

[2] Health and Medical Services

(1) Health Care Insurance

Health Care Insurance System

Overview

Outline of Health Care Insurance System

(As of June 2017)

System	Insurer (as of the end of March 2016)	Number of subscribers (March 2016)	Insurance benefits				Financial resources								
			Medical care benefits				Cash benefits	Premium rate	State subsidy						
			Co-payment	High-cost medical care benefit, Unitary high-cost medical/long-term care system	Hospital meal expenses	Hospital living expenses									
Health Insurance	JHIA-managed Health Insurance	Japan Health Insurance Association	37,165 [21,577 15,587]	<p>(High-cost medical care benefit system) • Maximum co-payment (Persons younger than 70) (average annual income: over approximately 11.60 million yen) ¥252,600 + (medical expenses - ¥842,000) × 1% (average annual income: between about 7.70 million yen and about 11.60 million yen) ¥167,400 + (medical expenses - ¥558,000) × 1% (average annual income: between about 3.70 million yen and about 7.70 million yen) ¥80,100 + (medical expenses - ¥267,000) × 1% (average annual income: under approximately 3.70 million yen) ¥57,600 (exempted from residence tax) ¥35,400 (Persons aged 70 or older but younger than 75) (More than a certain amount of income) ¥80,100 + (medical fee - ¥267,000) × 1%, outpatient (per person) ¥44,400 (General) ¥44,400, outpatient (per person) ¥42,000 (Household exempted from residence tax) ¥24,600, outpatient (per person) ¥8,000 (Especially household with lower income among household exempted from residence tax) ¥15,000, outpatient (per person) ¥8,000</p>	<p>(Co-payment for meal expenses) • Households with residential tax Per meal ¥360 • Household exempted from residence tax Per meal first 90 days ¥210 Per meal after 90 days ¥160 • Lower income household exempted from residence tax Per meal ¥100</p>	<p>(Co-payment for living expenses) • General (I) Per meal ¥460 + Per day ¥320 • General (II) Per meal ¥420 + Per day ¥320 • Household exempted from residence tax Per meal ¥210 + Per day ¥320 • Lower income household exempted from residence tax Per meal ¥130 + Per day ¥320 * Applicable to those aged 65 or older in long-term care beds * For patients with intractable/rare diseases, etc. and thus in high need for inpatient medical care, the amount of co-payment is the same as standard co-payment for meal expenses</p>	<p>• Sickness and injury allowance • Lump-sum birth allowance, etc.</p>	<p>10.00% (national average)</p>	<p>16.4% of benefit expenses, etc.</p>						
	Society-managed Health Insurance	Health Insurance Societies 1,405	29,136 [15,811 13,324]							<p>Same as above (with additional benefits)</p>	<p>Different among health insurance associations</p>	<p>Fixed amount (subsidy from budget)</p>			
	The insured under Article 3-2 of the Health Insurance Act	Japan Health Insurance Association	19 [13 7]							<p>After reaching compulsory education age until age 70 30%</p>	<p>• Sickness and injury allowance • Lump-sum birth allowance, etc.</p>	<p>Per day Class 1: ¥390 Class 11: ¥3,230</p>	<p>16.4% of benefit expenses, etc.</p>		
Seamen's Insurance	Japan Health Insurance Association	124 [58 66]	<p>Before reaching compulsory education age until age 70 20%</p>	<p>• Lower income household exempted from residence tax Per meal ¥100</p>	<p>Same as above</p>	<p>9.60% (sickness insurance premium rate)</p>	<p>Fixed amount</p>								
Mutual aid associations	National public employees	20 mutual aid associations	<p>8,774 [4,504 4,270]</p>	<p>70 or older but younger than 75 20% (*) (30% for persons with more than a certain amount of income)</p>	<p>* Reduced payment for multiple high-cost medical care For persons who have received high-cost care three times within a twelve-month period, the maximum co-payment of the fourth time and up will be reduced to: (Persons younger than 70) (average annual income: over approximately 11.60 million yen) ¥140,100 (average annual income: between about 7.70 million yen and about 11.60 million yen) ¥93,000 (average annual income: between about 3.70 million yen and about 7.70 million yen) ¥44,400 (average annual income: under approximately 3.70 million yen) ¥44,400 (exempted from residence tax) ¥24,600 (People aged 70 and over with more than a certain amount of income) ¥44,400</p>	<p>* For patients with intractable/rare diseases, etc. and thus in high need for inpatient medical care, the amount of co-payment is the same as standard co-payment for meal expenses</p>	<p>Same as above (with additional benefits)</p>	<p>Same as above</p>	<p>None</p>						
	Local public employees, etc.	64 mutual aid associations								<p>34,687</p>	<p>(*) 10% for those already turned 70 years old by the end of March 2014</p>	<p>• Reduced payment for persons receiving high-cost medical care for a long period Maximum co-payment for patients suffering from hemophilia or chronic renal failure requiring dialysis, etc.: ¥10,000 (patient younger than 70 with over average annual income of 7.70 million yen, receiving dialysis: ¥20,000)</p>	<p>• Lump-sum birth allowance, • Funeral expenses</p>	<p>Calculated for each household according to the benefits received and ability to pay</p>	<p>41% of benefit expenses, etc. 39.6 ~ 47.2% of benefit expenses, etc.</p>
	Private school teachers/staffs	1 Corporation													
Medical care system for the elderly aged 75 and over	[Implementing bodies] Wide area unions for medical care system for the elderly aged 75 and over	47	16,237	<p>10% (30% for persons with more than a certain amount of income)</p>	<p>Maximum co-payment Outpatient (per person) (Persons with more than a certain amount of income) ¥80,100 + (medical fee - ¥267,000) × 1% ¥44,400 (Multiple high-cost medical care) ¥44,400 (General) ¥44,400 ¥12,000 (Household exempted from residence tax) ¥24,600 ¥8,000 (Especially household with lower income among household exempted from residence tax) ¥15,000 ¥8,000</p>	<p>Same as above</p>	<p>Same as above, except for • Recipients of old-age Welfare Pensions Per meal ¥100</p>	<p>• Funeral expenses, etc.</p>	<p>Calculated using the amount of the per capita rate and income ratio of insured persons provided by wide area unions</p>	<p>• Premium Approx. 10% • Support coverage Approx. 40% • Public funding Approx. 50% (Breakdown of public funding) National : Prefectural : Municipal 4 : 1 : 1</p>					

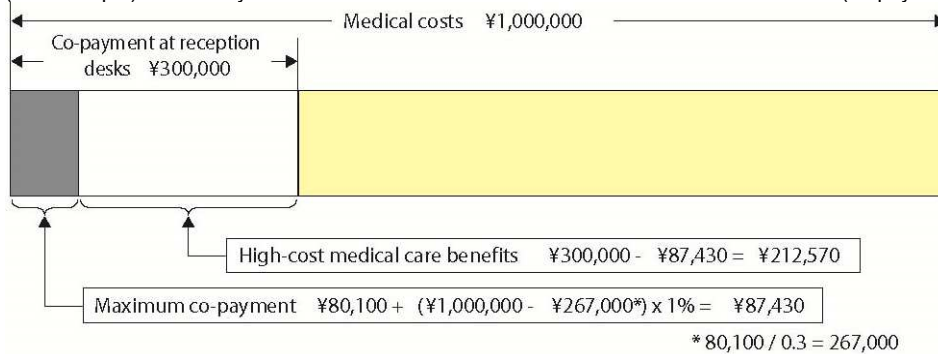
(Note) 1. Insured persons of medical care system for the elderly aged 75 and over include those aged 75 or older or 65-75 certified as having a specific disability by a wide area union.
2. Persons with a certain amount of income include those with a taxable income of ¥1.45 million (monthly income of ¥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 an elderly single-person household with a taxable income of 3.83 million and those with a total old income not more than ¥2.10 million are excluded. Lower income households exempted from residence tax is considered to be those with a pension income of ¥800,000 or less, etc.

3. Fixed-rate national subsidy for National Health Insurance shall be at the same level as that for the Japan Health Insurance Association-managed Health Insurance for those exempt from application of Health Insurance and those newly subscribed to the National Health Insurance on and after September 1, 1997.
4. The sums in the breakdown may not equal the total due to rounding.
5. The premium rate of Seamen's Insurance is the rate after the deduction resulting from the measure to reduce the burden of insurance premiums for insured persons (0.50).

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

- The high-cost medical care benefit system is for use in avoiding co-payments made for medical costs becoming too expensive for family budgets. Under this system, households pay co-payments for medical costs at the reception desks of medical institutions but then get reimbursed by insurers for any amount exceeding the monthly maximum amount.
- (*1) In case of hospitalization, a benefit in kind system has been introduced in which the monthly payment at the reception desks of medical institutions is limited to the maximum co-payment.
- (*2) In case of outpatient treatment, a benefit in kind system was introduced in April 2012 for use when the monthly payment exceeds the maximum co-payment at the same medical institution.
- The maximum co-payment is set up according to insured persons' income.

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



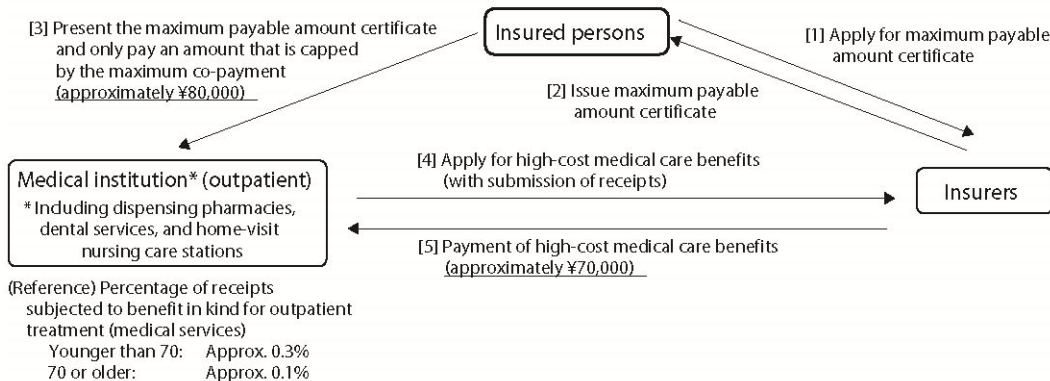
(Note) Per-household addition system

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

Detailed Information 2 Response to Benefit in Kind for Outpatient Treatment

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

Medical expense ¥500,000 (co-payment of 30%) Annual income: about ¥3.7 million –about ¥7.7 million for persons below 70 years old



Basic mechanism of benefit in kind

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

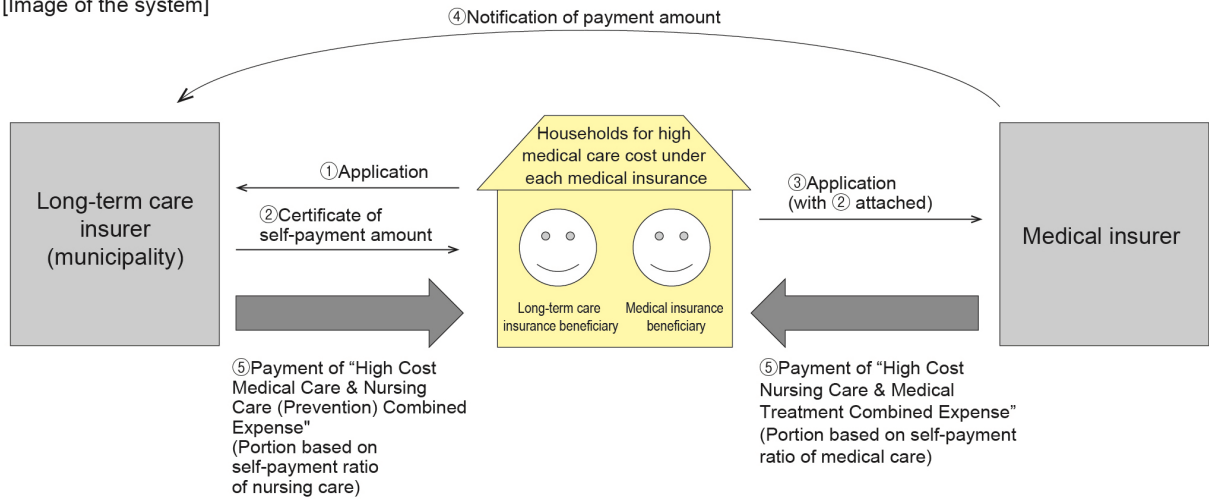
Detailed Information 3 Outline of High Cost Long Term Care Total Medical Care Cost System

○ The High Cost Long Term Care Total Medical Care Cost System is a system that reduces the burden of self-payment when the total self-payment of medical insurance including the long-term care insurance for medical expenses and long-term care insurance for one year (August 1 to July 31 of the following year) becomes expensive.

* In long-term care, the same system is called the "High Cost Total Medical Care (Prevention) Service Cost".

- 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 medical and long-term care insurers bear the burden according to the ratio of self-payment.

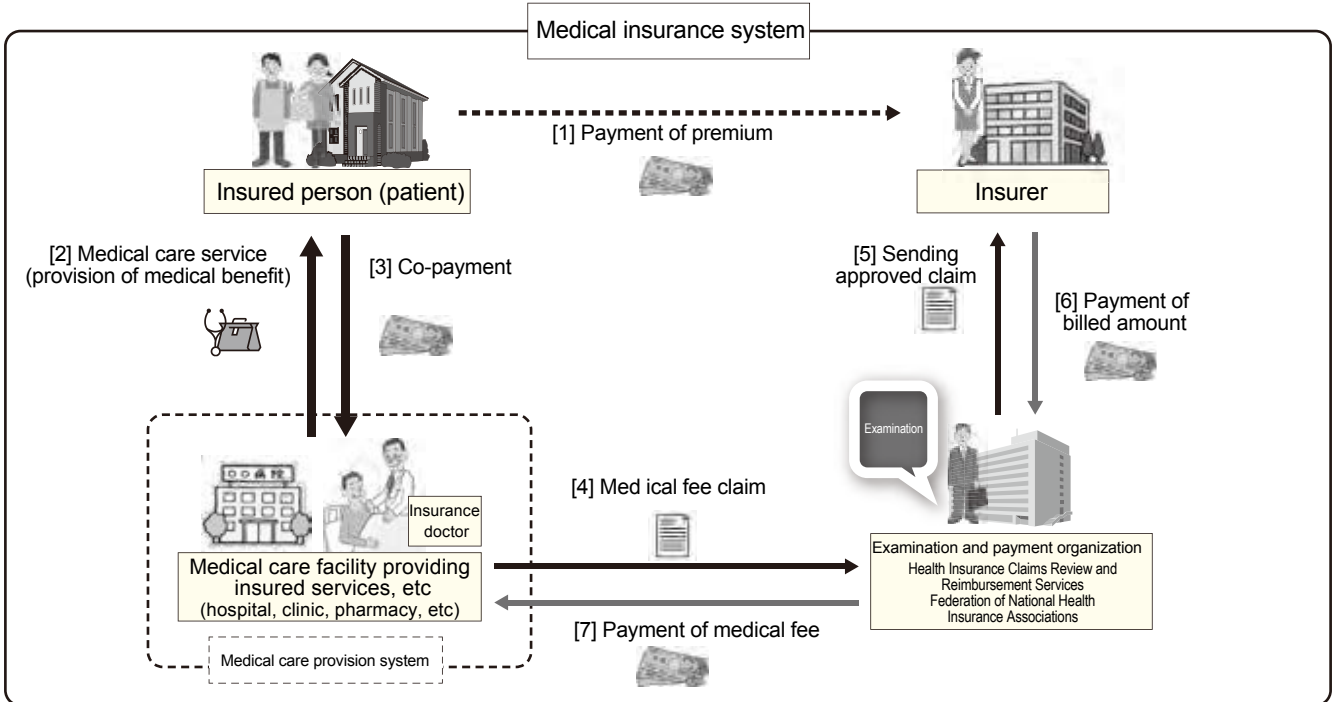
[Image of the system]



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 2015 Revision of Reimbursement of Medical Fees

Outline of the FY 2015 Revision of Reimbursement of Medical Fees

- Rebuilding the effective, efficient and high-quality medical care system and building the integrated community care system towards 2025
- Efforts will be made in promotion of the integrated community care system and in distribution/reinforcement and cooperation of medical functions.

Medical fees (core) +0.49%

{ Medical services +0.56%
 { Dental services +0.61%
 { Dispensations +0.17%

Drug price revision -1.22%

In addition to the above ratio,

- 0.19% by the drug price revision in response to the recalculation of market expansion and
- 0.28% by the enforcement of special measures for the recalculation of market expansion in response to items whose annual sales are extremely large.

Material price revision -0.11%

※ The measures for reduction of prices of newly listed drugs, revision of the criteria of replacement rates for special reduction of long-term listed items, for rationalization of evaluations on large pharmacies in front of hospitals, for rationalization of hospital meal expenses for enteral nutrition products provided as meals in hospitalization cases, for restriction on the number of fomentations provided for one prescription from the viewpoint of proper use of pharmaceutical products and for rationalization of dental materials whose cost-effectiveness has decreased will be taken separately.

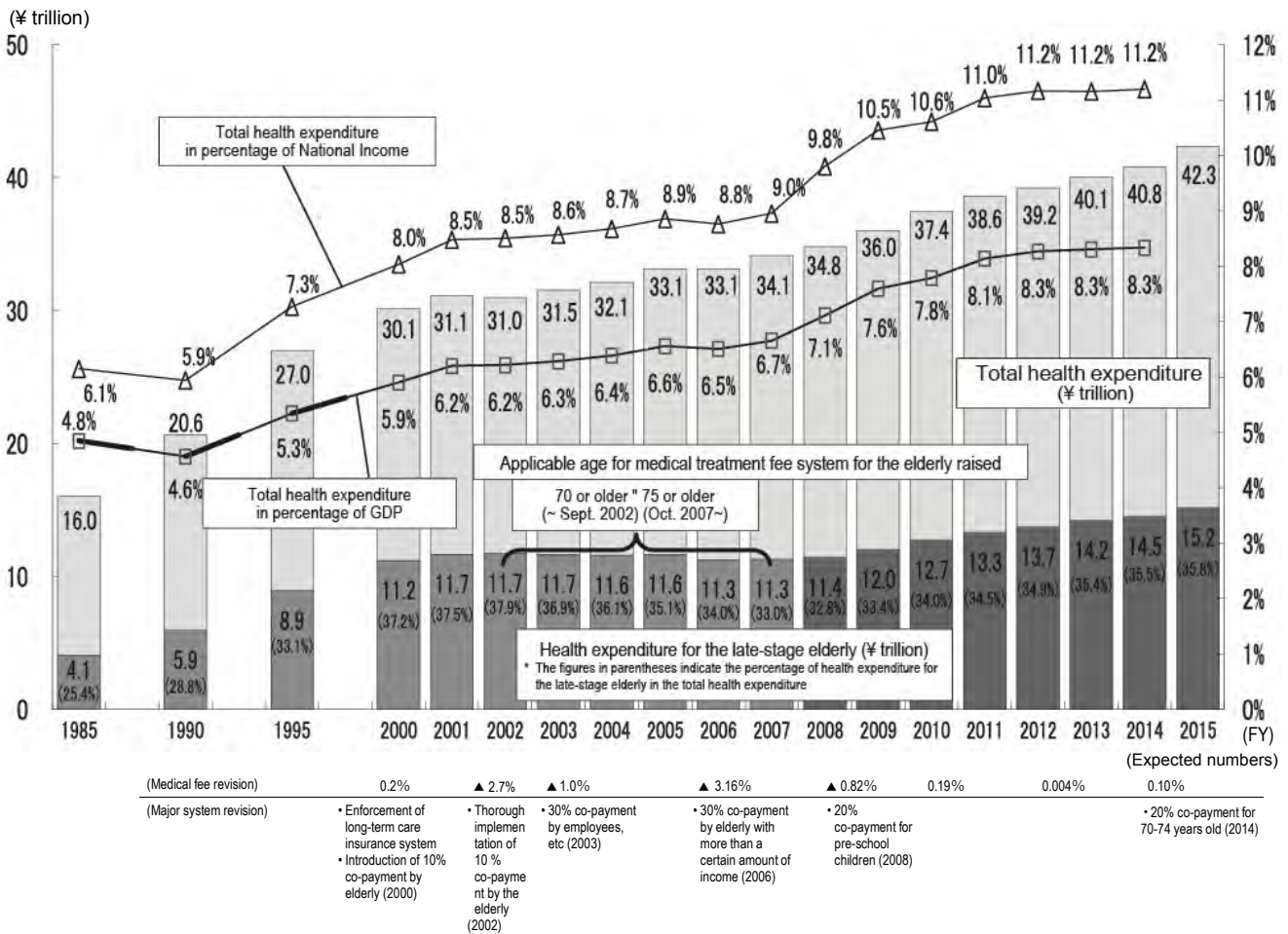
Basic Understanding of the FY2016 Revision of Reimbursement of Medical Fees

- As a result of the FY2014 revision of reimbursement of medical fees, it was found out that "functional division and cooperation of hospital beds" have progressed. It is necessary to further promote this area in the future. As regards "outpatient and in-home medical care," it is required to further strengthen "family physicians functions."
- It is also necessary to make enormous efforts for promotion of use of generic drugs and for rationalization of their prices.
- Based on these verification results of the FY2014 revision, the FY2016 revision of reimbursement of medical fees will be made from the following basic perspectives.

Basic perspectives of the revision	<p>The focuses are placed on "innovation" and "outcome, enhancing" "functional division and cooperation of hospital beds" and "family physicians functions".</p> <p style="text-align: center;">⇒ Realizing high-quality and efficient medical care with a central focus on citizens who live in local communities</p>
Perspective 1:	<p>Promotion of the "integrated community care system" and further distribution/reinforcement and cooperation of medical functions including "functional distribution and cooperation of hospital beds"</p> <ul style="list-style-type: none"> - Promotion of "functional division and cooperation of hospital beds" - "Incentives for team-based medical care" and "improvement of working conditions" through utilizing different types of professionals. - Ensuring high-quality "home medical care and home visit nursing care"
Perspective 2:	<p>Realization of safe and secure medical care for patients such as further promotion of "family physicians"</p> <ul style="list-style-type: none"> - Incentives for family physicians, dentists and pharmacists and pharmacies
Perspective 3:	<p>Enhancement of medical fields for which priority responses are required</p> <ul style="list-style-type: none"> - Incentives for high-quality cancer care including palliative care - Incentives for appropriate medical care for patients with dementia - Incentives for innovation and medical technologies
Perspective 4:	<p>Raising sustainability of the medical insurance system through streamlining and rationalization</p> <ul style="list-style-type: none"> - Review of the rules for calculation of generic drug prices - Rationalization of evaluation of large pharmacies in front of hospitals - Introduction of Health Technology Assessment (HTA).

Health Expenditure

Overview Changes in Health Expenditure



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

	1985	1990	1995	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
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
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	4.6
National Income	7.2	8.1	1.1	1.7	▲2.2	▲0.8	1.2	0.5	1.1	1.1	0.8	▲6.9	▲3.0	2.4	▲0.9	0.5	2.3	1.5	-
GDP	7.2	8.6	1.8	0.8	▲1.8	▲0.7	0.8	0.2	0.5	0.7	0.8	▲4.6	▲3.2	1.4	▲1.3	0.0	1.7	1.5	-

- (Note) 1. The national income and GDP are based on the national accounting announced by the Cabinet Office.
 2. National medical expenses (and those for advanced elderly. The same applies hereinafter) in FY2015 are estimates including the actual performance. The expenses for FY2015 are estimated by multiplying the national medical expenses for 2014 by the rate of increase in approximate medical expenses in 2015 (figures written in italics in the table above).
 *The budget freezing measure for co-payment ratios of persons aged 70 to 74 was lifted (10%→20%). 20% is applied to persons who reached 70 years of age in April 2014 or after and the ratio of 10% is left unchanged for persons who reached 70 years of age in March 2014 or before.

