2011

THE 2011 NATIONAL BLOOD COLLECTION AND UTILIZATION SURVEY REPORT

The 2011 National Blood Collection and Utilization Survey Report

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1. Executive Summary

The Assistant Secretary for Health, along with the Department of Health and Human Services (DHHS) operating divisions [Centers for Disease Control and Prevention (CDC), Centers for Medicare and Medicaid Services (CMS), Food and Drug Administration (FDA), the Health Resources and Services Administration (HRSA), and the National Institutes of Health (NIH)] sponsored the 2011 National Blood Collection and Utilization Survey (NBCUS), which was conducted under contract to AABB.

The objectives of this survey were to generate national estimates for the amount of blood collected and transfused in the United States in 2011, to provide comparisons with previous years, to provide data for national biovigilance safety monitoring, and to collect baseline data on patient blood management programs in the United States.

The facilities surveyed included all non-hospital-based blood collection organizations (blood centers), a sample of hospitals from the American Hospital Association (AHA) database, AABB member hospitals not in the AHA database, and a sample of cord blood banks. Hospitals reporting fewer than 100 inpatient surgeries per year were not included. Non-AABB member hospitals with annual surgical volumes between 100 and 999 were stratified and randomly sampled at a rate of 40% for each US Public Health Service (USPHS) region, while all hospitals reporting 1,000 or more surgeries per year were included in the sample.

The overall response rate for the 2011 NBCUS was 44.1% (1490/3381). For blood centers, the response rate was 94.1% (128/136); for hospitals, it was 42.3% (1342/3175); and for cord banks, it was 28.6% (20/70). Response rates for hospitals were lower than in previous surveys, most likely because of economic pressures on staffing in hospitals, health information technology (IT) implementation pressures, and the increase in the length of the 2011 survey, which was expanded to 31 pages in order to assess trends in patient blood management.

Statistical procedures were used to verify that the sample was representative of the study population and to develop sample weights to accurately produce national and regional estimates.

Blood Collection

The 2011 NBCUS estimates that a total of 15,721,000 Whole Blood (WB) and Red Blood Cell (RBC) units were collected, a significant decline of 9.1% ($p<0.001$). Blood centers were responsible for the collection of 14,686,000 units, or 93% of the supply; hospitals collected 1,036,000 units (7%). Therapeutic collections that were not intended for transfusion are not included in this report.

RBC apheresis collections, including allogeneic,

directed, and autologous donations, accounted for 1,978,000 units. While the increase from 2008 was small (2.7%), it was statistically significant ($p<0.005$) and perhaps more important in a period of overall collection decline (**Figure 1-1**).

Blood Transfusion

The estimated total number of WB/RBCs transfused in 2011 was 13,785,000 units, 8.2% fewer units transfused than in 2008 ($p<0.001$). In addition, significantly fewer autologous units were transfused ($p<0.001$).

While the total number of platelets transfused in 2011 (2,169,000 apheresis-equivalent units) was not significantly different from the number transfused in 2008, there was a significant increase in the number of apheresis platelets transfused ($p<0.05$). The transfusion of WB-derived platelets (WBD) decreased by 23.6%, although this difference was not statistically significant. Transfusion of plasma decreased by 13.4% ($p<0.001$). Evolving use of prothrombin complex concentrates (PCCs) may have had an impact on the use of fresh frozen plasma for warfarin reversal.

Trends in US Blood Supply

The available allogeneic supply of WB/RBC units, after accounting for testing and other product loss, was 14,472,000 units. This number exceeds transfusions of allogeneic WB/RBCs (13,720,000) by a margin of 752,000 units, approximately 5.2% of available supply. Amounts transfused and available are comparable to those reported in 2001. The oversupply reported in the 2009 NBCUS Report was adjusted by blood collectors over the intervening three years.

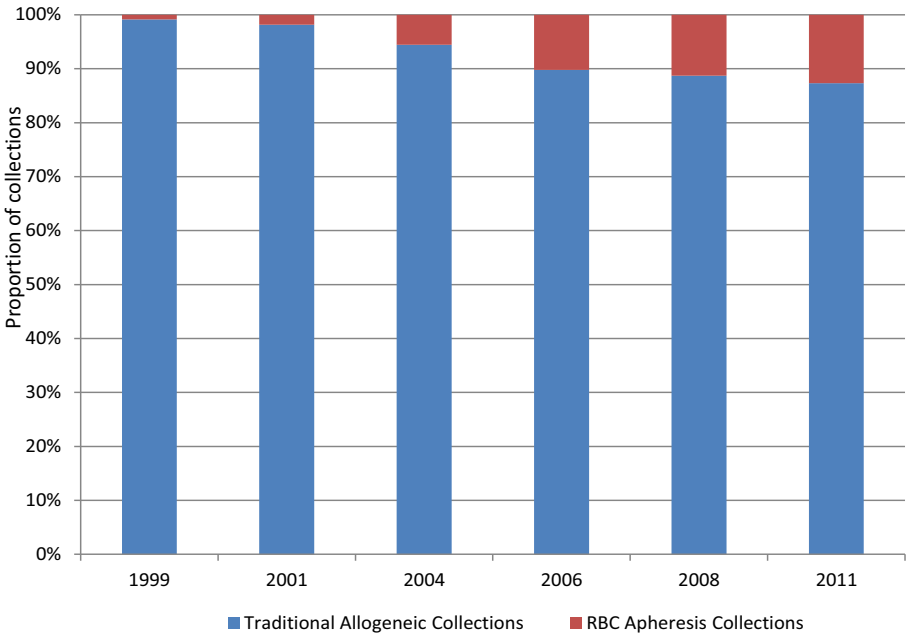


Figure 1-1. Growth in use of RBC apheresis technology.

Allogeneic blood collection in the US population of individuals aged 16 to 64 was 76.2 units per 1,000 persons in 2011, compared with 85.2 units per 1,000 persons aged 16 to 64 in 2008. This donation rate per unit population is the lowest reported since 1997. On the basis of the number of donors reported in the 2011 survey year, only 4.5% of the US population aged 16 to 64 donated in 2011, a drop from the 5.4% of the total age eligible US population reported to have donated in 2008.

The US WB/RBC transfusion rate in 2011 was 44.0 allogeneic units transfused per 1,000 overall population. This rate is lower than the allogeneic transfusion rate in 2008 (48.8/1,000 population) and approaches the rates reported in the 1990s. It is possible that this decline in transfusion rate is a residual of the recession, but more likely it is an indication of the growing adoption of blood management practices.

Biovigilance

After several years of biovigilance developments on the part of DHHS and AABB, hemovigilance and donor vigilance systems have been established for the reporting of adverse reactions in patients and donors. Participation in both of these programs remains low, consistent with the early participation patterns reported by other voluntary hemovigilance programs throughout the world. The 2011 NBCUS collected data on adverse transfusion reactions in patients and severe adverse reactions in blood donors related to collection. An estimated total of 51,000 transfusion-related adverse reactions were reported for 2011, a number not significantly different from that reported in 2008. The adverse reaction rate (adverse reactions/total components transfused) was 0.24%, compared to 0.25% in 2008 and 0.26% in 2006. The actual rate of adverse reactions is likely to be more than what was reported to the transfusion service.

Approximately 21,000 severe adverse donor reactions were reported by blood collectors in 2011, a rate of 0.13% of collection procedures. This rate was not significantly different from that reported in 2008 of 0.09%, or 16,000 adverse donor reactions. This increase may be due to increased awareness and reporting of donor reactions or to inconsistent application of the reaction definitions.

Patient Blood Management

Patient Blood Management (PBM) is an evidence-based, multidisciplinary approach to optimizing the care of patients who might need transfusion. It encompasses all aspects of patient evaluation and clinical management surrounding the transfusion decision-making process, including the application of appropriate indications and the minimization of blood loss and optimization of patient red cell mass. The questions, designed by a team of experts in the field of PBM, were intended to assess the degree to which this evidence-based, patient-oriented initiative has gained traction in US hospitals and blood centers.

Of those facilities responding to the NBCUS, 30% reported that they have a PBM program; 98% of those facilities were transfusing hospitals. While many facilities do not have formal programs, there is broad implementation of many programs designed to reduce blood loss and associated allogeneic transfu-

sion in patients. The most common programs existing in hospitals were preoperative and intraoperative interventions, including preoperative laboratory assessment for anemia (in 47% of reporting hospitals), parenteral iron supplementation (in 82% of reporting hospitals), and intraoperative blood recovery (in 64% of reporting hospitals).

Additional survey results are described in Chapter 5, Patient Blood Management. These will serve as baseline indicators of hospital progress in this patient-centered domain.

2. Key Findings

The results of the 2011 NBCUS provide an update of US blood collection and transfusion services and related activities in the 2011 survey year to the analyses made by the six previous nationwide surveys, conducted in 2009, 2007, 2005, 2002, 2000, and 1998. Notable findings from the 2011 NBCUS and comparisons with the 2009 survey are listed below.

New Findings

Collection

- Total WB/RBC collections decreased significantly ($p<0.001$) from 17.3 million units in 2008 to 15.7 million units in 2011 (9.1% decrease).
- 17,984,000 individuals presented to donate in 2011.
- Of the presenting donors, 9,203,000 allogeneic nondirected donors successfully gave blood, compared to 10,805,000 allogeneic donors in 2008, for a drop of 14.8%.
- The collection of red blood cells by apheresis increased by 2.7% ($p<0.005$) from 1,926,000 in 2008 to 1,978,000 in 2011.
- The number of units rejected for unacceptable test results decreased significantly (19.4%, $p<0.001$) to 102,000 from 127,000 in 2008. However, the percentage of collections with positive test results was 0.7% in 2011, the same percentage reported in 2008. Other units discarded (not including outdated products) by blood collectors numbered 1,030,000 (6.6%).
- Autologous collections totaled 113,000, a decrease of 55.5% from 2008 ($p<0.001$).
- The number of apheresis platelet products produced increased by 18.1% over the number produced in 2008 ($p<0.001$), to 2,516,000 units.
- In 2011, platelet concentrates were derived from 1,110,000 units of WB, a decrease of 10.3% ($p<0.05$) from the 2008 production of 1,964,000 units.
- A total of 5,926,000 units of plasma were produced for transfusion in 2011, an increase of 4.0% from 2008 ($p<0.05$).
- Approximately 1,690,000 units of cryoprecipitate were produced in 2011, an increase of 15.6% from 2008 ($p<0.001$).
- There were 13.3% fewer leukoreduced components prepared in 2011 than in 2008, totaling 14,758,000 components.
- There were 21,000 severe donor adverse events reported by blood collectors in 2011. These occurred in 0.13% of collection procedures.

Transfusion

- The total number of WB/RBC units transfused in 2011 was 13,785,000 units, for an 8.2% decrease from 2008 ($p<0.001$).
- There were 65,000 autologous units of WB/RBCs transfused in 2011, for a decrease of 59.4% ($p<0.001$) from 2008.
- Apheresis platelet transfusion increased significantly by 11.9% from 1,761,000 in 2008 to 1,970,000 units in 2011 ($p<0.05$).
- Plasma transfusions decreased 13.4% ($p<0.001$) in 2011, for a total of 3,882,000 units transfused.
- There was a differential of 752,000 WB/RBC units collected over those transfused in the United States in 2011.
- The amount paid by hospitals for plasma frozen within 24 hours after phlebotomy (PF24) averaged $56.08 nationally, an amount significantly higher than the 2008 average of $53.85 (4.1%, $p<0.001$).
- Thirty percent of responding hospitals reported having a Patient Blood Management program in place in 2011.
- The total number of all components transfused in 2011 was 20,933,000, a decrease of 11.6% from 2008.
- The number of irradiated RBC units transfused increased 9.7%, for a total of 3,013,000 units (13.4% of all units transfused), from 2008 to 2011.
- Allogeneic blood collection in the US population aged 16 to 64 was 76.2 units per 1,000 persons in 2011, compared with 85.2 units per 1,000 persons aged 16 to 64 in 2008.
- Although the difference was not statistically significant, there was a 28.8% decrease in reported cases of transfusion-related acute lung injury from 2008 to 2011.
- Adverse transfusion reactions were reported to hospital transfusion services for 0.24% of transfused components.

3. Blood Collected and Processed in the United States

Trends in Collection

Whole blood (WB) and Red Blood Cell (RBC) collections for the survey years 1989 through 2011 are illustrated in **Figure 3-1.** Total collections, which reached a high of 17.3 million units in the year 2008, decreased significantly ($p<0.001$), by 9.1%, to 15.7 million units in 2011.

In 2011, autologous donations **(Figure 3-2)** continued to decline significantly ($p<0.001$) from the previous survey year (2008). Autologous collections included 113,000 manual collections and 4,000 apheresis red cell collections (included in the red cell apheresis totals of **Table 3-1**), or less than 1% of total collections. In 2011, the practice of donating for the use of a designated patient (directed donations) also continued to decline to a small fraction of overall collections, with only 45,000 manual collections units and 1,000 directed red cell apheresis collections reported.

Total WB/RBC Collections

The total of WB-derived (WBD) and apheresis RBCs collected in the United States in 2011 was 15,721,000 (±200,000) units, before laboratory testing **(Table 3-1)**. Blood centers collected 14,686,000 units, or 93.4% of the total. The remaining 1,036,000 units (6.6%) were collected by hospitals, a proportion comparable to previous years. Compared to total collections from 2008, collections in 2011 decreased by 9.1% ($p<0.001$).

The only category of collection types to show an increase in 2011 was RBC apheresis collections, which increased by 2.7% ($p<0.005$) and represented 12.6% of total collections.

All other collection types declined between 2008 and 2011. The number of units rejected for unacceptable disease- marker test results also decreased significantly, by 19.4% ($p<0.001$), from 2008; however, the percentage of test-rejected units out of total units collected and tested was 0.7% in 2011, the same percentage reported in 2008. In 2011, an additional 1,030,000 units were rejected for reasons besides testing, and they were not available for transfusion. These numbers cannot be compared with previous data, as in 2008 some blood collectors included outdated units when they answered this question. In 2011, outdated units were specifically excluded from this question and captured in a separate response. In summary, 14,589,000 units were available for transfusion (92.8% of units collected).

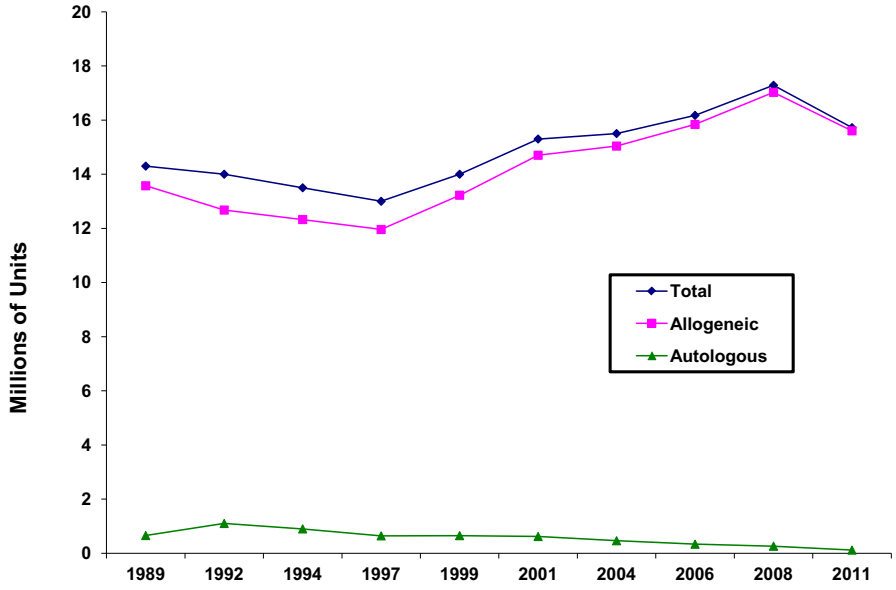


Figure 3-1. Allogeneic, autologous, and total whole blood and red cell collections, 1989-2011.

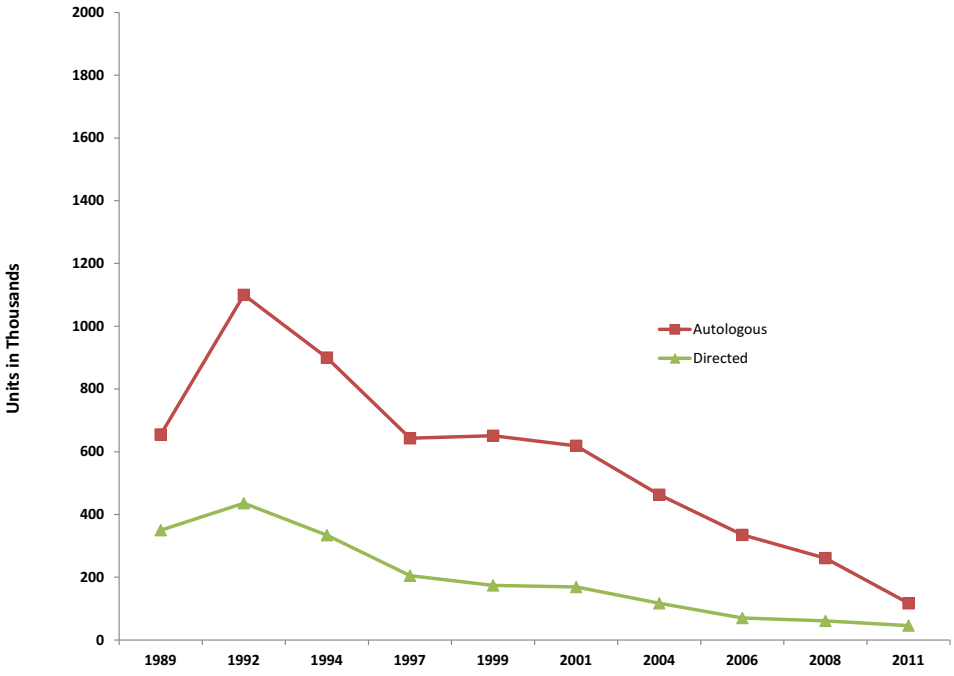


Figure 3-2. Autologous and directed whole blood and red cell collections, 1989-2011.

Table 3-1. Estimated 2011 Collection and Transfusion by US Blood Centers and Hospitals for Whole Blood (WB) and Red Blood Cells (RBC) (expressed in thousands of units)

	Blood Centers	Hospitals	2011 Combined Total	±95% CI	% of Total Collections/ Transfusions	2008 Total	% Change 2008-2011
Collections							
WB Allogeneic (excluding directed)	12,659	927	13,586*	188	86.4	15,047	-9.7
WB Autologous	79	34	113*	11	0.7	253	-55.5
WB Directed	23	22	45*	9	0.3	61	-25.9
RBC Apheresis	1,925	52	1,978*	24	12.6	1,926	2.7
Total Supply	14,686	1,036	15,721*	200	100.0	17,286	-9.1
Rejected on Testing	92	10	102*	5	0.7	127	-19.4
Rejected for Other Reasons	964	66	1,030	32	6.6	--	--
Available Supply (minus Rejected on Testing)	14,594	1,026	15,619*	198	99.3	17,159	-9.0
Available Supply (minus all Rejected Units)	13,630	960	14,589	187	92.8	--	--
Transfusions							
Allogeneic (excluding Directed)†	176	13,507	13,684*	553	99.3	14,782	-7.4
Autologous	2	63	65*	12	0.5	159	-59.4
Directed (to designated patient)	0	37	37	18	0.3	73	-49.7
Total	178	13,607	13,785*	557	100.0	15,014	-8.2
Outdated WB/RBCs	171	199	370*	29	2.4	447	-17.3

*Significantly different from 2008 data.
†Including pediatric units transfused.

WB Collections

Donations of WB in 2011 totaled 13,744,000. These collections, reported according to the type of donation, are shown in **Table 3-1**. Community allogeneic donations, excluding directed donations, accounted for 98% of total WB collections; directed donations totaled 0.3%; and autologous donations contributed 0.8%.

Allogeneic donations (nondirected) totaled 13,586,000 (±188,000), of which 93.2% were collected by blood centers and 6.8% by hospitals. There was a significant decrease in nondirected allogeneic donations between 2008 and 2011 of 9.7% ($p<0.001$). Directed allogeneic donations declined by 25.9% to 45,000 (±9,000) units ($p<0.01$).

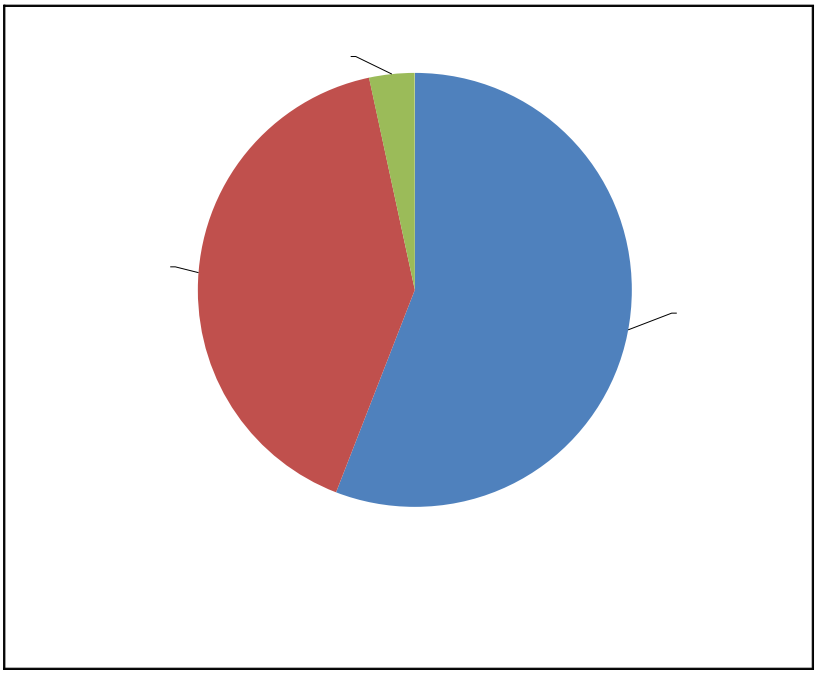
Autologous, or self-directed, units totaled 113,000 (±11,000), a decrease of 55.5% from 2008 ($p<0.001$). Hospitals collected 29.9% of all autologous units.

RBC Apheresis

In addition to WB collections, 1,978,000 (±24,000) RBC units were collected by apheresis. Apheresis RBC collections in 2011 increased by 2.7% ($p<0.005$) from 2008, when 1,923,000 RBC units were collected. There were 976,000 RBC apheresis collection procedures **(Figure 3-3)**, which suggests that almost all procedures yielded double red cell products (eg, two units), which is a greater number of procedures yielding two than in previous years. RBCs collected by apheresis constituted 12.6% of the total WB/RBC supply in 2008.

While 99.7% of the RBC apheresis collections were allogeneic, nondirected units, a small number of units collected by RBC apheresis either were for autologous use (4,000 units) or were directed for the use of a specific patient (1,000 units).

RBC apheresis collections occurred largely in blood centers, accounting for 97.4% of such units. In 2008, 115 blood centers and 46 hospitals reported RBC apheresis collections. In 2011, 117 blood centers reported employing this technology, and 37 hospitals reported collecting RBCs by apheresis. However, a 26.8% increase in the number of hospital RBC apheresis collections was reported in 2011. Among the institutions that reported RBC apheresis collections, the mean number of units collected by blood centers was 16,413 (vs. 15,188 in



2008) and that by hospitals was 364 (vs. 529 in 2008), calculated by using unweighted data. The minimum number of units collected by any facility reporting apheresis collections was 2 and the maximum was 87,320.

Non-RBC Components Produced

Non-RBC component units collected or processed include apheresis platelets, plasma, and granulocytes as well as platelets, plasma, cryoprecipitate, and granulocytes from whole blood. The total number of non-RBC components produced for transfusion in 2011 was 11,887,000 (WBD platelets counted as individual concentrates, not as apheresis-equivalent units).

Platelets

An estimated 1,340,000 platelet pheresis procedures were completed **(Figure 3-3)**, yielding 2,321,000 apheresis units at collection and 2,516,000 apheresis platelet components for distribution **(Figure 3-4)**. The overall split rate was 1.9. The number of available apheresis platelet products increased by 18.1% from 2008 **(Table 3-2)**. Blood centers collected 92.1% of apheresis platelets.

