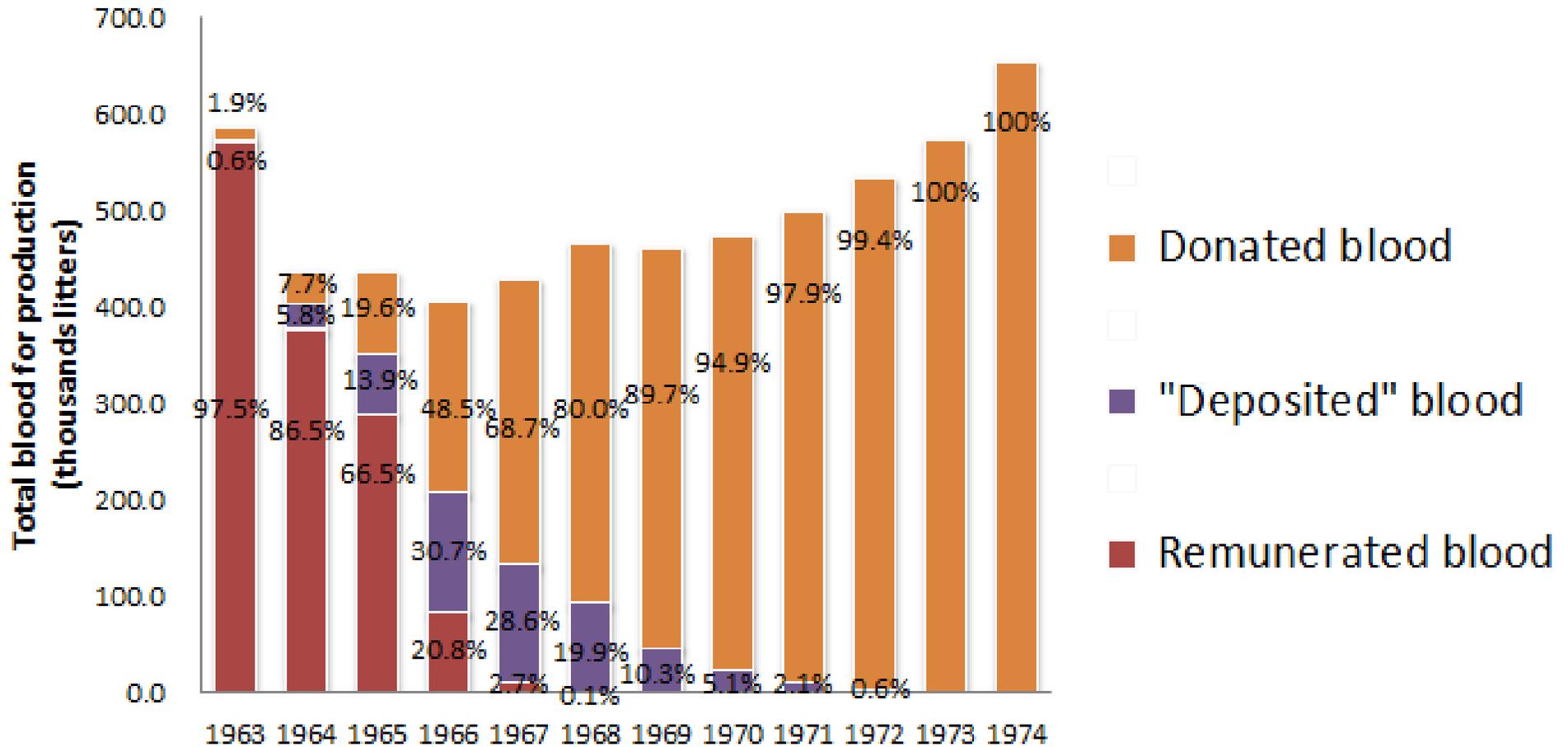# Over View of Blood Management System in Japan

Ikuma Nozaki, MD, PhD

JICA Adviser for Infectious Disease and Laboratory Services

Japan achieved 100% VNRBD for transfusion in 10 years (1964-1973)