Detailed Data 1

National Medical Care Expenditure of OECD Countries (2013)

Country	Total medical care expenditure in GDP		Per capita medical care expenditure		Remarks
	(%)	Rank	(\$)	Rank	
U.S.A	16.4	1	8,713	1	
Switzerland	11.1	2	6,325	2	
Netherlands	11.1	2	5,131	4	
Sweden	11.0	4	4,904	5	
Germany	11.0	4	4,819	6	
France	10.9	6	4,124	12	
Denmark	10.4	7	4,553	7	
Canada	10.2	8	4,351	10	
Belgium	10.2	8	4,256	11	
Japan	10.2	8	3,713	14	
Austria	10.1	11	4,553	7	
New Zealand	9.5	12	3,328	18	
Greece	9.2	13	2,366	25	
Portugal	9.0	14	2,482	23	
Norway	8.9	15	5,862	3	
Spain	8.9	15	2,928	21	*
Australia	8.8	17	3,866	13	*
Italy	8.8	17	3,077	20	

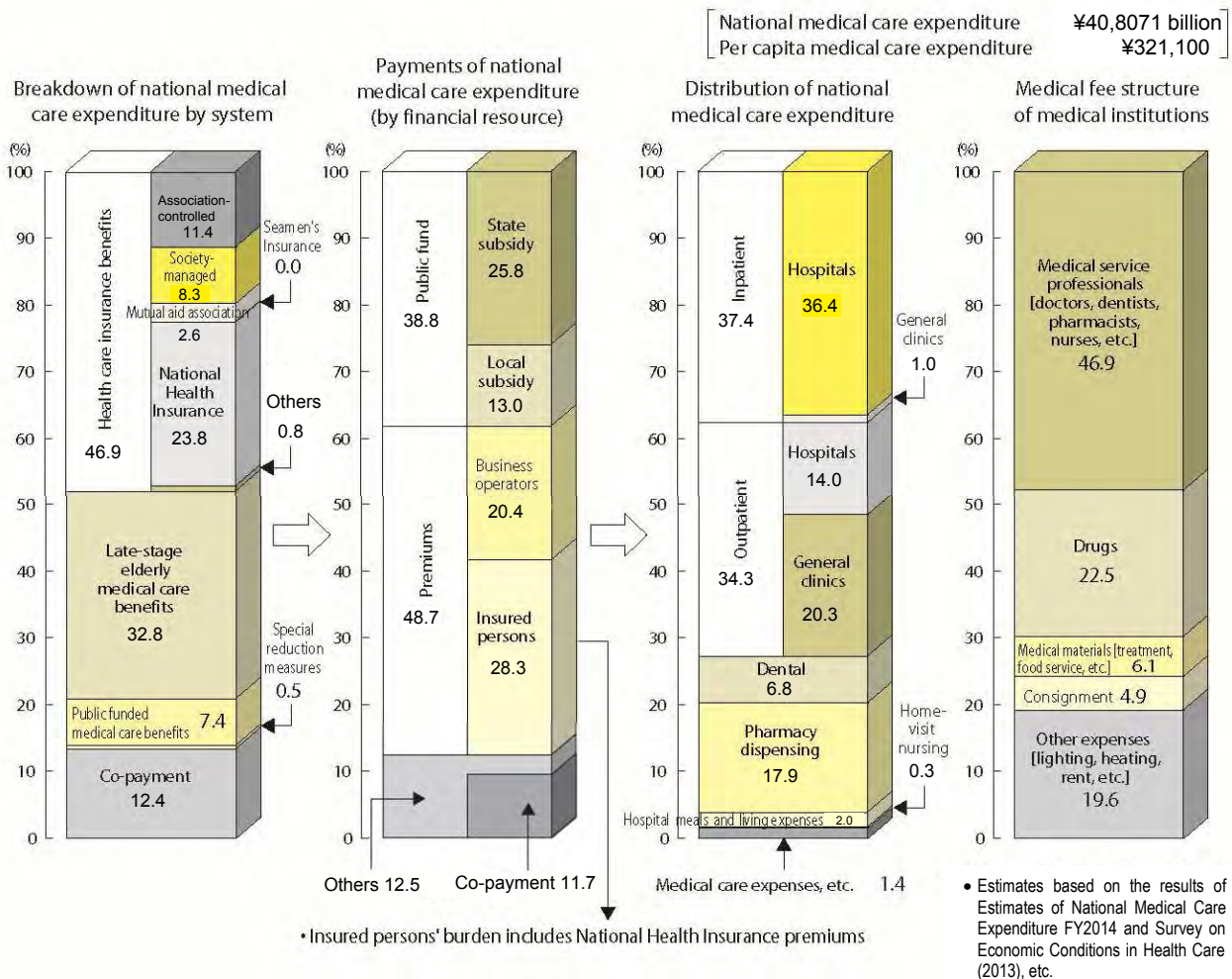
Country	Total medical care expenditure in GDP		Per capita medical care expenditure		Remarks
	(%)	Rank	(\$)	Rank	
Iceland	8.7	19	3,677	15	
Slovenia	8.7	19	2,511	22	
Finland	8.6	21	3,442	17	
U.K.	8.5	22	3,235	19	
Ireland	8.1	23	3,663	16	*
Slovakia	7.6	24	2,010	28	
Israel	7.5	25	2,428	24	
Hungary	7.4	26	1,719	29	
Chile	7.4	26	1,623	30	
Czech Republic	7.1	28	2,040	27	
Korea	6.9	29	2,275	26	
Luxembourg	6.6	30	4,371	9	*
Poland	6.4	31	1,530	32	
Mexico	6.2	32	1,048	33	
Estonia	6.0	33	1,542	31	
Turkey	5.1	34	941	34	
OECD average	8.9		3,453		

Source: "OECD HEALTH DATA 2015"

(Note) 1. The rank in this table indicates the rank among OECD member countries.
 2. The figures marked with "*" indicate the figures for 2012.

Detailed Data 2

Structure of National Medical Care Expenditure (FY 2014)



Detailed Data 3

Changes in National Medical Care Expenditure and Percentage Distribution

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

Year	National medical care expenditure	Medical fees of medical treatment 5)	Inpatient medical fees			Outpatient medical fees		Dental medical fees	Pharmacy dispensing medical fees 2)	Hospital meals and living expenses 3)	Home-visit nursing medical fees	Medical care expenses, etc. 5)			
			Hospitals	General clinics	Hospitals	General clinics									
Estimated amount (¥100 million)															
2008	348,084	254,452	172,298	82,154	128,205	123,685	4,520	126,247	48,613	77,634	25,777	53,955	8,152	605	5,143
2009	360,067	262,041	178,848	83,193	132,559	128,266	4,293	129,482	50,582	78,900	25,587	58,228	8,161	665	5,384
2010	374,202	272,228	188,276	83,953	140,908	136,416	4,492	131,320	51,860	79,460	26,020	61,412	8,297	740	5,505
2011	385,850	278,129	192,816	85,314	143,754	139,394	4,359	134,376	53,421	80,954	26,757	66,288	8,231	808	5,637
2012	392,117	283,198	197,677	85,521	147,566	143,243	4,323	135,632	54,434	81,197	27,132	67,105	8,130	956	5,597
2013	400,610	287,447	201,417	86,030	149,667	145,523	4,144	137,780	55,894	81,886	27,368	71,118	8,082	1,086	5,509
2014	408,071	292,506	205,438	87,067	152,641	148,483	4,158	139,865	56,956	82,909	27,900	72,846	8,021	1,256	5,543
Percentage distribution (%)															
2008	100.0	73.1	49.5	23.6	36.8	35.5	1.3	36.3	14.0	22.3	7.4	15.5	2.3	0.2	1.5
2009	100.0	72.8	49.7	23.1	36.8	35.6	1.2	36.0	14.0	21.9	7.1	16.2	2.3	0.2	1.5
2010	100.0	72.7	50.3	22.4	37.7	36.5	1.2	35.1	13.9	21.2	7.0	16.4	2.2	0.2	1.5
2011	100.0	72.1	50.0	22.1	37.3	36.1	1.1	34.8	13.8	21.0	6.9	17.2	2.1	0.2	1.5
2012	100.0	72.2	50.4	21.8	37.6	36.5	1.1	34.6	13.9	20.7	6.9	17.1	2.1	0.2	1.4
2013	100.0	71.8	50.3	21.5	37.4	36.3	1.0	34.4	14.0	20.4	6.8	17.8	2.0	0.3	1.4
2014	100.0	71.7	50.3	21.3	37.4	36.4	1.0	34.3	14.0	20.3	6.8	17.9	2.0	0.3	1.4

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, some of the expenses that were subjected to national medical care expenditure were transferred to long-term care insurance fees and are no longer included in national medical expenditure on and after FY 2000.
2. Pharmacy dispensing was included in outpatient medical fees until they were newly classified as a separate item in FY 1977.
3. Figures until FY 2005 indicate "hospital meal expenses" (total amount of hospital meal expenses and standard co-payment) and figures since FY 2006 indicate the total amount of hospital meal expenses, standard co-payment for meal expenses, hospital living expenses, and standard co-payment for living expenses.
4. Medical treatment fees at health service facilities for the elderly are not included in national health expenditure on and after FY 2000 because these fees are those who are certified for long-term care need.
5. "Medical fees of medical treatment" and "medical care expenses, etc." were included in "general medical fees" until they were newly classified as a separate item in FY 2008.

Detailed Data 4

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

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

(Note) 1. Terms are defined as follows.

- a. Medical fees: Expenses paid for medical care services received at insurance medical care facilities providing insured services, etc. (excluding insurance pharmacies, etc.). (Benefit in kind)
- b. Dispensing: Refers to the expenses paid when receiving medicine at an insurance-covered pharmacy (benefits in kind)
- c. Meal and living: Meal and living expenses during hospitalization. (Benefit in kind)
- d. Home-visit nursing: Expenses paid for home-visit nursing care services received that are provided by the offices of the specified service providers. (Benefit in kind)
- e. Medical treatment, etc.: Expenses paid for prosthetic devices supplied or treatment by judo therapists received 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 mail/living expenses, and basic fees of home-visit nursing.

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

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

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

Source "Annual Report on 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 2014 Settled Account)

(Unit: ¥100 million)

		Government-managed Health Insurance/ JHIA-managed Health Insurance	Society-managed Health Insurance	National Health Insurance (municipalities)	Seamen's Insurance	Medical care system for the elderly aged 75 and over
Operating revenue	Premium (tax) revenue	77,342	72,230	27,902	295	10,631
	National treasury contribution	12,559	33	30,549	30	44,351
	Prefectural contribution	-	-	10,411	-	13,089
	Municipal contribution	-	-	8,192	-	11,500
	Grants for late-stage elderly	-	-	-	-	55,995
	Grants for early-stage elderly	-	-	33,550	-	-
	Retirement grants	-	-	6,077	-	-
	Others	197	1,153	16,455	1	224
Total		91,028	76,023	133,135	326	135,791
Operating expenditure	Insurance benefit expenses	50,739	37,577	93,585	195	134,289
	Late-stage elderly support coverage	17,552	15,977	18,098	64	-
	Levies for early-stage elderly	14,342	13,910	14	41	-
	Contributions for retirees	2,959	2,906	-	12	-
	Others	1,716	5,019	20,630	6	704
	Total		87,309	75,389	132,328	318
Balance of ordinary revenue and expenditure		3,719	634	807	8	798

		Government-managed Health Insurance/ JHIA-managed Health Insurance	Society-managed Health Insurance
Non-operating revenue	Deferred repayment of state subsidy	-	-
	Non-operating subsidy for benefits, etc.	-	281
	Adjustment premium revenue	-	1,117
	Subsidies to financial adjustment programs	-	1,005
	Transfer from reserves, etc. and surplus carried forward	-	3,943
	Others	1,134	120
Total		1,134	6,466
Non-operating expenditure	Contribution to financial adjustment programs	-	1,110
	Others	-	208
	Total		-
Balance of non-operating revenue and expenditure		1,134	5,149 (1,205)
Balance of total revenue and expenditure		3,726	5,782 (1,840)
Reserve fund, etc.		10,647	38,027

- (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 ¥346.8 billion for use in covering the settlement of accounts. The amounts of the national subsidy, etc. for National Health Insurance (operated by municipalities) and the late-stage medical care system for the elderly were adjusted in the following fiscal year.
 3. The figures in parentheses for the Society-managed Health Insurance indicate the net balance between non-operating revenue and expenditure and the balance between total revenue and expenditure, but exclude transfers from reserves, etc. and surpluses carried forward).
 4. Contribution to health care services for the elderly is included in "others" of operating expenditure for each system.
 5. Reserve fund, etc. indicates reserves for the Japan Health Insurance Association-managed Health Insurance. It includes reserves, a reserve fund (¥3,379 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 FY2013 was added to FY2014 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

1. Creation of new funds and stronger cooperation of medical and long-term care (related to the Act on Promotion of the Establishment of 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
2. 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
 - [3] 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.

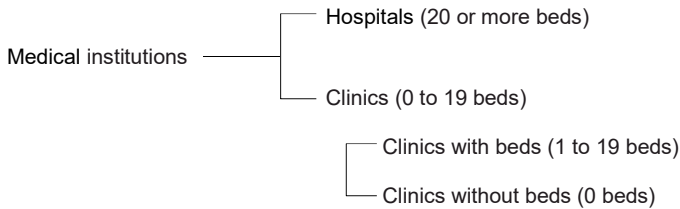
Types of Medical Institutions

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.



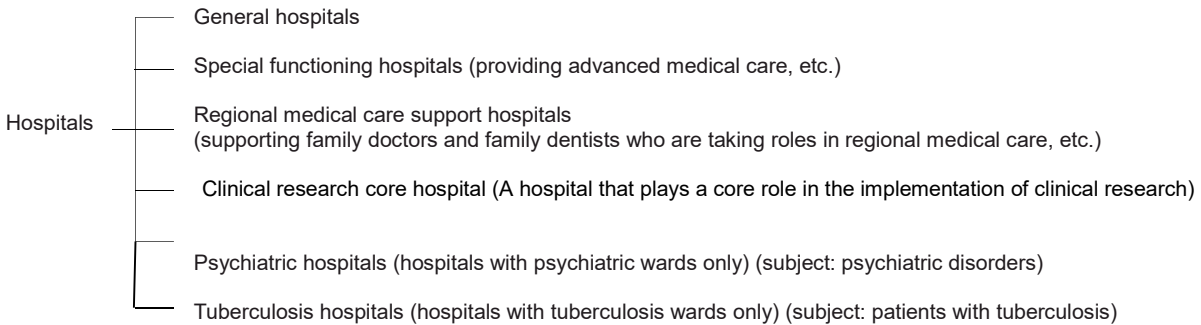
Hospitals are required to provide truly scientific and appropriate treatment to injured or sick people and are expected to have substantial facilities.

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

2. Types of Hospitals

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

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



Detailed Information 1 Outline of Special Functioning Hospitals

Purpose

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

Roles

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

Requirements for Approval

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

* The number of approved hospitals (as of June 1, 2017) 85

Detailed Information 2 Regional Medical Care Support Hospital System

Purpose

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

Roles

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

Requirements for Approval

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

* The number of approved hospitals (as of April 30, 2016) 524 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

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

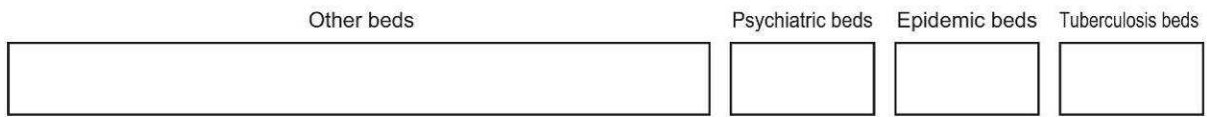
Requirements of Approval

- Number of specified clinical researches conducted (in the past three years)
 - Number of specified clinical researches conducted by its own.....4 or more clinical trials led by doctors or one or more clinical trials led by doctors and 80 specified clinical researches
 - Number of specified clinical researches conducted jointly with different facilities.....2 clinical trials led by doctors or 30 specified clinical researches
- Number of papers on specified clinical researches (in the past three years)45
- Number of cases where assistance was provided for specified clinical researches conducted by other medical institutions (in the past year)15
- Training on high-quality clinical researches
 - Number of workshops held for persons who conduct specified clinical researches (in the past year)6
 - Number of workshops held for persons who support specified clinical researches (in the past year)6
- Having 10 specified clinical departments
- Number of hospital beds: Having at least 400 hospital beds
- Staff deployment
 - Doctors and dentists: 5
 - Pharmacists: 10
 - Nurses, etc.: 15
 - Clinical research coordinators, etc.: 12
 - Data managers: 3
 - Biological statisticians: 2
 - Persons who have experience in working in pharmaceutical affairs approval examination bodies: 1
- Facilities: Must have clinical research facilities with equipment to ensure accuracy of researches and intensive care units
- The requirements for approval concerning the number of new specified clinical researches conducted and the number of 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, 2017) 11 Hospitals

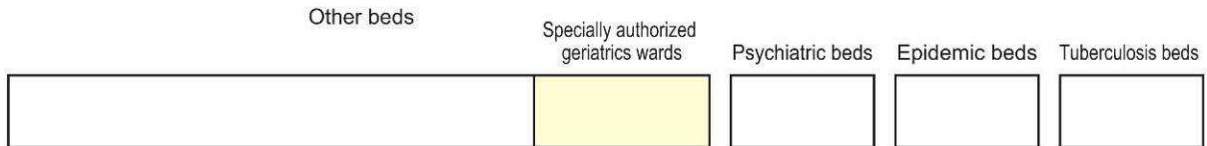
Detailed Information 3 Revision of Bed Classification

[At the beginning (from 1948)]



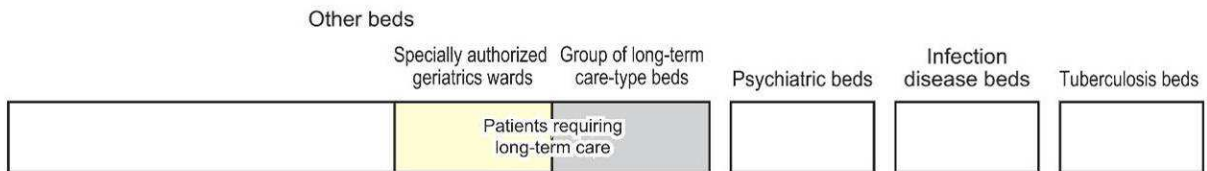
- Progress of aging
- Changes in disease structure

[Introduction of specially authorized geriatrics wards (1983)]



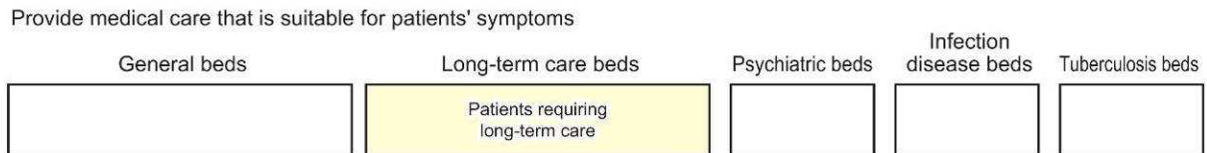
- In order to cope with the progress in aging and changes in disease structure, it was necessary to create facilities to provide medical care not only for elderly but for "patients requiring long-term care" in general.

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



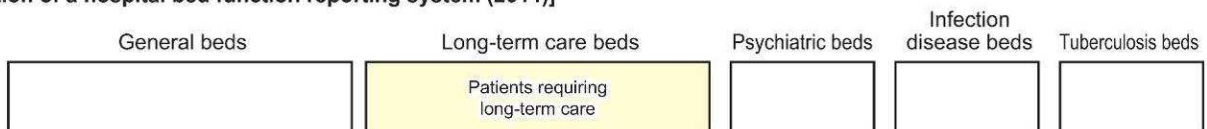
- The number of patients requiring long-term care increased due to changes in disease structure caused by the rapid progress in the birth rate decline and aging. Although various systems have been created, including long-term care-type bed group system, patients with various symptoms are still intermingled.

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



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

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



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

Trends with Medical Institutions

Overview

Changes in Number of Medical Institutions (Hospitals and Clinics)

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

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

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

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

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

Detailed Data 1

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

	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
Total	9,077	9,026	8,943	8,862	8,794	8,739	8,670	8,605	8,565	8,540	8,493	8,480
National	304	294	292	291	276	275	274	274	274	273	329	329
Public medical institutions	1,377	1,362	1,351	1,325	1,320	1,296	1,278	1,258	1,252	1,242	1,231	1,227
Social insurance organizations	129	129	125	123	122	122	121	121	118	115	57	55
Medical corporations	5,644	5,695	5,694	5,702	5,728	5,726	5,719	5,712	5,709	5,722	5,721	5,737
Private	760	677	604	533	476	448	409	373	348	320	289	266
Others	863	869	877	888	872	872	869	867	864	868	866	866
20-99 beds	3,616	3,558	3,482	3,391	3,339	3,296	3,232	3,182	3,147	3,134	3,092	3,069
100-299 beds	3,855	3,865	3,862	3,875	3,876	3,875	3,882	3,877	3,882	3,873	3,873	3,888
300-499 beds	1,125	1,118	1,120	1,123	1,111	1,106	1,096	1,090	1,087	1,083	1,091	1,098
500+ beds	481	485	479	473	468	462	460	456	449	450	437	425

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

	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
Total	9,077	9,026	8,943	8,862	8,794	8,739	8,670	8,605	8,565	8,540	8,493	8,480
Psychiatric hospitals	1,076	1,073	1,072	1,076	1,079	1,083	1,082	1,076	1,071	1,066	1,067	1,064
Tuberculosis sanatorium	2	1	1	1	1	1	1	1	1	-	-	-
General hospitals	7,999	7,952	7,870	7,785	7,714	7,655	7,587	7,528	7,493	7,474	7,426	7,416

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

Detailed Data 3 Changes in Number of Beds by Bed Type and Number of Beds per Hospital

	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
Total	1,631,553	1,631,473	1,626,589	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
Psychiatric beds	354,927	354,296	352,437	351,188	349,321	348,121	346,715	344,047	342,194	339,780	338,174	336,282
Infectious disease beds	1,690	1,799	1,779	1,809	1,785	1,757	1,788	1,793	1,798	1,815	1,778	1,814
Tuberculosis beds	13,293	11,949	11,129	10,542	9,502	8,924	8,244	7,681	7,208	6,602	5,949	5,498
Long-term care beds	349,450	359,230	350,230	343,400	339,358	336,273	332,986	330,167	328,888	328,195	328,144	328,406
General beds	912,193	904,199	911,014	913,234	909,437	906,401	903,621	899,385	898,166	897,380	894,216	893,970
Number of beds per hospital	179.7	180.8	181.9	182.8	183.0	183.3	183.8	184.0	184.3	184.3	184.7	184.7

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

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

	Bed utilization rate											
	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
Total	84.9	84.8	83.5	82.2	81.7	81.6	82.3	81.9	81.5	81.0	80.3	80.1
Psychiatric beds	92.3	91.7	91.1	90.2	90.0	89.9	89.6	89.1	88.7	88.1	87.3	86.5
Infectious disease beds	2.6	2.7	2.2	2.2	2.4	2.8	2.8	2.5	2.4	3.0	3.2	3.1
Tuberculosis beds	48.6	45.3	39.8	37.1	38.0	37.1	36.5	36.6	34.7	34.3	34.7	35.4
Long-term care beds	93.5	93.4	91.9	90.7	90.6	91.2	91.7	91.2	90.6	89.9	89.4	88.8
General beds	79.4	79.4	78	76.6	75.9	75.4	76.6	76.2	76.0	75.5	74.8	75.0
Long-term care beds for nursing care	94.1	93.9	94.2	94.5	94.9	94.6	93.9	93.1	92.9	92.1

	Average length of stay											
	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
Total	36.3	35.7	34.7	34.1	33.8	33.2	32.5	32.0	31.2	30.6	29.9	29.1
Psychiatric beds	338.0	327.2	320.3	317.9	312.9	307.4	301.0	298.1	291.9	284.7	281.2	274.7
Infectious disease beds	10.5	9.8	9.2	9.3	10.2	6.8	10.1	10.0	8.5	9.6	8.9	8.2
Tuberculosis beds	78.1	71.9	70.5	70	74.2	72.5	71.5	71.0	70.7	68.8	66.7	67.3
Long-term care beds	172.6	172.8	171.4	177.1	176.6	179.5	176.4	175.1	171.8	168.3	164.6	158.2
General beds	20.2	19.8	19.2	19	18.8	18.5	18.2	17.9	17.5	17.2	16.8	16.5
Long-term care beds for nursing care	268.6	284.2	292.3	298.8	300.2	311.2	307.0	308.6	315.5	315.8

Source: "Hospital Report", Health Statistics Office to the Director-General for Statistics and Information Policy, MHLW

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

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, 2017).
- (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 (as of the end of May 2017)

Classification	Number of facilities	Number of persons admitted
National Hansen's Disease Sanatoriums	13	1,468

* The number of persons admitted is of May 1, 2016.

Classification	Number of facilities	Students quota (persons)
Training schools for nurses (National Hansen's Disease Sanatoriums)	2	100

[National Hospital Organization]

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

(Reference) Number of hospitals (as of October 1, 2016)

Institutions	Number of hospitals	Number of beds
National Hospital Organization	143	54,529

[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, 2017)

Institutions	Specialized diseases, etc.	Number of hospitals	Number of beds
National Cancer Center	Cancer and other malignant neoplasm	2	1,003
National Cerebral and Cardiovascular Center	Cardiovascular diseases, cardiac diseases, cerebral apoplexy, hypertension	1	612
National Center of Neurology and Psychiatry	Mental diseases, neurological diseases, muscular diseases, mental retardation and other developmental disorders	1	474
National Center for Global Health and Medicine	Infection diseases and other diseases, International medical cooperation for developing countries.	2	1,223
National Center for Child Health and Development	Child health and development (pediatric care, maternity, paternal medicine, etc.)	1	490
National Center for Geriatrics and Gerontology	Geriatrics and gerontology (senile dementia, osteoporosis, etc.)	1	383

(Reference) Number of facilities (as of April 1, 2017)

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

* Institution names were made after April 1, 2016.

[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, 2017))

Classification	Number of facilities	Number of beds
Hospital	57	15,990

Classification	Number of facilities	[Admission capacity]
Long-term care health facilities	26	2,479

Classification	Number of facilities	[Student capacity]
Nursing School	7	885

Medical Professionals

Overview

Number of Physicians, etc.

The number of Physicians and dentists are increasing every year. As of December 31, 2014, there are 311,205 Physicians and 103,972 dentists.

