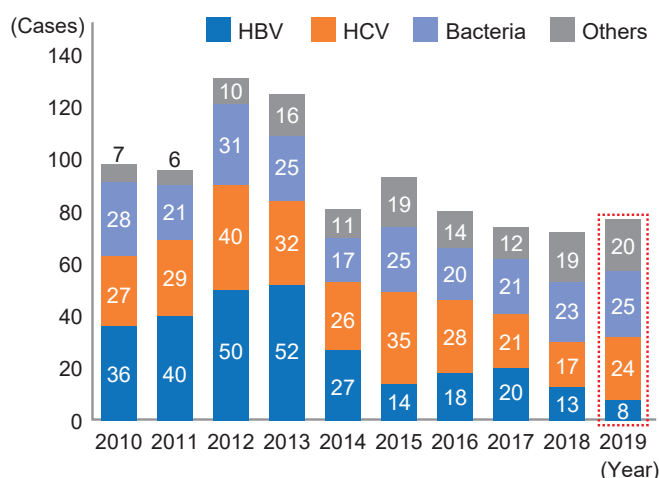


Infectious Cases that were Probably Related to Transfused Blood Components (2019)

JRCS analyzed and evaluated suspected cases of transfusion-transmitted viral and other infections (TTI) reported voluntarily by medical institutions to JRC blood centers as well as retrospective study (lookback study) cases based on post-donation information. In 2019, there were 2 cases of bacterial infection, 5 cases of HEV infection, 2 cases of parvovirus B19 infection, and 1 case of HGV infection, confirmed by detections of bacteria in the relevant blood bags and viral nucleic acid in repository samples of the involved or subsequent blood donations.

Yearly number of cases reported to JRC blood centers as suspected transfusion-transmitted infections, and the breakdown and analysis results of the reported cases by pathogen in 2019.



Pathogen	Number of reported cases	Confirmed cases
HBV	8	0
HCV	24	0
Bacteria	25	2
CMV	7	0
HEV	7	5
Parvovirus B19	3	2
HAV	1	0
HGV	1	1
EBV	1	0
Total	77	10

The 2 cases of bacterial infection were both due to platelets. The 5 cases of HEV infection consisted of 2 cases voluntarily reported by medical institutions and 3 cases identified by lookback studies. The other confirmed cases consisted of 2 cases of human parvovirus B19 infection and 1 case of hepatitis G virus (HGV) infection.

Summary of Case Reports

(Cases confirmed to be TTIs with detection of pathogenic agents in the blood donor samples and/or the relevant blood bags) (2019)

Bacteria

- Voluntary reports: Cases reported by medical institutions as suspected transfusion-transmitted bacterial infections

Case No.	Blood component (year and month of blood collection)	Primary disease	Age	Sex	Symptoms	Onset time (after starting the administration)	Blood culture results of post-transfusion		Patient outcome
							Blood component	Patient blood	
1	Ir-PC-LR* (2019.4)	B-cell lymphoma	50s	F	Fever	Next day	<i>Staphylococcus aureus</i>	<i>Staphylococcus aureus</i>	Recovered
2	Ir-PC-LR (2019.8)	Myelodysplastic syndrome	40s	M	Chills, fever	2 hrs 30 min	<i>Staphylococcus aureus</i>	<i>Staphylococcus aureus</i>	Recovering

* Reported as having an abnormal appearance on the day of transfusion.

Response to suspected bacterial infection via transfusion

- When bacterial infection is suspected, **stop the transfusion immediately and provide appropriate treatment**.
- Keep the residual bag appropriately** ^{Note)} and notify the medical representatives of your local JRC blood center.
- Bacterial culture test of the residual bag** should be performed only when the specimen can be collected under aseptic conditions.
- Please provide the residual bag** when bacterial infection is suspected. It is helpful to identify the cause.

Note) Tighten clamp of the transfusion set and return the bag and set to the transfusion department. Then, seal the top and bottom of the drip cylinder with a tube sealer (if you don't have a tube sealer, ligate them with a clamp or other instruments), put the bag and set in a plastic bag and store it clean in a refrigerator (not in a freezer).

HEV

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

Case No.	Blood component (year and month of blood collection)	Primary disease	Age	Sex	Pre-transfusion test			Post-transfusion test		ALT		Patient outcome
					Test items	Test result	Duration before transfusion	Positive conversion items	Duration after transfusion	Maximum (IU/L)	Duration after transfusion	
1	Ir-WRC-LR (2018.6)	Acute lymphatic leukemia	60s	M	HEV-RNA IgA-HEV-Ab IgM-HEV-Ab IgG-HEV-Ab	Neg.	8 days	HEV-RNA	14 wks	443	247 days	Recovered
2	FFP-LR (2018.12)	Obstetrical DIC	30s	F	None			IgA-HEV-Ab	10 wks	677	65 days	Recovered