Platelet concentrates were derived from 1,762,000 units of WB, a decrease of 10.3% ($p<0.05$) from the 2008 volume (1,964,000 units). There were 130,000 platelet concentrates made into pools. Platelets were prepared from approximately 8.2% of all allogeneic WB collected, down from 13.9% in 2008. Blood centers produced 990,000 units (89.2%) of which 114,000 were pooled into Acrodose* products, while

**Acrodose Platelets are a therapeutic dose of whole blood derived platelets that are equivalent to apheresis platelets, and made available through a pooling technology called Acrodose Systems. This product consists of ABO-matched whole blood-derived platelets that are leukoreduced, pooled, and bacteria tested.*

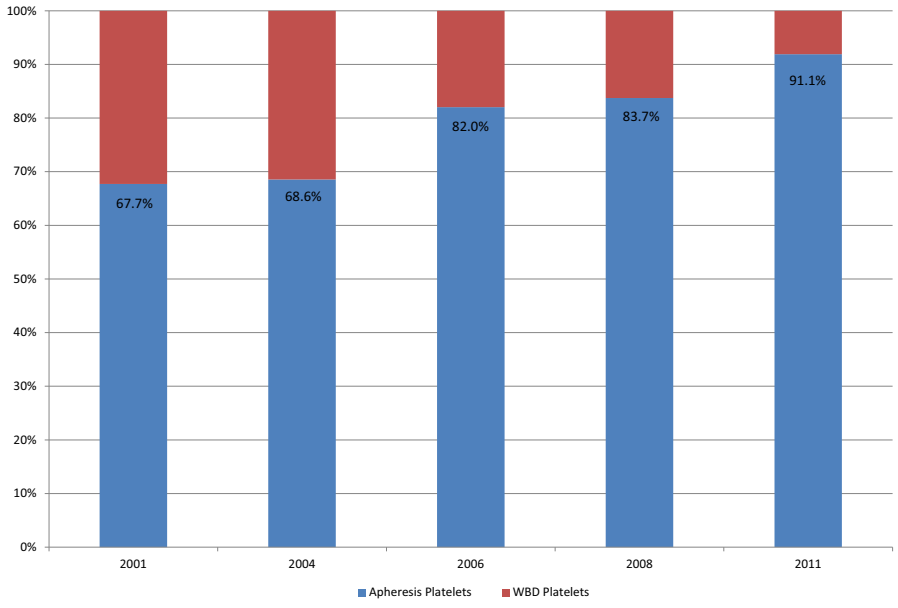


Figure 3-4. Apheresis platelets as percent of total platelets produced.

Table 3-2. Estimated 2011 Collection and Transfusion by US Blood Centers and Hospitals for Non-Red-Blood Cell Components (expressed in thousands of units)

	Blood Centers	Hospitals	2011 Combined Total	±95% CI	2008 Total	% Change 2008-2011
Collection/Production						
Apheresis Platelets Collected	2,137	184	2,321*	81	2,024	14.7
Aphereis platelets Produced	2,313	203	2,516*	79	2,130	18.1
WB-Derived Platelet Concentrates‖	198	24	222 (1,110)*	16	393 (1,964)	-43.5
Total Platelets Produced	2,511	227	2,738*	86	2,523	8.5
Plasma Collected and Produced	5,409	517	5,926*	168	5,700	4.0
Cryoprecipitate‡	1,598	92	1,690*	60	1,462	15.6
Transfusions						
Apheresis Platelets§	17	1,953	1,970*	161	1,761	11.9
WB-Derived Platelet Concentrates‖	2	197	199 (993)	60	260 (1,300)	-23.6
Total Platelets Transfused	19	2,150	2,169	168	2,021	7.3
Plasma§	34	3,848	3,882*	219	4,484	-13.4
Cryoprecipitate‡	8	1,086	1,094	120	1,109	-1.3
Outdated NonRBC Components	301	521	821	80	900	-8.7

*Statistically different from 2008.
†For these components, the 2008 confidence interval was not available. In these cases the P-value was calculated assuming that the standard error in 2008 was comparable to that in 2011.
‡Includes individual units and pools expressed as individual units using average 5 units per pool.
§Including pediatric transfusions.
‖Apheresis equivalent units; numbers in parenthesis represent individual platelet concentrates produced from whole blood donations.

hospitals produced 120,000 (10.8%), 17,000 of which were reported to have been pooled. In 2011, hospitals produced slightly more of the WBD platelets than in 2008, when they produced only 8.9% of platelets made from WB.

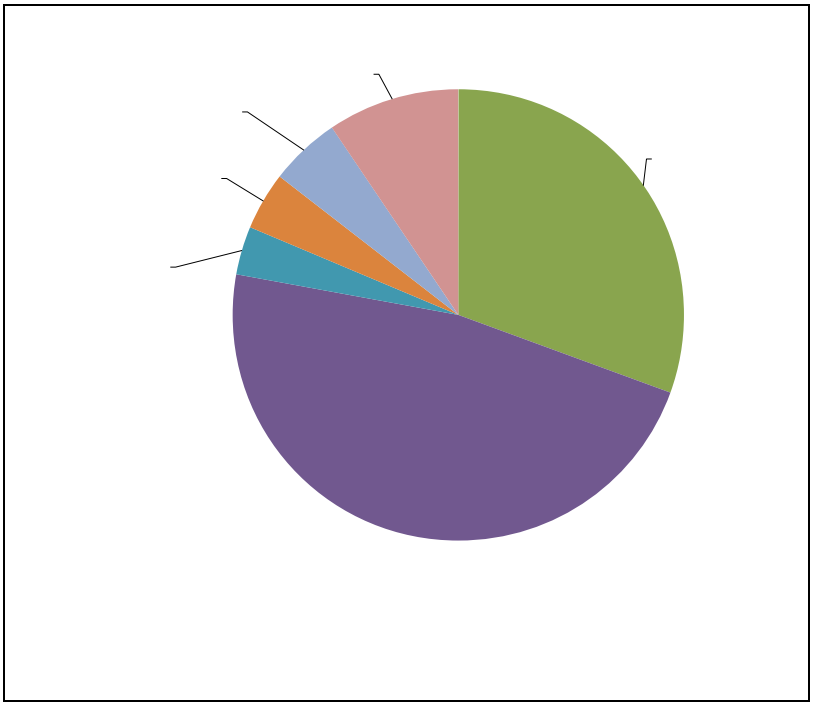
In 2011, the most common number of platelet concentrates reported to be pooled together for transfusion was five units. This is consistent with the pattern seen in 2008 and a change from earlier surveys in which the most common size of platelet pools was six platelet concentrates. For comparison with the production of apheresis platelets, it is assumed that five platelet concentrates are equivalent to one unit of apheresis platelets. Thus 1,110,000 units of WB platelets represent 222,000 apheresis-equivalent units.

A total of 2,738,000 platelets (apheresis equivalents) were collected in 2011, an increase of 8.5% from 2008; this total was made up of 91.9% apheresis collections and 8.1% platelet concentrates from WB, including those pooled into Acrodose products **(Figure 3-4)**.

Three hospitals and two blood centers reported preparing platelets by using the Intersol platelet additive. Intersol platelet additive solution allows the volume of plasma transfused along with platelets to be decreased. Approximately 20,000 apheresis platelets were collected with Intersol, less than 1% of total apheresis platelets prepared.

Plasma

A total of 5,926,000 units of plasma were produced for transfusion. This total includes 1,813,000 units of WBD fresh frozen plasma (FFP), 2,802,000 units of 24-hour plasma, 300,000 units of cryo-reduced plasma, 560,000 units of liquid plasma, and 251,000 units of plasma from apheresis collections. This amount is an increase of 4.0% from 2008 ($p<0.05$). Blood centers produced 91.3% of the plasma (5,409,000 units), and hospitals produced the other 517,000 units. A total of 81,000 plasmapheresis procedures were reported, generating 205,000 units of apheresis plasma for transfusion. Other apheresis procedures produced 246,000 units. The remaining 5,475,000 units of plasma were derived from WB **(Figure 3-5)**. In all, 293,000 units of group AB plasma were distributed (5.0% of the plasma produced for transfusion).



In addition, 8,195,000 units of plasma were produced that were intended for further manufacture, with 96.6% coming from blood centers. Overall, this was a 7.4% decrease from 2008 levels.

Cryoprecipitate

In 2011, 830,000 individual units of cryoprecipitate were produced and 172,000 cryoprecipitate pools were prepared. Assuming approximately five individual units per pool, an estimated 1,690,000 individual units were produced. This was an increase of 15.6% over 2008. Blood centers accounted for 94.6% of cryoprecipitate produced.

Granulocytes

There were 2,607 granulocyte units produced; these are prepared from both apheresis and WB buffy coat units. This is a 15.5% increase over the amount produced in 2008. Hospitals reported producing 41.8% of this total, an increase from the 23% hospital contribution in 2008.

4. Blood Transfused in the United States

Whole Blood (WB) and Red Blood Cells (RBCs) Transfused

Transfusions of WB and RBCs of all donation types totaled 13,785,000 units **(Table 3-1)**. This total represents a statistically significant 8.2% drop from 2008 in the number of units transfused ($p<0.001$). Transfusions of WB increased in 2011to approximately 21,000 units, accounting for 0.15% of total WB/RBC transfusions, compared to 2008, when only approximately 5,000 WB units were reported to be transfused (0.03% of 2008 WB/RBC transfusions). All other types of transfusions contributed to the reduction in transfusions. The number of allogeneic, nondirected units transfused was 7.4% less than that reported in 2008 ($p<0.001$). Of the RBC units transfused, 21.9% (2,991,000 units) were Group O-positive RBC units and 5.4% (735,000 units) were Group O-negative units. Of the total available supply of allogeneic units, 94.8% were used in allogeneic transfusions, comparable with the use of 87.9%, 93.4% and 95.5% in 2008, 2006, and 2004, respectively, which suggests an adjustment of supply to demand.

Autologous transfusions continued to decline significantly ($p<0.001$). There were 59.4% fewer units transfused (65,000 units) than in 2008. The number of autologous units transfused represented 55.3% of the 117,000 units (manual and automated collections combined) donated preoperatively by patients in 2011. The practice of crossing over autologous units to the community supply is no longer reported to occur. Nearly half of all autologous donations were not used.

Directed donations accounted for 37,000 units transfused; this is a large but not statistically significant decrease from the 73,000 such units reported in 2008. The number of units transfused to the intended patient represented approximately 71.9% of the 45,000 units collected (manual and apheresis collections combined). However, some directed units (5,000 units) were reported to have been crossed over for transfusion to non-designated patients (the community supply), bringing the total transfused to 90.6% of the collected total. Nevertheless, many hospitals and blood centers reported that they were unable to retrospectively distinguish between nondirected and directed allogeneic units. Of the hospitals reporting 10 or more directed units transfused, 15.7% were children's hospitals.

Pediatric Transfusions

There were large decreases in the number of pediatric transfusions reported in 2011, 30.8% fewer than in 2008 **(Table 4-1)**. These transfusions represent 1.9% of all transfused RBCs. In 2011, hospitals reported the

Table 4-1. Pediatric Transfusions by US Blood Centers and Hospitals in 2011 (Expressed in thousands of units)

	2011		2008	% Change
Pediatric Transfusions	Adult Equivalent Units Used in Whole or Part for Pediatric Patients	Total Number of Aliquots Transfused	Adult Equivalent Units Used in Whole or Part for Pediatric Patients	Adult Equivalent Units Used in Whole or Part for Pediatric Patients
WB/RBCs	265	263	383	-30.8
Apheresis Platelets	127	90	170	-25.3
Plasma	58	37	101	-42.6

number of pediatric transfusions of adult-equivalent units, used in whole or in part, by component type. A total of 425,000 units, including WB/RBCs, platelets, and plasma, were transfused to pediatric patients, approximately 31.2% less such transfusion overall than in 2008. Hospitals reported the number of aliquots transfused separately from full units transfused, indicating that 263,000 aliquots of WB/RBC units, 37,000 aliquots of plasma, and 90,000 aliquots of platelets were transfused. This distinction in this report between units and aliquots may be responsible for the decline reported above.

Transfusion Recipients

The 2011 National Blood Collection and Utilization Survey (NBCUS) captured the number of recipients of transfused RBCs of each donation type. Based on unweighted data, the reported number of recipients of allogeneic red cell units was 1,279,000 per 3,517,000 units transfused by 791 facilities that reported the numbers of transfusion recipients, or 2.75 units per recipient. This number was very comparable to the 2.6 units per recipient reported in 2008. Autologous recipients received an average of 1.3 units per transfusion, as compared to 1.4 in 2008. Recipients of directed units received an average of 1.9 units per transfusion in 2011, compared to 1.7 units per recipient in 2008. Finally, for recipients of pediatric RBC units, the ratio in 2011 was 1.8 units per recipient, a decrease from the reported rate of 2.0 units per recipient in 2008.

Extrapolation of the ratios of units per recipient population, defined as unique individual patients receiving a transfusion one or more times in the 2011 calendar year, proportionally to the weighted totals of WB/RBCs transfused yields a national estimate of 5.0 million total WB/RBC recipients in 2011. This number is approximately the same as the number of transfusion recipients estimated in 2008. That approximately the same number of patients were transfused in 2011 as in 2008, but with fewer units transfused, suggests that the rate of transfu-

sion did not keep up with the growth of the US population.

Non-RBC Components Transfused

National estimates for non-RBC components transfused in 2011 are presented in **Table 3-2.**

An estimated total of 2,169,000 platelet units were transfused to US patients in 2011, an increase of 7.3% from 2008 **(Figure 4-1)**. The transfusion of apheresis platelets increased by 11.9%, from 1,761,000 to 1,970,000 units ($p<0.05$).

In this report, as described in Chapter 3, platelets are reported by using apheresis equivalents. For comparison with the transfusion of apheresis platelets, it is assumed that five WB-derived (WBD) platelet concentrates are equivalent to one unit of apheresis platelets. Thus, 199,000 apheresis- equivalent units of WBD platelets represent 993,000 individual WBD platelets.

The decline in the transfusion of WBD platelet concentrates continued in 2011, with 199,000 apheresis-equivalent units transfused in 2011, compared with 260,000 from the 2008 survey, for a decrease of 23.6%. The ratio of apheresis concentrates to WBD platelet concentrates used has increased from that reported in 2008 (6.8 apheresis units transfused for every pool of WBD concentrates) to 9.9 apheresis units for every pool of WBD platelets in 2011.

The combined total of WBD and apheresis plasma resulted in 3,882,000 units transfused, significantly fewer (13.4%, $p<0.001$) than the number transfused in 2008 (4,484,000 units). Reporting institutions indicated the amounts of the various types of plasma transfused as shown in **Figure 4-2.** The results, for which overlap is possible, are as follows:

- Fresh frozen plasma (FFP) represented only 36.9% of plasma transfused (1,433,000 units), which is a much smaller proportion of all transfused plasma than that in 2008, when 53.8% of the plasma transfused was frozen within 8 hours after phlebotomy (2008 FFP: 2,411,000 units). The 2011 survey is the second survey year with a decline of 20% or more in the transfusion of FFP as compared to other types of plasma. However, this survey included a question about the transfusion of thawed plasma, and a portion of the plasma that was previously reported as either FFP or plasma frozen within 24 hours after phlebotomy (PF24) most likely would have been included in the thawed category.
- Transfusion of PF24 also decreased to only 27.2% of the transfused plasma in 2011 (1,056,000 units), a decline of almost 40% from 2008 (1,742,000 units). This change may be related to the addition of the thawed plasma category described above.
- Jumbo plasma accounted for 1.6% (61,000 units) of plasma transfused.
- Cryoprecipitate-reduced plasma is prepared from FFP that is thawed and centrifuged, with the cryoprecipitate removed by centrifugation. Cryoprecipitate-reduced plasma accounted for 2.7% of the total plasma transfused (106,000 units), a decrease from 2008 (4.7%, 188,000 units).

Table 4-2. Outdated Components as a Percentage of the Total Number of Units of Each Type Processed* for Transfusion in 2011.

	WB/RBCs	Whole-Blood Derived Platelets (both individual concentrates and pools)	Apheresis Platelets	Plasma	Cryoprecipitate (both individual concentrates and pools)	Granulocytes	All Components
Outdated Total	375,986	301,724	321,070	128,759	56,344	103	1,183,986
Processed/Produced	15,842,412	1,762,163	2,515,696	5,925,800	1,690,093	2,607	27,738,770
Percent Oudated	2.4%	17.1%	12.8%	2.2%	3.3%	4.0%	4.3%
Reported Wasted	†	48,697	24,724	108,316	51,548	45	233,330
Percent Wasted	--	2.8%	1.0%	1.8%	3.1%	1.7%	0.8%
Transfused	13,785,000	993,000	1,973,000	3,882,000	1,094,000	3,360	21,730,360
Unaccounted	1,681,426	418,742	196,901	1,806,725	488,201	(901)	4,824,424

*Number reported as processed or produced by a facility; this may differ slightly from the number reported as collected.
†These data were not collected in 2011 survey.

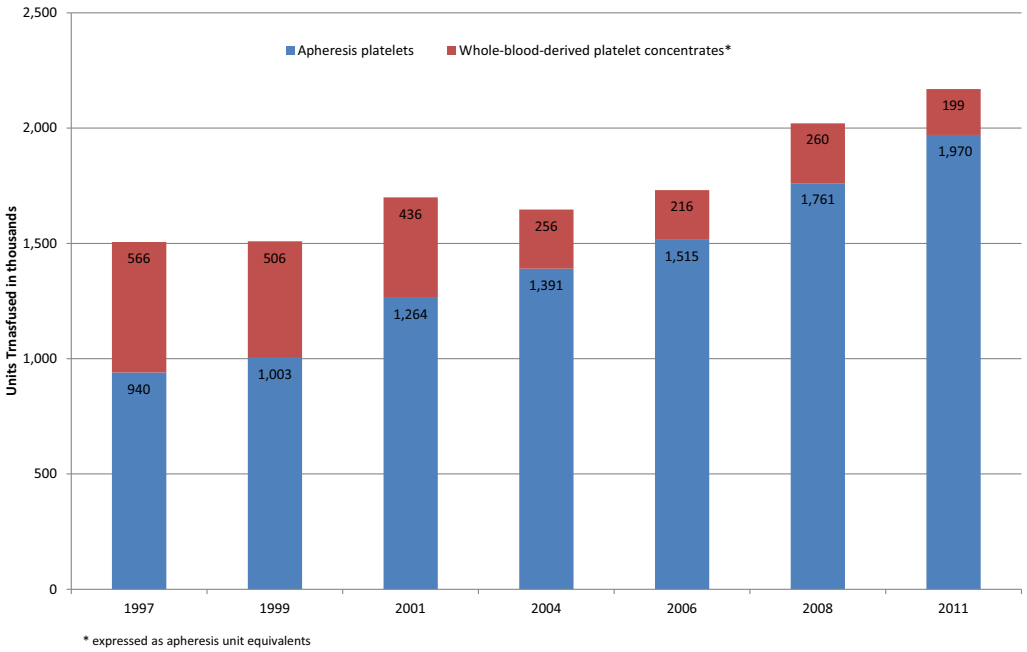


Figure 4-1. Trends in platelet transfusion, 1997-2011.

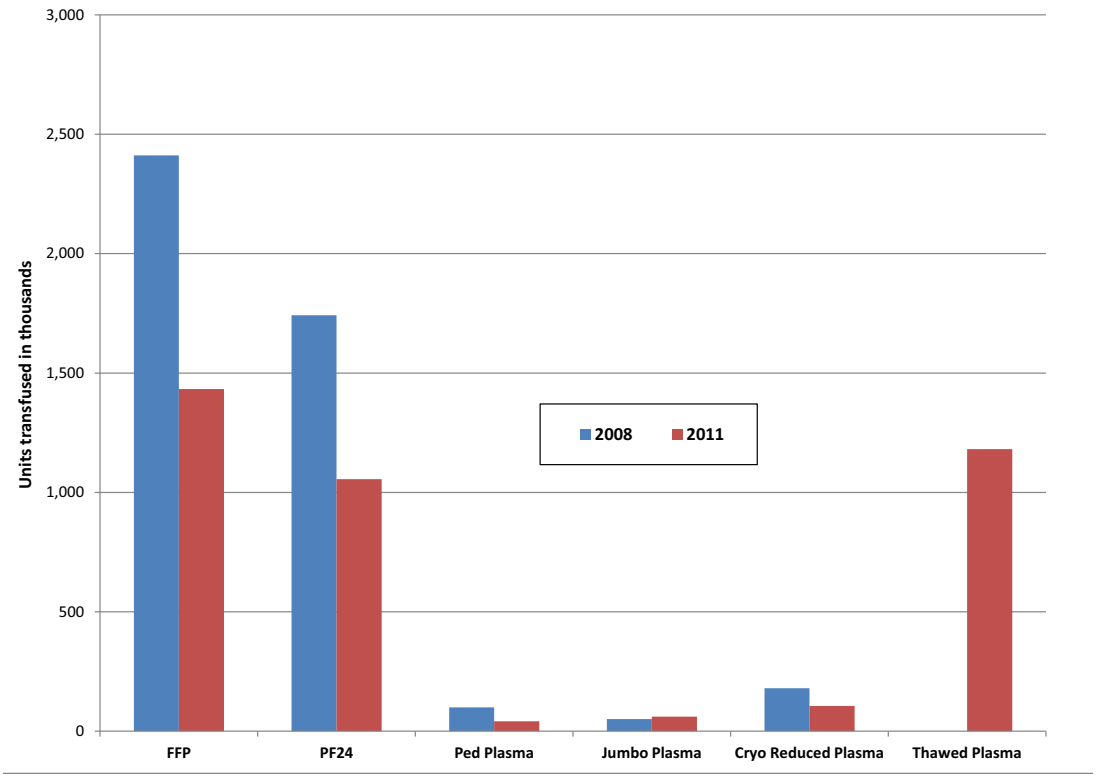


Figure 4-2. Types of plasma transfused, 2008-2011.

- Plasma transfused to pediatric patients, whether pediatric FFP (100-mL size) or plasma of other types, accounted for 1.1% (42,000 units) of the total plasma transfused, a drop from the 100,000 units transfused in 2008.
- In 2011, the survey assessed transfusion of the following additional categories of plasma: Group AB plasma, liquid plasma, thawed plasma, and directed plasma transfused to intended recipients.
  - Of all plasma transfused, 142,000 units, or 3.6%, were Group AB plasma.
  - Liquid plasma is separated no later than 5 days after the expiration date of the WB and stored at refrigerator temperature (1-6° C). Very little liquid plasma (2,000 units) was transfused.
  - Thawed Plasma is derived from FFP or PF24, thawed at 30-37° C and maintained at 1-6° C for 1-5 days. There were 1,181,000 units of thawed plasma transfused, amounting to 30.4% of all plasma transfused. Hospitals were queried in a separate question for the percentage of plasma given as thawed plasma. The average amount among all hospitals was 16.7%, with larger hospitals using more thawed plasma than small hospitals **(Figure 4-3)**.

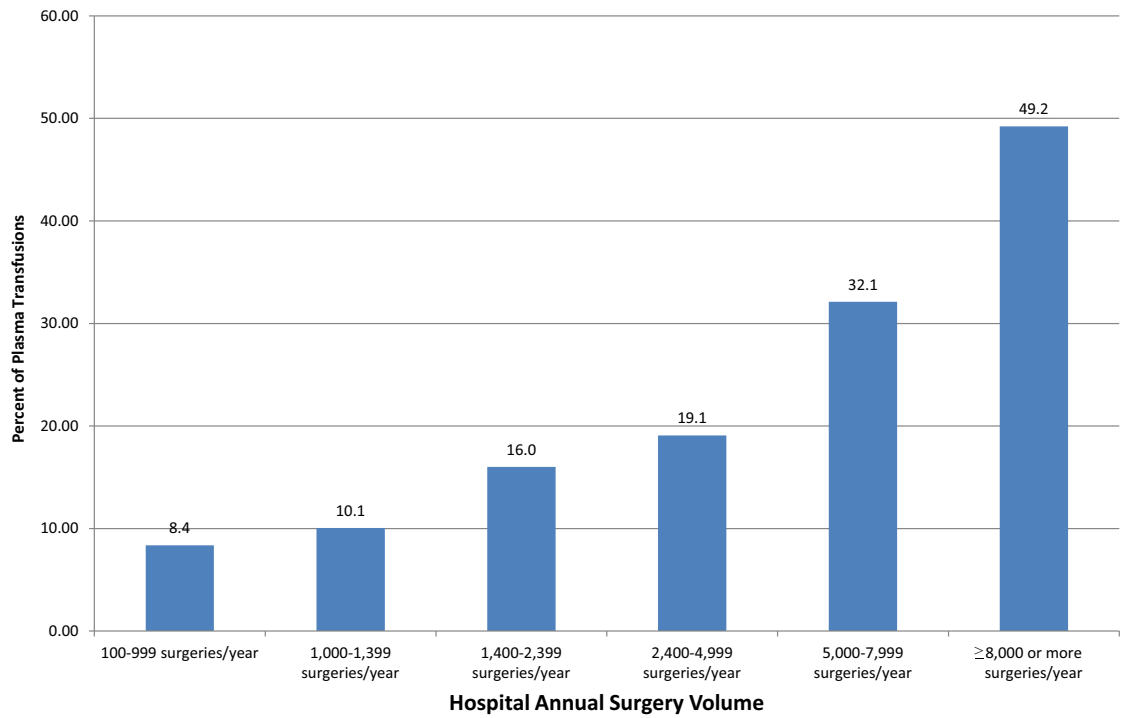


Figure 4-3. Percent of plasma transfused as thawed plasma (average = 16.7%).

- Only 400 units of directed plasma were reported to have been transfused.

