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## Transfusion-associated adverse events and implementation of blood safety measures - findings from the 2017 National Blood Collection and Utilization Survey

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### Abstract

**BACKGROUND:** Serious transfusion-associated adverse events are rare in the United States. To enhance blood safety, various measures have been developed. With use of data from the 2017 National Blood Collection and Utilization Survey (NBCUS), we describe the rate of transfusion-associated adverse events and the implementation of specific blood safety measures.

**STUDY DESIGN AND METHODS:** Data from the 2017 NBCUS were used with comparison to already published estimates from 2015. Survey weighting and imputation were used to obtain national estimates of transfusion-associated adverse events, and the number of units treated with pathogen reduction technology (PRT), screened for *Babesia*, and leukoreduced.

**RESULTS:** The rate of transfusion-associated adverse events requiring any diagnostic or therapeutic interventions was stable (275 reactions per 100,000 transfusions in 2015 and 282 reactions per 100,000 transfusions in 2017). In 2017 among US blood collection centers, 16 of 141 (11.3%) reported screening units for *Babesia* and 28 of 144 (19.4%) reported PRT implementation; 138 of 2279 (6.1%) hospitals reported transfusing PRT-treated platelets. In 2017, 134 of 2336 (5.7%) hospitals reported performing secondary bacterial testing of platelets (50,922 culture-based and 63,220 rapid immunoassay tests); in 2015, 71 of 1877 (3.8%) hospitals performed secondary testing (87,155 culture-based and 21,779 rapid immunoassay tests). Nearly all whole blood/red blood cell units and platelet units were leukoreduced.

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### CONFLICT OF INTEREST

The authors have disclosed no conflicts of interest.

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**CONCLUSIONS:** Besides leukoreduction, implementation of most blood safety measures reported in this study remains low. Nationally, hospitals might be shifting from culture-based secondary bacterial testing to rapid immunoassays.

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To improve the safety of the US blood supply, various safety measures have been implemented in accordance with federal regulations, including screening for relevant transfusion-transmitted infections,<sup>1</sup> risk-mitigation strategies for bacterial contamination of platelets,<sup>2</sup> and other safeguards to prevent transfusion-related adverse events.<sup>3</sup> However, transfusion-associated adverse events still occur, with approximately 275 reactions per 100,000 transfusions resulting in a transfusion-associated recipient adverse event requiring a diagnostic or therapeutic intervention in 2015, and 9.4 reactions per 100,000 transfusions resulting in a life-threatening recipient reaction.<sup>4</sup> Implementation of additional measures to mitigate the risk of transfusion-associated adverse events could further improve transfusion safety.

Currently implemented safety measures primarily focus on reduction of the risk of transfusion-transmitted infections (TTIs); ensuring transfusion of blood group-compatible products; and product collection-, storage-, and manufacturing-related quality assurance.<sup>3</sup> TTIs are rare but can result in significant morbidity and mortality.<sup>5</sup> Sepsis due to bacterial contamination of platelets is the most common TTI and is reported to occur in up to 1 in 2300 platelet transfusions.<sup>6–8</sup> Among red blood cells (RBCs), the most common TTI is babesiosis, which can result in recipient death in up to 20% of transfusion-associated transmissions.<sup>9–11</sup> Recently approved safety measures can lower the risk of these TTIs. Pathogen reduction technology (PRT) can mitigate the infectious and some noninfectious risks of platelet transfusion.<sup>8,12–17</sup> The US Food and Drug Administration (FDA) has approved screening tests for *Babesia microti*<sup>18</sup> and in May 2019 published guidance for screening blood donations for babesiosis.<sup>18</sup> The FDA has also approved secondary rapid tests that detect the presence of bacteria in platelet units.<sup>19</sup> However, the majority of transfusion-related adverse events are noninfectious.<sup>20</sup> Among these, febrile nonhemolytic reactions can be prevented by reducing cytokines and chemokines through prestorage leukoreduction, for which the FDA has approved technologies.<sup>21</sup> Finally, alloimmunization resulting in the development of recipient antibodies due to exposure to donor antigens can lead to acute or delayed reactions. Molecular genotyping of donors or recipients can reduce the occurrence of alloimmunization.<sup>22</sup> With the exception of babesiosis screening (the FDA intends to require compliance with babesiosis screening guidance beginning in May 2020),<sup>18</sup> uptake of these additional safety technologies is not required, and therefore results from voluntary implementation by blood collection organizations or transfusing facilities.