● Post-donation information: A case reported by the medical institution provided with the co-component for the above-mentioned voluntarily reported case No. 1

Case No.	Blood component (year and month of blood collection)	Primary disease	Age	Sex	Pre-transfusion test			Post-transfusion test		ALT		Patient outcome
					Test items	Test result	Duration before transfusion	Positive conversion items	Duration after transfusion	Maximum (IU/L)	Duration after transfusion	
1	FFP-LR (2018.6)	Hepatocellular carcinoma	60s	M	HEV-RNA IgA-HEV-Ab IgM-HEV-Ab IgG-HEV-Ab	Neg.	1 day	IgM-HEV-Ab IgG-HEV-Ab	14 wks	◆	◆	Recovered

● Post-donation information: Cases identified by lookback studies through detailed examinations of source plasma for plasma derivatives

◆ No comparative data.

Case No.	Blood component (year and month of blood collection)	Primary disease	Age	Sex	Pre-transfusion test			Post-transfusion test		ALT		Patient outcome
					Test items	Test result	Duration before transfusion	Positive conversion items	Duration after transfusion	Maximum (IU/L)	Duration after transfusion	
1	Ir-RBC-LR (2019.3)	Transverse colon cancer	80s	M	HEV-RNA IgA-HEV-Ab IgM-HEV-Ab IgG-HEV-Ab	Neg.	1 day	IgA-HEV-Ab IgM-HEV-Ab IgG-HEV-Ab	23 wks	◆	◆	Recovering
2	Ir-PC-LR (2018.12)	Retroperitoneal hemorrhage Aortic valve stenosis	80s	F	HEV-RNA IgA-HEV-Ab IgM-HEV-Ab IgG-HEV-Ab	Neg.	4 days	HEV-RNA IgG-HEV-Ab	29 wks	◆	◆	Recovered

◆ No comparative data.

Parvovirus B19

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

Case No.	Blood component (year and month of blood collection)	Primary disease	Age	Sex	Pre-transfusion test			Post-transfusion test		Patient outcome
					Test items	Test result	Duration before transfusion	Positive conversion items	Duration after transfusion	
1	Ir-RBC-LR (2019.1)	Lymphoproliferative disease	50s	M	B19-DNA	Neg.	7 days	B19-DNA B19-IgG-Ab	2 days	
2	Ir-RBC-LR (2019.7)	Hemolytic anemia	< 10yrs	F	B19-DNA	Neg.	2 days	B19-DNA	12 days	

HGV

● Voluntary reports: A case identified as suspected transfusion-transmitted viral infection by a published case report

Case No.	Blood component (year and month of blood collection)	Primary disease	Age	Sex	Pre-transfusion test			Post-transfusion test		Patient outcome
					Test items	Test result	Duration before transfusion	Positive conversion items	Duration after transfusion	
1	FFP-LR (2016.10)	Decompensated cirrhosis Hepatitis C	50s	F	HPgV-RNA	Neg.	0 days	HPgV-RNA	7 days	

Risks of infection with hepatitis viruses via transfusion

- ▶ Donated blood is tested for HBV and HCV (blood donated on or after August 5, 2020 is tested for HEV as well). However, the risks of TTI remain due to the possibility of the window period. The recipients are at risk of being infected with HBV, HCV, HEV, etc. and developing hepatitis.
- ▶ In the package insert, it has been notified that in case of suspected HBV or HCV infection, the recipient shall be tested for hepatitis virus markers at pre- and post-transfusion and followed. If necessary, however, the recipient shall also be tested for HEV markers and followed.
- ▶ If the recipient is confirmed with hepatitis virus infection or presents with symptoms of hepatitis, provide appropriate treatment. In addition, when the recipient requires an immunosuppressive intervention for the management of his/her primary disease, consider the relevant risks adequately, such as liver disorder due to hepatitis virus infection.
- ▶ For HEV infection, consider, as necessary, seeking advices on relevant tests and treatment strategies from a hepatologist at a liver disease care liaison hospital, etc.
- ▶ If you suspect transfusion-transmitted viral infection in a recipient, please provide information regarding the event to JRCS.

Safety measures for TT-HEV infection by JRCS

- ▶ Blood components donated on and after August 5, 2020 are screened using a nucleic acid amplification test (individual NAT). For more details, refer to the notification issued in July 2020 titled "Introduction of Hepatitis E Virus Nucleic Acid Amplification Testing (HEV-NAT) as a Further Safety Measure for Blood Components for Transfusion." (<http://www.jrc.or.jp/mr/product/information/>)
- ▶ At blood donation sites, we are raising awareness of sources of HEV infection and TTI risks and conducting thorough interviews with donors.
- ▶ Prospective donors are deferred from donating for 6 months after their eating raw or undercooked meat or entrails of pigs, boars, or deer, which are at risk of transmitting HEV to humans.

In case of any 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."

Transfusion Information 2009-171

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

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