[2] Health and Medical Services

(1) Health Care Insurance

Health Care Insurance System

Overview

Outline of Health Care Insurance System

(As of April 2020)

				Number of subscribers		Insurance bene	fits				l resources
	Sys	stem	Insurer (as of the	(March 2019)		Medical care benefits				. .	
	,		end of March 2019)	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	Cash benefits	Premium rate	State subsidy
Hea	General employees	JHIA- managed Health Insurance	Japan Health Insurance Association	39,400 [23,757] [15,643]		(average annual income: between about 7.70 million yen and about 11.60 million yen) ¥167,400 + (medical expenses – ¥558,000) x1% (average annual income:	(Co-payment for meal expenses)	(Co-payment for living expenses) •General (I) (II) (III) Per meal ¥460 + Per day ¥370 •Household exempted	Sickness and injury allowance Lump-sum birth allowance, etc	10.00% (national average)	16.4% of benefit expenses, etc.
Health Insurance	ees	Society -managed Health Insurance	Health Insurance Societies 1,391	29,539 16,718 12,821		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 (exempted from residence tax) ¥35,400	residence tax Per meal first 90 days ¥210	from residence tax Per meal + Per day ¥370	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	16 [11 [5]]		(Persons aged 70 or older but younger than 75) (average annual income: over approximately 11.60 million yen) ¥252,600 + (medical expenses – ¥842,000) x1% (average annual income: between about 7.70 million yen and about 11.60 million yen) ¥167,400 + (medical expenses – ¥558,000) x1%	+160 •Lower	•Lower income household exempted from residence tax Per meal ¥130 •Per day ¥370	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	119 58 61	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	Applicable to those aged 65 or older in long-term care beds For patients with		9.60% (sickness insurance premium rate)	Fixed amount
Mutual		ional public mployees	20 mutual aid associations		reaching compulsory education age until age 70 30%	under tappicantiated 51 animology 11, 4000 (version) outpatient (per person) ¥18,000 (vf144,000 (version) ¥24,600, outpatient (per person) ¥8,000 (Especially household with lower income among household exempted from residence tax) ¥15,000, outpatient (per person) ¥8,000		intractable/rare diseases, etc. and thus in high need for inpatient	Same as	-	_
Mutual aid associations		ocal public loyees, etc.	64 mutual aid associations	8,575 4,537 4,038	Before reaching compulsory	 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-	above (with additional benefits)	-	None
ations		/ate school chers/staffs	1 Corporation		education age 20%	benefits paid Reduced payment for multiple high-cost medical care For persons who have received high-cost care 		payment for meal expenses		-	
		rmers, self-	Municipalities 1,716		70 or older but younger than 75 20% (30% for	three times within a twelve-month period, the maximum co-payment of the fourth time and up will be reduced to: (Persons younger than 70) (average annual income: over approximately 11.60 million yen)					41% of benefit expenses, etc.
	e	mployed, etc.	NHI associations 162		persons with more than a certain amount of income)	¥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					28.4~ 47.4% of benefit expenses, etc.
National Health Insurance (NHI)	E	Retired sons under nployees' Health isurance	Municipalities 1,716	30,256 Municipalities 27,517 NHI associations 2,739		million yen) ¥44,000 (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 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 (Neduced payment for persons receiving high-cost medical care fora long period Maximum co-payment for patients suffering from hemophilia or chronic renal failure requiring dialysis, etc.: ¥20,000 (Unitary high cost medical/long-term care benefit system) Reduced payment for persons whose total co- payments of health care and long-term care insurances for a year (every year from August to July of the next year) is extremely high. Maximum co-paymentis 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 47		Same as above, except for • Recipients of old-age Welfare Pensions Per meal ¥100	Calculated using the amount of the per capita rate and insurance income persons ratio of by wide by wide unions About 10% of benefits, expenses, turance insurance funding) provided by wide area unions About 10% of benefits, etc. are borne as funding) At i 1 : 1 In addition about 40% of the expenses, the premiums 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.

. 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%)

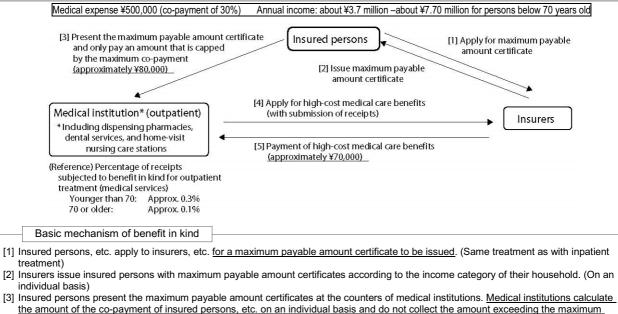
	at reception 300,000	Medical costs ¥ 1,000,000	
Maxim		bst medical care benefits ¥300,000-¥87,430=212,570 ¥80,100 + (¥1,000,000 - ¥267,000 %) ×1% = ¥87,430	
		*80,100÷0.3=267,000	

(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.



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.

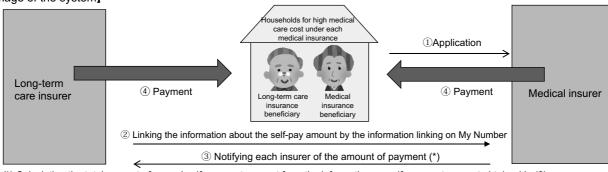
① Payment requirement: If the sum of self-payment of medical insurance and nursing care insurance exceeds the limit set for each income category in a household with medical insurance, an amount exceeding the limit is paid from the total amount.

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".

[Image of the system]

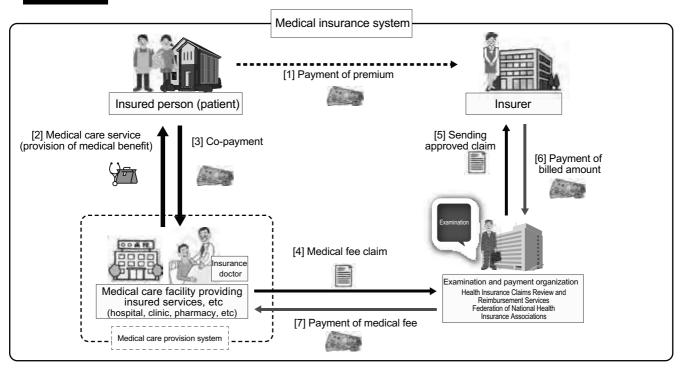


(*) Calculating the total amount of annual self-payment amount from the information on self-payment amount obtained in (2), to calculate the amount of High Cost Total Medical Care payment amount. This calculated amount of payment is apportioned among the insurers according to the ratio of the self-payment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

Insured Medical Treatment System

Overview

Conceptual Chart of Insured Medical Treatment



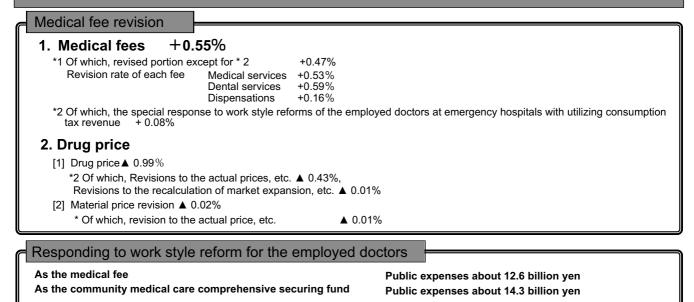
Medical fees are classified into three types: medical, dental, and dispensing fees.

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

Detailed Information

Outline of the FY 2020 Medical fees revision

The FY 2020 Medical fee revision



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.

Detailed Information Outline of the FY 2020 Medical fees revision

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]	3 Differentiation and strengthening of medical functions, and promotion of _cooperation and the Community-based Integrated Care System
 [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 	 [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	4 Improving the stability and sustainability of the system through optimization and efficiency
[Examples of Specific Directions]	[Examples of Specific Directions]
Evaluation of family doctors' functions	Promotion of the use of generic drugs and follow-on biologics
 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 	Utilization of cost-effectiveness evaluation system Appropriate evaluation based on prevailing market prices, etc.
Promotion of evaluation that also focuses on outcomes	Evaluation of inpatient care according to medical functions and patients' conditions (Re- listed)
 Appropriate evaluation of areas that require prioritization 	Functional differentiation of outpatient care and promotion of prevention of progression
 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 	 Promotion of appropriate use of pharmaceuticals through collaborative efforts among physicians, in-house pharmacists, and pharmacy pharmacists
pharmacies from physical to human services, and evaluation of in-hospital pharmacist services	

· Utilization of ICT in medical care

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

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

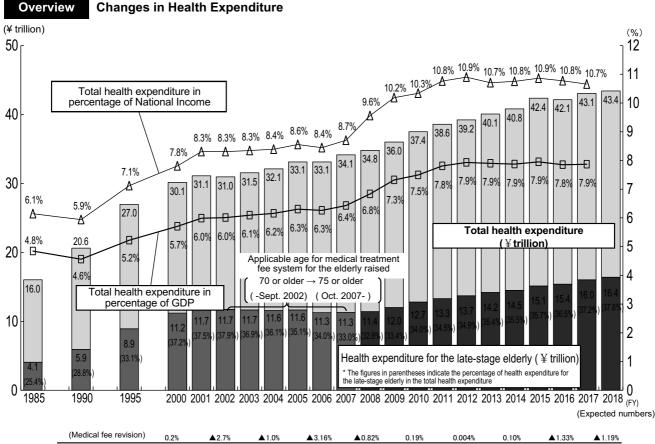
Differentiation and strengthening of medical functions, and promotion of cooperation and the Community-based Integrated Care System

- 1.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

${\rm I\!\!I}$ 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



_	(Inedical lee revision)	0.2%	▲ 2.7%	▲ 1.0%	▲3.16%	▲ 0.82%	0.19%	0.004%	0.10%	▲ 1.33%	▲1.19%
	(Major system revision)	Enforcement of long-term care insurance system Introduction of 10%co-payment by elderly (2000)	Thorough implemen tation of 10 %co-payme nt by the elderly (2002)	• 30% co- payment by employees, etc (2003)	• 30% co- payment by elderly with more than a certain amount of income (2006)	20% co-payme nt for pre- school children (2008)			• 20% co- payment for 70-74 years old* (2014)		

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

<year-on-y< th=""><th>ear g</th><th>rowt</th><th>h rate</th><th>e of N</th><th>atior</th><th>nal He</th><th>ealth</th><th>Expe</th><th>enditu</th><th>ıre></th><th></th><th></th><th></th><th></th><th></th><th></th><th></th><th></th><th></th><th></th><th></th><th>(%)</th></year-on-y<>	ear g	rowt	h rate	e of N	atior	nal He	ealth	Expe	enditu	ıre>												(%)
	1985	1990	1995	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
Total health expenditure	6.1	4.5	4.5	▲1.8	3.2	▲0.5	1.9	1.8	3.2	▲0.0	3.0	2.0	3.4	3.9	3.1	1.6	2.2	1.9	3.8	▲0.5	2.2	0.8
Health expenditure for the late-stage elderly	12.7	6.6	9.3	▲5.1	4.1	0.6	▲0.7	▲0.7	0.6	▲3.3	0.1	1.2	5.2	5.9	4.5	3.0	3.6	2.1	4.4	1.6	4.2	2.4
National Income	7.2	8.1	2.7	2.4	▲3.0	▲0.4	1.4	1.3	1.2	1.3	▲0.0	▲7.2	▲2.9	2.4	▲1.0	0.4	4.0	1.4	2.8	0.3	3.3	-
GDP	7.2	8.6	2.7	1.2	▲ 1.8	▲0.8	0.6	0.7	0.8	0.6	0.4	▲4.0	▲3.4	1.5	▲1.1	0.1	2.6	2.2	2.8	0.7	2.0	-

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

2. National medical expenses (and those for advanced elderly. The same applies hereinafter) in FY2018 are estimates including the actual performance. The expenses for FY2018 are estimated by multiplying the national medical expenses for FY2017 by the rate of increase in approximate medical expenses in FY2018 (figures written in italics in the table above).

*The budget freezing measure for co-payment ratios of persons aged 70 to 74 was lifted (10%→2 0%). 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.

Country	care expenditure		Per capita m care expend (\$)		Remarks	Country	Total medic care expend in GDP (%)	diture	Per capita m care expendi - (\$)	ture	Remarks
		Rank	(\$)	Rank				Rank	(\$)	Rank	
U.S.A	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			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	
U.K.	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		

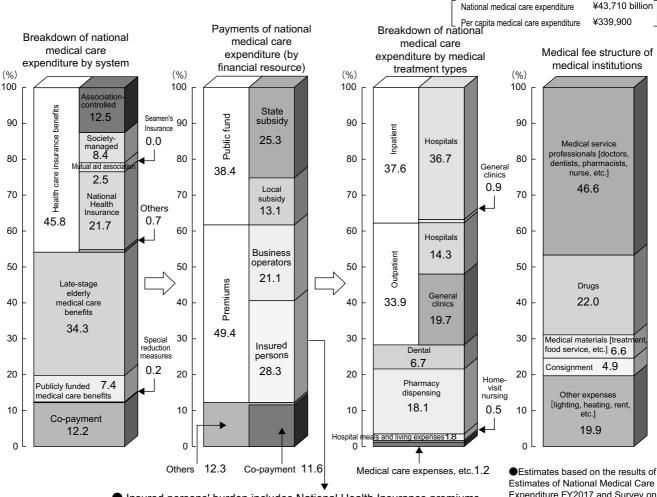
Detailed Data 1 National Medical Care Expenditure of OECD Countries (2019)

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 2017)