* Data source: White paper (1963 – 74), Ministry of Health

Legal Basis of Blood Services in Japan

Blood Law

Law on Securing Stable Supply of Safe Blood Products requires
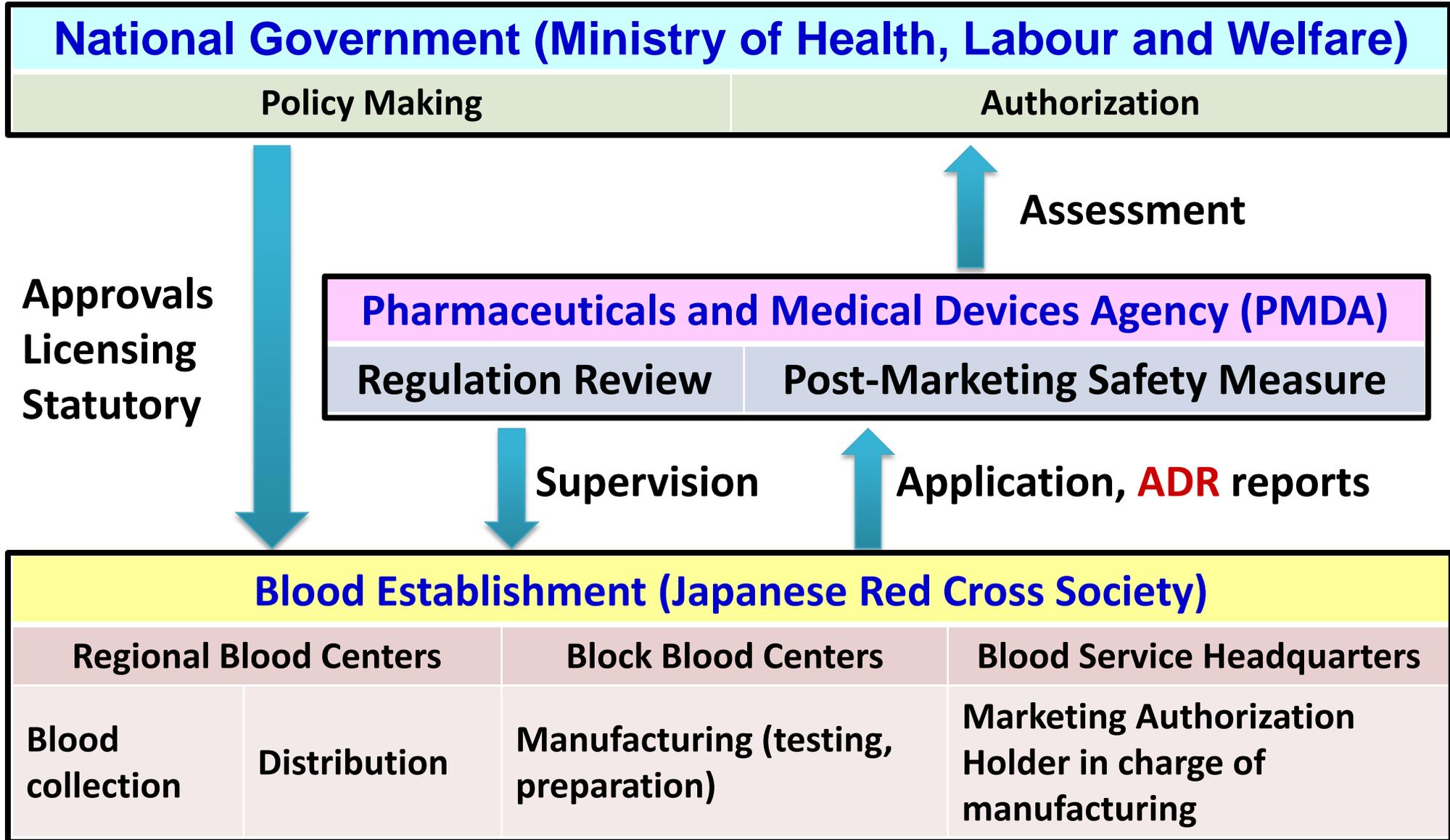- Self sufficiency and stable supply
- Appropriate use
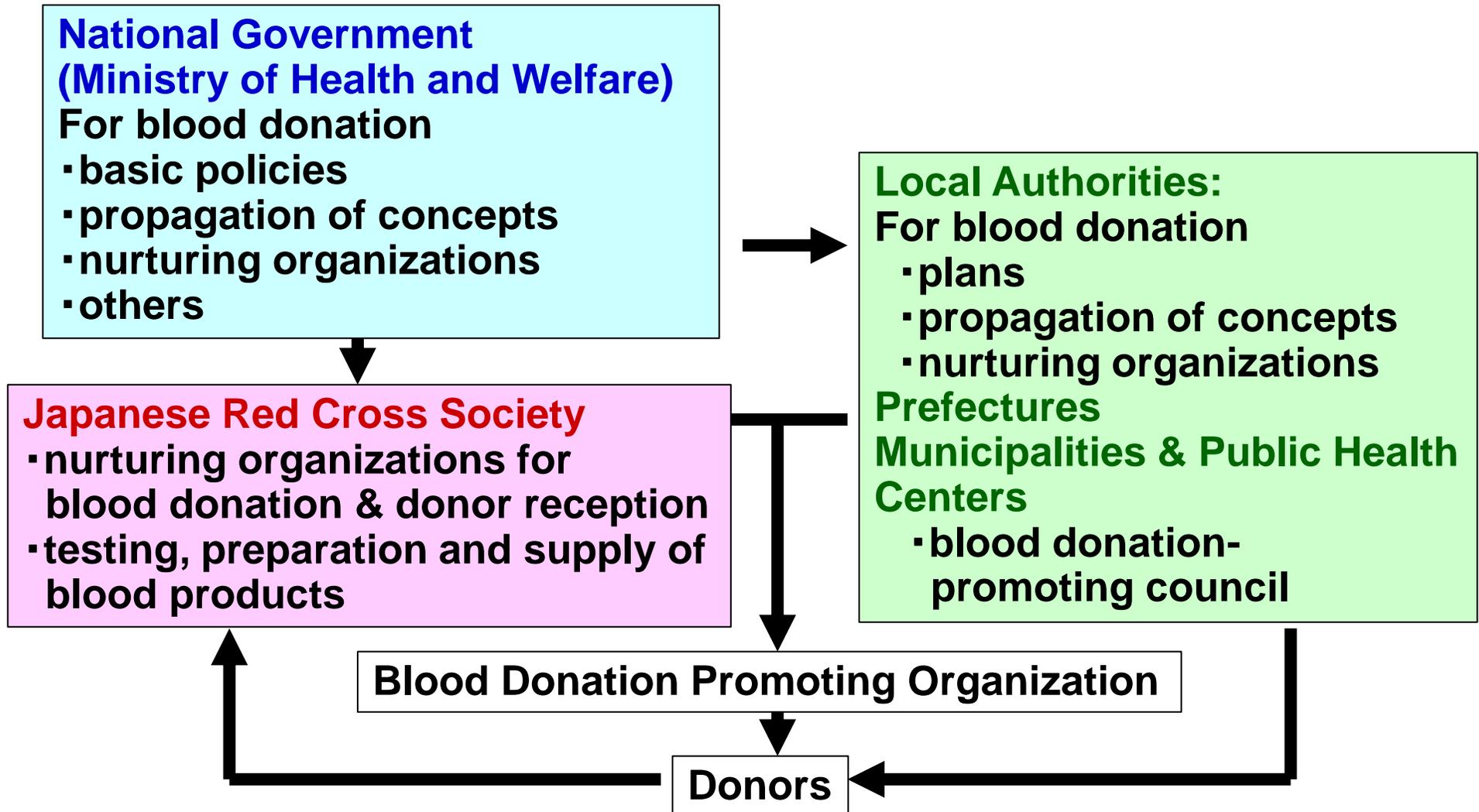
Revised Pharmaceutical & Medical Devices Act(PMD Act)

