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Medical social workers	38
Mental health welfare counselors	1,016
Nutrition counselors	980
Total	27,886

Source: "Report on Regional Public Health Services and Health Promotion Services", Administrative Report Statistics Office to the Director-General for Statistics and Information Policy, MHLW (Modified by Health Service Bureau) (as of the end of FY2018)

#### Detailed Data 2 Changes in Number of Public Health Nurses

(Unit: person)

	FY2007	FY2008	FY2009	FY2010	FY2011	FY2012	FY2013	FY2014	FY2015	FY2016	FY2017	FY2018
Municipalities	14,483	14,498	14,613	14,179	15,015	14,753	14,920	14,850	14,935	15,035	15,227	15,193
Designated cities / special wards	5,604	5,964	6,094	6,081	6,280	6,256	6,564	6,586	6,829	6,928	7,107	7,512
Subtotal	20,087	20,462	20,707	20,260	21,295	21,009	21,484	21,436	21,764	21,963	22,334	22,705
Prefectures	3,889	3,800	3,737	3,640	3,689	3,659	3,603	3,607	3,613	3,661	3,659	3,637
Total	23,976	24,262	24,444	23,900	24,984	24,668	25,087	25,043	25,377	25,624	25,993	26,342

Source: FY2007: "Report on Regional Public Health Services and Health Services for the Aged", Administrative Report Statistics Office to the Director-General for Statistics and Information Policy, MHLW

FY2008 onward: "Report on Regional Public Health Services and Health Promotion Services", Administrative Report Statistics Office to the Director-General for Statistics and Information Policy, 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, litate Town, and Aizuwakamatsu City) due to the effect of the Great East Japan Earthquake.

# **Health Promotion Measures**

# Overview

# **History of National Health Promotion Measures**

1st National Health Promotion Measures (FY 1978-1988)	(Basic concept)  1. Lifetime health promotion Promotion of primary prevention of geriatric diseases  2. Promotion of health promotion measures through three major elements (diet, exercises, and rest) (special focus on diet)	(Outline of measures) (1) Lifetime health promotion	(Guidelines, etc.)  Dietary guidelines for health promotion (1985) Report on nutritional content labelling for processed food (1986)  Announcement of a weight scale diagram and table (1986) Report on smoking and health (1987)
2nd National Health Promotion Measures (FY 1988-1999) (Active 80 Health Plan)	(Basic concept)  1. Lifetime health promotion  2. 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)	(Outline of measures) (1) Lifetime health promotion • Enhanced health checkup and guidance system from infants and small children through to the elderly (2) Establishment of health promotion bases • Establishment of health promotion bases • Establishment of health promotion facilities, etc. • Securing sufficient manpower such as health fitness instructors, registered dietitians, and public health nurses (3) Dissemination and enlightenment of health promotion • Promoting the use of and revising recommended dietary allowances • Promoting recommended exercise allowance • Promoting the system to approve health promotion facilities • Action plan for tobacco control • Promoting a system of nutrition information labelling for meals eaten outside home • Promoting cities with health oriented cultures and health resorts • Conducting studies on health promotion, etc.	(Guidelines, etc.)  Dietary guidelines for health promotion (by individual characteristics: 1990)  Guidelines for nutrition information labeling for meals eaten outside home (1990)  Report on smoking and health (revised) (1993)  Exercise and Physical Activity Guidelines for Health Promotion (1993)  Promoting guidelines on rest for health promotion (1994)  Committee report on action plan for tobacco control (1995)  Committee report on designated smoking areas in public spaces (1996)  Physical activity guidelines by age (1997)
3rd National Health Promotion Measures (FY2000-2012) (National Health Promotion Movement in the 21st Century (Health Japan 21))	(Basic concept)  1. Lifetime health promotion Focusing on primary prevention, extension of healthy life expectancy, and enhanced quality of life  2. Setting specific targets to serve as an indicator for national health/medical standards and promotion of health promotion measures based on assessments 3. Creation of social environments to support individuals' health promotion	(Outline of measures) (1) National health promotion campaign  Dissemination and enlightenment of effective programs and tools with regular revision  Dissemination and enlightenment of the acquisition of good exercise habits and improved dietary habits with a focus on metabolic syndrome (2) Implementation of effective medical examinations and health guidance  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) (3) Cooperation with industry  Further cooperation in voluntary measures of industries (4) Human resource development (improving the quality of medical professionals)  Improved training for human resource development in cooperation between the government, prefectures, relevant medical organizations, and medical insurance organizations (5) Development of evidence-based measures  Revision of data identification methods to enable outcome assessments	(Guidelines, etc.)  Dietary guidelines (2000)  Committee report on relevance to designated smoking areas (2002)  Sleep guidelines for health promotion (2003)  Guidelines on implementation of health checkups (2004)  Japanese Dietary Reference Intake (2005 edition) (2004)  Guidelines for well-balanced diet (2005)  Manual for smoking cessation support (2006)  Exercise and Physical Activity Reference for Health Promotion 2006 (exercise guidelines for health promotion 2006 (Exercise Guidel 2006)  Exercise guidelines for health promotion 2006 (Exercise Guidel 2006)  Japanese Dietary Reference Intake (2010 edition) (2009)
4th National Health Promotion Measures (from FY 2013) (The second term of National Health Movement in the 21st Century (Health Japan 21 (the second term))	[Basic Concept]  1. Extension of healthy life expectancy and reduction of health disparities  2. Lifetime health promotion [prevention of onset and progression of lifestyle-related diseases, maintenance and improvement of functions necessary, establishment of social environment]  3. Improvement of lifestyle and social environment  4. Setting specific targets to serve as an indicator for national health/medical standards and promotion of health promotion measures based on assessments.	Coutline of measures]  (1) Focusing on extension of healthy life expectancy and reduction of health disparity  Comprehensive promotion for lifestyle diseases and promotion of efforts supporting areas such as medical and long-term care.  (2) Prevention of onset and progression of lifestyle diseases (Prevention of NCD (Non-Communicable Diseases))  Promotion measures focused on primary prevention of cancer, cardiovascular disease, diabetes and COPD in addition to prevention of progression.  (3) Maintenance and improvement of necessary functions for healthy social life.  Promotion of mental health programs for mind, and health of the next generation and the elderly.  (4) Development of social environment for supporting and protecting health.  Providing information on the activities of companies working voluntarily on promoting health and evaluating these activities.  (5) Improvement of lifestyle and social environment relating to nutrition, dietary habits, physical activity/exercise, rest, alcohol, smoking, dental and oral health, etc.  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.	[Guidelines, etc.]  2013 Physical activities for healthy life (2013)  Active Guideline—Physical activities for healthy life (2013)  Manual for supporting non-smoking (2nd edition) (2013)  2014 Sleeping guideline for healthy life (2014)  Japanese Dietary Reference Intake (2015 edition) (2014)  A report on effects of smoking on health by a study group (FY2016)  Smoking Cessation Supporting Manual (Second Edition) (2018)

#### **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 (approximately

15,000 persons)

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 2019	Plan to formulate in FY 2020	Plan to formulate in FY 2021	No plan
Health center-designated cities	84	84	0	0	0	0
Special wards in Tokyo	23	23	0	0	0	0
Other municipalities	1,634	1,529	11	13	55	26

(As of January 1, 2020)

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

Prefecture	No. of municipalities	Formulated	Formulation rate	FY 2019	FY 2020	FY 2021or later	No plan
Hokkaido	175	136	77.7%	2	1	33	3
Aomori	38	38	100.0%	0	0	0	0
lwate	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	34	100.0%	0	0	0	0
Fukushima	56	49	87.5%	1	2	3	1
Ibaraki	44	44	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	55	93.2%	2	1	1	0
Chiba	51	49	96.1%	1	1	0	0
Tokyo	37	29	78.4%	0	0	3	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	67	88.2%	1	2	5	1
Gifu	41	41	100.0%	0	0	0	0
Shizuoka	33	33	100.0%	0	0	0	0
Aichi	50	50	100.0%	0	0	0	0
Mie	28	26	92.9%	1	1	0	0
Shiga	18	18	100.0%	0	0	0	0
Kyoto	25	19	76.0%	0	0	1	5
Osaka	35	32	91.4%	0	0	0	3
Hyogo	36	36	100.0%	0	0	0	0
Nara	38	38	100.0%	0	0	0	0
Wakayama	29	24	82.8%	1	0	1	3
Tottori	18	18	100.0%	0	0	0	0
Shimane	18	18	100.0%	0	0	0	0
Okayama	25	24	96.0%	1	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%	0	1	0	0
Kagawa	16	16	100.0%	0	0	0	0
Ehime	19	19	100.0%	0	0	0	0
Kochi	33	33	100.0%	0	0	0	0
Fukuoka	56	51	91.1%	1	3	1	0
Saga	20	17	85.0%	0	0	2	1
Nagasaki	19	19	100.0%	0	0	0	0
Kumamoto	44	39	88.6%	0	1	4	0
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	1	2
	1,634	1,529	93.6%	11	13	55	26

(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	378,356	307.0
Diabetes mellitus	3,289	13,891	11.3
Hypertensive diseases	9,937	9,997	8.1
Heart diseases (excluding hypertensive)	1,732	205,518	166.7
Cerebrovascular diseases	1,115	102,956	83.5

# Source:

receiving medical treatment>

<Number of deaths, Death rate>

<The estimated number of patients "Patient Survey 2017", Health Statistics Office to the Director-General for Statistics,</p> Information Policy and Industrial Relations, MHLW "Vital Statistics", Vital, Health and Social Statistics Office to the Director-General for

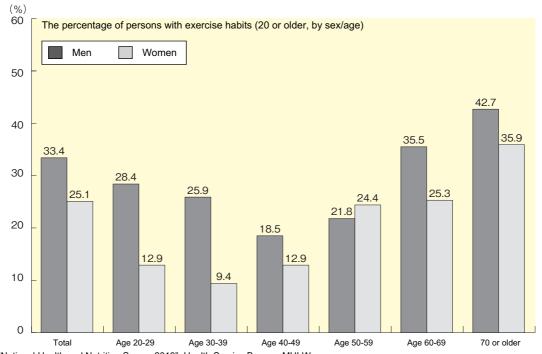
Statistics, Information Policy and Industrial Relations, MHLW (2020 preliminary data)

#### **Detailed Data 3 Prevalence related to Diabetes**

	Males (survey samples: 1,013)		Females (survey samples: 1,399)	
Age	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

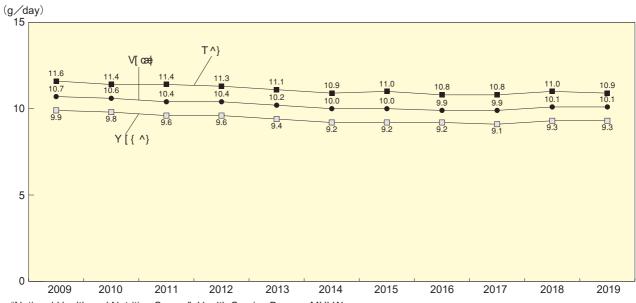


Source: "National Health and Nutrition Survey 2019", Health Service Bureau, MHLW (Note) Persons with exercise habits: Those who have been continuing daily exercise of 30 minutes or longer at least 2 days a week for at least a year.