Insured persons' burden includes National Health Insurance premiums

Detailed Data 3

Changes in National Medical Care Expenditure and Percentage Distribution

	National	General			Impatient			Outpatient	[]		Dental	Pharmacy	Hospital	Medical treatment	Home-visit
Year	medical care expenditure	medical fees	Hospitals	General clinics	medical fees	Hospitals	General clinics	medical fees	Hospitals	General clinics	medical fees	dispensing medical fees 2)	meals and living expenses 3)	fees at health service facilities for the elderly 4)	nursing medical fees
							Estimated	amount (¥1	00 million)						
1962	6,132	5,372	2,948	2,424	2,344	2,072	272	3,028	875	2,153	759		•	•	
1965	11,224	10,082	5,499	4,583	4,104	3,635	469	5,978	1,864	4,113	1,143			•	
1970	24,962	22,513	12,121	10,392	8,799	7,801	998	13,714	4,320	9,394	2,448				
1975	64,779	59,102	32,996	26,106	25,427	22,640	2,787	33,675	10,356	23,319	5,677				
1980	119,805	105,349	62,970	42,379	48,341	43,334	5,007	57,008	19,636	37,372	12,807	1,649			
1985	160,159	140,287	92,091	48,195	70,833	65,054	5,778	69,454	27,037	42,417	16,778	3,094			
1990	206,074	179,764	123,256	56,507	85,553	80,470	5,082	94,211	42,786	51,425	20,354	5,290		666	
1995	269,577	218,683	148,543	70,140	99,229	94,545	4,684	119,454	53,997	65,456	23,837	12,662	10,801	3,385	210
2000	301,418	237,960	161,670	76,290	113,019	108,642	4,376	124,941	53,028	71,913	25,569	27,605	10,003	•	282
2001 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
2002	315,375	230,100	164,077	76,854	117,231	112,942	4,337	122,023	51,389	72,565	25,875	38,907	9,835		348
2004	321,111	243,627	164,764	78,863	118,464	114,047	4,417	125,163	50,717	74,446	25,377	41,935	9,780	•	392
2005	331,289	249,677	167,955	81,722	121,178	116,624	4,555	128,499	51,331	77,167	25,766	45,608	9,807		431
2006	331,276	250,468	168,943	81,525	122,543	117,885	4,658	127,925	51,058	76,867	25,039	47,061	8,229	•	479
2007	341,360	200,418	173,102	83,316	126,132	121,349		130,287 age distribu	51,753 ution (%)	78,534	24,996	51,222	8,206	•	518
1962	100.0	87.6	48.1	39.5	38.2	33.8	4.4	49.4	14.3	35.1	12.4				.
1965	100.0	89.8	49.0	40.8	36.6	32.4	4.2	53.3	16.6	36.6	10.2				
1970	100.0	90.2	48.6	41.6	35.2	31.3	4.0	54.9	17.3	37.6	9.8				
1975	100.0	91.2	50.9	40.3	39.3	34.9	4.3	52.0	16.0	36.0	8.8				
1980	100.0	87.9	52.6	35.4	40.3	36.2	4.2	47.6	16.4	31.2	10.7	1.4			
1985	100.0	87.6	57.5	30.1	44.2	40.6	3.6	43.4	16.9	26.5	10.5	1.9			
1990	100.0	87.2	59.8	27.4	41.5	39.0	2.5	45.7	20.8	25.0	9.9	2.6		0.3	
1995	100.0	81.1	55.1	26.0	36.8	35.1	1.7	44.3	20.0	24.3	8.8	4.7	4.0	1.3	0.1
2000	100.0	78.9	53.6	25.3	37.5	36.0	1.5	41.5	17.6	23.9	8.5	9.2	3.3	•	0.1
2001	100.0	78.0	52.9	25.1	37.0	35.6	1.4	40.9	17.3	23.7	8.4	10.3	3.2	•	0.1
2002	100.0	76.9	52.5	24.4	37.3	35.9	1.4	39.6	16.6	23.0	8.4	11.4	3.2	•	0.1
2003	100.0	76.4	52.0	24.4	37.2	35.8	1.4	39.2	16.2	23.0	8.0	12.3	3.1	•	0.1
2004	100.0	75.9	51.3	24.6	36.9	35.5	1.4	39.0	15.8	23.2	7.9	13.1	3.0		0.1
2005	100.0	75.4	50.7	24.7	36.6	35.2	1.4	38.8	15.5	23.3	7.8	13.8	3.0	•	0.1
2006	100.0	75.6	51.0	24.6	37.0	35.6	1.4	38.6	15.4	23.2	7.6	14.2	2.5		0.1
2007	100.0	75.1	50.7	24.4	36.9	35.5	1.4	38.2	15.2	23.0	7.3	15.0	2.4	·	0.2
	National	Medical									Dental	Pharmacy	Hospital	Home-visit	Medical

	National	Medical									Dental	Pharmacy	Hospital	Home-visit	Medical	
Year	medical care expenditure	fees of medical treatment 5)	Hospitals	General clinics	Impatient medical fees	Hospitals	General clinics	Outpatient medical fees	Hospitals	General clinics	medical fees	dispensing medical fees 2)	meals and living expenses 3)	nursing medical fees	care expenses, etc. 5)	
						I	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	360,067	262,041	178,848	83,193	132,559	128,266	4,293	129,482	50,582	78,900	25,587	58,228	8,161	665	5,384	
2010	374,202	272,228	188,276	83,953	140,908	136,416	4,492	131,320	51,860	79,460	26,020	61,412	8,297	740	5,505	
2011	385,850	278,129	192,816	85,314	143,754	139,394	4,359	134,376	53,421	80,954	26,757	66,288	8,231	808	5,637	
2012	392,117	283,198	197,677	85,521	147,566	143,243	4,323	135,632	54,434	81,197	27,132	67,105	8,130	956	5,597	
2013	400,610	287,447	201,417	86,030	149,667	145,523	4,144	137,780	55,894	81,886	27,368	71,118	8,082	1,086	5,509	
2014	408,071	292,506	205,438	87,067	152,641	148,483	4,158	139,865	56,956	82,909	27,900	72,846	8,021	1,256	5,543	
2015	423,644	300,461	211,860	88,601	155,752	151,772	3,980	144,709	60,088	84,622	28,294	79,831	8,014	1,485	5,558	
2016	421,381	301,853	214,666	87,187	157,933	154,077	3,856	143,920	60,589	83,332	28,574	75,867	7,917	1,742	5,427	
2017	430,710	308,335	219,675	88,660	162,116	158,228	3,888	146,219	61,447	84,772	29,003	78,108	7,954	2,023	5,287	
								age distrib								
2008	100.0	73.1	49.5	23.6	36.8	35.5	1.3	36.3	14.0	22.3	7.4	15.5	2.3	0.2	1.5	
2009	100.0	72.8	49.7	23.1	36.8	35.6	1.2	36.0	14.0	21.9	7.1	16.2	2.3	0.2	1.5	
2010	100.0	72.7	50.3	22.4	37.7	36.5	1.2	35.1	13.9	21.2	7.0	16.4	2.2	0.2	1.5	
2011	100.0	72.1	50.0	22.1	37.3	36.1	1.1	34.8	13.8	21.0	6.9	17.2	2.1	0.2	1.5	
2012	100.0	72.2	50.4	21.8	37.6	36.5	1.1	34.6	13.9	20.7	6.9	17.1	2.1	0.2	1.4	
2013	100.0	71.8	50.3	21.5	37.4	36.3	1.0	34.4	14.0	20.4	6.8	17.8	2.0	0.3	1.4	
2014	100.0	71.7	50.3	21.3	37.4	36.4	1.0	34.3	14.0	20.3	6.8	17.9	2.0	0.3	1.4	
2015	100.0	70.9	50.0	20.9	36.8	35.8	0.9	34.2	14.2	20.0	6.7	18.8	1.9	0.4	1.3	
2016	100.0	71.6	50.9	20.7	37.5	36.6	0.9	34.2	14.4	19.8	6.8	18.0	1.9	0.4	1.3	
2017	100.0	71.6	51.0	20.6	37.6	36.7	0.9	33.9	14.3	19.7	6.7	18.1	1.8	0.5	1.2	

Source: "Estimates of National Medical Care Expenditure", Health Statistics Office to the Director-General for Statistics and Information Policy, MHLW (Note) 1. With the launch of long-term care insurance system in April 2000, cares of the use

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

A win the read to long-term care insurance speakers in a plonger included in national medical expension 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 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

35 5."Medical fees of medical treatment" and "medical care expenses, etc." were included in "general medical fees" until they were newly classified as a separate item in FY 2008.

Detailed Data 4

Changes in Health Expenditure for the Elderly in the Later Stage of Life

											Health
	FY	Total	Medical fees	Inpatient	Outpatient	Dental	Dispensing	Hospital meals and living	Home-visit nursing	Medical treatment etc.	service facilities for
	FY 1983	33,185	31,966	17,785	13,405	776	640	•	•	579	the elderly
	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
mil	FY 1996	97,232	82,181	42,314	36,789	3,078	4,620	4,816	323	1,094	4,198
£100	FY 1997	102,786	85,475	44,205	37,965	3,305	5,606	4,869	479	1,073	5,285
nt (≩	FY 1998	108,932	88,881	46,787	38,584	3,511	6,900	4,967	657	1,101	6,426
nom	FY 1999	118,040	94,653	49,558	41,181	3,915	8,809	5,115	858	1,169	7,436
alaı	FY 2000	111,997	94,640	48,568	41,871	4,200	10,569	4,612	235	1,271	670
Actu	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	•
ļ	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 posthetic 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 2016 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	84,142	78,475	26,515	303	11,300
	National treasury contribution	11,897	27	31,035	29	46,951
9	Prefectural contribution	-	-	11,078	-	13,908
berat	Municipal contribution	-	-	7,904	-	12,228
Operating revenue	Grants for late-stage elderly	-	-	-	-	59,021
even	Grants for early-stage elderly	-	1	35,226	-	-
ue	Retirement grants	-	-	2,944	-	-
	Others	174	1,121	35,896	2	241
	Total	96,213	79,624	150,599	335	143,649
0	Insurance benefit expenses	55,751	39,246	92,655	205	142,574
pera	Late-stage elderly support coverage	17,699	16,796	17,040	63	-
ting	Levies for early-stage elderly	14,885	14,991	12	32	-
expe	Contributions for retirees	1,093	1,032	-	4	-
Operating expenditure	Others	1,805	5,183	39,393	6	754
re	Total	91,233	77,248	149,100	311	143,328
	Balance of ordinary revenue and expenditure	4,979	2,376	1,499	24	320

		Government-managed Health Insurance/ JHIA-managed Health Insurance	Society-managed Health Insurance
	Deferred repayment of state subsidy	-	
	Non-operating subsidy for benefits, etc.	-	365
	Adjustment premium revenue	-	1,154
Non-operating	Subsidies to financial adjustment programs	-	1,041
revenue	Transfer from reserves, etc. and surplus carried forward	-	2,903
	Others	7	50
	Total	7	5,519
New exercises	Contribution to financial adjustment programs	-	1,146
Non-operating	Others	-	13
expenditure	Total	-	1,283
Balance of non-o	operating revenue and expenditure	7	4,236 (1,333
Balance of total	revenue and expenditure	4,987	6,611 (3,708
Reserve fund, et	С.	18,086	43,702

(Note) 1. The above figures indicate medical service revenue and expenditure.

- 2. The operating revenue of the National Health Insurance (operated by municipalities) includes an extra-legal transfer from the Municipal General Account of ¥252.6 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 (¥3,971.7 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

(2) Medical Care Provision System

Outline of the Draft Act on Amendatory Law to the Related Acts for Securing Comprehensive Medical and Long-Term Care in the Community. (revised in 2014)

As measures based on the Act on Promotion of Reform for the Establishment of a Sustainable Social Security System, an efficient and high-quality medical care system will be established, and necessary improvements, etc. will be made for relevant laws, including the Medical Care Act and the Long-Term Care Insurance Act, etc., to secure regional medical and long-term care in an integrated manner. I Outline Creation of new funds and stronger cooperation of medical and long-term care (related to the Act on Promotion of the Establishment of 1 Regional Long-Term Care Facilities, etc.) [1] Establishment of new funds in prefectures through utilization of the increased consumption tax revenue for medical and long-term care businesses listed in the business plans of prefectures (role allotment of medical institutions, promotion of home medical and long-term care, etc.) [2] Formulation of basic policies by the Minister of Health, Labour and Welfare for stronger cooperation of medical and long-term care Securing an efficient and effective medical care system in regions (related to the Medical Care Act) [1] Reporting on medical functions of hospital beds (advanced acute phase, acute phase, recovery phase, and chronic phase), etc. to prefectural governors by medical institutions, and formulation of community health care vision (appropriate future regional medical care system) based on the reports in medical care plans by prefectures [2] Legally establishing functions of prefectural center for securing medical practitioner that provide support for securing doctors 3. Establishment of integrated community care system and fair balance of cost sharing (related to the Long-Term Care Insurance Act) [1] Enhancement of community support programs, including promotion of home medical and long-term care, etc., with transfer of prevention benefits (home-visit long-term care and day care services) to community support programs to make them more diverse Community support programs: Programs implemented by municipalities using the financial resources of long-term care insurance [2] Focusing the functions of special nursing homes for the elderly on support for persons with medium to severe long-term care needs who have difficulty living at home Enhancement of reduction of insurance premiums for persons with low-income [4] Raising the co-payment of users with income above a certain level to 20% (however, the maximum monthly amount of general households will remain unchanged) [5] Including the assets to the requirements for "supplementary benefits" to compensate for meal and living expenses of facility users with low-income 4 Others [1] Clarification of specific acts of medical care aid and creation of a new training system for nurses that engage in these acts using procedure manuals [2] Establishment of a system for investigating medical accidents [3] Merger of medical corporation associations and medical corporation foundations, and measures to promote transfer to medical corporations without contribution [4] Discussion of measures to secure long-term care personnel (implementation period of the revised qualification system of certified care workers will be postponed from FY2015 to FY2016)

II Enforcement Date

The promulgation date. However, measures related to the Long-Term Care Insurance Act will be gradually enforced in October 2014 or later, and those related to the Long-Term Care Insurance Act in April 2015 or later.

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 (20 or more beds)
Medical institutions	
	Clinics (0 to 19 beds)
	Clinics with beds (1 to 19 beds)
	Clinics without beds (0 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.

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).

	General hospitals
	Special functioning hospitals (providing advanced medical care, etc.)
Hospitals	 Regional medical care support hospitals (supporting family doctors and family dentists who are taking roles in regional medical care, etc.)
	Clinical research core hospital (A hospital that plays a core role in the implementation of clinical research)
	Psychiatric hospitals (hospitals with psychiatric wards only) (subject: psychiatric disorders)
	Tuberculosis hospitals (hospitals with tuberculosis wards only) (subject: patients with 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
 - . Doctors Twice as many as ordinary hospitals, etc. In addition, half the number of doctors specified by the staff More than half of the doctor's placement criteria must be from any of the 15 specialists.
 - · Pharmacists The minimum standard is 1/30 of the number of patients. (That for ordinary hospitals is 1/70 of the number of patients) • Nurses, etc. The minimum standard is 1/2 of the number of patients. (That for ordinary hospitals is 1/3 of the number of patients)
- · Deployment of at least one registered dietitian.
- 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.
- * The numberofapproved hospitals (as of April 1,2020)86

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.

* The number of approved hospitals (as of December, 2018) 607 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 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

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.