With use of data from the 2017 National Blood Collection and Utilization Survey (NBCUS), we estimated the uptake of these additional blood safety technologies in the United States. Specifically, we calculated the rate of transfusion-related reactions, the number of platelets units treated with PRT, the number of RBC units screened for *B. microti*, the proportion of hospitals performing culture-based or rapid immunoassay tests to screen platelets for bacterial contamination, the number of donors or recipients tested with molecular genotyping methods, and the proportion of RBC/whole blood units that were leukoreduced.

## METHODS

All data analyzed were obtained from the 2017 NBCUS, which is a Web-based survey of all blood collection centers in the United States and a statistical sample of transfusing hospitals. Detailed methods are described elsewhere.<sup>23,24</sup> Blood collection centers for the 2017 NBCUS were identified from the FDA Blood Establishment Registration database, and transfusing hospitals were identified from the 2015 American Hospital Association database. Exclusion criteria included hospitals with fewer than 100 inpatient surgeries per year, hospitals located outside of the 50 states or Washington, DC, hospitals owned by the Department of Defense, and specialty and rehabilitation hospitals. Of 3783 facilities that met inclusion criteria, hospitals performing 100 to 999 inpatient surgeries annually were sampled at 40% for a total of 2847 sampled transfusing hospitals.

Survey weighting was used to obtain national estimates of the number of transfusion-associated adverse events, the number of units treated with PRT, the number of units screened for *Babesia*, and the number of leukoreduced units, following the same method used for previous surveys<sup>4,24</sup> and described elsewhere.<sup>25</sup> National estimates of the rates of adverse reactions were calculated using the total number of units (including red blood cells, PLTs, plasma, and cryoprecipitate) transfused as the denominator.<sup>25</sup> Survey respondents determined whether a transfusion-related adverse event was life threatening; the NBCUS recommended definition of life-threatening adverse events was adverse events requiring major medical intervention following transfusion, including vasopressors, intubation, or transfer to the intensive care unit.

Summary statistics were calculated for blood collection centers that treated platelet units with PRT, screened donors for *Babesia*, leukoreduced blood products, or genotyped donors. Summary statistics were also calculated for hospitals that transfused PRT-treated units, had a policy to transfuse only leukoreduced units or white blood cell–filtered units at bedside, performed secondary testing to detect bacterial contamination of platelets, or performed genotyping of transfusion recipient red blood cell antigens. Mean and median percentage of total red blood cell units screened for *Babesia* were calculated for all facilities that answered this question. Mean and median percentage of total units leukoreduced were calculated for those facilities that reported number of leukoreduced units. In calculating an estimate for number of units leukoreduced by blood collection centers, any responses of zero were considered missing, as it is unlikely that blood collection centers would leukoreduce no units. Testing conducted by hospitals to detect bacterial contamination of platelets was assumed to be secondary testing. Primary testing is the initial test to screen for bacterial contamination performed by the blood collection facility, and secondary testing is any additional test.<sup>2</sup> Mean percentages of total donors and recipients genotyped were also calculated.

## RESULTS

The response rate for the 2017 NBCUS was 94% (61/65) for community-based blood collection centers, 85% (92/108) for hospital-based blood collection centers, and 86% (2435/2847) transfusing hospitals.