Act on Securing Quality, Efficiency and Safety of Pharmaceuticals, Medial Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics requires
- Safety as <u>biological products & prescription drugs</u>
- Post-marketing procedures
- Pharmacovigilance - Haemovigilance for blood products

Blood Service and Regulation

National Government (Ministry of Health, Labour and Welfare)	
Policy Making	Authorization

Assessment

Approvals Licensing Statutory

Pharmaceuticals and Medical Devices Agency (PMDA)	
Regulation Review	Post-Marketing Safety Measure

Supervision **Application, ADR reports**

Blood Establishment (Japanese Red Cross Society)			
Regional Blood Centers		Block Blood Centers	Blood Service Headquarters
Blood collection	Distribution	Manufacturing (testing, preparation)	Marketing Authorization Holder in charge of manufacturing

Promoting Blood Donations

**National Government
(Ministry of Health and Welfare)**
For blood donation
· basic policies
· propagation of concepts
· nurturing organizations
· others

Local Authorities:
For blood donation
· plans
· propagation of concepts
· nurturing organizations
**Prefectures
Municipalities & Public Health
Centers**
· blood donation-
  promoting council

Japanese Red Cross Society
· nurturing organizations for
  blood donation & donor reception
· testing, preparation and supply of
  blood products

Blood Donation Promoting Organization

Donors

Wide Area Management System since 2012

Hokkaido

Kinki
- Shiga
- Kyoto
- Osaka
- Hyogo
- Nara
- Wakayama

Kyushu
- Fukuoka
- Saga
- Nagasaki
- Kumamoto
- Oita
- Miyazaki
- Kagoshima
- Okinawa

Tohoku
- Aomori
- Iwate
- Miyagi
- Akita
- Yamagata
- Fukushima

Kanto-Koshinetsu
- Ibaraki
- Tochigi
- Gunma
- Saitama
- Chiba
- Tokyo
- Kanagawa
- Niigata
- Yamanashi
- Nagano

Tokai-Hokuriku

Blood Center
- Toyama
- Ishikawa
- Fukui
- Gifu
- Shizuoka
- Aichi
- Mie

Chugoku-Shikoku
- Tottori
- Shimane
- Okayama
- Hiroshima
- Yamaguchi
- Tokushima
- Kagawa
- Ehime
- Kochi

(As of December, 2016)

■7 Block Blood Centers

●47 Regional Blood Centers

180 Branches of Blood Centers (Including 129 Blood Donation Rooms)

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Testing & Preparation at Block Blood Centers

