日本赤十字社
Japanese Red Cross Society

# Haemovigilance by JRCS 2020

**Safety Vigilance Division,**
**Technical Department,**
**Blood Service Headquarters**

## Haemovigilance system of the Japanese Red Cross Society

Haemovigilance is a system that monitors blood products for transfusion ("transfusion blood products") for any adverse events throughout all steps from blood collection, testing, and manufacturing, up to recipient follow-up; analyzes and assesses the causes; takes appropriate safety measures; and thus prevents any transfusion blood product-related harm from occurring or expanding. The Japanese Red Cross Society (JRCS) has addressed donor adverse reactions, transfusion-transmitted infections (TTI), and transfusion adverse reactions since the start of its blood service. In 1982, the JRCS established internal procedures for reporting adverse reactions in donors, and in 1983, it assigned medical representatives (MR) to all JRC blood centers across Japan to attend to transfusion adverse reactions and infections. During this time, the JRCS also introduced hepatitis virus and HIV marker tests for donated blood as an anti-TTI measure, and in 1993, it established a system to centrally collect and analyze information on transfusion adverse reactions and TTIs. Then, in 1996, JRCS began a specimen storage system that stores aliquots of all donated blood over 11 years for analysis purposes. This system enabled investigation of transfusion blood products associated with TTIs and was useful not only in confirming causal relationships between transfusions and TTIs but also in identifying new adverse reactions and infections that may emerge in the future. Further, the usage of expired stored specimen was made available for research and development with the enforcement of policies in the Guideline on the Use of Donated Blood in Research and Development (Pharmaceutical and Food Safety Bureau (PFSB) Notification No. 0801-1; issued by the Director of PFSB, Ministry of Health, Labour and Welfare (MHLW) on August 1, 2012). Initially, the Steering Committee of Committee on Blood Products, Pharmaceutical Affairs and Food Sanitation Council, MHLW was responsible for assessing whether or not the usage of stored specimen in particular research and development programs was appropriate. This policy was later discontinued under the Partial Amendment to the Act on Securing Stable Supply of Safe Blood Products (Pharmaceutical Safety and Environmental Health Bureau (PSEHB) Notification No. 0827-2; issued by the Director of PSEHB, MHLW on August 27, 2020), which prompted the JRCS to be responsible for the assessment from 2021.

Meanwhile, transfusion blood products are categorized as pharmaceuticals in Japan and are thus regulated by the Act on Securing Quality, Efficacy, and Safety of Pharmaceuticals and Medical Devices (Pharmaceuticals and Medical Device Act: PMD Act) and require marketing approvals alike pharmaceuticals. Additionally, the JRCS collects human source blood from donors as a blood establishment based on the Act on Securing Stable Supply of Safe Blood Products (Blood Act). Currently, the JRCS is Japan's only blood establishment that collects blood, markets transfusion blood products, and manufactures source plasma for plasma derivatives.

With the amendment to the Blood Act in 2019, blood establishments other than the JRCS are also permitted to collect blood and once licensed they can now collect blood for use in research and development of drugs, medical devices, or regenerative medicine and as source material for other items that improve the quality of medical care or health and hygiene. For the manufacturing and distribution of transfusion blood products derived from donated blood, the JRCS complies not only with the PMD Act and its enforcement regulation but also with the Ministerial Ordinance on Standards for Manufacturing Control and Quality Control for Pharmaceuticals and Quasi-pharmaceuticals (Good Manufacturing Practice (GMP) Ministerial Ordinance) and the Ministerial Ordinance on Standards for Quality Assurance for Pharmaceuticals, Quasi-pharmaceuticals, Cosmetics, and Regenerative Medicine (Good Quality Practice (GQP) Ministerial Ordinance). The JRCS's Blood Service Headquarters (which serves as marketing authorization holder and the safety management section) as well as JRC blood centers and Central Blood Institute facilities (both of which serve as safety execution sections) collaboratively attend to post-marketing activities in compliance with the Ministerial Ordinance on Standards for Post-Marketing Safety Assurance for Pharmaceuticals, Quasi-pharmaceuticals, Cosmetics, Medical Devices, and Regenerative Medicine (Good Vigilance Practice (GVP) Ministerial Ordinance). MRs at blood centers are responsible for collecting information on transfusion adverse reactions and TTIs and providing information on transfusion blood products to health care professionals. The safety management section then analyzes and assesses the information, reports serious transfusion

adverse reactions and TTI cases to the Pharmaceutical and Medical Devices Agency (PMDA) pursuant to the PMD Act, and further, performs a series of activities such as collecting basic data on safety measures, product removal, and revisions to package inserts (on precautions). Additionally, the JRCS conducts epidemiological studies related to blood safety and reports results to respective committees in the Committee on Blood Products, Pharmaceutical Affairs and Food Sanitation Council, MHLW, thereby contributing to safety efforts for transfusion blood products. As transfusion blood products are categorized as a "combination product equivalent to pharmaceuticals" that combine pharmaceuticals (blood and blood components) and medical devices (blood bags), the JRCS also collects, assesses, and analyzes information on any health hazards caused by malfunctions in blood bags used by patients, just as it does with transfusion adverse reactions and TTIs.

Pharmaceuticals are also subject to pharmacovigilance. The World Health Organization defines pharmacovigilance as "the science and activities relating to the detection, assessment, understanding and prevention of adverse drug effects or any other possible drug-related problems," which is in close agreement with post-marketing safety assurance activities that the Japanese GVP Ministerial Ordinance stipulates. In addition, the International Conference on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) developed the E2E Guideline, "Pharmacovigilance Planning," which was implemented in 2005. Around the same time, the amended former Pharmaceutical Affairs Act was fully enforced in April 2005, mandating compliance with GQP and GVP ministerial ordinances as a requirement for marketing authorization.

The haemovigilance concept is considered to have developed in Western countries, since most of such countries regulate transfusion blood products apart from pharmaceuticals and thus need to develop separate safety monitoring systems for transfusion blood products. However, as transfusion blood products are categorized as pharmaceuticals in Japan, the same vigilance system as that for pharmaceuticals is applied to blood and blood components. Therefore, a characteristic feature of the Japanese haemovigilance system is that it is similar to the pharmacovigilance system.

## 1. Total number of blood donations and supply of blood products for transfusion

Figure 1 shows the number of blood donations by type between 2011 and 2020. The total number of blood donations in 2020 was 5,024,859, including 125,292 of 200 mL whole blood donations, 3,246,842 of 400 mL whole blood donations, and 1,652,725 of blood component donations (1,098,905 of plasma donations and 553,820 of platelet donations). The number of donations decreased during 2011 to 2018, but plasma donations have been on an increasing trend since 2019 in response to the need to secure source plasma for the increasing demand in immunoglobulin products.

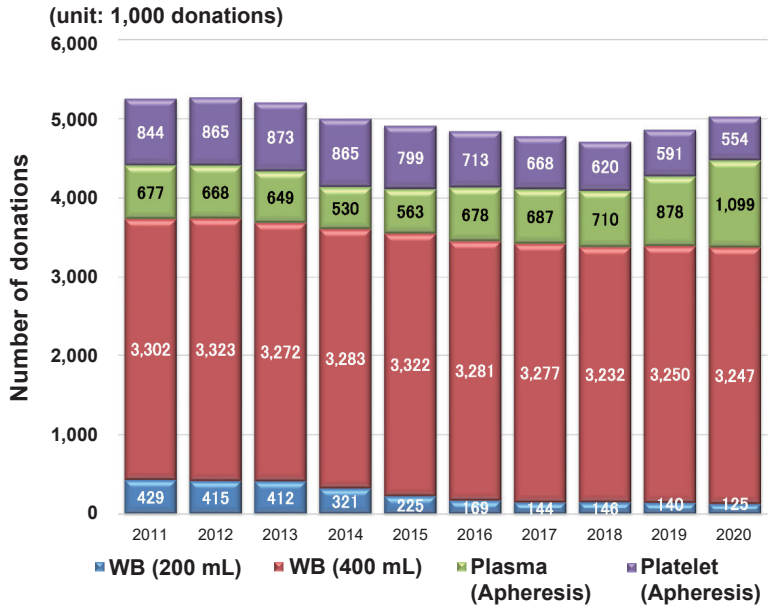



**Figure 1. Number of blood donations by year**

Figure 2 shows transfusion blood product supply between 2011 and 2020. In recent years, the supply of red blood cell (RBC) products and plasma products has been on a decreasing trend due to the promotion of proper use.

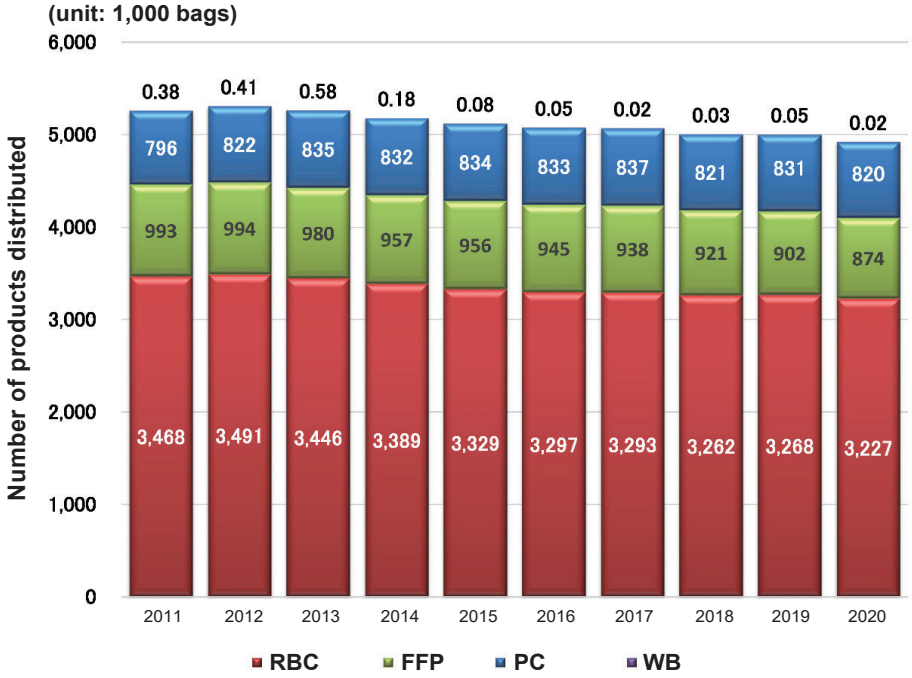



**Figure 2. Supply of transfusion blood products**

## 2. Transfusion adverse reaction and transfusion-transmitted infection cases

Figure 3 shows the breakdown of reported suspected transfusion adverse reaction and TTI cases (including cases reported by medical institutions and cases addressed based on post-donation information) in 2020. Until 2017, all suspected transfusion adverse reaction and TTI cases were subjected to detailed investigation (request to medical institutions to fill in case reporting forms). In January 2018, however, the investigation method was changed to one that collects information on transfusion-related adverse events more broadly; among the reported adverse events, suspected transfusion adverse reaction and TTI cases evaluated as serious (1. cases evaluated as serious by physicians, 2. cases evaluated as not serious by physicians but determined by the JRCS to require detailed investigation based on the symptoms, 3. cases suspected of being TTIs) and transfusion adverse reactions not indicated in package inserts (i.e., unknown adverse reactions) are subjected to detailed investigation.

In 2020, the JRCS received 2,634 case reports on adverse reactions (non-hemolytic adverse reactions: 2,532 cases; hemolytic adverse reactions: 39 cases; suspected transfusion-associated GVHD: 0 cases; and infections: 63 cases) from medical institutions across Japan. Cases evaluated as serious by physicians in charge or the JRCS (non-hemolytic adverse reactions: 638* cases; hemolytic adverse reactions: 18* cases; infections: 63* infections) were submitted as individual case safety reports (ICSR) to PMDA, in accordance with the PMD Act. Some adverse reaction cases that have not been spontaneously reported by medical institutions to the JRCS are published in literature and by academic societies. When the JRCS obtains such information, it investigates at the concerned medical institutions on causal relationships and severity (See "3) Information on individual transfusion adverse reaction and transfusion-transmitted infection cases obtained from literature and academic societies").

