THE 2007 NATIONAL BLOOD COLLECTION AND UTILIZATION SURVEY

Report

The United States Department of Health and Human Services 2007 National Blood Collection and Utilization Survey was conducted under contract (HHSP23320062209TC) with the AABB.

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Table of Contents

List of Tables

1. Executive Summary

The Assistant Secretary for Health and the Office of Public Health and Science along with the DHHS operating divisions [CDC, Centers for Medicare and Medicaid Services (CMS), Food and Drug Administration (FDA), and the National Institutes of Health (NIH)] sponsored this survey, which was conducted under contract to AABB (formerly the American Association of Blood Banks). The purpose of this national survey was twofold—to assess the amount of blood collected and transfused in the United States in 2006 and to establish the baseline denominators for the US Biovigilance Network.

The facilities surveyed included all non-hospital-based blood collection centers (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. Hospitals with annual surgical volumes between 100 and 1,399 were stratified and randomly sampled at a combined rate of 40%, while all hospitals with 1,400 surgeries or more were included in the sample.

The 2007 NBCUS response rate for blood centers was 91.4% (128/140); for hospitals, 59.9% (1,707/2,848); and for cord blood banks, 51.9% (14/27). Statistical procedures were used to verify that the sample was representative of the study universe and to develop sample weights to produce national estimates.

Important Trends in the US Blood Supply

The supply of available allogeneic Whole Blood (WB) and Red Blood Cell (RBC) units after accounting for test discards was 15,688,000. This number exceeded transfusions of allogeneic WB/RBCs (14,461,000) by a margin of 1,227,000 units—7.8% of available supply. This excess of supply is cause for optimism. These data, combined with the lowest rate of units outdated in recent years, suggest that hospitals and blood centers continue to improve efficiencies in delivering the appropriate product when needed.

This supply was provided by 9,553,000 allogeneic donors who successfully gave blood—2,726,000 (28.5%) of whom were first-time donors and 6,828,000 (71.5%) of whom were repeat donors. These repeat allogeneic donors provided 11,697,000 donations, the equivalent of 1.7 donations per donor. These data on the number of first-time and repeat donors are the first national estimates available and should in subsequent surveys enable the blood banking community to track participation rates. The allogeneic blood col-

lection rate was 84.1 units per thousand US population of donor age (18-64 years) in 2006 compared to 83.1 units per thousand in 2004. The US WB/RBC transfusion rate in 2006 was 48.9 units per thousand persons in the overall US population, statistically unchanged from 2004 (**Figure 11-4**).

Blood Collection

The NBCUS indicates that the total supply of WB/RBCs in 2006 was 16,174,000 units before testing. This is 5.8% more than was reported in 2004; however, the difference might be attributable, in part, to changes in weighting application in the two years.*

Blood centers were responsible for the collection of 15,378,000 units or 95.1% of the supply, whereas hospitals collected 796,000 units or 4.9%. Much of the increase in collections can be attributed to the contribution of collections by red cell apheresis. Apheresis collections accounted for 1,619,000 RBC units, an increase of 96.4% over 2004. Blood centers reported 99% of the red cell apheresis collections (**Figure 1-1**).

Blood Transfusion

The total number of WB/RBCs transfused in 2006 equaled 14,650,000 units. This 3.3% increase in transfusion activity from 2004 was not statistically significant.†

The total number of platelet units provided to patients in 2006 was 10,388,000, a small (5.2%) but not statistically significant increase over 2004. The transfusion of apheresis platelets increased 9.0% from 8,338,000 to 9,092,000 platelet concentrate equivalent units (one apheresis platelet pack = six platelet concentrate equivalent units). The transfusion of whole-blood-derived platelet concentrates continued a downward trend, decreasing 15.7% from 1,537,000 units in 2004 to 1,296,000 units in 2006, although this difference was not statistically significant.

**Blood center data were not weighted for nonresponse in the 2004 data. The 2006 data were weighted to represent the full national supply. Therefore, the 2004 collection totals may have been slightly underrepresented, making the increase between the years seem greater than it actually was.*

†Allogeneic units transfused (including the pediatric contribution expressed as adult equivalent units) equalled 14,461,000.

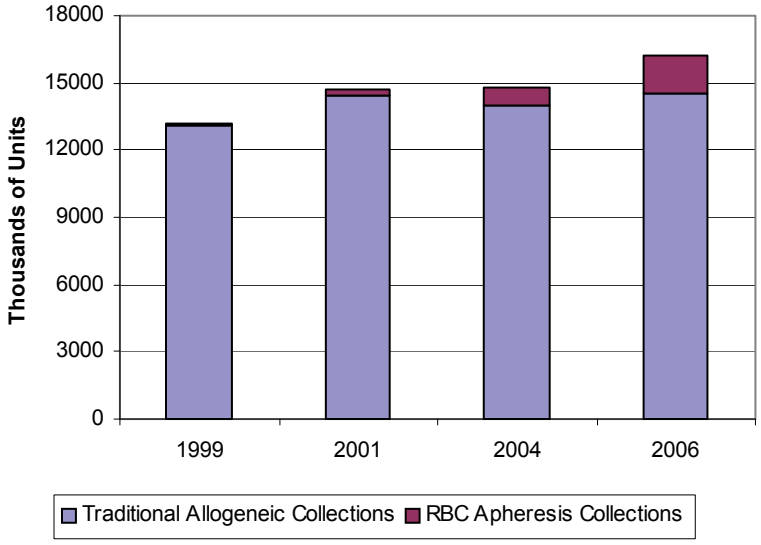

Figure 1-1. Growth in use of RBC apheresis technology.

Biovigilance

In the interval between the 2005 and the 2007 NBCUS reports, there has been a coordinated effort between the public and private sectors to develop the US Biovigilance Network (USBVN). The USBVN was created by an interorganizational task force of leaders from the transfusion and cellular therapies community, and coordinated in a public-private partnership between the transfusion and transplantation community and the federal government, with shared responsibilities for program development, operation and management, and funding.

The USBVN will provide a central, coordinated system for identifying adverse events and near-miss incidents occurring at any point in the collection, processing, distribution, transfusion, or transplantation processes for blood, tissue, and cellular products. The network's data can be analyzed to identify where practices can be improved to provide better experiences for donors and better outcomes for patients.

It is anticipated that the hemovigilance module of this system, within the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN), will begin operations for a limited number of facilities in 2009. To help establish a baseline, data were collected for major adverse transfusion reactions for 2006.

An estimated total of 72,000 transfusion-related adverse reactions were reported for 2006. These were defined as events that required any diagnostic or therapeutic intervention. This represents an adverse reaction rate of approximately 0.32% of all components transfused. This rate is on the lower end of rates reported by hemovigilance systems in other countries, with rates of 0.3% to 0.7%. A fine tuning in the reporting of adverse reactions is anticipated as educational materials harmonize definitions nationally and consistent standards of reporting are applied in the context of the USBVN.

Another module of the USBVN will seek to identify and track donor adverse reactions. National baseline data for severe adverse reactions were collected for the first time in this survey. Approximately 11,000 severe adverse donor reactions were reported by blood collectors in 2006, for a rate of approximately 0.07%.

2. Key Findings

The results of the 2007 NBCUS provide an update of US blood services and related activities assessed by the four previous national surveys conducted in 2005, 2002, 2000, and 1998. Notable findings from the 2007 NBCUS and comparisons with the 2005 report were as follows:

- Total WB/RBC collections in 2006 increased from 2004 by 5.8%, to 16.2 million units.
- Total WB/RBC transfusions in the same period increased by 3.3%, to 14.7 million units.
- Autologous collections declined significantly by 26.9% to 335,000 units.
- The margin between test-negative allogeneic WB/RBC units collected and those transfused in 2006 was 1,227,000 units.
- RBC apheresis collections were significantly higher by 96.4% for a total of 1.6 million units.
- Test losses declined significantly to 151,000 units.
- The total number of all components transfused in 2006 was 30,044,000.
- There was a statistically significant 20.3% decrease in the number of outdated WB/RBC units.
- The transfusion of whole-blood-derived platelet concentrates continued to decrease (–15.7%), while the use of apheresis platelets increased by 9.0%.
- A total of 492 hospitals reported the cancellation of elective surgery on one or more days due to blood inventory shortages. This affected 412 patients, 25% fewer than in 2004.
- The average hospital cost of a unit of RBCs increased by 6.4%.
- The WB/RBC collection rate per thousand US donor population (estimated at 18-64 years of age) was 84.1 units in 2006, compared to 83.1 in 2004.
- The WB/RBC transfusion rate of 48.9 units per thousand US population, compared to 49.6 in 2004.
- The transfusion of leukocyte-reduced (LR) components decreased 12.1%—9.9% for prestorage LR components and 52.7% for poststorage LR components.
- The rate of adverse transfusion reactions reported to the hospital transfusion service was 0.32%.
- The rate of severe donor reactions was 0.07%.
- Of the 9,553,000 allogeneic donors who successfully gave blood, 28.5% were first-time donors and 71.5% were repeat donors.
- The donation rate for repeat donors was 1.7 donations per donor in 2006.

3. Introduction and Methods

The Assistant Secretary for Health and the Office of Public Health and Science along with the DHHS operating divisions [CDC, Centers for Medicare and Medicaid Services (CMS), Food and Drug Administration (FDA), and the National Institutes of Health (NIH)] sponsored this survey, which was conducted under contract to AABB (Bethesda, MD). This report presents the results of the fifth NBCUS, conducted in 2007. The Office of Management and Budget (OMB) control number for the information collected was 0990-0313. In 2005, as in 2007, the survey was conducted by DHHS under contract with AABB. Previous surveys in 2002, 2000, and 1998 were conducted by the National Blood Data Resource Center, a wholly owned subsidiary of AABB.

Objectives

The objectives of the survey were to generate national estimates for blood collection and utilization activities in the US in 2006; to provide comparisons with previous years; to provide baseline data for national biovigilance safety monitoring; and to characterize business practices in the blood collection, transfusion medicine, and cellular therapies community.

The survey instrument was designed to capture quantitative data regarding blood collection, processing, transfusion, and final disposition, as well as other information describing current policies and practices, and the adoption of new technologies by the blood community.

Data Collection

The 23-page questionnaire, cover letter, and postage-paid return envelope were mailed in August 2007 to the 3,044 facilities in the sample described below. Survey packets were addressed to the director of either the blood center or the hospital blood bank or transfusion service. A reminder postcard was mailed a month later. A second mailing of the survey questionnaire was sent to 2,025 initial nonresponders six weeks later. Facilities that did not respond by the September deadline were contacted by e-mail, telephone, or both. Data collection via paper surveys concluded on December 31, 2007. Survey nonresponders were then invited to complete an abbreviated web-based survey consisting of critical questions from the survey. Web-based data collection concluded on January 31, 2008.

Data coding, keying, and verification were performed by Westat (Rockville, MD). Validation of survey data was achieved by comparison with 2004 survey data and by direct contact with individual respondents as necessary.

Sampling Frame

The sampling frame for the 2007 NBCUS was compiled from two data sources. The first source was the AABB database, which is a list of all non-hospital-based blood collecting facilities and cord blood banks in the 50 states. This list also contains hospitals that are members of the AABB. The second source was the comprehensive 2006 AHA hospital database.

Non-federal (state, county, city, corporation, etc) hospitals located within the 50 United States (or the District of Columbia) and Veteran's Affairs hospitals providing general medical and surgical; children's general medical and surgical; cancer; heart; obstetrics and gynecology; eye, ear, nose, and throat; or orthopedic services were considered eligible population members. The sampling frame was restricted to hospitals with annual inpatient surgical volumes of greater than 100.

To prepare the AABB database for sampling, hospitals on the AABB list were matched to the AHA database and the AHA identification numbers were assigned to avoid duplication. Hospitals on both lists were included, subject to the hospital eligibility criteria given above. Hospitals unique to AABB were included in the study with certainty (ie, a probability of 1.0). Within the AABB database, the facilities were categorized into three groups: hospitals unique to AABB, blood collection centers, and cord blood banks. The final list of eligible facilities (from both AABB and AHA) contained a total of 4,219 hospitals, blood collection centers, and cord blood banks.

Sample Selection

The NBCUS sampling frame consisted of all eligible hospitals in the 2006 AHA dataset and all hospitals unique to AABB, as well as all blood collection centers and cord blood banks on the AABB list. A total sample of 3,044 facilities was selected from the combined frame. Hospitals from the AHA dataset were stratified into six categories according to annual inpatient surgical volume. The strata are defined as follows: 100-999 surgeries, 1,000-1,399 surgeries, 1,400-2,399 surgeries, 2,400-4,999 surgeries, 5,000-7,999 surgeries, and 8,000 or more surgeries. Hospitals of unknown surgical volume, such as those unique to the AABB database for which no surgical volume could be determined, were assigned to an additional group. Hospitals with 1,400 or more surgeries were sampled at a rate of 100%. Hospitals with 100-999 surgeries and 1,000-1,399 surgeries were sampled at rates of 33% and 66%, respectively. **Table 3-1** shows the sampling frame counts and the sampling rates by strata.

Response Rates

Table 3-2 summarizes the outcome of data collection efforts for blood centers, collectively, and for hospitals by surgical volume. After eliminating ineligible institutions (29 sampled institutions that had ceased operations, changed status, or chose to be reported for by an affiliate), the combined response rate was 61.3%. The response rate for blood centers was 91.4% (128/140). The response rate for sampled

Table 3-1. Sampling Frame Counts and Sampling Rates

Type of Facility	Total Population	Sample	Sampling Rate (%)
Hospitals			
100-999 surgeries/year	1,577	525	33.3
1,000-1,399 surgeries/year	368	245	66.6
1,400-2,399 surgeries/year	658	658	100.0
2,400-4,999 surgeries/year	831	831	100.0
5,000-7,999 surgeries/year	344	344	100.0
≥8,000 surgeries/year	235	235	100.0
Unknown surgical volume	35	35	100.0
Blood Centers	144	144	100.0
Cord Blood Banks	27	27	100.0
Total Facilities	4,219	3,044	72.1

Table 3-2. Response Rates by Type of Facility and Surgical Volume

Type of Facility	Number Eligible	Respondents	Response Rate (%)
Hospitals			
100-999 surgeries/year	520	304	58.5
1,000-1,399 surgeries/year	243	131	53.9
1,400-2,399 surgeries/year	654	386	59.0
2,400-4,999 surgeries/year	825	514	62.3
5,000-7,999 surgeries/year	343	214	62.4
≥8,000 surgeries/year	234	139	59.4
Unknown surgical volume	29	19	65.5
Blood Centers	140	128	91.4
Cord Blood Banks	27	14	51.9
Total Facilities	3,015	1,849	61.3

hospitals was 59.9% (1,707/2,848). Response rates by surgical volume classes ranged between 53.9% and 62.4%. The total number of individual survey responses from the hospital sample was 1,707. Slightly more than half, 51.9%, of the cord blood banks responded.

Edit and Imputation Procedures

Internal consistency of the 2007 NBCUS data was ensured by developing machine edit specifications to check the logic and internal consistency of the data before imputation. Imputation was limited to critical questions only. Missing data for these questions were imputed using a model-based regression method for continuous and categorical variables for both hospitals and blood centers. "Check all that apply" variables were imputed together as a unit. Missing items on the survey questionnaires were imputed using the following four steps:

1. A preliminary hot deck imputation of missing items.
2. Searching for key covariates through stepwise regression modeling.
3. Re-imputation of missing items using predictive means matching, through nearest neighbor matching on regression predicted values.
4. Cycling through steps 2 and 3 until the process converged.

The imputation models were developed separately for blood centers and hospitals and included region and transfusion volume and/or collection volume strata, as appropriate. Imputed cases were flagged to allow the analyst to identify which cases were imputed.

