

Donor haemovigilance and donor relief system in Japan

Japanese Red Cross Blood Service HQs

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Background

- The Law for securing stable supply of Safe Blood Products assigns the role of blood collecting service to promote and collect blood donation and protect donors.
- Donor hemovigilance is critical for the donor safety and availability of blood products. The data of donor reactions have been collected since 1996.
- Two fatal reactions have been recorded since then. Both cases were falling accidents probably due to vasovagal reaction.
- Each Red Cross blood center had its own relief system. The amount and period of compensation were not standardized.
- In Oct 2006, Japanese government issued the guideline for the relief system for Injury to health with blood donation.

The Law for Securing Stable Supply of Safe Blood 2003

Basic Principles

- 1) To improve the **safety** of blood products
- 2) To secure the **stable supply** of blood products through the **domestic non-paid blood donations**
- 3) To promote the **appropriate use** of blood products
- 4) To ensure fairness and improve **transparency** in managing the blood program.

The Law for Securing Stable Supply of Safe Blood

Responsibilities of The national government

- To plan and implement basic and comprehensive measures to secure a stable supply of safe blood
- To educate and enlighten Japanese citizens to donate blood
- To plan and implement measures to promote the proper use

Responsibilities of

Local authorities

(prefectural and municipal governments)

- To deepen the understanding of the need for blood donations among local residents
- To assist the smooth operation of blood collection

Responsibilities of JRC Blood Services

(Blood Collecting Service)

- To promote and receive blood donations
- To protect donors

(Manufacturer/Marketing license holder)

- To secure a stable supply of safe blood
- To develop technology for the safety of blood products
- To collect/provide information to medical institutions

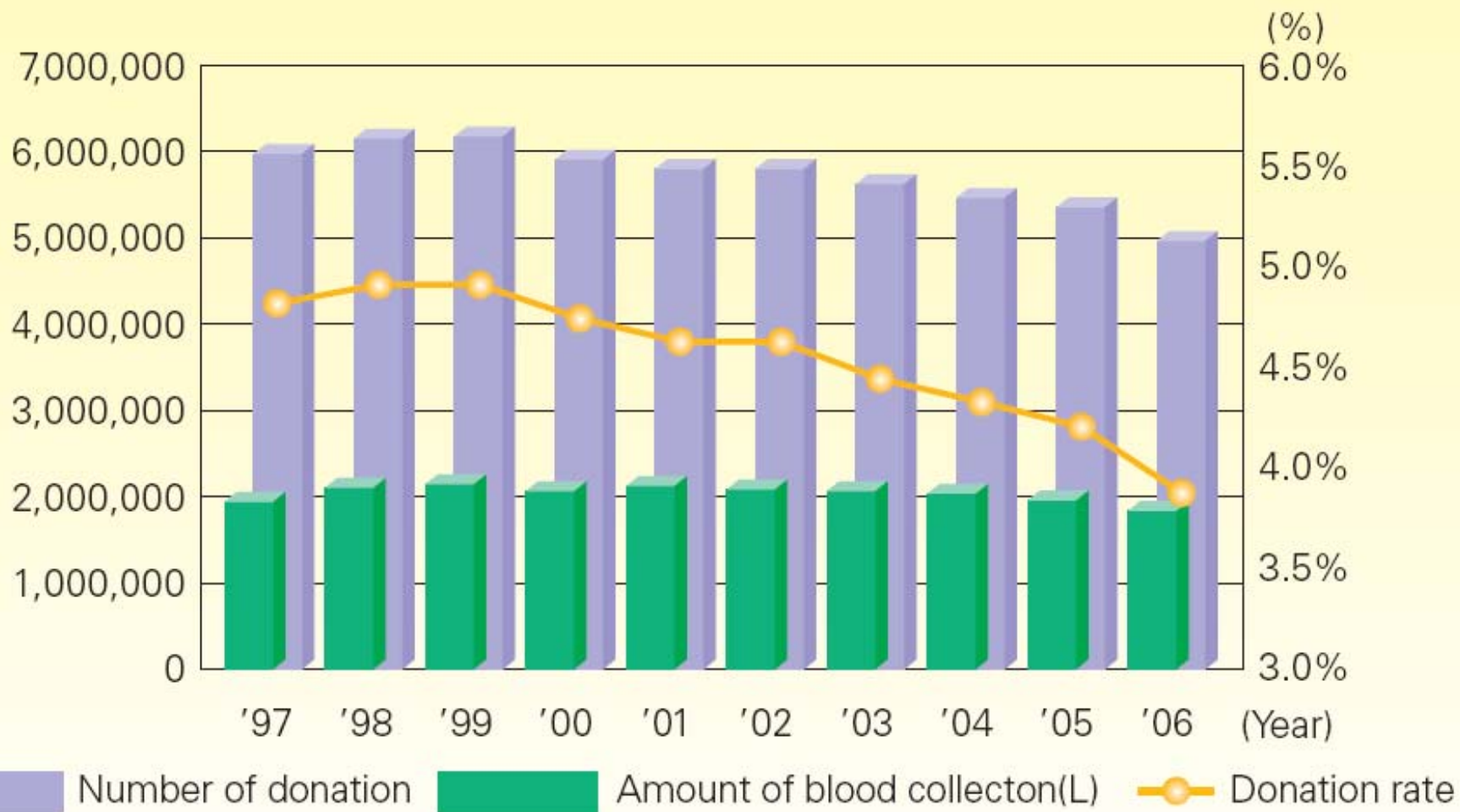
Responsibilities of Medical professionals