* Note that the figures account for some cases that fall under multiple categories.

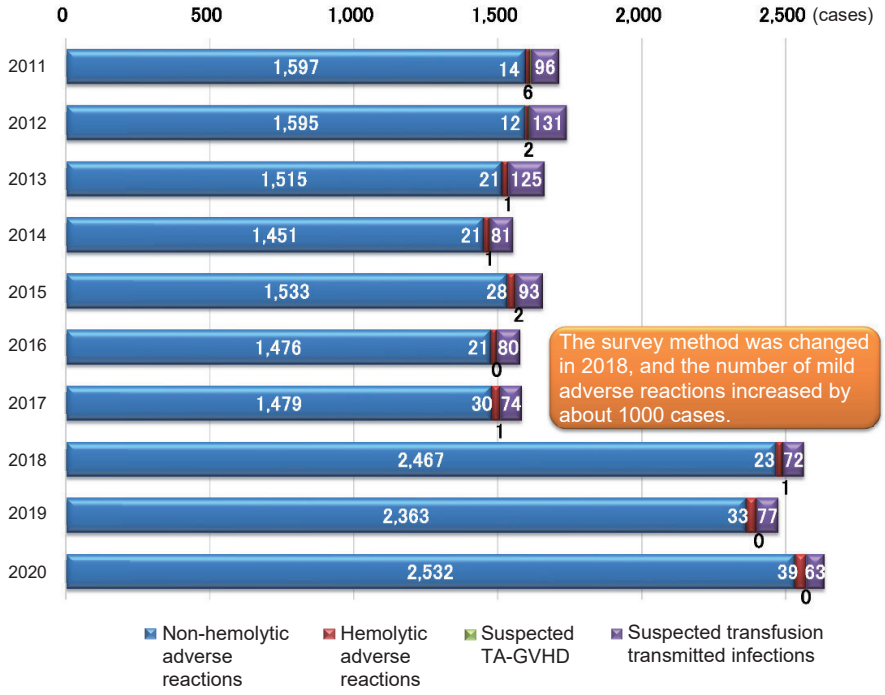



**Figure 3. Number of spontaneous transfusion adverse reaction and TTI case reports***

*Excludes cases learned through literature or from academic societies.

## 1) Transfusion adverse reactions

### (1) Non-hemolytic adverse reactions

Figure 4 shows the number of cases reported as non-hemolytic adverse reactions by medical institutions between 2018 and 2020. Figure 5 shows a breakdown by symptom for 2020, and Figure 6 indicates the number of cases according to serious/non-serious for 2020. The number of transfusion-related acute lung injury (TRALI) and transfusion-associated circulatory overload (TACO) cases are included in that for dyspnea. Two-thirds of the reported non-hemolytic adverse reactions were allergic symptoms. Serious adverse reactions accounted for 25.2% of all non-hemolytic adverse reactions and mainly comprised severe allergies, dyspnea, and decreased blood pressure.

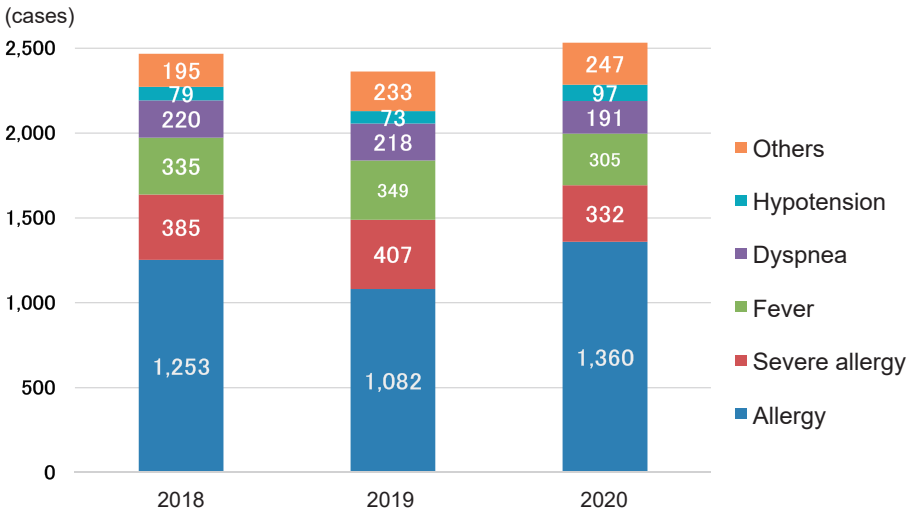



**Figure 4. Number of reported cases by symptom**

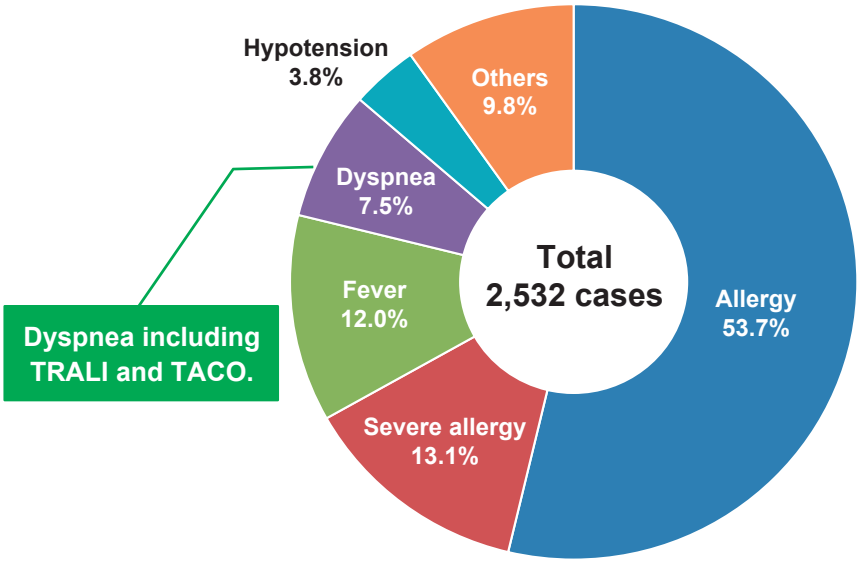



**Figure 5. Number of reported non-hemolytic adverse reaction cases by symptom (2020)**

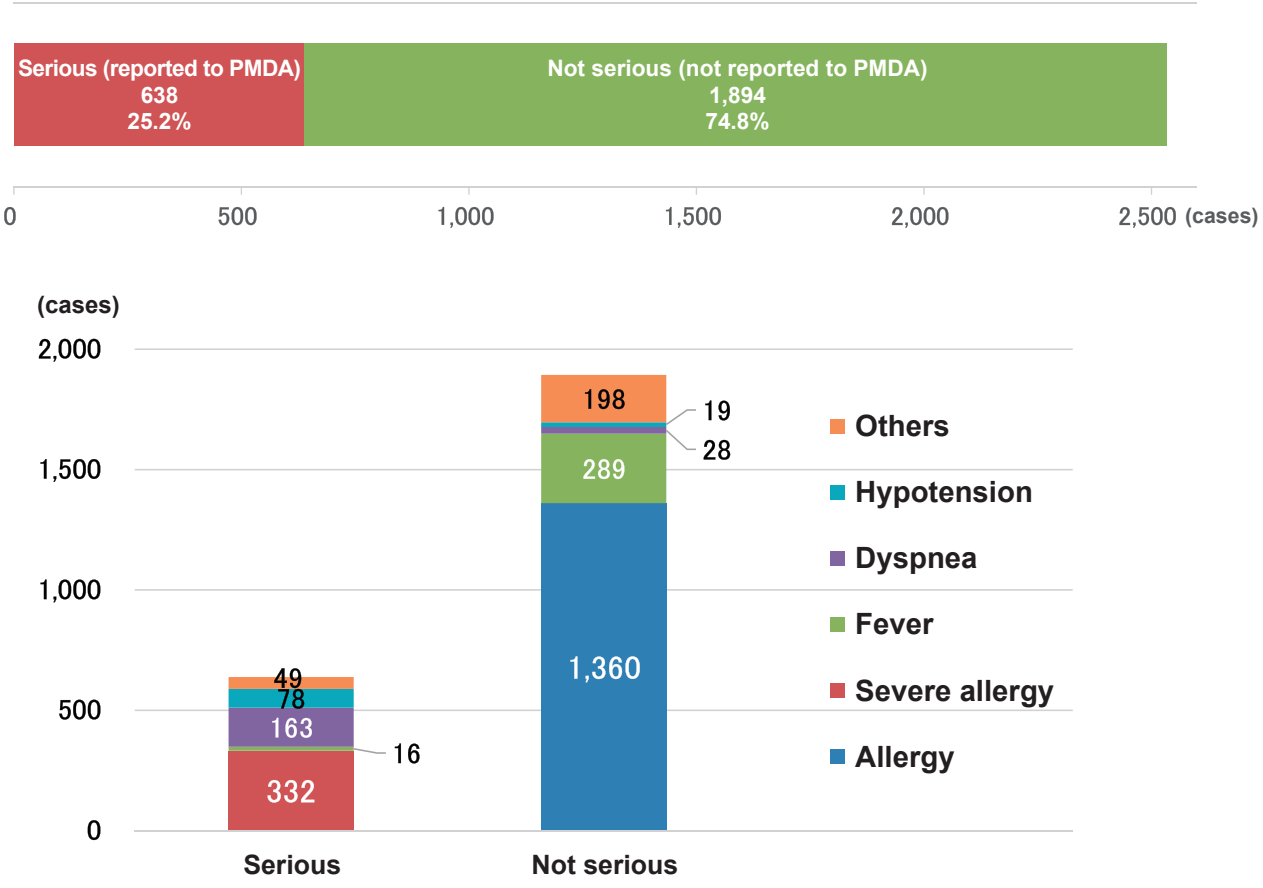



**Figure 6. Number of reported serious* and non-serious adverse reaction cases (2020)**

*Serious cases: cases evaluated as serious by physicians and cases evaluated as not serious by physicians but determined by the JRCS to require detailed investigation based on the symptoms

### [Evaluation of TRALI and TACO cases]

Among transfusion adverse reaction and TTI cases reported by medical institutions, for those that are suspected of being TRALI and TACO, the JRCS performs evaluations for TRALI and TACO in cooperation with respiratory specialists and shares the results to the medical institutions. TRALI is evaluated based on the TRALI diagnostic criteria that were proposed at the Consensus Conference in 2004 (Transfusion. 2004; 44:1774-89). TACO evaluation, on the other hand, has no unified criteria like those for TRALI. The JRCS commenced TACO evaluation from April 2012, using original criteria which exclude patients who were originally susceptible to circulatory overload due to heart failure, hemodialysis treatment, and the use of heart lung machines. This helps to clarify if transfusion was the sole cause of the circulatory overload. Figure 7 shows TRALI and TACO evaluation results in 2020.

