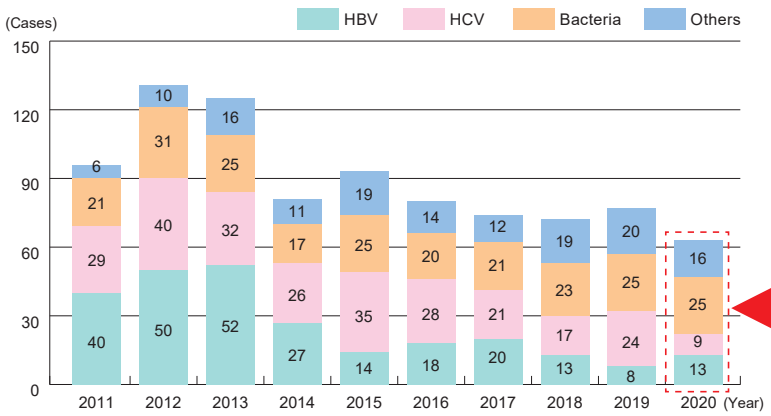
Infectious Cases that were Likely Related to Transfused Blood Components (2020)

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 2020, there were 2 cases of HBV infection, 2 cases of bacterial infection, and 6 cases of HEV infection, confirmed by detection 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 2020.



Pathogen	Number of reported cases	Number of confirmed cases
HBV	13	2
HCV	9	0
Bacteria	25	2
CMV	3	0
HEV	11	6
Parvovirus B19	1	0
HTLV-1	1	0
Total	63	10

Summary of case reports
(Cases confirmed to be TTIs based on detection of pathogens in relevant items such as samples of donated blood) (2020)

Bacteria

● **Voluntary report:** 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	Time to onset (from start of administration)	Blood culture results of post-transfusion		Patient outcome
							Blood component	Patient blood	
1	Ir-PC-LR (2020.6)	Myelodysplastic syndrome	80s	F	Chills and shivering, fever, hypotension	Approx. 4 hrs	*Enterococcus faecium*	*Enterococcus faecium*	Recovering
2	Ir-PC-LR (2020.9)	Acute lymphatic leukemia	40s	F	Chills and shivering, fever, vomiting, watery stool, hypotension, decreased oxygen saturation	15 min	*Escherichia coli*	*Escherichia coli*	Recovered (with sequelae)

What to do when transfusion-related bacterial infection is suspected

- When bacterial infection is suspected, **stop the transfusion immediately and provide appropriate treatment.**
- **Keep the residual bag appropriately**[*1] and notify medical representatives of your local JRC blood center.
- **A bacterial culture test on 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 so that causes can be investigated.

*1 Tighten the clamp of the transfusion set, and return the bag and the set to the transfusion department. Then, seal the top and bottom of the drip cylinder with a tube sealer (or, if no tube sealers are available, firmly ligate the parts using other equipment such as forceps), put the bag and the set themselves in a plastic bag and store it in a sanitary manner in refrigerators (not in freezers).

HBV

● **Post-donation information:** Cases identified through lookback studies conducted based on reported positive conversion of blood screening test results

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 results	Positive conversion items	Duration after transfusion	Maximum (IU/L)	Duration after transfusion	
1	Ir-PC-LR (2020.1)*1	Acute myeloid leukemia	70s	F	HBs-Ag HBs-Ab HBc-Ab	Neg.	HBV-DNA	23 wks	715	38 wks	Not recovered
							HBs-Ag	38 wks			
2	Ir-PC-LR (2020.8)*2	Acute myeloid leukemia	30s	M	HBs-Ag HBs-Ab HBc-Ab	Neg.	HBV-DNA HBs-Ag	7 wks	◆	◆	Unknown

*1 The concerned donated blood was negative for HBV-NAT, but positive for HBV-NAT at the time of the subsequent donation, 5 weeks later.
*2 The concerned donated blood was negative for HBV-NAT, but positive for HBV-NAT at the time of the subsequent donation, 4 weeks later.
◆ No comparative data.

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 results	Duration before transfusion	Positive conversion items	Duration after transfusion	Maximum (IU/L)	Duration after transfusion	
1	Ir-PC-LR (2020.4)	Aplastic anemia	60s	M	None			IgA-HEV-Ab	6 wks	2,650	42 days	Recovering
2	FFP-LR (2019.6)	Aortic valve stenosis/ insufficiency	70s	M	None			HEV-RNA IgA-HEV-Ab	8 wks	455	58 days	Recovering
3	Ir-WRC-LR (2019.12)	Secondary myelofibrosis	60s	F	None			HEV-RNA IgA-HEV-Ab	30 wks	288	206 days	Recovering

● **Post-donation information:** A case identified through lookback studies conducted based on through assessment of source plasma for plasma derivatives

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 results	Duration before transfusion	Positive conversion items	Duration after transfusion	Maximum (IU/L)	Duration after transfusion	
1	Ir-RBC-LR (2019.5)	Hemorrhagic rectal ulcer Central nervous system vasculitis	Un-known	F	HEV-RNA IgA-HEV-Ab IgM-HEV-Ab IgG-HEV-Ab	Neg.	0 days	IgM-HEV-Ab IgG-HEV-Ab	38 wks	355	89 days	Recovered

● **Post-donation information:** A case identified through lookback studies conducted based on information concerning HEV-NAT positivity of blood donors

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 results	Duration before transfusion	Positive conversion items	Duration after transfusion	Maximum (IU/L)	Duration after transfusion	
1	Ir-PC-LR (2020.2)	Extranodal NK/ T-cell lymphoma	50s	F	HEV-RNA IgA-HEV-Ab IgM-HEV-Ab IgG-HEV-Ab	Neg.	1 day	HEV-RNA	4 wks	66	17 days	Recovering

● **Post-donation information:** A case reported by the medical institution that was provided with the blood component derived from a subsequent donation by the donor in the above voluntary report No. 1. This report was made in a lookback study of the voluntary report 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 results	Duration before transfusion	Positive conversion items	Duration after transfusion	Maximum (IU/L)	Duration after transfusion	
1	Ir-PC-LR (2020.5)	Acute lymphatic leukemia	20s	M	HEV-RNA IgA-HEV-Ab IgM-HEV-Ab IgG-HEV-Ab	Neg.	1 day	HEV-RNA IgG-HEV-Ab	6 wks	275	42 days	Recovered

Safety measures for TT-HEV infection by JRCS

▶ **Blood and blood components donated on and after August 5, 2020 have been screened using a nucleic acid amplification test (individual NAT).**

As of July 2021, there have been no cases of HEV infection identified in donated blood after the introduction of HEV-NAT.

For more details on the introduction of HEV-NAT, 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." (https://www.jrc.or.jp/mr/product/information/pdf/info_202007.pdf)

▶ At blood donation sites, we raise awareness of the sources of HEV infection and infection risks for recipients, as well as conduct thorough interviews with donors.

▶ Prospective donors are deferred from blood donations for 6 months after their eating raw or undercooked meat or entrails of pigs, boars, or deer, which have the risk of transmitting HEV to humans.

In case of any suspected adverse reactions or infections related to transfusion of blood components, please notify medical representatives of your local JRC blood center immediately. You may be asked to provide items such as residual products and the recipient's samples for investigation of causes. 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.

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