### Detailed Data ) 5 j YfU[ Y'cZgU'h']bHJ\_Y (Aged 20 or Older, by Sex/Age)

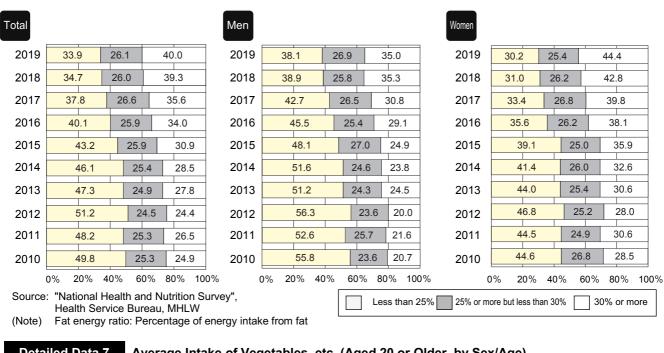
(g/day)

	G€€J	G€F€	ŒFF	ŒFG	2013	2014	2015	2016	2017	2018	2019
T ^}	11.6	11.4	11.4	11.3	11.1	10.9	11.0	10.8	10.8	11.0	10.9
Y[{ '	\} 9.9	9.8	9.6	9.6	9.4	9.2	9.2	9.2	9.1	9.3	9.3
V[ Œ	<b>†</b> 10.7	10.6	10.4	10.4	10.2	10.0	10.0	9.9	9.9	10.1	10.1

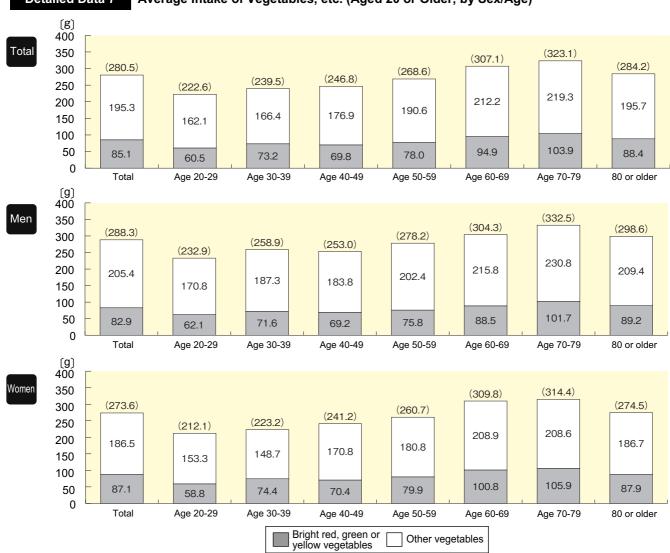


<sup>&</sup>quot;National Health and Nutrition Survey", Health Service Bureau,  $\operatorname{\mathsf{MHLW}}$ 

#### **Detailed Data 6** Secular Trend in Distribution of Fat Energy Ratio (Aged 20 or Older)

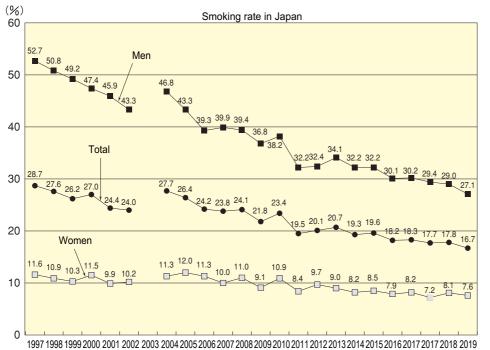


#### **Detailed Data 7** Average Intake of Vegetables, etc. (Aged 20 or Older, by Sex/Age)



Source: "National Health and Nutrition Survey 2019", Health Service Bureau, MHLW The figures in parentheses indicate the total intake of "bright red, green or yellow vegetables" and "other vegetables (Note)

### Detailed Data 8 Smoking Rate in Japan



Smoking rates in other countries (%)

Country	Men	Women
Japan	29.0	8.1
Germany	22.3	15.3
France	28.2	22.9
Netherlands	17.8	13.4
Italy	23.5	15.1
United Kingdom	17.0	16.2
Canada	12.8	9.7
United States	11.5	9.1
Australia	14.0	10.8
Sweden	11.0	9.2

Source: OECD Health Statics 2020

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 life-spans 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.

Prevention (1st, 2nd and 3rd)

Acute Phase

Recovery and Chronic Phases

**Each Measure** 

Prevention of palindromia, complications, and aggravations \*Cardiovascular diseases such as cerebral apoplexy, and hypertension

#### [Foundation] Collect treatment information on cardiovascular issues and establish a system of provision

▶establish official framework to collect and utilize treatment information on cardiovascular issues

#### 1. Prevention of cardiovascular issues and creation of awareness and appropriate knowledge

Prevention of illness and aggregation of cardiovascular issues and public awareness of cardiovascular issues (prevention and responses at early stage of pathogeny. etc) from childhood

#### 2. Fulfillment of a system for providing healthcare, medical and welfare services

- ① Widespread medical checkups and promotions to tackle cardiovascular issues ▶ Popularize measures for special medical checkups and health instructions, etc. and promote measures to improve the execution rate
- ② Establish an emergency system ► Establish a transportable system more speedily and appropriately from emergency sites to medical institutions
- ③ Establish a medical service system for cardiovascular issues including securing emergency medical services ► Build a medical service system that can respond to problems
- medical, nursing care and welfare services in collaboration with various health professionals
- ⑤ Rehabilitation measures ► Promote services based on the status of the acute, recovery, mainten ance and living phases
- ® Provide accurate information and consultation support on cardiovascular issues ▶ Comprehensive measures for providing accurate information and consultation for patients based on scientific grounds
- ① Palliative care for cardiovascular issues > Promote appropriate palliative care from the first stage of treatment in collaboration with various health professionals and regions
- ® Support people experiencing delayed effects from cardiovascular issues ▶ Establish a support system for those experiencing delayed effects including torpor of hands and legs, alogia, epilepsy, higher brain dysfunctions, etc.
- Support combining treatment with employment assistance for patients ► Promote measures for combining treatment with assisting work situations, etc.
- necessary medical systems continually from childhood to adulthood

#### 3.Promete research on cardiovascular issues

- O Promote research on disease states, prevention, diagnosis, treatment, rehabilitation, etc. to prevent cardiovascular sickness
- Promote from basic study to actualized study for development of diagnosis and treatment methods, etc. in collaboration with industries and the medical industry
   Promote research on evidence based policy

### 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

#### **Purpose**

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

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

### 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

#### Legal measures

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

### 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.

### 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]

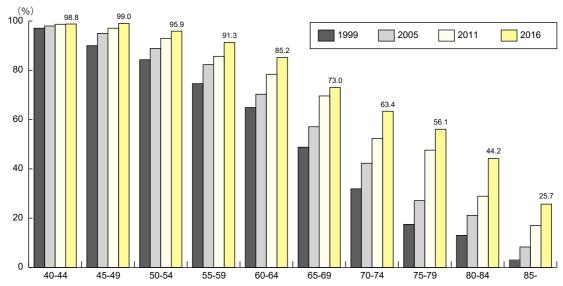
1989	A Study Group on the Dental Health Policy for Adults made public its interim report in which the "8020 (Eighty-Twenty) Campaign" calling for the retention of 20 or more teeth even at age 80 was proposed.
1991	"Promotion of 8020 Campaign" was set to be the major objective for the Dental Hygiene Week (June 4-10).
1992	"8020 Campaign promotion measure projects" launched for dissemination and enlightenment of the 8020 Campaign (until 1996).
1993	8020 Campaign promotion support projects launched for smooth implementation of 8020 Campaign promotion measure projects (until 1997).
1997	Municipal dental health promotion projects (menu projects) launched.
2000	Prefecture-led "8020 Campaign promotion special projects" launched.
2006	The results of the "Survey of Dental Diseases (2005)" was published to reveal that the percentage of persons achieving 8020 reached over 20% for the first time since the survey started.
2011	The Act on Advancement of Dental and Oral Health was approved.
2012	The "Basic Matters regarding the Advancement of Dental and Oral Health" was announced by the Minister in accordance with the "Act on Advancement of Dental and Oral Health".  "Health Japan 21 (second campaign)", 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
	8020 reached over 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	Released the "Survey Results of Dental Diseases in 2016 (Overview)". Those who achieved the 8020 Movement exceeded 50%.
2018	The interim evaluation of "Basic Matters regarding the Advancement of Dental and Oral Health" was compiled.

## [8020 Campaign and the "Basic Matters regarding the Advancement of Dental and Oral Health", "Health Japan 21 (second campaign)"]

The "Basic Matters regarding the Advancement of Dental and Oral Health" and "Health Japan 21 (second campaign)", announced in July 2012, mutually harmonized and provided further advancement of the "8020 Campaign". Both set the goal of "raising the percentage of those retaining 20 or more teeth at age 80" and the FY2022 target value of 60%. Efforts for dental and oral health promotion through dental health measures (8020 Campaign) throughout life continue to be important.