* The number of approved hospitals (as of April 1, 2020) 13 Hospitals

Detailed Information 4 Revision of Bed Classification

Other beds		Psychiatric beds	Enidomio bodo	Tobarda is had
				i uberculosis bed
78, 96.2 Mark 999 Science 200 Supplies 200 St				
geriatrics wards (1983)]			
Other beds	Specially authorized geriatrics wards		Epidemic beds	Tuberculosis bed
to create facilities	s to provide medical ca			
group system (19	92)]			
Other beds				
			Infection disease beds	Tuberculosis bec
P	atients requiring long-term care			
caused by the rap been created, inc	pid progress in the birl	th rate decline and agi	ng. Although vario	ous systems hav
erm care beds (200	00)]			
	a anna - Anna - Anna Anna	Psychiatric beds	Infection disease beds	Tuberculosis bec
			Infection	
Long-	term care beds	Psychiatric beds	disease beds	Tuberculosis bed
	Changes in diser Geriatrics wards (Other beds I geriatrics vards (Other beds I norder to cope v to create facilities long-term care" i I group system (19 Other beds Specially aut geriatrics v P The number of pa caused by the ra been created, inc are still interming trable for patients' sy Long- In order to promo information on m important. reporting system (Specially authorized geriatrics wards In order to cope with the progress in ag to create facilities to provide medical ca- long-term care" in general. If group system (1992)] Other beds Specially authorized Group of long-ter- geriatrics wards Group of long-ter- geriatrics wards Group of long-ter- geriatrics wards care-type beds Patients requiring long-term care The number of patients requiring long-ter- caused by the rapid progress in the birl been created, including long-term care are still intermingled. Corem care beds (2000)] table for patients' symptoms Long-term care beds Patients requiring long-term care In order to promote division/cooperation information on medical functions implei	Changes in disease structure geriatrics wards (1983)] Other beds Specially authorized geriatrics wards Psychiatric beds () for order to cope with the progress in aging and changes in dis to create facilities to provide medical care not only for elderly long-term care" in general. I group system (1992)] Other beds Specially authorized Group of long-term geriatrics wards care-type beds Psychiatric beds Patients requiring long-term care Psychiatric beds Patients requiring long-term care increased du caused by the rapid progress in the birth rate decline and agi been created, including long-term care-type bed group syster are still intermingled. term care beds (2000)] table for patients' symptoms Long-term care Psychiatric beds Patients requiring long-term care beds (2000)] table for patients requiring long-term care Sychiatric beds Patients requiring long-term care Sychiatric beds Patients requiring long-term care Psychiatric beds Patients requiring Long-term care beds Psychiatric beds Psychiatric beds Patients requiring Long-term care beds Psychiatric beds Psychiatric beds Patients requiring Psychiatric beds Psychiatric beds Patients requiring Psychiatric beds Psychiatric beds Patients requiring Psychiatric beds Psychiat	Changes in disease structure I geriatrics wards (1983)] Other beds Specially authorized geriatrics wards Psychiatric beds Epidemic beds geriatrics wards Psychiatric beds Epidemic beds for order to cope with the progress in aging and changes in disease structure, it to create facilities to provide medical care not only for elderly but for "patients r long-term care" in general. I group system (1992)] Other beds Specially authorized Group of long-term geriatrics wards care-type beds Patients requiring long-term care Patients requiring long-term care increased due to changes in disease beds Patients requiring long-term care increased due to changes in disease beds long-term care beds (2000)] table for patients' symptoms Long-term care beds Patients requiring long-term care Infection disease beds Patients requiring Long-term care beds Psychiatric beds Infection disease beds Infection disease beds Patients requiring Long-term care Psychiatric beds Infection disease beds Patients requiring Long-term care beds Psychiatric beds Infection disease beds Patients requiring Long-term care Psychiatric beds Infection disease beds Patients requiring Long-term care beds Psychiatric beds Infection disease beds Patients requiring Long-term care beds Psychiatric beds Infection disease beds Patients requiring Long-term care beds Psychiatric beds Infection disease beds

hospital beds and long-term care beds in each hospital ward was created.

Trends with Medical Institutions

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

Year	Hospitals	National (regrouped)	Public (regrouped)	Others (regrouped)	General clinics	Dental clinics
1877	159	12	112	35		
1882	626	(330)		296		
1892	576	(198)		378		
1897	624	3	156	465		
1902	746	4	151	591		
1907	807	5	101	691		
1926	3,429	(1,680)		1,749		
1930	3,716	(1,683)		2,033		
1935	4,625	(1,814)		2,811	35,772	18,066
1940	4,732	(1,647)		3,085	36,416	20,290
1945	645	(297)		348	6,607	3,660
1950	3,408	383	572	2,453	43,827	21,380
1955	5,119	425	1,337	3,357	51,349	24,773
1960	6,094	452	1,442	4,200	59,008	27,020
1965	7,047	448	1,466	5,133	64,524	28,602
1970	7,974	444	1,388	6,142	68,997	29,911
1975	8,294	439	1,366	6,489	73,114	32,565
1980	9,055	453	1,369	7,233	77,611	38,834
1985	9,608	411	1,369	7,828	78,927	45,540
1990	10,096	399	1,371	8,326	80,852	52,216
1995	9,606	388	1,372	7,846	87,069	58,407
1996	9,490	387	1,368	7,735	87,909	59,357
1997	9,413	380	1,369	7,664	89,292	60,579
1998	9,333	375	1,369	7,589	90,556	61,651
1999	9,286	370	1,368	7,548	91,500	62,484
2000	9,266	359	1,373	7,534	92,824	63,361
2001	9,239	349	1,375	7,515	94,019	64,297
2002	9,187	336	1,377	7,474	94,819	65,073
2003	9,122	323	1,382	7,417	96,050	65,828
2004	9,077	304	1,377	7,396	97,051	66,557
2005	9,026	294	1,362	7,370	97,442	66,732
2006	8,943	292	1,351	7,300	98,609	67,392
2007	8,862	291	1,325	7,246	99,532	67,798
2008	8,794	276	1,320	7,198	99,083	67,779
2009	8,739	275	1,296	7,168	99,635	68,097
2010	8,670	274	1,278	7,118	99,824	68,384
2011	8,605	274	1,258	7,073	99,547	68,156
2012	8,565	274	1,252	7,039	100,152	68,474
2013	8,540	273	1,242	7,025	100,528	68,701
2010	8,493	329	1,231	6,933	100,461	68,592
2014	8,480	329	1,227	6,924	100,995	68,737
2016	8,442	323	1,213	6,902	100,995	68,940
2010	8,412	327	1,213	6,874	101,329	68,609
2017	8,372	324	1,211	6,874	101,471	68,613
2010 Source: 1875 102		of Rublia Hoalth" Minis	,	0,041	102,103	00,013

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

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 and Information Policy, MHLW (Note) The figures in parentheses indicate the total number of public sector medical institutions.

Detailed Da	ata 1	Changes	Changes in Number of Hospitals by Establishing Organization and Number of Beds										
	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	
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	
National	291	276	275	274	274	274	273	329	329	327	327	324	
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	
Social insurance organizations	123	122	122	121	121	118	115	57	55	53	52	52	
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	
Private	533	476	448	409	373	348	320	289	266	240	210	187	
Others	888	872	872	869	867	864	868	866	866	855	846	838	
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	
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	
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	
500+ beds	473	468	462	460	456	449	450	437	425	418	411	408	

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

Detailed Data 2

Changes in Number of Hospitals by Hospital Type

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

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

D	eta	ilec	I D	a	'a '	2
				4 ° U		

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
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
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
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
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
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
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
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

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

Deta	ailed	Dat	a 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
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
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
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
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
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
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
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

		Average length of stay										
	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
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
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
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
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
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
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
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

Source: "Hospital Report", Health Statistics Office to the Director-General for Statistics and Information Policy, MHLW (Note) 1. The figures for March 2011 only include only the reported number of patients for 11 institutions (one in Kesen

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 lwate 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 Earthquake.

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

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

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)

2

80

Training schools for nurses (National Hansen's Disease Sanatoriums)

[National Hospital Organization]

(Defense as) Number of featilities

- (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 April1, 2020)

Institutions	Number of hospitals	Number of beds
National Hospital Organization	143	53,104

[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, 2020)

Institutions	Specialized diseases, etc.	Number of hospitals	Number of beds
National Cancer Center	Cancer and other malignant neoplasm		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.		1,191
National Center for Child Health and Development	Child health and development (pediatric care, maternity, paternal medicine, etc.)		490
National Center for Geriatrics and Gerontology	Geriatrics and gerontology (senile dementia, osteoporosis, etc.)	1	383
(Reference) Number of facilities (as of April 1, 20	20)		
Classifica	tion Number of facilities	Students auot	a (persons)

 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 April 1, 2020)

Classification	Number of facilities	Number of beds
Hospital	57	15,555
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

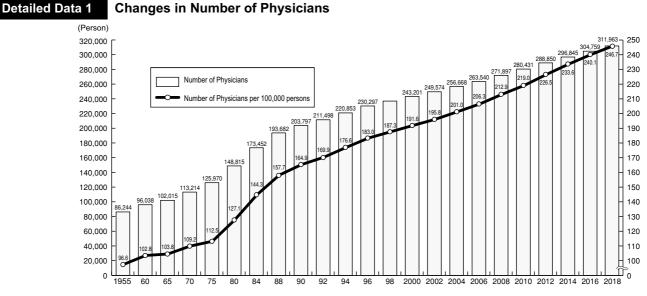
Overview

W 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

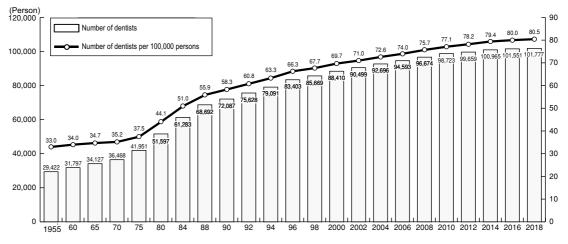
3 persons 7 persons 1 persons s 2018", Health Statistics Office to the Director-General for Statistics acilities. Pharmacist are employees in pharmacies or medical 62,118 persons 39,613 persons 1,210,665 persons 347,675 persons 347,675 persons 39.1 persons 39.2 persons 39.3 persons 30.3 persons 30.4 persons 30.4 persons
7 persons 1 persons s 2018", Health Statistics Office to the Director-General for Statistics acilities. Pharmacist are employees in pharmacies or medical 62,118 persons 39,613 persons 1,210,665 persons 347,675 persons 94.8 persons 30.0 persons 39.1 persons 39.2 persons 13.1 persons 13.1 persons 13.4 persons
1 persons s 2018", Health Statistics Office to the Director-General for Statistics acilities. Pharmacist are employees in pharmacies or medical 62,118 persons 39,613 persons 1,210,665 persons 347,675 persons 347,675 persons 39.1 persons 39.2 persons 39.1 persons 30.1 persons 30.1 persons 30.0 persons 31.1 persons 30.0 persons 33.4 persons
s 2018", Health Statistics Office to the Director-General for Statistics acilities. Pharmacist are employees in pharmacies or medical 62,118 persons 39,613 persons 1,210,665 persons 347,675 persons 24.8 persons 29,0 persons 39,1 persons 39,1 persons 39,2 persons 13,1 persons 36,0 persons 13,4 persons
acilities. Pharmacist are employees in pharmacies or medical 62,118 persons 39,613 persons 1,210,665 persons 347,675 persons 24.8 persons 52.0 persons 39.1 persons 39.2 persons 39.2 persons 13.1 persons 13.1 persons 36.0 persons 13.4 persons
39,613 persons 1,210,665 persons 347,675 persons 94.8 persons 52.0 persons 39.1 persons 39.2 persons 39.2 persons 13.1 persons 13.1 persons 13.4 persons
39,613 persons 1,210,665 persons 347,675 persons 24.8 persons 52.0 persons 39.1 persons 39.2 persons 39.2 persons 13.1 persons 13.1 persons 13.1 persons 13.4 persons
1,210,665 persons 347,675 persons 52.0 persons 39.1 persons 39.2 persons 52.3 persons 13.1 persons 13.1 persons 13.4 persons 13.4 persons
347,675 persons 94.8 persons 52.0 persons 99.1 persons 99.2 persons 95.3 persons 13.1 persons 56.0 persons 13.4 persons
94.8 persons 52.0 persons 39.1 persons 39.2 persons 15.3 persons 13.1 persons 56.0 persons 13.4 persons
52.0 persons 39.1 persons 39.2 persons 55.3 persons 13.1 persons 56.0 persons 13.4 persons
52.0 persons 39.1 persons 39.2 persons 55.3 persons 13.1 persons 56.0 persons 13.4 persons
52.0 persons 39.1 persons 39.2 persons 55.3 persons 13.1 persons 56.0 persons 13.4 persons
39.1 persons 39.2 persons 05.3 persons 13.1 persons 56.0 persons 13.4 persons
39.2 persons 05.3 persons 13.1 persons 56.0 persons 13.4 persons
05.3 persons 13.1 persons 56.0 persons 13.4 persons
I3.1 persons 66.0 persons I3.4 persons
66.0 persons 13.4 persons
13.4 persons
•
rt 2017", Health Statistics Office to the Director-General for
9 persons
8 persons
6 persons
7 persons
6 persons
7 persons
ices 2018", Administrative Report Statistics Office to the licy, MHLW
5 persons
18)
5 9 1 1



Source: "Statistics of Physicians, Dentists and Pharmacists", Health Statistics Office to the Director-General for Statistics and Information Policy, MHLW * Medical facility employees

Detailed Data 2

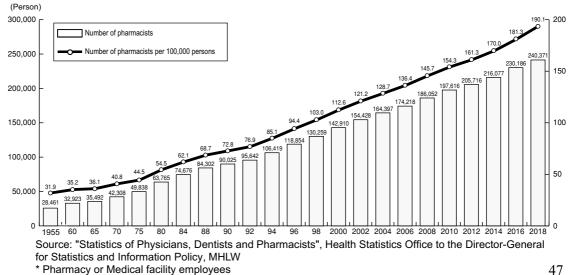
Changes in Number of Dentists

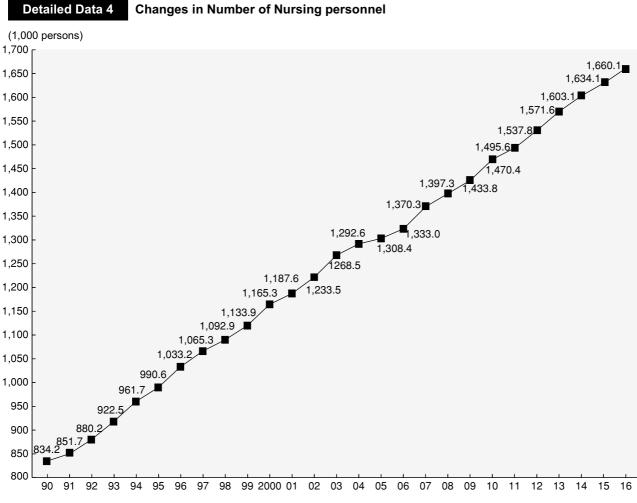


Source: "Statistics of Physicians, Dentists and Pharmacists", Health Statistics Office to the Director-General for Statistics and Information Policy, MHLW * Medical facility employees

Detailed Data 3

Changes in Number of Pharmacists





Source: Health Policy Bureau, MHLW

Conforming Rate to the Statutory Number of Doctors and Nurses Designated in the Medical Care Act and Sufficiency Status (Results of FY2017 On-Site Inspection)