## Adverse reactions

Table 1 shows the number of recipient adverse reactions requiring any diagnostic or therapeutic intervention reported in 2015 and 2017, as well as rates of reactions per number of component transfused. For all adverse reaction categories, the 2015 and 2017 number of reaction 95% confidence intervals (CIs) overlapped. The total number of units transfused was 16,029,000 units in 2017 and 17,227,000 in 2015. The total rate of reactions reported in 2017 was 282 reactions per 100,000 units transfused (95% CI, 264.9–298.7), similar to the rate in 2015 (275 reactions per 100,000 units transfused). The rate of life-threatening adverse reactions dropped from 9.4 reactions per 100,000 units transfused in 2015 to 4.7 reactions per 100,000 units transfused in 2017 (95% CI, 3.0–6.4). Rates of TTIs reported in 2017 were 0.23 (95% CI, 0.13–0.34), 0.039 (95% CI, 0–0.090) and 0.068 (95% CI, 0.010–0.125) reactions per 100,000 units transfused for bacterial, viral, and parasitic infections, respectively. All rates of TTIs were lower in 2017 than in 2015. Febrile, nonhemolytic reactions, mild to moderate allergic reactions, delayed serologic transfusion reactions, and transfusion-associated cardiac overload all occurred at similar rates in 2015 and 2017. Posttransfusion purpura was reported to have had the largest increase between 2015 and 2017 among all categories, occurring at a rate of 1.8 reactions per 100,000 transfusions in 2015 to 3.7 reactions per 100,000 transfusions in 2017 (95% CI, 2.7–4.7). The estimated rates of transfusion-associated dyspnea, severe allergic reactions, transfusion-related acute lung injury, and acute hemolytic transfusions reactions from ABO incompatible antibodies or from other antibodies were all lower in 2017 than in 2015.

## Pathogen reduction technology

Among 153 blood collection centers that participated in the 2017 NBCUS, 144 (94%) answered the survey question on PRT implementation; 28 (19.4%) of these facilities reported using PRT to treat apheresis platelet units. Among 2279 hospitals that responded to the PRT question, 138 (6.1%) reported transfusing PRT-treated apheresis platelets. In 2017, 68,000 apheresis platelet units were treated with PRT (95% CI, 34,000–102,000), and 65,000 PRT-treated apheresis platelet units were transfused (95% CI, 39,000–91,000). Of collection centers reporting use of PRT for apheresis platelets, a median of 5.5% and mean of 21.2% of all their apheresis platelets were treated with PRT. Of hospitals reporting transfusing PRT-treated apheresis platelet units, a median of 31.4% and a mean of 44.8% of all apheresis platelet units transfused were treated with PRT.

## *Babesia* screening

In 2017, 141 of 153 (92%) blood collection centers answered the question on *Babesia* screening, and 11.3% (16 of 141) of these blood collection centers reported screening blood donations for *Babesia*. In 2017, 901,000 (95% CI, 154,000–1,647,000) RBC units were screened for *Babesia*. For centers reporting number of units prepared from donations screened for *Babesia* in 2017, a median of 79.3% of all RBC units collected were screened for *Babesia*. The mean number of units prepared from donations screened for *Babesia* by reporting facilities was slightly lower, at 63.1%, likely due to large blood collection centers that collect blood in both endemic and nonendemic states and therefore test a smaller percentage of their RBC supply.

### Bacterial screening of platelets

The number of hospitals that reported performing secondary bacterial testing on platelets increased from 3.8% (71/1877) in 2015 to 5.7% (134/2336) in 2017 (Table 2). In 2017, among hospitals performing more than 8000 annual inpatient surgeries, 20% reported secondary bacterial testing of platelets (an increase from 15% in 2015); among hospitals performing fewer than 8000 annual inpatient surgeries, 4.5% reported secondary bacterial testing of platelets (an increase from 2.7% in 2015).

In 2017, hospitals reported a total of 50,922 culture-based tests and 63,220 rapid immunoassay tests (Table 3). In 2015, hospitals reported a total of 87,155 culture-based tests and 21,779 rapid immunoassay tests. In 2017, 13 culture-based tests and 10 rapid immunoassay tests were reported as having a confirmed positive result (in 2015, 50 and 8, respectively).