- To use blood products appropriately
- To collect/provide information on the safety of blood products

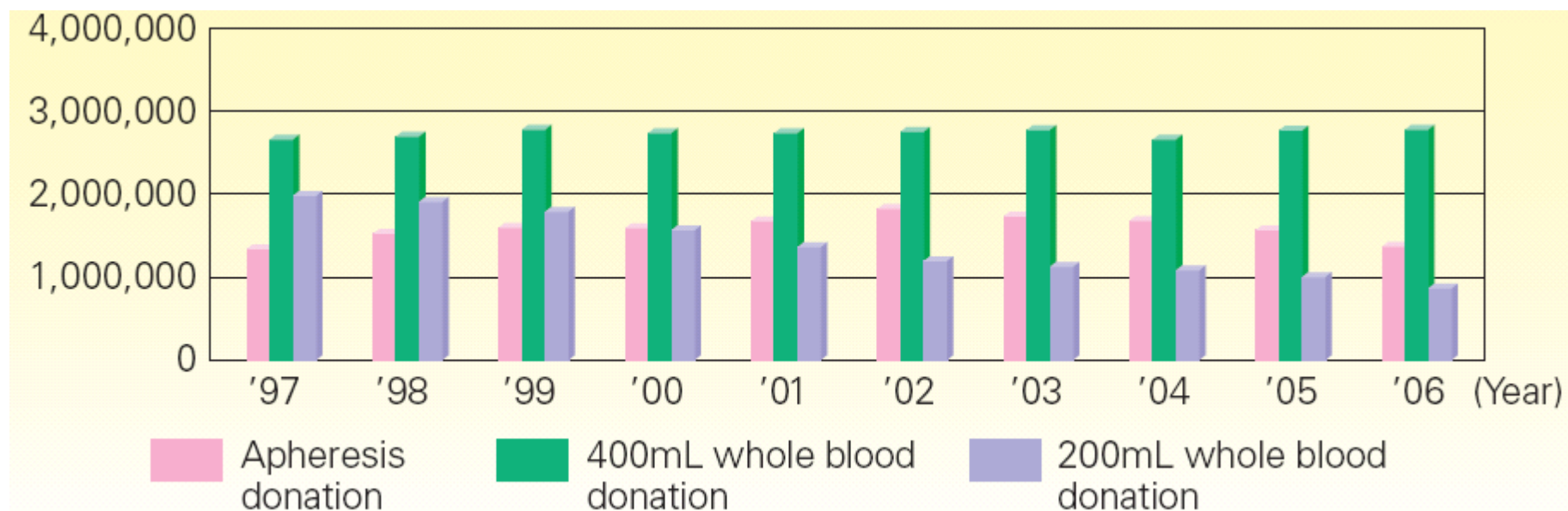
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- To take the informed consent from patients
 - To keep the records of transfusion for 20 yrs

(The amendments of the Pharmaceutical Affairs Law in 2003)