Sampling Weights

The final sampling weights for hospitals were calculated for each stratum using a three-stage process. In the first stage, a base weight was computed as the reciprocal of the selection probability for each stratum to adjust for differences in the sampling rates applied to the strata. The base weight for hospitals was calculated as follows:

$$\text{Base Weight} = \frac{\text{Number in Surgical Volume Stratum}}{\text{Number Sampled in Surgical Volume Stratum}}$$

The "number sampled" in the denominator includes all units sampled, including those later determined to be ineligible. These ineligible units remain in the denominator because they represent other, unidentified ineligible units in the sampling frame. If these ineligibles were removed from the raw weight calculation, resulting data estimates would be overstated. **Table 3-3** shows the number in each stratum, the number sampled, and the results of the base weight calculation.

In the second stage, a weighting class adjustment (WCA) was derived to correct for imbalance among the strata due to different response rates from the units in the sample, and differences in surgical volume between responding and nonresponding units. The numerical adjustment was computed as the ratio of weighted (ie, using the base weight) surgical volume for all eligible units in the sample (ie, respondents and nonrespondents) to weighted surgical volume for all responding units in the stratum. This WCA was calculated as follows:

$$\text{WCA} = \frac{\text{Weighted surgical volume for all eligible units (respondents and nonrespondents)}}{\text{Weighted surgical volume for all responding units}}$$

Table 3-3. Raw Sampling Weights

Type of Facility	Number in Stratum	Number Sampled in Stratum	Raw Sampling Weight
Hospitals			
100-999 surgeries/year	1,577	525	3.00
1,000-1,399 surgeries/year	368	245	1.50
1,400-2,399 surgeries/year	658	658	1.00
2,400-4,999 surgeries/year	831	831	1.00
5,000-7,999 surgeries/year	344	344	1.00
≥8,000 surgeries/year	235	235	1.00
Unknown surgical volume	35	35	1.00
Blood Centers	144	144	1.00
Cord Blood Banks	27	27	1.00
Total Facilities	4,219	3,044	

Table 3-4 displays the number of eligible facilities, the number of responding facilities, and the computed weighting class adjustments for each stratum. Only eligible sample members were included in this calculation.

The final sampling weight was then calculated as the product of the base weight and the WCA. The final sampling weights appear in **Table 3-5** together with the base sampling weights from **Table 3-3** and the weighting class adjustment from **Table 3-4**.

Survey Respondents

Table 3-2 summarizes the outcome of data collection efforts—collectively for blood centers and by surgical volume for hospitals. The individual sites (regional blood centers) of large collectors such as the American Red Cross Blood Services and United Blood Services were enumerated separately. The combined survey response rate was 61.3%, as stated above, representing an increase over the combined survey response rate of 58.4% for the 2005 survey. The response rate for blood centers was 91.4% (128/140). The overall response from eligible sampled hospitals that reported for themselves was 59.9% (1,707/2,848). Response rates by surgical volume classes ranged from 53.9% to 62.4%, with the 2007 rates increasing for the smaller surgical volume hospitals but decreasing slightly for the larger surgical volume hospitals in comparison to 2005. The actual number of hospitals that responded to the current survey was greater in 2007 by 103 (1,707 vs 1,604). The additional facilities were distributed across all geographic regions.

An abbreviated, web-based, critical items survey was available for approximately 30 days to facilities that had not responded to the paper

Table 3-4. Weighting Class Adjustments

Type of Facility	Number Eligible in Weighting Class	Number Eligible and Responded in Weighting Class	Weighting Class Adjustments
Hospitals			
100-999 surgeries/year	520	304	1.78
1,000-1,399 surgeries/year	243	131	1.89
1,400-2,399 surgeries/year	654	386	1.70
2,400-4,999 surgeries/year	825	514	1.61
5,000-7,999 surgeries/year	343	214	1.61
≥8,000 surgeries/year	234	139	1.69
Unknown surgical volume	29	19	1.53
Blood Centers	140	128	1.09
Cord Blood Banks	27	14	1.93
Total Facilities	3,015	1,849	

Table 3-5. Final Sampling Weights

Type of Facility	Raw Weight	Weighting Class Adjustment	Final Sampling Weight
Hospitals			
100-999 surgeries/year	3.0038	1.78	5.34
1,000-1,399 surgeries/year	1.5020	1.89	2.84
1,400-2,399 surgeries/year	1.0000	1.70	1.70
2,400-4,999 surgeries/year	1.0000	1.61	1.61
5,000-7,999 surgeries/year	1.0000	1.61	1.61
≥8,000 surgeries/year	1.0000	1.69	1.69
Unknown surgical volume	1.0000	1.53	1.53
Blood Centers	1.0000	1.09	1.09
Cord Blood Banks	1.0000	1.93	1.93

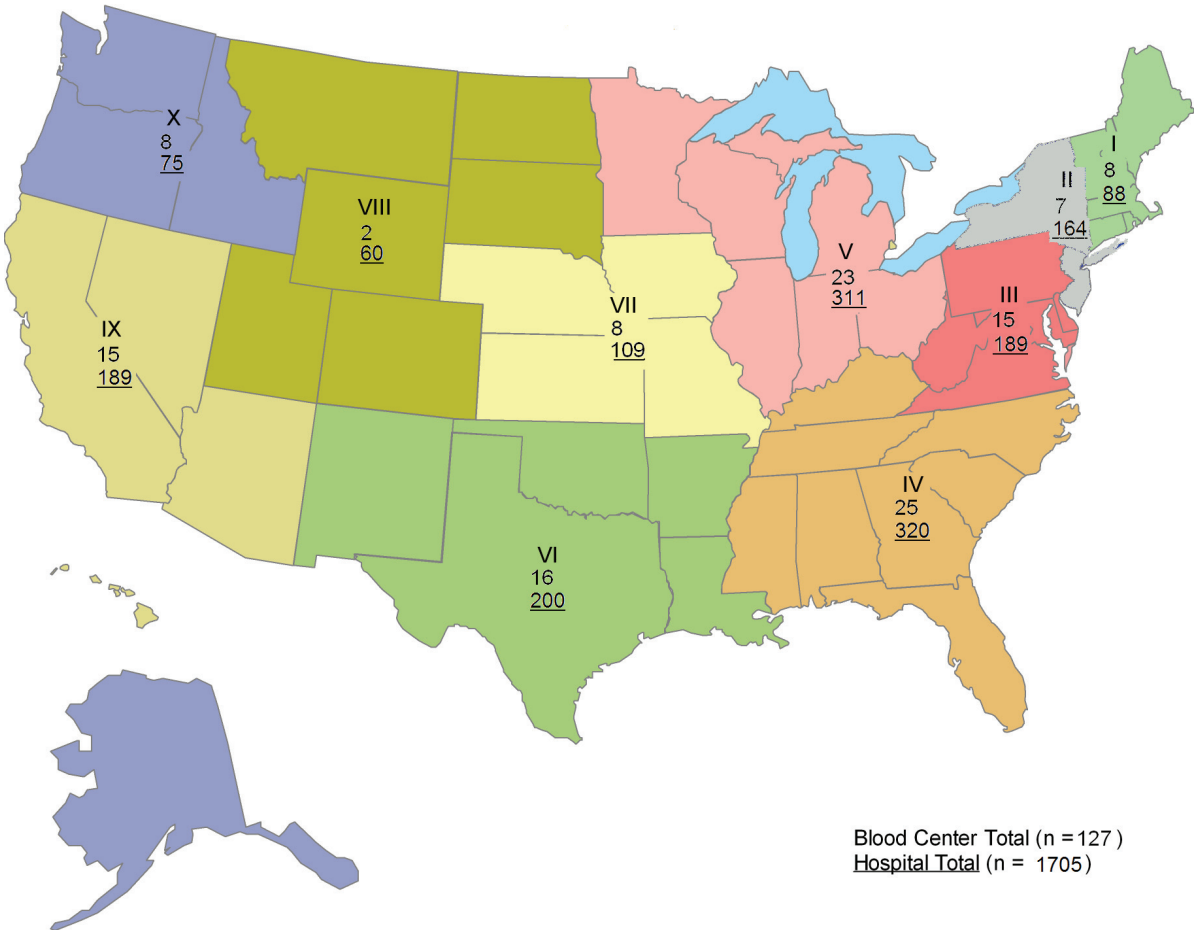

Figure 3-1. Distribution of blood center and hospital respondents by USPHS region.

survey. The 20 institutions responding via the Internet represent a response rate of 1.7% for those blood centers and hospitals that had not responded on a paper form. Use of the web-based critical item questionnaire increased the response from blood centers by 1.4% and from hospitals by 0.6%. Because electronic data collection was employed to collect only essential data elements, its utility as a potential mode of data collection for any future NBCUS could not be assessed.

Figure 3-1 illustrates the distribution of responding blood centers and hospitals among the 10 geographic regions as defined by the US Public Health Service (USPHS; **Table 3-6**).

Characterization of Respondents

The majority of blood centers self-identified as such. However, 19 centers selected the centralized transfusion service option, "A local or regional blood center that collects blood from donors and supplies blood, components, and crossmatched blood products to participating facili-

Table 3-6. United States Public Health Service Regions

USPHS Region	States
I	CT, ME, MA, NH, RI, VT
II	NJ, NY, (PR, VI)*
III	DE, DC, MD, PA, VA, WV
IV	AL, FL, GA, KY, MS, NC, SC, TN
V	IL, IN, MI, MN, OH, WI
VI	AR, LA, NM, OK, TX
VII	IA, KS, MO, NE
VIII	CO, MT, ND, SD, UT, WY
IX	AZ, CA, HI, NV, (Guam, American Samoa, CNMI, FSMI, RMI, Palau)*
X	AK, ID, OR, WA

*Although these territories and possessions are a part of the USPHS regions, the NBCUS did not survey hospitals and blood centers outside of the 50 United States.

ties, such as a centralized transfusion service," to describe themselves. Hospital respondents identified themselves either as a transfusion service (1,383), or as a hospital-based blood bank and transfusion service that collects blood (236). Another classification option available to survey respondents was "An independent facility that collects, process, manufactures, stores, or distributes cellular therapy products." This option was chosen by 12 respondents.

Limitations of the Survey

The weights described here account for the probabilities of selection that vary by stratum, survey nonresponse, and multiple chances of selection given the nature of establishment samples. Sampling strata were used as nonresponse adjustment cells, and were effective to the extent that facilties within the same strata are (on average) similar. Several respondents provided data for themselves as well as other facilities included in either the sample or on the sampling frame. These other facilities were both contained within the same sampling stratum as well as in other sampling strata compared to the responding facility. In these instances, an overall joint probability of selection was calculated as a function of the probability of selection associated with the constituent facilities. In all cases, the overall joint probability of selection evaluated to 1.0, as one or more of the constituent facilities were associated with a probability of 1.0.

4. Blood Collected and Processed in the United States

Total WB/RBC Collections

The total whole-blood-derived and apheresis RBCs collected in the US in 2006 were 16,174,000 (±688,000) units, before laboratory testing (**Table 4-1**). Blood centers collected 15,378,000 units, or 95.1% of the total. The remaining 796,000 units (4.9%) were collected by hospitals. Compared to total collections from 2004, 2006 collections increased 5.8%.*

The increase is primarily attributed to a 96.4% increase in RBC apheresis collections that accounted for 10% of total blood collections in 2006. The total units rejected on testing decreased by 44.1% in 2006. Between 2004 and 2006, testing methods were licensed and implemented by many blood collection facilities; these measures appear to have reduced the discard rate due to laboratory testing. This resulted in 16,023,000 usable units collected in 2006 ($p<0.05$), 99.1% of those collected.

**Statistical comparisons were conducted for significant differences between the 2006 and 2004 data. Because the variance estimates for 2004 were not readily available, these tests assumed that 2004 and 2006 variances were equal.*

Whole Blood Collections

Donations of WB in 2006 totaled 14,555,000. These collections, reported according to the type of donation, are shown in **Table 4-1**. Community donations, excluding directed donations, accounted for 87.5% of collections; directed donations totaled 0.4%; and autologous donations contributed 2.1%. A total of 1,619,000 RBC units (10%) were collected by apheresis, discussed below.

Allogeneic donations totaled 14,151,000 (±621,000) of which 95.3% were collected by blood centers and 4.7% by hospitals. The percentage increase in allogeneic donations between 2004 and 2006 was 1.9%, which was not statistically significant. Directed donations declined by 40.1%, to 70,000 units ($p<0.001$). Of these, 43.3% were eventually used as part of the community supply.

Autologous, or self-directed units, totaled 335,000 (±20,000), a decrease of 26.9% compared to 2004 ($p<0.001$). Hospitals collected 27.8% of all autologous units.

RBC Apheresis

In addition to WB collections, 1,619,000 (±99,000) RBC units were collected by apheresis, which typically yields a double vol-

Table 4-1. Estimated 2006 Collection and Transfusion by US Blood Centers and Hospitals of Whole Blood (WB) and Red Blood Cells (RBCs) (expressed in thousands of units)

Activity	Blood Centers	Hospitals		2006 Combined Total	±95% CI	% of Total Collections/ Transfusions	2004 Total	% Change 2004-2006
		Total	±95% CI					
Collections								
WB Allogeneic (excluding directed)	13,486	665	122	14,151	621	87.5	13,890	1.9
WB Autologous	242	93	13	335*	20	2.1	458	–26.9
WB Directed	47	22	7	70*	9	0.4	116	–40.1
RBC Apheresis	1,603	16	5	1,619*	99	10.0	824	96.4
Total Supply	15,378	796	131	16,174	688	100.0	15,288	5.8
Rejected on Testing	137	14	4	151*	11	0.9	270	–44.1
Available Supply	15,241	782	129	16,023*	684	99.1	15,019	6.7
Transfusions								
Allogeneic (excluding directed)	716	13,262	340	13,978	439	95.4	13,720	1.9
Autologous	7	182	16	189*	16	1.3	270	–30.0
Directed (to designated patient)	0	125	31	126	31	0.9	132	–4.7
Pediatric	5	352	61	357*	61	2.4	60	495.7
Total Transfusions	729	13,921	376	14,650	468	100.0	14,182	3.3
Outdated WB/RBCs	131	269	17	400*	20	2.5	503	–20.6

*Significantly different from 2004 data.

ume of RBCs. Apheresis procedures in 2006 yielded a 96.4% increase in RBC units in comparison to the 824,000 collected in 2004, which was statistically significant ($p<0.001$). RBCs collected in this manner contributed 10.0% of the total WB/RBC supply in 2006. Autologous RBC collections accounted for 0.7% of the apheresis total and directed donations accounted for 0.1% of the total.

The growth of apheresis collections occurred largely in blood centers that accounted for 99.2% of reported units. In 2004, 115 blood centers and 30 hospitals reported apheresis collections. In 2006, 118 blood centers reported employing this technology, and 33 hospitals reported collecting RBCs by apheresis. Among institutions that reported RBC apheresis collections (unweighted data), the mean number of units collected by blood centers was 12,419.24 and by hospitals was 284.30. The minimum number of units collected by any facility reporting apheresis collections was 4 and the maximum was 74,563.

Note: In the 2007 survey, responding institutions provided the actual number of products resulting from apheresis procedures. This is in contrast to the 2005 survey, where an adjustment of 1.9 units/RBC apheresis procedure was made, based on consultation with participating blood centers.

Non-RBC Components Produced

Non-RBC component units collected or processed include apheresis platelets and plasma as well as platelets, cryoprecipitate, and granulocytes from whole blood. The total number of non-RBC components produced for transfusion in 2006 was 11,106,000 (apheresis platelets counted as platelet doses, *not* as concentrate equivalent units).

