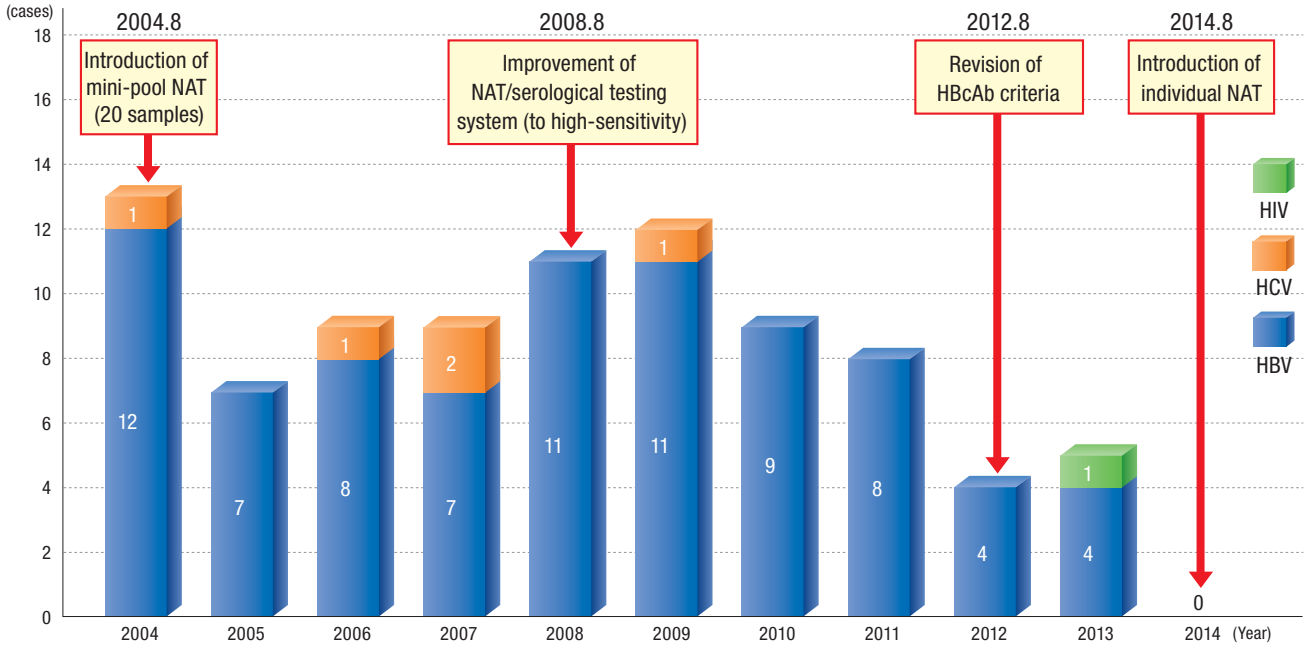
Efficacy of the safety measures to prevent transfusion transmitted infections (HBV, HCV, and HIV)

The Japanese Red Cross Society (JCRS) has recently implemented two safety measures against blood components for transfusion. One was the revision of criteria for anti-HBc antibodies (HBcAb) in August 2012 and the other was the renewal of Nucleic Acid Amplification Test (NAT) system for HBV, HCV, and HIV from 20 pool NAT to individual NAT (ID-NAT) in August 2014. This report summarizes the findings on the effectiveness of these safety measures.

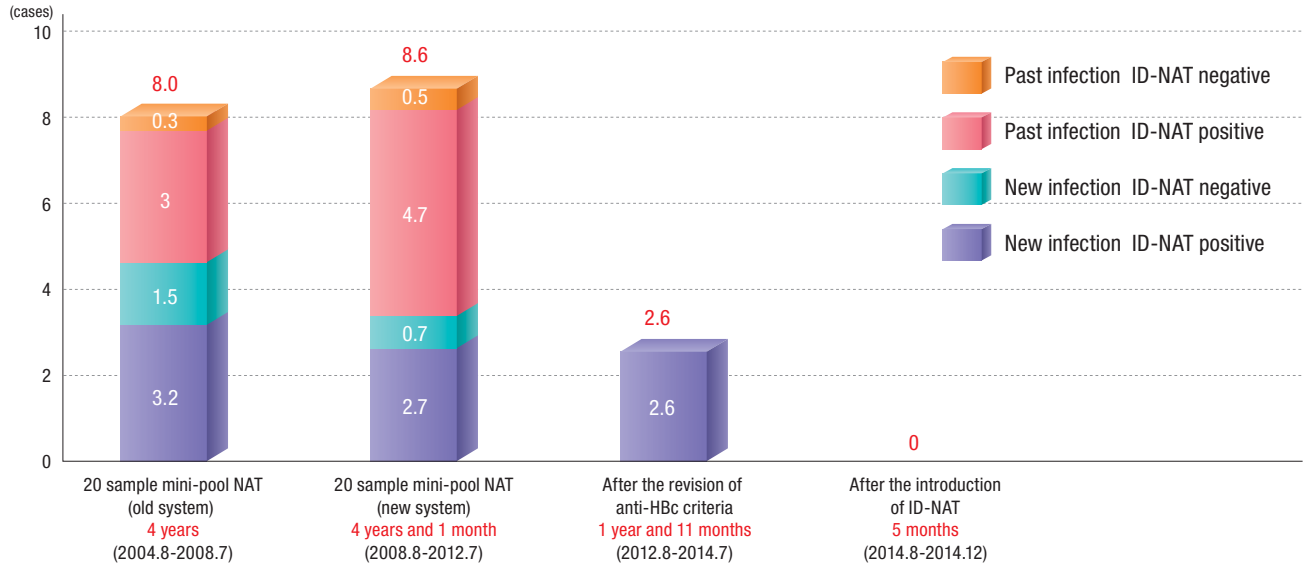
The numbers of confirmed cases of transfusion transmitted infection (HBV, HCV, or HIV), by year of blood donation (as of December 31, 2014)



Note) The numbers of the cases were derived from involved blood donations.