Annual number of donation and amount of blood collection

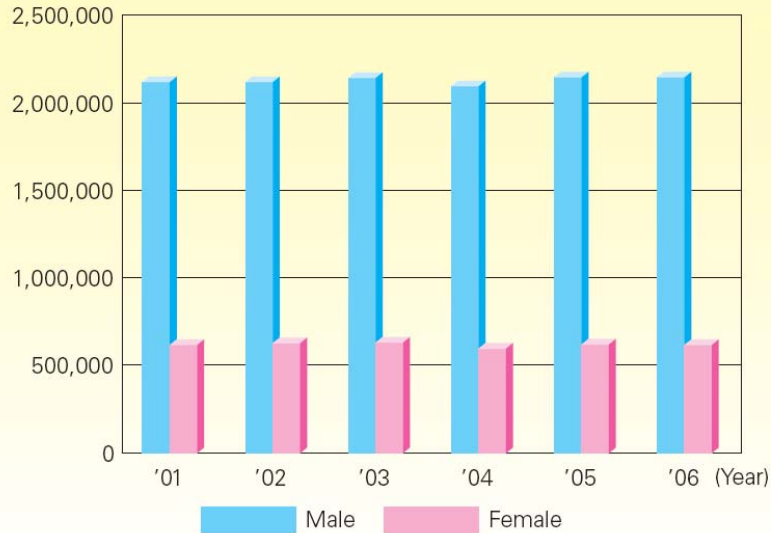


Annual number of donation by types

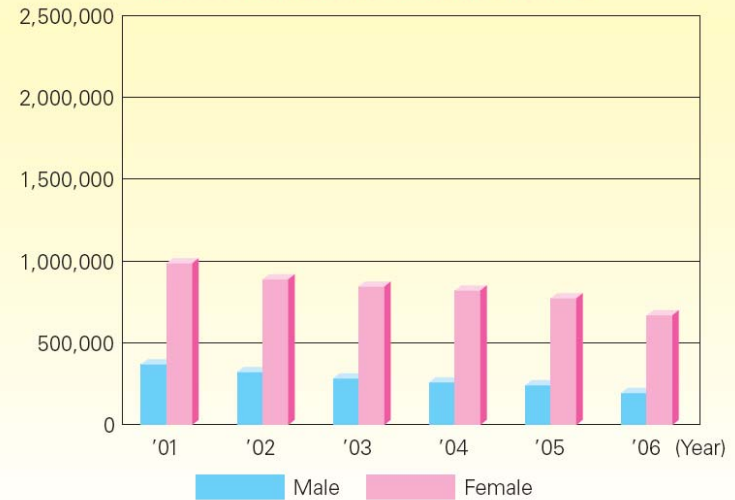


Annual number of donation by gender and types

400mL whole blood donation



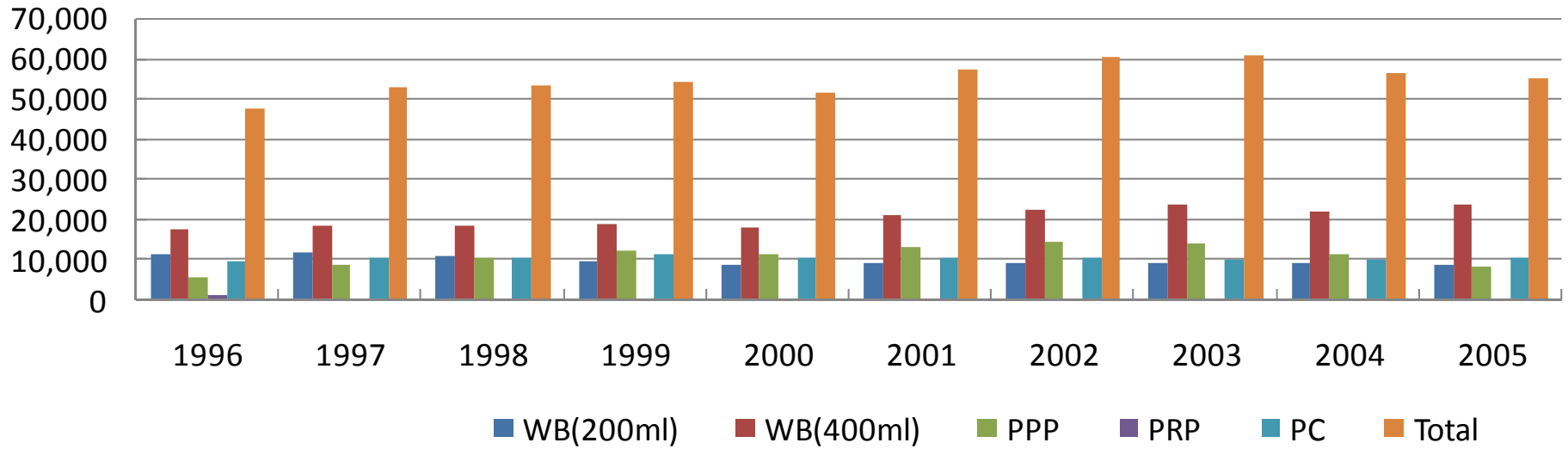
200mL whole blood donation



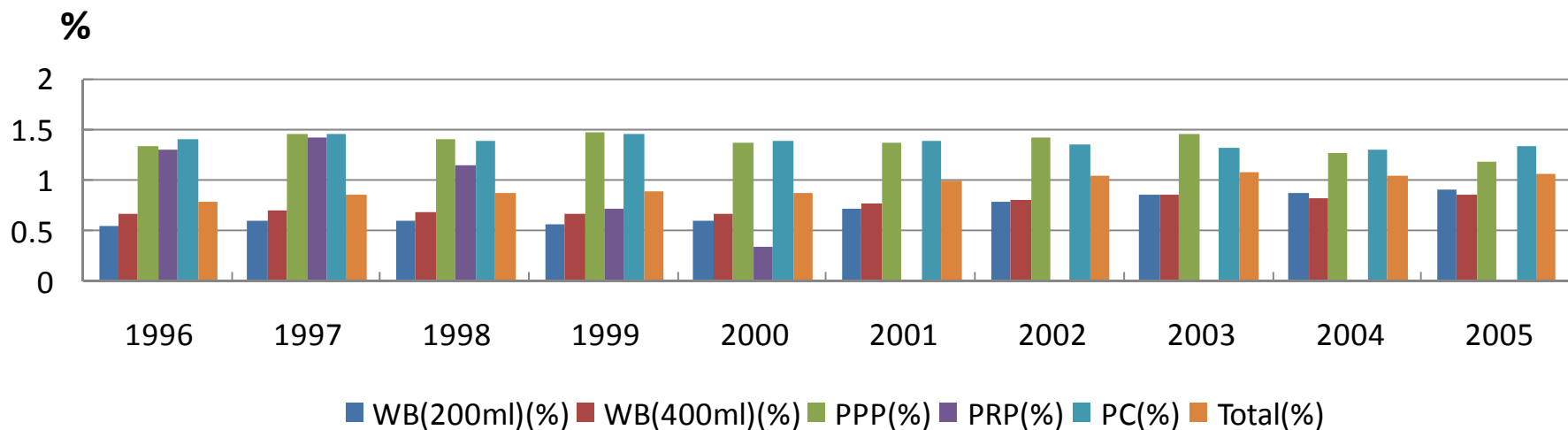
Apheresis donation



Yearly trend of the numbers of adverse events in donors



Yearly trend of incidence rates of reactions (percent)



Donor complications : Average(FY2004-2006)

	Attendances (Average of last 3years)	Haematoma	Nerve injury	VVR	Citrate toxicity
Whole blood (200ml and 400ml)	3,790,000	3,300 80/100,000	280 7/100,000	26,000 720/100,000	
Apheresis (Platelet and Plasma)	1,630,000	8,300 500/100,000	120 7/100,000	11,600 710/100,000	500 30/100,000

Incident rates of **VVR** by gender in FY2006

	Male	Female
VVR	18867	18266
Total No	3261974	1976196
rate of VVR(%)	0.578	0.924

Incident rates of **VVR** by type of donation and gender in FY2006

	Whole Blood (200ml)		Whole Blood (400ml)		Apheresis (plasma)		Apheresis (platelet)	
	Male	Female	Male	Female	Male	Female	Male	Female
VVR	2010	5000	14354	6296	812	3573	1691	3397
Total No	222124	761385	2149237	625966	343396	356295	547217	232550
rate of VVR	0.91%	0.66%	0.67%	1.01%	0.24%	1.00%	0.31%	1.46%