Platelets

Platelet concentrates were derived from 2,396,000 units of WB, a decrease of 43% ($p<0.001$) of the 2004 volume (**Table 4-2**). Platelets were prepared from 16.9% of all allogeneic WB collected, vs from 30.3% of the total collection in 2004. Blood centers processed 2,215,000 units (92.4%), while hospitals produced 181,000 (7.6%).

An estimated 1,167,000 plateletpheresis procedures were completed, yielding 1,823,000 apheresis platelet components. This volume indicates a split rate of 64% overall. For comparison with production of WB-derived platelets, it is assumed that the number of platelets in each apheresis collection is equivalent to six units of platelet concentrates, yielding the equivalent of 10,939,000 platelet concentrate units. This was a significant increase of 19.4% from 2004 ($p<0.001$). Blood centers collected 94.1% of apheresis platelets, while hospitals were responsible for 5.9%.

Plasma

A total of 5,684,000 units of plasma were produced for transfusion. This is an increase of 22.2% from 2004, which is statistically significant ($p<0.001$). Blood centers produced 93.0% of the plasma (5,286,000 units), and hospitals produced the remaining 7% (398,000 units). A total of 124,000 plasmapheresis procedures were reported, generating 578,000 units of apheresis plasma for transfusion.* The remaining 5,106,000 units of plasma

**See page 36 for a discussion of therapeutic apheresis.*

Table 4-2. Estimated 2006 Collection and Transfusion by US Blood Centers and Hospitals of Non-Red-Blood-Cell Components (expressed in thousands of units)

Activity	Blood Centers	Hospitals		2006 Total	±95% CI	2004 Total	% Change 2004-2006
		Total	±95% CI				
Collection/Production							
Apheresis Platelets†	10,297	642	185	10,939 (1,823)*	569	9,161	19.4
WB-Derived Platelet Concentrates	2,215	181	65	2,396*	233	4,202	–43.0
Total Platelets	12,512	823	204	13,335	660	13,362	–0.2
Plasma‡	5,286	398	88	5,684*	306	4,651	22.2
Cryoprecipitate	1,173	24	9	1,197	95	1,164	2.8
Transfusions							
Apheresis Platelets†	411	8,681	509	9,092 (1,515)	526	8,338	9.0
WB-Derived Platelet Concentrates	223	1,073	176	1,296	212	1,537	–15.7
Total Platelets	634	9,754	534	10,388	589	9,875	5.2
Plasma‡	215	3,795	140	4,010	168	4,089	–1.9
Cryoprecipitate	56	938	68	993	73	890	11.6
Outdated Non-RBC Components	424	451	46	875*	58	1,079	–18.9

*Significantly different from 2004 data.
†platelet concentrate equivalent units (apheresis packs); includes splits.
‡for transfusion, includes apheresis plasma.

were derived from whole blood. In addition, 8,730,000 units of plasma were produced that were intended for further manufacture, with 97.9% coming from blood centers—overall, a 12% increase from 2004 levels. This is due to the increased demand for plasma for fractionation worldwide and to more blood collection facilities meeting the European certification criteria.

Cryoprecipitate

A total of 1,197,000 units of cryoprecipitate were prepared. This increase of 2.8% over 2004 was not statistically significant. Blood centers accounted for 98.0% of cryoprecipitate produced.

Granulocytes

Granulocytes, which are prepared from both apheresis and WB buffy coat units, totaled 5,766 units produced. This is a 56% decrease from the amount produced in 2004. Blood centers reported 87.3% of this total.

5. Blood Transfused in the United States

Whole Blood and Red Blood Cells Transfused

Transfusions of WB and RBCs of all donation types totaled 14,650,000 (±468,000) units, a 3.3% increase from 2004 (see **Table 4-1**). Allogeneic units transfused, including pediatric units expressed as adult equivalent units, accounted for 98.7% of units transfused or 14,461,000 units. The 3.3% increase in the transfusion of allogeneic units (community, directed, and pediatric combined) was not statistically significant compared with 2004. In contrast, there was a significant increase ($p<0.001$) in pediatric transfusions reported in 2006. This appears to be attributable to an increase in the response by pediatric hospitals in the sample rather than to a change in transfusion practice.

The percent of available allogeneic units (directed and pediatric use included) that was used in transfusions was 93.4% in contrast with 95.5% and 93.7% in 2004 and 2001, respectively.

The number of autologous units transfused (189,000) represented 56.4% of the 335,000 units donated preoperatively by patients in 2006. Autologous units accounted for 1.3% of all units transfused in 2006. Autologous transfusions, which were statistically unchanged from 1999 and 2001, declined significantly from 2001 to 2004, and again from 2004 to 2006 ($p<0.001$). Only a very small number of units (3,000 or 0.8% of the autologous units collected) were reported to have been crossed over to the community supply in 2006.

Directed donations, the donation of allogeneic blood for a designated patient other than the donor, accounted for 126,000 (±31,000) units transfused. Of the 70,000 (±9,000) directed units donated, 30,000 were reported to have been crossed over to be transfused to non-designated patients, leaving a considerable gap between the reported number of directed units collected and the reported number transfused, with approximately 84,000 directed collections not accounted for. Only an additional 2,000 units of apheresis RBCs were directed collections (reported as apheresis collections for purposes of comparison with the previous survey). It is not clear why this accounting is at odds.

WB and RBC Recipients

The 2007 NBCUS captured the number of recipients of transfused WB/RBCs of each donation type. Based on unweighted data, 1,597 facilities reported transfusing 8,275,000 allogeneic units (including directed) to 2,740,000 recipients or 3.0 units per recipient, an increase from 2.7 units per

recipient in 2004. Autologous recipients received an average of 1.6 units per transfusion (1.5 in 2004 and 1.6 in 2001). Finally, for recipients of pediatric units, the rate was 2.7 units per recipient, a slight increase over the rate of 2.3 per recipient in 2004.

Extrapolating the ratios of 3.0, 1.6, and 2.7 units per recipient population proportionally to WB/RBCs transfused yields a national estimate of 5.0 million total WB/RBC recipients in 2006. This represents a 6.6% decrease in transfusion recipients compared to the estimated 5.3 million recipients of 2004, but approximately the same number as in 2001.

Non-RBC Components Transfused

National estimates for non-RBC components transfused in 2006 are presented in **Table 4-2**.

An estimated total of 10,388,000 platelet units were transfused to US patients in 2006, an increase of 5.2% from 2004. The transfusion of apheresis platelets increased by 9.0% from 8,338,000 to 9,092,000 platelet concentrate equivalent units.

The transfusion of platelet concentrates (derived from whole blood) continued on a downward trend, declining 15.7% to 1,296,000 from the previous survey estimate of 1,537,000. This has been the trend in platelet usage since 1994 and is a smaller (and not statistically significant) decrease than in previous surveys.

The combined total of FFP and apheresis plasma resulted in 4,010,000 units transfused, a decrease of 1.9% over the 2004 volume (4,089,000). Reporting institutions indicated the volumes of transfused plasma that had been processed by a variety of methods as shown in **Figure 5-1**. The results, for which overlap is possible, are as follows.

- FFP represented 77.2% of plasma transfused (3,094,000 units).
- Plasma, Frozen Within 24 Hours After Phlebotomy, accounted for 15.3% of that transfused (613,000 units).
- Jumbo plasma accounted for 1.8% (73,000) of plasma transfused.
- Pediatric-sized plasma accounted for 1.0% (42,000 units) of plasma transfused.
- Cryoprecipitate-reduced plasma, a new category on the survey, accounted for 4.7% of the total plasma transfused (188,000 units).

In this survey, use of donor retested plasma and solvent/detergent-treated plasma was not included, because the 2004 survey indicated that these represented less than 1% of the plasma transfused, and the product was withdrawn from the US market.

The median volume of plasma reported transfused during a single transfusion episode was 300 mL (n = 1,396), the same as reported in the 2005 and 2002 surveys.

Cryoprecipitate transfusions increased by 11.6% to 993,000 units. An additional 10,000 units were reportedly issued for fibrin sealant, compared with 15,000 units reported for 2004 (a 36% decline), continuing the downward trend since 2001. Other uses of cryoprecipitate were not assessed.

Granulocytes, prepared from both apheresis and WB buffy coat units, resulted in a total of 1,652 units transfused, compared with 2,174 reported for

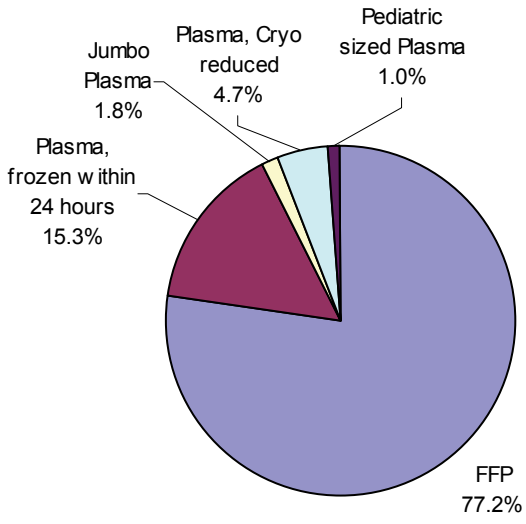

Figure 5-1. Types of plasma transfused in 2006.

2004, a 24.4% decrease. Because of the specialized nature of these transfusions and the hospitals that perform them, the apparent decline in granulocyte transfusions may be affected significantly by hospital sampling and response.

The total number of units of all components transfused in the United States in 2006, both RBC and non-RBC components, was 30,044,000, an increase of 1,006,000 (3.5%) in comparison with 2004.

Platelet Dosage

Institutions reporting platelet transfusions indicated the number of therapeutic doses of each type of platelets. Hospitals reported the transfusion of 1,196,000 doses of plateletpheresis products and 248,000 whole-blood-derived platelet concentrates (see **Figure 5-2**). Blood centers reported the transfusion of 36,000 plateletpheresis doses and 9,000 whole-blood-derived platelet concentrates. Overall, the ratio of apheresis platelet concentrate doses transfused to whole blood-derived doses transfused changed dramatically in 2006 to 4.8:1 from the 3.7:1 ratio reported for 2004 and 2.2:1 reported for 2001. This indicates a trend toward apheresis platelet use.

Hospitals reporting whole-blood-derived platelet concentrate doses also indicated the most common

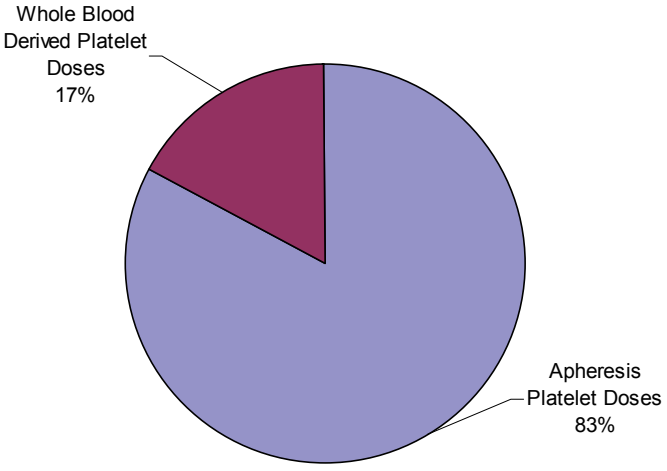

Figure 5-2. Therapeutic platelet doses transfused by hospitals and blood centers in 2006.

dosage of that product used in their institutions (**Figure 5-3**; n=459). As in 2004, the majority of hospitals in 2006 (45.8%) reported using six concentrates. However, an increasing percentage reporting using five or fewer: 18.3% reported using five and 17.4% reported fewer than five, for a total of 35.7% compared to 22.9% reporting five or fewer in 2004.

Outdated Units

The national estimate for the number of units of WB and all components outdated by blood centers and hospitals in 2006 was 1,276,000 (**Table 5-1**). Blood centers accounted for 43.5% of all outdates. Allogeneic, non-directed RBC outdates were shared evenly between blood centers and hospitals in 2006, while hospitals were responsible for most of the directed and autologous outdates (89.3% and 97.4%, respectively). Most non-RBC components, with the exception of whole-blood-derived platelets, were outdated by hospitals.

Outdated WB and RBCs totaled approximately 401,000, of which 252,000 were allogeneic, non-directed RBC units. The remaining outdates were: autologous units (131,000), directed units (5,000), and whole blood (13,000). The percentage of outdated WB/RBCs contributed by each collection type is illustrated in **Figure 5-4**. The mean number of units outdated by blood centers was 940, an increase from 923 in 2004, while the mean for hospitals was 69, a large increase from 2004 (33 units) but lower than that seen in previous surveys (eg, 114 units averaged in 2001). As shown in **Table 5-1**, outdated WB/RBCs accounted for 2.4% of all WB/RBC units processed in 2006.

Because many facilities reported difficulty in gathering data regarding blood group for WB/RBC outdates, the current survey inquired only about group

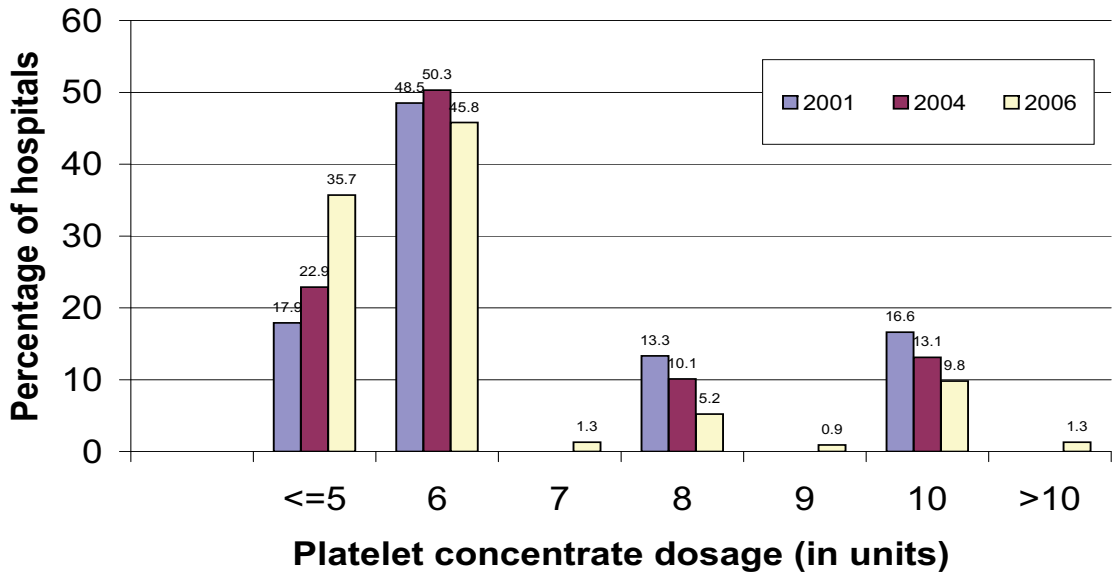

Figure 5-3. Most common platelete concentrate dosage reported by hospitals.

Table 5-1. Outdated Components as a Percentage of the Total Volume of Each Type Processed for Transfusion in 2006

	WB/RBCs	Whole-Blood-Derived Platelets	Apheresis Platelets	Plasma	Cryopre-cipitate	All Components
Outdated Total	401,000	533,000	197,000	111,000	34,000	1,276,000
Processed/Produced	16,745,000	2,396,000	1,811,000	5,684,000	1,197,000	27,833,000
Percent Outdated	2.4	22.2	10.9	2.0	2.8	4.6

O-positive and -negative outdates (**Figure 5-5**). In 2006 such outdates accounted for 12.2% of the total outdated allogeneic WB/RBCs: 8% of outdated units were group O positive and 4% were group O negative. Previous surveys suggested a comparable outdate percentage for group O units (9% and 4%, respectively).