Number of Medical Professionals

• Physicians	311,205 persons
• Dentists	103,972 persons
• Pharmacists	288,151 persons

Source: "Survey of Physicians, Dentists and Pharmacists 2014", Health Statistics Office to the Director-General for Statistics and Information Policy, MHLW

• Public health nurses	60,472 persons
• Midwives	38,486 persons
• Nurses	1,176,859 persons
• Assistant nurses	358,302 persons

Source: Health Policy Bureau, MHLW (2015)

• Physical therapists (PT)	77,139.8 persons
• Occupational therapists (OT)	42,136.1 persons
• Orthoptists	7,732.9 persons
• Speech language hearing therapists	14,252.0 persons
• Orthotists	104.4 persons
• Clinical radiologic technologists	50,960.4 persons
• Medical technicians	64,080.0 persons
• Clinical engineers	23,741.4 persons

Source: "Survey of Medical Institutions and Hospital Report 2014", Health Statistics Office to the Director-General for Statistics and Information Policy, MHLW

* Full-time equivalent numbers

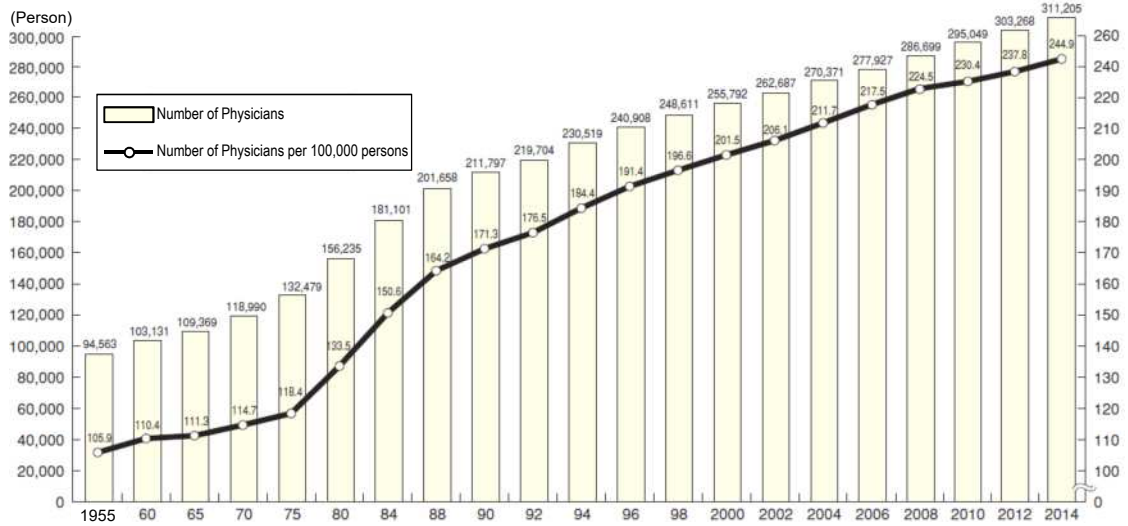
• Dental hygienists	123,831 persons
• Dental technicians	34,640 persons
• Massage and shiatsu practitioners	116,280 persons
• Acupuncturists	116,007 persons
• Moxibustion practitioners	114,048 persons
• Judo therapists	68,120 persons

Source: "Report on Public Health Administration and Services 2016", Administrative Report Statistics Office to the Director-General for Statistics and Information Policy, MHLW

• Emergency life-saving technicians	53,857 persons
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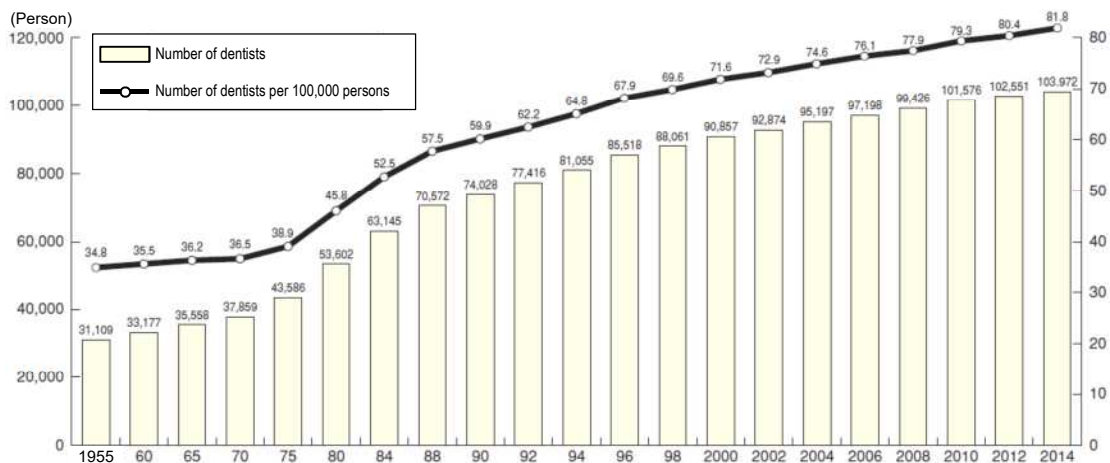
Source: Health Policy Bureau, MHLW (as of March 31, 2017)

Detailed Data 1 Changes in Number of Physicians



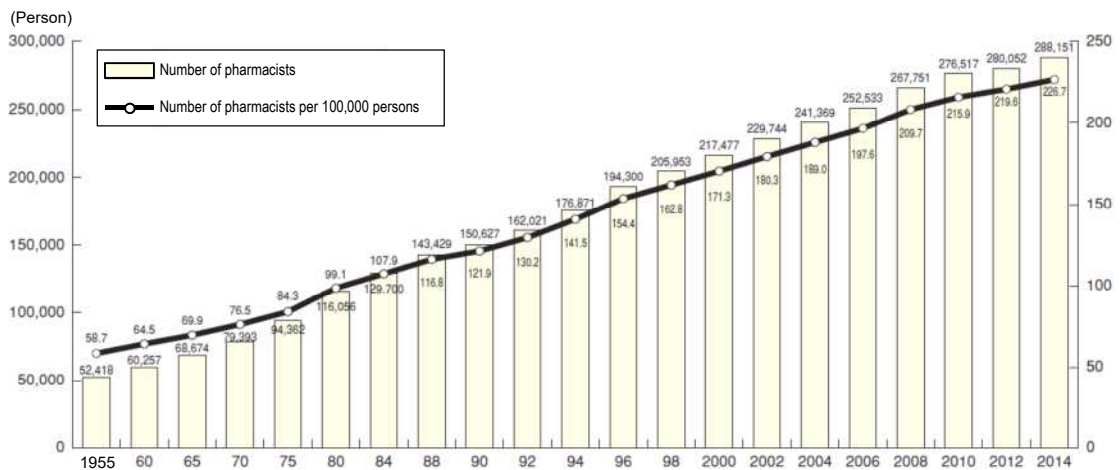
Source: "Survey of Physicians, Dentists and Pharmacists", Health Statistics Office to the Director-General for Statistics and Information Policy, MHLW

Detailed Data 2 Changes in Number of Dentists



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

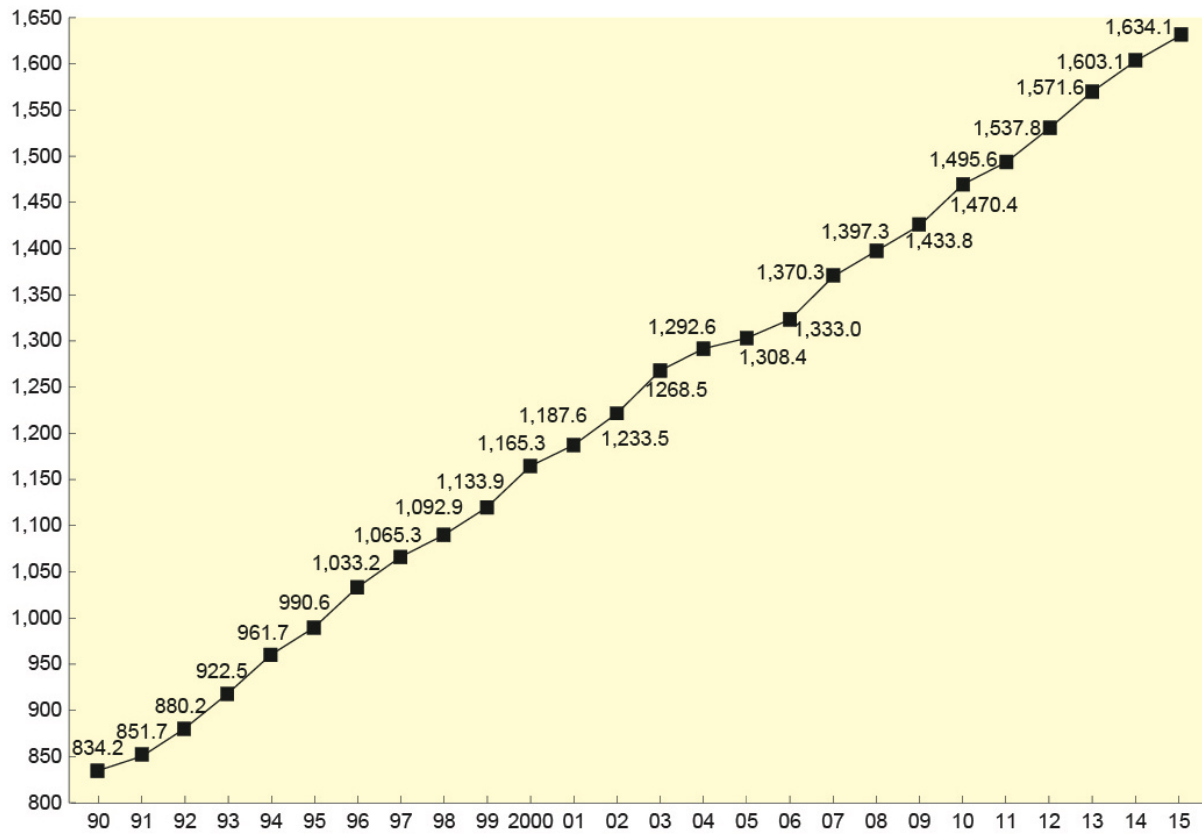
Detailed Data 3 Changes in Number of Pharmacists



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

Detailed Data 4 Changes in Number of Nursing personnel

(1,000 persons)



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 FY2013 On-Site Inspection)

Detailed Data 1 Regional Conforming Rates

(Unit: %)

Classification \ Region	Nationwide	Hokkaido Tohoku	Kanto	Hokuriku Koshinetsu	Tokai	Kinki	Chugoku	Shikoku	Kyushu
Doctors	95.5	89.4	97.7	92.6	96.6	98.8	95.1	93.9	96.3
Nurses	99.3	99.5	98.9	99.0	99.6	99.3	99.0	98.9	99.7

Detailed Data 2 Nationwide Achievement Status

Classification	Hospitals with insufficient number of doctors	Hospitals with sufficient number of doctors	Total
Hospitals with sufficient number of nurses	7,572 (94.4)	350 (4.4)	7,922 (98.8)
Hospitals with insufficient number of nurses	90 (1.1)	9 (0.1)	99 (1.2)
Total	7,662 (95.5)	359 (4.5)	8,021 (100.0)

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

(Explanation of terms)

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

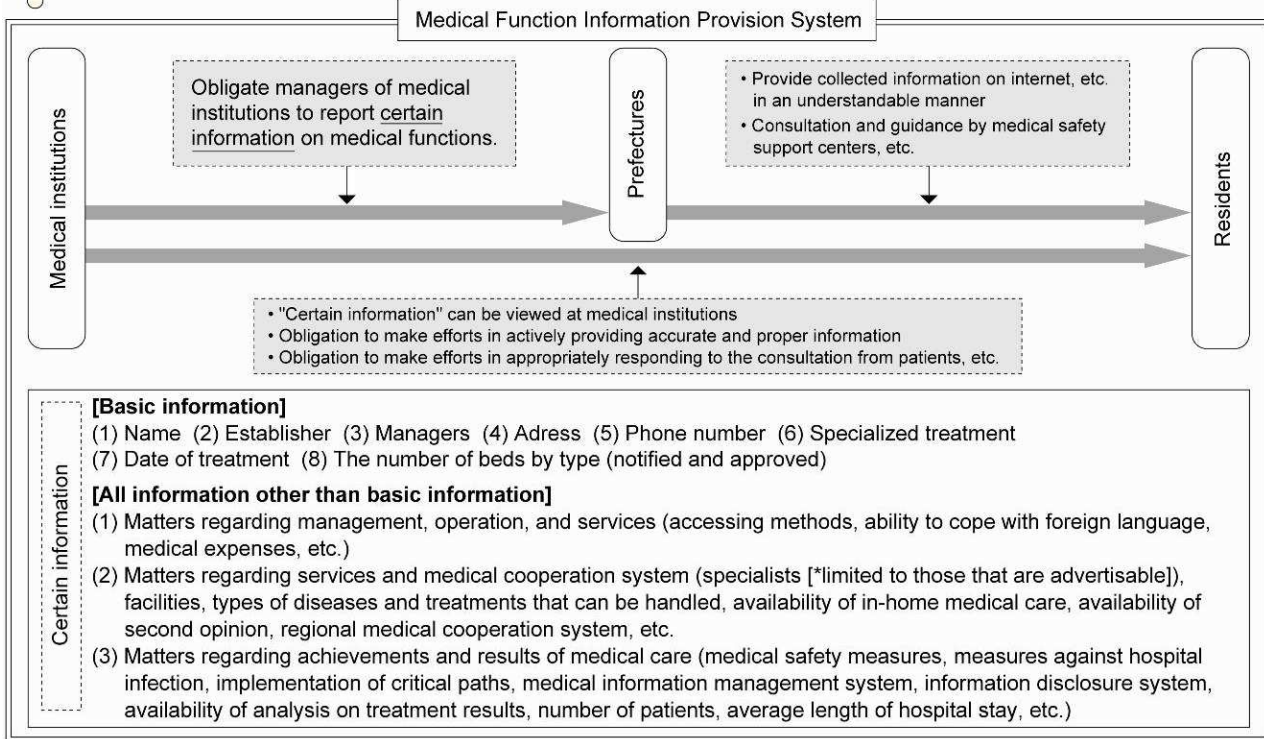
Provision of Medical Function Information

Overview

Creation of Medical Function Information Provision System

Enforced April 1, 2007

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



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

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

[Overview of the revised system]

Obligation to provide treatment plans at the beginning of hospitalization

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

(Items to be described in the treatment plan)

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

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

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

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

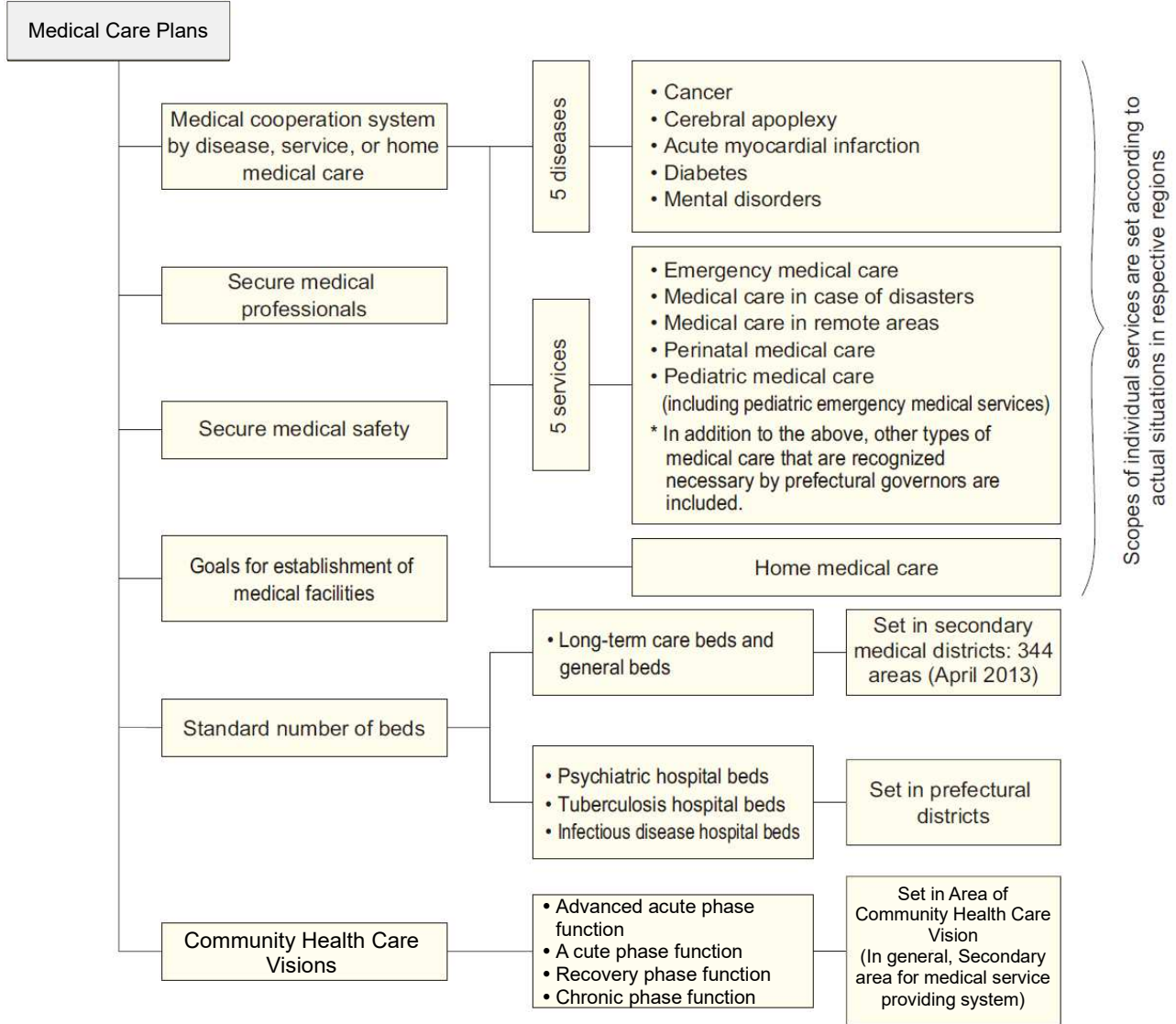
Medical Care Plan

Overview 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 2016)

Classification	Standard number of beds	Number of existing beds
Long-term care beds and general beds	1,047,679	1,226,345
Psychiatric hospital beds	307,589	333,800
Tuberculosis hospital beds	4,195	5,227
Infectious disease hospital beds	1,908	1,857

Detailed Data

Standard Number of Beds in Prefectural Medical Care Plans and Number of Existing Beds

(As of April 1, 2013)

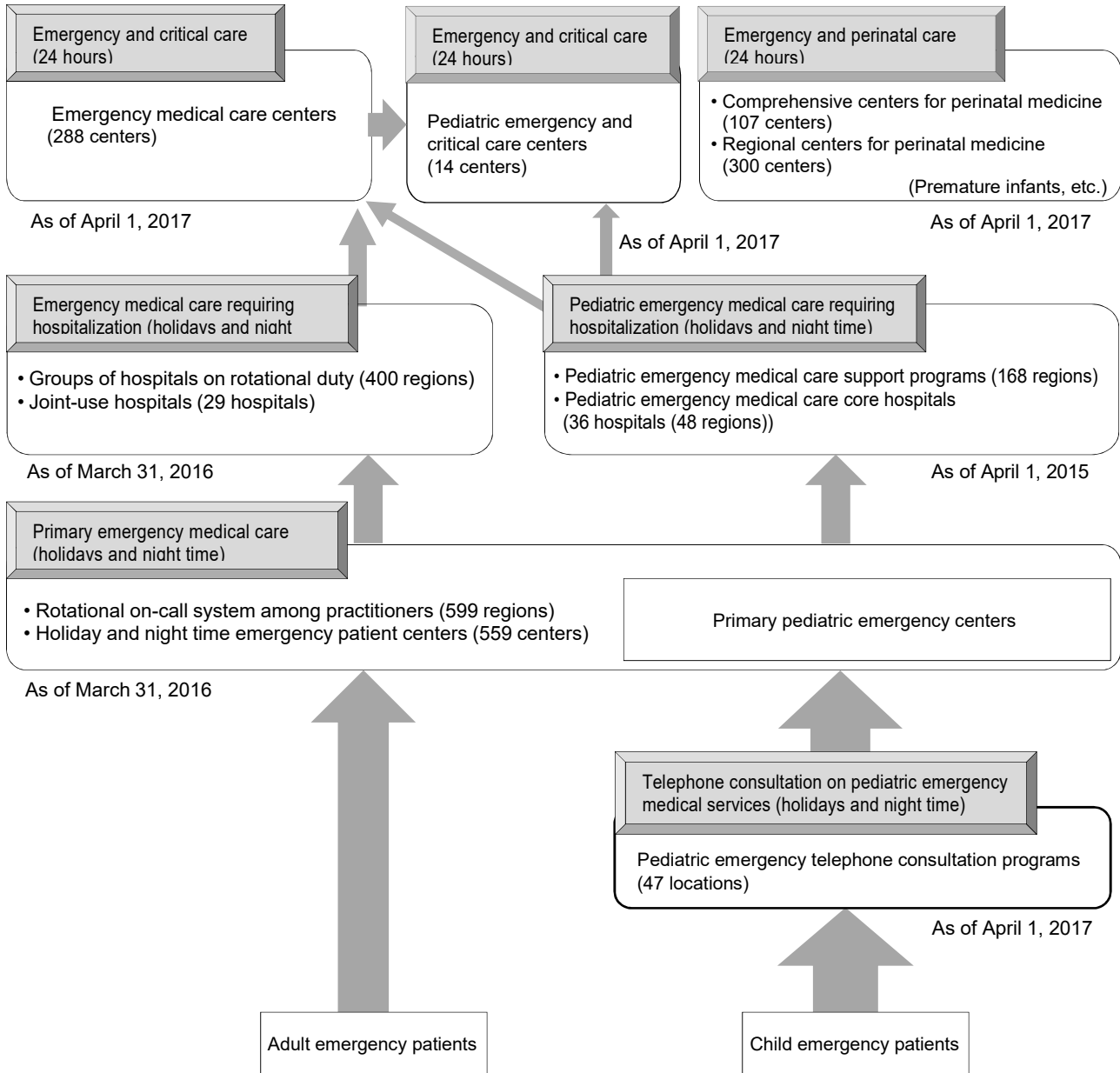
No.	Classifi	General beds and long-term care beds			Psychiatric hospital beds		Tuberculosis hospital beds		Infectious disease hospital beds	
		Number of secondary medical areas	Standard number of beds	Number of existing beds	Standard number of beds	Number of existing beds	Standard number of beds	Number of existing beds	Standard number of beds	Number of existing beds
1	Hokkaido	21	59,648	76,777	19,612	19,612	143	220	98	94
2	Aomori	6	11,320	12,937	4,453	4,453	60	60	32	29
3	Iwate	9	11,157	13,192	4,325	4,325	30	116	40	38
4	Miyagi	4	17,174	18,661	6,181	6,181	62	62	28	28
5	Akita	8	8,791	10,962	4,053	4,053	38	44	36	30
6	Yamagata	4	10,150	10,995	3,650	3,650	34	30	20	18
7	Fukushima	7	15,351	19,812	6,969	6,969	60	98	36	36
8	Ibaraki	9	17,890	24,511	7,350	7,350	60	128	48	48
9	Tochigi	6	12,140	15,908	5,129	5,129	65	65	32	28
10	Gunma	10	14,341	18,572	5,063	5,063	55	65	52	52
11	Saitama	10	49,623	50,470	14,024	14,024	118	150	85	72
12	Chiba	9	45,899	46,857	12,680	12,680	64	130	60	58
13	Tokyo	13	95,627	105,221	22,393	22,393	398	435	130	124
14	Kanagawa	11	59,985	60,189	14,129	14,129	166	166	74	74
15	Niigata	7	21,051	21,766	6,673	6,673	41	60	36	36
16	Toyama	4	10,235	13,946	3,135	3,135	82	82	22	22
17	Ishikawa	4	9,910	14,148	3,756	3,756	62	92	18	18
18	Fukui	4	6,471	8,813	2,298	2,298	22	49	20	16
19	Yamanashi	4	6,144	8,315	2,319	2,319	20	32	20	28
20	Nagano	10	17,801	19,018	4,811	4,811	42	74	46	46
21	Gifu	5	14,552	16,939	4,033	4,033	95	127	30	30
22	Shizuoka	8	28,623	31,259	6,763	6,763	103	108	48	48
23	Aichi	12	52,796	54,987	12,696	12,696	183	181	76	72
24	Mie	4	13,612	15,650	4,708	4,708	60	30	24	24
25	Shiga	7	10,279	11,746	2,310	2,310	73	63	34	34
26	Kyoto	6	24,786	28,516	6,290	6,290	300	300	38	38
27	Osaka	8	67,263	87,573	18,859	18,859	514	480	78	78
28	Hyogo	10	53,747	52,964	11,334	11,334	138	150	58	54
29	Nara	5	13,747	14,199	2,897	2,897	50	40	28	24
30	Wakayama	7	8,496	11,270	2,099	2,099	27	20	32	32
31	Tottori	3	5,665	6,495	1,914	1,914	21	21	12	12
32	Shimane	7	7,885	8,255	2,322	2,322	16	16	30	30
33	Okayama	5	18,781	21,879	5,502	5,502	54	136	26	26
34	Hiroshima	7	26,284	31,358	8,939	8,939	85	155	36	26
35	Yamaguchi	8	16,585	20,824	5,913	5,913	37	60	40	40
36	Tokushima	3	7,025	10,828	3,847	3,847	37	37	16	23
37	Kagawa	5	8,886	11,596	3,357	3,357	35	118	24	18
38	Ehime	6	15,165	17,726	4,890	4,890	54	54	28	26
39	Kochi	4	8,403	14,592	3,622	3,622	60	107	11	11
40	Fukuoka	13	49,713	65,192	21,344	21,344	191	252	66	66
41	Saga	5	9,187	10,886	4,223	4,223	30	30	24	24
42	Nagasaki	8	16,185	19,459	7,884	7,884	70	122	38	38
43	Kumamoto	11	19,053	25,446	8,920	8,920	54	127	48	48
44	Oita	6	11,720	15,224	5,247	5,247	38	50	28	40
45	Miyazaki	7	11,762	13,191	5,837	5,837	26	77	32	31
46	Kagoshima	9	16,769	24,647	9,670	9,670	183	141	44	45
47	Okinawa	5	10,002	12,574	5,377	5,377	39	67	26	24
	Total	344	1,047,679	1,226,345	333,800	333,800	4,195	5,227	1,908	1,857

- (Note) 1. The standard number of beds is as of the public announcement date of each prefecture.
2. The public announcement date differ depending on the date of reviewing medical care plans in respective prefectures.