The rates of **VVR** with medical treatment or falling accidents in FY 2006

per 100,000

	Whole Blood (200ml)		Whole Blood (400ml)		Apheresis (plasma)		Apheresis (platelet)	
	Male	Female	Male	Female	Male	Female	Male	Female
10's	0.374	0.497	0.723	2.534	0.000	0.477	0.000	0.000
20's	0.333	0.427	0.566	1.599	0.000	0.501	0.071	0.735
30's	0.000	0.117	0.211	0.771	0.353	0.110	0.159	0.437
40's	0.320	0.000	0.177	0.430	0.000	0.417	0.328	0.721
50's	0.000	0.106	0.168	1.845	0.000	1.318	0.000	0.000
60's	0.000	0.000	0.314	3.219	0.000	0.542		

Incident rates of **citrate toxicity** by gender

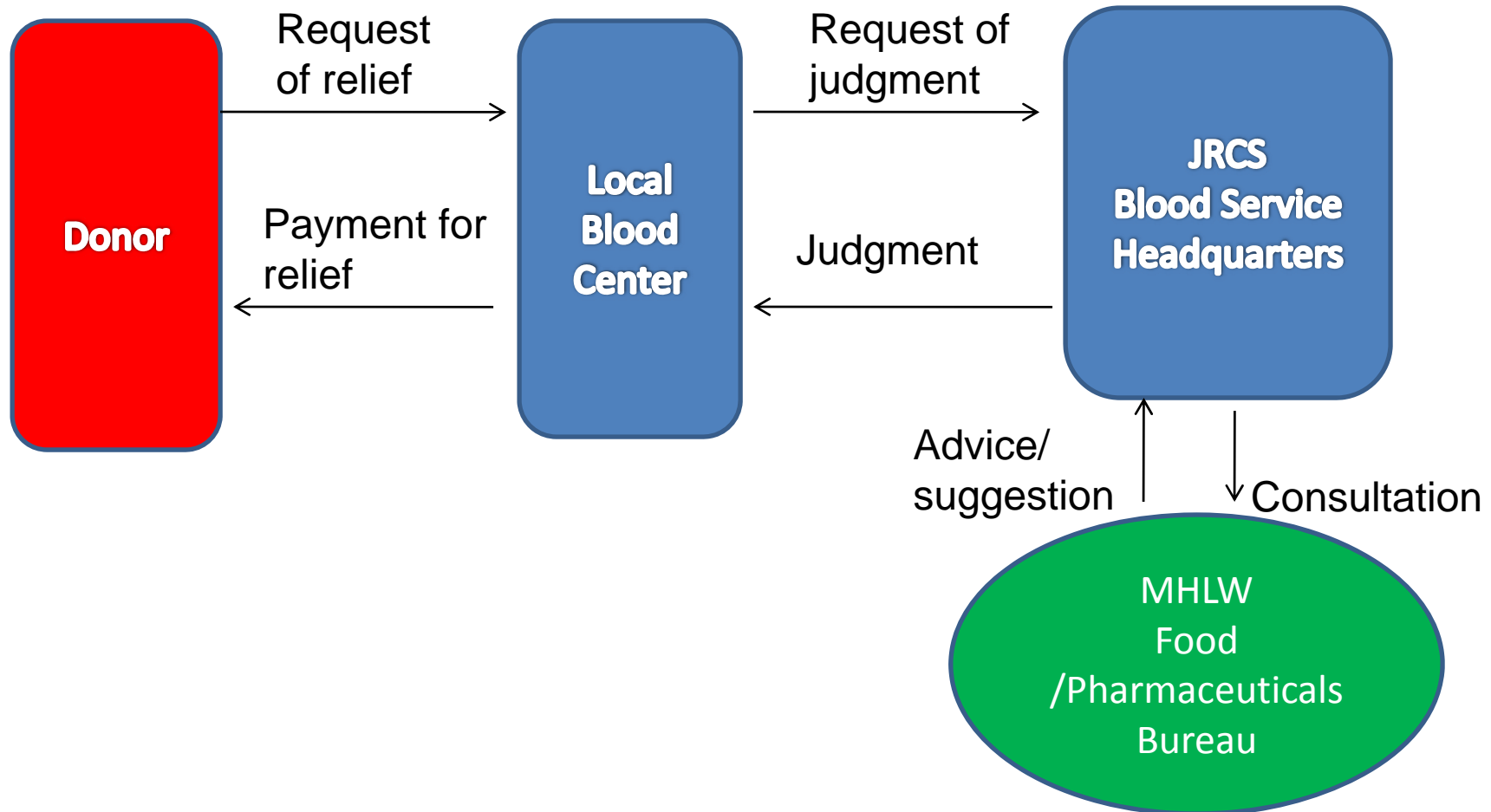
	Male	Female
Citrate toxicity	137 / 890613	329 / 588845
rate	0.015%	0.056%