When asked how institutions routinely order plasma transfusions to nonpediatric patients, most transfusing facilities (60.4%) reported routinely transfusing plasma to nonpediatric patients on the basis of perceived level of coagulation factor deficiency or degree of bleeding. In 6% of the transfusing facilities, the dosage was based on patient weight. Other facilities reported transfusing a standard number of units regardless of patient weight (12.9%); 11.6% reported that the number of units transfused was not consistent with any of the above factors, while 9.1% reported that they did not know how plasma was routinely transfused.

Cryoprecipitate use was reported as 1,094,000 units or unit equivalents. This is a very small decrease (1.3%) from the amount transfused in 2008 (1,109,000) and is not statistically significant.

Transfusion of granulocytes, prepared from both apheresis and WB buffy coat units, increased significantly ($p<0.05$). A total of 3,360 units were transfused, compared with 1,013 reported to be used in 2008. Because these numbers are so small, the response rate and the specific facilities responding to the survey potentially lead to distorted estimates (eg, more units transfused than produced).

The total number of units of all components transfused in the United States in 2011, both RBC and non-RBC components, was 20,933,000, a decrease of 2,736,000 (11.6%) from 2008.

Platelet Dosage

Facilities reporting WBD platelet concentrate doses indicated the most common dosage used in their institutions (**Figure 4-4**; n=548). In 2011, the majority of hospitals (56.2%) reported five or fewer platelets in a dose, yielding a weighted average of 5.0 concentrates per dose.

Outdated Units

The national estimate for the number of units of WB and all other components outdated by blood centers and hospitals in 2011 was 1,184,000 units. Outdated WB and RBCs totaled 376,000 units, of which 86.8% (327,000) were allogeneic, nondirected red cells. The remaining outdates were: autologous units (38,000), directed units (2,000), and WB (9,000). The percentage of outdated WB/RBCs contributed by each collection type is illustrated in **Figure 4-5.** The percentage of directed units collected that outdated (5.3%) increased from the number of directed-unit outdates in 2008 (4.8% of reported directed collections), whereas the autologous unit outdate rate remained essentially unchanged (32.8% in 2011 and 31.8% in 2008). Approximately 6.4% of units processed for transfusion as WB outdated in 2011. Only 2.1% of allogeneic red cell donations were outdated in 2011. As shown in **Table 4-2**, outdated WB/RBCs accounted for 2.4% of all WB/RBC units processed in 2011. The total number of WB/RBC units outdated was 15.9% lower than the 2008 total.

As in 2008, the current survey inquired about outdates of blood Group O-positive and O-negative units **(Figure 4-6)**. In 2011, they accounted for a total of 12.5% of the total outdated allogeneic WB/RBCs, a rate slightly higher than the total

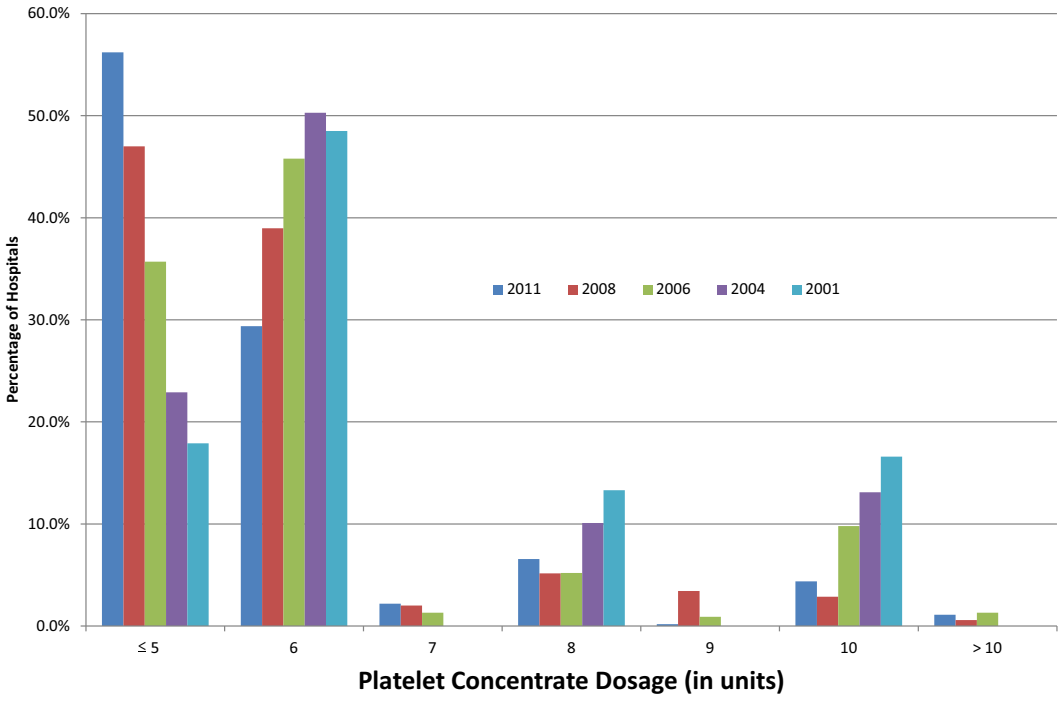


Figure 4-4. Most common platelet concentrate dosage reported by hospitals.

of 8.4% reported in 2008 but comparable with the rate reported in 2006: 12.2% Group O units of all RBC outdates. Nine percent of outdated RBC units were Group O-positive and 3.3% were Group O-negative. While 2.1% of all allogeneic red cells processed were outdates, only 0.5% of the Group O units (both Group O-positive and Group O-negative) processed were outdated.

As has been the case in previous surveys, WB-derived (WBD) platelet concentrates accounted for the greatest percentage of total individual components outdated, 25% of total outdates, or 302,000 units outdated. This number represents 17.1% of the WBD platelets processed in 2011 whereas in 2008, 24.4% of WBD platelets processed outdated. There were 37.1% less units outdated than reported in 2008. In addition to outdates, 2.8% of produced WBD platelets were reported as wasted, with the reasons given as breakage, out of temperature, and non-outdated units that could not be transfused.

There were 321,000 apheresis platelets units outdated in 2011, representing 20.1% of total outdates. Of the apheresis platelets produced, 12.8% were outdated, compared to the 12.7% outdated in 2008. An additional 1.0% of apheresis platelets were wasted in 2011.

Outdated plasma totaled 129,000 units, 2.2% of the plasma units processed for transfusion. An additional

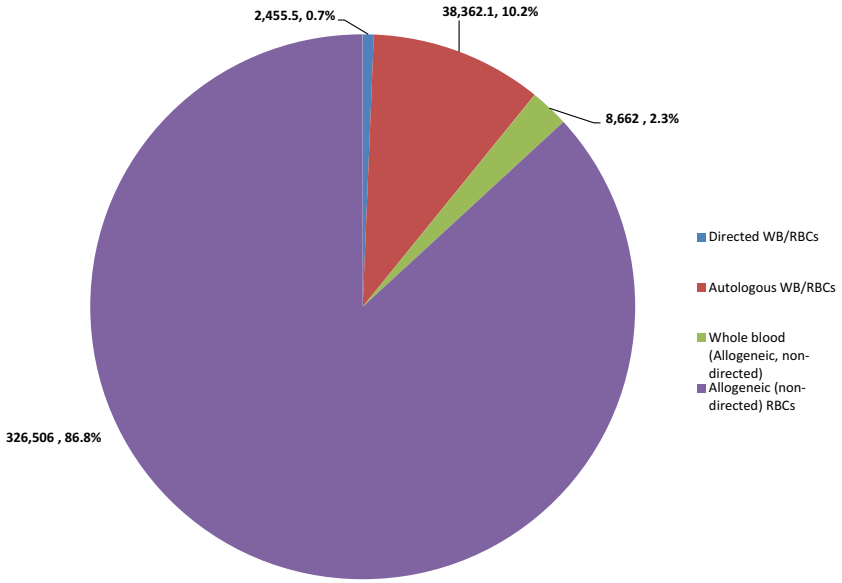


Figure 4-5. WB/RBC outdates by collection type.

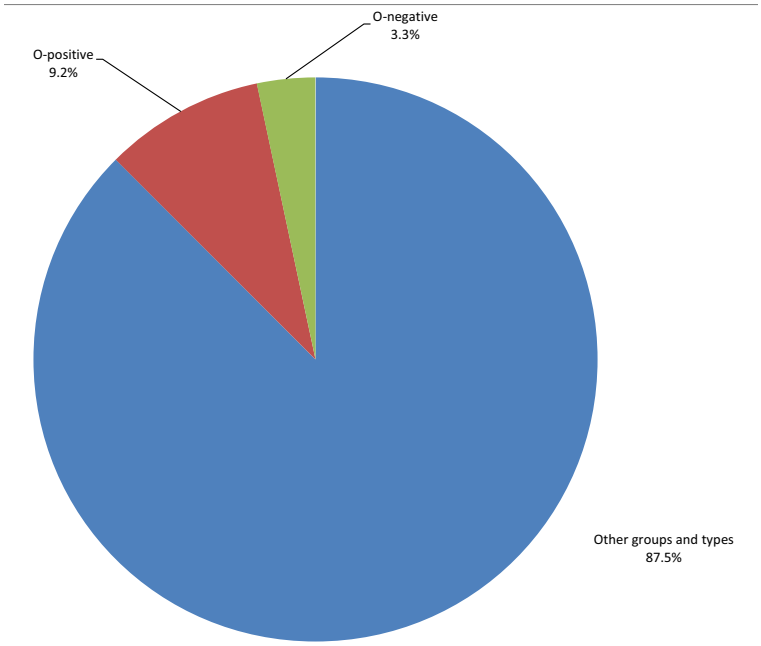


Figure 4-6. Percentage of allogeneic RBC outdates by blood group and type.

1.8% of plasma was wasted in 2011. The number of outdated cryoprecipitate units in 2011 was 56,000, or 3.3% of the cryoprecipitate processed. Of the cryoprecipitate produced in 2011, 3.1% was reported wasted. In addition, 4% of granulocytes produced were outdated and 1.7% was reported wasted in 2011.

Apheresis platelets, plasma, and cryoprecipitate combined accounted for 42.7% of all outdated units, 10.8% more than in 2008. Overall, 2011 utilization efficiency was very comparable to that reported in 2008. The percentage of outdated units of those processed or produced in 2011 was 4.3% compared to that in 2008, when 4.7% were outdated.

5. Patient Blood Management

In 2011, a new section on patient blood management (PBM) was added to the National Blood Collection and Utilization Survey (NBCUS) questionnaire. PBM is an evidence-based, multidisciplinary approach to optimizing the care of patients who might need a blood transfusion. It encompasses all aspects of patient evaluation and clinical management surrounding the transfusion decision-making process, including the application of appropriate indications, the minimization of blood loss, and the optimization of patient red cell mass. The questions, designed by a team of experts in the field of PBM, were intended to assess the degree to which this evidence-based, patient-oriented initiative has gained traction in United States (US) hospitals and blood centers.

Of the facilities that responded to the PBM section entry question, 30% responded that they have a PBM program. Of these, 98% were hospitals. Of all respondents, 31% of hospitals and 11% of responding blood centers reported providing some elements of a PBM program. These programs were coordinated by many different combinations of medical professionals. Fifty-one percent of hospital PBM programs were coordinated by a combination of medical and other staff, while 34% were coordinated by a medical director only. Other hospital staff who were reported to coordinate or share coordination of PBM programs included nurses, blood bank staff, anesthesiologists, cardiologists, hematologists/oncologists, risk management staff, healthcare improvement staff, transfusion committees, blood utilization committees, and patient safety officers.

There were 201 hospitals (15%) that reported having Transfusion Safety Officers (TSOs). Of the hospitals reporting established programs for patients who refuse blood, 19% had a TSO. Of the hospitals reporting that they did not have such a program, 10% reported having a TSO. Of those with a TSO, 25% reported having part-time TSOs, and 61% reported full-time TSOs. In the hospitals having a TSO, 81% of the TSOs were hospital employees, and 14% were blood center employees. Approximately 43% of the blood center employees were reported to be full-time, and 80% of the hospital employees were full-time.

Forty-one percent of hospitals participated in performance benchmarking programs relating to transfusion medicine. Sixty-four percent of facilities (805/1250) provide formal transfusion training to their staff. Hospitals were most likely to provide formal transfusion training to nurses (94.6%; **Table 5-1**). While hospitals did not report whether they have residents on staff, only approximately one in four facilities offer formal transfusion training to pathology residents (24%), to hematology/

Table 5-1. Formal Provider Training

	Transfusion Training (%)	PBM Training in Facilities with PBM Programs (%)
Physicians and mid-level providers new to medical staff	23.6	57.5
Nurses	94.6	73.0
Internal Medicine Residents	18.0	35.6
Family Practice Residents	15.1	25.8
Surgical Residents	16.5	30.3
Anesthesia Residents	17.4	28.8
Ob-Gyn Residents	12.7	27.1
Pediatrics Residents	13.6	14.7
Hematology/Oncology Residents	22.3	32.2
Pathology Residents	24.0	34.5
Other	13.7	18.3

oncology residents (22%), and to physicians and mid-level providers new to the medical staff (24%). Hospitals were least likely to provide formal transfusion training to obstetrics-gynecology residents (13%), pediatric residents (14%), and family practice residents (15%). Even fewer facilities reported providing formal PBM training (9%). Of these, they were most likely to offer PBM training to nurses (73%) and to new physicians and mid-level providers (58%). Hospitals that did offer formal PBM training were least likely to offer that training to pediatric residents (15%).

Ninety-two percent of survey respondents reported the use of transfusion guidelines. While many institutions have institution-specific guidelines, 85% of the guidelines used were predominantly based on one of the national guidelines **(Figure 5-1)**. Other hospitals indicated that they based their transfusion guidelines on recommendations from The Joint Commission, the New York State Department of Health, the American Society of Hematology, the hospital's own internal transfusion committee, and/or multiple sources of evidence-based practices.

In 2011, 57% percent of transfusing hospitals reported having an established program to treat patients who refuse any or all blood components for religious, cultural, or personal reasons, compared to only 15% in 2008. In 35.2% of all hospitals, patients facing elective surgical procedures associated with a high likelihood of blood loss were evaluated for factors predictive of preoperative and postoperative anemia. This evaluation was reported in 54.0% of hospitals reporting PBM programs. Only 259/1363 hospitals (19.0%) reported having a formal program in place to manage a patient's anemia before surgery. In hospitals reporting PBM programs, 33.0% reported the presence of these programs.

Many hospitals have put in place interventions to reduce the likelihood of allogeneic transfusions. Among preoperative interventions, reporting hospitals were more likely to use parenteral iron supplementation (82%) and clinical and laboratory assessments for anemia (44% and 47%, respectively) or potential bleeding risk (42%), than erythropoietin (22%) or preoperative autologous donation (37%; **Figure 5-2**). Among intraoperative inter-

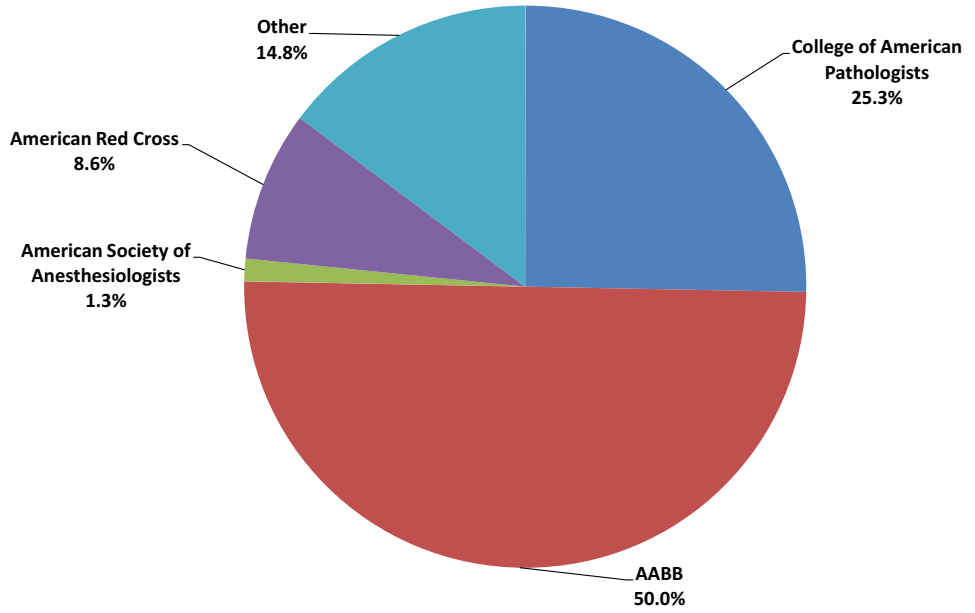


Figure 5-1. Use of national transfusion guidelines.

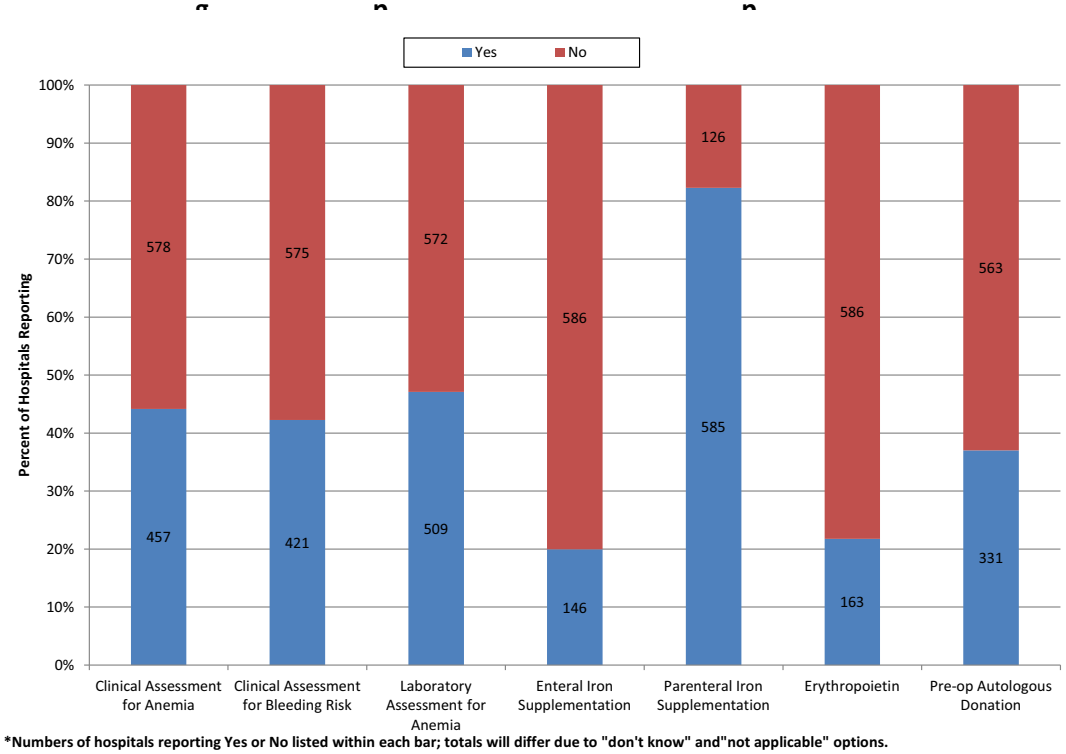


Figure 5-2. Pre-operative PBM interventions implemented.

ventions, the most common intervention reported was intraoperative blood recovery, performed by 64% of reporting hospitals **(Figure 5-3)**. Hospitals were less likely to engage in acute normovolemic hemodilution (33%) or the use of topical or systemic hemostatic agents (37%) and were least likely to have implemented postoperative PBM interventions **(Figure 5-4)**. The most common intervention in place was the restrictive use of postoperative transfusion in 27% of reporting hospitals.

Hospitals were queried on how the success of interventions intended to improve PBM was measured. The responses varied between hospitals: success was commonly measured by transfusion per medical/surgical admission in 28% of reporting hospitals, by total components transfused in 55% of reporting hospitals, and by other measures in 17% of reporting hospitals. These other measures included the crossmatch-to-transfusion ratio, reviews of clinical waste, blood utilization, and other audits, the percentage of patients transfused per selected International Classification of Diseases, Ninth Edition (ICD-9) codes [ie, coronary artery bypass graph (CABG) only or knee/hip replacements), average blood component per case (CABG only), and percentage of inappropriate transfusions.

Most reporting hospitals require the ordering provider to obtain and document informed consent for transfusion (95%). Seventy-five percent of all reporting hospitals require the physician to document the reason or clinical justification for transfusion in the medical record according to transfusion guidelines, regardless of whether the hospitals have PBM pro-

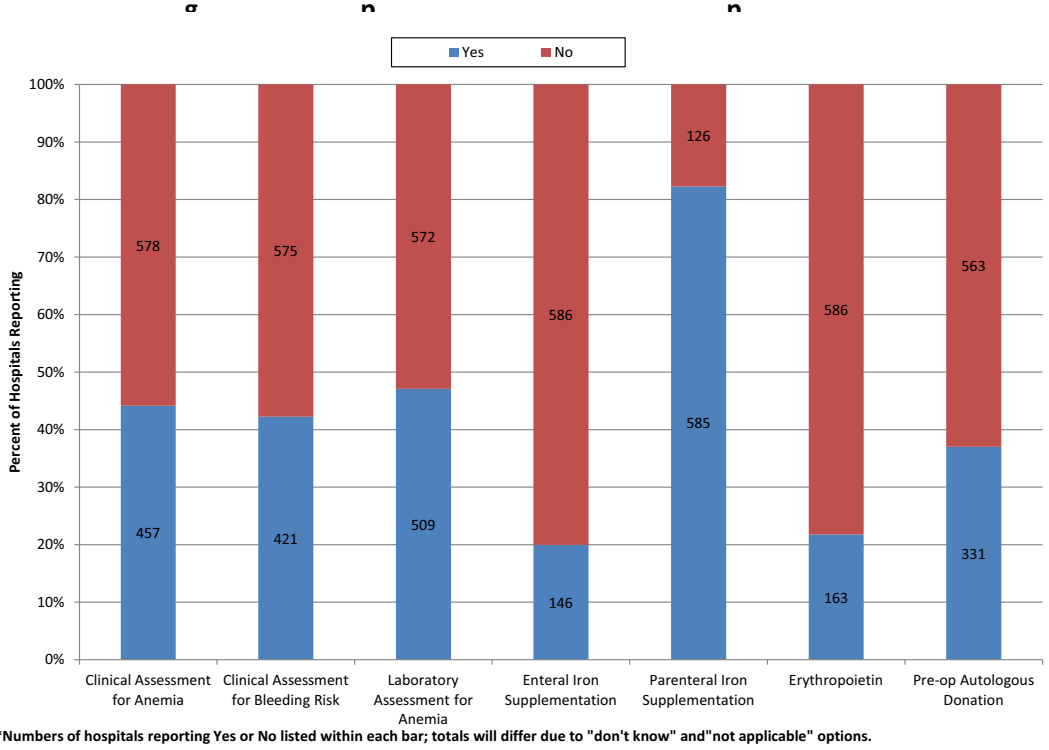


Figure 5-3. Intra-operative PBM interventions implemented.

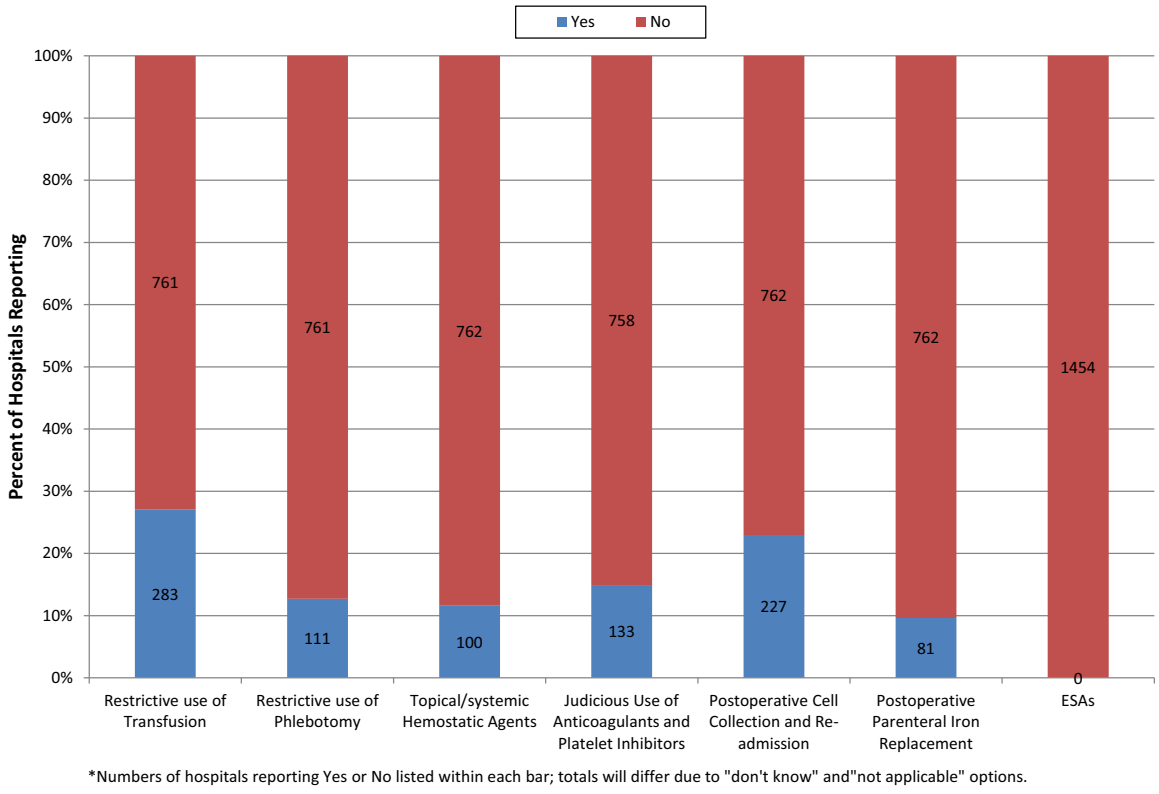


Figure 5-4. Post-operative PBM interventions implemented.

grams in place. Most reporting hospitals (74%) also require that relevant pretransfusion laboratory results are documented in nonemergent transfusions. The percentage of patients undergoing high-blood-loss surgical procedures that had a type-and-screen completed before the start of the surgical procedure averaged 93.6%, with a median of 98% and a range from 5% to 100% of patients.