Detailed Data 1

Regional Conforming Rates

			J						(Unit: %)
Region Classification	Nationwide	Hokkaido Tohoku	Kanto	Hokuriku Koshinetsu	Tokai	Kinki	Chugoku	Shikoku	Kyushu
Doctors	96.4	91.5	97.7	96.0	98.4	99.0	94.9	95.0	97.0
Nurses	99.2	99.6	98.9	99.8	99.1	98.8	99.2	98.6	99.7

Detailed Data 2

Nationwide Achievement Status

	Hospitals with insufficient number of doctors	Hospitals with sufficient number of doctors	Total
Hospitals with sufficient number of nurses	7,486 (95.4)	272 (3.5)	7,758 (98.9)
Hospitals with insufficient number of nurses	79 (1.0)	8 (0.1)	87 (1.1)
Total	7,565 (96.4)	280 (3.6)	7,845(100.0)

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

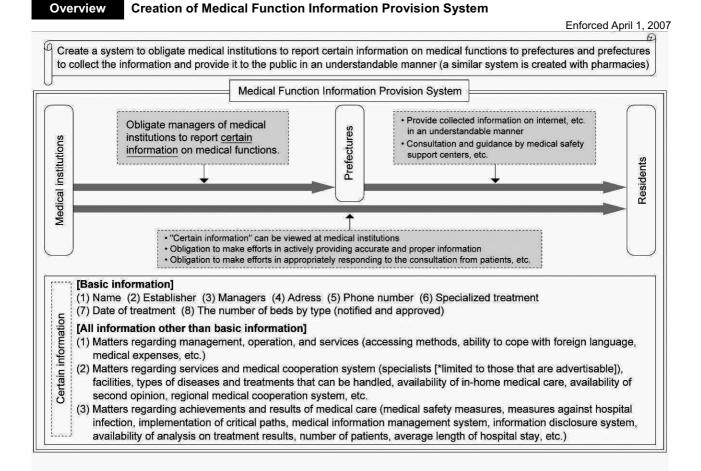
(Explanation of terms)

• 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



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
 - Anne 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

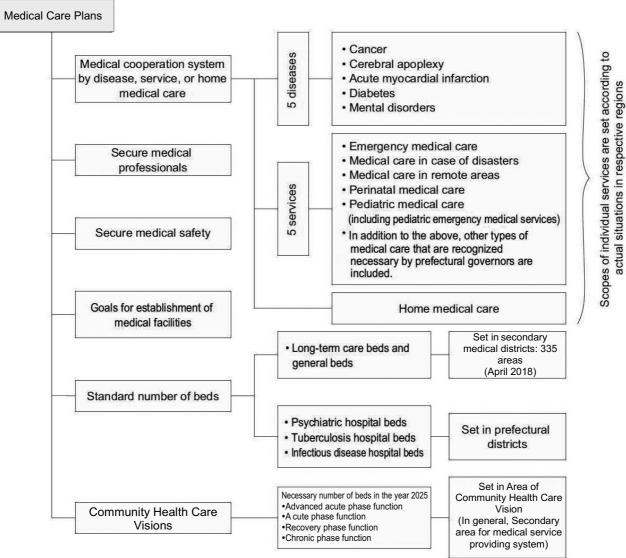
Overview

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

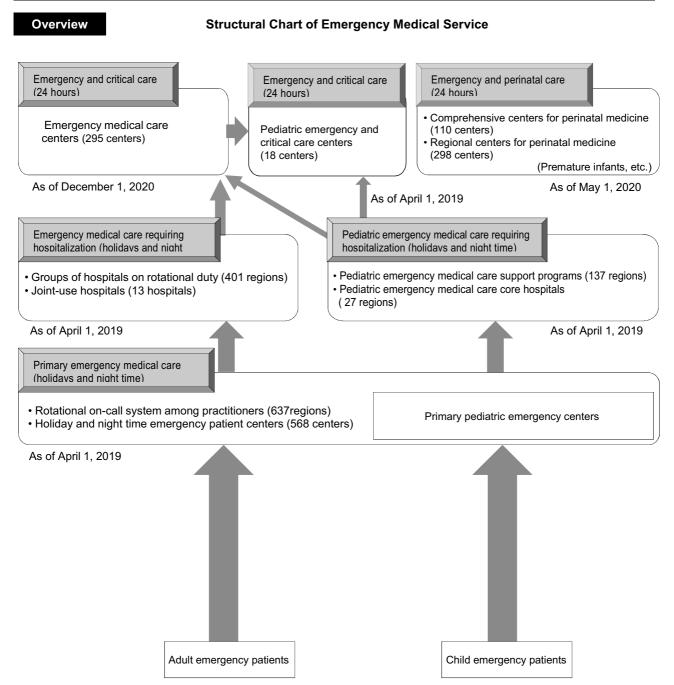


3. Status of standard number of beds and number of existing beds

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

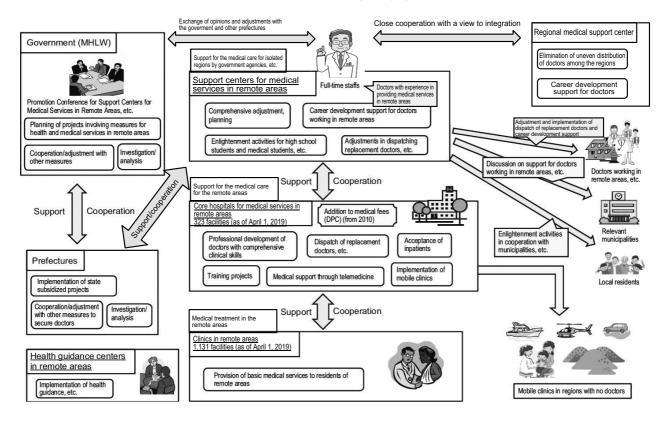


Medical Services in Remote Areas

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	601	12.8

* 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)

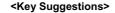
1,131 clinics (including National Health Insurance direct managed clinics) are established as of April 1, 2019

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).



[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.)
- O 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
- O Improved quality of medical professionals
 O 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.]

- O 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]

- O 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.
- O 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)
- O 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)
- O 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)
- O Model projects for investigation/analysis of deaths related to medical practices (from FY2005)
- Training projects for developing human resources to engage in coordination/mediation of medical disputes (FY2006)
- Discussion on investigation of causes and prevention of recurrences of deaths caused by medical accidents, etc. (from April 2007 to December)
- Japan Obstetric Compensation System for Cerebral Palsy (from January 2009)
- O Liaison Conference of Alternative Medical Dispute Resolution Organizations (from March 2010)
- Discussion on utilization of autopsy imaging for determination of cause of death (from September 2010 to July 2011)
- Discussion on ideal no-fault compensation system that will contribute to the improvement of medical care quality (from August 2011 to June 2013)
- Enforcement of investigation system for medical accidents (October 2015~)
- O Promotion of Patient Safety Action (PSA) (from FY2001)
 O Obligation for medical institutions, etc. to make efforts in providing appropriate consultations to patients (revision of law in 2006)
- O 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)
- 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)
- O 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] 5. Insufficient guidance system 1. Training was voluntary 5. Insufficient guidance system 2. Training programs were not clearly defined 6. Insufficient evaluation of training achievements 3. Mainly focused on straight training for specialized doctors 7. Unstable status/work conditions " part-time jobs 4. Remarkably large disparities existed among institutions 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) 2004 Enforcement of the new system 2010 Revision of the system

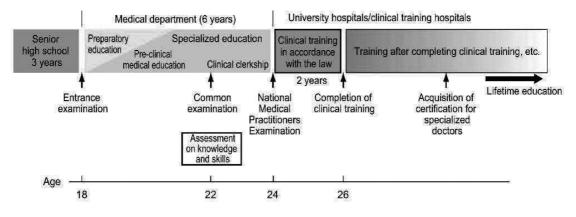
O 2015 Revision of the system

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

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

[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%

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

Classification	University	Clinical resident
Classification	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%

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

Outline of 2010 System Reform

(1) Flexible Training Program

- Training program standards are revised to offer more flexibility while maintaining the basic ideas and achievement goals of clinical training.
- "Compulsory courses" comprise of internal, emergency, and community medicine. Surgery, anesthesiology, pediatrics, obstetrics and gynecology, and psychiatry are included in "elective compulsory courses", of which two courses are selected for training.
- Training periods are no less than 6 months for internal medicine, no less than 3 months for emergency medicine, and no less than 1 month for community medicine.
- Training programs are available for those who wish to become obstetricians or podiatrist (hospitals with 20 or more recruitment quotas for internship).

(2) Reinforcement of standards for designation of core clinical training hospitals

• Requirements for designation of core clinical training hospitals includes the annual number of inpatients being 3,000 or more and placement of 1 or more preceptors for each of 5 interns, etc.

(3) Revision of recruitment quotas for internship

- Establishment of a limit on the total number of recruitment quotas that reflects the number of training applicants and the limit of recruitment quota in each prefecture for conducting appropriate regional arrangement of medical interns.
- A recruitment quota of each hospital is set after taking into consideration the actual results of accepting of interns in the past and dispatching doctors, etc. and making necessary adjustment with the prefectural limit.

(4) Provision for the review

• Provisions of Ministerial Ordinance on Clinical Training shall be reviewed within 5 years from the enforcement of Ordinance, and necessary measures to be taken.

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.

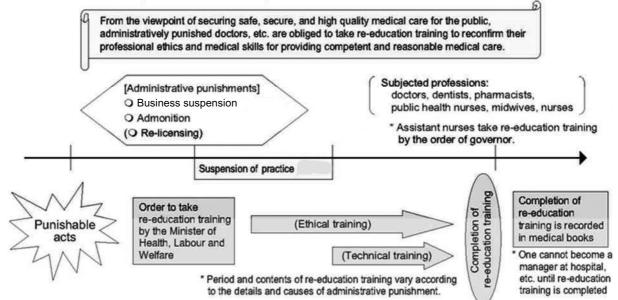
(5) Revision of recruitment quota setting

- 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.

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 service programs to become corporate bodies without losing the non-profit status of medical practices. [Around the time of the system establishment] Granting continuity of administration of Reducing the difficulties of administering medical medical institutions institutions by private persons → Securing stability of regional medical care (aiming to make fund collection easier) 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 54,790 (as of March 31, 2019) Of which 54,416 are associations (15,153 without contribution and 39,263 with contribution) and 374 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 305 (as of April 1, 2019) 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.

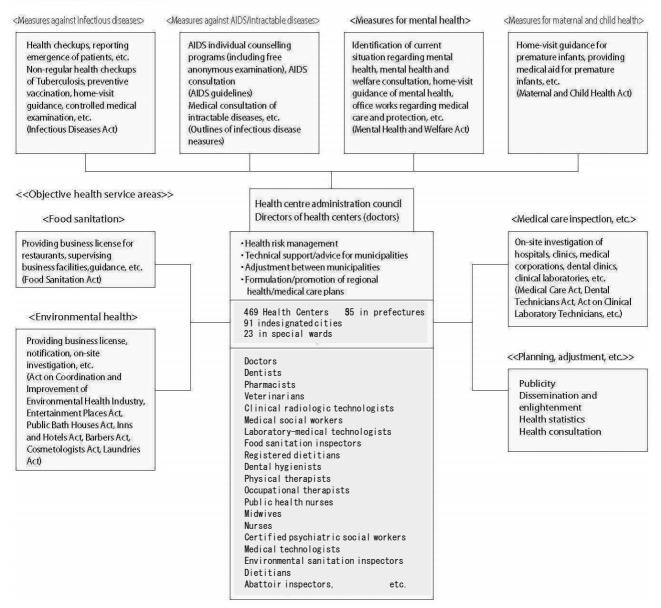
Overview

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 355 locations in 47 prefectures, 91 locations in 85 designated cities, and 23 locations in 23 special wards under the Community Health Act (As of April 1, 2020).

<<Personal health service areas>>



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

Changes in Number of Health Centers

FY	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
otal number of ealth centers	549	535	518	517	510	494	495	495	494	490	486	480	481	469	472	469
Prefectures	411	396	394	389	380	374	373	372	370	365	364	364	363	360	359	355
Cities	115	116	101	105	107	97	99	100	101	102	99	93	95	86	90	91
Special wards	23	23	23	23	23	23	23	23	23	23	23	23	23	23	23	23

Source: Health Service Bureau, MHLW

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

Detailed Data 1

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

Occupation	Number of personnel				
	Person				
Doctors	730				
Dentists	78				
Pharmacists	2,905				
Veterinarians	2,226				
Public health nurses	8,326				
Midwives	48				
Nurses	145				
Assistant nurses	5				
Radiology technicians, etc.	443				
Medical technologists, etc.	665				
Registered dietitians	1,223				
Dietitians	56				
Dental hygienists	323				
Physical/occupational therapists	83				
Others	10,646				
<included column="" in="" the="" upper=""></included>					
Medical social workers	46				
Mental health welfare counselors	1,068				
Nutrition counselors	974				
Total	27,902				

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 FY2017)

Detailed Data 2 Changes in Number of Public Health Nurses

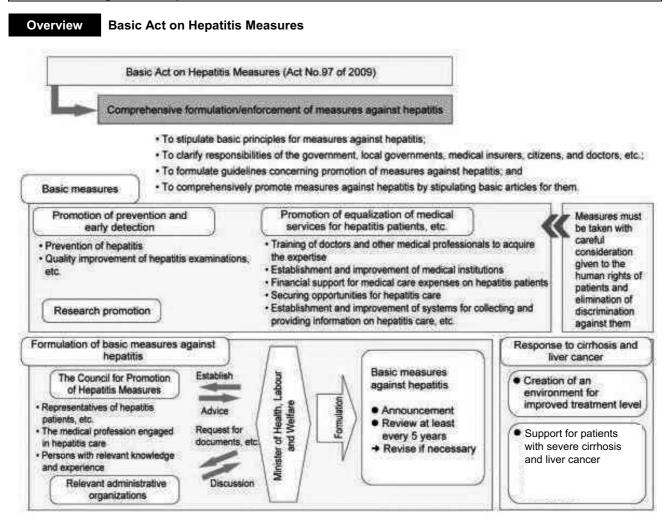
													(Unit	person)
	FY2005	FY2006	FY2007	FY2008	FY2009	FY2010	FY2011	FY2012	FY2013	FY2014	FY2015	FY2016	FY2017	FY2018
Municipalities	15,315	14,519	14,483	14,498	14,613	14,179	15,015	14,753	14,920	14,850	14,935	15,035	15,227	15,193
Designated cities / special wards	5,524	5,563	5,604	5,964	6,094	6,081	6,280	6,256	6,564	6,586	6,829	6,928	7,107	7,512
Subtotal	20,839	20,082	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	4,014	3,935	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	24,853	24,017	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: FY2005-2009: "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.