The total number of WB/RBC outdated units was significantly fewer than the 2004 total by 20.6% ($p<0.001$). Only 2.4% of WB/RBC units outdated, compared with 3.2% from the 2004 survey. The percentage of directed and autologous units outdated (1.2% and 32.7%, respectively) fell from their 2004 levels of 9% and 44.2%. Still, more than one-third of the autologous donations were not used.

There was a significant (–18.9%) decrease in outdates of other components as well ($p<0.001$). As has been the case in previous surveys, whole-blood-derived platelet concentrates accounted for the greatest percentage of total components outdated, 41.8% (533,000/1,276,000; **Figure 5-6**). There were 229,000 fewer whole-blood-derived platelet units outdated than reported in 2004. Outdated platelets from WB accounted for 22.5% of all whole-blood-derived platelets processed in 2006.

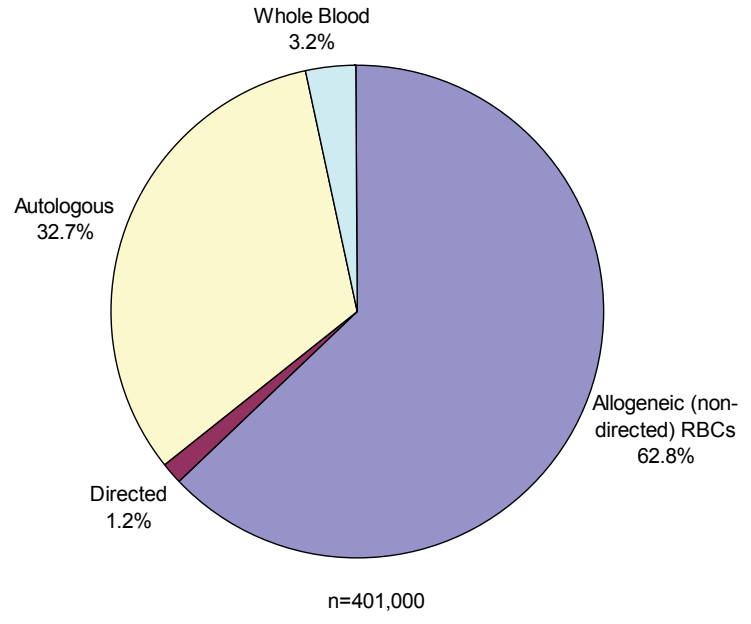

Figure 5-4. WB/RBC unit outdates by collection type.

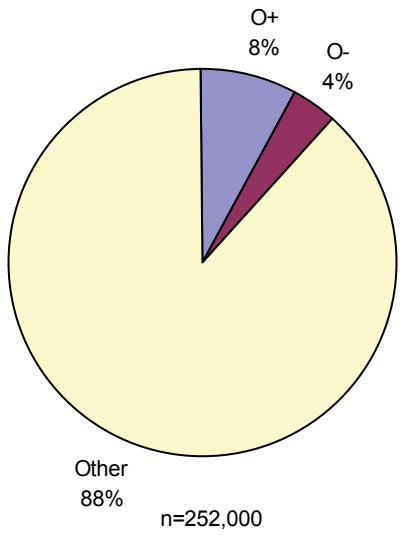

Figure 5-5. Percentage of allogeneic RBC outdates by blood group and type.

Apheresis platelets, plasma, and cryoprecipitate combined accounted for 26.8% of all outdated units, almost 7% more than in 2004. This can be attributed to the increased outdates in plasma and cryoprecipitate.

Overall, efficiency of utilization of all blood components continues to improve with a decrease in outdated WB/RBC and platelet components. The percentage of processed units to be outdated declined slightly from 2004 to 2006, from 5.8% to 4.6%.

Apheresis platelets contributed 197,000 units, or 15.4% of total outdates. This volume represented 10.9% of apheresis platelets processed, down 7.1% from 2004 and indicating better utilization of apheresis platelets in 2006. Some of this improved utilization may be due to the PASSPORT 5- to 7-day platelet study, where platelets had extended shelf life and were less likely to outdate.

Outdated plasma units totaled 111,000, only 2.0% of the plasma units processed for transfusion. Plasma from whole blood contributed 96,000 units to the total and apheresis plasma accounted for 15,000 units.

The number of outdated cryoprecipitate units was 34,000, 2.8% of the cryoprecipitate processed.

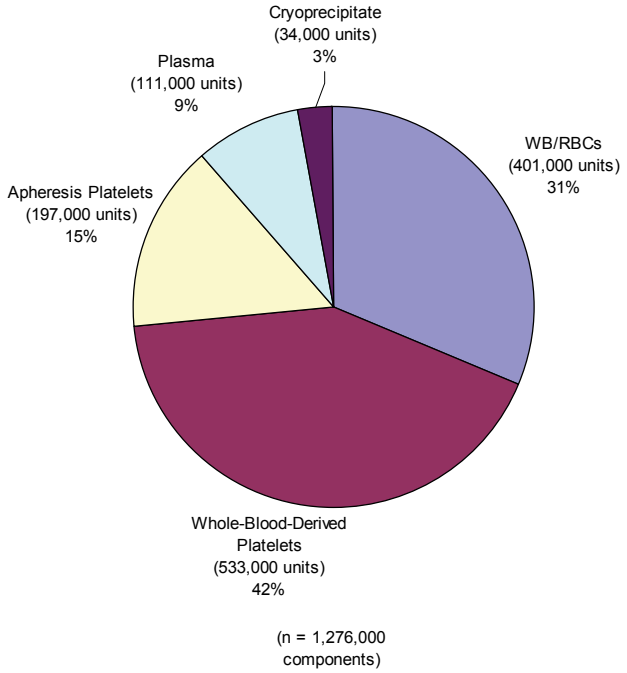

Figure 5-6. Outdates by component type.

6. Component Modification

Prestorage Leukocyte Reduction

Blood components are leukocyte reduced (LR) to reduce the risk of febrile nonhemolytic reactions, transmission of cytomegalovirus infection, and HLA alloimmunization that may lead to platelet refractoriness. Other indications exist, but are controversial. Leukocyte reduction may occur during collection or at some time before components are placed in inventory; this is considered prestorage leukocyte reduction. A total of 13,913,000 (51.4%) component units, including pediatric aliquots were leukocyte reduced by blood centers and those hospitals that collect blood (**Table 6-1**). Blood centers produced 13,495,000 units (97.0%), and hospitals produced 418,000 units (3.0%).

Table 6-1. Blood Components Modified by Prestorage Leukocyte Reduction in All Facilities in 2006

Blood Component	Prestorage Leukocyte-Reduced	% of Total Units Leukocyte-Reduced
All Facilities		
WB/RBCs	11,312,000	70.6
WB-Derived Platelets	897,000	37.4
Apheresis Platelets	1,688,000	92.6
Other Component Units	16,000	0.2
Total Component	13,913,000	51.3

The most frequently LR components were WB/RBCs and apheresis platelets. The percent of all WB/RBCs that were leukocyte-reduced before storage in 2006 was 70.6% (an increase of 9% over 2004). Although 92.6% of apheresis platelets produced were reported to be leukocyte-reduced, this is most likely

Table 6-2. Change in Number of Prestorage Leukocyte-Reduced Blood Component Units Processed in All Facilities from 2004 to 2006 (expressed in thousands of units)

	Blood Centers			Hospitals			All Facilities		
Modification	2006	2004	% Change	2006	2004	% Change	2006	2004	% Change
Leukocyte-reduced, prestorage	13,495	12,094	11.6	418	755	–44.6	13,913	12,849	8.3

Table 6-3. Estimated Number of Blood Component Units Modified by Irradiation or Leukocyte Reduction and Transfused by All Facilities in 2006

Blood Component	Irradiated Units	Prestorage Leukocyte-Reduced Units	Poststorage Leukocyte-Filtered Units	Total Leukocyte-Reduced Units	Irradiated: % of Total Units	Leukocyte-Reduced: % of Total Units
ALL FACILITIES						
WB/RBCs	1,153,000	7,886,000	190,000	8,076,000	7.9	55.1
WB-Derived Platelets	343,000	673,000	69,000	742,000	26.5	57.2
Apheresis Platelets†	641,000	1,206,000	5,000	1,212,000	42.3	80.0
Other Component Units	184,147	510,440	28,600	539,040	3.7	10.8
Total Components	2,322,000	10,275,000	293,000	10,569,000	10.3	47.0
BLOOD CENTERS*						
WB/RBCs	80,000	208,000	3,000	211,000	0.5	1.4
WB-Derived Platelets	66,000	87,000	0	87,000	5.1	6.7
Apheresis Platelets†	24,000	58,000	0	59,000	1.6	3.9
Other Component Units	10,000	7,000	0	7,000	0.2	0.1
Total Components	180,000	361,000	3,000	364,000	0.8	1.6
HOSPITALS						
WB/RBCs	1,073,000	7,677,000	188,000	7,865,000	7.3	53.7
WB-Derived Platelets	277,000	586,000	69,000	654,000	21.4	50.5
Apheresis Platelets†	617,000	1,148,000	5,000	1,153,000	40.7	76.1
Other Component Units	174,000	504,000	29,000	532,000	3.5	10.6
Total Components	2,141,000	9,914,000	291,000	10,205,000	9.5	45.4

*Acting as hospital transfusion services.
†Apheresis platelet units (*not* platelet concentrate equivalents).

a reporting anomaly, because the collection process provides leukocyte reduction.

Blood centers are taking on more of the responsibility for leukocyte reduction. Component units leukocyte-reduced before storage increased by 11.6% in blood centers, and declined by 44.6% in hospitals (**Table 6-2**). Overall prestorage leukocyte reduction increased by 8.3% from 2004 (**Figure 6-1**).

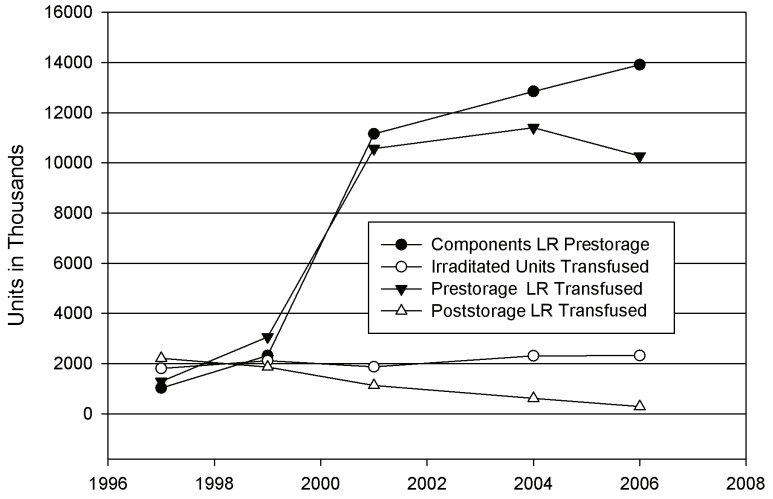

Figure 6-1. Component modification trends (all components).

Transfusion of Irradiated and Leukocyte-Reduced Components

Table 6-3 summarizes the types and numbers of irradiated and leukocyte-reduced blood component units transfused during 2006. A total of 180,000 irradiated units were reported as transfused by blood center transfusion services and 2,141,000 by hospital transfusion services. In total, 10.3% of all component units transfused were irradiated.

In 2006, some 10,569,000 LR component units were transfused, 364,000 (3.4%) by blood center transfusion services and 10,205,000 (96.6%) by hospital transfusion services. Of the total LR units transfused, 97.3% were leukocyte-reduced before storage and 2.8% after storage. Substantial proportions of all RBCs and platelets transfused in 2006 were leukocyte-reduced: 55.1% of WB/RBCs, 57.2% of whole-blood-derived

Table 6-4. Irradiated, Prestorage Leukocyte-Reduced and Poststorage Leukocyte-Filtered Component Units Transfused in 2006 and 2004 (expressed in thousands of units)

	Units			
Modification	**2006**	**2004**	**Change 2004-2006**	**% Change**
Total, all units	12,890	14,334	–1,444	–10.1
Irradiated	2,322	2,310	12	0.6
Leukocyte-reduced, total	10,569	12,024	–1,455	–12.1
Prestorage	10,275	11,405	–1,130	–9.9
Poststorage	293	619	–326	–52.7

platelets, and 80% of apheresis platelets (see previous comment regarding apheresis platelets).

Table 6-4 summarizes the changes that occurred between 2004 and 2006 in numbers of irradiated and LR component units transfused. During this period, the number of irradiated units transfused remained essentially constant, whereas LR units transfused decreased by 12.1%. While in 2004, there was an increase in transfusion of prestorage leukocyte-reduced units when compared to prior years, in 2006 this declined by 9.9%, most likely reflecting a shift toward cost sensitivity in the market. Continuing the trend of declining poststorage leukocyte reduction observed in 1999, 2001, and 2004, transfusion of poststorage LR units declined by 52.7% in 2006 (**Figure 6-1**).

7. Current Issues in Blood Collection and Screening

In 2006, 12,142,000 individuals came to donate blood, of whom 2,588,000 were deferred before donating. The majority (96.5%) presented at blood centers with only 3.5% presenting at hospital donor centers. Of the 9,554,000 allogeneic donors who successfully gave blood, 2,726,000 (28.5%) were first-time donors and 6,828,000 (71.5%) were repeat donors. These repeat allogeneic donors provided 11,697,000 donations, the equivalent of 1.7 donations per donor.

On the basis of predonation screening, the deferral rate was 21.3%. Hospitals had a slightly higher rate (28.9%) compared to blood centers (21.0%). Predonation screening includes physical assessments, such as determining hematocrit / hemoglobin levels, and administering the Donor History Questionnaire (DHQ).

Because Chagas disease is a growing concern in the US blood collection community, the 2007 survey specifically asked blood collecting organizations how many donors were deferred based on their responses to the standard DHQ question regarding Chagas disease. There were 764 presenting donors deferred because of their response to the history of Chagas disease screening question.*

As is exhibited in **Figure 7-1,** an additional 151,000 units, from 1.2% of donors (0.9% of units tested) are rejected on testing (including infectious disease testing, bacterial contamination, etc). Testing loss was significantly lower than in the previous survey ($p<0.001$), most likely due to the implementation of new testing platforms between 2004 and 2006.

Only 77.5% of individuals presenting to donate ultimately provide a usable unit, not including units lost to insufficient collection volume.

Severe Donor Adverse Events

For the purposes of this survey, severe donor adverse events were defined as adverse events occurring in donors attributed to the donation process that included, for example, major allergic reaction, arterial puncture, loss of consciousness of a minute or more, loss of conscious-

**Laboratory tests for antibodies to* Trypanosoma cruzi, *the agent of Chagas disease, were introduced in January 2007, the year following this survey. The small number of individuals identified through the DHQ suggests that those donors who would be detected by a valid screening test either do not report or do not know of their exposure to the parasite.*

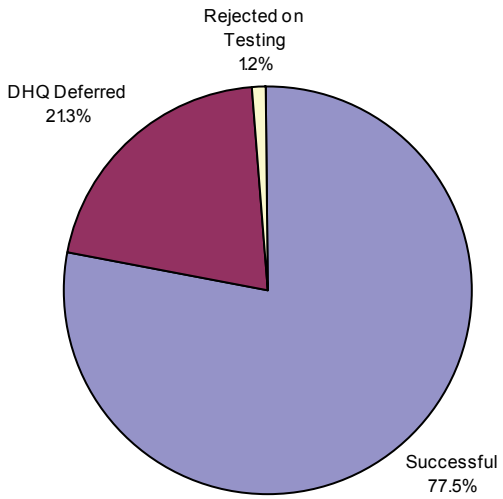

Figure 7-1. Deferral rates for presenting allogeneic donors.

ness with injury, nerve irritation, etc. There were 11,000 of these events reported by collection organizations for 2006. The rate of severe adverse events was 11,000/16,174,000 collected units (0.07%).

