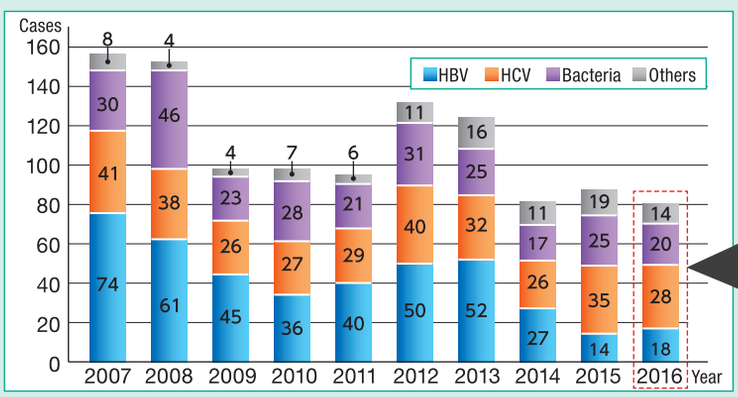
Infectious Cases that were Probably Related to Transfused Blood Components (2016)

JRCS analyzed and evaluated suspected cases of transfusion-transmitted viral and other infections reported voluntarily by medical institutions to JRC blood centers as well as retrospective study (Lookback study) cases based on post-donation information. In 2016, there were 1 case of HBV infection, 3 cases of HEV infection, and 1 case of bacterial infection that were confirmed by detection of viral nucleic acid in a repository sample of the involved blood donation or bacteria in the relevant blood bags.

The yearly number of cases reported to JRC blood centers as suspected transfusion-transmitted infections, and the breakdown and analysis of suspected cases in 2016 by pathogens.



Pathogens	Number of reported cases	Number of confirmed cases
HBV	18	1
HCV	28	0
Bacteria	20	1
CMV	7	0
HEV	4	3
HAV	1	0
B19	2	0
Total	80	5

A total of 46 cases including 18 HBV cases and 28 HCV cases were reported to JRCS as suspected transfusion-transmitted infections. One confirmed case of HBV was reported for the first time after introduction of individual nucleic acid amplification test (NAT). No cases of HCV, on the other hand, were confirmed to be a transfusion-transmitted infection. For cases of suspected CMV infections, 7 cases were reported. However, none of them were confirmed as a transfusion-transmitted infection. They were actively collected by the cooperation of medical institutions since previous year.

Summary of Case Reports (Cases confirmed to be transfusion transmission for which pathogenic agents were detected in the sample and/or the relevant blood bags from the concerned donors) (2016)

HBV

● Post-donation information: A case revealed by Lookback studies based on positive conversion identified at screening of donated blood

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	Acute myeloid leukemia	Ir-PC-LR (2015.11)* Ir-PC-LR (2015.12)*	70s	F	HBV-DNA HBs-Ag HBs-Ab HBc-Ab	Neg.	400 days 9 days 9 days 9 days	HBV-DNA HBs-Ag	12 wks 13 wks	38	10 wks	Remission

* The concerned donated blood was negative for HBV-NAT, but positive for HBV-NAT at the time of donation in January 2016.
** It was reckoned from the date of transfusion with blood components collected in November 2015.

HEV

● Voluntary report: Cases reported by medical institutions 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		ALT		Recipient's outcome
					Test items	Test results	Period to transfusion	Positive conversion items	Interval after transfusion	Maximum (IU/L)	Interval after transfusion	
1	Acute myeloid leukemia	Ir-RBC-LR (2015.9)	40s	F	HEV-RNA	Neg.	140 days	IgA-HEV-Ab	11 wks	1252	11 wks	Recovery
2	Myelodysplastic syndrome	Ir-PC-LR (2016.6)	50s	M	IgA-HEV-Ab	Neg.	49 days	IgA-HEV-Ab	9 wks	1200	9 wks	Remission

HEV

● Post-donation information: A case revealed by Lookback studies based on close investigation of source plasma for 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 outcome
					Test items	Test results	Period to transfusion	Positive conversion items	Interval after transfusion	Maximum (IU/L)	Interval after transfusion	
1	Mitral valve incompetence	Ir-RBC-LR (2015.6)	80s	F	HEV-RNA IgM-HEV-Ab IgG-HEV-Ab	Neg.	3 days	IgG-HEV-Ab	56 wks	267	7 wks	Recovery

Bacteria

● Voluntary report: A case reported by a medical institution as a 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	Aplastic anemia	Ir-PC-LR (2016.5)	60s	M	*Citrobacter koseri*	*Citrobacter koseri*	Abdominal pain, vomiting, diarrhea, shivering, fever, inflammatory response	47 min.	Recovery, with sequelae

Importance of preserving pre-transfusion recipient samples and infection tests

Among the suspected cases of transfusion-transmitted infections reported by medical institutions in 2016, the following cases were assessed by both medical institutions and JRCS as "no cause of imputability to transfusion" based on the results of tests on the recipient blood and the donated blood: Three cases of HBV (17% of reported HBV cases) and four cases of HCV (14% 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 three HCV cases.

⊙ **If pre- and post-transfusion recipient samples are appropriately preserved according to the "Guidelines for lookback studies of blood products," an additional examination may reveal the pre- and post-transfusion status of infection.**

Transfusion-transmitted bacterial infection cases

Components	Before introduction of the diversion pouch and leukocyte reduction procedures (2000-2006)		After introduction of the diversion pouch and pre-storage leukocyte reduction (2007-2016)	
	Number of cases (fatal case)	Implicated bacteria	Number of cases (fatal cases)	Implicated bacteria
Red blood cells	3 cases (0)	*Yersinia enterocolitica* (2 cases) *Bacillus cereus*	0 cases (0)	
Platelets	2 cases (2)	*Staphylococcus aureus* *Streptococcus pneumoniae*	10 cases (0)	*Streptococcus dysgalactiae ssp. equisimilis* (3 cases) *Staphylococcus aureus* (2 cases) *Streptococcus agalactiae* *Serratia marcescens* *Streptococcus pyogenes* *Escherichia coli* *Citrobacter koseri*

Analysis of cases suspected as transfusion-transmitted bacterial infection revealed no confirmed cases of bacterial infection from red blood cells since introduction of the diversion pouch and pre-storage leukocyte reduction procedures (2007). However, bacterial infections from platelets have occurred approximately 1 case a year, and most of the cases were related to day 4 platelets including the day of collection. Visual inspection regarding the presence of swirling, aggregates, etc., should therefore be conducted just before transfusion. If any abnormalities are found, please stop using the component and contact the medical representative of the JRC blood center.
If a transfusion-transmitted bacterial infection is suspected, please conduct blood cultures of the recipient immediately and store the residual blood component bag appropriately according to the "Guidelines for lookback studies of blood products."

[Reference]
Guidelines for lookback studies of blood products [March 2005 (partial revision: July 2014)], Blood and Blood Products Division, Pharmaceutical and Food Safety Bureau, Japan Ministry of Health, Labour and Welfare
http://www.mhlw.go.jp/new-info/kobetu/iyaku/kenketsugo/dl/140814_02a.pdf

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 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 samples, refer to the "Guidelines for lookback studies of blood products."

Issued by:
Medical Information Division, Technical Department, Blood Service Headquarters, Japanese Red Cross Society
1-2-1 Shiba-Koen, Minato-ku, Tokyo 105-0011, Japan
* For more information, please contact the medical representatives of your local JRC blood center.

For blood products and transfusion information
Japanese Red Cross Society
Haemovigilance Information English website
Japanese Red Cross Society Haemovigilance Information Search