Measures against Hepatitis



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 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 0 • To reduce liver cirrhosis and liver cancer, and set as much reduction as possible of the incidence of liver hepatitis so that the past achievements can be cancer appropriately reflected on such measures 2 Matters concerning measures to take in preventing 7 Matters concerning promotion of research and hepatitis development of medicine to use hepatitis- related medical Necessary to disseminate correct knowledge about care hepatitis to prevent new infections, 0 To promote preventive measures for infection of o Necessary to proceed with research and development of mother-to-child hepatitis B virus, and promote hepatitis medicine-related new medicines, including periodic hepatitis B vaccination. medicines related to treatment of hepatitis B and cirrhosis, and make a prompt review of clinical trials and 3 Matters concerning improvement of a system to use research in light of recent trends concerning hepatitis implementing hepatitis examinations and their medicine capabilities To inform all citizens that they need to receive 0 8 Matters concerning public awareness and dissemination of hepatitis virus test at least once information concerning hepatitis is and matters concerning To continue to develop a system that allows for examination of the hepatitis virus tests with due 0 respect for the human rights of hepatitis patients, etc. consideration to the convenience of the examinee... o Necessary to disseminate information and enlighten To make such efforts that a hepatitis virus test can be 0 people to promote receipt of hepatitis virus tests, carried out together with a medical examination, while prevent new infections. discontinue unfair making the concerned parties understand, such as discrimination against hepatitis patients, protect their medical insurers and employers. human rights, and create an environment where people can live a secure social life 4 Matters concerning securing of a system to use providing hepatitis-related medical care 9 Other important matters concerning the promotion of Necessary to further develop the regional hepatitis clinical care hepatitis measures network so that all hepatitis patients can receive continuous and appropriate hepatitis medicine. To strengthen and enhance support for hepatitis 0 To make further efforts for increase of hepatitis virus inspection 0 patients and their families, etc. and follow-up after the inspection To promote review of how to support cirrhosis and Necessary to enlighten stakeholders such as business operators 0 0 liver cancer patients.
To require the national government to urge the local and get their understanding and cooperation so that the employees can receive medical treatment continuously while governments to make a plan and set a target continuing to work 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 5 Matters concerning prevention of hepatitis and human 0 resource development for hepatitis medical care hepatitis virus infection, have proper knowledge about the possibility of infection, act appropriately to prevent Necessity to develop human resources with knowledge about 0 new infection, acquire correct knowledge and make the prevention of hepatitis infection and those capable of efforts for responding appropriately not to cause linking appropriate hepatitis care after infection is known, discrimination against hepatitis patients, etc. such as hepatitis medical coordinator.

Health Promotion Measures

Overview	History of National He	alth 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 Establishment of health checkups and a complete health guidance system from infants and small children through to the elderly (2) Establishment of health promotion bases Establishment of health promotion centers, municipal health centers, etc. Securing sufficient human resources, including public health nurses and dietitians (3) Dissemination and enlightenment of health promotion councils Promotion Establishment of municipal health promotion councils Promoting the use of recommended dietary allowances Nutritional content labelling for processed food Conducting studies on health promotion, etc. 	 (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 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 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 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 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 Setting specific targets to serve as an indicator for national health/medical standards and promotion of health promotion measures based on assessments 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 due to come 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 	 (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 Guide 2006) (2006) Exercise Dietary Reference Guide 2006) (2006) Japanese Dietary Reference Intake (2010 edition) (2009)
4 th National Health Promotion Measures (from FY 2013) National Health exercise promotion (Health Japan 21 (2 ⁿ⁰)	 [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. 	outcome assessments etc. [Outline 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) (Supplemental Revision) (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.
- 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 2018

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 2018 (approximately 5,032 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

<Significant differences in lifestyle-related situations by income>

- At present, the proportion of regular smokers, the proportion of those without medical checkup, and the proportion of those with less than 20 teeth are significantly higher for household members, in both men and women, with household income of less than 2 million yen comparing with household income is 6 million yen or more.
- The mean daily step of household members in both men and women is significantly lower with household income of less than 2 million yen comparing household income is 6 million yen or more.

<For those with1 to 39 working hours per week, the proportion of those without medical checkup is high in both men and women>

• The proportion of those without medical checkup among those with1 to 39 working hours in the average per week is 26.3% in men and 29.4% in women, which are higher than those who work for other working hours.

<The proportion of those who eat balanced diet is over 40%, but there is a difference by income>

- The proportion of those who eat balanced diets with staple foods, main dishes and side dishes twice per day or more "almost every day" are 45.4% in men and 49.0% in women.
- By income, the proportion of those who responded "almost every day" was significantly lower in both men and women with household income of less than 2 million yen, comparing with household income of 6 million yen or more.

<For the first time, the smoking situation of "heated tobacco products" was investigated. In addition, the situation of passive smoking is under improving>

- Regarding the tobacco products currently used by persons who habitually smoke, the percentages of "only cigarettes", "only heated tobacco products" and "both cigarettes and heated tobacco products" were 68.1% and 22.1%, 8.5% in men, and 76.1%, 14.8%, 8.8% in women.
- The proportion of participants who were exposed to passive smoking in home, workplace, school, restaurant, amusement places, administration agency and medical institutions has significantly decreased.

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

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

(As of January 1, 2020)

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
Iwate	32	32	100.0%	0	0	0	0
Miyagi	34	34	100.0%	0	0	0	0
Akita	24	24	100.0%	0	0	0	0
Yamagata	34	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	42	37	92.5%	0	0	1	2
Onnawa	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

	The estimated number of patients receiving medical treatment (1,000 persons)	Number of deaths (Person)	Death rate (Per 100,000 persons)
Malignant neoplasms	1,782	376,392	304.2
Diabetes mellitus	3,289	13,837	11.2
Hypertensive diseases	9,937	9,548	7.7
Heart diseases (excluding hypertensive)	1,732	207,628	167.8
Cerebrovascular diseases	1,115	106,506	86.1

Source:

<The estimated number of patients "Patient Survey 2017", Health Statistics Office to the Director-General for Statistics and Information Policy, MHLW

<Number of deaths, Death rate> "Vital Statistics", Vital, Health and Social Statistics Office to the Director-General for Statistics and Information Policy, MHLW

(2019 preliminary data)

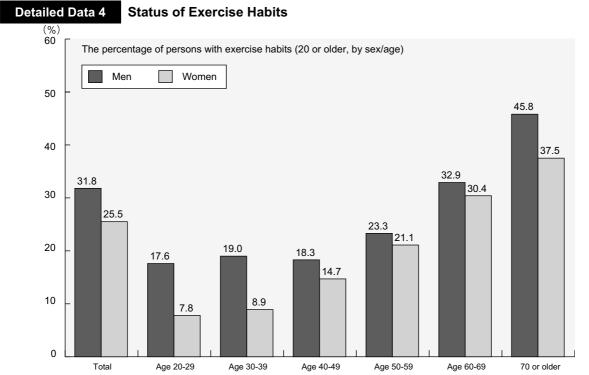
Detailed Data 3

receiving medical treatment>

Prevalence related to Diabetes

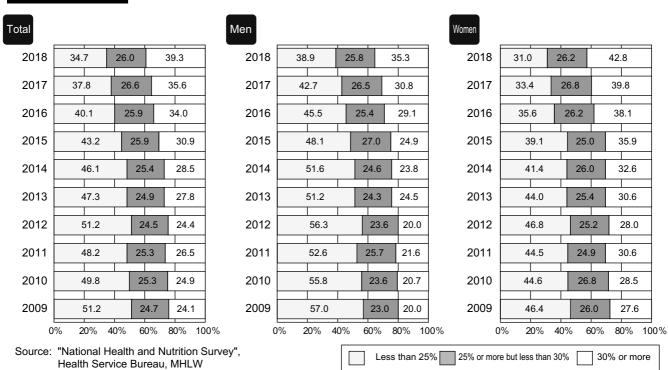
	Males (survey s	amples: 1,201)	Females (survey samples: 1,729)		
Age	Strongly suspected of having diabetes	With possibilities of having diabetes	Strongly suspected of having diabetes	With possibilities of having diabetes	
20-29	0.0%	0.0%	0.0%	2.5%	
30-39	1.0%	3.9%	0.5%	3.7%	
40-49	6.8%	6.2%	3.5%	5.7%	
50-59	18.6%	13.0%	4.7%	13.9%	
60-69	24.8%	15.2%	12.8%	20.8%	
70 or older	24.6%	22.3%	15.7%	25.4%	

Source: "National Health and Nutrition Survey 2018", Health Service Bureau, MHLW



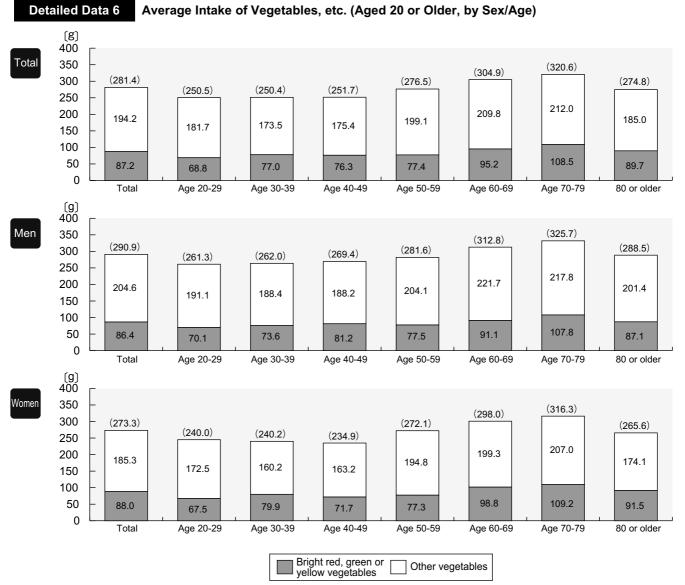
Source: "National Health and Nutrition Survey 2018", Health Service Bureau, MHLW (Note) Persons with exercise habits: Those who have been continuing daily exercise of 30 minutes or longer at least 2 days a week for at least a year.

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



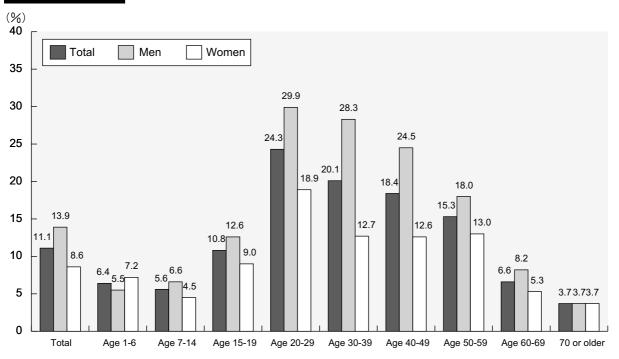
(Note) Fat energy ratio: Percentage of energy intake from fat

Detailed Data 5



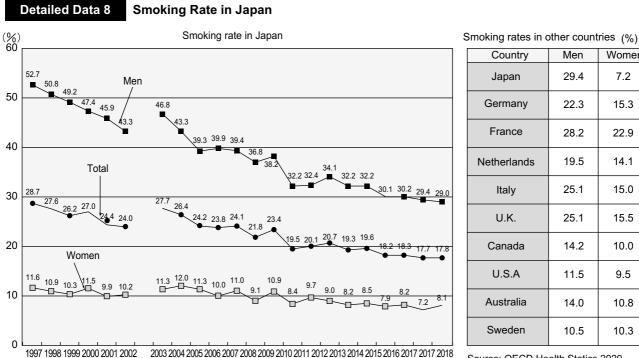
Source: "National Health and Nutrition Survey 2018", Health Service Bureau, MHLW

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



Detailed Data 7 Percentage of Persons Skipping Breakfast (Aged 1 or Older, by Sex/Age)

Source: "National Health and Nutrition Survey 2018", Health Service Bureau, MHLW



Country	Men	Women
Japan	29.4	7.2
Germany	22.3	15.3
France	28.2	22.9
Netherlands	19.5	14.1
Italy	25.1	15.0
U.K.	25.1	15.5
Canada	14.2	10.0
U.S.A	11.5	9.5
Australia	14.0	10.8
Sweden	10.5	10.3

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.

Dental Health Promotion

Overview

8020 (Eighty-Twenty) Campaign

[History of 8020 (Eighty-Twenty) Campaign]

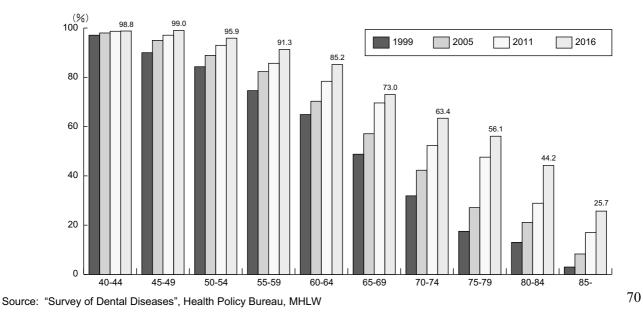
1989	A Study Group on the Dental Health Policy for Adults made public its interim report in which the "8020 (Eighty-Twenty) Campaign" calling for the retention of 20 or more teeth even at age 80 was proposed.
1991	"Promotion of 8020 Campaign" was set to be the major objective for the Dental Hygiene Week (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)"]

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

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.