Emergency Medical Service System

Overview

Structural Chart of Emergency Medical Service

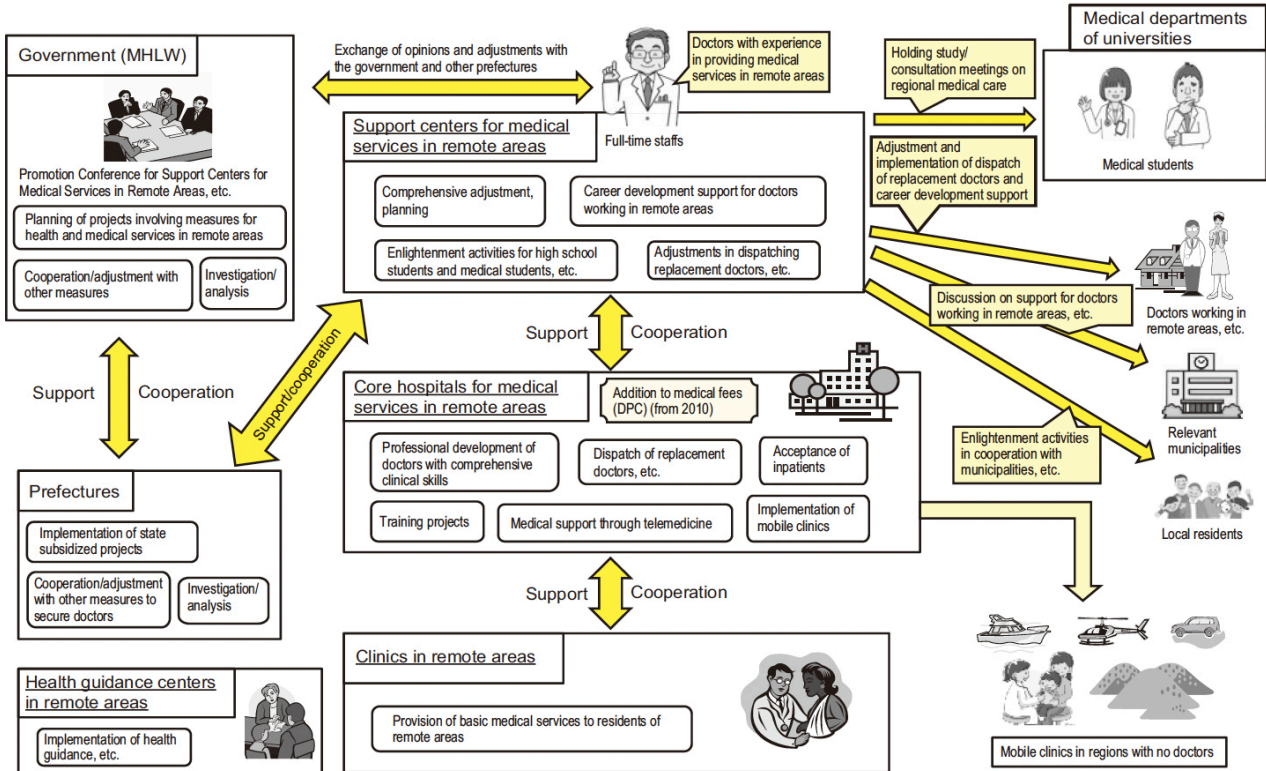


Medical Services in Remote Areas

Overview

Structural Chart of 11th Measures for Health and Medical Services in Remote Areas (FY2011-2017)

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 in plans for health and medical services in remote areas

As does the 10th plan, the new 11th plan for health and medical services in remote areas, which started in FY2011, provides that "prefectural office to support medical services in remote areas" are established in each prefecture to continue promoting broad-based measures for health and medical services in remote areas.

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	635	12.3

* 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 takes more than one hour one way to go to medical institutions using ordinary means of transportation.

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 January 1, 2015
- (2) Core hospitals for medical services in remote areas (subject to assistance of operational expenses, facility establishment expenses, and equipment installment expenses)
312 hospitals are designated as of January 1, 2016
- (3) Clinics for medical services in remote areas (subject to assistance of operational expenses, facility establishment expenses, and equipment installment expenses)
1,105 clinics (including National Health Insurance direct managed clinics) are established as of January 1, 2016

Medical Safety Measures

Overview

Medical Safety Measures

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

<Key Suggestions>

[Improved medical quality and safety]

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

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

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

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

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

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

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

<Measures>

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

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

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

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

Improved Quality of Doctors

Overview

History of Clinical Training System

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



[Issues of the conventional system]

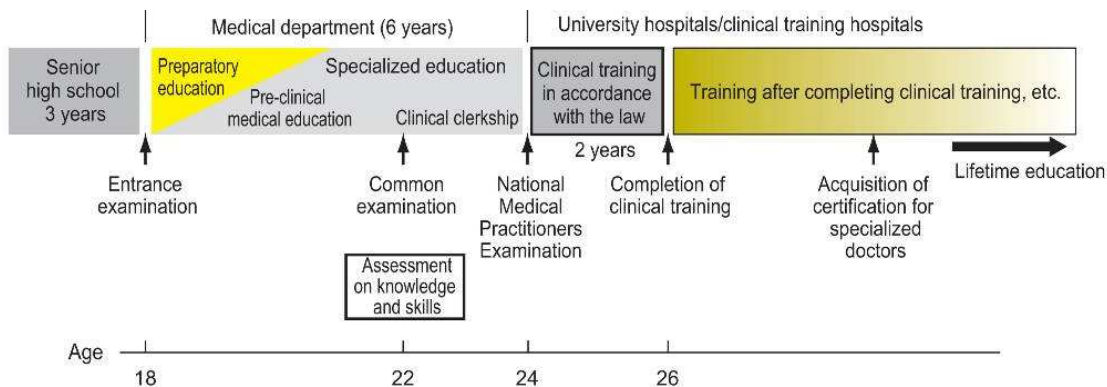
1. Training was voluntary
2. Training programs were not clearly defined
3. Mainly focused on straight training for specialized doctors
4. Remarkably large disparities existed among institutions
5. Insufficient guidance system
6. Insufficient evaluation of training achievements
7. Unstable status/work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

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

Overview of Clinical Training System

1. Medical Education and Clinical Training

- Article 16-2 of the Medical Practitioners Act
Doctors to engage in clinical practice must take clinical training in hospitals attached to universities with medical training courses or hospitals designated by the Minister of Health, Labour and Welfare for no less than 2 years.



2. Basic Ideas of Clinical Training

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

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

3. Status of Execution

[1] Clinical resident training facilities (FY2017)

Clinical resident training hospitals (core type)	909
Clinical resident training hospitals (cooperative type)	1,493
University hospitals (core type equivalent)	122
University hospitals (cooperative type equivalent)	18

[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%

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

Classification	University hospitals	Clinical resident 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%

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.

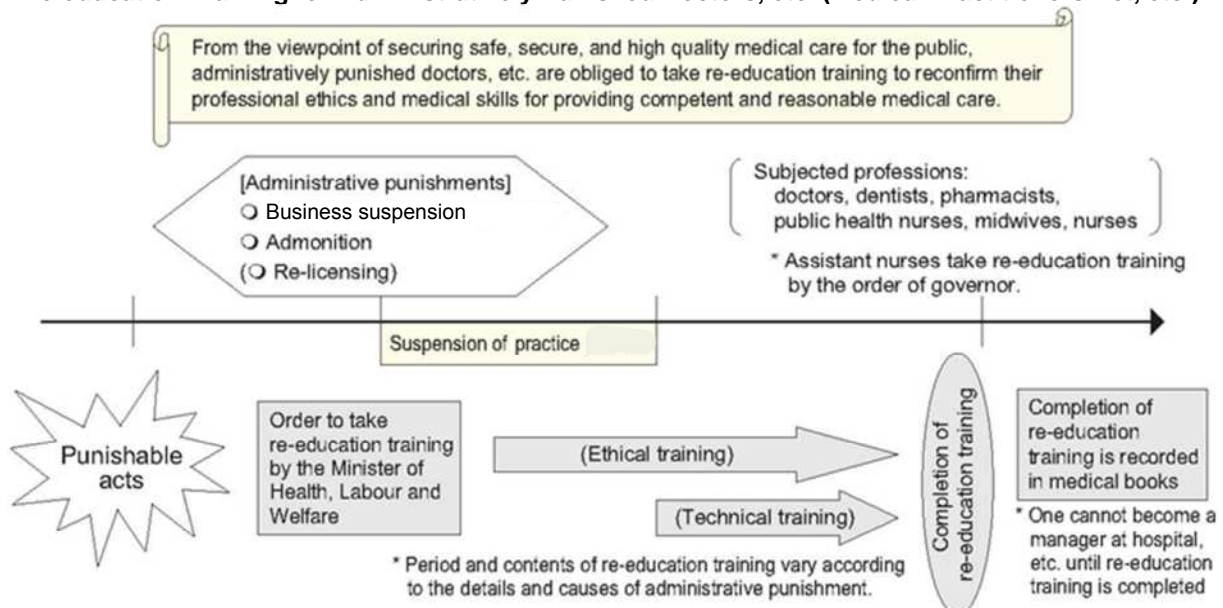
(5) Revision of recruitment quota setting

- 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

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

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



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

2. Establishment

- Associations or foundations based on the Medical Care Act.
 - Prefectural approval
(An organization opening a medical institute in more than 2 prefectures shall obtain approval from a governor at its main address.)
- (Number of corporations)
- Medical corporations 53,000 (as of March 31, 2017)
Of which 52,625 are associations (12,439 without contribution and 40,186 with contribution) and 375 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 281 (as of April 1, 2017)



3. Operation

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

(3) Health Promotion/Disease Measures

Health Centers, etc.

Overview

Activities of Health Centers

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

Health centers are established in 363 locations in 47 prefectures, 93 locations in 74 designated cities, and 23 locations in 23 special wards under the Community Health Act (As of April 1, 2017).

<<Personal health service areas>>

<Measures against infectious diseases>

Health checkups, reporting emergence of patients, etc. Non-regular health checkups of Tuberculosis, preventive vaccination, home-visit guidance, controlled medical examination, etc. (Infectious Diseases Act)

<Measures against AIDS/intractable diseases>

AIDS individual counselling programs (including free anonymous examination), AIDS consultation (AIDS guidelines) Medical consultation of intractable diseases, etc. (Outlines of infectious disease neasures)

<Measures for mental health>

Identification of current situation regarding mental health, mental health and welfare consultation, home-visit guidance of mental health, office works regarding medical care and protection, etc. (Mental Health and Welfare Act)

<Measures for maternal and child health>

Home-visit guidance for premature infants, providing medical aid for premature infants, etc. (Maternal and Child Health Act)

<<Objective health service areas>>

<Food sanitation>

Providing business license for restaurants, supervising business facilities, guidance, etc. (Food Sanitation Act)

<Environmental health>

Providing business license, notification, on-site investigation, etc. (Act on Coordination and Improvement of Environmental Health Industry, Entertainment Places Act, Public Bath Houses Act, Inns and Hotels Act, Barbers Act, Cosmetologists Act, Laundries Act)

Health centre administration council
Directors of health centers (doctors)

- Health risk management
- Technical support/advice for municipalities
- Adjustment between municipalities
- Formulation/promotion of regional health/medical care plans

481 Health Centers 363 in prefectures
95 in designated cities
23 in special wards

Doctors
Dentists
Pharmacists
Veterinarians
Clinical radiologic technologists
Medical social workers
Laboratory-medical technologists
Food sanitation inspectors
Registered dietitians
Dental hygienists
Physical therapists
Occupational therapists
Public health nurses
Midwives
Nurses
Certified psychiatric social workers
Medical technologists
Environmental sanitation inspectors
Dietitians
Abattoir inspectors, etc.

<Medical care inspection, etc.>

On-site investigation of hospitals, clinics, medical corporations, dental clinics, clinical laboratories, etc. (Medical Care Act, Dental Technicians Act, Act on Clinical Laboratory Technicians, etc.)

<<Planning, adjustment, etc.>>

Publicity
Dissemination and enlightenment
Health statistics
Health consultation

* 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	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Total number of health centers	663	641	594	592	582	576	571	549	535	518	517	510	494	495	495	494	490	486	480	481
Prefectures	490	474	460	459	448	438	433	411	396	394	389	380	374	373	372	370	365	364	364	363
Cities	137	136	108	109	111	115	115	115	116	101	105	107	97	99	100	101	102	99	93	95
Special wards	36	31	26	24	23	23	23	23	23	23	23	23	23	23	23	23	23	23	23	23

Source: Health Service Bureau, MHLW

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

Detailed Data 1 Number of Full-time Medical Personnel at Health Centers by Occupation

Occupation	Number of personnel
	Person
Doctors	740
Dentists	88
Pharmacists	2,847
Veterinarians	2,268
Public health nurses	8,253
Midwives	53
Nurses	140
Assistant nurses	8
Radiology technicians, etc.	489
Medical technologists, etc.	778
Registered dietitians	1,153
Dietitians	109
Dental hygienists	333
Physical/occupational therapists	89
Others	10,804
<Included in the upper column>	
Medical social workers	37
Mental health welfare counselors	1,148
Nutrition counselors	1,014
Total	28,152

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 FY2015)

Detailed Data 2 Changes in Number of Public Health Nurses

(Unit: person)

	FY 1998	FY 1999	FY 2000	FY 2001	FY 2002	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015
Municipalities	15,355	15,366	15,643	15,856	16,004	15,908	15,629	15,315	14,519	14,483	14,498	14,613	14,179	15,015	14,753	14,920	14,850	14,935
Designated cities / special wards	4,167	4,450	4,584	4,696	4,907	5,047	5,281	5,524	5,563	5,604	5,964	6,094	6,081	6,280	6,256	6,564	6,586	6,829
Subtotal	19,522	19,816	20,227	20,552	20,911	20,955	20,910	20,839	20,082	20,087	20,462	20,707	20,260	21,295	21,009	21,484	21,436	21,764
Prefectures	4,620	4,535	4,481	4,439	4,311	4,242	4,178	4,014	3,935	3,889	3,800	3,737	3,640	3,689	3,659	3,603	3,607	3,613
Total	24,142	24,351	24,708	24,991	25,222	25,197	25,088	24,853	24,017	23,976	24,262	24,444	23,900	24,984	24,668	25,087	25,043	25,377

Source: FY1998: "Report on Regional Public Health Services", Administrative Report Statistics Office to the Director-General for Statistics and Information Policy, MHLW

FY1999-2007: "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

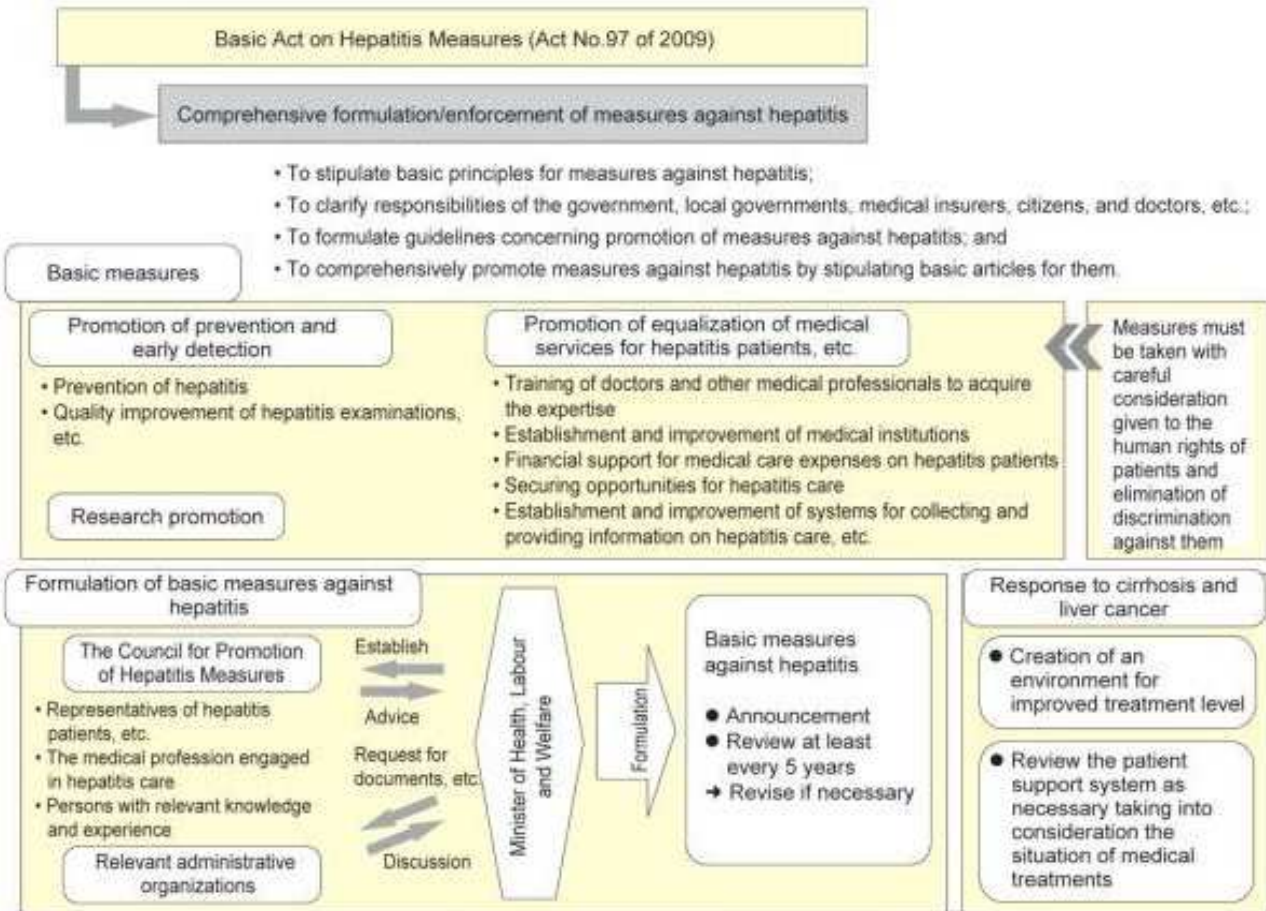
FY2008 onward: "Report on Regional Public Health Services and Health Promotion Services", Administrative Report Statistics Office to the Director-General for Statistics and Information Policy, MHLW

(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, Iitate Town, and Aizuwakamatsu City) due to the effect of the Great East Japan Earthquake.

Measures against Hepatitis

Overview

Basic Act on Hepatitis Measures



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

1 The basic direction to take in promoting the prevention of hepatitis and hepatitis-related medical care

- To reduce liver cirrhosis and liver cancer, and set as much reduction as possible of the incidence of liver cancer

6 Matters concerning surveys and research on hepatitis

- To evaluate and verify research achievements comprehensively, and promote hepatitis research as the basis for comprehensive promotion of measures against hepatitis so that the past achievements can be appropriately reflected on such measures

2 Matters concerning measures to take in preventing hepatitis

- Necessary to disseminate correct knowledge about hepatitis to prevent new infections,
- To promote preventive measures for infection of mother-to-child hepatitis B virus, and promote periodic hepatitis B vaccination.

7 Matters concerning promotion of research and development of medicine to use hepatitis- related medical care

- Necessary to proceed with research and development of hepatitis medicine-related new medicines, including medicines related to treatment of hepatitis B and cirrhosis, and make a prompt review of clinical trials and research in light of recent trends concerning hepatitis medicine

3 Matters concerning improvement of a system to use implementing hepatitis examinations and their capabilities

- To inform all citizens that they need to receive hepatitis virus test at least once
- To continue to develop a system that allows for examination of the hepatitis virus tests with due consideration to the convenience of the examinee..
- To make such efforts that a hepatitis virus test can be carried out together with a medical examination, while making the concerned parties understand, such as medical insurers and employers.

8 Matters concerning public awareness and dissemination of information concerning hepatitis is and matters concerning respect for the human rights of hepatitis patients, etc.

- Necessary to disseminate information and enlighten people to promote receipt of hepatitis virus tests, prevent new infections, discontinue unfair discrimination against hepatitis patients, protect their human rights, and create an environment where people can live a secure social life

4 Matters concerning securing of a system to use providing hepatitis-related medical care

- Necessary to further develop the regional hepatitis clinical care network so that all hepatitis patients can receive continuous and appropriate hepatitis medicine.
- To make further efforts for increase of hepatitis virus inspection and follow-up after the inspection
- Necessary to enlighten stakeholders such as business operators and get their understanding and cooperation so that the employees can receive medical treatment continuously while continuing to work

9 Other important matters concerning the promotion of hepatitis measures

- To strengthen and enhance support for hepatitis patients and their families, etc.
- To promote review of how to support cirrhosis and liver cancer patients.
- To require the national government to urge the local governments to make a plan and set a target concerning measures against hepatitis after consultation with the stakeholders based on the actual circumstances in the community
- To request each citizen to confirm his/her own hepatitis virus infection, have proper knowledge about the possibility of infection, act appropriately to prevent new infection, acquire correct knowledge and make efforts for responding appropriately not to cause discrimination against hepatitis patients, etc.

5 Matters concerning prevention of hepatitis and human resource development for hepatitis medical care

- Necessity to develop human resources with knowledge about the prevention of hepatitis infection and those capable of linking appropriate hepatitis care after infection is known, such as hepatitis medical coordinator.

Health Promotion Measures

Overview

History of National Health Promotion Measures

<p>1st National Health Promotion Measures (FY 1978-1988)</p>	<p>(Basic concept)</p> <ol style="list-style-type: none"> Lifetime health promotion <ul style="list-style-type: none"> Promotion of primary prevention of geriatric diseases Promotion of health promotion measures through three major elements (diet, exercises, and rest) (special focus on diet) 	<p>(Outline of measures)</p> <ol style="list-style-type: none"> Lifetime health promotion <ul style="list-style-type: none"> Establishment of health checkups and a complete health guidance system from infants and small children through to the elderly Establishment of health promotion bases <ul style="list-style-type: none"> Establishment of health promotion centers, municipal health centers, etc. Securing sufficient human resources, including public health nurses and dietitians Dissemination and enlightenment of health promotion <ul style="list-style-type: none"> 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. 	<p>(Guidelines, etc.)</p> <ul style="list-style-type: none"> 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)
<p>2nd National Health Promotion Measures (FY 1988-1999) (Active 80 Health Plan)</p>	<p>(Basic concept)</p> <ol style="list-style-type: none"> Lifetime health promotion 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) 	<p>(Outline of measures)</p> <ol style="list-style-type: none"> Lifetime health promotion <ul style="list-style-type: none"> Enhanced health checkup and guidance system from infants and small children through to the elderly Establishment of health promotion bases <ul style="list-style-type: none"> Establishment of health science centers, municipal health centers, health promotion facilities, etc. Securing sufficient manpower such as health fitness instructors, registered dietitians, and public health nurses Dissemination and enlightenment of health promotion <ul style="list-style-type: none"> Promoting the use of and revising recommended dietary allowances Promoting recommended exercise allowance Approving health promotion facilities Action plan for tobacco control Promoting a system of nutrition information labelling for meals eaten outside home Promoting cities with health oriented cultures and health resorts Conducting studies on health promotion, etc. 	<p>(Guidelines, etc.)</p> <ul style="list-style-type: none"> 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)
<p>3rd National Health Promotion Measures (FY2000-2012) (National Health Promotion in the 21st Century (Health Japan 21))</p>	<p>(Basic concept)</p> <ol style="list-style-type: none"> Lifetime health promotion <ul style="list-style-type: none"> 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 	<p>(Outline of measures)</p> <ol style="list-style-type: none"> National health promotion campaign <ul style="list-style-type: none"> 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 Implementation of effective medical examinations and health guidance <ul style="list-style-type: none"> Steady implementation of health checkups and health guidance with a focus on metabolic syndrome for insured persons/dependents aged 40 or older by Health Care Insurers (from FY2008) Cooperation with industry <ul style="list-style-type: none"> Further cooperation in voluntary measures of industries Human resource development (improving the quality of medical professionals) <ul style="list-style-type: none"> Improved training for human resource development in cooperation between the government, prefectures, relevant medical organizations, and medical insurance organizations Development of evidence-based measures <ul style="list-style-type: none"> Revision of data identification methods to enable outcome assessments 	<p>(Guidelines, etc.)</p> <ul style="list-style-type: none"> 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 guidelines for health promotion 2006 (Exercise Guide 2006) (2006) Japanese Dietary Reference Intake (2010 edition) (2009)
<p>4th National Health Promotion Measures (from FY 2013) (National Health exercise promotion (Health Japan 21 (2nd)))</p>	<p>[Basic Concept]</p> <ol style="list-style-type: none"> Extension of healthy life expectancy and reduction of health disparities Lifetime health promotion [prevention of onset and progression of lifestyle-related diseases, maintenance and improvement of functions necessary, establishment of social environment] Improvement of lifestyle and social environment Setting specific targets to serve as an indicator for national health/medical standards and promotion of health promotion measures based on assessments. 	<p>[Outline of measures]</p> <ol style="list-style-type: none"> Focusing on extension of healthy life expectancy and reduction of health disparity <ul style="list-style-type: none"> Comprehensive promotion for lifestyle diseases and promotion of efforts supporting areas such as medical and long-term care. Prevention of onset and progression of lifestyle diseases (Prevention of NCD (Non-Communicable Diseases)) <ul style="list-style-type: none"> Promotion measures focused on primary prevention of cancer, cardiovascular disease, diabetes and COPD in addition to prevention of progression. Maintenance and improvement of necessary functions for healthy social life. <ul style="list-style-type: none"> Promotion of mental health programs for mind, and health of the next generation and the elderly. Development of social environment for supporting and protecting health. <ul style="list-style-type: none"> Providing information on the activities of companies working voluntarily on promoting health and evaluating these activities. Improvement of lifestyle and social environment relating to nutrition, dietary habits, physical activity/exercise, rest, alcohol, smoking, dental and oral health, etc. <ul style="list-style-type: none"> 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. 	<p>[Guidelines, etc.]</p> <ul style="list-style-type: none"> 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)

Outline of the Health Promotion Act

Chapter 1. General Provisions

(1) Purpose

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

(2) Responsibilities

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

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

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

(1) Basic policies

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

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

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

(3) Guidelines on implementation of health checkups

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

Outline of Results of National Health and Nutrition Survey 2015

National Health and Nutrition Survey

- Objective: Amassing basic information for comprehensive promotion of national health in accordance with the Health Promotion Act (Act No.103 of 2002)
- Subjects: Households in 300 unit areas randomly selected from unit areas established in the Comprehensive Survey of Living Conditions 2015 (approximately 5,700 households), and members of households aged 1 or older (approximately 15,000 persons)
- Survey items: [Survey on physical condition] Height, weight, abdominal circumference, blood pressure, blood tests, number of steps taken when walking, interview (medication status, exercise)
[Survey on nutritional intake] Food intake, nutrient intake, etc., dietary situation (skipping meals, eating out, etc.)
[Survey on lifestyle] General lifestyle encompassing dietary habits, physical activities, exercise, rest (sleep), alcohol usage, smoking, dental health, etc.