Average pretransfusion laboratory results were reported for blood products transfused **(Table 5-2)**. For red cells, the average pretransfusion hemoglobin was 7.9, and the median was 8.0 (n=506 hospitals). The average pretransfusion platelet count was 32,055, and the median was 20,000 (n=480 hospitals). For plasma, 203 hospitals reported the average pretransfusion internal normalized ratio was 2.5, and the median was 2.0. The average pretransfusion partial thromboplastin time (PTT) reported was 53.1, and the median was 50 (n=154 hospitals). For cryoprecipitate, the average pre-transfusion fibrinogen reported was 106.7, and the median was 100 (n=196 hospitals).

The standard red cell order for nonbleeding patients in 246 (23.5%) hospitals was one unit and two units in 763 (72.8%) of hospitals. The remaining 39 reporting hospitals reported other standard red cell orders. Fifty-two percent of reporting hospitals (705 hospitals) have implemented Computerized Physician Order

Table 5-2. Average Pre-transfusion Laboratory Results

	Average	Median	Min	Max	n
Average Pre-transfusion Hemoglobin	7.9	8.0	6.0	12	506
Average Pre-transfusion Platelet Count	32,055	20,000	2000	250,000	480
Average Pre-transfusion INR	2.5	2.0	1.0	8.7	203
Average Pre-transfusion PTT	53.1	50	17	110	154
Average Pre-transfusion Fibrinogen	106.7	100	45.0	202	196

Entry (CPOE), and 327 of these facilities (46.4%) have CPOE systems that include transfusion guidelines or an algorithm to assist with proper transfusion ordering.

6. Component Modification

Leukocyte Reduction

Blood components are leukocyte reduced to reduce the risk of febrile nonhemolytic reactions, transmission of cytomegalovirus infection, and HLA alloimmunization that may lead to platelet refractoriness. Leukocyte reduction may be conducted during collection, at some time before components are placed into inventory, and after storage; these are categorized as "before or after storage, but not at bedside" leukocyte reduction. A total of 14,758,000 (55.7%) component units, including pediatric aliquots were LR by blood centers and those hospitals that collect blood **(Table 6-1)**. Components can also be LR at the bedside at the time of transfusion, although this practice in increasingly less common **(Figure 6-1)**.

The most frequently leukocyte-reduced (LR) components were whole blood/red blood cells (WB/RBCs) and apheresis platelets. Because of the decline in collections, the percentage of components that are leukocyte reduced is more important than the actual overall number of LR components. While fewer WB/RBC units were leukocyte reduced, 84.8% of all WB/RBCs were leukocyte reduced before or after storage in 2011, a rate that is an increase of 4% over 2008. It is expected that apheresis platelets are leukocyte reduced through the collection process; however, only 86.6% were reported as having been leukocyte reduced in 2011. There was a 91% drop in the number of other types of components that were leukocyte reduced in 2011. It is unclear whether this is a change in practice or in reporting.

Compared to 2008, blood centers produced 15.0% fewer LR components in 2011, while hospitals produced 25.6% more LR components **(Table 6-2)**. Overall, the number of LR components prepared decreased by 13.3% from 2008, as 93.8% of all LR components were prepared at blood centers.

Transfusion of Irradiated and LR Components

Table 6-3 summarizes the types and numbers of irradiated and LR blood component units transfused during 2011. A total of 3,013,000 irradiated units (13.4% of all units transfused) were reported as transfused by blood center transfusion services and hospital transfusion services.

In 2011, 11,897,000 LR component units were transfused by blood center transfusion services and by hospital transfusion services. Of all LR units transfused, 98.9% were leukocyte reduced before or after storage (not at bedside), and only 1% were leukocyte reduced at bedside. Substantial proportions of all RBCs and platelets reported transfused in 2011 were leukocyte reduced: 70.5% of WB/

Table 6-1. Blood Components Modified to Achieve Prestorage Leukocyte Reduction in All Facilities

Blood Component	2011 Leukocyte-Reduced Prestorage	2011 Leukocyte-Reduced % of Total Available Components	2008 Leukocyte-Reduced Prestorage	2008 Leukocyte-Reduced % of Total Available Components
WB/RBCs	12,371,000	84.8	13,791,000	80.4
WB-Derived Platelets	371,000	33.4	926,000	47.1
Apheresis Platelets*	2,009,000	79.8	2,225,000	104.5
Other Component Units	7,000	0.1	74,000	1.0
Total Components	14,758,000	55.7	17,016,000	60.0

*Rounding error may generate unexpected percentages of LR platelets, as apheresis platelets are generally LR in the collection procedure.

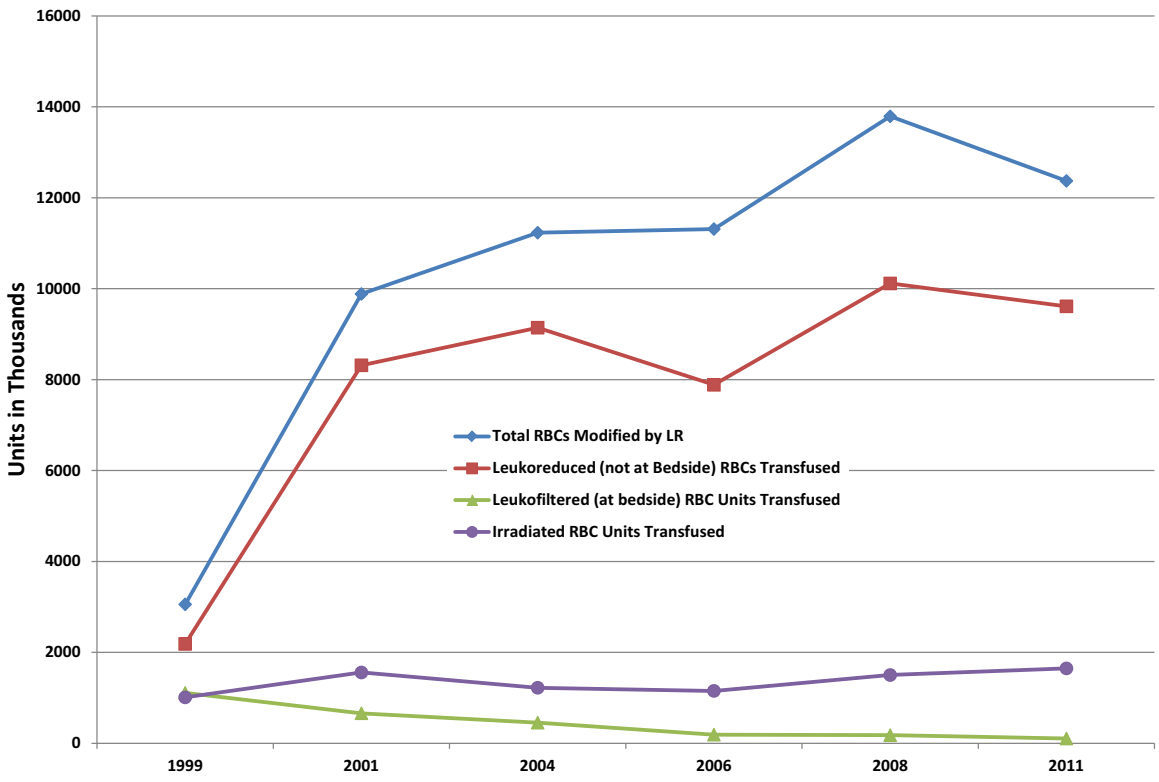


Figure 6-1. Transfusion of modified red cell components.

Table 6-2. Change in Number of Blood Components Modified to Achieve Pre-Storage Leukocyte Reduction by Facility Type from 2008 to 2011 (expressed in thousands of units)

	Blood Centers			Hospitals			All Facilities		
Modification	2011	2008	% Change	2011	2008	% Change	2011	2008	% Change
Components leukocyte reduced before storage (not at the bedside)	13,837	16,283	-15.0	921	733	25.6	14,758	17,016	-13.3

Table 6-3 Estimated Number of Blood Component Units Modified by Irradiation or Leukocyte Reduction and Transfused by All Facilities in 2011

Blood Component	Components Irradiated	Components Leukocyte Reduced Before or After Storage (not at the Bedside)	Components Leukocyte Reduced by Filtration (at the Bedside)	Total Leukocyte Reduced Units	Irradiated: % of Total Units Transfused	Leukocyte Reduced: % of Total Units Transfused
WB/RBCs	1,648	9,612	106	9,718	12.0	70.5
WB-Derived Platelets	340	361	6	367	34.2	37.0
Apheresis Platelets	915	1,567	10	1,577	46.4	80.1
Other Component Units	110	235	0	235	1.9	4.1
Total Components	3,013	11,775	122	11,897	13.4	52.8

Table 6-4. Total Number of Irradiated and Leukocyte Reduced Red Blood Cell (RBC) Units Transfused in 2011, Compared with RBC Units Transfused in 2008 (expressed in thousands of units)

	Red Blood Cell Units			
Modification	2011	2008	Change 2011-2008	% Change
Irradiated	1,648	1,502	146	9.7
Leukocyte-Reduced, total	9,717	10,294	-577	-5.6
Before or After Storage (not at the bedside)	9,612	10,115	-503	-5.0
At the bedside	106	179	-73	-40.8

RBCs, 37% of WBD platelets, and 80% of apheresis platelets.

Table 6-4 and Figure 6-1 summarize the trends in the numbers of irradiated and LR RBC components transfused. Between 2008 and 2011, the number of irradiated RBC units transfused increased 9.7%, while the proportion of units irradiated has increased from 10% (2008) to 12% (2011) of all units transfused.

Transfusing facilities were asked whether they had a policy in 2011 to transfuse only LR components: 73% responded that they did have such an LR-only policy in place. Those facilities that responded in the negative were asked whether they have a policy to transfuse only LR units to cardiac patients. Only 10.45% of those without an LR policy for all patients had an LR policy for cardiac patients in 2011.

While the actual number of LR RBC units transfused in 2011 decreased by 5.6%, a rate slightly lower than the overall declining trend of transfusion, the proportion of LR RBC units transfused increased slightly, from 68.6% (2008) to 70.5% (2011), which is indicative of continued utilization of these modified components **(Figure 6-1)**. However, the declining trend of bedside leuko-filtration observed in previous years continued with a decrease of 40.8% in 2011.

7. Current Issues in Blood Collection and Screening

Donors

In 2011, 17,984,000 individuals presented to donate blood. Much as reported in earlier surveys, most donors presented at blood centers (93.5%), and only 6.5% presented to donate at hospital donor centers. Of the presenting donors, there were 9,203,000 allogeneic nondirected donors who successfully gave blood in 2011, compared to 10,805,000 allogeneic donors in 2008, for a drop of 14.8%. In 2011, 2,840,000 (30.9%) were first-time donors and 6,364,000 (69.1%) were repeat donors.* These repeat allogeneic donors provided 9,534,000 donations, the equivalent of 1.5 donations per repeat allogeneic donor, the same rate of donation reported in 2008.

There were 43,000 directed donors reported who successfully donated an allogeneic unit intended for a specific patient, and 46,000 units were collected (manual and apheresis collections combined). Many blood centers and hospitals reported that they were unable to specify which donors had directed their donation.

There were 89,000 autologous donors reported who successfully donated a unit intended for themselves. Facilities reported 117,000 units collected (manual and apheresis collections combined) for a rate of 1.3 units per autologous donor.

Of the 17,984,000 presenting individuals, 2,455,000 were deferred for various reasons (13.7% in 2011, compared to 12.6% in 2008). The deferral rate was slightly higher in hospital collection environments (16.5%) than in that in blood centers (13.5%). Donors were most commonly deferred for low hemoglobin (48.8% of deferrals), defined as not meeting Food and Drug Administration (FDA) blood hemoglobin level requirements for blood donation. As seen in **Figure 7-1**, other categories for deferral included high- risk behavior associated with men who have sex with other men (MSM; 0.4% of deferrals), other high-risk behavior (as identified on the Donor History Questionnaire, or DHQ; 1.0%), prescription drug use (3.6%), tattoos/piercings (4.0%), specific foreign travel (7.4%), and other medical reasons (19.2%). High-risk behavior deferrals are intended to reduce the risk of transmission of infectious diseases, including HIV and hepatitis viruses. Deferrals for other medical reasons may include exposure to human-derived growth hormone, bovine insulin, Hepatitis B Immune globulin, or unlicensed vaccines or presenting with physical conditions or symptoms that disqualify a person from donating blood. Another

**Repeat donors as defined by the reporting facility.*

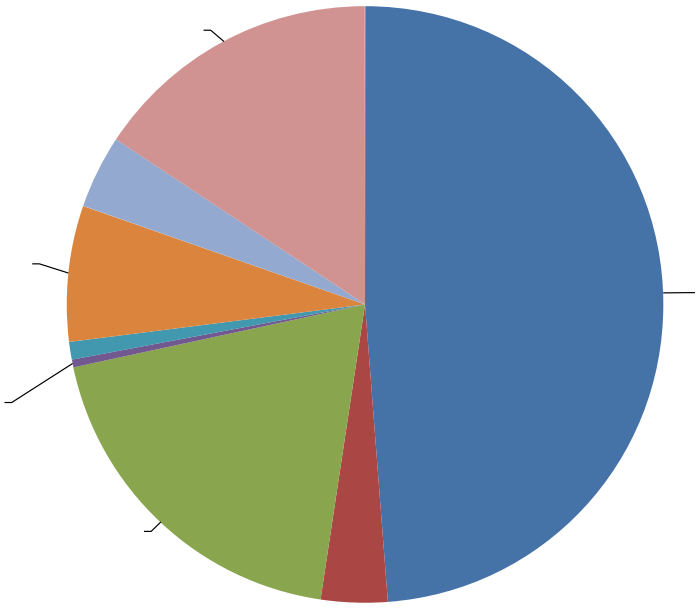


Figure 7-1. Donor deferrals 2011.

15.7% of donors were deferred for other reasons, which included low weight, inadequate interdonation interval, being under the donation age, and language.

There were 102,000 units, from 1.1% of donors (0.7% of the total units tested), that were discarded for abnormal disease marker results.

Collection from younger donors has been an area of interest in recent years. In 2011, 3,202,000 units were collected from donors aged 16-24. This number represents approximately one-fifth of all allogeneic collections (20.5%). Of these donations, 1,646,000 were collected from high school–age donors (16-18 years old), representing 10.5% of all donations. This survey also determined that 1,219,000 donations, or 7.8%, were collected from people over the age of 65 years in 2011.

There were 1,735,000 units collected from minority populations (including African, Asian, and/or Hispanic). While some facilities were unable to specifically report by population, these donations continue to contribute substantially to the nation's blood supply (11.1%), a slight increase from the percentage reported for 2008.

Mobile blood drive sites were the source of 10,466,000 units, or 66.6% of collected units. Of these, approximately 11%, or 1,155,000 donations, were from automated collections. In 2011, blood centers obtained the greatest proportion of their collections through mobile blood

drives (67.5%), while hospitals reported the use of mobile blood drives for 52.7% of collections; these rates represent an increase of 5% from 2008 for both facility types.

Donor Hemovigilance

This survey has allowed the collection of baseline donor hemovigilance data for the US donor population. For the purposes of this survey, severe donor adverse events were defined as adverse events occurring in donors that were attributed to the donation process, including major allergic reaction, loss of consciousness of a minute or more, loss of consciousness with injury, and nerve irritation. In this survey, 21,000 of these events were reported by collection organizations for 2011 **(Table 7-1)**. The rates of severe adverse events were 21,000/16,141,000 collection procedures (0.13%) in 2011 and 16,000/17,779,000 collection procedures (0.09%) in 2008. These rates were not statistically different, however; the variability may be due to inconsistent application of the definition of severe reactions.

As in 2008, the rate of severe adverse reactions per unit collected was the same as that by procedure; in 2011, it was 0.13% (21,000/15,721,000 units collected). There were no differences between the reaction rates for manual collections and for automated procedures, nor were there differences between blood centers and hospital collectors in reaction rates. Additional aggregate detail about donor reactions is expected in the coming years with greater participation nationally in the national donor hemovigilance program, Donor Hemovigilance Analysis and Reporting Tool (Donor HART). Blood donation, either through traditional manual WB collection processes or using automated procedures, rarely results in an untoward consequence.

Table 7-1. Donor Adverse Reaction Rate by Facility and Procedure Type

	Reaction Rate for Manual Collection Procedures (%)		Reaction Rate for Automated Collection Procedures (%)		Overall Rate (%)	
	2011	2008	2011	2008	2011	2008
Blood Center	0.14	0.09	0.10	0.11	0.13	0.09
Hospital	0.10	0.10	0.15	0.06	0.11	0.90
Total	0.13	0.09	0.11	0.10	0.13	0.09

8. Current Issues in Blood Transfusion

United States Population Trends

Figure 8-1 illustrates the trends in the estimated rates of whole blood/red blood cell (WB/RBC) collection and transfusion in the United States from 1980 to 2011. The rate of collection was calculated from the national estimate of total allogeneic WB and RBCs collected per 1,000 donors aged 16 to 64 for a given survey year. The rate of transfusion was calculated from the national estimate of allogeneic WB/RBC units transfused per 1,000 total population of all ages for that year. For comparison, the figure also includes the collection rate of allogeneic WB/RBC units collected per 1,000 total population (all ages) since 1997. Population estimates were obtained from the United States (US) Bureau of the Census.*

Allogeneic blood collection in the United States was 76.2 units per 1,000 persons aged 16 to 64 in 2011 compared with 85.2 units per 1,000 such persons in 2008.† This donation rate is the lowest rate per unit of population reported since 1997. According to the number of donors reported in the 2011 survey year, only 4.5% of the US population aged 16 to 64 donated in 2011, which represents a large drop from the 5.4% of the total age-eligible US population reported to have donated in 2008. This 10.6% decrease in collection rate can be attributed to the combined factors of a 2.5% increase in population and an 8.2% decrease in the number of units collected.

The rate of donations in the population aged 16- to 24 was 80.8 units per 1,000 persons in 2011, which is lower than the same cohort's rate in 2008 (84.8 per 1,000 persons) but higher than the eligible population overall (76.2 units per 1,000 persons) and the rate for persons aged 25 to 64 (75.1 units per 1,000 persons). This survey also assessed blood collection from older Americans. Donations were successfully collected from 1,219,000 donors over the age of 65 at a rate of 29.4 units per 1,000 persons.

The US WB/RBC transfusion rate in 2011 was 44.0 allogeneic units transfused per 1,000 overall population. This rate is 10.3% lower than the allogeneic transfusion rate in 2008 (48.8/1,000 population) and approaches the rates reported in the 1990s, but it still was substantially higher than rates reported in Canada and European countries.‡

**http://www.census.gov/popest/data/index.html.*

†*Allogeneic blood collection per 1,000 total population in 2011 was 50.1 units.*

‡*Hofmann, A. 2011; Economics of Blood Transfusion. Presentation to the HHS Advisory Committee for Blood Safety and Availability; June 2011. http://nih.granicus.com/ViewPublisher.php?view_id=22*

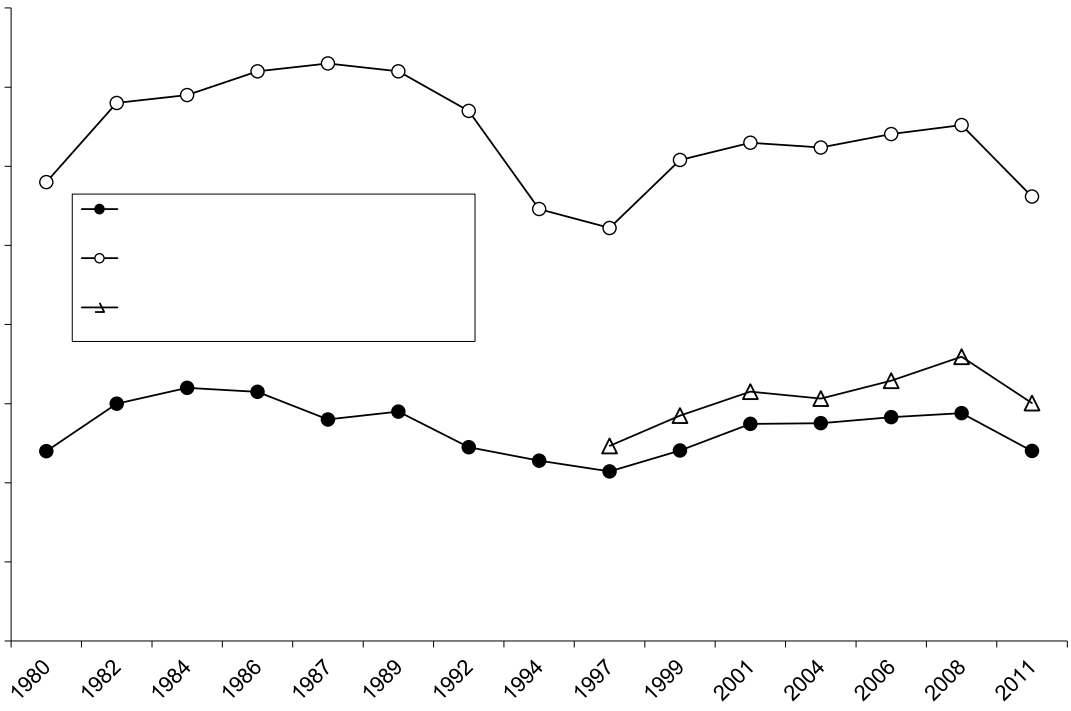


Figure 8-1. Trends in estimated rates of blood collection and transfusion in the United States, 1980-2011.

It is unclear with a single data point whether this lower transfusion rate is a residual of the recession or part of a trend in blood conservation.

Trends in Utilization

Figure 8-2 illustrates the relationship between allogeneic WB/RBC collections and transfusions from 1989 to 2011, as well as the margin between units collected and those transfused. The trend of increasing numbers of collections reported since 1997 was reversed in the period between 2008 and 2011, with only 15.6 million allogeneic RBC units collected, for an 8.3% decrease from 2008. Allogeneic collections in 2011 were comparable to those reported in 2006.

The available supply of both WB/RBCs and non-RBC components was sufficient to meet overall transfusion demands in 2011. Any reported shortages covered later in this chapter were likely to have been local in nature. The margin between allogeneic WB/RBC supply and demand depicted in **Figure 8-2** indicates a correction to the previously observed oversupply of WB/RBC components.

In 1989, allogeneic collections totaled 13.6 million, with a margin of 1.9 million, or 14% of supply. By

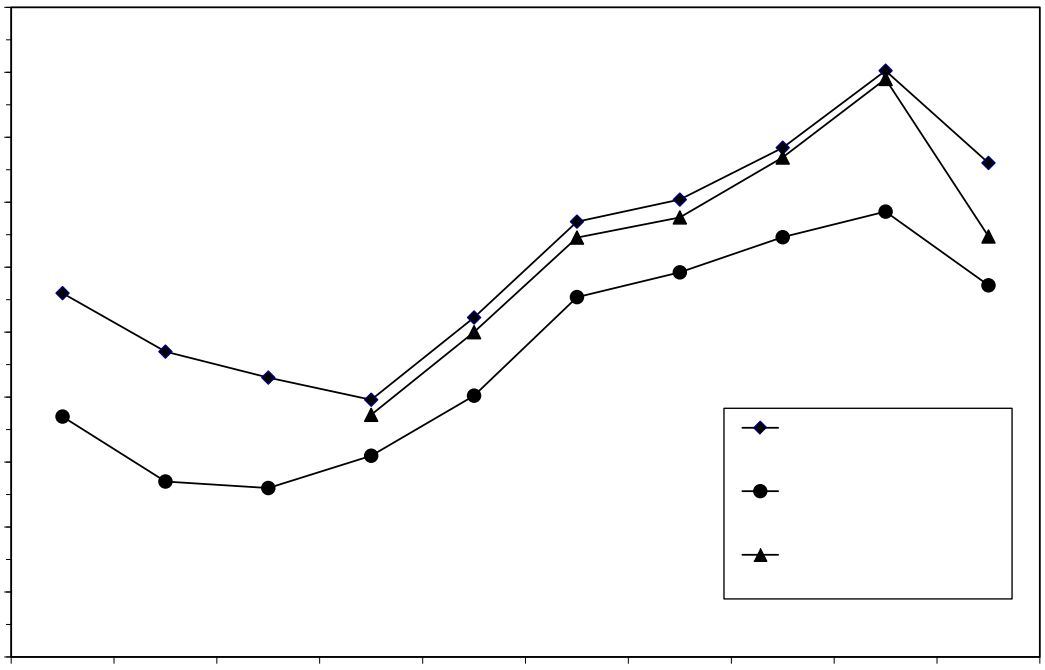


Figure 8-2. Allogeneic whole blood and red blood cell collections and transfusions, 1989-2011.