Guidelines for Relief of Donors who had the Health Damage Relating to Blood Collection

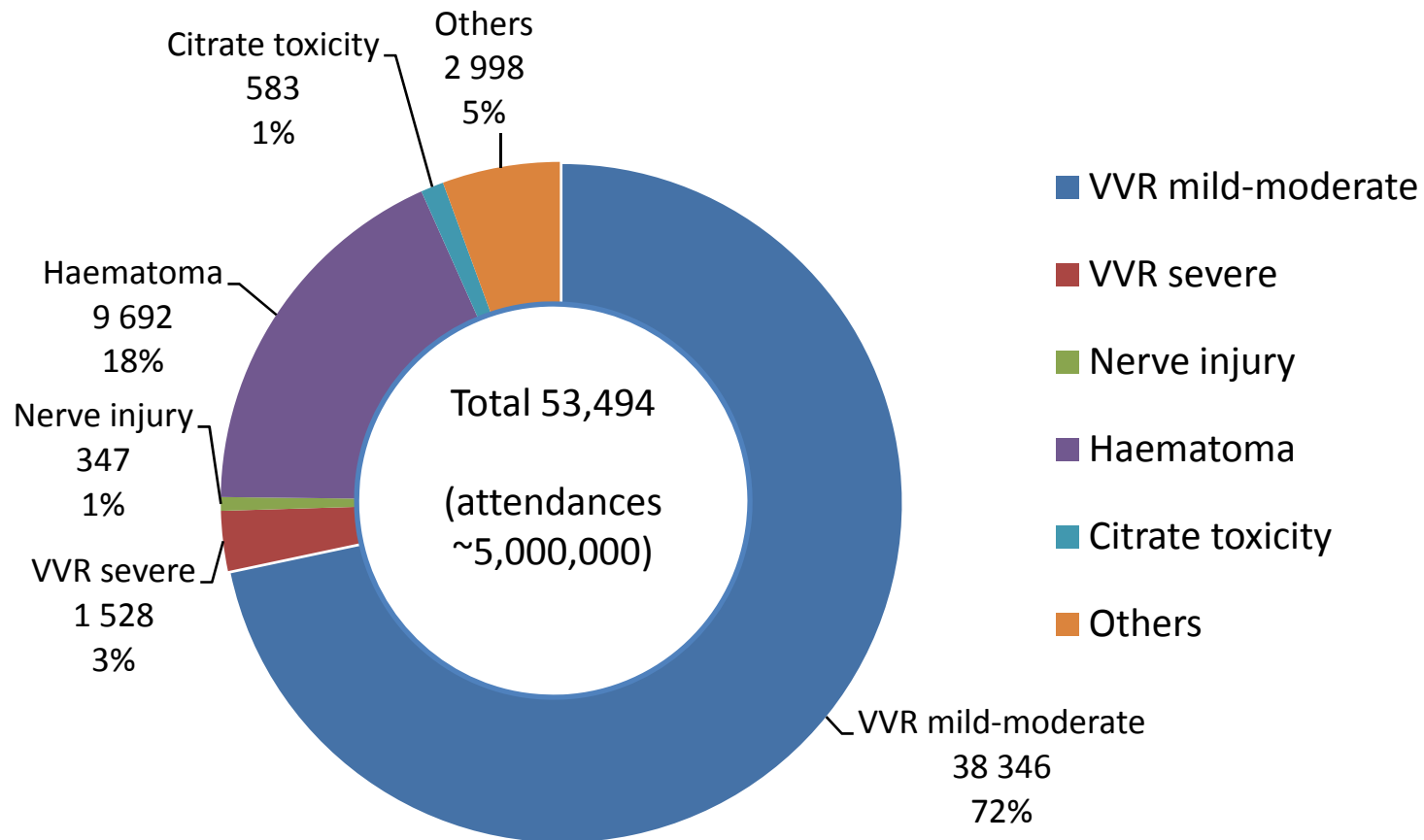
01.Oct.2006

Japanese Government issued a guideline for the payment of medical expense, medical benefits, accidental injury benefits, accidental death benefits and funeral assistance, which will be provided for the health damage of donors according to the degree of damages.