Key points of the results of the survey

- <The younger generation has more problems in terms of nutritional balance>
- The younger generation are less likely to eat well-balanced meals based on the combination of staple foods, main dishes and side dishes. The frequency of eat out and use of take-away meals is high among this generation.
- For women in their 20s to 30s in particular, the intake of protein, calcium, dietary fiber, potassium, etc. tends to be lower than for people aged 60 years or above.
- < Passive smoking is reported with "restaurant" most often, exceeding 40% >
- Passive smoking is associated as follows: 41.4% with "restaurant", 33.4% with "game center" and 30.9% with "workplace".
- < Proportion of people sleeping for less than 6 hours per day on average has increased >
- The proportion has been increasing in the recent several years. The disturbing factors for less sleeping hours are "work" for men, and "child care" and "housework" for women.
- < The proportion of presumably helping each other in the community is increasing >
- The proportion of those thinking that "they help each other" in their community accounts for 55.9%, an increase of some 5 percentage points compared to the proportion in the previous survey (2011).

Detailed Data 1
Population Projection for Japan (Estimated in January 2012)
[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 2016	Plan to formulate in FY 2017	Plan to formulate in FY 2018 or later	No plan
Health center-designated cities	73	73	0	1	0	0
Special wards in Tokyo	23	23	0	0	0	0
Other municipalities	1,645	1,448	40	44	90	23

(As of January 1, 2017)

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

Prefecture	No. of municipalities	Formulated	Formulation rate	FY 2016	FY 2017	FY 2018 or later	No plan
Hokkaido	175	126	72.0%	3	7	34	5
Aomori	38	37	97.4%	1	0	0	0
Iwate	32	32	100.0%	0	0	0	0
Miyagi	34	34	100.0%	0	0	0	0
Akita	24	23	95.8%	0	0	1	0
Yamagata	35	35	100.0%	0	0	0	0
Fukushima	57	45	78.9%	1	3	6	2
Ibaraki	44	44	100.0%	0	0	0	0
Tochigi	24	24	100.0%	0	0	0	0
Gunma	33	32	97.0%	1	0	0	0
Saitama	60	50	83.3%	3	3	4	0
Chiba	51	30	58.8%	5	8	8	0
Tokyo	37	31	83.8%	1	0	1	4
Kanagawa	28	26	92.9%	1	0	1	0
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	17	17	100.0%	0	0	0	0
Yamanashi	27	27	100.0%	0	0	0	0
Nagano	76	66	86.8%	0	3	5	2
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	20	71.4%	4	2	1	1
Shiga	18	18	100.0%	0	0	0	0
Kyoto	25	18	72.0%	0	1	3	3
Osaka	37	34	91.9%	0	0	3	0
Hyogo	37	37	100.0%	0	0	0	0
Nara	38	27	71.1%	5	4	0	2
Wakayama	29	18	62.1%	1	0	6	4
Tottori	19	19	100.0%	0	0	0	0
Shimane	19	19	100.0%	0	0	0	0
Okayama	25	25	100.0%	0	0	0	0
Hiroshima	20	20	100.0%	0	0	0	0
Yamaguchi	18	18	100.0%	0	0	0	0
Tokushima	24	21	87.5%	1	2	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	30	53.6%	10	10	6	0
Saga	20	18	90.0%	0	0	2	0
Nagasaki	19	19	100.0%	0	0	0	0
Kumamoto	44	38	86.4%	0	1	5	0
Oita	17	17	100.0%	0	0	0	0
Miyazaki	25	25	100.0%	0	0	0	0
Kagoshima	42	40	95.2%	2	0	0	0
Okinawa	40	35	87.5%	1	0	4	0
	1,645	1,448	88.0%	40	44	90	23

(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	1,626	372,801	298.2
Diabetes mellitus	3,166	13,454	10.8
Hypertensive diseases	10,108	6,830	5.5
Heart diseases (excluding hypertensive)	1,729	197,807	158.2
Cerebrovascular diseases	1,179	109,233	87.4

Source:

<The estimated number of patients receiving medical treatment> "Patient Survey 2014", 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 (2016 preliminary data)

Detailed Data 3 Prevalence related to Diabetes

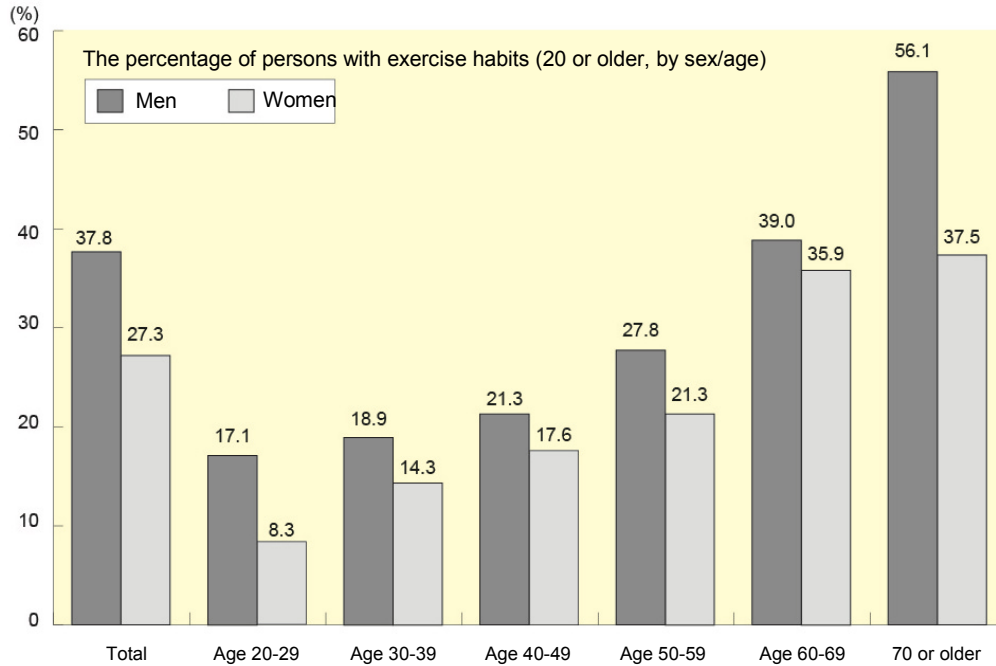
Age	Males (survey samples: 5,752)		Females (survey samples: 8,337)	
	Strongly suspected of having diabetes	With possibilities of having diabetes	Strongly suspected of having diabetes	With possibilities of having diabetes
20-29	0.6%	0.5%	0%	0.8%
30-39	1.4%	1.8%	1.1%	3.1%
40-49	5.4%	7.2%	1.7%	7.5%
50-59	12.2%	10.2%	6.2%	12.1%
60-69	20.7%	15.5%	12.6%	17.4%
70 or older	23.2%	17.7%	16.7%	20.8%

When the above figures are applied to the estimated population as of October 1, 2012, the estimated numbers nationwide are as follows:

- Those strongly suspected of having diabetes: approx. 9.5 million persons
- Those with possibilities of having diabetes: approx. 11 million persons

Source: "National Health and Nutrition Survey 2012", Health Service Bureau, MHLW

Detailed Data 4 Status of Exercise Habits



Source: "National Health and Nutrition Survey 2015", Health Service Bureau, MHLW

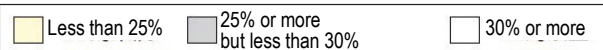
(Note) Persons with exercise habits: Those who have been continuing daily exercise of 30 minutes or longer at least 2 days a week for at least a year.

Detailed Data 5 Secular Trend in Distribution of Fat Energy Ratio (Aged 20 or Older)

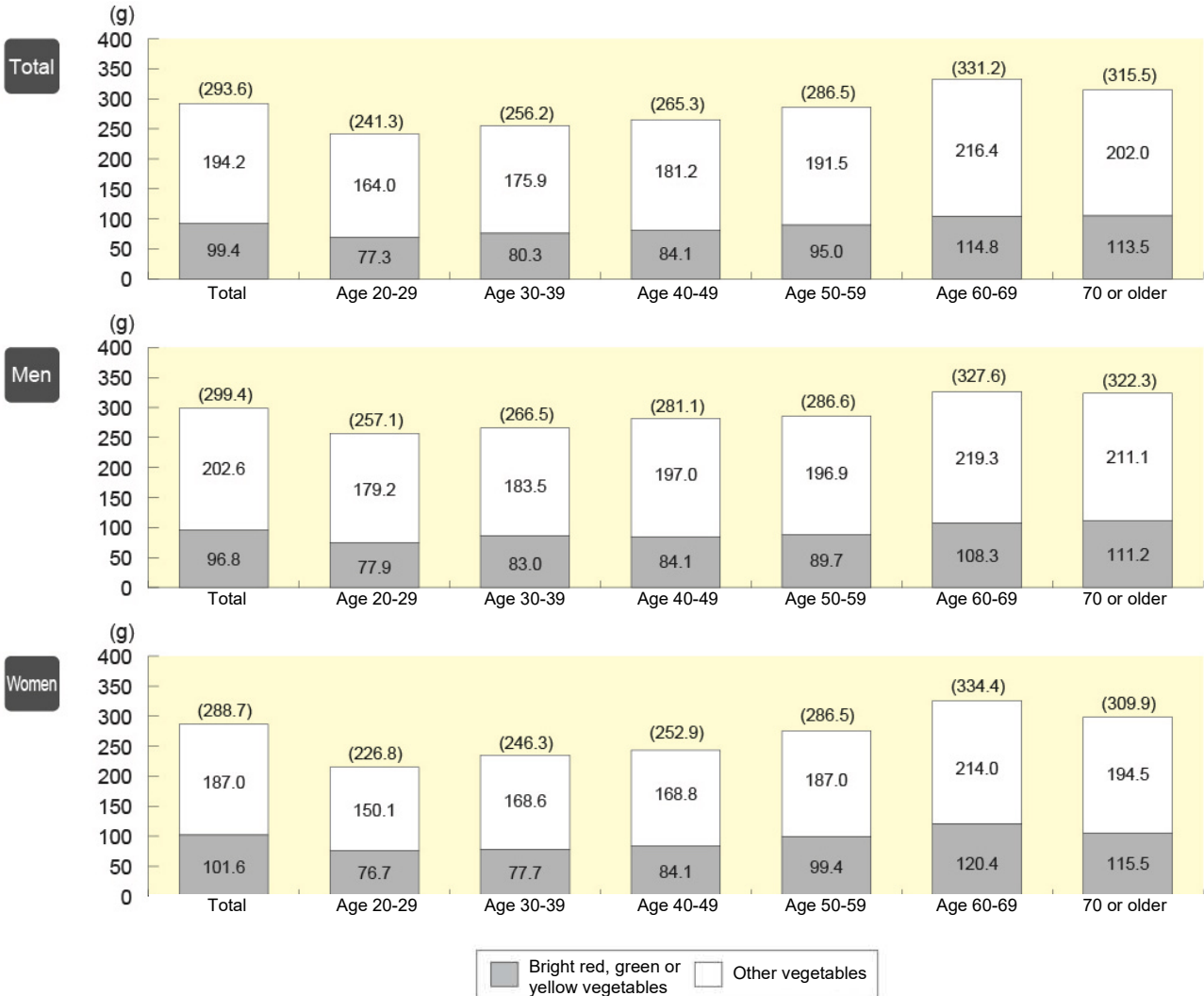


Source: "National Health and Nutrition Survey", Health Service Bureau, MHLW

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

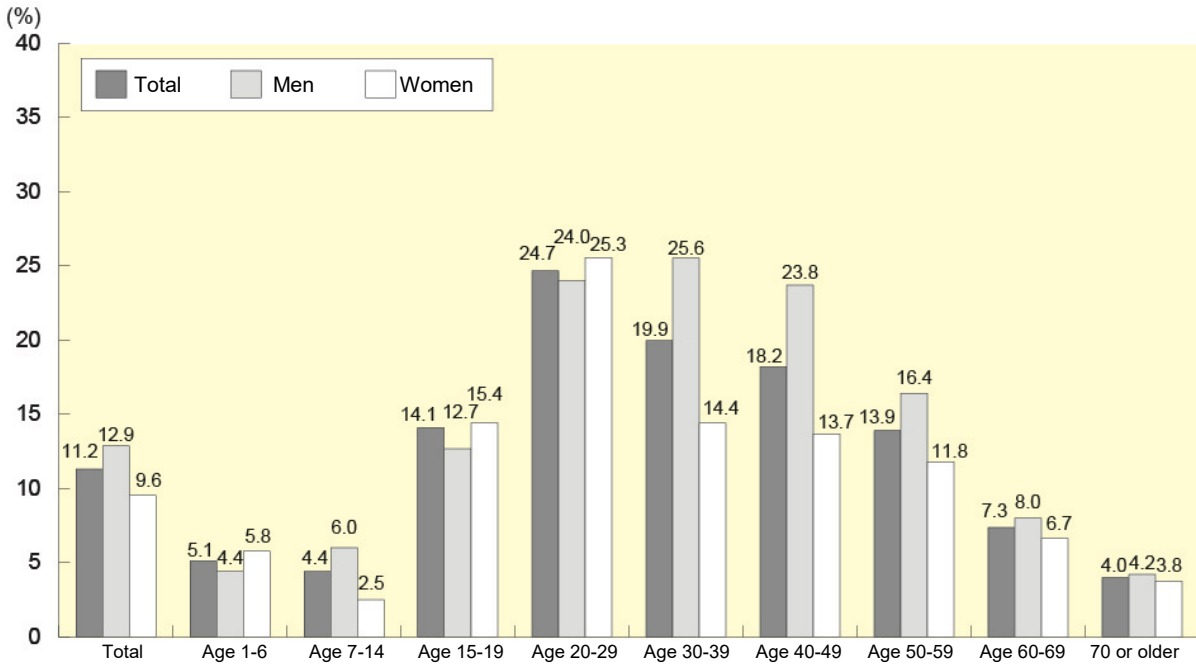


Detailed Data 6 Average Intake of Vegetables, etc. (Aged 20 or Older, by Sex/Age)



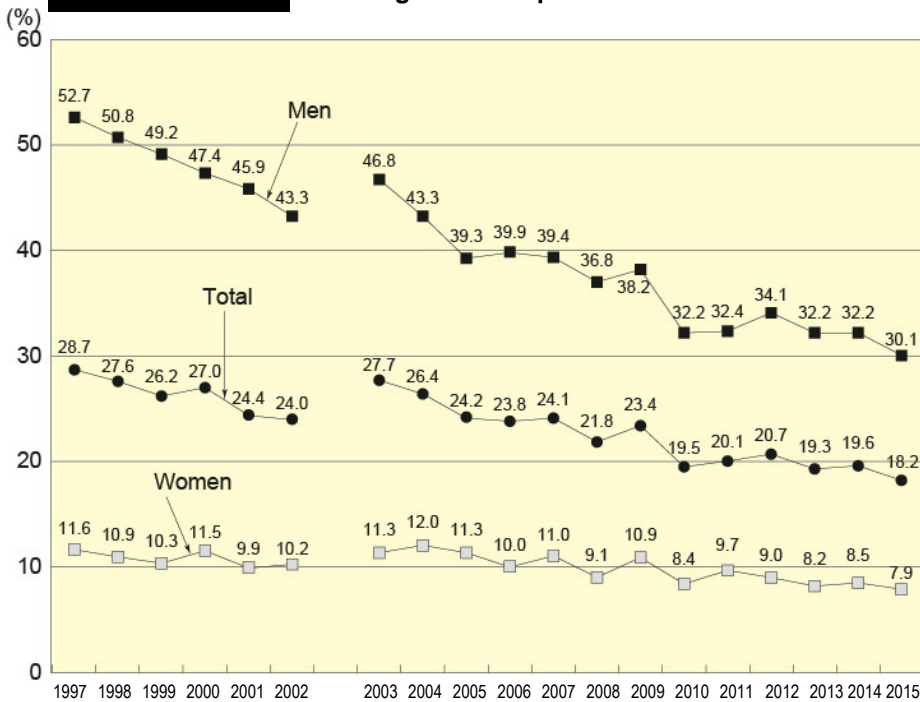
Source: "National Health and Nutrition Survey 2015", Health Service Bureau, MHLW
 (Note) The figures in parentheses indicate the total intake of "bright red, green or yellow vegetables" and "other vegetables (excluding bright red, green or yellow vegetables)".

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



Source: "National Health and Nutrition Survey 2015", Health Service Bureau, MHLW

Detailed Data 8 Smoking Rate in Japan



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.

Country	Men (%)	Women (%)
Japan	(32.2)	(8.4)
Germany	32.4	9.7
France	34.8	27.3
Netherlands	(33.3)	(26.5)
Italy	35.6	27.4
U.K.	(31.0)	(25.0)
Canada	28.1	22.1
U.S.A.	(28.3)	(16.2)
Australia	32.8	19.2
Sweden	(22.0)	(20.0)
	22.0	21.0
	(19.9)	(15.5)
	19.1	15.8
	(23.9)	(18.0)
	21.6	17.4
	(16.6)	(15.2)
	19.9	16.3
	(16.5)	(18.8)
	12.8	15.7

Source: WHO Tobacco ATLAS (2012) "National Health and Nutrition Survey 2011" for the figures for Japan

(Note) The figures in parentheses are from WHO Tobacco ATLAS (2009) and the National Health and Nutrition Survey 2010

Dental Health Promotion

Overview 8020 (Eighty-Two) Campaign

[History of 8020 (Eighty-Two) Campaign]

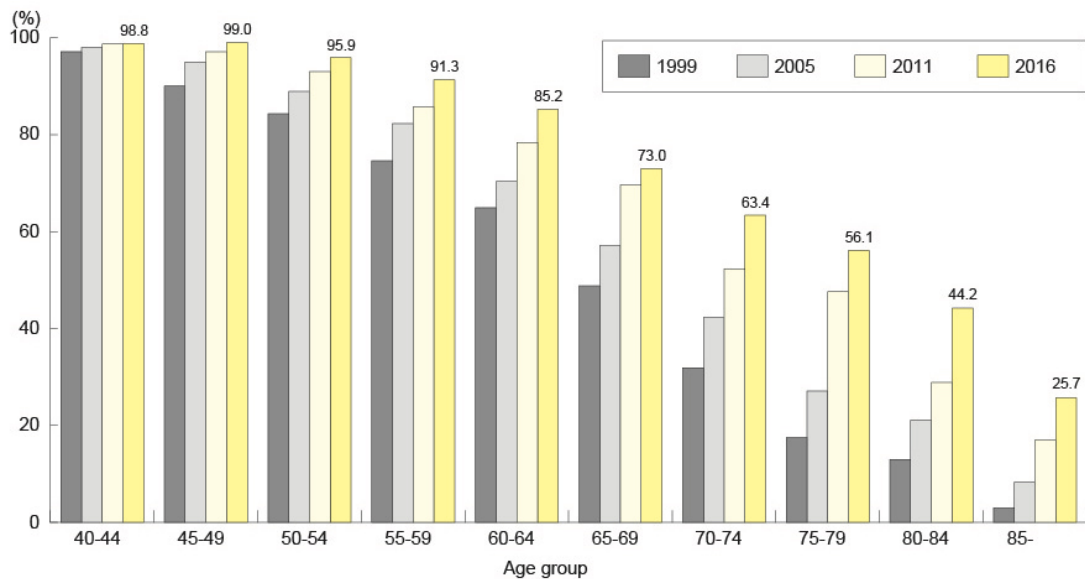
1989	A Study Group on the Dental Health Policy for Adults made public its interim report in which the “8020 (Eighty-Two) Campaign” calling for the retention of 20 or more teeth even at age 80 was proposed.
1991	“Promotion of 8020 Campaign” was set to be the major objective for the Dental Hygiene Week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

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

The “Basic Matters regarding the Advancement of Dental and Oral Health” and “Health Japan 21 (second campaign)”, announced in July 2012, mutually harmonized and provided further advancement of the “8020 Campaign”. Both set the goal of “raising the percentage of those retaining 20 or more teeth at age 80” and the FY2022 target value of 50%. Efforts for dental and oral health promotion through dental health measures (8020 Campaign) throughout life continue to be important.

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

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

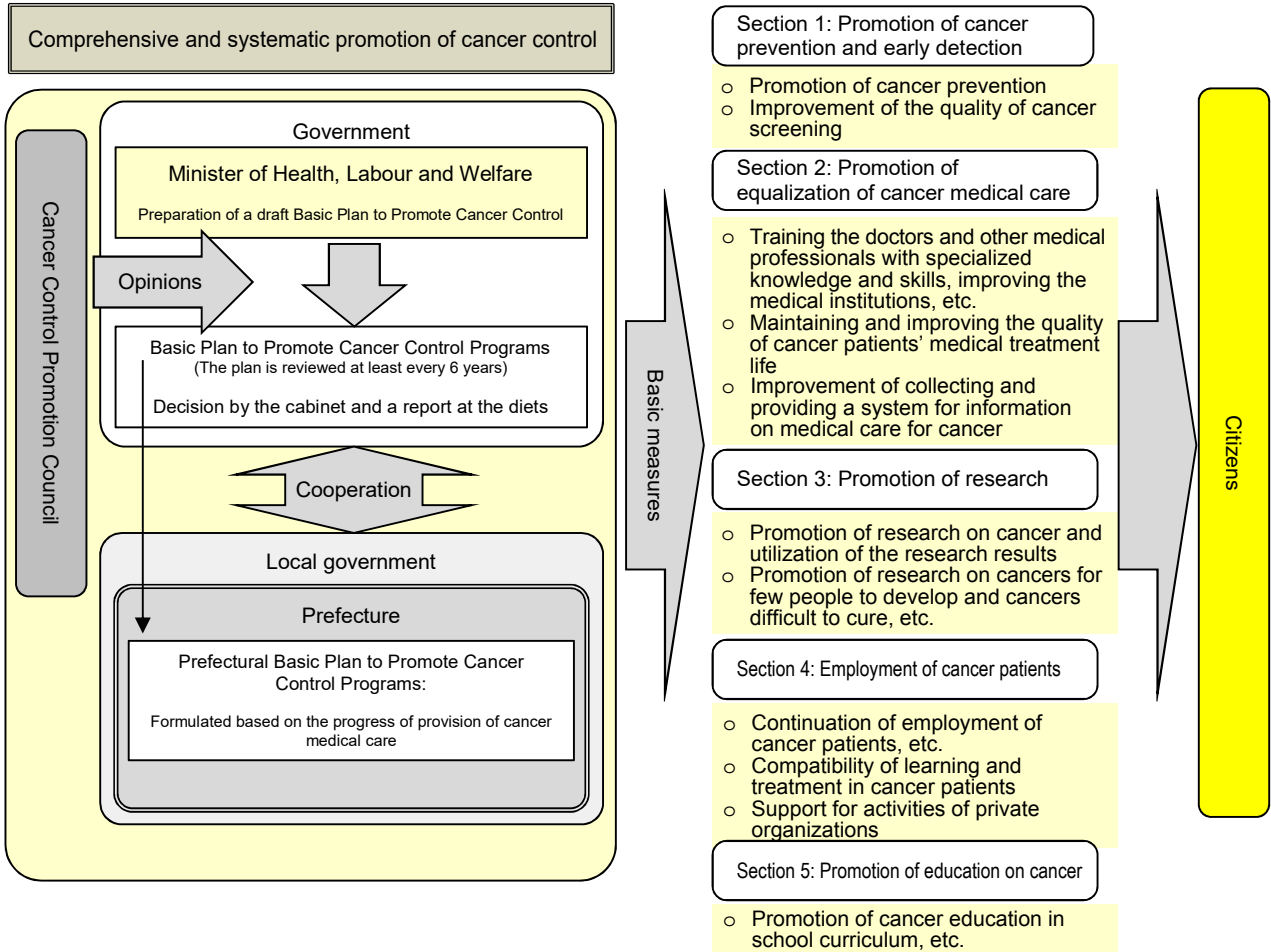


Source: “Survey of Dental Diseases”, Health Policy Bureau, MHLW

Cancer Control Measures

Overview

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



Basic Plan to Promote Cancer Control Programs (Cabinet decision on June 2012)

* Items included from the second term

Priority issues

(1) Further improvement of radiotherapy, chemotherapy, and surgical therapy, and development of the specialist medical professionals

(2) Promotion of palliative care from when first diagnosed with cancer

(3) Promotion of cancer registry

* (4) Improved cancer measures for the working generations and children

Overall goals [10 year goals from FY2007]

(1) Decreasing the number of deaths from cancer (20% decline in the age-adjusted mortality rate of those younger than 75)

(2) Reducing the pain of all cancer patients and their families, and maintaining or improving the quality of their recuperation

* (3) Establishing a society in which people can live with a sense of security even though they have cancer

Measures by area and individual goals in measuring their achievements

1. Cancer medical care

- [1] Further improved radiotherapy, chemotherapy, and surgical therapy, and promotion of team medical care
- [2] Development of specialist medical cancer care professionals
- [3] Promotion of palliative care from when first diagnosed with cancer
- [4] Establishment of regional medical/long-term care service provision systems
- (New) [5] Efforts to rapidly develop/approve drugs/medical devices, etc.
- [6] Other (rare cancers, pathological diagnoses, and rehabilitation)

5. Early detection of cancer

Achieving a cancer screening rate of 50% within five years (40% with gastric, lung, and colon cancer for the time being).

