



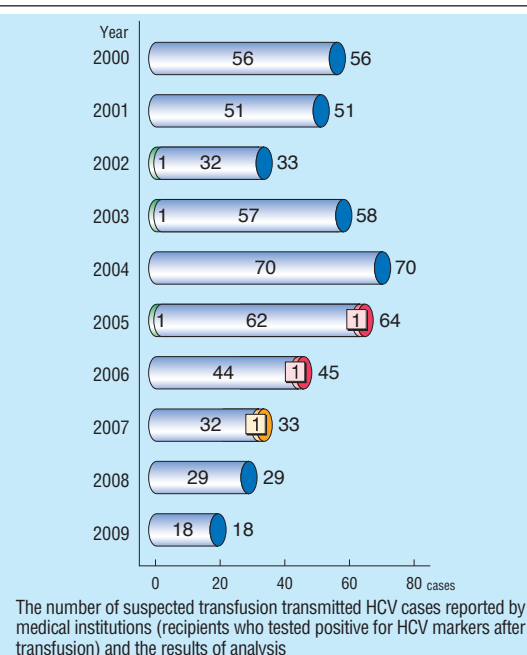
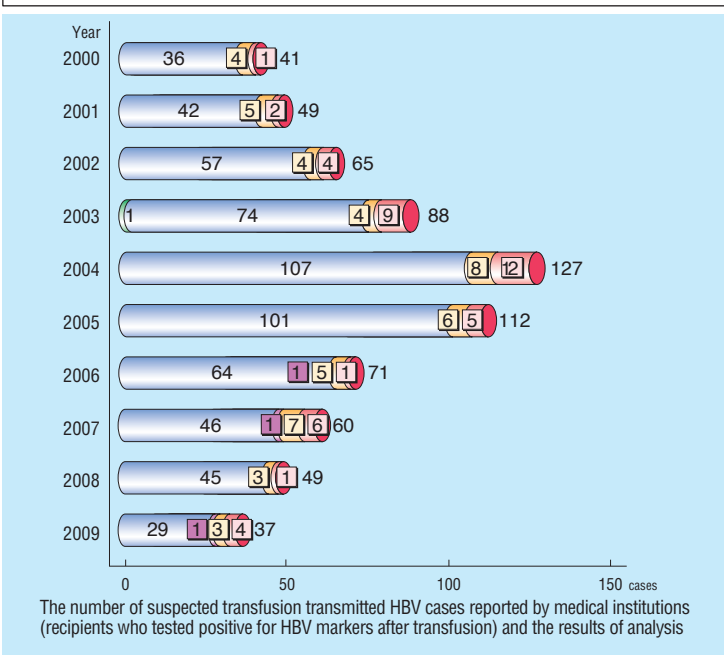
Infectious Cases of Probably Related to Transfused Blood Components (2009)

JRCS analyzed and evaluated suspected transfusion transmitted viral and other infectious cases reported voluntarily by medical institutions to JRC blood centers and lookback study cases based on the post-donation information. In 2009, seven cases of HBV infection and one case of HEV infection were confirmed by a positive HBV DNA or HEV RNA test in repository sample of involved donation. The cases of suspected bacterial infection revealed one positive case for *Serratia marcescens* blood component and one positive case of *Streptococcus agalactiae* (a group B *Streptococcus*) component.

The Number of Cases Reported to JRC Blood Centers and/or Examined in Response to Post-donation Information on Suspected Transfusion-transmitted Infections,* and the Results of Analysis [HBV and HCV infections] (2000 to 2009)

* Eight cases each of HBV infection and HCV infection for which a relationship with transfusion was denied both by the reporting medical institution and JRCS were excluded (see Importance of Pre-Transfusion Recipients' Sample Storage and Infection Test for Confirmation on the backside)

The repository sample of the donation was non-reactive by ID-NAT (voluntary report)	Viral nucleic acid was detected in the repository sample of the donation, but transfusion is unlikely to have caused infection* (voluntary report)	Viral nucleic acid was detected in the repository sample of the donation, and transfusion transmission was confirmed (voluntary report)	Viral nucleic acid was detected in the repository sample of the donation, and transfusion transmission was confirmed (lookback study)
Unanalyzable cases (voluntary report)	* Viral genotypes, etc. were different between the concerned donor and the recipient		



Summary of Case Reports (Transfusion transmission confirmed cases in which viral nucleic acid or bacteria was detected in the repository sample and/or relevant component of the concerned donor) (2009)

[HBV]

Voluntary reports: Cases reported by medical institutions

Case no.	Primary disease	Blood component* (year and month of blood collection)	Age	Sex	Pre-transfusion test			Post-transfusion test**			ALT		Recipient's sample
					Test items	Result	Period to transfusion	Test items	Result	Period from transfusion	Maximum (IU/L)	Period from transfusion	
1	Trauma due to a traffic accident	FFP-LR* (2008.3)	10s	M	HBV-DNA, HBsAg, HBcAb	Neg.	0 day	HBsAg	Pos.	20 wks	3110	20 wks	Available
2	Ischemic cardiomyopathy, etc.	RCC-LR (2008.12)	60s	M	HBsAg, HBsAb, HBcAb	Neg.	1 day	HBsAg	Pos.	24 wks	1079	24 wks	Available
3	Acute myeloid leukemia	Ir-PC* (2009.4)	60s	F	HBsAg, HBsAb, HBcAb	Neg.	190 days	HBsAg	Pos.	16 wks	◆	◆	Available

* The relevant donor had tested negative for HBV-DNA, but then turned positive for the screening test at the next donation.