Diversion Devices

Bacterial contamination of platelets has been one of the most frequent transfusion-associated infection risks. The most common cause of bacterial contamination is the inoculation of bacteria on the skin surface at the time the needle is inserted into the arm at donation.

As an additional mechanism to prevent bacterial contamination, collection of blood components using unit diversion devices has been implemented at some institutions. This device, integrated with the blood collection pouch, diverts the initial aliquot of blood into a separate but connected pouch. In so doing, the possibility that a skin plug harboring bacteria will contaminate the collection bag is reduced. In 2006 half (50.4%) of all institutions used diversion devices for collecting apheresis platelets; 37.6% used them for whole blood collections.

Issue of Blood to Non-Hospital Transfusion Services and Military Installations

Institutions collecting blood sometimes issue blood to home transfusion services, freestanding surgery centers, or other off-site non-hospital transfusions services such as dialysis centers. Additionally, blood may be issued for use by military installations. Thirty-six percent of collection sites issued 67,000 units of blood to off-site non-hospital transfusion services. The majority, 82.0% or 55,000 units, were RBCs, followed by platelets (14.1%), and FFP (3.9%).

Although fewer collection centers (16.6%) issue blood to military installations, the number of units issued is over three times what is issued to other off-site non-hospital transfusion services. Of the 222,000 units that were issued, RBCs accounted for 68.1% of all issued units, followed by FFP (18.5%), platelets (7.6%), and cryoprecipitate (5.8%).*

**While the number of units issued was reported to the survey, much of this blood was not transfused and was returned for civilian use. There was also some overlap between sites that house Veterans Administration hospitals and military hospitals and there may have been reporting overlap for some of these sites.*

8. Current Issues in Transfusion and Transplantation

Blood Inventory Shortages

The current and previous surveys asked hospitals to indicate the number of days in the past year that elective surgery was postponed because of blood inventory shortages, as well as the number of days that they were unable to meet other blood requests. The results are based on actual (unweighted) responses.

A total of 117 hospitals (6.89%) reported that elective surgery was postponed on one or more days in 2006 because of blood inventory shortages. **Table 8-1** provides a characterization of cancellation reports in 2006 and prior survey years. This represented considerably fewer hospitals reporting surgery delays than in 2004 and 2001. The range of days postponed (1-120) was wider than in 2004. However, two hospitals were outliers, reporting 50 and 120 days of surgical delays. The remaining hospitals reported between 1 and 16 days of delay in 2006, a much narrower range than in previous survey years. There were no significant differences between hospitals when grouped by surgical volume.

Hospitals indicated separately that the total number of surgical procedures that were postponed was 412 compared with 546 in 2004. This is a decrease of 25%. Numbers of surgeries postponed varied widely among hospital strata, but hospitals performing between 1,400 and 2,399 surgeries reported the highest numbers of surgeries

Table 8-1. Cancellation of Elective Surgeries by US Hospitals, 1997-2006

Year	% Hospitals with Cancellation of ≥1 Day	Range of Days	Median Number of Days	Number of Patients Affected
1997	8.60	1-21	2.0	Not determined
1999	7.40	1-150	2.0	568
2001	12.70	1-63	2.0	952
2004	8.40	1-39	2.0	546
2006	6.89	1-120	3.0	412

postponed because of blood shortages.

Hospitals indicated the number of days in which nonsurgical blood requests were not met. Of responding hospitals, 13.5% (231/1707) experienced at least one day in which nonsurgical blood needs could not be met vs 16.0% (257/1604) in 2004. The total number of days reported was 5,460 and the range was 1 to 365. There is a slight increase in the mean number of days of unmet nonsurgical needs for all respondents between 2004 (19.27) and 2006 (22.0). Six hospitals reported 365 days in which nonsurgical blood requests were not met in 2006, whereas eight reported an entire year of unmet need in 2004.

Also, hospitals were asked to indicate the number of days on which the regular or standing order was incomplete. The total number of days was 44,910. On any given day, 123 hospitals are without their standing order. It is likely that most facilities estimated this number given the round values that were reported. This data element is probably best used as an indicator of customer service.

Although standing orders were incomplete on numerous occasions, the more important variables are the number of postponed surgeries (a 25% improvement over 2004) and the unmet nonsurgical blood need (2.5% fewer hospitals reporting, although those reporting unmet need reported an overall increase of 2.7 days).

Bacterial Testing

The 2007 NBCUS included a new section on bacterial testing that all facilities were asked to complete. Only 27.3% of the institutions performed bacterial testing of platelets in 2006. Of the 127 blood centers responding, 117 (92.1%) reported testing; however, only 29.6% of hospitals reported testing.

Respondents were asked to indicate the test methods for platelet components. Among the 74% reporting testing of apheresis platelets, 35% of respondents reported using culture-based testing. Of those reporting testing of whole-blood-derived platelets singly (96%), 67% reported using pH methods and another 34% reported using glucose methods (respondents were told to check all that apply). Swirling methods were chosen by 15% and culture-based testing by 12% of those reporting. Among the 75% reporting on pooled whole-blood-derived platelets, the most common method was pH testing for bacterial contamination (18%).

Approximately 1,485,000 units were tested for bacteria in 2006. Culture-based methods accounted for 57% of the units tested (826,000) and for 283 (52.4%) of the 540 confirmed positives. Blood centers accounted for 87% of the culture-based testing and for only 26.3% of the alternative method testing. Considerably more false-positive results (12,000) were reported with alternative methods of testing (1.8% vs 0.15% reported for culture-based testing).

Biovigilance

Since the 2005 NBCUS, public and private sectors have coordinated efforts to develop the USBVN. In order to establish a baseline, data were collected for major adverse transfusion reactions for 2006. It is anticipated that the NBCUS will collect biovigilance-related data until the USBVN achieves the statistical robustness required to accurately sample US transfusion practice.

An estimated total of 72,000 transfusion-related adverse reactions occurred in 2006. These were defined as events that required any diagnostic or therapeutic intervention. This represents an adverse reaction rate of approximately 0.32% (72,000/22,466,000), a rate on the lower end of the rates reported through other national hemovigilance reporting systems (0.3%-0.7%).

Implementation of the USBVN and the promulgation of common definitions and reporting criteria should increase the rate at which reactions are recognized and reported. The smaller the surgical volume of the hospital, the higher the rate of transfusion-related adverse reactions reported (see **Figure 8-1**). This may be related to the frequency with which patients are transfused or to the reporting thresholds possible at smaller facilities. It is generally understood that many adverse events are not recognized and/or reported to the transfusion service and that there is a need for additional education at all points in the transfusion chain.

Of the adverse events reported, 1,522 were reported as transfusion-related acute lung injury (TRALI). The frequency of TRALI is generally acknowledged to be approximately 1/5,000 transfusions.* On the basis of this rate, one would expect approximately three times the rate reported; therefore TRALI appears to be underdiagnosed or underreported, or occurring at a lower frequency than previously reported. The numbers reported for other reaction types to be tracked by the USBVN are included in **Table 8-2**.

Participants reported whether or not they had an electronic system for tracking events. Events were defined as unplanned, unexpected, and undesired occurrences. Only 34% of the responding hospitals reported having such a system to track events, which suggests that the planned electronic event tracking capabilities of the USBVN will be of use to the many hospitals without systems of their own.

**Goldman M, Webert KE, Arnold DM, et al. Proceedings of a consensus conference: Towards an understanding of TRALI. Transfus Med Rev 2005;19:2-31.*

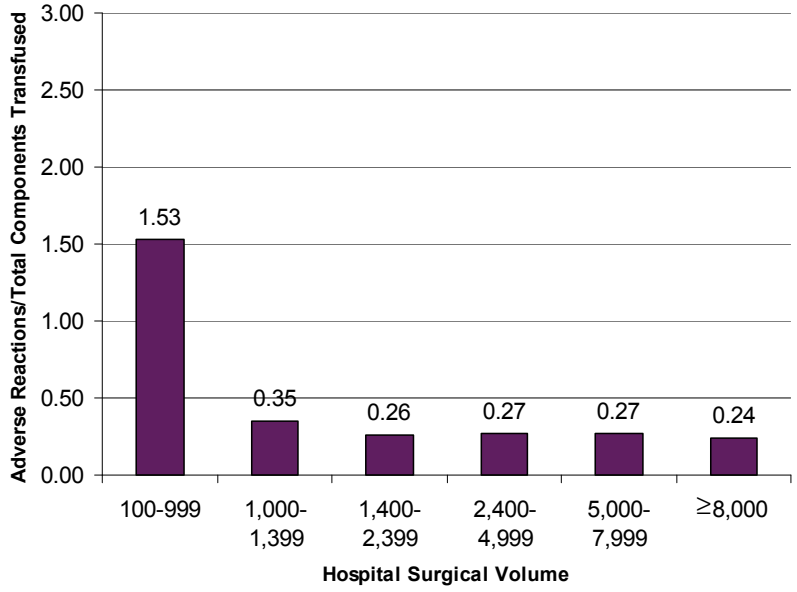

Figure 8-1. Rate of adverse transfusion reactions by hospital annual surgical volume.

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

Adverse Transfusion Reactions	Number of Occurences	Rate (All Components) from Reporting Facilities n=22,466,000*
Total number of occurrences that required any diagnostic or therapeutic intervention	72,000	1:312
Severe allergic reactions	4,944	1:4,540
Delayed hemolysis	1,770	1:12,681
Transfusion-related acute lung injury (TRALI)	1,522	1:14,748
Transfusion-associated circulatory overload (TACO)	1,110	1:20,222
Posttransfusion sepsis	240	1:93,525
Reactions that were life-threatening, requiring major medical intervention following the transfusion, eg, Vasopressors, blood pressure support, intubation, or transfer to the ICU	236	1:95,110
Acute hemolysis	141	1:159,191
ABO incompatibility	64	1:350,719

*Apheresis platelets counted as doses (*not* as concentrate equivalents).

Therapeutic Apheresis

A total of 27.2% of facilities reported that they perform therapeutic apheresis procedures. Among blood centers, 52.8% provide therapeutic apheresis and among hospitals, 26.4% perform these services. The total number of therapeutic apheresis procedures was 112,109, 20% (22,821) by blood centers and 80% (89,288) by hospitals. The specific indication for which the most facilities reported performing therapeutic apheresis was thrombotic thrombocytopenic purpura treatment, with 25,791 procedures (23% of all therapeutic apheresis procedures). There were 16,706 procedures for hemochromatosis and 10,798 procedures for myasthenia gravis (15% and 10% of all therapeutic apheresis procedures, respectively). Other therapeutic apheresis procedures were peformed for Guillain-Barré syndrome, multiple sclerosis, sickle cell disease, chronic inflammatory demyelinating polyradiculoneuropathy, and Goodpasture's syndrome, each less than 5% of all reported procedures. An additional 42,744 procedures were categorized as "other" (38% of all therapeutic apheresis procedures). (See **Table 8-3**.)

Crossmatch Procedures

Transfusing facilities reported the total number of crossmatch procedures, as well as the percentage of procedures performed serologically and electronically. Weighted hospital data on crossmatch procedures indicate that

Table 8-3. Therapeutic Apheresis Procedures in 2006 by Specific Indications

	Blood Centers	Hospitals	Total Procedures	% of Total Procedures
Total	22,821	89,288	112,109	100
Other	9,603	33,141	42,744	38
Thrombotic thrombocytopenic purpura	6,557	19,234	25,791	23
Hemochromatosis	858	15,849	16,706	15
Myasthenia gravis	1,934	8,864	10,798	10
Sickle cell disease	936	3,876	4,812	4
Chronic inflammatory demyelinating polyradiculoneuropathy	835	3,252	4,087	4
Guillain-Barré syndrome	1,227	2,415	3,643	3
Multiple sclerosis	509	1,722	2,231	2
Goodpasture's syndrome	363	935	1,298	1

18,774,000 procedures were performed in 2006, compared to 11,221,000, an increase of 67.3%. Of the crossmatch procedures reported, serologic methods were estimated to account for 93.6% and only 4.4% were estimated to be performed electronically.

In order to calculate the crossmatch to transfusion ratio, the total number of allogeneic WB/RBC units transfused was used as the denominator (14,461,000). The overall C:T ratio was 1.3 procedures per unit transfused.

When analyzed by surgical volume, the smaller hospitals had the lowest C:T ratios. Hospitals with fewer than 999 surgeries/year reported a 0.99:1 C:T ratio, (which is within the range of error); hospitals performing from 1,000 to 1,399 surgeries reported C:T ratios of 1.05:1. The largest two strata >5,000 surgeries reported closer to a 1.4:1 C:T ratio. Smaller hospitals were more likely to report performing crossmatches serologically; larger-sized hospitals were more likely to report use of some electronic crossmatch procedures (**Figure 8-2**).

Red Cell Age

In follow up to earlier surveys, the 2007 survey has attempted to clarify the data on the average age of a unit of RBCs at the time of transfusion. In this survey, 573 hospitals responded, an increase from the 488 responding in the last survey. The data were not weighted. Hospitals were asked to indicate whether they reported a calculated age or an estimate of age. The estimated mean age was 16.4 days and the mean calculated age was 19.5 days at transfusion. Only 7.8% (or 45 hospitals) were able to calculate and report the component age at transfusion.

Platelet Age

In the 2007 survey, 350 hospitals responded with an average age of whole-blood-derived platelets at transfusion. Again, the data were not weighted. Hospi-

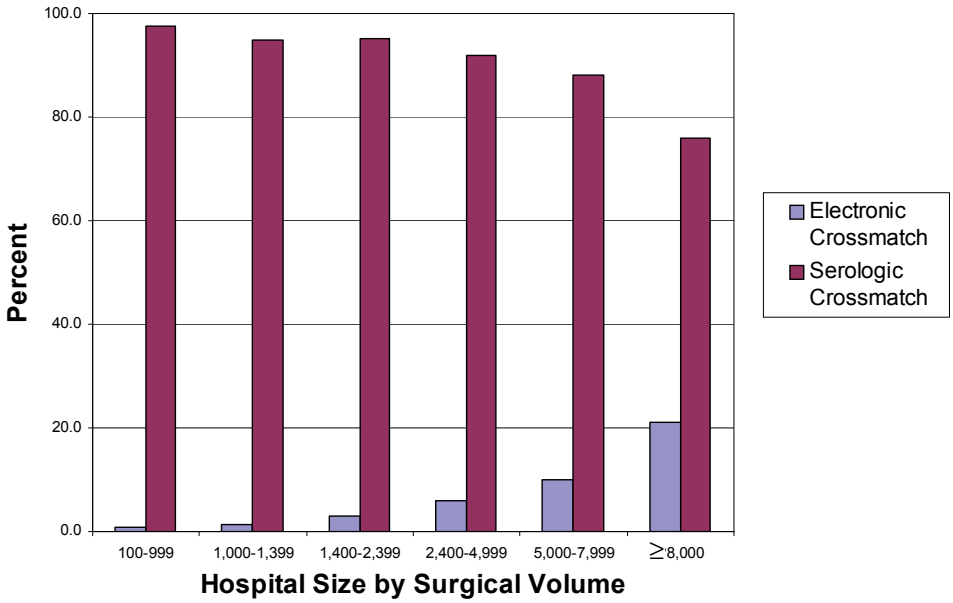

Figure 8-2. Electronic and serologic crossmatch by hospital size.

tals were asked to indicate whether they reported a calculated age or an estimate of age. The estimated mean age was 2.09 days and the mean age for the calculated days was 2.33 days at transfusion. Only 6% (21 hospitals) were able to calculate the component age at transfusion. Quite a few more hospitals (661/1707 or 39%) responded with an age for apheresis platelets at the time of transfusion. The mean reported age for 5-day apheresis platelets at transfusion was 3.2 days, whether calculated or estimated by the hospital. Surprisingly, 7-day apheresis platelets were transfused at 2.4 days (estimate) to 2.8

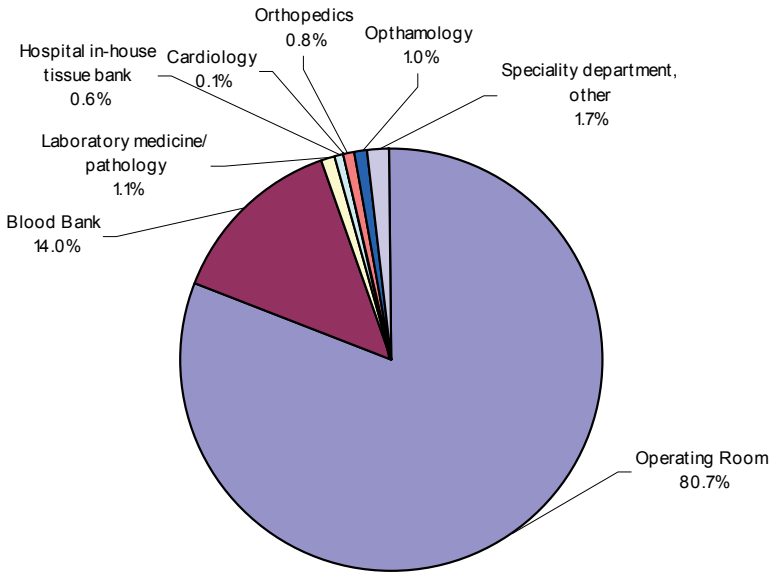

Figure 8-3. Department with the most responsibility for human tissue.

days (calculation). Only 17 (1%) and 53 (8%) hospitals were able to provide calculated values for 7-day and 5-day components, respectively.