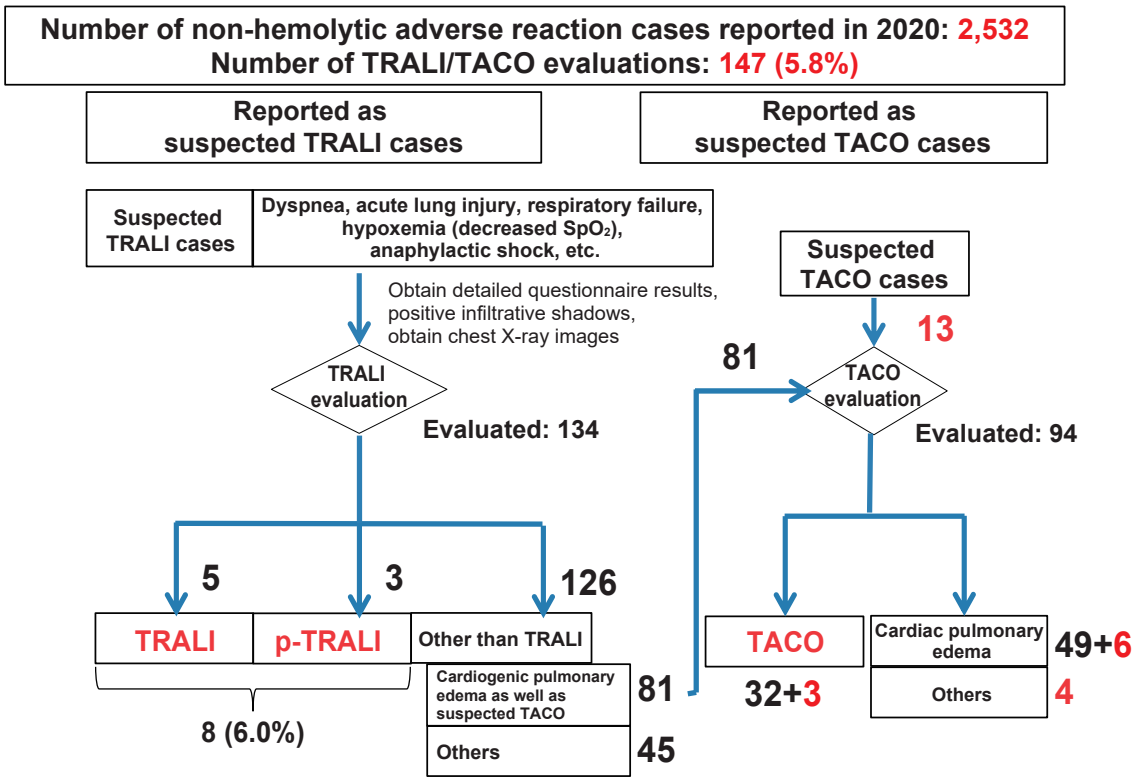



**Figure 7. TRALI and TACO evaluation results (2020)**

### [TRALI]

- Of the 2,532 non-hemolytic adverse reaction cases reported by medical institutions in 2020, TRALI evaluation was performed on suspected TRALI cases, as well as 134 cases of dyspnea and hypoxemia (decreased $SpO_2$) with bilateral infiltrates on chest x-ray.
- The TRALI evaluation confirmed 5 cases of TRALI, and 3 cases of possible TRALI (p-TRALI).
- Among the above 8 cases, leukocyte antibodies were detected in blood products in 2 cases, and a positive cross-match (including computer cross-matching) with patient lymphocytes was detected in 1 case.
- Of the 126 cases that were not diagnosed as TRALI, 81 cases were suspected of being cardiogenic pulmonary edema and were evaluated for TACO as well.

- The remaining 45 cases included cases in which data required by the diagnostic criteria (e.g., chest x-ray and data on pre-transfusion respiratory function) were insufficient and cases which did not meet the diagnostic criteria (e.g., cases that substantially exceeded the time-to-onset criteria and cases with pre-existing acute respiratory failure), in addition to cases evaluated as "other adverse reactions" (e.g., allergic and anaphylactic dyspnea).

**[TACO]**

- In 2020, 94 cases were evaluated for TACO, comprising 81 cases classified as cardiogenic pulmonary edema when evaluated for TRALI and then further evaluated for TACO as well as 13 cases that were reported by medical institutions to be suspected TACO. Of these two types of cases, 32 and 3 cases, respectively, were diagnosed as TACO. Of note, patients with pre-transfusion heart failure, hemodialysis treatment, and the use of heart lung machines were excluded since the conditions give rise to circulatory overload in the first place. Even if patients met the TACO criteria, those who fell under these exclusion criteria were diagnosed as cardiac pulmonary edema and not as TACO.
- Figure 8 shows the gender ratio and used blood products in cases evaluated as TACO in 2020, and Figure 9 shows the cumulative data on TACO evaluations by the JRCS from April 2012 to 2020. TACO tends to develop among the elderly. RBC, including that in combined products, was the most commonly involved component and was used in about 80% of TACO cases from April 2012 to 2020.

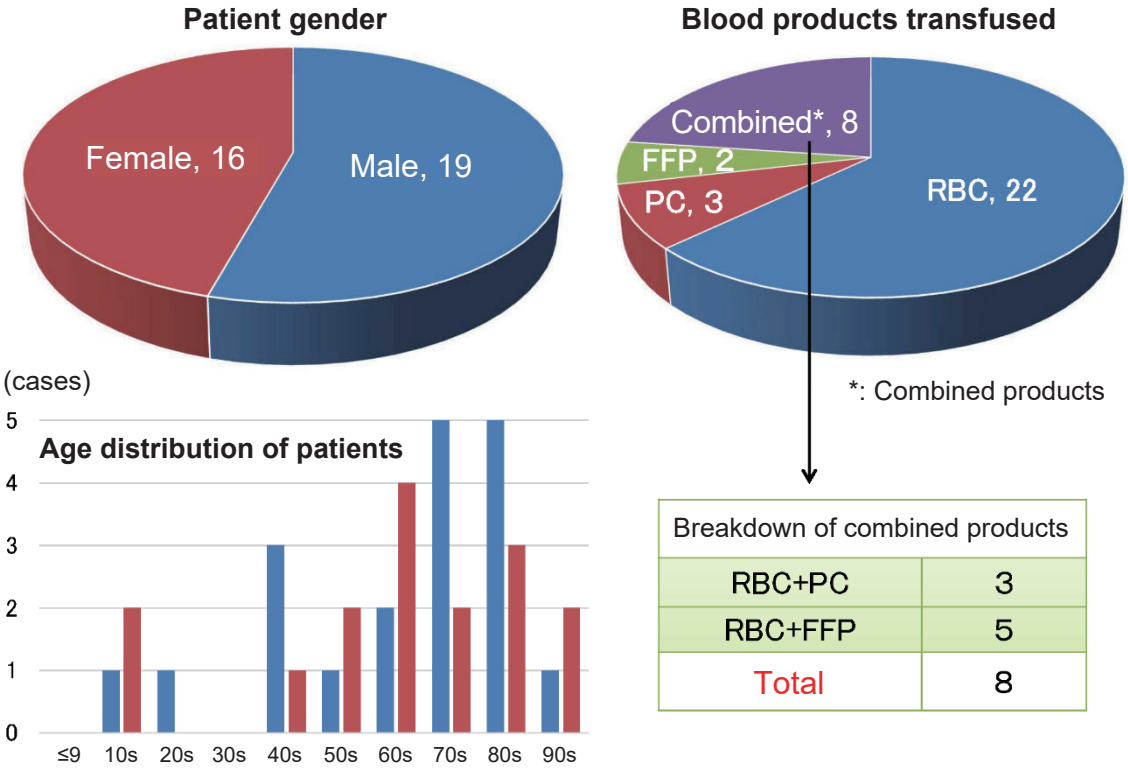



**Figure 8. Patient gender ratio and blood products used in TACO cases (2020)**

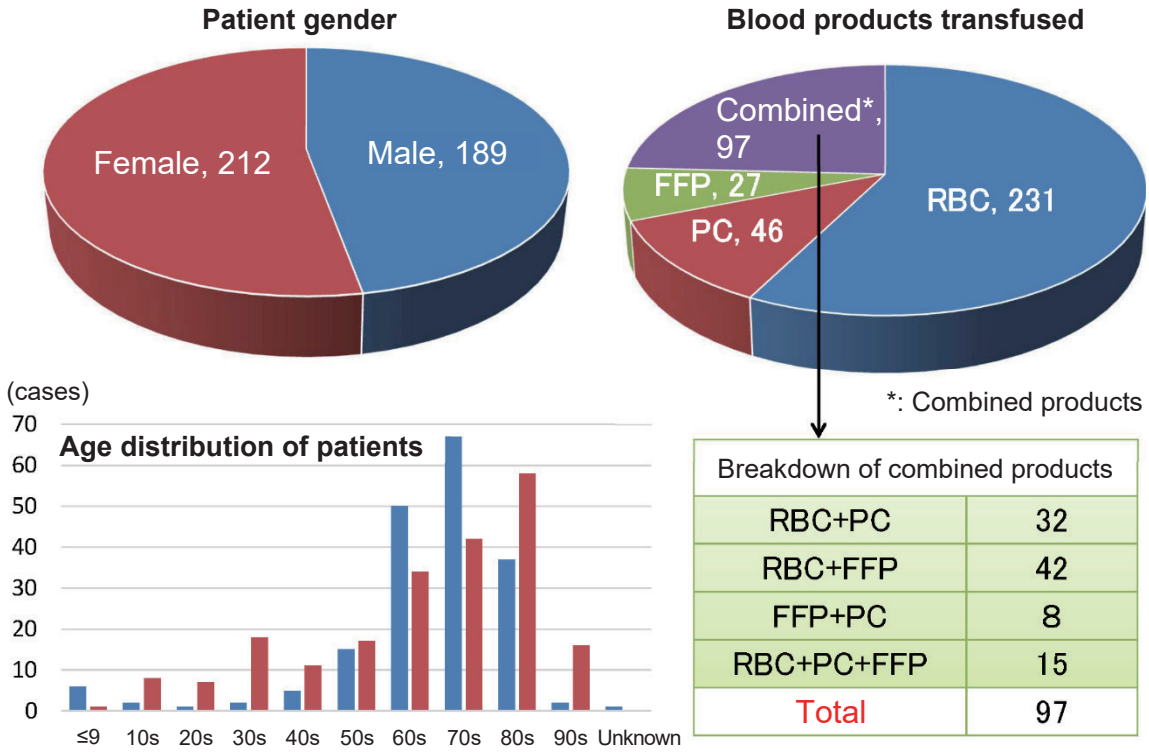



**Figure 9. Patient gender ratio and blood products used in TACO cases (April 2012–2020)**

**[Discussion on and future agendas of TRALI and TACO]**

- Among cases reported as suspected TRALI, less than 5% were actually diagnosed as TRALI. There were no cases of deaths deemed attributable to TRALI in 2020.
- As a safety measure against TRALI, the JRCS manufactures fresh frozen plasma (FFP) preferentially derived from 400 mL blood donations by male donors. While almost 100% of FFP made from 400 mL blood donations are derived from male donors, less than 20% of FFP made from 200 mL blood donations and 70% of FFP made from apheresis donations are derived from male donors.
- In 2020, 147 cases were evaluated for TRALI and TACO. Eight cases were diagnosed as TRALI (including p-TRALI). On the other hand, 35 cases were diagnosed as TACO and 55 cases, as cardiac pulmonary edema, accounting for a large portion of total.
- Because TACO is a form of cardiac failure due to circulatory overload, it is important to understand the patient's potential risk of cardiac failure by measuring pre-transfusion NT-proBNP* levels or decline in renal function. This is an issue that needs to be addressed going forward. When transfusing to patients who demonstrate heart failure risks before blood transfusion, the transfusion rate and volume need to be carefully decided and also monitored during the transfusion.
  *NT-proBNP: N-terminal pro-brain natriuretic peptide
- The JRCS has been evaluating cases for TACO based on its own evaluation criteria, which excludes pre-transfusion heart failure and hemodialysis treatment since they are risk factors for circulatory overload. Using such exclusion criteria was thought to help clarify if the circulatory overload was caused by transfusion alone and to examine whether TACO occurs even when transfusion is appropriately performed. However, it was found that many TACO cases occurred regardless of the exclusion criteria and despite appropriate transfusion.

- In response to the revision of international TRALI and TACO evaluation criteria (Transfusion. 2019; 59:2465-76, ISBT Working Party on Haemovigilance in collaboration with IHN and AABB.2018.) and upon internal discussions, the JRCS decided to evaluate TRALI and TACO cases with new criteria from April 2021.