Donor Relief System in Japan



Number of adverse events in donors (Oct 2006-Sep2007)



Number of Cases applied to Donor Relief System

Oct 2006-Sept 2007

VVR	141	Allergic Reactions	3
VVR/Fall	131	Skin Eruption	5
Haematoma	107	Hyperventilation	9
Site Pain	45	Thrombophlebitis	11
Nerve Injury	172	Convulsion	4
RSD(CRPS type I)*	3	Others	167
Citrate Toxicity	3	Total**	801

*RSD: Reflex sympathetic dystrophy
CRPS: Complex regional pain syndrome

**Including 71 overlapping case

Cases of Adverse Reactions and Relief

	Adverse reactions		Relief	
VVR	Mild	38,346	VVR	141
	Severe	1,528	VVR/Fall	131
Haematoma	9,692		107	
Site Pain			45	
Nerve Injury	347		172	
RSD(CRPS type I)			3	
Citrate Toxicity	583		3	
Allergic Reactions			3	
Skin Eruption			5	
Hyperventilation			9	
Thrombophlebitis			11	
Convulsion			4	
Others	2,998		167	
Total	53,494		801	

Cases Relieved classified by gender

	Male	Female
VVR	49	92
VVR/Fall	62	69
Haematoma	54	53
Site Pain	25	20
Nerve Injury	107	65
RSD(CRPS type I)	3	0
Citrate Toxicity	1	2
Allergic Reactions	3	0
Skin Eruption	5	0
Hyperventilation	1	8
Thrombophlebitis	8	3
Convulsion	4	0
Others	98	69

Amount of medical expenses etc. (standard)

- ✓ Medical expenses: Co-payment will be paid by JRC if donors can use public insurance.
- ✓ Medical benefits: maximum ¥4,480 (€28) per day (hospital visit or stay), maximum ¥35,800 (€230) per month.
- ✓ Benefits for disabilities: ¥440,000 to 11,792,000 (€2,800 to 74,600) according to the grade of disability.
- ✓ Accidental death benefits: ¥8,800,000 (€55,700)
- ✓ Funeral assistance: ¥199,000 (€1,300)

Total amount paid (from Oct 2006 to Sep 2007)

	VVR	VVR w/fall	Haema- toma	Nerve injury	Hyper- ventilation	Site pain	Citrate toxicity	Thrombo- phlebitis	Allergic reaction	RSD (CRPS type I)	Skin eruption	Others	Sum
Cases (1)	70	73	39	84	1	18	2	5	0	1	2	75	370
Medical expenses	544,564	1,053,111	196,889	938,254	5,450	262,363	73,022	18,470	0	6,400	16,190	877,090	3,991,803 = €25,000
Cases (2)	70	71	38	83	1	18	2	5	0	1	2	72	363
Medical benefits	443,480	676,400	438,920	1,876,400	8,960	206,000	17,920	44,800	0	4,480	17,920	895,840	4,631,120 = €29,000
Decline benefits (1)-(2)	0	2	1	1	0	0	0	0	0	0	0	3	7

Medical expenses per case	7,779	14,426	5,048	11,170	5,450	14,576	36,511	3,694	0	6,400	8,095	11,695	10,789 = €68
Medical benefits per case	6,335	9,527	11,551	22,607	8,960	11,444	8,960	8,960	0	4,480	8,960	12,442	12,758 = €81

Summary

- Approximately 1% of donors suffered from a certain health damage due to blood donation.
- VVR is the major incident among these complications.
- Severe VVR tends to occur in young and old 400ml whole blood donors.
- Donor relief system has been successfully implemented.
- Approximately 1.4% of donors with adverse events received medical treatments and the payments. Higher percentage of donors with nerve injury and VVR/fall needed medical treatments.