1997, the difference between units collected and transfused had decreased to 862,000 units when the available supply variable was introduced, which demonstrated that actual available units (ie, units that have passed all laboratory tests and are available for transfusion) had decreased to 632,000, only 5.3% of the supply. In response to increasing demand for RBCs in 1999, blood centers successfully increased allogeneic collections to 13.2 million, increasing the available margin to 7.5% in spite of an 8.3% increase in transfusions. Between 2001 and 2008, utilization growth increased at a slower rate than increases in collection. In 2011, however, there was a significant decrease ($p<0.001$) in available allogeneic collections to 15.5 million units. With a comparable decrease in the number of units transfused, there remained a margin of 1.7 million units, or 11.5% of supply. However, in the 2011 survey, an additional calculation to assess WB/RBC availability was performed, removing additional units that were rejected for reasons besides testing. This calculation yielded a reduction in available allogeneic supply to only 14.5 million units and an actual margin of only 752,000, or 5.2% of the available supply. Amounts transfused and available are comparable to those reported in 2001.

Additional information about availability was obtained in 2011. In the course of deliberations on how to communicate the status of the blood supply to HHS during disasters, AABB's Interorganizational Task Force on Domestic Disasters and Acts of Terrorism settled on a simple quantitative approach that reports the US blood center on-shelf blood supply in terms of days of available supply. AABB has been collecting and reporting on data supply daily for task force and HHS use. The organizations that submit data to AABB are America's Blood Centers, the American Red Cross, and Blood Centers of America. The data are aggregated and disseminated through AABB's Center for Data and Special Programs in collaboration with the National Blood Exchange. The first complete year for these supply estimates was 2008. **Figure 8-3** indicates the overall national days of Type O red cell supply throughout the 2011 calendar year, as compared to the 2008 calendar year. These availability data do not represent possible geographic differences in availability, however; blood can be moved quickly from one location to another through the use of various supply networks. In 2008, the available supply of O-negative units remained fairly constant, and there was an increase in the supply of O-positive units at the end of

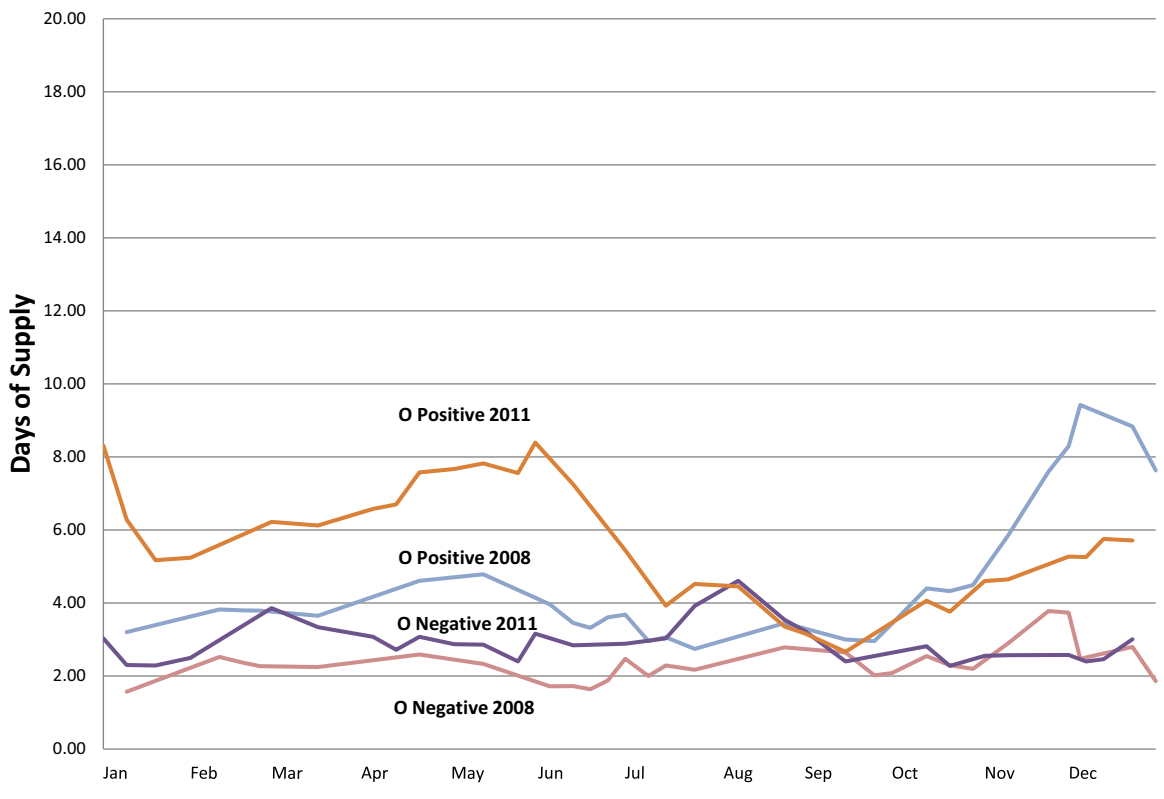


Figure 8-3. Days of Group O blood supply 2008 and 2011.

2008 that carried through into 2009 and beyond. In 2011, available O-negative units never dropped below two days' supply. However, the O-positive supply curve has been more volatile, showing the oversupply that began in 2008 lasting into mid-2011. By middle to late 2011, O-positive days of availability approached the number of supply days seen in the middle of 2008.

Blood Inventories

Hospitals were asked to indicate the number of days in the survey year that elective surgery was postponed because of actual blood inventory shortages and the number of days that hospitals were unable to meet other nonsurgical blood requests. In addition, since 2008, the survey has queried the numbers of days on which a hospital's regular order was incomplete and for specification of which components had shortages.

A total of 45 hospitals (3.3%) reported that elective surgery was postponed on one or more days in 2011 because of blood inventory shortages. **Table 8-1** provides a characterization of cancellation reports in 2011 in comparison with previous survey years. In 2011, there were fewer hospitals (approximately 27%) reporting surgery delays than in 2008, although the numbers were small in both years. Days of delay reported in 2011 ranged from 1 to 14, with a median of 2 days. In 2011, as in 2008, shortages were rare and significant for only a very few hospitals.

Hospitals indicated separately that the total number of postponed surgical procedures was 435, compared with 325 in 2008, when weighted data were used. These differences were not significant. Of those reporting delays, the hospitals in the smallest surgical size strata (100-999 surgeries per year) reported more of the delayed surgeries than did hospitals doing more surgery. The weighted average number of days

Table 8-1. Cancellation of Elective Surgeries by US Hospitals, 1997-2011*

Year	% Hospitals with Cancellation of ≥1 Day	Range of Days	Median No. of Days	Number of Patients Affected
1997	8.6	1-21	2	Not determined
1999	7.4	1-150	2	568
2001	12.7	1-63	2	952
2004	8.4	1-39	2	546
2006	6.9	1-120	3	412 (721 weighted)
2008	4.4	1-100	2	151 (325 weighted)
2011	3.3	1-14	2	173 (433 weighted)

*All data is unweighted.

postponed was 2.4 days, with averages of approximately 3.0 surgeries postponed.

Of responding hospitals, 10.3% (141 hospitals) reported at least one day on which nonsurgical blood needs could not be met; this report was unchanged from the 2009 National Blood Collection and Utilization Survey (NBCUS) report, in which 13.2% (213 hospitals) reported unmet need. The total number of days reported was 1,641, and the range was 1 to 365. There was a large difference between the mean number of days (obtained by using weighted data) of unmet nonsurgical needs reported for all respondents in 2008 (21.7 days) and that reported in 2011 (1.8 days). Components continued to be available throughout the country. Only two hospitals reported 365 days on which nonsurgical blood requests were not met in 2011, whereas five reported an entire year of unmet need in 2008.

Hospitals were asked to indicate the number of days on which their regular or standing order of components was incomplete for different components. In 2011, the total number of "reported days incomplete" reported by hospitals for all components was 37,857 unweighted (91,169 days weighted), compared with 45,322 unweighted days in 2008. The weighted means of order- incomplete days across all hospitals were 18.9 days for red cell orders, 3.3 days for plasma orders, 7.6 days for apheresis platelet orders, and 1.2 days for WB platelet orders **(Figure 8-4)**.

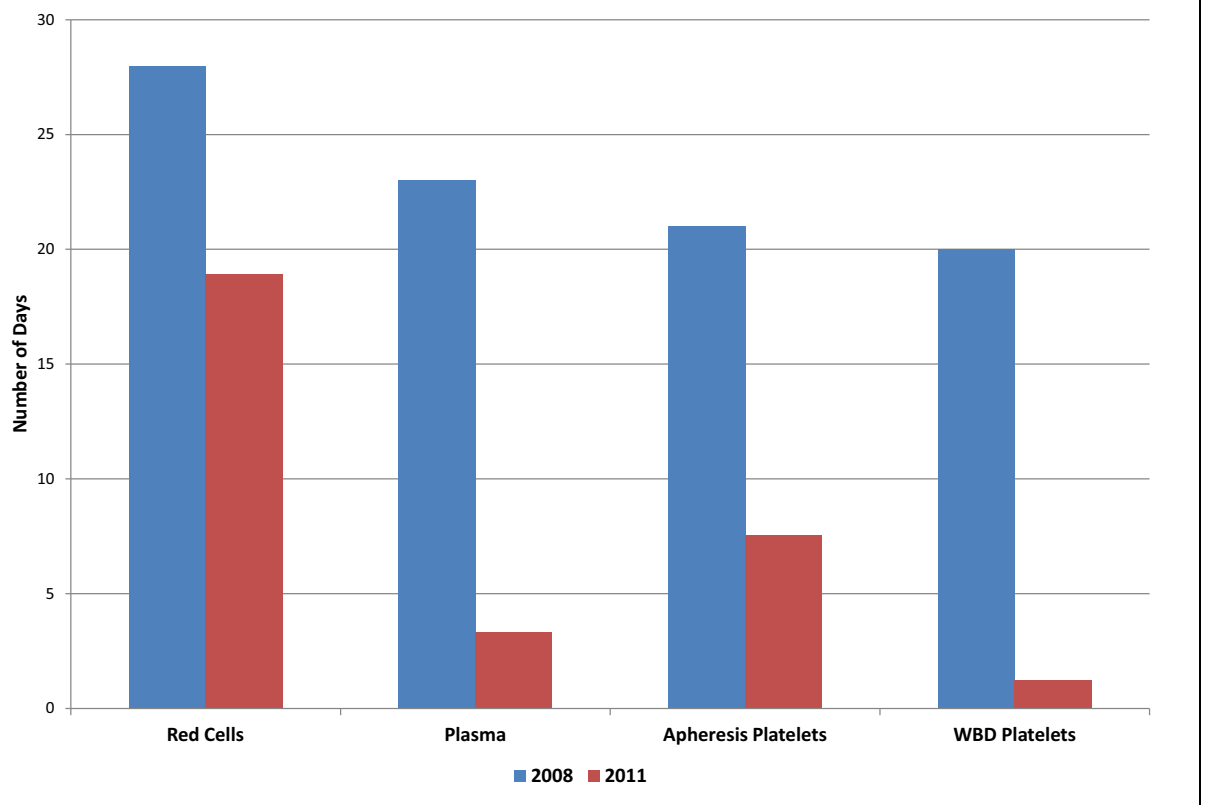


Figure 8-4. Average number of days a hospital order was incomplete.

Blood centers reported maintaining an average weekday inventory estimate of 156 units of group O red cells. Average hospital weekday inventories varied by numbers of surgeries performed, with the largest hospitals maintaining the largest inventories (estimated 126 units) and the smallest averaging 23 units. The number of Group O units in uncrossmatched inventory that was considered to be critically low also varied by hospital surgical strata, with the smallest hospitals reporting a threshold of 37 units and the largest hospitals reporting a threshold of 99 uncrossmatched Group O units. Blood centers acting as centralized transfusion services reported 224 uncrossmatched Group O units as the critical inventory threshold. All numbers reported were notably higher than those reported in previous years, which indicates that there may be more hospital demand for Group O units and that the expanded availability has made this possible.

Blood Use

Hospitals were asked to indicate the number of RBC and platelet units distributed to individual hospital services [eg, Surgery, Hematology/Oncology, Transplant, and the Intensive Care Unit (ICU)] in 2011 **(Figures 8-5 and 8-6)**. The services responsible for the highest use of RBCs were General Medicine (31%), Surgery (20%; general, orthopedic, and cardiac surgery combined), and Hematology/Oncology (15%). Among the depart-

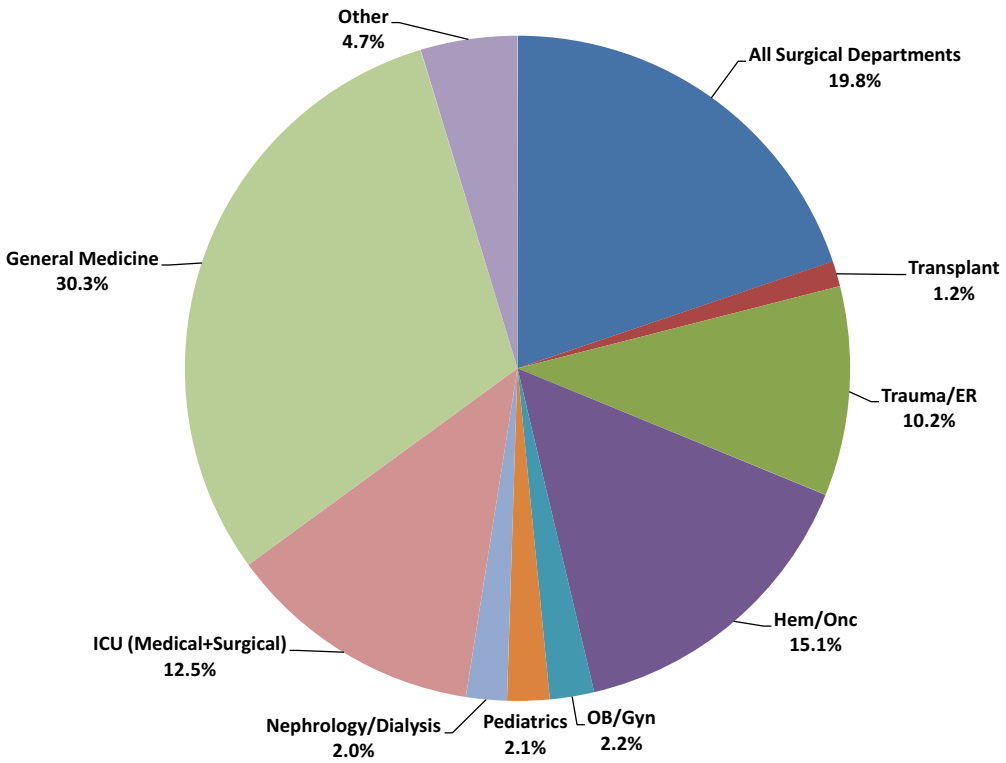


Figure 8-5. Red blood cell use by hospital service in 2011.

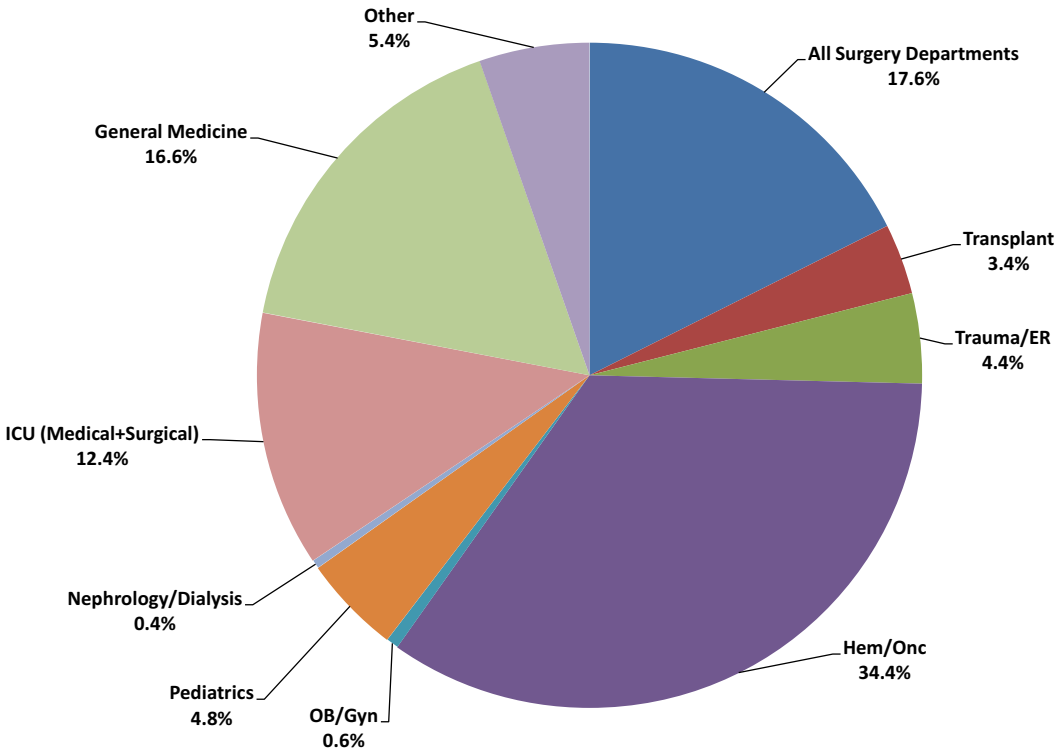


Figure 8-6. Platelet use by hospital service in 2011.

ments that were included in the "Other" category were Anesthesiology and Outpatient departments. Hospitals able to report these data by hospital service accounted for 43% of the total US WB/RBC transfusions.

The services reporting the greatest use of platelet products were Hematology/Oncology (34%), Surgery (18%; general, orthopedic, and cardiac surgery combined), General Medicine (17%), and the ICU (12%). Cardiac surgery made up 50% of the overall platelet use in surgery. Hospitals able to report these data by service accounted for approximately 51% of US platelet transfusions.

Bacterial Testing

In 2011, only 194 institutions (14.2%) reported performing bacterial testing of platelets, compared with 30.6% in 2008. Of the 119 blood centers responding to this question, 116 (97.5%) reported performing bacterial testing; however, only 6.3% of all hospitals reported testing. This is a large change from 2008, when 26.7% of hospitals reported testing. Of the hospitals that did report testing, 78% had hospital blood collections.

Respondents were asked to indicate the methods used to detect bacterial contamination of platelet components. Of the 138 facilities that reported testing apheresis platelets, 95.8% reported using culture-based testing, including an enhanced bacterial detection system (eBDS). Others

reported using rapid immunoassay [platelet pan genera detection (PDG)] and swirling. Of the 49 facilities that reported testing WB-derived (WBD) platelets singly, 46.9% reported using rapid immunoassay methods (eg, PDG) and 14.3% used pH/glucose methods. (Note: These methods are not considered as acceptable in meeting AABB or College of American Pathologists (CAP) accreditation requirements.) Among the 84 facilities testing pooled WBD platelets, 79.8% used culture-based methods including eBDS, and the others used rapid immunoassay (PDG). Overall, blood centers were more likely to use culture-based testing, whereas many of the testing hospitals employ rapid immunoassays (eg, PDG) or other methodologies, including eBDS.

Approximately 1,660,000 platelet units or 44.2% of platelets produced were reported tested for bacteria in 2011. Each apheresis split unit, individual WBD units, or platelet pool was counted as a testable unit. Because both AABB and the CAP require testing, it is likely that many facilities did not report their activity. Of those that reported, culture-based methods accounted for 94.0% of the units tested (1,561,000 units) and for 390 (97.0%) of the 401 confirmed positives. In 2008, there were no reports of blood centers using rapid immunoassay methods, but, in 2011, a small number were doing so. The false-positive rates reported were 0.06% for culture-based methods and 0.20% for rapid immunoassay. The rate of false-positive test results was lower in 2011 than in 2008 (0.26% and 0.29% false-positive tests were reported for culture-based methods and alternative methods, respectively).

Crossmatch Procedures

Transfusing facilities reported the total number of crossmatch procedures. Weighted hospital data on crossmatch procedures indicate that 19,651,000 procedures were performed in 2011, only 1.2% less than the 19,881,000 procedures in 2008, although approximately 8% less units were transfused.

Hospitals reported 5,508,000 electronic crossmatch procedures, or 28% of the total procedures reported. Manual serologic procedures accounted for 61% of the crossmatch procedures. Only 3% were reported to be automated serologic crossmatch procedures. The remaining procedures were not categorized.

To calculate the crossmatch-to-transfusion ratio, the total number of allogeneic WB/RBC units transfused (13,720,000) was used as the denominator. The overall crossmatch-to-transfusion ratio (C:T) was 1.4 crossmatch procedures per unit transfused, a ratio slightly higher than that reported in both 2008 and 2006 (C:T 1.3:1).

Red Cell Age

In follow-up to the earlier surveys, the 2011 survey attempted to determine the average age of a unit of RBCs at the time of transfusion. In this survey, 576 facilities responded, a decrease from the 750 that responded in the last survey. The overall mean age for a red cell unit at transfusion was 17.9 days. Hospitals were asked to indicate whether they reported a calculated age or an estimate of age. The estimated mean age and the calculated mean age at transfusion were both 17.9 days, the same as was reported in 2008. Only 15.5% (89 hospitals) of hospitals respond-

ing to this question were able to calculate the component age at transfusion.

Platelet Age

In the 2011 survey, 228 hospitals responded with an average age of WBD platelets at transfusion. Overall, the average age was 3.2 days at transfusion. Hospitals were asked to indicate whether they reported a calculated age or an estimate of age. The estimated mean age was 3.14 days, and the mean calculated age was 3.96 days at transfusion. Only 25.4% of facilities responding to this survey (58 facilities) were able to calculate the component age at transfusion.

Quite a few more hospitals (708 hospitals, or 51.9% of hospitals overall) responded with an age for apheresis platelets at the time of transfusion. Overall, the average age was 3.06 days at transfusion. The mean reported age was 3.11 days for the calculated average and 3.05 for the estimated average.

Only 10.9% (74 hospitals) of hospitals responding to this question had the tools to calculate the apheresis platelet component age.

Biovigilance

Hemovigilance

An estimated total of 51,000 transfusion-related adverse reactions occurred in 2011. A reaction is defined as an undesirable response or effect in a patient that is temporally associated with the administration of blood or blood component(s) and that may or may not be the result of an incident or an interaction between a recipient and the blood product. The rate of adverse reactions is 0.24%, or 2.4 per 1,000 units transfused, a rate that does not differ from the reported 2.5 reactions per 1,000 units transfused in 2008 and that is below the range of other national hemovigilance reporting systems (3-7 events per 1,000 units transfused). It is likely that many adverse reactions are not reported to the transfusion service at all. Additional education is needed at all levels of the transfusion chain regarding adverse transfusion reactions and the ways to report them for full implementation of hemovigilance in the United States.

