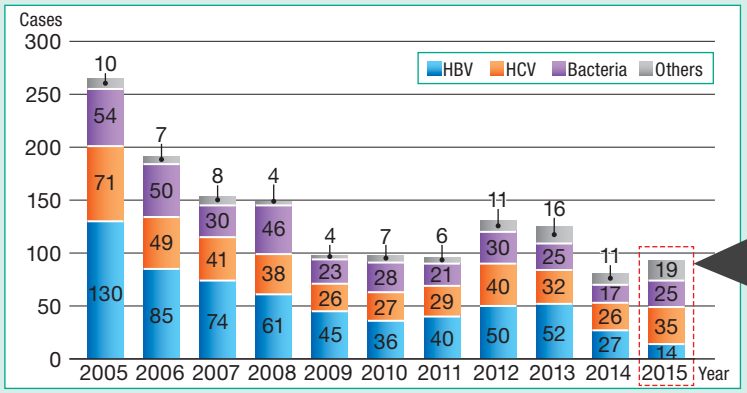
Infectious Cases that were Probably Related to Transfused Blood Components (2015)

JRCS analyzed and evaluated suspected cases of transfusion-transmitted viral and other infections reported voluntarily by medical institutions to JRC blood centers and retrospective study (Lookback study) cases based on post-donation information. In 2015, there were 3 cases of HEV infection, 1 case of parvovirus B19 infection, and 2 cases of bacterial infection that were confirmed by detection of viral nucleic acid or bacteria in a repository sample of the involved blood donation.

The yearly number of cases reported to JRC blood centers as suspected transfusion-transmitted infection, and the breakdown and analysis of suspected cases in 2015 by pathogen.



Pathogen	Number of reported cases	Number of confirmed cases
HBV	14	0
HCV	35	0
Bacteria	25	2
CMV	10	0
HEV	4	3
HAV	1	0
HSV	1	0
HIV	1	0
HTLV-1	1	0
B19	1	1
Total	93	6

A total of 93 cases including 14 HBV cases and 35 HCV cases were reported to JRC blood centers as suspected transfusion-transmitted infections. HBV declined to about half that of the previous year, but HCV was almost the same. However, none were confirmed to be transfusion-transmitted infection. Among 19 other cases, 10 cases were suspected to be CMV infection. These were obtained by active collection of cases with the cooperation of medical institutions. None were confirmed to be transfusion-transmitted CMV infection.

Summary of Case Reports (Confirmed cases of transfusion transmission for which pathogenic agents were detected in the repository sample and/or relevant components from the concerned donor)(2015)

HEV

● Voluntary reports: Cases reported by medical institutions as transfusion-transmitted viral infection

Case no.	Primary disease	Blood component (year and month of blood collection)	Age	Sex	Pre-transfusion test			Post-transfusion test		ALT		Recipient's outcome
					Test items	Test results	Period to transfusion	Positive conversion items	Interval after transfusion	Maximum (IU/L)	Interval after transfusion	
1	Myeloma	Ir-PC-LR (2015.2)	50s	F	HEV-RNA IgA-HEV-Ab IgM-HEV-Ab IgG-HEV-Ab	Neg.	6 days	HEV-RNA IgA-HEV-Ab IgM-HEV-Ab IgG-HEV-Ab	16 wks	449	16 wks	Recovery
2	Hodgkin's lymphoma	Ir-PC-LR (2015.3)	60s	M	HEV-RNA IgA-HEV-Ab IgM-HEV-Ab IgG-HEV-Ab	Neg.	21 days	HEV-RNA IgA-HEV-Ab IgM-HEV-Ab IgG-HEV-Ab	16 wks	646	15 wks	Recovery

● Post-donation information: A case reported by a medical institution based on Lookback studies on positive conversion identified in the HEV-NAT trial

Case no.	Primary disease	Blood component (year and month of blood collection)	Age	Sex	Pre-transfusion test			Post-transfusion test		ALT		Recipient's outcome
					Test items	Test results	Period to transfusion	Positive conversion items	Interval after transfusion	Maximum (IU/L)	Interval after transfusion	
3	Acute myeloid leukemia	Ir-PC-LR (2014.12)	70s	M	HEV-RNA IgM-HEV-Ab IgG-HEV-Ab	Neg.	5 days	HEV-RNA	2 wks	615.5	10 wks	Remission