Tissue

Forty-three percent of all surveyed institutions reported maintaining an inventory of, or using, human tissue for transplantation. Of these institutions, 80.7% reported that their operating rooms had the most responsibility for ordering, receiving, storage, tracking, and issuing human tissue, as illustrated in **Figure 8-3**. The second most commonly reported department with responsibility for tissue was the blood bank (14%). As detailed in **Table 8-4**, in 2006, the total number of human tissue implants/grafts that reporting facilities used or implanted was 229,115. This dramatic increase from the 3,095 implants reported in 2004 is most likely the result of the addition of a separate tissue section to the NBCUS questionnaire that was distributed to all hospitals and blood centers. The total number of implants discarded was 8,178; the total number returned to the supplier was 7,353.

Table 8-4. Human Tissue Implants/Grafts Used in 2006

	Blood Centers	Hospitals	All Facilities
Used/Implanted	14,236	214,879	229,115
Discarded	1,885	6,294	8,179
Returned	1,422	5,931	7,353
Total Reported	17,543	227,103	244,647

Of institutions that used or maintained an inventory of human tissue, 12.3% reported maintaining an inventory of human skin. The most common average daily inventory of human skin maintained was 2 square feet. The total average daily inventory of human skin reported was 2,999 square feet, more than a third of that total coming from hospitals with 2,400-4,999 surgeries/year.

In 2006, 43 adverse events associated with human tissue implants/grafts were reported. Of those, 14 events (32.6% of all adverse reactions) were related to virus transmission; 15

Table 8-5. Adverse Events Associated with Tissue Transplants

	Blood Centers	Hospitals	All Facilities	% of Total Reported Human Tissue Transplanted	% of All Tissue Adverse Reactions
Viral Transmission	0	14	14	0.006	32.6
Bacterial Infection	4	11	15	0.007	34.9
Structural Failure	0	12	12	0.005	27.9
Other Adverse Events	0	2	2	0.001	4.7
All Adverse Events	4	39	43	0.019	100.0

(34.9%) were related to bacterial infection; and 12 (27.9%) were related to structural failure. (See **Table 8-5**.) It is likely that structural failures are underreported, because the failures may occur long after the transplant procedure. The number of adverse tissue events occurring in the total number of human tissue implants/graft procedures (43/229,115) was 0.02% (1 adverse reaction per 5,300 tissue procedures). With the implementation of the Transplantation Transmission Sentinel Network (TTSN)* it is anticipated that there will be growing recognition and reporting of adverse events associated with tissue transplantation.

**TTSN is a web-based system designed to collect data on organ and tissue donation and implantation, including adverse outcomes. The system is the result of collaboration between the CDC and the United Network for Organ Sharing (UNOS) and is being piloted in 2008.*

9. Component Costs

Hospitals were requested to report the average dollar amount paid per unit in 2006 for each of eight specific components. The mean hospital cost for each component is presented in **Table 9-1** and compared with the 2004 value. **Table 9-2** displays the average hospital cost of each component by region of the country and provides a statistical comparison with the national average. Average component costs are stratified by hospital surgical volume in **Table 9-3**.

Red Blood Cells

The mean of the average amount paid nationally for a unit of leukocyte-reduced RBCs in 2006 was $213.94 (**Table 9-1**). This was a minor increase from the 2004 average of $201.07. When analyzed by United States Public Health Service (USPHS) region, the mean hospital amount paid was significantly higher than the national mean in the Northeastern and Southwestern states (Regions I, II, and IX). Significantly lower means were found in the Southeastern and Central states (Regions IV, V, VI, and VII).

When analyzed by surgical volume, the largest hospitals (hospitals reporting at least 8,000 surgeries per year) paid significantly lower than the mean price for RBCs, an average of $206.64, while the other surgical strata clustered around the mean (**Table 9-3**).

Table 9-1. Mean Hospital Amount ($) Paid per Selected Component Unit in 2006 and 2004

Component	Average Amount Paid ($)*		
	2006	2004	% Change
Red cells, leukocyte filtered	213.94	201.07	6.4
Plasma, frozen within 24 hours of phlebotomy	59.84	56.29	6.3
Whole-blood-derived platelets, not leukocyte reduced, not irradiated	84.25	63.67	32.3
Apheresis platelets, leukocyte reduced	538.72	510.05	5.6
Cryoprecipitate	53.31	—	—

*Calculations are based on unweighted estimates.

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

USPHS Region	Number of Hospitals*	Mean Dollar Values†									
		RBCs		Plasma, frozen		WB Derived Platelets		Apheresis Platelets		Cryoprecipitate	
		Avg	*p*-value	Avg	*p*-value	Avg	*p*-value	Avg	*p*-value	Avg	*p*-value
I	82	253.03	<0.0001	58.68	0.4271	77.00	0.3295	554.76	0.1718	54.40	0.7082
II	160	243.16	<0.0001	59.47	0.7819	79.83	0.7314	598.23	<0.0001	62.46	0.1897
III	161	209.77	0.0871	57.08	0.0629	72.49	0.1317	538.45	0.9748	45.72	<0.0001
IV	312	196.72	<0.0001	54.27	0.0172	79.52	0.6980	513.70	0.0001	43.66	<0.0001
V	302	199.87	<0.0001	59.00	0.7593	85.16	0.9294	516.80	0.0003	53.08	0.9530
VI	196	206.72	0.0014	63.43	0.2023	60.90	0.0003	540.66	0.7710	51.81	0.6475
VII	108	199.58	<0.0001	52.55	0.0004	133.56	0.2298	485.38	<0.0001	45.80	0.0001
VIII	57	223.63	0.1066	78.06	0.0013	139.00	0.2496	591.82	0.0723	59.69	0.0350
IX	186	238.56	<0.0001	62.25	0.2711	176.17	0.0903	555.94	0.0050	64.11	0.0278
X	42	222.89	0.0627	84.51	0.1296	175.00	0.0979	596.75	0.0628	85.03	0.0221
All Hospitals	1,606	213.94		59.84		84.24		538.72		53.31	

*The number of responses for each blood component varies because some hospitals did not provide answers to all questions.
†Calculations are based on unweighted estimates.

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

		Mean Dollar Values†									
		RBCs		Plasma, Frozen		WB-Derived Platelets		Apheresis Platelets		Cryoprecipitate	
Annual Surgical Volume	Number of Hospitals*	Avg	*p*-value	Avg	*p*-value	Avg	*p*-value	Avg	*p*-value	Avg	*p*-value
100 – 999	294	216.53	0.3514	72.89	<0.0075	97.69	0.3889	545.35	0.5285	58.85	0.3797
1,000 – 1,399	127	211.49	0.5237	59.25	0.7836	107.32	0.3159	544.20	0.5784	57.17	0.4679
1,400 – 2,399	367	216.69	0.2687	59.41	0.8165	89.02	0.6697	538.62	0.9858	53.64	0.9037
2,400 – 4,999	485	213.19	0.7250	57.30	0.0633	77.27	0.3471	539.86	0.8103	53.86	0.8532
5,000 – 2,399	204	214.00	0.9845	56.57	0.0622	74.78	0.2879	535.79	0.7004	50.51	0.2696
≥8,000	129	206.64	<0.0093	52.27	<0.0001	84.22	0.9990	522.54	0.0109	48.23	0.1041
All Hospitals	1,606	213.94		59.84		84.25		538.72		53.31	

*The number of responses for each blood component varies because some hospitals did not provide answers to all questions.
†Calculations are based on unweighted estimates.

Plasma

The hospital cost for Plasma Frozen Within 24 Hours After Phlebotomy averaged $59.84 nationally (**Table 9-1**), 6.3% higher than the 2004 average of $56.29. When analyzed by USPHS Region, hospitals paid more in Region VIII, the Mountain states, and statistically less in Regions IV and VII, the Southeast and the Central states.

The hospitals with the smallest surgical volume (100-999 surgeries per year) reported an average cost for plasma for transfusion ($72.89) that was significantly higher than the overall mean (**Table 9-3**). The largest hospitals (>8,000 surgeries per year) had costs of $52.27, significantly lower than the mean.

Whole-Blood-Derived Platelets

The national hospital average paid for a unit of whole-blood-derived platelet concentrate (individual concentrate, not pooled), not leukocyte reduced or irradiated, was $84.25 in 2006 (**Table 9-1**). This was a large increase (32.3%) over the 2004 cost. The increase may reflect costs associated with bacterial detection requirements for this product.

Hospitals in USPHS Region VI, the South Central states, paid significantly less for whole-blood-derived platelets than the national norm. There were no cost differences reported by hospital surgical volume.

Apheresis Platelets

For a unit of apheresis platelets hospitals paid an average of $538.72 in comparison with $510.05 in 2004, a small increase of 5.6%. When stratified by surgical volume, the largest hospitals paid significantly less than other hospitals.

The mean was significantly higher in USPHS Regions II and IX, New York-New Jersey and the Pacific Southwest. The mean hospital cost was significantly lower for apheresis platelets in Regions IV, V, and VII, the Southeast, Central, and North Central states.

Cryoprecipitate

The average hospital cost for a unit of cryoprecipitate was $53.31 in 2006. This was the first time the price for this component was reported on the NBCUS. As with many of the other components, the price was lower as hospital surgical volume increased, although differences from the mean were not statistically significant.

Hospitals paid significantly more for cryoprecipitate in USPHS Regions VIII, IX, and X, the Mountain and Western states. The mean hospital cost for a unit of cryoprecipitate was significantly lower than the US mean in USPHS Regions III and IV, the Mid-Atlantic and Southeastern states.

Hematopoietic Progenitor Cells

This survey queried the cost of hematopoietic progenitor cells (apheresis, marrow, and cord) to hospitals. The response rate to this question was very low, with only 23, 9, and 7 hospitals reporting costs of apheresis, marrow, and cord blood products, respectively. The variance and standard deviations were so high as to render the data nonrepresentative. This response rate also suggests that many hospitals using these products do not purchase them externally but collect them for their own use.

Reimbursement

The Centers for Medicare and Medicaid Services (CMS) hospital outpatient prospective payment system (OPPS) reimbursement rates for the five components assessed are reported in **Table 9-4**. Although hospital costs for components increased from 5.6% to 32.3% between 2004 and 2006, most CMS OPPS reimbursement rates increased 20.8 to 60.7%, except for the rate for plasma for transfusion, which decreased by 25.9%. On the basis of these figures, the reimbursement for a unit of RBCs is approximately 76% of the average hospital cost; for a unit of plasma for transfusion, approximately 118% of the average cost; for a unit of whole-blood-derived platelets, approximately 61% of the average cost. For a unit of apheresis platelets, reimbursement covers 92% of the average cost paid by hospitals; for cryoprecipitate, reimbursement is approximately 88% of the average hospital cost of a unit.

CMS OPPS rates are reported here because they are the only simple 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 nearly impossible to tease apart from the other aspects of the DRG. Other payers, besides Medicare, pay for blood using varying mechanisms that are not included in this report.

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

	Reimbursement Code		Reimbursement Rate		
Blood Component	CPT/ HCPCS	APC	2006†	2004*	% Change
Red Blood Cells (leukocyte-reduced)	P9016	954	163.16	119.26	36.8
Fresh Frozen Plasma (frozen between 8 and 24 hours after phlebotomy)	P9017	955	70.40	95.00	–25.9
Whole-blood-derived platelets	P9019	957	51.50	41.44	24.3
Apheresis platelets (leukocyte-reduced)	P9035	09501/1014	493.12	408.81	20.6
Cryoprecipitate	P9012	952	47.10	29.31	60.7

*Department of Health and Human Serives. Medicare program; Chages to the Hospital Outpatient Prospective Payment System and Calendar Year 2004 Payment Rates; Final rule w/ comment period.
†Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Final rule w/ comment period.
CMS = Centers for Medicare and Medicaid Serives; CPT = current procedural terminology; HCPCS = health-care common procedure coding system; APC = ambulatory patient classification.

Summary

In summary, the average hospital cost of a unit of platelets derived from whole blood increased by 32.3% between 2004 and 2006. RBCs, plasma for transfusion, and apheresis platelets increased in cost by less than 7% in the same period. Average costs for the components assessed were generally higher in US Public Health Service Regions VIII, IX, and X (Mountain and Western states); and lower in Regions IV, V, VI, and VII (Southeastern and Central states). As seen in previous surveys, larger hospitals typically pay less than the national average for blood components, which is likely the result of more favorable pricing agreements with a supplier based on the volume purchased. Suppliers may also offer hospitals preferential pricing for components that are closer to expiration, an option that would only be feasible for a large transfusion service.

10. Cellular Therapy Products

Because of increased interest in hematopoietic transplantation and novel cellular therapies, the 2007 NBCUS collected data on collection, processing, and infusion of cellular therapy products, including hematopoietic progenitor cells collected by apheresis (HPC-A), HPCs derived from marrow (HPC-M), and HPCs from cord blood (HPC-C).

This year, the survey included questions on the collection, processing and infusion of donor lymphocyte infusions (or unmanipulated nonmobilized peripheral blood mononuclear cells), hematopoietic stem/progenitor cells (expanded), immunotherapies (natural killer cells, dendritic cells, T cells, other), non-hematopoietic stem cells [mesenchymal stem cells (MSC or multipotent stromal cells per ISCT recommendations), other], and other products.

Public cord blood banks were identified and surveyed, including AABB member and nonmember cord blood banks, blood centers, and hospitals in this survey. The majority of independent cord blood banks are private, in that the cells are collected, stored, and processed at the private expense, and for the future use, of a family. Twenty-eight cord blood banks were included in the sample for the 2007 NBCUS and 14 of them submitted responses. Three of those reporting were private banks; the remainder provided both types of services.

Characterization of Reporting Facilities

The relative proportions of collection, processing, and infusion activities performed by 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 these are most often part of a stem cell transplant procedure, which is a hospital-related activity. The number of hospitals collecting autologous HPC-A products exceeds the number collecting allogeneic HPC-A products (77 vs 56), both reduced from the 2005 survey. More blood centers and hospitals reported collecting cord blood in 2006 than in 2004.