47 **Regional Blood Centers**

Prefecture A
| Blood collection |

Prefecture B
| Blood collection |

Prefecture C
| Blood collection |

7 **Block Blood Centers**

| Testing |

| Preparation |

| Supply-demand management |

47 **Regional Blood Centers**

| Supply | | Supply | | Supply |

| Medical institutions |
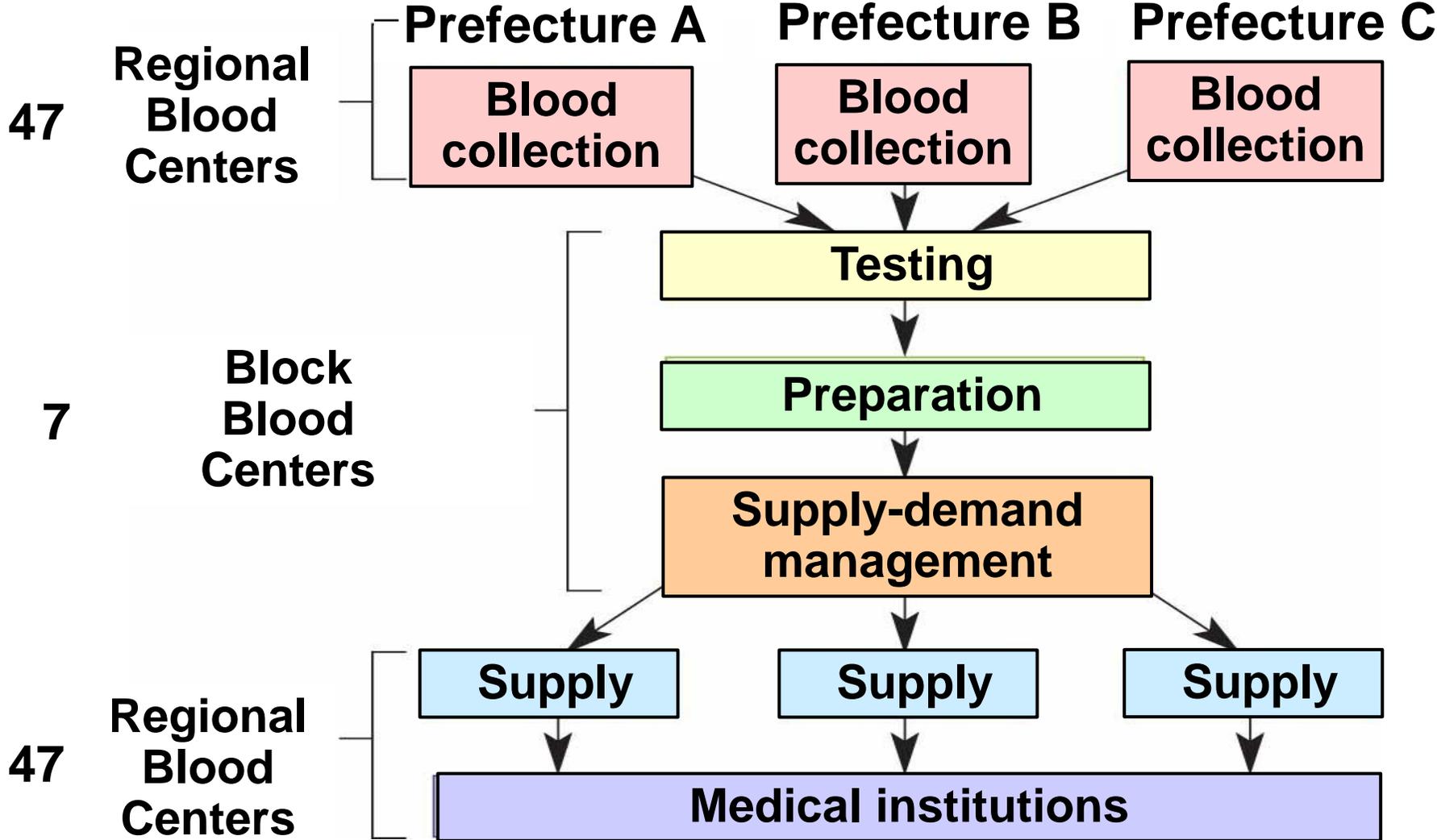
Blood Donation and Blood Products

Blood Donation

Whole blood
（200mL, 400mL）
- Red Cells
- Plasma

Plasma pheresis
Platelet pheresis
- Plasma
- Platelets

Blood Products
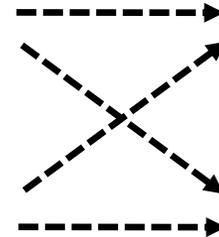
Fresh Frozen Plasma

Plasma Derivatives

Measures for Blood/Donor Safety

Donor identification by drivers license etc.