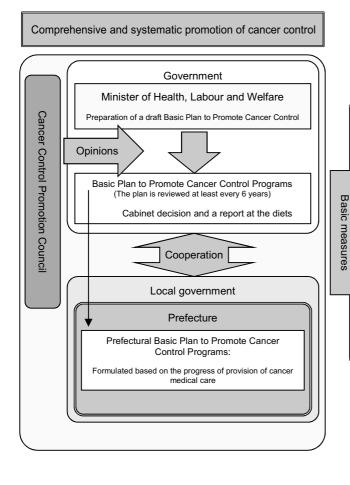
	-		•		-		-	•		
Age Year	40-44	45-49	50-54	55-59	60-64	65-69	70-74	75-79	80-85	85+
1999	97.1%	90.0%	84.3%	74.6%	64.9%	48.8%	31.9%	17.5%	13.0%	3.0%
2005	98.0	95.0	88.9	82.3	70.3	57.1	42.3	27.1	21.1	8.3
2011	98.7	97.1	93.0	85.7	78.4	69.6	52.3	47.6	28.9	17.0
2016	98.8	99.0	95.9	91.3	85.2	73.0	63.4	56.1	44.2	25.7

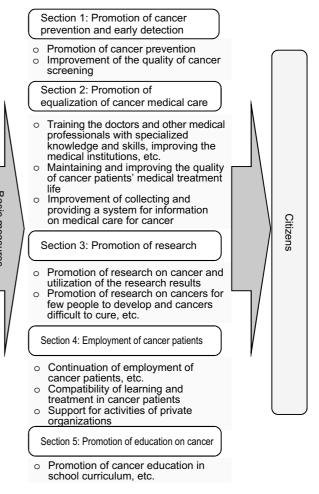


Cancer Control Measures

Overview

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





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

1. Overall goal

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

① Improvement of cancer prevention and screening based on scientific evidence ② Realization of patient-oriented cancer medicine

3 Establishment of a society where patients can live peacefully while maintaining dignity

2. Measures of each	section				
1. Cancer prevention	a. Improvement of cancer care	3. Coexistence with cancer			
 Primary cancer prever Early detection and screening of cancer (Secondary prevention) 	(2) Surgery, radiation therapy, drug therapy, and immunotherapy for cancer.	 (1) Palliative care after cancer diagnosis (2) Consultation support and information provision (3) Cancer measures and cancer patient support based on social cooperation (4) Social problems, including employment statuses of cancer patients (5) Cancer measures according to life stages 			
 (1) Cancer research (2) Human resource development (3) Cancer education and awareness 					
3. Comprehensive a	and systematic promotion of cancer measures				
	 Further cooperation among persons concerned Planning by prefectural governments Efforts of the people, including cancer patients Cooperation with patient organizations S. Necessary financial m efficient and prioritized Comprehension of go 7. Review of basic plans 	d budgets al achievements			

 Cancer registration (Collection of information on cancer treatment by the national cancer registration or in-hospital cancer registration) National cancer registry: The government records and preserves information on cancers, treatment and outcomes in Japan in a database so that it is used and provided for the government and prefectures. 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					
Pata Collection Prefecture National Government (National Cancer Center) (all) (2) Clinics Reporting Record linkage and Consolidation (designated clinics) Cancer Cancer Cancer Information Information Record linkage and Consolidation Record linkage and Consolidation Municipalities Death Certificate • Vital status • Unreported cancer cases O National subsidies, etc • National subsidies, etc • 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 Information on confirmation of existence is provided to hospitals that submit a notification 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 requirements such as that non-anonymous information is provided to a researcher only 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 iscense 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					
 Otilization of cancer registries information Government and prefectures⇒ Enhancement of cancer control measures, provision of information to medical institutions, disclosure of statistics and consultation services for patients Medical institutions⇒Provision of appropriate information to patients, analysis and evaluation of cancer medical care, improvement of the quality of cancer medical care Researchers who receive cancer registries information⇒Contribution to the improvement of the quality of cancer medical care 					

Detailed Data Statistics on Cancer

Item	Current status	Source
Number of deaths	Total of 376,392 persons (27.3% of all causes of death) [220,315 males (31.1% of all causes of death)] [156,077 females (23.2% of all causes of death)] \rightarrow "1 in every 3.7 Japanese die of cancer"	Vital Statistics of Japan (2019 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: 62%, Female: 47% \rightarrow "1 in every 2 persons will contract cancer in Japan"	Estimates by Center for Cancer Control and Information Services, National Cancer Center (2014)
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	¥3,818.7 billion * 12.4% of all medical care expenditures for general practice	Estimates of National Medical Care Expenditure (FY 2017)

Measures against allergic diseases

ve	ŕVI	eν	~

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

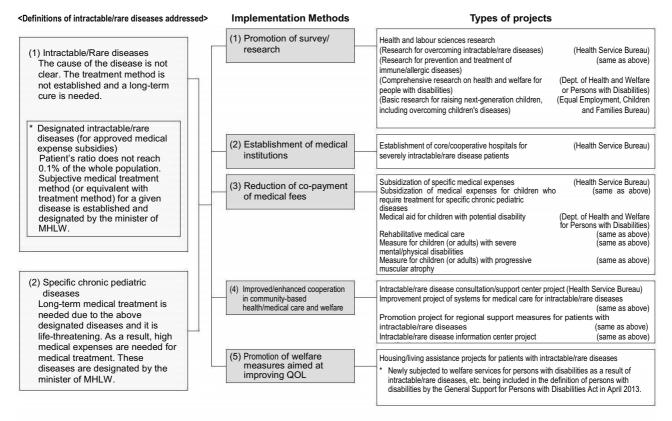
\sim	asic principles	at any disease other than the six diseases mentioned above may be where necessary, there is no plan at this moment to add any disease.
(2) Pro (3) Est qua	proving living conditions by taking comprehensive measur oviding appropriate medical care for allergic diseases rega tablishing a system by which appropriate information can l ality of life. omoting researches on allergic diseases and disseminating	ardless of the location of residence. be obtained and a support system to maintain and improve the
	Basic Guidelines for Promotion of ontrol 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

Intractable/Rare Disease Measures

Overview

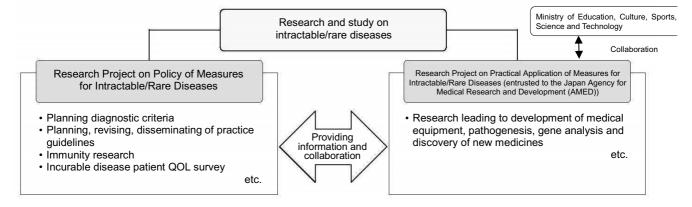
Outline of Intractable/Rare Disease Measures

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



Research project overcoming intractable/rare diseases

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



Detailed Data Designated intractable/rare diseases

No.	Disease Name	No.	Disease Name	No.	Disease Name
1	Spinobulbar muscular atrophy	103	CFC syndrome	205	Fragile X syndrome related disease
2	Amyotrophic lateral sclerosis Myelopathic muscular atrophy		Costello syndrome Charge syndrome	206	Fragile X syndrome Tmc/Art,: truncus arteriosus
4	Primary lateral sclerosis	106	Cryopyrin associated periodic fever syndrome	208	Corrected TGA
	Progressive supranuclear palsy Parkinson's disease	107	Systemic-onset juvenile idiopathic arthritis TNF receptor associated periodic sydrome		TGA Single ventricle
7	Corticobasal degeneration	109	Atypical hemolytic uremic syndromé Blau syndrome	211	Hypoplastic left heart syndrome Tricuspid atresia
9	Huntington disease Neuroacanthocytosis	111	Congenital myopathy	213	Pulmonary atresia with intact ventricular septum
10	Charcot-Marie-Tooth disease Myasthenia gravis	112	Marinesco – Sjogren's syndrome	214	Pulmonary atresia with ventricular septal defect Tetralogy of Fallot
12	Congenital myasthenic syndrome Multiple sclerosis / Optic neuromyelitis	113	Muscular dystrophy Non- dystrophic myotonia syndrome Hereditary periodic paralysis	216	Double outlet right ventricle (DORV)
13	Multiple sclerosis / Optic neuromyelitis Chronic inflammatory demyelinating polyradiculo	115	Hereditary periodic paralysis Atopic myelitis		Ebstein disease Alport's syndrome
	neuropathy/Multifocal motor neuropathy				· · ·
15 16	Inclusion body myositis Crow-Fukase syndrome	117	Syringomyelia Myelomeningocele	219	Galloway-Mowat syndrome Rapidly progressive glomerulonephritis
17	Mutiple-system atrophy	119	Isaacs syndrome	221	Anti-glomerular basement membrane disease
	Spinocerebellar degeneration (except multiple-system atrohpy) Lysosomal storage disease		Hereditary dystonia Nerve ferritin disease	222	Primary Nephrotic syndrome Primary membranoproliferative glomerulonephritis
	Adrenoleukodystrophy Mitaabandriid diagagaga	122	Brain table hemosiderosis	224	Purpura nephritis
21	Mitochondrial diseases	123	Autosomal recessive leukoencephalopathy with baldness and degenerative spondylosis	225	Congenital nephrogenic diabetes insipidus
22	Moyamoya disease	124	Autosomal dominant cerebral artery disease with subcortical infarct and leukoencephalopathy	226	Interstitial cystitis
23	Prion disease		Autosomal dominant cerebral arteriopathy with subcortical infarction and leukoencephalopathy		Osler disease
24 25	Subacute sclerosing panencephalitis Progressive multifocal leukoencephalopathy	126	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 28	Idiopathic basal ganglia calcification diseases Systemic amyloidosis	129 130	Epilepticus type (biphasic) acute encephalopathy Congenital insensitivity to pain with anhidrosis	231 232	α1-antitrypsin deficiency Camey complex
29	Ulrich disease	131	Alexander disease	233	Wolfram syndrome
30 31	Distal muscular dystrophy Beth Rem myopathy	132	Congenital supranuclear pasly Moebius syndrome	234 235	Peroxisomal disease (excluding adrenoleukodystrophy) Accessory thyroid hypergasia disease
32	Autophagic vacuolar myopathy	134	Nervous system malformation/De Morsier sysdrome	236	Pseudohypoparathyroidism
34	Schwarz Yanperu syndrome Neurofibromatosis	135	Aicardi syndrome Hemimegalencephaly	238	Adrenocorticotropic hormone insensitivity Vitamin D-resistant rickets/osteomalacia
35			Hemimegalencephaly Focal cortical dysplasia	239	Vitamin D-dependent rickets/osteomalacia
30 37	Epidermolysis bullosa Pustular psoriasis (universal)	139	Nerve cell migration disorder Congenital cerebral white matter asplasia	241	Phenylketonuria High tyrosinemia type 1
38	Stevens-Jonson syndrome Toxic epidermal necrosis	140	Dorabe syndrome	242	High tyrosinemia type 2 High tyrosinemia type 3
40	Takayasu's disease	142	Myoclonic epilepsy absences	244	Maple syrup urine disease (MSUD)
	Giant cell artritis Polyateritis nodosa		Epilepsy with myoclonic cataplexy Lennox-Gastaut syndrome	245	Propionic acidemia Methylmalonic acidemia
43	Microscopic polyangiitis	145	West syndrome	247	Isovaleric adidemia
44	Multiple vasculitis granulomatous disease Esosinophilic multiple vasculitis granulomatous disease		Otawara syndrome Early myoclonic encephalopathy	248	Glucose transporter 1 deficiency Glutaric acidemia type 1
46	Malignant rheumatoid arthritis	148	Infant epilepsy with migratory focus seizure	250	Glutaric acidemia type 2
	Buerger's disease Primary antiphospholipid antibody sysdrome		One side convulsions, hemiplegia – epilepsy syndrome Ring chromosome 20 syndrome	251	Urea cycle disorders Lysinuric protein intolerance
49	Systemic lupus erythematosus	151	Rasmussen's encephalitis PCDH19 related syndrome	253	Congenital malabsorption of falate Porphyria
50 51	Dermatomyositis / polymyositis Systemic scleroderma	152	PCDH19 related syndrome Refractory frequent partial seizures intussusception acute encephalitis	254 255	Porphyria Multiple carboxylase deficiency
52	Mixed connective tissue disease	154	Epilepsy with continuous spikes and waves during slow sleep (CSWD)	256	Muscle type glycogen storage disease
53 54	Sjogren's sndrome Adult-onset Still's disease		Landau-Kleffner syndrome Rett syndrome	257	Glycogen storage disease Galactose- 1 – phosphate uridvltransferase deficiency
55	Relapsing polychondritis	157	Sturge-Weber syndrome	259	Galactose- 1 – phosphate uridyltransferase deficiency Lecithin-cholesterol acyltransferase deficiency
	Bechet's disease Idiopathic dilated cardiomyopathy	159	Tuberous sclerosis Xeroderma	260	Sitosterolemia Tangier disease
58 59	Hypertrophic cardiomyopathy Constrictive cardiomyopathy	160	Congenital ichthyosis	262	Primary hyperlipidemia Cerebrotendinous xanthomatosis
60	Aplastic anaemia	162	Familial benign chronic pemphigus Pemphigoid (including acquired epidermolysis bullosa)	264	Abeta-lipoproteinemia
61 62	Autoimmune hemolytic anemia Paroxysmal nocturnal	163	Idiopathic acquired systemic anhidrosis Oculocutaneous ablinism	265 266	Lipodystrophy Familial Mediterranean fever
63	Idiopathic thrombocytopenic purpura	165	Pachydermoperiostosis syndrome	267	Hyper-IgD syndrome
64 65	Thrombotic thrombocytopenic purpura Primary immunodeficiency syndrome		Pseudoxanthoma elasticum Marfan syndrome	268	Nakajo-nisimura syndrome Purulent gonitis • pyoderma gangrenosum • hirsutism syndrome
66	IgA nephropathy Polycystic kidney	168	Ehlers-Danlos syndrome Menkes disease	270	Chronic nonbacterial osteomyelitis Spondylarthritis ankylopojetica
68	Ossification of the ligamentum flavum	170	Okushipitaru horn syndrome	272	Fibrodysplasia ossificans progressive
69	Ossification of the posterior longitudinal ligament Extensive spinal canal stenosis	171	Wilson's disease	273	Congenital scoliosis with rib anomaly Osteogenesis imperfecta
71	Idiopathic femoral head necrosis	173	Hypophosphatasia VATER syndrome	275	Thanatophoric dysplasia
	Pituitary ADH secretion disorders Pituitary TSH secretion hyperthyroidism		Nasu-Hakola disease Weaver's syndrome		Achondroplasia Lymphangiomatoris/gorham's disease
74	Pituitary PRL secretion hyperthyroidism	176	Coffin-Lowry syndrome	278	Huge lymphatic malformation (cervicofacial lesion)
	Cushing's disease Pituitary gonadotropin secretion hyperthyroidism		Arima sydrome Mowat - Wilson syndrome		Huge venouse malformation [neck oropharyngeal diffuse lesion] Huge arteriovenouse malformation (cervicofacial or limb lesion)
77	Pituitary growth hormone secretion hyperthyroidism	179	Williams' syndrome	281	Klippel-Trenauray-Weber sydrome
	Anterior pituitary hypothyroidism Familial hypercholesterolemia (homozygous)		ATR-X syndrome Crouzon syndrome		Congenital thropoietic anemia Acquired pure red cell aplasia
80	Thyroid hormone insensitivity syndrome	182	Apert syndrome	284	Diamond-blackfan anemia
82	Congenial adrenal cortex enzyme deficiency Congenital adrenal hypoplasia	184	Pheiffer syndrome Anley-Bixler syndrome	286	Fanconi anemia Hereditary sideroblastic anemia
83	Addison's disease Sarcoidosis	185	Coffin Siris syndrome Trothmund-Thomson syndrome	287	Epstein-Barr virus Autoimmune hemorrhaphilia XIII
85	Idiopathic interstitial pneumonia	187	Kabuki syndrome	289	Cronkhite-Canada syndrome
86 87	Pulmonary arterial hypertension Pulmonary venous obstruction/pulmonary capillary		Polysplenia syndrome Asplenia sysndrome	290 291	Chronic nonspecific multiple ulcers of the small intestine Hirschsprung disease (entire colon type or small intestine type)
	hemangiomatosis				
	Chronic thromboembolic pulmonary hypertension Lymphangioleiom yomatosis		Branchio-oto-renal syndrome Werner's syndrome	292 293	Cloacal exstrophy Persistent cloaca
90	Retinitis pigmentosa	192	Cockayne's syndrome	294	Congenial diaphragmatic hernia
91 92	Bad chiari sysdrome Idiopathic portal hypertension		Prader-Willi syndrome Sotos' syndrome	295 296	Infant giant liver hemangioma Biliary atresia
93	Primary biliary cirrhosis	195	Noonan's syndrome	297	Alagille syndrome
	Primary sclerosing cholangitis Autoimmune hepatitis	196 197	Young Simpson's syndrome 1p36 deletion syndrome	298	Hereditary pancreatitis syndrome Cystic fibrosis
90	Crohn's disease	198	4psyndrome	300	IgG4-related disease
96			5psyndrome		Heredomacular dystrophy
96 97	Ulcerative colitis Eosinophilic gastrointenstinal disease	200	No. 14 chromosome father disomy syndrom	302	Leber's hereditary optic neropathy
96 97 98 99	Eosinophilic gastrointenstinal disease Chronic idiopathic pseudo-bowel obstruction	200 201	No. 14 chromosome father disomy syndrom Angelman syndrome 303	303	Ascher syndrome
96 97 98 99 100	Eosinophilic gastrointenstinal disease	200 201 202	No. 14 chromosome father disomy syndrom	303 304	

