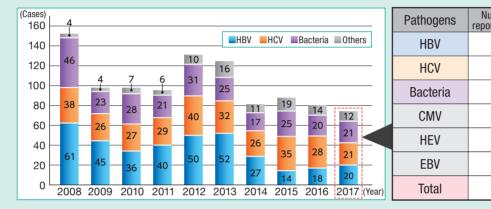
Transfusion Information

Infectious Cases that were Probably Related to Transfused Blood Components (2017)

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 2017, there were 3 cases of bacterial infection, 1 case of HBV infection, and 4 cases of HEV 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 results of suspected cases in 2017 by pathogens.



Pathogens	Number of reported cases	Number of confirmed cases
HBV	20	1
HCV	21	0
Bacteria	21	3
CMV	6	0
HEV	5	4
EBV	1	0
Total	74	8

The 3 cases identified to have bacterial infection were all due to platelets. In the confirmed case of HBV, the residual products were negative for HBV-individual nucleic acid amplification test (NAT), but positive for HBV-NAT at the time of later donation. The HBV was confirmed by a subsequent lookback study. Among the cases classified as "Others," infection was confirmed only in the 4 cases of HEV.

Summary of Case Reports

(Cases confirmed to be transfusion-transmitted infections with detection of pathogenic agents in the samples and/or the relevant blood bags from the concerned donors) (2017)

Bacteria

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

(Case	Primary disease	Blood component (vear and month of	Age	Sex	Symptoms	Onset time (after	Blood culti post-tra	Outcome	
	no.	Trimary discase	blood collection)	Ago	JUX			Recipient blood	Blood component	
	1	Myelodysplastic syndrome transformation	Ir-PC-LR (2017.3)	80s	M	Chills and shivering, fever, vomiting, blood pressure fluctuation, oxygen saturation decreased	5hrs	Lactococcus garvieae	Lactococcus garvieae	Remission
	2*1	Acute myeloid leukemia	Ir-PC-LR (2017.7)	< 10 yrs	F	Shivering, vomiting, pallor facial, fever, tachycardia, oxygen saturation decreased	20 min	Escherichia coli	Escherichia coli	Death
	3	Acute myeloid leukemia	Ir-PC-HLA-LR (2017.12)	30s	F	Shivering, vomiting, oxygen saturation decreased, fever, hypotension	30 min	Klebsiella pneumoniae	Klebsiella pneumoniae	Recovered with sequelae

^{*1} Summary of case reports is written in "Transfusion Transmitted Bacterial Infection through Platelet Components" of Transfusion Information 1712-156.

Measures against suspected bacterial infection

- When bacterial infection is suspected in a case, discontinue blood transfusion immediately and take appropriate measures.
- Store the residual blood component bag appropriately Note) and notify the medical representatives of your local JRC blood center
- <u>Bacterial culture test on the residual blood component bag</u> should be performed only when the specimen can be collected under aseptic conditions.
- Please provide the residual products when bacterial infection is suspected. It is helpful to identify the cause.

Note) Please firmly tighten the clamp of the blood transfusion set and return it to the Blood Transfusion Division. Then, seal the top and bottom of the drip cylinder with a tube sealer (if there is no tube sealer, ligate them with a clamp or other instruments), put the whole bag in a plastic bag and store it clean in refrigerated storage (not frozen storage).

HBV

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

Case		Blood component			Pre-transfus	ion test	Post-transf	usion test		ALT	
no.	Primary disease	(year and month of blood collection)	Age	Sex	Test items	Test results	Positive conversion items	Interval after transfusion	Maximum (IU/L)	Interval after transfusion	Outcome
1	Myelodysplastic syndrome	Ir-PC-LR (2017.5)* ²	70s	М	HBV-DNA HBs-Ag HBs-Ab HBc-Ab	Neg.	HBV-DNA	6 wks	*3	*3	Non- recovered

^{*2} The concerned donated blood was negative for HBV-DNA, but positive for HBV-DNA at the time of donation in June 2017.

