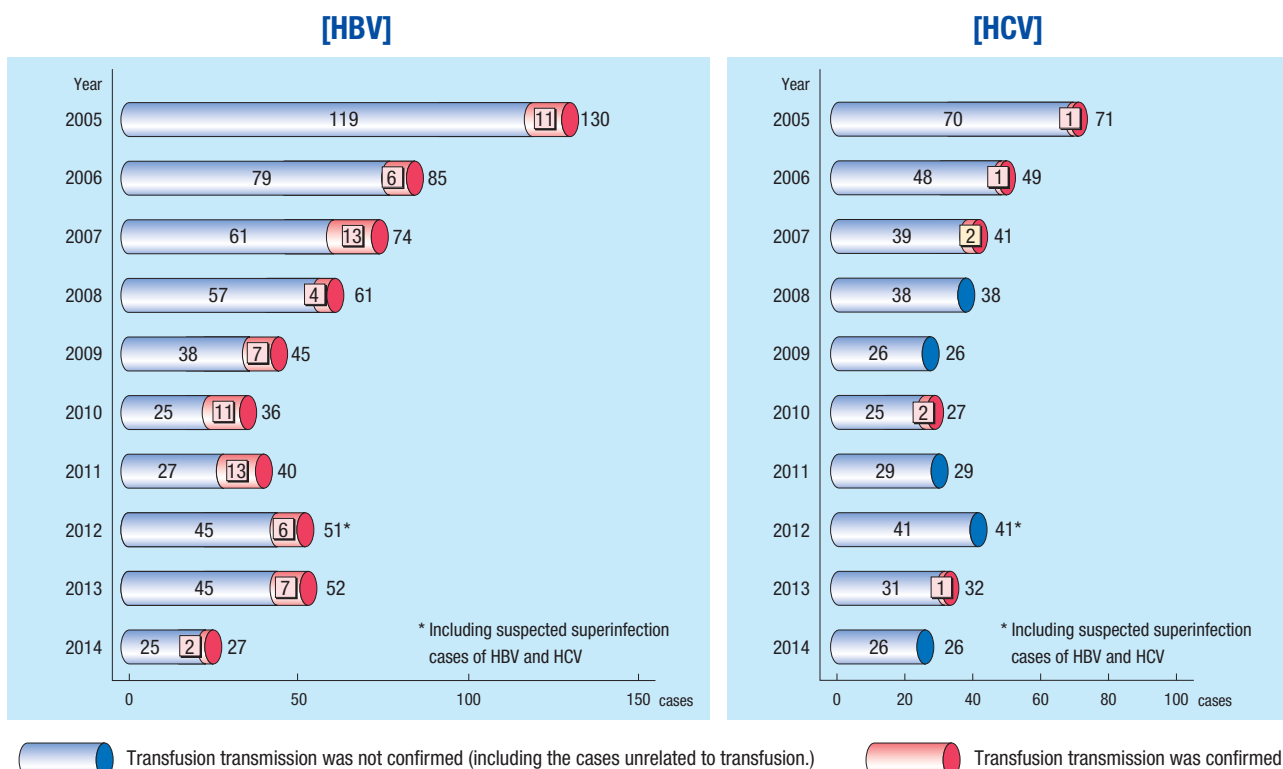


## Infectious Cases of Probably Related to Transfused Blood Components (2014)

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 post donation information. In 2014, two cases of HBV infection and four cases of HEV infection were confirmed by a positive viral nucleic acid test on a repository sample of the donation involved.

## The Cases Reported to JRC blood Centers as suspected Transfusion Transmitted Infections [HBV and HCV Infections] (2005 to 2014)



Since 2009, no fulminant hepatitis has been identified in the transfusion transmission confirmed cases.

## 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) (2014)

### [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	
					Test items	Result	Period to transfusion	Positive conversion item	Period from transfusion	Maximum (IU/L)	Period from transfusion
1	Unstable angina	FFP-LR (2013.6)	60s	M	HBV-DNA, HBsAg, HBsAb, HBeAb	Neg.	1-2 days	HBV-DNA	19 wks	1107	36 wks

● 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	
					Test items	Result	Period to transfusion	Positive conversion item	Period from transfusion	Maximum (IU/L)	Period from transfusion
2	Gastric cancer Alzheimer's dementia	Ir-RCC-LR (2013.9)	90s	M	HBsAg	Neg.	220 days	HBV-DNA	13 wks	◆	◆

◆ No increase in ALT or no comparative data available.