The 186 facilities that completed the cellular therapy section of the 2007 questionnaire were asked to describe their program as one of the following:

- A blood center performing HPC collections only (6.9%)
- A blood center collecting, processing, and/or storing HPCs (21.5%)
- An HPC collection facility within a hospital (8.0%)
- An HPC collection, processing, and storage

Table 10-1. Autologous Cellular 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 2004	% Change 2004-2006
HPC-A	22	1,643	77	15,749	1	193	17,585	14,083	24.9
HPC-M	1	1	24	188	0	0	189	195	–2.9
HPC-C	4	225	16	932	6	95,406	96,563	2,349	4,010.8
Lymphocytes	2	2	4	30	0	0	32	565	–94.3
Hematopoetic stem/ progenitor cells, expanded	0	0	1	73	1	145	218		
Immunotherapies	4	25	7	113	0	0	138		
Nonhematopoietic stem cells	0	0	2	28	1	338	365		
Other products	1	2	2	12	0	0	15	*	
All Products		1,899		17,125		96,081	115,105	17,297	565.5

*105 Cells Generated in Culture were collected in 2004.

Table 10-2. Allogeneic Cellular 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 2004	% Change 2004-2006
HPC-A	21	540	56	3,497	1	93	4,130	3,298	25.2
HPC-M	1	2	43	766	0	0	768	665	15.4
HPC-C	5	14,390	4	12,128	7	17,510	44,028	14,398	205.8
Lymphocytes	8	78	36	670	1	4	752	1,023	–26.5
Hematopoetic stem/ progenitor cells, expanded	0	0	1	37	1	96	133		
Immunotherapies	0	0	5	88	0	0	88		
Nonhematopoietic stem cells	0	0	1	41	1	164	204		
Other products	1	1	3	80	0	0	81	*	
All Products		15,012		17,306		17,866	50,184	19,650	155.4

*262 Cells Generated in Culture were collected in 2004.

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 2004	% Change 2004-2006
HPC-A	10	928	55	20,801	1	285	22,014	14,684	49.9
HPC-M	4	47	38	590	1	2	639	754	–15.2
HPC-C	4	8,199	16	3,080	10	151,950	163,229	32,125	408.1
Lymphocytes	2	32	27	653	1	4	689	1,136	–39.4
Hematopoetic stem/ progenitor cells, expanded	0	0	0	0	0	0	0		
Immunotherapies	0	0	5	104	0	0	104		
Nonhematopoietic stem cells	0	0	7	103	0	0	103		
Other products	1	1	2	18	0	0	19	*	
All Products		9,206		25,350		152,241	186,798	49,092	280.5

*393 Cells Generated in Culture were processed in 2004.

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

Product Type	Blood Centers		Hospitals		Cord Blood Banks		All Facilities		
	No.	Infusion Episodes	No.	Infusion Episodes	No.	Infusion Episodes	Infusion Episodes	Episodes 2004	% Change 2004-2006
HPC-A	11	467	79	10,009	1	10	10,486	7,280	44.0
HPC-M	3	94	50	831	0	0	925	615	50.4
HPC-C	4	436	28	480	3	56	972	639	52.1
Lymphocytes	1	13	25	517	0	0	530	494	7.4
Hematopoietic stem/progenitor cells, expanded	0	0	2	31	0	0	31		
Immunotherapies	0	0	7	259	0	0	259		
Nonhematopoietic stem cells	0	0	8	118	0	0	118	*	
Other products	1	1	6	618	0	0	619	643	–3.8
All products		1,012		12,862		66	13,940	9,818	42.0

*147 Cells Generated in Culture were infused in 2004.

Product Type	No. of Recipients			Recipients 2004	% Change 2004-2006
	Autologous	Allogeneic	Total		
HPC-A	5,783	2,634	8,417	6,050	39.1
HPC-M	170	748	918	571	60.7
HPC-C	10	838	848	624	35.9
Lymphocytes	8	454	462	380	21.6
Hematopoietic stem/progenitor cells, expanded	2	29	31		
Immunotherapies	69	49	118		
Nonhematopoietic stem cells	3	25	28	*	
Other products	117	30	147	641	–77.0
All products	6,161	4,808	10,969	10,811	1.5

*147 Recipients for Cells Generated in Culture in 2004.

facility within a hospital (35.0%)
- A cord blood collection facility only (11.5%)
- A cord blood processing/storage facility only (9.2%)
- An HPC processing/storage facility within a hospital (7.7%)

Of those responding that they performed some collection activity, 69% reported collecting products for third-party vendors, including cord blood banks, National Marrow Donor Program, and other suppliers of cellular therapy products. Of those facilities that collect for third parties, most collect HPC-A (83%) and HPC-M (62%) products. Twenty-four percent collect HPC-Cs and 12% collect other products.

Of the facilities reporting that their program collects cord blood, 89.7% use a nurse/midwife or obstetrician to perform the collection, the other 10.2% report using a dedicated cord blood bank collector.

Of hospitals reporting collection activity for cellular therapy products, those with higher surgical volumes generally were more likely to have the higher levels of collection activity, consistent with previous surveys. The reported volume of these collections is shown in **Table 10-5** and **Figure 10-4**.

Interestingly, 5.7% of the respondents to this section reported using some cellular therapy products for cardiac applications.

Collections

Autologous and allogeneic cellular therapy product collections are illustrated in **Tables 10-1** and **10-2**, and **Figure 10-1**. HPC-C products made up the largest category of cellular therapy products collected in 2006 (85.1%), exceeding the volume of all other products. HPC-A products made up the next largest group, at 13.1% of all collections. The majority of HPC-A products were autologous; there was a 25% increase in autologous HPC-A collections since 2004. The change was seen at both blood centers and hospitals, which showed 13% and 25% increases, respectively, in autologous HPC-A collections in comparison to 2004. Allogeneic HPC-A

Table 10-5. Cellular Therapy Product Collections by Hospitals, by Surgical Volume

Surgeries Per Year	Number of Facilities	% of Facilities	Collections		
			Autologous	Allogeneic	Total
100-999	3	3.3	320	0	320
1,000-1,399	1	1.1	28	0	28
1,400-2,399	8	8.9	2,540	1,362	3,902
2,400-4,999	17	18.9	2,291	357	2,648
5,000-7,999	19	21.1	1,482	547	2,028
≥8,000	42	46.7	10,702	3,527	14,228
Unknown surgical volume			82	11,515	11,597
All hospitals	90	100.0	17,445	17,306	34,752

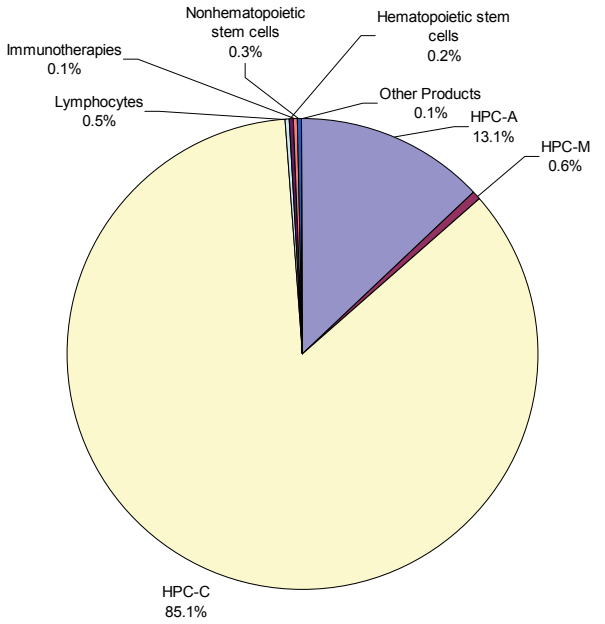

Figure 10-1. Collection of all cellular therapy products.

collections had also increased a proportionate 25% from 2004. These approach the numbers of products reported collected in 2001. It is not clear if this is because of the increased use of HPC-A over HPC-M or because of increased transplant applications.

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) increased dramatically. This increase is likely due to the recruitment of more cord blood banks as participants in the survey, the vigorous marketing on behalf of private cord blood banks, and federal funding for the C.W. Bill Young Cell Transplantation Program.

Two of the cell therapy product categories from the 2005 survey (lymphocytes and cells generated in culture) were either better defined in the 2007 survey or expanded to include new types of products. These product lines—stem cells and immunotherapies—are primarily collected in small numbers and in hospital environments, with the exception of nonhematopoietic stem cells, which are also collected by cord blood banks (**Tables 10-1** and **10-2**). These are predominantly MSCs, which can act as "stem cells" in a variety of applications.

Processing

Processing activity for cellular therapy products is displayed in **Table 10-3** and **Figure 10-2**. The increase in processing of HPC-C units was to be expected with the inclusion of more cord blood banks in the survey sample. Blood banks and hospitals also processed more HPC-Cs in 2006 than in 2004, suggesting increased popularity of the practice (163,224 HPC-C collections processed in total). There is normally greater than a 1:1 ratio of collected to processed units, because of inadequate collection, contamination, etc. However, as with the 2004 survey, that inverse ratio was not reported in 2006. Underreporting of cord blood collections is most likely responsible for the higher ratio of processing to collection reported here. Cord blood banks that reported processing but not collecting cord blood might be processing collections from several hospitals, perhaps not all of them being represented on this survey or having reported on this section. Some cell therapy pro-

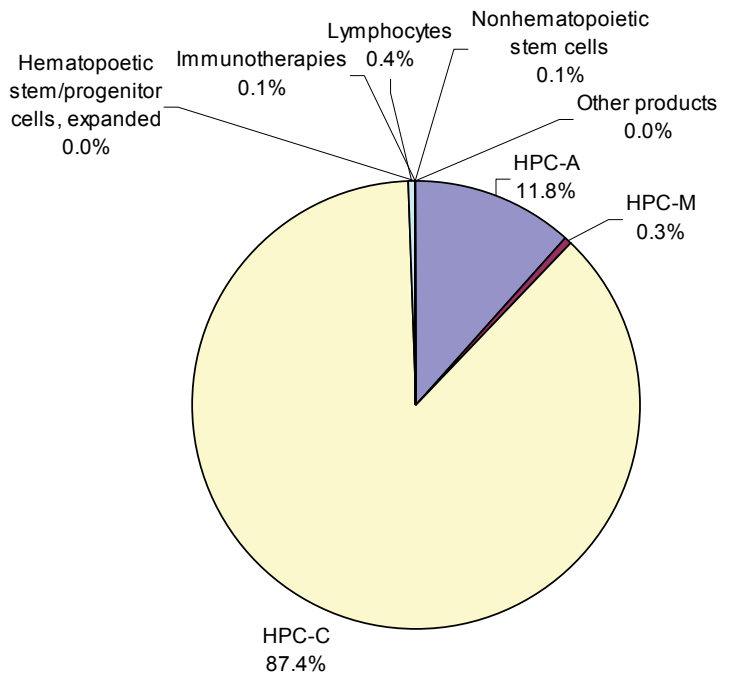

Figure 10-2. Processing of all cellular therapy products.

Infusion

There was an attempt to elicit better responses to the cellular therapies section for the 2007 survey and it appears to have been successful. Issue/infusion activity (**Table 10-4** and **Figure 10-3**) increased in comparison to 2004 for all cell therapy product types (42% increase overall) to numbers comparable to the 2001 survey. There was a 44% increase in HPC-A procedures reported, as well as an increase in both autologous and allogeneic recipients (26% and 80%, respectively). The number of HPC-M infusion procedures increased by 50%,

cessing facilities might also perform contract work for other collection or administration facilities.

Processing of HPC-A increased by 50% over 2004. Most of the increase in processing was seen at hospitals (55% over 2004 volume), where the increase was seen in the numbers of units processed, rather than in numbers of hospitals reporting activity. Hospitals report performing more manipulations of products in preparation for more transplant and more double transplant procedures.

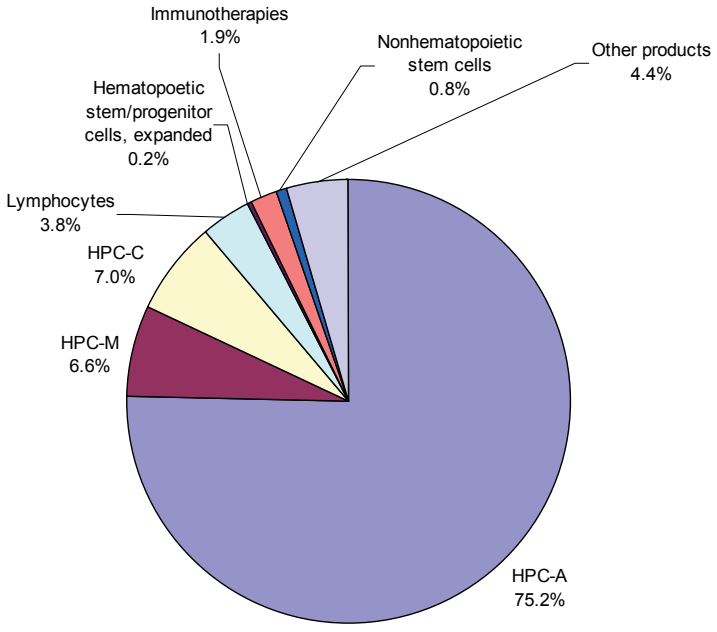

Figure 10-3. Infusion of cellular therapy products.

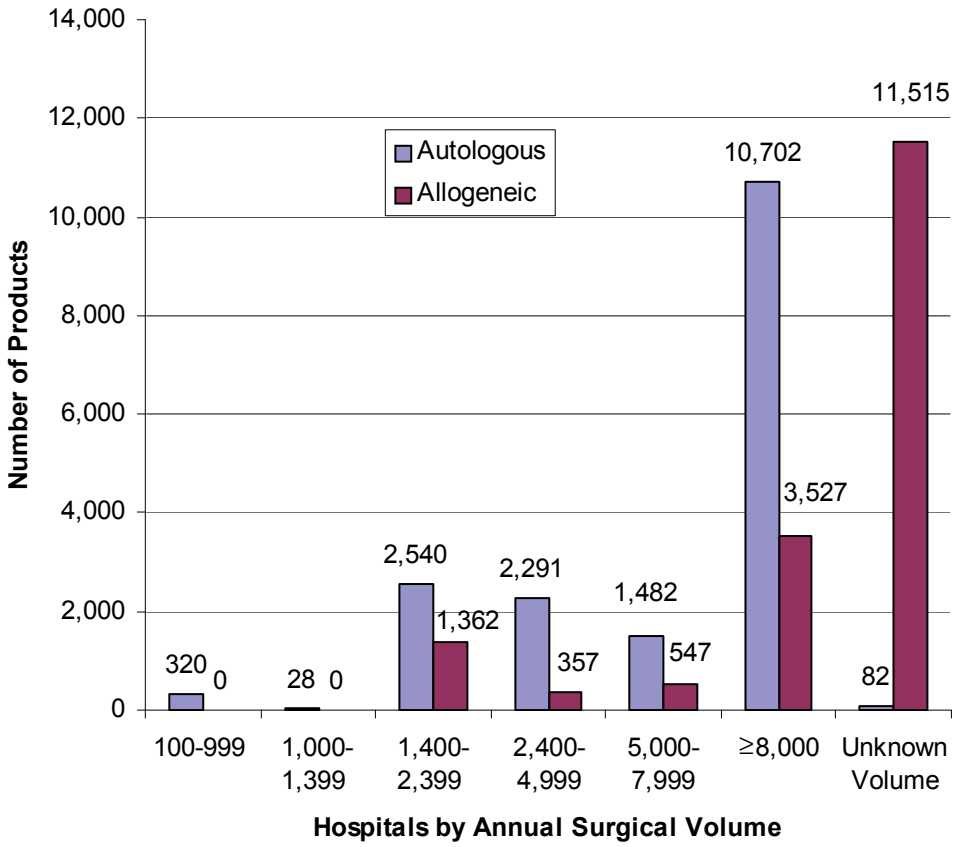

Figure 10-4. Cellular therapy product collections by hospitals.

while the number of both autologous and allogeneic recipients increased by 61%. Twenty-eight hospitals and four blood centers infusing HPC-Cs accounted for 94.2% of the 1,000 infusions reported. Although autologous (or family) cord blood banking remains a popular option, the data show that infusions of autologous HPC-C are rare events with just four recipients reported in 2004 and 10 in 2006. Most infusions in the private banking system are currently for siblings needing transplants. It is not clear if the autologous infusions reported were truly autologous or if they were for siblings and incorrectly reported. Numbers of recipients of other cellular therapies are listed in **Table 10-4**, providing an indication of the distribution of the procedures among hospitals and the numbers of patients to whom they are given.