Medical interviews following questionnaire

Skin disinfection to prevent bacterial contamination

Diversion of initial 25mL blood for laboratory tests

Tests for transfusion-transmissible agents

Pre-storage leukoreduction to antigen & pathogen exposure

Irradiation to prevent post-transfusion GVHD

Inventory hold of plasma to get rid of possible pathogen

identified through following donations

Tests for Blood Quality

- ABO typing
- Rh(D) typing
- RBC antibody screening
- ALT (GPT)
- Glycoalbumin

- serologic test for syphilis
- HBs antigen, HBs antibody, HBc antibody
- HCV antibody
- HIV-1/2 antibody
- HTLV-1 antibody
- human parvovirus B19 antigen

- Nucleic acid amplification test (NAT)
    HBV
    HCV
    HIV

Statistics for 2016

Donation applicants	5,579,776	Deferral	738,175 (13.2%)
Blood donations	**4,841,601 (86.8%)**	Male	3,489,340
		Female	1,352,261
Whole blood donations	3,449,829	200mL	168,758
		400mL	3,281,071
Apheresis donations	1,391,772	Platelet	713,405
		Plasma	678,367

Population of Japan (as of Oct 2016)
Total **126,933,000**
Male 61,766,000
Female 65,167,000

Unqualified	Syphilis	HBsAg	HBcAb	HCVAb	HIVAb	HBV NAT	HCV NAT	HIV NAT
91,861 (1.9%)	4,480	1,392	15,443	1,059	2,966			
	HTLV-1	H.Parvo.B19		ALT	Irregular Ab			
				54,809	3,404			

Preparation (total)	Whole blood	Red blood cells	Platelets	Plasma
5,074,024 (bags)	55	3,303,004	841,332	929,633

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Effects of the Safety Measures on TT-Hepatitis
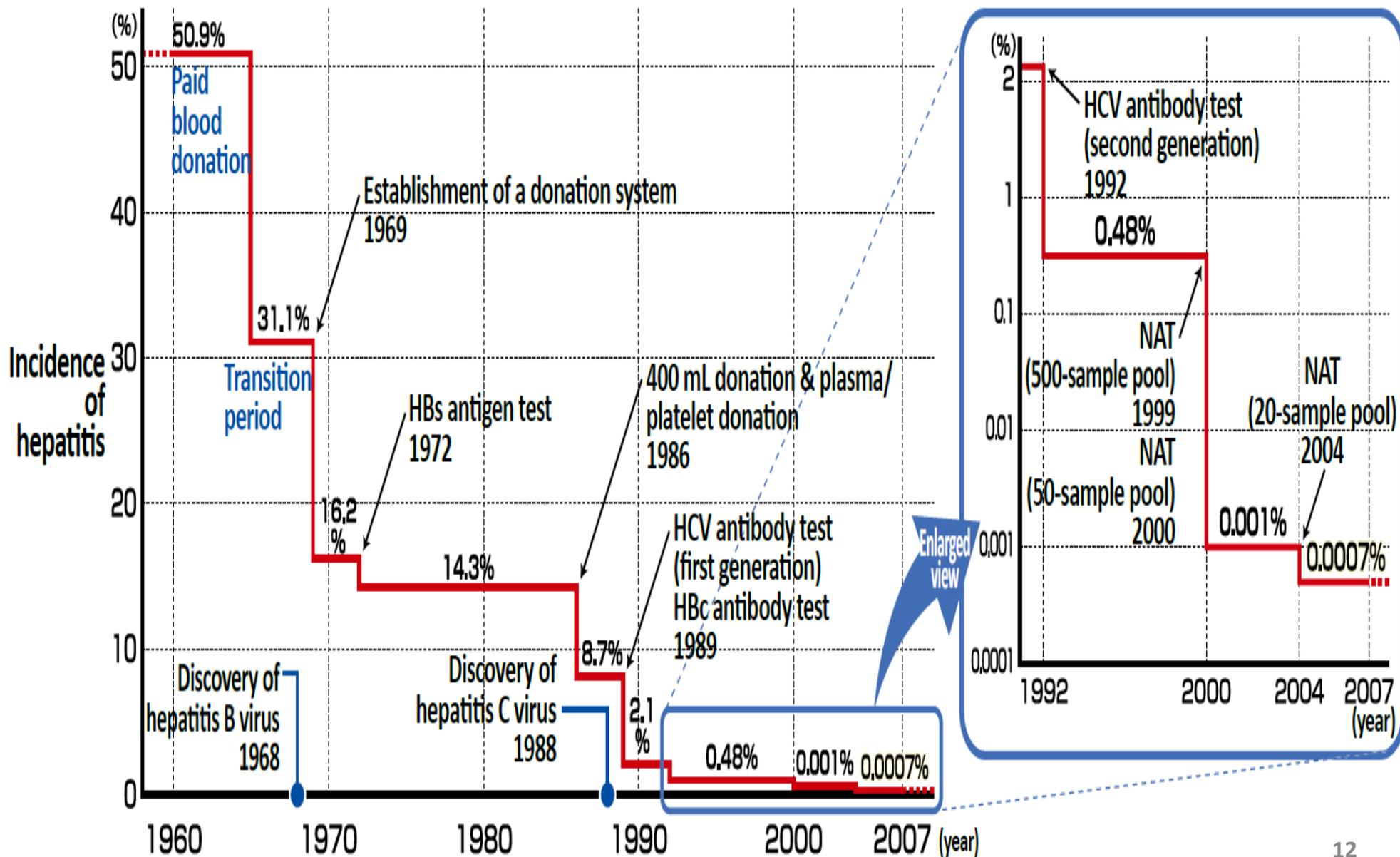
Donations by Age of Donors