Detailed Data Designated intractable/rare diseases

No.	Disease Name
307	Canavan disease
308	Progressive leukoencephalopathy
	Progressive myoclonic epilepsy
310	Congenital syndrome
311	Congenital tricuspid stenosis
312	Congenital mitral valve stenosis
313	Congenital pulmonary vein stenosis
314	Left pulmonary artery right pulmonary artery initiation
315	Nail Patera syndrome/LMX 1 B-related nephropathy
316	Carnitine circuit disorder
317	Triple enzyme deficiency
	Citrin deficiency
	Sepiapterin reductase (SR) deficiency
320	Congenital glycosylphosphatidylinositol (GPI) deficiency
321	Nonketotic hyperglycinemia
	β-ketothiolase deficiency
323	
	Methyl glutamic nuria
	Hereditary autoinflammatory disease
326	Marble bone disease
327	Idiopathic thrombosis (limited to those due to hereditary thrombophilia)
328	Anomalous anterior segment formation
329	Aniridia
330	Congenital tracheal stenosis / Congenital subglottic stenosis
331	Idiopathic multicentric Castleman disease
332	Gelatinous drop-like corneal dystrophy
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.)	Identification of the situation with infection and information provision	General medical institutions	Medical insurance applied (partial cost sharing)	
Novel influenza infection, etc.	Hospitalization	Designated medical institutions for specific/Type 1/Type 2 infectious disease	Medical insurance applied with public funds (for hospitalization)	

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

Development of hospitalization procedures respecting patients' human rights

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

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

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

Development of countermeasures against zoonoses

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

Development of regulation on possession of pathogens, etc.

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

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	1. Those aged 3 months or older but younger than 90 months 2. Those aged 11 years or older but younger than 13 years										
Tuberculosis	Those younger than 1 year old										
Hib infection (Haemophilus influenzae type B)	Those aged 2 months or older but younger than 60 months										
Pneumococcal infectious disease (limited to one that is of infants)	Those aged 2 months or older but younger than 60 months										
Varicella	Those aged 12 months or older but younger than 36 months										
Hepatitis B	Those younger than 1 year old										
Human papillomavirus infection	Females who are in the period between the first day of the fiscal year in which they turn 12 years old and the last day of the fiscal year in which they turn 16 years old										
Rotavirus infection disease (Implemented from October, 2020)	1 titer: From 6 weeks to 24 weeks after birth 5 titer: From 6 weeks to 32 weeks after birth										
Influenza	 Those aged 65 years or older Those aged 60 years or older but younger than 65 years suffering from cardiac, renal, or respiratory disorders, etc. 										
Pneumococcal infectious disease (limited to one that is of the elderly)	 Those aged 65 years Those aged 60 years or older but younger than 65 years suffering from cardiac, renal, or respiratory disorders, etc. 										

* 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, 2020)

	Ca	tegory A diseases	Category B diseases						
Benefit type	Qualification	Details and amount of benefit	Benefit type	Qualification	Details and amount of benefit				
Subsidy for medical care expenses	Recipients of medical services due to illness caused by vaccination	Amount equivalent to co-payment calculated based on the case of health insurance	Subsidy for medical care expenses	Recipients of medical services due to illness caused by vaccination	Amount equivalent to co-payment calculated based on the case of health insurance				
Medical allowance	Same as above	Inpatient: 8 days or more per month: (month) ¥37,000 Inpatient: less than 8 days per month: (month) ¥35,000 Outpatient: 3 days or more per month: (month) ¥37,000 Outpatient: less than 3 days per month: (month) ¥35,000 Inpatient and outpatient treatment (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: (month) ¥37,000 (month) ¥37,000 (month) ¥37,000 (month) ¥37,000 (month) ¥37,000 (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) (¥644,300) 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				
		Class 3: (annual) ¥3,034,800	Lump-sum benefit for	The bereaved will be beneficiary in case the deceased who died from	¥7,372,800				
Lump-sum death benefit	The bereaved of the person who died of diseases caused by vaccination	¥44,200,000	survivors	vaccination was not the main wage earner of the family					
Funeral allowance	Hosts of funerals for those who died of diseases caused by vaccination	¥209,000	Funeral allowance	Hosts of funerals for those who died of illness caused by vaccination	¥209,000				

* The medical care covered by the benefits of the medical expenses and medical allowances for Category B disease shall be the medical care required when it is deemed necessary to be admitted to a hospital or clinic.
 * Deadline for claiming a health problem in category B diseases

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

 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.
 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. 81

Tuberculosis Measures

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

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	·		*2,088	* 1.7

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>

(Note) 1. The figures for 1998 and later do not include those of atypical mycobacteria positive.
 2. The increase in the number of deaths and the mortality rate after 2017 includes the impact of revisions to the cause of death classification, etc.
 3. The figures indicated by "*" are preliminary data.

Detailed Data 2

Tuberculosis Incidence by Prefecture (as of the end of 2018)

	Prefecture or City	Incidence
Prefectures with the	Yamagata	6.0
lowest incidence	Miyagi	7.2
	Akita	7.5
	Niigata	7.9
	Iwate	8.5
Prefectures with the	Osaka	20.5
highest incidence	Nagasaki	16.6
	Нуодо	15.1
	Aichi	14.9
	Oita	14.8

Detailed Data 3

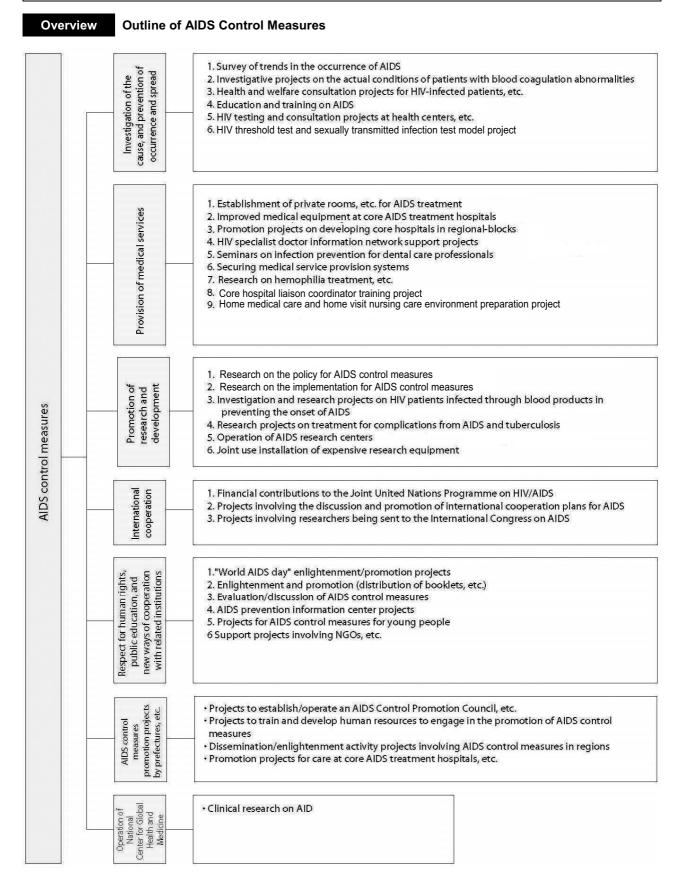
International Comparison of Tuberculosis Incidence

Country	Incidence
U.S.A.	2.7
Canada	4.9
Sweden	4.9
Australia	5.9
Netherlands	4.6
Denmark	4.4
France	7.4
U.K.	7.9
Japan	12.3

Source: WHO's global tuberculosis database

*Data is referred to one at 2017 except Japan.

AIDS Control Measures



Detailed Data 1 Changes in Number of HIV Carriers and AIDS Patients by Nationality and Gender

Category	Nationalit	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	Japar	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	730	17,197	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	28	1,024	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	758	18,221	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
	nationa	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	891	21,727	100.0
AIDS		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	280	7,797	80.9
		Female	0	0	3	2	2	3	0	1	5	9	11	15	12	10	12	21	24	20	19	19	11	20	22	19	15	15	16	18	11	13	11	18	21	15	9	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	289	8,219	85.3
		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	33	991	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	39	1,422	14.7
	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	328	9,641	100.0

Source: "AIDS Surveillance Report 2018", 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 2018, UNAIDS Re	port)
--	-------

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	2018	5.90 million [5,100,000-7,100,000]	0.31 million [270,000-380,000]	0.2 [0.2-0.3]	0.20 million [160,000-290,000]			
Asia Pacilic	2010	4.80 million [3,600,000-6,800,000]	0.31 million [220,000-430,000]	0.2 [0.1-0.3]	0.24 million [190,000-300,000]			
East/South Africa	2018	20.60 million [18,200,000-23,200,000]	0.80 million [620,000-1,000,000]	7 [5.9-7.9]	0.31 million [230,000-400,000]			
East/South Ainca	2010	17.50 million [15,900,000-19,100,000]	1.10 million [1,000,000-1,200,000]	7.8 [6.9-8.5]	0.72 million [640,000-800,000]			
Eastern Europe,	2018	1.70 million [1,500,000-1,900,000]	0.15 million [140,000-160,000]	0.9 [0.8-1.0]	38,000 [28,000-48,000]			
Central Asia	2010	0.88 million [810,000-950,000]	0.12 million [100,000-130,000]	0.5 [0.4-0.5]	32,000 [27,000-37,000]			
Latin America	2018	1.90 million [1,600,000-2,400,000]	0.10 million [79,000-130,000]	0.4 [0.3-0.5]	35,000 [25,000-46,000]			
	2010	1.40 million [1,200,000-1,700,000]	97,000 [80,000-120,000]	0.4 [0.3-0.5]	41,000 [34,000-50,000]			
Caribbean Coast	2018	0.34 million [290,000-390,000]	16,000 [11,000-24,000]	1.2 [1.0-1.4]	6,700 [5,100-9,100]			
Cambbean Coast	2010	0.29 million [260,000-340,000]	19,000 [16,000-22,000]	1.3 [1.1-1.4]	13,000 [10,000-16,000]			
Middle East /	2018	0.24 million [160,000-390,000]	20,000 [8,500-40,000]	0.1 [<0.1-0.1]	8,400 [4,800-14,000]			
North Africa	2010	0.20 million [150,000-280,000]	19,000 [13,000-30,000]	<0.1 [<0.1-0.1]	9,600 [6,900-14,000]			
Western/Central Africa	2018	5.00 million [4,000,000-6,300,000]	0.28 million [180,000-420,000]	1.5 [1.2-1.9]	0.16 million [110,000-230,000]			
Western/Central Amca	2010	6.20 million [5,000,000-7,600,000]	0.40 million [310,000-500,000]	2.5 [1.9-3.1]	0.39 million [300,000-480,000]			
Western Europe / Central Europe /	2018	2.20 million [1,900,000-2,400,000]	68,000 [58,000-77,000]	0.2 [0.2-0.3]	18,000 [9,400-16,000]			
North America	2010	1.90 million [1,700,000-2,000,000]	80,000 [74,000-86,000]	0.3 [0.3-0.3]	26,000 [23,000-30,000]			
Total	2018	37.90 million [32,700,000-44,000,000]	1.70 million [1,400,000-2,300,000]	0.8 [0.6-0.9]	0.77 million [570,000-1,100,000]			
ισται	2010	33.20 million [27,600,000-39,200,000]	2.20 million [1,900,000-2,400,000]	0.8 [0.6-0.9]	1.50 million [1,300,000-1,700,000]			

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

Source: UNAIDS 2018 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

	<u>-</u>
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". By the end of FY 2018, the stockpiled should be about 10 million people for H5N1 type (Chin Hai stock). In FY 2019, it is planned to stockpile H7N9 type.
Capacity development for pandemic influenza vaccine	Development of capacity to produce pandemic influenza vaccine by cell culture technology for the whole population within 6 months

Organ Transplantation and Hematopoietic Stem Cell Transplantation

Overview

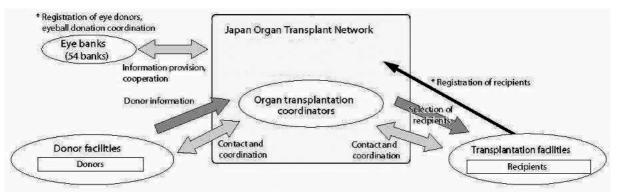
Organ Transplantation System

[Organ Transplantation System]

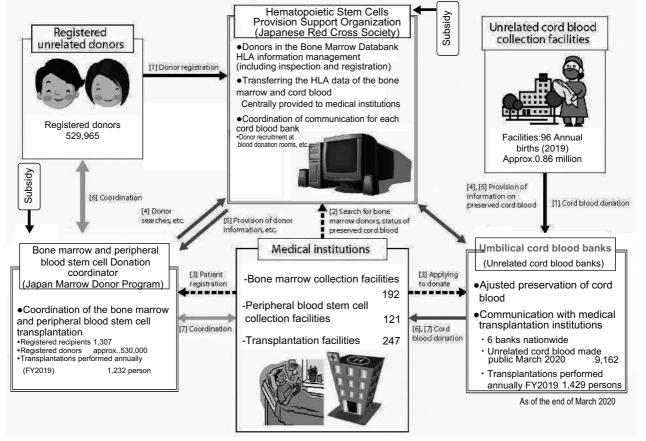
The traditional kidney transplantation system was reviewed and a new centralized nationwide kidney transplantation network established in FY1995. Enforcement of the "Act on Organ Transplantation" in October 1997 enabled multiple organ transplantations and the pertinent network.

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

1 Accumulated Number of Organ Transplantations

	Number of donors		Number of transpla	Registered transplant	
		Under brain death		Under brain death	applicants
Heart	532 persons	532 persons	531 cases	531 cases	809 persons
Lung	446 persons	446 persons	544 cases	544 cases	388 persons
Liver	571 persons	571 persons	610 cases	610 cases	341 persons
Kidney	2,089 persons	629 persons	3,905 cases	1,235 cases	12,757 persons
Pancreas	417 persons	413 persons	414 cases	411 cases	206 persons
Small intestine	21 persons	21 persons	21 cases	21 cases	4 persons
Eyeball (cornea)	20,694 persons	281 persons	33,474 cases	531 cases	1,591 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, 2020. The number of patients on waiting lists is as of March 31, 2020.