#### 

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%	3.0%
2005	98.0	95.0	88.9	82.3	70.3	57.1	42.3	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

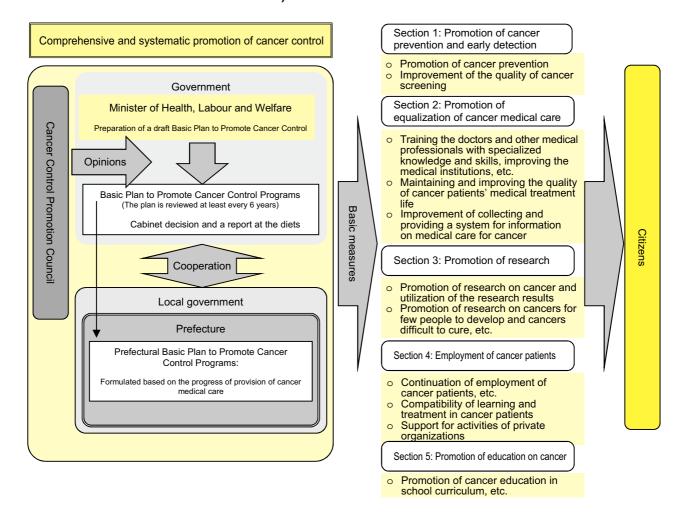


Source: "Survey of Dental Diseases", Health Policy Bureau, MHLW

### **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 2. Improvement of cancer care 1. Cancer prevention 3. Coexistence with cancer Primary cancer prevention Palliative care after cancer diagnosis Cancer genome medicine (2) Consultation support and information provision Early detection and (2) Surgery, radiation therapy, drug therapy, and screening of cancer (3) Cancer measures and cancer patient support immunotherapy for cancer. (Secondary prevention) (3) Team medicine based on social cooperation (4) Social problems, including employment Cancer rehabilitation statuses of cancer patients Supportive therapy (6) Rare and refractory cancers (Measures according to cancer (5) Cancer measures according to life stages characteristics) (7) Childhood cancers and cancers of AYA (\*) generation and the elderly (\*) Adolescent and Young Adult (8) Pathological diagnosis Cancer registration (10) Efforts towards early development and approval of pharmaceuticals and medical equipment 4. Improvement of infrastructure to support the above Cancer research (2) Human resource development Cancer education and awareness 3. Comprehensive and systematic promotion of cancer measures Further cooperation among persons Necessary financial measures and concerned Planning by prefectural governments efficient and prioritized budgets Comprehension of goal achievements Efforts of the people, including cancer 3. Review of basic plans patients Cooperation with patient organizations

#### Outline of Cancer Registry Promotion Act

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

- O National cancer registry: The government records and preserves information on cancers, treatment and outcomes in Japan in a database so that it is used and provided for the government and prefectures.
- O Hospital-based cancer registry: Hospitals record and preserve detailed information on cancers, treatment and outcomes for the purpose of accurately grasping 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

- O The national cancer registry grasps the status of cancers, treatment and outcomes as accurately as possible by means of broad information collection:
- O The Hospital-based cancer registry aims to collect necessary information without fail through the national cancer registry and to disseminate and enhance such information;
- O The Act aims to collect detailed information on cancer treatment with the aim of enhancing cancer control measures;
- O 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
- O It aims to strictly protect individual information stored in cancer registries

#### **National Cancer Registry** National Government (National Cancer Center) Prefecture Data Co. Recording National Cancer Registry Database (1) Hospitals (all) Record linkage and Consolidation Reporting Recording Record linkage and Consolidation (2) Clinics Collection (designated Cancer Information nformation Information Information clinics) Record linkage Recording and Consolidation Death Certificate · Vital status Municipalities Death Certificate Unreported cancer cases 0 National subsidies, etc Information is used and provided for conducting researches and studies necessary for cancer control measures taken by the government and local governments 0 Information on confirmation of existence is provided to hospitals that submit a notification Data use 0 Information is provided to persons who conduct researches and studies that contribute to the improvement of the quality of cancer medical care (there are additional Expert panel requirements such as that non-anonymous information is provided to a researcher only advice and when there is a consent of the person involved) \*The time limit of preservation of non-anonymous information is specified by a Cabinet Order Establishment of prefectural cancer databases (integrated preservation of data of regional cancer registries) Protection of information (Appropriate management of information. Prohibition of unintended use. Penalties for disclosure of secrets. No request for disclosure of information and etc.is permitted)

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

- O Government and prefectures⇒ Enhancement of cancer control measures, provision of information to medical institutions, disclosure of statistics and consultation services for patients
- O 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	Total of 378,356 persons (27.6% of all causes of death) [220,965 males (31.3% of all causes of death)] [157,391 females (23.6% of all causes of death)] → "1 in every 3 Japanese die of cancer"	Vital Statistics of Japan (2020 preliminary data)
Incidence rate	977,393 persons (Not including carcinoma in situ) [558,869 males] Sites often affected: ① prostate, ② stomach, ③ large intestine, ④ lung, ④ liver [418,510 females] Sites often affected: ① breast, ② large intestine, ③ lung, ④ stomach, ⑤ uterus	National Cancer Registration patients number and incidence rate Report 2017 (2017)
Lifetime risk	Male: 65.5%, Female: 50.2% → "1 in every 2 persons will contract cancer in Japan"	Estimates by Center for Cancer Control and Information Services, National Cancer Center (2017)
Patients and persons receiving treatment	The estimated number of patients receiving medical treatment is 1,782,000  •The estimated number of inpatients on the dates of survey is 126,100  •The estimated number of outpatients on the dates of survey is 183,600	Patient Survey (2017)
Medical care expenditure for cancer	¥3,954.6 billion  * 12.6% of all medical care expenditures for general practice	Estimates of National Medical Care Expenditure (FY 2018)

### 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 Hepatits 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



1

Minister of Health, Labour and Welfare Request for documents, etc.

Basic measures against hepatitis Announcement

- · Revies 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

#### Basic Guidelines for Hepatitis Measures in Brief (formulated on May 16, 2011, revised on June 30, 2016)

- 1 The basic direction to take in promoting the prevention of hepatitis and hepatitis-related medical care
  - To reduce liver cirrhosis and liver cancer, and set as much reduction as possible of the incidence of liver cancer
- 2 Matters concerning measures to take in preventing hepatitis
  - Necessary to disseminate correct knowledge about hepatitis to prevent new infections,
  - To promote preventive measures for infection of mother-to-child hepatitis B virus, and promote periodic hepatitis B vaccination.
- 3 Matters concerning improvement of a system to use implementing hepatitis examinations and their capabilities
  - To inform all citizens that they need to receive hepatitis virus test at least once
  - To continue to develop a system that allows for examination of the hepatitis virus tests with due consideration to the convenience of the examinee...
  - 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.
- 4 Matters concerning securing of a system to use providing hepatitis-related medical care
  - Necessary to further develop the regional hepatitis clinical care network so that all hepatitis patients can receive continuous and appropriate hepatitis medicine.
  - To make further efforts for increase of hepatitis virus inspection and follow-up after the inspection
  - 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
- 5 Matters concerning prevention of hepatitis and human resource development for hepatitis medical care
  - Necessity to develop human resources with knowledge about the prevention of hepatitis infection and those capable of linking appropriate hepatitis care after infection is known, such as hepatitis medical coordinator.

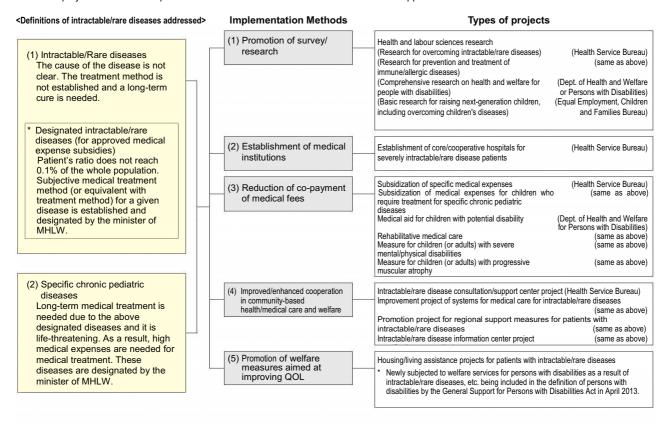
- 6 Matters concerning surveys and research on hepatitis
  - To evaluate and verify research achievements comprehensively, and promote hepatitis research as the basis for comprehensive promotion of measures against hepatitis so that the past achievements can be appropriately reflected on such measures
- 7 Matters concerning promotion of research and development of medicine to use hepatitis- related medical care
  - Necessary to proceed with research and development of hepatitis medicine-related new medicines, including medicines related to treatment of hepatitis B and cirrhosis, and make a prompt review of clinical trials and research in light of recent trends concerning hepatitis medicine
- 8 Matters concerning public awareness and dissemination of information concerning hepatitis is and matters concerning respect for the human rights of hepatitis patients, etc.
  - 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
- 9 Other important matters concerning the promotion of hepatitis measures
  - To strengthen and enhance support for hepatitis patients and their families, etc.
  - To promote review of how to support cirrhosis and liver cancer patients.
    To require the national government to urge the local
  - 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
     To request each citizen to confirm his/her own
  - 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.

### Intractable/Rare Disease Measures

#### Overview

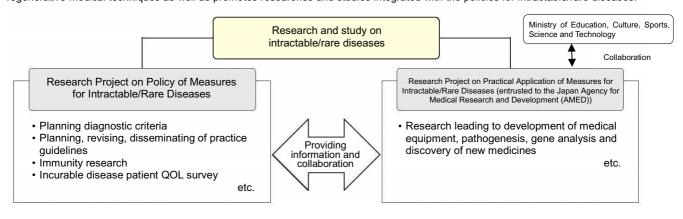
#### **Outline of Intractable/Rare Disease Measures**