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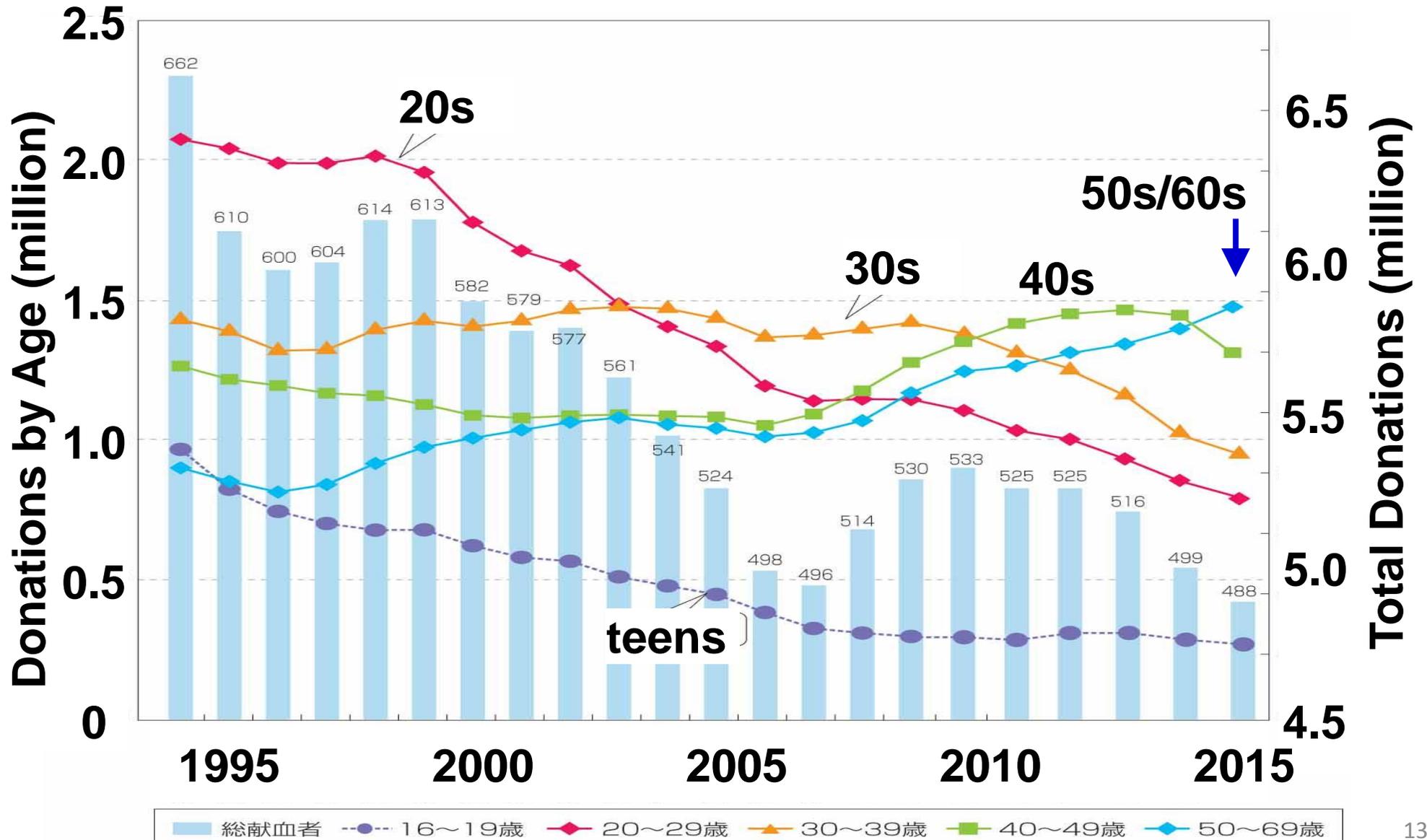
Flow of Money in Blood Services