2. There have been 682 persons of brain death tests conducted nationwide under the Act on Organ Transplantation since the enforcement of the law until March 31, 2020. In the five 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 (347 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 (5 persons).

5. The number of liver and kidney cases includes the number of cases of liver kidney simultaneous transplants (26 cases) and the number of registered liver kidney simultaneous transplant applicants (37 persons).

Detailed Data 2 Changes in N	umbers of Hematopoietic Stem Cell Transplantations Performed
------------------------------	--

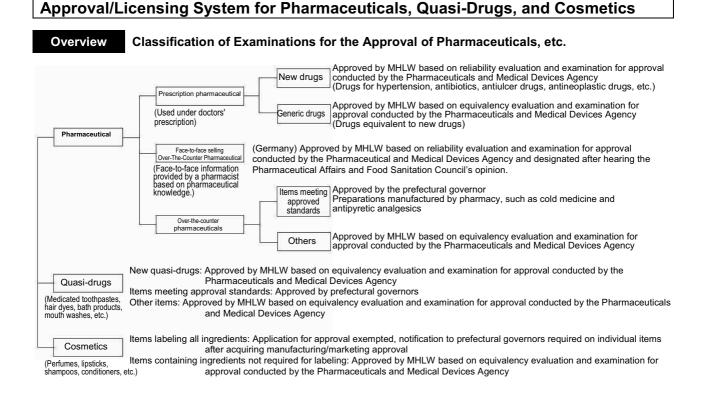
	Unrelated donors		Number	of unrelated transplan	tations
	Number of registered donors	Number of registered cord blood	Bone marrow	Peripheral blood stem cell	Cord blood
FY 1991	3,176	-	-	-	-
FY 1992	19,829	-	8	-	-
FY 1993	46,224	-	112	-	-
FY 1994	62,482	-	231	-	-
FY 1995	71,174	-	358	-	-
FY 1996	81,922	-	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	1,429
Total	-	-	23,309	925	18,629

Source: Japan Marrow Donor Program, Japanese Red Cross Society

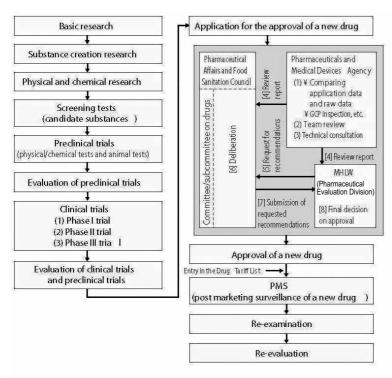
* The figures for cord blood stem from FY1996 to FY1998 indicate the number of transplantations coordinated by cord blood banks before the establishment of the Japanese Cord Blood Bank Network.

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

(4) Pharmaceuticals, etc.



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 2019)

Cat	Category Pharmaceuticals		Class 1	Class 2		Cosmotion	Total
Cal	legory	Pharmaceuticais	pharmaceuticals	pharmaceuticals	Quasi-drugs	Cosmetics	Total
Mar	rketing	1,054	280	774	1,406	3,828	6,288

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. (2019)

		Prescription pharmaceuticals	Face-to-face selling / OTC pharmaceuticals	Quasi-drugs	Cosmetics
Manufacturing	Approval	721	440	1,466	0
Marketing	Approval with partial revision	2,135	165	159	0
Approval	Total	2,856	605	1,625	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.

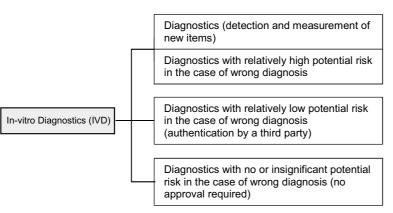
		(A	As of the end	of 2019)
Category	Pharmaceuticals	Quasi-drugs	Cosmetics	Total
Manufacturing	2,098	1,913	3,797	7,808

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



Examined by Pharmaceuticals and Medical Devices Agency and approved by Minister of Health Labour and Welfare

Authentication by an accredited certification body

Notified to the Pharmaceuticals and Medical Devices Agency

Detailed Data 1	Number of Licenses for Marketing IVD
	$(\Lambda_{0} \text{ of the end of } 2010)$

	(As of the end of 2019)
	IVD
Marketing	158

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 (2019)

	Medicines for in-vitro diagnosis
Approval	55
Approval with partial change	76
Total	131

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 2019	
IVD	
Manufacturing	209

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	
<cla< th=""><th>ssification of medical devices> Highly controlled medical devices Medical devices with significant potential risk to human life and health in the case of malfunctioning or side effects</th><th><type (no="" approval<br="" approvation="" certification="" of="" standard)="">(Certification standard exist) Certification</type></th><th> Examined by Pharmaceuticals and Medical Devices Agency and approved by Minister of Health Labour and Welfare Authentication by an accredited certification body </th></cla<>	ssification of medical devices> Highly controlled medical devices Medical devices with significant potential risk to human life and health in the case of malfunctioning or side effects	<type (no="" approval<br="" approvation="" certification="" of="" standard)="">(Certification standard exist) Certification</type>	 Examined by Pharmaceuticals and Medical Devices Agency and approved by Minister of Health Labour and Welfare Authentication by an accredited certification body
Medical devices	Controlled medical devices Medical devices with potential risk to human life and health in the case of malfunctioning or side effects	(No certification standard) Approval (Certification standard exist) Certification	Examined by Pharmaceuticals and Medical Devices Agency and approved by Minister of Health Labour and Welfare Authentication by an accredited certification body
	General medical devices Medical devices with no or insignificant potential risk to human life and health in the case of malfunctioning or side effects	Notification	Notified to Pharmaceuticals and Medical Devices Agency

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

		-		(As of the end of 2019)
Category	Class 1 medical devices	Class 2 medical devices	Class 3 medical devices	Total
Marketing	733	1,093	915	2,741

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 (2019)

		Medical devices
	Approval	0
Manufacturing	Approval with partial change	0
	Total	0
	Approval	0
Import	Approval with partial change	0
	Total	0
	Approval	458
Marketing	Approval with partial change	577
	Total	1,035

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

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

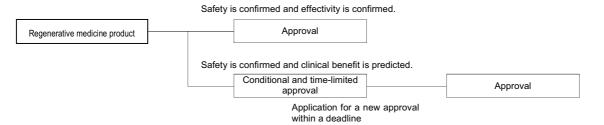
(As of the end of 2	
Medical devices	
Manufacturing	4,375
Repairs	6,689

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 (2019)

	Regenerative medicine product
Marketing	13

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 (2019)

	Regenerative medicine product
Approval	2
Approval with partial change regarding manufacture and sales	2
Total	4

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

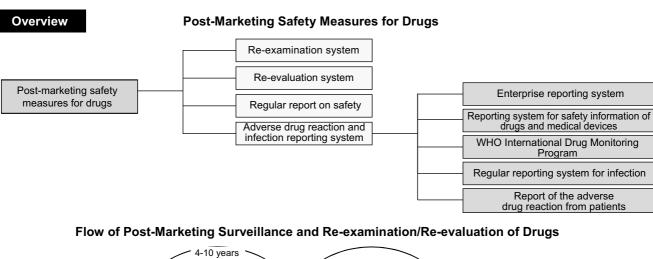
Detailed Data 3 Number of Licenses for Manufacturing Regenerative medicine product

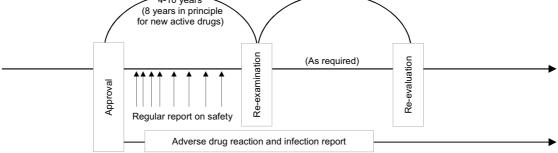
(As of the end of 2019)

	Regenerative medicine product
Manufacturing	14

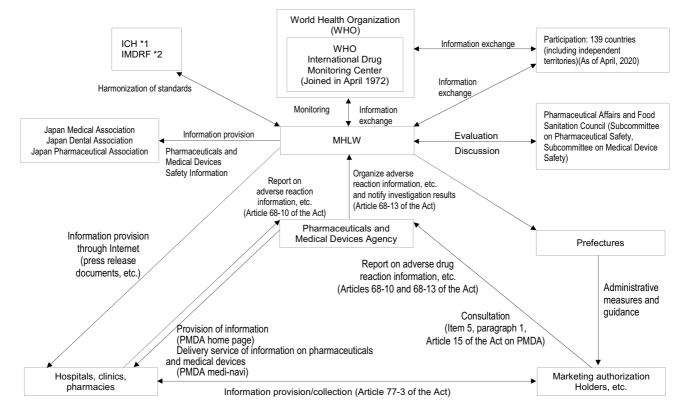
Source: Survey conducted by Pharmaceutical safety and Environmental Health Bureau, MHLW.

Post-Marketing Measures for Drugs/Medical Devices





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 FY2019)

	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
4,033	142	0

* In case that the same items are reexamined more than once, calculated figures are based on actual reexamination. Source: Survey conducted by Pharmaceutical safety and Environmental Health Bureau, MHLW

Detailed Data 2 Results of Prescription Drug Re-evaluation

(As of the end of FY2019)

(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)
		Reports from r	narketing author	ization holders No	ite 1)	
FY	Reports on adverse drug reactions Note 2)	Reports on infectious diseases Note 2)	Reports on research results	Reports on overseas measures	Regular reports on infectious diseases	Reports on adverse drug reactions from medical professionals Note 3)
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	Regular reports on	Reports on adverse drug reactions
	adverse	infectious	research	overseas	infectious diseases	from medical professionals
	event Note 1)	diseases Note 2)	results	measures	Intectious diseases	(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)	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.

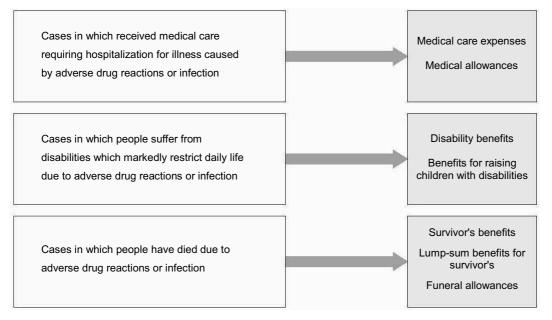
[Relief System for Infections Acquired through Biological Products]

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.

Detail	led Data	C	hang	es ir	n Sta	tus o	f Ad	vers	e Dru	ıg Re	eactio	on R	elief	Payn	nent	s (as	of th	ne en	d 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
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
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
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

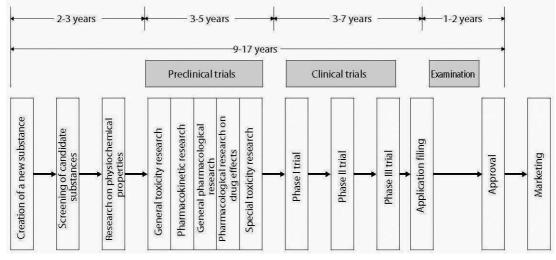
Source: Pharmaceutical and Medical Devices Agency

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

Cotogony	Number of		Drug sales		Prescription drug sales (included)		
Category	enterprises	Percentage	(¥100 million)	Percentage	(¥100 million)	Percentage	
Capital of less than ¥100 million	143	47.1%	4,682	3.9%	2,887	4.1%	
¥100 million - 5 billion	109	35.8%	29,589	24.9%	23,283	33.3%	
¥5 billion or more	52	17.1%	84,838	71.2%	43,651	62.5%	
Total	304	100.0%	119,109	100.0%	69,821	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, 2019, 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

					(Unit: ¥100 million, %
Year	Production	Percent change from the previous year	Export	Import	Total domestic production
1979	5,669	23.1	_	_	_
1989	12,195	9.9	2,266	2,972	12,819
2003	14,989	-0.3	4,203	8,836	19,407
2004	15,344	2.4	4,301	9,553	21,102
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	19,498	-2.0	6,676	16,206	28,686

Overview Production of Medical Devices, etc.

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

Detailed Data Production by Medical Device Type

(Unit: ¥100 million, %) Category Production Percentage Typical example Sterile tubes and catheters for vascular 5,293 27.1 1. Devices for surgical procedures procedures, sterile blood transfusion sets Whole body X-ray CT units, general-purpose 2. Diagnostic imaging system 3,071 15.8 ultrasonic diagnostic imaging devices Stents, hip replacements 3. Biological function assisting 15.2 2,958 devices/substitutes Discrete automatic clinical chemical analyzers, 4. Medical specimen testers 1,832 9.4 luminescence immune measurement devices Electronic endoscopes, sphygmomanometers 5. Bio-phenomena monitoring 9.3 1,813 measuring/monitoring devices Gold silver palladium alloy for dental casting, 6. Dental materials 1,305 6.7 dental ceramics Electronic massaging devices for home use, 7. Medical devices for home use 666 3.4 in-ear hearing aids Eyeglasses for sight correction, 8. Ophthalmologic devices and 637 3.3 related products contact lenses Dental unit, 522 2.7 9. Dental equipment Dental drive device and hand-piece 10.Others 1,401 7.2 100.0 Total 19,498

Source: "Annual Report on the Survey of Pharmaceutical Industry Productions 2018", 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]

- 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.
 Pharmacists, in cooperation with prescribing physicians and dentists, will explain effects, side effects, directions for use, etc. of
- 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.
- Doctors and dentists can freely prescribe drugs necessary for patients even when the particular drugs are not stocked in their own hospitals or clinics.
- 4) Issuing prescriptions to patients allows them to know which drugs they are taking.
- 5) Reduced outpatient dispensing work of hospital pharmacists allows them to engage in hospital activities for inpatients which they should essentially perform.

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

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

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

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

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

Blood Programme

Overview

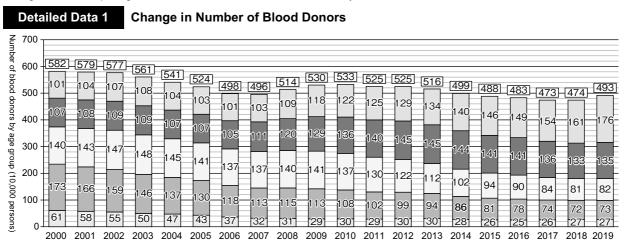
[Blood Products]

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

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

[Status of Blood Donation]

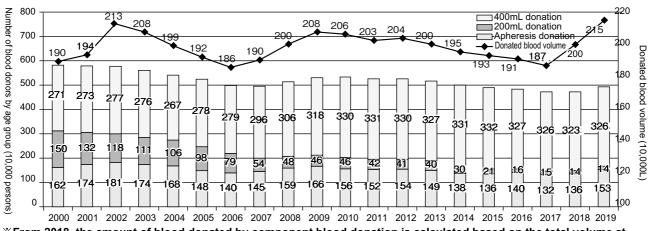
In recent years, due to an increase in the amount of blood donated per person, the required amount of blood can be secured with a smaller number of people than before, and the total number of blood donors is declining. On the other hand, looking at the number of blood donors by age group, the proportion 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.



□ Age 16-19 □ Age 20-29 □ Age 30-39 □ Age 40-49 □ Age 50-69 □ 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





%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