### Genotyping

In 2017, 22.5% (32/142) of responding blood collection centers reported molecular genotyping of donors (compared to 19% [31/162] in 2015), and of those centers that genotyped donors, a mean of 2.7% of all donors per facility were genotyped (mean of 6.4% in 2015) (Table 4). Additionally, 1.3% (31/2347) of responding transfusing hospitals reported genotyping recipients (compared to 1.6% [31/1883] in 2015), and among those who reported molecular genotyping of recipients, a mean of 10.5% of all recipients were genotyped (mean of 17.4% in 2015).

### Leukoreduction

In 2017, 1886 hospitals (79.7%) reported having a policy in place to only transfuse leukoreduced components, a slight increase from 77.9% in 2015. In 2017, 11,057,000 (95% CI, 10,490,000–11,624,000) RBC/whole blood units were reported to have been leukoreduced (Table 5). This accounted for 95.8% of all collected RBC/whole blood units. The median percentage of RBC/whole blood units leukoreduced by blood collection centers was 96.9%. In 2017, 2,540,000 (95% CI, 2,393,000–2,686,000) platelet units were leukoreduced, which was 99.2% of all collected platelet units. The median number of apheresis platelet units leukoreduced by centers was 100%.

An additional 82,000 (95% CI, 47,000–117,000) RBC/ whole blood units were leukoreduced at the bedside by hospitals in 2017. This accounted for 0.8% of all transfused RBC/whole blood units. A total of 23,000 (95% CI, 12,000–34,000) platelet units were leukoreduced at the bedside in hospitals, which is 1.2% of all transfused platelet units in 2017.

## DISCUSSION

Even though the overall rate of transfusion-associated adverse events remained stable from 2015 to 2017, the estimated rate of life-threatening transfusion-associated adverse events was lower in 2017 compared to 2015.<sup>4</sup> This might be attributable to increased efforts to improve early recognition and mitigation of transfusion-associated adverse events.<sup>26</sup> During

2017, less than one-fourth of blood collection facilities and transfusing hospitals had implemented the blood safety measures included in this study besides leukoreduction. Increased uptake of these interventions could improve blood transfusion safety and prevent transfusion-associated adverse events.

The findings reported here reflect NBCUS data reported for the 2017 calendar year. During this time, two assays for screening donors for babesiosis were used under investigational new drug application protocols and were FDA approved in March 2018.<sup>27</sup> Under the investigational new drug designation, these assays for screening donations for *B. microti* were used widely in *Babesia*-endemic states (Northeast and upper Midwest).<sup>28</sup> Screening donations collected in *Babesia*-endemic states for *Babesia* has been demonstrated to mitigate the risk of transfusion-transmitted babesiosis.<sup>28</sup> This indicates that screening for *B. microti* has helped to mitigate risk of transfusion-transmitted babesiosis when used in states where the pathogen is endemic. Because screening of all donations collected in *Babesia*-endemic states is expected to begin by May 2020,<sup>18</sup> the number of facilities and the proportion of donations screened for *B. microti* are expected to increase, and the burden of transfusion-transmitted babesiosis should continue to decrease.

PRT has been shown to effectively neutralize most pathogens recognized to be transmissible through transfusion, including viruses (e.g., HIV, hepatitis B virus, hepatitis C virus, cytomegalovirus, West Nile Virus, Zika virus), bacteria (gram-negative and gram-positive), and parasites (e.g., *B. microti*).<sup>29</sup> In 2017, almost 20% of US blood collection centers reported treating apheresis platelet units with PRT, and among these blood collections centers, a median of 5.5% of all collected apheresis platelets were treated with PRT. The present findings indicate that PRT-treated apheresis platelets currently constitute a small proportion of the overall national supply. However, adoption of PRT by hospitals might expand as facilities may seek to further mitigate the risk of TTIs, particularly sepsis attributed to bacterial contamination of platelets, for which fatalities continue to be reported nationally.<sup>30,31</sup>