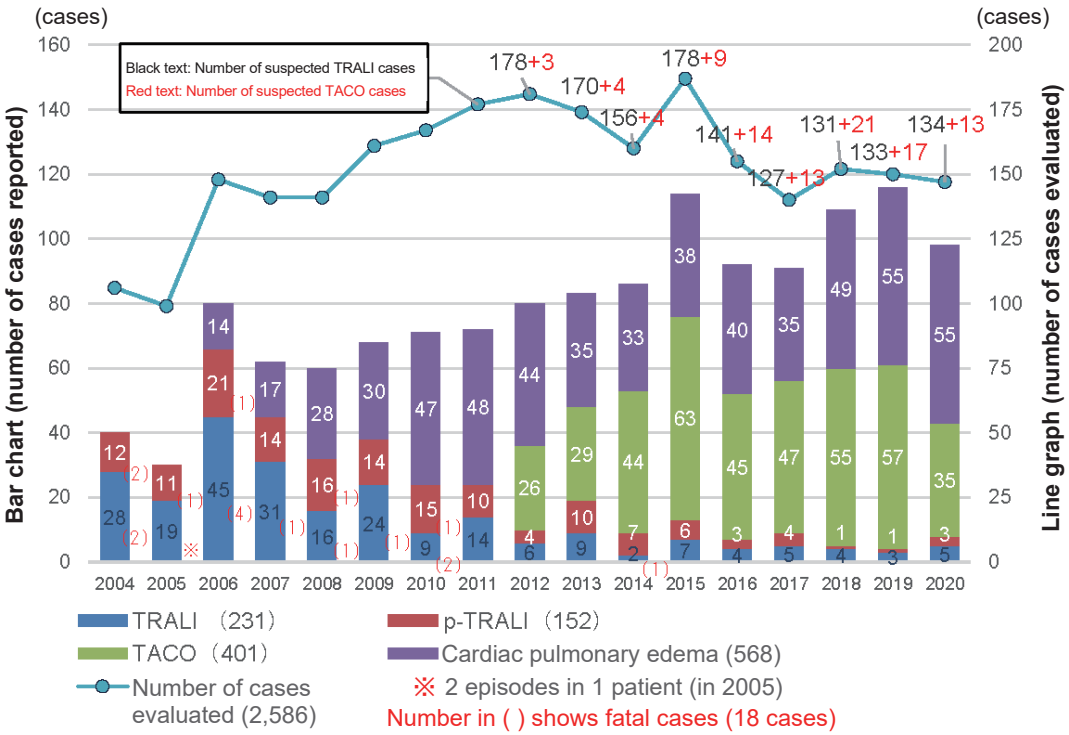
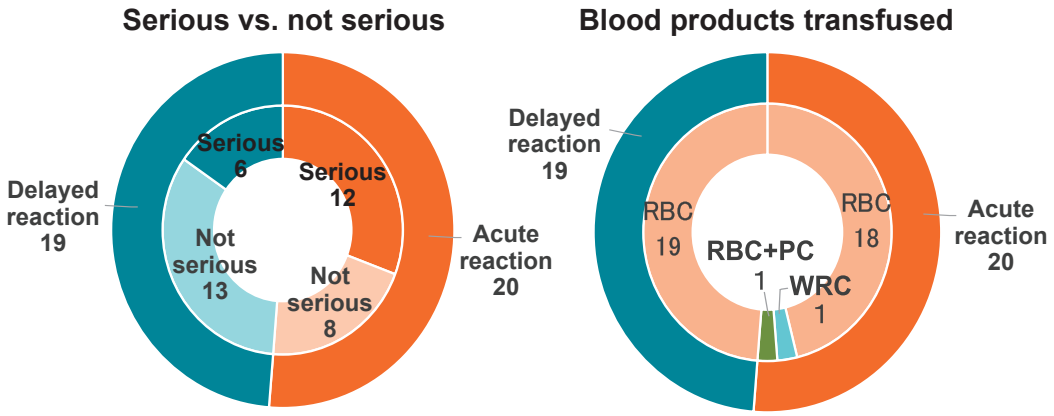



**Figure 10. Evaluation of TRALI and TACO cases (2004-2020)**

### (2) Hemolytic adverse reactions

In 2020, 39 hemolytic adverse reactions were reported by medical institutions, including 18 serious cases (Figure 11). Of these cases, 20 cases were acute reactions, and 19 cases were delayed reactions. Of the 17 cases investigated by the JRCS, irregular antibodies were detected in patient blood in 7 cases (of which 5 cases were acute reactions and 2 cases were delayed reactions). In these cases, anti-Rh and Kidd antibodies as well as autoantibodies were detected. RBC was used in all cases.




| | Serious | | Not serious | |
|---|---|---|---|---|
| Acute reaction | 5 | anti-C+anti-e+autoantibody: 1<br>Autoantibody: 4 | | |
| Delayed reaction | 3 | anti-Jk$^{a}$: 2<br>anti-Jk$^{b}$: 1* | 3* | anti-E+anti-Jk$^{b}$: 1<br>anti-C: 1<br>anti-Jk$^{a}$: 1 |

* Reported by medical institutions

**Figure 11. Number of reported hemolytic adverse reaction cases and antibodies detected from patients (2020)**

### (3) Transfusion-associated graft versus host disease (TA-GVHD)

- No cases of suspected TA-GVHD were reported by medical institutions in 2020.
- There have been no confirmed cases of TA-GVHD caused by JRCS's transfusion blood products since 2000.

## 2) Transfusion-transmitted infections

### (1) Cases reported as suspected transfusion-transmitted infections

Figure 12 shows the breakdown of suspected TTI cases (including cases reported by medical institutions and cases detected through post-donation information) reported in 2020 and annual trends in the number of such cases. In 2020, a total of 63 cases were reported, including 13 cases of suspected HBV, 9 cases of suspected HCV, 25 cases of suspected bacterial infection, and 16 cases of other infections.

Of these, cases identified as TTIs were 2 HBV infections, 6 HEV infections, and 2 bacterial infections (Table 1). For HCV and HIV, no TTI cases have been identified since the introduction of the nucleic acid amplification test (NAT) on individual samples (individual NAT: ID-NAT; Figure 13).

When viruses and other pathogens are found in blood products and in patient blood, viral TTIs are concluded based on sequential homology in genetic analyses or otherwise, by confirming recipient infection through lookback investigations prompted by post-donation information received from donors and confirming that there are strong causal relationships with transfusion. Meanwhile, bacteria TTIs are concluded based on consistency in bacterial strain in genotype tests (pulsed field gel electrophoresis: PFGE) and toxinotype tests.

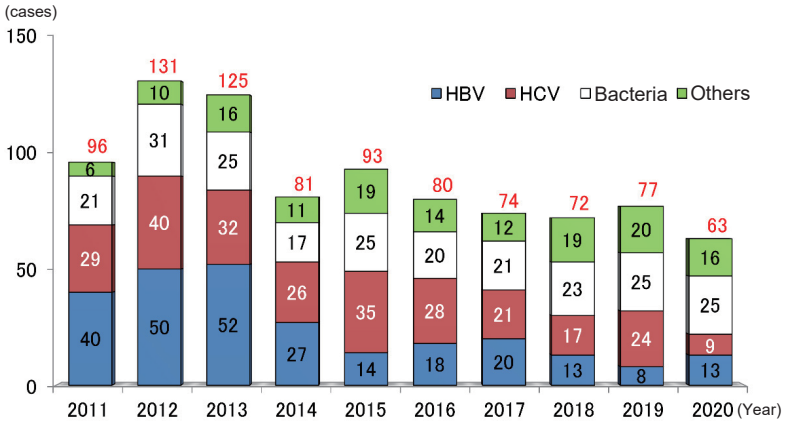



**Figure 12. Number of reported suspected TTI cases by pathogen**

**Table 1. Analysis results of reported suspected TTI cases by pathogen (2020)**

| Pathogen | Number of reported cases | Number of confirmed TTI cases | Number of non-TTI cases | |
|---|---|---|---|---|
| | | | Positive in pre-transfusion test | Negative in pre- and post-transfusion test |
| **HBV** | **13** | **2** | **1** | **0** |
| **HCV** | **9** | **0** | **0** | **0** |
| **Bacteria** | **25** | **2** | **0** | **0** |
| **CMV** | **3** | **0** | **1*** | **0** |
| **HEV** | **11** | **6** | **0** | **0** |
| **Parvo B19** | **1** | **0** | **0** | **0** |
| **HTLV-1** | **1** | **0** | **0** | **0** |
| **Total** | **63** | **10** | **2** | **0** |

*Considered unrelated to transfusion and possibly related to transmission through breast milk.

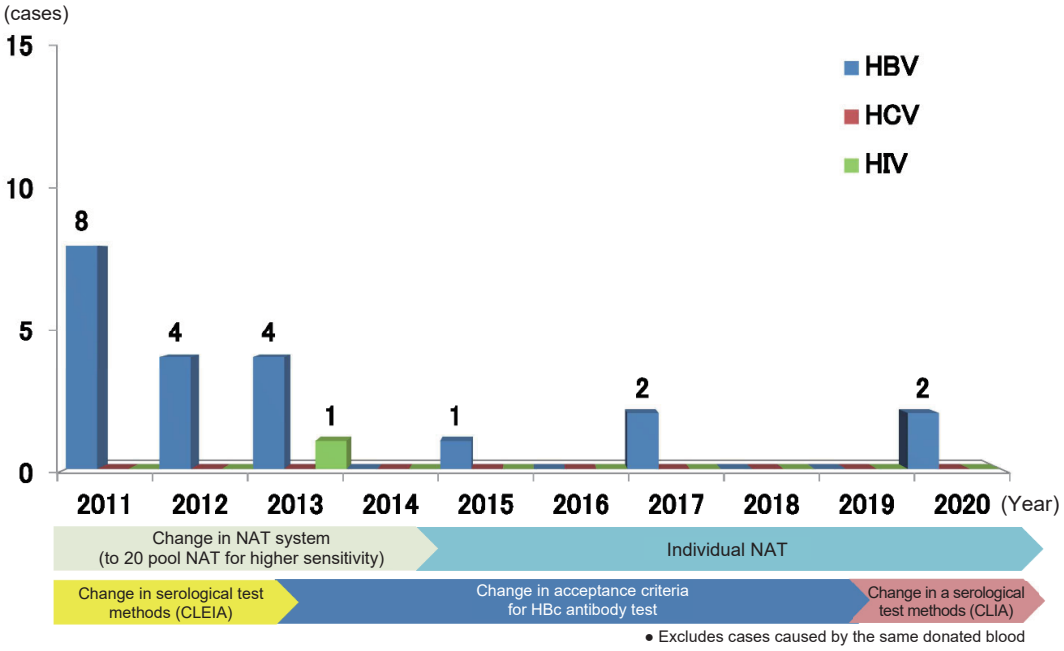



**Figure 13. TTI by year of blood collection (HBV, HCV, HIV)**

### (2) Summary of cases identified as transfusion-transmitted infections

The following shows a summary of cases identified as TTIs.

#### [HBV]

Of the 13 suspected TTI cases reported in 2020, 2 cases were identified as TTIs through lookback studies which were conducted based on screening results that showed positive conversion of donated blood.

**Table 2. Cases identified as transfusion-transmitted HBV infections (2020)**

| Primary disease | Blood product (year and month of blood collection) | Age | Sex | Pre-transfusion test | | Post-transfusion test | | ALT | | Recipient's outcome |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Test criterion | Test result | Positive conversion criterion | Time from transfusion | Maximum (IU/L) | Time from transfusion | |
| Acute myeloid leukemia | Ir-PC-LR (2020.1) | 70s | F | HBs-Ag HBs-Ab HBc-Ab | Neg. | HBV-DNA | 23 wks | 715 | 38 wks | Not recovered |
| | | | | | | HBs-Ag | 38 wks | | | |
| Acute myeloid leukemia | Ir-PC-LR (2020.8) | 30s | M | HBs-Ag HBs-Ab HBc-Ab | Neg. | HBV-DNA HBs-Ag | 7 wks | - | - | Unknown |

#### [HEV]

Of the 11 suspected TTI cases reported in 2020, 3 cases were identified as TTIs through spontaneous reports from medical institutions, and 3 cases, through lookback studies.