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



### 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 Spinobulbar muscular atrophy	No. 103	Disease Name    CFC syndrome	No. 205	Disease Name Fragile X syndrome related disease
2	Amyotrophic lateral sclerosis	104	Costello syndrome	206	Fragile X syndrome
	Myelopathic muscular atrophy Primary lateral selectors	105	Charge syndrome Cryopyrin associated periodic fever syndrome		Tmc/Art,: truncus arteriosus Corrected TGA
			Systemic-onset juvenile idiopathic arthritis		TGA
6	Parkinson's disease	108	TNF receptor associated periodic sydrome		Single ventricle
8	Corticobasal degeneration Huntington disease	110	Atypical hemolytic uremic syndrome Blau syndrome		Hypoplastic left heart syndrome Tricuspid atresia
9	Neuroacanthocytosis	111	Congenital myopathy Marinesco – Sjogren's syndrome	213	Pulmonary atresia with intact ventricular septum
	Charcot-Marie-Tooth disease Myasthenia gravis	112	Marinesco – Sjogren's syndrome Muscular dystrophy	214	Pulmonary atresia with ventricular septal defect 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
	Inclusion body myositis	117	Syringomyelia		Galloway-Mowat syndrome
			Myelomeningocele Isaacs syndrome	220	Rapidly progressive glomerulonephritis Anti-glomerular basement membrane disease
18	Spinocerebellar degeneration (except multiple-system atrohpy)	120	Hereditary dystonia	222	Primary Nephrotic syndrome
19	Lysosomal storage disease	121	Nerve ferritin disease	223	Primary membranoproliferative glomerulonephritis
21	Adrenoleukodystrophy Mitochondrial diseases		Brain table hemosiderosis  Autosomal recessive leukoencephalopathy with baldness and		Purpura nephritis Congenital nephrogenic diabetes insipidus
			degenerative spondylosis		
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		Osler disease
24	Subacute sclerosing panencephalitis Progressive multifocal leukoencephalopathy	126 127	Perry syndrome Frontotemporal lobar degeneration	228	Obliterating bronchiolitis Pulmonary proteinosis (autoimmunity/hereditary)
26	HTLV-1-associated myelopathy	128	Vickers staff brainstem encephalitis	230	Alveolar hypoventilation sysdrome
27	Idiopathic basal ganglia calcification diseases	129	Epilepticus type (biphasic) acute encephalopathy	231	α1-antitrypsin deficiency
			Congenital insensitivity to pain with anhidrosis Alexander disease	232	Camey complex Wolfram syndrome
30	Distal muscular dystrophy	132	Congenital supranuclear pasly	234	Peroxisomal disease (excluding adrenoleukodystrophy)
31	Beth Rem myopathy Autophagic vacuolar myopathy	133	Moebius syndrome Nervous system malformation/De Morsier sysdrome	235	Accessory thyroid hypergasia disease Pseudohypoparathyroidism
33	Schwarz Yanperu syndrome	135	Aicardi syndrome	237	Adrenocorticotropic hormone insensitivity
34	Neurofibromatosis Pemphigus	136	Hemimegalencephaly Focal cortical dysplasia	238	Vitamin D-resistant rickets/osteomalacia
35	Pemphigus Epidermolysis bullosa	13/ 138	Nerve cell migration disorder	239	Vitamin D-dependent rickets/osteomalacia Phenylketonuria
37	Pustular psoriasis (universal)	139	Congenital cerebral white matter asplasia	241	High tyrosinemia type 1
	Stevens-Jonson syndrome Toxic epidermal necrosis	140	Dorabe syndrome  Medial temporal lobe epilepsy with hippocampal sclerosis	242	High tyrosinemia type 2 High tyrosinemia type 3
40	Takayasu's disease	142	Myoclonic epilepsy absences	243	Maple syrup urine disease (MSUD)
41	Giant cell artritis	143	Epilepsy with myoclonic cataplexy	245	Propionic acidemia
	Polyateritis nodosa Microscopic polyangiitis	144 145	Lennox-Gastaut syndrome West syndrome	246	Methylmalonic acidemia Isovaleric adidemia
44	Multiple vasculitis granulomatous disease	146	Otawara syndrome	248	Glucose transporter 1 deficiency
			Early myoclonic encephalopathy	249	Glutaric acidemia type 1
46	Malignant rheumatoid arthritis Buerger's disease	149	Infant epilepsy with migratory focus seizure One side convulsions, hemiplegia – epilepsy syndrome	251	Glutaric acidemia type 2 Urea cycle disorders
48	Primary antiphospholipid antibody sysdrome	150	Ring chromosome 20 syndrome	252	Lysinuric protein intolerance
50	Systemic lupus erythematosus Dermatomyositis / polymyositis	151 152	Rasmussen's encephalitis PCDH19 related syndrome	253	Congenital malabsorption of falate Porphyria
			Refractory frequent partial seizures intussusception acute encephalitis	255	Multiple carboxylase deficiency
			Epilepsy with continuous spikes and waves during slow sleep (CSWD)  Landau-Kleffner syndrome		Muscle type glycogen storage disease
54			Rett syndrome	258	Glycogen storage disease Galactose- 1 – phosphate uridyltransferase deficiency
55	Relapsing polychondritis	157	Sturge-Weber syndrome	259	Lecithin-cholesterol acyltransferase deficiency
			Tuberous sclerosis Xeroderma	260	Sitosterolemia Tangier disease
58	Hypertrophic cardiomyopathy	160	Congenital ichthyosis	262	Primary hyperlipidemia
	Constrictive cardiomyopathy Aplastic anaemia		Familial benign chronic pemphigus Pemphigoid (including acquired epidermolysis bullosa)		Cerebrotendinous xanthomatosis
61	Autoimmune hemolytic anemia	163	Idiopathic acquired systemic anhidrosis	265	Abeta-lipoproteinemia Lipodystrophy
62	Paroxysmal noctumal	164	Oculocutaneous ablinism	266	Familial Mediterranean fever
	Idiopathic thrombocytopenic purpura Thrombotic thrombocytopenic purpura	166	Pachydermoperiostosis syndrome Pseudoxanthoma elasticum		Hyper-IgD syndrome Nakajo-nisimura syndrome
65	Primary immunodeficiency syndrome	167	Marfan syndrome	269	Purulent gonitis • pyoderma gangrenosum • hirsutism syndrome
	IgA nephropathy Polycystic kidney		Ehlers-Danlos syndrome Menkes disease		Chronic nonbacterial osteomyelitis Spondylarthritis ankylopoietica
68	Ossification of the ligamentum flavum	170	Okushipitaru horn syndrome	272	Fibrodysplasia ossificans progressive
69	Ossification of the posterior longitudinal ligament	171	Wilson's disease	273	Congenital scoliosis with rib anomaly
	Extensive spinal canal stenosis Idiopathic femoral head necrosis	173	Hypophosphatasia VATER syndrome	275	Osteogenesis imperfecta Thanatophoric dysplasia
72	Pituitary ADH secretion disorders	174	Nasu-Hakola disease	276	Achondroplasia
74	Pituitary TSH secretion hyperthyroidism Pituitary PRL secretion hyperthyroidism	1/5 176	Weaver's syndrome Coffin-Lowry syndrome	277	Lymphangiomatoris/gorham's disease Huge lymphatic malformation (cervicofacial lesion)
75	Cushing's disease	177	Arima sydrome	279	Huge venouse malformation [neck oropharyngeal diffuse lesion]
76 77			Mowat - Wilson syndrome Williams' syndrome	280	Huge arteriovenouse malformation (cervicofacial or limb lesion) Klippel-Trenauray-Weber sydrome
78	Anterior pituitary hypothyroidism		ATR-X syndrome	282	Congenital thropoietic anemia
79	Familial hypercholesterolemia (homozygous)	181	Crouzon syndrome	283	Acquired pure red cell aplasia
	Thyroid hormone insensitivity syndrome Congenial adrenal cortex enzyme deficiency	182 183	Apert syndrome Pheiffer syndrome		Diamond-blackfan anemia Fanconi anemia
82	Congenital adrenal hypoplasia	184	Anley-Bixler syndrome	286	Hereditary sideroblastic anemia
83	Addison's disease Sarcoidosis	185	Coffin Siris syndrome	287	Epstein-Barr virus Autoimmune hemorrhaphilia XIII
85	Idiopathic interstitial pneumonia	187	Trothmund-Thomson syndrome Kabuki syndrome	289	Cronkhite-Canada syndrome
86	Pulmonary arterial hypertension	188	Polysplenia syndrome	290	Chronic nonspecific multiple ulcers of the small intestine
	Pulmonary venous obstruction/pulmonary capillary hemangiomatosis	189	Asplenia sysndrome	291	Hirschsprung disease (entire colon type or small intestine type)
88	Chronic thromboembolic pulmonary hypertension	190	Branchio-oto-renal syndrome		Cloacal exstrophy
89	Lymphangioleiom yomatosis	191	Werner's syndrome	293	Persistent cloaca
91	Retinitis pigmentosa Bad chiari sysdrome	193	Cockayne's syndrome Prader-Willi syndrome	295	Congenial diaphragmatic hernia Infant giant liver hemangioma
92	Idiopathic portal hypertension	194	Sotos' syndrome Noonan's syndrome	296	Biliary atresia
93	Primary biliary cirrhosis Primary sclerosing cholangitis	195 196	Noonan's syndrome   Young Simpson's syndrome	297	Alagille syndrome Hereditary pancreatitis syndrome
95	Autoimmune hepatitis	197	1p36 deletion syndrome	299	Cystic fibrosis
96	Crohn's disease	198	4psyndrome	300	IgG4-related disease
98	Ulcerative colitis Eosinophilic gastrointenstinal disease	200	5psyndrome   No. 14 chromosome father disomy syndrom	302	Heredomacular dystrophy Leber's hereditary optic neropathy
99	Chronic idiopathic pseudo-bowel obstruction	201	Angelman syndrome 303	303	Ascher syndrome
			Smith-Magenis syndrome 22q11.2 deletion syndrome	304	Juvenile-onset bilateral sensorineural hearing loss Delayed endolymphatic hydrops
102	Rubinstein - Teibi syndrome	204	Emanuel syndrome	306	eosinophilic sinusitis
	•		•		

## Detailed Data Designated intractable/rare diseases

No.	Disease Name
	Canavan disease
308	Progressive leukoencephalopathy
309	
310	
311	
312	
313	
	Left pulmonary artery right pulmonary artery initiation
	Nail Patera syndrome/LMX 1 B-related nephropathy
	Carnitine circuit disorder
	Triple enzyme deficiency
	Citrin deficiency
319	
320	
321	
	β-ketothiolase deficiency
	Aromatic L-amino acid decarboxylase deficiency
	Methyl glutamic nuria
	Hereditary autoinflammatory disease
326	
327	
328	
329	
330	Congenital tracheal stenosis / Congenital subglottic stenosis
331	Idiopathic multicentric Castleman disease
332	
333	Hutchinson - Gilford syndrome

### **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		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.)	Hospitalization	Designated medical institutions for Type 1 infectious disease [1 hospital in each prefecture designated by prefectural governors]	Medical insurance applied with
Type 2 (Avian influenza (H5N1, H7N9), Tuberculosis, SARS, etc)		Designated medical institutions for Type 2 infectious disease [1 hospital in each secondary medical service area designated by prefectural governors]	public funds (for hospitalization)
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.)		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)

<sup>\*</sup> 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	Those aged 3 months or older but younger than 90 months     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	Those aged 12 months or older but younger than 24 months     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	Those aged 12 months or older but younger than 24 months     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	Those aged 6 months or older but younger than 90 months     Those aged 9 years or older but younger than 13 years
Tetanus	Those aged 3 months or older but younger than 90 months     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	<ol> <li>Those aged 65 years or older</li> <li>Those aged 60 years or older but younger than 65 years suffering from cardiac, renal, or respiratory disorders, etc.</li> </ol>
Pneumococcal infectious disease (limited to one that is of the elderly)	Those aged 65 years     Those aged 60 years or older but younger than 65 years suffering from cardiac, renal, or respiratory disorders, etc.
• •	

<sup>\*</sup> Those born between April 2, 1995 and April 1, 2007, are subjected to routine vaccination with Japanese encephalitis before they reach the age of 20.

