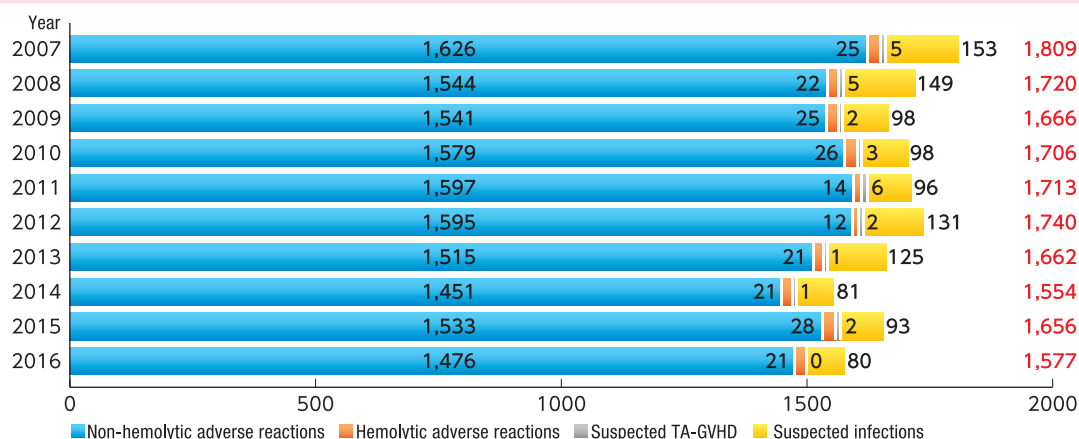


Non-hemolytic Adverse Transfusion Reactions Reported to JRC Blood Centers (2016)

Suspected transfusion-associated adverse reactions and/or transfusion-transmitted infectious cases were reported by medical institutions to JRC blood centers. This issue of Transfusion Information shows the most frequently reported cases of non-hemolytic adverse transfusion reaction cases in 2016, including changes in the number of transfusion-related acute lung injury (TRALI) and transfusion-associated circulatory overload (TACO) cases.

Changes in the number of reported adverse reactions and infectious cases (number of reported cases from medical institutions, including ones assessed as “no cause of imputability to transfusion”)

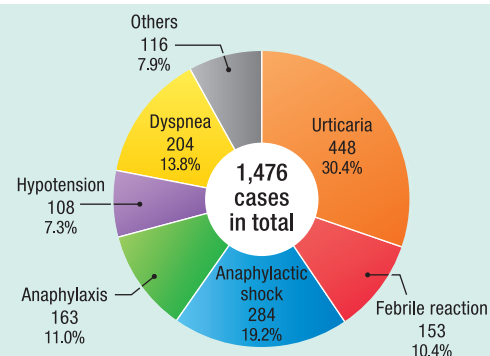


1,476 cases of non-hemolytic adverse transfusion reactions were reported in 2016. These accounted for 93.6% of the 1,577 cases reported as transfusion-related adverse reactions and infections.

Non-hemolytic adverse transfusion reactions (2016)

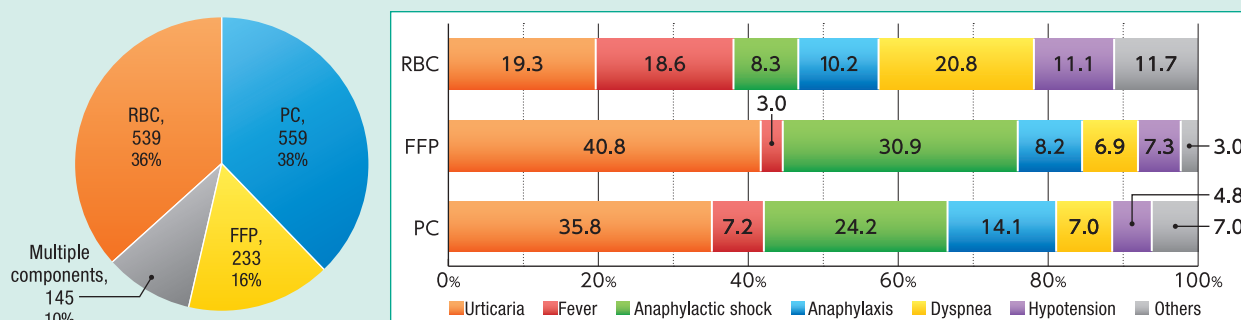
Breakdown of cases by symptoms

Adverse reaction cases reported by medical institutions are summarized by symptoms. Severe cases predominantly had the following symptoms: anaphylactic shock, anaphylaxis, hypotension, and dyspnea. These cases account for 51.4% of the total number. Note that the cases of suspected transfusion-related acute lung injury (TRALI) and transfusion-associated circulatory overload (TACO) are all included in dyspnea.



Type of transfused blood components and breakdown of adverse reactions (by symptoms)

Most of the non-hemolytic adverse reactions were caused by platelets or red blood cells. For plasma and platelets, urticaria and anaphylactic shock are relatively common.