**Table 3. Cases identified as transfusion-transmitted HEV infections (2020)**

| | Primary disease | Blood product (year and month of blood collection) | Age | Sex | Pre-transfusion test | | | Post-transfusion test | | ALT | | Recipient's outcome |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Test criterion | Test result | Time to transfusion | Positive conversion criterion | Time from transfusion | Maximum (IU/L) | Time from transfusion | |
| Spontaneous report | Aplastic anemia | Ir-PC-LR (2020.4) | 60s | M | None | | | IgA-HEV-Ab | 6 wks | 2,650 | 42 days | Recovering |
| | Aortic valve stenosis and incompetence | FFP-LR (2019.6) | 70s | M | None | | | HEV-RNA IgA-HEV-Ab | 8 wks | 455 | 58 days | Recovering |
| | Secondary myelofibrosis | Ir-WRC-LR (2019.12) | 60s | F | None | | | HEV-RNA IgA-HEV-Ab | 30 wks | 288 | 206 days | Recovering |
| Lookback study | Rectal ulcer hemorrhage, central nervous system vasculitis | Ir-RBC-LR (2019.5) | 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 |
| | Extranodal NK/ T-cell lymphoma | Ir-PC-LR (2020.2) | 50s | F | HEV-RNA IgA-HEV-Ab IgM-HEV-Ab IgG-HEV-Ab | Neg. | 1 day | HEV-RNA | 4 wks | 66 | 17 days | Recovering |
| | Acute lymphocytic leukemia | Ir-PC-LR (2020.5) | 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 |

**[Bacteria]**

Of the 25 suspected bacteria TTI cases reported in 2020, 2 cases were identified as TTIs through PFGE, which showed consistency in bacterial strain.

**Table 4. Cases identified as transfusion-transmitted bacterial infections (2020)**

| | Blood product (year and month of blood collection) | Primary disease | Age | Sex | Symptoms | Time to onset (after the start of transfusion) | Post-transfusion blood culture results: Blood product | Post-transfusion blood culture results: Recipient's blood | Recipient's outcome |
|---|---|---|---|---|---|---|---|---|---|
| Spontaneous report | Ir-PC-LR (2020.6) | Myelodysplastic syndrome | 80s | F | Chills and shivering, fever, blood pressure decreased | approx. 4 hrs | *Enterococcus faecium* | *Enterococcus faecium* | Recovering |
| Spontaneous report | Ir-PC-LR (2020.9) | Acute lymphocytic leukemia | 40s | F | Chills and shivering, fever, vomiting, watery stool, blood pressure decreased, oxygen saturation decreased | 15 min. | *Escherichia coli* | *Escherichia coli* | Recovered (with sequelae) |

### 3) Information on individual transfusion adverse reaction and transfusion-transmitted infection cases obtained from literature and academic societies

#### (1) Cases in Japan

Table 5 shows domestic case reports found in literature and from academic societies in 2020. The domestic cases in Table 5 were not reported by medical institutions to the JRCS and only found in literature or information by academic societies. For these cases, the JRCS's MRs interviewed with the authors and medical institutions they were with on the severity of adverse reactions and on blood products used. Cases confirmed, based on investigation results, to be serious transfusion adverse reactions and TTIs were submitted as ICSR to the PMDA.

**Table 5. Domestic transfusion adverse reaction cases obtained through literature search (2020)**

| No | Suspected blood product | Age | Sex | Adverse event | Journal |
|---|---|---|---|---|---|
| 1 | Ir-RCC-LR | 88 | F | Delayed hemolytic transfusion adverse reaction | Kanto Regional Meeting of the Japanese Society of Internal Medicine, 2019; 655th: 49. |
| 2 | FFP-LR | 59 | M | Acute pulmonary edema | Respir Med Case Rep.2020; 29:101016 |
| 3 | Ir-RBC-LR | 70s | F | Acute hemolytic transfusion adverse reaction | Japanese Journal of Transfusion and Cell Therapy. 2020; 66(1):80 |
| 4 | Ir-RBC-LR | 40 | F | Chills, shivering Peripheral cyanosis | Japanese Journal of Transfusion and Cell Therapy. 2020; 66(2):437 |
| 5 | Ir-RBC-LR | 53 | F | Delayed hemolytic transfusion adverse reaction | Japanese Journal of Transfusion and Cell Therapy. 2020; 66(2):436 |
| 6 | Ir-RBC-LR | 82 | F | Delayed hemolytic transfusion adverse reaction | Japanese Journal of Transfusion and Cell Therapy. 2020; 66(2):436 |
| 7 | Ir-RBC-LR | 50s | M | Hemolytic adverse reactions | Japanese Journal of Transfusion and Cell Therapy. 2020; 66(2):436 |
| 8 | Ir-RBC-LR | 64 | F | Delayed hemolytic transfusion adverse reaction | Japanese Journal of Transfusion and Cell Therapy. 2020; 66(2):435 |
| 9 | RBC-LR | 70s | F | Delayed hemolytic transfusion adverse reaction | Japanese Journal of Transfusion and Cell Therapy. 2020; 66(2):412 |

**[Summary]**

- Cases except No. 2 were hemolytic adverse reactions in which the involvement of irregular antibodies was suspected. In Case No. 1, anti-E antibodies were detected before the transfusion, and also anti-c antibodies were detected after the transfusion. Case No. 3 was positive for irregular antibodies in the pre-transfusion test, but identification of irregular antibodies remained difficult. A request for testing was made to a blood center, and it was revealed that the patient in which anti-Jk3 antibodies were identified after the transfusion had the rare blood type, Jk (a-b-). Case No. 4 was a patient with bilateral hydronephrosis and cervical cancer. The patient received RBC transfusion for anemia, and 90 minutes after the start of transfusion, the patient experienced fever and peripheral cyanosis with chills and shivering. A pre-transfusion irregular antibody test identified anti-M antibodies, and the symptoms were considered to be adverse reactions to transfusion of M-antigen-positive RBC. Case No. 5 presented with hemolytic reactions after the transfusion. Detailed examination revealed anti-E, anti-c, anti-$Fy^b$, and anti-$Jk^b$ antibodies. Case No. 6 was negative for irregular antibodies before the transfusion but developed hemolytic adverse reactions afterward and was found to have anti-C and anti-e antibodies 10 days post-transfusion. Case No. 7 showed hemolysis after blood transfusion, and detailed examination revealed anti-$Xg^a$ antibodies in post-transfusion patient samples. Case No. 8 experienced hemolysis on the day after the transfusion. It was considered that immunity against antigens E and c was induced by the transfusion, resulting in a delayed hemolytic transfusion reactions (DHTR). In Case No. 9, multiple antibodies (anti-E and anti-c) were likely produced at different timings throughout the total of 4 transfusions, resulting in 2 DHTRs.
- Case No. 2 showed a rapid progression of respiratory failure approximately 4 hours after plasma exchange. Acute pulmonary edema was suspected, and extracorporeal ultrafiltration was performed and diuretics were administered, but the respiratory condition did not improve, and the patient died on the following day.

### (2) Cases outside of Japan

Since transfusion blood products prepared by the JRCS are distributed (supplied) only in Japan, the JRCS monitors transfusion adverse reactions and TTI cases outside of Japan by collecting and investigating case reports on adverse reactions and TTIs caused by foreign blood products that are equivalent in terms of product type and efficacy. Among them, cases of TTIs and unknown severe adverse reactions are submitted as ICSR to the PMDA. Table 6 indicates overseas cases collected in 2020.

**Table 6. Cases outside of Japan learned through literature search and submitted as ICSR to the PMDA (2020)**

| No | Country | Suspected blood product (equivalent product in Japan) | Age | Sex | Adverse event | Journal |
|---|---|---|---|---|---|---|
| 1 | U.S. | RBC-LR | 30s | F | Powassan virus infection | Clin Infect Dis.2020 |
| 2 | Spain | RBC-LR | 32 | F | Central retinal artery occlusion | Arch Soc Esp Oftalmol.2020;20 |
| 3 | Brazil | RBC-LR | 26 | F | Dengue hemorrhagic fever | Transfusion.2020 |
| 4 | China | RBC-LR | 40 | M | Babesiosis | Transfusion and Apheresis Science.2020 |
| 5 | U.S. | RBC-LR | 35 | F | Acute hepatitis E | Cureus.2020;12(9) |
| 6 | Czech | RBC-LR | 36 | M | Babesiosis | Folia Parasitologica.2020;67(3):1 |
| 7 | Brazil | RBC-LR | 29 | M | HTLV-2 infection | Journal of the Brazilian Society of Tropical Medicine.2020 |
| 8 | France | RBC-LR<br>FFP-LR | 50s | M | Hepatitis E | Emerg Infect Dis.2020;26(12):2881-2886 |
| 9 | France | FFP-LR | 50s | M | Hepatitis E | Emerg Infect Dis.2020;26(12):2881-2886 |
| 10 | U.S. | PC-LR | 63 | M | Bacterial infection | Transfusion.2020 |

**[Summary]**

- Case No. 1 is a Powassan virus infection case in the US. Anti-Powassan virus IgM antibodies and neutralizing antibodies were detected in the serum of a patient who received transfusion. A lookback study detected Powassan-RNA in products manufactured at the same time using blood from a particular donor. The case was considered to be possible TTI, given that the donor was bitten by a tick in a forest 1 month before the blood donation; viral RNA was detected in products manufactured at the same time; and IgM and neutralizing antibodies were detected in post-donation serum.
- Case No. 2 is a central retinal artery occlusion case in Spain. The patient suddenly lost vision in the right eye 1 hour after the transfusion. There were no clinical findings other than an increase in D-dimer, and it was considered that accelerated formation of intravascular thrombus may have caused the retinal arterial ischemia.
- Case No. 3 is a dengue virus (DENV) infection case in Brazil. Post-transfusion patient samples tested positive for DENV-RNA, and a lookback study detected DENV-RNA in the donor's archived samples. The case was deemed to be a case of potential transfusion-transmitted DENV due to the 100% homology between the patient and donor's DENV-RNA.
- Case No. 4 is a *Babesia* infection case in China. After transfusion, symptoms such as fever and jaundice developed, and investigations identified *Babesia microti* in the bone marrow and peripheral blood. Because the patient had no history of tick bites or overseas travel and had frequently received blood transfusions before the onset, the *Babesia* infection was likely caused by the transfusion.
- Case No. 5 is an HEV infection case in the US. The patient visited a medical institution for jaundice, and HEV-IgM antibodies were detected in the patient's samples. Since the patient had received a blood transfusion 16 days prior, and there were no HEV infection risk factors other than the blood transfusion, the case was considered to be potential HEV TTI.
- Case No. 6 is a *Babesia* infection case in the Czech Republic. The patient presented with hepatosplenomegaly after transfusion, and the *Babesia* infection was confirmed by a lymphocyte transformation test.
- Case No. 7 is an HTLV-2 infection case in Brazil. The patient who had received frequent blood transfusions for sickle cell disease since early childhood was diagnosed as an HTLV-2 carrier in a community-based HTLV-1/2 prevalence survey on patients with blood disorders. Since there were no risk factors other than blood transfusion, transfusion was considered to be the cause.
- Case No. 8 and 9 are HEV infection cases attributable to French S/D-treated plasma products. Case No. 8 showed elevated liver enzymes after transfusion, and post-transfusion samples were positive for HEV-IgM and IgG antibodies and HEV-RNA. As a result of a lookback study, HEV-RNA was detected from the blood of one donor whose blood was used in the transfused plasma product, and genome sequences of both HEV-RNA matched. Case No. 9 also showed elevated hepatic enzymes after transfusion, and post-transfusion samples were positive for HEV-IgM and IgG antibodies and HEV-RNA. A lookback study found HEV-RNA in one donor associated with the plasma product, and homology between both HEV-RNA was confirmed.
- Case No. 10 is a bacterial infection case in the US. The transfusion-transmitted bacterial infection was caused by bacterial contamination due to a small breakage at the port of the suspected blood bag. The patient presented with septic shock symptoms immediately after the transfusion and died 17 hours after onset. Bacteria were not detected in the donor samples of the suspected product, but the same three types of bacteria were detected in the suspected product and patient samples. In addition, the suspected product was platelets treated with pathogen reduction and was suspected of being contaminated by bacteria after the treatment.