Legend:
- Flow of Blood
- Flow of Money

Citizens

Medical Institutions

Transfusion

Partial Payment Medical Fee

Blood Donations

The Japanese Red Cross Society

Blood Products For Transfusion

Payment for Blood Products

91.3%

Source Plasma

Pay for Source Plasma 6.4%

Domestic Fractionators

Plasma Derivatives

Payment for Blood Products

Health Insurance Premiums

Japan Health Insurance Association, Health Insurance Societies etc

Payment for Medical Services

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JRC Haemovigilance: Number of Reports

Started in 1993

Legend:
- Non hemolytic TRs
- Hemolytic TRs
- Suspected TA-GVHD
- Suspected TTIs

Sample Storage

Look Back

Most reports are of Non-Hemolytic TRs

Decrease in TTI since 2004

Years (y-axis): 1994, 1996, 1998, 2000, 2002, 2004, 2006, 2008, 2010, 2012, 2014, 2016

X-axis: 0, 500, 1000, 1500, 2000
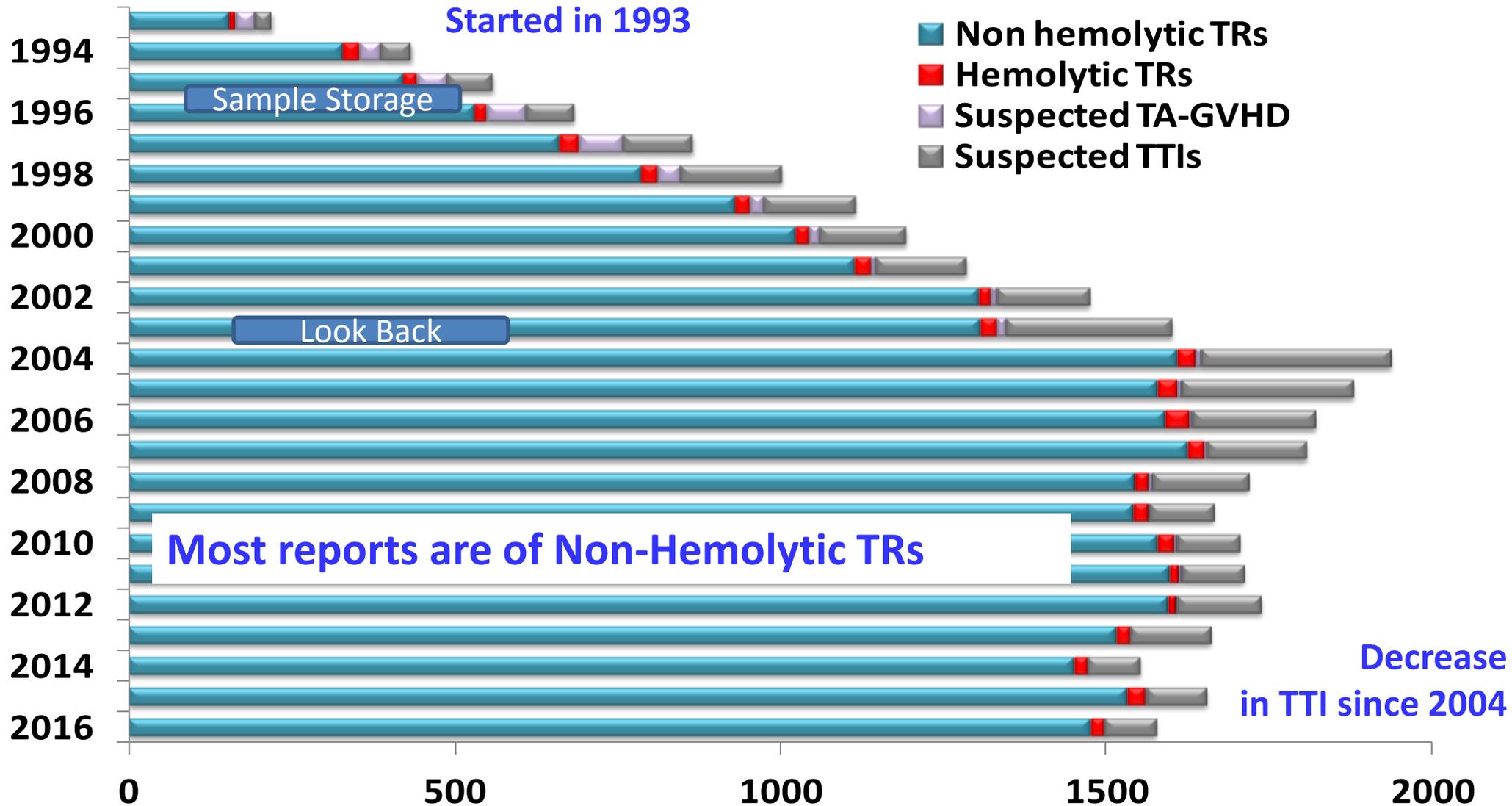
Total number & esp. TTI have decreased since 2004.