Uptake of certain safety measures such as secondary bacterial testing and genotyping remains low in the United States. In 2017, about 6% of transfusing hospitals performed secondary bacterial testing of platelets, up from 4% in 2015; larger hospitals were more likely to do testing than smaller hospitals (20% vs. 2%). This study indicates a potential shift from culture-based secondary testing to rapid immunoassay testing between 2015 and 2017. Future surveys will continue to collect information on bacterial testing to identify trends. Serologic compatibility testing of components and transfusion recipients is one of the oldest safety measures of blood transfusion, beginning in the early 1900s.<sup>32</sup> Despite the availability of molecular testing that could improve matched component-recipient compatibility,<sup>33</sup> the uptake of genotyping by both blood collection centers and transfusing facilities remains relatively low. Facilities that performed genotyping did so for only a small percentage of their donors or recipients, which may indicate that testing is performed on a subpopulation of patients, such as those requiring chronic transfusions.<sup>34</sup> As this technology was recently approved by FDA,<sup>19,35</sup> future surveys will continue to track uptake and barriers to implementation of molecular genotyping in the United States.



These findings are subject to the following limitations. First, the calculation of national estimates for questions regarding genotyping and bacterial testing of platelets was not possible due to low response rates for these questions. Second, NBCUS questions that ascertained implementation of PRT and *Babesia* screening were newly added to the 2017 survey; therefore, trends in implementation of these safety measures could not be assessed. Further monitoring of uptake as part of future surveys will continue. Third, a higher proportion of products are reported to have been subjected to leukoreduction in 2017 than in 2015. As previously stated, we used different statistical methods to estimate leukoreduction, which may have impacted the estimates as reported here. Fourth, because the NBCUS does not collect data on the state in which donations are collected, stratifying the *Babesia* screening data into *Babesia*-endemic and nonendemic states was not possible. General limitations of the NBCUS are described elsewhere.<sup>25</sup>

These findings describe the implementation of a number of transfusion safety measures at both blood collection centers and hospitals in the United States. Continued monitoring of implementation of these safety measures is important to assess efforts in improving the safety of the blood supply.

## ABBREVIATIONS:

<b>FDA</b>	US Food and Drug Administration
<b>NBCUS</b>	National Blood Collection and Utilization Survey
<b>PRT</b>	pathogen reduction technology
<b>TTIs</b>	transfusion-transmitted infections

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**TABLE 1.**  
Transfusion-associated adverse reactions in the United States: National Blood Collection and Utilization Survey, 2015 and 2017

Adverse transfusion reactions	Number of reactions (95% CI)			Reactions per 10,000 components transfused (95% CI)		
	2017	2015	2017*	2015	2017*	2015*
Total number of reactions that required any diagnostic or therapeutic intervention <sup>†</sup>	45,165 (41,800–48,529)	47,297	281.8 (264.9–298.7)			274.6
Febrile, nonhemolytic transfusion reaction	19,317 (18,148–20,486)	20,339	120.5 (114.2–126.8)			118.1
Mild to moderate allergic reactions	14,170 (12,951–15,389)	14,694	88.4 (81.9–94.9)			85.3
Delayed serologic transfusion reaction	2,981 (2,465–3,496)	3,280	18.6 (15.5–21.7)			19.0
Transfusion-associated circulatory overload	1,877 (1,679–2,074)	1,958	11.7 (10.5–12.9)			11.4
Hypotensive transfusion reaction	1,462 (1,250–1,673)	1,565	9.1 (7.8–10.4)			9.1
Delayed hemolytic transfusion reaction	770 (613–927)	770	4.8 (3.8–5.8)			4.5
Transfusion-associated dyspnea	1,036 (660–1,412)	1,300	6.5 (4.1–8.8)			7.5
Severe allergic reactions	398 (285–512)	584	2.5 (1.8–3.2)			3.4
Transfusion-related acute lung injury	243 (193–294)	293	1.5 (1.2–1.8)			1.7
Posttransfusion purpura	579 (427–730)	305	3.7 (2.7–4.7)			1.8
Acute hemolytic transfusion reaction (other antibodies)	135 (97–173)	169	0.84 (0.60–1.08)			0.98
Acute hemolytic transfusion reaction (ABO)	33 (13–53)	90	0.21 (0.08–0.33)			0.52
Transfusion-transmitted viral infection	6 (0–13)	8	0.039 (0.000–0.090)			0.046
Transfusion-transmitted bacterial infection (previously asked as posttransfusion sepsis)	37 (20–54)	60	0.23 (0.13–0.34)			0.35
Transfusion-transmitted parasitic infection	10 (2–19)	16	0.068 (0.010–0.125)			0.093
Transfusion-associated graft-versus-host disease	0 <sup>‡</sup>	1				0.0058
Reactions that were life threatening, requiring major medical intervention <sup>§</sup>	758 (487–1,029)	1,616	4.7 (3.0–6.4)			9.4

\* Total components transfused was 16,029,000 in 2017. All 2015 rates are calculated using 17,227,000 total components transfused.