## 3. Measures in foreign countries and studies

The JRCS reports to the PMDA when it obtains information on measures that countries outside of Japan have taken for pharmaceuticals equivalent to the JRCS's transfusion blood products. Foreign

measures that require such reporting are defined as "the discontinuation of production, import, or distribution, recall, and disposal of relevant foreign pharmaceuticals and other measures taken for relevant foreign pharmaceuticals to prevent health hazards from occurring or expanding" in Article 228-20 of the Enforcement Regulations of the PMD Act. The JRCS also files reports to the PMDA when it obtains information on studies demonstrating that "adverse reactions or infectious diseases associated with JRCS's pharmaceuticals or equivalent foreign pharmaceuticals may cause cancer, other serious diseases, disorders, or death"; that "trends in adverse reactions or infectious diseases associated with the JRCS's pharmaceuticals or equivalent foreign pharmaceuticals have significantly changed"; or that "the JRCS's pharmaceuticals do not demonstrate efficacy for which they were approved" as specified in Article 228-20 of the Enforcement Regulations of the PMD Act.

Although the JRCS does not distribute (supply) its transfusion blood products outside of Japan, based on Article 68-10 of the PMD Act and Article 228-20 of the Enforcement Regulations of the PMD Act, it files reports to the PMDA on non-JRCS transfusion blood products used abroad as long as they use the same active ingredients, regardless of any difference in administration route, dosage, and efficacy.

Table 7 shows measures taken in foreign countries in 2020 that JRCS reported. There were no studies that JRCS reported in 2020.

**Table 7. Measures in foreign countries that JRCS obtained and reported (2020)**

| No. | Source | Title |
|---|---|---|
| 1 | Europe (ECDC) | Rapid Risk Assessment: Cluster of pneumonia cases caused by a novel coronavirus, Wuhan, China. (2020/1/17) |
| 2 | | Coronavirus disease 2019 (COVID-19) and supply of substances of human origin in the EU/EEA-second update. (2020/12/10) |
| 3 | U.S. (FDA) | Important Information for Blood Establishments Regarding the Novel Coronavirus Outbreak. (2020/2/4) |
| 4 | | Updated Information for Blood Establishments Regarding the Novel Coronavirus Outbreak. (2020/5/11) |
| 5 | | Alternative Procedures for Blood and Blood Components during the COVID -19 Public Health Emergency: Guidance for Industry. (2020/4) |
| 6 | | Use of Serological Tests to Reduce the Risk of Transfusion -Transmitted Human T-Lymphotropic Virus Types I and II (HTLV-I/II); Guidance for Industry. (2020/2/6) |
| 7 | Australia (TGA) | TGA approves reduction of the deferral period for whole blood donors with sexual activity risk factors. (2020/4/15) |
| 8 | | TGA approves reduction of the deferral period for blood and plasma donors. (2020/8/4) |

## [Summary]

- Reports No. 1 and 2 are the latest information on the prevalence of COVID-19 and blood donation issued by the European Centre for Disease Prevention and Control (ECDC) to blood establishments. Pneumonia of unknown etiology was reported in Wuhan, China on December 31, 2019 and was subsequently found to be caused by SARS-CoV-2. In response to this, the ECDC issued a Rapid Risk Assessment. Regarding substances of human origin (SoHO), including transfusion blood products, it was recommended that blood donation and donation of tissues and organs should be deferred for 21 days from the date of possible exposure to SARS-CoV-2 or the date of return from Wuhan, China. It was also recommended that blood should not be donated for

at least 28 days after the resolution of symptoms and completion of treatment. Subsequently, in response to the epidemiological changes in COVID-19, information on SoHO supply, such as donor eligibility criteria, was updated.

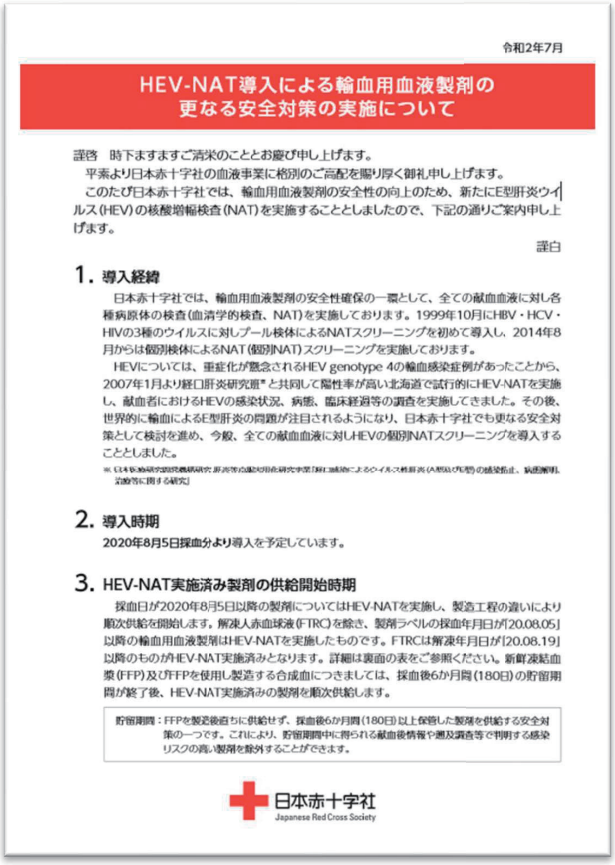
- Reports No. 3 and 4 are the latest information on the prevalence of COVID-19 issued by the US Department of Health and Human Services Food and Drug Administration (FDA) to blood establishments. Guidance on donor eligibility was revised and added to ensure sufficient blood donation, which significantly decreased due to the COVID-19 outbreak.
- Report No. 5 is on guidance issued by the US FDA, which presents alternative procedures for the handling of blood and blood products during the COVID-19 outbreak. Various guidance criteria on donor eligibility were revised and added to ensure sufficient blood donation, which significantly decreased due to the COVID-19 outbreak.
- Report No. 6 is the latest version of guidance on serological tests for human T-lymphotropic virus types 1 and 2 (HTLV-1/2) issued by the US FDA. Recommendations included those on blood donation deferral requirements based on HTLV-1/2 antibody screening test results; re-entry requirements for donors who were previously deferred due to HTLV-1/2 antibody positivity; and management (e.g., defining applicable period for lookback investigations) of products derived from HTLV-1/2-positive donors.
- Reports No. 7 and 8 are on information concerning the reduction of deferral periods in blood donations issued by the Australian Therapeutic Goods Administration (TGA). In April 2020, the TGA approved to reduce deferral periods for whole blood donors with sexual activity-based risk factors from 12 to 3 months since their last sexual contact. Subsequently, in August 2020, Lifeblood submitted an additional proposal to extend the scope of the reduced deferral period to plasmapheresis and plateletpheresis donors, and TGA approved.

## 4. Safety measures for blood products for transfusion

Safety measures are taken based on assessment and evaluation of transfusion adverse reaction and TTI cases reported by medical institutions and post-donation information obtained from donors. The following are safety measures that the JRCS took in 2020.

### 1) Safety measures for blood products for transfusion through implementing HEV-nucleic acid amplification test

As part of its efforts to ensure safety in transfusion blood products, the JRCS performs tests (serological tests and NAT) for various pathogens on all donated blood. In October 1999, the JRCS implemented NAT screening using pooled samples for the three viruses HBV, HCV, and HIV, and in August 2014, it initiated ID-NAT. In January 2005, HEV-NAT was tested in Hokkaido, where there were cases of HEV genotype 4 TTI which can potentially become severe. From January 2007, the HEV-NAT was conducted on a trial basis in Hokkaido, where HEV-positivity was high, and the status on HEV infections, pathology, and clinical course in donors was investigated. Subsequently, transfusion-transmitted HEV attracted worldwide attention. After discussions on further safety measures, the JRCS introduced ID-NAT HEV screening for all donated blood collected on August 5, 2020 and onward (Figure 14). Figure 15 shows changes in the number of transfusion-transmitted HEV infections. A total of 45 cases of transfusion-transmitted HEV infections were identified between 2002, when transfusion-transmitted HEV infection was confirmed for the first time in Hokkaido, and 2020. In 2020, spontaneous reports and lookback studies identified 3 cases of HEV infections, respectively; however, there have been no identified HEV blood product-associated infections caused by blood collected after the introduction of HEV-NAT on August 5, 2020.



令和2年7月

**HEV-NAT導入による輸血用血液製剤の更なる安全対策の実施について**

謹啓　時下ますますご清栄のこととお慶び申し上げます。
平素より日本赤十字社の血液事業に格別のご高配を賜り厚く御礼申し上げます。
このたび日本赤十字社では、輸血用血液製剤の安全性の向上のため、新たにE型肝炎ウイルス(HEV)の核酸増幅検査(NAT)を実施することとしましたので、下記の通りご案内申し上げます。

謹白

**1. 導入経緯**

日本赤十字社では、輸血用血液製剤の安全性確保の一環として、全ての献血血液に対し各種病原体の検査(血清学的検査、NAT)を実施しております。1999年10月にHBV・HCV・HIVの3種のウイルスに対しプール検体によるNATスクリーニングを初めて導入し、2014年8月からは個別検体によるNAT(個別NAT)スクリーニングを実施しております。
HEVについては、重症化が懸念されるHEV genotype 4の輸血感染症例があったことから、2007年1月より経口肝炎研究班*と共同して陽性率が高い北海道で試行的にHEV-NATを実施し、献血者におけるHEVの感染状況、病態、臨床経過等の調査を実施してきました。その後、世界的に輸血によるE型肝炎の問題が注目されるようになり、日本赤十字社でも更なる安全対策として検討を進め、今般、全ての献血血液に対しHEVの個別NATスクリーニングを導入することとしました。

**2. 導入時期**

**2020年8月5日採血分より**導入を予定しています。

**3. HEV-NAT実施済み製剤の供給開始時期**

採血日が2020年8月5日以降の製剤についてはHEV-NATを実施し、製造工程の違いにより順次供給を開始します。解凍人赤血球液(FTRC)を除き、製剤ラベルの採血年月日が[20.08.05]以降の輸血用血液製剤はHEV-NATを実施したものです。FTRCは解凍年月日が[20.08.19]以降のものがHEV-NAT実施済みとなります。詳細は裏面の表をご参照ください。新鮮凍結血漿(FFP)及びFFPを使用し製造する合成血につきましては、採血後6か月間(180日)の貯留期間が終了後、HEV-NAT実施済みの製剤を順次供給します。

貯留期間：FFPを製造後直ちに供給せず、採血後6か月間(180日)以上保管した製剤を供給する安全対策の一つです。これにより、貯留期間中に得られる献血後情報や遡及調査等で判明する感染リスクの高い製剤を除外することができます。