### **Detailed Data**

#### Benefits type and Amount of Relief System for Injury to Health with Vaccination (As of April,1, 2021)

	Ca	tegory A diseases		Ca	ategory B diseases
Benefit type	Qualification	ion Details and amount of benefit		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: Inpatient: less than 8 days per month: Outpatient: 3 days or more per month: Outpatient: less than 3 days per month: Inpatient and outpatient treatment within the same month: (month) ¥37,000 (month) ¥37,000 (month) ¥37,000	Medical allowance	Same as above	Inpatient: 8 days or more per month: Inpatient: less than 8 days per month: Outpatient: 3 days or more per month: Outpatient: less than 3 days per month: Inpatient and outpatient treatment within the same month:  (month) ¥37,000 (month) ¥37,000 (month) ¥37,000 (month) ¥37,000
Pension for rearing children with disabilities	Fosterers of children younger than 18 with certain disabilities caused by vaccination	Class 1: (annual) ¥1,581,600 (additional amount for long-term care):(annual) (¥844,300) Class 2: (annual) ¥1,266,000 (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) ¥2,809,200 Class 2: (annual) ¥2,247,600
Disability Pension	Those aged 18 or older with certain disabilities caused by vaccination	Class 1: (annual) ¥5,056,800 (additional amount for long-term care):(annual) (#844,300) Class 2: (annual) ¥4,045,200 (additional amount for long-term care):(annual) (#562,900)	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) ¥2,457,600
Lump-sum	The bereaved of the person who	Class 3: (annual) ¥3,034,800	Lump-sum benefit for survivors	The bereaved will be beneficiary in case the deceased who died from vaccination was not the main	¥7,372,800
death benefit	died of diseases caused by vaccination	¥44,200,000		wage earner of the family	
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	¥209,000

<sup>\*</sup> 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

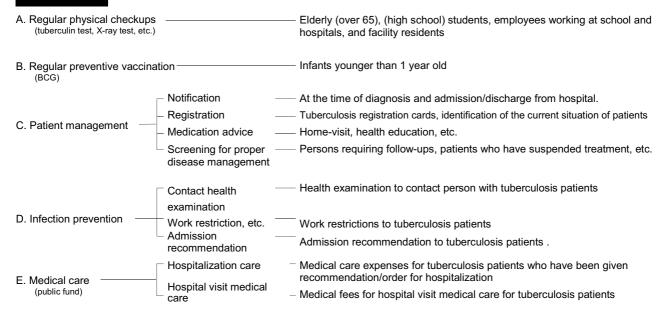
<sup>(</sup>Note) 1. The term of claims for subsidy for medical care expenses and medical allowance shall be within 5 years after the payment of the expenses eligible for the benefits.

<sup>2.</sup> 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**



#### **Detailed Data 1** Changes in Number of Newly Notified Tuberculosis Patients, Incidence, and the Mortality

Year	Number of newly notified patients	Incidence	Number of deaths	Mortality
	(Person)	(Per 100,000 persons)	(Person)	(Per 100,000 persons)
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			* 1,909	*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>

<sup>&</sup>quot;Vital Statistics", Vital, Health and Social Statistics Office to the Director-General for Statistics and Information Policy, MHLW

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

<sup>2.</sup> 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 2019)

	Prefecture or City	Incidence
Prefectures with the lowest incidence	lwate Akita Fukushima Miyagi Hokkaidou	6.8 6.8 6.9 7.3 7.4
Prefectures with the highest incidence	Osaka Gifu Hyogo Nara Kyoto	18.4 14.6 14.0 14.0 13.7

### **Detailed Data 3**

### International Comparison of Tuberculosis Incidence

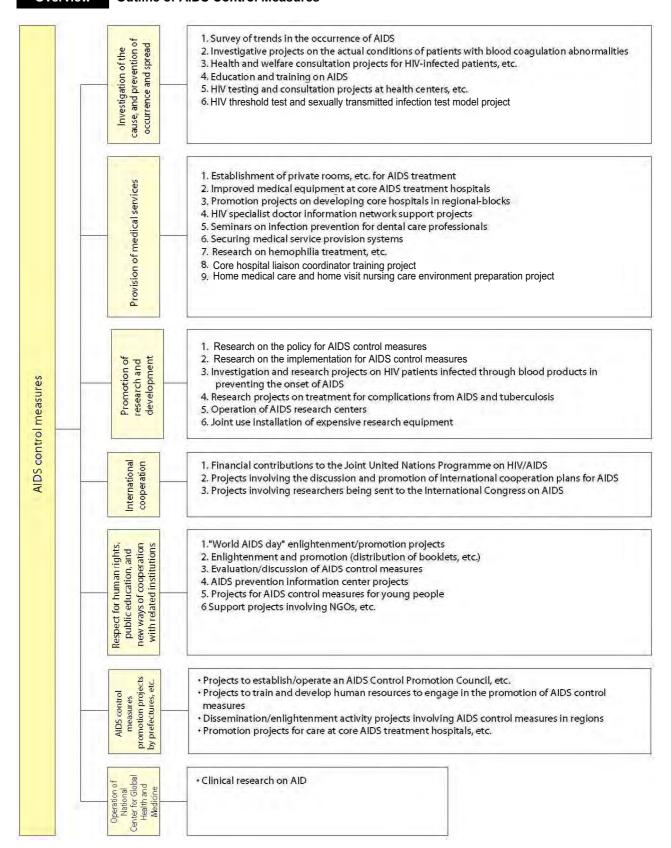
Country	Incidence
United States	3.0
Canada	5.6
Sweden	5.5
Australia	6.6
Netherlands	5.3
Denmark	5.4
France	8.9
United Kingdom	8.0
Japan	11.5

Source: WHO's global tuberculosis database \*Data is referred to one at 2018 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	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	17,208	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	1,025	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	18,233	83.9
	Foreign	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	2,008	9.2
		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	1,498	6.9
		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	3,506	16.1
	Total		0	0	55	23	80	66	200	442	277	298	277	376	397	422	530	462	621	614	640	780	832	952	1,082	1,126	1,021	1,075	1,056	1,002	1,106	1,091	1,006	1,011	976	940	903	21,739	100.0
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	359	386	421	419	387	438	409	379	376	348	328	281	7,798	80.8
		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	422	4.4
		Total	5	3	9	11	17	21	24	37	58	100	119	171	182	168	224	260	245	252	271	309	302 3	55	365	378	401	436	435	405	449	422	390	394	369	343	290	8,220	85.2
	Foreign	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	995	10.3
		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	431	4.5
		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	1,426	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	9,646	100.0

Source: "AIDS Surveillance Report 2019", 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 2019, 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	2019	5.80 million [4,300,000-7,200,000]	0.30 million [210,000-390,000]	0.2 [0.1-0.3]	0.16 million [94,000-240,000]
Asia Pacilic	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	2019	20.70 million [18,400,000-23,000,000]	0.73 million [580,000-940,000]	6.7 [5.7-7.6]	0.30 million [230,000-390,000]
East/South Airica	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,	2019	1.70 million [1,400,000-1,900,000]	0.17 million [140,000-190,000]	0.9 [0.8-1.0]	35,000 [26,000-45,000]
Central Asia	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	2019	2.10 million [1,400,000-2,800,000]	0.12 million [73,000-180,000]	0.4 [0.3-0.6]	37,000 [23,000-56,000]
Edili 7 menod	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	2019	0.33 million [270,000-400,000]	13,000 [8,700-19,000]	1.1 [0.9-1.4]	6,900 [4,900-10,000]
	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 /	2019	0.24 million [170,000-400,000]	20,000 [11,000-38,000]	<0.1 [<0.1-0.1]	8,000 [4,900-14,000]
North Africa	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	2019	4.90 million [3,900,000-6,200,000]	0.24 million [150,000-390,000]	1.4 [1.0-1.7]	0.14 million [100,000-210,000]
Western/Central Amca	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 /	2019	2.20 million [1,700,000-2,600,000]	65,000 [49,000-87,000]	0.2 [0.2-0.3]	12,000 [8,700-19,000]
North America	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	2019	38.00 million [31,600,000-44,500,000]	1.70 million [1,200,000-2,200,000]	0.7 [0.6-0.9]	0.69 million [500,000-970,000]
Total	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]

<sup>\*</sup>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 2020 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

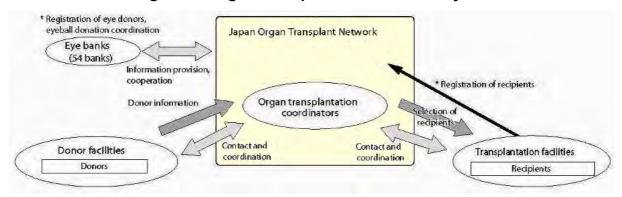
**Organ Transplantation System** 

#### [Organ Transplantation System]

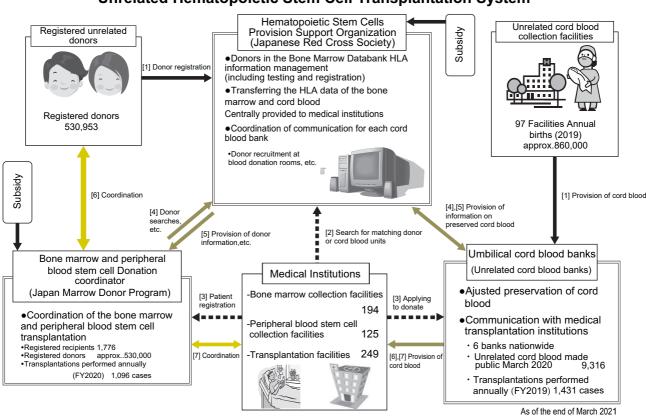
The traditional kidney transplantation system was reviewed and a new centralized nationwide kidney transplantation network established in FY1995. Enforcement of the "Act on Organ Transplantation" in October 1997 enabled multiple organ transplantations and the pertinent network.