The rates reported for the various types of transfusion-related adverse reactions are included in **Table 8-2.**

There were significant decreases in the reported rates of febrile nonhemolytic transfusion reactions ($p<0.001$), severe allergic reactions ($p<0.001$), and posttransfusion purpura (PTP; $p<0.001$). There were significant increases in the reported rates of delayed serologic transfusion reactions ($p<0.005$), delayed hemolytic transfusion reactions ($p<0.05$), transfusion-associated circulatory overload (TACO; $p<0.05$), sepsis ($p=0.05$), and life-threatening reactions ($p<0.05$; **Figure 8-7**). Of the other adverse reactions, there were only 327 reports of transfusion- related acute lung injury (TRALI), or 1:63,940 **(Figure 8-8)**. This 28.8% decrease in reported TRALI cases as compared to 2008, while not statistically significant, may reflect the impact of TRALI mitigation strategies, but it could also represent a decline in identification and reporting. In support of this decrease indicating a real change in TRALI occurrence is the 2011 FDA summary report,* which shows a drop in the number of fatal-

**Fatalities Reported to FDA Following Blood Collection and Transfusion, Annual Summary for Fiscal Year 2011. http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/TransfusionDonationFatalities/ucm302847.htm*

Table 8-2. Transfusion-Related Adverse Reactions Reported to the Transfusion Service

Adverse Transfusion Reactions	Number of Occurrences 2011	2011 Reactions: Components Transfused (n=20,933,000 total components)
Total number of reactions that required any diagnostic or therapeutic intervention	50,570	1:414
Febrile, nonhemolytic transfusion reaction	21,865	1:957
Mild to moderate allergic reactions	14,106	1:1,484
Delayed serologic transfusion reaction	2,560	1:8,178
Transfusion-associated circulatory overload (TACO)	1,512	1:13,843
Hypotensive transfusion reaction	1,132	1:18,494
Delayed hemolytic transfusion reaction	1,018	1:20,569
Transfusion-associated dyspnea (TAD)	909	1:23,023
Severe allergic reactions	491	1:42,647
Transfusion-related acute lung injury (TRALI)	327	1:63,940
Post Transfusion Purpura	209	1:100,001
Acute hemolysis (due to other causes)	168	1:124,525
Posttransfusion sepsis	59	1:353,138
Acute hemolysis (due to ABO incompatibility)	42	1:495,207
Posttransfusion virus transmission	36	1:585,726
Transfusion-associated graft-vs-host disease	22	1:931,398
Reactions that were life-threatening, requiring major medical intervention following the transfusion; eg, vasopressors, blood pressure support, intubation, or transfer to the ICU	317	1:66,131

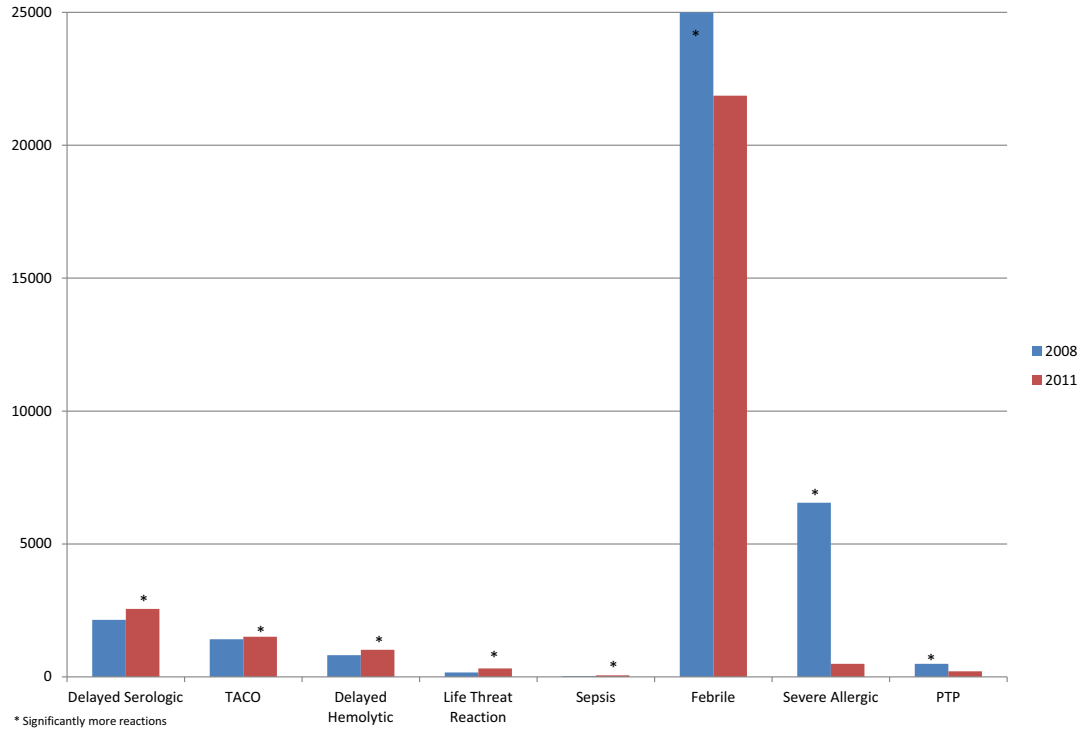


Figure 8-7. Adverse reactions by type, 2008 and 2011.

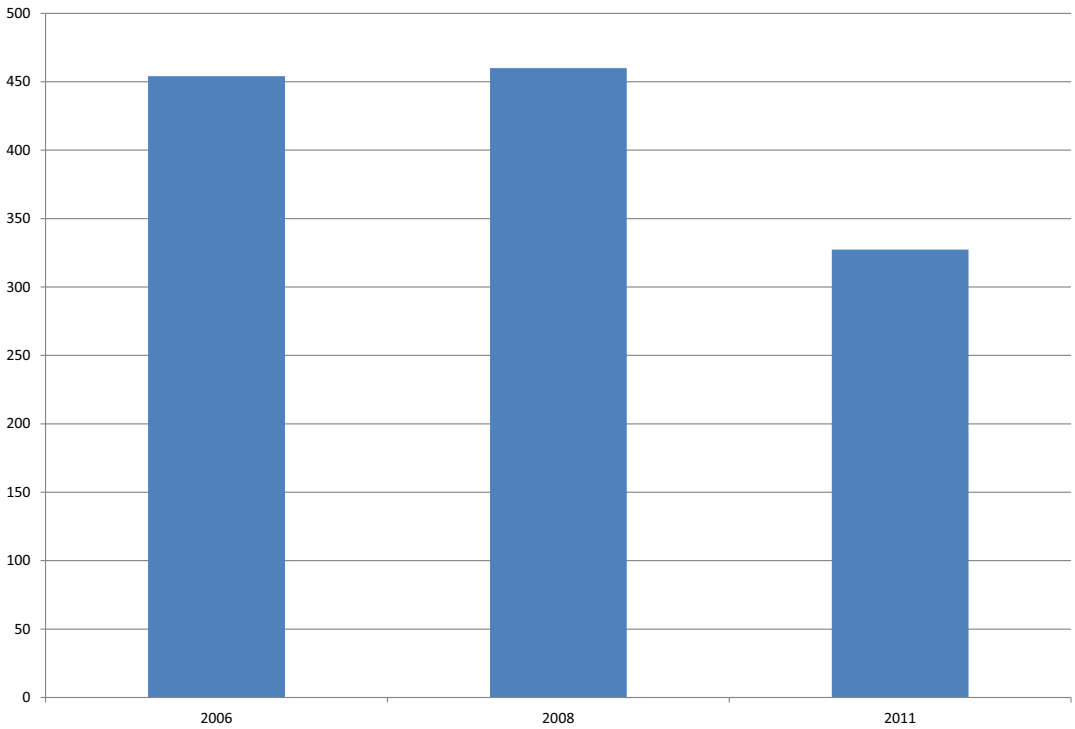


Figure 8-8. Reported TRALI by survey year.

ities attributed to TRALI from 16 in Fiscal Year 2008 to 10 in Fiscal Year 2011.

Participants reported whether they had an electronic system for tracking events, which were defined as unplanned, unexpected, and undesired occurrences. Forty-seven percent of hospitals reported having such a system to track events, which is comparable to the 52% reported in 2008. Hospitals reported 182,000 sample collection errors, nearly twice the 96,000 reported in 2008. Of these errors, 5,747 were wrong blood in tube (WBIT) errors (3.2% of sample collection errors). Hospitals with surgical volumes of 1,000 to 1,399 had a higher rate of WBITs per sample tested (0.06%), as well as of WBITs per sample error (9.1%). An estimated 18,643,784 patient specimens were submitted for testing in the blood bank, a 3.3% decrease from the estimated 19,290,000 specimens submitted in 2008. The error rate per specimen submitted was 0.98%, nearly twice the rate reported in 2008 (0.5%); this rate should be interpreted as a positive finding, as more hospitals become comfortable with reporting errors and events.

Tissue and Tissue Biovigilance

Fifty-five percent of all surveyed institutions reported maintaining an inventory of, or using, human tissue for transplantation. Of these institutions, most (84.7%) maintain and use human tissue, and the others (15.3%) reported using, but not maintaining, an inventory of human tissue.

As detailed in **Table 8-3**, the total number of human tissue implants or grafts that reporting facilities used or implanted was 496,000 in 2011, which represents a 25% increase in reported use from 2008. Tissue use reported through this survey instrument has increased each year of reporting since 2004, when the question was first included on the survey. The total number of implants or grafts reported to have been discarded was 10% greater than that reported in 2008. The number of implants or grafts that were reported returned increased to 35,000, and the number removed or explanted was 10,000. Reporting of this information has increased substantially since 2008.

There were 167 hospitals that reported maintaining an inventory of human skin (24.2% of the total number of hospitals reporting maintenance and use of human

Table 8-3. Human Tissue Implants/Grafts Used in 2011.

	2011			2008	
	Blood Centers	Hospitals	All Facilities	All Facilities	% Change 2008-2011
Used/implanted	6,000	490,000	496,000	398,000	25
Discarded	186	11,000	11,000	10,000	10
Returned	1,000	34,000	35,000	15,000	133

tissue). This tissue product is used for burn applications, traumatic wounds, and integument problems.

Hospitals reported the departments with primary responsibility for human tissue **(Figure 8-9)**. The surgery departments (45.3% of reporting hospitals) and the operating room (28.9% of reporting hospitals) most often had primary responsibility, including the ordering, receiving, storage, tracking, and/or issuance of human tissue.

Hospitals reported on the role of the blood bank/transfusion services in the use of human tissue **(Figure 8-10)**. It is clear that, most often, blood bank/transfusion services do not have a role in the use of human tissue in hospitals. However, in 2011, when they did play a role, blood banks were most likely to be involved in and to have oversight of tissue storage, to be involved in tissue issuing, and to have oversight of tissue tracking.

In 2011, 41 tissue-related adverse events were reported, for a rate of 1:12,000 implants/grafts used **(Table 8-4)**. Of these 41, 36 were reported to the FDA or a source tissue establishment. Some facilities were able to provide additional detail about these reactions, with bacterial infection being the largest category of reported events (1:25,000 implants/grafts). Rates are comparable to those reported in 2008. Events that were not or were partially imputable to the graft/implant and that may have been included in the last survey were not included.

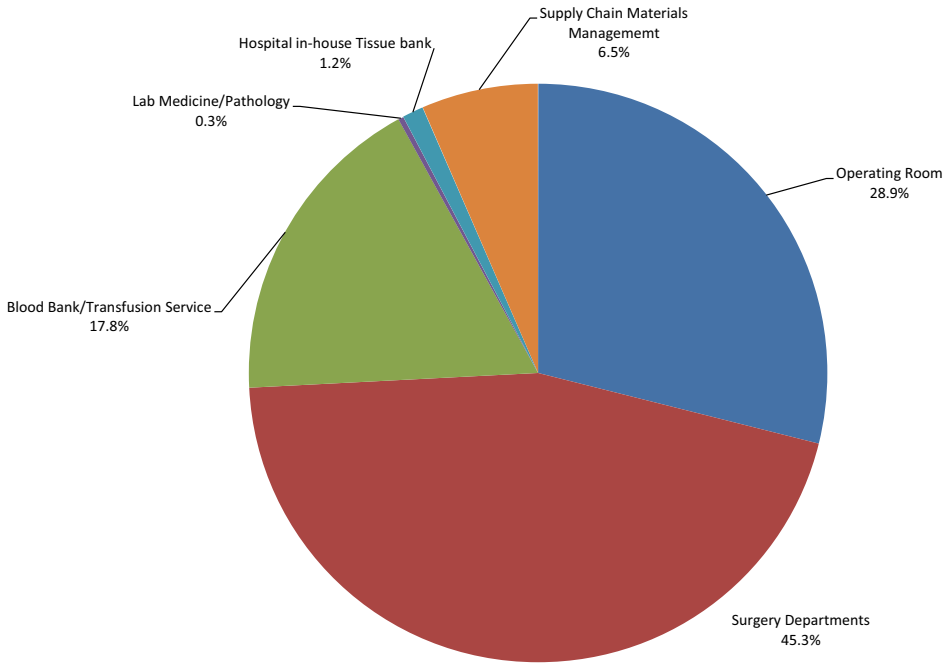


Figure 8-9. Department with primary responsibility for human tissue.

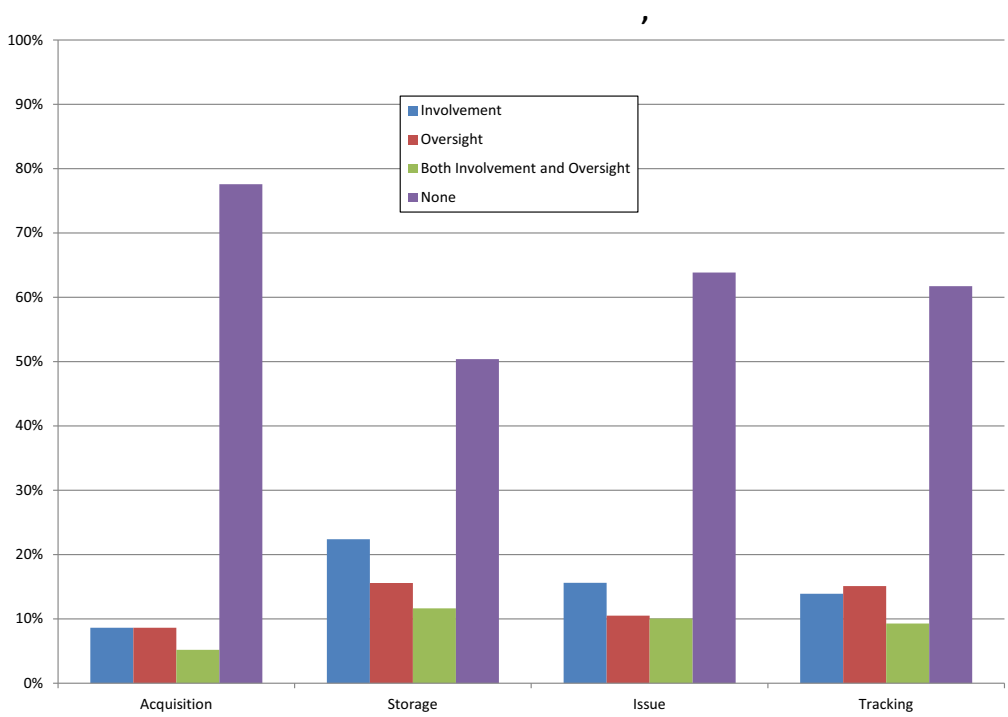


Figure 8-10. Role of blood bank/transfusion service in use of human tissue, 2011.

Table 8-4. Adverse Events Associated with Tissue Transplants in 2011,

	All Facilities	% of Total Reported Human Tissue Transplanted
Total Adverse Events	41	0.008
Viral transmission	0	0.000
Bacterial Infection	20	0.004
Fungal Infection	8	0.002
Graft Failure	3	0.001
Adverse Reactions of unknown cause	10	0.002
Events reported to FDA or Source Tissue Establishment	36	0.007

9. Component Costs

Hospitals were requested to report the average dollar amount paid per unit in 2011 for each of six specific components. In **Table 9-1**, the mean hospital cost for each component is presented and compared with the 2008 value. **Table 9-2** displays the mean hospital cost of each component by region of the country and provides a statistical comparison with the national average. The mean or average component costs are stratified by hospital surgical volume in **Table 9-3.**

All calculations are based on weighted estimates. Component costs are weighted in two respects. First, each component cost is weighted according to the number of units transfused by each facility. As a result, facilities that transfuse larger volumes of apheresis platelets will contribute more toward the estimated average component cost for apheresis platelets than will facilities with smaller transfusion volumes. Second, the sampling weights are also applied when calculating the average, which results in the final weighted estimates.

Red Blood Cells

The mean of the average amounts paid by hospitals for a unit of leukocyte-reduced (LR) RBCs in 2011 was $225.42 **(Table 9-1)**. This was a small increase (1.0%) from the 2008 average of $223.09. When analyzed by United States Public Health Service (USPHS) Region, the mean hospital amount paid in New England, New York–New Jersey, and California-Southwestern states (Regions I, II, and IX, respectively) was significantly higher than the national mean. Significantly lower means were found in the Southeastern, North Central, and Midwestern states (Regions IV, V, and VII, respectively).

When analyzed by surgical volume, the hospitals reporting 5,000 to 7,999 surgeries annually paid an average of $221.36 per unit, which is significantly lower than the mean price for RBCs ($p<0.05$). Smaller hospitals reporting 1,000 to 1,399 surgeries annually paid an average of $230.23 for each LR RBC unit, which is significantly more than the mean ($p<0.01$; **Table 9-3**).

Plasma

In 2011, hospitals reported the average dollar amount paid for plasma frozen within 8 hours of phlebotomy. The average was $57.91 per component unit **(Table 9-1)**, as compared to $57.78 in 2008 (0.2%). Analysis by USPHS Region indicated statistically higher costs in Regions VII, VIII, and X (Midwestern, Mountain, and Northwestern states, respectively) and significantly lower costs in Regions IV and V (Southeastern and North Central states) than the national average **(Table 9-2)**. Hospitals with a large surgical volume (≥8,000 surgeries

Table 9-1. Mean Hospital Amount ($) Paid per Selected Component Unit in 2008-2011*

Component	Average Amount Paid ($) 2011*	2008	% Change (2008-2011)	p-value
Red cells, leukocyte filtered	**$225.42**	$223.09	1.0	0.12
Plasma, frozen within 8 hours of phlebotomy	**$ 57.91**	$ 57.78	0.2	0.9
Plasma, frozen within 24 hours of phlebetomy	**$ 56.08**	$ 53.85	**4.1**	< 0.001
Apheresis platelets, leukocyte reduced	**$535.17**	$538.56	-0.6	0.47
Cryoprecipitate	**$ 62.41**	$ 65.10	-4.1	0.35

*Calculations are based on weighted estimates, which generally differ from the unweighted estimates by less than $1.00.

per year) paid significantly less than the mean for plasma frozen within 8 hours, whereas smaller hospitals paid significantly more **(Table 9-3)**.

The hospital cost for plasma frozen within 24 hours (PF24) after phlebotomy averaged $56.08 nationally **(Table 9-1)**, which is significantly higher than the 2008 average of $53.85 (4.1%, p<0.001). When analyzed by USPHS Region, hospitals paid statistically less per component unit in the South, in Regions IV (Southeastern states) and VI (South Central states). Hospitals paid statistically more per unit of PF24 in Regions I, III, and VII (New England, Mid-Atlantic, and Midwestern states, respectively). The smallest hospitals (100–999 surgeries per year) averaged costs of $60.58 per unit of PF24, which is significantly higher than the mean (p<0.01; **Table 9-3**).

Whole Blood-Derived (WBD) Platelets

The national hospital averages reported for a unit of WBD platelet concentrates (individual concentrates, not pooled) were widely variant and suggested reporting confusion between individual WBD platelet concentrates and pooled Acrodose platelet products. With the platelet product offerings in transition and with hospitals reporting discrepancies, the 2011 National Blood Collection and Utilization Survey (NBCUS) report does not include information on average prices paid for WBD platelets.

Apheresis Platelets

For a unit of apheresis platelets, hospitals paid an average of $535.17, which is essentially the same as the $538.56 paid in 2008 **(Table 9-1)**. The smaller hospitals (100–999 and 1,400–2,399 surgeries per year) paid significantly more in 2011 for apheresis platelets than did hospitals in other size categories **(Table 9-3)**.

The mean amount paid for apheresis platelets was significantly higher in USPHS Regions II, VI, and VIII (New York–New Jersey, South Central states, and

Table 9-2. Average Hospital Component Cost ($) by USPHS Region

		Mean Dollar Values									
		RBCs		Plasma, frozen (8hr)		Plasma, frozen (24hr)		Apheresis Platelets		Cryoprecipitate	
USPHS Region	No. of Hospitals*	Avg ($)	p-value	Avg ($)	p-value	Avg ($)	p-value	Avg ($)	p-value	Avg ($)	p-value
I	66	254.76	<.01	57.87	0.99	58.68	0.05	510.15	0.03	60.21	0.36
II	108	237.36	<.01	54.16	0.15	59.17	0.15	566.20	0.01	55.11	0.02
III	146	225.07	0.89	57.37	0.85	59.15	0.01	534.59	0.97	61.35	0.87
IV	191	213.49	<.01	53.16	< .01	52.32	< .01	531.30	0.42	49.65	< .01
V	194	212.30	<.01	53.98	< .01	55.22	0.25	502.47	<.01	77.85	0.13
VI	121	222.36	0.08	61.45	0.19	52.76	0.01	565.77	<.01	56.54	0.04
VII	75	209.03	<.01	74.23	0.05	60.24	< .01	507.78	0.25	69.31	0.75
VIII	42	253.26	0.19	64.91	< .01	61.45	0.11†	627.68	0.05	82.11	0.19
IX	104	246.80	<.01	64.79	0.12	56.70	0.73	526.27	0.34	66.33	0.29
X	51	230.68	0.65	72.42	< .01	63.70	0.09†	569.99	0.29	58.34	0.59
All Hospitals	1,098	225.42		57.91		56.08		535.17		62.41	

*The number of responses for each blood component varies because some hospitals did not provide answers to all questions. The number reported here is the maximum number of responses over the six survey questions.

†Based on more than 10 but fewer than 20 respondents.

Table 9-3. Average Hospital Component Cost ($) by Surgical Volume

		Mean Dollar Values									
		RBCs		Plasma, frozen (8hr)		Plasma, frozen (24hr)		Apheresis Platelets		Cryoprecipitate	
Annual Surgical Volume	No. of Hospitals*	Avg ($)	p-value	Avg ($)	p-value	Avg ($)	p-value	Avg ($)	p-value	Avg ($)	p-value
100-999	171	223.90	0.72	63.04	0.09	60.58	< .01	561.21	< .01	73.72	0.47
1,000-1,399	137	230.23	0.04	62.05	0.04	54.95	0.48	499.61	0.45	69.77	0.22
1,400-2,399	206	227.83	0.14	61.63	0.04	56.74	0.43	563.84	< .01	65.06	0.63
2,400-4,999	285	227.50	0.16	62.20	< .01	55.88	0.85	545.05	0.22	74.27	0.03
5,000-7,999	143	221.36	< .01	58.29	0.8	57.32	0.25	542.57	0.08	70.53	0.07
≥8,000	102	224.15	0.65	52.32	0.01	55.11	0.39	525.33	0.27	54.61	< .01
Unknown	54	225.60	0.96	54.50	0.07	52.16	0.09	498.30	< .01	45.99	< .01
All Hospitals	1,098	225.42		57.91		56.08		535.17		62.41	

*The number of responses for each blood component varies because some hospitals did not provide answers to all questions. The number reported here is the maximum number of responses over the six survey questions.

Mountain states, respectively; **Table 9-2**). The mean hospital cost was significantly lower for apheresis platelets in Regions I and V, the New England and North Central states, respectively.

Cryoprecipitate

The average 2011 hospital amount paid per component unit of cryoprecipitate decreased slightly, to $62.41, from $65.10 in 2008 (4.1%; **Table 9-1**). Hospitals with ≥8,000 annual surgeries paid significantly less ($54.61) **(Table 9-3)** than did the average hospital.

When stratified by USPHS Region **(Table 9-2)**, hospitals paid significantly less for cryoprecipitate in Regions II, IV and VI (New York-New Jersey, Southeastern, and South Central states, respectively).

Reimbursement

The 2011 Centers for Medicare and Medicaid Services (CMS) hospital outpatient prospective payment system (OPPS)* reimbursement rates for the six components assessed are reported in **Table 9-4**. Changes to hospital amounts paid for the different components ranged from a decrease of 4.1% to an increase of 4.1% between 2008 and 2011 **(Table 9-1)**, but the CMS OPPS reimbursement rate adjustments ranged from a decrease of 6.1% to an increase of 22.4%.

These figures show that a unit of apheresis platelets is the only component that is accurately reimbursed—that is, within 1% of the average cost paid by hospitals. The reimbursement for a unit of LR RBCs in 2011 was approximately 86.4% of the average hospital cost. For cryoprecipitate, reimbursement was approximately 80.9% of the average hospital cost of a unit. However, a unit of plasma for transfusion [fresh frozen plasma (FFP) or PF24] was reimbursed at 30% to 37% more than the reported average amount paid by hospitals in 2011.

CMS OPPS rates are reported here because they are the only clearly identifiable measure of Medicare reimbursement for individual blood components. Most Medicare reimbursement for blood is part of the diagnosis-related group (DRG) payment made for inpatient services and is impossible to tease apart from the other aspects of the DRG. Other payers besides Medicare pay for blood by using various mechanisms that are not included in this report.