HEV

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

Case	Primary disease Blood component (year and month of blood collection)			Pre-transfusion test		Post-transfusion test		ALT			
no.		(year and month of blood collection)	Age	Sex	Test items	Test results	Positive conversion items	Interval after transfusion	Maximum (IU/L)	Interval after transfusion	Outcome
1	Myelodysplastic syndrome	Ir-PC-LR (2015.10)	60s	M	HEV-RNA	Neg.	HEV-RNA IgA-HEV-Ab	2 wks 6 wks	341	6 wks	Recovered
2	Acute myeloid leukemia	Ir-PC-LR (2017.1)	60s	F	HEV-RNA	Neg.	HEV-RNA	15 wks	589	27 wks	Recovered
3*4	Multiple myeloma	Ir-RBC-LR (2017.7)	80s	F	HEV-RNA IgM-HEV-Ab IgG-HEV-Ab	Neg.	HEV-RNA IgM-HEV-Ab IgG-HEV-Ab	12 wks 13 wks 13 wks	679	11 wks	Death

^{*4} Summary of case reports is written in "Hepatitis E Virus (HEV) Infection" of Transfusion Information 1803-158.

Post-donation information: A case reported by the medical institution that provided the blood component derived from the last donated blood from the same donor. This case was reported in a lookback study following the voluntary reporting of case No. 2.

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	300	Blood component			Pre-transfusion test		Post-transfusion test		ALT			
1	no.	Primary disease	(year and month of blood collection)	Age	Sex	Test items	Test results	Positive conversion items	Interval after transfusion	Maximum (IU/L)	Interval after transfusion	Outcome
	1	Myelodysplastic syndrome	Ir-PC-LR (2016.12)	70s	F	None		HEV-RNA IgG-HEV-Ab	27 wks	36	19 wks	Recovered

Measures against suspected transfusion-transmitted infections (HBV, HCV, HIV)^{1, 2)}

	Pre-transfusion test	Post-transfusion test	- Treatment strategies
	Test items Test results	Test items Test results	- Treatment strategies
HBV	HBs-Ag HBs-Ab HBc-Ab Negative in all [not infected]	NAT after 3 months Positive [acute infection] - Negative [no infection] -	,
TIDV	HBs-Ag Positive in either of them HBs-Ab [carrier or HBc-Ab infection history]		In the case of carrier, → treatment is given as needed
116) (HCV-Ab Negative in all HCV-Core Ag [not infected] HCV-Ab Positive [infection HCV-Core Ag → Negative history]	HCV-Core Ag → after 1-3 months HCV-Core Ag Positive [acute infection] — Negative [no infection] —	-
HCV	HCV-Ab → Negative [early phase HCV-Core Ag → Positive of infection]		► Early treatment is needed
	HCV-Ab Positive in all Carrier]		→ Treat as needed
HIV	Negative [not infected] Positive (confirmatory test) [carrier]	HIV-Ab after 2 or 3 months Positive Negative [no infection]	→ Early treatment is needed → — → — → Treatment is needed.

When the physician suspects infection considering the infection risk, perform preand post-transfusion tests for virus-related markers and others. For interpretation of test results, please see the left column (Created based on Q&A from "Guideline for Lookback Study of Blood Products").

When other transfusion-transmitted infections are suspected, please contact the medical representatives of your local JRC blood center.

Reference: 1) Partial revision of "Guidelines for lookback studies of blood products" (Notification No. 0322-6 issued on March 22, 2018 by the Director of the Pharmaceutical Safety and

Environmental Health Bureau, Ministry of Health, Labour, and Welfare)

2) Partial revision of "Guidelines for Blood Transfusion Therapy" and "Guidelines for Blood Product Use" (Notification No. 1112-12 issued on November 12, 2014 by the Director of the Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour, and Welfare)

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."

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* 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



^{*3} No elevated ALT was observed, or there was no comparison data.