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**



### Detailed Data 1 Accumulated Number of Organ Transplantations

	Number	of donors	Number of transpla	ntations performed	Registered transplant
		Under brain death		Under brain death	applicants
Heart	580 persons	580 persons	579 cases	579 cases	918 persons
Lung	493 persons	493 persons	601 cases	601 cases	478 persons
Liver	621 persons	621 persons	666 cases	666 cases	337 persons
Kidney	2,154 persons	685 persons	4,032 cases	1,345 cases	13,335 persons
Pancreas	445 persons	441 persons	441 cases	438 cases	197 persons
Small intestine	23 persons	23 persons	23 cases	23 cases	7 persons
Eyeball (cornea)	21,160 persons	312 persons	34,389 cases	591 cases	1,716 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, 2021. The number of patients on waiting lists is as of March 31, 2021.
  - 2. There have been 742 persons of brain death tests conducted nationwide under the Act on Organ Transplantation since the enforcement of the law until March 31, 2021. 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 (371 cases) and the number of registered pancreatic kidney simultaneous transplant applicants (161 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 (6 persons).
  - 5. The number of liver and kidney cases includes the number of cases of liver kidney simultaneous transplants (30 cases) and the number of registered liver kidney simultaneous transplant applicants (41 persons).

### Detailed Data 2 Changes in Numbers of Hematopoietic Stem Cell Transplantations Performed

	Unrelate	ed donors	Number	of unrelated transpla	ntations
	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
Total	_	_	24,147	1,183	20,061

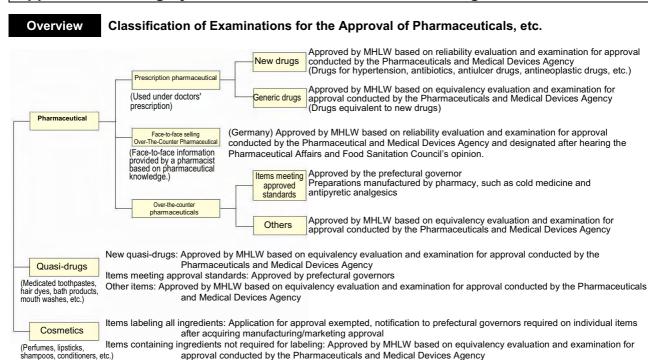
Source: Japan Marrow Donor Program, Japanese Red Cross Society

<sup>\*</sup> 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.

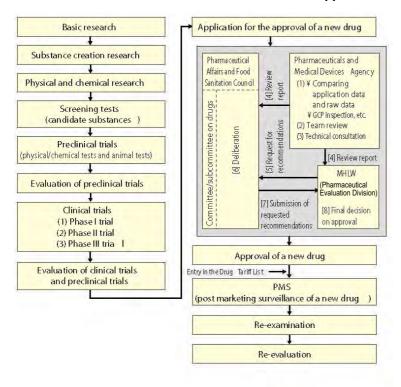
<sup>\*</sup> Number of donors is as of the end of the respective years.

### (4) Pharmaceuticals, etc.

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



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



(Note) The trials that are deemed necessary for application for the approval of a new drug can be roughly divided into two categories: preclinical (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.

#### [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 a 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.

### **Detailed Data 1**

### Number of Licenses for Marketing Authorization Holder of Drugs, etc.

(As of the end of 2020

					(73 01 1	IIIC CIIG OI 2020	
Cotogomi	Dharmasauticala	Class 1	Class 2	Ougoi drugo	Coomotico	Total	ı
Category	Pharmaceuticals	pharmaceuticals	pharmaceuticals	Quasi-drugs	Cosmetics	Total	
Marketing	1,037	274	763	1,458	3,957	6,452	ı

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. (2020)

		Prescription pharmaceuticals	Face-to-face selling / OTC pharmaceuticals	Quasi-drugs	Cosmetics
Manufacturing	Approval	964	463	1,893	0
Marketing	Approval with partial revision	2,249	162	225	0
Approval	Total	3,213	625	2,118	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 2020)

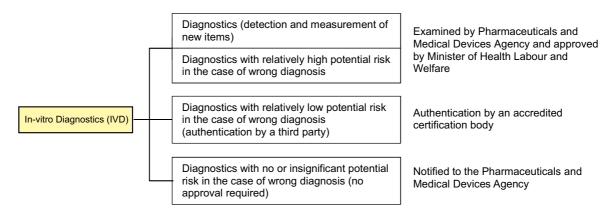
				JJ_J,
Category	Pharmaceuticals	Quasi-drugs	Cosmetics	Total
Manufacturing	2,047	1,958	3,876	7,881

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 2020)

	(, 10 0. 11.0 0.14 0. 2020)
	IVD
Marketing	167

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 (2020)

	Medicines for in-vitro diagnosis
Approval	98
Approval with partial change	85
Total	183

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

### **Detailed Data 3**

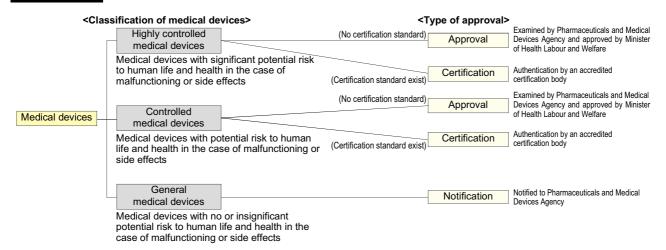
### **Number of Registrations for Manufacturing IVD**

(as of the end of	
IVD	
Manufacturing	216

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 2020)

Category	Class 1 medical devices	Class 2 medical devices	Class 3 medical devices	Total
Marketing	756	1,122	921	2,799

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 Manufacturing, Import, and Marketing Medical Devices (2020)

		Medical devices
	Approval	0
Manufacturing	Approval with partial change	0
	Total	0
	Approval	0
Import	Approval with partial change	0
	Total	0
	Approval	536
Marketing	Approval with partial change	580
	Total	1,116

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 2020)

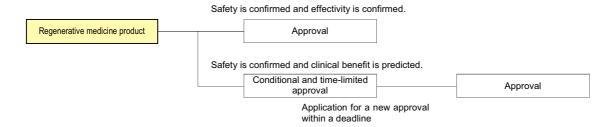
	Medical devices	
Manufacturing	4,442	
Repairs	6,526	

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 (2020)

	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 (2020)

	Regenerative medicine product
Approval	2
Approval with partial change regarding manufacture and sales	3
Total	5

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

### **Detailed Data 3**

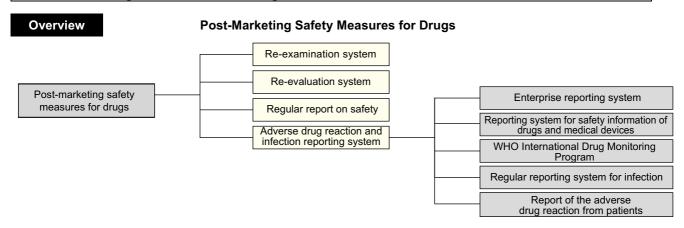
### Number of Licenses for Manufacturing Regenerative medicine product

(As of the end of 2020)

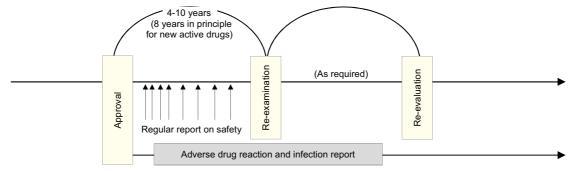
	Regenerative medicine product
Manufacturing	22

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

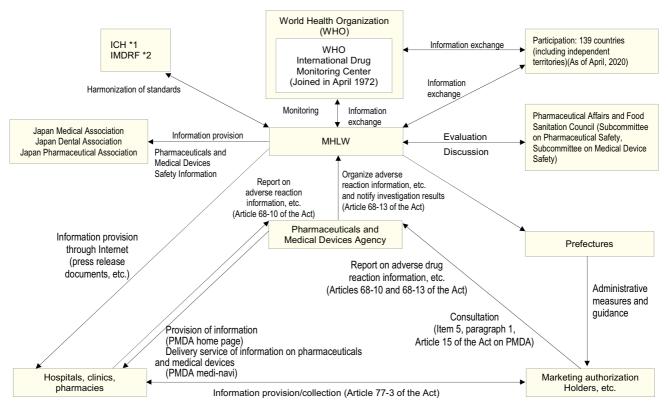
### Post-Marketing Measures for Drugs/Medical Devices



### 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 FY2020)

	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
4,216	142	0

<sup>\*</sup> 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 FY2020)

#### (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 2016): 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)

		te 1)					
FY	Reports on	Reports on	Reports on	Reports on	Regular reports on	Reports on adverse drug reactions	
	adverse drug	infectious	research	overseas	infectious diseases	from medical professionals Note 3)	
	reactions Note 2)	diseases Note 2)	results	measures			
FY 2015	50,977	88	1,219	1,273	1,102	6,129	
FY 2016	55,728	89	1,117	1,397	1,140	6,047	
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	

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 2) The sum consists of the number of adverse reaction reports based on the safety information reporting system and the number of post-vaccination side reaction reports. Note, however, that the number of post-vaccination side reaction reports is equivalent to the total number of reports related to cervical cancer preventive vaccine, hib vaccine, pediatric pneumococcal vaccine and influenza vaccine alone for FY 2012, and the total number of all vaccines for FY2013 and the following years.

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

### Detailed Data 4

### Changes in the Number of Fault Reports on Combination Drugs (Note1) Medical Devices

FY	Fault cases of combination(domestic)	Fault cases of combination drugs(Overseas)
2015	38	60
2016	661	1,126
2017	1,120	2,951
2018	1,653	2,542
2019	1.395	2.634

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 Note 1)

FY	Quasi-drugs (domestic)	Cosmetics (domestic)
FY 2015	323	114
FY 2016	146	71
FY 2017	119	97
FY 2018	163	83
FY 2019	119	80

Note 1) A report after the enforcement of the ministerial ordinance that revises a 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, Heisei 20, and was mandated.

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

		Reports from r				
FY	Reports on	Reports on	Reports on	Reports on	Pegular reports	Reports on adverse drug reactions from medical professionals
	adverse	infectious	research	overseas	infectious diseas	from medical professionals
	eventNote 1)	disease§ote 2)	results	measures	iniectious diseas	(Unit: case)
FY 2015	43,997	0	598	1,742	68	406
FY 2016	48,563	0	1,289	2,144	67	548
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

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

		Rep	orts from manufactu	rers	(Unit: case)	Reports on adverse
FY	Reports on adverse event Note 1)	Reports on infectious diseases Note 2)	Research reports	Reports on overseas measures	Regular reports on infectious diseases	drug reactions from medical professionals (unit: case)
FY 2015	35	0	0	0	14	0
FY 2016	88	0	0	0	34	0
FY 2017	110	0	0	0	34	0
FY 2018	163	0	0	0	34	0
FY 2019	1,145	0	1	2	62	0

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.