<Notes>

[Hypotension]

Hypotension without symptoms such as skin manifestations and dyspnea

[Anaphylaxis]

Multiple general symptoms including general flushing, urticaria, angioedema (e.g. face edema, pharyngeal edema) and dyspnea

[Anaphylactic shock]

“Anaphylaxis” with hypotension

Number of reported cases and frequency by components and symptoms (frequency based on the total number of bags supplied) (2016)

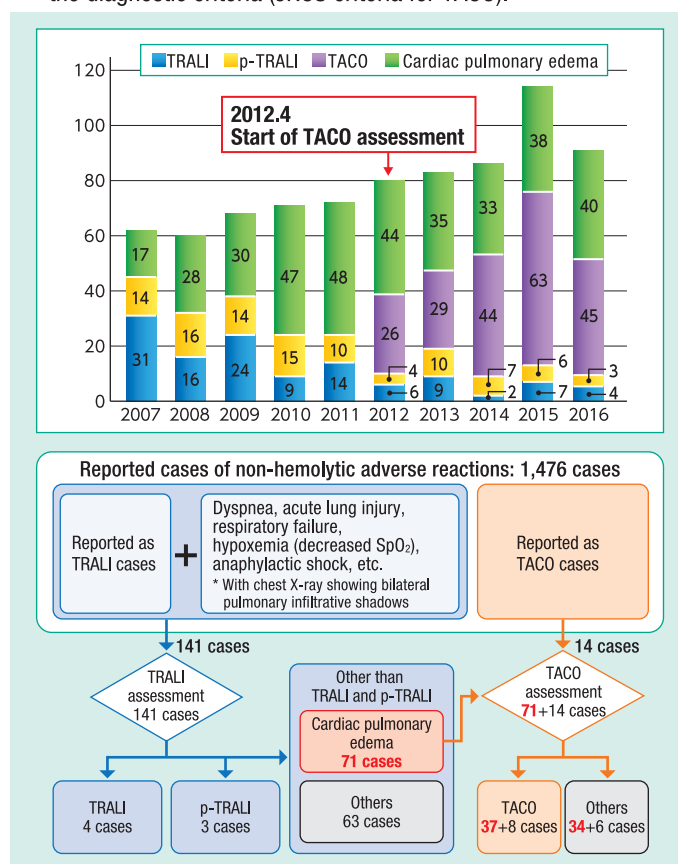
Components	Platelets	Red cells*	Plasma
Number of bags supplied	833,362	3,282,335	945,135
Urticaria	200 cases (approx. 1/ 4,200)	104 cases (approx. 1/ 32,000)	95 cases (approx. 1/ 10,000)
Fever	40 cases (approx. 1/ 21,000)	100 cases (approx. 1/ 33,000)	7 cases (approx. 1/ 140,000)
Hypotension	27 cases (approx. 1/ 31,000)	60 cases (approx. 1/ 55,000)	17 cases (approx. 1/ 56,000)
Anaphylaxis	79 cases (approx. 1/ 11,000)	55 cases (approx. 1/ 60,000)	19 cases (approx. 1/ 50,000)
Anaphylactic shock	135 cases (approx. 1/ 6,200)	45 cases (approx. 1/ 73,000)	72 cases (approx. 1/ 13,000)
Dyspnea	30 cases (approx. 1/ 28,000)	91 cases (approx. 1/ 36,000)	8 cases (approx. 1/ 120,000)
TRALI	1 case (approx. 1/830,000)	No cases	4 cases (approx. 1/ 240,000)
TACO	8 cases (approx. 1/100,000)	21 cases (approx. 1/ 160,000)	4 cases (approx. 1/ 240,000)
Others	39 cases (approx. 1/ 21,000)	63 cases (approx. 1/ 52,000)	7 cases (approx. 1/ 140,000)
Total	559 cases (approx. 1/ 1,500)	539 cases (approx. 1/ 6,100)	233 cases (approx. 1/ 4,100)

The blood components in the table include components irradiated before supply and components irradiated at medical institutions. Cases given two or more types of blood components in combination were excluded.

*Washed red cells, frozen-thawed red cells, and blood for exchange transfusion were excluded.

Number of TRALI and TACO cases by year (2007-2016)

Among adverse transfusion reactions presenting with dyspnea, suspected TRALI or TACO cases were evaluated based on the diagnostic criteria (JRCS criteria for TACO).



Leukocyte antibody derived from donors is considered as a major cause of TRALI. As a safety measure against this issue, fresh frozen plasma has been manufactured from male donors preferentially since 2011. As regards TACO, which has been gaining global attention recently, JRCS set its own criteria to start assessment in April 2012.

Among cases reported as suspected TRALI, the percentage of cases evaluated as TRALI has been decreasing, and most cases of other than TRALI or p-TRALI were categorized as cardiac pulmonary edema. Subsequently, they were assessed for TACO, resulting in the increasing trend of TACO cases.

In 2016, a total of 141 cases including cases reported as suspected TRALI or cases considered as suspected TRALI based on the symptoms were evaluated for TRALI. TRALI (or p-TRALI) was confirmed in 7 cases (5%), while 37 (26.2%) were finally assessed as TACO.

For patients at-risk of developing TACO described below, transfusion needs to be conducted with close monitoring of their condition to properly adjust the transfusion volume and rate.

Risk factors of developing TACO:

- Cardiac dysfunction (e.g. cardiotoxicity related to anticancer agents, chronic anemia)
- Renal dysfunction
- Hypoalbuminemia
- Preransfusion circulatory overload (excessive transfusion fluid infusion)
- Elderly patients (especially 70 years and older)
- Patients with low body weight

<Notes>

[Transfusion-related acute lung injury (TRALI)]

TRALI is defined as acute lung injury developing during or within 6 hours after transfusion (commonly within 1-2 hours after transfusion), with hypoxemia and dyspnea. Bilateral pulmonary infiltrates are indicated on frontal chest X-ray. Other findings such as circulatory overload are not observed. TRALI may be accompanied with fever and hypotension.

[Transfusion-associated circulatory overload (TACO)]

TACO is defined as congestive heart failure caused by circulatory overload of blood products, accompanied with dyspnea, tachycardia, hypertension, etc. Pulmonary congestion is indicated on chest X-ray.

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 blood products and transfusion information
Japanese Red Cross Society
Haemovigilance Information English website



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

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