6. Cancer research

Further promotion of research that contributes to anti-cancer measures. Formulation of new comprehensive cancer research strategies that specify the future direction of cancer research and concrete research items in the respective areas within two years in cooperation with the relevant ministries and agencies.

2. Cancer consultation support and information provision

Establishment of a consultation support system that alleviates the worries of patients and their families and is easier of use.

* 7. Childhood cancer

Establishment of core childhood cancer hospitals and commencement of the establishment of core institutions for childhood cancer within five years.

3. Cancer registry

Improving the accuracy of cancer registry through establishing an effective prognosis investigation system and increasing the number of medical institutions that implement hospital-based cancer registry, including discussing legal establishments.

* 8. Education/dissemination/enlightenment on cancer

Discussions on the ideal cancer education for children and the promotion of cancer education within health education.

4. Cancer prevention

The achievement of an adult smoking rate of 12%, underage smoking rate of 0%, passive smoking rates of 0% at administrative/medical institutions, 3% at home, 15% at eating/drinking places by FY2022, and with no passive smoking at workplaces by FY2020.

* 9. Social issues that include employment for cancer patients

The aim of establishing a society in which people can work and live with a sense of security, even though they have cancer, through facilitating understanding at workplaces and improving consultation support systems after clarifying their needs and issues with employment.

Plan to Accelerate Cancer Control Programs (December 2015)

Cancer control programs are implemented in line with the Basic Plan to Promote Cancer Control Programs (June 2012). The Basic Plan sets, as one of the overall goals, a 20% of decrease in the age-adjusted mortality rate of those younger than 75 in ten years from FY2007. However, it is predicted that this goal cannot be achieved if no change is made. In response to an instruction given by the Prime Minister at the Cancer Summit held on June 1, 2015, it was decided that the Ministry of Health, Labour and Welfare plays a leading role in formulating a Plan to Accelerate Cancer Control Programs which specifies, among the areas mentioned in the Basic Plan, 1) areas that are delayed and need to be accelerated; 2) specific measures that should be taken in a short and intensive manner for areas that contribute to the decrease in the mortality rate by accelerating the above areas. Three pillars of this plan are "prevention of cancer," "cancer medical care and research" and "coexistence with cancer."

Specific measures to be implemented

Prevention

- (1) Cancer screening
 - Setting of goals for detailed cancer examination rate
 - Disclosure of cancer examination rate of municipalities and insurers and of case examples
 - Formulation of guidelines for cancer screening for insurers
 - Introduction of incentives for persons who undergo cancer screening
- (2) Anti-smoking measures
 - Examination of necessary measures taking into account the Framework Convention on Tobacco Control (FCTC) and overseas anti-smoking measures
 - MHLW continues to request for the increase of the tax on cigarettes
 - Strengthening of passive smoking preventive measures in view of the Rugby World Cup and the Tokyo Olympic and Paralympic Games
- (3) Hepatitis measures
 - Preventing cancer from becoming worse through reducing the co-payment by patients
- (4) Cancer education at school
 - Implementation of "Comprehensive Cancer Education Support Project"

Medical care and research

- (1) Genomic medicine for cancer
 - Survey on actual
 - Development of centers for accumulation of all genomic information
 - Examination on tests and medical care of familial cancer
- (2) Development and dissemination of standard cancer care
 - Verification of standard cancer care for the elderly patients and those with other diseases
- (3) Provision of information on cancer medical care
 - Establishment of designated cancer hospital search system that can simply search hospitals from the viewpoint of patients
- (4) Childhood cancer/cancer of adolescent and young adult and rare cancers
 - Examination of system to provide childhood cancer medical care and of long-term follow-up system
- (5) Cancer research
 - Promotion of researches based on the "Health and Medicine Strategy," "The Plan for Promotion of Medical Research and Development" and the "10-year cancer research strategy".

Coexistence with cancer

- (1) Job assistance
 - Provision of consultation support services by designated cancer hospitals with a focus on continuity of work.
 - Nationwide job assistance and seminars for business owners at Hello Work (Public employment security offices)
 - Support such as responses to consultations from businesses by consultants of Occupational Health Support Centers
 - Formulating guidelines for businesses and raising awareness about them
- (2) Development and dissemination of supportive care
 - Promotion of researches on supportive care
- (3) Palliative care
 - Holding on-site trainings for palliative care teams
 - Creating a collection of cases of screening methods of patients' pain
 - Fostering home-visiting nurses for regional cooperation

Prevent avoidable cancer

Decrease the number of deaths from cancer

Live with cancer

Overcome "cancer" and establish a vibrant society of good health and longevity

Outline of Cancer Registry Promotion Act

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

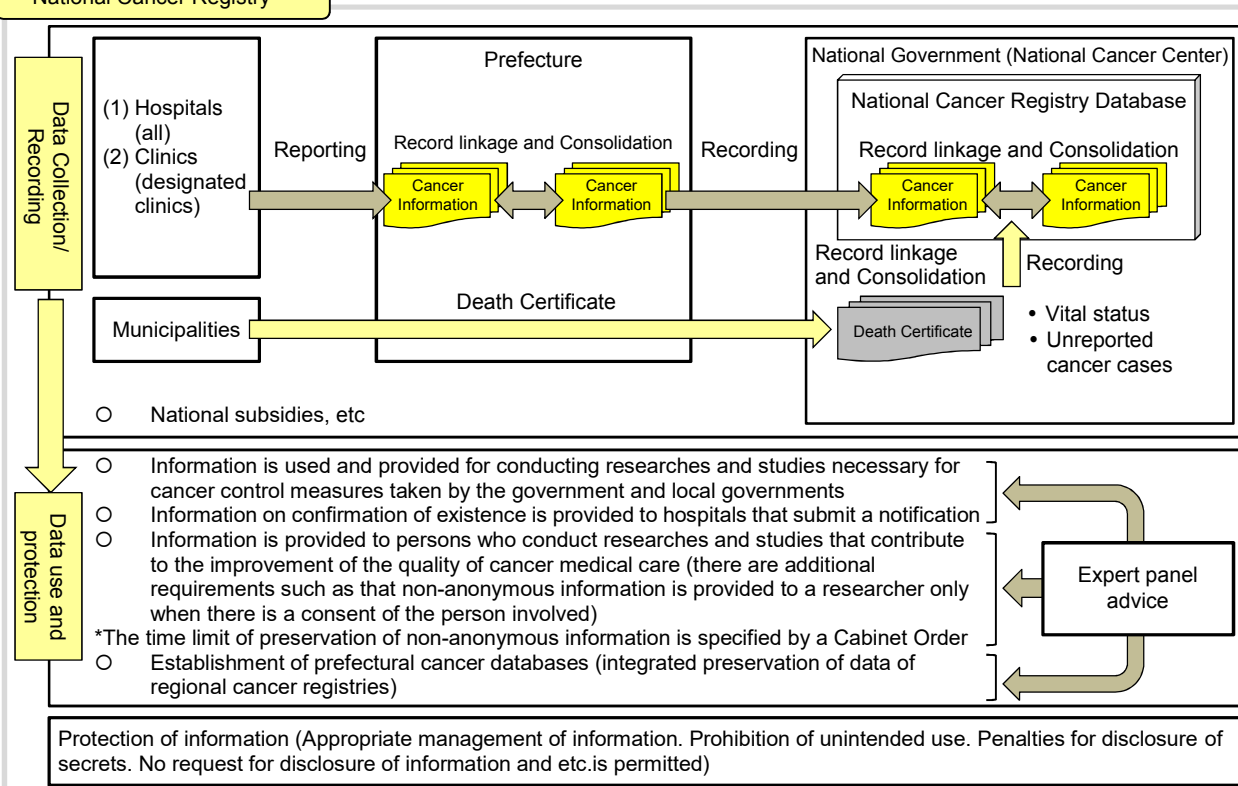
- National cancer registry: The government records and preserves information on cancers, treatment and outcomes in Japan in a database so that it is used and provided for the government and prefectures.
- Hospital-based cancer registry: Hospitals record and preserve detailed information on cancers, treatment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

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

National Cancer Registry



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

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

Utilization of cancer registries information

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

Detailed Data Statistics on Cancer

Item	Current status	Source
Number of deaths	<p>Total of 372,801 persons (28.5% of all causes of death) [219,672 males (32.6% of all causes of death)] [153,129 females (24.2% of all causes of death)] → "1 in every 3.5 Japanese die of cancer"</p>	Vital Statistics of Japan (2016 preliminary data)
Incidence rate	<p>865,238 persons (Not including carcinoma in situ) [503,970 males] Sites often affected: ① stomach, ② large intestine, ③ lung, ④ prostate, ⑤ liver [361,268 females] Sites often affected: ① breast, ② large intestine, ③ stomach, ④ lung, ⑤ uterus</p>	Estimates based on population-based cancer registry (2012)
Lifetime risk	<p>Male: 63%, Female: 47% → "1 in every 2 persons will contract cancer in Japan"</p>	Estimates by Center for Cancer Control and Information Services, National Cancer Center (2012)
Patients and persons receiving treatment	<p>The estimated number of patients receiving medical treatment is 1,626,000</p> <ul style="list-style-type: none"> •The estimated number of inpatients on the dates of survey is 129,400 •The estimated number of outpatients on the dates of survey is 171,400 	Patient Survey (2014)
Medical care expenditure for cancer	<p>¥3,448.8 billion * 11.8% of all medical care expenditures for general practice</p>	Estimates of National Medical Care Expenditure (FY 2014)

Measures against allergic diseases

Overview

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

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

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

Basic principles

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

Basic Guidelines for Promotion of Control Measures for Allergic Diseases

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

Ministry of Health, Labour and Welfare

Allergic Disease Control Promotion Council

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

(Members)

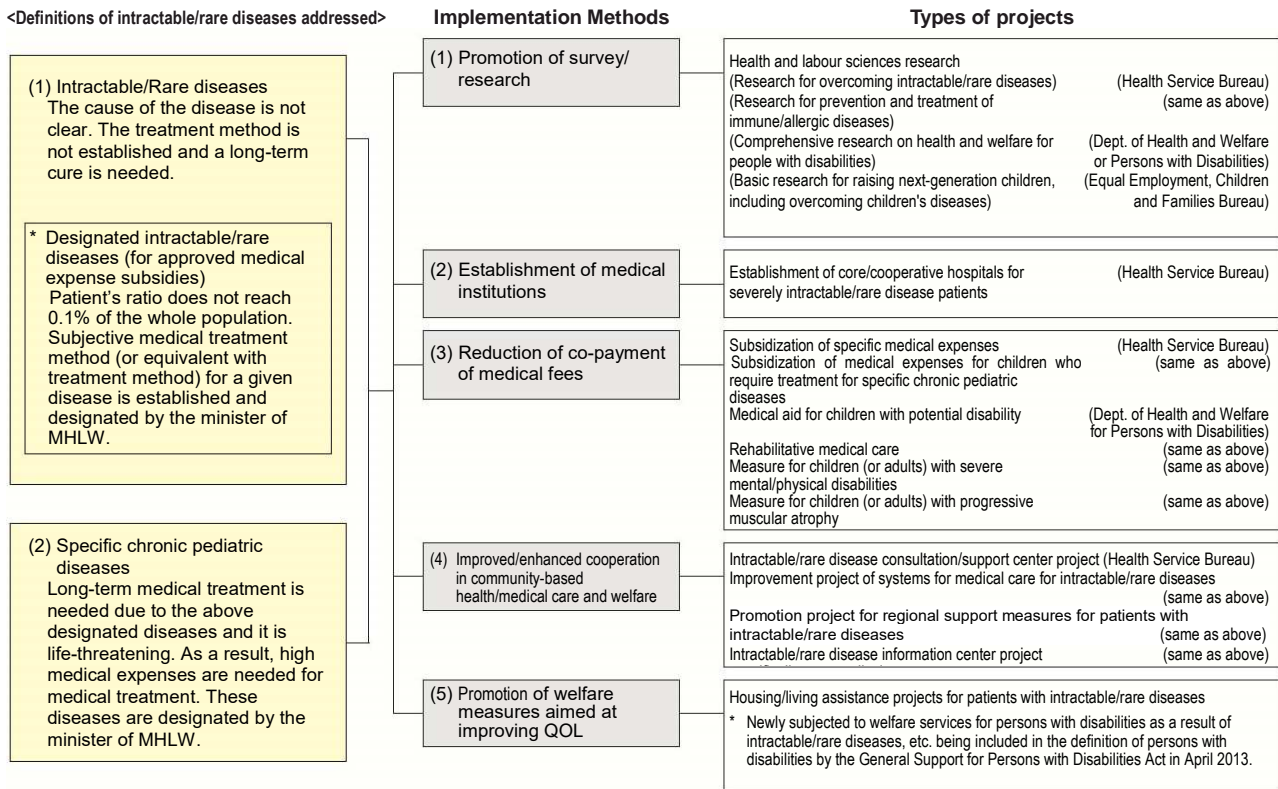
- Patients and their representatives
- Persons who involve in medical care for allergic diseases
- Persons who have academic experience

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

Intractable/Rare Disease Measures

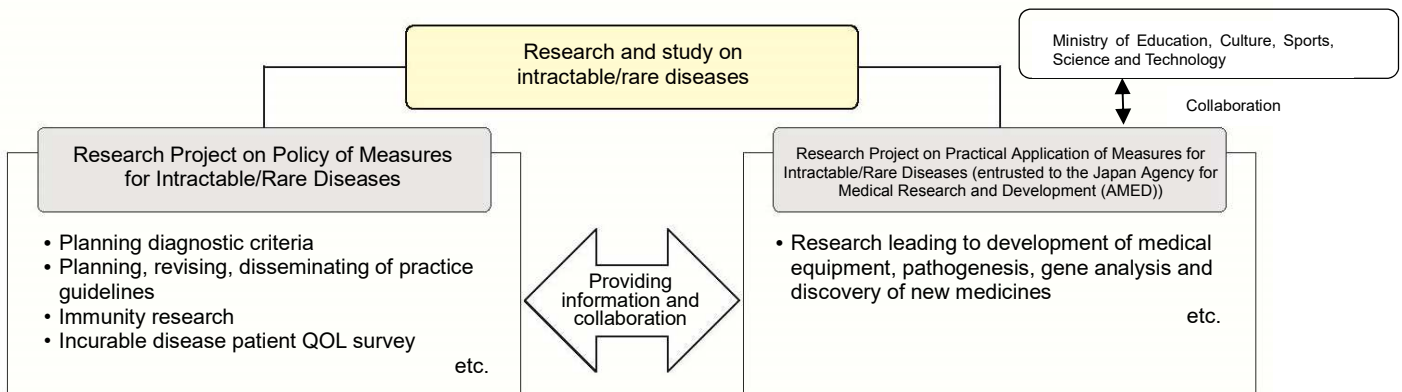
Overview Outline of Intractable/Rare Disease Measures

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

Detailed Data Designated intractable/rare diseases

No.	Disease Name
307	Canavan disease
308	Progressive leukoencephalopathy
309	Progressive myoclonic epilepsy
310	Congenital syndrome
311	Congenital tricuspid stenosis
312	Congenital mitral valve stenosis
313	Congenital pulmonary vein stenosis
314	Left pulmonary artery right pulmonary artery initiation
315	Nail Patera syndrome/LMX 1 B-related nephropathy
316	Carnitine circuit disorder
317	Triple enzyme deficiency
318	Citrin deficiency
319	Sepiapterin reductase (SR) deficiency
320	Congenital glycosylphosphatidylinositol (GPI) deficiency
321	Nonketotic hyperglycinemia
322	β -ketothiolase deficiency
323	Aromatic L-amino acid decarboxylase deficiency
324	Methyl glutamic nuria
325	Hereditary autoinflammatory disease
326	Marble bone disease
327	Idiopathic thrombosis (limited to those due to hereditary thrombophilia)
328	Anomalous anterior segment formation
329	Aniridia
330	Congenital tracheal stenosis

Infectious Disease Measures

Overview

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

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

Preventive administrative measures against outbreak and spread of infectious diseases

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

Types of infectious diseases and medical care system

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

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

Development of hospitalization procedures respecting patients' human rights

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

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

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

Development of countermeasures against zoonoses



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

Development of regulation on possession of pathogens, etc.



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

Development of measures against novel influenza



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

Immunization

Overview

Diseases and Persons Subjected to Routine Vaccination

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

* 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

Category 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) ¥36,300 Inpatient: less than 8 days per month: (month) ¥34,300 Outpatient: 3 days or more per month: (month) ¥36,300 Outpatient: less than 3 days per month: (month) ¥34,300 Inpatient and outpatient treatment within the same month: (month) ¥36,300	Medical allowance	Same as above	Inpatient: 8 days or more per month: (month) ¥36,300 Inpatient: less than 8 days per month: (month) ¥34,300 Outpatient: 3 days or more per month: (month) ¥36,300 Outpatient: less than 3 days per month: (month) ¥34,300 Inpatient and outpatient treatment within the same month: (month) ¥36,300
Pension for rearing children with disabilities	Fosterers of children younger than 18 with certain disabilities caused by vaccination	Class 1: (annual) ¥1,549,200 (additional amount for long-term care):(annual) (¥841,000) Class 2: (annual) ¥1,239,600 (additional amount for long-term care):(annual) (¥560,600)	Disability Pension	Those aged 18 or older with certain disabilities caused by vaccination	Class 1: (annual) ¥2,752,800 Class 2: (annual) ¥2,203,200
Disability Pension	Those aged 18 or older with certain disabilities caused by vaccination	Class 1: (annual) ¥4,954,800 (additional amount for long-term care):(annual) (¥841,000) Class 2: (annual) ¥3,966,000 (additional amount for long-term care):(annual) (¥560,600) Class 3: (annual) ¥2,974,800	Survivors' Pension	The bereaved will be beneficiary in case the deceased who died from vaccination was the main wage earner of the family (Pension shall be paid up to 10 years)	(annual) ¥2,408,400
Lump-sum death benefit	The bereaved of the person who died of diseases caused by vaccination	¥43,400,000	Lump-sum benefit for survivors	The bereaved will be beneficiary in case the deceased who died from vaccination was not the main wage earner of the family	¥7,225,200
Funeral allowance	Hosts of funerals for those who died of diseases caused by vaccination	¥206,000	Funeral allowance	Hosts of funerals for those who died of illness caused by vaccination	¥206,000

* Deadline for claiming a health problem in category B diseases

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

Tuberculosis Measures

Overview Outline of Tuberculosis Prevention Measures

- A. Regular physical checkups (tuberculin test, X-ray test, etc.) — Elderly (over 65), (high school) students, employees working at school and hospitals, and facility residents

- B. Regular preventive vaccination (BCG) — Infants younger than 1 year old

- C. Patient management
 - Notification — At the time of diagnosis and admission/discharge from hospital.
 - Registration — Tuberculosis registration cards, identification of the current situation of patients
 - Medication advice — Home-visit, health education, etc.
 - Screening for proper disease management — Persons requiring follow-ups, patients who have suspended treatment, etc.

- D. Infection prevention
 - Contact health examination — Health examination to contact person with tuberculosis patients
 - Work restriction, etc. — Work restrictions to tuberculosis patients
 - Admission recommendation — Admission recommendation to tuberculosis patients .

- E. Medical care (public fund)
 - Hospitalization care — Medical care expenses for tuberculosis patients who have been given recommendation/order for hospitalization
 - 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 population)
1960	489,715	524.2	31,959	34.2
1965	304,556	309.9	22,366	22.8
1970	178,940	172.3	15,899	15.4
1975	108,088	96.6	10,567	9.5
1980	70,916	60.7	6,439	5.5
1985	58,567	48.4	4,692	3.9
1990	51,821	41.9	3,664	3.0
1995	43,078	34.3	3,178	2.6
1999	43,818	34.6	2,935	2.3
2000	39,384	31.0	2,656	2.1
2001	35,489	27.9	2,491	2.0
2002	32,828	25.8	2,317	1.8
2003	31,638	24.8	2,337	1.9
2004	29,736	23.3	2,330	1.8
2005	28,319	22.2	2,296	1.8
2006	26,384	20.6	2,269	1.8
2007	25,311	19.8	2,194	1.7
2008	24,760	19.4	2,220	1.8
2009	24,170	19.0	2,159	1.7
2010	23,261	18.2	2,129	1.7
2011	22,681	17.7	2,166	1.7
2012	21,283	16.7	2,110	1.7
2013	20,495	16.1	2,087	1.7
2014	19,615	15.4	2,100	1.7
2015	18,280	14.4	1,956	1.6
2016	17,625	13.9	* 1,889	* 1.5

Source: <Number of newly registered patients / prevalence rate>
 "Aggregate Result of the Annual Reports of Surveillance of Tuberculosis", Health Service Bureau, MHLW
 <Number of deaths / Death rates>
 "Vital Statistics", Vital, Health and Social Statistics Office to the Director-General for Statistics and Information Policy, MHLW

(Note) 1. The figures for 1998 and later do not include those of atypical mycobacteria positive.
 2. The figures indicated by "*" are preliminary data.

Detailed Data 2 Tuberculosis Incidence by Prefecture (as of the end of 2016)

	Prefecture or City	Incidence
Prefectures with the lowest incidence	Yamagata	7.2
	Nagano	7.9
	Miyagi	7.9
	Akita	8.5
	Fukushima	8.6
Prefectures with the highest incidence	Osaka	22.0
	Tokyo	17.2
	Aichi	16.9
	Gifu	16.3
	Tokushima	16.0

Detailed Data 3 International Comparison of Tuberculosis Incidence

Country	Incidence
U.S.A.	2.8
Canada	4.6
Sweden	8.0
Australia	5.2
Netherlands	5.0
Denmark	5.6
France	7.0
U.K.	9.0
Japan	13.9

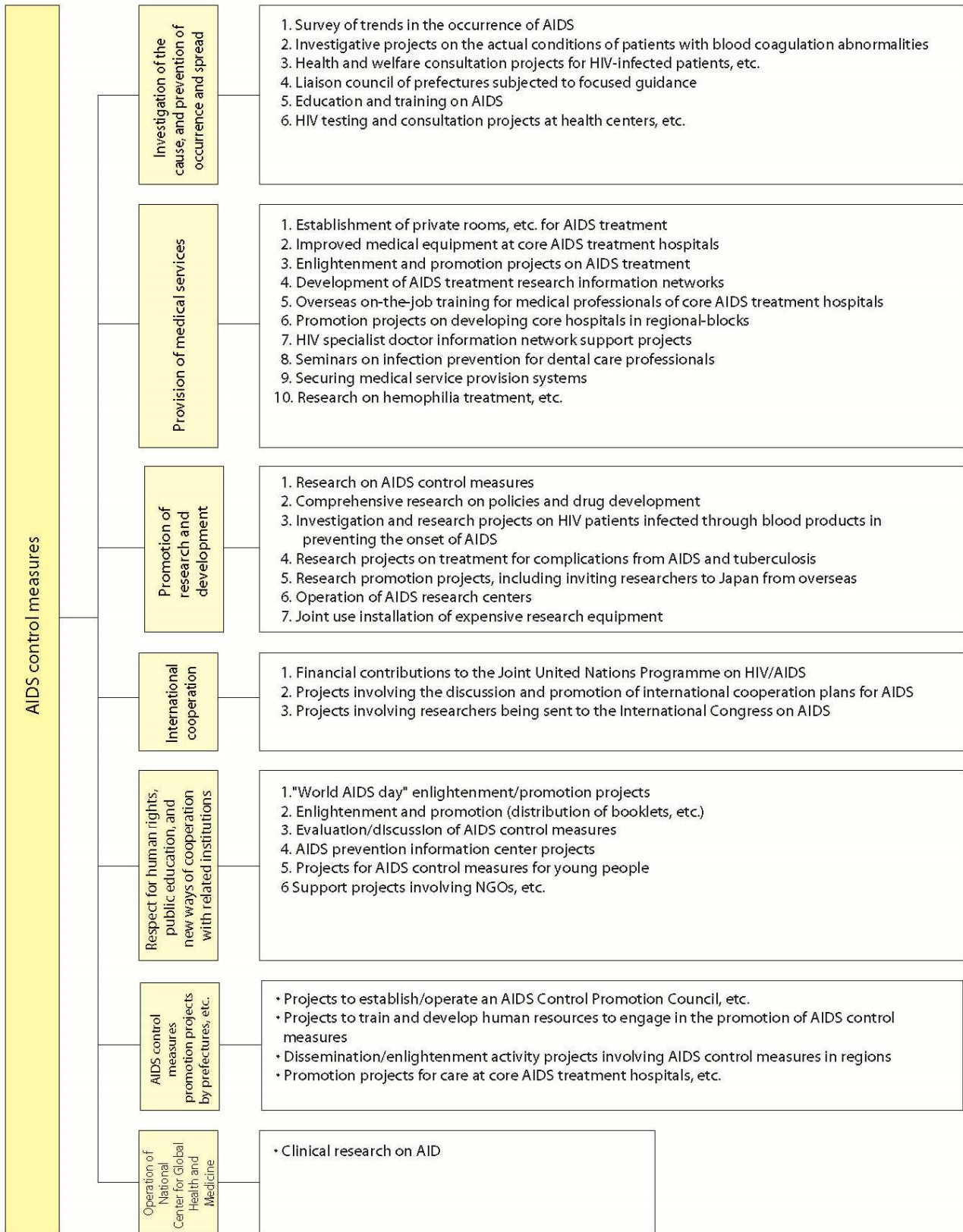
Source: WHO's global tuberculosis database

*Data is referred to one at 2015 except Japan.