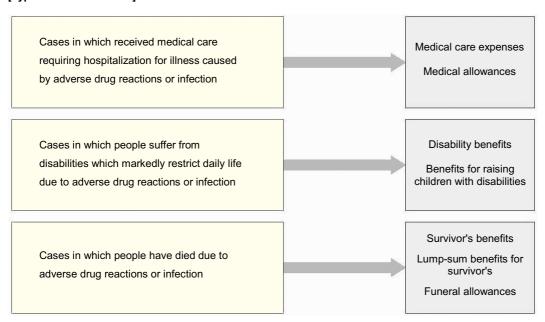
#### [Relief System for Infections Acquired through Biological Products]

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 o 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
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
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
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

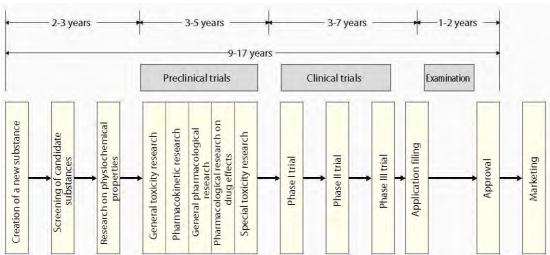
Source: Pharmaceutical and Medical Devices Agency

### 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

Catagory	Number of		Drug sales		Prescription drug sales (included)		
Category	enterprises	Percentage	(¥100 million)	Percentage	(¥100 million)	Percentage	
Capital of less than ¥100 million	136	46.6%	4,369	3.1%	2,862	2.5%	
¥100 million - 5 billion	99	33.9%	26,155	18.2%	20,387	17.8%	
¥5 billion or more	57	19.9%	112,927	78.7%	91,076	79.7%	
Total	292	100.0%	143,450	100.0%	114,325	100.0%	

Source: "Survey of the Prescription Pharmaceuticals Industry of Japan (FY2015", 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, 2020, 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	Evport 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	25,678	31.8	10,091	27,230	39,864

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

## Detailed Data Production by Medical Device Type (Unit: ¥100 million, %)

Viscens function substitute		(Unit: ¥100 million, %)										
2   Cannulseicatheters of assorted tip configurations   2,824   110,		Category	Production	Percentage		Category	Production	Percentage				
2	1	Visceral function substitute	3,049	11.9	40	Medical knife	66	0.3				
Medical mirror	2	Cannulae/catheters of assorted tip configurations	2 824	11.0	41	Dental engine	66	0.3				
A   Medical X-ray device and X-ray tube for medical X-ray device   2,259   8,8	-	, ,	-		42	Urine test or stercus test device	58	0.2				
Secretar			, -		43	Medical evacuator	56	0.2				
45   Nedecial washer   45   0.2					44	Medical microtome	56	0.2				
7 Physiotherapy device					45	Medical washer	45	0.2				
8			-		46	Dental cutting machine	42	0.2				
9	_		-		47	Dental ground materials	39	0.2				
10	_				48	Accessories designated due to the MHLW Act	37	0.1				
11   Eyeglasses for sight correction   885   3.4   12   Vision tester   562   2.2   13   X - ray film   530   2.1   14   Needles and puncture needle   459   1.8   15   0 lagnosis program.   3.2   0.1   14   Needles and puncture needle   459   1.8   15   0 lagnosis program.   3.2   0.1   15   0 lagnosis program.   3.2   0.1   16   0 lood collecting or transfusion device   428   1.7   17   Medical gap-filling adhesive   337   1.3   1.					49	Incubator	35	0.1				
12   Vision tester   562   2.2   13   X - ray film   530   2.1   14   Needles and puncture needle   459   1.8   1.8   1.7   16   Blood collecting or transfusion device   428   1.7   16   Blood collecting or transfusion device   428   1.7   17   Medical gap-filling adhesive   337   1.3					50	Dental calcium sulfate and calcium sulfates' goods	34	0.1				
13		, ,			51	Tampon for menstruation treatment	33	0.1				
14   Needles and puncture needle					52	Diagnosis program.	32	0.1				
15   Others		,			53	Plate materials	31	0.1				
16   Blood collecting or transfusion device   428   1.7     17   Medical gap-filling adhesive   337   1.3     18   Medical materials generator   225   0.9     19   Dental unit   213   0.8     20   Orthopedic instruments and apparatus (note)   205   0.8     21   Syringe barrel   178   0.7     22   Respiratory equipment   174   0.7     23   Hearing aid   162   0.6     instrument (note)   25   Bolod pressure test or pulse wave velocity test device   143   0.6     25   Blood pressure test or pulse wave velocity test device   132   0.5     28   Dental hand piece   132   0.5     30   Operating table and treatment table   121   0.5     31   Condom   116   0.5     32   Electrosurgical unit   92   0.4     33   Magnetic therapy apparatus   88   0.3     34   Ligation device and Suturing devices and   85   0.3     35   Acus or moxibustion device   80   0.9     38   Medical cauter   74   0.3     55   Radiological material diagnosis device   27   0.1     56   Opening or stoma device   26   0.1     57   Dental steamer and polymerization vessel   24   0.1     58   Vision corrective glass   22   0.1     59   Dental casting apparatus   21   0.1     60   Dental materials for root canal filling   21   0.1     61   Visual acutry chart and color anomaly test table   21   0.1     62   Medical inhalant   20   0.1     63   Perception test or physical function test device   19   0.1     64   Medical acutrifugal separator   17   0.1     65   Medical acutrifugal separator   17   0.1     66   Medical inhalant   20   0.1     67   Pneumothorax and pneumoperitoneum apparatus   14   0.1     68   Medical elevator   19   0.0     69   Neetical distincction apparatus   10   0.1     60   Dental materials		'			54	Medical light	30	0.1				
17   Medical gap-filling adhesive   337   1.3   1.3   1.3   Medical materials generator   225   0.9   1.9   Dental unit   213   0.8   1.5   0.9   0.1   0.					55	-	27	0.1				
18   Medical materials generator   225   0.9     19   Dental unit   213   0.8     20   Orthopedic instruments and apparatus (note)   205   0.8     21   Syringe barrel   1778   0.7     22   Respiratory equipment   174   0.7     23   Hearing aid   162   0.6     15   Instrument (note)   18   0.6     16   Instrument (note)   18   0.6     17   Instrument (note)   18   0.6     18   Instrument (note)   19   0.1     25   Blood pressure test or pulse wave velocity test device   143   0.6     26   Tooth crown materials   138   0.5     27   Electrical therapy apparatus for household use   137   0.5     28   Dental and piece   132   0.5     29   Medical disinfection apparatus   131   0.5     30   Operating table and treatment table   121   0.5     31   Condom   116   0.5     32   Electrosurgical unit   92   0.4     33   Magnetic therapy apparatus   89   0.3     34   Ligation device and Suturing devices and   85   0.3     35   Acus or moxibusition device   82   0.3     36   Suture   80   0.3     38   Medical cauter   74   0.3     76   Splint   6   0.0     77   Medical involator   6   0.0     78   Medical involator   18   0.5     79   Potental nameria and polymerization vessel   24   0.1     58   Vision corrective glass   22   0.1     59   Dental steamer and polymerization vessel   24   0.1     50   Chapteria stering apparatus   21   0.1     61   Visual acutry chart and color anomaly test table   21   0.1     61   Visual acutry chart and color anomaly test table   21   0.1     62   Medical inhalant   20   0.1     63   Perception test or physical function test device   19   0.1     64   Medical function test device   19   0.1     65   Medical inhalant   20   0.1     66   Hearing test device   15   0.1     67   Pneumothorax and pneumoperitoneum apparatus   14   0.1     68   Medical elevator   17   0.1     69   Medical disinfection apparatus   14   0.1     60   Medical disinfection apparatus   14   0.1     61   Visual acutry chart and color anomaly test table   21   0.1     62   Medical inhalant   20   0.1     63   Perception					56	Opening or stoma device	26	0.1				
19   Dental unit							24					
20 Orthopedic instruments and apparatus (note)   205   0.8		-			58		22					
21   Syringe barrel   178   0.7						*						
22 Respiratory equipment 174 0.7 23 Hearing aid 162 0.6 24 Medical puncture device and rotating instrument (note) 148 0.6 25 Blood pressure test or pulse wave velocity test device 143 0.6 26 Tooth crown materials 138 0.5 27 Electrical therapy apparatus for household use 137 0.5 28 Dental hand piece 132 0.5 29 Medical disinfection apparatus 131 0.5 29 Medical disinfection apparatus 131 0.5 31 Condom 116 0.5 32 Electrosurgical unit 92 0.4 33 Magnetic therapy apparatus 98 0.3 35 Acus or moxibustion device 82 0.3 36 Suture 80 0.7 38 Medical cauter 74 0.3 39 Medical cauter 74 0.3 30 Medical cauter 74 0.3 30 Medical cauter 74 0.3 30 Medical puncture device and rotating 148 0.6 40 Medical inhalant 20 0 0.1 40 Medical inhalant 20 0 0.1 40 Medical inhalant 20 0 0.1 40 Medical forceps 170 0.1 40 Medical forceps 170 0.1 40 Medical evator 170 0.1 40 Medical evator 170 0.1 40 Medical evator 170 0.1 41 Medical puncture device and rotating 170 0.1 41 Medical puncture device and rotating 171 0.1 42 Medical alevator 171 0.1 43 Medical cauter 74 0.3 44 Medical puncture device and rotating 172 0.1 45 Medical alevator 172 0.0 46 Medical evator 172 0.0 46 Medical evator 172 0.0 47 Medical puncture device and rotating 172 0.1 48 Medical puncture device and rotating 172 0.1 48 Medical disinfection apparatus 173 0.5 40 Medical disinfection apparatus 174 0.1 40 Medical puncture device 175 0.1 40 Medical rotation 175 0.1 40 Medical rotation 175 0.1 41 Medical rotation 175 0.1 42 Medical rotation 175 0.1 43 Medical rotation 175 0.1 44 Medical rotation 175 0.1 45 Medical rotation 175 0.1 46 Medical rotation 175 0.1 40 Medical rotation 175 0.1 41 Medical rotation 175 0.1 41 Medical rotation 175 0.1 42 Medical rotation 175 0.1 43 Medical rotation 175 0.1 44 Medical rotation 175 0.1 45 Medical												
23   Hearing aid   162   0.6						· ·						
24   Medical puncture device and rotating instrument (note)   148   0.6   63   Perception test or physical function test device   19   0.1   64   Medical centrifugal separator   17   0.1   65   Medical centrifugal separator   17   0.1   65   Medical centrifugal separator   17   0.1   65   Medical centrifugal separator   17   0.1   66   Medical centrifugal separator   17   0.1   66   Medical centrifugal separator   17   0.1   67   Pneumothorax and pneumoperitoneum apparatus   14   0.1		1 1 1 1										
18		•										
25   Blood pressure test or pulse wave velocity test device	24	·	148	0.6								
26 Tooth crown materials         138         0.5           27 Electrical therapy apparatus for household use         137         0.5           28 Dental hand piece         132         0.5           29 Medical disinfection apparatus         131         0.5           30 Operating table and treatment table         121         0.5           31 Condom         116         0.5           32 Electrosurgical unit         92         0.4           33 Magnetic therapy apparatus         89         0.3           34 Ligation device and Suturing devices and         85         0.3           35 Acus or moxibustion device         82         0.3           36 Suture         80         0.3           37 Dental impression material         76         0.3           38 Medical cauter         74         0.3	25		143	0.6								
27         Electrical therapy apparatus for household use         137         0.5           28         Dental hand piece         132         0.5           29         Medical disinfection apparatus         131         0.5           30         Operating table and treatment table         121         0.5           31         Condom         116         0.5           32         Electrosurgical unit         92         0.4           33         Magnetic therapy apparatus         89         0.3           34         Ligation device and Suturing devices and         85         0.3           35         Acus or moxibustion device         82         0.3           36         Suture         80         0.3           37         Dental impression material         76         0.3           38         Medical cauter         74         0.3		Tooth crown materials										
28         Dental hand piece         132         0.5           29         Medical disinfection apparatus         131         0.5           30         Operating table and treatment table         121         0.5           31         Condom         116         0.5           32         Electrosurgical unit         92         0.4           33         Magnetic therapy apparatus         89         0.3           34         Ligation device and Suturing devices and         85         0.3           35         Acus or moxibustion device         82         0.3           36         Suture         80         0.3           37         Dental impression material         76         0.3           38         Medical cauter         74         0.3           74         Medical incubator         6         0.0           75         Themomter         6         0.0           76         0.0         0.0         0.0	27	Electrical therapy apparatus for household use	137									
29         Medical disinfection apparatus         131         0.5           30         Operating table and treatment table         121         0.5           31         Condom         116         0.5           32         Electrosurgical unit         92         0.4           33         Magnetic therapy apparatus         89         0.3           34         Ligation device and Suturing devices and         85         0.3           35         Acus or moxibustion device         82         0.3           36         Suture         80         0.3           37         Dental impression material         76         0.3           38         Medical cauter         74         0.3	28											
30   Operating table and treatment table   121   0.5     31   Condom   116   0.5     32   Electrosurgical unit   92   0.4   33   Magnetic therapy apparatus   89   0.3   34   Ligation device and Suturing devices and   85   0.3   35   Acus or moxibustion device   82   0.3   36   Suture   80   0.3   37   Dental impression material   76   0.3   38   Medical cauter   74   0.3   Medical cauter   74   0.3   The most of the standard of the standard   9   0.0		-										
31 Condom         116         0.5           32 Electrosurgical unit         92         0.4           33 Magnetic therapy apparatus         89         0.3           34 Ligation device and Suturing devices and         85         0.3           35 Acus or moxibustion device         82         0.3           36 Suture         80         0.3           37 Dental impression material         76         0.3           38 Medical cauter         74         0.3           74 Medical incubator         9         0.0           75 Themomter         6         0.0           76 Splint         6         0.0           77 Medical incubator         6         0.0					03		10	0.0				
32         Electrosurgical unit         92         0.4           33         Magnetic therapy apparatus         89         0.3           34         Ligation device and Suturing devices and         85         0.3           35         Acus or moxibustion device         82         0.3           36         Suture         80         0.3           37         Dental impression material         76         0.3           38         Medical cauter         74         0.3           75         Medical incubator         6         0.0           76         0.0         0.0         0.0		, ,			70		9	0.0				
33 Magnetic therapy apparatus         89         0.3           34 Ligation device and Suturing devices and         85         0.3           35 Acus or moxibustion device         82         0.3           36 Suture         80         0.3           37 Dental impression material         76         0.3           38 Medical cauter         74         0.3           74 Medical rolled cotton         9         0.0           75 Themomter         6         0.0           76 Splint         6         0.0           77 Medical incubator         6         0.0					71	Medical pincette	9	0.0				
34 Ligation device and Suturing devices and         85         0.3           35 Acus or moxibustion device         82         0.3           36 Suture         80         0.3           37 Dental impression material         76         0.3           38 Medical cauter         74         0.3           75 Impression taking or maxillomandibular registration device         6         0.0           75 Themomter         6         0.0           76 Splint         6         0.0           76 Medical incubator         6         0.0		-			72	Medical rolled cotton	9	0.0				
35         Acus or moxibustion device         82         0.3         74         Medical scissors         6         0.0           36         Suture         80         0.3         75         Themomter         6         0.0           37         Dental impression material         76         0.3         76         Splint         6         0.0           38         Medical cauter         74         0.3         77         Medical incubator         6         0.0							6					
36 Suture         80         0.3         75 Themomter         6         0.0           37 Dental impression material         76         0.3         75 Splint         6         0.0           38 Medical cauter         74         0.3         77 Medical incubator         6         0.0												
37 Dental impression material         76         0.3         5plint         6         0.0           38 Medical cauter         74         0.3         77 Medical incubator         6         0.0												
38 Medical cauter         74         0.3         77 Medical incubator         6         0.0												
		,				-						
	39		69	0.3	78	Medical dilator	5	0.0				