A comparison of the category of "Other" between 2004 and 2006 is interesting. The questionnaire offered an expanded list of potential options from which to choose, so that the number of infusion episodes categorized as "Other" could be reduced. Nevertheless, 619 infusions were grouped into this category, only 4% fewer than in the prior survey. It is possible that these were misreported or that they represent tumor vaccines,

which are more commonly performed in academic hospitals. In these trials, recipients may receive multiple infusions or injections. These "other" products most likely come from the collection/processing category of "immunotherapy, nonhematopoietic, and other." Many of these commonly result in multiple infusions from the same product processing. They are also more likely to be autologous, with the exception of allogeneic MSCs for graft-vs-host disease treatment currently in clinical trials. Although the survey captured an additional 408 events under the new categories, clearly there is infusion and transplantation activity that does not fall into the predefined areas. Eighty percent of these other infusions were autologous and went to 117 recipients.

Summary

As seen in previous surveys, cord blood products represent a sizable proportion of collection (85.1%) and processing (87.4%) activities among surveyed facilities, but only a very small amount of the infusion activity (7.0%). In hospitals and blood centers, the majority of the cord blood activity is associated with the collection and storage of HPC-C from unrelated donors to provide a bank from which potential transplant recipients can identify a suitably matched cellular therapy product. Recent congressional funding of a National Cord Blood Inventory managed by the Health Resources and Services Administration (HRSA) will permit addition of up to 150,000 genetically diverse units to the public inventory. This will continue to be monitored for its growth and use.

11. Historical Perspectives

The Department of Health and Human Services 2007 NBCUS continues to be the major mechanism for assessing blood collections and utilization in the US. The current survey follows previous national blood surveys conducted in 2005, 2002, 2000, and 1998, and earlier assessments of blood services activities conducted by the National Heart, Lung, and Blood Institute and the Center for Blood Research. These continuous efforts allow trend analysis to extend back to 1989.

Time Trends

WB and RBC collections for the past 17 years are illustrated in **Figure 11-1**. Total collections, which dropped to a decade low of 12.6 million units in 1997, reached 15.3 million in 2001, due largely to an increase in allogeneic donations following the nation's response to the terrorist activities of September 11, 2001. Collections remained about the same in 2004 before increasing 5.8% to 16.2 million units in 2006.

Autologous donations, which declined dramatically over the period 1992 to 1997, appeared to level off at approximately 600,000 units from 1997 to 2001. In 2004, a declining trend re-emerged, continuing into 2006 where autologous collections comprised only 335,000 units, or 2.1% of total collections.

Figure 11-2 illustrates the trends in allogeneic WB/RBC collections and transfusions from 1989 to 2006, as well as the excess in collections over utilization, which is discussed below in the section on **Blood Supply Adequacy**. The rise in the number of allogeneic transfusions reported since

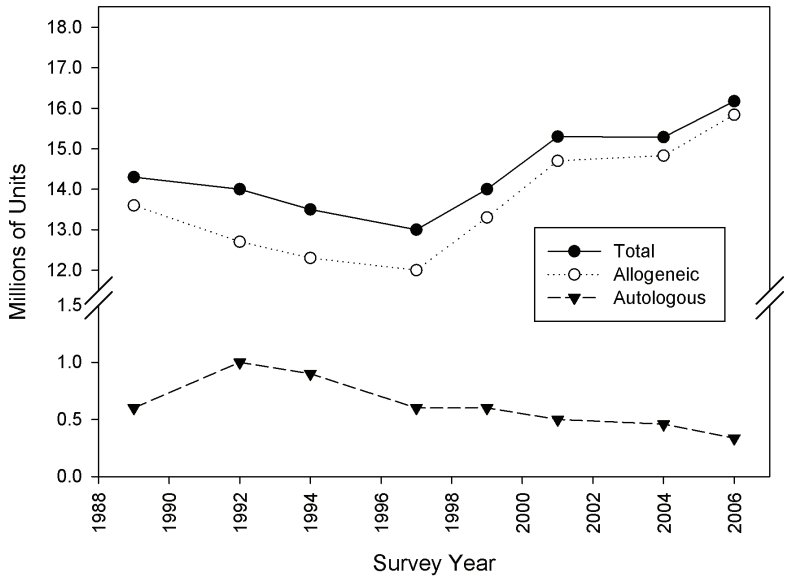

Figure 11-1. Allogeneic, autologous, and total whole blood and red blood cell collections 1989-2006.

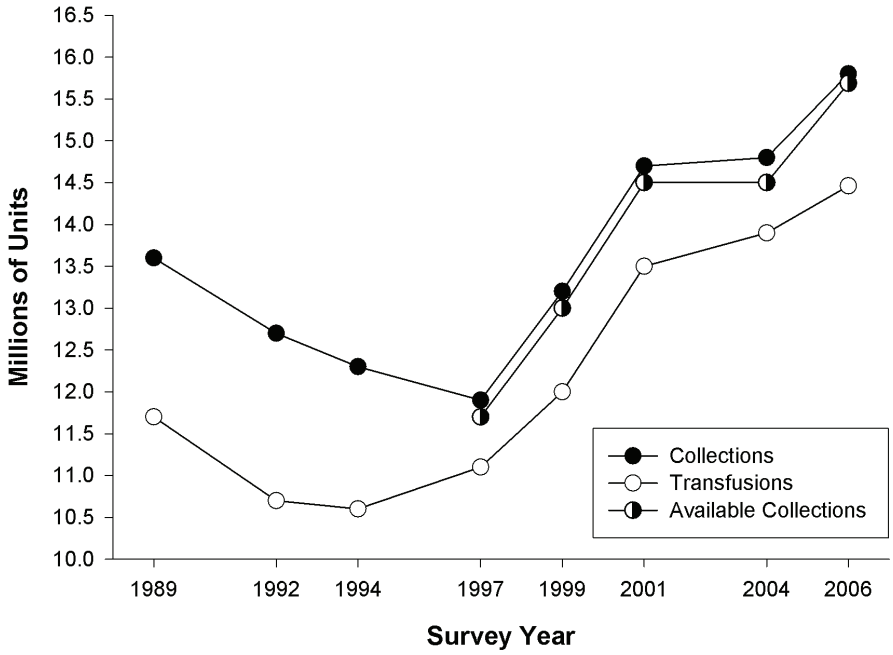

Figure 11-2. Allogeneic whole blood and red blood cell collection and transfusion, 1989-2006.

1994 reached a high of 14.5 million in 2006. The total increase in allogeneic transfusions in the nine years between 1997 and 2006 was 30.3%. The increase in allogeneic collections from 1997 to 2006 was 32.8%, reaching a high of 15.8 million units.

Platelet use overall between 2004 and 2006 increased by 5.2%, which was not statistically different. The decline in the use of whole-blood-derived platelet concentrates, first observed in 1999, continues, although not at the rate seen in previous surveys. **Figure 11-3** illustrates the increased use of apheresis platelets (+9.0%) and the decrease in transfusion of whole-blood-derived platelet concentrates (–15.7%). The ratio of apheresis platelets (in concentrate equivalents) to whole-blood-derived platelet concentrates used has increased from 1.7:1 in 1997 to 7.0:1 in 2006.

Blood Supply Adequacy

The available supply of both WB/RBCs and non-RBC components was sufficient to meet overall transfusion demands in 2006. With the increase in both the supply and the excess capacity, there is cause to be more optimistic than in previous reports regarding the adequacy of the US blood supply. Provided that there are open lines of communication and transportation between centers of needed products, in most cases, there is adequate supply to cover local and national needs.

An analysis of the margin between allogeneic WB/RBC supply and demand depicted in **Figure 11-2** provides an indication of sufficiency. In 1989, allogeneic collections totaled 13.6 million, with a margin of 1.9 million, 13.8% of supply. By 1997, the margin had decreased to 862,000, 7.2% of the sup-

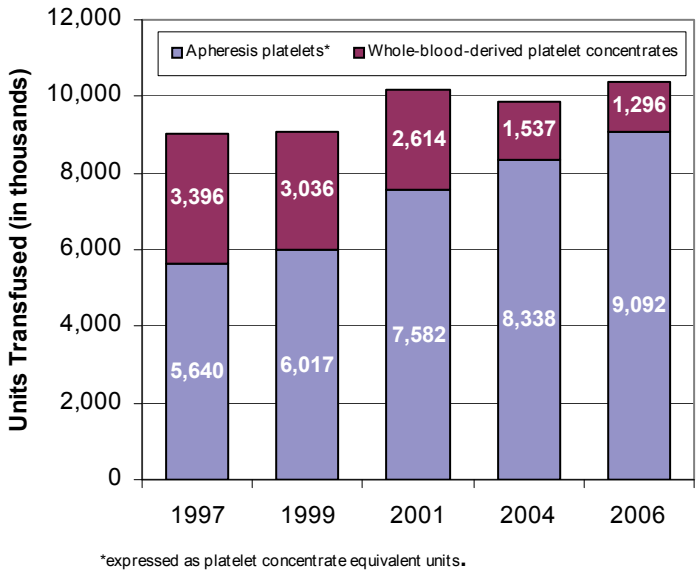

Figure 11-3. Trends in platelet transfusions.

ply. In response to a sharply increasing demand for RBCs, blood centers successfully increased allogeneic collections in 1999 to 13.2 million, increasing the margin to 9.1% in spite of an 8.1% increase in demand. Collections increased significantly ($p<0.0001$) in 2001 due largely to the extraordinary events of September 11; however, there was a concomitant increase in transfusions of similar magnitude. There were nearly 1.2 million excess units collected, or 8.0% of supply. The 2004 data indicated a reduction in the margin to 6% of supply. In 2006, however, there was an increase in allogeneic collections to 15.8 million units accompanied by a smaller increase in transfused units to yield a margin of 1.3 million units, or 8.5% of supply, a margin comparable to that seen in 2001.

A similar analysis can be performed using the *available* allogeneic supply. The available allogeneic supply is composed of those units that have passed all laboratory tests and are available for transfusion. In 2006, the available supply of screened allogeneic WB/RBCs, 15,688,000 units, exceeded transfusions of allogeneic WB/RBCs (14,461,000) by 1,227,000 units, almost twice the number seen in 2004. The 2006 available margin was 7.8%, compared to 4.5% in 2004. Due much to a significantly smaller loss of units to reactive test results ($p<0.001$), this margin of available supply is the highest achieved since 1997 and is cause for optimism.

In summary, 2006 NBCUS data indicate an increased margin of available supply, primarily due to the 44.1% decrease in test loss combined with significant increases in collection from red cell apheresis technologies (96.4%, $p<0.001$).

US Population Trends

Figure 11-4 illustrates the trends in the estimated rates of WB/RBC collection and transfusion in the US from 1980 to 2006. The rate of collection, the upper line, was calculated from the national estimate of total WB and RBCs collected per thousand population aged 18 to 64 for a given survey year to be consistent with historical data. The rate of transfusion, the lower line, was calculated from the national estimate of WB/RBC units transfused per thousand total population of all ages for that year.

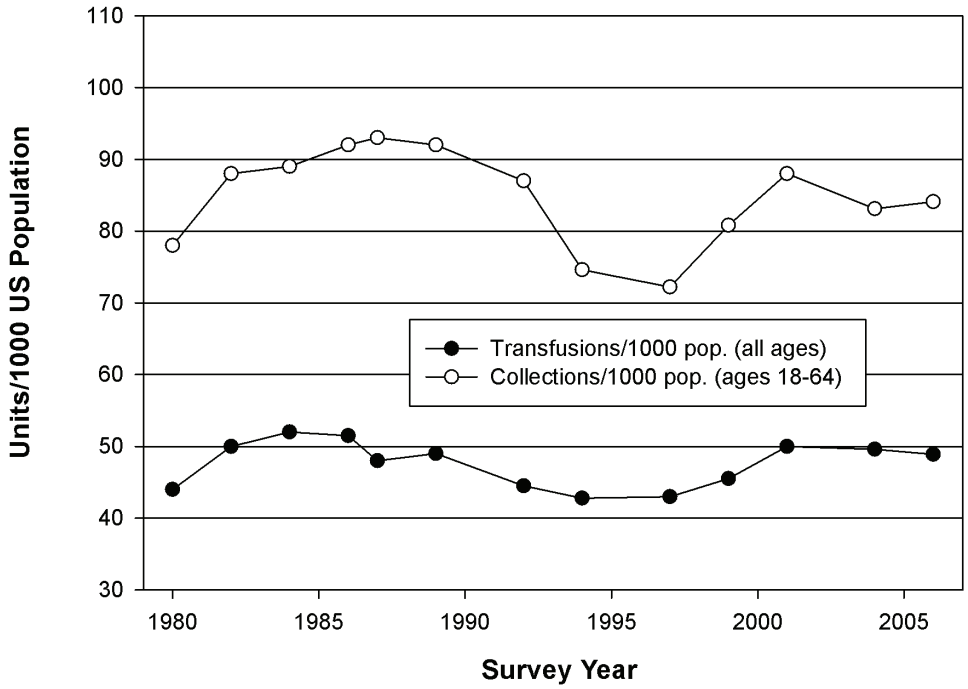

Figure 11-4. Estimated rates (per 1000 eligible population) of allogeneic blood collection and transfusion in the United States, 1980-2006.

Population figures were obtained from the US Bureau of the Census.

Allogeneic blood collection per thousand US population of donor age was 84.1 units in 2006 compared with 83.1 units in 2004 and 88.0 units in 2001. This shows a comparatively steady state for the donor age population if the 2001 collection year can be considered something of an anomaly.*

This is the first survey to report on actual numbers of donors and it will be interesting to track trends in future reports. Approximately 3.2% of the total US population donated in 2006. If the population is age-adjusted for donor eligibility (ages 16-64) the rate increases to 4.8% of the eligible population donated in 2006. Although there are certain indications that the potential eligible donor base may be smaller than previously assumed,† the rate of donations per 1,000 persons of eligible age (using the slightly reduced age categories imposed by the US Census) has remained constant, no doubt because of active recruiting and retention of qualified donors.

The US WB/RBC transfusion rate in 2006 was 48.9 units per thousand overall

**There is increasing recruitment of and collection from donors between the ages of 16 and 18 years of age. Adding this age cohort to the population of donor age reduces the rate of allogeneic blood collection to 80.3 units per thousand US population of donor age in 2006.*

†Riley W, Schwei M, McCullough J. The United States' potential blood donor pool: Estimating the prevalent donor-exclusion factors on the pool of potential donors. Transfusion 2007;47:1180-8.

population. Although not statistically different from the rate in 2004 (49.6/ 1,000 population), this suggests that the rate of transfusion may have approached a steady state, provided environmental factors remain constant.

Note: blood collection per thousand total population in 2006 was 52.9. The age-adjusted value of 84.1 was used in ***Figure 11-4*** *for consistency with historical analyses.*

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