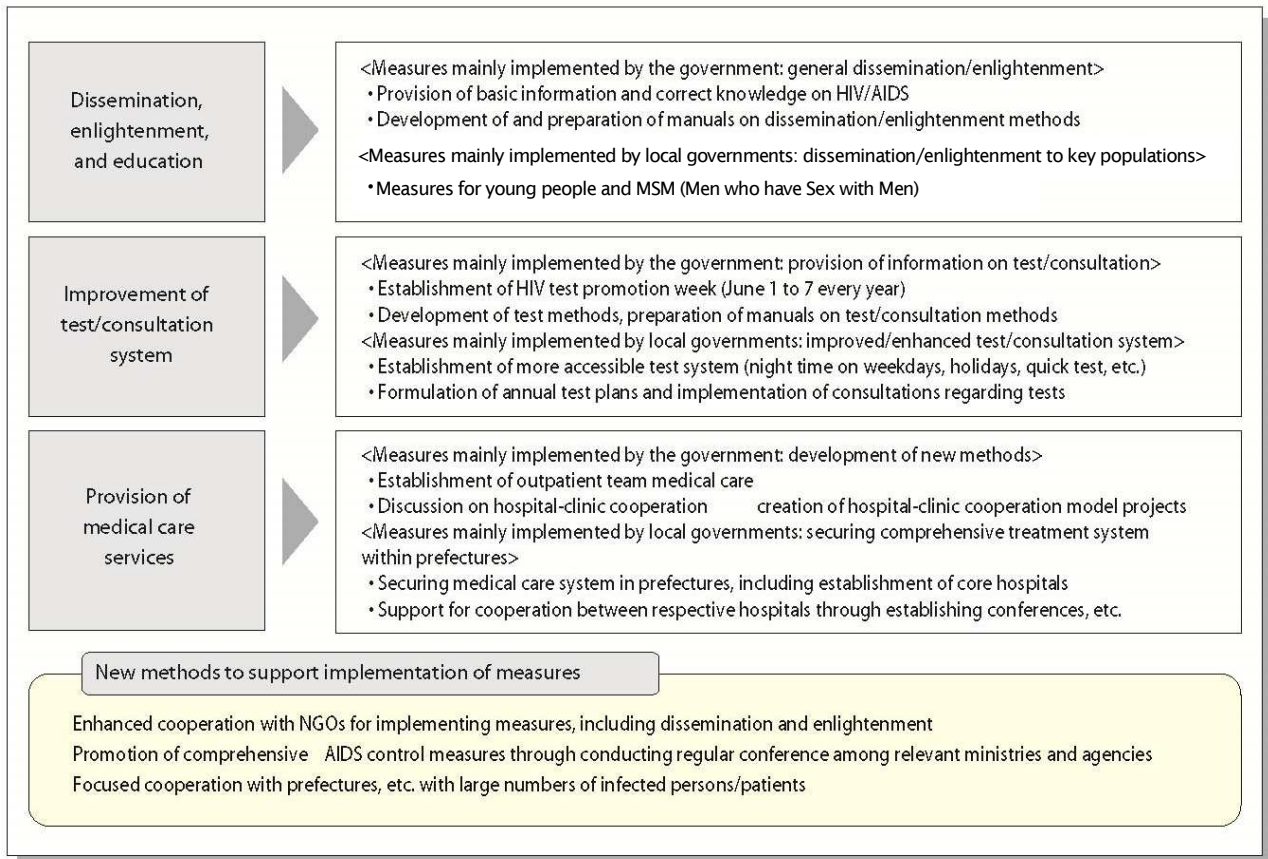
AIDS Control Measures

Overview

Outline of AIDS Control Measures



3 important areas on which measures should be focused



Detailed Data 1

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

Category	Nationality	Gender	1985	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	Total	Total % of
HIV	Japan	Male	0	0	34	15	35	27	52	108	102	134	147	189	234	261	379	336	475	481	525	636	709	787	931	999	894	956	923	889	963	959	860	14,040	78.4
		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	914	5.1
		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	14,954	83.5
	Foreign national	Male	0	0	10	4	21	11	26	45	33	37	47	65	49	58	39	53	59	55	48	62	60	76	76	60	71	59	71	65	97	82	88	1,527	8.5
		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	1,428	8.0
		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	2,955	16.5
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	17,909	100.0
AIDS	Japan	Male	5	3	6	9	15	18	24	36	53	91	108	156	170	158	212	239	221	232	252	290	291	335	343	359	386	421	419	387	438	409	379	6,465	80.0
		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	359	4.4
		Total	5	3	9	11	17	21	24	37	58	100	119	171	182	168	224	260	245	252	271	309	302	355	365	378	401	436	435	405	449	422	390	6,824	84.4
	Foreign national	Male	1	2	3	3	4	10	14	13	19	28	33	45	39	42	46	41	61	36	39	54	49	33	34	32	21	29	21	31	28	26	30	867	10.7
		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	395	4.9
		Total	1	2	5	3	4	10	14	14	28	36	50	63	68	63	77	69	67	87	56	65	76	65	51	53	53	30	33	38	42	35	33	38	1,262
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	8,086	100.0

Source: "AIDS Surveillance Report 2015", 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 2015, UNAIDS Report)

Region		Number of HIV infected patients (adults/children)	Number of newly infected HIV patients (adults/children)	Percentage of HIV-positive adults (%)	Number of persons died from AIDS (adults/children)
Asia Pacific	2015	5.10 million [4,400,000-5,900,000]	0.30 million [240,000-380,000]	0.2 [0.2-0.2]	0.18 million [150,000-220,000]
	2010	4.70 million [4,100,000-5,500,000]	0.31 million [270,000-360,000]	0.2 [0.2-0.2]	0.24 million [200,000-270,000]
East/South Africa	2015	19.00 million [17,700,000-20,500,000]	960,000 [830,000-1,100,000]	7.1 [6.6-7.6]	0.47 million [390,000-560,000]
	2010	17.20 million [16,100,000-18,500,000]	1.10 million [1,000,000-1,200,000]	7.6 [7.1-8.1]	0.76 million [670,000-860,000]
Eastern Europe, Central Asia	2015	1.50 million [1,400,000-1,700,000]	0.19 million [170,000-200,000]	0.9 [0.8-0.9]	47,000 [39,000-55,000]
	2010	1.00 million [950,000-1,100,000]	0.12 million [110,000-130,000]	0.6 [0.5-0.6]	38,000 [33,000-45,000]
Latin America / Caribbean Coast	2015	2.00 million [1,700,000-2,300,000]	0.10 million [86,000-120,000]	0.5 [0.4-0.6]	0.05 million [41,000-59,000]
	2010	1.80 million [1,500,000-2,100,000]	0.10 million [86,000-120,000]	0.5 [0.4-0.6]	0.06 million [51,000-70,000]
Middle East / North Africa	2015	0.23 million [160,000-330,000]	0.21 million [12,000-37,000]	0.1 [<0.1-0.2]	12,000 [8,700-16,000]
	2010	0.19 million [150,000-240,000]	0.02 million [15,000-29,000]	<0.1 [<0.1-0.1]	9,500 [7,400-12,000]
Western/Central Africa	2015	6.50 million [5,300,000-7,800,000]	0.41 million [310,000-530,000]	2.2 [1.8-2.7]	0.30 million [250,000-430,000]
	2010	6.30 million [5,200,000-7,700,000]	0.45 million [350,000-560,000]	2.6 [2.1-3.1]	0.37 million [290,000-470,000]
Western Europe / Central Europe / North America	2015	2.40 million [2,200,000-2,700,000]	91,000 [89,000-97,000]	0.3 [0.3-0.4]	22,000 [20,000-24,000]
	2010	2.10 million [1,900,000-2,300,000]	92,000 [89,000-97,000]	0.3 [0.3-0.4]	29,000 [27,000-31,000]
Total	2015	36.70 million [34,000,000-39,800,000]	2.10 million [1,800,000-2,400,000]	0.8 [0.7-0.9]	1.10 million [940,000-1,300,000]
	2010	33.30 million [30,800,000-36,100,000]	2.20 million [2,000,000-2,500,000]	0.8 [0.7-0.8]	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 2016 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. If the virus mutates into a form that can spread among humans, it could have a significant impact on people's well-being, health, lives and the national economy. The government is therefore implementing the following pandemic preparedness and response measures.

(Assumptions made in the National Action Plan)

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

Major events

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

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	National and local stockpiles for a total use of approx. 55.03 million people by FY 2016
Stockpiles of H5N1 pre-pandemic vaccine	Priority is given to stockpiling of vaccine stocks with a high "importance in crisis management". In FY2016, Chin Hai stocks are manufactured with its stockpile for about 10 million people as a goal.
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

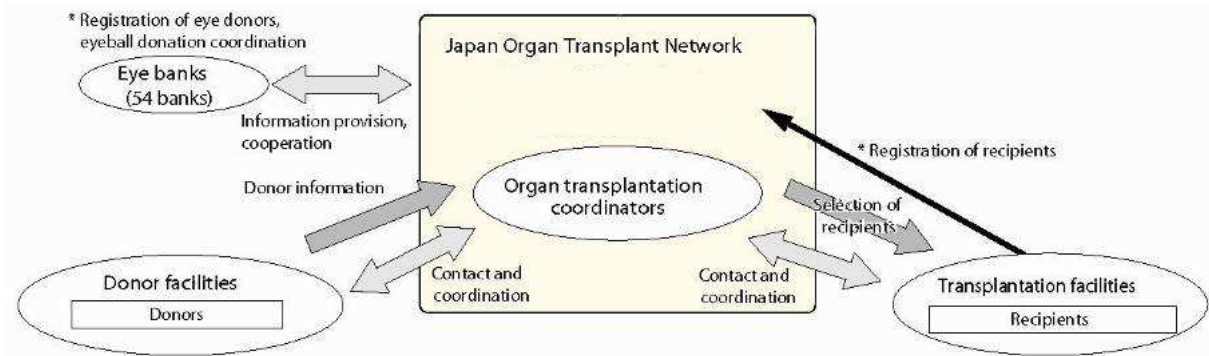
Overview Organ Transplantation System

[Organ Transplantation System]

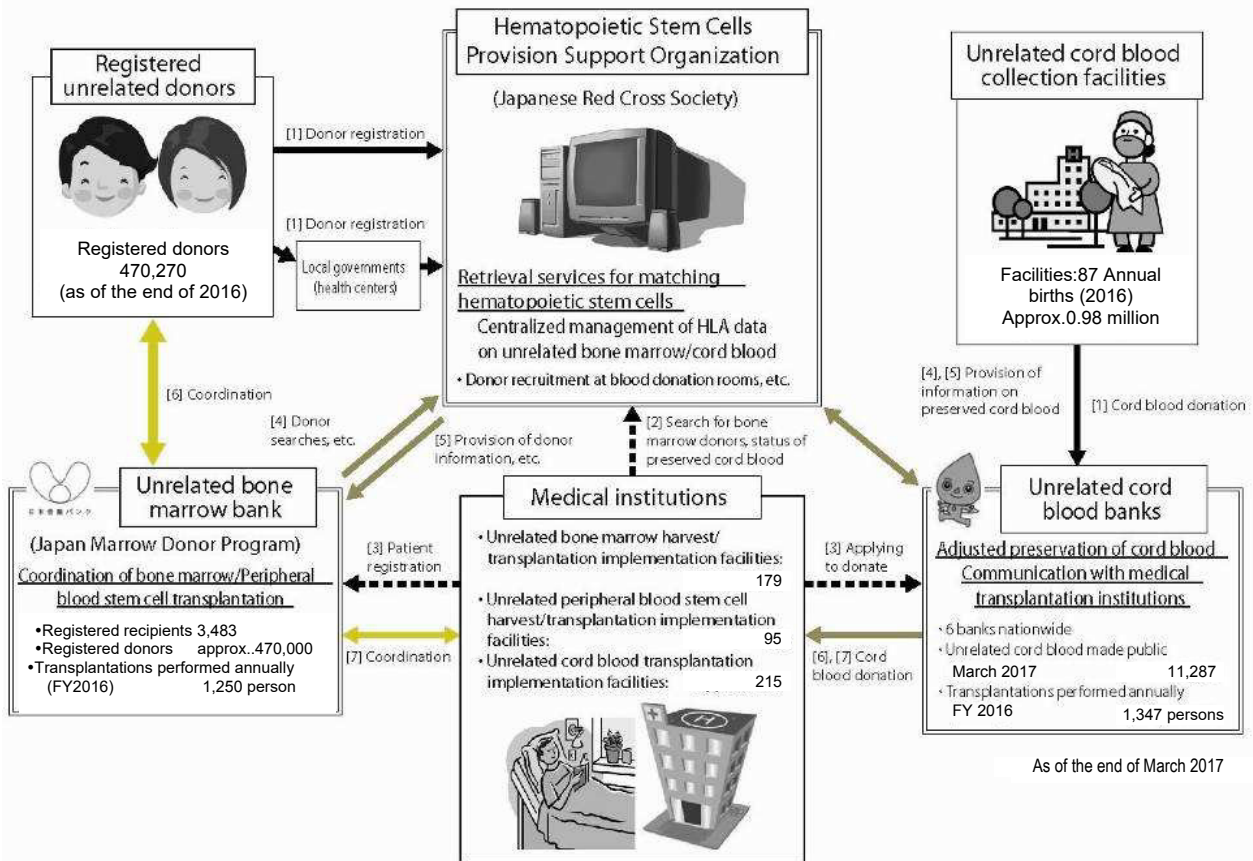
The traditional kidney transplantation system was reviewed and a new centralized nationwide kidney transplantation network established in FY1995. Enforcement of the "Act on Organ Transplantation" in October 1997 enabled multiple organ transplantations and the pertinent network.

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, etc.), mediation work, including enlightenment and promotion activities, is being carried out by eye banks at 54 locations nationwide.

Diagram of Organ Transplantation Network System



Unrelated Hematopoietic Stem Cell Transplantation System



Detailed Data 1 Accumulated Number of Organ Transplantations

	Number of donors		Number of transplantations performed		Patients on waiting lists
		Under brain death		Under brain death	
Heart	331 persons	331 persons	331 cases	331 cases	587 persons
Lung	290 persons	290 persons	350 cases	350 cases	319 persons
Liver	364 persons	364 persons	392 cases	392 cases	325 persons
Kidney	1,783 persons	406 persons	3,309 cases	799 cases	12,432 persons
Pancreas	297 persons	293 persons	296 cases	293 cases	194 persons
Small intestine	14 persons	14 persons	14 cases	14 cases	3 persons
Eyeball (cornea)	18,378 persons	179 persons	29,713 cases	341 cases	2,042 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, 2017. The number of patients on waiting lists is as of March 31, 2017.
 2. There have been 442 cases of brain death tests conducted nationwide under the Act on Organ Transplantation since the enforcement of the law until March 31, 2017. In the eighth case, 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 donors of pancreases and kidneys, the number of transplantations performed, and the number of patients on waiting lists include cases of simultaneous pancreas and kidney transplantations.
 4. The number of donors of hearts and lungs, the number of transplantations performed, and the number of patients on waiting lists include cases of simultaneous heart and lung transplantations.

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

	Unrelated donors		Number of unrelated transplantations		
	Number of registered donors	Number of registered cord blood	Bone marrow	Peripheral blood stem cell	Cord blood
FY 1991	3,176	-	-	-	-
FY 1992	19,829	-	8	-	-
FY 1993	46,224	-	112	-	-
FY 1994	62,482	-	231	-	-
FY 1995	71,174	-	358	-	-
FY 1996	81,922	-	363	-	1
FY 1997	94,822	-	405	-	19
FY 1998	114,354	-	482	-	77
FY 1999	127,556	-	588	-	117
FY 2000	135,873	4,343	716	-	165
FY 2001	152,339	8,384	749	-	221
FY 2002	168,413	13,431	739	-	296
FY 2003	186,153	18,424	737	-	699
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
Total	-	-	20,266	281	14,513

Source: Japan Marrow Donor Program, Japan Cord Blood Bank Network

* 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.

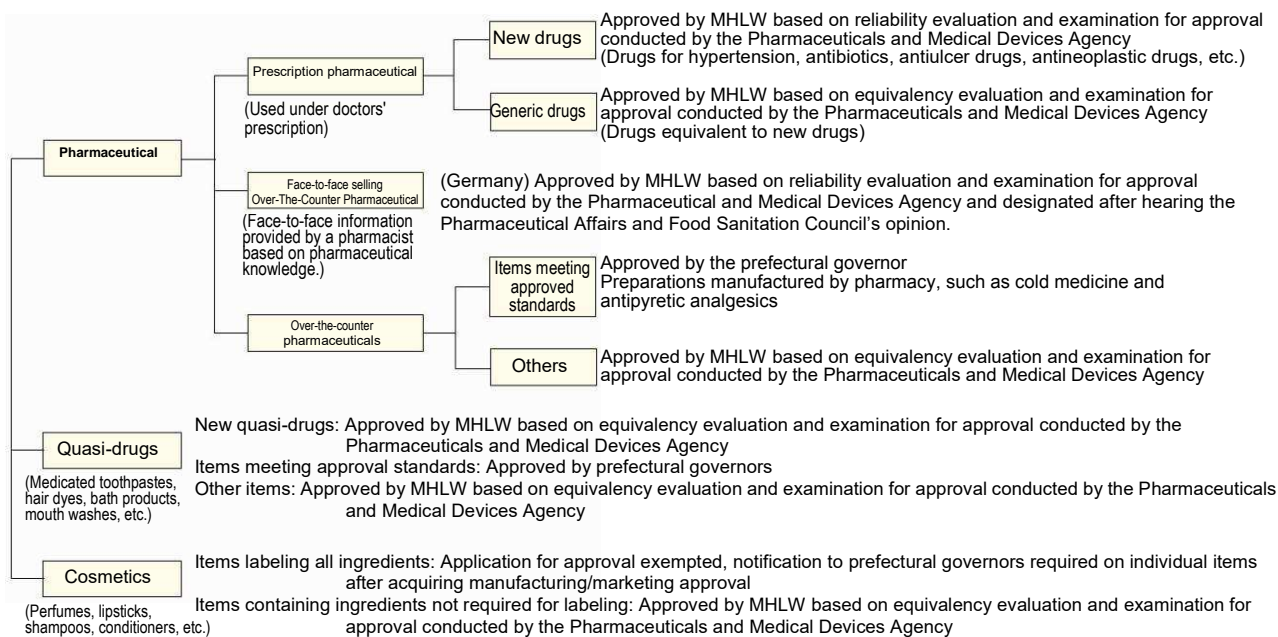
* Number of donors is as of the end of the respective years.

(4) Pharmaceuticals, etc.

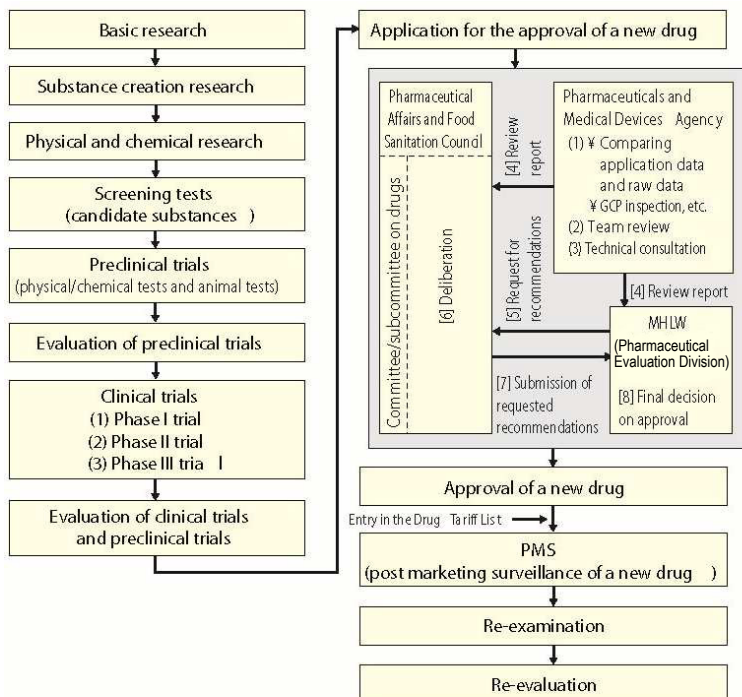
Approval/Licensing System for Pharmaceuticals, Quasi-Drugs, and Cosmetics

Overview

Classification of Examinations for the Approval of Pharmaceuticals, etc.



Flow of Examination for the Approval of a New Pharmaceutical



[Examination for the approval of a new drug]

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

(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.