Between 2004 and 2011, the average number of confirmed cases was approximately 9 per year. The number of confirmed cases decreased after the revision of HBcAb criteria in 2012, and no case has been confirmed since the introduction of ID-NAT in 2014 (data as of end of 2014).

Number of confirmed cases of transfusion transmitted HBV per year (categorized by the infection status of the blood donors)



Since the revision of the HBcAb criteria at the end of August 2012, there has been no confirmed case of transfusion transmitted HBV due to blood components derived from a blood donor with past infection. Furthermore, since the introduction of ID-NAT, there has been no confirmed case of infection due to blood components derived from blood with newly infected donors.

Pre-/Post-transfusion test items and preservation of patient blood samples

Excerpt (with partial modification) from the "Guidelines for the Transfusion Practice (revised version)", Blood and Blood Products Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour, and Welfare, September 2005 (partially revised in November 2014)

	Pre-transfusion test	Post-transfusion test
HBV	HBsAg HBsAb HBcAb	Nucleic acid amplification test (NAT) (NAT is conducted 3 months after transfusion, if all the pre-transfusion tests are negative)
HCV	HCV-Ab HCV core antigen	HCV core antigen test (HCV core antigen test is conducted 1-3 months after transfusion, if pre-transfusion tests are all negative or if the patient has a past HCV infection.)
HIV	HIV-Ab test	HIV antibody test (Considering the infectious risk, HIV antibody test is conducted before transfusion if infection is suspected. If the test result is negative, HIV antibody test is conducted again 2-3 months after transfusion.)

- If pre-/post-transfusion tests are not conducted routinely, the patient's pre-/post-transfusion blood samples should be collected (in sufficient volumes to allow the extraction of approximately 2 mL of blood plasma or serum) and stored below -20°C for as long as possible (at least 2 years), so that tests can be conducted according to the relevant guidelines if requested by the JRCS. (With neonates and infants, it is virtually impossible to collect a sufficient volume of blood to preserve 2 mL of blood plasma or serum; therefore, any collectable volume will be accepted.) Preventive actions should be taken, such as using disposable pipettes, to avoid contamination. It is recommended that a sterile blood sample tube with serum-separator is used for blood collection and centrifuge to separate serum before preserving. However, when difficult, it is acceptable to preserve approximately 2 mL of blood serum or plasma (blood cells removed) used for cross-compatibility test. In this case, heparin should not be used as an anticoagulant as it may interfere with the infection test.
- Even if pre-transfusion infection tests are being conducted, the patient's pre-transfusion blood samples should always be preserved as they become extremely important when investigating causal relationships between transfusion and infection.
- Considering the infectious risk, doctors should insist on testing a patient's sample for the above mentioned viral markers when transfusion transmission is suspected. This makes it possible to demonstrate the status of infection of the patient and, if infected, to start treatment in the early stage.

History of infection tests on donated blood (chronology)

Year	Month	Changes
2004	August	Reduced the pool size (50 samples → 20 samples) for the nucleic acid amplification testing (NAT) for HBV, HCV, HIV-1.
2008	August	Chemiluminescence enzyme immunoassay (CLEIA) replaced the previous testing method for HBsAg, HBsAb, HBcAb, HIV-1-Ab, HIV-2-Ab, HTLV-1-Ab, Treponema pallidum antibody, and human parvovirus B19 antigen.
		Changed the reagents and equipment for NAT for HBV, HCV, HIV-1, and HIV-2.
2012	August	Revised HBcAb test (CLEIA) criteria
2014	August	Introduced ID-NAT and changed equipment to test for HBV, HCV, HIV-1, and HIV-2

Requests regarding the management of transfusion-transmitted infections

Although the number of confirmed cases of transfusion-transmitted infections reported to JRCS is decreasing, it should be noted that our data does not cover all the infection cases. Some infectious diseases are not tested, and there are limitations in the detection of infectious agents, including unknown pathogens. Therefore, it is impossible to reduce the risk of transfusion transmitted infection to zero.

The JRCS will continue to improve the safety of blood components. We request all medical institutions to co-operate in look-back studies and/or transfusion-transmitted infections/adverse reactions reporting, in accordance with the safety measures.

Medical institutions are also requested to follow the Guidelines for the Transfusion Practice and take informed consent from the patients adequately, conduct pre-/post-transfusion tests, and ensure appropriate preservation of the patient's blood samples. Cases of transfusion adverse reactions and suspected transfusion-transmitted infections are to be reported to the medical representatives of JRC blood centers. The patient's blood samples (pre-/post-transfusion) and the blood bags used, etc. can be used in order to investigate the causal relationship. The patient's blood samples and the blood bags used should be stored according to the Guidelines for Look-Back Studies For Infections Related to Blood Products (revised)*.

* "Guidelines for Look-Back Studies For Infections Related to Blood Products", March 2005 (partial revision in July 2014), Blood and Blood Products Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour, and Welfare

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

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