Number of Established Cases of TRALI & TACO

(cases)

Legend:
- ■ TRALI
- ■ p-TRALI
- ■ Cardiogenic pulmonary edema
- ■ TACO   ( ) fatal cases

2012.4 TACO Assessment

(year)	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
TACO						26	29	44	63	45
p-TRALI (blue)		28	30	47	48	44	35	33	38	26
TRALI top	17									
TRALI	14	16 (1)	14	15 (1)	10	4	10	7	6	3
bottom	31 (1)	16 (1)	24 (1)	9 (2)	14	6	9	2 (1)	7	4
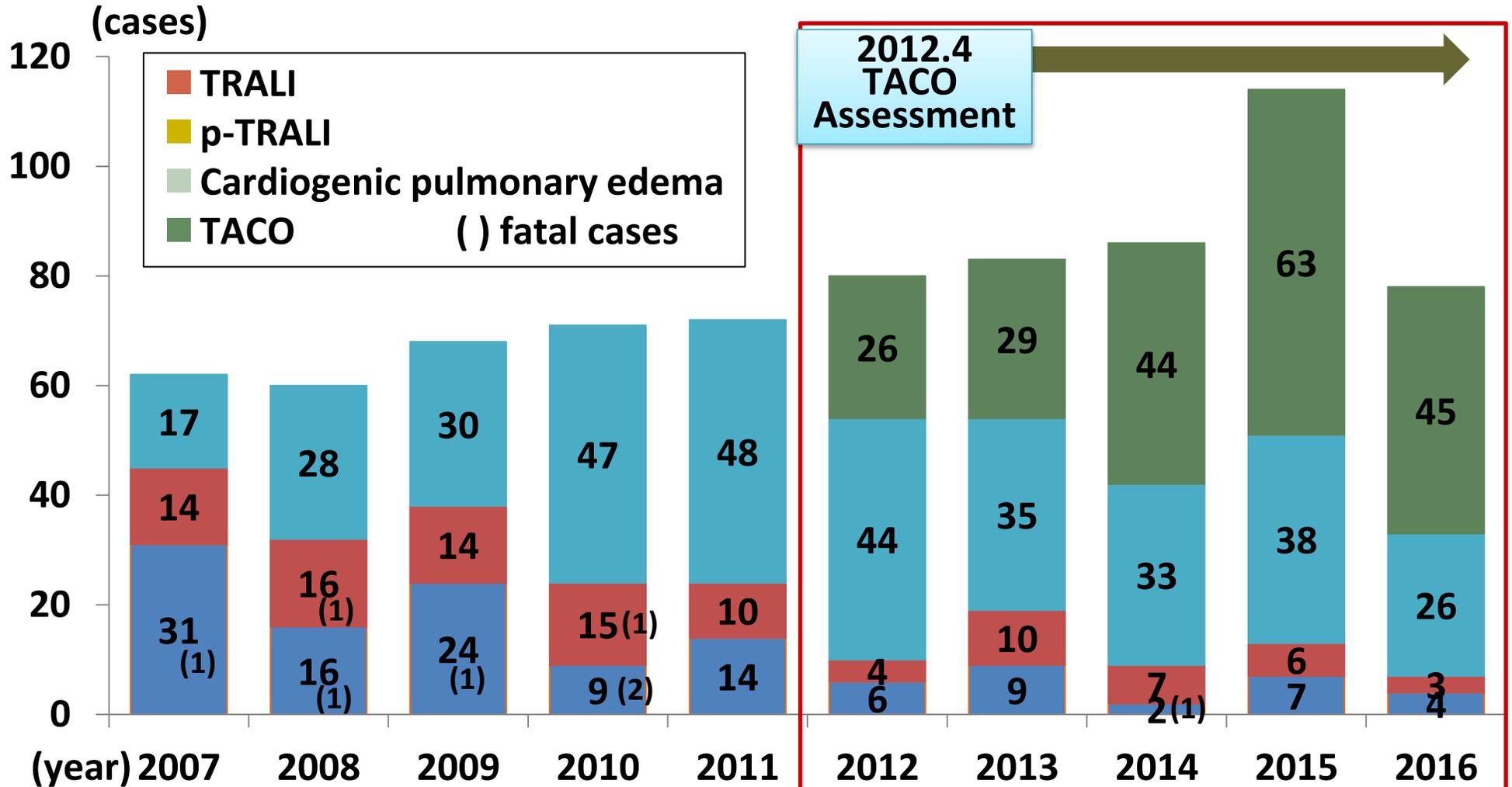
2011
FFP from 400mL WB prepared mainly from **male** donation

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Priorities in Blood Services

Sustainable blood service responsive to change in circumstances

1. efficiency
2. stable donation
3. "work-style" reforms
4. stable financial base

Brochures on Blood Services in Japan

http://www.jrc.or.jp/mr/english/index.html

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chezue tin ba dae

Special thanks to **Dr. Kazuma Ikeda,** **Okayama Red Cross Blood Center,** who prepare this presentation.