Post donation information: Cases reported by medical institutions based on lookback studies of positive conversion of a repeat donor

Case no.	Primary disease	Blood component* (year and month of blood collection)	Age	Sex	Pre-transfusion test			Post-transfusion test**			ALT		Recipient's sample
					Test items	Result	Period to transfusion	Test items	Result	Period from transfusion	Maximum (IU/L)	Period from transfusion	
4	Idiopathic thrombocytopenic purpura	Ir-PC (2008.4)	30s	F	NA	NA	NA	HBsAg	Pos.	31 wks	296	26 wks	Available (day following that of transfusion)
5	Atrioventricular septal defect, etc.	Ir-RCC-LR (2008.8)	<1	F	HBsAg	Neg.	95 days	HBV-DNA	Pos.	31 wks	461	27 wks	Unavailable
6	Myelodysplastic syndrome, etc.	Ir-PC (2008.9)	20s	F	NA	NA	NA	HBsAg	Pos.	38 wks	171	41 wks	Available
7	Acute aortic dissection, etc.	Ir-PC (2009.2)	70s	M	HBsAg	Neg.	0 day	HBsAg	Pos.	17 wks	◆	◆	Unavailable

* The type of the involved blood component of which viral nucleic acid was detected in the repository sample of the donation

** Test results at medical institutions (on the day of the positive test result)

◆ No increase in ALT or no comparative data available

[HEV infection]

- A Case reported by medical institutions based on a lookback study of positive results at quality control of the source plasma for the manufacturing of plasma derivatives

Case no.	Primary disease	Blood component* (year and month of blood collection)	Age	Sex	Pre-transfusion test			Post-transfusion test			ALT		Recipient's sample Pre-transfusion
					Test items	Result	Period to transfusion	Test items	Result	Period from transfusion	Maximum (IU/L)	Period from transfusion	
1	Spinal epidural abscess, etc.	Ir-RCC-LR (2008.8)	70s	M	HEV-RNA IgM-HEV-Ab IgG-HEV-Ab	Neg.	0 day	HEV-RNA	Pos.	2 wks	1336	3 wks	Available

* The type of the involved blood component of which the viral nucleic acid was detected in the repository sample of the donation

[Bacterial infection]

- Voluntary reports: Cases reported by medical institutions

Case no.	Primary disease	Blood component* (year and month of blood collection**)	Days after collection	Age	Sex	Post-transfusion test		Symptoms		
						Transfused component	Recipient's blood	Major complaints	Time of onset (from the start of transfusion)	Outcome
1	Acute myeloid leukemia	Ir-PC (2009.7)	day4	60s	M	<i>Serratia marcescens</i>	<i>Serratia marcescens</i>	Fever, hypotension, chills, shivering, dyspnea, nausea	approx.10 min	Recovered
2	Myelodysplastic syndrome	Ir-PC (2009.9)	day3	70s	M	<i>Streptococcus agalactiae</i> (group B Streptococcus)	<i>Streptococcus agalactiae</i> (group B Streptococcus)	Chills, shivering, wheezing, peripheral coldness, hypotension	approx.80 min	Recovered

* The type of the involved blood component which tested positive for bacterium

** Day of blood collection = day 1

Importance of Pre-transfusion Recipients' Sample Storage and Infection Test for Confirmation

In the reported cases of suspected transfusion-transmitted infections by medical institutions in 2009, it was evaluated that a relationship with transfusion can be denied for eight cases of HBV and eight cases of HCV by both medical institutions and JRCS.

Details

- ◆ Cases in which the viral nucleic acid was detected in the recipients' pre-transfusion samples: HBV: Five cases; HCV: Two cases.
- ◆ Cases in which the viral nucleic acid was not detected and the serological test was negative in the recipients' post-transfusion samples: HBV: Three cases; HCV: Six cases.

↳ It is important to store patients' pre-transfusion blood samples. In case the post-transfusion infection test is positive, the recipients' pre-transfusion samples should be tested to confirm the relationship.

Number of times that the nucleic-acid amplification test (NAT) was performed and the frequency of positive samples (July 1999 to July 2010)

The table below describes the number of positive NAT results against donated blood samples with seronegative results (HBsAg: Negative; HBcAb: Negative; HCV-Ab: Negative; HIV-1- and HIV-2-Abs: Negative; ALT level: Normal).

Pooled size of samples	Number of tested samples	Number of positive NAT confirmed by ID-NAT (frequency)		
		HBV	HCV	HIV
500 (Jul. 1999 to Jan. 2000)	2,140,207	19 (1/11×10 ⁴)	8 (1/27×10 ⁴)	0 (-)
50 (Feb. 2000 to Aug. 2004)	24,702,784	473 (1/ 5×10 ⁴)	72 (1/34×10 ⁴)	8 (1/309×10 ⁴)
20 (Aug. 2004 to Jul. 2010)	29,584,222	540 (1/ 5×10 ⁴)	42 (1/70×10 ⁴)	13 (1/228×10 ⁴)

In case any of adverse reactions and/or infections related to transfusion of blood components or administration of plasma derivatives, please notify the medical representatives of your local JRC blood center immediately. Please provide the residual products, the recipient's pre- and post-transfusion samples, and any other related materials; it is helpful to investigate and/or identify the cause. For storage of residual products and the recipient's samples, refer to the "Guidelines for lookback studies of blood products."

Online Haemovigilance Information for Healthcare Professionals

URL <http://www.jrc.or.jp/mr/english/>

Issued by:

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* For more information, please contact the medical representatives of your local JRC blood center.