	Category	Production	Percentage
79	Dental wax	5	0.0
80	Medical sew	4	0.0
81	Biological fluid test device	4	0.0
82	Medical treatment program	4	0.0
83	Dental filling instruments	4	0.0
84	Medical uncal	4	0.0
85	Stethoscope	4	0.0
86	Dental filling instrument	4	0.0
87	Surgical gloves and finger cot	3	0.0
88	Dental desiccator	2	0.0
89	Dental probe	2	0.0
90	Hernia supporters (note)	2	0.0
91	Dental broach	1	0.0
92	Medical snare	1	0.0

	Category	Production	Percentage
93	Medical lever	1	0.0
94	Medical Water sterilizers	1	0.0
95	For medical use only		0.0
96	Contact lenses (excluding for sight correction.)	1	0.0
97	Spatula	1	0.0
98	Medical spoon	1	0.0
99	Medical bougie	0	0.0
100	Contraceptive device	0	0.0
101	Medical hammer	0	0.0
102	Plexor	0	0.0
103	Smallpox vaccination device	0	0.0
104	Medical raspatory	0	0.0
105	Finger pressure substitute	0	0.0
	Total	25,678	100.0

Source: "Annual Report on the Survey of Pharmaceutical Industry Productions 2019", Health Policy Bureau, MHLW

### **Pharmacies**

### Overview

Separation of dispensing and prescribing functions in 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) By centrally and continuously grasping the patient's condition and medications taken by the pharmacy pharmacist and checking the prescription contents, it is possible to confirm whether the multiple medications and interactions caused by visiting multiple clinical departments exist, and to inprove the effectiveness and safety of drug therapy.
- 2) Pharmacists, in cooperation with prescribing physicians and dentists, will explain effects, side effects, directions for use, etc. of drugs to patients (patient compliance instruction) so that patients 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 even when the particular drugs are not stocked in their own hospitals or clinics.
- Issuing prescriptions to patients allows them to know which drugs they are taking.
- Reduced outpatient dispensing work of 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

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.

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

> Number of prescriptions to pharmacies Prescription receipt rate (%) = Number of prescriptions issued to outpatients (total) ×100

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

### **Blood Programme**

#### **Overview**

#### [Blood Products]

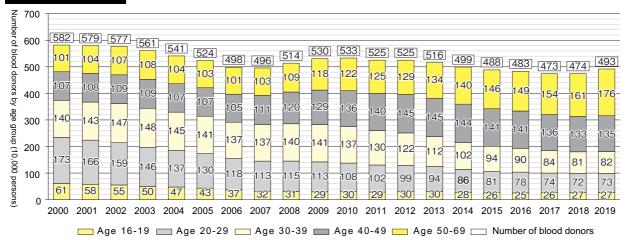
Blood products refer to all pharmaceutical products which are derived from human blood and are roughly classified into blood transfusion products and plasma derivatives. All of the blood transfusion products are supplied through blood donations in Japan. Regarding plasma derivatives, the domestic self-sufficiency 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	Туре	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]

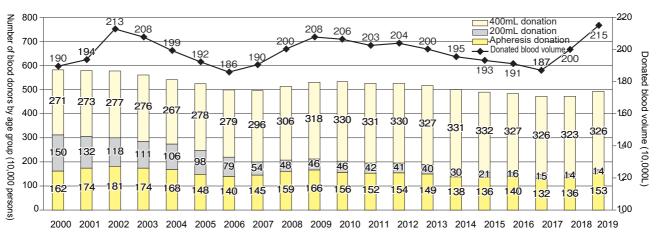
In recent years, due to an increase in the amount of blood donated per person, the required amount of blood can be secured with a smaller number of people than before, and the total number of blood donors is declining. On the other hand, looking at the number of blood donors by age group, the proportion of young people in the total blood population has decreased significantly compared to 10 years ago, but the number of teenagers has been improving since FY 2017. For the numbers of 20s and 30s, they turned to increase in the FY 2019.

#### **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



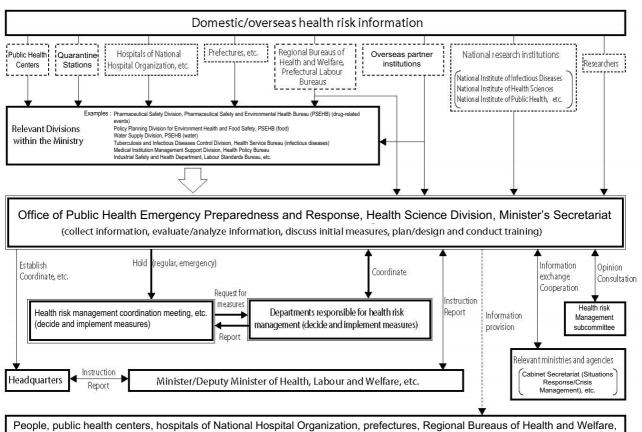
**☀From 2018, the amount of blood donated by component blood donation is calculated based on the total volume at the manufacturing stage** (including the amount of blood storage solution).

## (5) Health Risk Management System

### Health Risk Management System

Overview

MHLW Health Risk Management System Diagram



Prefectural Labour Bureaus, national research institutions, overseas partner institutions, etc.