**Department of Health and Human Services. Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2011 Payment Rates; Final rule with comment period..*

Summary

In summary, the average hospital costs for blood components were nearly the same between 2008 and 2011, with the exception of PF24, for which hospitals paid significantly more in 2011. Average amounts paid in 2011 for RBCs, FFP for transfusion, apheresis platelets, and cryoprecipitate all varied by less than 5% from 2008. Geographical regional costs, when they differ from the mean, tended to be higher in New England and New York–New Jersey (Regions I and II, respectively) and the Midwestern and Mountain states (Regions VII and VIII, respectively), and consistently lower in the Southeastern and North and South Central states (Regions IV, V, and VI, respectively). Smaller hospitals typically paid more than the national average for blood components. Large hospitals are able to

Table 9-4. CMS Hospital Outpatient Prospective Payment System Rates for Selected Blood Components

	Reimbursement Code		Hospital Average $ Paid	Reimbursement Rate			
Blood Component	CPT/HCPCS	APC	2011	2008*	2011†	% Change (2011-2008)	% Difference Between Hospital Average Paid and Reimbursed Rate
Red Blood Cells (leukocyte-reduced)	P9016	0954	225.42	185.15	194.86	5.2	-13.6
Fresh Frozen Plasma (frozen within 8 hours of phlebotomy)	P9017	9508	57.91	67.03	79.35	18.4	37.0
Fresh Frozen Plasma (frozen between 8 and 24 hours of phlebotomy)	P9059	0955	56.08	77.93	73.15	-6.1	30.4
Apheresis platelets (leukocyte-reduced)	P9035	9501	535.17	499.53	538.51	7.8	0.6
Cryoprecipitate	P9012	0952	62.41	41.24	50.49	22.4	-19.1

*Department of Health and Human Services. Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2008 Payment Rates; Final rule with comment period.
†Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2011 Payment Rates; Final rule with comment period.
CMS = Centers for Medicare and Medicaid Services; CPT = Current Procedural Terminology; HCPCS = Health-care Common Procedure Coding System; APC = Ambulatory Patient Classification.

obtain favorable pricing agreements with suppliers based on the volume purchased. Suppliers may also offer hospitals preferential pricing for components that are closer to expiration, an option that would be feasible only for large transfusion services.

10. Cellular Therapy Products

In the early 1980s, there were fewer than 1,000 transplants each year worldwide. Thirty years later (2011), more than 170,000 autologous donations were reported in the United States (in such procedures, a patient banks cells, undergoes a medical treatment – most often chemotherapy – and then receives a transplant of his or her own cells), as were more than 150,000 allogeneic donations (in which a related or unrelated donor provides cells for a patient).

The 2011 National Blood Collection and Utilization Survey (NBCUS) captured data on collection, processing, and infusion of cellular therapy (CT) products, including hematopoietic progenitor cells (HPC) collected by apheresis (HPC-A), HPCs derived from marrow (HPC-M), and HPCs from cord blood (HPC-C). As in previous surveys, the 2011 survey included questions on the collection, processing and infusion of donor lymphocyte infusions [DLI, or unmanipulated, nonmobilized, peripheral blood mononuclear cells (MNCs)], immunotherapies (natural killer cells, dendritic cells, T cells, and others), hematopoietic stem/progenitor cells (expanded), nonhematopoietic stem cells [mesenchymal stem cells (MSCs) or multipotent stromal cells (per recommendations), or others], and other products.

The 2011 CT responses are compared with the responses from the 2007 NBCUS, which reflected the CT activities in 2006. The 2009 NBCUS CT data were not reported, because of problems with the CT sample and the inability to appropriately weight the data for comparison. Data reported here are weighted except where noted.

Characterization of Reporting Facilities

AABB identified and surveyed a cohort of cord blood banks beyond its membership, as well as AABB member cord blood banks, blood centers, and hospitals in this survey. The majority of independent cord blood banks are private and handle HPC-Cs that are collected, stored, and processed at the private expense, and for the future use, of a family. Seventy cord blood banks were included in the sample for the 2011 NBCUS, and 20 of them submitted responses. Three respondents collected only autologous HPC-Cs, seven collected only allogeneic HPC-Cs, and four reported collecting both autologous and allogeneic products. The remaining facilities collect other CT products.

The relative proportions of collection, processing, and infusion activities performed by cord banks, blood centers, and hospitals are shown in Tables **10-1, 10-2, 10-3, and 10-4**, respectively. HPC-A and HPC-M collection, processing, and infusion activities continue to be more common in hospitals than in blood centers because

Table 10-1. Autologous Cell Therapy Product Collections Performed

	Blood Centers		Hospitals		Cord Blood Banks		All Facilities		
Product Type	No.	Products Collected	No.	Products Collected	No.	Products Collected	Products Collected	All Products 2006	% Change 2006-2011
HPC-A	18	5,442	56	14,829	8	2,223	22,493	17,585	27.9
HPC-M	1	3	9	67	1	4	74	189	-61.0
HPC-C	1	1	11	3,865	7	118,692	122,558	96,563	26.9
Lymphocytes	1	3	3	107	1	4	114	32	255.2
Immunotherapies	12	1,473	11	263	4	812	2,549	138	1746.8
Hematopoetic stem/progenitor cells, expanded	-	-	1	29	-	-	29	218	-86.5
Nonhematopoietic stem cells	-	-	2	16	1	102	118	365	-67.7
Other Products	4	263	4	97	1	24,560	24,920	15	166030.2
All Products		7,185		19,274		146,395	172,854	115,105	50.2

Table 10-2. Allogeneic Cell Therapy Product Collections Performed

	Blood Centers		Hospitals		Cord Blood Banks		All Facilities		
Product Type	No.	Products Collected	No.	Products Collected	No.	Products Collected	Products Collected	All Products 2006	% Change 2006-2011
HPC-A	17	1,399	43	3,679	7	683	5,760	4,130	39.5
HPC-M	-	-	33	870	4	102	972	768	26.6
HPC-C	2	5,713	6	3,599	11	140,049	149,361	44,028	239.2
Lymphocytes	5	675	21	368	3	25	1,067	752	41.9
Immunotherapies	-	-	5	175	2	14	189	88	114.8
Hematopoetic stem/progenitor cells, expanded	-	-	1	2	1	21	23	133	-82.7
Nonhematopoietic stem cells	-	-	1	22	-	-	22	204	-89.2
Other Products	-	-	2	55	1	91	146	81	80.2
All Products		7,786		8,770		140,984	157,540	50,184	213.9

Table 10-3. Cellular Therapy Products Processed

	Blood Centers		Hospitals		Cord Blood Banks		All Facilities		
Product Type	No.	Products Processed	No.	Products Processed	No.	Products Processed	Products Processed	All Products 2006	% Change 2006-2011
HPC-A	10	1,095	45	20,849	8	3,308	25,252	22,014	14.7
HPC-M	6	150	27	938	5	161	1,249	639	95.5
HPC-C	4	1,006	15	1,363	14	159,030	161,399	163,229	-1.1
Lymphocytes	4	40	22	391	2	46	476	689	-30.9
Immunotherapies	0	0	12	412	1	7	419	104	302.9
Hematopoetic stem/progenitor cells, expanded	0	0	2	5	0	0	5	-	-
Nonhematopoietic stem cells	0	0	6	229	2	2,594	2,822	103	2639.8
Other Products	1	24	6	2,200	1	20,762	22,986	19	120878.9
All Products		2,316		26,387		185,906	214,608	186,797	14.9

Table 10-4. Cellular Therapy Products Issued and/or Infused

	Blood Centers		Hospitals		Cord Blood Banks		All Facilities		
Product Type	No.	Infusion Episodes	No.	Infusion Episodes	No.	Infusion Episodes	Infusion Episodes	Episodes 2006	% Change 2006-2011
HPC-A	9	385	60	12,345	7	1,607	14,336	10,486	36.7
HPC-M	3	115	33	1,036	4	126	1,277	925	38.1
HPC-C	4	50	30	759	4	77	885	972	-8.9
Lymphocytes	3	33	28	492	4	49	574	530	8.2
Immunotherapies	-	-	9	803	-	-	803	259	210.0
Hematopoetic stem/progenitor cells, expanded	-	-	3	13	-	-	13	31	-59.1
Nonhematopoietic stem cells	-	-	8	318	1	231	549	118	365.5
Other Products	-	-	6	1,051	-	-	1,051	619	69.8
All Products		583		16,816		2,090	19,488	13,940	39.8

those activities are most often part of a stem cell transplant program, which is a hospital-based activity. The 141 facilities that completed the Cellular Therapy Section of the 2011 NBCUS described their program as performing the following activities (**Figure 10-1**):

- Collects HPCs (20%)
- Processes HPCs (15%)
- Stores HPCs (15%)
- Infuses/transplants HPCs (16%)
- Collects cord blood (7%)
- Processes cord blood (6%)
- Stores cord blood (8%)
- Infuses/transplants cord blood (10%)
- Other (3%)

Many programs perform more than one of these activities: 18 facilities reported that their program collects, processes, stores, and infuses HPCs; 13 programs collect, process, store, and infuse HPCs and also infuse/transplant cord blood. Eight programs collect, process, store, and infuse HPCs; infuse/transplant cord blood; and store cord blood. Six facilities collect and infuse only HPCs. A number of other individual combinations of functions were reported. Facilities reported "other" activities that included the collection of platelet-rich plasma, somatic cells, and nonmobilized, nonmanipulated MNCs for immunotherapies and research.

Of those programs responding that they performed some collection activity, 48% reported collecting

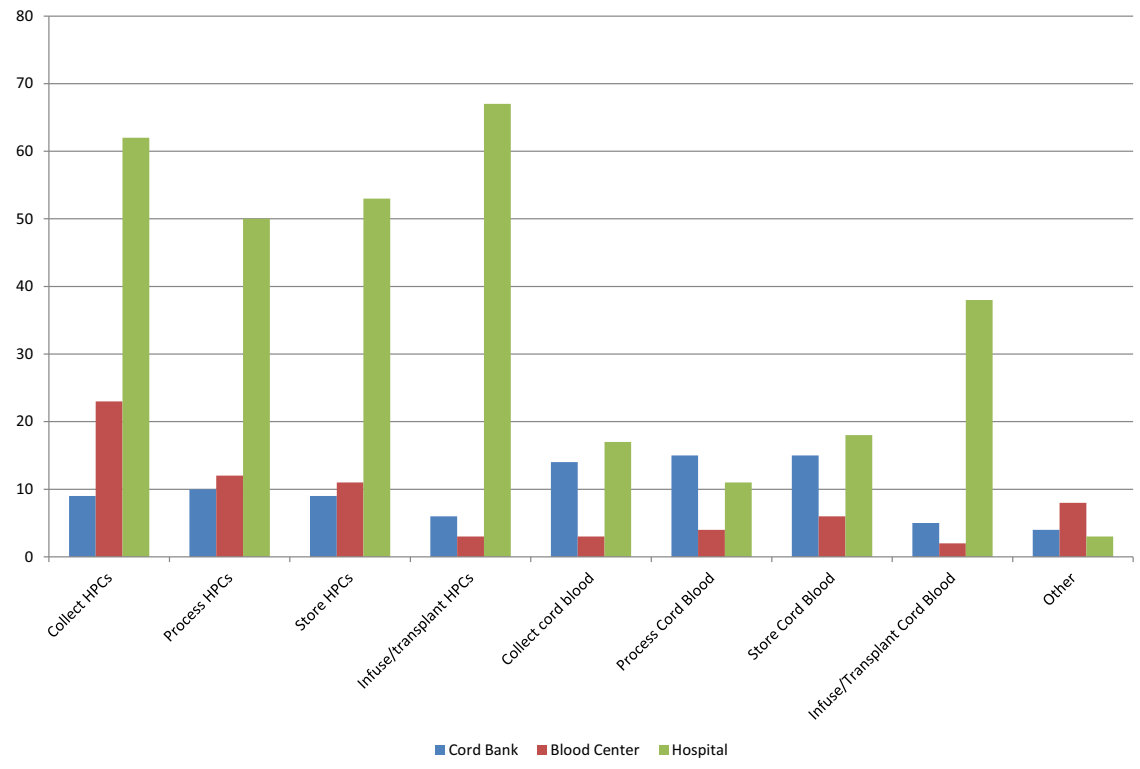


Figure 10-1. Cellular therapy activities performed by facility type 2011.

products for third-party vendors, including cord blood banks, the National Marrow Donor Program (NMDP), and other suppliers of CT products. Of those facilities that collect for third parties, most collect HPC-As (66%) and HPC-Ms (34%). Thirty-one percent collect HPC-Cs, and 10% collect other products. Those collecting HPC-As for third parties were most often collecting between 10 and 100 products per year. Those reporting collections of HPC-Ms for third parties were more likely to report collecting fewer than 10 products per year. Six cord banks collecting for third parties reported collecting more than 500 such products per year.

Of the facilities reporting that their program collects cord blood, 76% use a nurse midwife or obstetrician to perform the collection; the others reported using a dedicated cord blood bank collector or a combination of the two. Facilities reported their status regarding cord blood product licensure **(Figure 10-2)**. Thirty-three percent of eligible responding facilities either were licensed or were engaged in the licensure process. Of those eligible for licensure, two-thirds are not seeking licensure at this time.

Facilities that infuse or transplant were queried regarding the use of CT products for purposes other than hematopoietic reconstitution. Of the few that responded positively, six facilities were using CT products for cardiac applications, seven for immune therapies, and one each for

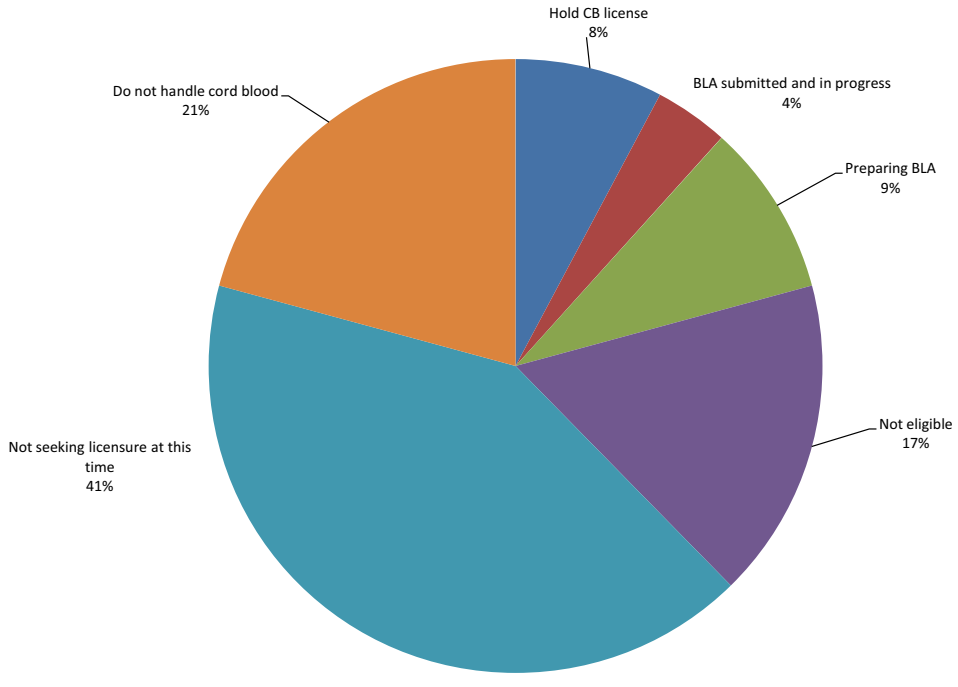


Figure 10-2. Cord blood licensure.

orthopedic applications and autoimmune disease. Eight reported other indications, including kidney transplant, prostate cancer, Crohn's disease, stroke, amyotrophic lateral sclerosis (ALS), and graft-versus-host disease.

Collections

Autologous and allogeneic CT product collections are illustrated in Tables **10-1 and 10-2** and **Figures 10-3 and 10-4**, respectively. HPC-C products made up the largest category of CT products collected in 2011: 94.8% of allogeneic collections and 70.9% of autologous collections. HPC-A products made up the next-largest group. The majority of HPC-A products collected were autologous (13.0%). There has been a 27.9% increase in reports of autologous HPC-A collections since 2006. Allogeneic HPC-A collections increased by 39.5%. Blood centers were responsible for 24% of HPC-A collections but for only approximately 5% of all CT products.

Private/family (or autologous) HPC-C collections (collections intended for the use of the family from whom they were collected and whose collection and storage costs are paid by the family) continued to increase over the reported collections in 2006 (26.9% increase). Allogeneic HPC-C collections have increased considerably since 2006 (239%), with the numbers reported now exceeding the numbers of autologous cord blood collections for the first time.

An increase in the collection of autologous immunotherapies by blood centers and a large increase in the collection of these products overall have occurred since 2006. Lymphocyte collections increased as well, particularly autologous cell collections, which

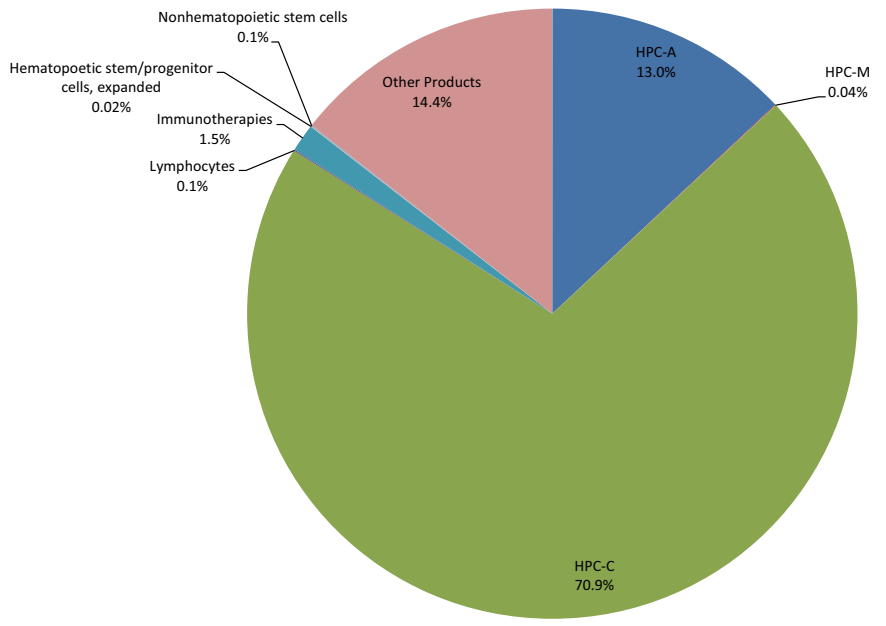


Figure 10-3. Autologous CT products collected in 2011.

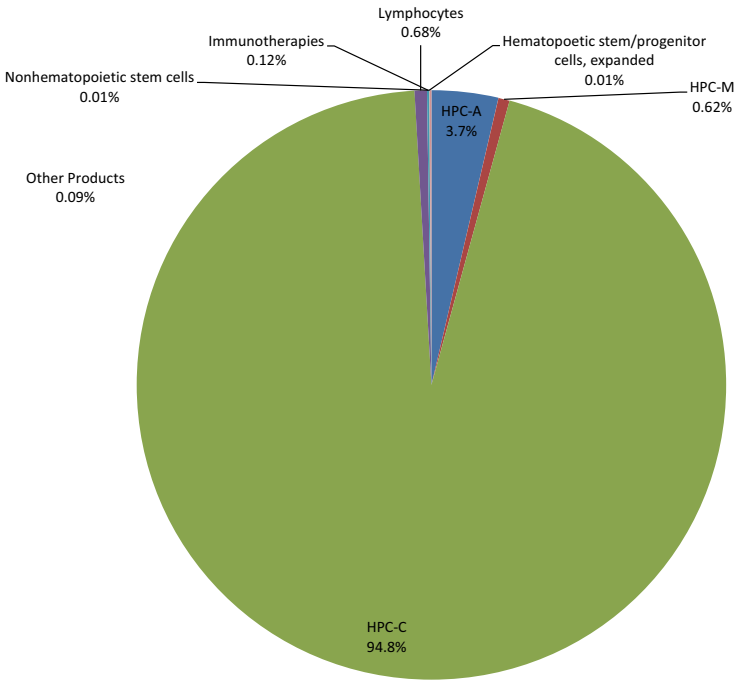


Figure 10-4. Allogeneic CT products collected in 2011.

increased by more than 250%. There were large increases in the number of other types of both autologous and allogeneic collections. Facilities reported that these included somatic cells for commercial use, parathyroid tissue, donor granulocytes, and MNCs.

Two product categories displayed decreases in both autologous and allogeneic collections: hematopoetic stem cell/progenitor cells and expanded and nonhematopoietic stem cells (MSCs or multipotent stromal cells). Autologous HPC-M collections decreased, while allogeneic HPC-M collections increased over the five-year period.

Processing

Processing activity for cellular therapy products is detailed in **Table 10-3** and **Figure 10-5**. The number of HPC-C units processed was very close to the number reported in 2006. The ratio of collected to processed HPC-C units was 1.7:1 because of inadequate collection, contamination, and other quality concerns.

Processing of HPC-M units increased by 95.5% in 2011 over the number processed in 2006. Increases in the number of units processed were seen in HPC-A, immunotherapies (natural killer cells, dendritic cells, T cells, and others), nonhematopoietic stem cells (eg, MSCs), and other products.

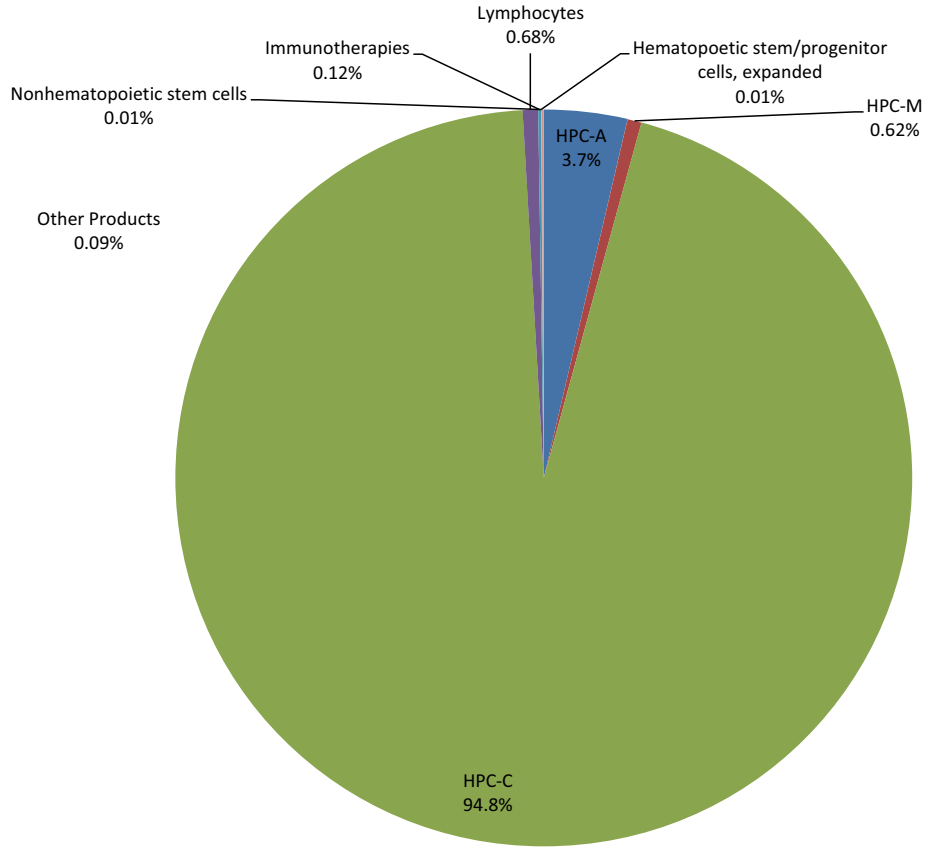


Figure 10-5. Processing of all CT products in 2011.

Infusion

Issue/infusion activity **(Table 10-4 and Figure 10-6)** increased in comparison to 2006 for all CT product types (39.8% increase overall) except hematopoietic stem/progenitor cells, expanded. A 37% increase in HPC-A infusion procedures was reported, as was an increase in both autologous and allogeneic recipients (50% and 58%, respectively). The number of HPC-M infusion procedures increased by 38%, while the number of allogeneic infusion recipients increased by 63%. The number of autologous HPC-M recipients decreased by 59%. While autologous (or family) cord blood banking remains a popular option, the data show that infusions of autologous HPC-C are rare events, with just 10 recipients reported in 2011.

Most infusions in the private banking system are currently used for siblings needing transplants. The numbers of recipients of other CTs are listed in **Table 10-5**, and they provide an indication of the distribution of the procedures among hospitals and the numbers of patients for whom they are prescribed.