日本赤十字社
Japanese Red Cross Society

**Figure 14. Notice on additional safety measure for transfusion blood products through HEV-NAT implementation**

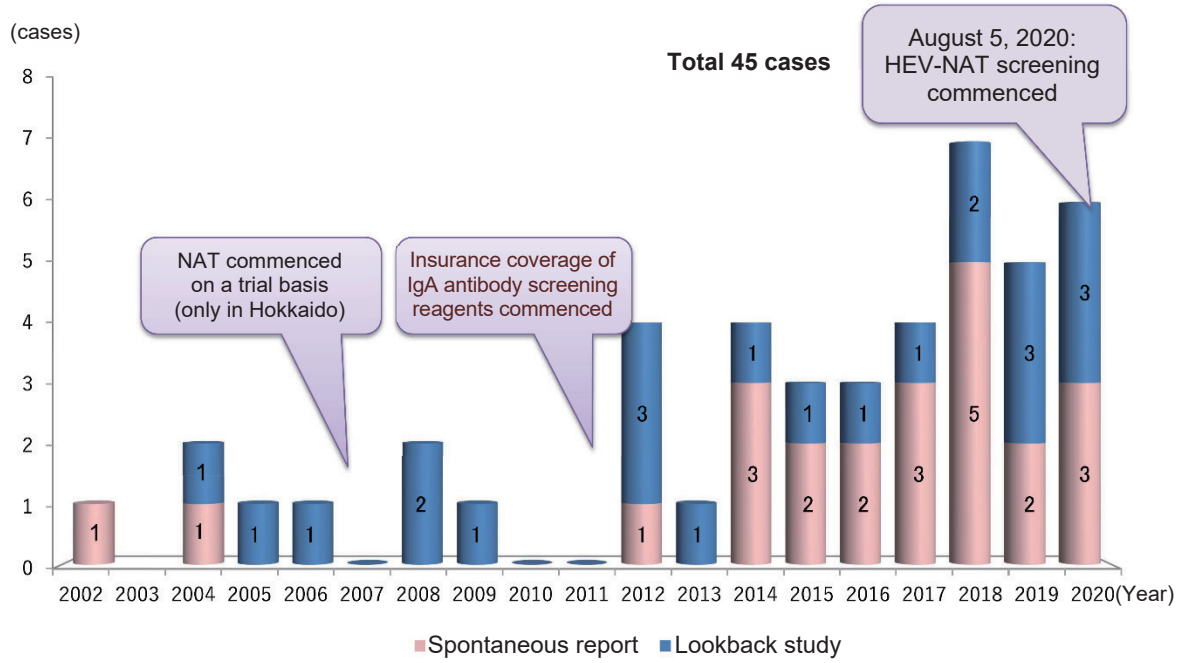
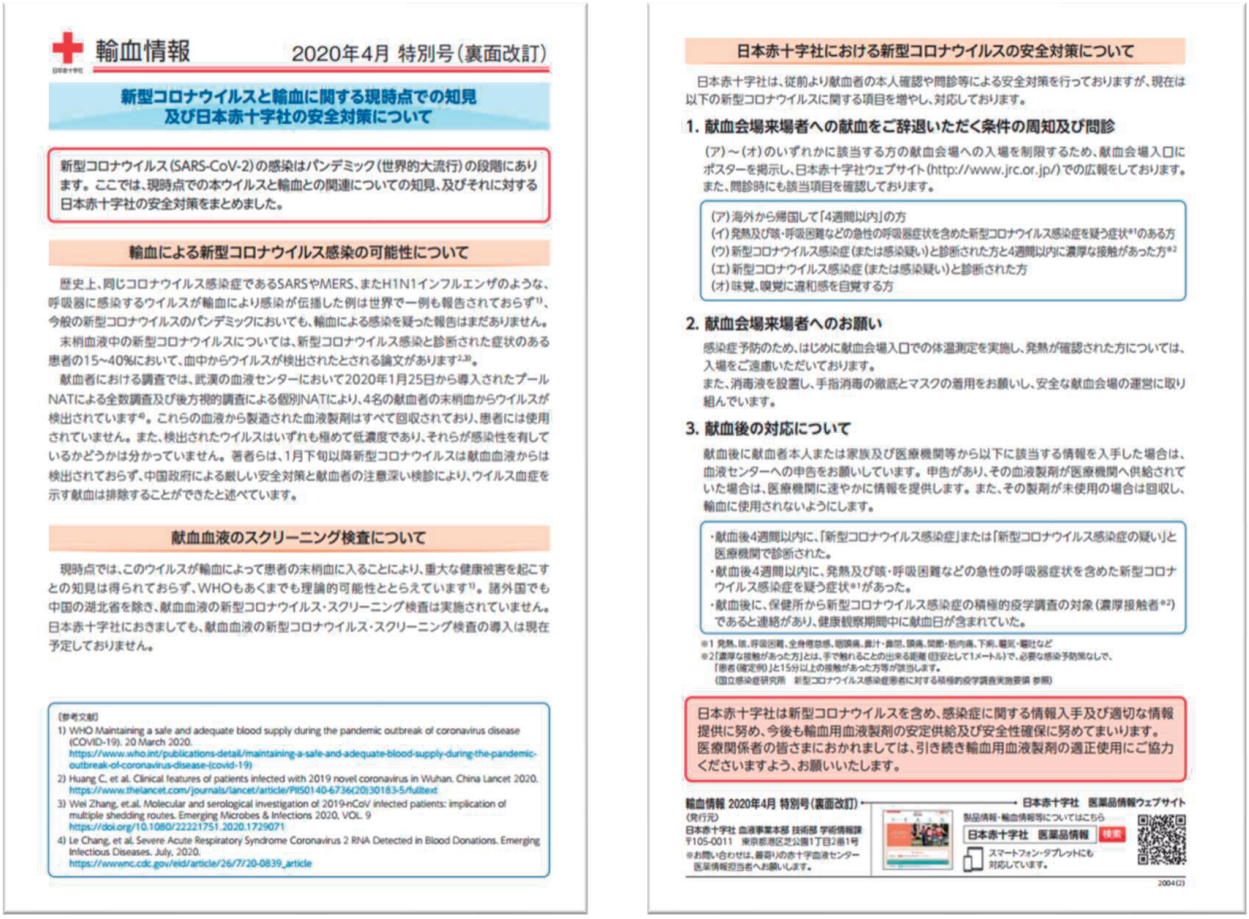



**Figure 15. Number of transfusion-transmitted HEV infection cases**

### 2) Safety measures against COVID-19

In response to the global COVID-19 pandemic, the JRCS issued a special issue of its *Transfusion Information* titled "Current knowledge on SARS-CoV-2 and blood donation and JRCS's safety measures" in April 2020 (Figure 16). The JRCS has been taking safety measures to ensure the safety of transfusion blood products by confirming the identification of blood donors and performing interviews. However, COVID-19 requires further measures at blood donation sites in order to prevent further spread of the pandemic. Thus, the JRCS is taking various safety measures, including communication to blood donors on: its measures against COVID-19 and particular requests to visitors of blood donation sites (Figure 17); eligibility of blood donation in relation to COVID-19 (Figure 18); and request for provision of post-donation information (Figure 19). Such measures are reviewed when there are any developments in the pandemic or when new knowledge is obtained.

Some researches confirmed that SARS-CoV-2 RNA could be detected in the blood of patients with COVID-19. However, successful virus culture using PCR-positive blood has not been reported worldwide, and no transfusion-transmitted SARS-CoV-2 infection cases have been confirmed. Therefore, transfusion-transmitted SARS-CoV-2 infection is considered a theoretical risk.



輸血情報　2020年4月 特別号（裏面改訂）

新型コロナウイルスと輸血に関する現時点での知見
及び日本赤十字社の安全対策について

新型コロナウイルス（SARS-CoV-2）の感染はパンデミック（世界的大流行）の段階にあります。ここでは、現時点での本ウイルスと輸血との関連についての知見、及びそれに対する日本赤十字社の安全対策をまとめました。

輸血による新型コロナウイルス感染の可能性について

歴史上、同じコロナウイルス感染症であるSARSやMERS、またH1N1インフルエンザのような、呼吸器に感染するウイルスが輸血により感染が伝播した例は世界で一例も報告されておらず[1]、今般の新型コロナウイルスのパンデミックにおいても、輸血による感染を疑った報告はまだありません。

末梢血液中の新型コロナウイルスについては、新型コロナウイルス感染と診断された症状のある患者の15~40%において、血中からウイルスが検出されたとされる論文があります[2,3]。

献血者における調査では、武漢の血液センターにおいて2020年1月25日から導入されたプールNATによる全数調査及び後方視的調査による個別NATにより、4名の献血者の末梢血からウイルスが検出されています[4]。これらの血液から製造された血液製剤はすべて回収されており、患者には使用されていません。また、検出されたウイルスはいずれも極めて低濃度であり、それらが感染性を有しているかどうかは分かっていません。著者らは、1月下旬以降新型コロナウイルスは献血血液からは検出されておらず、中国政府による厳しい安全対策と献血者の注意深い検診により、ウイルス血症を示す献血は排除することができたと述べています。

献血血液のスクリーニング検査について

現時点では、このウイルスが輸血によって患者の末梢血に入ることにより、重大な健康被害を起こすとの知見は得られておらず、WHOもあくまでも理論的可能性ととらえています[1]。諸外国でも中国の湖北省を除き、献血血液の新型コロナウイルス・スクリーニング検査は実施されていません。日本赤十字社におきましても、献血血液の新型コロナウイルス・スクリーニング検査の導入は現在予定しておりません。

（参考文献）
1) WHO Maintaining a safe and adequate blood supply during the pandemic outbreak of coronavirus disease (COVID-19). 20 March 2020. https://www.who.int/publications-detail/maintaining-a-safe-and-adequate-blood-supply-during-the-pandemic-outbreak-of-coronavirus-disease-(covid-19)
2) Huang C, et al. Clinical features of patients infected with 2019 novel coronavirus in Wuhan. China Lancet 2020. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)30183-5/fulltext
3) Wei Zhang, et.al. Molecular and serological investigation of 2019-nCoV infected patients: implication of multiple shedding routes. Emerging Microbes & Infections 2020, VOL. 9 https://doi.org/10.1080/22221751.2020.1729071
4) Le Chang, et al. Severe Acute Respiratory Syndrome Coronavirus 2 RNA Detected in Blood Donations. Emerging Infectious Diseases. July, 2020. https://wwwnc.cdc.gov/eid/article/26/7/20-0839_article

日本赤十字社における新型コロナウイルスの安全対策について

日本赤十字社は、従前より献血者の本人確認や問診等による安全対策を行っておりますが、現在は以下の新型コロナウイルスに関する項目を増やし、対応しております。

1. 献血会場来場者への献血をご辞退いただく条件の周知及び問診

（ア）～（オ）のいずれかに該当する方の献血会場への入場を制限するため、献血会場入口にポスターを掲示し、日本赤十字社ウェブサイト（http://www.jrc.or.jp/）での広報をしております。また、問診時にも該当項目を確認しております。

（ア）海外から帰国して「4週間以内」の方
（イ）発熱及び咳・呼吸困難などの急性の呼吸器症状を含めた新型コロナウイルス感染症を疑う症状※1のある方
（ウ）新型コロナウイルス感染症（または感染疑い）と診断された方と4週間以内に濃厚な接触があった方※2
（エ）新型コロナウイルス感染症（または感染疑い）と診断された方
（オ）味覚、嗅覚に違和感を自覚する方

2. 献血会場来場者へのお願い

感染症予防のため、はじめに献血会場入口での体温測定を実施し、発熱が確認された方については、入場をご遠慮いただいております。
また、消毒液を設置し、手指消毒の徹底とマスクの着用をお願いし、安全な献血会場の運営に取り組んでいます。

3. 献血後の対応について

献血後に献血者本人または家族及び医療機関等から以下に該当する情報を入手した場合は、血液センターへの申告をお願いしています。申告があり、その血液製剤が医療機関へ供給されていた場合は、医療機関に速やかに情報を提供します。また、その製剤が未使用の場合は回収し、輸血に使用されないようにします。