<sup>†</sup> Diagnostic tests were defined as “any test to confirm a reaction occurred” and therapeutic intervention was defined as “intervention to treat a reaction (e.g., vasopressors, intubation, transfer to intensive care to prevent impairment, permanent damage, or death).”

<sup>‡</sup> Zero events reported in the sample for 2017, so no national estimate of the number of occurrences could be made.

<sup>§</sup> For example, vasopressors, blood pressure support, intubation, or transfer to the intensive care unit.

**TABLE 2.**

Number of hospitals performing pretransfusion bacterial testing of platelet units: United States, National Blood Collection and Utilization Survey, 2015 and 2017

Annual inpatient surgical volume	Hospitals performing pretransfusion bacterial testing on platelets	
	2017	2015
All hospitals, total, % (n/N)	5.7 (134/2336)	3.8 (71/1877)
100–999 surgeries per year, % (n/N)	2 (9/498)	1 (3/424)
1000–1399 surgeries per year, % (n/N)	2 (6/335)	2 (4/244)
1400–2399 surgeries per year, % (n/N)	3 (16/485)	2 (7/363)
2400–4999 surgeries per year, % (n/N)	6 (37/593)	3 (17/489)
5000–7999 surgeries per year, % (n/N)	12 (29/239)	8 (16/199)
8000 or more surgeries per year, % (n/N)	20 (37/186)	15 (24/158)

**TABLE 3.**

Number of secondary tests performed for pretransfusion testing of platelet units by transfusing hospitals and number of confirmed positive results by type: United States, National Blood Collection and Utilization Survey, 2015 and 2017

Confirmed positive results/total tests (false positives, indeterminate results)		
Year	Culture-based testing	Rapid immunoassay (e.g., VERAX)
2017	13/50,922 (40, 3)	10/63,220 (255, 14)
2015	50/87,155 (62, 1)	8/21,779 (50, 5)

Genotyping of whole blood and RBC unit donors by blood collection centers and whole blood and RBC recipients by transfusing hospitals: National Blood Collection and Utilization Survey, 2017

TABLE 4.

Facility type	Question	Response
Hospital	Facilities responding to yes/no question, % (n/N)	92.8 (142/153)
	Facilities reporting genotyping for RBC antigens, % (n/N)	22.5 (32/142)
	Facility mean proportion genotyped, % (median)	2.7 (1.1)
	Facilities responding to yes/no question, % (n/N)	96.4 (2,347/2,435)
Blood collection center	Facilities reporting genotyping for RBC antigens, % (n/N)	1.3 (31/2,347)
	Facility mean proportion genotyped, % (median)	10.5 (3.4)

**TABLE 5.**

Components leukoreduced before storage at blood collection centers: National Blood Collection and Utilization Survey, 2017 (expressed in thousands)

	Units		% of total		2017 Median blood center % (mean %, n)	
	2017 (95% CI)	2015	2017	2015	2017	2015
Whole blood/RBCs	11,057 (10,490–11,624)	10,650	95.8	84.6	96.9 (70.7; n = 120)	
Apheresis RBCs	1,757 (1,584–1,929)		98.3		100.0 (84.2; n = 73)	
Whole blood-derived RBCs	9,295 (8,798–9,792)		89.2		96.8 (70.5; n = 119)	
All platelets	2,540 (2,393–2,686)		99.2			
Apheresis platelets	2,334 (2,188–2,480)	1,947	99.8	86.1	100.0 (92.0; n = 88)	