Bacteria

Voluntary report: Cases reported by medical institutions as suspected transfusion-transmitted bacterial infection

Case no.	Primary disease	Blood component (year and month of blood collection)	Age	Sex	Blood culture results of post-transfusion		Symptoms	Onset time (after administration)	Recipient's outcome
					Blood components	Recipient's blood			
1	Acute myeloid leukemia	Ir-PC-LR (2014.12)	Under 10	M	*Escherichia coli*	*Escherichia coli*	Fever, chills, tachycardia, hypoxemia, hypotension	25 min.	Recovery
2	Neuroblastoma	Ir-PC-LR (2015.6)	Under 10	F	*Staphylococcus aureus*	*Staphylococcus aureus*	Fever, generalized edema, weight gain, worsening heart failure	Unknown	Recovery, with sequelae

Parvovirus B19

Voluntary report: A case reported by a medical institution as a suspected transfusion-transmitted viral infection

Case no.	Primary disease	Blood component (year and month of blood collection)	Age	Sex	Pre-transfusion test			Post-transfusion test	
					Test items	Test results	Period to transfusion	Positive conversion items	Interval after transfusion
1	Diabetic nephropathy	Ir-RBC-LR (2015.8)	60s	M	B19-DNA	Neg.	1 day	B19-DNA	3 wks

Importance of preserving pre-transfusion recipient samples and infection tests

Among the suspected cases of transfusion-transmitted infection reported by medical institutions in 2015, it was judged that there was "no cause imputable to transfusion" in 3 cases of HBV (21% of reported HBV cases) and 3 cases of HCV (9% of reported HCV cases).

- Breakdown -
◆Viral genome detected in pre-transfusion recipient samples: Two HBV cases and one HCV case.
◆Viral genome and serological test of post-transfusion recipient samples turned out negative: One HBV case and two HCV cases.

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

History of safety assurance measures for blood and blood components (since 2000)

2000	Feb	Changed the pool size of minipool-NAT for HBV, HCV and HIV-1 (from 500 to 50)
2001	Mar	Implemented a six-month inventory hold of source plasma
2003	Jun	Nationwide introduction of lookback studies
2004	Aug	Changed the pool size of minipool-NAT for HBV, HCV and HIV-1 (from 50 to 20)
	Oct	Implemented the identification of donors
		Introduced the pre-storage leukocyte reduction (apheresis platelet concentrates)
2005	Apr	Implementation of Guideline for Lookback Study of Blood Products
	Jun	Implemented blood donor deferral criteria on history of travel to Europe (for more than 1 day)
	Jul	Started the supply of fresh frozen plasma after six-month inventory hold
2006	Mar	Introduced pre-storage leukocyte reduction (apheresis plasma)
	Oct	Introduced the diversion pouch (apheresis platelet concentrates)
2007	Jan	Introduced pre-storage leukocyte reduction (blood and blood components derived from whole blood collection)
	Mar	Introduced the diversion pouch (blood and blood components derived from whole blood collection)
2008	Jan	Introduced the diversion pouch (apheresis plasma)
	Aug	Changed the tests for HBsAg, HBsAb, HBcAb, HCV-Ab, HIV-1,2-Ab, HTLV-1-Ab, Treponema pallidum antibody, and human parvovirus B19 antigen (CLEIA)
		Changed the reagents and apparatuses used for NAT for HBV, HCV and HIV-1,2
2010	Jan	Easing of blood donor deferral on history of travel to Europe (for more than 1 day→for more than a total of 1 month)
2011	Apr	Subdividing the donor interview questions (14→23 items)
2012	Aug	Changed the determination criteria of HBcAb (CLEIA)
	Oct	Introduction of security measures against Chagas disease
2014	Aug	Introduction of individual NAT (ID-NAT) for HBV, HCV and HIV-1,2
2016	Apr	Changed determination criteria of liver function tests (ALT)
	Aug	Revision of the security measures against Chagas disease — Introduction of selective *T.cruzi* antibody testing on blood donors (CLIA)

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."

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

For blood products and transfusion information
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