・献血後4週間以内に、「新型コロナウイルス感染症」または「新型コロナウイルス感染症の疑い」と医療機関で診断された。
・献血後4週間以内に、発熱及び咳・呼吸困難などの急性の呼吸器症状を含めた新型コロナウイルス感染症を疑う症状※1があった。
・献血後に、保健所から新型コロナウイルス感染症の積極的疫学調査の対象（濃厚接触者※2）であると連絡があり、健康観察期間中に献血日が含まれていた。

※1 発熱、咳、呼吸困難、全身倦怠感、咽頭痛、鼻汁・鼻閉、頭痛、関節・筋肉痛、下痢、嘔気・嘔吐など
※2「濃厚な接触があった方」とは、手で触れることの出来る距離（目安として1メートル）で、必要な感染予防策なしで、「患者（確定例）」と15分以上の接触があった方等が該当します。
（国立感染症研究所　新型コロナウイルス感染症患者に対する積極的疫学調査実施要領 参照）

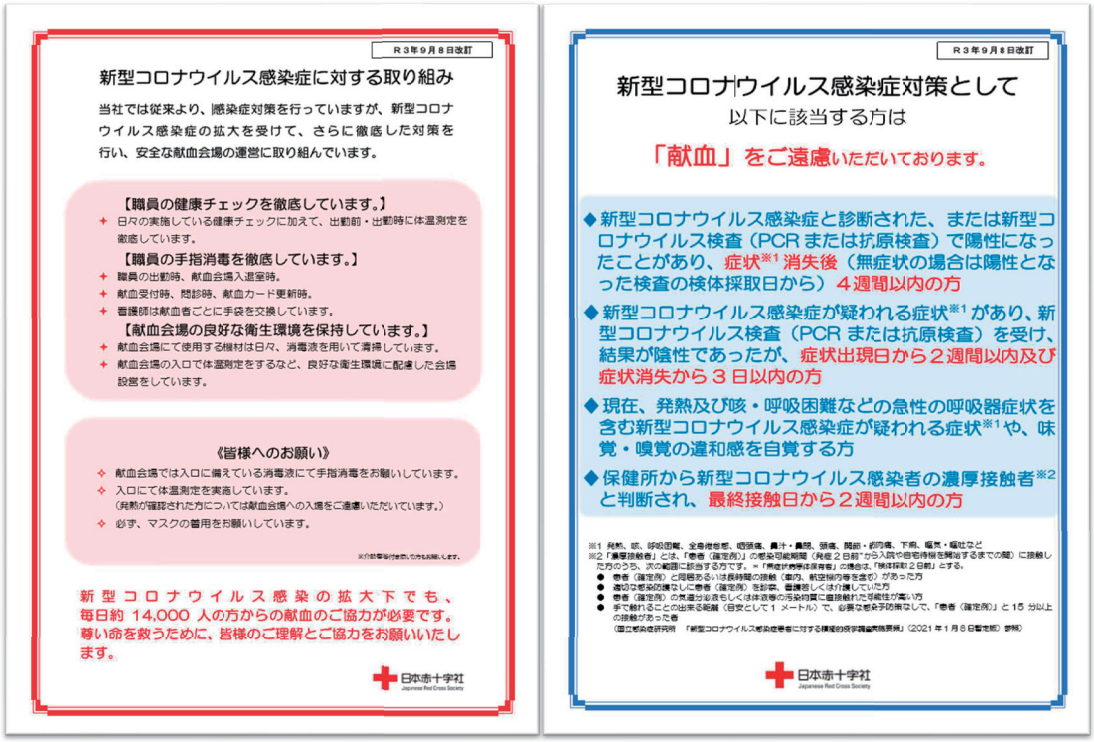
日本赤十字社は新型コロナウイルスを含め、感染症に関する情報入手及び適切な情報提供に努め、今後も輸血用血液製剤の安定供給及び安全性確保に努めてまいります。医療関係者の皆さまにおかれましては、引き続き輸血用血液製剤の適正使用にご協力くださいますよう、お願いいたします。

輸血情報 2020年4月 特別号（裏面改訂）
（発行元）
日本赤十字社 血液事業本部 技術部 学術情報課
〒105-0011 東京都港区芝公園1丁目2番1号
※お問い合わせは、最寄りの赤十字血液センター医薬情報担当者へお願いします。

日本赤十字社　医薬品情報ウェブサイト
製品情報・輸血情報等についてはこちら
日本赤十字社 医薬品情報 検索
スマートフォン・タブレットにも対応しています。

2004(2)

**Figure 16. Current knowledge on SARS-CoV-2 and blood donation and JRCS's safety measures**



R３年９月８日改訂

新型コロナウイルス感染症に対する取り組み

当社では従来より、感染症対策を行っていますが、新型コロナウイルス感染症の拡大を受けて、さらに徹底した対策を行い、安全な献血会場の運営に取り組んでいます。

【職員の健康チェックを徹底しています。】
- 日々の実施している健康チェックに加えて、出勤前・出勤時に体温測定を徹底しています。

【職員の手指消毒を徹底しています。】
- 職員の出勤時、献血会場入退室時。
- 献血受付時、問診時、献血カード更新時。
- 看護師は献血者ごとに手袋を交換しています。

【献血会場の良好な衛生環境を保持しています。】
- 献血会場にて使用する機材は日々、消毒液を用いて清掃しています。
- 献血会場の入口で体温測定をするなど、良好な衛生環境に配慮した会場設営をしています。

《皆様へのお願い》
- 献血会場では入口に備えている消毒液にて手指消毒をお願いしています。
- 入口にて体温測定を実施しています。
（発熱が確認された方については献血会場への入場をご遠慮いただいています。）
- 必ず、マスクの着用をお願いしています。

※の部分は任意で行われます。

新型コロナウイルス感染の拡大下でも、毎日約 14,000 人の方からの献血のご協力が必要です。尊い命を救うために、皆様のご理解とご協力をお願いいたします。

日本赤十字社

R３年９月８日改訂

新型コロナウイルス感染症対策として
以下に該当する方は
「献血」をご遠慮いただいております。

◆新型コロナウイルス感染症と診断された、または新型コロナウイルス検査（PCR または抗原検査）で陽性になったことがあり、症状※1 消失後（無症状の場合は陽性となった検査の検体採取日から）４週間以内の方

◆新型コロナウイルス感染症が疑われる症状※1 があり、新型コロナウイルス検査（PCR または抗原検査）を受け、結果が陰性であったが、症状出現日から２週間以内及び症状消失から３日以内の方

◆現在、発熱及び咳・呼吸困難などの急性の呼吸器症状を含む新型コロナウイルス感染症が疑われる症状※1 や、味覚・嗅覚の違和感を自覚する方

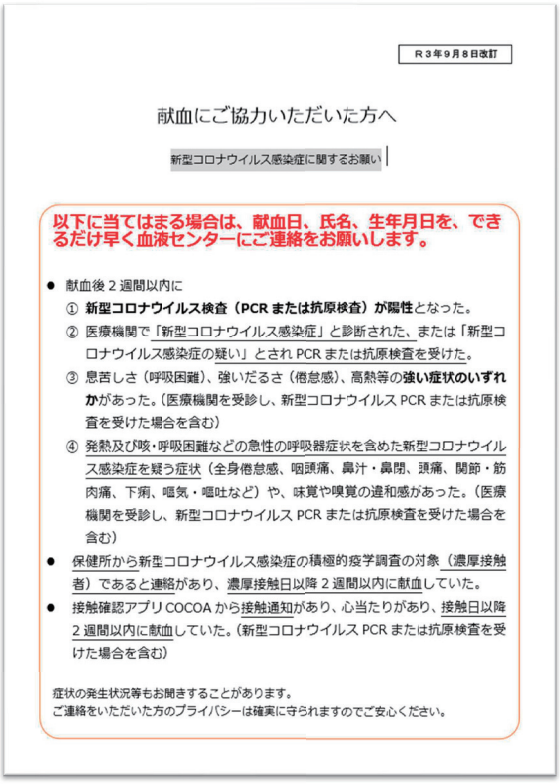
◆保健所から新型コロナウイルス感染者の濃厚接触者※2 と判断され、最終接触日から２週間以内の方

※1 発熱、咳、呼吸困難、全身倦怠感、咽頭痛、鼻汁・鼻閉、頭痛、関節・筋肉痛、下痢、嘔気・嘔吐など
※2「濃厚接触者」とは、「患者（確定例）」の感染可能期間（発症２日前*から入院や自宅待機を開始するまでの間）に接触した方のうち、次の範囲に該当する方です。*「無症状病原体保有者」の場合は、「検体採取２日前」とする。
- 患者（確定例）と同居あるいは長時間の接触（車内、航空機内等を含む）があった方
- 適切な感染防護なしに患者（確定例）を診察、看護若しくはケアしていた方
- 患者（確定例）の気道分泌液もしくは体液等の汚染物質に直接触れた可能性が高い方
- 手で触れることの出来る範囲（目安として１メートル）で、必要な感染予防策なしで、「患者（確定例）」と 15 分以上の接触があった者
（国立感染症研究所　「新型コロナウイルス感染症患者に対する積極的疫学調査実施要領」（2021 年１月８日暫定版）参照）

日本赤十字社

**Figure 17. JRCS's anti-COVID-19 measures and requests to visitors of blood donation sites (revised on September 8, 2021) (left)**

**Figure 18. Eligibility of blood donation in relation to COVID-19 (revised on September 8, 2021) (right)**



R３年９月８日改訂

献血にご協力いただいた方へ

新型コロナウイルス感染症に関するお願い

**以下に当てはまる場合は、献血日、氏名、生年月日を、できるだけ早く血液センターにご連絡をお願いします。**

- 献血後２週間以内に
  ① **新型コロナウイルス検査（PCR または抗原検査）が陽性**となった。
  ② 医療機関で「新型コロナウイルス感染症」と診断された、または「新型コロナウイルス感染症の疑い」とされ PCR または抗原検査を受けた。
  ③ 息苦しさ（呼吸困難）、強いだるさ（倦怠感）、高熱等の**強い症状のいずれか**があった。（医療機関を受診し、新型コロナウイルス PCR または抗原検査を受けた場合を含む）
  ④ 発熱及び咳・呼吸困難などの急性の呼吸器症状を含めた新型コロナウイルス感染症を疑う症状（全身倦怠感、咽頭痛、鼻汁・鼻閉、頭痛、関節・筋肉痛、下痢、嘔気・嘔吐など）や、味覚や嗅覚の違和感があった。（医療機関を受診し、新型コロナウイルス PCR または抗原検査を受けた場合を含む）
- 保健所から新型コロナウイルス感染症の積極的疫学調査の対象（濃厚接触者）であると連絡があり、濃厚接触日以降２週間以内に献血していた。
- 接触確認アプリ COCOA から接触通知があり、心当たりがあり、接触日以降２週間以内に献血していた。（新型コロナウイルス PCR または抗原検査を受けた場合を含む）

症状の発生状況等もお聞きすることがあります。
ご連絡をいただいた方のプライバシーは確実に守られますのでご安心ください。

**Figure 19. Request for provision of post-donation information (revised on September 8, 2021)**

## Afterword

This annual report describes the JRCS's safety measures which are developed and implemented based on analysis and assessment of primarily adverse reaction and infection information reported to the JRCS by medical institutions nationwide, as well as infection information obtained through post-donation information.

We extend our sincere appreciation to health care professionals and members of the JRC blood centers for their cooperation in our post-marketing safety vigilance operations.

The JRCS will continue contributing to haemovigilance in Japan and in the international community in compliance with applicable laws and regulations and strive to improve safety in transfusion medicine.

"Haemovigilance by JRCS 2020"

Edited by

Naoko Goto, Manager of the Safety Vigilance Division (Safety Management Supervisor)
Safety Vigilance Division, Technical Department, Blood Service Headquarters
Japanese Red Cross Society

Issued on

February 2022

Safety Vigilance Division, Technical Department, Blood Service Headquarters

Japanese Red Cross Society

1-2-1, Shiba-koen, Minato-ku, Tokyo, 105-0011 Japan