For the 2011 NBCUS, the list of potential options

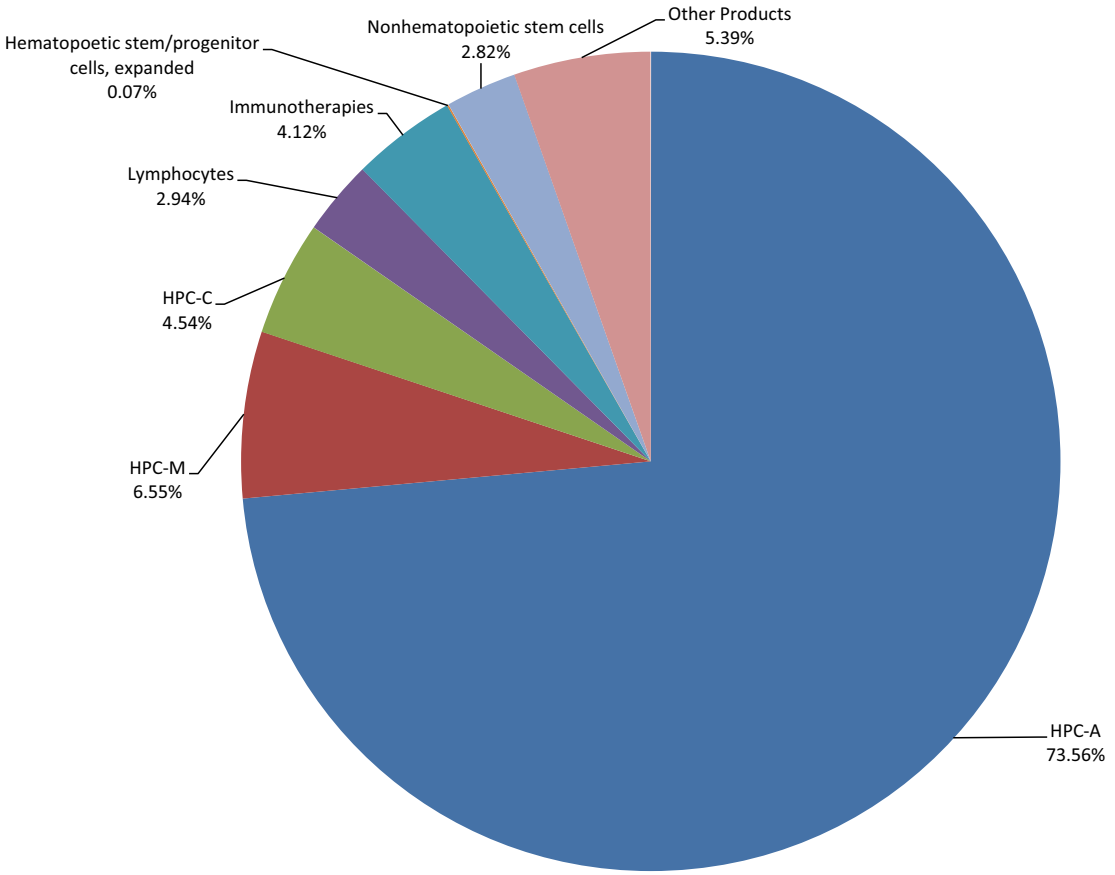


Figure 10-6. Infusions of CT products in 2011.

from which to choose was expanded in an effort to limit the number of infusion episodes that are categorized as "Other." Nevertheless, 1,051 infusions were grouped into this category, making up 5% of all infusions. It is possible that these represent the tumor vaccines, procedures which are more commonly performed in academic hospitals, as is consistent with all reports of such procedures being hospital-based. In these trials, recipients may receive multiple infusions or injections. These infusions are also 10 times as likely to be autologous infusions, with the exception of allogeneic MSCs for graft-versus-host disease treatment, which is currently in clinical trials. Ninety-one percent of these "other" infusions were autologous and went to 90 recipients.

Adverse Events

Adverse reactions are not uncommon in CT collections and infusions because of the underlying condition of the autologous patient/donor or the allogeneic recipient. **Table 10-6** shows that the numbers of severe donor-related adverse events for autologous donors, while small, are higher (0.04% of collections) than those in presum-

Table 10-5. Cellular Therapy Products Recipients

	No. of Recipients				
Product Type	Autologous	Allogeneic	Total	Recipients 2006	% Change 2006-2011
HPC-A	8,696	4,154	12,850	8,417	52.7
HPC-M	70	1,220	1,290	918	40.6
HPC-C	10	783	794	848	-6.4
Lymphocytes	67	338	405	462	-12.2
Immunotherapies	217	96	312	118	164.7
Hematopoetic stem/progenitor cells, expanded	33	14	47	31	53.0
Nonhematopoietic stem cells	16	108	125	28	345.8
Other Products	90	53	143	147	-2.5
All Products	9,200	6,768	15,968	10,969	45.6

Table 10-6. 2011 Adverse Events

	Number of Autologous Events	Autologous Event Rate per Collection or Infusion (%)	Number of Allogeneic Events	Autologous Event Rate per Collection or Infusion (%)
Severe HPC Donor-Related Adverse Events	78	0.04	17	0.01
Recipient Adverse Events (all products)	1,179	10.3	1,121	13.9
Severe Recipient Adverse Events (all products)	21	0.2	106	1.3

ably healthy allogeneic CT donors (0.01% of collections).

Adverse events in the patient or recipient are common and were reported in 10.3% of autologous infusion episodes and in 13.9% of allogeneic infusion episodes. Of these adverse events, only a small number of them were severe; a greater rate of severe reactions was reported in allogeneic infusion patients (1.6% of patients) than in autologous infusion patients (0.2% of patients). The reactions reported for allogeneic infusion patients were more likely to be severe (9.5% of their reactions were severe) than were reactions reported for autologous infusion patients (1.8% of their reactions were severe).

11. Platelet Facts

- Platelets are collected two in ways: they can be collected by platelet apheresis (an automated procedure whereby the platelets are separated from the donor's blood and retained, while the red cells and most of the collected plasma are returned to the donor), or they can be separated or derived from a unit of whole blood [whole blood-derived (WBD) platelets].
- Both apheresis platelets and WBD platelets are considered platelet products.
- WBD platelets are sometimes referred to as platelet concentrates, and each unit of WBD platelets comes from a single unit of whole blood.
- Approximately five platelet concentrates are the equivalent of an apheresis platelet unit, according to industry practice. Therefore, an apheresis-equivalent unit is equal to five WBD platelets.
- Each apheresis collection is a platelet collection procedure, but depending on the donor's platelet count, some apheresis collections produce more than one unit of platelets.
- An apheresis platelet collection can be split to produce more than one therapeutic unit; if it is split into two units, it is called a double collection, and if it is split into three units, it is called a triple collection.
- A platelet unit can be the product of an apheresis collection, a subproduct (split) of an apheresis collection, or a WBD platelet concentrate.
- A dose is the amount transfused to a patient at one time.

12. Appendix: Methods

Sample Frame and Selection

The sampling frame for the 2011 National Blood Collection and Utilization Survey (NBCUS) was constructed by AABB and was composed of three categories of institutions:

- Cord Blood Banks
- Blood Centers
- Hospitals

The cord blood banks and blood centers were identified by AABB and were selected with certainty.

The sample frame for hospitals was defined by using two sources of information, the American Hospital Association (AHA) membership and the membership of the American Association of Blood Banks (AABB). Eligible population members included nonfederal hospitals located within the 50 United States and the District of Columbia and Veterans Affairs hospitals. Most hospitals identified in the AHA membership have information regarding the number of inpatient surgeries performed in a year that could be used for stratification. Hospitals with known surgical volume of fewer than 100 annual inpatient surgeries were excluded from the sample frame. In addition, hospitals with 100-999 surgeries that were identified as Long-Term Care facilities were removed from the sample frame. Hospitals on the AHA list with inpatient surgical volume between 100 and 999 were sampled with a sampling probability of 40%. All hospitals with unknown surgical volume or with a known surgical volume of 1,000 or more inpatient surgeries per year were included in the sample. **Table A-1** summarizes the sample frame and sample design.

To control the random sample of smaller hospitals by geographic location, the hospital sample was further stratified by USPHS Region, so that a fixed sample size representing 40% was selected in each region, as shown in **Table A-2**.

Imputation of Data Items

Data Apportionment

A responding institution could provide data not only for itself but also for other institutions. A new record was created for each institution for which information could be obtained and which could be verified as being in the population of interest (even if not in the original sample frame). The information in the new record was created by copying certain categorical data from the responding institution's records and apportioning other data fields, as described elsewhere. Therefore, the information collected from another institution in this manner is not as complete as it would be if the full survey had been supplied.

Table A-1. NBCUS Sample Frame and Sampling Rates

Institution Type	Frame	Sample	Sampling Probability (%)
Cord Blood Banks	70	70	100
Blood Centers	133	133	100
Hospitals			
100– 999 surgeries per year (AHA)	1,644	657	40
100– 999 surgeries per year (AABB)	49	49	100
1,0001,399 surgeries per year	389	389	100
1,400–2,399 surgeries per year	617	617	100
2,400–4,999 surgeries per year	795	795	100
5,000–7,999 surgeries per year	338	338	100
8,000 or more surgeries per year	264	264	100
Unknown Surgical Volume	145	145	100
Total Facilities	4,444	3,457	

Item Imputation

Approximately 30 critical questions on responding blood center surveys were analyzed for missing data. Missing values were imputed on 58 responding blood centers, for a total of 133 imputed data items. In all cases, the imputation was based on models of association between variables. When an institution provided data on the 2008 survey, those data values were used. When those data were not available, the

Table A-2. Sample Selection for AHA Hospitals with 100-999 Surgeries Per Year

USPHS Region	Region Definition*	Population	Sample
I	CT, ME,MA,NH,RI,VT	71	28
II	NJ,NY	39	16
III	DE,DC,MD,PA,VA,WV	105	42
IV	AL,FL,GA,KY,MS,NC,SC,TN	302	121
V	IL,IN,MI,MN,OH,WI	337	135
VI	AR,LA,NM,OK,TX	303	121
VII	IA,KS,MO,NE	148	59
VIII	CO,MT,ND,SD,UT,WY	113	45
IX	AZ,CA,HI,NV	133	53
X	AK,ID,OR,WA	93	37
Total		1,644	657

*Restricted to the 50 states and the District of Columbia.

imputation was based on modeled relationships for the current survey responses. Imputed data fields are flagged to allow the analyst to identify the cases that were imputed.

Response Rates and Sample Weights

A responding institution could provide data not only for itself but also for other institutions. These data provided information for institutions that otherwise did not respond. However, that information added a level of complexity, as data were provided for institutions in the sample frame but not in the sample (hospitals with 100-999 surgeries) and for institutions not originally in the sample frame. Moreover, the information collected from another institution in this manner is generally not as complete as it would be if the full survey had been supplied.

Overall response rates are summarized in **Table A-3** and discussed in detail below.

Cord Blood Banks

Data were provided for only 20 of the 70 cord blood banks, including 8 cases for which the response was provided by another institutional entity (eg, the cord blood bank was a part of the reporting hospital), as summarized in **Table A-4**.

No attempt was made to model or use adjustment cell techniques to model the nonresponse patterns. The responding cord blood banks were weighted as if a random sample of 20 had been selected from the 70, and the adjusted weight for respondents is 3.5 (70/20).

Blood Centers

The initial sample frame contained 133 blood centers (or 90 blood centers if regional sub-centers are not counted separately). After the survey had been administered and responses had been obtained, it was discovered that three additional blood centers were mistakenly excluded from the sample frame. These three blood centers were included in the population of inference and were treated as nonresponders, as if the survey had been sent to them but they failed to respond. An additional five surveyed blood centers failed to respond.

The weights were adjusted for nonresponse by stratifying the blood centers by the

Table A-3. Response Rate Summary and Comparison with Previous Surveys

Facility Type	2011	2009	2007	2005
Blood Centers	96.3% (131/136)	93.3% (126/135)	91.4% (128/140)	92.3% (131/142)
Hospitals (all)	42.3% (1,342/3,175)	51.5% (1,529/2,970)	59.9% (1,707/2,848)	56.8% (1,604/2,825)
Cord Blood Banks	28.6% (20/70)	20.8% (5/24)	51.9 (14/27)	33.3% (3/9)
Total	44.1% (1,493/3,381)	53.1% (1,660/3,129)	61.3% (1,849/3,015)	58.4% (1,738/2,976)

Table A-4. Final Disposition of Cord Blood Banks

Category	Number
Respondents	20
Responded for themselves	12
Reported by a hospital	4
Reported by a blood center	4
Nonrespondents	50
Total	70

number of Red Blood Cell (RBC) collections (estimated or obtained separately for the nonrespondents) as shown in **Table A-5.**

The three blood centers that were missed in the survey operation were included in the population counts and were considered to be equivalent to the other nonrespondents (**Table A-6**).

Hospitals

The sample of hospitals offered some challenges. Whereas the sample design was straightforward, the resulting data were complicated, because hospitals reported for themselves and for other hospitals. In addition, blood centers could report transfusion information for hospitals. In this way, data were received for 24 hospitals that were in the sample frame but were not selected in the random sample. For the purposes of weighting, these cases are included as if they had been selected with certainty (base weight of 1.0), and the base weights for the random sample selected in each stratum were adjusted accordingly. In addition, data were received for 12 hospitals that were not originally in the sample frame; the data were retained but represent only themselves, with a final weight of 1.0.

Table A-7 summarizes the base weights for the hospital sample. The base weight is the inverse of the probability of selection. As mentioned earlier, the random sample of hospitals with surgical volume less than 1,000 procedures was further stratified by USPHS Region. When these weights were adjusted for the collection of data for 24 additional hospitals not selected in the sample, the resulting base weights varied slightly from 2.5, by Region.

After selection, it was determined that 79 institutions included in the sample frame were out-of-scope (eg, military) or were duplicate listings for the same hospital, as summarized in **Table 7-1**. Because it could not be guaranteed that all such out-of-scope institutions were identified in the sample frame, these cases were not removed from the sample frame for calculating the weights. The out-of-scope and duplicate institutions were retained in both the population counts and as respondents for the raking process (**Table A-8**).

Raking adjustments were made to the sample weights

Table A-5. Final Disposition of Blood Centers

Collections	In-Frame Respondents*	In-Frame Nonrespondents	Number Missed in Sample Frame	Total
RBC Collections >50,000	94	0	0	94
RBC Collections ≤ 50,000	34	5	3	42
Total	128	5	3	136

*Each regional office of the national blood centers is counted as a separate selection.

Table A-6. Weights for Blood Centers

Volume of RBC Collections	Total	Respondents	Weight
>50,000	94	94	1.0
≤ 50,000	42	34	1.2353

Table A-7. Base Weights for Hospitals

Surgical Volume	Sample Source	Number in Stratum (Adjusted)	Number Selected	Base Weight
100–999	Original Random Sample	1,620	633	2.375–2.5
		24	24	1.0
	Selected with Certainty	49	49	1.0
1,000–1,399	Original Sample	389	389	1.0
1,400–2,399	Original Sample	617	617	1.0
2,400–4,999	Original Sample	795	795	1.0
5,000–7,999	Original Sample	338	338	1.0
≥ 8,000	Original Sample	264	264	1.0
Unknown	Original Sample	145	145	1.0
Subtotal		4,241	3,254	
Not included in the Original Sample Frame		NA	12	1.0

Table A-8. Out-of-Scope Hospitals and Duplicate Listings

Description	Total Number
Military Hospitals	5
Duplicate of Blood Center	3
Duplicate of another Hospital in the Sample Frame	71
Total	79

to correct for differential response rates. This is a technique by which, generally, weights are adjusted within adjustment cells that are created to define categories or cells for which the cases have both similar values for the survey questions and similar likelihood of response. The first criterion is the most important. In this case, adjustments were calculated so that the weighted estimates would agree with the sample frame totals by surgical volume and by USPHS Region.

Raking is an iterative process whereby the weights are first adjusted so that the weighted totals match one marginal distribution. The totals estimated by using these adjusted weights are then compared to the second set of marginal totals and adjusted. The weights are adjusted iteratively until they converge — that is, until the changes made by successive iterations are insignificant. **Table A-10** summarizes the two population marginal distributions used in the raking process and the initial estimates using the design weights.

Table A-9 summarizes the response rates for hospitals in the original sample frame, including the 24 hospitals for which data were collected even though the hospital was not selected in the random sample.

The weights were adjusted by using all respondent cases, including those that were determined to be out-of-scope or duplicative. This was necessary because all out-of-scope hospitals could not be identified in the entire sample frame. Therefore, the weights were adjusted to agree with the only known population counts, namely, all hospitals in the original sample frame. The resulting weights when applied to only the in-scope cases provide estimates of the in-scope, unique hospitals. **Table A-11** and **Table A-12** summarize the raked weights and the final estimation for in-scope, unique hospitals, first by surgical volume and then by USPHS Regions.

Figure A-1 shows the USPHS Regions distribution of responding blood centers and hospitals. **Table A-13** and **Table A-14** provide summary information about the raking factors and results.

Table A-9. Response Rates for the Hospital Sample

Surgical Volume	Original Sample			Eligible Hospitals		
	Number	Response	Percentage	Number	Response	Percentage
100– 999	706	250	34.2	681	241	33.0
1,000–1,399	389	163	41.9	387	161	41.6
1,400–2,399	617	246	39.9	614	245	39.9
2,400–4,999	795	348	43.8	780	339	43.5
5,000–7,999	338	177	52.4	328	168	51.2
≥ 8,000	264	130	49.2	245	122	49.8
Unknown	145	68	46.9	140	66	47.1
Total	3,254	1,382	42.2	3,175	1,342	42.3

Table A-10. Known Population Totals and Initial Estimates using Base Weights for Respondents

USPHS Regions	Population (N)	Respondent Estimate (Base Wt)	Surgical Volume	Population (N)	Respondent Estimate (Base Wt)
I	200	92.36 (46%)	100–999	1,693	550.65 (33%)
II	261	131.25 (50%)	1,000–1,399	389	163 (42%)
III	380	199 (52%)	1,400–2,399	617	246 (40%)
IV	841	310.49 (37%)	2,400–4,999	795	348 (44%)
V	789	312.96 (40%)	5,000–7,999	338	177 (52%)
VI	637	222.04 (35%)	≥ 8,000	264	130 (49%)
VII	275	119.90 (44%)	Unknown	145	68 (47%)
VIII	194	72.87 (38%)			
IX	479	148.91 (31%)			
X	185	72.89 (39%)			
Total	4,241	1,682.65 (40%)		4,241	1,682.65 (40%)

Table A-11. Final Estimates by Surgical Volume Categories

Surgical Volume	Population Control Total	Raked Estimate (Total)	In-Scope Sample	Estimated In-Scope Total
100– 999	1,693	1,693	241	1,619.62
1,000–1,399	389	389	161	384.39
1,400–2,399	617	617	245	614.85
2,400–4,999	795	795	339	773.44
5,000–7,999	338	338	168	320.64
≥ 8,000	264	264	122	245.83
Unknown	145	145	66	140.12
Total	4,241	4,241	1,342	4,098.88

Table A-12. Final Estimates by USPHS Region

USPHS Region	Population Control Total	Raked Estimate (Total)	In-Scope Sample	Estimated In-Scope Total
I	200	200	75	191.71
II	261	261	122	258.85
III	380	380	169	374.90
IV	841	841	248	791.54
V	789	789	233	763.96
VI	637	637	165	615.54
VII	275	275	89	272.99
VIII	194	194	53	190.18
IX	479	479	128	454.22
X	185	185	60	185.00
Total	4,241	4,241	1,342	4,098.88

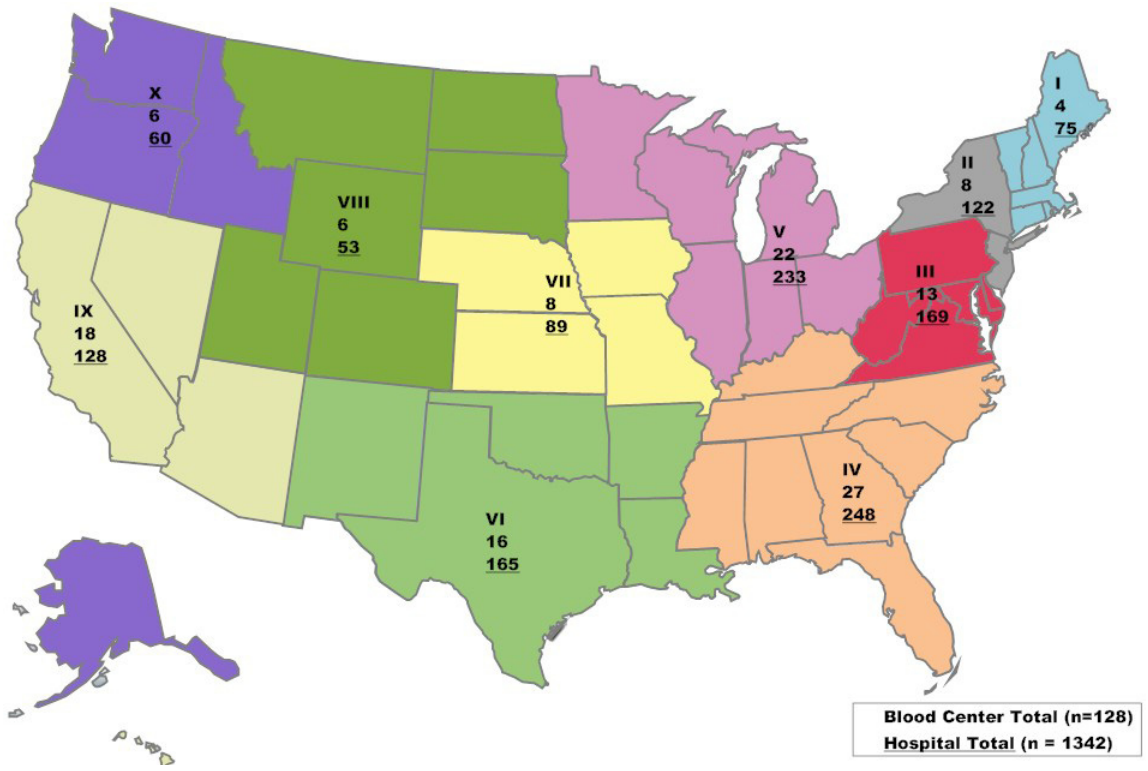


Figure A-1. Distribution of blood center and hospital respondents by USPHS Region.

Table A-13. Average Raking Factor and Average Final Weight by USPHS Region

Region	Number of respondents	Average Base Weight	Average Raking Adjustment (Ratio)	Average Final Weight
I	75	1.1843	2.1584	2.5561
II	122	1.0676	1.9873	2.1217
III	169	1.1598	1.1928	2.2184
IV	248	1.1957	2.6692	3.1917
V	233	1.3067	2.5092	3.2788
VI	165	1.3033	2.8624	3.7305
VII	89	1.3359	2.2960	3.0672
VIII	53	1.3371	2.6836	3.5883
IX	128	1.1048	3.2120	3.5486
X	60	1.2149	2.5380	3.0833

Table A-14. Average Raking Factor and Average Final Weight by Inpatient Surgical Volume

Surgical Volume	Number of Respondents	Average Base Weight	Average Raking Adjustment (Ratio)	Average Final Weight
100– 999	241	2.2166	3.0319	6.7204
1,000–1,399	161	1	2.3875	2.3875
1,400–2,399	245	1	2.5096	2.5096
2,400–4,999	339	1	2.2815	2.2815
5,000–7,999	168	1	1.9086	1.9086
≥ 8,000	122	1	2.0150	2.0150
Unknown	66	1	2.2130	2.2130

Variance Estimation

The grouped Jackknife method* was used to calculate variance estimates. The sample cases were divided into groups, with the original stratification taken into account, and replicates were defined by removing a group and recalculating the sample weights. To estimate the sample variance for a particular estimate (such as a weighted total or a ratio estimate), the point estimate is calculated for each replicate, and the sample variance is the variance between the replicate point estimates and the full sample point estimate.

**Valliant R, Brick M, Dever J. Weight adjustments for the grouped Jackknife variance estimator. J Offic Stat 2008; 24:469-88.*

Characterization of Respondents

Twenty-four blood centers (17.6%) that reported centralized transfusion service activity. When national blood centers were considered one entity, these 24 make up 29.9% of the blood centers. In 2008, 21 blood centers reported themselves to be centralized transfusion services, an increase from the 19 reported in 2006. These additional services are an area of potential growth for blood centers.

A total of 143 (10.6%) of responding hospitals characterized themselves as a hospital-based blood bank and transfusion services that collect blood; however, only 117 (81.8%) of these hospitals reported collection data. In 2008, 190 hospitals (12.4%) reported collection activity, a total that is down from 236 (13.8%) hospitals in 2006.

Limitations

The relatively low response rate for cord blood banks and hospitals is a limitation. Nonresponse increases the uncertainty of, or variability in, the estimates, and it may also introduce bias to the estimates, which is very difficult to assess. Nonresponse is effectively a second layer of sampling, a process that results in only a subset of respondents, for whom the mechanism creating the nonresponse is unknown. In some cases, this mechanism may be random or unrelated to the properties of interest, but that can be difficult to determine. The response rate is particularly low for

cord blood banks, and no attempt has been made to model the nonresponse process or adjust the weights. The raking procedure for hospitals is effective only to the extent that institutions within a location (USPHS Region) or "size," in terms of the surgical volume, are similar.

The Jackknife estimates of variability represent only the sampling error, and, therefore, they underestimate the uncertainty in the results. The uncertainty due to nonsampling errors such as measurement errors (eg, data entry errors or misreading of questions) and the variability due to item imputation are not reflected in the confidence intervals.

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