## [HEV]

### ● Voluntary reports: Cases reported by medical institutions suspected virus infection by transfusion

Case no.	Primary disease	Blood component (year and month of blood collection)	Age	Sex	Pre-transfusion test			Post-transfusion test		ALT	
					Test items	Result	Period to transfusion	Positive conversion item	Period from transfusion	Maximum (IU/L)	Period from transfusion
1	Burkitt's lymphoma	Ir-PC-LR (2011.11)	30s	F				HEV-RNA	126 wks	347	9 wks
2	Primary biliary hepatic cirrhosis (Liver transplant)	FFP-LR (2012.3)	60s	F	HEV-RNA	Neg.	3 days	HEV-RNA, IgG-HEV-Ab	37 wks	315	3 wks
3	Hepatic cirrhosis, hepatic cancer (Liver transplant)	Ir-PC-LR (2014.7)	40s	M	HEV-RNA, IgM-HEV-Ab, IgG-HEV-Ab, IgA-HEV-Ab	Neg.	1 day	HEV-RNA, IgM-HEV-Ab	12 wks	93	26 wks

### ● Post-donation information: Case reported by the medical institution receiving blood products that had been manufactured at the same time as the blood product transfused to voluntary report case No.2.

Case no.	Primary disease	Blood component (year and month of blood collection)	Age	Sex	Pre-transfusion test			Post-transfusion test		ALT	
					Test items	Result	Period to transfusion	Positive conversion item	Period from transfusion	Maximum (IU/L)	Period from transfusion
4	Myelodysplastic syndrome	Ir-RCC-LR (2012.3)	80s	F	HEV-RNA, IgM-HEV-Ab, IgG-HEV-Ab	Neg.	0 day	HEV-RNA, IgM-HEV-Ab, IgG-HEV-Ab	10 wks	811	10 wks

## Importance of preserving pre-transfusion recipient samples and infection tests

Among suspected cases of transfusion transmitted infection reported by medical institutions in 2014, imputability to transfusion was denied in 5 cases of HBV (19% of HBV cases reported) and 4 cases of HCV (15% of HCV cases reported), both by medical institutions and the JRCS.

- Breakdown -

- ◆ Viral genome was detected in pre-transfusion recipient samples: Five HBV cases and one HCV case.
- ◆ Both viral genome and serological tests of post-transfusion recipient samples turned out negative: Three HCV cases.

⇒ As a means to confirm transfusion transmitted infection, it is important to perform infection tests on the recipient patient's blood samples prior to blood transfusion.

## Number of times that the nucleic acid amplification test (NAT) was performed and the frequency of positive samples (Aug. 2004 to May. 2015) (Pooled size of samples: 20-pool samples)

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).

Period	Number of tested sample	Number of positive NAT confirmed by ID-NAT (frequency)		
		HBV	HCV	HIV
Aug. 2004 to Jul. 2008	18,514,278	334 (1:5.5×10 <sup>4</sup> )	32 (1:5.8×10 <sup>5</sup> )	11 (1:1.68×10 <sup>6</sup> )
Aug. 2008*1 to Jul. 2012	20,368,427	376 (1:5.4 x 10 <sup>4</sup> )	16 (1:1.27 x 10 <sup>6</sup> )	7 (1:2.91 x 10 <sup>6</sup> )
Aug. 2012*2 to Jul. 2014	9,927,699	68 (1:1.5 x 10 <sup>5</sup> )	4 (1:2.48 x 10 <sup>6</sup> )	1 (1:9.93 x 10 <sup>6</sup> )
Aug. 2014*3 to May. 2015	4,133,936	34 (1:1.2 x 10 <sup>5</sup> )	0	0

\*1 Changed reagents and apparatuses for NAT \*2 Revision of HBcAb criteria \*3: Introduction of individual NAT

**In case any of adverse reactions and/or infections related to transfusion of blood components, 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."**

Issued by:  
**Medical Information Division, Blood Service**  
**Headquarters, Japanese Red Cross Society**  
 1-1-3, Shiba Daimon, Minato-ku, Tokyo 105-8521, Japan

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

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