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

(As of the end of 2015)

Category	Pharmaceuticals	Class 1	Class 2	Quasi-drugs	Cosmetics	Total
		pharmaceuticals	pharmaceuticals			
Marketing	1,131	274	857	1,373	3,615	6,119

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. (2016)

		Prescription pharmaceuticals	Face-to-face selling / OTC pharmaceuticals	Quasi-drugs	Cosmetics
Manufacturing	Approval	0	0	0	0
	Approval with partial revision	1	0	0	0
	Total	1	0	0	0
Import	Approval	0	0	0	0
	Approval with partial revision	0	0	0	0
	Total	0	0	0	0
Marketing	Approval	718	446	1,741	0
	Approval with partial revision	2,882	199	233	0
	Total	3,600	645	1,974	0

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

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

(As of the end of 2016)

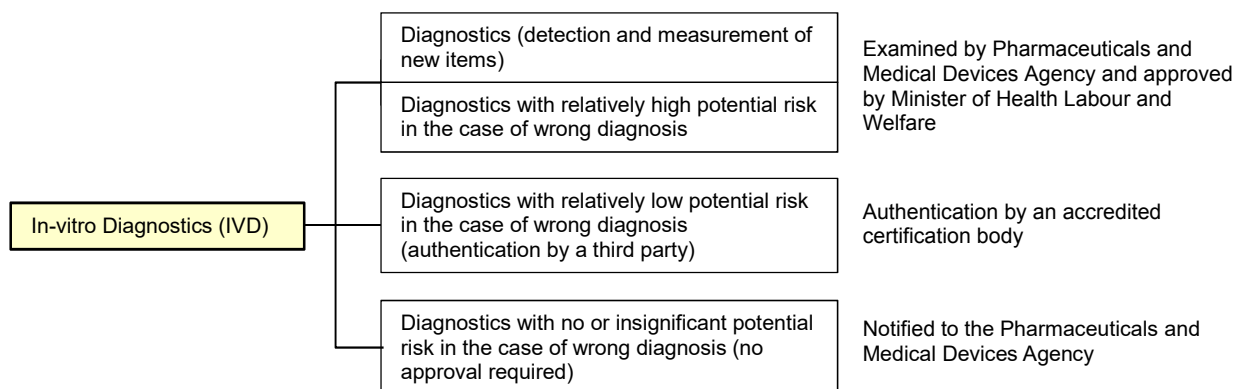
Category	Pharmaceuticals	Quasi-drugs	Cosmetics	Total
Manufacturing	2,211	1,776	3,614	7,601

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

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

Overview

Review for the Approval of IVD



Detailed Data 1

Number of Licenses for Marketing IVD

(As of the end of 2016)

	IVD
Marketing	149

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 (2016)

	Medicines for in-vitro diagnosis
Approval	103
Approval with partial change	108
Total	211

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

Detailed Data 3

Number of Registrations for Manufacturing IVD

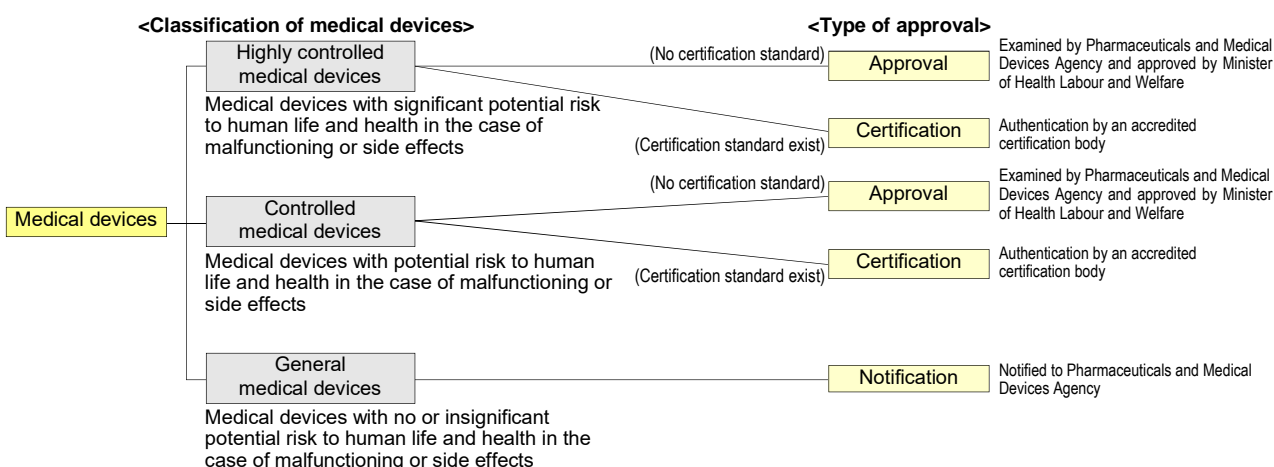
(as of the end of 2016)

	IVD
Manufacturing	198

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

Medical Device Approval/Licensing System

Overview Review for the Approval of Medical Devices



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

(As of the end of 2016)

Category	Class 1 medical devices	Class 2 medical devices	Class 3 medical devices	Total
Marketing	679	1,046	876	2,601

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 (2016)

		Medical devices
Manufacturing	Approval	0
	Approval with partial change	0
	Total	0
Import	Approval	0
	Approval with partial change	0
	Total	0
Marketing	Approval	593
	Approval with partial change	572
	Total	1,165

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

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

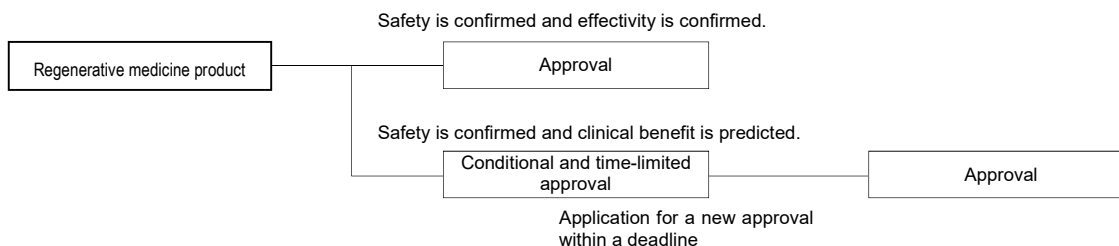
(as of the end of 2016)

	Medical devices
Manufacturing	4,078
Repairs	6,630

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 product (2016)

	Regenerative medicine product
Marketing	1

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 (2016)

	Regenerative medicine product
Approval	0
Approval with partial change regarding manufacture and sales	1
Total	1

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 2016)

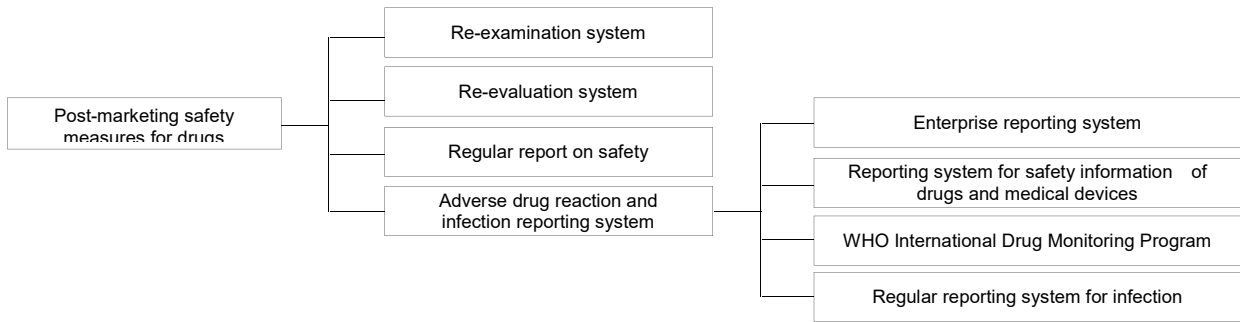
	Regenerative medicine product
Manufacturing	4

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

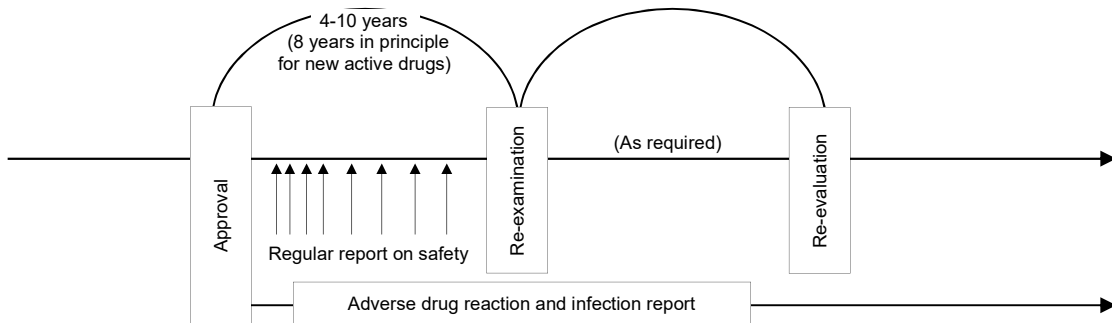
Post-Marketing Measures for Drugs/Medical Devices

Overview

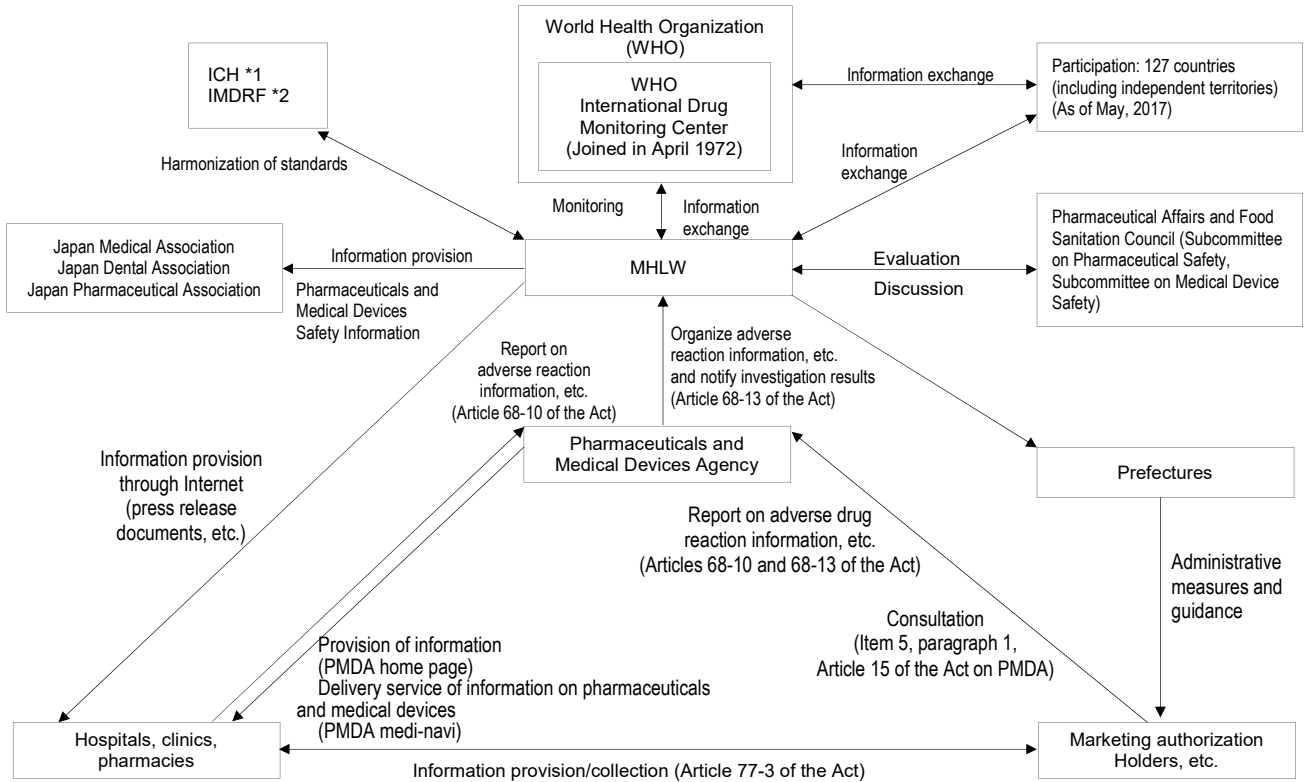
Post-Marketing Safety Measures for Drugs



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



Outline of the Adverse Drug Reaction, etc. Reporting System



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

Detailed Data 1 Results of Prescription Drug Re-examination

(As of the end of FY2016)

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
3,548	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 FY2016)

(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)

FY	Reports from marketing authorization holders ^{Note 1)}					Reports on adverse drug reactions from medical professionals ^{Note 3)}
	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	
FY 2012	41,254	159	884	1,134	1,117	4,147
FY 2013	38,329	98	962	1,317	1,138	5,420
FY 2014	49,198	78	1,099	1,219	1,098	6,180
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

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 in the Past 2 Years.

FY	Fault cases of combination	Fault cases of combination drugs(Overseas)
FY2014 ^(Note2)	0	0
FY2015	38	60
FY2016	661	1,126

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.

(Note2) No. of reports after the enactment of Pharmaceutical and Medical Devices Act on November 25, 2014. 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 2014	561	116
FY 2015	323	114
FY 2016	146	71

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.

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

FY	Reports from marketing authorization holders					Reports on adverse drug reactions from medical professionals ^{Note 2)}
	Reports on adverse event ^{Note 1)}	Reports on infectious diseases ^{Note 2)}	Reports on research results	Reports on overseas measures	Regular reports on infectious diseases	
FY 2012	22,234	0	3	1,337	69	522
FY 2013	25,554	0	5	1,669	75	489
FY 2014	30,618	0	20	1,779	73	420
FY 2015	43,997	0	598	1,742	68	406
FY 2016	48,563	0	1,289	2,144	67	548

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**No. of reports on adverse events including drugs produced by utilizing regenerative medicine over the last 3 years**

FY	Reports from manufacturers (Unit: case)					Reports on adverse drug reactions from medical professionals (unit: case)
	Reports on adverse event ^{Note 2)}	Reports on infectious diseases ^{Note 3)}	Research reports	Reports on overseas measures	Regular reports on infectious diseases	
^{Note 1)} FY 2014	12	0	0	0	5	0
FY 2015	35	0	0	0	14	0
FY 2016	88	0	0	0	34	0

Note 1) No. of reports after the enactment of Pharmaceutical and Medical Devices Act on November 25, 2014.

Note 2) Reports on adverse event of drugs produced by utilizing regenerative medicine, etc. including overseas cases.

Note 3) Reports on domestic cases

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

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

Overview

[Relief System for Adverse Drug Reactions]

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

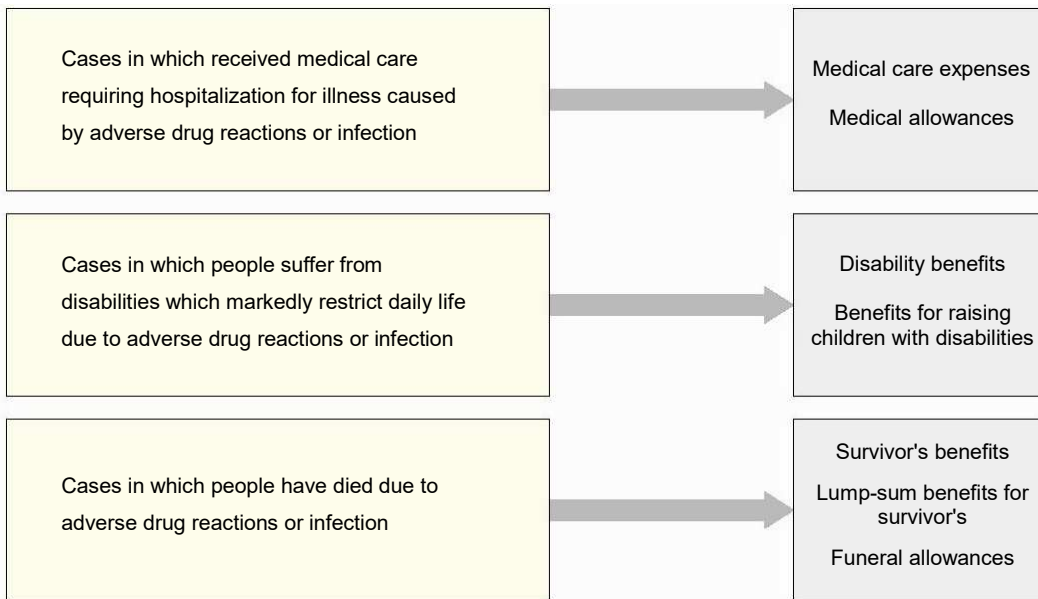
[Relief System for Infections Acquired through Biological Products]

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

[Responsible organization]

Pharmaceuticals and Medical Devices Agency

[Types of Relief Benefits]



[Activities on the Relief for Caused Damages]

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

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

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

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

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

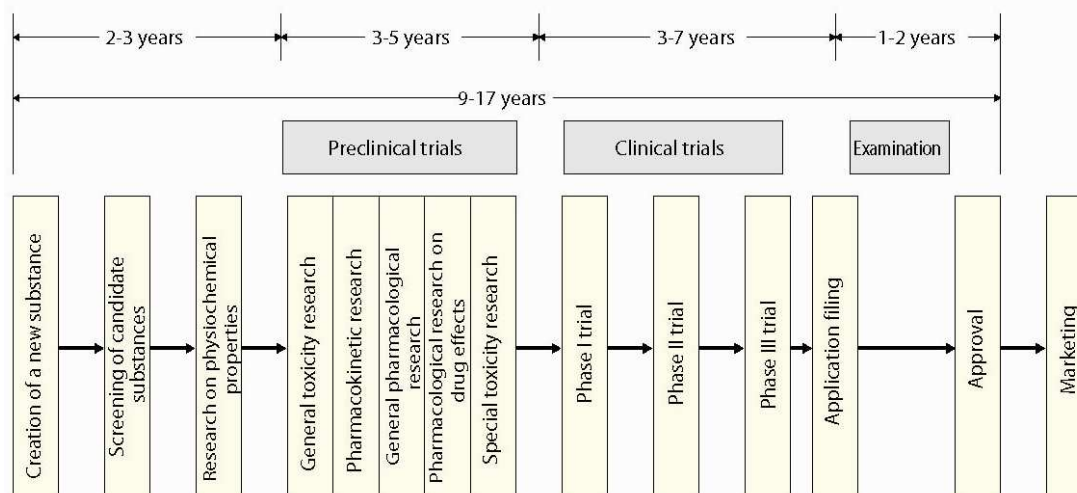
	FY1980- FY1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
Amount (¥1,000)	8,705,179	935,148	1,022,185	1,055,985	1,204,243	1,262,647	1,587,567	1,582,956	1,696,525	1,798,706	1,783,783	1,867,190	2,058,389	1,920,771	1,959,184	2,113,286	2,086,902	2,267,542
Number 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
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

Source: Pharmaceutical and Medical Devices Agency

Research/Development of Drugs and Pharmaceutical Industry

Overview Process and Period of New Drug Development

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



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

Category	Number of enterprises		Drug sales (¥100 million)		Prescription drug sales (included) (¥100 million)	
		Percentage		Percentage		Percentage
Capital of less than ¥100 million	149	45.3%	4,405	3.4%	2,950	2.8%
¥100 million - 5 billion	118	35.9%	31,159	23.8%	25,209	23.7%
¥5 billion or more	62	18.8%	95,084	72.8%	78,137	73.5%
Total	329	100.0%	130,648	100.0%	106,295	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, 2016, that were members of categorized organizations (15 organizations) of the Federation of Pharmaceutical Manufacturers' Association of Japan.

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

Medical Devices

Overview

Production of Medical Devices, etc.

(Unit: ¥100 million, %)

Year	Production	Percent change from the previous year	Export	Import	Total domestic production
1979	5,669	23.1	—	—	—
1989	12,195	9.9	2,266	2,972	12,819
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

Source: "Annual Report on the Survey of Pharmaceutical Industry Productions 2014, Health Policy Bureau, MHLW

Detailed Data

Production by Medical Device Type

(Unit: ¥100 million, %)

Category	Production	Percentage	Typical example
1. Devices for surgical procedures	5,208	26.8	Sterile tubes and catheters for vascular procedures, sterile blood transfusion sets
2. Diagnostic imaging system	2,920	15.0	Whole body X-ray CT units, general-purpose ultrasonic diagnostic imaging devices
3. Biological function assisting devices/substitutes	2,714	14.0	Stents, hip replacements
4. Bio-phenomena monitoring measuring/monitoring devices	2,054	10.6	Electronic endoscopes, sphygmomanometers
5. Medical specimen testers	1,807	9.3	Discrete automatic clinical chemical analyzers, luminescence immune measurement devices
6. Dental materials	1,328	6.8	Gold silver palladium alloy for dental casting, dental ceramics
7. Medical devices for home use	942	4.8	Electronic massaging devices for home use, in-ear hearing aids
8. Diagnostic imaging X-ray related units/instruments	492	2.5	Films for image recording and direct photography
9. Ophthalmologic devices and related products	500	2.6	Eyeglasses for sight correction, contact lenses
10. Others	1,491	7.6	
Total	19,456	100.0	

Source: "Annual Report on the Survey of Pharmaceutical Industry Productions 2015", Health Policy Bureau, MHLW

Separation of Dispensing and Prescribing Functions

Overview Separation of Dispensing and Prescribing Functions

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

[Advantages of separation of dispensing and prescribing functions]

- 1) Doctors and dentists can freely prescribe drugs necessary for patients even when the particular drugs are not stocked in their own hospitals or clinics.
- 2) Issuing prescriptions to patients allows them to know which drugs they are taking.
- 3) "Family pharmacies" can check for duplicate prescriptions, drugs interactions, etc. offered by multiple facilities through drug history management and thus improve efficacy and safety of drug therapies.
- 4) Reduced outpatient dispensing work of hospital pharmacists allows them to engage in hospital activities for inpatients which they should essentially perform.
- 5) 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.

Detailed Data Changes in Number of Pharmacies and Prescriptions

FY	Number of pharmacies	Number of prescriptions (10,000/year)	Number of prescriptions per 1,000 persons (per month)	Nationwide average rate of separation of dispensing and prescribing functions (%)
FY1989	36,670	13,542	95.2	11.3
FY1990	36,981	14,573	105.4	12.0
FY1991	36,979	15,957	111.7	12.8
FY1992	37,532	17,897	125.8	14.1
FY1993	38,077	20,149	140.6	15.8
FY1994	38,773	23,501	161.0	18.1
FY1995	39,433	26,508	182.5	20.3
FY1996	40,310	29,643	210.0	22.5
FY1997	42,412	33,782	238.1	26.0
FY1998	44,085	40,006	278.8	30.5
FY1999	45,171	45,537	307.3	34.8
FY2000	46,763	50,620	348.6	39.5
FY2001	48,252	55,960	393.7	44.5
FY2002	49,332	58,462	393.0	48.8
FY2003	49,956	59,812	418.8	51.6
FY2004	50,600	61,889	368.7	53.8
FY2005	51,233	64,508	425.2	54.1
FY2006	51,952	66,083	442.5	55.8
FY2007	52,539	68,375	481.0	57.2
FY2008	53,304	69,436	483.0	59.1
FY2009	53,642	70,222	494.1	60.7
FY2010	53,067 *	72,939	486.6	63.1
FY2011	54,780	74,689	498.3	65.1
FY2012	55,797	75,888	533.3	66.1
FY2013	57,071	76,303	510.2	67.0
FY2014	57,784	77,558	509.3	68.7
FY2015	58,326	78,184	513.1	70.0

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:

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

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

Blood Programme

Overview

[Blood Products]

Blood products refer to all pharmaceutical products which are derived from human blood and are roughly classified into blood transfusion products and plasma derivatives. All of the blood transfusion products are supplied through blood donations.

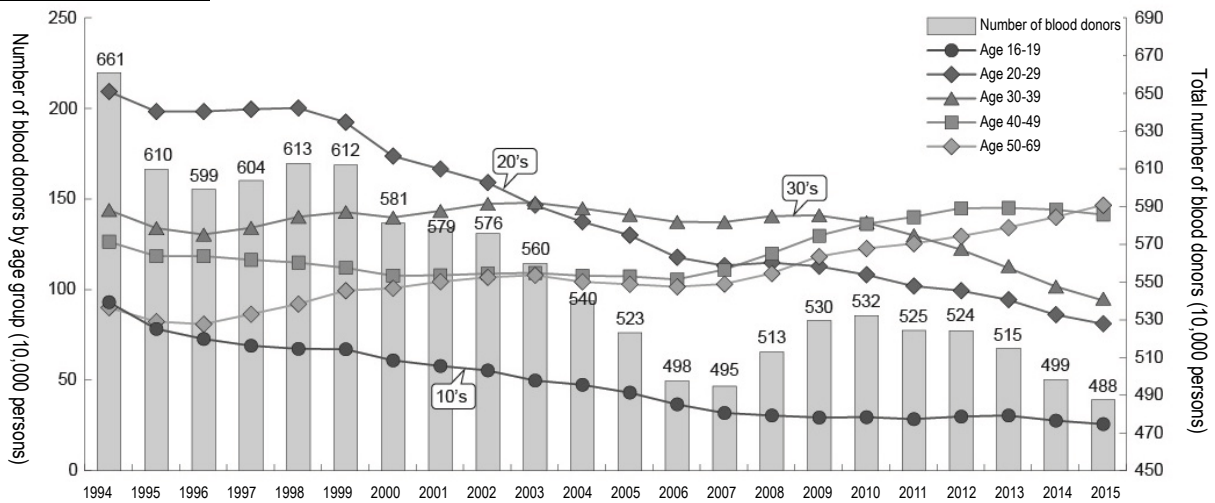
Regarding plasma derivatives, the blood coagulation factor products are supplied domestically. On the other hand, alternative recombinant product versions of plasma derived products are taking over the market. Some kinds of plasma derivatives, such as albumin preparations and hepatitis B immunoglobulin products, are still imported from overseas. From the viewpoint of "self sufficiency" and "securing stable supply", efforts are being made to establish a system for securing the domestic supply of all types of blood products including plasma derivatives.

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

[Status of Blood Donation]

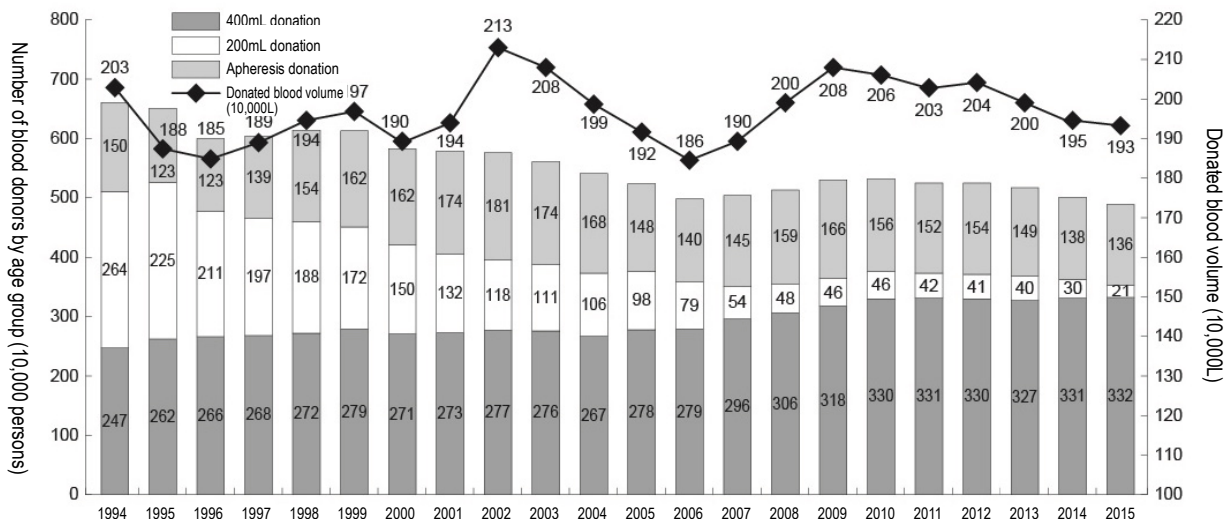
The number of blood donors has been on the downward trend in recent years. In particular, the number in the age groups of 10s, 20s and 30s is on a continuous downward trend. In addition to 200 ml, 400 ml blood and ingredient donations are becoming more prevalent.

Detailed Data 1 Change in Number of Blood Donors



Detailed Data 2

Changes in Number of Blood Donors by Donation Type and Donated Blood Volume



(5) Health Risk Management System

Health Risk Management System

Overview

HMLW Health Risk Management System Diagram

